Retrospective Cost Effectiveness Analysis of Implanet Jazz Sublaminar Bands for Surgical Treatment of Adolescent Idiopathic Scoliosis

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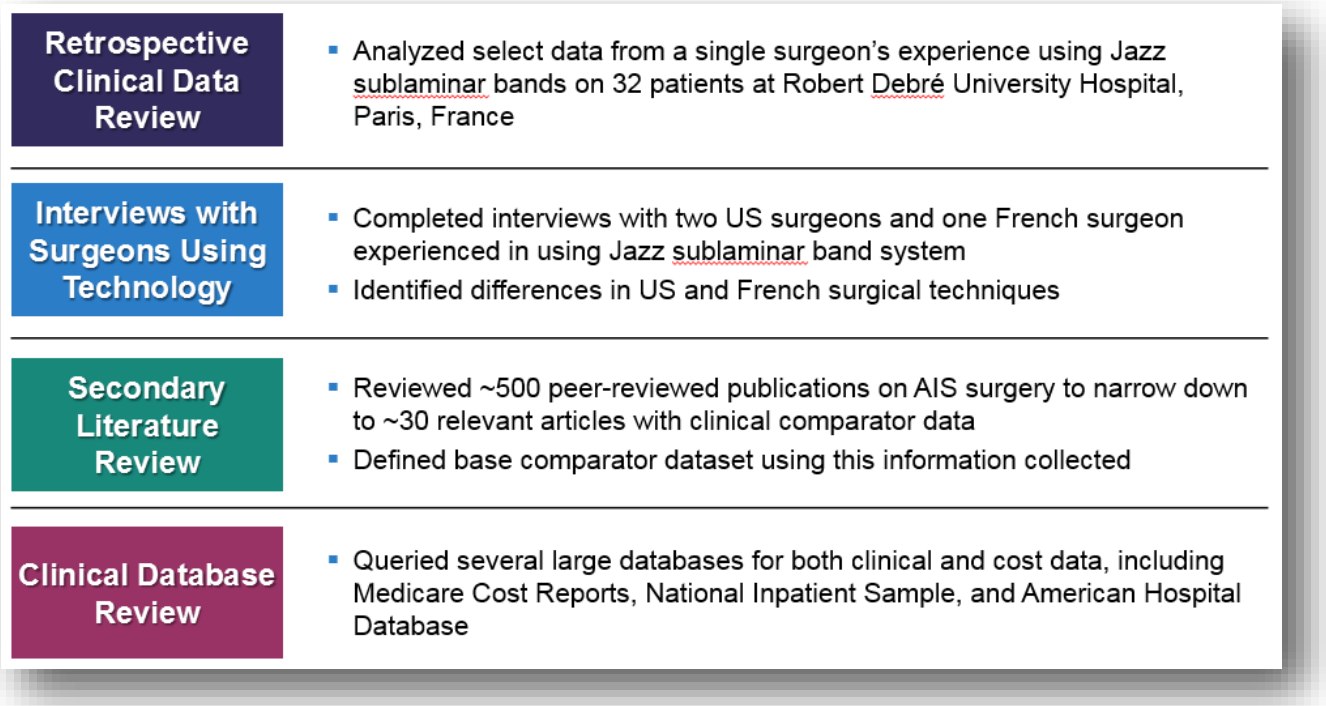
Short Title: Economic Impact of Novel Sublaminar Bands for AIS Fusion on Hospital Costs

Background and Objectives | Recent literature has shown clinical benefits of posteromedial translation using sublaminar bands, such as Implanet's Jazz bands, for treatment of AIS. This study was designed to estimate the economic impact of the Jazz system on US hospital costs associated with AIS fusion surgery, based on an analysis of several of the largest known cost drivers associated with spinal fusion surgery for treatment of AIS.

Methods | Data on surgical outcomes from recent surgeon experience with the Jazz system was compared to known surgical outcomes in the United States using pedicle screw constructs. The comparison was based on a retrospective analysis of 32 AIS surgeries performed at Robert Debré University Hospital in Paris using Jazz sublaminar bands, a comprehensive clinical literature review of AIS procedures, and qualitative interviews with a small number of US-based spine surgeons. Hospital costs were determined and validated using multiple sources, including peer-reviewed literature, Medicare Cost Reports, implant price lists from hospital systems, and other publicly available sources.

