

Nonwindowed Nonremovable Fiberglass Off-Loading Cast Versus Removable Pneumatic Cast (AircastXP Diabetic Walker) in the Treatment of Neuropathic Noninfected Plantar Ulcers

A randomized prospective trial

CARLO CARAVAGGI, MD^{1,2}
ADRIANA SGANZAROLI, MD¹
MATTEO FABBI, MD¹
PAOLA CAVAIANI, MD¹

ILEANA POGLIAGHI, MD¹
ROBERTO FERRARESI, MD³
FRANCESCA CAPELLO, MD¹
ALBERTO MORABITO, MD⁴

Neuropathic plantar ulcers are classical lesions secondary to diabetic polyneuropathy (1,2). The worldwide gold standard treatment is the nonremovable off-loading cast (3–5). However, the device is not widely used due to concerns related to risk factors of the off-loading cast (i.e., joint rigidity, additional ulcer formation beneath the cast, and infection of the ulcer enclosed in the cast). Our group recently demonstrated that it is possible to reduce the risk of side effects reported in literature by constructing the off-loading cast using fiberglass bandages of different rigidity. Considering the device's scarce application because of the side effects, we conducted a controlled, randomized, prospective trial to evaluate the safety and efficacy of a removable pneumatic cast walker in comparison with a nonremovable fiberglass off-loading cast.

RESEARCH DESIGN AND METHODS

Between January 2005 and October 2005, 60 consecutive diabetic patients with neuropathic plantar ulcers were seen and randomly assigned to two groups: group A, using an Aircast Pneumatic Walker (XP Diabetic Walker);

and group B, using the fiberglass off-loading cast.

All participants had peripheral neuropathy, as highlighted by insensitivity to 10 g monofilament and vibration perception threshold measured by biothesiometer at malleolus of at least 25 volts, and presented with a neuropathic ulcer on the whole part of the plantar surface of the foot, including ulcers correlated with Charcot neuroarthropathy deformities.

We excluded patients with superficial tissue infection, osteomyelitis, TcPO₂ (transcutaneous PO₂) >30 mmHg, ankle brachial index >0.6, severe visual deficit, severe problems of equilibrium, amputation of the contralateral limb, and bilateral plantar ulcers. Clinical characteristics (age, sex, type of diabetes, and duration of diabetes) of both groups were comparable. The mean area of the ulcer was 3.4 ± 3.0 cm² in group A and 3.9 ± 3.4 cm² in group B (NS). No statistical difference was seen between groups in the positioning of the ulcer on the plantar surface of the foot.

At the initial visit the ulcer area was traced using a transparent dressing and measured with an image analysis software device. A total of 29 patients were randomized to group A and 29 to group B.

One patient from each group was excluded due to noncompliance.

Surgical debridement was performed at each control visit (every 12 days), eliminating all nonviable tissue. The dressing in both groups consisted of a mesh of hyaluronic acid (6) (Haylofill; Fidia, Abano Terme, Italy) covered with polyurethane foam (exudate control) as a secondary dressing (Mepilex, Molnlycke). At each visit, patients in group A were informed about the importance of wearing the off-loading device as much as possible.

A statistical analysis was made of the surface area of the lesions, and proportions were computed for the site of the lesions according to the type of device used. Student's *t* test was used to compare the mean values of the surface area in the two groups. Kaplan-Meier was plotted to compare the rate of healing of the lesion between the two groups, and the log-rank test was used to test the difference in the healing rate of the two groups. Fisher's exact test was used to assess differences between the healing rate 90 days after the installation of the devices.

Aircast pneumatic off-loading device

The Aircast Pneumatic Walker (XP Diabetic Walker) is an off-loading device. Its key elements include a semi-rigid plastic shell surrounding the limb, a removable front panel allowing easy access to the injured site, four individual internal aircells inflated with manometer at 20–30 mmHg to hold the limb, a specifically designed rocker sole for improved off-loading, and a dual-density insole. A hole was made on the insole at the ulcer site in order to off-load the ulcer.

