The Adaptiva custom-made stem—our reasons for not using it anymore

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Abstract The Adaptiva custom-made stem is a hip stem anchored by fit and fill press-fit into the proximal femur and manufacture is based on computed tomography (CT) scanning. Its concept was developed for primary and revision hip arthroplasty in younger patients in our clinic. We present the advantages and the disadvantages of the system. After 66 months 98.9% of the patients are satisfied with the surgical outcome; 86% attained very good and 9% good results according to the Merle d'Aubigné score. Despite good clinical results and a high satisfaction rate, we stopped using this stem because we do not see any advantages in comparison with standard implants and feel that the price for a custom-made stem for primary hip arthroplasty is too high.

Résumé La tige prothétique Adaptiva est une tige sur mesure à ancrage sans ciment par ajustage à partir des données de scanner. Ce concept a été développé dans notre Centre pour les prothèses primaires et de révision chez les sujets jeunes. A 66 mois, 98,9 % des patients sont satisfaits de l'évolution, avec selon la cotation de Merle d'Aubigné 86% de très bons et 9% de bons résultats. Malgré les bons résultats cliniques et le haut degré de satisfaction nous avons arrêté la fabrication de cette tige car nous ne voyons pas d'avantage en comparaison d'implants standards et le prix d'une prothèse sur mesure pour une arthroplastie primaire est trop élevé.

Introduction

Alloarthroplasty of the hip joint has been one of the most successful surgical procedures of the last century. The main problem of hip replacement remains, however, aseptic loosening and the danger of invalidity for the patient [6]. Anchoring of artificial joints in the bone is accomplished by form-fit, press-fit, and bony ingrowth in and on the surface of the implant.

The use of bone cement usually allows excellent initial form-fit anchoring. If loosening occurs, however, removal of well-adhering cement may be difficult, and the loss of bone substance may be so serious that the revision leads to considerable difficulties. Usually, cemented anchoring is therefore limited to older patients and special indications, while cementless implantation techniques with precise fit is preferred for younger patients. This inspired the Orthopaedic University Hospital in Tübingen to develop an individual stem, custom-fitted to the patient's anatomy with preoperative computed tomography of the femur to achieve the best possible fit between vital bone tissue and stem surface. The objective was to attain contact all around the medial and lateral stem in the metaphysis and diaphysis of the femur and thus to allow broad stress distribution and contact surface. This should result in a very high initial stability [11]. By definition of the resection depth, the implantation depth relative to the greater trochanter tip and the implantation angle, the surgeon should be able to implant the stem in exactly the best position as was defined in the preoperative simulation (Fig. 2). There was no intraoperative device to measure the resection depth intraoperatively and only a mechanical device to measure the implantation angle. The initial contact of the stem to the bone on the medial and lateral side averages 80% [16].

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Fig. 1 Adaptiva stem with individual rasp

Designing the stem with a square cross section and additional vertical ribs in the proximal ventral area should increase rotational initial stability (Fig. 1).

The material of the stem is a titanium alloy (Ti-6AL-4V), which complies with the American Society for Testing and Materials (ASTM) norms F1185 and F1472 and International Standards Organisation (ISO) 5832/III, and the microporous surface structure is designed for secondary stability.

The Adaptiva custom-made stem also offers the possibility of individual improvement in joint geometry in order to attain the best possible mobility, good stress transmission, and correction of the leg position. The specific possibilities of positioning the head include correction of anteversion, of leg length discrepancy, and of medial offset. The physiological offset thus attained could increase abduction strength and mobility, as well as the muscular stability in general and thus the life expectancy of the stem. The costs of an Adaptiva stem with the necessary computed tomography (CT) scans are two to three times the costs of a standard stem.

This rotation-stable, titanium straight stem was implanted in patients younger than 60 in primary and revision surgery. In all cases a press-fit cup was used. We used Bauer's lateral surgical approach. Diclofenac 50 mg

tds was administered for 1 to 2 weeks as postoperative ossification prophylaxis.

