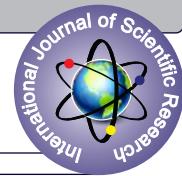


A COMPARATIVE STUDY ON THE EFFICACY OF TOTAL CONTACT CASTING (TCC) VERSUS PATELLAR TENDON BEARING (PTB) CASTING WITH BOHLER'S WALKING IRON IN TREATMENT OF NEUROPATHIC PLANTAR FOOT ULCER



Orthopaedics

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ABSTRACT

Introduction: Neuropathic plantar ulceration is one of the serious hazard to the person with anaesthetic feet who leads an active life. The entire history of a plantar trophic ulcer is dominated by mechanical factors. The results of treatment with local applications and dressings were poor indeed until putting the neuropathic foot in a total contact plaster became the standard treatment. Apart from Total Contact Casting there are several offloading techniques and custom made orthoses readily available including a simple customized PTB (Patellar Tendon Bearing) cast to the affected limb. Addition of walking iron with PTB cast may enhance the mobility, increasing patients self-esteem and finally reduce the disability.

Material and methods: In this Prospective parallel group randomized controlled open level trial, conducted in the Department of Physical Medicine and Rehabilitation, IPGME&R, SSKM Hospital, Kolkata between 15th January, 2012 to 14th July, 2013 (Eighteen months) 54 (27 in each group) patients with neuropathic plantar foot ulcer, residents of Kolkata and surrounding districts, attending the Physical Medicine and Rehabilitation OPD at IPGME&R, SSKM Hospital, Kolkata were included and studied if they fulfilled the inclusion and exclusion criteria after getting Institutional Ethics Committee clearance, informed written consent.

Results: Numerical data were compared between groups using student's unpaired t test when normally distributed or by Mann – Whitney's u test if otherwise. The Chi – Square test or Fisher's exact test employed for intergroup comparisons of categorical variables. The combined results of these studies yields an average rate of successful healing of 75.5% after an average of 38.7 days in the cast but for the lack of literature we found difficulty to compare our results in case of PTB casting with walking iron as it has not been extensively studied like TCC. The results of our study indicate that pressure off-loading using the TCC and PTB casting with walking iron are equally effective in the treatment of neuropathic plantar foot ulcer.

Conclusion: Mostly male of 3rd and 4th decade were affected with neuropathic plantar foot ulcer aetiologically diabetes followed by Hansen's with primary anatomic site of involvement either forefoot or hindfoot. Both TCC and PTB are helpful to reduce ulcer depth, and ulcer area which are statistically significant (p value < 0.001). Approximately 30% of the ulcer healed quite well in both the groups after the period of 3 weeks of treatment but majority of the ulcer (85.2% in TCC group & 77.8% in PTB group) healed at the end of the study by both form of treatment.

KEYWORDS

Neuropathic plantar ulceration, Total Contact Casting (TCC), PTB (Patellar Tendon Bearing) cast

INTRODUCTION:

Neuropathic plantar ulceration is one of the serious hazards to the person with anaesthetic feet who otherwise leads to an active life. The only way to heal a plantar ulcer is to rest it. The entire history of a plantar trophic ulcer is dominated by mechanical factors. It starts from trauma or excessive local pressure and is maintained by repeated minor injuries; it heals readily without special treatment if rested completely, and its recurrence can be prevented by careful regulation of stresses on the scar. Conditions involving insensitivity of the foot including diabetes, leprosy, hereditary neuropathy, tabes dorsalis, herniated nucleus pulposus resulting in neuropathy, etc. Total contact plaster became the standard treatment. The earliest published report of casting for trophic ulcerations dates back to 1930.¹ Dr.Joseph Khan in India described an ambulatory technique for the treatment of plantar ulcers occurring in patients with Hansen's disease (leprosy) as an alternative to prolonged, expensive periods of bed rest in the hospital. The regularity and speed with which these trophic ulcers heal in a walking plaster is most impressive and support the concept that the ulceration is related mainly to mechanical factors. Dr.Paul Brand and his associates refined and popularized the technique Total Contact Casting in the early 1960s.² Since then Total Contact Casting (TCC) is an important mode and **gold standard** among the methods used to heal neuropathic foot ulcers. Apart from TCC there are several offloading techniques and custom made orthoses readily available including a simple customized Patellar Tendon Bearing (PTB) cast, PTB cast along with Bohler's walking iron (BWI). There is a grey zone regarding the comparative efficacy of Total Contact Casting and PTB casting with Bohler's walking iron in the treatment of neuropathic plantar foot ulcers. Hence this project is a humble attempt to compare the effectiveness of Total Contact Casting and PTB casting with Bohler's walking iron in the treatment of neuropathic plantar foot ulcers.

