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REVIEW ARTICLE

Textile Implants: Silk Suture Manufacturing Technology

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Abstract

Silk is one of the natural protein filaments which have highly oriented molecular structure. Hence, it has high tenacity as compared to that of other polymer filaments. Due to its biocompatibility, it is highly suitable as medical implants. In this review, the details pertaining to the conversion of silk filament into silk sutures are covered. These details include i) degumming of silk using various reagents like alkalis, acids, enzymes, soaps etc, ii) dyeing of silk sutures using sulphol black, logwood black etc., iii) Doubling and twisting of silk sutures, iv) different types of braiding techniques commonly used for the manufacture of silk sutures and v) coating of silk sutures using reagents like bees wax, silicone etc. SITRA has developed a process technology and a suitable machine to encapsulate braided silk suture thread with polymeric silicon. The silicon process is not affected by normal autoclaving temperature like other alternatives such as bee wax and ethyl cellulose.

Keywords: Silkworm, sutures, polymer filaments, sericin, logwood black, braiding, bee wax, silicone.

Introduction

Silk and wool are the two most important protein fibres used in textile and used in medical field in the form of sutures. The silk filament is produced by the silkworm. It consists of two triangular filaments of fibroin. These two triangular filaments are bind together using a gun called sericin. The main composition of silk is fibroin and sericin. The molecules present in silk are highly oriented and parallel to the silk filament axis (Morton and Hearle, 2008). Hence, the tenacity of silk filament is high as compared to other protein fibres like wool, cashmere, alpaca etc. (Brundtland, 2014). Because of its mechanical properties, silk has been used as suture from the beginning of medical history and also used in textile production for centuries. Any sutures used in surgical procedures need the following characteristics (Moynihan, 1920).

1. Tensile strength
2. Knot strength
3. Elasticity
4. Memory
5. Degradability
6. Tissue reactivity
7. Free from infection

Silk sutures also have the above properties and are generally categorized as non-absorbable surgical sutures. They are composed of naturally occurring proteins called fibroin. Before the silk is used as a suture, silk filaments are treated with processes such as removal of sericin, bleaching, braiding and coating before it is used as sutures (Covidien, 2014). On the part of silk suture development, SITRA (The South Indian Textile Research Association, India) has developed a suitable process technique and machine to coat the silk filament with polymeric silicon which helps to reduce the capillary activity. In this review, the details pertaining to the conversion of silk filament into silk sutures are covered in the below sections.

Silk filament formation

The silk filament is produced by silkworm. The silkworm has two silk glands or sericteries. By using these two silk glands, the silkworm produces two fibroins. The two fibroins are surrounded by sericin which helps to bind fibroins with each other. The outcome of the product from silk form is called 'cocoon' and the cocoon formation process is called as 'cocoon spinning'. The rate of filament production per silk worm is varied from 360 to 480 mm/min (Panda, 2012).

Composition of silk filament

The silk filament is composed of two types of proteins. They are i) fibroin and ii) sericin. Sericin is chemically a gum material which is used to bid the two triangular filaments of fibroin. They also contain other natural impurities namely, fat, waxes, inorganic salts and colouring matter. The composition of proteins and other natural impurities present in the bombyx mori silk is given in Table 1 (Mondal *et al*., 2007; Mitra *et al*., 2009; Futura, 2014). Bombyx mori silk is widely used to produce suture for many centuries. Even the silk protein is foreign protein to human body; it helps for cell adhesion and proliferation in the human body. Sericin is one of the compositions present in silk. It has been identified as the foreign material which induces unwanted immunogenic reactions in the body.

Table 1. Composition of bombyx mori silk filament.

Component	Content (%)
Fibroin	70-80
Sericin	20-30
Wax matter	0.4-0.8
Carbohydrates	1.2-1.6
Inorganic matter	0.7
Pigment	0.2

However, the silk protein such as fibroin supports the growth or production of cells by multiplication of parts (Kerans *et al*., 2008). Hence, the removal of sericin from the silk is used as the manufacture of biocompatible materials used in medical field.

