An Original Paper

Primary Total Knee Arthroplasty Using the MJS Knee System

By:
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ABSTRACT

Between July, 2000 and September, 2002, 587 consecutive primary total knee arthroplasties were performed on 469 patients using the posterior cruciate ligament (PCL) sparing, MJS Total Knee System. Of these cases, there are 89 consecutive cases with a minimum of 2-year follow-up which are the basis for this study. The pre-operative diagnosis was osteoarthritis in all cases. The average pre-operative total range-of-motion (ROM) was 100.4°. The pre-operative Hospital for Special Surgery (HSS) score was 58.0 and there was no statistical difference in HSS score based on gender (p = 0.140). At the most recent follow-up, the average total ROM was 124.5° (standard deviation: ± 6.4°, range: 105° to 140°). The average HSS score at one year was 95.5 (standard deviation: ± 3.0, range: 83 to 98) and at two-years improved to 97.0 (standard deviation: ± 3.1, range: 77 to 99). There was no statistical difference in HSS score based on gender at one-year (p = 0.314) or at two years (p = 0.400) follow-up. There was one (3%) post-operative complication due to deep sepsis (*Staph aureus*) that was identified 3 months following the index procedure. Radiographic evaluation at the most recent follow-up for all patients across both groups revealed well fixed and aligned components without evidence of component-cement or cement-bone interface debonding. From these results we conclude that the prospective, short-term results of the MJS Knee System parallel other successful primary, cruciate-retaining TKA systems at the similarly reported time frames. Therefore, the continuation of the use and monitoring of this device is warranted.

INTRODUCTION

The goals in performing primary total knee arthroplasty (TKA) are well understood including relief of knee pain, restoration of joint function, and development of a durable prosthetic composite. However, there exist many recommendations and criteria for component use, fixation methods, and degree of constraint to achieve these goals. [**1,2**] Primary total knee arthroplasty (TKA) is proven to be both efficacious and cost effective. The introduction of new components, as well as changes in component design are a result of meticulous review of clinical, radiographic and engineering test results across cooperative multiple surgical centers. The foundation or, baseline for the comparative review of results begins with the dissemination of early outcomes. The reporting of early and subsequent prospective results becomes a model by which the surgical community of users is able to prospectively monitor various user small number outcomes. The purpose of this study is to report the prospective, short-term results (minimum two-year) of a recently developed total knee arthroplasty system and to build a reported baseline for comparison of other user results of the same component system.

MATERIALS AND METHODS

Between July, 2000 and September, 2002, 587 consecutive primary total knee arthroplasties were performed in 469 patients using the posterior cruciate ligament (PCL) sparing, MJS Total Knee System (MJS knee System, Osteoimplant Technology, Inc. Baltimore, MD) (Figure 1). Of these, there are first 89 consecutive cases in which two-year follow-up was achieved. TKA candidates were assessed using the Hospital for Special Surgery (HSS) knee rating scale. All radiographic and clinical evaluations were performed by the operating surgeon (MJS). Study data were recorded and statistically assessed using PC-SAS (SAS Institute, Inc., Cary, NC). Analysis of variance was applied to identify statistically significant differences between the component groups.

There were 53 (60%) female and 36 (40%) male patients with 42 (47%) left and 47 (53%) right knees involved. The average age for all patients combined was 71.0 years (standard deviation: ± 9.7 years, range: 47.4 years to 90.3 years). There was no statistical difference in age based on gender ($p = 0.322$). The pre-operative diagnosis was osteoarthritis in all cases. The average pre-operative knee extension was 6.3 (standard deviation: ± 7.2°, range: 0° to 30°) and the average pre-operative flexion was 108.8° (standard deviation: ± 9.3°, range: 90° to 125°). The average pre-operative total range-of-motion (ROM) was 100.4° (standard deviation: ± 14.3°, range: 70° to 125°). Pre-operative radiographic review revealed 66 (74%) of the knees in varus (average 7.2°, standard deviation ±2.5°, range: 4° to 12°), 16 (18%) knees in valgus (average 13.3°, standard deviation ±6.0°, range: 5° to 20°), and 7 (8%) knees in neutral. The pre-operative HSS score was 58.0 (standard deviation: ± 10.1, range: 36 to 82) and there was no statistical difference in HSS score based on gender ($p = 0.140$).

Figure 1
Image of the posterior cruciate ligament (PCL) sparing,
MJS Total Knee System, Osteoimplant Technology, Inc. Baltimore, MD

