



The cementless AGC 2000 knee prosthesis : 20-year results in a consecutive series

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One hundred and fourteen AGC 2000 porous-coated cementless total knee arthroplasties were performed in 102 patients between 1984 and 1986. We report their 20-year results with patient assessment, Hospital for Special Surgery knee score, weight-bearing radiographs done under fluoroscopic control and survivorship analyses. All patients could be accounted for. With prosthesis revision as a failure criterion, the cumulative survival rate of all prosthetic components at 20 years was 84.4%. The fall in success rate was primarily due to early tibial and late patellar component failure. The cumulative survival rate of the tibial component was 97.2% and that of the femoral component was 100% at 20 years.

Keywords : total knee arthroplasty ; AGC knee prosthesis ; long-term results ; survivorship.

remained almost unchanged since 1986, except for an attempt to increase the strength of the polyethylene. In 1993 gamma sterilisation of the components in argon gas was introduced in order to reduce oxidation and enhance the wear properties of the polyethylene (23).

Several studies have shown good long-term results of the AGC knee arthroplasty system. Ritter *et al* (19) reported a survival rate of 98.86% at 15 years of the AGC posterior cruciate-retaining total knee replacement with revision of one or more of the components as the end point. Worland *et al* (23) found a survival of 97% at 14 years of the AGC total knee with a cemented posterior cruciate-retaining design. Ranawat *et al* (18) showed a 15-year survivorship of 94.1% for the total condylar knee arthroplasty with posterior cruciate ligament sacrifice and early cement technique. Gill *et al* (8)

INTRODUCTION

In spite of newer developments in operative techniques, prosthetic design and instrumentation, there continues to be a concern that total knee implants will not survive the lifetime of younger patients (20). Due to changes and improvement in implant design, materials and fixation, the long-term outcome of one design of total knee replacement has been a difficult clinical question to answer (19).

The AGC 2000 (Anatomically Graduated Component, Biomet, Warsaw, USA) system was introduced in 1983 and the prosthetic design has

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showed a survivorship of 96.3% of cemented, PCL-retaining total knee arthroplasty at 15 years.

We have previously reported the results of a cohort of cementless AGC implants with follow-up studies carried out after 3 years (16), 5-7 years (17) and 10 years (22).

The present study is a 20-year follow-up of this cohort, with particular interest in the survival of the patellar component.

MATERIALS AND METHODS

One hundred and fourteen cementless total knee arthroplasties with the AGC 2000 total knee prosthesis were performed consecutively in 102 patients between April 1984 and April 1986. Ninety-eight knees had osteoarthritis and 16 knees had rheumatoid arthritis. The results of a clinical and radiographical evaluation at 3, 5-7 and 10 years in these patients have been published (16, 17,22).

The present study includes the same population 20 years postoperatively with an average observation time of 19.4 years (range : 18.8 to 20.6).

Eighty-three patients with 93 knees died before the present evaluation, leaving 19 patients with 21 knees. Of these surviving patients, 15 had primarily been diagnosed with osteoarthritis and 4 with rheumatoid arthritis. The median age at follow-up was 85 years (range : 61 to 97).

Of the survivors, 14 patients with 15 knees were examined clinically and radiographically. None of these patients had undergone knee revision. No patient was lost to follow-up, but 5 patients (6 knees) did not participate in the clinical evaluation. One patient was not interested in coming in for the examination, 2 patients were unable to participate because of old age and illness. Two of these patients (3 knees) had undergone revision due to failure.

The study was carried out with approval from the local ethics committee and the patients were all examined after informed consent.

Operative technique and postoperative care

The AGC 2000 is a non-constrained, PCL-retaining, condylar prosthesis with a flat-on-flat articulation. The tibial component is non-modular and metal-backed. It has a central stem and a compression-moulded polyethylene plateau with a minimum thickness of 8 mm. The patellar component, which was applied in all cases,

is metal-backed with a moulded polyethylene bearing. All the components, except the central tibial stem, are porous titanium-coated with a mean pore size of about 300 µm. The tibial components were all inserted without the use of cement, and only 3 femoral and 6 patellar components were cemented.

