An evaluation of the use of the Maxxcare Pro Evolution Heel Boot in a rehabilitation care setting

KEY WORDS
- Evaluation
- Heel boot
- Heel protection
- Heel pressure ulcers
- Offloading

An evaluation was conducted across six rehabilitation wards in the South-East Wales area to observe the performance of the Maxxcare Pro Evolution Heel boot in this care setting and to review the acceptance of the boot among a cohort of patients with restricted mobility at risk of pressure damage. Seventeen patients were included in this evaluation and all were deemed to be either at risk of developing pressure damage or had existing pressure damage to the heel. The mean age of the cohort was 75 years. Patients were monitored for 14 days during which skin assessments were conducted. The Maxxcare Pro Evolution Heel boot has been designed to offload the heel during extensive periods of unrelieved pressure whilst in bed or in a sitting position. The findings from this evaluation suggest that the Maxxcare Pro Evolution Heel boot was effective in protecting the heels of patients at risk of developing pressure damage in a rehabilitation setting.

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Preventing pressure damage in compromised patients with restricted mobility is a challenge for clinicians. The heels are particularly susceptible to developing pressure ulceration due to the complex anatomy and physiology of the foot. The calcaneus bone is the largest bone in the foot and is often subjected to prolonged periods of unrelieved pressure over a small contact area when patients have restricted mobility or are bedbound. The International Pressure Ulcer Guidelines (National Pressure Ulcer Advisory Panel [NPUAP], European Pressure Ulcer Advisory Panel [EPUAP] and Pan Pacific Pressure Injury Alliance [PPPIA], 2014) recommend that heels are floated whilst a patient is temporarily bedbound but suggest that heel suspension devices are preferable for long-term offloading or in those patients who are agitated or restless. The Maxxcare Pro Evolution Heel boot is designed to offload and redistribute pressure away from the heel with a view to preventing pressure damage over the calcaneal bone and associated soft tissue structures. The boot has a series of four air-filled cells, which provide protection to the ankle joint whilst keeping the foot in a comfortable position. Based on previous research performed in a hospital setting, the Maxxcare Pro Evolution Heel boot evaluation was conducted over a 14-day period (Lyder and Ayello, 2008).

THE VULNERABLE HEEL

The incidence of pressure ulceration after admission to hospital in the UK is estimated to range between 4–10% and the data suggests that the heels are the second most common site for developing pressure damage after the sacrum (National Institute for Health and Clinical Care Excellence [NICE], 2014)

The heel of the foot plays an important role in human biomechanics. It supports weight-bearing and human locomotion as it absorbs shock, pressure and shear from the ground reaction forces (Valmassy, 1995). However, during extensive periods of unrelieved pressure the heels become particularly vulnerable to soft tissue breakdown due to pathophysiological factors associated with compromised tissue perfusion, hypoxia, impaired nutrition and chronic inflammation (Salcido et al, 2011). This is often observed in patients with restricted mobility or those confined to prolonged periods of bed rest.

Figure 1. Example of Maxxcare Pro Evolution Heel boot offloading the left foot

Figure 2. Size guide

Implementing an effective heel protection programme involves adopting a multi-faceted approach which includes performing a risk assessment and undertaking a comprehensive examination of skin integrity in those patients deemed at high risk of pressure damage (NICE, 2014). The strength of evidence suggests that the ideal pressure-redistributing techniques for offloading the heels should reduce pressure, friction and shear; separate and protect the ankles; maintain heel suspension; and prevent foot drop (Black, 2004).

HEEL PROTECTION

The Maxxcare Pro Evolution Heel boot has been designed to offload the heel during extensive periods of unrelieved pressure. It maintains heel suspension whilst the patient is bedbound and reduces pressure, friction and shear in those at risk of developing pressure ulceration to the vulnerable heel area. Removable air-tubes protect the ankle and sides of the foot whilst the patient is in a sitting position and the Maxxcare Pro Evolution Heel boot has a thin non-slip base which is suitable for transferring between bed and chair. The Invacare instructions for use recommend that the Maxxcare Pro Evolution Heel boot may be worn for mobilising and for the prevention of foot drop. However, patient mobilisation and the prevention of foot drop with the Maxxcare Pro Evolution Heel boot was not explored for the purpose of this 14-day evaluation.

AIMS AND OBJECTIVES

The aim of the evaluation was to observe the performance of the Maxxcare Pro Evolution Heel boot in a rehabilitation setting and review the acceptability of the boot in a cohort of patients with restricted mobility at risk of pressure damage.