Figure 1: US Cost Effectiveness Research Methodology



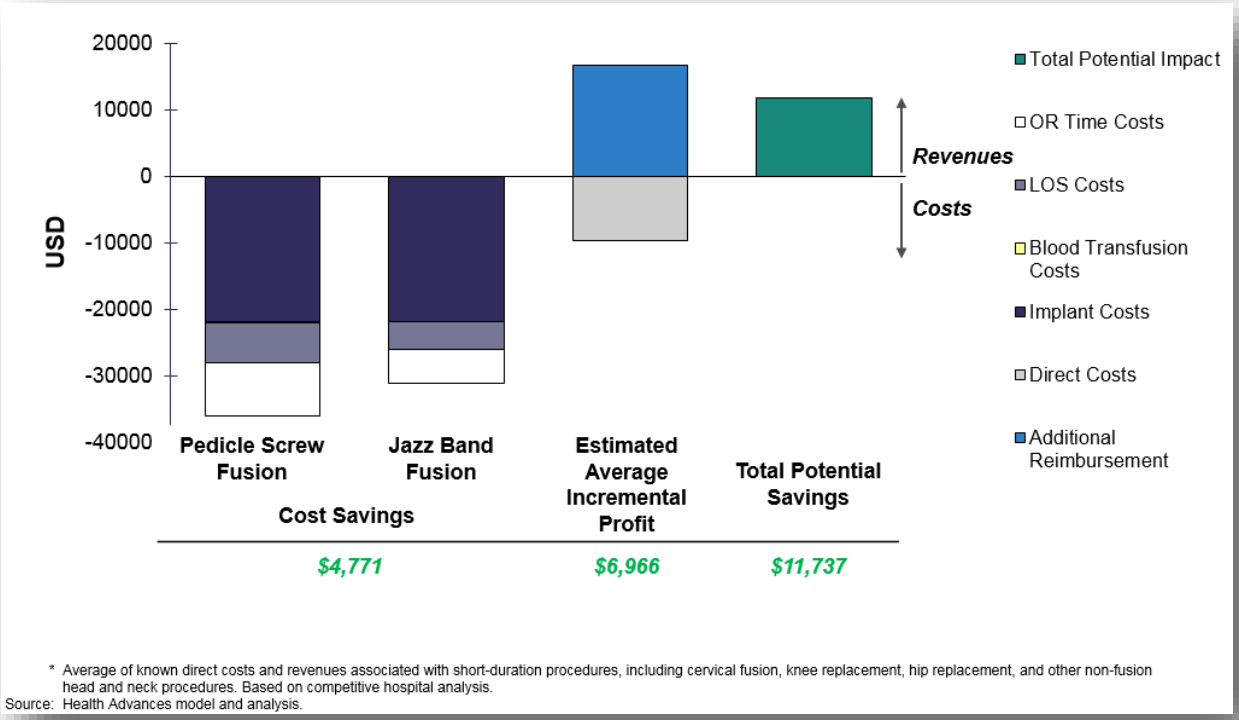
Key differentiating metrics of the Jazz system identified in the literature, and confirmed in interviews, include shorter operative time, reduced blood loss and transfusion rates, lower implant volumes, shorter length of stay (LOS) in a US hospital, and reduced radiation exposure, all of which are significant known cost drivers associated with AIS spinal fusion surgery.

Results | Quantifiable savings from the shorter operative times, lower transfusion rates, and shorter US hospital LOS associated with Implanet's Jazz system are estimated to ***reduce US hospital costs by approximately $4,771 per procedure***. Given that many US hospitals which perform AIS spinal fusion procedures are conducting more than 100 surgeries each year, overall realized savings *could total US$500,000 per year per hospital*.

In addition, because the shorter procedure duration associated with the Jazz sublaminar bands is significant, it may allow hospitals to perform an additional orthopedic or spine surgery during the extra time freed-up from each AIS spinal fusion performed with Jazz. Recent studies evaluating the estimated profit contribution of orthopedic and spine surgeries vary, but ***incremental profit contributions*** of common US surgical cases that could be performed in the time saved as a result of the faster Jazz Technique ***can total ~$4,400 to $8,200 per procedure,*** depending on procedure type, performing institution, and payer mix.[i,ii] If one of these procedures is able to be added to the surgical schedule for each AIS surgery performed with Jazz, *each US hospital could realize incremental profits of $440,000 to $820,000 per year,* assuming an average annual volume of 100 AIS procedures.

The Jazz system also has additional areas of potential benefit to the hospital, surgeons, and patients such as lower radiation exposure times for both OR staff and patients due to the elimination of intraoperative O-arm use, reduction in intraoperative anesthesia and postoperative pain medications, reduced need for correction of misplaced pedicle screws, and improved clinical outcomes, including improved sagittal angle as well as Cobb angle correction. These benefits were not quantified in economic terms in this study.

Figure 2: Expected US Hospital Net Savings and Profit Contribution per Procedure



* Average of known direct costs and revenues associated with short-duration procedures, including cervical fusion, knee replacement, hip replacement, and other non-fusion head and neck procedures. Based on competitive hospital analysis.

Source: Health Advances model and analysis.

Limitations | This study did not allow for a direct comparison of all of the costs associated with spinal fusion surgery. The study relied on a thorough retrospective clinical literature review assessing the impact of five key clinical factors on overall costs to the hospital associated with AIS fusion surgery compared with data from 32 AIS cases performed at the Robert Debré University Hospital in Paris, as well as a qualitative feedback from two US surgeons' initial experience with Jazz sublaminar bands. Future research will be required to confirm comparable experience across a larger number of US surgeons, to refine the specific costs associated with each of these major cost drivers of AIS surgery across a broader panel of US institutions performing these procedures, and to quantify the total expected savings from the use of the Jazz system in US hospitals.

