Aug. 26, 1969 E. E. SCHMITT ET AL 3,463,158

POLYGLYCOLIC ACID PROSTHETIC DEVICES

Filed Jan. 9, 1967 4 Sheets-Sheet 1

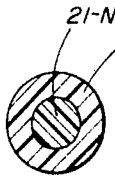


FIG-1

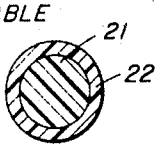


FIG-2

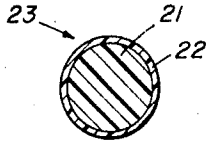


FIG-3

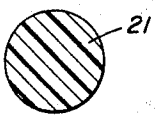


FIG-4

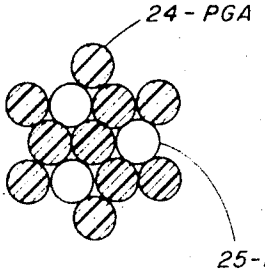


FIG-5

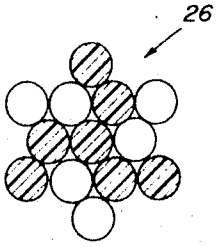


FIG-6

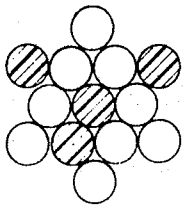
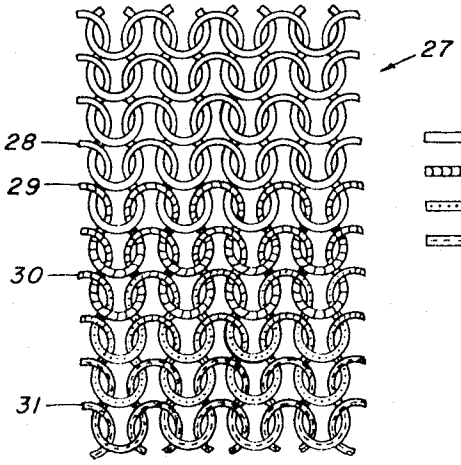


FIG-7



- 100% NON-ABSORBABLE
- 75% NON-ABSORBABLE - 25% PGA
- 50% NON-ABSORBABLE - 50% PGA
- 25% NON-ABSORBABLE - 75% PGA

FIG-9

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POLYGLYCOLIC ACID PROSTHETIC DEVICES

Filed Jan. 9, 1967 4 Sheets-Sheet 2

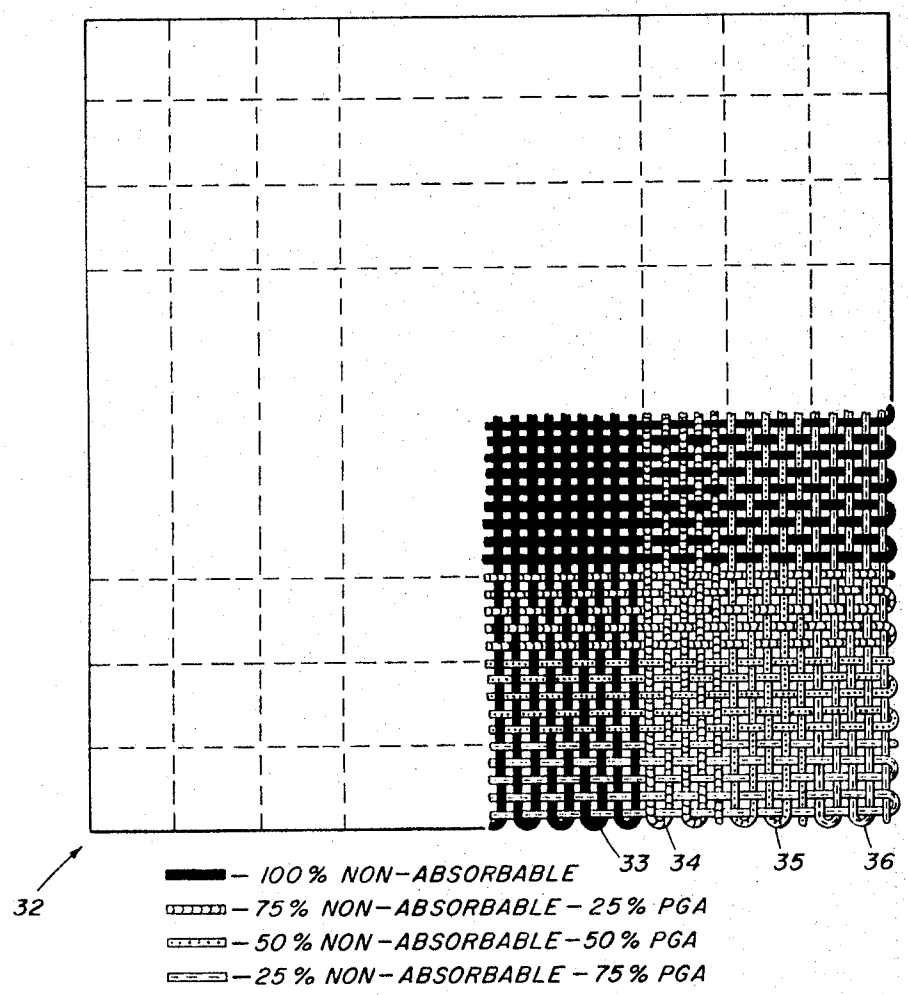

FIG - 8

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Aug. 26, 1969 E. E. SCHMITT ET AL 3,463,158

