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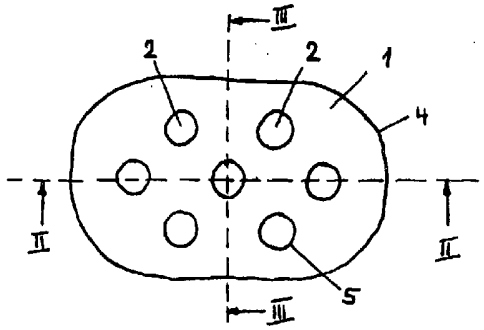
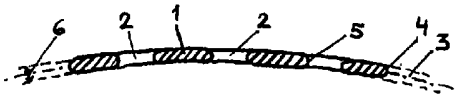
(54) Title: BONE AUGMENTATION DEVICE

(57) **Abstract**

The bone augmentation device is used for attachment of soft tissues to bone by means of sutures. It comprises a curved bone plate (1) with several through holes (2). The bone plate (1) lies in a curved plane (3) having a curvature R_{PL} in the range of 25 to 100 mm. The edges (4) of the plate (1) are rounded with a curvature R_{EP} in the range of 0,2 to 0,7 mm and the edges (5) of the through holes (2) are rounded with a curvature R_{EH} in the range of 0,2 to 0,8 mm. The device according to the invention prevents the suture from cutting through the bone and prevents gapping between the soft tissue (tendon) and bone which would result in a poor healing. The consequence is that a stable repair will facilitate healing.





Bone augmentation device

This invention concerns a bone augmentation device

Bone augmentation devices are used for attachment of soft tissues to bone by means of sutures.. Attachment of soft tissue to bone is a technique frequently required in orthopaedic surgical procedures. It is used in repair of soft tissue avulsions from bone as well as in reconstructive procedures. Augmentation devices are used in particular for attachment of avulsed tendons, ligaments and joint capsules to bone.

They are indicated for the following fields of application:

A) shoulder instability and rotator cuff tears

The shoulder is dislocated more frequently than any other human joint causing limitation of motion and pain in athletes and nonathletes of all ages.

B) knee instability

C) tenodosis and ligamentous repair of the foot, ankle and wrist

One state of the art procedure of soft tissue attachment to bone is the classic Bankart procedure which is a widely accepted method of treating anterior-inferior gleno-humeral instability of the shoulder. It uses sutures that are inserted directly through transosseous tunnels. Although the surgical exposure involves minimal trauma and skin incision and leads to excellent clinical results with reported recurrence rate of only 3,5 to 4,0 % , the procedure of reattaching the torn ligament or tendon can be time consuming and difficult. While modifications that decrease the operating time for standard rotator cuff and Bankart lesion repair are available, these approaches are technically demanding.

Another method for soft tissue attachment to bone is the use of surgical staples which, however, have a tendency to cut through the bone and tendon.

The above discussion of materials, devices and the like is included in this specification solely for the purpose of providing a context for the present invention. It is not suggested or represented that any of these matters formed part of the prior art base or were common general knowledge in the field relevant to the present invention as it existed in Australia before the priority date of each claim of this application.

It is an object of the invention to overcome or at least alienate one or more of the foregoing problems.

According to one aspect of this invention there is provided (claim 1) a bone augmentation device for attachment of soft tissues to bone by means of sutures, including a curved bone plate with rounded edges and with at least one through hole, wherein

A) said bone plate lies in a curved plane having a curvature R_{PL} in the range of 25 to 100mm;

B) said rounded edges of the plate have a curvature R_{EP} in the range of 0,2 to 0,7 mm;

C) the edges of the through holes are rounded with a curvature R_{EH} in the range of 0,2 to 0,8 mm; and

D) the bone plate is made of a non-resorbable implant material.

The device aims to prevent the suture from cutting through the bone and prevent gapping between the soft tissue (tendon) and bone which would result in a poor healing. The consequence is that a stable repair will facilitate healing.

The device preferably includes a perforated curved plate having a curvature R_{PL} in the range of 25 to 100 mm. For application to the humerus the curvature R_{PL} should be in the range of 35 to 70 mm, preferably in the range of 45 to 55 mm.

In order to prevent damage of the suture at the edges of the plate the edges at the outer periphery of the plate are rounded with a curvature R_{EP} in the range of 0,2 to 0,7 mm and the edges of the through holes are rounded with a curvature R_{EH} in the range of 0,2 to 0,8 mm.

The curvature R_{EP} of the peripheral edges purposefully is chosen in the range of 0,25 to 0,50 mm and preferably in the range of 0,3 to 0,4 mm. The curvature R_{EH} of the edges of the through holes purposefully is chosen in the range of 0,30 to 0,50 mm and preferably in the range of 0,35 to 0,45 mm.

The maximum thickness of the plate is below 1 mm and preferably below 0,75 mm. The maximum convex surface area F of the plate - including the area of the through holes - should be in the range of 100 - 250 mm^2, preferably in the range of 125 - 175 mm^2.

