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. On implantation, in living mammalian tissue, the polyglycolic acid is absorbed, and replaced by living tissue. The polyglycolic acid as a gauze, felt or velour protects a wound surface, such as a burn, traumatic injury, or surgical incision, and may be left at least partially embedded, as in a scab, with the part below the healed tissue surface being absorbed, and that above the tissue surface dropping off with the scab, or be completely embedded.
1 POLYGLYCOLIC ACID PROSTHETIC DEVICES


Related data subsequent to the original parent application hereof, and incorporated herein by this reference on improvements in manufacturing of polyglycolic acid, and its use for surgical purposes are disclosed in:


2 POLYMERIZABLE INTO POLYGLYCOLIC ACID OF CONSISTENTLY HIGH MOLECULAR WEIGHT.


U.S. Ser. No. 34,593, May 4, 1970, now abandoned, Schmitt and Bailey — SOLUTIONS OF POLYGLYCOLIC ACID.

U.S. Ser. No. 117,998, Feb. 23, 1971, Semp — STERILE SURGICAL GLOVES.

U.S. Ser. No. 118,974, Feb. 25, 1971, Ramsey and DeLapp — PREPARATION OF POLYGLYCOLIC ACID IN FINELY DIVIDED FORM.


FIELD OF INVENTION

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

PRIOR ART


U.S. Pat. No. 3,155,095, A. M. Brown "Anastomosis Method and Means" shows an internal and external absorbable coupling for the joining of vascular vessels.

U.S. Pat. No. 3,559,214, W. J. Pangman, Feb. 2, 1971, COMPOUND PROSTHESIS, shows one form of implantable prosthesis, typically used to be implanted deep in the female breast. A foam type external layer is used to permit tissue invasion to aid in firm adherence to the chest wall, and to covering tissues.


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-absorbable or absorbable material. It may be continuous or staple.

A "staple" is used to designate a group of shorter filaments which are usually twisted together to form a longer continuous thread.

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 “fabric” is a three dimensional assembly of filaments, which may be woven, knitted, felted or otherwise formed into a flexible sheet having two layer dimensions and a thinner thickness dimension. A fabric may be cut to a desired size before or at the time of use. Except where limited specifically or by context, the word fabric includes both absorbable and non-absorbable cloth, or a fabric or cloth that is partially of absorbable polyglycolic acid.

A “dressing” is a woven, knitted, felted or braided fabric, of at least one layer, which is designed to protect a wound and favor its healing. As used herein, the term dressing includes bandages, insofar as they contact the wound itself. The dressing may be entirely internal. A “bandage” is a strip of gauze, or other material used to hold a dressing in place, to apply pressure, to immobilize a part, to obliterate tissue cavities or to check hemorrhage. Except insofar as the bandage comes in contact with a wound, or the exudate from a wound, there is no need for the bandage to be of polyglycolic acid. If the bandage may be in a position where absorbability by living tissue of at least part of the bandage is desirable, at least that part should be of polyglycolic acid.

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 in compression, bending and shear 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 fit into or adjacent to and furnish mechanical support and reinforcement to a bone, or bones, or gland, or organ, for support during a healing process. The size and shape of the prosthetic devices, or protheses, is controlled by usage. For example, in the human body, in the case of a bone fracture, a pin is used to reinforce a bone, and is of such size as to be a tight driving fit into a central portion of the bone, or a hole drilled into a bone. Such a pin can be from about 1/16 inch diameter and % inch long for finger bones, or for children, up to 1¼ inch diameter and 6 inch length to reinforce the femur, or thigh bone of large adult humans, or even larger for valuable race-horses or other mammals.

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 PGA fabric 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.

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 45 to 90 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 compressive 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 Tees, for artery, vein or intestinal repair, nerve splicing, 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.

