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Clinical Study

# A prospective study of lumbar facet arthroplasty in the treatment of degenerative spondylolisthesis and stenosis: cost-effective assessment from the total posterior spine (tops$^{tm}$) system ide study: 2-year model revision and sensitivity analyses based on 305 subjects

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**Abstract**

**BACKGROUND CONTEXT:** A previous cost-effectiveness analysis published in 2022 found that the total posterior spine (TOPS$^{TM}$) system was dominant over transforaminal lumbar interbody fusion (TLIF). This analysis required updating to reflect a more complete dataset and pricing considerations.

**PURPOSE:** To evaluate the cost-effectiveness of TOPS$^{TM}$ System as compared with TLIF based on an updated and complete FDA investigational device exemption (IDE) data set.

**STUDY DESIGN/SETTING:** Cost-utility analysis of the TOPS$^{TM}$ system compared to TLIF.

**PATIENT SAMPLE:** A multicenter, FDA IDE, randomized control trial (RCT) investigated the efficacy of TOPS$^{TM}$ compared to TLIF with a current population of n=305 enrolled and n=168 with complete 2-year follow-up.

**OUTCOME MEASURES:** Cost and quality adjusted life years (QALYs) were calculated to determine our primary outcome measure, the incremental cost-effectiveness ratio. Secondary outcome measures included: net monetary benefit as well at willingness-to-pay (WTP) thresholds.

**METHODS:** The primary outcome of cost-effectiveness is determined by incremental cost-effectiveness ratio. A Markov model was used to simulate the health outcomes and costs of patients undergoing TOPS$^{TM}$ or TLIF over a 2-year period. alternative scenario sensitivity analysis, one-way sensitivity analysis, and probabilistic sensitivity analysis were conducted to assess the robustness of the model results.

**RESULTS:** The updated base case result demonstrated that TOPS$^{TM}$ was immediately and longitudinally dominant compared with the control with an incremental cost-effectiveness ratio of −9,637.37 $/QALY. The net monetary benefit was correspondingly $2,237, both from the health system's perspective and at a WTP threshold of 50,000 $/QALY at the 2-year time point. This remained true in all scenarios tested. The Alternative Scenario Sensitivity Analysis suggested cost-effectiveness irrespective of payer type and surgical setting. To remain cost-effective, the cost difference between TOPS$^{TM}$ and TLIF should be no greater than $1,875 and $3,750 at WTP thresholds of $50,000 and 100,000 $/QALY, respectively.

FDA device/drug status: Not applicable.

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**CONCLUSIONS:** This updated analysis confirms that the TOPS$^{TM}$ device is a cost-effective and economically dominant surgical treatment option for patients with lumbar stenosis and degenerative spondylolisthesis compared to TLIF in all scenarios examined. 

*Keywords:* Cost analysis; Cost-effectiveness; Lumbar spondylolisthesis; Lumbar stenosis; Motion preservation; Decision analysis; TOPS$^{TM}$; Total posterior spine system

## Introduction

Over 250 million people are diagnosed with lumbar degenerative spine disease worldwide every year [1]. Degenerative spondylolisthesis (DS) is characterized by the mal-alignment and displacement of one lumbar vertebra relative to another with a female to male preponderance of 1.3:1 [2]. For decades, spinal fusion has been the principal surgical intervention in patients with severe lumbar stenosis and degenerative spondylolisthesis with cases increasingly annualy [3]. The determination to proceed with a fusion is multifaceted and has been shown to be highly variable [4,5]. The efficacy of decompression alone compared to decompression with fusion has yielded conflicting results [6−9]. Disparate results often spearhead investigation into alternative and innovative treatments. There has similarly been increasing focus on the patient experience, quality of life, motion preservation, and adjacent segment disease. The total posterior spine (TOPS$^{TM}$) System is a motion preserving alternative for decompression and stabilization at one level in the lumbar spine, L2−L5 [10]. This innovative technology is indicated for moderate-to-severe stenosis, degenerative spondylolisthesis, ligamentum flavum thickening and/or facet hypertrophy, causing back, and leg pain.

Increases in healthcare costs will inevitably result in additional strain on both the patient and collective health care system. The current trajectory estimates an increase in healthcare-related costs from $4.3 trillion dollars in 2021 to $6.2 trillion dollars by 2028 [11,12]. Lower back pain is an expensive work-related disability and was ranked as the greatest contributor to global disability impacting 83.0 million people, according to the 2010 Global Burden of Disease study examining 291 medical conditions [13,14].

Consequently, to comprehensively evaluate best care practices, we must assess more than clinical outcomes alone. It is imperative to understand the immediate and longitudinal cost-effectiveness of the interventions used to treat DS. Given that fusion is shown to be only moderately cost-effective compared to conservative care it is only reasonable to evaluate the efficacy and cost-effectiveness of motion preservation alternatives, such as facet replacement [15]. In healthcare, cost-effectiveness is evaluated using different methods, such as simple incremental calculations and decision analytical modeling [16]. While decision analytical modeling provides a comprehensive approach to evaluating cost-effectiveness, it has limited ability to describe the relationships between clinical events and how parameters can change relative to one another. The purpose of this study was to therefore perform an update to the early cost-utility analysis previously published in 2022, comparing TOPS$^{TM}$ to TLIF [17]. This assessment is based on an updated dataset of n=305 enrolled and n=168 with complete 2-year follow-up from the FDA investigational device exemption (IDE) trial. We similarly evaluated cost and quality of life (QOL) from multiple perspectives with particular interest in covariates such as pain, patient-reported outcomes, adjacent segment disease, return to work, and reoperation rates. Our previous analysis of 1-year follow-up data revealed that the TOPS$^{TM}$ System was cost-effective ($6,158 per QALY) compared to TLIF at 2 years [17]. Economic dominance was achieved at 6-years in an extrapolated time horizon. An increase in the sample size with more long-term follow-up from the IDE study created an opportunity to reinform the model and update our assessment of cost-effectiveness.

