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Economic Analysis of Hydrosurgical Disc Space Preparation For Interbody Fusion

Bryan Fox, MD[†], William Sukovich, MD[††], Mitchell Hardenbrook, MD[†††], Rudolph Taddonio, MD[††††]

[†]Duke University Medical Center, Durham, NC, [††]Martha Jefferson Spine Center, Charlottesville, VA,[†††]Naval Medical Center, Portsmouth, VA; [††††]Stamford Hospital, Stamford, CT

Summary

An economic model has been developed to assess the impact of the SpineJet Hydrosurgery System on the utilization of medical resources. Clinical and pre-clinical (cadaver model) data, peer reviewed journal articles, and expert opinion were used to formulate the model. Analysis shows that the cost of the SpineJet XL devices ($1010 per procedure) is more than offset by the cost savings afforded by their use. Additional economic benefit is achieved when longer-term savings are considered.

Background

Lumbar interbody fusion is a complex and costly surgical intervention that is only considered when more conservative treatment has failed in the treatment of low back pain. Over 150,000 of these procedures are performed each year yielding a range of outcomes and complications for patients and correspondingly varying costs for the institutions providing care. The SpineJet XL instruments were designed specifically to better enable surgeons performing Transforaminal Lumbar Interbody Fusion (TLIF), however they may be used in other posterior (PLIF) approaches and anteriorly (ALIF), as well. TLIF has been shown to be far less costly than ALIF[1] and result in fewer complications than PLIF[2].However, concerns have been documented about the adequacy of disc space preparation in the unilateral TLIF procedure[3]. The SpineJet XL devices are surgical instruments tools for the surgeon to use in preparing the disc space for interbody fusion they are not a therapy or prosthetic; they replace some manual surgical instruments and do not require any other changes to surgical methods. The advantages offered to the surgeon are improvements in efficiency, safety, and consistency. Advantages to the hospital are shorter procedures, fewer instruments to process, and more predictable overall lower costs.

Methods

As laid out by Polly, et al[4], two economic models were formulated. The first, accounts for costs and offsets in the index hospitalization, and the second includes the cost of revisions for failed fusions. A sensitivity analysis was performed to show how the economic outcomes would shift based on changes to the assumptions in the models. A Monte Carlo simulation was performed to show the distribution of total cost savings resulting from the expected variation of input variables between institutions, surgeons, and patients.

Data

The data used for the analysis was derived from four sources: clinical experience reported by users of the SpineJet Hydrosurgery System; experimental results of cadaver studies comparing the performance of the SpineJet Hydrosurgery System to conventional instruments; peer reviewed journal articles; and expert opinion.

The tables following show the data utilized to build the cases analyzed in the economic models.

Table 1
O.R. Time Savings (Clinical Experience)

Application	Time Saved
Disc Preparation	10.25 minutes per level
Difference based on 1.4 levels per case[†] [9]	14.35 minutes per case

†1.4 levels per case is used based on the average number of levels in the procedures where the SpineJet XL was used and is validated by Potter[9] as typical over a large sample.

Table 2
Instrument Usage (Cadaver Studies)

Method	Resterilizable Instruments Used for Disc Preparation
Conventional	7.5
SpineJet XL	2.5
Absolute Difference	5
Relative Difference	67% fewer with SpineJet XL

Table 3 Insertions and Withdrawals (Cadaver Studies)	
Method	**Number of Instrument Insertions and Withdrawals for Disc Preparation**
Conventional	124 per level
SpineJet XL	21 per level
Absolute Difference	103 per level
Relative Difference	83% fewer with SpineJet XL

Table 4 Nucleus Removal* as a Proportion of Endplate Surface Area (Cadaver Studies)	
Method	**% Prepared**
Conventional	81%
SpineJet XL	95%
Absolute Difference	14%
Relative Difference	17% more with SpineJet XL
*Soft tissue removal from the intervertebral space	

Table 5 Nucleus Removal in the Posterior Contralateral Sector as a Proportion of Endplate Surface Area (Cadaver Studies)	
Method	**% Prepared**
Conventional	45%
SpineJet XL	88%
Absolute Difference	43%
Relative Difference	96% more with SpineJet XL

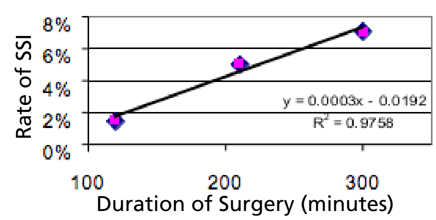
Table 6 Endplate Prepared* as a Proportion of Endplate Surface Area (Cadaver Studies)	
Method	**% Prepared**
Conventional	70%
SpineJet XL	86%
Absolute Difference	16%
Relative Difference	23% more with SpineJet XL
*Soft tissue and cartilage removed from the endplate	

Table 7 Endplate Prepared* as a Proportion of Endplate Surface Area (Cadaver Studies)	
Method	**% Endplates Damaged**
Conventional	48%
SpineJet XL	23%
Absolute Difference	25%
Relative Difference	53% less with SpineJet XL
*Preservation of the hard endplate without excavation of the underlying cancellous bone	

