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Process of Warp Knitting Mesh for Hernia Repair and its Mechanical Properties

Abstract
Polypropylene monofilament is selected to fabricate the mesh used for hernia repair, and the mesh is warp knitted on a Tricot machine with a compound needle (gauge E 18); an atlas structure is used. The mesh with 18 to 20 courses per centimetre has the best mechanical properties. The heat-setting conditions are confirmed on the basis of trials. It can be concluded that the heat-setting temperature between 125 °C to 128 °C and the time between 5 to 8 minutes benefit the mechanical properties of the mesh.

Keywords: *hernia; warp knitting; medical textile; mechanical property*

Indroducion

In the past ten years, the application of bio-textiles for implants has greatly developed in the new field of tissue engineering. A shortage of organic implantations and the very high cost of the operation are presently the main problems in surgical implant operations. There is also the danger of sudden/shock rejection. In the past five years, about ten thousand persons have died while waiting for various tissue implants [1]. For this reason, the role of synthetic polymers and textile structure in tissue culture has become increasingly important in the medicinal field. For example, using synthetic material to repair hernia has become the major method in operations to repair external hernias.

Inguinal hernia repair remains one of the most commonly performed operations worldwide. There are three methods of external hernia repair: tension repair, low-tension repair and tension-free repair [2]. All of the traditional repair methods involve tension repair. Hernia repair has traditionally been accomplished by an approximation of tissue to tissue. Since these structures are not normally in apposition, their approximation may be associated with undue tension on the suture line. For this reason, the recovery ratio is as high as 10 to 15 percent during 5 years after the operations. On the other hand, using synthetic material to repair hernias resolved the tension problem, and the tension-free repair method has become the major internationally-used method of repairing external hernias. The recovery ratio of the method is 0.1% for the original hernia and 2% for the recurrent hernia [2]. According to reports, polypropylene monofilament mesh is the best repair material which has so far been used in hernia repair operations and other abdomen defect operations [3]. It is reported that this material has been used in the fixation operation of the kidney and the diorthosis operation of the breast. Although the polypropylene monofilament mesh has many advantages compared to other materials, the meshes on the market still have some problems. For example, they may curl and shrink in the body under heat [3]; the handle may be too hard, etc. So, our task is to study the knitting and heat setting technologies, and analyse the main factors influencing the mechanical properties of the mesh.

Required properties of the mesh for hernia repair

The fabrics used for implant must meet certain biological properties and medicinal functional properties. The biological properties include innocuity, sterilising, bio-compatibility, bio-absorbency or bio-inertness. As repair material, the medical functional properties of the mesh used for hernia repair include:

- having enough strength, being able to resist the stress from the inner abdomen before the new healthy tissue comes into being;
- having an appropriate pore size, rational pore distribution and a high pore ratio;
- in order to decrease the chance of infection and sinus tract formation, the size of the three dimensions between the constituent filaments must exceed 10 μm;
- maintain good dimensional stability after the material is implanted into the body, in other words, it cannot shrink or become deformed;
- having good stability in structure, can easily be cut into any shape needed and is easy to suture onto tissue;
- having a soft handle, being easy to mould, increases the feasibility of operation, decreases discomfort to the patient, and increases the success of the operation.

Designing and processing the mesh for hernia repair

Selection of material

Synthetic biomaterials area comprised of two categories, namely absorbable and non-absorbable synthetic materials. Using the former may result in a void syndrome, which may be caused by macromolecule material in the future. But in fact, this kind of material cannot cause enough fibroblasts to regenerate. An external hernia may recur if the material was absorbed by the tissue. So, non-absorbable material, which is inert to tissue, is still the best material to fabricate the mesh used for hernia repair. Decades ago, it became evident that the use of multifilament and braided suture materials frequently resulted in infection and sinus tract formation. This was due to the presence of spaces smaller than the size of neutrophilic granulocytes between the constituent filaments. A few microns more in any of its three dimensions can theoretically increase the chance of infection and sinus tract formation. Bacteria averaging one micron in size can hide in such small spaces, become protected from neutrophilic granulocytes, and proliferate. On the other hand, monofilament can form a wider space between fibres, which cannot harbour bacteria.

We chose polypropylene monofilament mesh to repair hernia both for its physical performance, biological inactivity and compatibility. Our decision is based on the following factors:

Firstly, polypropylene is itself innocuous; it can resist any pollution when it is spun into fibre. Secondly, it has strong chemical stability for its good chemical inactivity and structural compatibility. Thirdly, it belongs to the family of non-absorbable materials. It absorbs the least dampness; it will not be absorbed when used in medical operations, and its properties will not change even in the slightest. Fourthly, its melting point can reach 170°C, and so it can stand high-temperature disinfection. Fifthly, the monofilament of polypropylene has a very good dynamic performance, with low density and weight and high durability. Sixthly, it has a smooth surface, easily wrapped by the newly-formed tissues. Seventhly, the distance between each monofilament is longer than 10 μm, which can prevent the multiplication of bacteria and avoid any infection caused by the use of compound biomaterials [2].

