

[54] **BONE PROSTHESIS**

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Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 833,824, June 16, 1969, abandoned.

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

[51] Int. Cl. A61f 1/24, A61f 1/00

[58] Field of Search .. 128/92 R, 92 C, 92 CA, 92 BC, 128/334 R; 3/1

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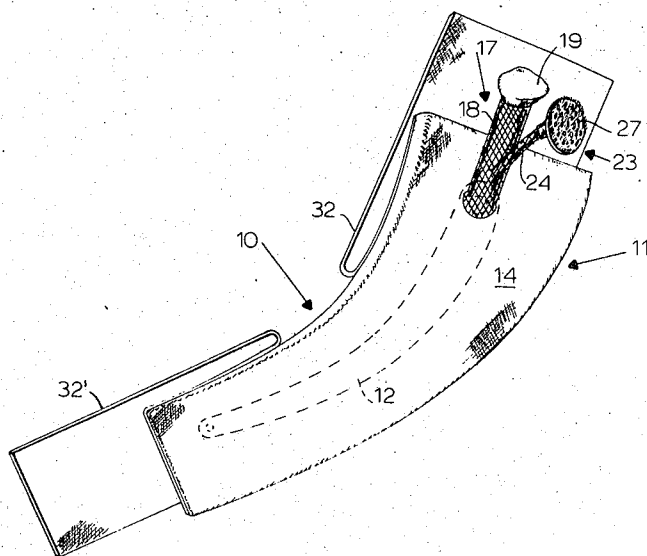
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[57] **ABSTRACT**

A prosthetic device with sub-periosteal, periosteal, or bone surface attachment for stress support, comprising a rigid reinforcing member and an elastomer-impregnated fibrous or woven fabric covering such member and firmly fixed to it. In one embodiment, a fibrous reinforced elastomer condyle-like member is affixed to one end of such reinforcing member, and a flexible pedicle extends outwardly from such condyle-like member and has at its remote end a bone-attaching head comprising a flat or disc base with a bone-exposed covering or coating of a tissue-ingrowth-receptive, open-pore fabric, to assist in providing a joint function. There is also affixed to the bone-exposed face of the elastomer-covered reinforcing member a coating of such tissue-ingrowth-receptive, open-pore fabric. All the elements where attached are firmly fixed to each other, the reinforcing member being also suitably sutured to the elastomer-impregnated fabric. The fiber and fabric parts are advantageously of Dacron, the fabric being preferably of Dacron velour; and the elastomer is advantageously silicone rubber. The device is adapted for insertion as a load-bearing element. A method for making the above device is also provided.

