STUDIES AT SITRA IN THE AREA OF MEDITECH

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COIMBATORE

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SITRA: COE FOR MEDITECH

- **SITRA involved in a number of Meditech related projects:**

  I) Bacterial Filtration Efficiency Tester
  II) Functional Spacer Fabrics for Medical Inlays in Orthopedic Shoes
  III) Speciality 3D Compression Bandages for Lymphedema
  IV) Barbed, Bi – Directional Surgical Sutures
  V) Instrument to Assess Barrier Properties of OT Apparels to Blood & Blood Borne Pathogens

Current Meditech Projects in SITRA

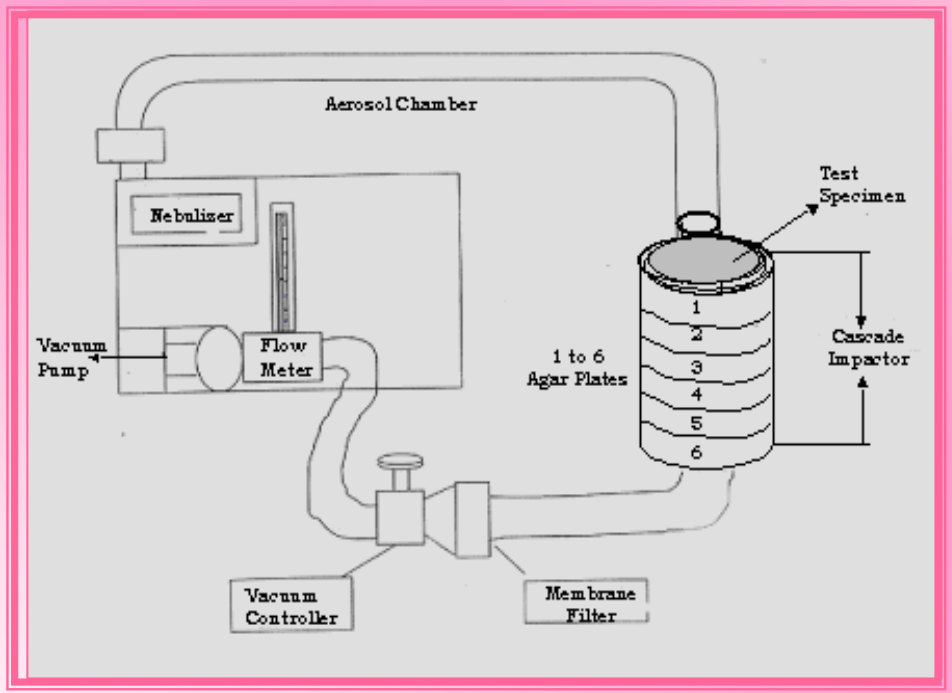
Bacterial Filtration Efficiency Tester
— Healthcare workers involved in treating and caring for injured, sick and patients exposed to biological aerosols capable of transmitting diseases
— These diseases caused by a variety of micro organisms and pose significant risks to life and health

Need for Development

—	**Indigenous instruments are not available to assess bacterial filtration characteristics**
—	**Imported instruments are cost-prohibitive**
—	**Hence, SITRA has designed and fabricated one instrument**

SBFET

SITRA's Bacterial Filtration Efficiency Tester



Line Diagram of SBFET

SBFET Developed By SITRA

Special Features of SBFET

—	**The Nebulizer used is capable of delivering mean particle size of bacterial aerosol at 3.0 µm ± 0.3 µm**
—	**The test method is specifically designed for measuring BFE using S. Auerus as the challenge organism. S. Auerus is found to be the leading cause of nosocomial infections**
—	**The test method allows the aerosol challenge to be directed either through the face side or inner side of the test specimen, allowing evaluation of BFE related to patient-generated aerosols and wearer-generated aerosols.**

A Model Test Report from the Tester

S. No.	Test Particulars	Results		
1.	Area of test specimen	ϕ 100 mm		
2.	Flow rate of aerosol	28.3 L/min		
3.	Aerosol Particles Deposited in Agar Plates	Plate Nos.	Control (C)	Test (T)
		1.	3728	257
		2.	2991	224
		3.	2318	187
		4.	1416	147
		5.	949	78
		6.	762	56
		Total	12164	949
		Avg	2027.33	158.16
4.	Bacterial Filtration Efficiency $\frac{C - T}{C} \times 100$	92.19%		

Barrier Properties of Woven Surgical Gowns

- Single use surgical products proved superiority in terms of resistance to bacteria.
- Majority of Indian hospitals, only woven products
- Exact number of washing cycles of surgical apparels yet to be established
- In Coimbatore, surgical gowns are used up to 30 washes, 50 washes and still the fabric gets torn in many hospitals
- Hence, an investigation conducted at SITRA to assess the barrier properties of surgical gowns

BARRIER PROPERTIES OF WOVEN SURGICAL GOWNS (contd..)

