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DESIGN AND DEVELOPMENT OF A MEASUREMENT PROCEDURE FOR THE ASSESSMENT OF OFFLOADING EFFICACY IN THERAPEUTIC WALKERS AND WITH AIR PRESSURE MATTRESS.

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Academic Year 2019/2020

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Abstract

This work aims to face up with two different problems that every day affect the clinical and hospital environments: the first one known as Pressure Ulcers affect about 30% of people in healthcare institutions. This problem is well known by clinicians but still, there is no a standard and an efficient treatment; in recent years alternating pressure air mattresses are under study and the aim was to test the efficacy of one of this mattresses but due to the restrictions of Covid-19, it was no longer possible to continue in this way. Instead, a standard laboratory procedure is proposed.

The other big problem that nowadays clinicians have to face up with is the Diabetic Foot. Diabetes mellitus, in fact, is increasing globally, and it is one of the most challenging health care dilemmas in the 21st century. In 2015, 415 million people over the world were estimated to have diabetes, and this number is projected to rise to 642 million by the year 2040. The Diabetic Foot is strictly related to this pathology and there is a growing need to avoid amputations in diabetic patients. In this scenario, special walkers are going to be a first treatment to heal ulcers. In this thesis, two different types of walkers made by Optima Molliter are tested and results are very promising in fact the pressure redistribution is reached with unloading peaks of more than 50% in particular zones of the foot.

1. INTRODUCTION

This thesis aims to face up with two still unsolved complications in hospital and clinical environments that affect patient's life in a very negative way. This two are Pressure Ulcers (PU) that affect a big part of hospitalized patients and the second one is the Diabetic Foot (DF) that comes as a consequence of diabetes.

PU (also known as pressure sores, bedsores, decubitus ulcers and pressure injuries) are wounds due to local interference with circulation and have been known about since the time of the ancient Egyptians. Prolonged pressure on a part of the body due to the weight of the body or a limb, mixed with a shearing force can cause Pus, especially in patients with poor nutrition [1]. Pressure and shearing forces can interrupt the blood circulation to underlying tissues. This results in oxygen depletion in soft tissues and muscles [2]. Annually, PU affect an estimated 250,000 to 500,000 individuals in Canada with an overall estimated prevalence of 26.0 % in healthcare institutions. In Germany, the prevalence rate is estimated to be 10 to 25 % among ward patients and as high as 30 % in rehabilitation centers. In one Austrian public hospital, incidence rates were between 1.39 % and 7.98 % for Stage 1, 0.14 % and 1.52 % for Stage II, and 0 % and 0.88 % for Stage III PU [3].

Diabetes mellitus, instead, is a pathology that is increasing globally, and it is one of the most challenging health care dilemmas in the 21st century. In 2015 415 million people over the world were estimated to have diabetes, and this number is projected to rise to 642 million by the year 2040. [4] Two of the main types of diabetes are type 1 and type 2. Diabetes is due to either the pancreas not producing enough insulin or the cells of the body not responding properly to the insulin produced. There are three main types of diabetes mellitus:

- Type 1 diabetes results from the pancreas's failure to produce enough insulin due to the loss of beta cells. This form was previously referred to as "insulin-dependent diabetes mellitus" (IDDM) or "juvenile diabetes". The loss of beta cells is caused by an autoimmune response. The cause of this autoimmune response is unknown.
- Type 2 diabetes begins with insulin resistance, a condition in which cells fail to respond to insulin properly. As the disease progresses, a lack of insulin may also develop. This form was previously referred to as "non-insulin-dependent diabetes mellitus" (NIDDM) or "adult-onset diabetes". The most common cause is a combination of excessive body weight and insufficient exercise.

Type 1 diabetes accounts for a small percentage of the total burden of diabetes in the population. Type 2 diabetes is the most common type of diabetes in fact it constitutes about 85‑90% of all diabetes in developed countries and accounts for an even higher percentage in developing countries.

The DF is the most serious complication of diabetes mellitus [5] and due to the increasing number of cases the economic consequences, for both patient and society, are very large and every effort to improve the care of these patients is worthwhile.

1.1. PRESSURE ULCERS

INTERNATIONAL NPUAP/EPUAP PRESSURE ULCER CLASSIFICATION SYSTEM

A PU is localized injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear. A number of contributing or confounding factors are also associated with PU. [6]

According to the National Pressure Ulcer Advisory Panel, the European Pressure Ulcer Advisory Panel and the Pan Pacific Pressure Injury Alliance, ulcers are classified in:

Category/Stage I: Non-blanchable Erythema

Intact skin with non-blanchable redness of a localized area usually over a bony prominence. Darkly pigmented skin may not have visible blanching; its color may differ from the surrounding area. The area may be painful, firm, soft, warmer or cooler as compared to adjacent tissue. Category/Stage I may be difficult to detect in individuals with dark skin tones. May indicate “at risk” individuals (a heralding sign of risk).

Figure 1: stage I ulcer

Category/Stage II: Partial Thickness Skin Loss

Partial thickness loss of dermis presenting as a shallow open ulcer with a red pink wound bed, without slough. May also present as an intact or open/ruptured serum- filled blister. Presents as a shiny or dry shallow ulcer without slough or suspected deep tissue injury. This Category/Stage should not be used to describe skin tears, tape burns, perineal dermatitis, maceration or excoriation.

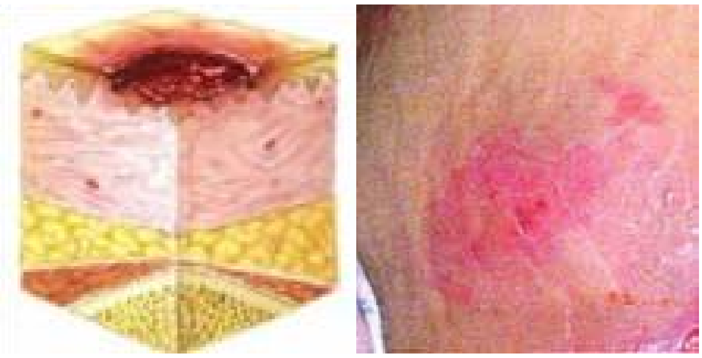

Figure 2: stage II ulcer

Category/Stage III: Full Thickness Skin Loss

Full thickness tissue loss. Subcutaneous fat may be visible, but bone, tendon or muscle are not exposed. Slough may be present but does not obscure the depth of tissue loss. May include undermining and tunneling. The depth of a Category/Stage III PU varies by anatomical location. The bridge of the nose, ear, occiput and malleolus do not have subcutaneous tissue and Category/Stage III ulcers can be shallow. In contrast, areas of significant adiposity can develop extremely deep Category/Stage III PU. Bone/tendon is not visible or directly palpable.

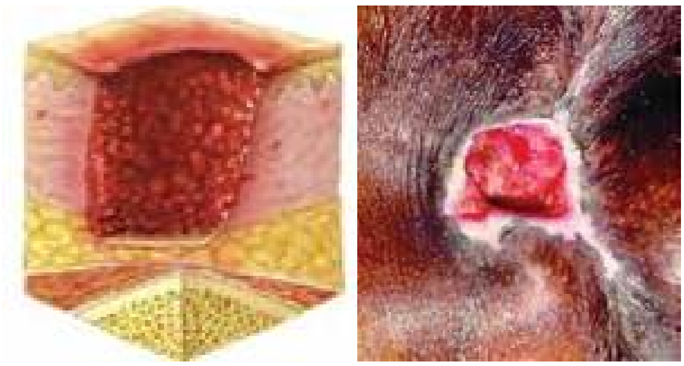

Figure 3: stage III ulcer

Category/Stage IV: Full Thickness Tissue Loss

Full thickness tissue loss with exposed bone, tendon or muscle. Slough or eschar may be present on some parts of the wound bed. Often include undermining and tunneling. The depth of a Category/Stage IV PU varies by anatomical location. The bridge of the nose, ear, occiput and malleolus do not have subcutaneous tissue and these ulcers can be shallow. Category/Stage IV ulcers can extend into muscle and/or supporting structures (e.g., fascia, tendon or joint capsule) making osteomyelitis possible. Exposed bone/tendon is visible or directly palpable.

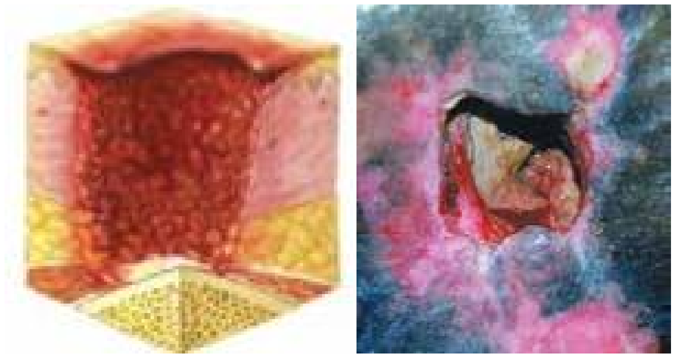

Figure 4: stage IV ulcer

Unstageable: Depth Unknown

Full thickness tissue loss in which the base of the ulcer is covered by slough (yellow, tan, gray, green or brown) and/or eschar (tan, brown or black) in the wound bed. Until enough slough and/or eschar is removed to expose the base of the wound, the true depth, and therefore Category/Stage, cannot be determined. Stable (dry, adherent, intact without erythema or fluctuance) eschar on the heels serves as ‘the body’s natural (biological) cover’ and should not be removed.

Figure 5: Unstageable ulcer

Suspected Deep Tissue Injury: Depth Unknown

Purple or maroon localized area of discolored intact skin or blood-filled blister due to damage of underlying soft tissue from pressure and/or shear. The area may be preceded by tissue that is painful, firm, mushy, boggy, warmer or cooler as compared to adjacent tissue.

Deep tissue injury may be difficult to detect in individuals with dark skin tones. Evolution may include a thin blister over a dark wound bed. The wound may further evolve and become covered by thin eschar. Evolution may be rapid exposing additional layers of tissue even with optimal treatment.

Figure 6: Suspected deep tissue injury

More severe cases require intensive therapy, have longer healing times and are associated with a higher incidence of complications. In the United States, the average hospital treatment cost associated with stage IV PU range from $124,327 to $129,248 USD, whereas in the UK the estimated cost of treatment varies from £1,214 to £14,108 per case. Similar costs are seen in Canada, where the estimated average monthly cost of PU management among individuals with a spinal cord injury in 2010 was $4,475 CDN [3].

1.2. DIABETIC FOOT

Diabetic foot ulcers (DFUs) may be a consequence of both Type 1 and Type 2 diabetes. Studies show that inability to heal foot ulcers is the cause of 85% of lower extremity amputation of diabetic subjects. This is one of the major causes of hospitalization of diabetic patients and it results in an increase in the morbidity and mortality [7].

There are several classification systems for DFUs, the Wagner classification system for foot ulcers is widely used and it includes the following grades:

Wagner grade 0 → No ulcer

Wagner grade 1→ Superficial ulcer (up to but not through dermis)

Figure 7: Wagner grade 1 ulcer

Wagner grade 2→ Ulcer extension involving ligament, tendon, joint capsule or fascia (no abscess or osteomyelitis)

Figure 8: Wagner grade 2 ulcer

Wagner grade 3→ Deep ulcer with abscess and/or osteomyelitis

Figure 9: Wagner grade 3 ulcer

Wagner grade 4 → Gangrene of portion of the foot

Figure 10: Wagner grade 4 gangrene

Wagner grade 5 → Extensive gangrene of the foot

Figure 11: Wagner grade 5 gangrene

The Texas Diabetic Wound Classification System and The PEDIS classification system are mainly used for research purposes.
Detailed scoring systems may be useful in comparing data from different centers, while simpler scoring systems may be more easily used in clinical practice. [4]

Pathogenesis of diabetic foot ulcer

DFUs results because of the combination of different risk factors, in this thesis we will discuss the two main risk factors that are peripheral neuropathy and peripheral vascular disease, but others are linked with arterial insufficiency, trauma, foot deformities and resistance to infection.

• **Peripheral neuropathy**

Neuropathy is a disease that affects the body nerves that, depending on the affected one, can cause damages in sensation and disease in movement. Peripheral neuropathy is a serious complication in patients with diabetes that affects up to 30-50% of the diabetic population. [8,9], and represents one of the major risk factors for the development of DFUs [7].

• **Peripheral vascular disease**

Diabetes represents a risk factor for peripheral vascular disease (PVD). PVD is an atherosclerotic occlusive disease of the lower extremity that leads to the thickening of capillaries basement membranes, hardening of arterial walls, then, acute or chronic ischemia can occur as a consequence of blockages of large and medium-sized arteries. The combination of PVD with artery disease contributes to the development of ulcers and progresses to gangrene due to the inadequate blood flow. Arterial blood supply of diabetic people is in almost case inadequate, for this reason, peripheral ischemia represents the cause of ulcer formation in 35% of the case. [7]

1.3. PRESURE ULCER TREATMENT

The common preventive strategies widely used in these cases, as a fundamental complement in the PU treatment, include the use of pressure reduction devices or support surfaces. Among these kinds of devices there are the static devices that provide a constant pressure redistribution, increasing the contact surface with the skin and reducing the force exerted per unit of area; and dynamic devices thath offer a cyclically variable pressure. Static devices include mattresses, covers, cushions, wheelchair cushions, and positioning support made from viscoelastic materials, memory foam, gel, or water, and air. On the other hand, dynamic devices comprise alternating and low-air-loss mattresses, air fluidized beds, air cells with alternating insufflation, dynamic flotation systems, and continuous low-pressure devices [10]. In this work, we will focus on dynamic devices and in particular on alternating pressure air mattresses because it has been established that alternating pressure air systems are more effective than standard hospital foam mattresses to reduce the incidence of PU [11].

