A Review of Total Contact Casts for Offloading Diabetic Foot Ulcers

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Abstract

Dr Paul Brand was the first to widely use Total Contact Casting (TCC) in the mid 1960’s to offload the insensate foot in Hansen’s disease (Sinacore et al, 1987). It has since been identified as a ‘Gold Standard’ for offloading diabetic foot ulceration within the diabetic foot-care community (Boulton, 2004). Keywords: Diabetes, Total contact casting, Total contact cast were entered into Medline and Scopus and 32 papers were identified for review. Four broad areas of research were identified within the TCC literature: Specific pressure and biomechanical related studies, Safety of TCCs, Alternative Treatments to TCCs and Other studies/papers. TCC has been shown in the literature to be of benefit in offloading diabetic foot ulceration and future research in this area would benefit from centring on the instant TCC concept as this provides the benefits of TCC more cost effectively with less training required.

Keywords:

Total Contact Cast Diabetic foot ulcer, Offloading Removable Cast Walker, Instant Total Contact Cast

Introduction

Diabetic foot ulceration and related amputations were estimated in 2001 to cost the National Health Service £252 million (Boulton et al, 2005). Total Contact Casting (or Total Contact Casts - TCC) has been used for off-loading diabetic foot ulcers (DFUs) since the mid 1960s after it was initially developed for the insensate foot in Hansen’s disease (Sinacore et al, 1987). Several studies have been published in the last 20 years investigating many aspects surrounding TCCs; consequently TCC has become regarded by clinicians in the diabetic foot community as the ‘Gold Standard’ for off-loading the diabetic foot (Boulton, 2004).

The future of offloading treatments would appear to be with the use of instant TCC’s as these do not require extensive training to apply and are more cost effective. This article will critically review the key papers published regarding TCC and alternative offloading treatments to establish the most effective treatment for healing DFUs.

Search strategy
Scopus and Medline were searched for keywords:

**Diabetes**

*Total contact casting (Scopus 39, Medline 40)*

*Total contact cast (Scopus 63, Medline 30)*

Papers were rejected that were:
General diabetic foot ulcer reviews, Charcot related, orthopaedic specific, foreign language or unavailable; this resulted in 32 papers combined from Scopus and Medline and the key papers are discussed.

This review will consider four areas covered within the TCC literature:
- Specific pressure and biomechanical related studies
- Safety of TCCs
- Alternative Treatments to TCCs
- Other studies/papers

Most of the relevant papers identified pressure and biomechanical factors for consideration therefore the majority of the review will address these issues.

**Pressure and Biomechanical Related Studies**

The aim of TCC is to reduce plantar pressures by increasing the weight-bearing surface of the foot (Sinacore *et al*, 1987). Although TCC has been applied to the diabetic foot since the 1960’s, it was in the mid to late 1980’s that investigators started to look for evidence that TCC reduce the healing times of DFUs. Sinacore *et al* (1987) casted thirty subjects with foot ulcers (27 diabetic and 3 control). All subjects had a degree of sensory neuropathy and vascular investigations identified six subjects with an Ankle Brachial Pressure Index (ABPI) of less than 0.66. Although the paper states that an ABPI greater than 0.45 is required for healing, many clinicians in the UK would exclude any subject with an ABPI of < 0.7 from a clinical trial (Personnel Communication, 2005). The results of the study were encouraging with 81.8% of the DFUs healing in 43.6 ± 51.9 days compared to the non-diabetic group healing in 129 ± 145 days however these surprising results were attributed to the greater foot deformity present in the non-diabetic group. These encouraging results could not be attributed to the redistribution of plantar pressures, as pressure monitors were not fitted inside the casts however this study did provide a baseline for others to follow.

In one of the first controlled clinical trials for TCC, Mueller *et al* (1989) compared...
TCC with traditional dressing treatment in forty subjects with diabetes. Again the study could not conclude that TCC reduced pressures however the data showed that TCC was more efficient at healing DFUs than traditional dressing regimen.

