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A clinical, radiological and biomechanical study of the TARA hip prosthesis

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Summary. We reviewed 60 patients with 72 TARA (total articular replacement arthroplasty) resurfacing hip prostheses. To analyse the behaviour of the femoral component a radiographic study was done and a two-dimensional finite element model was constructed. The stem of the femoral component plays a role in the load transfer mechanism. Stress shielding is seen in the proximal femur but depends on the interface conditions. When only the dome of the cup is assumed to be bonded to the bone, the stresses in the head increase dramatically and there is no more stress shielding. Five years after implantation radiographic signs of loosening of the femoral component were seen in 6.8% of the implants placed without notching in the femoral neck and in 28.6% of the components with notching (significant difference, $P = 0.0005$). Signs of loosening of the acetabular component were seen in 37.7% 5 years postoperatively. The cumulative survival rates of the femoral and acetabular components were 89.7% and 85.6% respectively 5 years after implantation. The overall clinical results are represented by an integration of the clinical results (Harris Hip Score System), the radiographic results and the survival analysis. This gave a success rate of only 72% 5 years after implantation.

Because of the disappointing results of conventional total hip replacement in young, active patients [9, 13], resurfacing prostheses became popular in the 1970s and 1980s [2, 7, 18, 28, 38]. The results were again disappointing. In Europe, where the Wagner surface replacement was used predominantly, a number of clinical studies and retrieval analyses were reported [1, 4, 16, 21, 34]. Although the precise causes of the failures have not been demonstrated beyond doubt, a number of hypotheses have been suggested, such as excessive wear particles causing osteolysis of the interfaces, the difficulty of the surgery, inviting errors, the thin polyethylene cup, disturbances of the vascularity under the metal head, and biomechanical causes related to load transfer, stress shielding and interface failure. Biomechanical finite element analyses of the Tharies prosthesis [32], the ICLH prosthesis [31], the Wagner prosthesis [24, 25] and the Gerard prosthesis [39] have been published. In all cases, it was found that the relatively rigid metal resurfacing cup produces unnatural stress-shielding effects in the underlying bone and stress concentrations in the bone around the cup rim. It has been hypothized that the stress-shielding effects cause bone resorption and the stress concentrations produce interface failure and subsequent relative motion, progressively causing lack of stability [25].

The TARA (total articular replacement arthroplasty) resurfacing prosthesis [36] has a thin stem which may have two potential advantages over other surface replacements. First of all, it may provide a guide for implantation, thereby producing a more reproducible orientation. Secondly, the stem may provide additional stability to the prosthesis, thereby reducing the frequency of aseptic failure. The purpose of this study was to test these potential advantages in a biomechanical and a follow-up study. In a finite-element analysis, the contribution of the stem in the load-transfer mechanism was investigated. For the follow-up study, a series of patients with TARA hip replacements performed between 1981 and 1986 were studied clinically and radiographically. By integrating data, an attempt was made to give an overall impression of the clinical outcome of the TARA prosthesis.

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Patients and methods

Between January 1981 and December 1985, 72 TARA hip prostheses were placed in 60 patients, 26 on the right side, 22 on the left side and 12 bilaterally. Twenty-one patients were male and 39 female. The ages ranged from 25 to 70 years, with 18 patients younger than 50 years, 26 between 50 and 60 years and 16 patients beyond 60 years. The hip diseases involved osteoarthritis (45 hips), rheumatoid arthritis (9 hips) and avascular femoral head necrosis (18 hips). Fourteen hips had undergone a previous femoral osteotomy. Initially, surgical exposure was according to Smith-Petersen (32 hips), but after 1983 the Watson Jones anterolateral exposure (40 hips).

In the clinical follow-up study, pain, walking ability and function were rated according to the Harris Hip Score System [20]. The subjective verdict on the hip was registered as satisfactory, fair or unsatisfactory.

