Biocompatible and Resorbable Polymeric Materials for Surgical Sutures

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***Abstract* – As implants in human body, sutures are one of the largest groups of materials and have been in use for many centuries. Along with the development of the synthetic resorbable polymers, i.e. poly(glycolic acid) (PGA) in the early 1970s, a new research direction has opened on biocompatible rebsorbable polymers for sutures.**

This article reviews some of the available information with regard to developments on chemistry, properties, biocompatibility and biodegradability, and performance of resorbable polymeric sutures.

***Index Terms* – suture materials, biomaterials, biocompatible polymers, resorbable polymers.**

I. INTRODUCTION

A suture is a biomaterial device, either natural or synthetic, used to link blood vessels and bring tissues together [1]. Thus, its major functions are to draw and hold together tissues following their separation by surgery or trauma. Sutures are the most widely used materials in wound closure, they have registered tremendous growth during the last two decades and have become the largest group of biomaterials having a huge market exceeding $1.3 billion annually [2].

An ideal suture should have the following characteristics: easy to handle, elicit minimal tissue reaction, does not support bacterial growth, possess high tensile strength, easy to sterilize, elicit no allergic reaction, no carcinogenic effect, is absorbed by human tissues after serving its function. Thus, a suture should not only be very strong, but also be able to simply dissolve into body fluids and lose strength at the same rate that the tissue gains strength.

Suture materials are characterized by various methods involving physical and mechanical properties, handling characteristics, and biological and biodegradation behavior. Mechanical properties, such as tensile strength (knotted and unknotted tensile strengths), percentage elongation, modulus of elasticity, stress relaxation, and creep are measured routinely. As capillarity is related to the ability to transport bacteria, it also needs to be measured. Other parameters measured are swelling and coefficient of friction, pliability, packaging memory, knot security, knot tie-down, knot slippage, tissue drag, etc., and they are used to understand these suture materials functions and range of applications.

Three main classes of suture materials are known: collagen, synthetic absorbable and nonabsorbable. They can be classified as follows:

I – silk or synthetic fibers of monofilament, twisted, or braided;

II – cotton or linen fibers or coated natural or synthetic fibers in which the coating contributes to suture thickness without adding strength;

III – metal wire of monofilament or multifilament.

Sutures are designed to meet many different needs [3]. Sutures for abdominal surgery, for example, are different from sutures used in cataract surgery. No type of suture is ideal for every operation, therefore surgeons and medical designers have come up with sutures with varying qualities: one may be more absorbable, but less flexible, while another may be exceedingly strong, but difficult to knot. Designers of a new suture material have to take into account many factors, as follows: the rate of suture degradation, length of the suture, the knot, material elasticity, memory. Suture manufacturers use specially designed machines to test and study sutures. New suture designs are also evaluated by subjecting them to chemical tests, such as soaking them in various solutions, and testing on animals.

Suture materials are frequently coated, especially braided or twisted sutures, to facilitate their handling properties, particularly to induce a significant reduction in tissue drag and increasing the ease of sliding knots during knotting. Traditional coating materials used are bees wax, paraffin wax, silicone, poly(tetrafluoroethylene) (PTFE), etc. The trend is toward a coating material that has a chemical property similar to the suture to be used. The coatings depend on whether the suture is absorbable (Poloxamer 188 and calcium stearate with a copolymer of glycolic acid and lactic acid) or nonabsorbable (wax, silicone, fluorocarbon, etc.) [4].

Absorbable natural suture materials are made of catgut or reconstituted collagen (RC), or from cotton, silk, or linen. Synthetic nonabsorbable sutures may be made of PP, poly(ethylene glycol terephthalate) (PET), poly(butylene glycol terephthalate) (PBT), polyamide (PA), different types of Nylons, or Goretex®.

Catgut and regenerated collagen are the two absorbable natural sutures available. Catgut was the staple absorbable suture material through the 1930s, while physicians used silk and cotton when a nonabsorbable material was needed. Catgut sutures are well known for their great toughness and tenacity. The basic constituent of catgut is collagen, which is the main constituent of skin and the major structural protein found in all multicellular organisms.

