

Total contact casting for diabetic foot ulcers treatment: a literature review

Tratamento das úlceras no pé diabético com gesso de contato total: revisão da literatura

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ABSTRACT

Diabetes prevalence is 8.1% in the South and Central American population. Diabetic foot ulcers (DFU) and Charcot neuroarthropathy (CN) are important complications resulting from neuropathy of the diabetic foot. One of the biggest effects of the global diabetes epidemic, besides the devastating health consequences for people with diabetes, is its economic impact. Diabetes complications are causing economic havoc to those living with the disease, their families and ultimately whole countries, threatening economic development. On this scenario, foot off-loading is considered an essential part of adequate treatment associated with the management of glycemia control, peripheral arterial disease control, infection control and with tissues debridement. Therefore, it becomes important perform a review of literature evidence-based about using off-loading for treatment of DFU. The purpose of this article is to highlight the evidence-based literature on off-loading the DFU with Total Contact Casting (TCC) demonstrating why it should be integrated into the standard of care of DFUs in Brazil and Latin America.

RESUMO

A prevalência de diabetes é de 8,1% na população da América Latina. As úlceras do pé diabético e a neuropatia de Charcot são importantes complicações decorrentes de neuropatia da síndrome do pé diabético. Um dos maiores efeitos da epidemia global de diabetes, além das devastadoras consequências para a saúde dos pacientes, é seu impacto econômico. As complicações do diabetes resultam em gastos muito significativos para aqueles que vivem com a doença, suas famílias e países inteiros, em última análise, ameaçando o desenvolvimento econômico desses países. Nesse cenário, o uso do gesso de contato total é considerado uma parte essencial do tratamento adequado associado ao controle da glicemia, controle da doença arterial periférica, controle da infecção e desbridamento dos tecidos desvitalizados. Portanto, torna-se importante realizar uma revisão de literatura com objetivo destacar a literatura baseada em evidências a cerca do uso do gesso de contato total para o tratamento das úlceras diabéticas e indicar sua integração ao tratamento padrão no Brasil e na América Latina.

INTRODUCTION

Diabetes prevalence is 8.1% in the South and Central American population.⁽¹⁾ In Brazil, it is estimated that 11% of people over 30 years of age have type 2 diabetes.⁽²⁾ Diabetic foot ulcers (DFU) and Charcot neuroarthropathy (CN) are important complications resulting from neuropathy of the diabetic foot.⁽³⁾ These two events can lead to amputation, causing functional loss, decrease in quality of life and significant socioeconomic setbacks to patients, their families and the healthcare system.⁽⁴⁾

In Brazil, approximately 323,000 people develop DFUs each year; 97,200 of those require hospital admission, leading to 46,300 amputations and 12,400 deaths annually due to DFUs.

Furthermore, the annual cost associated with these hospital admissions is estimated to be 264 million dollars with the cost of amputation of nearly 128 million dollars.⁽⁴⁾

People with diabetes carry a risk of amputation that may be more than 25 times greater than people without diabetes; therefore, the ultimate goal is to prevent the “amputation stairway” of compounding steps from diabetes and neuropathy to amputation. Through comprehensive management, a large proportion of amputations can be prevented.⁽⁵⁾ Off-loading is considered an essential part of treatment along with the management of peripheral arterial disease, infection control, debridement, maintenance of an optimal wound environment, and regular wound and patient assessments.

The current review aims to highlight the evidence-based literature on off-loading the DFU with Total Contact Casting (TCC) demonstrating why it should be integrated into the standard of care of DFUs in Brazil and Latin America.

METHODS

A literature search of PubMed for evidence regarding off-loading for the management of DFUs was conducted by the authors. The search algorithms used for each of the topics are detailed in Appendix 1. Criteria for inclusion in the supporting evidence were based on study design.

We used GRADE (Grading of Recommendations Assessment, Development and Evaluation) approach to define the quality level of evidence supporting each evidence and the strength of recommendation for treatment. In the GRADE approach, the quality of evidence is ranked as follows: 1) high, further research is very unlikely to change confidence in the estimate of the effect; 2) moderate, further research is likely to have an important effect on confidence in the estimate of the effect and may change the estimate; 3) low, further research is very likely to have an important effect on confidence in the estimate of the effect and is likely to change the estimate; and 4) very low, any estimate of effect is very uncertain.