25 Claims, 16 Drawing Figures



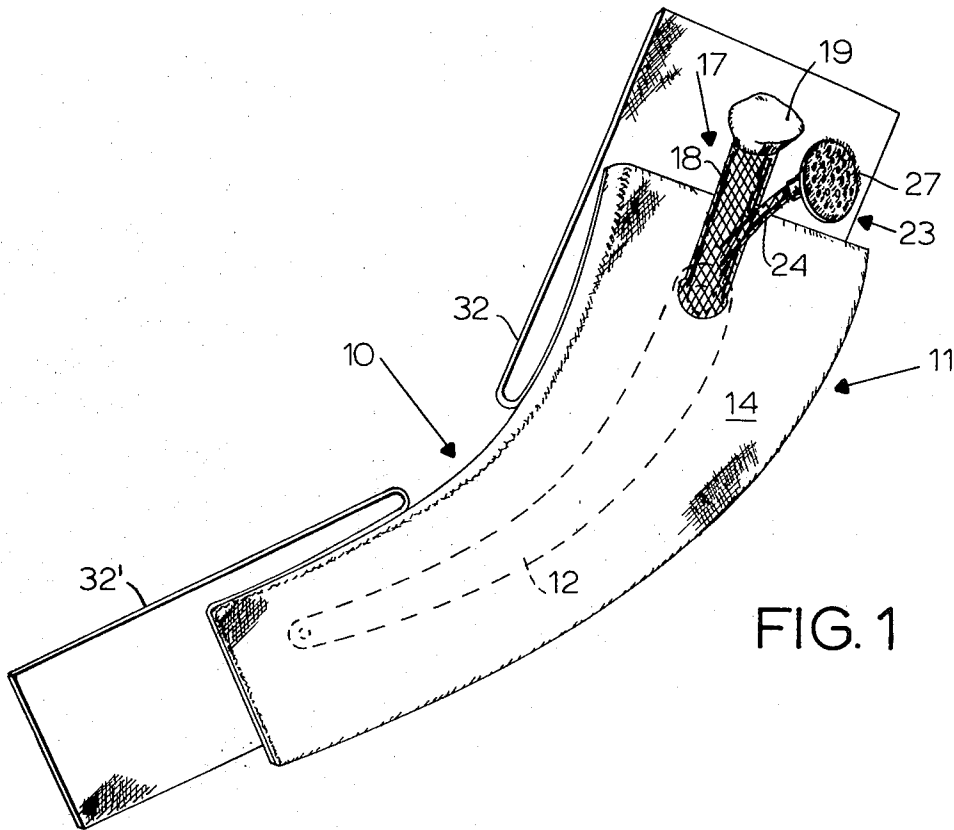


FIG. 1

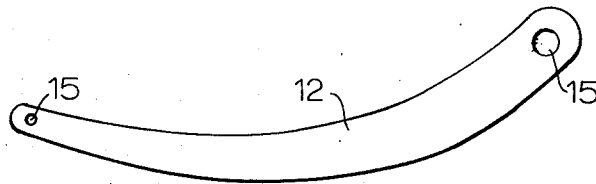


FIG. 2

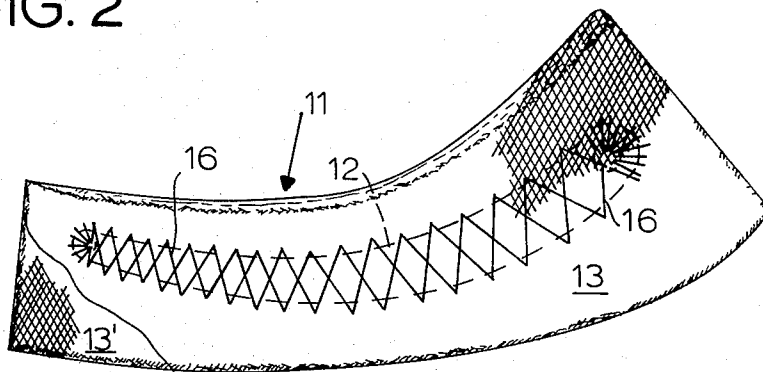


FIG. 3

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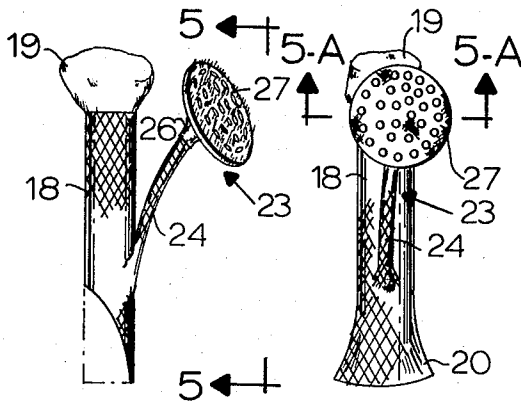