POLYGLYCOLIC ACID PROSTHETIC DEVICES

Filed Jan. 9, 1967 4 Sheets-Sheet 3

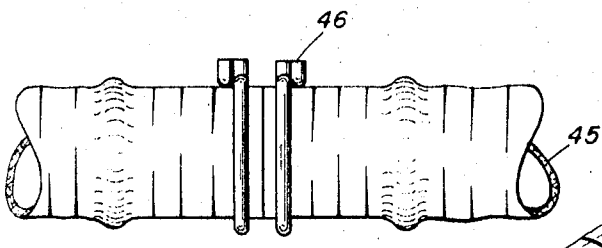
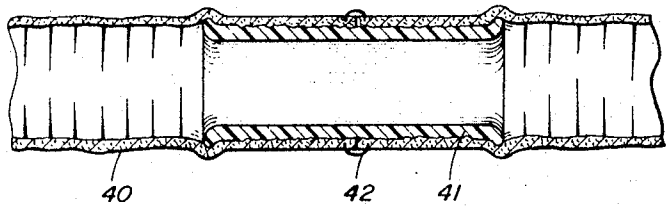


FIG-14

FIG-10

FIG-11



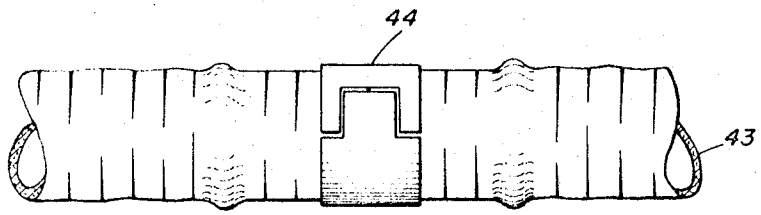


FIG-13

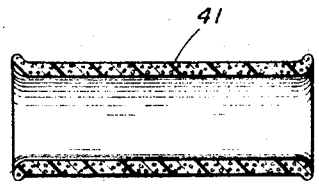


FIG-12

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Aug. 26, 1969 E. E. SCHMITT ET AL 3,463,158

POLYGLYCOLIC ACID PROSTHETIC DEVICES

Filed Jan. 9, 1967 4 Sheets-Sheet 4

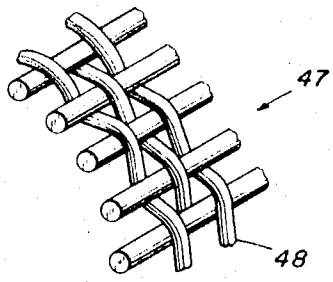

FIG-15

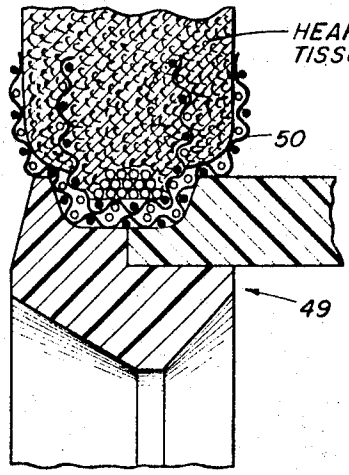

FIG-16

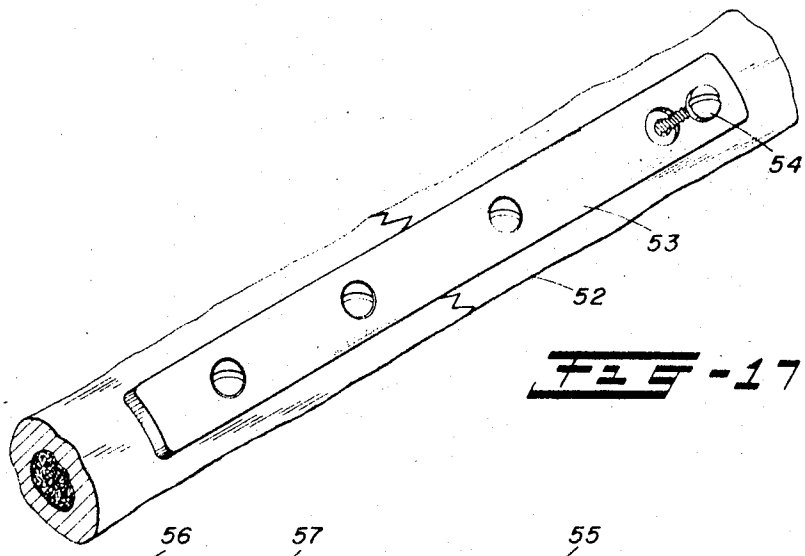

FIG-17

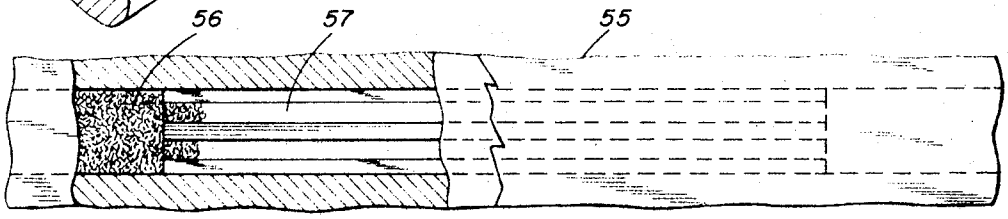

FIG-18

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United States Patent Office 3,463,158 Patented Aug. 26, 1969

3,463,158

POLYGLYCOLIC ACID PROSTHETIC DEVICES

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Filed Jan. 9, 1967, Ser. No. 608,068
Int. Cl. A61b 17/04
U.S. Cl. 128—334 8 Claims

ABSTRACT OF THE DISCLOSURE

Polyhydroxyacetic ester, also called polyglycolic acid (PGA), has surgically useful mechanical properties as a solid prosthesis, such as reinforcing pins, screws, plates, or thin sheets. The polyglycolic acid can form a single or bicomponent fabric, either mixed uniformly, or in discrete areas with non-absorbable fibers. In either form, on implantation, in living mammalian tissue, the polyglycolic acid is absorbed, and replaced by living tissue. Fabric structures of an intermixture of PGA and non-absorable material are particularly useful in tissue repair or replacement so that living tissue mechanically unites about the non-absorbable fiber structure, locking it into place.

