

## New Medicine Recommendation

# VACOCast Diabetic Boot for the management of foot ulcers in the diabetic population

### Recommendation: RED

- Medicine is supplied by the hospital for the duration of the treatment course.
- Primary care initiation or continuation of treatment is not recommended unless exceptional circumstances such as specialist GP.
- Red medicines are those where primary care prescribing is not recommended. These treatments should be initiated by specialists only and prescribing retained within secondary care. They require specialist knowledge, intensive monitoring, specific dose adjustments or further evaluation in use. If however, a primary care prescriber has particular specialist knowledge or experience of prescribing a particular drug for a particular patient it would not always be appropriate for them to expect to transfer that prescribing responsibility back to secondary care. There should be a specific reason and a specific risk agreement, protocol and service set up to support this.
- Primary care prescribers may prescribe RED medicines in exceptional circumstances to patients to ensure continuity of supply while arrangements are made to obtain on going supplies from secondary care

All patients should be under the care of a diabetic foot team. The appropriate point of supply for the VACOCast Diabetic Boot is this specialist service. The VACOCast Diabetic Boot is recommended for the management of foot ulcers in the diabetic population where a total contact cast is contra-indicated (presence of infection/ ischaemia / daily inspection required), not tolerated or until casting can be provided (NICE NG19).<sup>3</sup>

### Background

The management of foot ulceration in the diabetic population is a significant problem for the NHS. The National Diabetes Foot Care Audit found that, in England approximately 60,000 people with diabetes present with diabetic foot ulceration each year.<sup>1,2</sup> An annual cost to the NHS (2014-15) was estimated to be approximately £1 billion on foot ulcer management.<sup>1</sup>

The risk of lower limb amputations for diabetics is approximately 23 times greater than non-diabetics, with around 7000 people / year with this condition requiring leg, foot or toe amputation. The survival rate following amputation is poor, with only half of diabetic patients with leg amputations surviving more than 2 years.<sup>1</sup>

NICE have recommended a care pathway for patients with diabetic foot ulcers which states that one or more of the following should be offered as standard care for treating diabetic foot ulcers:

- Offloading.
- Control of foot infection.
- Control of ischaemia.
- Wound debridement.
- Wound dressings.<sup>3</sup>

The recommended first line treatment is to offer a non-removable cast to offload plantar neuropathic, non-ischaemic, uninfected forefoot and midfoot diabetic ulcers. The central goal of any treatment program designed to heal these wounds is effective reduction in pressure (off-loading). However, this is not readily available in primary care, although clinicians have the option to request funding for a non-removable cast. Alternatively, patients can attend an out patient clinic to have a non-removable cast applied. NICE recommends that an alternative offloading device is offered until casting can be provided.<sup>3</sup>

The International Working Group for the Diabetic Foot Group launched their new guidelines in May 2019, in which they identified that the Total Contact Cast (non-removable cast) was now not the only gold standard for offloading non complicated diabetic foot ulcers. The guideline states that prefabricated removable knee-high walkers that are rendered nonremovable have been shown to be as effective as the non-removable cast.<sup>4</sup>

They recommend that:

- A non-removable knee-high device with an appropriate foot-device interface (total contact cast or non-removable walker), is used as the first line of treatment for uncomplicated neuropathic ulcers
- Where the non-removable device is contra-indicated or not tolerated to use a removable knee-high device.<sup>4</sup>

Whilst the non-removable cast has been shown to be the most effective method of offloading there are disadvantages to its use. It is relatively high cost, requiring application by fully trained, experienced practitioners and can restrict the patients normal daily activities such as bathing, walking and sleeping. It is not indicated where there is ischaemia, infection or when the ulcer requires daily inspection.<sup>5</sup>

Prior to the VACOCast Diabetic Boot being available on Drug Tariff, the only option for offloading for patients in the community, unless they were being treated through a secondary care route, was to have an ankle boot.<sup>6</sup> As a result, many patients are not receiving, or face a delay in getting effective offloading as part of their treatment.