## Methods

### Model design

This study utilized updated 2-year follow-up data from the patient population of an ongoing multicenter randomized controlled trial (RCT) investigating the clinical safety and effectiveness of the TOPS$^{TM}$ System compared to TLIF (Pivotal FDA IDE Study). The patient population was randomized preoperatively (2:1) to the investigational TOPS$^{TM}$ cohort or the control TLIF cohort. Randomization was carried out using an online secured database. A total of 52 surgeons over 37 US hospitals (16 academic and 21 community) were involved in the study. Both procedures were performed in inpatient hospital settings only and all TLIFs were standardized as “open” and required either DePuy Synthes Spine, Inc, Raynham, MA (Capstone system) or Medtronic PLC, Minneapolis, MN (Solera system). A total of 305 participants have been enrolled at the time of preparing this manuscript, with 168 subjects reaching the 2-year clinical composite success assessment. While all subjects were enrolled under Institutional Review Board authorization and patient informed consent. The most up to date RCT data can be found on the FDA website (summary of safety and effectiveness data) [18] and is summarized in Table 1.

Following the precedent presented in the second panel on cost-effectiveness health and medicine by the US Public

Table 1
Baseline RCT data

| | TLIF | TOPS |
|---|---|---|
| Baseline health state | 96 | 210 |
| *Minimal* | 0 | 0 |
| *Moderate* | 4 | 8 |
| *Severe* | 22 | 50 |
| *Crippled* | 38 | 86 |
| *Bedbound* | 32 | 66 |
| Post-surgical health state | 86 | 200 |
| *Minimal* | 55 | 148 |
| *Moderate* | 20 | 37 |
| *Severe* | 6 | 12 |
| *Crippled* | 3 | 2 |
| *Bedbound* | 2 | 1 |
| Adverse events* | 18 | 38 |
| *Serious* | 7 | 16 |
| Surgery | 6 | 12 |
| Supplemental | 1 | 4 |
| *Non-serious* | 11 | 22 |
| Surgery | 1 | 5 |
| Supplemental | 10 | 17 |

* At any postoperative timepoint.

Health Service, our study evaluated the cost-effectiveness of the TOPS™ System compared to TLIF by examining two principal measures of outcome: cost and utility [19]. Cost was assessed from two perspectives: societal and health system. Societal costs include direct and indirect costs, such as productivity losses, which can be measured in lost workdays. Health system costs were determined by evaluating direct medical costs including time in the operating room, hospital facility fees, medications postoperatively prescribed, follow-up visits, complications of surgery and device, and secondary surgeries. Utility outcomes were expressed as quality adjusted life years (QALYs) and were calculated from the SF-12 survey data from the RCT via SF-6D utility indexes. Comparative cost-effectiveness analysis was calculated as the incremental cost effectiveness ratio (ICER), as defined by the difference in cost over the difference in utility between the TOPS™ System and control TLIF. Cost-effectiveness will be delineated by a value under the willingness-to-pay (WTP) threshold of $100,000 per QALY, with additional analyses conducted at $50,000 per QALY and $150,000 per QALY thresholds. The value of the intervention in monetary terms is determined by calculating the net monetary benefit (NMB).

## Markov model

A Markov model was constructed to analyze perioperative and postoperative costs and QALYs for both TOPS™ and TLIF (Fig. 1). The model was based on five health states (Minimal, Moderate, Severe, Crippled, Bedbound) over 13 cycles, each representing a subsequent time point. Cycle lengths began as smaller increments closer to the date of intervention (6-week, 3-month, and 6-month) and increased to annual timepoints beginning at the fourth

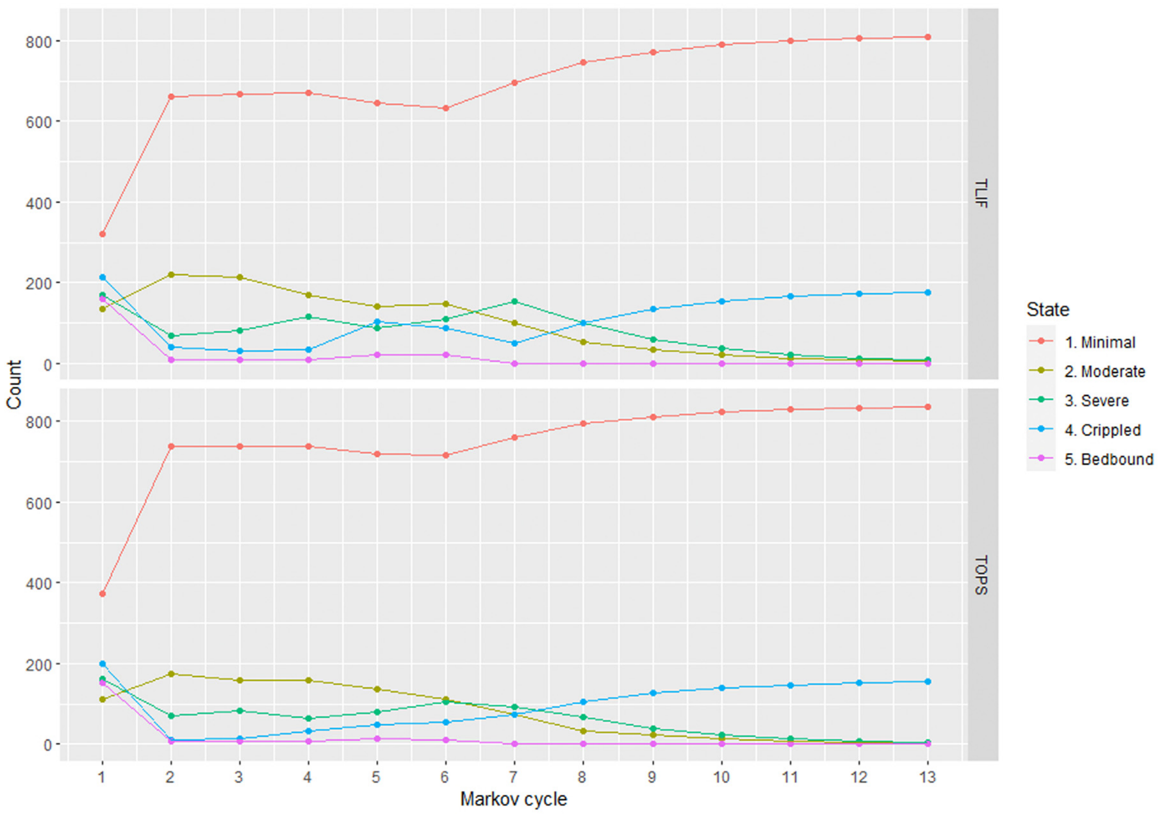


Fig. 1. Markov model patient results.