In surgical techniques involving internal organs, hemorrhage may be a major problem. Some of the organs have such tissue characteristics that it is very difficult to use sutures or ligatures to prevent bleeding. For example, the human liver may suffer traumatic damage or exhibit tumors or for other reasons require surgery. In the past it has been very difficult to excise part of the liver or to suture the liver without the combined problems of the sutures cutting out and hemorrhage at the surface causing such major complications as to either prevent surgery or cause an unfavorable prognosis. It is now found that a sponge or pad or velour of polyglycolic acid may be used to protect the surface and permit new feats of surgical intervention. For instance polyglycolic acid filaments may be formed into a woven gauze or felted sponge of a velour, preferably the construction is fairly tight by textile standards, and such sponge may be placed on the surface of the bleeding organ such as the liver or a lung with either gentle suturing to hold the element or with ties in the nature of ligatures to hold the element in position with a certain amount of body fluids flowing into the sponge and being absorbed, which results in hemostasis and prevention of further loss of body fluids. If a liver or lung is so repaired, the organ may be replaced in the body cavity and the wound closed. Note the technique in Dirsch U.S. Pat. No. 2,143,910, supra. The polyglycolic acid elements usually maintain a substantial portion of their strength for at least 7 to 15 days which permits healing processes to occur and then the polyglycolic acid is absorbed by the body so that in healthy living tissue with good blood supply, the prosthetic device is completely absorbed in 60 to 90 days.

Pads, bandages or sponges of polyglycolic acid are extremely useful in surgical techniques in which it is the intent to remove the major portion or all of such sponges, felt or pad but, through inadvertence or accident, part of it may remain. For instance in a surgical operation, one of the problems which arises is the lint from cotton sponges remaining in the wound. If polyglycolic acid sponges are used, any small fragments which are accidently displaced are absorbed without
incident and even if a sponge is left in the wound, the deleterious effects are minimal. It is not desired that large volumes filled with sponges, particularly if the sponges are or become saturated with blood, remain in body cavities. The absorption of the blood clot appears to present more of a problem than the PGA. The location is also critical as some locations are more sensitive to blood clots than others. Small sponges result in minimal side effects.

The use of polyglycolic acid as a sponge or pad is particularly advantageous for surface abrasions. In the past it has been necessary to put on a dressing and avoid having the non-absorbable dressing grow into the tissue at all costs. Because the polyglycolic acid absorbs, if elements of polyglycolic acid gauze are beneath the regenerating tissue level, the tissue will regenerate and absorb polyglycolic acid with the residual polyglycolic acid in the scab falling off when the scab is displaced.

Even in cosmetic surgery or skin surgery, where in the past it has been quite customary to use silk sutures and, after the tissue is regenerated sufficient to be self retaining, remove the sutures so that they do not leave scars, the use of polyglycolic acid sutures now permits implantation of sutures through the skin with the part below the skin surface being absorbed and the part above the skin surface falling off when it is no longer retained by the polyglycolic acid below the skin. The resulting minimal degree of scarring at the skin surface is highly advantageous.

In surgery various tissues need to be retained in position during healing. Defects and wounds of the abdominal wall, chest wall and other such tissues need to be reconstructed. For a hernia, a permanent splice or reinforcement is often desired as shown in Usher U.S. Pat. No. 3,054,406, SURGICAL MESH or U.S. Pat. No. 3,124,136, METHOD OF REPAIRING BODY TISSUE. For some surgical procedures, a temporary reinforcement is desired to provide strength while body tissues are healing; and after the body tissues have assumed the load, foreign components are no longer desired. Tissue retention using the general techniques disclosed in the Usher patents, supra, are readily accomplished using either an absorbable PGA monofilament or polyfilament fabric or mesh or by using a non-absorbable material such as polyethylene or polypolypropylene or polyester woven as a bicomponent mesh or knit with PGA. The use of a bicomponent fabric has the advantage of giving additional early strength for holding the tissues in position during initial regeneration with the PGA portions being absorbed, and permitting body tissues to invade and reinforce the permanent mesh.

