### REDUCING THE COST BURDEN OF DFUs USING TOTAL CONTACT CASTING TCC-EZ®

# MAKING THE CASE

### INTRODUCTION: THE CHALLENGE

Prevalence of diabetes continues apace in the UK: the 2004-05 to 2013-14 Quality Outcomes Framework (QOF) shows that there are now 3.33 million people diagnosed with diabetes, and an estimated 590,000 undiagnosed adults. By 2025 it is estimated that 5 million people will have diabetes in the UK. Most cases will be type 2 diabetes: the result of the rapid rise in obesity and of an ageing population.

In 2010/11 in the UK diabetes cost around £23.7bn in both direct and indirect costs. The current cost of direct patient care (treatment, intervention and complications) for those living with diabetes is estimated at £9.8bn (£1bn for type 1 diabetes; £8.8bn for type 2 diabetes) (Hex et al, 2012). Around 80% of spend is used to treat complications associated with diabetes. Of this £600m-£700m is spent each year on foot ulcers and amputations (Diabetes UK, 2012; 2014). Amputation is major complication of poorly managed diabetes: it is the most common cause of lower limb amputation in the UK. In England in 2015 there were 135 diabetes-related amputations per week — 80% of these were preventable (Diabetes UK, 2015).

The impact of a diabetic ulcer on 5-year survival rates is significant: around 56% of people with diabetes who have an ulcer survive for 5 years (Kerr, 2012). Only 48% of patients with diabetes who undergo an amputation survive for more than five years post amputation (Robbins et al, 2008; Wounds International, 2013). The common complications of diabetes, including amputation, have higher mortality rates than a number of cancers, including prostate and breast cancer, and Hodgkin's disease (Snyder and Hanft, 2009).

#### **IMPROVING CARE**

To combat the growing problem, Diabetes UK launched Putting Feet First in 2013, and commissioners and NHS healthcare planners were tasked with delivering an integrated foot care pathway that provides the right treatment at the right time and in the right place for all people with diabetes. They were asked to:

- Set up referral within 24 hours to a multidisciplinary (MDT) specialist foot care team for patients with ulcers
- Ensure appropriate referral to a foot protection team which has expertise in assessing and managing foot disease
- Create local diabetes networks to join up and improve foot care.

Clinical Commissioning Groups (CCGs) need to improve foot care across the pathway to boost patient outcomes and reduce the number of preventable ulcers, and subsequent amputations. This can only be achieved through integrated care provided by MDTs with a clear treatment pathway, in particular for referral and treatment of new ulcers (Kerr, 2012). Diabetes UK is pushing for all CCGs to have a NICE-compliant diabetic foot pathway from primary care to MDT. The move to fully optimised MDTs can be complex requiring both changes to process and entrenched behaviours. However, the costbenefits are clear, as are improvements to the patient journey and experience. Targeted prevention and immediate access to MDTs, comprising physicians, nurses, podiatrists, dieticians and clinical psychologists can result in reduced cost, faster healing, fewer amputations and improved survival (Kerr 2012).

Savings from MDTs substantially outweigh the cost of establishing the team. For example, lower-extremity amputation rates (major and minor combined) at James Cook University Hospital, Middlesbrough, fell by two-thirds after the introduction of an MDT. The annual cost of the team is estimated at £33,000 (2010/11 prices). Savings to the NHS from averted amputations are estimated at £249,000, more than seven times the cost of the team.

Quality-adjusted life-year (QALY) gains over a 5-year perspective for a 1-year cohort of patients who averted major amputation are estimated at £151,000 (valued at £25,000 a QALY) (Kerr 2012). However, around 20% of hospitals providing diabetes care do not have MDTs.

Many Trusts do not have adequate pathways or MDTs to support rapid referral and treatment of patients with new ulcers. This was evidenced by a recent survey undertaken in February 2016 among podiatry leads in the UK aimed at scoping current provision, capacity and access of total contact casting (TCC). The survey shows that current capacity for TCC is restricted because plaster rooms in acute settings are at capacity and unable to take on any new activity (Table 1).

