Development of a medical device for ankle injuries diagnosis

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Abstract: Biomedical Engineering plays a key role in the development of devices that tend to eliminate the variability in regards to the evaluation of the diagnosis, helping in making decisions less dependent on the experience and clinical sensitivity. In Orthopedics, the assessment of injuries that affect the joints involves movements that are only limited by the patient’s capacity to support pain. A biomechanical device that controls these movements induced by the physician and able to assess the degree of injury in the same way for all patients is a major contribution to this clinical practice. The main purpose of this thesis is the design of a medical device for the diagnosis of more frequent musculoskeletal injuries, ankle sprains. To that purpose, we identify the requirements able to diagnose the ruptures of the lateral ligaments of the talocrural joint, based on the detailed knowledge of existing devices, and we propose a solution taking into account their feasibility through additive techniques (3D printing). The device called Lisbon Ankle Testing Device (LATeD) permits plantar flexion and dorsiflexion movements (within an amplitude proximal of 90°) internal and external rotation (within an amplitude of ±50°) adduction and abduction (within an amplitude of ±20°) and anterior and posterior displacement (within an amplitude of 4 mm). The result is the creation of the prototype of this device which specifically details the mechanism adopted and provides all relevant information for its construction.

Keywords: Biomedical Engineering, Orthopaedic, Biomedical device, Ankle sprains, Talocrural joint, Lateral ligaments.

1. Introduction

In the past 40 years, there have been notorious progresses concerning the health of the Portuguese population. This situation can be explained due to the increase of healthcare supply, its wider coverage and generalized accessibility, as well as the significant increase of human, financial and technical resources provided by the national healthcare system [1].

The technological development throughout the years made it possible for engineers to develop devices that support the diagnosis and medical treatment of injuries, ensuring a better quality of life to our society.

The combined action between Engineering and Medicine, gave origin to the Biomedical Engineering field, which aims to develop any type of device, software or other similar pieces that allow for a faster and better diagnosis, treatment or prevention of a disease or injury. These developments bring several advantages to clinical practice, such as decreasing the execution time of tasks, optimizing existing resources, and obtaining higher quality and patient satisfaction. In particular, systems related to the musculoskeletal system have been studied by one of the sub-areas of Biomedical Engineering, Biomechanics, which has provided important contributions to orthopaedics and rehabilitation medicine [2]. In fact, the development of orthopaedic rehabilitation devices and systems has been one of the greatest contributions of biomechanics.

It is in this context that this dissertation was developed, aiming to provide an aid apparatus in the diagnosis of the most common ankle injuries (Figure 1.1.), particularly at the level of acute joint instability...
(sprains). The usual mechanism of injury corresponds to the inversion of the foot, and occurs when the joint exceeds the acceptable anatomic limit. This type of injury usually occurs when the individual steps on uneven ground or during the practice of sports. The twist occurs first in the anterior talo-fibular ligament followed by calcaneofibular ligament [4].

These lesions are diagnosed by a limited set of information, such as visual inspection, palpation and the results of manually performed tests, which lack objectivity and accuracy. These limitations result in a qualitative classification of the severity degrees of various sprains severity levels. An auxiliary diagnostic method would decrease the dependency of a subjective personal analysis and possibly introduce a quantitative measurement for the damage evaluation, which would allow a more accurate diagnosis. Aware of these limitations, Orthopaedics Doctor Francisco Guerra Pinto established contact with the Biomechanics research group of the Department of Mechanical Engineering of the Technical University of Lisbon, with the purpose at developing a medical device to help health professionals in the diagnosis of ankle sprains, one of the most frequent musculoskeletal injuries. A challenge to which my Masters Degree’s thesis attempts to adress.

The device designed in this paper, also known as the Lisbon Ankle Testing Device (LATeD), aims to improve the patients’ quality of life, by allowing a quantitative diagnosis and, consequently, a treatment according to the the ligament rupture severity. The accuracy with such medical devices, in particular LATeD, perform repetitive movements, guarantees an identical analysis of the severity of injuries for all users, making the device an asset in clinical practice.

