Journal of Orthopaedic Experience & Innovation
Clinical, Economic, and Innovative Orthopaedic Experience

Stevenson, Maryann, and Andrew Wickline. 2020. "23-Hour TKA in 10 Opioid Pills or Less through 90 Days: A Non-Selected Prospective Consecutive One Year Cohort." *Journal of Orthopaedic Experience & Innovation*, July.

Manuscripts

23-hour TKA in 10 opioid pills or less through 90 days: A non-selected prospective consecutive one year cohort

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Keywords: rehabilitation, outpatient, physical therapy, opioid, multimodal, total knee arthroplasty

Journal of Orthopaedic Experience & Innovation

Background
Modern treatment protocols for pain management following total knee arthroplasty (TKA) rely heavily on opioid medications. The growing concerns over the opioid epidemic and complications from their use remain problematic. The primary purpose of this study was to enhance multimodal perioperative pain control to reduce opioid consumption after TKA.
Methods
386 prospective and consecutive patients who consented for unilateral TKA were enrolled in a 4 month long multi-modal protocol including a robust education and optimization program with home-based physical therapy. Patients also received a continuous adductor canal block (CACB) with ropivacaine. Opioid consumption, Numeric Rating Scale (NRS) Pain scores, KOOS Jr, and ROM was recorded at baseline and postoperative days 1,2,3 and 3 weeks, 6 weeks, and 12 week.
Results
Though 12 weeks, 86.3% of patients undergoing TKA required 10 pills or less and 18.9% required no opioid pills. 50.5% took only tramadol rather than stronger opioids. Additionally, 85.4% of patients required no formal physical therapy (PT) through 12 weeks. 63.2% of patients were discharged the day of surgery, and 91.2% were discharged by the first postoperative day. 311 of 386 (80.6%) patients completed all KOOS Jr. evaluations. The mean KOOS Jr score increased from 53.1 at baseline to 71.8 at 6 weeks and 90.0 at 12 weeks. Mean flexion was 109.2 deg at 3 weeks and 115.8deg at 6 weeks. The 90 day readmission rate was 1.2%.
Conclusion
A novel multimodal protocol combining consistent and patient specific preoperative education, CACB, and self-directed and unsupervised postoperative rehabilitation dramatically reduces narcotic needs, formal physical therapy needs, and decreases length of stay following TKA.

INTRODUCTION

The opioid epidemic has been well described as a national health crisis. Surgical procedures such as joint arthroplasty are arguably one of the more common vehicles for exposing patients to opioids. More than 50 million surgical procedures are performed each year in the United States, and approximately 80% of patients receive opioids after surgery to manage their postoperative acute pain. As many as 6.5% of patients that take opioids to manage pain after surgery may become persistent opioid users, representing 2.6 million people (Brummett et al. 2017). Previous authors have shown that narcotics are over-prescribed (Hannon, Calkins, et al. 2019; Huang and Copp 2019). The number of opioid

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I have also developed a new, innovative recovery technique for total knee replacement called the "Therapy-Free Total Knee Replacement." This Therapy-Free protocol decreases pain, saves money, and accelerates recovery, allowing patients to recovery in the comfort of their own homes. This robust program of preoperative patient education and optimization has led to a 2X lower complication rate than the top 200 orthopedic hospitals in the nation.
I currently teach anterior hip replacement and outpatient joint replacement techniques to surgeons in the USA and India. I also spend time educating surgeons and patients about my Therapy-Free, narcotic-free joint replacement method.
I completed my fellowship training at the Cleveland Clinic. I am the founder of the total joint replacement program at St. Elizabeth Medical Center and initiated the Accelerated Outpatient Recovery System for both the hospital and Apex Surgery Center. In my spare time I enjoy hot rods and road racing.
Disclosure Financial support was provided to the Investigator's institution by Avanos Medical to cover the budgeted costs necessary to conduct the study protocol and hire a research coordinator. The lead author has accepted no funds personally nor did his practice benefit financially from this study.

pills necessary for successful postoperative total knee arthroplasty (TKA) recovery appears to range from at least 90-156 opioid pills despite aggressive surgical window multimodal techniques (Hannon, Calkins, et al. 2019; Huang and Copp 2019).

Beginning in 2016, a new protocol was established to meet the forecasted demand for outpatient total knee arthroplasty. A robust, four-month patient engagement program was put in place with an emphasis on patient education on all phases of the arthroplasty process as well as appropriate representation of the post-surgery process with attention on goal setting and realistic expectations. A new simplified perioperative home recovery protocol was developed by the author to decrease post-op pain and swelling. Finally, a continuous adductor canal block with a catheter (CACB) and large reservoir pain pump in addition to the standard multimodal techniques was instituted to allow for reliable and rapid discharge.

Early observations from this new protocol suggested a dramatic improvement in patient satisfaction with marked decreased opioid consumption observed in the first 3 days postoperatively. Based on these early observations, a research grant was obtained to investigate what was perceived to be a significant reduction in opioid use and physical therapy (PT) requirements relative to previously described TKA pain management studies. The goal was to quantify the average number of narcotics needed with this new protocol and show that home-based therapy may be one of the methods to decrease postoperative pain while attaining satisfactory outcomes.

