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Effect of Computer Assisted Designing / Manufacturing (CAD-CAM) Insoles in Leprosy Affected Patients

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ABSTRACT

Background: Elevated plantar pressures during walking are a causative factor in the development of plantar ulcers. Plantar pressure can be redistributed but not eradicated and reducing stress at one location may simply displace the risk of ulceration to a different area of the foot. To achieve such redistribution, computer-assisted designing/manufacturing (CAD/CAM) technology was used to fabricate the insole with improved customization for patients with anesthetic feet due to leprosy.
Objective: The objective of this study was to assess the effect of the CAD-CAM insoles in leprosy patients, using a close-ended questionnaire.
Methodology: A qualitative cross-sectional study was conducted to identify the impact of CAD-CAM insole on footwear. Random sampling was done to recruit leprosy-affected patients coming to the institute. With a 3 month of period, the data were collected through the feedback from the patients.
Result: 40 patients' feedback was taken there was both positive and negative feedback from the patients. The ulcer healing has significantly increased among 60 % of the patients. 90 % of patients were comfortable with the weight of the CAD-CAM footwear when compared to previous footwear (MCR) which they were using.
Conclusion: Significant improvement was found among the patients.

Keywords: Leprosy, CAD-CAM insole, plantar ulcers, Peak pressure distribution.

INTRODUCTION

Leprosy or Hansen's disease is an ancient bacterial disease that, although curable, continues to be a significant health problem in many parts of the world. Leprosy results from infection with the Mycobacterium leprae bacillus, which produces a chronic infection in humans that affects mainly peripheral nerves and skin but may also, affect sites such as the eyes, mucous membranes, bones. [1] Leprosy is eradicated, but some populations have leprosy in India.

Neuropathy is a nerve problem that causes pain, numbness, tingling, swelling, or muscle weakness in different parts of the body. It usually begins in the hands or feet and gets worse over time.[3] The posterior tibial nerve is frequently affected in leprosy leading to loss of sensation and sweating, and intrinsic muscle paralysis in the foot, predisposing to ulcer formation. [4]

Ulcers and neuropathic bone disorders develop by overload, repetitive mechanical stress, and shear; diabetic gangrene from metabolic and vascular factors; direct injury

or cutting; continuous pressure resulting in ischemia; heat or cold.[2] High foot pressures have been shown to be predictive of future foot ulceration. Although reduced plantar tissue thickness has not yet been shown to be predictive of future foot ulceration, it has been strongly associated with a history of ulceration. This is clinically important, indicating that patients with thin plantar tissue pads are at increased risk of foot ulcer development.[5] The repetitive application of high plantar pressures during daily activities can therefore lead to pressure ulcerations on the weight-bearing areas of the plantar surface, usually on the heel and metatarsal heads of the first, second, and fifth toes.[6]

Tropic ulcer treatment should aim at wound management, correction of deformity, restoration of sensation, reconstitution of normal skin, elimination of abnormal pressures, and eradication of deep-seated infections.

Off-loading pressure is the key to the successful management of a tropic ulcer. The best off-loading device is a total contact cast (TCC)/plaster boot. TCCs should be applied only after debridement and removal of all dead tissue. Its greatest advantage is that it is a non removable device and thus eliminates the problem of unreliability. The drawbacks of TCCs are that they are technically demanding and, if wrongly applied, can lead to more ulcers. [7]

Recurrent ulcers can lead to shortening and amputation of the affected limb and delayed or non-healing ulcers can transform into squamous cell carcinoma. Therefore, prevention of ulcers is critical to preventing disability.

Although protective footwear can reduce the prevalence of ulcers, the role of orthoses in protective footwear in preventing ulcers has not been satisfactorily studied. The consensus statement on prevention of disability in leprosy emphasizes the accessibility of footwear with soft insoles and orthoses to all those with anesthetic feet.

The footwear or orthosis has an insole in Micro Cellular Rubber (MCR) which has major disadvantages wound is not healing, equal distribution of pressure is not there and due to social stigma, some patients are not using the MCR Footwear, normal insole fabrication takes more time and human error may happen.

