Medical Instrumentation: SITRA’s Contribution

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Abstract
Medical textile is one of the technical textiles which provide the advanced medical devices used by the healthcare professionals for enhancing their medical procedure. However, lot of manufacturing and quality evaluation equipments/instruments are available to produce and evaluate the quality of the product for conventional textiles. In case of medical textile, since, it is in growing stage, the development of manufacturing equipment and quality evaluation instrument is limited. Hence, SITRA has made an attempt to design and develop the manufacturing equipments as well as quality evaluation instruments and the same is detailed in this review. In this review, testing instruments developed by SITRA are explained in detail. SITRA has designed fabrication instruments like bacterial filtration efficiency tester and blood penetration resistance tester. Bacterial filtration efficiency tester could be used to assess the barrier properties of medical apparels such as surgical face masks against air-borne pathogens. Air-borne pathogens such as Staphylococcus aureus are used for the bacterial filtration efficiency test. Blood penetration resistance tester is used to assess the resistance of materials used in the protective clothing for penetration by blood and blood-borne pathogens. Apart from these instruments, SITRA has also developed manufacturing equipment like Barb creating equipment which is used to introduce barbs on the surface of monofilament form sutures. The produced sutures from this equipment are called as “Barbed Bi-directional surgical sutures” which is used for knotless operation procedure.

Keywords: SITRA, medical textile, bacterial filtration efficiency tester, blood penetration resistance tester, sutures.

Introduction
SITRA is one amongst the chain of textile laboratories in the country sponsored by the Textile industry and supported by the Ministry of Textiles, Govt. of India. It is an autonomous scientific research organization registered in May 1951 under the Societies Registration Act. It is governed by a Council of Administration which includes representatives of the Industry, the Central and State Governments and the scientists from reputed Institutions. SITRA has been recently designated as ‘Centre of Excellence for Medical Textiles’. SITRA is known for the bench marking exercises in spinning productivity which has helped the textile mills in India to constantly increase their productivity and thereby to stay competitive. At present, SITRA has a membership of around 250 textile units spread all over India and overseas. Over the past 5 decades, SITRA has been helping mills to fix work assignments for operatives in various departments based on scientific assessment. Work assignment studies jointly referred by both management and workers are also being taken up. SITRA has been undertaking techno-economic viability studies for more than three decades. As Centre of Excellence (CoE) for Meditech, SITRA has developed a number of testing instruments for evaluation of quality attributes of Meditech products. These instruments are not indigenously available and imported equipments are cost-prohibitive. Three major Meditech quality evaluation instruments (Vasudevan and Chellamani, 2013) developed by SITRA in the recent past are enumerated in this review.

Meditech instruments

Bacterial filtration efficiency tester: SITRA’s Bacterial Filtration Efficiency Tester (SBFET) is shown in Fig. 1 (Chellamani and Thiruppavai, 2009). The surgical apparel is clamped between a stage cascade impactor and an aerosol chamber. The bacterial aerosol is introduced into the aerosol chamber using a nebulizer and a culture suspension of Staphylococcus aureus.

Fig. 1. Bacterial Filtration Efficiency Tester developed by SITRA (Chellamani and Thiruppavai, 2009).
Barrier properties of woven surgical apparels: Woven surgical apparels that are regularly used in a leading hospital at Coimbatore were collected and their quality particulars evaluated. The apparels are made out of cotton yarns with quality specifications as given in Table 2. Surgical apparels were collected from the hospitals in Coimbatore and they were subjected to ‘0’ wash, 5 washes, 10 washes, 15 washes, 20 washes, 25 washes and 30 washes in an industrial laundering machine. Every time, after a wash, the fabric samples were sterilized in an autoclave. Conditions maintained during the sterilization process are given in Table 3. Then, all the surgical apparels were evaluated for bacterial filtration efficiency as per the above procedure. The fabric samples were also tested for air permeability (volume of air passed through a given area of fabric in a given time at a given pressure) as per standard procedure (Designation ASTM D 737–04–Standard test method for air permeability of textile fabrics). Bacterial filtration efficiency (BFE) and air permeability of surgical apparels subjected to different number of washes are shown in Fig. 2.

Table 1: Model test report.