A detailed analysis of all available radiograph was performed. The results are reported for 1-year intervals. Two hundred and eighty-five postoperative radiographs of 71 hips were analysed in total. The magnification factor of the radiographs was measured on the basis of the projected diameter of the prosthetic head and data on the real diameter. All measurements were corrected by the magnification factor. The position of the femoral component was determined by the angle between a line through the femoral shaft and a line through the projected distal part of the head of the prosthesis (Fig. 1). In addition, the position of the femoral component was determined by measuring the distance *KL* between the edge of the head of the prosthesis and the cortical outline of the femoral neck (Fig. 1). To assess the effect of notching of the prosthesis in the femoral neck, the distance between the femoral cup and the cranial border of the femoral neck on the first postoperative radiograph was measured. A change in this distance on subsequent radiographs was noted as a sign of migration. Radiographic loosening of the femoral component was assumed if migration of more than 2 mm occurred or if radiolucency of more than 2 mm around the stem of the prosthesis was seen.

The acetabular component was studied radiographically by determining migration and radiolucencies at the interface. Migration was measured relative to the Köhler line and the Hilgenreiner line. Radiolucencies were assessed in three zones according to De Lee and Charnley [12]. Radiographic loosening of the cup was assumed if migration of more than 5 mm was measured, if deformation with subluxation had occurred or if radiolucency of more than 2 mm was seen in one or more zones.

Survival analysis was performed separately for the femoral and the acetabular components. The actuarial method was used to estimate the cumulative survival percentages. To give a better impression of the frequency of success and failure, the clinical, radiological and survival results were integrated, using the actuarial method.

A two-dimensional finite-element model was constructed for the biomechanical analyses of the femoral TARA component (Fig. 2). The model was side-plated to account for the three-dimensional integrity of the resurfacing shell [25]. Cancellous and cortical bone were assumed to be linearly elastic and homogeneous. Loads were variable in magnitude and direction (Fig. 2). The effect of the stem was studied by varying its length between the normal full size, about one-third of that size and no stem at all, the latter representing a similar configuration to other surface replacements. Cup and stem interface conditions were varied as well, assuming either full bonding or sliding contact. Finally, the effects of notching of the prosthesis in the superior bone rim were investigated.

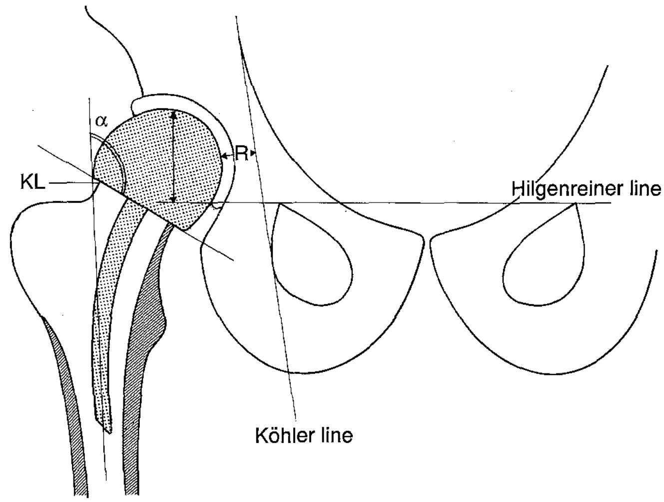

Fig. 1. Diagram of the roentgenogram of the pelvis after implantation of a TARA prosthesis, with angle α between the axis of the femur and the distal part of the femoral component, and distance *KL* between the edge of the head and the cortical outline of the femoral neck

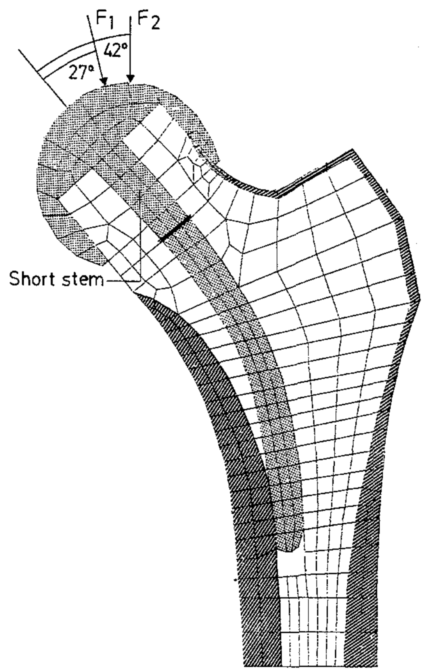

Fig. 2. A mesh of the femoral component of the TARA prosthesis for a two-dimensional finite analysis, with the load varying in direction, and the length of the stem varying from normal length, to short stem, to no stem at all

