

This Sheet Has Been Replaced



5 TITLE

Implant for implantation in humans or animals comprising flexible, thread-shaped elements

TECHNICAL FIELD

10 The present invention relates to an implant for implantation in, in particular, humans, which implant comprises flexible, thread-shaped elements and is particularly suitable for replacing ruptured articular ligaments. The implant is intended to be a temporary implant which
15 disintegrates in time into fragments which are so small that they can be transported away by the blood and excreted through the kidneys.

STATE OF THE ART

Every year, millions of people are affected by damage to articular ligaments and tendons. A damaged ligament can be treated by
20 surgical intervention or by conservative therapy. In spite of the fact that leading orthopaedic experts agree that surgical intervention is to be preferred in most cases, conservative therapy remains the most frequently used alternative. A major reason for this is that existing operative techniques using existing implants are considered to be inadequate.

25 A common feature of all types of reconstruction is that the surgeon has to use some form of replacement material to replace the damaged tissue. The most frequently used type of replacement material is tissue of the patient himself (autograft) which the surgeon takes from other parts of the body. This tissue is often supplemented with a synthetic
30 material as reinforcement (augmentation implant). Alternatively, use is made of only a synthetic material (prosthetic implant). Implant materials which have been tried over the last 20 years in addition to autografts are inter alia tendons from animals (xenografts), deceased humans (allografts), synthetic materials in the form of non-degradable bands
35 (Dacron, polyethylene, polypropylene, carbon fibres, polytetrafluoroethylene), and a degradable band made of polydioxanone.

Temporary implants for implantation in humans or animals comprising flexible, thread-shaped elements are previously known. One such has been described in Swedish patent specification 457392. The

implant according to this patent specification consists of a bioresorbable material and is intended to replace completely or partly a tendon, a ligament or a cruciate ligament. The implant has an elongate shape and is flexible. Its main characteristic is that the structure has longitudinal
5 grooves or ducts intended to serve as initial growth guides for new fibrous tissue. Furthermore, a large number of bioresorbable materials are also known and used for other types of implant.

TECHNICAL PROBLEM

10 In certain cases, the synthetic non-degradable implant materials have proved to have inadequate tissue-affinity and in the majority of cases inadequate elasticity with creep or fatigue failure as a consequence.

Biological tendon tissue from the patient himself, animals or deceased humans has not proved to be an optimum alternative either. The
15 absence of a natural blood supply means that the elasticity and the strength are already reduced after a few weeks. Moreover, there is always a risk of transmitting infection when using implants from other humans and animals. In cases where tissue is taken from other parts of the body, the patient may suffer temporary or permanent harm from the wound created
20 at the place from where healthy tissue has been taken.

SOLUTION

It has therefore long been a requirement to produce a resorbable implant without the abovementioned shortcomings and,
25 according to the following invention, a porous, in humans or animals biodegradable, biocompatible implant for implantation in humans or animals comprising flexible, thread-shaped elements has consequently been produced, which is characterized in that the thread-shaped elements consist of a number of thread bundles containing up to several thousand
30 threads which in turn contain 50 to 500 filaments with a combined density of 5 to 120 tex, the thread bundles having a twist of 0 to 150 revolutions/metre and being held together by weft threads with a distribution density of a few threads per cm up to roughly 100 threads per cm calculated in the longitudinal direction of the thread-shaped element.

35 According to the invention, it is suitable for the weft threads to consist of the same type of thread as the other threads in the thread-shaped element.

According to the invention, the material in the threads should consist of a linear block polymer with a molecular weight of at least 10^4

Dalton, preferably at least 10^5 Dalton, comprising urea groups and urethane groups and also ester groups at such a distance from one another that, after hydrolysis of the same, fragments arise which are so small that they can be excreted from a human body, and also comprising
5 primary NH_2 -end groups and/or OH-end groups which can be replaced by, for example, monoamines such as butylamine or ethylamine.

The implant according to the invention preferably consists of a central isotropic part for essentially absorbing constant loading, and a movable outer part for absorbing forces caused by extension and/or
10 compression.

According to the invention, the implant consists of an articular ligament implant or tendon implant.

DESCRIPTION OF THE FIGURE

15 The invention will be described in greater detail below with reference to the appended figure which shows in perspective what an embodiment of the implant according to the present invention looks like.