The surgery was performed in ultraclean-air operating rooms using exhaust suits. Peroperative antibiotics, usually methicillin, were administered. Under tourniquet haemostasis, the operation was performed using a mid-line incision. A calibrated distractor with extramedullary alignment rods was used to ensure mechanical axis and balanced tensioning of the collateral ligaments. Postoperatively the patients were required to begin quadriceps exercises followed by active knee motion and full weight-bearing on the second postoperative day.

Survivorship analysis

Two failure criteria were used in this study. In the first analysis, failure was defined as a prosthesis which was revised or revision planned as a result of septic or aseptic loosening. In the second analysis, failure was determined by radiographic signs of loosening and/or significant pain as defined by a Hospital for Special Surgery score of 15 or less.

A survivorship analysis was carried out using the methods described by Armitage *et al* (3) and Dobbs (5) and 95% confidence intervals were calculated as described by Machin and Gardner (14). Using the survivorship data it was then possible to derive a Kaplan Meier plot.

Clinical evaluation

Knee function was evaluated in two ways, by standardised methods to facilitate comparison to earlier analyses of the patient population as well as comparison to other studies.

Patient assessment was registered as described by Aichroth *et al* (1) in 'A knee function assessment chart'. A knee-rating score was assigned to each patient based on the Hospital for Special Surgery knee score (12). This rating system is divided into six categories : pain, function, range of motion, muscle strength, flexion deformity and instability. Subtractions are made for walking aids, extension lag and varus or valgus deformity. On the basis of these ratings, scores of 85 or greater were defined as being excellent, scores between 70 and 84 as being good, 60 to 69 as fair and less than 60 as being failures.

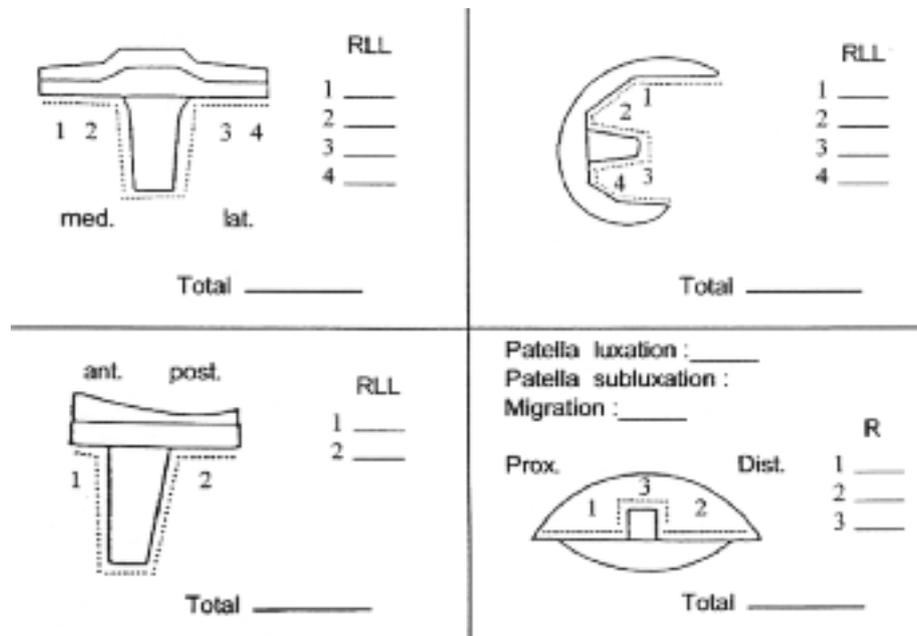


Fig. 1. — Radiolucencies > 1 mm were measured according to the guidelines of the Knee Society, dividing the femur into 4 zones, the patella into 3 zones and the tibia into 6 zones (7).

Radiographic evaluation

Weight-bearing anteroposterior and lateral radiographs were taken under fluoroscopic control, ensuring parallelism between the x-ray beam and the bone-prosthesis interface. Additionally, skyline images of the patella were attempted as accurately as possible.

The Knee Society Roentgenographic Evaluation System was developed to create a uniform reporting system of total knee arthroplasty. This system was used in the analysis of the knee radiographs (7). The femur, patella and tibia are divided into zones (fig 1). In each zone, radiolucencies over 1 mm were registered. In addition, the tibio-femoral angle (anatomical axis), component position, height of the joint space and formation of osteolytic cysts were noted, as well as any sign of polyethylene wear.