The recommendation levels are 1) strong, patients should receive the recommended course of action, and 2) weak, contextual evaluation of the recommendation by the clinician for a particular patient.

Off-loading the diabetic foot

Off-loading to redistribute pressure is a cornerstone in the treatment of DFUs and is recommended by

multiple clinical guidelines.^(6,7) Furthermore, even with optimal management of other factors, DFU healing is unlikely to occur without adequate pressure relief.^(8,9)

Off-loading options include removable devices (e.g., custom-made footwear, post-operative shoe, shoe modification, half-shoe, walkers, etc.), non-removable devices (e.g., total contact casts), surgical techniques and other assistive devices such as wheelchairs, crutches and best rest (Figure 1). Each device has its pros and cons and varying levels of evidence supporting them. Regardless, the efficacy of any off-loading strategy is greatly dependent on patient adherence.⁽¹⁰⁾

Currently in Brazil, the most commonly used off-loading device is the boot walker, which has shown some efficacy, specifically in early stages of CN.⁽⁵⁾

Total Contact Casting: The Gold Standard

Total Contact Casting is considered the gold standard based on its proven efficacy in 8 randomized controlled trials showing an overall healing rate of 89.5% in a mean of 33.5 days.⁽¹¹⁻¹⁶⁾ Specifically, a recent RCT comparing TCC, healing sandals (HS) and a shear-reducing removable boot (SRB) in 73 patients with DFUs found TCC was superior for percentage of patients reaching wound closure (88.9% TCC; 50% HS and 40% SRB) and time to healing (5.4±2.9 TCC vs. 8.9±3.5 HS weeks, P<0.001).⁽¹⁵⁾

When compared to other devices, such as the removable cast/walker, for TCC 65% of patients healed in 50.4 mean days and for half-shoes, 58% of patients

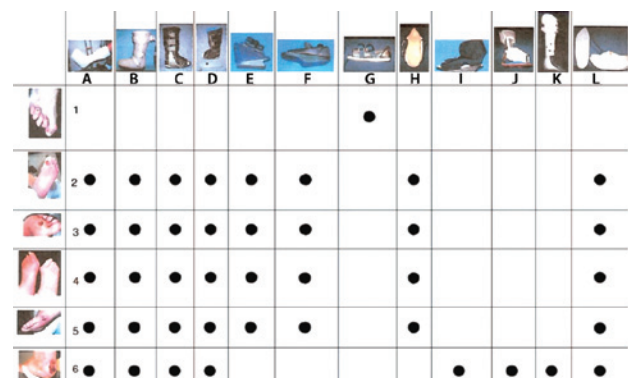


Figure 1. Off-loading algorithm for diabetic foot ulcer showing off-loading methods and ulcer locations. A) Total Contact Cast; B) Charcot Restraint Orthotic Walker boot; C) prefabricated walker; D) DH walker; E, IPOS shoe; F) OrthoWedge; G) postoperative shoe; H) healing sandal; I) reverse IPOS; J) L'nard splint; K) palleta tendon-bearing brace; L) MABAL shoe. 1, dorsal digit; 2, plantar digit; 3, plantar metatarsal; 4, medial metatarsal; 5, lateral metatarsal; 6, heel. (Reprinted with permission from *Ostomy Wound Management*)⁴⁰

healed in 60.1 mean days.⁽¹¹⁾ Furthermore, An analysis of comparative healing rates of advanced wound care products such as negative pressure wound therapy and bioengineered skin substitutes, showed TCC use resulted in 88% healing, more than 32 points greater than the next most effective therapy.⁽¹⁷⁾ These results have been further confirmed by a recent Cochrane review, which concluded that non-removable casts are the most effective off-loading devices for DFUs.⁽¹⁸⁾

How does TCC work?

Total Contact Casting redistributes pressure away from the plantar surface and redirects body weight from the foot to the lower leg. By locking the ankle at 90 degrees, TCC eliminates the propulsive phase of gait, shortens stride length, decreases walking velocity and diminishes vertical forces. In support of this, studies have demonstrated that TCC decreases pressure in the fifth, fourth and first metatarsal heads by 32%, 63% and 69%, respectively, and decreases heel pressure by 45%.⁽¹⁹⁾ Thus TCC successfully eliminates shear and pressure forces while its custom fit accommodates volume changes in the patient's foot and leg over time.

