Value in Single Use Instruments for Total Knee Arthroplasty: Patient Outcomes and Operating Room Efficiency

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ABSTRACT

The US healthcare system is moving towards a value-based model to increase the quality of patient outcomes while simultaneously reducing cost. Total Knee Arthroplasty (TKA) has been shown to be one of the most clinically and cost effective procedures in orthopedics. Single use instruments, relative to traditional metal instruments, provide the potential to reduce costs while maintaining or improving quality in TKA. Single use instruments, delivered terminally sterile, are ready for immediate use. Single use instruments are designed with the following goals: reducing the direct cost of processing and sterilizing traditional instruments, decreasing operating room turn-around time, reducing the logistical burden of loaner instrumentation, and reducing infection risk.

Methods

The study design was a case-control series of patients undergoing primary TKA by a single surgeon using either single use instruments or traditional reusable instruments. Local IRB approval was obtained and retrospective patient information was collected in an anonymized fashion. Consecutive patients who received TKA with the GMK Sphere Medially Stabilized Knee (Sphere knee) implanted with GMK Efficiency Single Use Instrumentation (Efficiency instruments) and MyKnee patient specific instruments (PSI) cutting blocks (Medacta USA, Chicago, IL, USA) at a single hospital were compared with patients who received the same prosthesis implanted with traditional instruments and the same PSI blocks during the same time period. Minimum 6-week follow-up was obtained. Outcome measures included pre- and post-operative Knee Society Score (KSS), pre- and post-operative hip-knee-angle (HKA), and major perioperative complications including re-admission, infection, reoperation, and revision. Cost and economic measures associated with the instrumentation were collected or estimated for each group.

Results

Between 2013 and 2015, 100 patients met the inclusion criteria. These included fifty-one consecutive patients implanted with Efficiency instruments compared with forty-nine patients implanted with traditional instruments. There were no significant differences in baseline demographic or surgical variables. The mean HKA went from 176.9° to 179.3° with Efficiency instruments, and from 177.0° to 178.9° with traditional instruments. The mean KSS Objective score went from 48.7 to 84.0 with Efficiency instruments, and from 50.2 to 83.9 with traditional instruments. The mean KSS Functional score went from 41.6 to 72.8 with Efficiency instruments, and from 38.7 to 76.4 with traditional instruments. None of these differences were statistically significant. There were no significant differences in the rates of re-admission, infection, reoperation, or revision. Economic analysis of the case-control data demonstrates potential savings of $1,198 per total knee arthroplasty when Efficiency instruments are utilized compared to traditional instruments.

Conclusion

Initial experience indicates that Efficiency instruments perform as well as traditional instruments in clinical outcomes and offer significant potential per-case cost savings based on the economic model developed.

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BACKGROUND

Total Knee Arthroplasty (TKA) has been proven to be clinically and cost effective in alleviating pain, restoring function and giving back quality of life for patients with advanced osteoarthritis. The improved quality of life offered by this procedure has helped drive significant growth in the number of TKAs performed. This growth in the United States is projected to increase from 719,000 cases in 2010[1], to 3.5 million cases by 2030[2]. This anticipated year over year growth is expected to strain the budgetary limits inherent in the health care system, as well as outpace the availability of trained surgeons.[3] Another compounding factor is the US healthcare system transforming from a fee-for-service system to a value-based system that rewards quality care delivered at reduced costs. Of significant relevance for TKA procedures is the recent launch of the Comprehensive Care for Joint Replacement (CJR) model by the Centers for Medicare and Medicaid Services (CMS)[4]. With these changes in reimbursement, providers must evaluate all aspects of TKA procedures to ensure financial viability while delivering high quality patient care to this rapidly growing patient population.

Providers are searching for ways to care for more people while continuing a sustainable business model. Utilization of single use instruments is gaining significant attention because of the potential to provide additional efficiencies in total joint arthroplasty. Single use instruments currently provide several advantages, including increased patient safety, increased operating room (OR) efficiencies, reduced risk of delayed or cancelled TKA cases due to compromised loaner instruments, and reduced direct costs and time associated with processing, sterilizing, handling and storage of traditional metal instrumentation.

