Cementless Bony Ingrowth Total Hip Prosthesis (Anatomical Contact Porous Coated Total Hip Prosthesis) Design using Computed Axial Tomography and Computer Aid Design

Young-Hoo Kim¹, Young-Pil Park² and Jin-Suck Suh³

The purpose of this study is to design an Anatomical Contact Porous Coated Total Hip Prosthesis (ACP) which can transmit stress to the bone more physiologically and which can also eliminate the shortcomings of the currently available total hip prosthesis as much as possible. In the designing process, we have utilized computed axial tomography (CAT) and computer aid design (CAD). To obtain the shape of the femoral canal non-destructively, computed axial tomography data was obtained from fourteen male and fourteen female cadaver femurs and from twenty male and twenty female patients. To create the medullary canal in the computer, the actual dimension of each CAT-scan images were traced and digitized. For each femur a close-fit prototype of the stem was made with polyester and this was inserted into the corresponding femur in usual surgical manner. To test the accuracy of the fit of the prototype in the canal, an image of the cross-section of the canal with the polyester stem was obtained by CAT-scan in the same way that the original CAT-scan of the canal of the femur was done. We then had our computer display fit ratio between the prototype and the canal. We made sure all of the prototypes fit in the canal anatomically, especially around the defined regions (proximal medial and distal lateral regions). Further improvement was made on the fit of the stem in the canal by optimized computer programming. From studies on the shape and the size of the femoral canals of the sixty-eight femurs, eight sizes of ACP femoral stems were designed for each side. Also, on the basis of the anthropometric measurement of the acetabuli in twenty-eight cadaver hips and in the hips of forty patients with femoral neck fracture, different sizes of ACP hemispheric acetabular components were designed, ranging from 40 and 70 millimeters with 2 millimeter increments.

Key Words: *Femoral canal, acetabulum, computed axial tomography, computer aid design, Anatomical Contact Porous Coated Hip Prosthesis.

Patients with a certain degree of hip deformity and disease have the choice of continuing disability, hip arthrodesis, excision arthroplasty, or total hip replacement arthroplasty.

Arthrodesis has been used extensively in the past as the procedure of choice for the treatment of patients with osteoarthritis and also patients with infected hip joints (Lipscomb and McCaslin 1961; Piggot 1960; Stinchfield and Cavallaro 1950; Thompson 1956). It relieves the pain and provides stability of the joint, however it is attended by a high incidence of complications that may lead to poor results. The rate of non-union is between 6 and 70 per cent (Lipscomb and McCaslin 1961; Piggot 1960, Stinchfield and Cavallaro 1950; Thompson 1956), and even when the operation is successful the patients often have back pain, pain in the knee, and a gait that is slow, asymmetrical and arrhythmic (Gore et al. 1975). Also, hip arthrodesis imposes a fairly substantial morbidity and inconvenience to a modern, urban, mobile, and often relatively sedentary population.

Excision arthroplasty can be employed either as a primary or as a salvage operation (Clegg 1977; Haw and Gray 1976; Katayama et al. 1962; Mallory 1978; Nelson 1971; Parr et al. 1971; Tuli and Mukherjee

---

Received January 22, 1988
Accepted March 2, 1988

Department of Orthopedic Surgery¹ and Radiology¹, Severance Hospital, Yonsei University College of Medicine, Seoul, Korea.

Department of Mechanical Engineering², Yonsei University, Seoul, Korea.

This study was supported by grant 1985 China Medical Board-Yuhan through Yonsei University College of Medicine.

Address reprint requests to Dr. Y H Kim, Department of Orthopedic Surgery, Severance Hospital, Yonsei University College of Medicine, C.P.O. Box 8044, Seoul, Korea.
1981). It produces a hip that is free of pain, increases the range of motion, corrects deformity, and tends to yield permanent results. These desirable features, however, are offset by disadvantages: shortening of the limb, an abnormal gait that is characterized by the instability of the joint, fatigability, and often accompanied by the need of a walking aid.

Total hip arthroplasty has been established as a successful form of treatment. However, despite the excellent short-term results, some long-term studies of total hip replacement arthroplasty reported component loosening or migration. From various studies, it seems clear that by ten years after total hip arthroplasty, radiographic evidence of failure of fixation on the femoral component is at least 30 per cent (Stauffer 1982), and in some series as high as 70 per cent (Sutherland et al. 1982). Similarly, radiographic evidence of failure of fixation of the acetabular component by ten years is at least 11 per cent (Stauffer 1982), by twelve to fifteen years it is approximately 40 to 45 per cent (Charnley 1979; Sutherland et al. 1982), and these figures continue to rise with the passage of time.

Failure of fixation is more prevalent in young adults. Chandler et al. (Chandler et al. 1981) found that in patients who had total hip arthroplasty at thirty years of age or younger, acetabular fixation problems (45 per cent) were more than twice as common as femoral component fixation problems (21 per cent). Fifty-seven per cent had either radiolucent lines greater than 2.0 millimeters in width at the cement-bone interface, or a migration of components, or required revision within five years of surgery.

Even more sobering is the evidence of failure of fixation in revision surgery. Kavanagh et al. (Kavanagh et al. 1985) reported that at 4.5 years after the revision surgery, the incidence of a complete radiolucent zone at the cement-bone interface on the acetabular side was 70.9 per cent, and migration of the component was identified in 9.1 per cent. A complete radiolucent zone was seen around the cement on the femoral side in 63.6 per cent of the cases and 35.8 per cent of the femoral components had shown subsidence (Kavanagh et al. 1985).

