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Stubstad

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[54] **ARTICULATING PROSTHESIS WITH LIGAMENTOUS ATTACHMENT**

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[52] **U.S. Cl.** ..... **3/1**, 128/92 C, 128/DIG. 21

[51] **Int. Cl.** **A61f 1/24**

[58] **Field of Search** ..... 3/1; 128/92 C, 92 CA, 128/92 R, DIG. 21

[56] **References Cited**

UNITED STATES PATENTS

3,196,462	7/1965	Robinson	3/1
3,176,316	4/1965	Bodell	3/1
3,545,008	12/1970	Bader	3/1
3,462,765	8/1969	Swanson	3/1
3,593,342	7/1971	Niebauer	3/1

FOREIGN PATENTS OR APPLICATIONS

1,061,009	11/1953	France	128/92 C
1,122,634	5/1956	France	128/92 C

OTHER PUBLICATIONS

"A Permanently Attached Artificial Limb" by C. W. Hall et al., The Bulletin of the Dow Corning Center for Aid to Medical Research, Vol. 9, No. 4, Oct. 1967, page 13.

"Silicone Rubber Implants for Replacement of Arthritic or Destroyed Joints in the Hand" by A. B. Swanson, Surgical Clinics of North America, Vol. 48, No. 5, October 1968, pages 1113–1127.

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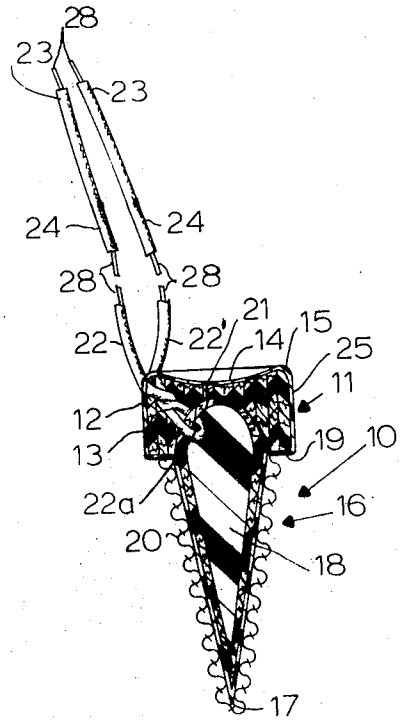
[57] **ABSTRACT**

A prosthesis useful in the repair or replacement of damaged or diseased joints in the human body, in particular of those which require unrestricted orbiting motion such as the base of the thumb, carpal bones of the wrist, shoulder joints and the like. A molded body portion replaces at least the articulating portion of the bone to be treated and one or more ligamentous elements. The body portion is suitably made of a biocompatible elastomer, especially one which is reinforced with a fibrous material such as a web or mesh of Dacron or Teflon. The ligamentous element can be a cord, flat tape or a tube such as a fabric tube of Dacron or Teflon, and in some embodiments is protected against tissue ingrowth over at least its intermediate length. In a carpal-metacarpal prosthesis for a thumb, for example, the body portion also has a metacarpal stem portion having a tissue-ingrowth-receiving surface, such as a complete or partial covering of Dacron velour, the core of such stem being suitably a biocompatible elastomer.

19 Claims, 7 Drawing Figures



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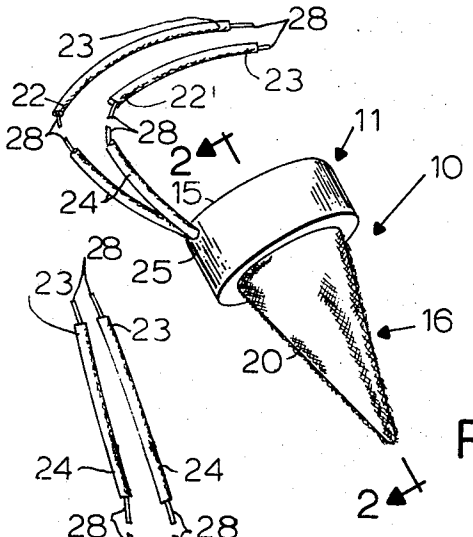