In common with other surgical procedures, it is often desirable that a bicomponent structure be used which provides the spacing desired for non-absorbable elements, with the PGA element holding the structure in a desired geometrical configuration at the start of the healing process. As the polyglycolic acid element is absorbed, regenerated tissue invades and replaces the dissolved PGA so that the non-absorbed element is left in a desired configuration, interlaced with living tissue in a stress-transferring relationship.

The choice of a non-absorbable reinforcement, a partially absorbable reinforcement, or a completely absorbable reinforcement is a matter of surgical judgement, based upon the condition of the patient, the body structure under treatment, and other medical factors. The present PGA fabric, or bicomponent fabrics using PGA for the absorbable portion greatly expand the scope of reinforcement available to a surgeon, and permits using absorbable structures for reinforcement in many new medical techniques.

For instance, a PGA sponge may be used in a cavity after tooth extraction to stanch the flow of blood. The sponge is either absorbed by regenerating tissue, or disintegrates into the mouth, permitting improved recovery after extractions.

The PGA may be exposed to moisture during storage before use, or may be of a lower molecular weight, both of which increase the rate of absorption by the body tissues, so that the surgical sponge in an extraction, or the prosthesis implant, has a controllable rate of absorption.

The medical uses of PGA include, but are not necessarily limited to:

A. Pure PGA

1. Solid Products, molded or machined
   a. Orthopedic pins, clamps, screws and plates
   b. Clips (e.g., for vena cava)
   c. Staples
   d. Hooks, buttons and snaps
   e. Bone substitute (e.g., mandible prosthesis)
   f. Needles
   g. Non-permanent intrauterine devices (spermicide)
   h. Temporary draining or testing tubes or capillaries
   i. Surgical instruments
   j. Vascular implants or supports
   k. Vertebral discs
   l. Extracorporeal tubing for kidney and heart-lung machines

2. Fibrillar Products, knitted or woven, including veils
   a. Burn dressings
   b. Hernia patches
   c. Absorbent paper or swabs
   d. Medicated dressings
   e. Facial substitutes
   f. Gauze, fabric, sheet, felt or sponge for liver hemostasis
   g. Gauze bandages
   h. Dental packs

3. Miscellaneous
   a. Flake or powder for burns or abrasions
   b. Foam as absorbable prosthesis
   c. Substitute for wire in fixations
   d. Film spray for prosthesis devices

B. PGA in Combination with other Products

1. Solid Products, molded or machined
   a. Slowly digestible ion-exchange resin
   b. Slowly digestible drug release device (pill, pellet)
   c. Reinforced bone pins, needles, etc.

2. Fibrillar Products
   a. Arterial graft or substitutes
   b. Bandages for skin surfaces
   c. Burn dressings (in combination with other polymeric films.)

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:

$$\text{CH}_2\text{C}=-\text{OH} \xrightarrow{\text{H}_2\text{O}} \text{H}-\left(\text{O}-\text{CH}_2\text{C}^\cdot\text{O}\right)\text{-OH}$$

hydroxyacetic acid polyhydroxyacetic ester (PGA)

Preferably \( n \) is such that the molecular weight is in the range of about 10,000 or more. Above 500,000 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 the 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, d,l-lactic acid, its optically active forms, homologs, and analogs. In general plasticizers tend to interfere with crystallinity, orientation, etc. and weaken the prosthesis but are useful for sponges and films. Other substances may be present, such as dyes, antibiotics, antiseptics, anaesthetics, and antioxidants. Surfaces can be coated with a silicone, beeswax, and the like to modify handling or absorption rate.

The polymerization of glycolide occurs 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 U.S. Pat. No. 2,668,162, Lowe, "Preparation of High Molecular Weight Polyhydroxyacetic Ester," and U.S. Pat. No. 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 triphehyl phosphite or San-

to-Nox, a disulfide aromatic phenol, can be added as color stabilizers.

**DRAWINGS**

FIG. 1 shows a broken bone, the ends of which are held in position by an internal fluted pin of polyglycolic acid.

FIG. 2 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.

FIG. 3 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.

