

# Evaluating a removable knee-high cast walker within the diabetic foot pathway

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## Article points

1. The VACOCast® Diabetic boot was evaluated in 20 patients.
2. Patient satisfaction with the boot was high.
3. The boot is an option patients with ulceration for whom a non-removable device is contraindicated.

## Key words

- Charcot foot
- Community
- Offloading
- Ulceration

## Declaration

This evaluation was supported by an educational grant to fund postgraduate education for podiatrists

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**Offloading is a key component of the diabetic foot care pathway. The team at Solent NHS Trust evaluated the use of a removable cast walker, the VACOCast® Diabetic boot (OPED Ltd), in 20 patients. The subjects had either foot ulceration or Charcot arthropathy and required effective offloading. The patients were followed up for a maximum of 8 weeks, with 45% (n=9) progressing to full healing of ulceration within this period. In the remaining 40% (n=8) with wounds either a reduction in wound size or improvement in wound bed condition or infection status was observed, with no improvement in 5% (n=1). In the patients with an active Charcot arthropathy 5% (n=1) improved, with no improvement reported in 10% (n=2).**

The incidence and cost of diabetic foot disease is recognised to be an increasing problem. Between 5% and 7% of people with diabetes will develop ulceration, at a cost of £935mn to the NHS (Kerr, 2017). Therefore, it is essential that successful diagnosis and effective care is delivered, including optimising diabetes control, optimising vascular flow, debridement and dressing the wound, and offloading the foot (International Best Practice Guidelines, 2013; National Institute for Health and Care Excellence [NICE], 2016).

Offloading of the foot for patients with diabetes has been identified as “the most important intervention” to heal a neuropathic plantar ulcer (International Working Group for the Diabetic Foot [IWGDF], 2019). NICE and IWGDF have published guidelines for which the most effective method of offloading to improve the outcomes for patients and to prevent the complications which can lead to amputation (NICE 2016; IWGDF, 2019).

Appropriate offloading should be offered to any patient who clinically needs it as soon as possible with the device selected based on the clinical presentation and patient preference.

Non-removable knee-high devices with an appropriate foot–device interface are recommended as the most effective offloading method. This

includes ulcers which are complicated with mild ischaemia or infection. Non-removable devices may not be acceptable to patients because they restrict daily activities such as bathing, driving and sleeping (Health Quality Ontario, 2017). The use of a total contact cast also requires frequent application by a fully trained, experienced practitioner, which adds additional costs (Armstrong et al, 2004; Health Quality Ontario, 2017).

Offloading should also be considered in wounds which are complicated with moderate ischaemia or infection, or a combination of mild ischaemia and infection (IWGDF, 2019).

The team at Solent NHS Trust evaluated the use of a removable cast walker in the diabetic foot pathway to determine the potential outcomes and costs in wounds where a non-removable device was contraindicated, or not acceptable to the patient.

## The VACOCast Diabetic boot

The removable cast walker which was evaluated was the VACOCast® Diabetic boot (OPED Ltd), which is a knee-high offloading device that can be used either as removable or non-removable, depending on the patient’s requirements. The boot comes with tamperproof seals as standard issue if a non-removable option is required.

The VACOCast Diabetic (VCD) boot consists of an outer lightweight plastic shell which is cast stable and set at a 90° angle. It has a high shaft to ensure good stability, and a removable rocker sole to provide a safe physiological gait.

An inner vacuum pad, the VACO12, surrounds the entire foot and lower leg. This allows individual adjustment to the contour of the foot and lower leg, in order to safeguard offloading as well as to accommodate minor foot deformities. This pad contains thousands of small Styrofoam beads, which use multiple contact points with adjacent beads to reduce impact energy and reduce and redistribute pressure over a larger area. VACO12 technology is patented by the manufacturer OPED. When the boot is applied to the limb, the Styrofoam beads inside the inner pad mould to the patient's anatomy. Air is then extracted from the vacuum pad in a few seconds with the small vacuum pump provided. This vacuum effect causes the beads to solidify, which supports the foot and leg and provides a total contact surface while avoiding pressure.

