UNIVERSITA' POLITECNICA DELLE MARCHE

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MEASUREMENT OF PRESSURE DISTRIBUTION AND OFFLOADING EFFECTIVENESS IN AN ACTIVE SEAT CUSHION

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Summary

1 Introduction

Nowadays the increase of population over 65 years of age is growing faster leading to the elevated rates of diabetes, obesity and cardiovascular disease [1]. These diseases can affect patients' mobility making necessary assistance during daily activity and the usage of wheelchair and special beds. The decreased mobility and the prolonged use of these latest systems can lead to the development of pressure ulcers (PU) [1].

Pressure ulcers is one of the most frequent burden. It is the third more expensive disease of the twenty century after cancer and cardiovascular disease[2]. It negatively impacts the health due to its debilitating complications epositioning and pressure ulcer prevention.

Pressure ulcers are defined as a 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[3]. To better understand, pressure ulcer is a localized area of soft tissue over a bony prominence in which unrelieved pressure higher than the capillary pressure (estimated to be 32 mmHg) may leads to ischaemia, cell death and even tissue necrosis [2]. The development of pressure ulcers is caused primarily by a reduction of blood flow and it can occur when the patient is forced to remain for a long period of time in a wheelchair or in bed. Reduced blood flow can occur when an individual is sat for extended period, such that, the skin and underlying soft tissue becomes starved of oxygen and nutrients providing negative effect on the affected tissue, leading to the development of pressure ulcers [4]. There are several factors that affect pressure ulcers development but the three main causes are: the amount of pressure applied to this vulnerable tissue, the time of which the unrelieved pressure is applied and the subject's tolerance to injury [4]. The dangerous threshold of pressure which is applied over bony prominences is assessed to be greater than 32 mmHg, but this value still remain questionable because it is strictly correlated to the period of time of the unrelieved pressure [2].

The 50% of the 1.4 million people who depend to wheelchair for mobility develop tissue breakdown due to the prolonged use of a wheelchair. The greatest proportion of the body weight is supported by ischial tuberosities during sitting but other areas over bony prominences are severely affected by great pressure applied on them in a sitting position, such as sacrum, trochanter, popliteal fossa (located at the back of the knee) bony prominence of the spine, scapula and heels [5].

Several treatments are available to heal pressure ulcer, but prevention is better than treatment, not only to reduce the patient' suffering but also from an economic point of view. The treatment costs are much higher than prevention cost [6]. Pressure ulcers prevention consists of a reduction of the amount of pressure over a bony prominence implemented with a reduction of the time of exposure [6]. Many modalities to prevent pressure ulcers include the repositioning of the patient, push-up of the subject and rise the body part at risk for pressure ulcers development [7]. Another way to prevent pressure ulcers formation is the adoption of special wheelchair cushion. There are two different types of cushion used in PU prevention: static cushion made of foam, gel and viscoelastic materials and active cushion. The last ones are connected to a PC and designed to provide alternative strategy to promote tissue perfusion reliving pressure [7]. A particular characteristic that an active seat cushions should have, is their function to achieve the offloading effectiveness. A suitable cushion has to provide a proper posture but in this particular case, it has to offload pressure in the most vulnerable body parts, redistributing pressure over more tolerant areas, increasing the contact surface between cushion and patient [8].

In this work, an active seat cushion is presented. It is composed of an array of 7 x 7 air cells connected to a compressor and a PC. It allows the user to regulate pressure inside each cell promoting pressure relief when a mass is applied on it. The presented cushion system performs a checkboard pattern of inflation and deflation of the air cells, acting to decrease pressure between wheelchair users and the cushion itself, in order to increase tissue reperfusion. In this study, the analysis of the current cushion operation modality is performed, measuring the interface pressure between cushion and subject using a pressure sensor matrix placed on the cushion surface.

The aim of this work is to determine the effectiveness of the active seat cushion designed to prevent pressure ulcers development measuring, and analysing the cushion system characteristics and its operation modality. The cushion current modality of operation is studied in detail, providing a verification of its procedure of inflation and deflation of the air cells with a checkboard pattern to relieve and redistribute pressure. Starting from the assessment of the current cushion efficacy to prevent pressure ulcers, a successive modality of operation is presented to increase its offloading effectiveness to relieve pressure and redistribute it over a larger surface.

1.1 Pressure ulcers

The National Pressure Ulcer Advisory Panel (NPUAP) and The European Pressure ulcers Advisor Panel (EPUAP) define pressure ulcer (PU) as a 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 [3]. NPUAP is an American non-profit organization working on prevention and management of pressure ulcers. EPUAP composed in London deals with prevention, research and provides guidelines to manage pressure ulcers in the Europe [2]. To better analyse what is a pressure ulcer, it can be though as an injury that affects the skin and the underlying tissues as a result of pressure applied over the bony prominences for a prolonged period of time [9]. The combination of the above mechanism and other risk factors presented some pages below, cause tissue ischemia and arrest of nutrition and oxygen supply to the tissues involved, leading in the worst case, to tissues necrosis [9].

Pressure ulcers is the third more expensive disease of the twenty century after cancer and cardiovascular disease [2]. It impacts negatively the health due to its debilitating complications and the social gain [10].

From data obtained by Associazione Italiana Ulcere Cutanee Onlus, in Italy 2 million people suffer from chronic skin injuries and the decubitus ulcers affects 8% of hospitalized patients and from 15% to 25% of those in long-stay facilities. According to the EPUAP, a pilot survey conducted across 26 hospitals in Italy, Belgium, Portugal, Sweden and UK, in 5947 patients the 18,3% have pressure ulcers [11]. In particular in Italy the 8.3% of patients present pressure ulcers. The assessment of the total cost to prevent and treat pressure ulcers in Europe is not available but the EPUAP reports that in the UK for example, the cost for PU to NHS would be between £1.760 million and

£2.640 million each year [11]. The incidence rates relative to the pressure ulcers differs according to the clinical setting. In America it is estimated to be from 0.4% to 38% of pressure ulcers develop in the inpatient department, from 2.2% to 23.9% in long term care facilities and from 0 to 17% in home care setting [2]. The incidence rate that can be considered suitable for all setting should be less than 2% [2].

Pressure ulcers affect more frequently elderly people with 60\80 years of age who are confined in wheelchair or bed for longer period of time [2][9]. In some cases, pressure ulcers appear in young patients with a neurological impairment due to the loss of sensory perception or due to a damaged level of consciousness. Perception of pain prevents prolonged pressure over bony prominence, the physiological behaviour consists to feel pain and changing the position relieving body area at high pressure [2].

1.1.1 Pressure ulcers aetiopathogenesis

The development of pressure ulcers is defined as a combination between physiological actions and external conditions [1]. The tissue ischemia is the leading cause of pressure ulcers in combination with other factors [9].

The physiological capillary pressure ranges based on different segments between 16 mmHg and 33 mmHg[2]. This datum is very relevant because when the external pressure applied over a body prominence is greater than 33 mmHg, it causes capillaries occlusion. Occlusion of blood vessels make the underlying and surrounding tissues to be anoxic. If this event last over the time, cells death occurs leading to a subsequent soft tissues necrosis and ulceration[2]. Pressure ulcers occur over bony prominences in which pressure applied on them compresses the underlying tissues when the subject is in contact with an hard support surface for long time[1] (Figure 1).

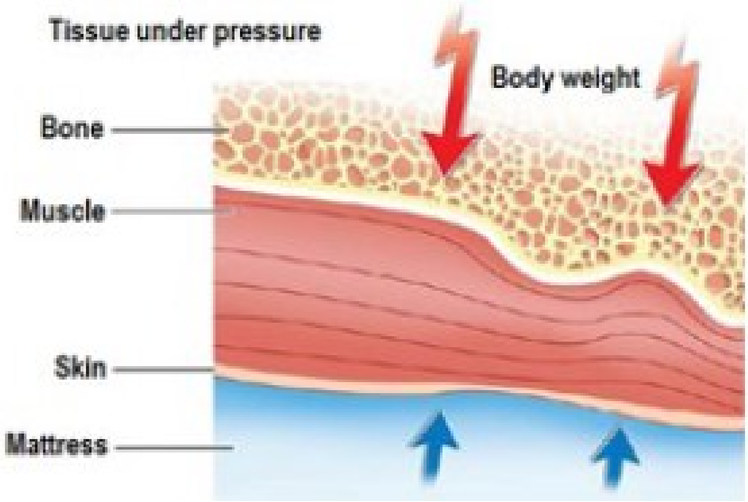

Figure 1 Tissue under pressure[6].

Prolonged pressure is the main leading factors[2]. Time of pressure duration and the entity of pressure can be seen in an inverse relationship: lower pressure requires more time to cause pressure ulceration and tissue necrosis, continuous higher pressure requires shorter time to cause pressure ulceration[2]. When the soft tissues under high pressure applied can became compressed and sheared resulting in tissue distortion due to the contact between the skeleton on a hard support surface that can be a chair, bed or shoes[9]. Distorted tissues are compressed and stretched out avoiding blood flow to pass freely making them ischemic[9]. In addition to that, compression of soft tissues block lymph fluid drainage, leading the accumulation of waste products and proteins in the affected tissues contributing the formation of PU[1][9].

1.1.2 Risk factors

Until now, pressure ulcers and their characteristics have been presented but one of the most important things to consider is that the development of PU depends on a great number of factors.

There are two types of risk factors: extrinsic factors including pressure that are the main relevant factors in the pressure ulcer development and intrinsic factors that contributes to it. For this reason the first type are called primary factors whereas the last ones are called secondary factors[2].

Pressure can be considered as the heading factor and it is defined as the perpendicular load or force applied on a unit area of the body (equation 1),

$$Pressure = \frac{\text{body weight}}{skin\ contact\ surface\ area} \qquad (1)$$

Equation 1 pressure calculation

From this equation it can be seen that there is a direct proportion between pressure, body weight and the time of application, there is also an indirect proportion between pressure and the area of the skin contact[2].

The pressure is not the only causative effect but it has to be taken into account the stiffness and the composition of the tissue in which the pressure is exerted[2]. For example on sacrum and ischial tuberosity there is a relatively thick soft tissue and the surface of skin contact is wide but the blood vessels in this area are not adapted for weight-bearing and for this reason ischemia can develop rapidly[9].

The shearing is another causative factor because when the body glides on a surface, the skin remain stationary and the bony structure and muscle are affected by this shifting causing deformation of soft tissue and stretching of blood vessels that in turn block the blood flow causing ischemia[2][12].

When the skin brush on the surface friction occurs[12]. Friction is considered as both indirect and direct factors because it is necessary to cause shearing forces but in the other hand when the skin is weak because of pressure ischemia it is more susceptible to friction and the probability to became infected increase[2][9].

Position of the patient is an extrinsic factor to cause pressure ulcers because it determines the susceptible pressure points. An example can be the ischial ulcer that is the most common in patient who use wheelchair that spend lot of time sitting causing pressure in this susceptible areas[2].

Combined pathologies like loss of movement, failure of reactive hyperaemia and loos of sensation contribute to develop pressure ulcers[9].

The moisture is an other extrinsic factor that cause maceration and weakens skin barrier make skin more susceptible to pressure ulcers[2][13]

There are many indirect causes that contribute to develop a pressure ulcer, some of them a reported below[9].

- Age-related physiological alterations that induces pressure ulcer development.
- Diabetes mellitus that affect the 11% of the adult over the 70 years of age.
- Heart failure, atrial fibrillation, myocardial infarction and pulmonary disease affect the tissue oxygen tension that can be detrimental for wound healing.
- Peripheral vascular disease dangerous for wound healing.
- Loss of sensation and pain.
- Nutritional condition and malnutrition affect the incidence risk to develop pressure ulcers.

1.1.3 Pressure ulcers classification

The development of pressure ulcers is due to an unbalanced match between an external load applied on the skin and the ability of the skin itself and the undelying tissues to withstand this load[14].

Pressure ulcers can be primarily classified in superficial PU and deep ones both showing different aetiology. Superficial PU develops mainly as a result of shear and trauma to the tissue whereas the deep PU develops as a result of high pressure applied near the bony prominence in a prolonged period of time[14]. There are several grading systems to classify the severity of PU but the most important scale is that one provided by the EPUAP[9]. The EPUAP grading system consists of four different severity stages described below(Figure 2).

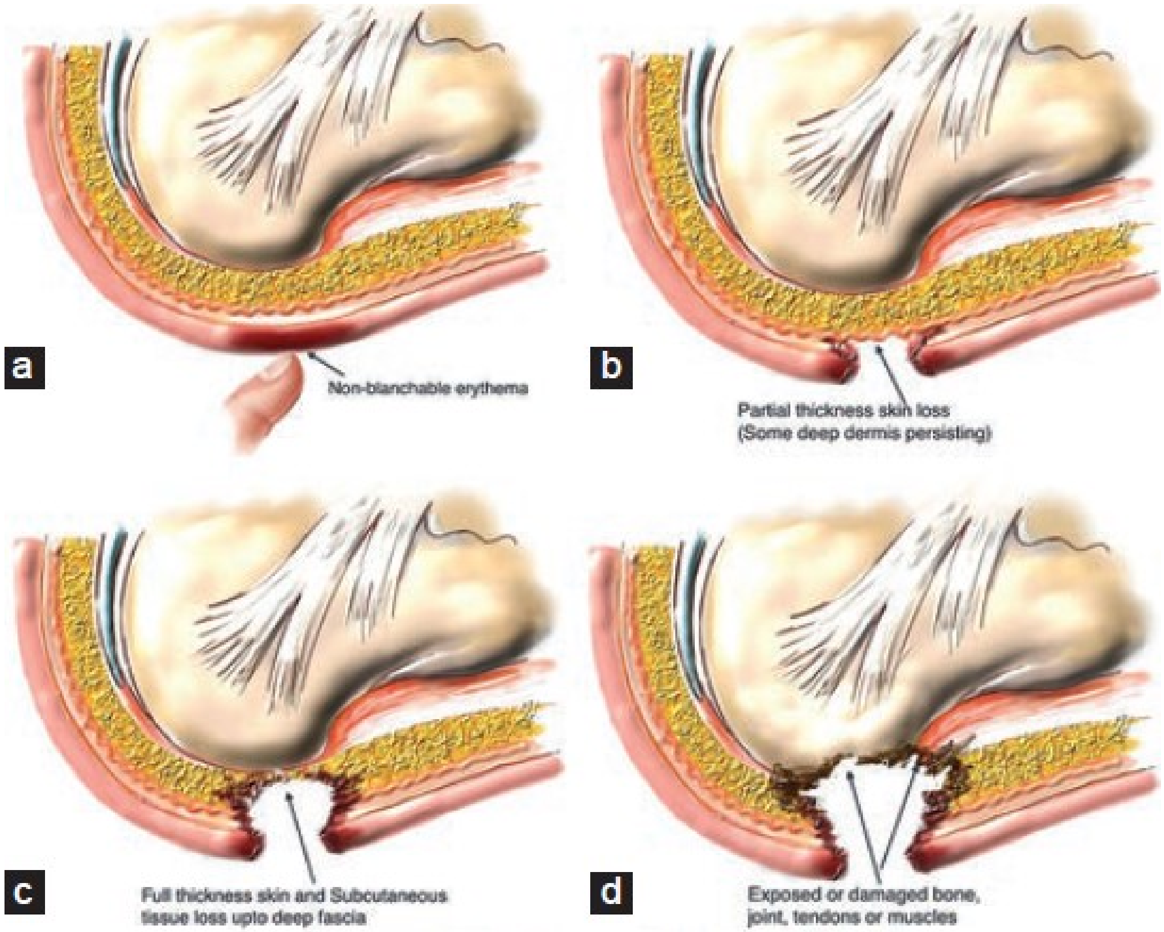

Figure 2 Four different grading of pressure ulcers[9].

The classification depends on the degree of severity and the depth of the damage[9].

A pressure ulcer of grade one is defined by EPUAP as non-blanchable erythema[11] (Figure 3). Pressure ulcer defined by this category is the most superficial type and presents a discoloured area, red in white people and purple or blue in subjects with a darker colour of the skin. In this category the skin is not broken, and the pressure ulcers do not turn white when pressure is applied on them[9][15].

The skin involved may be warm and hard or squishy on touching and the main characteristics are: it presents a non-blanchable erythema of the skin difficult to see in patients with a darker skin, an oedema with induration can be present, the area can be warm and if the subject presents an eschar the characterization is difficult to make[9][15].

Figure 3 Pressure ulcer grade one[3].

A pressure ulcer of grade two is defined by EPUAP as a partial thickness. This type of PU involves the epidermis or the deeper layer of the skin that is the dermis[9][11] (Fig. 4). It can consist of an open wound or a blister and it is characterized by a partial thickness skin loss of dermis represented as a shallow open ulcer with a red wound bed or it can be also present an intact or open serum-filled blister[9][11].