METHODS

An evaluation of the Maxxcare Pro Heel Evolution boot *(Figure 1)* was undertaken across six rehabilitation wards within the Aneurin Bevan University Health Board. Local governance approval was given to conduct a small-scale evaluation where the Maxxcare Pro Evolution Heel boot would be used as part of routine care in patients with restricted mobility at risk of pressure damage.

All patients across the six rehabilitation wards were screened, and those with the capacity to provide informed consent were given an information leaflet for inclusion in the trial. The evaluation period started on 16 June and ended in September 2017. Patients were assessed on four separate occasions during the 14-day evaluation period:

- Day 0
- Day 3
- Day 7
- Between day 10 and day 14, depending on when the patient was being discharged from the care setting.

Patient demographic data including gender, age and medical history were recorded along with measurements of the circumference (cm) of the posterior heel to the anterior region of the ankle joint, to ensure patients were issued with the correct size boot *(Figure 2)*. An assessment of current pressure ulcer risk was established using the Waterlow score and all patients were categorised as being either at risk (10+), high risk (15+) or very high risk (20+) of pressure damage. The type of mattress was also recorded as being either static or dynamic.

During each assessment, photographs were taken

Table 1. Baseline characteristics of the 17 patients

Patient	Gender	Age	Medical history	Waterlow score	Risk level	Skin damage	Mattress type
1	m	78	Pneumonia	23	Very high	Category 2	Dynamic
2	f	57	Diabetic	23	Very high	Category 2	Dynamic
3	f	75	Anaemia	19	High risk	Category 1	Dynamic
4	m	77	Rheumatoid arthritis	19	High risk	Intact	Static
5	m	75	Quadriplegic	23	Very high	Category 1	Static
6	m	84	CVA	22	Very high	Intact	Dynamic
7	f	87	Bullous pemphigoid	28	Very high	Intact	Dynamic
8	f	57	COPD	21	Very high	Intact	Dynamic
9	f	78	Biliary cirrhosis	19	High risk	Intact	Dynamic
10	f	49	MCA infarct	16	High risk	Intact	Static
11	f	61	Multiple fracture	13	At risk	Intact	Static
12	f	82	Risk of falls	17	High risk	Intact	Static
13	m	82	CVA	19	High risk	Intact	Dynamic
14	m	83	Leukaemia	23	Very high	Intact	Dynamic
15	m	72	CVA	17	High risk	Intact	Dynamic
16	f	92	Fractured spine	23	Very high	Intact	Dynamic
17	m	80	CVA	18	High risk	Intact	Static

CVA = cerebrovascular accident; MCA infarct = middle central artery infarct

of the patients' heels and a skin assessment was performed. Patients were also asked to rate their comfort whilst the boots were in place.

Clinicians were asked to rate if they agreed or disagreed that the heels were being effectively offloaded whilst the patients were wearing the Maxxcare Pro Evolution Heel boot. This was recorded using the 5-point Likert scale (Likert, 1932). Opinions on ease of application and removal were also collected. The data was compiled at the end of the 14-day evaluation period and transferred into an Excel database [Microsoft, 2010] for analysis.

RESULTS

Over the 12-week recruitment period, 163 patients were screened. Seventy-nine (48%) of these patients were unable to provide informed consent due to a lack of capacity, 19 patients were unable to participate in the evaluation due to a decline in general health, 16 patients had a Waterlow score below 10 and another 9 patients were at high risk of falls. The remaining 23 patients were mobile and no longer confined to a bed or chair.

A total of seventeen patients were included in the evaluation. These patients were deemed to be either at risk of developing a heel pressure ulcer (n=13) or had existing pressure damage to the heel (n=4).

Baseline characteristics

Out of the seventeen patients, 8 were male and 9 were female. Patients age ranged from 49 to 92 years. (mean age 75 years). Four patients had pre-existing damage to the heels. Two had

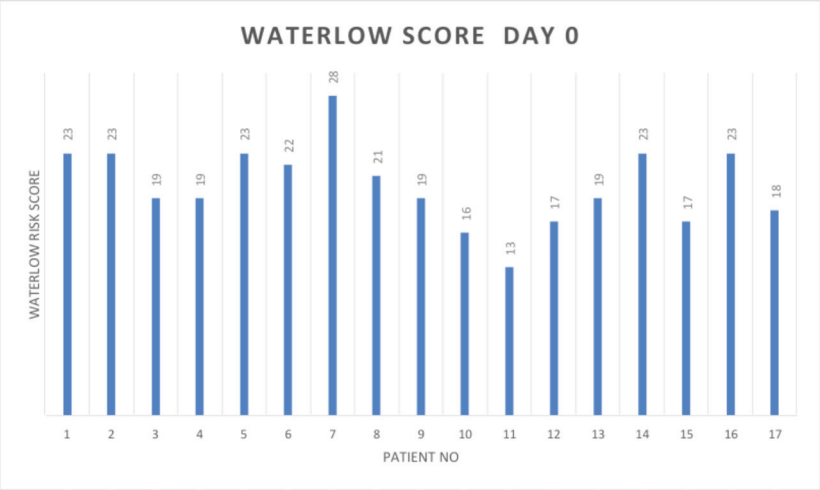

Figure 3. Waterlow score for the total cohort

Table 2. Mattress type used for the patients			
Mattress type	At risk	At high risk	At very high risk
Dynamic	0	7	5
Static	3	2	1