#### Table 1

Questions	Results	
What capacity do you currently have for TCC per week?	<ul> <li>Of the responses:</li> <li>✓ 30-40% indicated no capacity for TCC where they work</li> <li>✓ 50-60% have less than 7 TCC slots per week</li> <li>✓ 10% have more than 8 TCC slots per week</li> </ul>	
How many patients can you have in TCC at any one time?	Responses ranged from 0-40 patients in TCC	
Who provides your total contact casting — podiatry, orthopaedics, orthotist, plaster room etc?	Majority of responses said TCC is applied by plaster technicians	
Where is this provided — acute/community	Over 90% indicated this was provided within an acute setting	
What % of diabetic foot patients do you think should be in a TCC?	This ranged from 15% to 50% of all patients with foot ulceration and Charcot. All patients with active Charcot and non-healing neuropathic foot ulceration of 6 weeks or more	

**Explanation of how to use this guide:** This document can be used to make the case for implementing effective prevention and management measures and may be supported by data from your own care setting. As well as economic impact, it is important to know the impact of interventions on patient quality of life and outcomes

### **OFFLOADING EVIDENCE**

Plantar pressure can be reduced through the use of several modalities including casts, walkers, therapeutic footwear and surgery. TCC has been used for offloading DFUs since the 1960s and has come to be regarded as a 'gold standard' treatment for offloading (Boulton and Armstrong, 2004).

TCC has been shown to:

- Reliably reduce plantar pressure by 84-92% (Lavery et al, 1996)
- Increase healing rates in plantar ulcers 90% in 5-8 weeks (Armstrong et al, 2001).

However, the least effective offloading method — the post-operative shoe — remains the most used. Despite improving patient outcomes, reducing health service costs and being recommended for use, just 3.7% of eligible DFUs receive TCC, according to findings of a 5-year retrospective study of 25,000 people with diabetes (Fife et al, 2014).

NICE recommends non-removable offloading devices that reduce peak plantar pressures and redistribute pressure from the ulceration site in

#### Comparison of TCC-EZ vs traditional TCC: A five-year retrospective analysis of 25k DFUs

The analysis showed that

- Four times as many patients were casted in clinics using TCC-EZ (Fife, 2014)
- TCC-EZ enforces patient compliance (not removable)
- ✓ TCC-EZ significantly reduces signs of infection were observed with TCC-EZ (Overall infection was less with TCC vs non-TCC)
- TCC-EZ outcomes are comparable to/better than traditional casting
- ✓ TCC-EZ is easy to apply and remove
- TCC-EZ reduces amputations by half 2.2% with TCC; 5.3% non-TCC (Fife et al, 2014)

patients with acute foot problems (NICE, 2015). Yet, to date, few studies directly relate offloading to clinical outcomes (Mahmood et al, 2015). When compared to a removable cast, TCC significantly improves compliance. Research shows that patients treated with removable devices wore it for a total of 28% of their daily activity, none achieving more than 60% wear during active hours (Armstrong et al, 2003).

### OVERCOMING PERCEPTIONS: IMPROVED HEALING AND INCREASED CAPACITY

Under-use of TCC represents lost opportunities in healing wounds, improving patients' lives and maximising health service efficiencies (Sambrook et al, 2015). However, there are numerous reasons why TCC may not be used, including:

- Time-consuming to apply (45–60 minutes)
- Lack of skills or confidence in applying TCC
- Lack of specialist/cast technician with training/experience in applying TCC safely
- Fear of causing harm (further tissue damage)
- Impact on patient lifestyle (psychosocial issues)
- Patient compliance (often patients prefer removable devices following negative experience with TCC).

These issues can result in variation in the use of TCC, and different levels of care being offered across the UK. This variance can be addressed through the use of TCCs that are easily applied, do not require extensive training to apply, improve patience compliance, and patient experience, such as TCC-EZ.

### **CASE FOR TCC-EZ**

TCC-EZ is a single-component roll-on, lightweight woven sock. It creates an instant cast, which immobilises and stabilises the foot and ankle. Complemented by a boot attachment it provides stability and strength, enabling weight bearing.

- It takes under 10 minutes to apply TCC-EZ a quarter of the time taken to apply a traditional cast (Bohn, 2009)
- 100-patient study showed that clinicians applied TCC-EZ in a busy clinic with initial competency and no additional training was needed. The system can be included in everyday practice
- No patient had serious complications caused by application errors (Jensen et al, 2008)
- Improved patient concordance lightweight, increased comfort, increased mobility (detachable boot avoids need for crutches), greater independence
- Improved healing due to natural healing chamber; active wound healing between 5–8 weeks.





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### TCC-EZ®

With an average healing time of 6 weeks compared to up to 52 weeks for removable interventions, TCC-EZ in effect frees up 46 weeks of clinician time. Some 90% of DFUs are healed in 33 days with TCC and 65% with removable walkers in 50 days. This reduces the amount of ongoing demand on the health service and addresses a nationwide unmet need to significantly reduce re-ulceration.