Results

Biomechanical analysis

It was found that the stress patterns in the bone surrounding the prosthesis are strongly affected by the bonding characteristics of the latter. When both the stem and the interior of the cup are assumed to be fully bonded to the bone, the cancellous bone in the head, particularly superiorly, is to a great extent stress shielded, and the load is transferred mainly inferomedially to the cortex (Fig. 3, C1). When only the dome of the cup is assumed to be bonded to the bone (through cement) and the remaining cup and entire stem can slide without friction against the bone, the stresses in the head increase dramatically and there is no more stress shielding (Fig. 3, C4). The stress concentration in the bone near the tip of the stem (Fig. 3) signifies that the stem does play a role in the load-transfer mechanism, and hence contributes to the stability of the prosthesis. This is again confirmed when the effects of a full-size stem, a short stem and no stem at all are compared (Fig. 4, A1–A3), where proximal stress are less with a short stem than with no stem, and less again with a full-size stem than with a short stem. This means that on the one hand the stability of the prosthesis increases when a stem is present, and that it increases with increasing stem length, but on the other hand that the amount of stress shielding in the femoral head increases as well. The effects of notching were not extensive; in fact, only a very localized stress concentration effect was found.

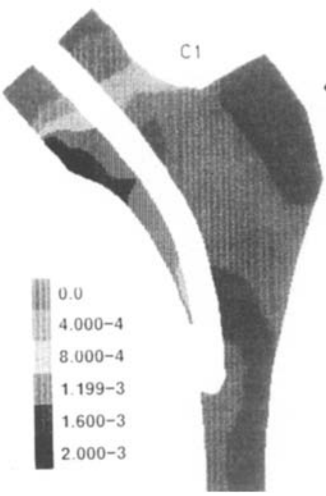

Fig. 3. The stress pattern in the proximal femur after implantation of a TARA prosthesis is represented by the Von Mises stress. In this model low stresses are seen under the cup when all interfaces are fully bonded *(C_1)*. This pattern changes to load transfer at the tip of the stem when only the dome of the cup is assumed to be bonded *(C_2)*

Complications

Complications during surgery occurred in 22 hips. In 13 cases this was related to an incorrect position of the femoral or acetabular component. In 7 cases this was corrected during the same operation. Peripheral nerve lesions were observed in 11.1% of cases. Three patientes suffered a lesion of the lateral femoral cutaneous nerve, while in five a lesion of the femoral or sciatic nerve occurred, with full recovery in four. Postoperative wound complications were noticed in 9.7% (7 cases). In four patients a superficial infection was seen and in three a wound haematoma. Nine patients suffered from general complications; in two of them the complications led to death. One patient developed pancreatitis and one suffered an ischaemic heart attack. In 34 hips extra-articular ossifications were seen; in 14 cases they were classed as grade 2 or 3 in Brookers classification (1973). One patient developed deep infection three years postoperatively. Aseptic loosening is discussed below.

Clinical results

The mean follow-up time was 60 months (range 1–97 months). Average operating time was 115 min (range 75–195 min). In 56 hips a total TARA implant was placed, while in 16 hips only a femoral component was used. Eighteen hips were excluded from clinical evaluation because the patients had died (8 hips), the TARA prosthesis was replaced (6 hips) or the patient was untraceable (4 hips).

No or only slight pain was registered in 68.5% of the hips. In 14.8% of the hips the patients complained of marked or severe pain. After dividing the patients into three categories according to preoperative diagnosis, a better pain score was noticed in patients with rheumatoid arthritis (Mann-Whitney test, $P < 0.005$). A significant relationship between pain score and subjective assessment of the patient was found (Mann-Whitney test, $P = 0.0003$). Gait and activity scores were improved in 85.2% and 88.9% of cases, respectively. The mean preoperative Harris Hip Score was 35 points (range 10–68). At follow-up this was improved to 83.5 points (range 34–100). The mean Harris Hip Scores for the osteoarthritic group (82.0 points), the rheumatoid arthritis group (96.0 points) and the avascular necrosis group (83.5 points) were not significantly different (Kruskall-Wallis test, $P = 0.08$).

