The Anatomical Graduated Component total knee replacement
A LONG-TERM EVALUATION WITH 20-YEAR SURVIVAL ANALYSIS

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The long-term success of total knee replacement is multifactorial, including factors relating to the patient, the operation and the implant. The purpose of this study was to examine the 20-year survival of the cemented Anatomical Graduated Component (AGC) total knee replacement. Between 1983 and 2004, 7760 of these were carried out at our institution. Of these, 6726 knees which received the non-modular metal-backed tibial component with compression-moulded polyethylene and had a minimum two-year follow-up were available for study. In all, 36 knees were followed over 20 years with a survival of the tibial and femoral components together of 97.8% (95% confidence interval (CI) 0.9851 to 0.9677), with no implants being revised for polyethylene wear or osteolysis. Age > 70 was associated with increased survival (99.6%, 95% CI 99.0 to 99.8) (p < 0.0001) but pre-operative valgus alignment reduced survival (95.1%, 95% CI 90.0 to 97.6) (p = 0.0056). Age < 55 (p = 0.129), pre-operative varus alignment (p = 0.707), osteonecrosis (p = 0.06), rheumatoid arthritis (p = 0.247), and gender (p = 0.666) were not statistically associated with failure.

We attribute the success of the AGC implant to its relatively unconstrained articular geometry and the durability of a non-modular metal-backed tibial component with compression moulded polyethylene.

Patients often ask how long their total knee replacement (TKR) will last, and whether there are any predisposing factors that might precipitate failure or impede the success of their joint replacement. At present long-term reports in the literature describe the original Total Condylar total knee replacement designs and the Anatomic Graduated Component (AGC, Biomet, Warsaw, Indiana) TKR which were implanted over 20 years ago and demonstrate success rates between 91% and 98% at 10 to 26 years.1-11 Rand and Ilstrup,12 in 1991, reported the outcome of 9200 TKRs and noted four variables which were significantly associated with excellent long-term survival: a primary TKR, a diagnosis of rheumatoid arthritis, age > 60 years, and the use of a cemented condylar prosthesis with a metal-backed tibial component. In the presence of these variables a survival exceeding 97% was achieved at ten years. In 2003 a similar message was published when it was noted that age > 70 years, a diagnosis of rheumatoid arthritis, and retention of the posterior cruciate ligament with a cemented metal-backed tibial prosthesis offered the greatest chance for success.13 Our 15-year results using the AGC non-modular TKR with compression-moulded polyethylene showed a 98.6% survival rate.14 The purpose of this paper is to report the 20-year survival of the AGC prosthesis and note whether there are any other factors which may contribute to the outcome.

Patients and Methods
Between September 1983 and December 2004, 7760 primary cemented AGC TKRs were performed. In all, 533 TKRs in 482 patients were lost to follow-up (6.9%). A minimum follow-up of two years was selected, extending up to 22 years with a mean of 6.9 years. A total of 536 AGC TKRs in 405 patients where an all-polyethylene tibial component had been implanted were excluded from the analysis, since their outcome has been reported before.15 There remained 6726 TKRs in 4408 patients to form the study group. A total of 2118 patients underwent simultaneous bilateral TKR, with a constrained condylar TKR (Zimmer, Warsaw, Indiana) being implanted in one knee. There were 4235 AGC TKRs in total. The surgery was performed by six surgeons using similar surgical techniques, instrumentation and post-operative rehabilitation programmes. The AGC was the most commonly implanted device at our centre over the past 24 years, but the selection criteria for this implant were not defined. They were
determined by the surgeon, generally independent of the deformity or diagnosis. Pre-operative antibiotics were administered routinely and thromboembolic prophylaxis was provided by intravenous heparin and graduated compression stockings, as has been previously reported. The mean age at operation was 69.9 years (23 to 93) and 2664 patients (60%) were women, representing 4007 (60%) TKRs. The diagnosis leading to TKR was osteoarthritis in 6427 knees (96%), rheumatoid arthritis in 214 (3%), and osteonecrosis in 68 (1%). During this study period 1278 (29%) patients, involving 1920 knees (29%) died. The remainder of the variables are noted in Table I. The AGC TKR used in this study was the cemented posterior cruciate ligament-retaining prosthesis with a metal-backed, non-modular tibial component with compression-moulded polyethylene (Himont 1900 resin, DuPont, Wilmington, Delaware). There were three different methods of sterilisation during the study: gamma irradiation in air (1887), gamma in argon with first barrier (non-sealed plastic wrap) package (1547) and gamma in argon with second barrier (totally sealed plastic wrap) package (2876). A cut-off period of two months both prior to and immediately following each change over date between sterilisation techniques was used in order to insure that the prior sterilisation technique’s prosthesis was properly cleared from our inventory. This resulted in an otherwise unbiased exclusion of 416 knees, none of which failed or had to be revised. The articular geometry is non-conforming, with a relatively flat-on-flat coronal plane design which allows complete interchangeability of size (Fig. 1). All the patellae were resurfaced with a cemented patellar component. Knee Society Scores (KSS), pain scores, and function scores as well as Knee Society radiographic scores were collected at each follow-up visit. These were scheduled for six months, one year, and every two years thereafter. Time to failure was recorded with

