Abstract:

Objective

The single use flexible ureteroscope (fURS), the LithoVue is an important recent development. We aim to measure the capability of this instrument and to assess if there is a benefit to switching to single use instruments.

Patients and Methods

The LithoVue was compared to Olympus URF-V and Stortz Flex Xc ex-vivo. An analysis of reusable fURS usage was performed to evaluate damage, durability and maintenance costs. This was then compared to the projected costs of using single use instruments.

Results

Flexion, deflection and irrigation flow of the LithoVue was equivalent, if not better than reusable instruments. An analysis of 234 procedures with 7 new Olympus URF-V scopes, revealed 15 scope damages. Staghorn stones and lower pole/midzone stones were significant risk factors for damage, p=0.014. Once damage occurred, it was likely to occur again. Total repair costs were $162,628 (£92,411), the mean cost per case is $695 (£395). Factoring in the purchase cost, cleaning and repair costs, and the cumulative cost of 28 reusable fURS cases is approximately $50,000 (£28,412). If the LithoVue was priced at $1200 AUD, switching to a single use scope would cost approximately $35,000 (£19,888).

Conclusion

The LithoVue is analogous to reusable fURS scopes in regard to standard technical metrics. Depending on its purchase cost it may also represent a cost saving for hospitals when compared to the cumulative costs of maintaining reusable fURS. Additionally, urologist may consider to use the scope in cases in which reusable scope damage is anticipated.

Introduction

The miniaturization of endourological instruments and improvements in laser lithotripsy have revolutionised the approach to renal stones (1) (2). Flexible ureteroscopy (fURS) is increasingly used as a first-line treatment and it is not surprising, that in some countries it exceeds all other modalities by up to 30% (3). fURS has become popular with urologists, as it is to learn, is associated with high stone free rates and is acceptable to patients (4) (5) (6).

The initial purchase cost of reusable fURS instruments, combined with cleaning is significant. Furthermore, these instruments are delicate and can be damaged easily, repair costs can be substantial (7) (8). There is also the recognised issue of scope degradation over time which can cause inconsistent performance (9). It is these issues of durability, degradation and repair cost that is limiting the use and uptake of fURS in some countries (10) (11).

As an alternative to reusable fURS instruments, a single use digital fURS scope has been developed, the LithoVue (Boston Scientific, Marlborough, MA). The advantages of a single use fURS instrument is that will eliminate the inconsistent performance of reusable instruments while also avoiding the expensive reprocessing and repair costs (7) (8) (9) (12).

The objective of this study was to evaluate the new single use fURS scope (LithoVue), and assess if it could be an alternative to reusable fURS. The LithoVue, was compared *ex-vivo* to 2 commonly used reusable fURS in terms of maneuverability and functionality. The cost of maintaining a reusable fURS was determined and compared to cost of using the LithoVue to assess if there is a economic benfit of using single use over reusable fURS.

Methods

fURS assessment

The LithoVue, URF-V (Olympus, Tokyo,, Japan) and the Flex-Xc (Karl Storz, Tuttlingen, Germany) were examined *ex-vivo*. Flexion and deflection was measured with a empty working channel, then with a variety instruments in the working channel (hydrophilic guide wire, PTFE-Nitinol guidewire, 200µm laser fiber, 1.9Fr nitinol basket and 3Fr biopsy forceps). Irrigation flow was determined by connecting the instruments to a 1 litre (L) bag of 0.9% saline at 100cm, then with a pressure bag set at a pressure of 250mmHg. Flow rate (ml/s) was measured with an empty working channel, and with instruments in the working channel.

Cost analysis

An analysis of consecutive fURS procedures over a 30 month period was performed. The start of this dataset coincided with the acquisition of 7 new reuseable URF-V fURS scopes. Only procedures that involved laser lithotripsy of renal stones were include in the analysis. Data extracted includeded patient characteristics (age, sex), stone details (side, size, number, position in collecting system, staghorn or partial staghorn stone) and operative details and scope damage. All instruments were sterilised through the STERIS System E1.

