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Quantification de l'instabilité latérale chronique de cheville et de ses différents facteurs de risque sur la vitesse angulaire en inversion lors d'un traumatisme simulé

Matthieu Lalevée

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Normandie Université

THÈSE

Pour obtenir le diplôme de doctorat

Spécialité STAPS

Préparée au sein de l'Université de Rouen Normandie

Quantification de l'instabilité latérale chronique de cheville et de ses différents facteurs de risque sur la vitesse angulaire en inversion lors d'un traumatisme simulé

Présentée et soutenue par
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Thèse soutenue le 10/02/2023
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THESE DE DOCTORAT DE L'UNIVERSITE DE ROUEN NORMANDIE

QUANTIFICATION DE L'INSTABILITE LATERALE
CHRONIQUE DE CHEVILLE ET DE SES DIFFERENTS
FACTEURS DE RISQUE SUR LA VITESSE ANGULAIRE EN
INVERSION LORS D'UN TRAUMATISME SIMULE

Présentée et soutenue publiquement le 10 Février 2023 par

Matthieu LALEVEE

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- Monsieur le Professeur Charles Court.
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A mon épouse, mes enfants, mes parents.

Quantification de l'instabilité latérale chronique de cheville et de ses différents facteurs de risque sur la vitesse angulaire en inversion lors d'un traumatisme simulé.

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Partie 1 : État de l'art sur l'instabilité latérale chronique de la cheville.

1.1 Epidémiologie.

L'entorse du plan ligamentaire latéral de cheville (ELC) est l'une des atteintes les plus fréquentes de l'appareil locomoteur (1). Selon la HAS, son incidence en France est de deux millions de cas par an, 6000 cas par jour et représente 7 à 10% des consultations d'urgence hospitalières (2,3). La méta-analyse de Doherty et al. retrouve une incidence plus élevée chez les femmes, les sujets jeunes et les sportifs (1). Aux Etats Unis, près de la moitié des entorses de la cheville (49,3%) surviennent lors d'une activité sportive, le basket-ball, le football américain et le football étant associés aux incidences les plus élevées (4).

Les ELC présentent un taux élevé de récives et un nombre important des traumatismes de cheville surviennent dans un contexte d'instabilité latérale chronique de cheville (ILCC) (5). Les individus ayant présenté au moins un antécédent d'ELC ont 3.5 fois plus de risques de présenter une ELC en comparaison à une population sans antécédent et jusqu'à 47% des patients étant victimes d'une ELC rapportent des antécédents de traumatismes de cheville (6).

Définissant un sujet actif comme un sujet inférieur à 40 ans, pratiquant le sport même occasionnellement ou appartenant à l'armée, Lin et al. retrouvent une prévalence d'ILCC dans une population active de 25%, et de 46% chez les sujets ayant au moins un antécédent d'ELC (5). Attenborough et al. ont réalisé une revue systématique de la littérature chez les sportifs et évaluent à 28% la prévalence d'instabilité perçue et déclarée par le patient, à 50% l'existence d'au moins une récive d'ELC et à 40% les patients présentant des symptômes résiduels conséquents à une ou plusieurs ELC (7).

Zhang et al. ont réalisé une étude transversale chez 198 athlètes élités (8). Dans cette population, 85,9 % de ces athlètes avaient déjà subi au moins une ELC et la prévalence d'ILCC était de 64,6 %. Le détail par sport de ces prévalences est exposé dans le Tableau 1.

Ankle sprain history and prevalence of chronic ankle instability (CAI) in different sports.

Sport	Total	Ankle Sprain History		CAI Prevalence		
		Previous Ankle Sprain	No Ankle Sprain	No CAI	Unilateral CAI	Bilateral CAI
		n (%)	n (%)	n (%)	n (%)	n (%)
All	198	170 (85.9)	28 (14.1)	70 (35.4)	50 (25.3)	78 (39.4)
Diving	24	22 (91.7)	2 (8.3)	6 (25.0)	8 (33.3)	10 (41.7)
Basketball	40	34 (85.0)	6 (15.0)	13 (32.5)	9 (22.5)	18 (45.0)
Weightlifting	19	16 (84.2)	3 (15.8)	6 (31.6)	3 (15.8)	10 (52.6)
Badminton	20	15 (75.0)	5 (25.0)	7 (35.0)	5 (25.0)	8 (40.0)
Track and field	20	17 (85.0)	3 (15.0)	8 (40.0)	5 (25.0)	7 (35.0)
Fencing	23	17 (73.9)	6 (26.1)	15 (65.2)	3 (13.0)	5 (21.7)
Sanda	12	10 (83.3)	2 (16.7)	4 (33.3)	3 (25.0)	5 (41.7)
Trampolineing	20	19 (95.0)	1 (5.0)	5 (25.0)	8 (40.0)	7 (35.0)
Gymnastics	20	20 (100.0)	0 (0.0)	6 (30.0)	6 (30.0)	8 (40.0)

Tableau 1 : Zhang C, Chen N, Wang J, Zhang Z, Jiang C, Chen Z, et al. The Prevalence and Characteristics of Chronic Ankle Instability in Elite Athletes of Different Sports: A Cross-Sectional Study. *JCM*. 16 déc 2022;11(24):7478.

1.2 Définition de l'instabilité latérale chronique de cheville.

La définition de l'ILCC est restée floue durant de nombreuses années limitant fortement la comparabilité des études (9). En 2014 l'International Ankle Consortium a publié une déclaration définissant les critères d'inclusion pour le recrutement des patients présentant une ILCC dans les recherches contrôlées (10,11). Ces critères sont dès lors utilisés comme référence pour définir la condition d'ILCC dans le domaine scientifique (Figure 1).

Ainsi, une cheville présentant les critères suivants sera considérée comme présentant une ILCC :

1. Antécédent d'au moins une ELC de la cheville.
 - Associés à des symptômes inflammatoires
 - Ayant entraîné au moins un jour d'interruption dans les activités physiques désirées.
 - L'épisode initial d'ELC doit avoir eu lieu au moins 12 mois avant le début de l'étude.

2. Associés à :

- Une ou plusieurs récurrences d'ELC
- ET/OU au moins deux épisodes de dérobements de cheville dans les 6 mois précédant l'étude
- ET/OU une sensation d'instabilité de la cheville

Est reconnu comme "ELC" toute lésion traumatique aiguë du complexe ligamentaire latéral de l'articulation de la cheville résultant d'une inversion excessive de l'arrière-pied ou d'une flexion plantaire et d'une adduction combinée du pied.

Est reconnu comme "dérobements" la survenue d'épisodes incontrôlés et imprévisibles d'inversion excessive de l'arrière-pied (généralement lors du contact initial pendant la marche ou la course), qui n'entraînent pas d'ELC.

Est reconnu comme "sensation d'instabilité de cheville" la situation dans laquelle, au cours des activités de la vie quotidienne ou sportives, le sujet a l'impression que l'articulation de la cheville est instable avec crainte de subir une ELC. Cette sensation d'instabilité doit être confirmée par un questionnaire validé portant sur l'instabilité de la cheville : Ankle Instability Instrument OU Cumberland Ankle Instability Tool OU Identification of Functional Ankle Instability score (12–14).

L'intégralité des critères est exposée dans la Figure 1.

TABLE 1

**STANDARD INCLUSION CRITERIA
ENDORSED, AS A MINIMUM, BY THE
INTERNATIONAL ANKLE CONSORTIUM FOR
ENROLLING PATIENTS WHO FALL WITHIN THE
HETEROGENEOUS CONDITION OF CHRONIC
ANKLE INSTABILITY IN CONTROLLED RESEARCH**

Inclusion Criteria

1. A history of at least 1 significant ankle sprain
 - The initial sprain must have occurred at least 12 months prior to study enrollment
 - Was associated with inflammatory symptoms (pain, swelling, etc)
 - Created at least 1 interrupted day of desired physical activity
 - The most recent injury must have occurred more than 3 months prior to study enrollment
 - We endorse the definition of an ankle sprain as “an acute traumatic injury to the lateral ligament complex of the ankle joint as a result of excessive inversion of the rear foot or a combined plantar flexion and adduction of the foot. This usually results in some initial deficits of function and disability”¹⁵
2. A history of the previously injured ankle joint “giving way,” and/or recurrent sprain, and/or “feelings of instability.”
 - We endorse the definition of “giving way” as “the regular occurrence of uncontrolled and unpredictable episodes of excessive inversion of the rear foot (usually experienced during initial contact during walking or running), which do not result in an acute lateral ankle sprain”¹⁵
 - Specifically, participants should report at least 2 episodes of giving way in the 6 months prior to study enrollment
 - We endorse the definition of “recurrent sprain” as “two or more sprains to the same ankle”¹⁵
 - We endorse the definition of “feeling of ankle joint instability” as “the situation whereby during activities of daily living (ADL) and sporting activities the subject feels that the ankle joint is unstable and is usually associated with the fear of sustaining an acute ligament sprain”¹⁵
 - Specifically, self-reported ankle instability should be confirmed with a validated ankle instability-specific questionnaire using the associated cutoff score. Currently recommended questionnaires:
 - Ankle Instability Instrument¹⁶: answer “yes” to at least 5 yes/no questions (this should include question 1 plus 4 others)
 - Cumberland Ankle Instability Tool²⁶: score of ≤ 24
 - Identification of Functional Ankle Instability⁴⁰: score of ≥ 11
3. A general self-reported foot and ankle function questionnaire is recommended to describe the level of disability of the cohort, but should only be an inclusion criterion if the level of self-reported function is important to the research question. Currently endorsed questionnaires:
 - Foot and Ankle Ability Measure²¹: activities of daily living subscale $< 90\%$, sport subscale $< 80\%$
 - Foot and Ankle Outcome Score³⁷: score of $< 75\%$ in 3 or more categories

Figure 1: Gribble PA, Delahunt E, Bleakley C, Caulfield B, Docherty C, Fourchet F, et al. Selection criteria for patients with chronic ankle instability in controlled research: a position statement of the International Ankle Consortium. *Br J Sports Med.* juill 2014;48(13):1014-8.

1.3 Conséquences cliniques de l'instabilité latérale chronique de cheville

Les ELC sont considérées bénignes dans la croyance populaire. Cependant jusqu'à 60% des sujets présentant une ELC présenteront des séquelles physiques au niveau de cette cheville (4,6). D'après l'étude de Anandacoomarasamy et al. qui ont suivi 19 patients ayant présenté un premier épisode d'ELC et 19 témoins appariés, après 29 mois de suivi, seuls 5 sujets avaient complètement récupéré de cette ELC (15). Les 14 sujets restants (74%) présentaient des douleurs, un œdème, une sensation d'instabilité ou de faiblesse comme présenté dans la Figure 2. L'évaluation de la qualité de vie à l'aide du questionnaire Short Form-36 (SF-36) révélait une différence significative concernant la santé physique entre les deux groupes, en défaveur du groupe ELC.

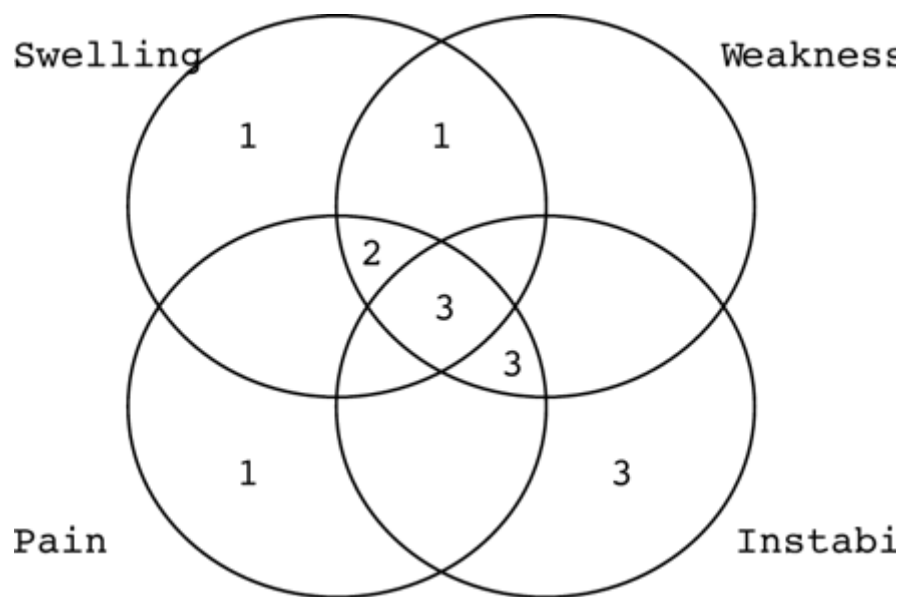


Figure 2: Anandacoomarasamy A, Barnsley L. Long term outcomes of inversion ankle injuries. *British Journal of Sports Medicine*. 1 mars 2005;39(3):e14-e14.

Ces symptômes se chronicisant rentrent fréquemment dans le cadre d'ILCC (11,16). Konradsen et al. ont évalué 648 ELC à 7 ans du traumatisme (17). Trente-deux pour cent des sujets rapportaient des douleurs chroniques, des gonflements ou des récives. Une douleur séquellaire était présente dans 16 % des cas et dans 4%

des cas les douleurs étaient présentes au repos et représentaient un handicap majeur pour le patient.

La déclaration de consensus de l'International Ankle Consortium de 2016 stipulait que l'une des conséquences substantielles à long terme des ILCC est l'arthrose post traumatique de cheville (11). Cette arthrose post traumatique pourrait être à l'origine de ces douleurs. Dans une étude IRM comparant des sujets présentant une ILCC à des témoins appariés Wilkstrom et al. retrouvaient une atteinte dégénérative du cartilage plus importante dans le groupe ILCC (18). Valderrabano et al. ont étudié une cohorte d'arthroses post traumatiques de cheville et ont conclu que les ELC chez les sportifs étaient l'une des causes les plus fréquentes (19). Hirose et al. ont réalisé une étude cadavérique incluant 33 chevilles avec des lésions ligamentaires latérales et 93 chevilles témoins appariées sans lésion ligamentaire, et ont observé une atteinte cartilagineuse plus importante dans le groupe présentant des lésions ligamentaires (20). Enfin, Sugimoto et al. ont évalué sous arthroscopie le cartilage de 99 chevilles présentant une ILCC avec un âge moyen de 29 ans (21). Ils ont observé des lésions cartilagineuses dans 76,8 % des cas dont 41,4 % de lésions sévères.

1.4 Impact socioéconomique.

Les ELC et ILCC sont très fréquentes et représentent une charge financière importante pour les systèmes de santé (5,11).

Les coûts directs sont ceux correspondant à la mise en œuvre de la stratégie thérapeutique. D'après la revue systématique de Bielska et al. le coût direct d'une ELC est estimé entre 292 à 2268 USD (22). Ce dernier varie avec la gravité de la lésion, la stratégie thérapeutique choisie et le pays dans lequel le traitement est dispensé. Supputant un coût direct de 500 euros par ELC en France associé à une incidence de deux millions d'ELC par an le coût direct annuel pourrait être de 1 milliard d'euros (2,3).

A ces coûts directs s'ajoutent des coûts indirects correspondant à la perte de production du sujet due à ce traumatisme. Il est par exemple rapporté qu'un quart des personnes souffrant d'une ELC sont incapables d'aller à l'école ou au travail pendant

plus de 7 jours après la blessure initiale (1). Les coûts indirects sont généralement 2 à 3 fois plus élevés que les coûts directs (22).

Les coûts directs et indirects observés dans la revue systématique de Bielska et al. sont présentés dans le Tableau 2.

Direct and indirect cost summary by injury type (2016 USD).

	Ankle sprain [1,4-7]
Number of papers (%) ^a	5/32 (16%)
Direct costs (2016 USD)	\$292-\$2268 (n = 5)
Out-of-pocket and indirect costs (2016 USD)	\$1482-\$4343 (n = 2)
Overall costs (direct and indirect) (2016 USD)	\$1809-\$5271 (n = 2)
Mean duration of unemployment	7-29 days (n = 2)

^a Some reviewed papers assessed multiple injury types.

Tableau 2 : Bielska IA, Wang X, Lee R, Johnson AP. The health economics of ankle and foot sprains and fractures: A systematic review of English-language published papers. Part 2: The direct and indirect costs of injury. *The Foot*. juin 2019;39:115-21.

Outre ces coûts directs et indirects, il faut également prendre en compte les coûts à long terme des ILCC et de l'arthrose de cheville (11). Il est impossible de chiffrer précisément ces coûts. L'International Ankle Consortium conclut que, bien que les estimations de coûts diffèrent d'un pays à l'autre, les ELC et les ILCC entraînent des coûts sociétaux substantiels (11).

1.5 Comment améliorer la situation ?

L'impact clinique et socioéconomique des ELC et des ILCC est majeur. Paradoxalement leur prise en charge a peu évolué durant les 20 dernières années (23,24). Une méta-analyse réalisée par Doherty et al. en 2017 sur la prise en charge des ELC recommande : l'usage d'anti-inflammatoires non stéroïdiens, de rééducation et

d'immobilisation par attelle pour diminuer le risque d'ILCC (24). Ces mêmes conclusions et recommandations étaient déjà présentes dans la revue de 2003 d'Osborne et al. sur ce même sujet (23).

Dans ce contexte, nous avons réalisé une revue de la littérature intitulée "*Current Challenges in Chronic Ankle Instability. Review and Perspective*", publiée dans le journal *Foot and Ankle Clinics*, avec pour objectifs :

1. de faire le point sur l'état actuel des connaissances sur l'ILCC.
2. d'orienter les recherches scientifiques à mener dans ce domaine pour tenter d'améliorer la situation.
3. de définir les facteurs à intégrer dans ces recherches.

Current Challenges in Chronic Ankle Instability

Review and Perspective

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Jason M. Wilken, PT, PhD^{f,*}

KEYWORDS

• Ankle instability • Ankle sprain • Functional • Mechanical • Risk factors

KEY POINTS

- Chronic ankle instability (CAI) often leads to disability and ankle osteoarthritis resulting in a significant long-term socioeconomic burden. The management of CAI has changed little.
- CAI, relevant to multiple fields and specialties, is commonly addressed in terms of either mechanical instability or functional impairment. Basic research is needed to foster reliable translational research encompassing both mechanical and functional aspects.
- A thorough accounting of the many risk factors for CAI is needed. The development of effective preventative and treatment strategies is contingent on understanding how and why some people develop CAI after a simple ankle sprain, whereas others do not.
- Sprain simulators assessing ankle inversion and angular inversion velocity could help diagnose and quantify CAI. Such measurements will play a role in understanding the relative importance of each risk factor in CAI.

INTRODUCTION

Injuries to the ligaments of the ankle are common and represent an important socioeconomic burden.¹ The incidence of ankle sprains is approximately 7/1000 person-years in the general population and can be as high as 45/1000 person-years in physically active people,² with both direct and indirect financial burden.¹ Despite the frequency and impact of ankle sprains, treatment has changed little over the

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past three decades.³ Although many individuals successfully recover from ankle sprains, nearly one-third experience chronic ankle instability (CAI) with significant short- and long-term consequences for patients, including ankle osteoarthritis.⁴

There are several reasons that may explain why we have been unable to improve the management of ankle sprain and CAI to avoid these consequences. First, CAI is a complex multifaceted condition relevant to multiple specialties, with each working to address instability from their unique point of view.⁵ For example, orthopedists and sport medicine specialists primarily focus on the mechanical aspect of CAI associated with anatomical lesions amenable to surgical treatments.⁶ Conversely, physiotherapists and physiatrists primarily focus on rehabilitative interventions and function.⁷ As a result of this siloed approach to research, few studies rigorously address both aspects together. Given its complexity, a multidisciplinary approach combining the strengths of all interested parties is essential to advance the understanding and management of CAI, encompassing both functional and mechanical aspects.⁸

Second, the mechanisms whereby some patients progress to CAI following a simple sprain, whereas others manage to cope and return to a normal life, are not well understood.^{1,9} An improved understanding of why some individuals develop CAI and others are able to effectively cope would be a crucial step in the management of CAI, in particular by developing preventive care. Third, CAI involves many risk factors. The accumulation of these risk factors could explain, at least in part, the occurrence and severity of CAI. A detailed accounting of potential risk factors is needed for rigorous evaluation; however, a comprehensive accounting of the risk factors appears to be lacking.

Finally, diagnostic and measurement tools to identify and track individuals at risk of CAI, before and after an acute sprain, and to propose preventive treatments are desperately needed. Currently available tools are primarily limited to questionnaires focused on sprain history and their consequences, making preventive management impossible.

Our review aimed to detail these different aspects of CAI point-by-point to guide researchers and clinicians in their research prospects.

WHY SHOULD WE IMPROVE CHRONIC ANKLE INSTABILITY MANAGEMENT?

According to a recent systematic review by Lin and colleagues,¹⁰ the overall prevalence of CAI after a sprain is 25%, and in otherwise healthy adolescent athletes, the prevalence of CAI is 20% following an ankle sprain.¹¹ Despite over one-fifth of individuals progressing to CAI, ankle sprains are still considered benign injuries by many athletes and the general population.¹² It is therefore essential to advance efforts to inform the scientific and clinical community of the deleterious effects of CAI.

Michels and colleagues¹³ recently showed that 1 year after an ankle sprain, 15.8% of patients have a recurrence, 8.1% remain subjectively unstable, and 6.7% suffer from residual pain. These issues seem to persist over time. In a 6.5-year follow-up study of ankle sprains, 6% of patients were unable to maintain their occupational activities, whereas 15% could only continue their original occupation with some handicap.¹⁴ Articular lesions are one potential source of the persistent limitations. The incidence of osteochondral lesions following an ankle sprain is between 37 and 89% in the literature.^{15,16} Sugimoto and colleagues¹⁷ arthroscopically assessed the cartilage of 99 CAI ankles, finding only 23.2% of ankles with normal cartilage, whereas all the others (76.8%) presented with cartilage damage, of which 41.4% had serious lesions.

Further, Valderrabano and colleagues¹⁸ found a 55% history of prior ligamentous lesion from sports injuries in a study of individuals with post-traumatic ankle

osteoarthritis, leading them to conclude that ankle sprains are one of the main cause of post-traumatic ankle osteoarthritis. Finally, the 2016 International Ankle Consortium stated that there is growing evidence that an important consequence of ankle sprain, and the resulting high rate of CAI, is post-traumatic ankle osteoarthritis, affecting young patients and making the majority of surgical cases of post-traumatic ankle osteoarthritis.¹

This growing body of literature supports efforts to communicate the importance of successful management of ankle sprains. Ankle sprains and especially CAI have a direct impact on patient lives, in particular because they frequently cause articular lesions that can require surgical treatment. It is therefore essential to treat CAI before the appearance of these consequences.

FUNCTIONAL AND MECHANICAL INSTABILITY

The pathophysiological concepts pertaining to CAI are frequently divided into mechanical and functional instability.^{19,20} This division could stem from background differences between specialties. On the one hand, orthopedic surgeons will look for mechanical factors such as ligament laxity or gastrocnemius tightness because their experience allows them to correct these anatomical problems.²¹ On the contrary, the physical therapists or physiatrists primarily focus on functional instability and factors such as deficits in proprioception or weakness of the evertors.²² The differing perspectives are evident in the scientific literature, with most studies only assessing mechanical or functional instability and far fewer addressing both perspectives.⁵ The mechanical aspect of instability involves anatomical structures such as ligaments or bone deformities, whereas the functional aspect is rather linked to proprioceptive and neuromuscular deficits.²³

Initially, the study of CAI focused on ligamentous laxity and its mechanical aspects was predominant until Freeman introduced the concept of functional instability represented by the persistence of symptoms following an ankle sprain.^{24,25} Only considering ligamentous laxity in mechanical instability is a narrow point of view. For instance, Yoshimoto and colleagues²⁶ showed that the recurrence of ankle sprain after surgical ligament reconstruction is higher with varus inclination of the tibial plafond. Many other factors are likely involved in mechanical instability, such as syndesmotic injury or lack of ankle dorsiflexion.^{27,28} Similarly, the functional aspect of CAI is much more than persistent symptoms after an ankle sprain, including for example impaired proprioception or muscle weakness.^{29,30}

Freeman was one of the first to develop a theory linking functional and mechanical instability.^{24,25} His concept was that a ligament injury, which would be the cause of mechanical instability, can also be responsible for functional instability. This is because a ligament lesion can cause partial deafferentation resulting in sensorimotor impairment, leading to functional instability of the ankle. Now over 50 years later, Hertel and colleagues³¹ have proposed an updated model of CAI fully encompassing its known mechanical and functional aspects. This model includes 8 primary components: primary tissue injury, pathomechanical impairments, sensory-perceptual impairments, motor-behavioral impairments, personal factors, environmental factors, component interactions, and the spectrum of clinical outcomes. These 8 components interact through 3 so-called conjectural constructs or self-organization, perception-action, and neurosignature.

This CAI model goes beyond the mechanical and functional aspects and includes interactions between its different components and considering the whole person. The triggering factor of CAI is represented in this model by the sprain and the

ligamentous injury. Once the patient has sprained his ankle, they enter a loop where these 8 components influence the occurrence of a CAI. For instance, risk factors such as the pathomechanical impairments of ligamentous laxity or restricted range of motion and the motor-behavioral impairment or muscle weakness can contribute to the development of CAI. These components interact within what they called the self-organization, which is specific to each patient and represents the control of the patient's motion which is influenced by different constraints.

The different pathological factors also interact through perception-action cycles and the neurosignature. The perception-action cycles represent what the patient perceives and what the motor response to that perception will be and the neurosignature, which is influenced by many factors like genetics and the patient's lived experience, would represent the central processing of the perception-action cycles. These three conjectural constructs are unique to each person and will determine, by interacting with the risk factors, whether the patient would experience CAI or effectively cope after a sprain. This concept effectively illustrates the influence of each risk factors on the outcome and the fact that the CAI functional and mechanical aspects must be considered together and not divided.

However, this model does not provide detailed information regarding the primary risk factors influencing the prevention or management of CAI, or their relative importance. For instance, we do not know whether ankle laxity should be considered a more important risk factor for CAI than evertor muscle weakness. Going further, we also do not know which ligaments should be considered. What they call the primary tissue injury can include damage to the anterior talofibular ligament and calcaneofibular ligament, however, syndesmotic, cervical, or deltoid ligament involvement could also influence CAI.^{27,32} The model does not provide information on the importance of the accumulation of these different risk factors. It is possible that a patient with six of these risk factors is more likely to develop CAI than a patient with only 2 risk factors. Finally, risk factors may be modifiable or non-modifiable. For example, an ankle varus can be medically or surgically corrected in some individuals, whereas the patient's age cannot.

In summary, the mechanical and functional aspects of CAI are closely related. Basic research that crosses medical specialties must be carried out to then allow reliable translational research encompassing the mechanical and functional aspects of CAI.

PROGRESSION FROM ACUTE SPRAIN TO CHRONIC ANKLE INSTABILITY

Our understanding of why some patients develop CAI after an acute sprain, whereas others are able to cope and return to normal life is limited. Understanding the differences between these two groups will be a crucial step in managing CAI. Knowing a priori what pushes the patient towards instability would allow preventive care to allow more individuals to successfully cope with an ankle sprain and avoid instability.

Wikstrom and colleagues³³ define a copers as a patient who has had a severe sprain but is able to resume weight-bearing activity for at least 12 months without injury, episodes of giving way and/or feelings of instability. Comparing CAI and copers patients 1 year after sprain to controls, Doherty and colleagues³⁴ showed that CAI patients had a deficit in dynamic balance compared with controls and copers. In a recent systematic review, Yu and colleagues³⁵ concluded that CAI patients exhibit adaptive strategies (primarily hip flexion to maintain stability) when landing and increased frontal ankle displacement compared with copers. Understanding these differences could allow early detection of patients at risk of CAI after a sprain and to implement preventive care.

Donovan and colleagues³⁶ performed a literature review in 2012 and classified the presence of CAI impairments in 4 different domains: limited range of motion, decreased strength, impaired postural control and altered movement strategies. They have developed a rehabilitation protocol specifically designed to address these 4 different domains of impairments. This helps improve CAI management, but this does not explain the origin of the differences between individuals with CAI and copers.

As described by Hertel and colleagues,³¹ ligamentous injury in an ankle sprain may trigger sensorimotor changes via inflammatory and pain mediators that would result in specific sensory-perceptual and motor-behavioral impairments. Each patient would react differently to this and some of them would develop CAI. However, many factors could influence this pathway from acute sprain to CAI. Miklovic and colleagues³⁷ considered that the use of Donovan and colleagues³⁶ above-mentioned protocol can treat a large majority of CAI patients. But they did not know whether they should apply this same protocol in early rehabilitation for acute ankle sprain. They therefore decided to carry out a review of the literature to find out whether the 4 impairments they described in CAI would be present in patients with acute and subacute ankle sprains. Their conclusion was that similar domains of impairment were present in these different groups and that their rehabilitation protocol could also be applied to acute sprains. Because these impairments are present immediately after the injury, one can wonder if some of them could have been present before the trauma and if doing prophylactic rehabilitation could have avoided the initial trauma.

There are many risk factors for ankle sprain and CAI that align with both mechanical and functional concepts. Some of them could be present even before the trauma (ie, hindfoot varus), and some of them would appear after the acute sprain. As described by Hertel and colleagues³¹ all these factors interact. It is likely that the more risk factors an individual has the more likely they are to sprain their ankle and develop CAI. The ankle sprain occurrence would be an addition of one of these risk factors (ligamentous laxity), which would destabilize the patient's homeostasis and cause them to develop CAI. Therefore, the most important point would be to be acquainted of these risk factors and then to understand the relative impact of each of them in sprain and CAI occurrences. A patient could either never have sprained their ankle or present an acute sprain or become copers or develop CAI. The important point would be to monitor these risk factors to correct those that are correctable. According to this theory, it would also be possible to provide prophylactic treatment, for example in athletes to avoid a first episode of acute sprain, or to prevent a subject from developing CAI after an acute sprain.

RISK FACTORS FOR CHRONIC ANKLE INSTABILITY

To collect all the CAI risk factors currently present in the literature, we conducted a rapid review using PubMed and the keywords "ankle AND lateral AND (instability OR unstable) AND (risk factor OR predict* OR relationship)". All studies available in PubMed up to May 2022 were screened. Comparative studies and systematic reviews of comparative studies involving CAI patients (comparing CAI to controls or copers or assessing recurrence of ankle sprain after treatment) were included. Case reports, narrative review, expert opinion, editorial, cadaveric studies, finite element analysis studies, or studies involving instability concurrent with ankle fractures were excluded as well as studies written in a language other than English. Only the risk factors presenting significant results in the studies were collected. The level of evidence for each article was classified according to Marx and colleagues^{38,39} and the grade of evidence for each risk factor was assessed according to Wright and colleagues.⁴⁰ The

risk factors were classified into mechanical, functional, personal, and environmental factors.

Following this process, 324 study titles were reviewed and 53 studies were selected. These 53 studies reported 68 significant findings for CAI risk factors, some of which were recurrently present in these studies (Fig. 1). The studies selected and grades of evidence for each risk factor are summarized in Table 1.

One of the most frequently reported risk factors was a prior history of ankle sprain and its severity.⁴¹ Nevertheless, this factor is already in the mind of all providers and researchers and was not included as an independent risk factor because we consider it more of a consequence of CAI than a risk factor. The indirect consequences of this trauma will in any case be included in the risk factors (ie, rupture of the anterior talofibular ligament).

Foremost among several mechanical risk factors identified in the literature was ligamentous laxity. Involvement of the anterior talofibular and calcaneofibular ligaments, and associated laxities are commonly a focus in ankle sprain literature.^{42–49} These two were indeed the most studied presenting, respectively, good and fair grades of evidence, but syndesmotic and subtalar laxity were also reported as CAI risk factors, although both of these were present with lower levels of evidence.^{42,50,51} The presence of deltoid laxity as a risk factor for lateral instability is controversial. The latter is more frequently related to medial insufficiency associated with flatfoot or Progressive Collapsing Foot Deformity.⁵² Its presence in lateral ankle instability may be biased by its strong pathomechanical connection with syndesmotic lesions.⁵³ It is more likely that syndesmotic laxity is the true risk factor for CAI and that deltoid insufficiency is indirectly related to CAI as it correlates with syndesmotic lesions.

The presence of decreased ankle dorsiflexion has also been recognized as a risk factor for CAI with fair evidence.^{49,54–56} Our review does not specify whether this lack of dorsiflexion comes from an isolated gastrocnemius tightness, from a global retraction of the triceps surae, or from an anterior tibiotalar impingement.⁵⁷ Others were present with inferior evidences such as ankle and hindfoot varus or dysplasia involving the surrounding bones.^{58–66} An anterior position of the fibula with respect to the tibia was also found as risk factor but we are unable to inform whether this is a consequence of ligamentous laxity or a real independent factor.^{67,68}

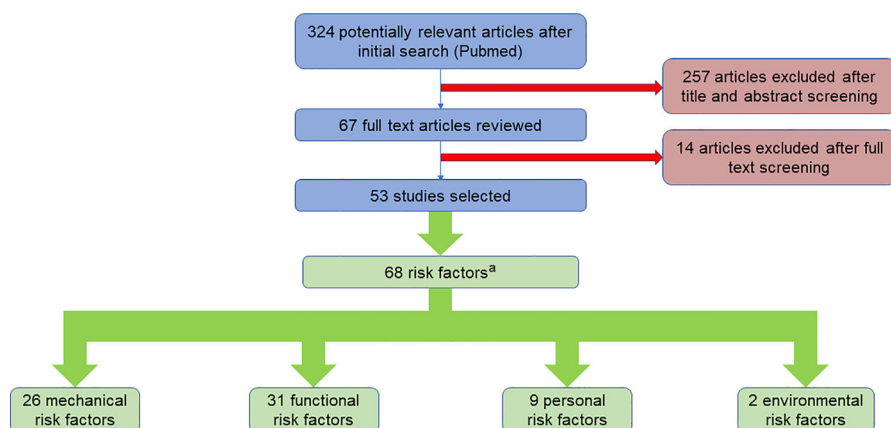


Fig. 1. Flow chart for structured literature review of CAI. ^aSome of them were present multiples times in different studies.

Table 1
Literature survey for risk factors of chronic ankle instability

Risk Factors	References	Level of Evidence	Grade of Evidence	Correctable?
Mechanical				
ATFL rupture—anterior drawer laxity	42–47	1 to 4	A—good	Yes
CFL rupture—varus tilt laxity	42–45,48,49	2 to 4	B—fair	Yes
Decreased ankle dorsiflexion	49,54–56	2 to 3	B—fair	Yes
Ankle and hindfoot varus	26,58–61	3 to 4	C—poor quality	Yes
Bony dysplasia (syndesmosis, talus, calcaneus)	62–66	3	C—poor quality	No
Anterior position of the fibula	Weerasekar et al. ⁶⁷ 2021, Hubbard ⁶⁸ 2006	3	C—poor quality	No
Syndesmotic and deltoid ligament laxity	Kim et al. ⁵⁰ 2005	3	C—poor quality	Yes
Subtalar laxity (interosseous and cervical ligaments)	Denegar ⁴² 2002, Song et al. ⁵¹ 2021	4	I—insufficient	Yes
Functional				
Impaired neuromuscular control (including proprioception and balance deficits)	22,46,49,50,69–85	1 to 4	A—good	Yes
Altered gait patterns (walking, running, jumping...)	52,70,86–88	1 to 3	A—good	Yes
Strength deficit (evertors and plantarflexors)	22,46,47,89,90	1 to 4	A—good	Yes
Personal				
Increased BMI	46,47,70	1 to 3	A—good	Yes
Generalized laxity	91,92,104	1 to 3	A—good	No
Young age	Pourkazemi et al. ⁴⁶ 2018, Fousekis ⁴⁷ 2012	1	A—good	No
Kinesiophobia	Alshahrani ⁹⁵ 2022	4	I—insufficient	Yes
Environmental				
Sport	Pourgharib Shahi et al. ⁹³ 2021, Mailuhu et al. ⁹⁴ 2019	2 to 3	B—fair	Yes

Abbreviations: ATFL, anterior talofibular ligament; BMI, body mass index; CFL, calcaneofibular ligament.

We divided the functional CAI risk factors into three groups according to the description by Donovan and Hertel^{31,36}: impaired neuromuscular control, altered gait patterns, and strength deficit. Our results were consistent with those of these previous authors. Impaired neuromuscular control included notably proprioception, balance deficits, and delayed peroneal reaction time,^{22,46,49,54,69–85} whereas altered gait patterns were a functional impairment when walking, running, or jumping.^{52,73,86–88} Strength deficits were primarily represented by evolver weakness and less frequently by plantarflexor weakness.^{22,46,47,89,90} These 3 groups of functional factors were all established with good evidence in the literature.

Personal and environmental factors were less studied, but good evidence was present regarding increased body mass index, generalized laxity, young age, and sports participation as risk factors for CAI,^{46,47,70,91–94} whereas kinesiophobia was present with a low level of evidence.⁹⁵ It can also be noted that 75% of these risk factors can be medically or surgically corrected. Our opinion is that the management of CAI or acute sprains or prevention strategies must involve all these risk factors. As most of them can be present even before the first ankle sprain, we propose a model considering these risk factors as constitutional or consequential. Their detection and correction should be done either in anticipation before the initial injury or after the initial injury to allow the patient to cope with these factors and return to a normal life or as a treatment of CAI (Fig. 2).

In conclusion, functional risk factors are more studied and more validated than mechanical factors in the literature, but both should be included in the CAI management. We propose a model encompassing the mechanical and functional risk factors by considering them either as constitutional (present on the subject before the initial sprain) or consequential (developed after the trauma) with a cumulative effect of these risk factors. This model, unlike previous models, allows prevention and prophylactic management of constitutional risk factors to prevent initial ankle sprain, which could be effective for example in the sports field. We exposed an example of subject interaction with our cumulative risk factor model in Fig. 2.

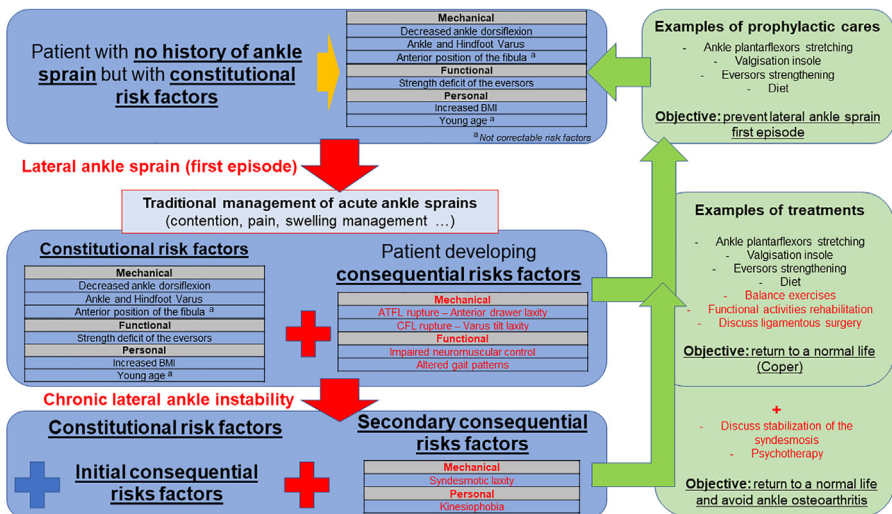


Fig. 2. Example of subject interaction with our cumulative risk factors model.

DIAGNOSING AND MEASURING CHRONIC ANKLE INSTABILITY

Diagnosing and measuring CAI is currently challenging. The most commonly used tools for this purpose are questionnaires like the Cumberland Ankle Instability Tool, the IdFAI, or the Foot and Ankle Ability Measure.^{96,97} These questionnaires are limited by taking into account the history of ankle sprain in their items and therefore cannot be used in prevention. They are nonetheless routinely used in research to define study groups. The International Ankle Consortium has made recommendations on the selection criteria for patients with CAI including these questionnaires and their appropriate thresholds.⁹⁸

As mentioned earlier, many studies focus only on the CAI mechanical or functional aspect. It is difficult to construct a study encompassing these two aspects as well as the personal and environmental risk factors that we have previously defined. In this way, sprain simulators have shown promising results.^{99,100} These tools focus directly on the behavior of the ankle in the event of a sudden inversion motion. Assessment criteria typically used with these tools are maximum ankle inversion and maximum inversion velocity during the simulated trauma.^{101–103} Ankle sprain simulators enable research encompassing the mechanical, functional, and all other CAI aspects. It can be discussed a theoretical risk of spraining the ankle during the simulated trauma, but according to Chu and colleagues¹⁰¹ real ankle sprains involve inversion velocities over 500°/s and the use of a device simulating inversion trauma involving velocities less than 300°/s will exclude any risk of injury. A limitation of these studies is that most of them were performed in static positions or when landing, but not when walking and running, which might better reflect the actual conditions whereby ankle sprains occur.⁹⁹ These simulators could play a role in quantifying CAI as well as understanding the relative importance of each of its risk factors.

SUMMARY

CAI remains common and presents a significant socioeconomic burden. Progress in this area has been limited by the fact that different groups work on different CAI aspects (mainly mechanical and functional), whereas these factors fundamentally interact and need to be considered together. We performed a systematic review to collect the different risk factors for CAI and divided them into mechanical, functional, personal, and environmental for clarity, but all must be studied together. We have proposed a cumulative model including these risk factors that influence ankle sprains and CAI occurrences. Unlike previous CAI models, our model allows prophylactic management of patients at risk of ankle sprain, as well as CAI management. This model can be used for further research.

CLINICS CARE POINTS

- Alert patients with an ankle sprain sufficiently severe that they have sought medical care to concerns related to the risk for chronic ankle stability (CAI).
- Consider the multitude of risk factors for CAI when counseling patients who have suffered an ankle sprain.
- When evaluating CAI, consider both mechanical instability and functional impairment.
- Use established questionnaires to best capture functional impairment related to CAI.
- A course of physical therapy is warranted to address neuromuscular dysfunction for patients with CAI.

- Mechanical risk factors, such as hindfoot varus or lack of ankle dorsiflexion, should be part of CAI management and can be corrected prophylactically.

DISCLOSURE

The authors have nothing relevant to disclose.

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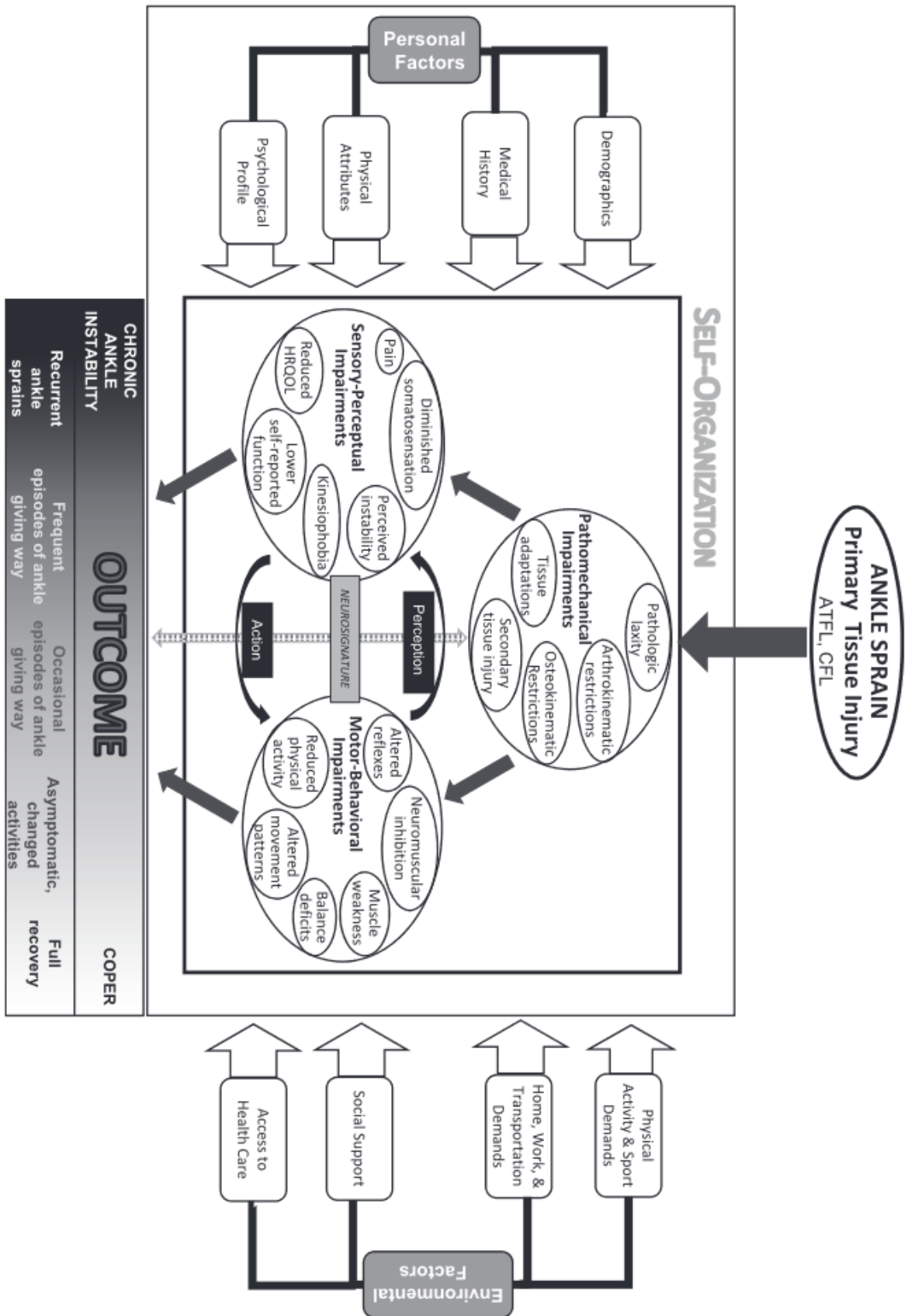
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1.6 Conclusions (Partie 1).

L'ILCC présente des conséquences cliniques et socioéconomiques majeures. Nous avons réalisé une revue de la littérature afin d'identifier les domaines pouvant être améliorés et les points suivants ont été soulignés (25).

1. La littérature scientifique est divisée en ILCC mécanique et ILCC fonctionnelle. Cependant, l'ILCC englobe ces deux aspects qui devraient être évalués de concert dans les études scientifiques.
2. A la suite d'une ELC, il est actuellement impossible de différencier les sujets qui vont évoluer vers l'ILCC de ceux capables de retrouver une homéostasie et une cheville stable, appelés "copers". Comprendre les différences entre ces deux populations permettrait d'améliorer la prise en charge des ELC pour prévenir l'ILCC.
3. Il n'existe pas d'outil permettant de diagnostiquer ou quantifier l'ILCC. Les outils utilisés actuellement sont des questionnaires ayant comme défaut d'être basés sur les antécédents d'ELC, empêchant ainsi toute action prophylactique. Ils évaluent par ailleurs essentiellement l'aspect fonctionnel de l'ILCC.

Hertel et al. proposent un modèle d'ILCC englobant ses aspects fonctionnels et mécaniques (26) (Figure 3). Ce modèle comprend 8 composantes primaires : (1) les lésions ligamentaires initiales (première ELC), (2) les déficiences pathomécaniques, (3) les déficiences sensorielles et perceptives, (4) les déficiences motrices et comportementales, (5) les facteurs personnels, (6) les facteurs environnementaux, associés à, (7) l'interaction entre ces composantes, et la résultante de cette interaction, nommément, (8) le spectre des résultats cliniques (allant de "coper" à ILCC). Ces composantes interagissent par le biais de trois constructions conjecturales : (I) l'auto-organisation, (II) le cycle perception-action et (III) la neurosignature.



The updated model of chronic ankle instability (CAI). The outcome is determined at least 12 months after the initial ankle sprain. Abbreviations: ATFL, anterior talofibular ligament; CFL, calcaneofibular ligament; HRQOL, health-related quality of life.

Figure 3 : 1. Hertel J, Corbett RO. An Updated Model of Chronic Ankle Instability. Journal of Athletic Training. 1 juin 2019;54(6):572-88.

Ce modèle d'ILCC va au-delà des aspects mécaniques et fonctionnels et inclut les interactions entre ces différentes composantes et considère la personne dans son ensemble. Le facteur déclenchant est représenté dans ce modèle par l'ELC. Le sujet entre ensuite dans une boucle où ces 8 composantes influencent la survenue d'une ILCC. Par exemple, les facteurs de risque inclus dans les déficiences pathomécaniques (ex : la laxité ligamentaire et/ou la diminution des amplitudes articulaires) et ceux inclus dans les déficiences motrices et comportementales (ex : la faiblesse musculaire) interagissent entre eux et peuvent contribuer au développement d'une ILCC. Ces composantes interagissent au sein de ce qu'ils appellent l'auto-organisation du sujet, spécifique à chaque patient et représentant "le contrôle du mouvement du patient influencé par différentes contraintes". Au sein de cette auto-organisation, ces interactions sont médiées par les cycles perception-action et la neurosignature. Les cycles perception-action représentent ce que le patient perçoit et la réponse motrice résultante à cette perception. La neurosignature, qui est influencée par de nombreux facteurs comme la génétique et le vécu du patient, représente le traitement central des cycles perception-action. Ces trois constructions conjecturales sont uniques à chaque personne et détermineront, avec les facteurs de risque, si le patient évoluera vers une ILCC ou s'il deviendra un "coper" à la suite d'une ELC.

Cependant, les auteurs ne fournissent pas d'informations détaillées sur les facteurs de risque devant être inclus dans ce modèle. De même nous ne connaissons pas l'impact relatif de chacun de ces facteurs sur la survenue d'ILCC. Par exemple, nous ne savons pas si la laxité de la cheville doit être considérée comme un facteur de risque plus important d'ILCC en comparaison à la faiblesse des muscles éverseurs. Pour aller plus loin, nous ne savons pas non plus quels ligaments doivent être pris en compte. Ce qu'ils appellent la lésion tissulaire primaire peut inclure des dommages du ligament talo-fibulaire antérieur et/ou du ligament calcanéo-fibulaire. L'atteinte associée de ces deux ligaments est-elle un facteur de risque plus important d'ILCC qu'une atteinte isolée du ligament talo-fibulaire antérieur ? Nous ne pouvons répondre à cette question. De même l'existence d'une hyperlaxité constitutionnelle, l'atteinte de la syndesmose, du ligament cervical ou deltoïde pourraient influencer la survenue d'ILCC (27,28). Aussi, ce modèle ne fournit pas d'informations sur l'importance de l'accumulation de ces différents facteurs de risque. Il est possible qu'un patient présentant six de ces facteurs de risque soit plus susceptible de développer une ILCC

en comparaison à un patient présentant seulement 2 facteurs de risque. De plus, ces facteurs de risque peuvent être corrigéables ou non corrigéables. Par exemple, un varus de l'arrière pied peut être corrigé médicalement ou chirurgicalement chez un sujet, alors que son âge ne peut l'être. Enfin, certains de ces facteurs de risque peuvent être considérés comme constitutionnels car étaient présents avant le premier épisode d'ELC (ex : varus de l'arrière pied), alors que d'autres apparaîtront après le ou les épisodes d'ELC (ex : laxités ligamentaires).

Ainsi, les aspects mécaniques et fonctionnels de l'ILCC sont étroitement liés. La recherche fondamentale doit outrepasser cette division et doit permettre d'évaluer l'ILCC de manière globale. Basé sur le modèle de Hertel et al. et ses limites, nous proposons un modèle cumulatif des différents facteurs de risque (Figures 4 et 5). Ce modèle inclut des facteurs de risques constitutionnels et d'autres consécutifs aux ELC. L'objectif pour le soignant, que le patient en soit à son premier épisode d'ELC ou au stade d'ILCC, sera de collecter et corriger ces facteurs de risque pour que le sujet évolue en "coper". Ce modèle cumulatif, contrairement aux précédents modèles d'ILCC présents dans la littérature permet une prise en charge prophylactique des sujets avant même le premier épisode d'ELC.

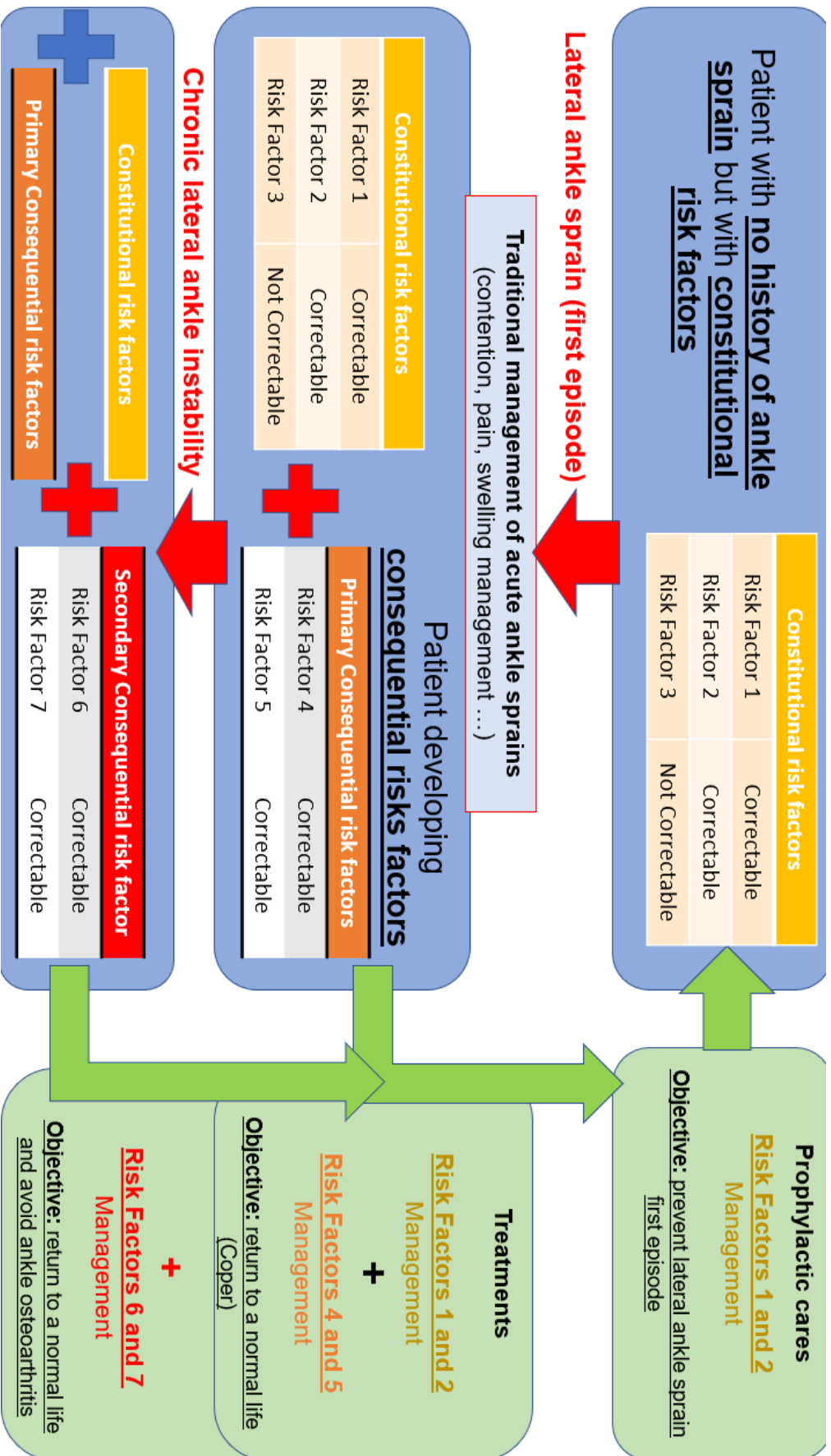


Figure 4 : Modèle cumulatif d'instabilité latérale chronique de cheville.

Nous avons réalisé une revue de la littérature afin de déterminer les facteurs de risque devant être intégrés dans ce modèle. Ces derniers sont exposés dans le Tableau 3.

Risk Factors	Studies levels of evidence	Risk factors grades of evidence	Correctable / Not correctable
Mechanical			
ATFL rupture – Anterior drawer laxity	1 to 4	A – Good evidence	Correctable
CFL rupture – Varus tilt laxity	2 to 4	B – Fair evidence	Correctable
Decreased ankle dorsiflexion	2 to 3	B – Fair evidence	Correctable
Ankle and Hindfoot Varus	3 to 4	C – Poor quality evidence	Correctable
Bone dysplasias (Syndesmosis, Talus, Calcaneus)	3	C – Poor quality evidence	Not correctable
Anterior position of the fibula	3	C – Poor quality evidence	Not correctable
Syndesmotic and deltoid ligament laxity	3	C – Poor quality evidence	Correctable
Subtalar Laxity (interosseous and cervical ligaments)	4	I – Insufficient evidence	Correctable
Functional			
Impaired neuromuscular control (including proprioception and balance deficits)	1 to 4	A – Good evidence	Correctable
Altered gait patterns (walking, running, jumping...)	1 to 3	A – Good evidence	Correctable
Strength deficit (eversors and plantarflexors)	1 to 4	A – Good evidence	Correctable
Personal			
Increased BMI	1 to 3	A – Good evidence	Correctable
Generalized Laxity	1 to 3	A – Good evidence	Not correctable
Young age	1	A – Good evidence	Not correctable
Kinesiophobia	4	I – Insufficient evidence	Correctable
Environmental			
Sport	2 to 3	B – Fair evidence	Correctable

Tableau 3 : Facteurs de risque d'instabilité latérale chronique de cheville.