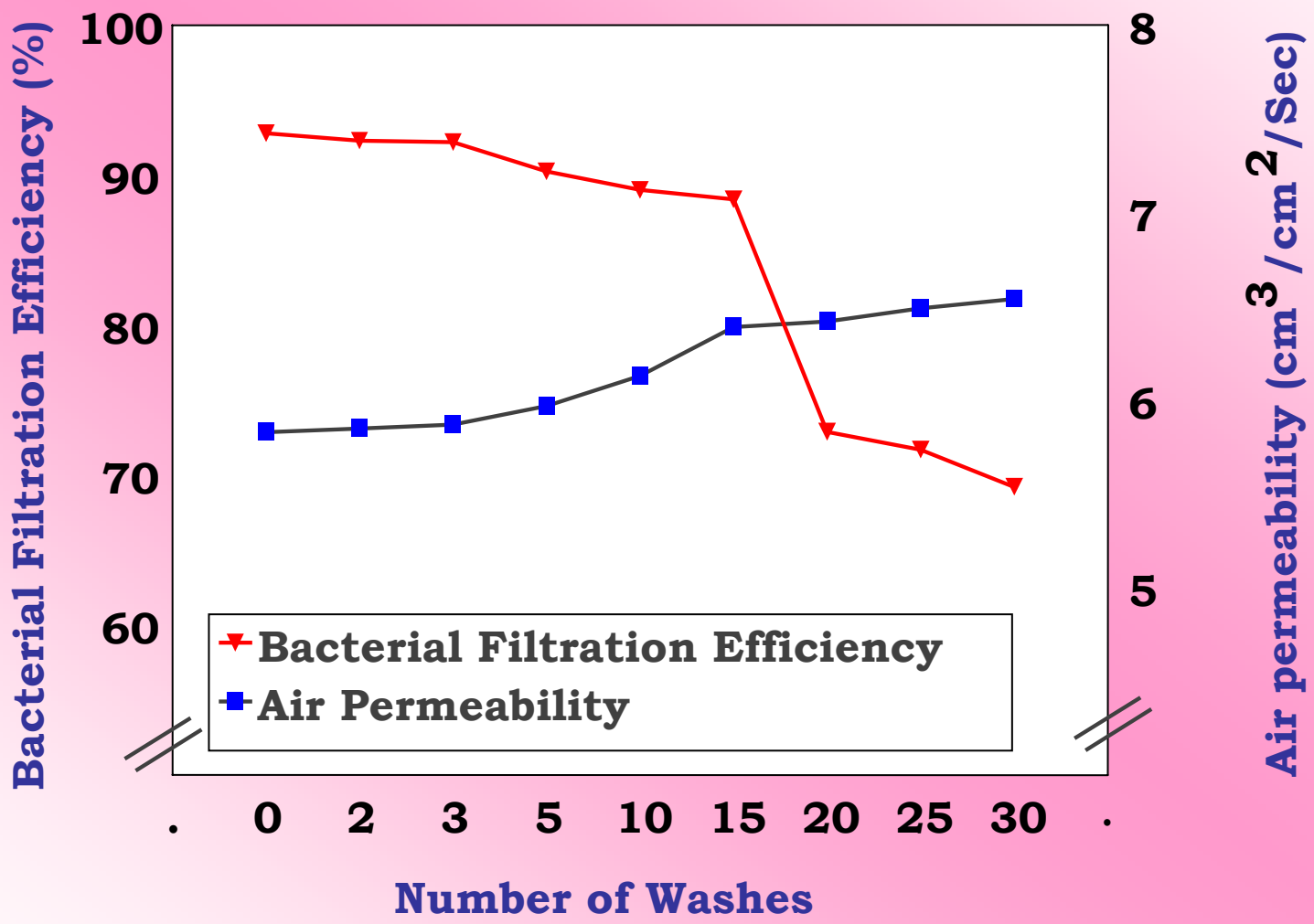
- Regularly used woven surgical gowns from a leading hospital in Coimbatore collected for quality evaluation
- The gowns are made using cotton yarns with quality specifications as follows:

Weave	Plain
Count of Warp (Ne)	41.8s
Count of Weft (Ne)	41.0s
Ends/Inch	142.0
Picks/Inch	72.0
Fabric Weight (gsm)	129.7

BARRIER PROPERTIES OF WOVEN SURGICAL GOWNS (contd..)

