**Developing consensus on clinical assessment of acute lateral ankle sprain injuries: protocol for an international and multi-disciplinary modified Delphi process [Study Protocol Document]**

**ABSTRACT**

**BACKGROUND:** Lateral ankle sprains are the most frequently incurred lower limb musculoskeletal injury by individuals who participate in sports and recreational physical activities. In order to ensure optimal management of individuals who have incurred an acute lateral ankle sprain injury, clinical assessments should evaluate whether mechanical and sensorimotor impairments are present in the acute phase of injury. Using a modified Delphi process, our aim is to inform discussions regarding the development of an international and multi-disciplinary consensus on the clinical assessment of acute lateral ankle sprain injury.

**METHODS:** An international and multi-disciplinary steering committee with varying levels of clinical, academic and research experience was formed to develop and conduct this study. The research methods were established amongst the steering committee members. The steering committee determined the study objective, inclusion criteria for the expert panel and developed the domains for an anonymous online questionnaire. Our modified Delphi process will start with an anonymous online questionnaire. Members of the executive committee of the International Ankle Consortium will be invited to participate.

The responses to the online questionnaire will be collated, analysed and used as the foundation for a subsequent consensus meeting of the executive committee of the International Ankle Consortium.

**CONCLUSION:** Our modified Delphi process will inform the development of a consensus guideline on the clinical assessment of acute lateral ankle sprain injuries. It is envisaged that this consensus guideline will help clinicians to identify anomalous mechanical and sensorimotor impairments known to contribute to the development of chronic ankle instability.

**Introduction***Epidemiology of lateral ankle sprain injury*

Lateral ankle sprain injury has been identified as one of the most prevalent musculoskeletal injuries sustained by people who partake in competitive sports or recreational physical activities.1-3 Internationally, lateral ankle sprain injuries account for a large percentage of all musculoskeletal injury patients visiting Emergency Departments. In the UK alone, lateral ankle sprain injuries account for 3-5% of all Emergency Department attendances.4 Similarly, over 200,000 ankle sprains are seen annually just in US Emergency Department,5,6 but the actual rates of occurrence in the population are likely to 2-3 times higher.7,8 For example, in the Netherlands alone, it has been estimated that 600,000 people sustain a lateral ankle sprain injury ever year.9

*Development of long-term symptoms and chronic ankle instability*

In spite of the high prevalence, lateral ankle sprain injuries are typically regarded as innocuous injuries that will resolve quickly with little or no treatment.8, 10 The reality is quite different, as the recurrence rate of lateral ankle sprain injury is very high and coincides with the development of several long-term symptoms.11-13 Following an acute lateral ankle sprain injury, pain and swelling are commonplace,14 contributing to reduced functional capacity,14 and occupational absence.15 The development of these symptoms, which also include “giving-way” of the ankle joint, a subjective reporting of ankle joint instability and recurrent ankle sprain are archetypical of a condition known as chronic ankle instability.16 Contemporaneous research highlights that up to 40% of individuals can be expected to develop chronic ankle instability within 1-year of sustaining their first-ever lateral ankle sprain injury.17 In agreement with this, a systematic review identified that approximately 33% of patients with a history of lateral ankle sprain injury will still experience pain and instability, 34% report at least one re-sprain, and up to 64% state that they have not recovered fully 1-year after the conclusion of the “standard of care”.18

*Post-injury deficits: mechanical and sensorimotor insufficiencies*

The progression of chronic symptoms following lateral ankle sprain injury are founded in a combination of mechanical and sensorimotor impairments, which are observed after the injury.11-13, 19 Isolated injuries of the lateral ligamentous complex of the ankle joint following lateral ankle sprain injury are rare.20 Peroneal tendon pathologies, concomitant ligamentous and syndesmotic injuries, anterolateral impingement or osteochondral lesions are highly prevalent in individuals following lateral ankle sprain injury,21 and in persons with chronic ankle instability.22 Perhaps most pertinently, it has been identified that chronic ankle disorders such as ankle joint osteoarthritis affect almost 20% of the community population, with the majority being attributable to a previous ankle sprain injury.23 Furthermore, a body of literature is available to support the presence of sensorimotor impairments in subjects with CAI, manifesting as anomalies across a “spectrum” of human movement.24-28 These anomalous movement patterns are considered to be at the crux of the long-term sequalae of chronic ankle instability.29 A recent cohort study serially tested individuals after they had sustained a first-time lateral ankle sprain injury;17 these individuals displayed apparent sensorimotor aberrancies during static postural control,30-32 dynamic balance,33, 34 gait,35, 36 and jumping/landing tasks37-40 in the acute and sub-acute phases of injury. Many of these aberrancies were deemed to have directly contributed to the development of chronic ankle instability.17

*Consensus on the clinical assessment of acute lateral ankle sprain injury*

Before effective management protocols for lateral ankle sprain injury can be developed and implemented, it is pertinent that a best practice, evidence-based approach in the clinical assessment of lateral ankle sprain injury must first be established. Second to diagnosis of the acute injury, the aims of the clinical assessment must address any mechanical and sensorimotor impairments present in a patient. Identifying the presence or absence of mechanical and sensorimotor impairments in the initial assessment may provide indication if the patient is at risk for the development of chronic ankle instability following their acute lateral ankle sprain injury. Furthermore, a structured clinical assessment guideline that assesses for these aberrancies can be subsequently used to ensure that the patient undertakes a more efficient and appropriate management pathway. A more robust rehabilitation protocol, may in turn, reduce the likelihood of the development of the long-term sequalae associated with chronic ankle instability.