FIG. 1

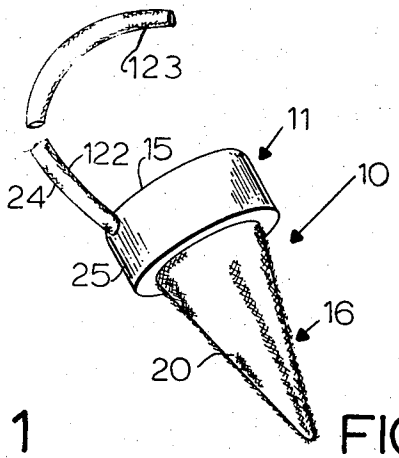

FIG. 3

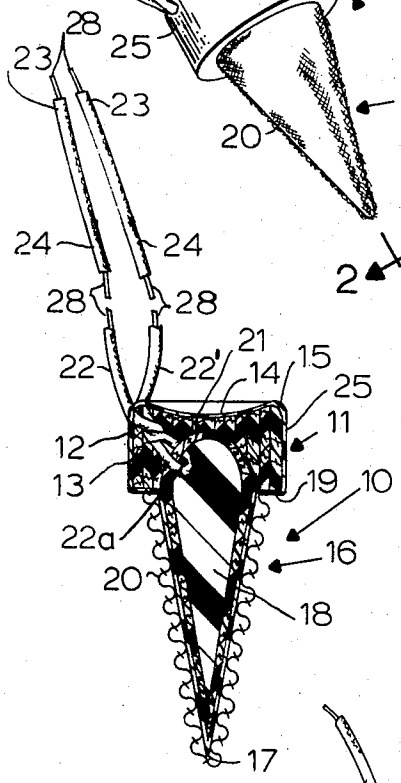

FIG. 2

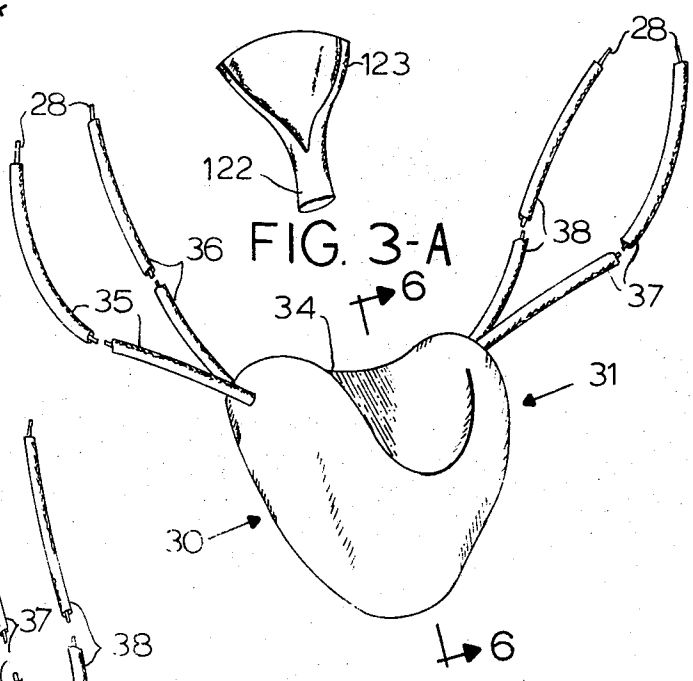

FIG. 3-A

FIG. 5

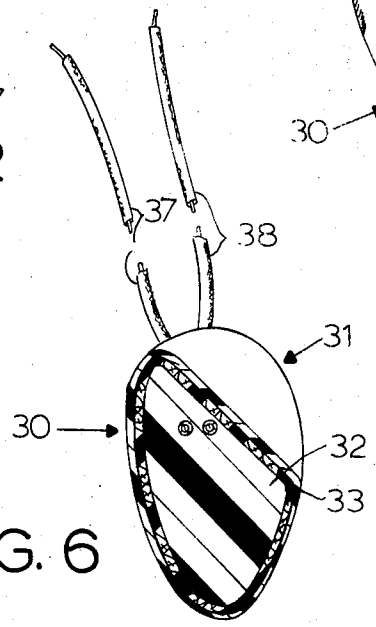

FIG. 6

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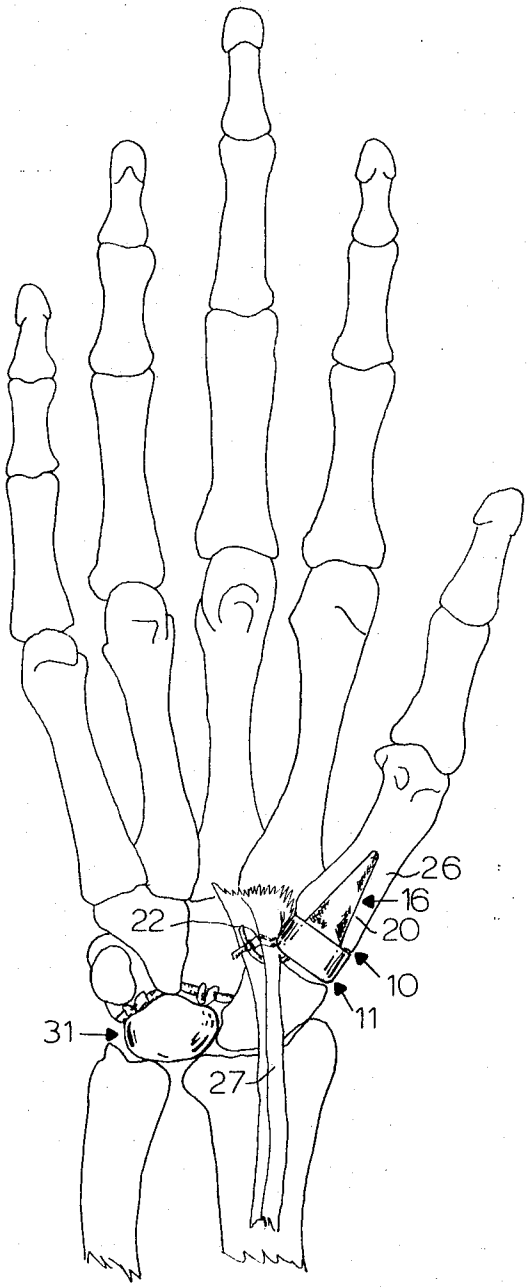
FIG. 4



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ARTICULATING PROSTHESIS WITH LIGAMENTOUS ATTACHMENT

BACKGROUND OF THE INVENTION

This invention concerns a prosthesis useful in the repair of damaged or diseased joints of the body, especially of joints which require an unrestricted orbiting motion. There are such joints at the base of the thumb where the first metacarpal bone articulates with the carpal bones, and also at the carpal bones of the wrist, shoulder joint and the like.

It is recognized that joint prostheses commonly used for repair of the metacarpal-phalangeal joints of the hand make use of integrally molded stems fitted into the intramedullary bone canals on either side of the joint as a means for maintaining alignment or resisting dislocation of the joint. However, special problems exist in certain joints of the body where the anatomy does not permit the use of integral stems fitted into opposing bones on either side of the joint. This is especially true in the wrist where the blood supply to the carpal bones can be easily upset or damaged by drilling or other gross manipulation of the bones. In addition, the repair of some joints such as the carpal-metacarpal joint of the thumb, carpal bones of the wrist, shoulder, ankle, etc., require an unrestricted orbiting ball-and-socket motion that does not allow use, in repair, of a reinforced stem and hinge prosthesis which has merely a preferential single plane of bending.

Replacement of the carpal-metacarpal portion of the thumb joint with a prosthesis has previously been attempted. However, the prosthesis of the prior art has relied upon reconstruction of the natural connective tissues to maintain position, although these tissues are often insufficient for the purpose, being subject to degenerative conditions similar to those affecting the joint articular surfaces; hence dislocation has frequently resulted.

