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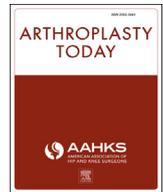
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Original research

Learning curve with a new primary total knee arthroplasty implant: a multicenter perspective with more than 2000 patients

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ABSTRACT

Background: This study provides an example for evaluating learning curve when introducing a new knee system.

Methods: Thirty-five investigators across 22 sites prospectively implanted 843 subjects with currently available products (group A). Seventy-seven investigators across 48 sites prospectively implanted 2330 subjects with the ATTUNE Knee System; in which the first 10 subjects for each surgeon were the learning curve cases (group B, N = 611), and the later subjects were designated as group C (N = 1719). Surgical time, rates of intraoperative and early postoperative complications, and patient-reported outcome measures (PROMs) at a minimum of 1 year were compared.

Results: Mean (standard deviation) surgical time was 72.0 (21.6) minutes for group A, 83.0 (24.2) for group B, and 72.1 (24.1) for group C ($P < .001$ for group B vs group C; $P = .955$ for group C vs group A). Intraoperative, early (<90 day) complication rates, and PROMs were similar for all groups.

Conclusions: The new knee system learning curve was characterized by a slightly longer surgical time with no negative impact on complications or PROMs.

Level of Evidence: III.

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Introduction

Although knee replacement systems, including instruments, have evolved over the past 5 decades into the contemporary

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orthopaedic knee procedures performed today, the surgical technique has remained essentially unchanged for the past 10 years. Contemporary innovations in total knee arthroplasty (TKA) are more subtle and typically include changes in implant and instrument design that through fine-tuning during surgery, surgeons may have the opportunity to optimize outcomes. Studying the learning curve even with more subtle procedure changes, may be beneficial to patients, training programs, and to surgeons considering adoption of new systems. Surgeons adopting new technology look to balance the anticipated patient benefits with the challenges associated with the surgical learning curve for the technology; however, the impact of the learning curve on outcomes is not well known. When comparing the effectiveness of a new primary total knee system, understanding the variability, magnitude, and duration of the learning curve may help inform surgeons whether the risk of getting through the learning curve is worth the end result.

Learning curves are known to differ between orthopaedic procedures and therefore cannot be generalized [1]. Presently, there are no consistent criteria for the reporting of learning curves [2,3]. The characterization of the learning curve associated with new technology and/or surgical technique may benefit from assessments that include the initial skill level of the surgeon, the learning rate, final level of skill achieved, and the duration of the learning period after which learning has stabilized. Although many studies recognize that surgeon performance improves with increasing experience or volume, very few quantify the nature or duration of the learning curve and impact on patient outcomes. A traditional approach to the design of trials of new surgical systems has included intensive training and supervision of surgeons or the requirement of participating surgeons to perform a fixed number of procedures before commencing the trial [1,2]. The goal of either strategy was to help surgeons efficiently get through the learning curve while minimizing risks to patients and to report on the steady-state skill level surgeons attain.

Although national joint registries are a valuable source of evidence on both established and new implant performance, the learning curve is inherently embedded in registry reports and cannot be stratified by case number of the surgeon between early and later cases. Therefore, learning curve is overwhelmed by later cases in the aggregate data. Hence, national joint registries are not the best approach to study learning curve.

While several editorials [3–5] support studying learning curve, few published articles [1,6–9] focus on the learning curve, its impact on outcomes, and even fewer on joint arthroplasty [9]. As well, in more general publications that report outcomes on subjects implanted with new technology, seldom describe when and how study surgeons and operating room staff ascended their individual learning curve before enrollment of study subjects. Readers are therefore ill-equipped to “judge whether results are attributable to the procedure itself or the delivery of the procedure by the surgeon” [3]. Simpson summarized that “the learning curve is part and parcel of that effectiveness—in the real world, the surgeons will have to ascend that learning curve on real patients, whose outcomes should count in the overall assessment” [3].