All of the operations were done by the head of the department and his staff. The aim of the study is to evaluate the midterm clinical and radiographic results of the Adaptiva stem in young patients and to critically review the benefit of a custom-made stem.

Material and methods

The first 175 custom-made stems of the Adaptiva type implanted at the Orthopedic University Hospital in Tübingen were evaluated.

The average age of our patients was 54 years (26–68 years). The right hip joint was replaced 96 times and the left 79 times. There were 13 bilateral implantations.

The most common reason for arthroplasty was idiopathic osteoarthritis (57%) followed by osteoarthritis secondary to dysplasia (20%), rheumatoid arthritis (10%), avascular necrosis (6%), post-traumatic osteoarthritis (3%), and protrusional osteoarthritis (2%). An Adaptiva stem was used in four cases (2%) as a revision stem following aseptic loosening.

In 140 cases (80%), the implantation of the Adaptiva stem was the primary operation on the affected hip. In 35 cases, one or more operations had been performed previously, e.g., proximal femoral osteotomies.

All patients with 175 implants underwent clinical and radiological evaluation before operation, after the operation, and after an average follow-up interval of 66 months (48–82 months) to provide middle-term clinical and radiological results.

Special attention was paid to functional parameters such as pain, walking ability and mobility, differences in leg length, and muscular insufficiency. Standardised X-rays of the pelvis and axial images of the operated hip were made for all patients pre- and immediately post-operatively, after

Fig. 2 Instructions for implantation

Fig. 3 Adaptiva stem 6 years after implantation with good clinical outcome

rehabilitation and prior to hospital discharge, and at the time of follow-up. The measurements were done by using a pencil on plain radiographs. Particular attention was paid to bone reconstruction processes, cortical hypertrophy and/or thinning, signs of loosening, and the presence of periarticular ossification.

Results

According to the medical records, all patients suffered from severe pain and marked limitation of joint mobility and walking ability before the operation.

At follow-up, 148 joints, or 84%, were completely without pain. Most complaints—multiple choices were possible—were due to trochanteric tendinitis ($n=11$), pain of muscular fatigue ($n=11$), sensitivity to weather changes ($n=4$), and tendonitis of the adductors ($n=2$). Groin pain was reported seven times, the contralateral hip was painful in two cases, and the lumbar spine in two cases. Only one patient complained of pain in the operated thigh.

The mobility of the operated hip was satisfactory in all patients. Most hips showed full extension. Average abduction was 30° and adduction contractures did not occur. Rotation averaged 50° .

Equal leg length was found in 76%. Improvement was achieved in 14%, while leg length discrepancy deteriorated in 10%. The common problem was that the legs were too long after the operation, because the surgeon could not reach the correct implantation depth.

Abductor weakness with limping was present in 68 hips before operation and after in 23 hips. This limping improved in 57 hips and deteriorated in 12 hips.

All patients attained a Merle d'Aubigné score of at least 4 for mobility at follow-up; 125 patients walked normally after operation, with a Merle d'Aubigné score of 6.

Only 3% of the patients had to use a cane for short distances after operation compared to 70% before.

The functional score according to Merle d'Aubigné showed very good results for 152 of the 175 implants (86%) for the parameters pain and walking ability and good results for another 16 (9%). The preoperative functional score according to Merle d'Aubigné showed poor results for all patients.

Of the patients, 86% attained very good and 9% good overall results according to the Merle d'Aubigné score (Fig. 3).

The average Harris hip score improved from 47 points before operation to 96 points at the time of follow-up. No patient had less than 51 points at the time of follow-up.

The most frequent intra- and perioperative complication was a greater trochanter fracture ($n=12$), which occurred without exception intraoperatively. Eight shaft fissures requiring wire cerclage occurred intraoperatively, particularly in those patients who received large-volume stems with prominent ventral ribs.

