Indian J Surg (April 2016) 78(2):105–111
DOI 10.1007/s12262-015-1327-3

ORIGINAL ARTICLE

Effective and Economic Offloading of Diabetic Foot Ulcers in India with the Bohler Iron Plaster Cast

Priyanka Saikia[1,2] · **Rajalakshmi Hariharan**[2] · **Nachiket Shankar**[3] · **Anil Kumar Gaur**[1] · **Naveen Matthew Jose**[2]

Received: 10 May 2015 / Accepted: 19 August 2015 / Published online: 26 August 2015

Abstract Economic constraints are a major obstacle to the implementation of offloading casts in India. The aim of this study is to monitor the healing and activity limitations related to Bohler iron plaster cast (BIPC) when used for offloading diabetic neuropathic plantar foot ulcers. Thirty patients were cast for 1 month and evaluated for healing using the Pressure Ulcer Scale for Healing (PUSH), and for activity limitation using the Lower Extremity Functional Scale (LEFS). The change in the scores after intervention was the outcome measure. There was good healing as evidenced by a statistical difference in mean PUSH scores. The baseline PUSH score of 9.76–0.41 (T1-SEM) was greater than follow-up PUSH score of 6.32+0.41 (T2+SEM) and the p value <0.0001. Improvement was seen in ulcer area, exudate, and tissue type. There was no mobility effect as there was no significant difference in LEFS. Significant negative correlation was there between PUSH and LEFS. The r value was less than −0.7 both at baseline and after intervention. The combined benefits of good healing, lack of affect on lower extremity function, the ease of application and dressing, and relative affordability make BIPC a commendable offloading modality for the management of diabetic plantar ulcers.

✉ Priyanka Saikia
drpriyankasaikia@gmail.com

[1] Present address: Department of Physical Medicine and Rehabilitation, All India Institute of Physical Medicine & Rehabilitation (AIIPMR), Haji Ali, Mahalaxmi, Mumbai 400034, Maharashtra, India

[2] Department of Physical Medicine and Rehabilitation, St. John's Medical College & Hospital, Sarjapur Road, Bengaluru 560034, Karnataka, India

[3] Department of Anatomy, St. John's Medical College and Hospital, Sarjapur Road, Bengaluru 560034, Karnataka, India

Keywords Offloading · Total contact cast · Diabetic foot ulcers · Bohler iron plaster cast · Lower extremity function · Neuropathic ulcer healing

Introduction

The "epidemic" of diabetes mellitus (DM) is a global phenomenon, and India holds the dubious distinction of being the "diabetic capital of the world" [1–4]. Among all the complications, the most common is the diabetic foot ulcer (DFU) which often becomes the most devastating, culminating in unexpected consequences like amputation [5–9].

The two primary tenets for healing diabetic foot ulcers remain as appropriate debridement of all necrotic tissue and pressure dispersion from the ulcer site (offloading). Offloading of unperceived areas of plantar stress is critical for preventing and effectively treating clinical manifestations of diabetic foot disease, particularly neuropathic ulcers and fractures or acute inflammatory arthropathy. Total contact cast (TCC) and comparable alternative offloading methods should be the cornerstone of treatment interventions and the first line of defence for healing neuropathic plantar ulcers [10].

Though TCC is optimal for protection, healing, and offloading, it is seldom used in the clinic because of other factors (such as ease of application, a need for frequent wound inspection, interference with mobility, cosmetic acceptability, safety, and overall compliance with wearing the device). Several alternative methods are more popular, such as removable cast walkers, irremovable cast walker, adhesive felt padding, "half-shoe" or wedged forefoot shoe, ankle-foot orthosis, and therapeutic footwear [11].

These methods are not easy to implement in developing nations for various reasons. The gold standard [12–17] TCC requires skill and the cumulative expense of repeat

applications. The alternative footwear, on the other hand, is expensive and not easily available.