RESULTS

Survivorship analysis

With revision and planned revision as failure criteria, the cumulative success rate of the AGC 2000

prosthesis at 20 years with regards to all the components was 84.4% (95% CI, 70.8-97.6) (fig 2). The reason for the sudden drop off in the curve after 13 years is due to 4 revisions combined with a number of dropouts. The cumulative success rate of the femoral component was 100% and that of the tibial component was 97.2% (95% CI, 93.9-100) (fig 3). The latter result was due to 3 tibial components revised due to aseptic loosening at 8 months and 22 months and septic loosening 3 years post-operatively. There was no tibial component loosening after that.

No radiographic loosening nor significant pain was registered in the present series, resulting in the survivorship of the knee prosthesis with this endpoint in mind being unchanged from the 10 year analysis, 86.9% (95% CI, 77.5-96.3) (22).

Failures and revisions

Since the last study was carried out 10 year post-operatively (22), review of the medical charts of patients since deceased, as well as the interviews of

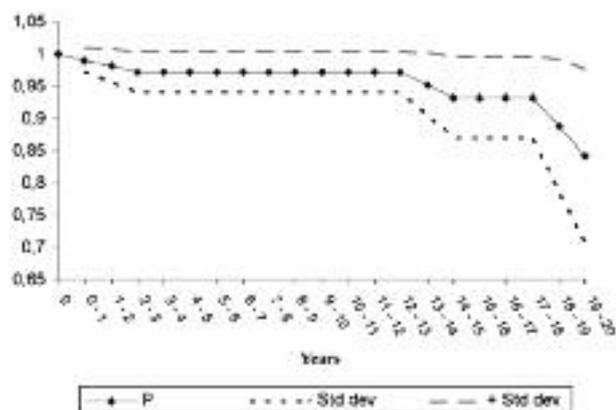


Fig. 2. — Kaplan-Meier plot showing survivorship of 114 cementless porous-coated AGC 2000 knee prostheses over a 20-year period.

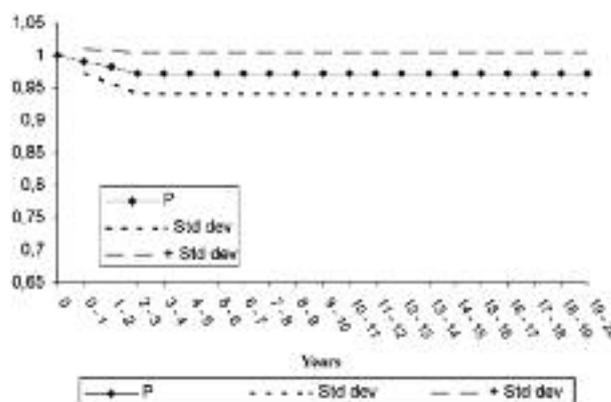


Fig. 3. — Kaplan-Meier plot showing survivorship of the tibial prosthesis over a 20-year period.

the 19 patients living showed that a total of 3 patients (4 knees) had since undergone revision in one form or other.

In 2 knees, revision of the patellar component was carried out 13.8 and 14.7 years postoperatively. In the first case, both the patella polyethylene lining and the metal-backing were fragmented. The metal-backing was securely fixed in the bone, while the polyethylene was found in several pieces. The patellar component was removed and not replaced, since the patella was found to be too thin. After the revision, the patient has had no complaints. In the second case, the patient experienced sudden pain and reduction in movement due to disconnection of the component. The metal backing was fixed but the polyethylene was found in loose pieces in the joint. The patient was successfully re-operated with removal of the patella polyethylene and metal backing followed by cementation of a new patellar component. In the two above mentioned cases, the femoral and tibial components were found to be satisfactory.

The remaining two revisions were carried out in both knees belonging to a patient diagnosed with rheumatoid arthritis. The first revision was carried out 18 years postoperatively after the patient experienced sudden pain and a squeaking noise in her left knee. Per-operatively, the knee joint was found with severe metallosis as well as universal wearing

down of the polyethylene. The patella polyethylene was fragmented and its metal backing was worn down with severe damage to the femoral condyles and tibia polyethylene. After revision with a Total Condylar 3 prosthesis, the patient has had no complaints. Regarding her right knee, revision was carried out 19 years postoperatively, when she began to experience pain during movement in addition to a sense of instability. Radiographic examination showed a total posterior dislocation of the tibia and severe wear of the patella. Peroperatively, the dislocation was confirmed with an intact but undercut femur prosthesis. The knee was replaced with an S-ROM prosthesis with good results.