Reconstituted collagen (RC) has low immunologic activity, is prepared either by enzymatic digestion of native collagen-rich tissues or by extraction with salt solutions. RC sutures prepared from bovine long flexor tendons are similar in appearance to catgut and are almost exclusively used in microsurgery. The mechanical and thermal stability of RC fibrils can be increased by maturation *in vitro* when

incubated in air, at 37°C [5]. RC sutures are used in ophthalmic surgery, as well as for other applications.

II. BIOCOMPATIBLE AND RESORBABLE SYNTHETIC SUTURE MATERIALS

Following the successful development of the synthetic absorbable polymer, PGA in the early 1970s, a series of polymers and copolymers based on a few cyclic lactones, presented in Fig. 1, were synthesized, characterized and produced at commercial scale.

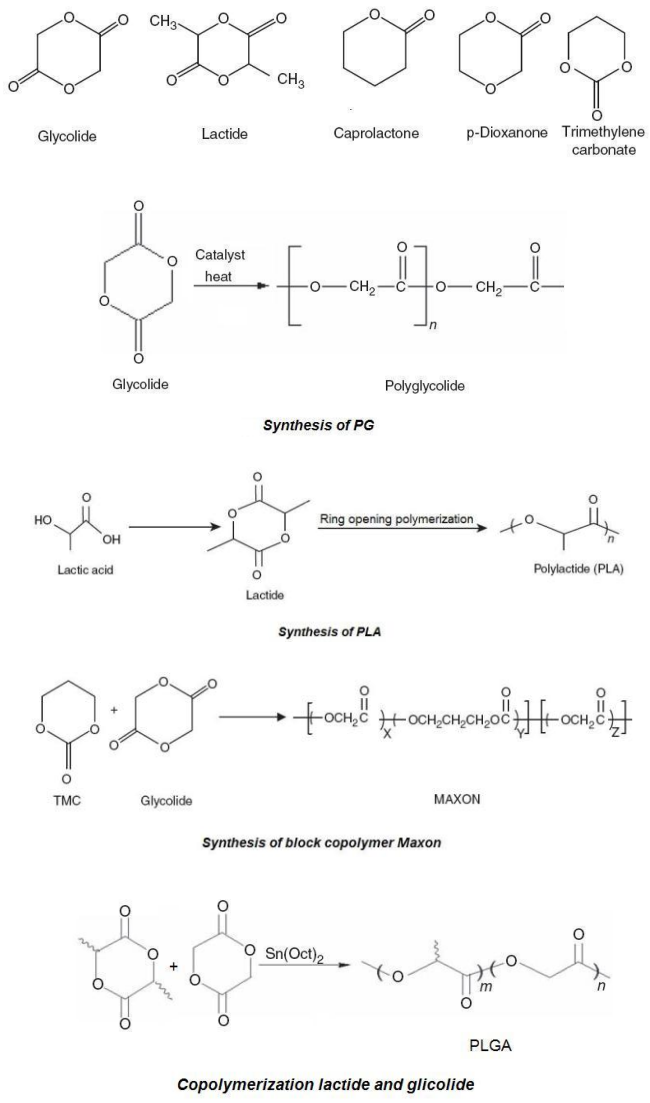

Fig. 1. Monomers and polymers used for synthetic biocompatible resorbable sutures

Thus, new surgical practice needs synthetic absorbable suture materials, such as: Dexon® (Davis & Geck Corp), Vicryl® (Ethicon), PDO (Ethicon), PDOII® (Ethicon), Maxon® (Davis & Geck), Monocryl® (Ethicon) and Biosyn® (US Surgical, Norwalk, CT). New sutures are being developed all the time, in order to better respond to specific surgical demands. The suture materials properties are studied through laboratory experiments, whose results are validated in extensive studies and trials [6]. Absorbable sutures are now well known to behave favorably *in vitro* and in an animal model [7]. The most important advantage of synthetic biocompatible resorbable sutures is their reproducible degradability inside the biological environment. This property will enable sutures to have minimum chronic undesirable tissue reactions. Due to the development of these polymers, they have replaced natural fibers (cotton, linen and catgut) for wounds closure. Today, surgeons have the possibility to choose among a large number of suture materials with various chemical, physical, mechanical and biological properties.