2. Anatomical planes

In this section, are presented the definitions relevant to better explain the position and relative movement between the anatomical segments of the human body are presented.

The anatomical reference planes, also known as cardinal planes, are planes that correspond to delimitations of the human body which facilitate the description of structural positions. They consist of a set of three mutually perpendicular planes, each of them intersecting a single common point, the centre of mass, and enabling the division of the body into two parts of equal mass (Figure 2.1) [5,6,7,8,9].

- **Sagittal plane**, also known as anterior-posterior plane. Divides the body vertically into two halves: right and left;
- **Transverse plane**, also called horizontal plane. It divides the body into two halves: superior and inferior;
- **Frontal plane**, also known as coronal plane. It divides the body vertically into anterior and posterior halves;

![Figure 1.1 - Anterior talo-fibular ligament (ATFL) and calcaneofibular ligament.](image)

![Figure 2.1 - Anatomical planes](image)
3. Ankle Complex

The ankle complex comprises three joints: the talocrural joint, the subtalar joint, and the distal tibiofibular syndesmosis (Figure 3.1).

![Figure 3.1 - Complex ankle; 1 – Tibia, 2 – Fibula, 3 – talocrural joint, 4 – Talus, 5 – Subtalar joint and 6 - Calcaneus [11]](image)

The talocrural joint is a simple hinge-joint between the leg and the foot. The leg bones (tibia and fibula) form a sort of slot and the curved top bone of the foot (Talus) fits between them. The talus is connected by ligaments to the tibia and fibula [12,13]. Each ligament is a semi-elastic structure made of many strands of collagen fibres. The ligaments of the ankle hold the ankle bones and joint in position. They protect the ankle joint from abnormal movements especially twisting, turning, and rolling of the foot. Ligaments usually stretch within their limits, and then go back to their normal positions. When a ligament is forced to stretch beyond its normal range, a sprain occurs. A severe sprain causes actual tearing of the elastic fibres [5,6,14].

The lateral ligament is made up of three separate bands: one at the front (anterior talo-fibular ligament: ATFL), one in the middle (calcaneofibular ligament: CFL) and one at the back (posterior talo-fibular ligament: PTFL). The AFTL is usually injured in sprains or tears of the ankle ligaments, and sometimes the middle band is affected (Figure 3.2) [5].

![Figure 3.2 - Lateral ligaments of the talocrural joint; 1 – talocrural joint and 2 – Talu-fibular ligament (ATFL) [5].](image)

A joint between the talus and the calcaneus forms the subtalar joint. It is classified as a flat synovial joint, which is stabilized by the cervical ligament (Figure 3.3) [13].

![Figure 3.3 -Subtalar joint; 1 - cervical ligaments [13].](image)

The third joint of the ankle complex is the distal joint, located between the tibia and fibula. This joint is a syndesmosis that allowing limited movement between the two bones, being stabilized by a thick interosseous membrane and the anterior and posterior tibiofibular ligaments (Figure 3.4) [5,12,13].

![Figure 3.4 - Tibiofibular joint; 1 – Opening to the vessel, 2 – Interosseous membrane, 3 – Opening to the peroneal artery and 4 – Malleolus [5].](image)
These three joints work together to allow a coordinated movement of the foot (Figure 3.5).

Foot and ankle motion occurs in accordance to three defined cardinal planes: sagittal-plane motion (plantar flexion-dorsiflexion and anterior displacement), frontal-plane motion (adduction-abduction), and transverse-plane motion (internal rotation-external rotation). Hence, the motion in the sagittal plane occurs around a transverse axis, the one in the frontal plane occurs at a sagittal axis and the third one in the transverse plane occurs at a longitudinal axis.

Table 3.1 introduces the anatomical planes and axis of rotation in each of the movements of the complex of the ankle.

![Figure 3.5 – Axis of rotation of the leg and foot][15].