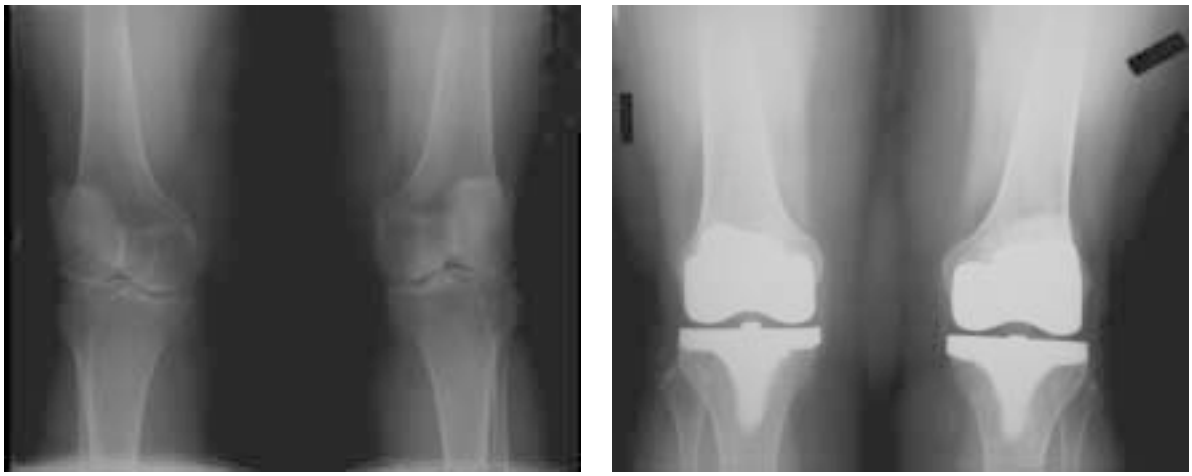
RESULTS

All TKA cases were performed by the senior author (MJS) at two separate facilities. All components were implanted with cement. Post operative blood transfusions were necessary in two (6.7%) cases (1 autogenous unit, 1 allogneic unit). There were no intra-operative complications. Postoperative anticoagulation therapy involved aspirin alone (11 cases, 10%), or aspirin in conjunction with non-steroidal anit-inflammatory drugs (NSAIDS) (78 cases, 90%). Following the primary TKA procedure (post-operative day 1), all patients were ambulating with a walker as tolerated. Continuous passive motion (CPM) machines were used in all cases during the hospital stay only. Patients were subsequently progressed through lesser walking aids (crutches, cane) and through full weight-bearing by six-nine weeks post-operatively. Forty-four patients (50%) were discharged directly to home without subsequent physical therapy, 24 patients (27%) were discharged to home with in-home physical therapy, 15 patients (17%) were admitted to a rehabilitation unit following discharge, and 6 patients (7%) had been discharged to the rehabilitation unit and had in-home physical therapy. The post-operative physical therapy pathway was a function of immediate post-operative patient compliance and insurance. There was no significant measurable effect of post-operative physical therapy on patient outcome at one or two years follow-up.

There was no clinical evidence of pulmonary thrombosis at the most recent follow-up. At one year follow-up, the average post-operative knee extension was 0.2 (standard deviation: ± 1.1°, range: 0° to 6°) and the average post-operative flexion was 119.7° (standard deviation: ± 5.7°, range: 107° to 128°). The average post-operative total range-of-motion (ROM) was 124.5° (standard deviation: ± 6.4°, range: 105° to 140°). At two years follow-up, the average post-operative knee extension was 0.0 (standard deviation: ± 0.0°) and the average post-operative flexion was 124.9° (standard deviation: ± 4.7°, range: 115° to 130°). The average post-operative total range-of-motion (ROM) was 124.9° (standard deviation: ± 4.7°, range: 115° to 130°). The average HSS score at one year was 95.5 (standard deviation: ± 3.0, range: 83 to 98) and at two-years improved to 97.0 (standard deviation: ± 3.1, range: 77 to 99). There was no statistical difference in HSS score based on gender at one-year ($p = 0.314$) or at two years ($p = 0.400$) follow-up.

There was one (3%) post-operative complication due to deep sepsis (Staph aureus) that was identified 3 months following the index procedure. All components were removed at that time, the debrieded and an antibiotic impregnated spacer was prepared and implanted, and routine IV antibiotics administered for a minimum of six weeks. Following this, new revision components were implanted and the patient is functioning well with no evidence of recurrent sepsis.

Radiographic evaluation at the most recent follow-up for all patients across both groups revealed well fixed and aligned components without evidence of component-cement or cement-bone interface debonding. All cement interfaces were uniform, complete, and without evidence of fracture (Figures 2A & 2B).



Figures 2A and 2B
Pre-operative and 2-years post-operative radiographs of patient receiving simultaneous, bilateral total knee arthroplasty using the MJS total knee arthroplasty system.

DISCUSSION

Primary total knee arthroplasty has a well defined history of prospective results across many component designs. We report excellent short-term results (one year and two-year) using the MJS Knee System for knees in which the PCL is retained. We also reported both one-year and two-years follow-up intervals to emphasize the small but progressive increase in knee function (flexion, extension and total ROM) as well as the relative increase in HSS score.