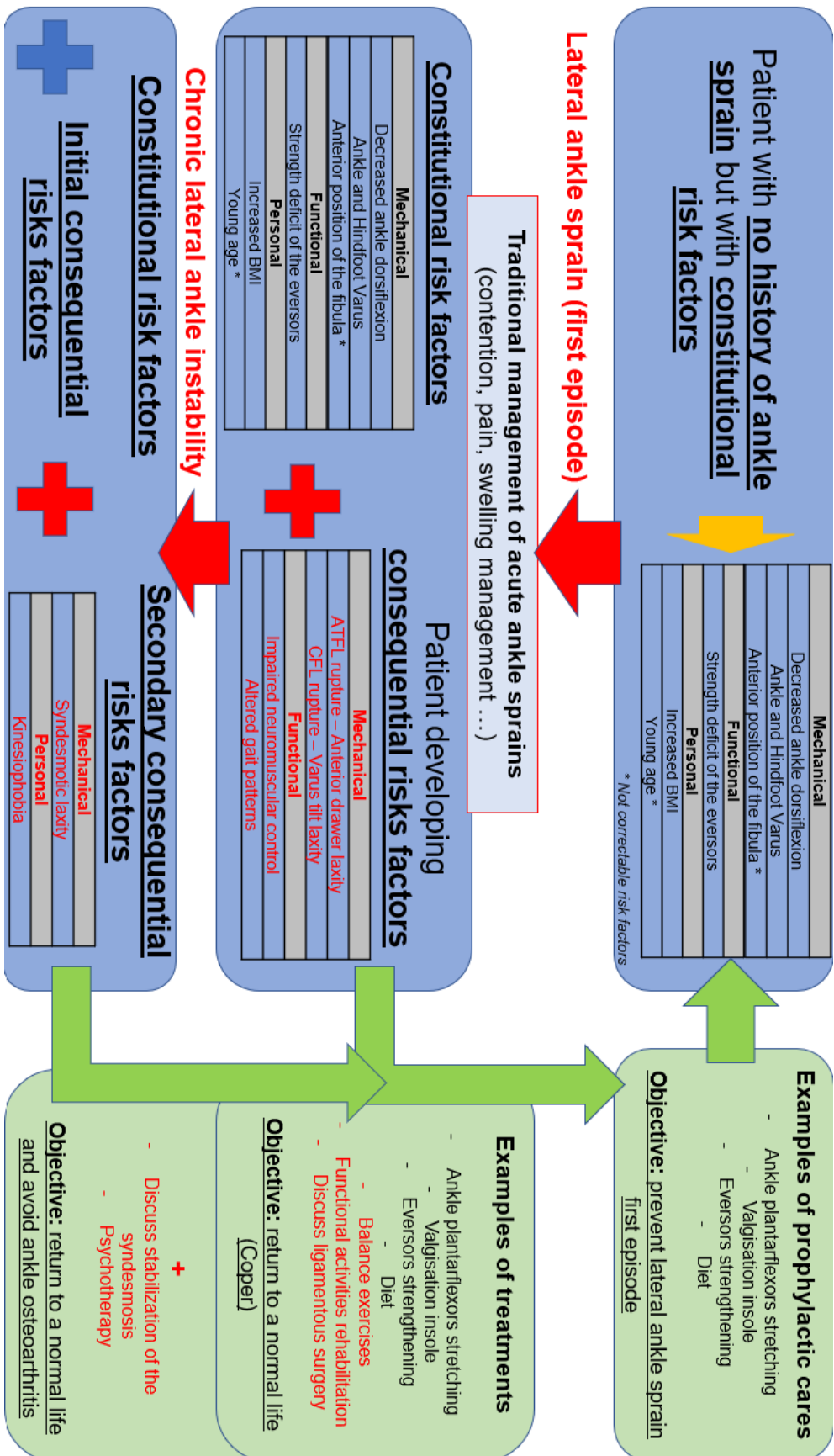


Figure 5 : Exemple d'un patient interagissant avec le modèle cumulatif d'instabilité latérale chronique de cheville

Enfin, disposer d'un outil de mesure de l'ILCC, pourrait permettre d'évaluer l'impact relatif de chaque facteur de risque sur la survenue d'ILCC. Il serait ainsi possible d'identifier les potentiels "copers" et les sujets à risque d'évoluer vers l'ILCC après un épisode d'ELC. Il pourrait être également possible de dépister les sujets à risque d'ELC de manière prophylactique. En accord avec notre revue de la littérature, les simulateurs d'entorses pourraient permettre d'évaluer l'ILCC sur l'inversion maximale et la vitesse angulaire en inversion lors d'un traumatisme simulé, tout en englobant tous les aspects de l'ILCC sans qu'il soit nécessaire de les diviser en ILCC mécanique et fonctionnelle (25,29,30).

Dans la deuxième partie de notre travail, nous exposerons les différentes étapes réalisées nécessaires au développement d'un simulateur d'entorse et nous présenterons les résultats d'une étude ayant pour objectif de différencier un groupe de sujets ILLC d'un groupe de témoins à l'aide de cet outil.

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Partie 2 : Quantification de l'instabilité latérale chronique de cheville sur la vitesse angulaire en inversion lors d'un traumatisme simulé.

2.1 Développement d'un simulateur d'entorse

La plupart des simulateurs d'entorse développés précédemment produisaient des traumatismes simulés en inversion dans une position debout statique ou lors d'un atterrissage après un saut (1–3). Or, il a été démontré que le caractère inattendu du traumatisme est nécessaire pour permettre une analyse fiable de l'inversion (3,4). En effet la pro-activation et la contraction protectrice des fibulaires lors d'un traumatisme attendu pourrait limiter l'inversion et l'interprétation des données (5,6). L'imprévisibilité du traumatisme nous semblait difficile à obtenir avec ces méthodes. Nous avons donc opté pour un traumatisme simulé pendant la marche afin de nous rapprocher au maximum des conditions d'une véritable ELC. Un autre point important de ces simulateurs d'entorse est leur aspect sécuritaire afin d'éviter tout risque de blessure pour les sujets. D'après Chu et al. la vitesse maximale en inversion lors d'un traumatisme simulé doit être inférieure à 300°/sec pour prévenir tout risque de blessures (7).

Nous sommes rentrés en contact avec la société ICC Physio®, qui a développé une botte d'instabilité reproduisant des mouvements d'inversion similaires à ceux d'une ELC pendant la marche. La botte d'instabilité Myolux Athletik est dédiée à la rééducation de la cheville après un épisode d'ELC ou dans le cadre d'une ILCC. Cette botte a été utilisée dans plusieurs études sans qu'aucune blessure ne soit rapportée (5,6,8,9). Nous avons signé un contrat avec ICC Physio® qui nous a gracieusement fourni une paire de chaussures Myolux Athletik pour nos travaux de recherche. **(Annexe 1).**

Cette botte peut être configurée manuellement en position stable ou instable. Afin d'incorporer le caractère inattendu, nous avons intégré une gâche électromagnétique au chausson permettant de contrôler à distance le déclenchement de l'instabilité pendant la marche du sujet (Figure 6).

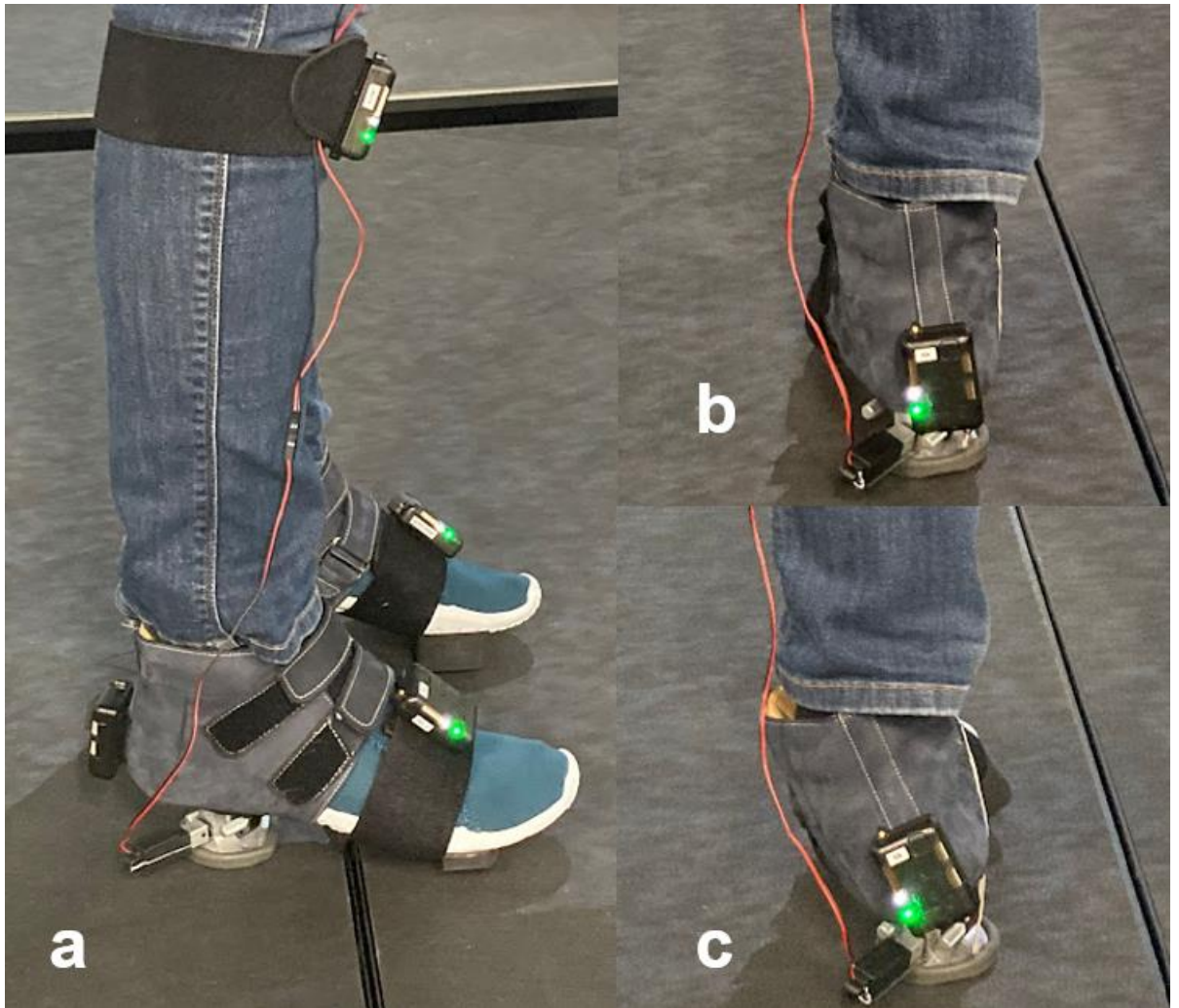


Figure 6 : Chaussons d'instabilité Myolux Athletik.

- a. Vue latérale
- b. Vue postérieure : Position stable
- c. Vue postérieure : Position instable

Afin de permettre l'analyse des mouvements pendant la marche et le traumatisme simulé, nous avons acquis des centrales inertielles (Isen 3.0 STT Systems®). Pour cela, nous avons obtenu un financement à hauteur de 9 840 euros de la fondation Charles Nicolle dans le cadre d'un appel à projet pour matériel innovant (**Annexe 2**).

Enfin, pour améliorer au maximum la sécurité des sujets pendant nos recherches, nous avons travaillé avec le laboratoire d'analyse du mouvement de l'University of Iowa Hospitals & Clinics (Iowa City, USA). Ce dernier est équipé d'un tapis roulant combinant la marche en réalité virtuelle et la sécurisation des sujets par

un harnais en suspension afin d'éviter tout risque de chute et de blessure (Computer Assisted Rehabilitation Environment system (CAREN) virtual reality treadmill, Motek®, Figure 7).

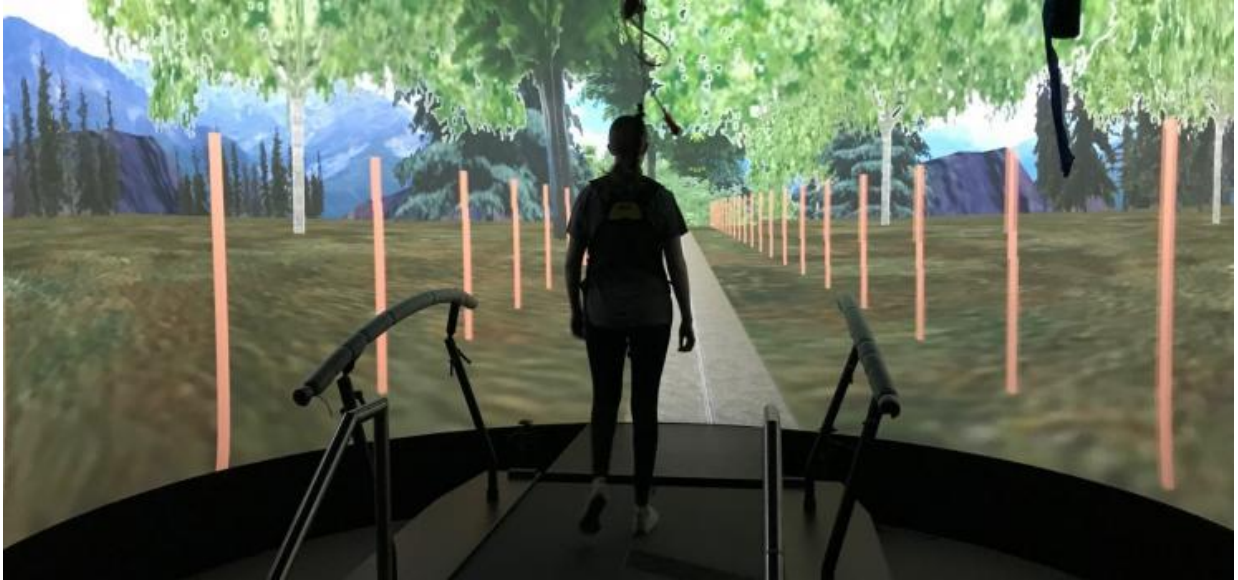


Figure 7 : Computer Assisted Rehabilitation Environment system (CAREN) virtual reality treadmill, Motek®.

Après avoir développé ce matériel, nous avons soumis notre projet à l'Institutional Review Board (IRB) for human subjects research afin d'obtenir un accord d'éthique. Cette étape essentielle a été validée le 1er Août 2022 et nous avons pu commencer nos travaux de recherche à travers deux études (**Annexe 3**).

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2.2 Etude pilote.

Une étude pilote a été menée pour tester notre dispositif simulant un traumatisme en inversion. Les objectifs étaient de confirmer son innocuité, ainsi que de clarifier la méthodologie nécessaire pour comparer des sujets instables à des témoins.

Ce manuscrit suivant a été soumis au *Journal of Foot and Ankle Research*.

Journal of Foot and Ankle Research

Assessing chronic lateral ankle instability with a sprain stimulator: a pilot study.

--Manuscript Draft--

Manuscript Number:	
Full Title:	Assessing chronic lateral ankle instability with a sprain stimulator: a pilot study.
Article Type:	Methodology
Funding Information:	
Abstract:	<p>Background: Chronic Lateral Ankle Instability (CLAI) represents a significant socioeconomic burden. Paradoxically, its management has changed little over the years, notably because research is divided into functional and mechanical instability, whereas CLAI encompasses both. Sprain simulators can encompass both functional and mechanical instability by assessing the maximal ankle inversion velocity (MIV) during a simulated inversion trauma. We built a sprain simulator capable of producing a sudden ankle inversion motion during walking and conducted a pilot study that aimed to:</p> <p>Confirm the safety of the device.</p> <p>Clarify assessment criteria to be used.</p> <p>Define a minimum number of subjects to be included in order to differentiate CLAI from controls.</p> <p>Methods: We enrolled 10 physically active subjects. They completed CLAI questionnaires, and we split the ankles into CLAI and control groups according to the International Ankle Consortium position statement. Each subject walked with instability boots on a treadmill. Instability was triggered remotely. Gait analysis was performed using Inertial Moment Units. Inversion velocities during the first stance phase after the onset of instability were analyzed.</p> <p>Results: Seven ankles were excluded 6 composed the CLAI group and 7 the control group. The highest MIV value was 293.1°/s and was below the previously established injury risk threshold (300°/s). No falls or injuries were noted. Mean MIV values were respectively 204.1+/-49.4°/s and 171.2+/-76°/s in the CLAI and control groups (p=0.383) with a coefficient of variation of 33.4%. To account for the large intersubject variability in MIV, we normalized these values by the average MIV of the 5 stance phases of the same foot preceding the simulated trauma. Mean Ratio MIV values were respectively 1.22+/-0.12 and 1.12+/-0.09 in CLAI and control groups (p=0.107) with a coefficient of variation of 9.2%.</p> <p>Considering our preliminary results, we would need to have at least 60 feet to find a statistically significant difference between CLAI and controls.</p> <p>Conclusions: Our protocol was safe. We recommend using normalized parameters such as Ratio MIV for future studies. At least 30 subjects would be required to observe a significant difference between CLAI and controls using this protocol.</p>
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Are you submitting to a Thematic Series?	No

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Assessing chronic lateral ankle instability with a sprain stimulator: a pilot study.

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Assessing chronic lateral ankle instability with a sprain stimulator: a pilot study.

ABSTRACT

Background: Chronic Lateral Ankle Instability (CLAI) represents a significant socioeconomic burden. Paradoxically, its management has changed little over the years, notably because research is divided into functional and mechanical instability, whereas CLAI encompasses both. Sprain simulators can encompass both functional and mechanical instability by assessing the maximal ankle inversion velocity (MIV) during a simulated inversion trauma. We built a sprain simulator capable of producing a sudden ankle inversion motion during walking and conducted a pilot study that aimed to:

1. Confirm the safety of the device.
2. Clarify assessment criteria to be used.
3. Define a minimum number of subjects to be included in order to differentiate CLAI from controls.

Methods: We enrolled 10 physically active subjects. They completed CLAI questionnaires, and we split the ankles into CLAI and control groups according to the International Ankle Consortium position statement. Each subject walked with instability boots on a treadmill. Instability was triggered remotely. Gait analysis was performed using Inertial Moment Units. Inversion velocities during the first stance phase after the onset of instability were analyzed.

Results: Seven ankles were excluded 6 composed the CLAI group and 7 the control group. The highest MIV value was 293.1°/s and was below the previously established injury risk threshold (300°/s). No falls or injuries were noted.

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2 control groups (p=0.383) with a coefficient of variation of 33.4%. To account for the
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4 large intersubject variability in MIV, we normalized these values by the average MIV of
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6 the 5 stance phases of the same foot preceding the simulated trauma. Mean Ratio MIV
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8 values were respectively 1.22+/-0.12 and 1.12+/-0.09 in CLAI and control groups
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10 (p=0.107) with a coefficient of variation of 9.2%.
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15 Considering our preliminary results, we would need to have at least 60 feet to find a
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17 statistically significant difference between CLAI and controls.
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21 *Conclusions:* Our protocol was safe. We recommend using normalized parameters
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23 such as Ratio MIV for future studies. At least 30 subjects would be required to observe
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25 a significant difference between CLAI and controls using this protocol.
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BACKGROUND

Lateral ankle sprain (LAS) is one of the most common injuries and is generally considered benign and without consequences [1]. However, this injury frequently occurs in the context of chronic lateral ankle instability (CLAI), which represents a significant socioeconomic burden [2]. According to Donovan et al. 20% of patients after a first episode of LAS will develop CLAI [3]. The 2016 International Ankle Consortium concluded that a major consequence of LAS and CLAI is post-traumatic ankle osteoarthritis, with considerable direct and indirect societal costs [2]. Paradoxically, LAS and CLAI management has changed little over the years although numerous research studies have been conducted [4,5].

One strong limitation of these researches is the fact that they are conducted by different teams from different background and specialties whereas CLAI involves many risk factors belonging to these different fields [6,7]. The easiest example is the frequent division between functional and mechanical instability in the literature [8,9]. Physiotherapists or physiatrists mainly try to solve the functional components of this instability like lack of proprioception or altered gait patterns [10–12], whereas orthopedic surgeons are focus on mechanical components like ligamentous laxities because corresponding to their domain of expertise including treatment possibilities [13–15]. This division precludes the possibility of conducting comprehensive studies to portray a complete picture of CLAI [6]. Research on CLAI must encompass both the functional and mechanical aspects of CLAI to allow for relevant conclusions.

Another limitation is the lack of tools to diagnose or quantify CLAI. The most commonly used currently are questionnaires such as the Cumberland Ankle Instability Tool or the Identification of Functional Ankle Instability (IdFAI) questionnaires [16,17]. Both of those are a posteriori questionnaires based on previous LAS, preventing

1
2 prophylactic management. Moreover, these questionnaires only assess functional
3 CLAI without considering its mechanical aspect.
4

5 Sprain simulators could overcome these limitations [18,19]. Using a simulator to
6 assess CLAI allows to encompass both functional and mechanical instability [6].
7 Promising studies were able to differentiate CLAI subjects from controls using
8 maximum ankle inversion angle and maximum ankle inversion velocity during
9 simulated inversion trauma [20,21]. The use of these quantitative criteria could allow a
10 priori diagnosis and quantification of CLAI, opening the possibility of prophylactic
11 treatments, as well as assessing the relative importance of each risk factor for CLAI
12 [6]. However, most of these previous studies have evaluated CLAI in a static position
13 or during landing.
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28 We built a sprain simulator capable of producing a sudden ankle inversion motion
29 during walking and we conducted a pilot study that aimed to:
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- 32 1. Confirm the safety of the device.
- 33 2. Test and clarify assessment criteria to be used to compare CLAI and controls.
- 34 3. Define a minimum number of subjects to be included in order to differentiate
35 CLAI from controls.
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48 **METHODS**

49 **1. Study design**

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51 We performed a prospective study in physically active subjects in the Human
52 Performance and Clinical Outcomes Laboratory at University of Iowa. This study
53 received institutional review board approval (IRB 202202219) before its start and
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complied with the Health Insurance Portability and Accountability Act (HIPAA). Each subject received detailed information and signed an informed consent form before the start of the study. The CONSORT (Consolidated Standards of Reporting Trials) extension for pilot and feasibility trials recommendations were followed [22].

2. Study protocol

The instability boot (Myolux Athletik®) that we used was developed and validated for CLAI rehabilitation. The device consists of a boot that surrounds the foot and ankle, ensuring stability of the ankle joint, maintaining the ankle to prevent excessive motion and injury (Figure 1).

Gait analysis was performed on a treadmill (Computer Assisted Rehabilitation Environment system (CAREN) virtual reality treadmill, Motek®) and each subject walked on the treadmill with the boots, secured by a suspension harness to prevent falls (Figure 2).

Prior to the gait analysis, each subject completed three questionnaires for each ankle: the Cumberland Ankle Instability Tool, the IdFAI, and the Foot Ankle Ability Measurement (FAAM) [16,17,23]. They also informed their age, Body Mass Index (BMI), gender, sport practice (type of sport, for leisure or competition, mean sports hours per month).

These instability boots were initially locked in a stable position while the subject walked. The inversion instability was triggered remotely by the observer at a random time after at least 3 minutes of walking. The instability boots were coupled with Inertial Moment Units (Isen 3.0 STT Systems®). Data from these IMUs were collected through the iSen software interface. All subjects were video recorded from the back and this

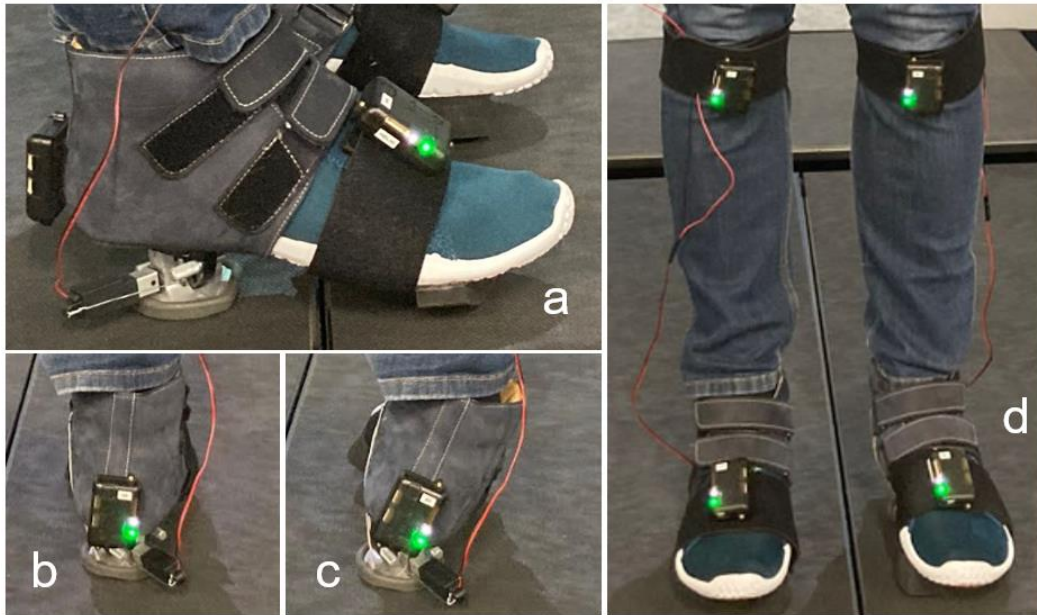


Figure 1: Instability boots.

- a. Lateral view right foot, b. Posterior view right foot, boot in stable position,*
- c. Posterior view right foot, boot in unstable position, d. Front view*

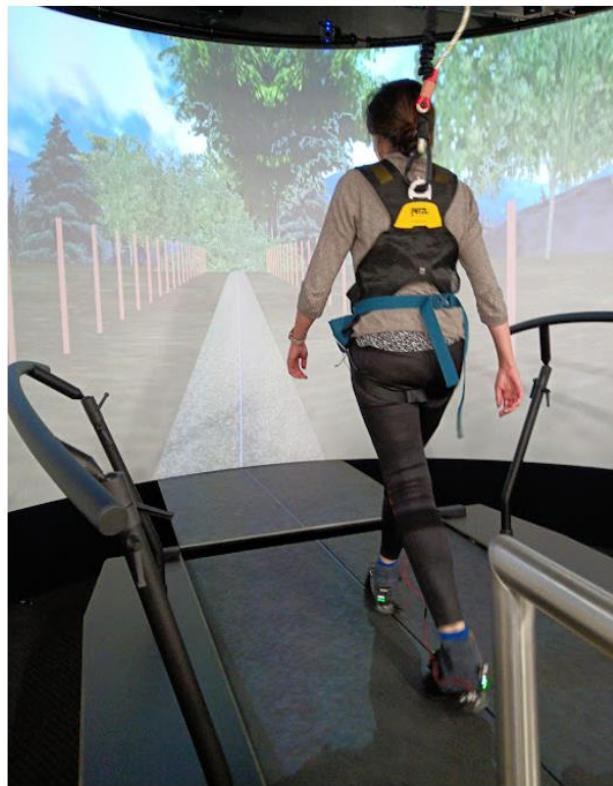


Figure 2: Subject walking on the virtual reality treadmill secured by a harness.

1 video was synchronized with the gait analysis to improve data interpretation. The
2 instability was triggered during the swing phase. The inversion angles and velocities
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4 during the first stance phase after the onset of instability were analyzed.
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10 **3. Population**

11 Recruitment emails were sent to introduce the study and to engage volunteers.
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14 The subjects included were physically active. According to Lin et al. [24],
15 physically active population includes athletes, military personnel, or active subjects
16 under the age of forty. Subjects younger than 18 years, heavier than 95 kg (209 lbs),
17 with a history of ankle sprain in the past 3 months, neurological or sensorimotor
18 impairment, osteoporosis, or any active lower extremity disorder were excluded.
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30 According to the International Ankle Consortium position statement on CLAI patient
31 selection criteria in controlled research [25]:
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- 35 - The CLAI group included ankles with at least one LAS whose first episode
36 occurred more than 12 months before the start of the study AND at least one
37 recurrent LAS OR at least two ankle giving ways in the 6 months before the
38 study OR a feeling of ankle instability confirmed by a Cumberland Ankle
39 Instability Tool score less than 25 or an IdFAI score greater than 10.
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- 48 - The Control group included ankles with no history of LAS, giving way, or feeling
49 of ankle instability on previous questionnaires.
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- 52 - Ankles that did not meet these criteria were excluded from the analysis as well
53 as contralateral ankles in cases of unilateral CLAI.
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58 As a pilot study, only 10 subjects were included.
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3 **4. Safety of the device.**
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6 According to Chu et al. true ankle sprains involve inversion velocities greater than
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8 500°/s and the use of a device simulating inversion trauma involving velocities less
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10 than 300°/s will preclude any risk of injury [20]. Therefore, we evaluated the safety of
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12 this device by assessing the relationship between maximum inversion velocities (MIV)
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14 in our pilot study and this threshold.
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22 **5. Assessment Criteria**
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25 According to the literature the maximal inversion angle (MIA) and maximal inversion
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27 velocity (MIV) during the simulated trauma are accurate parameters to assess CLAI
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29 [20,21]. We therefore tested them in our pilot study.
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36 **6. Minimum number of subjects to include.**
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39 Minimum number of subjects to include in order to find a significant difference between
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41 the CLAI and the Control groups was calculated according to preliminary results of this
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43 pilot study.
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50 **7. Statistical analysis**
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53 Normality and heteroskedasticity of data were assessed with the Shapiro-Wilk test and
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55 the Levene's test. The groups were compared using Student T test for normal and
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57 Mann-Whitney U test for nonnormal variables. Gender percentage and type of sport
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practice (Leisure or Competition) between groups were compared using 2-tailed Fisher exact test. Power calculation was done using the preliminary results, a type 1 risk of 5%, a type 2 risk of 20% and a bilateral test. Alpha risk was set to 5% ($\alpha = 0.05$). Statistical analysis was performed with EasyMedStat (version 3.21.4; www.easymedstat.com).

RESULTS

1. Population

Twenty ankles (10 subjects) were included in this pilot study, 7 were excluded (Figure 3). The CLAI group consisted of 6 ankles and the control group of 7 ankles (Table 1).

Mean number of LAS was 3.5 +/- 1.6 in the CLAI group and 0 in the control group ($p=0.003$). Demographics, sport characteristics and ankle instability questionnaire results are exposed in the Table 1.

2. Safety

On these 13 ankles included in the analysis the mean maximal inversion velocity (MIV) during the simulated trauma was 186.4 +/- 62.2°/s. The highest value reported in this pilot study was 293.1°/s and was below the previously established threshold for injury risk (300°/s according to Chu et al. [20]).

No falls or injuries were reported in this pilot study.

3. Assessment Criteria

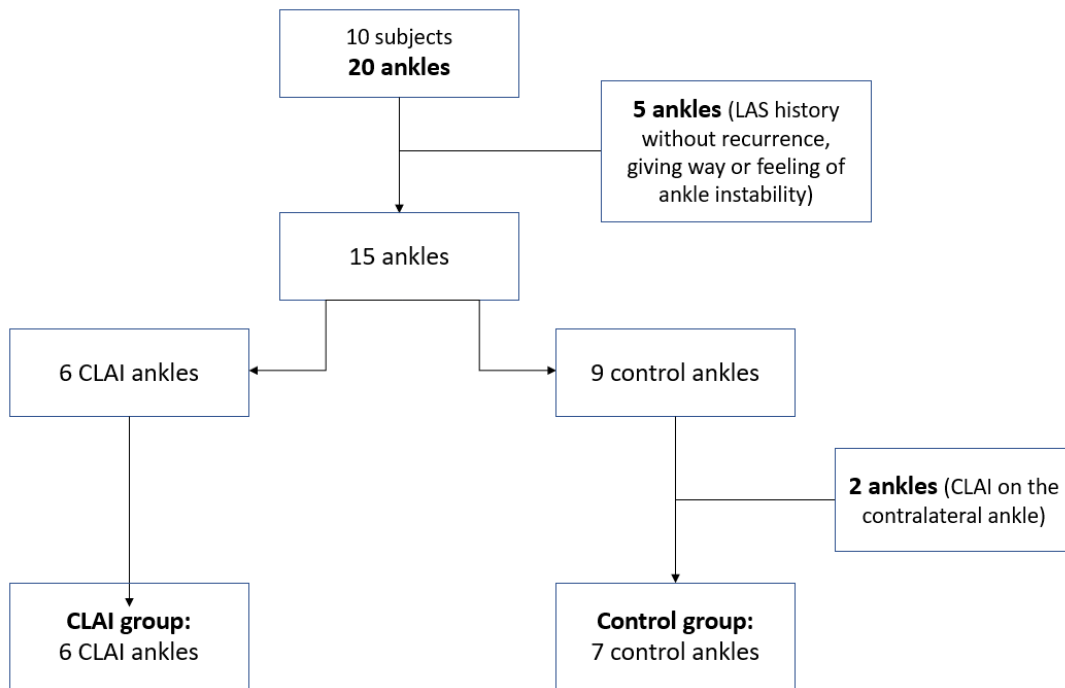


Figure 3: Flow Chart.

LAS, Lateral Ankle Sprain; CLAI, Chronic Lateral Ankle Instability

Table 1: Demographics, sport characteristics and ankle instability questionnaire results.

	CLAI group (n=6)	Control group (n=7)	<i>P</i> values
Age (years; mean+/-SD)	29.7 +/- 6.5	28.7 +/- 6.8	0.8
Body Mass Index (kg/m ² ; mean+/-SD)	26.2 +/- 5.5	26.7 +/- 4.7	0.72
Gender	3 Women (50%)	2 Women (28.6%)	0.59
Sport	- Running (n=2) - Golf (n=1) - Triathlon (n=1) - Volleyball (n=1) - Weightlifting (n=1)	- Running (n=2) - Cycling (n=2) - Soccer (n=2) - Tennis (n=1)	NA
Competition / Leisure	2 Competition (33.3%)	2 Competition (28.6%)	0.99
Sports hours / month (mean+/-SD)	22.5 +/- 9.4	19.6 +/- 13.4	0.66
Number of LAS (mean+/-SD)	3.5 +/- 1.6	0	0.003
CAIT score (mean+/-SD)	24 +/- 5.9	29.2 +/- 1.4	0.04
IdFAI score (mean+/-SD)	17 +/- 9.4	2 +/- 2.3	0.003
FAAM Activities of Daily Living Subscale (mean+/-SD)	81.7	83.1	0.62
FAAM Sports Subscale (mean+/-SD)	30.5	31.7	0.07

CLAI, Chronic Lateral Ankle Instability ; SD, Standard Deviation ; LAS, Lateral Ankle Sprain ; CAIT, Cumberland Ankle Instability Tool ; IdFAI, Identification of Functional Ankle Instability ; FAAM, Foot Ankle Ability Measurement

3.1 Maximal inversion angle (MIA).

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3 It was not appropriate to assess the MIA during the simulated trauma. Walking with
4 these boots generated a progressive increase in foot inversion during the stance phase
5 from initial contact (heel strike) to the push-off phase (Figure 4). The simulated trauma
6 caused an increase in inversion velocity during the loading phase, but this period did
7 not correspond to the MIA of the stance phase because the inversion gradually
8 increased until the push phase. Therefore, this criterion was not accurate for our study
9 and we did not collect this variable.

3.2 Maximal inversion velocity (MIV)

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Conversely, there was an increase in MIV during the simulated trauma. This increase in inversion velocity occurred during the loading phase, between the heel strike and the midstance phase (Figure 4). We collected the MIV at this time.

Mean MIV values were respectively 204.1 +/- 49.4°/s and 171.2 +/- 76°/s in the CAI and control groups (p=0.383). The coefficient of variation for this variable was 33.4%.

3.3 Inversion angle at MIV time (IAMIV)

As mentioned previously, the MIA was not accurate in this pilot study. Instead, we assessed the inversion angle at the MIV time (IAMIV). To achieve this, we located the time at which the inversion velocity was highest during the simulated trauma (MIV time) and collected the angular inversion value at that very moment (Figure 4). This value reflects the angular distance the ankle covered in inversion before the subject was able to start counteracting this motion and decrease the inversion velocity.

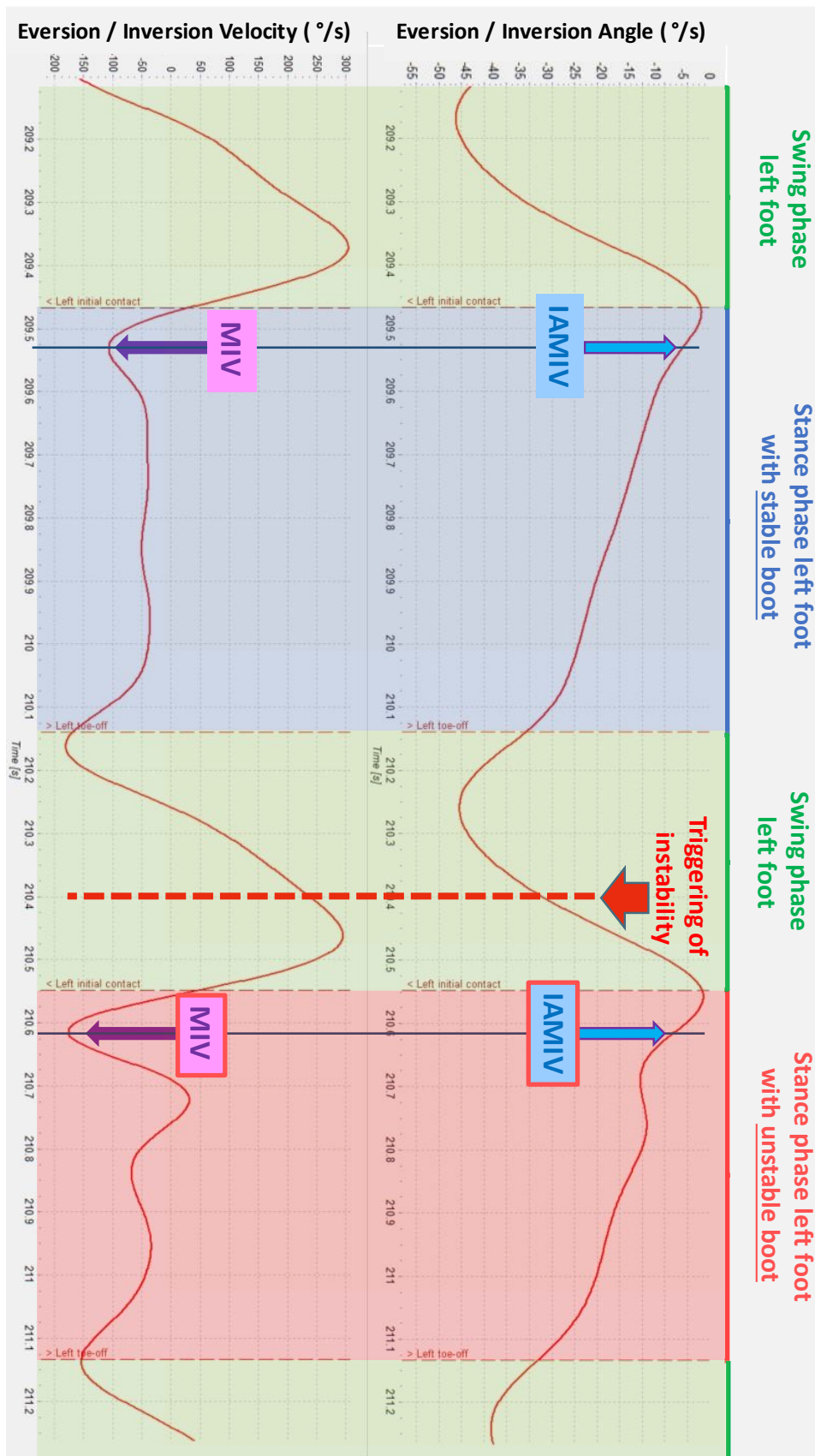


Figure 4: Eversion/Inversion angles and velocities curves during the onset of ankle instability.

MIV, Maximal Inversion Velocity; *IAMIV*, Inversion Angle at MIV time (*IAMIV*)

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Mean IAMIV values were respectively 24.8 +/- 4° and 16.9 +/- 10.9° in CAI and control groups (p=0.213). The coefficient of variation of this variable was 42.5%.

3.4 Ratio of maximal inversion velocity (Ratio MIV)

To account for the large intersubject variability in MIV, we normalized these values by the average MIV of the 5 stance phases of the same foot preceding the simulated trauma (Figure 5).

$$\text{Ratio MIV} = \frac{(-5\text{MIV} + -4\text{MIV} + -3\text{MIV} + -2\text{MIV} + -1\text{MIV})/5}{\text{MIV (simulated trauma)}}$$

Mean Ratio MIV values were respectively 1.22 +/- 0.12 and 1.12 +/- 0.09 in CAI and control groups (p=0.107). The coefficient of variation of this variable was 9.2%.

3.5 Ratio of the maximal inversion velocity (Ratio IAMIV)

To account for the large intersubject variability in IAMIV, we normalized these values by the average IAMIV of the 5 stance phases of the same foot preceding the simulated trauma.

$$\text{Ratio IAMIV} = \frac{(-5\text{IAMIV} + -4\text{IAMIV} + -3\text{IAMIV} + -2\text{IAMIV} + -1\text{IAMIV})/5}{\text{IAMIV (simulated trauma)}}$$

Mean Ratio IAMIV values were respectively 1.16 +/- 0.16 and 1.03 +/- 0.13 in CAI and control groups (p=0.132). The coefficient of variation of this variable was 13.9%.

4. Minimum number of subjects

Based on the coefficient of variation of these variables, the MIV ratio had the lowest variability in our pilot study. Considering the MIV ratio as our primary assessment criterion and using our preliminary results on this variable, we would need to have at

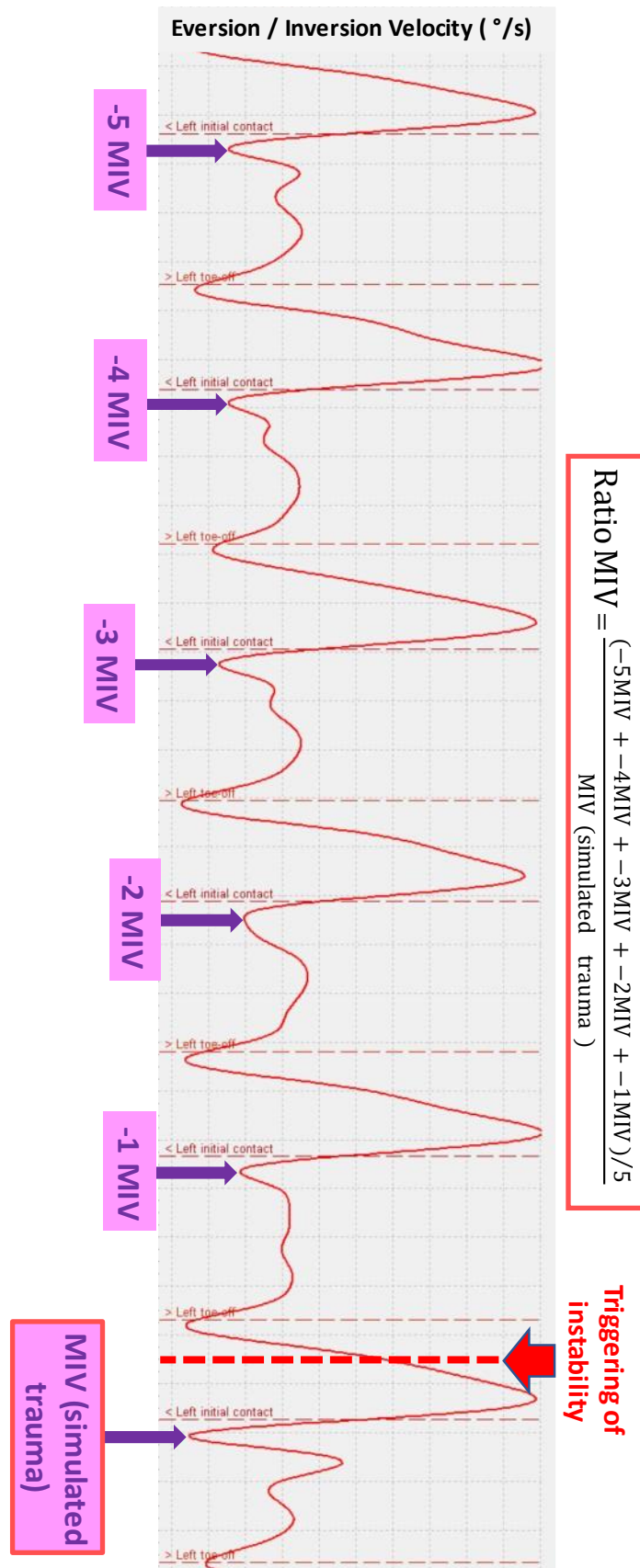


Figure 5: Eversion/Inversion velocities curve during the onset of ankle instability showing the calculation of the Ratio MIV.

MIV, Maximal Inversion Velocity

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least 18 feet per group to find a statistically significant difference between CLAI and controls.

Considering that we were able to include 6 CLAI and 7 controls by recruiting 20 feet (10 subjects) in this pilot study, using the same recruitment pattern, at least 60 feet (30 subjects) would need to be included to achieve 18 feet per group.

DISCUSSION

In this pilot study, we evaluated the suitability of a sprain simulator coupled with inertial moment units to gauge CLAI. According to the previously published threshold, we have confirmed the safety of this device. Maximal inversion angle during the simulated trauma was not a suitable criterion for this protocol to assess CLAI. The MIV better reflected the ankle reaction motion to the boot destabilization and the IAMIV reflected the moment the subject was able to react and reverse the increase of inversion velocity to avoid LAS. Because these two variables had high intersubject variabilities, we normalized these values and recommend using the MIV Ratio and IAMIV Ratio for future studies. Using Ratio MIV as primary assessment criterion at least 30 subjects would be required to observe a significant difference between CLAI and controls.

Many sprain simulators have been tested previously. They are ideal tools to assess the entire CLAI encompassing all areas and risk factors. Most of them assess inversion during a landing or in a static standing position by triggering an inversion motion [18,19,26–28]. Sprain simulators may be limited by the fact that unexpected trauma is required to assess the CLAI [27,29,30]. Indeed, in case of expected trauma, peroneal muscles contraction occurs even before the onset of trauma and prevents reliable measurement [30]. This unexpected character cannot be perfectly reproduced

1 during landing or in static position. However, it is easier to control patient safety and
2 avoid LAS by using these protocols. On the other hand, our device reproduced a
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4 simulated trauma in real conditions, during walking, and the unexpectedness of the
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6 simulated trauma is easier to reproduce. Respecting the safety of the protocol could
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8 be more difficult.
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12 Our first objective was to confirm this safety. This boot (Myolux Athletik®) was
13 developed to prevent injuries during its use and is dedicated to CLAI rehabilitation.
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15 Several studies have already involved this device without reporting any injuries [29–
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17 33]. To reinforce the safety of the device, subjects were secured by a safety harness
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19 on the treadmill. No subjects triggered the harness in this pilot study and no falls or
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21 injuries were reported. According to Chu et al. LAS involved inversion trauma greater
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23 than 500°/sec and it is recommended that sprain simulators not exceed 300°/sec to
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25 avoid injury [20]. No ankle has gone beyond this threshold in our study, but one has
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27 come close (293°/sec). Given the high variability we reported for this parameter, it
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29 would make more sense to define a threshold using normalized values such as Ratio
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31 MIV.
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40 We followed the International Ankle Consortium position statement for inclusion
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42 of CLAI and controls [25]. Complying with these criteria required us to exclude many
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44 patients. Some of these patients can be considered copers. However, we chose not to
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46 analyze them because this group of excluded ankles was very heterogeneous. The
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48 biggest problem was the fact that most had contralateral CLAI, which we know can be
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50 biasing [34,35]. Dedicated coppers studies should be conducted to improve knowledge
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52 of patients' ability to avoid CLAI after LAS.
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58 Our population included physically active subjects. Based on the results of our
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60 questionnaires, the CLAI group, reported higher aggravation values on the
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1 Cumberland Ankle Instability Tool and the IdFAI, but not on the FAAM subscales,
2 showing that even though this group suffered from CLAI, its impact on their lives
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4 seemed minor. This is probably due to the fact that, according to our inclusion criteria,
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6 only young subjects (less than 40 years) were included in this study. It is likely that
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8 older subjects' inclusion in our CLAI group would result in the inclusion of more painful
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10 post-traumatic ankle osteoarthritis that would therefore likely limit daily activities [36].
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15 Benefiting from this simulator to quantify CLAI would allow studies to better
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17 understand CLAI, such as the difference between copers and patients evolving
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19 towards CLAI after LAS. It would also be possible to know the respective impact of
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21 each CLAI risk factor [6]. For example, we are still unable to answer the question of
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23 whether an isolated LAS of the anterior talofibular ligament (ATFL) or a LAS involving
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25 both the ATFL and the calcaneofibular ligament has higher risk of progressing to CLAI.
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27 Similarly, we are unable to quantify the relative impact of hindfoot varus alignment or
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29 lack of proprioception on CLAI occurrence. Having a device to quantify CLAI would be
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31 an important step in improving its understanding and management.
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38 We acknowledged several limitations in our study. First, this is a pilot study
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40 involving only a few subjects, which limits the possibilities of drawing conclusions about
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42 CLAI. This however, was not the purpose of this study which was done to clarify our
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44 study protocol and confirm its safety. This pilot study will allow for well-conducted
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46 studies involving a larger number of patients to attempt to clarify CLAI. Second, the
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48 subjects' walking was not perfectly normal, as the boots altered the walking pattern.
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50 While not perfect, it is better to walk in this boot and experience a simulated trauma
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52 than to jump on a platform or experience a sudden motion in a static position. Third,
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54 the assessment criteria we defined and the safety we confirmed are only validated for
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56 our device and protocol, which limits the external reproducibility of our study. Each
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sprain simulator should have its own assessment criteria and independently confirm its safety.

CONCLUSIONS

We confirmed the safety of our device and protocol in this pilot study. Given the large intersubject variability in inversion angles and velocities during walking, we recommend using normalized parameters such as Ratio MIV and Ratio IAMIV for future studies. Using Ratio MIV as primary assessment criterion, at least 30 subjects would be required to observe a significant difference between CLAI and controls.

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2.3 Comparaison de sujets présentant une instabilité latérale chronique de cheville à des sujets témoins sur la vitesse angulaire en inversion lors d'un traumatisme simulé.

Nous avons réalisé une deuxième étude comparant des sujets atteints d'ILCC à des témoins en utilisant ce dispositif et en suivant les paramètres définis dans l'étude pilote précédente.

Nous avons pour objectif de soumettre ce manuscrit au *British Journal of Sports Medicine*.

1 **Evaluation of chronic lateral ankle instability with a sprain stimulator: a**
2 **controlled study in physically active subjects.**

3
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36

37 **ABSTRACT**

38 Objectives: Differentiate subjects with chronic lateral ankle instability (CLAI) from
39 controls and quantify functional CLAI as well as impairments in activities of daily living
40 and sports using a sprain simulator.

41 Methods: Forty-five physically active subjects were included and assigned to a CLAI
42 group, a control group, or excluded according to the International Ankle Consortium
43 selection criteria. Each subject walked on a treadmill with instability boots after
44 completing the Identification of Functional Ankle Instability (IdFAI) and the Foot Ankle
45 Ability Measurement (FAAM) questionnaires. A simulated trauma was unexpectedly
46 triggered by the observer. Maximal inversion velocities (MIV) were measured at this
47 very moment using inertial moment units. We normalized these values by the average
48 MIV of the 5 stance phases of the same foot preceding the simulated trauma (Ratio
49 MIV).

50 Results: Twenty-six ankles were excluded, 32 composed the CLAI group and 32 the
51 control group. Mean MIV were $213.5 \pm 54.7^\circ/\text{s}$ and $177 \pm 64.2^\circ/\text{s}$ ($p=0.02$), and mean
52 Ratio MIV were 1.22 ± 0.13 and 1.08 ± 0.08 ($p<0.001$) in the CLAI and Control groups
53 respectively. In multivariate analysis, Ratio MIV was associated with higher values of
54 IdFAI ($\beta=42.8$ [12.9;72.8], $p=0.006$), lower values of FAAM Activities of Daily Living
55 Subscale ($\beta=-14.1$ [-27.8;-0.5], $p=0.04$) and lower values of FAAM Sports Subscale
56 ($\beta=-7.2$ [-13.7;-0.6], $p=0.03$) whereas MIV was not.

57 Conclusion: Inversion velocities caused by a sprain simulator clearly differentiated
58 CLAI from controls. Ratio MIV showed good ability to quantify functional CLAI as well
59 as impairments in activities of daily living and sports. This tool could be used in further
60 studies to improve CLAI understanding.

61 **INTRODUCTION**

62

63 Lateral Ankle Sprain (LAS) and Chronic Lateral Ankle Instability (CLAI) represent an
64 significant socioeconomic burden especially in athletic populations [1,2]. According to
65 the International Ankle Consortium the evidence is growing that an important
66 consequence of LAS, and the subsequent high rate of CLAI, is ankle joint post-
67 traumatic osteoarthritis [1,3]. To attempt to prevent them, this consortium recommends
68 further research to determine mechanisms that engender CLAI after a LAS and to fully
69 elucidate the paradigms between LAS, CLAI and ankle joint post-traumatic
70 osteoarthritis [1,4].

71 To guide such researches, selection criteria for CLAI subjects in controlled
72 research has been provided [5]. However, other issues limit this investigation. There is
73 no tool available to diagnose and quantify CLAI. Those available are questionnaires.
74 According to Donahue et al. accurate prediction of ankle stability status can be
75 achieved by combining the Cumberland Ankle Instability Tool (CAIT) and the Ankle
76 Instability Instrument [6]. Following their recommendations, these authors developed
77 the Identification of Functional Ankle Instability (IdFAI) questionnaire, which is a
78 combination of the latter two [7]. However, this questionnaire focuses on the functional
79 CLAI. Newer models of CLAI encompass the interaction between mechanical and
80 functional CLAI, and some propose a cumulative effect of these factors [8,9]. Moreover,
81 the mechanical component of CLAI should not be summarized to ligamentous laxities,
82 as ankle varus or lack of ankle dorsiflexion also play an important role [10–12].
83 Studying CLAI without considering all of its features could lead to erroneous
84 conclusions.

85 Sprain simulators allow for fundamental research on CLAI by assessing
86 inversion angle and velocities [13–15][**Pilot Study**]. Gauging CLAI by these criteria
87 could provide a holistic approach including both functional and mechanical aspects of
88 CLAI.

89 Therefore, we conducted a study that primarily aimed to differentiate CLAI
90 subjects from controls using a sprain simulator. We also aimed to assess the ability of
91 this tool to quantify functional CLAI as well as impairments in activities of daily living
92 and sports. We hypothesized that differentiation between CLAI and controls would be
93 observed in our study.

94

95 **METHODS**

96 **1. Study design**

97 We performed a prospective study in physically active subjects in the Human
98 Performance and Clinical Outcomes Laboratory at University of Iowa. This study
99 received institutional review board approval (IRB 202202219) before its start and
100 complied with the Health Insurance Portability and Accountability Act (HIPAA).

101 Each subject received detailed information and signed an informed consent
102 form before the start of the study. The STROBE (STrengthening the Reporting of
103 OBservational studies in Epidemiology) recommendations were followed [16,17].

104

105 **2. Study protocol**

106 The instability boots (Myolux Athletik®) we used were built and tested to ensure the
107 safety of the participants [**Pilot Study**]. Gait analysis was performed on a treadmill
108 (Computer Assisted Rehabilitation Environment system (CAREN) virtual reality

109 treadmill, Motek®) and each subject walked on the treadmill with the boots, secured
110 by a suspension harness to prevent falls (**Figure 1**).

111 Prior to gait analysis, each subject completed two questionnaires for each ankle:
112 the IdFAI and the Foot Ankle Ability Measurement (FAAM) [7,18]. They also informed
113 their age, Body Mass Index (BMI), gender, sport practice (type of sport, for leisure or
114 competition, mean sports hours per month).

115 These instability boots were initially locked in a stable position while the subject walked.
116 The inversion instability was triggered remotely by the observer at a random time after
117 at least 3 minutes of walking. The instability boots were coupled with Inertial Moment
118 Units (Isen 3.0 STT Systems®). Data from these IMUs were collected through the iSen
119 software interface. All subjects were video recorded from the back and this video was
120 synchronized with the gait analysis to improve data interpretation. The instability was
121 triggered during the swing phase. The inversion angles and velocities during the first
122 stance phase after the onset of instability were analyzed

123

124 **3. Population**

125 Recruitment emails were sent to introduce the study and to engage volunteers. The
126 subjects included were physically active. According to Lin et al. [19], physically active
127 population includes athletes, military personnel, or active subjects under the age of
128 forty. Subjects younger than 18 years, heavier than 95 kg (209 lbs), with a history of
129 ankle sprain in the past 3 months, neurological or sensorimotor impairment,
130 osteoporosis, or any active lower extremity disorder were not included. According to
131 the International Ankle Consortium position statement on selection criteria for CLAI
132 patients in controlled research [5]:

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134

135 **Figure 1:** Gait analysis of a subject.

136 1. *Computer Assisted Rehabilitation Environment system (CAREN, Motek®):*
 137 *treadmill.*

138 2. *Computer Assisted Rehabilitation Environment system (CAREN, Motek®):*
 139 *virtual reality screen.*

140 3. *Security Harness.*

141 4. *Instability boots (Myolux Athletik®) coupled with Inertial Moment Units (Isen 3.0*
 142 *STT Systems®).*

143 5. *Gait analysis software (Isen 3.0 STT Systems®).*

144 6. *Video recording.*

145

- 146 - The CLAI group included ankles with at least one LAS whose first episode occurred
 147 more than 12 months before the start of the study AND at least one recurrent LAS OR
 148 at least two ankle giving ways in the 6 months before the study OR a feeling of ankle
 149 instability confirmed by an IdFAI score greater than 10.
- 150 - The Control group included ankles with no history of LAS, giving way, or feeling of
 151 ankle instability on previous questionnaires.
- 152 - Ankles that did not meet these criteria were excluded from the analysis as well as
 153 contralateral ankles in cases of unilateral CLAI.

154

155 **4. Assessment Criteria**

156 According to the literature we assessed in both groups:

- 157 - The maximum inversion velocity (MIV) during the loading phase of the simulated
 158 trauma **[Pilot Study]**.
- 159 - The inversion angle at the MIV time (IAMIV). To achieve this, we located the
 160 MIV during the simulated trauma and collected the angular inversion value at
 161 that very moment **[Pilot Study]**. This value reflects the angular distance the
 162 ankle covered in inversion before the subject was able to start counteracting
 163 this motion and decrease the inversion velocity.
- 164 - We normalized the MIV by the average MIV of the 5 stance phases of the same
 165 foot preceding the simulated trauma **[Pilot Study]**.