Degumming process

The sericin is removed from the silk material by using degumming process. Removal of sericin improves the lustre, colour, hand and texture of the silk filament. The sericin acts like a protection layer against dyeing of silk filament (Gurumurthy, 2012). There are four different methods in degumming process. They are i) boiling with soap, ii) alkalis, iii) acids and iv) enzymes (Mehra *et al*., 1998).

Boiling with soap: Oil based soaps are used for degumming the silk. The soaps used in these methods are natural and readily soluble in water. Depending upon the nature of silks, three different kinds of soaps are used. They are i) pure oil soap containing 65% fatty anhydrides, ii) Monopol soap made from sulphonated castor or linseed oil containing 65-75% fatty anhydrides, iii) Marseilles soap produced from olive oil contain 60-63% fatty anhydrides. The quantity of soaps required for completing the degumming process depends upon the nature and type of silk filaments.

Degumming with alkalis: Caustic soda, sodium carbonate, sodium silicate, trisodium phosphate, boarx, sodium bicarbonate are some of the alkalis used for degumming process. On the variety of alkalis, sodium carbonate is mostly used for degumming process. The degumming with alkalis process alone causes stock dirty, yellowish, thin and harsh on the silk filaments. To avoid this problem, mixture of soap and alkalis are used. The surfactant with alkalis has also been recommended for best degumming process. Some of the surfactants used in the degumming process are alkyl aryl sodium sulphonates, sodium lauryl sulphate, ethylene oxide condensates like polyoxylene alkyl ethers, polyethylene glycol ethers etc. Silk is thoroughly wetted using wetting agent. After that, the silk is kept in the mixture of alkali and surfactant for 30 min at temperature around 75-80°C. The sericin is degummed during this alkali process. After the silk is fully degummed, it is washed with warm water to remove the residual sericin and alkalis. The silk filament is then neutralized by rinsing with mild citric acid or acetic acid solution for neutralizing any residual alkaline present in the silk material after degumming process (Gurumurthy *et al*., 2013).

Degumming with acids: Silk degumming is better for using the acids under controlled processing conditions. Some of the acids used for degumming process are succinic acid, tartaric acid and monochloroacetic acid. Dilute acids are used in the acidic degumming process. They attack peptide bonds liking aspartic and glutamic acids present in the sericin. Hence, the sericin undergoes hydrolysis and it can be removed from the silk filaments by subsequent washing.

Degumming with enzymes: This process gives mild action to the silk filaments. The degumming of sericin is uniform in the silk filaments. It results soft handle of the silk filaments. The enzymatic degumming process reduces the effect of lousiness than the classical boiling-off in soap methods with either acids or alkaline media. Pretreatment of silk with alkaline solution is required for effective degumming. Treating of silk filament with alkaline solution causes to swell the sericin from the surface of silk filaments. It results effective and uniform removal of sericin from the surface of silk filaments. There are three different types of enzymes. They are i) trypsin, ii) papain and iii) bacterial enzymes. Trypsin is a sericin protease. It is most active in the pH range from 7-9. In this enzymatic process, the enzyme concentration is maintained as 12% for 1-4 h at 37°C. Since sericin is a polar and less crystalline protein with higher lysine and arginine content, the sericin can be easily hydrolyzed by trypsin. However, the fibroin present in the silk filament is not affected by trypsin. Because the fibroin has less polarity, higher crystalline and lower content of lysing and arginine amino acids as compared to that of sericin. Papain is a sulphydryl based enzyme derived from papyrus latex. It is most active in the pH range from 5-7.5 at the temperature of 70-90°C. This enzymatic process is activated by adding the sulphydryl agent with low concentration for effective enzymatic action. Addition of surfactant is required to aid in wetting of sericin and results effective degumming process. After degumming process, the silk filaments are washed with warm water for removing the sericin, residual enzymes and its relevant additives. Alcalase is the bacterial based enzyme. It is most active in the pH of 9. The silk filaments are treated with alcalase for 1 h at 60°C for effective degumming process. In general, combination of alkali and surfactant is preferred for degumming of silk filaments.