According to the preoperative plan only 18 hips required a normal implantation angle between -5 and 15° ; 64 hips required an implantation angle between 16 and 25° , 35 even between 26 and 35° , 2 between -6 and -14° , 35 between -15 and -25° , and 21 between -26 and -35° . The resection depth missed its target by an average of 6 mm. The planned implantation depth, measured in relation to the tip of the greater trochanter, was on average 16 (range: -2 – 30 mm), the implantation depth measured postoperatively was on average only 10 mm (range: -13 – 22), and at the time of follow-up the implantation depth was measured with an average of 11 mm (range: -12 – 24 mm). Only 44 stems were implanted within a range of 8 mm from the desired implantation depth. Most stems did not reach the final implantation depth.

There were three cases of reversible damage to the femoral and sciatic nerve. There was one patient with problems of wound healing and one postoperative dislocation. None of the Adaptiva stems had to be replaced during the follow-up period.

Radiological signs of loosening, such as osteolysis or migration of the stem, were not observed in any of the 175 stems at the time of follow-up. In comparison to the intraoperative X-rays, there was no subsidence of the stem of more than 2 mm after rehabilitation or at the time of follow-up. A total of 101 stems showed cortical hypertrophy at the time of follow-up (Fig. 4), especially around the distal stem, particularly in the Gruen zones 3 and 5, and to a lesser extent in 2 and 6. This was sometimes accompanied by calcar hypotrophy, but not in all cases. Calcar hypotrophy without cortical hypertrophy was observed in 32 patients; cortical hypertrophy in the diaphysis, but without calcar hypotrophy was found in 33 patients.

Fig. 4 Adaptiva stem with painless cortical hypertrophy around the distal stem

None of the press-fit cups showed clinical or radiological signs of loosening. Periarticular ossifications was observed in 11% of the patients. In nearly all cases these were isolated small grade 1 ossifications according to Arcq [4].

Discussion

Young, active patients, like most of those in our patient cohort, not only have high demands on stability and durability of a hip, but are especially at risk of implant loosening [6, 14, 21]. Bone cement, a material for filling and fitting, resolves the problem in older people, but for younger people surgeons have looked for alternatives without cement.

The fixation of hip stems without form-filling cement suffers from lack of adequate fit into the individual bone cavity [2]. Differences in the cross-sectional shapes of intramedullary stems are thought to affect the strains in the femur, and therefore a close proximal fit has been proposed as particularly advantageous. Hua and Walker showed in their cadaver series that custom-made stems consistently produced a pattern of strain distribution, which was closer to normal than that of standard stems [13]. Hua and Walker also showed that custom-made stems exhibited low values for relative motion under load [12].

It was postulated that improved implant fit might increase the longevity of noncemented total joints. We,

therefore designed the Adaptiva custom-made stem based on a series of CT X-rays. The stem derived directly from the three-dimensional reconstruction of the inner contour of the femur. The principle of the device is a fit and fill press-fit into the proximal femur especially on the medial and lateral side. Martini et al. were able to show in measurements of bone mineral density (BMD) that 10 days after operation there was a mean increase in the BMD of the replaced hip of 8% with a maximum of 24% [17]. Götze et al. showed in cadaveric femurs a high primary stability in custom-made Adaptiva femoral stems with respect to subsidence, rotation, and interface motion [9].

We did not use the stem as a special stem for particular cases but as our standard implant for patients under the age of 60 and also in four cases as a revision stem after failed primary hip replacement. The short-term results have been excellent. After a short follow-up of 19 months, 92% showed very good and 6% good results according to Merle d'Aubigné [18]. After an average follow-up of 66 months, we still have 86% very good and 9% good results according to Merle d'Aubigné and a high level of satisfaction on the part of the patients. After an average follow-up of 66 months and a follow-up rate of 100%, we found no cases of loosening despite the low average age of our patients of 54 years.

Despite this good news we have decided to abandon the principle of the custom-made Adaptiva stem for several reasons.

