Radiological changes in second- and third-generation Zweymüller stems

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The Alloclassic and Endoplus femoral stems have the same grit-blasted surface and are hot forged from the same titanium alloy. Only the external form of the implants differs slightly. It was our aim to examine the differences in radiographic bone response between the Alloclassic (second generation) and the Endoplus (third generation) femoral stems.

We compared 79 prostheses in 70 matched patients studied over a minimum of two years. Radiolucent lines, adaptive bone remodelling, subsidence, heterotopic bone formation and lysis were recorded in the Gruen zones.

Radiolucencies were mainly found in zones 1 and 7 but to a greater extent in the Endoplus than in the Alloclassic group (p < 0.001 in zone 1, p < 0.05 in zone 7). We found lucent lines in three or more Gruen zones in seven patients all of whom were in the Endoplus group (p < 0.05). Zones 2 and 6 had a significantly higher rate of lucencies in the Endoplus group (p < 0.001). We encountered a combination of proximal lucent lines in zones 1 and 7 with distal hypertrophy of the cortical bone in zones 2, 3, 5 and 6 in eight patients, all from the Endoplus group (p < 0.05). In other patients bone atrophy (stress shielding) in zones 2 and 6 was seen more frequently in the Endoplus than in the Alloclassic group (p < 0.001). In neither group was there radiological evidence of osteolysis.

Heterotopic bone formation and subsidence occurred with similar frequency in both groups.

Our study shows that a small change in the form of the femoral implant can result in statistically significant radiological changes in bone remodelling. Whether this will result in clinical compromise is unknown. However, it seems likely that the Endoplus femoral stem will perform differently from the Alloclassic.

In the 1980s Zweymüller developed a cementless, straight, tapered femoral stem with a rectangular cross-section, made from Ti6Al7Nb.1,2 The Alloclassic femoral implant, introduced in 1986, has been referred to as the second rendition and the Endoplus implant, introduced in 1992, as the third.3 Published reports with a minimum follow-up of at least ten years have established uniform and satisfactory radiological and clinical outcomes for the Zweymüller femoral stem.4-8 Garcia-Cimbrello et al4 and Grubl et al7 showed excellent results in a follow-up study over ten to 13 years with no need for revision of the stem for aseptic loosening. Although they described lucent lines with subsidence in some hips, all became stable. Traulsen, Hassenplug and Hahne9 described a survival rate of 96% for the stem after ten years in a series of 165 cases. Ten-year follow-up studies are not yet available for the Endoplus stem.

Both types of stem have the same grit-blasted surface, hot forged from titanium alloy.

The surgical techniques of bone preparation and insertion are identical and both have a finely structured surface with a mean roughness of 3 to 5 µm². Only the external form of the implants differs. Our goal was to discover whether there are any radiological differences between the Alloclassic and the Endoplus stems.

Patients and Methods
From a pool of 257 patients, two groups of 70 were matched for age, gender, weight, height and bone type. The match for age was within five years, and for weight within 10 kg. Matching of both types was categorised according to Dorr et al.10 Table I gives the details of both groups.

There were 79 Endoplus stems (PLUS Endoprosthetic, Rotkreuz, Switzerland) implanted into 70 patients and 79 Alloclassic stems (Centerpulse, Zurich, Switzerland) in 70 patients. All patients were evaluated radiologi-
cally. In those with bilateral endoprostheses, only the right side was included. All had two-week and a minimum of two-year-follow-up radiographs. The diagnosis at the time of operation for the Endoplus group was degenerative arthritis in 56 patients and fracture of the femoral neck in 14. For Alloclassic patients the diagnosis was degenerative arthritis in 55 and fracture of the femoral neck in 15. All acetabular implants were metal-backed with a modular polyethylene-articulating surface. The diameter of the femoral head was 28 mm in 65 of the Endoplus patients and in 16 of the Alloclassic patients. Femoral heads of 32 mm were used in five of the Endoplus and in 54 of the Alloclassic patients. All were made of cobalt-chrome except for 35 of the Endoplus group and 34 of the Alloclassic group which were manufactured in ceramic. No stem had hydroxyapatite or cement fixation.

A single orthopaedic surgeon (MW), who was not involved in the surgery or rehabilitation, reviewed all radiographs as the independent observer. The other author (DKL) implanted all the hips using the same posterior mini-incision technique with the same rehabilitation programme and the same follow-up protocol.11,12 Patients were allowed, if able, to bear weight on the first post-operative day. The surgery was performed in two different hospitals; in one, only the Alloclassic stem was available and in the other, only the Endoplus stem.