AIMS AND OBJECTIVES: To compare the effectiveness of total contact casting and PTB casting with Bohler's walking iron in the healing of neuropathic plantar foot ulcer.

MATERIAL AND METHODS:

Before the start of the study clearance of the Institutional Ethics Committee was taken. Individual informed written consent was taken from each patient to include in the study group.

STUDY AREA:

Department of Physical Medicine and Rehabilitation, IPGME&R, SSKM Hospital, Kolkata.

STUDY POPULATION:

Patients with neuropathic plantar foot ulcer, residents of Kolkata and surrounding districts, attending the Physical Medicine and Rehabilitation OPD at IPGME&R, SSKM Hospital, Kolkata were included in the study if they fulfilled the inclusion and exclusion criteria.

STUDY PERIOD:

Eighteen months (15th January, 2012 to 14th July, 2013)

SAMPLE SIZE: n=54 (27 in each group)

The difference in the ulcer size (measured as ulcer surface area in mm²) between the two groups was considered as the primary outcome of the study. It is estimated that 27 subjects need to be studied in each group in order to detect the difference in 10 mm² in the ulcer area between the groups at the end of six weeks of treatment, with 80% power and 5% probability of type 1 error. The calculation assumes standard deviation of 13 mm² for ulcer area on the basis of earlier published studies.^{3,4}

STUDY DESIGN:

Prospective parallel group randomized controlled open level trial.

INCLUSION CRITERIA:

- Grade 1 and grade 2 plantar ulceration (Wagner classification).
- Age of the patients 18 years and more.
- Unilateral involvement.
- Ambulatory patients.

EXCLUSION CRITERIA:

1. Grade 3, 4, 5 plantar ulceration (Wagner classification).
2. Patients unwilling to have cast on extremity.
3. Age less than 18 years.
4. Excessive leg or foot swelling.
5. Patients unable to comply with follow up visits.
6. Patients unsafe in mobility while in cast.

STUDY TECHNIQUE:

After getting Institutional Ethical Committee clearance, patients were included after taking informed consent as per inclusion and exclusion criteria. Study parameters along with demographic data were recorded at the initial visit (visit 1). Patients were divided into two groups randomly. One group treated with Total Contact Casting (TCC) and second group treated with PTB casting with Bohler's walking iron. Both groups received education regarding routine care of the cast and warning signs. The debridement of the ulcer was done under strict aseptic condition and all the patients were advised to follow the advice and report accordingly if they face any problem. After doing both type of casting, the patients were examined and assessed at the interval of 1st week (visit 2), 3rd week (visit 3) and 6th week (visit 4).

INTERVENTION:

Before the cast is applied, the ulcers were debrided off all necrotic tissue and hypertrophic edges are shaved to create a smooth transition from the ulcer's bed to adjacent skin without an intervening shelf of keratin. The wound was then cleaned with 10% solution of povidone iodine. Single sterile gauze dressing (5×5) cm was used to cover the each ulcer, in order to limit bulk and prevent excessive pressure.

TOTAL CONTACT CASTING (TCC):

Patient was placed in the prone position with the involved limb's knee flexed to 90 degrees and the ankle in neutral position. The plantar surface of the ulcerated foot should be parallel to the floor. A small amount of cotton padding was placed loosely between adjacent toes to absorb any moisture and prevent maceration. Then roller cotton 10-15 cm wide was applied from the knees to toes. The distal end of the roller cotton was then folded back over the dorsal aspect of toes and secured with paper tape. Wrinkles in the roller cotton are avoided to prevent an uneven surface at the interface with the skin. Then plaster was applied loosely and was moulded exactly to match the contour of the foot, ankle and leg without any formation of wrinkles. The cast was applied 2 cm distal to the fibular head to a point distally up to covering of the toes. Usually two rolls of plaster (15 cm) adequate to create a three layer inner shell. A rocker sole was created by layering plaster cast (15 cm) on the bottom of the cast from heel to toe. Then a rubber chappal was attached to the layered plaster cast to complete the rocker sole, with the help of two roll of plaster. The whole thing was then reinforced with one to two roll of 10 cm plaster cast.