Our study used the Bohler iron plaster cast (BIPC), a modification of the gold standard TCC, i.e., a non-removable windowed fiberglass cast with orthotic metal uprights and footplate. It requires less expertise in application and also allows monitoring of the ulcer via window. The ensuing drainage negates weekly re-application, making it relatively economical for our affected population.

BIPC has been in practice in our hospital for over a decade as the primary modality of offloading for diabetic foot ulcers. However, till date, there have neither been studies on the BIPC nor on the functional effects of offloading devices, making ours a pilot study.

In the general population, diabetes is known to be associated with increased disability, poorer physical functioning, and an increased risk of being unable to do mobility related tasks [18]. Offloading devices themselves are assumed to restrict mobility as well.

We aimed to evaluate BIPC for the two primary concerns of an offloading modality—(1) its effects on ulcer healing and (2) lower extremity function.

The Pressure Ulcer Scale for Healing (PUSH) and Lower Extremity Functional Scale (LEFS) scales were used to assess healing and functional mobility respectively (refer to Tables 1 and 2).

Our objective was to study the differences in scores at first visit and 1 month after intervention with BIPC, in PUSH and LEFS respectively.

Materials and Methods

Thirty consecutive diabetic patients with plantar ulcers (forefoot/mid-foot/hindfoot; Wagner grade 2 or 3; palpable peripheral pulses) were enrolled after taking an informed consent. Informed consent was obtained from all individual participants included in the study. We excluded patients with Wagner grade 4 or 5 ulcers (as gangrene is a contra-indication to casting), lower limb edema (edematous limbs are unfit for casting as increase or decrease in girth may cause excessive pressure or improper contact, respectively), and/or those requiring an assistive device for unstable mobility.

Subjects were evaluated twice, i.e., before application of the cast and 1 month after. A questionnaire which included history, clinical examination, PUSH, and LEFS was used for the same. The ulcer was debrided as necessary until healthy tissue was encountered. Patients were taught home dressing with normal saline, which was to be done daily. The patient was made sensory conscious and foot care education was imparted for the unaffected foot viz., avoidance of barefoot walking, daily foot inspection, hygiene and moisturization, careful trimming of nails, and customized footwear.

Subjects were instructed to do daily dressing of the wound and followed up at 2-week intervals for clinical examination, monitoring of home care, and wound debridement.

The cast was worn until 1 month or earlier if an event required cast change or discontinuation (swelling, loosening, ulcer worsening, or non-compliance).

Repeat assessment of PUSH and LEFS was done after completion of 1 month of BIPC use. Bohler iron was continued till complete healing based on the felt need of the subjects.

Bohler Iron Plaster Cast

BIPC is a modification of the TCC with two salient differences—firstly, it incorporates a Bohler iron (orthotic metal uprights with rubber heel footplate) in the non-removable fiberglass cast (refer to Fig. 1) and secondly, a "window" over the ulcer site (refer to Fig. 1).

Casting procedure began with tubular stockinet being placed onto the lower limb, and then covered with German cotton (Sofwrap) to adequately protect the skin, particularly over bony prominences. Then fiberglass (3 M Scothcast) was applied, with bands measuring 10, 7.5, and 5 cm. The toes were left free. A window was left in the cast boot at the ulcer site to allow daily wound assessment and care. A Bohler iron was placed over the fiberglass—medial and lateral uprights on the respective borders of the leg; the heel below the mid-foot. Non-articulated Bohler iron used for forefoot ulcers (refer to

Table 1 Pressure Ulcer Scale for Healing (PUSH)

Length X Breadth (cm^2)	0 0	1 <0.3	2 0.3–0.6	3 0.7–1.0	4 1.1–2.0	5 2.1–3.0	Sub-score 1
		6 3.1–4.0	7 4.1–8.0	8 8.1–12.0	9 12.1–24	10 >24.0	
Exudate Amount	0 None	1 Light	2 Moderate	3 Heavy			Sub-score 2
Tissue Type	0 Closed	1 Epithelial tissue	2 Granulation tissue	3 Slough	4 Necrotic tissue		Sub-score 3
Total PUSH score[a]							= (1+2+3)

