

This invention relates to an implantable fixing means for extra-oral applications, comprising a basic member adapted to be implanted in the bone and having a screwthread-pressing or screwthread-cutting helix near the top edge of the member and an implant post connectable to the member.

The implantation of artificial ligaments connecting relatively movable parts of the human skeleton has been practised for many years. For example, if an intra-articular autologous reconstruction is unsuccessful in cases of injury or chronic instability of the cruciate ligaments of the knee joint, a cruciate ligament replacement of synthetic material can be implanted. A special polytetrafluoroethylene, which has become known under the name GORE-TEX®, for example, has proved satisfactory for this, since it is biochemically inert and therefore particularly compatible physically.

It was long assumed that the fixing means for such artificial ligaments played only a secondary role, since they grow together with tissue belonging to the body in the course of time. Some time ago, however, it was found that the tissue reaction to an implanted cruciate ligament replacement varies considerably, so that reliable growth of the artificial ligament into the tissue of the body itself cannot be assumed in every case (Rusty N., Dandy DJ, Naylor CPE. The clinical, arthroscopic and histological findings after replacement of the anterior cruciate ligament with carbon-fibre. J. Bone Joint Surg (Br) 1983; 65-B: 308-9). Thus in many cases the fixing means are required to perform their function over a long period, for example in order to be able to withstand the considerable forces which occur in the knee joint even under normal movement.

There are several proposals in the literature and practice for fixing artificial ligaments. In addition to the conventional Sherman bone screw, special cortical screws have been developed for specific fixing eyelets. Richard clips have also been used, and have barbs for reliable fit in pre-drilled bone. Bollard-like fixing means consisting of a carbon fibre/polysulphone material having a split shank which is expanded by knocking in a central pin. Finally, special implantable fixing toggles have been proposed and, in conjunction with cortical screws, special passage bushes (Andrew A. Amis, The strength of

artificial ligament anchorages, J. Bone Joint Surg (Br) 1988: 70-B: 397-403).

The fixing means known hitherto for artificial ligaments are either very expensive in respect of their implantation or not stable enough to withstand permanently without damage the unusually high forces which occur, for example, in the area of the knee joint. As a result deformation or even breakage of the fixing means or damage of the surrounding bone material constantly recurs, and in many cases makes fresh and expensive operations necessary.

Fixing means for extra-oral applications are required, however, not only for artificial ligaments but also in other areas.

In the case of serious skin injury, for example severe burns, it is necessary, more particularly in order to avoid infection, to cover the parts concerned as quickly as possible with material suitable for the purpose. In this connection there are in particular problems in connection with rapid and reliable fixing of the covering material, since the destroyed areas are very sensitive to pressure and pain and may at the same time have marked plasticity and be of small area, for example in the face area. No practicable proposal has hitherto been disclosed to solve these problems.

A fixing means of the generic type is known from US-A 4 781 591 or GB-A 2 162 753.

Like GB-A 2 162 753, US-A 4 781 591 shows a screwthreaded member in which the screwthread-pressing or screwthread-cutting helix extends substantially over the entire length of the basic member. It is relatively difficult for the operator to ensure fast and accurate tightening of the fixing means using this known fixing means and cutting of the required screwthread in the bore hole previously made in the bone.

While US-A 4 781 591 discloses no special means for countersinking the fixing means in the bone, GB-A 2 162 753 proposes providing the top end of the basic member with oppositely situated notches in which a correspondingly constructed screwdriver can engage. With the known fixing means it is impossible to obtain optimal alignment of the basic member, particularly

also with regard to the fact that an implant post may have to be accommodated.

The object of the invention, therefore, is to develop the implantable fixing means according to the preamble in such manner that it can be implanted rapidly and reliably in any bone material whatsoever, while there should be a guarantee that any implants to be fitted thereto can be aligned accurately.

According to the invention, this problem is solved by an implantable fixing means according to claim 1 or claim 2. Advantageous aspects are the subject of claims 3 to 6.