Scope damage

Damage reports were obtained from the supplier (Olympus). Expenses are reported in Australian dolla ($) and Great Bristish Pound (£). Minor repairs accounted for <5% the cost and were excluded from the analysis. Damage was considered major when the repair cost exceed $10,000 (£5,680). Data extracted on damaged fURS scopes and undamaged scopes was compared to identify risk factors for damage. Fianlly, 3 patients with renal stones were consented for treatment with the Lithovue. Movement, ergonomics, visibility, image quality and treatment outcome were both objectively and subjectively assessed.

Statistical analysis

The graphical representation of the observed cost of our reuseable scopes was generated by assuming an initial purchase cost of $26,372 (£14,985) and fixed cleaning costs of $26.20 (£14.90) per case for URF-V scopes. At each repair time point, the cost was divided by the number of scopes that had performed that number of cases . In this way, we average the repair costs as if they were happening to a single scope which allows comparison to the fixed cost estimates for disposable scopes. Two prices for the single use fURS scope were used because at the time of analysis the manufacturer had not released the sale price of the instrument. Comparisons between cases with and without major damage were performed with either Student's T-test or Fisher's exact test. Tests were two sided with significance set at 0.05. Analysis was performed using Stata v12.0SE (College Station, TX).

Results

Comparison of fURS scopes.

With an empty working channel, the LithoVue had a similar range of movement to the URF-V and Flex Xc. Flexion of the LithoVue is 285°, URF-V is 180° and Flex Xc is 283°. Deflection for the LithoVue is 286°, URF-V is 270° and the Flex Xc 219°. The range of movement of all scopes is summarised in table 1. At height of 100cm, irrigation flow through the LithoVue was greater than the URF-V and the Flex Xc (0.53ml/s versus 0.43ml/s and 0.46ml/s). This was maintained with different instruments in the channel and when a pressure bag was applied, flow rates are summarised in table 2. Figure 1 shows the flexion and deflection of the LithoVue with an empty channel and with a laser fiber and stone basket in the working channel is shown.

Risk factors for scope damage

234 renal stone procedures were performed with 7 new Olympus URF-V instruments, named (A-G) over a 30 month period. 178 patients (77.3%) were completely stone free, while 51 (22.7%) patients

required further treatment. 15 major scope damages occurred during the time period. Patient age, sex, operation side, number of stones, stone size and operator experience was not associated with damage. Staghorn stones and stones in the lower pole calyx or mid zone calyx were statistically significant risk factors for scope damage, p=0.016 and p=0.074 respectively. The risk factors for scope damage risk factors are shown in table 3.

Type of damage and durability

The total number of procedures performed per instrument varied from 58 (scope A) to 20 (scope G). 34 separate different types of damage were reported during the 15 episodes of scope repair. The commonest type of scope damage reported was bending tube leakage, this occurred in 6 of the 7 scopes (B, C, D, E, F and G) and occurred a total of 17 times. One scope (E), had the bending tube rubber repaired on 4 different occasions. The mean number of uses of a new Olympus URF-V scope before damage occurred was 11 cases. After repair the mean number of uses before damage occurred again was 19. Data on number of scope uses and damage is summarised in table 4.

Cost analysis of reusable fURS scopes

The total repair cost for the 7 new scopes over this time period was $162,628 (£92,411). The mean cost per case (repair cost only) is $695 (£395). This varied from $361 (£205) (scope A) to $1,179 (£670) (scope E). This does not include initial purchase cost, processing costs, cleaning and other indirect costs such as transport and staff time used in arranging service and repair. So the actual cost per case is higher. Scope repair costs and scope cost per case is summarised in table 4.

The cost analysis of using URF-V scopes compared to single use fURS instrument is shown in Figure 2. The cumulative cost of 28 cases for the reusable fURS scope is approximately $50,000 (£28,412). If the single use disposable fURS is priced at $2500 (£1420), then it would cost approximately $72,000 (£40,913) for 28 cases. This would make using reusable fURS scopes more economical. If the single use disposable fURS is priced at $1,200 (£682), then the cost for 28 cases is $35,000 (£19,888). This would represent a considerable cost saving and suggest that switching to the single use fURS would make sense from an economic point of view.

