Arthroplasty Today 4 (2018) 348–353

Contents lists available at ScienceDirect

Arthroplasty Today

journal homepage: http://www.arthroplastytoday.org/

Original research

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

John-Paul Whittaker, MB, ChB FRCS [a], Kimberly A. Dwyer, PhD [b], James Howard, MD, MSc, FRCSC [c], Verdonna Huey, MS, BSN [b, *], James Lesko, PhD [b], Ryan M. Nunley, MD [d], Peter Verdonk, MD, PhD [e]

[a] Robert Jones and Agnes Hunt Orthopaedic Hospital, England, UK
[b] DePuy Synthes Joint Reconstruction, Warsaw, IN, USA
[c] London Health Science Centre – University Hospital, London, Ontario, Canada
[d] Washington University Orthopaedics, St. Louis, MO, USA
[e] Monica Camputs O.L.V., Middelares Hospital, Antwerpen, Belgium

ARTICLE INFO

Article history:
Received 19 March 2018
Received in revised form
16 May 2018
Accepted 17 May 2018
Available online 9 July 2018

Keywords:
Total knee arthroplasty
Learning curve
Adverse events
Clinical outcomes
ATTUNE

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.

Introduction

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

Present Affiliations: Peter Verdonk, Antwerp Orthopedic Center, Monica Hospitals, Antwerp, Belgium and Department of Orthopaedic Surgery, Antwerp University Hospital, Antwerp, Belgium.

One or more of the authors of this paper have disclosed potential or pertinent conflicts of interest, which may include receipt of payment, either direct or indirect, institutional support, or association with an entity in the biomedical field which may be perceived to have potential conflict of interest with this work. For full disclosure statements refer to https://doi.org/10.1016/j.artd.2018.05.004.

* Corresponding author. DePuy Synthes Joint Reconstruction, P0 Box 988, Warsaw, IN 46581-0988, USA. Tel.: +1 574 372 5932.
E-mail address: vhuey@its.jnj.com

https://doi.org/10.1016/j.artd.2018.05.004

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, bicompartmental, patellofemoral joint replacement, patellectomy),