The average figure for revision of primary total hip arthroplasty during the first ten years after implantation is 10 per cent. However, a report from the Mayo Clinic indicated that after only 4.5 years following revision total hip arthroplasty, 9 per cent of the patients had a second revision (Kavanagh et al. 1985). Similarly, Sutherland et al. (Sutherland et al. 1982) reported that after an average follow-up of only three years, 16 per cent of the revision patients required an additional revision.

Despite major improvements recently in implant designing and also in the technology of acrylic fixation for long-term durability of total hip arthroplasty, acrylic cement proved to be the weak link in the system. Two approaches to this problem have been simultaneously developed: optimization of acrylic fixation and cementless fixation. Many of the design parameters outlined in the review of modern implant systems are directed toward improving the durability of acrylic fixation. The fatigue life of acrylic cement has been effectively doubled by techniques of centrifugation and vacuum mixing (Harris et al. 1982; Wixon et al. 1987) which dramatically reduce porosity. Nevertheless, the essential nature of methylmethacrylate remains soft and brittle. For this reason, there is currently widespread, renewed, and concerted interest in the philosophy of fixing implants to the bone in a direct manner without an interposed grouting medium.

Of particular interest to us in this regard is the employment of porous implants or porous implant surfaces that permit development of a biological fixation to the host bone by tissue ingrowth. With a biological fixation, a large number of fixation points can be obtained by tissue ingrowth and the load transmitted from the prosthesis to the bone can be distributed over a larger surface area, thereby minimizing the stress applied to the bone-implant interface (Kennedy et al. 1979; Pilliar and Bratina 1980).

In our project, we attempted to design a cementless, porous coated prosthesis with an optimal shape - which we named Anatomical Contact Porous Coated Total Hip Prosthesis (ACP) - that can transmit stress to the bone more physiologically. For this purpose, we have documented in this study the characteristics of the qualitative data derived from the CAT-scans and the entire design process.

**MATERIALS AND METHODS**

We confined our studies to the left femoral canal in fourteen male and fourteen female cadaver femurs and in twenty male and twenty female patients. Also we employed computed axial tomography to obtain the shape and the size of the femoral canal non-destructively. The first step was to identify the orientation of the femur and standardize its dimensions. For this purpose, three plastic markers (vascular catheters) were placed on the femurs. One was placed around the neck where the head would later be resected to provide an opening of the canal. The other
two plastic markers were placed along the anterior and lateral surfaces of the femur to identify the anterior and lateral sites on each CAT-scan image.

Fig. 1-A. The cortical bone is clearly visible as a dense white area; and the canal is traced along the outer periphery of the dark area within the white.

Fig. 1-B. At the calcar femorale where the canal is no longer hollow but is filled with trabecular bone, the distinction between the bone and the canal blurs slightly.

Figs. 1-A and 1-B. Cross-sectional CAT-scan images of the femoral shaft and the calcar femorale region.

Fig. 2-A. Looking down the computer generated medullary canal.

Fig. 2-B. Frontal view of the computer generated medullary canal.

Figs. 2-A and 2-B. Computer generated medullary canal of the femur.
 Fig. 3. Three dimensional shape of the medullary canal of the femur is obtained using the computer program “SKELETON I”.

One by one the femurs were placed on the table of a GE CT/T 9800 scanner equipped with a high resolution detector array. The flat table on which a femur rested during the CAT-scan provided the Z-axis for the femur. Scout view was obtained to verify accurate positioning of the femur. Then the CAT-scan was conducted, starting 25 centimeters below the femoral head and advancing upward at 10 millimeter intervals to 2 centimeters below the lesser trochanter, and at 5 millimeter intervals thereafter up to the head of the femur. There were twenty-four sections. An image was obtained from each section. The CAT-scan was done at 80 KVP, 70 MA, and 4 seconds of scan time. The matrix size was $512 \times 512$ and the field of view was 15 centimeters in diameter.

To obtain the actual size of the medullary canal of the femur in the CAT-scan image, the following steps were taken: 1) Two orientation points were taken on a straight line on the outer density of the medullary canal of the most distal portion of any given cadaver femur and the distance between them on the

Fig. 4. The X-Y coordinate of the points on the perimeter of the femoral canal are obtained with the program “DIGITIZE”.

Volume 29
Fig. 5. Each CAT-scan image is traced on a transparent plastic paper. The Z-coordinate direction and sequential number are written on each tracing image.

Fig. 6. Each tracing image is transferred onto a plaster plate of corresponding thickness with the CAT-scan interval, which is trimmed along the line of the tracing image.
screen was read and printed on the right hand margin of the frame. 2) Then, the actual distance of the same reference points on the sample cadaver femur was measured. 3) The latter distance was divided by the former to obtain the magnification ratio. 4) All sequential images on the CAT-scan screen were magnified by the magnification ratio to obtain the actual size of the medullary canal of the femur. Eventually we confirmed that the actual size of medullary canal could be obtained directly in the CAT-scan image simply by selecting the window width 1600, and center 300 (Fig. 17).

Photographs were taken for each section of the canal. The cortical bone was clearly visible as dense areas of white and the canal was traced along the outer periphery of the dark areas within the white area (Fig. 1-A). At the calcare femorale where the canal is no longer hollow but is filled with trabecular bone, the distinction between the bone and the canal blurred slightly (Fig. 1-B), yet it was still possible to trace the canal within a reasonable degree of confidence.

The medullary canal of the femur was constructed on the computer (Figs 2-A and 2-B) using our program called “SKELETON I” (Fig. 3). The following steps were taken in this process: 1) First, the actual dimension of each CAT-scan image was traced on transparent plastic paper. 2) They were digitized and stored in the IBM/PC-AT computer data file, using “DIGITIZE” (Fig. 4). 3) Then, they were stacked in order, keeping the relation of the Z-axis on each image (which had been input into this array to allow for this purpose), thus forming the medullary canal.

