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AN OBSERVATIONAL STUDY OF COMPARISON BETWEEN EFFICACY OF PLASTER BOOT VSREGULAR DRESSING IN CASE OF DIABETIC FOOTULCER

General Surgery

Dr. Vishnu Pratap* Ex-Junior Resident, Department of General Surgery, LTMMC, Mumbai. *Corresponding Author

Dr. S. Prabhakar Professor, Department of General Surgery, LTMMC, Mumbai.

Dr. Pallavi Shambhu Assistant Professor, Department of General Surgery, LTMMC, Mumbai.

ABSTRACT

Diabetes Mellitus is one disease which is growing at a fast pace both in India and Worldwide.1 This growth is especially seen among young obese individuals most commonly of type 2 Diabetes Mellitus. Individuals with this disorder often suffer from foot ulcers. Taking a multidisciplinary approach to diabetic foot disorders, many centres from around the world have noted consistent improvement in limb salvage rates. One approach amongst them is the usage of Plaster Boot dressings for treatment of Diabetic Foot Ulcers. Plaster Boot or Total contact casts as they are commonly referred, have been used for decades to promote healing of plantar ulcerations secondary to neuropathy. Plaster Boot is a method of dressing for Diabetic Foot Ulcers which is based on the principle of offloading. This means that the ulcer healing is promoted by distributing the weight along the devices or casts used for the same. One of the major concerns in wound healing in diabetic patients is adequate blood supply which is promoted with the help of offloading devices such as Plaster casts given as a boot to encourage mobilization of the patient.

KEYWORDS

Diabetes Mellitus, Plaster Boot, Total Contact Cast, Ulcer, Wound healing

INTRODUCTION

Total contact casts (TCCs), removable walkers and plaster boots have been shown to be extremely effective in off-loading the diabetic foot. These can reduce plantar pressures up to 87%.[2,3,4] This effect may be achieved, among other mechanisms, by limiting ankle motion and redistributing load to the device itself. For these reasons, devices that only extend to the ankle, such as cast shoes and forefoot off-loading shoes, may be less effective in off-loading the foot than devices that extend above the ankle, as do TCCs and plaster boots. Various therapeutic footwear designs can effectively off-load at-risk foot regions. Among these designs, rocker-bottom outsoles, custom-made insoles, and some shoe inserts (e.g., metatarsal pads and medial arch supports) may reduce forefoot peak pressure between 16% and 52% compared with control.[4,5] The design and placement of such devices is critical, however, and difficult to establish without pressure.

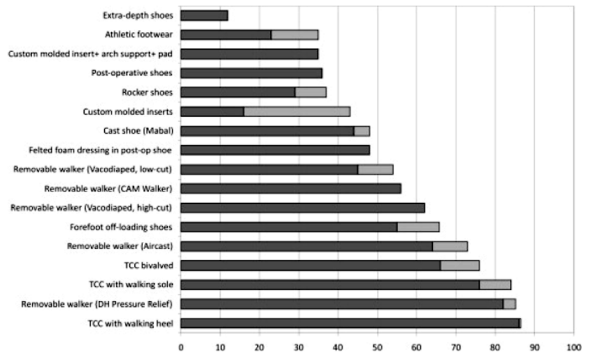

Figure1: The off-loading capacity of different modalities used for the prevention and treatment of diabetic plantar foot ulcers is expressed as percentage of peak pressure reduction at the first metatarsal head region compared with a control condition. The lighter bars show the range in measured peak pressure reduction over different studies.

The "total contact cast" or Plaster Boot is a casting technique that is used to heal diabetic foot ulcers and to protect the foot during the early phases of Charcot fracture dislocations. The cast is used to heal diabetic foot ulcers by distributing weight along the entire plantar aspect (sole) of the foot. It is applied in such a way to intimately contact the exact contour of the foot; hence, the designation "total contact cast."

By relieving the pressure on the prominent areas of the foot, the ulcers are permitted to heal if the cast is applied in such a way that the patient can remain ambulatory during the treatment of the ulcer. The principle involved here is that the cast is moulded to the contours of the foot from the back of the heel through the arch region, in the region of the metatarsals, around them and even to the toes. Pressure is expressed in terms of force or pounds over area per square inch. Therefore, if the weight-bearing area is enlarged the pressure per unit of weight-bearing area diminishes. In this way the pressure which has been concentrated on the bony prominence is distributed over the entire plantar aspect of the foot, allowing reversal of the mechanism that caused the ulcer to occur.