Standard anteroposterior (AP) radiographs of the affected side were taken at two and at six weeks after operation, at six and 12 months, and thereafter annually for up to 13 years. Care was taken to standardise the radiographic technique. In all cases the two-week, post-operative radiograph was on the screen for comparison with each subsequent film. The findings were considered to be positive for radiolucent lines if there was a gap of 1 mm at the bone-prosthetic interface which involved more than half of each Gruen zone. Bone adaptation required value judgement and was assessed in a similar fashion. Stress shielding was graded according to the protocol of Bugbee et al.13 Briefly, AP and Lowenstein lateral radiographs were taken to match the contrast and orientation of the two-week post-operative radiograph. The femur was then divided into 16 discrete

<table>
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<tr>
<th>Category</th>
<th>Endoplus group</th>
<th>Alloclassic group</th>
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<tbody>
<tr>
<td>Male:female</td>
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<td>48:22</td>
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<tr>
<td>Mean age in yrs (range)</td>
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<td>68.76 (36 to 95)</td>
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<td>Mean weight in kg (range)</td>
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<td>Mean height in m (range)</td>
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<td>Bone type10</td>
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<td></td>
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<tr>
<td>A</td>
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Table I. Patient details of the Endoplus and Alloclassic stems
areas. The criterion for bone remodelling at each site was simply whether the bone appeared darker, thinner or more osteopenic on the two-year radiographs compared with the first post-operative films.

The mean duration of follow-up was 44.6 months (24 to 120) for Endoplus and 46.8 months (24 to 120) for Alloclassic patients. Radiolucent lines, lysis and adaptive bone remodelling were evaluated in the zones described by Gruen, McNiece and Amstutz.14 The measurement of subsidence was performed according to Sutherland et al.15 Subsidence was defined as a change in the distance between the top of the stem and the top of the greater trochanter over time. Heterotopic ossification was assessed according to the classification system of Brooker et al.16

Statistical analysis. All data were analysed statistically and p values determined by the two-tailed Fisher exact test. A level of 0.05 was used to indicate statistical significance.

Results
In both groups radiolucencies were mainly found in zones 1 and 7. Figure 1 shows the incidence of lucent lines which was significantly higher in the Endoplus group compared with the Alloclassic group (p < 0.001 in zone 1, p < 0.05 in zone 7).

The first post-operative radiographs showed no radiolucencies in either group. After two years there were distinct radiological changes (radiolucent lines) in Gruen zones 1 and 7. Zones 2 and 6 had a significantly higher rate of radiolucency in the Endoplus group (p < 0.001). We found lucent lines in three or more Gruen zones in seven patients from this group (p < 0.05).

Figure 2 shows the occurrence of bone atrophy (stress shielding) which was found mainly in Gruen zones 1 and 7 in both groups. The Endoplus group had a higher incidence of stress shielding in these two zones but it did not reach statistical significance. Zones 2 and 6 showed greater bone atrophy in the Endoplus group (p < 0.001 for zone 2 and p < 0.001 for zone 6).

In addition, we encountered a combination of proximal lucent lines in zones 1 and 7 with distal hypertrophy of the cortical bone in zones 2, 3, 5 and 6 in eight patients, all from the Endoplus group (p < 0.05; Fig. 3). This was not observed in the Alloclassic group. The Harris hip scores for the eight Endoplus patients with these radiological abnormalities was not different from those of the Alloclassic group.11 No patient had a pain score below 40.

Precise measurement revealed that four Endoplus and one Alloclassic stem had subsided by up to 5 mm but this observation did not correlate with radiolucent lines. Two stems in the Endoplus and two in the Alloclassic group were inserted in a slightly varus position. In neither group was there evidence of infection or osteolysis.

Heterotopic ossification of grade I was found in two patients from the Endoplus and in one from the Alloclassic group. Three patients in each group developed ossification of grade II and one from the Endoplus group had grade-III heterotopic ossification. No patient from either group required revision surgery.
Discussion

This study allowed the unique opportunity to examine a single surgeon’s experience with two implants which differed only slightly in external shape, in order to determine if they would show radiological differences. Radiological remodelling was more unpredictable with the Endoplus than with the Alloclassic stem. According to Zweymüller and Zweymüller, Lintner and Böhm only clinical and radiological follow-up studies will show the quality of the implant. The use of a minimum of two-yearly radiological comparative studies of bone remodelling has been validated in the orthopaedic literature. Early radiological findings have been shown to predict the subsequent clinical outcome as described by Khalily and Whiteside and Kobayashi et al. Several studies of more than ten years in duration have revealed excellent and consistent results for the Alloclassic prosthesis.

Tapered femoral systems have also been shown to be reliable. The surface texture of both implants is grit-blasted by the same technique. Many prostheses with grit-blasted surfaces have shown osseointegration. As can be seen in Figures 4 and 5, the most important difference between these two implants is the larger proximal surface of the Endoplus stem. The trochanteric wing is unchanged.