The boot is removed by opening the valve and letting air flow inside the inner vacuum pad which then becomes soft again. This process can be repeated as needed to adjust to the contours of the foot and accommodate the wound as it progresses.

The VCD boot is available in three sizes. It comes with tamperproof seals, a second liner and sole, a toe protector and mouldable foam insole, which can all be removed and washed. Other options which can be ordered from the manufacturer include calf extension straps and a lock which can be used to make the boot non-removable.

### Methods

The VCD boot was evaluated by the diabetic foot multidisciplinary team at the University Hospital of Southampton and Solent NHS Trust. It was used in wounds where a non-removable device was contraindicated (eg, where infection was present, or the boot was not acceptable to the patient), with patients selected from the clinic's routine patient population. Patients were only invited to participate in the evaluation if they fitted the inclusion criteria:

- Aged 18 years or over
- Could understand and consent to participate
- Foot ulceration and/or Charcot arthropathy assessed as suitable for the VCD boot

- A foot that was of a size and shape to fit into the device

Exclusion criteria:

- History of poor adherence
- Unable to understand how to use the boot
- Foot deformity that would not be accommodated in the VCD boot
- Known or suspected sensitivity to any components of the device
- Non-ambulatory
- Assessed as at risk of a fall.

There were no changes to routine care. Other than encouraging patients to wear the boot for as long as possible, no restrictions were placed upon their lifestyle aside from good diabetes management. The VCD boot was used in accordance with the indications in the product insert leaflet and applied according to the manufacturer's instructions for use.

The primary outcome was to identify if using the VCD boot within the current diabetic foot care pathway facilitated a reduction in foot complications (reduction in ulcer size and/or stability/temperature difference of active Charcot arthropathy). Secondary outcomes included the durability of the device, patient safety and acceptability, and the potential cost implications of using the boot.

Once patients had given consent to participate, an initial assessment was undertaken that included demographics such as age and sex, and diabetes history (duration of the diabetes and glycaemic control). The foot complication was reviewed and fully documented.

If the presenting complication was an ulcer, it was graded using both the SINBAD and TEXAS scores (Lavery et al, 1996; Ince et al, 2008). A reduction in wound size and the condition of the wound bed were used as parameters of healing. The wound size was established by measuring the circumference and depth. A simple method of estimating the circumference was to measure the maximum length and width of the wound, then multiplying this figure to give the result in mm<sup>2</sup>. When patients presented with more than one wound, the largest was selected for observation. Photography was used to monitor progress.

The wound bed was described by estimating the percentage of healthy tissue (granulation and epithelial) in comparison to devitalised tissue

(necrosis and slough), the level of wound exudate and infection status (Dowsett and Newton, 2008). Where infection was present the treatment was documented. The wound care regimen was also recorded to establish routine practice.

Patients who presented with a Charcot deformity and no ulceration were included in the study because offloading is an important element of care of the Charcot foot to prevent further complications.

A diagnosis of acute Charcot was made by a combination of clinical suspicion, history, visual inspection, confirmation on X-ray and a difference in temperature of 2°C or more between the affected and unaffected foot. At each visit, the temperature was measured using a laser thermometer over the affected area.

Following the initial assessment, patients who were allocated a VCD boot had this applied by the clinician, with an assessment of fit, patient comfort, stability and ability to mobilise. The patient (or other responsible person) was taught how to apply and remove the boot. If necessary, an EVENup device (OPED) was offered to balance the contralateral limb.

At subsequent clinic appointments, the patient and the presenting complication was reassessed and documented, and treatment given. Data was collected on the patient's ability to wear the boot safely, the time spent in the device, and the terrain on which it was used. The VCD boot was also examined for wear and tear.

The patients were followed up for a maximum of 8 weeks. If the VCD was discontinued before this, either for a clinical reason or at the patient's request, the reason was documented. Patients could withdraw at any time. The clinician could discontinue the use of the boot if they considered that it was unsafe for the patient.

The analysis was performed using an Excel spreadsheet.