PTB CASTING WITH BOHLER'S WALKING IRON:

The patient sitted on the edge of a table with involved limbs knee flexed at 90 degree and the foot is steadied on a low chair with ankle at 90 degree. A roller cotton 10 -15 cm wide was applied from toes to knee (up to just above of the femoral condyle). A bit of extra padding needed over knee. Then three 15 cm and three 10 cm plaster of paris cast was applied from toes to knee extending up to superior pole of patella. Then the cast is firmly moulded round the inferior patellar ligament, femoral condyles and over medial tibial flare. The cast was moulded into a triangular shape. The anterior portion of the cast was then trimmed from the upper pole of the patella. Posterior portion of the cast was trimmed to one finger breadth below the level of the cast indentation that was made anteriorly into the patellar tendon. The posterior wall of the cast should be low enough to allow 90 degree flexion of knee without having the cast edge rub on the hamstring tendon. Then a Bohler's walking iron of size 12 or 14 is fitted to the affected limb incorporating with the plaster of paris (POP) cast.

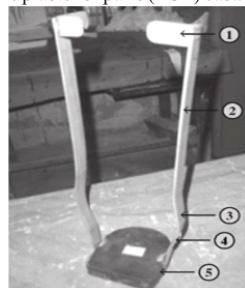


Figure 1: Bohler's Walking Iron (BWI), a simple device with two metallic vertical bars and one sole to bear weight, being made with rubber. 1. Metal cross pieces (bars), 2. Metal side bars, 3. Rounded flares of side bars, 4. Terminal part of the side bars 5. Rubber heel.



Figure 2: a patient with total contact cast



Figure 3: a patient after PTB cast with walking iron

PARAMETERS STUDIED:

1. Size (mm^2) of the ulcer.
2. Depth (mm) of the ulcer.
3. Downgrading of Wagner classification.
4. Complete ulcer healing time in weeks/days.

ASSESSMENT:

In consecutive four visits - visit 1 (0 week), visit 2 (1st week), visit 3 (3rd week) and visit 4 (6th week) using the parameters mentioned above and all the data documented in our stipulated proforma.



Figure 4: CASE 1 – Before TCC



Figure 5: CASE 1 – After 6 weeks of TCC



Figure 6: CASE 2 – Before TCC



Figure 7: CASE 2 – After 3 weeks of TCC



Figure 8: CASE 3 – Before PTB cast with Walking iron



Figure 9: After 6 weeks of PTB cast with walking iron



Figure 10: CASE 4 – Before PTB cast with Walking iron



Figure 11: CASE4 – After 3 weeks of PTB cast with walking iron

After that a master chart was prepared and results were analyzed.

STUDY TOOLS:

Sterile gloves, Povidone iodine, Chlorhexidine, Sterile gauze piece, Surgical blade, Dissecting forceps, Measuring tape, Sterile probe(blunt tip), 5.07(10g) Simmes-Weinstein monofilament, Transparent sheet, Marker pen, Case record form, POP cast (15 cm,10 cm), Bohler's Walking iron (No. 12 or 14), Plaster cutting machine, Camera, Sphygmomanometer, Stethoscope, etc.

INVESTIGATIONS:

1. Blood examination: Hb%, TLC, DLC, ESR, Sugar, CRP,
2. Radiological examination: x-ray, 3.Culture sensitivity of wound

discharge (if required)

RESULT ANALYSIS:

All the data collected during this study period were analyzed by using statistical software Statistica version 6 [Tulsa, Oklahoma: StatSoft Inc., 2001] and GraphPad Prism version 4 [San Diego, California: GraphPad Software Inc., 2005]

Numerical data were compared between groups using student's unpaired t test when normally distributed or by Mann – Whitney's u test if otherwise. The Chi – Square test or Fisher's exact test employed for intergroup comparisons of categorical variables. Kaplan – Meier survival analysis attempted to study the trend in ulcer healing in terms of number of days to complete the healing. The trends were compared between groups by log – rank test. All analysis was two tailed and p value <0.05 was considered statistically significant.