Conclusions | The Jazz system appears to result in lower overall costs to the hospital associated with performing spinal fusion surgeries for AIS. The major drivers of cost savings include reduced procedure time, shorter length of stay, and lower blood transfusion rates. Additional prospective studies are underway to quantify the exact cost savings associated with adoption of this technology in several US hospitals.

Introduction

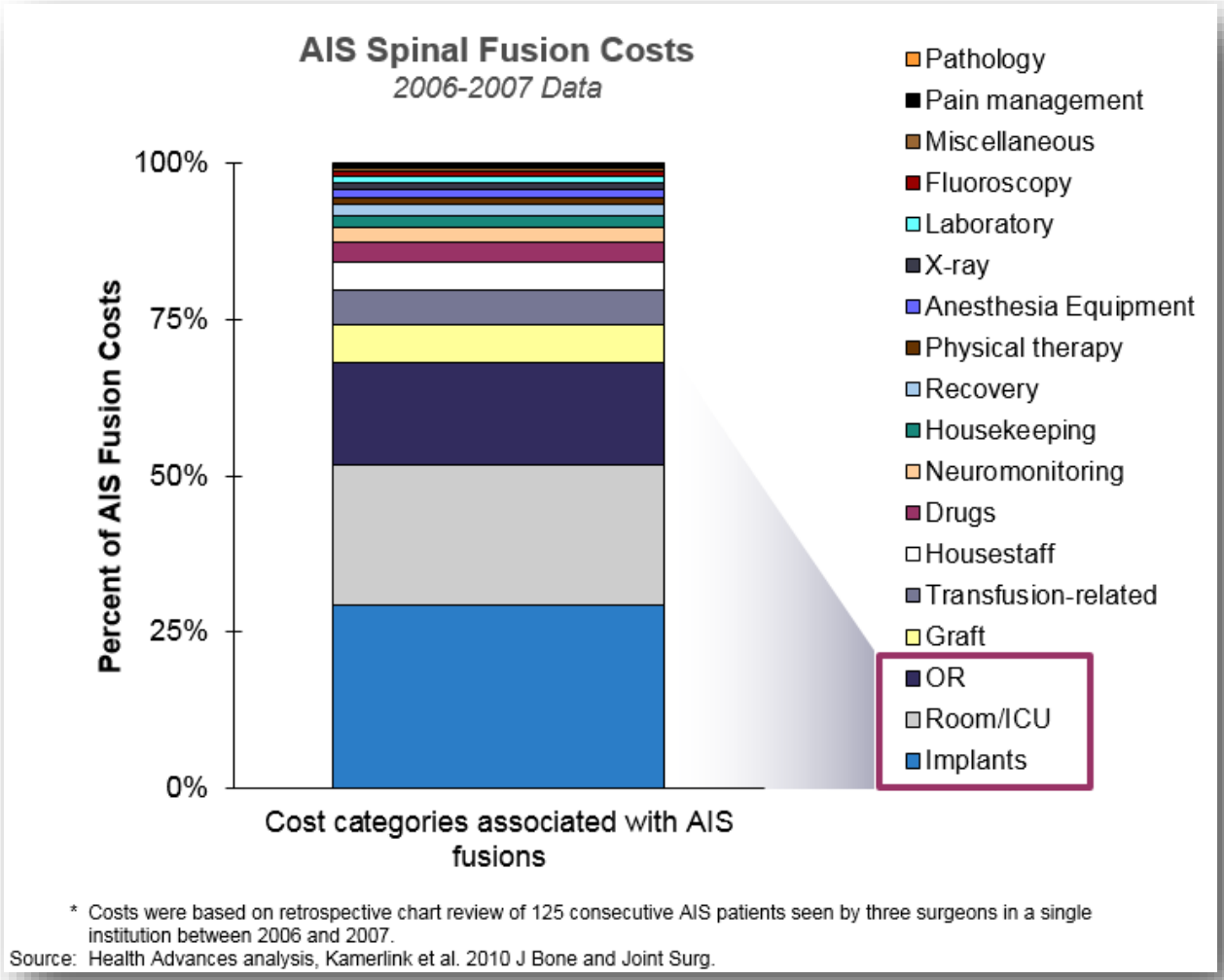
Adolescent idiopathic scoliosis (AIS) is the most common type of scoliosis in adolescents, affecting nearly 2% to 3% of children between the ages of 10 and 16 years.[iii] Patients with severe curves or curves with a high likelihood of progression are surgically managed, undergoing spinal fusion surgery in an effort to prevent curve progression and to correct deformity. US hospital expenditures associated with AIS management surpassed $500 million in 2007, and have continued to increase dramatically in recent years. A recent analysis of adjusted US hospital charges and costs associated with AIS spinal fusion surgery demonstrated that adjusted hospital charges and costs nearly doubled from 2001 to 2011, a significantly greater increase compared to other inpatient pediatric admissions, and likely indicative of a genuine change in hospital economics associated with AIS spinal fusions over that timeframe.[iv]

