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RESEARCH ARTICLE

A STUDY ON THE FUNCTIONAL CHARACTERISTICS OF POLYPROPYELENE NONWOVEN DISPOSABLE OPTHALMIC SURGICAL DRAPES FOR BETTER BARRIER PROTECTION AND USERS COMFORT

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ABSTRACT

Infections are the major concern for the causes of diseases in any eye surgical procedures at Ethiopia. Modern surgical are employed with latest technology to know how to cure the infections rather than far-sighted of spreading. Using medium like polyethylene surgical drapes in ophthalmic surgery has no potential source of wound contamination especially when wetted with blood or saline. The comfort level of these drapes is very less to the user groups. Also reusable drapes made from woven fabrics on the repeating wash cycles could alter the final resistance to barrier penetration. To improvise the comfort level of the users and to prevent diseases from the site infections, an appropriate design were developed in this research works to investigate about the functional characteristics of disposable surgical drapes made from polypropylene nonwoven fabrics integrating with polyethylene sheet. The significance of the surgical drapes was studied through the quality evaluation of structural and comfort properties. Comparison was made with existing surgical drapes made with woven fabrics. The chance of barriers penetration through nonwoven is less observed which offers highest protection as well as good wearing comfort than the woven surgical drapes.

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INTRODUCTION

Infections in healthcare industries are more concern to major public health problem in most of the developing countries like Ethiopia. Currently the overall incidence of health care associated infection has been increased and problem of these infections is still staggering (Kelemua Gulilat, 2014). Ethiopia is the second most populous country in sub-Saharan Africa, with a population of over 82.8 million people. Ethiopia experiences a heavy burden of eye related disease mainly attributed to infectious diseases. The spreading of infection and diseases are caused by inadequate use of barrier terminologies during the eye surgical procedures. In the operating theatre, infective organisms can be spread either directly by means of instruments, hands and penetration of drapes and gowns, or indirectly through air contamination (Ashley Blom, 2000). Air contamination, caused by shedding of bacteria by theatre personnel, is a significant cause of wound contamination. Special clothing can prevent shedding. Barrier protection and comfort level of the patient can produce by appropriate usage of textile as medium. 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-makers, however, are challenged on two fronts, making the fabric to meet the highest levels of protection, but also creating clothing that is comfortable. 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.

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). It should

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have blood and fluid resistant to strike-through, resistant to punctures and tears, flexible to contour to patient's body, lint free to prevent contamination of the surgical wounds (EN 13795, 2007). The draping material should not possess any negative effect towards the environment and surgery. The negative effects can be minimized by the proper choice of the material compositions.

Nonwoven Fabrics

The passage of bacteria through surgical drapes poses a major concern. It should have a resistance to penetration by aqueous fluids of any textile materials commonly used to make surgical drapes. Untreated woven fabrics are rapidly penetrated; non-woven synthetic materials resisted longer and tightly woven cotton fabrics resisted the longest. The particles penetrated woven drapes, but not non-woven drapes. Using polypropylene as a fibre for disposable surgical drapes it has melting point of polypropylene (160-170°C) gives an advantage in many nonwovens. PP fiber can be softened sufficiently to bond to one another without destroying fiber properties (Ha'eri, 1981). The success of PP growth in medical textile is environmentally favorable, it is recyclable, low density, high specific volume, chemical resistant, excellent strain resistant, low surface tension, mildew and stain resistant, comfortable to skin (Robert, 2002). The major technologies used to manufacture nonwoven fabrics are, hydroentangling, carded thermal bonding, spunbonding and meltblowing. All of these processes are used to make non-woven fabrics that compete in the medical marketplace (Howard, 1987).

Barrier and Comfort Properties

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 breathable, sterilizable, flexible, and extremely resistant to blood and viral penetration (Daveonport 1990). Most of the fabrics available to produce surgical drapes will not meet the specific requirements. Thus, it is important to study area and to identifying the gaps level for health care protection and comfort attitude in term of medical textiles for better intervention. A better approach is to use a more hydrophobic fiber to make the fabric. Another approach is to increase the bonding. Development of spun bond and SMS fabrics increase the barrier properties solution for a better drape 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.