166
$$\text{Ratio MIV} = \frac{(-5\text{MIV} + -4\text{MIV} + -3\text{MIV} + -2\text{MIV} + -1\text{MIV})/5}{\text{MIV (simulated trauma)}}$$

- 167 - We normalized the IAMIV by the average IAMIV of the 5 stance phases of the
 168 same foot preceding the simulated trauma **[Pilot Study]**.

169
$$\text{Ratio IAMIV} = \frac{(-5\text{IAMIV} + -4\text{IAMIV} + -3\text{IAMIV} + -2\text{IAMIV} + -1\text{IAMIV})/5}{\text{IAMIV (simulated trauma)}}$$

170 To address our primary objective, we compared CLAI subjects and controls on
171 MIV, IAMIV, Ratio MIV and Ratio IAMIV. To address our secondary objectives, we
172 assessed the correlations between these parameters, the IdFAI score, the FAAM
173 Activities of Daily Living Subscale and the FAAM Sports Subscale.

174

175 **5. Statistical analysis**

176 Normality and heteroskedasticity of data were assessed with the Shapiro-Wilk test and
177 the Levene's test. The groups were compared using Student T test for normal and
178 Mann-Whitney U test for nonnormal variables. Gender percentage and sport practice
179 between groups were compared using 2-tailed Fisher exact test.

180 Spearman's correlations were used to assess linear dependence between the
181 explanatory variables (MIV, IAMIV, Ratio MIV, Ratio IAMIV) and the IdFAI score, the
182 FAAM Activities of Daily Living Subscale and the FAAM Sports Subscale. Correlations
183 with p values less than 0.2 were considered in the multivariate analysis. A multivariate
184 logistic regression was performed to assess the relation between groups and the
185 explanatory variables. Multivariate linear regressions were performed to assess the
186 relation between, the IdFAI score, the FAAM Activities of Daily Living Subscale, the
187 FAAM Sports Subscale and the explanatory variables. Data were checked for
188 multicollinearity with the Belsley-Kuh-Welsch technique. Heteroskedasticity and
189 normality of residuals were assessed respectively by the Breusch-Pagan test and the
190 Shapiro-Wilk test.

191 Based on previous literature and power calculation, 60 feet (30 subjects) were
192 required to find a statistically significant difference between CLAI and controls, using
193 Ratio MIV as primary assessment criterion **[Pilot Study]**.

194 Alpha risk was set to 5% ($\alpha = 0.05$). Statistical analysis was performed with
195 EasyMedStat (version 3.21.5; www.easymedstat.com).

196

197 **RESULTS**

198 **1. Population**

199 Ninety ankles (45 subjects) were included in this study. Twelve were excluded because
200 of LAS history without meeting CLAI criteria, and 6 were excluded because they had
201 giving ways or feeling of instability without LAS history. Eight ankles were excluded
202 from the control group because they had CLAI on the contralateral side (Figure 2).
203 Finally, CLAI and control groups consisted of 32 ankles each (Table 1).

204 Mean number of LAS was 5.2 +/- 6.9 in the CLAI group and 0 in the control group
205 ($p < 0.001$). Demographics, sport characteristics and ankle instability questionnaire
206 results are exposed in the Table 1. No falls or injuries were reported in this study.

207

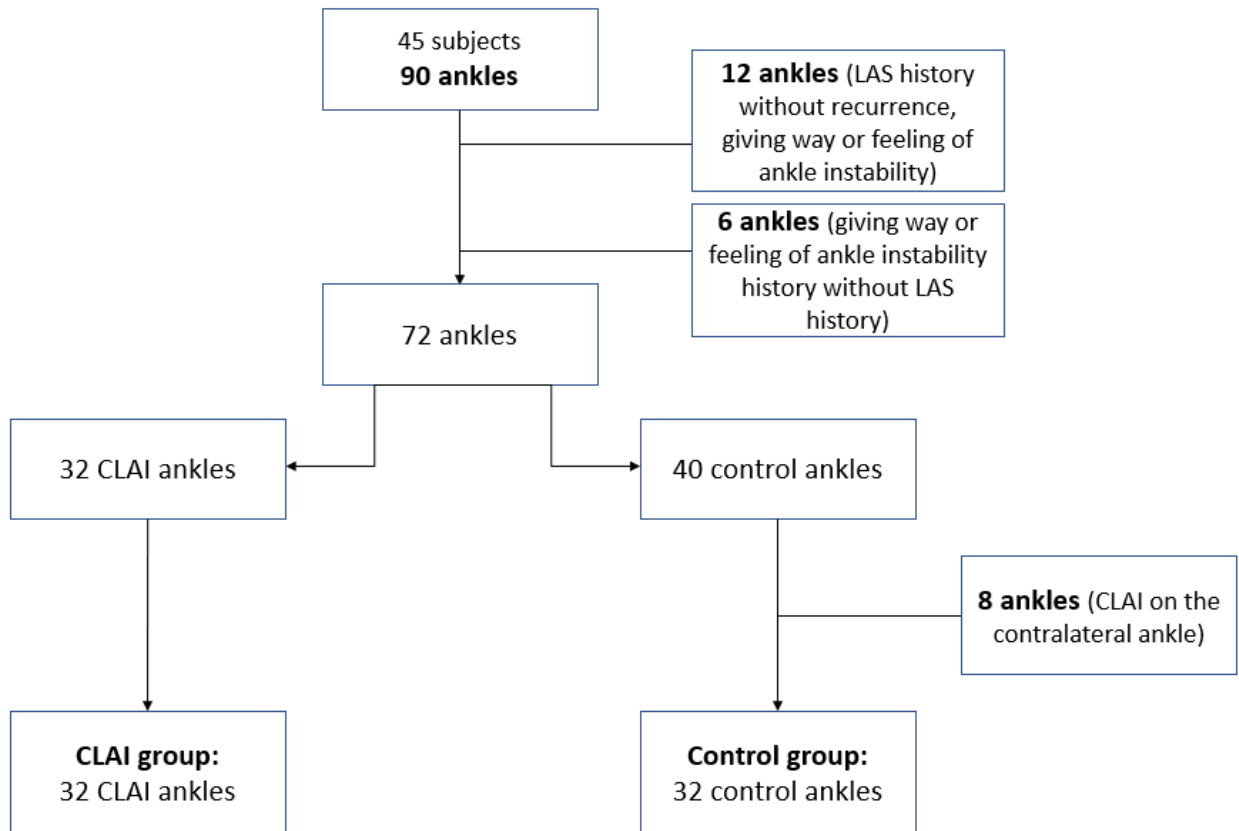
208 **2. Comparison between CLAI and Controls**

209 Mean MIV values were respectively 213.5 +/- 54.7 °/s and 177 +/- 64.2 °s in the CLAI
210 and Control groups ($p = 0.02$) (Figure 3a).

211 Mean Ratio MIV values were respectively 1.22 +/- 0.13 and 1.08 +/- 0.08 in the
212 CLAI and Control groups ($p < 0.001$) (Figure 3b).

213 Median IAMIV values were respectively 20 (IQR 16.4) and 11.3 (IQR 12) in the
214 CLAI and Control groups ($p = 0.03$) (Figure 3c).

215



216

217

218 **Figure 2:** Flow Chart.

219 *LAS, Lateral Ankle Sprain; CLAI, Chronic Lateral Ankle Instability*

220

221

222 **Table 1:** Demographics, sport characteristics and questionnaire results.

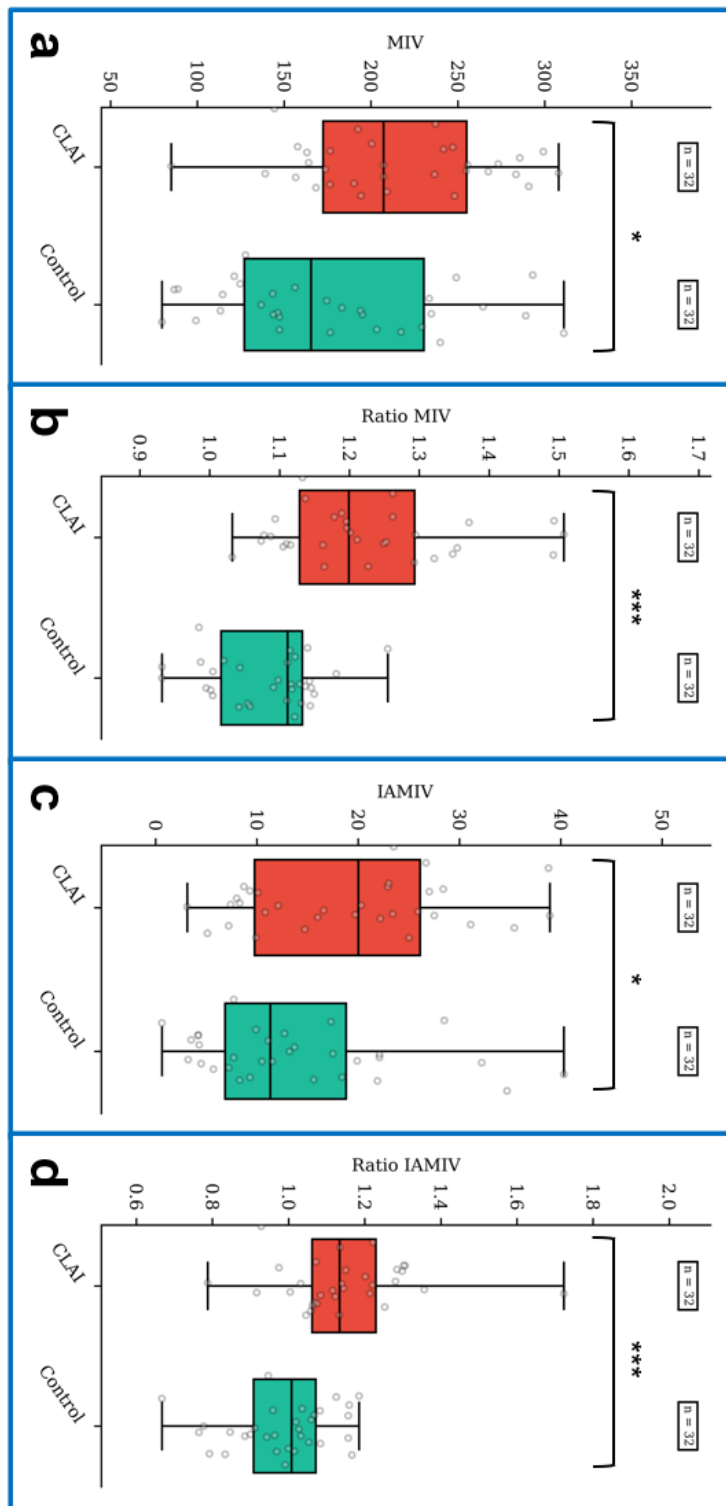
	CLAI group (n=32)	Control group (n=32)	P values
Age (years; mean+/-SD)	25.8 +/- 5.5	28.2 +/- 6.6	0.25
Body Mass Index (kg/m ² ; mean+/-SD)	23.5 +/- 3.2	23.8 +/- 3.1	0.69
Gender	10 Women (31.2%)	12 Women (37.5%)	0.79
Sport	<ul style="list-style-type: none"> - Running (n=10) - Cycling (n=7) - Basketball (n=4) - Weightlifting (n=4) - Tennis (n=3) - Soccer (n=1) - Golf (n=1) - Triathlon (n=1) - Volleyball (n=1) 	<ul style="list-style-type: none"> - Running (n=13) - Tennis (n=4) - Cycling (n=3) - Weightlifting (n=2) - Soccer (n=2) - Table Tennis (n=2) - Swimming (n=2) - Dance (n=2) - Basketball (n=1) - Volleyball (n=1) 	0.33
Competition / Leisure Sports hours / month (mean+/-SD)	7 Competition (21.9%) 19.9 +/- 9.8	4 Competition (12.5%) 18.1 +/- 11.7	0.51 0.23
Number of LAS (mean+/-SD)	5.2 +/- 6.9	0	<0.001
IdFAI score (mean+/-SD)	17.2 +/- 13.4	2.5 +/- 2.4	<0.001
FAAM Activities of Daily Living Subscale (mean+/-SD)	81.3+/-5.9	83.8+/-0.7	<0.001
FAAM Sports Subscale (mean+/-SD)	30.6+/-2.2	31.8+/-0.5	<0.001

223

224 CLAI, Chronic Lateral Ankle Instability ; SD, Standard Deviation ; LAS, Lateral Ankle Sprain ; IdFAI,
225 Identification of Functional Ankle Instability ; FAAM, Foot Ankle Ability Measurement

226

227



228

229 **Figure 3:** Comparisons between CLAI and Control groups.

230 a. Comparison on Maximum Inversion Velocity (MIV)

231 b. Comparison on Ratio MIV

232 c. Comparison on Inversion angle at the MIV time (IAMIV)

233 d. Comparison on Ratio IAMIV

234 * $p < 0.05$; ** $p < 0.01$; *** $p < 0.001$

235 Mean Ratio IAMIV values were respectively 1.13 (IQR 0.17) and 1.01 (IQR 0.16)
236 in the CLAI and Control groups ($p < 0.001$) (Figure 3d).

237 In multivariate analysis, Ratio MIV ($OR = 1.9 \times 10^{-7}$ [$1.1 \times 10^{-11}; 0.003$], $p = 0.002$)
238 and Ratio MIA ($OR = 1.1 \times 10^{-4}$ [$1 \times 10^{-7}; 0.12$], $p = 0.01$) were associated with lower rates
239 of Control whereas IAMIV ($OR = 0.96$ [$0.88; 1.05$], $p = 0.33$), and MIV ($OR = 1.0$,
240 [$0.98; 1.01$], $p = 0.62$) were not associated with the groups.

241

242 **3. Ability to quantify functional CLAI**

243 Univariate analyses between the IdFAI and MIV, IAMIV, Ratio MIV and Ratio IAMIV
244 are exposed in the Table 2 and Figure 4.

245 In multivariate analysis, Ratio MIV ($\beta = 42.8$ [$12.9; 72.8$], $p = 0.006$) and Ratio IAMIV
246 ($\beta = 24.3$ [$7.6; 41$], $p = 0.005$) were associated with higher values of IdFAI, whereas MIV
247 ($\beta = -0.01$ [$-0.04; 0.02$], $p = 0.49$) and IAMIV ($\beta = 0.04$ [$-0.24; 0.33$], $p = 0.77$) were not.

248

249 **4. Ability to quantify impairments in activities of daily living**

250 Univariate analyses between the FAAM Activities of Daily Living Subscale and MIV,
251 IAMIV, Ratio MIV and Ratio IAMIV are exposed in the Table 2.

252 In multivariate analysis, Ratio MIV ($\beta = -14.1$ [$-27.8; -0.5$], $p = 0.04$) was associated
253 with lower values of FAAM Activities of Daily Living Subscale, whereas Ratio IAMIV
254 ($\beta = -4.1$ [$-11.7; 3.6$], $p = 0.3$) was not.

255

256

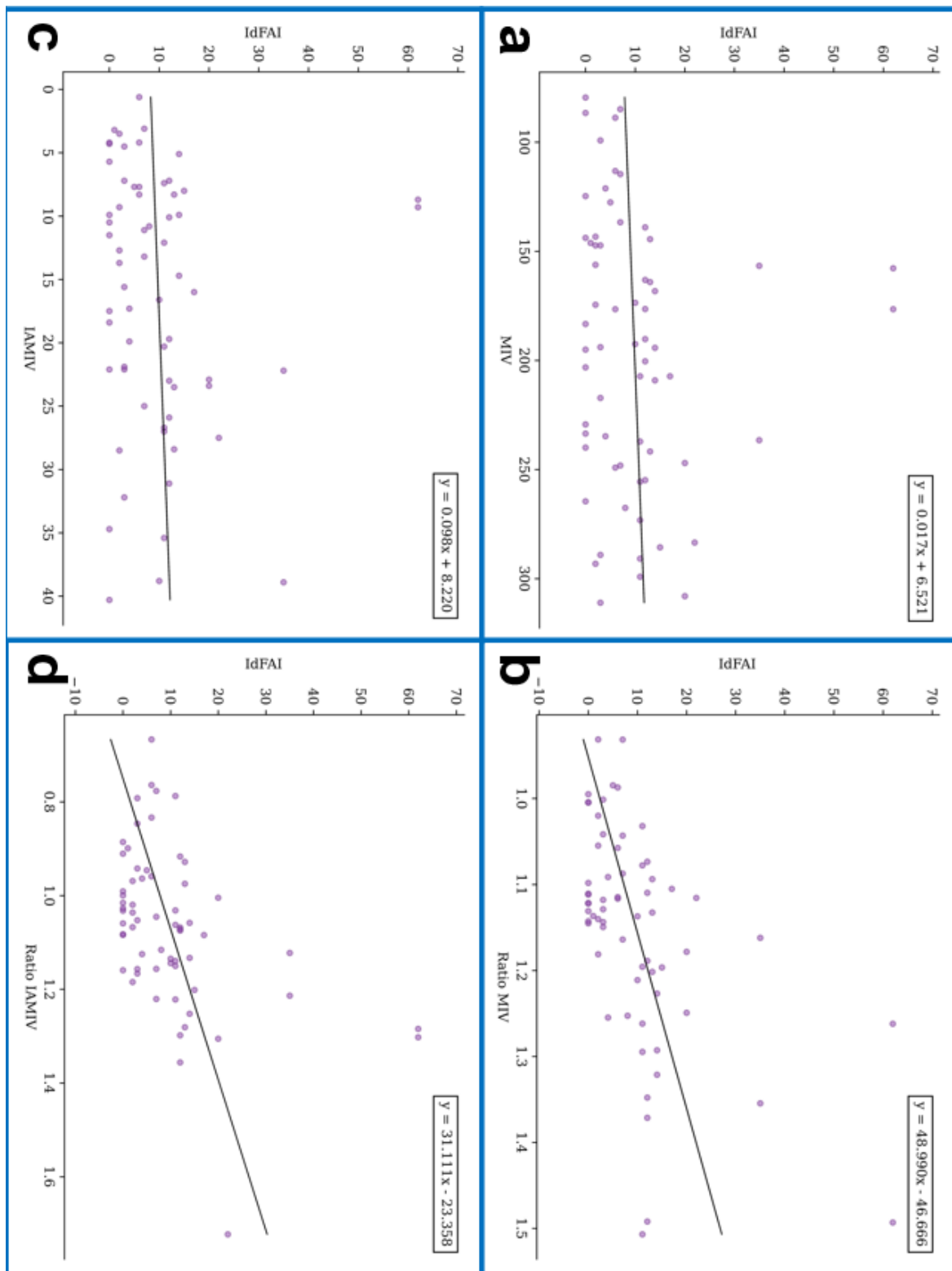
257 **Table 2:** Univariate analyses.

	MIV	IAMIV	Ratio MIV	Ratio IAMIV
IdFAI	$\rho=0.22 / p=0.08$	$\rho=0.19 / p=0.14$	$\rho=0.44 / p<0.001$	$\rho=0.5 / p <0.001$
FAAM Activities of Daily Living Subscale	$\rho=-0.08 / p=0.52$	$\rho=0.04 / p=0.77$	$\rho=-0.45 / p<0.001$	$\rho=-0.29 / p=0.02$
FAAM Sports Subscale	$\rho=-0.05 / p=0.71$	$\rho=-0.06 / p=0.67$	$\rho=-0.43 / p<0.001$	$\rho=-0.2 / p=0.1$

258 *MIV, Maximum Inversion Velocity ; IAMIV, Inversion angle at the MIV time ; IdFAI, Identification of*
 259 *Functional Ankle Instability ; FAAM, Foot Ankle Ability Measurement ;*

260

261



262

263 **Figure 4:** Correlation diagrams between the Identification of Functional Ankle
 264 Instability (IdFAI) questionnaire and:

- 265 a. Maximum Inversion Velocity (MIV)
- 266 b. Ratio MIV
- 267 c. Inversion angle at the MIV time (IAMIV)
- 268 d. Ratio IAMIV

269 **5. Ability to quantify impairments in sports activities**

270 Univariate analyses between the FAAM Sports Subscale and MIV, IAMIV, Ratio MIV
271 and Ratio IAMIV are exposed in the Table 2.

272 In multivariate analysis, Ratio MIV ($\beta=-7.2$ [-13.7;-0.6], $p=0.03$) was associated
273 with lower values of FAAM Sports Subscale, whereas Ratio IAMIV ($\beta=1.2$ [-2.2;4.6],
274 $p=0.47$) was not.

275

276 **DISCUSSION**

277 In this study CLAI and controls were clearly differentiated on inversion velocities
278 and angles during a simulated trauma caused by a sprain simulator. Ratio MIV showed
279 a good capacity in quantifying functional CLAI as well as impairments in activities of
280 daily living and sports.

281 Several studies used sprain simulators to compare CLAI and controls
282 [13,15,20]. However, we were the first to our knowledge to perform a gait analysis
283 during an unexpected simulated trauma while walking. The unexpectedness of the
284 trauma is necessary to allow reliable inversion acquisition at that time, otherwise
285 peroneals preactivation and their anticipated contractions control the inversion motion
286 [21–23]. The unexpectedness of the trauma in our protocol could be thwarted by a
287 poorer safeness. We did not report any falls or injuries in our study. However, in our
288 study, 2 ankles slightly exceeded ($311^\circ/s$ and $308^\circ/s$) the previously established injury
289 risk threshold of $300^\circ/s$ of MIV [14]. To define this threshold, Chu et al. used a case
290 reporting $632^\circ/s$ of MIV during an actual sprain [24]. Defining a precise threshold for
291 injury risk would probably require more data on actual sprains, especially since MIV
292 intersubject variability was high in both our study and the one of Chu et al. [14]. Each

293 subject has his own ligamentous laxity and maximal ankle range of motion. Therefore,
294 we recommend using normalized parameters such as Ratio MIV in an attempt to define
295 a more precise threshold for injury risk.

296 We increased the accuracy of our data collection using Ratio MIV and Ratio
297 IAMIV. The Ratio MIV showed a good ability to quantify functional CLAI, activities of
298 daily living, and sports impairments. However, this is not enough to give a complete
299 picture of CLAI. This sprain simulator should also be tested on mechanical instability
300 to prove its ability to measure CLAI globally [8]. It should also be used to try to weight
301 all CLAI risk factors. This would allow to determine the relative importance of each
302 factor in the occurrence of CLAI after first LAS episode [9].

303 In our study, 6 ankles were excluded because of giving way antecedents or
304 feeling of instability with no history of LAS (Figure 2). This shows the importance of
305 having a tool to a priori evaluate the risk of LAS in order to enable preventive care.

306 Our study has several limitations. Only physically active individuals under the
307 age of forty were included, which limits the extrapolation of our findings to the general
308 population. However, physically active people are the most affected by LAS and CLAI
309 and they represent a significant part of the general population. Similarly, we composed
310 our group according to the International Ankle Consortium recommendations, which
311 could have caused selection bias and we considered questionnaires (IdFAI and FAAM)
312 to represent functional CLAI and daily life impairments. Nevertheless, these are the
313 current reference recommendations on the subject. The subjects' walking was not
314 perfectly normal, as the boots altered the walking pattern. Although not perfect, this
315 mechanism probably better reflects an actual LAS than jumping on a platform or
316 experiencing a sudden motion in a static position.

317

318 **CONCLUSIONS**

319 Inversion velocities caused by a sprain simulator clearly differentiated CLAI from
320 controls in our study. Ratio MIV showed good ability to quantify functional CLAI as
321 well as impairments in activities of daily living and sports. This tool should be used in
322 future studies in an attempt to provide a complete picture of CLAI encompassing its
323 functional and mechanical aspects which may lead to improved LAS and CLAI
324 management.

325

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329

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333

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414

2.4 Conclusions (Partie 2).

Notre simulateur d'entorse s'est avéré sans risque et était en mesure de différencier des sujets instables à des témoins sur la vitesse angulaire maximale en inversion lors d'un traumatisme simulé.

Conformément à notre modèle et à notre revue de la littérature, l'étape suivante consiste à tenter de quantifier l'impact relatif de chaque facteur de risque sur la survenue d'ILCC. Pour ce faire, nous avons pour objectif de définir des paramètres permettant de quantifier indépendamment chaque facteur de risque, puis de tenter de corrélérer ces paramètres à la vitesse angulaire en inversion lors d'un traumatisme simulé pour essayer de pondérer l'importance relative de chacun de ces facteurs de risque dans la survenue d'une ILCC.

L'objectif final serait de développer un score prédictif de survenue d'ELC englobant tous les facteurs de risque et leurs pondérations.

Dans la troisième partie, nous détaillerons les méthodes envisagées pour quantifier chaque facteur de risque.

Partie 3 : Projet de quantification et de pondération des facteurs de risque pour l'élaboration d'un score prédictif d'entorse du plan ligamentaire latéral de cheville.

3.1 Introduction.

L'objectif de cette partie est de préciser le modèle cumulatif d'ILCC précédemment décrit afin de connaître l'importance relative de chacun des facteurs de risque dans la survenue d'une ILCC à la suite d'une ELC. L'objectif à terme serait de pouvoir répondre par exemple aux questions suivantes : un sujet présentant des lésions combinées du ligament talo-fibulaire antérieur et du ligament calcanéo-fibulaire a-t-il un risque plus élevé de développer une ILCC en comparaison à un sujet présentant une lésion isolée du ligament talo-fibulaire antérieur ? Ou encore, est-ce qu'un varus de l'arrière-pied de 3 degrés représente un facteur de risque plus important de survenue d'ELC qu'un déficit de contraction maximale excentrique en éversion de cheville de 5 N.m ?

Pour cela, la première étape est de disposer d'outils et de paramètres permettant d'identifier et de quantifier indépendamment et aisément chaque facteur de risque, ce que nous ébauchons dans ce chapitre.

3.2 Facteurs de risque mécaniques.

3.2.1 Laxités ligamentaires.

Dans notre revue de la littérature les atteintes des ligaments talo-fibulaire antérieur et calcanéo-fibulaire étaient des facteurs de risques reconnus d'ILCC (1–7). Mais d'autres laxités ligamentaires étaient également retrouvées dans la littérature comme l'atteinte de la syndesmose ou la laxité sous talienne (1,8–10).

L'échographie est un outil reconnu dans le diagnostic des lésions ligamentaires (11). Il permet une analyse dynamique de ces structures. Cho et al. ont comparé l'échographie dynamique aux radiographies en stress et à l'IRM pour évaluer la laxité du ligament talo-fibulaire antérieur par rapport à l'arthroscopie qui était considérée comme gold standard. L'échographie dynamique et l'IRM avaient permis de

diagnostiquer l'atteinte ligamentaire dans 100% des cas contre 85.7% des cas pour les radiographies en stress (12,13). Plusieurs équipes retrouvent de bons résultats concernant l'évaluation de la laxité des ligaments talo-fibulaire antérieur et calcanéo-fibulaire (14,15).

Des études similaires ont été réalisées au niveau de la syndesmose, et les résultats sont également encourageants (16,17). Une équipe a également évalué l'intérêt de l'élastographie échographique au niveau de la syndesmose et du ligament deltoïde (18,19). Grâce à cet outil, ils ont pu quantifier les différences de tension des structures ligamentaires en plaçant la cheville dans différentes positions.

En ce qui concerne la laxité sous-talienne, sa place comme facteur de risque d'ILCC reste à confirmer (1). D'après une revue systématique de la littérature sur le sujet réalisée par Michels et al. il semblerait que cette laxité soit à prendre en compte dans l'ILCC, mais que les radiographies en stress ne permettaient pas de la diagnostiquer (20). L'échographie dynamique doit être testée (21).

3.2.2 Déficit d'extension de cheville.

La présence d'une limitation de l'extension de cheville est également reconnue comme un facteur de risque d'ILCC (22–24). Ce déficit peut avoir plusieurs origines comme la brièveté isolée des gastrocnémiens, la rétraction globale du triceps sural, ou la présence d'un conflit antérieur tibio-talien. La brièveté isolée des gastrocnémiens est fréquente et est associée à de nombreuses pathologies du pied et de la cheville (25). Cette dernière impacte la marche des sujets comme nous l'avons montré dans de précédentes études ((26,27), **Annexes 4 et 5**). Koshino et al. ont comparé des sujets présentant une ILCC à des témoins et ont retrouvé une activité électromyographique plus importante du gastrocnémien médial ainsi qu'une inversion plus importante de la cheville pendant la phase d'appui dans le groupe ILCC (28). Cet excès d'inversion pourrait favoriser l'ILCC. Pierre Barouk, dans une série comprenant 354 allongements des gastrocnémiens retrouvait une instabilité de cheville subjective (déclarée par le patient) dans 52.5% des cas en préopératoire (29). Après allongement, 79% de ces 52.5% ne ressentaient plus d'instabilité.

Un autre élément à prendre en compte, décrit par Denegar et al., est la diminution du glissement postérieur du talus pendant l'extension de la cheville (8).

Cette dernière semble secondaire à l'atteinte ligamentaire et pourrait limiter l'extension par translation antérieure du centre de rotation tibio-talien (8,30). Ce manque d'extension et de glissement postérieur du talus dans la mortaise tibio-talienne pourrait également diminuer la stabilité de l'articulation tibio-talienne. La partie postérieure du corps du talus étant plus étroite, un défaut de remplissage de la mortaise pourrait être également une cause d'instabilité.

Quelle que soit la cause, il nous semblait primordial de disposer d'un outil permettant de quantifier cette limitation de l'extension de la cheville. Nous avons ainsi développé et validé un équinomètre. Le manuscrit suivant a été soumis au journal *PlosOne* et des révisions mineures sont en cours d'évaluation.

PLOS ONE

Reliability of a new computerized equinometer based on Silfverskiöld test to measure gastrocnemius tightness --Manuscript Draft--

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Full Title:	Reliability of a new computerized equinometer based on Silfverskiöld test to measure gastrocnemius tightness
Short Title:	Reliability of a new equinometer
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Keywords:	gastrocnemius tightness; equinometer; ankle dorsiflexion; Reliability; force application
Abstract:	<p>Background: Several tools exist to measure tightness of the gastrocnemius muscles; however, few of them are reliable enough to be used routinely in the clinic. The primary objective of this study was to evaluate the intra- and inter-rater reliability of a new equinometer. The secondary objective was to determine the load to apply on the plantar surface of the metatarsal heads to achieve the highest reliability when measuring gastrocnemius tightness.</p> <p>Methods: The equinometer consisted of a goniometer and an electronic dynamometer, hooked up to a computer. Three raters carried out three trials of passive dorsiflexion by applying controlled pressure to the metatarsal heads of both ankles in 29 healthy subjects under two experimental conditions: knee extended (KE) and knee flexed at 30 degrees (KF). The equinometer continuously recorded the ankle dorsiflexion values (in °) corresponding to each 1 N interval of plantar pressure between 4 N and 20 N. The intra- and inter-rater reliability of the ankle dorsiflexion were evaluated through the intra-class correlation (ICC) coefficients in each of the pressure intervals.</p> <p>Results: The intra-rater ICC in KE and KF was between 0.84 and 0.98. The inter-rater ICC in KE and KF was between 0.59 and 0.92. The pressure interval between 14 N and 15 N had the highest intra-rater (ICC=1) and inter-rater reliability ($0.87 \leq ICC \leq 0.99$). A more refined analysis of this interval found that a load of 14.5 N yielded the best reliability.</p> <p>Conclusions: This compact equinometer has excellent intra-rater reliability and moderate to good inter-rater reliability. Since this reliability is optimal in the 14-15 N range, this load should be used going forward in clinical practice, especially when aiming to define a pathological threshold for tightness of the gastrocnemius muscles.</p>
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Opposed Reviewers:	
Response to Reviewers:	<p>To the Editorial Board and the Reviewers,</p> <p>We would like to thank the Editorial Board and the Reviewers for the precious comments on our manuscript. These comments will certainly make the manuscript more robust and understandable. We have considered the comments of the 2 reviewers and we have modified our manuscript accordingly. We hope that our modifications will meet your expectations. We left in this letter the comments from the 2 reviewers. As requested, you will find in our new submission, a version highlighting the</p>

19

Abstract

20 *Background:* Several tools exist to measure tightness of the gastrocnemius muscles; however,
21 few of them are reliable enough to be used routinely in the clinic. The primary objective of this
22 study was to evaluate the intra- and inter-rater reliability of a new equinometer. The secondary
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29 equinometer continuously recorded the ankle dorsiflexion values (in °) corresponding to each
30 1 N interval of plantar pressure between 4 N and 20 N. The intra- and inter-rater reliability of
31 the ankle dorsiflexion were evaluated through the intra-class correlation (ICC) coefficients in
32 each of the pressure intervals.

33 *Results:* The intra-rater ICC in KE and KF was between 0.84 and 0.98. The inter-rater ICC in
34 KE and KF was between 0.59 and 0.92. The pressure interval between 14 N and 15 N had the
35 highest intra-rater (ICC=1) and inter-rater reliability ($0.87 \leq \text{ICC} \leq 0.99$). A more refined analysis
36 of this interval found that a load of 14.5 N yielded the best reliability.

37 *Conclusions:* This compact equinometer has excellent intra-rater reliability and moderate to
38 good inter-rater reliability. Since this reliability is optimal in the 14-15 N range, this load should
39 be used going forward in clinical practice, especially when aiming to define a pathological
40 threshold for tightness of the gastrocnemius muscles.

41

42 **Keywords:** gastrocnemius tightness; equinometer; ankle dorsiflexion; reliability; force
43 application

44 **Introduction**

45 Various studies have shown that limited ankle dorsiflexion is a key contributor to
46 decompensation of foot and ankle pathologies [1–3]. This limitation in ankle dorsiflexion can
47 be caused by tightness of the gastrocnemius muscles [3–12]. The gastrocnemius tightness
48 prevalence in the general population might be as high as 50% according to Kowalski et al. [13].
49 However, the current lack of a diagnostic threshold makes this number uncertain. This
50 tightness is in most cases the result of a degenerative process, with a decrease in tendon
51 elasticity over time [13,14]. Gastrocnemius tightness, increasing with age, is known to be a
52 predisposing factor for certain pathologies such as Achilles tendinopathy [3,6,7], plantar
53 fasciitis [15], metatarsalgia [13,14] or even hallux valgus [3,5,6]. These pathologies result in
54 pain, reduced mobility, reduced participation in physical or social activities, thus affecting the
55 quality of life of patients.

56 Given these factors, the diagnosis and treatment of gastrocnemius tightness appears to be
57 crucial. However, it can be challenging to quantify this tightness. In clinical practice, there are
58 several methods for evaluating gastrocnemius tightness. Currently, the Silfverskiöld test is
59 widely used for this diagnosis [16,17]. This test evaluates if the equinus contracture can be
60 reduced by flexing the knee. However, there is no consensus on the amount of pressure to
61 apply on the sole of the foot, nor on the increase in ankle dorsiflexion needed to make the
62 diagnosis. Likewise, it is important to note that the reliability of this test is highly questionable.
63 Indeed Molund et al. [17] have demonstrated a poor to average reliability for this test. A
64 goniometer is also one of the methods used clinically. It is based on the practitioner’s end-of-
65 stroke perception [18,19] either with the subject weightbearing [20,21] or with a measuring
66 device [22,23]. However, the main limitations of goniometer measurements are its lack of
67 reliability, its operator-dependent nature and the fact that stiffness cannot be quantified solely
68 by recording the change in an angle, without knowing the load applied to the foot [19].

69 To get around this lack of reliability and validity, several other methods have been proposed
70 for evaluating ankle dorsiflexion. For example, Munteanu *et al.* [20] and Bennell *et al.* [21]
71 proposed a functional approach that evaluates active ankle dorsiflexion during a controlled
72 lunge motion. While this approach is reliable, it cannot be used in every clinical situation,
73 especially when the patient is in pain, and does not control how much load is applied on the
74 sole of the foot. An alternative method consists of evaluating the mobility in ankle dorsiflexion
75 by measuring the angle between the foot and lower leg on a photograph when a load is applied
76 to the metatarsal heads [24]. Beyond the challenges of applying this technique in routine
77 clinical practice, the inability to stabilize the foot and the impossibility of quantifying the
78 pressure placed on the metatarsal heads are significant limitations of these systems.

79 Lastly, measurement systems with a computerized interface have also been developed to
80 measure the ankle range of motion with greater accuracy [8,22,23] but their cost and bulk
81 means they are not well suited to clinical practice. Other than being affordable and easy to use
82 clinically (transport, installation, use), a device to measure ankle dorsiflexion or “equinometer”
83 must have good inter- and intra-rater reliability for measuring ankle dorsiflexion, while
84 quantifying the load applied on the sole of the foot.

85 Given the limitations of the previously mentioned devices, we designed an electronic
86 equinometer with computerized interface consisting of a goniometer to measure the ankle
87 dorsiflexion and a dynamometer to quantify the load applied to the metatarsal heads. The
88 entire unit is light, low profile and easy to transport.

89 Thus, the primary objective of this study was to evaluate the intra- and inter-rater reliability of
90 a new equinometer for measuring gastrocnemius tightness. The secondary objective was to
91 determine the load to apply on the metatarsal heads to achieve the highest possible reliability.
92 We hypothesized that the equinometer will be reliable between and within raters and that a
93 specific load value can be identified that will ensure the best measurement reliability.

94

95 **Materials and methods**

96 The IRB of the Hôtel Dieu in Paris, France approved this study protocol on February 18, 2021
97 (Ref. # IORG0009918). Every subject was given an information letter describing the study.
98 Subjects who agreed to participate in the study provided their written consent. The subjects'
99 data were anonymized.

100 **Subjects**

101 Twenty-nine healthy adult volunteers were enrolled in the study between March 1 and April 30,
102 2021 (*Table 1*). The only inclusion criterion was being greater than 18 years of age. The
103 subjects were recruited through an ad placed at a kinesiology and massage therapy training
104 institute (IFMK Saint Michel, Paris, France) and at a hospital (Clinique Mégival, Dieppe,
105 France).

106 The exclusion criteria were the presence of pain in the lower limbs due to a recent injury or an
107 active disease that prevents the examination from being done, and any cognitive or psychiatric
108 disorder that prevents the subject from providing informed consent.

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Table 1. Subjects' characteristics

Features	Subjects Mean \pm SD (min-max)
Number	29
Age (years)	24.60 \pm 3.29 (22–32)
Sex (Male (M)/Female (F))	17M/12F
Height (cm)	175.33 \pm 5.47 (167–185)
Mass (kg)	72.60 \pm 8.91 (61–90)
Body Mass Index (kg/m ²)	23.54 \pm 1.86 (20.07–25.54)

Mean \pm SD = Mean and standard deviation; min=minimum value;

max= maximum value

117

118 **Materials**

119 The equinometer (Fig. 1) was designed to be easy to transport, easy to assemble and easy to
120 use in a clinical context. The device that we developed to measure angles and load applied at
121 the metatarsal heads had the following components:

- 122 • An electronic twin-axis goniometer (model SG110, Biometrics Ltd, Ladysmith, VA,
123 USA)
- 124 • An electronic dynamometer (MyoMeter, Biometrics Ltd, Ladysmith, VA, USA)
- 125 • A portable data acquisition system (DataLOG, Biometrics Ltd, Ladysmith, VA, USA)

- 126 • A laptop equipped with software (Analysis Software, Biometrics Ltd, Ladysmith, VA,
127 USA) for processing of data generated by the goniometer and dynamometer
- 128 • A rigid postoperative shoe (Perculight, Romans Industrie™, Romans sur Isère, France)
129 in which the subject's foot was positioned during testing

130 Fig 1. Equinometer with its various components: A= electronic twin-axis goniometer, B= MyoMeter electronic
131 dynamometer, C= DataLOG and D= rigid shoe.

132

133 **Measurement protocol**

134 The three raters (R1, R2, R3) were orthopedic surgeon and physiotherapists. They were all
135 trained beforehand on their execution. The orthopedic surgeon was the rater with the longest
136 experience using the equinometer.

137 **Subject positioning**

138 The subjects were installed supine on an adjustable-height table. Manually, and using a skin
139 marker, the plantar surface of the head of the 2nd metatarsal where the manual pressure will
140 be applied to move the ankle into passive dorsiflexion was marked on the foot. This skin marker
141 is transferred to an adhesive graph paper applied directly to the foot, and then reattached on
142 the sole of the shoe (Fig 2).

143 Fig 2. Identifying the head of the 2nd metatarsal. A: manual identification of the head of 2nd metatarsal; B: the
144 adhesive graph paper is positioned on the sole of the foot; C: the marker of the head of the 2nd metatarsal head is
145 transferred to the adhesive graph paper; D, E: the adhesive graph paper is attached to the shoe by checking the
146 positioning of the foot in the shoe; F: the load is applied on the sole of the foot by the electronic dynamometer.

147

148 Two experimental conditions were tested:

- 149 - Knee in full extension (KE)



Fig 1. Equinometer with its various components:
 A= Electronic twin-axis goniometer,
 B= MyoMeter electronic dynamometer,
 C= DataLOG
 D= Rigid shoe.

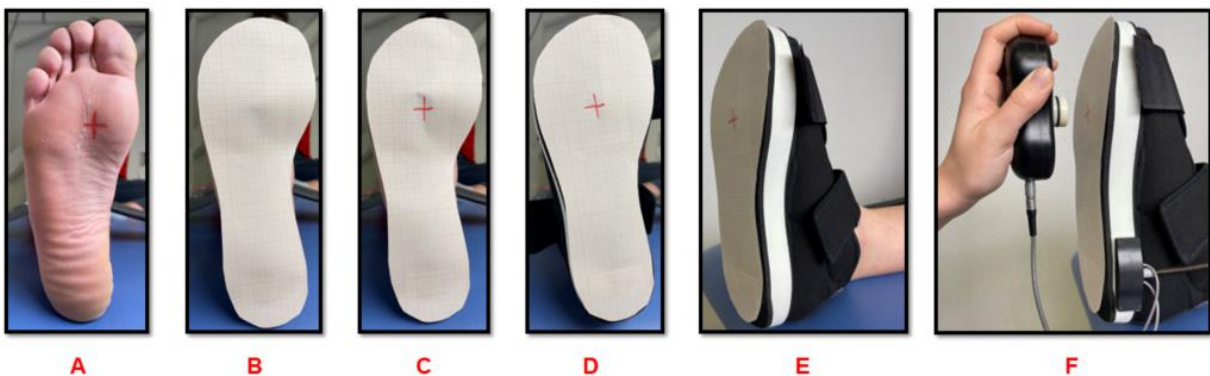


Fig 2. Identifying the head of the 2nd metatarsal.
 A: manual identification of the head of 2nd metatarsal;
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 D, E: the adhesive graph paper is attached to the shoe by checking the positioning of the foot in the shoe;
 F: the load is applied on the sole of the foot by the electronic dynamometer.

150 - Knee in 30° flexion (KF). To hold the knee in 30° flexion [8], a half-roll was placed in
151 the popliteal fossa. The size and position of this cushion was adjusted to obtain 30°
152 flexion and was confirmed with the goniometer.

153 **Subject set-up and goniometer calibration**

154 The subject was given a rigid postoperative shoe based on their regular shoe size. The
155 goniometer was placed with double-sided tape on the sole of the shoe; one arm was placed
156 on the shoe and the other on the medial malleolus (Fig. 3). The ankle was placed in the
157 anatomical reference position “F90°” (foot at 90° relative to the leg axis). This was used to
158 calibrate the goniometer before measuring dorsiflexion. The “F90°” position was obtained with
159 two measurements, using an external digital level (AGT™ Professional, Buggingen, Germany):
160 a first measurement, with the digital level positioned on the tibial crest to ensure its horizontality
161 (0°, Fig. 3); then once this position is maintained, a second measurement is taken on the sole
162 of the foot to ensure its verticality (0°, Fig 3). The angle formed between the sole of the foot
163 and the leg segment is therefore 90° and constitutes the starting position for each
164 measurement. The “F90°” is checked for each measurement following the same protocol.
165 Once the “F90°” had been confirmed, the electronic goniometer was calibrated using the
166 computer and software (set to zero).

167 Fig 3. F90 measurement and positioning of the electronic goniometer on the sole of the rigid shoe and the medial
168 malleolus. A: the leg segment is strapped to the table to keep it in position; B: the digital level is positioned on the
169 tibial crest to ensure its horizontality; C: a second measurement is taken on the sole of the foot to ensure its
170 verticality; D: one of the arms of the goniometer is placed on the sole of the shoe. The other arm is positioned on
171 the medial malleolus, the application of force is perpendicular to the sole of the foot.

172 **Taking measurements**

173 The rater stands across from the subject after having set the table height. The rater manually
174 applies gradual pressure through the dynamometer on the sole of the shoe at the landmark
175 previously made that corresponds to the head of the 2nd metatarsal. The direction of the
176 pressure was perpendicular to the sole. The dynamometer recorded the load applied by the

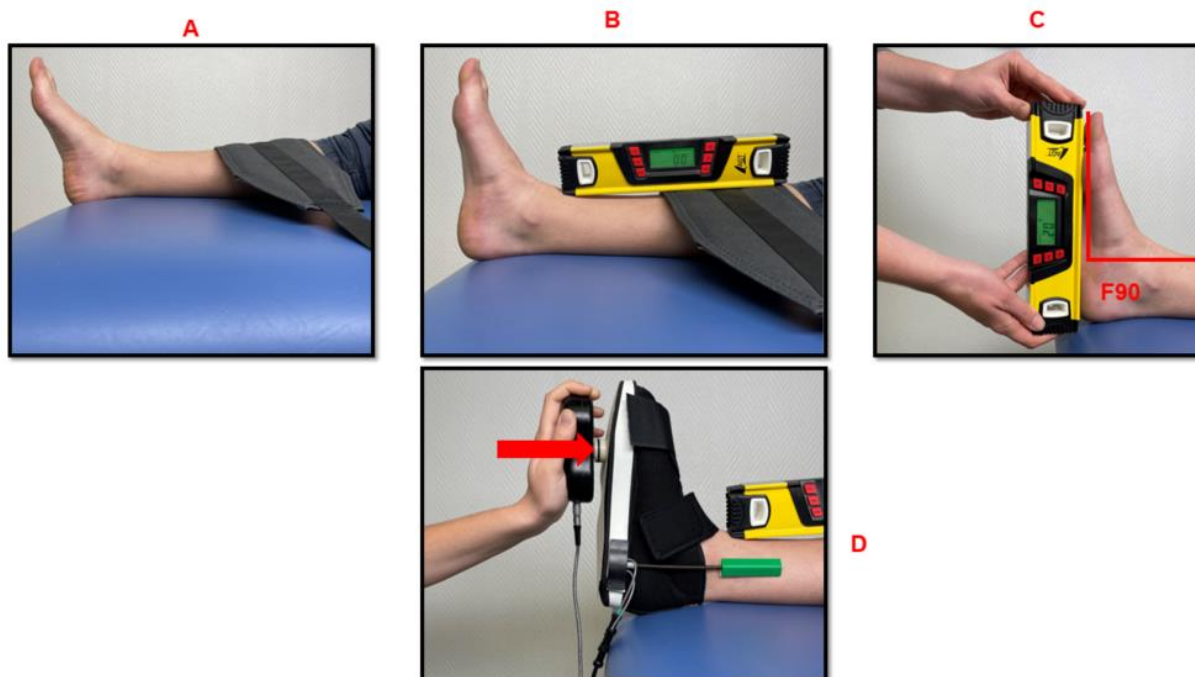


Fig 3. F90 measurement and positioning of the electronic goniometer on the sole of the rigid shoe and the medial malleolus.
 A: the leg segment is strapped to the table to keep it in position;
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 C: a second measurement is taken on the sole of the foot to ensure its verticality;
 D: one of the arms of the goniometer is placed on the sole of the shoe. The other arm is positioned on the medial malleolus, the application of force is perpendicular to the sole of the foot.

177 rater on the subject's foot. Three successive trials were done by the three raters on each of
178 the subject's two ankles. The trials were done with the lower leg under passive conditions; the
179 subject had been instructed to let the rater move his/her ankle. The rater ensured there was
180 no muscle contractions by looking at the tibialis anterior and extensor tendons subcutaneously.
181 All the trials were done at 1-minute intervals, alternating between KE and KF :

- 182 • Trial 1 with the knee extended (KE)
 - 183 ○ One minute interval, new measurement of the F_{90°
- 184 • Trial 1 with the knee in 30° flexion (KF)
 - 185 ○ One minute interval, the rater removed the markers and then replaced them for
 - 186 Trial 2, new measurement of the F_{90°
- 187 • Trial 2 with the knee extended (KE)
 - 188 ○ One minute interval, new measurement of the F_{90°
- 189 • Trial 2 with the knee in 30° flexion (KF)
 - 190 ○ One minute interval, the rater removed the markers and then replaced them for
 - 191 Trial 3, new measurement of the F_{90°
- 192 • Trial 3 with the knee extended (KE)
 - 193 ○ One minute interval, new measurement of the F_{90°
- 194 • Trial 3 with the knee in 30° flexion (KF)
 - 195 ○ The rater removed the markers to position them on the other ankle

196 Six measurements were done on both ankles, resulting in 12 measurements per subject. The
197 order in which the ankles (left or right) were tested was randomized for each subject. The 12
198 measurements of passive dorsiflexion were done by three different raters, one after the other,
199 thus 36 measurements of passive dorsiflexion per subject. The markers were detached
200 between trial 1 and 2 and also between trial 2 and 3. After each subject, markers were cleaned
201 and then repositioned by each new rater with new double-sided tape.

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206 **Statistical analysis**

207 The DataLOG measured data continuously during the entire push and release phases by each
208 rater in each trial. These data were then collected by the Analysis Software with output of load
209 in Newtons and a corresponding angle in degrees (dependent variable). The data were then
210 exported to a spreadsheet and processed by the study personnel. Data was extracted solely
211 in the push phase on the sole of the shoe; 16 intervals of 1 N load were chosen for this study.
212 The maximum value of the ankle dorsiflexion angle in degrees for each push phase was
213 analyzed: between 4 N and 5 N, between 5 N and 6 N and so on until the interval between
214 19 N and 20 N. The statistical analysis was done using the software R™ (version 4.0.4, Bell
215 Laboratories, Murray Hill, USA). Figure 4 summarizes how the data were analyzed.

216 The mean, SD and standard error of measurement (SEM) were calculated. The SEM was
217 calculated as $SEM = SD \times (1-r)^{1/2}$, where “r” is the coefficient of reliability. The 95% confidence
218 interval of the minimum detectable change (MDC) was used to look for clinically relevant
219 changes in the dorsiflexion peak. The MDC is the minimum change that is not due to a
220 measurement error. The MDC was calculated as the product of the SEM, the z score for the
221 95% confidence level and $\sqrt{2}$.

222 The intra-rater reliability was measured with Intraclass Correlation Coefficients (ICC) both for
223 single measures, both comparing the three trials and taking the average of the three trials. The
224 intra-rater reliability for single measures (SM) was calculated using a two-way random, single
225 score ICC (ICC_{2,1}) whereas the intra-rater reliability for average measures (AVG3M) was
226 calculated using a two-way random, average score ICC (ICC_{2,3}) [12].

227 The inter-rater reliability was calculated for each force level using a two-way random, single
228 score ICC (ICC_{2,1}).

229 For interrater reliability:

230 o The Single Measure ICC is an index for the reliability of each single rater

231 o The AVeraGe ICC is the average of the three trials for each rater

232 o The reliability is assessed by comparing the three raters

233 For the intrarater reliability:

234 o The Single Measure ICC is an index for the reliability of each trial

235 o The AVeraGe ICC is the average of the three raters for each trial

236 o The reliability is assessed by comparing the trials

237 The statistical analysis was repeated for both experimental conditions: KE and KF.

238 The loading interval where the inter- and intra-rater ICC was the best was then refined in 0.1-
239 N increments (Fig. 4).

240 Fig 4: Example of how the data were collected between 4 N and 5 N. The DataLOG registers data continuously
241 during the push phase between 0 and 20 N. Then the maximum angle value is extracted in the interval of interest.
242 For example, for the interval between 4 N and 5 N, the data from each of the 3 raters are extracted for each leg (left
243 and right) and in the two conditions (KE and KF). For each condition, three trials were done. The statical analysis
244 was carried out for each condition. The procedure was repeated for each chosen interval, then a more refined
245 analysis made in the interval between 14 N and 15 N, where the ICC values were the highest.

246 **Results**

247 Of the 58 ankles tested in this study, six had incomplete data due to recording errors. The left
248 ankle of Subject 7 had no data. For Subject 8, data from rater 3 are missing for the left ankle.
249 For Subject 9, one of the three trials by rater 3 on the right ankle is missing. For Subject 18,
250 the measurements for the KF and KE are missing for rater 1. For Subject 28, data for KF by
251 rater 3 are missing for the right ankle. The data from these six ankles were excluded from the
252 analysis. These data were missing due to a problem with the software at the beginning of the
253 study which was corrected. We had no problems with the latest measurements.

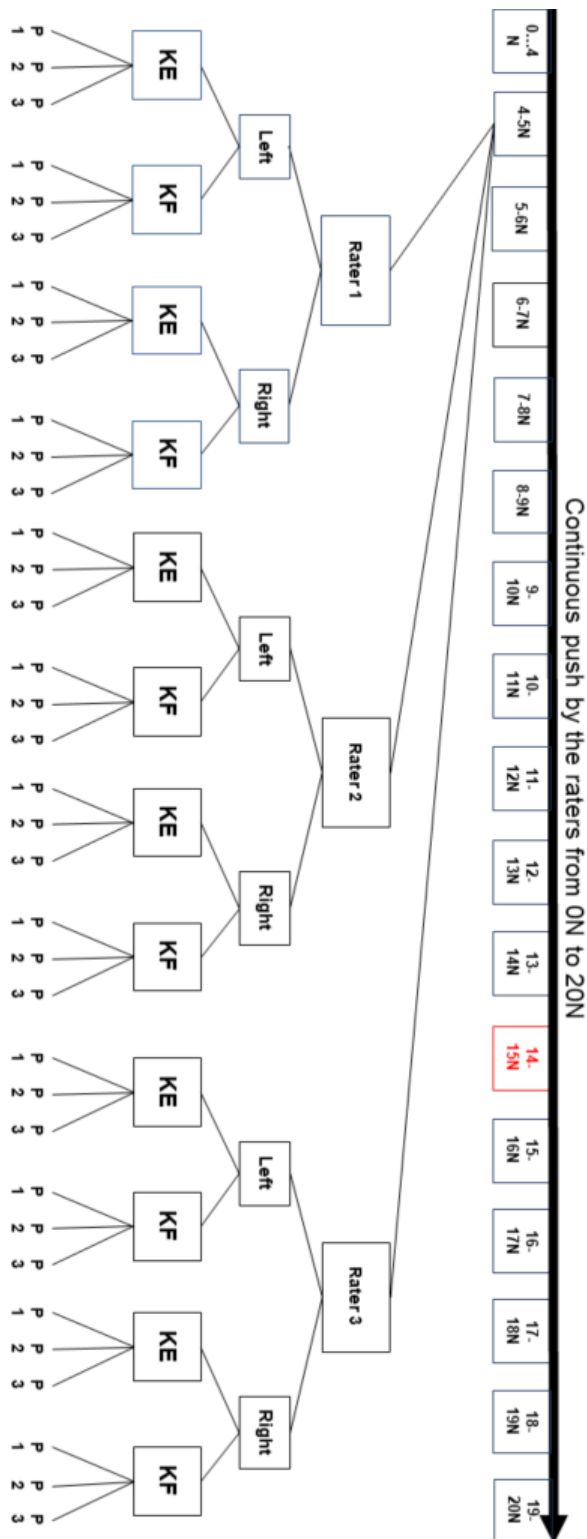


Fig 4. Example of how the data were collected between 4 N and 5 N. The DataLOG registers data continuously during the push phase between 0 and 20 N. Then the maximum angle value is extracted in the interval of interest. For example, for the interval between 4 N and 5 N, the data from each of the 3 raters are extracted for each leg (left and right) and in the two conditions (KE and KF). For each condition, three trials were done. The static analysis was carried out for each condition. The procedure was repeated for each chosen interval, then a more refined analysis made in the interval between 14 N and 15 N, where the ICC values were the highest.

254 *Table 2* shows the intra-rater reliability for ankle dorsiflexion measured by the three raters in
255 the two conditions (KE and KF). The ICC values were between 0.84 and 0.99 (corresponding
256 to a good and excellent reliability respectively, according Koo *et al.* [25]). The lowest ICC
257 values were in the early intervals with the lowest applied forces; the lowest ICC (0.84) was
258 found in the 4–5 N interval for rater 2 in the KE condition. Conversely, the highest ICC values
259 were in the intervals with higher applied forces, up to a certain point beyond which the reliability
260 decreased. In fact, the 14–15 N interval had the ICC closest to 1 for each rater for KE and KF
261 (ICC *single measure* KE = 0.97 for R1, 0.96 for R2 and 0.98 for R3; ICC *single measure* KF =
262 0.98 for R1, 0.99 for R2 and 0.96 for R3, *Table 2*). The ICC for the 14–15 N interval for each
263 rater is shown in Fig. 6.

264 *Table 3* shows the mean values with SD, the ICC with confidence interval, the SEM, the MDC
265 of the ankle motion during KE and KF for the inter-rater assessment. The ICC were between
266 0.59 and 0.91 (corresponding to a moderate and excellent reliability respectively, according
267 Koo *et al.* [25]) The ICC showed low agreement between the raters, especially for the lower
268 force levels, with the lowest ICC (0.59) found in the 4–5 N interval in the KE condition. The
269 ICCs were higher in the KF condition and followed the same trend as in the KE condition. The
270 14–15 N interval had the highest ICC both in the KE (ICC = 0.82; 95%CI = 0.74, 0.88) and KF
271 (ICC = 0.9; 95%CI = 0.86, 0.94) conditions. Fig 5 shows the inter-rater ICC in 0.1 N increments
272 between 14–15 N.