Table 8 Variable Costs [5,6]	
Catergory	**Cost**
Operating Room Time	$58 per minute
Reusable Instrument Processing	$17 per instrument

Table 9 Complications, Failure Rates, Costs [1,4,7,8,9,10,11,16,17]		
Catergory	**Frequency**	**Cost**
Pseudarthrosis	10%	$19,101
Herniation	1%	$12,361
Nerve Injury	9%	$1,161
Incidental durotomy	8%	$2,185
Surgical Site Infection	3%	$67, 568

Figure 1
Surgical Site Infection v. Duration of Surgery[16]



Results

Index Hospitalization Model

Basic index hospitalization costs and offsets can be analyzed straightforwardly by examining the cost of the SpineJet XL versus the direct reductions in hospital resource consumption. A nine hundred and seventeen dollars savings are realized as a result of the superior efficiency of the SpineJet HydroSurgery System, offsetting 90% of the $1010 device cost. Additional savings that result from the SpineJet's improved safety and effectiveness can also be estimated. Expert opinion forecasts reductions in complications due to the 83% fewer instrument insertions and withdrawals and the superior disc space preparation (see Tables 4, 5, 6, and 7). Correlation of the rate of surgical site infection to the duration of surgery (see Figure 1) allows estimation of the reduction in surgical site infections as a result of the time savings provided by the SpineJet XL. The combination of savings from improved efficiency and safety more than offsets the cost of the SpineJet XL and provides a net $303 economic benefit to the hospital for the index hospitalization.

Table 10 Basic Costs & Offsets	
Category	**Cost**
Cost of SpineJet XL	$1,010
Savings in operative time = $58 per min x 14.35 min (1.4 levels per procedure [9])	$832
Savings in Instrument processing = $17 per instrument x 5 instruments	$85
Basic net cost when using the SpineJet XL	$93

Table 11 Reduced Complications Rates & Savings		
Category	**Absolute Reduction Rate**	**Savings Per Surgery**
Herniation	0.4%	$53
Nerve Injury	3%	$30
Incidental Durotomy	1%	$22
Surgical Site Infection	0.4%	$291
Additional savings from reduced complications		$396

Longer Term Model

The frequency of pseudarthrosis requires consideration whenever the economics of lumbar interbody fusion are evaluated. The rationale for believing that the SpineJet Hydrosurgery System may have some impact on the rate of pseudarthrosis is based on the significance of the cross-sectional area provided for fusion[12], the need to preserve the endplate as a strong foundation for the implant[13], and the importance of removing soft tissue that can interfere with osseous ingrowth[14] or inhibit the effectiveness of rhBMP[15]. If we consider that fusion is likely to fail if either the cross-sectional area of the construct is insufficient to withstand the forces to which it is exposed, or if the strength of the vertebral body cannot support the load placed upon it, we can see that the SpineJet XL can be anticipated to have a positive impact in preventing pseudarthrosis. Expert opinion conservatively estimates reductions in pseudarthrosis due to superior soft tissue removal, greater cross-sectional area of the disc space prepared for fusion, and less damage to the endplates.Thus the total expected economic benefit from using the SpineJet Hydrosurgery System for disc preparation for lumbar interbody fusion is $1067 per surgery.

Table 12 Reduced Failure Rate & Savings		
Category	**Absolute Rate Reduction**	**Savings per Surgery**
Pseudarthrosis	4%	$764

Sensitivity Analysis

In order to assess the predictability of the savings estimated a sensitivity analysis is performed, using high and low values of key parameters to recalculate costs and offsets. Savings that reverse as a result of small changes to any of a number of parameters would need to be evaluated carefully for an institutions particular cost profile. Savings that withstand variation in more than one dimension can be considered more predictable.

Tables 11, 12 and 13 reflect the impact on the components of the cost savings when the assumptions underlying the estimates are varied. The sensitivity analysis shows that even when the most sensitive variables are set to the lowest expected values a positive economic benefit can be anticipated from using the SpineJet Hydrosurgery System for disc preparation for lumbar interbody fusion.

Table 13 Sensitivity To Basic Costs & Offsets	
Category	**Cost**
Cost of SpineJet XL	$1010
Savings in operative time = $(50 to 66) per min x 14.35 min	$717 to $947
Savings in Instrument processing = $(14 to 20) per instrument x 5 instruments	$70 to $100
Basic net cost when the most sensitive parameter is varied	$208 to ($22)

Table 14 Reduced Complications Rates & Savings		
Category	**Range of Absolute Rate Reduction**	**Range of Savings Per Surgery**
Herniation	0.2 to 0.6%	$25 to $74
Nerve Injury	1 to 5%	$12 to $58
Incidental Durotomy	0.5 to 1.5%	$11 to $33
Surgical Site Infection	0.2 to 0.6%	$145 to $436
Additional savings from reduced complications when the most sensitive parameter is varied		$251 to $541

