



Diabetes Care

THE ONLY DEVICE WHICH HAS PROVED ITS **EFFICACY** IN THE HEALING OF THE DIABETIC PLANTAR **LESIONS GRADE IA and IIA**
(according to the Texas University classification)



Emerging Treatments and Technologies

ORIGINAL ARTICLE

An Off-the-Shelf Instant Contact Casting Device for the Management of Diabetic Foot Ulcers

A randomized prospective trial versus traditional fiberglass cast

ALBERTO PIAGGESI, MD
SILVIA MACCHIARINI, DPM
LOREDANA RIZZO, MD
FRANCESCA PALUMBO, MD

ANNA TEDESCHI, MD
LAURA AMBROSINI NOBILI, DPM
ELISA LEPORATI, DPM
VINCENZO SCIRE, DPM

ILARIA TEOBALDI, DPM
STEFANO DEL PRATO, MD, PHD

OBJECTIVE— This study was designed to test the safety, effectiveness and costs of off-loading with a novel, off-the-shelf irremovable device in the management of diabetic foot ulceration (DFU).

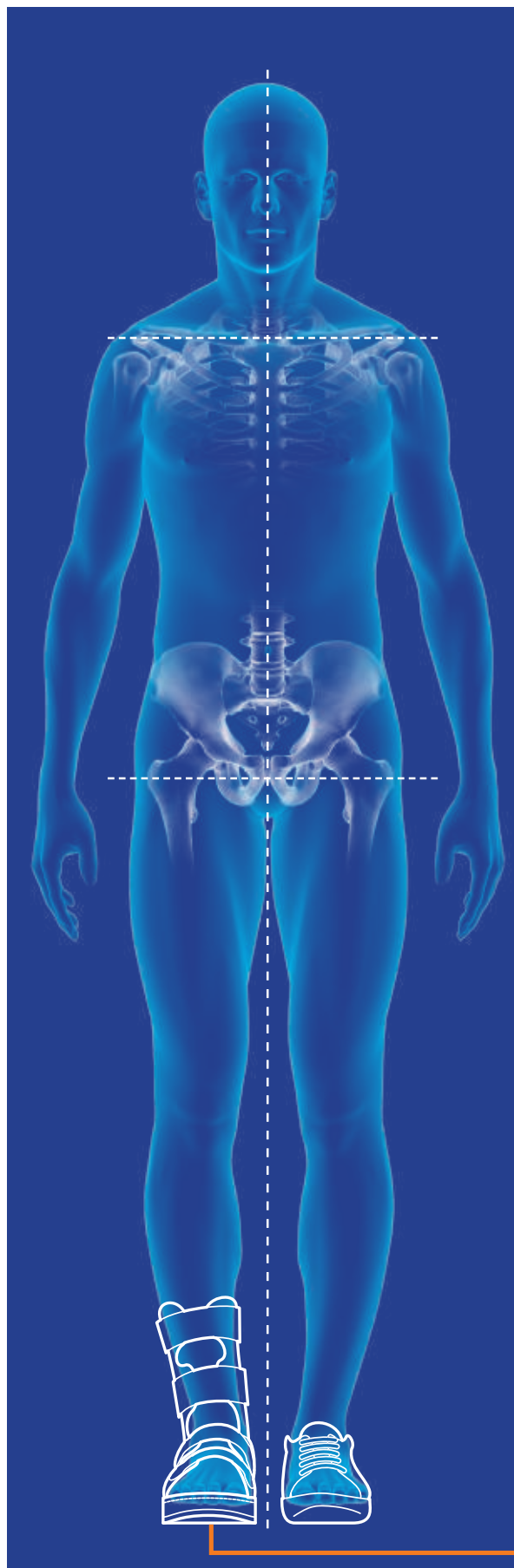
RESEARCH DESIGN AND METHODS— We prospectively evaluated off-loading of neuropathic plantar ulcers in 40 diabetic outpatients attending our diabetic foot clinic and compared healing rates at the 12-week follow-up, number and severity of adverse events, healing time, costs and applicability of the device, and patients' satisfaction between those randomly assigned to Total Contact Cast (TCC; group A) or to the **Optima Diab** walker (group B). Deep or infected ulcers were excluded.

RESULTS— No difference between groups A and B was observed in healing rates at 12 weeks (95 vs. 85%), healing time (6.5 4.4 vs. 6.7 3.4 weeks), and number of adverse events (six versus four). Treatment was significantly less expensive in group B, which showed a mean reduction of costs of 78% compared with group A (P 0.001). Practicability was more favorable in group B, with a reduction of 77 and 58% of the time required for application and removal of the devices, respectively (P 0.001). Patients' satisfaction with the treatment was higher in group B (P 0.01).

CONCLUSIONS—The **Optima Diab** walker is as safe and effective as TCC in the management of DFU, but its lower costs and better applicability may be of help in spreading the practice of off-loading among the centers that manage the diabetic foot.

