

Acceptance and satisfaction of micro-cellular rubber ready-made footwear among patients with insensitive feet due to leprosy

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Summary

Introduction: Footwear is an integral part of disability management in leprosy programmes and rehabilitation. Suitable footwear for anaesthetic feet has been a challenging aspect of leprosy work.

Objective: To examine the acceptance and satisfaction of ready-made micro-cellular rubber footwear for insensitive feet among patients with leprosy.

Methods: A prospective follow-up study was conducted at The Leprosy Mission Hospital, Purulia, West Bengal, India. The sample consisted of 125 leprosy affected people with plantar anaesthesia without any ulcer or deformity and on regular follow-up.

Results: Of the 125 ready-made micro-cellular rubber footwear taken by subjects, 83 (66.4%) completed the study and used the footwear for six months or more, 19 (15.2%) withdrew due to footwear breakage, loss, foot drop, and non-usage for personal reasons and the remaining 23 (18.4%) participants defaulted in the subsequent visit.

Conclusion: The study found that the ready-made MCR footwear was accepted well by persons with insensitive feet due to leprosy in a leprosy endemic district. The durability of the footwear was good with the minimum level of wear and tear. Using the ready-made MCR footwear will protect the foot and will reduce the stigma attached to custom made MCR footwear.

Keywords: Micro-cellular rubber, footwear, leprosy, disability, stigma, ready-made footwear

Introduction

Leprosy is a leading cause of permanent physical disability among communicable diseases.¹ An estimated three million people live with disability due to leprosy.² A patient's feet are more important than his hands for freedom and locomotion. He may be able to work with a paralysed hand, but if he cannot walk, he will probably be unable to undertake the essential activities of daily life and moving from one place to another while performing activities.³ Insensitive feet do not register pain, burns, cuts or other wounds/injuries and hence, are often neglected.⁴ The anaesthetic area may not tolerate otherwise normal heat due to the absence of reflex dilatation of the blood vessels, and patients may develop blisters on contact with hot substances.⁴ Prolonged standing and walking for long distances cause micro-ischemic changes in the musculature of the sole resulting in fibroses, callosities and trophic ulcers. Plantar anaesthesia is a serious and preventable consequence of leprosy, leading to debilitating ulcers, often chronic and recurrent and severe enough to demand prolonged hospitalisation. In some patients, plantar ulcers lead to problems of disability, socioeconomic loss and psychological trauma. However, plantar ulcers can be prevented by minimising the amount of heat, pressure and sheer force that an anaesthetic foot is exposed to during walking. In addition to this, research has shown the benefits of incorporating suitable footwear for anaesthetic feet, and this has become a common protocol in the management of plantar anaesthesia among government and non-governmental organizations.⁴

Providing suitable footwear for anaesthetic feet has been a challenging aspect of leprosy work. The introduction of microcellular rubber (MCR) footwear in the late 1940s enhanced the quality of care for anaesthetic feet.⁵ Most of the leprosy rehabilitation centres had their own footwear unit and supplied custom made MCR footwear to people with plantar anaesthesia. Proper footwear with regular self-care can prevent the development of foot ulcers, and ulcer related complications.⁶ Many studies reported that custom made MCR footwear provided comfort, encouraged early healing of wounds and ulcers, and prevented further injury and disability. However, people with insensitive feet often continue to neglect the use of protective footwear resulting in ulcers and deformities, loss of productivity, stigma and enormous physical and mental suffering for them and their families. The footwear issued by the hospitals are obviously different from the footwear seen in the community, and so becomes a symbol of the disease.⁵ Due to this reason, the acceptance of custom made MCR footwear has been difficult in the prevention of impairment and disability programme (POID). Other factors such as footwear durability, cultural and social acceptability play major roles in footwear acceptance.

During the last decade, this approach has been superseded through encouraging appropriate, locally acceptable footwear delivered to patients with anaesthetic feet.⁷ Therefore, it is crucial to intensify the efforts to find rational solutions to prevent plantar ulcers through better footwear which is affordable, durable, and cosmetically acceptable. Today, there is a plethora of footwear manufacturers, who have flooded the market with fashionable and affordable footwear, within the economic reach of the common man or woman. These footwear models come with adjustable velcro straps and attractive multi-coloured designs. The Leprosy Mission Trust India took this opportunity to explore the market and arrive at the best footwear options for leprosy-affected people. Therefore, the study aimed to examine the acceptance and satisfaction of ready-made MCR footwear for insensitive feet among patient with leprosy.

Methods

This prospective follow-up study sample consists of 125 people with leprosy who regularly visited The Leprosy Mission Hospital, Purulia, West Bengal, India (TLM Hospital). The study was conducted over the period of one year from June 2008 to May 2009.