In-vivo assessment of the LithoVue

The LithoVue was utilised in 3 patients for the treatment of renal calculi. The mean number of stones was 1.5 and the mean stone size was 9mm. 2 stones were located in the midzone and 1 was located in the lower pole and was repositioned. No patient was stented pre-operatively, and an access sheath was used in all cases. Complete stone fragmentation and clearance was achieved in all cases. There were no scope damages. Subjective assessment of ergonomics, movement and image quality by performing complete pyeloscopy, stone extraction and laser lithotripsy proved the LithoVue to be an excellent fURS scope. LithoVue image quality is shown in figure 3.

Discussion

Flexible ureteroscope design and functionality has improved significantly over the past 20 years. The modifications to device diameter, flexion, deflection and imaging have made fURS the first-line treatment for renal stones in some countries (13) (14) (15). Despite this, the initial purchase cost, maintenance cost, performance degradation and poor durability remain significant issues associated with both fiberoptic and digital reusable fURS use (10) (11) (16).

In this study, we found that reusable fURS damage was a common occurrence, with major damage occurring after a mean of 11 cases. Similarly, Martin *et al*, reported an average of 12.5 cases until damage occured (17). These findings were also confirmed by several other authors (10) (18). In addition to this, we noted that once a scope was damaged, the durability of the instrument was compromised, with the same damage occurring multiple times. This finding has also been reported in the literature (12) (19). To avoid the initial high puchase costs, poor durabilty and repair costs associated reusable scopes, the single use fURS scope was developed.

We found the LithoVue to be functionally comparable to 2 of the most commonly used reusable fURS scopes. With a clear working channel and a variety different instruments in the channel, the LithoVue had equivalent, if not superior flexion and deflection to the Olympus URF-V and Karl Stortz Flex-Xc. Irrigation flow was also similar. Analogous findings were also reported in a recent study examining the LithoVue in human cadavers (11). With the equivalence of the LithoVue to reusable instruments established, the only remaining issue regarding its introduction is the financial viability of single use fURS scopes versus reusable scopes (7) (8) (9).

To assess this, we performed an analysis of reusable fURS scope usage at our institution. The initial purchase cost, cleaning overheads and repair expenses per case were calculated and compared to projected costs of purchasing and using single use instrument instead. The mean cost per case for repairs alone was $695 (£395). These costs did not include purchase cost and cleaning so the final cost is higher per case. These findings are similar to repair rates reported in the literature, so we feel accurately represent the cost per case for reusable scopes (18).

If the initial purchase cost of a new reusable digital fURS scope is approximately $26,372 (£15,092) and cleaning costs fixed at $26.23 (£15.01) per case. Then the approximate cost of 28 fURS cases is approximately $50,000 (£28,412) when the repair costs are averaged over the number of available scopes. If the LithoVue is priced at $1,200 (£682), 28 procedures would cost approximately $35,000 (£19,888) and using a sinlge use fURS woud make finincial sense. However, if the LithoVue was priced at $2500 (£1420) then it would cost more than repairing reusable and would not make financial sense.

An additional outcome of this study was that we identified risk factors for reusable fURS scope damage. We found that staghorn stones and stones located in the lower pole to be significant risk factors for scope damage. Instead of switching to only single use instruments, the LithoVue could be held in reserve for cases in which damage is anticipated. Thus, the risk of reusable scope damage would be eliminated, reducing the cost of maintaining a reusable fURS and decreased the average cost per case. Performance degradation is a well-recognised drawback of reusable fURS. Overtime there can be a loss of flexion, deflection and in the case of fiberoptic instruments image quality. This loss of functionaluity could affect the outcome of stone surgery. The fact that the LithoVue would never be affected by performance degradation is an additional advantage of single use instruments over reusable instruments.

Limitations of the study include, that we only compared the singLithoVue to reusable digital fURS instruments ex-vivo and to a reusable digital scope for the financial comparison. Fiberoptic fURS are less expensive to purchase than digital fURS scopes and can be more durable. It is possible that single use fURS may not cheaper than resuable fiberoptic fURS. However, digital fURS scopes, both single use and reusable have siginifiant advantages over fiberoptic. Particulaly with regard to movement and image quality (20). An additional limitiation was, that we only used the LithoVue in a small number of patients and it was not possible to draw any conclusions on the durabilty of the instrument. However, it is worth noting that if a single use scope broke during a case, it would still be cheaper to use more than one single use instrument than repairing a reusable digitial fURS scope. Ultimately, individual Urology departments will have to look at their own reusable scopes and determine their repair and maintenance costs to determine there is an economic benefit to switching to the single use fURS scopes.