To design a close-fit prototype of the stem, we conducted a careful study of the relationship between the stem and the curved nature of the femoral canal. We noted that if the greater trochanter is resected along the vertical lateral side of the canal shaft, the canal is exposed and a wide enough opening is present and a stem that fills the entire canal can be easily inserted; however, if the greater trochanter is to be conserved, the path of insertion remains curved and a stem that fills the entire canal cannot be inserted. Hence the shape of the stem is determined for two purposes: easy insertion and to fill the canal as much as possible. In determining the desired shape of the stem we followed, what we call, the "load transfer principle", i.e., the stem must be firmly in touch with the proximal medial and the distal lateral areas of femur.

The following steps were taken to create close-fit polyester prototypes. For each cadaver femur: 1) A

Fig. 7. Constructed male plaster mold of the medullary canal of the femur.

Fig. 8. Constructed female plaster mold of the medullary canal of the femur.
Fig. 9. Female polyester mold of medullary canal of the femur.

Fig. 10-A. Close-fit prototype of a femoral stem.

Fig. 10-B. Fitting test of plaster made prototype in the polyester canal of the femur.

Figs. 10-A and 10-B. Close-fit prototype of stem fitting as much as possible in the area between the resected neck level and 2 centimeters below the lesser trochanter.
CAT-scan section of the medullary canal was traced using transparent plastic paper. 2) The Z-coordinate direction and sequential number were marked on the traced image (Fig. 5). 3) Each of them was transferred again onto a plaster plate of corresponding thickness with the CAT scan interval. 4) Then, the plaster plates were trimmed along the outline of the images (Fig. 6). 5) All of the plaster slices were put together to construct a male mold of the medullary canal of the femur (Fig. 7). 6) After that, a female plaster mold was made from the male plaster mold (Fig. 8). 7) Another female mold was made with polyester in the same manner for a stronger resistancy (Fig. 9). 8) The plaster male medullary mold was gently pushed into the polyester female mold and then pulled out. 9) The male mold was carefully carved for easy insertion, mostly around the areas of the proximal lateral and distal medial surfaces while conserving the proximal medial and distal lateral regions as much as possible (Figs. 10-A and 10-B). 10) When the desired plaster prototype of the stem was obtained, a replica was made with polyester.

To test the accuracy of the fit of the final prototype, each polyester prototype was inserted into the corresponding cadaver femur in the usual surgical manner. Images of the cross-section of the medullary canal with polyester stem were obtained by CAT-scan (Fig. 11). These CAT-scan images were superimposed on the original CAT-scan films of the femur. Then the perimeter line of the femoral canal and stem, absolute frame and coordinate of the Z-axis were marked (Fig. 12).

The X-Y coordinate of the points on the perimeter of the femoral canal and the stem were obtained by executing the program “DIGITIZE” with a manual

**Fig. 11.** To test fit between the stem and the canal quantitatively, cross-sectional images of the medullary canal with polyester are obtained by CAT-scanning in the same way as CAT-scanning of the medullary canal of the corresponding femur.

**Fig. 12.** CAT-scan images are superimposed on the original CAT-scanning films of the femur and the perimeter line of the femoral canal and stem are marked.
The digitizing data are verified with the program “SECT I".

To correct any mis-shape due to carving the pro-

Fig. 14-A. The fit ratio means the ratio of the distance be-
tween the center of the stem and a data point on the stem to the distance between the center of the stem and the corresponding data point on the medullary canal.

Fig. 14-B. The fit ratio is calculated with the program “Femur II".

Figs. 14-A and 14-B. To quantitate the fit between the femoral canal and the stem, the computer displays the fit ratio between the prototype and the canal.
SECT II

Start

Read: stem data
    canal data

Angle = 0°

Angle = Angle + 10°

Draw sectional shape

Modify the drawing

No

Stop

Save the modified data

End

**Fig. 15.** The digitized data of the stems and canals are programmed with "SECT II" to correct any error while carving the prototype manually.

totypical manually, digitized data of the stems and the canals were programmed by computer. Applying the “load transfer principle” again, the data were manipulated in the following manner. The cross-sectional shape was displayed in the X-Y plane and the longitudinal sectional shape was displayed in the Y-Z plane. The Y-Z plane is defined as a 90 degrees rotation of the X-Y plane at the rotating axis passing through the origin in the X-Y plane. The rotating axis was the Y-axis first and then the X-axis. The Y-axis is defined as a zero degree rotation of the Z-axis, and the X-axis as a -90 degrees rotation of the Z-axis. Whenever each longitudinal sectional shape was displayed, the shape of the stem was modified by the proper commands. These commands let the computer increase or decrease the data point value on the stem edge. This process is repeated by rotating the Z-axis by every 10 degrees. The work was done using "SECT II" (Fig. 15).

After all of the data was modified, the X-translation of the stem in the canal was carried out on the computer to verify the smooth passage of the stem (Fig. 16-A). If there was any friction point, that point of the stem was carved out by manipulating the data. This was done with the program “ANIM” (Fig. 16-B).

On the computer, each prototype was inserted into the corresponding computer created medullary canal of the sixty-eight femurs to verify the fit, and then we decided on a standard shape of the prototype. When this was done, the sixty-eight prototypes were divided into eight groups, reasonably according to their sizes, and then the average size was determined in each group.

To determine the shape and size of the acetabular component, the anthropometry of the acetabulum was measured in the twenty-eight cadaver hips and the hips of the forty patients with femoral neck fracture during total hip replacement surgery.

