Economic and Safety Benefits of Bolt® Navigation in Spine Surgery

Introduction

The Bolt Navigation System is a hand-held spine navigation system that offers enhanced accuracy, reduced radiation exposure, improved operational efficiency, and reduced cost. This white paper explores the economic and safety benefits of the Bolt System by analyzing data from multiple studies with a particular focus on improved outcomes/reduced reoperations, lowering radiation exposure, and improved operational efficiency.

Improvement in Pedicle Screw Placement Precision

One of the primary benefits of the Bolt System, clinically and economically, is that it improves the accuracy of implant placement. In a recently published peer reviewed clinical study in *The Spine Journal*[1], the **Bolt Navigation System demonstrated superior accuracy compared to fluoroscopy-assisted techniques and comparable accuracy to CT-Navigation (CT-Nav) in placing pedicle screws.**

Improved accuracy reduces the incidence of complications such as nerve damage and costly revisions to replace mis-placed hardware. A comprehensive literature review of the economics of image-guided surgery in spinal procedures highlights the broader economic impact of the use of navigation in the placement of spine hardware. These studies demonstrate that the average cost of revision surgery ranged from $17,650 to $39,643[2]. The use of image-guided navigation was associated with lower rates of screw misplacement (1.20% to 15.07%) and reoperation rates (0% to 7.42%). **Based on this, the cost savings gained by the use of image guided navigation for the placement of pedicle screws was $71,286 per 100 cases[3].**

Traditional CT-based navigation systems.

The Bolt hand-held spine navigation syatem

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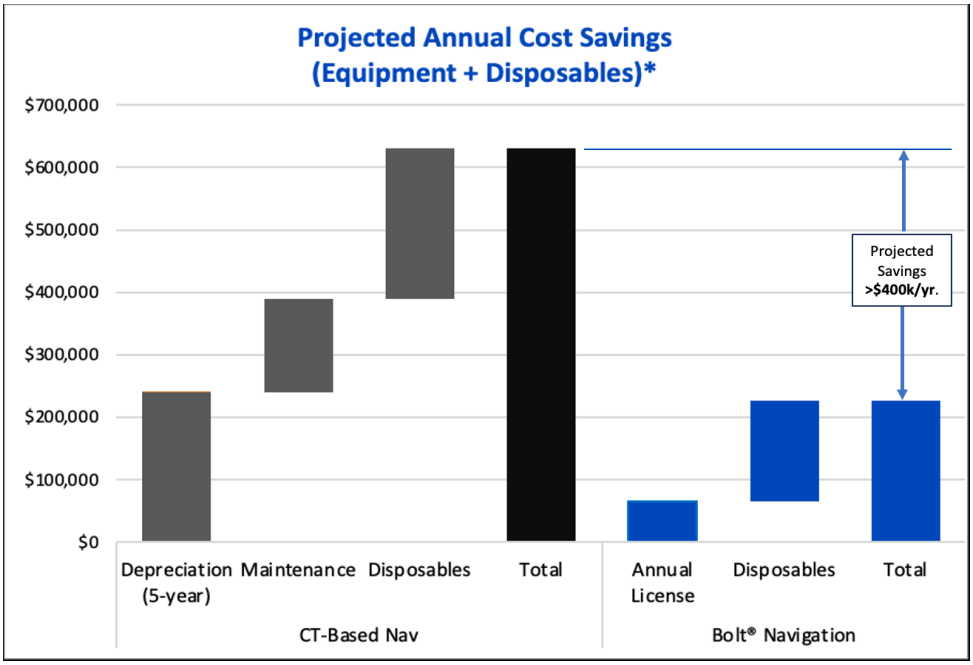
Figure 1:
Illustrating that the use of Bolt presents an estimated annual savings 175 hours of OR time worth approximately $1 million for facilities performing 300 spinal fusions annually as compared to legacy CT-based navigation systems.



*Assumes 2 surgeons @ 100 proc/yr. CT-Based Nav based on market averages (ie $1,200/proc. for disposables, $150k /yr. maintenance, $240k/yr. depreciation.

Operational and Capital Savings – Time and Cost

Due to the simplicity of the Bolt System, it dramatically reduces set-up and room turn times.

The time savings offered by the Bolt can result in substantial financial benefit. The set-up time for traditional CT-Nav, including equipment set-up and initial registration, has been reported to take up to 40 minutes for lumbar spine fusion procedures, significantly increasing the overall facility operating costs and reducing the number of procedures annually. The Bolt System utilizes existing pre-operative imaging (CT or MR), and no additional set-up or technician is required, reducing the system set-up time to <5 min. per procedure. Further, it requires minimal distraction to the surgical team to do so.

It is estimated that the average cost of OR time per minute is $93[3].

Based on this, Figure 1 illustrates that the use of **Bolt presents an estimated annual savings 175 hours of OR time worth approximately $1 million for facilities performing 300 spinal fusions annually** as compared to legacy CT-based navigation systems.

While the initial investment of acquiring traditional image-guided CT-based navigation systems can be significant and typically includes a capital investment depreciated over multiple years, annual maintenance fees, and ongoing per-procedure disposable costs, the cost of the Bolt System is significantly less and requires no upfront capital investment. Figure 2 shows projected equipment savings of over $400k per year comparing Bolt to traditional CT-based navigation systems.

The cost savings scenario based on lower set-up time combined with the lower cost-per-procedure equipment costs illustrates how the savings and the return on investment can be quickly realized through enhanced efficiency and reduced complication rates associated with the Bolt system.

