

[54] **ARTIFICIAL JOINT PROSTHESIS USING Al_2O_3 MATERIAL**

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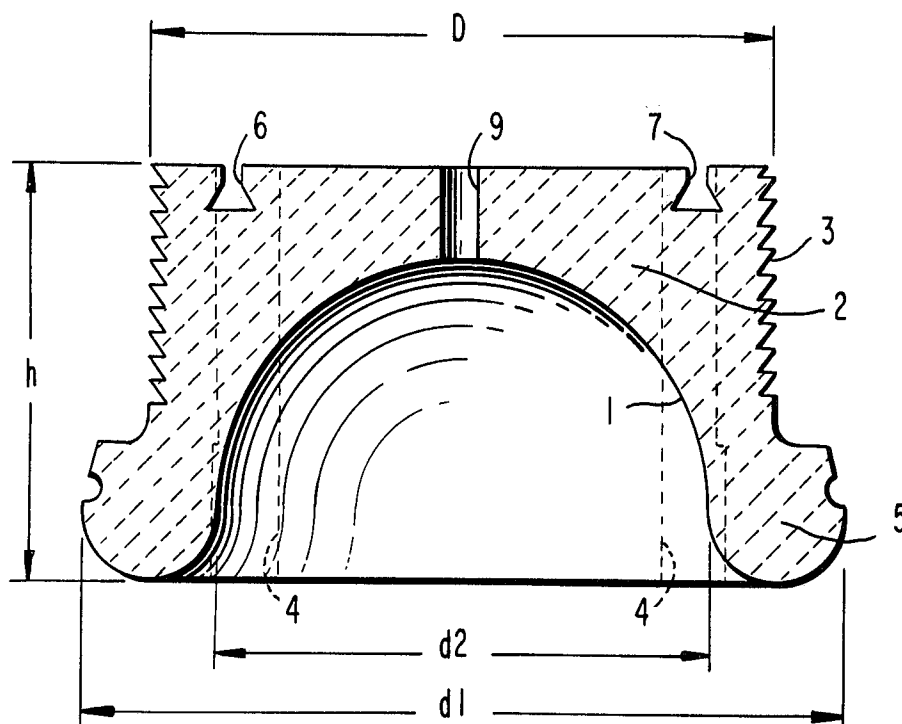
Primary Examiner—Ronald L. Frinks