For the Charcot foot, the plaster boot is used in two ways. In the initial treatment of the Charcot foot when the breakdown is occurring and the foot is quite swollen and reactive, the cast is applied to control the movement of the foot and support its contours. In this instance the patient is often asked not to bear weight on the foot. In the second instance when the foot has already become deformed and ulceration has occurred, the principle using the cast is the same as described for the foot that has become deformed due to paralysis of the small muscles.

The plaster boot, when used for the described applications, is a very effective treatment. A prerequisite is that the foot must have an adequate blood supply, and therefore, the foot must be monitored quite carefully. The cast must be applied by someone who has experience with the applications and use of this cast. The cast must be changed at regular, short intervals of a week or two. The reason for this caution is that the diabetic who has insensitive feet runs the risk of having other sores or areas of irritation occur under the cast.

The cast is applied in a different fashion than normal casts. It is common to have the patient lie on his or her stomach on the casting table with the leg pointed straight up. The ankle should be bent to a neutral position if possible. In this way the doctor applying the cast has access to the sole of the foot which is the all-important area. A thin dressing is applied over the ulcer. A thin layer of stockinette is applied and protective cast padding applied between the toes. Cast padding is applied very thinly up the limb and then secondary foam padding is applied over the toes at the bony prominences on the inner and outer side of the ankle and often times of the sides of the cast and the front of the shin. Once this has been accomplished, the plaster undercoat is applied very carefully and smoothly to the foot and leg, completely encasing the toes and going up the leg. The sole of the cast is quite carefully and intimately molded to the contours of the sole of the foot.

These valleys are then filled in with plaster of Paris so that the sole of the cast is flat. The cast is often at this point reinforced by fiberglass and a special curved or rocker-bottom sole is applied to relieve the stresses of walking if the patient is to be allowed to bear weight.

These casts are then changed weekly or every other week depending on the physician, his or her experience with each individual patient, and the amount of swelling in the leg. Casting is continued until the ulcer is healed, and the foot is ready for appropriate shoe wear and orthotics. In the case of the Charcot process, casting is continued until the patient's fractures heal and the foot no longer needs a cast for protection. Because of the prolonged need for immobilization, the physician typically may convert the treatment to a removable walking boot. The total contact casting technique is an effective treatment for ulcers and Charcot foot problems.[6,7,8]

CASE STUDY

Here collected data of the patients admitted with diabetic foot ulcer in General surgery department at a tertiary care hospital were studied. Case records of all the patients with diabetic foot ulcer were reviewed with attention to Healing process, Hospitalization and Amputation Rate. Plaster Boot dressing was given to these patients for a period of 4 days and 4 sessions and healing rates of the same were studied based on scores to assess healing rate. At the end of each session wound was assessed and based on the same wounds were evaluated for further trial of Plaster Boot dressings.

INCLUSION CRITERIA:-

- Patients of all ages and sexes.
- All clinically diagnosed cases diabetic foot ulcers
- Patients giving consent for the study.
- Patients belonging to PEDIS grade 1 and 2

EXCLUSION CRITERIA:-

- Patients not giving consent for the study.
- Patients having bony injuries which prevent application of boot
- Patients having skin conditions preventing application of boot dressing for a prolonged period of time
- Patients with critical limb ischemia (ankle pressure <50mHg)
- Patients belonging to PEDIS grade 3and 4 classification

Assessment of the outcome of this study is based on the PEDIS score for diabetic foot ulcer wound which is depicted in figure 6 previously.

Diabetic foot ulcers are classified according to the five categories: perfusion, extent, depth, infection and sensation based on the **PEDIS** classification system.

1) Perfusion was determined by a combination of physical examination and non-invasive vascular studies. Clinical signs were based on the absence of dorsal pedal or posterior tibial artery pulses of the involved foot. Non-invasive criteria included the ankle-brachial index (ABI), toe-brachial index (TBI), transcutaneous oxygen pressure ($TcpO_2$) and ankle/toe pressure.
2) Extent was estimated by multiplying the largest diameter by the second largest diameter measured perpendicular to the first diameter and expressed as cm^2. To standardize the score of the extent category, we allocated ulcers to one of the following groups as performed previously : skin intact, $<1\ cm^2$, $1–3\ cm^2$, or $>3\ cm^2$.
3) Depth was evaluated using a sterile blunt nasal probe and imaging tests.
4) The diagnosis of infection was based principally on the presence or absence of symptoms and signs of inflammation, and the presence of secretion, the results of laboratory tests and imaging tests.
5) Sensation was evaluated with a 10-g monofilament and/or a 128-Hz tuning fork sensation on one or more sites of the foot.

