Assessment of Removable Short Total Contact Cast in Comparison to Irremovable Total Contact Cast in the Management of Diabetic Neuropathic Ulcers

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Abstract

Purpose: To Compare between removable short total contact cast (rsTCC) and irremovable total contact cast (iTCC) in management of diabetic neuropathic ulcers.

Methods: From July 2010 to June 2011, 50 patients suffering from diabetic neuropathic ulcers presented to Zagazig University hospitals were randomly divided into 2 groups, one group (26 patients) was treated with rsTCC and the other group (24 patients) was treated with iTCC. Follow-up for four months to all patients was done in the outpatients clinics, where the neuropathic ulcers were evaluated and managed. The outcome of both groups was compared as regard healing of the ulcers and duration of healing.

Results: 14 patients (53.8%) were males and 12 patients (46.2%) were females in the first group while in the second group 12 patients (57.1%) were males and 9 patients (42.9%) were females after exclusion of 3 cases. There were no significant differences between the 2 groups in any of the demographic or clinical variables. The mean duration of healing was (54.6±16.2 days) in the first group and (51.6±16.1 days) in the second group, with no statistically significant difference between the two groups (p=0.701) as regard healing rates in both groups.

Conclusion: rsTCC is as effective as iTCC in the treatment of diabetic neuropathic plantar ulcers concerning proportion of patients that achieved healing and its duration.

Key Words: Diabetic neuropathic ulcers — Removable short contact cast — Diabetic — Neuropathic ulcers.

Introduction

IN individuals with diabetes mellitus, lower extremity amputation is most frequently preceded by development of peripheral neuropathy and minor foot trauma caused by repetitive elevated plantar loading III. Neuropathic ulcers are typically located on weight-bearing surfaces; the importance of excessive pressure on the sole of the foot in the pathogenesis of diabetic neuropathic ulcers is well established [2]. Complete relief of pressure from the ulcerated area is the key to effective healing. Use of a total contact cast (TCC) is considered the gold standard for management of neuropathic plantar ulcers; nevertheless, management of patients with a TCC poses several problems [3]. Proper TCC application with avoidance of iatrogenic lesions requires skilled cast technicians and is an expensive and time-consuming process [4]. The use of a TCC is absolutely contraindicated in patients with infection or critical ischemia. A TCC is also contraindicated in patients who are very elderly, have visual or equilibrium problems, have a contralateral foot ulcer, or have varicose veins. For these reasons, TCCs are rarely used [5].

The aim of this study is to compare between rsTCC and iTCC in management of diabetic neuropathic ulcers.

Patients and Methods

From July 2010 to June 2011, fifty patients suffering from diabetic neuropathic ulcers presented to Zagazig University hospitals were randomly divided into 2 groups, one group (26 patients) was treated with rsTCC and the other group (24 patients) was treated with iTCC.

Inclusion criteria included diabetic patients with neuropathic foot ulcers with a surface area of at least 2cm² or more.

Exclusion criteria included infected or ischemic ulcers. Ulcers were classified as infected if there is purulent discharge or two or more of the following local signs; hotness, redness, lymphangitis or
tenderness. Plain X-ray was done to exclude osteomyelitis. Ulcers were classified as ischemic if ankle-brachial index is less than 0.9. Also we excluded patients with more than one ulcer in the same foot.

All selected ulcers were Grade 1 according to Wagner’s classification (superficial ulcers involving the full skin thickness not penetrating down to ligaments, muscles or bone). Because infected and ischemic ulcers were excluded, all ulcers in our study would be classified as Grade 1 (superficial ulcers not involving tendon, capsule or bones), Stage A (non infected non ischemic ulcers) according to the University of Texas classification.

For both groups, diabetes was controlled by insulin. And the ulcer callus was properly debrided and dressing was done, then 2 special socks named stockinette were applied without wrinkles with rubber foam (Microfoam 3M; 3M Health Care) was applied on the deeper sock over bony prominences like the chin of tibia and both malleoli to avoid their injury. Then a roll of Soft Cast fiberglass bandage (Softcast 3M; 3M Health Care) was applied dry circularly till the mid-leg for rsTCC group and till below knee for iTCC group, with the ankle maintained at right angle all the time of cast application. A Scotch cast fiberglass bandage (Scotchcast 3M; 3M Health Care) was applied as an L-splint covering the entire sole of the foot extending till the mid-leg for rsTCC group and till below knee for iTCC group. The distal end is widened in such a way that the support for the toes is sufficiently guaranteed. A second Scotch cast bandage is applied as a U-splint around the ankle extending till the mid leg for rsTCC group and till below knee for iTCC group. A second layer of Soft Cast was applied dry circularly till the mid leg for rsTCC group and till below knee for iTCC group. All bandages are applied dry to allow sufficient time for moulding the cast to help compliance by making the patient not in need to wear cast shoe, and putting adhesive strips to help compliance by making the patient not in need to close the rsTCC by a crepe bandage. Every three weeks at the follow-up visit, the cast is opened, callus is debrided, ulcer area is calculated by multiplying maximum length by width, new stockinettes are applied and the same cast was applied again until ulcers healed.

