DEVELOPMENT OF FUNCTIONAL SPACER FABRICS FOR MEDICAL INLAYS IN ORTHOPEDIC SHOES

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Abstract

Foot problems are symptoms of diabetes nellitus. Diabetes will result in narrowing of the blood vessels in the leg (peripheral vascular disease). Bacteria can spread from the infected area into the tissue of the foot, and the body's own ability to fight off bacterial infection is impaired as a result of the poor blood flow into the foot. The Essential Quality attributes of an insole used in diabetic shoes are, Cushioning Energy, Compression set, Water Absorption, Shock Absorption and Anti Bacterial Activity. Most of the materials that are commonly employed for the manufacture of diabetic shoe insoles do not satisfy the stipulated quality requirements.

SITRA has attempted to develop shoe insoles , using warp knitted spacer fabrics. SITRA has selected nylon for spacer materials as well as for the top layer of the insole. Silver coated nylon was used as the top layer since these materials have inbuilt anti bacterial property. A clinical study was performed to evaluate the effectiveness of SITRA's insole material and their ability to relieve problems of diabetic patients like plantar fascitis (heel pain), over pronate (flat feet) etc·

Summary of Conclusions

- SITRA has developed 3D warp knitted spacer fabrics which can be used as insole/liners in diabetic shoes/slippers in combination with Micro Cellular Polymer (MCP).

- SITRA has selected nylon for spacer materials as well as for the top layer of the insole. Silver coated nylon was used as the top layer since these materials have inbuilt anti bacterial property.

- SITRA insoles satisfy all the essential quality specifications (stipulated by International Standard Forming Bodies). These quality specifications include,
  i) Cushioning Energy ii) compression set iii) water absorption and water penetration resistance iv) shock absorbency and v) Anti bacterial property.

- SITRA insoles can be treated with poly urethane (PU) and these insoles are especially suitable for patients with wound in the leg.

- Views of the diabetic patients with regard to the suitability or otherwise of the shoes/slippers made using SITRA insole/SITRA liner materials were obtained from selected diabetic patients. Most of the patients have rated shoes made using SITRA insole/SITRA liner as superior as compared to shoes made using conventional materials.

1.0 INTRODUCTION

Diabetes is a metabolic disorder, which results from the total or partial absence of the hormone, insulin, which is produced in the pancreas.

Foot problems are symptoms of diabetes mellitus. Diabetes will result in narrowing of the blood vessels in the leg (peripheral vascular disease). Bacteria can spread from the infected area into the tissue of the foot, and the bodies' own ability to fight off bacterial infection is impaired as a result of the poor blood flow into the foot. In extreme cases, the infection can spread to the entire foot and no longer be controlled with medication. To avoid these complications, local pressure alleviation from the tissue lesions and replacement of medically adapted shoe with a tailor-made, orthopedic shoe are to be attempted.

Orthopedic shoes combine a variety of materials and they provide support and softness. They either relieve pressure or distribute loads more evenly on the soft parts of the feet, or the leg or spinal joints by equalising the pressure.

At present, materials used as orthopedic shoe inlays & liners are:

i) Micro Cellular Rubber (MCR)

and

ii) Silicon Gel.

The main drawbacks of the above materials are

i) Poor thermo physiological properties

ii) Compression and resilience properties deteriorate with time

iii) Mouldability, maintenance of original thickness when moulded into 3D shape, washing and drying properties are rather poor.

iv] Prone to microbial contamination.

Spacer fabrics can be produced with can release pressure, improve climatic condition and can be treated with antimicrobial finishes. Spacer fabrics are three-dimensional structures and they consist of two outer textile layers, which are linked with file threads[1]. These file threads provide a defined distance between the outer layers, which varies from to 1.0 to 10mm. The construction influences the functionality of the three dimensional structure regarding thermoregulation, breathability, pressure stability and pressure elasticity.

The number of patients with diabetes increases year by year. As per available statistics, more than 40 million diabetics are there in India and most of them have the risk of lesions on the lower extremities[2]. An advanced stage of the disease is the reduced feel for 'Aches'.

Necessary steps useful for diabetic patients are,

i) Pressure release & soft bedding of the foot

and

ii) Measures to prevent infections.