Methodology

Polypropylene spun bond and spun melt spun nonwoven fabrics with varying thickness of 40 and 50 GSM were used to produce the ophthalmic surgical drapes. The drapes produce from nonwoven fabric is compared with the reusable woven surgical drapes having 140 GSM made with 100% cotton. The significant variance among the surgical drapes has been estimated on structural and comfort properties recommended by European standard with respect to the critical area of surgical drapes (Figure 1). Because, the critical zone of a product has a greater chance of being involved in the transfer of infection carriers on the operation site, or vice versa.

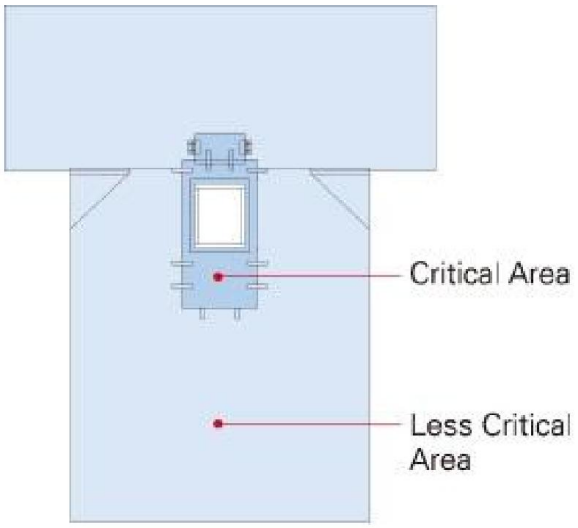


Figure 1. Critical and less critical area of the surgical drapes

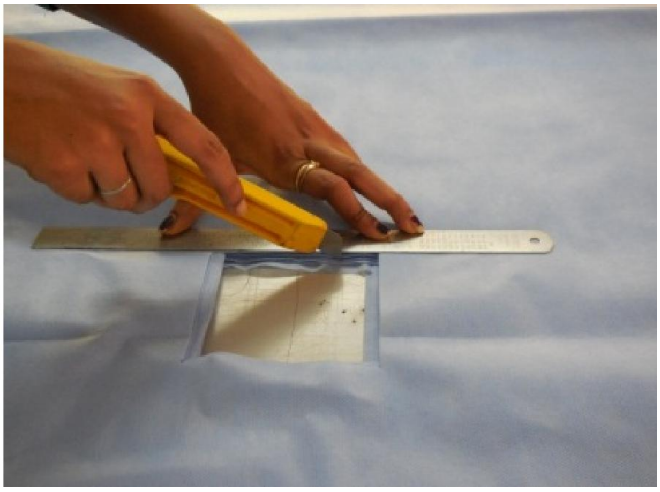
The main process in design and manufacturing of surgical drapes will be categorized into three distinct features:

1. Design processes on polypropylene nonwoven
2. Design process on polyethylene sheets
3. Integration of nonwoven and polyethylene sheets

Design processes on polypropylene nonwoven

Polypropylene nonwoven fabric is used to create drape for the ophthalmic surgery. The fabric were spread and cut through knife roller cutting machine with the recommended dimensions (Figure 2). Surgical opening on the fabric in the critical zone of the surgical drapes were carefully made through knife without leaving any trace of lint projection in the cutting edges. This zone will create an opportunity to make ease to perform the surgical procedure.

(a)



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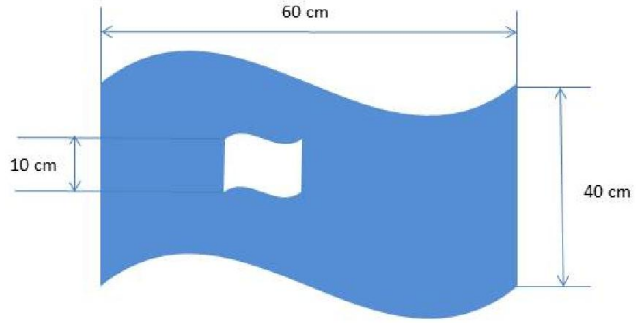


(c)

Figure 2. Process involved in the development of surgical drapes from polypropylene nonwoven fabric a) Spreading, b) Cutting and c)Dimension of surgical drape

