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Original Research Article

ReliefP, an automated bedsore prevention device, primary benchtop evaluation

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ABSTRACT

Background: Few disease states ever present themselves to an attainable and near-term solution as pressure ulcers. Bedsore develops when blood supply to the skin is cut off for more than 2 to 3 hours. As the skin dries, bedsore first starts as a red, painful area, which eventually turns purple. Left untreated, skin can break open and the area can become infected.
Method: A set of 50 subjects were identified who are willingly volunteering in the test. As the COVID-19 pandemic has extensively limited access to the hospital and patients, it was decided to conduct the experiment in-house.
Results: For all the 50 volunteers, the device was able to relieve the high-pressure point under the patient heel within 20 mins. The mean time taken is 11 mins 6 sec.
Conclusions: This preliminary study provides some initial data supporting the hypothesis that the RelifP device can identify and relieve the high-pressure area and equalize the pressure throughout. This technology can positively impact prevention in bedsores and reduce the pain and distress borne by the affected patient and caregivers.

Keywords: Pressure ulcer, Bedsore, Prevention, Benchtop testing

INTRODUCTION

Few disease states ever present themselves to an attainable and near-term solution as pressure ulcers. Realizing a goal of preventing preventable pressure ulcers benefits millions of people worldwide who are affected and tens of thousands who die from complications from pressure ulcers on an annual basis. Economic savings through prevention, mostly accruing to public payers, extend to many tens of billions of Euro and Dollars annually.[1]

Bedsores can happen when a person is bedridden or otherwise immobile, unconscious, or unable to sense pain. Bedsores are ulcers that happen on areas of the skin that are under pressure from lying in bed, sitting in a wheelchair, or wearing a cast for a prolonged time. Bedsores are also called pressure injuries, pressure sores, pressure ulcers, or decubitus ulcers.

Bedsores can be a serious problem among frail older adults. They can be related to the quality of care a person receives. If an immobile or bedridden person is not turned, positioned correctly, and given good nutrition and skincare, bedsores can develop. People with diabetes, circulation problems and poor nutrition are at higher risk.

A singular goal-preventing preventable pressure ulcers-when addressed systematically and collectively holds the promise of compelling and sustaining pressure ulcer incidence near zero. Incentivizing prevention and creating

conditions intolerant of pressure ulcer incidence applied to the whole healthcare hierarchy, is the right strategy.

Bedsore develops when blood supply to the skin is cut off for more than 2 to 3 hours. As the skin dries, bedsore first starts as a red, painful area, which eventually turns purple. Left untreated, skin can break open and the area can become infected.

Bedsore can become deep. It can extend into the muscle and bone. Once bedsore develops, it is often very slow to heal. Depending on the severity of bedsores, the person's physical condition, and the presence of other diseases (such as diabetes), bedsores can take days, months, or even years to heal. They may need surgery to help the healing process and may often lead to morbidity.

Bedsores often happen on the: Buttocks area, heels of the feet, shoulder blades, back of the head and backs and sides of the knees.

Unrelieved pressure upon weight-bearing tissues can produce lesions, identified by their etiology as pressure ulcers (AHCPR, 1992). The prevalence of pressure ulcers for elderly nursing home residents has been estimated between 2.3% and 28%. (AHCPR, Brandeis et al, Smith et al and Young et al). The prevalence rate among other populations with mobility impairments is even higher; it has been estimated that between 50% and 80% of persons with spinal cord injury will develop a pressure ulcer; Gosnell, Richardson et al, Rodriguez and Salzberg et al. Even the lowest of these estimates aptly demonstrates that pressure ulcers are a significant health care problem. According to 1999 health care financing administration (HCFA) data, inadequate attention to prevent pressure ulcers was the most frequently cited quality of care deficiency in the long-term care setting Lyder et al.[2]

Experimental data

This study aims to assess the impact of ReliefP product (developed by Medtive research pvt. ltd) on automatic sensing and relieving pressure from 50 subjects' heel of feet in the supine position, with any intervention of healthcare professional

Product description

ReliefP is a fully automated bedsore prevention device, which automatically relieves the high-pressure zone between the contact of patient and the underlying surface. The device assesses the contact pressure between the patient and the underlying contact surface and using its inbuilt software, and using its patented underlying fluid chambers, it inflates the underlying chambers to relieve and redistribute the pressure to a low-pressure zone.