MATERIALS AND METHODS

STUDY DESIGN

This study is an IRB-approved, prospective, single surgeon, consecutive patient case series that was registered with clinicaltrials.gov (NCT03647709). All patients received written and oral information about the observational study and signed an informed consent document. Due to the observational nature of the study, no patient elected to opt out. We chose four hundred as the number of knee replacement patients to study as that would exceed any other previous prospective study on opioid use. Fourteen patients were excluded from the study. Nine patients were enrolled but did not ultimately have surgery and were excluded for various reasons such as lack of medical clearance, lack of insurance coverage and last-minute decision to hold off on surgery. A total of five patients had surgery but were not included in the data set. Four were completely unreachable post-operatively and one patient had pre- and postoperative difficulty answering the questions due to a history of a stroke preoperatively. This left a total of 386 patients included in the data set.

Some colleagues have asked for a comparison to a previous cohort of patients or have recommended that the study should have been set up that way. The senior author respectfully disagrees on the basis of "primum non nocerem". It is the author's personal experience that formal postoperative therapy results in a larger number of complications and greater need for postoperative office visits as compared to a home-based protocol (data presented in poster presentation at World Arthroplasty Conference). Additionally, the patients required greater numbers of narcotics due to the pain associated with formal therapy at the time. Therefore, it would be unethical to subject patients to greater risk of complications and narcotic use and narcotic addiction if they were randomized to the conventional model used by most US surgeons. We would ask each surgeon who performs TKA to take 100 consecutive patients and use their state-wide opioid database for 12 weeks postoperatively and determine their *personal* patient 90-day opioid use and use this as a comparator to our study.

PRE-OPERATIVE PROTOCOL

The preoperative protocol consisted of a detailed education booklet, a required education class, insistence on patient coach identification and participation, early laboratory data to allow for patient optimization, and one pre-op therapy visit to explain post-op mobilization and safety issues.

The education booklet has nearly every detail that the senior author has been asked about by patients over the past 18 years of practice. This includes nutrition, what to expect, how to make the house safe, what clothes to wear, and what to expect every single day after surgery through 14 days. It has the exact slide deck that is used in the education class with areas to take notes. The inside cover has each patient's individual treatment plan so that every provider that cares for the patient knows what the plan is for the facility stay and 6 weeks postoperatively. It is not the booklet that most surgeons use that typically was developed by the hospital system to cover all different surgeons and approaches. It is specific to the author's individual practice. It is required to be read by both patient and coach. It is required to be available at every preoperative visit in the office, at the preoperative education class and therapy visit, as well as the decision for surgery visit with the surgeon. It is required to be present for surgery. Every staff member involved with the patient's care is required to read and understand the booklet in order to provide consistent patient messaging. When all patient care providers ask for the book upon arrival, patients and their coaches recognize that they need to thoroughly understand the treatment plan.

The coach is whomever the patient designates that will be available for most if not all patient visits and who will be personally involved with the patient's recovery. This is typically a spouse or the child of the patient but sometimes is a good friend or a neighbor who has watched the patient struggle with arthritis and wants to be involved with the process. A coach is vital to the outcome. All patients were required to designate a coach.

The education class was taught by a dedicated health professional who also assisted in surgery. It was not taught by a hospital member who normally would be responsible for explaining all of the myriad options and approaches of the multiple surgeons within that hospital system. This again provided consistency of message and lessened the variability that can make patients anxious. The office team member who taught the class was able to reach out to the surgeon and discuss specific patients who had not fully engaged in the education process. The surgeon then had the option of cancelling the patient who had not fully committed.

Every patient had albumin, hemoglobin, hemoglobin A1c, abnormal renal function, and coagulation studies optimized for 4-6 weeks prior to surgery to decrease in facility and postoperative complication risk and readmission risk. This was done through the surgeon's office as it is our current opinion that internists are unaware that there is more to "pre-op clearance" than a cardiac evaluation.

Every patient and their coach met with the surgeon to develop a personalized postoperative plan for arrival, surgery, discharge, medications, and recovery. All laboratory data, radiographic data, and consultations were personally reviewed by the author to understand each patient's

potential risks. Shared decision making was employed to determine best perioperative practice for each individual patient taking into account their medical history, medications, age, and recent laboratory data. A variety of post-op medications were discussed including acetaminophen 1000mg q8 for 3 weeks (if no liver dysfunction), prednisone 5 mg po daily for 3 weeks (if not insulin-requiring diabetic), Celebrex 100 mg po bid or meloxicam 7.5mg po BID (if no contraindication), gabapentin 300mg q8 prn (if normal GFR), tramadol 50 mg q6 prn or oxycodone 5mg (#10). Each patient used one or more of the aforementioned medications and had their own "patient specific pain plan".

This study specifically included one 50mg dose of tramadol as one opioid pill which has not been deemed as an opioid in multiple other studies to date. Several patients had used tapentadol (Nucynta) or hydrocodone in the past and requested this medication instead of tramadol or oxycodone. Patients over 70 years of age were routinely advised against oxycodone unless they had used it in the recent past. Aspirin 81mg po BID was used as DVT prophylaxis for all patients that were not already on anticoagulation for another reason and did not have additional risk factors such as previous DVT or genetic predisposition. All prescriptions were electronically sent prior to surgery.