Polyglycolide or poly(glycolic acid) (PGA)

Poly(α-ester)s are thermoplastic polymers with hydrolytically labile aliphatic ester linkages in their backbone. Although all polyesters are theoretically degradable, only aliphatic polyesters with reasonably short aliphatic chains between ester bonds can degrade over the time frame required for suture materials [8].

PGA is the simplest linear aliphatic polyester. Owing to its controllable hydrolytic degradation, PGA and its copolymers with LA, ε-CL and TMC are widely used as materials for the synthesis of resorbable sutures and are being evaluated in the biomedical field [9].

PGA can be obtained through several different processes, starting from different materials: polycondensation of GA, ring-opening polymerization (ROP) of GL (see Fig. 1), solid-state polycondensation (SSP) of halogenoacetates, acid catalyzed reaction of carbon monoxide, formaldehyde, etc. The ROP of GL in the presence of stannous octanoate and heating is the most common synthetic method used to obtain high molecular weight polymers (polymers with M_w=20,000–140,000 are suitable for fiber extrusion and suture manufacturing).

PGA is a highly crystalline polymer (≈ 45–55%), having glass transition temperature between 35-40°C and its melting point in the range 225–230°C; it is soluble only in highly fluorinated solvents (i. e., hexafluoroisopropanol, hexafluoroacetone sesquihydrate) that can be used to obtain polymer solutions for melt spinning and film preparation. Fibers of PGA show excellent mechanical properties (high strength and modulus) due to the polymer high crystallinity. A self-reinforced PGA composite is stiffer than any other degradable polymeric system used clinically and has been shown to exhibit a modulus of approximately 12.5 GPa [10].

Concerning its biodegradable character, PGA undergoes hydrolytic degradation through nonspecific cleavage of the ester backbone [11]. The degradation process is erosive and appears to take place in several steps during which the polymer is converted to its initial monomer GA. The first step involves diffusion of water into the amorphous regions of the polymer, cleaving the ester bonds; the second step starts after the erosion of amorphous regions, leaving crystalline chains susceptible to the hydrolytic attack. Upon collapse of the crystalline regions, the polymer chain dissolves. When exposed to physiological conditions, PGA decomposes under enzymes (esterase type) attack and the degradation product, the same GA, is nontoxic and it can easily enter the tricarboxylic acid cycle, during which it is gradually decomposed up to water and carbon dioxide. A part of the GA is also excreted by urine. Studies carried out using sutures made from PGA have shown that the material loses half of its strength after 2 weeks and 100% after 4 weeks. Figure 2 shows the rate of the *in vitro* degradation of PGA. The polymer is completely resorbed by the organism in a timeframe of 4–6 months [12,13].

The water sorption and its penetration into the PGA, PLA and their copolymers initiate the hydrolytic degradation, followed by the decay of their mechanical properties. The tensile tests on co/terpolymers of LL, ε-CL and GL showed

that the tensile strength was strongly dependent on the draw ratio [14].

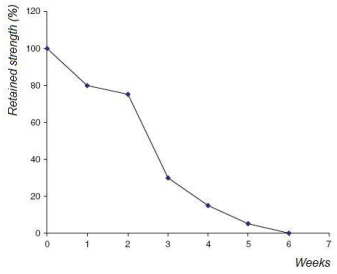

Fig. 2. The rate of the *in vitro* degradation of PGA

Comparing the biodegradability of Monocryl® monofilaments with poly(trimethylene carbonate-ε-caprolactone)-block-poly(*p*-dioxanone) [poly(TMC-e-CL)-block-PDO] copolymers, it was ascertained that the biodegradability of PDO homopolymer is much lower compared with that of the copolymer Monocryl®, probably due to the presence of the GL in the copolymer structure.

PGA is particularly useful in subcutaneous and intracutaneous closures, abdominal and thoracic surgeries. With its high initial tensile strength, it has guaranteed holding power through the critical wound healing period.

Polylactide or poly(lactic acid) (PLA)

PLA polymers are leading biomaterials having applications in biomedical and pharmaceutical industries as resorbable implant materials, wound closure, bone fixation devices and vehicles for controlled drug delivery [9]. They are characterized by high mechanical strength, inherent biodegradability and biocompatibility. However, their clinical applications are sometimes affected by their high hydrophobic character and consequent poor water uptake, which results in a slow hydrolytic degradation rate.

