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**ORIGINAL ARTICLE**

## Ordinary Dressing versus Dressing with Total Cast Offloading in Management of Diabetic Foot Heel Ulcer, Comparative Study.

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### ABSTRACT

**Background:** Neuropathic and vascular changes in diabetic patients put them at risk for developing chronic foot wounds after minor trauma and change the normal distribution of pressure causing a breakdown in the integrity of the skin. Therefore offloading therapy have an important role to redistribute the pressure to improve healing. Aim of the work : To compare the effect of using total offloading Contact Cast Application in Heel ulcers versus regular surgical dressing in Diabetic Foot patients.

**Methods:** This patient preference clinical trial study (PCT) was conducted at Vascular Surgery Department, Zagazig University Hospitals. Dividing patients into 2 groups (on patient preference after explanation the procedures advantages and disadvantages): Group A: This group was treated by total contact cast and regular surgical dressing. Group B: This group was treated by surgical dressing only.

**Results:** There is statistically significant difference between the studied groups regarding area of ulcer baseline, at 2 and 4 weeks (there is significant decrease in area and number of patients with ulcer among contact cast group). There is non-significant difference between them regarding surface area at 6, 8, 10 and weeks (only two patients within contact cast group at 8 weeks and 1 on 10 and 12 weeks had ulcer with higher decrease in surface area). There is statistically non-significant difference between the studied groups regarding age or gender, Smoking, hypertension, previous debridement and osteomyelitis.

**Conclusions:** The study can be concluded that there is a positive prognostic role for total contact cast application in healing of heel ulcers in diabetic foot patients. TCC achieves foot unloading by transfer of load from the leg directly to the cast wall and greater proportionate load sharing by the heel helping us preventing more major amputations and provides a better and earlier outcome than regular surgical dressing.

**Key words:** Diabetic foot, Total Cast Offloading, Heel Ulcer, TCC

### INTRODUCTION

Diabetes mellitus related complications cause very high burden on country and still rising, superadded by the global increase in the prevalence of obesity and unhealthy lifestyles. The prevalence of diabetes according to latest estimates shows 382 million people globally in 2013, expected to rise to 592 million by 2035[3]. In developing countries, foot ulcers, infection and amputations are the greatest fears of diabetes. They are a leading causes of disability, morbidity, and mortality among

diabetic patients, 15% of all people with diabetes will suffer an ulcer at some period of their life[4]. 25% of them will have to undergo foot minor or major amputations. The impairment of healing process may be caused by impaired vascularity, nerve damage and deficiency of growth factors[5,6]. Neuropathy and vascularity changes in diabetic patients place them at high risk for developing chronic foot ulcers and wounds after negligible trauma or after continuous pressure causing interruption in the integrity of the skin. The

first step toward a successful treatment plan is exact diagnosis of the underlying cause as if patients have severe ischemia, vascular reconstruction may be needed before any other interventions. Less-invasive procedures also may be needed giving good prognosis with some types of diabetic foot ulcers as in neuropathic ulcers particularly when combined with pressure reduction techniques[7]. Total contact cast worked by equalizing plantar pressure, because the entire plantar surface of the foot was in contact with the internal surface of the cast, creating a larger surface area, redistributing pressure across the whole foot[8].

### METHODS

**Technical design** these patients preference clinical trial study (PCT) was conducted at Vascular Surgery Department, Zagazig University Hospitals. Assuming that healing with total contact cast application vs. regular dressing only with diabetic foot heel ulcer was 90% to 35% the sample size was calculated to be 48 using openepi with power of test 80% and C.I. 95 %<sup>(13)</sup>. They were divided into two groups as follows (on patient preference after explanation the procedures advantages and disadvantages due to impossible blinding of this intervention): Group A: This group was treated by total contact cast and regular surgical dressing. Group B: This group was treated by surgical dressing only. Written informed consent was obtained from all participants, the study was approved by the research ethical committee of Faculty of Medicine, Zagazig University. The study was done according to The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

**Inclusion criteria:** The inclusion criteria in our study indicate that Patients aged must be over 18 years old with Ulcers confined to heel area of Type 1-2-3 heel ulcer according to Wagner classification with Palpable distal pulsation<sup>(1)</sup>.

