SURGICAL TECHNOLOGY INTERNATIONAL Volume 37 - Nov, 2020 - PMID: 33245139

Surgical Tray Optimization and Efficiency: The Impact of a Novel Sealed Sterile Container and Instrument Tray Technology

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ABSTRACT

Introduction: As bundle payments have begun focusing on orthopaedic procedures, particularly total knee arthroplasties (TKAs), surgeons and hospitals have evaluated methods for improving efficiency. Few studies have investigated the impact of novel, sealed-container and instrument-tray technology on turnover and costs. Therefore, the purpose of this study was to compare traditional and sealed container-sterilized TKA surgical trays by: 1) investigating the setup and clean-down time in the operating room (OR); 2) examining trays processing time in central sterile supply (CS); and 3) estimating OR and CS costs and waste produced.

Materials and Methods: An interdisciplinary team determined points throughout a TKA tray single-case life cycle that could cause variations in turnover time. The times were recorded for two different TKA tray configurations. Process A utilized instruments housed in vendor trays that were "blue" wrap sterilized, while Process B employed optimized trays that were sealed container-sterilized. Times were recorded during preoperative setup and postoperative clean down in the OR and CS. Reductions in mean OR or CS times were used to estimate cost savings. Wastes were analyzed for each method. Statistical analyses using Student t-tests

were used to determine statistical differences and a p-value of less than 0.05 was considered significant.

Results: Overall, the use of optimized trays and sealed sterilization containers reduced the turnover time by 57 minutes and the number of trays by a mean of three. OR and CS processing yearly savings were estimated to be $249,245. Waste disposal was an estimated 10,590 ounces and 450 ounces for traditional and sealed containers, respectively.

Conclusion: Novel sealed sterilization containers demonstrated increased efficiency in the total turnover time of TKA trays. This is important for surgeons participating in bundle payments who perform surgery in a hospital and ambulatory surgery center. Reduced turnover time could potentially increase case load and decrease the need for extra instrumentation or loaner trays. This simple means of increasing efficiency could be used as a model for surgeons wishing to streamline surgical trays and reduce costs.

INTRODUCTION

Surgical procedures have been assessed as generating large amounts of waste and inefficiencies.[1,2] Due to bundled payments in orthopaedic surgery and a migration to outpatient surgery centers, there have been different approaches to increase operating room (OR) efficiencies and lowering costs. This is especially true for total knee arthroplasty (TKA) cases as it is projected that 1.3 million procedures will be performed in the United States this year.[3,4] Approaches to increase efficiencies in the OR have included patient-specific instrumentation, single-use instrumentation, and simple surgeon initiatives to remove unused instrumentation from surgical trays.[5–7]

These efficiency methods aim to decrease OR turnover time and the number of surgical trays that must be processed following a procedure; however, each of the approaches have some potential weaknesses. Producing patient-specific instrumentation involves the use of advanced imaging and manufacturing which may have associated high costs.[5,8,9] Similarly, in this era of "green" technologies, single-use instruments may prove to contribute to increased wastes and disposal costs.[6,10–13] Also, initiatives to remove unused instrumentation from surgical trays may reduce the amount of trays used, but the processing continues to be reliant on traditional methodology including the use of sterilization "blue" wrap.[1,7,14,15] Newer sterilization technologies, that intend to decrease the amount of time, waste, and ultimately costs, should also be examined.

Novel sealed sterilization containers capable of providing an alternative to long autoclave times encountered with "blue" wrapped and rigid container-sterilized surgical trays may decrease central sterile supply (CS) processing time. Additionally, customized procedure-specific surgical trays that organize and utilize all available space for instruments have been developed to decrease the number of trays for TKAs. If utilized together, these new technologies may increase OR and CS efficiency through simplicity and design. However, to our knowledge, there have been few studies investigating the impact that these new technologies could potentially have in a clinical setting. Therefore, the purpose of this study was to compare the efficiency of traditionally wrapped and sealed container-sterilized TKA surgical trays by: 1) investigating the setup and clean-down time in the OR; 2) examining the surgical trays processing time in CS; and 3) estimating OR and CS costs and the amount of waste produced for each method.

