A STUDY ON POLYPROPYLENE OPHTHALMIC SURGICAL DRAPES

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BONAFIDE CERTIFICATE

Certified that this project report titled "A STUDY ON POLYPROPYLENE OPHTHALMIC SURGICAL DRAPES" is the bonafide work of Mr. M.Kalyana Kumar who carried out the research under my supervision. Certified further, that to the best of my knowledge the work reported herein does not form part of any other project report or dissertation on the basis of which a degree or award was conferred on an earlier occasion on this for any other candidate.

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ABSTRACT

Barrier effect is one of the very important characteristics in Ophthalmic Surgical drapes, between the sources of infection and the user (i.e. a healthy person), as well as good wearing comfort. This parameter has assumed a lot of significance mainly because this is one of the key parameters affecting the surgical performance.

Based on the findings, the existing product and the functional design process utilizing a study of Polyethylene surgical drapes do not fulfill the surgical performance. Research was done by designing the two Polypropylene nonwoven surgical drapes, Spun Melt Spun [SMS] and Spunbond to fulfill the surgical performance.

It was found out that, the Spun Melt Spun surgical drape offered better structural barrier effect as well as good wearing comfort than the Spun Bond and Polyethylene surgical drapes. The existing product had provided a firm foundation for undertaking the new product redesign. These are evaluated with reference to their structural properties.

Keywords:

Polypropylene, Structural barrier effect, Nonwovens.

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

List of symbols, Abbreviations or Nomenclature

PP	-	Polypropylene
SMS	-	Spun Melt Spun
SSI	-	Site Infection
HIV	-	Human Immunodeficiency Virus
CJD	-	Creutzfeldt-Jalob Disease
ETO	-	Ethylene oxide
OR	-	Operation room
LT	-	Linearity of load
WT	-	Tensile Energy
RT	-	Tensile resilience
B	-	Bending rigidity
2HB	-	Hysteresis of bending moment
G	-	Shear stiffness
2HG	-	Hysteresis of shear force at 0.5° shear angle
2HG5	-	Hysteresis of shear force at 5 ° shear angle
LC	-	Linearity of compression
WC	-	Compressional energy
RC	-	Compressional resilience

CHAPTER 1
INTRODUCTION

The first uses of textiles in medical area came from the efforts of recovering from illnesses and healing wounds, but as the importance of healthcare became important in humanlife, people tried to discover and develop more complicated textile products which do not only protect humanbody, but also save humanlife. With new discoveries in area of both textile and medicine, fabric technology advances with the medical industry's need for better, stronger, more protective attire, more and more developments will help protect and provide comfort for medical personnel.

Fabric-makers, however, are challenged on two fronts, making the fabric to meet the highest levels of protection, but also creating a garment that is comfortable and does not impede wearers from performing their jobs to their best abilities. Too often, medical personnel must choose between protection and comfort. In the past, to increase protection for the wearer, comfort had to be sacrificed. Impervious and heavy drapes are numerous and have been developed. They provide the protection but are very uncomfortable for the wearer. Conversely, more comfortable surgical drapes were, by definition, less protective. Indeed, fabric-makers have made huge strides in the design of new materials for this purpose

Design is a process best undertaken through an organized effort and a problem solving approach. Understanding the complex set of requirement that must be addressed by a successful new product, Ophthalmic Surgical drapes must have a barrier effect between the sources of infection and the user, as well as good wearing comfort. By their end users, legal, financial or other requirements, the existing product and the functional design process utilizing a study of surgical drapes (Polyethylene) does not fulfill the requirements. Design analysis is a major thrust of this surgical research. Successful creation of this new design named Spun Melt Spun and Spun Bond drapes had made a great boon to the surgical users.

CHAPTER 2

LITERATURE REVIEW

2.1 Disposable Drape

The main purpose of draping in medical application are to cover the patient to create a sterile barrier and also to prevent migration of microbes from non-sterile to sterile areas, to maintain a sterile field throughout the surgical procedure and also to prevent from the surgical site infection(SSI). Kevin Frey CST, MA (1985), shows the ideal characteristics of drapes. It should have

1. Blood and fluid resistant to strike-through
2. Resistant to punctures and tears
3. Flexible to contour to patient's body
4. Lint free to prevent contamination of the surgical wounds

From his conclusion the draping material should not possess negative effect towards the environment and surgery. The negative effects can be minimized by the proper choice of the material compositions.

However, studies show that the Increasing awareness on the need for better infection control, particularly with respect to human immunodeficiency virus (HIV), Creutzfeldt-Jakob disease (CJD) and hepatitis B, has drawn attention toward providing improved bacterial barriers, microbial penetration resistance of single-patient drapes and gowns is much superior to that of reusable drapes and gowns

Another factor in the reusable/disposable dynamics is pricing. Reusable drapes and gowns have a relatively higher initial cost but can be used between 50 and 100 times. Still, they involve other overhead and logistics costs such as sterilization and laundering. Thus, when total costs are considered, the single-patient nonwoven products tend to prove less expensive than the reusable alternatives.

2.2 Polypropylene Fibre

Olefin fiber is a manufactured fiber in which the fiber-forming substance is any long-chain synthetic polymer composed of at least 85% by weight of propylene units. This highly crystalline thermoplastic resin is built up by the chain-growth polymerization of propylene (CH2=CHCH3), a gaseous compound obtained by the thermal cracking of ethane, propane, butane, or the naphtha fraction of petroleum.

The melting point of polypropylene (160-170°C) is an advantage in many nonwovens. PP fiber can be softened sufficiently to bond to one another without destroying fiber properties. Nonwoven fibers made from polypropylene can therefore be fusion-bonded, eliminating the need for chemical binders. The benefits of this technique are from both energy saving and environmentally friendliness

2.2.1 Fiber Structure of Polypropylene

Polypropylene fibers are composed of crystalline and non-crystalline regions. The spherulites developed from a nucleus can range in size from fractions of a micrometer to centimeters in diameter. The a-axis of the crystal unit cell is aligned radially and the chain axis is homogeneously distributed in planes perpendicular to this radial direction. Each crystal is surrounded by non-crystalline material. Fiber spinning and drawing may cause the orientation of both crystalline and amorphous regions. If the extension is less than 0.5%, the spherulite deformation is elastic and no disruption of the structure occurs, otherwise spherulites are highly oriented in the direction of the force and finally are converted to microfibrils. These highly anisotropic microfibrillar structures lead to anisotropic fiber properties.

2.2.2 Crystallinity of PP Fiber

The degree of crystallinity of PP fiber is generally between 50-65%, depending on processing conditions. Crystallization occurs between glass transition temperature (Tg) and the equilibrium melting point (Tm). The crystallization rate of PP is fast at low temperature. It is reported that the crystallization rate decreases with increasing crystallization temperatures and also decreases with the increase of molecular weight. A Para crystalline structure with only 45% crystallinity resulting from immediate quenching after extrusion was observed. A significantly higher crystallinity of 62% was achieved when quenching further downstream of the die. Heat setting removes the residual strains and produces a defect-free and stable crystalline structure to make fiber/fabrics dimensionally stable. It also improves the percentage of overall crystallinity. The smectic structure changes to a more perfect monoclinic structure. During the process of heat setting if the temperature is above 70°C. At 145°C the conversion is almost complete. In comparison to the predominantly smectic form, the monoclinic form does not experience any major change in crystalline structure during the course of drawing and heat setting.

2.2.3 Mechanical Properties

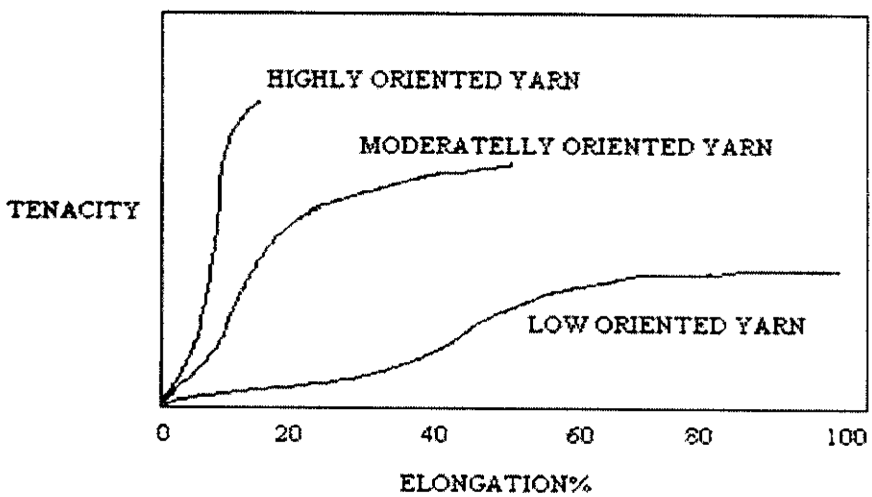
Table 1 Physical Properties of Polypropylene

Moisture regain	<0.1%
Refractive index	1.49
Thermal conductivity	0.95 in/ft^2.hr
Coefficient of linear thermal expansion	4.0 x 10^{-5}
Heat of fusion	21 cal/g
Specific heat	0.46 cal/g.C
Density of melt at 180° C	0.769 g/cc
Heat of combustion	19,400 lb

Oxygen index	17.4
Decomposition temperature range	328-410°C
Dielectric constant (0.1 M Hz)	2.25
Dissipation factor (0.1 M Hz)	<0.0002
Specific volume resistivity	$>10^{16}$.cm

The general physical properties of PP fibers are shown in Table 1. Polypropylene fibers are produced in a variety of types with different tenacities designed to suit varying market requirement. Fibers for general textile uses have tenacities in the range of 4.5-6.0 g/den. High tenacity yarns up to 9.0 g/den are produced for the use in ropes, nets and other similar applications. High performance PP fibers have been made with high strength and high modulus. The techniques include ultra-drawing, solid state extrusion and crystal surface growth. The filaments with tenacities over 13.0 g/den can be made.