Many surgeons have advocated for aggressive pre-operative therapy to ready a patient for surgery. It has been the author's opinion for the last 5 years that prehabilitation may lead to upregulation of nocioceptors prior to surgery and thereby may increase postoperative pain. Additionally, the author's personal experience with weight loss and muscle building required months of daily aggressive workouts to achieve a noticeable difference. The cost associated with that type of program seemed prohibitive in a healthcare system where costs are already at a staggering price. Preoperative usage of physical therapy to "strengthen the extremity" was therefore discouraged.

In the holding area, patients received oral celecoxib (200mg) if not contra-indicated, oral tranexamic acid (1300mg), oral gabapentin (300mg), oral acetaminophen (1000mg), and IV dexmethasone (8mg if not diabetic). Patients under 70 with no history of glaucoma or urinary retention issues received a scopolamine patch. No patient was given pre-op opioids unlike many other multi-modal protocols. Patient expectations for discharge and for strict adherence to written post-op protocol were reinforced. Patients then received an ultrasound-guided adductor canal single-shot block followed by placement of an indwelling catheter by the anesthesia service in a separate block area. The catheter was secured to the thigh using a transparent adhesive dressing.

SURGICAL PROCEDURE AND DISCHARGE PLAN

Anesthesia included general anesthesia with sevoflurane or spinal anesthesia with lidocaine, chloroprocaine, or bupivacaine based on anesthesiologist and patient preference. It was not possible to control for the type of anesthesia or the use of intraoperative opioids due to the multiple anesthesia providers used throughout the study duration.

All but 4 patients received a cemented, computer navigated, posterior stabilized Stryker Triathlon knee (Stryker, Inc, Kalamazoo, MI) with a standard medial parapatellar arthrotomy. A single patient received a computer navigated, cementless Stryker Triathlon knee due to a history of cement sensitivity. Three patients were determined at time of surgery to have only single compartment disease and received a partial knee replacement. Alignment of the prosthesis was based on the mechanical axis with considerable varus or valgus outliers being allowed to remain up to three degrees of their preoperative deformity to allow for soft tissue considerations. The patella was always resurfaced but never everted and no tourniquet was used throughout the entire case. A periarticular block was administered with 40cc of bupivacaine, 30 mg of ketorolac (if not contra-indicated), 18 cc of saline and for those under 70 years old without an opioid sensitivity, 10 mg of morphine to fill a 60cc syringe. The block was administered along the medial tibial elevated tissue and circumferentially along the meniscal beds with care being taken not to over anesthetize the posterolateral corner which may result in a temporary foot drop. A large reservoir pain ball (400 ml ON-Q Pain Relief System, Avanos Medical, Alpharetta, GA) over filled to 550ml with ropivacaine was started in the recovery room.

Patients were discharged when tolerating oral food, vital signs were stable, passing a voiding trial, and after passing a therapy safety evaluation. Patients needed to be able to navigate stairs, walk 50 feet, and perform bed and bathroom transfers safely. A discharge risk calculator was not employed. Once discharged, patients followed a home therapy protocol consisting of 40 minutes ice and elevation (toes above the nose), and 8 minutes of 4 simple exercises to be performed hourly from 7 am to 9pm for 2 weeks. Exercises were 10 ankle pumps, 10 passive/active-assisted knee extensions, 10 knee flexion exercises in a chair (heel slide), and a short walk to help prevent deep vein thrombosis (DVT) and pneumonia. Home therapy and home nursing was highly discouraged. It has been the author's experience that these individuals actually cause more harm than good with well-intentioned but incorrect advice. Additionally, there is significant cost associated with these services making its questionable value even less. Patients were allowed to progress from walker to cane to no assistive device as they desired. No digital engagement platform was employed as attempts to use one previous to this study had a 60% compliance rate.

Preoperative anxiety or depression medications were identified and recorded. Any preoperative opioid use within 3 months prior to surgery was also identified and recorded.

OUTCOME MEASURES

Baseline, 6 week and 12 week knee injury and osteoarthritis outcome junior scores (KOOS JR.) and patient compliance with the therapy protocol were recorded. Numeric Rating Scale (NRS) pain scores were documented postoperative days (POD) 1-3, 2 weeks, 3 weeks, 6 weeks and 12 weeks. Range of motion (ROM) at 3 and 6 weeks was measured. Total opioid usage was tallied. Every patient was queried through the New York State Internet System for Tracking Over-Prescribing (NYS I-STOP) opioid database. This prescription monitoring system verified that no patient received opioids from another prescriber. Total pill count includes every oral opioid from post-acute care unit (PACU) discharge to the orthopedic floor all the way through 12 weeks after surgery. A single research coordinator made every call to every patient and verified pill usage at each data point. Patients also used their handbook which had an opioid diary to reference.