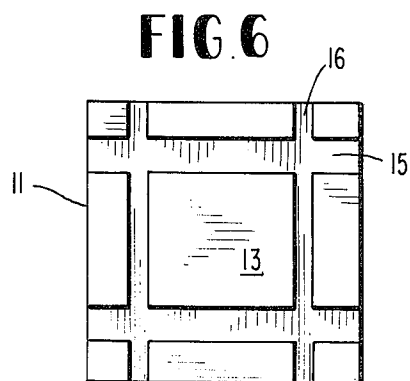
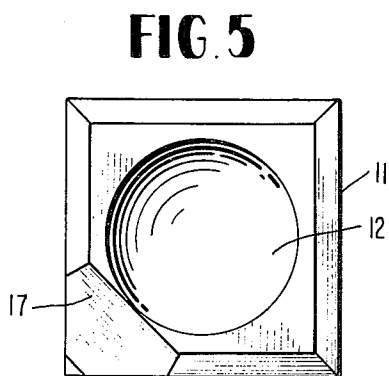
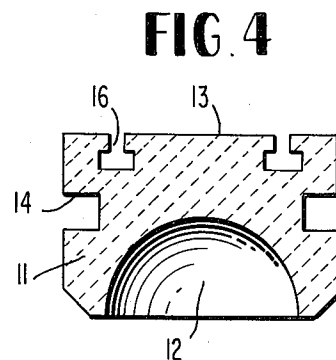
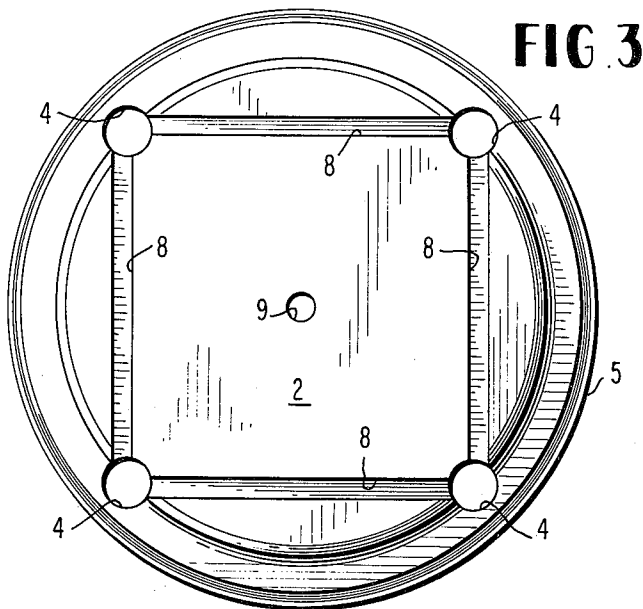
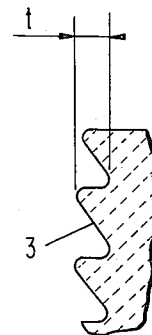
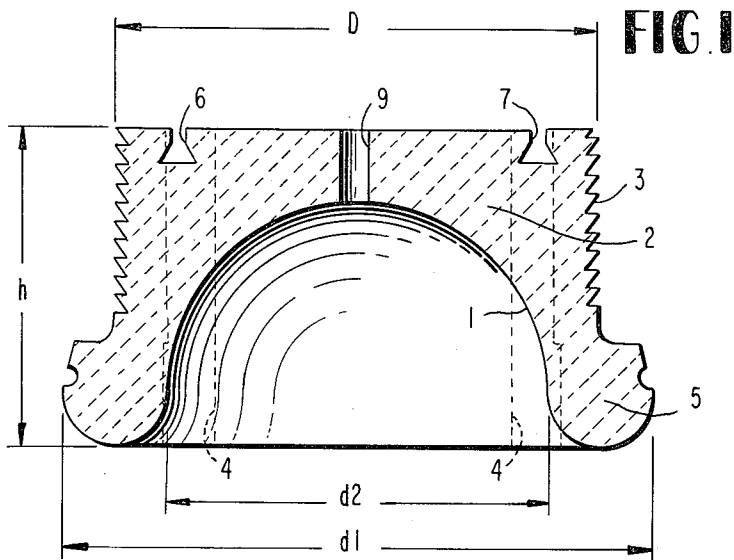
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ABSTRACT

Prosthesis made of biologically compatible material, such as Al_2O_3 , can be directly implanted in bone tissue without cement and without biologically deleterious effects. At least one surface is provided by means of which the load forces are transmitted directly between the prosthesis and the bone tissues. A socket may be polygonally shaped, or may be cylindrical with a helically exterior screw thread. Exterior grooves are provided, into which bone tissue grows to firmly bond the prosthesis in place and means is provided to prevent rotation prior to bone tissue growth.

