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**Porous titanium femoral sleeves and their use in revision knee surgery**

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(56) Related Art  
**D2 : US 5716412 A (DECARLO Jr. et al) 10 February 1998**  
**D1 : WO 1983/002555 A1 (UNITE STATES MEDICAL CORPORATION) 04 August 1983**

**ABSTRACT**

The invention concerns monolithic foam sleeves that includes titanium or titanium alloy foam having a porosity of 50 to 85% and possess a proximal end, a distal end, an interior wall that defines an interior channel and extends from the proximal end to the distal end; and a terraced outer surface that tapers such that said sleeve is widest at the distal end and most narrow at the proximal end.

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**INVENTION TITLE:**

**POROUS TITANIUM FEMORAL SLEEVES AND THEIR USE IN  
REVISION KNEE SURGERY**

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The following statement is a full description of this invention, including the best method of performing it known to us:-

## POROUS TITANIUM FEMORAL SLEEVES AND THEIR USE IN REVISION KNEE SURGERY

### RELATED APPLICATIONS

5           [0001] This application claims priority to U.S. Patent Application No. 61/058,254, filed June 3, 2008, the disclosure of which is incorporated herein in its entirety.

### FIELD OF THE INVENTION

10           [0002] The invention concerns, *inter alia.*, porous titanium femoral sleeves and their use in revision knee surgery.

### BACKGROUND OF THE INVENTION

15           [0003] Typical knee prostheses include a tibial component, a femoral component, and a patellar component. The femoral component generally includes a pair of spaced apart condylar portions, the superior surfaces of which articulate with a portion of the tibial component. A femoral stem assembly, used to provide stability to the replaced knee joint, seats within the medullary canal of a distal portion of a femur, and is typically coupled to the femoral component by specialized coupling devices, such as a collar and bolt. Some prosthetic knee joints include a structure known as a Morse taper post that extends from the inferior surface of the femoral component to mate with a femoral sleeve that is securable to the femoral stem assembly. The femoral component may include a boss having a slot for receiving the components of the modular junction.

20           [0004] Knee replacement surgery requires the replacement of the distal end of the femur and the proximal end of the tibia. Implant loosening, infection, and device wear are well-documented failure modes of primary knee arthroplasty. In cases where the primary implants fail, a secondary operation is required to replace the faulty device. The factors associated with device failure, including infection and osteolysis, often lead to a deterioration of bone quality in proximity to the implanted knee replacement devices. Upon removal of the faulty device, large bone defects are

often encountered on both the tibia and the femur. These defects are often characterized by large cavitory voids along with cortical rim defects. Traditionally, treatment of these defects required the removal of a large amount of stable cortical bone to facilitate the implantation of a metal replacement for the bone defect.

[0005] Revision knee arthroplasty has existed since the first primary knees failed and the problem encountered due to bone loss upon revision is therefore not a new problem. Noiles *et. al.*, US 4,846,839 (“the 839 patent”), disclose a method for affixing a prosthesis to bone that incorporates flanges being placed on the femoral stem conforming to the anatomy of the femoral canal. The geometry of the device transfers stresses to the bone in a manner that generally corresponds to the types of stress transfers that occur in natural bone. The prior art also mentions coating or roughened surfaces that could be applied to stepped tibial sleeves to improve fixation with the bone.

[0006] Blaylock *et al.*, U.S. Published Patent Application No. 200410162619 (“the 619 application”), describe a femoral augment system to replace bone defects as described in US 200410172137. The proposed invention incorporates U-shaped augments made of a highly porous tantalum material. The intent of the device is said be minimization of bone loss while providing a stable basis for a femoral implant. The device, however, does not incorporate the stepped design and therefore does not optimally transfer stress from the implant to the bone. The device also does not contain a means for mechanically fixing the femur to the femoral augment. The femur must be cemented to the femoral augment that provides for a decreased rotational stability compared to a mechanical lock.

[0007] While much research has been invested into devices that can be used when a primary knee implant fails, there are still important improvements that are needed. Areas of needed improvements include improved transfer of stresses to the bone in a manner that generally corresponds to the types of stress transfers that occur in natural bone and improved rotational stability.

## SUMMARY OF THE INVENTION

[0008] In one aspect, the present invention provides a femoral component of a knee joint prosthesis which includes a monolithic foam sleeve, the sleeve comprising titanium or titanium alloy foam possessing: a proximal end, a distal end, an interior wall that defines an interior channel and extends from the proximal end to the distal end, and a terraced outer surface that tapers such that the sleeve is widest at the distal end and most narrow at the proximal end, wherein the titanium or titanium alloy foam has a porosity of 50 to 85%, and the sleeve includes an adapter which can be affixed to the interior channel of the sleeve at the distal end of the sleeve, the adapter having a channel in communication with the interior channel of the sleeve and an exterior geometry generally corresponding to the shape of the interior channel of the sleeve .

[0008a] In another aspect, the present invention provides a method of forming a femur implant comprising jointing a femoral component including a pair of condyle surfaces and a cam box to a femoral sleeve assembly, the femoral sleeve assembly comprising: a monolithic foam femur sleeve, said femur sleeve comprising titanium or titanium alloy foam having a porosity of 50 to 85% and possessing: a proximal end, a distal end, an interior wall that defines an interior channel and extends from the proximal end to the distal end, a terraced outer surface that tapers such that said sleeve is widest at the distal end and most narrow at the proximal end, and a distal notch defined in the distal end, the distal notch extending from anterior to posterior and receiving the cam box of the femoral component, a titanium insert that has a porosity of less than 10% and is positioned within said sleeve such that a portion of the titanium insert is exposed within said outer surface, and a femoral adapter that is affixed to the titanium insert, the femoral adaptor having a channel extending there-through.

## SUMMARY OF OPTIONAL EMBODIMENTS OF THE INVENTION

[0009] In some embodiments, the sleeve is constructed of a material that has a porosity of 60 to 80%. In certain sleeves, the titanium alloy is Ti6Al4V. . In some embodiments, commercially pure titanium (CP titanium) is used to construct the foam sleeve.

[0010] The sleeves can have a substantially circular cut to account for the intercondylar notch present at the distal posterior aspect of the femur.

[0011] The shape and size of the terraced outer surface can generally correspond to the shape the distal end of the femur of a mammal. In some embodiments, the terraced outer surface's most distal layers are substantially rectangular and become increasingly circular proximally.

[0012] In certain embodiments, the terraced outer surface's most distal layers are substantially polygonal in shape and become increasingly circular proximally. In some preferred embodiments, the polygon is simple (i.e., does not cross itself) and may be convex (i.e., any line that is drawn through the polygon (not tangent to an edge or corner) meets the boundary exactly two times).

[0013] In certain embodiments, the sleeve additionally includes a distal notch.

[0014] Certain sleeves have the additional feature of an adapter that is affixed to the interior channel of the sleeve at the distal end of said sleeve, has a channel in communication with the interior channel of the sleeve; and an exterior geometry generally corresponding to the shape of the interior channel of the sleeve. In some embodiments, the channel in the adaptor is offset in the medial/lateral plane or the anterior/posterior plane by a distance between 2 mm and 8 mm relative to the center of the interior channel of the sleeve.