The degree of orientation achieved by drawing influences the mechanical properties of PP filaments. The greater the degree of stretch, the higher the tensile strength and the lower the elongation. Commercial PP monofilaments have an elongation-at-break in the range of 12-25%. Multifilament and staple fibers are in the range of 20-30% and 20-35%, respectively.



2.2.4 Thermal Properties

Polypropylene fibers have a softening point in the region of 150°C and a melting point at 160-170°C. At temperatures of -70°C or lower, PP fibers retain their excellent flexibility. At higher temperature (but below 120°C) PP fibers nearly remain with their normal mechanical properties. PP fibers have the lowest thermal conductivity of all commercial fibers. In this respect, it is the warmest fiber of all. Dr Robert C Portnoy (2002) shows the success of PP growth in medical textile by

Economic aspects

1. It has a secure raw materials (monomer) situation
2. It shows a high performance/cost ratio
3. It is easy to process
4. It is good substitution for other materials

Ecological aspect

1. It is environmentally favorable
2. It is recyclable

Technical aspects

1. Low density
2. High specific volume
3. Chemical resistant
4. Excellent strain resistant
5. Low surface tension
6. Mildew and stain resistant
7. Comfortable to skin
8. Low static property

2.3 Nonwoven Fabrics

Nonwoven fabrics are flat, flexible, porous sheet structures that are produced by interlocking layers or networks of fibres, filaments, or film-like filamentary structures. They generally fall into two categories depending on end uses

1. Disposable
2. Durable

They provide the basis for a wide variety of consumer, industrial, and healthcare products uses around the world.

Disposable end uses of non-wovens account for about 60% of total nonwoven fabric consumption in the USA and Japan, about 50% in Europe and the remaining consumption are durable nonwovens. Disposable uses include all those in which the nonwoven product is disposed of after limited use, such as drapes, diapers, etc.

2.3.1 Definition

EDANA Definition

According to European Disposable and Nonwoven Association [EDANA] Nonwovens are a manufactured sheet, web or bat of directionally or randomly oriented fibers, bonded by friction, and/or cohesion and/or adhesion, excluding paper or products which are woven, knitted, tufted, stitch bonded incorporating binding yarns or filaments, or felted by wet milling, whether or not additionally needled. The fibers may be of natural or man-made origin. They may be staple fibres or continuous filaments.

2.3.2 Technology

According to Howard P.Corcoran (1987), the major technologies used to manufacture nonwoven fabrics are

1. Hydroentangling
2. Carded thermal bonding
3. Spunbonding and Meltblowing

All of these processes are used to make non-woven fabrics that compete in the medical marketplace

Thermal bonded fabrics are generally made by carding staple fiber into a wide web that is then compressed and bonded with heat. The basic fiber was can be made from polypropylene, polyester, or other fibers including bicomponent fibers. When homopolymer fibers are used, thermal bonding can be achieved by adding a low melting material into the web which promotes the bonds or by selective melting of small areas of the sheet which can be seen on the resulting pattern in the material. When bicomponent fibers are used, only the lower melting polymer is used to make the bonds. The most common bicomponent fibers used today for this application are 50/50 sheath/core PP/PET fibers.

Hydroentangled and needled non-woven fabrics are also produced from a carded web of fibers. However, in these processes the bonding or consolidation of the fiber web into a sheet is accomplished by entangling the fibers by needle punching or water jets (hydroentangling). In the case of hydroentangling, water jets are used for the needling process. A scrim or backing can also be used. The backing may be another non-woven product, a paper product, or even a woven fabric. In the product made in this fashion, the backing material is what generally determines the barrier properties.

Spunbond processes are direct from polymer to sheet process with high mass production that results in very low commercial costs. They are often combined with melt blowing to give improved barrier and cover properties with very low fabric weights. Coatings, fibers, and other additives can be applied in secondary processes. The fiber produced in spinning can be either homopolymer or bicomponent. Fiber diameters are often as low as 20 microns for the spunbond process and as low as 2 microns for the meltblown process.

2.3.3 Barrier and Comfort Properties

K.E.Daveonport and Dr.Fit-Patrick (1990) discuss about the material breathability and drape construction for physical comfort and the ability to remain focused during medical/surgical procedure. Protection from the infection and safety for patient and healthcare professional is the major concern, shows the barrier fabrics for medical applications would be a low cost non-woven material that is breathable, sterilizable, flexible, and extremely resistant to blood and viral penetration. The following is a discussion of techniques being considered to produce such a fabric.

1. Increased basis weight
2. Coatings and films
3. Lower denier fibers
4. Meltblown layers
5. Bicomponent fibers
6. Sheath/core
7. Additives
8. Splittable

The easiest way to increase the barrier properties of a non-woven fabric is to increase the basis weight. In reality this may have little effect on the barrier properties but will definitely have a major effect on the cost and comfort of the fabric or garment. A better approach is to use a more hydrophobic fiber to make the fabric. Another approach is to increase the bonding; however, this will reduce the flexibility of the fabric and can give the garment a stiff, "boardy" feel.

Development of SMS fabrics increase the barrier properties solution for a better gown fabric that is able to deliver the highest level of protection and a greater degree of comfort with a new, unique and innovative combination of raw materials and fabric construction. This material protects medical personnel from viral infections and maintains a high level of breathability comfort even as the wearer's temperature (and perspiration) rises. SMS is a unique, triple-layered fabric and employs an active fabric technology that membrane sandwiched between inner and outer fabrics made of continuous fine filaments. The inner layer provides a soft touch to the wearer's skin while the outer layer provides additional repellency and strength. These fabrics have a layer of meltblown fibers sandwiched between two layers of spunbond fabric. The meltblown fibers have a fiber diameter of approximately 2 microns and provide an excellent barrier layer while still leaving the fabric breathable.

2.4 Sterilization

David J.Hurrell (1998) confers, Nonwovens used in medical applications have unique microbial problems and their control is a complex task. Use of nonwovens in the United States medical community has greatly expanded in recent years as evidenced by the fact that over half of the drapes used in surgery are nonwovens. The microbiological integrity of nonwovens has been the object of numerous studies ranging from the sterilization of nonwovens to the evaluation of the barrier properties of nonwovens. Test data generated with nonwovens generally support the fact that nonwovens contribute positively to the reduction of microorganisms in the medical environment. This contribution has been part of the medical communities' awareness of the benefits of and actions aimed at improving the hygienic nature of their environment as they take steps towards aesthetic.

The sterilization processes that have traditionally been used for medical products include steam, ethylene oxide (ETO), ionizing radiation (gamma or E-beam), low-temperature steam and formaldehyde, and dry heat (hot air). These methods can be divided into three categories, based on the nature of the sterilant and its reaction with microorganisms

1. Physical processes (ionizing radiation, dry heat)
2. Physicochemical processes (steam, steam/formaldehyde)
3. Chemical processes (ETO, glutaraldehyde).

Whereas the most widely used traditional chemical processes to kill micro-organisms were based on alkylating agents such as ETO and the various aldehydes, most of the new methods are oxidative processes based on "peroxy" compounds. These include sterilant based on compounds such as hydrogen peroxide, peracetic acid, peroxysulphates, chlorine dioxide, and ozone. For the most part, the microbial action of these chemicals has been recognized for many years.

CHAPTER 3

RESEARCH OBJECTIVES

The following are the objectives of the present study

To produce ophthalmic surgical drapes from nonwoven fabrics such as Spun melt spun [SMS] and spunbond.

To study the performance characteristics on the dimensional and physical properties of Nonwoven drapes.

To compare the performance properties and also the comfort properties for both Spun melt spun [SMS] and spunbond ophthalmic surgical drapes.

Statistical hypothesis to show the significant difference between SMS and spun bond ophthalmic surgical drapes by using student's t test.

CHAPTER 4

METHODOLOGY

4.1 Process Parameter

Based on the polypropylene nonwoven fabrics such as spun melt spun [SMS] and spun bond, the ophthalmic surgical drapes is designed through the following flowchart

PP Non Woven Fabrics

↓

Cutting& Folding

↓

Heat setting & Punching

↓

Adhesives process

↓

Sterilization

↓

Packing of drape

Fig.2 Flow Chart of Drape Processing

4.1.1 Cutting& Folding

Designing the ophthalmic surgical drapes, at first, Marking and Cutting take place for both nonwoven fabrics SMS and spun bond according to the dimension 60×45 cm. Knife roller cutting machines used for cutting operation. After cutting the manual folding of samples are carried out towards the upward direction from the lay at the dimension of 22cm.