### **VACOCast Diabetic Boot product information**

This is an all-in-one product which is an alternative to the non-removable cast and walker boots available. It consists of an outer lightweight plastic shell and an inner vacuum pad, which surrounds the entire foot and lower leg. The plastic shell has a high shaft to ensure good stability. The separate inner vacuum pad allows individual adjustment to the contour of the foot and lower leg, in order to safeguard offloading as well as to accommodate any minor foot deformities. The outer shell has a removable rocker sole to provide a safe and physiological gait, whilst there is a low friction velour liner covering the inner vacuum pad, a toe protector and a mouldable foam insole for additional offloading – all of which are removable for cleaning. Each boot has an individual serial number allowing accurate records can be kept.<sup>7</sup>

The core technology of the VACOCast Diabetic Boot is VACO12 Technology. This uses the VACO principle where the inner vacuum pad is filled with thousands of small Styrofoam beads. Each bead has 12 contact points with neighbouring beads. These 12 contact points pass on energy multi-dimensionally to the next 12 beads. The weakened energy is then passed on again via another 12 contact points. The impact energy is reduced and distributed throughout a larger area via these contact points, therefore reducing pressure. Unlike traditional foam materials, the VACO12 system requires only a little space.<sup>7</sup>

When the boot is applied to the limb, the Styrofoam beads inside the inner pad mould perfectly to the patients anatomy. Using the vacuum pump provided, air is extracted from the vacuum pad in just a few seconds. This vacuum effect causes the beads to solidify, while avoiding pressure and provide a total contact surface, so supporting the foot whilst relieving pressure.<sup>7</sup>

By opening the valve and letting air flow inside the inner vacuum pad it becomes soft again and can be re-adjusted if necessary to the contours of the foot. This process can be repeated as needed to accommodate the wound correctly as it heals.<sup>7</sup>

The VACOcast Diabetic Boot is available in 3 sizes (small, medium and large).

### **Post Market Evaluation**

#### **Off loading strategies in diabetic foot syndrome – evaluation of different devices. Gotz J et al. International Orthopaedics 2017;41: 239-246<sup>8</sup>**

Twenty patients with diabetes and polyneuropathy and ten healthy patients (age 50-65) as a control group were included in the study.

The aim of the study was to assess the value of four different offloading devices (TCC, postoperative shoe, vacuum cushioned removable cast walker (RCW) (VACODiaped<sup>®</sup> - now known as VACOcast Diabetic Boot) and an air cushioned RCW (Aircast<sup>®</sup> diabetic pneumatic walker) in patients with diabetes and neuropathy. These results were compared with walking in barefoot conditions and in normal shoes.

Plantar pressure distribution was measured with a resistive sensor F-Scan in shoe system. The pedobarographic examination was performed with sensor insoles in barefoot condition, with sneakers, post-operative shoes, VACODiaped<sup>®</sup> and Aircast<sup>®</sup> diabetic pneumatic walker. The control group passed through the same test protocol except TCC. The order of the different devices was randomised.

After an adaption phase of 50m patients had to walk a distance of about 10m at a comfortable walking speed. Four sequences for each device were recorded for each patient.

The foot was divided into three regions: forefoot (area from metatarsal heads I-V to the toes), hindfoot (region of the heel) and midfoot (region in between).

It was demonstrated that the effectiveness of the post-operative shoe was less in the group of diabetic patients and also that contact area, maximal force and force time integral were significantly elevated in the diabetes group ( $p \leq 0.05$ ). All the other devices showed a significant decrease in these parameters demonstrating their efficacy. In regards to the forefoot the TCC was the most effective device. The VACODiaped<sup>®</sup> achieved the most homogeneous distribution of forces along the entire sole, with peak pressure in forefoot and hindfoot being lower than those found when using the other devices. The VACODiaped<sup>®</sup> was also found to provide the least impairment of gait patterns.

The most effective reduction of force was achieved by TCC (75%) and VACODiaped (64.3%) with the VACODiaped<sup>®</sup> resulting in the most homogeneous distribution of forces all over the foot.

The report concludes that a customized device like the TCC/ non-removable cast is still the most proven offloading device. However, a removable cast walker being based on vacuum pads and a cushioning sole, provides better results concerning force distribution.

#### **Evaluating a removable knee- high cast walker within the diabetic foot pathway. Bowen G and Spruce P, The Diabetic Foot Journal 2019; 22(3): 52-9<sup>9</sup>**

The podiatry team at Solent NHS Trust evaluated the removable cast walker, VACOcast Diabetic Boot (VCD Boot), in 20 patients where a non- removable device was contraindicated, or not acceptable to the patient. The subjects had either foot ulceration (n=17) or Charcot arthropathy (with no ulceration) (n=3) and required effective offloading.

