Case report:

Outcome of treatment of Eichenholtz stage III charcot neuroarthropathy by using bilayer insole: a single center study

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Abstract

Introduction: Insoles are recommended for the treatment of patients with neuropathic foot to distribute the foot plantar pressure while preventing recurrent ulceration. Different types of insole are available but the cost is the major limiting factor. Thus, it is justifiable to conduct this study to evaluate the efficacy of cost effective locally-designed bilayer Lunairmed insoles as an adjunctive treatment for patients with Eichenholtz Stage III Charcot neuroarthropathy in our centre. ***Methods:*** This was a prospective observational study conducted in tertiary centre, Malaysia from September 2016 to September 2017. A total of ten patients with Stage III Charcot neuroarthropathic foot without ankle instability were included. All patients were evaluated for foot plantar pressure by using Tekscan, short form (SF-36) and American Orthopaedic Foot and Ankle Society(AOFAS) score before and after using insoles. ***Results:*** Fifteen out of twenty feet showed reduction in peak plantar pressure (PP) and force-time-integral (FTI) at forefoot and heel after using bilayer Lunairmed insoles. There was a mean reduction of 24.8% of total foot PP. ***Conclusion:*** Locally designed bilayer Lunairmed insoles could be used to reduce PP in Eichenholtz Stage III Charcot neuroarthropathic foot without ankle instability.

Keywords: Eichenholtz Stage III; Charcot foot; bilayer Lunairmed insoles; SF-36; AOFAS score

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Introduction

Charcot neuroarthropathy of the foot is characterized by sensory and peripheral autonomic neuropathy which leads to generalized swelling, instability and deformity of the foot. The goals of treatment for Charcot neuroarthropathy are to achieve a plantigrade, stable, shoeable foot and to prevent recurrent ulceration.[1,2,3] The recommended treatments for plantigrade and stable Stage III Charcot foot consist of usage of different types of insoles to prevent recurrent ulceration. Few authors had published the outcome of non-operative management of Charcot neuroarthropathy using custom made insoles in their centres with success rate of up to 59% in preventing recurrent ulcers.[4,5] Characteristics of various materials had been studied butclinical significance of usage of such material in clinical practise is yet to be determined. Furthermore, no data has been published regarding the treatment outcome of patients with Stage III Charcot neuroarthropathy using locally

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designed bilayer Lunairmed insoles. We hypothesize that this insoles could significantly reduce plantar foot pressure, reduce pain, enable return of physical function and better quality of life. The purpose of this study is to find out the effectiveness of the usage of bilayer Lunairmed insoles in management of patients with Stage III Charcot neuroarthropathy in our centre.

Materials and methods

This is a non-randomized prospective observational cohort study. The study was performed after obtaining the approval from Ethical Committee of our institution and all patients recruited in this study has signed an informed consent form. Patients above 18 years old who were diagnosed with Stage III Charcot neuroarthropathy (consolidation phase) treated in our centre between September 2016 to July 2017 were recruited in this study using the guidelines outlined in Eichenholtz classification.[7] Patients with any forefoot or major amputation, patients who were non-ambulator, too ill to carry out foot pressure analysis, with foot ulcer, and pregnant patients were excluded from the study.

Lunairmed bilayer insole is an insole consists of 2 layers of Lunairmed material [Fig 1]. It has a closed cell and perforated structure and has low density but high resilient. Kwan et al tested this material on healthy subjects and showed no reduction in peak pressure but it could reduce force time integral in forefoot and whole foot.[6] However, no studies were done using Lunairmed insoles in diabetic patients or patients with foot deformity. Currently, custom-made Lunairmed bilayer insoles is the insole of choice for patients with Eichenholtz stage III Charcot neuroarthropathy in our centre because of its cost-effectiveness and patients' compliance. The sum of thickness of the insole given were 12mm.

