

Ten-Year Evaluation of Geometric Total Knee Arthroplasty

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One hundred ninety-three geometric total knee arthroplasties (TKA) were performed between 1972 and 1975 in 129 patients (66 women, 63 men; mean age, 69 years) with osteoarthritis. Of these, 102 knees were followed for a mean of 11 years. Eighty-three percent of the patients had mild or no pain. The revision rate was 20%, and the surgical complication rate was 12%. By actuarial analysis, the probability of retaining a geometric prosthesis at 10 years was 78%. With revision or moderate to severe pain as the end point, the predicted implant survival was 69% at 10 years. Lucent lines >1 mm were present in 38% of the knees and progressed in 34%; they were more frequent in knees with $\geq 3^\circ$ of varus axial alignment ($p < 0.05$) or $\geq 4^\circ$ of varus placement of the tibial component ($p < 0.05$). The geometric prosthesis has provided a functional result in 69% of knees at 10 years, despite being the first two-part component knee replacement retaining the cruciate ligaments and using early surgical instrumentation and implant design.

The prosthesis for total knee arthroplasty (TKA) has developed into a condylar design. Early resurfacing implant designs failed primarily because of loosening.¹² Cementless fixation of implants has been advocated to avoid problems with loosening that result from cement failure.⁴ However, problems

with cementless tibial implant fixation have been reported.¹⁰ The long-term results with cemented prostheses serve as a baseline for comparison with cementless devices. The geometric prosthesis is most susceptible to loosening because there is a kinematic mismatch between a geometrically partially constrained implant with a single axis of rotation and cruciate ligament retention.⁸ In addition, the need for alignment, precise instrumentation, and soft tissue balancing was not fully appreciated during the early experience with this device.

MATERIALS AND METHODS

One hundred ninety-three geometric total knee prostheses were implanted between February 1972 and March 1975 in 129 patients (63 men and 66 women) with diagnoses of osteoarthritis. At the follow-up evaluation (mean \pm SD, 10.8 ± 1 years; minimum, 8 years), 102 knees in 69 patients (29 men and 40 women) were available for review. Of the remaining knees, 22 had been revised to other implants and 4 had an arthrodesis; 65 of the patients had died. Of the 22 knees revised to another implant, failure of the geometric knee occurred in six patients between eight and 12 years after implantation. The knees available for evaluation were 56 right knees and 46 left knees. Mean (\pm SD) age at operation was 69 ± 7 years; for these patients mean height was 163 ± 10 cm, and mean weight was 71.2 ± 13.2 kg. Only four knees had undergone prior operation (two patellectomies, two medial meniscectomies, one upper tibial valgus osteotomy, two debridements, and one arthroscopy). Associated hip disease was present on the ipsilateral side in five, contralateral side in six, and both sides in three. Contralateral knee disease was present in 89 patients.

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Pain and ambulatory function were evaluated preoperatively, one year postoperative, and at the last examination. Physical examinations for ligamentous stability and range of motion were performed at the same time intervals. Complete data were available for all patients preoperatively. At one year, physical examination data were available for 93 knees; the remainder were evaluated by questionnaire. At the last examination, physical examination data were available for 59 knees; the remainder were evaluated by questionnaire.

Standing anteroposterior and lateral roentgenograms were evaluated preoperatively, two weeks postoperative, one year postoperative, and at last examination according to described techniques¹¹ to reveal axial alignment and component orientation. Lucent lines were quantified according to zone (Fig. 1). Roentgenograms were available for 80 knees before the operations, 85 knees at two weeks, 76 knees at one year, and 81 knees at the last examination. Malrotated roentgenograms were excluded from measurement; therefore for some patients the data were incomplete concerning component positioning at each time interval. Progression of lucent lines was defined as an increase in length or width by at least 1 mm on sequential roentgenograms.