**Exclusion criteria:** Patients with Chronic illness like severe liver disease, cardiac disease, chronic pulmonary disease, any Medical condition likely to require systemic corticosteroids during the study period, Pregnancy, Concurrent arterial disease,, Concurrent venous insufficiency or Wagner classification type 4-5 must be excluded from study[1] .

**Methods:** All patients were subjected to the following:

**A : Clinical assessment :** Full medical history including: Demographic data including age, sex and

special habits of medical importance, The presenting complaint of the patient, Past history of previous operations and postoperative events (e.g. wound infection and respiratory complications) and chronic disease (e.g. cardiac diseases, liver diseases and diabetes mellitus) Full general and local clinical examination including: General examination for vital signs and other comorbidities and local examination is done for the diabetic foot wound regarding its depth, size, Wagner classification of ulcer. The size is obtained by use E-Z graph (transparent sheet used to document the size and shape of wound), and the exposed layers of tissue were documented.

**B: Investigations:** X-ray was done to denote the presence of osteomyelitis or Charcot joint and routine laboratory investigations including CBC, coagulation profile, kidney function test, liver function test and viral markers.

**C: Technique:** Placing the patient supine with 45 degree flexed knee with leg support or prone but prone position may be the easier to operator from having to hold the extremity off the table. Also the patient is more comfortable as he/she did not get cramps in the thigh or hip. The prone position allows the assistant to hold the appropriate position of the foot to the leg, usually ninety degrees to the leg. This position also allows the gastro-soleus complex to shift proximally on the leg thereby removing their bulk allowing for the cast to fit more snugly.

Before applying total contact cast, hypertrophic marginal callus, necrotic tissue, infected and foreign material around the ulcer were debrided. Wound was then irrigated with saline and properly dressed with a povidone iodine soaked gauze pad. Once the ulcer became clean, total contact cast was applied. Interdigital padding was given first.

Stocky net is applied as first layer then we apply cotton soft band 50/50 method after that we apply foam sheet parts on bony prominences to reduce friction and pressure on them. Then, we started to wrap first layer of soft cast then we start to form the supporting hard layer by hard cast wrap in shape of heel and U shaped slabs and finally application and wrapping of soft cast. We used to open the cast by anterior fissure by the date of next wound dressing in order to prepare it to be easily removed for wound dressing.

**D: Postoperative follow up:** Patients had follow up in two-week interval and total contact cast was changed every follow up visit. Ulcer healing was evaluated using a grading scale that deals with

symptom and ulcer stat changes considering failure if ulcer get worse than before treatment (failure) or no change (failure) and considered as partial satisfaction in minimal or moderate disappearance of ulcer (partial healing) and Complete disappearance of ulcer as (complete healing).

**STATISTICAL ANALYSIS**

The collected data were coded, processed and analyzed using the SPSS (Statistical Package for Social Sciences) version 15 for Windows® (SPSS Inc, Chicago, IL, USA). Qualitative data was presented as number and percent. Comparison between groups was done by Chi-Square test. Quantitative data was tested for normality by Kolmogrov-Smirnov test. Normally distributed data was presented as mean ± SD. P < 0.05 was considered to be statistically significant.

**RESULTS**

There is statistically non-significant difference between the studied groups concerning age or gender. There is statistically non-significant difference between the studied groups concerning special habits as smoking and hypertension and non-significant difference also regarding previous debridement and osteomyelitis. There is statistically non-significant difference between the studied groups regarding type or grade of ulcer. Five patients (21.7%) and four ones (16%) had neuropathic ulcer. Larger percentage within both groups (34.8% and 48% in constant cast application and regular surgical dressing groups respectively) had grade 3 ulcer.

There is statistically significant difference between the studied groups regarding area of ulcer baseline, at 2 and 4 weeks (there is significant decrease in area and number of patients with ulcer among

contact cast group (table 1) as using total contact cast early in patient with grade 1 and 2 wagner classification had a dramatic effect in decreasing healing time (figure1).

