RESEARCH ARTICLE

Comparative Cost Analysis of Single-use Sterile versus Reprocessed Distal Radius Volar Plate Sets

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Abstract

Background: With the rise in distal radius fracture (DRF) incidence and treatment through open reduction internal fixation, there are increasing concerns in the current medical cost containment climate. To help reduce costs, manufacturers are introducing sterile packed kits. The purpose of this study is to compare the costs of the single use kit (SK) against conventional reprocessed DRF surgical sets (RS).

Methods: A four-year retrospective review at three surgical centers was performed to determine a company's RS average sterilization and processing costs. RS instrumentation cost was estimated by straight-line depreciation from the original purchase price. RS implant costs were calculated from the list price. SK list cost was obtained from the same company. Incidence of surgical delays was estimated by a survey of 23 hand surgeons and cost of delays was obtained from surgical center reports. Sensitivity analysis on delay frequency was performed to assess a range of overall costs.

Results: OR delays were estimated at one out of 100 cases, with an average cost of $11 per case. For RS, average instruments, implants, and sterilization costs per case was $47, $2882, and $39. The total RS cost of $2,978 and the SK was $1,667 with a difference of $1,313 per case.

Conclusion: RS was found to cost $1,313 more per case than the SK in an ambulatory surgical setting and potentially more cost effective. Ultimately, pricing is highly variable at each center based on negotiated and contractual pricing.

Level of evidence: IV

Keywords: Distal radius fractures, Open reduction internal fixation (ORIF), Operating room costs, Single use sterile sets, Sterilization costs

Introduction

Distal radius fractures are one of the most common fractures treated by surgeons, and the incidence has been steadily rising (1). More than 640,000 fractures were reported in 2001, accounting for one-sixth of all emergency department visits in the United States (1-3). Operative techniques, implants, and instruments have improved, the frequency of surgical treatment of these fractures has increased, particularly open reduction internal fixation (ORIF) with volar locking plates (4).

ORIF is often more expensive than other treatment options, which, in the current climate of medical cost containment, is concerning (5). Studies have shown 61% – 82% of the total costs for an operatively treated distal radius are related to the surgical encounter (5-7). Recently, Kazmers et al reported the breakdown of all surgical encounter costs for distal radius ORIF with the implants being the greatest contributor (32%), followed by facility utilization (23%), surgeon fees

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(23%), anesthesia (14%), and other (8%) (8). Bhat et al concluded that variations in implant cost played a substantial role in the surgery center profit margin (9).

In an effort to reduce implant-related costs, medical device manufacturers have introduced sterile packed kits with one-time use instruments and individually packed sterile implants. For distal radius fractures (DRF), a medical device manufacturer has developed a sterile single use distal radius kit (SK). The kit includes individually packed sterile plates, screws, and one-time use instruments. The one-time use instruments include drill guides, depth gauge, and screwdriver. The primary purported benefits of the SK are: 1) elimination of all implant sterilization and processing costs and, 2) reduced operating room (OR) delays due to unavailable implant sets related to processing, packaging, or restocking issues. A secondary benefit for the manufacturer's sales team is eliminating the need to reorder and restock used implants in reprocessed sets (RS). The purpose of this study is to evaluate and compare the costs of SK against a conventional RS from the selected manufacturer to determine if the SK is more cost effective than the RS in the treatment of ORIF of distal radius fractures.

Materials and Methods

Following IRB approval, a four-year retrospective chart and financial records review between 2015 and 2019 was conducted. Surgical cases at three independent surgical centers with a high volume of hand surgery procedures were reviewed and distal radius ORIF was identified by CPT codes 25607, 25608, 25609. Inclusion criteria were DRF treated with DePuy Synthes (West Chester, PA) 2.4 mm variable angle LCP two column volar locking plates from the RS set since the SK sets are not currently being used at the surgical centers. Cases were excluded if concomitant other with surgical procedures, other than carpal tunnel release. Other cases excluded were revision surgery and augmented fixation with percutaneous pinning, external fixation, dorsal plating, or bridge plating. The surgery center records did not include OR delay frequency or duration, therefore an anonymous electronic survey was conducted among the 23 hand surgeons at the three surgical centers to estimate the frequency and duration of OR delays due to unavailable distal radius implants, from any manufacturer, for planned cases.

We developed a model to compare the costs between RS and SK by assuming the following costs to be the same between RS and SK: 1) stocking and storage costs 2) disposal costs 3) power instrumentation 4) case set up and turnover time. We assumed there would be no case delays or cancelations using the SK as there would be a set available at all times and would be restocked daily. We also assumed that no additional implants or instruments, not in the SK, other than power instrumentation, would be needed. We calculated average costs of the following variables to include in our model: 1) instruments 2) implants 3) sterilization and processing, and 4) cost of delays associated with missing and/or unsterilized implants or instruments.