When choosing the diameter of the monofilament, we mainly put the strength and knitting performance into consideration. The diameter decides the strength of the monofilament, which in turn decides the strength of the fabric. Therefore the greater the monofilament diameter is, the stronger the fabric becomes. However, the greater the monofilament diameter is, the poorer will be the monofilament's performance. The value of the monofilament's bending rigidity is in proportion to the fourth power of the diameter. The bigger the monofilament diameter is, the less bendable the monofilament will become, and so very difficult to bend and knit into loops. Furthermore, the diameter of the monofilament is limited by the knitting elements. The trials showed that the polypropylene monofilament in Ø 0.15mm (equal to 160 dtex) is appropriate for knitting.

Structural design of the mesh

Here we selected the three-open atlas structure, according to the properties required to knit the mesh for hernia repair. The stability of the structure should be taken into account above all when the mesh is designed. The mesh has to be cut into a certain shape before being sewed with the tissues in operation, so the material should have excellent structural stability and sewing performance. Woven fabric is made by interlacing warps and wefts. Its stability is determined by factors such as tightness of the fabric, the friction force between the warps & wefts, and the entanglement of fuzzy fibres. As a woven fabric made of monofilaments does not show the advantages concerned with the factors mentioned above, it can be imagined that the structural stability of such a woven fabric is considerably poorer. On contrary, the warp knitting mesh is made by the interlacement of one or some systems of yarns. The knitted fabric made from monofilaments has good dimensional stability after heat setting, and the stitches are not easy to drop, so it is suitable for the structural requirements of hernia-repairing mesh.

The size of pores among the filaments, the distribution of these pores, and the void content are the key factors that influence the effect of the operation. The basic concept of tissue engineering is to cultivate the cells on the open supporting material with the aim of reinforcing or repairing the required tissues or organs, and regenerating new tissues. The material for reinforcement or repair acts as a foundation that the cells adhere to, crawl and grow on. Here the pivotal problem is how to implant the cells onto the supporting material for reinforcement or repair, and so to grow the appropriate tissue structure. The size of pores is one of the key factors which affects the growth of the cells. In the work [2] the autors stated that "an increasing strength of tissue attachement with increasing implantation time and pore size range" could be observed. A larger pore can increase the volume of the tissues implanted and decrease the volume of material for support, reinforcement or repair, and is also an advantage for the transport of nutrition and excretion of wastes. The open atlas strstitch is, far example, a sucture which can be distributed evenly. The size of the pores and the void content can be adjusted easily by changing the density of the fabric.

In addition, the thickness and the weight of the fabric are also two indexes for evaluating the performance of the hernia mesh. The smaller the thickness and weight are, the less uncomfortable the patient will feel, and the less their feeling of illness, and so the better the effect of the operation will emerge. This is why we chose only one guide bar to knit the basic structure.

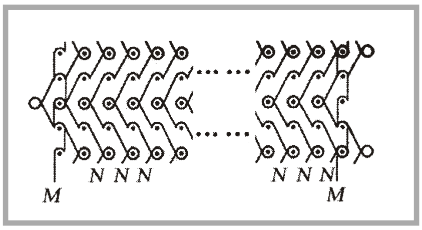

Figure l. The structure design of warp knitted mesh for hernia repair.

Technical parameters of the mesh's knitting

The fabric was produced on a Tricot machine using compound needles. The gauge of the machine is E l8. Because be manufacturing the fabric, only one guide bar was used to knit the basic atlas structure, the selvage was not smooth unless another guide bar was used to fill it up and strengthen it. Here we used an open pillar stitch. The pattern of the selvage is designed as demonstrated in Figure 1. The needle at the side of fabric was removed to make sure that the monofilament will not knit at the side. The next wale on the position M was added to the pillar stitch. If we thread two monofilaments on position N, the selvage formed will be more stable. The knitting technical parameters were as follows:

- ***Specification of machine***
  Type of machine: Tricot machine
  Machine Gauge: E 18
  Number of guide bars: 2
  Speed of machine: 400 rpm
- ***Material***
  A: 160 dtex (Ø 0.15mm) polypropyene monofilament
  B: 120 dtex polyester (only used at the selvages)
- ***Threading and lapping***
  GBl: 1-0/1-2/2-3/2-1// full A