There is significant difference between the studied groups regarding duration of healing (longer in regular dressing group (table 2). Patients underwent total contact cast had significantly shorter duration till complete healing than those underwent regular surgical dressing (figure 2).

There is non-significant difference between them regarding surface area at 6, 8, 10 and weeks (only two patients within contact cast group at 8 weeks and 1 on 10 and 12 weeks had ulcer with higher decrease in surface area).

There is statistically non-significant difference between the studied groups regarding area of ulcer baseline, at 6, 8, 10 and 12 weeks. There is significant difference between them regarding surface area at 2 and 4 weeks. There is significant difference between the studied groups regarding healing rate at 6 weeks, 56.5% of patients within contact cast group had complete healing for no patients within regular dressing group.

At 12 weeks, there was significant difference between both groups regarding presence of complete healing, 82.6% versus 48% within contact cast group and regular dressing groups respectively had complete healing. Also there is significant difference between the studied groups regarding duration of healing (longer in regular dressing group (table3). Patients underwent total contact cast had significantly shorter duration till complete healing than those underwent regular surgical dressing 4:10 in TCC group and 8:12 in ordinary dressing only group (figure 3).

**Table (1)** Comparison between the studied groups regarding change in ulcer area over time

Cm2	Groups		Test	
	Total Contact cast group	Regular surgical dressing group	Z	P
<b>Pre area:</b>	N=23	N=25		
Mean ± SD	15.21 ± 11.62	17.94± 8.63	-1.407	0.159
Range	12 (3 – 38.5)	16 (4 – 35)		
<b>At 2 week:</b>				
Mean ± SD	6.28 ± 5.88	10.48 ± 5.59	-3.022	0.003*
Range	3.75 (0.75 – 20)	8 (4 – 22)		
<b>At 4 weeks:</b>				
Mean ± SD	2.07 ± 2.06	6.04 ± 4.13	-3.844	<0.001**
Range	3.75 (0.75 – 20)	4.75 (2 – 17.5)		
<b>At 6 weeks:</b>				
Mean ± SD	2.68 ± 3.29	2.4 ± 2.27	-0.301	0.763
Range	2.68 (0.35 – 5)	1.5 (0.5 – 8.75)		

Cm2	Groups			Test	
	Total Contact cast group	Regular surgical dressing group		Z	P
<b>At 8 weeks:</b>					
Mean ± SD	3	2.36 ± 2.55		-0.966	0.334
Range	3	1.5 (0.5 – 8.75)			
<b>At 10 weeks:</b>					
Mean ± SD	1.5	2.87 ± 2.94		-0.442	0.659
Range	1.5	2 (0.5 – 8.75)			
<b>At 12 weeks:</b>					
Mean ± SD	1.5	2.87 ± 2.94		-0.442	0.659
Range	1.5	2 (0.5 – 8.75)			