CONCLUSION

The single use fURS scope, the Lithovue is comparable *ex-vivo* to two of the most popularly used reusable scopes available. The main advantage of the instrument is that it will have not maintenance or repair costs. Depending on the purchase cost, it may be more economical to use a single use scope than purchasing and maintaining resusable scopes. If not, urologists may wish to use the instrument for cases in which reusable scope damage may occur in particular lower pole stones and staghorn stones.

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FIGURE LEGENDS

Figure 1: Manoeuvrability of LithoVue Scope

A; flexion and deflection with a Hydrophilic guidewire in the working channel. B; flexion and deflection with 1.9Fr stone basket. C; flexion and deflection with 200µm laser fiber.

Figure 2. Cumulative cost of repair and/or acquiring equipment.

The red line is observed cost of reusable scope (assuming that cost of reusable scope is of $26,372.30 (£15,092), a cleaning cost of $26.23 (£15.01) per use and that the repair costs are averaged over the number of available scopes. Dark blue line is if disposable fURS scope unit costs $2500 (£1420) percase, light blue lins is if it costs $1,200 (£682).

Figure 3. LithoVue Image quality and laser lithotripsy

Pyelopscopy, stone identification, repositioning with basket and laser lithotripsy.

Table 1: Range of movement of fURS scopes

	LithoVue	Olympus URF-V	Stortz Flex Xc
Flexion			
Clear channel	285°	180°	283°
Hydrophilic guidewire	247° (-13.3%)	165° (-8.4%)	238° (-15.9%)
PTFE-Nitinol guidewire	228° (-20%)	134° (-25.6%)	192° (-32.2%)
200µm laser fiber	277° (-2.8%)	180° (-0%)	262° (-7.4%)
1.9Fr stone basket	270° (-5.3%)	175° (-2.8%)	254° (-10.2%)
3Fr Biopsy forceps	142° (-50.1%)	112° (-37.8%)	164° (-42.1%)
Deflection			
Clear channel	286°	270°	219°
Hydrophilic guidewire	251° (-12.2%)	236° (-14.2%)	171° (-21.9%)
PTFE-Nitinol guidewire	233° (-14%)	195° (-29.1%)	140° (-36.1%)
200µm laser fiber	270° (-5.6%)	254° (-7.7%)	193° (-11.9%)
1.9Fr stone basket	260° (-9.1%)	256° (-6.9%)	185° (-15.5%)
3Fr Biopsy forceps	130° (-54.6%)	170° (-38.2%)	113° (-48.4%)

PTFE; Polytetrafluoroethylen. µm; micrometre. Fr; French.

Table 2: Irrigation Flow in Different fURS Scopes

	LithoVue	Olympus URF-V	Stortz Flex Xc
Specifications			
Length (mm)	680	670	700
Distal end diameter (Fr)	7.7	8.3	8.5
Working channel (Fr)	3.6	3.6	3.6
Light source	Integrated	External	Integrated
Flow rate 100 cm H2O (ml/s)			
Empty channel	0.53	0.43	0.46
200µm laser fiber	0.25	0.189	0.187
1.9Fr stone basket	0.155	0.125	0.104
Flow rate 250 mmHg (ml/s)			
Empty channel	1.2	1.111	1.31
200µm laser fiber	0.699	0.421	0.78
1.9Fr stone basket	0.378	0.233	0.373

PTFE; Polytetrafluoroethylen. µm; micrometre. Fr; French. ml/s; millilitres/second

