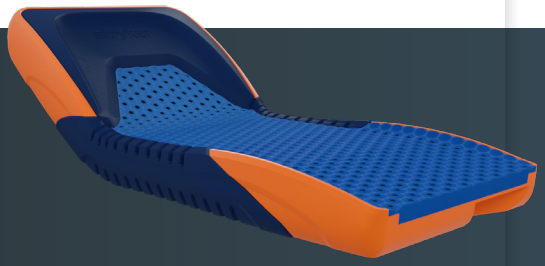
stryker

An Observational Study[1]



Evaluating the safety and performance of a powered gel-support surface system in **effectively reducing HAPUs/HAPIs in the acute care setting as part of a bundle of care**

Summary

Hospital acquired pressure ulcers (HAPUs), also known as pressure injuries, are a major burden for patients and caregivers as they can increase discomfort, length of stay, cost, morbidity and mortality.

This liability is impacted by the incidence rate of pressure ulcers, commonly found to range from 7.8% to 54% worldwide (Shi et al., 2021)[5]. A comprehensive bundle of care helps prevent and treat pressure ulcers as mentioned in the EPUAP/NPIAP/PPPIA 2019: Prevention and Treatment of Pressure Ulcers/Injuries: Clinical Practice Guideline.

This bundle of care includes the support surface that the patient is placed on for the duration of their stay. For this study, a retrospective survey-based approach was used to determine the impact of the IsoTour Support Surface System, when implemented as part of a bundle of care, to assist in the treatment and prevention of pressure ulcers.

The survey was designed to determine safety and performance of the device, score the usability of the device, detect risk factors, identify additional mitigation techniques and collect real world data.

We found that a statistically significant proportion of patients entering the care setting with existing pressure ulcers experienced a reduction in severity ($p < 0.001$). Further, 95.8% of the total patient pool ($n = 313$) did not develop a new pressure ulcer by the end of treatment ($p < 0.05$). Additionally, healthcare providers indicated they also value the IsoTour System, as 98% rated the usability of the system as 'Acceptable' or better.

Altogether, this study illustrates how the IsoTour System, when implemented as part of a comprehensive care strategy, can help treat and prevent pressure ulcers and ease the burden of healthcare providers.

Background

Patients experiencing HAPUs/HAPIs face decreased quality of life including progressively increased length of stay, increased costs, and higher readmission rates. Additionally, patients with HAPUs/HAPIs experience heightened morbidity and mortality rates. The negative impact also falls onto the health care providers as cost and longer lengths of stay add further burden to already strained hospital staff. Thus, HAPUs/HAPIs negatively impact the quality of recovery for patients and patient care delivery by caregivers.[1]

The European Pressure Ulcer Advisory Panel, National Pressure Injury Advisory Panel and Pan Pacific Pressure Injury Alliance (EPUAP/NPIAP/PPPIA) Prevention and Treatment of Pressure Ulcers/Injuries: Clinical Practice Guideline (2019) defines pressure injuries as 'localized damage to the skin and/or underlying tissue, as a result of pressure or pressure in combination with shear' (NPIAP Guidelines, 2019)[2]. Several factors can influence pressure injury formation but can be summarized into two main categories:
1) a patient's status (bodyweight, age, soft tissue condition and various comorbidities) and
2) mechanical load (time, degree, and type) (Coleman et al., 2014; NPIAP Guidelines, 2019).[2,3]
Typically, a pressure injury is the result of soft tissue deformation due to body weight and/or prolonged contact with a medical device.

Pressure Injuries/Pressure Ulcers can range in severity and can result in a pressure injury, which can range in severity from Stage I (defined by intact skin and non-blanchable redness in a localized area) to Stage IV (full tissue loss with exposed bone, muscle, or tendon). Some pressure injuries are graded as 'Unstageable,' where full tissue loss with a slough covering prevents complete staging, or 'Deep Tissue Injury' where an internal wound occurs under otherwise intact skin (Edsberg et al., 2016; NPIAP Guidelines, 2019). Pressure ulcers occur when there is a lack of blood flow, and typically develop in patients that are confined to a bed or wheelchair, but can also be caused by a cast, splint, poorly fitting prosthetic device or other medical devices.

