

Post Total Contact Casting Healing Pattern in Leprotic Chronic Plantar Foot Ulcer

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Abstract

Introduction: role of TCC in diabetic foot ulcer is well established in literature. Hansen's disease is very common in the tropical country like India but rarely seen in developed world. That's why there is scarcity of literature about the efficacy of TCC in leprotic neuropathic ulcer.

Objective: (1) to observe overall improvement pattern of plantar foot ulcer after doing Total Contact Casting. (2) To look for the time duration to heal the ulcer.

Study design: Longitudinal analytical study.

Sample size: 22.

Study duration: 7 months.

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

Inclusion criteria: Grade 1 and grade 2 plantar ulceration (WAGNER classification), Ulcers treated previously with local dressing, antibiotics and orthosis but no improvement, Ambulatory patients.

Exclusion criteria: Grade 3 ulcer (WAGNER), Age less than 18 years, Patients unwilling to have cast, Grossly deformed foot.

Methodology: After taking institutional ethical committee clearance the patient fulfilling the above criteria the assessment of ulcer was done by Wagner's grading, site and size of the ulcer after getting the patient's consent. Then the ulcers were debrided off under aseptic condition and TCC (Total Contact Casting) was done.

Outcome measures: Duration to heal, improvement in the size of the ulcer, downgrading of WAGNER classification.

Assessment: At 0 week, 1st week, 3rd week and 6th week.

Result analysis: as per the statistical analysis by Statistical version 6 [Tulsa, Oklahoma: Stat Soft Inc., 2001] and Graph Pad Prism version 5 [San Diego, California: Graph Pad Software Inc., 2007] it was shown that the surface area and width of ulcer were improved with statistical significance due to TCC. Interestingly there was no difference noted in improvement of hind foot and fore foot ulcers.

Conclusion: TCC is helpful in improvement of size of ulcer in short period of time without any anatomical variation of site of ulcer.

Key words: Leprosy, neuropathic foot ulcer, TCC, plantar foot ulcer.

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Introduction:

Neuropathic plantar ulceration is one of the serious handicap to the patient with anaesthetic feet in active life. The only way to heal a plantar ulcer is to provide rest it. If the patient walks on the ulcer, it spreads and osteomyelitis ensues; the scarring and distortion make further inevitable ulceration until walking finally becomes impossible. Neuropathic trophic plantar ulceration can be seen in variety of conditions involving insensitivity of the foot including diabetes, leprosy, hereditary neuropathy, tabes dorsalis, herniated nucleus pulposus, treated for months and years by various forms of local applications and dressings requiring high cost, time and money. To receive this treatment patients have to walk from their homes on bandaged feet, continuing

the mechanical stresses which are largely responsible for worsening ulceration.

Therefore it is necessary to treat the patients by methods which allow ambulation. Before the era of total contact casting (TCC) results were poor with other conservative means. 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. The recurrence/worsening of ulceration can be avoided not by TCC but also by the wearing of shoes which provide conditions similar to those in a plaster. These strengthen the idea that mechanical loading of the neuropathic foot is clearly part of the aetiology of foot ulceration and is subsequently a major factor in delaying wound healing. Therefore, off-loading the affected plantar areas is an important component of prevention and treatment. A number of off-loading mechanisms are available, but not all of them are evidently practical.

Total contact casting has been time tested over many years. The earliest published report of casting for trophic ulcerations dates back to the 1930s¹. Dr Joseph Kahn in India described an ambulatory technique for the treatment of plantar ulcers occurring in the patients with Hansen's disease as an alternative to prolonged, expensive periods of bed rest in the hospital. Dr Paul Brand² and his associates refined and popularised the current technique in the early 1960s at the Gillis W. Long Hansen's Disease Center in Carville, Louisiana². Total contact casting as a treatment of neuropathic plantar surface ulcerations has since been applied to a variety of conditions involving insensitivity of the feet.