FIG. 4 is a portion of a woven tube of certain individual strands which are at least in part absorbable.

FIG. 5 is an adhesive bandage, having a polyglycolic acid gauze pad to contact a wound.

FIG. 6 is 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.

FIG. 7 is a cross-section of a wound with polyglycolic acid fabric reinforcing the tissue layers.

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 percent 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 Examples 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°–285° C. at a pressure of less than 15 mm. of Hg. The distillate, about 238 parts by weight 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 SnCl₂ · 2H₂O.

A heavy walled glass tube having a bore of about 3/10 inch and sealed at one end is charged with 3 parts of the substantially pure glycolide composition, 0.04 part of a 0.1 percent ether solution of SnCl₂ · 2H₂O (about 0.0013 percent of SnCl₂ · 2H₂O 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 5/32 inch 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 varying 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. 90 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 0.002 inch diameter fibers and used to form strands.

Additional PGA, similarly produced is used to form sheets, or tubes. These 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 prosthesis devices shown in the drawings. The PGA maybe molded or machined or extruded to a desired configuration.

Also because of the tremendous strength of the solid PGA, a surgical needle can be formed on the end of a PGA suture by either fusing the PGA of the suture, or molding additional PGA onto the suture end, the needle being bent and pointed as may be surgically preferred for a specific surgical procedure. The ends or edges of mono-component or bi-component fabrics containing PGA may be rendered rigid by molding such edges, with or without additional solid PGA to a desired configuration. It is often easier to insert and retain a flexible fabric prosthetic tube if the end of the tube is of a size and shape to be inserted into the severed end of a vessel.

Other methods and current improvements in the production, spinning and treatment of PGA are set forth in the related data following the cross-references, supra.

FIG. 1 shows a different type of splice for a broken bone in which a broken bone 55 is joined 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.

FIG. 2 shows a broken bone 52 joined by a PGA splice bar 53 which is held to the bone by PGA screws 54.

FIG. 3 shows a heart valve 49 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.

FIG. 4 shows a section of a woven tube having bi-component strands 48 in the periphery. Such a woven tube is conventionally used as a prosthetic device. By incorporating PGA containing strands, the union of the natural artery to the artificial artery is strong because there is not a sharp line of demarkation.

In FIG. 5 is depicted a strip of adhesive tape 58 on which is placed a gauze pad 59 of PGA. The adhesive tape and gauze pad is guarded by protective strips 60 during shipment and storage. An outer protective envelope may be used. Other than using PGA for the wound contacting pad, the construction is conventional.

In FIG. 6 is shown an operation on a kidney 61 after surgical intervention, the kidney is wrapped by PGA strips 62. These may be tied together or sutured together by the surgeon. Slits 63 in the kidney may be used to aid in retention of the PGA strips during recovery, or the strip may be woven, knitted or felted so as to be retained in position by the configuration of the tie.

In FIG. 7 is shown a defect in a lining wall, for instance the peritoneal wall. The tissue 66 is placed between two PGA fabric patches 67, and sutured thereto byloop sutures 68. The loop sutures may pierce one or both PGA fabric patches, and the tissue may close the defect 64 completely, or with a gap or overlap, as the surgeon prefers.

Such an absorbable patch retains the tissue in position during healing, and if an adequate regeneration of tissue is expected, may be entirely absorbable. If an inadequate strength of tissue is expected, a bi-component fabric may be used, with non-absorbable reinforcing elements, such as a mesh, remaining to strengthen the tissue.

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.

Following the method set forth in the American Society for Testing and Materials, 1969 Books of Standards, Part 27, Plastics — General Methods of Testing, Nomenclature, ASTM, 1916 Race St, Philadelphia Pa. 19103, May 1969, procedure 709–66 at page 303 to 310, (procedure B); a flexure strength of about 40,000 pounds per square inch and a flexure modulus of 1.2 to 1.4 x 10^6 pounds per square inch is developed by the solid bars of PGA. For an unfilled plastic these values are spectacularly high. It is even more remarkable that such high strength values are developed by a polymer that is absorbable by living mammalian tissue.