MATERIALS AND METHODS

This study was designed and implemented to gather and compare TKA surgical tray efficiency data for two different processes at a non-academic community-based hospital. It was formulated as a control comparison to evaluate the impact of novel surgical tray utilization and sterilization. Process A surgical tray data was used as a control cohort and represented contemporary sterilization techniques that the hospital used. Process B surgical tray data was used as a study cohort and represented new tray optimization and sterilization technologies. The TKA case data were recorded sequentially and therefore not randomized. Standard protocols were followed in the OR and central CS to ensure patient protection and infection control. Patient-identifying information was not recorded. The study was part of a hospital quality improvement initiative and was therefore determined to be exempt from Institutional Review Board review.

Surgical data

All patients undergoing primary unilateral TKA by a single surgeon between February 5, 2019 and October 9, 2019 were included in the study. The Stryker Triathlon™ Total Knee System (Stryker Orthopaedics, Mahwah, New Jersey) was used. There were 500 total knee arthroplasties performed by the surgeon in 2018, a number used to calculate the approximate number performed per year for cost calculations. The surgical teams had previous experience with the two processes.

Sterilization data

Tray utilization and sterilization techniques differed for the two processes. Process A utilized six vendor trays for the organization of the TKA system that were wrapped with Halyard Smart-Fold™ (Halyard Health, Alpharetta, Georgia) sterilization "blue" wrap during autoclaving. This wrap is composed of three-layer polypropylene fabric and designed to wrap instrument trays in one step as opposed to older models that required two separate wrappings for each surgical tray. Upon sterilization in the autoclave, each wrapped tray must be inspected in CS and the OR for perforations and dryness to be considered sterile. To achieve dryness after steam sterilization, wrapped trays remain in the autoclave and are dried at high temperatures.

Process B employed EZ Trax™ Universal TKA (K1 Medical Technologies, Woodbridge, Connecticut) tray configurations. The greater organization and space utilization of instruments provided by this TKA-specific surgical tray enabled all TKA instrumentation to be housed in three, one-level trays. The three TKA trays were held and sterilized in three One Tray® (Innovative Sterilization Technologies, Dayton, Ohio) sealed sterilization containers. The containers utilized three filters (two in the base and one in the lid) that were placed to create an efficient flow pattern of steam during sterilization. Due to the filter size, number, and positioning, instruments in the containers are FDA 510(k) cleared and validated to run on a sterilization cycle that requires a limited dry time. A hard-plastic clip was used to fasten the containers' lids before autoclaving to provide assurance that the container had remained closed and sterile.

The hospital had historically used sterilization "blue" wrap, while One Tray® sealed sterilization containers had been used for approximately 3 years. The CS continued to use a mixture of sterilization wraps and containers after the introduction of sealed containers. Therefore, CS employees were familiar with "blue" wrap, the sealed container sterilization procedure, and a high volume of orthopaedic cases prior to the study.

Table I
Operating-room datapoints

Preoperative Datapoints Collected
1) If TKA-specific surgical trays were ready for use
2) Number of TKA-specific surgical trays
3) Number of OR staff present for room setup
4) Time the case cart transporting surgical trays entered
5) Time the OR staff determined the OR was ready
6) Time the patient entered the OR

Postoperative Datapoints Collected
7) Time the TKA case ended
8) Time the case cart transporting surgical trays exited

Datapoints collected preoperatively and postoperatively in the operating room for total knee arthroplasty specific surgical trays per total knee arthroplasty case.
TKA=total knee arthroplasty, OR=operating room