It is an object of the present invention to overcome the aforesaid disadvantages of prostheses known to the prior art. The invention does so by providing a prosthesis constructed of biocompatible materials, particularly useful in a joint requiring the unrestricted orbiting motion. It is a further object to provide such a prosthesis having a flexible ligamentous attachment which can be arranged to secure the articulating end of the prosthesis into its natural position and wherein the prosthetic ligament can be located to lie in a plane of neutral or nearly neutral motion.

It is an advantage of this invention that orbiting motion is preserved in the joint. Another advantage is that the stability of the prosthesis is maximized. Further advantages are that motion is substantially unrestricted and that dislocation is prevented along the axis of the attached ligament or ligaments. Further advantages will become apparent from the description which follows.

SUMMARY OF THE INVENTION

This invention relates to a prosthetic joint, particularly such as is useful in joints requiring unrestricted orbiting motion, such as a carpal-metacarpal joint of the thumb, carpal bones of the wrist, shoulder joint, foot, and the like. In a particular manner, the invention relates to a prosthesis of this type comprising a shaped body portion and incorporating or including a synthetic ligament which is molded into or attached to the prosthesis, thereby maintaining alignment and resisting dislocation of the joint.

The prosthesis of this invention comprises (1) a shaped body portion adapted to replace a carpal or any other bone or an articular portion thereof and (2) a synthetic flexible ligamentous element affixed to said body portion and adapted to tie or affix by tissue invasion to an adjacent tendon, ligament, or bone.

The shaped body portion is molded of a biocompatible elastomer, especially silicone rubber, which is compatible with body fluids and tissues, is resistant to attack by such fluids and tissues, and has a long useful life with high resistance to breakdown by exposure in the environment of its use. The elastomeric portion may be suitable reinforced, and this is advantageously effected by molding into the device, at the time of making, a reinforcing web or mesh of a biocompatible material, such as a fibrous material, advantageously Dacron mesh or web. The articular portion of the prosthesis is shaped to conform generally to the shape of the portion or bearing surface of the bony portion which the prosthesis is to replace.

In addition, in one embodiment there is molded or otherwise formed as an integral part of the whole device, a stem adapted to fit into the medullary space in the bone to be repaired, after resection of the articular head of such bone. The stem is molded also of biocompatible elastomer and is provided with a complete or at least a partial covering of a tissue-ingrowth-receiving, open pore fabric surface, advantageously Dacron mesh or velour, so that the stem receives an ingrowth of bony or other tissue in the intramedullary area and becomes firmly attached to the bone. The body portion of this embodiment, of which the stem portion is an integral part, is designed to replace not only the resected articular head portion of the bone into which the stem is implanted, but also the excised bone adjacent to this bone. The interior of the stem and body portions can be reinforced as described above. Such a prosthesis is useful, for instance, in repairing a thumb joint. Thus, with tissue ingrowth from the metacarpal bone into the stem and with the attachment of the ligamentous member to carpal tissues, for instance, a continuity of strength is provided through the prosthesis, resisting dislocation of the thumb while providing unrestricted natural orbital motion of the thumb.

The prosthesis also includes at least one ligamentous element integral therewith which can be tied or otherwise attached to a body tissue, for example, to an associated bone or other suitable tissue. The ligamentous element can be made of a polymeric material, advantageously Dacron (polyethylene terephthalate) or Teflon (polymerized tetrafluoroethylene), adapted to invite tissue-ingrowth and having suitable strength and flexural fatigue resistance. Woven fabric, mesh or velour, forms are advantageously used.