FIG. 4

FIG. 5

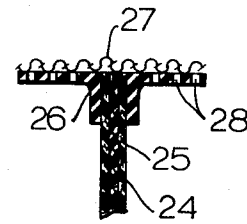


FIG. 5-A

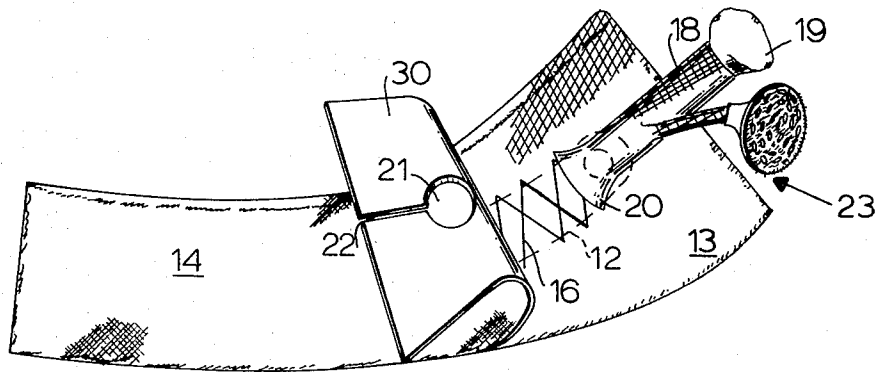


FIG. 6

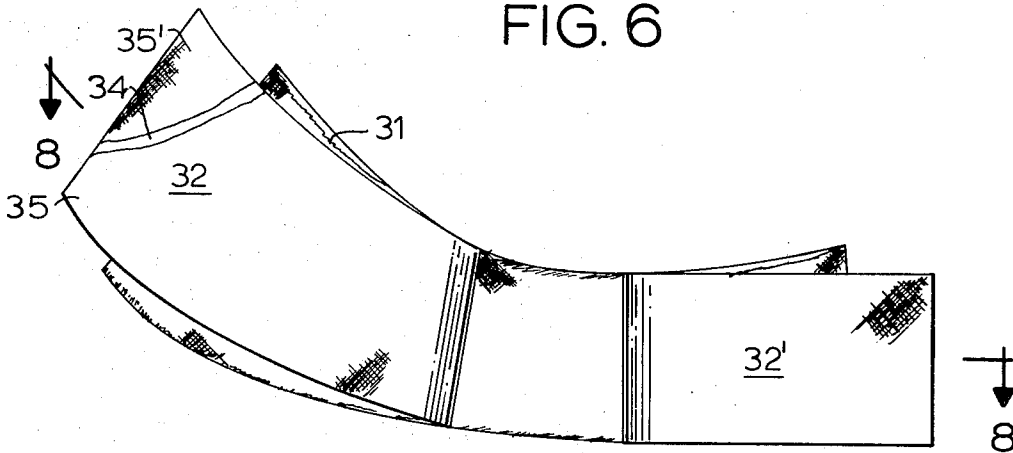
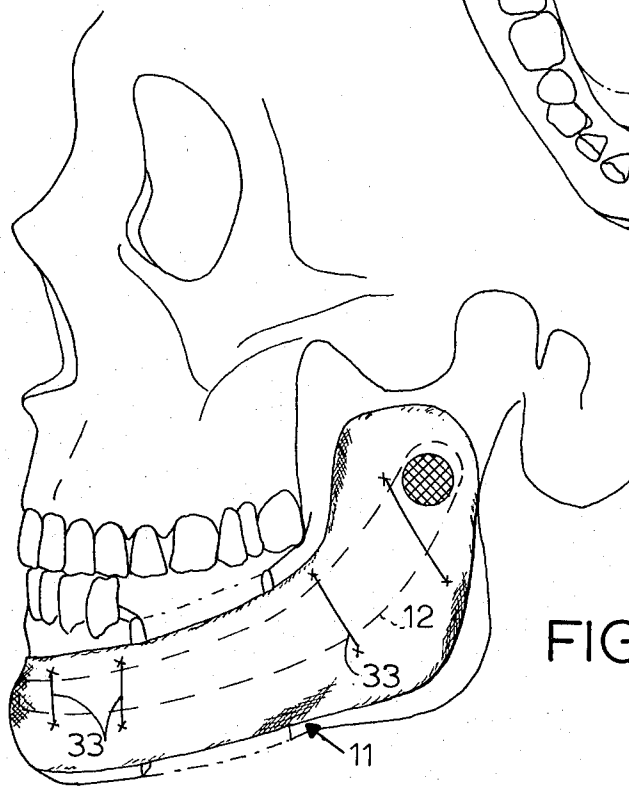
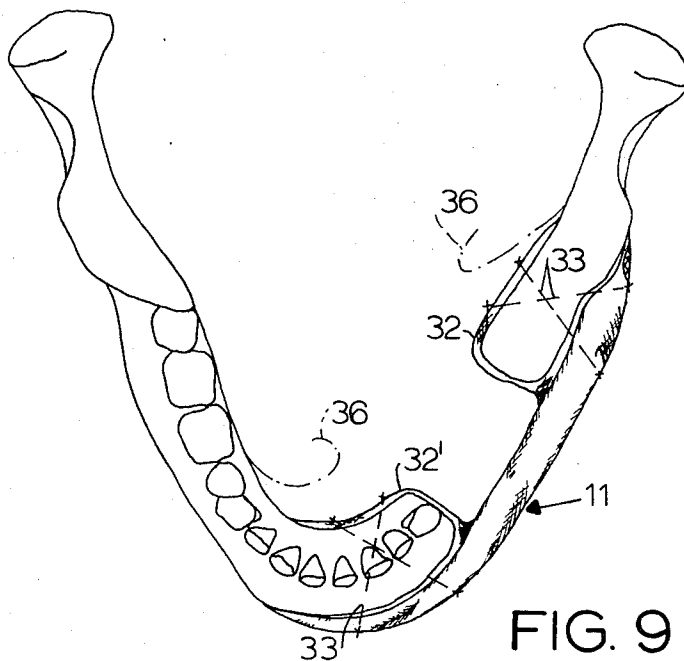
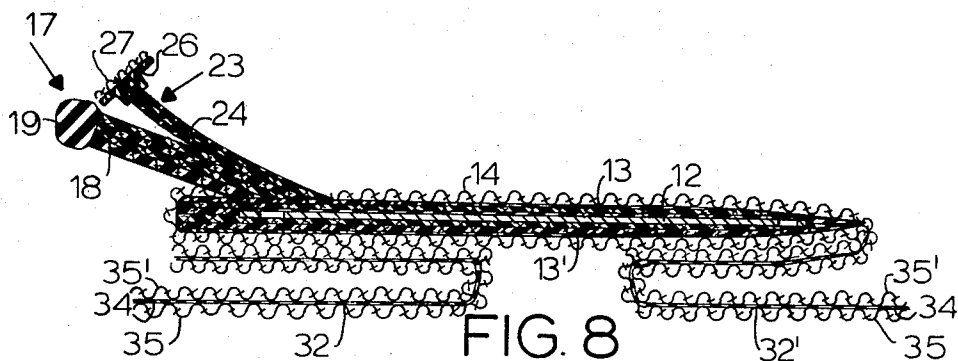