Table II
Central sterile supply datapoints

Decontamination Datapoints Collected
1) Time the case cart transporting surgical trays entered
2) Time hand/ultrasonic washing of TKA instrumentation began
3) Time hand/ultrasonic washing of TKA instrumentation finished
4) Number of decontamination washers needed for TKA instrumentation
5) Time the first decontamination washer with TKA instrumentation began

Final Processing Datapoints Collected
6) Time the last decontamination washer with TKA instrumentation finished
7) Number of CS staff for TKA-specific surgical tray assembly
8) Time TKA-specific surgical tray assembly began
9) Time TKA-specific surgical tray assembly finished
10) Number of large (40 x 47 inches) sterilization wraps used
11) Number of sterilization trays were rewrapped
12) Number of sterilization filters used

Sterilization Datapoints Collected
13) Time TKA-specific surgical tray sterilization began
14) Sterilization pre-conditioning time
15) Sterilization time
16) Dry time
17) Time TKA-specific surgical tray sterilization finished

Datapoints collected during decontamination, final processing, and sterilization in central sterile supply for total knee arthroplasty specific surgical trays per total knee arthroplasty case.
TKA=total knee arthroplasty, CS=central sterile supply

Study setup

An interdisciplinary team of researchers, OR managers, CS managers, and surgeons met to determine critical timepoints to be captured throughout TKA surgical tray's "single-case life cycle." Critical timepoints were defined as periods with potential variation in the amount of time that TKA surgical trays were handled and sterilized, and any possible variable that could potentially affect this. It was agreed that the two main areas within the hospital that surgical tray efficiency could be investigated were the OR and CS.

Overall, there were 25 different datapoints recorded throughout the process. In the OR, a total of 8 datapoints was recorded (Table I), while a total of 17 datapoints was collected in CS (Table II).

In each OR, there was one registered nurse and one to two surgical technicians during preoperative setup. The surgical trays were deemed ready for use by the OR registered nurse if all wrapped trays or sealed sterilization containers were picked prior to the OR staff beginning tray transfer from the case cart to the sterile back table. Trays were also considered not ready if any perforation or wetness was found in the wrapped trays or if the sealed containers were improperly sealed. The number of TKA-specific trays counted did not include any

Table III
Study points collected

	control cohort	sealed container cohort
Number of cases	44	185
OR datapoints	333	1413
CS datapoints	741	1679
Number of surgical trays	6	3

OR=operating room, CS=sterile central supply

Table IV
Operating room timing

	change in time* (minutes)	p-value
Preoperative tray transfer	2	0.25
Postoperative clean down	3	0.004
Total	5	

*change in time = control time—study time

Table V
Operating room timing

	change in time* (minutes)	p-value
Hand/ultrasonic wash	1	0.25
Machine wash	3	0.033
Assembly	8	0.003
Total	12	

*change in time = control time—study time

Table VI
Surgical tray assembly

	Type of material used	Material per tray (n)	Material per case (n)
Control cohort	sterilization wrap	1	6*
Study cohort	container filter	3	9

*does not include 1% rate of rewraps

Table VII
Autoclave sterilization

	Change in time* (minutes)	p-value
Pre-conditioning	0	0.15
Sterilization	0	0.5
Dry	40	<0.00001
Total	40	

*change in time = control time—study time

additional instrumentation or equipment used that was unique to the surgeon (i.e., leg holder or general orthopaedic instrument trays). Preoperatively, the time was recorded when the case cart entered, when the OR team determined the room was ready, and when the patient was transported to the room. Due to events that were not directly affected by tray transfer but did create large variation in when the patient was transported into the OR, the preoperative setup time was defined as the time the case cart entered to when the OR was determined to be ready. Postoperatively, the time was recorded when the case ended and when the case cart exited the OR.