<table>
<thead>
<tr>
<th>Test particulars</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Area of test specimen</td>
<td>Ø 100 mm</td>
</tr>
<tr>
<td>Flow rate of aerosol</td>
<td>28.3 L/min</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Aerosol particles deposited in agar plates</th>
<th>Plate numbers</th>
<th>Test</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>257</td>
<td>3728</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>224</td>
<td>2991</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>187</td>
<td>2318</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>147</td>
<td>1416</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>78</td>
<td>949</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>56</td>
<td>762</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>949</td>
<td>12164</td>
</tr>
<tr>
<td></td>
<td>Average</td>
<td>158.16</td>
<td>2027.33</td>
</tr>
</tbody>
</table>

Bacterial filtration efficiency:

\[
\text{C} - \frac{\text{T}}{\text{C}} \times 100 = 92.19\%
\]

\[\text{T} = \text{With fabric specimen in the cascade impactor}, \]

\[\text{C} = \text{Without fabric specimen in the cascade impactor}.\]

The aerosol is drawn through the medical apparel using a vacuum attached to the cascade impactor. The six stage cascade impactor uses six agar plates to collect aerosol droplets, which penetrate the medical apparel material. Control samples are collected with no test specimen clamped in the test apparatus to determine the upstream aerosol counts. The agar plates from the cascade impactor are incubated at 37±2°C for 48±4 h and counted to determine the number of aerosol particles collected. The ratio between the aerosol particles deposited in the agar plates–when there is no test specimen in the apparatus and the aerosol particles prevented from deposition due to test specimen is expressed as the bacterial filtration efficiency. This test method has been specifically designed for measuring bacterial filtration efficiency of medical apparels 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 28.3 L/min. This flow rate is within the range of normal respiration and within the limitations of the cascade impactor. 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 efficiencies related to both patient-generated aerosols and wearer-generated aerosols. The mean particle size of the bacterial aerosol generated is maintained at 3.0±0.3 µm as per relevant ASTM specifications (Designation F 2101–07). A model test report giving the bacterial filtration efficiency of woven surgical apparel is depicted in Table 1.

Table 2: Quality specifications of medical apparels.

<table>
<thead>
<tr>
<th>Weave</th>
<th>Plain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Count of warp (Ne)</td>
<td>41.8s</td>
</tr>
<tr>
<td>Count of weft (Ne)</td>
<td>41.0s</td>
</tr>
<tr>
<td>Ends/Inch</td>
<td>142.0</td>
</tr>
<tr>
<td>Picks/Inch</td>
<td>72.0</td>
</tr>
<tr>
<td>Fabric weight (gsm)</td>
<td>129.7</td>
</tr>
</tbody>
</table>

These apparels are without any special finishes.

Table 3: Process conditions during sterilization.

<table>
<thead>
<tr>
<th>Process parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterilization temperature</td>
<td>121°C</td>
</tr>
<tr>
<td>Sterilization time</td>
<td>30 min</td>
</tr>
<tr>
<td>Drying time</td>
<td>25 min</td>
</tr>
<tr>
<td>No. of cycles</td>
<td>3.0</td>
</tr>
</tbody>
</table>

Fig. 2. Bacterial filtration efficiency and air permeability of surgical apparels.
However, no norms or guideline values have been established till date for the bacterial filtration efficiency of woven medical apparels. Guideline values for BFE are available for non-woven operation theatre garments (ASTM F 2100, 2007). BFE should be greater than 95% for the medical apparel to be considered as safe as an operation theatre garment. Assuming minimum BFE for a woven medical garment to be around 85% (BFE of woven garment will always be lower than that of non-woven garment due to the difference in fabric structure), the study indicates that woven surgical apparels can be safely used only up to 17 to 18 washes or so. The reduction in BFE of woven apparels with repeated washings is fully substantiated by the increase in air permeability of the respective fabrics. Increase in fabric air permeability with repeated washings is an indication that the fabric structure gets opened up with repeated washings due to which the BFE of the fabrics starts deteriorating. However, the exact number of washes up to which the surgical apparel can be used may be influenced by the type of weave, thread density of the fabric etc. This aspect needs further investigation. In order to increase the longevity of medical apparels, the available options are:

1. Use of non-woven medical apparels
2. Use of woven medical apparels treated with appropriate anti-microbial finishes.

**Blood penetration resistance tester**

As infectious diseases like AIDS, hepatitis, SARS etc. have reached alarming levels, the knowledge and means of protection from these diseases need to be improved. In an operation theatre, the body of the person to be operated works as a source of infection. Unless the doctors and other co-workers are protected from outside, they might be infected as well. Therefore, these personnel use a protective garment called surgical apparel to safeguard from undesirable infection (Behera and arora, 2009). Different kinds of raw materials are used for manufacturing surgical apparels. They are i) 100% Cotton and Polyester/Cotton blended fabrics, ii) Micro filament fabrics and iii) Multilayer fabrics. Two kinds of surgical apparels are used at present in hospitals and they are disposables, manufactured using non-woven fabrics and Reusables made using woven fabrics. Single-use surgical apparels are made from non-woven materials. Non-woven is defined as “a manufactured sheet, web or batt of directionally or randomly oriented fibres or filaments, excluding paper and paper products, that are woven, knitted, tufted or stitch bonded and have not been converted into yarns”. The three most commonly used non-woven fabrics for the surgical apparels and drapes are spunlace, spunbond-meltblown-spunbond (SMS) and wet-laid (Chellamani and Balaji, 2010). The spunlaced fabric is a hydro-entangled material consisting of wood pulp and polyester fibres. The SMS fabric refers to a fabric consisting of three thermally or adhesively bonded layers (spunbond layer provides the strength and the meltblown layer provides the barrier properties). The wet-laid fabric consists of wood-pulp fibres. The fibres are suspended in water to obtain a uniform dispersion and then they are separated from the slurry by drawing the water through a fine mesh screen (Weicao, 2007). The use of surgical apparel when it came into existence was to protect the patients from surgical team members. So, the requirement was just to have a relatively loosely woven, readily permeable and comfortable cotton material. But, with the growing concerns about the emergence of hazards associated with the transmission of blood-borne pathogens, its purpose suddenly has changed into protecting the surgeon and paramedical staff from the patients as well. Therefore, the surgical apparel ought to protect the blood-borne pathogens from penetrating through the fabric and the fabric needs to be liquid proof. At the same time, the apparel must provide comfort to the wearer by allowing heat and humidity to exchange between interior and exterior of the body. In other words, the fabric should be barrier resistant as well as comfortable to wear. Therefore, the major requirements of the fabric are that they resist the penetration of liquids, particularly blood and at the same time be sterile, breathable, flexible and inexpensive (Numi et al., 2003). In view of the non-availability of indigenous instruments for assessing the barrier properties of the treated fabrics, these fabrics are at present mostly imported together with the relevant test certificates. Due to this, the cost of the treated fabrics (treated against the penetration of blood and other body fluids) is rather high and this stands in the way of majority of the Indian hospitals going for treated surgical apparels.

**Design and fabrication of a blood penetration resistance tester:** SITRA has designed and fabricated a blood penetration resistance tester using the following principles (Chellamani et al., 2012).

1. Measurement of resistance of fabrics to the penetration of blood under constantly increasing hydrostatic pressure.
2. Sensing the presence or otherwise of blood traces on the fabric specimen using capacitive type sensors.

SITRA’s blood penetration resistance tester (SBPRT) is shown in Fig. 3 and 4. A 70 watts diaphragm type compressor is connected to a 1.5 L air reservoir (AR) (with drain valve). The output of the reservoir is connected to a charge valve. This valve is used to control the air supply to pressure regulator (PR). The charge flow regulator is kept between distributor–1 and pressure regulator. The distributor–1 has two outlets. One outlet is connected to test head and the other outlet is connected to distributor–2. The distributor–2 has three outlets. One outlet is connected to pressure sensor and the second outlet is connected to vent flow regulator. The third outlet is connected to exhaust valve. Vent flow regulator adjusts the exhaust air quantity from the test head through the vent valve.
Fig. 3. SITRA’S Blood Penetration Resistance Tester (Chellamani et al., 2012a).

Fig. 4. SITRA’S Blood Penetration Resistance Tester – Line diagram (Chellamani et al., 2012a).