<table>
<thead>
<tr>
<th>Table I. Patient characteristics</th>
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<tbody>
<tr>
<td>Number (%)</td>
</tr>
<tr>
<td>Age of patient at time of operation (yrs)</td>
</tr>
<tr>
<td>≤ 55</td>
</tr>
<tr>
<td>56 to 70</td>
</tr>
<tr>
<td>≥ 71</td>
</tr>
<tr>
<td>Missing values</td>
</tr>
<tr>
<td>Pre-operative alignment</td>
</tr>
<tr>
<td>Varus (4° to -25°)</td>
</tr>
<tr>
<td>Normal (5° to 10°)</td>
</tr>
<tr>
<td>Valgus (11° to 40°)</td>
</tr>
<tr>
<td>Missing values</td>
</tr>
<tr>
<td>Bilaterality (knees)</td>
</tr>
<tr>
<td>Unilateral</td>
</tr>
<tr>
<td>Simultaneous</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Table II. The Knee Society scores and component values pre- and three to seven years post-operatively. All values mean (sd)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-operative</td>
</tr>
<tr>
<td>Score</td>
</tr>
<tr>
<td>Function</td>
</tr>
<tr>
<td>Pain</td>
</tr>
<tr>
<td>Stairs</td>
</tr>
<tr>
<td>Walking</td>
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<tr>
<td>Flexion (*)</td>
</tr>
<tr>
<td>Extension (*)</td>
</tr>
<tr>
<td>Alignment (*)</td>
</tr>
<tr>
<td></td>
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* paired t-test

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<tr>
<th>Table III. The occurrence of radiolucent lines at the tibial interface</th>
</tr>
</thead>
<tbody>
<tr>
<td>Follow-up time (yrs)</td>
</tr>
<tr>
<td>Number with radiolucenty (%)</td>
</tr>
<tr>
<td>Number of implants examined</td>
</tr>
</tbody>
</table>
Kaplan-Meier survival analysis performed with aseptic loosening or revision of any component as the endpoint and allowed for the calculation of asymmetrical 95% confidence intervals (CI).\textsuperscript{19} Failure mechanisms were recorded and have previously been reported.\textsuperscript{20}

**Statistical analysis.** Variables associated with revision were analysed by Cox's proportional hazards regression with a level of statistical significance of \( p \leq 0.05 \). Pre- and post-operative scores were analysed by the paired \( t \)-test on the change between pre-operative and the first post-operative score for each knee between two and nine years follow-up.

The patient variables tested were age, pre-operative alignment, gender, diagnosis and bilaterality for association with survival of the prosthesis.