Table 2
TOPS transition probabilities

| From health state | Transit to health state | | | | | Time range |
|---|---|---|---|---|---|---|
| | Minimal | Moderate | Severe | Crippled | Bedbound | |
| Minimal | 1.00 | 0.00 | 0.00 | 0.00 | 0.00 | Surgery-6W |
| | 0.87 | 0.09 | 0.03 | 0.00 | 0.01 | 6W−3M |
| | 0.90 | 0.07 | 0.03 | 0.00 | 0.00 | 3M−6M |
| | 0.89 | 0.07 | 0.03 | 0.01 | 0.00 | 6M−12M |
| | 0.87 | 0.08 | 0.05 | 0.00 | 0.00 | 12M−24M |
| | 0.95 | 0.05 | 0.00 | 0.00 | 0.00 | 24M−36M |
| | 1.00 | 0.00 | 0.00 | 0.00 | 0.00 | 36M−48M+ |
| Moderate | 0.88 | 0.12 | 0.00 | 0.00 | 0.00 | Surgery-6W |
| | 0.46 | 0.34 | 0.17 | 0.03 | 0.00 | 6W−3M |
| | 0.43 | 0.40 | 0.10 | 0.07 | 0.00 | 3M−6M |
| | 0.40 | 0.36 | 0.12 | 0.12 | 0.00 | 6M−12M |
| | 0.31 | 0.23 | 0.23 | 0.15 | 0.08 | 12M−24M |
| | 0.57 | 0.29 | 0.14 | 0.00 | 0.00 | 24M−36M |
| | 0.50 | 0.00 | 0.50 | 0.00 | 0.00 | 36M−48M+ |
| Severe | 0.80 | 0.16 | 0.04 | 0.00 | 0.00 | Surgery-6W |
| | 0.00 | 0.55 | 0.36 | 0.09 | 0.00 | 6W−3M |
| | 0.06 | 0.38 | 0.44 | 0.06 | 0.06 | 3M−6M |
| | 0.17 | 0.67 | 0.00 | 0.16 | 0.00 | 6M−12M |
| | 0.00 | 0.34 | 0.33 | 0.33 | 0.00 | 12M−24M |
| | 0.00 | 0.25 | 0.25 | 0.50 | 0.00 | 24M−36M |
| | 0.00 | 0.34 | 0.33 | 0.33 | 0.00 | 36M−48M+ |
| Crippled | 0.73 | 0.20 | 0.07 | 0.00 | 0.00 | Surgery-6W |
| | 0.00 | 0.50 | 0.50 | 0.00 | 0.00 | 6W−3M |
| | 0.00 | 0.50 | 0.50 | 0.00 | 0.00 | 3M−6M |
| | 0.00 | 0.00 | 0.00 | 0.50 | 0.50 | 6M−12M |
| | 0.25 | 0.00 | 0.50 | 0.25 | 0.00 | 12M−24M |
| | 0.00 | 0.33 | 0.67 | 0.00 | 0.00 | 24M−36M |
| | 0.00 | 0.00 | 0.00 | 1.00 | 0.00 | 36M−48M+ |
| Bedbound | 0.70 | 0.19 | 0.06 | 0.03 | 0.02 | Surgery-6W |
| | 0.00 | 0.00 | 1.00 | 0.00 | 0.00 | 6W−3M |
| | 1.00 | 0.00 | 0.00 | 0.00 | 0.00 | 3M−6M |
| | 0.00 | 0.00 | 1.00 | 0.00 | 0.00 | 6M−12M |
| | 0.00 | 0.00 | 0.00 | 0.00 | 1.00 | 12M−24M |
| | 0.00 | 0.00 | 1.00 | 0.00 | 0.00 | 24M−36M |
| | 0.00 | 0.00 | 0.00 | 0.00 | 1.00 | 36M−48M+ |

Markov cycle at 12 months. The health states were evaluated and determined from Patient Reported Outcome Survey metrics for pain and disability: Visual Analog Scale (VAS) and Oswestry Disability Index (ODI). These metrics were then associated with different costs and utility scores, which were redistributed based on preoperative health states and the probability of transition between health states (Tables 2 and 3). Input parameters were constructed using two pertinent events: serious and nonserious adverse events (Table 4). Direct costs were determined from Medicare and private commercial payer data, with total costs compared to published TLIF costs. The base case assumed a 50/50 split between Medicare and private rates, as it was more realistic based on the patient demographic. Medications were determined from the RCT data and costs per health state for each time point were used to determine total costs for various disability levels. Indirect costs were determined by evaluating work status from the Zurich Questionnaire and using national average annual wages.

*Base case scenario and sensitivity analysis*

The base case scenario was formed based on two major assumptions: 1) direct costs and health benefits accrued within a 2-year time horizon of accruing costs and health benefits, were calculated using an equal 50/50 composition of inpatient Medicare and private insurer rates and 2) the TOPS™ strategy is equal in initial surgical costs to TLIF, thus removing the $4,000 upcharge in our initial analysis (Table 5 and 6). This update reflects the most accurate scenario and current financial climate. Since payer type and surgical setting invariably influence the cost-effectiveness outcomes, an alternative scenario sensitivity analysis (ASSA) was included for perspective (Table 7). Similarly, a one-way sensitivity analysis (OWSA) was conducted to identify the parameters associated with the greatest uncertainty and thus greatest effect on conclusions. This is presented in Tornado diagrams (Figs. 2−4). Tornado plot variable definitions are found in Supplementary Table 1

