DEVELOPMENT OF A CLASSIFIER AND A SIMULATOR TO SUPPORT THE DESIGN OF AN ANTI-DECUBITUS ACTIVE MATTRESS

Brunzini, Agnese;
Rossi, Marta;
Mandolini, Marco;
Cappelletti, Federica;
Germani, Michele

Università Politecnica delle Marche, Department of Industrial Engineering and Mathematical Sciences

ABSTRACT

Approximately 10% of hospitalized patients develops decubitus ulcers that quickly degenerates into chronic illness that reduces the quality of life and requires expensive clinical management. The use of an anti-decubitus active mattress, that automatically redistributes the pressure loads, reduces the occurrence of new lesions and promotes the healing of the pre-existing ones.

The aim of this work is to design and develop two tools to support the design of an anti-decubitus active mattress. Almost all the systems found in literature are based on the classification of pressure maps through machine learning and are difficultly usable in the design context.

This work proposes a pressure map Classifier and an Interactive Simulator of the mattress, based on a simpler logic, by integrating image processing techniques and functioning simulations. The Classifier can recognize the patient's pressure maps and classify them according to six reference sleep postures. The Interactive Simulator allows to understand the operating mechanisms of the mattress and to test the controller and the various control logics in the absence of a physical prototype.

Keywords: New product development, User centred design, Simulation, Images Classifier, Active Anti-decubitus Mattress

Contact:
Brunzini, Agnese
Università Politecnica delle Marche
Italy
a.brunzini@pm.univpm.it

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1 INTRODUCTION

Decubitus ulcer consists in tissue damage caused by compression forces, traction and friction on the bony prominences and affects most of the immobilized subjects. It quickly degenerates into a chronic illness that reduces the quality of life and requires a demanding and expensive clinical management. To understand the importance of injury prevention and immediate management, it's worth to consider for a hospitalized patient, 2h of continuous pressure at 70mm/Hg are sufficient to cause irreversible skin lesions. Approximately 10% of hospitalized patients develop skin lesions; mortality from ulcers is between 23% and 37%. The injury management costs are a worldwide emergency: direct costs are estimated between 15k€ and 18k€ per year per patient. Moreover, also indirect costs such as the job loss, the change in social condition and the infective risks must be taken into account.

Currently only passive mattresses that cyclically inflate/deflate in specified sections exist and the healthcare professionals or caregivers have to frequently change the patient's position, according to a protocol dictated by common sense and by custom, without knowing the accuracy of the change of posture. There is no device that is currently able to control the amount of pressure overload created by the different postures and the consequent risks.

For this reason, active anti-decubitus mattress (Active Medical Device (AMD)) represents a very interesting solution, able to adapt its behaviour to those one of the users, and therefore able to determine better conditions especially for immobilized subjects. An active mattress can automatically modify itself with mechanical actions and customized decompression and redistribution of pressure loads, on the basis of objective data collected by pressure sensors, thus overcoming the operator task of moving the patient frequently and casually. With AMD, the occurrence of new lesions can be reduced, and the healing of the pre-existing ones can be promoted and speeded up.

The design and development of active anti-decubitus mattress usually require the development of numerous physical prototypes to understand their potentialities and test their effectiveness, due to the high variability of parameters involved (pressure, body weight, etc.). These activities are very expensive as well as time consuming and therefore comes the need to support companies in the design and development of such AMDs, to save time and costs.

The aim of this work is the design and development of tools intended to support the design process of an anti-decubitus mattress (as AMD) that can be monitored and managed remotely, and that will be effective in the prevention and treatment of pressure ulcers. In the following some characteristics of the new device are described. The AMD considered in this study wants to be able to monitor 24/7 the patient`s condition and readjust itself (with automatic change in the contact surfaces) on the basis of changes in contact pressure values and patient positions, in order to redistribute the pressure peaks. In this way the mattress can avoid the occurrence of pressure sores, and manage the existing ones, preventing chronicity and restoring tissues. The device, processing the data detected by the pressure sensors, recognizes the overloading areas, and automatically starts continuous mechanical actions targeted to decompression and redistribution of loads. The mattress is thought to be divided in several sensorized cells; each one can inflate and deflate in an autonomous and independent way. Endowed with extremely simple and effective user interface, it can be consulted on most popular devices (PC / Tablet / Smartphone). The mattress is designed to transmit to a remote management platform (cloud) all the information collected during the functioning. The acquired data will enable the clinician to tele-monitoring the "automatic" adaptation of the device during the various stages of the treatment, also managing the alarms and any interventions carried out remotely.