**Results**

The pre- and post-operative variables and KSS knee and function scores are noted in Table II, with a statistically significant improvement in all variables.

\begin{table}[h]
\centering
\begin{tabular}{|c|c|c|c|c|c|}
\hline
Time (yrs) & Number at risk & Number of failures & Number deceased & Survival & 95\% confidence interval \\
\hline
3 & 6027 & 16 & 271 & 0.9976 & 0.9960 to 0.9985 \\
5 & 4444 & 32 & 595 & 0.9945 & 0.9921 to 0.9961 \\
10 & 1550 & 47 & 1370 & 0.9884 & 0.9841 to 0.9916 \\
15 & 341 & 55 & 1781 & 0.9780 & 0.9677 to 0.9851 \\
20 & 36 & 55 & 1909 & 0.9780 & 0.9677 to 0.9851 \\
\hline
\end{tabular}
\caption{Abridged survival analysis with tibial or femoral component revision as the endpoint}
\end{table}

\begin{table}[h]
\centering
\begin{tabular}{|c|c|c|c|c|c|}
\hline
Interval (yrs) & 5 & 10 & 15 & 20 & Success rate \\
\hline
Implants remaining & 4441 & 1552 & 342 & 36 & \text{Overall aseptic survival at interval} \\
\hline
Overall aseptic survival at interval & 0.9945 & 0.9884 & 0.9780 & 0.9780 & \text{55 failures, 99.2\% success} \\
\hline
Failure & & & & & \text{Tibial} \\
\hline
Tibial & 0.9948 & 0.9901 & 0.9828 & 0.9828 & \text{48 failures, 99.3\% success} \\
\hline
Femoral & 0.9993 & 0.9970 & 0.9939 & 0.9939 & \text{11 failures, 99.8\% success} \\
\hline
Age (yrs) & & & & & \text{≤ 55} \\
\hline
≤ 55 & 0.9798 & 0.9703 & 0.9703 & - & \text{7 failures, 98.2\% success} \\
\hline
56 to 70 & 0.9921 & 0.9830 & 0.9642 & 0.9642 & \text{39 failures, 98.6\% success} \\
\hline
≥ 71 & 0.9979 & 0.9956 & 0.9956 & 0.9956 & \text{9 failures, 99.7\% success} \\
\hline
Diagnosis & & & & & \text{Osteoarthritis} \\
\hline
Osteoarthritis & 0.9946 & 0.9885 & 0.9768 & 0.9768 & \text{52 failures, 99.2\% success} \\
\hline
Osteonecrosis & 0.9636 & 0.9636 & 0.9636 & 0.9636 & \text{2 failures, 97.1\% success} \\
\hline
Rheumatoid arthritis & 1.0000 & 0.9919 & 0.9919 & 0.9919 & \text{1 failure, 99.5\% success} \\
\hline
Gender & & & & & \text{Male} \\
\hline
Male & 0.9950 & 0.9878 & 0.9757 & 0.9757 & \text{22 failures, 99.2\% success} \\
\hline
Female & 0.9941 & 0.9888 & 0.9794 & 0.9794 & \text{33 failures, 99.2\% success} \\
\hline
Alignment (°) & & & & & \text{Varus ≤ 4} \\
\hline
Varus ≤ 4 & 0.9953 & 0.9899 & 0.9839 & 0.9839 & \text{32 failures, 99.3\% success} \\
\hline
Neutral ≥ 5 to ≤ 10 & 0.9971 & 0.9904 & 0.9814 & 0.9814 & \text{5 failures, 99.4\% success} \\
\hline
Valgus ≥ 11 & 0.9930 & 0.9785 & 0.9513 & 0.9513 & \text{9 failures, 98.2\% success} \\
\hline
\end{tabular}
\caption{Survival analysis of 6726 knee replacements for all variables}
\end{table}

\begin{table}[h]
\centering
\begin{tabular}{|c|c|c|c|c|}
\hline
Indication for revision & Number of knees (%) \\
\hline
Loosening of the tibial component & 44 (0.7) \\
Loosening of the femoral component & 7 (0.1) \\
Loosening of the tibial and femoral components & 4 (0.6) \\
Infection & 13 (0.2) \\
Loosening of the metal-backed patellar component & 15 (0.2) \\
Isolated patella revision & 19 (0.3) \\
Total & 102 (1.5) \\
\hline
\end{tabular}
\caption{All causes of failure}
\end{table}