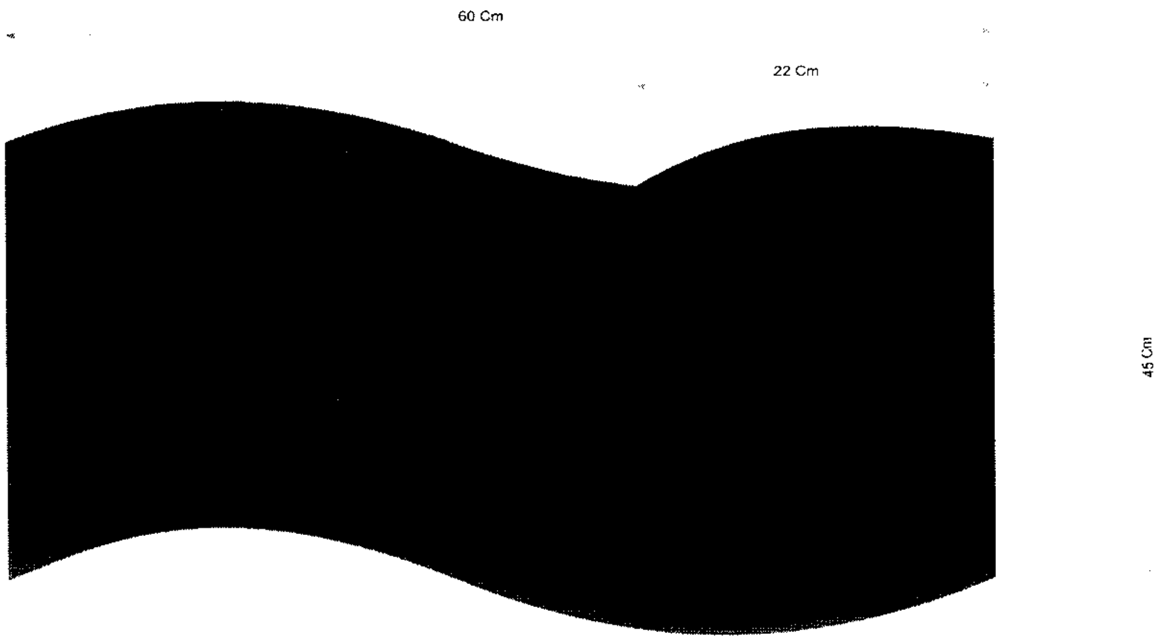


Fig.3 Cutting and Folding

Folding of fabric build fluid bag to collect fluids such as saline, etc., during the ophthalmic surgery .Marking and cutting of the fabrics shows the full sight of the surgical drapes 60×45 cm.

4.1.2 Heat setting & Punching

To create a fluid bag by embracing the two surface of base material and folding of material. Heat setting takes place at right angles towards the folding area at 115°C- for spun melt spun fabric and 100°C for Spunbond fabric, with respect to 8 cm dimension from the edge of the sample.

Punching afford a surgery area on the respective spot 3cm at mid of the sample by using standard dies. Dies ranges from 3cm, 4cm and 5cm.

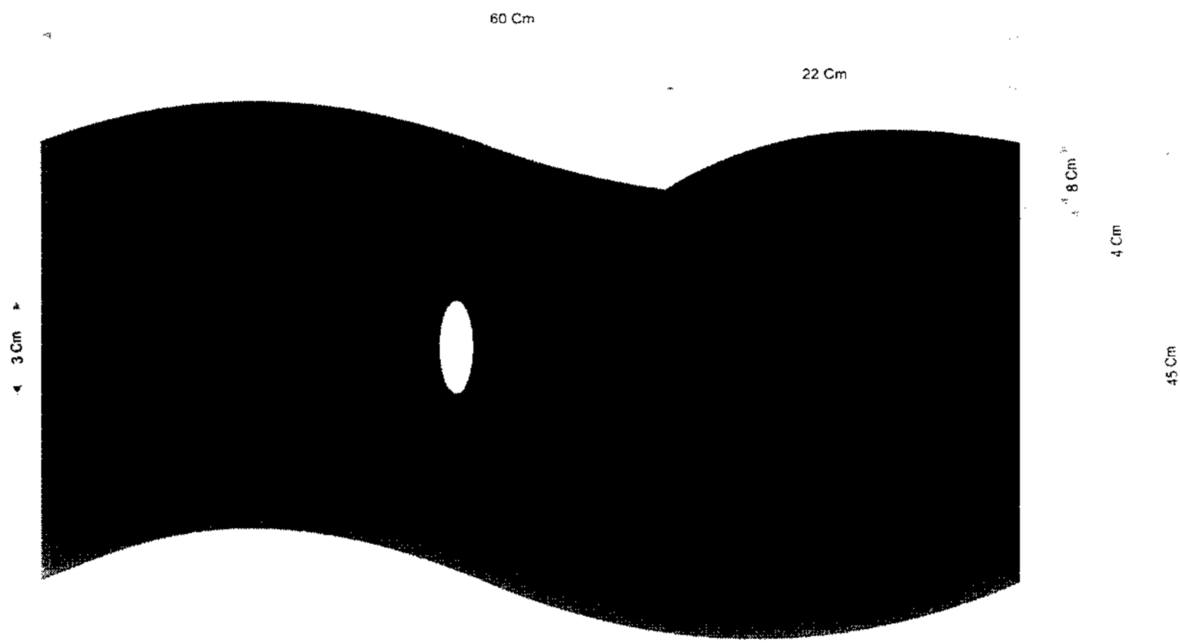


Fig.4 Heat setting & Punching

Heat setting shows good resistance to split the fluid bag and helps to hold the fluid collection for a long time surgery. Normally two type of drapes available with hole or without holes. With hole drapes helps the surgeon performance easily

4.1.3 Adhesives Process

A special no-allergic vinyl adhesives used for this process. Which are applied encircled the surgical area and fluid bag. Adhesive area prevents from trembling and holds the drape stay on position during surgery. Metal plate in the fluid bag build crease for good opening to allow fluid easily in to the bag during surgery.

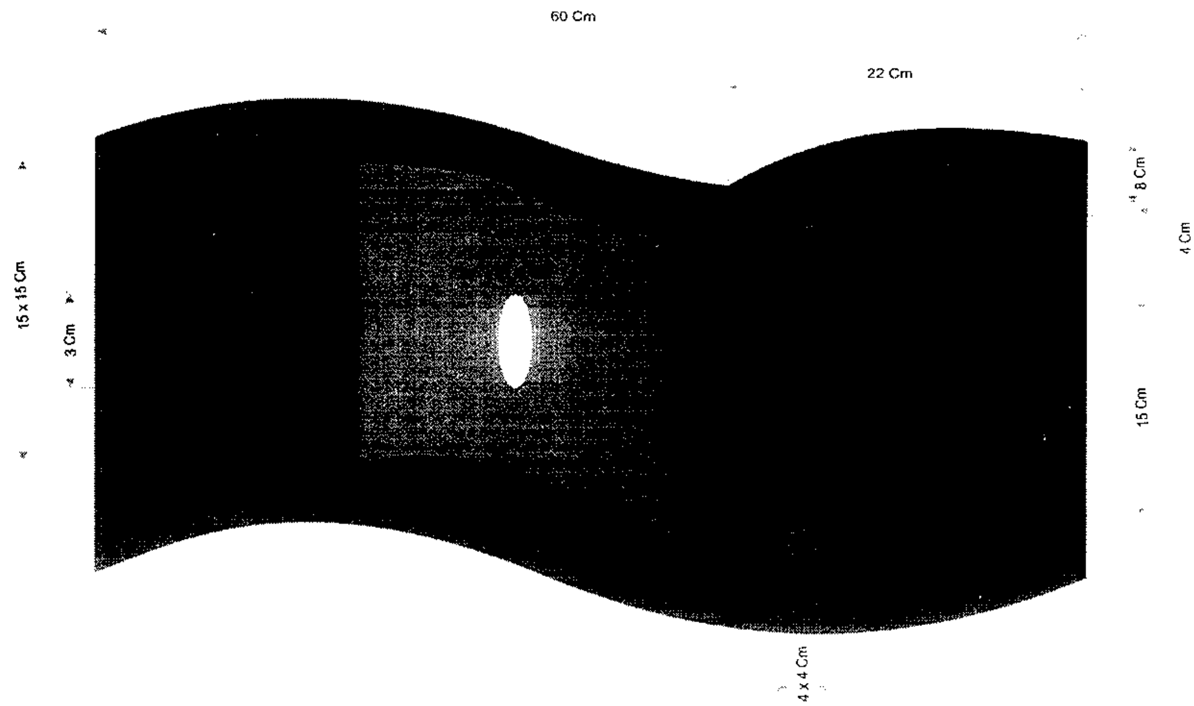


Fig.5 Adhesives Process

The adhesive encircled the surgical area and fluid bags are covered by the releasing paper. Dimension of releasing paper 10×10cm in surgical area and 4× 4cm in the fluid bag. The main function of this releasing paper is to prevent form the sticking of material. During surgery the releasing paper taken out and the adhesive drapes with correct suit of surgical area is worn over the infectivity.

4.1.4 Sterilization

Nonwoven drape reduces the level of bacterial contamination, controls and/or kills the bacteria commonly associated with surgical drapes and wound infections, takes an active role in maintaining an aseptic field at the wound site, that the Sterilization is safe to the staff and the patient. This process involved to kill the micro-organism contamination by using chemical methods under ETO gas in presence of 90 % carbon dioxide and 10 % of ethylene oxide.

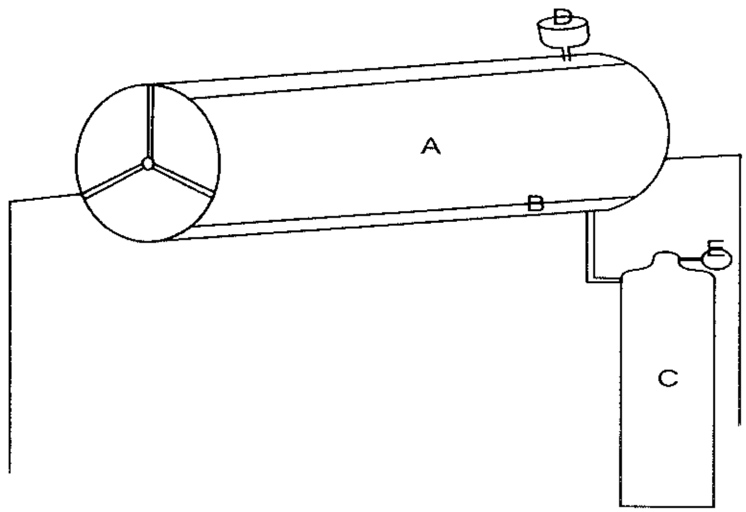


Fig. 6 Sterilizing High Pressure Beam Machine
A- Beam B- Perforated plate C- ETO E-Pressure Gauge D-Temperature Control

In a high pressure beam the surgical drapes is placed between the two perforated plate, temperature maintained at 45°C for 5-8 hrs. The pressure inside the beam should be maintained 20 lbs thought out the process. The ability of the silanequat to chemically bond to the nonwoven substrate and still provide for the broad spectrum control of microorganisms made it well suited to the safety challenges encountered in this application .and that the fabric retains all of the positive handling and appearance characteristics desired by the operation room [OR] and surgical staff.

