

Healing of a chronic stage 4 sacral pressure injury in a paralyzed spinal cord injury patient using a novel, non-invasive perfusion enhancement system: a case study

¹Linda Seaman , ²Erica Kelly

Abstract

Introduction: Pressure injuries (PIs) are a common and costly complication that can result in severe pain, increased length of stay, and decreased quality of life. PI incidence is higher in those who have chronic health conditions resulting in impaired mobility. Patients with spinal cord injuries (SCI) are among the highest risk patients for developing PIs due to associated motor and sensory impairment

Case Presentation: 64-year-old gentleman sustained a level 4 cervical spine fracture with incomplete cord injury and subsequent paraplegia and impaired sensation. After the acute and rehabilitative treatment and therapy, the patient was admitted to a skilled nursing facility for continued long-term care. The patient was diagnosed with a Stage 4 (PI), initially treated with sharp surgical debridement and negative pressure wound therapy (NPWT). After 132 days, a novel, non-invasive perfusion enhancement (NIPE) system was introduced, utilized both on the bed and wheelchair. Complete healing of the Stage 4 PI occurred in 118 days after initiation of the system.

Conclusion: A non-invasive perfusion enhancement system (NIPE) used in supplement to standard treatment measures is beneficial to the healing of a Stage 4 PI. Additional subjective data suggest that the system is also effective for reducing pain associated with pressure injury and mobility impairment.

Keywords: Pressure injuries, ischemia, vasocompression, non-invasive perfusion enhancement system

Introduction

Pressure injuries (PIs) are a common, significant health issue, particularly in patients with chronic conditions that impair mobility. In the United States, it is estimated that 2.5 million patients suffer from PIs annually.¹ Patients with spinal cord injury (SCI) are among the highest risk patients for developing PIs due to associated motor and sensory impairments. More than 50% of people with SCI develop a PI at some point in their lives.²

A PI is defined as localized damage to the skin and/or underlying tissue, typically over a bony prominence.³ PIs vary in severity from intact skin, to partial thickness skin loss, to open ulcers that extend to subcutaneous fat or further into bone, tendon, or muscle.⁴ PIs result in decreased quality of life for patients and families, increased mortality, and higher healthcare costs.⁵

On average, US healthcare institutions spend \$20,000 to \$150,000 to treat individual PIs.¹ PI are also one of the highest litigated hospital-acquired conditions, with 17,000 lawsuits filed annually and 83% settled in favor of the plaintiff.⁶ Treatment costs increase with wound severity, with Stage 3 and Stage 4 PIs being most expensive. Brem and colleagues⁴ found that the cost of a Stage 4 hospital-acquired PI patient averaged \$129,248 during a single hospital stay. Stage 3 and 4 PIs often require complex, costly wound care interventions, such as negative pressure wound therapy (NPWT), frequent dressing changes, specialty surfaces, and

sharp, surgical, or enzymatic debridement.⁷ Despite extensive treatment, Stage 3 and 4 PIs typically require an excessive amount of time to heal, the majority taking greater than 8 weeks to heal completely.⁸

Currently, there is a growing body of evidence supporting reperfusion injury following periods of ischemia as a probable cause of pressure injury.⁹ Tissue ischemia occurs when vascular compression is sustained for a critical duration, leading to the build-up of toxic metabolites and depletion of oxygen and nutrients.¹⁰ Tissue reperfusion following periods of ischemia is necessary to re-establish oxygen and nutrient delivery, however it can elicit pathogenic processes that exacerbate local insult and induce pressure injury formation.¹¹⁻¹⁵ It is plausible that reperfusion injury can also have a detrimental effect on the healing of a pre-existing pressure injury through this same process. Thus, an intervention focused on minimizing vascular compression to prevent ischemia and reperfusion injury would be beneficial for PI treatment by preventing wound advancement and promoting optimal tissue perfusion for healing.

