

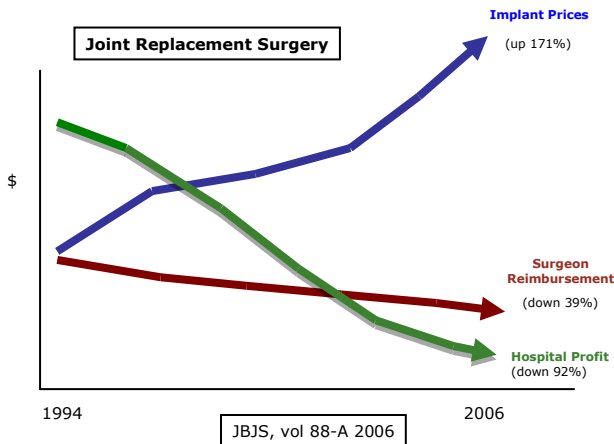
Surgeon Ownership in Medical Device Distribution: Economic Analysis of an Existing Model

John Steinmann DO, Gail Hopkins MD, Paul Burton DO, John Skubic MD

Background:

Healthcare costs, per capita, in the United States are nearly twice that of our European counterparts and threaten our ability to compete in a global economy. Equally important is the financial burden these costs place on businesses and individuals. Although much is talked about with regard to rising healthcare costs, little effective change has been made.

The costs of orthopedic implants continue to rise, over 13% annually, in a market in which hospital profit and physician reimbursement continue to decline.



Hospitals have implemented various cost containment strategies but few have directly involved surgeons. Surgeon owned and managed distribution is a novel business model that may substantially reduce hospital implant costs by reducing the need for sales and marketing efforts while also improving the efficiency of distribution functions. The purpose of this exhibit is to describe the operations of a surgeon owned distributorship and review its economic effects on local hospitals.

Methods:

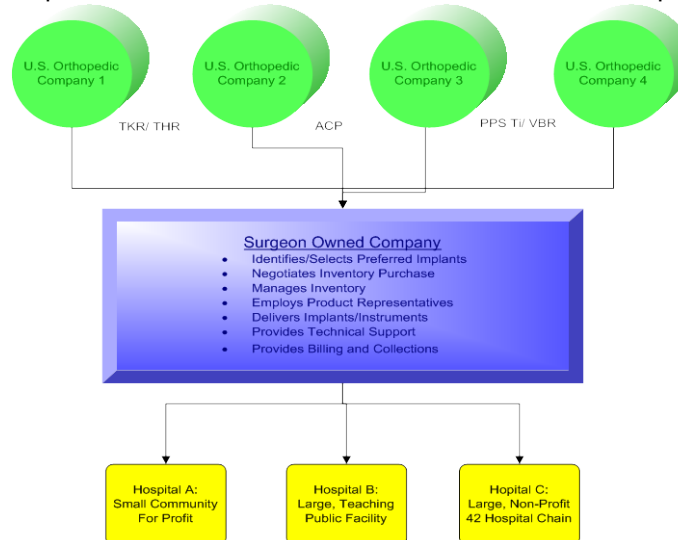
Concerned by the annual escalation of orthopedic implant prices, and driven by the belief that the current method of distribution was inefficient and far too costly, four orthopedic surgeons created a distribution company to provide comprehensive distribution services for joint replacement and spinal implants. The surgeons desired to introduce market forces through competition into the process of orthopedic implant purchase. They believed they could perform distribution services more efficiently, and therefore, sell equivalent orthopedic implants to the hospital at significantly reduced price.

Prior to initiating this distribution model, this surgeon group investigated and affirmed the following important questions:

- Is it legal?
- Does the model meet Standards of Professionalism?
- Does the model provide hospital/community benefit?
- Is there a reasonable return on investment?
- Are implant systems with preferred features available for purchase?

Operations:

Each surgeon owner invested personal capital to fund the purchase of joint replacement and spinal implant inventory and to fund company operations. The surgeon owned company hired staff with medical and orthopedic experience to support standard distribution functions and provide these distribution services to three local hospitals.



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This study retrospectively reviewed all cases in which the distribution company was the implant supplier and compared those implant costs with the average contract cost (not list price) of like implants purchased by these three hospitals during the same time period. All implant systems used and compared in the study were FDA cleared products from U.S. Companies.