CROSS REFERENCES

This application is a continuation-in-part of application Ser. No. 320,543, filed Oct. 31, 1963 now U.S. Patent 3,297,033, Jan. 10, 1967, "Surgical Sutures."

Field of invention

This invention relates to absorbable surgical elements of polyhydroxyacetic ester hereafter called polyglycolic acid (PGA).

Prior art

The use of submucosal tissue and ribbons therefrom internally is described in such patents as United States Patent 2,167,251, Rogers, "Surgical Tape of Sumucosa Tissue," July 25, 1939, United States Patent 2,143,910, Didusch, "Ribbon Gut and Method of Using the Same," Jan. 17, 1939, and United States Patent 2,127,903, Bowen, "Tube for Surgical Purposes and Methods of Preparing and Using the Same," Aug. 23, 1938.

U.S.P. 2,836,181, J. S. Tapp, "Flexible Nylon Tube and Method for Preparing Same" shows a braided heat crimped formic acid treated nylon tube spliced into a blood vessel, with the crimp permitting a desired degree of flexibility.

U.S.P. 3,099,016, M. L. Edwards, "Heart Valve" shows a plastic cardiac valve, in which a fabric is emplaced in a ring around the valve, and sutured to the heart tissue, to permit the heart tissue to grow to such fabric, and hold the valve in position in the heart.

U.S.P. 3,054,406, F. C. Usher, "Surgical Mesh," Sept. 18, 1962, shows the use of a polyethylene woven mesh fabric implanted in the human abdominal wall for reinforcing and healing defects.

U.S.P. 3,108,357, W. J. Liebig, "Compound Absorbable Prosthetic Implants, Fabrics and Yarns Therefor" shows flexible fabrics of mixed absorbable and non-absorbable textile fibers for implantation, and reinforcement of tissue.

U.S.P. 3,124,136, F. C. Usher, "Method of Repairing Body Tissue," Mar. 10, 1964, shows the use of knitted linear polyethylene mesh attached to each side of a tissue defect. The polyethylene is non-absorbable and permanently reinforces the tissue at the site of the defect. Additional details appear in Usher, Ochsner and Tuttle "Use of Marlex Mesh in the Repair of Incisional Hernias," The American Surgeon 24, 116–121 (December 1958).

U.S.P. 3,155,095, A. M. Brown "Anastomosis Method and Means" shows an internal and external asorbable coupling for the joining of vascular vessels.

United States Patents 3,272,204, "Absorbable Collagen Prosthetic Implant With Non-Absorbable Reinforcing Strands," Artandi and Bechtol, Sept. 13, 1966, 3,284,557, "Process For Crimping An Artificial Implant For Use In An Animal Body," Seymour Polansky, Nov. 8, 1966, and 3,276,448, "Collagen Coated Fabric Prosthesis," Richard L. Kronethal, Oct. 4, 1966, each disclose collagen in combination with non-absorbable fibers as surgical prostheses.

SUMMARY

Definitions in the textile trades are frequently somewhat ambiguous. For purposes of the present application, certain terms are defined:

A "filament" is a single, long, thin flexible structure of a non-absorable or absorbable material. It may be continuous or staple.

"Staple" is used to designate a group of shorter filaments which are usually twisted together to form a long, continuous thread.

Non-absorbable surgically acceptable filaments include filaments of polyalkylenes, such as polyethylene, preferably linear polyethylene with a density of about 0.94 or higher, or polypropylene, preferably isotactic polypropylene; or a polyamide, such as nylon; or a polyester, such as Dacron; or a polyacrylonitrile, such as Orlon or Creslan; or a halogenated polyalkylene, such as polytetrafluorethylene, such as Teflon, or other halogenated polyalkylene, such as Kel-F or FEP; or cotton, or silk, or linen; or a metal such as stainless steel, tantalum, silver, gold, or platinum. The above are illustrative. Any non-absorbable material which is essentially inert in living mammalian tissue, particularly human tissue, is usable as a non-absorbable filament. Those materials having a comparatively high tensile strength and flexibility are preferred.

An absorbable filament is one which is absorbed, that is digested or dissolved, in living mammalian tissue.

A "thread" is a plurality of filaments, either continuous or staple, twisted together.

A "strand" is a plurality of filaments or threads twisted, plaited, braided, or laid parallel to form a unit for further construction into a fabric, or used per se, or a monofilament of such size as to be woven or used independently.

A "bi-component filament" is a filament composed of two separate materials. As used herein, the term is limited to a filament having one non-absorbable component and one absorbable component. The components may be adjacent. The most easily formed and preferred bi-component filament is a sheathed filament with an internal non-absorbable material coated, or sheathed, approximately concentrically, with an absorbable component.

A "bi-component thread" includes a thread of bi-component filaments or a blend of different separate monofilament components twisted together, or both.

A "bi-component strand" is a strand of one or more bi-component filaments, or two different filament materials, or both, at least one component of which is absorbable.

A "bi-component fabric" is a woven, knitted, felted, adhesively united, or otherwise formed fabric of at least two dimensions, or fabric tube having separate strands of bi-component materials or strands of two separate components, at least one component of which is absorbable.