One of the most important features of TCC is that it is non-removable, which ensures off-loading compliance further contributing to its superior outcomes compared to removable devices.⁽¹¹⁾ To this end, studies have shown that the only way for a removable device to produce healing outcomes comparable to TCC is for it to be made non-removable.^(13,20)

In addition to the mechanical impact described, TCC also works at the cellular level to impact wound healing. In that way, TCC can be viewed as an active treatment. Specifically, a study on wound histology under TCC vs. controls (no cast) and found a higher prevalence of inflammatory elements such as hyperkeratosis, fibrosis, and cellular debris in control patient wounds. In contrast, a higher prevalence of reparative elements such as cutaneous annexes, capillaries, and granulating tissue were found in TCC-treated wounds.⁽²¹⁾ In this way, TCC creates a Healing Chamber™ impacting both the micro- and macro-environments of the wound.

Total Contact Casting: Given the evidence, why is it not more widely used?

Though the evidence is clear, a recent US study found that only 2.2% of eligible patient visits utilized off-loading and the most common method used was the post-operative shoe, despite the lack of evidence to support its efficacy.⁽²²⁾ Therefore, the question remains as to why TCC is not first-line therapy for DFUs.

Barriers to the use of TCC can stem from the clinician, organization and the patient themselves. Clinician-related barriers can include a lack of skill, time to train, availability of training, and previous negative experience. Organization-related barriers can include profitability and cost concerns, inventory and supply problems. Patient-related barriers can include compliance and transportation concerns.⁽¹⁰⁾ From an organizational perspective, as noted in the introduction, there are high costs of treating diabetes and its related complications in Brazil, therefore it is also important to note that evidence has demonstrated TCC to be a cost-effective solution. Specifically, a large retrospective study using data from the US wound registry found the average cost of TCC treatment per patient was half the cost of treatment of DFUs when TCC was not used.⁽²³⁾

Evolution of TCC systems

“Traditional” TCC systems require multiple steps and supplies and therefore significant time and skill to apply. However, new technology such as that of TCC-EZ® Total Contact Casting System (Derma Sciences, Inc., Princeton, NJ) has led to a product with very few steps and an average time to apply of less than 10 minutes.⁽²⁴⁾ Products that have this ease of application can help minimize training time and facilitate adoption into hospitals and clinics.

Consensus guidelines recommend TCC as standard of care for DFUs

The evidence discussed thus far is further supported by a recent consensus guidelines document on the use of off-loading in the management of DFUs that concluded that adequate off-loading increases the likelihood of DFU healing and should be considered part of the standard of care. Furthermore, TCC was identified as the preferred method for off-loading DFUs, because it has most consistently demonstrated the best healing outcomes and is a cost-effective treatment.⁽¹⁰⁾

Additional consensus statements concluded that advanced therapeutics are unlikely to succeed in improving wound-healing outcomes unless effective off-loading is obtained and that off-loading should not be treated as a less than important part of the treatment plan. To this end, clinicians must ensure adequate off-loading on an ongoing basis. As discussed, patient adherence is the key to ensuring adequate off-loading, and thus the most effective devices are those that are non-removable.⁽¹⁰⁾

It is clear that TCC has the data to support its use as first-line therapy for DFUs and to further support

this initiative the authors have planned a prospective comparative clinical evaluation of the TCC-EZ[®] system vs. the Brazilian standard of care for off-loading with a walker boot.

CONCLUSIONS

In summary, Total Contact Casting is the most efficacious and cost-effective approach to heal DFUs. The use of Total Contact Casting for DFU management in Latin America will help achieve improved outcomes related to patient care and healthcare costs by improving healing and decreasing complications.