The reduction in re-ulceration rates enables more patients to be seen with the same resource, enabling Trusts to meet waiting time targets and provide more effective, efficient treatment with the same/existing resources.

Freeing up capacity and lowering costs, along with reducing unplanned admissions is key to reducing the burden on the health service.

TCC-EZ can be easily used in the community and/or integrated into community podiatry services within established clinics. This means that the patient benefits both from having TCC-EZ and continuity in their care. Podiatry is ideally placed to offer TCC-EZ within its services — this will improve clinical outcomes, aid compliance, allow for greater productivity, and avoid undue waste and duplication.

### PATHWAY

TCC-EZ is an effective modality for treating DFUs and is key to improved healing times and reduction of re-ulceration. However, prevention of further ulceration is central to follow-up care in the treatment pathway. Once the ulcer has healed the patient should be transferred to suitable insoles or orthotic shoes.

It is essential that these are available to safeguard the patient's skin integrity. The MDT plays a significant role in ensuring that each patient's needs are identified and met — the tie up between all levels of care is pivotal to this working, in particular the communication between care services.

### What cost savings could you make in your practice using TCC-EZ?

TCC is considered a cost-effective treatment; the average total cost of treatment per patient is \$11,946 ( $\pounds$ 7,697\*) versus \$22,494 ( $\pounds$ 14,493\*) when TCC is not used (Fife et al, 2010). Using TCC-EZ to offload enables the foot ulcer to heal faster, frees up capacity by reducing clinical time needed to apply the cast, and reduces overall treatment costs.



Providing TCC-EZ to a group of patients with active diabetic foot ulceration results in benefits and savings across the health economy. By using TCC-EZ services, Solent NHS Trust Podiatry is already seeing benefits. These include:

- Overall savings on management of DFUs seen across the health system thanks to reduced healing times
- Reduction in likelihood of secondary infection, less risk of infection and reduced cost of antibiotics/antimicrobial dressings and reduction in resistance/MRSA
- Reduction in non-elective admission for foot infection
- Reduction in minor and major amputations 95% of all amputations start with a single ulcer — healing the ulcer will prevent admission and amputation

	TCC-EZ (applied in clinic)	Non-TCC traditional model of care	TCC plaster room
Average cost to the CCG	£922.50	£2,797.20 (Kerr, 2012)	£852.00
Average healing time	5-8 weeks	52 weeks	5-8 weeks
Average total appointment time	45 minutes	45 minutes	90 minutes +*

\*excludes transfer and waiting time

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- Faster healing times, which enable vulnerable patients to undergo other much-needed procedures, including renal transplant and hip operations
- Greater compliance preventing re-ulceration and ongoing prevention of re-ulceration
- Greater productivity allowing more patients to be managed under the same block contract, and a reduction in waiting time
- Reduction in the high amputation (minor/majors) rate for the CCGs; improved position when compared to other CCGs
- Clinical outcome-focused care
- Establishing a centre of excellence for the management of diabetic foot ulceration.

The positive impact on cost and capacity can be felt across the CCG in other (underfunded) services that play an integral part in the overall management of diabetes, for example, mental health.

### How can you drive support to reduce the number of non-elective hospital admissions for DFUs?

Since its introduction in 2010/11 the Commission for Quality and Innovation (CQUIN) payment framework has encouraged NHS organisations to improve care quality by making a proportion of income conditional on quality and innovation — and to share results of improvements in clinical practice in secondary care.

In other words, the framework enables commissioners to reward excellence in improving care by linking a proportion of providers' income to the achievement of local quality improvement goals.

Data show that TCC-EZ costs less than non-TCC methods, takes less time to apply, reduces time to healing, reduces the incidence of re-ulceration and can result in savings (both in terms of time and money) — all of which are key decision drivers for commissioners.

Teams can use the CQUIN framework to support the drive to reduce the number of patients requiring non-elective hospital admission for diabetic foot disease and contribute to the push towards reducing diabetes related amputations by:

- Identifying the issues by analysis: audit case loads and assess eligibility of patients for TCC-EZ
- Setting timetable, scope and milestones for reducing the case load, improving patient experience and outcomes by using TCC-EZ
- Explaining levels of funding needed
- Setting out how existing resources would be used to free up capacity and improve patient experience and outcomes
- Detailing savings across the CCG, not just in podiatry
- Using real-world data from pilots/other CCGs to strengthen the case for change
- Setting out how to evaluate the project (with the aim of publishing the results)
- Reviewing and deliver against financial requirements.