14 Claims, 9 Drawing Figures





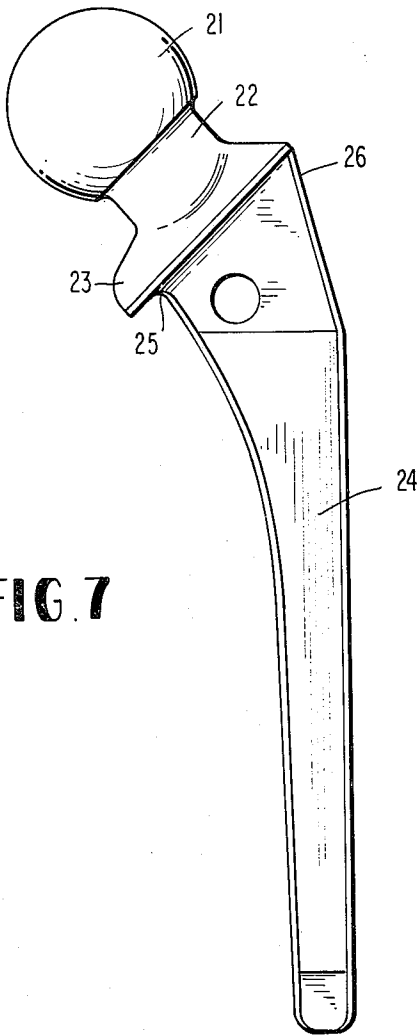


FIG. 7

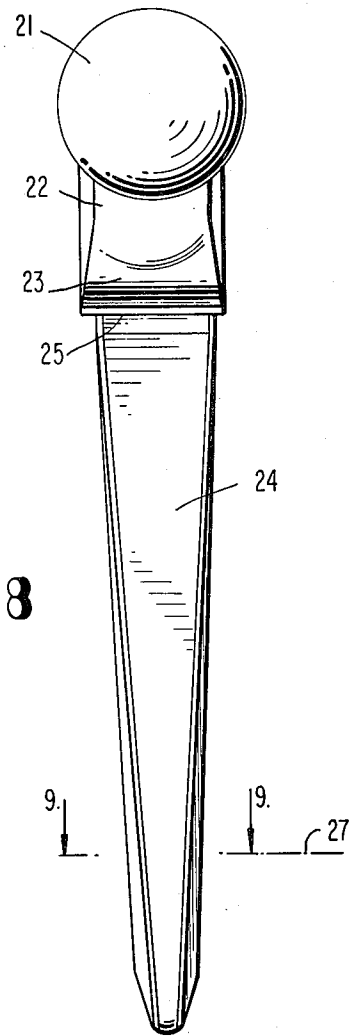


FIG. 8

FIG. 9



ARTIFICIAL JOINT PROSTHESIS USING Al_2O_3 MATERIAL

The invention relates to a socket for a hip joint prosthesis of ceramic material for implantation without cement.

The hip joint prostheses used hitherto generally consist of plastic sockets and a metal part for the replacement of the head of the femur, or of metal sockets and a plastic part as a replacement of the head of the femur. These parts and especially the sockets, hitherto were mostly anchored and fixed in the hip bone with bone cement.

Hip joint prostheses made of ceramic, especially of a compact aluminum-oxide-ceramic, have also been proposed already. These ceramic prostheses have the advantage, as compared to the metal and metal-plastic combination prostheses, that the friction, gliding and wear characteristics of ceramic, especially of aluminum oxide ceramic, are much superior to those of the metals and plastics. Moreover the ceramic has a much better body compatibility than plastics and metals.

In order to be able to utilize this greater body compatibility of the ceramic implants, it is however necessary, to implant and secure them without the use of plastic cements. The sockets of hip joint prostheses used hitherto for implantation without cement, consisted essentially in imitations of the socket shapes, which had been known from plastic socket constructions. The surface facing the bone, was generally essentially hemispherical or cup shaped and had grooved patterns of various kinds. The disadvantage of this construction consisted in the fact that for a firm anchoring in the bone, either complicated puncture patterns had to be chiselled into the hip bone, or else the growing of bone into the grooved structure took some time, so that patients were exposed to a relatively long period of immobilization. This is however undesirable because of the danger of thrombosis.

In the case of the metal sockets for hip joint prostheses, a screw-type fastening is already known. (Total endoprosthesis according to Ring). In the case of this construction, however, the overall height amounts to several times the diameter of the socket, the diameter of the thread is considerably smaller than the diameter of the hemispherical cavity of the socket. This construction however, can not be used for a ceramic socket, especially one of compacted aluminum-oxide-ceramic, since it does not take into consideration the material characteristics of ceramic and since there would be the danger of breaking of the long screw during fastening.

According to the present invention, the construction described in the following pages in more detail, and which at the same time has a number of advantages, is provided for the socket of hip joint prostheses made of aluminum-oxide-ceramic. It has been discovered that the socket of the invention will permit a load to be applied, even in case of cement-free implantation, very soon after the operation and nevertheless grows very firmly into the body even in the succeeding period, while under strain, and is completely integrated into the bone connection mechanism.

Sockets made of various metal alloys for cement-free implantation have also been proposed already. Screws or else long pegs served for their attachment, which are screwed or driven into the adjacent bone space.

However it turned out that the bio tolerance of plastic cements, plastics and metals is not very favorable.

Therefore, the danger exists of a loosening of the socket after the cemented-in socket has remained in the body for some time. This danger of loosening is particularly great in case of the metallic sockets implanted without cement.