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REFERENCES

- International Diabetes Federation Online [Internet]. IDF diabetes atlas. 6th ed. IDF; 2014. [cited 2015 Apr 3]. Available from: <http://www.idf.org/diabetesatlas/update-2014>
- International Diabetes Federation Online [Internet]. Diabetes in Brazil 2014. IDF; 2014. [cited 2015 Jun 6]. Available from: <http://www.idf.org/membership/saca/brazil>
- Lima AL, Fernandes TD, Godoy-Santos AL, Savio EL, Bicudo EL. Directrices panamericanas para el tratamiento de infecciones en úlceras neuropáticas de las extremidades inferiores. *Rev Panam Infectol*. 2011;13(1 Supl 1):S10.
- Rezende KF, Ferraz MB, Malerbi DA, Mello NH, Nunes MP, Pedrosa HC, et al.. Predicted annual costs for inpatients with diabetes and foot ulcers in a developing country-a simulation of the current situation in Brazil. *Diabet Med*. 2010;27(1):109-12.
- Parisi MC, Godoy-Santos AL, Ortiz RT, Sposeto RB, Sakaki MH, Nery M, et al. Radiographic and functional results in the treatment of early stages of Charcot neuroarthropathy with a walker boot and immediate weight bearing. *Diabet Foot Ankle*. 2013;4: doi:103402/dfav4.i0.22487.
- Steed DL, Attinger C, Collaizi T, Crossland M, Franz M, Harkless L, et al. Guidelines for the treatment of diabetic ulcers. *Wound Rep Regen*. 2006;14(6):680-92.
- International Best Practice Guidelines: Wound management in diabetic foot ulcers [Internet]. London: Wounds International; 2013. [cited 2015 Jun 5]. Available from: http://www.woundsinternational.com/media/issues/673/files/content_10803.pdf
- Snyder RJ, Kirsner RS, Warriner RA 3rd, Lavery LA, Hanft JR, Sheehan P. Consensus recommendations on advancing the standard of care for treating neuropathic foot ulcers in patients with diabetes. *Ostomy Wound Manage*. 2010;56(4 Suppl):S1-24.
- Boulton AJ. Pressure and the diabetic foot: clinical science and off-loading techniques. *Am J Surg*. 2004;187(5):17S-24.
- Snyder RJ, Frykberg RG, Rogers LC, Applewhite AJ, Bell D, Bohn G, Fife CE, Jensen J, Wilcox J. The management of diabetic foot ulcers through optimal off-loading: building consensus guidelines and practical recommendations to improve outcomes. *J Am Podiatr Med Assoc*. 2014;104(6):555-67.
- Armstrong DG, Nguyen HC, Lavery LA, van Schie CH, Boulton AJ, Harkless LB. Off-loading the diabetic foot wound. *Diabetes Care*. 2001;24(6):1019-22.
- Armstrong DG, Lavery LA, Wu S, Boulton AJ. Evaluation of removable and irremovable cast walkers in the healing of diabetic foot wounds. *Diabetes Care*. 2005; 28(3):551-4.
- Katz IA, Harian A, Miranda-Palma B, Prieto-Sanchez L, Armstrong DG, Bowker JH, et al. A randomized trial of two irremovable off-loading devices in the management of plantar neuropathic diabetic foot ulcers. *Diabetes Care*. 2005;28(3):555-9.
- Piaggese A, Macchiarini S, Rizzo L, Palumbo F, Tedeschi A, Nobili LA, et al. An off-the-shelf instant contact casting device for the management of diabetic foot ulcers. *Diabetes Care*. 2007;30(3):586-90.
- Lavery AL, Higgins KR, La Fontaine J, Zamorano RG, Constantinides GP, Kim PJ. Randomized clinical trial to compare total contact casts, healing sandals and a shear-reducing removable boot to heal diabetic foot ulcers. *Int Wound J*. 2014 [epub ahead of print, DOI: 10.1111/iwj.12213].
- Mueller NJ, Diamond JE, Sinacore DR, Delitto A, Balir VP 3rd, Drury DA et al. Total contact casting in treatment of diabetic plantar ulcers. Controlled clinical trial. *Diabetes Care*. 1989;12(6):384-8.
- Greenhagen RM, Wukich DK. Total contact casting for neuropathic ulcers: A lost art? *J Diabetic Foot Complications*. 2009;1:4:85-93.
- Lewis J, Lipp A. Pressure-relieving interventions for treating diabetic foot ulcers. *Cochrane System Rev*. 2013;1:CD002303.
- Wertsch JJ, Frank LW, Zhu H, Price MB, Harris GF, Alba HM. Plantar pressures with total contact casting. *J Rehab Res Dev*. 1995;32(3):205-9.
- Gutekunst DJ, Hastings MK, Bohnert KL, Strube MJ, Sinacore DR. Removable cast walker boots yield greater forefoot off-loading than total contact casts. *Clin Biomech (Bristol, Avon)*. 2011;26(6):649-54.
- Piaggese A, Viacava P, Rizzo L, Naccarato G, Baccetti F, Romanelli M. Semiquantitative analysis of the histopathological features of the neuropathic foot ulcer: effects of pressure relief. *Diabetes Care*. 2003;26(11):3123-8.
- Fife CE, Carter MJ, Walker D, Thomson B, Eckert KA. Diabetic foot ulcer off-loading: The gap between evidence and practice. Data from the US Wound Registry. *Adv Skin Wound Care*. 2014;27(7):310-6.
- Fife CE, Carter MJ, Walker D. Why is it so hard to do the right thing in wound care? *Wound Repair Regen*. 2010;18(2):154-8.
- Jensen J, Jaakola E, Gillin B, Riley EK. Total contact casting system overcoming the barriers to utilizing a proven gold standard treatment [Poster]. *Dermascience: TCC-EZ Evidence*; 2008. Available from: <file:///Users/ednarother/Downloads/Jensen%20Poster%20PDF.pdf>

