Logistical and Economic Advantages of Sterile-Packed, Single-Use Instruments for Total Knee Arthroplasty

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ABSTRACT

Background: Total knee arthroplasty (TKA) is well established as a clinically successful and cost-effective procedure. The transition of the US healthcare system from a fee-for-service model to a value-based care model requires careful examination of patient care to ensure both quality and efficiency. Sterile-packed, single-use instruments have been introduced as a tool to help streamline the operating room (OR) logistics while reducing sterilization requirements. The aim of this study was to examine the potential logistic and economic benefits of single-use instruments compared to traditional, reusable instruments for TKA.

Methods: Four variables related to TKA costs and logistics were modeled in this study: OR turnover time, tray sterilization, tray management time, and 90-day infection rates. Model input data for traditional instruments and single-use instruments were based on peer-reviewed literature. A total of 200 sites and 500 cases per site were simulated using the Monte-Carlo-Technique.

Results: The median total cost savings with single-use instruments was $994 per case. The largest driver for cost savings was tray sterilization. Sites with higher staff wages and sterilization costs had a larger probability of realizing greater cost savings with adoption of single-use instruments. In cases using single-use instruments, up to 51% of operating days could have accommodated an additional procedure due to the time savings in OR turnover.

Conclusion: This cost modeling study observed significant potential for logistical and economic improvements in TKA with single-use vs reusable instruments. Although few studies have been conducted to measure the impact of single-use instruments in practice, the results of these simulations motivate further investigation.

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financially accountable for the quality and global cost of care from patient admission through 90 days postdischarge [7]. With these changes in reimbursement, providers must evaluate all aspects of TKA procedures to ensure financial viability while delivering high-quality care from patient admission through 90 days postdischarge [7]. With these changes in reimbursement, providers must evaluate all aspects of TKA procedures to ensure financial viability while delivering high-quality care from patient admission through 90 days postdischarge [7].

The GMK Efficiency single-use instruments (Medacta International, Castel San Pietro, Switzerland) come terminally sterile and can streamline the instrumentation logistics and OR turnover for each TKA case, as all of the opened Efficiency instruments and trays are disposed of at the end of the case [24]. One Efficiency set includes all of the instruments for preparation, resection, and sizing of the tibia, femur, and patella as well as the trials and the system-specific gap spacers, alignment aids, and recut guides (Fig. 1). The general use instruments, such as retractors and osteotomes, are not included as single-use instruments, so at least 1 tray of reusable instruments is still sterilized and used in each case. Efficiency instruments can be used in combination with traditional or patient-specific cutting blocks, such as MyKnee Patient Matched Instrumentation (Medacta International; Castel San Pietro, Switzerland).

There are many factors associated with TKA costs and logistical efficiencies that can be highly variable between different facilities, surgeons, and cases [30–32]. Cost modeling through probabilistic simulations can be an effective means of gaining insights into the range of potential savings and better understanding the key factors that may drive variations in savings. This study aimed at investigating the range of potential cost savings for TKA procedures performed with GMK Efficiency single-use instrumentation compared with traditional, reusable instruments through a probabilistic cost model that incorporates variance around multiple key cost-drivers.
Table 1
Model Inputs and Literature Sources for Resource Variables.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Model Sampling Level</th>
<th>Instruments</th>
<th>Normal Distribution Model Input (Mean ± SD)</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>90-d Infection rate (%)</td>
<td>Site</td>
<td>Traditional</td>
<td>0.58% ± 0.07%</td>
<td>[12,32–34]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Single-use</td>
<td>0.6 × TIIR</td>
<td>Parametera[19]</td>
</tr>
<tr>
<td>Trays used per case (n)</td>
<td>Case</td>
<td>Traditional</td>
<td>8 ± 2</td>
<td>[19,20,35–38]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Single-use</td>
<td>1 ± 0</td>
<td>Parameterb[24]</td>
</tr>
<tr>
<td>OR turnover time (min)</td>
<td>Case</td>
<td>Traditional</td>
<td>38.4 ± 7.7</td>
<td>[9]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Single-use</td>
<td>Time savings</td>
<td>[19,29,37,38]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>17.5 ± 3.5</td>
<td></td>
</tr>
<tr>
<td>Tray management time (min)</td>
<td>Case</td>
<td>Traditional</td>
<td>355 ± 71</td>
<td>[13]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Single-use</td>
<td>80 ± 16</td>
<td>[24]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>79 ± 15</td>
<td>[19,44]a</td>
</tr>
<tr>
<td>TKA procedure time (min)</td>
<td>Case</td>
<td>Traditional</td>
<td>79 ± 15</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Single-use</td>
<td>80 ± 72</td>
<td></td>
</tr>
</tbody>
</table>