The invention is based, on the one hand, on the surprising finding that it is possible to obtain satisfactory and rapid, and also very accurate, tightening of the basic member in the bone with well-centred cutting of the required screwthread by means of the helix construction according to the invention, which is provided only near the top edge of the basic member, in conjunction with the special member insertable into the blind bores at the end face of the basic member, that part of the basic member which is not provided with the helix acting as a centring aid. This also guarantees accurate alignment of an implant, for example.

According to another aspect of the invention, the head of the implant post is provided with a magnetic or non-magnetic adhesion surface. If the fixing means is used for covering material for injuries, the basic member according to the invention can be very easily implanted, more particularly, in the entire head area, since bones can be found directly beneath the skin at very many places here, so that practically no muscle tissue has to be destroyed on implantation. The fixing means can rapidly and reliably be fitted around the damaged areas and then serve to fix the required covering material. The fixing means according to the invention is, of course, not restricted to the applications already mentioned, but can be used for the corresponding fixing of any materials to bone. For example, hair replacement parts can also be fixed in this way. Since, when the covering material is fixed, there are no appreciable tensile forces, the invention proposes recessing a magnet in the head of the implant post or providing hook and loop fasteners, adhesive surfaces or other equivalent fixing means.

According to the invention, the helix extends over a maximum of 1.5, but preferably over 1 to 1.25, turns of the basic member and may have a pitch of between 1 and 2, more particularly and preferably 1.5. With such a design of the helix it is possible reliably to anchor the basic member in the bone material without having to provide a screwthread over its entire length. When used as fixing means for covering material for injuries, the basic member may even terminate just beneath the helix, i.e. be kept relatively short and therefore be turned into the bone material very quickly and yet at the same time reliably. Precisely in this application, a reliable fit of the basic member in the bone material is achieved without having to penetrate too deeply.

The helix itself can be constructed with a flank angle of about 60° or, when used in very sensitive bone areas, for example in the head area, in which a sharp-edged helix could easily result in cracking or splintering, be made round.

Because of its low sensitivity to body fluids and its high stability to tensile forces, titanium or a titanium alloy has proved to be very favourable material for the basic member.

The basic member may be externally coated so as to be tissue-friendly. A plasma coating of hydroxylapatite has proved most suitable for the purpose. Rejection reactions by the tissue surrounding the basic member can be reliably avoided with this material, which is inter alia also the main constituent of tooth enamel.

To prevent unintentionally deep penetration of the member into the bone material, this being important particularly in the case of sensitive bone areas, the basic member should have a widened top edge zone.

In one advantageous embodiment of the invention, a spacer bush is provided which can be fitted as an extension to the top edge of the basic member. One particular advantage of the spacer bush is that it enables the basic member, which initially takes 4 into the bone under the re-closing skin, to be extended rigidly to beyond its top edge, without its being irritated by deformation movements. Advantageously, the spacer bush consists of electrically insulating material. Ceramic material, for example aluminium oxide, magnesium oxide and/or zirconium oxide, is

particularly suitable for this to ensure the best possible skin compatibility of the spacer bush. With regard to the configuration of the spacer bush it has also been found advantageous for it to engage in the basic member by means of an internal taper, to ensure a strong frictional and positive connection between the parts.

Thus, holes or rows of holes in which the implant post engages can be provided in the material for fixing. In one embodiment of the invention, the implant post has a widened head which after the implant post has been pushed through one of the fixing holes engages over and fixes the material for fixing. In another embodiment of the invention, this fixing can be effected by means of one or more hooks on the head of the implant post. In the fixing of artificial ligaments the corresponding bunch of fibres can be fused, for example, to form rectangular lugs into which correspondingly shaped implant posts are already fused. To enable the artificial ligament to be adapted in respect of length, it is advantageous to provide a number of rows of holes at its ends.

Other details and advantages of the invention will be explained in detail below with reference to the drawings wherein:

Fig. 1 is a longitudinal section through a preferred embodiment of the fixing means according to the invention for use in artificial ligaments.

Fig. 2 is a longitudinal section through another embodiment of the fixing means according to the invention, also for use in artificial ligaments, but lengthened by a spacer bush.

Fig. 3 is a longitudinal section through another embodiment of the fixing means according to the invention for use for covering material for injuries, and

Fig. 4 is a plan view of the embodiment according to Fig. 3.