Comparisons of continuous variables such as range of motion and ordered categoric variables were made with the Wilcoxon rank-sum test. Comparison of proportions was made with a χ^2 test or, when appropriate, with Fisher's exact test. Changes in continuous variables were tested with the signed-rank test, and changes in proportions were tested with the sign test. Prosthesis survival was estimated by using nonparametric statistics.⁷

RESULTS

The functional results were satisfactory. Moderate or severe pain on weight bearing was present in 96 of 102 knees preoperatively compared with only 17 of 99 knees at the last examination ($p = 0.0001$; Table 1). Walking ability improved, with eight of 69 patients

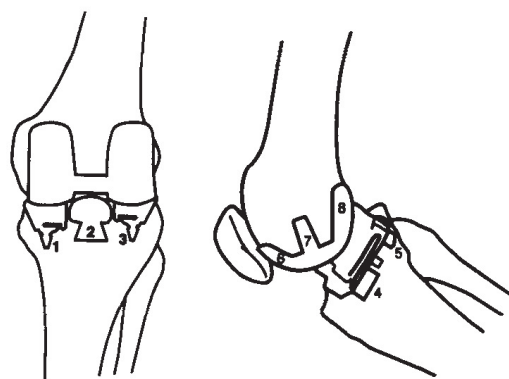


FIG. 1. This diagram of anteroposterior and lateral views shows zones for measurement of radio-lucent lines.

(16 of 102 knees) able to walk more than four blocks preoperation compared with 33 of 54 patients (50 of 81 knees) at the last examination ($p = 0.0001$; Table 2). The need for walking aids decreased, from 53 of 69 patients (77 of 102 knees) requiring aids before the operation to 25 of 66 patients (38 of 93 knees) at the last examination ($p < 0.05$; Table 3). The range of motion of the knee remained unchanged (Table 4). Knee extension improved significantly but flexion did not.

The axial alignment of the limb improved immediately after operation (Table 5). The decreased axial alignment at the last examination suggested some implant settling and recurrence of deformity. However, other measurements of implant position did not change. There was no significant correlation between the duration of implant function and postoperative axial alignment.

Lucent lines were localized to the bone-cement interface except for three instances of

TABLE 1. Pain on Weight Bearing

Time	Number of Knees					Total
	None	Mild	Moderate	Severe	Unavailable	
Preoperative	0	6	55	41	0	102
Last examination	65	17	13	4	3	102

TABLE 2. Walking Distance

Walking ability	Number of Knees	
	Preoperative	Last examination
>6 blocks	2	48
4-6 blocks	14	2
1-3 blocks	52	20
Indoors	31	5
Bed-to-chair	2	6
Unavailable	1	21
Total	102	102

tibial component-cement lucency at the last examination (the prosthesis-cement lucent lines were complete in two of these three knees). The bone-cement lucent lines were localized to the tibial component with the exception of three femoral components (Table 6). Lucent lines increased in frequency from 5% at two weeks to 22% at one year and 38% at last examination. They were most frequently located under the medial and lateral aspects of the tibial component. Tibial lucent lines ≥ 2 mm in width were present in two knees at one year and in 31 knees at the last examination. Progression of lucent lines from two weeks to the last examination occurred in 34%. At the last examination, lucent lines were seen in nine of 15 knees with $\geq 3^\circ$ of varus as the initial postoperative axial alignment, compared with 17 of

TABLE 3. Use of Walking Aids

Aid	Number of Knees	
	Preoperative	Last examination
None	25	55
Cane	58	27
Crutch	5	3
Crutches	12	3
Walker	2	5
Unable to walk	0	6
Unavailable	0	3
Total	102	102

TABLE 4. Range of Motion

	Mean \pm SD	
	Preoperative (n = 102)	Last examination (n = 54)
Extension	$-9^\circ \pm 10^\circ$	$-2^\circ \pm 4^\circ$ *
Flexion	$101^\circ \pm 22^\circ$	$98^\circ \pm 12^\circ$
Range	$92^\circ \pm 37^\circ$	$96^\circ \pm 13^\circ$

* $p = 0.0001$.