Given the paucity of publications that focus on learning curve, delivery of care in the operating room, and the potential impact on subjects, the purpose of this study was to characterize the learning curve from the perspective of surgical time and subject outcomes as a part of the introduction of a new primary TKA system. This multicenter study was designed to commence enrollment with the first product usage of a new system, thereby enabling surgeons to evaluate the safety and effectiveness of adopting new technology into their clinical practice.

Material and methods

A total of 90 investigators enrolled subjects into 3 studies that were part of the same program. Each participating center obtained institutional review board or ethics committee approval before enrollment. All selected implanting surgeons were medium- to high-volume experienced joint surgeons and/or fellowship trained in primary TKA. Surgeons who enrolled ATTUNE cases received didactic and hands on sawbones/cadaver training before enrolling their first ATTUNE subject. Written informed consent was provided by all study subjects before their inclusion into their respective study. Data through November 2017 are presented here for a total of 3173 subjects who were prospectively consented and enrolled. The studies were nonrandomized, and investigators who enrolled both groups A and B subjects did so sequentially (group A cases first, followed by group B cases). Most surgeons enrolled only 1 of the 4 possible configurations (cruciate-retaining fixed bearing [CR FB],

cruciate-retaining rotating platform [CR RP], posterior-stabilized fixed bearing [PS FB], and posterior-stabilized rotating platform [PS RP]), consistent with their standard of care. Participating centers were instructed to follow their standard of care regarding the surgical process and with respect to patellar resurfacing.

Currently available TKA cohort (group A)

From October 2011 to March 2015, 35 investigators across 22 sites (from the United States, United Kingdom, Australia, and New Zealand) consented and enrolled 843 subjects (843 primary TKA) across all 4 configurations (211 CR FB, 210 CR RP, 212 PS FB, 210 PS RP) with a combination of currently available products: 3% NexGen Complete Knee Solution (Zimmer, Warsaw, IN), 7% Triathlon Knee System (Stryker, Kalamazoo, MI), or 90% P.F.C. SIGMA Knee System (DePuy Synthes, Warsaw, IN). Surgeons implanted the knee and configuration per their standard practice. This cohort was registered on www.clinicaltrials.gov under registration number: NCT01497730.

New knee system cohort (ATTUNE, groups B and C combined)

From November 2012 to July 2015, 77 investigators across 48 sites (22 of whom also participated in the group A study) consented and enrolled 2330 primary TKA subjects with the ATTUNE Knee System (DePuy Synthes, Warsaw, IN) in 2 clinical studies across multiple regions (Australia, Austria, Belgium, Canada, Hong Kong, Germany, Korea, Malaysia, New Zealand, Singapore, Switzerland, Thailand, United Kingdom, and United States) across all 4 configurations (586 CR FB, 541 CR RP, 636 PS FB, 567 PS RP). The 22 investigators who had previously enrolled in the group A cohort remained with their previously selected configurations apart from 1 investigator who contributed to another configuration. Investigators who had not previously enrolled into the group A cohort were allowed to implant 1 configuration with the exception of 4 surgeons who implanted a second configuration to help the study team complete enrollment. The 2 clinical studies which comprise the combination of groups B and C were registered on www.clinicaltrials.gov under registration numbers NCT01746524 and NCT01754363.

Learning curve cohort (group B)

In post hoc summaries of ATTUNE subject data (groups B and C combined), it was observed that mean surgical time among the first several cases for each surgeon was longer than later cases, but leveled off with minimal further reduction between 5 and 10 cases. Based upon these post hoc summaries, it was decided to treat the first 10 ATTUNE subjects for each surgeon as group B. In instances where it was known that a surgeon had previously implanted ATTUNE (before study participation, or other configurations for study enrollment), only ATTUNE cases which were known to be among the surgeon's actual first 10 ATTUNE implantations were deemed to be group B. A total of 611 of the 2330 ATTUNE subjects were included in group B.

