NelDerm® Heel P.O.D.™ versus Pressure Relief Ankle Foot Orthosis: A Preliminary Investigation

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Study Design:

The National Pressure Ulcer Advisory Panel defines a pressure ulcer as an area of localized tissue damage affecting the skin and subcutaneous tissues owing to pressure, shear, friction, or a combination of these factors[1]. The heel is the most common site of facility acquired pressure ulcers[2]. These ulcers pose a major health concern for critically ill and bed bound patients in hospital wards, long term acute care hospitals, and skilled nursing facilities. In the United States, pressure ulcers account for approximately 2.5 million hospitalizations and costs the health system between $9.1-$11.6 billion annually[3].

Pressure ulcer formation is driven by both internal and external contributing factors. Internal factors include malnutrition, hypoperfusion, and underlying diseases which can lead to immobility. External factors include direct pressure, temperature changes, friction, shear forces, and moisture[4]. Oftentimes these patients suffer from comorbid conditions, such as diabetes mellitus or peripheral vascular disease, which interrupt the regular macro- and micro-nutrient circulation required for adequate wound healing[5].

Immobility is one of the key driving forces in creating ulcers. Studies have shown that two hours of immobility in bed bound and postoperative patients can produce soft tissue injury[6]. An external pressure of 32mmHg above the arterial pressure and 10mmHg above the venous pressure system can produce soft tissue necrosis and skin breakdown. These pressures are easily exerted by common surfaces such as hospital beds, firm mattresses, and leg rests of wheelchairs [7].

Appropriate offloading of bony prominences is a chief component of pressure ulcer prevention. The National Pressure Injury Advisory Panel updated the *Guidelines for Prevention and Treatment of Pressure Ulcer's* in 2019 and recommend elevating the heels using a specifically designed heel suspension device or a pillow/foam cushion in order to offload the heel completely and in a manner that the weight of the leg is evenly distributed along the entire calf without placing pressure on the Achilles tendon or the popliteal vein[8]. Various offloading devices have been introduced in order to achieve this goal; however, studies have yet to specify a design which significantly reduces ulceration risk more than another design[9].

The purpose of this study is to perform a preliminary investigation of the clinical and practical effectiveness of the NelDerm® Heel Pressure Offloading Device™ (POD) (Figure 1) compared to a standard pressure relief ankle foot orthosis (PRAFO) device. The hypothesis is that the NelDerm® Heel POD™ may require less time to perform a dressing change.

A time trial was designed to compare the recorded time of both the application and the removal of each device. The Heel P.O.D.™ was compared to three different PRAFO devices and, on average, the Heel P.O.D.™ demonstrated 87.5% less time to apply and 57.5% less time to remove when compared with the PRAFO devices. (Table 1 & 2)

Dressing: cast padding and elastic bandage				
Time (seconds)	EHOB™ TRUVUE® Heel Protector	Prevalon® Heel Protector III	Mölnlycke® Z- flex ™ Heel Boot	Heel P.O.D.™
Device Application	8.25	6.73	16.49	2.35
Device Removal	2.08	1.53	3.65	1.08
Dressing Application	101.05	101.05	101.05	101.05
Dressing Removal	41.99	41.99	41.99	41.99
Total	153.37	151.37	162.19	146.47

Table 1. Time trial with 4'' bandage roll, 4'' elastic bandage.

Dressing: 4'' bandage roll, 4'' elastic bandage [Decubitus Ulcer]				
Time (seconds)	EHOB™ TRUVUE® Heel Protector	Prevalon® Heel Protector III	Mölnlycke® Z-flex ™ Heel Boot	Heel P.O.D.™
Device Application	8.19	7.01	15.43	2.30
Device Removal	2.17	2.19	3.45	1.02
Dressing Application	40.36	40.36	40.36	40.36
Dressing Removal	16.19	16.19	16.19	16.19
Total	66.91	65.75	75.43	59.67

Table 2. Time trial with cast padding and elastic bandage.

Discussion:

Despite innovations in treatment strategies and medical equipment, the incidence of pressure ulcers is rising principally due to the growth in the at-risk population with multiple comorbidities leading to heel ischemia[10]. By comparing the heel blood flow repayment hyperemia with offloading between diabetic and non-diabetic groups, Mayrovitz *et al* discovered the partial-heel offloading caused a blunted hyperemic response when compared to full offloading in both groups. The diabetic group showed reduced perfusion to the heel even with full pressure relief compared to non-diabetic group[11]. The reduced microvascular vasodilatory capacity in diabetics may be problematic in preventing heel pressure ulcers. Full offloading allowed more blood flow to the heel compared to partial offloading preventing ischemia. NelDerm® Heel POD™ potentially provides complete offloading of the heel, while the PRAFO devices may only provide partial offloading.

The research on the efficacy of heel pressure offloading devices is sparse. After a systemic review in 2011, McGinnis *et al* concluded that while current guidelines recommend the use of pressure relieving devices for all patients with heel pressure ulcers, there is insufficient evidence to determine the relative effectiveness of the devices. In the authors' recommendation of device selection, consideration and priority should be given to the quality of life of the patients as well as ease of use, reliability, and costs associated with the device [12].

The aim of this preliminary investigation is to compare NelDerm® Heel POD™ to PRAFO devices. Based on findings, the Heel POD™ appears to offer more efficient dressing changes without the requirement of removing the device. This feature could lead to less discomfort for the patient and more efficiency for healthcare providers (Figure 2). The completely offloaded heel design could improve visualization and assessment of heel wounds. Furthermore, the Heel POD™ could offer less complicated dressing application/removal coupled with improved comfort for the patient. Disinfecting and cleansing the device could also be more efficient and reproducible due to the design.

These preliminary findings open up the possibility for additional analyses to highlight the potential advantages of the NelDerm® Heel POD™. The Heel POD™ allows for greater visualization of bony prominences in order to assess skin integrity and wound progression, decrease the skin temperature within the device, allow the ability to weight bear with the device in place, and be more hygienic when compared to the standard PRAFO.

One study design in particular could include a comparative analysis of the internal temperature of the device while in use. Increase in temperature and moisture may lead to increased bacterial burden on the device surface, delayed wound healing or wound infection. The water-resistant outer material of the Heel POD™ is simple to disinfect with sanitizing wipes. A study could naturally highlight general hygiene of the Heel POD™ compared to other devices. With many heel offloading devices containing restrictive and enclosed designs, patients that attempt to bear weight while wearing the devices are often unstable and may be subject to increased fall risk. The ease of design could also warrant a study to examine patient safety while wearing the current device. Although not recommended, should the patient decide to ambulate with the device in place, the Heel POD™ could allow for safer ambulation.

In this preliminary investigation, NelDerm® Heel POD™ yielded more time-efficient dressing changes when compared to other PRAFO devices.

Figure 1. NelDerm® Heel P.O.D.™

Figure 2. Dressing change with Heel P.O.D.™

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