EUROPEAN JOURNAL OF BIOMEDICAL AND PHARMACEUTICAL SCIENCES
http://www.ejbps.com

ISSN 2349-8870
Volume: 5
Issue: 8
481-493
Year: 2018

TO EVALUATE THE EFFICACY OF MCR FOOTWEAR IN THE MANAGEMENT OF DIABETIC FOOT ULCER

Dr. Anunay Kumar[1] and Dr. Chandrashekhar Mahakalkar*[2]

[1,2]Department of Surgery, JNMC Sawangi, Wardha, MH, India.

***Corresponding Author: Dr. Chandrashekhar Mahakalkar**
Department of Surgery, JNMC Sawangi, Wardha, MH, India.

Article Received on 13/06/2018 **Article Revised on 03/07/2018** **Article Accepted on 23/07/2018**

ABSTRACT

Background: This study was carried out to evaluate the efficacy of MCR footwear in the management of diabetic foot ulcer. **Methods:** Diabetes is a common endocrine disorder and worldwide problem. The present study entitled "To evaluate the efficacy of MCR footwear in the management of diabetic foot ulcer" was carried out in the department of General surgery, Acharya Vinoba Bhave Rural Hospital, affiliated to Jawaharlal Nehru Medical College, Sawangi, wardha from AUGUST 2015 to JULY 2017. This study was conducted after the due clearance from Institutional Ethical Committtee. A Total number of 60 patients were admitted to the surgery ward with diabetic foot ulcer and out them 30 were given MCR footwear and were called at 3months and 6 months follow up and were studied prospectively. **Results**: In the present study, maximum number of patients were found in the age group more than 50years. The male to female sex ratio was 11: 4 in the patients with diabetic foot ulcer. The maximum number of patients were having past history of smoking. The maximum number of patients with MCR footwear were having nerve conduction velocity between 40-45 at 3months and 6 months follow up. The surface area of ulcer of patients with diabetic foot ulcer were improving in patients with MCR footwear at 3 months and 6 months follow up. **Conclusion:** In my study, MCR footwear are beneficial with diabetic foot ulcer patients.

KEYWORDS: Diabetic foot ulcer, MCR footwear.

INTRODUCTION

Diabetes is a common endocrine disorder and worldwide problem. The estimated number of patients with diabetes in this country today is 32 million. A majority of diabetic patients develop foot ulcers in one point of time or other during the course of their illness. The diabetic foot disease is one of the most frequent causes of hospitalization and is one of the most expensive complication of diabetes. We can get a measure of the problem by knowing in our country the frequency, types and causes of diabetic foot lesions, and the way the injury and infection contribute to it.

The etiopathogenesis of diabetic foot lesions are multifactorial. Diabetic neuropathy, vasculopathy, poor control of diabetes and bacterial infection are some of them.[1]

The reasons for diabetic foot are

1. Foot is the most vulnerable part of body for injury and infection neglected by patient.
2. The site of preference for neuropathy and ischemia is also foot.

The diabetic foot problem is one of the most common and most preventable complications of diabetic mellitus by doing regular inspection of foot daily, by wearing appropriate shoes, searching for redness and others sign of trauma and by avoiding deep trimming of nails, smoking, and use of chemicals or sharp instruments to trim calluses. The primary approach to the problem must begin with an understanding of the basic metabolic abnormalities of diabetic.

According to ***Modi et al***., overall incidence of diabetics in India is 1.2%. The death in each year is due to its complications (2.1% in urban, 1.5% in rural), which are usually common in age group of 40 – 60 years affecting both sexes equally. The complications are more prevalent among the people of lower economic due to negligence, illiteracy and poverty.[2]

According to ***Lord Moynihan's*** "Surgery has been made safe for patients. We must now make the patient safe for Surgery".

According to ***Wilman et al***[3], diabetic foot ulceration is a worldwide health problem approximately 15% of the 10 million diabetic patients in USA will develop foot ulcer at some time in their life time. The foot ulcer in this population is extremely debilitating and dramatically increases the risk of lower extremity amputation.

Various studies have been conducted and a number of procedures and techniques have evolved with varying degree of success. It is common to see patients with foot ulcers due to complications of diabetes. Moreover, diabetic foot lesions form a good bulk of patients in our hospital, routine work. Treatment of these ulcers forms a challenging task as well.

I have therefore, in my present thesis attempted to study and analyze the diabetic foot lesions.

In this Clinical Study of Diabetic Foot, cases are studied in JAWAHAR LAL NEHRU MEDICAL COLLEGE SAWANGI (MEGHE). Careful evaluation of mode of presentation and treatment of diabetic foot is done.

MATERIALS AND METHODS

- It is a prospective case control study and was conducted at Department of General Surgery, Jawaharlal Nehru Medical College and Acharya Vinoba Bhave Rural Hospital, Sawangi (Meghe), Wardha of Datta Meghe Institute of Medical Sciences (DU) during a period of august 2015 to july 2017. The study was conducted on patients of Diabetic Foot Ulcer. The prior approval from institutional ethics committee was taken with Reg. No. DMIMS (DU) / IEC/2015 -16/1652. Informed consent was obtained from all the patients. A total 60 patients were studied over the duration of 2 years. Nerve conduction velocity studies were done before every procedure to demonstrate conduction rate of the nerve.

Patients were followed up at 3 months and 6 months to assess the overall outcomes and various complications. Patient more than 18 years of age with Type I and Type II Diabetes Mellitus and having changes in foot were considered for the study.

Patients with Diabetic Ketoacidosis, Cerebrovascular accidents(CVA) and those requiring ICU setup were excluded from the study. Also patients already using MCR footwear and with history of amputation were excluded from the study.

University of Texas Diabetic Wound Classification*

Stages	**Description**
Stage A	No infection or ischemia
Stage B	Infection present
Stage C	Ischemia present
Stage D	Infection and ischemia present
Grade	Description
Grade 0	Epithelialized wound
Grade 1	Superficial wound
Grade 2	Wound penetrates to tendon or capsule
Grade 3	Wound penetrates to bone or joint

Initial Evaluation

Detailed demographic profile will be recorded and complete history including history of present illness, duration of DM, treatment history, onset of foot lesions and its progression and other relevant detail will be recorded. The foot lesions and foot deformities will be identified, marked and sketched on transparent sheets to document the size and site of lesion for further comparison and follow up and then photographs will be taken. The size of the lesions will be calculated by using sketched transparent sheets as maximum diameter x maximum diameter perpendicular to the first measurement.

All the baseline investigations including Complete blood count, Kidney function test, Liver function test, fasting blood sugar, post meal blood sugar Chest X ray, X- ray foot and leg will be done. Glycemic control will be evaluated with HbA_{1c}.

