Microsection analysis of cortical form-fit of a custom femoral component in total hip arthroplasty: an in vitro study

Ulf Gunther Leichtle,1 Carmen Ina Leichtle,1 Franz Martini2
1University Hospital Tübingen; 2Schwarzach Hospital, Germany

Abstract

Custom femoral components have been developed for total hip arthroplasty to maximize cortical form-fit and thereby to reduce the problems of stress shielding and aseptic loosening. Limited information is available about how much endosteal cortical contact can actually be achieved with these expensive implants. The aim of this study was therefore to verify the exact cortical contact of a custom made stem using microsections and comparing it to a standard stem with similar design. In 8 human femurs (3 matched pairs and 2 separate specimens), custom femoral prostheses (Adapta; 5 femurs: 3 matched and 2 separate) and conventional femoral prostheses (Alloclassic; 3 matched femurs) were implanted. Endosteal cortical contact was determined from CAD planning drafts and microsections cut from the specimens with a diamond saw. Microsection analysis of the paired femurs showed that contact between prosthesis and bone varied clearly along the length of the femoral stem. Total cortical contact was considerably greater in custom prostheses than conventional prostheses (custom, 47%; conventional, 32%), but markedly less than the total contact predicted by the manufacturer (84% to 90%). The custom prosthesis had more lateral cortical contact on CAD planning drafts (cortical contact: medial, 60%; lateral, 53%) than on specimen microsections after implantation (medial, 64%; lateral, 24%).

In summary, the philosophy of anchorage of both prostheses types could be confirmed. However, areas of cortical contact of the custom made prosthesis were considerably smaller compared to the pre-operative planning.

Introduction

For endoprosthesis treatment of the arthritic hip joint a variety of implants is available. The femoral components of conventional total hip endoprostheses are usually available in standardized shapes in various sizes to offer surgeons the opportunity to select the best fitting size. More recently, custom femoral components have been designed, based on the concept don’t fit the bone to the prosthesis, but the prosthesis to the bone (Aldinger, 1983), but there is controversy about the relative benefits of custom prostheses. It has been suggested that a high percentage of cortical form-fit of custom implants may decrease the frequency of aseptic loosening and improve long-term stability; however, bone density studies (post-operative follow-up, 5 years) have shown that a custom femoral component (evolution hip endoprosthesis) may not prevent a reduction in periprosthetic bone density and stress shielding, despite a high form-fit. Clinical long-term results remain to be seen. An early custom endoprosthetic design from the 1980s (Evolution) was circumferentially fitted to fill the entire medullary canal, and implantation of this voluminous stem necessitated removal of almost the entire cancellous bone of the proximal femur. Therefore, to decrease the large loss of cancellous bone, another custom endoprosthesis was developed (Adapta hip endoprosthesis). The 3-dimensionally fitted, round-oval design of the earlier model (Evolution) was replaced with a 2-dimensionally fitted case form (Adapta). This longitudinally fitted, rectangular prosthesis stem (Adapta) was designed to have improved proximal press- and form-fit, homogeneous force transmission, improved rotational stability and decreased loss of cancellous bone. The stem was designed to contact the entire length of the medial and lateral cortex, and the anterior and posterior sides of the femoral stem were not fitted to the cortical bone, allowing preservation of the anterior and posterior cancellous bone (Figure 1).

Problems with custom implants include the higher cost compared with conventional, standardized endoprostheses. Achieving optimal custom prothetic fit requires strict adherence to implantation depth, implantation angle, and specific site for opening the marrow cavity. Planning errors may cause poor surgical results. Every custom prosthesis is unique and standardized quality control is difficult or impossible. Although the developer of the custom prosthesis had requested 50% minimum cortical contact, the manufacturer has claimed that it is possible to achieve 85% to 90% cortical contact on the medial and lateral sides of the femoral stems at the metaphysis (Adapta prostheses). This high cortical contact in the proximal part of the femur would be expected to decrease the problem of stress-shielding and decrease micromotion at the bone-prosthesis interface, allowing better bone ingrowth. However, a biomechanical study showed only comparable, not greater initial stability of this custom femoral stem (Adapta) than a conventional femoral stem (Alloclassic), and the clinical and radiographic outcomes also were not improved compared with a conventional cementless hip prosthesis. Furthermore, a study with computed tomography (CT) in femur specimens showed that endosteal bone contact of these custom implants was only 21%. The CT scans had been analyzed with a special software program that described the periprosthetic inner cortical bone structure, stem surface and contact between the implant and endosteal bone. But despite high quality CT scans, new software programs and improved hardware, a comparative study of CT scans and microsections of the proximal femur showed that the analysis of the interface between the implant and bone was hindered by artefacts from scattered radiation.