[0015] Another feature that can be present in the sleeves of the instant invention are one or more titanium inserts that have a porosity of less than 10% and is positioned within said sleeve such that a portion of said insert is exposed within said outer surface. Such inserts can provide an area of increased strength that is useful, for example, in accommodating a screw or other attachment hardware.

[0016] [Left Intentionally Blank].

[0017] [Left Intentionally Blank].

BRIEF DESCRIPTION OF THE DRAWINGS

- [0018] Figure 1 presents an example of a femoral sleeve.
- [0019] Figure 2 presents a front view of a femoral sleeve.
- [0020] Figure 3 presents a top view of a femoral sleeve.
- [0021] Figure 4 shows an example of a femoral sleeve with TC3 femur.
- [0022] Figure 5 shows an example of a taper adapter.
- [0023] Figure 6 presents an example of a femoral sleeve with a taper adapter.

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[0024] Figure 7 shows an example of a TC3 femur with sleeve and taper adapter, anterior-medial.

[0025] Figure 8 presents an example of a TC3 femur with sleeve and taper adapter, posterior-medial.

5 [0026] Figure 9 shows an example of a femoral sleeve.

[0027] Figure 10 presents an example of a femoral sleeve with taper adapter and TC3 femur.

[0028] Figure 11 presents an example of a femoral sleeve modified to fill a bone with a medial defect only.

10 [0029] Figures 12 A-C present alternate geometries of femoral sleeves.

[0030] Figure 13 shows an embodiment whose geometry provides a more polygonal shape in the outer surface's most distal layers and becomes increasingly circular proximally.

[0031] Figures 14 A and B present a taper adapter that is smaller in  
15 thickness compared to those shown in Figure 5.

#### DETAILED DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

[0032] In a revision knee surgery, establishing a stable femoral base is critical to long-term implant survivorship. The present invention provides femoral  
20 implant devices that can be used to fill cavitary femoral defects and establish a stable femoral plateau without sacrificing healthy bone. The devices are made of a highly porous titanium structure that facilitates bone ingrowth. In addition, the devices provide a stable basis for replacement femoral components to be fixed to definitively through mechanical interlock or cementation.

25 [0033] The present invention includes a family of femoral sleeves based upon the design of the S-ROM femoral sleeves. The basic sleeve geometry is described by Noiles *et. al.* in US 4,846,839. Unlike the prior art sleeves, the sleeves of the instant invention are made of a highly porous titanium material that has a high coefficient of friction on the exterior bone-contacting surface to encourage bone  
30 ingrowth. The internal surface of the sleeve is smooth and provides a substrate for cementation of a femur or permanent fixation of a femoral taper adapter. The femoral taper adapter can be permanently fixed to the porous titanium sleeve through

a sintering process. The adapter has an exterior geometry designed to match the interior geometry of the sleeve and an interior geometry to mate with the femoral taper adapter. The adapter provides a means for mechanically fixing the femoral sleeve to the femur.

5           **[0034]** The base component of the system is the porous titanium sleeve with the stress transferring steps as shown in **Figure 1**. A front view and top view of the sleeve are shown in **Figures 2** and **3** respectively. Unlike prior devices, the sleeves of the present invention are made of a highly porous titanium material that has a high coefficient of friction on the exterior bone-contacting surface to encourage bone  
10 ingrowth. By using a material that is highly porous throughout, bone growth is encouraged in a manner substantially greater to any coating or roughened surface finish mentioned in the prior art.

**[0035]** **Figure 4** shows a sleeve in combination with Total Condylar 3 (TC3 femur). When the term "TC3 femur" is used herein, it refers to DuPuy's brandname  
15 for articles generically referred to as "stabilized femur", "revision stabilized femur", or "varus valgus constrained femur".

**[0036]** The internal surface of the instant sleeves, in contrast to the outer surfaces, is relatively smooth and provides a substrate for cementation of femoral components. In some embodiments, the interior wall has a low coefficient of friction  
20 of 0.3 – 0.7. In contrast, in some embodiments, the outer surfaces of the device can have a coefficient of friction of 0.7 – 1.5.

**[0037]** Occasionally after removal of the defective femoral component, the cavitory or peripheral rim defects are only present on either the medial or lateral side of the femur. To avoid excessive bone loss the femoral sleeve can be offset medially  
25 or laterally. Such devices are essentially a "half sleeve" with the sleeve being eccentric in only a single side of the device.

**[0038]** The device can be formed of layers in which the geometry of each layer is formed to conform to the anatomy of the distal femur. In some embodiments, the most distal layers are substantially rectangular and become increasingly circular  
30 proximally. A distal notch can be removed from the sleeve to account for a posterior stabilized cam box. A substantially circular cut from the device to account for the inter-condylar notch present at the distal posterior aspect of the femur can be utilized.

[0039] Other aspects of the invention concern methods of forming femur implants including joining the femoral sleeve to the femoral component. In some embodiments, the joining involves attaching the femoral sleeve to the femoral component through a morse taper between the femoral component boss and the taper adapter internal channel. Some examples of fastening systems are described in United States Patent No. 5,824,097, the disclosure of which is incorporated herein by example.

[0040] In some embodiments, the geometry of the femoral sleeve is such to be contained within the PFC Sigma TC3 femur as shown in **Figure 5**.

[0041] The femoral sleeve includes a family of sleeves adapted to fit into the various sizes of TC3 femurs. The interior geometry of the sleeve is hollow to allow cementation of a femoral component and a stem extension. The femoral sleeve is placed into the distal femur and provides a platform for attaching a femoral component with distal augments. The femoral sleeve is configured in a manner to allow a 10 mm or 15 mm distal augment to be used with the femoral component. The sleeve geometry is optimized for use with a TC3 femur but would also function with other femur geometries.

[0042] Another embodiment of the femoral sleeve incorporates a taper adapter that is press-fit and sintered to the titanium foam sleeve. This embodiment allows superior cementless fixation to the distal femur while providing a rigid mechanical lock between the sleeve and the femur. Current DePuy femoral sleeves are attached to the TC3 femur through the use of the femoral adapter. The attachment method for the porous titanium sleeves would be identical to that of the current DePuy revision sleeves. **Figure 5** shows the taper adapter and **Figure 6** shows the assembly of the taper adapter and the porous titanium sleeve.

[0043] The sleeve/taper assembly can be mechanically fixed to the TC3 femur through the use of the femoral adapter as shown in **Figures 7 and 8**.

[0044] Other aspects of the design are illustrated by **Figure 9** which shows one example of a tapered femoral sleeve. **Figure 10** presents an example of such a femoral sleeve with taper adapter and TC3 femur. **Figure 11** presents an example of a femoral sleeve modified to fill a bone with a medial defect only.

[0045] Figures 12 A-C and 13 show an embodiment where the terraced outer surface's most distal layers are substantially polygonal and become increasingly circular proximally. One skilled in the art can recognize other polygonal variations.