Developing structured, best practice, evidence-based guidelines for the clinical assessment of lateral ankle sprain injury could be achieved by a systematic expert opinion approach. The Delphi method involves a sequence of questionnaires or surveys used to ascertain expert consensus on clinical issues.41, 42 Using this approach, our aim is to inform discussions regarding the development of an international and multi-disciplinary consensus on the clinical assessment of acute lateral ankle sprain injury, which may help clinicians identify anomalous mechanical and sensorimotor impairments known to contribute to the development of chronic ankle instability. We will use a modified Delphi method in a group of clinicians, academicians and researchers. This procedure will serve as part of the preparation for the 7th International Ankle Symposium executive committee meeting and the development of a consensus article on the clinical assessment of lateral ankle sprain injuries.

**Methods and Design**

In order to inform an international and multi-disciplinary consensus on the clinical assessment of acute lateral ankle sprain injuries we will undertake a modified Delphi method. A Delphi process is used to form an expert consensus based on the feedback from a group of experts participating in subsequent rounds.43 Our modified Delphi process will start with an anonymous online questionnaire. The responses to the online questionnaire will be collated, analysed and used as the foundation for a subsequent consensus meeting of the international, multi-disciplinary expert group.

**Steering Committee**
An international (Ireland, USA, Switzerland) and multi-disciplinary research group (DSB, AR, CD, PG, ED) with different levels of clinical, academic and research experience was formed to develop and conduct this study. The research methods were established amongst the steering committee members in weekly face-to-face meetings and via email following a literature search in PubMed. The steering committee determined the study objective, inclusion criteria for the expert panel and developed the domains for the online questionnaire. Pilot testing of the online questionnaire was undertaken (4 physiotherapists) and the feedback from this process was used to inform the development of a final draft of the online questionnaire.

**Generation of Online Questionnaire**

The online questionnaire consists of a number of distinct sections including: (1) participant demographics; (2) subjective assessment and patient reported outcome measures; (3) diagnostic imaging; (4) objective assessment (including asssessment of bony integrity, ligamentous integrity, range of motion, arthrokinematics, strength, neurodynamics, postural balance); (5) performance assessment. The online questionnaire is available as an online supplement.

**Selection of International Experts (participants and recruitment)**

Members of the executive committee of the International Ankle Consortium (n = 14) will be invited to participate. All members of this committee have published more than 3 peer-reviewed articles on the topics of lateral ankle sprain and chronic ankle instability, have presented at national and/or international symposia on these topics, and have contributed to previous consensus statements.11-13, 44, 45

**Ethics**
The online questionnaire includes an informed consent section which is required to be answered before participants can continue to the main sections. The methods of this study and content of the online questionnaire was approved by the University College Dublin Human Research Ethics Committee (LS-E-17-77-Remus-Delahunt). As part of the consent process, participants will agree to partake in the online questionnaire, as well as the consensus meeting that will take place a day before the 7th International Ankle Symposium, which is scheduled to take place at the University of North Carolina at Chapel Hill, USA, in September 2017.

**Delphi Procedure (data collection and data analysis)**

An email will be sent to all members of the executive committee of the International Ankle Consortium requesting their participation in the online questionnaire. To collate the responses to the online questionnaire we will use Google Forms as the hosting platform. The advantage is that participant responses can be conducted remotely and automatically downloaded to Microsoft Excel for aggregation and analysis. Participants will be required to complete the online questionnaire within 4 weeks of receiving the invitation email. A reminder email will be sent to all participants two weeks after the initial invitation email. With reference to the online questionnaire, participants will be requested to respond to questions related to the importance of different constructs of the clinical assessment of acute lateral ankle sprain injuries on a scale of 1 to 5 (1 = strongly disagree; 2 = disagree; 3 = no opinion; 4 = agree; 5 = strongly agree). They will also have the opportunity to elaborate further on how they would assess certain structures or functions by providing expanded answers to open-ended questions. The data from the responses to the online questionnaires will be collated and analysed. A cut-off score of ≥75% agreement is proposed for consensus. The results of the online questionnaire will then be presented by one of the authors to the participants at the executive committee meeting of the International Ankle Consortium, which is scheduled to take place the day before the 7th International Ankle Symposium (14th of September 2017). These results will then be utilized by the executive committee to formulate a consensus guideline on the clinical assessment of acute lateral ankle sprain injuries.

**Discussion**
We plan to collate and analyse the responses to the online questionnaire in a meaningful and statistically rigorous way to inform the development of a consensus guideline on the clinical assessment of acute lateral ankle sprain injuries. The development of this guideline will allow clinicians to undertake a thorough, best-practice and evidence-based clinical assessment of acute lateral ankle sprains injuries. This will allow them to identify anomalous mechanical and sensorimotor impairments known to contribute to the development of chronic ankle instability. The identification of such impairments could facilitate the administration of an evolved “standard of care” for lateral ankle sprain injury patients that may help to reduce the risk for the development of chronic ankle instability.

**Dissemination Plan**

The findings of this research project will be disseminated through peer-reviewed publications and presentations of the findings at national and international conferences.

**Delphi Study Status**

The online questionnaire will be completed by the end of July 2017. The responses to the online questionnaire will be collated and analysed in August 2017. The results of the online questionnaire will be presented to the executive committee members of the International Ankle Consortium the day before the 7th International Ankle Symposium. A peer-reviewed article detailing the consensus guideline on the clinical assessment of acute lateral ankle sprains will be subsequently published.

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