—	Surgical gowns collected from local hospitals and allowed to '0' wash and 5, 10, 15, 20 25 and 30 washes using industrial laundering machine.
—	After every wash, the fabric samples were sterilised in an autoclave.
—	All the samples evaluated for bacterial filtration efficiency
—	The fabric samples also tested for air permeability.

Bacterial Filtration Efficiency and Air Permeability of Surgical Gowns (Woven – Green)



SITRA's BFET

- SITRA'S BFET is suitable for testing non-woven Meditech also
- Testing of face masks carried out
- Melt Blown Non-woven
- Gsm range : 20 to 40
- BFE : 97 to 98%

Tests Carried out for BFE using SITRA's Bacterial Filtration Efficiency Tester

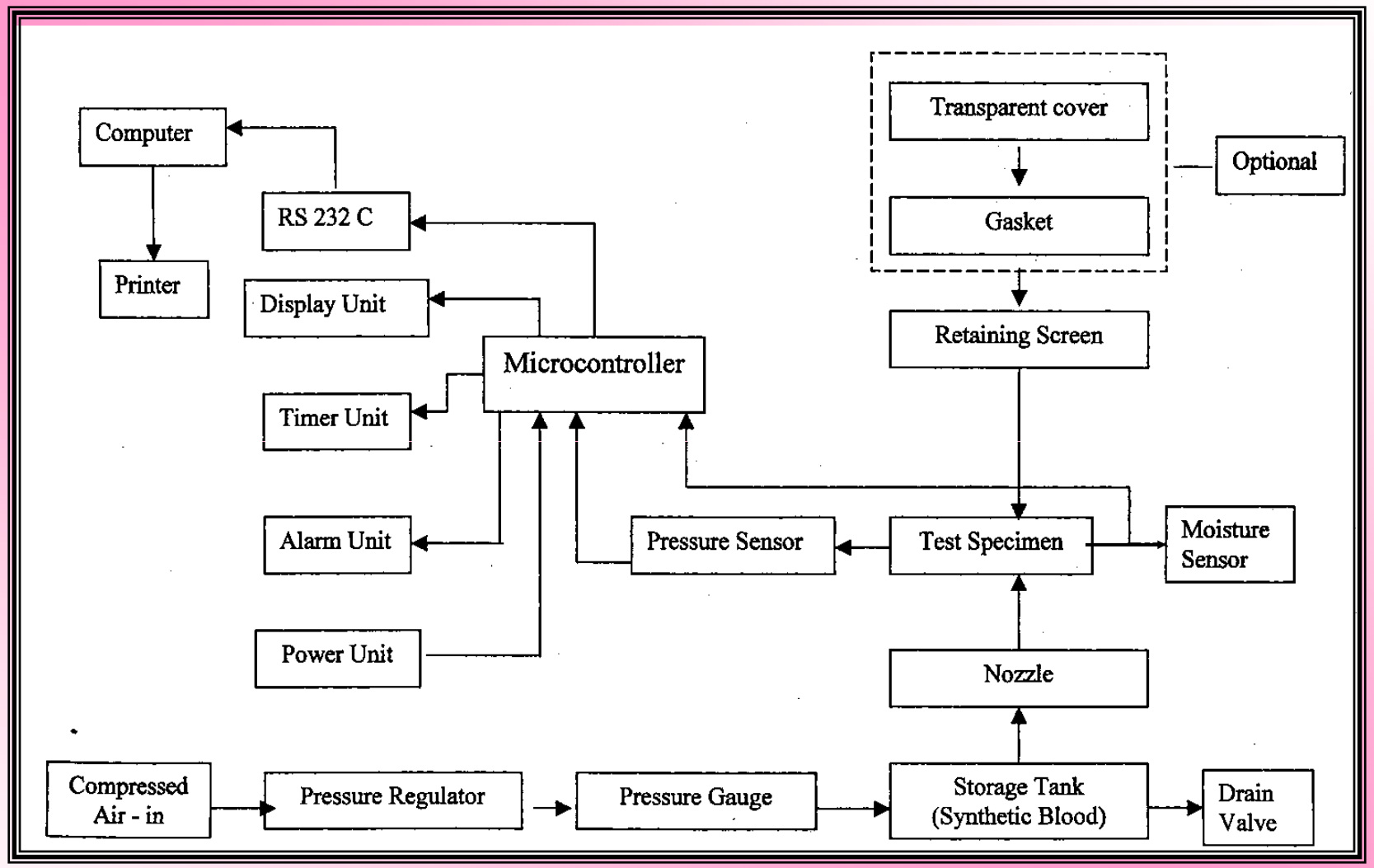
1. Sri Balaji Creations, Salem
2. Thea-tex Healthcare (India) Pvt. Ltd, Pune
3. Corporation of Madurai, Madurai, TN
4. AIM Filter Tech Pvt. Ltd, Pune
5. Kovai Medical Centre and Hospital (KMCH), Coimbatore
6. Alpha Foam Pvt Ltd, Pune