The main objectives of the project are,

— To develop 3 D spacer fabrics as base material for shoe-inlays, particularly for diabetic patients

and

— Identification and application of appropriate antimicrobial finishes to shoe-inlays.

2.0 Materials used at present as Inlays & Liners for Diabetic Shoes

At present, inlays are commonly made by using the following materials,

a) Micro Cellular Rubber (MCR)
b) Micro Cellular Polymer (MCP)
c) Silicon gel
d) Polyurethane (PU) material
e) Croslite material

The Essential Quality attributes of an insole used in diabetic shoes are,

i) Cushioning Energy
ii) Compression set
iii) Water Absorption
iv) Water Resistance (Time for Water Penetration)
v) Shock Absorption
vi) Anti Bacterial Activity

These quality characteristics were evaluated for the five materials commonly used for making inlays and they are given in Table 1.

Table 1 – Quality Attributes of Inlays made out of Different Materials

Sl.No	Properties	Type of Materials				
		MCP Insole	**MCR Insole**	**Silicon Gel**	**PU Insole**	**Croslite**
1	Cushioning Energy (N.mm) Walking	296	256	58	27	268
	Running	460	400	101	40	400
2	Compression Set (%)	48	36	16	6	42
3	Water Absorption (%)	12	10	9	28	5
4	Water resistance (Time for water penetration)	Not penetrating				
5	Shock Absorption (kN)	0.7	0.9	2.5	3.5	5.0
6	Anti Bacterial Activity - Bacterial Reduction (%)	NIL	NIL	NIL	NIL	NIL

The methods employed for assessing the above properties and the instruments used for the same are given in **Annexure – I.**

Relevant Standards/Guidelines values for the quality attributes are given in Table-2.

Table 2. Applicable Standards / Guidelines Values for Quality Attributes

Sl.no	Properties	Standards/Guideline Values	Reference
1	Cushioning Energy (N.mm) Walking	Good- 120 Average- 90 Poor- 60	SATRA TM 59:2002
	Running	Good- 180 Average- 120 Poor- 80	
2	Compression set (%)	Maximum 20	SATRA TM 64: 1996[8]
3	Water Absorption (%)	Not less than 35	EN 12746:2000 Method A[9]
4	Water Resistance (Time for water penetration-min)	Less than 1.0	ISO 5404:2002[10]
5	Shock Absorption (kN)	Less than 5.0	EN ISO 20344: 2004[11]
6	Anti bacterial activity -Bacterial Reduction%	100	AATCC 100;2004[12]

Comparison of Table 1 & Table 2 , reveals the following:

- With respect to cushioning Energy, MCP, MCR and croslite are found suitable to be used for insole. However, for compression set, MCP, MCR and Croslite insoles are not found to be suitable.

- For the shock absorption properly all the materials are found suitable. On the other hand for attributes like water Absorption & water Resistance, none of the material is found suitable.

- Materials like MCP, MCR, Silicon Gel and PU insoles can't be treated for anti bacterial activity. In the case of Croslite, Croslite Ag+ materials are available in the market which have inbuilt anti bacterial property

- It is quite evident that none of the 5 material that are commonly employed for the manufacture of diabetic shoe insoles satisfy all the stipulated quality requirements. Hence, SITRA has attempted to develop shoe insoles which will meet all the quality specification, using warp knitted spacer fabrics.

3.0 Spacer Fabrics for Diabetic Shoe Insoles

3.1 Production of Warp Knitted Spacer Fabrics

Warp knitted spacer fabrics are structures that consist of two separately produced fabric layers which are joined back to back. The two layers can be produced from different materials and can have completely different structures[3]. The yarns which join the two face fabrics can either fix the layers directly or space them apart. It is this three dimensional space which is the special feature of these structures. Typically, spacer fabrics can be from 1 to 15 mm thick, with the two faces being from 0.4 to 1 mm thick. The major single feature of warp knitted spacer fabrics is that virtually any thickness can be obtained, depending upon the type of machinery used and the type of yarns and structures used.

