Treatment of chronic plantar ulcer of the diabetic foot using an irremovable windowed fibreglass cast boot: prospective study of 177 patients

Caroline Michaux, Hugues Parquet, Olivier Bourron, Pascale Pradat-Diehl,
Agnes Hartemann, Georges Ha Van

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Title: Treatment of chronic plantar ulcer of the diabetic foot using an irremovable windowed fiberglass cast boot: prospective study of 177 patients

Authors:

- 1. Georges HA VAN¹, MD**
- 2. Caroline MICHAUX¹, MD**
- 3. Hugues PARQUET¹, MD**
- 4. Olivier BOURRON¹, MD**
- 5. Pascale PRADAT-DIEHL¹, MD**
- 6. Agnes HARTEMANN¹, MD**

**¹Teaching Hospital Pitie-Salpetriere Department of Diabetology: Diabetic Foot Unit
47-83 Boulevard de l'Hopital 75013 PARIS, FRANCE**

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Corresponding author: Dr Georges HA VAN, ghavan@sfr.fr

Treatment of chronic plantar ulcer of the diabetic foot using an irremovable windowed fiberglass cast boot: prospective study of 177 patients

ABSTRACT:

Objective: To evaluate the level of healing of chronic neuropathic plantar ulcers (NPU), using an irremovable windowed fiberglass cast boot (WCB) which is only opened after healing.

Method: A single center prospective study of a cohort of 177 diabetic patients with chronic NPU was carried out

Results: The ~~D~~duration of NPU was 604 ± 808 days, with a mean surface area of 4.6 ± 6.5 cm², a mean depth of 1.04 ± 1.08 cm, and a mean volume of 5.9 ± 17.7 cm³. After a mean of 96 days of wearing a WCB (min 9D, max 664D, median 68D) the level of healing reached was 83.6%, although-and 29 patients did not heal (16.4 %). The compliance was excellent-(at 95%). NPUs with bigger volumes (p=0.037) as well as those located at the heels at the heels-(p=0.004) as well as NPUs with bigger volumes (p=0.037) ~~had~~ hadve significantly lower healing levels.

Twenty one patients had moderate Peripheral Arterial Disease (PAD) (12%), and 24 patients were osteotomized for underlying osteomyelitis (14%), before inclusion. Moderate PAD (p=0.970) or operated osteomyelitis (p=0.128) did not modify the level of healing significantly, which were of 81% and 70.8% respectively.

Complications: 12 ulcers due to the WCB (i.e. 7%) and 2 other ulcers being moderately infected, resulting in 2% of toe amputation, but there were no major amputation ~~nor~~ phlebitis.

Conclusion: The treatment of old and deep NPU's of the diabetic foot by wearing a WCB without opening the boot prior to healing, offers very high ulcer recovery levels provides a good ulcer healing level. We changed the WCB were changed in only in 26 cases (14.6%). In addition, Compliance was excellent and of order of 95%. Furthermore, Moderate PAD or a recent osteotomy did not affect the efficacy of WCB.

Introduction

Off-loading diabetic foot ulcers is an indispensable element of their healing. The gold standard for the treatment of neuropathic plantar ulcers (NPU) of the diabetic foot is the Total Contact Cast (TCC) which allows a strict and mandatory treatment. It is the best answer to the lack of compliance observed with other ways of off-loading (1, 2). In this way, the rate of healing of un-complicated NPU treated by TCC is 90% within a mean time limit of 42 +/- 29 days (3, 4, 5). The superiority of TCC is confirmed by randomized studies comparing total contact casting to a removal boot (5), an irremovable cast (6), and a removable small boot (7). But the TCC has several inconveniences such as, the necessity to open the boot every 10 – 15 days in order to treat the ulcers and to check the skin tolerance to TCC, and the impossibility of monitoring the state of the wound continuously. Furthermore, TCC is contraindicated in patients with peripheral arterial disease (PAD) or infection, except for certain cases of moderate PAD and moderate infection (3), because the foot and the ulcer are not visible in cases of aggravation or local complications. All these inconveniences has led to the under usage of TCC, as shown in a previous study where TCC was used in only less than 2% of cases in 865 American diabetic foot centers (8). In a prior report, we described a technique using an irremovable WCB which was much caulked, making it unnecessary to open the whole boot upon total healing of the NPU, since the regular monitoring of the healing process and the administration of local treatments can only be made through the window (10). The main objective of this study was to demonstrate the efficiency of the WCB on the rate of healing of ulcers by compelling compliance with the treatment (2) of very old, or of big and deep NPUs which may also be associated with moderate PAD (3) or with post-ostectomy of osteomyelitis adjacent to the ulcer. The secondary objectives were to confirm the tolerance to the technique and to evaluate its complications.