Z Mann Whitney test \*\*p≤0.001 is statistically highly significant

**Table (2)** Comparison between the studied groups average healing time

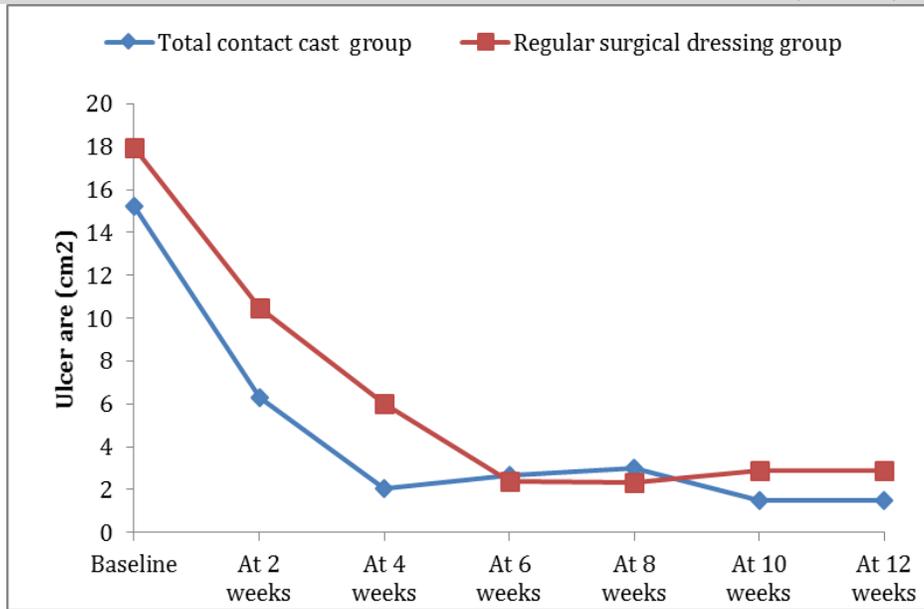
Average healing time	Groups				Test	
	Total Contact cast group	Regular surgical dressing group			χ <sup>2</sup>	P
	N=23 (%)	N=25 (%)				
<b>At 6 weeks:</b>						
Complete healing	13 (56.5)	0 (0)			17.64	<0.001**
Failed healing	3 (13)	5 (20)				
Partial healing	7 (30.4)	20 (80)				
<b>At 12 weeks:</b>						
Complete healing	19 (82.6)	12 (48)			Fisher	0.017*
No	4 (17.4)	13 (52)				

\*\*p≤0.001 is statistically highly significant \*p<0.05 is statistically significant χ<sup>2</sup> Chi square test

**Table (3)** Comparison between the studied groups regarding duration of ulcer healing.

Duration (week)	Groups			Test	
	Total Contact cast group	Regular surgical dressing group		t	P
	N=19 (%)	N=11 (%)			
Mean ± SD	6.42 ± 1.71	10.18 ± 1.66			
Range	4 – 10	8 – 12		-5.683	<0.001**

t independent sample t test \*\*p≤0.001 is statistically highly significant



Figure

Figure (1) Multiple line graph showing comparison between the studied groups regarding change in ulcer area

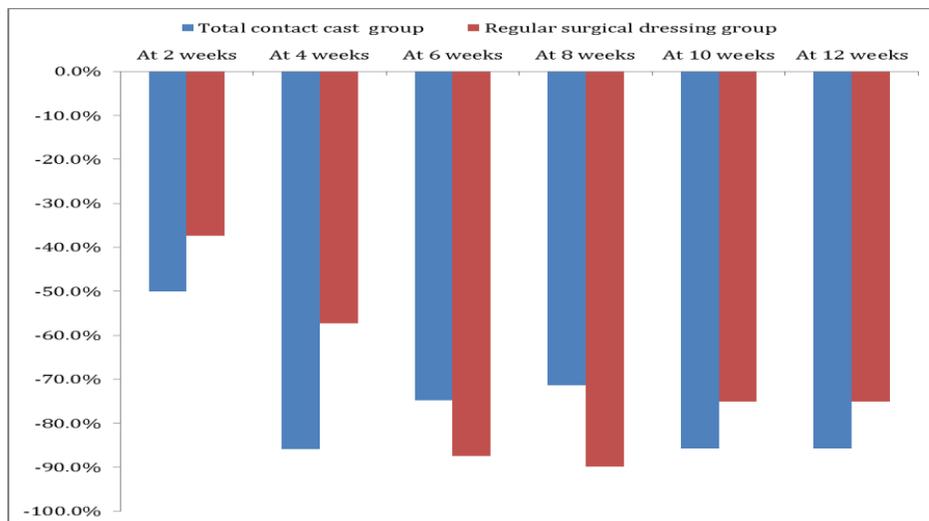


Figure (2) combined bar chart showing percent change in surface area in both groups over time

