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Manipulation Rate Is Not Increased After Customized Total Knee Arthroplasty

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ABSTRACT

Background: Manipulation under anesthesia (MUA) is a standard treatment for arthrofibrosis after total knee arthroplasty (TKA), with reported rates of 1.5-6%. Customized TKA may have better outcomes by matching individual patient anatomy. However, a previous study reported an unacceptably high rate of MUA for customized TKAs. This study reports the incidence of MUA in a large cohort of second generation customized TKAs.

Methods: Data was collected prospectively on 360 2nd generation ConforMIS iTotal cruciate retaining TKAs. MUA was performed for clinically significant arthrofibrosis. Range of motion (ROM) and New Knee Society Scores (KSS) were evaluated at regular intervals for two years.

Results: 11/360 (3.05%) knees underwent MUA. ROM overall improved from 115° to 125°, and from 112° to 122° in patients undergoing MUA. KSS objective and functional scores in MUA patients increased from 57 to 98 and 41 to 90, respectively, and in the entire cohort increased from 65 to 96 and 45 to 86 at 2 years ($p<0.05$). No MUA patients underwent revision surgery.

Discussion and Conclusion: Customized TKA with second generation ConforMIS iTotal implants results in a MUA rate consistent with the literature for all designs. Additionally, patients exhibit significant increases in ROM and Knee Society Scores.

BACKGROUND

Arthrofibrosis can occur after total knee arthroplasty (TKA), with an incidence reported of 1-13%. [1] Manipulation under anesthesia (MUA) is a common first-line treatment for stiffness after TKA. The incidence of patients undergoing MUA after a TKA has been reported between 1.5-6%. [2–7] It is often recommended that MUA be done within 6-12 weeks of surgery if possible in order to achieve optimal gains in range of motion. [1,2,4,5,8–10] MUA has been shown to be effective at increasing range of motion, with gains of 33° persisting at long-term follow-up. [11] These gains have been shown to be similar to open or arthroscopic release. However, patients who undergo MUA have a significantly higher rate of eventual revision surgery, with an odds ratio of 2.43 in a review of a large national database. [3] MUA is generally considered safe, although low rates of fracture, wound dehiscence, patellar tendon avulsions, quadriceps strain or rupture, hemarthrosis, heterotopic ossification, and pulmonary embolism have been reported. [12,13]

Risk factors for arthrofibrosis include decreased preoperative range of motion, higher complexity of surgery (history of trauma, length of surgery), and history of prior surgery. [6,14–16] Additionally, after surgery, poor patient

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motivation, immobility, delay in starting rehabilitation, poor pain tolerance, and infection can contribute to development of arthrofibrosis. [10,17,18]

Prosthesis design has been implicated as a possible contributor to arthrofibrosis, although overall results are mixed. Several studies have compared cruciate-retaining (CR) versus posterior stabilized (PS) prostheses, with some finding decreased range of motion with CR designs, but others showing no significant difference. [4,19–21] Ultracongruent TKA's have also been shown to have similar rates of MUA as compared to conventional designs. [22]

A recent prospective evaluation has also reported that patients undergoing CR TKA with a patient-specific design have a significantly higher rate of postoperative stiffness and need for manipulation versus matched controls [23]. In the patient-specific design group, the mean range of motion from flexion to extension was 3-98° postoperatively, versus 2-111° in the posterior stabilized controls, and 2-117° in the cruciate-retaining controls. Of patients receiving the patient-specific implant, 6/21 underwent MUA, versus 0/53 in the control group. [23] Given these results, the present study seeks to investigate the incidence of MUA in a large cohort of knees implanted with a newer generation of the patient-specific CR design.

METHODS

The study protocol was reviewed and approved by the institutional review board. Data was collected prospectively at 9 institutions on 360 cemented, total knee arthroplasties performed using the cruciate-retaining iTotal implant (ConforMIS, Billerica, Massachusetts). The ConforMIS iTotal CR has evolved since its genesis through several design changes, the Generation 1 (G-1), to the current design, the Generation 2. All arthroplasties in the present study were performed with the second generation device. All TKAs were performed via the medial parapatellar approach. Manipulation under anesthesia was performed for clinically significant arthrofibrosis and reduced range of motion as judged by individual surgeons.

Inclusion criteria were clinically significant osteoarthritis of the knee requiring a total knee replacement in patients over 18 years of age. Exclusion criteria were simultaneous bilateral procedures, BMI > 40, fixed varus or valgus deformity >15°, rheumatoid or other inflammatory arthritis, history of prior implant surgery on the treated knee, compromised posterior cruciate ligament (PCL) or collateral ligament, and osteoporosis.