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 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, 1/4 inch 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 3/8 inches 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 com-
complete there was nothing to indicate that the PGA had ever been present.

The size of the intermedullary rod varies with the size of the bone being reinforced. For finger bones the rod can be rather small and short. For the femur of a large man, the diameter and length are proportionally greater. A length of several diameters in each part of the bone adjacent the fracture gives greater stability. The inserted pin may be tubular, with a central hole large enough to permit circulation of fluids, without weakening the pin unduly, the pin may be fluted, to aid in rotational fixation. In insertion, the pin can be driven into the ends of the bone at the fracture, but usually a tight frictional fit is more easily obtained if the medullary canal is drilled or reamed to accurately frictionally engage the bone pin.

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

Obviously an implanted prosthetic device cannot be completely examined until autopsy, and the duration and type of use is not subject to complete control in humans.

EXAMPLE 6

The unique absorbability of polyglycolic acid in surgical procedures permits the construction of devices in which non-absorbable elements are positioned and held in place during the implantation stage by a polyglycolic acid portion of the device but with the polyglycolic acid dissolving and being absorbed. The tissue in regenerating fills the areas formerly occupied by the polyglycolic acid and locks into place and retains the surgical element.

The use of bi-component materials in a bi-component fabric is disclosed in U.S. Pat. No. 3,463,158 supra. Major prosthetic elements can be readily retained in location by using a bi-component element. For example heart valves which are of a non-dissolving permanent material may be wound with the bi-component material which permits the polyglycolic acid to be absorbed with the remaining material forming a strong interlock with regenerating tissue to hold the valve in place as shown in FIG. 3.

EXAMPLE 7

Becoming of increasing interest and importance is the implantation of cosmetic devices. For example, some women, do to partial surgical removal of breast tissue because of malignancies or traumatic injuries, are left with smaller breasts than are considered desirable. Additionally, some women are not as well naturally endowed as may be required for the styling trends or fashion at a particular time. In the past, among the first surgical contributions to increasing the size were the injections of silicones. The silicones enlarge the appearance of the breast, but inherently remain shiftable and hence the silicone is apt to migrate from the desired location to some other area.

A non-migrating prosthetic implantation has been used which consists of a plastic sponge or a plastic bag partially filled with a liquid having a viscosity adjusted to simulate that of natural tissue. The bag is implanted through a slit under the breast, to raise the mammary tissue away from the underlying chest wall which permits surgical reconstruction which has a very natural appearance and resilience. See U.S. Pat. No. 3,559,214 supra.

A difficulty that is encountered is the possibility of displacement of such an implanted bag from the location of choice from the effects of gravity or pressure. It is found that if the bag to be used is constructed from a physiologically inert material such as polypropylene or a silicone film, the bag can be formed with a surface roughness in which, through loops, or fusion of filaments of polypropylene or other material there is formed a bag to which the non-absorbable filament are attached. If polyglycolic acid as a bi-component material is stitched, woven, felted or otherwise formed into such appendant structures, the element may be readily implanted and the polyglycolic acid portions are dissolved out with naturally occurring tissue replacing the polyglycolic acid and thus becoming intermeshed with the elements attached to the prosthetic bag which interlocks the bag in location in the body tissues, primarily the chest wall, and hence the implanted prosthetic device is firmly locked into the tissues and protected from accidental displacement.

In one embodiment, the implanted prosthetic device is an implantable bag containing viscous liquid therein, which may be a single cell or a sub-divided cell, with a puncturable area in a selected location so that after implantation, a hypodermic needle may be used to puncture through the skin and intervening tissues, the puncturable area and into the main volume of the prosthetic device which permits hypodermic removal or addition of additional liquid so that with a minimum inconvenience, time and expense, the enhancing volume may be modified with changing fashions or the desires of the user.