Copolymerization of LL (*levo* isomer) with other co-monomers is used to modify the PLA properties and to control its degradation according to the specific applications in the field [15–17]. The synthesis of PLAs of high M_w for suture applications can be carried out by the ring opening polymerization of the cyclic diester (LL) of LA (see Fig. 1). Due to the chiral nature of LA, several distinct forms of polylactide exist: poly-L-lactide (PLLA or PLA in common use) which is a crystalline polymer, while the polymerization of a racemic mixture of L- and D-lactides (DL) usually leads to poly-DL-lactide (PDLLA) which is amorphous.

It was reported that the PLA has a crystallinity of ≈ 37%, a glass transition temperature in the range 50-80°C and a melting temperature between 173-178°C. The initial tensile strength of the PLA fibers is lower than that of the commercially available sutures such as PDO, Vicryl®, silk and Ethilon® (Nylon 6 and Nylon 66 monofilament suture). The handling characteristics of PLA sutures were found to be superior to those of the monofilament sutures such as PDO and Ethilon® and comparable with the multifilament sutures such as Vicryl® and silk. A composite consisting of PDLA and bioglass was used as a coating for degradable sutures such as Vicryl® [9].

The *in vitro*, in the subcutis, and in the achilles tendon of rabbits studies revealed that, although PDLA had a lower initial tensile strength than Maxon®, it showed more prolonged tensile strength retention (TSR). When PLA sutures were exposed to physiological saline solution (0.9 wt% NaCl aqueous solution) at 37°C, the knotpull strength decreased by 12% after 28 days. In Figure 3, the rate of degradation of PLA is presented.

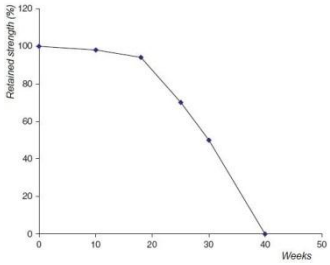

Fig. 3. The rate of the *in vitro* degradation of PLA

The diagram shows that during the hydrolytic degradation of PLA, the molecular mass decreases and its distribution becomes continuously broader with the increasing degradation time. The conclusion is the PLA thread is a suitable suture for wounds that require healing time up to 28 weeks.

Poly(lactide-co-glycolide) (PLGA)

Copolymers of GA with both LL and DL have been developed for both devices and drug delivery applications. For suture applications, LL-co-GL copolymer must have a high concentration of GL in order to achieve the required mechanical and biodegradation properties. PLGA is synthesized by means of random ROP of two different monomers (see Fig. 1) and, depending on the LA/GA ratio, different forms of PLGA can be synthesized. All PLGAs are amorphous rather than crystalline and show a glass transition temperature in the range 40–60°C. Unlike the corresponding homopolymers which show poor solubilities, PLGA can be dissolved by a wide range of common solvents, including chlorinated solvents, tetrahydrofuran, acetone, or ethyl acetate.

The PLGA biodegradability is highly related to its crystallinity and the solution pH [18]. The copolymer PLGA has been shown to undergo bulk erosion through the hydrolysis of ester bonds and the rate of degradation depends on a variety of parameters, including the LA/GA ratio, M_w, the shape and structure of the matrix [19]. The degradation products, LA and GA, are common by-products of various metabolic processes in the body, under normal physiological conditions, and there is a minimal systemic toxicity associated with PLGA. The *in vivo* rate of degradation depending on the LA/GA ratio is presented in Figure 4.

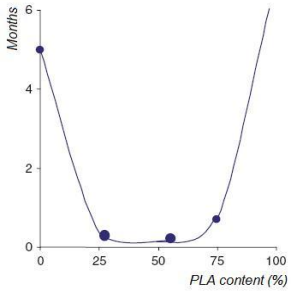

Fig. 4. The *in vivo* rate of degradation versus PLA content in the PLGA copolymer

Experimental data show that the resistance to hydrolytic degradation is more pronounced at either end of the co-polymer composition. For example, a copolymer of 50% GA and 50% DL degrades faster than either corresponding homopolymer. Copolymers of LL with 25–70% GA are

amorphous due to the disruption of the regularity of the polymer chain by the other monomer.