Diabetes Care 30:586–590, 2007

OPTIMA PROJECT



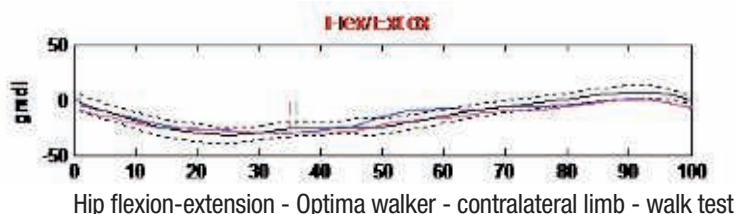
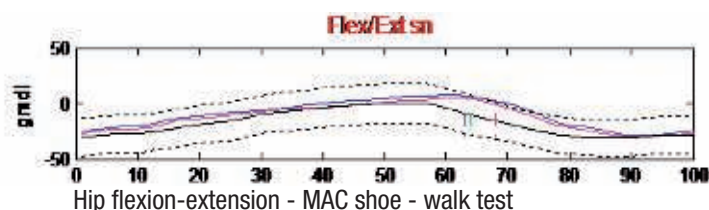
**Movement Analysis Laboratory,
Polytecnic University of Marche Region,
departement of Informatics,
Management and Automation Engineering**



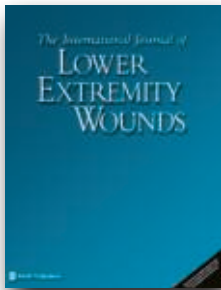
Dipartimento Ingegneria Informatica,
Gestionale e dell'Automazione
Università Politecnica delle Marche



The evaluation of the walking tests made on patients suffering from neuropathic diabetes has not demonstrated any significant difference in the flexion and in the extension of the hip, when we compare a foot with an **Optima** device to a contralateral foot with normal shoes (made for the first prevention). The present control groups refer to the tests made on patients wearing normal shoes.



OPTIMA DIAB



The International Journal of Lower Extremity Wounds

The Use of a Dermal Substitute (Integra) to Preserve Maximal Foot Length in a Diabetic Foot Wound With Bone and Tendon Exposure Following Urgent Surgical Debridement for an Acute Infection

Giacomo Clerici, Ezio Faglia, Maurizio Caminiti, Vincenzo Curci and Antonella Quarantiello

INT J LOW EXTREM WOUNDS 2009; 8; 209 DOI: 10.1177/



Dott. GIACOMO CLERICI

INTEGRA & OPTIMA MOLLITER ALLIED TO REDUCE AMPUTATIONS

ABSTRACT

In this report, the authors present the case of a 62-year-old female patient who was admitted to our hospital with an acute deep foot infection. The patient was taken immediately to the operating room where she underwent surgical debridement to completely remove all infected tissues; at the end of this first surgical step, all 5 metatarsal bones remained exposed dorsally.

Once eradication of infection was completed, we had to decide whether to perform a transmetatarsal amputation at proximal levels, which would have allowed healing by first intention but would have left the patient with a smaller foot stump, or amputation at more distal levels followed by coverage of healthy tendon and bone tissues with a dermal regeneration template (Integra, Integra Life Sciences Corporation, Plainsboro, NJ), which would have preserved the foot stump length and allowed better walking.

We opted for the second choice, and the use of a dermal template actually enabled our patient to maintain a considerable foot stump length, much longer than would have resulted from an amputation with immediate primary closure.



Wet and foul smelling gangrene of the fifth toe with forefoot abscess and deep infection of the dorsum of the foot.



Urgent surgical debridement.



Toes disarticulation. Soft dorsal tissues were cleansed until healthy tissue was reached in the healthy midfoot area.



Distal metatarsal amputation.

DISCUSSION

Despite improvements in the management of the diabetic foot, the presence of ischemia or infection, which are risk factors for amputation and mortality, remains a challenge for clinicians. In our experience, these complications most often result from delayed treatment. Treatment delay can allow the rapid spread of infection and tissue necrosis, resulting in severe loss of substance.

In these cases, limb salvage requires aggressive debridement with or without minor amputation, frequently at very proximal levels. In such situations, the challenge is to preserve maximal residual stump length, thereby providing patients the greatest possibility of rehabilitation and continued mobility. The present clinical study evaluates the use of a dermal substitute for preserving maximal foot length in diabetic patients presenting with exposed healthy tendon and bone tissues. In comparison to techniques that use regional flaps and free flaps, dermal substitutes offer unique advantages in terms of ease of use and lower invasiveness.

It may be speculated whether a similar result could have been achieved using advanced dressings or bioengineered skin substitutes. However, whether such dressings can cover the tendon and bone tissues adequately and how these types of dressings affect healing time are unanswered questions. In conclusion, the use of the dermal substitute Integra for treating exposed tendon and bone tissues following treatment for deep wound infections in diabetic patients allowed timely wound healing and preserved maximal foot length, improving walking ability in this patient. Such treatment should constitute part of the comprehensive management of diabetic wounds.