category 1 pressure ulcers, and the remaining 2 patients had category 2 pressure damage to the heels *(Table 1)*.

Risk assessment

Figure 3 shows the Waterlow scores for the total cohort. These patients were categorized as either being at risk (10+), high risk (15+) or very high risk (20+) of developing pressure damage. One patient was categorized as being at risk, 8 patients were at high risk and another 8 patients were at very high risk. The Waterlow scores in those patients that completed the evaluation remained stable in 6 patients, decreased in 2 patients and increased in a further 5 patients.

Sixteen of the patients were on an appropriate mattress based on their level of risk according to local clinical guidelines. One very high-risk patient had requested a static mattress when a dynamic mattress would have been the preferred choice based on their risk score *(Table 2)*.

Reported outcomes

Thirteen patients completed the evaluation. Two patients withdrew consent, 1 patient died and another 1 patient became acutely unwell and lost capacity to remain in the evaluation. Eleven patients with intact skin completed the evaluation with no evidence of pressure injury to the soft tissue overlying the calcaneal bone. One of the patients with a category 2 pressure ulcer had a reduction in wound surface area of almost 50%. This patient will be discussed in further depth as a case study. The patient recruited with category 1 pressure damage had complete resolution within 3 days of wearing the Maxxcare Pro Evolution Heel boot. This suggests that the boot may also be used as an adjunct therapy to promote wound healing in patients with existing pressure damage.

Patient Comfort

Thirteen (76%) patients reported that the boots were comfortable to wear. The evaluation found that most patients felt the boots were very good at offloading the heels whilst they were in bed. They also found them comfortable to wear and reported that they were easy to apply and remove. These patients are discussed further in the case presentations.

During the data collection period, the temperature in the ward exceeded 25°C due to extreme warm weather conditions. Within this period, 2 patients withdrew consent from the evaluation because they felt that it was too hot to wear boots.

Clinician feedback

Feedback from the clinicians that applied and removed the boots was also positive. They stated that the boots were easy to apply and remove with minimal instruction required. One hundred percent of clinicians involved in the evaluation reported that the boots effectively offloaded the heels while patients were in bed.

Limitations

This was a small-scale product evaluation and as such there was no comparison with alternative offloading devices. The evaluation was performed in a hospital setting where many patients were unable to provide informed consent (48%) and this had a substantial impact on recruitment. There is a need to conduct a further large-scale randomised controlled study to establish the

efficacy of the Maxxcare Pro Evolution Heel boot in the general population at risk of developing pressure damage.

CASE PRESENTATIONS

Case presentation 1

A 57-year-old lady was admitted to a rehabilitation ward, following the amputation of her left leg after she had developed complications from an infected diabetic foot ulcer 10 months earlier. The lady was a type 1 diabetic with nephropathy, requiring dialysis for end stage renal disease 3 times a week. She was wheelchair dependent and used her right leg to transfer from bed to chair with assistance. She was assessed as being at very high risk of developing pressure damage, with a Waterlow score of 23. For 5 months, her category 2 pressure ulcer was being dressed daily, but she had difficulty in finding an appropriate pressure-relieving device to offload the heel to help her move from her bed to a chair. On examination, the wound was clean and protected with an appropriate dressing. The wound measured 3.4 cm^2 in surface area *(Figure 4)*.

The Maxxcare Pro Evolution Heel boot has a non-slip base to help patients to move from bed to chair. After application of the Maxxcare Pro Evolution Heel boot, the patient reported that her foot felt more comfortable and the foot plate of her wheelchair no longer felt uncomfortable. By day 7, the wound had decreased in size by 1.9 cm^2 and the wound continued to improve. On day 14, the wound had decreased to less than 0.5 cm^2 in surface area *(Figure 5)*. Due to her positive experience, she continued to wear the boot post-evaluation.