Efficiency instruments are a complete, terminally sterile, single-use instrumentation solution for total knee replacement. The durability and functionality of these instruments was attained through attention to design detail and the combination of special medical grade composite technopolymers with high precision manufacturing processes. The Efficiency instruments come pre-packaged and terminally sterile (Figure 1). Each TKA procedure requires one tray with implant size specific instruments in combination with two smaller traditional instrument trays includes all necessary instruments and trials to perform the procedure. Instrument sets are shipped to the hospital 3 to 4 days prior to the case. Weighing approximately 6 pounds, the Efficiency instrument package is easy to handle and to store. The smaller trays and reduced number of traditional trays dramatically reduces the time and effort in handling trays in Sterile Processing Department (SPD) and accelerates OR setup and turnover. Efficiency instruments are designed for use with or without PSI blocks. For the purposes of this study, the MyKnee PSI blocks were used (Figure 2). MyKnee allows a surgeon to conduct pre-operative 3D planning, based on CT or MRI images of the patient's knee.

Figure 1. GMK Efficiency Single Use Instruments: General Set, Femoral Tray, Tibial Tray, and Patellar Tray. Each tray is terminally sterilized.

Figure 2. MyKnee PSI Blocks

The purpose of the present study was to compare a case series of PSI TKAs with Efficiency instruments to a control series with traditional instruments. Clinical, radiographic and outcome metrics were the primary endpoints. In addition, the case series data were analyzed for economic efficiencies between the two options and assess the potential to reduce cost.

METHODS

At a single site, patients undergoing a TKA with PSI blocks were retrospectively placed in two groups for comparison: Efficiency instruments versus traditional instruments. IRB approval was obtained and retrospective patient information was collected on 100 patients. Between 2013 and 2015, fifty-one patients were selected based on receiving the Sphere knee with Efficiency instruments and PSI blocks. Each patient completed a six-week follow-up visit. The same data was collected on forty-nine patients, each receiving a Sphere knee implanted with traditional instruments and PSI blocks. The surgical procedures for patients receiving a Sphere knee with Efficiency instruments and those with traditional instruments were done over the same time period for comparative purposes. Clinical and radiographic outcomes were analyzed with t-tests and chi-square tests.

RESULTS

Table 1 demonstrates the pre-operative characteristics of the two comparison groups, including demographic, surgical, and radiographic variables. There were no significant differences in pre-operative characteristics ($p < 0.05$).

Patient Characteristics	Efficiency Instruments	Traditional Instruments
AGE	66.4 (37-87)	70 (49-87)
SEX		
Female	34	33
Male	17	16
LATERALITY		
Left	21	27
Right	30	22
DIAGNOSIS		
DJD	50	48
Failed Unicompartmental Knee	1	2

Table 1. Baseline characteristics of single use versus traditional instrument groups

The observed clinical results for patients receiving a Sphere knee utilizing Efficiency instruments were comparable to implants utilizing traditional instruments (Table 2). No subsidence, migration or loosing occurred at last follow-up (range 6 weeks to 1 year) for all patients based on x-ray evaluation.

Measurement	Efficiency Instruments	Traditional Instruments
AVERAGE HKA ANGLE		
Pre-Operative (MyKnee Plan)	176.9 ± 4.3°	177.0 ± 5.1°
Post-Operative	179.3 ± 2.8°	178.9 ± 3.0°
AVERAGE KSS SCORES		
Pre-Operative		
Objective	48.7 ± 10.1	50.2 ± 8.7
Functional	41.6 ± 18.6	38.7 ± 17.0
Post-Operative		
Objective	84 ± 11.7	83.9 ± 10.3
Functional	72.8 ± 19.0	76.4 ± 18.9
OPERATIVE TIME (MINUTES)		
OR time	91.6 ± 15.9	91.5 ± 16.4
Tourniquet time	31.3 ± 8.1	30.1 ± 7.7

Table 2. Clinical results of Efficiency and traditional instruments

Table 3 demonstrates the rates of major perioperative complications including re-admission, infection, reoperation, and revision. There are no statistically significant differences.