Table- 1: Comparison of age distribution between groups (n=54): (TCC and PTB)

Age in years	Intervention group		TOTAL Number (%)	Chi – Square Test
	TCC Number (%)	PTB with BWI Number (%)		
18 to 34	6(11.1)	3(5.6)	9(16.7)	p-value-0.439
35 to 49	9(16.7)	11(20.4)	20(37)	
50 to 64	10(18.5)	8(14.8)	18(33.3)	
65 and above	2(3.7)	5(9.3)	7(13)	
Total	27(50)	27(50)	54(100)	

Table- 2: Comparison of Gender distribution between groups (n=54):

Intervention Group	SEX		Total	Fisher's exact test (2-tailed)
	Male Number (%)	Female Number (%)		
TCC	17(62.96)	10(37.04)	27(100)	p value = 1.001
PTB With BWI	16(59.26%)	11(40.74)	27(100)	
Totals	33(61.1)	21(38.9)	54(100)	

Table-3: Comparison of WAGNER grade of ulcer between groups (n=54):

Intervention group	WAGNER GRADE		TOTAL Number (%)	Fisher's exact test
	Grade-1 Number (%)	Grade-2 Number (%)		
TCC	7(25.9)	20(74.1)	27(100)	p-value-0.745
PTB With BWI	5(18.5)	22(81.5)	27(100)	
Total	12(22.2)	42(77.8)	54(100)	

Table-4a: Descriptive statistics of numerical variables of the study -TCC group [n=27]

Variables	Mean	Median	Lower Quartile	Upper Quartile	Std. Dev.
Age in years	46.6	46.0	35.0	62.0	16.39
Length of the ulcer(mm):					
V1_Length	23.1	20.0	15.0	29.0	10.27
V2_Length	18.6	18.0	12.0	25.0	9.72
V3_Length	9.6	10.0	0.0	14.0	9.16
V4_Length	2.6	0.0	0.0	0.0	6.77
Width of the ulcer(mm):					
V1_Width	17.4	14.0	11.0	25.0	8.10
V2_Width	13.8	12.0	8.0	19.0	7.53
V3_Width	7.4	7.0	0.0	10.0	7.31
V4_Width	2.4	0.0	0.0	0.0	6.43
Depth of the ulcer (mm):					
V1_Depth	5.6	5.0	3.0	6.0	3.31
V2_Depth	3.9	3.0	2.0	5.0	2.74
V3_Depth	1.9	2.0	0.0	3.0	1.65
V4_Depth	0.3	0.0	0.0	0.0	0.72

Area of the ulcer(mm²):

V1_Area	474.9	300.0	176.0	676.0	423.54
V2_Area	320.2	190.0	110.0	400.0	341.47
V3_Area	131.8	77.0	0.0	150.0	226.35
V4_Area	47.7	0.0	0.0	0.0	145.94

- Numerical variables, other than age, are mostly normally distributed (except at visit 4) by Kolmogorov-Smirnov test.

COMMENTS:

- Mean age of the patients assigned to the TCC group was 46.6 years with a SD of 16.4 years and median age was 46 years.
- Mean depth of the ulcer of TCC group was 5.6 mm at the beginning of the study which decreased subsequently with every visit and finally reached to 0.3 mm at the 4th or final visit.
- Mean surface area of the ulcer of patients assigned to the TCC group at the beginning of the study was 474.9 mm² with a SD of 423.54 mm² which was decreased subsequently to 47.7 mm² at the end of the study.

Table-4b: Descriptive statistics of numerical variables of the study –PTB With BWI group [n=27]

Variables	Mean	Median	Lower Quartile	Upper Quartile	Std. Dev.
AGE	51.1	49.0	41.0	60.0	13.99
Length of the ulcer(mm):					
V1_Length	23.1	21.0	16.0	31.0	8.25
V2_Length	19.7	19.0	15.0	28.0	8.20
V3_Length	10.9	14.0	0.0	19.0	8.40
V4_Length	2.7	0.0	0.0	0.0	5.25
Width of the ulcer(mm):					
V1_Width	18.1	17.0	12.0	26.0	8.08
V2_Width	15.9	16.0	10.0	22.0	7.90
V3_Width	9.3	9.0	0.0	16.0	7.80
V4_Width	2.3	0.0	0.0	0.0	4.70
Depth of the ulcer (mm):					
V1_Depth	3.8	4.0	3.0	5.0	1.42
V2_Depth	2.6	2.0	2.0	4.0	1.50
V3_Depth	1.4	1.0	0.0	3.0	1.31
V4_Depth	0.3	0.0	0.0	0.0	0.67
Area of the ulcer(mm²):					
V1_Area	481.0	368.0	208.0	806.0	361.22
V2_Area	370.8	324.0	135.0	660.0	276.94
V3_Area	146.8	99.0	0.0	256.0	153.97
V4_Area	29.0	0.0	0.0	0.0	66.90

COMMENTS:

- Mean age of the patients assigned to the PTB with BWI group was 51.1 years with a SD of 13.99 years and median age was 49 years.
- Mean depth of the ulcer of patients belonging to PTB with BWI group was 3.8 mm at the beginning of the study which decreased subsequently with every visit and finally reached to 0.3 mm at the 4th or final visit.
- Mean surface area of the ulcer of patients assigned to the PTB with BWI group at the beginning of the study was 481.0 mm² with a SD of 361.22 mm² which was decreased to 29 mm² at the end of the study.