All the clinical scores reported relate to between three and seven years post-operatively only. It has been noted previously that scores begin to deteriorate after seven years.\textsuperscript{21} The incidence of tibial interface radiolucent lines is shown in Table III and did not exceed 9\% at any study interval. The relationship of time on the development of these lines gave
an odds ratio of 0.989 per year (p = 0.11). Logistic regression indicates that with increasing time from implantation there is a diminishing chance of a radiolucency developing. At 20 years’ follow-up, when only 30 implants were available for analysis, only one implant had a tibial radiolucent line. In contrast, erosive osteolysis was not noted at any follow-up. The overall survival at 20 years was 97.8% (95% CI, 0.9677 to 0.9851) with revision of the tibial or femoral component as the endpoint (Table IV). The survival rate at 20 years for the tibial component was 98.3% (95% CI 97.4 to 98.9) and for the femoral component was 99.4% (95% CI 98.6 to 99.7) (Table V). Applying regression analysis, age > 70 years was 4.6 times less likely to be associated with failure (p < 0.001), and pre-operative valgus alignment (11° to 40° of anatomical valgus) was 2.8 times more likely to be associated with failure (p = 0.006). Age 55 years and under was not statistically associated with failure (odds ratio (OR) = 1.9, p = 0.128), neither were pre-operative varus alignment (OR = 1.2, p = 0.707), osteonecrosis (OR = 3.9, p = 0.06), rheumatoid arthritis (OR = 0.3, p = 0.247), bilaterality (OR = 1.01, p = 0.9767) or gender (OR = 1.1, p = 0.666). There were 48 tibial revisions, 11 femoral revisions, and 34 patellar revisions throughout the study (Table VI).22 The survival of the prosthesis at 20 years with the endpoint of aseptic loosening of the tibial, femoral or patellar components was 94.58% (95% CI 0.9073 to 0.9686) (Table VII) and at the same interval with the addition of infection as a cause of failure, was 93.11% (95% CI 0.8935 to 0.9558) (Table VIII). Of the 13 failures associated with an infection, nine were successfully treated with a two-stage revision procedure, but two required a repeat two-stage exchange with delayed reimplantation. Two required an above-knee amputation and nine an arthrodesis.

Sterilisation by gamma irradiation in air was associated with a survival of 0.9885 (95% CI 98.12 to 99.30) at ten years and 0.9790 (95% CI 96.69 to 98.68) at 20 years for tibial and femoral failure. Survival for implants sterilised by gamma irradiation in argon with first barrier package was 0.9907 (95% CI 98.29 to 99.50) at ten years and 0.9793 (95% CI 95.30 to 99.10) at 12 years. Gamma irradiation in argon with second barrier package survival was 0.9857 (95% CI 96.09 to 99.48) at ten years.

Discussion

Many designs of TKR are currently available but the results at 20 years are known for few, except the total condylar-type,1-9 which when performed with retention of the posterior cruciate ligament has a survival of 98.6%,5,6 and with substitution of the posterior cruciate ligament a survival ranging from 90.7% to 92.9%.1-4 The survival of the Press-Fit Condylar prosthesis (PFC, DePuy, Warsaw, Indiana) with cruciate retention was reported to be 92.6%8 and with cruciate substitution was 91.5%,7 both at 15 years of follow-up. In our study, the AGC TKR, when considering survival of the tibial and femoral components, was found to be 97.8% at 20 years, with no implants being revised for polyethylene wear or osteolysis. This might be a reflection of the use of a non-modular, compression-moulded polyethylene implant. Other authors have found polyethylene wear to be a leading cause of failure and revision.22,23 Osteolysis, a problem often associated with articular and backside polyethylene wear, has been noted with TKRs that use modular tibial components.24,25 This problem has not so far been reported with the AGC TKR, and could be due to non-modular metal-backed tibial components with compression-moulded polyethylene being more resistant to backside wear, oxidation, and the negative impact of a deterioration of the locking mechanism in vivo.25 Other strategies to reduce polyethylene wear have included all-polyethylene tibial components,26 mobile-bearing TKRs,27,28 and improved locking mechanisms, but none have the documented long-term survival to match that of the AGC TKR which has been in use since 1983. In this study we found two variables that affected the survival of