One of the potential drivers of increased costs associated with AIS spinal fusions is likely the shift in utilization of the historical gold-standard hook techniques, which declined in favor of pedicle screw techniques. New data for all-pedicle-screw or hybrid constructs demonstrated improved correction and stabilization of spinal deformities, as compared to hooks and pedicle screw constructs, and so were widely adopted. With this transition, the implant density associated with AIS spinal fusion surgeries has increased dramatically and the average number of implants used per case has nearly doubled in some institutions, resulting in increased implant costs.[v] Given the economic constraints of the US healthcare industry, and increasing scrutiny surrounding implant costs, several studies have attempted to compare the cost differences amongst hook, hybrid, and pedicle screw constructs to better understand the clinical and economic implications of the shift in techniques, but consensus has not yet been reached.[vi]

The sublaminar band system was developed over 10 years ago by several French surgeons and consists of implants which allow AIS correction by posteromedial translation. A novel sublaminar band has been developed to provide an alternative technique for AIS spinal fusion surgeries. This has been broadly adopted within the French hospital system, is being widely utilized in other European countries, as well as in AIS surgeries in 14 countries around the world. It was recently introduced in select US hospitals for both AIS and neuromuscular scoliosis. Sublaminar bands have been shown to provide similar coronal and axial correction, while offering improved sagittal correction. Other preliminary clinical data are also promising, with surgeons noting several advantages to the sublaminar band technique, including reduced

implant volumes, shorter operative time, reduced blood loss and lower transfusion rates, and shorter postoperative hospital stays and recovery times. A reduction in radiation exposure for the patients, surgeons, and staff has also been widely documented, due to the reduced need for intraoperative imaging. As the technique gains broader adoption within the United States, it is important to consider its impact on hospital economics, particularly given the recent transition in surgical techniques to all-screw constructs, and cost implications associated with that trend. The purpose of this study was to quantify the economic impact of the Jazz sublaminar band system on key drivers of US hospital costs associated with AIS spinal fusion procedures.

Figure 3: US Hospital Cost Breakdown for AIS Surgeries



* Costs were based on retrospective chart review of 125 consecutive AIS patients seen by three surgeons in a single institution between 2006 and 2007.

Source: Health Advances analysis, Kamerlink et al. 2010 J Bone and Joint Surg.

Methods

Cost Savings Analysis

Given the relatively small total number of AIS spinal fusions per year in a given hospital, as well as the variety of confounding factors that impact the outcomes of surgical procedures, including patient and curve characteristics such as the severity of AIS curvature, and individual surgeon training and technique, most studies reporting surgical and outcomes data on various techniques of AIS are limited in scope. To date, no prospective clinical trials have directly compared the differences in surgical and clinical outcomes between pedicle screw constructs (the "Pedicle Screw Technique") and Jazz sublaminar bands (the "Jazz Technique"), but several studies have reported on the outcomes of pedicle screw constructs and sublaminar bands separately. Preliminary studies have documented the results of AIS fusions performed using other sublaminar bands and identified several key improvements in surgical outcomes compared to pedicle screw constructs, all of which are also known drivers of cost, including shorter operative time, lower intraoperative blood loss, and reduced radiation exposure.[vii] Interviews with a limited number of surgeons experienced in using the Jazz sublaminar bands in the United States and in France confirmed these improvements and also identified shorter length of stay as an additional improvement over the All-Pedicle-Screw Construct. As such, we focused the analysis on four of the largest known cost drivers: implant volume and costs, operating room time and costs, blood transfusion frequency and costs, and length of stay and costs. Reduced radiation exposure is an important clinical improvement, impacting patients, surgeons, and hospital staff. The economic impact on hospitals was not quantified in this study, however, due to the limited information available on the actual cost impact associated with the use of fluoroscopy and other radiographic imaging on patients, surgeons and staff.

To evaluate the differences between procedure techniques, we compared an unpublished dataset of information compiled from a retrospective chart review of 32 AIS cases, performed by a surgeon at the Robert Debré University Hospital in Paris, using Jazz sublaminar bands in 32 patients to available published literature on surgical outcomes associated with pedicle screw constructs. Assumptions regarding the differences in key metrics across the Pedicle Screw Technique and the Jazz Technique are presented in Table 1. All of the data on the Pedicle Screw Technique was obtained from a combination of relevant sources, including peer-reviewed articles, data obtained from the Medicare National Inpatient Sample, and qualitative interviews with US board-certified orthopedic surgeons specializing in treatment of spinal scoliosis. An in-depth literature review was performed to validate and quantify differences

in the surgical techniques. Two US board-certified orthopedic surgeons were interviewed to confirm findings in clinical literature and identify any differences between AIS procedures performed in France and in the US to ensure we could draw comparisons across datasets.