ELIGIBILITY CRITERIA

People with leprosy who had plantar anaesthesia without any ulcer and deformity, residing within a 40 kilometre distance from the research centre, who accepted the readymade MCR footwear and were willing to use it and report footwear conditions regularly for 6 months, were included in this study.

Identification of potential supplier to supply readymade footwear

An intensive search was made for possible footwear manufacturers to fabricate a suitable model of footwear of their own design, with an MCR insole, at a reasonable price for use by people with plantar anaesthesia; three reputable companies were identified. Negotiations were carried out with the companies to produce a small quantity of readymade MCR footwear in various sizes for testing under field conditions for durability, effectiveness and acceptability.

Foot evaluation and footwear prescription

A physiotherapist was assigned to evaluate subjects for eligibility and recruit participants. The participants were educated about the study, and gave informed consent before commencement of the study. Each participant underwent detailed sensory testing using 10 g Semmes-Weinstein monofilaments (SWM) and voluntary muscle testing of their feet.⁸ Plantar anaesthesia was defined as inability to feel the 10 g monofilament at two sites or more out of 10 sites on each foot. All participants were allowed to choose the footwear according to their preference and comfort, and the investigator did not influence the participant at any time during selection of the footwear (Figures 1a, and 1b).

OUTCOME MEASURES

Semi-structured questionnaire

A semi-structured questionnaire was used to interview the participants, comprised of basic information and footwear-related questions. The basic information questions covered details of disease and treatment history, occupation and footwear status. The footwear related questions covered usage, problems and satisfaction in regards to the footwear of the participant.

Footwear acceptance

Twelve different models of ready-made MCR footwear, and two custom made footwear for males and females each were displayed in a wooden showcase in the footwear department.



Figure 1. Ready-made MCR footwear.

The physiotherapist explained details about the study and showed the footwear to those who were eligible and allowed them to choose the footwear they preferred. The physiotherapist facilitated the process of selection of footwear with the patients and the response was documented.

Follow-up foot and footwear examination

Plantar sensory testing and foot muscle strength were tested at recruitment and each follow-up visit. The footwear condition was also inspected for any damage by the physiotherapist in each follow-up visit and recorded. The participants' satisfaction and comfort on the readymade footwear was measured by asking them a question "Are you satisfied with the footwear and do you experience any discomfort while using the footwear?" The response was recorded as binary data; 0, not satisfied/discomfort; and 1, satisfied/comfortable. Similarly, the usage of the footwear was recorded as 0, not regular and 1, regular use. Foot hygiene was

assessed by observing and palpating the skin surfaces of the foot, toe nails and presence of any dry skin and cracks on the plantar foot.

Self-care teaching

In addition, all the participants were motivated to take proper care of the footwear, and self-care was demonstrated to them for regular self-care activities for their feet. The participants were requested to come for monthly follow-ups for 6 months for foot assessment, and examination of the footwear for wear and tear. At each follow-up visit, the footwear was inspected for to see if any damage and the participant were questioned about the usage, problems and satisfaction of the footwear, and answers were recorded. In case of minor damage, the footwear was repaired and given back to the participant. When the footwear had major problems, it was taken back and custom made footwear was given.

All the data was entered into a Microsoft excel spreadsheet and analysed. We performed a descriptive statistical analysis (frequency distribution).

Results

A total of 153 eligible people were identified; of these, 125 accepted the ready-made MCR footwear, while 28 (16 female and 12 male) were given custom-made footwear; most of the women showed interest in footwear without a back strap. Among the 125 subjects, ages ranged from 14 to 74 years, 113 were males and 12 were females. Ninety-six (76.8%)

Table 1. Demographics details of participants ($n = 125$)

Status	Male ($n = 113$)		Female ($n = 12$)		Total ($n = 125$)	
	N	%	N	%	N	%
Age						
14–30	34	30.1	8	66.7	42	33.6
31–45	51	45.1	3	25.0	54	43.2
46–60	22	19.5	1	8.3	23	18.4
Above 60	6	5.3	0	–	6	4.8
Occupation						
Cultivation	51	45.1	4	33.3	55	44.0
Labour	39	34.5	0	–	39	31.2
Business	11	9.7	0	–	11	8.8
House wife	1	0.9	7	58.3	8	6.4
Student	6	5.3	1	8.3	7	5.6
Teacher	3	2.7	0	–	3	2.4
Retired Professional	2	1.8	0	–	2	1.6
World Health Organization (WHO) Disability Grade						
I	66	58.4	8	66.7	74	59.2
II	47	41.6	4	33.3	51	40.8
Outcome						
Completed	74	65.5	9	75.0	83	66.4
Default	21	18.6	2	16.7	23	18.4
Withdrawn	18	15.9	1	8.3	19	15.2