### Patient demographics

Twenty patients were provided with the VCD boot for offloading between September 2017 and January 2018. They were predominantly male (85%;  $n=17$ ). The age ranged from 41 to 80 years with a mean age of 60 years. Their diabetes history ranged from 10 to 31 years, with a mean of 18.8 years. Nearly all (95%;  $n=19$ ) had type 2 diabetes, and only 5% ( $n=1$ )

had type 1 diabetes.

The patient group had an increased risk of diabetic complications, with a BMI  $\geq 30$  (85%;  $n=17$ ), and elevated HbA<sub>1c</sub> levels of 67–110 mmol/mol (95%;  $n=19$ ). Only 5% ( $n=1$ ) of patients had acceptable glycaemic control (HbA<sub>1c</sub> 42 mmol/mol). The mean HbA<sub>1c</sub> of the group was 79.3 mmol/mol.

### Foot complications

A total of 20 patients with ulceration ( $n=17$ ) or Charcot arthropathy ( $n=3$ ) were included in the evaluation.

Neuropathic foot ulcers were present in 85% ( $n=17$ ) of the patient group. Ulcers had been present from 1 to more than 12 weeks (mean 4.3 weeks). Most were plantar ulcers (80%;  $n=16$ ), with only 5% ( $n=1$ ) in the dorsal area. The wounds were mainly new (50%;  $n=10$ ), with the remainder re-ulceration (5%;  $n=3$ ) or ulcers that had developed following amputation where the sites had broken down (20%;  $n=4$ ).

The remaining patients had no ulceration, but presented with Charcot arthropathy (15%;  $n=3$ ). This was confirmed by X-ray and there was an increase of 2°C recorded in the affected foot.

All of these patients required offloading, and the VCD boot was selected for different reasons. In 60% ( $n=12$ ) of patients the a wound was infected and therefore a non-removable knee-high device was not indicated. There were patients (30%;  $n=6$ ) who were suitable for a non-removable boot, but it was not available or acceptable to the patient. In the remaining 10% of patients ( $n=2$ ), the decision to use a VCD boot was based on a clinical decision to change from another knee-high device which was no longer appropriate.

In total, data was recorded on 64 follow-up appointments where patients attended for routine re-assessment. No additional appointments were required for device- or wound-related problems.

## Results

### Wound progression

The wounds progressed to healing in 45% ( $n=9$ ) of patients, defined as 100% epithelial tissue in the wound bed. The initial wound circumference ranged from 12mm<sup>2</sup> to 1,076mm<sup>2</sup> and initial depth from 1 mm to probe to bone (TEXAS 1–3, SINBAD 2–5).

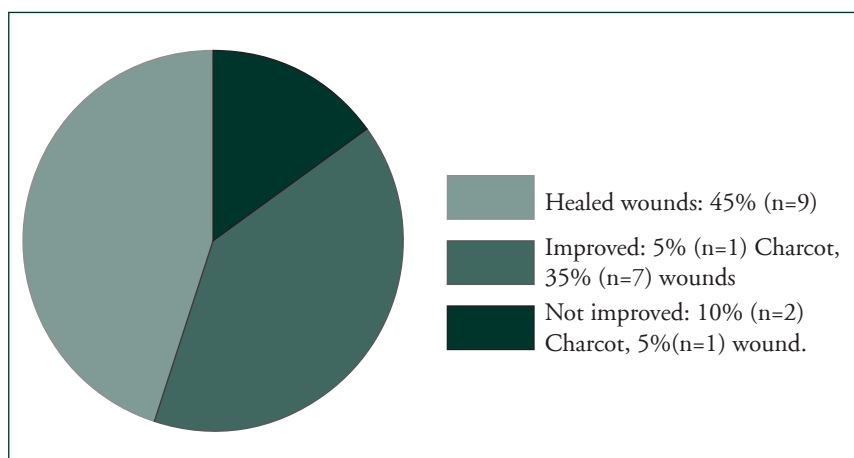


Figure 1a: Wound healing at 8 weeks.