**RESULTS**

All of the manually carved prototype fit in the canal less than satisfactorily. Further improvement was made with our program “SECT II” (Figs. 18-A and 18-B).

Table I demonstrates the average cross-sectional area ratio in the twenty-eight cadaver femurs before and after the data manipulation. The area ratio was defined as the ratio of the cross-sectional area of the stem to that of the medullary canal. The average area ratio in the manually carved prototype was 0.45:1, which was increased to 0.54:1.

Table II illustrates the average fit ratio of the stem in the medullary canal of the twenty-eight cadaver femurs. In this table, the fit ratio was calculated in terms of the relationship between the stem and the femoral canal on the upper sixteen levels. The average fit ratio in the manually carved stem was 72 per cent, which was improved to 79 per cent in the computer modified stem.

Table III demonstrates the fit ratio of the priority contact region between the stem and the bone (i.e., proximal medial half and distal lateral half). In the manually carved stems, the average fit ratio was 76 per cent and this was improved to 86 per cent in the computer modified stems.
Anatomical Contact Porous Coated Total Hip Prosthesis

Fig. 16-A. X-translation of the stem in the canal is attempted to note any obstacle.

Fig. 16-B. If there is an obstacle, that portion is trimmed off using the program "ANIM". Figs. 16-A and 16-B. After all data are modified, passage of the stem in the canal is checked.
Young-Hoo Kim et al.

Fig. 17. CAT density threshold is varied to obtain the real size of the medullary canal of the femur. Based on these trials of different CAT density threshold, a CAT density threshold of 1600 is used to generate a data base of actual size of the femur for the prototype stem design.

Table I. Average cross-sectional area ratio

<table>
<thead>
<tr>
<th>area ratio</th>
<th>no. of discs</th>
<th>A</th>
<th></th>
<th>B</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>mean</td>
<td>S.D.</td>
<td>mean</td>
<td>S.D.</td>
</tr>
<tr>
<td>1</td>
<td>0.516</td>
<td>0.12</td>
<td></td>
<td>0.580</td>
<td>0.12</td>
</tr>
<tr>
<td>2</td>
<td>0.455</td>
<td>0.06</td>
<td></td>
<td>0.474</td>
<td>0.05</td>
</tr>
<tr>
<td>3</td>
<td>0.403</td>
<td>0.05</td>
<td></td>
<td>0.416</td>
<td>0.02</td>
</tr>
<tr>
<td>4</td>
<td>0.397</td>
<td>0.05</td>
<td></td>
<td>0.412</td>
<td>0.05</td>
</tr>
<tr>
<td>5</td>
<td>0.417</td>
<td>0.08</td>
<td></td>
<td>0.456</td>
<td>0.06</td>
</tr>
<tr>
<td>6</td>
<td>0.410</td>
<td>0.07</td>
<td></td>
<td>0.476</td>
<td>0.07</td>
</tr>
<tr>
<td>7</td>
<td>0.428</td>
<td>0.05</td>
<td></td>
<td>0.502</td>
<td>0.07</td>
</tr>
<tr>
<td>8</td>
<td>0.427</td>
<td>0.05</td>
<td></td>
<td>0.509</td>
<td>0.06</td>
</tr>
<tr>
<td>9</td>
<td>0.436</td>
<td>0.07</td>
<td></td>
<td>0.534</td>
<td>0.06</td>
</tr>
<tr>
<td>10</td>
<td>0.457</td>
<td>0.09</td>
<td></td>
<td>0.553</td>
<td>0.06</td>
</tr>
<tr>
<td>11</td>
<td>0.457</td>
<td>0.09</td>
<td></td>
<td>0.553</td>
<td>0.06</td>
</tr>
<tr>
<td>12</td>
<td>0.463</td>
<td>0.07</td>
<td></td>
<td>0.586</td>
<td>0.07</td>
</tr>
<tr>
<td>13</td>
<td>0.491</td>
<td>0.10</td>
<td></td>
<td>0.637</td>
<td>0.09</td>
</tr>
<tr>
<td>14</td>
<td>0.492</td>
<td>0.09</td>
<td></td>
<td>0.668</td>
<td>0.08</td>
</tr>
<tr>
<td>15</td>
<td>0.509</td>
<td>0.1</td>
<td></td>
<td>0.686</td>
<td>0.05</td>
</tr>
<tr>
<td>16</td>
<td>0.499</td>
<td>0.11</td>
<td></td>
<td>0.674</td>
<td>0.06</td>
</tr>
</tbody>
</table>

A: Manually Carved Stem
B: Computerized Modified Stem

The three dimensional shape of the femoral stem and the canal was contrived in order to confirm the acceptability of the fit of the selected eight stems (Figs. 19-A and 19-B). This work was done with our program “SKELETON II” (Fig. 20).

After a thorough study of the shape and the size of the femoral canals in the sixty-eight femurs, stem 1 prototype was fit into seven femurs, stem 2 into eight, stem 3 into ten, stem 4 into eleven, stem 5 into ten, stem 6 into nine, stem 7 into seven and stem 8 into six femurs.

ACP stem 1 has a 10 millimeter distal diameter with a 125 millimeter stem length; stem 2 has an 11 millimeters diameter with a 130 millimeter length; stem 3 has a 12 millimeter diameter with a 135 millimeter length, stem 4 has a 13 millimeter diameter with a 140 millimeter length; stem 5 has a 14 millimeter diameter with a 145 millimeter length, stem 6 has a 15 millimeter diameter with a 150 millimeter length; stem 7 has a 16 millimeter diameter with a 155 millimeter length; and stem 8 has a 17 millimeter diameter with a 160 millimeter length (Figs. 21-A and 21-B).
Anatomical Contact Porous Coated Total Hip Prosthesis

Fig. 18-A. A manually carved prototype of the stem fits the canal more or less satisfactorily, particularly in the defined priority regions.