It is possible to understand that the design of such complex product requires the knowledge of a lot of information (e.g., parameters to consider, pressure distribution, typical threshold values, etc.) which is difficult to derive without physical prototypes. The two tools proposed in this paper want to overcome the absence of the physical mattress allowing:

- The simulation of the mattress used by different patients, the identification of the data acquired by the sensors (in absence of active control of the mattress), and the classification of pressure maps;
- The testing in advance of the controller and the various control logics.

The result is therefore the development of a classifier and a simulator that help to design the anti-decubitus mattress, by early understanding its functioning, behaviour and representative parameters.

2 STATE OF THE ART

The analysis of sleeping postures is the main goal of medical devices designed to prevents the onset of decubitus ulcers. For these systems, another important objective is the recognition and tracking of overloaded points on the patient's body on the mattress. In literature, several studies have proposed different ways to monitor the sleep positions automatically. Some examples of techniques, used to monitor and study sleep posture patterns, are the use of video cameras and microphones or of inertial sensors such as accelerometers, magnetometers, and gyroscopes. In the first case, the major downside involves lighting issues because low light levels add noise to the images, and, even when near-infrared cameras are used, the images still produced non-uniformity and artefacts. In the second case, the main drawback is that sensors are attached to the body, and it can result uncomfortable or harmful to the patient (Liu et al., 2013). A valid alternative is the utilization of pressure sensors in the mattress. The sensors, that are unobtrusive and don't interfere in the comfort of users, can record when changes in body posture occur. Moreover, they are stable instruments that are not affected by changes in the environment. Nevertheless, in order to have satisfying results, an accurate definition of sensors' type and distribution over the mattress should take place during the design phase.

Hsiu-Chen and Rong-Chin (2013) used pressure sensors, buried in the mattress, in order to study the pressure distribution mapping of the human body. Then, from the data collected and by the aid of a mathematical morphology algorithm, they defined three modes of support firmness. Liu et al. (2013) collected and analysed pressure images for sleep posture recognition, using a dense pressure sensitive textile bedsheet. They determined six classes of sleeping postures and developed three heuristics based on sparse representation to classify sleep postures. However, in their studies, they focused only on steady state sleep postures, without considering the transitions from one posture to another.

Other studies used Machine Learning (ML) techniques to recognise and classify different sleep body postures. For example, Yousefi et al. (2011) developed an image-based processing algorithm (kNN Classifier) to keep an unobtrusive and informative record of patient's bed posture over time, but the algorithm does not detect the limb position and does not predict at-risk regions of body for developing pressure ulcers. In its improved version (based on Support Vector Machine (SVM)), the algorithm was able to detect body posture and to track limbs displacement. However, in this case, it extracted several data from sensors in the mattress (e.g., pressure map, level of moisture, temperature, mobility/activity and blood pressure), significantly increasing the cost of the anti-decubitus device. Even more recent studies continued to use ML techniques to estimate sleep postures, such as in Islam and Lubecke (2022), Jeng et al. (2021), and Rasouli and Payandeh (2019). Almost all the systems found in literature are based on machine learning and are difficultly usable in the design context, since they required a long time to be developed.

Moreover, several observational prospective studies can be found on the state of the art, to analyse the efficacy and effectiveness of anti-decubitus mattress (Li Bai et al. 2020, Meaume and Marty 2020, Beeckman et al. 2019). These works are extremely important to analyse the real effects of anti-sores devices and consequently optimize them; however, the physical device or prototype is obviously always needed.