4.2 Sample Parameter

4.2.1 Comparison of Results

Comparison of results made between

Sample 1	- Spun melt spun ophthalmic surgical drape
Sample 2	- Spun bond ophthalmic surgical drape

4.2.2 Assessment of Quality

Assessments of quality made on the ophthalmic surgical drapes are

Barrier Properties	- Micro-Organism and Fluid Permeation
Safety	- Chemical Resistance
Transmission Properties	- Air Permeation
Hand Properties	- Compression and Bending
Durability	- Shear and Tensile Strength
Appearance	- Drape and Crease Recovery

4.3 Statistical hypothesis

Each of the above characteristic are independently affected the performance and comfort of the ophthalmic surgical drapes. Taking in to consideration the sample is analyzed and the values are noted. The value obtained from the results are incorporated to find out the significant difference between two mean X_1 and X_2 of the sample, using the statistic

$$T = \frac{\overline{X}_1 - \overline{X}_2}{S\,(\ 1/n_1 + 1/n_2)} \qquad \ldots\ldots\ldots\ldots (4.1)$$

$$S^2 = \frac{(X-X_1^2)+ \quad (X-X_2^2)}{n_1+n_2-2} \quad \ldots\ldots\ldots\ldots (4.2)$$

4.3.1 Procedure for testing hypothesis

The various steps in testing of a statistical hypothesis in a systematic manner are

1. Set up null and alternative hypothesis

   Ho: ì $_1$ = ì $_2$

   H1: ì $_1$ ≠ ì $_2$

2. Level of significance at 5 %, degree of freedom n_1+n_2-2
3. Compute the test statistic Z= t-E(t) / s E(t) under the null hypothesis
4. Compare the compute valve of Z in the step with the significant value at given level of significance.
5. If |z| ‹ significant value, Ho may be accepted at 0.5% level of significance
6. If |z| › significant value, Ho may be rejected at 0.5% level of significance for a single tail test (right tail (or) left tail).

CHAPTER 5

RESULTS AND DISCUSSIONS

5.1 Barrier Properties

5.1.1 Micro-Organism

The evaluation is done by rating the fungus growth in contact to test material and the viewing of the inhibition zone around the test sample. The tested results of pp ophthalmic surgical drapes are given as follows.

Table 2 Evaluation of Micro Organism

50 GSM samples	% covered in 5 day	% covered in 10 day	% covered in 15 day	% covered in 20 day
SMS	0	0	0	0
Spunbond	0	0	0	0

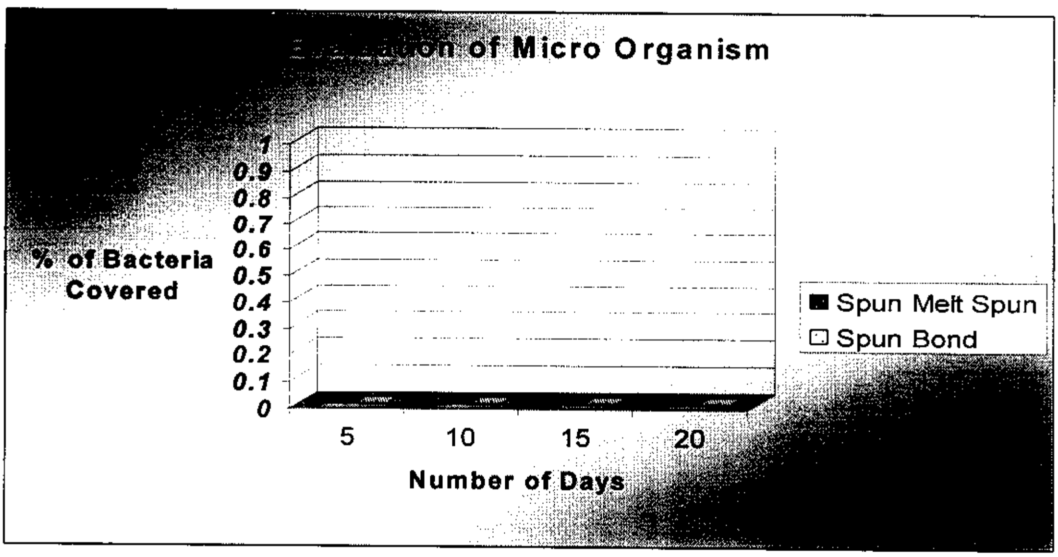


Fig. 7 Micro Organism of Surgical D

Identifying the growth of micro-organism is carried out by mean of exposing the surgical drapes to number of day like 5, 10, 15and 20. From the given results Fig .7 shows that the micro-organism covered with in all the days for both spun melt spun and spunbond ophthalmic surgical drapes covered 0% and the statistical hypothesis of calculated value (0.1) is lesser than tabulated value (2.78) at 5 % significant level. Hence Ho is accepted, their is no significant difference between SMS and spunbond ophthalmic surgical drapes. Ophthalmic surgery not take more than 5 hours, even though it's sterile the drapes kept for long time the growth of bacteria is less by sterilization process.

5.1.2 Fluid Permeation

Water drop spreading is a spontaneous flow of a liquid in a porous substrate. The transport of liquid into a fibrous assembly in the drape material may be caused by external force. Because capillary forces are caused by wetting and wicking is a result of spontaneous wetting of capillary system.

Water drop spreading can be visualized as a spontaneous displacement of a solid-air interface with a solid-liquid interface. The liquid movement in any porous medium, which is governed by the liquid's properties, liquid-medium surface interaction, and geometry configurations of the porous structure in the medium. So the fabric is tested under the water drop-spreading test and the results are obtained as follows

Table 3 Evaluation of Fluid Permeation

50 GSM samples	% covered in 1 hr	% covered in 2 hr	% covered in 3 hr	% covered in 4 hr
SMS	0	0	0	0
Spunbond	0	10	13	15

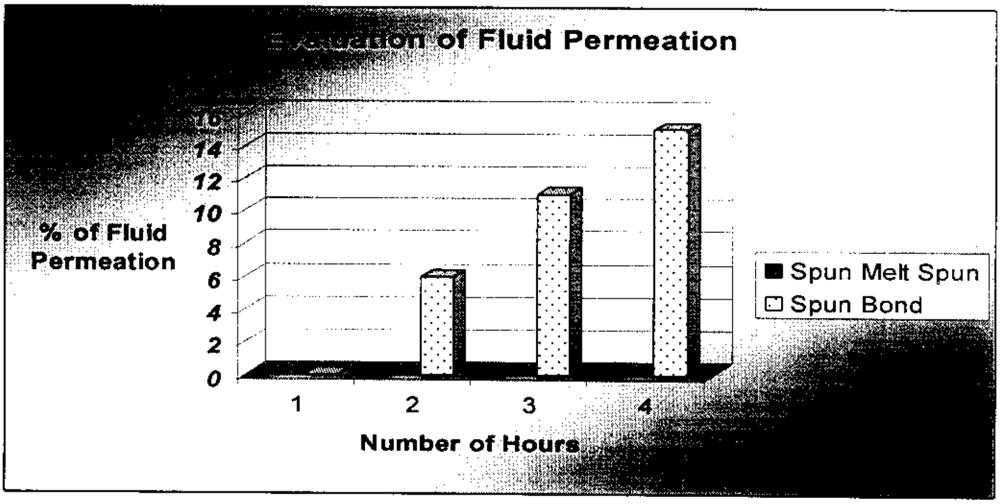


Fig.8 Fluid Permeation of Surgical Drape

From the results Fig. 8 show, spun bond have higher area covered by fluid drops spreading in %value than the SMS surgical drape drapes and the statistical hypothesis of calculated value (2.87) is greater than tabulated value (2.78) at 5 % significant level. Hence Ho is rejected, their is a significant difference between SMS and spunbond ophthalmic surgical drapes. The absorption or spreading by fluid on the material increases when the resistance to water flow is low, when the density is more. So at constant time, the area covered by spreading of water is reduced. That means when the density of the drape is more, the more will be the resistance to the absorption of fluid.

5.2 Safety

5.2.1 Chemical Resistance

Table 4 Evaluation of Chemical Resistance

Medicine	Chemical composition	Changes	
		SMS	Spun bond
Adrenaline	Bitartrate	PASS	PASS

Lignocaine	Sodium chloride Hydro chloride	PASS PASS	PASS PASS
Decadran	Phosphate Methyl paraben	PASS PASS	PASS PASS
Garamycin	Sulphate Methyl paraben	PASS PASS	PASS PASS
Hyaluronidase	ovine sodium chloride	PASS	PASS

Medicine used during the ophthalmic surgery having various chemical compositions. PASS or FAIL Testing carried out to the surgical drapes by using the above chemical compositions. From the results both the SMS and Spunbond drapes shows no change. This is due to the amount of chemical composition used in the medicine are around 1-2%.

5.3 Transmission Property

5.3.1 Air Permeation

The measurement of air permeability is playing a vital role in the manufacturing and performance of the drapes i.e. in assessing, comfort of the drapes, drapes quality and finally the structure. The air permeability of a fabric is very sensitive indicator of the drapes construction and the material being used.

