

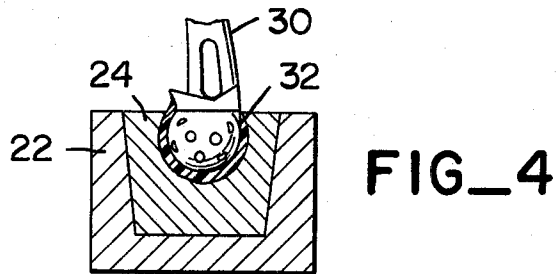
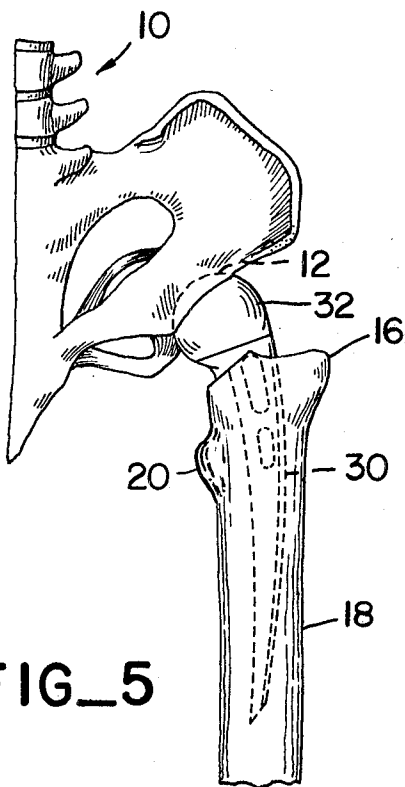
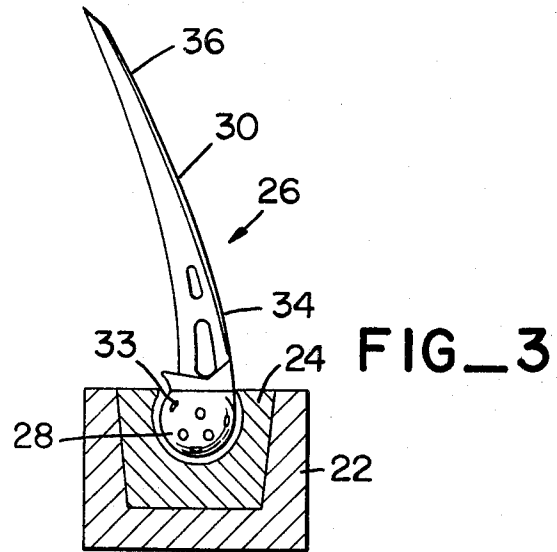
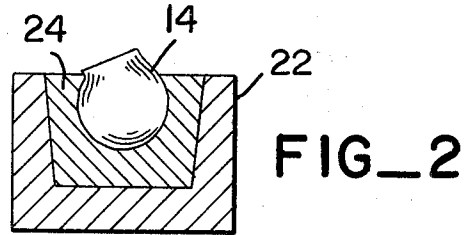
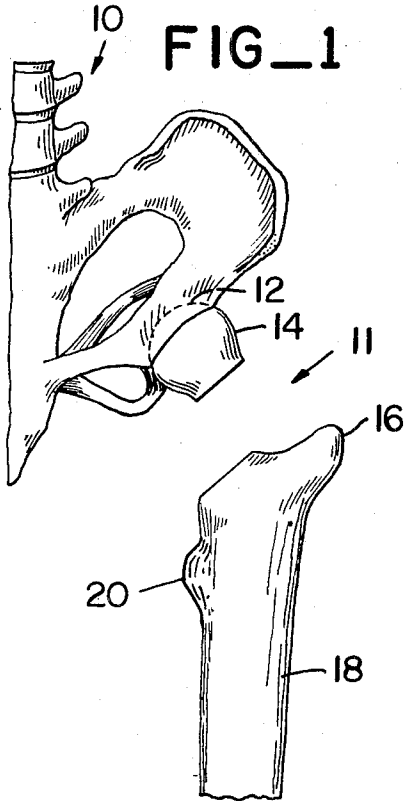
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HIP PROSTHESIS

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HIP PROSTHESIS

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ABSTRACT OF THE DISCLOSURE

A prosthetic device, for replacing an irregularly-shaped skeletal component, having an outer configuration substantially corresponding to the outer configuration of the skeletal component. The device is formed by first surgically removing the skeletal component from the patient, forming a mold of the component, and thereafter modifying the outer configuration of a stock prosthesis to provide a composite prosthesis exhibiting the desired configuration. The composite device is then inserted, as a replacement for the skeletal component, in the patient.