Figure 1 shows the basic set-up of a warp knitted machine in which guide bars 1 and 2 knit the front base fabric on the front needle bar only and guide bars 5 and 6 knit the other separate base fabric on the back needle bar only. Guide bars 3 and 4, which carry the spacer threads knit on both needle bars in succession. The thickness of the spacer depends upon the distance between the two needle bars and can be varied between 1 and 15 mm. In theory the material used in guide bars 1 and 2, 3 and 4 ; and 5 and 6 can be different, as well as the structure of the two base fabrics can be completely different. It is possible to vary the structure from an inelastic, elastic, solid, net or a specific textured surface independently in each face fabric. Further more, the compression and resilience properties of the spacer can be altered at will, depending upon the material and the pattern chains of the threads in guide bars 3 and 4.

Figure 2 shows the structure of a spacer material. The end cross-sectional view of a spacer produced on a warp knitting machine and its compressional capability are illustrated in figures 3 and 4 respectively. One of the major characteristics of these materials is that the spacer yarn is knitted-in the two base structures and can not be pulled-out or fray or ladder when cut during shaping or moulding the product[4].

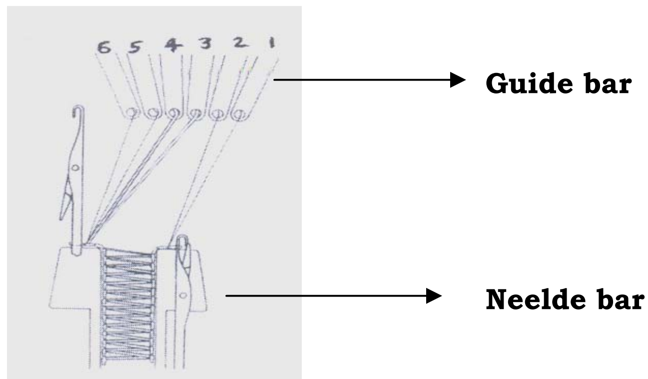


Figure 1 Major knitting elements of a warp knitting machine

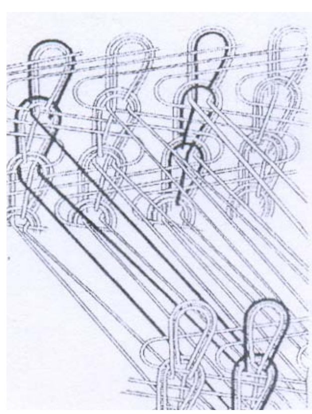


Figure 2 Structure of warp knitted spacer fabric

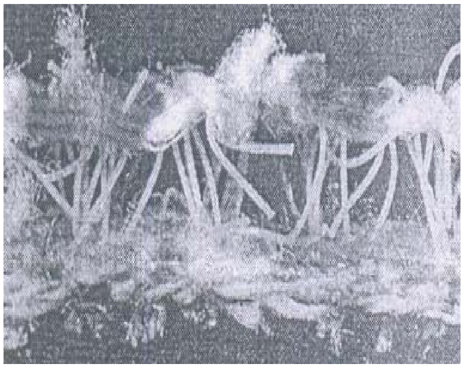


Figure 3 Cross sectional view of warp knitted spacer fabric

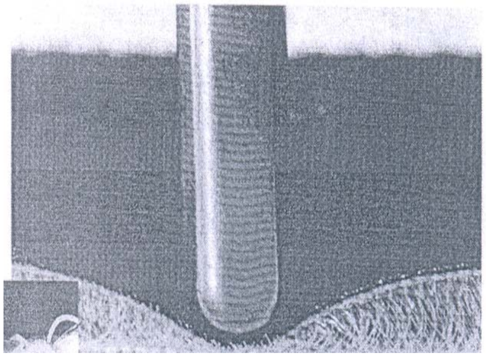


Figure 4 Compression property of spacer fabric

Special features of 3D Spacer fabrics with respect to diabetic shoe insoles [5,6] are,

i) Consequent pressure release and soft bedding of feet to prevent lesions

ii) Creation of a permanent pressure – stable air-conditioned zone, even under the load of the human body.

Hence, warp knitted spacer fabrics are ideally suited for shoe insoles.