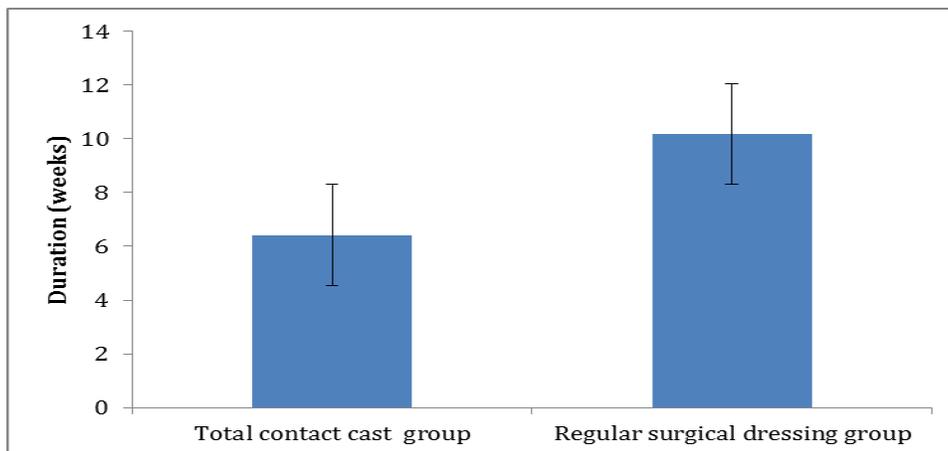


Figure (3) Simple bar chart showing comparison between the studied groups regarding duration

## DISCUSSION

Diabetes is the most common risk factor for foot ulcers (open sores), especially those with nerves problems, leg vascularity, or both. Amputation is one of common consequences (surgical removal of part of the limb). Foot ulcers lead to physical disability side by side with loss of quality of life also diabetic foot ulcers have financial impact leading to economic burden (healthcare costs, industrial disability). Preventing foot ulcers occurrence by educating people with diabetes about looking after their feet seems to improve people's foot care knowledge and traits in the short term. But there is insufficient evidence that only education, without any other preventive measures, will efficiently decrease the occurrence of foot ulcers and amputations [9]. The predictable annual incidence rate of DFUs arrays from 2% and 4% in developed countries. The prevalence can be higher in developing countries related to socioeconomic variances and inconsistent standards of wound caring [10]. In a randomized controlled trial of 325 patients, Litzelman et al., [11] start that significant reduction in DFUs may be obtained by procedures including observation, education, training on best practices for foot care and footwear, and continuing self-care management and so preventing serious Complications as chronicity, osteomyelitis, and amputation. Complications can be reduced when multidisciplinary foot care teams care for these individuals. Diabetic foot ulcers used to be treated with regular dressings and frequent debridement in addition to minimizing weight bearing on the affected foot. Proper reduction in pressure (offloading) is one of crucial elements in diabetic foot heel ulcer healing [12]. In our study we compared between ordinary surgical dressing alone and total contact cast with ordinary dressing in 48 diabetic foot patient with heal ulcers. Merheb et al., [13] have evaluated the efficiency of TCC in treating non-healing foot ulcers in 16 Lebanese diabetic foot patients. The average age of the patients was 59 years, 81% were male, Sahu et al., [14] used total contact casting (TCC) in opposite to traditional dressing treatment (TD) in the management of neuropathic diabetic ulcers. By assigning 31 patients with diabetic foot ulcers without any gross infection, osteomyelitis or gangrene were assigned randomly to group A (the TCC group 15 patients) and group B (TD in 16 patient). In the group A, TCC was used initially with instructing patient to decrease his ambulation and movement during their usual daily activity.

