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(54) **Title:** REINFORCING IMPLANTS FOR TISSUE SUTURES

(54) **Titre:** IMPLANTS DE RENFORT POUR SUTURES TISSULAIRES

(57) **Abstract**

The invention concerns a reinforcing implant for tissue sutures used for mechanically reinforcing stitched tissue zones, and consisting of a textile lap based on polyuronic acid or one of its salts

(57) **Abrégé**

Cet implant de renfort pour sutures tissulaires destiné à être mis en oeuvre pour renforcer mécaniquement les zones tissulaires suturées, est constitué d'une nappe textile réalisée à base d'acide polyuronique ou de ses sels.

REINFORCEMENT IMPLANTS FOR TISSUE SUTURES

The invention relates to an implant intended to provide mechanical reinforcement, in particular for manual or mechanical tissue sutures.

In surgical operations, in particular in the domain of thoracic surgery, it is usual either to sever and thus remove a part of certain organs, which must then be reclosed with sutures, or to repair existing structures, this being more particularly in the cardiovascular domain.

In either case, manual or mechanical sutures are inserted (by means of a pair of forceps with two branches, one of which is equipped with staples, the other being used as an anvil), intended to limit any leakages, whether they are blood leakages or air leaks, in particular in the context of lung surgery. This tightness with respect to blood and/or to air poses a real problem for the practitioner, since the sutures inserted weaken the tissues, which have a tendency to tear, these tissues also already being weakened by the pathology. This fragility leads to air leaks in the context of lungs, and more generally blood leakages, which require drains to be implanted and maintained, leading, in the case of prolonged leakages, to an increase in the length of hospitalization of the patient and, consequently, to a significant increase in the corresponding costs.

In order to overcome these major drawbacks, it has been proposed to implant reinforcement implants which are made of PTFE (polytetrafluoroethylene) and which are in the form of a cylindrical or parallelepipedal sheath or sleeve, intended to move into position by simply sliding over the two branches of a pair of suturing forceps of a type which is known per se. The activating of such a pair of forceps induces the fitting of staples on both sides of the suture line, thus attaching said sleeve to the organ in question. On certain types of forceps, this activation also induces the severing of the organ and of the sleeve, in such a way that only a part of said sleeve remains on the residual organ, acting as a splint-type suture reinforcement.

Flat PTFE splints also exist which, when cut into bands, reinforce manual sutures made using a resorbable or nonresorbable thread.

While, certainly, the implanting of such an implant leads to the mechanical reinforcement of the suture, on the other hand, besides its most particularly high price, such an implant is not bioresorbable. This drawback is particularly troublesome in the event of infection.

The use, in the same way, of cylindrical or flat splints prepared from glutaraldehyde-fixed bovine pericardium has also been proposed. In the same way as in the case above, with such an implant, a high price is encountered. Moreover, and especially, the viral

innocuity of these products is uncertain and, in particular, the innocuity with respect to prions is entirely questionable and random.

In other words, the use of such splints may serve as a vector for the transmission of viruses or of prions and therefore, because of this, prove dangerous. Moreover, such splints are also not bioresorbable.

The object of the invention is to provide implants for reinforcing tissue sutures, which have bioresorption, elasticity as well as flexibility properties which make it possible to adjust perfectly to the tissue support and optimize the tightness of the sutures with respect to gas and/or blood, this being at a reasonable cost price.

The object of the invention is also to provide an implant which is totally innocuous, after sterilization, with regard to the transmission of viruses or of prions.

Another object of the invention is to provide a reinforcement implant for tissue sutures which is capable of promoting the cicatrization of the tissues thus protected, with the aim of reducing the length of drainage and of hospitalization, and therefore the costs, and of not constituting an aggravating factor in the event of infection. This resorbable implant makes it possible to obtain a decrease in the inflammatory reaction.

Finally, the invention is also directed toward providing a reinforcement implant for tissue sutures

which is capable of exhibiting a certain tightness, in particular with respect to air and to biological fluids (blood, lymph, digestive juices), in the organs thus sutured.

This reinforcement implant for tissue sutures, which is intended to be used for mechanically reinforcing sutured tissue zones, is characterized in that it consists of a textile sheet made from polyuronic acid, or from the salts thereof.

This fibrous or filamentous textile sheet can be of the woven, knitted or unwoven type.

While, certainly, the cicatrizing and contact hemostatic properties of polyuronic acid, or of the compounds thereof, are known, on the other hand, its use as a reinforcement implant for sutures, which is as one with the sutures, has never been proposed.

According to the invention, the polyuronic acid $[C_6H_8O_6^-]_n$ is employed directly, in the form of oxidized cellulose obtained from plants (plants, wood), or in the form of calcium alginate, i.e. calcium salts of polyuronic acid $[C_6H_8O_6^-]_n\ Ca^{2+}{}_m$.

Advantageously, this calcium alginate is obtained from algae.