OR, operating room; SD, standard deviation; TIIR, traditional instrument infection rate; TKA, total knee arthroplasty.

a Procedure time not affected by single-use instruments.
b Parameters were also examined in a sensitivity analysis.

Methods

Cost Modeling Approach

The Monte Carlo technique was used for this study to simulate a wide variety of potential scenarios and outcomes related to performing a primary TKA procedure with traditional, reusable instruments vs single-use instruments. Four variables were identified that would potentially be affected by the type of instrumentation, which included sterilization costs, logistics for tray management (receiving, packing, storing, etc.), OR turnover time (instrument setup and cleanup), and treating surgical site infections during the first 90 days postdischarge. These variables were subdivided into a resource variable (eg, number of trays to sterilize per case; Table 1) and a unit cost variable (eg, cost of sterilizing 1 tray; Table 2). A total of 200 sites (eg, hospitals) and 500 cases per site were simulated (100,000 total cases).

Briefly, the Monte Carlo simulation technique draws a random value from the probability distribution of each variable for each simulation and repeats this process for thousands of simulations to gain insight into the range of potential outcomes. In this study, some of the variables were sampled at the site level (eg, cost of sterilizing 1 tray) so that they would be fixed across the 500 cases performed at that site. The rest of the variables were individually sampled at the case level (eg, number of trays used in each case). The value of each resource variable (eg, number of trays to sterilize) was multiplied by its respective unit cost variable (eg, cost to sterilize each tray) to estimate the costs for each case (Fig. 2).

The probability distributions were constructed for each of the input variables based on literature reports of measurements from clinical studies or estimates from expert panels (Tables 1 and 2). In some cases, variances were imputed due to a lack of available data. Details on the construction of each probability distribution are described in Appendix A. Briefly, all cost variables were modeled as lognormal distributions [39], and the activity variables were assumed to follow normal distributions. Costs were adjusted for inflation to 2018 US dollars based on the US medical care Consumer Price Index [40]. The OR turnover time with traditional instruments and turnover time savings with single-use instruments were assumed to be positively correlated (r = 0.8), so multivariate sampling techniques were used for that part of the simulation.

Modeling the Effect of Time Savings During OR Turnover

Two approaches were used to examine the effect of reducing OR turnover time. In the primary model described above, the costs related to each of the variables were modeled based on the concept of time-driven activity-based costing (TDABC). This accounting approach measures the personnel time and consumables required for each activity and multiplies those resource requirements by the unit costs (personnel wages, consumable costs, etc.). TDABC has been suggested as a more conservative and accurate accounting approach compared to traditional accounting methods for TKA [41,42].

The second modeling technique examined the effect of OR turnover time on underutilization and overutilization of the OR. Single-room OR blocking was assumed where a surgeon and the support team would be allotted the space for a full 8-hour, 10-hour, or 12-hour day. The mean surgical procedure time was assumed to be equal for traditional and single-use instruments [19]. A simple scheduling technique was assumed where the cases were scheduled back-to-back with 2 hours allotted for each case, based on a mean turnover time of 38 minutes and mean procedure time of 79 minutes (total = 117 minutes; Table 1). For example, an 8-hour OR block had 4 cases scheduled each day. The Monte Carlo technique was used to determine the length of each procedure and turnover time. If the scheduled cases for the day finished with at least 2 hours to spare, an additional case could have been completed that day. If the scheduled cases took longer than the allotted time for the OR over the course of the full day, the extra time was considered as staff overtime.