There were no changes to routine care and other than encouraging patients to wear the boot for as long as possible, no restrictions were placed upon their lifestyle.

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 (n=16) with only 1 in the dorsal area. The wounds were mainly new (n=10), with the remainder re-ulceration (n=3) or ulcers that had developed following amputation where the sites had broken down (n=4).

All of these patients required offloading and the VCD Boot was selected for different reasons.

In 60% (n=12) of patients the wound was infected and therefore a TCC was not indicated. There were 6 patients (30%) who were suitable for a TCC, 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.

Data was recorded for a total of 64 follow up appointments, no additional appointments were required for device or wound related problems.

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 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. 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 5% (n=1). 60% (n=12) of the patients had an initial wound infection, at the end of the evaluation period this had decreased to 25% (n=5), with no new wound infections developing.

In patients with Charcot arthropathy 5% (n=1) improved, with no improvement reported in 10% (n=2).

From the patients healing data (45%), it was estimated 16 clinician appointments per week were saved ( this included podiatry appointments and community nursing time for dressing changes).

The study concludes that, 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.<sup>4</sup> 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

### **Cost**

The NHS list price for the VACO cast diabetic boot is £149 per boot irrespective of size. In the evaluation by Bowen and Spruce, above, patients were followed up at week 1, week 2 and then 2 weekly.<sup>9</sup>

The unit price for the TCC-EZ protective boot (the brand used in the community evaluation by Bowen and Spruce)<sup>9</sup> is £41 with an individual cast price of £54.<sup>7</sup> With a non-removable cast, the cast is frequently replaced and in the community evaluation study this was done after 24 hours, at 5 days and then weekly.<sup>7</sup>

Patients receiving either a non-removable cast or the VACOCast diabetic boot will also be offered an overshoe device for the contra- lateral limb, to protect the knees, hips and back from device related injury.

A comparison of treatment costs was conducted in one evaluation as follows:<sup>7</sup>

| Comparative Price of TCC-EZ® and VACOcast Diabetic Boot With Consumables |        |                |                           |                               |        |                |                           |
|--|--------|----------------|---------------------------|-------------------------------|--------|----------------|---------------------------|
| TCC- EZ - price  |        |                |                           | VACOcast Diabetic Boot- price |        |                |                           |
| Consumables  |        |                |                           | Consumables                   |        |                |                           |
|  | Number | Unit Price (£) | Total Price at Week 1 (£) |                               | Number | Unit Price (£) | Total Price at Week 1 (£) |
| Protective Boot  | 1      | 41             | 41                        | VCD Boot                      | 1      | 149            | 149                       |
| Even Up  | 1      | 18             | 18                        | Even Up                       | 1      | 18             | 18                        |
| Cast   | 3      | 54             | 162                       |                               |        |                |                           |
| Total  |        | £113           | £221                      | Total                         |        | £167           | £167                      |

| Comparative Price of TCC-EZ and VACOcast Diabetic Boot With Consumables. |        |               |                             |                               |        |                |                             |
|--|--------|---------------|-----------------------------|-------------------------------|--------|----------------|-----------------------------|
| TCC- EZ - price  |        |               |                             | VACOcast Diabetic Boot- price |        |                |                             |
| Consumables  |        |               |                             | Consumables                   |        |                |                             |
|  | Number | Unit Cost (£) | Total Cost Over 8 Weeks (£) |                               | Number | Unit Price (£) | Total Cost Over 8 Weeks (£) |
| Protective Boot  | 1      | 41            | 41                          | Boot                          | 1      | 149            | 149                         |
| Even Up  | 1      | 18            | 18                          | Even Up                       | 1      | 18             | 18                          |
| Cast   | 10     | 54            | 540                         |                               |        |                |                             |
| Total  |        | £113          | £599                        | Total                         |        | £167           | £167                        |