Inclusion/exclusion criteria

Eligibility criteria were similar across all 3 groups. Male and female patients between 22 and 80 years of age diagnosed with noninflammatory degenerative joint disease were eligible for enrollment unless excluded for 1 or more of the following exclusions: psychosocial disorders limiting rehabilitation, previous partial knee replacement (including unicompartmental, bicompartamental, patellofemoral joint replacement, patellectomy),

Table 1
Minimum 1-year PROMs: group B vs group C with standard deviations (SDs).

Min 1-year PROMS	Scale	(Unadjusted) mean \pm SD		Covariate adjusted, <i>P</i> -value
		Group B, N = 539	Group C, N = 1456	
Knee injury and osteoarthritis outcome score				
Activities of daily living	0-100	85.0 \pm 16.9	87.1 \pm 13.9	.014
Pain	0-100	84.8 \pm 16.7	86.0 \pm 15.4	.205
Symptoms	0-100	78.9 \pm 16.5	80.0 \pm 15.0	.120
Function in sport and recreation	0-100	57.5 \pm 30.5	58.3 \pm 29.6	.778
Quality of life	0-100	70.4 \pm 24.4	71.4 \pm 22.4	.774
Oxford Knee Score	0-48	40.2 \pm 7.4	40.8 \pm 6.8	.427
Patient's knee implant performance questionnaire				
Overall	0-100	71.0 \pm 19.4	73.5 \pm 18.5	.019
Confidence	0-10	7.9 \pm 2.1	8.2 \pm 1.9	.042
Stability	0-10	8.1 \pm 2.2	8.4 \pm 1.9	.083
Satisfaction	0-10	7.8 \pm 2.2	8.0 \pm 2.0	.066
Modifying activities	0-10	6.0 \pm 3.4	6.5 \pm 3.4	.003

previous primary TKA in the affected knee, prior high tibial osteotomy, those experiencing radicular pain from the spine or a patient who was pregnant or lactating. In addition, if a patient required a bilateral TKA, only the first knee replacement was to be enrolled into the study.

Data collection and analysis

Surgical time was the time from first incision to the last stitch. Patient-reported outcome measures (PROMs) included the Knee injury and Osteoarthritis Outcome Score [10], Oxford Knee Score [11], and the Patient's Knee Implant Performance Questionnaire [12,13]. Subjects were seen preoperatively for a clinical assessment and to collect medical history, PROMs, and radiographs. Subjects returned to the clinic at less than 1 year (1-303 days) and again at a minimum of 1 year (304-668) for clinical and radiographic follow-up and to complete PROMs. The intervals were continuous to accommodate a broad range of standard of care.

The purpose of this study was to investigate a learning curve effect on surgical time, intraoperative adverse events, early

postoperative adverse events (<90 days), and PROMs; radiographic analysis was not examined for a learning curve effect. Surgical time was compared for group B vs group C and for group C vs group A. Adverse event comparisons were restricted to local (operative site) adverse events which were either device related and/or procedure related; intraoperative and early postoperative adverse events (<90 days) were compared for group B vs group C, and for group C vs group A cases. Minimum 1-year PROMs were compared for group B vs group C.

Statistical analysis

Demographic summaries and comparisons of surgical time and complications were carried out with all consented and enrolled subjects, whereas comparisons of PROMs were done with the exclusion of subjects who had major inclusion/exclusion protocol deviations. Surgical times were compared with a 2-sided independent samples t-test, and complication rates were compared with Fisher's exact test. PROMs were compared with analysis of covariance models including configuration, age,