273 *Tables 4 and 5* show the results of the refined analysis for the interval between 14 N and 15 N.
274 Except for R2 in the KE condition and R3 in the KF condition, the intra-rater ICCs were all 1.
275 For the inter-rater ICC, the highest values (>0.98, *Table 4*) were achieved when the testing
276 was done in KF. An applied load of 14.5 N had the highest inter-rater and intra-rater ICC
277 values.

278

279 Fig 5. The inter-rater ICC for each interval in the KE and KF condition, with emphasis on the 14–15 N
280 interval. A = inter-rater ICC for each interval in the two conditions. B = Emphasis on the interval between

281 14 N and 15 N that had the best inter-rater ICC. KE = knee extended, KF = knee flexed, X-axis: load
282 applied in Newtons, Y axis: ICC values

283 Fig 6: The intra-rater ICC for the three raters in the KE and KF condition, with emphasis on the 14–15 N
284 interval. A = intra-rater ICC for each rater and each interval in the two conditions B = Emphasis on the
285 interval between 14 N and 15 N that had the best intra-rater ICC. KE = knee extended, KF = knee flexed
286 X-axis: load applied in Newtons, Y axis: ICC values

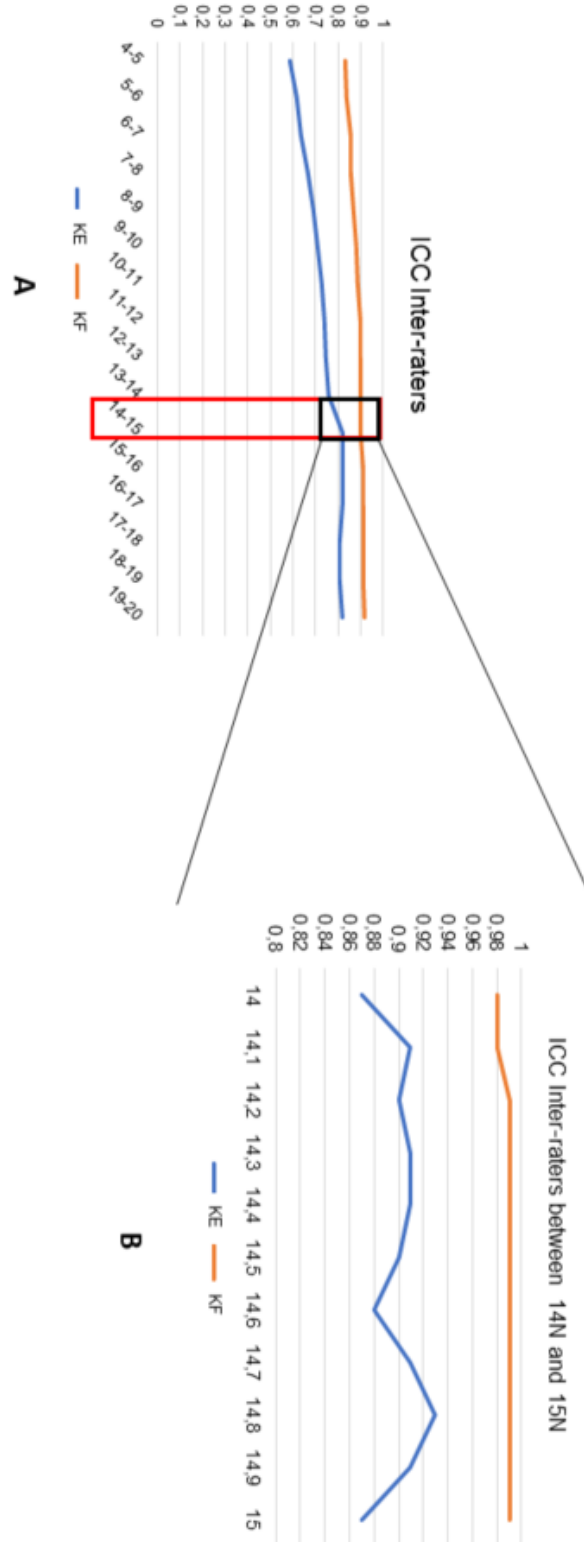


Fig 5. The inter-rater ICC for each interval in the KE and KF condition, with emphasis on the 14–15 N interval.

A = inter-rater ICC for each interval in the two conditions.

B = Emphasis on the interval between 14 N and 15 N that had the best inter-rater ICC.

KE = knee extended, KF = 281 knee flexed, X-axis: load applied in Newtons, Y axis: ICC values

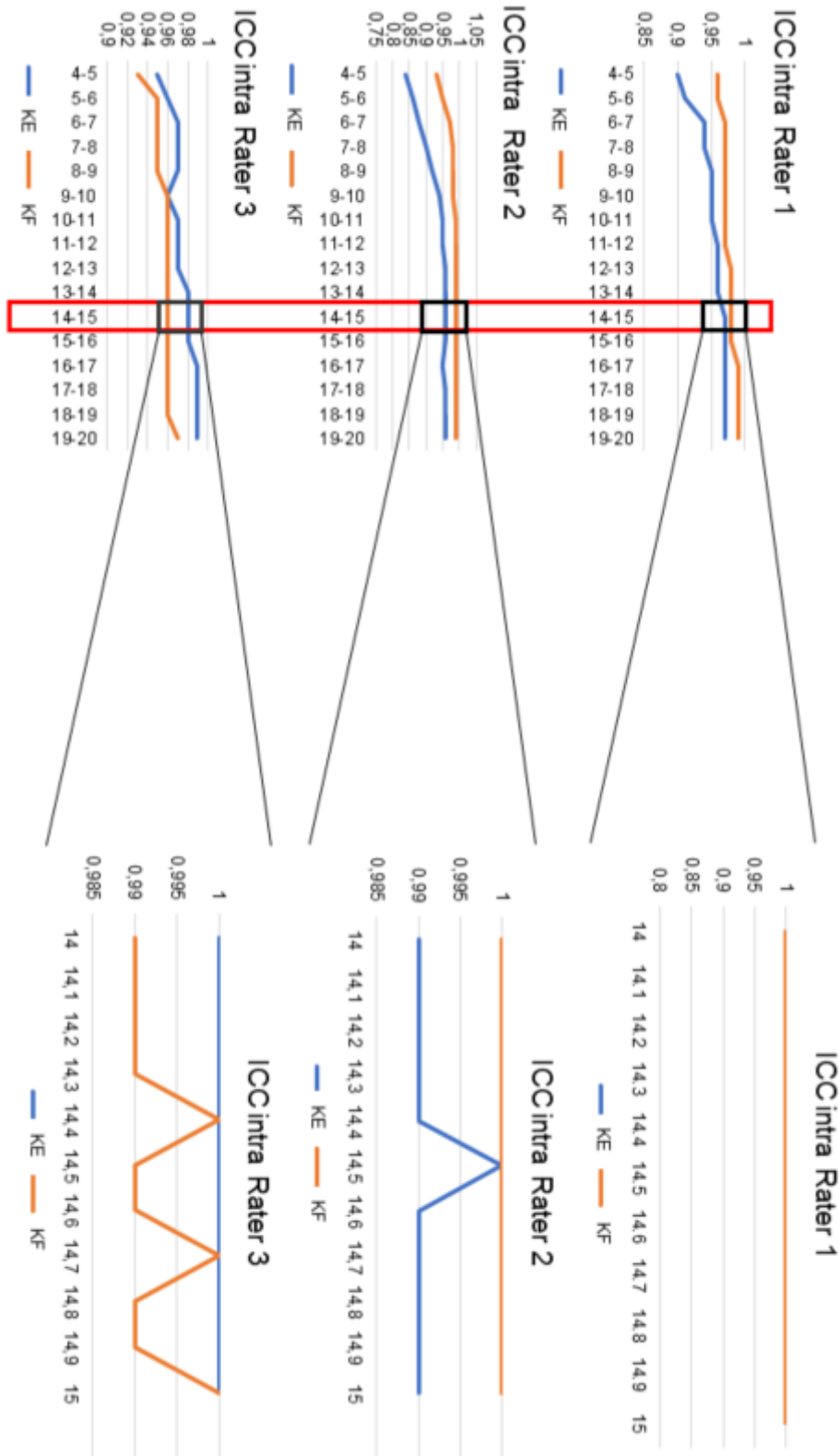


Fig 6. The intra-rater ICC for the three raters in the KE and KF condition, with emphasis on the 14–15 N interval.

A = intra-rater ICC for each rater and each interval in the two conditions

B = Emphasis on the interval between 14 N and 15 N that had the best intra-rater ICC.

KE = knee extended, KF = knee flexed X-axis: load applied in Newtons, Y axis: ICC values

Table 2. Intra-rater Reliability of Single Measures (SM) Versus the Average of 3 Measures (AVG3M), ankle Range Of Motions (degrees), MDC and SEM for Ankle Dorsiflexion Measured by the 3 Raters, with the Knee Extended (KF) and Knee Flexed (KF).

		4-5 N	5-6 N	6-7 N	7-8 N	8-9 N	9-10 N	10-11 N	11-12 N	12-13 N	13-14 N	14-15 N	15-16 N	16-17 N	17-18 N	18-19 N	19-20 N
R	SM (ICC _{2,1})	0.9 (0.86 ; 0.93)	0.91 (0.87 ; 0.94)	0.94 (0.91 ; 0.96)	0.94 (0.92 ; 0.96)	0.95 (0.93 ; 0.97)	0.95 (0.93 ; 0.97)	0.95 (0.93 ; 0.97)	0.96 (0.94 ; 0.97)	0.96 (0.94 ; 0.97)	0.96 (0.95 ; 0.98)	0.97 (0.96 ; 0.98)	0.97 (0.96 ; 0.98)	0.97 (0.96 ; 0.98)	0.97 (0.96 ; 0.98)	0.97 (0.96 ; 0.98)	0.97 (0.96 ; 0.98)
	AVG3M (ICC _{2,3})	0.96 (0.95 ; 0.98)	0.97 (0.95 ; 0.98)	0.98 (0.97 ; 0.99)	0.98 (0.97 ; 0.99)	0.98 (0.97 ; 0.99)	0.98 (0.98 ; 0.99)	0.98 (0.98 ; 0.99)	0.99 (0.98 ; 0.99)	0.99 (0.98 ; 0.99)	0.99 (0.98 ; 0.99)	0.99 (0.99 ; 0.99)	0.99 (0.99 ; 0.99)	0.99 (0.99 ; 0.99)	0.99 (0.99 ; 0.99)	0.99 (0.99 ; 0.99)	0.99 (0.99 ; 0.99)
	Mean ± SD (°)	9.7 ± 5.44	11.85 ± 6.15	13.86 ± 6.54	15.73 ± 6.91	17.42 ± 7.2	18.89 ± 7.4	20.26 ± 7.63	21.51 ± 7.85	22.63 ± 8.02	23.75 ± 8.25	24.35 ± 8.24	24.85 ± 8.44	25.51 ± 8.77	25.97 ± 8.88	26.35 ± 9.04	26.95 ± 9.3
	SEM (°)	0.43	0.49	0.52	0.55	0.57	0.59	0.61	0.62	0.64	0.66	0.67	0.7	0.75	0.76	0.81	0.85
	MDC (°)	1.2	1.35	1.44	1.52	1.58	1.63	1.68	1.73	1.76	1.83	1.86	1.95	2.07	2.12	2.23	2.35
K	SM (ICC _{2,1})	0.84 (0.78 ; 0.89)	0.86 (0.81 ; 0.91)	0.88 (0.83 ; 0.92)	0.9 (0.85 ; 0.93)	0.92 (0.88 ; 0.94)	0.94 (0.91 ; 0.96)	0.95 (0.93 ; 0.97)	0.95 (0.93 ; 0.97)	0.96 (0.95 ; 0.97)	0.96 (0.95 ; 0.98)	0.96 (0.95 ; 0.98)	0.96 (0.94 ; 0.97)	0.95 (0.93 ; 0.97)	0.96 (0.93 ; 0.97)	0.96 (0.94 ; 0.98)	0.96 (0.94 ; 0.98)
	AVG3M (ICC _{2,3})	0.94 (0.91 ; 0.96)	0.95 (0.93 ; 0.97)	0.96 (0.94 ; 0.97)	0.96 (0.95 ; 0.98)	0.97 (0.96 ; 0.98)	0.98 (0.97 ; 0.99)	0.98 (0.97 ; 0.99)	0.98 (0.98 ; 0.99)	0.99 (0.98 ; 0.99)	0.99 (0.98 ; 0.99)	0.99 (0.98 ; 0.99)	0.99 (0.98 ; 0.99)	0.99 (0.98 ; 0.99)	0.99 (0.98 ; 0.99)	0.99 (0.98 ; 0.99)	0.99 (0.98 ; 0.99)
	Mean ± SD (°)	9.65 ± 5.06	12.05 ± 5.39	14.16 ± 5.78	15.95 ± 6.24	17.58 ± 6.57	19.14 ± 6.82	20.53 ± 7.09	21.75 ± 7.33	22.83 ± 7.55	23.7 ± 7.85	24.47 ± 8.06	25.26 ± 8.25	25.49 ± 8.29	26.12 ± 8.49	26.89 ± 8.05	27.56 ± 8.3
	SEM (°)	0.4	0.43	0.46	0.5	0.52	0.54	0.56	0.58	0.6	0.63	0.66	0.69	0.71	0.74	0.72	0.75
	MDC (°)	1.11	1.18	1.27	1.37	1.44	1.5	1.56	1.61	1.66	1.76	1.84	1.91	1.98	2.05	1.99	2.08
R	SM (ICC _{2,1})	0.95 (0.93 ; 0.97)	0.96 (0.95 ; 0.98)	0.97 (0.95 ; 0.98)	0.97 (0.96 ; 0.98)	0.97 (0.95 ; 0.98)	0.96 (0.95 ; 0.98)	0.97 (0.95 ; 0.98)	0.97 (0.96 ; 0.98)	0.97 (0.96 ; 0.98)	0.98 (0.97 ; 0.98)	0.98 (0.97 ; 0.99)	0.98 (0.98 ; 0.99)	0.99 (0.98 ; 0.99)	0.99 (0.98 ; 0.99)	0.99 (0.98 ; 0.99)	0.99 (0.98 ; 0.99)
	AVG3M (ICC _{2,3})	0.98 (0.98 ; 0.99)	0.99 (0.98 ; 0.99)	0.99 (0.98 ; 0.99)	0.99 (0.99 ; 0.99)	0.99 (0.98 ; 0.99)	0.99 (0.98 ; 0.99)	0.99 (0.98 ; 0.99)	0.99 (0.99 ; 0.99)	0.99 (0.99 ; 0.99)	0.99 (0.99 ; 0.99)	0.99 (0.99 ; 1)	0.99 (0.99 ; 1)	1 (0.99 ; 1)	1 (0.99 ; 1)	1 (0.99 ; 1)	1 (0.99 ; 1)
	Mean ± SD (°)	11.98 ± 7.31	14.39 ± 7.57	16.34 ± 7.93	18.06 ± 8.19	19.54 ± 8.37	20.87 ± 8.57	21.76 ± 8.5	22.89 ± 8.72	23.92 ± 8.91	24.89 ± 9.07	25.81 ± 9.18	26.68 ± 9.3	27.48 ± 9.47	27.86 ± 9.63	28.32 ± 9.8	29.01 ± 10.13
	SEM (°)	0.59	0.61	0.63	0.66	0.68	0.69	0.69	0.71	0.73	0.74	0.75	0.76	0.77	0.8	0.84	0.88
	MDC (°)	1.62	1.68	1.76	1.82	1.88	1.92	1.92	1.97	2.02	2.05	2.08	2.11	2.14	2.22	2.34	2.44
K	SM (ICC _{2,1})	0.96 (0.94 ; 0.97)	0.96 (0.95 ; 0.98)	0.97 (0.96 ; 0.98)	0.97 (0.96 ; 0.98)	0.97 (0.96 ; 0.98)	0.97 (0.96 ; 0.98)	0.97 (0.96 ; 0.98)	0.97 (0.96 ; 0.98)	0.98 (0.96 ; 0.98)	0.98 (0.97 ; 0.99)	0.98 (0.97 ; 0.99)	0.98 (0.98 ; 0.99)	0.99 (0.98 ; 0.99)	0.99 (0.98 ; 0.99)	0.99 (0.98 ; 0.99)	0.99 (0.99 ; 1)
	AVG3M (ICC _{2,3})	0.99 (0.98 ; 0.99)	0.99 (0.98 ; 0.99)	0.99 (0.99 ; 0.99)	0.99 (0.99 ; 0.99)	0.99 (0.99 ; 0.99)	0.99 (0.98 ; 0.99)	0.99 (0.99 ; 0.99)	0.99 (0.99 ; 0.99)	0.99 (0.99 ; 0.99)	0.99 (0.99 ; 1)	0.99 (0.99 ; 1)	0.99 (0.99 ; 1)	1 (0.99 ; 1)	1 (0.99 ; 1)	1 (1 ; 1)	1 (1 ; 1)
	Mean ± SD (°)	18.14 ± 9.58	20.37 ± 10.15	22.22 ± 10.42	23.74 ± 10.78	24.44 ± 10.45	24.6 ± 10.22	25.37 ± 10.44	26.26 ± 10.62	27.06 ± 10.79	27.77 ± 10.96	28.46 ± 11.07	28.99 ± 11.33	29.48 ± 11.56	29.91 ± 11.96	30.29 ± 12.25	30.84 ± 12.32
	SEM (°)	0.77	0.81	0.83	0.85	0.84	0.84	0.87	0.88	0.9	0.91	0.92	0.95	0.98	1.05	1.1	1.15
	MDC (°)	2.13	2.25	2.29	2.37	2.32	2.34	2.41	2.45	2.49	2.53	2.56	2.65	2.73	2.92	3.06	3.2
R	SM (ICC _{2,1})	0.93 (0.9 ; 0.95)	0.95 (0.93 ; 0.97)	0.97 (0.96 ; 0.98)	0.98 (0.97 ; 0.98)	0.98 (0.97 ; 0.99)	0.98 (0.98 ; 0.99)	0.99 (0.98 ; 0.99)	0.99 (0.98 ; 0.99)	0.99 (0.98 ; 0.99)	0.99 (0.98 ; 0.99)	0.99 (0.98 ; 0.99)	0.99 (0.98 ; 0.99)	0.99 (0.98 ; 0.99)	0.99 (0.98 ; 0.99)	0.99 (0.98 ; 0.99)	0.99 (0.98 ; 0.99)
	AVG3M (ICC _{2,3})	0.98 (0.97 ; 0.98)	0.98 (0.98 ; 0.99)	0.99 (0.99 ; 0.99)	0.99 (0.99 ; 0.99)	0.99 (0.99 ; 1)	0.99 (0.99 ; 1)	1 (0.99 ; 1)	1 (0.99 ; 1)	1 (0.99 ; 1)	1 (0.99 ; 1)	1 (0.99 ; 1)	1 (0.99 ; 1)	1 (0.99 ; 1)	1 (0.99 ; 1)	1 (0.99 ; 1)	0.99 (0.99 ; 1)
	Mean ± SD (°)	17.37 ± 9.53	19.6 ± 10.14	21.48 ± 10.63	22.92 ± 11.03	24.17 ± 11.41	25.26 ± 11.78	26.28 ± 12.1	26.35 ± 11.98	27.1 ± 12.18	27.66 ± 12.68	28.26 ± 12.9	28.06 ± 12.63	28.12 ± 12.95	28.62 ± 13.16	29.26 ± 13.58	27.56 ± 13.2

R 3	SEM (°)	0.76	0.8	0.84	0.87	0.9	0.93	0.96	0.98	0.99	1.07	1.09	1.09	1.15	1.17	1.24	1.35	
	MDC (°)	2.1	2.23	2.34	2.42	2.51	2.59	2.66	2.71	2.76	2.96	3.01	3.01	3.2	3.25	3.43	3.73	
	SM (ICC _{2,1})	0.93 (0.89 ; 0.95)	0.95 (0.92 ; 0.96)	0.95 (0.92 ; 0.96)	0.95 (0.92 ; 0.96)	0.95 (0.93 ; 0.97)	0.96 (0.94 ; 0.97)	0.96 (0.94 ; 0.97)	0.96 (0.94 ; 0.97)	0.96 (0.94 ; 0.97)	0.96 (0.94 ; 0.98)	0.96 (0.94 ; 0.97)	0.96 (0.94 ; 0.97)	0.96 (0.94 ; 0.98)	0.96 (0.94 ; 0.97)	0.96 (0.94 ; 0.97)	0.96 (0.94 ; 0.97)	0.97 (0.95 ; 0.98)
	AVG3M (ICC _{2,3})	0.97 (0.96 ; 0.98)	0.98 (0.97 ; 0.99)	0.98 (0.97 ; 0.99)	0.98 (0.97 ; 0.99)	0.98 (0.98 ; 0.99)	0.99 (0.98 ; 0.99)	0.99 (0.98 ; 0.99)	0.99 (0.98 ; 0.99)	0.99 (0.98 ; 0.99)	0.99 (0.98 ; 0.99)	0.99 (0.98 ; 0.99)	0.99 (0.98 ; 0.99)	0.99 (0.98 ; 0.99)	0.99 (0.98 ; 0.99)	0.99 (0.98 ; 0.99)	0.99 (0.98 ; 0.99)	0.99 (0.98 ; 0.99)
	Mean ± SD (°)	18.01 ± 8.33	20.41 ± 8.64	22.2 ± 8.94	23.73 ± 9.2	24.99 ± 9.42	26.07 ± 9.66	27.02 ± 9.88	27.9 ± 10.16	28.61 ± 10.42	29.33 ± 10.56	29.42 ± 10.43	30.03 ± 10.53	30.17 ± 10.56	30.36 ± 10.77	31.19 ± 11	31.46 ± 11.13	
	MDC (°)	1.85	1.92	1.98	2.04	2.09	2.14	2.19	2.28	2.36	2.39	2.41	2.41	2.43	2.49	2.6	2.72	2.85

KE = Knee Extended; KF = Knee Flexed; SM= Single Measures; AVG3M= Average of 3 measures; R1= Rater 1; R2= Rater 2; R3= Rater 3. Mean ± SD= Mean and Standard Deviation of ankle Range Of Motion (Degrees); SEM= Standard Error of the Measurement.; MDC= Minimum Detectable Change.

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Table 3. Inter-rater Reliability of Ankle Range of Motion (degrees) with the Knee Extended (KE) and Knee Flexed (KF)

		4-5	5-6	6-7	7-8	8-9	9-10	10-11	11-12	12-13	13-14	14-15	15-16	16-17	17-18	18-19	19-20	
K E	Mean ±	10.43 ±	12.76 ±	14.78 ±	16.57 ±	18.16 ±	19.62 ±	20.83 ±	22.04 ±	23.11 ±	24.11 ±	24.88 ±	25.61 ±	26.2 ±	26.68 ±	27.21 ±	27.87 ±	
	SD	5.93	6.36	6.75	7.09	7.34	7.55	7.66	7.89	8.09	8.33	8.45	8.64	8.85	8.99	8.98	9.26	
	ICC _{2,1} (95% CI)	0.59 (0.46; 0.7)	0.62 (0.5; 0.72)	0.64 (0.53; 0.74)	0.67 (0.56; 0.76)	0.69 (0.59; 0.78)	0.71 (0.61; 0.79)	0.73 (0.63; 0.81)	0.74 (0.65; 0.82)	0.75 (0.66; 0.83)	0.76 (0.67; 0.84)	0.82 (0.74; 0.88)	0.82 (0.75; 0.88)	0.82 (0.74; 0.88)	0.81 (0.73; 0.88)	0.81 (0.71; 0.88)	0.82 (0.73; 0.89)	
	SEM (°)	0.47	0.51	0.54	0.56	0.59	0.6	0.61	0.63	0.65	0.67	0.69	0.71	0.75	0.77	0.79	0.83	
	MDC (°)	1.31	1.4	1.49	1.56	1.62	1.67	1.7	1.75	1.8	1.87	1.92	1.98	2.07	2.13	2.19	2.3	
K F	Mean ±	17.83 ±	20.12 ±	21.97 ±	23.46 ±	24.54 ±	25.32 ±	26.24 ±	26.85 ±	27.6 ±	28.27 ±	28.71 ±	29.05 ±	29.29 ±	29.64 ±	30.26 ±	30.1 ±	
	SD (°)	8.99	9.53	9.91	10.27	10.36	10.53	10.79	10.88	11.09	11.35	11.43	11.45	11.64	11.93	12.25	12.22	
	ICC _{2,1} (95% CI)	0.83 (0.76; 0.88)	0.84 (0.78; 0.89)	0.86 (0.8; 0.9)	0.86 (0.81; 0.91)	0.87 (0.82; 0.91)	0.88 (0.83; 0.92)	0.89 (0.84; 0.92)	0.89 (0.84; 0.92)	0.9 (0.85; 0.93)	0.9 (0.85; 0.93)	0.9 (0.86; 0.94)	0.9 (0.86; 0.94)	0.91 (0.86; 0.94)	0.91 (0.86; 0.94)	0.91 (0.86; 0.94)	0.91 (0.86; 0.95)	0.92 (0.87; 0.96)
	SEM (°)	0.72	0.76	0.79	0.82	0.83	0.85	0.87	0.89	0.91	0.94	0.96	0.97	1.01	1.05	1.1	1.17	
	MDC (°)	1.99	2.11	2.19	2.26	2.29	2.35	2.42	2.47	2.53	2.61	2.65	2.68	2.79	2.91	3.06	3.24	

KE = knee extended; KF = knee flexed; Mean ± SD= Mean and Standard Deviation; ICC= Intraclass Correlation Coefficient; (95% CI)= 95% Confidence Interval; SEM= Standard Error of the Measurement.; MDC= Minimum

Detectable Change; °= degrees.

Table 4. Intra-rater Reliability of Single Measures (SM) Versus the Average of 3 Measures (AVG3M) and 95% Confidence Intervals for Ankle Dorsiflexion Measured by the 3 Raters for the interval 14N-15N

			14	14.1	14.2	14.3	14.4	14.5	14.6	14.7	14.8	14.9	15	
KE	SM (ICC _{2,1})	R1	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	
		R2	0.99 (0.99; 1)	0.99 (0.99; 1)	0.99 (0.99; 1)	0.99 (0.99; 1)	0.99 (0.99; 0.99)	1 (1; 1)	0.99 (0.99; 1)	0.99 (0.99; 1)	0.99 (0.99; 1)	0.99 (0.99; 1)	0.99 (0.99; 1)	0.99 (0.99; 0.99)
		R3	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)
	AVG3M (ICC _{2,3})	R1	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)
		R2	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)
		R3	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)
KF	SM (ICC _{2,1})	R1	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	
		R2	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	
		R3	0.99 (0.99; 0.99)	1 (1; 1)	0.99 (0.99; 1)	0.99 (0.99; 1)	1 (1; 1)	0.99 (0.99; 1)	0.99 (0.99; 1)	1 (1; 1)	0.99 (0.99; 1)	0.99 (0.99; 0.99)	1 (1; 1)	
	AVG3M (ICC _{2,3})	R1	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)
		R2	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)
		R3	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)	1 (1; 1)

KE = knee extended; KF= knee flexed; SM= Single Measures; AVG3M= Average of 3 measures; R1= Rater 1; R2= Rater 2; R3= Rater 3.

Table 5. Inter-rater Reliability of Ankle Range of Motion (degrees) with the Knee Extended and Knee Flexed for the interval 14N-15N

		14	14.1	14.2	14.3	14.4	14.5	14.6	14.7	14.8	14.9	15.0
K E	Mean ± SD	24.08±8.73	24.62±8.52	24.55±8.47	24.63±8.48	24.55±8.51	24.83±8.52	24.84±8.68	24.9±8.62	25.13 ± 8.56	25.13 ± 8.68	25.24 ± 8.56
	ICC _{2,1} (95% CI)	0.87 (0.82; 0.92)	0.91 (0.9; 0.94)	0.9 (0.84; 0.93)	0.91 (0.9; 0.94)	0.91 (0.91; 0.93)	0.9 (0.88; 0.93)	0.88 (0.87; 0.93)	0.91 (0.87; 0.93)	0.93 (0.86; 0.93)	0.91 (0.88; 0.93)	0.87 (0.87; 0.92)
	SEM	2.19	2.15	2.12	2.11	2.14	2.15	2.17	2.16	2.16	2.20	2.25
	MDC	6.06	5.97	5.89	5.86	5.93	5.96	6.02	5.99	6.0	6.1	6.2
K F	Mean ± SD	10.94±31.05	4.84±31.67	4.3±32.14	2.8±33.11	0.55±32.8	14.02±30.15	1.08±33.22	5.42±31.2	2.00 ± 31.99	1.45 ± 32.55	-1.78 ± 34.09
	ICC _{2,1} (95% CI)	0.98 (0.97; 0.99)	0.98 (0.97; 0.99)	0.99 (0.98; 0.99)	0.99 (0.98; 0.99)	0.99 (0.99; 1)	0.99 (0.99; 0.99)	0.99 (0.99; 1)	0.99 (0.98; 0.99)	0.99 (0.99; 0.99)	0.99 (0.98; 0.99)	0.99 (0.98; 0.99)
	SEM (°)	2.43	1.47	1.5	1.79	1.59	2.16	1.38	1.67	1.42	1.86	1.55
	MDC (°)	6.73	4.07	4.17	4.96	4.4	5.98	3.82	4.63	3.93	5.16	4.30

KE = knee extended; KF = knee flexed; Mean ± SD= Mean and Standard Deviation; ICC= Intraclass Correlation Coefficient; (95% CI)= 95% Confidence Interval; SEM= Standard Error of the Measurement.; MDC= Minimum Detectable Change;

294 Discussion

295 The primary objective of this study was to evaluate the intra- and inter-rater reliability
296 of a new equinometer based on Silfverskiöld test. Since the diagnosis of gastrocnemius
297 tightness is made on the difference in dorsiflexion between the knee flexed (KF) and the knee
298 extended (KE), we performed the measurements in the KE and KF positions. The secondary
299 objective was to determine a load to apply on the metatarsal heads to ensure the best
300 reliability. We hypothesized that the equinometer will be reliable in the two positions. Based
301 on our reliability analysis, our hypothesis is confirmed. In fact, for the intra-rater reliability, the
302 ICC values are all higher than 0.95, which translates to excellent reliability (*Tables 2, 4*). For
303 the inter-rater reliability, the ICC values are lower, pointing to moderate to good reliability
304 between the three raters (*Tables 3, 5*). However, there was a difference between the KE and
305 KF conditions. The lowest ICC values were obtained in the KE condition at the lower end of
306 the applied force range (*Table 3*). Conversely, the best inter-rater ICC values were obtained in
307 the KF condition (*Table 3*). For the second objective – to determine a reliable load – the
308 statistical analysis showed that the interval between 14–15 N had the best inter- and intra-rater
309 reliability (*Fig. 5, 6*). In this interval, the intra-rater ICC in both conditions (KE, KF) was excellent
310 (*Table 4, Fig 6*). The highest inter-rater reliability was always obtained with a flexed knee (ICC
311 >0.98, *Table 5, Fig 5*). Within the 14–15 N interval, an applied force of 14.5 N appears to
312 provide the best intra- and inter-rater reliability. However, it is important to note that this
313 measurement is not a critical threshold determining gastrocnemius tightness.

314 Quantifying gastrocnemius tightness by measuring ankle dorsiflexion has a genuine
315 clinical application [3]. Despite a confirmed need, the measurement is problematic due to a
316 lack of affordable tools that can be used in routine clinical practice and with a well-defined
317 protocol, especially the amount of force to apply when measuring the passive dorsiflexion. As
318 suggested by Gatt *et al.* [10], quantifying the force applied to the foot when measuring
319 dorsiflexion is a determining factor. Without this specific value, the evaluation has poor
320 reliability because different practitioners are likely to use different loads during the procedure.

321 Thus, it may be impossible to study the effectiveness of a treatment or to compare the results
322 between different practitioners or different trials in the clinical or experimental context. The
323 equinometer described here sought to solve this problem by providing a standardized method
324 with a reliable load application. But the value presented as reliable in the present study does
325 not constitute a threshold determining gastrocnemius tightness.

326 The intra-rater ICC obtained in this study was above 0.95, which is excellent reliability
327 when compared to several studies of similar tools that were labelled as reliable [12,26–28].
328 However, it should be noted that for Larsen *et al.* [26] and Worsley *et al.* [28] the investigations
329 were carried out in weight bearing conditions. Finally, like Wilken *et al.* [12], in view of our
330 results, it seems that a single measurement is sufficient to obtain excellent reliability, rather
331 than 3. This element is important to consider in order to develop a tool that can be easily used
332 in clinical routine. Our inter-rater ICC values are not as good as those reported by Wilken *et*
333 *al.* [12], who however used pushing intervals higher than the present study (between 10 N.m
334 and 25 N.m) in non-weightbearing condition (ICC > 0.92). However, according to Koo *et al.*
335 [25] (where values less than 0.5 are indicative of poor reliability, between 0.5 and 0.75 are
336 moderate reliability, between 0.75 and 0.9 are good reliability, and greater than 0.90 are
337 excellent reliability), the inter-rater ICC values obtained in our study have good reliability for
338 intervals above 12–13 N and moderate reliability for loads between 4 N and 12 N. The
339 reliability was good to excellent in the 14–15 N interval [25]. The lower inter-rater reliability in
340 the intervals other than 14–15 N can be explained by an accumulation of inaccuracies in
341 certain steps of the measurement protocol inherent to the rater. The manual placement of the
342 electronic goniometer remains operator-dependent and can lead to measurement variability if
343 there are even (minimal) differences in placement between raters. Next, despite being
344 standardized, the manual palpation of the load application point on the shoe via a foot landmark
345 may have led to inaccuracies. Lastly, the orientation of the pushing force applied by the rater
346 could affect the result. Wilken *et al.* believe that one of the reasons for the excellent inter-rater
347 reliability in their study was that they followed closely a standardized protocol that reduced the

348 risk of human error [12]. Meyer *et al.* [29], who also used pushing intervals higher than the
349 present study (10 N.m) in non-weightbearing condition also found differences in the ICC
350 between the KE and KF conditions. This difference can be attributed to the extensibility of the
351 gastrocnemius muscles playing a role in the KE condition. In fact, the differences in extensibility
352 between subjects could influence the measurement reliability, as evidenced by the confidence
353 intervals of the ICC. Lastly, the MDC was between 1.3° and 2.3° in the KE condition and
354 between 1.99° and 3.24° in the KF condition (*Table 3*). Also, the very low SEM (between 0.47°
355 and 0.83° for KE and between 0.72° and 1.17° for KF, *Table 3*) is evidence of high
356 measurement accuracy and minimal random or systematic errors. These values are consistent
357 with other published values [26,28,30].

358 Determining the load application values to ensure the highest reliability was our study's
359 second objective. Our statistical analysis pointed to the 14–15 N interval, both for the intra-
360 and inter-rater comparisons. It appears that a load of 14.5 N provided the highest reliability. To
361 our knowledge, no other study has proposed such a precise load application interval to ensure
362 the highest possible intra- and inter-rater reliability. Knowing the optimal force application value
363 is relevant both clinically and experimentally. It is important to specify that the value presented
364 as reliable in the present study does not constitute a threshold determining gastrocnemius
365 tightness. Increasing the pressure would increase ankle dorsiflexion but would not change
366 gastrocnemius tightness. The first step was to develop a reliable tool and the second step will
367 be to define the angular threshold of dorsiflexion by comparing pathological and control
368 patients. Once again, increasing load would only change the angular threshold but not the
369 tightness. Also note that the SEM and MDC were the lowest within this interval (*Table 2 & 5*).
370 This is related to the fact that investigating such small force increments (0.1 N) within a 1 N
371 interval likely increases the effect of any shaking or oscillating by the rater during the
372 measurement. This may have gone unnoticed when looking at larger intervals.

373 Our study has several limitations. First, the reliability data were not obtained in ankles
374 with documented pathology. As proposed by Worsley *et al.*, [28] a more in-depth study in

375 groups of patients with different conditions is needed to evaluate a tool under more realistic
376 use conditions. Second, we did not validate our equinometer by comparing its output with other
377 tools that are said to be reliable and valid. While some studies evaluated the validity of their
378 tool with a motion analysis system [12], there is currently no gold standard. Third, the
379 placement of the goniometer's arms on the ankle then its fixation with double-side tape may
380 have led to measurement inaccuracies, especially for force values within a given interval. We
381 used specific anatomical landmarks to limit this effect. Also, the transposition of the load
382 application point on the shoe from a point on the foot, even when using graph paper, may be
383 a source of error. However, given our reliability results, this potential source of error could be
384 considered acceptable. For the KF position, there is no standardization of knee flexion range
385 in the literature, so we chose 30° of knee flexion according to DiGiovanni et al. [8] and because
386 it facilitated the subject's installation and the ability to maintain the knee in position. Lastly, our
387 study has no direct clinical application. Its purpose was solely to validate a new equinometer
388 that our team has developed. We only analyzed data between 4 and 20N, whereas some
389 authors propose higher forces [10–12]. However, we designed our device according to Barouk
390 *et al.* recommendations [5] in order to be as close as possible to the forces used during
391 patients examination by physicians when performing a Silfverskiöld test. This step is an
392 essential prerequisite to using this tool in clinical practice and for research purposes, with the
393 goal of defining normal values and a pathological threshold value for gastrocnemius tightness.

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400 **Conclusion**

401 Our study presents a standardized method for measuring ankle dorsiflexion by using a new
402 equinometer that combine digital goniometer measurement with quantification of the load
403 applied to the foot. This method has good intra- and inter-rater reliability. The equinometer was
404 most reliable when pushing on the foot with a force between 14 and 15N. However, this does
405 not inform the angular threshold for diagnosing gastrocnemius tightness. This validates a new
406 equinometer as a reliable device. Further studies should be performed using these parameters
407 to attempt to define the pathological threshold for gastrocnemius tightness.

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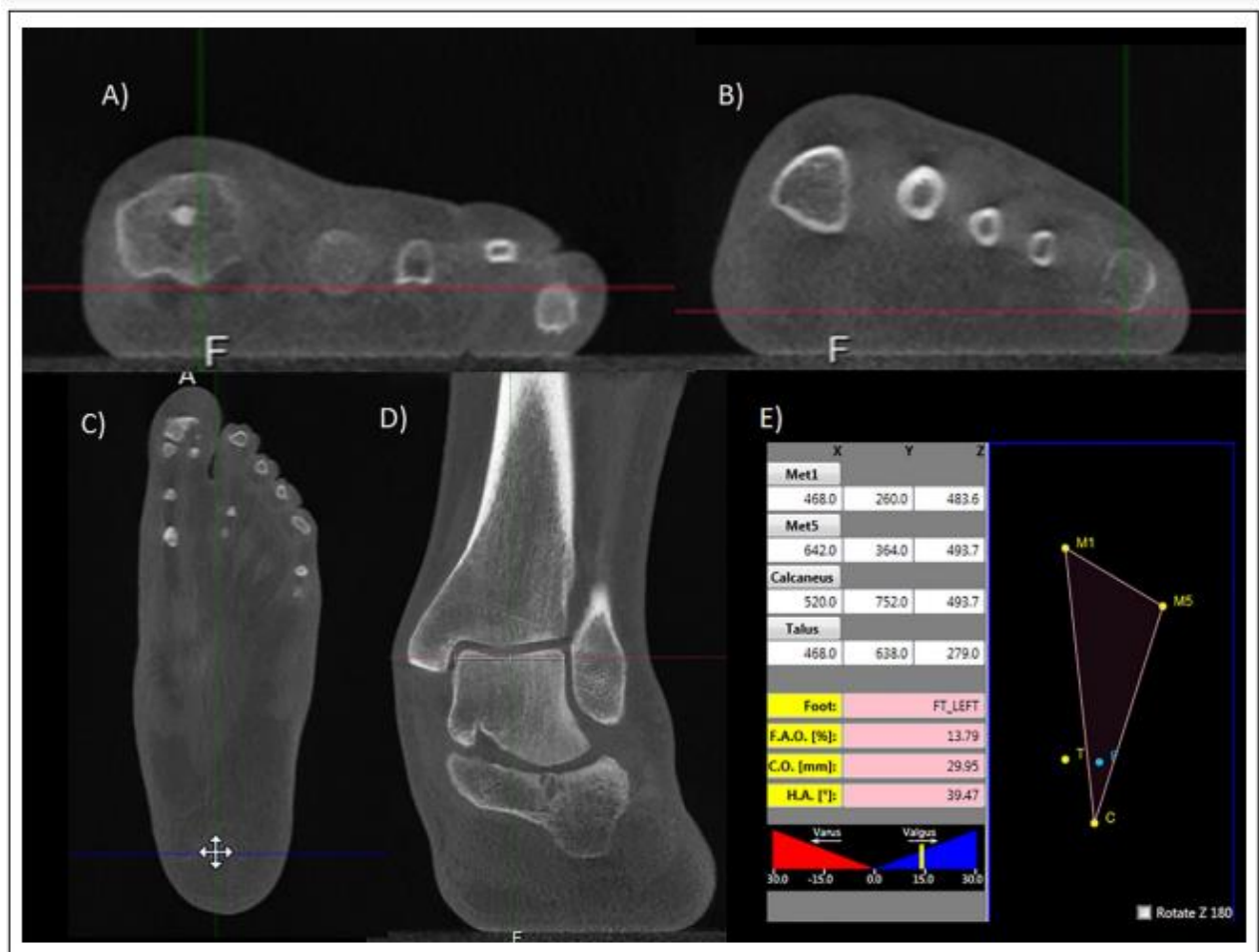
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3.2.3 Varus de la cheville et de l'arrière pied.

Le morphotype en varus de l'arrière pied est également retrouvé comme facteur de risque d'ILCC (31–34).

Lintz et al. ont décrit sur des scanners en charge la mesure du Foot and Ankle Offset pour quantifier la déformation de l'arrière pied (35). Le Foot and Ankle Offset représente l'offset entre le centre du tripode (comprenant les têtes du 1er et du 5^{ème} métatarsiens ainsi que la partie la plus plantaire de la grosse tubérosité du calcaneus) et le centre de la cheville comme représenté dans la Figure 8.



Foot and Ankle Offset (FAO) semiautomatic measurement. Using the 3 planes (x, y, z), the most plantar voxel of the first metatarsal is found (A) in the 3 planes, followed by the most plantar voxel of the fifth metatarsal (B), the most plantar voxel of the calcaneus (C) and the most proximal and central voxel of the talus (D). The software calculates (E) positioning of the foot tripod (M1-M5-C) and the expected position of the ankle joint center (F). The percentage of displacement in subject's talus position (T) in relation to this axis (M1-M5-C-F) is determined as the FAO.

Figure 8 : Barbachan Mansur NS, Lalevee M, Maly C, Dibbern K, Lee HY, Godoy-Santos AL, et al. Association Between Middle Facet Subluxation and Foot and Ankle Offset in Progressive Collapsing Foot Deformity. Foot Ankle Int. janv 2022;43(1):96-100.

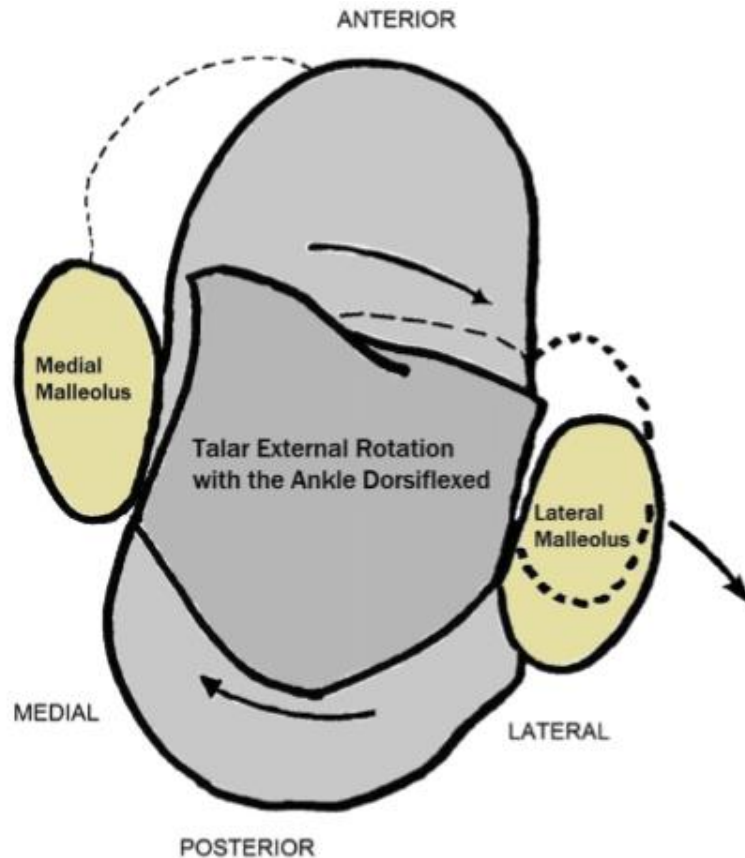
Ce paramètre est validé dans la littérature pour quantifier de manière tridimensionnelle les déformations de l'arrière pied (35–40). Lintz et al. ont comparé 34 sujets présentant une ILCC à des témoins en utilisant ce paramètre. Un Foot and Ankle Offset négatif, représentant un varus plus important (-2.2% vs +2.6%, $p < 0.001$), était associé au groupe ILCC (33).

Nous avons pu tester ce paramètre dans différentes études et ce dernier a démontré sa fiabilité ((39,41–43), **Annexes 6 et 7**). Nous le considérons donc comme un paramètre pertinent pour quantifier le varus de l'arrière pied.

3.2.4 Dysplasies et malpositions osseuses.

Les dysplasies osseuses, notamment du talus, du calcaneus et de l'extrémité distale du tibia ont été également retrouvées comme facteurs de risque potentiels d'ILCC (44–48). Ces dernières sont cependant peu évaluées dans la littérature et doivent être étudiées plus profondément.

Une position trop antérieure de la fibula apparaît de manière un peu plus constante comme potentiel facteur de risque d'ILCC (49,50). Cette dernière pourrait être secondaire à la position en inversion forcée présente lors du traumatisme (8). Elle pourrait par ailleurs limiter l'extension de cheville, empêchant le glissement postérieur et la rotation latérale du talus dans la mortaise tibio-fibulaire, comme illustré dans la Figure 9 (51).



With the ankle in dorsiflexion, an external rotation force on the foot will cause the talus to rotate externally and separate the mortise.

Figure 9 : Mulligan EP. Evaluation and management of ankle syndesmosis injuries. *Physical Therapy in Sport*. 1 mai 2011;12(2):57-69.

Pour évaluer ces dysplasies et malpositions osseuses, l'utilisation d'images scanographiques permet une segmentation automatique et une reconstruction tridimensionnelle des segment osseux ainsi qu'une analyse précise de la position des articulations et de la distance entre les os (52,53). L'utilisation d'un Cone Beam permettrait de réduire le taux d'irradiation par rapport à un scanner traditionnel tout en bénéficiant d'une imagerie en charge. (54).

Nous avons testé ces différents outils dans une étude évaluant des pieds plats ((55), **Annexe 8**). Nous prévoyons donc d'appliquer ce même protocole pour comparer des sujets atteints d'ILCC à des témoins afin d'évaluer ces facteurs de risque et de voir s'ils peuvent être intégrés dans un score prédictif d'ELC.

3.3 Facteurs de risque fonctionnels.

3.3.1 Altération du contrôle neuromusculaire.

L'altération du contrôle neuromusculaire est un facteur de risque d'ILLC reconnu dans la littérature (1). Cette dernière englobe notamment les troubles de la proprioception et de l'équilibre (56). En accord avec les travaux de Hertel et al., le Star Excursion Balance Test (SEBT) est un outil validé pour évaluer ces déficits (56–58).

Le SEBT se réalise en appui monopodal. Il est demandé au sujet d'effectuer un contact le plus loin possible dans 8 directions différentes avec le pied controlatéral. Ces 8 directions sont guidées par des marqueurs au sol en forme d'étoile (Figure 10). La moyenne des distances dans ces 8 directions normalisées par la longueur de la jambe est ensuite calculée.



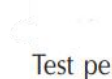
 The posteromedial reach of the Star Excursion Balance Test performed while balancing on the left limb.

Figure 10 : Hertel J, Braham RA, Hale SA, Olmsted-Kramer LC. Simplifying the Star Excursion Balance Test: Analyses of Subjects With and Without Chronic Ankle Instability. RESEARCH REPORT. 2006;36(3).

3.3.2 Altération de la démarche

L'altération de la démarche est définie par Hertel et al. comme affectant les activités de marche, de course, de saut ou les changements brusques de direction (56,59). Les analyses quantifiées de la marche ont notamment montré des anomalies d'activités au niveau des muscles fibulaires associés à une position accrue de la cheville en inversion, ce qui pourrait favoriser la survenue d'une ELC (28,60–64).

Evaluer ces mouvements de manière simple et pratique est difficile. Des scores validés, basés sur de simples analyses vidéos, permettant d'évaluer les activités de saut et de changements brusques de direction sont disponibles (65–69). Le Landing Error Scoring System permet une analyse des sujets sautant d'une hauteur de 30 cm avec une avancée correspondant à 50% de leur taille et devant rebondir le plus haut possible (Figure 11). Les sujets sont filmés et différents paramètres sont recueillis sur analyse vidéo (65–67).



The standardized jump-landing task consists of 2 segments: (1) subject jumps down from box and lands on ground and (2) subject immediately jumps vertically upward as high as possible.

Figure 11 : Padua DA, Marshall SW, Boling MC, Thigpen CA, Garrett WE, Beutler AI. The Landing Error Scoring System (LESS) Is a Valid and Reliable Clinical Assessment Tool of Jump-Landing Biomechanics: The JUMP-ACL Study. Am J Sports Med. oct 2009;37(10):1996-2002.

Le Cutting Movement Assessment Score reprend ces mêmes principes lors de changements brusques de directions (68,69). Les paramètres recueillis pour ce score sont exposés dans le Tableau 4.

Cutting movement assessment score tool.

Camera	Variable	Observation	Score
	Penultimate contact		
Side/ 45°	Clear PFC braking strategy (at initial contact) <ul style="list-style-type: none"> • Backward inclination of the trunk • Large COM to COP position – anterior placement of the foot • Effective deceleration – heel contact PFC 	Y/N	Y = 0/N = 1
	Final Contact		
Front/ 45°	Wide lateral leg plant (approx. > 0.35 m – dependent on subject anthropometrics) (at initial contact)	Y/N	Y = 2/N = 0
Front/ 45°	Hip in an initial internally rotated position (at initial contact)	Y/N	Y = 1/N = 0
Front/ 45°	Initial knee 'valgus' position (at initial contact)	Y/N	Y = 1/N = 0
All 3	Foot not in neutral foot position (at initial contact) Inwardly rotated foot position or externally rotated foot position (relative to original direction of travel)	Y/N	Y = 1/N = 0
Front/ 45°	Frontal plane trunk position relative to intended direction; Lateral or trunk rotated towards stance limb, Upright, or Medial (at initial contact and over WA)	(at L/TR/U/M)	L/TR = 2/ U = 1, /M = 0 Y = 1/N = 0
Side/ 45°	Trunk upright or leaning back throughout contact (not adequate trunk flexion displacement) (at initial contact and over WA)	Y/N	Y = 1/N = 0
Side/ 45°	Limited Knee flexion during final contact (stiff) ≤ 30 (over WA)	Y/N	Y = 1/N = 0
Front/ 45°	Excessive Knee 'valgus' motion during contact (over WA)	Y/N	Y = 1/N = 0

Key: PFC: Penultimate foot contact; COM: Centre of mass; COP: Centre of pressure; WA: weight acceptance; TR: Trunk rotation; Y: Yes; N: No; L: Lateral; TR: Trunk rotation; U: Upright; M: Medial.

Tableau 4 : Dos'Santos T, McBurnie A, Donelon T, Thomas C, Comfort P, Jones PA. A qualitative screening tool to identify athletes with 'high-risk' movement mechanics during cutting: The cutting movement assessment score (CMAS). *Physical Therapy in Sport*. 1 juill 2019;38:152-61.

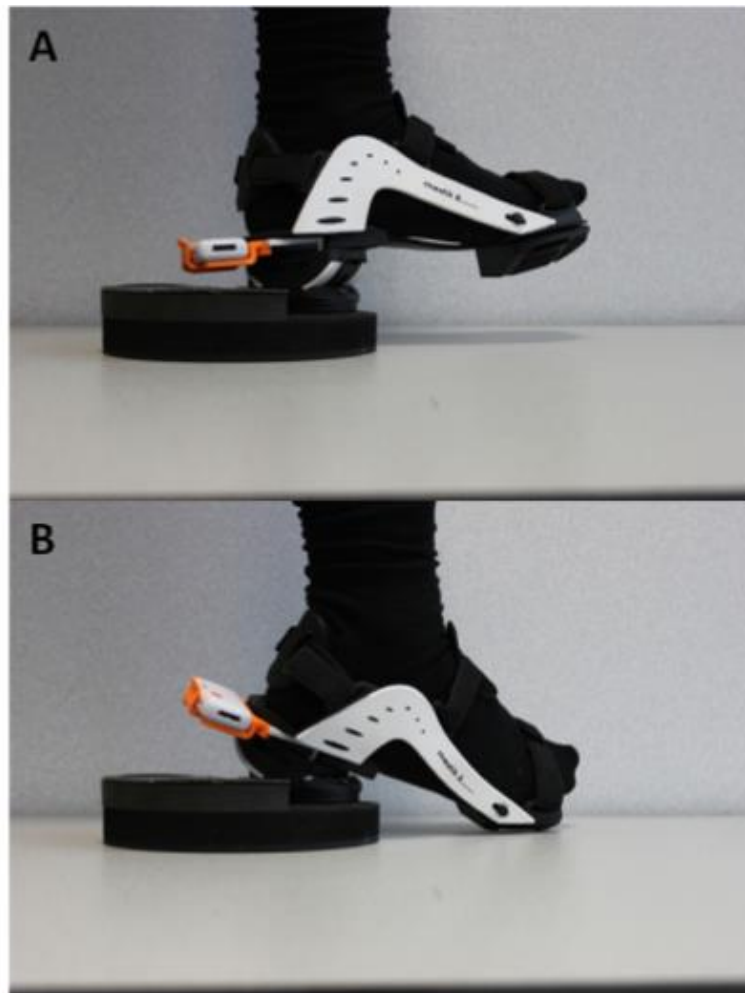
Il n'existe pas de scores similaires pour évaluer les activités de marche et de course. La réalisation d'une analyse du mouvement serait trop fastidieuse pour permettre l'utilisation en routine d'un score. Dans une étude récente, Hemler et al. ont analysé la relation entre l'analyse quantifiée de la marche et l'usure de la semelle chez 14 sujets et observaient une corrélation entre les forces de réaction au sol et l'usure des chaussures (70). Il pourrait être envisagé d'évaluer l'usure des chaussures à usage quotidien et des chaussures de sport des sujets et d'intégrer ces paramètres dans le score prédictif d'ELC, mais cela nécessite des études complémentaires au préalable.

Au total, le Landing Error Scoring System, le Cutting Movement Assessment Score et l'usure des chaussures devront être validés contre des analyses quantifiées de la marche et comparés chez des sujets ILCC et témoins afin de savoir s'ils peuvent être intégrés dans le score prédictif d'ELC.

3.3.3 Défaut de force musculaire.

Un déficit de force, notamment excentrique au niveau des éverseurs, est un facteur de risque d'ILCC reconnu dans la littérature (4,5,71–73).

Terrier et al. ont réalisé une étude, qui comprenait 12 sujets présentant une ILCC et 12 sujets témoins, comparant l'isocinétisme au contrôle de mouvement d'inversion de cheville en position debout en utilisant l'appareil Myolux E-evolution (Figure 12) (74).



Experimental set up of the functional test (weight bearing ankle inversion control). Subjects kept the knee extended and were in single leg stance on a Myolux™ device. For each trial: upper panel (A) illustrates the starting position whereas lower panel (B) illustrates the ending position.

Figure 12 : Terrier R, Degache F, Fourchet F, Gojanovic B, Forestier N. Assessment of evertor weakness in patients with chronic ankle instability: Functional versus isokinetic testing. *Clin Biomech (Bristol, Avon)*. janv 2017;41:54-9.

Au total le test de contrôle en inversion était plus à même de différencier les sujets ILCC des témoins et de quantifier les déficits de forces en comparaison à l'isocinétisme. Ce paramètre nous semble donc pertinent et pourrait être intégré dans le score prédictif d'ELC.

3.4 Facteurs de risque personnels et environnementaux.

En ce qui concerne les facteurs de risque personnels et environnementaux reconnus comme facteurs de risque d'ILLC, de nombreux tests et paramètres sont déjà validés pour les quantifier.

L'indice de masse corporelle (IMC) peut être facilement évalué à l'aide d'une toise et d'un pèse-personne, et l'âge nécessite seulement d'être recueilli (4,5,75).

La laxité généralisée peut être quantifiée à l'aide de l'indice de Beighton (76–79).

La kinésiophobie, peut être évaluée par la Tampa Scale for Kinesiophobia (80,81). Toutefois, ce facteur doit être confirmé car il n'était pas suffisamment présent dans la littérature.

Enfin la pratique du sport devra détailler, le type de sport, le niveau (loisir, compétition) et le nombre d'heures de pratique (82,83).