Table 2
Model Inputs and Literature Sources for Unit Cost Variables.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Model Sampling Level</th>
<th>Median (IQR)</th>
<th>Lognormal Model Input (Location, Scale)</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infection treatment ($/case)</td>
<td>Case</td>
<td>$30,020 ($19,104–$47,033)</td>
<td>(10.31, 0.67)</td>
<td>[12]</td>
</tr>
<tr>
<td>Tray sterilization ($/tray)</td>
<td>Site</td>
<td>$57.87 ($44.50–$77.23)</td>
<td>(4.07, 0.41)</td>
<td>[19,26,37,38]</td>
</tr>
<tr>
<td>OR turnover time ($/min)</td>
<td>Site</td>
<td>$5.72 ($4.46–$7.60)</td>
<td>(1.75, 0.40)</td>
<td>[30]</td>
</tr>
<tr>
<td>Tray management time ($/min)</td>
<td>Site</td>
<td>$1.03 ($0.71–$1.52)</td>
<td>(0.03, 0.56)</td>
<td>[19]</td>
</tr>
</tbody>
</table>

IQR, interquartile range; OR, operating room.
For single-use instruments, the 90-day infection rate for a given site was multiplied by a reduction factor of 0.6, which assumes that single-use instruments will reduce the infection rate by 40% relative to traditional instruments at a given site. With Efficiency single-use instruments, only 1 tray of instruments needs to be sterilized to complete a TKA case [24]. Considering that surgeons often have specific preferences for customized instrument sets, an additional 1 or 2 trays of reusable instruments could be required. A parametric sensitivity analysis was carried out to examine the effect of changing the infection rate reduction factor and the number of trays sterilized with single-use instruments. The risk of infection with single-use instruments vs traditional instruments was varied from 60% (base case) to 40%, 80%, or 100% (equal infection risk). The number of trays sterilized in conjunction with single-use instruments was increased from 1 (base case) to 2 or 3.

**Analysis of Model Outcomes**

The mean costs per case were calculated for each of the 200 sites for traditional and single-use instruments and the distribution of costs, or cost savings, was examined across the 200 sites. Cost comparisons between traditional and single-use instruments were calculated using Wilcoxon’s matched-pairs signed-rank test by pairing costs within each site. The top and bottom 10% of sites, based on total cost savings with single-use instruments, were queried to determine which variables significantly differed between those sites (eg, do sites with savings in the 90th percentile have greater OR costs per minute compared to sites in the 10th percentile of savings?). Statistical comparisons between the top and bottom 10% of sites were made using 2-tailed t-tests with the Holm-Sidak method to correct the P values for multiple comparisons. The parametric analysis parameters were analyzed through repeated measures (within each site) 2-factor analysis of variance that also accounted for the difference between traditional and single-use instruments. Differences were deemed statistically significant for multiplicity-adjusted P values < 0.05.

**Cost Savings With Single-Use Instruments**

The median and interquartile range (IQR) of total costs per case was $1391 (IQR = $1128-$1687) for traditional instruments and $406 (IQR = $308-$515) for single-use instruments (P < .0001; Fig. 3). The dispersion of total costs observed with single-use instruments was dramatically reduced compared to traditional instruments, as demonstrated qualitatively by the frequency distributions (Fig. 3) as well as the IQRs (single-use: $207 per case vs traditional: $559 per case). Within each site, these cost differences between instrument types translated to a median total cost savings of $994 per case (IQR = $759-$1231). The smallest mean cost savings observed by a site was $4.50 per case and the largest was $1829 per case (Fig. 4).

**Cost-Drivers for Traditional vs Single-Use Instruments**

For traditional instruments, the largest cost-driver was tray sterilization (median = $480/case), followed by tray management...
logistics ($372/case), OR turnover time ($225/case), and 90-day infections ($199/case). For single-use instruments, the greatest cost-driver was OR turnover time (median = $123/case), followed by 90-day infections ($101/case), tray management logistics ($85/case), and sterilization ($60/case; Fig. 5). Cost distributions for each of the metrics tended to have a smaller dispersion for single-use ($85/case), and sterilization ($60/case; Fig. 5). Cost distributions for each of the metrics tended to have a smaller dispersion for single-use instruments compared to traditional instruments (Fig. S1).

