Development of customized support for the prevention of Pressure Ulcer (PU) using multi-materials printing

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Abstract: Pressure Ulcers (PU) seems to be one of the most challenging healthcare problems around the world. It may result in significant morbidity, mortality and is associated with high cost in terms of treatment and care. PU is considered to be the third most expensive disorder after cancer and cardiovascular diseases. Though, modern medical science has launched a variety of treatment methods, prevention is the best way to overcome. As it could be seen from the current market design, most of the products provide a cushioning effect to the end user, but this lacks in product customization. Further, these products are not custom made to meet the end user needs and these products are expensive to be used. Understanding the above intricacies, the current research is focused entirely to be different from the existing product design, working, manufacturing methods and materials for the development of a product to redistribute the pressure for the reduction of PU. The projected design purely depends only on mechanical materials and mechanical behaviors. In this work, the number of phases of design was carried out through Solid Works software. The deformation and stress analysis was carried for all the design phases for obtaining the better design. Finally, the prototype is developed through Additive Manufacturing (AM) technology with the multi-material combination. The final prototype was evaluated experimentally using emed® sensing platform for the flexibility and pressure distribution also compared with the existing cushions.

Keywords: Additive Manufacturing; Customized Cushions; Multi–material printing; Pressure Ulcers
1. Introduction

Pressure ulcer also known as bedsores or decubitus ulcers is one of the major healthcare problems in the world [1]. It can be defined as localized damage of skin and underlying tissue due to prolonged pressure and or pressure with shear and friction that usually occur on to the bony areas of the body [1]. Two kinds of people face this problem, namely; bed-bound patients and patients in wheelchair [1]. Bed-bound patients faces serious issues due to bedsores, mostly on the bony parts such as the ankles, heels, shoulders, coccyx or tailbone, elbows and at the back of the head [2].

On the other hand, wheelchair patients have a higher risk of developing pressure sores on their buttocks, tailbone and shoulder blades. Care for such sores is often prolonged, with a usual hospital stay of 40 to 150 days, and is an expensive process, nearly $5 billion annually [3], also the mortality rates are also increasing rapidly [4], PU resulted in 29,000 death in 2013 which is up from 14000 in 1990 [1].

PU results in poor quality of life of the patients, loss of functions, greater risk of death and higher health care costs [5]. Current treatment of PU includes reducing pressure on the affected skin, caring for the wounds, controlling pain, preventing infection and maintaining good nutrition [6]. In some extreme cases, the damaged tissue is removed by surgery. Reducing pressure on the affected skin is done by repositioning and by using special support devices. Use of special support devices like gel-foam mattresses, water beds, alternating mattresses, air-fluidized mattresses, low-air-loss beds, heel protectors, foot waffle air-cushions, etc. are involved. But, these cannot completely stop PU from occurring, but can delay their occurrence [6]. Foam material is commonly used as it is cheaper and its contour can be changed easily but it was not effective [7].

Super bed platform systems are used for reducing the pressure between the body and support surfaces effectively but are very expensive and not available to all patients worldwide [8,9]. Some mattresses and overlays require frequent turning and repositioning. Other kind of mattresses like multi pulsating dynamic mattresses, low-air-loss mattresses, alternating pressure overlays were also not effective without frequent repositioning [10,11]. Sandbags, ring and donut shaped devices were avoided as they increased pressure and friction [12]. Honey comb structured mattresses were developed and implemented for the reduction of PU but they are not as much as effective. Air cushion dual compartment and honeycomb cushion displaying the best mechanical properties for the distribution of pressure 21 kPa and 21.41 kPa respectively presenting the lower values in comparison to the others types of cushions [13]. Therefore, there is need for a specially designed mattress to relieve the pressures in order to prevent pressure ulcer development [14].

The selection of materials and manufacturing plays a vital role in the application of support structures design. The selection of materials and the structure of support surface should be durable, washable and be able to maintain the body posture as well as it should be of comfortable, safe, stable, light in weight, easy to use and mainly cost effective as compared to other mattresses [14].