| Comparative Cost TCC v VACOcast Diabetic Boot (Consumables and Clinician Time) |   |                         |  |         |   |                         |  |         |
|--|---|-------------------------|--|---------|---|-------------------------|--|---------|
| Comparative Cost of Care   | Cost of TCC (Band 6 Podiatrist) Over 8 weeks. (10 visits) |                         | Cost of VACOcast Diabetic (Band 6 Podiatrist) over 8 weeks. (6 visits) |         | Cost of TCC (Band 7 Podiatrist) over 8 weeks. (10 visits) |                         | Cost of VACOcast Diabetic (Band 7 Podiatrist) over 8 weeks. (6 visits) |         |
|  | 1 staff   | 2 staff Band 6 + Band 3 | 1 staff  | 2 staff | 1 staff   | 2 staff Band 7 + Band 3 | 1 staff  | 2 staff |
| Consumables  | £599.00   | £599.00                 | £167.00  | N/R     | £599.00   | £599.00                 | £167.00  | N/R     |
| Staff Costs  | £210.70   | £294.0                  | £126.42  | N/R     | £248.40   | £331.70                 | £149.04  | N/R     |
| Total  | £809.70   | £893.0                  | £293.42  | N/R     | £847.40   | £930.70                 | £316.04  | N/R     |

It was assumed that a 45 minute appointment was required which includes routine care.

Where the cost of 2 staff is calculated, the cost of the second clinician is a Band 3 support worker.

These comparative costs illustrate the potential cost savings over an 8 week time period per patient associated with the VACOcast diabetic boot compared to TCC of:

- between £516.28 and £599.58 (if band 6 podiatrist) and
- between £531.36 and £614.66 (if band 7 podiatrist)

## **References**

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- <sup>1</sup> NHS Digital, National Diabetes Foot Care Audit <https://digital.nhs.uk/data-and-information/clinical-audits-and-registries/national-diabetes-foot-care-audit>
- <sup>2</sup> NHS Digital. National Diabetes Foot Care Audit 3<sup>rd</sup> Annual report (England and Wales 14<sup>th</sup> July 2014 – 31<sup>st</sup> March 2017) <https://files.digital.nhs.uk/73/39E604/ndfa-3ar-rep-1.pdf>
- <sup>3</sup> NICE NG19 Diabetic foot problems: prevention and management <https://www.nice.org.uk/guidance/ng19/chapter/Recommendations#diabetic-foot-ulcer>
- <sup>4</sup> IWGDF Guidelines on the prevention and management of diabetic foot disease (2019) <https://iwgdfguidelines.org/wp-content/uploads/2019/05/IWGDF-Guidelines-2019.pdf>
- <sup>5</sup> Armstrong D.G. et al. Offloading the diabetic foot wound, a randomised clinical trial. Diabetes Care 2001 Jun; 24(6): 1019-1022 <https://care.diabetesjournals.org/content/24/6/1019>
- <sup>6</sup> NHSBSA Drug Tariff, March 2020, p522 available online: <https://www.nhsbsa.nhs.uk/sites/default/files/2020-02/Drug%20Tariff%20March%202020.pdf>
- <sup>7</sup> Bowen G (Clinical Lead for Podiatry Solent NHS Trust) and Spruce P (Clinical Director TVRE Consulting), An Evaluation Of The VACOcast Diabetic Boot™ Within The Community, file data provided to MLCSU by OPED UK Ltd: [enquires@oped.biz](mailto:enquires@oped.biz) . A summary of the corresponding study can be accessed online: [https://opedmedical.com/fileadmin/user\\_upload/CIME\\_Summary\\_UK\\_An\\_Evaluation\\_of\\_VACOcast\\_Diabetic\\_Boot\\_TM\\_Within\\_The\\_Community\\_Bowen\\_Spruce\\_181119.pdf](https://opedmedical.com/fileadmin/user_upload/CIME_Summary_UK_An_Evaluation_of_VACOcast_Diabetic_Boot_TM_Within_The_Community_Bowen_Spruce_181119.pdf)
- <sup>8</sup> Gotz J et al. Off loading strategies in diabetic foot syndrome – evaluation of different devices. International Orthopaedics 2017;41: 239-246 <https://www.ncbi.nlm.nih.gov/pubmed/27942889>
- <sup>9</sup> Bowen G and Spruce P, Evaluating a removable knee-high cast walker within the diabetic foot pathway. The Diabetic Foot Journal 2019; 22(3): 52-9 <https://www.diabetesonthenet.com/resources/details/evaluating-removable-knee-high-cast-walker-within-diabetic-foot-pathway>