Measurement	Efficiency Instruments	Traditional Instruments
Infection	0	0
DVT	0	0
Fracture	0	0
MUA	3	1
Internal Arthrotomy Injury	1	0

Table 3. Major perioperative complications between reusable versus traditional instrument groups

DISCUSSION

In the United States, total knee arthroplasty is projected to grow from 719,000 surgeries/year in 2010 to 3.5 million surgeries/year in 2030. Providers need to prepare for the rising demand in volume and cost of TKA procedures. It is paramount for hospitals and Ambulatory Surgery Centers (ASCs) to remain financially viable in a changing reimbursement environment.

Given the direction of the US healthcare system, providers need to give serious consideration to all opportunities to reduce costs while maintaining or improving patient outcomes. Various advancements in TKA technology have helped achieve these goals with new implant designs, minimally invasive techniques and patient specific

cutting blocks. Single use instrumentation provides the next potential area of opportunity for providers to gain additional efficiencies in TKA procedures while maintaining the quality of care.

Based on this initial experience, potential benefits of using single use instruments compared to traditional instruments were identified and categorized. These categories include Patient Safety, Operating Room Efficiencies, Sterile Processing and Logistical Efficiencies. Moreover, a financial model was developed to estimate the potential economic benefit per procedure given single use instruments are purchased by the hospital on a per-case basis.

Patient safety

As in any surgical procedure, the possibility for complications resulting from a TKA exists. One of the more frequent and costly is the risk of infection. TKA infections can have devastating consequences for patients. Post-operative care for infections requires additional treatments that may include one or more hospital readmissions, antibiotic therapy, additional surgical procedures and, in extreme cases, joint fusion or amputation. Depending on the timing of when the infection occurs, the hospital may now be financially responsible for the cost of treating the infection under the CJR or other bundled payment arrangements. Notwithstanding the patient related concerns and clinical issues, the cost of an infection is high, particularly considering the evolving reimbursement methodologies that span longer periods of care.

Turning to intraoperative concerns, traditional instruments may become contaminated during the procedure or found to have residual contamination such as bone debris from a previous case. Often, such findings necessitate re-sterilizing extending anesthesia and operative time. Because Efficiency instruments have never been used before and are provided terminally sterile, Efficiency instruments reduce the likelihood of needing to rely on immediate use steam sterilization (IUSS), formerly known as flash sterilization. A major concern of IUSS is that its convenience may lead to inappropriate use or improper sterilization. Minimizing the use of IUSS has been integral in efforts to reduce infection rates in orthopedic procedures.[5]

The annual rate of infection for TKA patients is reported between 1 to 2%[6] with the cost of treating the infection ranging from $25,546 to $36,848[6-8]. In addition, studies have shown that the infection rate within 90 days of implantation is 0.9%[9]. Efficiency instruments are provided to the facility pre-packaged and terminally sterilized through a validated sterilization process. A recent publication involving similar single use instruments reported a dramatic decrease in TKA infections, from 3% to 0.2%, when using single use instruments compared to traditional metal instruments. This significant reduction was most likely attributed to enhanced maintenance of sterility and decreased risk of contamination[7]. Another advantage of Efficiency instruments is that fewer instruments are opened and exposed during the surgical procedure; hence, there are fewer instruments introduced to the sterile field that can be exposed to contaminants. (Figure 3a & 3b)

Figure 3a. Traditional instruments for a total knee case

Figure 3b. Efficiency instruments and MyKnee blocks for a total knee case.

In building an economic model for Efficiency instruments, cost savings related to a reduction in infection rates may be significant. For modeling purposes, only the costs associated with infection in 90 days were included given the timeframe associated with bundled payments and the CJR. At 90 days, the published infection rate for TKA procedures is 0.9%. The potential impact on reducing the rate of infection by utilizing Efficiency instruments was estimated conservatively at 10%. Utilizing the infection rate for TKA at 90 days and the average cost of treating an infection, the estimated infection cost on a per-case basis is $281 (0.9% x $31,197). Multiplying this figure by the estimated reduction in infection rate of 10% provides and estimated cost reduction of $28 per case.