In the design context, finite element simulations have been accomplished to compare the performance in reducing pressure between a new patented mattress design and alternative suggested designs (Alwasel et al. 2022); however, they only give indications on the mattress components dimensioning.

Therefore, what emerges is the lack of simple systems, easy to be used and able to support the design of medical devices, such as anti-decubitus mattresses, reducing time and resource efforts in developing and testing prototypes, and giving helpful suggestions about the sensors choice. The tools proposed in this paper, i.e. a pressure map classifier and a simulator of the mattress, face these problems allowing a better comprehension of the functioning mechanics of the device and consequently supporting its design and optimization.

3 MATERIALS AND METHODS

Starting from the main problems identified, i.e. supporting in a simple and effective way the design and development of a complex medical device such as an active anti-decubitus mattress, two requirements need to be satisfied:

- Identification of significant parameters for the classification of sleeping postures;

- Simulation of mattress use to understand its operating mechanisms, test its control logics, and define its dimensioning and needed sensors.

Several approaches exist for the design and development of different kinds of tools. For example, the critical steps from the Stanford Design School's protocol include: empathizing, defining the problem, ideating, prototyping, and testing (Huang et al., 2018). In this way, the design is based on the "trial and error" approach via prototyping, and some application examples can be found in literature (Brunzini et al., 2018). However in this case, the design method by fast trying and fast failing has been discarded because of the high costs of the production of the physical prototype (due to the large number of sensors, valves, pump, electronics, materials and mechanical components integrated in the mattress). Also, several kinds of image classifiers for sleep body postures are available in scientific literature. Instead, in this case, a template matching approach has been selected, because more intuitive, faster, and cheaper. Being faster and easier, it allows giving rapid suggestions during the design phase of the active mattress, avoiding delay during the project execution.

Therefore, the fulfilment of the two requirements mentioned above has been reached through the development of a pressure map classifier and a mattress simulator. Both tools have been developed in MatLab by MathWorks and their functions has been divided in two categories (Table 1):

- Design support purpose;
- Design support purpose and use in the final mattress (dual scope).

Table 1. Definition of classifier and simulator functions

FUNCTIONS	DESIGN SUPPORT	USE IN THE MATTRESS
Definition of sleep postures	X	X
Definition of six reference pressure maps	X	X
Definition of pressure maps of different patients	X	
Recognition and classification of pressure maps according to the six sleep postures	X	X
Estimation of the rigid transformation that the pressure maps have undergone	X	X
Communication between controller and simulator	X	
Commands from the controller	X	X

In the following paragraphs, the research method and logics implemented to develop the tools are presented.

3.1 Definition of sleeping positions

The first step for the development of the images classifier is the definition of the standard positions that a patient can take when lying in bed. According to the literature, the resting position is the configuration of the body assumed by a person in bed. Through the study of the state of the art (Yousefi et al., 2011a; Liu et al., 2013), six basic sleeping positions have been identified: left and right log, left and right foetus, supine open legs and supine closed legs. Table 2 presents and describes the features of the six basic sleeping positions.

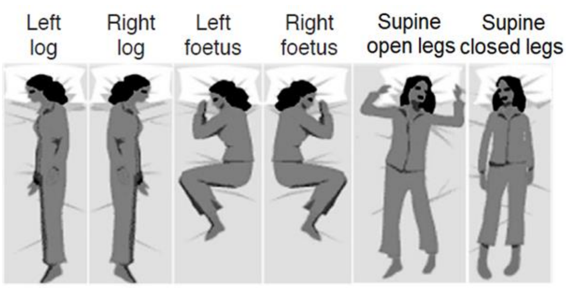

Figure 1. Basic sleeping positions

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Table 2. Description of the six basic sleeping positions

POSITIONS	DESCRIPTION
Right/ Left Log	Lying on one side with both arms extended along the hips.
Right/ Left Foetus	Curled up in a foetal position on the right/left side. It is the most common sleeping position, adopted by 41% of the population.
Supine Open Legs	Lying on the back with legs open and both arms open and bent upwards.
Supine Closed Legs	Lying on the back with leg closed and both arms along the hips.