Dyeing

Generally black colour is preferred for dyeing silk filament particularly medical application (suture) for improving the silk filament visibility during operation procedure (Trusilk, 2014; Dolphin, 2014; Hicare, 2014). There are two types of dyes are used for colouring the silk filament to convert the traditional natural silk filament into a suture material used in modern surgery. They are i) Sulphol black (CI 53185) meeting with European pharmacopoeia, ii) logwood black (CI 72920) compiling both European pharmacopoeia and US pharmacopoeia (CNC, 2014; Dolphin sutures, 2014; Catgut, 2014).

Sulphol black: Sulphol black dye is also known as sulphur dyes. Sulphur dyes are insoluble in water. To convert the sulphur dyes in soluble form, the dye substrates are mixed with caustic soda and sodium sulphide. After dyeing the silk filaments are oxidized using air or by treating with oxidized chemicals. Excess dyes are removed by water washing (Textile, 2014). After washing the silk filaments are neutralized by treating with mild acid solution such as citric acid or acetic acid solution which helps to remove the residual dyes and metal salts present in the surface of silk filaments.

Logwood black: Logwood black is obtained from logwood tree, campeachy or bloodwood tree. The chips of logwood tree are boiled and extract the solution called “hematoxylin”. Hematoxylin is a complex phenolic compound and is similar to flavonoid colouring agents of flowers. Logwood requires a mordant to colour and fix the same in the silk filaments. The metallic salt such as ferrous sulphate is used to improve the colour fastness property like fastness to light, perspiration, washing and rubbing. The silk filaments along with logwood extract are kept in dye bath and temperature raised up to 80°C for 1 h. After dyeing, the silk filament is washed with warm water and rinsed with citric acid or acetic acid solution for removing the residual metal salts present in the silk filaments. Rinsing with mild acid solution helps to keep the silk filaments in neutralize condition (Elkinvanaeon, 2014).

Doubling and twisting

After dyeing of silk filaments, they are taken for doubling process. Doubling is usually carried out using 2-6 filaments and the product is called as plied filaments. After doubling, the twist is inserted in to plied filaments. The twist is ranged from 17-21 TPI. It provides additional strength to plied silk filaments.

Braiding

Braiding is simplest way of fabric formation. Diagonal interlacing of yarns forms a braided structure. In braid structure there are no warp or weft yarns as in the case of woven structures. The process of braiding does not involve shedding, beating and take-up mechanisms. The yarns or filaments in the form of single or multiple strands can be directly feed to the creel in the braiding machine. The feed packages can be in the form of cones, cheeses, bobbin, spools etc. (Anon, 2007; Chellamani and Balaji, 2011). Braid material is flexible than monofilament sutures. Hence, the knotting is quite easier in case of braided sutures. Even though the diameter of monofilament suture is same as braided sutures, the knot strength of braided suture is higher than the monofilament sutures.

Types of braided architecture

Braided architecture is generally classified as biaxial and triaxial structures. Biaxial includes circular and flat braids. *Circular braids:* Circular (tubular or round) braids are formed hollow or around a centre core. Circular braids have a hollow, round or oval cross section. Hollow braids made for fluid transmission field (tube, flexible and rigid pipe production), thick or thin walled beams and electric cables. Round braids are used for manufacturing solid rods, bar and rope manufacturing. Figure 1 and 2 show the round and hollow braided fabric structures (Adanur, 1995).

Fig. 1. Round braided fabric structure (Adanur, 1995).