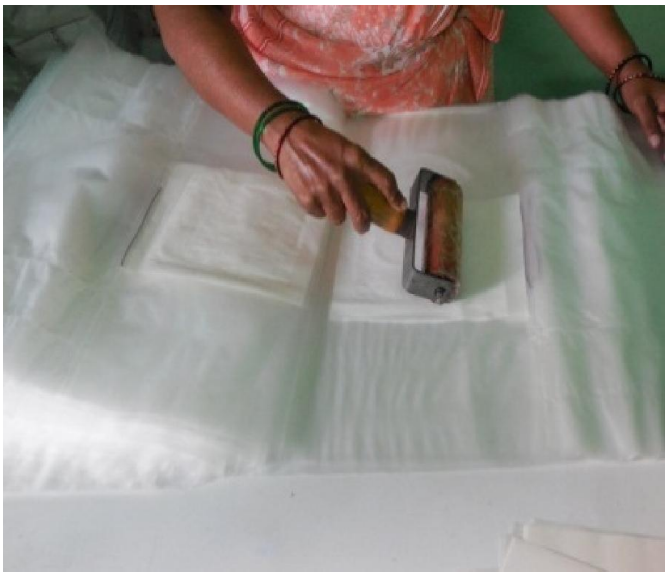
Design process on polyethylene sheet

Polyethylene sheets were used to create critical area and fluid bag to collect waste fluids and saline during the surgical procedure (Figure 3). Fluid bag is created by embracing the two surfaces of the base material and folded edge were sealed by using heat setting. Heat setting was takes place at right angles towards the folding area at 60°C. A special kind of no-allergic vinyl adhesive was used to applied encircled the surgical area and fluid bag to prevents from trembling and holds the drape stay on position during surgery. The adhesive enclosed the surgical area and fluid bags were covered with the releasing paper.

Integration of nonwoven fabric and polyethylene sheets

Integrating polyethylene fluid bag with non woven fabric is to create complete set of critical area of the surgical drapes (figure 4). The adhesive process can be aided for the better barrier protection. Incise of the drapes were attained by punching a surgery area on the respective spot of 3cm at mid of the critical area by using standard dies. Metal plates in the fluid bag build crease for good opening to allow fluid easily in to the bag during surgery. During surgery the releasing paper will be taken out and the adhesive drapes with correct suit of surgical area is worn over the infectivity.

(a)



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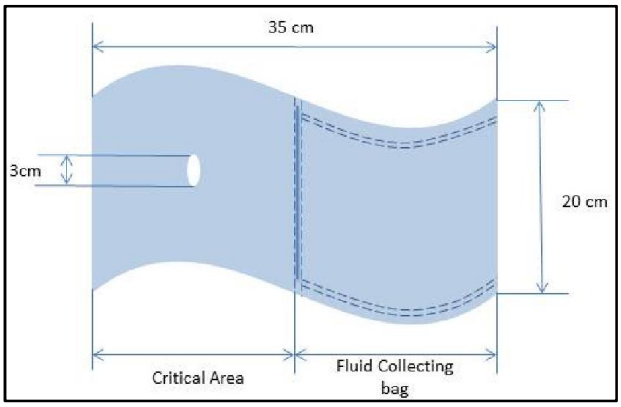
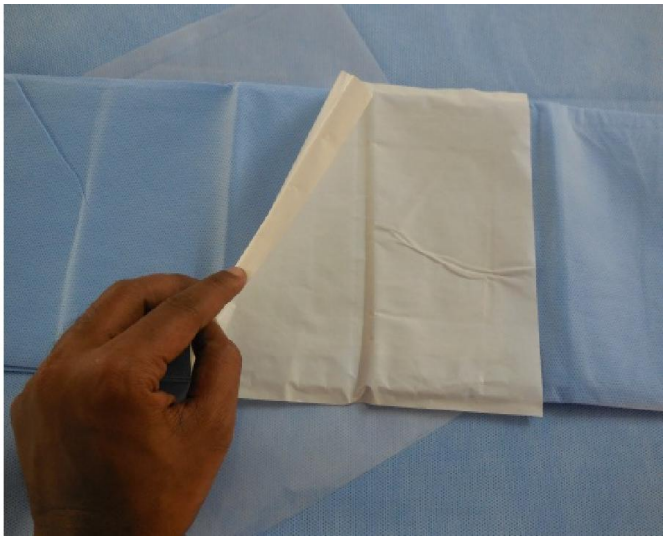


(c)

Figure 3. Process involved in the development of critcial area and fulid collecting bag with polyethyelene sheet a)Sealing edges for fluid collecting bag b) adhesieve for critcial area c) Dimension of polyethylene sheet

(a)