Fig 1. Bilayer Lunairmed Insole

Foot pressure analysis using Tekscan, AOFAS score and SF-36 were used as the outcome measures in this study. Plantar foot pressure will be measured using TekscanMat Scan Pressure Assessment Systems, Sensor Matscan Version 6.3 (TekScanInc, South Boston, USA). A calibration is performed for all participants before recording. Plantar pressure will be recorded in static with calibration done for each patient prior to the analysis. The foot will be divided into 12 anatomical regions: lateral and medial heel, midfoot, metatarsal head of 1^{s} till 5th toes and all toes. Peak pressure (PP) and force-time-integral (FTI) for each region will be mapped out by the machine. The PP is defined as the maximum pressure recorded by the sensors in the region during stance phase. The FTI is defined as the total sum of pressure multiplied with contact time and total sensor area of the measured region. Thus, FTI can also be explained as the total force applied to the foot in a given region. In this study, we would like to use metatarsal head of 1st toe as region of interest as it was reported to be most common region for plantar ulceration. The insole studied will be deemed successful if there is a significant reduction of PP and FTI at the metatarsal head of the big toe and moderately successful when there is no reduction in PP but presence of decrease in FTI.[8] The insole is considered a failure if both PP and FTI is found to have no significant reduction. The change in plantar foot pressure particularly at the forefoot and hindfoot and the pressure redistribution pattern after the intervention were analysed.

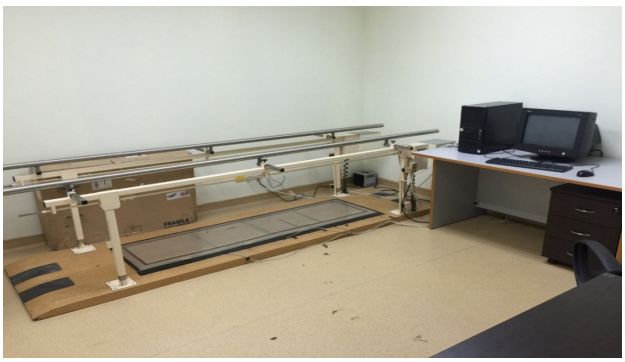

Fig 2. Tekscan used for foot plantar pressure measurement

Patients were assessed at baseline and at 3 months follow up. All treatments given to patients involved in this study strictly followed the current recommended treatment protocol practised in this institution. Patients and family members were informed that their records and images will be reviewed for research purposes and they were granted the opportunity to forbid such use of their data.

Results

A total of 10 patients with the mean age of 60 and

mean body weight of 88kg were included in this study. All bilayer Lunairmed insoles were custom made to fit patients' feet. Patients were encouraged to use the insoles together with post op shoes. None of them developed foot ulceration during this follow up period. No amputations done. Mean follow up time for these group of patients were 3 months.

Table 1. Median barefoot peak pressure (PP) and median force time integral (FTI) before and after using Lunairmed bilayer insole.

Region	Peak Pressure, PP [KPa]		Force Time Integral, FTI [%bw*s]	
	Before	After	Before	After
TF (total foot)	176.1	132.4	319.9	177.8
MH (medial heel)	115.5	88.2	43.9	25.6
LH (lateral heel)	138.5	100.4	33.9	25.9
MF (midfoot)	93.8	76.7	60.2	22.2
M1 (1st metatarsal head)	64.7	59.4	24.4	11.4
M2 (2nd metatarsal head)	83.7	75.9	22.9	15.4
M3 (3rd metatarsal head)	79.0	77.4	28.0	17.6
M4 (4th metatarsal head)	59.6	68.9	14.7	12.5
M5 (5th metatarsal head)	38.9	45.9	3.0	2.5
T1 (hallux)	19.7	17.9	0.7	0.1
T2 (toe 2)	31.6	16.0	0.8	0.1
T3 (toe 3)	0	0	0	0
T45 (4th and 5th toes)	0	0	0	0

Plantar foot pressure measurement was done in all 20 feet. Median values of PP and FTI of barefoot and with Lunairmed insoles are shown in Table 1. Fifteen out of 20 feet had reduction of total foot PP. Thirteen feet had reduction of PP at the medial heel, lateral heel, midfoot and base of 1st metatarsal head. The insole was successful in 7 out of 10 patients in decreasing PP and FTI of 1st metatarsal head. The redistribution of the PP and FTI was found to be similar with the load transfer algorithm described by Bus et al where the maximum load transfer was noticed between midfoot and hindfoot.[8] There was 18.2% reduction of PP at the midfoot and 8% reduction of PP at 1st metatarsal head. Reduction of total PP of 24.8% noted.