Appendix 1. Search Algorithm for Each of the Topics

For each topic (written in italics) the complete search algorithm employed is shown below.

- (1) Off-loading diabetic foot or foot ulcer: off-loading [All Fields] AND (“diabetic foot” [MeSH Terms] OR (“diabetic” [All Fields] AND “foot” [All Fields]) OR “diabetic foot” [All Fields] OR (“diabetic” [All Fields] AND “foot” [All Fields] AND “ulcer” [All Fields]) OR “diabetic foot ulcer” [All Fields]).
- (2) Management diabetic foot ulcers: (“organization and administration” [MeSH Terms] OR (“organization” [All Fields] AND “administration” [All Fields]) OR “organization and administration” [All Fields] OR “management” [All Fields] OR “disease management” [MeSH Terms] OR (“disease” [All Fields] AND “management” [All Fields]) OR “disease management” [All Fields]) AND (“diabetic foot” [MeSH Terms] OR (“diabetic” [All Fields] AND “foot” [All Fields]) OR “diabetic foot” [All Fields] OR (“diabetic” [All Fields] AND “foot” [All Fields] AND “ulcers” [All Fields]) OR “diabetic foot ulcers” [All Fields]).
- (3) Pressure diabetic foot: (“pressure” [MeSH Terms] OR “pressure” [All Fields]) AND (“diabetic foot” [MeSH Terms] OR (“diabetic” [All Fields] AND “foot” [All Fields]) OR “diabetic foot” [All Fields]).
- (4) Total contact cast or casting: total [All Fields] AND (“Contact” [Journal] OR “contact” [All Fields] OR “Contact” [Journal] OR “contact” [All Fields]) AND cast [All Fields] OR casting [All Fields].
- (5) Diabetic footwear: diabetic [All Fields] AND footwear [All Fields].
- (6) Guidelines diabetic ulcers: (“guideline” [Publication Type] OR “guidelines as topic” [MeSH Terms] OR “guidelines” [All Fields]) AND diabetic [All Fields] AND (“ulcer” [MeSH Terms] OR “ulcer” [All Fields] OR “ulcers” [All Fields]).
- (7) Diabetic foot infection: (“diabetic foot” [MeSH Terms] OR (“diabetic” [All Fields] AND “foot” [All Fields]) OR “diabetic foot” [All Fields]) AND (“infection” [MeSH Terms] OR “infection” [All Fields] OR “communicable diseases” [MeSH Terms] OR (“communicable” [All Fields] AND “diseases” [All Fields]) OR “communicable diseases” [All Fields]).
- (8) Nonremovable cast: nonremovable [All Fields] AND cast [All Fields].
- (9) Predict diabetic foot: predict [All Fields] AND (“diabetic foot” [MeSH Terms] OR (“diabetic” [All Fields] AND “foot” [All Fields]) OR “diabetic foot” [All Fields]).
- (10) Good quality of care: good [All Fields] AND quality [All Fields] AND care [All Fields].
- (11) Charcot foot: charcot [All Fields] AND (“foot” [MeSH Terms] OR “foot” [All Fields]).