Operating room efficiencies

There are multiple steps involved in preparing traditional instruments for TKA procedures that may be optimized with the utilization of Efficiency instruments (Table 4):

Efficiency	Rationale
Reduced time spent organizing the case cart	Efficiency instruments come specifically prepared for each implant procedure
Reduced time spent on point-of-use cleaning	Efficiency instruments come specifically prepared for each implant procedure
Reduced management of instruments	Allow for fewer instruments that require management and maintenance during the procedure enabling operating room staff to focus on more productive activities related to the implant procedure
	Eliminate any potential issues related to a limited number of traditional instruments. Limited availability of instruments can make operating room turnover more difficult leading to procedure delays
	Efficiency instruments are in new working order for each case as they are single-use. They do not
	Have the same issues as traditional instruments of working improperly due to repeated use and processing cycles
	Greatly reduce or eliminate the need for loaner instrumentation
Reduction in operating room set-up and turnover time	With fewer instruments to manage and transport, the time associated with operating room set-up and turnover time is reduced
	Significantly reduce the risk of delaying or cancelling the TKA procedure because of compromised sterilization or missing traditional instruments

Table 4. Potential operating room efficiencies associated with Efficiency instruments

These efficiencies support less variability in operating room turnover time leading to more efficient use of the operating room. This is a key consideration, as more efficient turnover of the operating room may allow for additional cases to be scheduled in a given operative day without increasing operating room staff or requiring additional resources.

An economic model was developed to quantify the potential benefits based on the categorization of benefits described above. This model establishes a potential economic benefit of $1,198 per TKA procedure utilizing single use instrumentation compared to traditional instrumentation (Table 5).

Category	Key Assumptions	Economic Benefit
Patient Safety Reduced Risk of Infection	• Rate and Cost of Infection • Reduced Risk of Infection	**$28** ($23 - $33)
OR Turnover Time	• Decreased procedure set up time • Decreased post-procedure activities	**$0** ($17 - $25)
Operating Room Efficiencies	• Time Savings per TKA procedure • Reduced set up and turnover time facilitates scheduling one additional operating room procedure • Operating room contribution margin per hour	**$348**
Sterilization	• Cost to Sterilize One Tray • Number of Trays Requiring Sterilization	$704 ($375 - $1,100)
Logistics Loaner Instrumentation	• Time Savings • Hourly Wage • Time available for other tasks	**$118** 10.2 hrs
Total Potential Economic Benefit		**$1,198**

Table 5. Summary of potential economic benefit

The use of Efficiency instruments speeds operating room turnover time by favorably affecting both procedure set-up time as well as post-procedure activities. Based on initial clinical experience with Efficiency instruments, the decrease in procedure set up time was estimated to be 15 to 20 minutes per procedure. In addition, the decrease in time spent on post-procedure activities was estimated to be an additional savings of 10 to 15 minutes.

For economic modeling purposes, estimating cost savings relative to the time saved in operating room preparation and turnover were not included. This is because labor costs for most facilities is fixed; the operating room staff will still be present regardless of time savings, and will redirect to other activities.

However, the economic model does account for additional procedure capacity within the operating room given the potential time savings for each TKA procedure when utilizing Efficiency instruments. Assuming a facility were to schedule TKA procedures utilizing Efficiency instruments consecutively, the time savings associated with each case could allow for an additional operating room procedure to be scheduled without requiring additional operating staff time. For example, assuming the average TKA procedure with traditional instruments lasts 60 to 120 minutes[10], approximately four TKA procedures could be scheduled during an eight-hour period.

However, by scheduling the same four TKA procedures with Efficiency, at least 60 to 75 minutes could be saved that in turn, could be utilized to complete an additional procedure.

Average operating room contribution margin per hour has been calculated at $1,773[11] and can vary significantly by surgeon[12]. Because of this variability, the model utilized a common procedure, carpal tunnel syndrome surgery, as a conservative proxy for the additional procedure that could be scheduled in the time saved by utilizing single use instruments in consecutive TKA procedures. The Medicare hospital outpatient payment rate for this procedure was utilized as the payment rate is based on hospital reported costs. For carpal tunnel syndrome surgery, the Medicare hospital outpatient payment rate is $1,393[13]. As the clear majority of costs related to this procedure are fixed costs, the reimbursement amount was utilized to approximate procedure contribution margin.