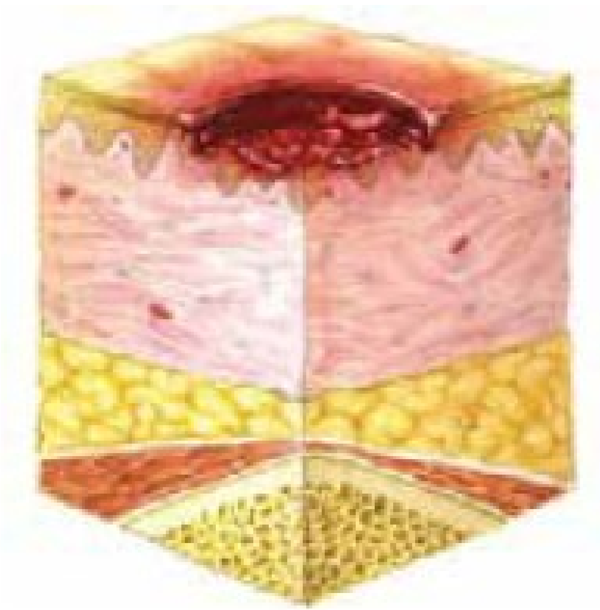

Figure 4 Pressure ulcer of grade two[3].

The pressure ulcers of grade three is defined by EPUAP as full thickness skin loss[11] (Fig.5). This category is characterized by damage occurred to both skin (loss of thickness) and soft underlying tissue avoiding muscle and bone injuries[15][9]. Slough may be present, and the ulcer appears as a deep cavity involving damage and necrosis of subcutaneous tissue that may spread down to, without affected muscles and bones[9]. Pressure ulcer of grade three may be represented by undermining and tunnelling[11].

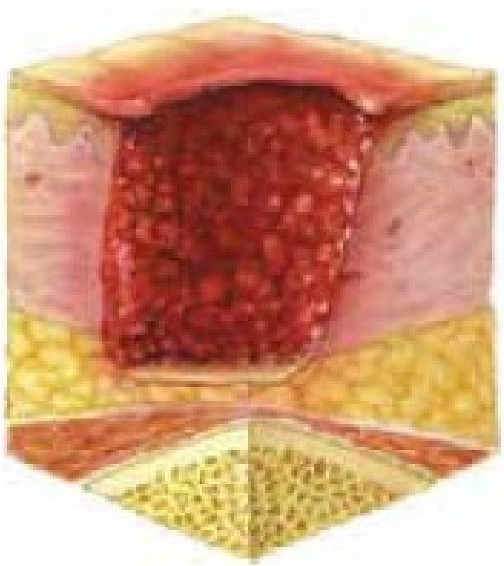

Figure 5 Pressure ulcer of grade three[3].

A pressure ulcer of grade four is defined by EPUAP as full thickness skin loss with some greater differences from grade three[11] and it is considered as the most severe type of PU[15] (Fig.6)In this stage the thickness tissue loss is present and characterized by the exposure of the underlying muscles, tendons and bones. The skin is acutely damaged and the surrounding tissues die[9].The grade four of PU is also very dangerous because increase the risk of progression of life threatening infections[15].

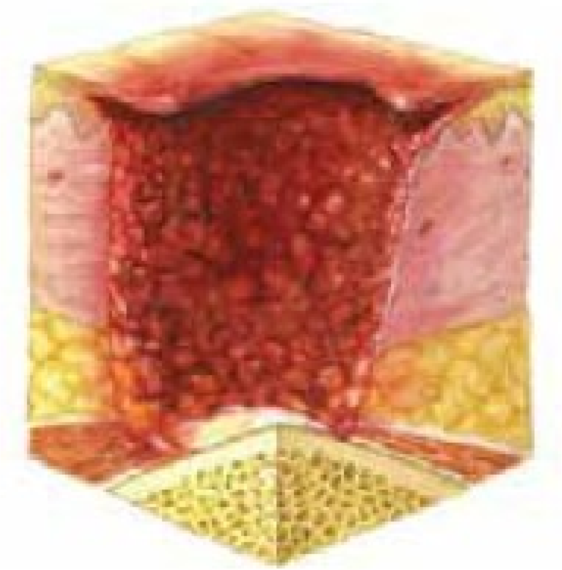

Figure 6 Pressure ulcer of grade four[3].

To conclude some articles report un other category that is defined as the unstageable pressure ulcer[15](Fig.7). This last type of pressure ulcer is something that is covered by dead or slough tissue and for this reason the injury level of the wound remain undetermined. This injury is not estimable until a medical professional removes this dead tissue[1][15].

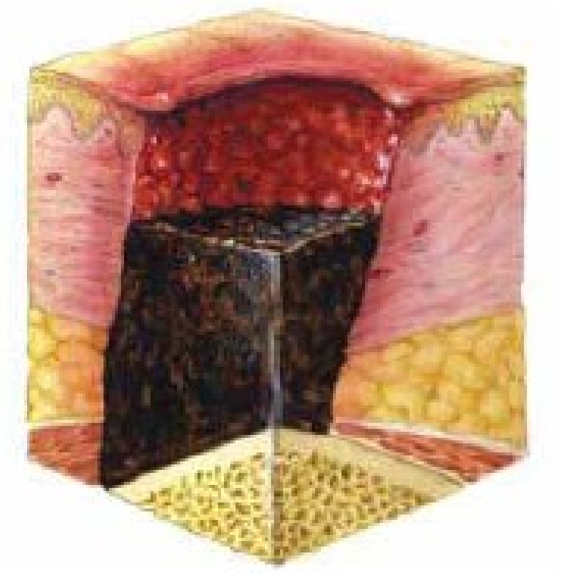

Figure 7 Unstageable pressure ulcer[3].

Resuming, a hallmark of pressure ulcers is the area of the skin injured and the quantity of the underlying tissue affected[1]. Indeed, other assessments of pressure ulcers encompass the area of the body affected, the condition of the underlying tissues, the presence of undermining and tunnelling and the quantity of exudate, odour and tenderness[1].Assessment scale are presented in order to estimate the risk pressure ulcers degree.

The factors presented in the previous part are necessary to be looked for in the pre-ulcer period in order to make a proper pressure ulcer assessment in a patient[2]. The main characteristics that an assessment scale should have is a high sensitivity and high specificity to properly predicts the risk of pressure ulcers development and it has to be clear and suitable for each healthcare setting[2]. The principal scale assessment are the Norton scale, Braden scale and Waterlow scale[2]. The Norton scale was developed in 1962 by D. Norton et al[2]. It scores five categories including: physical condition, activity, mobility, incontinence and mental conditions with score from 1 to 4 for each of the above categories[1]. If the obtained score is less that 14 high risk for pressure ulcers development occurs[1]. This scale does not include nutritional factors and shearing forces but a revisited Norton scale exist in which diabetes, haematocrit, haemoglobin, temperature and other factors are taken into account during the assessment[2]. For what concern the Braden scale: activity, mobility, friction, sensory perception, moisture and nutrition are included to assess the risk[1]. This scale has been developed by Bergstorm in 1987[2]. It is considered as an inverse scaling tools in which four points are used to estimate each category with an high score that means lower risk and a low score that implies high risk[1][2]. It is considered the best scale and it is available a modified Braden scale used for children with an age of about 9 years[2]. The last type of scale assessment is the Waterlow scale developed by Judy Waterlow in 1987[2]. This scale presents an incremental positive scoring modality that can be seen problematic due to the risk of over assessment and it is also a very complex scale due to its large number of parameters to consider[2].

NPUAP developed a type of scale that is called PUSH tool and it is a pressure ulcer scale for healing in which the grade of pressure ulcer is assessed based on the size of wound and the exudate amount[1].

Beyond all these scales it is important to monitor constantly a pressure ulcer[1]. Computed tomography and magnetic resonance imaging are the best technique to determine the extent of tissues involved[1].

1.1.4 Treatment

Several types of treatment exist to healing pressure ulcers or at least to reverse the original factors which has caused the wound. The range of cost for pressure ulcers for treat them is varied from 1.71€ to 470.49€ across all settings per patient per day[16].

Firstly, to provide the pressure ulcers healing the assessment of the severity through assessment scales and imaging technique is needed. The assessment and the removing of the causative factors are not easy because pressure ulcer is a combination of pathology such as diabetes, pressure, loss of sensation.

The best way to act is remove the causative effects when it is possible, for example alleviate pressure, shear and friction and keep under control all the associated conditions[9]. To manage pressure ulcers the relieving pressure is needed. The limb or the affected area has to be elevated in order to promote the venous and lymphatic drainage, removing the weight bearing and the pressure from the area[9]. Sometimes non-weight bearing physiotherapy is needed[9]. After that, other management such as necrotic tissue debriding, clean the wound, manage and remove bacterial load and selecting the suitable wound dressing[17]. Pressure reducing devices are also used in order to prevent pressure ulcer formation but sometimes are also used as treatment [17].

Pain assessment is another procedure to make before treating. It can be completed during repositioning, dressing or debridement because patients at higher risk of pressure ulcers may not have the sensation of pain[17].

The overall goal of the treatment and management is to remove pain dressing the wound, adjusting pressure offloading surfaces, repositioning the patients and provide analgesia[17].

Pressure ulcer in stage III or IV needed debridement. To perform debridement, sharp is needed an advancing cellulitis and sepsis is present. Autolytic, enzymatic and mechanical debridement is performed if there is nonurgency[17].

Dressing is required to maintain the wound moist in order to promote healing and the suitable dressing is chosen based on the wound characteristics[17].

Surgical approach is required when patients present pressure ulcer at stage III and IV that did not respond properly to the previous method or when the quality of life must be improved rapidly[17].

The newest technologies are the use of growth factors and the electromagnetic therapy such as the ultrasound.

With ultrasound technique the dead tissue is removed with low frequency energy waves [9]. A laser technology is also used to remove dead tissue though focused beams of light[9].

1.2 Pressure ulcers in wheelchair seating

World Health Organization in 2008 reports that in 650 million of disabled people in the world, 10 % of them need to use a wheelchair during their daily activity and this number is growing due to the population ageing [2].

Patients in sitting position on a wheelchair present a high risk to develop pressure ulcers. As it said before lot of factors affect the development of pressure ulcers and the main aspects to consider for a subject in a wheelchair are 3. In this paragraph these three aspects are explained and taken into consideration: the first one is the risk pressure threshold which is the dangerous pressure in which the occlusion of blood vessels occurs and when the pressure overcome the threshold also the tissue necrosis arise. The second aspect considered are the areas of the human body at risk of pressure ulcers formation, which are the bony prominences. The third aspect in close correlation between the risk pressure threshold is the time, period of time in which pressure is applied.

When the body is placed on a solid surface such as a cushion, two main forces act on the body: stress perpendicular to the skin (normal stress which is the pressure applied) and stress parallel to the skin (shear stress)[5]. In a wheelchair the total force acting on the subject is equal to the force acting on the buttocks, the force action on the tight minus the supported forces of the foot and backrest[5]. Some papers report that the weight distribution for a seated subject is 75% on their buttocks and thighs, 19% on the feet, 4%on their back and the remained 2% on their arms[18]. The greatest proportion of the body weight is supported by ischial tuberosities during sitting but other areas over bony prominences are severely affected by great pressure applied on them in a sitting position, such as sacrum, trochanter, popliteal fossa (located at the back of the knee) bony prominence of the spine, scapula and heels[5][19].

The 50% of the 1.4 million people who depend to wheelchair for mobility develop tissue breakdown at ischium and coccyx due to prolonged sitting[20]. A problem associated to this risk is the relatively thick covering of the tissue on the sacrum and ischial tuberosity in this wide supporting surface. In this case blood vessels are not suitable for weight-bearing and this increase the risk of ulceration[9]. It already known that the physiological capillary pressure ranges from 12 to 32 mm Hg. Pressure higher that 32 mmHg alters blood circulation and oxygenation causing tissue necrosis and if the pressure is maintained for a critical duration ulceration occurs[6]. But the risk pressure threshold is determined also by other factors such as the stiffness and the composition of the tissues and it is very difficult to determine precisely a value for which pressure ulcers occurs. The capillary pressure in which ischemia develop is still debatable[2]. Some article reported that the incidence of pressure ulcers increases in patients who present peak pressure at 60 mm Hg or higher[12]. Others, report that the average pressure over the ischial tuberosities increases over 100 mm Hg in the pressure ulcers formation[2].

Not only the tissue composition alters and affects the pressure ulcers formation, but the value of interface pressure also varies from person to person based on his\her physiological and pathological conditions and based on the body weight.

In conclusion, it must be considered interface pressure in conjunction with other measures such as skin temperature, tissue perfusion and humidity[20].

Time is another aspect to consider in the analysis of pressure ulcers formation during sitting. It is still questionable the period of time a person should be seated on a wheelchair. Guidelines report that seated duration does not exceed 2 hours, especially in those patients with ill in which the mobility is quite or completely loss[21]. From a physiological point of view, cells under pressure are destroyed and taken to death between 2 and 4 hours[21]. Necrosis takes place and pressure ulcers arise if ischemia continue for 1 or 2 hours[9].

One of the main preventions for pressure ulcers formation is the decrease of pressure in the critical areas and reducing of time of exposure[6].

It is achieved using special support surface, repositioning and changing position to the patients and rising the affected body parts[6].

Some clinical practice guidelines [22] suggest to perform a pressure relief every 30 minutes lasting 30 seconds. Other studies suggest that a push up pressure relief has to last from 1.5 to 4 minutes for a recovery of the tissue oxygenation[22].

The NPUAP suggests that if reducing the hazards of immobility, promote eating and breathing and facilitate the rehabilitation, the time of sitting could be imitated to periods of 60 minutes or less, 3 times a day[18].

Another paper suggests that the movement should occur every 15 minutes whereas other discuss that the period of sitting without movement does not last for more than 2 hours[18].

Some interesting and useful information to study the sitting behaviour are the attitude of nondisabled subjects to change the posture every 9 minutes in the sagittal plane during sitting and every 6 minutes in the frontal plane[14]. It is useful to assess the effectiveness of pressure reliefs that will be presented later.

One of the many prevention strategies is the pressure relief in which a wheelchair push-up of the subject can be performed every 20 minutes. This method provide good effectiveness for pressure ulcers prevention[20].

In the last part of this chapter that has provided an analysis of some critical aspects of patients who rely on a wheelchair, a brief introduction to another important aspect has to be done.

As said previously the greater proportion of body weight during sitting is located over the ischial tuberosities, Bone resists to large forces respect to the muscle and fats which are more vulnerable leading to blood vessels occlusion[5]. During sitting the compression forces between the hard support and the bony prominences is transferred to muscles and fast becoming compressed[5].

A distinction can be done according to the wheelchair user's physical body.

A wheelchair user who is more vulnerable to tissue damage under the gluteal area is a patient with little muscle tone and less able to withstand to tissue deformation[5].

A heavy wheelchair user could be less vulnerable to tissue damage if she\he presents more fat and muscle padding which compensate for his\her body weight[5].

A skinny wheelchair user with flaccid gluteal tissues present high risk to develop pressure ulcers[5].

Weight distribution is essential in the design of cushions for wheelchair in which the weightbearing should be equally shared from the ischial tuberosities to the nearby areas around the trochanters[5].

1.2.1 Pressure ulcers prevention modalities for wheelchair users

There are several modalities to prevent pressure ulcers. Prevention consists to decrease the amount of pressure acting on body parts and reduce the time of exposure[6]. Prevention is better than treatment, not only to reduce the patient' suffering but also from an economic point of view. The treatment costs are much higher that prevention cost[6].

The assessment of prevention cost is about 2.65€ to 87.57€ per patients per day across all different settings[16]. Some modalities to reduce pressure and exposure time in order to prevent pressure ulcers include the repositioning of the patient, push-up of the subject, rising body part that are at risk for PU development, recline and wheelchair tilt-in-space[6][7]. These strategies have been evaluated to provide a good effectiveness in the pressure ulcers prevention because they are able to promote the blood reperfusion[7].

To relieve pressure another modality of prevention is the adoption of special wheelchair cushion. A suitable cushion has to provide a functional and a proper posture but, in this particular case it has to decrease pressure by off-loading the pressure in the critical areas to redistribute it into the more tolerant areas and as a second way a cushion has to distributing pressure over a larger support area[8]. Now, a distinction has to be made between two different types of cushion: static wheelchair cushion and active or dynamic cushion.

1.2.2 Static wheelchair cushions

There are several types of cushion available in commerce. Different material used in the design of wheelchair cushion can lead to different responses to pressure relief[22]. The most popular and efficient are those made of gel, viscoelastic foam, foam, air-filled and a combination of the previous ones. Static cushions are able to reduce pressure increasing the contact area in order to mould patient into their materials[18]. Gel cushion are available in order to increase the body contact area due to its texture.

For what concern the viscoelastic foam cushions, they provide moulding of the patient with them to distribute body weight[18]. They are heat-sensitive but at the same time may be softer for some patients or harder for others[18].