DETAILED DESCRIPTION

20 The figure shows a section of an articular ligament according to the present invention comprising only three thread bundles 1. The articular ligament usually consists of, for example, 1 to 500 such thread bundles depending on where in the body it is to be used. As can be seen from the figure, these thread bundles 1 are lightly twisted with a twist of 10 to 150
25 revolutions per metre. This twist is primarily intended to prevent entanglement of filaments and/or threads across the width of the ligament.

The thread bundles 1 consist of up to several thousand threads 2 which in turn each contain 50 to 500 filaments. Each thread bundle can thus contain a very large number of filaments from a few hundred up to
30 several hundred thousand.

In order for the thread bundles 1 to be held together, they are bound together by weft threads 3 which are preferably applied in a weaving machine and using the simplest possible type of weave, usually plain weave. The distance between the weft threads can vary from a
35 distribution density of a few threads per cm up to roughly 100 threads per cm depending on the desired firmness of the ligament. The closer the threads lie, the more rigid and firm the ligament. The weft threads 3 suitably consist of the same material as the threads 2 in the thread bundles 1.

The thread bundles 2 do not have to have the same thickness throughout the ligament. If the implant is to be used as an articular ligament in a knee, it is suitable for the thread bundles in the central part of the ligament to be made somewhat thicker than the outer parts so that loads across the ligament are as much like the autologous ligament as possible, that is to say with a central isotropic part which is essentially to absorb constant loading while the outer thread bundles can be more easily movable so as to be capable of freely absorbing the forces caused by extension and/or compression which arise, for example, during bending and torsion of a knee joint. The thread bundles can therefore slide somewhat in relation to one another.

The construction according to the invention is loose, which affords an enhanced possibility of immigration of connective tissue cells into the ligament. The strength and the elasticity of the construction can be adapted, which makes it possible for the patient to be active soon after an operation, development of the correct type of collagen fibre thus being stimulated. Adaptation is effected by varying the number of thread bundles, the number of threads in the thread bundles and the density of the weft threads. The strength in an articular ligament according to the present invention can vary between 50 MPa and 500 MPa. The modulus of elasticity in an articular ligament according to the present invention can vary between 100 MPa and 1500 MPa.

The construction according to the present invention affords a number of advantages in comparison with previously known implants, namely maximum utilization of the thread strength as a result of a small filament angle in the fibre strand (small cosine ϕ factor), and adapted but limited mobility between the fibre strands, a loose construction to enhance the possibility of immigration of the body's own connective tissue cells, and adapted strength and elasticity.

The material in the filaments and the threads should be degradable in the body and preferably consists of those linear block polymers comprising urea groups and urethane groups which comprise hydrolyzable ester groups and are described in Swedish patent specification 505703. Other materials which are degradable and resorbable in the body can also be used.

The invention is not limited to the embodiment described above but can be modified in various ways within the scope of the patent claims.



PATENT CLAIMS

5

1. Porous, in humans or animals biodegradable, biocompatible implant for implantation in humans or animals comprising flexible, thread-shaped elements, characterized in that the thread-shaped elements consist of a number of thread bundles (1) containing up to several
10 thousand threads (2) which in turn contain 50 to 500 filaments with a combined density of 5 to 120 tex, the thread bundles (1) having a twist of 0 to 150 revolutions per metre and being held together by weft threads (3) with a distribution density of a few threads per cm up to roughly 100 threads per cm calculated in the longitudinal direction of the thread-
15 shaped element.
2. Implant according to Claim 1, characterized in that the weft threads (3) consist of the same type of thread as the other threads (2) in the thread-shaped element.
3. Implant according to any one of Claims 1 and 2, characterized
20 in that the material in the threads (2) consists of linear block polymers with a molecular weight of at least 10^4 Dalton, preferably at least 10^5 Dalton, comprising urea groups and urethane groups and also ester groups at such a distance from one another that, after hydrolysis of the same, fragments arise which are so small that they can be excreted from a
25 human body, and also comprising primary NH_2 -end groups and/or OH-end groups which can be replaced by, for example, monoamines such as butylamine or ethylamine.
4. Implant according to any one of Claims 1-3, characterized in that the implant consists of a central isotropic part for essentially absorbing
30 constant loading, and a more movable outer part for absorbing forces caused by extension and/or compression.
5. Implant according to any one of Claims 1-4, characterized in that it consists of an articular ligament implant or tendon implant.