The purpose of the present in vitro study using microsections was to investigate, whether the high cortical form-fit calculated in the CAD-planning of the individual stems (Adapta) can be reached by exact implantation in human bones and to compare the results with a conventional (Alloclassic SL) femoral component with a similar design. Therefore we developed a modified method to embed the entire proximal femur and the implanted femoral stem in polymethylmethacrylate and this enabled the creation of...
Materials and Methods

Human cadaver femurs (8 specimens; 3 matched pairs and 2 separate specimens) were dissected and deep frozen until further processing. A custom prosthesis (Adaptiva, endoPro, Kleinostheim, Germany) was implanted in 5 femurs (3 of the matched specimen pairs and 2 individual specimens) and a conventional prosthesis (Alloclassic Hip System, Zimmer, Warsaw, IN) was implanted in 3 femurs (3 of the matched specimen pairs).

The 5 custom prostheses were manufactured with data from CT scans of the corresponding femurs at defined intervals along the bone, and computer planning gave information about resection height, implantation depth, implantation angle, and the size of the final standard rasp before progressing to the custom implant rasp. Implantation of the 3 conventional prostheses was planned with anteroposterior and lateral radiographs, and templates were compared with the radiographs to determine size of the prosthesis.

The femurs were stabilized in a holding clamp during the implantation procedure to ensure stable fixation. The femoral stems were implanted press-fit (cementless), with attention to achieve the exact resection height, implantation depth, and implantation angle calculated by the manufacturer. Anteroposterior and lateral radiographs and computed tomography scans were made of all femurs after implantation to document the implant position.

After implantation of the prostheses, the proximal femurs (proximal half: length 21 to 23 cm; diameter ≤ 6 cm) including the implanted prostheses were embedded in polymethylmethacrylate (PMMA, Merck-Schuchardt, Hohenbrunn, Germany) with a modified method of embedding developed specifically for large specimens. Microsections were cut from the cement blocks (20 sections per specimen; section thickness, 1 mm) along the entire length of the prosthesis, at 8 mm intervals starting at the proximal prosthesis base, with a diamond band saw in contact point mode (EXAKT 310 CP, EXAKT Apparatebau GmbH & Co.KG, Norderstedt, Germany). Care was taken to position the sections perpendicular to the longitudinal axis of the femoral stem.

The CAD planning drafts and the specimen sections were scanned true-to-scale (Epson GT 7000 Photo Scanner with Epson TWAIN software, Seiko Epson Corp., Nagano, Japan) and were analyzed with evaluation software (CorelDRAW Version 9.0, Corel Inc., Mountain View, California, United States of America). A measuring tape was attached to the specimens and CAD images to ensure they were scanned 1:1 without image distortion (Figure 2). Each microsection was divided into 6 regions (medial, posteromedial, posterolateral, lateral, anterolateral and anteromedial) (Figure 3). The length of cortical contact along the medial and lateral edges of the prosthesis was measured.

Table 1. Cortical contact of custom and conventional femoral components.

| Region along stem       | Length of contact between prosthesis and bone (mm) | Custom | Conventional |
|-------------------------|---------------------------------------------------|--------|--------------|
| Proximal third (inter-   |                                                   |        |              |
| trochanteric) Medial    | (femoral neck)                                   | 6.2 (1.2 to 10.9) | 100% | 1.6 (0 to 10.5) | 60% |
| Lateral (great trochant-| (proximal neck)                                  | 1.6 (0 to 10.3) | 10% | 0.6 (0 to 3.3) | 60% |
| er) Width of implant    |                                                   | 10.5 (9.2 to 11.3) | --- | 11.2 (10.5 to 12.2) | --- |
| Middle third (subtrochanteric) Medial | (mid-shaft) | 6.6 (1.5 to 9.8) | 60% | 6.4 (0 to 10.2) | 60% |
| Lateral (mid-shaft)     |                                                   | 3.7 (0.5 to 8.5) | 40% | 2.7 (0 to 10) | 40% |
| Width of implant        |                                                   | 8.9 (7.6 to 9.8) | --- | 9.9 (9.2 to 10.8) | --- |
| Distal third (diaphyseal)|                                                   |        |              |
| Medial (distal)         |                                                   | 2.2 (0 to 8.3) | 60% | 2.8 (0 to 9) | 60% |
| Lateral (distal)        |                                                   | 4.4 (0 to 7.5) | 60% | 4.2 (0 to 9) | 60% |
| Width of implant        |                                                   | 7.3 (6 to 8.3) | --- | 8.5 (6.8 to 9.5) | --- |
| Total prosthesis        |                                                   | --- | 47% | --- | 32% |

N=3 custom and 3 conventional prostheses implanted in matched femurs. Data (length of contact between prosthesis and bone) reported as mean (range) (percentage of prosthesis width).

