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A Prospective Randomized Study of Minimally Invasive Total Knee Arthroplasty Compared with Conventional Surgery

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Background: Despite intense debate regarding whether minimally invasive techniques for total knee arthroplasty improve clinical outcomes over standard techniques, few prospective randomized trials addressing this debate are available in the literature. We therefore designed this multicenter study to assess the overall safety and effectiveness of a minimally invasive approach without the use of computer navigation in comparison with conventional knee arthroplasty.

Methods: We prospectively randomized 134 patients (101 women and thirty-three men, with an average age of 70.1 years) to undergo surgery for total knee arthroplasty with use of either minimally invasive knee instruments (sixty-six patients) or a standard approach (sixty-eight patients). The follow-up period was one year.

Results: On the basis of our sample size, no significant difference was detected between the groups in any of the relevant clinical areas assessed: total range of motion, Knee Society total and function scores, and visual analog scores for pain and activities of daily living. Patients who underwent minimally invasive surgery had a longer mean surgical time (by 5.6 minutes) and had less mean blood loss (by 17 mL). Radiographic measurements demonstrated reliable implant positioning in both groups. Seven patients in each group had an adverse event related to their procedure.

Conclusions: On the basis of the numbers, no significant advantage to minimally invasive total knee arthroplasty over a conventional technique was observed. Greater sample sizes and a longer follow-up period are required to fully determine the long-term safety and efficacy of this minimally invasive surgical technique.

Level of Evidence: Therapeutic Level II. See Instructions to Authors for a complete description of levels of evidence.

Studies of minimally invasive surgery techniques for total knee arthroplasty have resulted in a wide range of clinical results. Although certain analyses have associated minimally invasive surgery approaches with early benefits, such as decreased pain, improved time to functional recovery, and enhanced range of motion[1-6], others have failed to demonstrate any substantial differences between these techniques and conventional methods in the postoperative period[6-8]. Unfortunately, only a small number of these studies have been prospective randomized comparisons of minimally invasive surgery and conventional total knee arthroplasties, and even fewer have offered such a comparison without the use of computer navigation accompanying the minimally invasive surgery approach[5,7,8]. As such, major debate continues in the orthopaedic community regarding whether minimally invasive surgery techniques are truly beneficial to patients undergoing total knee arthroplasty.

We conducted a prospective randomized multicenter study, without the use of computer navigation in the minimally invasive approach or the standard approach. Our objective was to assess the overall safety and effectiveness of a minimally

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invasive procedure in comparison with a standard surgical technique using clinical and radiographic outcomes. We hypothesized that there would be no difference between the two surgical techniques.

Materials and Methods

Following approval of the ethics review board of each center, patients consented to be included in the study after receiving comprehensive information regarding the study protocol and other details. Inclusion criteria for this study dictated that the patient required either a primary unilateral or bilateral total knee replacement, was eighteen to eighty years old, provided informed consent, was available for follow-up through at least two years, and was in stable health, meaning free of conditions or treatment for conditions that would pose an excessive operative risk. Patients were excluded if they were known to have insufficient femoral or tibial bone stock, a body mass index of >35 kg/m^2, a failed total or unicondylar knee replacement of the affected knee, an active local or systemic infection, collateral ligament insufficiency, knee flexion of <90°, a fixed flexion deformity of >15°, a varus or valgus deformity of >20°, and/or an immunosuppressive disorder, such as acquired immunodeficiency syndrome (except inflammatory arthritis). The study was registered at ClinicalTrials.gov (NCT00853398).

If patients met these inclusion and exclusion criteria, they were randomized into one of the two treatment groups. Five separate sites participated in this study, with five high-volume surgeons performing each operation. Participating surgeons were required to have completed at least ten mini-