Other standard implants show even better clinical results [15]. Long-term results of the cement-free Zweymüller total hip prostheses showed an average Harris hip score of 86.6 after a mean follow-up of 8.9 years [22], long-term results with the BiContact system showed a Harris hip score of 84.3 points after 8.9 years [8], and with the Spotorno stem of 84% after 12 years [3]. In these studies the survival rate of the Zweymüller stems after 10 years was 96%, of the BiContact stems 97.1% after 11 years, and of the Spotorno stems 97% at 12 years. There is no data for the Adaptiva stem for such long periods of time.

The adherence to the planned implantation parameters seemed to be very difficult. Although the customised stem was planned to provide equal leg length we had—even after trying to equalise it with various neck lengths—10% of leg length inequality. In the majority of cases the operated leg was longer. The main reason being that the surgeon could not reach the correct implantation depth, despite the fact that he been provided with a simulation of the implantation procedure. The problem started with the fact that the resection depth was often missed and therefore the stem impacted with the medial cortex. In the majority of cases the very high and sometimes even negative implantation angles were confusing for the surgeon who was occasionally forced to remove cortical bone from the proximal

femur. When he did not remove it, the correct implantation was not possible in all cases. The comparison with standard implants showed no better leg length equality than the Adaptiva group, although the results from other standard implants show the same tendency.

Goldstein et al., for example, showed in their 2001 cohort with tapered stems a mean increase of length (center of rotation of the femoral head to the top of the lesser trochanter) of 9 mm and in their 2004 cohort with porous tapered stems of 6 mm [10].

Other studies confirm the high ratio of malpositioned stems in a total hip replacement (THR) population with custom-made stems. Rittmeister et al. [19] found that compared to preoperative planning 59 of 107 CTX custom-made hip stems were placed too high, 32 too low, and only 16 were placed within 1 mm. None of the examined variables such as body mass index, previous femoral osteotomy, or surgical approach served as a predictive value for CTX stem position in this cohort. This shows that limb length restoration and maintenance during THR is not only dependant on careful pre- and intra-operative assessment and planning but also of proper soft tissue tension and component design [7].

Götze et al. also found in their cadaveric femurs that compared to conventional straight cementless stems, custom-made stems did not extend the endocortical contact area. In most cases the desirable “fit and fill” of the proximal femur does not seem to be achieved with straight custom-made femoral components in femurs of regular geometry [9, 20]. Furthermore, the individual parameters of the stem and the individual operation plan do not allow economical computer-aided surgery.

Arabmotlagh et al. [1] showed that similar patterns of periprosthetic bone changes were seen in femora with straight and anatomical hip stems at 24 months postoperatively. Femoral bone loss was seen with straight and anatomical stems in the calcar region of interest (ROI). We also observed obvious calcar atrophy in 32 patients with standardised X-rays. Custom designed anatomical femoral hip stems seem to be unable to prevent periprosthetic bone resorption.

Furthermore 101 Adaptiva stems showed cortical hypertrophy, especially around the distal stem, particularly in the Gruen zones 3 and 5, and to a lesser extent in 2 and 6. In a patient who is not part of this study population, this led to a painful stress fracture so that we intend to replace the stem. Whether the painless hypertrophy of the cortical bone will lead to aseptic loosening or is only an intermittent sign of stress transmission remains to be seen.

In comparison with the results of Zweymüller, Bicontact or Spotorno cohorts, the results for proximal calcar atrophy and radiolucent lines and distal hypertrophy are even slightly worse [3, 24].

In particular the radiographic results of the custom-made Adaptiva stems do not corroborate the fixation concept of intertrochanteric fit and fill of femoral components.

Another problem remains unsolved. The price of a custom stem is twice or thrice as expensive as a standard stem [23]. In the meantime there are several cementless stems available other than the Adaptiva stem, such as the Bicontact stem (Aesculap) or the CLS Spotorno (Zimmer), which show excellent long-term follow-up results [3, 8, 22] with similar clinical improvements. In conclusion, we are more and more sceptical about the advantages of custom-made stems. We experienced good results with our four revision stems and could imagine that such cases may be a good indication for their use but conclude that in modern times a surgical inventory consisting of longer-stemmed standard implants or modular distal stems is more cost effective than designing custom devices on a case-by-case basis [5].

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