Table 3
TLIF transition probabilities

| From health state | Transit to health state | | | | | Time range |
|---|---|---|---|---|---|---|
| | Minimal | Moderate | Severe | Crippled | Bedbound | |
| Minimal | 1.00 | 0.00 | 0.00 | 0.00 | 0.00 | Surgery-6W |
| | 0.81 | 0.17 | 0.02 | 0.00 | 0.00 | 6W−3M |
| | 0.83 | 0.12 | 0.04 | 0.00 | 0.01 | 3M−6M |
| | 0.87 | 0.07 | 0.06 | 0.00 | 0.00 | 6M−12M |
| | 0.76 | 0.14 | 0.00 | 0.10 | 0.00 | 12M−24M |
| | 1.00 | 0.00 | 0.00 | 0.00 | 0.00 | 24M−36M |
| | 0.81 | 0.17 | 0.02 | 0.00 | 0.00 | 36M−48M+ |
| Moderate | 0.75 | 0.25 | 0.00 | 0.00 | 0.00 | Surgery-6W |
| | 0.67 | 0.28 | 0.05 | 0.00 | 0.00 | 6W−3M |
| | 0.40 | 0.40 | 0.20 | 0.00 | 0.00 | 3M−6M |
| | 0.36 | 0.36 | 0.21 | 0.07 | 0.00 | 6M−12M |
| | 0.50 | 0.33 | 0.17 | 0.00 | 0.00 | 12M−24M |
| | 0.75 | 0.25 | 0.00 | 0.00 | 0.00 | 24M−36M |
| | 0.67 | 0.28 | 0.05 | 0.00 | 0.00 | 36M−48M+ |
| Severe | 0.62 | 0.29 | 0.09 | 0.00 | 0.00 | Surgery-6W |
| | 0.00 | 0.17 | 0.67 | 0.16 | 0.00 | 6W−3M |
| | 0.17 | 0.33 | 0.33 | 0.00 | 0.17 | 3M−6M |
| | 0.29 | 0.00 | 0.57 | 0.14 | 0.00 | 6M−12M |
| | 0.15 | 0.14 | 0.14 | 0.43 | 0.14 | 12M−24M |
| | 0.62 | 0.29 | 0.09 | 0.00 | 0.00 | 24M−36M |
| | 0.00 | 0.17 | 0.67 | 0.16 | 0.00 | 36M−48M+ |
| Crippled | 0.73 | 0.12 | 0.03 | 0.09 | 0.03 | Surgery-6W |
| | 0.00 | 0.33 | 0.00 | 0.67 | 0.00 | 6W−3M |
| | 0.00 | 0.67 | 0.00 | 0.33 | 0.00 | 3M−6M |
| | 0.00 | 0.00 | 0.00 | 1.00 | 0.00 | 6M−12M |
| | 0.00 | 0.00 | 0.00 | 0.50 | 0.50 | 12M−24M |
| | 0.73 | 0.12 | 0.03 | 0.09 | 0.03 | 24M−36M |
| | 0.00 | 0.33 | 0.00 | 0.67 | 0.00 | 36M−48M+ |
| Bedbound | 0.54 | 0.32 | 0.11 | 0.00 | 0.03 | Surgery-6W |
| | 0.00 | 0.50 | 0.00 | 0.50 | 0.00 | 6W−3M |
| | 0.00 | 0.00 | 0.00 | 0.00 | 1.00 | 3M−6M |
| | 0.50 | 0.00 | 0.00 | 0.50 | 0.00 | 6M−12M |
| | 0.00 | 0.00 | 0.00 | 0.00 | 1.00 | 12M−24M |
| | 0.54 | 0.32 | 0.11 | 0.00 | 0.03 | 24M−36M |
| | 0.00 | 0.50 | 0.00 | 0.50 | 0.00 | 36M−48M+ |

for reference. Inherent to any base case cost-effectiveness analysis there will be uncertainty around model input parameters. For this reason, 38 input parameters were evaluated by individual variation of ICER values through an OWSA with each of the parameters being varied by ±20% of its base case value. The only input parameters not tested in this analysis are the trial-based health state transition probabilities, as varying the probability of a single health state transition, while keeping all other health states constant cannot be rationalized.

To address the limitations of the OWSA, a probabilistic sensitivity analysis (PSA) was conducted by varying input parameters simultaneously to determine cost-effectiveness in response to collective parameter uncertainty. Five-thousand iterations were presented in a scatter plot representing possible calculated cost-effectiveness outcomes (Fig. 5). Each of these iterations are of random sampling from probability and utility variables based on: 1) statistics derived from the data; and 2) cost variables that were not derived from the trials and sampled from Gamma distributions with a standard deviation of 15.3% of their respective base case values. The results of this PSA are additionally displayed in a cost-effectiveness acceptability curve, demonstrating the percentage of iterations that are cost-effective at any given Willingness-to-Pay threshold (Fig. 6).

## Results

### *Base case*

From the health system's perspective, the 2-year base case scenario favors TOPS™ over TLIF by $361.43 while imparting 0.0375 QALYs gained (Table 5). The ICER is therefore −9,637.37 $/QALY, suggesting that TOPS™ is already economically dominant at this time (Table 4). This contrasts with +6,158 $/QALY at 2-years in our previous analysis [17]. At the earlier 90-days and 1-year post-op time periods, the costs continue to be lower for TOPS™ compared to TLIF while imparting gains in QALYs, suggesting very early economic dominance. At 1-year, for

Table 4
"Health state" - specific inputs

| Parameters | Period | Value | Source |
|---|---|---|---|
| 1. Health state distribution for index surgery | | All | |
| *Minimal* | Preoperative | 0% | RCT (SF-12) |
| *Moderate* | Preoperative | 4% | |
| *Severe* | Preoperative | 27% | |
| *Crippled* | Preoperative | 39% | |
| *Bedbound* | Preoperative | 30% | |
| 2. Probability of serious adverse event (related procedure or device) | | | |
| *Minimal* | Postoperative | 0.06 | RCT (AE) |
| *Moderate* | Postoperative | 0.05 | |
| *Severe* | Postoperative | 0.10 | |
| *Crippled* | Postoperative | 0.13 | |
| *Bedbound* | Postoperative | 0.12 | |
| 3. Probability of nonserious adverse event (related procedure or device) | | | |
| *Minimal* | Postoperative | 0.18 | RCT (AE) |
| *Moderate* | Postoperative | 0.11 | |
| *Severe* | Postoperative | 0.24 | |
| *Crippled* | Postoperative | 0.18 | |
| *Bedbound* | Postoperative | 0.24 | |
| 4. Probability of Subsequent action following adverse event | | | |
| *Serious* | Supplemental procedure | 0.18 | RCT (AE) |
| | Surgery | 0.64 | |
| *Nonserious* | Supplemental procedure | 0.42 | |
| | Surgery | 0.09 | |

example, the updated ICER is now −7,795.28 $/QALY (Table 5) compared to +61,446 $/QALY in the prior analysis [17]. From a societal perspective, at 1-year, the updated ICER has similarly improved to −38,564.62 $/QALY compared to the previous 25,377 $/QALY. At the 2-year base case analysis, the findings converge, with an updated cost savings of $1,716.90 and QALYs gained of 0.0375, again resulting in an ICER of -45,780 $/QALY (Table 5). The updated net monetary benefit of TOPS™ compared to TLIF at the 2-years with a WTP of 50,000 $/QALY for health system and societal perspectives are $2,236.59 and $3,592.05, respectively (Table 6). This compares to the previous model's values of $2,142 and $4,275, for health systems and societal perspectives, respectively [17].