3.2 Material Selection For Diabetic Shoe Insoles

Diabetic shoe insoles ought to have good Thermal conductivity, Moisture regain, Elastic recovery & Dimensional stability (Liquid swelling) fibres like cotton, polyester, nylon, & viscose were compared for the above properties (fig 5, fig 6, fig 7, fig 8)

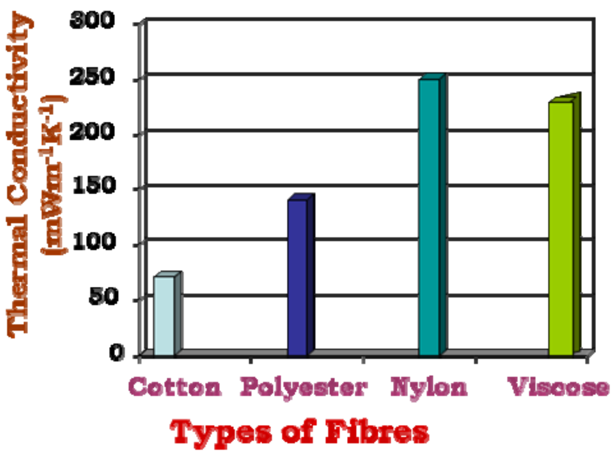


Figure 5. Thermal Conductivity of Different Fibres

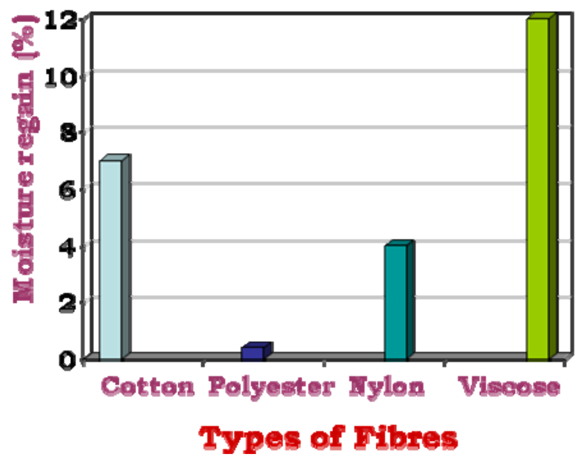


Figure 6. Moisture regain of Different Fibres

Among the 4 fibres, the cotton and Viscose have good moisture regain, Nylon & Viscose have good thermal conductivity.

Elastic Recovery

(Relative Grading)

- ✓ **Nylon - Excellent**
- ✓ **Polyester - Good**
- ✓ **Cotton - Poor**
- ✓ **Viscose - Poor**

Figure 7. Elastic Recovery of Different Fibres

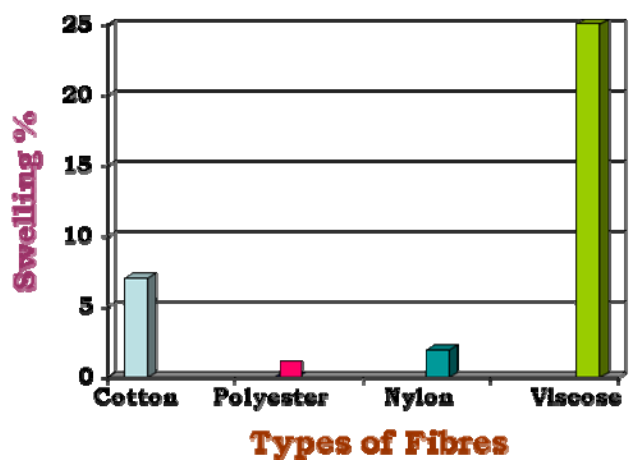


Figure 8. Liquid Swelling of Different Fibres

Higher the swelling – lower the dimensional stability, Nylon & Polyester have good Dimensional stability.

SITRA has selected nylon for spacer materials as well as for the top layer of the insole. Silver coated nylon was used as the top layer since these materials have inbuilt anti bacterial property[7].

3.3 Production of Spacer Fabrics

The Properties of nylon filament used for spacer fabric production in warp knitting machine is given in Table -3

Table 3. Properties of Nylon Thread Material

Sl.no	Properties	Values
1	Filament Denier	77
2	No of filaments	23
3	Tenacity (RKM) (CN/Tex)	35
4	Silver (Ag+) (mg/kg)	12.0

Using nylon filaments, spacer fabrics of 6mm thickness were produced in RD6N –Raschel warp knitting machine.