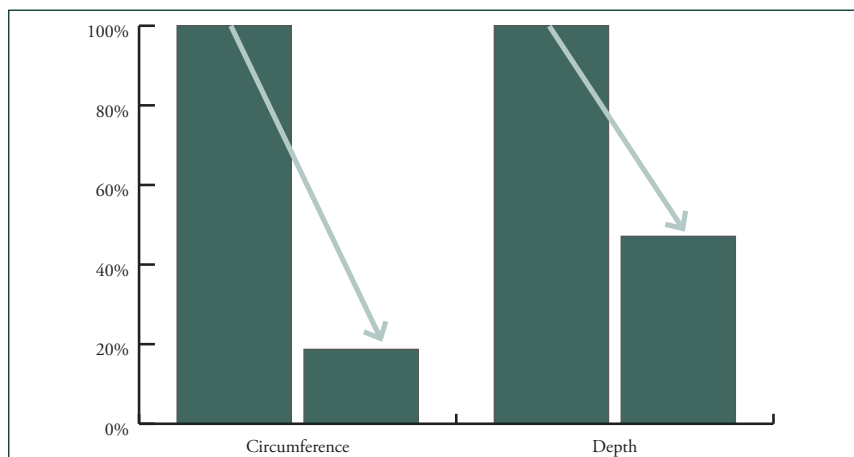


Figure 1b: Wound progression after 8 weeks.

| Patient | TEXAS start | TEXAS end | SINBAD start | SINBAD end | Outcome |
|---------|-------------|-----------|--------------|------------|---------|
| 1       | A2          | A0        | 3            | 1          | Heal    |
| 2       | A1          | A0        | 2            | 1          | Heal    |
| 3       | A1          | A0        | 2            | 1          | Heal    |
| 4       | B3          | A0        | 4            | 1          | Heal    |
| 5       | B3          | A0        | 3            | 1          | Heal    |
| 6       | A1          | A0        | 2            | 1          | Heal    |
| 7       | B1          | A0        | 3            | 1          | Heal    |
| 8       | A1          | A0        | 1            | 1          | Heal    |
| 9       | B1          | A0        | 2            | 1          | Heal    |

In the patients with foot ulcers that were still present at 8 weeks, it was calculated that there was an overall 81.3% reduction in wound circumference, and 52.9% reduction in depth (Figures 1a and 1b).

There was an observed increase in wound circumference in patient 11. However, epithelial tissue had migrated across the centre of the wound, causing two wounds. These had been measured individually and added together to give a higher circumference.

The wound bed status improved. At the start of the evaluation 55% (n=11) of wounds were observed to contain sloughy tissue, but at 8 weeks this had reduced to only 5% (n=1). This was confirmed by the photographs taken at each visit.

Exudate production is dependent on many factors within the wound. Exudate levels are a very subjective measurement and can be difficult to accurately assess. However, there was an increase in exudate level recorded in only 5% (n=1) of patients.

#### Infection status

Over half of patients (60%; n=12) had an initial wound infection. At the end of the evaluation period this had decreased to 25% (n=5) of patients, with no new infections developing. All patients with a diagnosis of mild infection, with two or more of the clinical signs of infection (Lipsky et al, 2012), were treated with systemic oral antibiotics as per the local antibiotics guidelines and the service’s antibiotic patient group directives. Only 45% (n=9) patients with a wound infection were treated with topical antimicrobial dressings.

#### Ulcer classification

The TEXAS and SINBAD classification systems were used at the initial assessment, and at each subsequent assessment to indicate ulcer progression (Lavery et al, 1996; Ince et al, 2008). They also demonstrate that some of the wounds were complex and therefore more difficult to heal. The TEXAS and SINBAD scores at the start and end of the evaluation period in the patients who progressed to healing are shown in Table 1.

Table 2 shows the scores for the patients who remained unhealed (40%; n=8). No patients were reported to have an increased score at the end of the evaluation, which would indicate deterioration in the wound. In 35% (n=7) of patients the classification suggested that the wounds either remained static or improved. However, in 5% (n=1) there was a discrepancy — the TEXAS score showed no improvement, but there was improvement with the SINBAD score.