### *Sensitivity analysis*

The TOPS™ intervention was cost-effective in all alternative scenarios tested (Table 7). Like the previous analysis, assuming a 100% Medicare population causes an inferior deviation in ICER and NMB, (ICER, −7,303.84 $/QALY; NMB at $100,000 WTP, $4,024.23) from base

Table 5
Base case results with medicare and private rates, both perspectives

| Health systems | | Tops | | Control | | | | |
|---|---|---|---|---|---|---|---|---|
| | Time horizon | *Cost** | *QALY* | *Cost* | *QALY* | *ΔCost*† | *ΔQALY*‡ | *ICER,*§ *$ per QALY* |
| | 90 d | $40,271.30 | 0.1793 | $40,277.53 | 0.1753 | −$6.23 | 0.004 | -$1,568.62 |
| | 1 y | $49,461.61 | 0.7273 | $49,588.18 | 0.7111 | −$126.57 | 0.0162 | -$7,795.28 |
| | 2 y (base case) | $54,381.77 | 1.4213 | $54,743.20 | 1.3838 | −$361.43 | 0.0375 | -$9,637.37 |
| | 6 y (extrapolated) | $73,203.28 | 4.0187 | $73,867.61 | 3.9314 | −$664.33 | 0.0873 | -$7,613.50 |
| | 10 y (extrapolated) | $90,157.49 | 6.3543 | $91,081.04 | 6.2403 | −$923.56 | 0.114 | -$8,103.79 |
| Societal | 90 d | $40,523.12 | 0.1793 | $40,612.07 | 0.1753 | −$88.95 | 0.004 | -$22,396.32 |
| | 1 y | $51,245.02 | 0.7273 | $51,871.19 | 0.7111 | −$626.17 | 0.0162 | -$38,564.63 |
| | 2 y (base case) | $58,512.18 | 1.4213 | $60,229.07 | 1.3838 | −$1,716.90 | 0.0375 | -$45,780.15 |
| | 6 y (extrapolated) | $85,927.76 | 4.0187 | $89,633.44 | 3.9314 | −$3,705.68 | 0.0873 | -$42,468.84 |
| | 10 y (extrapolated) | $110,091.77 | 6.3543 | $115,084.30 | 6.2403 | −$4,992.53 | 0.114 | -$43,807.11 |

* Cost of TOPS cohort
† ΔCost = TOPS cost - Control Cost
‡ ΔQALY = TOPS QALY - Control QALY
§ ICER = ΔCost / ΔQALY; 'Dominant' indicates that TOPS costs less while yielding a higher QALY

Table 6
Net monetary benefits, both perspectives

| Health systems | Time horizon | Tops | | Control | | NMB, based on three WTP thresholds† | | |
|---|---|---|---|---|---|---|---|---|
| | | *Cost** | *QALY* | *Cost* | *QALY* | WTP=$50,000 | WTP=$100,000 | WTP=$150,000 |
| | 90 d | $40,271.30 | 0.1793 | $40,277.53 | 0.1753 | $204.82 | $403.41 | $602.00 |
| | 1 y | $49,461.61 | 0.7273 | $49,588.18 | 0.7111 | $938.41 | $1,750.26 | $2,562.10 |
| | 2 y | $54,381.77 | 1.4213 | $54,743.20 | 1.3838 | $2,236.59 | $4,111.74 | $5,986.89 |
| | 6 y | $73,203.28 | 4.0187 | $73,867.61 | 3.9314 | $5,027.15 | $9,389.97 | $13,752.80 |
| | 10 y | $90,157.49 | 6.3543 | $91,081.04 | 6.2403 | $6,621.87 | $12,320.18 | $18,018.49 |
| Societal | 90 d | $40,523.12 | 0.1793 | $40,612.07 | 0.1753 | $287.54 | $486.13 | $684.72 |
| | 1 y | $51,245.02 | 0.7273 | $51,871.19 | 0.7111 | $1,438.01 | $2,249.86 | $3,061.70 |
| | 2 y | $58,512.18 | 1.4213 | $60,229.07 | 1.3838 | $3,592.05 | $5,467.21 | $7,342.36 |
| | 6 y | $85,927.76 | 4.0187 | $89,633.44 | 3.9314 | $8,068.50 | $12,431.33 | $16,794.15 |
| | 10 y | $110,091.77 | 6.3543 | $115,084.30 | 6.2403 | $10,690.84 | $16,389.16 | $22,087.47 |

* Includes TOPS cohort cost.
† NMB = (ΔQALY *WTP threshold) - ΔCost.

case (9,637.37 $/QALY, NMB at $100,000; $4,111.74) (Table 6). In comparison, when 100% commercial payers are considered, there is corresponding improvement in the ICER (−11,970 $/QALY) and NMB at $100,000 WTP ($4,199.25). These trends all appear similar to our earlier work [17].

The OWSA results reveal that among input parameters, facility fee has the greatest effect on cost, with the difference between the two strategies centered around −$924 (Fig. 2). Our previous analysis's cost difference was centered around $300, and this same input parameter has the greatest impact on the ICER (Fig. 4) [17]. The utility difference between the strategies centers around 0.114 and is most impacted by the minimal health states (Fig. 3). Holistically, OWSA results for cost, effect, and ICER favor the TOPS™ intervention compared to the TLIF control (Figs. 2−4).

In the PSA, the effect difference ranged from −0.02 to 0.2. The cost difference ranged from -$20,000 to $20,000 (Fig. 5). Of the 5,000 iterations simulated, a total of 4,627 iterations fell below the WTP line, suggesting that TOPS™ is highly likely to be cost-effective compared to TLIF in most scenarios (Fig. 5). This is further illustrated in the acceptability curve, representing 92.5% of the simulations at a WTP of $100,000 per QALY (Fig. 6). This represents a substantial increase from the prior analysis where only 63.1% of the iteration simulations favored TOPS™ [17].

## Discussion

The results of this updated 2-year analysis appear to be far superior to what we previously reported from the 1-year dataset. The findings suggest that TOPS™ is economically dominant in all scenarios, a conclusion that only previously attained at an extrapolated 6-year timeframe. Economic dominance is defined as an intervention that is less costly while affording greater benefit compared to a control. At the 2-year base case, the value of −9,637.37 $/QALY far exceeds the ICER of +6,158 $/QALY presented in our previous early analysis. In reviewing the literature, we can compare the 10-year extrapolated ICER of TOPS™ (−8,103.79 $/QALY) to the 10-year ICER of a decompression and fusion (3,281 $/QALY) and decompression alone (1,040 $/QALY), again illustrating a marked difference between interventions [20]. At the most stringent WTP threshold of 50,000 $/QALY, TOPS™ remains cost-effective, until the cost difference between the interventions exceeds $1,875. This amount increases to $3,750 at the 100,000 $/QALY WTP threshold.

