

Surgeon Ownership in Medical Device Distribution

An analysis of cost savings

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Abstract

Background

Surgeon ownership in medical device distribution is a new model that proposes to effectively reduce the costs associated with surgical implants. This model introduces effective market forces into the purchase of implants by establishing a legal framework whereby the surgeon (decision maker) also becomes the purchaser through ownership and management of a stocking distributorship.

Methods

Five existing surgeon-owned distributorships were retrospectively reviewed, and the pricing from these distributorships was compared to 2010 pricing from the best contract or capitated rate for non-surgeon owned distributorships for like implants at the same hospital.

Results

The average first year cost savings associated with the surgeon owned distributorships was 36%, with a total savings for 2010 of \$2,456,521 and an average savings per distributorship of \$490,304. For those distributorships in business for two or more years, the average annual price increase from the surgeon owned entities was -1.76%, which represents a marked improvement given the reported annual price increases in non-surgeon owned distributorships of 7-13% from 1995 (Healy 2006).

Conclusions

This study demonstrates that surgeon owned distribution companies are capable of providing considerable healthcare savings through lower implant costs and reduced annual price escalations as compared to traditional implant distributorships. (The American Association of Surgeon Distributors has established Standards ensuring the ethical and legal application of this model.)

Clinical Relevance

It is expected that these savings will result in improved access, improved hospital clinical support, and an overall reduction in healthcare costs to society.

Introduction

Healthcare costs in the United States continue to place an overwhelming burden on individuals, businesses, local and federal governments. Although some of the rise in health care costs can be attributed to technological advances and an aging population, significant costs are also attributable to fundamental flaws in the economics of healthcare delivery in the United States. One prominent flaw results from separation between the decision maker (usually a healthcare provider) and the purchaser (usually a hospital, government, or insurance company). This creates a 'market failure' whereby typical market forces are not available to control costs. Market failure due to separation of the decision maker and purchaser is intrinsic to many facets of our current healthcare system.

A visible example of this market failure is the orthopedic and spinal implant marketplace. With these types of implants, the surgeon typically selects the specific product to be used based on his/her determination of which implant is best for the patient (usually on a case by case basis). Occasionally, a patient will have such a unique condition that only one or two products will meet their need. For a large majority of patient conditions, however, several competitive products are available. When multiple appropriate product options are available, the surgeon will make a selection based on a combination of factors including: personal experience, preference for product features, sales relationships, marketing, and company loyalty. Once the surgeon selects a specific implant, it is purchased by a hospital or surgery center. The costs of the implants are then borne by the hospital or reimbursed by third-party insurers including Medicare in certain circumstances.

Under the current healthcare paradigm, the purchaser (hospital) is given an order from the surgeon for a specific implant. The purchasing hospital is left with very little leverage in creating competition or in negotiating the price for a specific implant.

Although it is not appropriate for a hospital or government program to specify the brand of surgical implant to be used by a surgeon for a specific patient, one solution is to place the surgeon in a purchasing position. Restoring the roles of decision maker and purchaser to a single entity would thus re-establish normal market forces to, in theory, reduce surgical implant costs. The paradigm shift would align surgeon's decision making algorithm with the priorities of the patient and society – to provide the optimal implant for each patient while eliminating unnecessary expense.

The need for effective market forces in orthopedics is underscored by the growing cost burden of orthopedic procedures and the disproportionate impact of implant costs. By 2030, the demand is projected to increase by 173% for total hip arthroplasties and by 673% for total knee arthroplasties, representing over 4 million primary hip and knee replacements (Kurtz and others 2007). Implant costs account for the largest single expense in total hip and knee replacement operations (Scott and others 2009). Measurable implant cost savings thus has the potential to result in the most significant reduction in the cost for these procedures.