For some time it has been known, that certain types of ceramic and a few types of glass ceramic have a considerably more favorable body compatibility as compared to metals and plastics. This is particularly true for Al_2O_3 ceramic, whereby we understand by Al_2O_3 ceramic, a ceramic which contains 95% aluminum-oxide or more, especially 99% Al_2O_3 . Extensive animal experiments and first results of cement-free implantations of parts of joint prostheses made of compact Al_2O_3 ceramic, show that a firm anchoring of such parts without the help of cement is possible. In case of favorable conditions, for example, after an immobilization of the respective joint for a few weeks to months, a mechanically very strong connection develops between the implant and the surrounding bone tissue.

For the cement-free implantation of hip joint sockets for total prostheses made of Al_2O_3 ceramic, sockets of various other shapes have also been proposed and used already; one socket construction of this type has at its rear an essentially hemispherical shape, into which deep grooves have been worked in. It carries a peg at its crest, which is round and which likewise has deep grooves. This socket construction is similar to known sockets made of plastic and, in case of cement-free implantation, it has the disadvantage that there is no genuine protection against twisting. Until such time that the tissue has grown firmly to the surface, or the bone tissue has grown into the grooves and channels, there exists the danger of twisting of this type of socket in case of even slight movement in the joint, as a result of which this growing-in, or -on, can be delayed or even prevented.

One form of socket for total hip joint prostheses made of Al_2O_3 ceramic, according to the invention for cement-free implantation, has an angular shaped rear portion. It can be triangular, square, pentagonal or hexagonal. This angular rear portion is provided with grooves and channels, a part of which can also have some dovetailed or similar reverse tapering, and can grow into the bone tissues for a better anchoring of the socket.

The invention also relates to the thigh part of a total hip joint prosthesis for the cement-free implantation, especially prostheses consisting of Al_2O_3 ceramic and prostheses made of a combination of a ceramic head with a metal shaft, in which case, the metal shaft is covered with a vitreous material such as a glaze, enamel or a glass ceramic, as described and claimed in the copending application of Gunther F. A. Heimke and Peter Griss, Ser. No. 440,444, filed Feb. 7, 1974, corresponding to German Application No. P 23 06 552.3.

The thigh parts of total hip joint prostheses are attached, at present, mostly by means of plastic cement in the marrow space of the femur. These prostheses consist of metal alloys, the composition of which is selected such that they will show the least possible corrosion phenomena in a biological environment. The transfer of a load from the thigh prosthesis to the femur takes place in the case of these prostheses essentially by the intermediation of the bone cement, which in its plastic state, closely follows the inside contour of the femur. During shaping the shaft of a metal thigh prosthesis for implantation with the aid of bone cement, no

special attention need be given to the load transfer from the prosthesis to the femur. Since this part of the prosthesis is surrounded entirely by bone cement, aspects of tissue tolerance and avoiding of movements between bone tissue and the implant are of no consequence during shaping of said part. Therefore, in case of the metal prostheses for implantation with plastic cements, one needs to consider only mechanical aspects for the shaping of the shaft of the prosthesis.

Prior to the general introduction of bone cements for the attachment of joint prostheses in the adjacent bone space, it was also customary to introduce or drive into the marrow space of the femur thigh parts of hip joint prostheses even without bone cement. This method of attachment however, was unsatisfactory. In many cases these parts of prostheses sunk deeper and deeper into the femur, since the bone decomposed in areas where the load was too high. In many other cases, the prosthesis became loose after a time, since a firm connection between the shaft of the prosthesis and the bone tissue did not occur because of the unfavorable biological tolerance of the metals.

Because certain types of ceramic, for example compacted Al_2O_3 ceramic with 99% Al_2O_3 content, as well as certain glass ceramics have an excellent tissue compatibility, especially in regard to bone tissue, it has been found that under certain conditions, a mechanically firm connection between the surfaces of such implants and the bone tissue develops.

This now results in the possibility of anchoring the thigh parts of total hip joint prostheses without cement and mechanically solidly in the marrow space of the femur. This cement-free implantation is very desirable, since the plastic bone cements available hitherto had many and serious drawbacks.

However, up to now there did not exist any prosthesis constructions for this cement-free implantation, in the case of which the introduction of the load from the implant into the femur is accomplished in such a way, that bending and tension strains in the adjacent surfaces between the implant and the bone are avoided as much as possible, and high pressure loads are eliminated. In the case of the use of total ceramic prostheses, one must naturally also take the characteristics of compact Al_2O_3 — ceramic into consideration.