Subjects in group B (TD) dressing was prescribed and patients were advised to avoid bearing weight on the affected limb. Males were Twenty-four (77.4%) and females were 7 (22.6%). The mean age was 60 + 7.52 years. Thompson et al., [15] worked on two different management for diabetic foot ulcers, TCC (total contact cast) with a skin substitute versus standard wound care with TCC. Total study sample was of 13 adults (males = 11, females = 2; Table). Group A (male = 6, female = 1), and group B (male = 5, female = 1). The mean of age in group A was 58.5 years (range, 44-78 years; SD, 12.96 years), whereas the mean for group B was to some extent younger at 55.17 years (range, 30-77 years; SD, 18.32 years). Regarding the healing rates, Robert and Greenhagen [16] reported that healing rates was between 73% and 100% from 1 month to several weeks. Sahu et al., [14] started that there is decrease in healing time in ulcers treated with TCC with a mean duration of 48 + 7 days (6-7 casts) than those treated with TD that have average of 58 + 9 days to complete healing of ulcers. In our study, there is higher rate of infection in regular dressing group. Merheb et al., [13] reported that twelve of 16 (75%) ulcers were infected. Thompson et al., [15] stated that the wound closure rate was (92.3%) as the majority of patients had wound closure during the progress of the study, only one patient in each group not accomplishing wound closure; both of them had Charcot foot. Also infection in the progress of study reported in one patient in each group, and both of these patients had Charcot foot as well. In our study, comparing complete healing at 6 and 12 weeks in 6 weeks 56.5% of patients within contact cast group had complete healing for no patients within regular dressing group and in 12 weeks, 82.6% versus 48% within contact cast group and regular dressing groups respectively had complete healing. Mueller et al., [17] concluded that the rate of diabetic ulcer healing in 19 of 21 patients (91%) with using TCC within 42 days on average. Merheb et al., [13] reported that success rate of healing is 75% as complete foot ulcer closure occurred in 75% of patients without complications or recurrence during first year of follow-up. The rest did not reach complete healing and required other later interventions. Sahu et al., [14] found that failure of healing occurred in three (20%) foot ulcers in the TCC group and 6 (37.5%) in the TD group. Thompson et al., [15] found that patients with multiple comorbidities as advanced age and type 1 diabetes had the longest healing time in group A. In

our study, there is no relation between the type and grade of ulcer and complete healing at 12 weeks in total contact cast group. But, the type and grade of ulcer affect complete healing at 12 weeks in regular dressing group. Also, osteomyelitis have negative outcome among contact cast group (all patients with complete healing had no osteomyelitis). Finally, we can say that rest, limb elevation of the diseased foot and reducing the pressure are essential components of treatment and should be started at first presentation in order to avoid major amputation that may occur specially with heal ulcer. Ill-fitting footwear should be replaced with a postoperative shoe or another type of pressure-relieving footwear with all its varieties. Elraiyah et al., [18] stated the benefits of TCC and irremovable cast walkers in the management of diabetic foot ulcers in reducing relapse rate comparing with regular footwear. To be considered as the best available evidence for off-loading techniques. Merheb et al., [13] established that the effectiveness of TCC in treatment of diabetic foot ulcers is highly reliable. Westra et al., [19] reported that being a knee-high and non-removable device gives TCC superiority in offloading, giving an optimal 'shaft effect'. However, walking comfort may be affected. These results give directional help during decision-making in offloading choice. Sahu et al., [14] concluded that TCC is a more effective technique than dressing only for management of diabetic plantar ulcers reducing the hazards of amputation.

### CONCLUSIONS

The study can be concluded that there is a positive prognostic role for total contact cast application in healing of heel ulcers in diabetic foot patients. TCC achieves foot unloading by transferring of load from the leg directly to the cast wall and greater proportionate load sharing by the heel helping us preventing more major amputations.

TCC requires careful application, close follow-up and patient compliance with scheduled appointments to minimize complications. It minimizes the risks of amputation and provides a better and earlier outcome than regular surgical dressing. The high efficacy of the total contact cast with the low risk of major complications will continue to make it a gold standard for the treatment of neuropathic foot ulcers and have very good outcomes regarding diabetic foot infected ulcers type 1,2,3 with caution of osteomyelitis that increase risk of failure.

**Limitation of work** Limited ability of blinding, limited possibility to re-evaluate at the long-term

follow-up. Assuming that the cast was applied for ulcers with any grade above 3 or 4, infection must be cleared before cast placement. Finally, the absence of a standardized approach and a multidisciplinary team approach including podiatrists may have also been contributed.

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**Conflict of interest:** None

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