Surgeon ownership of medical device distribution is a novel model that places the surgeon in the position of value-driven implant purchasing, which re-establishes market forces, creates competition, and has the potential to result in substantial healthcare savings. The purpose of this study is to determine if there is evidence of significant cost savings resulting from surgeon ownership of medical device distribution. A secondary goal is to determine whether any cost savings achieved with a surgeon owned distributorship model would be sustained over time. Our null hypothesis is that surgical implant costs to the hospital are the same regardless of whether the implants are provided by a surgeon owned distributor or the conventional paradigm. Given the historical trend for annual inflation of surgical implant costs, we also hypothesized that the cost of implants sold by surgeon owned distributorships (SD) would increase each year.

Materials and Methods

In order to test this hypothesis, a study sample and control were selected from the American Association of Surgeon Distributors (AASD) member database. The AASD is a nonprofit public benefit company that has established recognized compliance standards for certifying distributorships with physician ownership. Surgeon owned distributors may become members of the Association by satisfying all requirements of membership which include the submission of a 12-month log of consecutive surgical cases. The submitted case data is de-identified for any patient specific information prior to submission. Permission was received from each SD for their data to be used in the analysis. Institutional Review Board approval for this study was waived because no individual patient-specific information was utilized in this study.

Criteria for inclusion were availability of a 12-month interval of data ending in July 2011, and hospital willingness to provide independent verification of implant pricing. Based on these criteria a sample population of five surgeon distributorships (SD) was selected.

The hospital pricing for implants supplied by the SD was compared to the best current contract pricing for implants of like quality and function supplied by non-surgeon owned distributorships (NSD) to the same hospital. Current hospital pricing for the NSD was provided by hospital purchasing departments and published hospital capitated rates.

For those distributorships that have been operational for 2 or more years, annual and cumulative data was reported. Comparison of the year to year pricing for each SD would provide data on surgical implant price inflation under the SD model.

One hundred percent of surgical cases from the SD inception through the study date were included in the data set analyzed.

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Results

Five distributorships fulfilled the eligibility for inclusion. The distributorships represented 18 surgeons in four states and are profiled in **Table 1**. Twelve of the surgeons specialize in general orthopedics and total joint arthroplasty and six of the surgeons are principally specialized in the treatment of spinal disorders. The distributorships have been in continuous operation for an average of 2.3 years (range: 1.0 to 4.4 years).

Table 1

	Start of Operation	# Surgeons –Spine	# Surgeons -TJA/Gen Ortho	Total Surgeons
SD1	February 2006	3	2	5
SD2	March 2007	2	2	4
SD3	November 2009	0	1	1
SD4	June 2010	1	0	1
SD5	July 2010	0	7	7

The study sample represents 1,366 surgical procedures (total knee replacement: 487, total hip replacement: 231, anterior cervical fusion: 154, posterior lumbar fusion: 247). The volume of cases varied according to the number of surgeons served by the distributorship and the practice complexions represented. The volume of cases for each distributorship in the sample was meaningful for each of the procedure types surveyed (minimum: 20 anterior cervical fusions by SD4; maximum: 189 total knee replacements by SD5), **Table 2**.

Table 2. Hospital Implant Prices: Surgeon vs Non-Surgeon Distributorships

Total Knee Replacement	Procedures	SD Price	NSD Price	Average Annual Savings
SD1	90	\$3,588	\$5,385	\$161,730
SD2	116	\$3,889	\$6,573	\$311,344
SD3	92	\$3,285	\$5,568	\$210,036
SD5	189	\$3,817	\$4,288	\$92,799
Total Hip Replacement		SD Cost	NSD Cost	Average Annual Savings
SD 1	35	\$5,128	\$7,295	\$75,845
SD2	78	\$4,630	\$7,117	\$193,986
SD3	52	\$4,250	\$6,900	\$137,800
SD5	66	\$4,288	\$4,694	\$29,370
Anterior Cervical Fusion		SD Cost	NSD Cost	Average Annual Savings
SD1	91	\$2,092	\$2,651	\$50,869
SD2	43	\$2,140	\$2,230	\$3,870
SD4	20	\$1,345	\$3,861	\$50,320
Posterior Lumbar Fusion		SD Cost	NSD Cost	Average Annual Savings
SD1	118	\$6,410	\$11,007	\$542,446
SD2	83	\$13,564	\$14,628	\$88,312
SD4	46	\$4,892	\$15,931	\$507,795