5 [0046] Figures 14 A and B show taper adapters that have smaller thickness than the design presented in Figure 5. This design can be varied as needed for a particular sleeve or implant need.

[0047] The sleeves of the instant invention use highly porous Ti or Ti alloy constructs that have a rough outer surface. The rough surface has an open cell  
10 structure for making cancellous bone implants and cell and tissue receptors. This structure has been found to be superior to other porous metallic implant materials whose "porosity" is artificially produced via some form of surface treatment that does not result in a truly complete, open porosity. However, without any further treatment such implant surfaces typically are not sufficiently rough and such a  
15 surface roughness is an important structural property for initial stability of cementless fixation devices.

[0048] The outer surface of the sleeve can be roughened by conventional salt or sand blasting. Such methods are commonly used to induce a macro surface roughness. In such blasting, the surface may be exposed to a high velocity stream of  
20 salt or sand that physically gouges away parts of the surface. Depending on the conditions used, at least the outer 10 or 20 microns are impacted by the process. In the case of salt blasting, residual salt can be removed by an aqueous rinse. Conventional machining or glass bead blasting are typically not the method of choice due to its high porous nature with the open cell structure of the implants. Glass  
25 fragments can become intraped and present issues after implant. Traditional machining can reduce the porosity of the surface.

[0049] In some embodiments, the inner channel is not subjected to salt or sand blasting and is not as rough as the outer surface. In certain embodiments, the inner surface is smoothed by inserting a metal insert with a relatively smooth surface  
30 into the interior channel. The interior channel can also be mechanically smoothed by a grinding, burnishing, blasting, or spraying process to create a surface capable of mating with the boss of the femoral component. Because porosity is more important

to the outer surface (for bone ingrowth) than the inner channel, any loss of porosity by this process is not as important as a loss at the outer surface.

[0050] The Ti or Ti alloy foams can be made, for example, by conventional techniques that mix Ti or Ti alloy powder with a pore-foaming agent (PFA). The powder mixture can be compacted under high pressure to form green bodies. The PFA can be removed from the green body which can then be sintered to form to article.

[0051] The Ti or Ti alloy powder also can be present in a wide variety of particle sizes and particle size distributions. Certain preferred particle size ranges are from about 20 $\mu$ m to about 100 $\mu$ m, from about 25 $\mu$ m to about 50 $\mu$ m, and from about 50 $\mu$ m to about 80 $\mu$ m.

[0052] The term "CP titanium" refers to commercially pure titanium which is well known to those skilled in the art. CP titanium is an unalloyed titanium. Typically, CP titanium contains over 98% pure titanium.

[0053] The term "pore forming agent" refers to a material that can be mixed with a metal powder and removed after the mixture is compacted. Such materials are also known in the art as "pore forming" materials. In some embodiments, the pore forming agents are be removed by a liquid. Suitable liquids include aqueous solutions and water. Pore forming agents include water soluble salts such as sodium chloride, potassium chloride, lithium chloride, potassium sorbate, sucrose, or mixtures thereof. After the extractible particulates are removed, the extraction agent or solvent can be removed via evaporation optionally using heat and/or vacuum.

[0054] The pore forming agent (PFA) can be present in a wide variety of particle sizes and particle size distributions suitable to produce a desired pore size and pore size distribution. Certain preferred particle size ranges are from about 200 $\mu$ m to about 600 $\mu$ m, from about 200 $\mu$ m to about 350 $\mu$ m, and from about 350 $\mu$ m to about 550 $\mu$ m. Those skilled in the art will recognize that the proportions of metal powder and PFA will vary depending upon the type of structure sought to be produced. In certain embodiments of the present invention, the ratio of metal powder to PFA is about 40:60 to about 10:90.

[0055] After treatment to remove the PFA, the green body typically consists of a metal skeleton, which can be subsequently bonded together through high-temperature sintering process to produce Ti or Ti alloy foams with highly porous structures.

5 [0056] Metal powder and PFA are weighed and their respective densities are used to find the volume of each. These values are used to calculate the volume porosity of the mixture, which is generally given with respect to the PFA. Porosity can be determined by measuring the weight of a sintered sample and calculating its volume using the following formula:

10 
$$\% \text{ Porosity} = \text{weight}/(\text{density of solid metal} * \text{volume}) * 100.$$

Porosity can also be determined by analyzing cross-section images. Images are taken of mounted, polished cross-sections of the metal foam material. The metal reflects the light and appears white, while the pores appear black.

[0057] The mixtures of metallic powder and pore forming agents can be  
15 compacted by uniaxial compacting, multi-axial compacting, or isostatic compacting. The method of compacting each layer of the multilayer article can be selected independently. In some embodiments, the preferred method of compacting is cold isostatic press (CIP).

[0058] Sintering techniques are well known to the skilled artisan. In some  
20 embodiments, the sintering can be conducted in a temperature range that is about 1000 to 1400 °C.

[0059] The implant can be cleaned prior to any process step or  
implantation. The cleaning can be performed, for example, with detergent, deionized (DI) water, and ultrasonic bath in 100% alcohol. Such treatment can be useful in  
25 removing grease and dust. Sometimes, it may be desirable to dry the implant in an oven after such cleaning.

[0060] Another method of cleaning the article is water jet cleaning (at a  
pressure of 3000 psi, for example) which can remove any weak connections on the surface pores that might otherwise fall off as debris when the implant surface is  
30 subjected to friction such as rubbing.

[0061] The cleaned implant can be subjected to heat treatment. In some embodiments, the treatment is at a temperature of at least 800 °C. This step typically removes volatile impurities such as titanate residue.

5 [0062] The femoral sleeves of the instant invention offer combination of advantages not found in the art. These advantages include (1) stress transferring steps of porous titanium to optimize stress transfer and bone ingrowth, (2) a geometry optimized to minimize bone loss, (3) a variation of porous titanium surface roughness optimized for contact with bone, titanium or bone cement, and (4) highly porous sleeve optimized to fill either a medial or lateral defect without sacrificing  
10 good bone.

[0063] The invention is illustrated by the following examples that are intended to be illustrative but not limiting.

#### Example 1

15 [0064] A rubber mold is created with a void approximately the shape of the femoral sleeve. A titanium powder/salt powder mixture is placed into the mold. A metal mandrel is placed into the mold and powder mixture creating the interior channel of the sleeve. The mold and mandrel assembly is then placed into the isostatic press and compacted into solid form. The solid form is machined to form  
20 the final exterior terrace profile. The solid form is immersed in reverse osmosis water to remove the major portion of salt. The taper adapter is press-fit into sleeve. The entire assembly is sintered and entire part shrinks by approximately 13%.

#### Example 2

25 [0065] Example 1 is performed using commercial pure titanium powder (Phelly Materials, Inc. Bergenfield, NJ, USA) particle size: 45 - 75 μm and NaCl (Fisher Scientific International Inc. Hampton, NH, USA) particle size: 250 - 425 μm. The titanium and salt are mixed in a ratio of approximately 25:75 Ti:PFA by volume. The mixture is added to a mold and compressed into a green body at a compaction  
30 pressure of 22 ksi. The green body is placed in a water bath until the NaCl dissolved. The resulting metal skeleton is dried at 65 °C for 4 hours, and then sintered at 1204 °C for 2hrs. A highly porous femoral sleeve results.