Unlike viscoelastic foam, foam cushions are able to functions in the appropriate way based on the quality of the foam. If the quality is poor or the patient's weight overcome the tolerable range capacity of the cushion, the cushion may bottoming-out[18]. A point in favour for this type of cushion in its affordability[18].

Static air cushions are light and provide an easier moulding of patient into them and show greater ability to accommodate lightweight individual and support heavier subjects[18].

1.2.3 Active wheelchair cushions

For every wheelchair user who are not able to perform by themselves postural changes, active cushions have been designed to provide alternative strategy to promote tissue perfusion reliving pressure[7].

The aim of these works involved in the development of active cushions is to provide a pressure relieving in those sites where higher pressure is observed, performed at frequent intervals of time allowing tissue reperfusion. Since time and pressure are the main factors to consider in the development of the alternating system, the proper alternating pattern of deflation and inflation is still discussed[7].

A brief description of how these active cushions are designed is reported in Nakagami et al.[23]. These cushions are in general made up by a certain numbers of automatic self-regulating alternating pressure air cells. Air cells are connected through valves with air pump to provide inflation and deflation. A battery and a microprocessor are incorporated in the cushion system and a series of pressure sensors are integrated in the system to measure inner air cells pressure.

In this particular case [23] the cushion is able to adjust the inner air cells pressure through the use of bottoming out detecting sensors. Using these bottoming out detection sensors the system is able to automatically inflates the air cells to compensate the bottoming out(Figure 8).

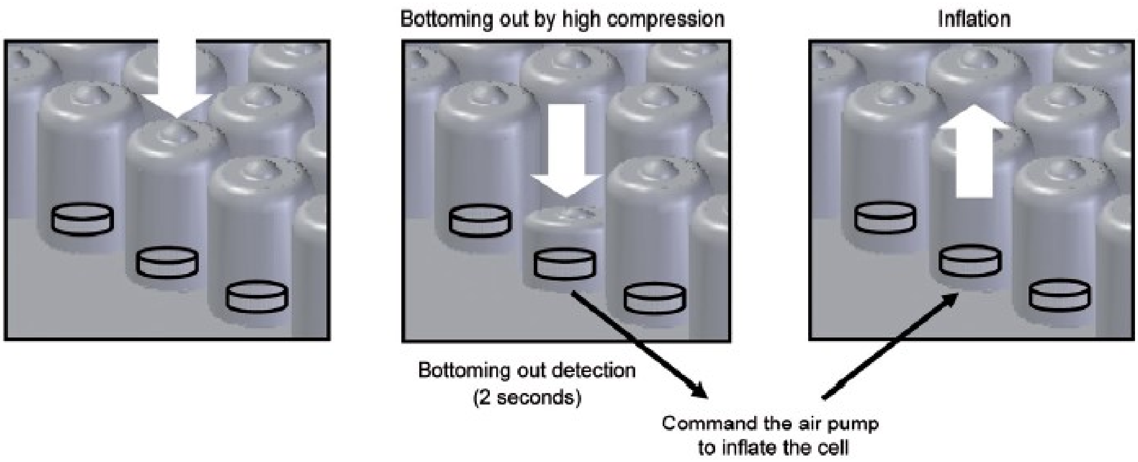

Figure 8 the functioning of the bottomin out system.[23]

The alternating cushion has air cell lines in which, when one air cell line deflates, the other one which is the opposite inflates keeping its inner pressure. At the beginning all the air cell lines deflate when pressure is applied, after that the bottoming out detecting sensors record the bottoming out phenomena induced the inflation and deflation in alternating way[23].

Another important work that provide useful information is the study of Carrigan et al.[24]. It can be considered the cornerstone study of the current work because of its verification tests performed on a developed dynamic cushion and the way in which this cushion has been designed. According to Carrigan et al. [24] the ideal active cushion has to offload, reducing the effects of pressure magnitude and duration. A cushion should offload specific areas at higher pressure in predetermined time interval to promote reperfusion and prevent long pressure duration. This work introduces an active cushion with this working reducing pressure peak using a closed loop control system and monitoring continuously the pressure. The system is composed of an array of 62 air cells that work as both sensors and actuators because the internal air cell pressure detected is used as tool for detection and modulation of the interface pressure between cushion and subject. The cushion is divided in 2 parts: an active part which is in the most posterior region, it is used to modulate pressure and the passive part which is located in the anterior region and it only provides stability to the system.

The other parts of the system are the pneumatic and electronic components involved in the controlling of the internal pressure for the 62 air cells. A brief description of the system is depicted in figure below.

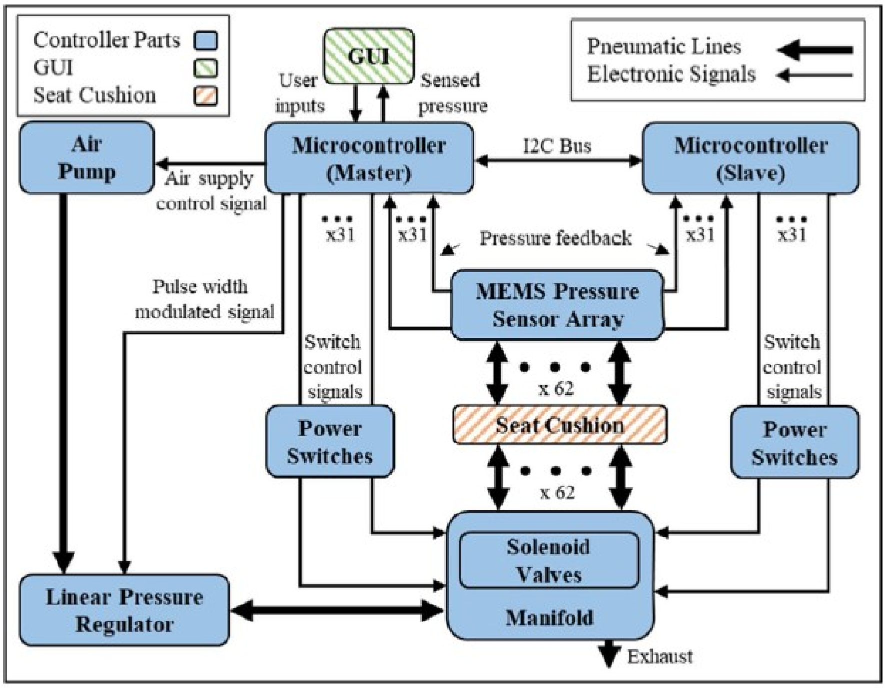

Figure 9 Pneumatic and electronic components and the control hardware of the cushion[24].

In this work [24] a series of tests have been performed with both rigid cushion loaded indenter and a subject. Test to analyse the interface and internal pressure mapping in which the article suggests that the sensed internal air pressure can be an analogue for the interface pressure and for that reason the internal pressure is the input to control the redistribution and the offloading algorithm. The redistribution test has been performed and it results in a decrease of contact pressure, increasing the immersion and a better distribution of pressure uniformly over the surface has been noticed. it can be concluded that the redistribution test provides a suitable output to prevent pressure ulcers. The last test performed in this article[24] is the offloading test. In this case an automated algorithm identify region at higher pressure above a threshold pressure value which is defined as the percentage of the linear sum of minimum and maximum internal pressure values. Once identified areas at higher pressure, the offloading capability of the cushion has been performed creating deflation of these areas at higher pressure and new higher pressure points are subsequently formed in other parts surrounding and supporting the previously offloaded cells. After that, pressure redistribution occurs to remove these new higher pressure points and to redistributes the pressure uniformly. Like Carrigan et al. other studies perform the interface pressure analysis applied on an active cushion by a subject subdividing the cushion in 2 or more than 2 parts, in order to obtain specific information about the behaviour of each body area due to the different weight and pressure impressed over the cushion.

For this reason, Aria et al. [6] develop a system composed of 12 air cell division cushions equipped with pressure sensors and an input for electro valve to provide the inflation and deflation of the air cell itself. Eight air cells for the ischial tuberosities region and only four cells for the thighs. This division is performed because previously in another work [25] has been demonstrated that the concentration of body weight during sitting is mainly applied on the ischial tuberosities areas which are more susceptible to pressure ulcers development. It is important to provide the measurement of pressure in a punctual way and the load concentration point measurements in order to use these information as a feedback needed to perform the pressure redistribution [6].

To prevent pressure ulcers the offloading of pressure over time on the ischial tuberosities is considered as a key factor[26]. Arias et al. [26] in another work develop an active cushion in which to analyse the pressure distribution the entire surface of the cushion has been divided in 8 regions, 4 on the right side and 4 on the left side. The division is implemented to evaluate in each regions the distribution and the pressure release especially in the ischial areas in order to assess the effectiveness of the cushion. Indeed, results show a decrease of interface pressure on the ischial tuberosities and an increase in the contact area in this cushion that work in the alternating mode respect to the static foam cushions [26].

All these active cushions described above, perform pressure release and redistribution though an alternating sequence of inflation and deflation of air cells cushion. Evaluate the interface pressure in different parts of the cushion is important to obtain precise information about the supporting areas in order to determine the suitable alternating sequence to prevent pressure ulcers [6].

The proper characteristics that an adequate alternating sequence has to provide are still under study and they are not sufficient to define the right sequence to prevent pressure ulcers [27]. the only information available is that the alternating sequence has to redistribute pressure over a large contact area especially on the ischial tuberosities in order to promote blood reperfusion and prevent pressure in wheelchair users [26][27]. This study [27] in particular, provides 3 different alternating sequences performed by a cushion system with 12 air cells and each cell presents a pressure sensor for inner pressure measurement. The more effective alternating strategies is the second one which aims to provide a mechanical simulation in order to promote blood flow by alternating pressure from the tight to buttocks and vice versa (Figure 10).[7]

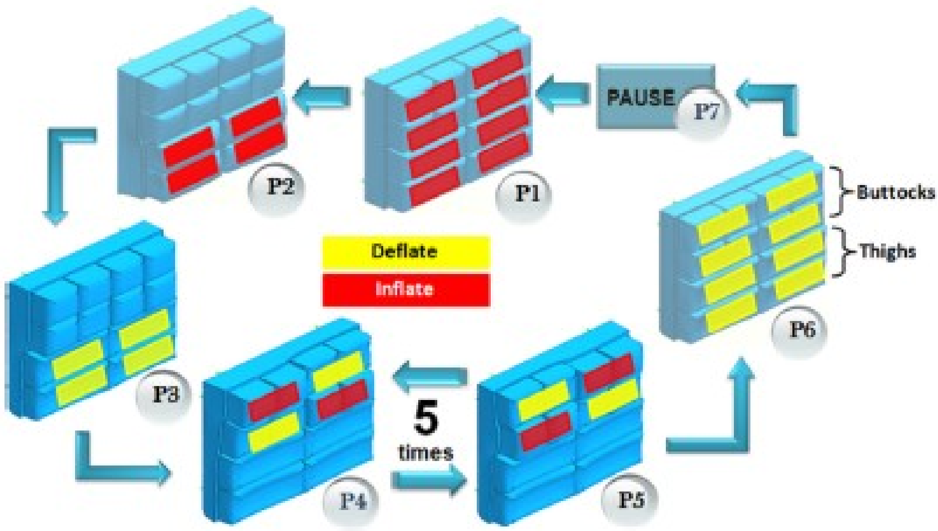

Figure 10 Alternating sequence that consists to inflation and deflation of air cells to promote blood flow reperfusion.[7]

The strategy provides movements on the sagittal and frontal plane like those performed by an healthy subject when he feels uncomfortable in his seated position over time[7].

The increase of new technologies has influenced the field of medical devices and it is useful to increase the effectiveness and the safety of them. Sazonov et al.[28] develops an air-filled cushion wheelchair with a pressure monitoring system to detect any changes of inner air pressure and body weight in order to aid the caregivers and the patients to detect pressure hazards through an audible and wireless alerts in real time.

This system is useful in order to control air loss or loss of sensory feeling to prevent pressure ulcers and bottoming out.[28]

2 Materials and Methods

Firstly, in the materials and methods section of this work the effectiveness of the DC Pressure seat cushion was analysed performing a series of tests to characterize the functioning of the system and processing all the data obtained from these acquisitions. After examined the functioning of the seat cushion, some considerations were done to optimize and explain the most significant outputs obtained.

The measurement of pressure distribution and the offloading effectiveness of the seat cushion has been performed measuring the interface pressure (IP) that is useful to estimate the capability of the cushion system surface to measure, release and distribute pressure [29].

2.1 Seat cushion system

In this work the DC Pressure active cushion was used. it is an active seat cushion intended for patients who are forced to stay for long periods of time in a wheelchair. The major users are those subjects affected by diabetes and the prolonged sitting position may provide on them pressure ulcers developments in the most susceptible body parts presented some pages before.

This seat cushion also presents an online user interface that allows nurses, physician and medical professionals to monitor the patient' s conditions and change some parameters based on patient's need. The DC Pressure cushion is an active seat cushion and its purpose is to prevent pressure ulcers formation using an alternating sequence of inflation and deflation of its air cells.

2.2 Cushion hardware component

From a hardware point of view, DC Pressure cushion system is composed by an array of 7 x 7 air cells for a total number of 49 cells (Figure 11). Each air cell presents a sensor that measures the inner air cell pressure.

Figure 11 left panel: Dc Pressure seat cushion composed of 7 x 7 array of air cells; right panel: single cushion air cell.

The total dimension of the cushion is 42 x 42 x 10 cm, dimension similar to the standard ones. Each air cell has a height of 5 cm with a diameter that increases slightly from bottom to top until 6 cm. The remaining 5 cm of height is the support in which the air cells are attached, and it contains the electric components, the tubing and valves system. The support is slightly tilted downward to provide a better comfort surface for the legs.

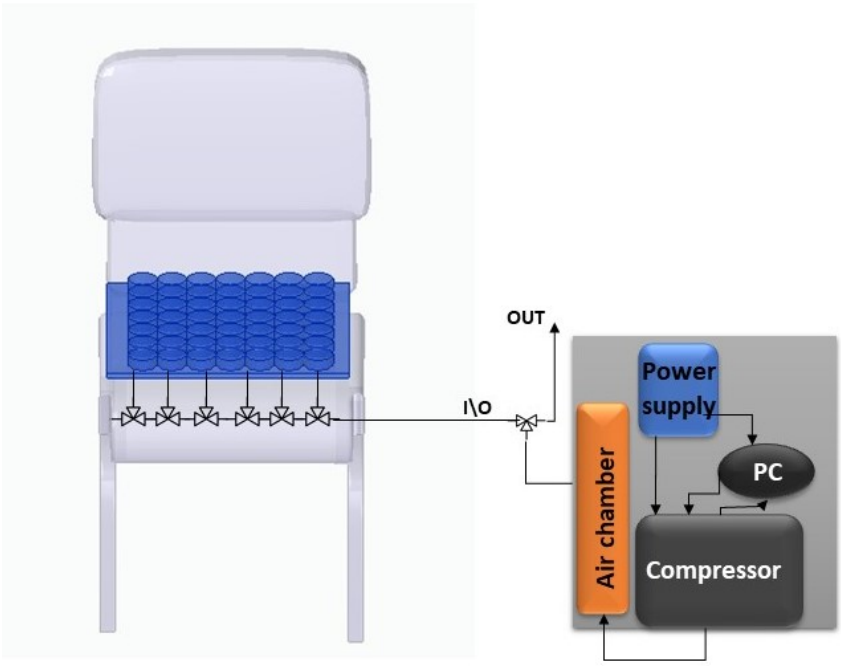

Figure 12 Dc Pressure cushion system block scheme with the hardware component and a standard chair.

The cushion is connected in parallel through three-ways valve to the air chamber that is in turn connected to a compressor providing the deflation and inflation of the cushion air cells.

A metal case with dimensions 39 x 47 x 16 cm contains the air chamber, compressor, battery and a PC (figure 12). The input and output to control the cushion are given by a monitor, mouse and keyboard connected to the PC. Each air cell is connected in parallel with a controlled three ways valve which is connected to the air chamber. The chamber is in turn connected in series with compressor in order to inflate and deflate the cushion cells. The pressure transducers provide information about the internal air cell pressure useful to perform the control and the regulation of the cushion's functioning. The PC that drives the compressor is connected to a monitor, keyboard and mouse to allow the user to control the inflation and deflation of the air cells. The PC inside the metal case drives opening and closing of the circuit that controls the compressor and the three way valves functioning, allowing the connection between the internal circuit and the air cells to control the pressure from the air reservoir to each air cell. The air cell valve opens in series with the air chamber valves allowing the proper control of internal pressure from the air cells to the air reservoir and vice versa, according to the parameters set in the software component. A standard chair has been used to support the cushion and to perform test on subjects. The support and the backrest are slightly tilted downward and backward respectively to provide better comfort. The support on which the cushion is positioned is a wood board fixed in the chair skeleton with the following dimensions: 46 x 42 x 6 cm.

