Uncemented Miller-Galante total knee replacement

The influence of alignment on clinical and radiological outcome in a 5 to 8-year follow-up

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Summary. *Sixty-one primary uncemented Miller-Galante total knee replacements were implanted in 55 patients between June 1988 and December 1990. The results of routine radiological and clinical follow up carried out at an average of 1.3 years and 6.2 years after operation were used for evaluation. The Knee Society clinical score improved from 47.8 points before operation to 83.3 points one year after, and had progressed further to 87.6 points at the recent follow-up. The functional score improved from 45 points before operation to 75.23 points at early follow up, and 81.3 points at the recent review. Although radiological analysis showed that the femoral and tibial components overall were placed perpendicular to the mechanical axis of the limb, sufficient correction of the mechanical axis was not achieved to within ± 10 mm deviation from the centre of the knee in 22 cases, with varus or valgus deformity remaining. No early or late infection occurred in this series. The uncemented Miller-Galante total knee replacement shows good biological fixation of both components. Wear of the metal-backed patellar and tibial polyethylene lead to a revision rate of 19% after 5 years.*

Résumé. *61 prothèses totales de genou non cimentées de Miller-Galante (55 patients) ont été implantées entre Juin 88 et Décembre 90. Pour l'évaluation, ont été relevés les résultats des contrôles de routine radiologique et clinique, faits en moyenne 1,3 ans et 6,2 ans après l'intervention. L'évaluation clinique (échelle de la Knee Society) montre une augmentation à partir de 47,8 points pré-opératoires à 83,3 points 1 an après l'intervention et 87,6 points à l'évaluation récente. Le score fonctionnel (de la Knee Society) montre une aug-*

mentation à partir de 45 points à 75,23 points à 1 an et 81,3 points à l'évaluation récente. Les implants fémoraux et tibiaux ont toujours été correctement placés par rapport à l'axe mécanique du membre. Cependant la correction de l'axe mécanique n'a pas été suffisante dans 22 cas où persiste un varus ou un valgus. Il n'y a pas eu d'infection de relevée dans cette série. La prothèse sans ciment de Miller Galante a une bonne fixation biologique des deux composants. L'usure de la rotule et du plateau tibial sont la cause d'un taux de 19% de reprise après 5 ans.

Introduction

The Miller-Galante Knee System was introduced in 1984 with the goals of minimal bone resection and optimal fit of the components. An exact Intramedullary Alignment Instrumentation System was designed to provide accurate alignment with a simple straightforward technique [13, 18]. Axial alignment of the implant is mandatory in order to achieve sufficient stability at the implant/bone interface [4, 7, 14, 18].

We began using this system at the Orthopaedic Hospital Speising, Vienna, Austria, in 1988. We have reviewed our first series of uncemented Miller-Galante total knee replacements with respect to the clinical and radiological outcome after a minimum of five years' follow-up. The position of the implant was assessed in relation to the various bone and joint axes of the knee and their relation to loosening.

Material and methods

Sixty-one primary uncemented Miller-Galante total knee prostheses (Zimmer Inc., Warsaw, Indiana) were implanted between June 1988 and December 1990. Assessment at follow

up was undertaken by independent observers not involved in the surgery. All radiographs were assessed without knowledge of the patients clinical history to avoid examiner bias. Clinical data were collected by different observers who did not see the radiographs. Both radiological and clinical data were available at an average of 1.3 years after operation (range 0.7 to 2.5 years) and at a recent follow-up at an average of 6.2 years (range 5.0 to 7.8 years).

The varus and valgus alignment of the femoral and tibial components was measured on standing anteroposterior radiographs with the patella facing forward, visualising the hip and ankle joints, with the X-ray tube at a distance of 2.5 m. Anteroposterior tilt of the femoral and tibial components was assessed from lateral radiographs with the patient prone and the tibia parallel to the film. The position of the patella was evaluated on lateral and tangential radiographs with the knee in 30° flexion.

The bone-implant interface was observed radiographically in all three components [5]. Bony ingrowth was determined as normal trabecular bone or sclerosis in contact with the implant. Clinical evaluation was based on the Knee Society clinical rating system [12].

Operation was carried out through a median skin incision except twice when a previous operation dictated a medial parapatellar approach. The posterior part of the tibial intercondylar eminence was sacrificed in 27 knees; the posterior cruciate ligament could be preserved in 34.