Custom-fabricated orthopedic insoles are engineered to provide adequate support and control of abnormal foot motion, reduce shock and skin friction to stabilize foot deformities, moderate plantar pressures to prevent the formation of foot ulcerations, and improve stability in walking so as to reduce foot pain. [7] They act primarily by redistributing and relieving high plantar pressure levels. According to K. Govindasamy et.al. Customized CAD/CAM insole technology is more effective in preventing recurrent ulcers of the foot due to leprosy as compared to footwear using MCR, with increased compliance and patient perceived comfort, usefulness, participation, and activity level. [9] The CAD-CAM unit was installed in the institute which was sponcerd by American leprosy mission (ALM), to finds the usability, comfort of insoles and the impact on leprosy affected patients the study was conducted.

MATERIALS & METHODS

A qualitative cross-sectional study was conducted in department of prosthetics and orthotics, SIHRLC, Karigiri to identify the effect of CAD-CAM insole in leprosy affected patients. A total 40 subjects with leprosy having insensitive foot were selected according to random sampling, the inclusion criteria were both male and female, aged 35-75, patients coming to institute. Subjects were introduced about the procedure and purpose of the study and they participated in the study at signing the consent form. Then the demographic data of the subject were taken. The demographic data like age, sex, height, year of deformity. Close-ended questionnaire was used to collect feedback regarding the effect of cad

cam insoles from the patients in day-to-day activities.

Each foot thoroughly assessed like Sensation of the foot, presences of Ulcer, Scar, Callus and corns, Range of motion of joints, Calcaneus valgus, varus angle, Gait pattern and other foot related issues.

The scanning of the foot was done using Foot Scanner by the U-SOLE scan software. Patients were asked to stand on the scanner in an upright position, one foot at a time. The scanner captured the images of the plantar aspect of the foot. The customized insole was designed based on the scanned image of the foot using CAD (Computer Aided Designing) software that is ISOLE CAD. The customized insole was produced in the CAM machine, which carved the insole from an Ethylene Vinyl Acetate (EVA) block, according to the output of the design. The carved insole was covered on the upper surface with a soft lining to reduce the friction between the insole and the foot by increasing the cushioning effect. [9] The insole was then fixed into the footwear and provided to the patient after minimal adjustments to improve the fit. Test re-test was conducted in 3 months. The cad cam insole with foot wear given to patient for 3 months; feedback of patients was collected with close ended questionnaires the questions include:

1. Comfortable with the model of the footwear
2. Presence of wound, corn and callus
3. Condition of wound like: healed, not healed
4. Liking the color of foot wear
5. Pain during standing/ walking/ walking on uneven surfaces: no pain/mild/moderate/ severe.
6. Instability during standing/ walking/ walking on uneven surfaces
7. Problem during donning and doffing of foot wear
8. Presence of Perspiration while using the insole.
9. Cad cam insole weight less than MCR foot wear.

Fig: 1 scanning of foot

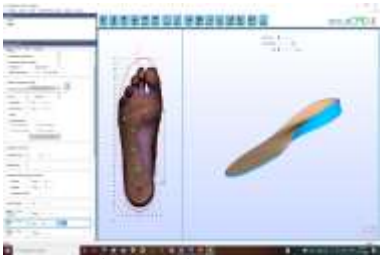


Fig: 2 Modification of insole by CAD software

Fig:3 Milling procedure

Fig:4 CAD-CAM insole

Fig: 5 Insole with foot wear

STATISTICAL ANALYSIS

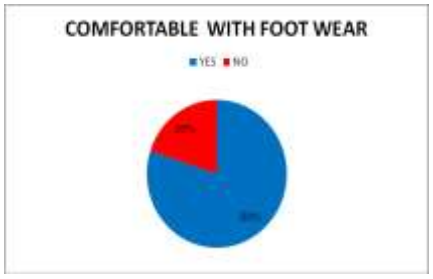
Chi square test was used to analyze all the questionnaires. Gender wise frequency distribution was between male and female. P value: less than 0.05 statistically significance was considered.

RESULTS

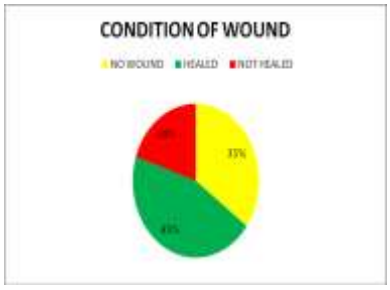
Out of 40 patients there were 16 female and 24 males. As it is a closed ended questionnaire, the answer of all questions was like yes/no, present/absence etc. Chi square test was used to find out the difference between in male and female and p values were given in the following table with all the variables. There is no significant effect in between male and female in all the variables except wound healing. But overall, the patients were satisfied with the CAD-CAM insoles.