2.3 Cushion software component

The software component of the DC Pressure cushion works in two ways: the offline and the online modality. The interface allows users to monitor the cushion state and regulate some parameter involved in the cushion operation.

The offline interface is that mostly used in this work in order to better regulate the parameters, changing them though the cushion file “config.ini” or directly from the offline user interface. For what concern the online interface, it requires a password and an ID to be used and it allows the remote control of the cushion system. The online modality provides a better user-friendly interface to guarantee the intelligibility of the system for the end users, in this case nurses and physician.

In the following lines the offline software interface is described, Figure 14 shows the main cushion offline interface.

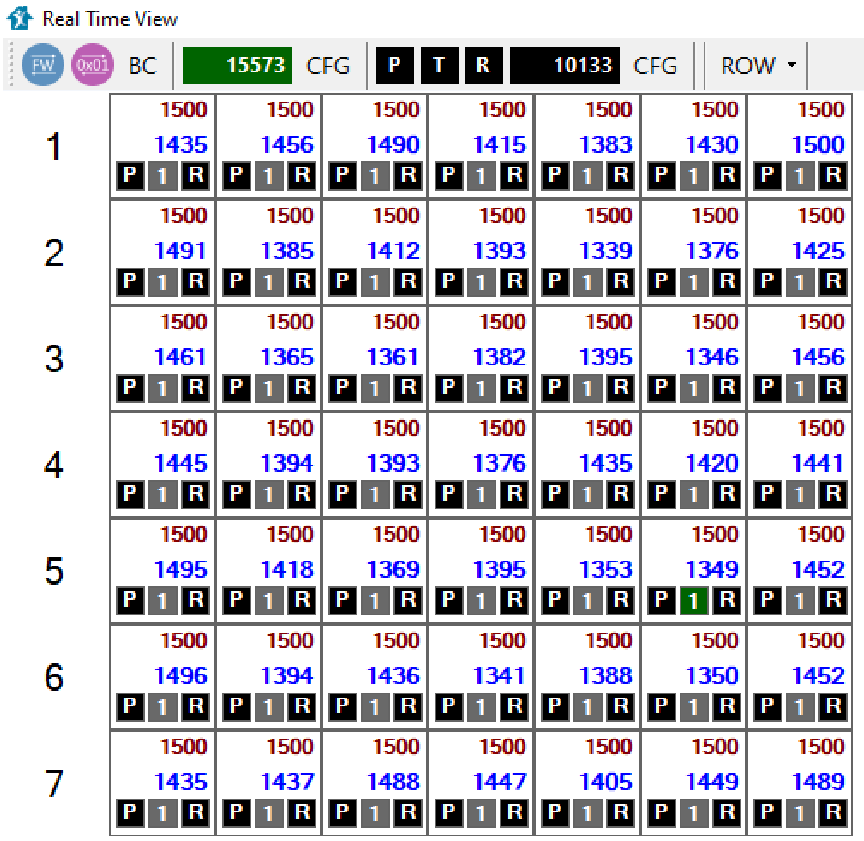

Figure 133 offline software interface.

This is the real time view of the cushion state which represents the pressure sensed in each air cell continuously in time.

As it can be seen in the figure 14, the interface is divided in seven rows and seven columns shaping a total number of 49 squares. Each square represents the cushion air cell. Inside the squares two numbers can be noticeable: the red one represents the setpoint pressure which is the pressure set by the developer or by the user, and the blue number which is the actual value of the air cell pressure recorded by the sensor.

The setpoint pressure is the initial pressure that each air cells have to reach during the initialization phase (the phase modalities are better explained some pages below) in order to provide a uniform inflation of the entire cushion area.

The pressure values in the interface are represented in Pa but the following results are reported in kPa and a conversion has been made in the data processing phase.

The upper row of the interface shows some important parameters and button needed to control the cushion. The green rectangle in the left part shows the pressure value in Pa of the air chamber connected to each air cell valve. The following black buttons P, T, and R are relevant to manually adjust the pressure because they reflect the valve status between the air chamber and the compressor. They represent the inflating, deflating and auto-regulating modality. The value in the black rectangle shows the atmospheric pressure. Since the valves are not differential the atmospheric pressure is needed by the system to perform some automatic adjustments.

The operation system updates the pressure values sensed by the transducers in real time with a defined scanning modality from the upper left square to the lower right square. To put the attention on a specific interface row in order to provide a quick pressure reading of the chosen one, the button ROW can be used to select the rows needed to be refreshed.

Another significant button to consider is P and R switches located on the lower part of square representing the air cell. If the user want to inflate or deflate a specific cushion air cell he/she has to press on P inside the square to open the air cell valve and at the same time, presses on the black P button or black T button in the upper menu to inflate or deflate the cell respectively. To block the air cell inflation or deflation the P swich inside the selected square has to be further pressed in order to close the valve between the air cell and the air chamber.

A single air cells pressure can be red frame by frame pressing on the cell itself on the interface and a new window like those in figure 15 appears.

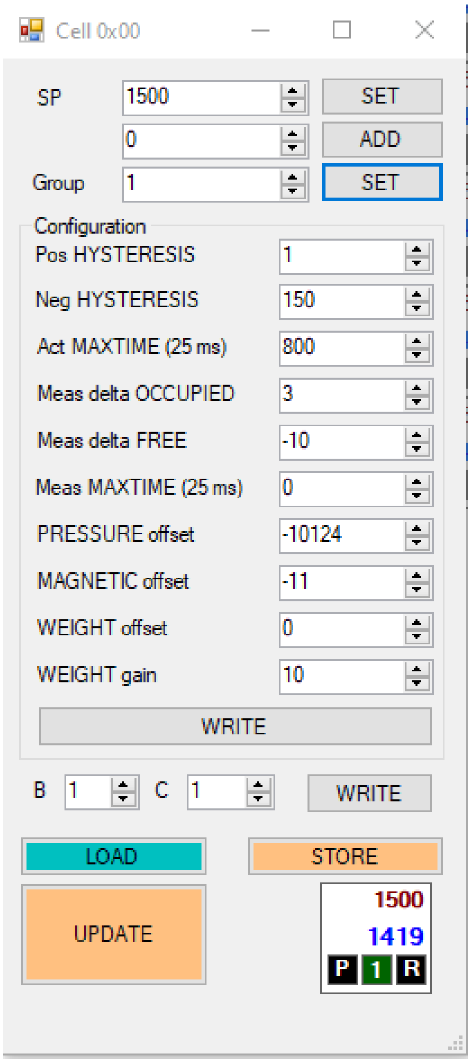

Figure 144 single cell control menu.

The SP value in the uppermost part of the single cell menu is the setpoint relative to the single cell which is the value of pressure in Pa that the cell has to reach during the initialization phase. In this menu other parameters are shown to be aware of and to change the state of the cell. These parameters have been remained with their default values for the tests.

2.3.1 DC Pressure cushion operation modality and description

In this section the operation modalities of the DC Pressure seat cushion are described.

Figure 16 shows the menu in which all the operation modalities performed by the cushion are listed. A right click on the mouse in the DC Pressure icon in the Windows bar allows to open the menu and select the desired command.

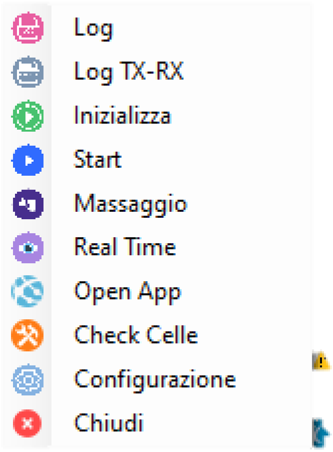

Figure 155 DC Pressure cushion command window with the operation modalities.

The command ‘Log’ is necessary to access into the cushion database interface using the ID and a Password.

The ‘initialization’ command prepares the cushion to work. It takes some minutes to bring all the inner air cells pressure at a value equal to 1,5 kPa which is the default setpoint value.

The ‘start’ command puts into operation the seat cushion performing at the first time some inflations and deflations to control if a mass is placed on its surface. The case in which a mass is identified by the cushion, the occupied air cells are connected in a close circuit acting on their valves. After some minutes the massage phase starts. The data recording is performed only in this phase after 30 seconds from the firing of the command. For this reason, the ‘start’ phase is placed under study during test to better characterize the cushion functioning.

The ‘massage’ command performs a series of inflations and deflations in a checkerboard pattern to provide pressure relief in higher pressure points of the subject’ skin.

The ‘real time’ allows to open the cushion interface described in figure 14. The ‘check cell’ is used to control if there are some malfunctioning air cells and finally the ‘configuration’ command enables the user to change the cushion operational parameters connecting to the local server.

A typical active cushion has to work in a specific way in order to be considered a potential device to prevent pressure ulcers. When a mass is applied on an active cushion, it has to identify region at high pressure values and act on them to reduce and redistribute pressure over a larger surface as it can be seen in the figure 17.

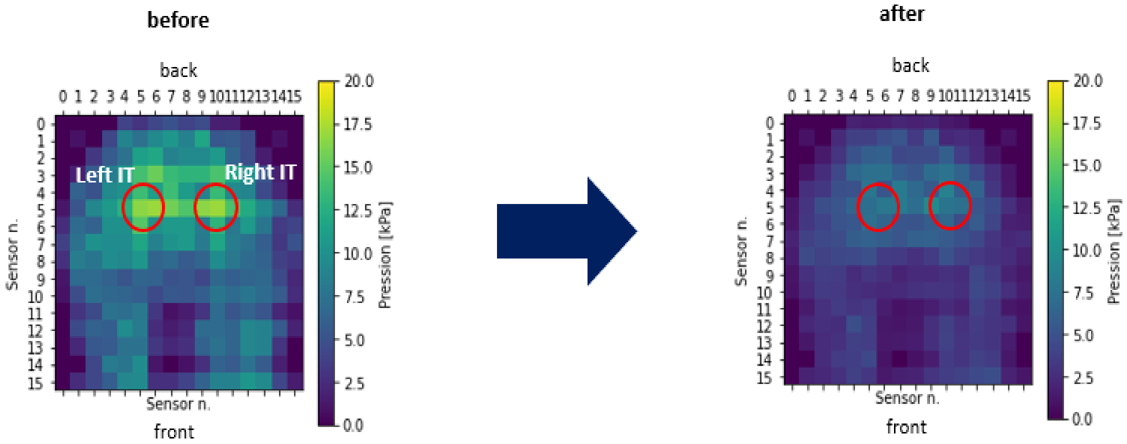

Figure 16 in left panel left and right ischial tuberosities (IT) are shown and circled in red, in these areas pressure reaches its highest value. In right panel the suitable operation modality of the cushion has been worked to reduce pressure on the right and left IT.

Currently, the cushion presented in this study works in a specific way performing a checkboard pattern of air cells deflation and inflation. This operation is better described below. The 'start' phase cited previously, requires a detailed explanation to better understand the cushion operation in order to provide an analysis of the cushion system. Firstly, the position routine stars with a series of inflation and deflation. When the cushion through sensors located in each air cell measures pressure higher than 1.6 kPa, deflation and inflation of the occupied cells occurs for some minutes. After some minutes, if a decrease of 50% of the total weight applied did not occur, the cushion recognizes that the mass is still applied on it and the massage phase begins to work.

The massage can be divided in two different phases: the system memorizes the current measured pressure in every odd air cell and this value is called setpoint MEM. Later, the drain valve located at the upstream circuit opens providing the deflation of the odd air cells until a pressure value of 0 kPa. Few seconds later the upstream circuit drain valve closes and the fill valve at the upstream circuit opens and the air cell pressure returns to setpoint MEM value. After some seconds the fill valve closes, and the drain valve opens.

The same procedure is repeated for the even air cells of the cushion. The massage phase starts when the ratio between the mean pressure of the occupied air cells and the values of sensibility alert of the air cell (generally equal to 4,2 kPa) is 70%. During the ‘start’ and ‘massage’ phase the air cells represented in the offline interface change their colour based on the level of pressure, for example the display value of the pressure end of scale which is about 4,26 kPa is visible in a red nuance.

The data acquired from the cushion are stored in a ‘*.dat’ file. Each recording is labelled with its time of acquisition and further modification and processing are needed to read the files in a user-friendly way. The cushion recording does not take place continuously in time but in a random manner according to the cushion operation.

The cushion is able to record data about the inner air cells pressure only when the ‘start’ button was pressed, for all the others commands the cushion is not able to record any data.

2.4 Pressure sensors matrix

In this study the Novel system which is a flexible pressure sensors matrix was used. It is composed of an hardware component that includes sensors matrix and the other devices that allows it to be connected to a PC to transfer data, and a software component to record and visualize in real time the acquisitions performed.

The Novel matrix is connected to the user PC via fibre optic cable and the acquisition box is powered by a battery.

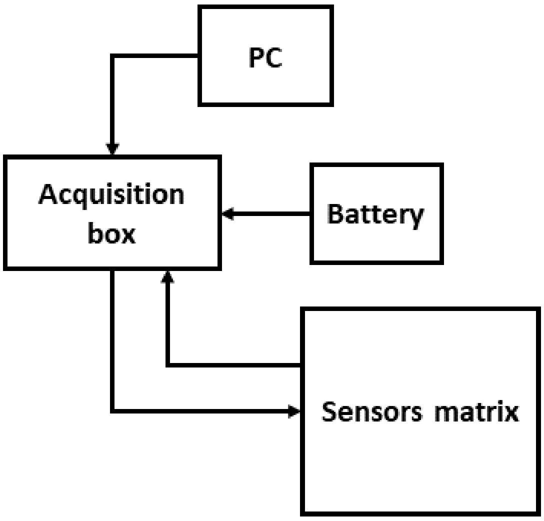

Figure 17 Novel system block scheme. The matrix is connected to a box, powered by a battery. The box is connected via fibre optic cable to the PC.

The Novel matrix is composed of an array of 16x16 pressure sensors with an area of 6,0 cm^2 for a total matrix area of 40x40 cm^2. The matrix has been used in every test performed to characterize and optimize the presented cushion. Through the use of matrix system placed on the DC Pressure cushion surface, values about the interface pressure, expressed in kPa, between the cushion and the mass applied has been acquired.

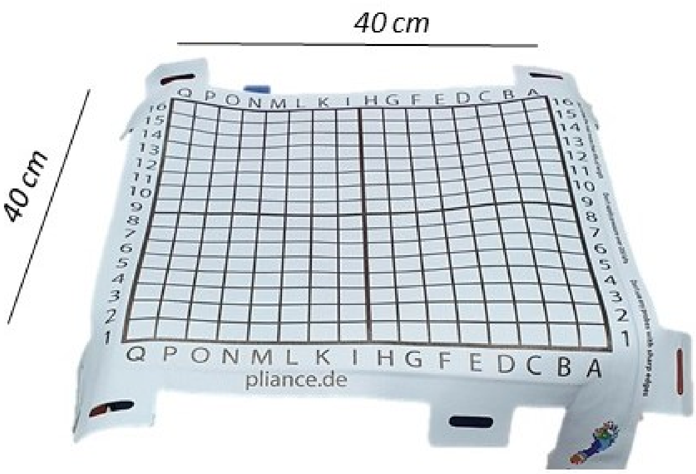

Figure 18 Novel pressure sensors matrix.

The piezoelectric pressure sensors provide a minimum measurable value of 1 kPa, a resolution of 1,25 kPa and full-scale value of 63,75 kPa. During each test the acquisition frequency has been set to 1 Hz.

Figure 19 shows the Novel system user interface. Before data acquisition the connection between all the system components and the calibration of the Novel matrix have been performed. As it can be seen in figure 19 the user interface is mainly divided in 2 parts. In the left panel the real time visualization of the pressure values recorded by each sensors is shown, whereas the right panel is further divided in three parts showing the peak pressure trend expressed in kPa, the total force trend expressed in Newton [N] and the area formed by the sensors activated during test expressed in cm^2.