Additional soft tissue procedures included lateral release in 22 knees and balancing of the collateral ligaments in 10 knees. The operations took between 90 and 120 min and a tourniquet was used in 39 cases.

All the surgeons rated the fit of components at operation as excellent and no complications were recorded during operation. Autologous bone grafts were taken from the resected tibial plateau in 16 knees to fill cystic defects at the femoral or tibia condyles.

The 61 total knee replacements were carried out in 55 patients, 15 in 13 men, and 46 in 42 women, on 25 left and 36 right knees. The average age at operation was 68.9 years (range 56 to 80 years), and at follow up was 74.5 years (range 62 to 87 years). The preoperative diagnosis was degenerative joint disease in 56 knees, without angular deviation in 18 knees, with a varus deformity in 28 and a valgus deformity in 10 knees, rheumatoid arthritis in 3, and loosening of medial unicondylar replacements in 2.

Patients had suffered from their disease for an average of 8.6 years before operation; all had retired at that time.

One patient died from a myocardial infarction on the 15th postoperative day, the other 4 deaths during the follow-up period were unrelated to the replacement. Two patients were lost to follow-up. Clinical and radiological data of 60 knees were available at one year after operation, and of 54 knees for the more recent follow-up.

Results

The Knee Society clinical score [12] averaged 47.8 points before operation (range 16 to 82); 83.3 points

at the early follow up (range 33 to 100) and 87.6 points (range 25 to 100) at the final follow-up.

The function score, using the same rating system, averaged 45 points (range 0 to 90) before operation, 75.2 points at the early follow-up (range 20 to 100) and 81.3 points (range 20 to 100) at the final follow up. In 54 stable implants (5 deaths, 2 lost for follow-up), the average difference in knee score between the preoperative and early evaluation was 36.5 points, which improved to 39.3 points at the final follow-up. In the function score for stable implants, the difference between the preoperative score and the evaluation at one year was 30.1 points (2 patients had deteriorated), and it improved further to 37.5 points at the final follow-up.

Nine revisions had to be performed because of polyethylene wear of the patellar component. This was treated by synovectomy, combined with changing the patellar implant to a cemented all polyethylene prosthesis. The tibial polyethylene plateau was changed in 3 knees because of surface changes such as signs of cold flow, loss of smoothness and lamination.

One revision was indicated because of patellar wear and loosening of the tibial component; all the implants were removed and changed to cemented components.

Bacterial cultures of material from all revised knees were sterile, and no early or late infection occurred in the series.

The average time to revision was 4 years (range 1 to 5 years).

Radiological results

The radiographs in 60 patients (one had died on the 15th postoperative day) taken at an average of 1.3 years after operation (range 0.7 to 2.5 years) revealed that 31 tibial components had been placed in an average varus of 88.1° (range 87° to 89°) in relation to the mechanical axis of the limb, 23 were in an average valgus of 92.2° (range 91° to 94°) and 6 were perpendicular to the mechanical axis.

The average postoperative varus/valgus alignment was 3.1° of varus (standard deviation: 2.04).

At the last review of 54 implants, there was almost no change in position with 28 tibial components in an average of 88° varus (range 87° to 89°), 21 in an average of 92.4° valgus (range 91° to 94°) and 4 were at exactly 90°.

Table 1. Axial alignment on anteroposterior and lateral radiography degrees

	Follow-up at 1 year		Last follow-up (min 5 years)	
	Average (s.d.)	Range	Average (s.d.)	Range
A/P femoral flexion	96.51 (2.32)	91–101	96.59 (2.13)	93–103
A/P tibial angle	88.61 (2.32)	85–94	88.81 (2.79)	85–94
Total valgus angle	5.12 (3.28)	(–1)–11	5.41 (3.64)	(–1)–15
Lateral femoral flexion	89.03 (2.26)	85–94	88.59 (2.45)	84–94
Lateral tibial angle	84.96 (3.5)	76–93	85.5 (3.24)	77–92

The tibial components were placed with a posterior tilt in 55 cases, an anterior tilt in 4 and in neutral, at 90° to the long axis of the tibia, in 2. The average tilt was 85.2° (range 76° to 93°). At the last follow-up of 54 knees, the tibial components showed almost no change with posterior tilt in 49 implants, anterior tilt in 2, and 2 were neutral. The average tilt was 85.5° (range 77° to 92°).