- Nerve conduction velocity (NCV): -It is a measurement of the speed of conduction of an electrical impulse through a nerve. NCS can determine nerve damage and destruction.

If the patients are newly diagnosed cases of DM, then the treatment for control of blood sugar will be initiated by the physicians as per standard protocol. In case of patients on regular diabetic treatment, they will be referred to their physicians for routine follow up. The patients will be then educated for regular foot examination, treatment and foot care and also instructed to avoid trauma. They will be provided with a check list to be filled weekly regarding proper foot examination, missing any medication dose, foot care and episodes of trauma.

All work up of initial evaluation and follow up visits will be done in Clinical Research Area. The samples will be drawn and submitted to Central Clinical Laboratory for blood examinations. The X- Rays and Color Doppler will be done in Radiology Department and Nerve conduction studies will be done in Department of Physiotherapy. All these areas are nearby and at a walking distance of 3-5 minutes.

Randomization

Then all the patients will be divided randomly in following two groups.

1. Group A

2. Group B

Randomization will be done by allocation sequence generated using a computer program. The sequential patient consenting to participate in the study will be allocated in the respective arm as per the allocation sequence.

Group A (Study): These patients will be provided with well filling specialized footwear with microcellular sole (MCR Chapel) (made of leather with soft and compressible planter surface distributing the pressure equally and avoiding pressure at ulcer points, prepared by Leprosy Foundation, Anandvan).

Group B (Control): These patients will not be provided with any specialized chapel and advised to use their routine footwear.

Follow up
Patients will be followed up for the duration of two years (24 months) after their enrollment in the study. Every patient will be followed up at 3 months and 6 months interval. The various activities and investigations to be done at each visit is listed in the following table.

***Activities*:** Following activities will be done in each visit.
Foot examination
- Sketching & Photography
- check list diary

These are to evaluate size, extent and to know the progression of the lesion.

Investigations
1. CBC, Blood sugar- to know the active infection and diabetic status respectively, will be monitored more frequently at 3 monthly intervals to intervene early if required.
2. HbA_{1c} – to know adequate control of blood sugar will be monitored 6 monthly.

Study Protocol
All patients admitted with the diagnosis of diabetic foot ulcer.

Initial Evaluation
Detailed demographic profile will be recorded and complete history including history of present illness, duration of DM, treatment history, onset of foot lesions and its progression and other relevant detail will be recorded. The foot lesions and foot deformities will be identified, marked and sketched on transparent sheets to document the size and site of lesion for further comparison and follow up and then photographs will be taken. The size of the lesions will be calculated by using sketched transparent sheets as maximum diameter x maximum diameter perpendicular to the first measurement.

Evaluation
Evaluation of patients profile and data generated from the study will be evaluated at the end of 2 year after completion of all the follow up visits for all the patients. The data will be evaluated by calculating absolute difference of 25% reduction in the size of ulcer at the end of 3 month and no recurrence of ulcer thereafter during the follow up period in minimum 80% of study group population at 95% confidence interval.

The other secondary parameters will be evaluated.
1. *Nerve conduction velocity (NCV):*-To determine progression or regression of nerve damages calculated in meter per second using the fixed points and the same equipment. It will be compared in both the groups at the time of enrollment in the study and at 3months and 6 months follow up.
2. *Glycemic control* assessed by Fasting blood sugar, Post meal blood sugar, HbA_{1c}will be assessed in both the groups.

Follow up
For follow up the patients then were subjected for vascular evaluation by Nerve conduction velocity after 3months and 6 months follow up for assessing the damage to the nerve.

For statistical analysis, the patients were divided into two groups.
1. Group A
2. Group B
1. Group A (patients with MCR Footwear)
2. Group B (patients with Non-MCR Footwear)

OBSERVATIONS AND RESULTS
The distribution of diabetic foot patients with MCR footwear follow up in diabetic foot ulcer, At 3months follow up 65% cases came with e/o infection and 3.33% cases came with deformity and at 6 months follow up 61.67% cases came with e/o infection and 6.67% cases came with deformity

At 3 months follow up 45% cases were in grade 1 ulcer, 15% were in grade 2 ulcer and 40% were in grade 3 ulcer and at 6 months follow up, 48.33% were in grade 1 ulcer, 38.33% were in grade 2 ulcer and 13.00% were in grade 3 ulcer.

Table 1: Comparison of diabetic foot patients according to follow up of diabetic foot ulcer in MCR and Non MCR patients.

	3 months		6 months		χ2-value MCR	χ2-value Non MCR
	MCR	Non MCR	MCR	Non MCR		
E/O Infection	24(80%)	16(53.33%)	4(13.33%)	11(36.67%)	26.79 p=0.0001,S	1.68 p=0.19,NS
χ2-value	4.80, p=0.028,S		4.35,p=0.035,S			
Deformity	7(23.33%)	9(30%)	1(3.33%)	6(20%)	5.19 p=0.02,S	0.80 p=0.37,NS
χ2-value	0.34,p=0.55,NS		4.04,p=0.044,S			
Status of ulcer						
Grade 1	12(40%)	14(46.67%)	21(70%)	5(16.67%)	18.38 p=0.0001,S	13.90 p=0.001,S
Grade 2	4(13.33%)	5(16.67%)	9(30%)	19(63.33%)		
Grade 3	14(46.67%)	11(36.67%)	0(0%)	6(20%)		
χ2-value	0.62,p=0.73,NS		19.41,p=0.0001,S			

Table 1 Shows comparison of diabetic foot patients according to followup of diabetic foot ulcer in MCR and Non-MCR patients. Out of 30 patients with MCR footwear, 24(80%) cases were having evidence of infection after 3 months follow up and 4(13.33%) cases were having evidence of infection after 6months follow up. Out of 30 patients with MCR sleepers, 7(23.33%) cases were having deformity after 3 months follow up and 1(3.33%) case was having deformity after 6 months follow up.

Out of 30 patients with Non-MCR footwear, 16(53.33%) cases were having E/O infection at 3months follow up and 11(36.67%) cases were having E/O infection after 6months follow up. Out of 30 patients with Non-MCR sleepers, 9 (30%) cases were having deformity after 3 months follow up and 6(20%) cases were having deformity after 6 months follow up.

Out of 30 patients with MCR footwear, 12(40%) cases were in grade 1, 4(13.33%) cases were in grade 2 and 14(46.67%) cases were in grade 3 after 3 months follow up and 21(70%) cases were in grade 1 and 9(30%) cases were in grade 2 after 6 months follow up.

Out of 30 patients with Non-MCR footwear, 14(46.67%) cases were in grade 1,5(16.67%) cases were in grade 2 and 11(36.67%) cases were in grade 3 after 3 months follow up and 5(16.67%) cases were in grade 1,19(63.33%) cases were in grade 2.