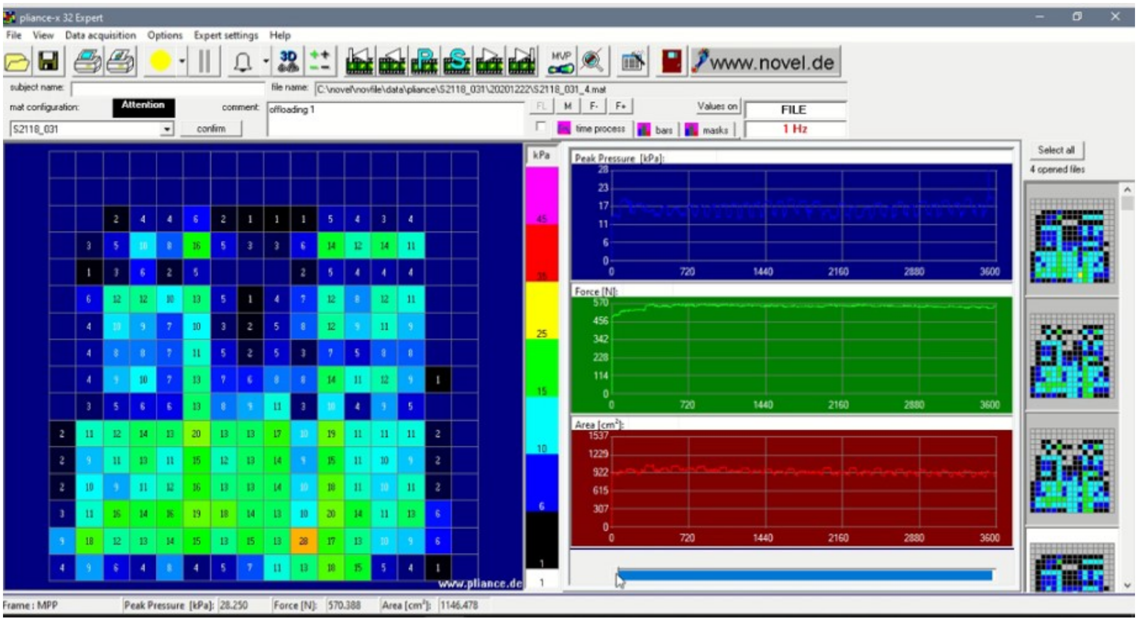

Figure 19 Novel system user interface. In the leftmost panel the real time pressure values recorded by matrix are shown, whereas in the rightmost part, trend of peak pressure, force and area over time are displayed.

After an acquisition has been performed, the software saves data in '.dat' file and also allow the user to save data in '.asc' and '.fgt' files. The second type of files contain information about pressure on each sensor over the acquisition duration, force integral calculated as the area under the force curve, and the maximum pressure time integral expressed as the area under the maximum pressure curve. The '.fgt' file contains information about the total force applied on the matrix over the duration of the acquisition and the coordinates of the centre of pressure displacement expressed in millimetres.

2.5 Acquisition protocol and data analysis

Each Novel matrix sensor is labelled by a number and a letter. The rows are signed by numbers from 1 to 16, the column labelled by letters from A to Q. This description is important to count and identify sensors. The matrix sensors are scanned from sensor Q16 to sensor A1, in which sensor Q16 was always positioned in the back left corner of the cushion and the A1 sensor in the front right corner of the matrix placed on the cushion.

The scanning modality of the cushion pressure sensors is different, it scans from the cell in the frontal right corner to the one located in the back left corner of the cushion. The scanning modalities have to be considered during the calibration procedure especially for data comparison.

As it seen previously, the cushion records data only during the 'start' modality. Data are stored in files containing the date in which the acquisition occurs, followed by other information measured by the cushion such as the inner air cell pressure measure by sensors in each cushion air cell. A subsequent processing of these data through Python scripts has been done, in order to extract information about the acquisition time and the internal air cell pressure expressed in Pa. Before extracting these information, data from the cushion are reported on a matrix composed by 49 columns for each cushion sensor and a variable number of rows (time) depending on the irregular sampling frequency used by the cushion. In each element of this cushion matrix, pressure values expressed in Pa were reported and subsequently converted in kPa.

For what concern the data obtained by Novel matrix, they are reported in Python with a matrix of 256 column for each pressure sensor and a certain number of rows for each data recorded in every second of the total duration of the acquisition, due to the 1 Hz sampling frequency chosen. In each element of this matrix pressure values expressed in kPa were reported.

In some test reported below, in which both Novel pressure data and Cushion pressure data are required, a time correlation between them, was done in order to obtain in the same period of time Novel pressure data and Cushion pressure data. For this correlation was considering that the cushion begins to record data 30 seconds after the 'start' command was given.

For each test, data processing begins from the above considerations and a successive processing is required to extract data features that have to be analysed.

In general, this information obtained from the data processing were the initial and final interface pressure and the percentage decrease of pressure between them.

Four different types of tests have been performed to analyse if the cushion achieves its purpose for which it was designed (pressure ulcers prevention, decreasing high pressure peak and redistribute pressure over the cushion area) and to develop a strategy to correct and optimize the cushion gaps.

2.5.1 Single cushion air cell characterization

Using the offline user interface of the cushion it is possible to control singularly the cushion air cells to inflate or deflate them according to the user purpose.

This test was conducted to characterize the performance of a single cell in order to study the behaviour of the cushion air cell when a mass is placed on it. A subsequent deflation of the activated cell was practiced to analyse the efficacy of the selected and the surrounding air cells to decrease and redistribute pressure applied by the mass.

At the beginning of the test, the cushion air cells were pre-inflated to their setpoint 1.5 kPa. The Novel matrix was placed on the cushion to acquire interface pressure data between cushion and the mass. A graphical description of the test is reported in figure 20.

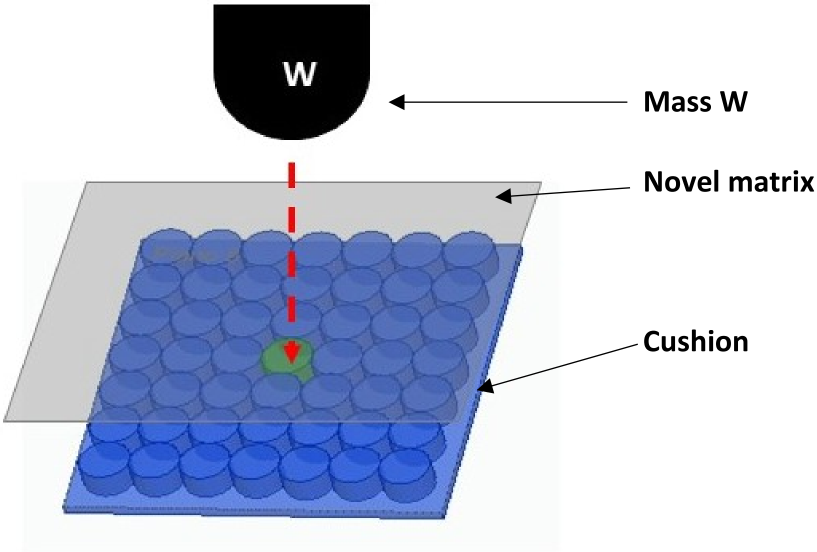

Figure 20 block scheme of the procedure. W is the mass applied on the selected cell (the green one).

A mass of 1.6 kg like a bowl with a dimeter of 23,5 cm and a height of 10 cm was placed on the central cell of the cushion. Subsequently, this selected cell was deflated below the mass. This study was conducted 10 times to test the repeatability of the air cell operation.

Since the cushion was not in the 'start' phase during this test, because only one cell was controlled through the interface, it was not possible to obtain data about the inner air cell pressure. Data about the interface pressure was collected through the Novel matrix in which an array of 6x6 sensors was considered to study the behaviour of the selected and the surrounding air cushion cells under this matrix portion. Data about the interface pressure were processed with Python to obtain information about the initial and final interface pressure (IP) of the selected cell and the other 8 surrounded air cells. The offloading delta of the selected cell expressed in percentage was further calculated, considering the maximum pressure recorded in the first 20 seconds and in the last 20 seconds.

To well understand, a representation of the Novel matrix and the activated sensors by the mass applied on them, is reported in figure 21. The colormap shows the mean pressure during the entire test highlighting a number of 13 activated sensors with a pressure value greater than zero. The four central sensors are those that covered the deflated cell.

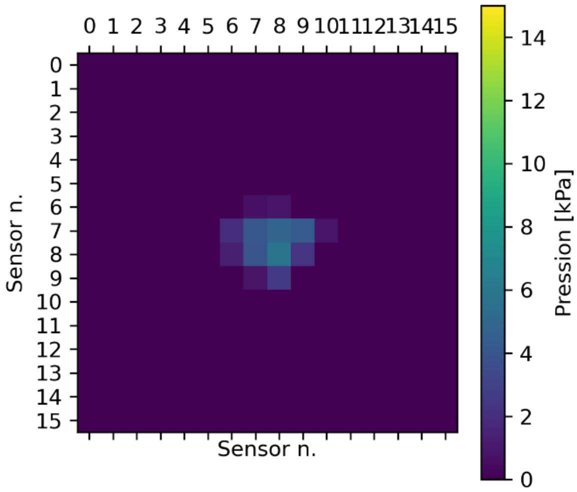

Figure 21 representation of the Novel sensor matrix with a colormap of the mean pressure recorded during test.

In this test the pressure trend over time for each Novel sensor was observed to understand the cushion behaviour after one cell was deflated.

2.5.2 Experimental design: test on subjects

In this section the cushion system operation during tests performed by a certain number of subjects was examined.

Ten healthy volunteers were recruited to test the efficacy of the cushion. The study was conducted in healthy subjects because of their sensibility to state, clearly and in a detailed way, any types of discomfort and problem with the use of the cushion [27].

In table 1 the participants' characteristics are shown, such as their age, weight and height. The different weights among all subjects provide more information regarding the cushion functioning based on different applied masses.

VOLUNTEERS	AGE	WEIGHT [KG]	HEIGHT [M]
Subject 1	25	50	1.67
Subject 2	32	85	1,80
Subject 3	28	67	1,80
Subject 4	24	90	1,90
Subject 5	20	55	1,70
Subject 6	24	70	1,90
Subject 7	24	55	1,75
Subject 8	25	60	1,70
Subject 9	28	65	1,70
Subject 10	24	75	1,85

Table 1 Subjects' characteristics.

Each subject’s test was conducted at Università Politecnica delle Marche and they wore tracksuit pants or pants without pockets and studs, to avoid the noise on the pressure interface records. To prepare the experimental environment the chair was positioned at centre room, the cushion positioned over the chair and each air cells were pre-inflated with a pressure value of 1.5 kPa. The Novel matrix was positioned on the cushion in order to acquire pressure interface data.

After this measurement environment was arranged, the volunteer sat on the cushion, positioning their feet on a footrest to ensure 90° at knee joint and 90° at hip joints (figure 22 and 23)

Figure 22 Novel matrix positioned on the DC Pressure seat cushion.

Figure 23 experimental procedure, subject sat on Novel matrix placed on the cushion with a footrest.

Maintaining this position, the first 60 seconds were recorded as baseline uniquely by Novel matrix, since the cushion was in off modality (the cushion records data only when it is in the 'start' modality). After that, the test lasted a period of 30 minutes in which, once the 60 seconds were passed, the 'start' command was activated and the data were recorded.

Data processing was done to obtain specific features from the test which was divided in 7 intervals of time with a length of 250 seconds. For each interval, mean and maximum interface pressure over time was calculated from Novel pressure data. In the seven intervals, values about the total contact area in cm^2 between the cushion and the subject was reported.

In each time interval the number of sensors activated by specific pressure range values were calculated. It is important to see the overall trend of the activated sensors: from those at low pressure values to those at higher pressure values.

Finally, pressure delta decrease expressed in percentage was calculated with the equation 2, in order to test the cushion 'start' modality efficacy to decrease pressure.

$$100 \text{ x } \frac{(max\ pressure\ of\ the\ final\ 250\ s - max\ pressure\ of\ the\ initial\ 250\ s}{\max pressure\ of\ the\ initial\ 250\ s} \qquad (2)$$

Equation 2 pressure delta decrease of each subjects' test expressed in percentage.

2.5.3 Manual offloading tests

The manual offloading test was conducted in 8 of the 10 subjects recruited in the previous test. The subject sat on the Novel matrix positioned on the cushion in the same way reported in the previous test.

VOLUNTEERS	AGE	WEIGHT [KG]	HEIGHT [M]
Subject 1	25	50	1.67
Subject 2	32	85	1,80
Subject 3	28	67	1,80
Subject 4	24	90	1,90
Subject 5	20	55	1,70
Subject 6	24	70	1,90
Subject 7	24	55	1,75

Subject 8	25	60	1,70
Subject 9	28	65	1,70
Subject 10	24	75	1,85

Table 2 Subjects' characteristics for manual offloading test.

In this case the cushion was positioned on the chair with the air cells pre-inflated at 1,5 kPa. The Novel matrix was placed between the cushion and the subject who was positioned in the same way described previously with the test on subjects.

After subject's positioning, two cushion air cells with the highest pressure values red by the cushion user interface, were deflated to reached a pressure value equal to zero.

These two air cells occupied a position under the subject's ischial tuberosities and using the offline user interface of the cushion, the unique deflation of these 2 cells were possible.

The test lasted a total of two minutes in which the first minute was considered as the baseline to stabilize subject's pressure, whereas in the second minute the cells offloading occurred.

During this test the cushion 'start' modality was not activated and the Novel interface pressure data were the unique data obtained in this acquisition.

From Novel files, the matrix described in the 'Data processing' section, with 120 rows and 256 columns was obtain. In this matrix, from 8 to 12 columns (depending on the subject' test characteristics) were extracted. These columns represent the Novel sensors located on the deflated cells and under the left and right IT of the patient. The columns report the interface pressure values over time recorded by the sensors.

For these selected columns, information about the mean and maximum initial and final interface pressure were calculated in the 20 seconds before the cells deflation and in the last 20 seconds after deflation of the total acquisition. The pressure decrease in percentage was also calculated considering the first 20 s and the last 20 s.

Information about mean and maximum interface pressure and pressure decrease in percentage were obtained dividing the Novel matrix in the buttock area (without considering the 8 or 12 sensors selected) and the legs area. This division was done to study the effects in the surrounded air cushion cells.

2.5.4 Intra subject test

The intrasubject test was performed 10 times on the same subject, specifically on the subject 1. In this test the cushion was placed over the standard chair and pre-inflated to 1,5 kPa. The Novel matrix was placed on the cushion surface and the subject was sat on the Novel/cushion system for about 30 minutes. Within these 30 minutes, the first minute was recorded as a baseline with the cushion turned off, after the first minute the cushion 'start' command was pressed. From this test, the repeatability of the cushion operation modality has to be tested over more tests performed on the same subject.

2.5.5 Calibration curve

The calibration curve was performed with data acquired from all the 10 volunteers recruited for the test on subjects. The first procedure was the time correlation between the Novel matrix pressure data and the cushion pressure data. The correlation was performed as previously discussed in the 'Data processing' section and, as a result, two matrices with the same number of rows were obtained for each subject.

Starting from this time correlation two file arrays were created, one containing the first frame of the cushion pressure data, and the other the first frame of the Novel pressure data. This process was repeated for all subjects, obtaining a total number of 20 file arrays.

All these file arrays were located in two different databases: one for the first frame of the cushion pressure data for all the subjects recruited, and the other one containing the first frame of the Novel pressure data for all the subjects.

Before starting the calibration procedure these databases were used to obtain two matrices: one for the Novel pressure data and the other one for the Cushion pressure data. Since the number of columns between these 2 matrices were different, only one

Novel sensor located on each single cushion air cell was taken. In this way a matrix of Novel pressure data with the same dimension of that one for the cushion pressure data was obtained. Starting from these processing a calibration curve was obtained through all these data acquired from the 10 subjects. A model prediction was obtained, and the root mean squared error (RMSE) before and after correction were calculated.

A test dataset was created from the first frame of one of the intra subject acquisition pressure data, then this dataset was used to test the model obtained from the calibration performed above.

3 Results

The results of each tests performed are shown in the sections below.

3.1 Single cushion air cell characterization

The results of this test are shown in the figures below.

In figure 24, a schematic representation reports in the left panel, the cushion and the air cells involved in the test. The central cell circled in red is that one deflated to 0 kPa under the mass applied. Nine air cushion cells are taken into consideration in order to study their behaviour when the loaded central air cell gets deflated. Each air cushion cells row is represented by a different colour: third row is green, the fourth row is yellow and the fifth row is orange. The cushion air cells colour coding is used to represent the air cells pressure values in the two graphs.

The first graph reports information about the interface pressure values in each of the 9 cells before deflating the central cell. The second graph reports the interface pressure values in each cell after cell deflation. These 2 graphs report the mean pressure values in each air cells calculated for all the 10 tests. It means that these pressure values are the mean calculate for the 10 tests.

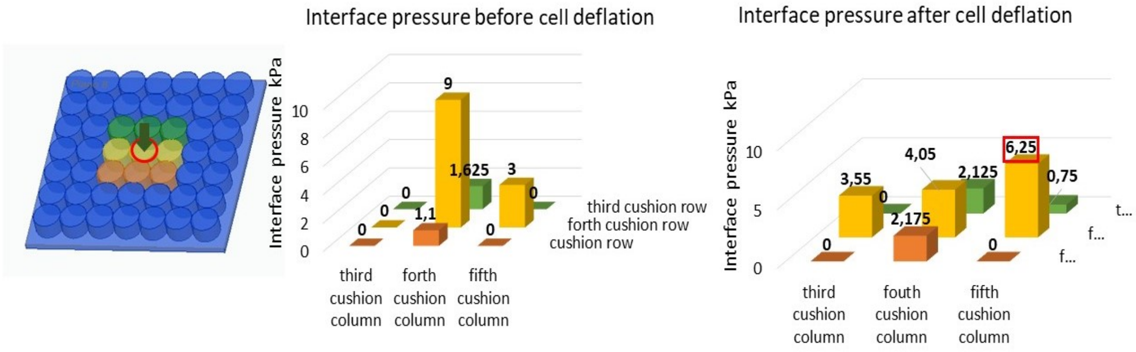

Figure 24 left panel shows the schematic view of the cushion with the studied air cells coloured in different way. The central deflated cell is circled in red. The 2 graphs above report interface pressure values in each cell recorded before and after cell deflation.