FIG. 7

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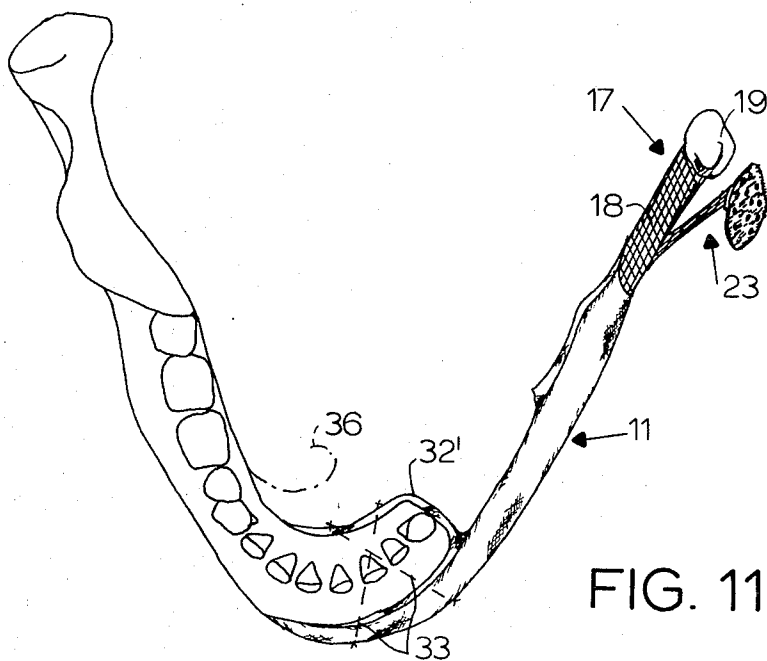


FIG. 11

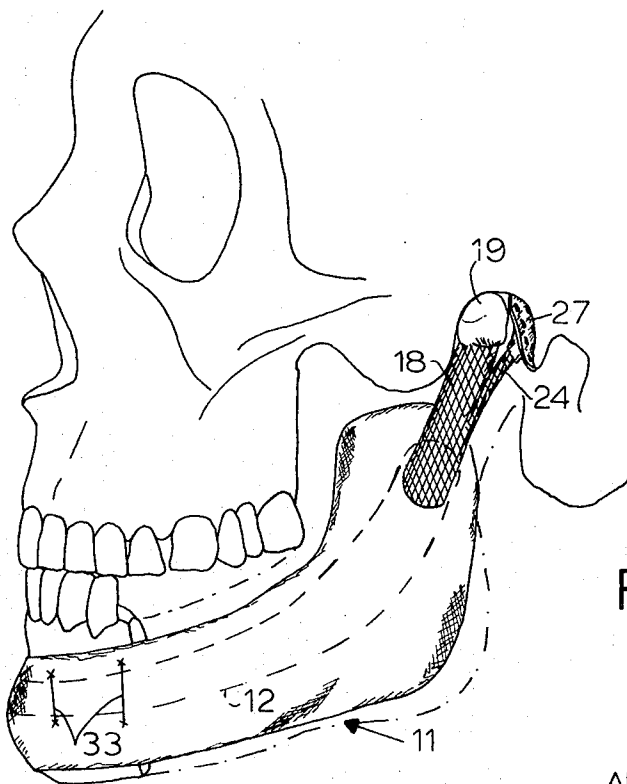


FIG. 12

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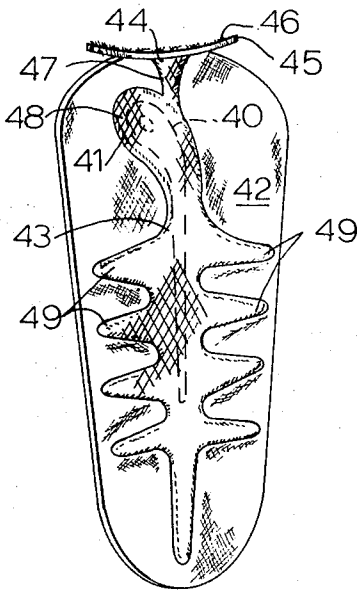


FIG. 13

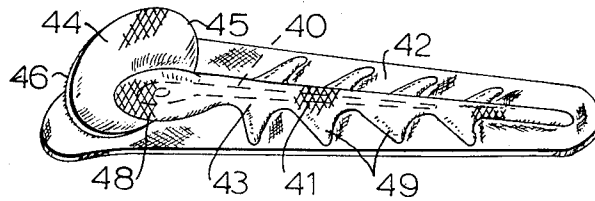


FIG. 14

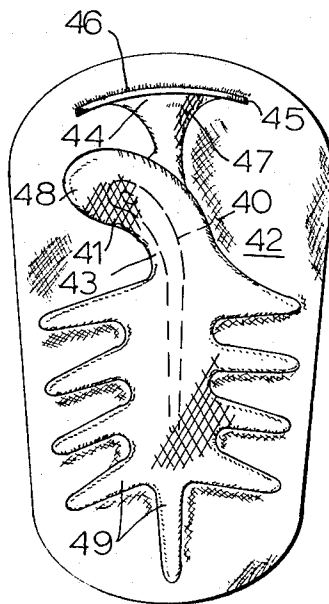


FIG. 15

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BONE PROSTHESIS

This application is a continuation-in-part of application Ser. No. 833,824, filed June 16, 1969, now abandoned.

BACKGROUND OF THE INVENTION

There are many instances where foreign substances are of necessity required for surgical implantation in human or animal tissue to achieve structural continuity. In some cases the exact dimensions, especially the length, are not attainable prior to the initial surgical procedure. For this reason it has become necessary to devise a solution to the problem of adaptability, regardless of what material is used so long as it can be cut and fashioned to some extent at the operating table. The particular form of the invention which is used as an example is for the jawbone, and it takes into account a flexible plastic which is in general use along with the combination of another plastic that has a rough and irregular surface for adaptation to bone.