**Example 3**

[0066] The femoral sleeve from Example 2 is joined to a femoral component by attaching the femoral sleeve to the femoral component through a morse taper between the femoral component boss and the taper adapter internal channel.

[0067] Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", and variations such as "includes" and "including", will be understood to imply the inclusion of a stated integer or step or group of integers or steps but not the exclusion of any other integer or step or group of integers or steps.

[0068] The reference to any prior art in this specification is not, and should not be taken as, an acknowledgment or any form of suggestion that the prior art forms part of the common general knowledge.

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CLAIMS

1. A femoral component of a knee joint prosthesis which includes a monolithic foam sleeve, the sleeve comprising titanium or titanium alloy foam possessing:
  - a proximal end,
  - a distal end,
  - an interior wall that defines an interior channel and extends from the proximal end to the distal end, and
  - a terraced outer surface that tapers such that the sleeve is widest at the distal end and most narrow at the proximal end,wherein the titanium or titanium alloy foam has a porosity of 50 to 85%, and the sleeve includes an adapter which can be affixed to the interior channel of the sleeve at the distal end of the sleeve, the adapter having a channel in communication with the interior channel of the sleeve and an exterior geometry generally corresponding to the shape of the interior channel of the sleeve .
2. The component of claim 1, in which the sleeve has a porosity of 60 to 80%.
3. The component of claim 1 or 2, having a substantially circular cut from the sleeve to account for the inter-condylar notch present at the distal posterior aspect of the femur of a mammal.
4. The component of any one of claims 1 to 3, in which the shape of the terraced outer surface generally corresponds to the shape of the distal end of the femur of a mammal.
5. The component of any one of claims 1 to 4, in which the terraced outer surfaces most distal layers are substantially polygonal, preferably substantially rectangular, and become increasingly circular proximally.
6. The component of any one of claims 1 to 5, additionally comprising a distal notch.

7. The component of any one of claims 1 to 6, in which the titanium or titanium alloy is Ti6A14V or CP titanium.
8. The component of any one of claims 1 to 7, in which the channel in the adaptor is offset in the medial/lateral plane or the anterior/posterior plane by a distance between 2 mm and 8 mm relative to the centre of the interior channel of the sleeve.
9. The component of any one of claims 1 to 8, in which the adaptor has an interior channel to be mated with the boss of a femoral implant.
10. A method of forming a femur implant comprising jointing a femoral component including a pair of condyle surfaces and a cam box to a femoral sleeve assembly, the femoral sleeve assembly comprising:
  - a monolithic foam femur sleeve, said femur sleeve comprising titanium or titanium alloy foam having a porosity of 50 to 85% and possessing: a proximal end, a distal end, an interior wall that defines an interior channel and extends from the proximal end to the distal end, a terraced outer surface that tapers such that said sleeve is widest at the distal end and most narrow at the proximal end, and a distal notch defined in the distal end, the distal notch extending from anterior to posterior and receiving the cam box of the femoral component,
  - a titanium insert that has a porosity of less than 10% and is positioned within said sleeve such that a portion of the titanium insert is exposed within said outer surface, and
  - a femoral adapter that is affixed to the titanium insert, the femoral adaptor having a channel extending there-through.
11. The method of claim 10, wherein said sleeve has a porosity of 60 to 80%.
12. The method of claim 10 or 11, wherein the shape of the terraced outer surface generally corresponds to the shape of the distal end of the femur of a mammal.
13. The method of any one of claims 10 to 12, wherein the titanium alloy is Ti6A14V.
14. A femoral component of claim 1, substantially as hereinbefore described with reference to the accompanying drawings.

15. A method of forming a femur implant of claim 10, substantially as hereinbefore described with reference to the accompanying drawings.