Unfortunately there was inconsistency within the results as subjects were given walkers or crutches as required. If discrepancies are to be avoided then either all subjects should use walking aids or none at all so as to limit the differing forces applied to the foot and subsequently the ulcer. Weight-bearing time should be monitored, recorded and limited to a standardised amount. This would be hard to police however, would strengthen the study design. This research followed a previously published Case Study by Mueller and Diamond (1988) that considered the biomechanics of the foot in relation to TCC and DFUs. Obviously the results of a case study are considered of less power in the hierarchy of evidence (Woolf et al., 1990) however the paper does highlight some interesting points. It was the first to truly consider the role of lower limb biomechanics to TCC treatment and in the prevention of ulcer recurrence with post TCC orthopaedic footwear and accommodative insole therapy prescription. The study reported the available range of motion of the foot noting a fixed equinus deformity and subtalar varus with forefoot valgus, and attributed the causal factor of ulceration to these deformities. The collected data was used to manufacture an orthosis for ambulatory use post TCC which proved to be successful in preventing further ulceration. Unfortunately these findings cannot be applied to the wider population as they are specific to one subject however, they do add to the body of knowledge regarding TCCs and post ulcer preventative therapy.

Diamond et al (1993) assessed the effects that restricting the lower limb in a TCC for 40+ days has on joint range of motion. The authors measured the range of motion pre and post casting in thirty-seven subjects with diabetes compared with their contra lateral non-casted limb. Significant findings were only relevant in the dorsiflexion of the ankle joint with a relatively small value of 1° however the authors argue that the reduced stride length required to walk with a TCC could have limited dorsiflexion in the non-casted leg also. Healing times of ulcers was again around 42 days and the authors conclude that the quick healing of DFUs is preferable to a slight reduction in ankle dorsiflexion. These conclusions could be challenged in regards to the prevention of ulcer recurrence; 10° of dorsiflexion are required for normal gait therefore limited dorsiflexion will increase pressures on the forefoot from heel lift.
through the propulsion phase of gait until toe off. Ankle equinus has been reported to increase plantar pressures in the forefoot (Mueller and Diamond, 1988; Christensen and Albert, 1994); any treatment that increases the possibility of ankle equinus and subsequently an increase in plantar pressure could result in re-ulceration.

The first of the published studies to use pressure-monitoring devices was by Wertsch and Frank (1995), however the six subjects used were not diabetic and had no history of ulceration. They found an average decrease in plantar pressure between 32% and 69% depending on the area of the foot but the effects of shear stresses on the foot were not addressed. The limitations of TCCs are discussed in detail later (insensate foot in a cast that cannot be monitored, iatrogenic ulceration, time and skill limiting) however; this prompted a move to investigate other possible treatment modalities (Lavery et al, 1996). Various walking devices were assessed for reducing pressures over three areas; the 1st Metatarsal head, the 2nd-5th Metatarsal heads and the Great toe. The EMED Pedar in-shoe pressure measuring system was used to determine pressures on these selected areas but there was no attempt to standardise the gait of the subjects before measurement; for example, if the subjects had marked differences in the biomechanical make up of their foot (e.g. ankle equinus, forefoot invertus or plantarflexed 1st ray) then data between the subject groups may not be directly compatible. Results showed that the DH Walker device performed to a similar standard as the TCC and specifically over the 2nd-5th metatarsal area, reduced pressures more than the TCC. Royce Medical, the manufacturer of the DH Walker, funded the study. To further understand the relationship between pressure, glucose control and wound surface area in TCC Armstrong et al (1998) continued Lavery’s work. Again a small subject size was used (25), yet the paper did give a more detailed understanding of the relating factors. There was a relation between poor glucose control and the size of the presenting ulcer (poorer control correlating to larger presenting ulcers) and unsurprisingly a relationship between ulcer size and time to healing. High pressures also increased the time to healing highlighting that efficient and detailed examination of foot function is required in all DFU care. Again activity levels were not monitored and biomechanical factors were not standardised between subjects.