Table-5: Comparison of numerical variables (length, width and depth) between groups by Student's unpaired t-test [n=54]

Variables	Mean		Standard Deviation		p-value
	TCC Group	PTB with BWI Group	TCC Group	PTB with BWI Group	
AGE	46.6	51.1	16.39	13.99	0.277
V1_Length	23.1	23.1	10.27	8.25	0.988
V2_Length	18.6	19.7	9.72	8.20	0.630
V3_Length	9.6	10.9	9.16	8.40	0.580
V4_Length	2.6	2.7	6.77	5.25	0.971
V1_Width	17.4	18.1	8.10	8.08	0.725
V2_Width	13.8	15.9	7.53	7.90	0.328
V3_Width	7.4	9.3	7.31	7.80	0.354

V4_Width	2.4	2.3	6.43	4.70	0.942
V1_Depth	5.6	3.8	3.31	1.42	0.015
V2_Depth	3.9	2.6	2.74	1.50	0.041
V3_Depth	1.9	1.4	1.65	1.31	0.240
V4_Depth	0.3	0.3	0.72	0.67	1.000

COMMENTS:

- I. Unpaired t test revealed that there was no statistically significant difference between patients of TCC and PTB with BWI group regarding age of the patients, mean ulcer length and mean width of ulcer.
- II. A statistically significant difference was found between two groups when compared for mean depth of ulcer in the 1st and 2nd visit though it was not significant in the subsequent visits.

Table- 6: Comparison of surface area of ulcer between groups by Mann-Whitney U test

Variables	Rank Sum		U	Z	p-level
	TCC	PTB with BWI			
V1_Area	714.0000	771.0000	336.0000	-0.49305	0.622
V2_Area	678.5000	806.5000	300.5000	-1.10720	0.268
V3_Area	693.5000	791.5000	315.5000	-0.84770	0.397
V4_Area	722.5000	762.5000	344.5000	-0.34600	0.729

COMMENTS:

Mann-Whitney U test shows there is no statistically significant difference between this two treatment groups when compared for median ulcer surface area. These findings were consistent in the all four visits.

Table-7: Comparison of ulcer healing between groups at third visit (n=54):

Intervention Group	Outcome at v3		Total	Fisher's exact test (2-tailed)
	Healed Number (%)	Non healed Number (%)		
TCC	9(33.3)	18(66.7)	27(100)	p value = 1.00
PTB with BWI	8(29.6)	19(70.4)	27(100)	
Totals	17(31.4)	37(68.6)	54(100)	

COMMENTS:

Around one third of ulcer patients from each group (33.3% in TCC group & 29.6% in PTB with BWI group) found to have cured completely at third visit. Fisher exact test shows no statistically significant difference in ulcer healing between two treatment groups at third visit.

Table-8: Comparison of final outcome between groups (n=54):

Intervention Group	Outcome		Total	Fisher's exact test (2-tailed)
	Healed Number (%)	Non healed Number (%)		
TCC	23(85.2)	4(14.8)	27(100)	p value = 0.728
PTB with BWI	21(77.8)	6(22.2)	27(100)	
Totals	44(81.5)	10(18.5)	54(100)	

COMMENTS:

Around 85.2% ulcer patients from TCC group and 77.8% patients of PTB group found to have cured completely at the end of the study. The percentage of cast failure in TCC group was 14.8% and in PTB group 22.2%, at the end of six week.

Fisher exact test shows no statistically significant difference (p-value 0.728) in ulcer healing between two treatment groups when compared for final outcome.

Table-9: Univariate Logistic Regression: Covariates of ulcer healing among the study population (n=54)

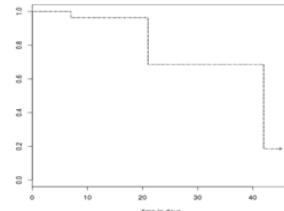
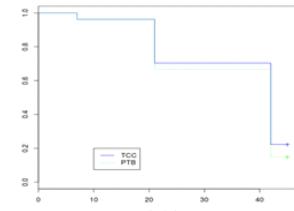
Independent Variables	Outcome Number (%)		Odds Ratio	95% Confidence Interval
	Healed	Non Healed		
Age Cont...	-		1.015	0.970 – 1.063

Sex	Male	25(46.3)	8(14.8)	3.04	0.578 – 15.99
	Female(Ref)	19(35.2)	2(3.7)		
Wagner grade	Grade 2	34(63)	2(3.7)	1.176	0.24 – 6.45
	Grade 1(Ref)	10(18.5)	8(14.8)		

COMMENTS:

Logistic regression shows, healing of ulcer among the study population did not differ significantly with the two treatment modalities. Two treatment modalities were found to be equally effective in terms of healing of ulcer at the end of 4th visit (six week).