The main purpose of treating neuropathic plantar ulcerations by total contact casting is to reduce excessive mechanical forces (including vertical pressure and horizontal shear) on the plantar surface of the feet as advocated by Brand³ and Ctercteco *et al*⁴, while maintaining ambulation. According to Coleman *et al*⁵, the TCC was designed to equalise loading of the plantar surface by equal "total contact" of the plantar skin with the cast material, thereby minimising pressures at an ulcer site. Since the first published report total contact casting has been applied in diabetic plantar foot ulcer in several studies and the results are very promising. It is now well accepted that TCC is the gold standard among methods used to heal diabetic foot ulcers^{6,7}.

Hansen's disease is very common in tropical countries like India. Leprosy is one of the few chronic illnesses that meet the demanding criteria for possible elimination,

i.e, it can be diagnosed by practical and simple diagnostic tools or by clinical signs alone, availability of an effective modality to interrupt its transmission in the form of MDT and a single significant reservoir of infection, humans. However, despite all the encouraging parameters which are sustainable, leprosy eradication seems a distant possibility considering the current scenario^{8,9}. New cases continue to occur in almost all endemic countries and high-burden pockets exist against a low-burden background. The number of new cases detected during 2011, as reported by 105 countries, was 219,075 and India topped the list with its contribution of 58.1 per cent to the pool¹⁰. There is scarcity of literature about the efficacy of TCC in leprotic neuropathic foot ulcer. The aim and objectives of our study is to observe overall improvement pattern of plantar foot ulcer after doing TCC and to look for the duration of ulcer healing.

Materials and Methods:

Before initiating the study clearance of The Institutional Ethics Committee was taken. Individual informed written consent was taken from each patient. The prospective analytical study was conducted on twenty-two (22) patients in the department of Physical Medicine and Rehabilitation, IPGME&R, SSKM Hospital, Kolkata, for a period of seven months (Feb' 12-Aug' 13).

The study included grade 1 and grade 2 plantar ulceration (WAGNER classification) which did not improve with local dressing, antibiotics and orthoses among ambulatory patients (age more than 18 years). The exclusion criteria of the study was patients unwilling to give consent, age less than 18 years, grade 3 ulcer (WAGNER), patients unsafe in mobility while in cast. Patients with leprotic neuropathic plantar foot ulcer, residents of Kolkata and surrounding districts, attending the Physical Medicine and Rehabilitation OPD at IPGME&R, SSKM Hospital, Kolkata who fulfilled the inclusion and exclusion criteria were included in the study.

Selected patients were included in this study for further assessment and intervention and examined at baseline first on the basis of the parameters like size of the ulcer, Wagner classification and other characteristics of ulcer. A detailed clinical history, examination and a baseline investigation were taken for all patients. To observe the improvement pattern the patients were identified individually with their name, address, contact number. All the patients 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. Before the cast is applied, the ulcers are 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.

For application of the 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. After proper positioning a small amount of cotton padding was placed loosely between adjacent toes to absorb any moisture and prevent maceration. Then a roller cotton 10-15cm 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 were avoided to prevent an uneven surface at the interface with the skin. Then plaster was applied loosely and was molded exactly to match the contour of the foot, ankle and leg without any formation of wrinkles. The cast was applied 2cm distal to the fibular head to a point distally up to covering of the toes. Usually two rolls of plaster (15cm) are adequate to create a three-layer inner shell. A rocker sole was created by layering plaster cast (15cm) 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 10cm plaster cast.

After casting, the patients were examined and assessed in consecutive four visits: visit 1 (0 week), visit 2 (1st week), visit 3 (3rd week) and visit 4 (6th week) on the



Fig 1- CASE 1 - Before TCC



Fig 2- CASE 1 - After 3 weeks of TCC



Fig 3- CASE 2 - Before TCC



Fig 4- CASE 2 - After 6 weeks of TCC

Table 1: Descriptive Statistics of Numerical Variables - Whole Cohort [n = 22]