Research design and methods

This study is a single center, non-randomized prospective study performed on a cohort from a multidisciplinary Diabetic Foot Unit , at the Department of Diabetology, ~~in~~^{at} a Teaching Hospital . Since the study involves current non-randomized treatment of patients at the clinic, there was no need for ethics committee consent.

- From June 1997 to May 2010, 177 patients were included in the study. Patients suffered from chronic NPU for more than 3 months, from recurrent NPU due to the lack of compliance, or from NPU of the mid-foot of the Charcot foot which is not possible to treat by therapeutic footwear.
- All patients had a clinical examination of their bone contact using the probe-to-bone test (PTB), and an arterial Doppler Ultrasound for the lower members in order to detect~~-detecting~~ the presence or absence of arterial constrictions or occlusion of the lower limbs especially of the anterior tibial, posterior tibial, and peroneal arteries, as well as the dorsal and plantar arteries. In addition, signs of osteomyelitis were looked for systematically by using radiography centered on the NPU zone.

The inclusion criteria were:

- The presence of a grade 1A to 2A plantar wound, based on the University of Texas (UT) classification (11,12).
- We have enlarged the therapeutic criteria for this procedure to include, deeper plantar wounds (3A), those being treated for slight infections (1B, 2B), those with moderate PAD, or conservative surgery by ostectomy in cases of osteomyelitis (13,14,15).

The exclusion criteria were:

- Major psychiatric problems
- The presence of critical ischemia

- An infection of the soft tissue up to level 3 or 4 of the PEDIS classification (11)
- The refusal of the patient to have a WCB placed

In order to limit the selection bias and to conserve the independence of the onset of wound healing, we matched only one wound with each patient [and](#) only the first treated wound using a WCB was included (patients having a second WCB for a new ulcer were not re-included). Moreover, in the case of bilateral WCB set on the same day, only the oldest wound was included and in cases of ulcers with the same age, we included the more serious wounds, according to the UT classification.

Results obtained for each patient

At inclusion, we recorded the age, sex, type of diabetes, duration of diabetes, insulin treatment, history of chronic ulcers, and the presence of a chronic ~~Charcot~~ foot.

Those who had a history of laser photocoagulation treatment were noted as positive for retinopathy.

Diabetic peripheral neuropathy was detected by the failure of the patient to sense the 10g of force applied by Semmes-Weinstein monofilaments over the 3 plantar areas, in 2 out of 3 occasions.

PAD was measured by taking the pulse and by arterial Doppler Ultrasound performed by an experienced member of the Diabetic Foot Unit.

Characteristics of the ulcer

For each wound the following was noted: the duration of the ulcer in days prior to WCB placement, its [localization](#) (forefoot, midfoot or hindfoot), its surface area in cm² (the longest x the widest), its depth in cm as measured by a sterile metallic probe. The volume of

the wound in cm³, was defined by the surface area calculated multiplied by the depth. In order to determine the severity of the ulcer, we used the University of Texas (UT) classification.