Instrument to Assess Barrier Properties of OT Apparels to Blood & Blood Borne Pathogens

—	**The proposed instrument is to evaluate the resistance of materials used in surgical apparels to penetration by blood and blood borne pathogens.**
—	**Synthetic blood is used as a simulant to blood**
—	**Synthetic Blood** **: A mixture of red dye/surfactant, thickening agent and distilled H_2O having surface tension & viscosity values approximately matching with that of blood**

Characteristics of Synthetic Blood

—	**The surface tension range for blood and body fluids (excluding saliva)** **Ω 0.042 to 0.060 N/m**
—	**The ST synthetic blood is adjusted to the lower end**
—	**Resulting ST of synthetic blood is** **Ω 0.042 ± 0.002 N/m**



Block Diagram of the Instrument Developed (Proto type)

Development of Barbed Bi-Directional Sutures

- Surgical sutures are the most frequently used biomaterial for wound closure and tissue approximation.
- However, they rely on the surgeon's ability to tie secured knots, which is a challenging and time consuming process.
- Improper tieing and handling can result in knot breakage or slippage.
- Further, the knot impedes wound healing, constricts blood flow, distorts tissue and increases scar formation.

Barbed, Bi-directional Surgical Sutures (contd..)

— To overcome these problems, attempts have been made to design self-anchoring sutures.

— Recently, a novel knotless suture has been developed in which bi-directional barbs are introduced into an absorbable monofilament suture using micro-machining techniques.

Magnified Mid-Section of Barbed Suture

Barbed, Bi-directional Surgical Sutures (contd..)

— The knotless design has significant potential in reducing scar tissue due to the absence of a significant foreign body reaction caused by knots.
— The barbed configuration anchors the sutures into tissue and provides adequate tissue adhesion while the wound heals under minimum residual tension and pressure.

Functional Spacer Fabrics for Medical Inlays In Orthopedic Shoes

- Diabetes is a metabolic disorder - total or partial absence of the insulin – which is produced from pancreas.
- Diabetes will result in narrowing of the blood vessels in the leg.
- Body's ability to fight off bacterial infection is impaired
- Local Pressure alleviation from the tissue lesions
- Use of Orthopedic Shoes

OBJECTIVES

—	**Develop base material for shoe-inlays for diabetic patients**
—	**Apply appropriate antimicrobial finishes to the shoe inlays and liners**