3.5 Résumé des différents facteurs de risque et des outils et paramètres proposés pour leur quantification (Tableau 5).

Risk Factors	Risk factors grades of evidence	Suggested tools	Suggested parameters
Mechanical			
ATFL rupture – Anterior drawer laxity	A – Good evidence	Stress Ultrasound	Drawer (mm)
CFL rupture – Varus tilt laxity	B – Fair evidence	Stress Ultrasound	Drawer (mm)
Decreased ankle dorsiflexion	B – Fair evidence	Equinometer	Ankle dorsiflexion (°) at a plantar pressure value (N.m)
Ankle and Hindfoot Varus	C – Poor quality evidence	Weight-Bearing CT	Foot and Ankle Offset (%)
Bone dysplasias (Syndesmosis, Talus, Calcaneus)	C – Poor quality evidence	Weight-Bearing CT	Automated segmentation and 3D distance mapping (mm)
Anterior position of the fibula	C – Poor quality evidence	Weight-Bearing CT	Automated segmentation and 3D distance mapping (mm)
Syndesmotic and deltoid ligament laxity	C – Poor quality evidence	Stress Ultrasound	Drawer (mm)
Subtalar Laxity (interosseous and cervical ligaments)	I – Insufficient evidence	Stress Ultrasound	Drawer (mm)
Functional			
Impaired neuromuscular control (including proprioception and balance deficits)	A – Good evidence	Star excursion balance test (SEBT)	Normalized reached distance to lower limb length (%)
Altered gait patterns (walking, running, jumping...)	A – Good evidence	- Walking and Sport shoes wear patterns - Landing Error Scoring System (LESS) - Cutting Movement Assessment Score (CMAS)	Scores and wear (mm)
Strength deficit (eversors and plantarflexors)	A – Good evidence	Myolux	Eccentric weight bearing ankle inversion control test (Angular velocity peak (deg/s))
Personal			
Increased BMI	A – Good evidence	Scale + Height gauge	BMI (Kg/m ²)
Generalized Laxity	A – Good evidence	Clinical assessment	Beighton Score
Young age	A – Good evidence	Age	Years
Kinesiophobia	I – Insufficient evidence	Questionnaire	Tampa Scale for Kinesiophobia
Environmental			
Sport	B – Fair evidence	Sport type and practice	Type of sport Hours / weeks Leisure / Competition

Tableau 5 : Résumé des outils et paramètres envisagés pour quantifier les facteurs de risque d'instabilité latérale chronique de cheville.

3.6 Conclusions et perspectives.

Devant l'impact clinique et socioéconomique majeur de l'ILCC, disposer d'un score prédictif d'ELC présente un double enjeu. Tout d'abord celui d'identifier les sujets à risque afin d'agir de manière prophylactique et d'éviter les premiers épisodes d'ELC. Ensuite de proposer des traitements adaptés à chaque sujet après une ELC afin de diminuer l'incidence d'ILCC.

Ces pathologies sont multifactorielles et la recherche dans ce domaine doit permettre d'englober l'ensemble de ces facteurs. Nous avons développé un simulateur d'entorse prenant en compte tous ces facteurs, qui a permis de différencier des sujets ILCC de témoins sur la vitesse en inversion lors d'un traumatisme simulé. Nous avons également réalisé une revue de la littérature permettant l'énumération de ces facteurs.

Certains de ces facteurs de risque sont constitutionnellement présents, laissant la place à une prise en charge prophylactique. D'autres sont consécutifs aux épisodes d'ELC et devront être traités pour éviter la survenue d'ILCC. Ces facteurs interagissent et se cumulent. Nous proposons un modèle d'ILCC reprenant ces différents points.

L'inconnue reste dans la part relative que joue chacun de ces facteurs dans la survenue d'ILCC. Nous souhaitons donc disposer d'outils fiables et simples permettant de quantifier chacun de ces facteurs. Ces facteurs seront ensuite évalués sur une cohorte de sportifs à l'aide de ces outils ainsi qu'à l'aide du simulateur d'entorse que nous avons développé. Chaque facteur pourra ainsi être pondéré sur la vitesse maximale en inversion. La pondération et le cumul de chacun de ces facteurs permettra d'établir un score prédictif de survenue d'ELC. Une fois établi, ce score sera mis à l'épreuve dans une étude de cohorte prospective permettant le recueil et le suivi des différents facteurs de risque ainsi que des épisodes d'ELC et de dérochements de cheville.

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Annexe 1

CONTRAT DE PARTENARIAT

ENTRE

La société **ICC PHYSIO**, société par actions simplifiée au capital de 14.340 euros, dont le siège social est 30 allée du Lac d'Aiguebelette, 73370 LE BOURGET DU LAC, immatriculée au Registre du Commerce et des Sociétés de Chambéry sous le numéro RCS 814 728 929,

Représentée par Monsieur Pascal TOSCHI en sa qualité de Directeur Général, ayant tous pouvoirs à l'effet des présentes,

Ci-après dénommée « **ICC PHYSIO** »,
D'UNE PART,

ET

Monsieur Matthieu LALEVEE, né le 13 janvier 1989 à Gérardmer (88), domicilié 38, Rue Maréchal Gallieni 76100 ROUEN, étudiant

Ci-après dénommé « **Matthieu LALEVEE** »

Le Centre d'Etudes des Transformations des Activités Physiques et Sportives (CETAPS, EA 3832) (Université de Rouen Normandie, UFR STAPS, Boulevard Siegfried, 76821 Mont Saint Aignan), représenté par son directeur Monsieur Olivier SIROST et par Monsieur. Maxime L'HERMETTE.

Ci-après dénommé « **CETAPS** »

Monsieur Franck DUJARDIN, Professeur des Universités et Chef du service de chirurgie orthopédique et traumatologique du Centre Hospitalier Universitaire de Rouen, 37 Boulevard Gambetta, 76000 Rouen.

Ci-après dénommé « **Franck DUJARDIN** »
D'AUTRE PART,

Et désignés ensemble « les Parties ».

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IL EST PREALABLEMENT EXPOSE CE QUI SUIT:

La société ICC PHYSIO est spécialisée dans la conception et la commercialisation de dispositifs médicaux de prévention, d'évaluation et de réadaptation de l'appareil musculaire. ICC PHYSIO a notamment développé le produit Myolux Athletik.

Monsieur Matthieu LALEVEE, dans le cadre de son projet de recherche (ci-après PROJET DE RECHERCHE en **annexe 2**) souhaite utiliser le dispositif Myolux Athletik.

LE PROJET DE RECHERCHE est réalisé auprès du Centre d'Etudes des Transformations des Activités Physiques et Sportives (CETAPS) de Rouen et sous la direction de Monsieur le Professeur Franck DUJARDIN et du Docteur Maxime L'Hermette.

La société ICC PHYSIO accepte de mettre à la disposition de Monsieur Matthieu LALEVEE le dispositif à titre gracieux aux conditions précisées dans le présent Contrat en échange de pouvoir bénéficier des résultats du PROJET DE RECHERCHE. Ce qui signifie que Monsieur Matthieu LALEVEE et le CETAPS, s'engagent à transmettre les résultats à ICC PHYSIO pour les exploiter de son côté, mais Monsieur Matthieu LALEVEE et le CETAPS restent pleinement propriétaires et libres de les exploiter sous toutes formes de productions scientifiques.

CECI ÉTANT EXPOSÉ, IL A ETE CONVENU ET ARRETE CE QUI SUIT :

ARTICLE 1. OBJET DU CONTRAT

Le présent contrat a pour objet de formaliser la mise à disposition du dispositif Myolux Athletik par ICC PHYSIO à Matthieu LALEVEE, le CETAPS et Franck DUJARDIN dans le cadre spécifique du PROJET DE RECHERCHE.

La mise à disposition est encadrée par les droits et obligations des Parties ci-après énoncées.

ARTICLE 2. ENGAGEMENTS DE MATHIEU LALEVEE, LE CETAPS ET FRANCK DUJARDIN

Matthieu LALEVEE, LE CETAPS et Franck DUJARDIN s'engagent à utiliser le dispositif uniquement à des fins de recherche scientifique.

Matthieu LALEVEE, LE CETAPS et Franck DUJARDIN s'engagent à utiliser le dispositif conformément à la documentation technique fournie par ICC PHYSIO (**Annexe 1**).

Matthieu LALEVEE, LE CETAPS et Franck DUJARDIN s'engagent à ne pas développer et produire de dispositif similaire au dispositif Myolux Athletik.

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**ARTICLE 3. LIVRAISON DU MATÉRIEL - RESERVE DE PROPRIETE - ENTRETIEN
DU MATÉRIEL - RESTITUTION**

Un procès-verbal constatant l'état du matériel et sa conformité au descriptif est dressé contradictoirement et signé par les parties ou leurs représentants habilités, au moment de la prise en charge du matériel. Il en sera de même au moment du retour, à l'issue de la durée de l'accord.

Pendant la durée du contrat, le matériel reste la propriété de ICC PHYSIO. Il est interdit pour Matthieu LALEVEE, LE CETAPS et Franck DUJARDIN de commercialiser le matériel pendant toute la durée de la mise à disposition.

Si un tiers prétendait à des droits sur ce matériel, par exemple par voie de saisie ou en cas d'ouverture d'un redressement judiciaire, Matthieu LALEVEE, LE CETAPS et Franck DUJARDIN s'y opposeraient et en aviseraient immédiatement ICC PHYSIO afin de lui permettre de sauvegarder ses droits.

Mathieu LALEVEE, LE CETAPS et Franck DUJARDIN sont tenus d'assurer le maintien en bon état d'entretien du matériel et de l'utiliser selon les directives qui sont données dans la documentation technique : les frais résultants d'une utilisation non conforme à ces directives ou d'un défaut d'entretien, seront à la charge de Matthieu LALEVEE, LE CETAPS et Franck DUJARDIN.

En accord avec le PROJET DE RECHERCHE, le matériel pourra être modifié par Matthieu LALEVEE, LE CETAPS et Franck DUJARDIN afin de permettre le déclenchement à distance de l'instabilité. Toujours en accord avec le PROJET DE RECHERCHE, le matériel sera couplé à des centrales inertielles et un électromyogramme.

En dehors de ces modifications inhérentes au PROJET DE RECHERCHE, il est interdit à Matthieu LALEVEE, LE CETAPS et Franck DUJARDIN d'intervenir eux-mêmes sur le matériel afin d'y réaliser ou faire réaliser des réparations ; les frais de remise en état qui en résulteraient seraient alors à sa charge.

Toute intervention qui devrait être effectuée par Matthieu LALEVEE, LE CETAPS et Franck DUJARDIN sera réalisée selon les conditions habituelles en vigueur qui sont portées à sa connaissance.

Tout désaccord entre les parties sur la nécessité d'une intervention de la société ICC PHYSIO afin de procéder à des réparations fera l'objet d'une recherche de solution amiable.

A l'expiration du contrat par arrivée du terme, ou par résiliation anticipée du contrat, Matthieu LALEVEE, LE CETAPS et Franck DUJARDIN rendra le matériel en parfait état à ses frais à ICC PHYSIO, après avoir dressé procès-verbal.

ARTICLE 4. RÉMUNÉRATION

La mise à disposition par ICC PHYSIO du dispositif MYOLUX ATHLETIK est effectuée à titre gratuit.

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ARTICLE 5. INDÉPENDANCES DES PARTIES

Matthieu LALEVEE, LE CETAPS et Franck DUJARDIN ne sont soumis à aucun lien de subordination envers ICC PHYSIO.

En conséquence, ils s'engagent à respecter les législations sociale, fiscale, juridique et déontologique le concernant sans que ICC PHYSIO ne puisse être inquiétée à ce sujet.

ARTICLE 6. RESPONSABILITÉS – ASSURANCE

Matthieu LALEVEE, LE CETAPS et Franck DUJARDIN sont entièrement responsables de la bonne exécution et de la fiabilité du PROJET DE RECHERCHE.

Matthieu LALEVEE, LE CETAPS et Franck DUJARDIN conservent la charge de leur responsabilité professionnelle pour laquelle ils doivent assurer les sujets inclus dans le PROJET DE RECHERCHE à leurs frais auprès d'une compagnie notoirement solvable.

ARTICLE 7. DURÉE DU CONTRAT

Le présent contrat est conclu pour la durée nécessaire à l'accomplissement de la mission de Matthieu LALEVEE, cette durée étant estimée à trois (3) ans. Le présent contrat prend effet à compter de sa signature.

A l'expiration de cette durée, et au cas où la réalisation du PROJET DE RECHERCHE ait pris du retard, le présent Contrat pourra être prorogé par un avenant au présent Contrat, et ce pour la durée nécessaire à la finalisation de l'étude. Les Parties s'engagent à se prévenir de tout projet de renouvellement deux mois avant la date d'échéance du contrat.

ARTICLE 8. RÉSILIATION

En cas d'inexécution totale ou partielle, de mauvaise exécution ou de violation d'une de ses dispositions rendant impossible la poursuite du contrat, le présent contrat pourra être résilié de plein droit après une mise en demeure adressée par lettre recommandée avec accusé de réception restée infructueuse pendant trente jours à compter de la réception de la mise en demeure, ou s'il ne peut être remédié au manquement. La lettre mentionnera l'intention de faire application de la présente clause.

La résiliation prendra effet à l'expiration du délai de trente jours.

Le contrat pourra être résilié de plein droit si l'exécution de tout ou partie du présent contrat est rendue impossible par un événement constitutif de force majeure qui

maintiendrait ses effets pendant une durée excédant trois mois à compter du jour où la force majeure a produit ses premiers effets. La résiliation prendra effet le lendemain du jour où le délai de trois mois a expiré.

Aucune indemnité ne pourra être réclamée de part ni d'autre au titre d'une résiliation intervenant conformément au titre du présent article.

ARTICLE 9. INTUITU PERSONAE

ICC PHYSIO met à disposition le dispositif MYOLUX ATHLETIK en raison de la personnalité de Matthieu LALEVEE. Par conséquent, le présent contrat est conclu intuitu personae.

Matthieu LALEVEE ne pourra donc en aucun cas se faire substituer un tiers sans l'accord écrit et préalable de ICC PHYSIO.

ARTICLE 10. CONFIDENTIALITÉ

Matthieu LALEVEE, LE CETAPS et Franck DUJARDIN s'engagent à respecter la confidentialité des informations qui seront portées à leur connaissance dans le cadre de l'exécution ou de la terminaison de sa mission, par écrit ou par oral (publications, notamment), directement ou indirectement, concernant ICC PHYSIO, ses projets et activités pendant la durée du présent Contrat et après son expiration pendant dix (10) années.

Matthieu LALEVEE, LE CETAPS et Franck DUJARDIN s'interdisent d'exploiter lesdites informations dans leur intérêt et/ou dans l'intérêt d'un tiers.

L'obligation de confidentialité ne s'applique pas aux informations qui :

- étaient déjà dans le domaine public à la date de leur communication à Matthieu LALEVEE, LE CETAPS et/ou Franck DUJARDIN ou qui deviendraient généralement accessibles au public par la suite, sans qu'il y ait eu faute ou négligence de la part de Matthieu LALEVEE, LE CETAPS et/ou Franck DUJARDIN;
- étaient déjà connues par Matthieu LALEVEE, LE CETAPS et/ou Franck DUJARDIN qui les a reçues avant qu'elles ne lui aient été communiquées par ICC PHYSIO ;
- seraient révélées sans restriction à Matthieu LALEVEE, LE CETAPS et/ou Franck DUJARDIN par un tiers en droit de les divulguer.

ARTICLE 11 – PROPRIÉTÉ INDUSTRIELLE

Les éléments de propriété intellectuelle et industrielle des parties (brevets, marques, études, logiciels, ...) restent la propriété pleine et entière de la partie détentrice.

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Matthieu LALEVEE, LE CETAPS et Franck DUJARDIN s'engagent à faire valider le PROJET DE RECHERCHE ainsi que toute publication en lien avec le PROJET DE RECHERCHE au préalable à ICC PHYSIO et de manière générale à lui transmettre toute information pertinente en lien avec le PROJET DE RECHERCHE susceptible d'intéresser ICC PHYSIO.

Il est expressément entendu entre les Parties que ICC PHYSIO pourra utiliser les résultats issus du PROJET DE RECHERCHE notamment dans le cadre du développement de ses futurs produits.

ARTICLE 12. DISPOSITIONS GÉNÉRALES D'INTERPRÉTATION

Le Contrat et ses annexes contiennent la totalité des accords des parties. Il annule et remplace toute disposition, contrat, écrit, courrier ou engagement antérieur.

Le fait pour une partie de ne pas exercer un droit ou une option qui lui est conféré par le présent contrat n'équivaut pas de sa part à une renonciation définitive d'exercice de ce droit ou de cette option sauf si cette renonciation est expressément organisée par une clause du présent contrat.

Le fait pour une partie de ne pas sanctionner une violation par l'autre partie d'une ou plusieurs clauses du contrat n'équivaut pas à une renonciation tacite de son droit de sanction des infractions commises.

Par ailleurs, l'illégalité d'une clause ne vaut que pour ladite clause et n'entraîne pas l'illégalité de l'ensemble du contrat.

Les Parties considèrent que le présent contrat, les annexes et tous avenants éventuels établis par écrit constituent l'entier et unique accord les liant. Toute modification sera obligatoirement établie par un document écrit portant la signature de chacune d'entre elles.

Les Parties considèrent que toutes modifications ou adaptations contractuelles ainsi prévues entreront dans l'économie générale des présentes et feront corps avec elles sauf mention contraire expresse.

ARTICLE 13. DISPOSITIONS FINALES

13.1 Juridiction compétente et loi applicable

Le Contrat est soumis à la loi française.

Les Parties s'efforceront de régler à l'amiable tous litiges survenant à l'occasion de l'interprétation ou de l'exécution du présent contrat. Les Parties disposeront de trente jours pour régler leur différend à l'amiable.

En cas d'échec du règlement amiable, toutes contestations relatives au présent contrat, même en cas de pluralité de défendeurs ou d'appel en garantie, seront de la compétence des juridictions de CHAMBERY (73).

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13.2 Election de domicile

Pour les besoins de l'exécution des présentes, annexes et avenants éventuels, et de leur suite, les parties font élection de domicile aux adresses figurant en tête des présentes.

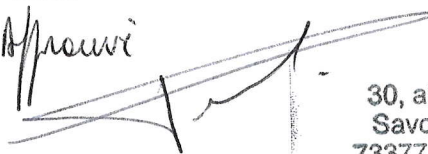
Fait à **Rouen**
Le **27 Avril 2020**

En quatre exemplaires originaux comprenant chacun deux annexes

Pour ICC PHYSIO

Représentée par Monsieur Pascal
TOSCHI*

lu et Approuvé



ICC-PHYSIO
30, allée Lac d'Aiguebelette
Savoie Technolac - BP 322
73377 LE BOURGET DU LAC
Tél. 04 79 25 71 00
Email : contact@iccphysio.com

Monsieur Matthieu LALEVEE*

lu et Approuvé



LE CETAPS


Représenté par son directeur M. Olivier
SIROST et par M. Maxime L'HERMETTE.



Lu et approuvé, le 30 04 2020
MLH

Monsieur Franck DUJARDIN*

lu et Approuvé



CHIRURGIE ORTHOPÉDIQUE ET TRAUMATOLOGIQUE
P^r Franck DUJARDIN
10001915734
HÔPITAL CHARLES NICOLLE
76031 ROUEN CEDEX

*Faire précéder la signature de la mention manuscrite « lu et approuvé » suivie du cachet commercial de l'entreprise. Sur chaque page, en ce compris les Annexes, les signataires ne devront pas omettre d'apposer leur paraphe.

Appel à projets Charles Nicolle 2020

Dossier de candidature pour équipements innovants

DEMANDEUR:

Nom LALEVEE
Prénom Matthieu
Titre et fonction Interne de chirurgie CHU/Faculté de médecine de Rouen, Doctorant au Centre d'Etudes des Transformations des Activités Physiques et Sportives de Rouen
Service Chirurgie Orthopédique et Traumatologique
Pôle Ostéo-Articulaire et Revêtement Cutané
Etablissement CHU de Rouen
Adresse de l'établissement 37 Boulevard Gambetta, 76000 Rouen
Téléphone 06.99.25.79.56
E-mail matthieu.lalevee@gmail.com

Le dossier complet doit impérativement être reçu avant le Jeudi 05 MARS 2020 :

- 6 exemplaires papier et agrafés seront adressés à l'adresse suivante :

**Appel à Projets Equipements Innovants 2020
Fondation Charles Nicolle-Normandie**

Direction Générale
CHU-Hôpitaux de Rouen
1 rue de Germont
76031 Rouen Cedex 1

- la totalité du dossier en version numérique (PDF) à :
eric.mallet@fondation-charlesnicolle.fr
copie marie.castets@chu-rouen.fr

Coordonné par la Fondation Charles Nicolle-Normandie, l'appel à projets est cofinancé par la Région Normandie, le CHU de Rouen, le CH Eure-Seine, le GH du Havre, le CHU de Caen, le CH Mémorial de Saint-Lô et le CH d'Alençon-Mamers. Il vise :

- à faciliter l'innovation dans les services par l'acquisition de matériels biomédicaux,
- le matériel ne peut se substituer aux projets de dotation des pôles
- pour des réalisations pouvant être adossées à un projet de recherche,
- d'un coût supérieur à 5.000 € et n'excédant pas 75.000 euros TTC (sauf cofinancement)
- s'inscrivant dans priorités de santé de la Région Normandie et donnant accès aux pratiques innovantes.

Pour toute demande concernant les Hôpitaux :

mettre en copie de votre e-mail le responsable local :

GH du Havre - Dr. Pascal LEROUX pascal.leroux@ch-havre.fr

CHI Eure-Seine - Dr. Christian RICHARD christian.richard@chi-eureseine.fr

CHU de Caen - Dr Eric SALOUX saloux-e@chu-caen.fr et Pierre LACOMBE lacombe-p@chu-caen.fr

CH Mémorial de Saint-Lô - Xavier BOUGEARD (xavier.bougeard@ch-coutances.fr)

CHI Alençon-Mamers - Edouard GALLAND egalland@ch-alencon.fr et Aurélie ALEXIS aalexis@ch-alencon.fr

Pour tout renseignement eric.mallet@fondation-charlesnicolle.fr - 06 82 39 62 24

marie.castets@chu-rouen.fr - 02 32 88 88 72 - 06 71 74 75 49

Appel à projets Charles Nicolle-Normandie 2020

Déclaration

Je soussigné, LALEVEE Matthieu

Titre et fonction : Interne de chirurgie au CHU et à la Faculté de médecine de Rouen, Doctorant au Centre d'Etudes des Transformations des Activités Physiques et Sportives de Rouen

Service : Chirurgie Orthopédique et Traumatologique

Pôle : Ostéo-Articulaire et Revêtement Cutané

Etablissement : CHU de Rouen (37 Boulevard Gambetta, 76000 Rouen)

m'engage à citer la Fondation Charles Nicolle-Normandie dans mes présentations et/ou publications liées au bénéfice de(s) l'appel(s) d'offre, à en informer cette dernière, à lui transmettre les tirés à part et répondre aux demandes d'évaluation.

à Rouen, le 04/03/2020

Signature du demandeur :



Validation

Le Chef de pôle (signature)

Date, Tampon du Service

CHIRURGIE ORTHOPÉDIQUE ET TRAUMATOLOGIQUE
Pr Franck DUJARDIN
10001915734
HÔPITAL CHARLES NICOLLE
76031 ROUEN CEDEX

le 5 mars 2020.

Je signe pour le Pr
P. Joly qui sera
informé des que
fouille



F. DUJARDIN

Information : pour améliorer la lisibilité des actions de la Fondation, le service biomédical apposera un autocollant sur le matériel.

LALEVEE Matthieu
Né le 13/01/1989 à Gérardmer
38 Rue Maréchal Gallieni
76100 Rouen
06.99.25.79.56
matthieu.lalevee@gmail.com

A l'attention des membres de la
Fondation Charles Nicolle

Objet : Candidature à la bourse de financement pour équipements innovants.

Mesdames, Messieurs,

Par la présente je souhaite soumettre ma candidature à la bourse de financement pour équipements innovants pour laquelle un appel à projets a été émis.

Je suis actuellement interne dans le service de Chirurgie orthopédique et traumatologique du Professeur Dujardin au CHU de Rouen. Dans le cadre de mon projet hospitalo-universitaire, je vais effectuer ma mobilité aux Etats-Unis dans le Département de chirurgie du pied et de la cheville de l'University of Iowa Hospitals and Clinics durant une année à compter du 1er septembre 2020.

J'ai également débuter ma thèse de sciences avec le Centre d'Etudes des Transformations des Activités Physiques et Sportives de Rouen. Cette dernière s'effectuera en cotutelle avec le service américain dans lequel je vais effectuer ma mobilité.

Mon sujet de recherche porte sur l'instabilité chronique de cheville. Nous souhaitons développer un appareil permettant de diagnostiquer et de quantifier cette dernière. Une fois ce matériel développé, je pourrai effectuer une partie des recherches et valider scientifiquement le matériel lors de mon année aux Etats Unis. Une fois validé, le projet est d'utiliser ce matériel pour la prise en charge des patients instables dans le service d'orthopédie traumatologie du CHU de Rouen.

Dans ce cadre, veuillez trouver mon dossier de candidature au financement de ce matériel.

En espérant que mon projet, par l'intermédiaire de ce dossier, retienne votre attention.

Je vous prie d'agréer, Mesdames, Messieurs les membres de la Fondation Charles Nicolle, l'expression de mes sentiments distingués.

Le 04/03/2020 À Rouen

Matthieu Lalevée



Dossier technique en 3 parties: A, B, et C

A- Concernant l'équipement biomédical demandé

Prendre au préalable contact avec les services biomédicaux concernés :

- CHU de Rouen : André GROSJEAN andre.grosjean@chu-rouen.fr
- GH du Havre : Helene BUGEL helene.bugel@ch-havre.fr
- CHI Eure-Seine : Olivier CHAUVIN olivier.chauvin@chi-eureseine.fr
- CHU de Caen : Pierre LACOMBE lacombe-p@chu-caen.fr
- CH Mémorial de Saint-Lô : Nathalie LORY-DOMINGE nathalie.lory@ch-stlo.fr
- CH d'Alençon – Mamers : Dominique LOISEAU dloiseau@ch-alencon.fr

1. Nom et référence de l'équipement (éventuellement de ses options et accessoires importants)

Chausson de déstabilisation de cheville Myolux Athletik® couplé à des centrales inertielles Isen 3.0 STT Systems®.

2. Présentation de l'équipement (notices de présentation du fournisseur en annexe)

- Equipement en développement destiné à diagnostiquer et quantifier l'instabilité chronique de cheville.
- Développement initial de l'appareil dans le cadre d'un projet de recherche (thèse de sciences).
- Une utilisation quotidienne dans le service d'orthopédie traumatologie du CHU de Rouen est envisagée pour la prise en charge des patients instables si l'appareil est validé scientifiquement.

3. Degré et nature de l'innovation (existe-t-il un équipement analogue dans la région ? L'innovation est-elle principalement technologique, technique, d'ordre organisationnelle, sociale ou collaborative ?)

Aucun appareil permettant le diagnostic et la quantification de l'instabilité chronique de cheville n'est actuellement disponible.

Le diagnostic de cette pathologie se base actuellement sur des scores cliniques prenant en compte les épisodes de traumatisme de cheville déjà survenus. Disposer d'un matériel permettant un diagnostic à priori (en amont des épisodes traumatiques) serait une évolution majeure dans la prise en charge de l'instabilité chronique de cheville. Cette pathologie étant multifactorielle, pouvoir pondérer chaque facteur de risque, grâce à cet appareil, permettrait de cibler les moyens de préventions efficaces afin de diminuer l'incidence des traumatismes de la cheville et des pathologies qu'ils engendrent.

4. Nombre estimé de patients/an qui pourront bénéficier de ce matériel innovant ? Proposez des progrès dans la prise en charge.

Il est difficile de quantifier réellement le nombre de patients qui pourront bénéficier de ce matériel. La première étape reste de le valider scientifiquement. D'un point de vue épidémiologique, le traumatisme de cheville est fréquent. D'après la Haute

Autorité de santé en 2018 (1) : *“son incidence en France est de 2 millions de cas par an et elle est à l’origine de 7 à 10% des consultations d’urgence hospitalière. Chaque jour, environ 6000 personnes en France consultent pour une entorse de la cheville.”*

Une part importante de la population pourrait donc bénéficier de ce type de matériel.

1. [https://www.has-sante.fr/upload/docs/evamed/CEPP-5487_A2T_15_mai_2018_\(5487\)_avis.pdf](https://www.has-sante.fr/upload/docs/evamed/CEPP-5487_A2T_15_mai_2018_(5487)_avis.pdf)

5. Devis daté et signé (joindre devis détaillé en cours de validité)

Le chausson Myolux Athletik® nous serait fourni gracieusement à visée de recherche scientifique par la société Myolux®.

Veuillez trouver en Annexe 1 le devis correspondant aux centrales inertielles et au logiciel d’analyse qui seront couplés au chausson Myolux®.

6. Coût d’investissement TTC : 9840 euros

- **Eventuel cofinancement prévu (structures et montants)**

Aucun cofinancement n’est prévu à ce jour.

7 Coût d’exploitation annuel :

Seul le matériel est biomédical est pris en charge par l’appel à projet.

L’étude économique représente un des critères d’analyse des candidatures.

A ce jour ce matériel représenterait un investissement unique (9840 euros) correspondant au coût de fabrication du matériel qui serait ensuite uniquement utilisé à visée de recherche scientifique dans un premier temps.

8 Marquage CE (joindre le justificatif)

Veuillez trouver en Annexe 2 et 3 les brochures commerciales des centrales inertielles et du logiciel d’analyse.

B En cas de projet de recherche clinique associé

1. Titre et objectifs du projet de recherche/ou d'utilisation, liés à l'acquisition du matériel biomédical innovant (*il n'est pas obligatoire à ce stade de fournir le plan statistique du projet*)

A new device quantifying chronic ankle instability in sport.

b. Specific aims/objectives:

- Primary Objective: Differentiate controls subjects from subjects with chronic lateral ankle instability (CLAI) on the angular inversion velocity during a fake lateral ankle sprain traumatism.
- Secondary Objective: Quantifying CLAI on angular inversion velocity.
- Hypothesis: The greater the CLAI, the greater the angular inversion velocity.

c. Significance:

CLAI is the most frequent pathology in sport (1). Defining and anticipating ankle sprain traumatisms is currently impossible because many factors can influence it (2), such as hindfoot varus (3), ligament laxity, weakness of evertors, proprioceptive defect...

CLAI is currently defined by scores: IdFAI(4), the Cumberland Ankle Instability Tool (5)... which are only a posteriori questionnaires (which include past ankle traumatisms).

The validation of a device that can quantify CLAI could be the first step to understand its pathophysiology. This would also allow us to validate and weigh each risk factor in its CLAI involvement. In this way, quantifying the CLAI a priori will become possible.

It will allow to develop a clinic predictive ankle sprain score, but also to develop prevention management and to quantify it with this same device.

d. Methods:

- Prospective comparative study.
- Population: Sportsmen.

We decided to work on sportsmen because CLAI and ankle sprains are frequent in this population (1).

* Inclusion criteria (4): Study Group: Subjects with a IdFAI score greater than 10. Control Group: Subjects with a IdFAI score equal to or less than 10.

* Exclusion criteria: Ankle sprain less than 6 weeks old at the time of the test, other musculoskeletal disorders of the lower limbs, no consent.

- Material :

We will use a device to simulate a sudden lateral ankle trauma associating inversion and medial rotation (6) using a validated device for ankle rehabilitation (Myolux Athletik®). It will be coupled with Inertial Measurement Units (IMUs) placed on the tibial tuberosity, the fifth metatarsal head and the posterior tuberosity of the calcaneus.

According to the literature (7,8), the device will produce a fake traumatism that will not exceed 30 degrees of inversion so as to present no risk of sprained ankle or other injuries to the subject. IMUs will measure angular velocity during the fake traumatism.

- Study plan :

Subjects will walk with 2 locked destabilization boots in a stable position. The examiner will be able to trigger instability in one of these boots during the swing phase, which will induce instability on this boot during next stance phase leading to a fake traumatism.

Data will be collected during the fake traumatism.

There will be 3 passages for each ankle of each subject with the same protocol for the subjects and the controls.

- Endpoints :

* Primary endpoint: Maximal ankle inversion angular velocity during the fake traumatism.

* Secondary endpoints: Mean ankle inversion angular velocity, delay between the start of the traumatism and contact with the ground.

- Statistical :

* Sample Size: The required number of subjects was calculated at 31 subjects per group (62 in total) according to the literature (7) (parameters used: minimum difference 75%, standard deviation 100%, $\alpha = .05$, $1 - \beta = .9$).

* Comparison between CLAI patients and controls on different endpoints using a Student Test.

* Assessing correlation between IdFAI score and primary endpoint using a Pearson correlation Test.

e.References:

1. Herzog MM, Kerr ZY, Marshall SW, Wikstrom EA. Epidemiology of Ankle Sprains and Chronic Ankle Instability. *Journal of Athletic Training*. 2 juin 2019;54(6):603-10.
2. Delahunt E, Remus A. Risk Factors for Lateral Ankle Sprains and Chronic Ankle Instability. *J Athl Train*. juin 2019;54(6):611-6.
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5. Hiller CE, Refshauge KM, Bundy AC, Herbert RD, Kilbreath SL. The Cumberland ankle instability tool: a report of validity and reliability testing. *Arch Phys Med Rehabil*. sept 2006;87(9):1235-41.
6. Fong DT-P, Ha SC-W, Mok K-M, Chan CW-L, Chan K-M. Kinematics analysis of ankle inversion ligamentous sprain injuries in sports: five cases from televised tennis competitions. *Am J Sports Med*. nov 2012;40(11):2627-32.
7. Ha SC-W, Fong DT-P, Chan K-M. Review of ankle inversion sprain simulators in the biomechanics laboratory. *Asia Pac J Sports Med Arthrosc Rehabil Technol*. oct 2015;2(4):114-21.
8. Chan Y-Y, Fong DT-P, Yung PS-H, Fung K-Y, Chan K-M. A mechanical supination sprain simulator for studying ankle supination sprain kinematics. *J Biomech*. 7 août 2008;41(11):2571-4.

2. Quelle équipe est le pilote du projet?

Comment le financement de la partie recherche ou d'utilisation est-il envisagé ?

Quels sont les autres financements obtenus (appel à projet européen, national ou régional, CPER, H2020, PHRC, GRR...)

Ce projet s'inscrit dans ma thèse de sciences qui fera l'objet d'une collaboration entre :

- Le service de Chirurgie orthopédique et traumatologique du CHU de Rouen
- Le Centre d'Etudes des Transformations des Activités Physiques et Sportives (CETAPS) de Rouen
- Le département de chirurgie du pied et de la cheville de l'University of Iowa Hospitals and Clinics, (USA).

C Pour la communication Grand Public, Résumé et titre explicités à destination du grand public

1. Fiche Résumé du matériel (photo du matériel)

Nom de l'équipement à expliciter pour le grand public et donateurs

Chausson de déstabilisation permettant de diagnostiquer et de quantifier l'instabilité de cheville.

- Chausson Myolux Athletik®



- Centrales Inertielles Isen 3.0 STT Systems®



2. Résumé du projet de recherche /ou du projet d'utilisation

Important: Formulation en langage "Grand Public" (10 à 20 lignes)

Les entorses de la cheville sont fréquentes et sont majoritairement secondaires à une pathologie nommée instabilité chronique de cheville.

Il n'existe aucun moyen à l'heure actuelle permettant de diagnostiquer et de quantifier cette instabilité de cheville.

Notre projet consiste à développer un appareil permettant de simuler un traumatisme de cheville pouvant conduire à une entorse, tout en restant dans les limites physiologiques (amplitudes articulaires) afin d'éviter tout risque de blessures pour le patient. Cet appareil couplé à un matériel de mesure nous permettrait le recueil et l'analyse des mouvements de la cheville et de la réaction du patient pendant le traumatisme simulé. Il nous permettrait ainsi de quantifier l'instabilité de cheville.

La validation scientifique de cet appareil nous permettrait de diagnostiquer les instabilités chroniques de cheville en amont des traumatismes. Il nous permettrait également d'évaluer ses facteurs de risque, de les quantifier et de développer des moyens de prévention adaptés à chacun.



TRINOMA

Service d'Orthopédie Traumatologie
du CHU de Rouen
37 Boulevard Gambetta
76000 ROUEN

DEVIS D-2020-03-7

Date : 04.03.2020 Echéance : 03.04.2020

Libellé : Système de capture de mouvement inertiel 6 capteurs

Référence	Description	Qté	Prix Unit. HT	TVA	Montant HT
MCP-MISC	Package iSen 6 capteurs Logiciel + capteurs inertiels	1.0	8 200.00	20.0	8 200.00
Montant total HT					8 200.00
Montant total TVA					1 640.00
Montant total TTC, EUR					9 840.00

Type de TVA: encaissements

Merci de bien vouloir envoyer vos commandes par email à :
commande@trinoma.fr

Conditions de paiement: 30 jours net

Toute commande vaut acceptation tacite de nos CGV:
<https://trinoma.fr/cgv.pdf>

Règlement par virement

Banque : Crédit Agricole Languedoc
IBAN : FR76 1350 6100 0085 1006 0843 504
BIC : AGRIFRPP835



STT-IWS

WI-FI, 400HZ INERTIAL SENSOR WITH ON-BOARD DATA STORAGE



Wireless

The system operates on a standard Wi-Fi protocol (2.4GHz and 5GHz). This feature turns STT-IWS inertial sensors into open and versatile devices.



400Hz

The sample rate is selectable by the user and can range from just a few Hertz up to 400Hz: that's an exceptionally high capture speed, challenging even most of the optical systems in the market.



Multi-sensor

The STT-IWS features several on-board sensors: triple-axis gyroscope, triple-axis accelerometer, triple-axis magnetometer, barometric pressure sensor, humidity sensor and internal temperature sensor.



Data logging

Although STT-IWS sensors typically work within Wi-Fi range, they can also operate autonomously. This is particularly interesting during on-field motion analysis. Once the capture has been triggered, the sensor can leave the Wi-Fi network coverage area and the data can be downloaded later on.



On-board processing

All sensors in STT-IWS are calibrated, and a sophisticated AHRS fusion algorithm provides real-time measurements of orientation, linear acceleration and altitude.



Integratable

STT-IWS features an analogue input for up to 8 ch. @ 1 kHz / 10-bit data (0-3.3 V). Also, an auxiliary serial port can be used for devices such as GPS receivers.



Synchronized data

All measurements are time-stamped automatically in order to guarantee an actual synchronization.



Accurate

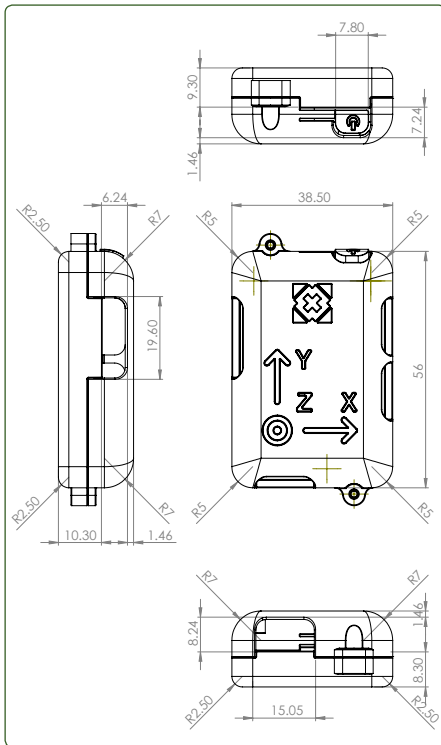
The accuracy of STT-IWS units is among the best of its kind: Pitch/roll < 0.5 degrees (RMS) and Heading < 2.0 degrees (RMS).



Ready for developers

Open-source GUI and API (C#) for Windows. Easily configure device settings plot real-time data. Log real-time data to file (CSV file format for use with Excel, MATLAB, etc.)

Technical specifications



SENSOR MEASUREMENTS

3-axis Gyroscope range	±2000 deg/s
3-axis Accelerometer range	±16g
3-axis Magnetometer range	±1300 μT
Barometric pressure sensor rate	300 to 1100 hPa
Sensors calibrated in temperature	Yes
Humidity sensor	Yes

ACCURACY

Static Pitch accuracy (RMS)	<0.5°
Static Roll accuracy (RMS)	<2°
Static Heading accuracy (RMS)	<2°

SAMPLE RATE

User-defined sample rate	Yes
Maximum sample rate	400Hz
Maximum number of STT-IWS units @ 400Hz	17

PHISICAL DIMENSIONS

L x W x H	56 (64) x 38 x 18 mm
Weight	46gr.

ANALOG INPUT

Usable channels	1 to 8
Sample rate	8kHz / 10-bit
Voltage	0-3.3V

DATA TRANSMISSION CHANNELS

USB port (Micro B)	1
Serial port	1
Wi-Fi (802.11n @ 5 GHz)	Yes
Bluetooth compatibility	Upcoming
Micro-SD Card for data logging	Yes

POWER MODES

Internal battery	Yes
USB connector	Yes
External power supply	Yes

BATTERY

Charging time	1.5h
Battery life (continuous data transmission)	3.5h
Battery level indicator	Yes
Battery health indicator	Yes



iSen 3.0

INERTIAL MOTION CAPTURE BASED ON 400HZ, WI-FI IMU



Wireless

The system operates on a standard Wi-Fi protocol (2.4GHz and 5GHz). This feature turns STT-IWS inertial sensors into open and versatile devices.



400Hz

The sample rate is selectable by the user and can range from just a few Hertz up to 400Hz: that's an exceptionally high capture speed, challenging even most of the optical systems in the market.



Flexible configurations

iSen 3.0 lets you work with any sensor configuration, from just a single STT-IWS sensor to a 17-sensor, full-body configuration – all of them working at 400Hz.



Synchronized

All measurements are automatically time-stamped in order to guarantee an actual synchronization.



Accuracy

The accuracy of STT-IWS units is among the best of its kind: Pitch/roll < 0.5 degrees (RMS) and Heading < 2.0 degrees (RMS).



Data logging

Although STT-IWS sensors typically work within Wi-Fi range, they can also operate autonomously. This is particularly interesting during on-field motion analysis. Just configure the capture and get them synchronized inside the wireless network, then set them to 'data logging mode' and let the subject walk out of the coverage area.



Video feedback

Enabling an inexpensive HD webcam or high-end, high-speed video camera for simultaneous video recording is straightforward.



Integratable

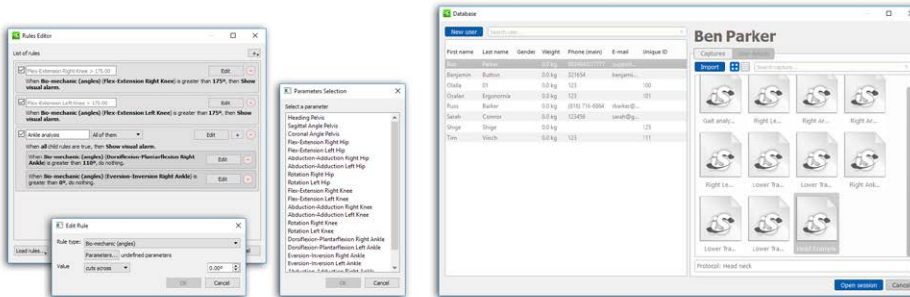
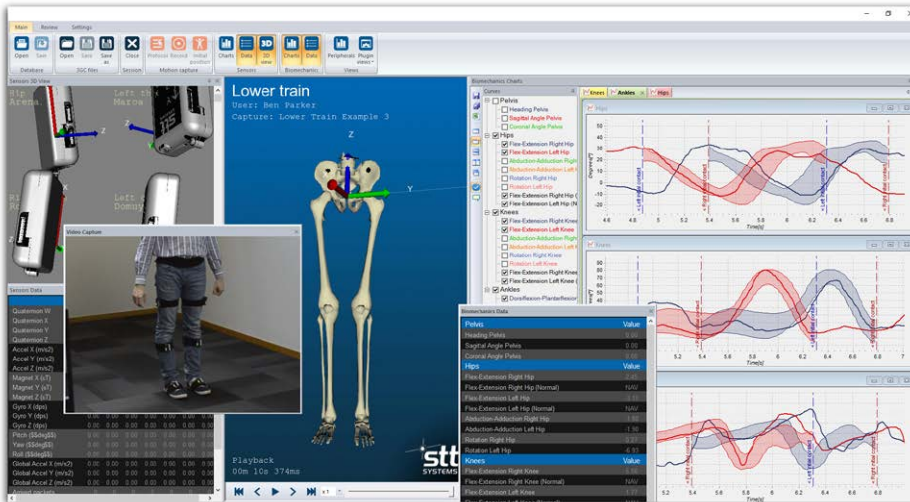
STT-IWS features an analogue input for up to 8 ch. @ 1 kHz / 10-bit data (0-3.3 V). Also, an auxiliary serial port can be used for devices such as GPS receivers.



Custom reports

The system can automatically generate a report with the results of the analysis. The template for that report can be edited easily by the user.

iSen software interface



DATABASE

Easily keep track of users and captures. Import/export files.

3D VISUALIZATION

See the motion in real time.

AUTOMATED REPORTS

Generate reports with a click and easily edit the templates.

BIOFEEDBACK & RULE EDITOR

Create your own lists of real-time events with visual / audio feedback.

INTEGRATIONS

Combine motion data with force plates, surface EMG, etc.

TIME EVENTS

Automated and manual events can be added.

NORMALIZED DATA IN GAIT

Display normalized curves as a quick reference.

REAL-TIME GRAPHS & STATS

All the information is updated instantaneously & displayed.

VIDEO SYNCHRONIZATION

Webcams & high-speed cams.

Sensor configurations



Choosing the right sensor configuration is crucial. Given a certain amount of sensors, the user can access protocols requiring that same amount or less.

1 STT-IWS

- ▶ Rigid body tracking.
- ▶ Basic gait & running.

2 STT-IWS

- ▶ Individual joint analysis (ankles, knees, hips, back segments, neck, shoulders, elbows).

4 STT-IWS

- ▶ Full single leg (pelvis-foot).

- ▶ Full single arm (shoulder to hand).

- ▶ Two-fold joint analysis (left and right simultaneous analysis of ankles, knees, hips, shoulders, wrists).

- ▶ Full spine (pelvis-neck).

5 STT-IWS

- ▶ Simple upper body tracking and analysis.
- ▶ Gait analysis (pelvis,

- both hips and both knees).

7 STT-IWS

- ▶ Full gait analysis protocol (pelvis, hips, knees and ankles).

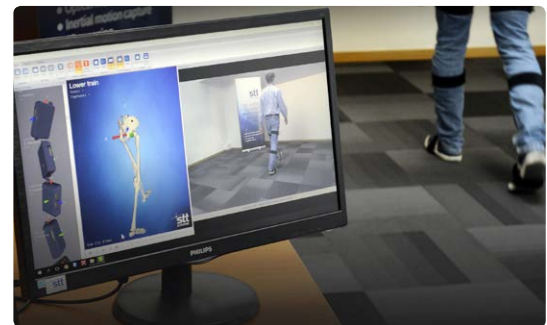
- ▶ Full upper body tracking.

14 STT-IWS

- ▶ Full body tracking.

17 STT-IWS

- ▶ Full body tracking.

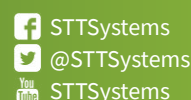


STT Systems

www.stt-systems.com

Parque Empresarial Zuatzu
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Phone: (+34) 943 31 77 77

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Contact us: info@stt-systems.com



STT has been working on motion capture and machine vision technologies since 1998

Annexe 3

MYOLUX

PI: Cesar de Cesar Netto

IRB ID #: 202201527

Project Details

I. Project Introduction

I.1 *Project to be reviewed by:*
IRB-01

I.2 *Project Title:*
MYOLUX: Validation of a potential device for diagnosing and quantifying chronic ankle instability.

I.3 *Short Title (optional):*
MYOLUX

I.4 *Provide a short summary of the purpose and procedures of the study proposed in this IRB application.*

- **DO NOT include information on studies not proposed in this application.**
- **Use LAY terminology only. This must be easily understandable by IRB community members and nonscientists.**
- **DO NOT cut and paste technical abstracts from funding applications that may not be understood by a general audience.**

In this study, we seek to investigate the combination of an ankle instability boot and Inertial Moment Units (IMUs) as a possible device to diagnose and quantify chronic ankle instability (CAI).

The instability boot will provoke a sudden inversion motion and the IMUs will record these motions, including maximal inversion angle and velocity. Previous studies suggest that CAI is associated with an increase in these values.

A cohort of physically active subjects will walk wearing the instability boots on a treadmill with a safety harness. Inversion ankle instability will be triggered remotely by the observer while the subject will be walking. Maximal inversion angle and velocity will be measured using IMUs coupled with the boots.

The cohort will include individuals with Chronic Ankle Instability (CAI group) and a control group with stable ankles (control group) determined using validated questionnaires. These two groups will be compared on inversion angles and velocities.

I.5 *Specify your research question(s), study aims or hypotheses (do not indicate "see protocol")*
AIM #1: Determine whether maximal inversion angle during sudden inversion instability differentiates between individuals with and without ankle instability.

AIM #2: Determine whether maximal inversion velocity during sudden inversion instability differentiates between individuals with and without ankle instability.

AIM #3: Determine if maximal inversion angle and velocity magnitude are associated with reported severity of ankle instability.

I.6 *Background and significance and/or Preliminary studies related to this project. (do not indicate "see protocol")*

Lateral ankle sprain is one of the most common injuries frequently occurring in a context of CAI (1). Anticipating an ankle sprain is currently impossible because many mechanical and functional factors can influence it (2,3). Another drawback is the fact that CAI is currently defined and quantified by scores like the Cumberland Ankle Instability Tool (CAIT) or the Identification of

Functional Ankle Instability Questionnaire (IdFAI), which are only a posteriori questionnaires, which include past ankle traumatism (4,5).

Therefore, the validation of a device that can quantify and/or diagnose CAI could change our practice and our view on this pathology. This device could help us to a priori diagnose individuals at risk for CAI, and better anticipate ankle sprains and injuries. It could also help us understand the relative importance of each risk factor in CAI.

Sprain simulators collecting maximal ankle inversion and maximal inversion velocity during simulated sprain traumatism have shown promising results in differentiating control and unstable patients (6–8). Unfortunately, most of them assess inversion when standing or landing and not when walking or running which is the most common context of these injuries.

Conversely, we will have boots dedicated to CAI (Myolux Athletik®, Appendix 1) allowing a controlled inversion motion for assessment of ankle stability without placing the subject at risk for an actual ankle sprain.

I.7

Literature cited / references (if attaching a grant or protocol enter N/A).

1. Herzog MM, Kerr ZY, Marshall SW, Wikstrom EA. Epidemiology of Ankle Sprains and Chronic Ankle Instability. *J Athl Train.* 2019 Jun 1;54(6):603–10.
2. Thompson C, Schabrun S, Romero R, Bialocerkowski A, van Dieen J, Marshall P. Factors Contributing to Chronic Ankle Instability: A Systematic Review and Meta-Analysis of Systematic Reviews. *Sports Med.* 2018 Jan;48(1):189–205.
3. Gehring D, Faschian K, Lauber B, Lohrer H, Nauck T, Gollhofer A. Mechanical instability destabilises the ankle joint directly in the ankle-sprain mechanism. *Br J Sports Med.* 2014 Mar;48(5):377–82.
4. Hiller CE, Refshauge KM, Bundy AC, Herbert RD, Kilbreath SL. The Cumberland Ankle Instability Tool: A Report of Validity and Reliability Testing. *Arch Phys Med Rehabil.* 2006 Sep;87(9):1235–41.
5. Simon J, Donahue M, Docherty C. Development of the Identification of Functional Ankle Instability (IdFAI). *Foot Ankle Int.* 2012 Sep;33(9):755–63.
6. Ha SC-W, Fong DT-P, Chan K-M. Review of ankle inversion sprain simulators in the biomechanics laboratory. *Asia-Pac J Sports Med Arthrosc Rehabil Technol.* 2015 Oct;2(4):114–21.
7. Chan Y-Y, Fong DT-P, Yung PS-H, Fung K-Y, Chan K-M. A mechanical supination sprain simulator for studying ankle supination sprain kinematics. *J Biomech.* 2008 Aug;41(11):2571–4.
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11. Donovan L, Hart JM, Saliba SA, Park J, Feger MA, Herb CC, et al. Rehabilitation for Chronic Ankle Instability With or Without Destabilization Devices: A Randomized Controlled Trial. *J Athl Train.* 2016 Mar 1;51(3):233–51.
12. Forestier N, Toschi P. The Effects of an Ankle Destabilization Device on Muscular Activity while Walking. *Int J Sports Med.* 2005 Jul;26(6):464–70.
13. Donovan L, Hart JM, Hertel J. Effects of 2 Ankle Destabilization Devices on Electromyography Measures During Functional Exercises in Individuals With Chronic Ankle Instability. *J Orthop Sports Phys Ther.* 2015 Mar;45(3):220–32.
14. Forestier N, Terrier R. Peroneal reaction time measurement in unipodal stance for two different destabilization axes. *Clin Biomech.* 2011 Aug;26(7):766–71.
15. Donovan L, Hart JM, Hertel J. Lower-Extremity Electromyography Measures During Walking With Ankle-Destabilization Devices. *J Sport Rehabil.* 2014 May;23(2):134–44.
16. Gates DH, Darter BJ, Dingwell JB, Wilken JM. Comparison of walking overground and in a Computer Assisted Rehabilitation Environment (CAREN) in individuals with and without transtibial amputation. *J Neuroengineering Rehabil.* 2012 Nov 14;9:81.
17. Beurskens R, Wilken JM, Dingwell JB. Dynamic stability of individuals with transtibial amputation walking in destabilizing environments. *J Biomech.* 2014 May 7;47(7):1675–81.

18. Beurskens R, Wilken JM, Dingwell JB. Dynamic stability of superior vs. inferior body segments in individuals with transtibial amputation walking in destabilizing environments. J Biomech. 2014 Sep 22;47(12):3072–9.

19. Gholizadeh H, Hill A, Nantel J. The effect of various arm and walking conditions on postural dynamic stability when recovering from a trip perturbation. Gait Posture. 2020 Feb;76:284–9.

20. Siragy T, MacDonald M-E, Nantel J. Restricted Arm Swing in People With Parkinson’s Disease Decreases Step Length and Time on Destabilizing Surfaces. Front Neurol. 2020;11:873.

II. Research Team

II.1 *Principal Investigator*

Name	E-mail	College
Cesar de Cesar Netto	cesar-netto@uiowa.edu	Carver College of Medicine

II. *Team Members*

2

UI Team Members

Name	E-mail	College	Contact	Key Prsn	UI COI	VAMC COI	Consent Process Involvement	Deactivated
Cesar de Cesar Netto, MD, PhD	cesar-netto@uiowa.edu	Carver College of Medicine	Yes	Yes	No		Yes	No
Matthieu Lalevee, MD, MSc	matthieu-lalevee@uiowa.edu	Carver College of Medicine	Yes	Yes	No		Yes	No
Jason Wilken, MPT, PhD	jason-wilken@uiowa.edu	Carver College of Medicine	Yes	Yes	No		Yes	No
Nacime Salomao Barbachan Mansur, MD, PhD	nacime-mansur@uiowa.edu	Carver College of Medicine	Yes	Yes	No		Yes	No
Kevin Dibbern, PhD	kevin-dibbern@uiowa.edu	College of Engineering	Yes	Yes	No		Yes	No
Kepler Carvalho, MD	kepler-carvalho@uiowa.edu	College of Engineering	No	No	No		Yes	No
Marie-Anne Melone, MD, MSc	marianne-melone@uiowa.edu	Carver College of Medicine	No	No	No		Yes	No

Non-UI Team Members

Name	Institution	Location	FWA	Role	DHHS	Contact	Key Prsn	UI COI	VAMC COI	Consent Process Involvement	Email
------	-------------	----------	-----	------	------	---------	----------	--------	----------	-----------------------------	-------

II.3 *The Principal Investigator of this study is:*
Faculty

II.6 *Identify the key personnel. The system will automatically designate the PI and all faculty members on the project as “key personnel.” For information about other team members who should be designated as “key personnel” please click on the help information.*

Name	Is Key Personnel
Cesar de Cesar Netto, MD, PhD	Yes
Matthieu Lalevee, MD, MSc	Yes
Jason Wilken, MPT, PhD	Yes
Nacime Salomao Barbachan Mansur, MD, PhD	Yes

Kevin Dibbern, PhD	Yes
Kepler Carvalho, MD	No
Marie-Anne Melone, MD, MSc	No

II.5 *Select research team member who is the primary contact for study participants.*
Matthieu Lalevee

III. Funding/Other Support

III.1 *Funding Sources*

Type Source Grant Title Name of PI on Grant

No Funding

* new source name

III.3 *Does any member of the research team have a financial conflict of interest related to this project according to the [Conflict of Interest in Research](#) policy? If yes, please indicate which members below.*

Name	Has Conflict of Interest
Cesar de Cesar Netto, MD, PhD	No
Matthieu Lalevee, MD, MSc	No
Jason Wilken, MPT, PhD	No
Nacime Salomao Barbachan Mansur, MD, PhD	No
Kevin Dibbern, PhD	No
Kepler Carvalho, MD	No
Marie-Anne Melone, MD, MSc	No

IV. Project Type

IV.1 *Do you want the IRB to give this project*
Regular (expedited or full board) review

IV.2 *Enter the date you will be ready to begin screening subjects/collecting data for this project. (If you do not have a specified date, add "upon IRB approval")*
01/3/2022

IV.3 *Are you requesting a [waiver of informed consent/authorization](#) (subjects will not be given any oral or written information about the study)?*
No

IV.5 *Describe the different study populations (subjects who are and are not giving consent)*
Subjects will be physically active volunteers. According to Lin et al. (10), a physically active population includes athletes, military men or active subjects under the age of forty.

IV.6 *Will subjects be provided with additional pertinent information after participation?*
No

IV.8 *Indicate type of study (check all that apply)*

- Other - The project involves verbal responses to screening questions before the subject gives consent to participate, to determine eligibility for the study. The pre-screening process only includes descriptive information about the potential participant.

IV.9 *List the earliest (beginning) date the data you wish to review were created:*
01 April 2022

IV.10 *List the latest (ending) date the data you wish to review were created:*
01 July 2024

IV.11 *Indicate sources of your data or specimens (check all that apply)*

- We will obtain screening information directly from the potential participant.

IV.12 *List ALL of the variables, including any identifiers or links to identifiers you plan to obtain/use for purposes of this study including any identifiers. (The information accessed should be the minimum data variables necessary for performing the desired analysis.)*
Screening: Potential participants will be asked the following yes/no questions during screening:
- Are you between the ages of 18 and 40?