Ingrowth of tissue is in many instances desirable at the end portion of the ligament, but often is undesirable over a predetermined intermediate portion of its length, depending upon the location of the device in the body. By "intermediate" is meant that portion of the length of the ligamentous element between the end portion to be attached to the bone or other tissue and the shaped body portion of the prosthesis. Such restriction of ingrowth enables the desired flexing and mobility of the ligamentous element and orbital motion of the parts involved. Accordingly, the portion which is

not to attach to the tissue, i.e., which is to be maintained free of attachment in the body, is made of or is impregnated with a biocompatible elastomer, such as silicone rubber, to prevent tissue ingrowth. However, in some locations the ligamentous element can be attachable by reception of tissue ingrowth at any point for its complete length, or it can be totally resistant to tissue ingrowth and affixed by tying around a body structure or by suturing thereto.

The ligamentous element can be in any desired form or shape, e.g., in the form of a cord, a tube (whether rounded or flat), or a tape, and advantageously is in the form of a pair of soft, contiguous or parallel, compliant or flexible fabric tubes of biocompatible material, such as Dacron or Teflon, which pair of tubes transfer tensile loads to an intended anchor or fixation site. The tubes may be reinforced with one or more cords, preferably made of Dacron, running through the interior of the tubes.

In one advantageous embodiment, the ends of the tubes where they are to be attached to the body tissue are cut and fanned or spread out into a flat sheet or sheets to develop still greater area of contact and load distribution to further minimize mechanical loading of the tissues to which the ligamentous element attaches, thereby avoiding interference with vascular and nutrient supply to the area. The flat type of attachment element or area of the ligament achieves wider load distribution and can be used in areas of the body where the simple tie cord or tube may not be tolerated due to high contact forces imposed that would tend to pinch off blood and nutrient supply. The attachment element is firmly affixed to the end of the ligamentous element, including being integral therewith.

In employing the article of this invention, where an articular portion of a bone and an adjacent articulating bone are to be replaced by the prosthesis, for instance, a metacarpal-carpal joint, the head of the metacarpal bone is resected and a portion of the medullary canal is drilled out. The trapezium then is excised, and the stem of the prosthesis is inserted into the intramedullary area of the metacarpus so exposed, and is sutured in place. The ligamentous element is extended over the tissue to which the prosthesis is to be anchored; for instance, in the case of insertion of the stem into a metacarpal bone the end of the ligamentous element is attached to carpal tissues. The attaching end of the ligament is either sutured to the tissue to which it is to attach, or the tissue may be incised and elevated to enable the two ends of the prosthetic ligament to be looped gently around a firm portion of tissue and the ligament ends secured by knotting them together. Tissue-ingrowth begins while the structure is immobilized. Thus, upon completion of the ingrowth process, typically a period of two to six weeks, a continuity of strength is provided through the prosthesis, resisting dislocation of the body structure so tested while providing unrestricted natural orbital motion of the thumb. The prosthetic ligament can be attached to the tissue to which it is to be anchored in the body in any desired manner, or a combination of several ways of so attaching the ligament can be employed. Some ways of attachment are to tie or suture the ligament around an adjacent tendon or around an adjacent bone; to tie the ligament through a hole drilled in an adjacent bone; by tissue ingrowth to the periosteum at the bone surface or to adjacent soft tissue, or to natural ligamentous tissue.

In another embodiment of this invention, there is provided a carpal lunate prosthesis which is molded of a biocompatible elastomer, suitably reinforced with a biocompatible fibrous material or fabric, such as described above. This prosthesis is made in the shape of the bone to be replaced, and affixed thereto are at least two ligamentous elements such as described above, disposed at each side of the article; corresponding to the dorsal and palmar sides; and advantageously there are two parallel ligament elements at each side. Upon emplacement in a wrist, after excision of the carpal lunate bone, the ligamentous elements are suitably affixed to adjacent body structures, preferably to the natural dorsal and palmar ligament sites for the lunate, in a manner similar to that described above.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be illustrated more in detail and as to some embodiments by the specific description herein and by the annexed drawings, wherein:

FIG. 1 is a perspective view of a trapezium prosthesis embodying the principles of this invention.

FIG. 2 is a cross-sectional view of the article of FIG. 1, taken on line 2—2 therein.