Another patient worth mentioning, is one primarily diagnosed with osteoarthritis who underwent revision of the tibial prosthesis 1.9 years postoperatively due to loosening. The patient was mostly satisfied with the result until he started experiencing pain in the same knee in 2005 and was offered a Total Condylar 3 revision which was carried out in early 2006. At this time, substantial metallosis, a loose femur prosthesis, polyethylene wear to the patella and cysts around the tibia stem were found.

Other than the above mentioned results, the knees have not posed any particular problems, other than occurrence of supracondylar fractures in 3 patients, one of which was treated with a 3-screw osteosynthesis, while the two others were treated

Table I. — Subjective assessment at 3, 5-7, 10 and 20 years post-operatively (n ~ # knees)

	3 years (n = 103)	5-7 years (n = 96)	10 years (n = 58)	20 years (n = 18)
Enthusiastic	65 (63%)	70 (73%)	45 (78%)	17 (94%)
Satisfied	26 (25%)	14 (15%)	8 (14%)	1 (6%)
Noncommittal	8 (8%)	7 (7%)	3 (5%)	0
Disappointed	3 (3%)	3 (3%)	2 (3%)	0
Unknown	1 (1%)	2 (2%)	0	0

Table II. — Pain during walking (n ~ # knees)

	3 years (n = 103)	5-7 years (n = 96)	10 years (n = 58)	20 years (n = 18)
None	73%	84%	92%	14 (78)%
Mild	16%	8%	3%	2 (11)%
Moderate	9%	6%	5%	2 (11)%
Severe	2%	2%	0%	0%

conservatively. In none of these cases did the fracture necessitate knee prosthesis revision.

Clinical results

At the time of follow-up only 19 patients (21 knees) were still alive. The subjective assessment from the patients living who had not been subjected to revision (17 patients, 18 knees) showed an overall rise in enthusiasm over the years (table I). At 20 years, one patient was satisfied, while there was enthusiasm about the remaining 17 knees. None were noncommittal or disappointed, as had been registered in earlier years (table I).

Of the deceased and not revised patients, only 3 cases had had problems with the operated knees. In two cases, approximately 10 years postoperatively, pain and increased scintigraphic activity in the medial tibial plateau led to fenestration of the subchondral bone. These implants were not radiographically loose. The thickness of the polyethylene was 8 mm in two cases and 16 mm in the last case. The BMI of these patients was not known. The operation was however not carried out in two cases ; in one case due to a concurring aneurysm of the aorta and in the other due to misplacement of the medical chart. One patient, with a polyethylene thickness of 8 mm, underwent fenestration of the subchondral bone after suffering pain for many

years. Radiographically there was an acceptable tibial component alignment, but the bone showed patchy halisteresis. Peroperatively, a seemingly necrotic bone was found. The operation had however a positive effect on the pain.

Regarding pain during walking, there was a tendency towards a higher incidence of pain in the earlier years after knee arthroplasty, which decreased over the first 10 years (table II). At the 10 year study, 92% of the patients had no pain, at 20 years 78% had no pain. Those who complained of pain were 11% (2 patients) who experienced mild pain and 11% (2 patients) who had moderate pain. All but one were still enthusiastic about the result. No patients complained of severe pain.

When assessing the walking distance, the percentage of patients who had a walking distance of less than 500 m was 26% 10 years postoperatively compared to 39% 20 years postoperatively. It was, however, clear that the impairment was primarily due to other age-related ailments. Seventy-two percent of the patients had a walking distance of less than 500 m due to other ailments such as back pain, vertigo and pain in other joints. In the remaining 28% (2 patients), the difficulty in walking was only partially due to the affected knee. These two patients were also amongst those who respectively complained of mild and moderate pain during walking.

Table III. — 20 year results according to the HSS knee rating system (n ~ # knees)

	Total (n = 15)	Normal (n = 8)	Other ailments (n = 7)
Excellent (> 85)	9 (60%)	6 (75%)	3 (43%)
Good (70-84)	2 (13%)	1(13%)	1 (14%)
Fair (60-69)	2 (13%)	0(0%)	2 (29%)
Poor (< 60)	2 (13%)	1(13%)	1 (14%)
Unknown	0	0	0
Average score		86	74

Of the 18 knees who were examined clinically, the median range of motion (ROM) was 110° (range : 88 to 120), with 3 knees having a flexion contracture greater than 5° (the greatest being a contracture of 20°).