Support surfaces are one of the major medical device interventions associated with mitigating risk of pressure injuries. Patients lie on support surfaces during their hospital stays. Support surfaces are specialized devices for pressure redistribution designed for management of tissue loads, microclimate, and/or other therapeutic functions (i.e., any mattress, integrated bed system, mattress replacement, overlay, or seat cushion, or seat cushion overlay)[2]. Support surfaces are an important element in pressure injury prevention and treatment because they help prevent tissue deformation and provide an environment that helps enhance blood flow to at-risk or injured tissue. Support surfaces can be made using various materials such as air, foam, and gel. Sometimes, more than one of these materials is used to in the design of a support surface.

Technological advances have led to the development of powered support surfaces, which include temperature management, moisture management and turning features, among other attributes. Support surfaces should always be implemented with individualized and comprehensive management plans for pressure injury prevention and treatment of a patient. Ongoing studies are dedicated to researching the impact of support surface design in the prevention and treatment of pressure injuries. These studies are instrumental to bridging a current gap in the field in determining the best strategy to limit HAPUs/HAPIs.

The industry has had a long history of using powered foam, foam-air combination, and fluidized air-bead surfaces. However, research on gel surfaces is nonexistent within the state of the art. This study focused on bridging this gap in clinical knowledge. The aim of this study was to evaluate safety and performance of the IsoTour powered gel support surface system in the context of pressure injuries. Specifically, this study observed the incidence rate of new pressure ulcers and tracked pressure ulcer severity during treatment. To this end, a retrospective survey-based study was performed where feedback was collected from healthcare professionals that used the IsoTour system in the last six months.

Results

A total of 313 surveys were completed from nine countries including Canada, France, Germany, Kuwait, Poland, Qatar, Saudi Arabia, UK, and USA. About half (n = 152) of the 313 patients were free from pressure ulcers at the time of admission. The other 161 patients were admitted with an existing pressure ulcer acquired in the community.

As previously stated, the objective of this study was to determine the safety and performance of the IsoTour System when used as part of a bundle of care in the treatment and prevention of pressure ulcers. To this end, we analyzed the 158 patient cases for treatment of existing pressure ulcers by calculating the change in pressure ulcer staging (Figure 1). Many patients (n = 122, 78%) were Stage 3 or greater (Stage 3+) and 22% (n = 35) were Stage 0-2 upon admission. Of the total number of patients admitted with a Stage 0-2 PU, 46% experienced a reduction in severity while of the total number admitted with a Stage 3+ PU, 69% experienced a reduction in severity ($p < 0.001$).

Reduction of severity is described as an observed improvement in mobility, reduction of wound volume and wound leakage. Overall, after being placed on the IsoTour System, in addition to the other mitigating strategies employed such as turning the patient, avoidance of incontinence and wound debridement, 68% of patients improved in their condition, (Figure 2).

Next, to determine the performance in terms of prevention of pressure ulcers, the new pressure ulcer incidence rate was analyzed using the entire patient population. While the average length of stay on the IsoTour System was 26.14 (max 66.4 and min 7) days the incidence rate of new pressure ulcers was 4.2% (n = 13 of 313 patients); thus, 95.8% of cases saw no new pressure ulcers ($p < 0.05$; 95% confidence interval 93.0% - 97.8%) (Figure 3 and 4).

Additionally, Usability of the device was evaluated based on a 5-point Likert scale (0 = 'Very good' to 4 = 'Very poor'). Survey results indicated 93% of respondents scored the IsoTour System as 'Very good' or 'Good' with a mean score of 0.42. Using the Clopper Pearson method, the usability of the device can be expected as 'acceptable', 'good' or 'very good' with a certainty of 98.4% (95% confidence interval 96.3 – 99.5%) (Figure 5).

Figure 5: IsoTour Support Surface System Usability ranking results from Likert Scale Survey of Healthcare Professionals.

Conclusion

The use of the Stryker's IsoTour System (IsoTour Gel Support Surface and IsoTour Pump) when used with other mitigating strategies (turning, avoidance of incontinence and wound debridement) was shown to benefit patients regarding pressure ulcer treatment and prevention. Additionally, the IsoTour System has a strong usability score amongst healthcare providers.

The outcomes of using a powered surface are influenced by other factors such as the healthcare setting, weight of patient, level of immobility and inactivity of the patient and locations of and numbers of pressure injuries in a patient. These limiting factors were considered when analyzing the data gathered from the survey and influence our key takeaways from this study: that the IsoTour System can help reduce HAPU/HAPIs in the acute care setting by up to 95.8% compared to the standard of care when implemented as part of an overall pressure ulcer and patient risk management program.