<table>
<thead>
<tr>
<th>Movement</th>
<th>Planes</th>
<th>Axis of rotation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dorsiflexion or Plantar flexion</td>
<td>Sagittal</td>
<td>-</td>
</tr>
<tr>
<td>Internal or external rotation</td>
<td>Transverse</td>
<td>Longitudinal</td>
</tr>
<tr>
<td>Adduction or Abduction</td>
<td>Frontal</td>
<td>Sagittal</td>
</tr>
<tr>
<td>Anterior displacement</td>
<td>Sagittal</td>
<td>Transverse</td>
</tr>
</tbody>
</table>

### 3.1. Ankle sprain

The ankle sprain is the most frequent pathology of the musculoskeletal system, with more than 75% occurring as the result of plantar flexion and inversion movements of the foot. This type of injury is usually associated with partial or complete tearing of the lateral ligament complex, more precisely, the anterior talo-fibular ligament (ATFL). Clinically, the most commonly sprained ankle ligament is the ATFL, followed by the CFL.

These injuries occur while running on uneven terrain, stepping in a hole, stepping on another athlete’s foot during an activity, or landing from a jump in an unbalanced position.

A sprain by eversion occurs less frequently, affecting the internal lateral ligament, located in the medial aspect of the ankle [12,13,16,17,18,19].

Ankle sprains are classified according to their severity, grade I, II or III [28].

Types of ankle sprains:

**Grade I – Mild:** mild stretching which only causes microscopic injuries in the ligament (Figure 3.6a);

**Grade II – Moderate:** more severe stretching that cause partial tear of the ligament (Figure 3.6b);

**Grade III – Severe:** abrupt stretching which causes complete tear of the ligament (Figure 3.6c);

![Figure 3.6 - Types of ankle sprains][20].
4. Mechanical design

4.1. Introduction

The new medical device called Lisbon Ankle Testing Device (LATeD) aims to address the needs related to the realization of the diagnosis of one of the most frequent musculoskeletal injuries, sprains (Figure 4.1).

![Figure 4.1 - New medical device called Lisbon Ankle Testing Device - LATeD.](image)

4.2. Features

This subsection will mention features that compose this new medical device.

4.2.1. Structural Features

In the development of this device the anthropometric measures of the Portuguese population were considered, so that the dimensions of the parts constituting the LATeD would be adjusted to the population. In addition, it was sought to develop a simple and intuitive device that could easily healthcare professionals, even those who were not familiar with the domain of mechanical systems. In the subchapter 4.3 parts that make up this new medical diagnostic device are referred.

4.2.2. Functional Features

The main functional features of the device consist in the ability to perform a set of movements (presented in Figure 4.2) through a force applied by the healthcare professional.

The movements of the device are presented in Figure 4.2 (adapted of [5,10]).

![Figure 4.2 – Movements of the device also known as LATeD: a) anterior displacement, b) Adduction and abduction, c) Plantar flexion and dorsiflexion) and d) Internal and external rotation;](image)

The method of diagnosis carried out with the aid of LATeD is based on the movements shown in Figure 4.2.

In the idealisation of this prototype, the movements of the foot were considered independent, to the extent that each occurs in a particular segment of the foot’s rotational axis. However, simultaneously conjugated movements were considered, given that the execution of one type of movement implies another. For example, the inverse movement also called supination is a combined movement of adduction and internal rotation, and the eversion motion, in turn, is a combined movement of abduction and external rotation.

In addition to the movement of inversion and eversion, the device is also able to perform the anterior drawer
test which is a combined movement of plantar flexion and internal rotation.

In this context, it is important to define the extent to which the movements occur in the device. The following Table 4.1 presents the values of the extent of the movements permitted by the LATeD:

<table>
<thead>
<tr>
<th>Movement</th>
<th>Extent permitted by the device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anterior displacement</td>
<td>~ 4 mm</td>
</tr>
<tr>
<td>Internal or external rotation</td>
<td>± 50 °</td>
</tr>
<tr>
<td>Adduction or Abduction</td>
<td>± 20 °</td>
</tr>
<tr>
<td>Flexion plantar or dorsiflexion</td>
<td>~ 90 °</td>
</tr>
</tbody>
</table>

**Table 4-1 - Values of extent of the movements permitted by the LATeD.**

**4.3. Device subsets and components**

The new medical device called Lisbon Ankle Testing Device (LATeD) consists mainly of three subsets: the support of the thigh, leg and foot. All these parts are properly screwed in order to ensure its structure (presents in Table 4.2).