Only one knee had instability greater than 5° (in this case 10°), but the patient was not affected by this whatsoever.

Looking at the Hospital for Special Surgery knee scores for the 15 knees that were examined, 73% of the knees were registered as good or excellent. Since many of the patients had concurrent ailments, which rendered the knee score biased, the scores were separated into two categories, one consisting of scores where patients had no concurring ailments and the other with scores from patients who were disabled by other physical disability. This comparison (table III) showed that amongst patients who did not have other ailments, 88% were now registered as good or excellent, compared with 57% in the other group.

The 3 patients (4 knees) pre-operatively diagnosed with rheumatoid arthritis showed knee scores of 91, 91, 94 and 74, giving an average of 87.5 (excellent) compared to an average score of 77 (good) in patients with osteoarthritis. The patient with the score of 74 was the only patient with rheumatoid arthritis who was disabled by other problems. This comparison highlights that this particular group with rheumatoid arthritis scored well, but the comparison to the osteoarthritis group, which contains scores of patients with concurrent problems, may not be entirely accurate.

Table IV. — Radiolucencies > 1 mm at the bone-prosthesis interface 20 years postoperatively

Zone	Patella	Femur	Tibia (AP)	Tibia (lateral)
1	4	0	0	0
2	5	3	1	0
3	3	2	0	N/A
4	N/A	0	0	N/A

Radiographic results

Of the original cohort, there have been no cases of radiographic loosening. The sole reason for the fall in survivorship was due to early cases of severe pain. Of the patients still living, 14 patients (15 knees) were examined radiographically. The median tibio-femoral angle was 3.7° of valgus (range of 3° of varus to 9° of valgus). Eight patients (8 knees) had radiolucencies greater than 1 mm (table IV). None of the radiolucencies were complete, and in all cases, trabeculae could be seen reaching the prosthesis. Since early radiographs have not been saved in the Danish hospital system, it has not been possible to include a series of radiographs to show this development. Three patients had radiolucencies around the femoral prosthesis, 2 other patients had radiolucencies around the tibial stem and 3 patients (one of which had a femoral radiolucency) had patellar radiolucencies. One knee had a 2 × 2 cm cyst in the medial femoral condyle.

In three cases, the tibial plateau was anteriorly depressed, in two cases about 3 mm and in one case 5 mm. None of these implants were loose.

A small amount of polyethylene wear was noted in 3 patients (4 knees). In 3 cases, it amounted to 2 mm of wear to the medial tibial plateau, and in 1 case the 2 mm wear was situated at the lateral tibial plateau (see radiographic evaluation). No data on preoperative deformity was registered in these patients.

Radiological changes were found in 9 patients (10 knees). Comparing these results with the clinical findings and subjective assessment, all of these patients were enthusiastic, none of them complaining of pain or suffering any handicap, except for

one patient. This patient had an extension lag of 20° as well as radiolucencies around the femoral pegs and the patellar component coupled with a depression of the anterior tibial prosthesis. She had been given an AGC 2000 prosthesis 20 years ago, due to post-traumatic arthrosis after a tibial condylar fracture 14 years earlier. In spite of these findings she was still very enthusiastic and suffered no knee pain.

The other patient to exhibit several radiological findings had incomplete radiolucencies around the tibia, depression of the anterior tibia and tibial polyethylene wear. She had no handicaps or complaints of any kind. The remaining patients had isolated radiological changes.

DISCUSSION

There have been many changes in types of total condylar prostheses on the market over the years. This has resulted in difficulty in carrying out long-term studies on any one type and few long-term results exist. The AGC knee prosthesis has remained virtually unchanged over the years, which makes the results from this survivorship analysis of the AGC knee prosthesis 20 years post-operatively very interesting.

Only 18% (19 patients, 21 knees) of the initial study population (102 patients, 114 knees) were still alive after so many years, but none of the patients included in the study were lost to follow-up, which meant that all the patients were accounted for.