FIGURE 1

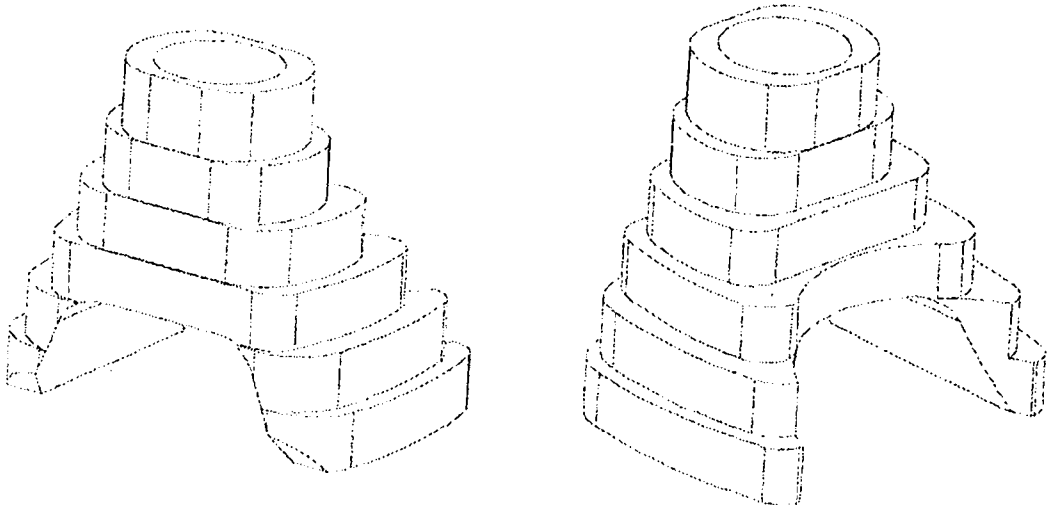
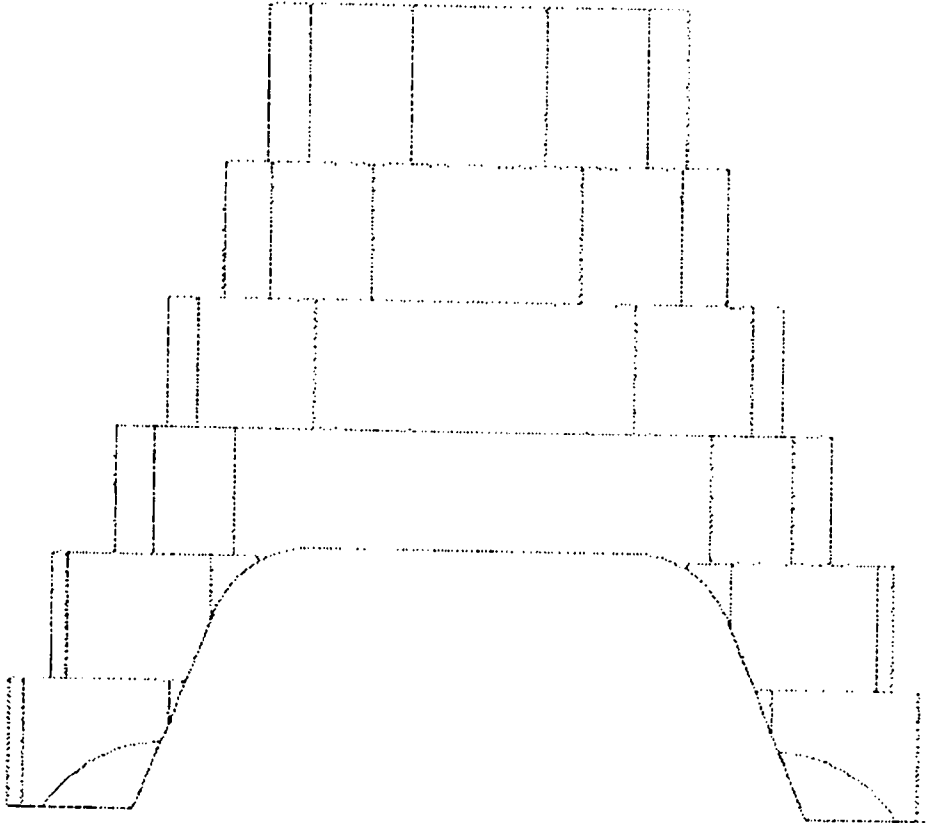
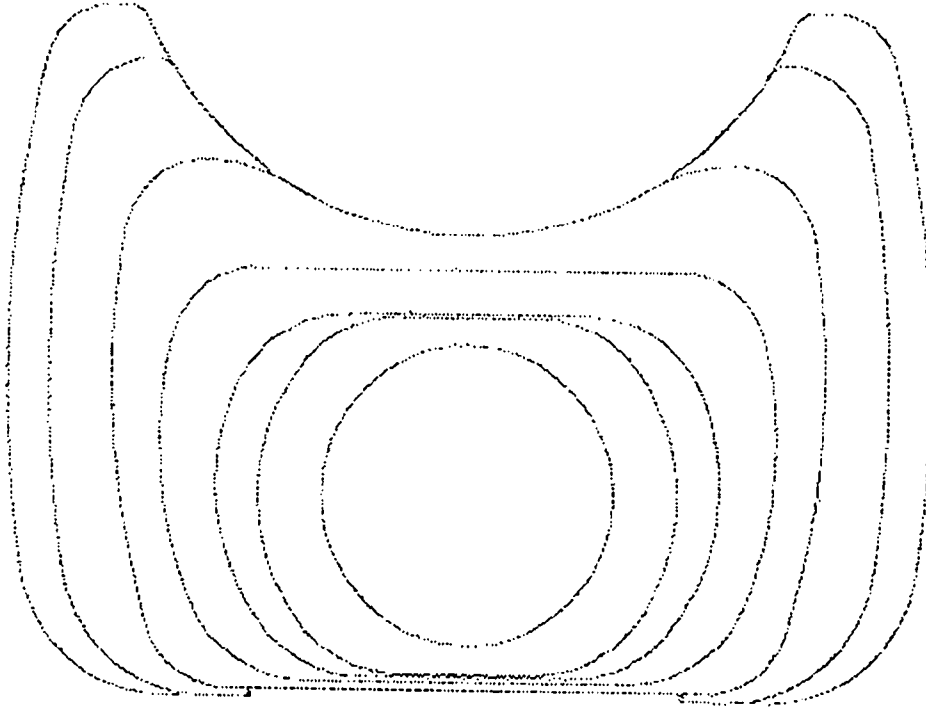