This invention relates to improvements in the art of forming prostheses and, more particularly, to providing a hip prosthesis having an irregularly-shaped hemispherical ball corresponding in outer irregular configuration to a naturally-occurring femoral head that is being replaced.

The replacement of human skeletal components has become most markedly accepted during the past two decades, especially in fresh fractures in elderly patients. Prostheses have proved to be an especially comfortable and prompt method for mobilizing such elderly patients. This upsurge in orthopedic surgery has been the by-product of the constant search for new and better methods of repairing the ravages of disease, injury and aging in the intracapsular areas of the human body, and has been made possible by the availability of new metallic alloys, as well as other materials that have been found to be relatively inert when disposed in live body tissue.

An orthopedic operation which typifies conventional prosthetic procedures is femoral head replacement arthroplasty, frequently used to relieve unbearable pain caused, for example, by an arthritic condition in the hip. In this operation, the top of the femur (upper leg or thigh bone), comprising the ball of the ball-and-socket construction of the hip joint, is trimmed or cut off entirely and a spherical prosthesis device is then attached either by inserting a shaft or stem of the device into the end of the remaining portion of the femur itself (intramedullary) or across the upper end of the femur. The spherically-shaped body of the device replaces the missing head of the femur and restores the desired movement while rendering the hip relatively painless and usable again. This type of prosthesis is especially valuable when the femoral head has been subjected to either avascular necrosis or irreparable fracture such as where the opposing ends of the fractured bone become relatively smooth, hardened, and well defined, but not joined (non-union).

Because the femoral head is not spherical in its natural form, conventional replacement arthroplasty may result in considerable discomfort and pain to the patient as the spherical prosthesis rotates within the articular cartilage of the acetabulum. As a result, within a relatively brief period of time, such as on the order of one to three years, an initially satisfactory hip prosthesis can wear away the cartilage of the acetabulum thereby exposing the underlying sensitive bone and causing considerable pain to the patient during continued ambulation as well as during other movement. Furthermore, the wear-

ing away of the cartilage and the resulting debris thus produced causes thickening, inflammation and pain in the synovial lining and capsule of the joint, even though the cartilage which covers the articulating ends of the bond is tough, elastic and porous.

Additionally the most importantly, the articulate cartilage, a sponge-like living tissue, must derive its nutrition from either the synovial fluid of the joint or from the diffusion of nutrients from the underlying bone. Furthermore, in order that adequate circulation of nutrients can occur throughout the cartilage, the cartilage must be subjected to intermittent unequal amounts of pressure, to provide a "pumping type" motion. It appears that intermittent pressure is naturally provided by the weight of the body being put on the hip joint by an activity such as walking. Because the head of the femur is of the irregular rather than of a smooth hemispherical shape, such ambulation apparently produces unequal pressure along the surface of the cartilage in the acetabulum and thereby creates the desired circulation of nutrients. Thus, when the head of the femur is replaced by a conventional osteal device having a regular hemispherical shape, the result is a slow degradation and necrosis of the cartilage in the acetabulum.

A further practical problem that exists for the orthopedic surgeon results from the fact that natural femoral heads vary greatly in size, depending, of course, upon the physical dimensions of the particular patient. As a result, the surgeon must necessarily maintain a large inventory of prosthetic devices to insure that a close approximation to all sizes will be readily available.

Thus, it is a principal object of this invention to provide a prosthesis that has an irregular outer configuration substantially corresponding to that of the natural skeletal member being replaced.

It is a further object of this invention to provide a femoral head replacement that corresponds in outer configuration to the actual femoral head being replaced.

It is another object of this invention to provide a process for forming such a correspondingly-shaped prosthesis during the brief period of time when the patient is on the operating table.