*SD = Surgeon Distributorship

**NSD = Non-Surgeon Distributorship

The implants sold by each of the five SDs varied, as did their pricing structure. The pricing structure of each SD, however, remained the same for each of the hospitals and surgery centers that it served. For the NSD control group, implant cost was determined as an average of the costs for same type implants provided by the NSD's at the hospitals/surgery centers served by the corresponding SD, **Table 2**. For each distributor, across all implant classes; the SD price was less than the NSD cost. For total knee replacement, the mean implant cost was \$1,814 (33%) less for the SD (\$3,640 vs. \$5,453). Hip replacement implant costs were \$1,937 (30%) less on average for the SD compared to the NSD (\$4,564 vs. \$6,501). For anterior cervical fusion cases, the SD implant cost was \$1,055 less for the SD (36%; \$1,859 vs. \$2,914). The lumbar fusion implant costs were \$5,567 (40%) less on average for the SD (\$8,289 vs. \$13,855). Across each of the implant lines studies, the SD implant cost was on average \$2,589 (32%) less than the NSD cost. Considering the 1,366 cases included in the sample population, the one-year cost savings to hospitals/surgery centers and society was \$2,456,521 (Table 2).

There was a variation of aggregate cost savings among the five distributorships, Table 3. The cost savings provided by the SD's ranged from 11% to 69%, with a mean aggregate annual savings of \$490,304 per distributorship. Following the trend for the distributorships, there was also marked variation in the cost savings per surgeon. The greatest cost savings occurred for a single surgeon spine implant distributorship (SD4: \$558,109). The least cost savings came from a total joint arthroplasty

distributorship serving seven general orthopedists (\$17,453 per surgeon over 12-months). While not specifically studied, the variation may be explained at least in part by differences in practice emphasis (general orthopedics vs. spine), geographic market price differences (four states represented), and distributorship scale. (Table 3).

Table 3. Aggregate Annual Savings for All Procedures and Percentage Cost Reduction

Distributorship	Surgeons	% Cost Savings	Total Aggregate Annual Savings	Annual Savings per Surgeon
SD1	5	36%	\$830,890	\$166,178
SD2	4	23%	\$597,512	\$149,378
SD3	1	40%	\$347,836	\$347,836
SD4	1	69%	\$558,109	\$558,109
SD5	7	11%	\$122,169	\$17,453
		Average: 36%	Average: \$490,304	Average \$247,792

*SD = Surgeon Distributorship

For those distributorships with greater than one year of data, annual changes in implant pricing are reported in Table 4. Three distributorships have been in existence for two or more years and thus have multi-year pricing data available (5 years, 4-years and 3-years respectively). The three distributorships (SD1, SD2 and SD3) have carried a combined total of ten product lines since inception. Over this twelve year combined experience, only one product line for one distributorship has seen a price increase (1% increase in total knee replacement implant prices for SD3 over a 3-year time course). Each of the other nine product lines has not had a price increase. Seven product lines for two distributorships received a price decrease and two were unchanged. The combined aggregate price change of the three distributorships in was -1.41%.

Table 4. Average Annual Change in Implant Pricing

Distributorship	Total Knee Replacement	Total Hip Replacement	Anterior Cervical Fusion	Posterior Lumbar Fusion
SD1 (5 yr average)	-0.6%	-2.4%	-1.6%	-1.0%
SD2 (4 yr average)	1%	-2%	-4%	-3%
SD3 (3 yr average)	0%	0%	n/a	n/a
Avg Price Change	0.24%	-1.40%	-2.70%	-1.76%

*SD = Surgeon Distributorship

From July 2007 to July 2011, the average cost of goods in the United States (CPI) rose by +8.34% (www.bls.gov/cpi/tables.html). Based on this index, the actual price of the implants sold by the SD decreased by 9.75% over the four years in constant dollars (8.34% - -1.41%).