All data was kept on a confidential platform, and data management, study site monitoring, and statistics services were performed by a third party independent of Avanos Medical (RCRI, Minneapolis, MN). Continuous data are reported as mean ± standard deviation (range minimum - maximum). Categorical data is summarized as percentages. Differences in proportions were compared using a Fisher Exact Test. A p-value less than 0.05 was considered to be

Table 1. Baseline Characteristic

Number of Subjects	386
Age (years)	
N	386
Mean ± SD	69.1 ± 8.2
Median	69
Min. Max.	46, 94
BMI	
N	386
Mean ± SD	31.6± 5.2
Median	31.8
Min. Max.	18.2, 40
Gender	
N	386
Female	226 (58.6%)
Male	160 (41.5%)
Knee	
N	385
Left	184 (47.8%)
Right	201 (52.2%)
Procedure	
N	385
TKA	382 (99.2%)
Partial	3 (0.8%)
ASA	
N	386
I	8(2.1%)
II	173 (44.8%)
III	200 (51.8%)
IV	5 (1.3%)

statistically significant.

RESULTS

DISPOSITION OF STUDY SUBJECTS

A full accounting of study subject disposition is provided in Table 1.

KNEE INJURY AND OSTEOARTHRITIS SCORE FOR JOINT REPLACEMENT SCORES

We encountered a problem with the online KOOS Jr data collection company which resulted in some patients not having verified questionnaires at all data points. Complete data set patients totaled 311. The KOOS Jr scores were averaged from this cohort. The mean KOOS Jr score increased from 53.1 (0-85) at baseline to 71.8 (34.2-100) at 6 weeks and 90.0 (52.5-100) at 12 weeks (Table 2).

NUMERIC RATING SCALE SCORES

The mean worst NRS knee pain at rest ranged from 2.4 (0 to 8) on POD1 to 0.2 (0 to 6) at 12 weeks and worst pain with motion ranged from 4.6 (0 to 10) on POD1 to 0.5 (0 to 7) at 12 weeks. Table 3 provides a complete presentation of all measured NRS pain scores.

OPIOID USE

Seventy-three patients (18.9%) required no opioid pills throughout the entire episode of care. Another 159 (41.2%) required 1-5 pills, 101 (26.2%) required 6-10 pills and 53 (13.7%) required more than ten pills. In total, 86.3% of patients used 10 or fewer opioids through 12 weeks postoperatively. In patients reporting taking at least one opioid pill, 195 (50.5%) took tramadol and 118 (30.6%) used oxycodone, hydrocodone, or nucynta. This pill total includes oral opioids given in hospital prior to discharge. If patients with a pre-op history of opioid use within three months or a history of anxiety/depression are excluded, 90.0% of patients succeeded with 10 pills or less.

Eighteen of the 56 patients (32%) who required greater than ten opioid pills reported using opioids in the preceding 3 months, compared to 12/330 (3.6%) who were not using opioids at baseline ($p < 0.0001$). When compared to the entire cohort, patients with pre-op opioid use in the previous 3 months were 60% more likely to use more than ten opioids. No patient that used preoperative opioids was narcotic free postoperatively.

Table 2. KOOS, JR Total Score

Number of Subjects	
Baseline, Prior to Surgery	
N	311
Mean ± SD	53.1 ± 11.9
Median	52.5
Min. Max.	0.0, 84.6
95% CI	(51.7, 54.4)
6 Weeks Post-Operative	
N	379
Mean ± SD	71.8 ± 11.8
Median	70.7
Min. Max.	34.2, 100.0
95% CI	(70.6, 73.0)
12 Week Post-Operative	
N	341
Mean ± SD	90.0 ± 8.2
Median	92.0
Min. Max.	52.5, 100.0
95% CI	(89.1,90.8)

One-hundred twenty-nine patients were currently being treated with a prescription medicine for anxiety or depression with 26 patients requiring over 10 opioids (20%). In comparison, two hundred thirty patients did not have this diagnosis and only 27 required greater than 10 opioids (10.5%) (p=0.0108).

The majority of opioid use was noted on the first three postoperative days; POD 1 (172/386, 45%), POD 2 (258/386, 66.8%), and POD 3 (230/386, 60.0%). In the patients who did require at least one dose of opioid, 73% were off opioids by day 10 and 91% off opioids by 21 days.

HOME BASED AND FORMAL PHYSICAL THERAPY RESULTS

All patients saw a physical therapist in the hospital or the ASC for instruction on their home program prior to discharge. At the three week visit, 347 (90%) were managing their therapy on their own at home without a therapist or home health aide or nurse. This reduced slightly to 328/386 (85.4%) at the 6 week visit but did not decline further. We were unable to tabulate the exact number of therapy visits per patient who used therapy. Home based therapy protocol provided a mean ROM of 109.2° (85-135) at 3 weeks and 115.8° (90-135) at 6 weeks (Table 4). Nine of 386 patients (2.3%) went to an inpatient rehab.

We tallied the number of patients who adhered to the at home PT protocol as compared to those who did not or who required formal PT. Adherence to the home PT protocol was directionally associated with the lack of opioid use at all measured time points. This difference was noted to be statistically significant at POD1, POD2, POD3, and 10 to 14 days ($p < 0.05$). Table 5 demonstrates this relationship.