The Harris Hip Score of patients with a Quetelet index lower than 25 was higher than that of patients with a index equal to or greater than 25 (Mann-Whitney test, $P = 0.003$). Based on the Harris Hip Score System, including all revised cases in the poor-outcome group, there were good to excellent results in only 51% of the hips (Table 1).

Radiological results

The average varus-valgus position of the prosthesis in relation to the femoral shaft was 145° (range 120°–155°).

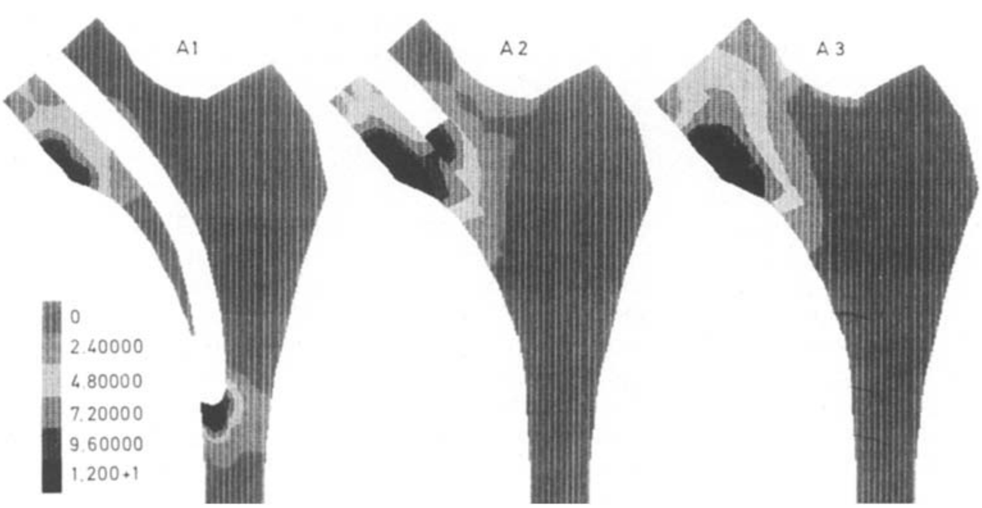

Fig. 4. The stress pattern in the proximal femur represented by the Von Mises stress, with varying stem length between no stem *(A_3)* and full size *(A_1)*. Stresses in the proximal part of the model decrease as the stem lengthens

Table 1. Clinical results of 60 hips, based on the Harris Hip Score System, including revised cases

Result	*n*	[%]
Excellent (90–100 points)	21	51
Good (80–90 points)	10	
Fair (70–90 points)	9	16
Poor or revised (<70 points)	20	33
Total	60	100

This is about the same as the 140° angle between the small femoral stem and the femoral cup of the TARA prosthesis. When the operated hips were divided into those with notching of the femoral cup in the femoral neck and those without notching, a significant difference was found in the distance between the cranial outline of the femoral neck and the distal edge of the femoral cup on radiographs 5 years postoperatively (Mann-Whitney test, $P = 0.005$). Prostheses with notching showed caudal migration.

In some of the implants a sclerotic line developed around the femoral stem. This line was observed on the medial side in 35.9% of the hips, on the lateral side in 54.7% and around the tip in 67%. This phenomenon suggests load transfer at the tip of the stem, according to the biomechanical analysis. In some cases there was complete radiolucency between this sclerotic line and the stem.

A large proportion of the cases showed demarcation around the acetabular cup, increasing in frequency and severity with time. After 5 years 27.6% of the hips showed demarcation of more than 2 mm at the cranial side of the cup. In 10.3% of the hips such a demarcation was noticed at the medial side of the cup, in 10.3% on the caudal side of the cup.

The definition of radiological loosening of the femoral and acetabular components was described above. Five years postoperatively, radiographic signs of loosening of the femoral component were present in 11.7% of cases; and loosening of the acetabular component in 37.7% of cases. There was a significantly higher incidence of radiological loosening of the femoral component in hips with notching of the prosthesis (De Lee statistics, $P = 0.0005$). Of hips without notching of the femoral component, only 6.8% showed radiographic loosening 5 years postoperatively (Fig. 5).