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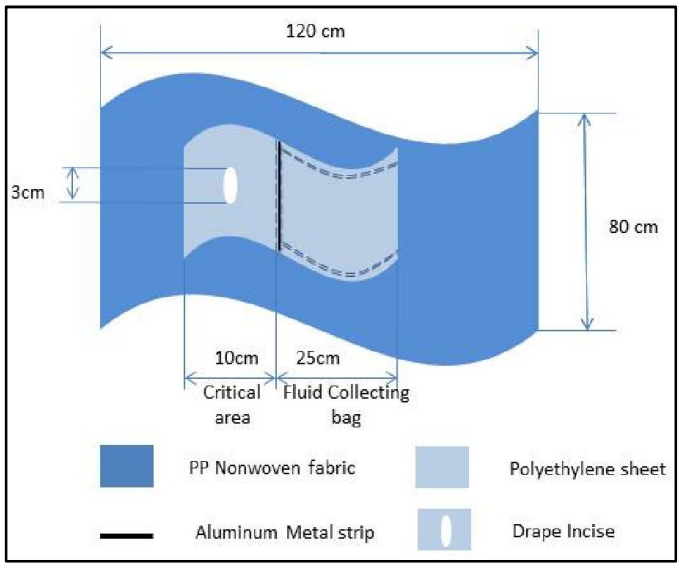

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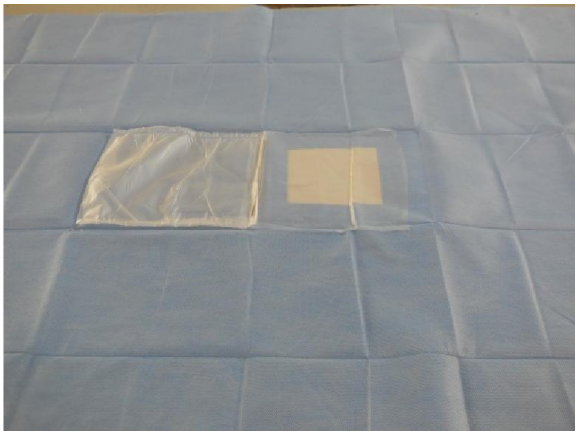

(d)

Figure 4. Integration process of non woven and polyethylene sheet a) adhesive b) attachment of releasing paper c) Overall dimension d) PP Ophthalmic surgical drape integrate with polyethylene sheets

RESULTS AND DISCUSSION

The evaluation of surgical drapes was carried with all the testing procedures related to EN 13795 European standard. The results are as follows.

Comfort properties

The measurement of air permeability plays 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. There is a significance of good air permeation in spun bond than spun melt spun nonwoven (Figure 5).

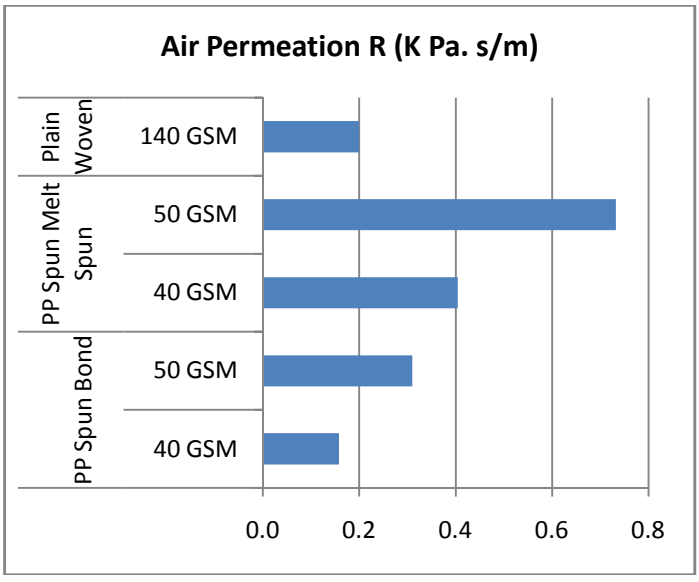

Figure 5. Quality characteristic of resistance to air permeation of ophthalmic surgical drapes

The Air permeability of drapes depends primarily on the cover factor. When the cover factor is more the resistance to the flow of air will be high (Saville, 2000).