Conventional pressure ‘reducing’ support surfaces seek to achieve lower values of maximal interface pressures on the skin by means of even distribution of pressure over the supported area. The aim of pressure reduction is to bring interface pressures down to a continuously tolerable level, at which the capillaries are still able to perfuse the tissues, delivering nutrients and oxygen, and removing waste products and microthrombi. However, in contrast, alternating pressure air mattresses are designed to prevent or treat PU by a different principle from conventional support surfaces. Alternating pressure air mattresses are designed to provide cyclic loading to the skin, so that each area of skin only experiences pressure intermittently, allowing hypoxia and other metabolic deficits to be redressed in the interim.

Pressure differentials between adjacent regions must be created to provide a pressure pattern which may be intermittently reversed to provide cyclic loading [12].

1.4. DIABETIC FOOT ULCERS TREATMENT

It's clear that must be improved the capacity of healing ulcers in order to reduce the number of amputations. For an efficient treatment of ulcers, are needed efficient diagnosis and protocols.

It has been demonstrated that most neuropathic ulcers are caused by high plantar foot pressure at sites of foot deformities, so these areas need to be offloaded with adequate therapy [13]. The international recommendations for preventing DFUs includes the prescription of appropriate footwear (insoles and shoes), foot care, regular foot checks, and education. These preventive steps have been proven to have positive effects on patient quality of life and in reducing healthcare costs. However, there is a need for long-term studies in which the pressure redistribution capacities of different types of insoles and footwear are compared and there is also a need for a global consensus on how to interpret the results from in-shoe pressure measurement devices. [14]

Nowadays, are available different devices for the offloading of the DFUs, such as walkers, half shoes, orthoses, and Total Contact Cast (TCCs), that are considered the gold standard for the management of neuropathic plantar ulcers [15].

Total contact cast (TCC)

The optimal therapy for the offloading of plantar pressure, considered as the "gold standard" is the total contact cast. TCC is a device that permits a total non-weight-bearing for the affected foot allowing at the same some degree of mobility. The efficacy of TCCs has been demonstrated by several studies, in terms of healing proportion is more effective than any other removable devices [16], in fact, it has been shown that TCCs are able to reduce plantar pressure at ulceration site by 84-92% [17].

The correct use of a total contact cast includes: (1) immobilization of the limb to limit additional stress on healing tissue; (2) reduction of swelling and decreased intravascular fluid pressure to improve microcirculation; (3) reduction of localized foot pressures through a total contact fit; (4) protection from further trauma with a hard outer shell; and (5) outpatient management with preservation of ambulatory status and workability [18].

But even if TCC is considered as the gold standard for the redistribution of pressure over the plantar of the DF, different disadvantages related to their use have been reported in the literature. First of all, they are expensive, technically difficult to use and time consuming to

place, also they require specialized staff for the application. Mobility is impaired and new ulcers may occur. Infection and PVD are considered as a contraindication for TCC, because of the risk for new ulcers to occurs due to the deterioration of blood supply [19].
For this reason, in the last years have been presented in the literature studies and randomized clinical trials for the demonstration of the efficacy of offloading walkers in the treatment of diabetic plantar foot ulcers.
In this thesis, we will focus on two different types of offloading walkers.

1.5. PRESSURE OFF-LOADING MEASUREMENTS FOR BOTH PRESSURE ULCERS AND DIABETIC FOOT TREATMENT

Laboratory evaluation techniques have centered largely on interface pressure (IP) measurement, typically analyzing discrete maximum and minimum levels, or average pressure [20]. All the laboratory measurements were carried out thanks to the use of pressure matrices.

In order to evaluate the system, for mattresses it is important to choose clinically relevant thresholds below which the interface pressure should remain, as these thresholds are considered to influence the reperfusion of the area previously under compression. Examples of such thresholds for what concerns PU and alternating pressure air mattresses are mean arteriolar (approximately 30mmHg), capillary (approximately 20mmHg) and venule (approximately 10mmHg) operating pressures, or some other set of clinically relevant pressures for selecting an appropriate support surface. [21]

Also, for plantar pressure measurements, pressure matrices are widely used to control and understand distribution of pressure between the sole and the foot and either with the ground. This may offer important information for the assessment of various foot pathologies, including those pathologies related to diabetes like the DF.

2. MATERIALS AND METHODS

2.1. MATTRESS MEASUREMENT PROCEDURE

2.1.1. PARTICIPANT SELECTION

The number of participants is important: our measurement will be on a number in between 10 and 20 healthy volunteers. As displayed in the figure below, in fact, in 22 reviewed articles, 18% used 10 and 20 subjects but also the other higher percentage are reached by studies that used a number of subjects in between 10 and 20 like 11, 15 and 19. [2,12,20–28]

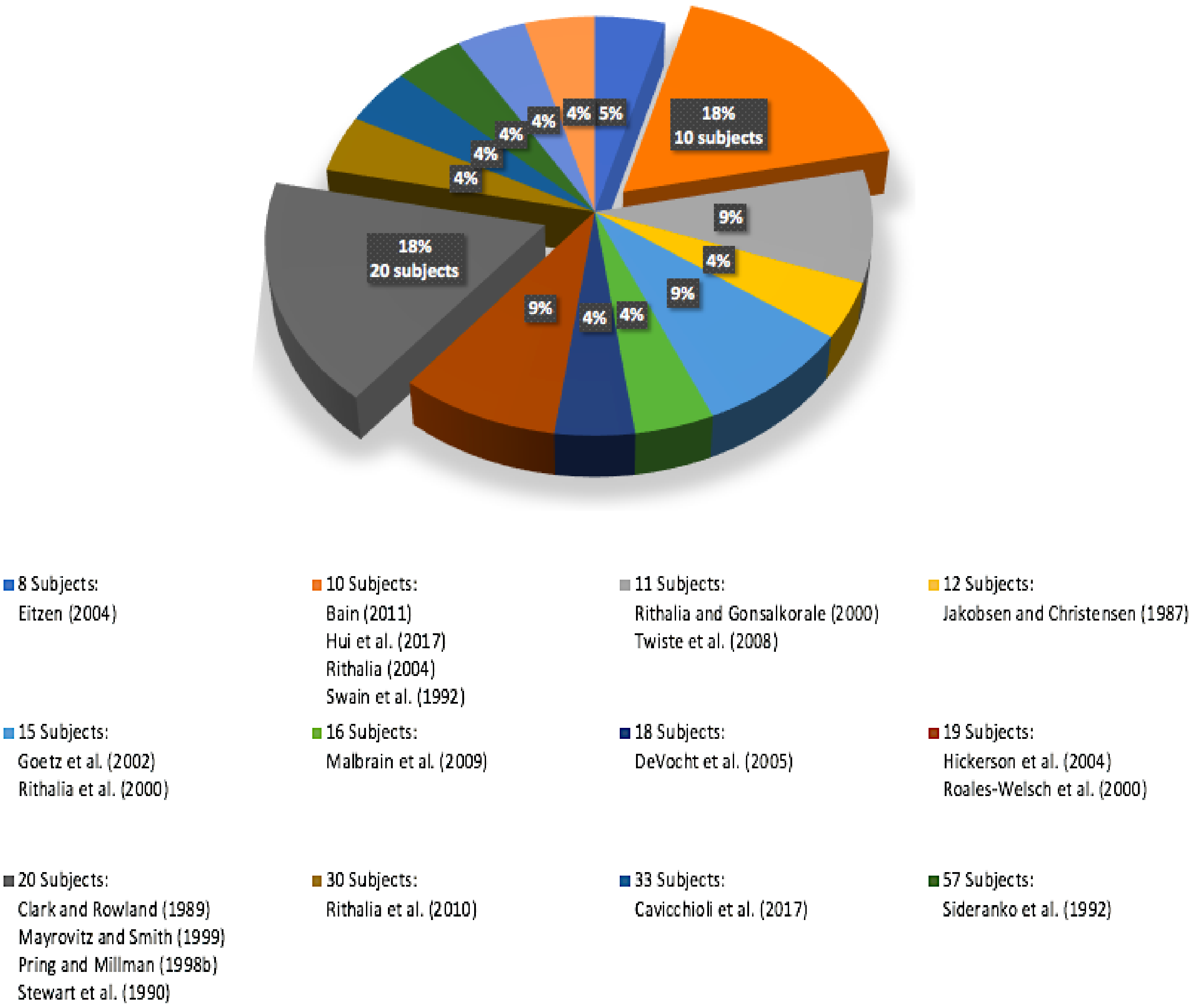

Figure 12: studied subjects

Subjects are chosen to provide a spread of males and females with a reasonable range of ages, weights and heights

2.1.2. SETUP

To define the measurement protocol for an alternating pressure air mattress firstly, the studied positions and points at higher risk to develop a PU, have to be defined.

- Back sleeper (Figure 13A) → as shown in figure 1 the critic points are the head, shoulders, elbow, sacrum and heels. With the 32x32 sensors pad probably we can detect those points with 4 recordings: one for the head the second for shoulder and elbow the 3rd for the sacrum and the last for heels.
- Side sleeper (Figure 13B) → in this case we have 6 relevant points (the inner tight can't be evaluated) and we can study them with 4 different position of the pad: one for the ear, one for the shoulder and elbow, one for the hip and the last for outer tight and heel.

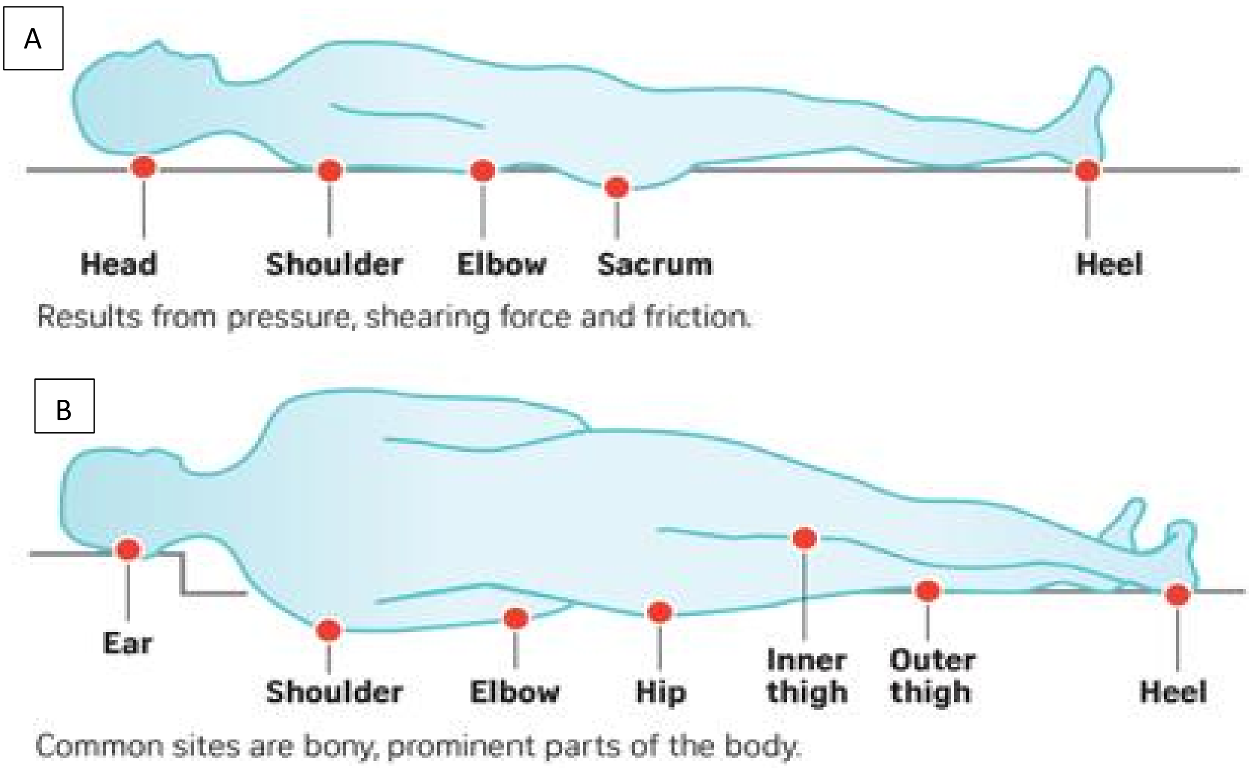

Figure 13: A) back sleeper position; B) side sleeper position.

- Sitting position (Figure 14) → the pad can be placed in 4 positions, one for heels, the second for buttocks, 3rd for the base of the spine and the last recording can be done for shoulders and the back of the head.