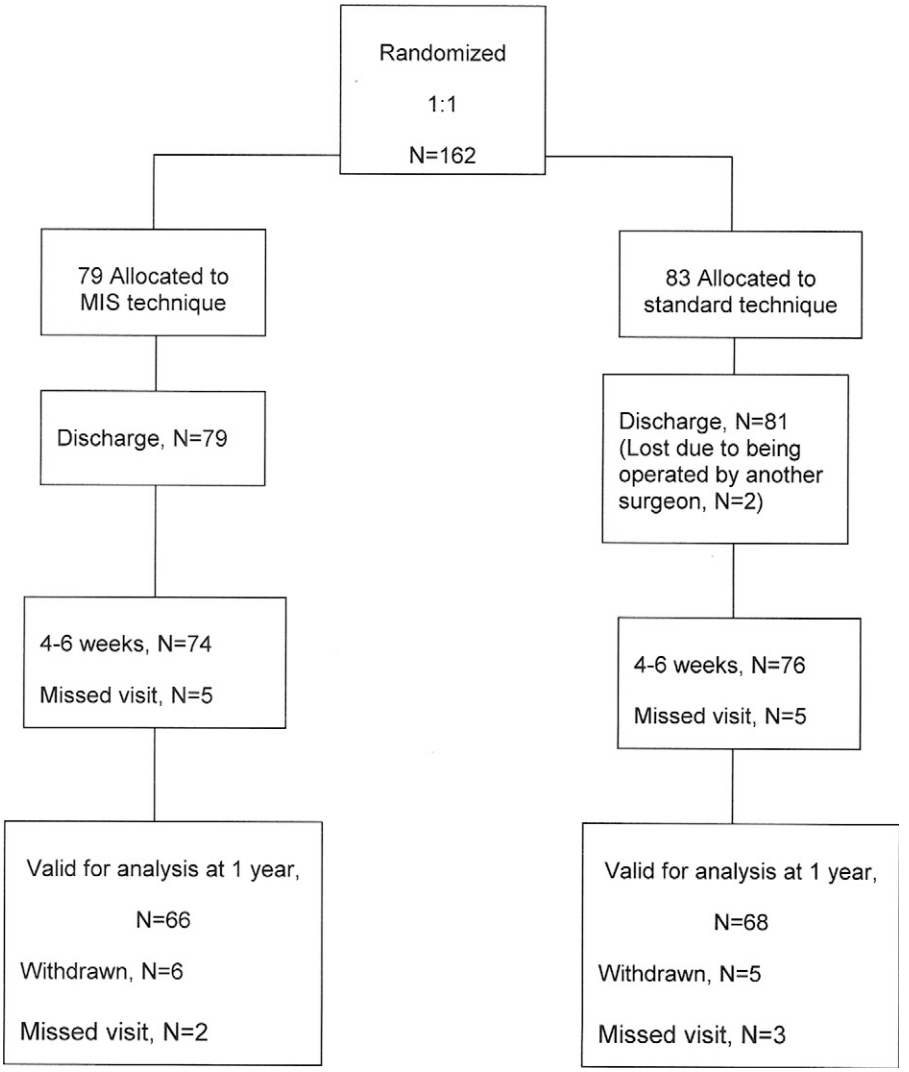

Fig. 1

Flow diagram of study participants. All analyses were performed on the 134 patients (sixty-six in the minimally invasive surgery [MIS] group and sixty-eight in the standard group) who had complete one-year follow-up data.

mally invasive knee arthroplasties prior to this study. Each site was provided with a separate randomization list.

From October 14, 2004, until September 28, 2006, 162 patients (Fig. 1) were randomized into the minimally invasive surgery group (without the concomitant use of computer navigation) and the standard procedure group. Two patients were declared lost to follow-up after surgery when the surgeon who performed the operation withdrew from the study. Additionally, eleven patients withdrew within one year, and fifteen were lost to follow-up at the one-year interval without reason.

Therefore, 134 patients (101 women and thirty-three men) were managed operatively and were evaluated. Of the 134 knees, sixty-six underwent minimally invasive surgery (the minimally invasive group) and sixty-eight had standard surgery (the standard group). Preoperatively, 110 knees (fifty-eight in the minimally invasive group and fifty-two in the standard group) were reported as being in varus alignment, twenty-one (six and fifteen, respectively) as being in neutral, and three (two and one, respectively) as being in valgus. There were sixty-eight right knees and sixty-six left knees. No bilateral procedures were performed. One of the patients randomized to undergo minimally invasive surgery was determined to have a prohibitively large knee that prevented prosthesis implantation with use of this technique, and therefore the procedure was converted to conventional total knee arthroplasty during surgery.