Discussion

The market failure associated with the current model of medical device distribution is evidenced by the increase in implant prices despite increases in volume and increases in the number of companies producing equivalent products (commoditization).. Any product cleared by the FDA under a 510(k) process is, by definition, substantially equivalent to a device currently marketed in the United States.

In industries where market forces act, such commoditization should result in dramatically reduced costs to society. The medical device industry has been shielded from this because of the unique circumstance whereby there exists separation between the individual making the implant choice and the party having to pay for that choice. Surgeon ownership in medical device distribution proposes to remove such separation and to establish more effective competition.

In 2009, there was an initial report from a single distributorship finding a 34% reduction in implant costs across three hospital systems (Steinmann and others 2009). No other studies have validated the cost savings associated with this model. This paper represents the first study of multiple SD in multiple states, utilizing many different manufacturers, and presents the effect of this model on the costs of medical devices to all contracted hospitals.

It is notable that cost savings were achieved in all products across all studied distributorships. In addition, these savings were significant, ranging from 11% to 69% and totaling \$2,456,521, with an average cost savings of 36% across all five SD. These savings are of importance for the years ahead when considering the anticipated increased demand and the annual increases that have been the norm for this industry.

The 2010-2011 Orthopaedic Industry Annual Report (OrthoWorld 2011) cited total United States orthopedic product sales of \$23.7 billion, with total joint reconstruction sales at \$7.3 billion. The escalation in total joint implant price over the 14-year period from 1994 through 2006 was reported to be 171% (average 13%) (Healy 2006). Surgeon owned distributorships have shown the ability to save 37% the first year and to keep annual escalations at or below 1.0%.

The substantial first-year reductions in implant prices and sustained downward pressure on annual price changes that result from surgeon ownership in medical device distribution will have a profound effect on healthcare costs associated with orthopedic implants. The magnitude of cost savings in total joint reconstruction is projected in Figure 1. Here it is assumed that the 13% annual escalations (reported by Healy 2006) associated with NSD would decrease for the next 20 years to 7.5%. It is further assumed that the SD model, with a first-year reduction in cost of 36%, would demonstrate a 1.5% annual escalation in price as opposed to the -1.76% change currently demonstrated. Figure 2 uses the same assumptions but includes all orthopedic implants, to demonstrate the broader potential cost savings associated with the SD model.

This calculation reveals that over the next 20 years, the SD model has the potential to save \$229 billion in total joint reconstruction costs alone (Fig. 1). This figure does not take into account the expected substantial increase in demand that was discussed previously, thus probably significantly understating the potential long-term savings associated with this model. When looking at this from the perspective of the entire orthopedic medical device industry, the potential savings exceed \$734 billion over 20 years (Fig. 2).

Figure 1. The Potential Economic Benefit of Surgeon Owned Distribution on Total Joint Reconstruction Devices