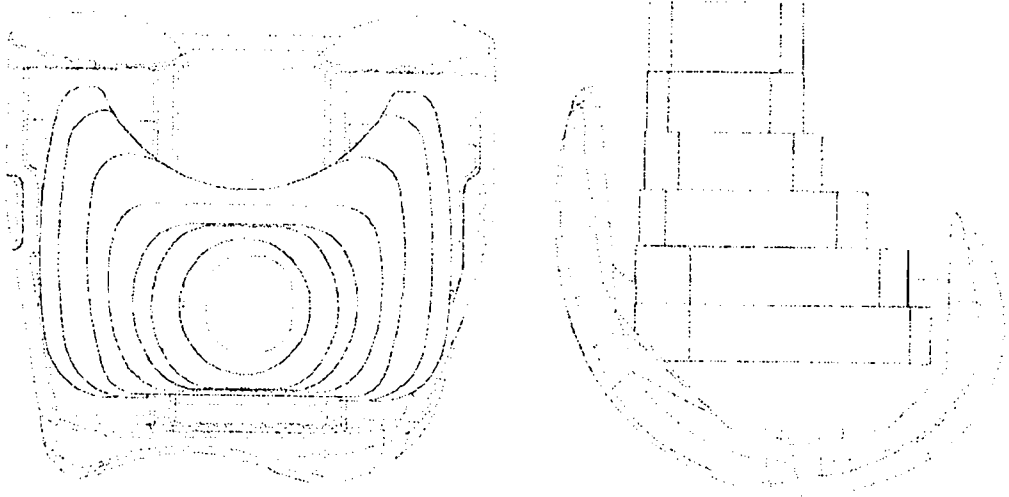
FIGURE 2



**FIGURE 3**



**FIGURE 4**



**FIGURE 5**

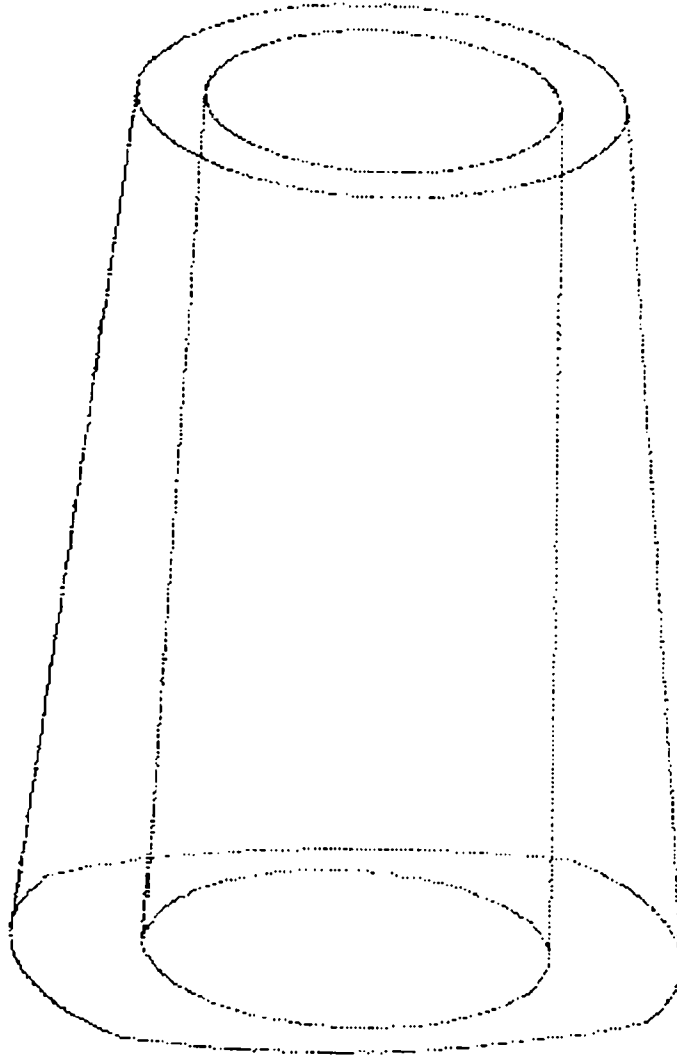
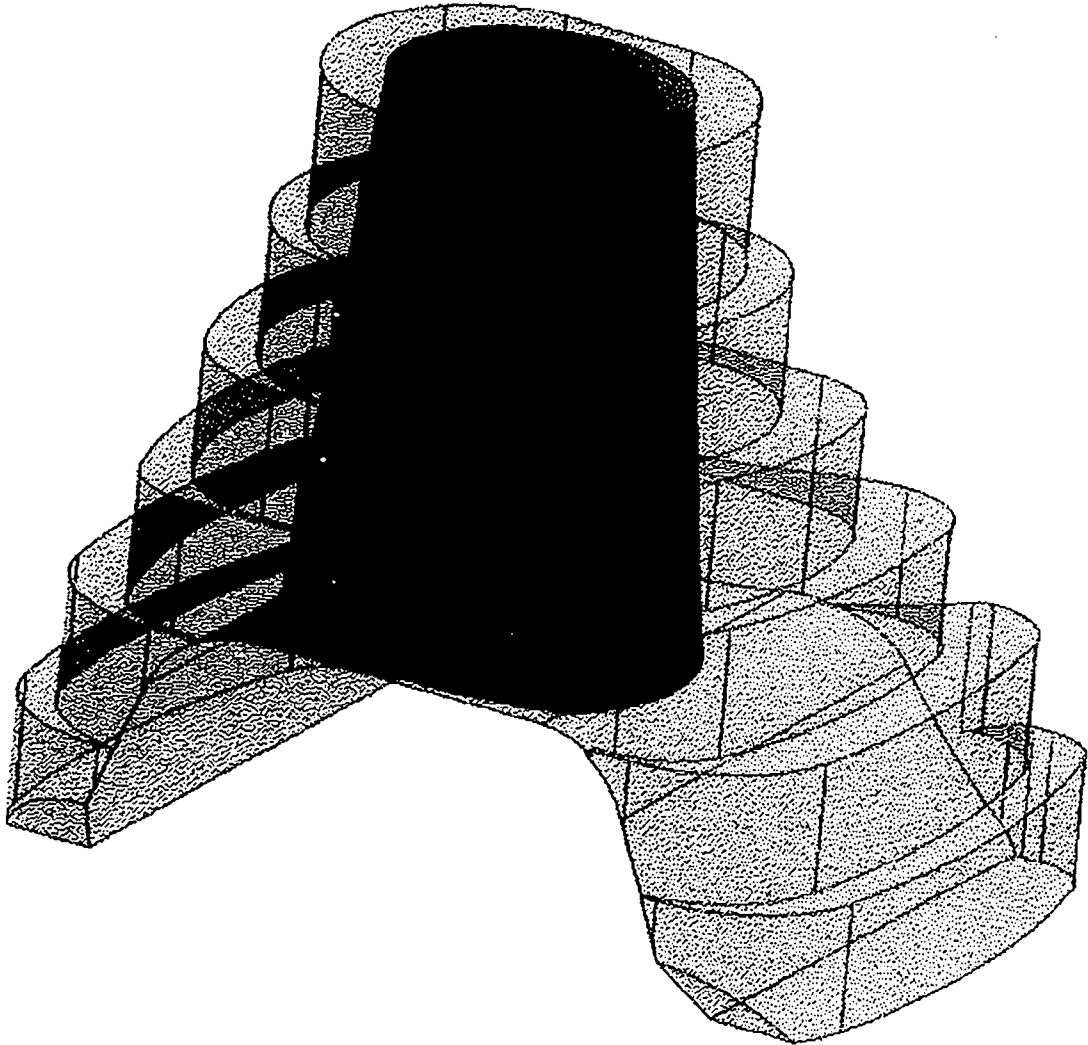




FIGURE 6



**FIGURE 7**

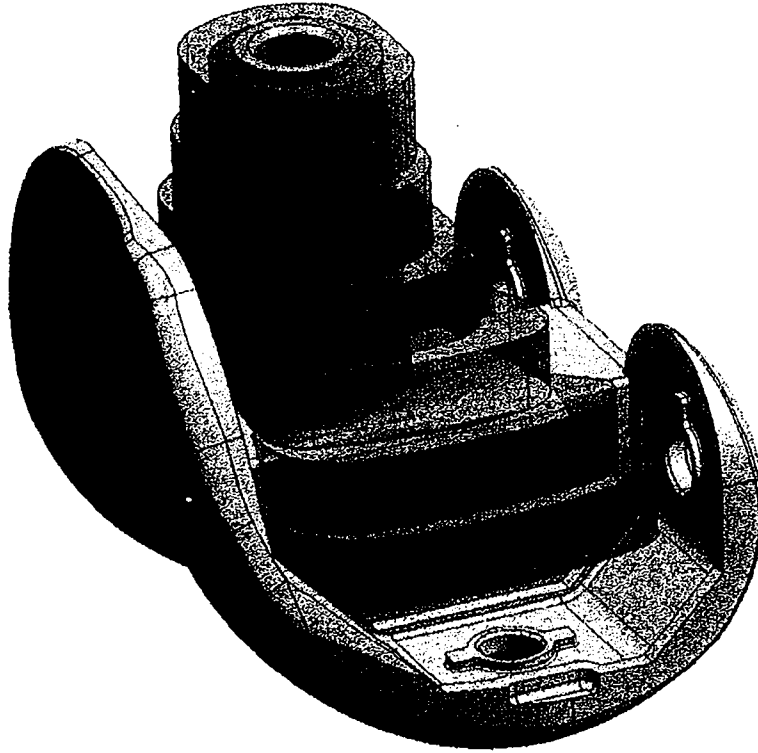
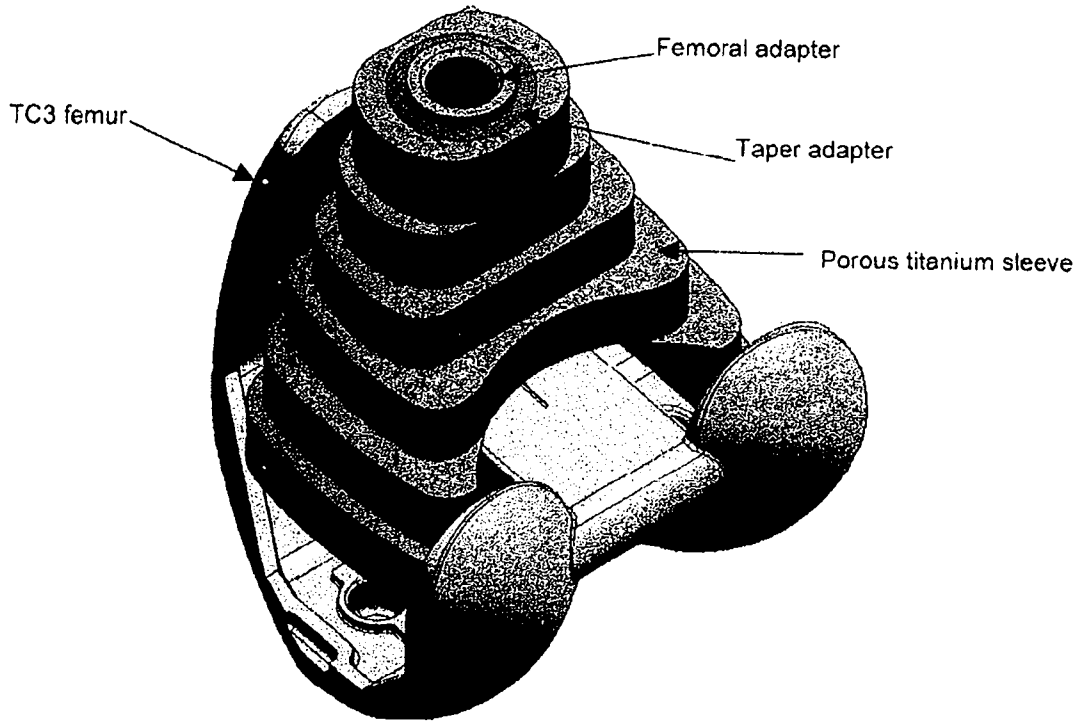


