

COMPREHENSIVE COSTS ASSOCIATED WITH FIBEROPTIC AND DIGITAL FLEXIBLE URETEROSCOPES AT A HIGH VOLUME TEACHING HOSPITAL

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Abstract

Introduction: Modern flexible ureteroscope (fURS) ownership costs are considerable. Most prior estimates focus exclusively on repair costs likely underestimating overall costs including those of acquisition and reprocessing. Furthermore, no prior cost analyses focus on latest generation digital fURSs which may differ due to unique purchase and repair prices. We sought to gain greater insight into the comprehensive costs associated with modern fURS use, particularly the difference between digital and fiberoptic models.

Methods: Utilization and repair data for fiberoptic Storz Flex X² and digital Flex X^c fURSs from 2011 to 2015 were reviewed. List price and repair costs were obtained from Storz. Per case reprocessing costs were estimated accounting for disposables, reagents, and labor. Maintenance costs were estimated by combining cost of repairs and reprocessing. Analyses were performed at both list pricing and standard discount rates. Global fURS costs were calculated to account for the cost of acquisition, repair, and maintenance of a new scope over its first 100 uses.

Results: Global costs associated with digital fURS ownership were 1.3-1.4x greater than fiberoptic on a per case basis (\$1008/1086 vs. \$715/835). The majority of expenses went towards scope repairs (73% vs. 71%) with instrument purchase (23% vs. 24%) and reprocessing (4% vs. 5%) being less costly. Repair rates were not significantly different between the fiberoptic and digital device (12.5 vs. 11.5, p=0.757).

Conclusions: Expenditures associated with ownership of modern fURSs are considerable and driven primarily by high cost of repairs. Digital instruments are more costly despite comparable rates of fURS damage.

Introduction

Ureteroscopy is now the leading procedure to treat upper urinary stones and is expected to grow with greater familiarity and access to instruments.¹ Advances in flexible ureteroscope (fURS) capabilities and design have been especially influential in the popularity of the procedure. Modern fURSs provide excellent image quality while maintaining small profiles. They also allow superb maneuverability, allowing treatment of stones anywhere in the kidney.²

One common criticism of fURSs is the high cost of ownership.^{3,4} In particular, fURS repair costs are substantial, making durability a critical component of investing in a new reusable scope.^{5,6} Repair costs are such a concern that single use disposable ureteroscopes are being developed to avoid costly scope damages and repairs altogether.⁷ In fact, a leading manufacturer of endourology equipment recently introduced one to the market (LithoVue™, Boston Scientific, MA).

To date, there is limited data characterizing costs associated with fURS ownership. To our knowledge no prior cost analyses have been performed with the newest generation digital fURSs. Further, most prior analyses have focused exclusively on repair costs and durability, underestimating true global costs of ownership including device acquisition and reprocessing. Such information is critical in assessing value and timely as disposable alternative options become available. We sought to address these concerns by characterizing the full economic burden associated with ownership and utilization of both fiberoptic and digital fURSs at a high volume teaching hospital.

Methods

Utilization and repair data was recorded prospectively for all fURS cases between 2011 and 2015 at a single high volume teaching hospital (n=2292). Case details including type of treatment and laterality were readily available for the prior 30 months (n=1025). The hospital owned three fiberoptic fURSs (Flex-X², Karl Storz, Germany) between the years 2011 and 2013.

An additional fiberoptic fURS was purchased for the years 2014/15 and two digital fURSs for 2015 (Flex-X^c, Karl Storz, Germany). Scopes were utilized by six different surgeons, each of whom works with trainees. Common practices were shared by all including routine use of ureteral access sheaths, reusable 200-micron holmium laser fibers, and aggressive attempts at stone removal.

Ureteroscopes were reprocessed using Sterrad NX® sterilization technique following manufacturer provided instructions. Instrument room employees participating in fURS sterilization each underwent training before being allowed to handle the scopes. Nearly half of the approximately 50-member workforce maintains this certification at any given time. All fURSs that failed leak tests were automatically sent for repair. Additionally, scopes were sent for repairs at the discretion of the surgeons and/or a certified service technician for alternative reasons such as loss of deflection or fiberoptic bundle damage. All damaged scopes were then interrogated by a Karl Storz field technician who in turn verified the damage and labeled it as minor or major. The manufacturer performed all repairs. Minor repairs were comprised exclusively of isolated external damage to the angle cover over the distal flexible tip of the scope that were able to be repaired locally and did not compromise scope function or sterility. All other repairs were considered major and were sent back to the manufacturer. In scenarios where multiple damages occurred simultaneously they were classified based upon the greatest degree of injury (i.e. major>minor) such that only one damage was reported for each instance.