Additive Manufacturing (AM), also known as Rapid Prototyping (RP) technology fabricates physical models and functional parts directly from 3D CAD models layer by layer, under computer control in a very short time [15–17]. Complex models that are very difficult to manufacture using conventional methods, can be manufactured by this AM technology. This technology has a broad span of application ranging from medical, automobile to aeronautical and space industries [16]. AM provides novelty in product development process by improving quality, reducing the time to market at reduced cost. The prime aim of this technology in health care is to develop customised products for individual patient requirement, thereby increasing their comfort [17]. The focus of this work is to
identify a suitable design and material to relieve pressure, thus preventing PU development and prototype the same with AM technology.

1.1 Main Causes of Pressure Ulcer development

There are three important factors for the development of PU such as pressure, shear and friction as shown in figure 1. Among these pressure has been accepted as the most important influencing factor involving in the development of PU [18]. Pressure may be defined as the sum of force applied perpendicular to the surface per unit area of application. However, in practice the suggested pressures between support surface and the soft tissue range from 32 to 35 mmHg more than that pressure will lead to irreversible tissue damage [19].

![Figure 1. Main causes of PU development Source:[14]](image)

The applied forces are in parallel to the skin surface known as shear forces and it induces shear stresses [20]. This happen when skin moves in one direction, and the underlying bone moves with another. These stresses thereby result in distorting cells, reducing blood flow and inducing ischemia and necrosis [20]. Friction is the resistance of one body sliding or rolling over another due to this more heat will be generated in a particular area and it leads to tissue damage. Hence, the need is to develop a novel methodology to eliminate these three factors and increasing the lifespan of patients from PU [20].

2. Data Collection through experiments

The mechanical factors such as force, interface pressure and surface area are collected from the experimental methods. Here, emed® sensing platform is selected for the measurement of force, peak pressure, pressure distribution and surface area of human buttocks. It is a precise electronic system for recording and evaluating the pressure distribution under static and dynamic conditions. The emed® systems are from the novel pedography measurement platform with calibrated capacitive sensors [14].

Three iterations were carried out and data taken for 22 able bodied persons as they sit on an emed® platform, each trial is taken for a period of 90000 milli seconds. Here, the maximum pressure occurs on the Ischial Tuberosity (IT) region for all the subjects. Similarly, number of trials for 22 normal subjects was carried out for attaining the accurate results. This type of pressure measurement helps to the development of customized PU prevention devices.
3. Design and Development

The National Pressure Ulcer Advisory Panel (NPUAP) gives recommendation for designing medical device that would prevent PU, which are as follows:

i. The medical devices should fit to the individual and should be designed for the correct size
ii. It should facilitate proper cushioning and protection to the skin
iii. It must be easy to remove, move and facilitate cleaning
iv. The staff must be educated regarding the use of the new device
v. The devices should not place directly under an individual who is bedridden or immobile[18]

Now the current manufacturing trend is mass production, where custom fit for individuals is not possible. AM technology can aid in achieving the goal of custom fit in making these preventive devices for PU. The aim of the research is to design, analyze and prototype a pressure reducing device (flexible mattress that would distribute the peak pressures) for PU prevention. The design and analysis was done virtually with the help of computer software’s alike Solid Works and ANSYS respectively. The designed final model was prototyped using PolyJet technology is the one of the AM technology can develop a prototype in the combination of two materials (digital materials) to provide maximum flexibility.

However, when selecting rigid materials for cushions having high strength but it lacks in flexibility. On the other hand, the rubber like materials having high flexibility but it lacks in strength. Hence, the combination of both rigid and rubber like materials have been selected for obtaining the better results. Numerous iterations were conducted to achieve optimum result with different composition and different hardness values. Finally, 56.75% Tango Plus material (Rubber like material) and 43.25 % Vero White Plus material (Rigid material) (Both are from poly methyl methacrylate (PMMA)) and Shore (A) hardness value of 60 have been selected. Assuming the value of Young’s modulus based on this proportion is calculated as below:

\[
\text{Young’s modulus of the digital material (E)} = 1100 \text{ MPa (Calculated based on the material Composition)}
\]

\[
\text{Poisson’s Ratio (Pr)} = 0.48 \text{ (for rubber like materials; [21])}
\]

