ABSTRACT: Polyhydroxyactic ester, also called polyglycolic acid (PGA), has surgically useful mechanical properties as a solid prosthesis, such as reinforcing pins, screws, plates, or cylinders. On implantation, in living mammalian tissue, the polyglycolic acid is absorbed, and replaced by living tissue.
Cylindrical Prosthetic Devices of Polyglycolic Acid

Cross-References


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.

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 nonabsorbable 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 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 "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 a 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 1/4-inch length for finger bones, or for children, up to 1/4-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, 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 wraparound 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.
- 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 3 days, and sometimes as much as 15 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 braided 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 underlyng tissues are damaged or surgically removed.

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

- 1. Pure PGA
- 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. Nonpermanent intrauterine devices (antispermocide)
- 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 velours
- 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

Miscellaneous

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

PGA in Combination with other Products

- b. 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 micro-organisms 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:

\[ \text{hydroxyacetic acid} \rightarrow \text{polyhydroxyacetic ester (PGA)} \]

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, \( \psi \)-lactide, its optically active forms, homologs, and analogs. In general plasticizers tend to interfere with crystallinity, orientation, etc. and weaken the prosthetic 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 triphenylphosphate or Santo-Nox, a disulfide aromatic phenol, can be added as color stabilizers.

**DRAWINGS**

FIG. 1 shows a spliced artery having an internal sleeve with slightly tapered ends, with a sewn splice.
second 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 resection 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 7,200 poises, and after 120 minutes, the ball drop time
is 580 sec./in. or about 6,700 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 prosthetic
device shown in the drawings. The PGA may be molded
or machined or extruded to a desired configuration.

In FIG. 1 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 FIG. 2 the artery walls 40 are joined together over a
flared end PGA tube 41 and the ends are joined by a suture
splice 42.

FIG. 3 shows the flared end PGA tube 41.

In FIG. 4 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.-lbs. 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 FIG. 5 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 at-
tachment of radiator hoses to radiators in automobiles and the
attachment of other flexible tubing to connectors. By a suit-
able choice of diameter and shape, as is well known in the in-
dustry, 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 posi-
tion during regeneration, but yet hold the vessels so tightly
that necrosis sets in because of an impaired blood supply to
the vessel walls.

While disclosed primarily for blood vessels, or vascular ves-
sels, because jointure of such vessels is of greatest interest at
present, obviously the same techniques and hollow splice
cylinders can be used on any of a variety of vessels in the body
of man or animals. Such tubes include fallopian tubes, sper-
matic ducts, bile ducts, ureters, sinus tubes, eustachian tubes,
tear ducts, or for absorbable drain tubes in body cavities, or
where a splice or jointure is required in any body tube. The
size of the hollow cylinder is preferably such that the lumen,
or internal diameter is about that of the tube being joined. The
ends of the cylinder are conveniently tapered, so that the ends
are readily insertable in the body tube, and for blood vessels so
that a minimum of turbulence is induced in flowing blood, and
hence thrombus formation is minimized. The PGA cylinder
appears to be essentially nonthrombogenic.

The splice PGA cylinder normally is of uniform diameter, as
usually the ends of the vessel to be spliced are the same. The
diameters may be made different to join vessels of different
sizes as may occur where a splice is to be made between ves-
sels not normally joined. T or Y-joints can be formed by mold-
ing or machining, with the various openings of a desired size,
with the PGA protheses to be completely covered by the ves-
sel walls. As the PGA protheses is absorbed, the vessel walls
must grow together within the vessel.

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 monocomponent or bicom-
ponent fabrics containing PGA may be rendered rigid by
moulding 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.

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 ab-
sorbable in living tissue, and that 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,
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 1.4X106 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 ef-
fact scar tissue remains at the site of the emplaced 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 protheses, the PGA is completely
absorbed, and a minimal or no trace of the in-
serted matter remains after a comparatively short period. This
complete absorption, without residual fibrotic tissue, is
unique, and an important contribution to surgery.

We claim:
1. An absorbable prosthesis for the anastomosis of vessels in the
tissue of a living mammal consisting essentially of a hollow
cylinder of polyglycolic acid, having an inner diameter approx-
imately the same as the body diameter of the subject ves-
sel, and a smooth outer surface of a diameter which is inserta-
ble in said vessel when stretched, whereby one end of a vessel
from traumatic or surgical sevarance may be emplaced over
each end of said cylinder, and fixedly positioned thereon, said
cylinder being open to and permitting the flow of body fluids,
and being absorbable by living mammalian tissue within a few
weeks.
2. The absorbable prosthesis of claim 1 inoperative con-
figuration with at least one circular cooperative clamp,
whereby in assembled relationship, with a vascular vessel end
on each end of said cylinder, the vascular vessel ends are
uniformly positioned and retained on said cylinder, tightly
tight enough to avoid substantial slippage, and loosely enough
to permit circulation into the vessel ends, and hence avoid necro-
sis.
3. The absorbable prosthesis of claim 2 in which the said
cooperative clamp is a single split ring, with inward tension
sufficient to hold the ends of said vascular vessels, when posi-
tioned over said vessels in place over said hollow cylinder.
4. The absorbable prosthesis of claim 2 having two circularly bent rod clamps, said clamps having radii of curvature such that the vascular vessels are held against the hollow cylinder with approximately uniform pressure, around the periphery of said cylinder sufficiently tight to retain the vascular vessels during regeneration, but loosely enough to avoid necrosis.

5. A method of anastomizing two vessels in living mammalian tissue comprising inserting one end of a hollow cylinder of polyglycolic acid having an inner diameter of approximately the inner diameter of one of the vessels in the end of each of the vessels, so that the ends of the vessels abut, and fastening the ends of the vessels in abutting relationship over said cylinder of polyglycolic acid, said cylinder being open to and permitting the flow of body fluids, and being absorbed by said living mammalian tissue within a few weeks.

6. The method of claim 5 in which the ends of the vessels are fastened in abutting relationship by suturing the ends together.