Variables	Valid number	Mean	Median	Minimum	Maximum	Std. Dev.	Standard error
Age	22	44.41	40.50	18.000	81.0	17.031	3.631
L_V1	22	22.95	23.50	10.000	39.0	7.895	1.683
W_V1	22	17.27	15.00	8.000	26.0	6.088	1.298
SA_V1	22	434.09	363.00	80.000	1014.0	271.911	57.972
L_V2	22	20.36	19.50	8.000	36.0	7.804	1.664
W_V2	22	14.45	12.50	6.000	24.0	5.804	1.237
SA_V2	22	331.09	255.00	48.000	828.0	232.096	49.483
L_V3	22	11.86	11.00	0.000	34.0	9.468	2.019
W_V3	22	8.82	9.00	0.000	20.0	7.062	1.506
SA_V3	22	161.18	99.50	0.000	680.0	181.154	38.622
L_V4	22	4.14	0.00	0.000	26.0	8.073	1.721
W_V4	22	3.64	0.00	0.000	18.0	6.898	1.471
SA_V4	22	65.86	0.00	0.000	416.0	128.454	27.386

L=Length, W=Width, SA=Surface area

basis of the all the data documented in our stipulated proforma and parameters like ulcer size, Wagner grade, time taken to heal ulcer and to look for any worsening of the ulcer.

The main outcome measure of the study was improvement of the size of the ulcer, downgrading of Wagner classification and time taken to heal the ulcer. TCC was removed and done again in each follow-up visit for the maximum period of 6 weeks and cast failure was considered in those patients who failed to achieve Wagner grade '0' after the period of six weeks. Then the results were analysed according to the standard statistical methods to look for the aims and objectives of the study.

Results:

The analysis was carried out by using software Statistica version 6 [Tulsa, Oklahoma: StatSoft Inc., 2001] and Graph Pad Prism version 5 [San Diego, California: GraphPad Software Inc., 2007]. In our study we attempted Kaplan-Meier survival analysis to study the trend in ulcer healing in terms of number of days to complete the healing. Out of 22 patients, 68.18% (n=15) were males and 31.82% (n=7) were females. In descriptive statistics of numerical variables all numerical variables were normally distributed. The mean age group was 44.41 with standard deviation of 17.031 (Table 1).

Among the study population majority of the ulcer were in forefoot (55%, n=12), followed by hindfoot (41%,

Table 2: Overall Distribution of the Ulcers

Site	No of cases	Per cent
Right great toe	1	4.55
Left 1st metatarsal head	4	18.18
Right midfoot	1	4.55
Right heel	5	22.73
Left heel	4	18.18
Right 1st metatarsal head	2	9.09
Right 2nd metatarsal	2	9.09
Right 3rd metatarsal head	1	4.55
Left 5th metatarsal head	2	9.09

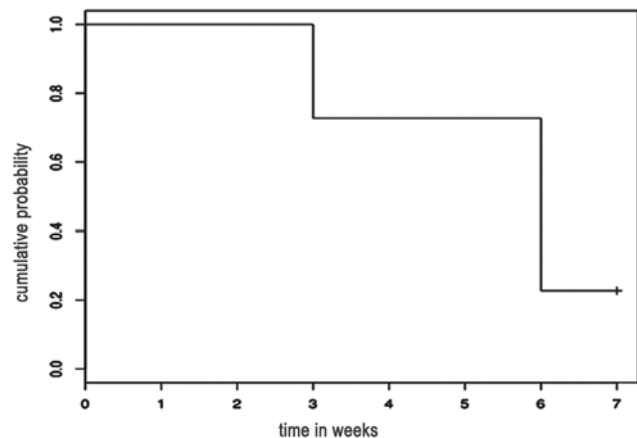
**Fig 5-** Kaplan Meier Curve Showing Cumulative Probability of Ulcer Healing

Table 3: Significance of Change in Ulcer Dimensions Over Time

Table 3a: Surface Area of Trophic Ulcer

Repeated measures ANOVA		No of data sets 4	F-value 50.170	p <0.001
Tukey’s multiple comparison test	Mean difference	q	p-value	95% CI of difference
SA_V1 vs SA_V2	103.00	4.4062	<0.05	15.704 to 190.30
SA_V1 vs SA_V3	272.91	11.675	<0.001	185.61 to 360.21
SA_V1 vs SA_V4	368.23	15.752	<0.001	280.93 to 455.52
SA_V2 vs SA_V3	169.91	7.2685	<0.001	82.613 to 257.21
SA_V2 vs SA_V4	265.23	11.346	<0.001	177.93 to 352.52
SA_V3 vs SA_V4	95.318	4.0776	<0.05	8.0222 to 182.61