Textilization of the calcium aginate: a unwoven fibrous sheet is prepared in the following way. A weigh-feeder is fed with calcium alginate fibers of given length, said feeder supplying a card. At the card outlet, a net is obtained which is folded over on itself several times, in order to form a cloth which is

bonded together by needle-punching or interlacement, or alternatively by spraying of fluid. In this way, a unwoven felt of relatively high density is obtained, which is able to confer high mechanical resistance on the implant for the purpose of fulfilling its suture reinforcement function. However, this density is not too high, so as to confer elasticity and flexibility on the implant such that perfect adjustment to the tissue support and, as a consequence, the desired optimum tightness with respect to blood and gas are achieved.

The textilization of the cellulose makes use of knitted fabric, which provides neighboring mechanical properties. It then undergoes a chemical oxidation treatment.

This felt or this knitted fabric can be used in flat splints which are cut, on demand, to the desired sizes. In addition, they are flexible to the point that they can be in the form of sheaths or sleeves which are able to move into position by simply sliding over the two branches of a pair of suturing forceps of a type which is known per se, and which is sold, for example, under the trademark SEAMGUARD by W.L Gore & Associates, Inc., or alternatively under the trademark PERIPATCH by Mitroflow International, Inc.

Advantageously, the implants thus obtained are made tight by impregnation, and in particular by soaking in an aqueous solution of an ester of polyuronic acid or of the salts thereof, and for example with a solution of 3% sodium alginate ester.

This aqueous solution of sodium alginate ester is prepared from Propylene Glycol Alginate, available in the pharmacopeia.

After this impregnation step, said implants are dried in a sterile atmosphere.

In this way, implants for reinforcing sutures are obtained which almost completely abolish air and liquid leakages from said sutures.

Such reinforcement implants for sutures are most particularly indicated for tissue sutures, in particular for lung tissues in the context of lobe exereses, in the context of surgery to reduce pulmonary volume, of surgery for pulmonary emphysema, of pneumothorax, of segmental and atypical resections (WEDGES) and of pulmonary bulla resections. In all these cases, tightness with respect to blood and gas are required.

The problems engendered by this tightness deficiency, in particular by the need to maintain the drainage, prolonging, as already mentioned, the patient's stay in hospital and in fact putting a significant strain on the cost resulting therefrom, but also on the morbidity, are in fact known.

However, such implants are also most particularly suitable in the context of bronchial, digestive, cardiovascular or urogenital suture reinforcements, which are only required to be bloodtight (bronchial sutures also needing to be gastight).

In the various contexts of implantation of the implant in accordance with the invention, it can be used:

- either as a reinforcement implant for a mechanical suture using a pair of suturing forceps of the type mentioned above, and therefore be in the form of a cylindrical or parallelepipedal sheath which fits over the two branches of the forceps,
- or more conventionally as a reinforcement implant for a manual suture made using threads and needles, and, in this case, it is in the form of bands or strips which are approximately rectangular in shape and are cut, on demand, from a sheet which is bigger in size.

The use of such a material based on polyuronic acid, or on the salts thereof, promotes airostasis, hemostasis and cicatrization, resulting in faster healing of the patients.

Its woven, knitted or unwoven structure also allows a conformation at manufacturing which is suitable for each of the mechanical stapler models available on the market, including for those used in video surgery or surgery under celioscopy. Depending on the type of forceps and the type of stapler, one or two sleeves are required (anvil and staple-loader, or anvil or loader isolated).

Moreover, the material used is both biocompatible and resorbable within a typical time period of three months.

In addition, given the plant origin of the material used, total innocuity of the implant, both with respect to viruses and with respect to prions, is obtained, conferring upon it, in fact, high safety of use.

Finally, by virtue of the nature of the compounds used, the cost for producing such implants proves to be entirely moderate and thus capable of promoting their development and the extension of the indications for implantation.

CLAIMS

1. Reinforcement sheath for sutures intended to be used for mechanically reinforcing tissue zones to be sutured, characterized in that it is formed from a sleeve made of fibrous or filamentous textile material obtained from polyuronic acid, or from the salts thereof, promoting cicatrization, and in that it is impregnated with a material for making tight consisting of an ester of polyuronic acid in aqueous solution, said sheath exhibiting tightness with respect to air and to biological fluids, and making it possible to adjust to the tissue support and to obtain tightness of the sutures with respect to.

2. Reinforcement sheath for tissue sutures according to Claim 1, characterized in that the textile sheet is woven.

3. Reinforcement sheath according to Claim 1, characterized in that the textile sheet is knitted.

4. Reinforcement sheath according to any one of the preceding claims, characterized in that the polyuronic acid is employed directly, in the form of oxidized cellulose obtained from plants.

5. Reinforcement sheath according to any one of Claims 1 to 3, characterized in that the polyuronic acid is employed in the form of calcium alginate.

6. Reinforcement sheath according to any one of the preceding claims, characterized in that the calcium alginate is obtained from algae.

7. Reinforcement sheath according to any one of the preceding claims, characterized in that the ester of polyuronic acid is a sodium alginate ester.

8. Reinforcement sheath according to any one of the preceding claims, characterized in that the impregnation material has been dried.

9. Reinforcement sheath for tissue sutures according to any one of the preceding claims, characterized in that it is parallelepipedal, intended to be fitted over the two branches of a pair of suturing forceps or over just one of said branches depending on the type of stapling desired.