<table>
<thead>
<tr>
<th>Subset</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Support of the thigh</td>
<td>Support to secure to the gurney</td>
</tr>
<tr>
<td></td>
<td>Support of the thigh</td>
</tr>
<tr>
<td>Leg</td>
<td>Support of the leg</td>
</tr>
<tr>
<td>Foot</td>
<td>Support of the ankle</td>
</tr>
<tr>
<td></td>
<td>Support of the foot</td>
</tr>
</tbody>
</table>

**Table 4.2 - Subsets and components.**

**4.3.1. Support to secure to the gurney**

The LATeD was designed to be secured to a gurney, through a support component placed at the end of the device (Figure 4.3). This component has a length 230 mm and a width 30 mm.

**4.3.2. Support of the thigh and leg**

For the part supporting the thigh, a semicircle structure was created, taking into account that the upper leg has a greater width at the proximal region compared to the width in the distal region. Thus, a length of 400 mm, a width of 192 mm in the proximal region, and a width of 170 mm in the distal region were considered (Figure 4.4).

Just like the previous part, the leg support also has a semicircle structure, since the leg has a greater width at the proximal region compared to the width at the distal region. Thus, this piece has a length of 200 mm, a width of 158 mm in the proximal region, and a width of 124 mm in the distal region (Figure 4.5).
Since the LATeD is intended to quantify the extent of the ankle injury, it is necessary to ensure that the patient's leg and thigh are both stable. Accordingly, grooves were drawn on these components so that tapes could be introduced making the device easily adjustable for each patient.

These two components allow the knee to be flexed with amplitude of approximately 90° (Figure 4.6). This enables those movements to present a greater extent.

### 4.3.3. Support of the foot

The component that supports the foot is composed of a material named ABS, measuring and has a length of 150 mm length and 164 mm width, under which is located the ankle support part (Figure 4.8). This component has undergone some changes, so that the movement triggered by health professionals were easy to perform. It was also necessary to put a tape in the distal part of the tibia and fibula while performing the anterior shifting movement (marked in Figure 4.7).

### 4.3.4. Ankle Support

The component that supports the ankle is also composed by ABS material, with 330 mm length and a 140 mm width, under which a #48 foot pad with the front cut off was placed. This allows the device to be used by anyone, from people with #34 shoe sizes to people with #48 shoe sizes (Figure). Besides this, sponges can be added to adjust the foot to the pad, giving some comfort to the patient and ensuring that the diagnosis is made with the utmost rigor.

### 4.3.5. Finishing touches.

After the construction of the parts that compose the LATeD, some finishing touches were made. The corners of the surfaces of the components were rounded to
ensure a uniform distribution of tension, thus avoiding tension "peaks" which are more susceptible to brake (Figure 4.9).

Figure 4.9 - Finishing touches.

5. Movements performed by the device called LATeD

An example of the combination of foot movements is given by the Figure 4.2.

Figure 5.1 - Subset of the foot.

5.1. Anterior and posterior displacement

The displacement of anteroposterior is a linear motion that occurs in the sagittal plan. The anterior displacement promotes a movement of the talus in direction to anterior in relation to tibia and fibula. On the other hand, the posterior displacement induces the motion of talus in a posterior direction. The device can reproduce the mechanical action performed by a healthcare professional through the component that makes the contact between the device and the heel of the patient.

The healthcare professional applies an external force on the calcaneus, prompting an anterior or posterior displacement of the talus, in relation to the leg bone (tibia and the fibula) (Figure 5.1). In addition, a foot-mounting bracket is used to avoid anterior displacement of the tibia and fibula during the movement.