Survival analysis

Additonal surgery was performed in 12 of the 72 cases. In 3 cases only the acetabular component was revised; in 3 hips an exploratory operation was performed. Six cases required conversion to a conventional total hip prosthesis. No further complications occurred in any of these six hips. A survival analysis of the TARA prosthesis was performed, according to the actuarial method. The analysis was based on the objective assessment of revision of the acetabular or femoral component at the end of the follow-up period. The survival rates for the femoral and

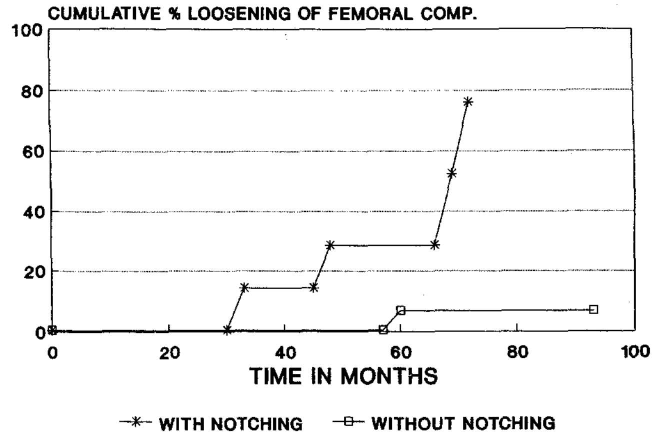

Fig. 5. Difference in cumulative percentages of radiological loosening of the femoral component in implants with notching versus without notching in the femoral neck (De Lee statistics, $P = 0.0005$)

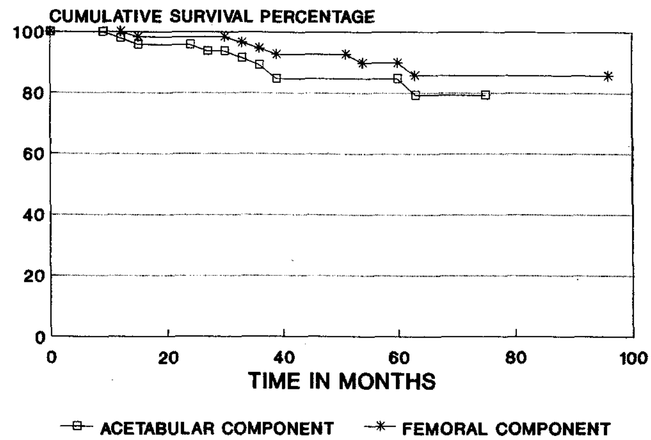

Fig 6. Survival curves of the TARA prosthesis, with separate lines for the acetabular and the femoral component

acetabular components 5 years postoperatively were 89.7% and 85.6%, respectively (Fig. 6).

Success and failure

To give a better impression of the incidence of success and failure, the clinical, radiological and survival data were integrated. The definition of failure was a hip with one or more of the following:

- Exchange of the femoral component
- Exchange of the acetabular component
- Total Harris Hip Score lower than 70 points
- Pain with radiographic signs of loosening of one or both components
- Deep infection

With this definition, 45 hips could be counted as successes and 22 hips as failures. For 5 hips information was lacking to score them as either a failure or a success. Using the actuarial method, it was estimated that a successful result will be present in 72% of hips after 5 years postoperatively and in 42.2% 6 years postoperatively (Fig. 7). The hips in the rheumatoid arthritic category