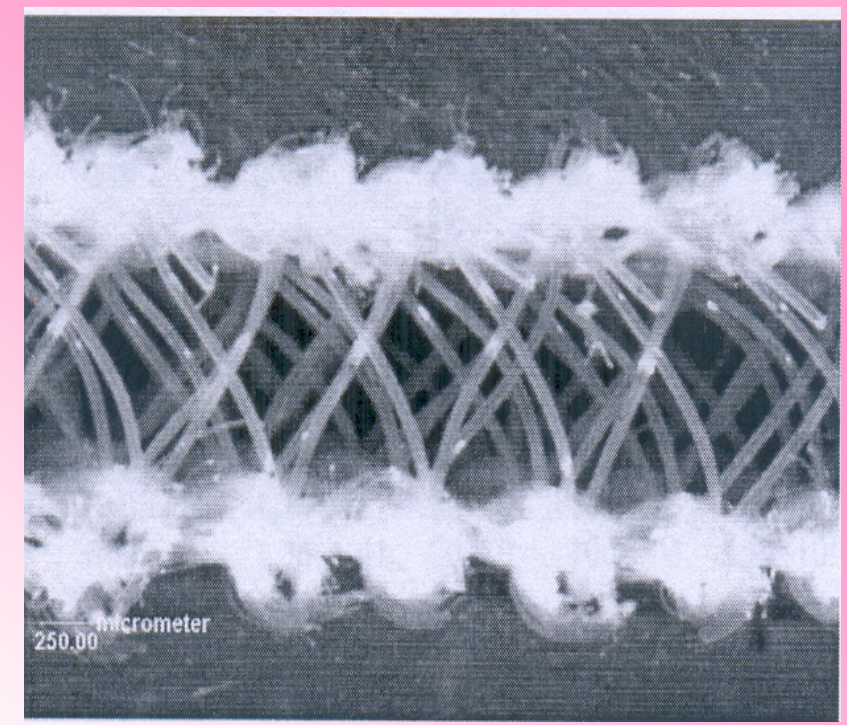
Materials used at present as Inlays & Liners

	Micro Cellular Rubber (MCR) **: Smoothness & comfort** **: Shock absorber to reduce the impact on heel bone, knee and pelvic area**
—	**Silicone Gel (Medical grade)** **: Absorbs impact during stance phase while walking** **: Silicone zone at the heel and metatarsal reduce skeletal shock and redistribute peak pressure**

Drawbacks of Material Used at Present for Orthopedic Shoe Inlays

- **Poor themophysiological properties**
- **Compression and resilience properties deteriorate with time**
- **Mouldability, maintenance of 3D shape, washing & drying properties poor.**
- **Prone to microbial contamination.**

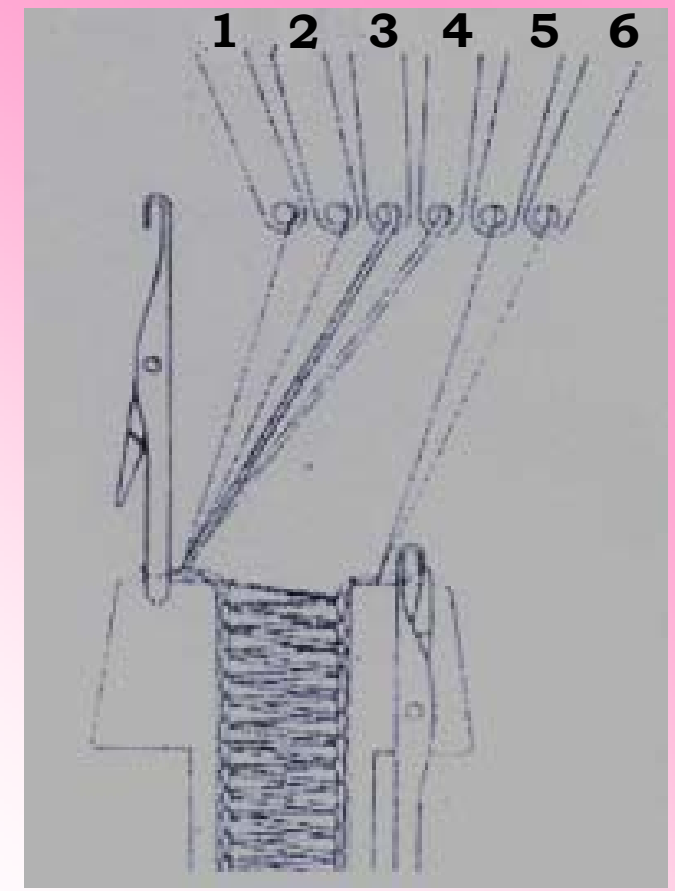
Appropriate Technology & Fibre for the Shoe Inlays Meant for Diabetic Patients



Profile of a three-dimensional spacer fabric

—	Warp knitted spacer textiles
—	Compressive elasticity and breathability
—	Faster healing for venous leg ulcer applications

—	Using spacers, fabrics of varying diameters can be made to provide correct level of pressure at different parts of the leg.



Major knitting elements of a Warp knitting machine

—	Guide bars 1 and 2 knit the front base fabric on the front needle bar
—	Guide bars 5 and 6 knit the other separate base fabric on the back needle bar
—	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 varied between 1 and 15 mm

Appropriate Technology & Fibre (contd..)