A similarly constructed element using the same joint bi-component displacing technique is available to fill out other areas in which external tissue contours are to be changed. For example, an individual may have been involved in an automobile accident or the victim of a tumor and with the removal of certain tissues, a disfiguring surface configuration remains. By filling in with a prosthetic element of suitable size and shape, the surface configuration can be reconstructed to the great psychological benefit of the subject.

Similar, but solid, devices may be implanted in the nose, chin or ears to modify, restore or correct the surface configuration of the subject. In some instances it is found that the psychological benefit to the subject far overshadows any surgical risks, costs or inconveniences resulting from the operative technique.

A bi-component system can be used to aid in retaining implanted devices such as internal pacemakers or hearing aids, such as in U.S. Pat. No. 3,557,775, supra.

In the case of extensive superficial abrasions, dressings, frequently gauze, pads or wrappings absorb blood or lymph and present a problem because the gauze dressings stick to the wound or are infiltrated by regenerated tissue. In the past, it has been customary to change dressings frequently to prevent such infiltration. Removing an adherent dressing can be quite painful.

EXAMPLE 8

An extensive surface abrasion from sliding on a concrete surface after falling off a motor cycle was debrided and wrapped with a gauze of PGA threads. The wound shows the tendency to bleed into the PGA gauze
but the porosity of the gauze aids in rapidly stopping the flow of blood. By using several layers of PGA gauze and permitting the blood to at least partially harden, a minimum amount of the PGA gauze is required and the main protective dressing is of ordinary cotton gauze wrapped around the injured area. A minimum of changing the dressing is required. The outer cotton gauze is removed for inspection to be sure that infection does not occur, but the PGA gauze is allowed to remain in position in the absence of infection. The PGA gauze partly heals into the tissue, and partly remains above the tissue. Fewer manipulative steps aid in preventing the entrance of new pathogens. After healing, the PGA gauze below the new skin surface absorbs in the body and the non-absorbed PGA and the scab separate readily. If desired, the PGA gauze which is not permeated with blood may be cut off and the remaining scab washed with water. The techniques for removing scabs from tissue are conventional. The scab is protected by cotton gauze wrapped from physical damage until the scab falls off in the course of healing. Regeneration continues unobstructed because there is no non-absorbed gauze such as is normally used for surface bandages.

EXAMPLE 9

In the controlling of epistaxis (nose bleed) at times a packing of cotton swabs have been used. By using felted PGA swabs of the same general texture, the bleeding is readily controlled but without any risks from retained foreign bodies. Part of the packing can be removed once bleeding has been controlled, and the remainder can be left until the blood clots are eliminated by natural processes with the PGA sponge being simultaneously eliminated without complications.

As in common with internal pads of PGA, the PGA itself absorbs without incident. Blood which saturates the pad may present more of a problem in absorption. The usual surgical techniques of removing blood where feasible should be used, but the ability of PGA sponges, felts and pads to absorb blood aids in preventing or controlling internal hemorrhage.

EXAMPLE 10

A second degree burn on the dorsal aspect of the arm measuring about 5×5 centimeters was debrided and cleansed in the usual manner with antiseptic soap and isotonic saline. The wound was then covered with two pads of PGA absorbable gauze impregnated with furacin and then wrapped in the usual fashion with a non-absorbable cotton gauze. The lesion was inspected routinely by the surgeon, and healed without incident. The cotton gauze was removed, and the PGA gauze parted at the healing line with no trauma to regenerating tissues.

Other medicaments may be used including tetracycline, chlorotetracycline, oxytetracycline, sulfadiazine, lincomycin, sulfasymazine, silver nitrate or other antibiotic or antiseptic agents desired by the treating surgeon. The PGA itself shows bacteriostatic action.