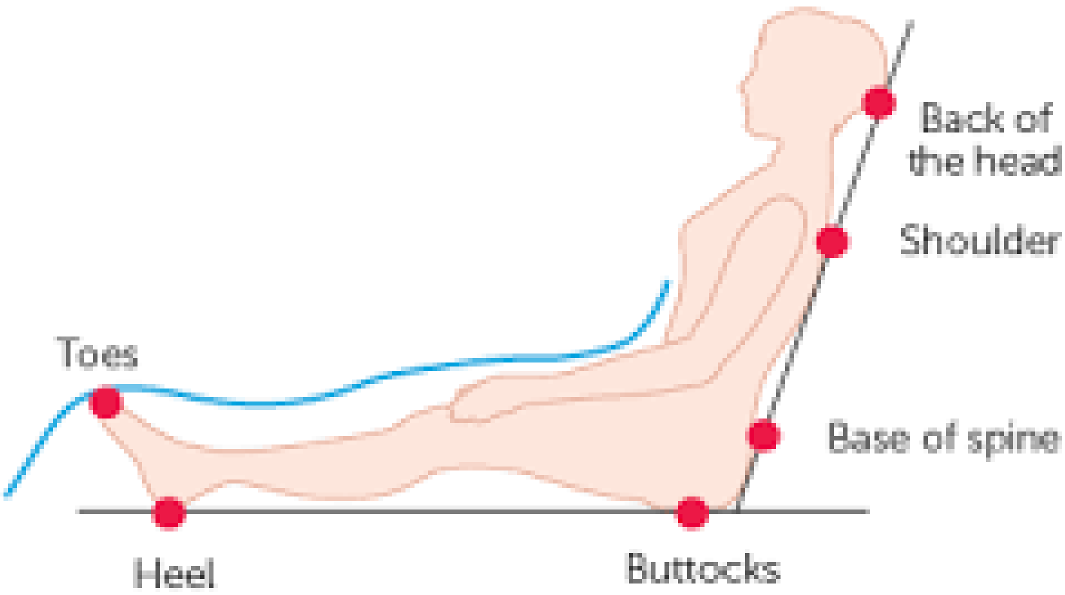

Figure 14: Sitting position

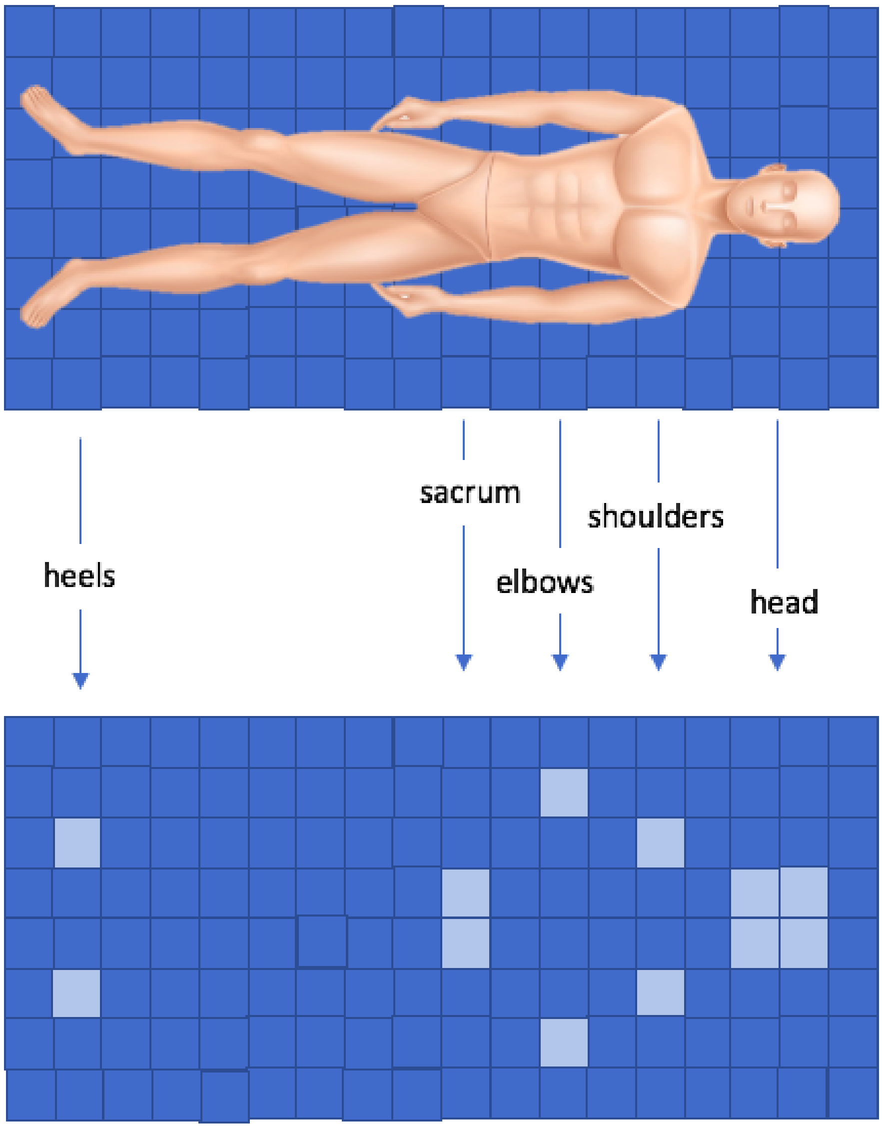

Figure 15: Deflate process

In this figure we can see how the deflate process will occur. After the baseline recording, the same test will be done with deflated cells for each region as shown in the figure. This image is for the back sleeper, the same will be done for the side sleeper position and sitting one.

2.1.3. TEST PROTOCOL

Static data are collected using the pliance® System in the volunteers. For all the session, the sampling rate is set at 10 Hz on the Pliance Acquisition Software.

The procedure has to be followed step by step in order to reduce variability between recordings.

- participants have to declare age and if they have hematomas or postural diseases than the laboratory technician has to measure:

- Height
- Mass

- Participant is asked to lie on the mattress wearing normal light clothing and to lay flat on his back on top of the pad, legs slightly separated, and arms folded loosely, comfortably on his chest.
- Special care is taken to ensure that no high-pressure points were applied to the pads (and potentially damaging them) as with a knee or elbow while the participant was getting on or off the pads. Two standard pillows were used to support the head.
- This condition is maintained 1 minute until the subject is totally relaxed. The subject will never know when the technician starts the recording.
- The recording can start: every record will last 1 minute and will be repeated for three times, after every three recordings the subject is asked to stand and leave the place, in this way the technician can control the position of the map and sensors can return to the initial configuration. After, the patient can return to lay relaxed on the mattress.
- In order to change the analyzed region of the body (as previously defined), the subject has to leave the position and the technician has to change the position of the map.

This procedure will be repeated for each setting, for each position of the pad will be recorded the baseline than with the deflated cells. The test will last 24 minutes for each setting.

2.2. WALKERS MEASUREMENT PROCEDURE

2.2.1. MATERIALS

- **WALKERS**

Due to the Covid-19 restriction the two footwears provided by Optima Molliter (Civitanova Marche, Italy) are worn by two participants, walkers were worn on the right foot, while the normal footwear was worn on the left one.

Walkers

- **Motus 2.0** (Molliter, Civitanova Marche, Italy): is designed for the offloading of diabetic ulcers and wounds in the acute phase management.

  Its characterized by a fully rocking removable sole with an innovative design, a modular insole composed of three layers of different stiffness that can be adapted according to the actual location of the ulcer, and a posterior rigid brace to block the ankle high up to the upper leg. [fig.16]

Figure 16: Motus 2.0 walker

- **Optima Diab:** (Molliter, Civitanova Marche, Italy) has been designed to serve as an off-the-shelf i-TCC and was proposed for the use in the management of DF ulceration. It’s characterized by a rigid fully rocking sole with an innovative design, a modular insole composed of three layers of different stiffness that can be adapted according to the actual location of the ulcer, and a posterior rigid brace to block the ankle high up to the upper leg. It can be also secured with a plastic lace on the leg in a way that permit it to being irremovable for the patient (Figure 17).

Figure17: Optima Diab walker

- **INSOLES**

Puzzle kit 3*3 (Molliter, Civitanova Marche, Italy): has been designed for the redistribution of the plantar pressure on the foot.

It's a modular insole composed of three layers of different stiffness that can be adapted according to the actual location of the ulcer (Figure 18).

It's especially used for the healing of ulcers in rearfoot, midfoot and forefoot and it can be used for personalized decompression of specific areas of the foot thanks to the structures of the three layers, which in turns can be divided into three parts.

The insoles of different harnesses are:

- Red: soft;
- Beige: moderately rigid;
- Blue: rigid.

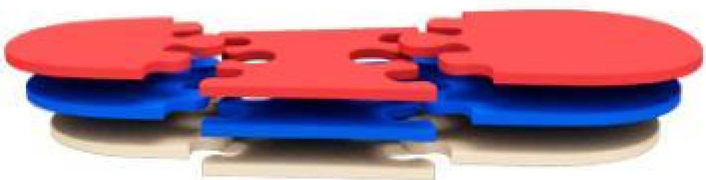

Figure 18: Modular insole

- **PEDAR-X SYSTEM**

Data were collected using Pedar-X® Insoles Measurement System (Figure 19) (Novel® GmbH, Munich, Germany), one of the most commonly used system for in-shoe pressure measurement [29].

The advantage of using in-shoe sensors is that they are flexible and embedded in the shoe such that measurements reflect the interface pressure in between the foot and the shoe.

Figure 19: Pedar-X System

Pedar-x components:

Figure 20: Pedar-X components

- Pedar Insoles (A)
- Pedar-x double insole cable (B)
- Pedar-x/xf box (C)
- Pedar-x fiber optic cable with fiber optic/USB adapter (D)
- USB cable (E)
- novel belt (F)
- Pedar-x battery (G)
- Pedar-x battery cable (H)
- Pedar-x battery charger (I)
- start/stop trigger (J)
- Bluetooth dongle (K)
- Velcro straps (L)
- SD card (M)

Pedar insoles (W series) (A) are connected through the insole cable (B) to the box (C). fiber optic cable with fiber optic/USB adapter (D) connects C and E to the computer. The battery supplies the current to the entire system and is connected to C trough the battery cable (H). Pedar-X box presents limited dimension and weight, 150 x 100 x 40 mm and 400 g of weight, in a way that is possible to insert the box in a Velcro straps around the subject's limb.
System can be connected to the computer via fiber optic cable (FOC) or via Bluetooth, allowing to acquire data even using wireless technology [30].

Each of the two insoles contain a matrix of 99 capacitive pressure sensors with various sensor active surface (mean sensor surface is around 1% of the total one in wide model insoles), embedded in a soft interface of 1.5 mm (the overall thickness is around 3.4 mm). (Figure 21) Because of its features, the pressure range for in-shoe measurements is calibrated in the range that goes between 15 and 600 kPa. If correctly maintained and used the system presents a pressure resolution of 2.5 kPa, an hysteresis less than 7% and an accuracy less of 2% FS [30].

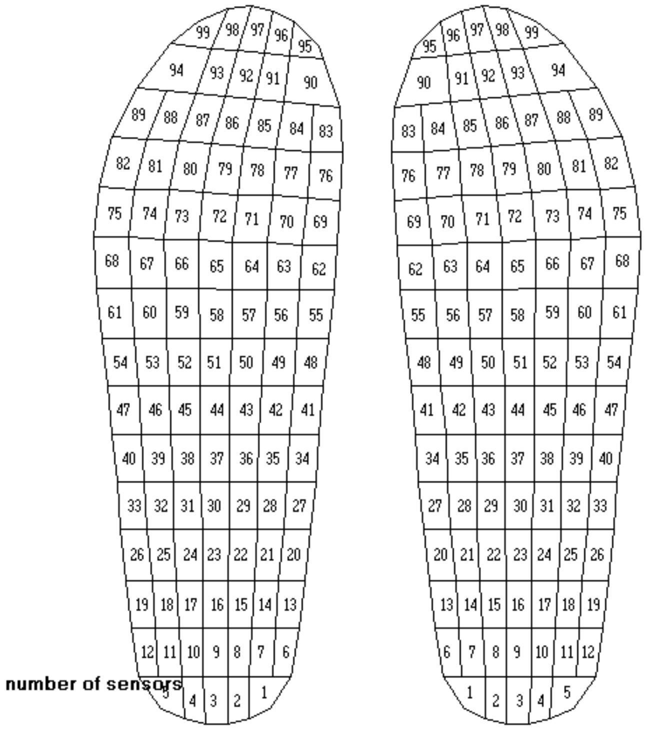

Figure 21: number of sensors of the Pedar-X Insoles

Capacitive Sensors

The sensor consists of two conductive electrically charged plates separated by a dielectric elastic layer. Once a pressure is applied the dielectric elastic layer bends, which shortens the distance between the two plates resulting in a voltage change proportional to the applied pressure [31].

Figure 22 shows the capacitive sensor construction of the Pedar® in-shoe systems (Novel, Germany)

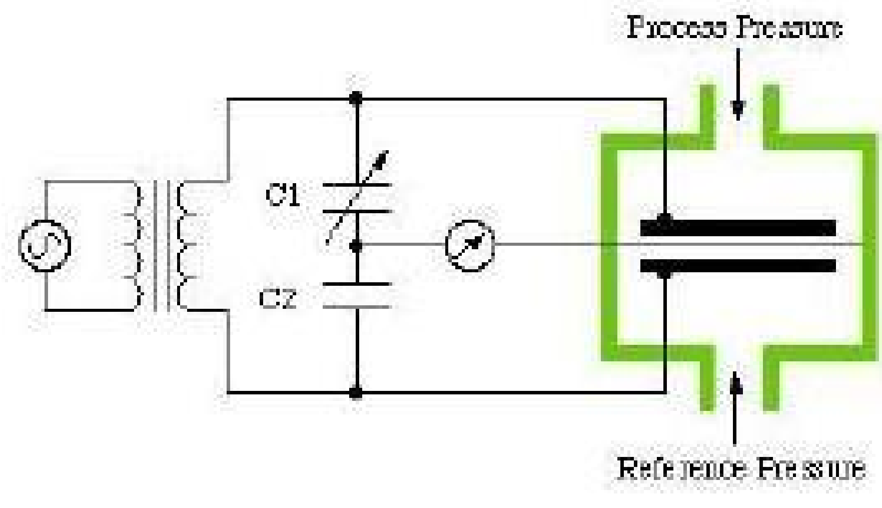

Figure 22: Capacitive pressure sensor construction

2.2.2. DATA ACQUISITION

All measurement per patient were performed in the laboratory of DIISM of the 'Università Politecnica delle Marche' using as measurement device the Pedar-X Insoles Measurement System (Novel® GmbH, Munich, Germany) [30].