Fig. 18-B. Further improvement in fitting the stem into the canal is made with the computer program 'SECT II'.

Figs. 18-A and 18-B. Optimal fit of the manually carved and modified prototype by computer.

The shape of the cross-section of the proximal stem of ACP is elliptical with round medial and lateral borders. The lateral border is wider than the medial border. The shape of the cross-section of the distal stem is round (Figs. 22-A and 22-B).

Our prosthesis is designed with threadlike, commercially pure titanium fiber-metal pads, circumferentially attached to the proximal one-third of the stem to promote optimal implant fixation.

The angle of the ACP stem-neck is 135 degrees, and the femoral neck is antverted by 6 degrees to promote anatomic reconstruction. The neck length of the stem has three variables; short, medium and long. For the stems with 10, 11, 12 and 13 millimeter diameters, the lengths are 29, 36 and 43 millimeters, respectively; for the stems with 14 and 15 millimeter diameters, they are 32, 39 and 46 millimeters, respectively; for the stems with 16 and 17 millimeter diameters, they are 33, 41, and 48 millimeters, respectively.

The Morse-type taper neck of this prosthesis has several advantages: 1) Versatility of its modular sizing can reduce inventory investment and storage requirements. 2) It can accept four different diameters of femoral heads: 22, 26, 28 and 32 millimeters. 3) All heads are available in three neck length options except the 22, which has two sizes. 4) Once the femoral head or endoprosthetic components is
Table II. Average fit ratio (Entrie Stem)

<table>
<thead>
<tr>
<th>fit ratio no. of discs</th>
<th>A mean</th>
<th>A S.D.</th>
<th>B mean</th>
<th>B S.D.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0.80</td>
<td>0.14</td>
<td>0.86</td>
<td>0.17</td>
</tr>
<tr>
<td>2</td>
<td>0.75</td>
<td>0.14</td>
<td>0.79</td>
<td>0.16</td>
</tr>
<tr>
<td>3</td>
<td>0.72</td>
<td>0.15</td>
<td>0.74</td>
<td>0.17</td>
</tr>
<tr>
<td>4</td>
<td>0.71</td>
<td>0.15</td>
<td>0.74</td>
<td>0.16</td>
</tr>
<tr>
<td>5</td>
<td>0.71</td>
<td>0.14</td>
<td>0.76</td>
<td>0.15</td>
</tr>
<tr>
<td>6</td>
<td>0.69</td>
<td>0.13</td>
<td>0.76</td>
<td>0.14</td>
</tr>
<tr>
<td>7</td>
<td>0.70</td>
<td>0.14</td>
<td>0.76</td>
<td>0.14</td>
</tr>
<tr>
<td>8</td>
<td>0.70</td>
<td>0.13</td>
<td>0.76</td>
<td>0.14</td>
</tr>
<tr>
<td>9</td>
<td>0.70</td>
<td>0.11</td>
<td>0.77</td>
<td>0.13</td>
</tr>
<tr>
<td>10</td>
<td>0.71</td>
<td>0.11</td>
<td>0.78</td>
<td>0.13</td>
</tr>
<tr>
<td>11</td>
<td>0.71</td>
<td>0.08</td>
<td>0.79</td>
<td>0.11</td>
</tr>
<tr>
<td>12</td>
<td>0.73</td>
<td>0.07</td>
<td>0.81</td>
<td>0.09</td>
</tr>
<tr>
<td>13</td>
<td>0.73</td>
<td>0.09</td>
<td>0.83</td>
<td>0.06</td>
</tr>
<tr>
<td>14</td>
<td>0.75</td>
<td>0.09</td>
<td>0.84</td>
<td>0.05</td>
</tr>
<tr>
<td>15</td>
<td>0.74</td>
<td>0.09</td>
<td>0.83</td>
<td>0.04</td>
</tr>
<tr>
<td>16</td>
<td>0.73</td>
<td>0.09</td>
<td>0.84</td>
<td>0.04</td>
</tr>
<tr>
<td><strong>Average</strong></td>
<td><strong>0.72</strong></td>
<td><strong>0.03</strong></td>
<td><strong>0.79</strong></td>
<td><strong>0.04</strong></td>
</tr>
</tbody>
</table>

A: Manually Carved Stem  
B: Computerized Modified Stem

Table III. Average fit ratio (Priority Region of Stem)