Table 3: Risk factors for reusable fURS scope damage

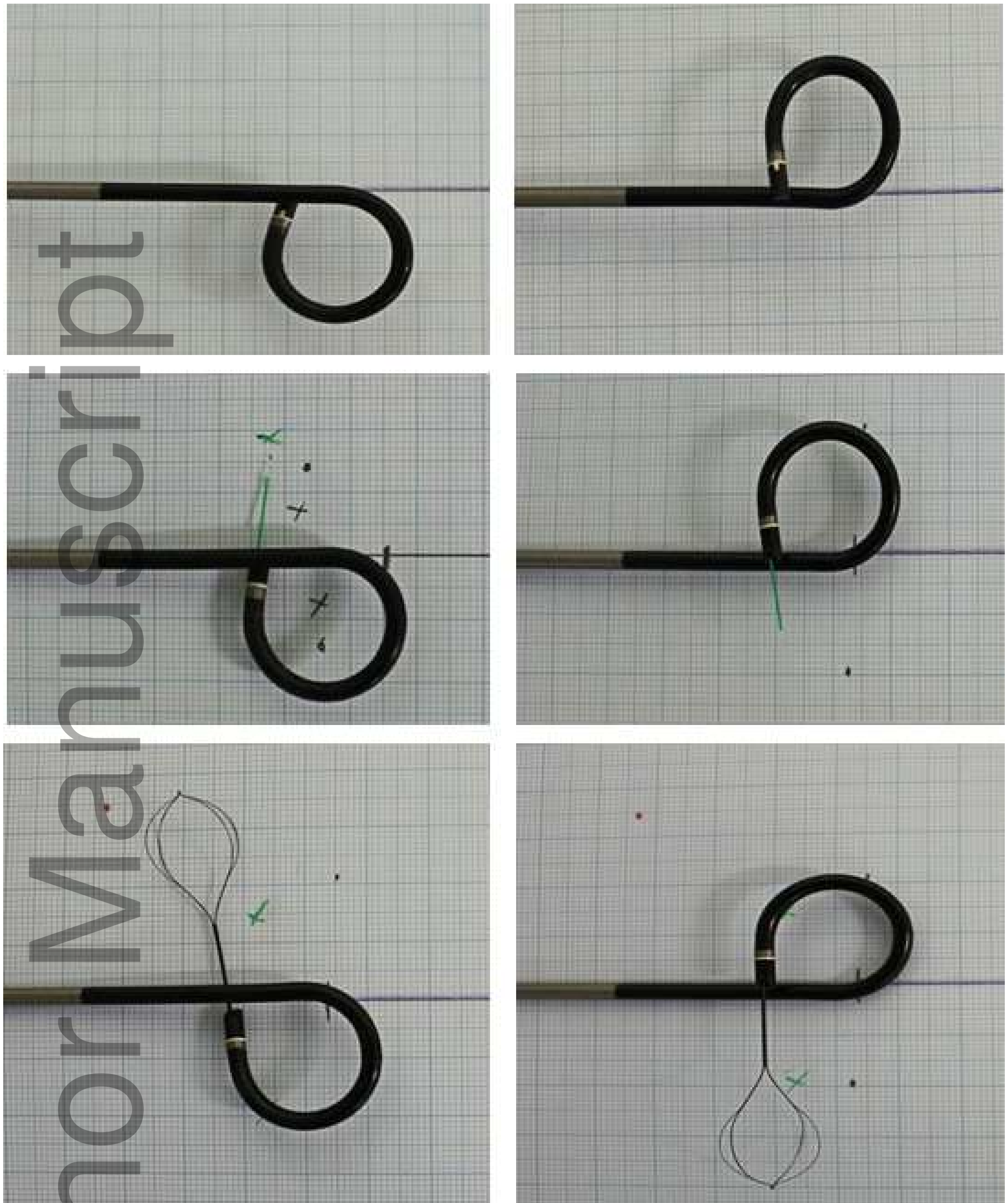
	Damage, N (%)	No damage, N (%)	P value
Total	15	219	
Age, mean (range)	50 (26-79)	55 (20-88)	0.2
Sex			
Male	9 (6.2)	137 (93)	>0.9
Female	6 (6.8)	82 (94)	
Side			
Left	12 (9.0)	121 (91)	0.10
Right	3 (3.0)	96 (97)	
Staghorn calculus			
Yes	3 (33)	6 (67)	0.014
No	12 (5.3)	213 (95)	
Non-staghorn calculi			
Lower pole			
Yes	11 (8.4)	120 (92)	0.016
No	1 (1.1)	93 (99)	
Mid zone			
Yes	0 (0)	49 (100)	0.074
No	12 (6.8)	164 (93)	
Upper pole			
Yes	0 (0)	32 (100)	0.2
No	12 (6.2)	181 (94)	
Pelvis/ureter			
Yes	1 (2.0)	50 (98)	0.3
No	11 (6.3)	163 (94)	
No. of stones, mean (range)	1.7 (1-3)	1.6 (0-5)	0.8
Stone size (mm), mean (range)	12.2 (5-33)	9.6 (1-42)	0.14
Operator			
Consultant/Fellow	7 (7.3)	89 (93)	0.8
Registrar	8 (5.8)	130 (94)	

N; Number. Mm; millimetre.