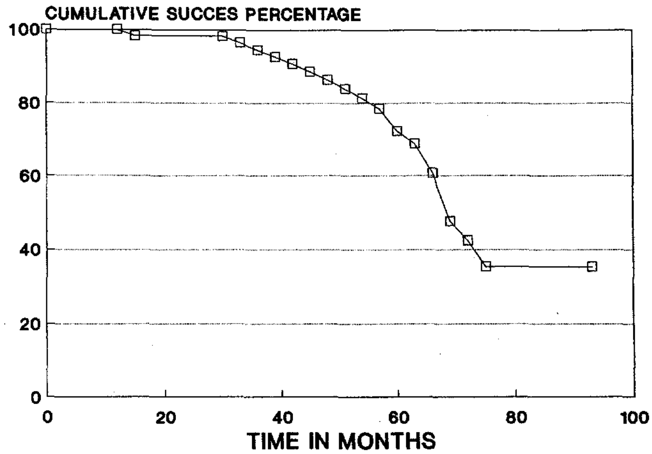

Fig. 7. After integration of radiological and clinical data, the cumulative percentage of "successes" diminishes with time, down to 72% 5 years after implantation

showed a higher success rate (De Lee statistics, $P=0.098$). Patients with a high body weight index showed a significantly lower success rate, suggesting a relation to biomechanical factors (De Lee statistics, $P=0.0097$).

Discussion

The early results of cemented resurfacing prostheses were acceptable [14, 18, 19, 37, 38], but it was evident that many complications were found after longer follow-up periods, e.g. a high rate of aseptic loosening and fractures of the femoral neck [4, 34]. The TARA prosthesis showed good results in the mid-long term as well, and there is even an impression that the revision rate is lower than that for other resurfacing implants [10, 22, 27], although Head (1984) found a high percentage (22.4%) of impending loosening on radiological examinations.

In reviewing publications about hip replacement, it becomes clear that it is hardly possible to compare results objectively. Although many authors use the Harris Hip Score system, the subjective components in the rating are obvious and make comparison difficult.

In our group of patients with an average follow-up period of 60 months a good clinical result was found in 51%. There were no radiological signs of loosening in 88.3% of the femoral components and in 62.7% of the acetabular components. A survival analysis showed that 5 years postoperatively, 89.7% of the femoral components and 84.7% of the acetabular components were still in situ. From a combination of all parameters studied it was concluded that 72.3% of the patients are doing well 5 years postoperatively. The difference between the survival analysis and the combined analysis is mainly caused by radiological findings in combination with pain scores. Patients with pain in combination with radiological signs of loosening are those in whom a revision is expected in the short term.

Radiological suspicioun of femoral loosening is mainly found in cases where the femoral component is placed with the edge of the cup through the cortex of the femoral neck (notching): radiological loosening was seen in 28.6% of such cases 5 years postoperatively, against 6.8% in components placed without notching. This significant difference shows that initial placement of the femoral component determines the clinical outcome of the TARA prosthesis.

The TARA prosthesis differs from other resurfacing prostheses because it has a thin intramedullary stem attached to the femoral cup. In biomechanical analyses, it has been shown that this intramedullary stem does have an influence on load transfer and stress concentrations in the bone near the edge of the cup. Cook et al. [11] compared the load transfer in the TARA prosthesis to that in four other resurfacing prostheses, using finite element method. He noted substantial differences in the stress patterns when a TARA prosthesis was placed. This is, of course, important, because the stress concentrations are though to be responsible for loosening [24, 25, 32, 34].

In converting the failed TARA prostheses to a conventional total hip replacement, no complications or problems were seen in this group of patients. Compared to revision of a conventional total hip, revision of a resurfacing prosthesis is an easy procedure [5, 8, 33, 35]. In revising a conventional total hip a high incidence of complications is often reported, e.g. perforation of the femoral shaft, fracture of the femoral shaft or perforation of the acetabulum [6, 15, 23]. The postoperative infectioin rate after revision of hip prostheses is also higher in cases with a conventional total hip compared to cases with a resurfacing prosthesis et al. [3, 26, 29, 35].

Conclusions

The overall clinical results of patients with the TARA hip prosthesis are inferior to those of patients with conventional total hip prostheses, mainly because of loosening of the acetabular component. The radiological follow-up of the TARA prosthesis shows a good result for the femoral component in cases in which this component was placed correctly, without notching in the femoral neck. Signs of loosening of the femoral component were seen in only 6.8% 5 years after implantation. Biomechanical analysis has proved the role of the stem of the femoral component in the load-transfer mechanism. This may explain the different behaviour of this component in relation to other resurfacing hip prostheses.

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