Table 5 Evaluation of Air Permeation

50 GSM sample	Air Permeation R (K Pa. s/m)				
SMS	00.67	00.86	00.75	00.62	00.76
Spunbond	00.26	00.32	00.52	00.41	00.04

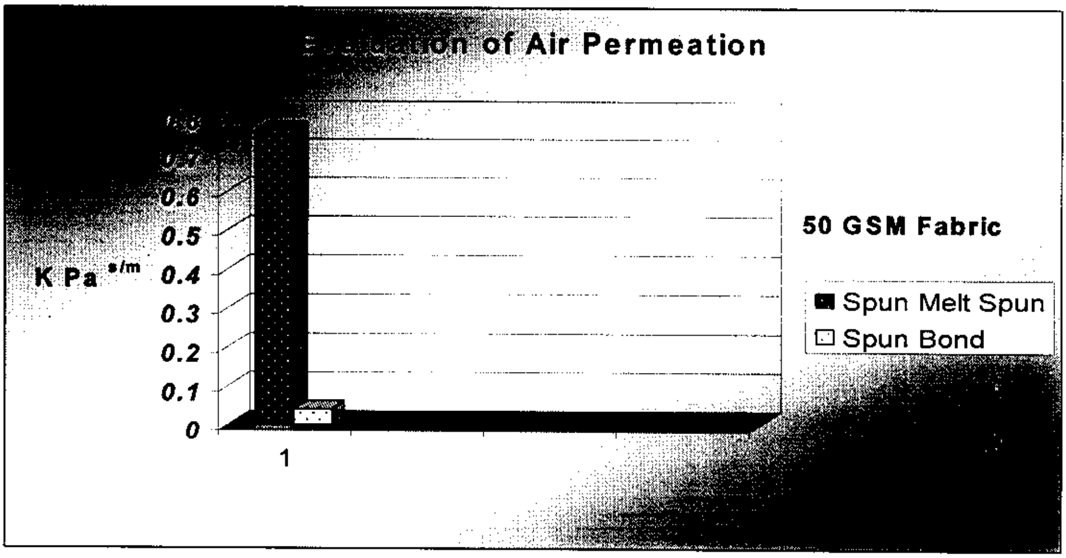


Fig. 9 Air Permeation of Surgical Drape

From the tested results, SMS show good air permeation than the spun bond and the statistical hypothesis of calculated value (4.66) is greater than tabulated value (2.78) at 5 % significant level. Hence Ho is rejected, their is a significant difference between SMS and spunbond ophthalmic surgical drapes. The Air Permeability of drapes depends primarily on the cover factor. When the cover factor is more the resistance to the flow of Air high. This does permit easy passage for the flow of air through in it. There are several factors which influencing the air permeability among which are type of fabric, construction, bulk density, thickness, air porosity etc., SMS fabrics have a layer of meltblown fibers sandwiched between two layers of spunbond fabric. The meltblown fibers have a fiber diameter of approximately 2 microns and provide an excellent barrier layer

5.4 Hand Properties

It is generally agreed that the stimulus leading response of the surgical drape are entirely determined by the physical and mechanical properties of the material. In particular the properties of a drape that affect its handle are dependant on its behavior at low loads and extensions are not at the level of load and extensions at which surgical drape failure occurs. The handle of a fabric is very important for fabrics, especially for clothing's. One must feel comfortable when the handle of the fabric is good, that means the feel of the fabric must be good. So it is must to have good handle properties. The fabric were tested in the Kawabata system, which is having specialized instruments, i.e. Compression (FB3), Bending (FB2), tensile and shearing (FB1).This instrument is very sensitive and gives best and accurate results

5.4.1 Compressibility

In this instrument, a probe exerts force on a fabric sample to determine its energy at compression. The sample is compressed in the direction of thickness to a maximum pressure of $5KN/m^2$ at a constant velocity, 20ì m/s.The tested results of pp ophthalmic surgical drapes are given as follows.

Table 6 Evaluation of Compressibility

50 GSM Sample	Compression		
	LC	WC ($gfcm/cm^2$)	RC (%)
SMS	0.370	0.086	22
Spun bond	0.024	0.007	10

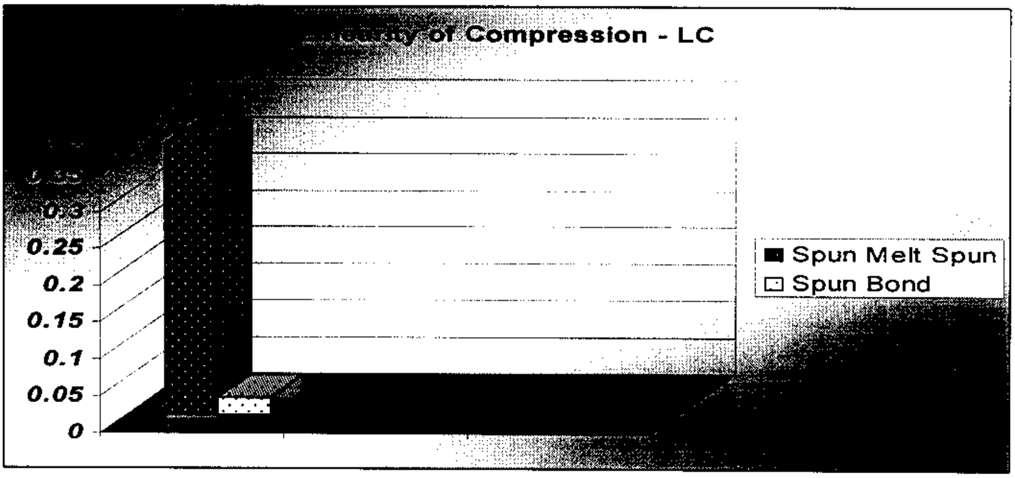


Fig.10 Compression Linearity of Surgical Drape

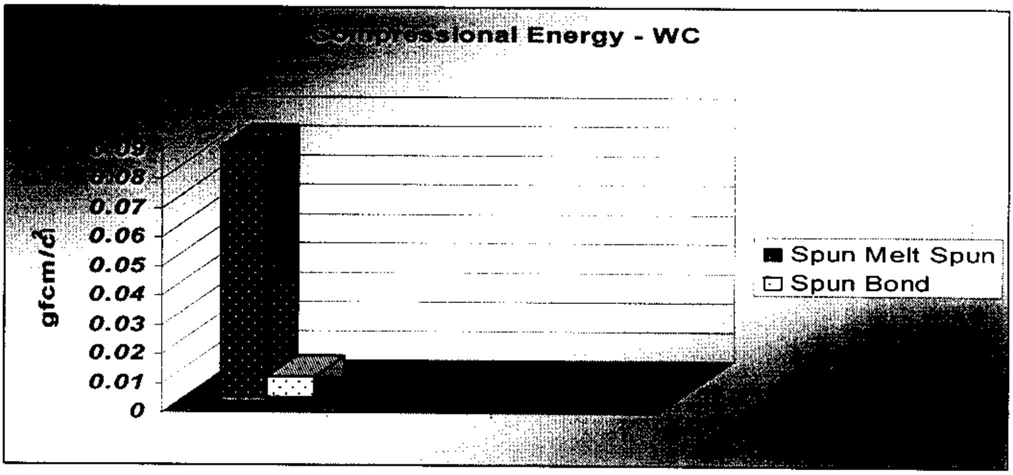
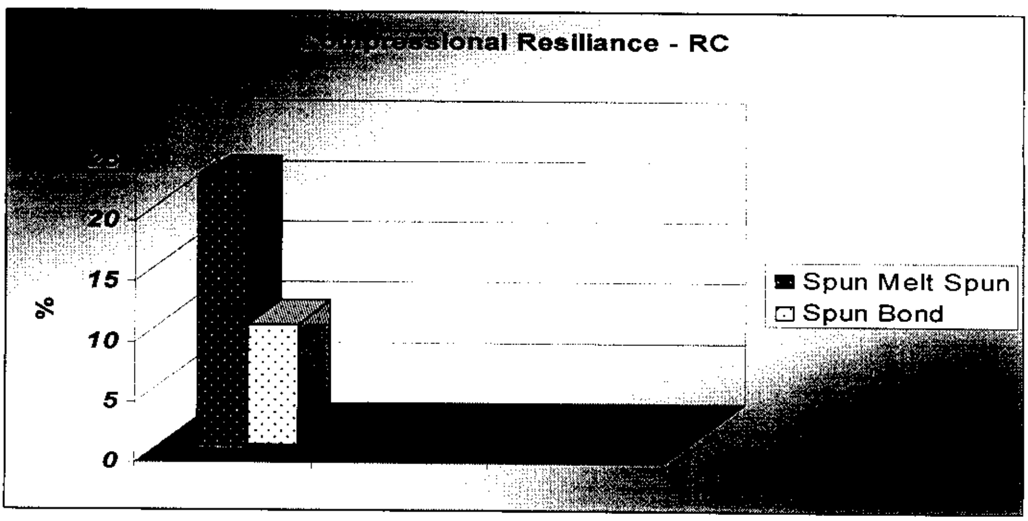


Fig.11 Compression Energy of Surgical Drape



From the results, the SMS surgical drapes show high compressional energy WC and compressional resilience RC values than the spun bond drapes, this is due fibers which are sandwiched and less lateral compressional force present in it.

5.4.2 Bending

One edge of the sample is held by affixed chuck, while the other is held by the moving chuck, enabling the measurement of bending properties. Pure bending is applied to the fabric 1cm in length with constant rate of curvature,5.0×10^{-3}/sec. the stiffness (slope) and Hysteresis are measured values of bending rigidity and bending moment can be known. The minute bending moment of the sample can be detected and the relationship between the Bending moment and the curvature can be measured accurately and quickly. This relationship is automatically recorded on the X-Y recorder unit. The tested results of pp ophthalmic surgical drapes are given as follows.

