Prophylactic Dressing for the Prevention of Pressure Ulcers

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Abstract

Pressure ulcers or “bed sores” cause tens of thousands of deaths each year, and significantly impair the lives of many geriatric and spinally impaired people. Due to the tremendous amount of medical costs that pressure ulcers result in, the market for pressure relieving devices is projected to be $2.8 billion in 2020 [1]. The leading contributors to the formation of pressure ulcers include substantial compression, shear stress, and maceration of the epidermis over a significant period of time (~2 hours at minimum),which causes tissue hypoxia. The standard of care for patients at risk for developing pressure ulcers is to turn them over every two hours to ensure that bony processes against the skin (e.g. sacrum, ischium, calcaneus) do not develop pressure ulcers; this is a highly effective, but very costly preventative measure. Device-based solutions such as alternating pressure mattresses are also somewhat effective, but prohibitively expensive for in-home use. One mechanism of preventing the formation of pressure ulcers would be to more evenly distribute pressure applied to bony processes of the skin, minimizing compressive forces against typically affected areas. Most commercial bandages fail to sufficiently distribute pressure because they rely on a thin foam layer for pressure distribution. A novel bandage constructed with a thicker and viscoelastic layer for pressure redistribution is herein proposed to provide a cost-effective method to reduce the incidence of sacral pressure ulcers.

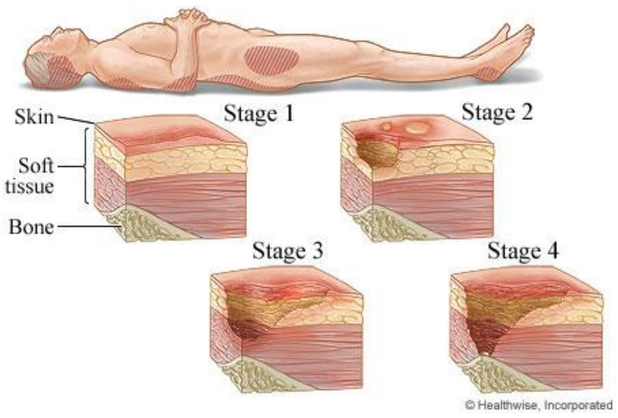

Figure 1: The four stages of pressure ulcer development [2].

Design

The dressing was constructed in a composite design of three major components: the wound contact surface, the inner pressure distribution layer, and the outer layer. The optimal wound contact layer allows for sufficient breathability to prevent maceration, and must be adhesive enough to remain on the skin for a duration of one week while not adhesive enough to cause debridement of the epidermis upon removal. The inner packing layer must adequately redistribute normal pressure forces applied to the epidermis, and must easily deform against shear forces to prevent deformation of the skin. The outer layer must have a sufficiently low coefficient of friction to minimize frictional shear forces applied to the dressing.

Wound contact layer test material: Mepitel Wound Contact Layer
Inner layer test material: Akton viscoelastic polymer
Outer layer test material: Mesh fabric (90% nylon, 10% spandex

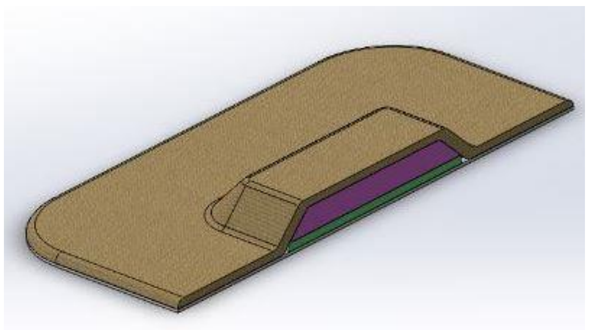

Figure 2: Dressing CAD model. Credit to Dae Hee Yun

Methods

Pressure Redistribution Test: A 4x4 array of force sensors placed in between the model sacrum and the porcine skin was used to approximate pressure distribution in this area (Figure 3). Peak pressure, average pressure and pressure variance were compared between test bandages. Redistribution of pressure away from contact points is necessary to show pressure redistribution.

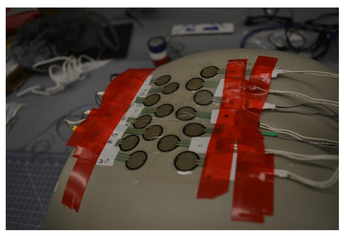

Figure 3: Experimental design of pressure redistribution test.