Pedar Acquisition tool

Pedar acquisition tool (by Novel®) shown in figure 23, allows data acquisition and permit to perform some pre-processing like identification of insole subareas (masks) of interest and permit to choose the sampling rate.

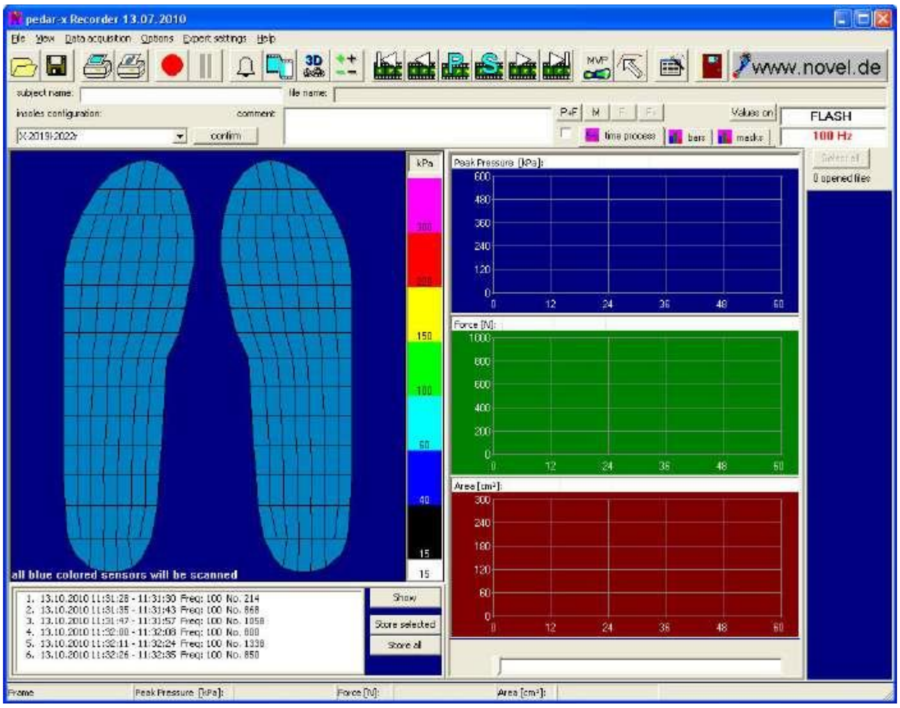

Figure 23: Pedar Acquisition tool

- **SUBJECTS**

Due to the Covid-19 restrictions, reference data were collected from two healthy young participants. Subjects were excluded if they suffered from pain in their feet within the last six months, had any surgery on their feet at any time in their life, or any callus under their feet.

- **PROCEDURE**

Prior to the test, participants were asked to remove their shoes.

Participants were equipped with normal footwear in the left foot and with the therapy walkers (Motus 2.0 and Diab) in the right leg. To minimize variability, a single person applied all walkers during the experiments, using a standardized technique: with the subject sitting opposite the caster, first the Pedar® insoles were placed inside the footwear, between the sock and sole of the footwear. After the insoles were connected by cables to the mobile unit (Pedar box) worn on the subject's belt and via FOC to the computer. Successively at the insole positioning, the left foot was placed inside the walkers following the procedure suggested from the company Optima Molliter.

After acclimating the walkers, each subject began to walk freely in the laboratory to reproduce its typical gait and to feel comfortable at the laboratory, for a period of approximately two minutes for each registration. After each two minutes registration the zero setting was performed in order to rest values. The volunteer is asked to repeat the procedure ten times for each configuration.

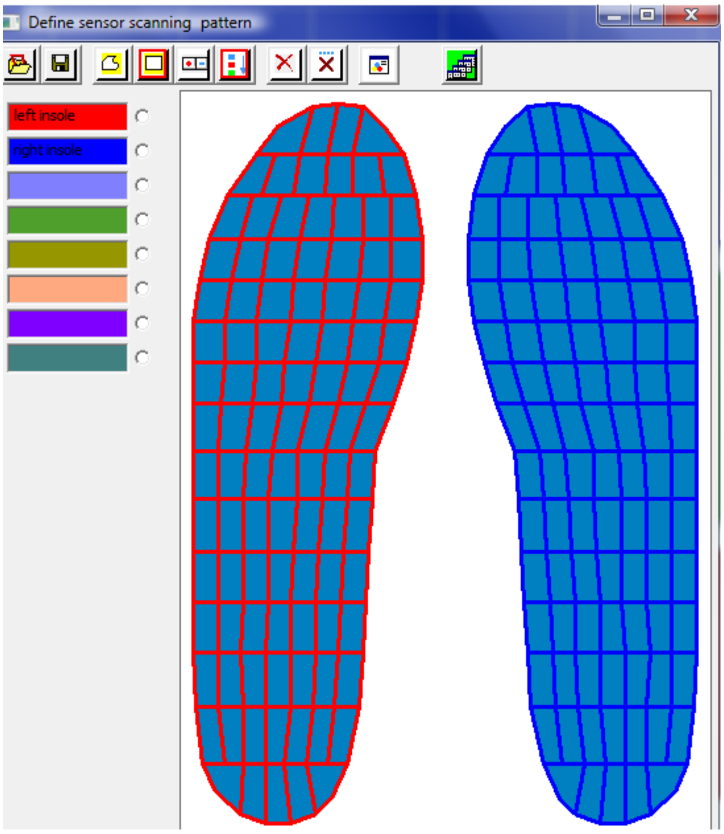

Figure 24: Zero setting

In-shoe dynamic data were collected using the Pedar® System in the volunteers during walking. For all the session, the sampling rate was set at 50 Hz on the Pedar Acquisition Software.

Figure 25: Motus acquisition data

The trial performed for the acquisition data procedure was structured as follow for both Diab and Motus 2.0 walkers:

- baseline
- tiptoe
- internal metatarsal
- external metatarsal
- internal sole
- external sole
- heel

In our study has been done bigger holes in five foot positions: tiptoe, internal and external metatarsal, external sole and heel part. In particular, holes have been created in these six zones in order to see how the pressure is re-distribute in healthy subject, during walking with the two different walkers. Also, smaller holes are done for another test in three positions: tiptoe, heel and external metatarsal to see how the redistribution pressure changes even with smaller holes (Figures 28,29,30). The holes have been created following the instruction provided by Molliter.

In our case study, the weight of all the subjects was less than 90 kg. The hole has been created on the beige insole. The holed insole has to be in the middle of the three layers. In accordance to this, the upper insole is composed by the soft (red) insole in the correspondence of the hole and the rigid one (blue) that cover the other part, in order to redistribute the plantar pressure. The middle layer is all made with the beige insole and the lower one configuration is opposite to the upper one. Two hole examples and soles configurations (external metatarsal and heel) are shown in figure 27.

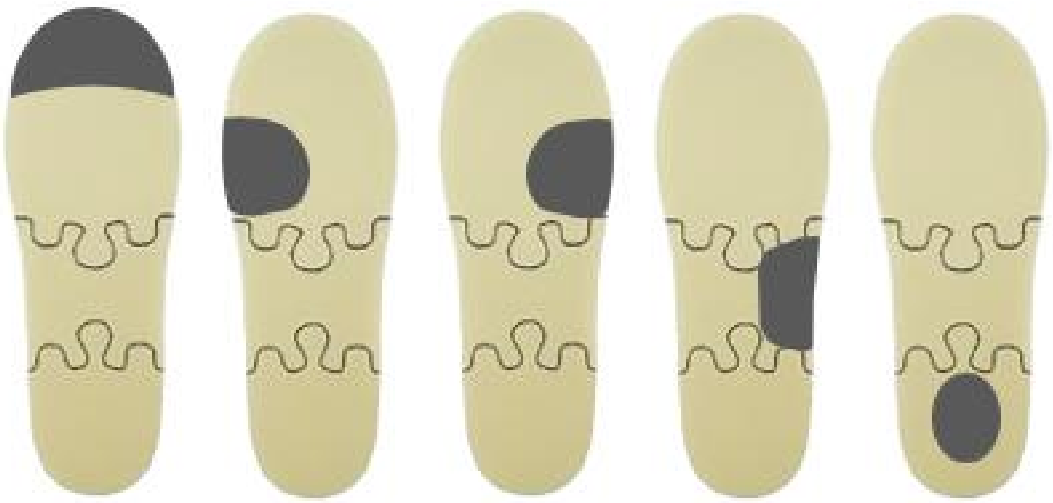

Figure 26: Insole bigger holes

Figure 27: Modified insoles with bigger holes

Figure 28: Internal Metatarsal small hole and activated sensors

Figure 29: Heel small hole and activated sensors

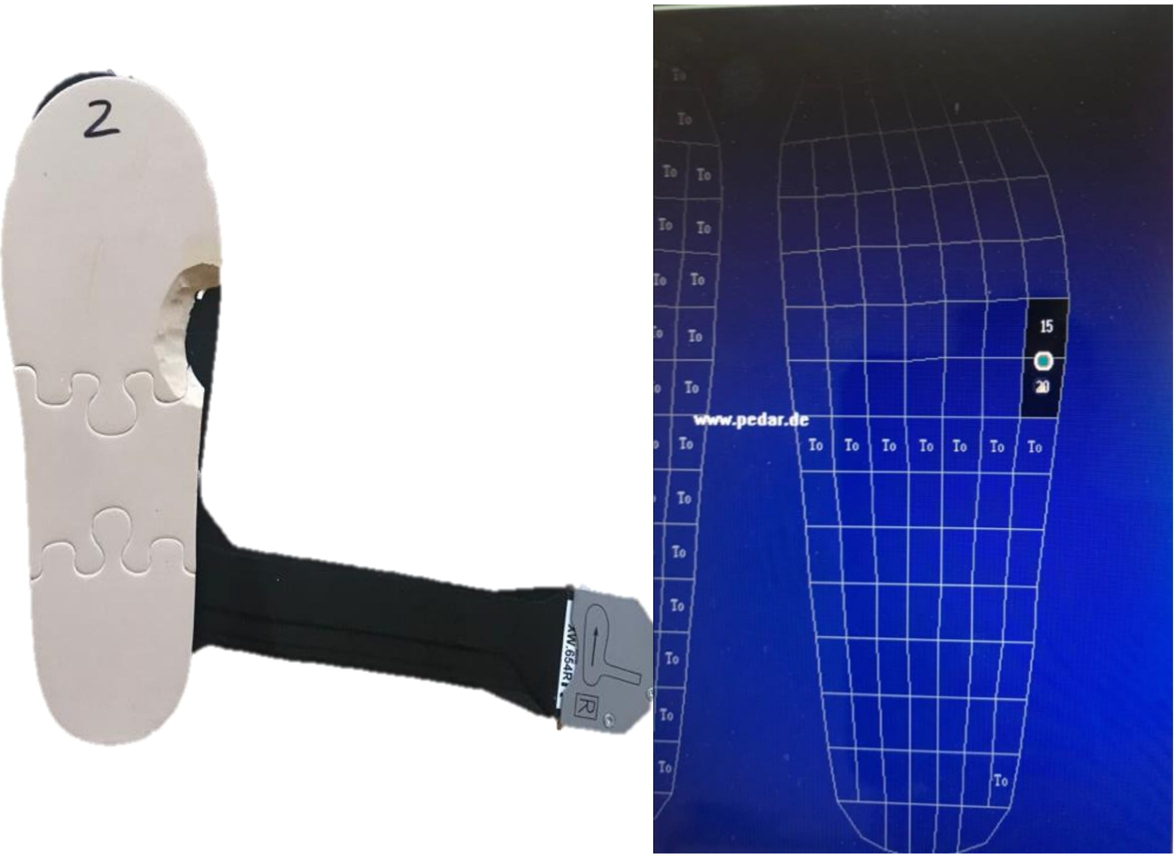

Figure 30: External Metatarsal small hole and activated sensors

2.2.3. DATA ANALYSIS

Analysis of the whole set of collected data was done using Novel Software and MATLAB®.

MATLAB

MATLAB (matrix laboratory) is a multi-paradigm numerical computing environment and proprietary programming language developed by Math Works. It has been used for the processing of all the data collected with Pedar acquisition tool, script has been created in order to obtain average values for each configuration for both Diab and Motus walkers.

Proper masks identified with Pedar Acquisition tool were created in MATLAB for the insoles, to detect five major areas of the foot [figure 28]. The masks used to analyze plantar pressure were adjusted proportionally to the width and length of the foot and were based on the Cavanagh's scheme [32]. The five areas and their size were:

- M1 rearfoot (27% of the foot length);

- M2 midfoot (28% of the foot length);

  Forefoot (25% of the foot length) which has been divided into two areas:
- M3 lateral forefoot (55% of the forefoot width);
- M4 medial forefoot (45% of the forefoot width);
- M5 hallux (20% of the foot length).

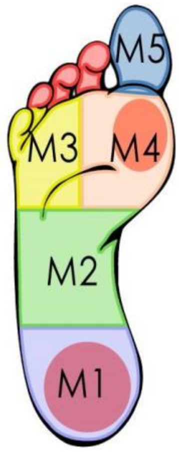

Figure 31: masks of the foot

The two minutes recordings have been cut to avoid noise linked with acceleration and deceleration phases. Mean and maximum pressure values for each configuration were calculated.

Peak Pressure (kPa)

The maximum pressure is the highest pressure recorded by the sensor in the reference interval of time.

Mean Pressure (kPa)

The average pressure is calculated by summing all the sensor recorded pressures and dividing by the number of samples in the reference time interval.