Moderate PAD without critical ischemia was defined as the presence of at least one of the following criteria: no posterior tibial and/or pedal pulsations by palpation with arterial lesions by Doppler Ultrasound of the leg of the study (but at least one of the three major leg arteries was detectable up to the foot) transcutaneous oxygen tension (TcPO₂) between 20 and 30 mm Hg, ankle-brachial index (ABI) between 0.5 and 0.9), history of revascularization (PTA or bypass) with no ischemic wound, no necrosis or gangrene (3). In the UT classification, these ulcers were classed as 1A or 2A according to the absence of severe ischemia.

Osteomyelitis was defined by the presence of positive probe to bone test together with radiological signs (demineralization, cortical erosion, bone lysis). If a conservative bone surgery (13, 14, 15) had been performed (limited osteotomy of the infected bone tissue) before installing the boot, the presence of post-surgical osteomyelitis was also noted, i.e. 3B in the UT classification.

Tolerance to the WCB

Tolerance was defined as the number of changes, due to breaking of the WCB or bad compliance with wearing the WCB and the complications linked with wearing it, such as: wounds forming due to the boot accompanied with or without infection, secondary infection of the wound under study, phlebothrombosis or secondary amputations.

Techniques of using the irremovable WCB (10)

All patients were treated with a below-knee irremovable WCB in which a window was cut over the site of the ulcer (Figure 1). Written and oral detailed explanations of the treatment

with the cast boot were given, and patient agreement was obtained before inclusion in the group.

All WCB were made by the same two physiotherapists of our team, and according to strictly defined rules established with one of the authors (GHV), who is a physician specialist in rehabilitation (10). In the majority of cases, patients were outpatient. The leg and foot were padded using four synthetic wadding Soffban^R bandages (w=15 cm and l= 2.7cm, Smith and Nephew^R), while bony protrusions (i.e malleoli and fibular head) were padded with five layers of bandage. Then, the bandages were covered with a water-repellent stockinette. A 1 cm layer of cotton was also placed underneath the plantar arch. Additional three layers of bandage was used as padding of the proximal and distal parts of the cast boot and around the window, in order to protect the skin from any sharp edges of the fiberglass. The casts were made with bands, measuring 10, 7.5, and 5 cm, of either Dynacast (Smith and Nephew) or Scotchcast (3M) fiberglass. The toes were left free. A double rubber heel was placed at the plantar aspect of the WCB opposite the site of fore- or hindfoot ulcers or on either side of midfoot ulcers. A window was cut in the cast boot at the ulcer site to allow daily wound assessment and care. The rubber heels were precisely perpendicular to the WCB and sufficiently high to ensure full protection of the ulcer from pressure and friction during walking. ~~The total time needed to make the WCB ranged from 90 to 120 min. Rubber heels must be~~ ~~The total time needed to make the WCB ranged from 90 to 120 min.~~ The WCB was worn without opening it until the ulcer was completely healed or until an incident that required emergency treatment occurred, such as intolerance to the boot, arterial or venous thrombosis, ulcer formation, or secondary osteomyelitis.

Follow-up

Mis en forme : Exposit

Following the installation of the WCB, patients were seen by the same physician at D+8, D+15, D+30 and then every month, in the Diabetic Foot Unit. Patients were also followed up by an outpatients' service, where a visiting care nurse replaced the dressing through the window of the WCB, daily or every other day (i.e. removal of hyperkeratosis, then replacement with vaselined gauze, or by alginate dressing in cases of exuding wounds).

Each patient signed a consent form with recommendations to limit their walking distances, and received a thromboembolic prophylaxis such as low molecular weight heparin (in accordance with the French Health Authority recommendations), together with weekly platelet monitoring until the removal of the WCB.

Patients were monitored until their wounds were healed, while wearing the WCB and up to a month after the removal of the boot, in order to avoid any complication or failure: e.g. N if new visible ulcers due to the WCB were detected or -If there was any doubt because of patient complaint of anything, we opened the WCB and replaced it in case of absence of skin ulceration.

Bone targeting antibiotic treatment was only given to cases of surgical osteotomy and for 6 weeks after the operation. However, in cases where the soft tissue was infected (stages 1B to 2B), antibiotic treatment was given for only 3 weeks.