Table 7 Evaluation of Bending

50 GSM Sample	Bending	
	B[g.cm^2/cm]	2HB[gf.cm/cm]
SMS	0.1088	0.0763
Spunbond	0.0338	0.0307

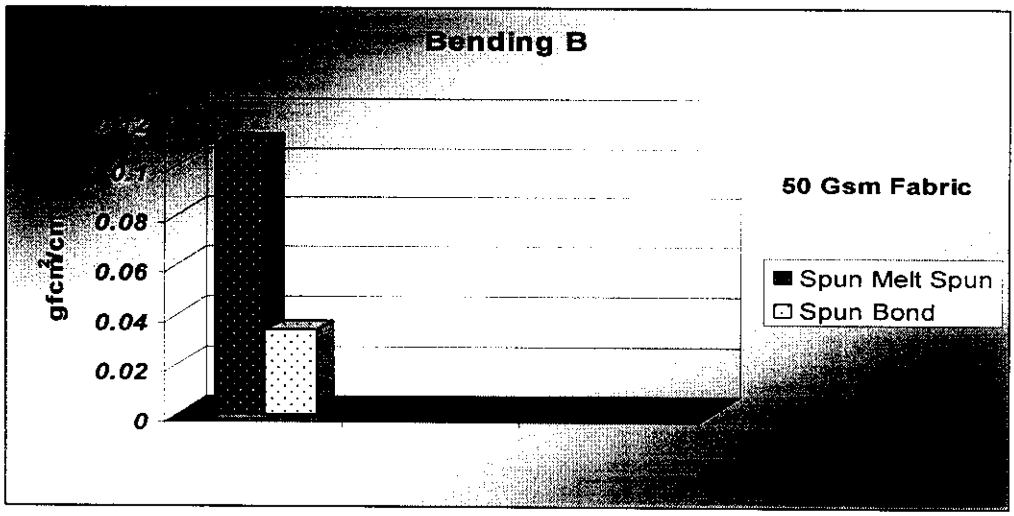


Fig.13 Bending rigidity of Surgical Drape

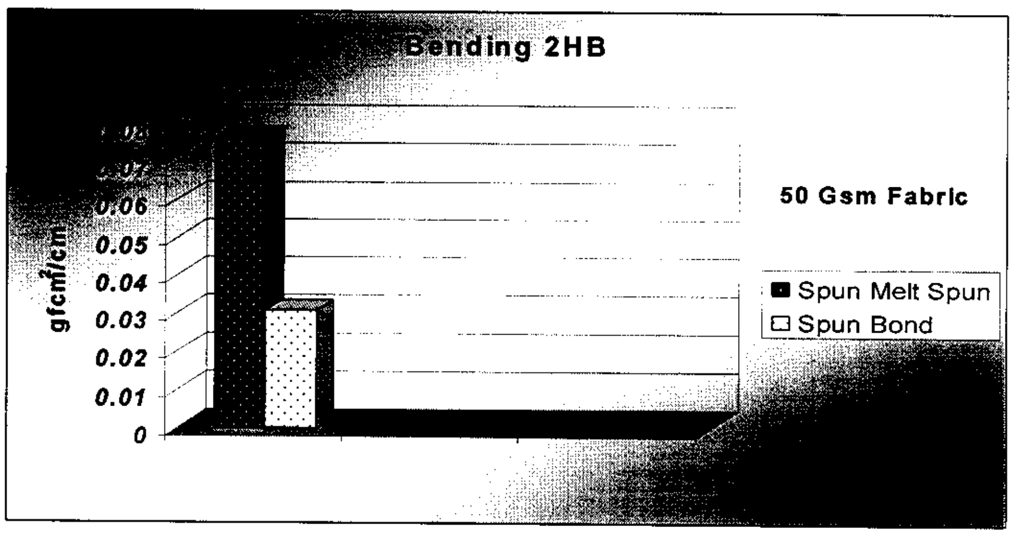


Fig.14 Bending Hysteresis of Surgical Drape

When comparing with the structure, the result shows SMS drape shows high bending rigidity than spunbond drapes. This is due to most of the fibres are integrated into the sandwiched structure and the inter fibre cohesion is high and more force is required to overcome the resistance due to the frictional force between the individual fibres , hence the bending rigidity of the SMS drape is greater . Similarly, while the bondings of structure increase the bending rigidity B, 2HB increases due to the high density.

5.5 Durability

5.5.1 Tensile Strength

The tensile testing is obtained by applying a tensile strain to a sample held by 2 chuck 'a' and 'B', by moving the back chuck B away from the front chuck A. chuck A is fixed to a torque detector. The initial distance between chuck A and B is 5 cm. the torque meter using a strain gauge installed on the axis of the drum detects the tensile stress. The tensile strain is detected by a potentiometer, which senses the movement of the chuck B, the output voltage of the potentiometer is proportional to the strain. Two tensile rates can be selected by changing gears (0.2 mm/sec or 0.1 mm/sec) when the output voltage of the tensile force reaches the present value, the motor turns automatically to a recovery motion. Another cycle or a repeat measurement can be done at this time. The tested results of PP ophthalmic surgical drapes are given as follows.

Table 8 Evaluation of Tensile Strength

50 GSM samples	Tensile strength		
	LT	WT Gfcm/cm^2	RT %
SMS	1.223	57.60	52.76
Spunbond	1.073	22.45	40.45

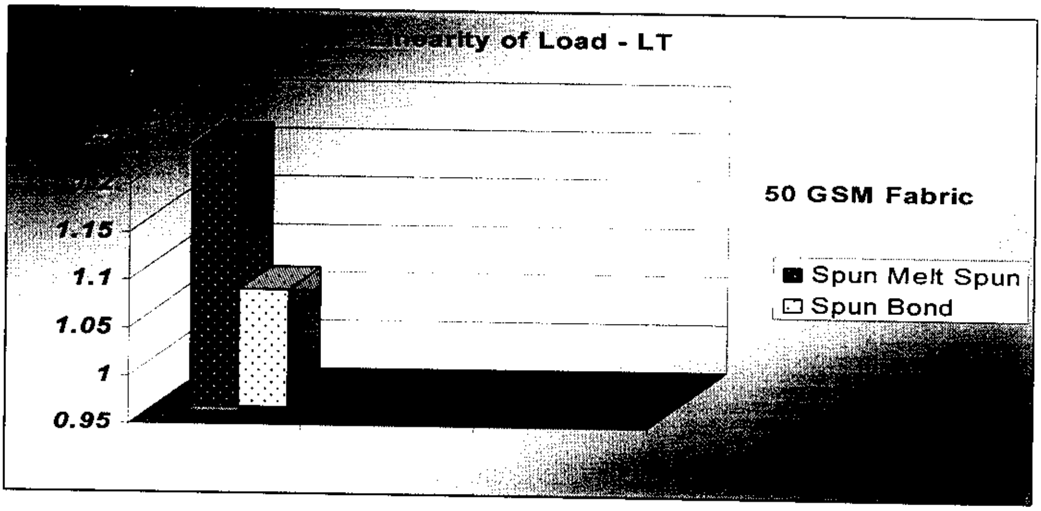


Fig. 15 Linearity of load extension of Surgical Drape

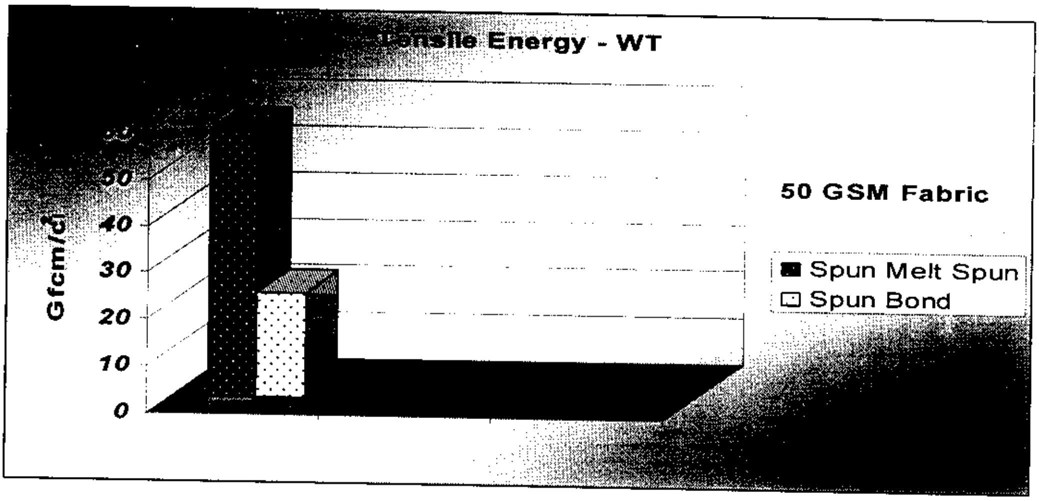


Fig. 16 Effect of Tensile energy - WT on Surgical Drape

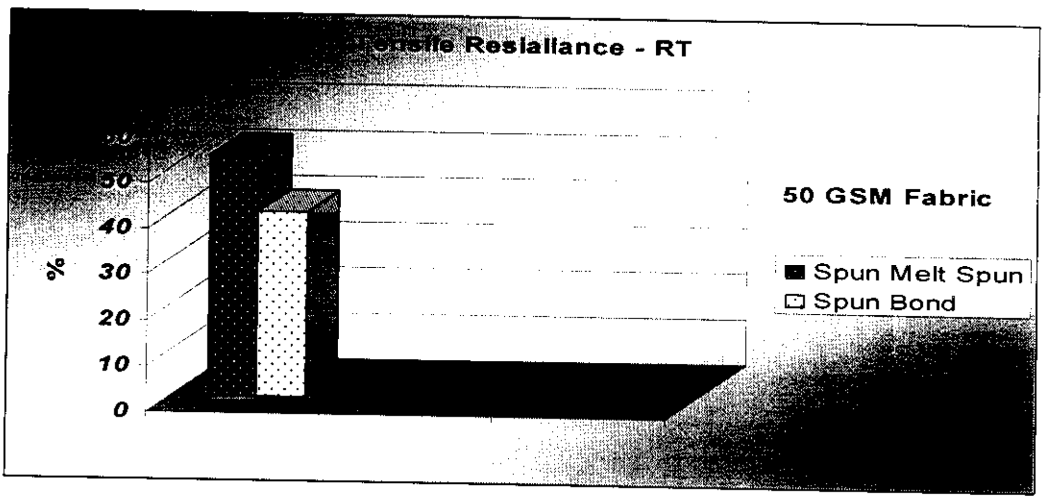


Fig. 17 Effect of Tensile resili... RT on Surgical ...