53 with more valgus axial alignment ($p < 0.05$). An initial coronal orientation of the tibial component $\geq 4^\circ$ of varus was seen in 21 of 45 knees with lucent lines at last examination, compared with five of 23 with a more valgus component orientation ($p < 0.05$).

By actuarial analysis with an end point of a geometric implant without revision, 78% of the TKAs were predicted to be functioning at ten years (Fig. 2). With an end point of revision or moderate or severe pain, 69% of the TKAs were predicted to be functioning at ten years. Ten-year survival was 73% for knees in varus alignment, 90% for knees between 0° and 4° of valgus, and 71% for knees between 5° and 9° of valgus. These differences were not statistically significant. The coronal tibial component orientation did not affect implant survival.

Revision procedures were performed in 38 (34 patients) of the 193 knees (20%). Twelve knees were revised to other geometric prostheses, 11 knees were revised to condylar prostheses, and 11 knees were revised to hinged prostheses. Four knees had arthrodesis for sepsis. The reasons for revision were implant loosening in 24 knees (tibial only, 20; both components, 4), axial malalignment in seven knees (varus, 6; valgus, 1), deep infection in four, instability in three, bone fracture in two, and tibial implant breakage in one. Some knees had more than one reason for revision.

Complications consisted of 12 surgical and 13 medical problems. The former included five deep and two superficial infections, one

TABLE 5. Alignment by Roentgenographic Assessment

	Preoperative	At 2 weeks	At 1 year	At last examination
Axial alignment	-9 ± 12 (n = 80)	3 ± 5 (n = 85)	2 ± 6 (n = 76)	0 ± 8 (n = 81)
Coronal femur	—	7 ± 4 (n = 85)	6 ± 4 (n = 76)	6 ± 4 (n = 79)
Coronal tibia	—	-4 ± 4 (n = 85)	-4 ± 4 (n = 76)	-5 ± 4 (n = 77)
Sagittal femur	—	10 ± 6 (n = 60)	11 ± 7 (n = 30)	10 ± 6 (n = 44)
Sagittal tibia	—	1 ± 7 (n = 77)	4 ± 7 (n = 39)	4 ± 9 (n = 69)

Values are mean ± SD; sample sizes in parentheses.

wound hematoma, one superficial wound necrosis, two stress fractures of the medial tibial plateau, and one tibial implant breakage. Thromboembolic complications consisted of three clinically symptomatic pulmonary emboli and two deep venous thromboses. There were five urinary tract infections and one case each of cardiac arrhythmia, pneumonia, and cerebrovascular accident.

DISCUSSION

The geometric prosthesis was a kinematic mismatch between a conforming prosthetic geometry and retained cruciate ligaments.^{3,8} Using measurements of the instant center of rotation, Ghelman *et al.*³ found that the prosthesis blocked motion at full flexion. Beyond 60° of flexion, there is increased tension in the posterior cruciate ligament—up to four times normal—and a tendency for the anterior lip of the tibial component to lift from the tibia.⁸ *In vitro* torsional testing of the geometric prosthesis revealed that high loads were transmitted to the tibial bone–cement interface with small angles of rotation.¹⁷ Therefore, *in vitro* testing would suggest that tibial loosening should be frequent with the geometric prosthesis.

Clinical results with the geometric knee are summarized in Table 7. A follow-up study of up to 8.5 years revealed failure in

18% of 71 knees.¹³ Pain relief in 80% in the present series compares favorably with previously reported series. The known revision rate of 20% of the 193 knees represents the minimum failure rate. The actuarial survival of a retained implant, 78% at 10 years, was higher than the success rate reported by Riley and Woodyard,¹³ 21%, but they included severe pain or prosthesis removal as an end point for failure. Because it is impossible to determine when severe pain begins or to assess pain accurately, the authors chose im-

TABLE 6. Lucent Lines

	Overall	Tibia	Femur
At 2 weeks			
n	87	87	82
Lucent lines (no.)	4	4	0
Lucent lines (%)	5	5	0
At 1 year			
n	79	79	77
Lucent lines (no.)	21	21	0
Lucent lines (%)	27	27	0
Progression since 2 weeks (%)	22	22	0
At last examination			
n	86	86	81
Lucent lines (no.)	33	33	3
Lucent lines (%)	38	38	4
Progression (%)			
Since 1 year	27	27	2
Since 2 weeks	34	34	3