Other covariates like age, gender, Wagner grade, of ulcer were also found to have no relationship with healing of ulcer among the study population.

**Fig:12: Kaplan Meier curve showing the cumulative probability of ulcer healing of the participants****Fig:13: Kaplan Meier curve showing the difference in cumulative healing rate of the ulcers according to the intervention****COMMENTS:**

A log-rank test was done to find out whether the difference in the healing rate was significant or not.

The difference in the healing rate between two intervention groups was statistically insignificant.

DISCUSSION:

Neuropathic plantar foot ulceration mostly due to the consequence of diabetes and Hansen's disease is one of the regularly treated condition in the department of Physical Medicine and Rehabilitation. In our parallel group randomized control study, conducted at the department of Physical Medicine and Rehabilitation at IPGME&R, over the period of eighteen months, we look for the efficacy of TCC and PTB casting with Bohler's walking iron (BWI) as a treatment modality in patients with neuropathic plantar foot ulcer affecting unilateral foot. After getting ethical committee clearance, we included total 54 patients and divided them in two groups (27 in each group). Fortunately we did not lose any of them; all the patients of both groups completed the study and attended all follow up visits. In our study we noticed mostly male in their middle age (mean age in TCC- 46 years, PTB with BWI- 51 years) were affected which is also corroborating with the study conducted by Mark Myerson et al⁵ showing a male predominance with mean age group of 4th and 5th decade. However the other study reported by Ezio Fagila et al³ showed the most of the patients are in their 6th decade with male dominance. Off-loading is an etiologic therapy of neuropathic plantar foot ulcers. It has been proven by literature that when correctly applied it not only interrupt the pathogenic chain which produces the ulceration but also to induce modifications in the histology of the ulcer, shifting it from a chronic inflammatory state to a much more evolutive condition. Most of the study done by Mark Myerson et al⁵, Ezio Fagila et al³, Brenner MA⁶ etc. reported that most of the ulcer their study group were diabetic patients. Interestingly we got nearly 55% in period of 6 weeks the healing rate in TCC group was 85% and in PTB with BWI group was 77%, though this difference in healing rate in between the groups was statistically insignificant. In the study by Ezio Fagila et al³ found 73.9% healing rate in TCC group. Sinacore DR⁷ noted healing in 82% of 33 ulcers after an average of forty four days in total contact cast. Helm et al reported a 73% rate of healing in twenty two patients with an average time to healing of thirty eight days. Whereas Bowker JH et al⁸, found healing in 100% of seven patients who wore a total contact cast for an average of six weeks. The combined results of these studies yields an average rate of successful healing of 75.5% after an average of 38.7 days in the cast but for the lack of literature we found difficulty to compare our results in case of PTB casting with walking iron as it has not been extensively studied like TCC. During the study some minor treatment complications occurred, none of which required cessation or change in treatment. The results of our study indicate that

pressure off-loading using the TCC and PTB casting with Bohler's walking iron are equally effective in the treatment of neuropathic plantar foot ulcer.

LIMITATION

- 1.. Sample size was small in each group.
2. Comparison of our result of improvement due to PTB casting with walking iron with standard literature was difficult due to paucity of previous evidences.

CONCLUSION

1. As per our study, mostly male of 3rd and 4th decade were affected with neuropathic plantar foot ulcer.
2. Both TCC and PTB casting with Bohler's walking iron are helpful to reduce ulcer depth, which is statistically significant (p value < 0.001).
3. Both form of treatment are helpful for statistically significant reduction of ulcer area at the initial visits up to 3 weeks.
4. Overall healing rate of ulcer was very good by both form of treatment. Although approximately 30% of the ulcer healed quite well in both the groups after the period of 3 weeks of treatment but majority of the ulcer (85.2% in TCC group & 77.8% in PTB with Bohler's walking iron group) healed at the end of the study by both form of treatment
5. As per our study both form of treatment were effective not only for reduction of ulcer dimension but also effective in respect to final outcome and healing.

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