Table 2. Usage of footwear and satisfaction by the participant ($n = 125$)

Follow-up		Regular usage		Satisfaction	
Month	Followed	Yes	No	Yes	No
1	71	70	1	71	0
2	65	63	2	63	2
3	58	57	1	55	3
4	58	56	2	57	1
5	53	50	3	48	5
6	83	83	0	81	2

participants were aged from 14–45 and most of the participants worked as farmers and labourers. Seventy-four participants (59%) had disability Grade I, 51 (41%) had disability Grade II and most of them (76%) were wearing ‘flip flop’ footwear, at the time of recruitment. Among the participants, 83 (66.4%) completed the study and used the footwear for 6 months and above, 19 (15.2%) withdrew due to footwear breakage (10), loss (4), foot drop(3), and non-usage for personal reasons (2) and the remaining 23 (18.4%) participants defaulted from their subsequent visits (Table 1).

Eighty-three participants completed the study. Among these, 73 visited the study centre at end the of 6 month follow-up; a field visit was done for the remaining 11 participants. In the follow-up, not all participants visited monthly and used to come in-between once in 2 months. However, the result tables were presented in monthly wise follow-up.

Among the participants, most were satisfied with the ready-made MCR footwear, and were regular users, and very few complained about discomfort of the new footwear. The usage of footwear and the participation satisfaction is shown in Table 2.

The footwear was examined by the physiotherapist at every follow-up visit. Table 3 shows that most footwear remained in a good or satisfactory condition throughout the six month period. Of the 83 pairs seen at the 6 month follow-up, only 11 pairs showed signs of wear and tear.

The participants’ feet were examined for foot hygiene at every follow-up visit and the results are shown in Table 4. There was no oedema in first two visits, one had oedema at every subsequent visit and three had oedema at end of 6 months. Small superficial wounds were reported in a few participants; one was in first and third follow-up, and two were in the

Table 3. Footwear status of the participants ($n = 125$)

Follow-up		Ready-made footwear condition			Wear & Tear		Breakage	
Month	Followed	Good	Satisfactory	Bad	Yes	No	Yes	No
1	71	71	0	0	0	71	0	71
2	65	63	0	2	2	63	2	63
3	58	55	3	0	3	55	0	58
4	58	53	3	2	5	53	2	56
5	53	47	4	2	6	47	2	51
6	83	72	9	2	11	72	2	81

Table 4. Foot status of the participant during the follow-up ($n = 125$)

Month	Follow-up	Foot hygiene			Oedematous foot		Other problems	
	Followed	Good	Satisfactory	Bad	Yes	No	Foot drop	Crack
1	71	69	1	1	0	71	0	3
2	65	64	1	0	0	60	0	3
3	58	57	1	0	1	65	0	1
4	58	56	1	1	1	57	2	2
5	53	51	1	1	1	52	1	2
6	83	80	3	0	3	80	0	2

second, fourth, fifth and sixth follow-up respectively. Three participants had foot-drop and very few had cracked soles during the study period (Table 4).

Discussion

This study aimed to examine the acceptance and satisfaction of ready-made MCR footwear for insensitive feet among patients with leprosy. Among the eligible patients, the ready-made MCR footwear was well accepted (83%) by people with anaesthetic feet. The satisfaction of readymade MCR footwear was good among those who completed the study and the durability of the footwear was a minimum of 6 months. The women were interested in footwear without a back strap. This may be due to their customs and cultural practices in the community as these women participants are from rural backgrounds. A similar study reported that 6.5% of participants preferred the flip-flop model footwear without back straps.⁹ The back-strap is a very important component in footwear for insensitive feet, as it prevents the footwear from slipping off the feet.

Among the participants who completed the study at the end of the 6 month follow-ups, the participants demonstrated good satisfaction levels and all of them used the readymade MCR footwear regularly. Lal *et al.* (2015) did a study in India, and reported that leprosy patients though having demonstrated good levels of satisfaction towards MCR footwear, usage of the MCR footwear declined during social occasions in the community due to footwear stigma.¹⁰ Therefore, ready-made MCR footwear might minimise the footwear stigma, and improve the usage of protective footwear during social events in the community.