The criteria for stopping the WCB treatment were the refusal of the patient for this type of treatment, severe foot infection, or severe ischemia placing the foot in danger.

Bad compliance criteria were: asking to remove the WCB or refusal to wear a new one in case of opening.

Outcomes

The duration of treatment of the study started on the day the WCB was posed and ended on the day of the final removal of the WCB.

The primary endpoint was the level of wound healing (defined as complete epidermis formation, lack of discharge, lack of tunneling) whatever the duration of healing.

The duration of healing and the tolerance to WCB were considered as secondary criteria.

Statistical analyses

Data are described as means $\pm$ SD for quantitative variables and samples, and as percentages for qualitative variables.

The main criteria of efficiency was defined as the proportion of patients having a wound healed without taking into account the length of time the WCB was worn. In order to estimate the probability of healing with time, a Kaplan Meier test was performed.

The main criteria were looked for in the following sub-populations: patients presenting with moderate PAD and patients having had an osteomyelitis treated by ostectomy.

Univariate analysis (Chi 2 test) was performed to determine the reasons behind wounds not healing, while quantitative variables were compared using the Student t-test. In cases where the validity criteria were not strong enough, corrections or non-parametric tests were employed.

The limit of significance was set as 0.05.

The main criteria for tolerance were the proportion of patients who had a complication throughout the study, estimations of the frequency of complications, and the reasons for the removal of the WCB (quantitative and qualitative analysis). A qualitative analysis of the reasons behind treatment failure (wounds not being healed) was also carried out.

All statistical analyses were done using the R development Core Team software (2008). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. ISBN 3-900051-07-0, URL

Results

Between 17th June 1997 and 4th May 2010, 254 NPU in 177 patients were treated by a WCB.

~~One NPU per patient was included, because of healing delays. We included one NPU for one patient.~~

Details of the characteristics of our group of 177 patients included in the study are shown in Table 1.

At inclusion, 74% (125/177) of the patients had a history of NPU and 24% of hospitalization for infected or ischemic NPU. ~~None of the patients~~ refused the WCB because it was a last resort treatment

The characteristics of the wounds are described in Table 2. The mean duration of the ulcers before inclusion was 604 ± 808 days; the mean duration of the heel wounds was higher, 765 ± 920 days, and 64% of the wounds dated more than 6 months. The mean area of the lesions was 4.6 ± 6.5 cm² and the mean depth was 1.04 ± 1.08 cm. The volume was significantly greater in wounds that were not healed (7.6 ± 12.9 cm³ versus 5.6 ± 18.6 cm³ $p=0.037$).

~~None of the patients were lost at follow up. We did not lose any of the patients in follow up.~~

The level of healing after an average of 96 days of wearing the WCB (min 9 d, max 664 d, median 68 d) was 83.6% (148/177), and only 29 patients did not heal (16.4%).

A quarter of the 177 patients had worn their WCB for at least 107 days.

Patients who failed to heal ($n=29$), had worn their WCB on average 74.4 ± 62.8 days versus 96 ± 94 days for the healed patients ($n=143$) ~~but~~ the difference was not statistically significant ($p\text{-value} = 0.135$).

The probability of ~~a lack of wound healing not having a wound healed~~ was 50% after 75 days of wearing the WCB (IC 95% [65 d; 84 d] (Figure 1) ~~(IC 95% [65 d; 84 d] (Figure 1)~~). The level of healing was not influenced by the duration of the ulcer (Tables 2). The number of healed heel wounds was significantly worse (40% of the heels did not heal, $p=0.004$), OR : 3.83 [1.24 ,11.87] but the mean volume of the unhealed

wounds of the heel was more than the average unhealed wound (14cm³ versus 7.6 cm³). The results, according to the UT classification of inclusion, are described in Table 2. At inclusion, we noted that 80% of patients had uninfected NPU (1A : 66 %, 2A : 8%, 3A : 6%) including 53 Charcot feet with NPU of the midfoot (31%), and 7.9 % of NPU with moderate infection (1B : 4.5%, 2B : 3.4%).