In CS, there were a total of five CS technicians who worked on differing tasks throughout the sterilization process. Only one CS technician hand washed and prepared the instruments for the decontamination washers. The hospital had a total of three decontamination washers. Assembly start time was recorded when the instruments were brought from the decontamination washers to the assembly area and the finish time was recorded when all complete wrapped or sealed containers were placed on a rack for the autoclave sterilizer. The hospital had a total of three AMCO 400 Series Medium Steam Sterilizers (Steris, Mentor, Ohio). The autoclaves provided a detailed printed receipt of each cycle and, therefore, allowed the pre-conditioning time, sterilization time, and dry time to be recorded.

OR savings were estimated by multiplying any reduction in total OR time by the product of the total number of TKAs performed each year (500) and an estimated $62 per OR minute.[16] The $62 per OR minute was reported in a 2004 study that contacted 100 United States hospitals that held at least 100 hospital beds and an operating room. The findings ranged from $21.80 to $133.12 per minute.[16] The following equation was used:

OR savings=(reduction in total OR time) x (500 cases) x ($62)

CS personnel savings were estimated by multiplying any reduction in hand/ultrasonic washing and assembly time by the product of the total number of TKAs performed each year (500) and the mean national wages per minute of a

CS employee. If an individual personnel step required more than one CS employee, then the total was multiplied by the amount of CS technicians involved. CS employees' wage per minute was calculated by taking the dividend of the mean national hourly rate ($18.34)[17] and 60 minutes ($0.31). The following equation was used:

CS personnel savings=(reduction CS time) x (500 cases) x ($18.34 per hour)/(60 minutes) x (# of CS emloyees)

The CS processing savings were estimated by multiplying any reduction in trays by the product of the total number of TKAs performed each year (500) and an estimated sterilization cost of $58.18 per tray.[5] The processing costs for preparation and sterilization per TKA tray were estimated in a previous study that compared costs of performing conventional, navigated, and patient-specific TKA instrumentation.[5] The following equation was used:

CS processing savings=(reduction in trays) x (500 cases) x ($58.18)

Disposal wastes were calculated by multiplying either total "blue" sterilization wrap or container filters by the product of the total TKAs performed each year (500) and the weight of each material. The dimensions of the sterilization wraps were 40 by 47 inches and each weighed 3.53 ounces. The container filters each weighed 0.1 ounces. The following equations were used:

Waste disposal=(# sterilization wraps) x (500 cases) x (3.53 ounces)

Waste disposal=(# filter wraps) x (500 cases) x (0.1 ounces)

All the observed and tabulated data were recorded and kept in an Excel® worksheet (Microsoft Corporation, Redmond, Washington). Total times of each step in the processing of the trays were calculated using the beginning and finishing times that were recorded. Mean total times were calculated. Control and study times were compared using independent samples *t*-tests. Data analyses were performed using SPSS version 24 (IBM Corporation, Armonk, New York) and significant differences were defined as a p-value less than 0.05.

RESULTS

The control cohort consisted of 44 TKA cases. In the OR and CS, 333 and 741 datapoints were collected, respectively. The study cohort consisted of 185 TKAs with 1413 and 1679 datapoints collected in the OR and CS, respectively (Table III). There were six control surgical trays used for every TKA compared to three in the study cohort.

Operating room

Preoperative and postoperative OR times were decreased by five minutes (12%) using the optimized surgical trays and sealed containers. Preoperative set-up time decreased by two minutes ($p=0.25$) while postoperative clean-down time significantly decreased by three minutes ($p=0.004$) when compared to the control cohort (Table IV). Both ORs utilized one sterile OR technician and one non-sterile RN for tray inspection and transfer to the back sterile OR table.

Decontamination

Decontamination time decreased by four minutes (7%) using the augmented surgical trays and sealed containers. The hand/ultrasonic washing of the instruments decreased by one minute ($p=0.25$) while the decontamination washer time decreased by three minutes when compared to the control cohort ($p=0.33$) (Table V). Both tray systems utilized a mean of two decontamination washers per case.