Within the literature reviewed, TCCs appear to be allowing DFUs to heal by reducing the pressure the foot and ulcer are subjected to. DFUs in the presence of deformity are less likely to heal due to increased pressures relating to the deformity
Another small study (21 subjects) reviewed the healing time of DFUs within TCCs of subjects with various deformities of the forefoot, midfoot and rearfoot (Sinacore, 1998). Results showed that midfoot deformities are most likely to increase the ulcer healing time, as the most common midfoot deformity was as a result of Charcot Neuroarthropathy. This deformity causes medial bulging of the longitudinal arch putting the tissues under abnormal stresses (Jeffcoate et al, 2000).

One issue regarding all the studies by Sinacore, Mueller and co-workers is that for intra-rater reliability they use the same two casters with several years of experience; this does not allow for inter-rater reliability of TCC manufacturing to be addressed.

When applying a TCC, consideration should be taken to a vulnerable opposing limb as excessive forces may cause further ulceration. Hartsell et al (2002) compared two materials used to make TCCs, the standard plaster-of-paris bandages and a fibreglass tape. They hypothesised that contra-lateral plantar parameters would be increased with TCC and the traditional TCC materials would cause greater plantar parameters than the fibreglass tape. Subjects had no musculoskeletal or neuromuscular pathology and there was no history of DFUs within the subject group. The mean age range was 34.1 compared to 55.4 for the studies involving diabetic subjects. It would be difficult to relate the findings of young, fit, healthy subjects with a normal gait to that of the typical diabetic patient with a foot ulcer who is likely to have other conditions as a result of micro-vascular disease also. Obviously ethical considerations were made regarding a study that could potentially develop ulceration on subjects with diabetes and a history of DFU, and this limited the study to healthy individuals. Perhaps a retrospective study assessing the incidence of ulceration on contra-lateral limbs and trying to attribute that to pressure, footwear worn or the materials of the TCC would provide satisfying results. The study found that TCC manufacturing materials did not adversely affect the opposing limb in regards to plantar pressures on the opposing limb. Hartsell and colleagues then used the same data collected in this study to look at the effects of different TCC materials on plantar pressures (Hartsell et al, 2004). They discovered no difference between the two materials and compared their results of peak pressure reductions to other studies by other teams. Direct parallels cannot be made between studies, as casting techniques are not standardised. Saltzman and colleagues carried out studies of a similar theme investigating what effects weight-bearing in the initial stages (< 48 hours) after manufacture (Saltzman et al, 2004). All authors suggest a time period to allow the
TCC to fully harden (between 30 and 60 minutes) (Armstrong et al, 1995; Lavery et al, 1997; Hartsell et al, 2002); Saltzman et al (2004) placed pedometers in TCCs after instructing the subjects to limit weight-bearing in the first 48 hours. The results from forty subjects showed that the entire group did weight-bearing in the first 48 hours and excessive weight-bearing in the first 24-48 hour period increased the healing time of the ulcers. It would be interesting to observe results from a group of subjects that had had enforced rest (i.e. hospital admission with bed rest); this would have added to the value of the study as the results of three groups (no weight-bearing, limited weight-bearing and excessive weight-bearing) could have been analysed.

It may be appropriate to conclude this section on pressure related studies with a review paper considering the many different offloading techniques by Boulton (2004). He considers the pathway to diabetic foot ulceration including neuropathy, abnormal pressures and other risk factors including ethnicity but concludes that neuropathy, deformity and trauma are the most common causes of DFUs. Boulton then considers the many types of offloading and pressure relief available including footwear, hosiery and ‘half shoes’, but concludes the TCC is the ‘gold standard’ for pressure management. It would seem that some offloading treatments have not been considered such as felt padding and newer modalities like the DH Walker (Zimny et al, 2003; Lavery et al, 1996) however; this may be due to the lack of published data in these areas.

It would appear that the majority of the studies into pressure relief and TCC concur that pressure relief is achieved by TCC. Unfortunately the studies lack power until a large multi-centre trial can be undertaken with a greater sample size and proven inter-rater reliability.