General Characteristics of Spacer Textiles

:	**Top layers to provide anti-microbial property**
:	**Middle and bottom layers to provide dimensional stability and abrasion resistance**
:	**Spacer material to have good wickability**

SITRA Inlay

- Six spacer fabrics joined together

1st & 2nd SF	Top Layer	PA 6.6 – multifilament with silver ions (% of silver 0.015)
	Middle & Bottom Layers	Nylon filament 78 D
Subsequent SF	All the layers	Polyester filament

SITRA Shoe Liner

—	Thin fabric layer (0.5 to 1.0 mm) made out of PA 6.6 multifilament with silver ions (% of silver 0.015)
—	Could be made either in weaving or in warp knitting
—	Polyester multifilament with silver ions can also be used for liner

Inlays to be placed inside the shoe

—	As per direction from doctors, inlays with different thickness at different points are prepared.
—	The final form of inlay varies from patient to patient

SPECIALITY 3D COMPRESSION BANDAGE FOR LYMPHEDEMA

What is Lymphedema?

- **Lymphatic drainage system (Secondary Circulation System) is impaired. The volume of lymphatic fluid – Exceeds the Lymphatic transport system capacity.**
- **Cabin-pressure during air flight less.**
- **Diminished pressure results ↓ in Lympathic system – fluid will remain extra cellular spacers.**
- **This gives rise to ↑ swelling in a Lymphedematous Limb**

Symptoms of Lymphedema

Swollen and Twisted Veins

Deep Venous Thrombosis (DVT)

Venous Ulcer

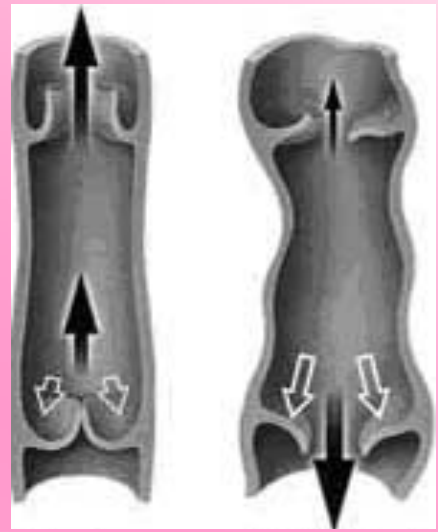
Basic Reason for Lymphedema

—	**Blood is pumped from the heart to the legs through arteries**
—	**After giving up oxygen and nutrients, blood returns to the heart through the veins**
—	**For this, blood from the legs must flow forward, against gravity**
—	**The flow is assisted by one-way valves inside the veins, which prevent the blood from flowing backwards**

Basic Reason for Lymphedema (contd..)

—	**Improper blood flow in lower legs due to damage to the valves**

—	**When the valves broken due to malnutrition or over work, the blood is flowing backwards**



Normal and incompetent valves
In healthy and in varicose veins

—	**Veins stretch, enlarge, bulge and twisted beneath the skin**

Treatment for Lymphedema

Compression Therapy

- Deliberate application of pressure to the lower limb, using a variety of materials

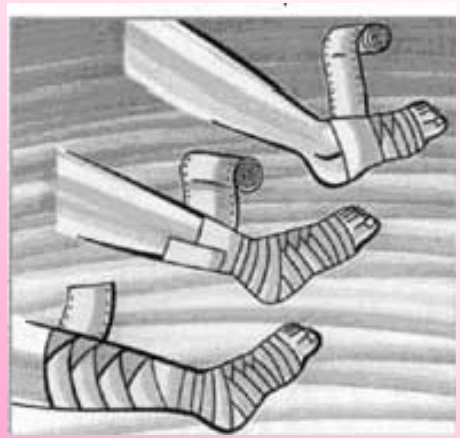
Compression Bandaging

- Compression therapy is the only promising treatment in prevention of vascular disorders in legs

Treatment for Lymphedema (Contd...)