LENGTH OF STAY

The mean LOS for all hospital patients was 20 hours (SD of 15.6 hours) due to the rehab outliers. The median was 11 hours. Please note that one statistical outlier, a patient who remained hospitalized for 8 days secondary to insurance issues, was removed from this analysis to provide a more accurate representation of LOS. As expected, the mean LOS was markedly shorter for patients undergoing TKA at an ambulatory surgery center at 6.2 hours (SD .75 hours) and the median was 6 hours. Admission to the hospital or ASC was scheduled 2 hours prior to surgical case start time. LOS was compartmentalized and defined as admission to hospital, preoperative treatment time, block time, OR time, PACU time, second stage or floor time, and finally leaving the facility.

The number of patients discharged home on the day of surgery was 244. One hundred nine patients were discharged home POD #1. The remaining 33 patients were discharged POD #2 or later.

ADVERSE EVENTS

All patients received an adductor canal block and an adductor canal catheter attached to an elastomeric ropivacaine reservoir. Eight patients (2%) had motor weakness on the day of surgery which resolved and was treated with a knee immobilizer. Three patients inadvertently pulled out their catheter and nine patients discontinued their catheter earlier than necessary (12/386= 3.1%). Two patients had uncontrolled pain on day of surgery and two on POD#1. (4/386 = 1%). Two patients complained of bleeding from the catheter site, one on POD#1 and one on POD#2.

There were a total of fourteen falls over the 12 weeks post-op with seven possibly having some connection to the adductor block/catheter as they were within the time frame of catheter usage. All 14 patients had no sequelae from their fall. One patient had saphenous paresthesias at 6 weeks post-op that had resolved by week 12.

ADVERSE EVENTS—READMISSIONS WITHIN 90 DAYS

Five patients (1.2%) were readmitted within 90 days. Two of these patients had been admitted to a rehab facility and one subsequently developed pneumonia and one developed

Table 3. NRS Scores

	Best with Rest	Worst with Rest	Best with Activity	Worst with Activity
Pain NRS POD #1				
N	386	386	386	386
Mean ± SD	1.0 ± 1.8	2.4 ± 2.3	2.9 ± 2.2	4.6 ± 2.3
Median	0.0	2.0	3.0	5.0
Min. Max.	0.0, 10.0	0.0, 8.0	0.0, 9.0	0.0, 10.0
95% CI	(0.9, 1.2)	(2.2, 2.6)	(2.7, 3.1)	(4.4, 4.8)
Pain NRS POD #2				
N	386	385	386	385
Mean ± SD	1.8 ± 2.0	3.4 ± 2.3	4.2 ± 2.0	5.9 ± 1.9
Median	1.0	3.0	4.0	6.0
Min. Max.	0.0, 7.0	0.0, 8.0	0.0, 8.0	0.0, 9.0
95% CI	(1.6, 2.0)	(3.2, 3.6)	(4.0, 4.4)	(5.7, 6.1)
Pain NRS POD #3				
N	386	386	386	386
Mean ± SD	1.0 ± 1.6	2.4 ± 2.1	3.3 ± 2.1	5.0 ± 2.0
Median	0.0	2.0	3.0	5.0
Min. Max.	0.0, 7.0	0.0, 8.0	0.0, 8.0	0.00, 9.0
95% CI	(0.8, 1.2)	(2.2, 2.6)	(3.1, 3.5)	(4.8, 5.2)
Pain NRS 10-14 Days				
N	386	386	386	386
Mean ± SD	0.5 ± 1.2	2.1 ± 2.0	2.0 ± 1.9	4.0 ± 2.1
Median	0.0	2.0	2.0	4.0
Min. Max.	0.0, 6.0	0.0, 8.0	0.0, 7.0	0.0, 8.0
95% CI	(0.4, 0.7)	(1.9, 2.3)	(1.8, 2.2)	(3.8, 4.2)
Pain NRS 3 Weeks				
N	386	386	386	386
Mean ± SD	0.3 ± 0.8	1.5 ± 1.9	1.3 ± 1.6	3.1 ± 2.1
Median	0.0	1.0	0.0	3.0
Min. Max.	0.0, 5.0	0.0, 8.0	0.0, 7.0	0.0, 8.0
95% CI	(0.2, 0.4)	(1.3, 1.7)	(1.2, 1.5)	(2.9, 3.3)
Pain NRS 6 Weeks				
N	386	386	386	386
Mean ± SD	0.1 ± 0.6	0.7 ± 1.5	0.5 ± 1.2	1.9 ± 2.0
Median	0.0	0.0	0.0	1.0
Min. Max.	0.0, 6.0	0.0, 8.0	0.0, 6.0	0.0, 8.0
95% CI	(0.0, 0.2)	(0.5, 0.8)	(0.4, 0.6)	(1.7, 2.0)
Pain NRS 12 Weeks				
N	340	340	340	340
Mean ± SD	0.0 ± 0.2	0.2 ± 0.7	0.0 ± 0.3	0.5 ± 1.2
Median	0.0	0.0	0.0	0.0
Min. Max.	0.0, 3.0	0.0, 6.0	0.0, 5.0	0.0, 7.0
95% CI	(-0.0, 0.0)	(0.1, 0.2)	(-0.0, 0.1)	(0.4, 0.7)

a UTI. Both required treatment at the hospital. One patient developed an infection requiring irrigation and debridement and IV antibiotics for 6 weeks. One patient with a preop history of bowel obstruction in the past developed another bowel obstruction requiring readmission and observation. One patient tore her quadriceps in an outpatient therapy office requiring operative intervention. During this study, no patient developed a deep venous thrombosis, pulmonary embolism, stroke, myocardial infarction, arrhythmia, or expired.