Cost of Instruments

Since the disposable instrumentation is included the cost of the SK, we only needed to calculate instrument cost estimates for the RS. Per case instrument costs were based on its depreciation. We used the formula: Yearly deprecation cost = ([initial cost of instrument] – [salvage value]) ÷ (estimated useful life in years). For simplicity, we assumed straight line depreciation and a salvage value of zero. Based on a review of the surgery center records, we estimated that every RS instrument tray would be utilized once every other day. Thus, the cost per case is estimated to be the yearly depreciation cost divided by 183 days. List price of the RS instruments was obtained from the manufacturer. The useful lifespan of the instruments was estimated to be 10 years based on a literature review and the experience of our surgery center's purchasing departments (10).

Cost of Implants

Current list price for RS implants, provided by the manufacturer, was used to calculate total implant cost. Implants included plates, cortical screws, and locking screws. Drill bits were assumed to be reused and were not included in the cost total. Cost of implants for the SK (included in the total kit price) was obtained from the manufacturer.

Cost of Sterilization and Processing

Sterilization and processing times and associated costs were obtained from the purchasing departments at the surgery centers and averaged for a per case estimate [Tables 1; 2]. The average hourly rate of a sterile processing technician is $25/hour [Table 1]. It was estimated by the surgery centers that a single technician can simultaneously process two trays at once. Therefore, the labor cost of sterilization and processing was determined by the formula: Labor cost = (hourly rate of sterile processing technician x total time of sterilization in hours) / two [Table 1]. It was assumed that the SK would not have any sterilization or processing costs associated with it.

Cost of operating room delays

Cost of case delays or additional operative time was determined through a survey of 23 hand surgeons operating at the three surgical centers at our institution. The surgeons were asked to estimate the proportion of delayed OR cases for distal radius ORIF due to the

Table 1. Estimated Sterilization Cost of Reprocessed Kits

Item	Estimated cost per tray
Steam indicators	$0.09 x 3 = $0.27
Tray wrap	$1.99
Washer Cycle	$3.29
Sterilizer Cycle	$4.51
Labor	[$25/hr x (139 min / 60 min/hr)]/2 = $28.96
Total	$39.02 / tray

Table 2. Estimated Time for Sterilization of Reprocessed Kit

Sterilization Process	Time
Soaking	minutes 20
Washer	minutes 40
Sterilizer	minutes 54
Biologic Test	minutes 25
Total	minutes 139

planned surgical set being unsterile or unavailable. We used the mode to estimate frequency of delays due to missing implants. Cost of operating room delays per minute was obtained from management reports of the surgical centers was based on the year to date (YTD) total operating costs from January 1, 2019 to July 31, 2019 subtracted by the OR supply costs. We assumed there was, on average, 540 available minutes per OR per day. We used the formula: Per minute OR cost = (YTD Total operating cost – YTD Supply cost) / (149 Days YTD x Number of Active Ors x 540 minutes). The total minutes per delay was based on a time estimate for re-sterilization obtained from the surgical centers [Table 2]. Furthermore, we conducted a sensitivity analysis on the frequency of OR delays to assess a range of delay costs.

Results

All 23 hand surgeons responded to the survey estimating DRF implant-related case delays. Nine (39.1%) estimated case delays occurred approximately once every 100 cases. Six (26.1%) estimated delays at once every 50 cases, while five (21.7%) estimated once every 200 cases. Only one (4.35%) hand surgeon estimated that delays occurred approximately once every 25 cases and two (8.7%) reported they had never had an implant-related delay. The mode value of 1 case delay per 100 cases was selected for cost calculations.

The number of distal radius cases analyzed was 120 cases. The average list price of RS implants was $2882 per case. The purchase price for the RS instrument tray was $87,000. Using straight line depreciation, under our assumption of a 10-year asset lifespan, the annual deprecation cost would be $8700, resulting in a cost per case of $48 [Table 3]. Sterilization and processing costs for each distal radius tray was found to be $39 per set [Table 1].

For OR delays, the mean per minute cost for the surgery centers was $7.78/minute (6.25 – 11.94). The total sterilization time for a reprocessed tray was 139 minutes, which translates to a delay cost of $1,081 [Table 2]. With the inclusion of another re-sterilization cost, the total cost of delay would be $1,149. Using the estimated rate of delay of 1% (1/100), the average expected cost per case due to OR delays is $11 [Table 3]. With a sensitivity analysis evaluating OR delay frequencies ranging from 0.5% (1/200) to 4% (1/25), total cost of delays per case for the RS ranged from $5.75 to $45.98.

The total cost per case using RS was found to be $2980 [Table 3]. The cost of each SK was $1,667. The RS was found to be $1,313 costlier per case [Table 3].

Table 3. Costs per Case for Reprocessed Sets and Sterile Kits

Reprocessed Set Cost Components	Cost per case
Cost of Instruments (depreciation)	$47.54 (1.6%)
Cost of Implants	$2881.52 (96.7%)
Sterilization	$39.02 (1.3%)
Operating Room Delay Cost	$11.49 (0.4%)
Total Cost of Reprocessed Set	$2979.57
Total Cost of Sterile Kit	$1,666.50
Total Cost Difference (RS – SK)	$1313.07

Discussion

The debate over using reusable versus disposable devices and instruments is a topic of interest in many surgical specialties. For example, it has been shown that reusable devices in laparoscopic surgery reduce the overall cost (11-13). Whereas disposable instruments have been shown to reduce surgical costs and improve efficiencies in hospital management related to lumbar spinal surgery (14). Other purported disposable benefits include elimination of sterilization costs, reduction in contamination risk, complete traceability of all implants, ease of billing, and new instruments for each case reducing the risk of damaged devices.