Costs associated with reprocessing were calculated by estimating relative amounts of associated materials, reagents, and labor (Table 1). Reprocessing costs were the same for both scopes as the process is identical.

Comprehensive cost analyses were estimated using standard purchasing and repair rates provided by the manufacturer. Such rates were based on an original equipment manufacturer (OEM) repair exchange agreement without a no fault insurance plan. Under this agreement, the hospital pays the manufacturer for the cost of repairs in exchange for a new scope each time one

is damaged. This policy is paid on a per case basis as opposed to a no fault insurance plan where the hospital pays a premium covering a specified number of scope damages per year.

Estimated costs were then applied to actual utilization and repair rates from the institution. Analyses were first performed using list pricing and then taking standard discount pricing provided by the manufacturer into account (15% off costs of digital and fiberoptic fURS purchase, 15% off fiberoptic fURS repairs, 5% off digital fURS repairs). List purchase price for the fiberoptic scope was \$20,285 with a major repair price of \$8,000 and a minor repair price of \$1,900. List purchase price for the digital scope was \$25,499 with a major repair price of \$10,521 and a minor repair price of \$1,200.

We assessed costs two ways. First, we calculated global costs of fURS ownership defined as combined cost of purchase, repairs, and reprocessing over 100 cases. We then estimated the cost of maintenance alone (repairs plus reprocessing) exclusive of scope acquisition fees. Analyses were performed for both the digital and fiberoptic model fURS at list price and assuming standard discount rates.

Statistical analysis was performed using IBM:SPSS Statistics Version 22 (Armonk, NY). Continuous measures were compared between groups using Student t-tests and categorical measures were compared between groups using Fisher's exact tests with $p < 0.05$ being considered statistically significant.

Results

Flexible ureteroscopy was performed 2292 times over the study period (2,143 fiberoptic, 149 digital, 93% vs. 7% respectively). Digital fURSs were used less because they only were available during the final study year. Review of the prior 1025 procedures indicated a majority to be active treatments whereby instruments were passed through the working channel (Table 2). Laser energy was applied in over half of the procedures. Only 12.7% of procedures were solely diagnostic. Additionally, ureteroscopy was performed bilaterally in 14.4% of procedures.

Damages occurred in 172/2143 cases using the fiberoptic fURS and 13/149 cases using the digital fURS (8.0% vs. 8.7%). Mean number of uses prior to requiring repair was not significantly different between groups with the digital fURS requiring repair every 11.5 uses and the fiberoptic fURS every 12.5 (p=0.757). A majority of repairs were major for both scope types (84.6% digital, 66.3% fiberoptic, p=0.43).

Global costs of fURS ownership were greater for the digital than fiberoptic scopes regardless of list pricing or discounts. At list price, total investment for purchase and utilization of a new digital fURS over 100 uses was 1.3 times as expensive as the fiberoptic fURS. The majority of expenses were associated with scope repairs (73% vs. 71%) with instrument purchase (23% vs. 24%) and reprocessing (4% vs. 5%) being less costly. Global per case costs were \$1,086 for the digital fURS compared to \$834.70 for the fiberoptic. Maintenance costs alone were similarly higher for the digital scopes (Table 4). When factoring in discount rates, global costs were 1.4 times greater for the digital fURS. Overall distribution of expenses remained similar with 70-75% of total expenditures spent on repairs.

Discussion

Our study is the first describing comprehensive costs associated with fURS ownership, repair, and reprocessing for both digital and fiberoptic instruments. Rarely has upfront investment for the purchase of the fURS been considered in such analyses, while the cost of reprocessing has never been included.^{3,5,17} We found that repairs account for the majority of expense (70-75%) and after 100 uses are nearly three times greater than the purchase price of the fURS itself. Distribution of costs between investment, repairs, and reprocessing was similar whether list pricing or discount rates were used and did not significantly differ for digital or fiberoptic models. Digital fURS costs were 1.3-1.4 times that of fiberoptic. However, this was driven by higher baseline costs rather than differences in repair rates.