- Are you physically active (any type of sport without any level and frequency of practice)
- Are you able to read and write in English and provide written informed consent?
- Do you have a history of lower limb conditions (excluding ankle sprains) that affect your life?
- Did you sprain your ankle in the past 2 months?
- Do you have any neurological or sensorimotor impairment?
- Do you have diagnosed osteoporosis or history of low energy fracture?
- Do you have any uncorrected visual or hearing impairment?
- Are you pregnant?
- Do you weigh more than 95kg (209lbs)?

IV.13 *A minimal risk study is a study in which the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.*

Explain why this study involves no more than minimal risk to subjects or to their privacy.

Screening: Low probability of loss of privacy and/or breach of confidentiality. Only yes/no responses to information required to screen potential subjects will be recorded on forms without identifiers. The screening form does not contain any identifiable information and only includes descriptive information.

Theoretical risks of ankle sprain and falls when the boot will become unstable during data collection exists and the subjects will be a priori informed of the risk. However, several measures will be taken to control these risks and allow subjects to participate in a secure manner.

The instability boot (Myolux Athletik®, Appendix 1) we will use, is a device developed and validated for CAI rehabilitation which hold the ankle to prevent excessive motion and injury. The device includes a boot that surrounds the foot and ankle providing stability at the ankle joint. This boot was already used in several studies involving a total of 34 control and 41 CAI subjects (11–15). None of these studies reported any injuries.

The study will be performed while walking on a treadmill with overhead safety harness. The subjects will walk on a treadmill and the suspension harness will be set so individuals are unable to fall to their knees or the ground. This system has been previously used for multiple studies evaluating balance and recovery from challenges to balance (16–20).

IV.14 *Explain why this consent waiver will not adversely affect the subject's rights and welfare.*

Screening: The form does not contain any personally identifiable information, and will be shredded if the potential participant does not enroll.

IV.15 *Explain why it is impracticable (not possible) to conduct this research without a waiver of consent/waiver of authorization.*

We are only requesting a waiver for the screening process. It would be a meaningful additional burden for every potential participant to undergo the entire consent process if they do not meet the basic pre-screening criteria. The waiver would increase the feasibility of completing this student project and reduce the burden of individuals who are interested but clearly not eligible to participate.

IV.16 *Will you be accessing any medical records or medical information, or do any of the data you plan to access meet the federal regulatory definition of protected health information (PHI)?*
No

IV.18 *Describe your plan to protect any subject and/or specimen identifiers from improper use and disclosure. (Identifiers include but are not limited to names, addresses, dates directly related to the subject [such as birth date, date of admission/discharge, date of clinic visit/procedure/diagnosis], social security number, medical record number, pathology accession number, or other account numbers, etc.)*

There are no subject identifiers collected during the screening process.

IV.19 *Describe your plan to destroy subject identifiers at the earliest opportunity consistent with the conduct of the research, or explain the health or research justification for retaining subject identifiers.*

There are no subject identifiers collected during the screening process.

V. Other Committee Review

V.1 *Does this project involve any substance ingested, injected, or applied to the body?*

- *Do not answer yes, if the involvement includes a device, wire, or instrument*

- No
- V.2 *Are any contrast agents used for any purpose in this study?*
No
- V.9 *Will any subject be asked to undergo a diagnostic radiation procedure (including radiographic, nuclear medicine, DEXA)?*
No
- V.14 *Will any subject be asked to undergo a radiation therapy procedure (including external beam therapy, brachytherapy, or nuclear medicine therapy)?*
No
- V.20 *Does this project involve the deliberate transfer of recombinant or synthetic nucleic acid molecules, or DNA or RNA derived from recombinant or synthetic nucleic acid molecules, into one or more human research participant?*
No
- V.21 *Will any portion of this project be conducted in the CRU, or does it use any CRU resources?*
No
- V.22 *Will this project use:*
 - *any resource/patients of the Holden Comprehensive Cancer Center*
 - *involve treatment, detection, supportive care, or prevention of cancer*

- No
- V.25.a *Will the study involve any of the following activity at UI Health Care, even if subjects or their insurance will not be billed for the item or service, and regardless of the study funding source (including studies with departmental or no funding)?*
 - *Procedures, tests, examinations, hospitalizations, use of Pathology services, use of clinic facilities or clinical equipment, or any patient care services, including services conducted in the Clinical Research Unit; or*
 - *Physician services or services provided by non-physicians who are credentialed to bill (ARNPs, Physician Assistants, etc.)*

- No
- V.26 *The study involves Department of Nursing Services and Patient Care nursing, nursing resources or evaluates nursing practices at UI Health Care.*
No

VI. Subjects

- VI.1 *How many adult subjects do you expect to consent or enroll for this project?*
45
- VI.2 *What is the age of the youngest adult subject?*
18.0
- VI.3 *What is the age of the oldest adult subject?*
40.0
- VI.4 *What is the percentage of adult male subjects?*
50
- VI.5 *What is the percentage of adult female subjects?*
50
- VI.6 *How many minor subjects do you expect to consent or enroll for this project?*
0

VI.13 *Describe EACH of your subject populations*

- *Include description of any control group(s)*
- *Specify the Inclusion/Exclusion criteria for EACH group*

There is no control group.

Inclusion criteria of our cohort are:

- Physically active subjects (According to Lin et al. (10), a physically active population includes athletes, military men or active subjects under the age of forty.)
- Under 40 years old

Exclusion criteria:

- Under 18 years old
- Weight over 95 kg (209 lbs.)
- Ankle sprain antecedent in the past two months
- Neurological or sensorimotor impairment
- Osteoporosis
- Any currently active affection of the lower limb

VI.14 *Provide an estimate of the total number of subjects that would be eligible for inclusion in each of your study populations (include your control population if applicable)*

45 subjects in total.

VI.15 *Describe how you will have access to each of your study populations in sufficient number to meet your recruitment goals.*

In Simpson et al. (9) study, the mean maximal inversion angle, when landing on an inverted platform, was $21.4^{\circ} \pm 2.9$ in CAI compared to $19^{\circ} \pm 2.9$ in control subjects. Considering these values, a type 1 risk of 5%, a type 2 risk of 20% and a unilateral test, 18 ankles per group would be necessary to find a significant difference between groups on our primary assessment criterion.

According to Lin et al. (10), the prevalence of CAI in a physically active population is approximately 25%. Therefore, we will need 18 ankles in our CAI group and considering that we will exclude contralateral ankle from the analysis in case of unilateral CAI.

Therefore, we will need to enroll 45 subjects.

VI.16 *Do you plan to recruit/enroll non-English speaking people?*

No

VI.18 *Do you propose to enroll any of the following in this study as subjects?*

- *Employee of the PI or employee of a research team member*
- *Individual supervised by PI or supervised by member of research team*
- *Individual subordinate to the PI or subordinate to any member of the research team*
- *Student or trainee under the direction of the PI or under the direction of a member of the research team*

No

VI.20 *Will subjects provide any information about their relatives?*

No

VI.23 *Will anyone (other than the subject) provide you with information about the subject (e.g. proxy interviews)?*

No

VI.26 *Is this project about pregnant women?*

No

VI.27 *Will this project involve fetuses?*

No

VI.28 *Does this project involve adult subjects who may be incompetent or have limited decision-making capacity on initial enrollment into the study?*

No

VI.32 *Does this project involve subjects whose capacity to consent may change over the course of the study?*

No

VI.37 *Does this project involve prisoners as subjects?*

No

VII.A. Project Description (A)

VII.A.1 *Where will project procedures take place (check all that apply)?*

- Human Performance and Clinical Outcomes Lab 21D Eckstein Medical Research Building, Iowa City, IA 52242

VII.A.2 *Is this project also being conducted by other researchers at their own sites (e.g. a multi-site collaborative project)?*

No

VII.B. Project Description (B)

VII.B.1 *Does this project involve any of the following (Check all that apply):*

- **Interventional** – Includes **Clinical (or Treatment) trial**, **Physiology intervention/study**, **Behavioral intervention/study**, **Diagnostic Trial**.
- **Clinical (or Treatment) trial** – A prospective biomedical or behavioral research study of new treatments, new drug or combinations of drugs, new devices, or new approaches to surgery or radiation therapy. (NIH and ClinicalTrials.gov & FDA)
- **Physiology intervention/study** – A pharmacologic or measurement study aimed at understanding basic mechanisms of disease and/or of normal human physiology, often without any therapeutic intent (though a clinical trial could include such components, often labeled as “translational” or “basic science” aims.) Measurements in such studies could include, but are not limited to, a blood draw, EKG, EEG, MRI, auditory or sensory testing, checking vital signs, DEXA scans, eye tracking, specimen collection, exercise, fasting, special diets, etc.
- **Behavioral intervention/study** – May be used to refer to studies of individual or group behavior. This option does not include drugs, biologics, or devices but could include psychotherapy, lifestyle counseling, behavior modification, etc.
- **Diagnostic trial** – Protocol designed to evaluate one or more interventions aimed at identifying a disease or health condition (ClinicalTrials.gov & FDA)
- **Observational**
- **Expanded Access** – A process regulated by the Food and Drug Administration (FDA) that allows manufacturers to provide investigational new drugs to patients with serious diseases or conditions who cannot participate in a clinical trial. Examples of expanded access include non-protocol access to experimental treatments, including protocol exception, single-patient IND, treatment IND, compassionate use, emergency use, continued access to investigational drug, and parallel track (ClinicalTrials.gov & FDA).
- **Registry** – The collection and maintenance of data (not including biologic samples) in which: (1) the individuals in the registry have a common or related condition(s), and/or (2) the individuals in the registry are interested in being contacted for future studies by investigators other than those listed in Section II of this project. (UI Guide)
-

Repository – The collection, storage, and distribution of human biologic samples and/or data materials for research purposes. Repository activities involve three components: (i) the collection of data and/or specimens such as blood, tissue, saliva, etc.; (ii) the storage of data or specimens, and data management function; and (iii) the sharing of data/specimens with recipient investigators other than the original investigators. (paraphrased from [OHRP](#))

-

Other

VII.B.2 *Does this project involve a [drug washout](#) (asking subject to stop taking any drugs s/he is currently taking)?*
No

VII.B.11 *Is there a separate, written protocol that will be submitted in addition to this IRB New Project form? (Note: a grant application is not considered to be a protocol)*
No

VII.B.18 *Does this project involve testing the safety and/or efficacy of a medical device?*
No

VII.C. Project Description (C)

VII.C.1 *Does this project involve any [research on genes or genetic testing/research](#)?*
No

VII.D. Project Description (D)

VII.D.1 *Check all materials/methods that will be used in recruiting subjects (you will need to attach copies of all materials at the end of the application):*

- Recruitment emails will be sent to introduce the study and will include research team contact information.

VII.D.8 *Will a member of the research team discuss the study with the subject in person prior to the subject agreeing to participate?*
Yes

VII.D.9 *Describe the physical location where the consent process will take place:*
The consent process will be an individual face-to-face interaction with one of the research team members and will take place at a private location identified to ensure comfort and privacy, allowing the potential participant the ability to freely ask questions. The location for consent will be the Human Performance and Clinical Outcomes Lab (WilkenLab) at 21D EMRB.

VII.D.10 *Will a member of the research team discuss the study with the subject by phone prior to the subject agreeing to participate?*
Yes

VII.D.11 *Describe:*
Potential participants can contact the study team to express interest in the study after seeing the emails. If they contact the study team, potential participants will be provided a general overview of the intent of the study consistent with the phone script or email response.

VII.D.12 *Who will be involved in the [consent process](#) (including review of consent document, answering subjects' questions)?*

Name	Consent Process Involvement
Cesar de Cesar Netto, MD, PhD	Yes
Matthieu Lalevee, MD, MSc	Yes
Jason Wilken, MPT, PhD	Yes
Nacime Salomao Barbachan Mansur, MD, PhD	Yes
Kevin Dibbern, PhD	Yes
Kepler Carvalho, MD	Yes
Marie-Anne Melone, MD, MSc	Yes

VII.D.15 *Check all materials that will be used to obtain/document informed consent:*

- Consent Document

- VII.D.16** *Are you requesting a [waiver of documentation](#) of consent (either no subject signature or no written document)?*
No
- VII.D.19** ***Before** the subject gives consent to participate are there any screening questions that you need to directly ask the potential subject to determine eligibility for the study?*
Yes
- VII.D.20** *List any screening questions you will directly ask the potential subject to determine eligibility.*
Inclusion Criteria:
- Are you between the ages of 18 and 40?
- Are you physically active (any type of sport without any level and frequency of practice)?
- Are you able to read and write in English and provide written informed consent?
- Exclusion Criteria:
- Do you have a history of lower limb conditions (excluding ankle sprains) that affect your walking?
- Did you sprain your ankle in the past 2 months?
- Do you have any neurological or sensorimotor impairment?
- Do you have any uncorrected visual or hearing impairment?
- Are you pregnant?
- Do you weigh more than 95kg (209lbs)?
- VII.D.21** *Will you keep a screening log or other record that would include information on people who do not enroll in the study?*
No
- VII.D.25** ***After** the subject agrees to participate (signs consent), are there any screening procedures, tests, or studies that need to be done to determine if the subject is eligible to continue participating?*
Yes
- VII.D.26** *List and describe screening*
Additional post-screening questions and activities will be completed consistent with the attached enrollment checklist. We will have participants answer questions and complete a series of activities to verify they meet the inclusion/exclusion criteria.
- We will verify their age is between 18 and 40 and record their gender.
We will record their height and weight, and verify their weight is less than 95kg (209lbs.)
We will ask them which they are mainly practicing.
We will ask them if they practice this sport for competition or leisure
We will ask them how long they exercise on average per month.
- VII.D.27** *Discuss how much time a potential subject will have to agree to consider participation and whether or not they will be able to discuss the study with family/friends before deciding on participation.*
Data collection will take place at scheduled times. If an individual would like additional time to consider participation and/or request additional time to speak with family or friends, their visit will be rescheduled at a later date.
- VII.D.28** *How long after the subject agrees to participate do study procedures begin?*
Immediately following consent.
- VII.D.29** *Provide a description of the enrollment and consent process for adult subjects*
- *Describe each study population separately including control population*
 - *Include when recruitment and consent materials are used*
 - *Use 3rd person active voice “The Principal Investigator will identify subjects. For example, the principal investigator will identify potential subjects, the study coordinator will discuss the study with subjects over the telephone and schedule the first study visit, etc...”*
 - *Describe the steps that will be taken by the research team to minimize the possibility of coercion or undue influence during the consent process*

The study population will consist of individuals that meet all of the listed inclusion and none of the exclusion criteria as verified using the pre-screening and post-consent questions and brief assessment as listed on the enrollment checklist.

Recruitment emails will contain contact information for the research study team and potential subjects will be invited to contact a member of the study team through email or by phone. Potential subjects receiving the recruitment email will be free to ignore this one if there are not interested in the study. If they contact a study team member, he will initially use the pre-screening checklist to assess eligibility. If they are eligible or wish to complete the pre-screening in person a study team member will work with the potential participant to identify a time for them to meet with a member of the study team. All other procedures will occur in the Human Performance and Clinical Outcomes Laboratory in 21D EMRB.

The study team member will conduct the consent process in a comfortable setting (21D EMRB) where the potential participant is able to ask as many questions they deem fit without pressure. To minimize the risk of coercion, the clinical providers will not be involved in the consenting process and will specify that the patient's participation, or lack thereof, in the study will have no effect on the care they receive. The study team member will verify that the potential participant meets all inclusion and exclusion criteria using the questions and activities listed on the enrollment checklist. Before reviewing the informed consent document, subjects will be provided a consent summary. The study team member will then review the entire consent form with the potential participant and the participant will sign the consent form only after all questions are addressed. No methods of coercion shall be used for recruitment.

VII.D.37 *Does the study include any form of deception (e.g., providing participants with false information, misleading information, or withholding information about certain study procedures)?*

Examples:

- *Procedure includes a cover story that provides a plausible but inaccurate account of the purposes of the research.*
- *Participants will be provided with false information regarding the particular behaviors of interest in the research.*
- *Procedures include a confederate pretending to be another participant in the study.*
- *Participants will be told that the research includes completion of a particular task, when in fact, that task will not be administered.*
- *Study is designed to introduce a new procedure (or task) that participants are not initially told about.*
- *If yes, a waiver of informed consent must be requested under question IV.3.*

No

VII.E. Project Description (E)

VII.E.1 *Will subjects be randomized?*

No

VII.E.3 *Will any questionnaires, surveys, or written assessments be used to obtain data directly from subjects in this study?*

Yes

VII.E.4 *List all questionnaires, surveys, written assessments and ATTACH each one to the application. (NOTE: You are NOT prohibited from attaching copyrighted materials to this application)*

Participants will complete three validated questionnaires before the test (the Cumberland Ankle Instability Tool (CAIT) (Appendix 2), the Identification of Functional Ankle Instability Questionnaire (IdFAI) (Appendix 3) and the Foot Ankle Ability Measure (FAAM) (Appendix 4).

VII.E.5 *Does this project involve creating any audiotapes, videotapes, or photographs?*

Yes

VII.E.6 *Provide a detailed description in sequential order of the study procedures following the consent process - DO NOT cut and paste from the Consent Document.*

Describe study populations separately if they will be participating in different procedures - include CONTROL population if applicable.

DESCRIBE:

- *What subjects will be asked to do/what happens in the study (in sequential order)*
- *The time period over which procedures will occur*

- *The time commitment for the subject for individual visits/procedures*
- *Long-term followup and how it occurs*

The approximate time required to complete all study activities (including consent) is 1.5 hours.

Potential participants will answer pre-screening questions as listed on the Enrollment Checklist. If they meet all inclusion and exclusion criteria they will be consented to participate.

Once consented, they will go through the post-consent portion of the Enrollment Checklist. If they do not meet all inclusion and exclusion criteria their participation will end at that point. Further, it is possible that additional information may come to light during study participation that indicates the individual does not meet the inclusion criteria at which point their participation would end.

Each subject will walk wearing bilateral instability boots on a secure treadmill supported by a harness. These instability boots will initially be locked in a stable position while subject walks. The inversion instability will be triggered remotely by the observer at a random time after at least 3 minutes walking. The instability boot will be coupled with three Inertial Moment Units (IMUs). Data from these IMUs will be collected and the inversion angles and velocities during the first stance phase following the triggering of the instability will be analyzed.

Each subject will respond to three validated questionnaires before the test (the Cumberland Ankle Instability Tool (CAIT) (Appendix 1), the Identification of Functional Ankle Instability Questionnaire (IdFAI) (Appendix 2) and the Foot Ankle Ability Measure (Appendix 3) (FAAM)).

Both ankles will be included in the analysis for each subject except in the case of unilateral CAI in which case the contralateral side will be excluded from the analysis to avoid bias. According to Hiller et al. (4), an ankle with a CAIT less than 27 will be included in the CAI group and an ankle with a CAIT greater than or equal to 27 will be included in the control group. These two groups will be compared on our assessment criteria.

The following steps will be part of the study procedures:

- Post-consent screen on Enrollment Checklist to verify inclusion/exclusion criteria.
- Data Collection Form(s) will be used to collect demographic (e.g. age and gender), anthropometric, sport activity information
- Completion of questionnaires.
- Participant setup – boots placement.
- Participant will be secured with a harness coupled to the treadmill.
- Participants will be informed when they are being recorded.
- Participant will walk, boots locked in a stable position, on a treadmill for 3 minutes.
- After that, the investigator will remotely trigger the instability of one boot (at a random time between 3- and 10-minutes' walk).
- The treadmill will stop.
- The same protocol will then be performed on the contralateral ankle.
- Boots will be removed.

VII.E.7 *Will you attempt to recontact subjects who are lost to follow-up?*

No - followup is not required in this study

VII.E.9 *Will subjects be provided any compensation for participating in this study?*

No

VIII. Risks

VIII.1 *What are the risks to subjects including*

- *emotional or psychological*
- *financial*
- *legal or social*
- *physical?*

The proposed study activities are considered no more than minimal risk which presumes that risks of the research are not greater, in and of themselves, than those ordinarily encountered in daily life. The risk benefit ratio of this proposed study is considered justifiable as it is relatively low risk and will provide valuable data and lay an important knowledge framework for chronic ankle instability understanding.

The primary risks to study participants are loss of privacy and/or breach of confidentiality, which are known risks inherent to all research studies. To protect privacy and prevent breaches of confidentiality, we

will use the minimal amount of identifiable information possible while still meeting the needs of the study. All study personnel will demonstrate knowledge of applicable regulations by completing courses of instruction through the CITI program. A code (e.g. P001) will be used to represent individuals on all study forms and files. Research team members will use standard practices to preserve the privacy of the participant as much as possible, such as refraining from discussing sensitive topics, referring to private health information or other personally identifiable information. Further, the video of participants will be kept in a restricted access location.

Secondary risks to study participants are the possibility of injury. Theoretical risks of ankle sprain and falls when the boot will become unstable exist. However, several measures will be taken to control these risks and allow you to participate in a secure manner.

The instability boot (Myolux Athletik®) we will use, is a device developed and validated for ankle instability rehabilitation which hold the ankle to prevent excessive motion and injury. The device includes a boot that surrounds the foot and ankle providing stability at the ankle joint. This boot was already used in several studies. None of these studies reported any injuries.

The study will be performed in a treadmill with overhead safety harness. You will walk on a treadmill and the suspension harness will be set so you are unable to fall to their knees or the ground. This system has been previously used for multiple studies evaluating balance and recovery from challenges to balance. All testings will be conducted by trained research staff. Furthermore, if at any time it appears participants cannot safely perform a test once begun, they will be stopped.

VIII.2

What have you done to minimize the risks?

- ***If applicable to this study ALSO include:***
 - ***How you (members of your research team at Iowa) will monitor the safety of individual subjects.***
 - ***Include a description of the availability of medical or psychological resources that subjects might require as a consequence of participating in this research and how referral will occur if necessary (e.g. availability of emergency medical care, psychological counseling, etc.)***

Study staff will speak with participants throughout the testing session to ensure safety and comfort. Risks to participants in the study are low since the protocol involves walking. The subject will be informed to indicate in person, or when not immediately evident, inform over the phone if any adverse event occurs. The event will be monitored and reported to the IRB in accordance with the governing policy and procedures. If an event occurs during the implementation of study procedures the most senior person locally available will be notified and a study team member can help facilitate securing appropriate medical or professional intervention if needed. In addition, a report of the adverse event will be provided to the IRB as required.

To minimize the risk of loss of confidentiality of data study activities will take place in the HPCO lab, away from other individuals. Collected data will be logged and tracked using a non-identifying participant code and time date code (alphanumeric subject ID and/or YYYYMMDD_TTTT) to protect participants identity. Study files will be carefully secured, paper copies through locked storage and electronic copies in a password-protected environment. Access to this information will be limited to properly trained individuals on the study team who require access.

VIII.3

Does this study have a plan to have an individual or committee review combined data from all subjects on a periodic basis (such as summary or aggregate safety and/or efficacy data)?

No

IX. Benefits

IX.1

What are the direct benefits to the subject (do not include compensation or hypothesized results)?

Participants will not receive direct benefit from participating.

IX.2

What are the potential benefits to society in terms of knowledge to be gained as a result of this project?

Other people might benefit from this study because the information gained as part of this study may play a role in diagnosing and preventing chronic ankle instability.

X. Privacy & Confidentiality

X.1

What are you doing to protect the privacy interests of the subjects?

The informed consent process and study procedures will be conducted in a private and secured laboratory space (21D EMRB) to minimize the likelihood of individuals observing their participation or overhearing

the participant's personal information. All data collection files and paperwork are coded at the time of collection (alphanumeric subject ID and/or YYYYMMDD_TTTT) ensuring there are no readily available links to the individual. Consent forms will be kept separate from data files. The participant video will be kept on a password restricted drive only accessible to authorized individuals. Further, we seek to collect no more data than necessary to answer the research question.

X.2 *Are you collecting the Social Security Number of any subjects for any purpose?*
No

X.4 *How will information/data be collected and stored for this study (check all that apply):*

- Electronic records (computer files, electronic databases, etc.) - Electronic records (computer files, etc.) will be stored on password protected computers and/or Dr. Wilken's RDSS network server drive. Access to the network requires both individual access to a University of Iowa computer using Healthcare ID and password, and permission to access the study folder which is controlled by Dr Wilken via HCIS. These steps serve to limit access to only study team members who can and need to have access. Only coded data will be retained.
- Paper/hard copy records (hard copy surveys, questionnaires, case report forms, pictures, etc.) - Data will be coded with links stored separately. Paper/hard copy study records will be stored in secured locations such as locked file cabinets in limited access locations.

X.5 *Do the confidentiality protections indicated above allow only members of the research team to access the data/specimens?*

Yes

X.7 *Does your study meet the NIH criteria for a [Certificate of Confidentiality](#) or will you be applying for Certificate of Confidentiality?*

No

XI. Data Analysis

XI.1 *Describe the analysis methods you will use, including, if applicable, the variables you will analyze*

Both subjects' ankles will be included in the analysis except in the case of unilateral chronic ankle instability in which case the contralateral side will be excluded from the analysis to avoid bias. According to Hiller et al. (4), an ankle with a Cumberland Ankle Instability Tool (CAIT) less than 27 will be included in the CAI group and an ankle with a CAIT greater than or equal to 27 will be included in the control group. These two groups will be compared on our assessment criteria.

These criteria will be collected using IMUs (STT®, Isen 3.0) at the very moment the boot will become unstable.

- Primary assessment criterion = Maximal inversion angle (°)
- Secondary assessment criterion = Maximal inversion velocity (°/sec)

A Shapiro Wilk test will be performed on each variable to know their normality distribution.

To answer AIM 1: Determine whether maximal inversion angle during sudden inversion instability differentiates between individuals with and without ankle instability.

Mean Maximal inversion angle in CAIT and control groups will be compared using a Student T test if normal and a Wilcoxon test if non-normal.

To answer AIM 2: Determine whether maximal inversion velocity during sudden inversion instability differentiates between individuals with and without ankle instability.

Mean Maximal inversion velocity in CAIT and control groups will be compared using a Student T test if normal and a Wilcoxon test if non-normal.

To answer AIM 3: Determine if maximal inversion angle and velocity magnitude are associated with reported severity of ankle instability.

Correlations between questionnaire (CAIT, IdFAI and FAAM) results and maximal inversion angle and velocity will be assessed using the Pearson correlation coefficient if normal and using the Spearman's rank correlation coefficient if not normal.

XI.2 *Provide the rationale or power analysis to support the number of subjects proposed to complete this study.*

In Simpson et al. (9) study, the mean maximal inversion angle, when landing on an inverted platform, was 21.4°±2.9 in CAI compared to 19°±2.9 in control subjects. Considering these values, a type 1 risk of

5%, a type 2 risk of 20% and a unilateral test, 18 ankles per group would be necessary to find a significant difference between groups on our primary assessment criterion.
According to Lin et al. (10), the prevalence of CAI in a physically active population is approximately 25%. Therefore, we will need 18 ankles in our CAI group and considering that we will exclude contralateral ankle from the analysis in case of unilateral CAI.
Therefore, we will need to enroll 45 subjects.

XII. Future Research

- XII.1** *Do you wish to keep any information about subjects involved with this research project so that members of the current research team may contact them in the future for your own research projects?*
Yes
- XII.2** *Do you wish to keep any information about subjects involved with this research project so that [other researchers](#) may contact them for future research?*
No
- XII.3** *List the data or information you will keep:*
First and Last name, Preferred phone number, Secondary phone number, Email address, Gender, Birth month, Birth year, Interest in contact for future studies.
- XII.4** *Does this project involve storing any data, tissues or specimens for future research?*
Yes – contribution for future use is mandatory for participation in the study

INFORMED CONSENT DOCUMENT

Project Title:

MYOLUX: Validation of a device for diagnosing and quantifying chronic ankle instability.

Principal Investigator: Cesar de Cesar Netto, MD, PhD (319) 678-7943

Research Team Contact: Matthieu Lalevee, MD, MSc (319) 621-9953

This consent form describes the research study to help you decide if you want to participate. This form provides important information about what you will be asked to do during the study, about the risks of the study, and about your rights as a research subject.

- If you have any questions about or do not understand something in this form, you should ask the research team for more information.
- You should discuss your participation with anyone you choose such as family or friends.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We are inviting you to participate in this research study because you:

- 1) are between the ages of 18 and 40 years old
- 2) are physically active
- 3) have no history of lower limb impairment (except ankle sprains)
- 4) have not sprained your ankle in the past 2 months
- 5) weight less than 95kg (209lbs)
- 6) are not pregnant
- 7) have no neurological or sensorimotor impairment
- 8) have no diagnosed osteoporosis or history of low energy fracture
- 9) do not have any uncorrected visual or hearing impairments
- 10) are able to read and write in English and provide written informed consent.

The purpose of this study is to determine whether maximal inversion angle and velocity during sudden inversion instability differentiates between individuals with and without ankle instability.

HOW MANY PEOPLE WILL PARTICIPATE?

45 subjects will take part in this study conducted by investigators at the University of Iowa.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for one visit of 2 hours.

WHAT WILL HAPPEN DURING THIS STUDY?

Study activities:

- After consent we will check the Enrollment Checklist to verify you are eligible to continue participating. If you are not, your participation in the study will end at that point.
- You will provide demographic information (height, weight, age, gender).
- You will provide information on your sports activity (type of sport, competition or leisure, hours of practice per month).
- You will complete three foot and ankle questionnaires (the Cumberland Ankle Instability Tool, the Identification of Functional Ankle Instability Questionnaire and the Foot Ankle Ability Measure)
- The investigator will attach instability boots to both of your ankles.
- The investigator will secure you with a harness coupled to the treadmill.
- You will walk, boots locked in a stable position, on a treadmill for 3 minutes.
- After that, the investigator will remotely trigger the instability of one boot (at a random time between 3- and 10-minutes' walk).
- Data (inversion angle and velocity) will be harvested from Inertial Moment Units attached to the boots; at the very moment the boot will become unstable.
- The treadmill will be stop after this time.
- The same protocol will then be performed on your contralateral ankle.
- Your trials will be video recorded from back. The video will be used for data quality control purposes.

Data Storage for Future Use

As part of this study, we are obtaining data about you, including data about your ankle motions. This data will be used to complete the above-mentioned study. We would also like to use this data in the future without additional consent, after this study is over.

Tests we might want to use to study your movement may not even exist at this time. Therefore, we are asking for your permission to store the data we collect today so that we can study them in the future. These future studies may provide additional information that will be helpful in understanding chronic ankle instability. It is possible that your movement information might be used to develop products or tests that could be patented and licensed. There are no plans to provide financial compensation to you should this occur.

If you agree now to future use of your data, but decide in the future that you would like to have it removed from future research, you should contact Cesar de Cesar Netto MD, PhD (319) 678-

7943 or Matthieu Lalevee MD (319) 621-9953. However, if some research with your data has already been completed, the information from that research may still be used.

We may attempt to contact you in the future to determine if you want to participate in future studies. In order to contact you we will also retain your name, address, phone number, and email address in a secure location to allow follow up at that time. You would be asked to provide consent for future studies, and participation in this study does not obligate you to participate in future studies.

Video Recording/Photographs

One aspect of this study involves making standard video recordings of you as you walk. The video will be used to both represent your normal walking and as a quality control measure for interpreting the data.

The videos and photos will only be available to study team members and will be retained indefinitely.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

The primary risk is a loss of privacy and/or breach of confidentiality, which are known risks associated with research studies. To protect privacy and prevent breaches of confidentiality, we will use the minimal amount of identifiable information possible while still meeting the needs of the study. A code will be used to identify you on study forms. Further, video collected during testing will be kept on a restricted access computer drive.

A secondary risk is the potential for injury or physical discomfort. Theoretical risks of ankle sprain and falls when the boot will become unstable exist. However, several measures will be taken to control these risks and allow you to participate in a secure manner.

The instability boot (Myolux Athletik®) we will use, is a device developed and validated for ankle instability rehabilitation which hold the ankle to prevent excessive motion and injury. The device includes a boot that surrounds the foot and ankle providing stability at the ankle joint. This boot was already used in several studies. None of these studies reported any injuries.

The study will be performed in a treadmill with overhead safety harness. You will walk on a treadmill and the suspension harness will be set so you are unable to fall to their knees or the ground. This system has been previously used for multiple studies evaluating balance and recovery from challenges to balance

All testings will be conducted by trained research staff, and if there are concerns you won't be able to perform a test safely it will be stopped.

WHAT ARE THE BENEFITS OF THIS STUDY?

You will not benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study because the information gained as part of this study may play a role in diagnosing and preventing chronic ankle instability.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study.

WILL I BE PAID FOR PARTICIPATING?

You will not be paid for being in this research study.

WHO IS FUNDING THIS STUDY?

The University and the research team are not receiving payments from other agencies, organizations, or companies to conduct this research study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

- If you are injured or become ill from taking part in this study, medical treatment is available at the University of Iowa Hospitals and Clinics.
- The University of Iowa does not plan to provide free medical care or payment for treatment of any illness or injury resulting from this study unless it is the direct result of proven negligence by a University employee.
- If you experience a research-related illness or injury, you and/or your medical or hospital insurance carrier will be responsible for the cost of treatment.

WHAT ABOUT CONFIDENTIALITY?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people, such as those indicated below, may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- federal government regulatory agencies,

- auditing departments of the University of Iowa, and
- the University of Iowa Institutional Review Board (a committee that reviews and approves research studies)

To help protect your confidentiality, we will use a code rather than your name on study documents, and carefully secure and restrict access to study files, both hard copy (through locked storage) and electronic (stored in password-protected environment). Access to information will be limited to only properly trained individuals on the study team who must have access. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

The University of Iowa Hospitals and Clinics generally requires that we document your participation in research occurring in a University of Iowa Health Care facility. This documentation will be in either your medical record or a database maintained on behalf of the institution reflecting that you are participating in this study. The information included will provide contact information for the research team as well as information about the risks associated with this study. We will keep this Informed Consent Document in our research files; it will not be placed in your medical record chart.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which otherwise qualify.

What if I Decide to Drop Out of the Study?

You may withdraw this consent at any time and discontinue further participation in this study without any consequence. Should you choose to withdraw, you must inform a member of the research team. There are no anticipated negative effects associated with withdrawal from the study. If you withdraw your consent, data collected on you up to that point may be included in analysis and published.

Will I Receive New Information About the Study while Participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

Can Someone Else End my Participation in this Study?

Under certain circumstances, such as concern for your safety, staff availability or other factors the researchers may terminate your participation in this study.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact Cesar de Cesar Netto MD, PhD (319) 678-7943 or Matthieu Lalevee MD (319) 621-9953. If you experience a research-related injury, please contact Cesar de Cesar Netto MD, PhD (319) 678-7943 or Matthieu Lalevee MD (319) 621-9953.

If you have questions, concerns, or complaints about your rights as a research subject or about research related injury, please contact the Human Subjects Office, 105 Hardin Library for the Health Sciences, 600 Newton Rd, The University of Iowa, Iowa City, IA 52242-1098, (319) 335-6564, or e-mail irb@uiowa.edu. General information about being a research subject can be found by clicking “Info for Public” on the Human Subjects Office website, <http://hso.research.uiowa.edu/>. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.

This Informed Consent Document is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by signing this Informed Consent Document. Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Subject's Name (printed):

(Signature of Subject)

(Date)

Statement of Person Who Obtained Consent

I have discussed the above points with the subject or, where appropriate, with the subject’s legally authorized representative. It is my opinion that the subject understands the risks, benefits, and procedures involved with participation in this research study.

(Signature of Person who Obtained Consent)

(Date)

Study ID (assigned post consent): _____

Date (YYYYMMDD): _____

Staff Name: _____

MYOLUX Study: Enrollment Checklist

PRE-SCREENING:

Inclusion Criteria: All must be checked YES to be eligible for the study

- | | | |
|--|--------------------------------|---------------------------------|
| 1. Are you between the ages of 18 and 40? | <input type="checkbox"/> _0 No | <input type="checkbox"/> _1 Yes |
| 2. Are you physically active (any type of sport without any level and frequency of practice) | <input type="checkbox"/> _0 No | <input type="checkbox"/> _1 Yes |
| 3. Are you able to read and write in English and provide written informed consent? | <input type="checkbox"/> _0 No | <input type="checkbox"/> _1 Yes |

Exclusion Criteria: All must be checked NO to be eligible for the study

- | | | |
|--|--------------------------------|---------------------------------|
| 1. Do you have a history of lower limb conditions (excluding ankle sprains) that affect your life? | <input type="checkbox"/> _0 No | <input type="checkbox"/> _1 Yes |
| 2. Did you sprain your ankle in the past 2 months? | <input type="checkbox"/> _0 No | <input type="checkbox"/> _1 Yes |
| 3. Do you have any neurological or sensorimotor impairment? | <input type="checkbox"/> _0 No | <input type="checkbox"/> _1 Yes |
| 4. Do you have diagnosed osteoporosis or history of low energy fracture? | <input type="checkbox"/> _0 No | <input type="checkbox"/> _1 Yes |
| 5. Do you have any uncorrected visual or hearing impairment? | <input type="checkbox"/> _0 No | <input type="checkbox"/> _1 Yes |
| 6. Are you pregnant? | <input type="checkbox"/> _0 No | <input type="checkbox"/> _1 Yes |
| 7. Do you weigh more than 95kg (209lbs)? | <input type="checkbox"/> _0 No | <input type="checkbox"/> _1 Yes |

Screening Result

- | | | |
|--|--------------------------------|---------------------------------|
| 1. Does the participant meet all inclusion criteria and none of the exclusion criteria as part of the screening? | <input type="checkbox"/> _0 No | <input type="checkbox"/> _1 Yes |
|--|--------------------------------|---------------------------------|

Study ID (assigned post consent): _____

Date (YYYYMMDD): _____

Staff Name: _____

POST-CONSENT:

Participant Information

1. What was their age at their last birthday: (Between ages 18 and 40?)	_____ yo
2. What is their gender?	<input type="checkbox"/> Male <input type="checkbox"/> Female
3. What sport do they mainly practice?	_____
4. Do they practice this sport for competition or leisure?	<input type="checkbox"/> Competition <input type="checkbox"/> Leisure
5. Approximately how long do you exercise on average per month?	_____ hours
6. What is the participant's height?	_____ m
7. What is the participant's weight?	_____ kg

Eligibility

7. Does the participant meet all inclusion criteria and none of the exclusion criteria?	<input type="checkbox"/> No <input type="checkbox"/> Yes
8. Is the participant enrolled into the study?	<input type="checkbox"/> No <input type="checkbox"/> Yes

Human Performance and Clinical Outcomes Lab

Coordinator Checklist – MYOLUX

Employee: _____

Date: _____

<u>Task</u>	<u>Start</u>	<u>End</u>	<u>✓</u>
Before Data Collection Begins			
Gather paperwork			
Prepare camera/video recorder			
Charge IMUs and Batteries			
Participant Arrives			
Review informed consent document with participant			
Review Enrollment Post-Screening Checklist			
Participant fills out CAIT, IDFAI and FAAM questionnaires			
Setup with Participant			
Put hygiene cover on bare feet			
Attach Instability Boots			
Turn on the IMUs			
Fasten the Belt holding the batteries			
Connect the batteries to the boots			
Attach the harness to the subject			
Acquisition 1			
Start recording video and ISEN software at the same time			
Calibrate IMUs			
Start the treadmill +/- environment video			
Let the patient walk for at least 3 minutes			
Trigger instability on a boot.			
Stop the treadmill.			
Acquisition 2			
Relock the unstable boot			
Calibrate IMUs			
Start the treadmill +/- environment video			
Let the patient walk for at least 3 minutes			
Trigger instability on the contralateral boot			
Stop the treadmill			
Complete IMU registration			
Stop the camera			
Remove harness and boots			
After Participant Leaves			
Transfer motion capture and videos to Network Drives in patient code folder			
Charge IMUs and batteries			

Cumberland Ankle Instability Tool (CAIT)

Please tick the ONE statement in EACH question that BEST describes your ankles.

	Left	Right	Score
1. I have pain in my ankle			
Never	<input type="checkbox"/>	<input type="checkbox"/>	5
During sport	<input type="checkbox"/>	<input type="checkbox"/>	4
Running on uneven surfaces	<input type="checkbox"/>	<input type="checkbox"/>	3
Running on level surfaces	<input type="checkbox"/>	<input type="checkbox"/>	2
Walking on uneven surfaces	<input type="checkbox"/>	<input type="checkbox"/>	1
Walking on level surfaces	<input type="checkbox"/>	<input type="checkbox"/>	0
2. My ankle feels UNSTABLE			
Never	<input type="checkbox"/>	<input type="checkbox"/>	4
Sometimes during sport (not every time)	<input type="checkbox"/>	<input type="checkbox"/>	3
Frequently during sport (every time)	<input type="checkbox"/>	<input type="checkbox"/>	2
Sometimes during daily activity	<input type="checkbox"/>	<input type="checkbox"/>	1
Frequently during daily activity	<input type="checkbox"/>	<input type="checkbox"/>	0
3. When I make SHARP turns, my ankle feels UNSTABLE			
Never	<input type="checkbox"/>	<input type="checkbox"/>	3
Sometimes during running	<input type="checkbox"/>	<input type="checkbox"/>	2
Often when running	<input type="checkbox"/>	<input type="checkbox"/>	1
When walking	<input type="checkbox"/>	<input type="checkbox"/>	0
4. When going down the stairs, my ankle feels UNSTABLE			
Never	<input type="checkbox"/>	<input type="checkbox"/>	3
If I go fast	<input type="checkbox"/>	<input type="checkbox"/>	2
Occasionally	<input type="checkbox"/>	<input type="checkbox"/>	1
Always	<input type="checkbox"/>	<input type="checkbox"/>	0
5. My ankle feels UNSTABLE when standing on ONE leg			
Never	<input type="checkbox"/>	<input type="checkbox"/>	2
On the ball of my foot	<input type="checkbox"/>	<input type="checkbox"/>	1
With my foot flat	<input type="checkbox"/>	<input type="checkbox"/>	0
6. My ankle feels UNSTABLE when			
Never	<input type="checkbox"/>	<input type="checkbox"/>	3
I hop from side to side	<input type="checkbox"/>	<input type="checkbox"/>	2
I hop on the spot	<input type="checkbox"/>	<input type="checkbox"/>	1
When I jump	<input type="checkbox"/>	<input type="checkbox"/>	0
7. My ankle feels UNSTABLE when			
Never	<input type="checkbox"/>	<input type="checkbox"/>	4
I run on uneven surfaces	<input type="checkbox"/>	<input type="checkbox"/>	3
I jog on uneven surfaces	<input type="checkbox"/>	<input type="checkbox"/>	2
I walk on uneven surfaces	<input type="checkbox"/>	<input type="checkbox"/>	1
I walk on a flat surface	<input type="checkbox"/>	<input type="checkbox"/>	0
8. TYPICALLY, when I start to roll over (or "twist") on my ankle, I can stop it			
Immediately	<input type="checkbox"/>	<input type="checkbox"/>	3
Often	<input type="checkbox"/>	<input type="checkbox"/>	2
Sometimes	<input type="checkbox"/>	<input type="checkbox"/>	1
Never	<input type="checkbox"/>	<input type="checkbox"/>	0
I have never rolled over on my ankle	<input type="checkbox"/>	<input type="checkbox"/>	3
9. After a TYPICAL incident of my ankle rolling over, my ankle returns to "normal"			
Almost immediately	<input type="checkbox"/>	<input type="checkbox"/>	3
Less than one day	<input type="checkbox"/>	<input type="checkbox"/>	2
1-2 days	<input type="checkbox"/>	<input type="checkbox"/>	1
More than 2 days	<input type="checkbox"/>	<input type="checkbox"/>	0
I have never rolled over on my ankle	<input type="checkbox"/>	<input type="checkbox"/>	3

Identification of Functional Ankle Instability (IdFAI)

Instructions: This form will be used to categorize your ankle stability status. A separate form should be used for the right and left ankles. Please fill out the form completely and if you have any questions, please ask the administrator. Thank you for your participation.

Please carefully read the following statement:

“Giving way” is described as a temporary uncontrollable sensation of instability or rolling over of one’s ankle.

I am completing this form for my **RIGHT/LEFT** ankle (circle one).

1.) Approximately how many times have you sprained your ankle? _____

2.) When was the last time you sprained your ankle?

Never > 2 years 1-2 years 6-12 months 1-6 months < 1 month

3.) If you have seen an athletic trainer, physician, or healthcare provider how did he/she categorize your most serious ankle sprain?

Have **not** seen someone Mild (Grade I) Moderate (Grade II) Severe (Grade III)

4.) If you have ever used crutches, or other device, due to an ankle sprain how long did you use it?

Never used a device 1-3 days 4-7 days 1-2 weeks 2-3 weeks >3 weeks

5.) When was the last time you had **“giving way”** in your ankle?

Never > 2 years 1-2 years 6-12 months 1-6 months < 1 month

6.) How often does the **“giving way”** sensation occur in your ankle?

Never Once a year Once a month Once a week Once a day

7.) Typically when you start to roll over (or 'twist') on your ankle can you stop it?

Never rolled over Immediately Sometimes Unable to stop it

8.) Following a typical incident of your ankle rolling over, how soon does it return to 'normal'?

Never rolled over Immediately < 1 day 1-2 days > 2 days

9.) During "Activities of daily life" how often does your ankle feel **UNSTABLE**?

Never Once a year Once a month Once a week Once a day

10.) During "Sport/or recreational activities" how often does your ankle feel **UNSTABLE**?

Never Once a year Once a month Once a week Once a day

Foot and Ankle Ability Measure (FAAM)

Foot and Ankle Ability Measure (FAAM)
Activities of Daily Living Subscale

Please Answer **every question** with **one response** that most closely describes your condition within the past week.

If the activity in question is limited by something other than your foot or ankle mark "Not Applicable" (N/A).

	No Difficulty	Slight Difficulty	Moderate Difficulty	Extreme Difficulty	Unable to do	N/A
Standing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walking on even Ground	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walking on even ground without shoes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walking up hills	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walking down hills	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Going up stairs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Going down stairs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walking on uneven ground	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Stepping up and down curbs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Squatting	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Coming up on your toes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walking initially	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walking 5 minutes or less	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walking approximately 10 minutes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walking 15 minutes or greater	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Foot and Ankle Ability Measure (FAAM)
Activities of Daily Living Subscale
Page 2

Because of your foot and ankle how much difficulty do you have with:

	No Difficulty at all	Slight Difficulty	Moderate Difficulty	Extreme Difficulty	Unable to do	N/A
Home responsibilities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Activities of daily living	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Personal care	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Light to moderate work (standing, walking)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Heavy work (push/pulling, climbing, carrying)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Recreational activities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Foot and Ankle Ability Measure (FAAM)
Sports Subscale**

Because of your foot and ankle how much difficulty do you have with:

	No Difficulty at all	Slight Difficulty	Moderate Difficulty	Extreme Difficulty	Unable to do	N/A
Running	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Jumping	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Landing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Starting and stopping quickly	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cutting/lateral Movements	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ability to perform Activity with your Normal technique	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ability to participate In your desired sport As long as you like	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Brièveté des gastrocnémiens et pathologies du pied. Une physiopathologie controversée

Isolated Gastrocnemius Tightness and Foot Disorders. An Undefined Pathophysiology

M. Lalevée · C. Latrobe · A. Laquievre · M. Ould-Slimane · R. Gauthé · X. Roussignol

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Résumé Introduction : La brièveté des gastrocnémiens est fréquente. Elle est associée à de nombreuses pathologies du pied et de la cheville. La physiopathologie de cette association n'est pas clairement établie. Nous avons réalisé une revue de la littérature afin d'apprécier les connaissances scientifiques actuelles sur l'impact d'une brièveté des gastrocnémiens sur la marche. Nous espérons ainsi affiner la compréhension de cette association entre brièveté des gastrocnémiens et pathologies du pied et de la cheville.

Matériel et méthode : La revue de la littérature a été effectuée à partir des moteurs de recherche Pubmed, Springer-Link et Science Direct.

Résultats : Les études basées sur des constatations cliniques et sur un raisonnement biomécanique semblent en accord pour admettre qu'une limitation de la dorsiflexion de cheville au passage du pas par mise en tension des gastrocnémiens impliquerait une hyperpression sur l'avant-pied.

Les études en laboratoires de marche ne mettent pas en évidence de diminution de la dorsiflexion de cheville au passage du pas, ni d'augmentation de la pression plantaire, chez des patients présentant une brièveté des gastrocnémiens. En revanche, elles mettent en évidence des mouvements définis comme compensateur par les auteurs, en particulier la présence d'un fessum de genou au passage du pas chez les patients rétractés.

Conclusions : Il existe une discordance entre la croyance commune et les résultats d'analyse de marche en laboratoire à ce sujet. Les connaissances scientifiques actuelles ne permettent pas d'expliquer l'augmentation de la prévalence des

pathologies du pied et de la cheville chez les patients présentant une brièveté des gastrocnémiens.

Mots clés Gastrocnémien · Brièveté · Marche

Abstract Introduction: Isolated gastrocnemius tightness is common and often associated with ankle and foot pathologies. The pathophysiology of this association is not clearly established. A review was performed to assess repercussion of gastrocnemius tightness on gait, and to evaluate scientific knowledge on this field.

Materials and methods: The review was conducted using the Pubmed, SpringerLink and Science Direct databases.

Results: Studies based on clinical findings and biomechanical basis, seem to show, that ankle dorsiflexion limitation during swing phase of gait, due to gastrocnemius tightening, lead to forefoot hyperpressure. These findings are not observed in dynamic optoelectronic studies involving patients with gastrocnemius tightness; in which knee fessum during swing phase seems to be a compensatory mechanism.

Conclusions: There is a difference between the common belief and laboratory analysis results on this subject. Current scientific knowledge cannot explain the increased prevalence of foot and ankle pathologies in patients with gastrocnemius tightness.

Keywords Gastrocnemius · Tightness · Gait

Introduction

L'existence d'une brièveté des gastrocnémiens est fréquente. Elle peut être une cause directe de consultation ou être découverte de façon fortuite lors de l'examen clinique du membre inférieur. Sa prévalence exacte est difficile à évaluer mais certains auteurs, comme Kowalski, [1] l'estiment proche de 50 %. Elle est asymptomatique dans la majorité des cas. Cependant, de nombreuses études cliniques émettent un lien entre la brièveté des gastrocnémiens et diverses

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pathologies du pied et de la cheville. L'explication la plus souvent avancée est la limitation de la dorsiflexion de cheville au passage du pas par mise en tension des gastrocnémiens. Elle serait alors indirectement responsable d'une hyperpression sur l'avant-pied. Paradoxalement, cette hypothèse de transfert de charge sur l'avant-pied n'est pas confirmée par de nombreuses études d'analyse de la marche.

Une revue de la littérature était réalisée afin de préciser les conséquences cliniques sur la marche d'une brièveté des gastrocnémiens et de valider des associations avec une pathologie de l'avant-pied ou de l'arrière-pied.

Rappels de biomécanique musculaire

Le triceps sural est composé des deux chefs du muscle gastrocnémien, bi-articulaires (traversant à la fois l'articulation du genou et celle de la cheville) et du muscle soléaire, mono-articulaire.

Cette caractéristique lui confère une mécanique particulière.

Cavagna et al. [2] se sont appuyés sur les travaux d'Archibald Vivian Hill [3], qui introduit un modèle musculaire à trois composantes dont deux élastiques, pour intégrer un concept de *storage output* à la biomécanique musculaire.

En observant qu'un muscle déjà étiré développe une force plus importante à la contraction, il présente ce concept d'emmagasinement restitution de l'énergie élastique. Le travail musculaire est rendu alors plus efficace et plus économique. Ce concept est à la base de la biomécanique des muscles bi-articulaires. Concernant les gastrocnémiens, lors de la marche, le passage du pas s'effectuant en extension de genou et en dorsiflexion de cheville, les deux chefs emmagasinent cette énergie élastique pour la restituer en flexion plantaire de cheville pour permettre et améliorer la propulsion.

Conséquences pathologiques de la brièveté des gastrocnémiens

DiGiovanni et al. [4] ont démontré qu'un groupe de patients présentant divers syndromes douloureux du pied (métatarsalgies, syndrome de Morton, arthrose idiopathique du Lisfranc, insuffisance du tendon tibial postérieur, aponévropathie plantaire, fractures de fatigue...) avait une dorsiflexion de cheville genou en extension inférieure à celle d'un groupe contrôle asymptomatique.

Jastifer et al. [5] ont montré qu'un groupe de sujets, présentant une rétraction de gastrocnémiens, avaient plus de douleur du pied et de la cheville en comparaison à un groupe de témoins.

De nombreux auteurs ont démontré qu'il s'agissait d'une des principales causes de métatarsalgies [6-8].

Barouk [9] l'associe aux hallux valgus juvéniles (avec une brièveté présente dans 78 % des cas), Solan [10] aux

aponévropathies plantaires et aux tendinopathies achilléennes, DiGiovanni [11] aux pieds plats, Lun [12] aux syndromes fémoro-patellaires, Wilder [13] aux périostites et aux fractures de fatigue.

De multiples conséquences pathologiques sont ainsi présentes dans la littérature. Lors d'un symposium en 2006, associant la SFMCP (Société Française de Médecine et Chirurgie du Pied) et l'AFCP (Association Française de Chirurgie du Pied), et consacré à la brièveté des gastrocnémiens, étaient rapportés par ordre de fréquence (série de 185 cas E. Toullec, L.S. Barouk, P. Barouk [8]) :

- hallux valgus : 72 % des patients présentant une brièveté des gastrocnémiens ont un hallux valgus ;
- métatarsalgies : 63 % ;
- griffes d'orteils : 30 % ;
- instabilité de la cheville : 27 % ;
- lombalgies : 17 % ;
- tendinopathie d'Achille : 7 % ;
- valgus de l'arrière-pied : 12,5 % ;
- arthrose du Lisfranc : 5,3 % ;
- aponévrosite plantaire : 4 % ;
- varus de l'arrière-pied : 3,5 % ;
- Haglund : 3 % ;
- pied creux : 2,8 %.

Méthodes

La revue de la littérature entre 1930 et 2017 était effectuée à partir des moteurs de recherche Pubmed, SpringerLink et Science Direct. Les mots clés utilisés étaient : *Gastrocnemius tightness, Ankle dorsiflexion, Gait, Kinematics, Plantar foot pressure*.

Les articles analysant l'impact sur la marche d'une brièveté isolée des gastrocnémiens étaient sélectionnés.

Les articles traitant des causes secondaires de brièveté des gastrocnémiens (notamment les causes neurologiques) étaient exclus.

Résultats

Brièveté des gastrocnémiens et cycle de marche : logique biomécanique et constatations cliniques

Selon Cazeau et Stiglitz [14], l'impact de ce raccourcissement sur la marche se retrouve principalement dans une zone allant du 60° au 88° percentile de la phase d'appui. Dans cette zone, le genou est en position d'extension et la cheville entre -5° et +10° de dorsiflexion. Ils définissent également un point critique à 70,6 % de la phase d'appui, où la résultante du vecteur de force sagittal (propulsion) et vertical

(élévation du centre de gravité) est maximale et centrée sur les têtes métatarsiennes.

Pour Maestro [8], l'équin qu'implique cette brièveté va limiter la dorsiflexion de cheville et transférer les contraintes sur l'avant-pied.

Kowalski [1] ajoute qu'à cette hyperpression s'associe un contact prématuré de l'avant-pied avec le sol et une augmentation de la vitesse d'impact au sol. Pour Kowalski [1], la brièveté des gastrocnémiens a pour conséquence complémentaire directe un valgus de l'arrière-pied, une horizontalisation du long fibulaire. Le premier métatarsien devient alors instable et favorise alors une surcharge des plaques plantaires latérales.

Selon ces auteurs, ce phénomène pourrait expliquer l'incidence accrue de pathologies du pied et de la cheville chez les patients présentant une rétraction des gastrocnémiens.

Brièveté des gastrocnémiens et analyse quantifiée de la marche

Plusieurs études récentes ont analysé la conséquence de cette brièveté dans des laboratoires d'analyse de la marche. Ces laboratoires peuvent inclure un système d'analyse du mouvement en trois dimensions (enregistrements recueillis par l'intermédiaire de mires placées sur la peau des patients), ou une plateforme de baropodométrie recueillant les pressions au sol, ou l'association des deux systèmes.

Wu et al. [15] ont montré qu'en comparaison à des sujets n'ayant pas de rétractions, les patients « gastro-courts » ont une augmentation de l'angle du pas sans différence significative sur la dorsiflexion de cheville.

You et al. [16] ainsi que Chimera et al. [17] retrouvent une augmentation des flexions de hanches et de genoux lors du passage du pas. Par contre, ils ne retrouvent pas de différence significative sur la dorsiflexion de cheville.

Lavery et al. [18] retrouvent une association entre position de la cheville en équin en extension de genou à l'examen clinique, et hyperpression sur l'avant-pied lors d'analyses baropodométriques chez des patients diabétiques. Ces auteurs ne disposaient pas de système 3D complémentaire d'analyse du mouvement.

Autres types d'analyse

Aronow et al. [19] retrouvent une association sur des modèles cadavériques entre rétraction des gastrocnémiens et surcharge de l'avant-pied. Sur une étude anatomique statique de dix membres inférieurs positionnés avec une flexion dorsale de 10° et une charge axiale de 350 N, il existait en tractant les muscles gastrocnémiens (traction maximale de 93 N) une augmentation de 59 % de la charge sur l'avant-pied et de 38 % sur le médiopied. À l'inverse, il existait une diminution de 18 % de la charge sur l'arrière-pied.

Chen et al. [20], lors d'une modélisation 3D, ont mis en évidence une diminution de la dorsiflexion de cheville et une surcharge sur les têtes métatarsiennes.

Discussion

Ces divergences en termes de résultats dans la littérature montrent les difficultés qui existent à caractériser de manière claire l'impact d'une brièveté des gastrocnémiens sur la marche. La logique biomécanique, les résultats d'analyses in vivo, d'analyses cadavériques, les modélisations 3D, montrent des résultats divergents.