[a] PUSH is composed of three components, viz. ulcer area, exudate amount, and tissue type, and final score is the culmination of the three sub-scores

Table 2 Lower Extremity Functional Scale (LEFS)

Lower Extremity Functional Scale (LEFS): Patient instructions: Today, do you or would you have any difficulty at all with these activities?	No difficulty 4	A little bit of difficulty 3	Moderate difficulty 2	Quite a bit of difficulty 1	Unable to perform activity or extreme difficulty 0
(1) Any of your usual work housework or school activities					
(2) Your usual hobbies recreational or sporting activities					
(3) Getting into or out of the bath					
(4) Walking between rooms					
(5) Putting on your shoes or socks					
(6) Squatting					
(7) Lifting an object like a bag of groceries from the floor					
(8) Performing light activities around your home					
(9) Performing heavy activities around your home					
(10) Getting into or out of a car					
(11) Walking two blocks (about 1/6th mile or about 250 m)					
(12) Walking 1 mile (1.6 km)					
(13) Going up or down ten steps (about 1 flight of stairs)					
(14) Standing for 1 h					
(15) Sitting for 1 h					
(16) Running on even ground					
(17) Running on uneven ground					
(18) Making sharp turns while running fast					
(19) Hopping					
(20) Rolling over in bed					
Total LEFS score:					

The LEFS measure is comprised of 20 items asking about difficulty performing a variety of everyday activities. Each item is scored by the subject as 0 (unable to perform) to 4 (no difficulty). LEFS score vary from 0 (low) to 80 (normal function). Overall, the minimum clinically important difference (MCID) is nine points

Fig. 1), and articulated (ankle joint) Bohler iron used for mid-foot, and hindfoot ulcers (refer to Fig. 1).

The Bohler iron was placed with footplate one and half inch away from the foot. A second layer of fiberglass was applied over the Bohler iron uprights to secure it in place. One inch heel raise was given to the contralateral shoe (as half inch gets compensated in gait during foot clearance).

Pressure Ulcer Scale for Healing

The Pressure Ulcer Scale for Healing (PUSH) tool was introduced by the National Pressure Ulcer Advisory Panel (NPUAP) to monitor the healing of pressure ulcers. Findings by Gardner [19] indicate that PUSH scores significantly decrease over time in healing neuropathic DFU. The study also suggests that total PUSH scores predict time-to-heal for DFU. Finally, measurements of size alone predict healing time for neuropathic DFU [20].

The PUSH tool, with the components of length times width, exudate amount, and tissue type, is a valid and sensitive measure of pressure ulcer healing. Minimum PUSH score possible is 0 (completely healed) and maximum possible is 17 (not healed).

Lower Extremity Functional Scale

The Lower Extremity Functional Scale (LEFS) was chosen for this study as it focuses on functionality. It is based on the World Health Organization's model of impairment, disability, and handicap at the time of its development in 1999. The LEFS tests for activity limitations among patients with musculoskeletal deficiencies of the lower extremity. The test has gained acceptance due to its high internal consistency (alpha= 9.96) and high test reliability [21].

There has been no floor or ceiling effect reported, and it appears to be applicable to all levels of function, as stated by Finch et al. Construct validity was supported by comparison with the SF-36 [21].

The LEFS is comprised of 20 items asking about difficulty performing a variety of everyday activities. Each item is scored by the subject as 0 (unable to perform) to 4 (no difficulty). LEFS score vary from 0 (low) to 80 (normal function).

Fig. 1 Bohler iron plaster cast: articulated (with ankle joint) for hind foot and non-articulated for forefoot ulcers

Overall, the minimum clinically important difference (MCID) is nine points [21].

Statistical Methods

Descriptive statistics were reported using mean and standard deviation (SD) for continuous variables, number, and percentages for categorical variables. Paired *t* test was used to compare the pre- and post-PUSH and LEFS scores. Pearson or Spearman Rank correlation coefficient was calculated to assess the relationship between variables. *P* value less than 5 % was considered as statistically significant. Statistical analyses were carried out using SPSS version 18.0.