It seems that the previous model was heavily influenced by the assumed $4,000 upcharge for the TOPS™ device. For a more 'real-world' economic scenario and equipoise, this was removed in this updated model. The transition probabilities for TOPS™ (Table 2) and TLIF (Table 3) demonstrate similar patient recovery trajectories as in the prior manuscript. With time, there is a discernibly greater distribution of patients transitioning to the minimal health state for TOPS™ than the TLIF cohort (Fig. 1). There is similarly a greater transition from the minimal to the crippled health states in TLIF patients compared to TOPS™ (Fig. 1). Not surprisingly, patient complications have been reported as having the greatest impact on health, disutility, cost, and resource allocation [21].

Initial assumptions did not appear to have a substantial effect on cost-effectiveness. These included a 2-year analytical time horizon for accruing health benefits and costs, while assuming a 50/50 split between Medicare and commercial payers as well as a 50/50 inpatient and outpatient surgical settings. The ICER was mostly similar irrespective of surgical setting, likely owing to short hospitalizations and bundled payment systems. The study found that the NMB was ∼$2,000 at the 50,000 $/QALY at 2-years for all evaluated scenarios. The utilities were similarly not impacted by the setting or payer. The OWSA was used to assess uncertainty associated with input parameters around the base case. The facility fee had the greatest impact on cost difference. This appears to stem from any revision operations, which were lower in the

Table 7
Cost-effectiveness of TOPS vs TLIF in alternative scenarios

| Scenario | | TOPS | | TLIF | | Difference | | Results | | Net monetary benefit§ | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1. Health systems 50/50 Insurance Inpatient (Base Case) | Timepoint | Cost | QALY | Cost | QALY | ΔCost* | ΔQALY† | ICER‡ | Status | $50,000 | $100,000 | $150,000 |
| | 3 mo | $40,271.30 | 0.1793 | $40,277.53 | 0.1753 | -$6.23 | 0.004 | -$1,568.62 | Dominant | $204.82 | $403.41 | $602.00 |
| | 1 y | $49,461.61 | 0.7273 | $49,588.18 | 0.7111 | -$126.57 | 0.0162 | -$7,795.28 | Dominant | $938.41 | $1,750.26 | $2,562.10 |
| | 2 y | $54,381.77 | 1.4213 | $54,743.20 | 1.3838 | -$361.43 | 0.0375 | -$9,637.37 | Dominant | $2,236.59 | $4,111.74 | $5,986.89 |
| | 6 y | $73,203.28 | 4.0187 | $73,867.61 | 3.9314 | -$664.33 | 0.0873 | -$7,613.50 | Dominant | $5,027.15 | $9,389.97 | $13,752.80 |
| | 10 y | $90,157.49 | 6.3543 | $91,081.04 | 6.2403 | -$923.56 | 0.114 | -$8,103.79 | Dominant | $6,621.87 | $12,320.18 | $18,018.49 |
| 2. Societal 50/50 insurance inpatient (base case) | Timepoint | Cost | QALY | Cost | QALY | ΔCost* | ΔQALY† | ICER | Status | $50,000 | $100,000 | $150,000 |
| | 3 mo | $40,523.12 | 0.1793 | $40,612.07 | 0.1753 | -$88.95 | 0.004 | -$22,396.32 | Dominant | $287.54 | $486.13 | $684.72 |
| | 1 y | $51,245.02 | 0.7273 | $51,871.19 | 0.7111 | -$626.17 | 0.0162 | -$38,564.63 | Dominant | $1,438.01 | $2,249.86 | $3,061.70 |
| | 2 y | $58,512.18 | 1.4213 | $60,229.07 | 1.3838 | -$1,716.90 | 0.0375 | -$45,780.15 | Dominant | $3,592.05 | $5,467.21 | $7,342.36 |
| | 6 y | $85,927.76 | 4.0187 | $89,633.44 | 3.9314 | -$3,705.68 | 0.0873 | -$42,468.84 | Dominant | $8,068.50 | $12,431.33 | $16,794.15 |
| | 10 y | $110,091.77 | 6.3543 | $115,084.30 | 6.2403 | -$4,992.53 | 0.114 | -$43,807.11 | Dominant | $10,690.84 | $16,389.16 | $22,087.47 |
| 3. Health systems 100% medicare inpatient | Timepoint | Cost | QALY | Cost | QALY | ΔCost* | ΔQALY† | ICER | Status | $50,000 | $100,000 | $150,000 |
| | 3 mo | $27,983.50 | 0.1793 | $27,988.00 | 0.1753 | -$4.50 | 0.004 | -$1,132.01 | Dominant | $203.09 | $401.68 | $600.27 |
| | 1 y | $35,693.96 | 0.7273 | $35,784.46 | 0.7111 | -$90.50 | 0.0162 | -$5,573.55 | Dominant | $902.34 | $1,714.18 | $2,526.03 |
| | 2 y | $39,874.69 | 1.4213 | $40,148.60 | 1.3838 | -$273.92 | 0.0375 | -$7,303.84 | Dominant | $2,149.07 | $4,024.23 | $5,899.38 |
| | 6 y | $55,835.67 | 4.0187 | $56,353.76 | 3.9314 | -$518.09 | 0.0873 | -$5,937.58 | Dominant | $4,880.92 | $9,243.74 | $13,606.56 |
| | 10 y | $70,175.15 | 6.3543 | $70,893.79 | 6.2403 | -$718.64 | 0.114 | -$6,305.69 | Dominant | $6,416.95 | $12,115.26 | $17,813.57 |
| 4. Health systems 100% private inpatient | Timepoint | ΔCost* | ΔQALY† | Cost | QALY | ΔCost* | ΔQALY† | ICER | Status | $50,000 | $100,000 | $150,000 |
| | 3 mo | $52,559.09 | 0.1793 | $52,567.05 | 0.1753 | -$7.96 | 0.004 | -$2,005.24 | Dominant | $206.55 | $405.14 | $603.73 |
| | 1 y | $63,229.26 | 0.7273 | $63,391.90 | 0.7111 | -$162.64 | 0.0162 | -$10,017.00 | Dominant | $974.49 | $1,786.33 | $2,598.18 |
| | 2 y | $68,888.84 | 1.4213 | $69,337.79 | 1.3838 | -$448.95 | 0.0375 | -$11,970.91 | Dominant | $2,324.10 | $4,199.25 | $6,074.41 |
| | 6 y | $90,570.90 | 4.0187 | $91,381.46 | 3.9314 | -$810.56 | 0.0873 | -$9,289.42 | Dominant | $5,173.39 | $9,536.21 | $13,899.03 |
| | 10 y | $110,139.82 | 6.3543 | $111,268.30 | 6.2403 | -$1,128.48 | 0.114 | -$9,901.90 | Dominant | $6,826.79 | $12,525.11 | $18,223.42 |
| 5. Health systems 50/50 insurance outpatient | Timepoint | Cost | QALY | Cost | QALY | ΔCost* | ΔQALY† | ICER | Status | $50,000 | $100,000 | $150,000 |
| | 3 mo | $23,350.80 | 0.1793 | $23,357.03 | 0.1753 | -$6.23 | 0.004 | -$1,568.62 | Dominant | $204.82 | $403.41 | $602.00 |
| | 1 y | $32,541.11 | 0.7273 | $32,667.68 | 0.7111 | -$126.57 | 0.0162 | -$7,795.28 | Dominant | $938.41 | $1,750.26 | $2,562.10 |
| | 2 y | $37,461.27 | 1.4213 | $37,822.70 | 1.3838 | -$361.43 | 0.0375 | -$9,637.37 | Dominant | $2,236.59 | $4,111.74 | $5,986.89 |
| | 6 y | $56,282.78 | 4.0187 | $56,947.11 | 3.9314 | -$664.33 | 0.0873 | -$7,613.50 | Dominant | $5,027.15 | $9,389.97 | $13,752.80 |
| | 10 y | $73,236.99 | 6.3543 | $74,160.54 | 6.2403 | -$923.56 | 0.114 | -$8,103.79 | Dominant | $6,621.87 | $12,320.18 | $18,018.49 |