FIG. 3 is a perspective view of a modified form of trapezium prosthesis embodying the principles of this invention, incorporating a single ligamentous element and that in the shape of a flat tube.

FIG. 3A is a fragmentary enlarged view in perspective of the end portion of the flat tube of FIG. 3 partially slit and fanned out in order to provide a superior attachment to an adjacent bone.

FIG. 4 is a schematic palmar view of the skeletal structure of a human hand with an article according to this invention in place and having the ligaments attached to a tendon.

FIG. 5 is a perspective view of a carpal lunate prosthesis according to this invention.

FIG. 6 is a cross-sectional view of the carpal lunate prosthesis of FIG. 5, taken on line 6—6 therein.

DETAILED DESCRIPTION OF THE EMBODIMENTS

In FIGS. 1 and 2 is shown an embodiment of this invention suitable as a thumb joint prosthesis **10**. This prosthesis **10** comprises a shaped body portion **11** of silicone rubber **12** reinforced with at least one embedded layer of Dacron mesh **13**, which can be just below each surface of the body portion **11** or can be arranged as an embedded coil or as a plurality of layers in the portion **11**. The body portion **11** also has a cylindrical outer wall **25**. The body portion **11** has a centrally concave or dished base surface **14** and a rounded shoulder **15** therearound adapted to articulate with a carpal bone in a wrist upon emplacement, as will be described below with reference to FIG. **4**.

At the surface of the body portion **11** opposite the concave surface **14** is a stem **16**, and a shoulder **19** on the body portion **11**. The stem **16** is conical in shape, tapering to a tip **17** remote from the body portion **11**, and it comprises a core **18**, also of silicone rubber, reinforced with Dacron mesh and having a Dacron velour coating **20** thereover completely covering the core **18** and secured thereto. This securement may be suitably by means of an adhesive such as silicone adhesive or

preferably bonded by direct impregnation of raw silicone rubber in an unvulcanized state, compression molded into the underside of the Dacron velour fibers.

Extending from the outer wall **25** close to the edge **15** near the base of the body portion **11** are two soft knitted tubes **22** and **22'** of Dacron or Teflon, of a sufficient length to enable ligamentous attachment of the prosthesis **10** to a suitable adjacent body structure. These two tubes **22** and **22'** advantageously may be parts of a single strand of knitted tubing which may be applied at the time the prosthesis is made by tying it at its mid-portion **22a** to a looped tape **21** comprising the reinforcing fabric within the stem portion **16.** The two loose ends are held in a predetermined position at the time of molding the body and stem portions **11** and **16** so that they project as the two tubes **22** and **22'** from the desired site of the body portion **11.** Each tube **22, 22'** may contain one or more central cords **28** to strengthen it and also to facilitate handling and placement of these ligamentous elements. Each cord **28** is preferably made from Dacron fiber and is attached to the body portion **11,** and it can be either attached or not attached to the tube **22** or **22',** as desired; attachment may be either by interweaving or by silicone rubber bonding. The cord **28** may be omitted, if that be desired.

As shown in FIG. **3,** it is possible to use only one such ligamentous element **122,** in which case it is desirable to have a larger diameter tube **122** in order to assure a strong connection and to enhance the stability of the device **10** as emplaced.

In order to secure attachment of a ligamentous element **22** or **22'** to a body structure, the two elements **22** and **22'** may be looped around a body member, for example an incised tendon, and knotted (Cf FIG. **4**). Alternatively, the attaching or outer end **123** of the element **122** of the prosthesis of FIG. **3,** is preferably slit, opened or fanned out or spread out flat, as shown in FIG. **3A** and is then sutured at the site of attachment to a bone, ligament, tendon or other structure, to hold the end **123** in place while tissue ingrowth occurs to effect permanent attachment. If it is desired that the ligamentous element **22** or **22'** or **122** does not attach elsewhere, where loss or partial loss of mobility is unwanted, the intermediate length **24** of the element **22** or **22',** i.e., from its connection with the body portion **11** to its distal end **23,** is coated with a tissue-ingrowth-resisting, body-compatible material, such as silicone rubber. Alternatively, a suitable fiber-reinforced elastomeric cord or tape can be employed, having a tissue-ingrowth-receiving fabric affixed at its outer end. In other words, the ligamentous element **22** or **22'** is resistant to tissue ingrowth throughout its length and has a tissue-ingrowth-receiving outer or attaching end.