Rates of fURS repair vary widely in the published literature for both digital and fiberoptic models. Our repair rate of every 11.5 - 12.5 cases is comparable to several prior studies, though published reports indicating greater durability of similar scopes also exist. Fiberoptic fURS repair rates range from 5.3 to 100 cases depending on the scope model and institution.⁸⁻¹⁰ Digital fURS repair rates vary as well from as low as every 11 cases to over 100.¹¹⁻¹³

There are many potential explanations for such wide discrepancies. In particular, the types of procedures the fURS is being used for, as well as the technique being practiced, are likely directly associated with risk of scope damage. For example, in the prior published report of the most durable experience using a fiberoptic fURS, only 50% of procedures were performed for treatment of stones, with only 4% being bilateral.¹⁰ Conversely, in our series, 83% of procedures were performed for stone treatment with 14% being bilateral indicating a much higher likelihood that instruments were passed through the working channel and laser energy was applied, both common causes of scope damage.

Another likely influence on our relatively high repair rate is our status as a teaching hospital for both residents and fellows. Flexible ureteroscopy is a core skill taught to all first year urology residents. Despite careful oversight of trainees, lack of familiarity with the steps and nuances of the procedure likely lead to increases in scope damage, particularly laser burns and working channel damage which were present in approximately one third of our repairs. Sharing similar concerns, Karaolides et al. found that requiring trainees to demonstrate competency on a simulation model prior to live operative room experience, as well as application of several technical guidelines meant to preserve scope integrity, led to a decrease in repair rates from every 10.6 to 21.6 uses.¹⁵

Furthermore, our standard technique for stone removal bears mention as it could contribute to our high rates of repair. We routinely remove all stone fragments meticulously via basket extraction rather than dusting with delayed passage. This technique has been suggested to be more efficacious in terms of stone-free rate and reduced likelihood of secondary stone

events.¹⁶ However, it is also more time consuming and requires more aggressive manipulation of the fURS including increased torquing to inspect anatomically unfavorable calyces, multiple passes of lasers and baskets through the working channel, and repeated passage of the scope through the sheath. This could explain some difference in our repair rates compared to prior studies where alternative techniques such as dusting or less aggressive attempts at complete stone removal may have been implemented. It also raises the question of the true cost effectiveness of the procedure, whereby less aggressive treatments may reduce the cost of scope repairs at the expense of secondary interventions for the patient with residual fragments.¹⁶ We suspect that the combination of our technique along with the training nature of our hospital likely plays a considerable role in our repair rate.

There may be several other explanations for our high repair rate as well. We routinely use reusable holmium laser fibers which have been suggested to correlate with increased fURS damages. Chapman et al found that use of disposable laser fibers decreased scope repairs by two thirds, hypothesizing that microfractures from laser reprocessing increased likelihood of energy leakage and subsequent working channel damage.¹⁴ Additionally, scopes in this study were reprocessed by a large number of employees in the instrument room. Though unclear if this is where the majority of damages occurred, prior studies have demonstrated that limiting handling to only the most experienced employees minimizes risk. Semins et al found that when fURSSs were processed exclusively by a designated and specialty trained urology specific staff, there was not a single damage from reprocessing among 478 cases.⁹

Rising costs of fURS ownership has the potential to threaten the profitability of the procedure. Tosoian et al. estimated that on a per procedure basis, ureteroscopy remains profitable until per case hospital expenditures approach \$1,200. They estimated spending \$605/case on repairs of fiberoptic flex-X² fURSSs and concluded that profitability was maintained with a net margin of \$594. Our per case repair costs using the same scope was similar (\$505-594). However, when the cost of digital equipment, scope acquisition, and reprocessing is factored in,

the cost/case is much closer to the breakeven point (\$1,008 -1,088) highlighting the need for each hospital to fully understand their expenses.⁵ Understanding global costs, impact of service agreements, and profit margins will be particularly important over the coming years as hospitals are offered opportunities to transition from traditional ownership of reusable fURSs to single use disposable alternatives.