Other objects and advantages will be apparent to those skilled in the art by reading the following specification in connection with the annexed drawings, in which;

FIG. 1 is a cross-section of a preferred form of hip joint socket made in accordance with the invention;

FIG. 2 is a fragmentary cross-section of a detail of FIG. 1;

FIG. 3 is a top view of the socket;

FIG. 4 is a cross-section of a modified form of socket;

FIG. 5 is a bottom view of the socket of FIG. 4;

FIG. 6 is a top view of the socket of FIGS. 4 and 5;

FIG. 7 is a side elevation of a preferred form of the thigh portion of the prosthesis;

FIG. 8 is a side elevation as viewed from the left of FIG. 7, and

FIG. 9 is a cross-section on the line 9—9 of FIG. 8.

A socket made in accordance with a preferred form of the invention made of aluminum-oxide-ceramic for implantation without cement will be explained in more detail on the basis of FIGS. 1-3. FIG. 1 shows a section through the socket; FIG. 2 the anchoring thread and FIG. 3, a view of the socket from above. The socket

contains the approximately hemispherical cavity 1, the surface of which is polished and on which the spherical head, likewise polished on its surface and consisting of the same ceramic, of the thigh element of the hip joint prosthesis, anchored in the femur, is mounted in a swivel-type manner. The body of the socket consists of aluminum-oxide-ceramic 2. According to the invention, this socket body is cylindrically-shaped in its upper part which faces the hip bone, with a cylinder diameter D , which is smaller than the total diameter d 1 of the socket, but larger than the diameter of the hemispherical cavity d 2 in the inside of the socket. The overall height h of the socket according to the invention is smaller than the diameter of the hemispherical cavity d 2.

The cylindrical part of the socket is provided on its outside surface with a thread 3. This thread 3 is made in such a manner that it can transfer forces, which act from the thigh on the socket, particularly favorably to the hip bone. These forces are, directed from below to above in the representation shown in FIG. 1. An example for a thread made in this way is shown in FIG. 2. On the outside of the cylindrical part having the diameter D , axially parallel grooves are worked in transverse to the thread. These grooves can be of a semicircular shape for example. They are designated by 4 in FIG. 3, which shows a view of the socket from above. These grooves interrupt the thread, whereby it appears to be particularly useful, to make this break as sharp-edged as possible. In FIG. 3, four such grooves have been drawn but, their number can also be greater or smaller than four. In the extension of these grooves there are holes which extend through the bead-shaped part 5 of the socket up to the front side of the socket. On the top side of the socket, that is, of the side projecting into the hip bone, a series of grooves is provided. In FIG. 1, these grooves consist of the dove-tailed grooves 6 and 7, which, in the view of FIG. 3, are represented by the grooves 8. Naturally, other arrangements of the grooves may also be selected according to the invention, but it will be particularly useful to provide the grooves existing on the top side with reverse-tapering, as given by the dovetail of the grooves 6 and 7. In the middle of the socket cavity, a hole 9 is provided.

During implantation of the socket according to the invention, for hip joint prostheses, one proceeds as follows: first an approximately round part is chiselled out, having a diameter which is still noticeably smaller than the diameter of the cylindrical part of the socket. Its depth is chiselled out to the point which approximately corresponds to the later seat of the socket. Subsequently, the preprocessed cavity is filed out further with a rasp, the diameter of which, measured across the outside teeth of the rasp, corresponds to the diameter D less twice the depth t of the thread. In the wall of this cylindrical hole, a thread is cut with a suitably shaped set of threading tools into the now cylindrical wall of the bone. At the same time the threading tool is dimensioned such that, after the last cutting process, the thread is about $\frac{1}{2}$ to 1 mm smaller in its diameter, than would correspond to the thread on the socket.

The grooves 6 and 7 or 8 are partly filled with the bone chips produced during the chiselling out of this cavity. Then the socket is moved close to pre-cut turns of the thread and is turned into the preprocessed thread with a tool which reaches into the continuous holes 4 or their extensions. Since the pre-cut thread was a little smaller than corresponds to the thread of the socket,

the application of some force is necessary for this, as a result of which, the socket thread forces itself firmly into the bone. This "forcing into" is assisted by the four grooves 4, which cut the thread. This assistance is the more favorable, the more sharp-edged these breaks are, as has already been explained further back.