A prototype of the device is developed and tested on 50 subjects to verify if the device can assess the pressure and then fully relieve it.

Material required

The device and tools used to conduct these experiments are as follows: RelifP full functional prototype, a laptop or desktop, minitab software

METHODS

ReliefP has a simple base architecture. The device is equipped with sensors, underlying individually controlled fluid reservoirs, and an MCU box for housing components. The device can transmit the data thru various wireless modules such as bluetooth and Wi-Fi, but for the experiment, we will use a USB connection to ensure the experiment is not interrupted due to any infrastructure-related challenges.

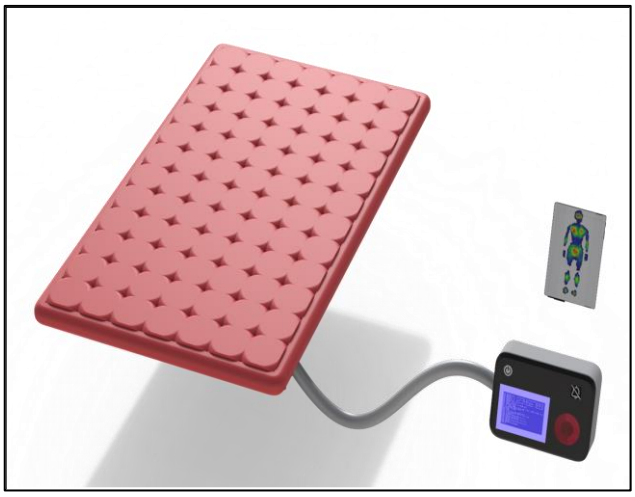

Figure 1: Device.

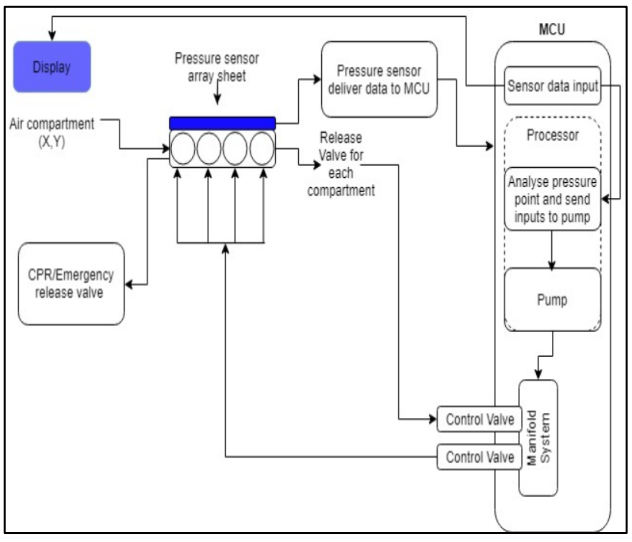

Figure 2: Flowchart of methodology.

A set of 50 subjects were identified who are willingly volunteering in the test. As the COVID-19 pandemic has extensively limited access to the hospital and patient, it

was decided to conduct the experiment in-house under the guidance of Dr. Vimal Kishore Kakani (Emed intensivist with 8 years of experience).

The prospective observational analytic study was conducted on the office premises. The study extended over a period of 7 days (4 to 10 Nov, 2021).

Since the study was conducted on informed volunteers, only verbal consent was taken. The volunteers were informed about the whole procedure and details were listed.

Volunteer age, sex, weight, and highest pressure at heel were recorded before initializing the device.

A maximum time of 20 minutes is set as a limit for the device to achieve pressure equilibrium. In case the device is not able to achieve pressure equilibrium in 20 mins, it will be noted as failed, as the device failed to relieve pressure in the set maximum time.

Ethical approval

The study was conducted in a controlled environment. The subjects are selected voluntarily and post introduction to procedure, a verbal consent was taken. As the study was not conducted for any clinical claim. The procedure only involved a pressure profile check for individuals at various ages and body types. Hence there was no need of ethical approval for the benchtop testing.

Outcome and predictor of success

Volunteers included in the study were noted for age, sex and weight. A pressure map of the volunteer heel is also captured using an inbuilt sensor in the device to observe the pressure distribution of the heel and also to note the highest-pressure point on the total pressure profile.

Statical analysis

Minitab software was used to do statistical calculation and analysis for the dataset.