Twenty one patients had moderate PAD (12%), Two patients graded 3C, with only one below-knee permeable artery found by Doppler Ultrasound had a WCB fitted, as they were very old and had dementia. They could not be trusted with complying strictly with just a therapeutic shoe, but there was less risk with a WCB being fitted as they were prevented from walking long distances. None of the patients needed revascularization after being included in the study. Out of the 32 wounds classed 3A, 3B or 3C, 10 wounds did not heal. Before inclusion, 24 ulcers were operated for osteotomy of the adjacent osteomyelitis (14%).

The presence of a moderate PAD (p=0.970) or of an osteotomy (p=0.128) did not significantly modify the degree of healing, which were 81% and 70.8% respectively.

Complications

Adverse effects attributed to wearing the WCB are listed in Table 3.

We noted that 26 WCBs were changed (14.6%), 12 superficial ulcers (7%) as well as 2 superficial NPUs were moderately infected. (1%)-. All of these 14 wounds healed, but we still had to resort to 6 toe amputations (4%) due to secondary infections, to trauma caused by the WCB or to external trauma of the exposed toes. We did not encounter any major amputations nor phlebitis.

Compliance with the protocol was excellent (95%). After opening the WCB, [there were only we had](#) 9 refusals to install new WCB: 7 patients due to psychological intolerance and 2 took off the WCB themselves.

Discussion

In this prospective study, in which we did not lose any of the patients to follow-up, the use of a WCB enabled us to treat very old [NPU](#)s, with deep or big surface areas [NPU](#)s in non compliant patients and who, in 74% of the cases had NPU antecedents. Despite these severe characteristics (17), the level of healing obtained was very satisfactory. The objective was to use only one WCB for one patient . The topical tolerance to the WCB and compliance with the procedure were excellent with only 14.6% [requiring of](#) replacement of the WCB . Only 4% of the wounds led to amputations of the toes which were not adequately protected from external traumas or by WCB.

TCCs are more often used on ulcers with small surface areas of 1 to 2 cm² and which have imprecise depths (4,5,6,7,9). The wounds in our study were older and deeper and more spread out than those used in TCCs described previously, which explains the reason why the healing process was longer even though the level of healing was still in the order of 83.6%. This is the first study which shows that irremovable casts can be used, without opening the WCB, over such long terms, with healing rates almost identical to newer, less spread out and less deep ulcers..

Hence, we carried out arterial Doppler Ultrasound -on all patients, including those patients who had 3 permeable arteries at the ankle. Moderate PAOD is defined as the absence of 1 or 2 out of 3 permeable arterial sectors at the ankle or after an angioplasty or a bypass. Indeed, the absence of any pulse or the measurement of the Ankle Brachial Index seemed to us to be less reliable than Doppler Ultrasound [in assigning the posing of a WCB. Consequently, Doppler ultrasound performed by a specialist is a better means of eliminating severe PAD and hence permitting the posing of a WCB. to be used in contraindicating the posing of a WCB which would remain unopened until healing. Consequently, Doppler ultrasound performed by a specialist is a better means of eliminating severe PAD and hence permitting the posing of a WCB.](#) Patients with moderate PAOD were classed under A in the UT classification, but were

also assigned to a sub-group (corresponding to level P2 in the PEDIS classification).

Furthermore, we did not find any ischemic complications and none of the patients underwent revascularization after inclusion. Wider indications for moderate PAD and for operated osteomyelitis by conservative osteotomy was possible without significantly reducing the level of healing, but which still needs to be confirmed in a much larger scale (18). The age of the wound does not influence the level of overall healing, but the larger volume seems to explain the lower level of healing seen in heel ulcers.

The limitations of the study are that it's a single-centre study in a diabetic foot Unit, lacks a control group and highlights the importance of experience needed in posing the WCB.

Furthermore, the daily distance walked by each patient was probably limited due to the weight of the WCB, but was not quantified (1). In addition, the cost of the WCB installation (although minimized by the absence of the opening of the WCB until complete healing), and that of the outpatient care, were not calculated precisely. Additionally, the posing of the WCB required about 2 hours and 2 physiotherapists.