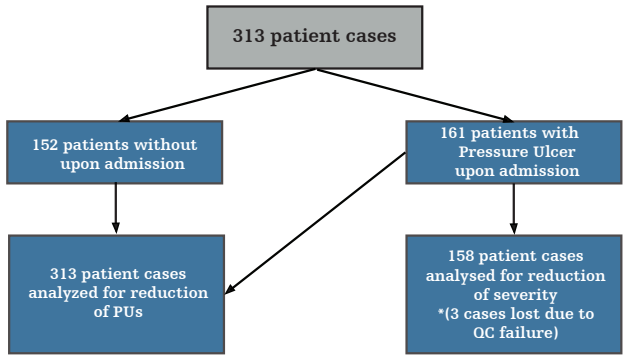


Figure 1: Division of patients analyzed during the survey study.

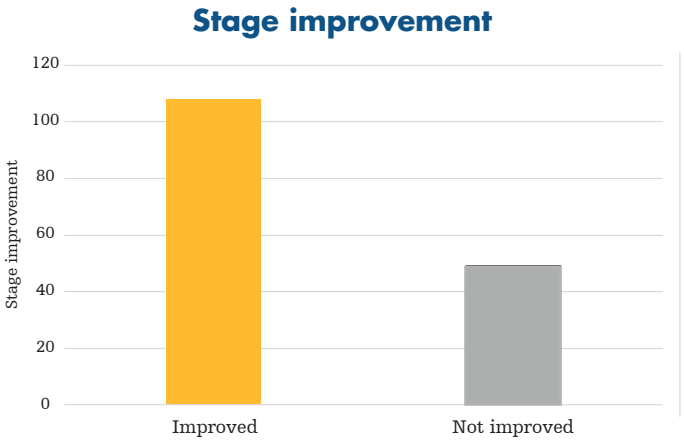


Figure 2: Pressure ulcer stage improvement.

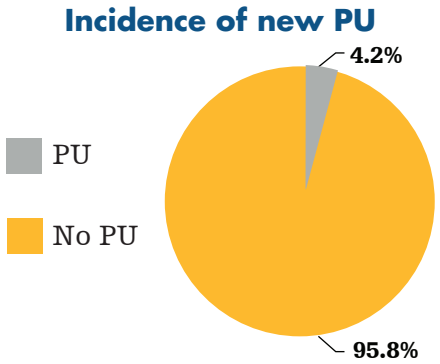


Figure 3: Incidence rate of new pressure ulcers (PUs). (n = 313 total patients).

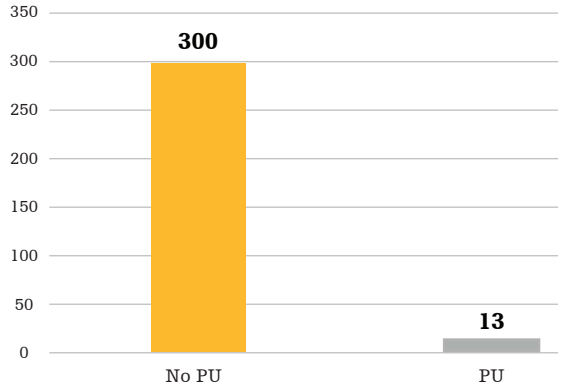


Figure 4: Incidence of new pressure ulcers (PUs). ($p < 0.05$)

References: 1.Stryker data on file **2.** European Pressure Ulcer Advisory Panel, National Pressure Injury Advisory Panel and Pan Pacific Pressure Injury Alliance. Prevention and Treatment of Pressure Ulcers/Injuries: Clinical Practice Guideline. The International Guideline. Emily Haesler (Ed.). EPUAP/NPIAP/PPPIA: 2019. **3.** Coleman, S., Nixon, J., Keen, J., Wilson, L., McGinnis, E., Dealey, C., Stubbs, N., Farrin, A., Dowding, D., Schols, J.M. and Cuddigan, J., 2014. A new pressure ulcer conceptual framework. Journal of advanced nursing, 70(10), pp.2222-2234. **4.** Edsberg, L.E., Black, J.M., Goldberg, M., McNichol, L., Moore, L. and Sieggreen, M., 2016. Revised national pressure ulcer advisory panel pressure injury staging system: revised pressure injury staging system. Journal of Wound Ostomy & Continence Nursing, 43(6), pp.585-597. **5.** Shi, C., Dumville, J.C., Cullum, N., Rhodes, S., Jammali-Blasi, A. and McInnes, E., 2021. Alternating pressure (active) air surfaces for preventing pressure ulcers. Cochrane Database of Systematic Reviews, (5).

05/2024
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