Table 1: AIS Spinal Fusion Technique Comparison of Key Metrics by Construct Type

	Metric	Pedicle Screw Constructs	Jazz Construct	Sources and Notes
Implant Volume	Pedicle Screws	~16-18	~6	Based on estimates in peer-reviewed clinical research and interviews with spine surgeons in the US and France.
	Jazz Bands	0	~7	
	Hooks	~4	~4	
	Connectors	~3	~3	
	Rods	2	2	
Blood Loss	Patients Receiving Transfusion	~30% of patients	0 of 32 patients	Based on estimates in peer-reviewed clinical research, National Inpatient Sample data, and experience of one French surgeon at the Robert Debré University Hospital in Paris (32 patient dataset)
Procedure Duration	Operative Time	~327 minutes	~197 minutes	Based on estimates in peer-reviewed clinical research and experience of one French surgeon at the Robert Debré University Hospital in Paris (32 patient dataset)
Length of Hospital Stay (US)	Length of Stay	~5-7 days	~3-5 days	Based on inputs from a US surgeon's experience using the Jazz system

Relevant comparator data for the Jazz Technique was derived from the 32 patient unpublished dataset from cases performed at the Robert Debré University Hospital in Paris and used to determine the number of implants used per patient, the average operative time per procedure, and the average blood loss and transfusion rates per patient. Institutional protocols

and practices surrounding the length of stay at the French children's hospital in which the data were collected prohibited us from drawing specific conclusions around the length of stay from this dataset. However, qualitative feedback from a US surgeon at the Florida Center for Pediatric Orthopaedics who had used both systems indicated a significant improvement in length of stay in patients receiving Jazz sublaminar band implants vs. all-pedicle screw systems. This feedback was included in this analysis, but should be further validated to confirm these preliminary, qualitative findings.

Table 2 displays the unit costs used in the analysis to determine the estimated impact of Jazz sublaminar bands on US hospital costs associated with AIS spinal fusions. Cost inputs were triangulated from a variety of sources, including hospital purchasing price lists for the relevant implants obtained from a sampling of hospitals, hospital surveys, peer-reviewed journal articles, and other published sources. Interviews with US surgeons validated the estimated costs associated with the implants.

Table 2: Average Unit Cost Assumptions for a Typical US Hospital

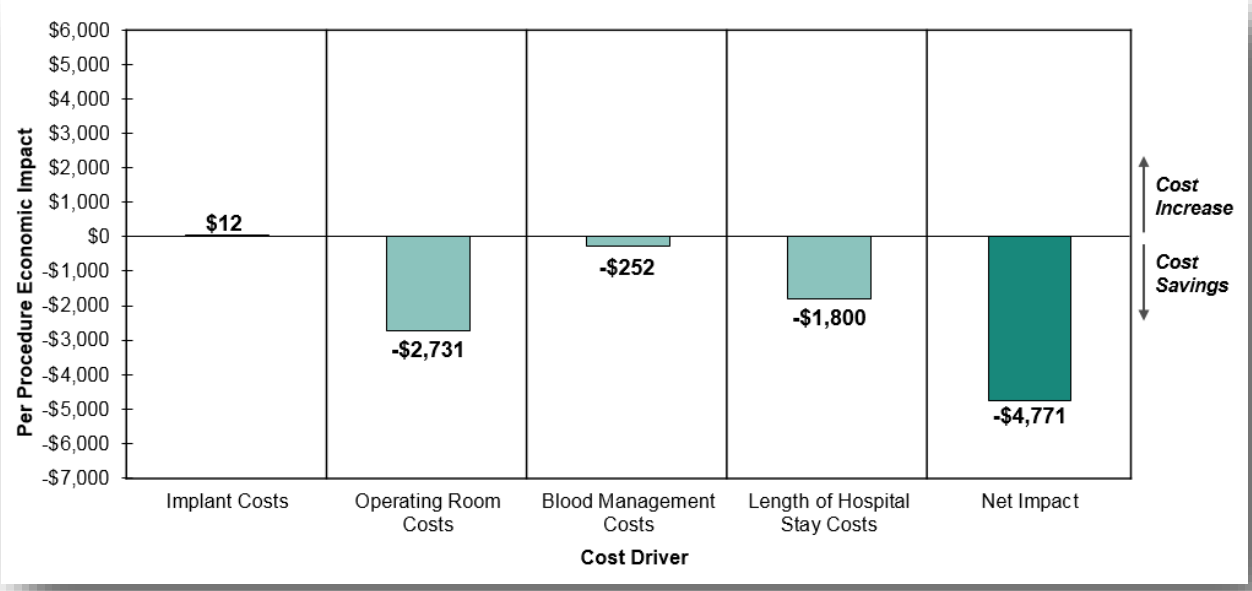
	Metrics	Estimated Cost per Unit (USD)	Sources
Implants	Pedicle Screws	~$922 per screw	Hospital Price Lists, Orthopedic Network News
	Jazz Bands	~$1,450 per band	Implanet
Blood Loss	Cost of Allogeneic Blood Transfusion	~$1,200 per unit	Mayo Clinic, Mao et al 2014 PLOSOne
Procedure Duration	Operative Time	$21.50 per minute	Medicare Cost Reports, Marcario A 2010 J Clin Anesthes, Fautsch M 2011 Bone and Science J
Length of Hospital Stay	Cost for 1 Day LOS on General Hospital Floor	$1,200 per day	Medicare Cost Reports, Kaiser Family Foundation, UCLA 2013, Critical Care Medicine 2005

A key distinction to note between hospital charges and costs is that hospital charges are what the hospital would bill a patient for each service or test if that patient were self-insured,

whereas costs are the amount the hospital actually spends to provide each service or test. While hospital charges are generally more accessible than hospital costs, they tend to grossly overstate a hospital's actual cost of products or services. Therefore, calculations of costs are often derived from charges using a hospital-specific cost to charge ratio to approximate hospital costs. This analysis, however, sought to assess the actual costs associated with each of the key metrics, as opposed to using overall costs calculated as percentage of charges, in order to be as precise as possible.