The device needs at least one through hole and preferably at least two through holes. For many applications 4 to 7 through holes are ideal. The through holes should have a diameter in the range of 1,70 to 2,00 mm and preferably in the range of 1,80 to 1,90 mm. The minimum distance between two centres of the through holes is in the range of 3,0 to 4,0 mm and preferably in the range of 3,4 to 3,8 mm.

The device may be made of any recognised implant material but titanium is preferred because it can withstand higher loads compared to plastic materials. Alternatively titanium offers the possiblity to design plates with reduced height.

The various features of novelty which characterize the invention are pointed out with particularity in the claims annexed to and forming part of this disclosure. For the better understanding of the invention, its operating advantages and specific objects attained by its use, reference should be had to the accompanying drawings, examples and descriptive matter in which are illustrated and described preferred embodiments of the invention.

In the drawings:

Fig. 1 is a top view of the device according to the invention;

Fig. 2 is a section along line II-II of Fig. 1; and

Fig. 3 is a section along line III-III of Fig. 1.

Figures 1 to 3 show a bone augmentation device for attachment of soft tissues to bone by means of sutures consisting of a curved plate 1 wholly made of titanium with a thickness of 0,7 mm. The plate 1 is provided with seven through holes 2 with a diameter of 1,85 mm and whose centres are regularly spaced at 3,6 mm from each other.

The plate 1 lies in a curved plane 3 having a curvature R_{PL} of 50 mm. The outer edges 4 of the plate 1 are rounded with a curvature R_{EP} of 0,35 mm and the edges 5 of the through holes 2 are also rounded with a curvature R_{EH} of 0,4 mm.
The plate 1 has a maximum convex surface area F - including the area of the through holes 2 - of approximately 150 mm^2.

Following is a short description of the method of operation with the device according to the invention.
First the tendon attachment site is selected by the surgeon. Using a burr, a trough which will later receive the tendon stump is selected. Holes are created in the bone at the desired attachment site. Suture stitches are created in the tendon, the end of the sutures are passed through the holes in the bone. The sutures are passed through the appropriate holes of the augmentation device. As the knots are tied the avulsed tendon and augmentation device are pulled onto the bone. the resulting repair is very stable and does not allow gapping between the end of the tendon and bone.

While the foregoing description and drawings represent the preferred embodiments of the present invention, it will be obvious for those skilled in the art that various changes and modifications may be made therein without departing from the true spirit and scope of the present invention.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A bone augmentation device for attachment of soft tissues to bone by means of sutures, including a curved bone plate with rounded edges and with at least one through hole, wherein

A) said bone plate lies in a curved plane having a curvature R_{PL} in the range of 25 to 100mm;

B) said rounded edges of the plate have a curvature R_{EP} in the range of 0,2 to 0,7 mm;

C) the edges of the through holes are rounded with a curvature R_{EH} in the range of 0,2 to 0,8 mm; and

D) the bone plate is made of a non-resorbable implant material.

2. Device according to claim 1, wherein the curvature R_{PL} of said plane is in the range of 35 to 70 mm, preferably in the range of 45 to 55 mm.

3. Device according to claim 1 or 2, wherein the curvature R_{EP} of said rounded edges is in the range of 0,25 to 0,50 mm, preferably in the range of 0,3 to 0,4 mm.

4. Device according to one of the claims 1 to 3 wherein the curvature R_{EH} of said edges of the through holes is in the range of 0,30 to 0,50 mm, preferably in the range of 0,35 to 0,45 mm.

5. Device according to one of the claims 1 to 4, wherein the maximum thickness of the plate is below 1 mm, preferably below 0,75 mm.

6. A bone augmentation device, substantially as herein described with reference to any one of the accompanying drawings.

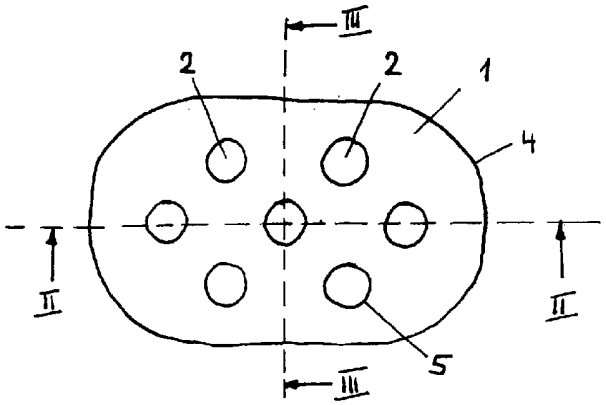


Fig. 1

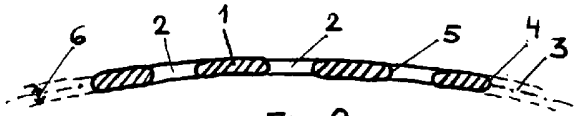


Fig. 2

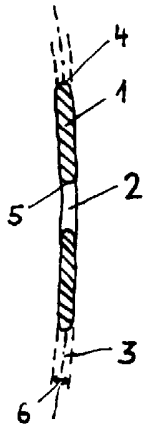


Fig. 3