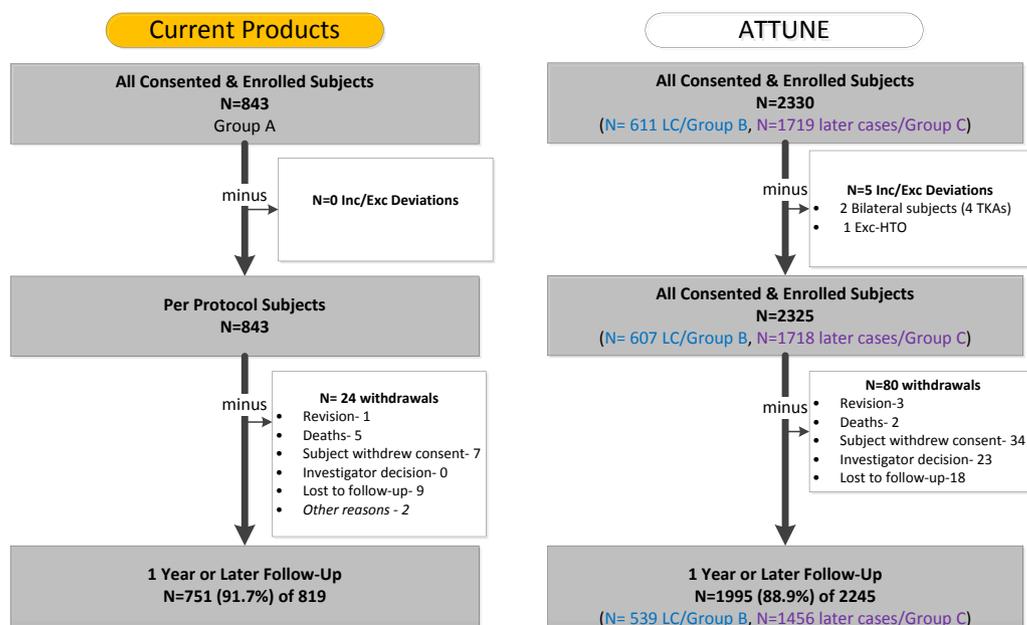


Figure 1. Subject flowchart.

Comparison of Surgical Time

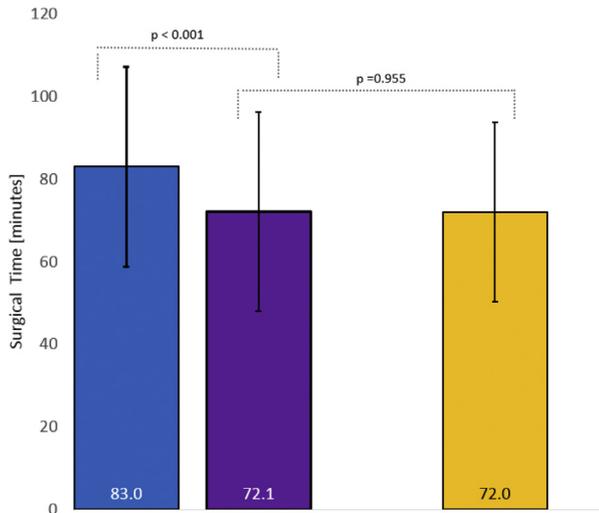


Figure 2. Mean surgical time and standard deviations (whiskers): group B (blue) vs group C (purple); group C (purple) vs group A (yellow).

body mass index, gender, preoperative PROMs, and post-operative time (days of follow-up) as covariates. Summaries of PROMs in Table 1 show raw-unadjusted mean (standard deviation [SD]), with *P*-values from respective analysis of covariance models. Because of the multiple comparisons of PROMs, a *P*-value threshold of 0.01 was utilized for determining statistical significance.

Results

Disposition of subjects for group A and the combination of groups B and C is presented in Figure 1. The dataset of all consented and enrolled subjects consisted of 843 from group A and 2330 from the combination of groups B and C. The per-protocol analysis data set excluded 4 knees in 2 subjects for major protocol deviations (both knees of staged bilateral knee replacement were enrolled) and 1 knee in 1 subject for medical history of high tibial osteotomy. Demographics for all consented and enrolled subjects were similar (group A vs the combination of groups B and C: mean [SD] age 65.6 [8.2] vs 64.5 [7.9]; female 58.6% vs 60.2%; mean [SD] body mass index 31.9 [6.4] vs 31.6 [6.1]; diagnosis [osteoarthritis] 98.2% vs 98.8%). Before minimum 1-year follow-up, there were 104 study withdrawals (24, group A; 80, groups B and C combined) for reasons shown in Figure 1.