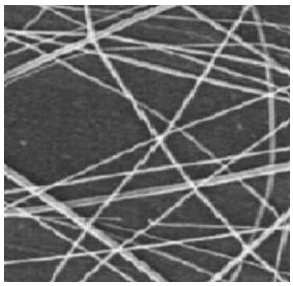

Fig. 5. Electrospun PLGA fibers

The major advantage of these copolymers can be attributed to their biocompatible character, good processibility which enables fabrication of a variety of structures and forms (electrospun PLGA fibers are shown in Figure 5), controllable degradation rates and their success as biodegradable resorbable suture materials.

Polyglyconate (PG)

Copolymers of GA with TMC have been prepared as both sutures (Maxon® copolymer, see Fig. 1) and as tacks and screws. Typically, these compounds are prepared as A–B–A block copolymers in a GL:TMC=2:1 ratio, with a GL–TMC center block (B) and pure GL end blocks (A). These materials have a better flexibility than pure PGA and are absorbed in approximately 7 months. GL has also been copolymerized with TMC and p-dioxanone to form a terpolymer suture (Biosyn®) that is absorbed within 3–4 months and offers reduced stiffness compared to pure PGA fibers [20]. The hydrolytic degradation of PG has been studied *in vitro* and it was observed that the relationship between polymer strength and M_w was more complex than expected [21]. However, data could be modeled using an empirically derived relationship between tensile strength and number average molecular weight (M_n). Changes in other mechanical properties, such as strain at break, were also found to be strongly dependent of M_n. These results demonstrated that absorbable PG suture might be suitable for microvascular anastomosis of arteries under ordinary stress and under tension up to a certain level.

Poly(e-Caprolactone) (PCL)

PCL is produced by the ROP of ε-CL. It is a semi-crystalline polymer with a melting point of 59–64°C and a glass-transition temperature of -60°C. The polymer has been regarded as tissue compatible and used as a biodegradable suture in Europe. The polymer undergoes hydrolytic degradation due to the presence of aliphatic ester linkages which are hydrolytically labile under physiological conditions [9].

Because the homopolymer has a degradation time of 2 years, copolymers have been synthesized in order to accelerate the rate of bioabsorption. For example, copolymers of ε-CL with DLL have yielded in materials with higher degradation rates. The introduction of the monofilament sutures of ε-CL and GL (Monacryl®) solved many of the problems with braided sutures that relate to tissue drag and trauma, as well as the possible potentiation of infection through the interstices of the braid structure.

Poly(L-lactide-co-ε-caprolactone)

The copolymer of LL with ε-CL exhibited good strength and flexibility, suitable for monofilament sutures, and it also showed improved handling characteristics. On the other hand, Prolene® (PP) and poly(L-lactide-co-ε-caprolactone) (PLA-ε-CL) sutures showed high knot-pull strength, despite low straight pull strength. A good correlation between tanδ and bending plasticity index was observed and the PLA-ε-CL sutures exhibited high tanδ, high bending plasticity and good resistance against untying [9].

Co/terpolymers of LL, ε-CL and GL are biodegradable in the human body and, therefore, have considerable potential for use in biomedical applications such as surgical sutures, nerve guides, bone fixation devices and drug delivery systems [22].

Polydioxanone (PDO or PDS)

Resorbable multifilament sutures, such as PLA and PGA, develop a greater amount of friction when penetrating tissues and have a higher risk of infection. So, monofilament sutures based on PDO having smooth and soft surface were introduced in the 1980s [23]. PDO suture has handling properties that are acceptable for use in vascular applications and it provides adequate mechanical support for sutured vessels to heal. In addition, PDO provides good flexibility due to the presence of an ether group in the polymer backbone.

PDO is prepared by the ROP of p-dioxanone to get a colorless, semicrystalline polymer with a very low glass transition temperature ranging from -10÷0°C. Being an aliphatic polyester, it undergoes degradation by the nonspecific cleavage of the ester bond. PDO can be considered a slow to moderate degrading polymer due to its high crystallinity and hydrophobicity.