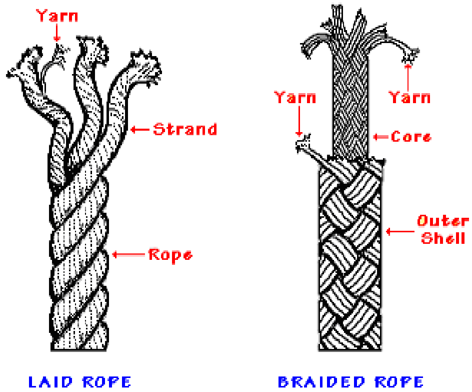
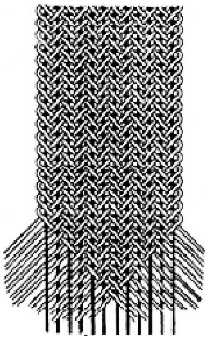


Fig. 2. Circular braided fabric structure (Adanur, 1995).

Fig. 3. Flat braided fabric structure (Adanur *et al*., 2003).

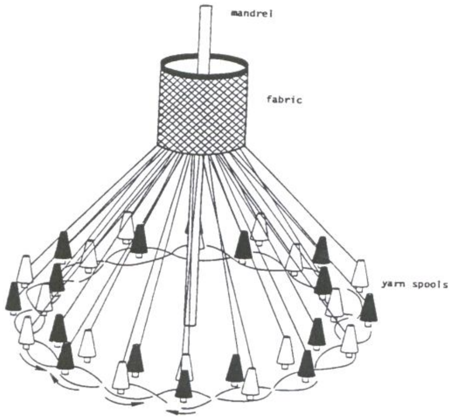
Fig. 4. Triaxial braided structure (Adanur *et al*., 2003).



Flat braids: Flat braid is made in the form of tape or flat strip. Tubular braiding machine have even number of carrier but flat braids have odd number of carriers. Size of the braid fabric is decided by number of carriers, linear density of yarn and number of yarns per carrier. Figure 3 shows the flat braided fabric structure (Adanur *et al*., 2003).

Triaxial braids: Biaxial braid structure is obtained with two sets of yarn carriers rotating in opposite directions which are the traditional braiding process. By inserting additional yarns in the axial direction, triaxial braided structure is obtained (Fig. 4) (Adanur *et al*., 2003). In general, for manufacturing of silk braided suture, circular braiding is preferred. Circular (tubular or round) braids are formed hollow or around a center core. A circular braiding machine consists of two sets of an even number of spools containing the braiding yarns. One set runs clockwise around the center of the machine and the other set turn in counter clockwise direction (Fig. 5).

Fig. 5. Circular braiding machine (Anon, 2007).



Coating

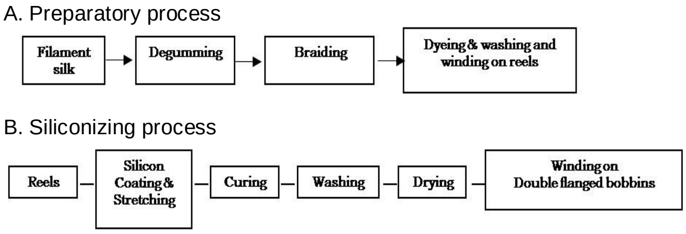
After braiding, the silk sutures are coated with either bee wax or silicone (Altman *et al*., 2003). The coating helps to reduce the capillarity and increase the surface smoothness to enhance for better suture material handling such as ease of pass through tissue and knotting during operation procedure (Glick, 1965; Covidien, 2014).

Two different types of coating are widely used for coating the silk suture material. They are i) Bees wax and ii) Silicone finish.

Bees wax: Bees wax is one of the materials used to coat the surface of braided silk sutures. About 200 g of bees wax is dissolved in 1 L of diethyl ether solvent at room temperature. The silk filament is immersed in the bees wax solution. The excess solution of bees wax present in the silk filament is removed and then dried the silk filament for 1 h at the temperature of 60°C. The bees wax pick up in the suture material is controlled by about 10% (Kawai *et al*., 1993). The main advantage of bees wax used in the suture is helps to stop the bleeding. Since, it is natural material, the tissue reaction such as inflammatory is very less and also it improves the living tissue absorption rate of the sutures.