Table 3b: Longitudinal and Transverse Length of Trophic Ulcer

Repeated measures ANOVA		No of data sets 4	F-value 92.432	p <0.001
Tukey’s multiple comparison test	Mean difference	q	p-value	95% CI of difference
L_V1 vs L_V2	2.5909	2.9102	ns	-0.73374 to 5.9156
L_V1 vs L_V3	11.091	12.458	<0.001	7.7663 to 14.416
L_V1 vs L_V4	18.818	21.137	<0.001	15.494 to 22.143
L_V2 vs L_V3	8.5000	9.5476	<0.001	5.1754 to 11.825
L_V2 vs L_V4	16.227	18.227	<0.001	12.903 to 19.552
L_V3 vs L_V4	7.7273	8.6796	<0.001	4.4026 to 11.052

Table 3c: Width of Trophic Ulcer

Repeated measures ANOVA		No of data sets 4	F-value 80.680	p <0.001
Tukey’s multiple comparison test	Mean difference	q	p-value	95% CI of difference
W_V1 vs W_V2	2.8182	4.1755	<0.05	0.29773 to 5.3386
W_V1 vs W_V3	8.4545	12.527	<0.001	5.9341 to 10.975
W_V1 vs W_V4	13.636	20.204	<0.001	11.116 to 16.157
W_V2 vs W_V3	5.6364	8.3510	<0.001	3.1159 to 8.1568
W_V2 vs W_V4	10.818	16.029	<0.001	8.2977 to 13.339
W_V3 vs W_V4	5.1818	7.6776	<0.001	2.6614 to 7.7023

n=9) then midfoot ulcer (4.55%). The overall distribution of the ulcers in the study is shown in Table 2. In our study most of the ulcer (63.64%) was in Wagner grade 2 and there was 36.36% Wagner grade 1 ulcer. Seventeen (77.27%) of the twenty-two ulcers were healed and five (22.73%) ulcers were stamped as non-healed ulcer at the end of six weeks, as those five ulcers failed to achieve Wagner grade ‘0’ at the end of six weeks. Among five cast failure ulcers two (40%) were from hindfoot and three (60%) from forefoot.

In our study the data revealed statistically significant

difference between subsequent visits starting from visit 1 to visit 4 with p-value <0.05, regarding the change in ulcer dimensions (length, width, surface area) over time by using Tukey’s Multiple Comparison Test except the change in length in between visit 1 and visit 2 where the p-value was insignificant. The change in ulcer dimensions over time shown in Table 3.

During the course of treatment only 27.27% (n=6) ulcers healed at the end of three weeks (Figs 1&2) with 95% confidence interval 8.66%-45.88% whereas 77.27% (n=17) ulcers healed at the end of six weeks (Figs 3&4)

Table 4: Comparison of Numerical Variables between Forefoot and Hindfoot Ulcers- Unpaired t Test

Variables	Mean fore	Mean hind	p-value	Valid No Forefoot	Valid No Hindfoot	Standard deviation Forefoot	Standard deviation Hindfoot
Age	44.25	45.67	0.858	12	9	18.071	17.306
L_V1	20.75	25.11	0.221	12	9	6.877	8.937
W_V1	16.00	18.44	0.380	12	9	5.608	6.876
SA_V1	357.17	511.56	0.209	12	9	215.628	328.851
L_V2	18.25	22.33	0.245	12	9	6.982	8.631
W_V2	13.42	15.44	0.449	12	9	5.961	5.940
SA_V2	276.58	384.56	0.308	12	9	206.306	267.344
L_V3	9.42	14.67	0.226	12	9	9.180	9.975
W_V3	7.75	10.11	0.473	12	9	7.899	6.431
SA_V3	134.17	197.33	0.454	12	9	158.649	221.293
L_V4	4.08	4.67	0.877	12	9	7.465	9.592
W_V4	3.92	3.67	0.938	12	9	7.141	7.280
SA_V4	63.42	76.44	0.828	12	9	115.461	155.903

with 95% confidence interval 59.76%-94.78%. Kaplan Meier curve (Fig 5) depicted that 22 ulcers in this study also reinforce the improvement pattern over time period(after 3rd week 27.27% and after 6 week 77.27% patients improved).