A "coated fabric" is a fabric which is coated with a substantially continuous sheet of a second material, as for example by hot melt coating, or coating from a solvent system, or with coating rolls, the base fabric of which may be wholly nonabsorbable, although it may contain an ab-

sorbable component. For the present invention, only a living tissue absorbable coating of PGA is considered as the coating layer.

A "solid prosthetic device" is a thin solid sheet, or plate, or tube, which may be split, or bar, or nail, or screw, or pin or other solid shape which has inherent mechanical strength to act as a solid discrete surgical reinforcing element, and has at least one dimension greater than 2 millimeters, and which may have a dimension as great as about 200 millimeters, or as required, to furnish mechanical support and reinforcement to a bone, or bones, or gland, or organ, for support during a healing process.

The support may be in part directive of growth, as for example in nerve tissue, which grows slowly, and as a result has regeneration impaired by the more rapid growth of scar tissue which can block the growth of the nerve tissue. With a wrap-around sheath of PGA sheet, or a split or solid tube used to support, place, hold and protect; regeneration of nerve tissue and function is greatly aided. Other factors may inhibit regeneration of nerve tissue or function, but with the exclusion of scar tissue, such other factors may be separately treated. PGA is particularly useful in splicing nerves because PGA is completely dissolved in tissue and leaves minimal or no residual scar tissue from the PGA.

A "graded transition section" is a portion of bi-component fabric, or bi-component strand, which by selection of strands for the fabric, or components for the strand or strands, has a changing composition, over a short distance, of 1 mm. to 15 mm. or more, so that a fabric or strand changes in composition from non-absorbable material, or substantially non-absorbable material, to predominantly or completely absorbable material, whereby living tissue can replace the absorbable component and a gradual transition accomplished between the nonabsorbable reinforcing prosthesis and the adjacent living tissue. With an arterial implant, for instance, a past cause of trouble has been the line of juncture between the implant and the natural artery wall. With a gradual transition, no sharp line of demarkation exists, and hence, failures between the prosthesis and tissue are minimized. With implants of the types shown by Usher, supra, the edges of the reinforcing element could cause difficulties. With a gradual transition, a line of potential risk is eliminated.

For different purposes and in different types of tissue the rate of absorption may vary but in general an absorbable prosthesis should have as high a portion of its original strength as possible for at least three days, and sometimes as much as fifteen days or more, and preferably should be completely absorbed by muscular tissue within from forty-five to ninety days or more depending on the mass of the cross-section. The rate of absorption in other tissues may vary even more.

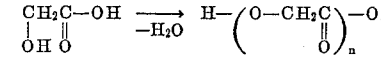
In common with many biological systems, the requirements are not absolute and the rate of absorption as well as the short-term strength requirement varies from patient to patient and at different locations within the body, as well as with the thickness of the section of PGA.

The PGA may be formed as tubes or sheets for surgical repair and may also be spun as thin filaments and woven or felted to form absorbable sponges or absorbable gauze, or used in conjunction with other structures as prosthetic devices, within the body of a human or animal where it is desirable that the structure have short-term strength, but be absorbable. The useful embodiments include tubes, including branched tubes or T's, for artery, vein or intestinal repair, nerve splacing, tendon splicing, sheets for tying up and supporting damaged kidney, liver and other intestinal organs, protecting damaged surface areas such as abrasions, particularly major abrasions, or areas where the skin and underlying tissues are damaged or surgically removed.

The synthetic character and hence predictable formability and consistency in characteristics obtainable from a controlled process are highly desirable.

The most convenient method of sterilizing PGA prostheses is by heat under such conditions that any microorganisms or deleterious materials are rendered inactive. A second common method is to sterilize using a gaseous sterilizing agent such as ethylene oxide. Other methods of sterilizing include radiation by X-rays, gamma rays, neutrons, electrons, etc., or high intensity ultrasonic vibrational energy or combinations of these methods. The present materials have such physical characteristics that they may be sterilized by any of these methods.

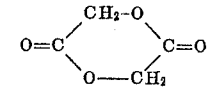
PGA can be considered as essentially a product of polymerization of glycolic acid, that is hydroxyacetic acid, which in simplified form is shown by the equation:



Preferably n is such that the molecular weight is in the range of 10,000 or more. Above 500,00 the polymer is difficult to mold.

In these molecular weight ranges the polymer has a melt viscosity at 245° C. of between about 400 and about 27,000 poises. Because the PGA is from a synthetic and controllable source, with a controlled molecular weight and controlled small percentage of comonomer, the absorbability, stiffness, and other characteristics can be modified.

Among several methods by which PGA can be prepared, one preferred route involves the polymerization of glycolide,



the cyclic dimeric condensation product formed by dehydrating hydroxyacetic acid. During polymerization of glycolide, the ring is broken and straight-chain polymerization occurs.

Small quantities of other materials may be present in the chain, as for example, de-lactic acid, its optically active forms, homologs, and analogs. In general, plasticizers tend to interfere with crystallinity, orientation, etc. and weaken fibers, but are useful for sponges and films. Other substances may be present, such as dyes, antibiotics, antiseptics, anaesthetics, and antioxidants. The surfaces of the fabric can be coated with a silicone, beeswax, and the like to modify the handling or absorption rate.

The polymerization of glycolide occcurs by heating with or without a catalyst, or may be induced by radiation such as X-rays, gamma rays, electron beams, etc. Polymers may also be obtained by condensing glycolic acid or chloroacetic acid with or without a catalyst under a variety of conditions. Good moldable objects or fibers are most readily obtained when the melt viscosity at 245° C. is about 400 to about 27,000 poises.

Polyhydroxyacetic esters have been described in United States Patent 2,668,162, Lowe, "Preparation of High Molecular Weight Polyhydroxyacetic Ester," and United States Patent 2,676,945, Higgins, "Condensation Polymers of Hydroxyacetic Acid."