62% of the hand surgeons in our practice indicated they would consider using the SK. Cost and convenience were recurring themes throughout the commentary in the survey. Interestingly, cost was perceived as either an advantage or disadvantage of the SK, depending on the respondent. This highlights the uncertainty of the cost differences between the RS and SK and the need for a cost analysis comparison.

We found in our study that using the SK imparted a significant cost saving compared to the RS for an ambulatory surgical center, based on list pricing. Even in the scenario where an alternative surgical set was chosen in the event that the selected manufacturer set was not sterile, thereby eliminating the cost of operating room delays, the RS would still remain significantly more costly than the SK by $1,302 per case, assuming the same cost of the implants from an alternative vendor.

The most significant variable in our analysis is the cost of the RS implants themselves, representing 97% of the overall cost. This is also the variable most influenced by the manufacturer's pricing strategy and sales goals. Implant pricing, at many facilities, is a determined through contract negotiations and can be highly dependent on regionality, local competition, and the manufacturer's internal sales goals. The significant pricing discrepancy between the RS and SK, especially considering that the SK includes unused implants, disposable instruments, and built in packaging/sterilization costs, is likely accounted for by historical expected negotiated price discounts on the RS set which might not apply to the new SK kit. Another potential cost reduction factored into the

SK price is diminished role of the sales representative in monitoring and restocking RS. Therefore, since instrument and processing costs are minimal in the final analysis, it is the negotiated implant cost that will determine the cost effectiveness of a reusable system versus a one-time use set for distal radius volar plate fixation.

Estimated operating room delays contributed to only a small proportion of the overall cost owing to its relative infrequency. However, different surgical centers will have differing rates of unplanned implant-related delays which could significantly affect the conclusions of this analysis. Also, we calculated RS per-case instrument cost based on data from our high-volume surgical centers. A center which performs fewer distal radius fracture cases would see an increase in this cost component. Additionally, the cost of OR delays being minimal in our study is most likely due to hand surgeons at our institution operating at ambulatory surgical centers. However, the cost of OR delays in other facilities such as a high-volume level 1 trauma center or community hospital where OR time and space are at premium, the cost of OR and treatment delays could be significantly higher and must be taken into consideration for future studies.

Processing and sterilization costs were a more significant contributor than operating room delay costs. Previous studies have found reduction or elimination of sterilization and processing costs to be an effective method in reducing surgical costs. Ottardi et al found that one-time use sterile sets for lumbar arthrodesis were more effectively stored and supplied within a hospital, based on the smaller kit size, which allowed for more efficient internal transport and faster supply upon request and these factors subsequently improved OR efficiency and turnover (14, 15). The cost benefits of one-time use cutting blocks for total knee arthroplasty has also been described (16, 17).

There are a limited number of studies evaluating the economics of one-time use sterile DRF trays. Fugarino et al found that reusable sets from a different manufacturer were more cost effective than the company's sterile, single use sets for 30 consecutive cases over a nine-month period (18). This conclusion was based on the single use sets requiring additional hardware that would have already been found in the conventional set. However, the authors cautioned that further studies on the economics of single use, sterile trays need to be conducted as other potential cost-saving factors of single use sets were not considered, including reduced operating time, reduced OR set up and take down, and reduced stocking costs (18). These factors were not included in our study as we believe their cost impact would be minimal and would not have any substantive effect on the analysis.

Our study is not without limitations. First, our cost comparison model is built off of estimates and assumptions, including the OR cost per minute, average reprocessing costs, the frequency of case delays by surgeon survey, and instrument utilization rate and depreciation. These factors will vary by facility; therefore, our results are not generalizable to all surgery centers and hospitals. In addition, this study compared prices from a single manufacturer and prices can vary between different manufacturers. Second, we assumed that the SK trays would always be available, restocked daily, with the appropriate plate size and side for each patient and the required number of screws, which may not always be the case if there were ordering errors or atypical demand for a particular plate size or screws on any surgical day. Although the manufacturer does sell pre-sterilized, separately stocked plates and screws for this scenario. Also, important to note is that, if an SK were accidentally contaminated it could not be re-sterilized. Third, the assumption that SK includes all instruments and implants needed for one case and will not require opening other sets other than a power drill is yet to be determined since SK has not yet been used at our surgical centers. Lastly, though added waste generation and cost of waste disposal in SK case may be negligible, with the shift to an ever-increasing disposable OR, the additive environmental impact could be substantial. Future directions for investigation would need to evaluate the specific hardware utilization from the SK and its cost variability in clinical practice.

In conclusion, we found in our model that the SK imparts a significant cost savings over RS for the DRF treatment based on manufacturer list pricing. However, this cost discrepancy could be significantly influenced by typical negotiated price discounts. Surgeons may adjust their clinical practice to capture these savings.

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