A new non-invasive perfusion enhancement (NIPE) system (The TurnCare Guardian System) has been shown in previous studies to benefit both the prevention and treatment of pressure injuries.^{9,16} The system involves the unique application of pressure gradients throughout a 3-dimensional, multichannel inflatable support surface on the sacral region. Rather than redistribute or alternate pressure, the system continuously applies and removes pressure in a precise, non-repeating fashion through the inflation and deflation of narrow, anatomically-aligned and shaped air chambers. This mechanism is intended to prevent sustained vascular compression and therefore enhance tissue perfusion. The novel system is designed specifically to simulate healthy movement to avoid sustained vascular compression for a critical duration. By preventing vascular compression, blood flow is reliably increased to the tissues, enhancing perfusion essential for wound healing.

Case Presentation

We report a case of a 64-year old male patient who has an incomplete level 4 cervical spinal cord injury with a Stage 4 pressure injury, treated using a novel, NIPE system (The TurnCare Guardian System).

The patient has a past medical history significant for hyperlipidemia, atherosclerotic heart disease, peripheral vascular disease, hypertension, and smoking. On June 5th, 2017, he suffered a Level 1 trauma: fall with a subsequent C4 spinal fracture and incomplete cord injury with paraplegia and impaired sensation. The C4 injury required decompressive lumbar laminectomy. Treatment included ICU care due to spinal shock and ventilatory support post injury. After his acute injury he was transferred to an acute rehab facility for aggressive therapy.

During his acute rehab stay, the patient developed a Deep Tissue Injury (DTI), documented on discharge as being covered in necrotic tissue. The patient was transferred to a skilled nursing facility, where he was evaluated by a wound care surgeon. An accurate assessment of the wound area was made by conducting a thorough evaluation of the size, depth, presence of granulation tissue, wound edges, skin temperature, and exudates and/or necrosis. On September 20, 2017, a conservative excisional debridement was performed with sharp surgical scissors due to the presence of nonviable necrotic tissue. The patient was diagnosed with a Stage 4 pressure injury with the initial measurement of 4.5 cm x 3.0 cm x 3.2

cm. Following debridement, negative pressure wound therapy (NPWT) was initiated. Additional treatment included increased nutritional support and offloading measures.

The interdisciplinary wound team at the study facility was seeking additional treatment options due to the persisting chronic wound with poor granulation and the patient's worsening pain. A novel, NIPE system was selected to enrich the blood supply to the starved tissues. Many treatment options were available, such as an air-fluidized bed, but the NIPE system was chosen. The NIPE system was clinically easy to use, was able to be utilized on multiple patient surfaces (bed and wheelchair), which in turn prevented mobility restrictions that the other surfaces impose. The team was compelled to implement additional wound management therapy that had the propensity to impact not only the wound healing trajectory, but also the patient's overall well-being. The NIPE system was introduced on January 3, 2018 with the sacral wound measuring 2.0 cm x 1.3 cm x 0.6 cm at the time of initiation. Wound care was provided per facility protocol and physician direction, including sequential wound measurements.

The NPWT was discontinued on January 10, 2018 and a collagen/oxidized regenerated cellulose (ORC) dressing was initiated on January 10, 2018. Proliferation of healthy granulation tissue was observed throughout the duration of use of the NIPE system, with a consistent decrease in pressure ulcer size, which was measured monthly by the wound care physician (Figure 1). Within days, staff noted improvement in the appearance of the wound and its surrounding tissue, as well as the overall skin health in the sacrococcygeal area. Tracking the healing percentage of wound volume per month showed a positive healing trajectory (Figure 2). The Stage 4 PI of this SCI patient healed within 118 days of initiation of the perfusion enhancement therapy without any complications. No additional treatment for this patient is anticipated, except for continued use of the non-invasive perfusion enhancement system and collagen/ORC dressing.