3.4 Production of Insoles, Socks and Liners

In general, diabetic insoles are made with thickness in the range of 20 to 25 mm. SITRA has made insoles using MCP material at the bottom (10mm thickness) and dyed silver coated nylon spacer fabrics as the top layer (12mm – two 6mm fabrics joined together) so that the insole has a total thickness of 22mm (SITRA Insole).

Liners were made using warp knitted fabrics made out of silver coated nylon threads (thickness 0.5mm – SITRA Liners).

Anti bacterial socks were also made using silver coated Nylon care yarns in Socks knitting machine (SITRA socks).

Quality attributes of SITRA insoles are given in Table – 4.

Table 4. Quality Attributes of SITRA's Insoles Together With Relevant Standards

Sl.no	Properties	Values of SITRA insoles	Standards/ Guideline values
1	Cushioning Energy (N.mm) Walking Running	135 230	120 180
2	Compression set (%)	10.0	Maximum 20 *
3	Water Absorption (%)	310	Not less than 35
4	Water resistance (Time for water Penetration – in Sec)	20	Less than 60
5	Shock Absorption (kN)	0.7	Less than 5.0
6	Anti bacterial Activity -Bacterial Reduction (%) **	99	100

* Lower the value, better is the property

** The method of assessing bacterial reduction% is given in **Annexure1(f).**

It is discernible that SITRA insoles satisfy all the essential quality specifications of a good diabetic insole.

SITRA insoles are given polyurethane coating (PU coating) at the face side. (Side which come in contact with the foot of the patient) these insoles are especially suitable for patients with wound in the leg.

4.0 Subjective Evaluation - Clinical Study

- A clinical study was performed to evaluate the effectiveness of SITRA's insole material and their ability to relieve problems of diabetic patients like plantar fascitis (heel pain), over pronate (flat feet) etc [13,14].

- Using SITRA Insoles and SITRA Liners, 20 pairs of shoes/slippers were made and they were given to 20 diabetic patients, as advised by Diabetic Foot Care Centre – Coimbatore.

- All the 20 Diabetic patients have the problem of increased pressure under one (or) more metatarsal heads when tested with mapping scan.

4.1 Deformities

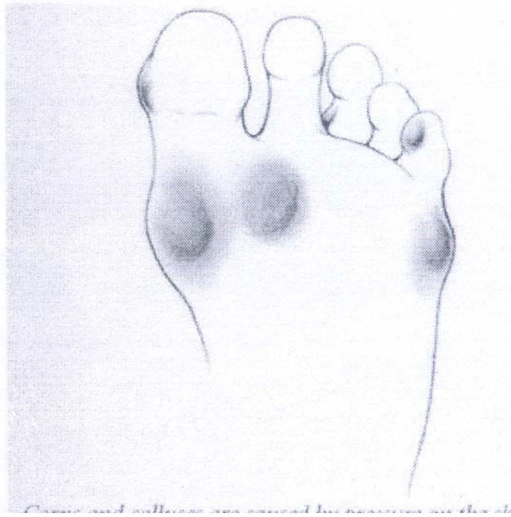
The selected 20 Diabetic patients have one or more of the following deformities.

1) Plantar Fasciitis (heel pain)
2) Calluses
3) Metatarsalgia
4) Morton's Toe
5) Over Pronation (Flat feet)
6) Wounds in leg

– **Plantar Fasciitis (Heel pain)**

Plantar fascitis is commonly traced to an inflammation of the base of the foot. People with varying flat feet (or) very high arches are more prone to plantar fascitis. It may became a chronic condition. This can be anywhere on the underside of the heel. In life time, it is estimated that a human being walks about 1,50,000 km equaling to almost 4 times around the world[15].