TABLE I Patient Baseline Characteristics Data for Both Groups

Parameters	Minimally Invasive Group (N = 66)	Standard Group (N = 68)
Age at surgery* *(yr)*	70.2 (68.6-71.9)	70.1 (68.5-71.7)
Body mass index* *(kg/m²)*	29.3 (28.2-30.4)	29.3 (28.1-30.4)
Male patients†	18 (27.3)	15 (22.1)
Female patients†	48 (72.7)	53 (77.9)
Primary diagnosis†		
Osteoarthritis	61 (92.4)	60 (88.2)
Rheumatoid arthritis	1 (1.5)	3 (4.4)
Osteonecrosis	0 (0)	2 (2.9)
Posttraumatic arthritis	4 (6)	3 (4.4)
Preop. knee score†	56.0 (52.3-59.8)	53.2 (49.5-57.0)
Preop. function score†	49.2 (44.4-54.1)	50.4 (45.5-55.2)
Preop. visual analog pain score†	56.7 (49.4-63.9)	53.4 (45.9-60.9)
Preop. visual analog score for activities of daily living‡	38.3 (30.5-46.0)	36.6 (28.6-44.7)

*The values are given as the mean, with the range in parentheses. †The values are given as the number of patients, with the percentage in parentheses. ‡The values are given as the mean, with the 95% confidence interval in parentheses.

Surgical Technique

All surgeons performed surgery according to the technique manuals for the minimally invasive surgery and standard techniques with use of the specific standard or minimally invasive Genesis II knee instruments (Smith and Nephew, Memphis, Tennessee) and using an anterior femoral cut first. Both minimally invasive surgery and standard surgery were performed with use of either a midvastus or medial parapatellar approach. On the basis of consensus among the investigators, minimally invasive surgery was defined as surgery requiring a skin incision of <15 cm and use of specific instrumentation. Spacer blocks were used to confirm ligament balancing in flexion and extension.

Intraoperative as well as postoperative pain management was identical for both the minimally invasive surgery and standard surgical techniques at each site; however, each site also employed their own pain management protocol. Because each site performed an equivalent number of minimally invasive and standard arthroplasties and no differences were observed between intraoperative and postoperative pain management, this aspect of the surgical technique was not taken into account for this study.

Postoperative Treatment

Walking was begun on the first postoperative day, with full weight-bearing allowed. Patients were mobilized with use of a walker, which was then replaced with a pair of crutches when sufficient stability was attained. Continuous passive motion was used from day 1 after surgery, and range of motion was increased as tolerated. Patients were routinely discharged on day 8 after surgery, with most patients going to an inpatient rehabilitation facility for another two to three weeks afterwards.

Follow-up examinations were carried out at hospital discharge, at four to six weeks after surgery, and at one year postoperatively. A few patients had been followed for two years at the early termination point of the study.

Radiographic measurements included the tibial angle (that is, the angle between the tibial axis and the tibial plateau in the coronal plane), the lateral tibial angle (the angle between the tibial axis and the tibial plateau in the sagittal plane), the femoral angle (the angle between the femoral axis and the distal line of the femoral component in the coronal plane), and the overall mechanical axis. These measurements were made at all study intervals.

Statistical Analyses

Intention-to-treat analysis was used for all clinical outcome variables and was performed by an independent blinded external statistician. The Student t test was used to determine any differences between intraoperative variables and for univariate comparison of postoperative parameters. Treatment comparisons for the continuous postoperative outcome variables were based on a marginal linear model[9,10], with the preoperative level of a variable used as a part of the outcome vector. Inferences on the correlation structure were based on a likelihood ratio test. On the basis of these, an unrestricted correlation structure was assumed in all models. Linear contrasts of fitted model esti-

TABLE II Intraoperative Data

Parameters	Minimally Invasive Group* (N = 66)	Standard Group* (N = 68)	P Value
Tourniquet time *(min)*	72.3 (67.6-77.0)	67.1 (62.9-71.3)	0.114
Duration of operation *(min)*	79.6 (75.0-84.2)	74.0 (68.7-79.3)	0.122
Blood loss *(mL)*	428 (359-498)	445 (372-518)	0.753
Incision length *(mm)*	123.8 (117.9-129.7)	185.6 (177.3-194.3)	<0.001

*The values are given as the mean, with the 95% confidence interval in parentheses.

mates were constructed and used to test the hypotheses of interest. Two-tailed tests were used throughout. Two-sided p values of <0.05 were considered to indicate significance.