### Table VII. Abridged survivorship analysis for tibial, femoral or patellar component

<table>
<thead>
<tr>
<th>Time (yrs)</th>
<th>Number at risk</th>
<th>Number of failures</th>
<th>Number of deceased</th>
<th>Survival</th>
<th>95% confidence interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>6027</td>
<td>19</td>
<td>271</td>
<td>0.9969</td>
<td>0.9952 to 0.9980</td>
</tr>
<tr>
<td>5</td>
<td>4444</td>
<td>38</td>
<td>596</td>
<td>0.9935</td>
<td>0.9911 to 0.9953</td>
</tr>
<tr>
<td>10</td>
<td>1550</td>
<td>61</td>
<td>1369</td>
<td>0.9946</td>
<td>0.9979 to 0.9983</td>
</tr>
<tr>
<td>15</td>
<td>340</td>
<td>70</td>
<td>1779</td>
<td>0.9735</td>
<td>0.9630 to 0.9811</td>
</tr>
<tr>
<td>20</td>
<td>34</td>
<td>74</td>
<td>1907</td>
<td>0.9458</td>
<td>0.9073 to 0.9686</td>
</tr>
</tbody>
</table>

### Table VIII. Abridged survival analysis for all causes of revision (tibial, femoral, patellar components, and infection)

<table>
<thead>
<tr>
<th>Time (yrs)</th>
<th>Number at risk</th>
<th>Number of failures</th>
<th>Number of deceased</th>
<th>Survival</th>
<th>95% confidence interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>6027</td>
<td>26</td>
<td>266</td>
<td>0.9956</td>
<td>0.9940 to 0.9972</td>
</tr>
<tr>
<td>5</td>
<td>4444</td>
<td>46</td>
<td>590</td>
<td>0.9922</td>
<td>0.9896 to 0.9942</td>
</tr>
<tr>
<td>10</td>
<td>1550</td>
<td>84</td>
<td>1357</td>
<td>0.9782</td>
<td>0.9725 to 0.9826</td>
</tr>
<tr>
<td>15</td>
<td>340</td>
<td>97</td>
<td>1766</td>
<td>0.9623</td>
<td>0.9504 to 0.9741</td>
</tr>
<tr>
<td>20</td>
<td>34</td>
<td>102</td>
<td>1893</td>
<td>0.9311</td>
<td>0.8935 to 0.9558</td>
</tr>
</tbody>
</table>
the AGC TKR at a follow-up of 20 years: age > 70 increased survival (99.6%), whereas pre-operative valgus angulation reduced survival (95.1%).

Variables examined that were not independently associated with success or failure were age < 55 years, pre-operative varus, rheumatoid arthritis, bilateral procedures, body mass index (BMI) and gender. Even though a statistical difference was noted, because this was such a large series of TKRs, the survival was 97.8% for all variables except osteonecrosis and pre-operative valgus angulation, which still had a survival of 96% and 95%, respectively. The influence of varus tibial alignment, combined with an increased BMI, on failure20 as well as late instability in valgus knees with a planovalgus foot22 has been described previously for this prosthetic. This 20-year survival analysis adds to the evidence of Rand et al., who, considering implant factors, found that a posterior cruciate ligament-retaining, metal-backed, non-modular cemented TKR with an all-polyethylene patellar component had the highest survival in their analysis of over 11 000 TKRs. Few implants today implement this strategy for improving long-term survival through non-modularity.

Limitations of this study were that data were collected prospectively and analysed retrospectively. Further, no clear selection criteria for this implant were established, which may have allowed a selection bias. A small proportion of patients were lost to follow-up and their status is unknown. The surgical technique has been gradually modified with the introduction of intramedullary instrumentation positioning the femoral component in some external rotation, a reduction in the number of lateral releases performed, and the type of cement used for fixation. The effect of these modifications during the course of the study remains unknown, although the reduction in the requirement for a lateral release in the presence of some external rotation of the femoral component has been recognised.22 The use of a cruciate-retaining non-modular cemented AGC TKR in the absence of a pre-operatively unstable deformity, implanted over the age of 70 years, gives a survival rate over 20 years of 98%.

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References