Outcome variables were compared between the age, sex, weight, highest pressure value before and after the device initialization, time taken by the device to reach equilibrium.

RESULTS

In all the 50 volunteers, the device was able to relieve the high-pressure point under the patient heel within 20 mins. The mean time taken is 11 mins 6 sec.

The mean age of volunteers was 49.4 years, a total of 18 volunteers were between 28 to 40 years, 21 were between 40 to 60 years and 11 were above 60 years, out of which 23 were female and 27 were male with a mean weight of 74.9 kg.

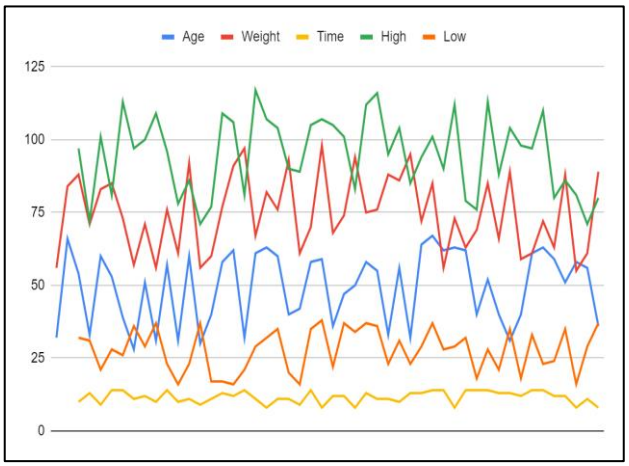

Figure 3: Study group age, weight, and measured data.

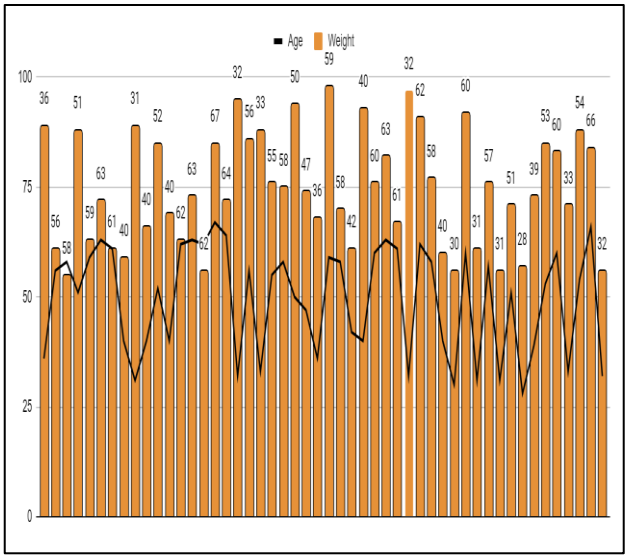

Figure 4: Age (line), weight (Bar) graph.

The mean highest pressure was 94.4 mmHg, ranging from the lowest pressure at 70 mmHg to the highest pressure of 120 mmHg when measured at the initiation of the device.

The mean highest pressure was 27.4 mmHg, ranging from the lowest reading of 16 mmHg to the highest at 38 mmHg when measured after the ReliefP device has equalized the pressure profile.

DISCUSSION

Bedsore is a preventable condition, but the prevention therapy is left out at the mere blind guess based on theoretical judgment rather than to an actual evidence-based prevention care. Numerous studies have been conducted, which pointed out that a method of pressure visualization will greatly impact the bedsore prevention

care. Pickenbrock et al conducted a study to compare the conventional method with the pressure visualization and concluded that the pressure visualization system provides better control in delivering targeted care.[3] Another detailed review conducted by Lyder et al pointed out that proper mechanical unloading of the high-pressure zone can reduce the incidence to a minimum.[4] On a similar idea, the product was developed to identify and display live pressure profiles of the patients. The study was conducted to validate the device output in a benchtop study. The ReliefP device was able to visualize the pressure profile and it was able to relive the high-pressure point in the given stipulated time. This evidence that ReliefP addresses the total care of pressure visualization with the functionality to relieve the high-pressure point.

CONCLUSION

This preliminary study provides some initial data supporting the hypothesis that the RelifP device can identify and relieve the high-pressure area and equalize the pressure throughout. This technology can positively impact prevention in bedsores and reduce the pain and distress borne by the affected patient and caregivers.

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Ethical approval: Not required

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