The femoral components were placed perpendicular to the femoral axis in the lateral view in 6 cases. An average flexion of the component of 2.5° (range 1° to 5°) was present in 40 cases, and 15 were placed in an average extension of 1.8° (range 1° to 4°). The axial alignment of the implants is shown in Table 1 [5].

Discussion

Advocates of uncemented total knee replacement have reported good overall results with various designs of implant [7, 10, 11, 13, 18]. Nevertheless, accurate placing of the components requires a high degree of surgical skill. Various intramedullary alignment guides make this easier.

The use of bone cement has well known risks which can be avoided by designs which do use it [7, 18]. In our series, we did not have to remove any femoral components, and only one metal tibial plateau had loosened in a knee with a severely destroyed patellar implant. The metal pegs of the revised patellar component showed solid bony fixation, so bony ingrowth was not considered to be the main problem [10, 13].

The goal of correct alignment by using intramedullary guides was not achieved in all our patients. Deviation from the correct alignment with the range achieved did not disturb the fixation of the implant, did not interfere with good clinical results and showed no increase of implant loosening.

The mechanical axis of the limb drawn from the centre of the hip to the centre of the talus passes at an average of 12 mm medial to the centre of the knee (range: 42 mm medial to 26 mm lateral). We divided our cases into two groups in relation to axis deviation; in group 1 ($n=31$) there was accurate alignment or ± 10 mm deviation, and in group 2 ($n=22$) there was more than 10 mm deviation of the axis. Differences in the Knee Score were not significant ($P=0.65$) between both groups. There was no significant difference in failure of the patellar component in the two groups ($P=0.84$).

The failure rate of the patellar components was 19%, so we also analysed the position of the component in lateral and anteroposterior radiographs. The average position of the metal-backed patellar component was 2 mm cranial to the centre of the bone in the lateral view, but this had no significant influence on failure ($P=0.34$). Measurements of patellar tilt on the anteroposterior or lateral radiographs were within measurement error levels ($\pm 1-3^\circ$) and were therefore not calculated for significance. Patellar thickness is difficult to measure on radiographs as cartilage and

Fig. 1. Bone reaction to wear around a patellar component

Fig. 2. Changes in synovial membrane due to polyethylene and metal wear following separation of the polyethylene and metal in metal-backed patellar components

Fig. 3. Retrieved patellar component showing polyethylene wear and separation of the polyethylene and metal

polyethylene are both radiolucent. Only indirect measurements such as the bony thickness preoperatively and that of bone and metal postoperatively were recorded. These values were of no statistical significance ($P=0.15$) for patellar failure or deterioration of range of motion. Clinical parameters, such as the patient's body weight and height were also not significant ($P=0.24$).

The use of metal backing of the patellar component is controversial [2, 6, 9, 16, 17]; failure rates of

up to 11% have been reported after 2 years of follow-up [4, 13, 15] and can increase up to 19% after five years, as we have shown.

Contributing to patellar failure are poor bone quality and obesity [3, 19, 20]. Factors affecting the position of the component, such as patellar thickness [1], tilting of the component along the transverse or sagittal axis of the patella, or a lateral position of the component, combine to give a worse prognosis [6, 8, 9, 19]. As the position of the component in our series was within a small range, none of these factors had a significant influence on failure or resulted in deterioration of the clinical result. There was also no correlation between the position of the component, or soft tissue release, and patella failure.

The design of the metal-backed Miller-Galante I patellar component with its thin layer of polyethylene is responsible for wear and ultimate failure [2, 9].

Wear of polyethylene and metal, either from the patellar or tibial component, causes synovitis and bony defects around the implants (Fig. 1). Revised patellar components showed severe lysis in the circumferential bone, but not at the metal-bone interface even when there was severe wear.

In our series, components with good bony ingrowth were not loosened by the presence of surrounding polyethylene wear granuloma. Synovectomy and removal of granulation tissue was therefore regarded as sufficient in revision operations (Fig. 2). All stable femoral and tibial components could be preserved, but all revised uncemented metal-backed patellar components (Fig. 3) were routinely changed to a polyethylene cemented patellar device.

The uncemented Miller-Galante I total knee replacement system provides instrumentation for good axial alignment of the perpendicular mechanical axis of the tibial and femoral components. Nevertheless, there remains a high rate of patellar complications which is inherent in the metal-backed patellar components and which diminished our good results.

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