The positions described in Table 2 have been chosen as reference, with only one difference: in the supine open legs position, given the near-immobility of the considered patients, the position was defined as "lying on the back with legs open and both arms extended along the hips".

3.2 Definition of six reference pressure maps

Based on the six basic sleeping positions previously defined, six reference pressure maps have been defined starting from the standard parametrization of human segments (limb length, abdomen length, chest length, shoulder width, hips width, head and neck height, etc.) normalized with respect to the height of the subject (Figure 2). In this way, changing the subject's height, it is possible to know the standard dimensions of the body segments for different subjects.

LENGTH OF BODY SEGMENTS	
Height	***1***
Head	0,13
h_G_Head	0,936
h_neck	0,87
h_shoulders	0,818
h_elbow	0,63
h_wrist	0,485
h_fingers	0,377
h_hip	0,53
h_knee	0,285
h_ankle	0,039
h_G_torso	0,72
h_shoulders_hips	0,288
Shoulders	0,129
Homerus	0,186
Forearm	0,146
Hand	0,108
Torso + Head	0,52
Foot	0,152
L_shoulders	0,259
L_torax	0,174
L_hips	0,191
L_foot	0,055

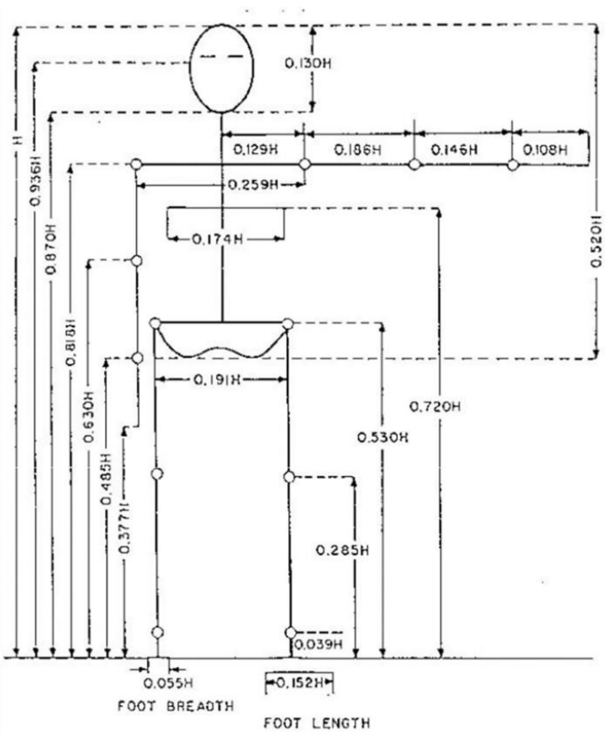

Figure 2. Measurements of body segments, normalized respect to the subject height (H)

The mattress is designed as a parallelepiped of 160 independent, squared cells with the sides of 10cm. The cells are arranged on the mattress on 20 longitudinal lines and 8 transversal columns. Therefore, the pressure map provided by the device can be assimilated to an image with a resolution of 20x8.
The 6 pressure maps have been created considering the cells of the mattress occupied by the body of the subject. Furthermore, in order to obtain pressure maps that realistically reproduce the behaviour of the mattress, also the mass of the body segments has been taken into consideration. The weight has been distributed on the maps following the percentage of body mass of specific body segments (head and neck 8%, shoulders 9%, chest 11%, abdomen 27%, arms and hands 13%, legs and feet 32%) (Table 3).

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The six reference pressure maps have been developed in MatLab by MathWorks, considering a 'standard' patient tall 160cm, with a weight of 65 kg, shoulder width of 41 cm and pelvis width of 31 cm. The result is shown in Figure 3.