As it can see, the interface pressure, after deflation was performed, decreases in the central cell, increasing in the surrounding air cells. A pressure distribution over a larger area occurs.

Some detailed information about the 10 tests are reported in table 3, where the standard deviation (SD) were calculated for each pressure value calculated in the 10 procedures.

Inner cell P [kPa] ± SD	**P of loaded cell [kPa] ± SD**	**P of deflated cell [kPa] ± SD**	**Offloading delta % ± SD**	**Initial IP [kPa] ± SD**	**Final IP [kPa] ± SD**	**Mean initial P, surrounding cells [kPa] ± SD**	**Mean final P, surrounding cells [kPa] ± SD**
1,2 ± 0,1	5,4 ± 0,1	-0,1 ± 0,1	55,8± 3,3	9,0±0,3	4,1 ± 0,1	0,7 ± 1,1	1,9 ± 2,2

Table 3 mean parameters in 10 tests of the selected air cell. SD for standard deviation, P for pressure and IP for interface pressure in kPa.

Table 3 shows the initial three pressure values obtained from the cushion: inner central cell pressure value in kPa, the pressure of the central cell when it was loaded in kPa and value recorded by the cushion when the cell was completely deflated.

The offloading delta percentage calculated as a mean of the 10 tests is reported to be slightly higher that 55%. In the last 4 columns the initial and final interface pressure of the deflated cell are calculated as means of the 10 tests, whereas data about interface pressure of all the surrounding cells are reported before and after the cell deflation.

As it can be seen from the table, the interface pressure of the central deflated cell decreases after deflation, whereas interface pressure of some of the other surrounding 8 air cells tend to increase.

Figure 25 shows the maximum and mean interface pressure trends recorded in one of the 10 tests calculated for the entire selected area of 6 by 6 array of Novel sensors. It can be noted that the maximum and mean pressure tends to abruptly decrease after cell deflation.

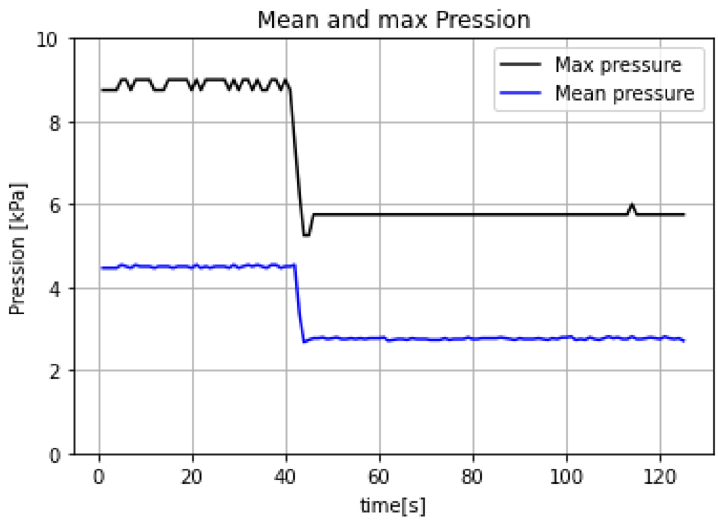

Figure 25 maximum interface pressure in black and mean interface pressure in blue calculated in a single test.

The maximum and mean pressure trends decrease whereas the area tends to increase, distributing pressure in a larger surface area, as seen in figure 26.

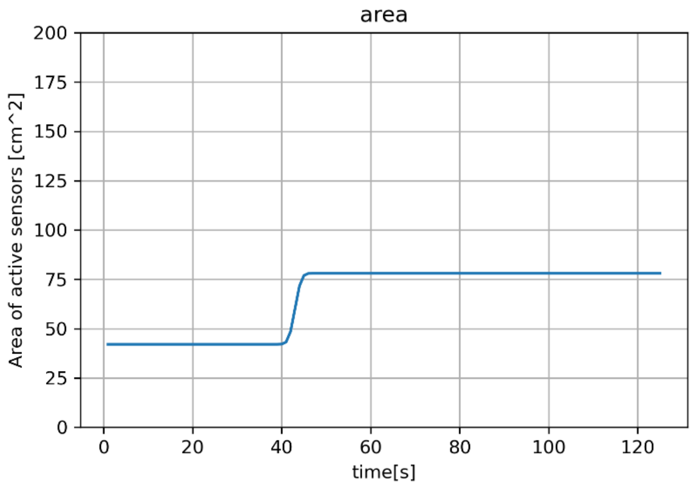

Figure 26 trend of the contact area between the mass and Novel matrix positioned on the cushion.

3.2 Test on subjects

The tests performed on the subjects are used to assess the efficiency of the current seat cushion, to study its behaviour on the subject when its operation modality (checkboard modality of operation) is implemented, after the command 'start' was pressed.

Some figures below show information about one of the subjects recruited in order to exampling and provide a visualization of what happen during current cushion modality of operation.

Figure 27 shows the trends of the maximum and mean interface pressure calculated over time. Note that the interface pressure are data obtained from Novel pressure matrix placed on the cushion. It can be noted that the maximum and mean interface pressure tends to decrease over time, showing irregular trends due to the alternating inflation and deflation of each air cushion cells under the Novel matrix.

Mean interface pressure presents a low and slightly decrease because of few greater peak pressures concentrated in a smaller contact area.

Figure 28 reports two colourmap in which the buttock print is well visible. The left panel shows the maximum interface pressure calculated in the first 250 seconds, in the right panel the maximum interface pressure calculated in the last 250 seconds is reported.

The yellow areas that can be appreciated in the first panel of figure 28 represent the peak pressure over the cushion exerted by the left and right ischial tuberosities. In the right panel, after about 30 minutes of cushion operation, the peak pressure in these two sites above descript decreases.

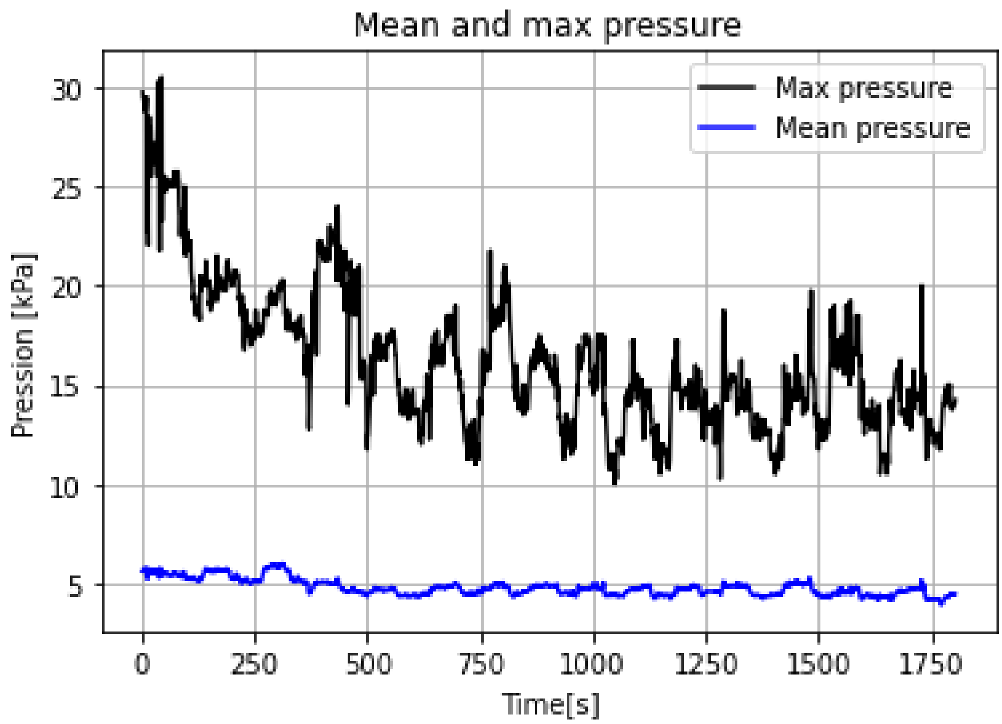

Figure 27 mean and maximum interface pressure trends of the subject 10 calculated for 30 minute by Novel matrix.

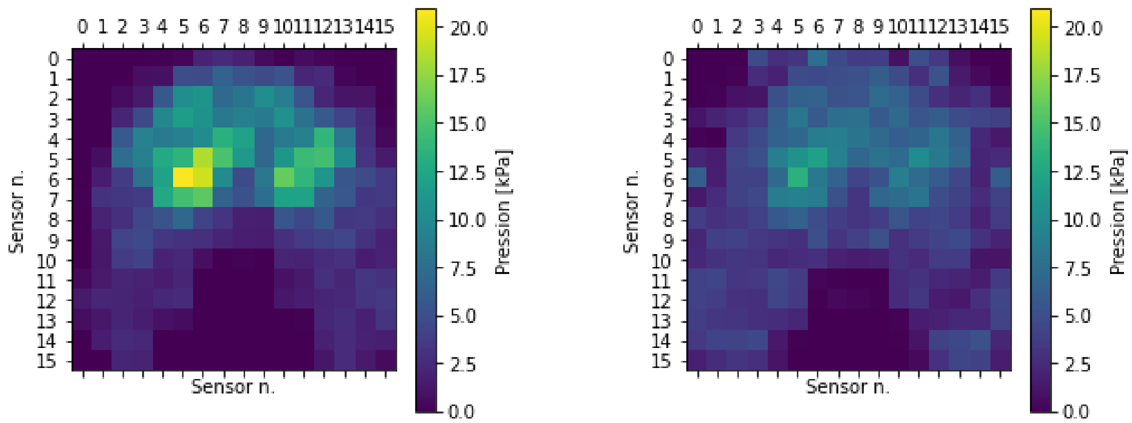

Figure 28 left panel shows the colourmap of the subject 10 seated on the cushion calculated at the beginning of acquisition, in the right panel the colourmap of the subject seated calculated at the end of the test.

Figure 29 shows the trend of the total contact area between subject and Novel matrix lying on the cushion during the total test duration. The total contact surface area increases over time.

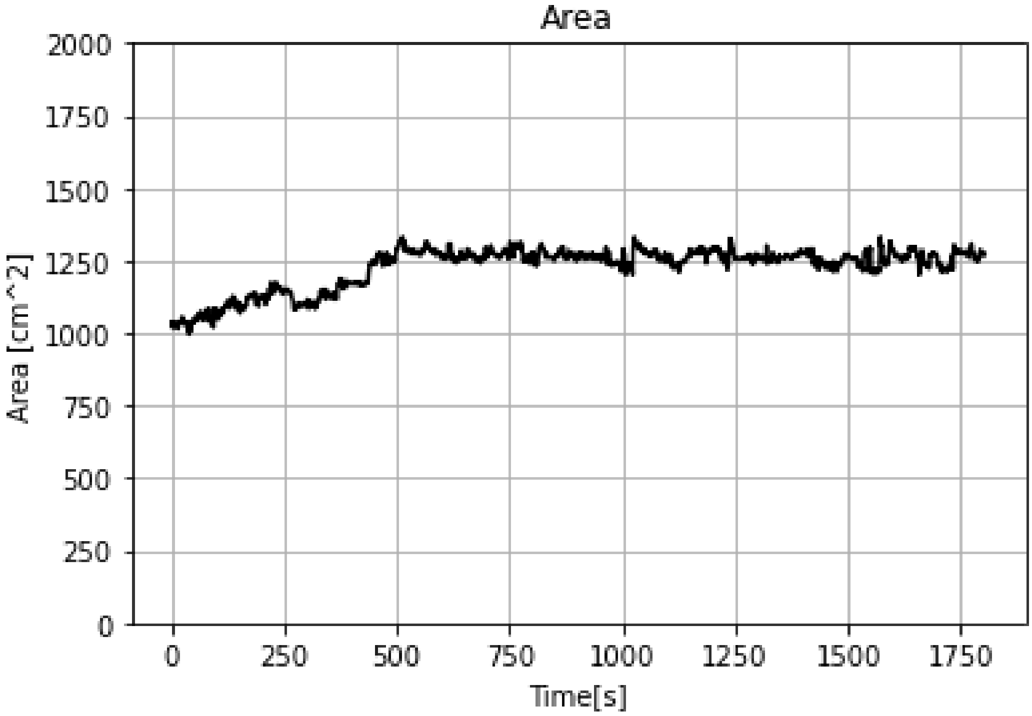

Figure 29 total contact area trend between the subject and Novel matrix lying on the cushion.

The interface pressure distribution over time is reported in figure below (figure 30). In this figure the number of sensors that are activated and that record specific range of pressure are depicted in 5 different colours. The red range shows the sensors that recorded highest values of interface pressure, from 12 kPa to 30 kPa. It can be noted that the number of sensors belonging to this range tend to decrease over time whereas the number of sensors which recorded interface pressure values from 1 to 4 kPa increase over time. Also, the number of sensors that belong to the yellow range, from 4 to 8 tend to increase.

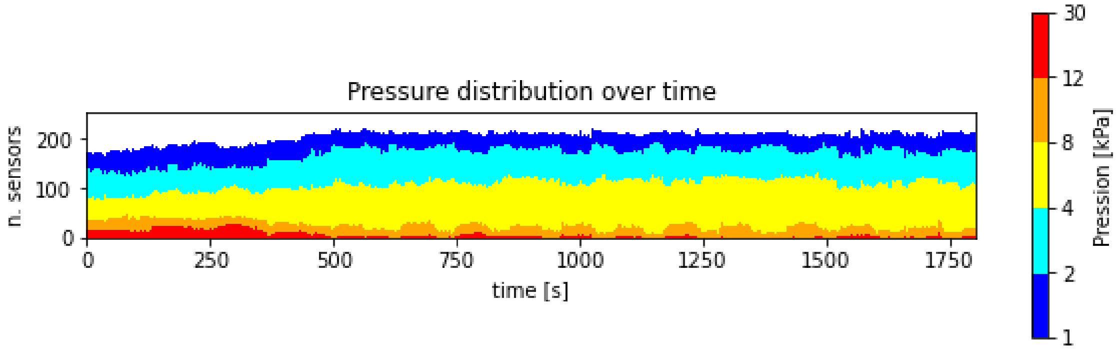

Figure 30 interface pressure distribution over time according to specific pressure ranges.

Table 4 reports maximum, mean interface pressure and total contact area referred to the same subject recruited for obtain the other plots above, calculated in the 7 intervals. In this case the entire acquisition was divided in seven intervals of 250 seconds and the results are reported below.

	Interval 1	**Interval 2**	**Interval 3**	**Interval 4**	**Interval 5**	**Interval 6**	**Interval 7**	**Delta %**
Max interface Pressure [kPa]	30,5	24,0	19,0	21,7	17,5	19,7	19,2	-37
Mean interface Pressure [kPa]	5,4	5,0	4,6	4,7	4,6	4,7	4,4	-18,5
Contact area cm^2	1087,6	1166,6	1276,6	1266,4	1268,1	1256,8	1257,2	+15,6

Table 4 maximum and mean interface pressure and contact area of the subject 10 calculated in each interval.

As it said previously the mean and maximum interface pressure decrease and the total contact area between subject and cushion increases.

The pressure decrease in percentage of 37% is seen for the maximum interface pressure respect to the initial maximum interface pressure, whereas for the mean interface pressure, the pressure decrease in percentage is 18,5% respect to the initial mean interface pressure. The increase of contact area is assessed to be 15,6 % respect the initial contact area.

Figure 31 reports the delta pressure decrease in percentage calculated for each subject, considering the mean interface pressure recorded at the beginning and at the end of the acquisition. The mean delta pressure decrease for all subjects calculated respect to the first 250 seconds is equal to 14,4 % with a standard deviation of ± 4,1 kPa.