Reported data are absolute data that are averaged between ten repetitions of the same configuration. For each configuration, to evaluate the performance the change in percentage with the baseline is calculated with the formula:

$$\% = \frac{mean\ data - mean\ baseline}{mean\ baseline} \times 100$$

3. RESULTS

In this section obtained results will be shown for both the participants and for both the analyzed walkers. The histogram shows mean pressure (light blue bars) and peak pressures (dark blue bars) for each part of the foot; in the insole figure instead, are reported for each part, the pressure change in percentage.

3.1.SUBJECT 1

3.1.1. MOTUS 2.0

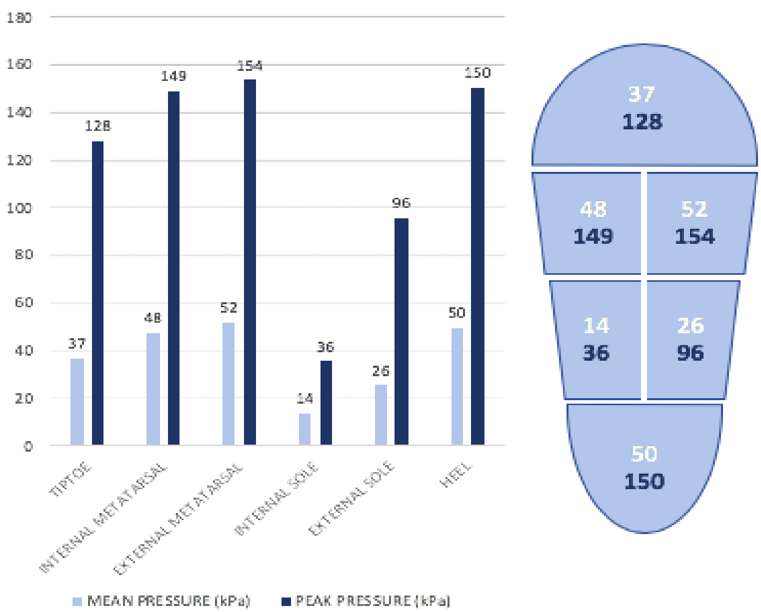

Figure 32: Baseline

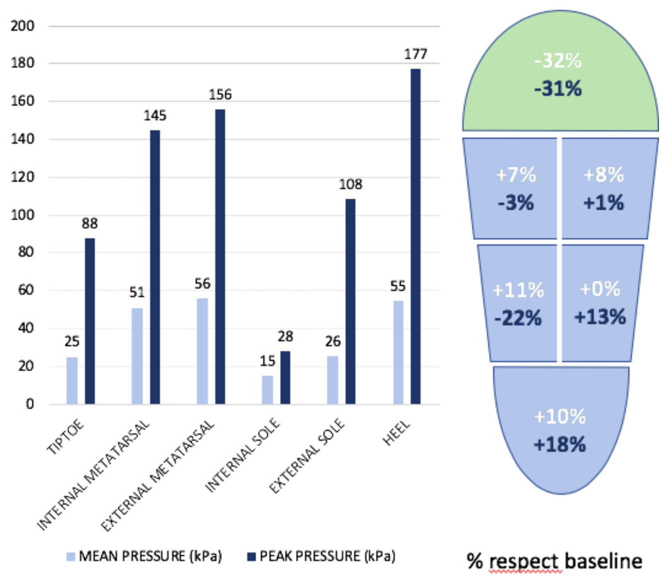

Figure 33: Tiptoe

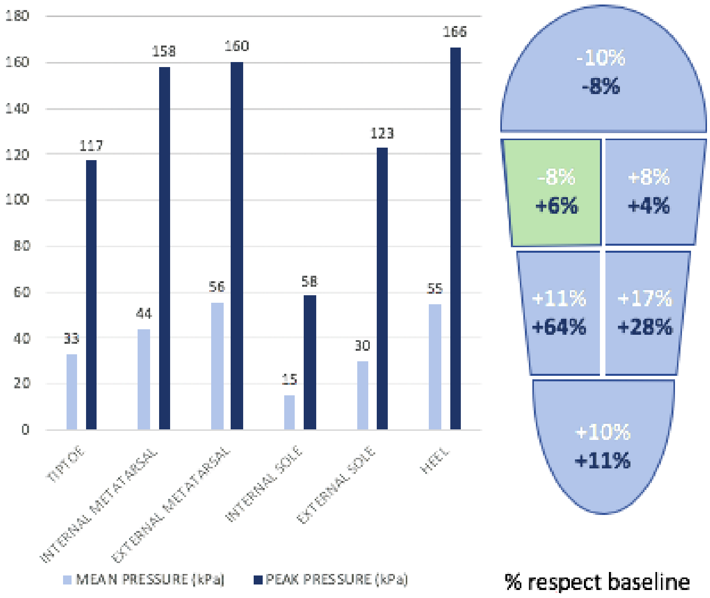

Figure 34: Internal Metatarsal

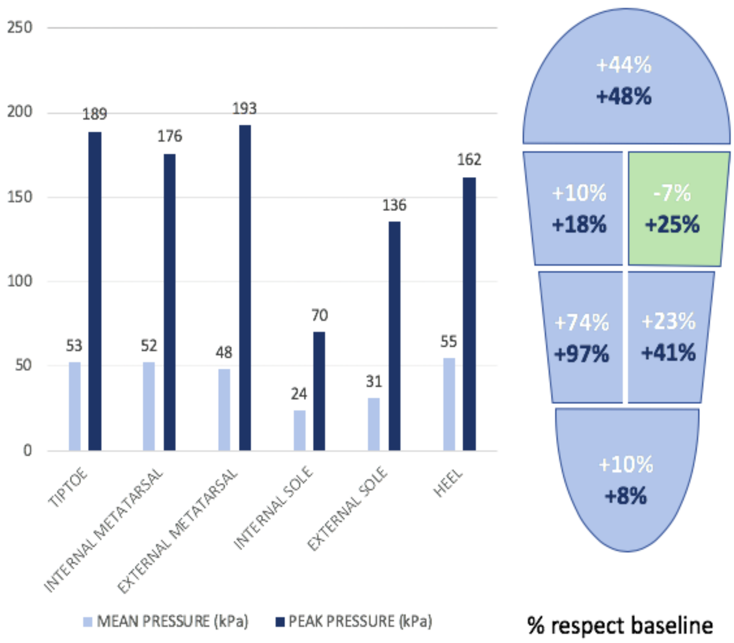

Figure 35: External Metatarsal

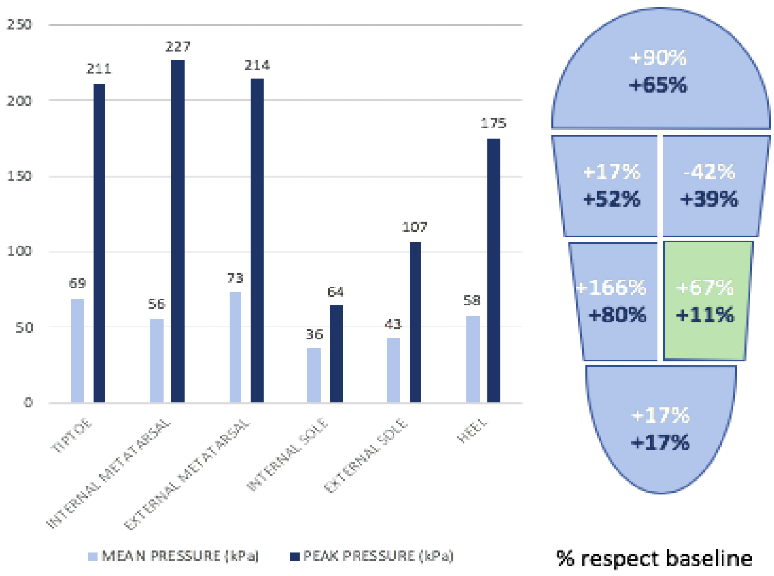

Figure 36: External sole

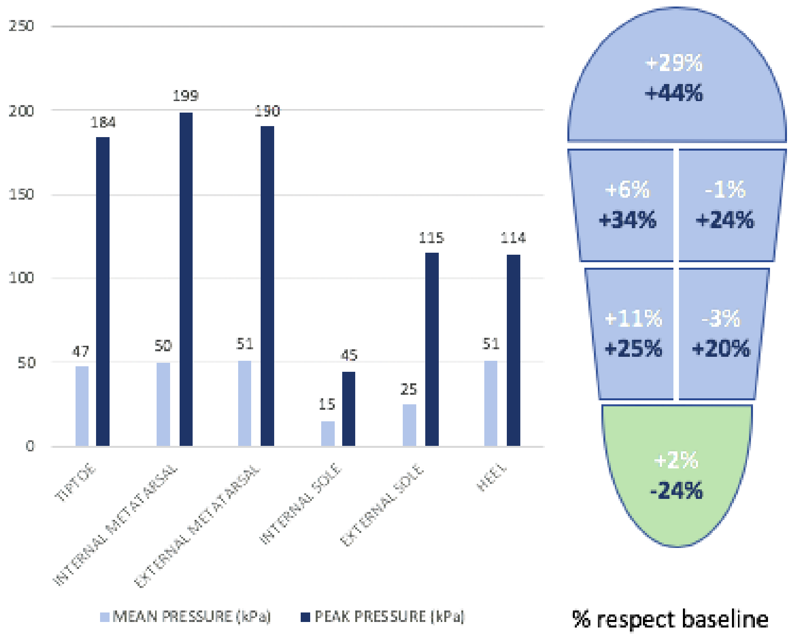

Figure 37: Heel

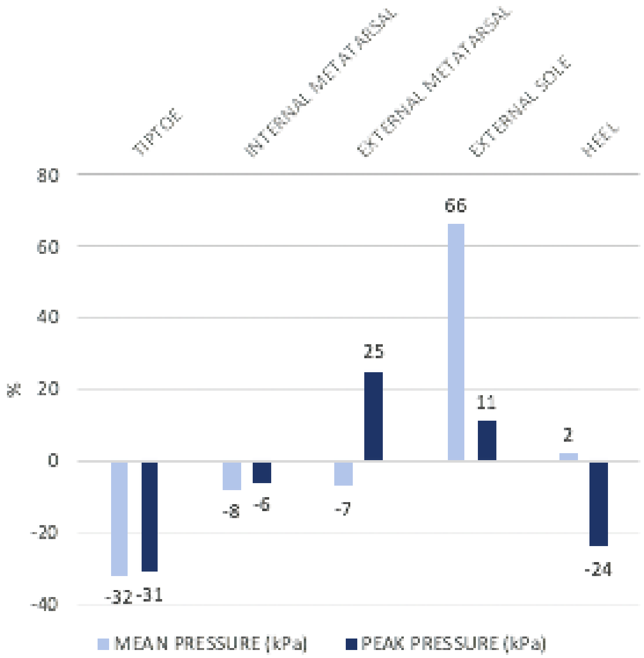

Figure 38: Percentage with bigger masks

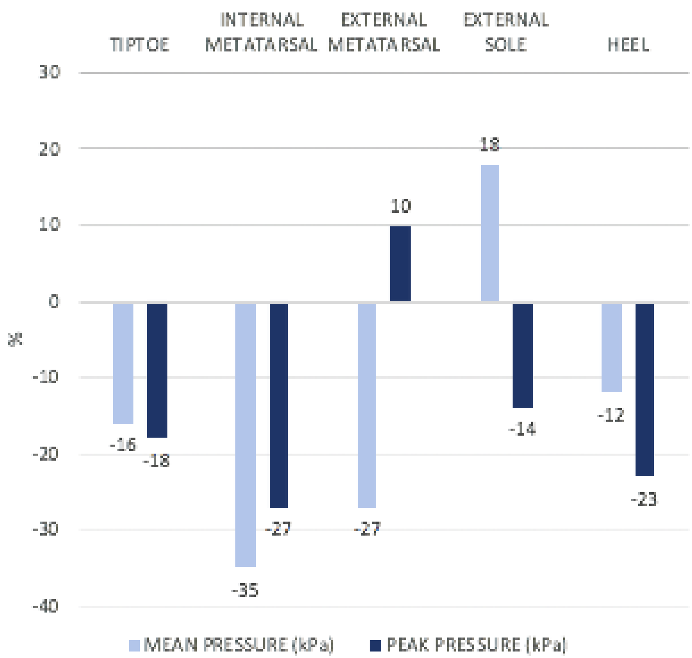

Figure 39: Percentage with smaller masks

3.1.2. DIAB

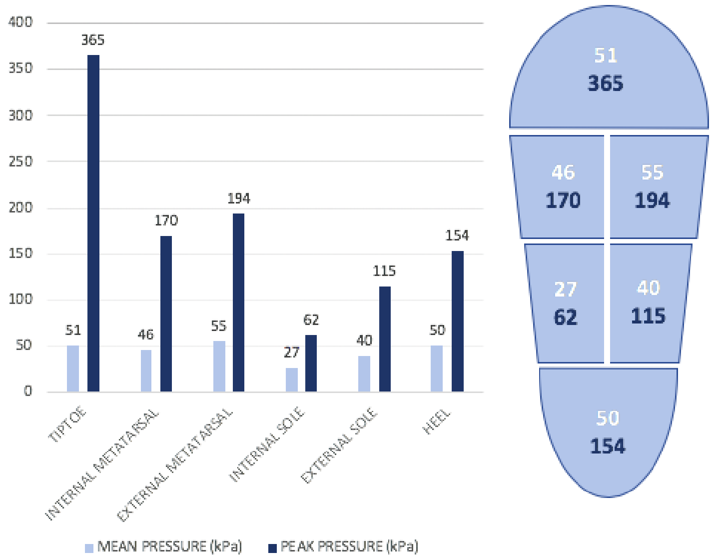

Figure 40: Baseline

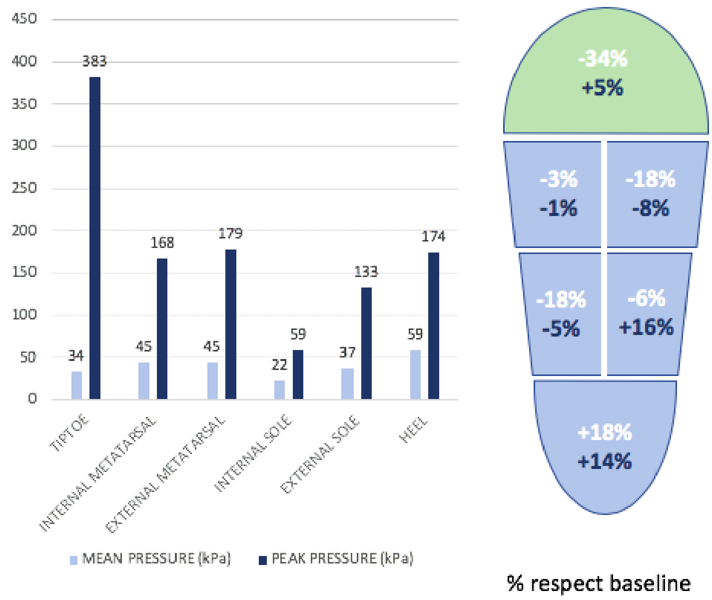

Figure 41: Tiptoe

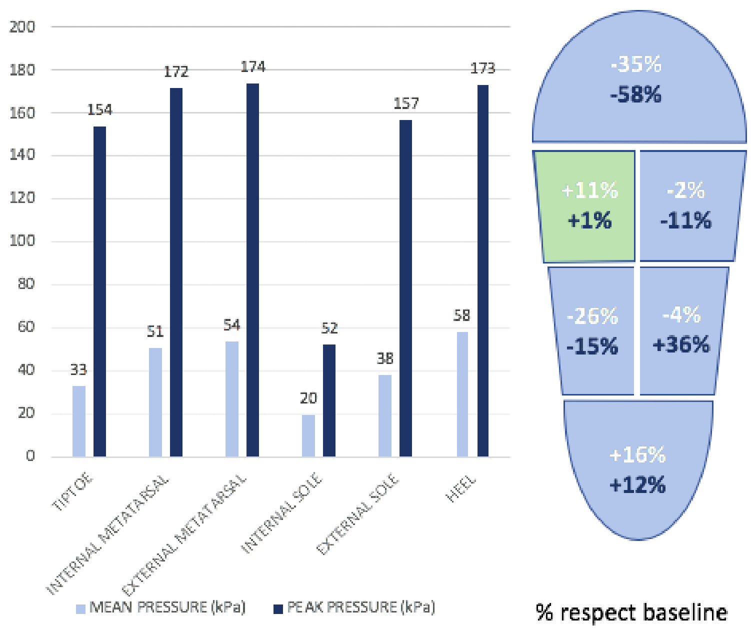

Figure 42: Internal Metatarsal

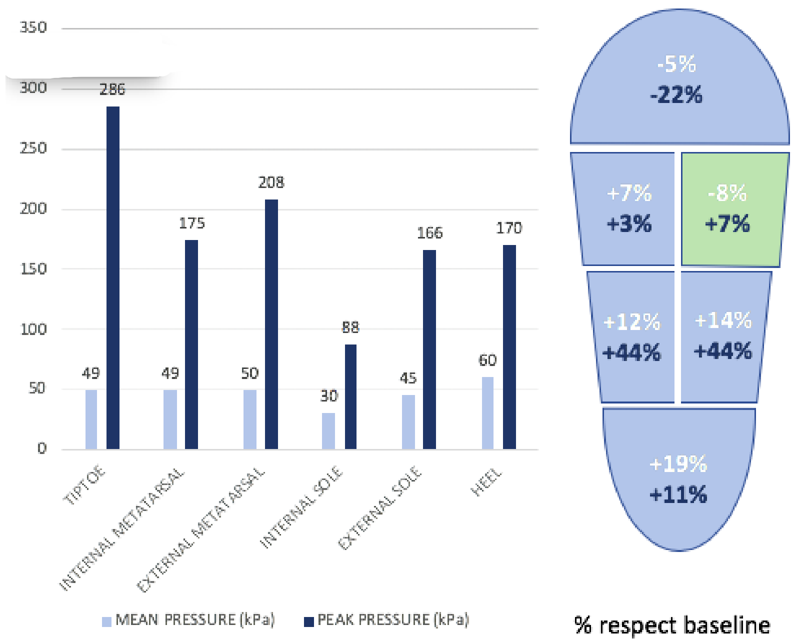

Figure 43: External Metatarsal

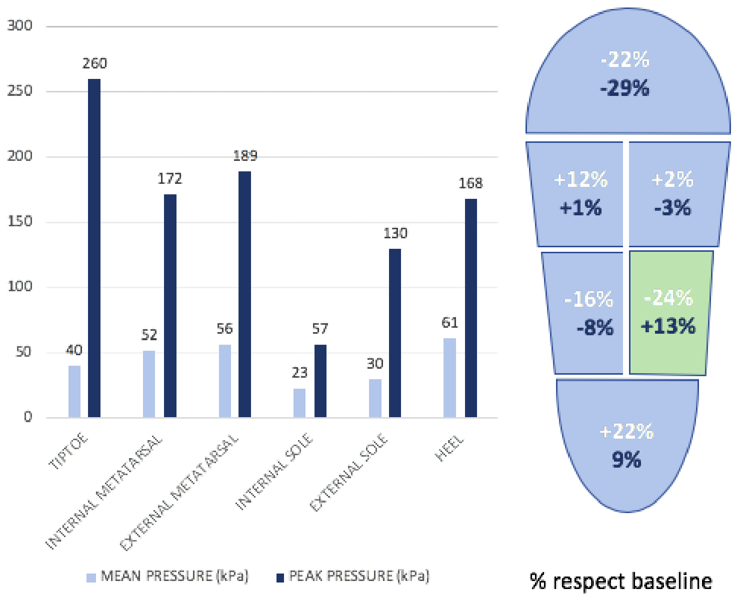

Figure 44: External Sole

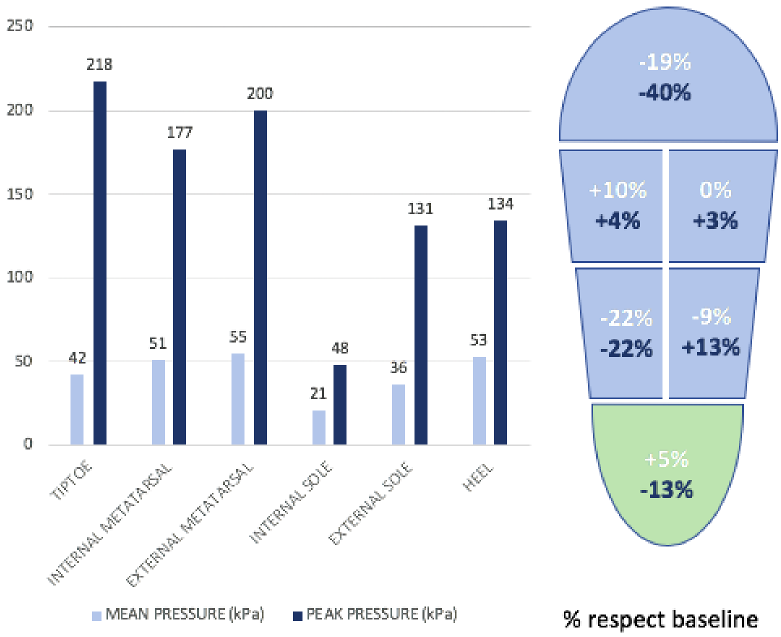

Figure 45: Heel

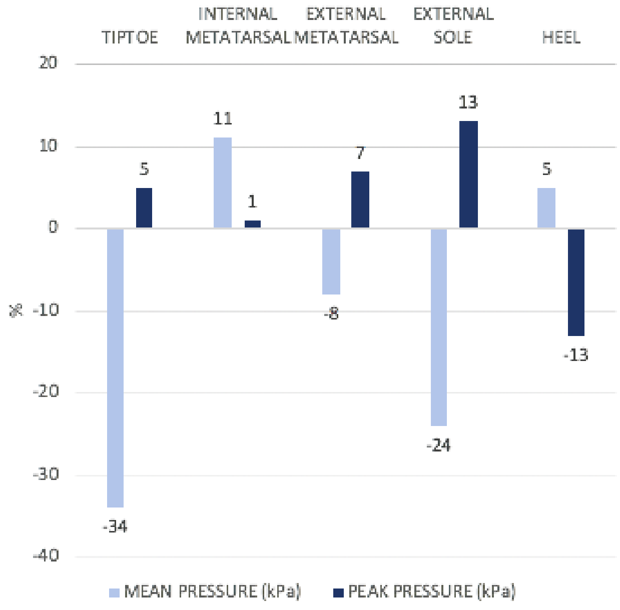