Obviously many variants of the embodiments described may be used. For instance, instead of a single reinforcing plate, separate reinforcing plates may be used on each side of a bone, and pins or screws used through the bone to hold the bone together. For traumatic injuries, the shapes and relationships of the bone reinforcing plates must be as varied as the types of injuries to be treated. Pins at various angles, or interlocking screws and bolts similarly may be used. A rod of PGA may be used on an internal absorbable suture bolster. Where convenient, the PGA may be colored for ease of identification. For example, a green colored plate or pin is readily distinguished in an operating field. Where the rigidity of a plate, pin or tube is not required, thin sheets of solid, woven, knitted, felted or sponge PGA may be advantageously used. A felted sheet is particularly useful on a burned or abraded surface, as body fluids partially penetrate the felted material, and on healing, that part of the felt which is in living tissue is absorbed, and the remaining part falls off as skin forms under the felt covered surface. A gauze or powder may be similarly used. Powdered PGA acts as a blood coagulant, and aids in scab formation, yet can be readily removed without pain, as that part which is internal is absorbed, and that part which is external is readily removed as tissue regenerates thereunder. For nerves, thin tubes, which are split can be used to protect and separate the nerve during regeneration of a myelin sheath on the nerve. The size and configuration of such tubes, split, or partial, or sheets is as varied as the body structures being reinforced or protected. Also a two component tube or sheet may be useful, with a non-absorbable and separable sheet, such as Teflon to establish a terminal surface of tissue growth. Such can be useful to repair the liver, or other organ whose surface has been damaged, or can be at the skin surface to insure that regeneration is limited, where desired for cosmetic or other reasons.

EXAMPLE 11

PGA is very effective as an entirely absorbable implant to control bleeding or hemorrhage.

In an adult New Zealand rabbit, after anesthesia, using conventional operative techniques, the abdomen was opened to expose the liver, the several lobes of the liver mobilized, and approximately 30 percent of the mass of the liver sliced off the top of the lobes. A felted PGA fabric, about 2 millimeters thick and large enough to cover the cut surfaces was placed on the cut surfaces, and fastened in position by stay sutures of PGA. The felted PGA fabric was rapidly permeated by blood, and arrested bleeding. After inspection to be sure that all major bleeding was controlled, the liver was replaced, and the incision closed. The recovery of the rabbit was uneventful.

Inspection after sacrifice at 15 days showed the cut surfaces to have healed, liver function to have been maintained, and no evidence of post operative hemorrhage was seen.

Inspection of animals sacrificed at longer periods showed both the PGA felt and the PGA sutures to be completely absorbed.

Bleeding was at least as well controlled, and with less distress to the animal, than comparable experiments using a denatured gelatin or an oxidized cellulose as a hemostatic agent.

If the bleeding does not appear adequately and promptly controlled, agents such as thrombin may be used in addition to the PGA felt.

We claim:

1. A bone pin for the fixture of severed bone ends during regeneration after a traumatic or surgical fracture consisting essentially of a pin of polyglycolic acid of a diameter to fit into the medullary canal of a frac-
tured bone end, either of natural size, or as drilled to a larger size, and a length of at least three times its diameter, whereby the bone pin is adapted to be a drive or friction fit in each bone end, so that the bone ends are held in fixed relationship in juxtaposition during regeneration of the bone, and the polyglycolic acid bone pin is later absorbed by the body fluids, permitting regeneration of marrow in the medullary canal.

2. A bone reinforcing plate of polyglycolic acid having high flexural strength and modulus, and a physical size of at least 1/16 inch by 3/4 inch by 1 inch, and shaped to conform generally to the surface configuration of a bone, said plate having holes therein adapted to receive fasteners to hold the plate in adjacent reinforcing configuration to living bone, during a healing process, and later be absorbed by living tissue.

3. A bone reinforcing assembly comprising the bone plate of claim 2, and a headed threaded bone screw adapted to tightly hold a fractured bone in a desired configuration during a natural healing process.

4. A headed threaded bone screw of solid polyglycolic acid, shaped to be threaded into and received by a living bone structure, to position and reinforce living bone structure during a healing process and which screw is later absorbed by living tissue.

5. A headed bone nail of solid polyglycolic acid shaped to be driven into and be received by a living bone structure, to give physical restraint to position and reinforce a living bone initially, and later be absorbed by living tissue.

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