The results from fig 15-17, SMS fabric have high density shows tensile energy WT, tensile resilience LT and RT is considerably increased than spun bond. This is due to the fabric construction the arrangement of fibre in the SMS fabric are three layered structure, thus the density of the spun melt spun is higher than the spun bond drape relatively show that the tensile force is higher for SMS than spunbond.

5.5.2 Shear Strength

A constant tension is applied on the fabric by weight mounted on the drum that rotates freely by moving clutch. A transducer connected with chuck B along the shear direction detects the shear force. After the sample is given constant tensile force by the attached drum, chuck B moves perpendicular to the direction of the tensile stress by a synchronous motor at a constant rate. The shear strain is detected by a potentiometer. When chuck B slides 8 degree of shear angle (standard condition), the motor automatically turns back. The upper limit of shear range can be adjusted from ± 1 degree to ± 8 degree.

The voltage signal is processed. In the shear tester test, the output voltage of shear force and shear angle are recorded directly by the X-Y recorder. The tested results of PP ophthalmic surgical drapes are given as follows.

Table 9 Evaluation of Shear Strength

50 GSM sample	SHEAR		
	G [gf/cm.dg]	2HG [g/cm]	2HG5 [g/cm]
SMS	6.63	9.75	10.91
spunbond	6.08	9.56	9.65

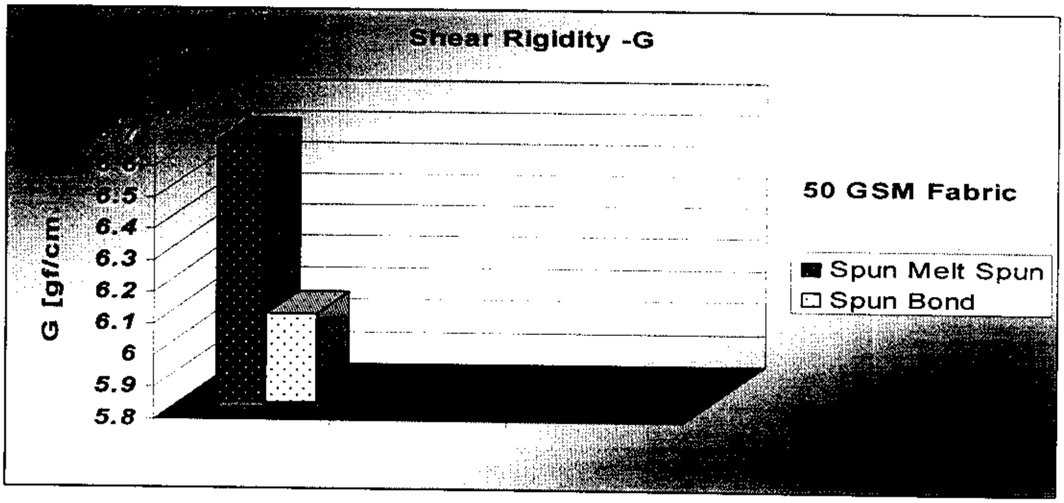


Fig.18 Shear stiffness of Surgical Drape

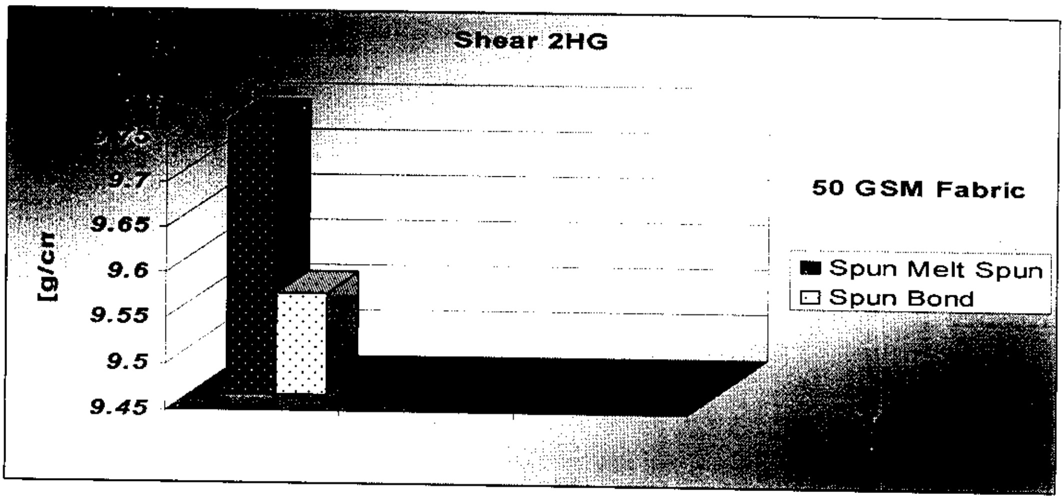


Fig.19 Hysteresis of shear force at 0.5° shear angle on surgical drape

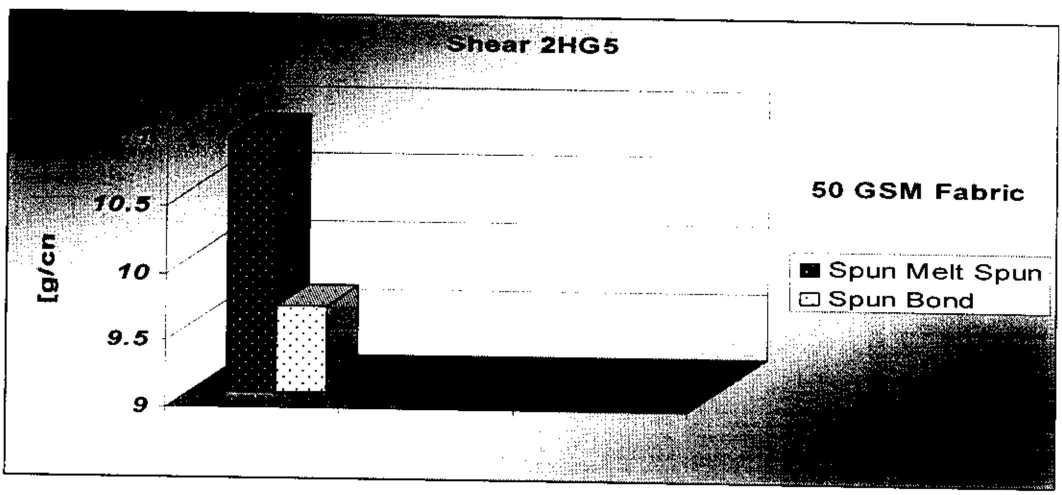


Fig.20 Hysteresis of shear force

From Fig18-20, the results show that SMS drapes increase shear rigidity G, 2HG and 2HG5 than spun bond drapes .Due to the increasing density of the fabric, this is related with bending rigidity. In construction of SMS the fibre arrangement are three layered structure, thus the density of the spun melt spun is higher than the spun bond drape relatively show that the shear resistance is higher for SMS than spunbond.

5.6 Appearance

5.6.1 Drape

The specimen deforms with multi-directional curvature and consequently the results are dependent to a certain amount upon the shear properties of the fabric. The results are mainly dependent, however, on the bending stiffness of the fabric.

Specimen held concentrically between two smaller discs and is allowed to drape into folds under its own weight. A light is shone from underneath the specimen and the shadow that the fabrics casts, is traced on to an annular paper of the same size. The stiffer a fabric is, the large is the area of its shadow compared with the unsupported area. To measure the areas involved the whole paper ring is weighted and then the shadow part of the ring is cut away and weighted. The paper is assumed to have constant mass per unit area so that the measured mass is proportional to area. The tested results of PP ophthalmic surgical drapes are given as follows.

Table 10 Evaluation of Drape coefficient

50 GSM sample	Drape coefficient				
SMS	85	82	81	86	82
Spunbond	60	69	68	68	60

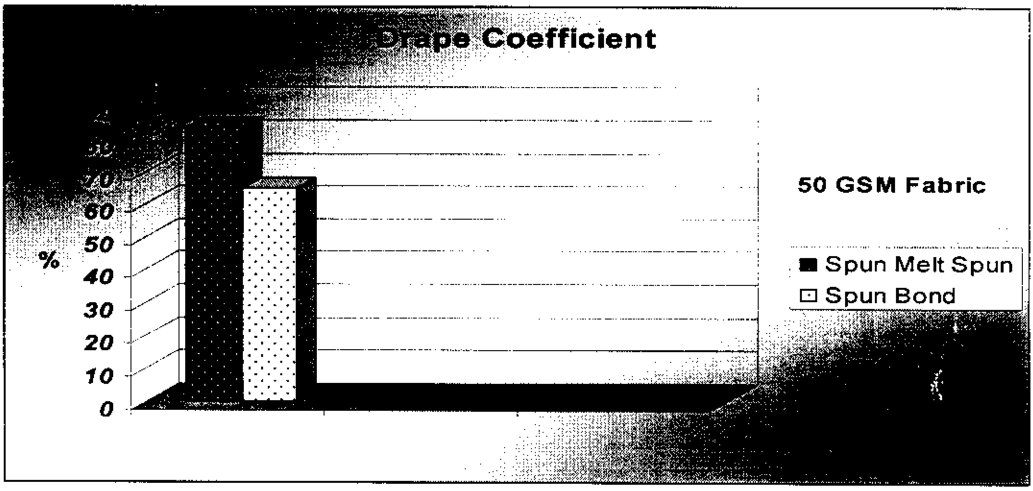


Fig.21 Drape coefficients of Surgical Drape

From Fig 21, the results show that SMS fabric having higher drape coefficient than the spunbond fabric and the statistical hypothesis of calculated value (14.5) is greater than tabulated value (2.78) at 5 % significant level. Hence Ho is rejected, their is a significant difference between SMS and spunbond ophthalmic surgical drapes. This is due to higher the drape coefficient the stiffer is the fabrics. The stiffer a fabric is the larger is the area of its shadow. Spun bond shows low drape coefficient results in less bending rigidity. The stiffness of a fabric in bending is very dependent on its thickness. Thus SMS fabrics having high thickness than spun bond fabric shows the high drape coefficient.