FIGURE 8



**FIGURE 9**

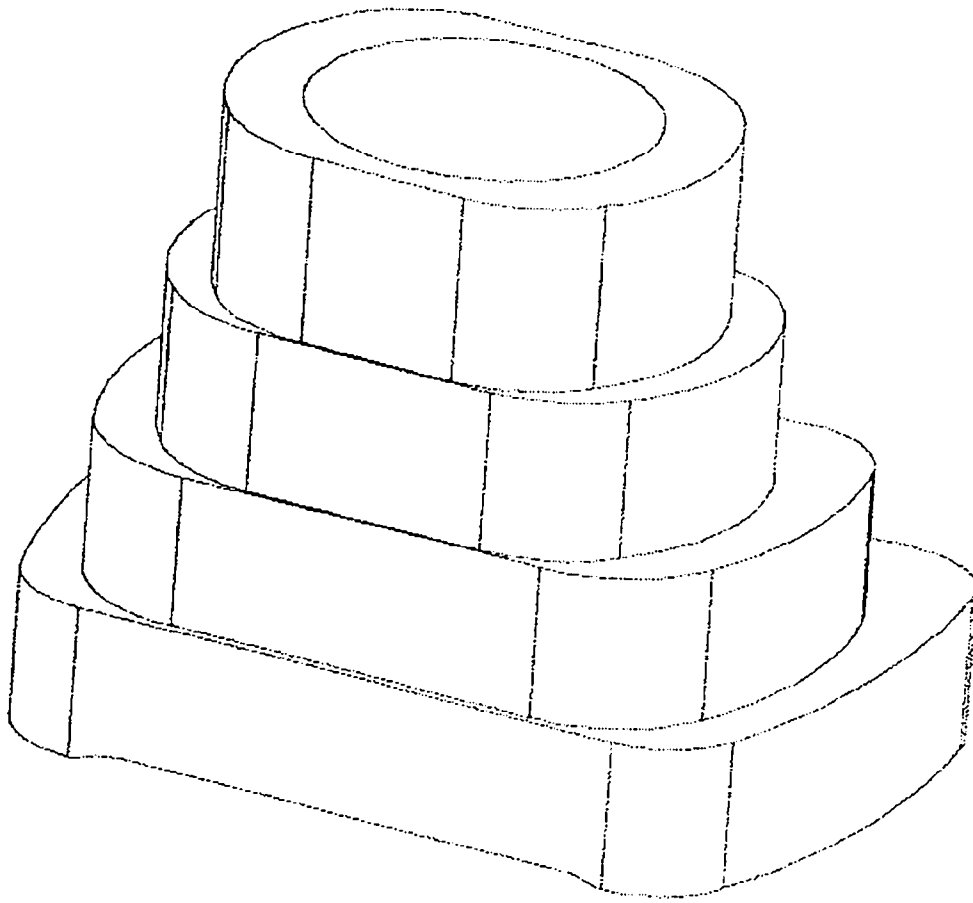
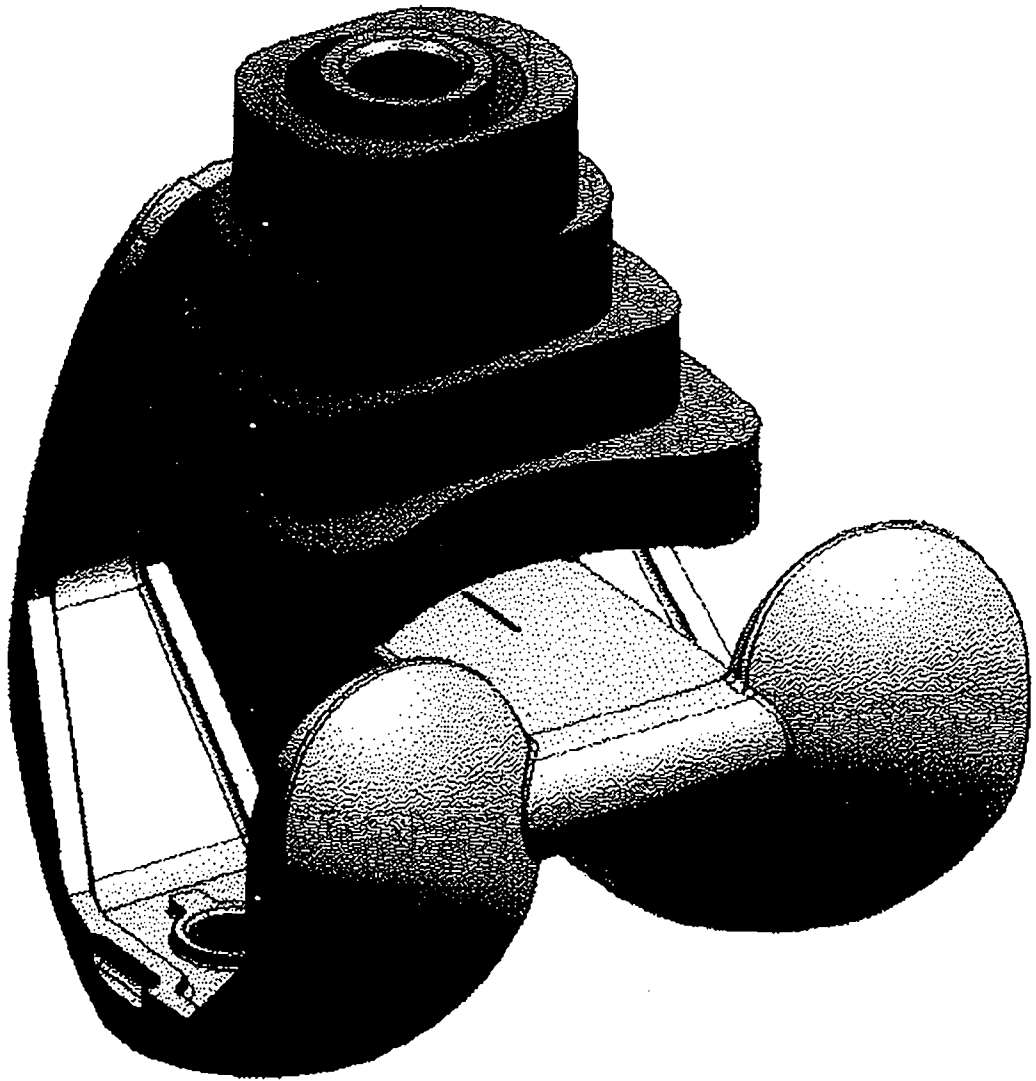