By this screwing in of the sockets into a somewhat smaller thread, the socket will be firmly anchored in the hip bone immediately after implantation. At the same time, it has been discovered to be particularly favorable, surprisingly, that the bone particles which were still separated during this screwing in, collect and remain in the grooves 4. It also turns out, that these bone chips collecting there considerably favor the growing-in of the live bone into the spaces 4.

After screwing in of the socket, it will be desirable to drill a hole of about half the socket height from the outside with a drill inserted into at least one of the holes, which are located in extensions of the grooves 4. A ceramic peg is pushed into this hole, the outside diameter of which corresponds to the inside diameter of these holes, and the length of which is similar to half the height of the socket. This peg serves as an additional protection against twisting until the socket has completely grown in.

The hole 9 serves for one thing, for letting the air, which is compressed during screwing in of the socket, escape, and for another, for the improvement of the admittance of synovia into the hemispherical cavity of the socket during subsequent use of the joint.

The construction of the socket for hip joint prostheses made of aluminum-oxide-ceramic, according to the invention, thus has the advantage that it results in a firm seat of the socket in the hip bone immediately after the implantation, so that it can withstand a strain very soon after the operation. Beyond that, it causes an acceleration of the growing-in process into the bone tissue, whereby the well known stimulation of the adhesion of bone tissue to the aluminum-oxide-ceramic will be favored additionally through the presence of bone particles belonging to its own body, precisely at those places where the growing together is particularly desirable for the attachment of the prosthesis.

Another form of socket according to the invention is shown in FIGS. 4 and 5 in the form of a square socket. This socket consists of a socket body 11, the inside of which contains the approximately hemispherical hollow space 12, in which the complementary shaped head of the thigh part of the total prosthesis is seated. The rear 13 of this prosthesis is made square as the top view shown in FIG. 6 shows. On the side, the socket has grooves 14. Grooves and indentations are also worked into the rear, which are designated by 15 and 16 in FIG. 6. Part of these grooves in FIGS. 4 and 6, the grooves designated by 16, have reverse tapers. Such grooves, channels or other indentations serve for the purpose of anchoring the socket firmly by means of growing-in tissue in the adjacent bone space. These grooves, channels and indentations can be filled with bone chips from the same patient during the operation and prior to the insertion of the socket in the hip bone.

Various polygonal configurations for the socket body can be used, but in case of square, pentagonal or hexagonal sockets, at least one corner on the front of the socket may be bevelled in order to avoid a chafing of the "iliopsoas." This bevelling is designated by 17 in the lower part of FIG. 5 for a square socket.

The socket according to this modification of the invention, has the advantage, as compared to hitherto known sockets made of Al_2O_3 ceramic, that it can be inserted without a special set of instruments. The space needed for the socket in the hip bone, can be worked out and prepared with the instruments customary in orthopedic surgery. Implantations of sockets of this type into large animals, such as sheep, have shown that these sockets have such a firm seat immediately after implantation, that they will not become loose even in the case of an immediate load on the joint, but that a mechanically firm connection develops with the surrounding bone tissue.

A preferred form of construction for the thigh part of a hip joint prosthesis is shown in FIGS. 7-9, in which the prosthesis is made of compacted Al_2O_3 ceramic. It consists of the spherical head 21, the transition part 22 with the collar 23 and the shaft 24. FIG. 8 shows a view of the same prosthesis viewed from the side of the center of curvature p of the shaft 24. The prosthesis is supported by the surface, designated by 25, and with the fillet there on the front side of the wall of the femur. It is favorable to make this surface 25 as broad as possible, in order to avoid any increase in pressure during introduction of the load from the prosthesis to the femur. The corresponding surface on the reverse side 26; the side facing away from the center of curvature of the shaft of the prosthesis, merely has to have the width which is required for reasons of strength. The widths of the shaft of the prosthesis at its upper end at the point where it joins surfaces 25 and 26, should therefore either be the same on both sides, or else the width on side 25; on the side facing the center of curvature, should be larger than on side 26, which is the side facing away from the center of curvature. At the same time, experience shows it to be particularly advantageous to select the width on the side of the shaft of the prosthesis, facing the center of curvature, to be no smaller than 10mm. According to the invention, the downward tapering of the shaft of the prosthesis is accomplished in such a manner, that the width on the side facing the center p of the curvature decreases more rapidly than on the side facing away from said center of curvature. In the lower part of the shaft, about at the level 27 of the FIG. 8, the width on the inside, that is, on the side facing the center of curvature, is smaller than on the outside of the shaft facing away from the center of curvature. Here, the width on the inside can amount to between 5 and 7mm and, on the outside, to between 8 and 9mm. The ratio between the inside and outside widths at the upper end of the shaft should be about 1.0 to 1.0. At the lower part of the shaft of the prosthesis, the ratio should however, be at the most 0.9 to 1.0.