However, Not opening of the WCB until healing allows daily monitoring of the wound by a nurse through the window of the WCB. According to our criteria, the WCB is sufficiently well tolerated to permit longer treatments up until complete healing.

We treated 53 midfoot wounds on the Charcot foot. They had the same degree of healing than for the other locations, most probably because they were rapidly treated by the WCB without having to wait 3 months of duration.

The absence of major amputations was probably due to NPU infection exclusion from our study and by the follow ups performed by specialists from a multidisciplinary group who were capable of detecting the degree of severity of the wounds immediately and of treating any aggravations rapidly. No doubt, the forced compliance with the therapy is a major factor

in the non-aggravation of the ulcers, as well as the reduction of infections, and hence amputations (4).

However, the factors which diminished the rate of healing were the depth of the wound and being located at the heel, especially for older and larger heel wounds.

The WCB allows the therapy of plantar ulcers, wherever they may be (fore-, mid- or hind-foot). Despite it having to be worn for a long term, tolerance for it ~~was~~ excellent, thanks to its internal caulking, it was not necessary to change the WCB in the majority of patients.

The inconvenience, which can also be considered as an advantage, is the weight of the WCB for the patient, whose walking distance becomes limited, as well as restrictive for going up and down stairs or driving a car.

Consequently, ~~the~~ wearing of WCB can be proposed for the treatment of the ulcers of patients with moderate PAOD or with a controlled bone infection (3,18), without opening it until complete healing is achieved. Indeed, it ~~ought to~~ ~~should~~ be offered to all patients, with NPUs without severe infection or PAOD nor severe osteomyelitis, as a reliable way of healing and of preventing amputations even if the NPU is old and deep.

This study confirms that the main treatment of NPU of diabetic patients remains off-loading and that the obligatory compliance achieved using irremovable boots leads to excellent levels of healing even of old and large wounds in low-adherent patients, whereas, the level of healing attained is much lower in controlled studies not using irremovable off-loading (18).

All specialized multidisciplinary groups caring for patients with diabetic feet (19) should master the technique to install irremovable casted boots, as effective means to treat less-observant patients. In this way, our WCB technical, is extremely valuable in ~~recovering fully~~ ~~full recovery~~ from all types of plantar ulcers, especially in healing long term, large and deep ulcers in less compliant patients. A randomized controlled trial would be helpful to confirm the efficiency and tolerance of the WCB

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- Authors Contribution: GHV researched data, wrote/ edited manuscript, CM researched data, OB reviewed manuscript /contributed to discussion, HP researched data, PPD contributed discussion, AH, contributed to discussion, reviewed manuscript.
- Dr Georges HA VAN is the guarantor of this work and as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis
- There are No conflict of interest for any of the authors

References

1. Armstrong DG, Lawrence A, Lavery LA, Boulton AJM: Activity Patterns of Patients With Diabetic Foot Ulceration Patients with active ulceration may not adhere to a standard pressure offloading regimen, *Diabetes Care* 26:2595–2597, 2003
2. Morona JK, Buckley ES, Jones S, Reddin EA, Merlin TL: Comparaison of the clinical effectiveness of different off-loading devices for the treatment of neuropathic foot ulcers in patients with diabetes: a systematic review and meta-analysis. *Diabetes Metab Res Rev* 2013 29: 183-193
3. Nabuurs-Franssen MH, Slegers R, Huijberts MS, Wijnen W, Sanders AP, Walenkamp G, Schaper NC Total contact casting of the diabetic foot in daily practice: a prospective follow-up study. *Diabetes Care*. 2005 Feb;28(2):243-7
4. Mueller MJ, Diamond JE, Sinacore DR, Delitto A, Blair VP 3rd, Drury DA, Rose SJ: Total contact casting in treatment of diabetic plantar ulcers. Controlled clinical trial. *Diabetes Care* 1989; 12: 384-388.
5. Armstrong DG, Nguyen HC, Lavery LA, Van Schie CHM, Boulton AJM, Harkless LB: Off loading the diabetic foot wound: a randomized clinical trial. *Diabetes Care* 2001; 24:1019-1022.
6. Caravaggi C, Faglia E, De Giglio, Mantero M, Quarantiello A, Sommariva E, Gino M, Pritelli C, Morabito A: Effectiveness and safety of a nonremovable fiberglass offbearing cast versus a therapeutic shoe in the treatment of neuropathic foot ulcers: a randomized study. *Diabetes Care* 2000; 23: 1746-1751.
7. Piaggese A, Macchiarini S, Rizzo L, Palumbo F, Tedeschi A, Nobili LA, Leporati E, Scire V, Teobaldi I, Del Prato S. An Off-the-Shelf Instant Contact Casting Device for the Management of Diabetic Foot Ulcers : A randomized prospective trial versus traditional fiberglass cast, *Diabetes Care*. 2007 Mar;30(3):586-90