Implant Systems

- 1) Fixed Bearing, Tricompartamental Knee Replacement
- 2) Metal on Highly Crosslinked Poly, Tapered Stem, Total Hip Replacement
- 3) Anterior Cervical Plate System
- 4) Titanium Polyaxial Pedicle Screw System

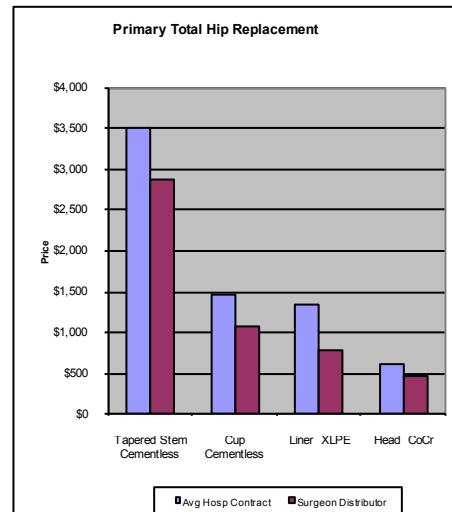
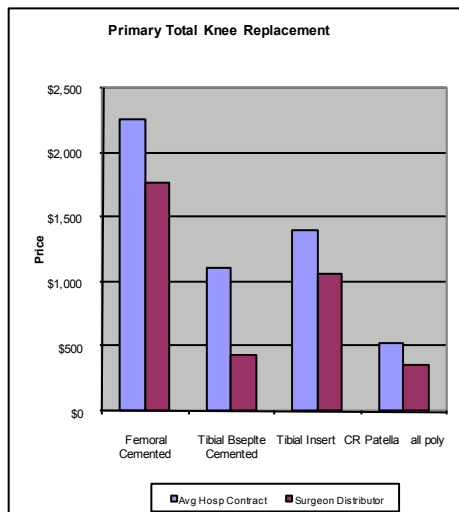
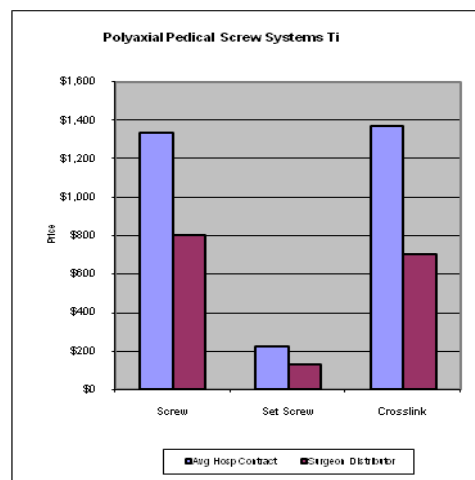
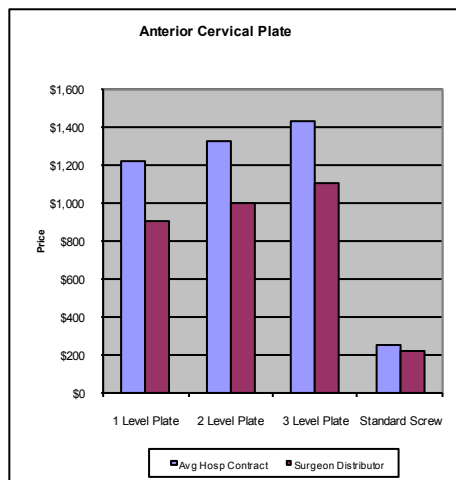
Results:

From May 2006 through May 2008, the surgeon owned company distributed implants for 544 cases:

- 155 Primary Total Knees Replacements
- 62 Primary Total Hip Replacements
- 199 Posterior Lumbar instrumentations
- 128 Anterior Cervical instrumentations.

Each hospital reported the average contracted price for these implant systems. Surgeon owned distributor prices were not included in calculating the average contracted price, and were reported separately.