In animal experiments and in experiments where the load transmission ratios were simulated as they exist in the human body, it turned out that prostheses according to the invention, are capable of bearing the usual overall loads without, at the same time, incurring pressures at any places which are higher than those corresponding to the pressure load in the natural bone. Thus, in the case of use of the prosthesis according to the invention, there is no danger of degeneration of the bone as a result of pressure necrosis.

As in the case of the sockets made of Al_2O_3 ceramic, the shaft of the thigh portion of the prosthesis made from this material will, over a period of time, become securely fixed within the femur due to the affinity of

this ceramic for the growing tissues, and because the ceramic is biologically compatible with these tissues.

We claim:

1. A socket for hip joint prostheses for cement-free implantation in bone tissue, comprising a biologically compatible material such as compacted Al_2O_3 ceramic, said socket being provided with an internal hemispherical cavity, an exterior upper load bearing surface portion of the socket being provided with at least one elongated groove to provide a direct physical connection with bone tissue grown after implantation and an exterior surface portion including means to prevent rotation of the socket directly after implantation, the overall height of the socket being less than the diameter of the hemispherical cavity, the transverse dimensions of the upper portions of the socket being less than the largest diameter of the socket but, larger than the diameter of the hemispherical cavity.

2. The invention defined in claim 1, wherein the upper exterior surface of said socket is provided with at least one groove having an undercut transverse profile to receive bone tissue grown after implantation.

3. The invention defined in claim 1, wherein an upper exterior surface of said socket is defined by a cylinder of revolution, and said elongated groove comprises a helical thread provided in said exterior surface.

4. The invention defined in claim 3, wherein the transverse profile of said thread includes one face disposed generally normal to the direction of the force of the load to be supported by the socket.

5. The invention defined in claim 3, wherein said means to prevent rotation comprises at least one elongated groove provided in said upper surface, and transversely intersecting at least some of the turns of said thread.

6. The invention defined in claim 3, wherein said socket is provided with a bore extending between the interior of the cavity and the upper exterior surface of the socket.

7. The invention defined in claim 3, wherein said socket includes an annular flange flaring outwardly from the hemispherical cavity.

8. The invention defined in claim 7, wherein said means to prevent rotation comprises a peg to be inserted in an axial direction through an opening provided in said annular flange and the bone tissue in alignment therewith.

9. The invention defined in claim 7, wherein the transverse profile of said elongated groove intersecting said threads is defined by a semi-cylindrical surface in axial alignment with said opening in the annular flange.

10. A socket for hip joint prostheses for cement-free implantation in bone tissue, comprising a biologically compatible material such as compacted Al_2O_3 ceramic, said socket being provided with an internal hemispherical cavity, an exterior upper load bearing surface portion of the socket being provided with at least one elongated groove to provide a direct physical connection with bone tissue grown after implantation and an exterior surface portion including means to prevent rotation of the socket directly after implantation, the overall height of the socket being less than the diameter of the hemispherical cavity, the transverse dimensions of the upper portions of the socket being at least substantially equal to the largest diameter of the socket and larger than the diameter of the hemispherical cavity, the exterior side surface of at least the upper portion of said socket being defined by a series of intersecting planes.

11. The invention defined in claim 10, wherein a lower portion of the exterior surface of the socket is defined by a plane intersecting an adjacent pair of said first mentioned planes and angularly related thereto.

12. The invention defined in claim 10, wherein said intersecting planes define a regular polygon.

13. The invention defined in claim 12, wherein said regular polygon has four sides.

14. The invention defined in claim 13, wherein a lower portion of the exterior surface is defined by a plane intersecting an adjacent pair of said first mentioned planes and angularly related thereto.

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