<table>
<thead>
<tr>
<th>fit ratio no. of discs</th>
<th>A mean</th>
<th>A S.D.</th>
<th>B mean</th>
<th>B S.D.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0.89</td>
<td>0.08</td>
<td>0.98</td>
<td>0.03</td>
</tr>
<tr>
<td>2</td>
<td>0.85</td>
<td>0.08</td>
<td>0.91</td>
<td>0.04</td>
</tr>
<tr>
<td>3</td>
<td>0.84</td>
<td>0.06</td>
<td>0.88</td>
<td>0.03</td>
</tr>
<tr>
<td>4</td>
<td>0.82</td>
<td>0.05</td>
<td>0.86</td>
<td>0.03</td>
</tr>
<tr>
<td>5</td>
<td>0.81</td>
<td>0.06</td>
<td>0.86</td>
<td>0.04</td>
</tr>
<tr>
<td>6</td>
<td>0.78</td>
<td>0.06</td>
<td>0.86</td>
<td>0.04</td>
</tr>
<tr>
<td>7</td>
<td>0.77</td>
<td>0.07</td>
<td>0.85</td>
<td>0.05</td>
</tr>
<tr>
<td>8</td>
<td>0.76</td>
<td>0.06</td>
<td>0.85</td>
<td>0.05</td>
</tr>
<tr>
<td>9</td>
<td>0.74</td>
<td>0.06</td>
<td>0.85</td>
<td>0.04</td>
</tr>
<tr>
<td>10</td>
<td>0.74</td>
<td>0.05</td>
<td>0.85</td>
<td>0.05</td>
</tr>
<tr>
<td>11</td>
<td>0.71</td>
<td>0.05</td>
<td>0.84</td>
<td>0.06</td>
</tr>
<tr>
<td>12</td>
<td>0.70</td>
<td>0.07</td>
<td>0.85</td>
<td>0.04</td>
</tr>
<tr>
<td>13</td>
<td>0.68</td>
<td>0.08</td>
<td>0.84</td>
<td>0.03</td>
</tr>
<tr>
<td>14</td>
<td>0.69</td>
<td>0.09</td>
<td>0.84</td>
<td>0.02</td>
</tr>
<tr>
<td>15</td>
<td>0.68</td>
<td>0.09</td>
<td>0.82</td>
<td>0.03</td>
</tr>
<tr>
<td>16</td>
<td>0.68</td>
<td>0.09</td>
<td>0.84</td>
<td>0.05</td>
</tr>
<tr>
<td><strong>Average</strong></td>
<td><strong>0.76</strong></td>
<td><strong>0.07</strong></td>
<td><strong>0.86</strong></td>
<td><strong>0.04</strong></td>
</tr>
</tbody>
</table>

A: Manually Carved Stem  
B: Computerized Modified Stem

**Fig. 19-A.** Looking down the 3-D image of the stem and canal.

**Fig. 19-B.** Frontal view of the 3-D image of the stem and the canal.

**Fig. 19-A and 19-B.** Three dimensional shape of the femoral stem and canal.

selected and impacted, it allows them to be firmly fixed to the stem. 5) Removal can be accomplished with a special instrument, allowing the surgeons to
options, extending the surgical latitude and complementing the versatility of ACP stem. The size of the ACP acetabular component ranges between 40 and 70 millimeters with 2 millimeter increments. This was based on anthropometric measurements of the acetabuli in twenty-eight cadaver hips and in the hips of forty patients with femoral neck fracture. The average diameter of the acetabulum was 47.2 millimeters ranging from 42 to 55 millimeters. Sizes larger than 55 millimeters were designed for patients with an unusually large acetabulum and also for revision cases.

Each acetabular cup consists of 1) a biocompatible titanium shell, 2) a polyethylene insert with a 22, 26, 28 or 32 millimeter inside diameter and a 15 degree lip angle, 3) two peripheral fixation pegs, 4.5 millimeters in diameter, to enhance torsional stability and reduce shear stress at the fixation interface, and 4) eleven optional central screw holes, 4.5 millimeters in diameter, for revision cases or for patients with poor bone quality. (Screws come in nine lengths: 25, 30, 35, 40, 45, 50, 55, 60 and 65 millimeters (Fig. 23-A). Each polyethylene insert locks independently of the peg or screw fixation and has a choice of ten locations to position the lip for maximum femoral head coverage and joint stability. The polyethylene inserts are interchangeable within their size groups (Fig. 23-B).

DISCUSSION

The General Electric 9800 scanner (GE CT/T 9800) has a spatial resolution at every 1 millimeter level and has very good resistance to artifacts resulting from large contrast changes. These findings are important since spatial resolution is the main factor in limiting perception when high contrast materials such as bone are scanned. Background noise has little effect on the perceptibility of the bone since the signal to noise ratio is so large. If artifacts arise from multiple sources and are small, they may be considered similar to background noise, and hence have little effect on the quantitative measurements of the bone (Kim et al. 1987).

The influence of CAT viewer control settings on anatomic measurements is mentioned elsewhere (Kim et al. 1987). Data input by means of digitizing films of the CAT scan has three major sources of error. 1) effect of viewer controls, 2) distortion in film reproduction, and 3) inaccuracy of digitizing either by manual input or by laser or other scanning devices when more
Fig. 21-A. Frontal view of the femoral stem.

Fig. 21-B. Side view of the femoral stem.

Figs. 21-A and 21-B. Final designed femoral stems.

SECTION A - A

Figs. 22-A. The cross-sectional shape of the proximal stem is elliptical with round medial and lateral borders. The lateral border is wider than the medial one.

SECTION D - D

Figs. 22-B. The cross-sectional shape of the distal stem is round.

Figs. 22-A and 22-B. Cross-sectional shapes of the femoral stem.
Anatomical Contact Porous Coated Total Hip Prosthesis

1. ACETABULAR METAL SHELL

Figs. 23-A. Acetabular titanium metal shell with two 4.5 millimeters peripheral fixation pegs and eleven optional central screw holes.

2. POLYETHYLENE LINER

Figs. 23-B. Polyethylene liner with a 15 degrees lip angle.
Figs. 23-A and 23-B. Final shape of acetabular metal shell and polyethylene liner.

than one person is involved in the project. We tried to minimize the cumulative effect of these inaccuracies by assigning each project to a single individual.

The contour following algorithm has two main sources of error. The first results from the rounding off of each contour data point to the nearest pixel. Since the edge response function is linear, interpolation between pixels may retain much of the accuracy that was lost by rounding. Second, the use of an absolute CAT density threshold may reflect artifactual or actual irregularities in the bone contours which are not present in the carefully reamed canal. This problem may be solved through the use of a floating CAT threshold which calculates the transition between cortical and cancellous bones based on CAT pixel density gradients, rather than absolute thresholds or by smoothing methods that diminished the effect of points that radically deviate from an otherwise smooth contour. The floating threshold has been incorporated.
into the contour algorithm.