In the instance where a flat bone must be dealt with from the standpoint of loss of extension, a way has been needed for enabling restoration without the necessity of multiple screws and other cumbersome and time consuming methods of handling in the operating room, most of which constitute short form repair, limited by the biological incompatibility of screws, plates etc. Thus, although methods may exist for extensions, they have been created for implantation of foreign substances by their placement in the center of a long bone directly into the bone marrow. There has as yet been no development that would provide firm fixation to the outside of the bone where it may or may not be flat and requires extension.

It is important that affixation of the prosthesis to the exterior of the bone be firm and long-term or even permanent, with minimal risk of infection. It is also very important in the case of a mandibular or temporomandibular prosthesis where a condyle or ball-and-socket restoration is provided, that no fixation of such condyle per se occur in situ, while means are provided to maintain the ball-and-socket relationship and free normal movement on the condyle stem.

The above and other objects and advantages are obtained by the present invention as will be evident from the description below. The present invention provides a prosthetic device which can be affixed sub-periosteally to a bone surface and in an advantageous embodiment provides also a condyle-like member and a pedicle, the latter being likewise sub-periosteally attached to maintain the condyle-like member in proper operating position and condition.

SUMMARY OF THE INVENTION

This invention concerns a prosthesis for the addition or repair to a missing or damaged bone; in the addition the prosthesis may be attached periosteally. The prosthesis may be applied to a substantially flat bone surface, and then at least one component of the prosthesis is a substantially flat element.

The design and plan as herein set forth encompasses the use of any preformed readily modifiable plastic substance that permits porosity and is sufficiently flexible to be lapped around the end of the bone, while at the same time the center core of the prosthetic device has

sufficient rigidity to maintain support. By simple cutting or separating along the perforations, the flattened edges of the leaf-like configuration of the supporting area is then rolled over the end of the bone and with or without further fixation, it is possible in many instances to maintain extension and support sufficient to carry the necessary load that is applied in normal function after a suitable period of healing.

The additional or optional use of the flattened mushroom-like end or disc of the pedicle permits the prefashioned prosthesis to be fitted into any socket or flattened area, while its perforations and the character of the plastic substances chosen will enable firm union into the socket allowing permanent movement on a flexible stem. There can be no permanent fixation of a ball and socket on a stem-like narrow section of the same plastic substance that is not subject to fatigue under repeated movements or stress. In the invention a main stem carries compressive loads, with rotation at the condyle; a pedicle carries tensile loads with flexibility.

In one embodiment the prosthesis comprises a flat, shaped, rigid reinforcing element (which may be of relatively rigid plastic, or, advantageously of light metal, especially titanium) and a covering thereover (suitably of fibrous material impregnated with silicone rubber or like material compatible with body fluids or tissues). The elastomer-impregnated fibrous or fabric covering is also flat, or substantially flat, and is contoured generally to the metal element. The covering is preferably made of a layer of fabric at each flat surface of the reinforcing element, preferably of Dacron fabric. A layer of such impregnated fabric may be placed on each flat face or surface of the metal or other rigid element and the whole sutured or adhered or otherwise secured together and eventually vulcanized in forming the desired prosthesis or component thereof. In a mandibular prosthesis, the metal element is suitably curved and tapered to conform to the shape of the mandible section to be repaired or replaced. Advantageously, the metal piece may also be sutured to the reinforced elastomer, e.g., by cross-stitching which passes around the metal element and through the layers of impregnated woven fabric. Alternatively, the metal and cloth may be joined by adhesives or through chemical priming.

The mandibular prosthesis is also provided at its bone-adjacent surface with one or two flexible flaps of open-pore, tissue-ingrowth-receptive fabric, especially of Dacron velour laminated with silicone rubber, and the Dacron velour surface in each instance is adapted to abut a bone surface when emplaced. In use, each flap is folded over a cut end of bone, the periosteal tissue layer having been laid back so that the flap can also abut the bone surface itself inside and outside of the mandible, so that tissue ingrowth can occur at these bone surfaces over a period of time, thoroughly bonding the prosthesis to the mandible. In another embodiment, part of the elastomer-impregnated fibrous layer, properly surfaced with open-pore fabric, is cut and folded over the cut end of bone. Affixation of the flap to the bone enables extension of the load-bearing element across the resected portion of the bone, which can also extend, if desired, to a bearing at the next available portion of bone. In any event, firm affixation

to the mandible is effected by such flap or pair of flaps. The area of the prosthesis between a pair of turned-back flaps bridges the resected portion of the mandible, where this has occurred. Both surfaces of such a flap are of the tissue-ingrowth-receptive material, so that such ingrowth eventually occurs with respect both to the bone and to the periosteum.