Table 1. *The specification of the fabrics at different course densities.*

Densities and weight of fabric		A	B	C	D
Wale density of the fabric off the machine, wpi		18.5	18.5	18.5	18.5
Course density, cpc	On the machine	14.9	16.0	18.0	20.0
	Off the machine	16.5	17.5	19.5	21.5
Weight of finished fabric, g/m2		102	104	108	114

wpi = wales per inch
cpc = courses per centimetre

Table 2. *Mechanical properties influenced by course density of the mesh.*

Course density, cpc		Weight, g/m2	Pushing strength, N	Void content, %
On the machine	Off the machine			
14.9	16.5	102	443.0	48.82
16.0	17.5	104	484.0	46.36
18.0	19.5	108	526.4	44.64
20.0	21.5	114	511.6	40.90

cpc = courses per centimetre

Table 3. *The mechanical properties of several meshes for hernia repair.*

Repair mesh	Broken strength, 10^4 N/m2	Void content, %	Softness, mg-cm	Thickness, Mils*
Marlex .TM. Mesh (From BARD)	128.34	41.30	786.3	25.9
Prolene .TM. Mesh (From Ethicon)	177.33	49.73	678.0	24.1
American Patent no.6,287,316	165.60	47.10	520.0	20.0
Mesh developed by ourselves (Sample A)	171.38	44.64	508.0	25.2

** l mil = 10^{-3} inch, i.e. 0.0254 mm.

GB2: l-O/O-l// only threaded at the selvages .

- ***Specifications of the fabric.*** We knitted 4 fabrics at different course densities, labelled as A, B, C, and D in the experiment.The specifications of the fabrics are shown in Table 1.

Mechanical properties of warp knitting mesh for hernia repair

Mechanical properties influenced by different densities

When the course density of the fabric is certain and established, wale density is the main factor which affects the mechanical properties of the fabric, including strength, flexibility, void content and the weight of fabric per square metre. The flexibility of the fabric is not easily defined for the edges of the fabric curl when the fabric is taken off the machine. However, the handle of the fabric will become rougher when the course density is increased. Table 2 shows some other mechanical properties affected by the dense of the fabric

Mechanical properties influenced by the heat-setting

The edges of the fabric are excessively coiled just after it comes off the machine, and the feel is rough and coarse. It has to be heat-set to improve this situation. The effect of the heat setting is affected by factors involving heating temperature, time length and the tension of the heat setting. The most important factor among them is temperature. In this experiment, the melt temperature of polypropylene monofilament used is 170~172°C. The PP monofilament begins to break and the strength will fall markedly when the temperature of heat setting is over 162°C, and some melt holes will appear on the fabric when the fabric is under a certain tension. Trials show that the heat setting temperature should range between 100°C and 150°C, and 120°C~140°C should be a better range. It will be most effective when the temperature is set between 125°C~130°C. The time of heat setting should be longer if the temperature is lower, and vice versa. When the temperature is between 100°C~120°C, the time is roughly 10~20 minutes, 5~10 minutes when the temperature is set at 120°C~140°C, and 1~5 minutes between 140°C~150°C. The fabric in trial-production was heat set at 125°C~128°C for 5~8 minutes. The pushing strength is up to 540N after heat setting, and 10% higher than the fabric before heat setting. The widthwise shrinkage in 100°C for 60 minutes is down to 1.5% from 6% before heat setting. At the same time, the lengthwise shrinkage is decreased from 4% before heat setting to 0.65%. This increases the stability of the fabric under heat. In addition, other advantages are obtained from from the heat setting, namely that the coils on the edge are improved and almost disappear, the handle of the fabric is improved, and the softness of the fabric is also increased.

Comparison of the characteristics of different hernia repair meshes

There are some hernia repair meshes available on the market at present. The main products are Marlex from the BARD in America, Prolene from Ethicon, Trelex from Meadox etc. In order to evaluate the quality of the mesh that we developed, we selected one finished sample of which the wale and course densities were 18 wpi and 18 cpc separately on the machine, and 18.5 wpi and 19.5 cpc after finish. The temperature of heat setting was between 125~128°C, and the time length ranged between 5~8 min. The characteristics of the four different meshes are compared in Table 3.

Conclusion

- So far, the PP monofilament appears to be the most suitable material for knitting into hernia repairing mesh. The atlas stitch is also an ideal structure for a repair mesh. The tricot machine with compound needles is the optimal machine to knit the mesh.
- The strength of the PP monofilament mesh is increased with the course density, and the void content will decrease with the increase in the course density. The handle of the fabric becomes more rigid with the increase of course density.
- The heat setting can solve the problem of coils on the edges, remarkably lower the heat shrinkage of the fabric, and also increase the strength and handle of the fabric. The optimal temperature of heat setting ranges is between 125°C~130°C, and the ideal time length is between 5~8 minutes.
- The option of a fabric with less density can help to produce larger pores among the filaments, as well as a better feeling in the patient, while in the meantime the heat setting can raise the decreased fabric strength.

References

1. *Rahul G Asai. Role of Synthetic Polymers and Textile Structure to Tissue Culture. Synthetic Fibres, April/June 2003: P16-21.*
2. *Bobyn, Wilson and MacGregor, Pilliar, Weatherly. Effect of pore size on the peel strength of attachment of fibrous tissue to porous-surfaced implants, Journal of Biochemical Materials Research, Vol 16, 1982, pps 571-584.*
3. *American patent, no. 6,287,316.*

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