Mean (SD) surgical time in minutes was 83.0 (24.2) for group B and 72.1 (24.1) for group C (*P* < .001); surgical time for group A was 72.0 (21.6) (*P* = .955 vs group C); Figure 2 displays these surgical time comparisons.

Device- or procedure-related intraoperative operative site adverse events were experienced by 1.5% (9/611) group B and by 0.8% (13/1719) group C cases (*P* = .142); the rate for group A was 0.6% (5/843) (*P* = .803 vs group C). Details for these 27 intraoperative Adverse Events are presented in Table 2 (all AEs were reported for distinct subjects). Device- or procedure-related operative site complications within 90 days postoperative were experienced by 9.3% (57/611) group B cases and by 8.1% (139/1719) group C cases (*P* = .351); the rate for group A was 10.3% (87/843) (*P* = .064 vs group C). The types of adverse events for groups A, B, and C are presented in Table 2 (numbers presented are the tally and percent of subjects who were reported at least 1 adverse event within the respective category).

Table 2 Type and frequency of intraoperative/postoperative adverse events.

Event, preferred term	Current products (N = 843)		ATTUNE (N = 2330)					
	Group A (N = 843)		Group B, learning curve (N = 611)		Group C, later cases (N = 1719)			
	#	%	#	%	#	%		
Intraoperative	Joint instability	0	0	4	0.65	4	0.23	
	Femur fracture	2	0.24	0	0	1	0.06	
	Complication of device insertion	0	0	1	0.16	1	0.06	
	Joint dislocation	0	0	0	0	2	0.12	
	Skeletal injury	0	0	1	0.16	1	0.06	
	Tendon rupture	1	0.12	1	0.16	0	0	
	Tibia fracture	1	0.12	0	0	1	0.06	
	Ligament injury	0	0	0	0	1	0.06	
	Ligament rupture	0	0	1	0.16	0	0	
	Tendon injury	1	0.12	0	0	0	0	
	Peroneal nerve palsy	0	0	0	0	1	0.06	
	Product quality issue	0	0	1	0.16	0	0	
	Procedural complication	0	0	0	0	1	0.06	
	Postoperative (<90 days)	Impaired joint movement	52	6.17	27	4.42	74	4.3
		Pain	6	0.71	12	1.96	22	1.28
Suspected infection (skin and wound)		9	1.07	6	0.98	10	0.58	
Reported infection		8	0.95	1	0.16	12	0.7	
Swelling/effusion		1	0.12	8	1.31	11	0.64	
Patella crepitation		6	0.71	2	0.33	6	0.35	
Hemarthrosis/hematoma		4	0.47	4	0.65	4	0.23	
Other		1	0.12	3	0.49	7	0.41	
Musculoskeletal/connective tissue related		2	0.24	3	0.49	5	0.29	
Instability		0	0	0	0	2	0.12	
Deep vein thrombosis		0	0	0	0	1	0.06	
Arthropathy		1	0.12	0	0	0	0	
Insert dislocation related to manipulation under anesthesia		0	0	0	0	1	0.06	

Minimum 1-year PROMs summaries for groups B and C are presented in [Table 1](#). With the exception of the Modifying Activities Patient's Knee Implant Performance Questionnaire subscore, all *P*-values comparing group B vs group C were greater than 0.01 and not considered to be statistically significant.