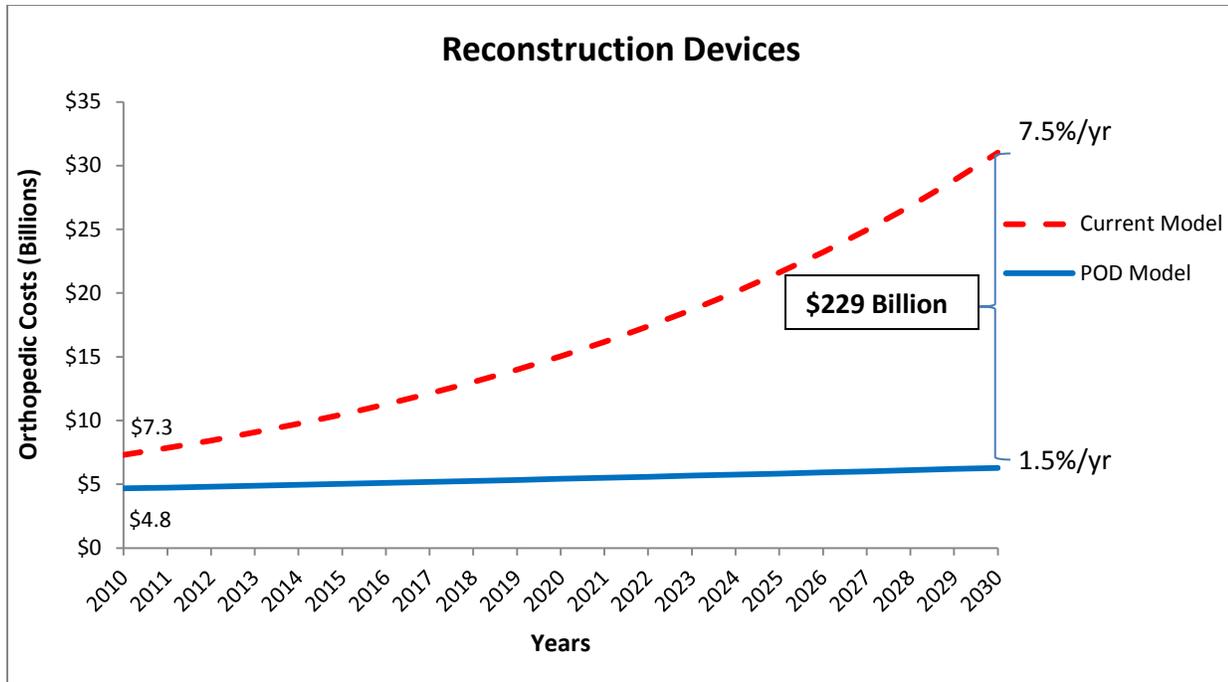
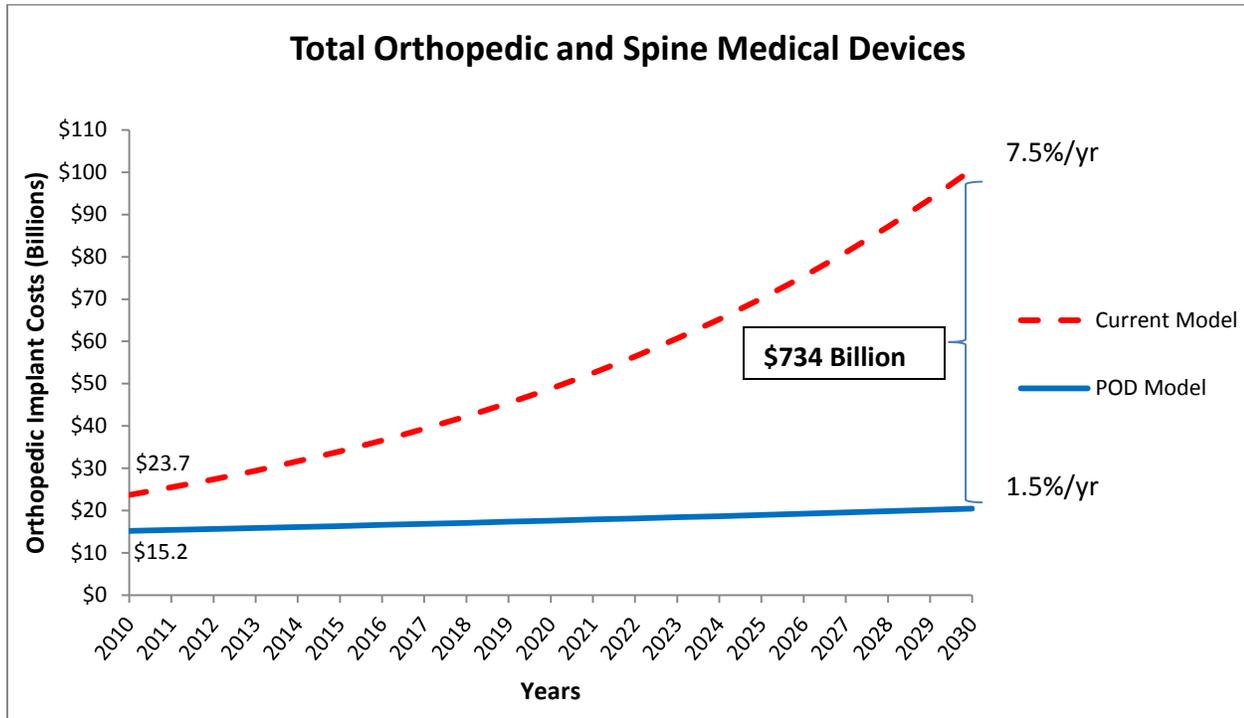