### Wound management

At all the assessments, the wound was sharp debrided and cleansed using an antiseptic wound cleansing solution. For most patients, a simple non-adherent dressing was applied. The cost of dressings was calculated for each patient, using the Drug Tariff unit price and the frequency of dressing change over the episode of care to give both an average weekly cost and an overall approximate cost.

- The overall cost ranged from £1.52 to £27.20 per patient per episode of care
- The mean cost of dressings for the treatment period was £6.62 per patient
- The weekly cost of dressings ranged from £0.25 to £2.87
- The mean cost of dressings per week was £1.03.

The potential cost savings were estimated using data from the patients who healed. The potential saving from dressing products was low due to the type of dressings used, with a total weekly saving for all patients of £3.22. However, by healing 45% ( $n=9$ ) patients, 16 clinician appointments per week were saved. This included podiatry appointments and community nursing time for dressing changes.

### Management of Charcot

The temperature increased in 5% ( $n=1$ ) of patients, reduced in 5% ( $n=1$ ) and was raised but remained static in 5% ( $n=1$ ).

### Use of the VCD boot

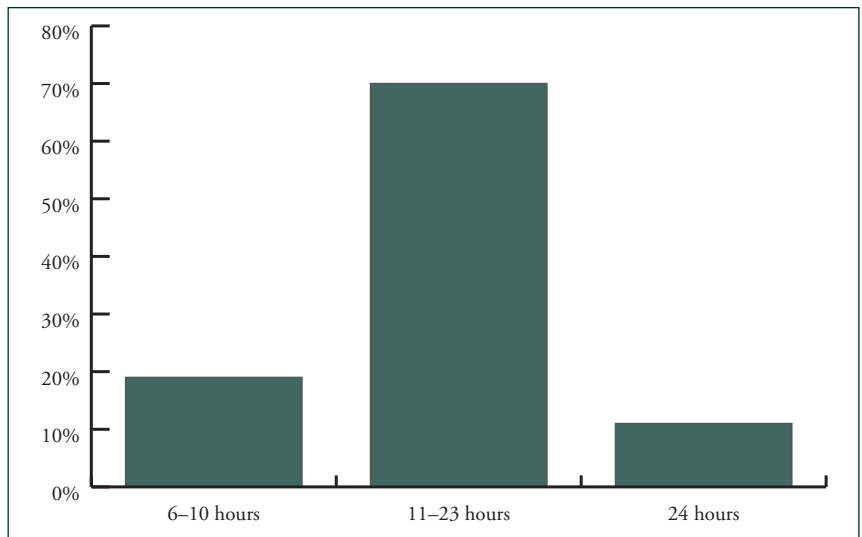
The use of removable cast walkers is often criticised because of poor adherence by the patient to wearing them for the prolonged periods needed to influence healing.

At each assessment, the patient was asked how many hours a day they wore the boot. The ideal is 24 hours, but it was recognised that patients may need to remove it for activities of daily living, such as showering and driving. *Figure 2* shows the relative wear times. There were no reports of the boot not being worn, although the reported duration of wear varied:

- At 11% ( $n=7$ ) of reassessments, 15% ( $n=3$ ) patients reported that they had worn the boot for 24 hours
- At 70% ( $n=45$ ) of reassessments, the length of time reported was 11–23 hours, with 90% ( $n=18$ ) of patients wearing the boot for this time period
- At 19% ( $n=12$ ) of reassessments, the boot was worn

**Table 2. Comparative Scores of TEXAS and SINBAD in unhealed patients.**

| Patient no | TEXAS start | TEXAS end | Outcome   | SINBAD start | SINBAD end | Outcome   |
|------------|-------------|-----------|-----------|--------------|------------|-----------|
| 10         | B3          | A1        | Improve   | 4            | 3          | Improve   |
| 11         | B3          | B1        | Improve   | 5            | 4          | Improve   |
| 12         | B1          | B1        | No change | 5            | 5          | No change |
| 13         | A1          | A1        | No change | 2            | 2          | No change |
| 14         | B3          | A1        | Improve   | 4            | 3          | Improve   |
| 15         | A1          | A1        | No change | 2            | 1          | Improve   |
| 16         | B1          | A1        | Improve   | 3            | 2          | Improve   |
| 17         | B1          | B1        | No change | 3            | 3          | No change |



*Figure 2: Patients reported their duration of wear at each appointment.*

for 6–10 hours. This time period was reported by 45% ( $n=9$ ) patients.