Debates revolve around the issue of soft tissue balancing, patient proprioception, improved functional range of motion, and bone stock preservation in the PCL retaining designs versus minimal soft tissue balancing and a more surgeon independent arthroplasty procedure associated with PCL sacrificing designs. Arguments have been made to convince surgeons to retain the PCL in an effort to best mimic normal knee joint function. Using gait analysis and EMG studies, Kelman, et al, evaluated PCL-sparing TKA function and determined that dynamic ROM was "consistently greater" in PCL-sparing TKA than in PCL-sacrificing devices, and that the performance of PCL-sparing devices more closely approximated normal knee function. [**3**] Likewise, Hoffman and Pace stated that since the mechanics of knee joint involve "rolling, gliding, and rotation of the femoral condyles," the goal of TKA should be to best replicate normal knee kinematics. [**4**] Scott and Volatile have also proposed that by retaining the PCL, the forces across the component and cement interfaces are dampened, thus minimizing component loosening and polyethylene wear. [**5**] While component constraint selection may sometimes be an issue of only surgeon preference and technical ability, all cases for this study were performed using a PCL sparing TKA system in which the indication is based on the combination of degree of bone deformity and soft-tissue insufficiency. From our pre-operative review we had a patient cohort of minimally deformed knees (from 12° varus to 20° valgus) with somewhat satisfactory total ROM prior to surgery (100.4°, standard deviation: ± 14.3°, range: 70° to 125°). Next to surgeon technical ability, minimally deformed, osteoarthritic knees may be the greatest predictor for successful outcome.

While this study cohort includes 89 patients, DVT prophylaxis of aspirin and NSAIDS seemed sufficient in prevent-

ing any clinical incidence of DVT or PE. However, while it is agreed that DVT is often clinically not reported and does not require subsequent treatment, the choice of prophylaxis agent is not. Recent meta-analysis of the comparison of agents by Brookenthal, et al, reported that while low-molecular-weight heparin performed better than warfarin, aspirin use as a prophylaxis agent was also well tolerated and showed trends of better performance than warfarin. [**6**]

A standard protocol to diminish risk of DVT and PE was developed and implemented. The protocol utilizes aspirin and NSAIDS when tolerated. Along with these pharmaceuticals, mechanical modalities were used in all cases, including long-leg TED hose, sequential compression devices (SCD) and early exercises (same day as surgery). This protocol was based on reducing the known post-operative causal factors of DVT, (Virchow's triangle: venous stasis, vessel wall damage and hypercoagulability). [**7**] The use of NSAIDS is known to decrease post-operative inflammation. This may also decrease swelling and increasing venous flow thus allowing earlier, more vigorous activity as well as reduce vessel wall inflammation. The mechanical modalities also contribute to this cascade of events. Aspirin, by itself, is controversial but is economical and effective. While anecdotal, the author believes using aspirin with an NSAID regularly is unique and more effective.

Post-operative physical therapy (PT) regimen following TKA is another debated issue that varies greatly from surgeon to surgeon. The goal of optimum and safe patient ambulation in the earliest amount of time is agreed upon, but the mechanism to achieve that outcome is confounded by outside variables ranging from the patient's self motivation to ambulate early, through the ability of their insurance to pay for subsequent care pathways. In a prospective randomized trial of the use of continuous passive motion (CPM) machines versus no machine (with standard in-house physical therapy, Pope, et al, found an early increase in ROM in the CPM group versus the non-CPM group. However, at one year, there was no statistical difference in ROM. [**8**] We observed similar results independent of post-operative pathway including no post-discharge PT, post-discharge rehab facility or home PT. Moreover, we also did observe a slight but not significant increase in ROM from the one-year follow-up to the two-year follow-up. This may be due to either the inherent error in the measuring device (HSS and physical ROM measurement) or, this observation may be due to the patient returning to a more normal and continued increase in activity of daily living (ADL) beyond the one year follow-up.

In conclusion, these results clearly achieve the goals of primary TKA and may be used as a baseline for outcome reference to other users of the MJS Knee System. Therefore, the continuation of use and careful monitoring of this device is warranted.

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TABLES

GENDER				
	Female	53 (60%)		
	Male	36 (40%)		
SIDE				
	Left	42 (47%)		
	Right	47 (53%)		
PATIENT AGE				
	Average	71 ± 9.7 years		
	Range	47.4 years to 90.3 years		
PRE-OPERATIVE KNEE ALIGNMENT				
		n (%)	Avg ± SD	Range
	Varus	66 (74%)	7.2° ± 2.5°	4° to 12°
	Valgus	16 (18%)	13.3° ± 6.0°	5° to 20°
	Neutral	7 (8%)		
RANGE OF MOTION (ROM)				
		Pre-Operative	Early Post-Op	2-Years Post-Op
	Extension	6.3° ± 7.2°	0.2° ± 1.1°	0.0° ± 0.0°
	Flexion	108.8° ± 9.3°	119.7° ± 5.7°	124.9° ± 4.7°
	Total ROM	100.4° ± 14.3°	124.5° ± 6.4°	124.9° ± 4.7°
HOSPITAL FOR SPECIAL SURGERY SCORE (HSS)				
			Avg ± SD	Range
	Pre-Operative		58.0 ± 10.1	36 to 82
	1-Year Post-Operative		95.5 ± 3.0	83 to 98
	2-Years Post-Operative		97.0 ± 3.1	77 to 99

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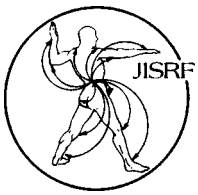

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