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SURGICAL SUTURES

Edward Emil Schmitt, Norwalk, Conn., and Rocco Albert Polistina, Port Chester, N.Y., assignors to American Cyanamid Company, Stamford, Conn., a corporation of Maine

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This invention relates to a synthetic absorbable surgical suture consisting of (1) a polyhydroxyacetic ester and (2) structural absorbable surgical elements of the same material.

Absorbable sutures in current use by the medical profession and veterinary profession for use in humans and animals are made from animal tissues, primarily of collagen, either by slitting natural collagen tissues, such as the serosa layer of an animal intestine and twisting, tanning, and sizing, or by regeneration of collagen from a casting or spinning operation. The sutures meeting with greatest acceptance are formed by slitting animal intestines, separating the serosa layer, then twisting and *chromacizing*. Because of the nature of the tissues being used, and natural biological variation, difficulty is encountered in getting uniformity of size, texture, strength, and absorption rate. Any material of biologic origin may have antigenic characteristics that in at least some instances cause complications. Necessarily, the sutures are of short segments. A usual length is about five feet.

Obviously, it has long been considered desirable to prepare an absorbable synthetic suture by a spinning process, such as used in the preparation of synthetic fibers, but no material has been known which could be so formed and which would meet medical requirements as to strength, handleability, non-toxicity, and also most importantly, predictable and uniform absorbability. Some of the common synthetic fibers such as nylon Orlon, polyethylene and polypropylene have been used instead of silk as non-absorbable sutures.

A suture to be acceptable must be reasonably strong, must have good handling characteristics, for example, it must be throwable so that the surgeon can place it where he desires, and it must have knot strength characteristics and knotability so that knots can be tied in the suture. The knot must be solid so that it will not slip and the strength of the knotted suture, while not as strong as in straight pull, is desirably as close to straight pull as possible. In many instances for testing, the suture is tied in a loop with a square knot, or a surgeon's knot, and the strength of the loop to failure, whether breakage or slippage occurs, is used as a criterion of the strength of the suture. The straight pull strength is not nearly as important as the knot pull strength.

Absorbable sutures are those which are absorbed in living tissue and for surgical purposes the absorption must be at a reasonably consistent rate, and must occur within a reasonable time period. For different purposes and in different types of tissue the rate of absorption may vary but in general an absorbable suture should have as high a portion of its original strength as possible for at least three days, and sometimes as much as fifteen days, and preferably should be completely absorbed by muscular tissue within from forty-five to ninety days. 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. In general, the medical profession has found it necessary to accept sutures which are less than perfect but which are available.

It has now been found that fibers of polyhydroxyacetic

esters, when stretch oriented, have knot strength, handleability, non-toxicity, and—most surprisingly—absorbability characteristics which are surgically desirable and conveniently close to the characteristics of collagen sutures, frequently referred to as "catgut." Because they are produced under controlled conditions, the present sutures have much more uniform overall properties. Since the sutures may be produced as a continuous strand, the packaging and handling of the sutures is particularly economical as contrasted with similar operations for "catgut."

Monofilament sutures are conveniently formed from the polyhydroxyacetic esters. Built-up polyfilamentary sutures are formed from a plurality of smaller filaments, which are spun, woven or braided. This is a new class of absorbable sutures. In the past absorbable sutures have been almost exclusively monofilament because of requirements in manufacture and limitations inherent in the material.

The polyhydroxyacetic esters 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 or 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 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.

The synthetic character and hence predictable formability and consistency in characteristics obtainable from a controlled process are highly desirable in the absorbable suture field. With sutures of catgut from natural sources, there is invariably a wider spread of strength characteristics than is to be expected with controlled synthetic products. A surgeon in using sutures is not nearly as concerned with the average strength or median strength as he is with the strength in the particular suture he is then emplacing. The surgeon must rely on the minimum assured strength of each suture rather than averages or medians for a group. Hence, a synthetic suture could even average weaker than catgut sutures but be stronger in useful strength if the minimum strength were higher than the minimum strength of catgut sutures. This could easily happen because of the greater uniformity of synthetic sutures.

Sterility is a most important characteristic of a suture. Any material to be used as a suture must have such physical characteristics that the suture can be sterilized. The most convenient method of sterilizing is by heat in which the suture is heated 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 sutures have such physical characteristics that they may be sterilized by any of these methods.

Polyhydroxyacetic ester is sometimes referred to as polyglycolide, or poly(glycolic acid) and 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:

$$\underset{\text{hydroxyacetic acid}}{\underset{|\quad\;\;\;\;\|}{\overset{}{CH_2{-}C{-}OH}}\atop{OH\quad O}} \xrightarrow[-H_2O]{} \underset{\text{polyhydroxyacetic ester}}{H{-}\left(O{-}CH_2\overset{\displaystyle O}{\overset{\|}{C}}\right)_n{-}OH}$$