An error can also result from trying to reduce the contour data to thirty-six points around each periphery for use in the stem design program by dropping points without regard to the curvature of the contour or angular spacing. Reducing data in this fashion may cause the loss of critical data which defines the curve and thus results in a straight line that falls away from the true canal contour. Later splining of this data cannot restore this lost curve. There are two simple solutions to this problem: first, eliminate the need for data reduction by accommodating all data in the stem design program; second, if data must be reduced, drop the data points according to the curvature of the contour so that the data points along the curves are clustered and points along the straight lines are dropped. The first solution is incorporated into the new stem design program which can accommodate sixty or more points per contour. The second solution has been added to the contour following algorithm.

However, we believe that the imperfect fit of the manually carved prototype is due to hand carving rather than possible errors mentioned above. We were able to eliminate this problem with the aid of the computer.

Although our ACP design procedure discussed so far has been developed primarily to produce a non-cemented prosthesis, it is not restricted to implants designed to make contact with cortical bone but can be applied to cemented prosthesis as well. The desired layer of thickness of cement can easily be obtained using this same procedure.

Currently, there are many different shapes and forms of the cementless porous coated femoral components available on the market. But they can be largely divided into two categories: those stems that are straight in the sagittal plane (Engel and Bobyn 1985; Harris and Galante 1986) and those that are curved (Hedley et al. 1984). The straight stem was preferred by many designers for the following reasons (Stillwell 1987): 1) During impaction, force can be confidently directed in a line with the axis of the stem, thus minimizing disruption of the prepared implant site and the bone-implant interface by toggling or rocking that can occur when impacting a curved stem. 2) Since force cannot be directed around corners but only in a straight line, the straight stem is ideal. 3) The straight stem also minimizes the amount of proximal bone that must be removed in order to orientate the triangular segment of the implant in a proper degree of anteversion. The true calcar femorale, a distal extension of the hypertrophied cancellous bone from the posterior aspect of the femoral neck, is retained with a straight stem design (Griffin 1982; Harty 1957). 4) Rotating the combined rod and triangular implant segments to a proper degree of anteversion is immeasurably easier with a straight stem than with a curved stem. 5) Finally, the same component can be used for both the right and the left femur.

However, there are also many disadvantages with a straight-stemmed prosthesis (Stillwell 1987): 1) A straight stem tends to straighten the femoral canal and rely on the three-point fixation (at the posterior margin of the proximal end, at the apex of the curve anteriorly at the level of the lesser trochanter, and at the posterior diaphyseal cortex at the tip of the prothesis). 2) The three-point fixation method requires the shaping of a cavity into which to insert the prosthesis. This cavity necessarily is incongruous with the natural cavity. This also means that the quality of the bone at the prosthesis-bone interface can be quite different in different areas of contact. While the prosthesis is firmly apposed to the cortical bone at a few points of maximum contact, it comes into contact with loose cancellous bone where the prosthesis falls away from the natural curves of the canal. 3) The prosthesis must be twisted in the canal in order to achieve normal anteversion of the femoral head and neck, which is a further departure from the natural anatomy. 4) Finally, if there has been either damage to the entire isthmus or if there is a pathologic degree of femoral bowing, the anterior curve to the femur will not allow a straight stem prosthesis to be inserted.

On the other hand, the curved stem is designed to specifically follow the natural curve of the proximal femur so as to optimize contact between the prosthesis and the medullary canal. Furthermore, femoral anteversion can be built into the prosthetic component so that the center of rotation of the prosthetic femoral head can attain a proper relationship to the femoral shaft. This anteversion helps to minimize dislocation in the position of full flexion. Another advantage of the curved femoral stem has to do with the fact that its axis of posterior rotation is outside the curved neutral axis of the stem. When pressure is applied anteriorly to the prosthetic head, this mechanical feature of the prosthesis helps to reduce rotational movement of the prosthetic stem within the canal. The stem gets its support from its interference fit, which provides even distribution of stress to the surrounding bone. In addition, subsidence is resisted by the posteriorly directed anatomical bow of the stem which abuts the distal end against the anterior cortex (Stillwell 1987).

Currently available curved stems also have several disadvantages: 1) They have an exaggerated curve.
Therefore, the radii of the curvature of the implant and the shaft do not always coincide. When this occurs, the curved stem tip impinges on the anterior cortex of the femur and inadvertently results in a three-point fixation. 2) Although the curved system conforms to the physiological contours of normal femoral anatomy and has multiple points of fixation in the medial and lateral plane, often fixation in the sagittal plane is inadequate. 3) Due to its curvature, the length of the curved stem tends to be shorter compared with the straight stem. 4) And, it is necessary to design independent right and left femoral components and therefore inventory is increased.

We have designed our prosthesis incorporating specific features to eliminate the drawbacks of the currently available models of hip prosthesis (straight as well as curved), as much as possible, as follows:

1) The stem of ACP is anatomically contoured to obtain total contact with the cortical bone. This feature is desirable, particularly for the proximal portion of the femur since the strength of cancellous bone is known to decrease rapidly at instances in excess of 3 millimeters from the cortical wall (Halawa et al. 1978). Attempts to fix femoral stems in weak cancellous bone seem to have been unsuccessful due to failure of the bone-cement interface (Sutherland et al. 1982).

2) ACP stems are longer than the commercially available curved stems and are comparable to straight stems in length. We have sought to obtain this length by lessening the stem curvature in the sagittal plane (6 degrees). This feature allows the ACP stem to engage firmly both in the proximal and in the isthmic portions of the canal, thus increasing the stability of the implant, and assuring correct alignment of the stem in the femoral shaft.