Durability has been a major concern in selecting MCR footwear as these patients walk on uneven terrain. The footwear materials, especially the upper straps and hard outer soles should be able to withstand high amounts of wear and tear forces, and thus would minimise the time and money spent in frequent repair and replacement. However, some modification was done to the front upper straps of the footwear for a few participants at the time of recruitment to enhance correct fitting, this further improving the participant's satisfaction. The durability of the upper straps and hard outer soles suggested that the leprosy patients with insensitive feet required two pairs of readymade MCR footwear per year. A similar study conducted in India, recommended that the leprosy patients with anaesthetic feet required two pairs of custom made MCR footwear in a year.¹⁰ Although the government adopted such recommendations to issue two pairs of custom-made MCR footwear, incorporating

cosmetically acceptable upper straps and outer sole of the footwear further improves the acceptance and usage of MCR protective footwear.

Before considering whether to prescribe suitable footwear to people with insensitive feet, it should be checked that the footwear should protect their feet comfortably for regular usage, and should not cause friction or tightness on the sole or the dorsum of the foot. Excessive friction from the footwear induces blisters and ulcers on the feet. In this study, the foot hygiene of most participants was good as a result of regular self-care practices. However, a few participants had adverse events of a small superficial wound and oedema during the study period. Three percent wounds reported at each follow-up visit were due to rat bites and simple blisters. However, no instances of pressure or friction induced ulcers from the ready-made MCR footwear were reported. In a few participants, foot oedema was present due to lepra reactions and it was controlled by medical treatment and the patients were advised to loosen the footwear straps to allow more space for oedematous feet. Each participant was educated on foot hygiene, and health education that included the importance of footwear in anaesthetic feet at every follow up.

The ready-made MCR footwear has more advantages over custom-made MCR footwear with single coloured straps produced in the hospitals, especially in high endemic leprosy districts. Many hospitals experience some difficulties in producing custom-made MCR footwear for insensitive feet, since it takes a long time to produce and ultimately patients have to wait for more than a few hours, sometimes a whole day, with a busy footwear unit. Such problems could be solved by distributing ready-made MCR footwear, thus minimising the patient's waiting time. In addition, with ready-made MCR footwear, both male and female patients have more choice to choose their footwear in terms of style, colour and design.

There are a few barriers in the way of supplying ready-made MCR footwear to patients with mutilated feet and plantar ulcers. Adaptive orthosis commonly incorporated into MCR footwear to treat plantar ulcers. Future research is needed to study the ready-made MCR footwear with adaptive orthosis for plantar ulcers management. There are other concerns that need to be addressed in successful manufacturing and delivering of ready-made MCR footwear to meet the demand, such as availability of MCR sheets, adjustable straps with different colours and designs for men and women. Identifying potential footwear manufacturing companies at a low cost has always been challenging.

The ready-made MCR footwear programme was implemented in the Leprosy Mission hospitals in India. The manufacturing companies are producing good quality footwear with contemporary designs for the hospital footwear unit. Periodically, the institution supplies the MCR insoles to the manufacturers and maintains strict quality control checks.

In recent years, there has been a shift from using custom-made protective footwear made in special workshops to commercially available footwear for normally shaped feet with plantar anaesthesia. Advances in modern footwear technology aid in producing various types of commercially available footwear incorporated with MCR or ethylene vinyl acetate (EVA) insoles. This footwear is readily available in the open market and is acceptable to people in the community, as it complies with the social and cultural norms of the society. Each patient should be assisted in choosing their appropriate footwear, thus enhancing footwear usage with good satisfaction.¹¹

The community can easily identify a leprosy-affected person through their footwear supplied by the government and non-government institutions especially in leprosy endemic areas. Therefore, providing ready-made MCR footwear will protect the plantar anaesthetic feet, prevent ulcers, and reduce the stigma attached to footwear among the leprosy-affected

people. It is recommended that future studies should be done in different regions and in different countries with various designs to determine the acceptance, durability and effectiveness of ready-made MCR footwear for people with insensitive feet affected by leprosy.

Conclusion

The study concluded that the ready-made MCR footwear was accepted well by people with insensitive feet due to leprosy in a leprosy endemic district. The durability of the footwear was good with minimum levels of wear and tear. The ready-made MCR footwear will be more helpful where there is a greater demand especially in leprosy-endemic areas. The ready-made MCR footwear will protect the feet and will reduce the stigma attached to custom made MCR footwear.

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Contribution of each author

Pitchaimani Govindharaj: Enrolled patients, conducted assessments, data cleaning and analysis, monitored results and wrote the first draft and revision of the manuscript.

Suresh Mani: Proof reading and revision of the manuscript.

Joydeeba Darlong: Supervised the study implementation and commented on the paper.

Annamma S. John: Proof reading and finalising the final draft for submission.

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