The processes described in the above two patents can be used for producing PGA from which prostheses may be made. Additives such as triphenylphosphite or Santo-Nox, a disulfide aromatic phenol, can be added as color stabilizers.

DRAWINGS

FIGURE 1 shows a cross section of a bi-component filament of about 25 percent non-absorbable material coated with about 75 percent absorbable polymer.

FIGURE 2 shows a cross section of a bi-component filament of about 50 percent non-absorbable material coated with about 50 percent absorbable polymer.

FIGURE 3 shows a cross section of a bi-component

filament with about 75 percent non-absorbable material coated with about 25 percent absorbable polymer.

FIGURE 4 shows a fiber of a non-absorbable filament.

FIGURE 5 shows a cross section of a polyfilamentary strand of 3 non-absorbable filaments and 10 absorbable filaments.

FIGURE 6 shows a cross section of a polyfilamentary strand with 6 non-absorbable filaments and 7 absorbable filaments.

FIGURE 7 shows a cross section of a polyfilamentary strand with 4 absorbable filaments and 9 non-absorbable filaments.

FIGURE 8 shows a woven fabric the central portion of non-absorbable strands graded in both warp and woof into a 75 percent non-absorbable, then 50 percent non-absorbable, then 25 percent non-absorbable strands.

FIGURE 9 shows a knitted fabric graded from a 100 percent non-absorbable strand through a 75 percent non-absorbable strand, then a 50 percent non-absorbable strand, to a 25 percent non-absorbable strand.

FIGURE 10 shows a spliced artery having an internal sleeve with slightly tapered ends, with a sewn splice.

FIGURE 11 is a cross section of a spliced artery having an internal sleeve with expanded ends.

FIGURE 12 shows a prosthetic sleeve formed of a unitary coupling of solid polyglycolic acid with slightly expanding ends to aid in holding a blood vessel about the sleeve.

FIGURE 13 shows the sleeve of FIGURE 12 in use in which an external spring clip of solid polyglycolic acid holds the ends of the blood vessel together.

FIGURE 14 shows the sleeve of FIGURE 12 in which two expandable annular clips are used to hold the ends of the blood vessel approximated.

FIGURE 15 is a portion of a woven tube of certain individual strands which are at least in part absorbable.

FIGURE 16 shows a portion of a heart valve emplaced in heart tissue using a fabric in part composed of polyglycolic acid to aid in holding the valve in place.

FIGURE 17 shows a broken bone, the ends of which are held together by a solid bar of polyglycolic acid held to the bone by polyglycolic acid screws.

FIGURE 18 shows a broken bone, the ends of which are held in position by an internal fluted pin of polyglycolic acid.

PGA for the construction of the prostheses shown in the drawings can be produced as set forth in the following examples, in which parts are by weight, unless otherwise clearly indicated:

EXAMPLE 1

100 parts of recrystallized glycolide (melting point 85.0 to 85.5° C.) are intimately mixed with 0.02 part of methoxyacetic acid, 0.03 part of phenoldisulfide (Santo-Nox), and 0.03 part antimony trifluoride. Separate glass tubes are each charged with approximately 20 grams of the mixture, deoxygenated by repeated evacuation and argon purging, then sealed under vacuum and heated to 185 to 190° C. for 4½ hours. On cooling a white opaque tough PGA is produced in a 97.5% yield with a melt viscosity at 245° C. of 5,000 poises. The polymer is reheated and spun into filaments at a temperature of about 230° C. at a speed of about 150 feet per minute. The filaments produced are cooled, then drawn at about 55° C. When drawn to five times the original length a strong tough filament is produced. The dry filaments are in condition for use.

EXAMPLE 2

The polymer of the preceding example is formed into a plurality of smaller filaments, seven of which are twisted into a polyfilamentary strand, which is sterilized and used following the techniques of Example 1.

Because it is a synthetic polymer the methods of forming are more versatile than in starting with naturally occurring materials.

EXAMPLE 3

Into a suitable reaction vessel there is charged 400 parts of a commercial glycolic acid which is then heated from room temperature to about 200° C. over a period of about four hours. When the pot temperature has reached 185° C., the pressure of the system is reduced from atmospheric pressure to 15 mm. of Hg, causing the water of condensation and/or esterification to distill off. The residue is allowed to cool and is pulverized into about 280 parts of a powder which is then added in small increments to a suitable pyrolysis chamber maintained at a temperature of about 250–280° C. at a pressure of less than 15 mm. of Hg. The distillate which weighed about 238 parts is dissolved in a minimum amount of hot ethyl acetate, and after decolorizing and purifying with active carbon, the distillate is recrystallized from the above solution to provide 160 parts of product having a melting point of about 82.5–84.0° C. The infrared spectrum confirms that the product is substantially pure glycolide.

The glycolide thus prepared is polymerized in the presence of an alcohol free of non-benzenoid unsaturation and free of any reactive groups other than alcoholic hydroxy groups and in the presence of $SnCl_2 \cdot 2H_2O$.

Into a heavy walled glass tube having a bore of about $\frac{3}{10}$" and sealed at one end is charged with 3 parts of the substantially pure glycolide composition, 0.04 part of a 0.1% ether solution of $SnCl_2 \cdot 2H_2O$ (about 0.0013% of $SnCl_2 \cdot 2H_2O$ based on the weight of the substantially pure glycolide composition), 0.0166 part of lauryl alcohol (0.346 mole percent based on the moles of the substantially pure glycolide composition), and a magnetic steel ball $\frac{5}{32}$" in diameter. The tube is evacuated and purged with argon. The tube is evacuated again to a vacuum of less than 1 mm. of Hg and the top is sealed. The reaction tube is placed in a vertical position in a closed glass chamber throughout which dimethyl phthalate is refluxed at 222° C. The boiling point of the dimethyl phthalate is controlled by decreasing the pressure of the system. At periodic intervals after melting, the viscosity of the reaction mixture is measured by raising the steel ball by means of a magnet and measuring the rate of the fall of the ball in sec./in. Ninety minutes after the melt is first achieved, the ball drop time is 550 sec./in. or about 7200 poises, and after 120 minutes, the ball drop time is 580 sec./in. or about 7600 poises.