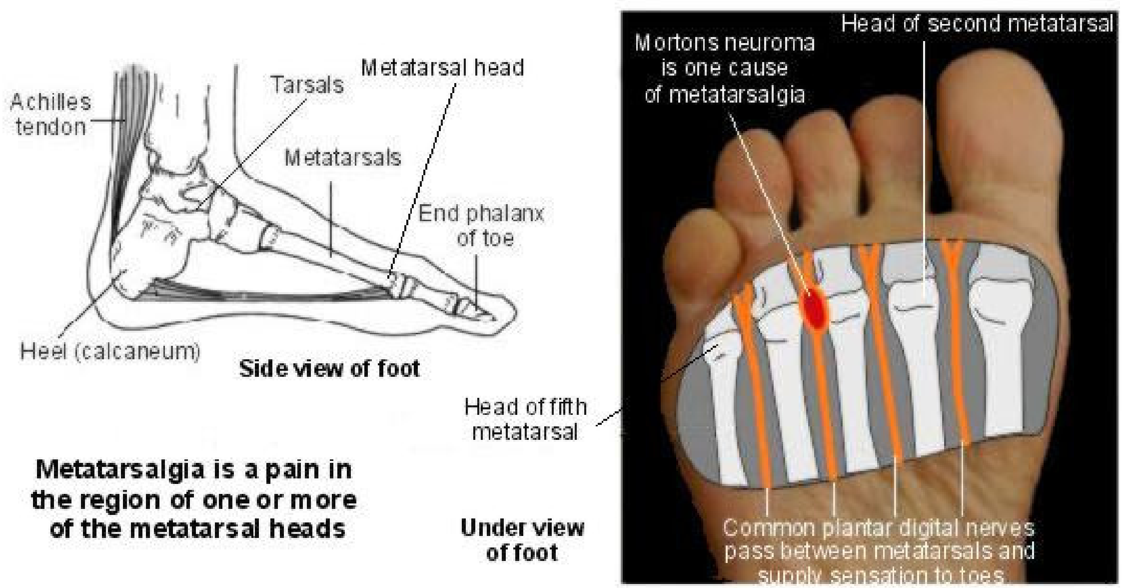
– **Calluses**



Corns and Calluses are caused by pressure on the skin

A calluses is an especially toughened area of skin which has become relatively thick and hard in response to repeated friction, pressure, or other irritation. Calluses are most often found on feet because of frequent walking. Calluses are generally not harmful, but sometimes lead to other problems, such as skin ulceration or infection.

– **<u>Metatarsalgia</u>**



Metatarsalgia is a general name given to pain in the front part of the foot under the heads of metatarsal bones. This is the area on the sole of the foot, just before the toes. It is sometimes called the ball of the foot. Metatarsalgia can be caused by a number of different conditions affecting the foot. It is really a symptom of other problems rather than a specific disease itself.

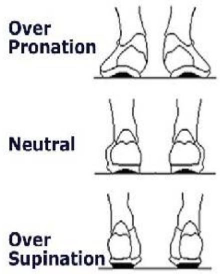
– **Morton Toe**

The Morton's Toe refers to having one or both of two abnormal, inherited conditions of the first metatarsal bone of the foot.

1. The first abnormal condition, and the most noted one, that can cause Morton's Toe is where the first metatarsal bone is shorter than the second metatarsal bone.

2. The second condition is when the first metatarsal bone is not as stable as it should be, and as a result, it has too much motion. Because of this excess motion, it can cause pains all over your body. This abnormal motion of the first metatarsal bone is known as "Hypermobility of the First Metatarsal Bone."

– Over Pronate (Flat Feet)



Pronation describes a slight inward rolling motion the foot makes during a normal walking or running stride. The foot (and ankle) roles slightly inward to accommodate movement. Some people, however, **over-pronate** and roll more than normal. With over-pronation, the arch of the foot flattens and causes excessive stress and pressure on the soft tissues of the foot. Over-pronation is more common in those with flat feet, and can lead to foot aches and pain, such as plantar fasciitis, Shin Splints and Knee Pain.

4.2 Evaluation

Views of the diabetic patients with regard to the suitability or otherwise of the shoes/slippers made using SITRA insole/SITRA liner materials were obtained from the 20 selected diabetic patients. The study was conducted for 4 weeks and at the end of each week, the patients view with regard to the usefulness or otherwise of SITRA Insole/Liner incorporated shoe was obtained.

