Evaluation of the HeelSphere for the Prevention and Treatment of Pressure Injuries

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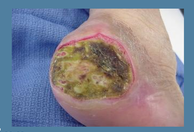
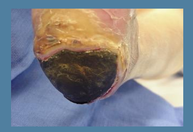
Background

Hospital-acquired pressure injuries (HAPIs) affect approximately 2.5 million individuals every year in United States acute care facilities. These injuries represent a substantial burden, with costs exceeding $26.8 billion and contributing to around 60,000 fatalities each year. Pressure injuries are particularly complex, often affecting the foot and leading to severe complications such as infection, osteomyelitis, sepsis, limb loss, and death. Effective heel offloading is essential for both prevention and treatment; however, current devices in the market exhibit significant shortcomings, including inefficient offloading and cumbersome designs. The HeelSphere is a newly patented medical device designed to address these gaps. The authors have conducted a clinical study to evaluate the effectiveness, safety, and comfort of this innovative device.

Problem

Hospital-acquired tissue injuries present a significant challenge to healthcare quality and impose a substantial economic burden. A recent article in the International Wound Journal emphasizes the need for hospitals to invest in quality improvement for early detection and prevention to mitigate these costs.() Notably, the heel accounts for 20-30% of these injuries, highlighting the critical need for effective offloading strategies. Current offloading methods, ranging from simple pillow placement under the calves to various medical devices often suffer from significant shortcomings:

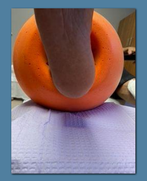
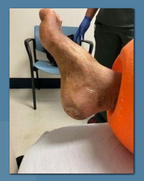
- Inefficient offloading
- Inconsistent application
- Improper positioning
- Immobility
- Device-related tissue injuries


Solution

The design of this newly patented device is a global foam sphere that is applied to the leg above the ankle to offload the heel effectively and reduce heel contact with the bed surface. The spherical design allows movement and gentle support; internal fluting allows for breathability and airflow, thus reducing moisture buildup. There are no straps. Its clamshell design allows for intuitive applications as well as removal. Wounds can be easily observed by healthcare personnel. Contemporary methods of treatment of foot and ankle ulcerations are facilitated by this device, i.e., grafting and wound vac applications. The device's technology also includes "smart" functionality via integrated sensors.



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Market

There is a robust market opportunity for products designed to address pressure injuries. The global all-site projections for treatment in 2026 are $11.2 billion. Projected estimates for diabetic pressure ulcers by 2025 are over $5.2 billion. The average cost of treatment of an unstageable pressure injury for a facility ranges from $75,000 to $150,000. Additionally, quality issues and the risk of potential litigation further underscore the urgent need for effective solutions in this market.

Study

An IRB-approved user study was conducted in a community hospital, adhering to predefined patient selection criteria. The study involved 28 inpatients, with data collected on multiple parameters over 72 hours. Participants were randomly assigned to receive the same device with two different material densities. The primary aims of the study were to assess the effectiveness and consistency of offloading related to positioning and to evaluate the safety and comfort of the device.

Results

The HeelSphere statistically demonstrated effective heel offloading, with 93% of patients reporting comfort while using the device. Notably, no issues or injuries were associated with its use during the study. Feedback from healthcare personnel indicated that the device was user-friendly and provided efficient offloading. Some slight variations in effectiveness were observed between the two material densities, which appeared to correlate to the patient's BMI.

The authors conclude that the HeelSphere is effective for preventing and treating HAPIs. Key advantages of its design include its unique global shapes, strapless application, appealing color, ease of use, compatibility with modern treatment modalities, and sensor capabilities. Additionally, the device is vacuum-packed, facilitating easier accessibility and storage.

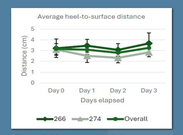

Figure 1: Measurement of distance between the heel and surface of the device over time.

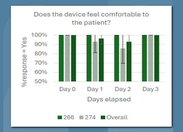

Figure 2: Patient reported device comfort over time. Error bars display the 95% 1-proportion confidence interval for non-unanimous answers.

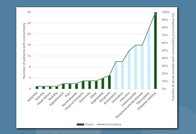

Figure 3: Reported comorbidities and pre-existing conditions, collected from patient interviews.

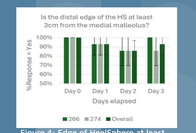

Figure 4: Edge of HeelSphere at least 3cm from medial malleolus