Table 1. Quality characteristics of comfort and structural properties of ophthalmic surgical drapes

Parameters	Properties	PP Spun Bond		PP Spun Melt Spun		Plain Woven
		40 GSM	50 GSM	40 GSM	50 GSM	140 GSM
Comfort Properties	Air Permeation R (K Pa. s/m)	0.2	0.3	0.4	0.7	0.2
	Resistance to liquid penetration (head/Cm)	72	78	90	95	55
	Lint count(Log10 (lint count))	2.2	2.4	2.1	1.8	2.5
	Cleanliness Particulates (IPM)	2.0	1.8	2.0	1.8	2.5
	Cleanliness Microbial (Log10 (CFU/100 cm²))	50	48	40	35	95
	Drape coefficient (%)	57	65	76	83	86
Structural Properties	Bursting strength - Dry (KPa)	191	201	192	203	213
	Bursting strength - Wet (KPa)	189	201	191	200	214
	Tensile Strength - Dry (Machine Direction (N))	96	100	110	119	200
	Tensile Strength- Dry (Cross Direction (N))	46	75	76	65	90
	Tensile Strength – Wet (Machine Direction (N))	95	100	110	119	211
	Tensile Strength- Wet (Cross Direction (N))	45	75	71	66	95

Whereas there is high air permeation of surgical drapes would possess greater chances for fluid permeation in terms of saline and waste blood. However the melt blown fibers have a fiber diameter of approximately 2 microns and provide an excellent barrier layer while still leaving the drape breathable for better comfort when compare to all other fabric structures.

The resistance to the liquid permeation is higher in spun melt spunand spun bonded fabrics drapes compare to the woven fabric drapes (figure.6).Moisture transport through textiles is the important factor which influences on thermo physiological comfort of the human being during the surgical procedure. The moisture can be transferred through a textile material in the form of vapors and liquids (Svitlana, 2010). The fibres produced in spun bonded nonwovens are spun filaments, whose diameters are in the range of 10-35 microns, whereas the fibres of melt blown nonwovens are usually discontinuous and much finer, typically less than 10 microns. It is mostly affect by the proper choice of basis weight and using fibers with a greater degree of fineness are known measures for improving the barrier properties of spun bond surgical drape.

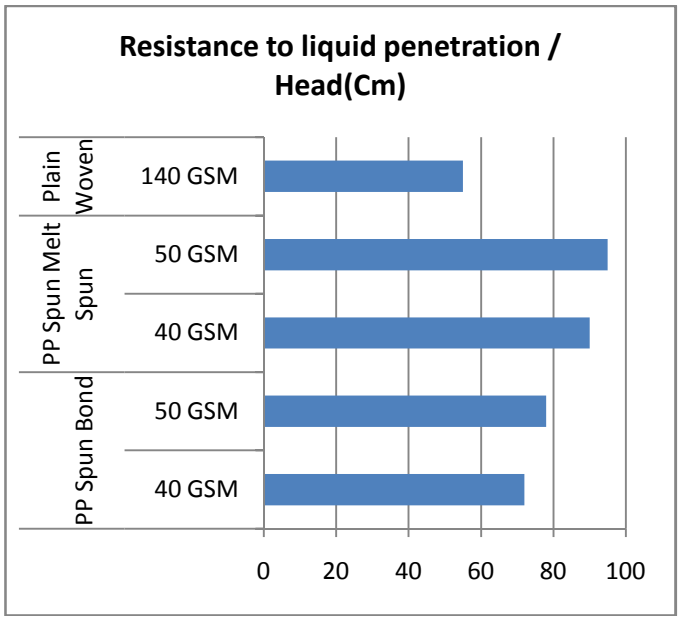

Figure 6. Quality characteristics of resistance to liquid permeation of ophthalmic surgical drapes

Woven surgical drapes made from cotton fibres tend to absorb the moisture and having properties of wicking to transfer the liquid to either surface. Further, the resistance to liquid permeation is less when compare to the nonwoven surgical drapes because of its hydrophilic in nature and it has high fabric pore structure.

Cleanliness determines the bio burden or the total content of viable microorganisms and the lint count of the surgical drapes. Cleanliness was evaluated on the finished product before sterilization. The test results are expressed as a number of CFU (colony forming unit)/100 cm^2. Only particles whose size range is between 3µm and 25µm have to be considered as linting, due to the fact that only particles of this size range are considered to be capable of carrying microorganisms. Plain woven fabrics have higher lint count and particulates (Figure 7) which has more than 2.5 µm in size lead to the formation of microorganisms. The tendency for the increases of the lint count is mainly due to surface properties of woven fabrics. It does high porosity causes less binding fibres inside to weave tighter fabrics. These projecting fibres on the surface of the fabric show higher cleanliness particulate matter.