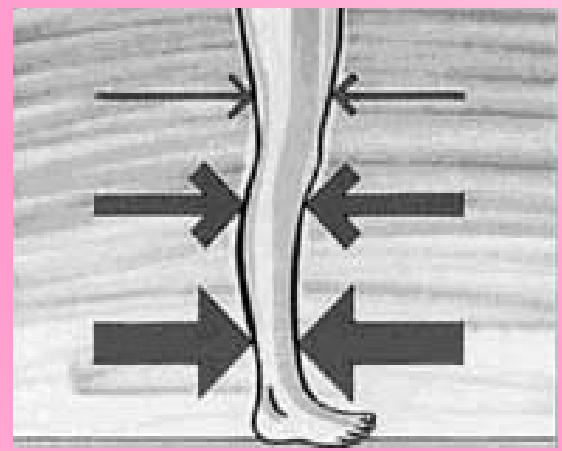
Compression Bandage

- Short stretch bandages more suitable after an operation or for a weeping ulcer



Compression Stockings

- Ideal option where compression is needed for a longer period of time
- Provides highest compression at the ankle (100%), less at the knee (70%) and the least in the thigh (40%)
- Helps for return of blood from the legs



Bandages for Lymphedema

1. **Crepe Bandages**

- **Warp – Cotton**
- **Weft – Viscose**
- **Warp High Twisted**

} **Stretch : 60%**

2. **Elastic Bandages**

- **Warp – Rubber filament**

+

P/C Material

- **Weft – P/C yarns**

} **Stretch : 400%**

- **Elastic Bandages – Intensive Treatment**
- **Crepe Bandages – After Intensive Treatment for Regular use**

Limitations of bandages (Lymphedema) used at present

A) Crepe Bandages: (Made out of Cotton & Viscose)

- Elasticity is low
- Mainly offer support than compression function

B) Elastic Bandages: (Made out of rubber filament & P/C material)

- Have allergic effects on skin
- Have low frictional resistance

Special Textile Structure for Compression Bandages

- **Spacer Fabrics – For potential use in oedema Treatment.**

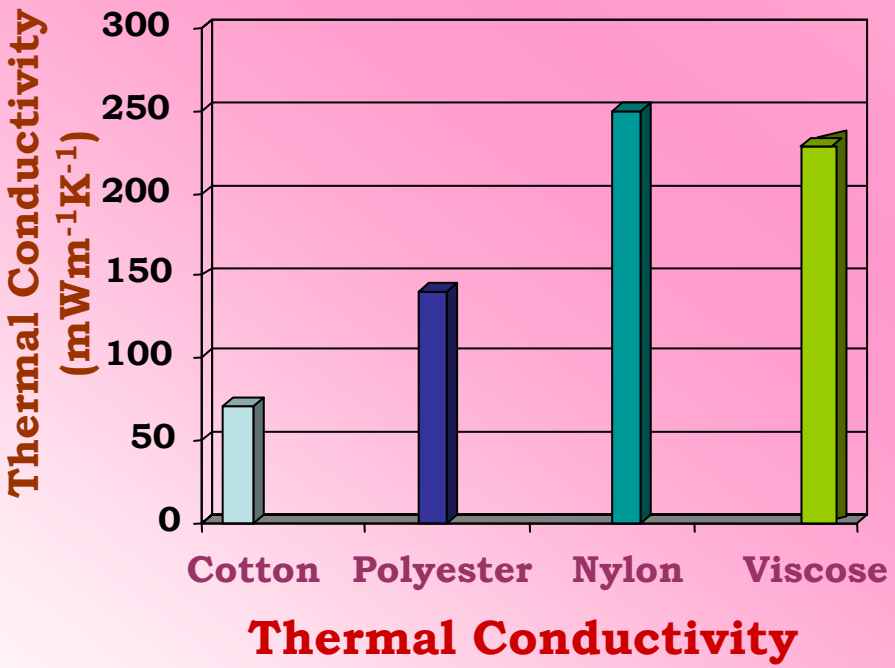
  *** Direction Oriented transport of Fluids & Heat by optimization of material & Technologies**