Results

Outcome measure was the difference in baseline and after intervention scores of LEFS and PUSH respectively. Out of the total of 30 patients, 24 completed the study. Six dropped out due to discomfort with BIPC. No complications developed apart from limb swelling in four patients, but did not warranty discontinuation and gradually subsided.

PUSH Results

There was good healing as evidenced by significant reduction in mean PUSH score 1 month after intervention, i.e., from 9.76 to 6.32. There was a statistical difference as the Pre-PUSH score of 9.76–0.41 (T1-SEM) was greater than Post-PUSH score of 6.32+0.41 (T2 + SEM) (refer to Fig. 2). The test was statistically significant with the *p* value <0.0001. Improvement was evident in all components of PUSH, viz. area, exudate, and tissue type.

Analysis of PUSH Domains

At baseline, it was observed that majority of the subjects had a mean ulcer area of >24 cm^2 (20 %), and cumulative majority was between area of 0.7–4.0 cm^2 (cumulative 53.33 %). After

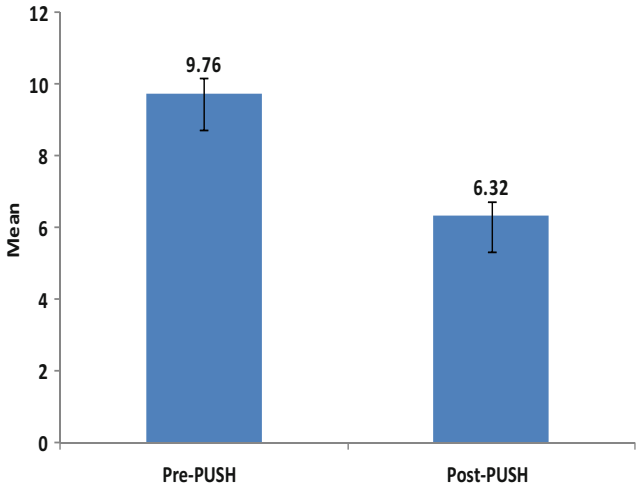

Fig. 2 Comparison of PUSH scores: at baseline (pre-PUSH) and after intervention (post-PUSH)

1 month, the ulcer area decreased in all subjects; majority showed reduction to <0.3 cm^2 (33.3 %) and 0.3–0.6 cm^2 (16.7 %).

At baseline, the exudate type was light (56.7 %) to moderate (23.3 %) for most subjects. Minority also showed heavy (6.7 %) exudate. After 1 month, majority had no exudate (58.3 %). Lesser subjects had light (33.3 %) to moderate (8.3 %) exudate. Heavy exudate had completely resolved.

At baseline, nearly equal number of ulcers had granulation (46.7 %) and slough (40 %) tissue. Minority were necrotic (6.7 %). At 1 month, ulcer tissue had improved to granulation (54.2 %) and epithelial (37.5 %) tissue in most. Minority persisted with slough (8.3 %) while none had necrotic tissue.

LEFS Results

There was no mobility effect as there was no significant difference in lower extremity function 1 month after intervention. The mean LEFS at baseline was 45.56±18.37 SD. After 1 month of intervention, it reduced to 45.44±15.40 SD. The *p* value was 0.966.

Correlation Between PUSH and LEFS

Significant negative correlation was there between PUSH and LEFS. At baseline, r value was −0.723 and after intervention, *r* value was −0.737. As the PUSH increased (i.e., ulcer worsened), the LEFS decreased (i.e., function worsened) and vice versa. This relation was significant both at baseline and 1 month after intervention.

Discussion

Offloading has an established role in the treatment of neuropathic ulcers, DFU being no exception. These non-weight bearing devices can lower plantar pressures and facilitate healing, but might be impractical if they interfere with functionality.