In detail, Fig. 1 shows a fixing means according to the invention comprising a basic member 10 which is turned into a pre-drilled hole in an exposed part of a patient's bone, where it can take to the bone. The basic member 10 preferably consists of titanium or a

titanium alloy and its outer surface is either roughened by knurling or sandblasting, or coated to be tissue-friendly in the manner already described. To promote the taking of the basic member to the bone, recesses 14, or lacunae, or perforations may be provided in the basic member. This is important particularly when the fixing means according to the invention is used for artificial ligaments.

The basic member 10 is open at the top and its inner surface is so constructed that the implant post 30 can be screwed in or inserted bayonet-fashion. The head 32 of the implant post is widened after the style of a mushroom so that after the implant post has been inserted through appropriate holes in the material for fixing, e.g. fixing eyelets or holes, it can engage therewith.

Directly beneath the end face of the basic member 10 is a helix having 1.25 turns, a pitch of 1.5 and a flank angle of 60° which penetrates into the bone material with a screwthread-cutting action. In the example according to Fig. 2 as compared with Fig. 1 a spacer bush 40 is provided which engages in the basic member 10 by means of an internal taper 42. In addition, in this case the top part of the implant post 30 is in the form of a hook 34 which, like the mushroom-shaped widening 32 in Fig. 1, is intended to engage corresponding fixing eyelets or holes in the material for fixing.

Finally, Fig. 3 shows an embodiment of the fixing means according to the invention of the kind preferred for fixing covering material for injuries. The head 12 of the basic member 10 is widened in order to prevent excessively deep turning of the basic member 10 into the bone by accident. Generally the basic member 10 is very short since it already terminates directly beneath the helix 20. The helix 20 itself, which again has 1.25 turns and a pitch of 1.5, is round in this construction and therefore presses into the bone material with a screwthread-pressing action. A magnet 36 is provided on the head of the implant post and can co-operate with a corresponding magnet for fixing cover material, for example, for injuries, or the most diverse other materials, e.g. hair replacement parts.

Finally, Fig. 4 is a plan view of the embodiment of the fixing means according to the invention shown in Fig. 3. At the edge of the widened head 12 of the basic

member 10 will be seen oppositely situated blind bores 16 for engagement of a special key required for quick insertion and removal of the basic member. The central circle in this illustration circumscribes the periphery of the implant post head, which bears a round magnetic plate 36 in its centre. The above-mentioned other fixing facilities, e.g., an adhesion surface for a hook and loop fastener or an adhesive surface, may also be provided instead, of course.



C L A I M S

1. An implantable fixing means for extra-oral applications, comprising a basic member (10) adapted to be implanted in the bone and having a screwthread-pressing or screwthread-cutting helix (20) near the top edge of the member and an implant post connectable to the member, characterised in that the head of the implant post (30) is widened mushroom-fashion (32) or is constructed in the form of a hook (34); in that the helix (20) extends over no more than 1.5 turns of the basic member (10); in that the helix (20) has a pitch of between 1 and 2; and in that the base member (10) has blind bores (16) at the top end face for engagement with a special key.

2. An implantable fixing means for extra-oral applications, comprising a basic member adapted to be implanted in the bone and having a screwthread-pressing or screwthread-cutting helix near the top edge of the member and an implant post connectable to the member, characterised in that a magnet (36) is recessed into the head of the implant post (30) or the head of the implant post (30) has at least one adhesive surface for a hook and loop fastener or at least one adhesion surface; in that the helix (20) extends over no more than 1.5 turns of the basic member (10); and in that the basic member (10) terminates just below the helix (20).

3. A fixing means according to claim 1 or 2, characterised in that the helix (20) extends over 1 to 1.25 turns of the basic member (10).

4. A fixing means according to any one of claims 1 to 3, characterised in that a spacer bush (40) is provided and can be fitted as an extension to the top edge (12) of the basic member (10).

5. A fixing means according to claim 4, characterised in that the spacer bush (40) engages in the open end of the basic member (10) by an internal taper (42).

6. A fixing means according to claim 2, characterised in that the helix (20) is of round construction.