Table 4: Reusable scope damage and costs per case

Scope	A	B	C	D	E	F	G	N, mean (range)
Total procedures	58	43	32	29	29	21	20	234
No. of repairs	2	2	2	2	3	2	2	15
No. of cases until 1st damage	29	18	5	17	4	3	1	11 (1 – 29)
1st damage	A, B	C, D	C, D, E	C, D	B, C, D, E	D, F	D	-
No. of cases until 2nd damage	29	20	23	12	18	16	13	19 (12 – 29)
2nd damage	A	A, D	D	A	A, C, D, F	D, F	E	-
No. of cases until 3rd damage	-	-	-	-	3	-	-	-
3rd damage	-	-	-	-	D, E	-	-	-
Procedures /damage ratio	29	22.5	16	14.5	9.7	10.5	10	16.3 (9.7-29)
Repair costs	\$20,930 £11,977	\$20,930 £11,977	\$20,930 £11,977	\$22,741 £13,014	\$34,179 £19559	\$21,707 £12,422	\$21,211 £12,138	\$162,628 £92,411
Cost/Case	\$361 £205	\$465 £266	\$654 £375	\$784 £448	\$1,179 £670	\$1,034 £591	\$1,061 £607	\$695 £395

No; number. A=Insertion tube leak. B=Failed electrical safety test. C=Angulation malfunction. D=Bending tube leak. E=Biopsy channel leaking. F=ETO connector leak. \$; Australian Dollar. £: British Pound



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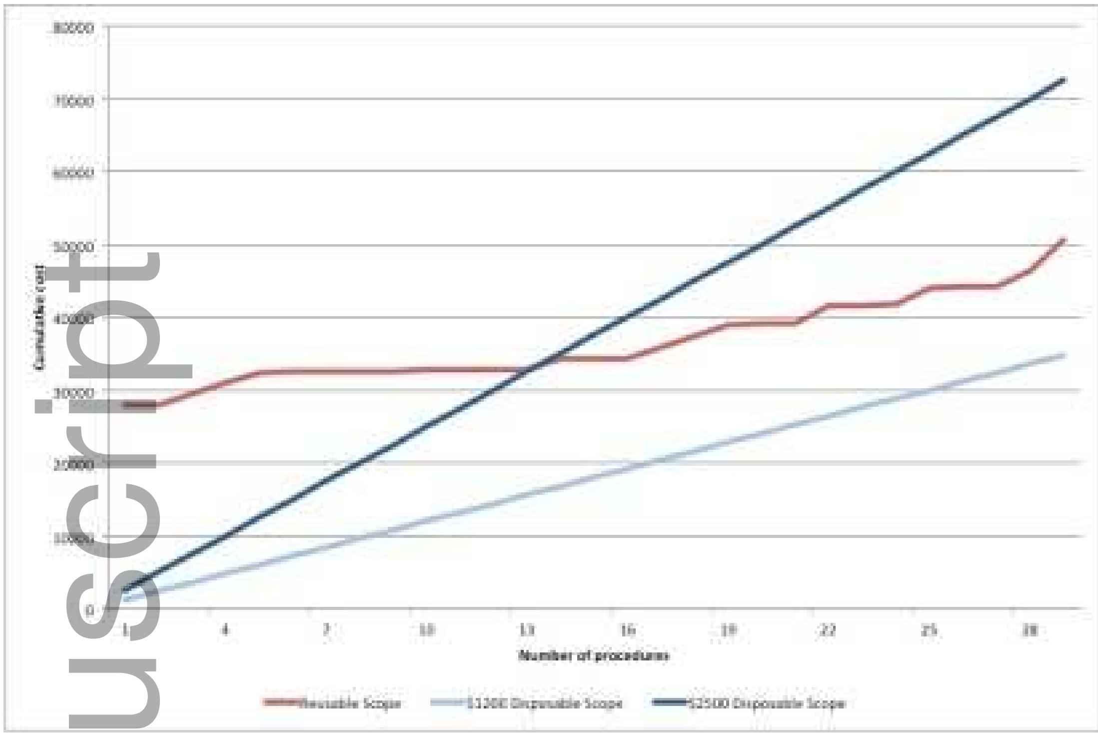