The PGA thus produced is spun into .002 inch diameter fibers and used to form bi-component strands.

Additional PGA, similarly produced is used to coat Dacron filaments, in varying weight ratios to form bi-component strands which are braided into tubular arterial implants to splice into sections of arteries.

Additional PGA, similarly produced is used to form sheets. These sheets are wrapped around nerves, traumatically severed, to protect such nerves from invasive scar tissue growth, while the nerve is regenerating.

Also the PGA so produced is fabricated into the prosthetic devices shown in the drawings.

As is shown in the drawings, a bi-component filament **23** was formed by dipping a non-absorbable filament **21** of Dacron into a PGA melt forming a PGA coating **22** on the surface of the non-absorbable Dacron **21**.

As shown in FIGURE 1 the dip was such that approximately 25% of the cross section was of Dacron and 75% of PGA.

In FIGURE 2 the structure is the same except that the relative proportions are changed to approximately 50% of each material.

In FIGURE 3 the structure is the same except that the proportions are changed such that approximately 75% of the cross section is of Dacron and about 25% on the surface is of PGA.

In FIGURE 4 a Dacron monofilament is shown.

In FIGURE 5 is shown a cross section of a bi-component thread. The bi-component thread consists of 3 non-

absorbable filaments **25** of Dacron and 10 absorbable filaments **24** of PGA.

FIGURE 6 is a similar bi-component thread except that the composition is changed to 6 non-absorbable filaments and 7 PGA filaments.

FIGURE 7 shows a cross section of a bi-component thread having 9 non-absorbable Dacron filaments, and 4 PGA filaments.

It is to be understood that in surgical use the ratios shown are not critical but are representative. In forming a graded transition section, either the bi-component filaments or the bi-component threads may change by discrete increments or gradually from a completely non-absorbable material to the completely absorbable PGA. The size of bi-component filaments and the size of bi-component threads are a matter of choice depending upon the location in which the resultant prosthetic device is to be used.

FIGURE 8 shows a woven fabric in which each of the warp and the woof are constructed, starting in the center, with a 100% non-absorbable material **33**, such as Dacron, and changing by 25% increments in discrete zones **34, 35** until the outer set of threads **36** in each direction is 25% non-absorbable and 75% PGA.

Such a construction permits the use of Dacron or linear polyethylene or isotactic polypropylene in the construction of a repair patch, such as shown in Usher, supra, but in which gradation from the fully reinforcing, non-absorbable material to absorbable material is gradual. The spacing between the threads in the fabric can be chosen for a particular application. Usually, if the prosthetic device is to be used for the repair of hernias, a comparatively widely spaced weave is desired. If used for an area in which liquid retention is critical, such as an artery or vein, the weave is much closer.

In FIGURE 9 is shown a knitted fabric **27**, in which the respective strands are 100% non-absorbable **28**, followed by two rows of 75% non-absorbable 25% PGA **29** followed by two rows of 50% non-absorbable 50% PGA **30**, followed by two rows of 25% non-absorbable 75% PGA **31**.

In such a graded construction, the rate of change with distance or the number of rows of a particular composition are adjusted to fit the desired use. For smaller patches the width of each proportion of components is smaller than for large potches.

In FIGURE 10 is shown an artery **37** which is joined together over a tapered end PGA tube **38** which forms a stent about which the ends of the artery wall are joined by a suture splice **39**. The tapered end is easier to insert in the artery.

In FIGURE 11 the artery walls **40** are joined together over a flared end PGA tube **41** and the ends are joined by a suture splice **42**.

FIGURE 12 shows the flared end PGA tube **41**.

In FIGURE 13 is shown a blood vessel **43**, the ends of which are each separately placed over the end of a flared PGA tube and which blood vessel is held in place with the ends adjacent to permit healing by a PGA spring clip **44**. PGA, such as produced in the above Example 3, shows an Izod impact strength of 0.14 ft. lb. per inch width or greater. It may be heated and formed into a desired shape which shape is retained on cooling, and by shaping as a flat spring clip, can be used to hold together the walls of a blood vessel **43** until natural regeneration takes place.

In FIGURE 14 is shown a similar splice of a blood vessel **45** but in which the ends are held together by an annular clip **46** of molded PGA. Such annular clips are well known for the attachment of radiator hoses to radiators in automobiles and the attachment of other flexible tubing to connectors. By a suitable choice of diameter and shape, as is well known in the industry, the radial compression at all points about the periphery may be caused to be approximately uniform and within a desired range. This is important in the splicing of blood vessels as it is desired to hold the blood vessel in position during regeneration, but yet not hold the vessels so tightly that necrosis sets in because of an impaired blood supply to the vessel walls.

FIGURE 15 shows a section of a woven tube having bi-component strands **48** in the periphery. Such a woven tube is conveniently used as a prosthetic device. Tapp, supra, shows a nylon tube for such purpose. By incorporating PGA containing strands into the ends of such a prosthetic device, the union of the natural artery to the artificial artery is much stronger because there is not a sharp line of demarkation.

FIGURE 16 shows a heart valve **49** such as shown by Edwards, supra, with a bi-component fabric **50** surrounding the heart valve and sewn into the heart tissue **51**. By suturing the heart tissue to a bi-component fabric, as the PGA portion of the fabric is absorbed, the heart tissue grows into the remaining non-absorbable structure and forms a more secure union.