Prior to initiation of the non-invasive perfusion enhancement therapy, the patient was assessed by the research team. The patient's pain level was assessed using a Numeric Pain Scale from 0-10. The patient reported that his pain on average was an 8/10, resulting in poor tolerance to manual repositioning, requiring the regular use of controlled substances for pain management. In addition to significant pain, the patient also reported an overall decrease in perceived wellbeing and mood. These factors all contributed to nightly disrupted sleep patterns. The patient was desperate for a solution that would help alleviate the pain from his persisting wound.

Informal staff interviews were performed with licensed and non-licensed professionals, validating the aforementioned patient report. In addition, the staff reported the patient frequently requested to be repositioned in bed due to pain and discomfort. They witnessed and validated his feelings of desperation regarding the constant pain from his wound. Staff reported that the patient had specific requests and preferences for positioning when out of bed. At the patient's request, his wheelchair was frequently in the tilted position, increasing the shearing force on the sacrococcygeal area.¹⁶ Of note, the SCI patient spent minimally 5 hours per day out of bed in a wheelchair.

A week post-initiation of the NIPE system, the patient's pain level was re-assessed using a Numeric Pain Scale from 0-10. He was both happy and emotional to report a substantial decrease in pain level, providing a rating of 3/10. His pain was assessed weekly thereafter, with pain levels ranging from 0-2/10 consistently each week. The patient also reported a significant improvement in his sleep and sense of well-being.

Follow-up discussion with staff revealed a notable decrease in the amount of pain medication needed. Staff also reported improved sleep patterns, improved social interaction and overall disposition, and a decrease in requests to be manually repositioned. In general, staff were surprised by how quickly and profoundly the patient's pain and overall demeanor improved. The SCI patient continued to spend minimally 5 hours per day out of bed, with his wheelchair in a tilted position. Additionally, staff were generally pleased with the ease of use of the perfusion enhancement system, reporting minimal impact on clinical workflow.

Discussion

In this case report, we have described the experience and continued results of a novel, non-invasive perfusion enhancement system in the setting of a SCI patient with a Stage 4 PI. The NIPE system is designed to restore the benefits of healthy movement through the continuous application and removal of pressure to avoid sustained vascular compression for a critical duration. Our findings suggest that a non-invasive perfusion enhancement system can be beneficial to the healing of full-thickness pressure injuries and may minimize the need for additional, costly wound management therapies, which in turn can have significant cost-reduction implications.

Pressure injuries develop due to the external application of pressure leading to sustained vascular compression. Tissue ischemia occurs when vascular compression is maintained for a critical duration, resulting in impaired blood flow and subsequent depletion of oxygen and nutrients with an accumulation of toxic metabolites. Reperfusion injury following ischemia further injures the already damaged tissues.

Wound healing is a complex process that requires optimal tissue perfusion. However, maintaining tissue perfusion in PI healing is a challenge due to the high-pressure locations of the wounds over bony prominences. Current standard-of-care protocols focus on pressure-relieving strategies, such as manual repositioning schedules and alternating pressure surfaces, and mitigation of contributing factors, such as shear, friction, and microclimate.^{17 18} Prior to this case study, there has been no report of a technology designed to target underlying ischemia and promote tissue perfusion for the treatment of full-thickness wounds.