Range of motion (ROM) and 2011 New Knee Society Scores (KSS) were evaluated preoperatively, and postoperatively at 6 weeks, 6 months, and annually thereafter. A paired t-test was used to compare pre-and postoperative results.

RESULTS

A total of 393 patients were offered participation in the study. 33 patients were excluded. (Table 1). 360 patients met eligibility criteria and agreed to participate, 154 male and 196 female. The mean patient age was 65.7 (range 40-96). Mean BMI was 30.1 (range 18.5-42). The mean patient age and BMI for patients undergoing MUA was 61.7 and 28.5, respectively. Mean preoperative range of motion was 115° (range 80-142°). A total of 298 patients had completed follow-up and outcome scores at one year, and 202 patients at 2 years.

Table 1: Excluded patients

Reason	**n**
BMI > 40	2
Active Malignancy	5
Simultaneous Bilateral TKA	1
Osteoporosis	3
Other physical disability of hip, spine, or contralateral knee	1
Fixed coronal deformity > 15°	1
Fixed flexion deformity > 15°	2
Unwilling or unable to comply with study requirements	14
Rheumatoid or other inflammatory arthropathy	4
Total	33

Preoperatively, ROM was 115° (2° extension to 117° flexion), and improved to 123° (0° extension to 123° flexion) in the entire cohort (p<0.001). Prior to surgery, 43 patients demonstrated a flexion contracture, of these 29 were 1-5°, 12 were 6-10°, and 2 11-15°. 57 patients had an extensor lag prior to surgery, 50 were 0-10°, and 7 were 10-15°. At one year, 11 patients had a flexion contracture, 10 were 1-5° and 1 11-15°. 6 patients had an extensor lag at one year, all were under 10°. All but two patients achieved ROM > 90° by one year, but both had ROM > 100° at their 6 month visits.

A total of 11/360 patients (3.05%) underwent MUA at an average of postoperative day 97 (Range 34-364). Of these patients, 8 were available for follow-up at one year, and 4 at two years. In patients who underwent MUA, ROM

improved minimally at one year from the index procedure from 116° (1° extension to 116° flexion) to 117° (-1° extension to 116° flexion) (p=0.78). ROM averaged 86.3° (65-107) for these patients immediately prior to undergoing MUA, and improved to 117.1° at the next scheduled visit.

Patients who underwent MUA, as well as patients in the entire cohort exhibited statistically significant (p<0.05) increases in KSS objective, functional, and satisfaction scores. (Tables 2 and 3) Expectation scores showed a slight decrease, but remained above the threshold for "met expectations." The MUA rate for centers with >40 patients enrolled was 2.4%, whereas the MUA rate for centers with <25 patients enrolled was 6.0%. No MUA was performed at 3/9 centers (including 1 center that enrolled 29 patients). At 1 year, all but 2 (99.2%) patients achieved functional range of motion (>90°).

Six patients have been revised at an average of 62 weeks. Four were polyethylene exchange for diagnoses of complex regional pain syndrome (CRPS), ligamentous laxity, infection, or scar tissue removal. None of these patients had previously undergone MUA, and all had range of motion of 105° or greater at 6 months after the index procedure. Additionally, one revision was performed for a peri-prosthetic fracture, and another for metal hypersensitivity. Thus, there are three patients who have been converted to a different prosthesis in this study. Based on the last follow-up of all patients, the revision rate was 1.7% (6/360, including polyethylene exchanges) and survivorship was 99.2% at an average follow-up of 1.9 years.

DISCUSSION

The rationale for creating a patient-specific TKA is to improve clinical outcomes and patient satisfaction. [24] Described benefits over an "off the shelf" implant include lower incidence of blood transfusions and adverse events, improved tibial plateau coverage, and more normal femoral rollback. [25–27] However, a prior study on the first generation (G1) iTotal implant demonstrated a 28.6% rate of MUA. [23]

The present study demonstrates a MUA rate of 3.05% for the cruciate-retaining, second generation (G2) ConforMIS iTotal implant, which is similar to rates reported throughout the literature, irrespective of implant design. [2–7] Additionally, patients overall achieved functional range of motion (>90°) at 1 year, including patients who underwent MUA. Although White et al. reported a markedly higher rate of MUA with a patient-specific design, the current findings are similar to data presented by Kurtz et al demonstrating a 3.8% incidence of MUA at 90 days with the ConforMIS G1 implant. [28] The difference in MUA rate in the present study compared to the White et al paper may be the result of design changes, or potentially due to the comparisons of one surgeon versus nine surgeons in nine centers.