Yet another embodiment of the invention provides a temporomandibular prosthesis with the mandibular component as described above, but also having a condyle-like element extending from one end of the rigid or metal reinforcing agent. This condyle-like element comprises a rigid stem or center bar, preferably terminating in a rounded head. A pedicle or ligamentous element, which may be shaped like a mushroom, extends from the rigid stem and has a terminal head, preferably shaped like a disc. The terminal head may be flat, being flexible and adaptive, and it supports a disc of tissue-ingrowth-receptive fabric, preferably of Dacron and especially Dacron velour. Such a disc can be round, square or of any desired shape, depending upon the bone surface available or other conditions. The disc is joined or affixed to the stem by a layer of silicone rubber. The pedicle extends from the rigid stem; in an optimal arrangement it joins the stem about midway of the stem's length, but it can originate at other locations. The ligamentous element or pedicle stem is of flexible elastomer internally reinforced with a fiber material such as Dacron. The disc of the pedicle can abut upon and conform to a tissue such as a bone surface freed of periosteal tissue and affixes thereto by tissue ingrowth, bony tissue or other tissue, especially fibrous tissue, being encouraged by the fabric structure to grow into the pile or open pores and thereby fix or secure the prosthesis to the bone. The rounded head of the condyle-like element fits movably or rotatably into a recess in the bone intended to receive it, such as a temporal bone, hip bone or other, and it is held in place without affixation by the action of the pedicle and disc or ligamentous element. Although this embodiment is described with respect to a temporomandibular prosthesis, the condyle-pedicle features are also useful at other skeletal sites, specially where joint function is desired, and it may there be used along with the straight or bridging element and the condyle-like articular ball surface mentioned before.

In practicing the method of making the device of this invention, a flat, shaped, relatively rigid reinforcing element, such as a titanium element, is placed between two layers of fabric, e.g., woven Dacron cloth, which have each been thoroughly impregnated with a silicone rubber or like physiologically compatible elastomer. The fabric and reinforcing agent are then sutured or adhered to bind them together. A layer of an open-pore fabric, such as a mesh or pile fabric, for example, may be thoroughly coated on the back, or non-pile face, with a dispersion of unvulcanized silicone rubber or other polymerizable bonding agent, without closing the pores of the face, and applied over the fabric layers covering the reinforcing element. The whole is vulcanized and cured to assure firm bonding.

Where a condyle-like or joint-like element is employed, it is affixed to a rigid reinforcing agent covered with a fabric impregnated with rubber as described above. The condyle stem is splayed at the base and

spread over the reinforcing element at one end thereof, and the fabric overlayer is fixed in place by suturing; or the open-pore fabric may be placed over the same around the condyle element and the whole vulcanized.

BRIEF DESCRIPTION OF DRAWINGS

The invention and some modes of carrying it out will be illustrated by the annexed drawings which, without limiting the invention, show some embodiments of the device of the invention. In the drawings:

FIG. 1 is a perspective view of a temporomandibular prosthesis.

FIG. 2 is a top view of a rigid reinforcing element useful in the prosthesis.

FIG. 3 is a top or plan view showing a mandibular prosthesis. The view is partially cut away to show the rigid element, the layers of impregnated fabric, and the binding suturing.

FIG. 4 is a view in elevation of the condyle-like element and pedicle of FIG. 1.

FIG. 5 is a view in elevation of the device of FIG. 4 taken 90° from FIG. 4.

FIG. 5A is a view in section of a portion of the pedicle, taken on the line 5A—5A of FIG. 5.

FIG. 6 is a plan view of a mandibular prosthesis, with the upper layer partly turned back to show suturing of the rigid member and attachment of the condyle element thereto.

FIG. 7 is a view in elevation of the mandibular prosthesis, showing two flaps.

FIG. 8 is a view in section taken on line 8—8 of FIG. 7.

FIG. 9 is a top view of a human lower jaw, showing use or placement of a mandible prosthesis when the condyle element is not used.

FIG. 10 is a view in side elevation of the skeletal structure only, showing the device and placement of FIG. 9.

FIG. 11 is a top view of a human jaw showing use of the mandible prosthesis when the condyle and pedicle are used.

FIG. 12 is a view in side elevation of the device and placement of FIG. 11.

FIG. 13 is a view in perspective of a modified form of a mandible prosthesis.

FIG. 14 is a side view in perspective of the prosthesis of FIG. 13.

FIG. 15 is a top plan view of the mandible prosthesis of FIGS. 13 and 14.

DETAILED DESCRIPTION OF THE INVENTION

The invention will be described more specifically with reference to two embodiments and with reference to the accompanying drawings.

In FIG. 1 is shown a temporomandibular prosthesis 10 comprising a mandible element 11 which has a flat, shaped, rigid reinforcing element 12 of titanium metal of curved configuration to conform to that of the mandible portion to be replaced. The element 12 is disposed between two layers 13 and 13' of woven Dacron fabric, which has been impregnated on both sides with silicone rubber 14. Apertures 15 may be provided at the ends of element 12 to receive sutures and assist in affixing the element 12 and the layers 13, 13' to each other. Sutures 16 are applied, suitably in cross-

stitching as shown in FIG. 3, and through the apertures 15, to pass around the element 12 and through the layers 13, 13'. Dacron sutures are suitable. Alternatively, the metal element 12 may have its surface suitably primed and secured to the layers 13, 13' by an adhesive.