Table 2: Distribution of diabetic foot patients according to follow up of nerve conduction velocity.

Velocity	On Admission		3 months		6 months		χ2-value
	No	%	No	%	No	%	
40-45	12	20	13	21.67	10	16.67	0.49 p=0.78,NS
45-50	35	58.33	33	55	30	50	0.85 p=0.65,NS
>50	13	21.67	13	21.67	20	33.33	2.86 p=0.23,NS

Table 2 Shows distribution of diabetic foot patients according to follow up of nerve conduction velocity. Out of 60 patients, On admission 20% cases were having NCV between 40-45, 58.33% cases were having NCV between 45-50 and 21.67% cases were having NCV >50.

At 3 months, 21.67% cases were having NCV between 40-45, 55% cases were having NCV between 45-50 and 21.67% cases were having NCV >50.

At 6 months, 16.67% cases were having NCV between 40-45, 50% cases were having NCV between 45-50 and 33.33% cases were having NCV >50.

Table 3: Comparison of diabetic foot patients according to velocity of diabetic foot ulcer in MCR and Non MCR patients.

Velocity	3 months		6 months		χ2-value MCR	χ2-value Non MCR
	MCR	Non MCR	MCR	Non MCR		
40-45	8(26.67%)	5(16.67%)	7(23.33%)	5(16.67%)	0.49 p=0.78,NS	3.19 p=0.20,NS
45-50	20(66.67%)	25(83.33%)	22(73.33%)	22(73.33%)		
>50	2(6.67%)	0(0%)	1(3.33%)	3(10%)		
χ2-value	3.24,p=0.19,NS		1.33,p=0.51,NS			

Table 3 Shows comparison of diabetic foot patients according to nerve conduction velocity of diabetic foot ulcer in MCR and Non-MCR patients.

Out of 30 patients with MCR footwear, 20(66.67%) cases were having velocity between 45-50 and 8(26.67%) cases were having velocity between 40-45 after 3months follow up and 22(73.33%) cases were having velocity between 45-50 and 7(23.33%) cases were having velocity between 40-45 after 6 months follow up.

Out of 30 patients with Non-MCR footwear, 25(83.33%) cases were having velocity between 45-50 and 5(16.67%) cases were having velocity between 40-45 after 3 months follow up and 22(73.33%) cases were having velocity between 45-50 and 5(16.67%) cases were having velocity between 40-45 after 6 months follow up.

Table 4: Distribution of diabetic foot patients according to HbA1C levels.

HbA1C	No of patients	%
<7	7	11.67
≥7	53	88.33
Total	60	100
Mean ± SD	9.53±1.79(6.30-16.60)	

Table 4 Shows distribution of diabetic foot patients according to HbA1C levels. Out of 60 patients, 7(11.67%) cases were having HbA1C level <7 and 53(88.33%) cases were having HbA1C level >=7.

Table 5: Comparison of diabetic foot patients according to HbA1C level in MCR and Non MCR patients.

HbA1C level	MCR	Non MCR	Total	χ2-value	p-value
<7	2(6.67%)	2(6.67%)	4(6.67%)	0.00	1.00,NS
≥7	28(93.33%)	28(93.33%)	56(93.33%)		
Total	30(100%)	30(100%)	60(100%)		
Mean ±SD	9.43±1.49	9.78±1.91	9.60±1.71		

Table 5 Shows comparison of diabetic foot patients according HbA1C level in MCR and Non-MCR patients.

Out of 30 patients with MCR footwear, 28(93.33%) cases were having HbA1C level ≥7 and 2(6.67%) cases were having HbA1C level <7.

Out of 30 patients with Non-MCR footwear, 28 cases were having HbA1C level ≥7 and 2 cases were having HbA1C level <7.

Table 6: Comparison of surface area of ulcer on admission, at 3 months and 6 months of diabetic foot patients in MCR and Non MCR group.

On Admission

Surface Area	MCR	Non MCR	Total	χ2-value	p-value
1 to 10 cm^2	13(43.33%)	24(80%)	37(61.67%)	10.74	0.005,S
11 to 30 cm^2	11(36.67%)	6(20%)	17(28.33%)		
>30 cm^2	6(10%)	0(0%)	6(10%)		
Total	30(100%)	30(100%)	60(100%)		
Mean ±SD	17.70±14.69	6.56±4.71	12.13±12.19		

Table 6.1 Shows comparison of surface area of ulcer on admission of diabetic foot patients in MCR and Non-MCR group. Out of 30 patients with MCR footwear, 13(43.33%) cases were having surface area of ulcer between 1-10, 11(36.67%) cases were having surface area between 11-30 and 6(10%) cases were having surface area >30.

Out of 30 patients with Non MCR footwear, 24(80%) cases were having surface area between 1-10 and 6 (20%)cases were having surface area between 11-30.

3 months

Table 6.2: Shows comparison of surface area of ulcer at 3months of diabetic foot patients in MCR and Non-MCR group.

Surface Area	MCR	Non MCR	Total	χ2-value	p-value
1 to 10 cm^2	20(66.67%)	22(73.33%)	42(70%)	0.49	0.78,NS
11 to 30 cm^2	8(26.67%)	7(23.33%)	15(25%)		
>30 cm^2	2(6.67%)	1(3.33%)	3(5%)		
Total	30(100%)	30(100%)	60(100%)		
Mean ±SD	11.13±11.81	8.13±6.52	9.63±9.57		

Out of 30 patients with MCR footwear, 20(66.67%) patients were having surface area between 1-10, 8(26.67%) patients were having surface area between 11-30 and 2 (6.67%)patients were having surface area >30 at 3 months follow up.

Out of 30 patients with Non-MCR footwear, 22(73.33%) patients were having surface area between 1-10, 7(23.33%) patients were having surface area between 11-30 and 1(3.33%) patient was having surface area >30 at 3 months follow up.

6 months

Table 6.3: Shows comparison of surface area of ulcer at 6months of diabetic foot patients in MCR and Non-MCR group.

Surface Area	MCR	Non MCR	Total	χ2-value	p-value
1 to 10 cm^2	25(83.33%)	17(56.67%)	42(70%)	5.31	0.021,S
11 to 30 cm^2	5(16.67%)	12(40%)	17(28.33%)		
>30 cm^2	0(0%)	1(3.33%)	1(1.67%)		
Total	30(100%)	30(100%)	60(100%)		
Mean ±SD	6.56±6.92	11±8.84	8.78±8.18		

Out of 30 patients with MCR footwear, 25(83.33%) cases were having surface area between 1-10, 5(16.67%) cases were having surface area between 11-30 and 0 cases were having surface area >30 at 6 months follow up.