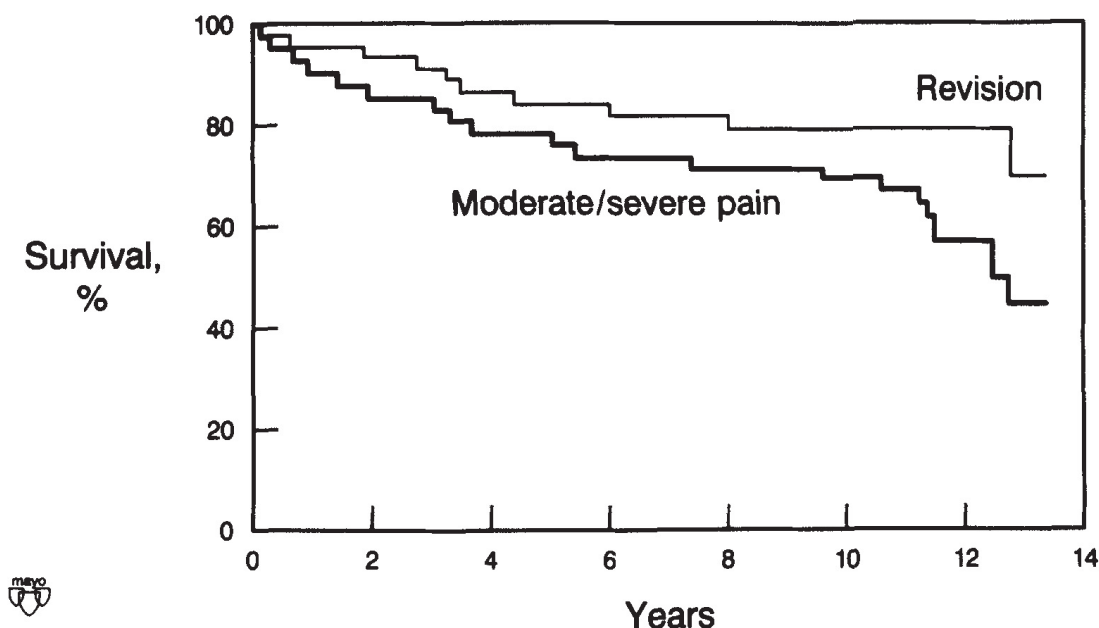


FIG. 2. Actuarial survival to revision or to moderate or severe pain.

plant removal or death as a more definitive end point. The success rate was 69% with pain or implant removal as an end point in the present series. The results in the present series should be less satisfactory than those in other series because only patients with osteoarthritis, and presumably increased functional demands, were included.

The incidence of radiolucent lines (38%) and the rate of progression (27%) after one year suggest a potential for symptomatic loosening. However, these results are better

than those in a group of 70 rheumatoid patients who had an 81% incidence of lucent lines and 37% incidence of progression at 6.5 years.¹⁶ Lucent lines were primarily tibial, suggesting problems with tibial fixation. Varus positioning of the tibial component or varus axial alignment of the limb correlated with the presence of lucent lines. This correlation confirms our previous findings and demonstrates the highly variable implant positioning achieved during this early experience with TKA.¹¹

TABLE 7. Reported Results With Geometric Knee Prostheses

Reference	Follow-up period (yr)	Number of Knees	Loosening (%)	Lucent lines (%)	Satisfactory (%)	Revision (%)
5, 15	2	119	12	—	84	—
1*	1	100	5	70	—	—
2	3.5	91	10	—	83**	—
9	4	150	3	—	84	5
6	5	63	14	—	63	—
14	7	51	6	43	—	—

* With Mark III designs.