Orthopedic Implant Systems Purchased by 3 Hospitals Comparison of Price: Surgeon Owned Distributor vs. Hospitals Average Contract Price

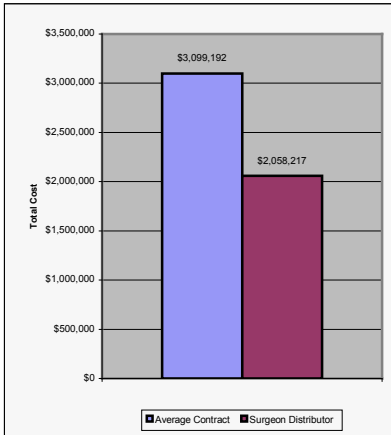


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The total cost of implants sold by the surgeon owned distributorship during the study period was \$2,058,217. The total cost of purchasing the equivalent implants using the hospitals average contract price during the study period would have been \$3,099,192. Hospital savings resulting from purchasing implants from the surgeon owned distribution company was \$1,040,974 representing a 34% savings.

Comparison: Total Cost of Orthopedic Implants Surgeon Owned Distributorship vs. Hospitals Average Contract



Conclusions:

The results of this study suggest that:

1. Surgeons can effectively establish a legally compliant distribution company able to provide comprehensive distribution services and supply of preferred implants.
2. Surgeon owned medical device distributorships are an effective means of reducing hospital costs related to orthopedic implants. This is accomplished by introducing market forces in the negotiation of implant purchases and more cost effectively distributing and selling those implants. Prospective socioeconomic benefits of this model are also anticipated but are more difficult to measure of project.

Legal Considerations:

Surgeon owned distributorships must:

- Adhere to all state and federal self-referral laws
- Demonstrate financial risk (investment)
- Perform all functions typical of medical device distributorships
- Offer pricing that represents the lowest average cost for like implants
- Sell membership interest at fair market value without concern for volume or value of referrals
- Distribute profits based on investment interest

Summary:

Surgeon ownership and/or management of implant distribution makes complete sense.

- Surgeons are the most qualified individuals to identify like quality and equivalence in competitive implant designs.
- Surgeons know their preferences and their surgical volumes and are therefore the most suited to manage the inventory and optimize the efficiency of the instrumentation set.
- Surgeons, as the decision maker, are in the best position to negotiate pricing with competitive manufacturers.
- Purchasing products in volume will nearly always result in considerable savings when compared to purchasing products one item at a time.
- Surgeons are the most appropriate individual to choose, and define the duties of the product representative.
- Surgeons have their patient's best interest at heart and are connected and committed to their community and hospitals.

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The trend depicted on the graph in this presentation, and reported by the Journal of Bone and Joint Surgery, vol.88-A, 2006, should concern us all. Orthopedic implant prices increase considerably year after year with little government or private challenge while the providers of health care (physicians and hospitals) are forced to accept a decrease in their reimbursement year after year. The continual rise in implant prices occurs due to the absence of effective market forces in this industry where the decision maker is disconnected from any financial consideration. This is compounded by the fact that products are purchased one at a time.

Hospital profitability is important to your patients and to your community. Profitable hospitals are better able to provide you, as a surgeon, with state of the art equipment and better able to retain a competent nursing staff. These and other necessary functions of the hospital suffer when financial viability is challenged. In addition, fair surgeon reimbursement is important to insure continued availability of high quality medical professionals. Based on Medicare payment methods to hospitals and based on Medicare reimbursement formulas, annual escalations in orthopedic implant prices eroded both hospital profitability and exert a negative influence on surgeon reimbursement.

This study demonstrates one viable solution to the growing disparity between healthcare payments to implant manufacturers and their representatives and payments to the hospitals and surgeons that provide care. While it is important to insure profitability for implant manufacturers to insure continued product innovation and support, the costs of implant sales, marketing and distribution, on the other hand, adds questionable value when considering the expense associated with these functions. The model depicted in the presentation very effectively insures manufacturing profitability while offering a far more cost efficient method of distribution. This model results in lower overall healthcare costs related to orthopedic implants, improves hospital profitability associated with these devices and provides a more fair compensation to the surgeon.

Disclosures

John Steinmann DO: Inland Spine Products, LLC ownership interest

Gail Hopkins MD: Inland Spine Products, LLC ownership interest

Paul Burton DO: Inland Spine Products, LLC ownership interest

John Skubic MD: Inland Spine Products, LLC ownership interest

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