Out of 30 patients with Non-MCR footwear, 17(56.67%) cases were having surface area between 1-10, 12(40%) cases were having surface area between 11-30 and 1(3.33%) case was having surface area >30 at 6 months follow up.

Table 7: Comparison of surface area of ulcer on admission with 3 months and 6 months group of diabetic foot patients in MCR group.

Surface Area	On Admission	3 months	6 months
1 to 10 cm^2	13(43.33%)	20(66.67%)	25(83.33%)
11 to 30 cm^2	11(36.67%)	8(26.67%)	5(16.67%)
>30 cm^2	6(10%)	2(6.67%)	0(0%)
Total	30(100%)	30(100%)	30(100%)
Mean ±SD	17.70±14.69	11.13±11.81	6.56±6.92
χ2-value	-	3.95	12.04
p-value	-	0.15,NS	0.0024,S

Table 7 Shows comparison of surface area of ulcer on admission, at 3 months and 6 months of diabetic foot patients in MCR group.

On admission out of 30 patients with MCR footwear, the maximum number of patients was 13 patients (43.33%) with surface area of ulcer ranging between 1-10 cm square.

At 3 months out of 30 patients with MCR footwear, the maximum number of patients was 20patients (66.67%) with surface area of ulcer ranging between 1-10 cm square.

At 6 months out of 30 patients with MCR footwear, the maximum number of patients was 25 patients (83.33%) with surface area of ulcer ranging between 1-10 cm square.

Table 8: Comparison of surface area of ulcer on admission with 3 months and 6 months group of diabetic foot patients in Non MCR group.

Surface Area	On Admission	3 months	6 months
1 to 10 cm^2	24(80%)	22(73.33%)	17(56.67%)
11 to 30 cm^2	6(20%)	7(23.33%)	12(40%)
>30 cm^2	0(0%)	1(3.33%)	1(3.33%)
Total	30(100%)	30(100%)	30(100%)
Mean ±SD	6.56±4.71	8.13±6.52	11±8.84
χ2-value	-	1.16	4.19
p-value	-	0.55,NS	0.12,NS

Table 8 Shows comparison of suface area of ulcer on admission, at 3 months and ay 6 months of diabetic foot patients with Non-MCR group.

On admission out of 30 patients with Non-MCR group, the maximum number of patients with surface area of ulcer ranging between 1-10 cm square was 24 patients (80%).

At 3 months out of 30 patients with Non-MCR group, the maximum number of patients with surface area of ulcer ranging between 1-10 cm square was 17 patients (56.67%).

At 6 months out 0f 30 patients with Non –MCR group, the maximum number of patients with surface area of ulcer ranging between 1-10 cm square.

Table 9: Comparison of surface area of ulcer on admission, at 3 months and 6 months of diabetic foot patients in MCR and Non MCR group.

	On Admission		3 months		6 months	
Surface Area	**MCR**	**Non MCR**	**MCR**	**Non MCR**	**MCR**	**Non MCR**
1 to 10 cm^2	13(43.33%)	24(80%)	20(66.67%)	22(73.33%)	25(83.33%)	17(56.67%)
11 to 30 cm^2	11(36.67%)	6(20%)	8(26.67%)	7(23.33%)	5(16.67%)	12(40%)
>30 cm^2	6(10%)	0(0%)	2(6.67%)	1(3.33%)	0(0%)	1(3.33%)
Total	30(100%)	30(100%)	30(100%)	30(100%)	30(100%)	30(100%)
Mean ±SD	17.70±14.69	6.56±4.71	11.13±11.81	8.13±6.52	6.56±6.92	11±8.84
χ2-value	10.74		0.49		5.31	
p-value	0.005,S		0.78, NS		0.021,S	

Table 9 Shows comparison of surface area of ulcer on admission, at 3 months and at 6 months of diabetic foot patients in MCR group and in Non-MCR group.

On admission out of 30, the maximum number of patients with surface area of ulcer ranging between 1-10 cm square with MCR footwear was 13 patients(43.33%) and in Non-MCR group was 24patients (80%).

At 3 months out of 30 patient, the maximum number of patients with surface area of ulcer ranging between 1-10 cm square with MCR footwear was 20 patients (66.67%) and in Non-MCR group was 22 patients (73.33%).

At 6 months out of 30 patients, the maximum number of patients with surface area of ulcer ranging between 1-10 cm square with MCR footwear was 25 patients (83.33%) and in Non-MCR group was17 patients(56.67%).

DISCUSSION

Diabetic foot care is one of the most ignored aspects of diabetes care in India. The provision of proper foot wear is the cornerstone of any diabetic foot care programme. The various types of shoes with different combinations of soles have been tried to minimize the reulceration or promote the healing of pre existing ulcers. None of such shoe or sole till date is fit to overcome the present problem of reulceration and no proper consensus could be established to advice the type of footwear a patient can have to decrease foot complications. With this background, the present study is conducted to find out efficacy of well fitted specialized footwear with microcellular sole, commonly called as MCR footwear, prepared by Leprosy Foundation, Anandvan. The sole is soft and elastic and can be tolerated by every patient; however this type of footwear has not been studied till date.

According to the world health organization and to the International Working group on the diabetic foot[4], diabetic foot is defined as the foot of diabetic patients with ulceration, infection and/or destruction of the deep tissues, associated with neurological abnormalities and various degrees of peripheral vascular disease in the lower limb. Foot lesions is described as any abnormality associated with the damage to the skin, nails or deeper

tissues of foot. Foot deformity is defined as structural abnormalities of the foot such as hammer toes, mallet toes, claw toes, hallux valgus, prominent metatarsal head, residuals of neuro-osteoarthropathy, amputations or other foot surgery.[4]

Foot ulcer is one of the most common and deadest complications of diabetes mellitus. This is also frequent cause of hospitalization and disability. Most of the patients with diabetic foot ulcers living in developing countries present to healthcare facilities fairly late with advanced foot ulcers because of poor economic status, inadequate knowledge of self-care, sociocultural reasons and poor and inadequate diabetes health care.

Diabetes mellitus, a metabolic disorder characterized by elevated blood glucose level, is a serious and growing problem. More than 23 million people in the United States are believed to have diabetes. It is estimated that by 2025, 300 million people worldwide prevalence will approach 5%.[5,6,7,8]

Prevalence of diabetes mellitus (DM) and impaired fasting glucose are reprted to be highly variable among rural and urban populations in India. A number of empidemeological studies with varying sample sizes have reported prevalence of diabetes with different geographical areas ranging from 1.6-12.4%[9], type 2 diabetes is a global health problem.[162] According to the recent global estimates of the World Health Organization, there will be 300 million people with diabetes by the year 2025.[10] It is estimated that the developing countries will bear the burnt of diabetes epidemic to the extent of 77% of the global burden, in the 21st century.[11] Number of diabetics in India was 31.7 million in the year 2002 and it is estimated that number of diabetics in 2030 will be 79.4 million in India.[11]

This randomized control trial study was done at JAWAHARLAL NEHRU MEDICAL COLLEGE from AUGUST 2015 to JULY 2017 with the sample size of 60 patients**.**

In the present study, out of total of 60 patients, 39(65%) patients were having past history of smoking. In the present study out of 30 patients with MCR footwear, 20(66.67%) patients were having past history of smoking and out of 30 patients with Non-MCR footwear 19(63.33%) patients were having past history of smoking. In the study of Ravinthar A et al[12], 56% cases were having history of smoking. In the study of Framingham et al[13], 42 out of 75 patients gave the history of smoking.