Fiberglass off-loading cast

In previous literature, we describe two types of fiberglass bandages of different rigidity that were used in the construction of a pressure-relief device (7). Before us-

From the ¹Department of Diabetic Foot Pathology, Ospedale di Abbiategrasso, Milan, Italy; ²IRCCS San Raffaele, University Vita Salute, Milan, Italy; the ³Department of Cardiology, Ospedale Policlinico, Milan, Italy; and the ⁴Medical Statistic Unit, University of Milan, Milan, Italy.

Address correspondence and reprint requests to Carlo Caravaggi, Ospedale di Abbiategrasso, Diabetic Foot Pathology, Pz Mussi 1, Abbiategrasso (Milano) 20080, Italy. E-mail: carlo.caravaggi@fastwebnet.it.

Received for publication 16 March 2007 and accepted in revised form 8 June 2007.

Published ahead of print at <http://care.diabetesjournals.org> on 11 June 2007. DOI: 10.2337/dc07-0990. A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

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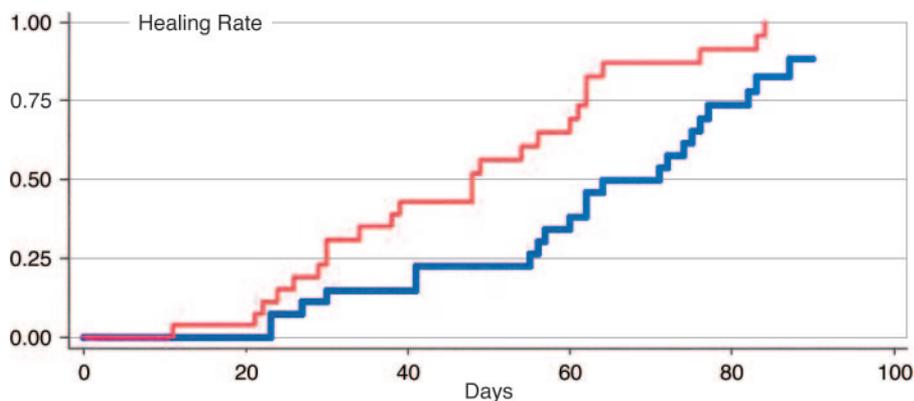


Figure 1—Kaplan-Meier estimate of healing proportion. Red line, fiberglass off-loading cast; blue line, Aircast. Log-rank $\chi^2 = 7.90$; $P < 0.005$.

ing both types of bandages, a tubular stockinet was placed onto the lower limb, which was first covered with German cotton to adequately protect the skin, especially bony protrusions. A walking stirrup was used for support when the ulcer was localized in the midfoot region, whereas a rubber heel was used when lesions were located on the forefoot, the plantar surface of the toes, or the heel.

RESULTS— Concerning side effects (ulcer infection, new ulcer due to the cast), no statistical differences were seen between the groups. Six patients in group A and five patients in group B did not finish the study when occurrence of serious infection of the ulcer required antibiotic therapy and surgical debridement. At the end of the study period (90 days), we observed a healing rate of

82.7% (24 of 29) in group B and 79.3% (23 of 29) in group A, with no statistical difference. The Kaplan-Meier curves showed a healing rate of 59.9 per month in group A versus 40.89 in group B (Fig. 1) ($P < 0.005$), with an average healing time of 71 days in group A and 48 days in group B.

CONCLUSIONS— The results of the study show that in the 90-day follow-up period the healing rate in both groups was similar, while the healing time of the fiberglass off-loading cast group was significantly lower. In conclusion, the nonwindowed nonremovable fiberglass off-loading cast should be considered the treatment of choice for neuropathic plantar ulcers. In addition, with its good rate of healing and low risk of complications,

the pneumatic cast walker could be considered a valid alternative.

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