Categories based on infection severity range from grade 1 (“no infection”) to grade 4 (“severe”). While “mild” infections (grade 2) can be easily treated, “moderate” infections (grade 3) can be complicated and limb-threatening. TABLE below explains the classification system in further detail. Symptoms that the patient presents with may vary. In fact, more than half of patients with a limb-threatening infection do not have systemic symptoms.

PEDIS Classification System:

Grade	Infection Severity	Clinical Manifestations	Treatment Parameters	Medications
1	Uninfected	Wound without purulence or inflammation	Outpatient	Topical antibiotics
2[b]	Mild	≥2: purulence or erythema, pain, tenderness, warmth, or induration; cellulitis ≤2 cm around ulcer; infection limited to skin/subcutaneous tissue; no other complications	Most not limb-threatening; most outpatient treatment	Cephalexin, trimethoprim-sulfamethoxazole (TMP-SMX), levofloxacin, amoxicillin-clavulanate, clindamycin
3[c]	Moderate	Infection as above plus >1: cellulitis >2 cm, streaking, deep tissue abscess, gangrene and with some life-threatening; involvement of muscle, tendon, joint, or bone	Most limb-threatening with some life-threatening; requires hospital treatment	TMP-SMX, amoxicillin-clavulanate, levofloxacin, ceftriaxone, linezolid, ertapenem, ticarcillin-clavulanate
4[d]	Severe	Infection plus systemic toxicity or metabolic instability; fever, chills, tachycardia, hypotension, confusion, vomiting, severe hyperglycemia, acidosis, or azotemia	Life-threatening; requires hospital treatment	Imipenem-cilastatin, vancomycin-ceftazidime, levofloxacin-clindamycin, piperacillin-tazobactam, ticarcillin-clavulanate

[a] PEDIS stands for perfusion, extent/size, depth/tissue loss, infection, and sensation.
[b] Medications for treatment can be oral.
[c] Medications for treatment are oral or parenteral, based on clinical situation.
[d] Medications for treatment are IV, at least initially.
Source: Reference 18.

RESULTS

Wound Assessment and Comparison

1. Assessment of wound on day 1

As all subjects (cases and control) were taken upto PEDIS score 2 so both the groups are comparable to each other. Attached below is one the patients on whom Plaster Boot dressing was applied. Below is the wound as seen on day 1:

2. Assessment of wound on day 10

Out of the 30 cases, 6 cases, that is, 20% cases did not show improvement of wound or showed deterioration of wound as per PEDIS score. Hence these were considered as failure of treatment. 80% cases showed improvement and were considered for another session of Plaster Boot dressing.

6.67% cases did not show any improvement and were not considered for Plaster Boot dressing and hence were given other forms of dressing. 13.3% cases showed deterioration of wound on day 10 and required either amputation or surgical debridement.

73.3% controls showed improvement of wound.
10% controls did not show any improvement of wound were continued with the regular dressing.

WOUND_DAY1 * CASE_CONTROL Cross tabulation				
		CASE_CONTROL		Total
		Case	Control	
WOUND_DAY1	Count	30	30	60
	% within CASE_CONTROL	100.0%	100.0%	100.0%
Total	Count	30	30	60
	% within CASE_CONTROL	100.0%	100.0%	100.0%

16.67% controls showed deterioration of wound which required surgical debridement or amputation.

According to Chi Square Test the p value for wounds with PEDIS score

1 on day 10 was not significant between cases and controls which showed Plaster Boot is equivalent to Regular dressing.

Wound on day 10					
			CASE_CONTROL		Total
			Case	Control	
WOUND_DAY10	1	Count	24	22	46
		% within CASE_CONTROL	80.0%	73.3%	76.67%
	2	Count	2	3	5
		% within CASE_CONTROL	6.67%	10.0%	16.67%
	3	Count	4	5	9
		% within CASE_CONTROL	13.33%	16.67%	30.0%
Total		Count	30	30	60
		% within CASE_CONTROL	100.0%	100.0%	100.0%

Attached below is the wound of the patient as seen on day 10 of the study.