In the present study out of 60 patients; On admission, 12 (20%) were having NCV between 40-45, 35 patients(58.33%) were having NCV between 45-50 and 13 patients(21.67%) were having NCV >50. At 3 months, 13 patients(21.67%) were having NCV between 40-45, 33 patients(55%) were having NCV between 45-50 and 13 patients(21.67%) were having NCV >50. At 6 months, 10 patients (16.67%) were having NCV between 40-45, 30 patients(50%) were having NCV between 45-50 and 20 patients(33.33%) cases were having NCV >50. In the present study with MCR footwear, maximum number of patients was 20(66.67%) with nerve conduction velocity between 45-50 and minimum number of patients was 2(6.67%) with nerve conduction velocity >50. According to study performed by Kakrani AL et al[14], NCV performed on 50 patients of diabetic neuropathy out of which all patients i.e. 100% had involvement of lower limb and only 24 patients i.e. 48% had involvement of upper limb also. Involvement of tibial and sural nerve is more common i.e. 86% and 82% respectively. 5) 42 patients i.e. 84% found to have distal symmetrical polyneuropathy, 2 patients i.e. 4% had isolated tibial nerve involvement, 4 patients i.e. 8% had pure sensory sural nerve involvement, and only 1 patient each of isolated medial and plantar nerve involvement. According to Farah N. Abass et al[15], Motor nerve conduction study that were performed in patients with and without DPN(diabetic peripheral neuropathy) and control subjects showed significant differences between these groups regarding the median motor conduction velocity, tibial latency, amplitude, conduction velocity, peroneal latency, amplitude, and conduction velocity. Motor nerves are large myelinated fast conducting fibers that are affected by hyperglycemia and subsequent metabolic and neurovascular derangement in diabetes. This study is in consistence with other ones in which motor nerve involvement is one of the important electrophysiological manifestation of DPN. Serum levels of TNF-a in peripheral neuropathy patients and its correlation with nerve conduction velocity in type 2 diabetes mellitus. Obesity and hyperlipidemia are risk factors for early diabetic neuropathy. In the study performed by Robert J.Hinchliffe et al, peripheral neuropathy predispose to the development of ulcer.

In the present study out of 60 patients, 7(11.67%) patients were having HbA1C level <7 and 53(88.33%) patients were having HbA1C level ≥7. In the present study of 30 patients with MCR footwear, 28 patients(93.33%) were having HbA1C level ≥7 and in the control group with Non-MCR footwear, 2 patients (6.67%) were having HbA1C level <7. In the study of Ravinthar A et al, 32 patients had high HbA1C level of which 72.9% showed poor wound healing rates. According to the study performed by Farah n abbas et al[16], 85% patients with DM having HbA1C level >6.4%, mean HbA1C level was 8.83. According to the study by Hajieh Shahbazian et al[17], out of 125 patients 29 patients were having HbA1C level <=7 and 96 patients were having HbA1C level >7.

In the present study out of 60 patients, 6(10%) cases were having fasting glucose level <=110 and 54(90%) cases were having fasting glucose level >110. In the present study out of 30 patients with MCR, 26 patients

were having FBS level >110 and 4 cases were having FBS level ≤110. According to the study performed by Farah N Abbas et al[18], 83% patients were having FBS level >126mg/dl.

According to the study performed by Gayle E Rieber et al[19]**,** patients assigned to therapeutic shoes did not have a significantly lower risk of reulceration compared with the controls.(risk ratio(RR) for the cork insert group, 0.88;95% confidence interval, 0.51-1.52 and RR for the prefabricated insert group,0.85;95% confidence interval, 0.48-1.48).

In the present study out of 60 patients, 27 patients (45%) were in Grade 1, 9 patients(15%) were in Grade 2 and 24 patients(40%) were in grade 3 at 3 months follow up and at 6 months follow up, 29(48.33%) patients were in grade 1, 23(38.33%) patients were in grade 2 and 8(13%) patients were in grade 3. In the present study out of 30 patients with MCR footwear, 12 patients(40%) at 3 months and 21 patients(70%) at 6 months were in grade 1. i.e, 70% cases were achieving ulcer healing at 6months. According to the study performed by Hilde Smith Strom et al[20], 47.5% cases out of 105 patients were achieving ulcer healing. According to study of Samson O Oyibo et al[21], out of 194 diabetic foot ulcer patients, 15% had lower limb amputation as a result of their non-healing ulcer, 65% patients had ulcer that healed completely at minimum follow up of 6 months.

In the study done by Tarig Elraiyah et al, 19 interventional studies, of which 13 were randomized controlled trials, including data from 1605 patients with diabetic foot ulcers using an off-loading method. The risk of bias in the included studies was moderate. This analysis demonstrated improved wound healing with total contact casting over removable cast walker, therapeutic shoes, and conventional therapy. There was no advantage of irremovable cast walkers over total contact casting. There was improved healing with half-shoe compared with conventional wound care. Therapeutic shoes and insoles reduced relapse rate in comparison with regular footwear. Data were sparse regarding other off-loading methods.

Although based on low-quality evidence (ie, evidence warranting lower certainty), benefits are demonstrated for use of total contact casting and irremovable cast walkers in the treatment of diabetic foot ulcers. Reduced relapse rate is demonstrated with various therapeutic shoes and insoles in comparison with regular footwear.

It is common to find irregularities in gait with people suffering with diabetes. A study conducted by Petrofysky[22] and other researchers (2006) has revealed that gait is impaired in people with diabetes and that there is more unsteadiness and tremor at the knee, hip and ankle in patients with diabetes during gait compared to the general population. But Cohen[23] (2011) has pointed out that correct management of diabetic foot problems can improve gait and allow diabetes patients to fit into their work and leisure shoes. During each phase of the gait cycle, the foot experiences varying magnitude of pressure. For example, during the heel strike phase, the heel of the foot experiences high amount of pressure, while the fore foot bears most pressure during the heel off phase. This explain why ulcers of the foot often occur at the heels and ball of the feet rather than at the midfoot. Therefore, a stable stance, ambulation and effective transfer of force through the lower limb is important to avoid the consequences of nerve injury, poor wound healing and disrupted functions.