Table 7 (***Continued***)

| Scenario | | TOPS | | TLIF | | Difference | | Results | | Net monetary benefit[§] | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 6. Health systems 50/50 insurance 50/50 | Timepoint | Cost | QALY | Cost | QALY | ΔCost[*] | ΔQALY[†] | ICER | Status | $50,000 | $100,000 | $150,000 |
| | 3 mo | $31,811.05 | 0.1793 | $31,817.28 | 0.1753 | -$6.23 | 0.004 | -$1,568.62 | Dominant | $204.82 | $403.41 | $602.00 |
| | 1 y | $41,001.36 | 0.7273 | $41,127.93 | 0.7111 | -$126.57 | 0.0162 | -$7,795.28 | Dominant | $938.41 | $1,750.26 | $2,562.10 |
| | 2 y | $45,921.52 | 1.4213 | $46,282.95 | 1.3838 | -$361.43 | 0.0375 | -$9,637.37 | Dominant | $2,236.59 | $4,111.74 | $5,986.89 |
| | 6 y | $64,743.03 | 4.0187 | $65,407.36 | 3.9314 | -$664.33 | 0.0873 | -$7,613.50 | Dominant | $5,027.15 | $9,389.97 | $13,752.80 |
| | 10 y | $81,697.24 | 6.3543 | $82,620.79 | 6.2403 | -$923.56 | 0.114 | -$8,103.79 | Dominant | $6,621.87 | $12,320.18 | $18,018.49 |
| 7. Health systems 100% medicare outpatient | Timepoint | Cost | QALY | Cost | QALY | ΔCost[*] | ΔQALY[†] | ICER | Status | $50,000 | $100,000 | $150,000 |
| | 3 mo | $16,453.50 | 0.1793 | $16,458.00 | 0.1753 | -$4.50 | 0.004 | -$1,132.01 | Dominant | $203.09 | $401.68 | $600.27 |
| | 1 y | $24,163.96 | 0.7273 | $24,254.46 | 0.7111 | -$90.50 | 0.0162 | -$5,573.55 | Dominant | $902.34 | $1,714.18 | $2,526.03 |
| | 2 y | $28,344.69 | 1.4213 | $28,618.60 | 1.3838 | -$273.92 | 0.0375 | -$7,303.84 | Dominant | $2,149.07 | $4,024.23 | $5,899.38 |
| | 6 y | $44,305.67 | 4.0187 | $44,823.76 | 3.9314 | -$518.09 | 0.0873 | -$5,937.58 | Dominant | $4,880.92 | $9,243.74 | $13,606.56 |
| | 10 y | $58,645.15 | 6.3543 | $59,363.79 | 6.2403 | -$718.64 | 0.114 | -$6,305.69 | Dominant | $6,416.95 | $12,115.26 | $17,813.57 |
| 8. Health systems 100% private outpatient | Timepoint | Cost | QALY | Cost | QALY | ΔCost[*] | ΔQALY[†] | ICER | Status | $50,000 | $100,000 | $150,000 |
| | 3 mo | $30,248.09 | 0.1793 | $30,256.05 | 0.1753 | -$7.96 | 0.004 | -$2,005.24 | Dominant | $206.55 | $405.14 | $603.73 |
| | 1 y | $40,918.26 | 0.7273 | $41,080.90 | 0.7111 | -$162.64 | 0.0162 | -$10,017.00 | Dominant | $974.49 | $1,786.33 | $2,598.18 |
| | 2 y | $46,577.84 | 1.4213 | $47,026.79 | 1.3838 | -$448.95 | 0.0375 | -$11,970.91 | Dominant | $2,324.10 | $4,199.25 | $6,074.41 |
| | 6 y | $68,259.90 | 4.0187 | $69,070.46 | 3.9314 | -$810.56 | 0.0873 | -$9,289.42 | Dominant | $5,173.39 | $9,536.21 | $13,899.03 |
| | 10 y | $87,828.82 | 6.3543 | $88,957.30 | 6.2403 | -$1,128.48 | 0.114 | -$9,901.90 | Dominant | $6,826.79 | $12,525.11 | $18,223.42 |

[*] ΔCost = TOPS cost - Control Cost.
[†] ΔQALY = TOPS QALY - Control QALY.
[‡] ICER = ΔCost / ΔQALY; 'Dominant' indicates that TOPS costs less while yielding a higher QALY.
[§] NMB = ΔQALY *WTP threshold - ΔCos.