8. Wu SC, Jensen JL, Weber AK, Robinson DE, Armstrong DG. Use of pressure offloading devices in diabetic foot ulcers Do we practice what we preach? *Diabetes Care* 31: 2118-2119, 2008
9. Faglia E, Caravaggi C, Clerici G, Sganzeroli A, Curci V, Vailati W, Off-Bearing Cast in the Healing of Diabetic Plantar Foot Ulcer : A randomized controlled trial, Diabetes Care. 2010 Jul; 33(7):1419-23
10. Ha Van G, Siney H, Hartemann-Heurtier A, Jacqueminet S, Greau F, Grimaldi A. Non removable windowed fiberglass cast boot in the treatment of diabetic plantar ulcers Efficacy, safety, and compliance *Diabetes Care* 2003, 26: 2848-2852
11. Schaper NC Diabetic foot ulcer classification system for research purposes: a progress report on criteria for including patients in research studies. Diabetes Metab Res Rev. 2004 May-Jun;20 Suppl 1:S90-5.
12. Armstrong DG, Lavery LA, Harkless LB. Validation of a diabetic wound classification system. The contribution of depth, infection, and ischemia to risk of amputation. *Diabetes Care* 1998;21:855-9.
13. Ha Van G, Siney H, Danan JP, Sachon C, Grimaldi A. Treatment of osteomyelitis in the diabetic foot. Contribution of conservative surgery. Diabetes Care. 1996;19:1257-60
14. Ha Van G, Martini J, Danan JP, Tauber JP, Grimaldi A, Role of conservative orthopedic surgery in the treatment of the diabetic foot, Diabetes Metab. 1996 Feb;22(1):80-86.
15. Aragon-Sanchez FJ, Cabrera JJ, Quintan-Marrero Y, Hernandez-Herrero MJ, Lazaro-Martinez JL, Garcia-Morales E, Beneit-Montesinos JV, Armstrong DG. Outcomes of surgical treatment of diabetic foot osteomyelitis: a series of 185 patients with histopathological confirmation of bone involvement *Diabetologia* 2008 51: 1962-70
16. Margolis DJ, Allen-Taylor L, Hoffstad O, Berlin JA. Diabetic neuropathic foot ulcers: the association of wound size, wound duration, and wound grade on healing. Diabetes Care. 2002, 25:1835-9
17. Prompers L, Schaper N, Huijberts M, Prediction of outcome in individuals with diabetic foot ulcers: focus on the differences between individuals with and without peripheral arterial disease, *Diabetologia* . 2008 May;51(5):747-55
18. Margolis DJ, Kantor J, Berlin JA. Healing of diabetic neuropathic foot ulcers receiving standard treatment. A meta-analysis. *Diabetes Care*. 1999, 22:692-695
19. Wukich DK, Armstrong DG, Attinger CE, Boulton AJM, Burns PR, Frykberg RG, Helleman R, Kim PJ, Lipsky BA, Pile JC, Pinzur MS, Siminerio L. Inpatient management of diabetic foot disorders: a clinical guide. *Diabetes Care* 2013, 36: 2862-2871