Table :1 Data of all the questionnaires

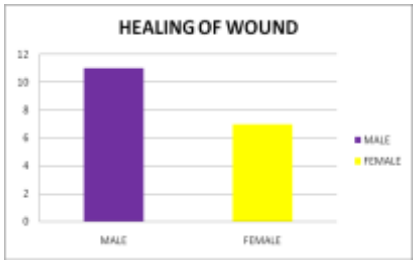
Variables		Female		Male		Total			
		No. (16)	%	No. (24)	%	No. (40)	%	Chi-square value	p-value
Comfortable with footwear model	Yes	12	75	20	83.33	32	80	0.4167	0.519
	No	4	25	4	16.67	8	20		
Wound	Present	13	81.25	13	54.17	26	65	3.0952	0.079
	Absent	3	18.75	11	45.83	14	35		
Wound condition	No wound	3	18.75	11	45.83	14	35	6.1045	0.047
	healed	7	43.75	11	45.83	18	45		
	Not healed	6	37.50	2	8.33	8	20		
Color of the footwear	like	12	75	17	70.83	29	72.50	0.0836	0.772
	unlike	4	25	7	29.17	11	27.50		
Pain during standing/ walking/ walking on uneven surfaces	No pain	6	37.50	15	62.50	21	52.50	4.7817	0.188
	mild	7	43.75	7	29.17	14	35		
	moderate	1	6.25	2	8.33	3	7.5		
	severe	2	12.50	0	0	2	5		
Instability during standing/ walking/ walking on uneven surfaces	yes	5	31.25	10	41.67	15	37.50	0.4444	0.505
	no	11	68.75	14	58.33	25	62.50		
Corn/ callus	yes	5	31.25	9	37.50	14	35	0.1648	0.685
	no	11	68.75	15	62.50	26	65		
Problem during donning &doffing of foot wear	yes	5	31.25	4	16.67	9	22.50	1.1708	0.279
	no	11	68.75	20	83.33	31	77.50		
Cad cam insole footwear weight is less than MCR footwear	yes	13	81.25	23	95.83	36	90	2.2685	0.132
	no	3	18.75	1	4.17	4	10		
Perspiration during use of cad cam	yes	11	68.75	10	41.67	21	52.52	2.8237	0.093
	no	5	31.25	14	58.33	19	47.50		



Graph:1



Graph:2



Graph: 3

DISCUSSION

80% populations were comfortable with the foot wear model. There is a significance differences of ulcer reduction were found between male and female, which is 0.047. Male patients having a better recover of ulcer than female. In other questionnaires, there was no significance effect between male and female. The main concern was, maximum female patients were not using the foot wear with cad cam insole inside the home due to social stigma, but it was suggested to use for both inside and outside of home.

Related joint pain was reduced in maximum patients. Around 25 patients get stability with the cad cam insole during standing, walking and on uneven surfaces. Corn was significantly reduced among the patients. Some leprosy patients were found donning and doffing difficulties in cad cam insoles with foot wear in day-to-day activities, due to lack of hand dexterity. 90 % of patients were comfortable with the weight of the CAD-CAM footwear when compared to previous footwear (MCR), that they were using. Around 70% patients of the populations like the appearances of foot wear.

With the recent advances in technology, the peak plantar pressures at risk sites can be effectively identified using tactile sensors. Based on the joint alignment of the foot identified through computerized scanning, orthoses can be either manufactured through computerized 3D printing or milling technology. While the newer technologies are attractive, providing simple and effective orthoses at the peripheral level is needed and effort should be made to include the provision of basic accommodative orthoses such as the tarsal platform, plantar metatarsal pads and medial arch support in leprosy programs to improve the effectiveness of the footwear provided. [4] Bulk production of ready to fit orthoses could help reduce the burden on the health care worker in peripheral settings. Availability of cost effective rigid and semi rigid, ready to fit anti-pronatory and supinatory orthoses for different foot sizes could help patients in remote location. Advances in technology will help in customizing the fabrication of orthoses and make it cost effective. The computerized fabrication of orthoses could become an ideal method in the future. Meanwhile, the bulk production of ready to fit orthoses can meet the immediate needs at peripheral health centres.

Limitation:

- Less sample sizes
- This footwear cannot be used in the wet areas if used there is high risk of damage to the footwear.

CONCLUSION

This study concludes that there is a significant advantage for leprosy patients with this footwear. Cad cam insole helps in reducing the plantar ulcer in neuropathic foot in leprosy patients.

Declaration by Authors

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