Radiolucent lines can be misinterpreted. According to Huiskes and Bugbee et al radioluencies are signs of stress shielding and it is possible that in time they may lead to aseptic loosening. Several ten-year follow-up studies with the Alloclassic stem have failed to show that these radiological changes lead to loosening of the femoral stem or clinical compromise and they confirm our two-year
radiological findings with the Alloclassic stem. Mostly, the lucenties appear in the proximal femur and do not progress.\textsuperscript{3,5,17} Zenz et al\textsuperscript{28} also described lucent lines in the proximal femur which did not progress. Radiolucenties in the proximal femur did not appear to influence the clinical outcome as shown by Dohle, Becker and Braum,\textsuperscript{29} Garcia-Cimbrello et al\textsuperscript{4} and Grubl et al.\textsuperscript{7} Radiolucenties may also be the product of the preparation and implantation. Minor deviations while rasping may disturb cancellous bone in the proximal femur.\textsuperscript{31} The recognition that the preparation of bone can lead to variations in radiolucenties resulted in the development of bone compaction broaches exactly duplicating the tapered systems inserted to attain an interference fit. The surface finish of the broaches and the size of the hand-powered sliding hammer were exactly the same in both groups. According to Ludwig, Melzer and Backofen\textsuperscript{32} radiolucent lines of more than 2 mm indicate loosening of the stem. Khalily and Whiteside\textsuperscript{19} maintained that the frequency of radiolucent lines had the greatest sig-

In both groups there was stress shielding in Gruen zones 1 and 7; this is not uncommon in hip arthroplasty.\textsuperscript{33-35} Continuous unloading of bone may lead to its resorption. The hypothesis of proximal stress shielding of bone has been proposed in theoretical as well as in experimental studies.\textsuperscript{36-39} Maloney et al\textsuperscript{40} observed that stress shielding correlated with the pre-operative condition of the bone. In eight patients (11\%) with the Endoplus stem, we found that the combination of proximal radiolucent lines in three or more zones with distal bone hypertrophy, could be interpreted as an indirect sign of an ongoing instability and stress concentration.\textsuperscript{41} This finding was statistically significant (p < 0.05). Ludwig et al\textsuperscript{32} noticed a positive correlation between distal bone hypertrophy and loosening of the stem in an analysis of 618 femoral stems.

Osseointegration cannot of course be demonstrated by conventional radiography.\textsuperscript{32} According to Böhm et al\textsuperscript{31} it should be complete between one and five years. Longer follow-up is necessary to determine the clinical and radiological significance of these findings in the Endoplus patients.

Follow-up studies for the Alloclassic group, over a minimum period of ten years, suggest that these radiological findings are not of clinical significance.\textsuperscript{4,5,9} Cadaver retrieval analysis has clearly shown osseointegration of the Alloclassic femoral stem despite advanced age, osteoporosis and rheumatoid arthritis.\textsuperscript{30,43} There has yet to be a study of the cadaver retrieval of Endoplus femoral stems but one report of early loosening of an Endoplus stem was thought to be due to a metal-on-metal articulation.\textsuperscript{44}

In both our groups full-weight-bearing was encouraged one day after surgery following the protocol of Woolson and Adler.\textsuperscript{45} In neither of the groups has further surgery been undertaken for a loose stem. However, it should be kept in mind that radiological signs consistent with loosening did not appear in the Alloclassic group. Varus positioning of some stems has not led to a radiologically visible reaction. In a previous study the varus position of the Alloclassic stem did not influence the clinical results.\textsuperscript{46}

Our study confirms that small variations of external configuration of the implant can have statistically significant radiological consequences. Measurements of the area and the polar area moments of inertia may have an effect. The area moment of inertia of the cross-section of a beam is related to its capacity to resist bending; the polar area moment of inertia measures a beam’s ability to resist torsion. The larger of each of these measurements in the Endoplus stem results in a ‘stiffer’ implant. Both designs of stem are made in 12 different sizes; and comparing each size, the Endoplus stem has a larger moment of inertia. At the stage
of pre-operative planning there is no indication of difference in size. Consistently, however, the Endoplus stem is slightly larger than the Alloclassic. The differences in the area and the polar area moments of inertia may explain the closer flexural match of the implant-to-bone interface for the Alloclassic stem. This may result in more reliable osseointegration for the more flexible Alloclassic implant.

The most important question remains unsolved. Which factors are responsible for the different radiological changes between these two stems? Manufacturing, procurement of the alloy, contamination and external form are possibilities. Another could be the manufacturing processes which might cause differences in the residual silica or grit-blasted surface variation. Subtle differences in the alloy in terms of unmeasured agents such as carbides or carbon could have affected the modulus or dielectrical potential. Slight variation in external dimensions could affect the area and the polar area moments of inertia and result in subtle interface modular differences which affect stability.

Continuing clinical follow-up will show if these early radiological interface findings and bone responses with the Endoplos femoral stem will correlate with compromised clinical results.

However, given the results of Khalili and Whiteside, there may be a higher incidence of aseptic loosening in the long-term studies for the Endoplos group. These early radiological findings are worrying and may yet affect the clinical results. Considering the excellent clinical and radiological follow-up studies over ten years of the Alloclassic stem, we have decided to stop using the Endoplos stem in favour of the Alloclassic, for the time being.

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

References

4. García-Cimbrello E, Cruz-Pardos A, Madero R, Ortega-Andreu M. The most important question remains unsolved. Which factors are responsible for the different radiological changes between these two stems? Manufacturing, procurement of the alloy, contamination and external form are possibilities. Another could be the manufacturing processes which might cause differences in the residual silica or grit-blasted surface variation. Subtle differences in the alloy in terms of unmeasured agents such as carbides or carbon could have affected the modulus or dielectrical potential. Slight variation in external dimensions could affect the area and the polar area moments of inertia and result in subtle interface modular differences which affect stability.

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