Figure 1 : Windowed Cast Boot

PRIMARY EFFICACY ENDPOINT

Figure 2: Kaplan Meier estimate of complete healing rate at study completion

Table 1: Characteristics of patients :

	Healed Ulcers N=148	Unhealed Ulcers n = 29	p	Total n= 177
Age (years)	57.7±10.1	53.8 ± 11.0	NS	57.0± 10.4
Sex M (n,%)	108 (74)	22(75)	NS	130(75)
Type 2 diabetes (n,%)	118 (80)	22 (76)	NS	140(79)
Diabetes duration (years)	16.0 ± 10.6	18.5 ± 9.8	NS	16.4± 10.5
Insulin treatment (n,%)	106 (72)	26(87)	NS	132 (75)
Retinopathy lasered (n,%)	53 (38)	17 (59)	NS	70(41)
Neuropathy (n,%)	148(100)	29(100)	NS	177(100)
Charcot foot (n,%)	45 (33)	8(27.6)	NS	53 (32)
Moderate PAD (n,%)	17 (11)	4 (14)	NS	21(12)
Ostectomy (n,%)	17 (11.5)	7(24)	NS	24(14)
Prior ulcers (n,%)	102 (73.4)	23(79)	NS	125(74)
Cast duration (days)	96 ± 94	74 ± 63	NS	93 ± 90

NS: non significant

PAD peripheral arterial disease

Table 2: Characteristics and classification UT of the ulcers at inclusion

Characteristics	Healed ulcers n= 148	Unhealed ulcers n=29	p	Total n= 177
Duration:mean $\pm$ sd (days)	612 $\pm$ 809.9	563.4 $\pm$ 810.6	NS	604 $\pm$ 807.9
Forefoot	541 $\pm$ 709	330 $\pm$ 418	NS	510 $\pm$ 676
Midfoot	655 $\pm$ 928	649 $\pm$ 596	NS	654 $\pm$ 892
Heel	754 $\pm$ 715	782 $\pm$ 1210	NS	766 $\pm$ 920
< 1 month n(%)	14(10)	5 (17)	NS	28 (9)
1 – 3 months	23 (16)	5(17)	NS	28 (16)
3-6 months	16 (11)	4 (14)	NS	20 (11)
> 6 months	93 (64)	19(65)	NS	112(64)
Forefoot: n (%)	70 (50)	12 (41)	NS	82(49)
Midfoot	54 (39)	7 (24)	NS	61 (36)
Heel	15 (11)	10 (34)	0.004	25(15)
Ulcer surface(cm ²)	4.3 $\pm$ 6.1	6.6 $\pm$ 8.0	NS	4.6 $\pm$ 6.5
Ulcer depth(cm)	1.01 $\pm$ 1.08	1.17 $\pm$ 1.1	NS	1.04 $\pm$ 1.08
Ulcer volume (cm ³)	5.6 $\pm$ 18.6	7.6 $\pm$ 12.9	0.037	5.9 $\pm$ 17.7
1A (UT)	103(70)	14(48)	NS	117(66)
1B	7(5)	1(3)	NS	8(4)
2A	10(7)	3(10)	NS	11(6)
2B	6(4)	0	NS	6(3)
3A	8(5)	3(10)	NS	11(6)
3B	14(9)	5(17)	NS	19(11)
3C	0	2(7)	NS	2(1)

UT: University of Texas Classification

NS non significant

Table 3: Complications of the WCB

	Healed ulcers	Unhealed ulcers	Total
n	148	29	177 (n,%)
Replacement of cast	19	7	26 (16)
Refusal to replacement			9 (5)
Broken cast			8 (4)
Infected ulcers by the cast			12(7)
Study Ulcer infection			2 (1)
Minor amputation			6 (4)
Major amputation			0
Deep venous thrombosis			0

Major amputation: above-knee and below-knee amputation

Minor amputation: toe amputation