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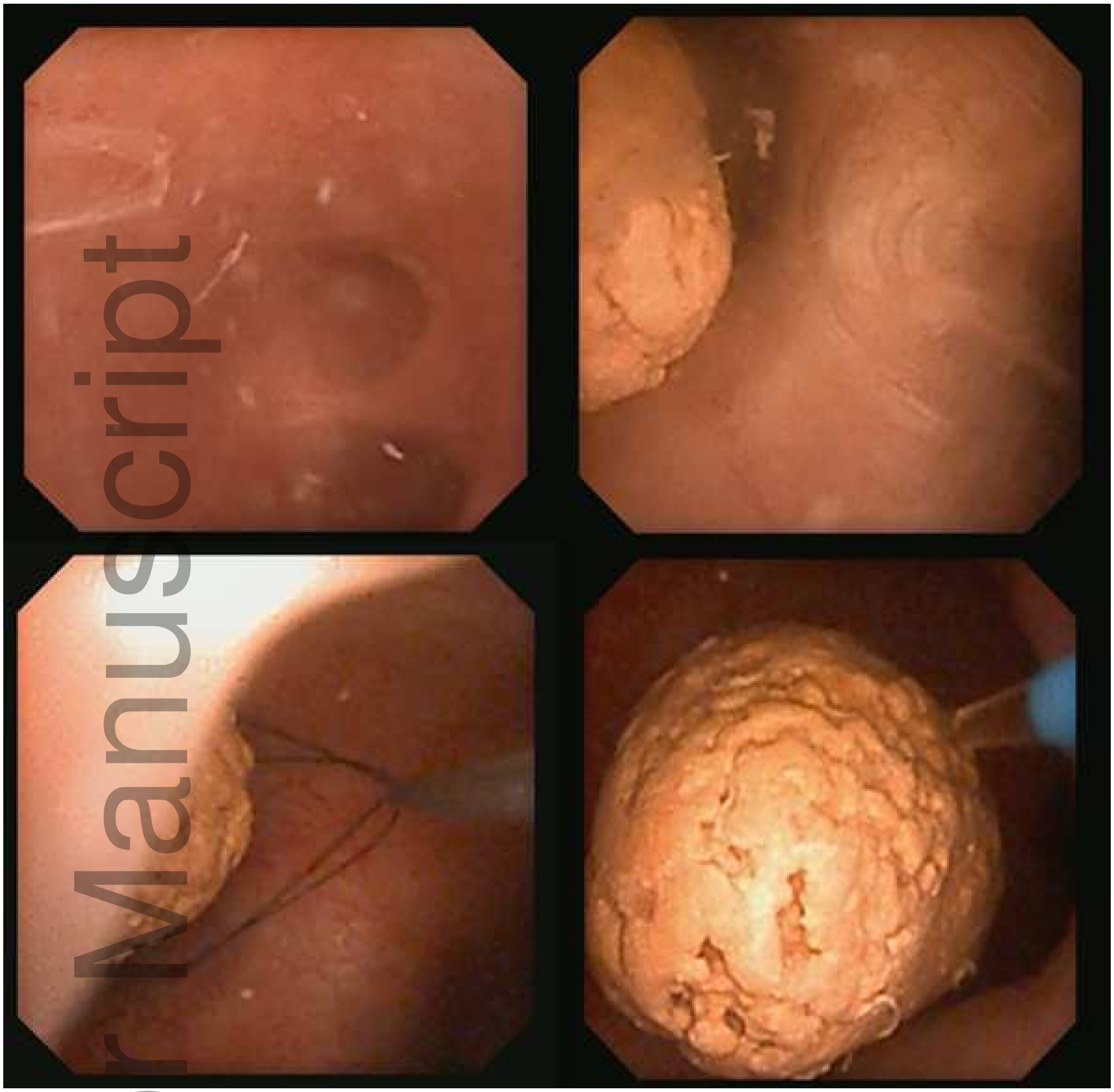

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