Final processing

The final assembly time significantly decreased by eight minutes (32%, $p=0.003$) compared to the control cohort (Table V). There was a mean of three CS technicians available for assembly of each tray system. For each control case, six large (40 by 47 inch) sterilization "blue" wraps were used and there were two instances of rewrapped (1%) trays. The sealed sterilization containers utilized nine filters per case (Table VI).

Sterilization

The total time in the autoclave was significantly decreased by 40 minutes (62%, $p<0.00001$) through utilization of the sealed sterile containers. The preconditioning and sterilization times were the same for each cohort ($p=0.15$, $p=0.5$). The dry time was significantly decreased by 40 minutes (93%, $p<0.00001$) when the sealed sterilization containers were used (Table VII).

Total time

Overall, the use of the universal TKA trays and sealed container technology decreased TKA surgical trays "single-case life cycle" by 57 minutes (30%).

Cost analysis

The use of the optimized TKA tray system decreased overall OR time by 5 minutes which would save an estimated $155,000 in OR variable costs per year. CS hand/ultrasonic washing and assembly time was reduced by 1 and 8 minutes, respectively, accounting for an estimated $6,975 in personnel savings per year. Lastly, the tray system reduced the number of surgical trays by three per case and would save an estimated $87,270 per year in preparation and sterilization costs.

Disposal of wastes

Total waste disposal for the sterilization wrap would be 10,590 ounces (662 pounds) compared to 450 ounces (28.13 pounds) of waste used with the sterile containers over the course of one year.

DISCUSSION

Due to the use of the universal TKA trays and sealed container technology, the TKA surgical trays "single-case life cycle" was decreased by 57 minutes. This, in combination with the reduction in surgical trays, would correspond to an estimated $249,245 reduction in variable OR and CS processing costs over one year. The hospital would also decrease waste disposal by an estimated 634 pounds. To our knowledge, this is the first study to combine tray reduction through the use of optimized TKA trays coupled with this particular sealed sterilization container as a means for increasing efficiency in the OR and CS.

The unique fact that these sealed sterilization containers can be put through a sterilization cycle with a limited dry time, eliminated 40 minutes of CS processing time alone. This could potentially create far-reaching opportunities for orthopaedic surgeons who wish to perform procedures in outpatient surgery centers. The ability to sterilize surgical trays in approximately 20 minutes may help to limit the number of purchased instruments or loaner trays that a surgical center must have on hand. Purchasing new trays for a surgery center can be expensive and increase the potentially already high overhead costs.

The change to sealed sterilization containers eliminated questions of holes in sterilization wrap, wet trays, and potential surgical delays due to emergency reprocessing. Durable containers provide assurance of continued sterility, whereas, sterilization wraps rely on hospital staff to notice any holes or rips in the wrap. In a 2017 study, only 55% of imperfections were detected in 240 sterilization wraps under OR lamps.[18] With the mean costs to a hospital that a periprosthetic joint infection can cause being \$25,546 ± \$39,875 (range, \$1,783 to \$134,602),[19] a 55% detection rate could potentially be costly.

This study has some limitations. The cases were not randomized and instead recorded sequentially. The control cases were not as well followed as the study cohort due to a lack of research personnel. Patient-reported outcomes were not available because patient identifying information was not recorded as part of the hospital's quality improvement initiative. The associated calculated savings were estimated based on previous studies that specifically investigated the many variables involved in calculating hospital costs. Due to this, all cost reductions are estimates and may not be specific to the hospital where this study was conducted. Despite these limitations, the results of this high-volume study show how optimized surgical trays used in conjunction with newer sterilization technologies can effectively reduce the overall surgical-tray processing time.