The estimated US costs associated with the Pedicle Screw Technique and the Jazz Technique were compared across several key cost drivers to estimate the economic impact of the Jazz Technique on hospital costs. Given the known variability in costs across individual hospitals due to their geographic location, size of institution, mix of patients, and general cost and operational management, individual assumptions on the cost inputs were evaluated across a representative range of sample hospitals to validate the strength of the conclusions. The cost impact was assessed using a minimum and maximum plausible value for each major assumption. A summary of the cost savings by key metric is shown below in Figure 4.

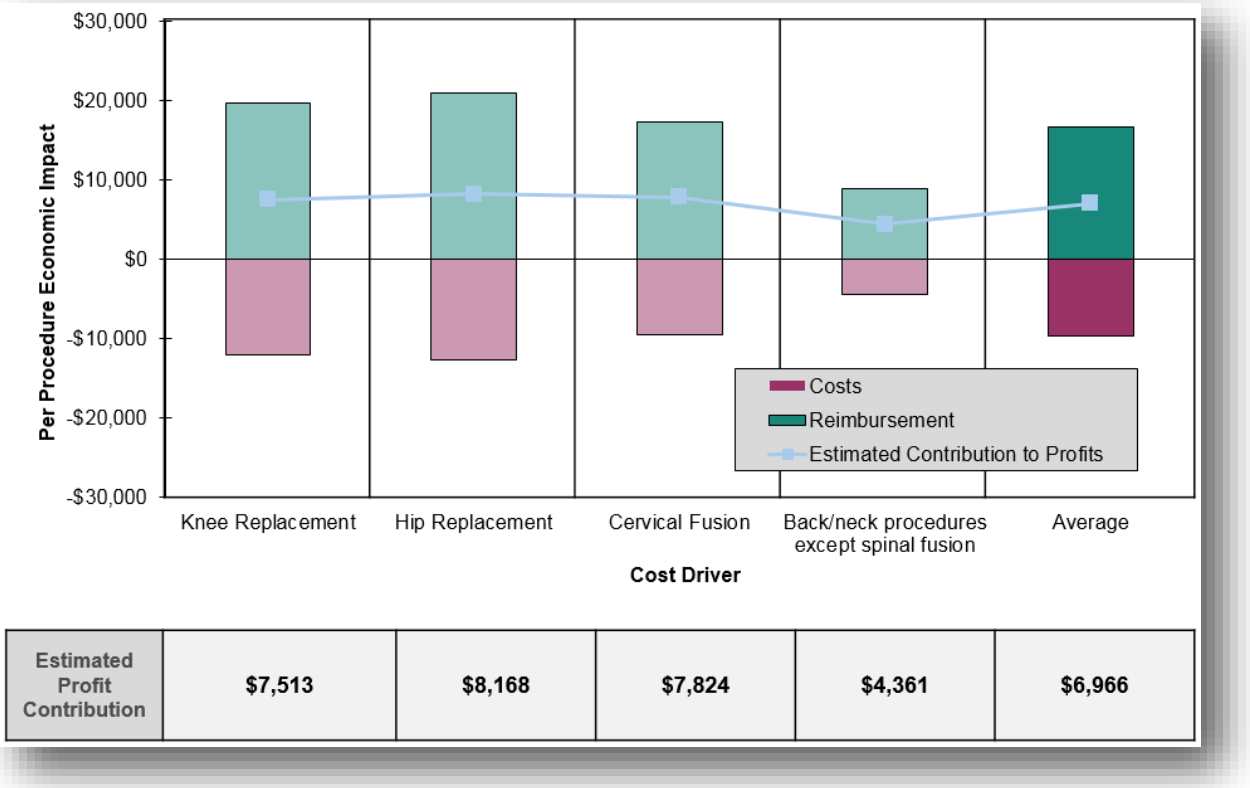
Figure 4: Estimated US Hospital Cost Savings per AIS Procedure by Cost Metric



Incremental Procedure Profit Contribution Analysis

Given the significant time savings that can result from use of the Jazz Technique, this analysis also sought to quantify the potential incremental profit that a hospital could realize by performing an additional procedure during the OR time saved for each AIS procedure performed with the Jazz Technique over the Pedicle Screw Technique. Limited data are available on the actual profit contribution associated with individual hospital inpatient procedures. Therefore, to conduct this analysis, published data on average reimbursement amounts and costs were analyzed to estimate the per-procedure profit contribution of four separate orthopedic procedures that could likely be performed within the amount of time saved. Data on average US private payer reimbursement, as well as direct costs per procedure for total knee replacement, total hip replacement, cervical spinal fusion, and a grouping of other non-fusion back/neck surgeries, are shown in Table 3.[viii] Data on the reimbursement and direct costs were based on peer-reviewed literature and a published white paper. The peer-reviewed literature was based on 2008 data from US hospitals in competitive markets. To estimate the profit contribution in 2012 dollars, the reimbursement and direct costs from literature were adjusted based on trends in US Medicare reimbursement for implant procedures and based on trends in costs based on the cost-to-charge ratios reported to Medicare. The published white paper data was based on 2012 dollars and was not converted. The reimbursement and direct costs were averaged across the four procedures to estimate the average expected profit contribution of an additional procedure that could be added to the OR schedule for each AIS performed using the Jazz Technique.