Site-Dependent Factors Affecting Cost Savings With Single-Use Instruments

On average, the sites that reduced costs the most by switching to single-use instruments had significantly higher sterilization costs and tray management costs compared to the sites saving the least (Table 3). There was an average of 2.5 more infection cases with traditional instruments among the 90th percentile of cost saving sites and an average of 0.7 more infection cases with single-use instruments in the 10th percentile of sites. This observation is actually a random effect attributable to the probabilistic nature of these simulations, considering that the overall infection rates across the sites were similar (≤10th percentile: 0.59% vs ≥90th percentile: 0.58%). The OR time cost, the OR turnover time, the average number of trays used per case, and the tray management time were not significantly different between the sites saving the most and the least (Table 3).

Underutilization and Overutilization of the OR

Assuming an 8-hour OR day, where 4 cases were scheduled per day, an extra case could have been completed (2+ hours of underutilized OR time) on 11% of the operating days when using single-use instruments compared to 0.1% of operating days when using traditional instruments. The proportion of days that could accommodate an additional case increased to 29% and 51% for 10-hour and 12-hour OR days with single-use instruments compared to 0.3% and 0.6%, respectively, for traditional instruments (Table 4). Similarly, the proportion of operating days where the OR was overutilized, resulting in staff overtime pay, was 35%-38% for traditional instruments and 0.1%-0.7% for single-use instruments across 8-hour, 10-hour, or 12-hour days. This translated to overtime pay costs averaging up to $1326 ± $568 per 100 cases for traditional instruments and $11.00 ± $19.00 per 100 cases for single-use instruments (Table 4).

Parametric Sensitivity Analysis

Varying the relative risk of infection for single-use vs traditional instruments from 0.4 up to 1.0 (equal infection risk), with 0.6 as the base case, did not significantly affect the total costs of single-use instruments vs traditional instruments ($P = .14; Fig. S2A). Even when equal infection risk was assumed, the mean total costs of traditional vs single-use instruments was $1412 ± $386 vs $509 ± $170, respectively ($P < .0001). Varying the number of trays that needed to be sterilized with the use of single-use instruments from 1 (base case) to 3 also did not significantly affect the total costs ($P = .31; Fig. S2B). The mean total cost with single-use instruments ranged from $424 ± $153 (1 tray) to $522 ± $160 (3 trays; $P = .31) compared to $1427 ± $374 for traditional instruments ($P < .0001).

Fig. 3. Frequency distribution of the mean total costs per case for traditional, reusable instruments vs single-use efficiency instruments across the 200 simulated sites.

Fig. 4. Frequency distribution of cost savings by site (paired analysis). Approximately 75% of sites saved at least $750 per case, 50% saved at least $1000 per case, and 25% saved over $1200 per case. The minimum savings was $4.50 and the maximum savings was $1829.

Fig. 5. On average, tray sterilization was the greatest cost-driver for traditional instruments, followed by tray management time, OR turnover time, and treating infections within the first 90 days postdischarge. For efficiency instruments, treatment of infections was the largest cost-driver on average due to the significant cost reductions achieved for tray sterilization, tray management, and OR turnover.
6

Discussion

Improving operational efficiencies both inside and outside of the OR and reducing the dispersion of costs are critical initiatives for many healthcare providers. Single-use instrumentation has the potential to facilitate time and cost efficiencies while bringing greater reliability and predictability to multiple steps in the global delivery of TKA compared to traditional, reusable instruments. By modeling the key cost-drivers that could be affected by single-use vs reusable instruments, this study observed that the majority of sites could potentially realize substantial cost savings, reduce opportunity costs of OR underutilization, and bring improved predictability to budgeting through less variance in the operating costs.

In a single-site clinical study, Siegel et al [19] reported cost savings of $480-$600 with single-use instruments vs traditional instruments for TKA, based on measurements of the resource requirements and costs associated with OR turnover and tray sterilization. Furthermore, they reported significantly fewer infections with single-use instruments (0.2% vs 3%; \(P < .006\)). In close agreement with those results, the present study estimated a median cost savings of $522 based on OR turnover and tray sterilization alone. Multiple studies have emphasized the importance of case turnover in the OR for optimizing productivity and achieving an increase in number of cases. Through interdisciplinary workflows, Cendan and Good [43] reported reductions in turnover time of 16 minutes, which translated to an increase of approximately 0.5 cases per day on average. This is very consistent with the present study that observed an additional case could be scheduled on up to 51% of operating days when using single-use instruments.