The suitability of the shoes/slippers was evaluated with reference to 12 different characteristics viz.)

1. Too heavy / light
2. Looks like hospital shoe

} Aesthetics

3. Comfortable to wear [soft feel]
4. Walking feel / running feel [foot pain]
5. Cushioning effect [compression set]
6. Insole back to original position

} Softness Related properties

7. Sweat absorption during walking/running
8. Water absorption [quick drying]
9. Thermal comfort [heat / cool]
10. Comfort walk during rainy time (outdoor)

} Moisture Related properties

11. Itching character
12. Leg ulcer curing time

} Body Comfort Related properties

A gist of the evaluation of the SITRA insole/Liners incorporated shoes/chappels by the diabetic patients is illustrated in Table 5.

Table 3: Views Of Diabetic Patients on SITRA Insole/Liners Incorporated Shoes / Chappels

Total No. of evaluations = 80

Sl. no	Quality parameters / Rating	Aesthetics		Softness Related Properties				Moisture Related properties				Body Comfort related properties	
	Rating	1	2	3	4	5	6	7	8	9	10	11	12*
1	Evaluations indicating SITRA material as superior to conventional material	22 28%	25 31%	41 52%	70 88%	23 29%	22 28%	65 81%	35 44%	57 72%	61 76%	52 65%	- -
		Avg = 29%		Avg = 50%				Avg = 68%				Avg = 65%	
2	Evaluations indicating SITRA material as same as conventional material	58 72%	55 69%	39 48%	10 12%	57 71%	58 72%	15 19%	45 56%	23 28%	19 24%	28 35%	- -
		Avg = 71%		Avg = 50%				Avg = 32%				Avg = 35%	
3	Evaluations indicating SITRA material as inferior to conventional material	0 0%	0 0%	0 0%	0 0%	0 0%	0 0%	0 0%	0 0%	0 0%	0 0%	0 0%	- -

**Three patients have given their views on leg ulcer curing time. All the three have rated SITRA material as superior.*

SITRA insole/liners were evaluated as superior to conventional materials by i) About 65 – 70% of the patients with regard to Moisture related and comfort related properties, ii) About 50% of the patients for softness related properties and iii) About 30 % of the patients for Aesthetics.

About 35 % of the patients, have rated SITRA insoles as equivalent to conventional material, for Moisture & Comfort related characteristics. 50 to 70 % of the patients rated SITRA material as equivalent to conventional material for softness and Aesthetics.

None of the patients have evaluated SITRA insole/liners as inferior to conventional material for any of the relevant quality attribute.

In General, most of the patients have rated shoes made using SITRA insole/SITRA liner as superior as compared to the conventional shoes (made using MCP materials). All the performance evaluation study sheets are enclosed in **ANNEXURE – II**.

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for insole and socks, water absorption and desorption.

10 Standard Test Method ISO 5404: 2002 Determination of water Resistance of heavy leathers.

11 Standard Test Method EN ISO 20344: 2004 personal protective Equipment, test method for foot wear.

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ANNEXURE – I

Methods Employed and Instruments used for evaluation of Quality Attributes of Inlays

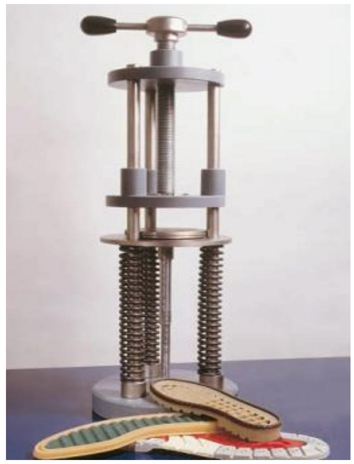
a) Determination of Cushioning Energy

Cushioning properties of insole materials were studied by using the test method SATRA 159. In this test, a sample is compressed under pressure equivalent to pressure during walking and running.

Cushioning Energy is the energy required to gradually compress a specimen of the material up to standard pressure and is measured using a tensile testing machine. This is expressed in N.mm

ANNEXURE – I (Contd.)

b) Determination of compression set



Compression Set Apparatus

During walking, a shoe sole (or top piece) is subjected to compression forces and deformation due to flexing with each step, which temporarily increases its area. By the completion of the step, practically all of this increase in area is lost. However, if the soling or top piece is slightly plastic, they do not completely recover and some of the increase in area is retained. Such a soling, therefore, gradually increases in size during wear.