Deformation Test: 4 stretch sensors were glued to a porcine skin model (Figure 4). A controlled horizontal force was applied along the bandage surface, and the resulting displacement of the skin was measured by strain gauges. The ideal dressing will minimize skin deformation, acting as an intermediate cushion to shear forces acting on the epidermis.

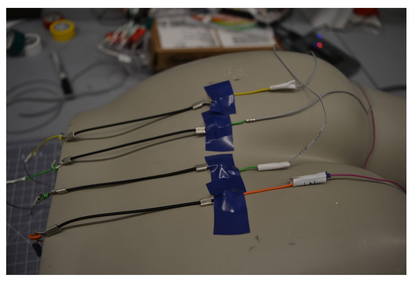

Figure 4: Deformation sensors attached to model sacrum

Results

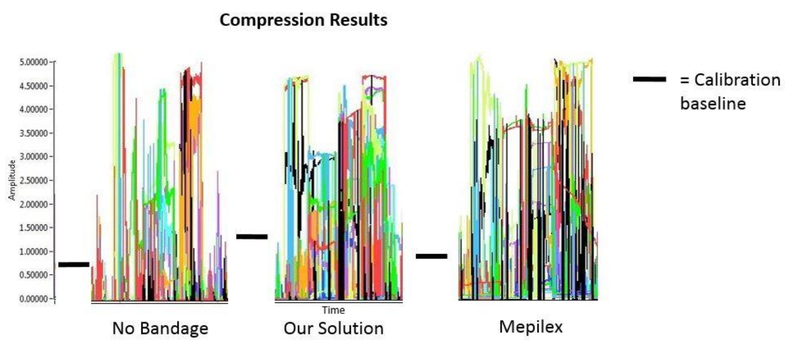

Figure 5: Data from pressure redistribution testing

Figure 6: Data from deformation testing

Future Steps

Adhesive Strength Test: Commonly referred to as a peel test, a tension gauge will be used to measure the amount of force required to remove the test adhesive wound contact layer from a controlled surface. A higher adhesive strength would correlate with greater epidermal insult upon removal of the bandage, so lower adhesive strength will be desired for an optimal bandage design.

Microclimate Test: Both temperature and moisture of skin will be measured to evaluate the heat conductivity and breathability of our bandage. The bandage will be used on real person at the tailbone region. The temperature and humidity sensor will be inserted under bandage by side. It will be a 2-hours test and data is collected every 10 minutes.

Shape design optimization: Shape and deformation of the bandage should redistribute pressure from sites that experience significant compressive forces. Our current dressing is rectangular, but can be redesigned to optimally distribute pressure in common sites of pressure ulcer formation (e.g. sacrum, ischium, calcaneus, back of head, inner leg). The current design, while functional, can be tested functionally and ergonomically against other candidate shapes.

FDA Clearance: Our device is likely to be considered Class 1 and will therefore be exempt from premarket approval, however will need to be properly labeled and manufactured under general controls.

Manufacturing: An adhesive bandage manufacturing system will need to be used as well as equipment to more precisely cut bandage components and package bandage materials.

Marketing & Reimbursement: Our device will need to be correctly coded for reimbursement and marketed to hospitals and assisted living facilities as a low cost disposable bandage to prevent pressure ulcer development.

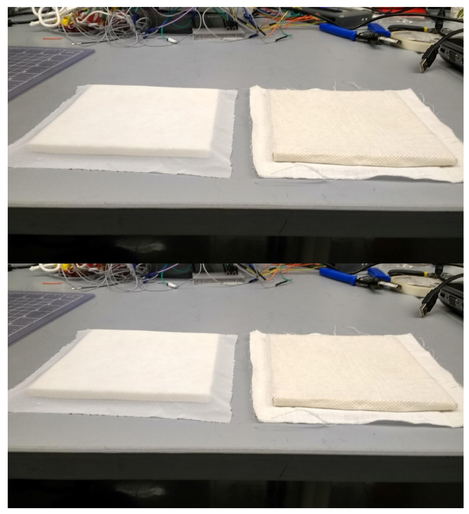

Figure 7: Current prototype of prophylactic dressing.

References

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