Table 2. Cortical contact of custom femoral components: comparison of CAD planning drafts and microsections of specimens.

| Region along stem       | Manufacturer's planning | Corresponding CAD planning slices | Microsection analysis |
|-------------------------|-------------------------|----------------------------------|-----------------------|
| Medial Cortical contact (mm) | -                       | 6.2 (2 to 11.6)                 | 6.4 (1.2 to 10.9)     |
| Width of implant (mm)    | -                       | 10.2 (8.5 to 11.4)              | 10.1 (8.6 to 11.4)    |
| Cortical contact 90%     | -                       | 60%                              | 64%                   |
| Lateral Cortical contact (mm) | -                       | 5.4 (1.5 to 11.6)               | 2.4 (0 to 10.3)       |
| Width of implant (mm)    | -                       | 10.2 (8.5 to 11.6)              | 10.1 (8.6 to 11.4)    |
| Cortical contact 84%     | -                       | 53%                              | 24%                   |

N = 3 custom prostheses. Cortical contact (length of contact between prosthesis and bone) and width of implant reported as mean (range); cortical contact also reported as percentage of prosthesis width.
Figure 2. Microsections (thickness, 1 mm) cut from proximal femur after implantation with custom prosthesis (Adaptiva, top row) and conventional prosthesis (Alloclassic, bottom row) (proximal, left; distal, right).

Figure 3. Microsection showing femoral stem surfaces divided into 6 regions for determination of cortical contact.

Discussion

The present results showed that the total average endosteal cortical contact of the custom femoral stem (Adaptiva) tested (47%) was greater than that achieved with a conventional femoral stem (Alloclassic) (32%), but less than the manufacturer’s prediction of 84% to 90% cortical contact (Tables 1 and 2).

The least cortical contact of the custom prosthesis was observed at the greater trochanter (lateral aspect of proximal third), and the cortical contact at the subtrochanteric (middle third) and diaphyseal (distal third) regions was only approximately 10% greater than that achieved with the conventional prosthesis; however, the cortical contact at the calcaneal (medial aspect of proximal third) was markedly greater for the custom than the conventional femoral stem (Table 1), consistent with the metaphyseal-intertrochanteric-diaphyseal anchoring concept of the custom prosthesis. Therefore, the current results support the philosophy of this custom implant with a good cortical contact along the entire length of the prosthesis.

The cortical contact of the conventional stem was primarily in the diaphyseal (distal third) and subtrochanteric (middle third) regions according to his philosophy, although contact was not necessarily planned in the metaphyseal (proximal third) region, some cortical contact was achieved (Table 1). This is evidence of an intertrochanteric-diaphyseal press-fit for immediate primary stability of this prosthesis. Although the first generation conventional (Zweymüller-Alloclassic) prosthesis had an average 3 mm subsidence in 13% to 50% patients, all other studies with this prosthesis have noted subsidence of >3 mm in only 1% patients or no patients. The rectangular shape of the basic design of the custom and conventional prostheses resulted in similar cortical contact for these 2 prostheses.

In the present analysis of the microsections of the custom prostheses, good medial contact was noted, consistent with planned contact, but less than half of the planned lateral contact was observed (Table 2). For the custom prosthesis stems, the discrepancy in cortical contact between the prediction by the manufacturer and the observed medial and lateral contact (Table 2) may have resulted from failure of the planning software of the manufacturer to accurately recognize the inner cortex on the CT scans. The construction software seemed unable to recognize the lateral metaphyseal cortex correctly in the preoperative CT scans, in planning, the cortical bone was often assumed to be too thick. Furthermore, it was often difficult to achieve the correct implantation depth and angle of anteversion of the prosthesis because of the exact identification of the reference point for depth (the highest point of the greater trochanter) and achieving the correct implantation depth may have increased the risk of developing a periprosthetic fracture.

Conclusions

Nevertheless, the study confirmed satisfactory cortical contact with both custom and conventional femoral components, even though the custom stem had less cortical contact than planned by the manufacturer. It appears advisable to reserve the custom femoral component for special indications, such as marked post-traumatic or congenital deformities of the medullary cavity, because cortical contact with the conventional implant may be comparable, with less elaborate planning and cost, than with the custom implant.

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