Safety of TCC

Many clinicians are unhappy about placing an insensate foot within a constricted, irremovable cast (Fabrin et al, 2000). Iatrogenic ulceration, where ulceration occurs whilst within the cast due to pressure or friction from cast materials is a concern identified by Wukich and Motko (2004) and Guyton (2005). Both studies identify a reduced risk with careful casting techniques; Wukich and Motko (2004) prospectively casted thirteen subjects a total of eighty-two times over an eighteen-month period and noted any place iatrogenic ulceration occurred. Any susceptible area was protected with additional padding in subsequent casts until ulcer resolution; the paper also
highlighted abnormal foot shapes as an area of potential difficulty. Guyton (2005) collected data on seventy subjects and reviewed 398 casts retrospectively; although prospective studies are the preferred method for data collection the large number of subjects strengthens this study above Wukich and Motko’s paper. Guyton’s results showed only one minor complication in every twenty TCCs, and highlights that iatrogenic ulceration with experienced clinicians is rare.

Helm et al (1991) identified the recurrence of ulceration post casting is as an issue as twenty (19.6%) of the one hundred and two subjects in their study re-ulcerated post TCC. This recurrence was thought to be mainly due to a lack of program compliance; for example not wearing the prescribed footwear post healing or the changes in foot shape as a result of Charcot Neuroarthropathy. The author’s identified the depersonalisation of the neuropathic limb as an issue when preventing recurrence of DFUs as subjects viewed the limb inanimate as they could not feel it. Unfortunately the study only briefly mentions the use of specialist footwear as a preventative means for DFU recurrence as the use of footwear as a preventative means for re-ulceration is widely acknowledged (Ucciolli et al, 1995; Busch and Chantelau, 2003). The strength of good footwear provision to prevent DFU recurrence is similarly not highlighted in a study by Matricali et al (2003) who suggest surgical correction should be considered. Only four from twelve subjects remained ulcer free eighteen months post TCC and this was attributed to poor compliance with foot treatment and diabetes control.

Alternative Treatments to TCCs
The disadvantages of TCC has been briefly mentioned as time consuming, possibility of iatrogenic ulceration and requiring skill and training to apply; therefore clinicians have looked towards other treatment modalities than can be as effective as TCC. A large retrospective study was completed by Birke et al (2002) comparing DFU healing rates using alternative off-loading methods. Four treatments were compared; an accommodative dressing (including felt padding), a healing shoe, a walking splint (a simplified version of a TCC) and a TCC in one hundred and twenty subjects. Results showed that one hundred and thirteen (94%) healed within $45.5 \pm 43.4$ days and there was no difference in healing time between each treatment. Standardised
dressings were not used between the off-loading treatments and this will have a bearing on the results and as the study was retrospective it could not be randomised.

Further continuing Lavery et al’s (1996) work, Armstrong et al (2001) performed the first randomised clinical trial into off-loading the DFU. They compared a TCC, a removable cast walker (RCW) and a half shoe in sixty-three subjects to measure the number DFUs fully healed at twelve weeks. The activity of the patients was also measured with a pedometer however there was no means of enforced compliance with this device. It was the enforced compliance of the TCC that the authors believed was responsible for the reduced healing time compared to the RCW and half shoe, results that contradict the findings of Birke et al (2002). There was also a significant reduction in the number of steps taken between the TCC and the half shoe, the restrictive qualities of the TCC making it harder to mobilise leading to less activity and weight-bearing. The same team compared a TCC with a RCW rendered irremovable (or instant - iTCC) with a layer of casting tape applied to the top (Katz et al, 2005). Previous research from the team had suggested that the RCW (DH Walker) could be as effective as the TCC (Lavery et al, 1996) and the hypothesis was that rendered irremovable; the RCW should be as effective as the TCC. Forty-one patients were randomly assigned to either group and results showed that there was no difference between the two devices. There were fewer complications (e.g. localised maceration) experienced by the iTCC group and there was significantly shorted application and removal times for the iTCC group. The results of this study are encouraging as application of the iTCC can be achieved with a lot less training than the TCC. This will allow the treatment modality to be used far more wide spread than traditional TCC manufacturing. The limited sample sizes could be overcome if this study was replicated in other centres. The Armstrong et al (2001) and Katz et al (2005) papers both address issues regarding the cost effectiveness of various treatments. Armstrong and colleagues suggest materials for the manufacture of a TCC are around $50-75 however that does not include the time of the clinician to manufacture the cast. RCW are estimated at between $150-200 but do not require much time to apply; RCWs can also be re-used for the duration of the DFU. Katz et al’s figures are slightly more helpful as they compare the cost of the TCC against that of the iTCC and are slightly more current. They report the difference in total cost of treatment is $52.20 with the iTCC averaging at 24.8% less than the TCC. These figures may seem expensive however; Shearer et al (2003) cost the monthly
management of a DFU in the UK at £300 and amputation costs at up to £10,000 prior to any rehabilitation costs on top of that. Considering the average duration of ulcer healing rate within a TCC was forty-three days the cost of TCC (and specifically iTCC) are considerably less in comparison.