A dermal regeneration template, Integra®, was used to compensate the loss of dorsal soft tissue for coverage of exposed tendon and bone tissues.



The patient was discharged from hospital on April 4, 2009, and provided with a postoperative shoe Optima PostOp, (Molliter srl, Civitanova Marche, Italy) specifically designed to allow the patient to walk even in the presence of a large foot ulceration.



Complete wound healing.



The patient was then provided with secondary prevention shoes, with rigid soles (rocker sole, Optima MAC2 Molliter - Civitanova Marche Italy) and customized insole made of Alkafoam and PPT to allow the patient to walk even in the presence of a large foot ulceration.



THE ESSENTIAL WOUND MANAGEMENT RESOURCE FOR CLINICIANS WORLDWIDE

Innovative approaches to diabetic foot care in Italy

09/02/10 | Diabetic foot ulcers | Alberto Piaggese

This short report reviews recent advances in the management of the diabetic foot in Italy and the importance of an integrated approach to care. It focuses on the work of the Diabetic Foot Clinic at the University Hospital of Pisa, which has contributed to research into off-loading devices and the use of antiseptics. This has led to improvements in diabetic foot management.



Points

- The introduction in Italy of the IWGDF consensus guidelines has led to a significant decrease in the number of major amputations in patients with diabetes
- The Diabetic Foot Clinic at the University Hospital of Pisa has conducted prospective clinical trials on alternative off-loading strategies, antiseptic use and application of nanotechnologies
- Superoxidised solutions may be more effective than povidone iodine in treating infections in diabetic foot ulcers

INTRODUCTION

In the past few years, management of the diabetic foot in Italy has improved significantly. This is because the national network of clinicians in charge of the management of this complex pathology has introduced the IWGDF Consensus Guidelines on the care of the diabetic foot. The incidence of major amputations has decreased significantly in the diabetic population for the first time since the St Vincent Declaration of 1989.

A key factor in achieving such a good result has been the integrated approach to the care of these patients, with extensive revascularisation, mainly endovascular, and early and aggressive surgical debridement performed by interventional diabetologists.

Our group contributed to the improvement of the management of the diabetic foot with three prospective clinical trials that produced evidence on off-loading, the use of antiseptics in the infected foot and the application of nanotechnologies to help prevent ulceration.

NEW ADVANCES IN DIABETIC FOOT CARE

The trial on **off-loading strategies** in the neuropathic foot compared the total contact cast (TCC) to the **OPTIMA DIAB[®] (MOLLITER)**, an off-the-shelf irremovable off-

loading device. The study found that **OPTIMA DIAB** was as effective and less expensive than the TCC in treating neuropathic plantar ulceration. This finding increases the possibility of extending this off-loading strategy to the many diabetic foot centres throughout Italy that cannot afford to use TCC [1].

The trial on the **role of antiseptics** in the management of infected diabetic foot ulcers demonstrated how Dermacyn[®] Wound Care (Oculus Innovative Sciences), a new super-oxidised solution, was more effective than povidone iodine in innovative approaches to diabetic foot care in treating infections and preventing re-infections in diabetic foot ulcers, when combined with revascularisation and surgical debridement. Superoxidised solutions, which have been used mainly in oral surgery, combine a strong antibacterial activity with a very low toxicity for eucaryotic cells and living tissues. They should be considered as the first choice option when a local antiseptic is required in diabetic foot ulcer care [2].

Points

- Nanotechnologies can be used as a preventative measure in both the neuropathic and ischaemic foot
- Future research needs to focus on prevention of ulcer recurrence, effective follow-up strategies and early diagnosis of Charcot foot disease

Another promising option in the prevention of the deterioration of the diabetic foot is the **application of nanotechnologies** to both the neuropathic and the ischaemic foot in the pre-ulcerative stage. Our experience with Difoprev[®] (LVM Technologies), a new device designed as a carrier for hydrating agents such as phosphatidylcholine, demonstrated how it was able to restore neuropathic dehydrated skin, preventing fissures and breaks that may lead to frank ulceration [3].

THE FUTURE

In the near future great attention will be focused on the prevention of ulcer recurrence by the implementation of effective follow-up programmes, and on the early identification and treatment of the Charcot foot, which still has a very poor prognosis both for limb preservation and for patient quality of life.

Author details:

Alberto Piaggese, MD, Professor of Endocrinology and Metabolism and Director, Diabetic Foot Section, University Hospital of Pisa, Italy.

References

1. Piaggese A, Macchiarini S, Rizzo L, et al. 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; **30** (3): 586-90.
2. Piaggese A, Goretti C, Mazzurco S, et al. Efficacy and safety of a new superoxidized solution in managing wide post-surgical lesions of the diabetic foot. A prospective, randomized clinical trial. *Int J Lower Extrem Wounds* 2010; in press.
3. Banchellini E, Macchiarini S, Dini V, et al. Use of nanotechnology-designed footsock in the management of preulcerative conditions in the diabetic foot: results of a single, blind randomized study. *Int J Low Extrem Wounds* 2008; **7** (2): 82-7.