"In addition to emphasis on optional blood glucose control, it is important that altered biomechanics in the diabetic foot must not be neglected". It should be therefore noted that footwear acts as the interface between the body and the ground during gait, in addition to protecting the feet from potentially harmful environmental factors. Footwear can be modified to alter mechanical loads on the lower extremity generally during the stance phase of gait (Working feet and footwear n.d) and whenever special footwear is provided, the supplier should make sure that it fits properly and allow the toes a wiggle room (around 10mm or 1cm gap between the longest toe and the end of the shoes).

By Shakoor[24] and his colleagues (2010) has shown that the entire lower extremity is considered to be an interrelated functional and mechanical unit, and alterations at one aspect of the lower extremity (e.g the foot) can have serious impact on distant areas such as the knee. Therefore, they concluded that footwear design and several aspects of footwear may substantially affect the loading patterns of the entire lower body. They pointed out that the heel lifts and heel height in walking shoes may affect loading.

The 'stiffness' imposed by shoe soles is another characteristics of footwear likely to affect joint loading. And Mueller[25] and his co-researchers (2006) reported that therapeutic footwear and orthotic devices are capable of protecting the foot from excessive plantar pressures during walking. Previous studies D'Ambrogi et al[26] (2005) have pointed out that peripheral neuropathy is responsible for remarkable changes of both structure and function of the foot in diabetic patients. They also observed alterations in plantar pressure distribution in diabetic patients with and without neuropathy, thus suggesting that functional changes may occur before neuropathy becomes evident. Human walking analysis (Versluys[27] 2009) has shown that during walking, there are periods when only one foot is on the ground (single support) and a period when both feet are on the ground (double support). Versluys (2009) analysed that double limb support occurs for two periods of 12% of the gait cycle and single limb support occurs for two periods of 38% of the gait cycle (in intact walking).

From biomechanics point of view, the main goal of footwear is to redistribute force over a large area (that is, to reduce pressure), thereby cushioning foci of elevated pressure. Normally, an insole that conformed to all curvatures of the foot can be used to redistribute the pressure throughout the surface of the foot. But it is important to identify how much the patients use their feet and in what activities.

This knowledge about both the amount and type of use of the feet is critical because, for example, much greater forces are transmitted through the planter tissues from running than walking. And a patient who is chair or bed bound might not need sophisticated footwear to protect the feet, whereas a very athletic patient who has significant foot problems might have to consider changing or altering his or her behavior as well as footwear (Bowker & Pfeifer[28] 2008). The result of a research work carried out by De Castro and his colleagues (2010) show that wearing inappropriate shoes can cause biomechanical imbalance, foot problems, pain and induce falls. The outcome of their work indicate that the percentage of the participant wearing shoe sizes bigger than their foot length was 69.2% for the men and 48.5% for the women. The method to design diabetic footwear is based on characterization of the biomechanical variables appropriate to footwear design. "Of most importance for a diabetic foot is the high pressures under the 1st MTP (metatarsophalangeal) joint. High pressures under the 1st MTP joint are known to be associated with ulceration" (Bernabeu et al[29] 2013).

Footwear materials are described as "natural and synthetic materials which are suitable for footwear manufacture or repair and have adequate wear properties as upper or sole materials" (British Standard, 2007 p. 4). There can be few solid materials in the world which at some time or the other have not been used for footwear (Thornton[30] 1970). Materials like, leather, fabric, wood, brass, glass, iron, e.t.c, are among the numerous materials that have been used or are used for footwear manufacture. But the choice of any of the materials mentioned above for shoe making would be a factor of its availability and suitability.

Upper Materials. Footwear upper materials are manufacture from a wide range of materials. The material which must have the necessary properties for making shoe uppers may be leather, woven, non-woven or knitted fabrics in natural and synthetic fibers, or polymers (Larcombe[31] 1975). Leather stands out as the most suitable material for footwear manufacture, but synthetic alternatives have been invented. The synthetic alternatives are mostly used in making ladies' fashion footwear, mainly because the cost to produce them is lower than that of natural leather products (Covington[32] 2009). "The elegance and durability of a shoe depend to a crucial extent on the quality of the materials used. In consequence, the first rule of shoe making is to exercise great care when selecting the leather for the upper and sole of the shoe" (Vass, 2006 p.96). Therefore, leather is seen as the most effective material for shoe upper because of its properties of plasticity and elasticity (Tyrrell & Carter 2009).

Leather: Leather is animal hide and skin so treated chemically as to make it permanently more resistant to decomposition, particularly when wet (International leather training class, 2001, Covington 2009). It is also described (Willcox[33] 1975) as the pelt of an animal which has been transformed by tanning into a stable, non-putrescible, flexible sheet material. But it can be made as stiff and as tough as wood, as soft and flexible as cloth and anything in between (Covington[34] 2009). Leather is considered as the most suitable material for the manufacture of footwear based on the fact that it provides the foot with good protection against injury, adverse weather conditions and it is extremely easy to work (Vass 2006). The suitability of leather for shoe manufacture is based on certain properties, namely; its abilities to exclude water, but allow air and water vapour to pass through the cross section of the upper. This is also referred to as water absorption and water-vapor permeability. Leather has good elastoplastic and viscous properties which provide reliable shape stability after stretching-lasting operations in shaping footwear on last (Ol'Shanskii et al[35] 2009). Covington (2009) explains that these properties are the basis of 'foot comfort' and are so important that many attempts have been made to mimic them in synthetic materials, the so called poromerics.

Leather remain the preferred material of choice for shoe making because of the way it feels, the way it interacts with and moulds to the feet, the way it looks and the way it wears in use. Leather has excellent performance properties such as high hydrothermal stability of modern chromium (III) tanned leather which allows it to be used in rapid mass production processes, in which shoe uppers are moulded directly onto melted polymeric soles. It also has good plasticity and elasticity properties, which allows it to be moulded to shape and will retain that shape unless it is subjected to moisture and heat. It is especially suitable for footwear manufacture due to the fact that a wide range of finishes, colors and textures can be applied to it. Commenting on the suitability of leather for shoe making, Willcox (1975) states that there is no other material that affords such universal comfort regardless of the season.

In the present, out of 60 patients, 30 patients with MCR footwear, maximum number of patients was 20 patients(66.67%) with nerve conduction velocity ranging between 45-50 and minimum number patients was 2 patients(6.67%) ranging >50 at 3 months of follow up. At 6 months follow up, maximum number of patients with nerve conduction velocity ranging between 45-50 increases to 22 patients (73.33%). This shows that there is improvement with time in the number of patients with

MCR Footwear with nerve conduction velocity ranging between 45-50.