These mechanical properties are used for the purpose of designing an accurate model with more deformation and less stress through ANSYS software. Numbers of design iterations were carried out through software for obtaining the better results. Here, the average body mass of an adult human is 62 kg (62*9.81= 608.92 N) according to a league table of the world's 'fattest' nations from the London School of Hygiene & Tropical Medicine taken as load applied on the mattresses. The weight distributed by a person when standing over a surface area of 20 cm², for 1 cm² = 50 N (1 mm² = 0.5 N). Based on the load values and the boundary conditions the deformation and stress values are evaluated for various design phases as shown in table 1.
Finally the best design was selected based on the deformation and stress values. The modified honeycomb structured design phase 5 as shown table 1 have the maximum flexibility and minimum stress. Hence, it is selected for mattress to redistribute pressure and will be prototyped through AM technology for validation.

The final design was modeled using Solid Works software and the model file is converted into .stl (Standard Tessellation Language) file format printing. Then the converted .stl file is imported into the Objet260 Connex (PolyJet) printer coupled with Objet Studio software. The inbuilt software will automatically orient the model in order to meet the requirement. The prepared file from the Objet Studio application is sent to the Objet260 printer as individual slices and the printing process was initiated. The print heads moves in the both X and Y direction along with their nozzles for printing the part on the build tray layer by layer.

The material consumption for development of prototypes is about 28 grams of Tango Plus (56.75%) and 16 grams of Vero White Plus (43.25 %) as digital material with shore hardness value of 60A and 44 grams of support material is used. It would take about 2.33 hours for manufacturing the new flexible mattress prototype to reduce PU of patients.

### 4. Results and Discussion

From the data collected through the experiments, it is evident that when pressure is distributed evenly throughout the area it will automatically reduce the PU. Figure 2 clearly stated that the force (weight of human body) applied on the emed® platform surface, peak pressure and surface area of the buttocks in a static condition varies from patient to patient. Therefore, individual surface customization is needed to adapt each individual body shape and posture.

| Phase 1 | Phase 2 | Phase 3 | Phase 4 | Phase 5 |
|---------|---------|---------|---------|---------|
| Max. Deformation: 0.78 mm | Max. Deformation: 0.85 mm | Max. Deformation: 0.34 mm | Max. Deformation: 0.49 mm | Max. Deformation: 4.3 mm |
| Max. Eq. Stress: 60.54 MPa | Max. Eq. Stress: 73.935 MPa | Max. Eq. Stress: 52.74 MPa | Max. Eq. Stress: 36.09 MPa | Max. Eq. Stress: 4.08 MPa |
Figure 2. Comparison of peak pressure, area and force

The results obtained from the analysis is 4.2911 mm deformation for the applied load of 450 N which is very high as compared other types of mattresses designs and also the stress induced in the new design is 4.0858 MPa which is very less compared to others.

Figure 3. Deformation and stress diagram

Finally the prototype is checked experimentally with emed® to obtain the flexibility, it has high flexibility as compared to other mattresses available in the market as shown in figure 4. It showed that the value of pressure at the interface when the patient is sitting without cushion (118.17 kPa) and with foam type cushion (24.03 kPa), air cushion (21 kPa) and honeycomb cushion (21.41 kPa). However, the developed cushion shows the value of interface pressure is about 19.64 kPa which is very less as compared to the other type of cushions.
This property will help to prevent PU from occurring by distributing the pressure to the sides. The product is developed by combination of Tango Plus and Vero White Plus and their material properties are suitable for washing and sterilization in hospitals. The same prototype can be made up in to a larger scale model to suit the entire body. The scaling must be done by more arrays of the prototype. This will relieve the pressure points on the skin underlying bony regions.

5. Conclusions

Novelty in this work is the unique design of structure used for the innovative flexible mattress, and have not been incorporated in any other mattresses. The prototype model can be scaled up into a bigger size for real time practical experimentation with patients in hospitals. This pressure reducing device can aid in PU prevention. The PU cannot be eliminated completely with this type of pressure reducing device (mattress) but, its occurrence can be slowed down reducing the need for frequent repositioning and healing period phase can be hastened. The novelty in this work is the adoption of AM technique for the development of the prototype for pressure reducing towards ulcer prevention and reduction of interface pressure.
Conflicts of Interest: “The authors declare that they have no conflicts of interest to report regarding the present study.”

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