#### References

Armstrong DG, Nguyen H, Lavery LA et al (2001) Off-loading the diabetic foot wound. Diabetes Care 24: 1019–22.

Armstrong DG, Lavery LA, Kimbriel HR, et al (2003) Activity patterns of patients with diabetic foot ulceration: patients with active ulceration may not adhere to a standard offloading regimen. *Diabetes Care* 26: 2595–7.

Bohn G (2009) Cost Effectiveness and Implementation of an Easy to Apply Total Contact Casting System for Diabetic Grade 2 Neuropathic Foot Ulcers in a Multi Physician Clinic. Clinical Symposium on Advances in Skin and Wound Care, October 2009, San Antonio, USA, Poster

Boulton A, Armstrong DG (2004) Off-loading in trials of neuropathic diabetic foot ulceration. Further evidence for a paradigm shift. *Diabetes Care* 27: 636–7

Diabetes UK (2012) Supporting, Improving, Caring: Factsheet. Diabetes UK. Available at http://bit.ly/1vD3dFU. (accessed 29.04.16)

Diabetes UK (2014) The Cost of Diabetes: 7. Available at https://www.diabetes.org.uk/ Documents/Diabetes%20UK%20Cost%20of%20Diabetes%20Report.pdf (accessed 27.04.2016)

Diabetes UK (2015). More than 135 diabetes amputations every week. Available at https:// www.diabetes.org.uk/About\_us/News/More-than-135-diabetes-amputations-everyweek/ (accessed 15.03.2016)

Fife CE, Carter MJ, Walker D (2010) Why is it so hard to do the right thing in wound care? Wound Rep Reg 18: 154-8

Fife CE, Carter MJ, Walker D et al (2014) Diabetic foot ulcer offloading: the gap between evidence and practice. Data from the US Wound Registry. *Adv Skin Wound Care* 27: 310–6 Health & Social Care Information Centre (2014) *Quality Outcomes Framework — Prevalence, Achievements and Exceptions report 2013-2014*. HSCIC. Available at http://www.hscic.gov.uk/catalogue/PUB15751/qof-1314-report-V1.1.pdf (accessed 04.05.16)

Hex N, Bartlett C, Wright D, Taylor M and Varley D (2012) Estimating the current and future costs of Type 1 and Type 2 diabetes in the UK, including direct health costs and indirect societal and productivity costs. *Diabetic Medicine* 29 (7): 855-862

Jensen J, Jaakola E, Gillin B et al (2008) TCC-EZ — Total Contact Casting System Overcoming the Barriers to Utilizing a Proven Gold Standard Treatment. Diabetic Foot Global Conference, 2008

Kerr, M (2012) Inpatient Care for People with Diabetes — The Economic Case for Change. NHS Diabetes. Available at http://bit.ly/1fX6wTQ (accessed 18.03.16).

Lavery LA, Vela SA, Lavery DC, Quebedeaux TL (1996) Reducing dynamic foot pressures in high-risk diabetic subjects with foot ulcerations. A comparison of treatments. *Diabetes Care* 19: 818–21

Mahmmod S, Lew E, Armstrong, DG (2015) Offloading diabetic foot ulcers: updates by the International Working Group in the Diabetic Foot. *The Diabetic Foot Journal* 18: 120-5 National institute for Health and Clinical Excellence (2015) *Diabetic foot problems*:

prevention and management. NICE. Available at https://www.nice.org.uk/guidance/ng19 (accessed 29.04.2016)

Robbins JM, Strauss G, Aron D et al (2008) Mortality rates and diabetic foot ulcers: Is it time to communicate mortality risk to patients with diabetic foot ulceration? *J Am Pod Med Assoc* 98: 489–93

Sambrook E, Delpierre T and Bowen G (2015) Advancing the gold standard in offloading the diabetic foot. *Wounds UK*, EWMA Special: 48-56

Snyder, RJ and Hanft, JR (2009) Diabetic foot ulcers — effects on quality of life, costs, and mortality and the role of standard wound care and advanced-care therapies in healing: a review. *Ostomy/wound management* 55 (11): 28

Wounds International (2013) Best Practice Guidelines: Wound Management in Diabetic Foot Ulcers. *Wounds International*. Available at: http://bit.ly/1DpEiZm (accessed 27.03.2016)