Conclusion

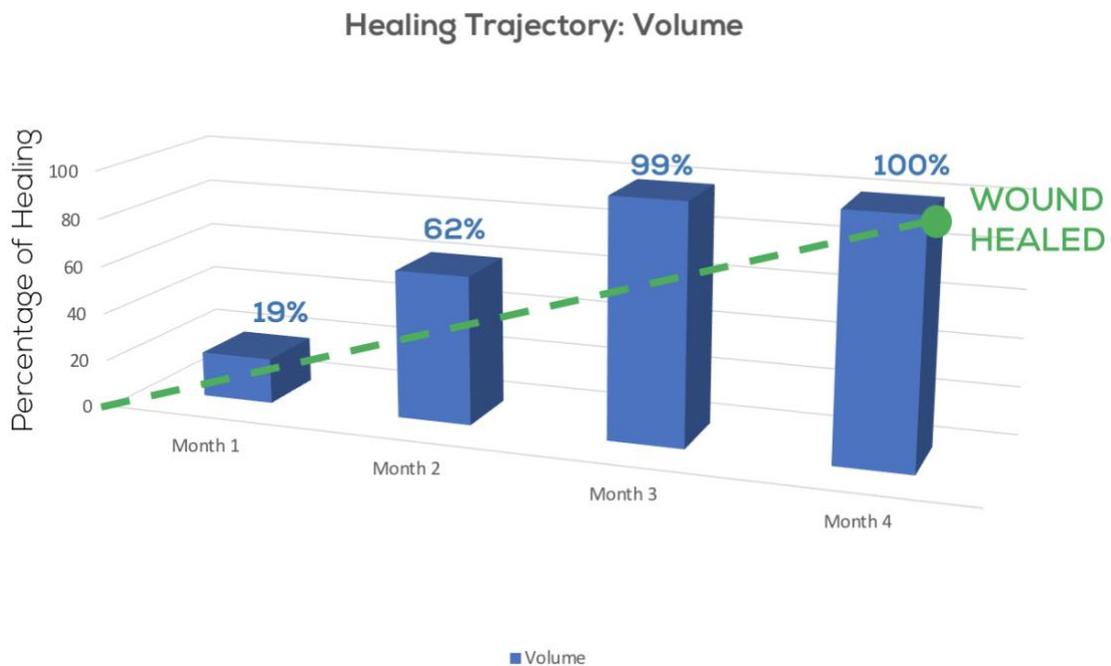
We found that a non-invasive perfusion enhancement system used in supplement to standard treatment measures is beneficial to the healing of a Stage 4 pressure injury. Additional subjective data suggest that the system is also effective for reducing pain associated with pressure injury and mobility impairment.

Figure 1.

Table 1.
Healing Trajectory of Stage 4 Pressure Injury: Volume

Date	Length (cm)	Width (cm)	Depth (cm)	Volume (cm ³)	Percentage healed from previous month	Percentage healed from initiation of perfusion enhancement therapy (January)
January	2.0	1.3	0.6	1.6	39%	N/A
February	2.2	1.2	0.5	1.3	19%	19%
March	1.5	1.0	0.3	0.5	62%	69%
April	0.3	0.1	0.2	0.006	99%	99%
May	0.0	0.0	0.0	0.0	100%	100%

Figure 2



Consent

Written informed consent was obtained from the patient for publication of this case report

Abbreviations

PIs: Pressure injuries; SCI: Spinal cord injury; NPWT: Negative pressure wound therapy; NIPE: Non-invasive perfusion enhancement; ORC: Oxidized regenerated cellulose

Competing interests

The authors declare that they have no competing interests

Authors' Contributions

LS was a major contributor in writing the manuscript. LS was responsible for the acquisition of data and performing assessments and interviews. LS assisted with analysis and interpretation of data. EK was a major contributor in writing the manuscript. EK assisted with extrapolation, analysis and interpretation of data and created graphs and tables. Both authors read and approved the final transcript

Author Details

¹Linda Seaman, MSN, BSN, RN, CCRN, TurnCare Inc, Palo Alto, California

²Erica Kelly , MOT, OTR/L, TurnCare Inc, Palo Alto, California.