Silicone: Silicone oil is sprayed on the suture from the distance about 10 cm and its pick up is maintained about 30%. A process technique and a suitable machine to encapsulate braided silk suture thread with polymeric silicon have been developed at SITRA. This method has many advantages. The main benefit of this method is that silicon, being an inert material, does not interact with the body tissue. Also the silicon process (Fig. 6) is not affected by the normal autoclaving temperature like the other alternatives such as bee wax and ethyl cellulose (Anon, 2008).

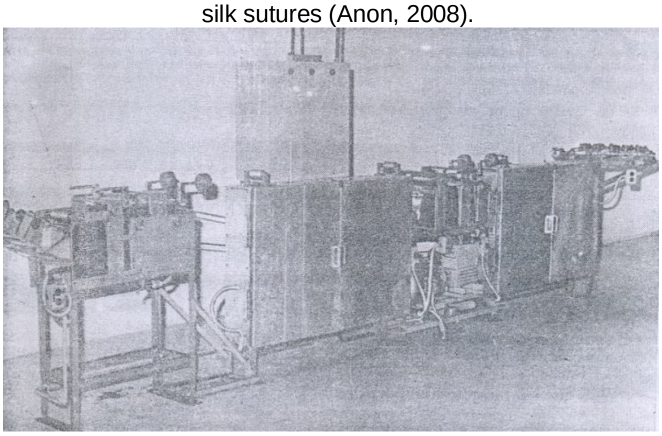
Fig. 6. Flow diagram for manufacture of siliconized silk sutures (Anon, 2008).



Coating machinery

The equipment developed by SITRA (Fig. 7) consists of a creel suitable to hold package of braided silk, an impregnation chamber containing silicon emulsion with two immersion rollers and two pairs of squeezing rollers. The two squeeze rollers decide the required amount of stretch, which corresponds to the size of the suture. The impregnated suture is dried in a thermostatically controlled oven at high temperature and this is followed by cold water wash and second drying. It is finally wound in double-flanged bobbins. The sutures produced by this process have totally non-capillary characteristics, low plastic memory, low knot slippage and lesser inflammatory response. They could be produced to the required tensile and knot strengths. They can stand ordinary/radiation sterilization (unlike those treated with bees-wax or ethyl cellulose) and are not affected by moisture.

Fig. 7. The siliconizing equipment for manufacture of silk sutures (Anon, 2008).



These sutures are easy to handle and very suitable for suturing nerve fibres, since they permit regeneration of nerves in the spinal column. Being inert, it is not necessary in some cases to remove them from the tissues. SITRA has received NRDC-India award for this development.

Packaging

After coating, the coated braided silk filament is wound in spool for continuous length of suture material or packed in desired length of material along with suture needle in the pouch. The spool or pouch is commonly sterilized using ETO (Ethylene Oxide) technique for suture disinfection purpose. The radiation sterilization can be used for silicone coated silk sutures.

Conclusion

In this review the manufacturing technology of silk suture material is mainly focused. From the ancient days onwards, silk is used as suture material. As the technology advancement, the suture strength is increased by means of braiding the silk filament. The tissue drag is reduced by means coating with smooth material on the surface of silk filament. Likewise the silk filament is used as surgical suture materials. SITRA has also contributed to develop suitable silicone coating technique for non-absorbable silk sutures. Since silk is biocompatible in nature, it can also be used for producing the biomaterials such as silk-fibroin based wound dressings for controlled drug delivery and artificial skin. Even the sericin which is removed by degumming process is also used in the many applications like sericin based membrane to separate the water from alcohol, sericin coating for protecting the surface against frost damage, membrane for proliferation and for manufacturing cosmetics and food products.

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