Figure 5: Adjusted Incremental Profit Contribution of Various US Orthopedic Procedures



Estimated Profit Contribution	$7,513	$8,168	$7,824	$4,361	$6,966

Results

Overall Savings

For the cost drivers analyzed, the average US hospital costs associated with the Pedicle Screw Technique was $35,094 per procedure while the average costs associated with the Jazz Technique was $30,323, resulting in a savings of ~$4,771 per procedure. The most significant savings resulted from reduced operative time, accounting for ~$2,731 in savings. Experience at the Florida Center for Pediatric Orthopaedics indicated a 1 to 2 day shorter length of stay associated with the use of the Jazz System, which translated to ~$1,800 in savings using average US hospital costs per day for an inpatient stay on a general floor, and reduced allogeneic transfusion rates also resulted in a slight reduction in costs of ~$258. The difference in implant costs was minimal, resulting in an additional cost of ~$12 based on the estimated average selling prices (ASPs) of pedicle screws and Jazz bands used in this analysis.

In addition to the savings generated as a result of reduced costs associated with operative time, length of stay, and blood loss, potential incremental profit contribution from additional procedures could reach ~$6,966, resulting in incremental profit contribution of

~$11,737 to an average US hospital per AIS spinal fusion performed (this includes accounting for the costs associated with OR time across the two procedures combined). Based on the cost analysis, a US hospital performing 100 AIS spinal fusions per year could realize over $477,000 in cost savings alone each year. Accounting for the potential incremental profit contribution of an additional procedure, the total impact on the average US hospital's profitability could reach nearly $1.17MM. The per procedure net savings and incremental profit contribution expected when the Jazz laminar band system is used in AIS procedures vs. the all-screw system are summarized in Figure 6 below.

Figure 6: Expected US Hospital Net Savings and Profit Contribution per Procedure

		Typical US Costs with Pedicle Screw Construct		Typical US Costs with Jazz Sublaminar Bands		Estimated US Hospital Cost Savings and Incremental Profit Contribution with Jazz
Typical Costs to US Hospitals	Implants	$21,811	–	$21,823	=	~($12)
	Blood Transfusions	$252	–	$0	=	~$252
	Operating Room Time	$7,891	–	$5,160	=	~$2,731
	Length of Inpatient Stay	$6,000	–	$4,200	=	~$1,800
Impact on US Hospital Costs Per Jazz AIS Fusion					=	Savings of ~$4,771
Incremental Profit[1]	Additional Procedure Possible Due to AIS Procedure Time Savings with Jazz	N/A		~$6,966	=	Incremental profit of ~$6,966
Total Incremental Profit Contribution to a Hospital Per Jazz AIS Fusion						+$11,737 per procedure

[1] Accounts for the average profit per procedure of four common procedures performed in orthopedic ORs, subtracting out the OR costs associated with those additional procedures.

Source: Health Advances interviews and analysis.

Discussion

The increasing costs associated with healthcare in the United States are putting additional pressure on hospitals to provide quality care at a lower cost. Understanding the cost implications associated with adopting a novel surgical technique or implant type is critical for hospitals to make thoughtful decisions regarding the adoption of various products and/or procedures moving forward. The costs associated with performing spinal fusions for treatment

of adolescent idiopathic scoliosis are thought to have increased over the last 10 years based on the significant increases in adjusted hospital charges and costs. Given the availability of novel techniques for performing AIS spinal fusions, it is critical to assess the economic impact of these techniques on hospitals, patients, and payers. This analysis sought to assess the economic impact of a novel sublaminar band surgical technique on the key drivers of costs associated with AIS spinal fusion procedures from the US hospital's perspective.

Jazz sublaminar bands have been shown in preliminary studies to provide similar improvement in frontal and axial curve correction, as well as improved sagittal curve correction, when compared to traditional AIS fusion techniques. Several other improvements in surgical outcomes which are expected to reduce costs associated with AIS fusions were also identified based on initial studies and surgeon experience, including reduced operative time, reduced blood loss and transfusion rates, and shorter length of stay. The economic analysis presented here demonstrates that the improvements in these metrics alone could result in significant cost savings compared to the traditional Pedicle Screw Techniques.