Then we calculated and compared the different variables between forefoot and hindfoot ulcers using Student's unpaired 't' test, unfortunately it fails to show any statistically significant difference and all the p-values were >0.05 (Table 4).

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 prospective analytical study, conducted at the department of Physical Medicine and Rehabilitation at IPGME&R, over the period of seven months, we look for the efficacy of TCC as a treatment modality in patients with leprotic neuropathic plantar foot ulcer affecting unilateral foot. After getting ethical committee clearance, we included total 22 patients. Fortunately we did not lost any of them; all the patients of study population completed the study and attended follow-up visits. It's worth to mention that in our study we noticed mostly male in their middle age (mean age-44.41 years) were affected which is corroborating with the study conducted by Myerson *et al*¹¹ showing a male predominance with mean age group of 4th and 5th decade. However the other study

reported by Fagila *et al*¹² showed the most of the patients are in their 6th decade with male dominance.

Off-loading is an aetiologic 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 Myerson *et al*¹¹, Fagila *et al*¹², Brenner¹³ etc reported that most of the ulcer in their study group were diabetic. Since the earliest published report regarding TCC in leprotic plantar foot ulcer by Dr. Joseph Kahn in India, there is some scarcity of literature about the role of TCC in Hansen's patients. In our study majority of the ulcer were grade-2. Only 36.36% were Wagner grade-1 ulcer. We excluded the patients of Wagner grade 3, 4, 5 at the very beginning. In our study most of the ulcer were in forefoot (55%) followed by hindfoot (41%) and midfoot (4%) ulcer which is quite favourable with the findings of the study done by Myerson *et al*¹¹ conducted on 71 neuropathic foot ulcers.

After statistical calculation we got statistically significant (p-value <0.05) difference by using repeated measure and Tukey's multiple comparison test in the reduction of ulcer length, width and surface area in subsequent visits except the reduction of length in between visit 1 and visit 2. This finding of reduction of ulcer dimensions over time course of our study did not differ from the recent study done by Fagila *et al*¹² published in 2010.

Achieving Wagner grade '0' was our final outcome which was also described by Boulton *et al*¹³. During our study period we got only 27.27% of the foot ulcer of total study population healed (Wagner grade '0') at the end of 3rd week. But majority of the ulcer (77.27%) of total study population healed after receiving treatment for 6 weeks which is at par the literature^{14,15}. In the study by Ezio Fagila *et al*¹² found 73.9% healing rate in TCC group of diabetic foot ulcer. Sinacore¹⁶ noted healing in 82% of 33 diabetic neuropathic 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. Similar finding also noted by Bowker *et al*¹⁷, who 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 but we found scarcity of literature after extensive search regarding leprotic plantar foot ulcer management. Till today it has not been extensively studied like diabetic foot ulcer. That's why we found difficulty to compare our data with other literature.

- In our study among the cast failure cases 60% were from forefoot but while comparing the different variables among the forefoot and hind foot ulcers by using Student's unpaired t test which did not revealed statistically significant difference and all the p-values were >0.05. However the other studies by Martin and Conti¹⁸, Sinacore¹⁹, etc showed the response was better in forefoot ulcer. During the study some minor treatment complications occurred, none of which required cessation or change in treatment. Last but not the least this study has limitation like small sample size, no control group, difficulty in assessing variation of improvement according to anatomical site due to small sample size.

Conclusion:

- TCC is definitely helpful in majority of the patients(77%) with leprotic plantar foot ulcer.
- Nearly ¼ patients responded well in 3 weeks time but most of the patients (74%) improved in 6 weeks.
- TCC is shown to be effective for statistical improvement of surface area, length and width of the ulcer.

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