Tray sterilization and tray management were not only the largest contributors to traditional instrument costs in this study but were also the primary areas for cost savings. Furthermore, these steps tend to be a significant impediment for efficient, multi-case surgical days, particularly in outpatient settings such as ambulatory surgical centers. Studies of single-use instrumentation and patient-specific instrumentation consistently conclude that significantly fewer trays need to be sterilized compared to traditional, reusable instruments (range, 4-12) [19,20,35–38]. However, the costs reported in the literature of sterilizing 1 tray are highly variable (range, $31-$100/tray) [19,26,37,38], which can result from operational and staff wage differences between sites and the accounting methods for estimating those costs. Consistent with this concept, Haas and Kaplan demonstrated that the total standardized personnel costs associated with TKA can vary from 68% of the median at the 10th percentile to 131% of the median at the 90th percentile across sites [30]. Based on the results of the present study, the large variations in tray sterilization costs as well as the wages of hospital staff could substantially impact the potential for cost savings with single-use instruments. The sites that saved the most had tray sterilization costs nearly twice that of sites saving the least (≥90th percentile mean: $92/tray vs <10th percentile mean: $48/tray). The aggregated wages of staff responsible for tray management also had a significant effect, with the sites in the ≥90th percentile of cost savings paying staff an average of $117/h vs only $40.20/h among the sites in the ≤10th percentile.

An important limitation to consider, which was not accounted for in the model, is the probability that necessary instruments or components will not be available at the time of the surgery. For reusable instruments, a set may not have been repacked properly before sterilization. This would cause delays in the case to acquire an additional sterilized set with the missing instruments or the use of flash (immediate-use) steam sterilization. It is also possible that a reusable or single-use instrument could be accidentally contaminated beyond the sterile field, requiring a sterile backup or replacement, but the probability of such an event would likely be equal for reusable and single-use instruments.

This study focused on a specific single-use instrument set that the authors were familiar with; however, these findings are likely
to be generalizable to other single-use instrument sets with a similar design (eg, included instruments). Additionally, the costs estimated in the present study were not intended to comprehensively represent the global cost of a TKA procedure. Rather this study focused on cost components that single-use instruments could affect. Based on TDABC studies, the cost of a global TKA procedure ranges from $9800 to $14,000 [41,42], so the costs studied herein account for approximately 10%-20% of the total TKA costs. The price of the single-use instruments was also not included in the model. Instead, the potential cost savings could be used by healthcare providers or manufacturers to estimate break-even pricing. Siegel et al [19] reported a quote of $490 for one single-use instrument system. In this study, 95% of the simulated sites realized cost savings exceeding $500 per case. Considering that cost savings were primarily driven by reductions in tray sterilization and logistical management costs, these variables should be accurately understood for the most reliable modeling results. The number of trays used along with tray sterilization costs were well reported in the literature but were quite variable. In contrast, estimates for the logistical management of traditional instrument loaner trays and the associated costs were not well measured or reported in the literature. The limitations of the literature data pose inherent limitations for any modeling study. To further enhance confidence in model outcomes, future studies that use a shadowing technique for TDABC would be important to more accurately estimate the resource requirements for loaner set management and elucidate the sources for variability in tray sterilization [42]. Based on the results of this economic model, clinical and economic studies at a variety of sites (large-volume vs small-volume hospitals vs ambulatory surgery centers) could be designed to measure the resource savings and validate or update the model studied herein.

Conclusions

This study used probabilistic modeling techniques to examine the range of potential logistical and economic advantages that healthcare providers may realize by using single-use instruments for TKA procedures compared to traditional, reusable instruments. Of the 200 simulated sites, 95% saved at least $500 per case and 48% saved at least $1000 per case. Sites with higher staff wages and sterilization costs had a greater probability of realizing substantial cost savings with the adoption of single-use instruments compared to traditional reusable instruments. Single-use instruments also dramatically reduced overtime in the OR and enabled the opportunity for a substantial increase in the number of cases. In conclusion, this modeling study suggests that single-use instruments have a compelling potential to help improve the quality and efficiency of delivering TKA procedures, warranting future prospective studies to measure the actual resource and cost savings observed in practice.