It is important to refer that the injury occurs when the displacement of talus is more than the expected in a healthy patient (value above of \(2 \text{ mm}\)).

Figure 5.2 – Anterior and posterior displacement.

5.2. Movement of internal and external rotation

The internal and external rotation takes place around a vertical axis that crosses tibia and fibula.

A rotation in the internal direction of this axis promotes an angular motion in this direction with maximum amplitude of \(50^\circ\).

A rotation in the external direction of this axis promotes an angular motion in this direction with maximum amplitude of \(50^\circ\).

Thus, by activating the mechanism in the internal direction, as illustrated in Figure 5.3, the internal rotation occurs. If this mechanism is not activated the external rotation takes place.

Figure 5.3 - Internal and external rotation.
5.3. Movement of adduction and abduction

The abduction and adduction movements occur in the transversal plane. The first movement consists of an applied force in the internal direction in such a way that the forefoot and midfoot are driven to the midline and the hindfoot is targeted far from the midline. The abduction movement occurs by an applied force in the external direction in a way that they are directed out of the midline and the hindfoot is targeted to the midline. This movement is not free, being limited, in this thesis, to ± 20° (Figure 5.4). If appropriate some of device dimensions can be adjusted in the future in order to increase this value.

Figure 5.4 - Adduction and Abduction movements.

5.4. Movement of plantar flexion and dorsiflexion

The plantar flexion and dorsiflexion movements occur in horizontal axis that crosses the two malleolus (internal and external malleoli). A rotation in the inferior direction promotes a movement of plantar flexion with maximum amplitude of 90° from the vertical position of the foot. The component that is shown in the Figure 5.5 is in contact with heel and talus in a way that the device can reproduce the mechanical action provided by a healthcare professional. After the force has been applied by the healthcare professional occurs the plantar flexion movement (upward force) or the dorsiflexion movement (downforce).

However, there are a wide range of devices on the market intended to diagnose the talocrural joint on the market. To have a real perception of the LATeD value, compared to other devices already on the market, it’s limitations and advantages were listed below.

5.5. Limitations of the LATeD:
1. The healthcare professional’s subjectivity;
2. Doesn’t quantify the force that is applied;
3. Doesn’t register the amplitude of the movement;

5.6. Advantaged of the LATeD:
1. Quantitative diagnosis, allowing the patient to receive the adequate treatment;
2. The movements are independent;
3. Accuracy with which desired movements are performed;
4. It serves as a stabilizer of the structures involved during the execution of the movement ensuring an accurate diagnosis;
5. Simple execution and easily adaptable to any gurney;
6. Conclusions

This dissertation intends to meet the needs related inherent to the diagnosis of ankle injuries. The prototype that resulted from this work, aims to assist healthcare professionals in the diagnosis of some of the most frequent musculoskeletal system injuries, such as sprains, ensuring the patients with a proper treatment.

On a first approach, a review of the musculoskeletal system of the lower limbs was formed, with a detailed description of bone formation, joints, muscles and movements that play a key role in the biomechanical function of the ankle.

The next step consisted in a literature review, mentioning what has been published regarding the researched content, so as to introduce concepts and new paradigms.

After this, a virtual model design using CAD software was carried out, following the defined specifications in accordance with the functionality, quality and maintenance of the device. The manufacturing process and associated costs were also analysed, as well as the placement of the medical device in the European market.

The designed product called LATeD aims to test the ankle joint, evaluating the ligaments that are subjected to efforts during ankle movements. This new medical device intends to guarantee a quantitative diagnosis, thus establishing itself as an asset in clinical practice.

In conclusion, this study explored one of the sub areas of the Biomedical Engineering field, to develop a new medical device with great innovative potential, undoubtedly allowing for a better diagnostic process creating advantageous conditions not only for the patient but also to healthcare professionals, due to the realization of a diagnosis based on the collection of more information.

References


[18] Ringleb, S. I., A three-dimensional stress MRI technique to quantify the mechanical properties of the ankle and subtalar joint – Application to the diagnosis of ligament injuries. Degree of Doctor of Philosophy, Drexel University.