La logique biomécanique d'une brièveté des gastrocnémiens est la limitation de la dorsiflexion de cheville en extension au passage du pas. Ce manque de flexion dorsale de la cheville n'a jamais été validé dans les études d'analyse du mouvement. Chen et al. [20] l'avaient retrouvé uniquement sur des modélisations 3D. Des attitudes compensatrices sont validées par des études réalisées en laboratoire de la marche. You et al. [16] et Chimera et al. [17] retrouvaient la présence d'un fessum de genou au passage du pas. Cette attitude permettrait une détente des muscles gastrocnémiens afin de conserver une dorsiflexion de cheville au passage du pas. Elle pourrait également expliquer la prévalence plus élevée de syndromes fémoro-patellaires dans cette population [12].

Wu et al. [15] retrouvaient une augmentation de l'angle du pas. Cette attitude est définie comme compensatrice par ces auteurs. La rotation du pied au sol permettrait selon eux une diminution des forces de contrainte sur l'avant-pied par médialisation du centre de gravité par rapport à ce dernier.

Concernant l'étude de Lavery et al. [18] qui retrouvaient une augmentation de la pression sur l'avant-pied, elle portait uniquement sur une population de diabétiques. Le travail d'Orendurff et al. [21] modère ces résultats. Pour eux, l'équin joue un rôle limité sur la surcharge de l'avant-pied chez les patients diabétiques car d'autres facteurs comme les déformations osseuses, l'épaisseur du tissu plantaire, les modifications de la posture et de la sensibilité, modifient l'appui plantaire.

Conclusion

Il est difficile de conclure sur ce sujet dans l'état actuel de la littérature. Elle est peu abondante et de faible niveau de preuve. Les études en laboratoire de marche réalisées in vivo, semblent être les plus aptes à refléter la réalité. Ces études ne confirment pas la logique biomécanique souvent présentée comme « évidente » par de nombreux auteurs : la brièveté des gastrocnémiens est à l'origine d'une limitation de la flexion dorsale de la cheville et d'un hyper appui

antérieur. Les études d'analyse de la marche montrent avant tout des attitudes compensatrices (flession du genou) sans pouvoir valider la surcharge mécanique de l'avant-pied.

Liens d'intérêts : Les auteurs déclarent ne pas avoir de lien d'intérêt.

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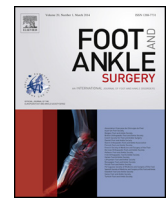


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A comparative study between isolated gastrocnemius tightness patients and controls by quantitative Gait analysis and baropodometry

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ABSTRACT

Background: Isolated gastrocnemius tightness (IGT) has been suggested as an etiologic factor in mechanical disorders of the foot and ankle without a clear pathophysiological mechanism in the literature. We hypothesized that restricted ankle dorsiflexion inducing increased forefoot pressure in IGT patients could be this pathophysiological mechanism.

Methods: Case/control experimental observational investigation. Forty lower limbs in 20 asymptomatic IGT patients were included and compared to controls. Quantitative gait analyses coupled with dynamic baropodometry were used for comparison between groups. The primary outcome was maximum ankle dorsiflexion during stance phase. Secondary outcomes were knee flexion and forefoot pressure.

Results: Maximum ankle dorsiflexion and maximum forefoot pressure were similar between groups. Increased knee flexion was found in the asymptomatic IGT group.

Conclusions: IGT induced compensatory knee flexion during stance phase, which probably prevents increased pressure on the forefoot by allowing ankle dorsiflexion.

Level of evidence: Level IV, Case/control experimental observational investigation.

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1. Introduction

The prevalence of isolated gastrocnemius tightness (IGT) is difficult to clearly assess because of current lack of consensual definition and validated measuring device, but IGT seems to be a frequent condition [1] that could reach 50% of the general population for some authors [2] and could be present in 96.5% in case of foot pathology [3]. IGT is associated with numerous disorders, notably of the forefoot [4,5], such as metatarsalgia or hallux valgus without a clear explanation [6]. In the surgical community, the most widespread hypothesis is that restricted ankle dorsiflexion increases plantar pressure during the mid-stance phase. Cazeau et al. [7] found that the time between the 60th and 88th percentiles of the stance phase was the setting for an increase of pressure on the forefoot: at this point the knee is in extension and the ankle in dorsiflexion. Same observations are present in 3D models [8] and cadaver studies [9],

where restricted ankle dorsiflexion was found with IGT. However, these studies [7–9] were not carried out in living subjects and are only suppositions.

Conversely, laboratory gait analyses in living subjects, did not find these results [10,11]. We are not aware of any study that supports the hypothesis that IGT restricts ankle dorsiflexion in mid-stance phase, except in patients with diabetes mellitus [12], and with neurologic and clubfoot deformities [13,14] which are specific populations with neuropathic involvement, but which are not the subject of our study. Two gait analysis studies [10,11] found increased knee flexion during gait without restricted ankle dorsiflexion. One of these studies [10] analyzed a small number of symptomatic gastrocnemius tightness patients (with forefoot associated pathologies), and both of them [10,11] analyzed ground reaction force using force plates, but not plantar pressure, in unilateral IGT patients. However, painful walking could modify gait, unilateral analyses could be modified by contralateral limb normal motion [15], and it is impossible to analyze precisely an increase of pressure on the forefoot using force plates which only give an overall reaction force of the entire plantar surface without

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possible analyses of located targeted pressure for example on the forefoot. Unlike force plates, dynamic baropodometry can separately assess the pressure on some parts of the foot like the forefoot, midfoot or hindfoot individually.

This discrepancy between clinical and laboratory findings could be due to compensatory mechanisms such as knee flexion found in these two studies which could be overridden under certain conditions. This hypothesis is strengthened by the increase of patellofemoral syndrome in case of IGT [16]. Nevertheless, there is no explanation for the pathophysiological link between IGT and foot pathologies. This insufficient comprehension of gastrocnemius tightness can lead to management errors such as unsuitable lengthening [17]. We suggest that gait analysis, including motion analyses coupled with dynamic baropodometry, in a population with asymptomatic bilateral IGT could give more precise data notably on ankle dorsiflexion and forefoot pressure during the mid-stance phase of gait. We performed a study comparing asymptomatic bilateral IGT patients and controls, using quantitative Gait Analysis and baropodometry.

The objective of this work was to measure knee and ankle range of motions along with peak forefoot pressure during gait. We hypothesized that restricted ankle dorsiflexion and increased forefoot pressure would be observed in IGT patients.

2. Methods

2.1. Inclusion/exclusion criteria

A case/control experimental observational study was done in order to assess the impact of IGT on Gait. All patients were volunteers and recruited from our University Hospital general orthopedic and trauma consultation according to following criteria. Inclusion criteria were age over 18 and under 65 years and pain-free walking. Exclusion criteria were selected in order to exclude pathologies leading to secondary equinus or which could bias measurement procedures. Patients with neurologic pathologies, with clubfoot pathologies or, more generally, with any pathology (spine, hip, knee, ankle and/or foot) liable to affect gait parameters were excluded. Patients with asymmetric Silfverskiöld test [18,19] (one lower limb with a positive test and one with a negative test), with hindfoot valgus greater than 10 degrees, with hindfoot varus, with genu recurvatum greater than 10 degrees or with genu flexum were excluded to avoid confounding biases in analyses.

2.2. Group composition

The study group comprised lower limbs, with positive Silfverskiöld test [18,19], and without associated pathology (forefoot and ankle pathologies, low back pain...), defining asymptomatic IGT. A positive Silfverskiöld test defined as negative ankle dorsiflexion with the knee fully extended and an increase of

≥ 10 degrees in dorsiflexion accompanying 90 degrees' knee flexion [4,20]. Angular measurements were taken manually by the investigator using a system fixed onto the leg and connected to a dynamometer, providing reproducible goniometry (Fig. 1). A traction force of 10 Newtons was applied along the limb axis. Particular attention was paid to the absence of contraction of Tibialis anterior muscle. To test the reproducibility of this measurement, 20 measures on 20 different patients were taken by two surgeons, and the interobserver measurement variation was acceptable (0.97 [0.91; 0.99]) (see Section 2.4).

The control group included lower limbs with negative Silfverskiöld test. The measurement method was identical.

2.3. Examinations

The motion analysis laboratory was equipped with two systems. The ZEBRIS® baropodometer was composed of two ZEBRIS FDM platforms (totaling $628 \times 62 \times 2.5$ cm) with a total of 34,048 receptors (1 per 0.8 cm^2), analyzing plantar pressure distribution.

The VICON® 3D motion analysis system recorded motion within a predefined space via 12 infrared cameras (6 VICON® Bonita and 6 VICON® Vantage) recording the positions of reflective markers. Twenty 14 mm diameter markers were positioned according to the VICON® plug-in gait lower body model [21]. Each patient was calibrated using the same protocol, placing markers in the standard anatomical position with neutral knee (0° of extension) and ankle (0° of dorsiflexion) positions in order to produce valid absolute angle data. Gait analysis used the individual patient's comfortable walking rhythm and speed; acceleration and deceleration phases were not recorded.

The main assessment criterion was maximum ankle dorsiflexion (in degrees) during the stance phase time. One of the secondary assessment criteria was the accompanying knee flexion (in degrees) at the same moment. The VICON® system enabled this measurement.

The other secondary assessment criteria were the maximum forefoot pressure (in $\text{N}/\text{cm}^2/\text{kg}$) and the rearfoot contact time (as percentage of cycle). These were recorded by the ZEBRIS® system. The software automatically generated the mean foot pressure values divided into 3 zones: Forefoot, Midfoot and Rearfoot.

Gait parameters and assessment criteria were collected during the same walking analysis and were analyzed by an independent observer. For each lower limb 6 gait passages about of 12 m each were recorded. For each criterion and passage, the mean value of the 6 passages was used for analysis.

2.4. Statistics

The requisite number of subjects and controls was calculated to be 16 lower limbs each, for alpha risk 5%, 90% power, including a-

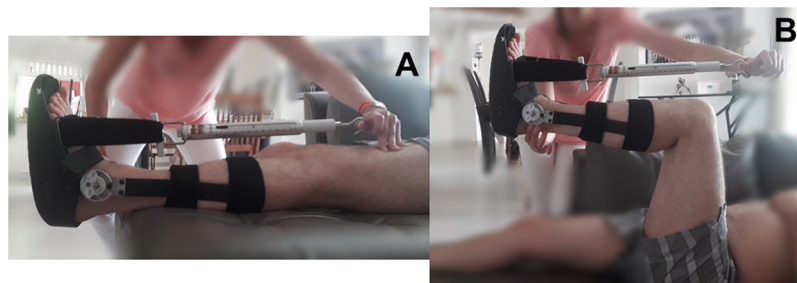


Fig. 1. Ankle angle measuring device.
A. Measurement with the knee in extension.
B. Measurement with 90° knee flexion.

Table 1
 Population data.

	Control group (n = 20) Mean ± SD (Range)	Study group (n = 40) Mean ± SD (Range)	p
Silfverskiöld test: Ankle dorsiflexion with knee in extension (degrees) = ST 0°	2.2 ± 2.6 (0–8)	−7.8 ± 6.1 (−31 to −1)	<0.001
Silfverskiöld test: Ankle dorsiflexion with knee in 90° flexion (degrees) = ST 90°	6.4 ± 4.1 (1–13)	7.7 ± 4.8 (0–15)	0.29
ST 90° - ST 0° =	4.2 ± 2.5 (0–8)	15.5 ± 5.1 (10–42)	<0.001
%male	40	51.2	0.43
Mean weight (kg)	65.7 ± 13.4 (51–88)	68.5 ± 13.7 (45–90)	0.44
Mean age (years)	37.8 ± 14.5 (24–60)	39.9 ± 13.6 (21–65)	0.57

priori variance and a difference of 5 degrees to be detected for the main assessment criterion. Interobserver variability of the manual angle measurement system was assessed with Intra class correlation coefficient. Maximal ankle dorsiflexion and knee flexion were compared using a Student t test. Maximum forefoot pressure and rearfoot contact time were compared using a Mann-Whitney test. All statistical analysis was made using GraphPad Prism® software except for the intra class correlation coefficient which was analysed with R® software.

2.5. Ethics

The study was approved by our University Hospital’s non-interventional research review board. Patients were given a clear explanation of the study protocol and provided informed consent prior to inclusion.

3. Results

The inclusion period was January 1, 2016 to January 1, 2019. Thirty patients were included. After clinical examination and Silfverskiöld test, 20 asymptomatic IGT were included in the study group and 10 in the control group. Each lower limb in both groups was analyzed individually (60 lower limbs overall).

The two groups were comparable for age, gender and weight (Table 1).

On manual measurement (Fig. 1), in comparison with the control group, the study group showed ankle plantarflexion (2.2° ± 2.6 in the control group versus −7.8° ± 6.1 in the study group, p < 0.001) with the knee in extension and greater ankle dorsiflexion gain with flexion of the knee. No difference was found in ankle dorsiflexion between groups with the knee in flexion (Table 1).

Table 2
 Comparison of quantitative gait analysis and baropodometry between study and control groups.

	Control group(n = 20) Mean ± SD (Range)	Study group (n = 40) Mean ± SD (Range)	p
Maximum Ankle dorsiflexion (degrees) = MAD	14.9 ± 3.0 (6.8–19.8)	14.4 ± 3.3 (6.5–21.1)	0.5
Knee flexion (degrees) = KF	3.4 ± 2.3 (0–7.1)	8.3 ± 3.7 (0.9–17.3)	<0.001
MAD - KF =	11.5 ± 3.6 (4.3–17.1)	6.1 ± 3.0 (1.3–13.7)	<0.001
Maximum forefoot pressure (Newton/cm²/kg)	0.69 ± 0.18 (0.41–1.06)	0.66 ± 0.12 (0.47–1.06)	0.45
Rearfoot contact time (% stance phase)	57.9 ± 4.8 (44.7–67.2)	59.5 ± 6.8 (37.3–72)	0.11

These findings matched the respective inclusion criteria for the study and control groups.

On quantitative gait analyses and baropodometric analyses, no significant difference was found between groups regarding maximum ankle dorsiflexion (p = 0.5), maximum forefoot pressure (p = 0.45) during stance phase, and rearfoot contact time (p = 0.11) (Table 2 and Fig. 2).

At the same time, increased knee flexion was found in the study group versus the control group (respectively 8.3° ± 3.7 and 3.4° ± 2.3, p < 0.001). The difference between maximum ankle dorsiflexion and knee flexion was less in the study group (p < 0.001) (Table 2 and Fig. 2).

4. Discussion

In the present study, IGT did not induce restricted ankle dorsiflexion or increased forefoot pressure during the mid-stance phase of gait in an asymptomatic bilateral IGT population. In contrast knee flexion was observed during this same mid-stance phase in subjects with IGT. Our hypothesis was rejected.

The authors deem that these results could be explained by the fact that knee flexion conserves ankle dorsiflexion by relaxing the proximal gastrocnemius muscles during mid-stance phase (Fig. 2). Thus, patients with IGT appear to conserve their ankle dorsiflexion thanks to the compensatory knee flexion found in the present study. This attitude could also explain the higher prevalence of patellofemoral pain syndrome in patients with IGT, as reported by Lun et al. [16]. Indeed, knee flexion during stance phase increases pressure in the patellofemoral compartment [22]. Nevertheless, gait analyses in patellofemoral pain syndrome did not find an increase in knee flexion during the stance phase [23]. IGT is probably not the only cause of

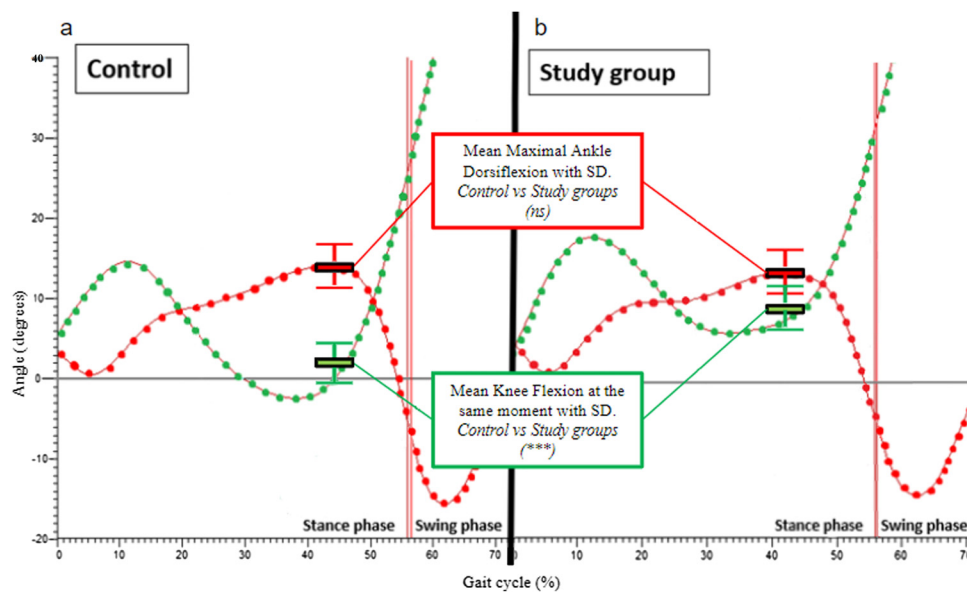


Fig. 2. Superimposition of VICON[®] analysis of ankle and knee gait cycle.

a. In a control group limb.

b. In a study group limb.

Ankle Gait cycle.

Knee Gait cycle.

ns: non significant.

***: $p < 0.001$.

SD: Standard deviation

patellofemoral pain syndrome and knee pain during analysis could lead to limiting knee flexion.

Our findings are in disagreement with common knowledge and several studies [7–9,11]. Aronow et al. [9] found, in patients with IGT, restricted ankle dorsiflexion and foot hyperpressure. These findings are based on fresh cadaver examinations, which could be biased, especially because cadaveric tissue may have different properties and more rigidity than living body tissue. Chen et al. [8] and Cazeau et al. [7] report similar findings to Aronow et al. [9] in 3D modeling studies. We believe that these studies could differ from quantitative gait analysis studies in living patients which are scarcer. Lavery et al. [11] found ankle dorsiflexion restriction and forefoot hyperpressure in an IGT population. However, they focused exclusively on a diabetic population, which may have been a confounding factor. The study by Orendurff et al. [24] lends weight to this hypothesis, showing that equinus played a minor role in forefoot overload in diabetic patients; they considered that other factors, such as bone deformity, plantar tissue thickness, impaired posture and sensitivity, affected plantar weight-bearing. Studies published by You et al. [12] and Chimera et al. [10] are more in accordance with our results. Neither dorsiflexion restriction nor forefoot hyperpressure was found in these studies focused on subjects with IGT, but compensatory knee and hip flexions were observed. No baropodometric analyses were performed in these two studies. Our findings are strengthened by those of others [25] according opposite functions to the soleus and the gastrocnemius. By coupling walking analysis and selective electrical stimulation, these authors found an increase in ankle dorsiflexion and knee flexion with selective contraction of the gastrocnemius during stance phase whereas selective electrical stimulation on the soleus provoked ankle plantarflexion and knee extension by limiting the tibial advance. We believe that these findings are complementary with ours. IGT can induce a more important function of this muscle compared to the soleus. And the balance described by Stewart et al. [25] could be disorganized in

favor of the gastrocnemius in case of tightness. This could explain the presence of knee flexion in our study, however we did not find an increase in ankle dorsiflexion. Others studies are necessary to confirm this.

The present study has some limitations. IGT was not associated with painful pathologies as metatarsalgia, hallux valgus, Achilles tendinopathy. The degree of tightness may thus have been lower than in subjects reporting associated painful discomfort. It would, however, have been more difficult to analyze gait parameters in subjects with pain. The force used to assess the tightness with our device is less than that of a weight-bearing. However, the threshold between pathological IGT and non-pathological IGT is scientifically unknown, according to this, our study does not claim to compare pathological IGT patients to controls but only patients having an unknown degree of IGT to controls. Results and conclusions are based on a bilateral IGT population. Conclusions must not be drawn regarding a unilateral IGT population because the relation between limbs in this context is currently unknown. We did not require subjects to adhere to any particular walking rhythm; they adopted their own comfortable walking speeds. This may have led to selection bias, with baseline intergroup differences. The option was nevertheless chosen as it seemed to us preferable to analyze gait under normal way of walking. Reflective markers were positioned by the same investigator using the same protocol in all patients, always in the standard anatomical position, and the system was calibrated daily. Nevertheless, the joint center may vary; measuring range of motion could have limited this bias, but this criteria, notably regarding the knee flexion/extension arc was biased by the knee flexion present at the beginning of the stance phase due to loading response which was more important than the knee flexion during the mid-stance phase which was nevertheless the one who interested us to assess gastrocnemius tightness. The Vicon[®] Plug-in Gait lower body model provides ankle angles by considering the foot as a single rigid segment, compensation by other mid and rearfoot joints could bias ankle angles.

Our results are in contradiction with some of those previously reported in the literature and the common belief in the surgical foot and ankle community namely that IGT induces ankle dorsiflexion defect in stance phase, and forefoot hyperpressure. We believe that this flexion of the knee during mid-stance phase compensates for IGT and reduces anterior hyperpressure. Energetically, it could induce a more important contraction of the quadriceps muscle than the normal gait. Our analysis may be biased, as it was performed over a short duration in rested subjects; it could be interesting to study the same parameters in subjects with muscular fatigue, to see whether gait characteristics are altered by decompensation of these parameters (no knee flexion compensation involving ankle dorsiflexion restriction and forefoot hyperpressure). This could explain the biomechanical link between IGT and the above-mentioned pathologies.

5. Conclusion

Comparison of gait parameters between lower limbs with IGT and control limbs in asymptomatic cases revealed compensatory knee flexion during stance phase, which probably prevents increased pressure on the forefoot by allowing ankle dorsiflexion during the mid-stance phase of gait despite a positive Silfverskiöld test. Causes that provoke decompensation of this phenomenon, such as muscle fatigue, could possibly explain the physiopathological link between IGT and foot pathologies.

Conflict of interest statement

We confirm that none of the authors have any conflict of interest.

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Declaration of Competing Interest

The authors report no declarations of interest.

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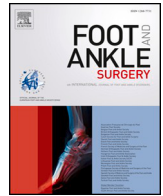
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Does tibialis posterior dysfunction correlate with a worse radiographic overall alignment in progressive collapsing foot deformity? A retrospective study

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ABSTRACT

Background: Posterior Tibial Tendon (PTT) dysfunction is considered to have an important role in Progressive Collapsing Foot Deformity (PCFD). The objective of our study was to assess the relationship between PTT status and three-dimensional foot deformity in PCFD.

Methods: Records from 25 patients with PCFD were included for analysis. The PTT was considered deficient in patients with a positive single heel rise test or a deficit in inversion strength. Three-dimensional foot deformity was assessed using the Foot and Ankle Offset (FAO) from Weight-Bearing-CT imaging. Hindfoot valgus, midfoot abduction and medial longitudinal arch collapse were assessed on X-Rays using hindfoot moment arm, talonavicular coverage angle and Meary's angle respectively. Deland and Rosenberg MRI classifications were used to classify PTT degeneration.

Results: PCFD with PTT deficit (13/25) had a mean FAO of $7.75 \pm 3.8\%$ whereas PCFD without PTT deficit had a mean FAO of $6.68 \pm 3.9\%$ ($p = 0.49$). No significant difference was found between these groups on the hindfoot moment arm and the talonavicular coverage angle (respectively $p = 0.54$ and 0.32), whereas the Meary's angle was significantly higher in case of PCFD with PTT deficit ($p = 0.037$). No significant association was found between PTT degeneration on MRI and FAO.

Conclusion: PCFD associated three-dimensional deformity, hindfoot valgus and midfoot abduction were not associated with PTT dysfunction. PTT dysfunction was only associated with a worse medial longitudinal arch collapse in our study. Considering our results, it does not appear that PTT is the main contributor to PCFD.

Level of Evidence: Level III, Retrospective Comparative Study

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1. Introduction

Early descriptions of flatfoot often identified Posterior Tibial Tendon (PTT) rupture as the trigger and main cause of the deformity [1–5]. PTT continues to be cited as the primary pathophysiological cause of flatfoot, important to assess and address in the event of dysfunction [2,6–8]. As a result, leading flatfoot classifications were based on the status of the PTT [6,9,10]. Johnson and Strom described a three-stage classification which is still cited as the benchmark [6]. Stage 1 describes a degenerative PTT with a normal length, stage 2 describes an elongated painful PTT, and stage 3 describes an elongated PTT which is painless due to rupture. This classification was modified by Myerson et al. and then by Bluman et al., but remains focused on the status of the PTT [9,10].

Recently, a group of subject-matter experts met to address inconsistencies present in these classifications, and after reaching consensus updated the previous name of Adult Acquired Flatfoot Deformity to Progressive Collapsing Foot Deformity (PCFD) [11,12]. The importance of the PTT in PCFD was a matter of debate during the expert consensus meeting and identified as a limitation of the previous classification systems [12]. Studies have shown that the PTT is not the only structure damaged and that the spring or the interosseous ligaments might play a more important role in PCFD collapse [13–15]. Further, some cases of advanced PCFD present with an intact PTT [16,17], and an isolated rupture of the PTT does not systematically lead to a foot collapse [18–20]. Facing these inconsistencies, the expert panel removed the PTT from the new classification system, which was supported with a strong consensus [11,12].

Multiple measurement approaches have been used to identify PCFD associated changes in foot structure [21–23]. Weight-Bearing CT (WBCT) allows the objective three-dimensional assessment of PCFD associated foot deformity using the Foot and Ankle Offset (FAO) [22,24–27]. This measurement is reliable and has been validated for PCFD assessment [21,25,28–31]. The status of the PTT in PCFD is routinely evaluated clinically, and magnetic resonance imaging (MRI) is considered the current gold standard for assessing PTT degeneration [32–35].

The primary objective of our study was to assess the relationship between PCFD associated three-dimensional changes in foot structure as measured using the FAO and the clinical status of the PTT. The secondary objectives were to assess the relationship of the following variables: clinical status of the PTT and hindfoot valgus, midfoot abduction, and medial longitudinal arch collapse; PTT degeneration on MRI and FAO; and PTT clinical status and PTT degeneration on MRI. We hypothesized that greater damage to the PTT would be associated with greater foot deformity.

2. Methods

We performed a retrospective study which received institutional review board approval (IRB #201904825) and complied with the Health Insurance Portability and Accountability Act (HIPAA). All data used was obtained on review of our WBCT database [36].

2.1. Population

Patients who were seen between 01/01/2019 and 12/31/2020 for a symptomatic PCFD and who completed a WBCT as standard of care were included. PCFD without available MRI, or with MRI performed with more than 3 months delay from the WBCT, were excluded. PCFD with history of prior foot surgery (reconstruction or fusion), and patients who presented with insufficient information in their medical files to define the clinical status of the PTT (Fig. 1) were also excluded. Clinical assessments, WBCT and X-Rays acquisitions were performed at the same time.

Finally, 25 PCFD were included in the analysis (19 Women, 6 Men, mean age 53.96 +/-14.9 years, mean BMI 33.2 +/-8.1 kg/m²).

2.2. Weight-bearing CT assessment

Weight-Bearing CT acquisitions were performed in a natural standing position with the feet approximately shoulder width apart (cone-beam CT extremity scanner; PedCAT; CurveBeam, Hatfield, PA). The Foot and Ankle Offset was measured as previously described using the Torque Ankle Lever Arm System (TALAS, CubeVue; Curvebeam LLC, Warrington, PA) and represents the offset between the center of the tripod and the center of the talar dome [24,30,37].

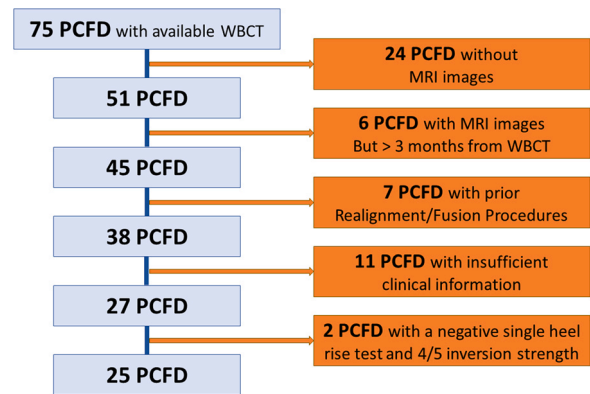


Fig. 1. Flow chart describing the selection of progressive collapsing foot deformity patients for inclusion.

The FAO assessments were performed by two independent fellowship-trained orthopedic foot and ankle surgeons.

2.3. Posterior tibial tendon clinical status

The findings from clinical assessments performed by a senior board-certified orthopedic foot and ankle surgeon were extracted from the medical record. If the single heel rise test was positive (Stage 3 or 4 according to Richter and Zech classification [38]) and/or the inversion strength was inferior or equal to 3/5 according to the Medical Research Council scale, the PTT was considered deficient [39–42]. If the single heel rise was negative (Stage 1 or 2 according to Richter and Zech classification [38]) and the inversion strength was equal to 5/5, the PTT was considered not deficient. Patients with a negative single heel rise test and an inversion strength at 4/5 were excluded (Fig. 1).

2.4. X-rays assessment

Weightbearing conventional radiographs were performed in a natural standing position. The PACS (Vue PACS™, Carestream, USA) software was used to evaluate the images. The hindfoot moment arm was measured on hindfoot alignment views as described by Saltzman and El-Khoury and used to quantify the hindfoot valgus [43]. The talonavicular coverage angle was measured on dorso-plantar views as described by Sangeorzan et al. and used to quantify the midfoot abduction [44]. The Meary's angle was measured on lateral views as described by Gould and used to quantify the medial longitudinal arch collapse [45]. These measurements were performed by two independent fellowship-trained orthopedic foot and ankle surgeons.

2.5. Magnetic resonance imaging assessment

Non-weightbearing 1.5 Tesla MRI were performed, sequences T1 and T2 were available, and PACS (Vue PACS™, Carestream, USA) software was used to evaluate the images. Assessment of the MRI images was performed by two independent fellowship-trained orthopedic foot and ankle surgeons. The PTT degeneration was classified according to Rosenberg et al. and Deland et al. classifications, following the PTT from its distal insertion and combining axial and sagittal views [13,32]. According to Rosenberg et al. a PTT type 0 corresponded to a normal tendon, a type 1 to an intact tendon but hypertrophied and heterogeneous, a type 2 to an intact but attenuated tendon (reduction of the diameter) and a type 3 to an absence of a portion of a tendon (marking a rupture) (Fig. 2) [32].

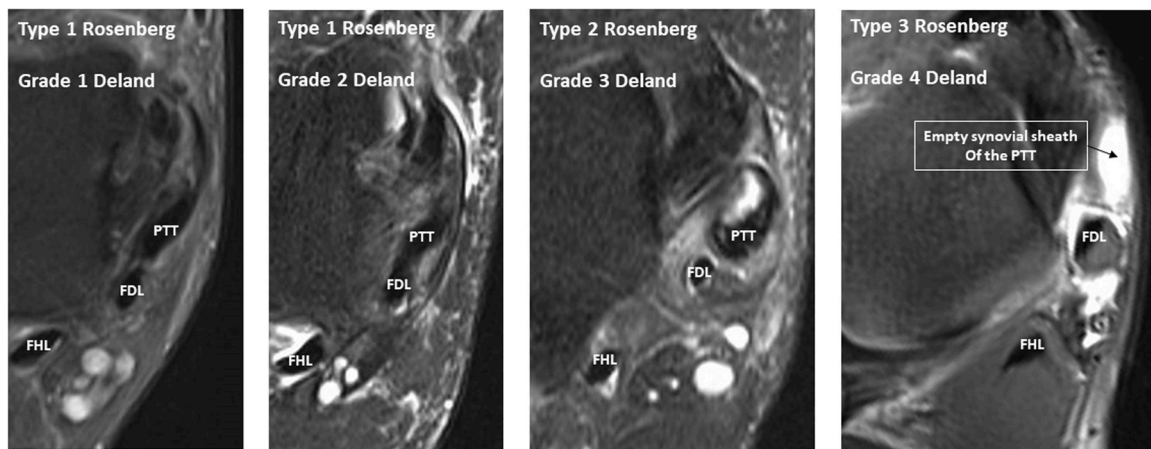


Fig. 2. Illustration of the stages/grades of Posterior Tibial Tendon degeneration according to Rosenberg et al. [32] and Deland et al. [13]. PTT, Posterior Tibial Tendon, FDL, Flexor Digitorum Longus, FHL, Flexor Hallucis Longus.

According to Deland et al. a grade 0 corresponded to an intact PTT with uniformly hypointense signal intensity, a grade 1 to a degenerated PTT (denoted as an increased signal intensity) involving less than 50% of the cross-section area of the tendon on axial images, a grade 2 to a degenerated PTT on more than 50% of the cross-section area, a grade 3 to partial tear with discontinuity of less than 50% of the cross-section area and a grade 4 to a tear with discontinuity of more than 50% of the cross-section area (Fig. 2) [13].

2.6. Statistical analysis

Interobserver reliabilities for the FAO, hindfoot moment arm, talonavicular coverage angle and Meary's angle were determined using the intraclass correlation coefficient (ICC). For the Rosenberg and Deland classifications, the interobserver agreements were determined with the use of absolute percentages of agreement and unweighted Cohen's kappa values. Interpretation of the values was made according to Landis and Koch [46].

We included the two independent readings in our statistical analysis (50 readings). Normality and heteroskedasticity of data were assessed with the Shapiro-Wilk test and the Levene's test. The difference in FAO, hindfoot moment arm, talonavicular coverage angle and Meary's angle between "PTT deficient PCFD" and "PTT non deficient PCFD" groups was assessed with the Student's T (unpaired). The difference in FAO between Rosenberg classification types was assessed with an ANOVA. The difference in FAO between Deland classification grades was assessed with the nonparametric Kruskal-Wallis test. The associations between PTT clinical status and Rosenberg and Deland classifications were evaluated using the Fisher's exact test. Statistical significance was set to 5% ($\alpha=0.05$) for all comparisons.

Statistical analysis was performed with EasyMedStat (version 3.11; www.easymedstat.com).

3. Results

The interobserver reliabilities (ICC) were 0.99 (95% CI, 0.977–0.995) for the FAO, 0.96 (95% CI, 0.913–0.983) for the hindfoot moment arm, 0.96 (95% CI, 0.903–0.981) for the talonavicular coverage angle and 0.98 (95% CI, 0.957–0.992) for the Meary's angle. The absolute percentage of agreement between the observers was 72% for Rosenberg and 68% for Deland classification. There were moderate agreements between observers for Rosenberg ($K=0.54$; CI [0.25;0.82]) and Deland ($K=0.58$; CI[0.36;0.8]) classifications.

3.1. FAO and PTT clinical status

Fifty-two percent (13/25) of the PCFD cases presented with a clinically deficient PTT and 48% (12/25) with a clinically non-deficient PTT. The distribution of the FAO measurements by the two readers is represented in Fig. 3 (mean $7.3 \pm 3.7\%$).

Patients with clinically deficient PTT had a mean FAO of $7.75 \pm 3.8\%$ whereas patients without PTT deficit had a mean FAO of $6.68 \pm 3.9\%$. No significant difference was found between groups ($p=0.49$) (Fig. 4).

3.2. X-Rays measurements and PTT clinical status

No significant difference was found between patients with clinically deficient PTT and patients without PTT deficit on the hindfoot moment arm and the talonavicular coverage angle (respectively 10.96 ± 5.2 vs 9.91 ± 4.6 mm, $p=0.54$ and 23.3 ± 10.4 vs 28.1 ± 13.2 degrees, $p=0.32$).

Patients with clinically deficient PTT showed significantly higher Meary's angle than patients without PTT deficit (respectively, 18.1 ± 8.2 vs 12.5 ± 7.9 degrees, $p=0.037$).

3.3. FAO and PTT degeneration on the MRI

Mean values of FAO for Rosenberg types 0, 1, 2 and 3 were $7.27 \pm 1.25\%$, $6.4 \pm 3.53\%$, $9.01 \pm 4.2\%$ and $8.95 \pm 4.56\%$, respectively, and differences were not significant ($p=0.189$) (Fig. 5).

Mean values of FAO for Deland grades 0, 1, 2, 3 and 4 were $7.27 \pm 1.25\%$, $6.38 \pm 4.03\%$, $5.44 \pm 3.05\%$, $7.21 \pm 1.84\%$ and $9.96 \pm 4.55\%$, respectively, and differences were not significant ($p=0.182$) (Fig. 6).

3.4. PTT clinical status and PTT degeneration on the MRI

The association between the PTT clinical status and the Rosenberg and Deland classifications were statistically significant ($p=0.037$ Table 1; $p=0.009$ Table 2).

3.5. Extreme deformities

Thirteen FAO readings were superior or equal to 10.13% (4th quartile, Fig. 3). Among them, 46.2% (6/13) corresponded to a clinically non deficient PTT and 46.2% (6/13) corresponded to PTT degeneration Rosenberg type 1 (Fig. 7).

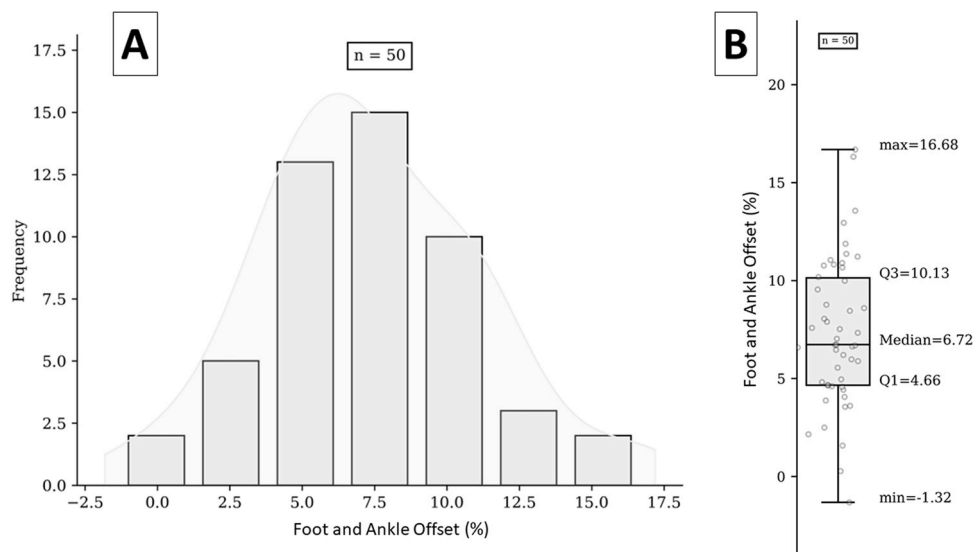


Fig. 3. Distribution of the Foot and Ankle Offset values as determined using Weight-Bearing CT imaging. A. Clustered column, B. Box and whisker plot.

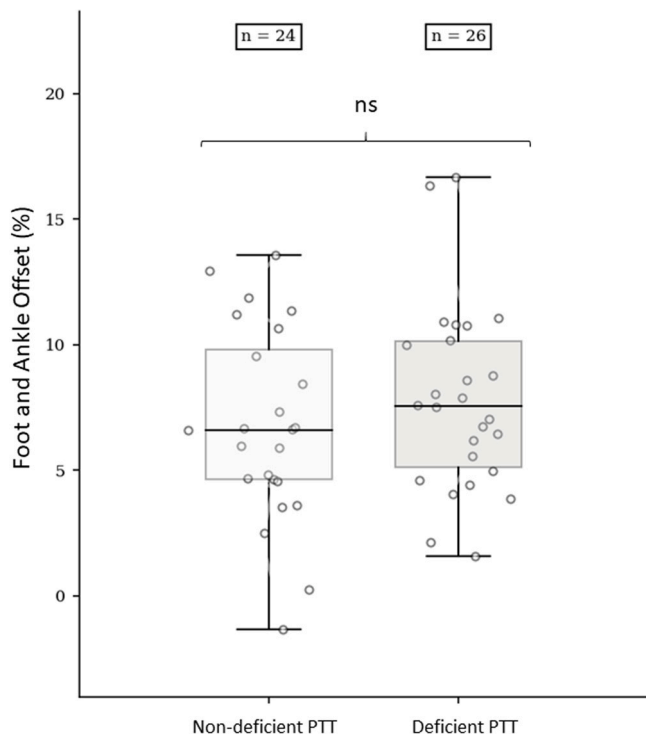


Fig. 4. Comparison between PCFD with deficient Posterior Tibial Tendon (PTT) and PCFD without deficient PTT on the Foot and Ankle Offset. *ns*, non-significant.

Thirteen FAO readings were inferior or equal to 4.66% (1st quartile, Fig. 2). Among them, 46.2% (6/13) had a clinically deficient PTT and 30.8% (4/13) had a PTT with significant damage seen on the MRI (Rosenberg type 2 or 3).

4. Discussion

In this study, a clinically diagnosed PTT deficiency was not associated with an increase in three-dimensional foot and ankle offset deformity, nor with an increase in hindfoot valgus and midfoot

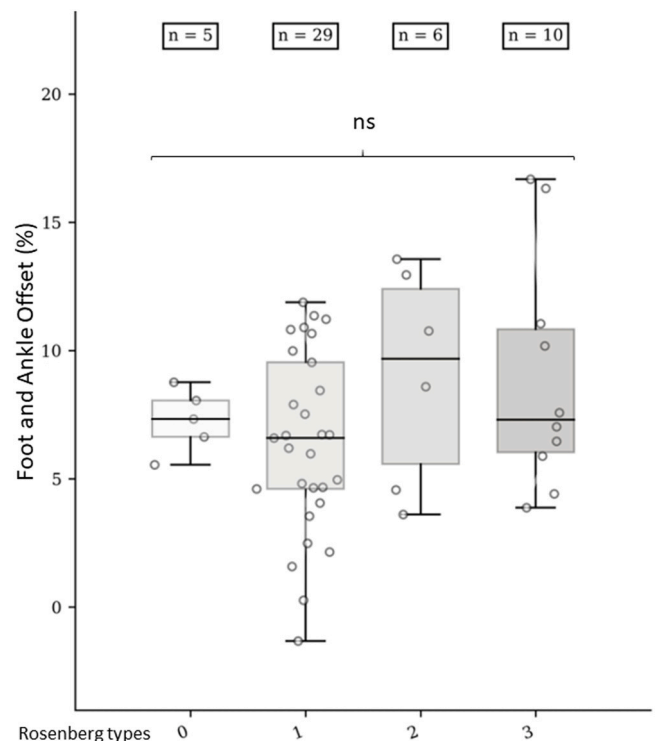


Fig. 5. Distribution of the Foot and Ankle Offset according to the Posterior Tibial Tendon degeneration on MRI (Rosenberg classification). *ns*, non-significant.

abduction in PCFD. Further, PTT degeneration identified on MRI was not associated with three-dimensional foot deformity. However, a PTT deficiency was associated with a worse medial longitudinal arch collapse. Although there was a significant association between the clinical status of the PTT and its degeneration on MRI, our hypothesis that greater damage to the PTT would be associated with greater overall foot deformity was not confirmed.

Our study supports the recent expert consensus decision to remove the PTT status from the PCFD classification system [11,12]. Although PTT damage is commonly observed in PCFD, it does not

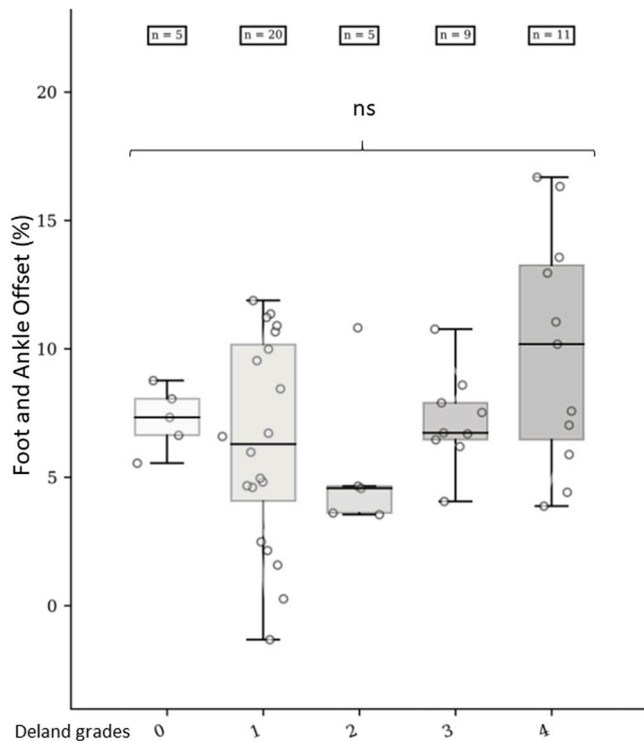


Fig. 6. Distribution of the Foot and Ankle Offset according to the Posterior Tibial Tendon degeneration on MRI (Deland classification). *ns*, non-significant.

Table 1

Contingency table between the presence or absence of clinical Posterior Tibial Tendon (PTT) deficiency and PTT degeneration on MRI according to the Rosenberg classification.

Rosenberg Clinical status	Type 0	Type 1	Type 2	Type 3	Total
PTT deficient	3	12	2	9	26
PTT non-deficient	2	17	4	1	24
Total	5	29	6	10	50

Table 2

Contingency table between the presence or absence of clinical Posterior Tibial Tendon (PTT) deficiency and PTT degeneration on MRI according to the Deland classification.

Deland Clinical status	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total
PTT deficient	3	6	1	8	8	26
PTT non-deficient	2	14	4	1	3	24
Total	5	20	5	9	11	50

appear to be the main precipitating factor for foot collapse and worsening deformity [13,15–18,20]. Further, Brillhault et al. demonstrated that the PTT was able to recover and regain its function after isolated bony realignment procedures [47] in individuals with PCFD. Although PTT is widely recognized as an important dynamic supporting structure of the foot which avoids foot collapse, deficits in the PTT do not appear to be a primary trigger for all PCFD. An isolated PTT rupture or harvesting the PTT does not universally end in

foot collapse and PCFD [17,19,20,48]. Our study reinforces this theory and basing PCFD management solely on the PTT status does not appear to be relevant. As mentioned in previous studies, spring ligament, interosseus ligament, deltoid ligament, plantar fascia, etc. must be also involved in PCFD management decisions [13,15].

Albano et al. did not find an association between the importance of radiological hindfoot valgus and the clinical and MRI status of the PTT, in a study similar to the one presented here [16]. Similarly, degenerative changes identified using histological analysis were associated with heel rise test performance, but not with the structural change of hindfoot valgus. According to the new PCFD classification system hindfoot valgus is only one of the five components of the PCFD deformity [11,12]. Using the FAO, which assessed the overall three-dimensional alignment of the foot encompassing the five components of the PCFD deformity [21], increased the impact of the results. Considering this new classification and our results, it appeared that only one of these deformities was affected by the PTT deficiency [12]. Indeed, the only significant findings we found among our measurements was that of the Meary's angle, representing the collapse of the medial longitudinal arch. On the other hand, the hindfoot valgus and the midfoot abduction did not seem affected by PTT deficiency in our study.

This study has several limitations, including reliance on existing clinical data collected at a tertiary care center. Due to reliance on existing data, an a priori power analysis was not performed, and the number of subjects included is modest. It is possible that increasing the cohort could result in a significant difference in FAO between PCFD with PTT deficiency and PCFD without PTT deficiency, however, the difference between groups was small. The PTT clinical status was subjectively assessed without precise force measurements, however, the single heel rise test and the inversion strength test, are well established and validated tools for PCFD assessment [6,10,38–40,42,49]. The FAO is a relatively new marker of three-dimensional foot deformity, but has been previously validated, with demonstrated reliability and relevance to recognize cavovarus, PCFD, and neutrally aligned feet [21,24,30,31,50]. We assessed the overall deformity, hindfoot valgus, midfoot abduction and medial arch collapse through measurements in our study. However, our measurements did not cover all the possible deformities we can encounter in PCFD. Therefore, our study did not inform whether a deficient PTT may be associated with peritalar subluxation or valgus talar tilt for instance [11,12]. Furthermore, we found an association between PTT deficit and collapse of the medial arch, but this did not inform on the real location of this collapse which can occur at the talonavicular, naviculocuneiform and/or first tarsometatarsal joints. Such important questions need more measurements and this should be advocated in future research [51–57]. We also did not consider the lower limb alignment which can be affected by PTT dysfunction [58–60]. Interobserver disagreement when staging PTT degeneration using MRI has the potential to influence the accuracy of study results. Although reliability was moderate, the assessments from both observers were retained in our statistical analysis (50 readings) to minimize the risk of bias in a single reviewer. Moreover, the MRI based assessment of degeneration was associated with the PTT clinical status as previously reported by El Khoury et al. and Albano et al. [16,33]. Although our study questions the previously considered importance of PTT in PCFD, our study does not directly inform decision making regarding procedures such as PTT repair or flexor digitorum longus transfer in PCFD management.

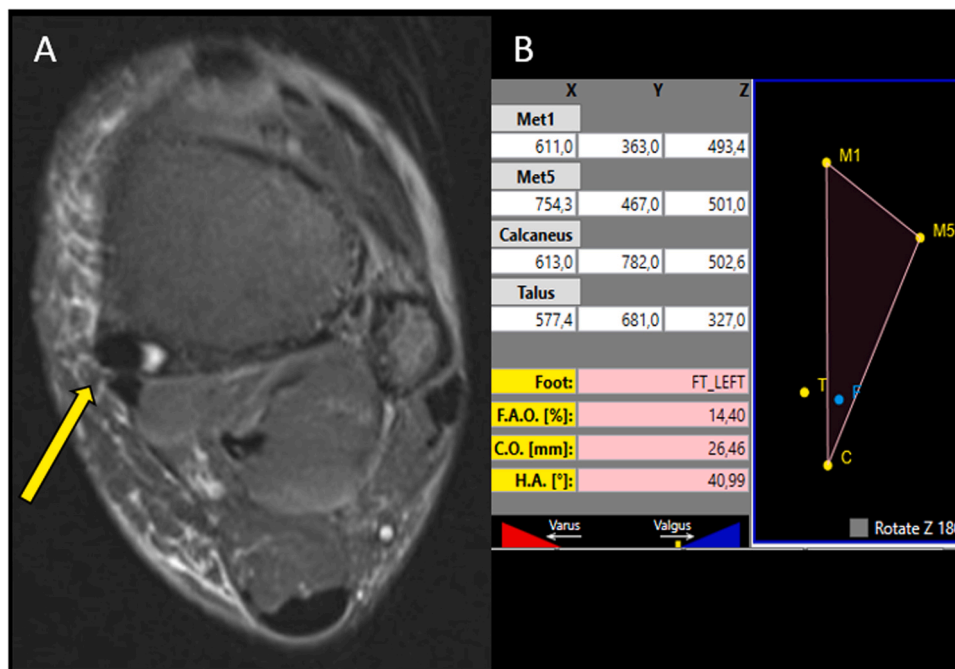


Fig. 7. Example of patient presenting a Progressive Collapsing Foot Deformity with a mild Posterior Tibial Tendon degeneration (Rosenberg type 1 | Deland grade 1) and a severe overall malalignment. A. Magnetic Resonance Axial T2 of the Posterior Tibial Tendon (Arrow). B. Foot and ankle offset value of 14.40% was calculated on Weight-Bearing Computed Tomography images (Torque Ankle Lever Arm System, TALAS, CubeVue; Curvebeam LLC, Warrington, PA).

5. Conclusions

PCFD associated three-dimensional foot deformity, hindfoot valgus, and midfoot abduction were not associated with the clinical presence or absence of PTT deficiency, nor with PTT degeneration findings on MRI in this study. PTT deficiency was only associated with a worse medial longitudinal arch collapse.

Patient with a severe three-dimensional misalignment can present with an intact PTT, and a patient with a mild deformity can present with a deficient PTT. Therefore, it does not appear that PTT is the main contributor to PCFD.

Ethical approval

IRB #201904825.

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Conflict of Interest

Dr. Bernasconi reports other from Curvebeam LCC, during the conduct of the study; other from Disior, outside the submitted work; and Member of the International Weightbearing CT Society. Dr. de Cesar Netto reports other from CurveBeam, other from Disior Analytics, personal fees from Medartis, personal fees and other from Zimmer-Biomet, grants, personal fees and other from Paragon28, personal fees and other from Artelon, other from Tayco Brace, personal fees and other from Nextremity, outside the submitted work; and Foot and Ankle Clinics/Elsevier - Editorial Services, Vice President International Weightbearing CT Society, Media Board Member Foot & Ankle International, AOFAS Committee member.

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Prevalence and pattern of lateral impingements in the progressive collapsing foot deformity

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Abstract

Introduction The prevalence of lateral bony impingements [i.e., Sinus Tarsi (STI), Talo-Fibular (TFI) and Calcaneo-Fibular (CFI)] and their association with Peritalar Subluxation (PTS) have not been clearly established for progressive collapsing foot deformity (PCFD). This study aims to assess the prevalence of STI, TFI and CFI in PCFD, in addition to their association with PTS. We hypothesized that STI and TFI would be more prevalent than CFI.

Materials and methods Seventy-two continuous symptomatic PCFD cases were retrospectively reviewed. Weightbearing computed tomography (WBCT) was used to assess lateral impingements and classified as STI, TFI and CFI. PTS was assessed by the percent of uncovered and the incongruence angle of the middle facet, and the overall foot deformity was determined by the foot and ankle offset (FAO). Data were collected by two fellowship-trained independent observers.

Results Intra-observer and inter-observer reliabilities for impingement assessment ranged from substantial to almost perfect. STI was present in 84.7%, TFI in 65.2% and CFI in 19.4%. PCFD with STI showed increased middle facet uncoverage ($p=0.0001$) and FAO ($p=0.0008$) compared to PCFD without STI. There were no differences in FAO and middle facet uncoverage in PCFD with TFI and without TFI. PCFD with CFI was associated with STI in 100% of cases. PCFD with CFI showed decreased middle facet incongruence ($p=0.04$) and higher FAO ($p=0.006$) compared to PCFD without CFI.

Conclusions STI and TFI were more prevalent than CFI in PCFD. However, only STI was associated with PTS. Conversely, CFI was associated with less PTS, suggesting a different pathological mechanism which could be a compensatory subtalar behavior caused by deep layer failure of the deltoid ligament and talar tilt.

Keywords PCFD · Progressive collapsing foot deformity · AAFD · Flatfoot · Impingement · Peritalar subluxation

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Introduction

The nomenclature and classification for flatfoot deformities was updated in 2020 [1]. The new classification consisted of five independent classes of deformity and adoption of the term progressive collapsing foot deformity (PCFD) [1]. Peritalar Subluxation (PTS) is now one of the levels formally cited as part of PCFD, yet little is known about the different stages of this challenging three-dimensional deformity [2]. The advent of Weightbearing Computed Tomography (WBCT) allows a better understanding of three-dimensional (3D) deformities [3–6], and has already proven its superiority in comparison to plain radiographs in the assessment of PTS [7]. Furthermore, the assessment of middle facet subluxation within the subtalar joint has proved a reliable and relevant tool for quantifying PTS [8–11].

Malicky et al. [12] noted that lateral impingements were frequent, and could represent one of the main causes of lateral foot pain in PCFD [13]. More recently, 3D analysis of PCFD cases, using distance mapping technology, identified decreased coverage in the subtalar joint, and decreased distances in the sinus tarsi and subfibular areas [11]. Another study found a correlation between degeneration of the interosseous ligament and lateral impingements [14]. With all these results in mind, it is likely that lateral impingements may be secondary to PTS, but this is not fully understood.

Lateral impingements are classically divided into Sinus Tarsi impingement (STI) and subfibular impingement. Prevalence of these impingements, and their relative importance in PCFD are controversial in the literature [12, 15]. It is also unclear whether subfibular impingement must be divided into Talo-Fibular impingement (TFI) and Calcaneo-Fibular impingement (CFI). Yoshida et al. [16] recently described TFI as part of subfibular impingement. However, the study composed of a small cohort of PCFD, so the prevalence and significance of TFI in PCFD remains unknown. Likewise, STI is also controversial [1], as it is sometimes considered a sign of PTS [9, 12, 14], and sometimes a sign of midfoot abduction [1, 15]. However, PTS and midfoot abduction are now recognized as two distinct deformities in the PCFD Classification [1]. It is, therefore, necessary to identify the specific roles of lateral impingements in PCFD to improve diagnoses, surgical planning and clinical outcomes for this patient population.

The primary objective of this study was to define the prevalence of lateral impingement subtypes in a PCFD population. The secondary objectives were to evaluate PTS among lateral impingement subtypes and determine the relationship between STI and two PCFD deformities, PTS and midfoot abduction. We hypothesized that STI and TFI

would be more prevalent and associated with less PTS than CFI, and that STI would be secondary to PTS but not to midfoot abduction deformity.

Materials and methods

This retrospective case–control, single-center, study received institutional review board approval (IRB #201904825) and complied with the Health Insurance Portability and Accountability Act (HIPAA).

Population

All patients presenting to our institution for symptomatic PCFD between 2019 and 2020 and who underwent a standard of care standing WBCT assessment (cone-beam CT extremity scanner; PedCAT; CurveBeam, Hatfield, PA), were included in the investigation. Patients under 18 years of age, those with prior foot surgery, individuals suffering from inflammatory diseases, tarsal coalition, infection and neuropathic subjects were excluded.

Seventy-two feet from 50 patients (33 females and 17 males) were included in this study with a mean age of 58 years (range 26–91) and a mean Body Mass Index of 32.8 (range 20.9–47.7).

Lateral impingements

Two fellowship-trained foot and ankle surgeons independently assessed all WBCT acquisitions with the built-in WBCT dataset analysis software (CubeVue, Curvebeam) allowing 2D sagittal, coronal, axial planar, and 3D volumetric assessments. One of the readers performed a second blinded assessment 2 weeks after.

Lateral impingement was assessed as described by Malicky et al. [12] Sinus Tarsi Impingement (Fig. 1), corresponded to an extra-articular bone conflict between the talus and the calcaneus. It was divided in a Direct STI, if a direct bone contact was present, and an Indirect STI, if “kissing” cysts and sclerosis were present in an area which is not usually loaded. Since patients with inflammatory diseases were not included, the presence of these signs would be presumptive evidence for abnormal osseous contact [12]. Talo-Fibular Impingement (Fig. 2), corresponded to a bone conflict between the talus and the fibula and CFI (Fig. 3), to a bone conflict between the calcaneus and the fibula were also divided in Direct and Indirect as above-mentioned.