References


Appendix A. Details of Model Inputs and Probability Distributions

**Probability Distributions for Each Activity Variable**

A normal distribution was assumed for all activity variables. The 90-day infection rate was selected from the distribution and held constant for each case performed at a given site. The distribution of infection rates was based on a mean and standard deviation calculated from the reported rates for traditional instruments [12,32–34]. For single-use instruments, the 90-day infection rate for a given site was multiplied by a reduction factor of 0.4, 0.6, or 0.8. This technique assumes that single-use instruments will reduce the infection rate to 40%, 60%, or 80% of the current rate at a given site. The concept of this reduction is based on the report of Siegel et al [19], who reported a reduction in infection rate from 3% with traditional instruments to 0.2% with single-use instruments. Furthermore, many other studies support the concept that reusable instruments can become contaminated after sterilization and increase the risk of surgical site infection [14–18]. Therefore, a reduction factor of 60% was used as a conservative base case and a parametric sensitivity analysis examined the effect of changing that reduction factor to 40% or 80%. The infection rate for each site was calculated through propagation of error. The manufacturer’s white paper on Efficiency single-use instruments estimated 1.3 hours (80 minutes) for tray management time [24]. A 20% coefficient of variation was imputed for a standard deviation of 16 minutes.

The tray management time involves everything outside of the OR and central sterilization department. Guedon et al [13] estimated 355 minutes dedicated to set management per case. No variance was provided, so a 20% coefficient of variation was imputed for a standard deviation of 71 minutes. The average time per tray was calculated by dividing 355 minutes by the mean number of traditional trays used (8) and the standard deviation was calculated through propagation of error. The manufacturer’s white paper on Efficiency single-use instruments estimated 1.3 hours (80 minutes) for tray management time [24]. A 20% coefficient of variation was imputed for a standard deviation of 16 minutes.

The TKA procedure time (incision to closure) was assumed to follow the same distribution for traditional and single-use instruments based on the findings of Siegel et al [19]. The average and standard deviation of procedure times were based on all patients reported by Gadinsky et al [44].

**Probability Distributions for Each Cost Variable**

All cost variables were modeled as lognormal distributions [39]. The location and scale metrics of the lognormal distributions were selected by iterative optimization to fit the median and inter-quartile range (IQR) values derived from the literature. Costs were adjusted for inflation to 2018 US dollars based on the US medical care Consumer Price Index [40]. The median and IQR for treatment of an infection were estimated from the data published by Cram et al [12] as the difference in postdischarge costs for patients with an infection vs patients with no complications. The mean or median cost of sterilizing 1 tray reported by 4 articles was used to calculate a median cost and IQR [19,26,37,38].

For the cost of OR turnover time, Haas et al [30] cited that the OR cost per minute without the surgeon is at least $5 per minute. Therefore, $5 per minute was used as a conservative median value. The IQR data reported by Haas et al for standardized personnel costs during surgery was used to estimate the 25th and 75th percentiles [30]. For tray management personnel costs, Siegel et al reported $0.84 per minute for central sterilization department personnel [19]. This cost was used as the median and the 25th and 75th percentile proportions reported by Haas et al for “Standardized personnel costs day of surgery, before surgery” were used to estimate the IQR [30].
**Fig S1.** Frequency distributions of costs related to each of the 4 modeled variables across all 200 simulated sites for traditional and Efficiency instruments. In addition to having a higher probability of lower costs for Efficiency instruments, the dispersion of costs tends to be much smaller.

**Fig S2.** Varying the infection risk reduction factor from 40% to 100% (equal risk) did not significantly affect the total costs or cost savings of using Efficiency instruments ($P = .14$). The average total cost with Efficiency instruments ranged from $384 \pm 144$ (at 40%) to $509 \pm 170$ (at equal risk). The number of trays that needed to be sterilized with the use of Efficiency instruments also did not significantly affect the total costs ($P = .31$). The average total cost with Efficiency instruments ranged from $424 \pm 153$ (1 tray) to $522 \pm 160$ (3 trays). The effect of these parameters was analyzed through repeated measures (within each site) 2-factor analysis of variance that also accounted for the difference between traditional and Efficiency instruments, which was statistically significant in each case ($P < .0001$).