Source of Funding
Smith and Nephew (Memphis, Tennessee) provided reimbursements to the study centers for documentation of the case report forms only.

Results

Patient demographics, preoperative Knee Society total and function scores, visual analog scores for pain and activities of daily living, and range of motion were comparable between the groups (Table I). The overall objective intraoperative results were similar for the standard and minimally invasive groups (Table II). The length of incision in extension was a mean (and standard deviation) of 123.8 ± 5.9 mm in the minimally invasive group compared with 185.6 ± 8.5 mm in the standard group. Other intraoperative indices were similar for the groups. The mean blood loss was 428 ± 289 mL (95% confidence interval, 359 to 498 mL) in the minimally invasive group compared with 445 ± 308 mL (95% confidence interval, 372 to 518 mL) in the standard group. The mean duration of surgery was 80 ± 19 minutes (95% confidence interval, 75.0 to 84.2 minutes) for the minimally invasive group and 74 ± 22 minutes (95% confidence interval, 68.7 to 79.3 minutes) for the standard group.

Data obtained during the hospital stay indicated similarity between the groups in terms of range of motion at day 3 and at discharge, although patients in the minimally invasive group had a mean range of motion at day 3 of nearly 7° better than those in the standard group (73.9° [95% confidence interval, 69.9° to 77.9°] compared with 67.1° [95% confidence interval, 61.9° to 72.4°]) (Table III).

Patients in the minimally invasive group had a mean baseline knee score of 56.0 (95% confidence interval, 52.3 to 59.8), improving to 62.6 (95% confidence interval, 56.9 to 68.2) at discharge, 88.8 (95% confidence interval, 85.4 to 92.1) at four to six weeks, and 86.3 (95% confidence interval, 81.0 to 91.6) at one year. Patients in the standard group had a mean baseline knee score of 53.2 (95% confidence interval, 49.5 to 57.0), improving to 64.8 (95% confidence interval, 58.8 to 70.9) at discharge, 85.7 (95% confidence interval, 82.4 to 89.1) at four to six weeks, and 84.0 (95% confidence interval, 79.0 to 89.0) at one year (see Appendix).

Similar outcomes were also noted between the groups in terms of the function score, the visual analog pain score, the visual analog activities of daily living score, and range of motion (see Appendix), indicating that, on the basis of the available numbers, there was no difference in these postoperative parameters between the two surgical techniques.

The difference in mean function score between the minimally invasive group and the standard group was –1.12 (95% confidence interval, –7.02 to 4.78) at baseline, 1.87 (95% confidence interval, –3.12 to 6.87) at discharge, 8.72 (95% confidence interval, 1.89 to 15.55) at four to six weeks, and 4.71 (95% confidence interval, –0.46 to 9.89) at one year. The difference in the mean activities of daily living scores between the minimally invasive and the standard group was 1.78 (95% confidence interval, –6.63 to 10.20) at baseline, 4.68 (95% confidence interval, –2.63 to 11.99) at discharge, 8.04 (95% confidence interval, 1.15 to 14.94) at four to six weeks, and –2.85 (95% confidence interval, –10.09 to 4.39) at one year. The confidence intervals of the function score and the activities of daily living score did not contain the value zero at the four to six-week interval. Because of multiple testing and the correlations between the tests, these results were not significant.

We found no significant difference in outcomes up to one year after surgery between patients managed with the minimally invasive technique and those managed with the standard technique.

Radiographic measurements demonstrated reliable implant positioning in both groups without any changes during the follow-up period. Both the tibial and femoral implant an-

TABLE III Range of Motion During Hospital Stay

	Minimally Invasive Group*	Standard Group*	P Value
Day 3	73.9 (69.9-77.9)	67.1 (61.9-72.4)	0.067
Discharge	93.9 (83.6-104.3)	90.8 (74.8-106.7)	0.177

*The values are given in degrees as the mean, with the 95% confidence interval in parentheses.