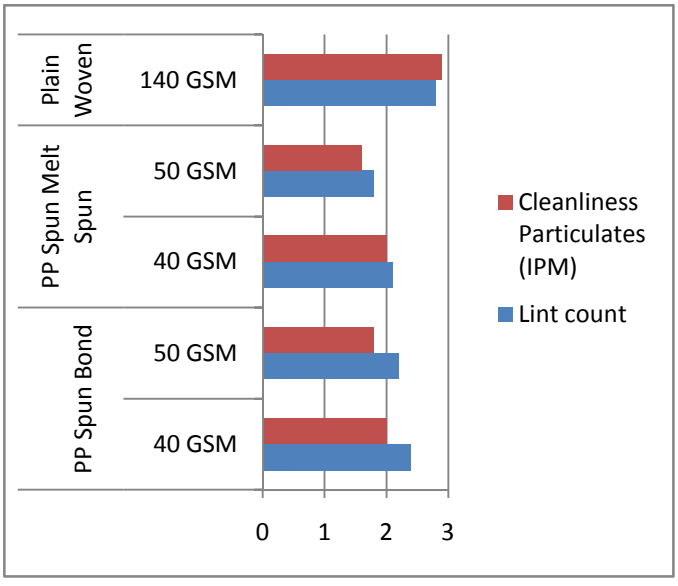

Figure 7. Quality of cleanliness of particulates and lint count of ophthalmic surgical drapes

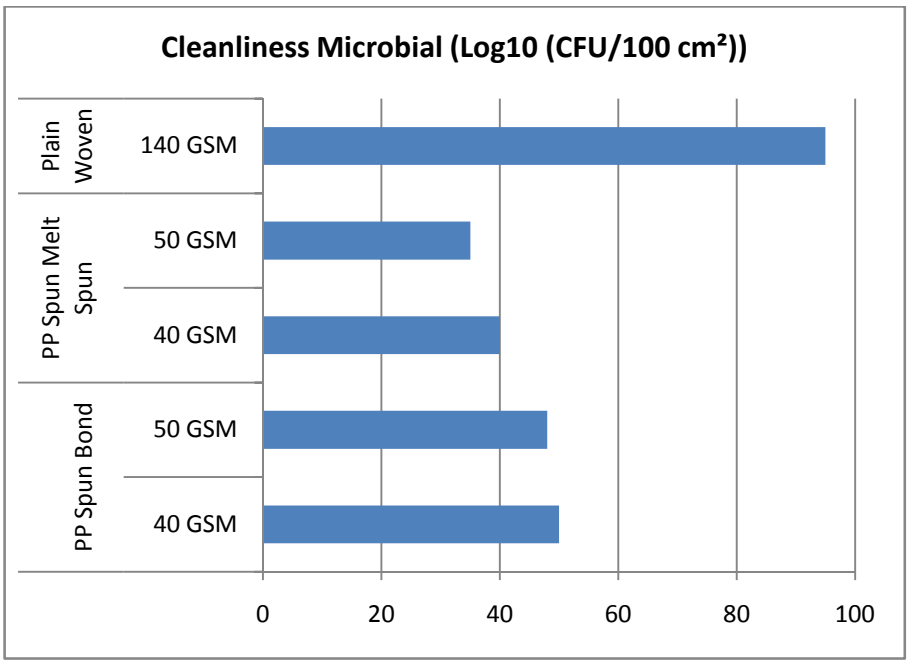

Figure 8. Quality of cleanliness of microbial count of ophthalmic surgical drapes