The compression set apparatus (due to SATRA) can be used to assess solid, cellular and micro-cellular rubbers under constant stress conditions (TM 64). Using this equipment, sample discs are cut from the sole or top piece material and are held between spring loaded-platens for a given time under a constant pressure. By using several spacers, tiers of specimens can be tested at the same time. The thickness of the discs is measured before and after the test and the decrease in thickness provides an indication of the compression set of the material.

$$\text{Compressional set (\%)} = \frac{\text{Initial Thickness} - \text{Final Thickness}}{\text{Final Thickness}} \times 100$$

c) Determination of Water Absorbency

Water Absorption Tester

1) Standard method : EN 12746:2000 (Method A)

2) Principle : Pendulum Lever principle

3) Sample size : 100 mm length
40 mm width

4) Water absorption (%) : $\frac{\text{Volume of water absorbed}}{\text{Volume of sample in cm}^3} \times 100$

d) Determination of Water Resistance

Water Resistance tester

1) Standard method : ISO 5404; 2002

2) Principle : Pendulum Lever principle

3) Sample size : 100 mm length
   40 mm width

4) Time taken for water to penetrate into the test specimen is recorded in seconds.

e) Determination of Shock Absorbency

Shock Absorbency Tester

1) Standard method : EN ISO 20344 ; 2004 [Method 5.17]

2) Principle : Impact principle

3) Sample size : 70 mm Dia

4) Drop height : 0.2 metre

5) Shock load applied on the specimen : 10 Joules

6) Shock absorption measured in terms of kN.

f) Determination of Anti Bacterial Activity

Antibacterial Activity of the spacer specimens (used as shoe insoles) was evaluated using SITRA's Bacterial Filtration Efficiency Tester (SBFET).

SITRA's Bacterial Filtration Efficiency Tester

This test method has been specifically designed for measuring bacterial filtration efficiency using (*Staphylococcus aureus*) as the challenge organism. The use of *S. aureus* is based on its clinical relevance as a leading cause of nosocomial infections. The test method has been designed to introduce a bacterial aerosol challenge to the test specimen at a flow rate of 28.5 liters/min.

ANNEXURE – I (Contd.)

This test method allows the aerosol challenge to be directed through either the face side or inner side of the test specimen, allowing evaluation of filtration efficiency. The mean particle size of the bacterial aerosol generated is maintained at 3.0 ± 0.3 μm as per relevant ASTM specifications (Designation F 2101 – 01).

A model test report giving the bacterial filtration efficiency of a test specimen is depicted in Table 6.

Table 6 Model test report

<table>
<tr><th>Sl. No.</th><th>Test Particulars</th><th colspan="3">Results</th></tr>
<tr><td>1.</td><td>Area of test specimen</td><td colspan="3">ϕ 100 mm</td></tr>
<tr><td>2.</td><td>Flow rate of aerosol</td><td colspan="3">28.5 L/min ± 0.5L</td></tr>
<tr><td rowspan="9">3.</td><td rowspan="9">Aerosol particles deposited in agar plates</td><td>Plate numbers</td><td>Control (C)</td><td>Test (T)</td></tr>
<tr><td>1.</td><td>3728</td><td>257</td></tr>
<tr><td>2.</td><td>2991</td><td>224</td></tr>
<tr><td>3.</td><td>2318</td><td>187</td></tr>
<tr><td>4.</td><td>1416</td><td>147</td></tr>
<tr><td>5.</td><td>949</td><td>78</td></tr>
<tr><td>6.</td><td>762</td><td>56</td></tr>
<tr><td>Total</td><td>12164</td><td>949</td></tr>
<tr><td>Average</td><td>2027.33</td><td>158.16</td></tr>
<tr><td>4.</td><td>Bacterial filtration efficiency of test specimen
$= \left\{ \frac{C - T}{C} \right\} \times 100$</td><td colspan="3">92.19%</td></tr>
</table>

Where,

C = Average plate count total for test controls

T = Plate count total for test sample.