An embodiment of the emplacement of a prosthesis according to this invention is shown schematically in FIG. **4,** which illustrates the restoration of a carpal-metacarpal thumb joint where orbital motion is natural and desirable, and is provided by the present invention. The articulating portion of the metacarpal bone **26** is resected, the intramedullary canal is drilled to a suitable depth, and the trapezium is excised. The stem **16** of a prosthesis **10,** such as shown in FIG. **1** is inserted into the drilled portion of the intramedullary canal of bone **26** and is sutured in place. The body portion **11** replaces both the articular portion of the bone **26** and the trapezium, and the wall of the bone **26** is held snugly against the shoulder **19** of the body portion **11.** The ligamentous elements **22, 22'** are brought to a suitably positioned adjacent tendon **27** (the flexor carpi radialis) where their outer ends **23** are inserted through an incision and tied to the incised tendon with slight slackness, and the excess ends are trimmed. The intermediate lengths of the elements **22, 22'** are secured under gentle tension, so that the body portion **11** rotates freely in an orbital motion when recovery of the patient is completed.

Alternatively, when the prosthesis of FIG. **3** is used, the procedure is the same up to the point of securing the ligamentous element. In this case, the cut and fanned out end **123** (FIG. **3A**) of the element **122** is sutured to adjacent structural tissue, such as bone, ligament, or tendon. For example, to attach to bone, the periosteum is elevated or removed, and the bone surface scarified to invite ingrowth. The fanned end **123** of the ligament **122** is then firmly and closely approximated to the bleeding bony surface, the periosteal and overlying tissue layers are then repositioned, sutured, and the wound closed.

A carpal lunate prosthesis **30** is shown in FIGS. **5** and **6.** The prosthesis **30** comprises a shaped body portion **31** of silicone rubber **32** which may or need not be reinforced with a plurality of layers **33** of Dacron mesh. Molded into the body **31** at approximately opposite ends of the long diameter of the top surface **34** of the body **31** at approximately the same position as the natural lunate ligaments are ligamentous elements **35, 36, 37,** and **38,** which are like the elements **22** and **22'** described above with respect to the metacarpal articular trapezium prosthesis. Upon emplacement in a wrist, after having first excised the carpal lunate bone, each pair of the ligamentous elements **35, 36** and **37, 38** are spread out and sutured to adjacent collateral ligaments, or they may be tied to the nearest adjacent carpal bone through a suitably drilled hole, or tied to an incised ligament or tendon.

It will be understood that the above specific description and drawings have been given for purposes of illustration only and that variations and modifications can be made therein without departing from the spirit and scope of the appended claims. The term "orbital" is used herein in the anatomical sense, i.e., having a motion similar to that of the eyeball.

Having now described the invention, what is claimed is:

1. A prosthesis for replacement of at least the articular portion of a bone to enable substantially unrestricted orbital motion in a joint in an animate body, comprising in combination a shaped body portion of biocompatible elastomer material conforming approximately to the shape of the bone portion to be replaced and having a contoured surface means to produce said orbital motion, and

fabric ligamentous means secured to said portion for attachment by tying to an adjacent structure in said body at least a portion of said fabric being tissue ingrowth receptive so as to be adapted to affixation by tissue ingrowth.

2. A prosthesis as in claim **1** wherein said shaped body portion is of silicone rubber.

3. A prosthesis as in claim **2** wherein said rubber is reinforced with fibrous material.

4. A prosthesis as in claim 3 wherein said fibrous material is a mesh of fabric selected from the group consisting of Dacron and Teflon.

5. A prosthesis as in claim 1 wherein said body portion has a centrally concave end surface, and a rounded shoulder therearound.