Measurements

Peritalar Subluxation was assessed according to de Cesar Netto et al. [9], using middle facet subluxation. Both

Fig. 1 Weightbearing CT assessment of a Sinus Tarsi impingement (STI). **a** Coronal plane, **b** Sagittal plane



Fig. 2 Weightbearing CT assessment of a Talo-Fibular impingement (TFI) in the Coronal plane

percentage of uncoverage and incongruence angle of the middle facet were collected.

Midfoot abduction was assessed using talonavicular coverage angle as described by Sangeorzan et al. [17] Global malalignment was assessed by the foot and ankle offset (FAO) as described by Lintz et al. [18].

All these measurements present validated intra-observer and inter-observer reliabilities [9, 19].

Statistical analysis

Lateral impingements inter-observer and intra-observer reliabilities were determined with the use of absolute percentages of agreement and unweighted Cohen's kappa values. Interpretation of kappa values was done according to Landis and Koch [20].



Fig. 3 Weightbearing CT assessment of a Calcaneo-Fibular impingement (TFI) in the Coronal plane

Normality of different variables was assessed using Shapiro–Wilk test and distribution histogram. Impingement groups were compared using Student's *t* test for normal, and Mann–Whitney *U* test for non-normal variables. Gender percentage between groups was compared using two-tailed Fisher's exact test. *p* values less than 0.05 were considered significant. Statistical analysis was performed with the online application EasyMedStat (version 3.7; www.easymedstat.com).

Results

The absolute percentage of inter-observer agreement regarding subfibular impingement assessment was 87.5% reflecting a substantial inter-observer agreement ($K=0.702$). The

absolute percentage of intra-observer agreement regarding SFI assessment was 95.8% reflecting an almost perfect intra-observer agreement ($K=0.901$). The absolute percentage of Inter-observer and intra-observer agreements regarding STI assessment was 93.1% reflecting a both inter-observer and intra-observer substantial agreement ($K=0.698$).

Prevalence

Sinus Tarsi Impingement was present in 84.7% (61/72 PCFD), TFI in 65.2% (47/72 PCFD) and CFI in 19.4% (14/72 PCFD) of cases. Overall subfibular impingement (including isolated TFI, isolated CFI and associated TFI and CFI) prevalence was 69.4% (50/72 PCFD). Indirect and Direct distributions of these different impingements are exposed in Fig. 4.

Sinus Tarsi impingement

Comparing PCFD with STI and PCFD without STI showed significant increases of middle facet uncoverage ($p=0.0001$), FAO ($p=0.0008$) and talonavicular coverage angle ($p=0.02$) in case of STI presence. No significant difference on middle facet incongruence ($p=0.5$) was found between groups (Table 1).

Comparing PCFD with Direct STI and PCFD with Indirect STI showed differences in middle facet uncoverage (respectively, means $41.8\% \pm 17.2$ and $31.6\% \pm 9.2$; $p=0.009$) and talonavicular coverage angle (respectively, $26.8^\circ \pm 12.7^\circ$ and $18.3^\circ \pm 8.7^\circ$; $p=0.007$). No significant difference on middle facet incongruence ($11.9^\circ \pm 7.4^\circ$ and $11.2^\circ \pm 5.2^\circ$; $p=0.78$) and FAO ($8.51 \pm 4.7\%$ and $7.36 \pm 5.2\%$; $p=0.34$) was found between these subgroups.

Fig. 4 Distribution of the different types of lateral impingements ($n=72$)

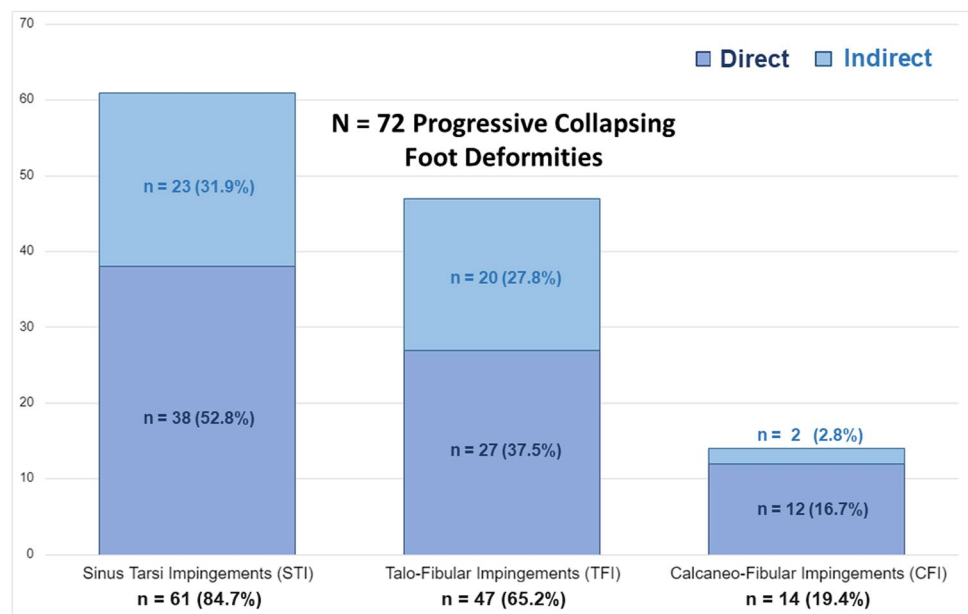


Table 1 Comparison between Progressive Collapsing Foot Deformities (PCFD) presenting Sinus Tarsi impingements (STI) and PCFD without STI ($n=72$ PCFD)

	PCFD with STI, N=61	PCFD without STI, N=11	p value
Body mass index (kg/m^2)	33.3 ± 6.5 (range 25.2–7.7)	29.9 ± 4.6 (range 20.9–36.9)	0.48
Age (years)	59.3 ± 15.2 (range 27–91)	50.6 ± 17.2 (range 26–72)	0.29
Gender (female)	28 (45.9%)	5 (45.5%)	1
Talonavicular coverage angle (degrees)	23.6 ± 12.1 (range 2.8–51.7)	14 ± 8.2 (range 4.7–27.9)	0.02
Middle Facet uncoverage (%)	38 ± 15.5 (range 7.5–84.9)	21.9 ± 3.9 (range 15.7–28.1)	0.0001
Middle Facet incongruence (degrees)	11.7 ± 6.7 (range 0–35.7)	10.1 ± 3.4 (range 4.2–15.4)	0.5
Foot and Ankle Offset (%)	8.1 ± 4.9 (range -2.2 to 24.2)	3.6 ± 1.7 (range 0.1–5.8)	0.0008

Talo-Fibular impingement

Patients presenting TFI had an STI associated in 91.5% (43/47) and CFI in 23.4% (11/47) of cases. Comparison among PCFD with TFI and PCFD without TFI did not display any significant difference on middle facet, FAO and talonavicular coverage angle measurements. Patients with TFI were significantly older (Table 2).

Calcaneo-Fibular impingement

Patients who presented with CFI had an STI associated in 100% and TFI in 64.2% (11/14) of cases. Comparing PCFD with CFI and PCFD without CFI showed a significant decrease in middle facet incongruence ($p=0.04$) and a significant greater FAO ($p=0.006$) in case of CFI. No significant difference on middle facet uncoverage ($p=0.92$) and on the talonavicular coverage angle ($p=0.23$) was found between groups. Patients with CFI were significantly older (Table 3). Comparing PCFD with Direct CFI and PCFD with Indirect CFI did not show any significant difference.

Impingements and PTS

Comparing PCFD without impingements and PCFD with isolated (without CFI) Indirect STI, a significant increase of middle facet uncoverage ($p=0.0003$) and in the FAO ($p=0.027$) was found in favor of Indirect STI presence (Figs. 5, 7). Comparing PCFD with isolated Indirect STI and PCFD with isolated Direct STI showed a significant increase of middle facet uncoverage ($p=0.003$) in favor of Direct STI presence (Fig. 5). Comparing PCFD with isolated STI and PCFD with CFI showed a significant decrease of middle facet incongruence ($p=0.032$) and a significant increase of FAO ($p=0.028$) in favor of CFI presence (Figs. 6, 7).

Discussion

Sinus Tarsi impingements and TFI were more frequent than CFI. Sinus Tarsi impingements was associated with PTS and midfoot abduction and with a progression of the PCFD deformity. In addition, Indirect STI were associated with less

Table 2 Comparison between progressive collapsing foot deformities (PCFD) presenting Talo-Fibular impingements (TFI) and PCFD without TFI ($n=72$ PCFD)

	PCFD with TFI, $N=47$	PCFD without TFI, $N=25$	p value
Body Mass Index (kg/m^2)	32.4 ± 6.4 (range 20.9–47.7)	33.7 ± 6.4 (range 25.2–46.8)	0.5
Age (years)	63.5 ± 13.5 (range 33–91)	46.6 ± 14 (range 26–72)	0.002
Gender (female)	22 (46.8%)	11 (44.0%)	1
Talonavicular coverage angle (degrees)	21.7 ± 12.3 (range 2.8–43)	22.9 ± 11.7 (range 5.3–51.7)	0.66
Middle Facet uncoverage (%)	35 ± 16.1 (range 7.5–84.9)	36.4 ± 14.1 (range 17–65.3)	0.7
Middle Facet incongruence (degrees)	10.6 ± 6.7 (range 0–35.7)	12.9 ± 5.1 (range 4.2–24.4)	0.063
Foot and Ankle Offset (%)	7.8 ± 5.5 (range –2.2 to 24.2)	6.7 ± 3.2 (range 0.1–12.1)	0.74

Table 3 Comparison between Progressive Collapsing Foot Deformities (PCFD) presenting Calcaneo-Fibular impingements (CFI) and PCFD without CFI ($n=72$ PCFD)

	PCFD with CFI, $N=14$	PCFD without CFI, $N=58$	p value
Body mass index (kg/m^2)	33.6 ± 7.9 (range 25.2–47.7)	32.5 ± 5.7 (range 20.9–46.8)	0.97
Age (years)	66.9 ± 15.4 (range 40–91)	55 ± 14.7 (range 26–87)	0.014
Gender (female)	9 (64.3%)	24 (41.4%)	0.15
Talonavicular coverage angle (degrees)	26.9 ± 15.5 (range 2.8–51.7)	21 ± 10.8 (range 4.1–45.7)	0.23
Middle Facet uncoverage (%)	38.1 ± 24.2 (range 7.5–84.9)	34.9 ± 12.4 (range 15.7–77.5)	0.92
Middle Facet incongruence (degrees)	8.6 ± 6.9 (range, 0–24.4)	12.1 ± 6 (range, 2.9–35.7)	0.039
Foot and Ankle Offset (%)	11.4 ± 6.4 (range –0.3 to 24.2)	6.4 ± 3.8 (range –2.2 to 18.1)	0.005

Fig. 5 Relationship between middle facet uncoverage and impingements. * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

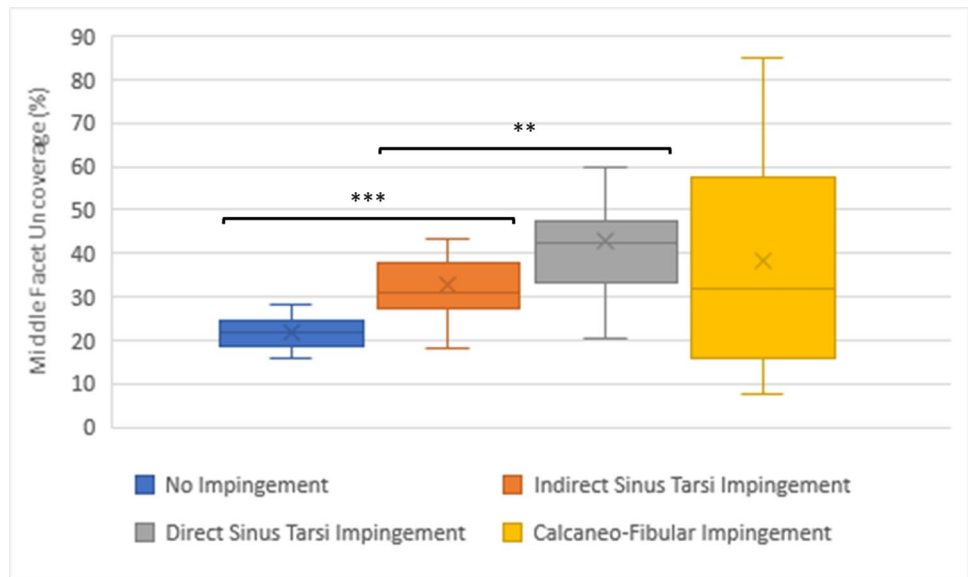
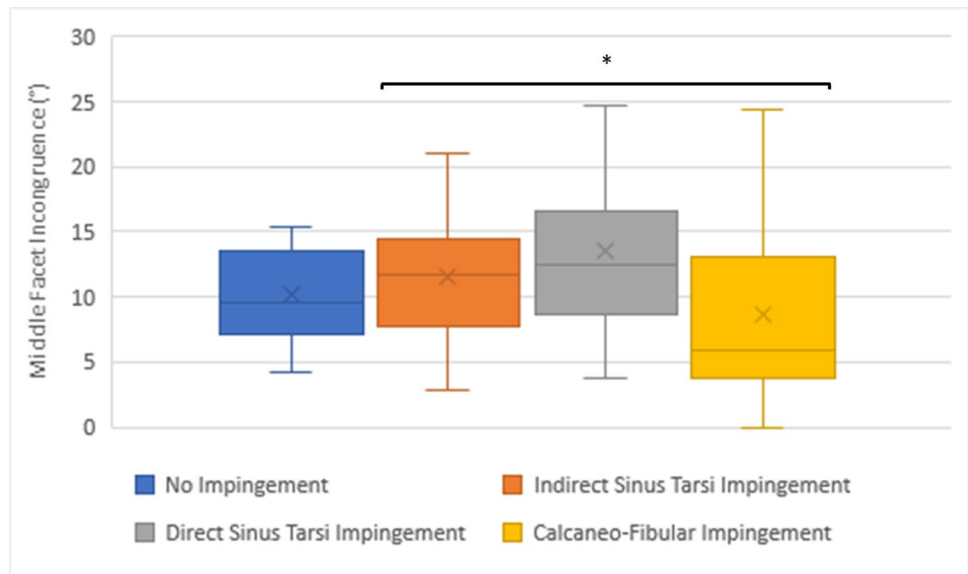


Fig. 6 Relationship between Middle Facet incongruence and impingements. * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

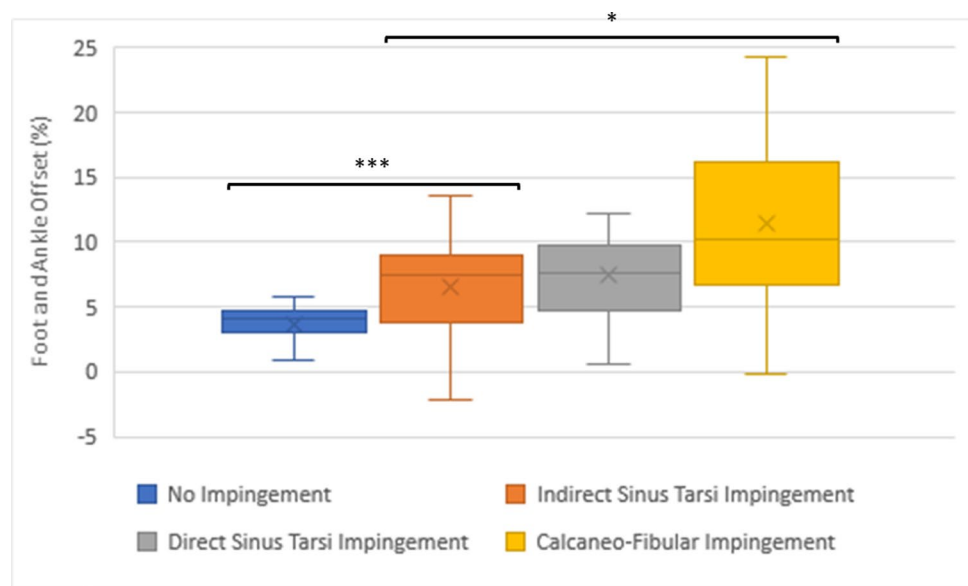


PTS than Direct STI. Calcaneo-Fibular impingements were associated with a greater overall foot deformity but showed relative signs of PTS reduction. Alternatively, TFI did not show any specific relation to the PTS course, which did not support our initial hypothesis.

Malicky et al. [12] were the first to describe lateral impingements and demonstrate their high prevalence in PCFD. However, their study was not performed with WBCT in a standing position but with a simulated WBCT that can introduce bias, such as inappropriate weight bearing, foot positioning or surrounding muscles reactions [21]. Moreover, their PCFD population presented with lateral foot pain and advanced stage PCFD which required surgical intervention, which may have led to overestimate the real prevalence within this condition. A similar study by Jeng et al. [15]

utilizing a regular WBCT assessment in a standing position described different results. In Malicky et al. [12] study, STI's prevalence was 92%, CFI's prevalence was 66% and CFI was always associated with STI. By contrast, the study by Jeng et al. [15] reported a prevalence of 38% for STI, 35% for CFI, and reported CFI was not consistently associated with STI. Unlike Malicky et al. [12], the Jeng et al. [15] study was based on a regular population of PCFD comprising all stages of the condition and is more appropriate to assess prevalence. Nevertheless, Jeng et al. [15] classified only direct bone contact as a positive sign of impingement and assessed STI exclusively in the coronal plane. We argue that indirect signs of impingement must be utilized in the analysis of PCFD as a sign of dynamic impingement. Further, the combination of coronal and sagittal planes is discriminating

Fig. 7 Relationship between foot and ankle offset and impingements. * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$



for STI assessments (Fig. 1). The present work, contrary to above-mentioned studies, integrated regular WBCT assessments in all stages PCFD population, and considered the indirect signs as real impingements. Thus, our reported prevalence findings (84.7% for STI and 19.4% for CFI) are likely more realistic than those previously reported. Additionally, our data supports the Malicky et al. [12] study's finding according to which CFI are always associated with STI.

Moreover, Yoshida et al. [16] recently described TFI as part of subfibular impingements, a divergence from two previous studies. However, this study only included a small PCFD cohort presenting with lateral foot pain, which makes the reported TFI prevalence likely unreliable. We report a prevalence of 65.2% for TFI, but no association with PTS, midfoot abduction, and overall deformity of the foot. It was therefore difficult to interpret this entity. We believe that TFI might be rather an early sign of tibiotalar arthritis or might be associated with the tibiotalar valgus component of the PCFD, but this deformity was not evaluated in our study.

Similarly, we believe that the relative reduction of the PTS associated with CFI was also related to the tibiotalar valgus component of the PCFD. As CFI were always associated with STI and reported a greater overall deformity (FAO) but a smaller amount of PTS, we believe that progression of the PCFD leads to an increased valgus alignment of the tibiotalar joint. Specifically, a failure of the deep layer of the deltoid ligament would cause a valgus talar tilt and could partially reduce the PTS by allowing the talus to return to a more normal position on the calcaneus. This could explain the decrease of the MF incongruence angle associated with CFI. Calcaneo-Fibular impingements could in this case represent a sign of severity in PCFD.

This study had several limitations. First, it was retrospective, which causes usual inherent biases. To control for these

biases, the groups were assessed for significant demographic differences before each comparison. The only differences identified were regarding age in that patients were older in cases with TFI and CFI presence than in those without. This difference is likely a reflection that a greater deformity takes longer to develop, which is why the group with the most severe deformity is older. We did not assess any clinical outcome measures in our study. Correlating clinical and radiological findings could help to determine the significance of different types of impingements in PCFD patient symptoms and should be considered in future studies. We only assessed the relationship between lateral impingements and two deformities (PTS and midfoot abduction) of the PCFD classification [1]. It is also possible that lateral impingements may have some relation with the three other PCFD deformities (hindfoot valgus, forefoot varus and ankle instability). However, lateral impingements were only mentioned as possible signs of PTS or midfoot abduction in the PCFD classification, so we chose to only analyze these two deformities. Further, there was no control group for comparison. Malicky et al. [12] have already used a control group and has already pointed out the discrepancy between PCFD and controls. Moreover, middle facet subluxation measurements were used to quantify PTS. Although these measurements have shown their reliability [9] and superiority [10, 11] compared to posterior facet subluxation, it is possible that three-dimensional measurements, such as 3D distance mapping or 3D volume and coverage measurements would be able to highlight more precise findings.

Conclusions

In conclusion, this study demonstrates that STI was associated with PTS, midfoot abduction, and was the most prevalent impingement, present in 84.7% of cases. Indirect STI was the first to appear in PTS natural evolution followed by Direct STI. Talo-Fibular impingements were frequent (65.2%) but were not associated with PTS nor overall foot deformity. Calcaneo-Fibular impingements were less frequent (19.4%), consistently associated with STI, and associated with a greater overall foot deformity. Conversely, CFI was associated with a relative reduction of the PTS that might be due to a valgus failure of the tibiotalar joint.

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Declarations

Conflict of interest François Lintz; personal fees from Curvebeam; patent TALAS issued. Cesar de Cesar Netto; paid consultant to Curvebeam, Ossio, Zimmer-Biomet, Nextremity, Paragon 28; stock options with Curvebeam; royalties from Paragon 28; media board member with Foot & Ankle International, treasurer for International WBCT Society, committee member for American Orthopaedic Foot & Ankle Society, Editor-in-Chief Foot and Ankle Clinics.

Ethical approval IRB #201904825.

Informed consent Not applicable.

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Annexe 8

scientific reports



OPEN

Coverage maps demonstrate 3D Chopart joint subluxation in weightbearing CT of progressive collapsing foot deformity

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A key element of the peritalar subluxation (PTS) seen in progressive collapsing foot deformity (PCFD) occurs through the transverse tarsal joint complex. However, the normal and pathological relations of these joints are not well understood. The objective of this study to compare Chopart articular coverages between PCFD patients and controls using weight-bearing computed tomography (WBCT). In this retrospective case control study, 20 patients with PCFD and 20 matched controls were evaluated. Distance and coverage mapping techniques were used to evaluate the talonavicular and calcaneocuboid interfaces. Principal axes were used to divide the talar head into 6 regions (medial/central/lateral and plantar/dorsal) and the calcaneocuboid interface into 4 regions. Repeated selections were performed to evaluate reliability of joint interface identification. Surface selections had high reliability with an ICC > 0.99. Talar head coverage decreases in plantar medial and dorsomedial (−79%, $p = 0.003$ and −77%, $p = 0.00004$) regions were seen with corresponding increases in plantar lateral and dorsolateral regions (30%, $p = 0.0003$ and 21%, $p = 0.002$) in PCFD. Calcaneocuboid coverage decreased in plantar and medial regions (−12%, $p = 0.006$ and −9%, $p = 0.037$) and increased in the lateral region (13%, $p = 0.002$). Significant subluxation occurs across the medial regions of the talar head and the plantar medial regions of the calcaneocuboid joint. Coverage and distance mapping provide a baseline for understanding Chopart joint changes in PCFD under full weightbearing conditions.

The transverse tarsal joint complex (Chopart articulations) is a key element of the peritalar subluxation (PTS) seen in progressive collapsing foot deformity (PCFD)¹. Through these structures, most of the pathological features associated with PCFD occur². Abduction of the midfoot, medial arch collapse, and forefoot varus may have substantial or minor contributions from the talonavicular and the calcaneocuboid joint^{3–5}. As PTS occurs in PCFD, structures distal to an initially fixed talus are expected to deviate dorsolaterally, contributing substantially to the described deformities^{6,7}. Prior work attempted to assess these behaviors using various methods like simulated weight-bearing computed tomography (WBCT) and fluoroscopy, finding abduction and eversion but conflicting results regarding plantar flexion through these joints^{8–10}.

The recent use of WBCT to evaluate PTS has produced important data to help understand this pathological functioning^{11,12}. Using two-dimensional tools in coronal plane imaging, the amount of subluxation at the posterior and middle facets was found to be correlated with PCFD diagnosis and severity^{6,11,13,14}. Dibbern et al. performed an objective three-dimensional (3D) WBCT analysis of the subtalar joint in PCFD using 3D distance maps (DMs) and introducing the concept of coverage mapping (CM)¹⁵. They showed that subluxation of the calcaneus underneath the talus was more prominent in the middle facet than in the posterior facet of the subtalar joint, while simultaneously identifying decreases in interbone distance in the sinus tarsi and subfibular regions, explaining lateral impingements in PCFD^{16,17}.

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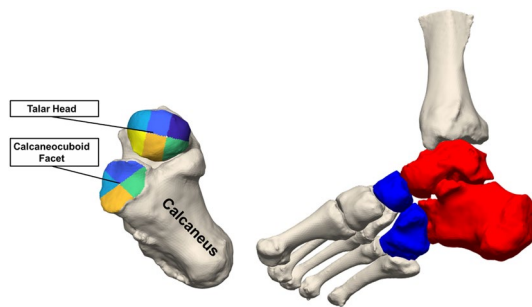


Figure 1. Chopart joint articulations were analyzed with respect to the talus and the calcaneus. The talar head was divided into 6 regions and the calcaneocuboid facet was divided into 4 regions using the principle axes of the joint surface (Left). The Chopart joint occurs between the red (talus and calcaneus) and blue (navicular and cuboid) bones (Right).

These CM and DM techniques may help improve understanding of bone positioning and interactions through the Chopart complex in PCFD as previous research has not directly assessed the articular interfaces of the talonavicular and calcaneocuboid joints under physiological load^{8,9}. Information provided by the 3D mapping specifically related to plantarflexion and subluxation may be of particular value in diagnosing, staging, and estimating treatment impacts in PCFD. Therefore, the objective of this study was to compare distance and coverage map differences between loaded Chopart joints of PCFD and control patients using full weightbearing CT. We hypothesized that a significant amount of decreased articular coverage, indicative of subluxation, would be present in the talonavicular and calcaneocuboid joints in PCFD compared to controls. We further hypothesized that medial widening and lateral narrowing of intra-articular distances would be observed in the talonavicular and calcaneocuboid joints consistent with subluxation. Finally, we sought to understand whether present gold standard methods for selection of articular surfaces are reliable for use in understanding joint interaction.

Methods

Design. This retrospective case control study obtained University of Iowa's institutional review board approval (IRB# 201904825). It complied with the both the Health Insurance Portability and Accountability Act (HIPAA) and the Declaration of Helsinki. Informed consent was obtained from all subjects. This manuscript follows the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE case-control) guidelines (Supplementary material: Appendix)¹⁸.

Sample. *PCFD group.* The first 20 patients with a PCFD were selected from a randomized list to have undergone a WBCT at our institution between 2014 and 2021. Adults (over 18 years old) with clinical diagnosis of PCFD were included. Patients presenting with a stage 1 (flexible) class A, B, C, D, or a combination of classes were admitted¹⁹. Patients were excluded if they were found to have a rigid deformity at physical examination, any prior PCFD surgery or metallic implants deterring visualization of the first and fifth rays. Class E deformities (valgus of the ankle) were also excluded¹⁹.

Control group. A matched control group of 20 feet was selected from adult volunteers that underwent WBCT. Individuals were excluded if they had any hindfoot complaint (current and prior), signs of any deformity or arthritis (hindfoot, midfoot and forefoot) noticeable during imaging assessment. A foot and ankle offset (FAO) below 5.2% was required for this group of patients²⁰.

Image acquisition. WBCT acquisition was conducted with patients instructed to bear weight in a natural, upright standing position with feet approximately at shoulder width to distribute weight evenly between their two lower limbs. Studies were performed with a cone-beam computed tomography (CT) scanner (HiRise®, LLC, Warrington, PA, USA).

Image assessments. *3D distance mapping.* The 3D boundaries of the talus, calcaneus, navicular, and cuboid were extracted from WBCT images using an automated segmentation protocol (Disior Bonelogic 2.0; Disior Ltd®, Helsinki, Finland). Resulting surfaces were exported as triangulated surface models to Geomagic Design X (3D Systems). Articular facets were selected in Geomagic Design X in two separate trials by the same reader¹⁵.

Distance measurements were performed along the talar head (articular surface for the navicular) and the articular surface for the cuboid on the calcaneus. Detailed regional analysis was conducted by dividing the talar head into six subregions (Fig. 1) using the principal axes of the joint surface²¹. The cuboid facet of the calcaneus was similarly divided into quadrants: medial, superior, lateral, and inferior. Measurements performed in articular areas were defined using the distance along the normal direction of vectors projected from the subchondral bone of the hindfoot (talar head and calcaneocuboid facet) to their respective midfoot counterparts (the posterior facets of the navicular and cuboid).

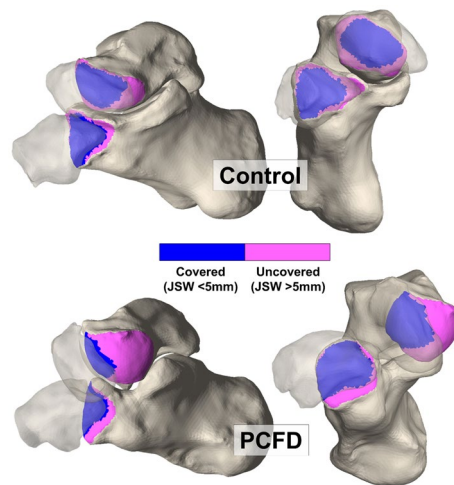


Figure 2. Medial and anterior views of the Chopart joint in representative coverage maps of control and Progressive Collapsing Foot Deformity feet. PCFD tended toward decreased medial coverage and increased lateral coverage in both the calcaneocuboid and talonavicular joints.

Coverage maps. Coverage percent was calculated by finding both the total area of each division and the total area of the division that was covered. The area covered divided by the total area of the division yields the coverage percent for that division. We defined coverage as anywhere on the joint that had a joint space width (JSW) of less than five millimeters. We chose a threshold of five millimeters in order to capture all possible parts of the joint that could be considered covered. Lintz et al., reports distances of approximately two millimeters in the talonavicular joint²². Other previous studies have used thresholds of four millimeters in joints in the foot²³. We wanted to ensure adequate characterization of coverage in the joint; the most prudent way to do so was to raise the coverage threshold by one millimeter. Since the method of distance measurement was based on the normal vectors, most regions that were uncovered were defined as such due to the lack of intersection of the normal vector with the opposing bone, not due to being greater than the five-millimeter threshold.

Colored CMs were created to assess coverage on the talar head and the calcaneocuboid (CC) facet¹⁵. Pink was chosen to highlight uncoverage of articular regions, as a result of the overall 3D deformity in PCFD, that were either completely uncovered or had distances greater than 5 mm. Blue indicated coverage of the joint with less than 5 mm distance between bones (Fig. 2).

The talonavicular coverage angle (TNCA) was obtained using the segmentation and the automatic angle tool based on two-dimensional (2D) projections of 3D axes²⁴. Finally, a repeatability study was performed to quantify variability in articular selections on the calcaneus and talar head. Models were recreated and the joint area was selected on each bone.

Statistical analysis. Statistical calculations were performed in MATLAB and Excel using Visual Basic for Applications. Normality was determined using the Shapiro–Wilk Test. *P* values for data sets that were normally distributed were calculated using a two-tailed Student’s *T*-test; *P* values for data sets that were not normally distributed were calculated using the Mann–Whitney–Wilcoxon *U* test. Pearson correlation was utilized for correlation between variables. Intraclass correlation coefficients were computed to evaluate interrater selections of the articular areas.

Ethics and means of dissemination. This work was conducted under University of Iowa’s institutional review board approval (IRB# 201904825). Subjects signed an informed consent prior to inclusion.

Transparency declaration. The author affirms that this manuscript is an accurate, honest, and transparent account of the study reported; that no important aspects of the study were omitted; and that any discrepancies from the study as planned (and, if relevant, registered) were carefully explained.

Results

No significant differences were found in the patient characteristics between PCFD and control groups with respect to age ($P=0.80$), sex ($P=1.00$), and BMI distributions ($P=0.40$) (Table 1).

Coverage maps. Significant decreases in coverage were seen in all middle and medial regions of the talar head of PCFD patients in comparison to controls (Fig. 3). The largest decrease in coverage was seen in the plantar medial ($-79%$, $p=0.003$) and dorsal medial regions ($-77%$, $p=0.00004$). Coverage also decreased in PCFD for both the dorsal middle ($-23%$, $p=0.001$) and plantar middle ($-26%$, $p=0.003$) regions. Corresponding increases in coverage were seen in both the dorsal lateral ($+21%$, $p=0.002$) and plantar lateral ($+30%$, $p=0.0003$) regions

Characteristic	Control (n = 20)	PCFD (n = 20)	P value
Male, No	6	6	–
Female, No	14	14	–
Age, mean ± SD, y	48.0 ± 19.9	49.5 ± 17.6	0.800
BMI, mean ± SD, kg/m ²	30.3 ± 8.7	32.7 ± 8.0	0.397

Table 1. Patient demographics of progressive collapsing flatfoot deformity and control patients. *BMI* body mass index, *PCFD* progressive collapsing foot deformity, – no entries.

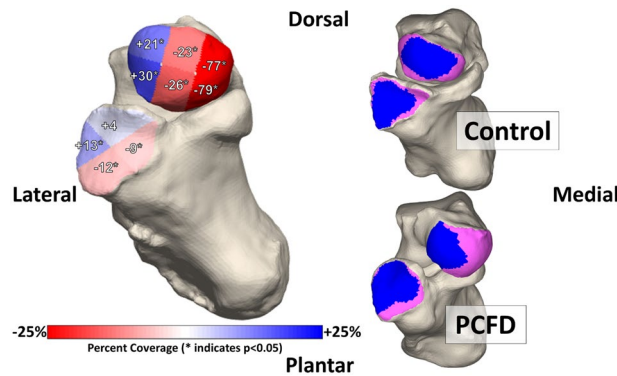


Figure 3. Average percent differences in coverage for the 6 talar head and 4 calcaneocuboid facet regions. Red represents a decrease in coverage from controls to Progressive Collapsing Foot Deformity patients while blue represents an increase.

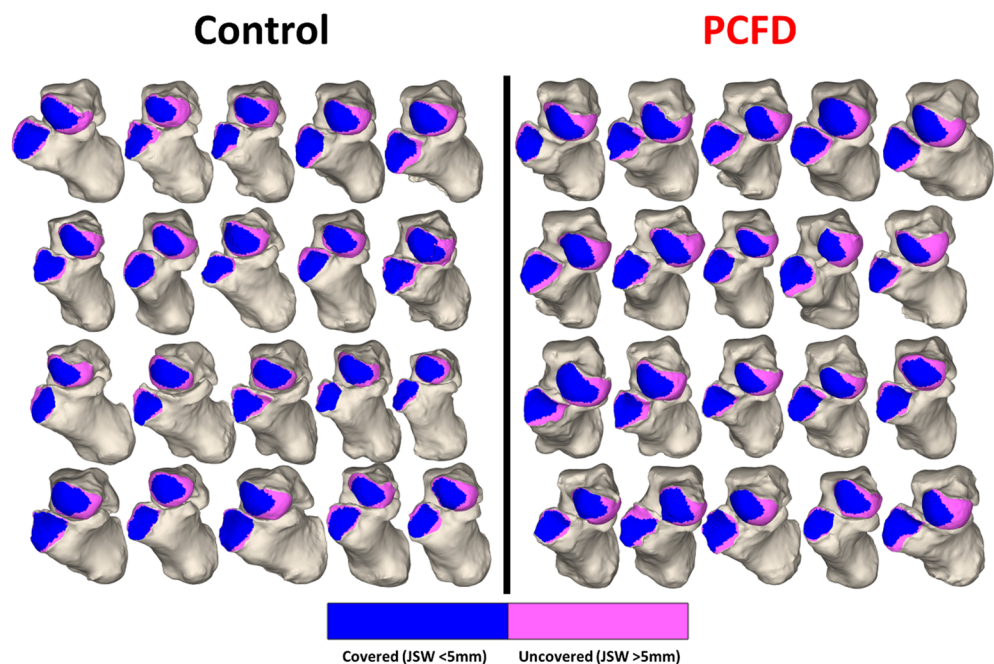


Figure 4. Chopart joint coverage maps for all control and Progressive Collapsing Foot Deformity feet. The navicular and cuboid are removed to show an anterior view of the talar head and calcaneocuboid facet. Pink indicates regions of uncoverage while blue represents regions of coverage.

Characteristic	Control, percent coverage			PCFD, percent coverage			Mean difference %	P values	
	Mean (%)	SD (%)	Median (%)	Mean (%)	SD (%)	Median (%)		T-test	MW test
Calcaneus	82.7	12.5	85.0	81.7	14.7	84.8	-1.1	0.649	-
Medial	83.1	12.9	86.9	75.9	13.0	76.0	-8.7	-	0.037
Plantar	87.9	10.2	92.1	77.4	16.1	83.7	-11.9	-	0.006
Dorsal	78.1	11.9	79.2	81.5	15.8	86.2	4.3	0.079	-
Lateral	81.5	12.6	85.2	92.0	5.4	93.7	12.8	-	0.002
Talus	53.3	29.8	59.9	49.0	37.2	54.0	-8.0	0.219	-
Dorsal									
Medial	21.5	16.5	15.9	5.0	8.7	1.4	-76.5	-	0.00001
Middle	78.2	12.0	74.9	60.4	18.4	66.3	-22.8	0.00121	-
Lateral	71.9	16.2	71.8	87.1	10.1	88.6	21.1	0.00154	-
Plantar									
Medial	13.6	11.9	8.8	2.9	4.5	0.8	-78.6	-	0.0003
Middle	64.3	17.8	68.2	47.6	14.7	50.9	-25.9	0.0032	-
Lateral	70.1	15.7	75.9	91.0	11.6	94.9	29.9	0.00004	-

Table 2. Means, medians, and standard deviations for 3-dimensional coverage maps, measured in percent coverage, and mean differences in the coverage percent in the Chopart joint when comparing patients with progressive collapsing foot deformity and controls, with *P* values for the comparisons. *MW test* Mann–Whitney U test, *SD* standard deviation, *PCFD* progressive collapsing foot deformity.

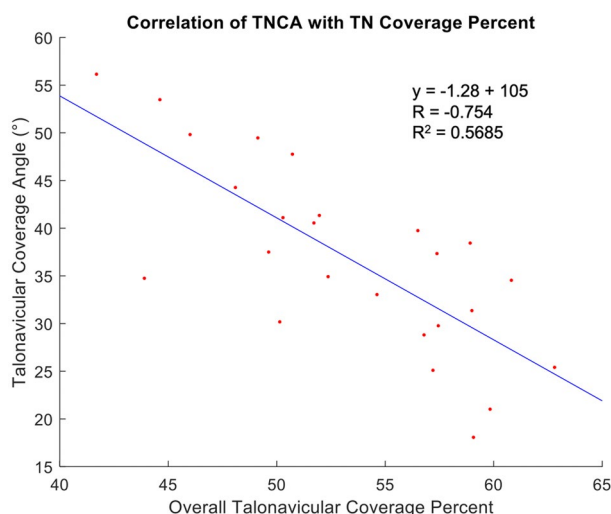


Figure 5. Correlation between the talonavicular three-dimensional (3D) coverage and the talonavicular coverage angle (TNCA). A moderate negative correlation was observed.

of the PCFD group. Overall coverage of the talar heads was similar among groups ($p=0.22$). CMs for every joint are shown in Fig. 4. Percent coverage for each subregion is reported in Table 2.

Changes in coverage were also observed in the calcaneocuboid facet. Coverage increased in the lateral region (+13%, $p=0.002$) but not in the dorsal (+4%, $P=0.79$) region of PCFD patients. A significant decrease in coverage was observed in both the plantar (-12%, $p=0.006$) and medial (-9%, $p=0.037$) regions. Changes in overall coverage of the calcaneocuboid facet were not significant ($p=0.649$) when comparing the studied groups. TNCA had a mean of 31.52° (SD ± 6.78) in controls and 45.13 (SD ± 7.08) in PCFD patients ($p<0.001$). Talonavicular coverage was negatively correlated ($r=0.75$) and influenced ($R^2=0.57$) by the TNCA (Fig. 5).

Distance maps. DM measurements for each joint (Fig. 6) are reported as means for each region in Table 3. There were no significant differences ($ps>0.224$) in the mean distances for either the calcaneocuboid or the talonavicular articulation when comparing both groups. Additionally, there were no clear trends toward increased or decreased distances across cases (Fig. 7).

Selection reliability. Selections of articular regions for the talus, calcaneus, cuboid, and navicular were compared across two trials taken at least 8 weeks apart. Average areas for each region are reported in Table 4

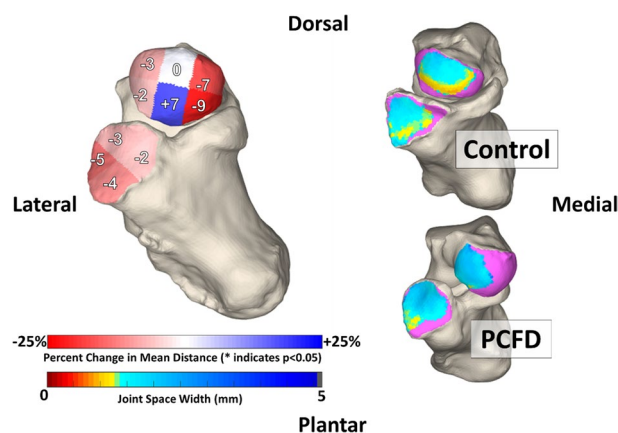


Figure 6. Average percent differences in distance for the 6 talar head and 4 calcaneocuboid facet regions. Red represents a decrease in decrease in distances from controls to Progressive Collapsing Foot Deformity patients while blue represents an increase.

Characteristic	Control, mm		PCFD, mm		Mean difference, %	P value
	Mean	SD	Mean	SD		
Calcaneus	1.73	0.40	1.67	0.32	- 3.6	0.256
Medial	1.91	0.37	1.86	0.30	- 2.3	0.688
Plantar	1.53	0.33	1.46	0.26	- 4.3	0.501
Dorsal	1.90	0.43	1.85	0.25	- 2.8	0.648
Lateral	1.62	0.32	1.53	0.24	- 5.3	0.362
Talus	1.53	0.43	1.50	0.57	- 1.9	0.654
Dorsal						
Medial	1.43	0.29	1.34	0.82	- 6.6	0.639
Middle	1.70	0.52	1.71	0.22	0.3	0.963
Lateral	1.81	0.49	1.76	0.25	- 2.9	0.680
Plantar						
Medial	1.38	0.43	1.26	0.97	- 8.6	0.648
Middle	1.39	0.27	1.48	0.18	6.6	0.224
Lateral	1.47	0.33	1.43	0.25	- 2.3	0.717

Table 3. Means and standard deviations for 3-dimensional distance maps, measured in millimeters, and mean differences in the distances in the Chopart joint when comparing patients with progressive collapsing foot deformity and controls, with P values for the comparisons. SD standard deviation, PCFD progressive collapsing foot deformity.

with intraclass correlations. Across all selections, the average difference was $9.4 \pm 38.1 \text{ mm}^2$ and the intraclass correlation coefficient for the areas was 0.9907.

Discussion

This study evaluated joint subluxation across the talonavicular and calcaneocuboid interfaces using distance and coverage mapping of full weightbearing CTs in patients with stage I flexible PCFD. Patients with PCFD presented with significant coverage changes in Chopart articular regions when compared to controls. The significant decrease in coverage on medial talar head and plantar medial regions of the calcaneocuboid interface supported our primary hypothesis. Interestingly, in our cohort there were no significant differences in calcaneocuboid or talonavicular distances refuting our second hypothesis. Finally, selection of these regions proved reliable with an ICC > 0.99.

In patients with PCFD, subluxation occurred on both the talar head and the calcaneocuboid facet. Significant subluxation was noted on the medial side of the talar head in patients with PCFD, specially on its plantar aspects (plantar medial: - 79%; $p = 0.003$; plantar lateral: - 77%; $p = 0.00004$). Parallely, the lateral regions on the talar head experienced an increase in coverage when compared to the controls (dorsal lateral: + 21%, $p = 0.002$; plantar lateral: + 30%, $p = 0.0003$). The changes in coverage on the plantar and dorsal subregions of the talar head were similar eliminating pure plantarflexion as the cause of this subluxation. This may indicate a tendency toward medial abduction and external rotation of the navicular as the root cause of these changes in coverage. These

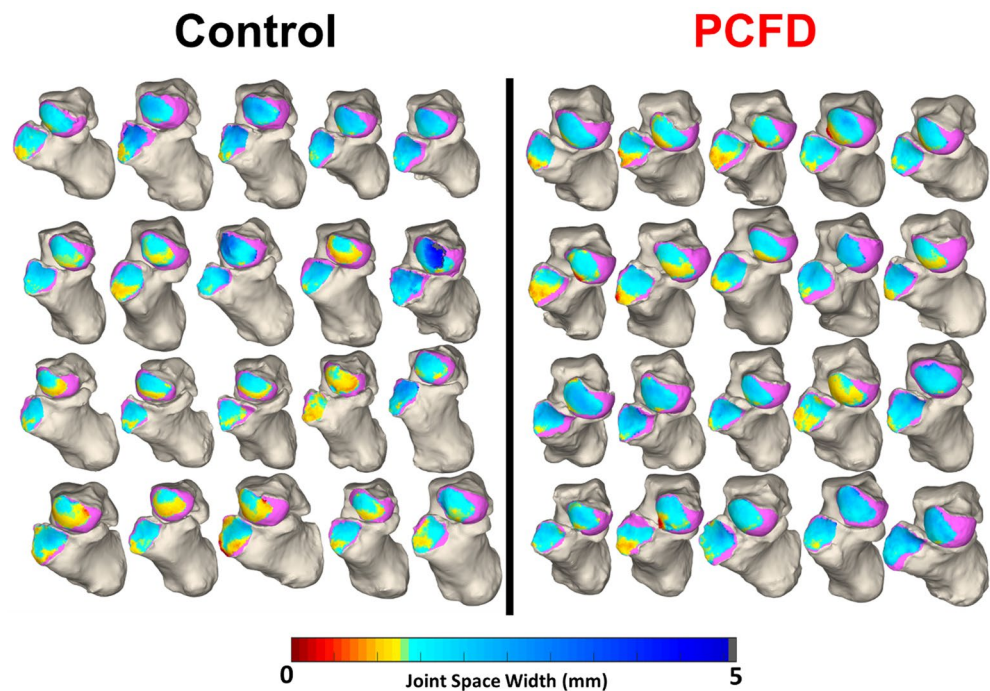


Figure 7. Chopart joint distance maps for all control and Progressive Collapsing Foot Deformity feet. The navicular and cuboid are removed to show an anterior view of the talar head and calcaneocuboid facet. Normal joint distances are shown in blue while distances over 5 mm are identified in gray and under 1.5 mm in green to yellow and under 1 mm in orange and red.

Characteristic	Trial 1		Trial 2		Difference	
	Mean, mm ²	SD, mm ²	Mean, mm ²	SD, mm ²	MoD ± SD, mm ²	ICC
Talus	946.7	155.9	947.6	144.9	-0.9 ± 59.7	0.9604
Calcaneus	486.4	71.5	471.8	59.5	14.5 ± 45.8	0.8475
Navicular	569.0	95.3	558.2	91.9	10.9 ± 16.4	0.9893
Cuboid	447.0	55.1	433.7	55.7	13.3 ± 30.4	0.9036

Table 4. Intraclass correlation coefficient for selected regions, determined from area of regions. *ICC* intraclass correlation coefficient, *MoD* mean of differences, *SD* standard deviation.

findings are in line with work by Louie et al., who was also able to identify a medial to lateral shift in coverage ($p < 0.0001$)⁸. However, Louie et al. found more pronounced plantar uncoverage than our cohort, potentially explained by differences in imaging acquisition (simulated weight-bearing CT and WBCT)⁸. Kitaoka et al. using cadaveric analysis, demonstrated a shift for a more central and dorsal contact distribution in PCFD patients⁵. Further, Malakoutikhah et al. observed a decrease in overall contact pressure and subluxation of the talonavicular joint when their finite model was collapsed¹⁰. These could contribute to the understanding that the deformity has a complex out of plane rotational component rather than a simple sagittal and axial movement^{23,25,26}. Phan et al., using dual fluoroscopy, were able to observe similar behavior at the talonavicular joints of flatfoot patients, demonstrating increasing abduction (9.29 ; $p = 0.003$) and external rotational (11.17 ; $p = 0.0032$) in comparison to controls⁹.

On the calcaneocuboid facet, significant subluxation occurred at the plantar (-12% , $p = 0.006$) and medial (-9% , $p = 0.037$) subregions in patients with PCFD. Increases in coverage on the lateral and dorsal subregions occur, but only the lateral increase in coverage was significant ($+13\%$, $p = 0.002$). Comparable compartment was observed by Phan et al. at the calcaneocuboid joints of flatfoot with higher external rotation movement (6.15 , $p = 0.351$). The fact that PTS produces instability at the subtalar joint and the calcaneus also moves around the talus may explain why coverage changes were not as large on the calcaneal cuboid joint. Similarly, Wang et al. noticed lesser movement at the calcaneocuboid joint in comparison to the talonavicular and subtalar joints²⁷. The study demonstrated 3.93° , 5.04° and 5.97° of dorsiflexion; 5.82° , 8.21° , and 15.46° of eversion; and 9.75° , 7.6° , and 4.99° of external rotation in normal feet during midstance in CC, talonavicular, and subtalar joints, respectively²⁷.

Differences in overall coverage were not observed in either joint when comparing PCFD and control patients ($p = 0.649$) in our study. This is similar to what Louie et al. reported, finding similar overall coverage of the talus

(62% vs. 56%) and navicular (98% vs. 92%) when comparing symptomatic flatfoot and neutral aligned subjects through CM. This is likely due to PTS increasing coverage and contact in some areas and decreasing by similar amounts in others thus providing a mean neutral value^{7,12,23}. Another argument, raised by Louie et al., is that some of the PCFD can be secondary to a pediatric flatfoot and present dysplastic alterations to bone and joint that could create abnormal cartilaginous relations in subluxed areas^{8,28,29}. The last possibility is that even in full weightbearing conditions, early PCFD may not experience true subluxation through the Chopart articulation. In this scenario hindfoot PTS, forefoot deformity, and ligamentous laxity cause changes through the midfoot that are within the compliance of highly mobile articulations.

This explanation is supported by the absence of differences seen among PCFD and controls in the overall and regional distance mapping ($p > 0.224$). Since our sample is composed of flexible (stage 1) middle-age PCFD patients (mean 49.5 years old), early signs of joint degeneration (narrowing) would not be expected. In contrast to the subtalar joint where forces applied to the region are primarily vertical, making impingement (especially sinus tarsi) a valuable marker of topography, the tarsal joints present perpendicular to gravity resulting in increased potential for shearing and decreased potential for static extraarticular impingement^{22,23}. A subluxation pattern might expect to see small decreases in distance on a side acting as a fulcrum to lever the opposing side out which would see an increase in distances. This pattern of DM changes were observed by Bernasconi et al. in their assessment of patients with asymptomatic pes planovalgus and controls, with decreases in distances superolaterally (-20% , $p = 0.097$) and increases superomedially ($+30.7\%$ increase, $p = 0.015$) and inferomedially ($+45.1\%$, $p = 0.001$) talonavicular regions³⁰. Similar to our study, no changes in distance were observed by this study at the calcaneocuboid joint³⁰.

To account for potential differences in coverage derived from variance in selection, we evaluated the current gold standard of manual selection at two time points. Surface selections had a high reliability with an ICC greater than 0.99. The mean areas of the for the cuboid and talar head articulations were 433.7 and 947.6 mm², respectively. Compared to the average area of the articular surfaces, the mean of differences between each trial averaged 9.4 ± 38.1 mm². The average difference between the two selections was at most 10% of the overall area. These differences are negligible relative to the magnitude of differences seen in the overall talonavicular and calcaneocuboid joints; they are likely to average out over a population. However, increased reliability may be important to consider when looking at subregional analyses of individual cases where local variance in selection may impact results more dramatically. Therefore, automated methods are desirable to increase reliability before considering these results in the context of individual cases.

This study has several limitations. As a retrospective study, it could not evaluate the linear progression of the disease. Additionally, patients were not followed over time to identify changes secondary to PCFD. The study's findings cannot be applied to class E (ankle valgus) and stage 2 (rigid) subjects which may involve later stage deformity. The matched control group consisted of a heterogeneous group of healthy volunteers. Although we observed statistically significant differences, previous sample calculations or power analysis were not performed. This could have underestimated the changes and contributed to similarities in overall coverage and distance mapping. Patient functional assessment was not executed, preventing correlation between symptoms and imaging findings. Finally, the use of WBCT and 3D coverage and distance mapping are still not widely accessible, decreasing the study's reproducibility.

Conclusion

In conclusion, our study results show that significant subluxation occurs on the medial region of the talar head and the plantar medial regions of the calcaneocuboid joint. To our knowledge, this is the first study to assess subluxation across the entire Chopart joint under full weightbearing conditions. These results provide a baseline to understand changes occurring at the transverse joint of PCFD patients, providing data that might help in disease management. Coverage and distance mapping provide objective information that could lead to earlier diagnosis and better assessment treatment impact when reestablishing joint interfaces. Future research is needed to increase reliability through automation and continue the search for more complete understanding of physiological bone congruence and changes associated with collapse and to halt articular degeneration in PCFD.

Data availability

According to the ICMJE data sharing policy, core records will be shared through Mendeley Data and available upon request. Requests should be addressed to the corresponding author.

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Author contributions

A.B.: had full access to all the data in the study and takes responsibility for the integrity and accuracy of the data analysis. Literature revision, study design, writing, paper submissions and data collecting. K.D.: literature revision, writing. M.L.: co-supervisor, writing, data collecting and paper submission. K.A.M.C.: literature revision, writing. F.L.: literature revision, writing. N.S.B.M. (Corresponding Author): Literature revision, study design, writing, paper submissions and data collecting. C.C.N.: supervisor. Literature revision, writing, study design, and paper submissions. Each author contributed to the refinement of the study protocol and approved the final manuscript.

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Competing interests

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Quantification de l'instabilité latérale chronique de cheville et de ses différents facteurs de risque sur la vitesse angulaire en inversion lors d'un traumatisme simulé.

Résumé

Les entorses du plan ligamentaire latéral de cheville (ELC) récidivent fréquemment définissant l'instabilité latérale chronique de cheville (ILCC). Ces pathologies ont un impact socioéconomique important. Disposer d'un score prédictif d'ELC présente un double enjeu. Tout d'abord celui d'identifier les sujets à risque afin d'agir de manière prophylactique et d'éviter les premiers épisodes d'ELC. Ensuite de proposer des traitements adaptés à chaque sujet après une ELC afin de diminuer l'incidence d'ILCC.

L'ILCC est multifactorielle et la recherche dans ce domaine doit permettre d'englober l'ensemble de ces facteurs. Nous avons développé un simulateur d'entorse, et ce dernier nous a permis de différencier des sujets ILCC de témoins par la mesure de la vitesse angulaire en inversion lors d'un traumatisme simulé. Ce paramètre, qui quantifie l'ILCC, prend en considération tous ces facteurs. Nous avons également réalisé une revue de la littérature permettant l'énumération de ces facteurs.

Certains de ces facteurs de risque sont constitutionnellement présents, laissant la place à une prise en charge prophylactique. D'autres sont consécutifs aux épisodes d'ELC et doivent être traités pour éviter la survenue d'ILCC. Ces facteurs interagissent et se cumulent. Nous proposons un modèle cumulatif d'ILCC reprenant ces différents points.

L'inconnue reste dans la part relative que joue chacun de ces facteurs dans la survenue d'ILCC. Nous souhaitons donc disposer d'outils fiables et simples permettant de quantifier chacun de ces facteurs. Ces facteurs seront ensuite évalués sur une cohorte de sportifs à l'aide de ces outils ainsi qu'à l'aide du simulateur d'entorse que nous avons développé. Chaque facteur pourra ainsi être pondéré sur la vitesse angulaire en inversion. La pondération et le cumul de chacun de ces facteurs pourrait permettre d'établir un score prédictif de survenue d'ELC. Une fois établi, ce score sera mis à l'épreuve dans une étude de cohorte prospective permettant le recueil et le suivi des facteurs de risque et des épisodes d'ELC.

Mots Clés : entorse de cheville, instabilité de cheville, facteurs de risque, vitesse angulaire en inversion

Chronic lateral ankle instability and its risk factors: quantification on angular inversion velocity during a simulated trauma.

Abstract

Recurrences of lateral ankle sprains (LAS) are common and define chronic lateral ankle instability (CLAI). Their socioeconomic impact is significant. Having a score that can predict LAS carries a double stake. First of all, identify the subjects at risk in order to act prophylactically and avoid LAS first events. In addition, to propose individualized treatments after a LAS aiming to reduce CLAI incidence.

CLAI is multifactorial and research in this field must encompass all these factors. We developed a sprain simulator, which allowed us to differentiate CLAI subjects from controls by measuring the maximal inversion velocity during a simulated trauma. This parameter, which quantifies CLAI, takes all these factors into account. We also conducted a literature review to identify these factors.

Some of these risk factors are constitutional, leaving room for prophylactic management. Others are consequential to LAS events and must be treated to prevent CLAI development. These factors interact and are cumulative. We propose a cumulative model of CLAI that takes these different points into account.

But we do not know the relative role that each of these factors plays in the CLAI occurrence. We therefore wish to have reliable and simple tools to quantify each of these factors. These factors will then be evaluated on a athletes' cohort using these tools as well as the sprain simulator we developed. Each factor will then be weighted on the maximal inversion velocity. The weighting and cumulation of each of these factors could allow us to establish a predictive score for LAS occurrence. Once established, this score will be tested in a prospective cohort study allowing follow-up and collection of risk factors and LAS events.

Keywords: lateral ankle sprain, chronic ankle instability, risk factors, inversion velocity