Figure 4. Day 0: The wound measured 3.4 cm^2

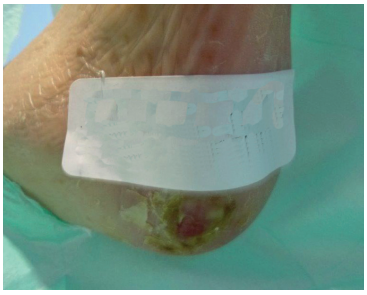

Figure 5. Day 14: the wound had decreased to less than 0.5 cm^2

Case presentation 2

A woman of 49 years had been admitted to a long-stay rehabilitation hospital following a left middle central artery infarct. The infarct had affected the right side of her body, leaving her with a lame density in her right arm and right leg, resulting in a right hemiparesis. Her mobility was limited and she spent most of her time in a wheelchair or in bed after her rehabilitation sessions with the physiotherapists. Her Waterlow score was 16, which suggested she was at high risk of developing pressure damage.

To prevent contraction of the right lower leg, the patient had a rigid splint attached to her shoe, which she wore during the day. As a result, the patient experienced constant pressure to her right heel. She had been provided with a pressure-redistributing cushion to sit on but had no pressure-redistributing devices for her heels. The patient was anxious about developing a sore heel and, although she had been lifting her leg to reposition it throughout the day, she found it quite challenging to reposition her heel during the night.

When approached, the patient was delighted to be part of the evaluation. The boots allowed the patient to continue with her rehabilitation exercises while she was in bed, offering additional relief by re-distributing the pressure at the heel. She commented on how soft and comfortable the boots felt to wear. The patient highlighted that the Maxxcare Pro Evolution Heel boots were easy to apply and remove, which she felt this was due to the large Velcro strap. She particularly liked the fact that once the boots were on the foot, they did not come off unless manually detached, requiring minimal re-adjustment whilst in bed.

Case presentation 3

A 61-year-old female was admitted to the rehabilitation unit, following surgery to her left leg to correct multiple fractures caused when she slipped on a wet bathroom floor. She was found sitting in the chair and was uncomfortable. Her right heel had to sustain all her weight, each time she sat herself up or

repositioned herself in bed. There were concerns that over time pressure damage may develop as a result. She was being nursed on a static mattress and the staff on the ward had occasionally used a pillow to float the heel off the mattress.

On examination, the patient's heel looked healthy and showed no signs of non-blanching erythema. The nurses, however, expressed concern that the patient was at risk of developing pressure damage and the provision of a heel offloading boot would benefit the patient in the prevention of any damage associated with repositioning while in bed.

At the end of the evaluation, the patient reported that she liked to have warm feet at night and liked the warmth that the boot provided. She also found the Maxxcare Pro Evolution Heel boot very easy to apply and remove, which she could do independently without the assistance from the nurses.

DISCUSSION

Preventing pressure damage in compromised patients with restricted mobility can often be a challenge for clinicians. In this evaluation, almost a third (29%) of the patient cohort had become immobile following a cerebrovascular accident or middle central artery infarct *(Table 1)*. One very high risk patient was included in the evaluation. This patient had post-operatively developed a category 2 pressure ulcer to the right heel whilst attempting to reposition in bed. Four patients had existing evidence of pressure damage at the start of the evaluation. One patient with severe spinal cord injuries had refused to be nursed on a dynamic mattress. The other three patients had evidence of pressure damage despite being nursed on a dynamic mattress.

The International Pressure Ulcer Guidelines (NPUAP, EPUAP, PPPIA, 2014) recommend that all patients at risk of pressure damage should have their heels floated whilst temporarily confined to bed rest; and that heel pressure-relieving devices should then be applied as a long-term offloading option or as standard care in patients who are agitated or restless (NICE, 2014; NPUAP, EPUAP, PPPIA, 2014, 2014). Despite these recommendations, only one high-risk patient from the total cohort had been provided with a pressure-relieving device to offload the heels prior to the evaluation.

Finding an appropriate offloading device that can limit the adverse effects of pressure, friction and shear forces while the patient is in bed or in a sitting position can be difficult. Patients following hip surgery or a cerebrovascular accident may have a reduction in strength, alterations in posture or muscular contractions in the lower limbs, which can pose significant difficulties with using an off-the-shelf pressure-relieving device. The Maxxcare Pro Evolution Heel boot has been designed to effectively offload the heel during extensive periods of unrelieved pressure whilst in bed or in a sitting position, whilst reducing friction and shear forces. The outcomes from this evaluation suggest that the Maxxcare Pro Evolution Heel boot could be effective at protecting the heels of patients at risk of pressure damage.

CONCLUSION

In conclusion, the results from this evaluation indicate that the Maxxcare Pro Evolution Heel boot could be an effective and well tolerated offloading device in the prevention and treatment of pressure damage in a rehabilitation setting. WUK

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