The condyle-like element 17 comprises a rigid stem 18 and rounded head or knob 19. The stem 18 is preferably made of Dacron woven fabric impregnated with silicone rubber, then rolled up in jelly-roll fashion and coated with a smooth surface of elastomer. The head 19 is vulcanized to the stem 18, and the base 20 is affixed to the mandible member 11 by splaying the base 20, placing the splayed ends over the end of the rigid or metal element 12, and vulcanizing the base 20 to the upper layer 13', prior to placement of the open-pore coating 14, which bears an adhesive layer 30, as shown in FIG. 6. A suitable aperture 21 and split 22 are provided in the fabric layer 14 to enable fitting this layer over the condyle element and down over the layer 13', after which the layers are vulcanized together. If desired, the condyle 17 can be sutured in place on the element 12 and the layer 13', and the vulcanizing done then in one step.

The condyle element 17 is shown in FIGS. 4, 5, and 5A also, and these figures show the structure of the ligamentous element or pedicle 23 in more detail. The pedicle 23 is made up of a flexible stem 24 and a head 26. The stem 24 may suitably be of silicone rubber internally reinforced with flexible Dacron fibers or fabric 25. The head 26 may be of flat or disc shape and to it is affixed a disc 27 of open-pore, tissue-ingrowth-receptive fabric, suitably substantially larger than the head or joining layer 26. The layer 26 is preferably of silicone rubber reinforced with Dacron. The fabric 27 is preferably Dacron and preferably has a pile such as Dacron velour, and it is coated on the back with medical rubber cement and vulcanized to the support 26, which is vulcanized to the stem 24; the latter, in turn, is vulcanized to the rigid stem 18. Perforations 28 are made in the disc 27 and the support 26 to promote gross tissue ingrowth.

In use, the condyle head 19 fits into a receptive skeletal bone cavity, e.g., in the temporal bone, and the disc 27 is placed against an adjacent face of the bone, underneath the periosteum, where it attaches by tissue ingrowth and provides ligamentous support for the condyle-like element 17 preventing its shifting or dislocation.

At the bone-facing surface 31 of the mandible prosthesis or element 11 are provided in the embodiments shown in the present drawings, a pair of flaps 32, 32', each of which is made up of two layers 35, 35' of the open-pore fabric described above, suitably Dacron velour, joined together by a layer of medical rubber adhesive 34. The flaps 32, 32' are affixed to one face of the mandible element 11, especially by vulcanizing through a layer of medical rubber adhesive over only a pair of their length, sufficient to effect firm bonding. The flaps 32, 32' then turn back upon themselves.

As shown in FIGS. 9 through 12, each flap abuts the concerned bone face, beneath the periosteum 36, which is held away during surgery; the device is temporarily bonded in place by suturing at 33, and tissue ingrowth occurs in very few weeks at the interface of

bone and velour and replaced periosteum to effect firm bonding.

Where only the mandibular prosthesis 11 is required, the condyle-pedicle combination can be removed from the prosthesis if so furnished, or it can be omitted in the manufacture thereof and the device applied in a lower jaw as shown in FIGS. 9 and 10. Where the condyle element and pedicle are employed, such application is shown in FIGS. 11 and 12, and the rear flap is cut away as unnecessary.

FIGS. 13, 14, and 15 show another modification. A relatively rigid reinforcing member 40 is embedded in an elastomeric covering 41, which, in this instance is adhered to a bottom oversize layer 42 of fabric, preferably Dacron velour. A condyle-like element 43 has a pedicle 44 with a head 45 covered with Dacron velour 46 and a stem 47. The condyle-like element 43 has a knob 48. If desired, the elastomeric member 41 may have a series of serrate-like extensions 49.

The above specific description and the drawings have been given for purposes of illustration only and modifications and variations can be made therein without departing from the spirit and scope of the appended claims.

Having now described the invention, what is claimed is:

1. A prosthetic device for replacement or repair of a damaged or missing bone structure and adapted to emplacement by sub-periosteal, periosteal or bone surface attachment, including in combination:

a shaped, relatively rigid reinforcing element, which when bent retains its shape, extending continuously from one end to the other,

an elastomer-impregnated fabric fully covering and fully enclosing said element, and contoured thereto, and

an open-pore, tissue-ingrowth-receptive fabric coating disposed over at least a portion of a surface of said impregnated fabric and being adapted to abut upon a bone surface when emplaced,

said reinforcing element and elastomer-impregnated fabric being firmly affixed to each other, and being compatible with body fluids, and at least a portion of said open-pore fabric being affixed to said elastomer-impregnated fabric.

2. The prosthetic device of claim 1 wherein said reinforcing element is substantially flat.

3. The prosthetic device of claim 1 wherein said reinforcing element is metal.

4. The prosthetic device of claim 1 wherein said reinforcing element is covered on each side with a layer of woven fiber compatible with body fluids and impregnated with silicone rubber.

5. The prosthetic device of claim 1 wherein an amount of openpore fabric is in part unattached to said impregnated fabric to form at least one flap, said flap being adapted to fold over and attach to a cut bone end and interior bone face when emplaced.