Discussion

Over the last 50 years, the field of hip and knee arthroplasty has continued to evolve. During this time, the development of innovative implant designs and surgical techniques has had a profound effect on patients worldwide. Many publications in the orthopaedic literature on new implant designs and techniques focus on outcomes and results in expert hands. In many cases, these studies do not document the learning curve associated with the technique or implant design. Furthermore, registry data are not well suited to reporting on learning curves with a specific implant as they report aggregate outcomes over time. The purpose of the present study was to provide an analysis of the learning curve as a part of the introduction of the ATTUNE Knee System. Overall, we found that surgeons experience a mild surgical time learning curve that was completed after 10 cases, with no apparent impact to patient outcomes or complication rate.

Development of surgical skills has been described in a 3-phase sequence [14]. The first step is gaining cognitive information related to indications, the decision to perform surgery, and available alternatives. Part of this phase is understanding how the new technology would affect patient outcomes as well as aspects of preoperative, intraoperative, or postoperative care related to the technology. The second step is task learning with the new technology. This skill can be developed through hands-on laboratory programs. In the present study, these 2 phases were addressed through didactic training followed by hands on sawbone/cadaver training before surgeons enrolled their first ATTUNE subject. The final phase in the development of surgical skills is independence. During this phase, learning is ongoing, and skills are further refined and perfected. The primary focus of the present study was during the phase in which surgeons began implanting ATTUNE implants in subjects.

We divided the surgeon experience into the learning curve phase (first 10 cases, group B) and later cases (group C). This was based on the observation that there was a modest increase in surgical time for the first 5–10 cases that was not demonstrated in later cases. As a result, the study was designed to compare the early learning curve period with later cases as well as results from other currently available products. The learning curve cases (group B) demonstrated an average surgical time of 83.0 minutes. This was statistically longer than the surgical time in group C cases (72.1 minutes) and group A cases (72.0 minutes). However, when interpreting these data, it is important to note that in this study all surgeons involved were moderate- to high-volume surgeons. Therefore, the learning curve period may be longer for lower volume or less experienced surgeons.

Surgical time alone is not the only variable that must be evaluated when considering adopting a new surgical technique or implant. Potential risks or complications that may be encountered as well as potential failure rates should be considered. Recent literature has demonstrated increased complications and risks with changes in surgical technique. For example, some studies evaluating adoption of the direct anterior exposure in total hip replacement have demonstrated not only increased surgical time in early cases but also increased complication rates and higher failure rates [15–18]. Considering findings such as those related to learning curves, we sought to evaluate complications as well as 1-year outcomes in the present study. There were no significant

differences in intraoperative or early postoperative complication rates between group B and group C cases. Outcome scores for the learning curve cases (group B) were consistent with later cases (group C). These data should provide surgeons who are considering adoption of this implant reassurance about anticipated outcomes in the learning curve phase.

The strengths of this study include a multicenter design with a relatively large sample size and deployment across a wide range of medical systems and countries. This increases the generalizability of the results. Furthermore, the focus of the study on evaluating the learning curve phase of implant use is unique. Many studies on new implant designs do not report on this time period. This type of information is important for surgeons considering adoption of a new TKA system as well as the patients who could be part of the learning curve phase. Therefore, this type of study should be considered when new TKA systems are released in the future.

The limitations of the present study are as follows. First, this type of study has not been replicated with other implant designs. This makes comparison of the results of this study more challenging. Second, not all surgeons contributed subjects to both current product (group A) and ATTUNE cohorts (combination of groups B and C); some surgeons only participated with ATTUNE implants. Third, we did not evaluate any potential impact of gaps in enrollment during the learning curve phase but simply focused on the number of cases completed. It is possible that any long gaps in enrollment could affect the length of the learning curve period for some surgeons. Finally, as noted previously, surgeons in this study were all experienced and/or fellowship-trained, moderate- to high-volume arthroplasty surgeons. Therefore, these results may not be generalizable to all surgical teams.

Conclusions

This study provides an example for collecting learning curve when introducing new products, which others may find useful in future study designs. The results demonstrated a modest learning curve; after approximately 10 cases, the surgical time was on par with prior standard of care. Interestingly, the learning curve did not introduce a negative effect on intraoperative adverse events, early postoperative adverse events, or PROMs.

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