We recognize several limitations. First, the cost of scope maintenance is only a part of the total expense of running a fURS program. Other capital investments such as a laser and video tower were not accounted for as they are commonly shared expenses with other departments. Similarly, disposables, which have the potential to be quite costly,¹⁷ were not captured as in most instances they are billed to the insurance company. Furthermore, our results do not take into account “opportunity costs” that may arise in the event a scope is damaged during a procedure. Cancellations and delays resulting from this scenario can be quite costly considering the high expense of operating room time. It is our practice to always have a backup fURS available for this purpose. Another limitation is that our findings may be specific to the types of fURSs we use. Cumulative costs of fURS ownership after 100 cases can vary by as much as 95% between models.³ Reprocessing costs may vary by institution as well. We suspect ours is on the low end, reflecting high familiarity from a large case volume; however, further multicenter studies are necessary to verify this. Another limitation is that specific procedural data were only available for the prior 30 months and did not distinguish which cases were performed with the fiberoptic or digital fURS. However, the case volume reviewed over this time period is still considerable, over 1000 cases, and is reflective of our standard practices which have not changed appreciably. Furthermore, given that we are a teaching hospital, our results may not be generalizable to community-based urology practices without trainees. Finally, our analysis assumes utilization of an OEM exchange agreement. Alternative service agreements exist, though we suggest that all hospitals that own fURSs try to determine unique repair rates prior to deciding on alternative arrangements. Two main alternatives to OEM agreements are outsourcing repairs which has been

found to be associated with poor durability¹⁸ and purchasing no-fault policies which cover a particular number of repairs on an annual basis but may be more expensive than necessary at hospitals able to maximize scope longevity.

Our study has several strengths as well. All damages to the fURS were recorded prospectively enhancing validity and minimizing likelihood for retrospective bias. Moreover, it captures the largest number of procedures over which scope damages have been recorded in the published literature. Finally, it includes the transition period from fiberoptic to digital fURS use within a single hospital, ensuring consistency in operative technique and reprocessing and minimizing potential for confounding.

Conclusions

Global costs associated with fURS ownership are driven largely by repair costs. Digital models have comparable durability but are more expensive. These findings are important as hospitals are presented with alternatives to fURS ownership, namely the use of disposable devices. Future studies are needed to investigate financial implications of such instruments relative to traditional reusable scope ownership.

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Table 1: Costs associated with fURS reprocessing on a per case basis

	Price (U.S. dollars)
Sterrad indicator	\$0.14
Sterrad tape	\$0.10
Wrapper	\$0.86
Underguard	\$0.59
Cyclesure	\$11.09
Cleaning brush	\$13.19
PPE for decontamination	\$2.00
Salary (\$3.40 for 15 minutes x 3 employees)	\$10.20
TOTAL	\$38.17

Table 2: Types of procedures for prior 1025 ureteroscopies

Procedure type	N (%)
Lithotripsy	506 (49.3%)
Stone removal alone	346 (33.8%)
Biopsy	26 (2.5%)
Laser ablation tumor/stricture	17 (1.7%)
Diagnostic only	130 (12.7%)
Bilateral	148 (14.4%)

Table 3: Types of fURS damage

Type of Damage	Digital fURS (n=13)	Fiberoptic fURS (n=172)	P-Value
Minor	2 (15.4%)	58 (33.7%)	0.43
Angle cover cut	2 (15.4%)	58 (33.7%)	
Major	11 (84.6%)	114 (66.3%)	0.26
Laser damage	2 (15.4%)	11 (6.4%)	
Shaft damage	1 (7.7%)	39 (22.7%)	
Distal end damage	0 (0%)	5 (2.9%)	
Vertebrae damage	1 (7.7%)	21 (12.2%)	
Working channel (non-thermal)	7 (53.8%)	38 (22.1%)	

Table 4: Costs of fURS maintenance and ownership on a per case and global basis assuming list pricing and discount rates

	Per Use			Global Cost (100 cases)				
	Repair Cost/Use	Reprocessing Cost/Use	Maintenance Cost/Use	Purchase Price (% total)	Repair Costs (% total)	Reprocessing Costs (% total)	Total Cost	Mean Cost/Use
List Price								
Digital	792.8	38.2	831.0	25,499.0 (23.5)	79,282.6 (73.0)	3,817.0 (3.5)	108,599.6	1,086.0
Fiberoptic	593.7	38.2	631.9	20,285.0 (24.3)	59,370.0 (71.1)	3,817.0 (4.6)	83,472.0	834.7
Discount Price								
Digital	753.2	38.2	791.4	21,674.2 (21.5)	75,318.8 (74.7)	3,817.0 (3.8)	100,810.9	1,008.1
Fiberoptic	504.6	38.2	542.8	17,242.3 (24.1)	50,464.5 (70.6)	3,817.0 (5.3)	71,524.8	715.2