The VCD boot was worn safely and no problems were reported when used on a range of surfaces which included home flooring, pavement and rough ground. Patients reported that they could put on and take off the boot and were able to mobilise when wearing it at each assessment. The majority of patients slept with the boot on, with the removable sole reported as being taken off at night at 58% ( $n=37$ ) of assessments.

### Wear and tear

The boot, liner and insert were examined at each visit for damages or changes which would reduce its effectiveness. No problems were observed with the outer casing, although one patient who wore the boot to work required a replacement boot and liner as the

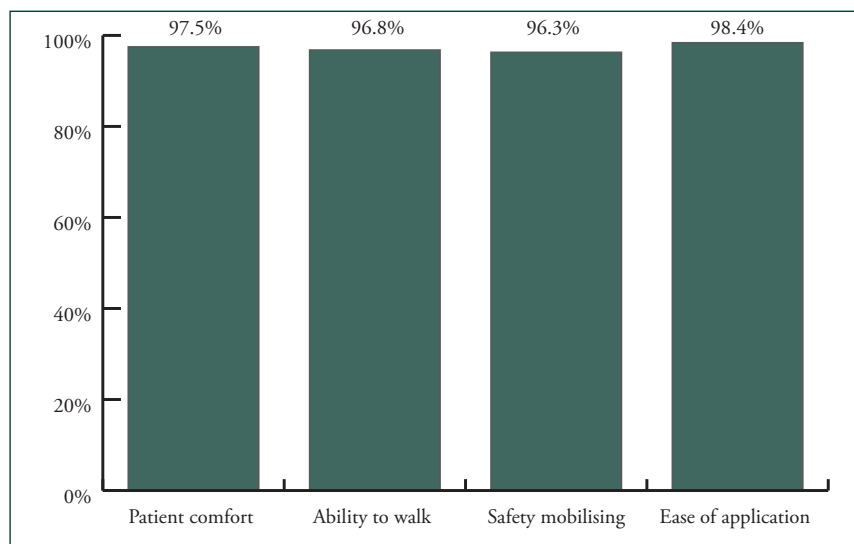


Figure 3: Patient experience with the VCD boot.

original became very worn. One patient had a problem with the insert failing to inflate, but this was replaced in clinic.

The VCD is supplied with a spare liner to allow for laundering. However, only 60% ( $n=12$ ) patients washed the liner, with the frequency ranging from one to four times. There was no smell detected from the liner at any assessment, and reports of staining or damage at only 12% ( $n=8$ ) of visits.

**Patient opinion of the VCD boot**

At each visit, patients rated their experiences with the boot using a visual analogue scale (0 = poor; 5 = excellent). The scores from each visit were totalled at the end of the evaluation. *Figure 3* indicates a high level of patient satisfaction with the VCD boot. However, 10% ( $n=2$ ) patients awarded the boot lower scores because the standard straps provided were not long enough for their very large legs. Longer straps can be ordered from the manufacturer if required, and this was undertaken.

**Use of additional equipment**

At each visit, the use of additional equipment was recorded. For most patients, the EVENup was the preferred option. However, one patient had a total contact cast on the contra-lateral limb, and another used his own heavy-soled boot. One patient wore a VCD boot on both limbs, because he had a foot ulcer on the other foot, while 10% ( $n=2$ ) of patients used crutches for additional stability.

**End of evaluation outcomes**

At the end of the evaluation, the patient outcome was documented.

**Patients with foot ulceration**

In 45% ( $n=9$ ) of patients, the wounds had progressed to healing within the 8 week evaluation period. However, 15% ( $n=3$ ) healed after 6 weeks and 5% ( $n=1$ ) healed at 7 weeks.

In 35% ( $n=7$ ) of patients where the wound had not healed, the ulcers had improved, as measured by a reduction in wound circumference and improved wound bed status.