In the present study of 60 patients, on admission 30 patients with MCR footwear, the maximum number of patients with surface area of ulcer ranging between 1-10cm square was 13 patients(43.33%), 11patients (36.67%) were having surface area of ulcer raging between 11-30cm square and 6 patients(10%) were having surface area ranging >30 cm square. When patients were called for follow up at 3 months, the maximum number of patients with surface area of ulcer ranging between 1-10 cm square increases from 11 patients(43.33%) to 20 patients(66.67%), 8 patients(26.67%) were having surface area of ulcer ranging between 11-30 cm square which was 11 patients(36.67%) at the time of admission and 2 patients(6.67%) were having surface area of ulcer >30 cm square which was 6 patients(10%) at the time of admission. When patients were called at 6 months follow up, the maximum number of patients with surface area of ulcer ranging between 1-10 cm square increases to 25 patients(83.33%) which was 20 patients(66.67%) at 3 months follow up and 5 patients(16.67%) were having surface area of ulcer ranging between 11-30 cm square. This improvement and decrease in the size of ulcer at regular follow up intervals was due to MCR Footwear.

In the study done by Dr. A. Sundarambal M.S. et al[36], 60 patients were randomized into group A (TCC), group B (AWC), and group C(modified MCR footwear) of 20 patients each. Ulcer survey was made on 1, 4, 7,14,21, and 28 thereafter every week or two weeks until wounds healed. most of the patients studied in the age group 51-60 years(53.33%), patients in age group 61-70 years were only 5 of them(8.3%). there were 40 males and 20 females, there was not significant difference in healing of ulcers based on the age of patient. Most of the patients in this study had duration of diabetes over 5 years. In group A patients most of the ulcers less than 2 cm square heal by up to 60 days, ulcers more than 3cms square take more than 100 days to heal, in group B patients average time taken for ulcers to heal is 60-100 days, in group C patients it takes more than 12 weeks to heal, some ulcers don't heal, remain same in size.

Edema was reported in 5 cases with 3 patients in AWC and 2 case in MCR group. The risk of infection increases with ulcer size more with the MCR group rather than AWC group.

Healing rate by various off-loading techniques			
	Total No. of Patients	**No. of healed subjects**	**Healing rate (%)**
TCC	20	19	95%
RCW	20	17	85%
MCR	20	9	45%

CONCLUSIONS

In the present study performed at JAWAHARLAL NEHRU MEDICAL COLLEGE with total number of 60patients, 2 groups were divided with 30 patients with MCR Footwear and 30 patients with Non–MCR footwear with the study duration of 2 years.

The objective of this study is to compare the efficacy of MCR footwear patients with Non-MCR footwear patients in the management of diabetic foot ulcer.

Out of 30 patients with MCR footwear, 20(66.67%) patients were having velocity between 45-50 and 8(26.67%) patients were having velocity between 40-45 after 3months follow up and 22(73.33%) patients were having velocity between 45-50 and 7(23.33%) patients were having velocity between 40-45 after 6 months follow up.

Out of 30 patients with Non-MCR footwear, 25(83.33%) patients were having velocity between 45-50 and 5(16.67%) patients were having velocity between 40-45 after 3 months follow up and 22(73.33%) patients were having velocity between 45-50 and 5(16.67%) patients were having velocity between 40-45 after 6 months follow up.

Out of 30 patients with MCR footwear, 28(93.33%) patients were having HbA1C level ≥7 and 2(6.67%) patients were having HbA1C level <7.

Out of 30 patients with Non-MCR footwear, 28 patients were having HbA1C level ≥7 and 2 cases were having HbA1C level <7.

Out of 30 patients with MCR footwear, 13(43.33%) patients were having surface area of ulcer between 1-10, 11(36.67%) patients were having surface area between 11-30 and 6(10%) patients were having surface area >30.

Out of 30 patients with Non MCR footwear, 24(80%) patients were having surface area between 1-10 and 6 (20%) patients were having surface area between 11-30.

At 3 months follow up, out of 30 patients with MCR footwear, 20(66.67%) patients were having surface area between 1-10, 8(26.67%) patients were having surface area between 11-30 and 2 (6.67%)patients were having surface area >30. Out of 30 patients with Non-MCR footwear, 22(73.33%) patients were having surface area between 1-10, 7(23.33%) patients were having surface area between 11-30 and 1(3.33%) case was having surface area >30.

At 6 months follow up, out of 30 patients with MCR footwear, 25(83.33%) patients were having surface area between 1-10, 5(16.67%) patients were having surface area between 11-30 and 0 patient were having surface area >30.

Out of 30 patients with Non-MCR footwear, 17(56.67%) patients were having surface area between 1-10, 12(40%) patients were having surface area between 11-30 and 1(3.33%) patient was having surface area >30.

From this RCT it is concluded that the MCR footwear has improved wound healing as assessed on reduction in ulcer surface area. The wound surface area has decreased at subsequent follow ups at 3 months and 6 months. Hence, MCR footwear are effective in prevention of foot complications.

Recommendation

It is recommended from this randomized controlled trial that the MCR foot wares are effective in reducing the surface area of foot ulcers and thus, in improving wound healing. It is also effective in prevention of other foot complications.

Based on these observations, the MCR footwear can be used as one of the treatment modality for the patients of diabetic foot and also for the prevention of foot complications.

It is further recommended that larger randomized controlled trials with long term follow ups are required to study the effects of other comorbities and reversal of complications in specific.