Majority patients were satisfied with the insoles evident by the increase of scores in all component before and after using bilayer Lunairmed insoles. Table 2 shows median values of patient reported outcome using SF-36 and AOFAS-hindfoot score before and after intervention. Significant improvement in physical functioning component, social functioning component and pain. Slight improvement was noted in components such as energy level, emotional well-being and general health.

Table 2. Median values of patient reported outcome using SF-36 and AOFAS-hindfoot score before and after intervention.

Components	Conservative Arm		Arthrodesis	
	Before	After	Before	After
Physical functioning	50.0	62.5	42.5	55.0
Role limitations due to physical health	12.5	62.5	0	50.0
Role limitations due to emotional problems	33.3	66.7	0	50.0
Energy/fatigue	50.0	60.0	42.5	55.0
Emotional well-being	58.0	76.0	54.0	62.0
Social functioning	50.0	68.8	37.5	75.0
Pain	67.5	82.5	55.0	56.3
General health	42.5	52.5	30.0	52.5
Change since previous year	50.0	75.0	37.5	62.5
AOFAS hindfoot score	74	87.5	33.5	59

Discussion

Charcot neuroarthropathy was first described by Jean-Martin Charcot in 1868. It is a progressive inflammatory process with sensory neuropathy which leads to osteolysis and destruction of joint architecture.[10]The incidence of Charcot neuroarthropathy involving the foot and ankle joint has been reported to be 7.5%. Nine percent of the reported cases were found to involve bilateral feet.[11] The incidence of Charcot neuroarthropathy in patients with diabetes mellitus was reported to be as high as 0.08-0.13%.[11]

Frykberg et al reported that role of neuropathy and foot pressures are independently related to ulceration in diabetic patients.[12] They found that patients whose area of foot with pressure above 6kg/cm^2 (85Psi) is more prone to develop ulcer. Charles et al in 2005 studied the effectiveness of nonoperative treatment in patients with Charcot arthropathy and reported that rate of amputation was around 2.7% while 49% of

115 patients studied has risk of recurrent ulceration.[13] Bus et al analysed the foot plantar pressure result of patients wearing insoles and reported that insoles were more effective in off-loading the first metatarsal head and the presence of medial arch support will effectively off-load the heel region. The load transfer algorithm was found by analysingforce time integral indicating that the load decrease in one specific region resulted in the increase of load in another region of the foot. The largest transfer of load was found to be between the heel and midfoot regions[8] and similar findings were observed in this study.

Leber C et al in 1986 compared the plantar pressure reduction capabilities of 7 types of different insoles material using Harris and Beath foot printing mat and found that most reduction in PP was noted in material like Plastazote, Spenco and Professional Protective Technology (PPT) insoles. A reduction of PP up to 53% was noted when using PPT and Plastazote. The difference in PP reduction could possibly be contributed by the difference in technology used in measuring plantar foot pressure and the patients group included in the study.[14]

The shift of pressure on the regions of the foot was also as predicted by the load shift algorithm reported by other authors.[8] The decrease in forefoot and heel pressure was compensated by the increase pressure at the midfoot region. However, the short follow up time in this study unable us to observe ulcer formation, its recurrence and durability of the material in this group of patients. A longer follow up time would definitely give more insight in the effectiveness of this material in preventing ulcer formation. The durability of this material could also be studied in a longer time frame.

Conclusion

Locally designed bilayer Lunairmed insoles could be used to reduce PP in Eichenholtz Stage III Charcot neuroarthropathic foot without ankle instability. However, a large scale study with long term follow up is needed to fully understand the long term efficacy in terms of prevention of recurrent plantar ulcers and durability of the insoles.

Ethical approval

Ethical approval was obtained from the Committee of Ethics and Reseaches of Hospital Universiti Kebangsaan Malaysia.

Conflict of interest

No conflict of interest has been disclosed by the authors.

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