For iTCC group, every three weeks at the follow-up visit, the cast is removed, callus is debrided, ulcer area is calculated by multiplying maximum length by width, and new iTCC was applied which was repeated until ulcers healing was achieved.

Patients were followed-up in the outpatient clinics for four months, and the ulcers were evaluated. The outcome compared was healing of ulcer and duration of healing.

Statistical analysis:

Spss version 17 was used for Statistical analysis. The distributions between groups for ulcer location, previous ulcers, the previous amputations and the number of healed ulcers were assessed using Fisher’s Exact Test, while age, sex, duration of diabetes, HAI c level and mean ulcer area were compared between both groups using independent t-tests.

To evaluate the healing characteristics of each group as a function of weeks of therapy and 2 groups’ mean time to closure, we used a Kaplan-Meier analysis (log-rank test).

Results

Among the 50 patients, 3 patients of the iTCC group were excluded from the study, because the ulcer became infected during the first time of cast exchange (one patient) and 2 patients refused to complete the study. The remaining 47 patients completed the study (26 patients in the rsTCC group and 21 patients in the iTCC group).

The mean age was 53.8±8.8 and 49.9±9.8 years in rsTCC and iTCC groups respectively, 14 patients (53.8%) were males and 12 patients (46.2%) were females in the first group, while in the second group 12 patients (57.1%) were males and 9 patients (42.9%) were females. The mean duration of DM was 15.6±6.1 and 17.9±6.5 years respectively, and the mean HbA1c value was 9.1±0.59 and 8.4±0.75 %Hb respectively, with history of previous foot ulcer in 5 patients (19.2%) and 4 patients (19%) in both groups respectively, and previous minor
amputation in 4 patients (15.3%) and 3 patients (14.2%) in both groups respectively. 24 and 20 ulcers were in the forefoot region in both groups respectively, while 2 and 1 ulcers were in the midfoot region in both groups respectively.

There were no significant differences between the 2 groups in any of the demographic or clinical variables (Table 1).

Twenty three patients (88.5%) in the rsTCC group and 19 patients (90.4%) in the iTCC group achieved complete healing, with no statistically significant difference between both groups (p=0.687). (Fig. 4) shows the Kaplan-Meier estimate of complete healing rates at the end of the study in both groups, showing no statistically significant difference between the two groups (p=0.701).

The mean duration of healing was 54.6±16.2 days in the rsTCC group and 51.6±16.1 days in the iTCC group with no statistically significant difference between both groups (p=0.520).

Fig. (1-A): Neuropathic plantar ulcer at the first metatarsal head before callus debridement.

Fig. (1-B): The ulcer after debridement at 14 days.

Fig. (1-C): The ulcer after 35 days of rsTCC.

Fig. (1-D): The ulcer with a notable decrease in size after 56 days.

Fig. (1-E): The ulcer was close to healing after 77 days and 84 days after rsTCC.

Fig. (1-F): The ulcer completely healed at 84 days of rsTCC.
Assessment of Removable Short Total Contact Cast

Fig. (2-A): Neuropathic plantar ulcer at left big toe after 7 days of rsTCC.

Fig. (2-B): The ulcer 28 days of the cast with decrease in size.

Fig. (2-C): The ulcer with complete healing after 42 days with rsTCC.

Fig. (3-A): A model of iTCC.

Fig. (3-B): rsTCC was opened longitudinally at a curved line along the anterior surface of leg and dorsum of foot.

Fig. (3-C): Leather was applied to the site of longitudinal opening of the cast.

Fig. (3-D): Leather was applied to the under surface of the cast to help compliance.

Fig. (3-E): Adhesive strips to help closure.
**Table (1): Patient characteristics in both groups.**

<table>
<thead>
<tr>
<th></th>
<th>rsTCC group</th>
<th>iTCC group</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>n</strong></td>
<td>26</td>
<td>21</td>
<td></td>
</tr>
<tr>
<td><strong>Age (years)</strong></td>
<td>53.8±8.8</td>
<td>49.9±9.8</td>
<td>0.553</td>
</tr>
<tr>
<td><strong>Sex: Male/female</strong></td>
<td>14 (53.8)/12 (46.2)</td>
<td>12 (57.1)/9 (42.9)</td>
<td>O.664</td>
</tr>
<tr>
<td><strong>Duration of diabetes (years)</strong></td>
<td>15.6±6.1</td>
<td>17.9±6.5</td>
<td>0.964</td>
</tr>
<tr>
<td><strong>A1C (%Hb)</strong></td>
<td>9.1±0.59</td>
<td>8.4±0.75</td>
<td>0.158</td>
</tr>
<tr>
<td><strong>Previous foot ulcer</strong></td>
<td>5 (19.2)</td>
<td>4 (19)</td>
<td>0.641</td>
</tr>
<tr>
<td><strong>Previous minor amputation</strong></td>
<td>4 (15.4)</td>
<td>3 (14.2)</td>
<td>0.623</td>
</tr>
<tr>
<td><strong>Ulcer location (forefoot/midfoot)</strong></td>
<td>24/2</td>
<td>20/1</td>
<td>0.581</td>
</tr>
<tr>
<td><strong>Mean ulcer area (cm²)</strong></td>
<td>3.2±0.86</td>
<td>2.8±0.62</td>
<td>0.402</td>
</tr>
</tbody>
</table>

Data are means±SD or n (%).