BIBLOGRAPHY

1. Bal A, Das A, Pendsey S, Suresh K, Vishwanathan V, Ambardekar P. Handbook of diabetic foot care. Diabetic Foot Society of India, Bangalore, 2005.
2. Ahmad J, Masoodi MA, Ashraf M, Rashid R, Ahmad R, Ahmad A, et al. Prevalence of diabetes mellitus and its associated risk factors in age group of 20 years and above in Kashmir, India. Al Ameen J Med Sci., 2011; 4(1): 38-44.
3. Wilman T, Mercke Y, Cerrito P, Taber S. Resection of the metatarsal head for diabetic foot ulcer. Am J Surg., 1998; 176: 436-41.
4. Peters EJ, Lavery LA. Effectiveness of the diabetic foot risk classification system of the International Working Group on the Diabetic Foot. Diabetes care., 2001; 24(8): 1442-7.
5. Wild S, Roglic G, Green A, Sicree R, King H. Global prevalence of diabetes: estimates for the year 2000 and projections for 2030. Diabetes care., 2004; 27(5): 1047-53.
6. Narayan KV, Boyle JP, Thompson TJ, Sorensen SW, Williamson DF. Lifetime risk for diabetes mellitus in the United States. Jama., 2003; 290(14): 1884-90.
7. Honeycutt AA, Boyle JP, Broglio KR, Thompson TJ, Hoerger TJ, Geiss LS, et al. A dynamic Markov model for forecasting diabetes prevalence in the United States through 2050. Health care management science, 2003; 6(3): 155-64.
8. King H, Aubert RE, Herman WH. Global burden of diabetes, 1995–2025: prevalence, numerical estimates, and projections. Diabetes care., 1998; 21(9): 1414-31.
9. Sadikot S, Nigam A, Das S, Bajaj S, Zargar A, Prasannakumar K, et al. The burden of diabetes and impaired fasting glucose in India using the ADA 1997 criteria: prevalence of diabetes in India study (PODIS). Diabetes research and clinical practice., 2004; 66(3): 293-300.
10. King H, Rewers M. Global estimates for prevalence of diabetes mellitus and impaired glucose tolerance in adults. Diabetes care., 1993; 16(1): 157-77.
11. Khatib NM, Quazi ZS, Gaidhane AM, Waghmare TS, Goyal R. Risk factors of type-2 diabetes mellitus in rural Wardha: A community based study. International Journal of diabetes in developing countries., 2008; 28(3): 79.
12. Enathur K. A Study of Prognostic Factors of Diabetic Foot in Relation to Plan of Management.
13. Shaw JE, Boulton AJ. The pathogenesis of diabetic foot problems: an overview. Diabetes. 1997; 46(Supplement 2): S58-S61.
14. Kakrani A, Gokhale V, Vohra KV, Chaudhary N. Clinical and nerve conduction study correlation in patients of diabetic neuropathy. J Assoc Physicians India., 2014; 62(1): 24-7.
15. Al-Sadik FNA. The value of nerve conduction study and F-wave latency in subclinical neuropathic type II diabetic patients. City., 2011; 2012.
16. Hussain Syed S, Gosavi S, Shami W, Bustamante M, Farah Z, Teleb M, et al. A review of sodium glucose co-transporter 2 inhibitors canagliflozin, dapagliflozin and empagliflozin. Cardiovascular & Hematological Agents in Medicinal Chemistry (Formerly Current Medicinal Chemistry-Cardiovascular & Hematological Agents)., 2015; 13(2): 105-12.
17. Shahbazian H, Yazdanpanah L, Latifi SM. Risk assessment of patients with diabetes for foot ulcers according to risk classification consensus of International Working Group on Diabetic Foot (IWGDF). Pakistan journal of medical sciences, 2013; 29(3): 730.
18. Jaleel MA, Raza SA, Fathima FN, Jaleel BNF. Ramadan and diabetes: as-saum (the fasting). Indian journal of endocrinology and metabolism, 2011; 15(4): 268. 207. Reiber GE, Boyko EJ, Smith DG. Lower extremity foot ulcers and amputations in diabetes. Diabetes in America, 1995; 2: 409-27.
19. Reiber GE, Boyko EJ, Smith DG. Lower extremity foot ulcers and amputations in diabetes. Diabetes in America, 1995; 2: 409-27.
20. Smith-Strøm H, Iversen MM, Graue M, Skeie S, Kirkevold M. An integrated wound-care pathway,

supported by telemedicine, and competent wound management—essential in follow-up care of adults with diabetic foot ulcers. International journal of medical informatics, 2016; 94: 59-66.
21. Jude EB, Oyibo SO, Chalmers N, Boulton AJ. Peripheral arterial disease in diabetic and nondiabetic patients: a comparison of severity and outcome. Diabetes care., 2001; 24(8): 1433-7.
22. Petrofsky JS, Cuneo M, Lee S, Johnson E, Lohman E. Correlation between gait and balance in people with and without Type 2 diabetes in normal and subdued light. Medical science monitor., 2006; 12(7): CR273-CR81.
23. Salsabili H, Forogh B, Rajabali S. Dynamic stability training improves standing balance control in neuropathic patients with type 2 diabetes. Journal of rehabilitation research and development, 2011; 48(7): 775.
24. Thorp L, Wimmer M, Foucher K, Sumner D, Shakoor N, Block J. The biomechanical effects of focused muscle training on medial knee loads in OA of the knee: a pilot, proof of concept study. J Musculoskelet Neuronal Interact., 2010; 10(2): 166-73.
25. Mueller MJ, Lott DJ, Hastings MK, Commean PK, Smith KE, Pilgram TK. Efficacy and mechanism of orthotic devices to unload metatarsal heads in people with diabetes and a history of plantar ulcers. Physical therapy., 2006; 86(6): 833-42.
26. Hsu C-C, Tsai W-C, Hsiao T-Y, Tseng F-Y, Shau Y-W, Wang C-L, et al. Diabetic effects on microchambers and macrochambers tissue properties in human heel pads. Clinical Biomechanics, 2009; 24(8): 682-6.
27. Hirsch M, Nguyen V. ESSENTIAL ARTICLES OF PM&R GAIT, ASSISTIVE DEVICES, PROSTHESES, ORTHOSES, and AMPUTATION-RELATED ISSUES. Rehabilitation, 1983; 64(12): 583-7.
28. Delmas L. Best practice in the assessment and management of diabetic foot ulcers. Rehabilitation Nursing, 2006; 31(6): 228-34.
29. Bernabéu JA, Germani M, Mandolini M, Mengoni M, Nester C, Preece S, et al. CAD tools for designing shoe lasts for people with diabetes. Computer-Aided Design., 2013; 45(6): 977-90.
30. Barma TS. Reinforced rubber footwear product. Google Patents, 1993.
31. Rich DC. Australian manufacturing, 1968–1988: Recession, reorganisation and renewal. Geo Journal, 1988; 16(4): 399-418.
32. Zengin A, Candas A, Crudu M, Maier SS, Deselnicu V, Albu L, et al. Eco-leather: Chromium-free Leather Production Using Titanium, Oligomeric Melamine-Formaldehyde Resin, and Resorcinol Tanning Agents and the Properties of the Resulting Leathers. Ekoloji Dergisi., 2012; 21(82).
33. Peterson EA, Peterson HW. Method of heat and tear sealing polyurethane foam material to thermoplastic film. Google Patents, 1964.
34. Widdemer JD. Graphite lubricated leather for use in garments footwear and other leather products; a method for lubricating leather with graphite and a graphite impregnated leather product. Google Patents, 1998.
35. Elliott J, Tudge J. The impact of the west on post-Soviet Russian education: Change and resistance to change. Comparative Education., 2007; 43(1): 93-112.
36. Bus SA, Valk G, Van Deursen R, Armstrong D, Caravaggi C, Hlaváček P, et al. The effectiveness of footwear and offloading interventions to prevent and heal foot ulcers and reduce plantar pressure in diabetes: a systematic review. Diabetes/metabolism research and reviews, 2008; 24(S1).