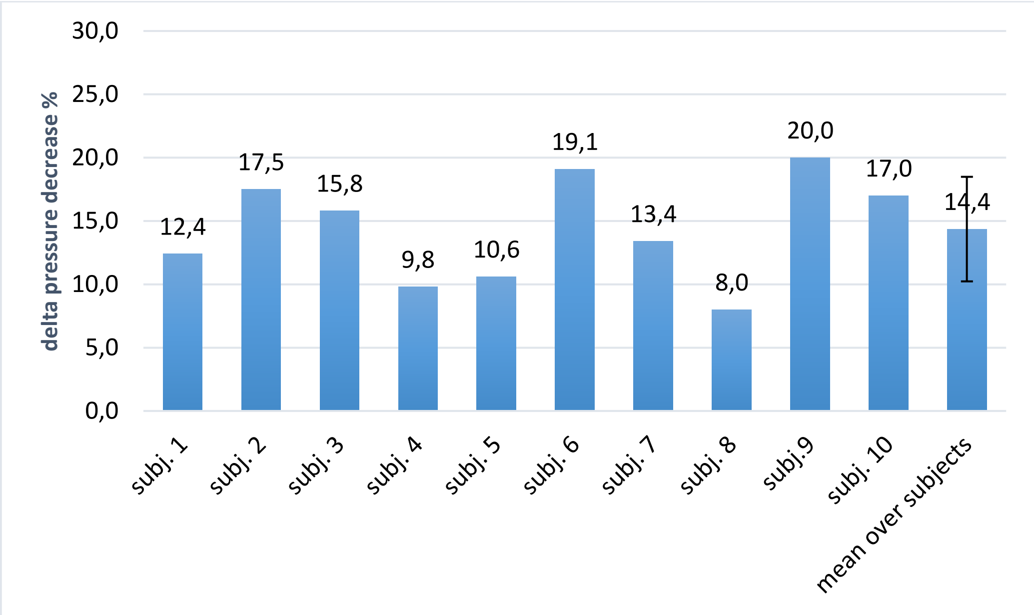

Figure 31 delta interface pressure decrease respect to the mean initial interface pressure calculated in the first 250 s, for all the subjects.

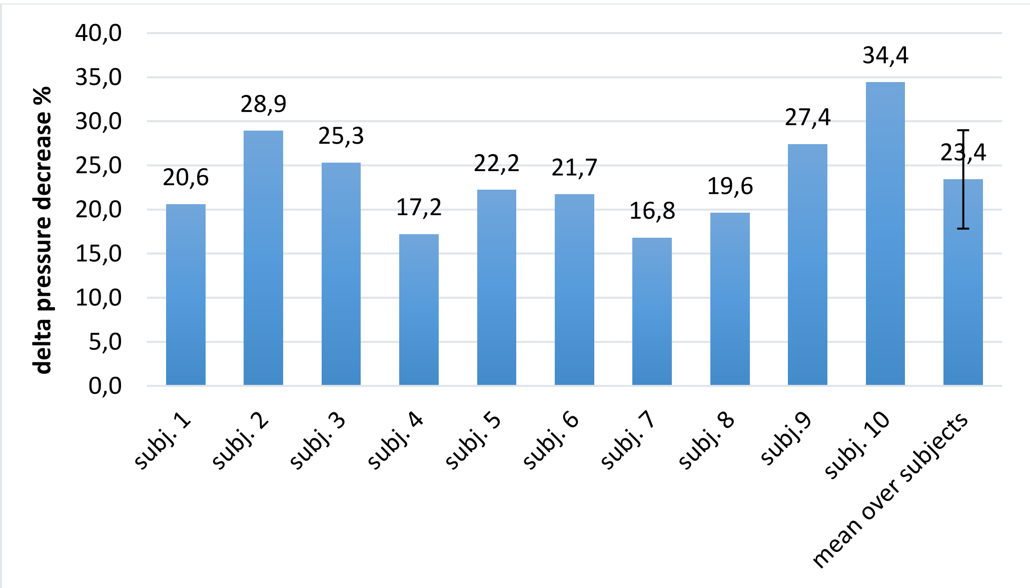

Figure 32 delta interface pressure decrease respect to the maximum initial interface pressure calculated in the first 250 s, for all the subjects.

Considering the mean over subjects, the intrasubject maximum pressure decrease in percentage is 23,4% with a standard deviation of ±5,6 kPa.

3.3 Manual offloading tests

As expected, the results from this test shows an interface pressure reduction in the left and right ischial tuberosities and a slight interface pressure increase around the deflated cells. Figure 33 shows in the left panel, the colourmap of the mean interface pressure calculated in 20 s before the deflation, whereas in the right panel the mean interface pressure calculated in 20 s after deflation is reported. These two colourmap are calculated from the same subject (number 9).

It can be noted that in the right panel the areas at high interface pressure disappear respect to the colourmap in the left panel.

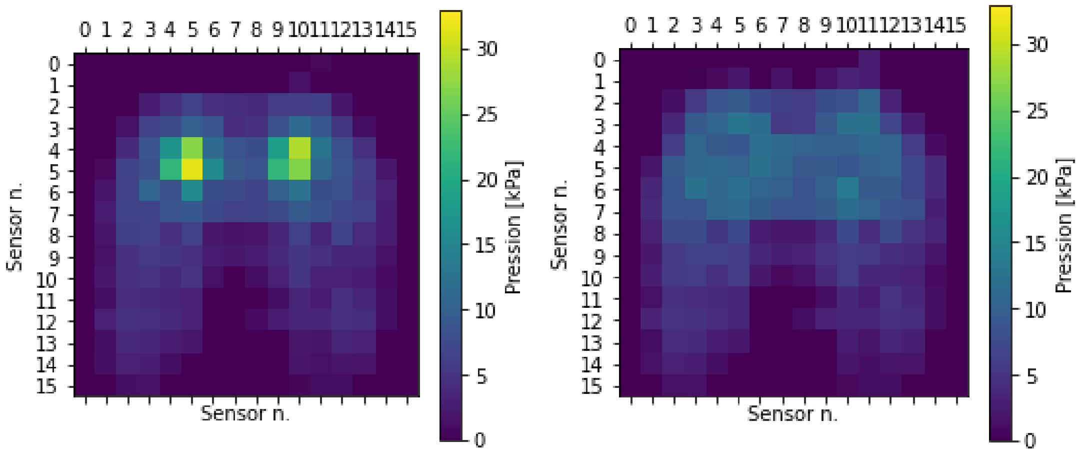

Figure 33 Colourmaps of subject number 9

Other information to understand the behaviour of the cushion when two air cells at high pressure peak were deflated are shown in figure 34. This figure reports two counter graphs acquired by subject number 9, calculated for the first 20 s before air cells deflation and the last 20 s after cells deflation.

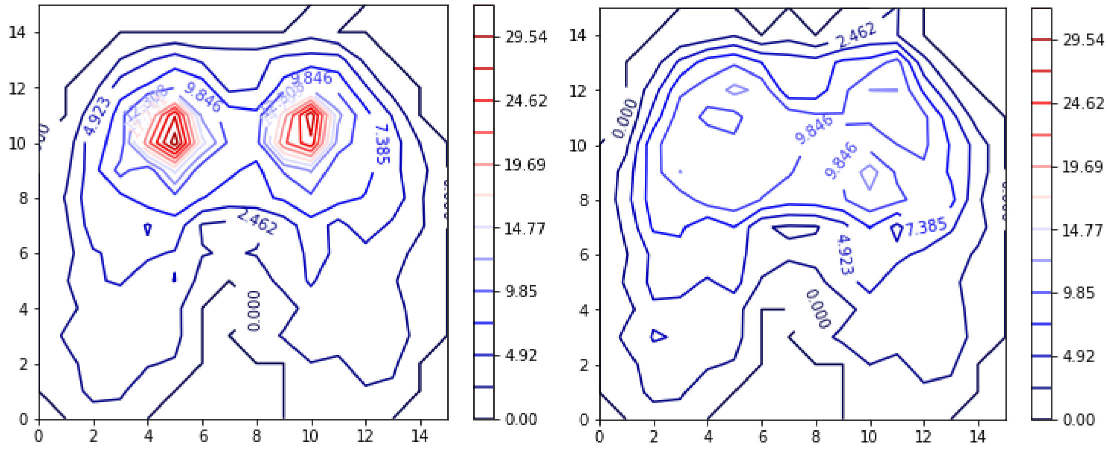

Figure 34 contour graphs of subject 9. left panel 20 s before air cells deflation, right panel 20 s after cells deflation.

The red areas in the left panel of this figure above became blue after deflation, it means that the interface pressure on left and right ischial tuberosities decreases, distributing pressure around these critical areas.

The last two figures below () show respectively, the difference between interface pressure calculated in the first 20 s and in the last 20 s and the same pressure difference but expressed in percentage.

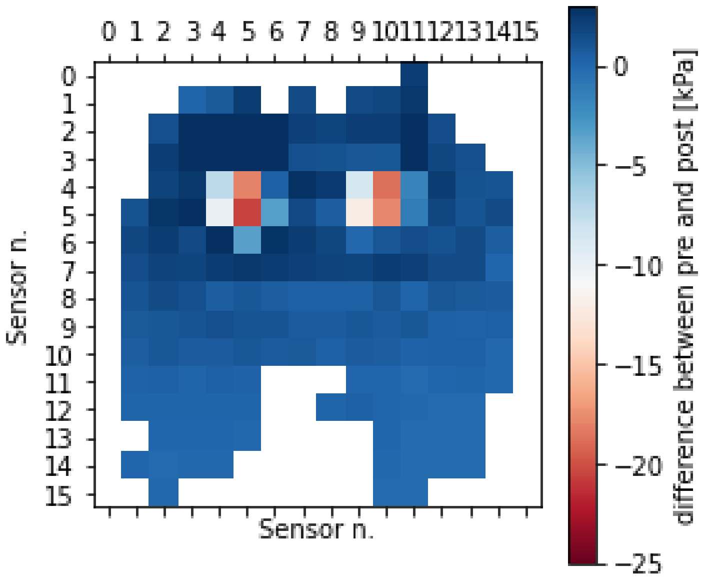

Figure 35 colourmap of subject 9 that shows the difference between interface pressure before and after air cells deflation.

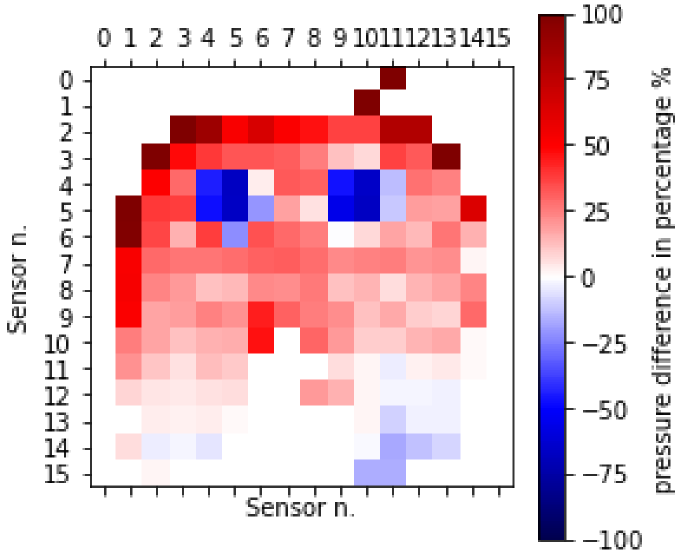

Figure 36 colourmap of subject 9 that shows the difference expressed in percentage between interface pressure before and after air cells deflation.

From these figures it is possible to appreciate the distribution of the body weight over the entire surface when two air cells at highest peak interface pressure values were deflated.

	Subject 1	Subject 2	Subject 3	Subject 4	Subject 5	Subject 6	Subject 7	Subject 8	Subject 9	Subject 10	Mean pressure ± SD
Mean pressure decrease left IT %	29,6	-47,8	-36,0	-39,8	-35,0	-59,8	-52,6	-38,3	-59,9	-45,4	-46,2±11,1
Mean pressure decrease right IT %	-36,8	-51,7	-51,4	-35,5	-46,0	-54,3	-38,0	-40,0	-58,8	-37,2	-46,8±8,9
Mean pressure decrease buttock area %	7,5	7,74	6,9	1,7	8,0	4,8	8,7	12,2	16,4	8,3	9,1±3,6
Mean pressure decrease legs area %	11,1	7,9	1,8	-2,2	5,5	6,2	3,1	7,6	9,7	0,6	6,0±3,8

Table 5 mean pressure decrease calculated for the 20 s before and after the air cells deflation expressed in percentage.

Table 5 reports interface pressure information about all subjects, providing a particular attention on the last column in which the mean pressure over the subjects and the standard deviation are reported.

In this table is interesting to note the slightly increase of the mean interface pressure around the ischial tuberosities and under the subjects' leg.

Table 6 show the maximum interface pressure decrease calculated in left and right ischial tuberosities for each subject. In the last column the mean pressure reduction over subjects expressed in percentage is reported.

	Subject 1	Subject 2	Subject 3	Subject 4	Subject 5	Subject 6	Subject 7	Subject 8	Subject 9	Subject 10	Mean pressure ± SD
Max pressure decrease left IT	-35,4	-42,7	-20,3	-48,0	-41,2	-56,5	-50,0	-31,0	-64,4	-46,2	-43,3±14,2
Max pressure decrease right IT	-25,5	-55,9	-46,3	-40,3	-37,7	-60,0	-43,8	-31,3	-64,3	-32,0	-44,9±14,4

Table 6 maximum pressure decrease calculated for the 20 s before and after the air cells deflation expressed in percentage.

Two graphs reported below, show the comparison between the effectiveness of the current cushion modality (checkboard pattern) to decrease pressure and the effectiveness of a future optimization cushion modality to decrease pressure precisely over ischial tuberosities (the areas at highest pressure value) done in this test.

Figure 37 shows the mean interface pressure decrease expressed in percentage for both current cushion modality of operation and the optimization cushion modality, either calculated for each subject. The mean over each subject and the standard deviation is reported. Figure 38 reports for each subject, the maximum interface pressure decrease in percentage for both current cushion modality of operation and the optimization cushion modality.

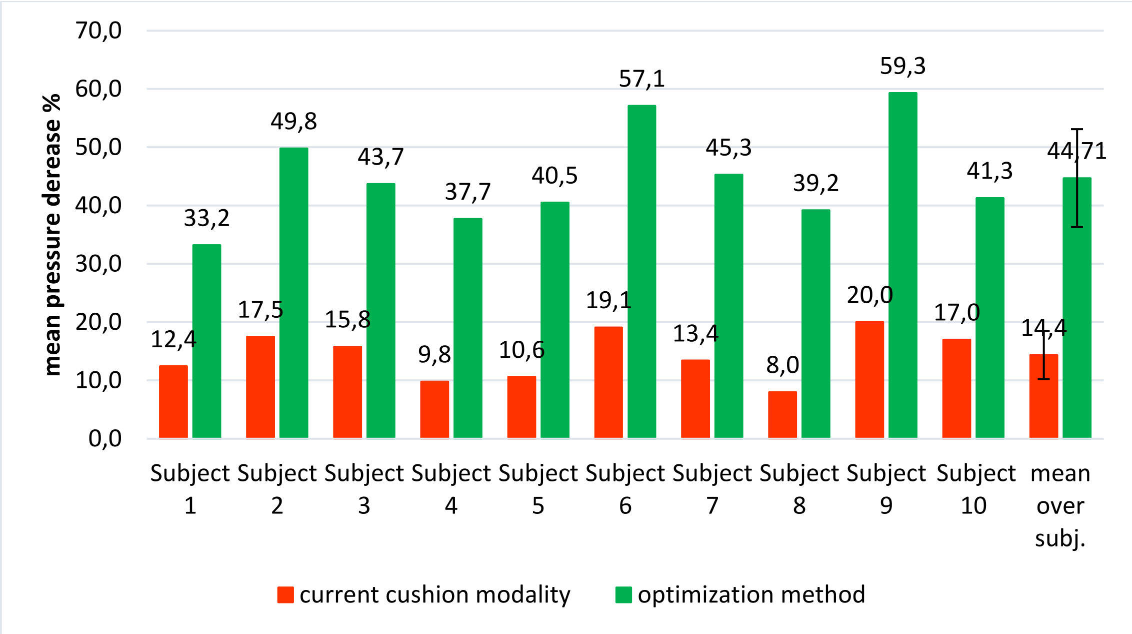

Figure 37 mean interface pressure decrease in % calculated for each subject in the current cushion modality and with the optimization method.

Note that, in either cases (figure 37 and figure 38) the localized decrease under the ischial tuberosities provide higher values of delta decrease in percentage respect to the current cushion operation modality.