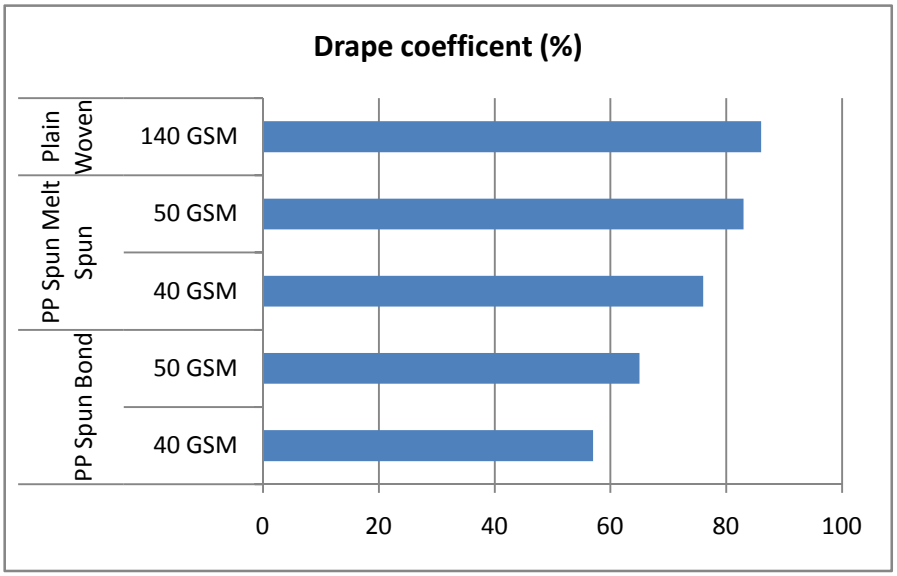

Figure 9. Quality characteristic of drape coefficient of ophthalmic surgical drapes

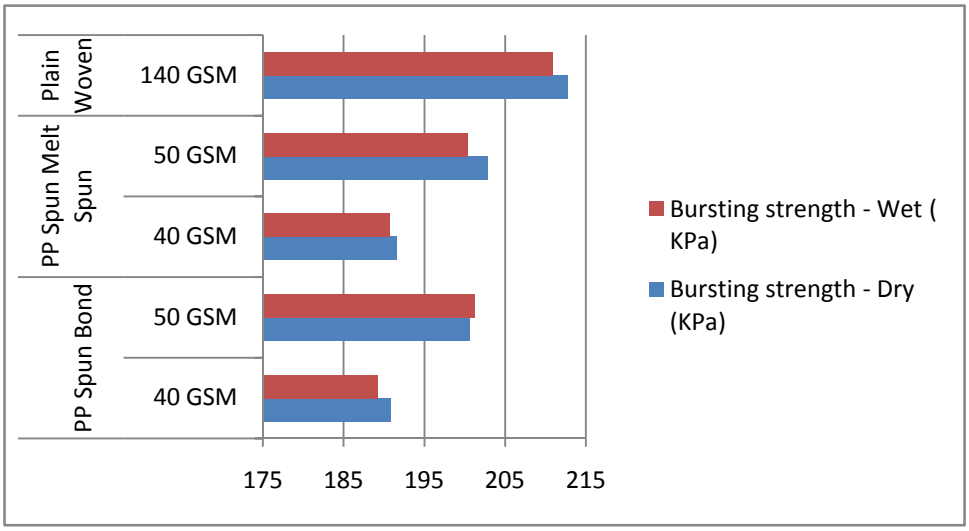

Figure 10. Quality of bursting strength in wet and dry condition of ophthalmic surgical drapes