6. A prosthetic device for repair of a resected mandible and adapted to emplacement by periosteal attachment, comprising in combination:

a flat, rigid, mandible shaped metal reinforcing element,

a layer of woven fabric embedded in elastomer and disposed at each flat surface of said reinforcing

element, covering and enclosing said reinforcing element, one said surface being adapted to face a mandible bone when emplaced,
 a coating of tissue-ingrowth-receptive cloth disposed over at least a portion of said one flat surface and adapted to abut said bone and to receive tissue ingrowth therefrom,
 securing means for fastening together said cloth and said elastomer, and
 means for binding said metal element to said elastomer, said elastomer being cured.

7. The prosthetic device of claim 6 wherein said securing means is a layer of elastomeric adhesive disposed between said silicone rubber and said cloth and polymerized to said silicone rubber.

8. The prosthetic device of claim 6 wherein said means for binding comprises sutures passing around said metal element and through said woven fabric layers.

9. A prosthetic device for repair of a damaged bone structure and adapted to emplacement by periosteal attachment, comprising in combination:

- a. a substantially flat, shaped, rigid reinforcing element,
- b. a elastomer-impregnated fibrous coating contoured to and enclosing said element,
- c. an open-pore, tissue-ingrowth-receptive fabric coating disposed over at least a portion of a surface of said fibrous coating and being adapted to abut upon and attach to a bone surface when emplaced,
- d. said reinforcing element, fibrous coating and fabric coating being firmly affixed to each other and being compatible with body fluids,
- e. a condyle-like element extending from one end of said reinforcing element and having a rigid stem and a rounded terminal head,
- f. a flexible pedicle projecting from said stem and having a flat terminal head, said head having an outer face adapted to fit against a bone surface when emplaced, and
- g. a tissue-ingrowth-receptive fabric disposed over said outer face,
- h. all of said components being firmly affixed to each other, and being compatible with body fluids.

10. The prosthetic device of claim 9 wherein said condyle-like element is of non-porous, smooth silicone rubber, stiffened and reinforced internally with woven Dacron fiber.

11. The prosthetic device of claim 9 wherein said pedicle is of non-porous, smooth silicone rubber reinforced internally with flexible Dacron fibers.

12. The prosthetic device of claim 9 wherein said tissue-ingrowth-receptive fabric is Dacron velour.

13. The prosthetic device of claim 9 wherein sutures are disposed around said reinforcing element and through said elastomer-impregnated fibrous coating to bind the same together.

14. The prosthetic device of claim 9 wherein said flat terminal head is disc shaped and said fabric extends substantially beyond the edges thereof.

15. In a bone prosthesis of physiologically compatible material suitable for implantation in a living body, a skeletal prosthetic element,

a generally flat imperforate disc adapted to serve as an ingrowth anchor for said prosthesis on a periosteal surface adjacent the intended position of said prosthesis, and

a single slender flexible pedicle joining said disc to said skeletal prosthetic element for continuously guiding it into a predetermined position by a hinge-like motion.

16. In a bone prosthesis

a skeletal prosthetic element having a condyle-like element comprising part of said skeletal prosthetic element,

a generally flat disc adapted to serve as an anchor for said prosthesis on a periosteal surface adjacent the intended position of said prosthesis, and

a slender flexible pedicle joining said disc to said skeletal prosthetic element for continuously guiding it into a predetermined position by a hinge-like motion.

17. The prosthesis of claim 16 wherein said pedicle is joined to said condyle-like element.

18. A bone prosthesis, comprising

a main member having a generally flattened shape, a condyle-like member connected to said main member by a thick stem portion and having a head, and

a pedicle having a thin stem connected to said thick stem portion and a head.

19. The bone prosthesis of claim 18 wherein said main member, said condyle-like member, and said pedicle comprise a physiologically compatible elastomer, said main member containing a relatively rigid reinforcing member.

20. The bone prosthesis of claim 19 wherein said main member, said stem portion, and said pedicle are covered with a physiologically compatible open-pore pile fabric.

21. The bone prosthesis of claim 20 wherein said main member is oversize relative to intended installations enabling trimming at time of surgery for each individual installation.

22. A prosthetic device for replacement or repair of a damaged or missing bone structure and adapted to emplacement by sub-periosteal, periosteal or bone surface attachment, including in combination:

a shaped, relatively rigid reinforcing element, which when bent retains its shape, extending continuously from one end to the other, an elastomeric covering fully enclosing said element, and contoured generally thereto, and

an open-pore, tissue-ingrowth-receptive fabric coating disposed over at least a portion of a surface of said elastomeric covering and being adapted to abut upon a supporting tissue surface when emplaced,

said reinforcing element and elastomeric covering being firmly affixed to each other, and being compatible with body fluids, and at least a portion of said open-pore fabric being affixed to said elastomeric coating.

23. The prosthetic device of claim 22 wherein said reinforcing element is substantially flat and sufficiently flexible for shape conformation at the time of emplacement.

24. The prosthetic device of claim 22 wherein said elastomeric element is reinforced by contained physiologically compatible fibers.

25. The prosthetic device of claim 22 wherein said elastomeric covering and the fabric coating thereon are 5
oversize relative to intended installations enabling trimming at time of surgery for each individual installation.

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