Figure 2. The Potential Economic Benefit of Surgeon Owned Distribution on Total Medical Devices



The demand will increase by 673% for total knee replacements and by 174% for total hip replacements over the next 20 years (Kurtz and others 2007). Payments made to hospitals for total joint arthroplasties are not enough to keep up with inflation (Scott and others 2009), causing concern for the financial feasibility of total joint procedures. With fewer surgeons to provide total joint procedures (Fehring 2010) and the economic disincentive for hospitals to provide total joint reconstruction services, continued access to these valuable surgical procedures may be threatened, particularly for seniors who represent the majority of total joint reconstruction patients. This threat to access further intensifies the need for significant change in the methods in which these products are acquired.

Legitimate concerns exist regarding this model. Those concerns question if the model will incentivize overutilization or the use of substandard products. Other concerns include the degree of transparency/disclosure and whether surgeons will continue to create such cost savings. In a separate ongoing study by the authors of this paper, the utilization of orthopedic implants by seven different surgeon distributors are compared to each distributors utilization for a 12-month period prior to the initiation of the distributorship, to analyze if there is evidence to support that utilization is influenced by this model. Preliminary results indicate no change in practice pattern following investment in the surgeon owned distributions under study.

A promising response to the concerns regarding the surgeon owned distribution model has been the development of Standards established by the American Association of Surgeon Distributors (AASD 2011) (Table 5).

Table 5. Standards and Criteria for Membership: American Association of Surgeon Distributors

1. Distributorship must maintain a business structure consistent with all Federal Stark and Anti-Kickback statutes.
2. Distributorship must demonstrate merit by proving to be the lowest average cost vendor of like implants during a comparable contract period.
3. Annual price increases must not exceed 3% above the consumer price index (CPI).
4. Distributorship must demonstrate adherence to the AASD Product Evaluation Policy.
5. Distributorship must demonstrate adherence to the AASD Employee Training Requirements.
6. Distributorship must demonstrate adherence to the AASD Disclosure Policy.
7. Distributorship must demonstrate investment risk and compliance with the AASD Investment and Distribution Policy.
8. Distributorship must submit utilization data annually consistent with the AASD Utilization Review Policy.
9. Distributorship must not leverage referrals to any hospital or surgery center.
10. Distributorship must be a legitimate free standing stocking Distribution Company with employees, contracts, address, business license and insurance.
11. Distributorship must have written contracts with hospitals and vendors for at least one year.
12. Distributorship pricing must not vary between hospitals.

These standards ensure an accredited SD is demonstrating legal compliance, cost savings, transparency, product quality evaluations, appropriate employee training, and utilization reporting.

As surgeons, we have an obligation to the highest level of care to the patient with whom we have a relationship. Given the reality of limited resources, surgeons need to be mindful of ways to continue to provide the highest quality of care to their patients at prices that our society can afford. Failure to do so will result in a threat to sustained access to important medical technologies that have the ability to improve the quality of life.

The SD model is a tested and viable model with great promise to re-establish market forces and reduce healthcare costs and preserve access to valuable healthcare services. Safeguards, such as those established by the AASD, will serve to protect the best interest of patients and society on an ongoing basis.

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