Table 3. Mean weight of male cadaver segments and ratio to total body weight (Dempster and Gaughran,1967)

SEGMENTS	MEAN WEIGHT(Kg)	% OF TOTAL
Total Body	61.190	100
Head and Trunk	34.637	56.34
Head and Trunk and Minus shoulders	28.077	46.02
Head and Neck	5.119	7.92
Shoulders	3.401	5.27
Thorax	7.669	10.97
Abdomino-pelvic headless trunk	16.318	26.39
Arm	1.636	2.64
Forearm	0.947	1.531
Hand	0.3783	0.612
Thigh	6.096	10.008
Shank	2.852	4.612
Foot	0.884	1.431

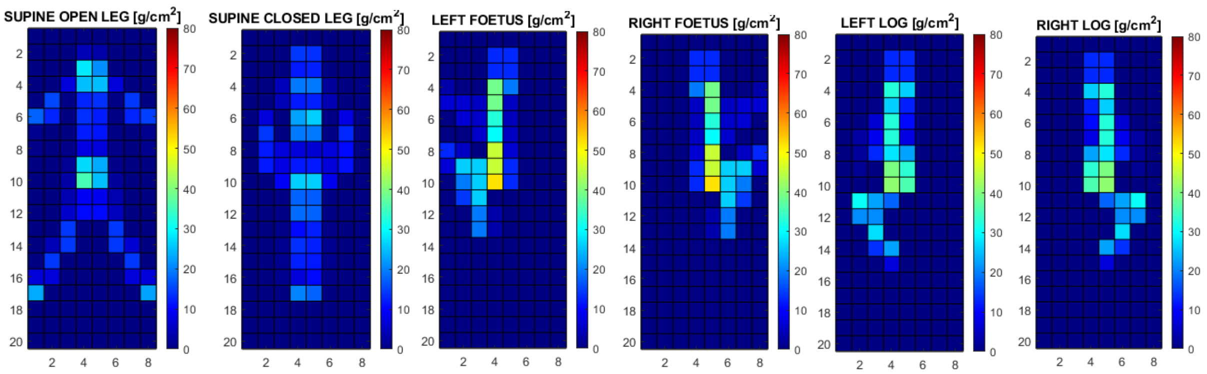

Figure 3. Definition of the six standard pressure maps. The colorimetric scale shows the pressure values exerted by the patient on each cell (g/cm^2).

3.3 Definition of pressure maps of different patients

In order to overcome the absence of the mattress prototype and thus to create a database of pressure maps of different patients, an algorithm has been developed to appropriately scale the reference pressure maps, according to the specific characteristics of the patient (weight, height, shoulder width and pelvis). These maps have been obtained by scaling the reference maps through two scaling coefficients. For transversal scaling, the coefficient is obtained as follows (eq. 1):

$$ScalingCoeffX = (shoulders + hips) / (41.44 + 30.56) \quad (1)$$

Similarly, the longitudinal scaling coefficient is calculated as follows (eq. 2):

$$ScalingCoeffY = height / 160 \quad (2)$$

However, the scaling coefficients cannot be applied directly to the standard maps because these are discretized into 20x8 pixel images, in which each pixel represents an area of 100 cmq. Since this resolution must remain unchanged, each map must be re-interpolated after scaling. For this purpose, the "imresize" function of Matlab has been used for scaling the maps with a bilinear interpolation.
The pressure value of each cell is obtained by normalizing the pressure value of the scaled map (in order to have a total unit weight) and multiplying it by the weight of the patient. Moreover, the patient can change position by moving on the bed in longitudinal and transverse directions and rotating in

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small angles. For this reason, in order to simulate the patient displacements on the mattress, three 'rigid' movements have been defined:

- Transversal translation (in the direction of the bed width);
- Longitudinal translations (in the direction of the bed height);
- Rotations.

Even in this case, the map resolution must remain unchanged, following the movement of the patient. For this reason, the maps have been re-interpolated through the MatLab functions "imtranslate" and "imrotate", with bilinear interpolation.