3) Slight curvature of the ACP stem can prevent the stem tip from impinging on the anterior cortex of the femur.

4) ACP is designed to minimize rotational instability by maximizing the filling of the stem in the proximal portion of the femur. Significant torsional forces are generated in many daily activities, particularly in rising from a chair or ascending stairs. When less close-fit prostheses are used, often migration of the femoral component into retroversion is evidenced (Dorr 1984; Tullos et al. 1984). The close-fit feature of ACP is intended to solve this problem.

5) ACP has a porous coating on the proximal one-third of the stem which eliminates the stress-shield effect on the bone while increasing interfacial shear strength by bone ingrowth into the pores. The bond between the porous fiber-metal material and substrate is formed at a comparatively low temperature. Also this technique retains the integrity of the microstructure of the titanium alloy. The fatigue notch effect is offset by the larger cross-sectional area of the proximal stem.

6) ACP has options to go with either a collared or collarless stem. The function of proximal medial collars has been a subject of considerable debate. Crowninshield et al. (Crowninshield et al. 1981; Crowninshield et al. 1980) reported that with a collarless prostheses the maximum calcar compressive stress is reduced by 80-90 per cent from physiologic levels. Collared prostheses have a potential to attenuate this loss of stress and to load the proximal femur at 50-70 per cent of physiologic levels. Also, Tarr et al. (Tarr et al. 1981; Tarr et al. 1979) have demonstrated in finite element stress analysis experimental studies that the collar increases stress transfer to the medial cortex only in conjunction with the most flexible prostheses, particularly those manufactured from a titanium alloy. We personally prefer a collared to a collarless prosthesis. However, to extend surgical latitude and also to accommodate different surgeon's philosophies, we designed ACP with both options.

7) ACP has a 135 degrees femoral neck-shaft angle. The angle has been determined on the basis of Noble's study (Noble et al. 1986), which again has been confirmed in our own study.

8) The Morse-tip neck of the ACP has the versatility of modular sizing, which helps to reduce inventory investment as well as storage requirements. As for the acetabular component also, there are several different models available on the market which can be divided into three groups according to their shapes: cylindrical, square and hemispheric. Cylindrical acetabular components leave large gaps between the implant and the bone and require removal of a bone stock if a better fit is desired. Moreover, with the cylindrical component, there is a higher rate of risk of medial wall penetration, as Judet et al. have reported (Judit et al. 1978). On the other hand, square acetabular components allow limited adaptability in component positioning in the acetabulum (Griss et al. 1976); malpositioning can lead to early failure, dislocation, or fracture of the pelvis.

Compared with the other two, hemispheric design has distinct advantages: 1) because its shape is congruent with the shape of the acetabulum, minimal bone resection is required; 2) risk of medial wall failure is less; and 3) there is greater adaptability for posi-
tion the component so as to maximize the area of contact between the implant and the bone. There is, however, one drawback: namely that, immediate stabilization is more difficult with the hemispheric design.

In our ACP model, we adopted the hemispheric design and sought to obtain immediate stabilization by using two peripheral fixation pegs and optional central screws.

Currently several techniques have been developed to enhance the stability of the acetabular implant. One is to engrave threads on the acetabular cups. Threaded acetabular cups have two disadvantages: 1) it requires excessive removal of the bone; 2) once the threads are cut, alteration of the orientation of the acetabular component is difficult, if not impossible.

Another technique uses independent screws to fix the acetabular component. However, this method can put intra-abdominal contents at risk if the screws are too long or malpositioned. Also, since the pull of screws can be divergent, there is a possibility that a screw may tighten the prosthesis in one direction, pulling it away from the bone. Moreover, whereas screw fixation is principally to resist the tensile movement, the acetabular component is not subjected to tensile forces. Therefore, this form of fixation seems to be superfluous in the majority of cases. Occasionally, however, this technique proves to be useful where a bone graft and acetabular component needs to be fixed to the host bone with the same screw.

A technique using peripheral pegs is claimed to be sufficient to stabilize the prosthesis against tilting and rotational force. One disadvantage of this method is the inevitable violation of the peripheral rim of the acetabulum.

Still another technique, spikes are set deep into the acetabulum for tight impaction and stabilization against rotational, translational, and tilting forces. A spiked acetabular component allows easy insertion and safeguards the peripheral rim of the acetabulum, yet at the same time, it may result in incomplete seating of the cup with limited contact between the porous surface and the prepared acetabular bed (Engh 1983).

ACP synthesizes the strong points of different methods: 1) peripheral fixation pegs are relatively smaller (4.5 millimeters in diameter) than other systems for less damage to the peripheral rim of the acetabulum; 2) there is an option of central screw fixation when revision cases with bone graft and also when peripheral fixation by pegs is not rigid enough.

ACKNOWLEDGEMENTS

The authors are most grateful to Gyu-Seop Lee, Ph.D., Department of Mechanical Engineering, Yonsei University, for his computer work. We also would like to express our appreciation to Vana E.M. Kim, Ph.D., for her advice and encouragement in preparing this paper.

REFERENCES


Charnley J: Low friction arthroplasty of the hip. Springer-Verlag, New York, 1979


Engh CA, Bulyo JD: Biological fixation in total hip arthroplasty. Slack, Inc., Thorofare, New Jersey, 1985


Harris WH, Calanfe JG: Harris/Calanfe porous hip prosthesis, Zimmer, Inc. Warsaw, Indiana, 1986
Anatomical Contact Porous Coated Total Hip Prosthesis