5.6.2 Crease Recovery

The ability of a fabric to resist creasing is in the first instance dependent on the fabric construction. The bending elasticity seems to be of the greatest importance in the phenomenon of creasing; creases appear when the material is distorted in such manner that part of it is stretched beyond its small power of elastic recovery.

In this test the specimens are tested, each measuring 40mm×15 mm, half of the specimen cut parallel to the longitudinal and the half parallel to the transverse the specimen are folded in two, the ends being by tweezers. Half the specimens are folded face to face and half of them back to back. The specimens are then placed under a 10 N load for 5 min. they are then transferred immediately to the holder of the measuring instrument and one leg of the specimen is inserted as far as the back stop. The instrument is adjusted continuously to keep the free limb of the specimen vertical. The crease recovery angle is measured, by reading the scale when the free limb is vertical, 5min after the removal of the load. The tested results of PP ophthalmic surgical drapes are given as follows.

Table 11 Evaluation of Crease Recovery

50 GSM sample	Crease recovery			
	Longitudinal		Transverse	
	Face-face	Back-back	Face-face	Back-back
SMS	105	102	101	98
Spunbond	85	83	82	80

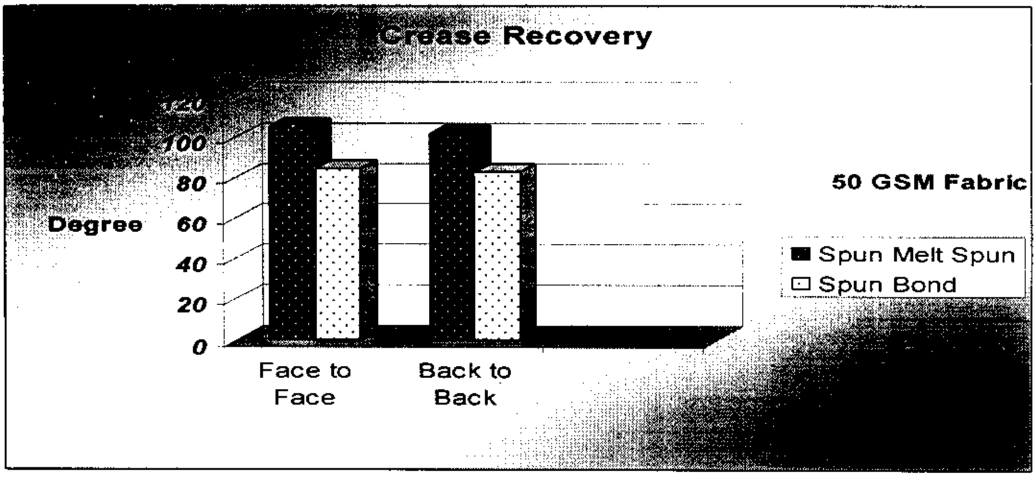


Fig. 22 Effect of Crease Recovery on Longitudinal Way

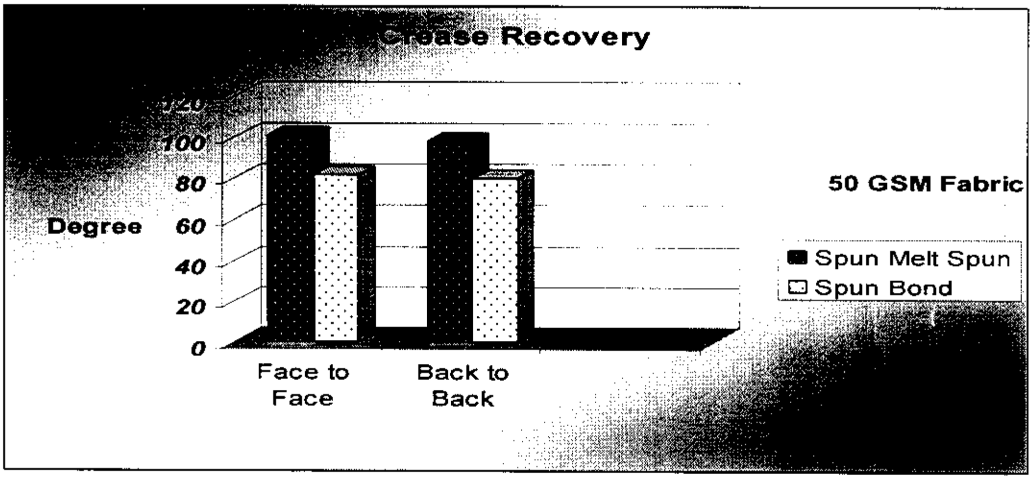


Fig. 23 Effect of Crease Recovery on Transverse way

When a fabric is creased the resulting deformation has two components; one is the displacement of fibres, another one is the stretching of the fibres on the outside of the curve. The relative importances of these two mechanisms depend on the radius of the curve that the fabric bent into. From the results, the spun bond crease recovery at low curvatures and the statistical hypothesis of calculated value (10.66) is greater than tabulated value (2.78) at 5 % significant level. Hence Ho is rejected, their is a significant difference between SMS and spunbond ophthalmic surgical drapes is governed by the frictional effects associated with the fibre movement and at the high elastic response of the fibre. SMS having good crease recovery because the fibre is dependent on the time-related effects, such as stress relaxation this is due to the fabric construction it's having three layered structure.

CHAPTER 6

CONCLUSION

Design is a process best undertaken through an organized effort and a problem solving approach. Understanding the complex set of requirement that must be addressed by a successful new product, Ophthalmic Surgical drapes must have a barrier effect between the sources of infection and the user (i.e. a healthy person), as well as good wearing comfort.

By their end user, legal, financial or other requirements, the existing product and the functional design process utilizing a study of surgical drapes (Polyethylene) does not fulfill the requirements. As fabric technology advances with the medical industry's need for better, stronger, more protective attire, more and more developments will help protect and provide comfort for medical personnel. Design analysis is a major thrust of this surgical research. Successful creation of these new methods named Spun Melt Spun and Spun Bond drapes had made a great boon to the surgical users.

The techniques used in this study effectively distinguish differences in comfort and physical performance of Spun Melt Spun and the Spun Bond Drapes and it has been concluded that Spun Melt Spun appears to be much better than the Spun Bond drapes. On average, when compared to other samples of the same composition, thicker and heavier fabrics performed better than the lighter and thinner types. The existing product had provided a firm foundation for undertaking the new product redesign. These are evaluated with reference to their barrier properties.

CHAPTER 7

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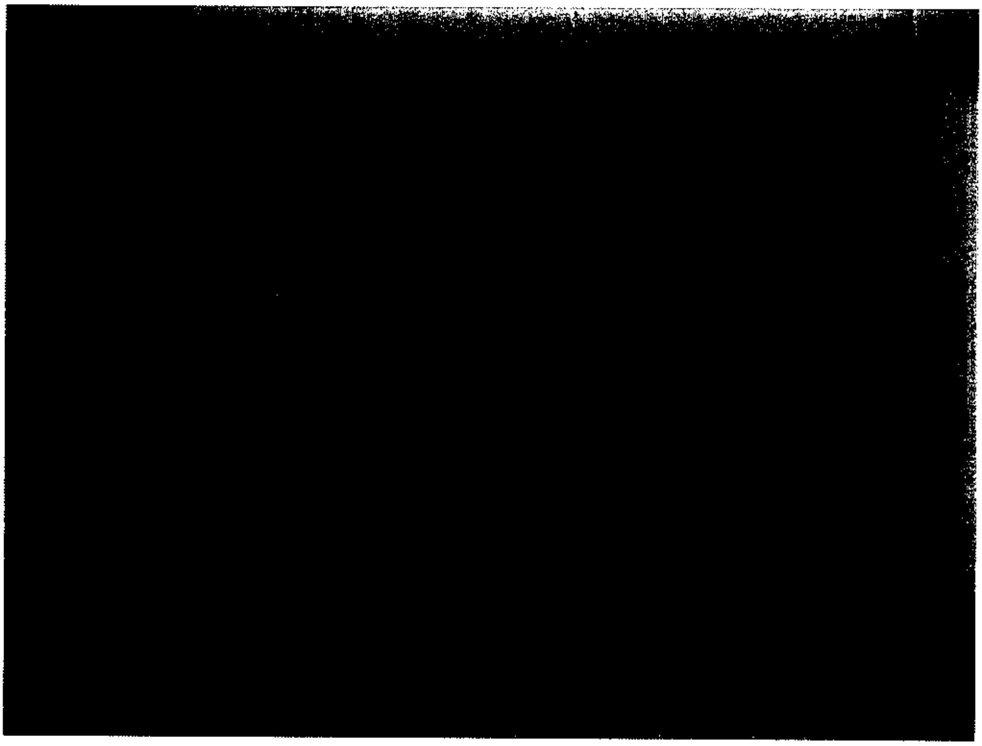
Sample of Spun melt Spun [SMS] Nonwoven Fabric

Sample of Spunbond Nonwoven Fabric

Photograph of ophthalmic surgical drape



Spun melt Spun [SMS] ophthalmic surgical drape