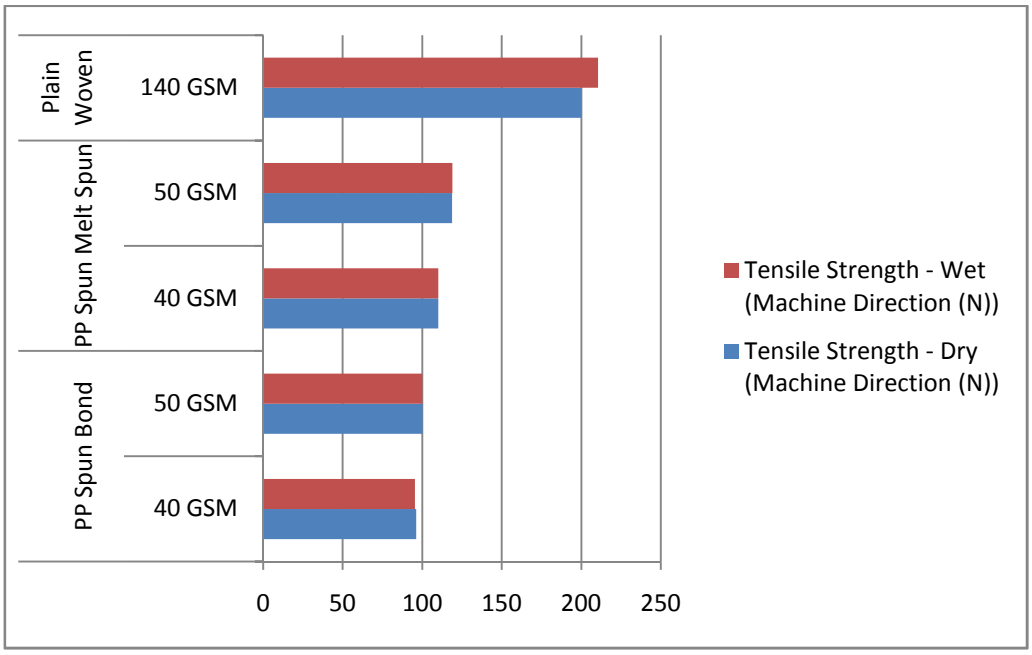

Figure 11. Quality of tensile strength in wet and dry condition of ophthalmic surgical drapes

Cleanliness on microbial activities is very less absorbed in SMS fabrics which is less as 40 CFU where there is higher thickness of the fabric is considered without any functional treatment of the fabrics. The main causes of higher cleanliness microbial observed in woven fabric the count near to 100 CFU (Figure 8). The results are due to the protruding fibres on the fabric surface which catches easily the growth of microbial activities on its surface. The drape coefficient of surgical drapes will decide the comfort level of the patient's during the surgery (Figure 9). The fabric 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.

There is a significant difference between SMS and spun bond ophthalmic surgical drapes are governed by the frictional effects associated with the fibre movement and at the high elastic response of the fibre. 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

Structural Properties

The surgical drapes consist of incise with fluid collection pouches and other non critical zones which are resistant to tearing, strikethrough and abrasions which provides secure attachment and it would reduced lint levels therefore decreasing the risk of airborne bacterial transmission. Tensile strength tests are generally used for woven fabrics where there are definite warp and weft directions in which the strength can be measured. However non-wovens do not have such distinct directions where the strength is at a maximum.

Bursting strength is an alternative method of measuring strength in which the material is stressed in all directions at the same time and is therefore more suitable for such materials. The result of surgical drapes in both dry and wet conditions (Figure 10) shows higher for woven fabrics when compare to other non woven. It is mainly due to the contribution of warp and weft twisted yarn. In nonwoven, SMS drape shows high bursting strength than spun bond. It is observed that with the increase in mass per unit area of SMS nonwovens the bursting strength as well as the extension on bursting increases. The level of pressure developed within the nonwoven structure at certain level of extension depends on the density of nonwoven. 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. The fatigues of surgical drapes are caused mainly by the changes in fabric structure and mechanical properties during long-term application. The arrangement of the fibres and their orientation distribution are related to the structure of the fabric. Changes in mechanical and transmission properties of textiles fabrics are important towards the surgical procedure. The results of woven fabric have higher strength in wet condition on both machine and cross direction of tensile strength. Due to the increased degree of crystallinity and hydrogen bonding between the molecules in the crystalline areas in cotton, moisture can't penetrate the molecules. Hence there is no act of lubrication and results in loss of strength when comparing with other polypropylene nonwovens drapes, SMS drape (Figure 11) shows higher strength than spunbond.

Since, the fabric construction and the arrangement of fibres are three layered structure. Hence, the density of the spun melt spun is higher than the spun bond drape relatively showed that the tensile force is higher for SMS than spunbond.

Conclusion

1. Development of spun melt spun nonwoven drapes integrating with polyethylene sheets delivered the highest level of barrier protection and greatest degree of comfort.
2. Using spun melt spun nonwoven having fibres which are less than 2 microns would provide an excellent barrier layer while still leaving the drape breathable for better comfort when compare to the drapes made from spun bond and woven fabric.
3. Resistance to liquid found very less in woven drapes due to its higher pores structure and having hydrophilic fibres which absorb and leads to the wicking behavior in greater extend.
4. Lint count of the woven fabrics is mainly caused by the protruding fibres on its surface which causes highgrowth of microbial content when the lint count is more than 3 µm.
5. When there is same composition of raw material, where the thicker and heavier fabrics performed better than the lighter and thinner types in all aspects of structural properties of surgical drapes.

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