The rate of MUA varied across institutions from 0-9%, with 3/9 centers reporting no manipulations. Centers with <25 patients enrolled reported a higher average manipulation rate (6.0%), versus those with >40 patients (2.4%)

Table 2: New Knee Society Scores for the entire cohort at 1 yr follow up (n=278)

	Pre-op	6-Week	6-Month	1-Year	p (Preop vs 1 yr)
Objective (0-100)	65	85	92	94	<0.001
Satisfaction (0-40)	14	25	31	34	<0.001
Expectations (0-15)	14	9	10	10	<0.001
Functional (0-100)	45	56	78	83	<0.001
Pain (0-100)	45	62	81	86	<0.001
Symptoms (0-100)	47	59	76	81	<0.001
ADL (0-100)	50	69	85	88	<0.001
Recreation (0-100)	19	36	59	69	<0.001
QOL (0-100)	18	45	65	72	<0.001
ROM	115	109	120	123	<0.001

Table 3: New Knee Society Scores for patients undergoing MUA at 1 yr follow up (n=8)

	Pre-op	6-Week	6-Month	1-Year	p (Preop vs 1 yr)
Objective (0-100)	57	75	83	92	0.021
Satisfaction (0-40)	9	20	24	29	0.007
Expectations (0-15)	14	7	9	10	0.051
Functional (0-100)	41	46	72	74	0.015
Pain (0-100)	38	53	74	76	0.010
Symptoms (0-100)	43	46	63	70	0.028
ADL (0-100)	45	61	80	81	0.009
Recreation (0-100)	11	25	54	64	0.001
QOL (0-100)	14	30	53	55	0.007
ROM	112	84	113	117	0.780

This may indicate that factors associated with higher MUA rates may include surgeon volume and experience with the patient-specific implant. However, a recent registry analysis of 59,696 TKAs found no association with volume and MUA. [29]

In addition to a lower manipulation rate, the present study also demonstrated good patient-reported outcomes. Across the entire cohort, patients reported statistically significant improvements in all KSS outcome measures with the exception of the expectation score. Pre-operatively, patients reported high expectations (expectation score of 14/15) for the surgical procedure. At the 6 week postoperative visit patient expectations had dropped, but on average patients reported the surgery to have met expectations (9/15, with 9 being the threshold for "met expectations"). By the 6 month visit, patient expectations had improved from the 6 week time point, with patients on average reporting the procedure to have marginally exceeded expectations (10/15). Throughout the current literature, patients often report unmet expectations after total knee arthroplasty, possibly due to excessive optimism about results. [30–32] A prior study using the 2011 KSS to evaluate TKA outcomes found that although patient satisfaction and all other scores improved after surgery, the expectation score decreased slightly, leading researchers to postulate that patients may be satisfied after TKA in different ways than expected. [33] Additionally, it is possible that patients receiving a patient specific design may have higher expectations for their outcomes as opposed to those who receive a conventional implant. An earlier study showed a high dissatisfaction rate (11.1%) with the earlier, G1 version of the iTotal implant. [23] However, the present study found that only 6/298 (2.0%) of patients reported being "dissatisfied" or "very dissatisfied" with their results at 1 year (KSS satisfaction score <10), with an average KSS satisfaction score of 34 in the entire study. This compares favorably with the existing literature, which reports overall patient satisfaction rates of 81-89%, as well as KSS satisfaction scores of 23-38 for primary TKA. [33,34,43–52,35–42] Revision surgery was rare, with only 1.7% (6/360) patients requiring revision surgery within 2 years. Three of these patients continue to have the device, yielding an implant survivorship of 99.2%.

Limitations to this study include a lack of standardized indications for undergoing MUA and incomplete follow up (298 of 360 patients at 1 years, including 8 of 11 patients who underwent MUA). However, patients who did not complete 1 year follow up did not report problems that would be indications for MUA at the 6 week or 6 month visit. Thus, it is unlikely that additional patients in the study will require MUA in the future. Strengths of the study include the size of the cohort (360 patients). Additionally, all patients in the study were prospectively recruited at 9 centers, thus providing a more robust estimate of expected MUA rates after surgery with the second generation iTotal CR device as compared to single center experiences.

In conclusion, the present study demonstrates an acceptable rate of MUA in a large cohort of patients who underwent TKA with the ConforMIS G2 iTotal CR patient-specific TKA. Additionally, patient reported outcomes demonstrated significant improvements in pain, function, and satisfaction. Further follow-up continues at all sites. Data from longer term follow-up on the entire cohort as well as the patients that experienced MUAs in this study population will provide a deeper understanding of overall survival, patient outcomes and long term effects of MUA on patients receiving this device.

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