BIPC is a traditional method of offloading which although has no documentation in literature, has been in practice in our hospital for over a decade as the primary modality of offloading for diabetic foot ulcers. Patient apprehension and non-compliance with the device prompted us to study its effect on functional status of the lower extremity, as most people cited vague discomfort with the BIPC. Also, lack of scientific data on the healing lead us to document the same.

Offloading achieves healing by the principle of redistribution of forces and reduction of peak plantar pressure. A variety of devices achieve this, and the superiority of certain devices over another depends primarily on the compliance. The first randomized trial of casting was published by Mueller et al. in 1989 [22]. The study compared TCC with accommodative footwear, and it reported significantly faster healing in the TCC, with an absolute risk reduction of 59 %. A second randomized trial was performed, in which the TCC was compared with a removable cast walker (RCW) and a half shoe [23]. Again, the TCC proved to be superior to the other two modalities in terms of time needed to complete healing.

Gait laboratory studies had confirmed that the RCW reduces pressure to approximately the same degree as the TCC [24, 25]. The superiority of TCC over the RCW in terms of wound healing was attributed to patient compliance, as a preliminary randomized trial of the TCC versus the "instant TCC" (rendering the RCW irremovable by wrapping it with one or two bands of plaster of Paris) confirmed equivalent efficacy of these two devices [26].

BIPC is another device which offloads the plantar pressure—to the below knee cast, iron uprights, and footplate specifically. Its efficacy in healing can be attributed to the fact that there is complete offloading of the foot (as the person walks on the "walking iron") versus the redistribution of forces from ulcerated to non-ulcerated plantar areas in other devices. It can be hypothesized that peak plantar pressure may effectively be abolished altogether by BIPC. Hence, we can explain the nil occurrences of new ulcers. Most offloading devices offload the "ulcer site," whereas BIPC offloads the entire foot.

One of the theoretical drawbacks to the creation of a wound cavity is pressure concentration at the cavity edges. However, studies conducted by Shaw et al. [27] and Petre et al. [28] did not find this phenomenon in any of the subjects' pressure distributions. In fact, they concluded that to optimize wound offloading, the cast should provide total contact everywhere except for the wound site, which should be mechanically isolated [28]. Our intervention, the BIPC, has the additional

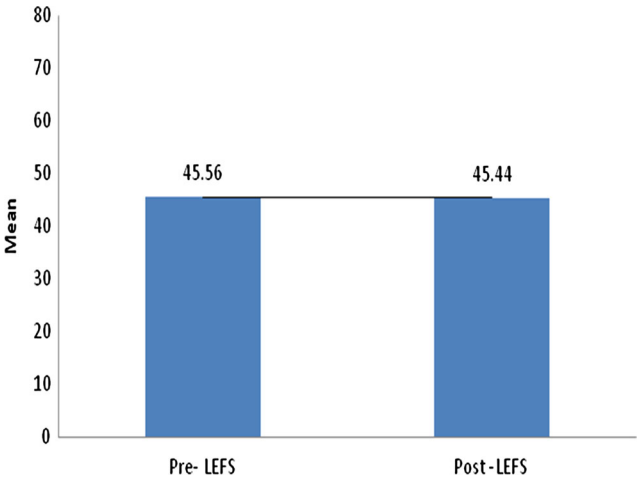

Fig. 3 Comparison of total LEFS scores at baseline (pre-LEFS) and at 1 month after intervention (post-LEFS)

benefit of isolation of the ulcer site along with complete offloading of the entire foot.

A prospective follow-up study by Marrigje et al. [29] proved that in comparison to pure neuropathic ulcers, moderately ischemic or infected ulcers can be treated effectively with casting and had a median duration of 34 days of cast treatment. Our population too had a mixed etiology of neuropathy, infection, and possible moderate ischemia, and significant healing was achieved in 30 days.

Impact of BIPC on Plantar Ulcer Healing and Lower Extremity Function

Our results showed that BIPC has a significant positive effect on healing. All aspects of the ulcer, viz. area, exudate, and tissue type, showed improvement after BIPC.