ADVERSE EVENTS REQUIRING HOSPITAL OR OUTPATIENT SERVICES WITHOUT READMISSION

Nine patients (9/386=2.3%) were treated for stiffness with

Table 4. ROM – Average for 3wk and 6wk visit.

	3wk	6wk
N	347	328
Mean ± SD	109.2 ± 8.2	115.8 ± 6.2
Median	110	116
Min., Max. (Range)	85, 135	90, 135

Table 5. Physical Therapy Adherence for Subjects Not Using Opioids During Follow-Up

	No Opiates During Follow-up	All other subjects
10 to 14 Days		
Adherence to Physical Therapy Protocol?		
Yes	164 (42.5%)	93 (24.1%)
No	68 (17.6%)	61 (15.8%)
P-value (difference between groups)	0.0371††	
3 Weeks		
Adherence to Physical Therapy Protocol?		
Yes	197 (51.3%)	121 (31.5%)
No	35 (9.1%)	31 (8.1%)
P-value (difference between groups)	0.2131††	
6 Weeks		
Adherence to Physical Therapy Protocol?		
Yes	227 (59.0%)	144 (37.4%)
No	5 (1.3%)	9 (2.3%)
P-value (difference between groups)	0.0914††	
12 Weeks		
Adherence to Physical Therapy Protocol?		
Yes	203 (60.2%)	96 (29.5%)
No	28 (8.3%)	10 (3.0%)
P-value (difference between groups)	0.5790††	

††Fisher's Exact

operative manipulation under anesthesia. The author is very aggressive with manipulation and if patients do not exceed 100 degrees flexion by 30 days, manipulation is strongly encouraged. One patient was seen for syncope and possible dehydration and was treated and sent home. Fifteen patients were evaluated for leg swelling with duplex ultrasound which was negative. Two patients had ultrasounds in the ER and 13 had outpatient office ultrasounds.

DISCUSSION

Huang et. al. recently published a prospective study in which they identified an average number of opioid pills needed for hip and knee replacement (Huang and Copp 2019). They found that with their current protocol, the average opioid-naïve TKA patient needs 78 oxycodone 10mg tablets postoperatively (or 156 oxycodone 5mg to compare to this study). Hannon et. al. published that the initial prescription for opioids should be thirty oxycodone 5mg pills compared to larger prescriptions (Hannon, Calkins, et al. 2019). When reviewing that protocol, it appears that patients used tramadol 100mg q8 hours in addition to the prescription of either 30 and 90 oxycodone. The median number of tramadol pills used was 60 tablets in addition to oxycodone immediate release. Dwyers' 2018 study noted that the average pills prescribed for TKA was 112 oxycodone 5mg (Dwyer et al. 2018). The AAHKS survey recently published suggested an average of 49 opioid pills being prescribed for TKA and did not count tramadol as an opioid. Only 1% of respondents used 14 pills or less. No data was provided as to the number of refill pills that were prescribed (Hannon, Keating, et al. 2019). The Mayo Clinic just published in 2020 that opioid naive TKA patients need a minimum of 50 opioid pills (Wyles et al. 2020).

By comparison, our data with an expanded multimodal protocol showed that 86% of non-selected patients required 10 total opioid pills or less through 12 weeks post-op. Again, this includes all doses given in the hospital prior to discharge as well as all doses at home. Fifty percent of those patients who used narcotics only used tramadol. When preoperative opioid users and patients who were discharged to a rehabilitation center are excluded, 90% of patients need 10 pills or less. We believe this to be the lowest published opioid usage for TKA in the United States.

It is hard to assess which aspect of the protocol leads to 5-15-fold reduction in opioid use as compared to the aforementioned studies. Education and patient engagement is perhaps the biggest factor. Surgeons need to expand the "multimodal" window to include 6 weeks preoperatively to 12 weeks postoperatively and not just the 24 hours the patient is in the facility. Controlling pain during the crucial first 72 hours alleviates anxiety and coincides with realistic goals set 6 weeks pre-operatively. Starting with a lower number of narcotics prescribed as demonstrated by multiple authors may be a part of the answer. Lastly, controlling well-intentioned but too aggressive formal therapy with a focus on early range of motion over strengthening is likely a significant factor.