FIGURE 17 shows a broken bone **52** joined by a PGA splice bar **53** which is held to the bone by PGA screws **54**.

FIGURE 18 shows a different type of splice for a broken bone in which a broken bone **55** is jointed by a PGA fluted pin **57** inserted into the bone marrow **56**. The pin is chosen of such size and shape as to fill the hollow in the bone and give mechanical strength and prevent motion at the break.

Absorbable splices or bone pins hold the bone in place until it has an opportunity to knit and then gradually dissolve. In the past, metallic reinforcing elements have frequently been used. Such metallic elements add weight to the body, and perhaps cause inflammation by their physical presence, or must be removed at a separate subsequent operation. Additionally, if a bone pin is used internally of a bone, the volume of bone marrow is markedly reduced. When the PGA bone pin dissolves, no scar tissue remains and bone marrow is regenerated through the bone permitting the bone marrow to accomplish its organic functions.

The drawings above are illustrative only of embodiment of the present invention in which various prosthetic devices are incorporated into the human body to aid impaired functions of natural elements. From the above drawings and descriptions, it will be obvious to those skilled in the art that many other modifications may be adapted for particular injuries or ills to which the flesh is heir.

The finding that polyglycolic acid, abbreviated PGA, is absorbable in living tissue, and has marked mechanical strength, as a fiber or solid, including sheet, and hence can be used as an element in, or as, a surgical prosthesis, is most unexpected and unpredictable.

Catgut, or regenerated collagen has in the past been used for tissue emplacement, but with collagen, as the collagen is absorbed, a fibrotic tract replaces the collagen, so that in effect scar tissue remains at the site of the emplanted collagen for many years, in many instances for life. Some patients are allergic to collagen. PGA is not a protein, has no amino acids, and has given no evidence of allergic reactions in thousands of implants. With the present PGA prostheses, the PGA is completely absorbed, and a minimal or no trace of the inserted matter remains after a comparatively short period. This complete absorption, without residual fibrotic tissue, is unique, and an important contribution to surgery.

As it is obvious that examination of such prosthetic devices in humans must wait until autopsy, after death from natural causes, experimental results were conducted on laboratory animals which would permit sacrifice and examination at selected periods. These are shown in the following examples:

EXAMPLE 4

Absorbable intermedullary rod

Longitudinal incisions were made on the superior surface of the hind legs of anesthetized rabbits to expose the

upper end of the femur, close to the point of attachment to the hip. At a point about 1" from the neck portion, the shaft of the femur was cut completely through by means of a small circular saw attached to an air drill. A hole about ⅛ inch in diameter was drilled through the bony process known as the greater trochanter vertically into the narrow cavity of the shaft portion of the femur. The cut ends of the femur shaft were approximated and while they were held firmly in place a medullary rod of polyglycolic acid about two inches in length and about ⅛ inch in diameter was driven through the hole in the trochanter into the marrow cavity past the point at which the shaft of the femur had been parted. The effect of the medullary rod was to hold the cut ends of the femur shaft firmly in place. The top end of the medullary pin was flush with the surface of the trochanter.

The parted soft tissues were approximated with sutures, the injured legs were splinted with wooden tongue depressors affixed to the leg with adhesive tape and the animals were returned to their cages. X-rays were taken of the injured legs at weekly intervals and the progress of new bone formation was observed. Animals were sacrificed at the end of 6, 12, 18, and 24 weeks and the femurs which had been operated upon were dissected out and examined. These femurs were compared with similarly resected femurs which had been repaired with Type 316 stainless steel pins of equivalent size to those made of PGA.

With both the experimental and control animals the course of healing was uneventful. The breaks were essentially healed by the 6th week. After sacrifice the femurs were split longitudinally and the effect of time on the implants were observed. As expected in the relatively short times used the stainless steel pin was essentially inert but since the internal space was largely occluded, where the metallic pin was present, there was no marrow tissue.

Where the medullary rod of polyglycolic acid had been used, at six weeks the overall structure of the rod was essentially unchanged but there were fissures developing on the surface and the cut ends which had been sharply defined were somewhat rounded. The rod was somewhat softened on the surface. There was a progressive increase in the amount of erosion of the PGA rod with time but this erosion was never associated with inflammation or other adverse reactors. By the 24th week the rod of polyglycolic acid was essentially digested and the bone now showed normal tissue architecture.

EXAMPLE 5

Absorbable bone plate affixed with absorbable pins

Femurs of the hind legs of rabbits were bisected as described in Example 4. The cut ends were reapproximated and immobilized by use of an internal support made from a sheet of polyglycolic acid approximately 1/16 inch thick ¼" wide and 1 inch long, shaped to conform generally to the bone by softening the plastic with heat and premolding it about a metal rod of suitable diameter. The premolded plate was centrally located over the cut bone and while held in position, small holes were drilled through the plate and completely through the bone with a 1/16 inch drill, two holes on each side of the bone break. Small PGA nails about ⅝ inch long and slightly over 1/16 inch in diameter made by flattening rod of this diameter by pressing against a heated surface were driven through the holes in the PGA plate and completely through the bone to hold the plate in place. The soft tissue was reapproximated, the broken legs splinted and the animals were returned to their cages. X-rays were taken weekly and animals were sacrificed at 3, 6, 12, 18 and 24 week intervals. The legs which had been operated upon were carefully dissected to determine the fate of the polyglycolic acid implant and to observe the course of healing. At 3 weeks the bone was partially knit and the PGA implant was essentially intact. By 6 weeks the break in the bone was healed and the PGA plate was showing signs of erosion. The nails also showed signs of breakdown, and the plate could be moved in relation to the bone. By the 12th week the nails were so weakened and the holes in the PGA plate so enlarged that the remains of the plate could be easily separated from the bone. By the 24th week the plate was almost completely absorbed, the bone was covered by the normal periosteal membrane and where absorption was complete there was nothing to indicate that the PGA had ever been present.