Wound on day 20					
			CASE_CONTROL		Total
			Case	Control	
WOUND_DAY20	1	Count	24	22	46
		% within CASE_CONTROL	100.0 %	100%	100 %
	2	Count	0	0	0
		% within CASE_CONTROL	0.0%	0.0%	0.0%
Total		Count	24	22	46
		% within CASE_CONTROL	100.0 %	100.0%	100.0 %

3. Assessment of wound on day 20

Out of the 24 cases, 100% cases showed improvement of wound and hence were continued Plaster Boot dressing or were considered for Split Skin Grafting.

In the Control group, 22 subjects showed improvement of wound amounting to 100% of the control group and were continued with regular dressing or considered for Split Skin Grafting.

According to Chi Square Test the p value for wounds with PEDIS score 1 was not significant and both the modalities of treatment were equivalent.

Attached below is the wound of the patient as seen on day 20 of the study:

4. Assessment of wound on day 30

Out of the 24 cases, 100% showed improvement and were considered for Split Skin Grafting.

Out of the Control group, 100% showed improvement of wound and were considered for Split Skin Grafting.

Hence both modalities of treatment showed equivalent results even on day 30 of treatment.

Wound on day 30					
			CASE_CONTROL		Total
			Case	Control	
WOUND_DAY 30	1	Count	24	22	46
		% within CASE_CONTROL	100.0%	100%	100%
	2	Count	0	0	0
		% within CASE_CONTROL	0.0%	0.0%	0.0%
Total		Count	24	22	46
		% within CASE_CONTROL	100.0%	100.0%	100.0 %

Attached below is the wound of the patient as seen on day 30 of the study:

Assessment of Duration Of Wound Healing

The mean duration of wound healing among the cases was 38.53

The mean duration of wound healing among the control group was 39.07.

The p value for Chi Square test was not significant and hence there was no significant difference in the duration of wound healing among cases and controls.

Assessment of WBC Count on Admission

Group Statistics				
	CASE_CONTROL	N	Mean	Std. Deviation
WBCCOUNTADMISSION	Case	30	13290.00	3237.533
	Control	30	17213.33	5577.834

The mean WBC count among cases was 13290 whereas the mean WBC count among controls were 17213.

WBC counts on admission were higher for the control group as compared to the cases and there is a significant difference between the two groups.

So the control group had higher infection rate in the wounds as compared to the cases.

Assessment of length of stay in hospital

The mean duration of stay in hospital among cases was 30.
The mean duration of stay in hospital among controls was 29.83.

The p value for Chi Square Test for the mean duration of stay in hospital among cases and controls showed no significant difference between the two groups.

CONCLUSIONS

The current study shows that with casting, in a wide range of ulcers, the majority of patients (75%) can be healed in a relative short time span (mean 30 days). As expected, the best results were obtained in patients with non-infected ulcers. In the current study, superficial infection in patients with pure neuropathic ulcers did not influence the results, but many of them (25%) did not show improvement or resulted in surgical intervention showing that regular monitoring of wound is important.

At present, infection is seen as a contraindication for Plaster Boot dressing, given the risks of spreading of the infection, the inability of daily wound inspection, and the need for daily dressing changes. In

case of increased exudation, the cast should be changed frequently and if required wound should be debrided. Peripheral arterial disease is usually seen as a contraindication for Plaster Boot dressing, because of fear of further deterioration of the blood supply and development of new ulcers.

There was no significant age or gender difference and the results were same for both categories.

The duration of Hospital stay was on an average of 30 days which has been the same for regular dressing as well. Although patients in whom Plaster Boot dressing was applied had lower evidence of infection showing that Plaster Boot dressing is effective in wounds with lesser infection. This has also been depicted by the WBC counts on admission of the patients in both the groups.

Patients in the Case group showed lower counts as compared to patients in the Control group.

In conclusion, casting therapy is applicable in daily practice in a wide range of patients, with good healing rates and relative few major complications. It can easily be applied on wounds with superficial infections and helps in better wound healing by additionally providing an aid to his/her mobility. The results of this study have shown equivalent efficacy for both Plaster Boot and Regular dressing for treatment of Diabetic Foot Ulcers.

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