TABLE IV Postoperative Radiographic Measurements

	Discharge			One Year		
	Minimally Invasive Group*	Standard Group*	P Value	Minimally Invasive Group*	Standard Group*	P Value
Implant positioning						
Femoral angle	94.6 (93.8-95.4)	95.6 (94.8-96.4)	0.0795	94.7 (93.9-95.5)	94.9 (94.1-95.7)	0.6654
Tibial angle	89.5 (88.9-90.2)	89.0 (88.5-89.5)	0.2319	90.1 (89.3-90.9)	89.3 (88.8-89.7)	0.0841
Lateral tibial angle	88.2 (87.7-88.8)	87.8 (87.2-88.4)	0.2549	88.9 (88.2-89.5)	88.3 (87.6-88.9)	0.2031
Anatomical axis						
Tibiofemoral alignment	4.2 (3.2-5.1)	4.6 (3.7-5.6)	0.4870	4.8 (3.6-5.9)	4.2 (3.3-5.1)	0.4222

*The values are given in degrees as the mean, with the 95% confidence interval in parentheses.

gles, as well as the anatomical axis, were comparable between the minimally invasive and standard surgical technique groups (Table IV). Lateral femoral angles were not measured.

Fourteen patients (seven in the minimally invasive group and seven in the standard group) had adverse events that were related to the procedure. One perioperative fracture of the medial femoral condyle occurred in the standard group and one tibial fracture occurred in the minimally invasive group. Postoperatively, six patients had limited flexion and underwent manipulation under anesthesia (four in the standard group and two in the minimally invasive group). One patient in the standard group had a local (contained to the involved knee and not systemic) bacterial infection, which was treated with antibiotics. Two patients in the minimally invasive group complained of pain with uncertain etiology. Skin necrosis (3 cm along the scar) was observed in one patient in the minimally invasive group. Finally, two patients (one in each group) complained of knee instability.

Discussion

In total knee arthroplasty, a skin incision of at least 9 cm is required to accommodate the implant. However, the cutoff between a normal and a minimal incision is not clearly defined. We utilized a mean incision length of 12.4 ± 2.4 cm in the minimally invasive group in comparison with 18.6 ± 3.6 cm in the standard group. Generally, an incision must be shorter than 14 to 15 cm to be accepted as a minimal incision[4,11,12]. With conventional incisions for total knee arthroplasty often already being shorter than 20 cm, the difference between the two approaches is marginal and certainly cannot be considered truly innovative. Some patients may not be candidates for minimally invasive surgery because of anatomical variants, in particular having a large amount of soft tissue surrounding the knee.

Intraoperative blood loss is a major concern in standard total knee arthroplasty, with a resulting increase in the risk of infection, fluid overload, and increased duration of hospitalization associated with blood transfusion[13]. Proponents of minimally invasive total knee arthroplasty often cite the ability to reduce blood loss through the use of small incisions to support its use, and this benefit has been noted in some studies[7,14]. In our study, the reduced incision employed for patients managed with minimally invasive surgery was not associated with a reduction in blood loss. This result is consistent with that observed by Kolisek et al.[8].

The potential benefits of decreased blood loss can be offset by the prolongation of operative times that has been observed with other minimally invasive techniques[5,7,15]. On the basis of the available numbers in our analysis, the duration of surgery for both groups was not significantly different, which is similar to results reported in other studies[6,8].

The range-of-motion results showed a slight, although insignificant, advantage for the minimally invasive group at day 3. By the time the patients had been discharged, however, range of motion was nearly identical between the groups. Although there was a trend toward better range of motion with the minimally invasive approach at four to six weeks, this advantage had almost completely disappeared at the time of the one-year follow-up (111° for the minimally invasive group compared with 108° for the standard group; see Appendix). Dalury and Dennis also noted a minor early advantage in range of motion in a group of patients undergoing minimally invasive total knee arthroplasty, which similarly disappeared with longer follow-up[16]. However, a separate analysis of arthroplasty with the Genesis II knee components indicated improved range of motion at one year postoperatively for those undergoing a minimally invasive procedure through a midvastus approach compared with a control group managed with use of a standard technique (125° compared with 116°, respectively)[1]. In a separate retrospective analysis of more than 300 patients, range of motion was again noted to improve substantially with a minimally invasive midvastus approach at both one and two years postoperatively[2].