Figure 46: Percentage with bigger masks

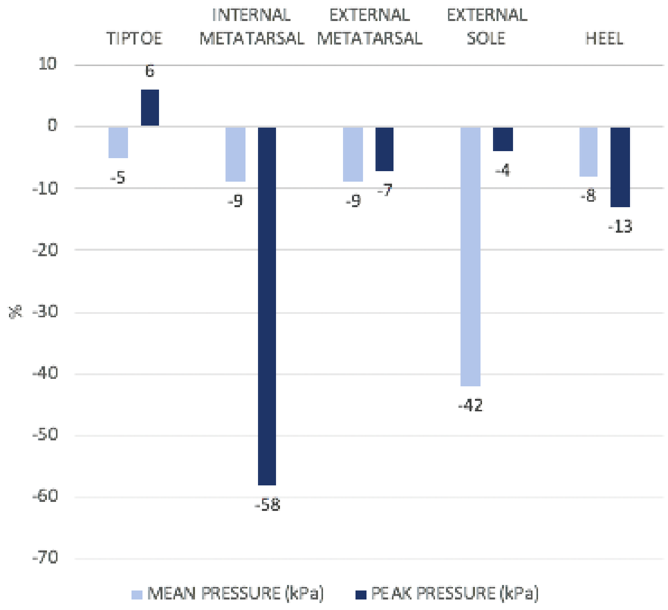

Figure 47: Percentage with smaller masks

3.2. SUBJECT 2

3.2.1. MOTUS 2.0

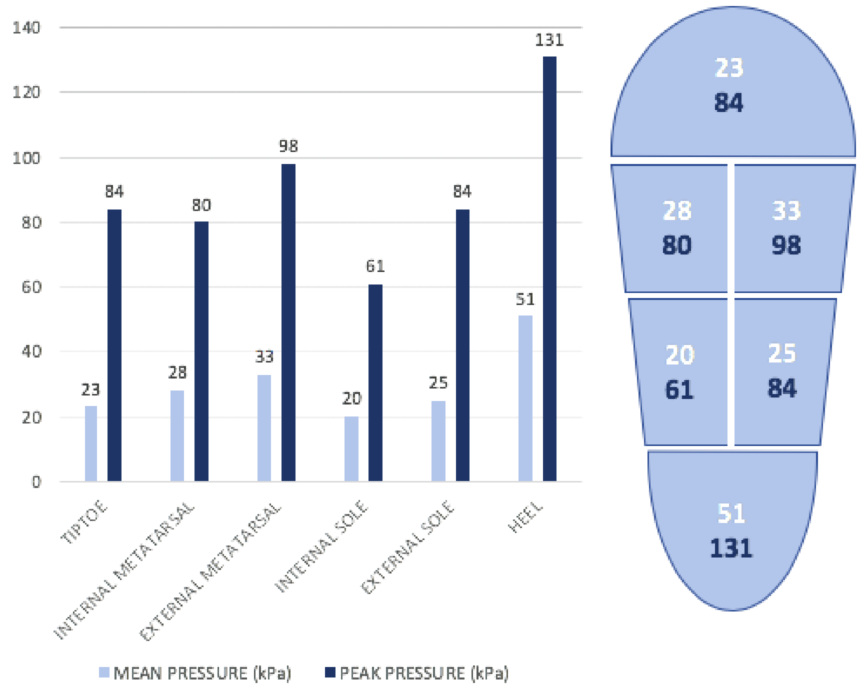

Figure 48: Baseline

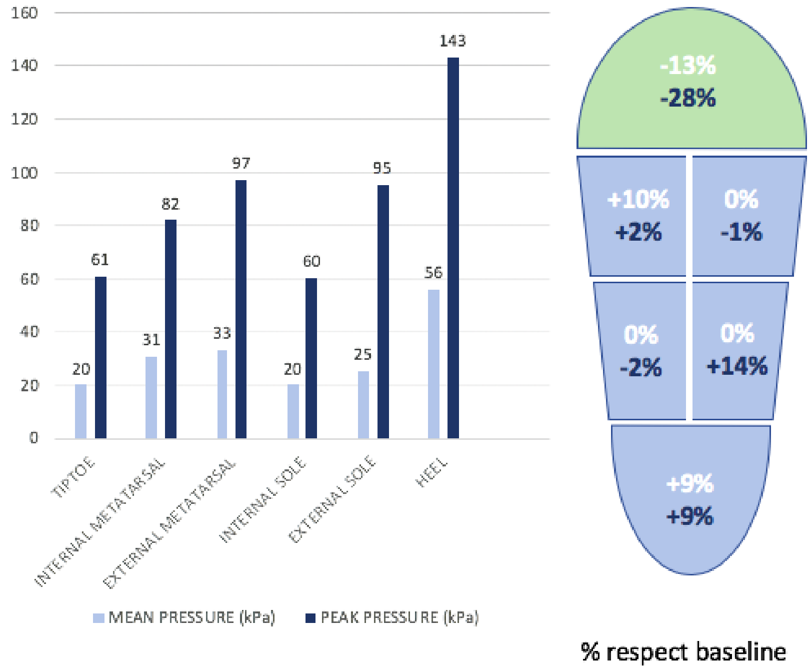

Figure 49: Tiptoe

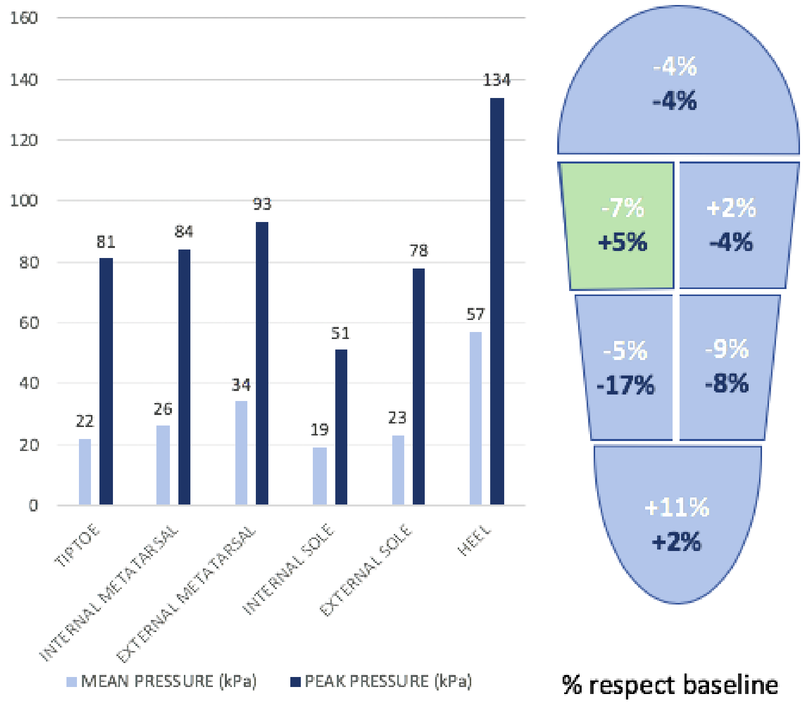

Figure 50: Internal Metatarsal

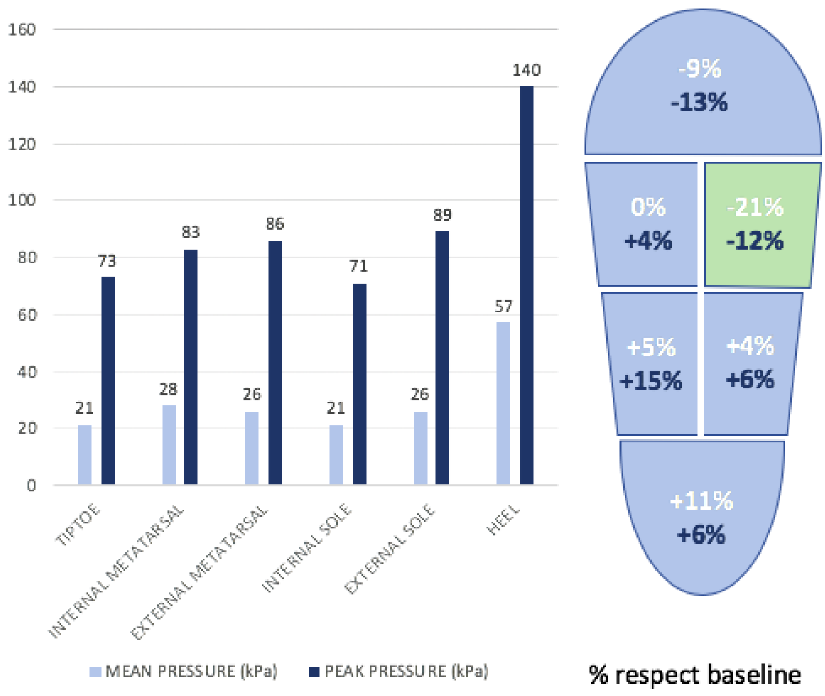

Figure 51: External Metatarsal

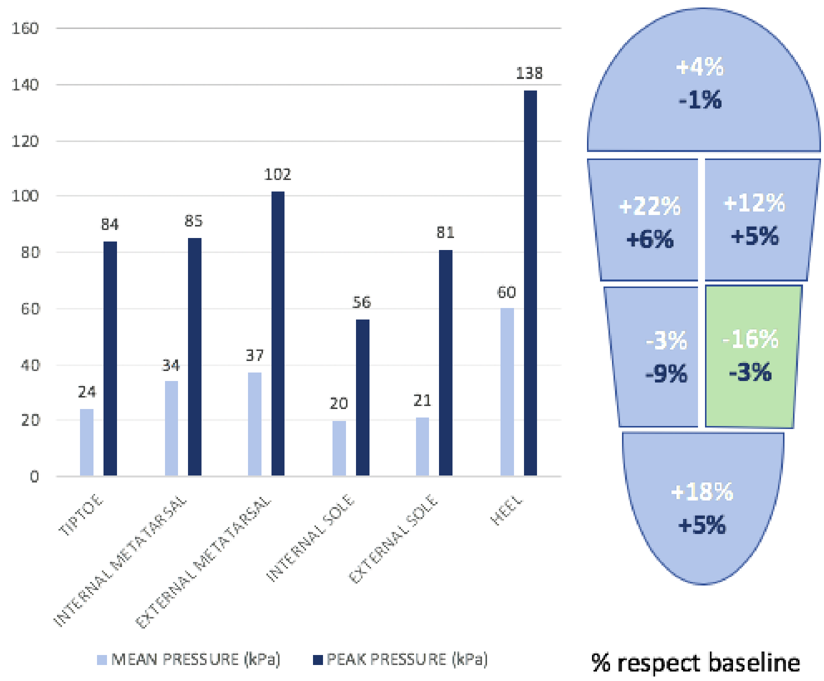

Figure 52: External Sole

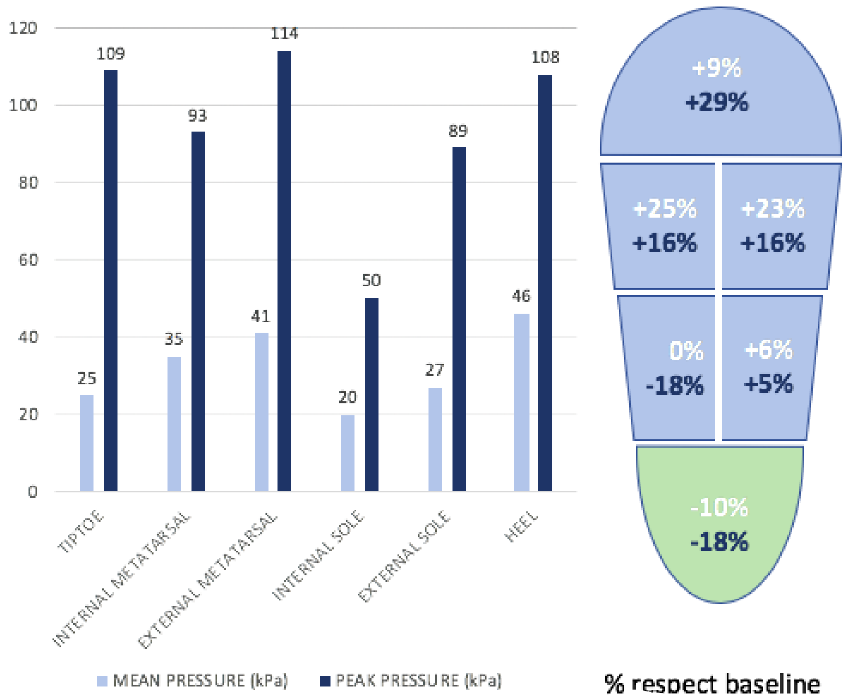

Figure 53: Heel

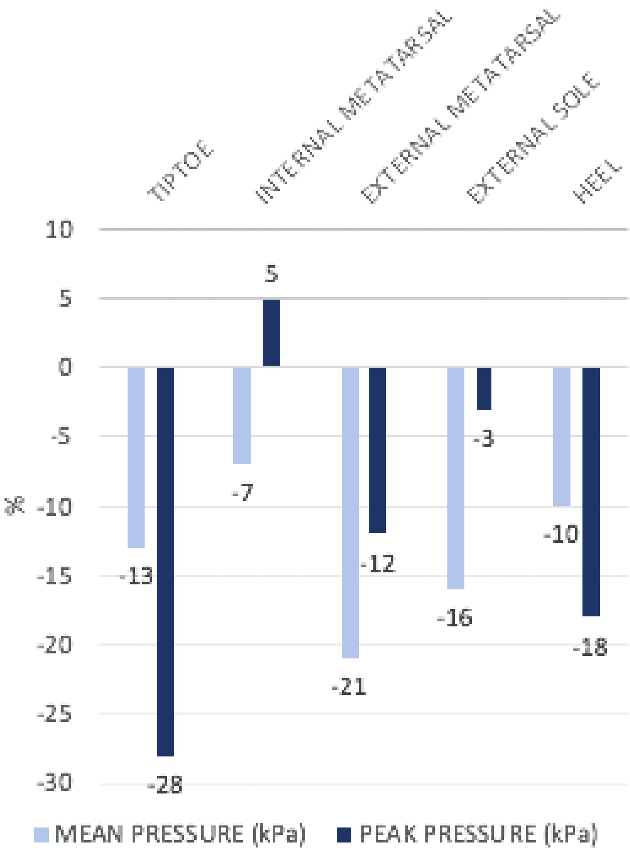

Figure 54: Percentage with smaller masks

3.2.2. DIAB

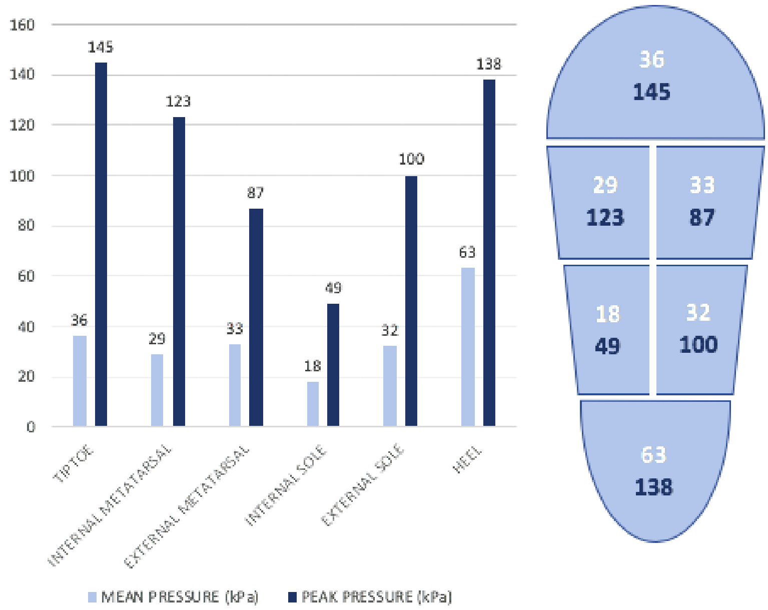

Figure 55: Baseline

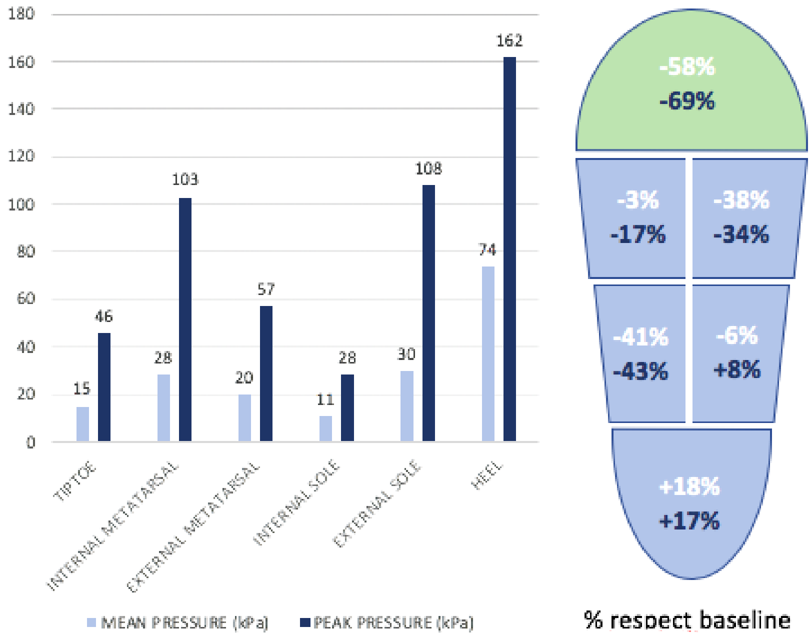

Figure 56: Tiptoe

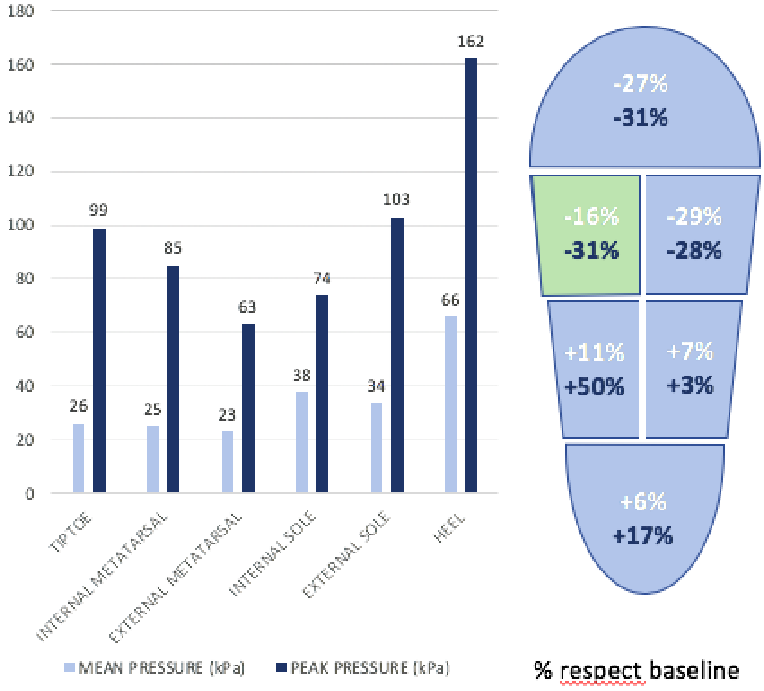

Figure 57: Internal Metatarsal

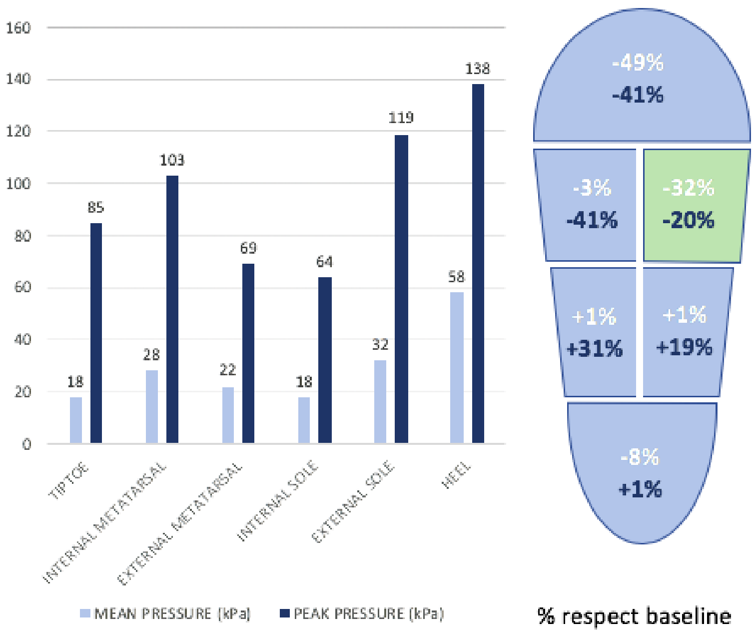

Figure 58: External Metatarsal

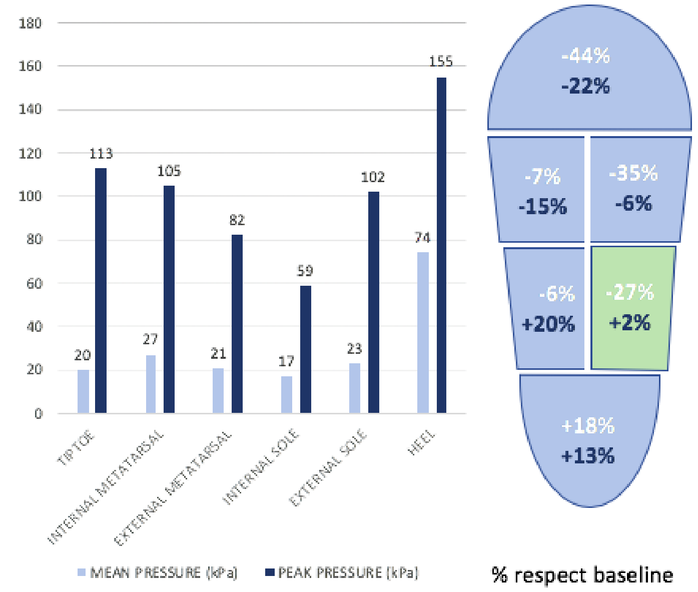

Figure 59: External Sole

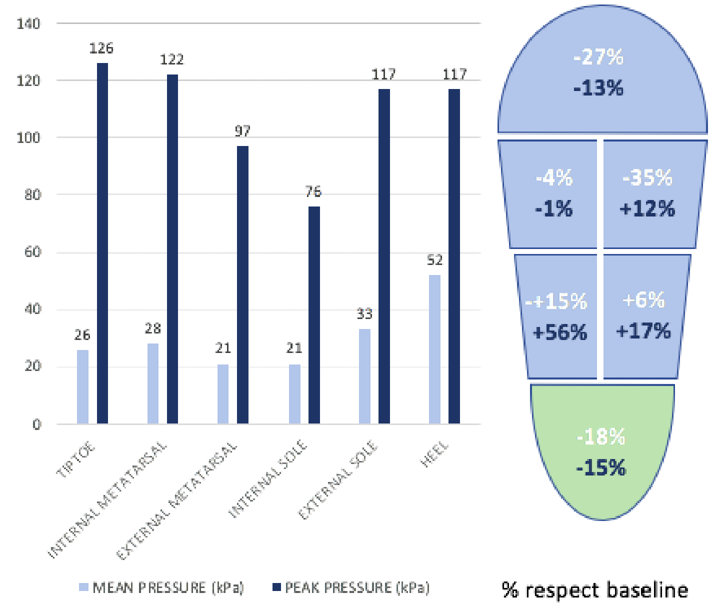

Figure 60: Heel

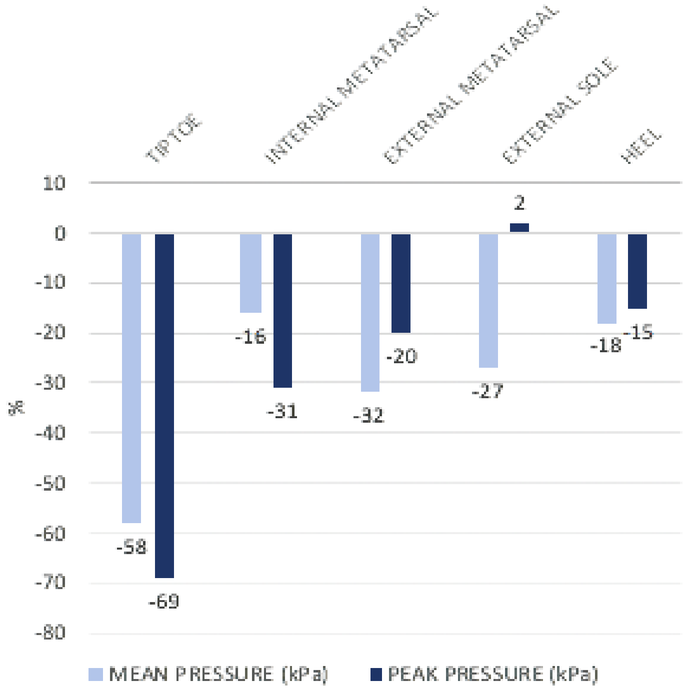

Figure 61: Percentage with smaller masks

3.3. Small holes

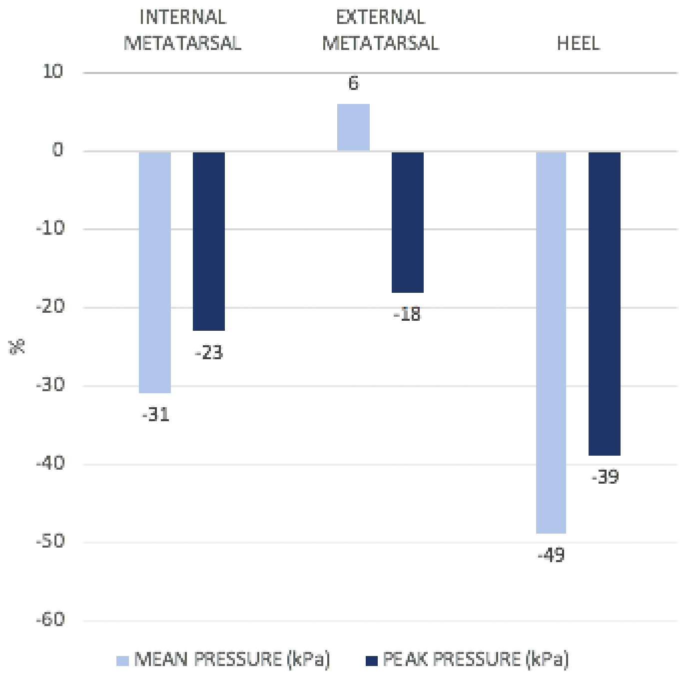

Figure 62: Motus 2.0 percentage with small masks

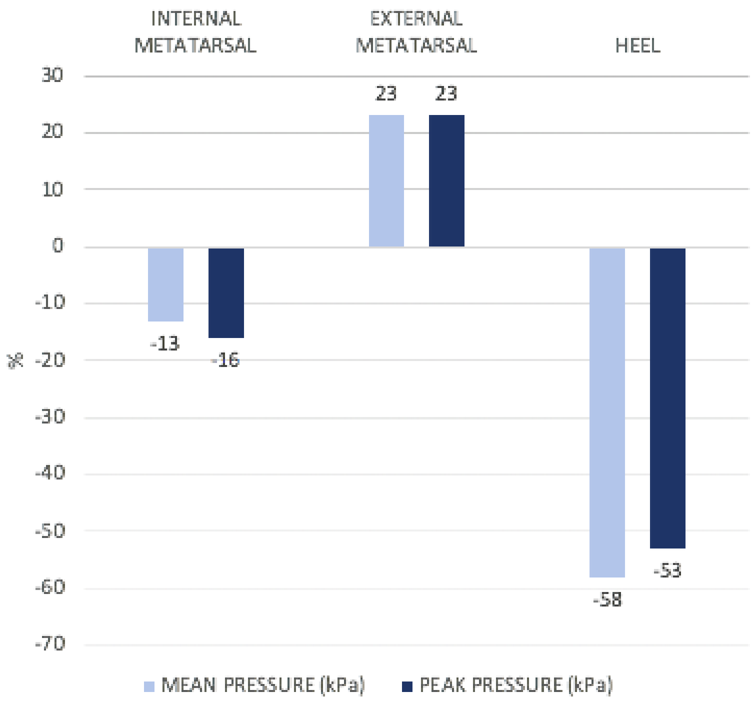

Figure 63: Diab percentage with small masks

4. DISCUSSIONS AND CONCLUSIONS

Due to the Covid-19 restrictions, the project has been reshaped. The trials on the APAM could not be done and also the trials on the walkers have been done on only two persons. Walker's obtained data are shown in the previous section.