The greatest reduction in costs results from the reduction in operative time required to perform an AIS spinal fusion surgery using the Jazz Technique. The significant reduction in operative time results in not only direct cost savings to the hospital, but it could also result in the realization of incremental additional profits if the hospital is able to perform an additional surgery, that would otherwise not have been performed at that hospital, within the time saved. Additional cost savings are driven by the potential to reduce a US hospital's overall length of patient stay and by the reduced costs associated with perioperative blood transfusions.

There are several limitations to this preliminary analysis. Several inputs to the model relied on retrospective data collected from a limited number of patient charts whose surgery was performed at a single institution by one surgeon. AIS spinal fusion surgical outcomes vary from surgeon to surgeon and the benefits of this novel technique may not be completely transferrable across surgeons and institutions. In particular, it is noted that learning a novel surgical technique requires a certain number of procedures before consistent results can be realized, so the estimated benefits of this novel technique will likely require each surgeon to move past the 'learning curve' in order to fully realize the projected savings.[ix]

The unpublished patient dataset was compared to previously documented surgical outcomes associated with AIS fusions performed using the Pedicle Screw Technique. While the analysis benefitted from a broad array of peer-reviewed clinical literature on the topic, a

prospective trial, as well as additional real-world experience, will be required to more fully understand and quantify the benefits of the Jazz Technique. Of particular note, anecdotal feedback from one US surgeon's experience was used to estimate the impact of the Jazz Technique on overall length of stay, so additional case data must be collected to validate this finding. Additionally, data availability forced us to limit the analysis to key drivers of cost for which we could find and readily access data. A variety of other potential areas of economic impact should be evaluated in any future studies, including longer-term clinical and quality-of-life (QOL) outcomes, complication and infection rates, and readmission rates, among others. A more detailed cost comparison would also account for preoperative assessments, as well as post-discharge rehabilitation and care.

Another limitation of this analysis was the inability to account for all costs associated with adolescent idiopathic scoliosis procedures. There are other hospital costs associated with performing the procedure which were not considered in this analysis, including a comparison of other direct costs such as surgical supplies, medications, preoperative, intraoperative, and postoperative imaging, postoperative rehabilitation, and direct and indirect costs including utilization of surgical and non-surgical staff. There are also potentially significant differences in indirect costs to the patients and their care-givers, including costs associated with quality-of-life and productivity in work or school (for patients), and lost wages for caregivers who take time off from work to provide care for a family member during the hospitalization and rehabilitation period.

This analysis found potential savings for US hospitals associated with reductions in transfusions, operating room time, and length of stay, as well as potential incremental profits that US hospitals could realize by adding an additional procedure into the schedule in the time saved due to the shorter AIS procedure duration. This incremental profit may not be realized by all hospitals if a hospital is not capacity constrained and turning away procedures, or if it is not able to draw in an additional procedure from another hospital to fill the additional time slot created. This incremental profit relies on having adequate demand for additional procedures that can be performed in the time saved, which may vary significantly from surgeon to surgeon or hospital to hospital. It also relies on the hospital's capacity to take on any potential downstream impact associated with this additional procedure/patient, such as additional hospital beds and appropriate postoperative nursing staff to cover the additional patient(s). Furthermore, the actual incremental profit may vary significantly from hospital to hospital depending on what procedures could be performed during the time saved, the average reimbursement for the

procedure based on the hospital's payer mix, and the actual costs associated with that procedure for the hospital, particularly for orthopedic or spine procedures where implant pricing can dramatically impact the profitability of a given procedure. Individual hospital administrators should assess all of these factors at their own institution to better understand whether incremental profit of this magnitude can be realized.

While limitations to this cost-effectiveness model exist, preliminary data and analysis of the Jazz Technique have demonstrated the potential to significantly reduce US hospital costs based on several key drivers of hospital costs associated with AIS fusion surgeries. Further prospective trials and research investigating the costs associated with AIS fusions should be performed to better understand the exact impact of the Jazz Technique on US hospital costs.

Conclusions

The hospital economic impact evaluation of Jazz sublaminar bands demonstrates that the use of Jazz sublaminar bands could potentially reduce the overall costs to the hospital associated with performing AIS spinal fusion procedures. These savings are directly associated with the shorter procedure duration, reduced blood loss and transfusion rates, and shorter lengths of stay (in the US surgeon's experience with Jazz). Further studies are needed to assess the actual impact of the technique in a variety of institutions to validate these findings and refine the economic impact for a given hospital or hospital system in a real-world setting.

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[i] Robinson JC 2011 Am J Managed Care Jun 1;17(6 Spec No.):e241-248
[ii] Accelero Health Partners 2011 White Paper Trends Impacting Today's Surgical Spine Cases
[iii] Martin et al. 2014 Spine
[iv] Martin et al. 2014 Spine
[v] Martin et al. 2014 Spine
[vi] Kamerlink et al. 2010 J Bone and Joint Surg
[vii] Kamerlink et al. 2010 J Bone and Joint Surg
[viii] Robinson JC 2011 American Journal of Managed Care, Accelero Health Partners 2011 White Paper Trends Impacting Today's Surgical Spine Cases
[ix] Surgeons experienced with the Jazz system who were interviewed for this project estimated that it takes approximately 10-15 surgeries to become fully efficient with this novel implant system and technique