4 RESULTS AND DISCUSSION

4.1 Sleep postures classifier

The Classifier is able to recognize the pressure maps, classify them according to the six sleep postures and estimate the rigid transformation that they have undergone (translations and rotations). This function has been implemented using the 'Image Processing Toolbox' of MatLab; specifically, the classification is done by aligning each simulated patient-specific map with each of the six reference pressure maps. The registration is carried out automatically, using an iterative Intensity-Based process, which is shown in Figure 4. It requires to specify the two images to be recorded, an optimizer, a metric and a type of transformation. The similarity metric of the two images is used to evaluate the accuracy of the recording; it requires two images in input and returns a scalar (quality index) that describes how similar the images are. The optimizer defines the methodology to maximize the quality index; the type of transformation defines the 2D transformation type that aligns the simulated image (called "moving image") with the reference image (called "fixed image", i.e., the reference pressure map).
The process begins with a transformation defined by a transformation matrix. The transformation is applied to the "moving image" with bilinear interpolation. Afterwards, the two images are compared using the specified metric and the quality index is calculated. The process ends when the quality index reaches the desired threshold value, or the maximum number of iterations is reached. Otherwise, the optimizer calculates a new transformation matrix, and the cycle starts again. Once aligned the simulated map with each of the six reference maps, the simulated map is classified based on the registration that presented the highest quality index.
The load history detected by each cell of the simulated mattress can be exported at the end of the simulation in .txt format. The classification of the patient's posture is the first step for the identification of the ulcer placement on the mattress.

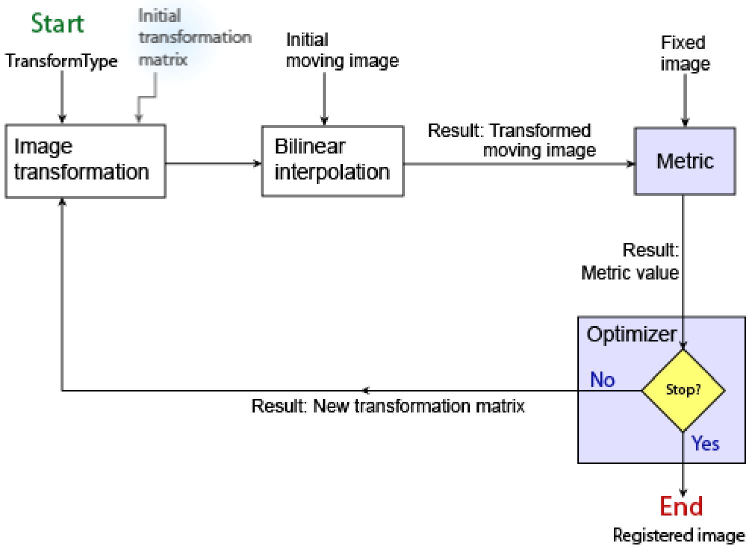

Figure 4. Image recordings with "intensity-based" methodology.

This sleep posture classifier has allowed a better understanding of the limitations imposed by the dimensions of the mattress' cells and a more in-depth comprehension of the pressures involved and the threshold values.

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4.2 The Interactive Simulator

The Interactive Simulator has been developed in order to understand the operating mechanisms of the anti-decubitus mattress during its use, as well as to start testing the controller and the various control logics, in the absence of a physical prototype. Even in this case, the Simulator has been developed in MatLab and its user interface is shown in Figure 5.

According to the mattress design, each cell is equipped with two sensors: a weight one and a pressure one. The first one measures the weight generated by the patient on each cell, while the second one measures the pressure inside each cell. Their outputs are simulated and reproduced on the left side of the graphical interface in Figure 5; in particular, the "Pressure map" represents the output of the weight sensors, while the "Cells pressure" shows the output of the pressure sensors inserted in each cell.

The simulator connects with the mattress controller via TCP / IP socket; the two applications, therefore, can be performed on two different machines. Controller and Simulator communicate using a predefined protocol, by sending data packets; the log of the exchanged packages is shown on the console, on the right side of the user interface in Figure 5. For each packet sent by the controller, there is a simulator response to verify that the communication was successful.