The effects of pressure relief on the histopathological features of neuropathic ulcers was recently assessed in a randomized study [17] from Pisa, which showed that pressure relief results in the wound appearing, in several respects, more like an acute wound in the reparative phase. We concluded that BIPC significantly improves ulcer healing.

Our second objective of studying impact on lower extremity function showed that BIPC has no significant effect. Neither the total score nor individual domains of LEFS showed any change. The mean level of functioning of our subjects remained 57 %, irrespective of the intervention. We concluded that BIPC does not have any impact on lower extremity function.

There was a significant negative correlation between PUSH and LEFS at baseline. As the PUSH increased (i.e., ulcer worsened), the LEFS decreased (i.e., function worsened) and vice versa. This relation was significant at baseline. Even at 1 month, even though LEFS showed no change, it still retained the same relation with ulcer status. So, size, discharge, and tissue characteristics significantly alter the ambulatory and functional status of a person with DFU.

We concluded that the presence of DFU itself has a significant negative impact on the lower extremity function, regardless of the presence or absence of an offloading device.

No previous studies on BIPC were found during our literature search for comparison.

Conclusions

Our pilot study results showed that BIPC significantly improves ulcer healing (refer to Fig. 2) and does not have any impact on lower extremity function (refer to Fig. 3).

There was a significant negative correlation between PUSH and LEFS which implies that size, discharge, and tissue characteristics significantly alter the ambulatory and functional status of a person with DFU.

We conclude that the combined benefits of good healing, lack of affect on lower extremity function, the ease of application and dressing, and relative affordability make BIPC a commendable offloading modality for the management of diabetic plantar ulcers.

Conflict of Interest All the authors declare that they have no conflict of interest.

Ethical Approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

References

1. Ramachandran A, Snehalatha C, Baskar AD, Mary S, Kumar CK, Selvam S, Catherine S, Vijay V (2004) Temporal changes in prevalence of diabetes and impaired glucose tolerance associated with lifestyle transition occurring in the rural population in India. Diabetologia 47:860–865
2. Sandeep S, Ganesan A, Mohan V. Development and updation of the diabetes Atlas of India (2010). Available from: www.whoindia.org/LinkFiles/NMH_Resources_Diabeletes_atlas.pdf
3. Jowett JB, Diego VP, Kotea N, Kowlessur S, Chitson P, Dyer DT, Zimme P, BlangeroJ J (2009) Genetic influences on type 2 diabetes and metabolic syndrome related quantitative traits in Mauritius. Twin Res Hum Genet 12:44–52
4. Ramachandran A, Wan Ma RC, Snehalatha C (2010) Diabetes in Asia. Lancet 375:408–418
5. Palumbo PJ, Melton LJ (1995) Peripheral vascular disease and diabetes. In: National Diabetes Data Group (ed) Diabetes In America, 2nd edn. GPO, Washington, DC, pp 401–408, **NIH publ. no. 495-1468**
6. Moss SE, Klein R, Klein BEK (1992) The prevalence and incidence of lower extremity amputation in a diabetic population. Arch Intern Med 152:610–616
7. Boyko EJ, Ahroni JH, Stensel V (1999) A prospective study of risk factors for diabetic foot ulcer: The Seattle Diabetic Foot Study. Diabetes Care 22(7):1036–1042
8. Frykberg RG, Habershaw GM, Chrzan JS (1998) Epidemiology of the diabetic foot: ulcerations and amputations. In: Veves A (ed) Contemporary endocrinology: clinical management of diabetic neuropathy. Humana Press, Totowa
9. Conway KP, Harding KG (2008) Wound healing in the diabetic foot. In: Bowker JH, Pfeifer M (eds) Levin and O'Neal's The Diabetic Foot, 7th edn. Elsevier, Philadelphia
10. Sinacore DR, Mueller MJ (2008) Off-loading for diabetic foot disease. In: Bowker JH, Pfeifer M (eds) Levin and O'Neal's The Diabetic Foot, 7th edn. Elsevier, Philadelphia
11. Guccione AA (1994) The effects of specific medical conditions on the functional limitations of elders in the Framingham study. Am J Public Health 84:351–358
12. Boninger ML, Leonard JA (1996) Use of bivalved ankle foot-orthosis in neuropathic foot and ankle lesions. J Rehabil Res Dev 33:16–22
13. Griffiths GD, Wieman TJ (1992) Meticulous attention to foot care improves the prognosis in diabetic ulceration of the foot. Surg Gynecol Obstet 174:49–51