Other studies/papers

One of the early studies into TCC was helpful in determining the healing rates of DFUs depending on their location (Walker et al, 1987). Based on Brand’s initial studies they designed a study to discover if TCC effectiveness depended on the location of the ulcer. Fifty-one subjects were included in the study and the subjects were broadly fitted into two groups, forefoot and other parts of the foot (non-forefoot). Results showed that casting was a very effective method of healing DFUs however, forefoot plantar ulcers healed significantly faster than all others (forefoot 30.57±20.76 days vs. non-forefoot 42.08±27.02 days).

Wherever possible, clinicians have avoided placing vulnerable limbs in TCC due to the potential limb loss that could occur. Two studies that did however treat challenging limbs reported encouraging findings (Nabuurs-Franssen et al, 2005; Sinacore, 1999). Sinacore casted post-transplant immunosuppressed diabetic patients and compared them to non-immunosuppressed diabetic controls. Despite it being a rather simple study with no pressure assessment or biomechanical standardisation, he reported no problems and concluded that the immunosuppressed group healed without complications but took several weeks longer than the non-immunosuppressed group. Nabuurs-Franssen et al (2005) placed ninety-eight subjects with vascular insufficient and/or mildly infected limbs in TCCs. When placing ischaemic-infected limbs in un-removable TCCs, ethical considerations must be taken, however the paper reports tight monitoring and controls on the study. Outcomes were successful in all situations except neuroischaemic heel ulcers with infection present and the best outcomes were understandably for those subjects without vascular disease or infection. This study will open the doors for further investigations into ischaemic and infected DFU management with TCC.

An interesting study conducted in Italy by Piaggesi and colleagues (Piaggesi et al, 2003) took histopathological samples from DFUs of subjects who had been wearing a TCC and subjects who had not. Alongside a marked reduction in ulcer size...
of those subjects in the TCC there was an increase in neo-formed capillaries and fibroblasts showing that the reduction in pressure had allowed for the development and growth of new tissue. This research demonstrates the effect of pressure relief at the cellular level and paves the way for further histopathological investigations regarding DFUs and off-loading.

Conclusion
The use of TCC for the healing of diabetic foot ulcers has been well documented within the literature. There has been extensive research into biomechanical and pressure relief studies and the future for TCC research would appear to be in treating problem limbs and studies into the iTCC concept. The iTCC is of value as it requires less training to apply, is more cost effective and could be used to standardise many treatment variables in future research.

Larger multi-centre RCTs are still required to further the evidence based knowledge in this field as the majority of current studies lack significant numbers of subjects to provide statistically significant data. Further work is also required in future prevention of re-ulceration post healing following the use of offloading devices such as the TCC and iTCC. Interesting studies may also be developed from the histopathological findings of Piaggesi et al (2003).

The idea that TCC is more expensive compared to traditional DFU management can be shown as untrue and with further development the iTCC can be used widespread across the world to combat the loss of the diabetic limb.

Bibliography