The controller can request the simulator to execute five different commands:

- *Initialization*: this command allows to remove the patient from the mattress, thus resetting the pressure map shown in "Pressure map". It allows also to set an initial pressure value to the mattress cells and to start a new simulation;
- *Inflation of specific cells*: this command allows to inflate the indicated cells until reaching the required pressure value;
- *Deflation of specific cells*: this command allows to deflate the indicated cells until reaching the required pressure value;
- *Communication between specific cells*: this command allows to ideally put in communication the indicated cells through the ducts used for the inflation / deflation of the cells. In this way, the communicating cells will tend to naturally assume a medium pressure level, redistributing the weight of the patient placed above them;
- *Inquiry*: the controller asks to the simulator the output of the pressure and weight sensors.

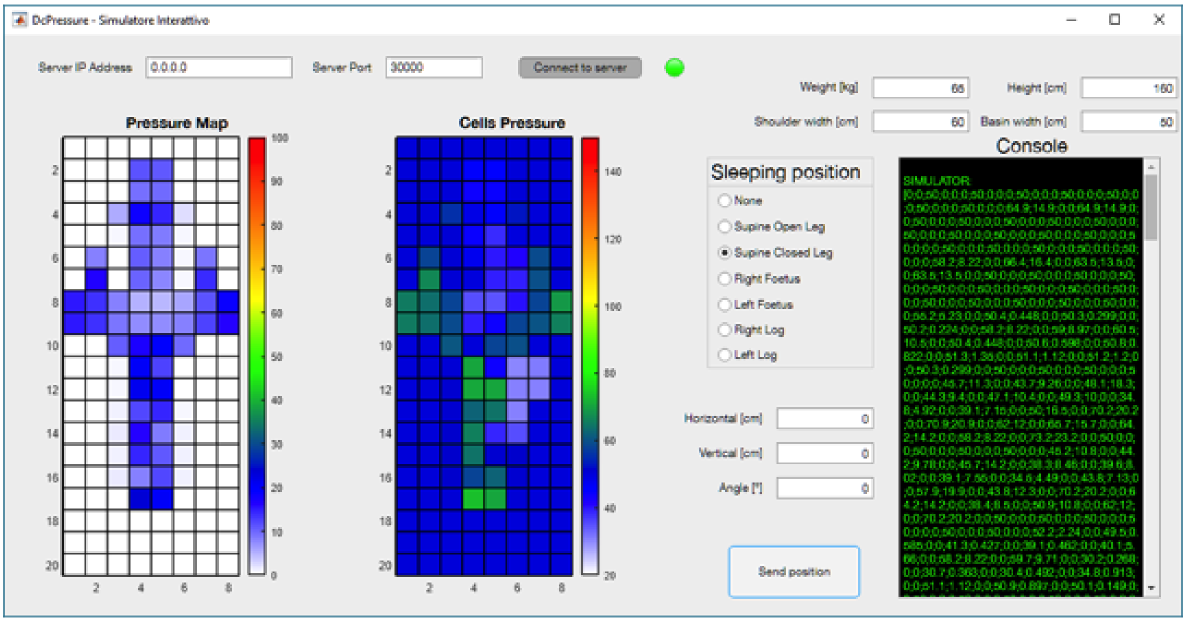

Figure 5. User interface of the Interactive Simulator

Once the simulation has started, the simulator allows to virtually position a generic patient on the mattress, in the desired sleep posture. The pressure map is calculated as explained in the previous paragraphs and it is customizable regarding the size and weight of the simulated patient. Furthermore, the maps can be rotated and translated during the simulation.