Table 15 Reduced Failure Rate & Savings		
Category	**Range of Absolute Rate Reduction**	**Savings per Surgery**
Pseudarthrosis	2 to 6%	$382 to $1146

Monte Carlo Simulation

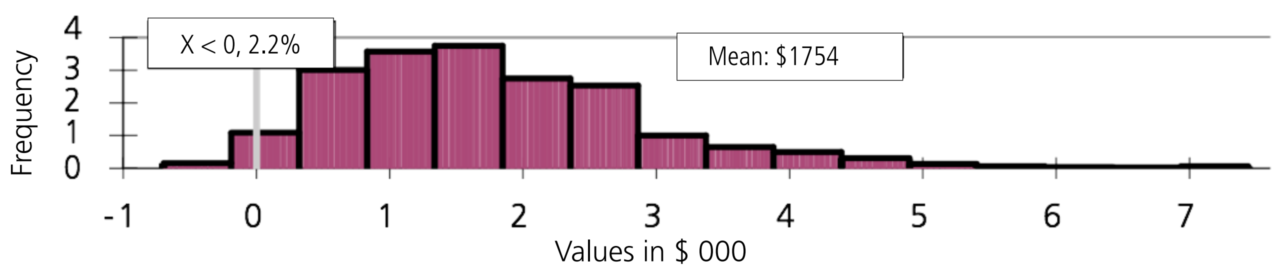
The Sensitivity Analysis demonstrated that the savings are robust; however, when all of the variables discussed above are examined in the context of actual cases performed by different surgeons at different institutions it is recognized that there will be variation around the mean values of expected savings. A Monte Carlo simulation is used to show how the results may vary by incorporating estimates of variables' dispersions and distributions, which are entered into a software application designed for this purpose (@Risk, Palisade Corp., Ithaca, NY). This variation is then incorporated in repeated iterations, calculating results for individual cases. The results of numerous iterations (we used 1000) are then compiled to show how results can be expected to be distributed as a result of the expected variability. The Monte Carlo Simulation shows that when all of the sources of variability are incorporated, use of the SpineJet HydroSurgery System results in a positive economic benefit 98% of the time with a mean Total Cost Savings of $1754.

Table 16
Monte Carlo Simulation Inputs

Parameter	Mean	Minimum (Mean–2 Std Dev)	Maximum (Mean+2 Std Dev)	Distribution	Basis
Levels Per Patient Per Surgery	1.4 disc levels	1	4	Discreet	Potter[9]
Disc Prep Time Savings	10.25 min/level	0	27.5	Discreet	Clinical Data
OR Time Cost	$58/min.	43	73	Uniform	Various Institutions
Reduction in Reusable Instrument Usage	5 instruments	0	9	Discreet	Cadaver Studies
Instrument Processing Cost	$17/instrument	14	20	Uniform	Yang[6]
Complication Rate Reductions	See Table 9	See Table 12	See Table 12	Uniform	Expert Panel
Complication Costs	See Table 9	Varies*	Varies*	Normal	See Table 9
Failure Rate Reduction	4%	2%	6%	Uniform	Expert Panel
Failure Costs	$19,101	$0*	$38,202*	Normal	Polly[4]

*50% of the Mean Complication or Failure Cost was used to estimate the Standard Deviation of those costs based on analysis of the 2004 Medicare Provider Analysis and Review database.

Distribution for Total Cost Savings



Discussion

The TLIF approach to lumbar interbody fusion was developed to address complications and morbidity associated with bilateral PLIF. Bilateral PLIF was developed as an improvement over ALIF. TLIF has been demonstrated to have economic advantages over ALIF and fewer complications than PLIF. The SpineJet Hydrosurgery System was designed to address the main weakness and primary concern with the TLIF approach adequacy of disc space preparation.Clinical experience and cadaver studies have demonstrated that the SpineJet Hydrosurgery System delivers greater efficiency with regards to shorter procedure time and reduced instrument usage. Safety and performance benefits include substantially fewer instrument insertions and withdrawals and a greater proportion of the disc space prepared for fusion with superior preservation of the hard endplate.

Reductions in the basic procedural costs have been shown to more than offset the cost of the SpineJet XL and additional savings can be anticipated when decreased complications and failure rate are considered. Sensitivity analysis shows that the economic benefits of the SpineJet Hydrosurgery System stand up when key parameters are varied.

Conclusion

In their article published in July 2003, Javernick, Kuklo and Polly concluded, "Development of newer instruments that can further help improve safe removal of disk using the unilateral approach is necessary."[3] The SpineJet Hydrosurgery System effectively meets that need and now has been shownto do so in an economically beneficial manner. The TLIF procedure has been documented to reduce costs compared to ALIF[1] and decrease complications compared to PLIF[2]. The SpineJet Hydrosurgery System addresses the major concern with the TLIF procedure adequacy of disc space preparation thereby enabling the adoption of an improved method while reducing both short and longer term costs.

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Notes

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