Other studies have shown comparable results. Capra et al.[7] investigated the impact that reducing the number of instruments for TKA and total hip arthroplasty (THA) cases would have on perioperative efficiencies. The authors compared the OR processing times of 38 TKA and THA cases before reduction of instrumentation to 58 cases after optimization. The two surgeons reduced the number of surgical trays by five and eight for TKA and THA, respectively. In TKA cases, a reduction of six minutes in perioperative setup time was recorded, while THA setup time was affected minimally. However, OR clean-down time was increased by two minutes of which the authors noted various facility-specific postoperative processes that could not be affected by reducing instrumentation. Annual CS sterilization savings were estimated to be \$159,600 due to less trays to process.[7] Similarly, Cichos et al.[20] compared pre- and post-implementation of optimized surgical trays for commonly used orthopaedic procedures. The surgeons removed 55% of instrumentation that was not routinely used from 102 total trays. In CS, this was associated with a 3.2-minute decrease in the mean instrument cleaning time and an overall one-minute decrease in mean total turnover time. The expected savings in annual processing costs were estimated to be \$170,865.[20]

Krohn et al.[21] completed a comprehensive analysis of sterilization procedures at two hospitals in Germany. The two hospitals used both sterilization wraps and sealed containers for sterilization processes. The total personnel time consumptions for each packaging option in OR and CS were compared. Mean sealed container processing used the least amount of time in OR, CS, and overall. Compared to one-step sterilization wraps, sealed container processing was a mean of 49 seconds faster in CS and a mean of 12 seconds faster in the OR for a total of a mean 60-second decrease. Sealed containers had the least amount of personnel and materials costs (€2.05) per usage. The most expensive packaging option was the one-step sterilization wrap (€3.87) which is about 88.5% higher per usage. The authors then proposed 33 theoretical scenarios in which material, personnel, or special costs are manipulated to investigate and compare the packaging options changes in cost. In almost all scenarios, sealed containers were the least expensive compared to the sterilization wrap. The only scenarios where sealed containers were not the best financial option were during extreme situations. Sterilization wraps had the least amount of cost when: 1) personnel costs were removed and the price for wraps was reduced by 75%; 2) when transport baskets were not used and the price for the wraps was reduced by 91%; and 3) when personnel costs were removed, transport baskets were not used, the price for wraps was reduced by 40%, and a large scale washing system was purchased during that year.[21] Although the sealed sterilization containers were not the same as in the current study, this highlights potential efficiencies associated with using containers even without the added benefit of the reduction in autoclave time.

CONCLUSION

This study suggests that the use of optimized trays and novel sealed sterilization containers provide for greater OR and CS efficiency. Despite different approaches to efficiently optimizing OR and CS processes, many hospitals continue to rely on conventional technology that does not influence one of the most important variables in surgical tray turnaround, the autoclaving process. The use of specific sealed sterilization containers led to the greatest reduction in time for a TKA surgical-tray single-case life cycle. With the mean TKA procedure lasting approximately 90 minutes, a 40-minute reduction in CS processing is clinically relevant and has the potential to increase operative caseload. An increasing number of TKAs are being performed each year, and many surgeons have transferred to outpatient surgical facilities. As a result, efficient management approaches to meet these demands are increasingly important. STI

AUTHORS' DISCLOSURES

Dr. Mont is a consultant for, or has received institutional or research support from, the following companies: CyMedica Orthopedics, Inc., Performance Dynamics, Inc., Kolon Pharmaceuticals, Inc., PeerWell, Inc., Sage Products LLC, TissueGene, Inc., OnGoing Care Solutions Inc., DJO Global, MicroPort Orthopedics, Inc., OrthoSensor, Inc., National Institutes of Health (NIAMS and NICHD), Stryker, Johnson & Johnson, Pacira Pharmaceuticals, Inc., and US Medical Innovations. Dr. Mont is on the editorial/governing board of the American Journal of Orthopedics, the Journal of Arthroplasty, the Journal of Knee Surgery, and Surgical Technology International. He is a board or committee member of AAOS. Dr. Marchand is a paid consultant for Innovative Sterilization Technologies, LLC and Stryker. This project was partially funded by Innovative Sterilization Technologies, LLC.

All other authors have no conflicts of interest to disclose.

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