Broadly, the present invention is directed to the formation of a prosthesis that corresponds in outer configuration to the irregular outer configuration of the skeletal component being replaced. This is accomplished by first removing the skeletal component from the patient. A rigid mold is then prepared that contains a void that is substantially identical with the outer configuration of the skeletal member. A preformed prosthetic device, having outer dimensions smaller than the skeletal component, is inserted in the mold and sufficient rapidly-setting plastic is introduced around the prosthetic device to fill the space therebetween. When the plastic has hardened, the mold is removed and the modified prosthetic device inserted into the patient by well-known orthopedic procedures.

In a preferred aspect, a thermosetting type of resinous material is employed so that curing, e.g., cross-linking, can be accomplished simultaneously with the sterilization of the device, to enable the fabrication to be completed in a brief period of time. However, thermoplastic resins are also useful in this invention.

While the invention, as described hereinafter, is directed to a femoral head prosthesis, it will be apparent to one skilled in this art that the teachings of the invention are applicable to any human ball-and-socket joint as well as in the practice of veterinary medicine.

The aforementioned objects will be better understood and other objects, as well as features and advantages of this invention, will become apparent when reference is

made to the following description, particularly in view of the attached drawing wherein:

FIG. 1 represents an elevational view of the ilium and the upper portion of the femur with the femoral head severed therefrom;

FIG. 2 is a cross-sectional view depicting the formation of a mold corresponding to the outer configuration of the femoral head;

FIG. 3 illustrates the positioning of an osteal device within the finished mold;

FIG. 4 is a cross-sectional view of a hip prosthesis including a coating of an appropriate plastic; and

FIG. 5 illustrates the arthroplasty inserted as a replacement for the natural femoral head.

Referring now to the drawing wherein similar characters of reference represent corresponding parts in each of the several views, there is shown innominate bone 10 and femur 11. Innominate bone 10 includes acetabulum 12 while femur 11 includes femoral head 14, greater trochanter 16, femoral shaft 18 and lesser trochanter 20. Femur 11 has been surgically severed to separate femoral head 14 from the remainder of femur 11. This type of surgical removal is well-known to those skilled in orthopedic operations.

Once femoral head 14 has been severed and removed from the patient, it is disposed in container 22. Container 22 is of sufficient size to receive a quick-setting investment for forming mold 24 around femoral head 14. The investment may be of a material such as plaster of Paris, or other suitable heat-settable substance that is readily available for the purpose of providing such investment patterns. Femoral head 14 can also be initially covered with a thin coating of wax or some other material that when dried will exhibit nonadhesive characteristics with respect to the investment that forms mold 24. In this manner, adherence of femoral head 14 to the solidified investment, because of natural bone porosity, will be prevented. When the investment has solidified forming female mold 24 around femoral head 14, mold 24 is removed from container 22 and divided to allow for removal of femoral head 14.

Mold 24 is then reassembled and a standard prosthetic device 26 having a hemispherically-shaped head portion 28 is disposed within the mold. Preferably prosthetic device 26 also includes stem 30 rigidly secured to head portion 28. Prosthetic device 26 may be formed of any suitable material that is clinically inert, exhibits minimal foreign body reaction when disposed within living tissue and is nonelectrolytic. Those forms of intramedullary hip prostheses that are commercially available are especially advantageous for use in this invention. Head portion 28 of prosthetic device 26 is preferably selected to have a slightly smaller outer configuration than the internal void provided by the investment 24.

By supporting prosthetic device 26 spaced from the surface of reassembled mold 24, a continuous gap is provided between device 26 and mold 24 to facilitate receipt of a free flowing thermosetting or thermoplastic liquid resin. By causing the resin to solidify into a rigid layer 32, the outer surface of device 26 will be substantially identical to the natural outer surface of femoral head 14. In a preferred aspect and as shown in FIGS. 3 and 4, prosthetic head 28 can be provided with a series of spaced-apart apertures or notches 33 so that physical contact between head 28 and rigid layer 32 can be enhanced.

By way of further example, it is noted that prosthetic devices are commercially available wherein head portion 28 is of standard diameter sizes such as 43, 45, 47 and 49 millimeters. Stem 30 can include rectilinear proximal and distal ends 34 and 36 that are separated by a relatively long curvilinear portion. The ends 34 and 36 are normally angled at approximately 140° with respect to each other to provide the proper angular relationship between replacement head portion 28 and femoral shaft 18.

An intramedullary stem of this type is well accepted in the orthopedic art.