**Table (2): Percentage of healed ulcer and healing time in both groups.**

<table>
<thead>
<tr>
<th></th>
<th>rsTCC group</th>
<th>iTCC group</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Healed ulcers</strong></td>
<td>23 (88.5%)</td>
<td>19 (90.4%)</td>
<td>0.687</td>
</tr>
<tr>
<td><strong>Ulcer healing time (days)</strong></td>
<td>54.6±16.2</td>
<td>51.6±16.1</td>
<td>0.520</td>
</tr>
</tbody>
</table>

Data are means±SD or n (%).

**Table (3): Test of equality of survival distributions for the different levels of treatment.**

<table>
<thead>
<tr>
<th></th>
<th>Chi-Square</th>
<th>df</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Log Rank (Mantel-Cox)</td>
<td>.148</td>
<td>1</td>
<td>.701</td>
</tr>
</tbody>
</table>

**Discussion**

Among available methods to relieve plantar ulcers resulting from overpressure, the use of off-loading casts, which can be fabricated in different manners and with different materials, is considered the gold standard [6]. However, it is well known that TCCs are not widely used [7]. Preparing such a type of TCC still remains a costly and time-consuming process. Another important issue is the high percentage of patients, such as those with vascular disease, bilateral ulcers, or lower limb amputation, who cannot tolerate TCCs [8].

In our study, nearly the same proportion of patients achieved complete healing without significant difference among rsTCC group (23/88.5%) and iTCC group (19/90.4%) suggesting that rsTCC is as effective as iTCC in the treatment of diabetic neuropathic plantar ulcers.

Faglia and Associates [9] reported 17 patients (73.9%) in the TCC group and 16 patients (72.7%) in the readymade removable walker group achieved complete healing; however, they differ from our study that they used a readymade removable device, and we used a removable cast. Also Piaggi, et al., [10] and Caravaggi, et al., [11] reported the same results; however, they differ from our study that they used a readymade nonremovable device, and we used a removable cast.

However Gutekunst, et al., [12] found that the TCC subjects experienced a higher proportion of ulcer healing (9/11, 82%) compared to the removable cast walker subjects (5/12, 42%), though there was no difference in average healing time between the groups for those individuals who healed. Also Armstrong, et al., [13] reported a significant difference in the healing rates between removable and nonremovable cast walkers.

The mean duration of healing was 54.6±16.2 days in the rsTCC group and 51.6±16.1 days in the iTCC group with no significant difference between both groups (p=0.520).

Faglia and Associates [9] reported that the mean duration of healing was 35.3±3.1 days in the TCC group and 39.7±4.2 days in the readymade removable walker group with no significant difference between both groups (p=0.708). In our study the mean duration of healing was longer than the other, which may be explained by larger mean surface.
area of the ulcers (3.2±0.86 and 2.8±0.62 cm² in both groups respectively) compared with their study (1.4±1.2 and 2.2±2.2 cm² in both groups).

Gutekunst, et al. [13] reported that the mean duration of healing was 95±61 days in the TCC group and 94±64 days in the readymade removable walker group with no significant difference between both groups (p=0.95), but the longer duration of healing may be attributed to including patients with superficial and deeper ulcers classified as Grade 1 and Grade 2 according to Wagner’s classification (meaning that superficial ulcers and ulcers penetrating as deep as bone, joint, capsule, tendon, or ligament were included), and would be classified as Stage A, Grades 1-3 in the University of Texas classification.

In the present study we did not discuss variation of total costs in both groups; however iTCC group with changing the whole cast more than one time was appearing to have more costs on the patients which should be discussed in details in later issues.

The whole number of patients with previous minor amputation in both groups which was 7 cases (14.7%), achieved complete healing of the ulcers, which might be due to more awareness and better compliance and more fear of diabetic foot lesions.

The effect of the site of the ulcers in both groups on healing time cannot be assessed properly due to small number of cases having mid foot ulcer in the present study.

**Conclusion:**

According to our results rsTCC is as effective as iTCC in the treatment of diabetic neuropathic plantar ulcers concerning proportion of patients that achieved healing and its duration. Moreover, considering that the rsTCC is much more accepted by patients being removable and lighter in weight helping patients compliance.

**References**