References

1. Berlowitz, D., Lukas, C. V., Parker, V., Niederhauser, A., Silver, J., & Logan, C. (2012). Preventing Pressure Ulcers in Hospitals: A Toolkit for Improving Quality of Care. Rockville, MD: Agency for Healthcare Research and Quality; 2011.
2. Sonenblum, S. E., & Sprigle, S. H. (2018). Buttock tissue response to loading in men with spinal cord injury. *PloS one*, 13(2), e0191868.
3. National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel and Pan Pacific Pressure Injury Alliance. Prevention and Treatment of Pressure Ulcers: Clinical Practice Guideline. Emily Haesler (Ed.) Cambridge Media; Osborne Park, Western Australia. 2004.
4. Brem, H., Maggi, J., Nierman, D., Rolnitzky, L., Bell, D., Rennert, R., ... & Vladeck, B. (2010). High cost of stage IV pressure ulcers. *The American Journal of Surgery*, 200(4), 473-477.
5. Agency for Healthcare Research and Quality (A.H.R.Q.). (2014, October). *Are We Ready for this Change?* Retrieved from: <http://www.ahrq.gov/professionals/systems/hospital/pressureulcertoolkit/putool1.html>
6. Berlowitz, D., & Schmader, K. E. (2017). Clinical staging and management of pressure-induced skin and soft tissue injury. *UpToDate*.
7. Peirce, S. M., Skalak, T. C., & Rodeheaver, G. T. (2000). Ischemia- reperfusion injury in chronic pressure ulcer formation: a skin model in the rat. *Wound repair and regeneration*, 8(1), 68-76.
8. Agrawal K, Chauhan N. Pressure ulcers: back to the basics. *Indian J Plastic Surg*. 2012;45(2):244
9. Bharucha, J. B., Seaman, L., Powers, M., Kelly, E., Seaman, R., Forcier, L., ... & Nodiff, S. (2018). A Prospective Randomized Clinical Trial of a Novel, Noninvasive Perfusion Enhancement System for the Prevention of Hospital-Acquired Sacral Pressure Injuries. *Journal of wound, ostomy, and continence nursing: official publication of The Wound, Ostomy and Continence Nurses Society*.
10. Peirce SM, Skalak TC, Rodeheaver GT. Ischemia-reperfusion injury in chronic pressure ulcer formation: a skin model in the rat. *Wound Repair Regen*. 2000;8(1):68-76.
11. Jiang LP, Tu Q, Wang Y, Zhang E. Ischemia-reperfusion injury-induced histological changes affecting early stage pressure ulcer development in a rat model. *Ostomy Wound Manage*. 2011;57(2):55-60.
12. Eltzhig HK, Eckle T. Ischemia and reperfusion—from mechanism to translation. *Nat Med*. 2011;17(11):1391.
13. Loerakker SE, Manders GJ, Strijkers K, Nicolay FP, Baaijens Bader DL, Oomens CW. The effects of deformation, ischemia, and reperfusion on the development of muscle damage during prolonged loading. *J Appl Physiol*. 2011;111:1168-1177.
14. Cui FF, Pan YY, Xie HH, et al. Pressure combined with ischemia/ reperfusion injury induces deep tissue injury via endoplasmic reticulum stress in a rat pressure ulcer model. *Int J Mol Sci*. 2016;17(3):284.
15. Kobara, K., Osaka, H., Takahashi, H., Ito, T., Fujita, D., & Watanabe, S. (2014). Effect of rotational axis position of wheelchair back support on shear force when reclining. *Journal of physical therapy science*, 26(5), 701-706.
16. Bharucha, J. B., Spriglio, R., Akopyants, S., Conelias, J., Conway, T., Bazonski, E., . . . Mishler, L. (2017). *Treatment of stage 2 sacral pressure ulcers with a novel perfusion enhancement surface (Q2 system – TurnCare, Inc.): Results of an initial feasibility study*. Manuscript in preparation.
17. National Pressure Ulcer Advisory Panel. Pressure injury prevention points. <http://www.npuap.org/resources/educational-and-clinical-resources/pressure-injury-prevention-points>. Published 2016. Accessed February 1, 2018.
18. Edsberg LE, Langemo D, Baharestani MM, Posthauer ME, Goldberg M. Unavoidable pressure injury: state of the science and consensus outcomes. *J Wound Ostomy Continence Nurs*. 2014;41(4):313-334