14. Wieman TJ (1998) Becaplermin Gel Studies Group: clinical efficacy of becaplermin (rh PDGF-BB) gel. Am J Surg 176(suppl 2A):74S–79S
15. Holstein P, Larsen K, Sager P (1976) Decompression with the aid of insoles in the treatment of diabetic neuropathic ulcers. Acta Orthop Scand 47:463–468
16. Wieman TJ, Griffiths GD, Polk HC (1992) Management of diabetic midfoot ulcers. Ann Surg 215:627–632
17. Piaggesi A, Viacava P, Rizzo L (2003) Semi-quantitative analysis of the histopathological features of the neuropathic foot ulcer—effects of pressure relief. Diabetes Care 26:3123–3128
18. Dolan NC, Liu K, Criqui MH, Greenland P, Guralnik JM, Chan C, Schneider JR, Mandapat AL, Martin G, Mcdermott MM (2002) Peripheral artery disease, diabetes, and reduced lower extremity functioning. Diabetes Care 25:113–120
19. Gardner SE, Hillis SL, Frantz RA (2011) A prospective study of the push tool in diabetic foot ulcers. J Wound Ostomy Continence Nurs 38(4):385–393
20. Thomas DR, Rodeheaver GT, Bartolucci AA (1997) Pressure ulcer scale for healing: derivation and validation of the PUSH Tool. Adv Wound Care 10(5):96–101
21. Binkley JM, Stratford PW, Lott SA et al (1999) The Lower Extremity Functional Scale (LEFS): scale development, measurement properties, and clinical application. Phys Ther 79:371–383
22. Mueller MJ, Diamond JE, Sinacore DR (1989) Total contact casting in treatment of diabetic plantar ulcers: controlled clinical trial. Diabetes Care 12:384–388
23. Armstrong DG, Nguyen HC, Lavery LA, van Schie CH, Boulton AJM, Harkless LB (2001) Offloading the diabetic foot wound: a randomized clinical trial. Diabetes Care 24(6):1019–1022
24. Lavery LA, Vela SA, Lavery DC, Quebedaux TL (1996) Reducing dynamic foot pressures in high risk diabetics with foot ulcerations: a comparison of treatments. Diabetes Care 19:818–821
25. Baumhauer JF, Wervery R, McWilliams J, Harris GF, Shereff MJ (1997) A comparison study of plantar foot pressure in a standardized shoe, total contact cast prefabricated pneumatic walking brace. Foot Ankle Int 18:26–33
26. Katz IA, Harlan A, Miranda-Palma B (2005) A randomized trial of two irremovable off-loading devices in the management of plantar neuropathic diabetic foot ulcers. Diabetes Care 28(3):555–559
27. Shaw JE, His WL, Ulbrecht JS (1997) The mechanism of plantar unloading in total contact casts: Implications for design and clinical use. Foot Ankle Int 18(12):809–817
28. Petre M, Tokar P, Kostar D (2005) Cavanagh Pr. Revisiting the total contact cast: maximizing off-loading by wound isolation. Diabetes Care 28(4):929–930
29. Nabuurs-Franssen MH, Sanders AP, Sleegers R, Walenkamp G, Huijberts MSP, Schaper NC, Wijnen W (2005) Total contact casting of the diabetic foot in daily practice: a prospective follow-up study. Diabetes Care 28:243–247