Multiple authors have shown that an organized preoperative educational format with a dedicated "joint coach" can have significant impact on patient outcomes and satisfaction (Gaffney et al. 2017; Stevenson, Neuwirth, and Sheth 2018). Education and strong patient engagement is the cornerstone of preoperative anxiety prevention. We believe that this patient engagement piece needs to be implemented in all multimodal pathways; essentially extending "multimodal" to 6 weeks pre-op and 12 weeks postop. It is our belief that using the hospital education class/book which attempts to cover all approaches, all possible DVT prophylaxis etc. of multiple surgeons is in no way equal to an education booklet that has been entirely penned by the patient's surgeon.

At annual meetings and in multiple journals, surgeons continue to debate about what is the right secret recipe in the periarticular cocktail as well as the pre-surgery medication admixture (Stevenson, Neuwirth, and Sheth 2018). Surgeons have long recognized the need to address the pain and anxiety that occurs between 36 and 72 hours after the surgical trauma of knee replacement. Liposomal bupivacaine at one point appeared to be the solution for this issue. Some studies since then have not identified additional benefit and do not advocate for its inclusion in perioperative protocols (Alijanipour et al. 2017; Smith et al. 2017).

Recent data published by Rames, et. al. suggest that single-shot adductor canal blockade did not add measurable difference compared to periarticular block alone in terms of pain medication usage (Rames et al. 2019). Our practice saw similar outcomes prior to this study and therefore added the catheter and ropivacaine reservoir to extend pain relief through 72 hours. Turner et. al. published that patients with a CACB saw reduced pain scores past 42 hours compared to single shot block (Turner et al. 2018). Our data shows very low opioid usage and low to moderate post-op VAS scores through the first 72 hours.

The postoperative care of patients after discharge has not seen a significant amount of interest until recently. The previous model of fee for service did not incentivize surgeons to address the post-operative costs or postoperative opioid usage. The combination of the opioid crisis and the increased emphasis on bundled payment programs have led surgeons to examine what happens to patients in the 90 days that follow joint replacement. Our practice noted that one of the primary reasons patients were reluctant to embark on a second knee replacement was fear of the post-op pain most often associated with strenuous post-op formal therapy. Other authors have also noted this (Gaffney et al. 2017).

We hypothesized that patients may have less pain and quicker recovery by reducing the emphasis on post-op strengthening and increasing the emphasis on early return of range of motion. An initial study showing proof of concept was presented at the World Arthroplasty Conference in a poster session. Subsequent authors have shown that formal therapy after total knee replacement may not be necessary (Prvu Bettger et al. 2020; Fleischman et al. 2019).

The 2018 AAOS textbook on postoperative orthopedic rehabilitation states that it generally takes 10-12 weeks of time coupled with formal therapy to achieve 110-120 degrees ROM (Haas, Ricciardi, and Reyes 2018). This study shows that using a home based protocol, the mean ROM was 109 degrees at 3 weeks and 115 at 6 weeks. The manipulation rate was 2.3% comparing favorably to the literature which suggests a rate of 4.3% (Werner et al. 2015). However, a zero manipulation rate would be ideal and moving forward, the office will refer patients to a therapist at the two week visit if ROM is less than 90 degrees but recognizes that there are just some patients that cannot comply with an at home protocol or a conventional formal therapy protocol.

We believe that aggressive formal post-op therapy may result in higher pain scores and increased opioid usage and delayed improvement in ROM due to increased swelling from current therapy protocols. We suggest that further study comparing different post-op therapy protocols be undertaken. In this study, 85% of patients did not need any formal therapy to achieve a satisfactory range of motion and pain relief through 12 weeks. This has significant implications on the post-discharge costs for insurers as well. An additional benefit for patients is elimination of therapy copays.

Limitations of the study include the fact that this is a single surgeon case series, it lacks a contemporary control group or any other cohorts. However, the "real world" aspect of this data can provide significant value to the surgeon whose practice includes a significant number of arthroplasties. This protocol requires a significant investment and dedication on the part of the surgeon to implement changes to the protocol from the moment that each patient decides to move forward with arthroplasty to 12 weeks following surgery. Further research on this paradigm including prospective, multi-center comparison studies is warranted to determine the generalizability of the results.

Another failure of this study was to document the exact reason patients took narcotics after the first 3 days. We naively assumed that patients used narcotics when pain exceeded the non-opioid choices for pain relief. Every patient was contacted by the same research pharmacist. A large number of patients who took few or no narcotics initially used narcotics late (after day 10). Anecdotally, these late-users stated that difficulty initiating sleep was the reason for use. In future studies it would be advantageous to document the reason for opioid use.

Total pill count was chosen over documenting morphine milligram equivalents (MME) unlike other studies. The practicing orthopedist doesn't routinely deal in MME and it makes many articles hard to interpret in real-world scenarios. MME and oral morphine equivalent daily dose (oMEDD) tablet validity has also been called into question in recent years (Schatman, Fudin, and Pratt Cleary 2016). We suggest that the American Association of Hip and Knee Surgeons (AAHKS) review the usefulness of oMEDD and MME to its delegates in light of the controversy surrounding its validity.

Some pain management specialists have suggested that any opioid given during the preoperative, intraoperative, or postoperative phase may lead to central opioid sensitization (Rivat and Ballantyne 2016). They have suggested that this may lead to increased opioid use after discharge. This study did not control for intraoperative opioid use. Future

studies could address this issue to determine if central opioid sensitization leads to greater post-op opioid usage.