6. A prosthesis as in claim 1 wherein there are provided a plurality of said ligamentous means.

7. A prosthesis as in claim 1 wherein said ligamentous means is a tube of fabric selected from the group consisting of Dacron and Teflon.

8. A prosthesis as in claim 7 wherein said tube is provided with at least one inner cord extending through the length of said tube and attached only to said shaped body.

9. A prosthesis as in claim 1 wherein said ligamentous means is of tissue-ingrowth-receiving fabric and has a tissue-ingrowth-resistant surface throughout its intermediate length.

10. A prosthesis for replacement of the combination of the articular portion of a first bone selected from the group consisting of the metacarpal and metatarsal bones and a second bone selected from the group consisting of the carpal and tarsal bones at a joint to enable substantially unrestricted orbital motion therein, comprising in combination:

a. a shaped body portion of biocompatible material conforming generally to the shape of said articular portion and said second bone and having a top face,

b. at least one fabric ligamentous element affixed to said body portion and adapted to attach to an adjacent body structure, each said ligamentous element being affixed at one of its ends to said body portion,

c. means to attach said element to an adjacent body structure,

d. a conical stem extending from the bottom of said body portion opposite said top face, and

e. a tissue-ingrowth-receiving fabric at least partially covering the surface of said stem, said stem being formed of a biocompatible elastomer.

11. A prosthesis as in claim 10 wherein said stem is made of silicone rubber reinforced with mesh fabric selected from the group consisting of Dacron and Teflon.

12. A prosthesis as in claim 10 wherein said ligamentous element comprises a pair of flexible knitted Dacron tubes arranged side by side and covered over the intermediate length of each with a tissue-ingrowth-resistant flexible elastomeric coating.

13. A prosthesis as in claim 10 wherein each said ligamentous element is a tube provided with a least one inner cord extending through the length of said tube attached only to said shaped body.

14. A prosthesis as in claim 10 wherein said fabric is Dacron velour.

15. A prosthesis for replacement of a bone in a human joint having orbital motion comprising a shaped body of biocompatible elastomer reinforced with biocompatible fibrous material and comforming generally to the shape of said bone and having a contoured surface means to produce said orbital motion, and at least one flexible fabric ligamentous element affixed to said body having at least a portion which is tissue ingrowth receptive whereby it is adapted to be attached to an adjacent body structure at the other end by tissue ingrowth so as to stabilize said joint against dislocation.

16. A prosthesis for replacement of a carpal lunate bone in a human wrist comprising a shaped body conforming approximately to the shape of said carpal lunate to be replaced and formed of silicone rubber, said body having a contoured upper face adapted to articulate with a carpal bone, at least one ligamentous element disposed at each end of said upper face, each of said elements being a flexible knitted tube of fabric selected from the group consisting of Dacron and Teflon and adapted to attach to an adjacent body structure to stabilize said shaped body when emplaced in said wrist.

17. A prosthesis as in claim 16 wherein a flexible cord is freely disposed within said tube and attached to said shaped body.

18. A bone prosthesis, comprising,

a. a molded body portion generally conforming to the shape of the bone to be replaced and provided with a contoured surface means adapted to produce an articulating motion with a cooperating joint part, and having

b. a stem portion covered with biocompatible fabric, and

c. at least one fabric ligamentous element secured to said body portion having at least a portion which is tissue ingrowth receptive, and adapted to attach to a body tissue by tissue ingrowth.

19. A prosthesis for replacement of a bone in a human joint having orbital motion comprising

a shaped body of biocompatible elastomer reinforced with biocompatible fibrous material and conforming generally to the shape of said bone and having a contoured surface means to produce said orbital motion,

a stem portion secured to said body portion and tapered therefrom and covered with biocompatible tissue-ingrowth-receptive fabric, and

at least one flexible fabric ligamentous element affixed to said body having at least a portion which is tissue ingrowth receptive whereby it is adapted to be attached to an adjacent body structure at the other end by tissue ingrowth so as to stabilize said joint against dislocation.

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