With revision or planned revision as failure criteria, this study has shown a cumulative success of 84.4% with a very high degree of patient satisfaction at 20 years. The data showed that there was an increased incidence of total prosthesis failure in the first 3 years after operation, followed by several years during which there were no problems registered. The first problems this study registered were isolated problems with the metal-backed patellar component in two cases around the 14th and 15th year mark and then no problems registered until the 19-20th postoperative year where one patient initially diagnosed with rheumatoid arthritis had both knees revised due to a combination of patellar

prosthesis fracture leading to total prosthesis wearing in one knee and dislocation with resulting prosthesis wearing in the opposite knee.

It has been stated that failure rates of prostheses are similar to those of mechanical devices, where there is an initial greater failure rate which reflects problems in manufacture or application. This development levels out until the device reaches the end of its life, when there once again is a rise in the failure rate (15). These findings correspond with what we discovered in the present series. The results would have been even better, had failure of the patellar component not been an issue.

In the present study, no radiographic signs of loosening nor significant pain were registered, resulting in a cumulative success of 86.9%, with this endpoint in mind. The result was obtained solely due to severe pain in the early postoperative years. The radiolucencies found were not complete and in all cases trabeculae could still be seen all the way out to the bone-prosthesis interface. These radiolucencies were primarily found localised to the inferior half of the patella and around the femur pegs, which may give some indication of where the maximum tension on the prosthesis may be found.

In this study, patellofemoral complications were the primary source of failure. It has been estimated that as many as 50% of complications after total knee arthroplasty are the result of patellofemoral problems (6). Especially metal-backed patellar components, like the ones examined in this study, have had numerous problems over the years (2,4,19). Schai *et al* (21), publishing survivorship of the PFC total knee replacement system, found that when they changed from metal-backed patellar components to all-polyethylene components, they saw a dramatic decrease in the need for revision. These components have also proven to be problematic, so there is still a need to discover a better solution.

No revisions were carried out due to displacement of the metal-backed tibial prosthesis. The tibial plateau was radiographically found to be slightly anteriorly depressed in 3 cases but none of the patients had any complaints. Our study therefore agrees with the overall tendency that a metal-backed tibial component is a good choice in the long-term.

The use of cement has also been a cause of debate over the years. Due to a fear that cemented prostheses would not stand the test of time, Hungerford *et al* (10,11) developed the porous-coated anatomic total knee prosthesis for use without cement, with fixation depending on the ingrowth of bone into the porous coating. The use of cement has gained popularity in recent times, but our study clearly shows both clinically and radiographically that failure has not come about due to prosthesis loosening and that a cementless procedure is still a viable alternative.

There have also been questions regarding whether or not to retain the posterior cruciate ligament in total knee arthroplasty. Some believe that with its retention, there is a greater ROM and improved stair-climbing ability while femoral roll-back during knee flexion is enhanced (2). On the other hand, PCL substitution is believed to prevent posterior subluxation of the tibia in addition to enhancing roll-back during deep knee flexion. It has been suggested that PCL substitution allows greater conformity, which in turn results in less stress in the polyethylene. Long term results, however, have shown that there is no difference of either design as long as the procedure is done well (19). In the present series, the technique was carried out with PCL retention. There was one registered case of knee dislocation but other than that, there was nothing to indicate that retention of the PCL was a problem. There is more to suggest that the cases of patellar component failure can be attributed to problems with metal backing than to increased polyethylene stress due to PCL-retention.

Comparison with other longer-term studies has shown that the AGC total knee replacement continues to show excellent survival characteristics in several studies. Based on the Finnish Arthroplasty Register, Himanen *et al* (9) registered approx 95% survival at 10 years, with no significant difference whether or not cement was used.

Worland *et al* (23) showed a 14-year survivorship of 97%. In this study, all patients had implantation with a cemented posterior cruciate-retaining design, with resurfacing of the patella using all polyethylene patella components. Keating *et al* (13) looking at 4,913 patients with the same knee prosthesis over a

17-year period, showed that the clinical survival rate with revision or loosening of one or more components as an endpoint was 98.9% at 15 years.

In general, the AGC total knee replacement has been shown to have excellent survival characteristics in spite of having a nearly flat-on-flat geometry. It is believed that the monobloc construction and direct compression-moulded polyethylene are two important factors for the overall success rate (11). On the basis of this series we recommend the continued use of the AGC 2000, but without metal-backing of the patellar component, in younger patients. Regarding the early failure of the tibial component, the addition of a hydroxyapatite coating could be an option. Further studies are needed to decide the best solution for this component.

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