In summary, this study demonstrated that an expanded multimodal protocol can be implemented in a high volume, non-academic community surgical setting. Ultra-low opioid use and very low rates of supervised physical therapy utilization can be achieved. Further modifications and improvements to this protocol should help progress toward the ultimate goal of opioid free TKA recovery. This is achievable in other parts of the world. We encourage other arthroplasty surgeons to start with 10 opioid pills as the initial prescription and try the other techniques listed to prevent the 13-14% permanent addiction to opioids associated with TKA in the US. We furthermore request that any US surgeon who has a lower number publish their results and contact us so that we might visit your site in order to improve care for all of our patients.

The following chart is provided in response to reviewers' desire to see a comprehensive algorithm.

Areas to focus on:

1. Highly organized, personalized education engagement platform that starts 6 weeks pre-op and extends 12 weeks post-op.
2. Optimize laboratory data through your office (don't rely on clearance physician).
3. Educate on dangers of opioids.
4. Require coach participation and personalize the total joint education class to your specific protocol.
5. Discourage pre-op therapy EXCEPT for education on how to control post-op swelling and how to perform ROM exercises and prevent DVT. Review the literature on prehabilitation. Consider how you personally feel after a 90-minute workout and then consider your 84 year old TKA patient doing that with an arthritic knee. Review data on nocioceptor upregulation.
6. Train all personnel involved in patient's outcome to say the same message and understand the pathway.
7. Have at least 4 education visits (in addition to booklet) for each patient pre-op as patients do not retain all of the information in a single visit. (initial decision to consider surgery, education class, one pre-op therapy evaluation taught by a therapist that endorses your plan, and decision for surgery visit with the surgeon).
8. Create a patient specific pain management plan WITH the patient so there is clear buy-in pre-operatively.
9. Only prescribe 10 opioid pills as initial prescription.
10. Optimize non-narcotic meds for post-op pain and swelling per each patient's unique medical history.
11. Do not use a tourniquet, pre-op opioids, or intrathecal opioids.
12. Use tranexamic acid for every patient pre-op and post-op and use 81mg aspirin for DVT prophylaxis in every patient that does not have a clear contraindication.
13. Consider the evidence for matching or partially matching the patient's native knee alignment and whether that may have some effect on post-op pain. As a believer in computer navigation with 16 years of consecutive cases shooting for perfect mechanical alignment, this is a hard concept to consider.
14. Do not use a drain.
15. Consider adductor canal block with a catheter and multi-day pump in conjunction with perioperative injections.
16. Train PACU staff and discharge staff to consider non-narcotic options while patients are in-facility.
17. Have facility therapy staff teach same messaging and understand and encourage home therapy protocol.
18. As with any other stress to a bone, such a **fracture**, do not recommend strengthening and high levels of weight-bearing activity. Instead focus on swelling reduction through ice and elevation (40min/hour) in conjunction with ROM exercises. No surgeon tells a tibial plateau fracture ORIF to start lunges and sit-to-stands in the first two weeks after ORIF. Ask yourself why you allow this to happen to your TKA patient.
19. Consider fewer exercises with more repetition. Our predecessors felt that patients didn't bend their knee enough; hence the use of the CPM. It is challenging for a CPM to achieve full extension and flexion over 90 degrees. This therapy protocol is essentially 5 minutes of CPM per hour while awake. Yet there is lower cost, patients take personal ownership of their outcomes, and overall ROM is higher.
20. Buy a separate "emergency phone" that is carried by the operative surgeon or his/her PA in order for patients to have rapid access to a knowledgeable team member. Patients do not call that often, in our experience, but greatly appreciate easy access and quality answers to questions.
21. Consider a ROM cutoff at the 2-week post-op visit to help determine who might need a professional therapist to help patients get back on track. Ensure that the therapist that is chosen understands the principles of early motion but limits strengthening that may increase swelling and pain and secondarily ankylosis.
22. Make sure that the patient understands that they are "on track". Every surgeon has performed hundreds if not thousands of this procedure. For the patient, this surgery is n of 1. Consider a post-op text messaging system in conjunction with a detailed post-op recovery book (in process now but was not used for this study). Patients are less anxious with daily and weekly reminders of what "normal" should feel like.
23. Make sure your staff and the patients know that refills on opioids are generally discouraged.
24. Consider how each of these areas help create value in a bundle and review the 90-day 1.2% readmission rate with this protocol.
25. Be personally responsible for making a patient permanently addicted to opioids. You are the prescriber of the post-op opioids.

ABBREVIATIONS

- OA = osteoarthritis
- TKA = total knee arthroplasty
- DVT = deep vein thrombosis
- POD = postoperative
- NRS = numeric rating scale
- NYS I-STOP = New York State internet system for tracking over-prescribing
- PACU = post-acute care unit
- MME = morphine milligram equivalent
- oMEDD = oral morphine equivalent daily dose
- AAHKS = American Association of Hip and Knee Surgeons
- LOS = length of stay

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