EXAMPLE 6

Arterial prosthesis made of a mixture of polyester and polyglycolic acid fibers

Yarn containing a mixture of polyglycolic acid monofilaments and polyester (polymer of ethylene glycol and terephthalic acid) monofilaments was made by combining sufficient monofilaments of PGA with a polyester yarn to make about 25% of the weight of the yarn polyglycolic acid. This yarn was converted into a tightly woven cloth which was in turn formed into a tube by wrapping cut pieces of suitable size about a mandrel and sewing together the open sides with polyester thread.

In this example where the arterial prostheses were to be used in rabbits, the tubes were only 3/16" in diameter.

The abdominal aorta was exposed by incision through the ventral wall; two clamps separated by about 1½ inches were placed on the abdominal aorta just distal to the renal artery. The approximately 1 inch of the abdominal aorta between the clamps was resected and a comparable length of prosthetic tubing made as described above was sewn in place. The clamps were removed, and the animal was observed closely until blood seepage had stopped. The abdomen was then closed and the animal returned to its cage. Sacrifices were made at the end of 1, 3, 6, 12, and 18 weeks and the prosthetic implant and the neighboring tissue was examined. After the first week there was little change in the prosthesis. The pores of the fiber were closed with fibrin and some new cell growth was noticeable at the cut ends of the blood vessel. By three weeks the fibrin clots had been partially replaced by new cells which represented the partial development of a pseudo intimal lining extending from the ends of the original vessel. The polyglycolic acid filaments were still intact but were showing indications of surface erosion on microscopic examination. By 6 weeks the pseudo intimal lining was complete. Blood vessels were beginning to develop in this tissue layer. Growth of cells was occurring through the pores of the prosthesis which were now substantially enlarged by the obvious diminution in size of the PGA filaments which were no longer continuous. Shredding of the PGA filaments was evident but the complete development of the pseudo intima prevented the shreds from entering the blood stream where they could represent foci for clot formation. By the twelfth week the PGA was essentially replaced by tissue elements which formed a well vascularized multicellular layer completely capturing the polyester filaments of the prosthesis. The picture at 18 weeks was similar to that at 12 weeks with more vascularization and greater organization of the cells of the inner lining and outer surface of the prosthesis. There was a conspicuous absence of any inflammatory response of abnormal tissue reaction. The absorption of the polyglycolic acid gave sufficient space in the fiber network to permit adequate cell growth and proper vascularization so that necrosis of tissue did not develop.

So far as inspection permits, similar results appear to be obtained in humans. Of course with humans, and larger animals proportionately sized prostheses must be used.

We claim:

1. A surgical prosthesis comprising non-absorable filaments shaped as a living tissue reinforcing element, and mixed with an coacting with said non-absorable filaments, in at least a part of the element, a structure consisting essentially of polyglycolic acid, whereby on implantation in living tissue, the polyglycolic acid structure is

absorbed by the living tissue which replaces the polyglycolic acid and interlocks with the non-absorable filaments, said prosthesis being sterile at time of implantation.

2. The prosthesis of claim 1 in which the reinforcing element comprises a non-absorbable strand fabric mesh section, and interwoven and graded thereinto, bi-component strands in a graded transition portion, the individual strands of which are of proportionately increasing polyglycolic acid composition and decreasing non-absorbable filament composition, at increasing distances from said non-absorable strand fabric mesh section.

3. The fabric of claim 2 in which individual strands are composed of a plurality of non-absorbable filaments and polyglycolic acid filaments with the proportionate number of polyglycolic acid filaments increasing away from the non-absorbable fabric section.

4. The surgical fabric of claim 2 in which the bi-component strands consist of at least one bi-component filament, with the relative polyglycolic acid proportion increasing away from the non-absorbable portion.

5. The surgical prosthesis of claim 1 in which the non-absorbable reinforcing element is a tubular fabric graft with a graded transition from a section of non-absorable strands to a section in which at least a predominant portion, by weight, of the strands consist of polyglycolic acid.

6. The surgical prosthesis of claim 1 in which the non-absorable filaments are coated with a substantially continuous layer of polyglycolic acid.

7. A bi-component strand for the fabrication or attachment of a surgical prosthesis comprising at least one filament of a non-absorbable material and united therewith polyglycolic acid.

8. The bi-component strand of claim 7 in which each filament of non-absorbable material is coated, approximately concentrically, with polyglycolic acid.

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U.S. Cl. X.R.

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UNITED STATES PATENT OFFICE

CERTIFICATE OF CORRECTION

Patent No. 3,463,158

August 26, 1969

Edward Emil Schmitt et al.

It is certified that error appears in the above identified patent and that said Letters Patent are hereby corrected as shown below:

Column 1, line 40, "Sumucosa" should read -- Submucosa --. Column 2, line 2, "asorbable" should read -- absorbable Column 3, line 67, "splacing" should read -- splicing --. Column 4, line 40, "de-lactic" should read -- d,l-lactic --. Column 6, line 12, "250-280° C." should read -- 250-285° C. --. Column 7, line 46, "potches" should read -- patches --. Column 10, line 72, "an" should read -- and --.

Signed and sealed this 4th day of August 1970.

(SEAL)
Attest:

Edward M. Fletcher, Jr.
Attesting Officer

WILLIAM E. SCHUYLER, JR.
Commissioner of Patents