In order to calculate the average contribution margin on a per-case basis, the Medicare hospital outpatient payment amount for carpal tunnel surgery was divided by the expected number of TKA procedures utilizing Efficiency instruments per day. This results in a per-case amount of $348.

Sterile processing

One of the clear benefits of Efficiency instruments is the reduced requirement to manage, package and sterilize instruments. The reduction in direct costs and time for these various steps facilitate workflow improvements that can lead to significant cost savings.

Single use instruments significantly reduce the number of instrument trays that must be managed for each TKA procedure. Traditional instruments can require 6 to 12 trays for each surgery[7]. Efficiency instruments require only one full tray of instruments to be sterilized at the facility. This greatly reduces the direct cost and administrative burden to inspect, wash, assemble, sterilize, package and transport traditional metal instruments.

For modeling purposes, the average number of traditional instrument trays sterilized compared to the sterilization requirements of Efficiency instruments results in eight (8) fewer trays requiring sterilization. The cost to sterilize one tray ranges from $75 to $100[7]. Utilizing the average of this range results in a cost per tray of $88. This results in total estimated cost savings in sterilization and preparation of $704 per case.

Logistical efficiencies

Another important consideration is the logistical requirements with traditional instruments. Hospitals rely on vendors to provide loaner instrumentation to complete the case. The use of loaner instruments creates various challenges logistically in managing the vast number of instruments and trays potentially across multiple vendors. Depending on caseload and delivery time of loaner instrumentation, overtime pay may be required to process the volume of instruments in preparation for surgical cases the next day. As single use instruments greatly reduce the number of instruments and trays, they may help eliminate overtime costs related to management and sterilization of traditional instrumentation.

It is recommended by several organizations, including the Association of periOperative Registered Nurses (AORN), the International Association of Healthcare Central Service Materiel Management (IAHCSMM), the Joint Commission: Accreditation, Health Care, Certification (TJC) and the Association for the Advancement of Medical Instrumentation (AAMI) that facilities have a program and procedures in place to handle loaner instrumentation. Typical program recommendations include various components to ensure proper handling and processing of loaner instrumentation[14] (Table 6):

Documented process for requesting loaner instrumentation
Time requirements for pre-procedure and post-procedure processing and in-servicing, as needed
Acquisition of loaner items, including a detailed inventory list (preferably with pictures)
Obtaining FDA-cleared manufacturers' written instructions for instrument care, cleaning, assembly, and sterilization
Cleaning, decontaminating and sterilizing borrowed instrumentation by the receiving facility
Transporting processed loaner instrumentation to point of use
Post-procedure decontamination, processing, and inventory documentation
Returning to the industry representative
Maintaining records of the transactions

Table 6. Loaner instrumentation program recommendations

Programs with these processes are critical to ensure that loaner instrument sets are as clean as possible and properly sterilized, limiting the risk of infection as well as ensuring instruments are in good working order for the case.

As evidenced in Table 6, the requirements to manage loaner instrumentation can be extensive. Often, the time and effort that goes into managing loaner instrumentation can be overlooked. One publication showed the effort to process one set of loaner instruments required for a surgical procedure can be extensive, as eight instrument

trays required at least 6.5 hours to process from delivery to sterile presentation. Following the surgical procedure, the loaner instruments were returned from the operating room, reprocessed and returned to the vendor. These steps required an additional 5 hours. In total, including pre-surgical and post-surgical reprocessing, the time invested for management of loaner instruments for a surgical procedure was at least 11.5 hours[15]. This demonstrates the significant burden that loaner instrumentation can place on a facility on a per case basis. In high volume settings, case load may be greater than loaner sets available on a given day. In such situations, traditional instrument sets used early in the day may be rushed through central processing to be used in cases late in the day. Expediting the sterile processing of traditional instruments introduces the potential for increased bio-burden and missed process steps (Table 6). Clearly, Efficiency instruments eliminate much of this burden.