The vent flow regulator is connected to the vent valve which is used to maintain uniform air pressure over the test specimen. Pressure sensor is used to measure air pressure present in the test head and provides the pressure details to the micro controller. The test head is used to hold the test specimen, synthetic blood, transmit probe and receiving probe. The instrument works as per ASTM Designation F 1670 -07. After fixing a sample in the test head, the test head is filled with synthetic blood. The sample is allowed to contact with a synthetic blood for about 5 min. Air pressure is developed in the air reservoir (AR) using compressor. After the completion of 5 min time period, the charge valve is operated to allow the pressurized air to the test head with the rate of 0.25 to 0.5 psig/stroke. The charge flow regulator regulates the inlet pressure to the test head. The test head obtains the full pressure of 2.0 psig within 6-14 sec. For the next 1 min, the test head pressure is maintained within the range of 2.0±0.2 psig. The preprogrammed microcontroller helps to maintain the pressure in the test head with the help of charge valve, vent valve and pressure sensor. Here, pressure sensor monitors the test head pressure and sends the pressure details to the micro controller. If the pressure is higher than 2.2 psig, the vent valve will operate to release the excess pressure. If the pressure is lower than 1.9 psig, the charge valve will operate to charge the required pressure to the test head.

After 1 min, the exhaust valve is operated to release the air pressure from the test head. For next 54 min, the sample is kept in test head in contact with synthetic blood without any pressure. The traces of blood present on the reverse side of the sample are sensed using capacitive type sensors. SITRA’s Blood Penetration Resistance Tester (SBPRT) has already been licensed for commercial manufacture and has also taken a provisional patent for this Instrument (Provisional patent No.4988/CHE/2012).

Barb creating equipment to produce Barbed, bi-directional surgical sutures

To close a wound, sutures must be knotted. Hence, certain general principles are followed to tie the knots and all kinds of suture materials (Dunn, 2009). Suture knots must be properly placed to be secure. Speed in tying knots may result in less than perfect placement of the suture strands. In addition to variables inherent in the suture materials, considerable variation can be found between knots tied by different surgeons and even between knots tied by the same individual on different occasions. Suture failure occurs at the knot since local stresses weaken the fibre. Tying knots requires time and extensive training. Because of the manner in which they are placed, conventional sutures are prone to various complications due to presence of knots and excessive wound tension. Potential problems include (Bendavid, 2001; Leung et al., 2003; Storch and Rice, 2005; Edlich and Long, 2008; Robins et al., 2008; Fleisher and Ludwig, 2010):

1. Knot breakages and slippage
2. Suture extrusion or ‘spitting’
3. Infection
4. Dehiscence
5. Reduced breaking strength and inflammation
6. Ischemia and scarring

In order to avoid problems associated with knotting of sutures, SITRA has undertaken a project to develop knotless sutures through the introduction of bi-directional barbs into absorbable monofilament suture using appropriate techniques. Equipment/Instruments to introduce bi-directional barbs on the absorbable mono filament suture are not commercially available in India. Hence, SITRA has ventured into fabricating appropriate equipment for the purpose.

Development of a barb creating equipment by SITRA: SITRA has designed and fabricated equipment for introducing barbs in suture materials (Chellamani et al., 2012). A barb in a suture thread is characterized by a set of dimensions as shown in Fig. 5. SITRA’s Barb Creating Equipment (SBCE) has the following features:

1. Facility to select desired barb depth and barb angle
2. Facility to alter the distance between barbs
3. Facility to select the helical angle of the suture on which the barbs are placed.
SITRA has conducted trials to optimize a) barb angle, b) helical angle of the monofilament suture and c) barb depth in the barbed suture. Using the optimum process variables, bulk samples of barbed sutures were produced. The barbs introduced on the thread are of bi-directional (ie) if barbs are to be introduced in a thread of 100 mm length, they are divided into two equal groups that face each other in opposing directions from the suture mid-point. The magnified mid-section of a barbed suture is shown in Fig. 8. Extending beyond the barbed sections are unbarbed sections of the monofilament for about 20 mm (10 mm on both the sides of the thread) in a suture thread of 100 mm length. The unbarbed sections on a barbed suture thread are to facilitate easy handling of the same during surgical procedures. SITRA has already taken a provisional patent for the barb creating equipment (Provisional patent No.528/CHE/2012).

Conclusion
The emerging trends in the advanced development of new products are essential for medical textiles especially health and hygiene sector. At the same time the quality evaluation of advanced meditech products are also essential. Hence, SITRA continuously focus on developing indigenous advanced technology and implementing the same for utilizing their benefit such as high production and its advanced protection against pathogens.

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