Layer 32 can be formed of any substance that solidifies at room temperature or by application of heat. Layer 32 should have permanent rigidity and strength, as well as clinical inertness, minimal foreign body reaction within the living tissue and nonelectrolytic characteristics. It is preferable that the solidification be the result of a temperature dependent catalytic crosslinking reaction so that curing and sterilization can be accomplished simultaneously. Examples of such materials include polymerizable solutions (sirups) of acrylic polymers and monomers such as are available from Rohm and Haas Company under the trademark Acryloid.

Conventional operative procedures employed for articular replacement of a femoral head with a prosthetic device include the steps of exposure, excision, seating and enclosure. The surgical procedure necessary for replacement of the prosthetic device of this invention will correspond to such well-known operative procedures. Through appropriate selection of investment and resin, the time required to modify prosthetic device 26 in accordance with this invention can be as brief as 30 minutes or even less. In this manner, modification can be easily accomplished while the patient remains on the operating table.

While one embodiment of this invention has been shown and described, it will be apparent that other adaptations and modifications of this device can be made without departing from the true scope and spirit of this invention—such as:

(1) Producing the head portion and stem portion or the prosthesis separately—so that adjustments can be made for the length of the “neck” of the prosthesis (re. the portion between the head and the stem) to correspond in length to that of the femoral neck.

(2) The application of a thin outer coating or overlay to further protect the resin layer.

What is claimed is:

1. In the surgical replacement of at least a portion of a skeletal member with a prosthetic device, the improvement comprising providing a prosthetic device having an outer configuration corresponding to the configuration of said at least portion, by the steps of: preparing a mold having a cavity corresponding to the outer configuration of said skeletal member; providing a prosthetic device adapted to be inserted into the cavity of said mold; disposing said prosthetic device in spaced relation within the cavity of said mold; and introducing sufficient liquified resin to fill the mold space around said prosthetic device and causing said resin to solidify and adhere to said prosthetic device, thereby providing a modified prosthetic device having the outer configuration of said skeletal member.

2. A surgical replacement in accordance with claim 1 wherein said mold is a female mold that is prepared by disposing an investment around said skeletal member.

3. A surgical replacement in accordance with claim 1 wherein said portion is a femoral head and said prosthetic device is the ball of an intramedullary hip prosthesis.

4. A surgical replacement in accordance with claim 1 wherein said resin is selected from the group consisting of thermosetting and thermoplastic resins.

5. A prosthetic device for replacement of a skeletal member and corresponding in outer configuration to a surface portion of the skeletal member, comprising: a base member having a surface portion of lesser dimensions than the surface portion of said skeletal member; and a separate rigid layer secured to at least a portion of said base member, said rigid layer having an outer surface corresponding in size and shape to the surface portion of said skeletal member.

6. A prosthetic device in accordance with claim 5 wherein said base member and said rigid layer are formed of dissimilar materials.

7. A prosthetic device in accordance with claim 5

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wherein said rigid layer is a plastic selected from the group consisting of thermosetting and thermoplastic resins.

8. A prosthetic device in accordance with claim 5 wherein said base member includes means for mounting said prosthetic device on said skeletal member in replacement for said surface portion thereof.

9. A prosthetic device in accordance with claim 5 wherein said skeletal member is a femur and the surface portion thereof is a femoral head whereby said prosthetic device is adapted to be mounted on said femur in replacement for said femoral head.

10. A prosthetic device in accordance with claim 8 wherein said mounting means includes an intramedullary stem.

11. A prosthetic device in accordance with claim 5 wherein said base member includes a plurality of indentations for increasing the area of contact between said base member and said rigid layer.

12. A process for replacing a human femoral head with a hip prosthesis having a semispherically-shaped head portion modified to correspond in outer configuration to the femoral head being replaced, comprising the steps of: surgically removing the femoral head from the patient; preparing a mold having a cavity corresponding to the outer configuration of said femoral head; provid-

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ing a prosthesis for insertion within the cavity in said mold; disposing said prosthesis in spaced relation within the cavity of said mold; introducing sufficient liquified resin to fill the mold space around said prosthesis; modifying the outer configuration of said prosthesis by causing said resin to solidify and adhere to the prosthesis; sterilizing said prosthesis; and surgically inserting said prosthesis in said patient in replacement for said femoral head.

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