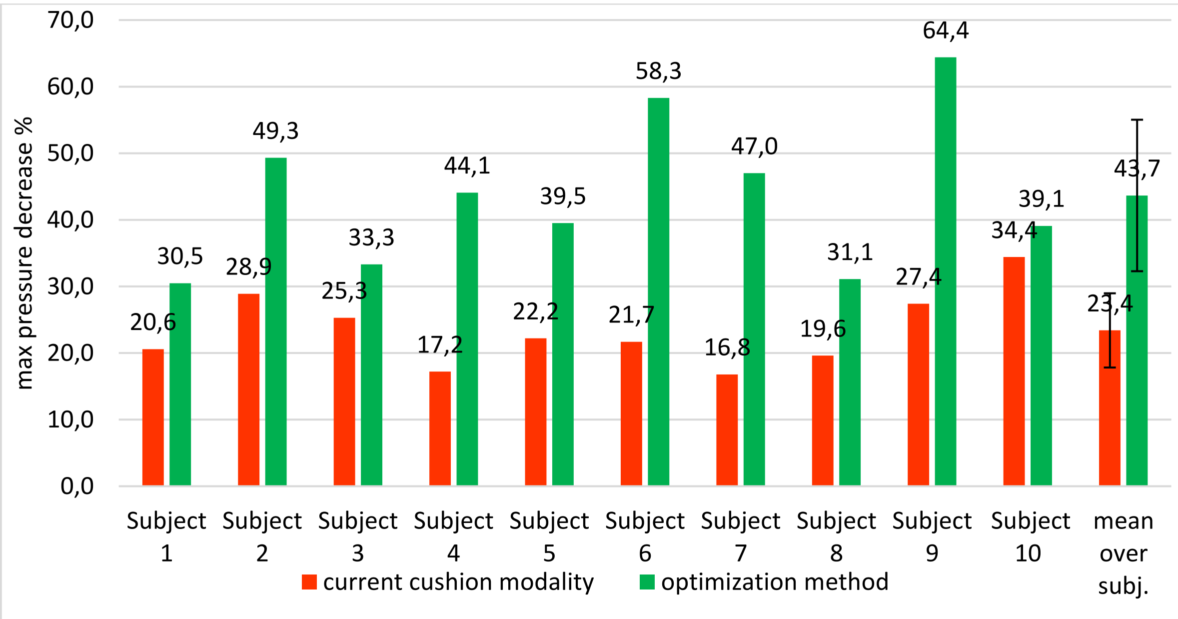

Figure 38 maximum interface pressure decrease in % calculated for each subject in the current cushion modality and with the optimization method.

3.4 Intra-subject test

The test performed 10 times for the same subjects is reported in the 2 graphs below. The first one shows the delta pressure decrease expressed in percentage calculated considering the mean initial interface pressure and the final mean interface pressure over each test. The trend is variable over the tests and the mean over subject is reported in the last bar with the standard deviation.

The second graph shows delta pressure decrease expressed in percentage considering the maximum initial interface pressure and the final maximum interface pressure over each test. In this case also the trend is variable and the mean over subjects with its standard deviation is reported.

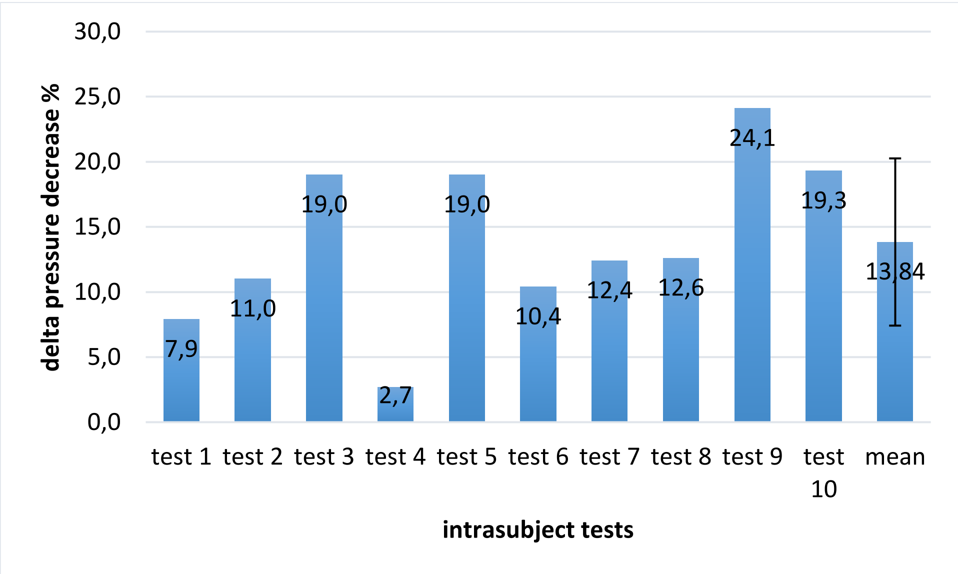

Figure 39 delta interface pressure decrease respect to the mean initial interface pressure calculated in the first 250 s, for 10 intrasubject tests.

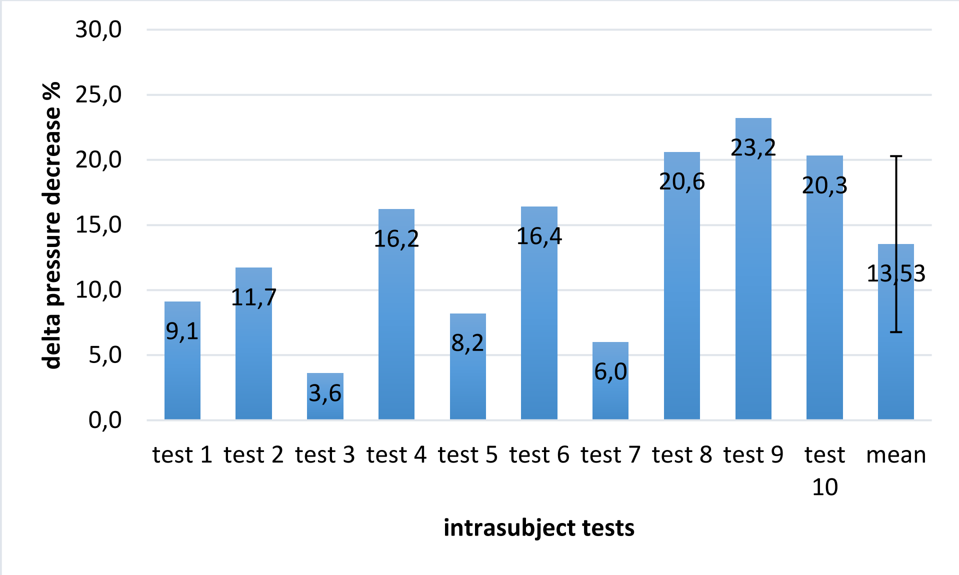

Figure 40 delta interface pressure decrease respect to the maximum initial interface pressure calculated in the first 250 s, for 10 intrasubject tests.

3.5 Calibration curve

In this section the results obtained from the calibration procedure are shown in figure below. A calibration between pressure data obtained from the cushion during the first minute of acquisition for each subject and, pressure data acquired by Novel pressure sensors matrix in the first minute for each subject is presented in figure 41.

The suitable calibration curve that interpolate the pressure data is a polynomial of grade two, providing an optimization of the root mean square error from 2,4 kPa before correction to 0,5 kPa after correction.

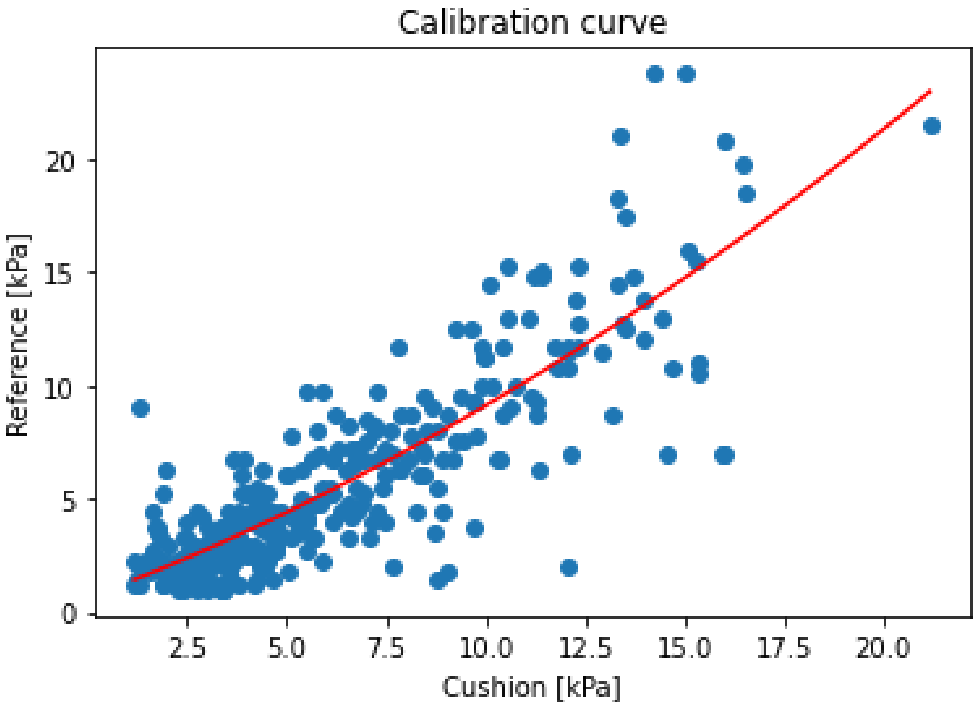

Figure 41 Calibration curve calculated with the first frame of each subject acquisition.

The curve reported above obtained from all subject pressure data is tested on the first frame of an additional subject test. Noted that the RMSE before correction is 1,5 kPa and after correction with the model obtained previously the RMSE is assessed to be 0,6 kPa (figure 42).

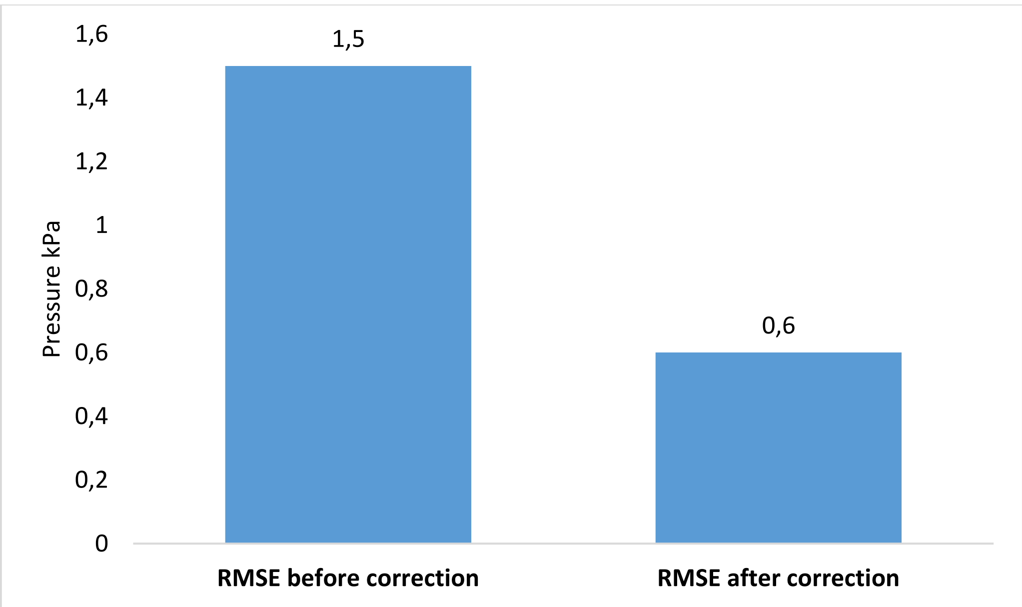

Figure 42 Comparison between the RMSE before and after correction calculated with the previous model for the test dataset

4 Discussion

In the presented work, the analysis of the cushion system characteristics and the operation modality are performed. The interface pressure measurement is used to assess the ability of the cushion to relieve and redistribute pressure over a larger surface [29]. The cushion characteristics and behaviour during one single cell deflation and during its checkboard pattern to operate, is analysed providing a detailed overview regarding the cushion operation to prevent pressure ulcers. Starting from these considerations a development of a new strategy to act for pressure ulcers prevention is presented.

Since the cushion system allows the user to control the inner pressure inside each cell using the user-cushion interface, the behaviour of the cushion is studied in this first test when a single cushion cell is deflated under a mass. Through this test, the offloading effectiveness of the cushion is analysed. Indeed, when the air cell under the mass is deflated the interface pressure on the selected cell decreases, increasing pressure around the surrounding cells. After deflation some cells present higher interface pressure than the others, due to the slight displacement of the mass when the cell deflated suddenly. The study is repeated 10 times and the repeatability of the experiment is confirmed, and an offloading delta decrease in percentage is assessed to be 55,8 % with a standard deviation of ± 3,3 over 10 tests. The offloading effectiveness is assessed because of a greater interface pressure reduction of the deflated cells and a consequent increase of the surrounding cells interface pressure. After air cell deflation an increase of contact area between cushion and mass is reported, replacing pressure over a larger surface.

The inter subjects test is performed over 10 recruited subjects with different weight and physical characteristics in order to test the cushion current operation modality to prevent pressure ulcers. From these tests it is noted that the maximum and mean interface pressure tend to decrease over time with an irregular pattern due to the checkboard modality of operation that simultaneously bring some cells at higher inner pressure and other ones reach inner pressure equal to zero. In the first 10 minutes a decrease of mean and maximum interface pressure between the subject and the cushion is identified, and over the remained minutes of acquisition the pressure trends remain unchanged. This behaviour is due to the cushion activity to offload the peak pressure in the first minutes. During test, each subject reports an increase of the contact area between himself/herself and the cushion, especially in the first 10 minutes when the greater pressure decrease occurs. It confirms the offloading characteristics of the cushion to decrease interface pressure peak, increasing the extent of the contact area between cushion and subject. The matrix sensors activated by high pressure peak (greater than 12 kPa) which are considered extremely dangerous, disappear over time during cushion activity. As expected, sensors activated by low pressure values (equal to or lower than 4 kPa) increase over time. An increase of sensors activated by pressure value from 4 to 8 kPa over time is reported. Pressure greater than 4 kPa is considered value at which the blood vessel occlusion occurs and, if it is associated with higher unrelieved pressure applied for a long period of time causes tissue necrosis and pressure ulcers [6]. Although the risk pressure threshold considered in this work is very low, values from 4 to 8 kPa can be considered slightly acceptable since the threshold value extent remains a questionable issue, and these pressure peaks are not localized in specific area due to the cushion operation modality that alternates these pressure peaks over the total contact area. From the test implemented on each subject, information about the efficacy of the cushion system over the inter subjects test is assessed to be 23,4 %, calculated with the initial and the final maximum interface pressure recorded for each subject acquisition in the total contact area between cushion and subject.

From the results obtained by the intra-subject test, a repeatability of the cushion is noted, considering the cushion activity on the same subject. Some delta interface pressure decreases are different from the others (Figure 40) because of the movement noise of the subject during the acquisition. The delta pressure decrease in percentage obtained from both the intra-subject test and the inter subject tests are comparable.

A suitable cushion system for pressure ulcers prevention must provide offloading characteristics in its operation modality during its activity. It consists of a first identification of the peak pressure point at the interface between cushion and patient. A successive automatic offloading of these higher pressure areas must be implemented, performing newly pressure peak points which are addressed to a subsequent offloading.

In this way the offloading of the highest pressure points and a redistribution of interface pressure occurs [24]. The cushion system presented in this study, identify if a mass is placed on them and after identification, automatically implements its checkboard modality of deflation and inflation of its air cells over the total cushion surface. This operation can be seen as a limit of the system, because positive results are obtained from the manual test offloading. During this test performed on the same subjects recruited for the inter subject test, the deflation of the air cells under the subjects' ischial tuberosities show cushion excellent capability to offload peak pressure points, redistributing the interface pressure over more tolerant body parts. From these results it can be appreciate that the localized offloading of highest pressure peak points is better than a general offloading of more than one air cells. From the manual offloading tests, interface pressure tends to redistribute from the ischial tuberosities to the back or frontal parts of the cushion.

A calibration curve of second degree is assessed to model the system and to obtain reliable pressure data from the cushion in order to provide further studies and controls about the cushion operation modality. The RMSE calculated in either cases reported in the results shows an improvement after correction.

Some limitations of the system which affected the present study procedures are related to pressure values recorded by the cushion. One of them is the compression of the adjacent air cells with each other that occurs under the cushion operation. Another problem is the quality of the air cell pressure sensors which are not differential, indeed the inner air cell pressure is calculated subtracting the pressure absolute value from the current atmospheric pressure sensed. A limitation is related to the cushion recording modality which records pressure data only when the 'start' modality is set. During long test another problem is noted, after cushion activity some air cells, especially those affected by higher pressure value tend to collapse over time. This is a problem related to the weak compressor power to further inflate after collapse and to the physical characteristics of the cushion air cells.

To conclude, the cushion system is able to identify when a mass is applied over its surface specifically, when the pressure recorded by its sensors is higher than 1,6. For further studies a suggestion is to increase this value performing a precise identification of the dangerous pressure points and immediately act on them.

5 Conclusion

In this work the capability of the cushion to manage pressure, offload and redistribute peak pressure areas and the real time pressure mapping is demonstrated. The cushion system characteristics with its operation modality is studied to understand the cushion activity and its way of operation to prevent pressure ulcers. Starting from the considerations reported in the previous chapters, improvements could be implemented in the next studies in order to improve the efficiency of the cushion system to prevent pressure ulcers development.

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