No clinically relevant difference was noted between our study groups in the area of patient-reported outcomes. There was no relevant difference in any of the four scoring outcomes: knee scores, function scores, visual analog pain scores, and the visual analog scores for the activities of daily living. Confidence intervals were used to express statistical variation and random

error. Because the sample sizes in both groups were rather small, we had broad 95% confidence intervals for all key outcomes. The 95% confidence intervals for the point estimates (differences of the mean between the minimally invasive and standard groups) typically contained the value zero. This means that there was no difference between the groups, with the exception of the function score and the visual analog score for the activities of daily living at the four to six-week interval, which indicated slightly better results for the minimally invasive group. A power analysis was not conducted a priori for the study. Hence, these results must be interpreted carefully. However, 95% confidence intervals of the differences in means between the groups provide an indication as to how much variability exists in the measured effect as well as the direction of the measured effect.

The 95% confidence interval of the difference in means for the function score at discharge was relatively small. The sample size was probably large enough for this variable to rule out the possibility of any large and clinically relevant effects. Variability was higher for the function score at other time points and for the visual analog activities of daily living score throughout the entire postoperative period. These confidence intervals did not exclude relevant clinical effects between the groups; further investigation is therefore needed to confirm these results.

Our original plan called for all patients to be followed for two years. The study was terminated after one year of follow-up since the initial clinical advantages of minimally invasive surgery have been shown to decrease over time. With no clinical difference observed during the first postoperative year, it was very unlikely that such a difference would occur between the first and the second year.

As with all other outcomes employed in our analysis, the literature has described a wide variety of clinical results with minimally invasive techniques. Bonutti et al. observed similarity in mean Knee Society scores between minimally invasive and standard groups[12]. Kolisek et al. also observed similar scores between these two techniques[8] at the time of the three-month follow-up. Seon and Song identified significantly improved scores on a 10-point visual analog pain scale on postoperative day 3 for patients who had been randomized to minimally invasive surgery in comparison with patients who had a standard approach, but the scores obtained at two weeks indicated equivalence between the cohorts[6]. Noting the lack of a clear benefit in other similar studies, some authors have taken a strong position against the use of minimally invasive techniques[17]. However, a clinically relevant advantage for patients managed with minimally invasive surgery in postoperative scoring has been noted by others[1,3].

Variances in the follow-up time points utilized in these studies preclude a proper comparison with our results, although the diversity in outcomes would appear to attest to the individualized nature of these separate minimally invasive techniques.

Implant misalignment has been cited as a potential risk factor with minimally invasive surgery techniques by Dalury and Dennis, who noted varus malalignment (<87°) of the tibial component in four of thirty patients who underwent total knee arthroplasty with minimally invasive surgery[16]. Radiographic data in our study indicated reliable implant positioning regardless of the surgical technique employed. Our results appear to be more consistent with what can commonly be expected with minimally invasive total knee arthroplasty, as a number of studies have also observed comparable radiographic results between minimally invasive and standard techniques[3,6,8,15]. Minimally invasive total knee replacement is technically more demanding than the use of standard surgical techniques. Even though the present study demonstrated no failure in the placement of the prosthesis in the minimally invasive group, less experienced surgeons may encounter difficulty.

Our study has several limitations. We acknowledge that the study was underpowered, given the small clinical differences in the primary outcomes between the groups. For example, with the 3° difference in range of motion at one year between the groups in our analysis, a sample size of 300 subjects per group would have been required to show significance. Although our study showed small effect sizes that were almost consistently in favor of the minimally invasive group, we do not believe they were large enough to be of clinical relevance.

Additionally, proponents of minimally invasive techniques often cite their positive impact on several quality-of-life outcomes, including length of hospital stay, reliance on pain medications, and the need for inpatient rehabilitation following discharge. Our study was not designed to assess any of these outcomes.

In conclusion, on the basis of the available patient numbers, our study failed to note a significant advantage for minimally invasive total knee arthroplasty over a conventional technique in any of the outcomes we measured. As we await the results of randomized prospective studies with greater sample sizes and longer follow-up periods to bring further clarity to this debate, we recommend a more measured approach and simply advise surgeons to carefully weigh the theoretical advantages of minimally invasive surgery against standard techniques before deciding on the proper surgical approach.

Appendix

(eA) Graphs depicting Knee Society scores, pain scores, activity scores, and range of motion for both the study groups are available with the electronic version of this article on our web site at jbjs.org (go to the article citation and click on "Supporting Data"). ■

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