For post-procedure activities, there is variability across facilities in terms of how loaner instrumentation is handled, whether instrument sets are stored on-site or returned to the vendor, and how much involvement the vendor has regarding the instruments. The model includes only 80 minutes of the total 5 hours included in the publication to address the handling of loaner instrumentation after the procedure. With this adjustment, the total time to address one set of loaner instrumentation is 7.8 hours, and the Non-Sterilization Related percentage of this time is estimated to be 30%. Assuming a fully-burdened hourly wage of $50, this results in estimated savings of $118 related to the decreased reliance on loaner instrumentation on a per-case basis. In addition to an expense savings, use of Efficiency instrumentation frees up staff time for other tasks. In this model, time spent in handling loaner instruments is estimated at 11.5 hours, whereas the comparable time for Efficiency instruments is estimated at 1.3 hours. This frees up 10.2 hours of staff time to perform other tasks.

Efficiency instruments represent an incremental cost to a TKA procedure. However, the potential benefits identified and corresponding economic model developed provides a framework for hospitals to evaluate the potential clinical and economic benefits associated with Efficiency instruments. Reduced sterilization costs are intuitive given the number of trays that require sterilization for traditional instruments. What the model also captures are more “hidden” costs that are associated with traditional instruments, including the reduction in infection risk and the costs associated with loaner instrumentation. Another consideration regarding Efficiency instrumentation is that the total weight of the instruments required is significantly reduced. Per AORN guidelines and AAMI standards, traditional instrument trays should weigh no more than 25 pounds per tray.[16] Assuming these guidelines and standards are followed, a TKA procedure utilizing traditional instruments comprised of eight trays to cover one surgical procedure may weigh up to 200 pounds. In comparison, the total weight of instruments required for one case when using Efficiency instruments is approximately 19 pounds.
In considering Efficiency instrumentation, one potential issue is the additional waste generated from these single use instruments. Taking into account the overall potential waste associated with a TKA procedure, the use of Efficiency instruments eliminates the need to reprocess instruments, thereby eliminating the use of water, chemicals, wrap, chemical and biological indicators, etc. that are required for traditional instruments. Additionally, Efficiency instruments can be disposed in general nonhazardous waste and do not require the use of sharps or biohazard disposal.

One limitation of this study is that it is one surgeon’s experience at one institution. Additionally, the benefits identified were based on retrospective observational patient outcomes, and not conducted in a randomized controlled trial. Subsequent clinical studies are required to validate the benefits identified in this paper. In this study, the potential economic benefits were derived from a model based on various assumptions. Changes in these assumptions could impact the results dramatically, and may vary based on each institutions experience. Finally, Imaging costs associated with PSI blocks was not factored into this analysis and should be considered when determining economic value.

CONCLUSION

The rapidly changing reimbursement environment coupled with high likelihood of significant growth in TKA procedures, providers will be well served by continually evaluating new ways to perform these procedures while maintaining high quality outcomes at reduced cost. GMK Efficiency Single Use Instruments were developed to accomplish both these goals. Efficiency instruments have been used in over 5000 TKA worldwide, during its Limited Market Release phase in accordance with the M.O.R.E Excellence Clinical Program, dramatically reducing the need and reliance on traditional instrumentation (i.e. reusable metal instrumentation). Efficiency instruments also offer the potential benefits of reduced risk of infection, increased operating room productivity, significant savings resulting from volume reductions in instrument tray processing and sterilization, and costs associated with loaner instrumentation. In total, the economic model developed in this paper establishes a realizable benefit of $1,198 per procedure when using Efficiency instruments.

List of Abbreviations

TKA – Total Knee Arthroplasty
CJR – Comprehensive Care for Joint Replacement
CMS – Centers for Medicare and Medicaid Services
AORN – Association of Peri Operative Registered Nurses
IAHCMSS – International Association of Healthcare Central Service Materiel Management
TJC – The Joint Commission: Accreditation, Health Care, Certification
AAMI – Association for the Advancement of Medical Instrumentation
PSI – Patient Specific Instruments
DVT – Deep Vein Thrombosis
MUA – Manipulation Under Anesthesia

Declarations

Ethics Approval and Consent to Participate
IRB approval was obtained on December 17, 2015 by the Western Institutional Review Board (WIRB Pro Num 20152691). The Board found that this research meets the requirements for a waiver of consent under 45 CFR 46.116(d).

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