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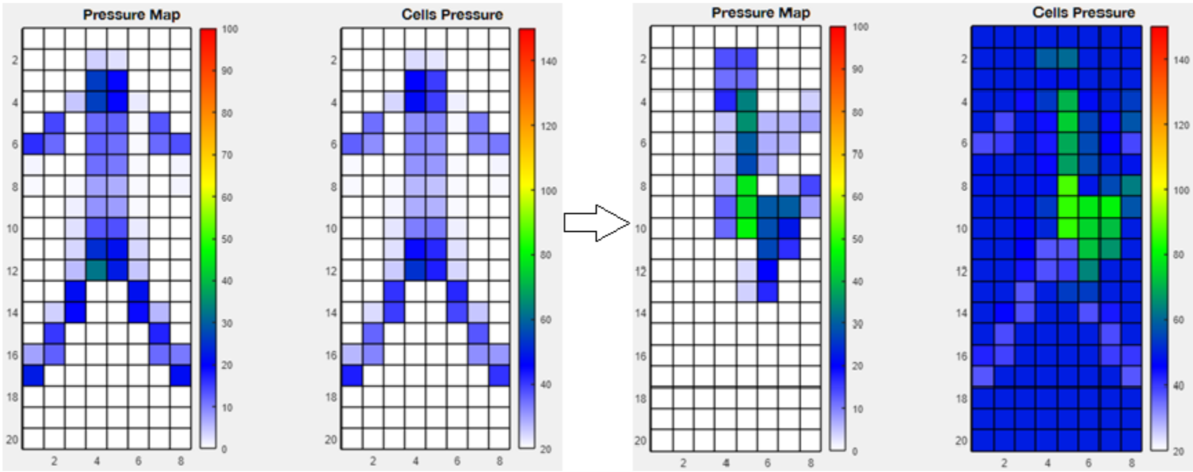

Figure 6. The correspondence between pressure maps and pressure values in the cells is lost moving away from the initialization of the system.

The Simulator allows to test different mattress control logics and to simulate the behaviour of the real mattress. In this way, it is possible to understand the effects that the inflation, deflation, and communication of the cells have on the patient pressure map.

For example, assuming to initialize the system with an initial pressure value of the cells equal to 20 g/cm2 and to place a patient (tall 160cm, with a weight of 65kg, a shoulders length of 60cm and a hips length of 50cm) on the mattress in 'supine open legs' posture, the weight and pressure sensors measure a variation in pressure and show the map. However, the correspondence between the outputs of the two sensors is not one-to-one. The value of air pressure inside the cells is conditioned by the weight of the patient, as well as by the amount of air present in the cell. If the patient changes posture, the result is shown in Figure 6. In this case, the patient's position has changed from "Supine open leg" to "Right foetus". It is evident from Figure 6 that the pressure in some cells is decreased because the patient's weight is no longer present on them. On the other hand, the pressure value of other cells on which the patient is still present has remained unchanged, while other cells, that previously were not loaded, have assumed high pressure values. Therefore, the correspondence between pressure maps and pressure values in the cells is lost moving away from the initialization of the system. This simulation has highlighted the need to use both the weight and pressure sensors on each cell, in order to recognize the cells on which the patient is actually present and thus his/her sleep posture. Moreover, this information is fundamental to track the position of any ulcers on the patient, and to correctly carry out the pressure offloading.

5 CONCLUSION

Decubitus ulcer represents a very serious public health problem because it interests all the immobilized subjects. It can quickly degenerate into a chronic illness that reduces the quality of life and requires a demanding and expensive clinical management, and, for this reason, several medical devices are continuously developed to both treat and prevent it. The present paper describes the definition and development of two tools able to support designers during the design and development of an active anti-decubitus mattress. In particular, a sleep postures classifier and an interactive simulator have been developed. The classifier is able to recognize the pressure maps, classify them according to the six sleep postures and estimate the rigid transformation that they have undergone. Its use during mattress design has allowed a better understanding of the limitations imposed by the dimensions of the mattress' cells and a more in-depth comprehension of the pressures involved and the threshold values. The simulator has allowed to test different mattress control logics and to simulate the behaviour of the real mattress. Its use during design activities has highlighted the need to use both the weight and pressure sensors on each cell, in order to recognize the cells on which the patient is actually present, his/her sleep posture, and which cells to deflate/inflate. The integration of basic image processing techniques, with virtual prototyping and simulation (typical for the design optimization) is the main contribution of this approach.

The main limitation of this work is the lack of the approach validation; it will be performed in future work, in order to apply the tools in the development and actual use of the anti-decubitus mattress.

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