** Pain relief.

The overall surgical complication rate, 12% (24 of 193 knees), and reoperation rate (excluding manipulations), 20% (38 of 193 knees), suggest better clinical results than anticipated for this implant, based upon the implant's biomechanical characteristics and variability in implant position and surgical technique. These results can be used as a baseline for comparison with current condylar implant designs and for prostheses fixed without cement.

The authors conclude that TKA with a geometric prosthesis has provided surprisingly durable results for ten years even though the implant design and surgical technique are considered unacceptable at the present time. These results with an early cemented implant design must be considered when newer alternatives of cementless implant fixation are being assessed.

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REFERENCES

1. Coventry, M. B.: Two-part total arthroplasty: Evolution and present status. *Clin. Orthop.* 145:29, 1979.
2. Cracchiolo, A., III, Benson, M., Finerman, G. A. M., Horacek, K., and Amstutz, H. C.: A prospective comparative clinical analysis of the first-generation knee replacements: Polycentric vs. geometric knee arthroplasty. *Clin. Orthop.* 145:37, 1979.
3. Ghelman, B., Walker, P. S., Shoji, H., and Erkman, M. J.: Kinematics of the knee after prosthetic replacements. *Clin. Orthop.* 108:149, 1975.
4. Hungerford, D. S., and Kenna, R. V.: Preliminary experience with a total knee prosthesis with porous coating used without cement. *Clin. Orthop.* 176:95, 1983.
5. Ilstrup, D. M., Coventry, M. B., and Skolnick, M. D.: A statistical evaluation of geometric total knee arthroplasties. *Clin. Orthop.* 120:27, 1976.
6. Imbert, J. C., and Caltran, M.: Le recul à 5 ans et l'évolution des prothèses à glissement du genou: De la prothèse "geometric" à la prothèse "anametric." *Rev. Chir. Orthop.* 67:499, 1981.
7. Kaplan, E. L., and Meier, P.: Nonparametric estimation from incomplete observations. *J. Am. Stat. Assoc.* 53:457, 1958.
8. Lew, W. D., and Lewis, J. L.: The effect of knee-prosthesis geometry on cruciate ligament mechanics during flexion. *J. Bone Joint Surg.* 64A:734, 1982.
9. Lowe, G. P., and McNeur, J. C.: Results of geometric arthroplasty for rheumatoid and osteoarthritis of the knee. *Aust. NZ J. Surg.* 51:528, 1981.
10. Rand, J. A., Bryan, R. S., and Chao, E. Y. S.: A comparison of cemented versus cementless porous-coated anatomic total knee arthroplasty. In Rand, J. A., and Dorr, L. D. (eds.): *Total Arthroplasty of the Knee: Proceedings of the Knee Society 1985-1986*. Rockville, Maryland, Aspen Publishers, 1987, pp. 195-212.
11. Rand, J. A., and Coventry, M. B.: Stress fractures after total knee arthroplasty. *J. Bone Joint Surg.* 62A:226, 1980.
12. Rand, J. A., Peterson, L. F. A., Bryan, R. S., and Ilstrup, D. M.: Revision total knee arthroplasty. *AAOS Instructional Course Lectures*, Vol. 35, St. Louis, C. V. Mosby, 1986, p. 305.
13. Riley, D., and Woodyard, J. E.: Long-term results of geometric total knee replacement. *J. Bone Joint Surg.* 67B:548, 1985.
14. Riley, L. H., Jr.: Total knee arthroplasty. *Clin. Orthop.* 192:34, 1985.
15. Skolnick, M. D., Coventry, M. B., and Ilstrup, D. M.: Geometric total knee arthroplasty: A two-year follow-up study. *J. Bone Joint Surg.* 58A:749, 1976.
16. Torisu, T., and Morita, H.: Roentgenographic evaluation of geometric total knee arthroplasty with a six-year average follow-up period. *Clin. Orthop.* 202:125, 1986.
17. Werner, F., Foster, D., and Murray, D. C.: The influence of design on the transmission of torque across knee prostheses. *J. Bone Joint Surg.* 60A:342, 1978.