In 5% ( $n=1$ ) of patients, the wound had epithelialised into two wounds which had been measured to give a greater circumference and exudate level had increased, although the condition of the wound bed had improved.

**Patients with Charcot**

The VCD boot was used on three patients with an acute Charcot presentation to stabilise the foot and prevent further complications, such as ulceration developing.

The Charcot foot improved in 5% ( $n=1$ ), measured by the temperature of the foot reducing by 2°C. The use of the boot was continued after the evaluation ended.

The foot remained static in 5% ( $n=1$ ). However, the patient was admitted for an elective amputation, which had always been a long-term consideration for this patient.

The Charcot foot deteriorated in 5% ( $n=1$ ), and the foot temperature continued to increase. This patient was withdrawn from the evaluation after 7 weeks and referred for non-removable casting.

**Potential cost of care**

The cost of care was demonstrated using data from the evaluation for healed patients (*Table 3*). This was calculated using the price of the VCD and EVENup on the contralateral limb. The cost of clinician time was estimated using a 45-minute appointment of a Band 6 clinician (NHS Pay Scale). Clinician time was calculated at the top of the pay scale with 23% added for sickness, annual leave and other absences. Routine care was also delivered at this appointment, and the use of the VCD did not incur any extra time. The frequency of change used in the evaluation was

to follow up at weekly intervals for 2 weeks, then at 2-weekly intervals. No additional appointments were required for wound- or device-related complications.

## Discussion

This small evaluation was undertaken on 20 patients, who presented with diabetic foot complications and required effective offloading, but where a non-removable device was not suitable. The removable VCD boot was used for offloading. The outcome evaluation was undertaken within routine best practice.

There was a high incidence of infection at the initial presentation and all patients who had infected wounds were treated with systemic antibiotics. The foot ulcers were not all simple wounds. Despite this 45% ( $n=9$ ) progressed to healing within 8 weeks, and reduction in either wound size, exudate and infection, or an improvement in the condition of the wound bed was recorded in the others. This was confirmed through TEXAS and SINBAD scores.

When the VCD boot was used on patients with Charcot, it provided stability for the foot, observed by recording any change in temperature on the foot as per standard Solent NHS Trust Podiatry Protocol. It was used as an ongoing treatment, or to provide support until an alternative intervention was available (either non-removable offloading or amputation).

While patients were advised to wear the boot for 24 hours, none of the patients adhered to this for the full treatment period. This is a consideration when using removable devices (IWGDF, 2019). However, the self-reported data suggest that the boot was worn regularly. Patients found the boot comfortable, were able to mobilise safely and apply and remove it without any assistance, allowing for self-care.

The VCD boot was durable and suitable for a range of terrains. There was damage reported by one patient with a dirty and demanding job, and this was replaced. Another patient had problems with the insert, but the design of the boot meant that this could be replaced. The liner could be removed for hygiene and infection control purposes.

The cost of using the VCD was demonstrated by a simple cost calculation which included clinician time. Foot ulceration in a person with diabetes has a high rate of recurrence of approximately 40%, to the extent that it has been described as being in remission rather than being cured (Jeffcoate et al, 2009;

**Table 3: Cost of using VCD boot over 8 weeks.**

|                 | Number             | Unit price | Cost over 8 weeks |
|-----------------|--------------------|------------|-------------------|
| VCD Boot        | 1                  | £149       | £149              |
| Clinician time* | Band 6, 45 minutes |            | £126.42           |
| <b>Total</b>    |                    |            | <b>£275.42</b>    |

Armstrong et al, 2017). The VCD is durable and can be reused by the same patient, providing further cost savings as well as instant access to an effective offloading device.

## Conclusion

For patients for whom a non-removable device is contraindicated, the VCD boot is an ideal solution that supports the recommendations for plantar ulcers complicated by ischaemia or infection (IWGDF, 2019). The flexibility to use the device as a non-removable option is also worth considering, allowing stepping up and down of offloading as the clinical condition changes. However, further studies are indicated to fully demonstrate the use of the VCD boot. ■

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