Data were collected in both subjects using the same procedure, equipment, and analyzed with the same algorithm. Performances are reported in mean and peak pressures (kPa) and calculated in percentage with respect to the baseline that is the initial condition with the normal setting of the insoles.
For the first subject, obtained data are reported in the previous section in two different ways. In fact, for both Motus 2.0 and Diab walkers, results, are obtained using bigger masks and then compared with data obtained with smaller masks. As we can see in figures 36 and 44, better results are obtained with smaller masks, in particular for the tiptoe, internal metatarsal, and the heel. Seen that, for the second subject, data are directly processed with smaller masks.

For both the walkers, we obtained in general good results. The pressures in fact are redistributed well: in particular in the Motus 2.0 with the tiptoe hole, the worsening of the other foot pressure is due to the load redistribution and also to the rigid insole. For the metatarsal holes (internal and external), instead, the redistribution effect is not so much visible due to lower pressure in that part. In the heel, there is the same effect of the tiptoe.

The same happens for the Diab walker: pressure redistribution works but for the first subject, with the tiptoe hole, there are not so good results even with smaller masks; it may be due to the subject's foot length, in fact, the walker is too small for that foot. For the second subject, we obtained more promising results probably due to the fact that the sizes of the walkers are more appropriate to the foot length, in particular, obtained results for both Motus 2.0 and Diab are very good especially for the tiptoe (Motus: -13%/-28%; Diab: -58%/-69%).