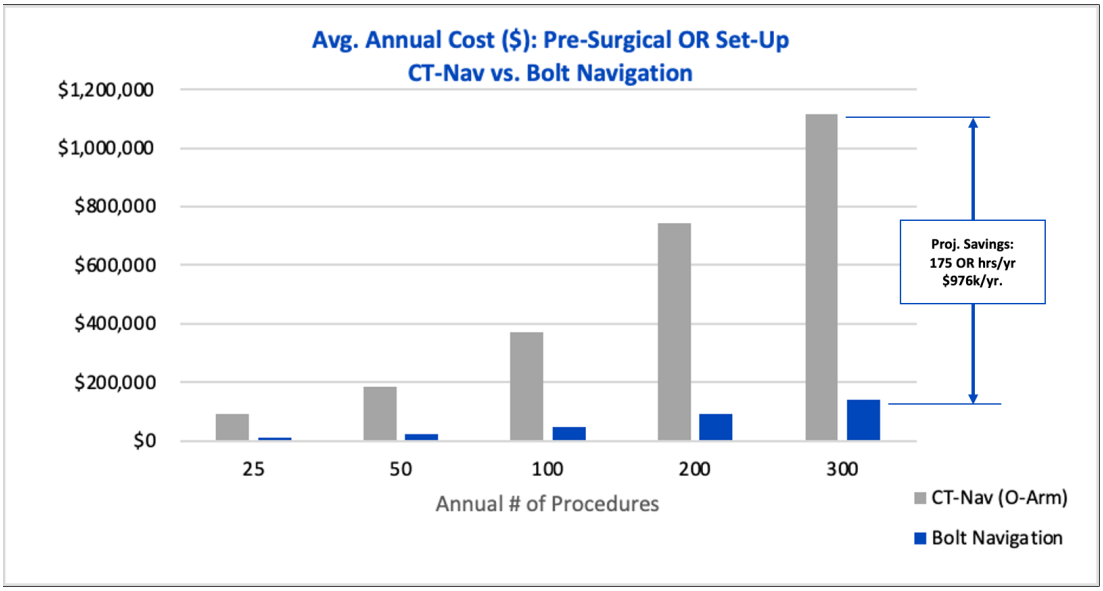


Figure 2:
Shows projected equipment savings of over $400k per year comparing Bolt to traditional CT-based navigation systems.

Radiation Reduction: Surgeon, Patient and Staff Safety

Nearly all spine fusion procedures use fluoroscopic or CT-based navigation that substantially increase radiation exposure to the patient, staff and surgeon. In fields such as orthopedic surgery, where radiation exposure is not regulated, a focus on procedure-based radiation reduction is even more critical. Though fluoroscopic guided spine surgery is the standard of care, reliance on intraoperative fluoroscopy inevitably increases radiation exposure for all in the operating room.

This notable increase is not without consequence. In a retrospective study of surgeons, **orthopedic surgeons were five- times more at risk for cancer compared with non-orthopedic surgeons.**[4] A similar study found increased rates of thyroid cancers among physicians in radiation-intensive procedures[5]. Studies further report **spine surgeons experience radiation exposure 10–12X greater than in other Orthopedic procedures and may approach or exceed guidelines for cumulative exposure.**[7]

Finally, **patients are also negatively impacted** by increased exposure and experience much higher doses of intraoperative radiation. This exposure **elevates the lifetime risk of solid malignancies 1.4–2.4%.**[6] It is important to note that radiation exposure is much higher in minimally invasive and percutaneous spine procedures, which represent a rapidly growing percentage of the spine cases being performed. This additional exposure is therefore underrepresented in the data above and the dangers are only continuing to increase.

The Bolt System typically utilizes the patient's diagnostic MRI and a limited number of intraoperative X-rays. In the aforementioned published clinical study a single lateral X-ray was used along with the patients diagnostic MRI. The Bolt System therefore reduces the radiation exposure for the operative team and patient by eliminating the requirement for an intraoperative CT scan or reducing the need for repetitive intraoperative fluoroscopic imaging.

Reduced medical implant waste

Screw misplacement is also a contributor to pedicle screw waste because of explanation. One study suggests implant waste contributes significantly to the cost of spine surgeries, finding that 11% of spine cases included implant waste. According to study estimations, approximately $126 million is wasted on spine surgeries in the US annually, the majority of which takes place in thoracolumbar pedicle screw fusion cases.[8] Adoption of the Bolt System offers reduced screw misplacement, reoperation rates, and fewer dollars spent on implant waste, contributing to significant economic advantages.

Conclusion

The Bolt Navigation System achieved an accuracy rate of 98.9% for pedicle screw placement, demonstrating non-inferiority to CT-nav and superiority to fluoroscopy-assisted techniques. It achieved these results by leveraging the patients existing diagnostic MRI and a limited number (n=1) intraoperative X-rays. Due to its compact size, relatively low cost and ease of operation, the economic benefits of utilizing the Bolt System are substantial encompassing reduced rates of revision surgery, improved operational efficiency, and elimination of annual maintenance fees. Further, it decreases radiation exposure to the surgical staff and patient.

The combined value of simplicity, cost-effectiveness, and high accuracy rates suggest that the Bolt is a viable and lower-cost alternative for improving the outcomes in spine fusion procedures. The Bolt systems not only enhance surgical outcomes but contributes to more efficient and cost-effective healthcare delivery.

References

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