Inside the body, PDO is broken down into glycoxylate and then excreted in the urine or converted into glycine and, subsequently, into carbon dioxide and water [24]. PDO has demonstrated no acute or toxic effects upon implantation. The monofilament loses 50% of its initial breaking strength after 3 weeks and is absorbed within 6 months, providing an advantage over Dexon® or other products for slow-healing wounds.

Poly(Trimethylene Carbonate) (PTMC)

ROP of TMC gives high molecular weight polymers with flexible chains. Unlike the previously described polyesters, PTMC undergoes surface degradation. The rate of the *in vivo* degradation was found to be much higher than the *in vitro* degradation. This is presumably due to the contribution of the enzymatic attack [24]. The low mechanical performance of the homopolymer led to the development of several co/terpolymers with other cyclic lactones, such as Maxon® and Biosyn®. A comparative study of mechanical properties of Maxon® and Biosyn® is given in Table 1.

TABLE 1. MECHANICAL PROPERTIES OF MAXON® AND BIOSYN®

Characteristic	**MAXON®**	**BIOSYN®**
Diameter (mm)	0.293	0.29
Knot pull strength (kg)	2.9	2.4
Young`s modulus (kpsi)	425	145
Straight-pull strength (kg)	3.9	3.7
Elongation (%)	30	44
Tensile strength (kg/mm^2)	56.2	55.3

The degradation studies consider that the absorption of these sutures was achieved through the action of mononuclear and multinuclear macrophages which were confined into the implant and sequestered by the fibrous

connective tissue capsule. These sutures thus were shown to maintain good strength with little or no absorption during the critical wound healing period and with minimal tissue reaction. Hydrolytic degradation studies showed that changes in mechanical properties of the copolymer were found to be strongly dependent on changes in the value of M_n [9].

Polyhydroxyalkanoates (PHAs)

PHAs are polyesters produced by microorganisms (like *Alcaligenes eutrophus* or *Bacillus megaterium*) as energy storage materials [25–27]. The most common PHA, poly(3-hydrobutyrate) (PHB), is a semicrystalline polyester (structures of different PHAs are presented in Figure 6), that undergoes hydrolytic degradation by surface erosion, these properties making it an attractive material for controlled release applications. Due to its relatively high melting point and rapid crystallization, the entrapment of drug is technically difficult.

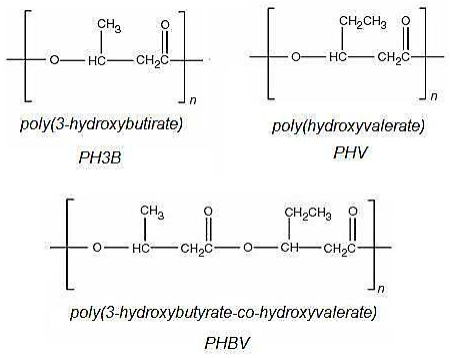

Fig. 6. Structures of the most known PHAs

The copolymers with 3-hydroxyvalerate, P(3HB-co-3HV)s, have similar semicrystalline properties, though their slower rates of crystallization result in matrices with different properties. PHB and P(3HB-co-3HV) matrices lose mass very slowly when compared to bulk-degrading PGA systems. P(3HB-co-3HV) melting point is 175°C and glass transition temperature 15°C, tensile strength 40MPa (close to that of PP). It sinks in water (while PP floats), which facilitates its anaerobic biodegradation in sediments. The biodegradation can be controlled by tuning the composition of the copolymer [9]. The biocompatibility is good, it is fully nontoxic [28] and, hence, suitable for medical applications. However, the commercialization of PHA sutures is impeded by the high cost of production.

III. CONCLUSION

Over the last decades, surgical suture materials have proved to be high competitive products of a mature industry. New sutures are constantly developed in order to better respond to specific surgical needs. Basic materials are modified depending on intended applications and to provide the surgeon with a suture material of optimal quality. The modern surgery imposes requirements that biocompatible resobable synthetic materials are able to fullfill, but the next step necessitates further progress in this area: the production of novel strong and elastic threads made of biocompatible absorbable natural polymers, such as polyoxyalkanoates, collagen, chitin, alginate, etc.

Therefore, researchers increasingly focus on the new generations of sutures, materials that can achieve not only antimicrobial activity, but also anesthetic and antineoplastic functions.

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