- **Provide more comfort while being worn**

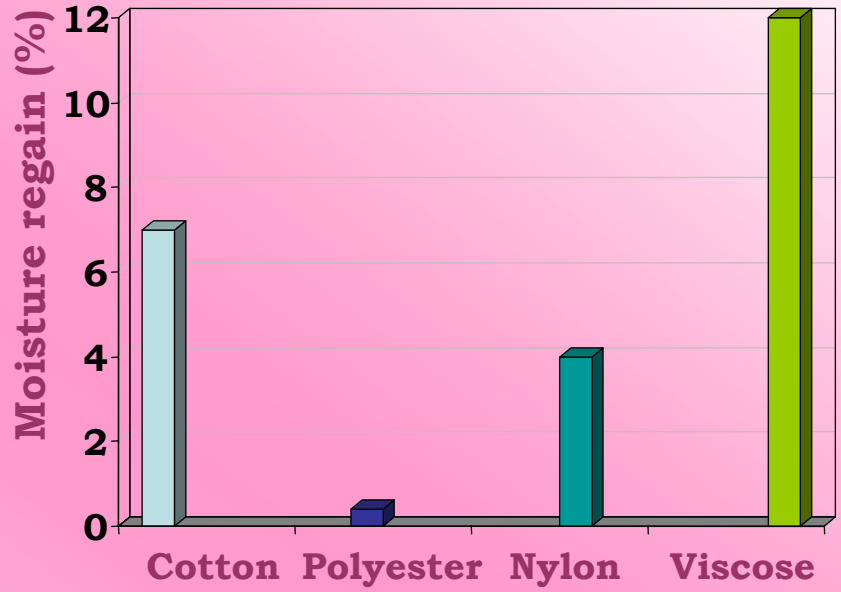
- **Duration time of treatment could be shortened**

Selection of Spacer Material

- Compression bandage ought to have good dimensional stability, thermal conductivity, Elastic recovery & Good Moisture regain.



Thermal Conductivity



Moisture regain

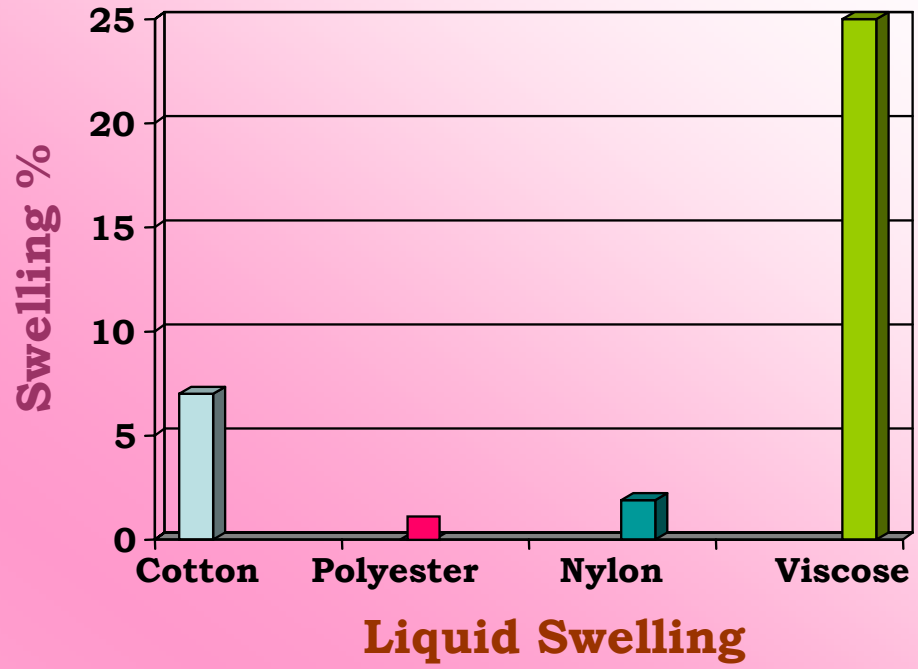
- ✓ Among the 4 fibers, the cotton & Viscose have good Moisture regain
- ✓ Nylon & Viscose have good thermal conductivity

Selection of Spacer Material (Contd...)

Elastic Recovery

(Relative Grading)

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



- ✓ **Higher the swelling - lower dimensional stability**
- ✓ **Viscose has poor dimensional stability**
- ✓ **Polyester has good dimensional stability**

Selection of Spacer Material (Contd...)

- **Cotton has good moisture regain and noticeably lower thermal conductivity. Hence cotton is suitable as surface layer which comes in contact with the skin. But cotton is not suitable as spacer material.**
- **Inorder to have good level of stretch for the compression bandage, core yarn with lycra as core and cotton as sheath may be used as a surface layer.**
- **Nylon has better thermal conductivity & Higher Elastic recovery. Hence Nylon is suitable as Spacer material (Threads).**

Selection of Spacer Material (Contd...)

- **Nylon & Polyester have good dimensional stability. One of these two may be used as the top layer.**

SITRA'S 3D Spacer Compression Bandage