FIGURE 10



**FIGURE 11**

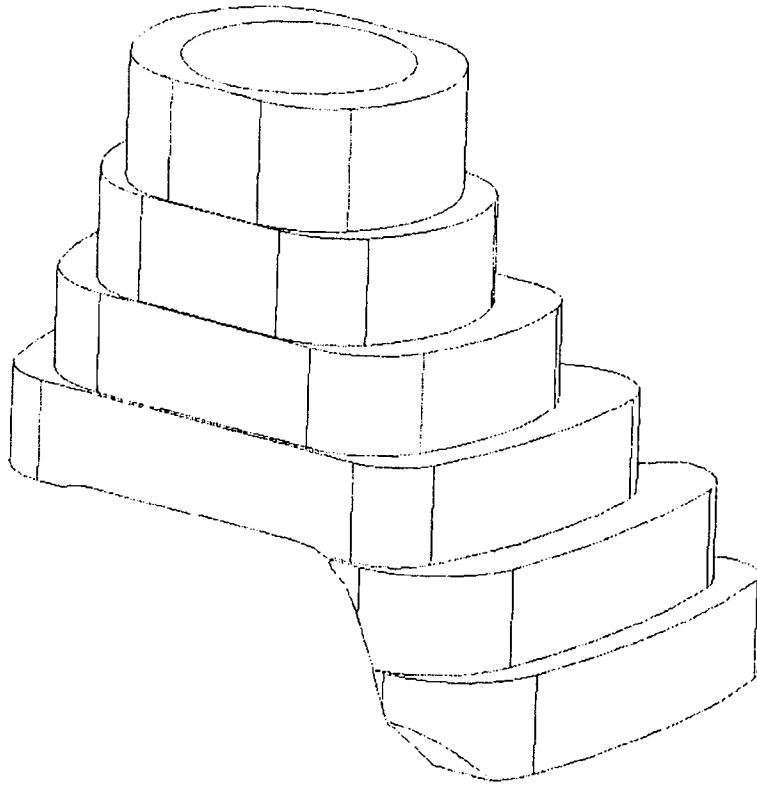
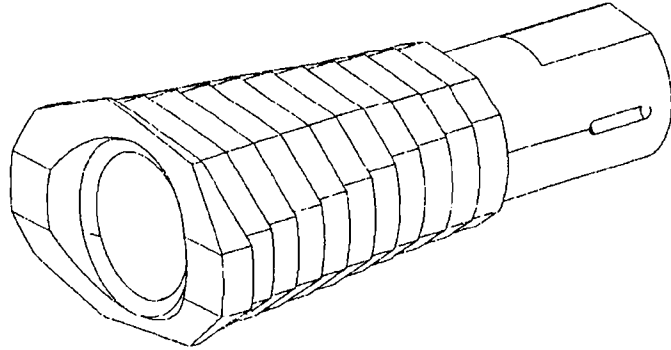
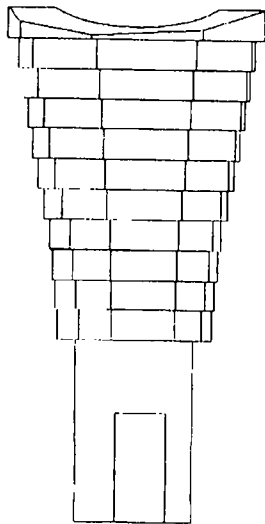


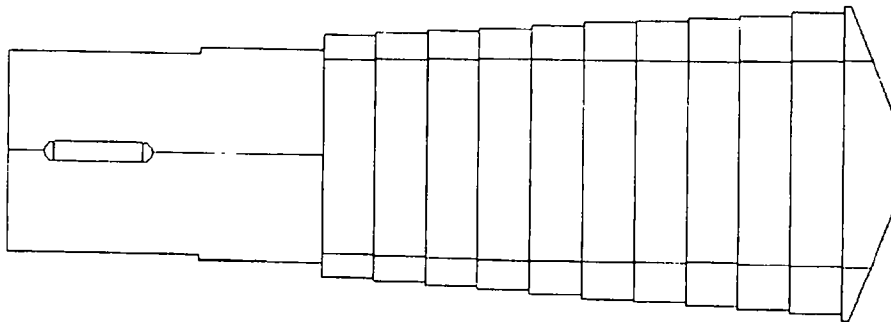
Figure 12



A



B



C

**Figure 13**

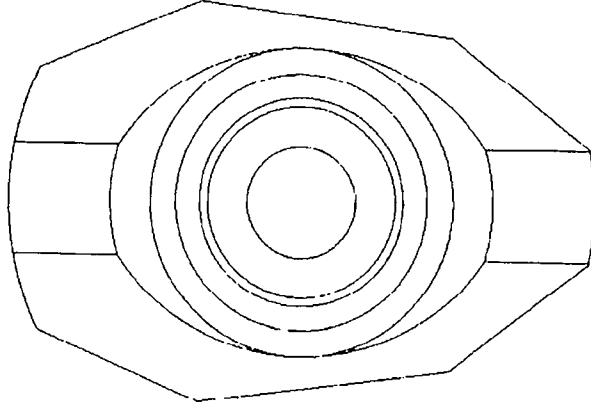
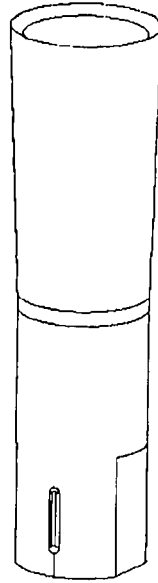
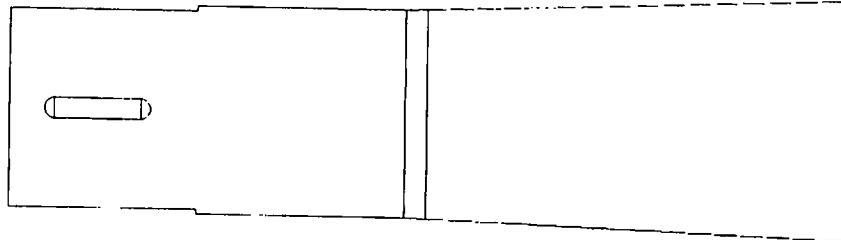




Figure 14



A



B