Optima Molliter proposed us to test also insoles with smaller holes in the tiptoe and heel that already gave good results with bigger holes but also, we tested the walkers with smaller holes in the external metatarsal that with bigger holes gave worse results. Those trials confirmed what shown with bigger holes for bot Motus and Diab. Filtering data with the proper small mask that considers only sensors shown in figures 28, 29, 30, obtained results are shown in Figures 62-63, for Motus 2.0 and Diab. For the tiptoe we obtained a mean pressure reduction of 31% and 13% and a peak pressure reduction of 23% and 16%; for the heel -49% and -58% for the mean pressure and -39% and -53% for the peak pressure. External metatarsal small holes cannot reduce in a satisfying way mean and peak pressures.

In conclusion, the present study demonstrates that offloading walkers for therapeutic treatment of foot ulcers are promising tools. In particular, those of the Optima Molliter obtained high performances during executed trials. The limitations of the present study are caused by imposed restrictions and so are linked with the small population on which the analysis has been performed. Another limitation is linked with the correspondence of the insole sensors with the holes and the patient's foot that it is not always perfect.

Future developments for this work could be:

- Test a bigger number of normal subjects;
- Apply all the measurement procedure to a patient population;
- Try to change the insoles positions (red, beige, blue) and see how the pressure redistribution changes.

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