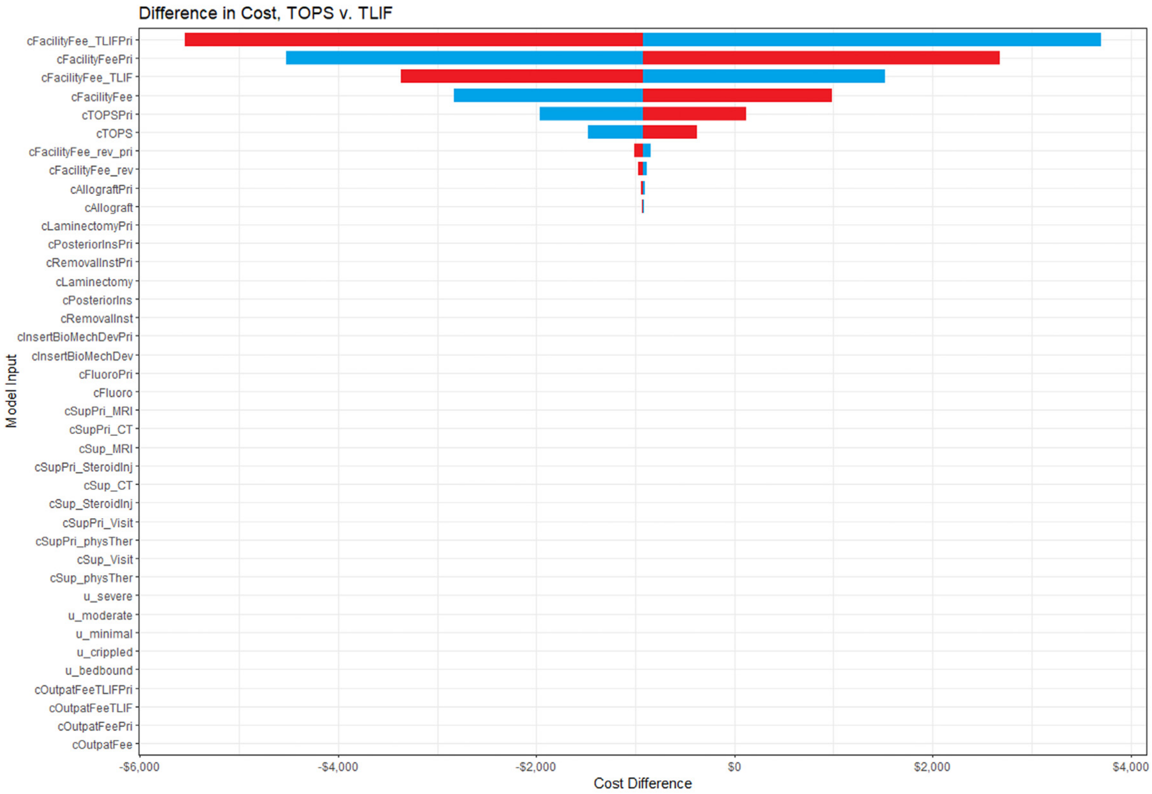


Fig. 2. OWSA results for costs of TOPS vs. control. Each parameter is varied by ±20% of its base case value.

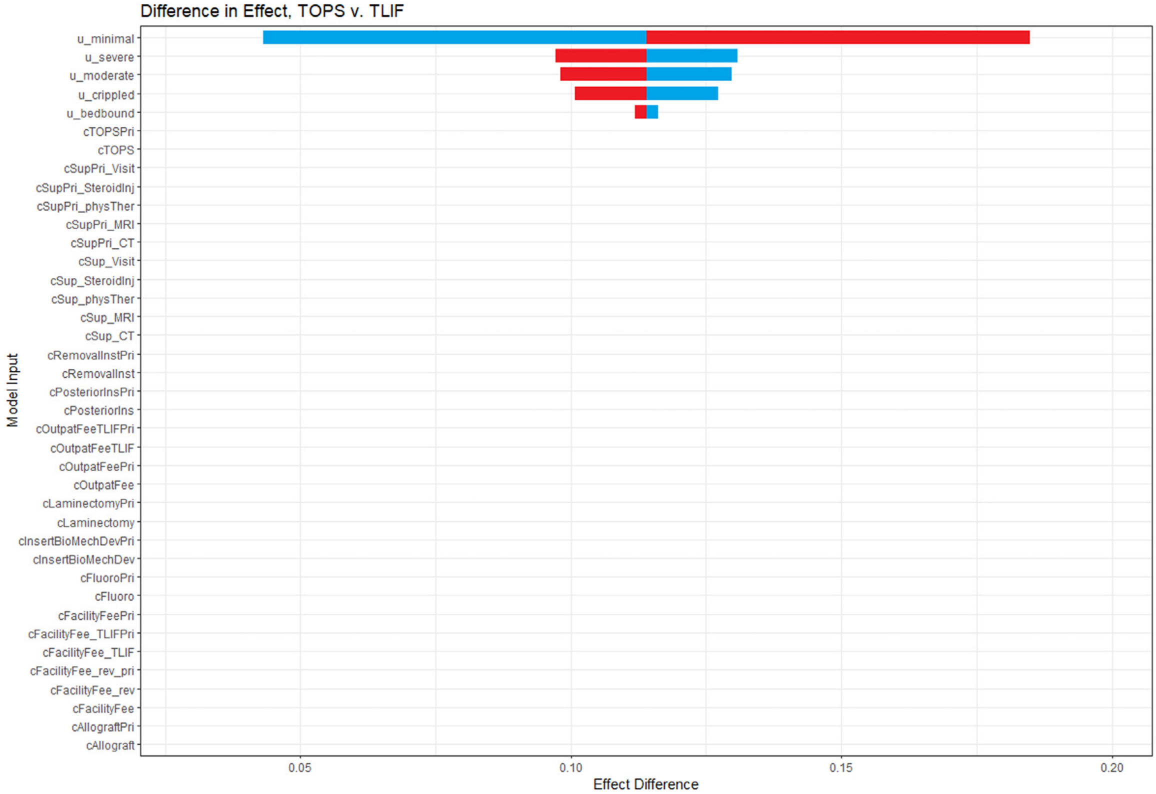


Fig. 3. OWSA results for effect of TOPS vs. control. Each parameter is varied by ±20% of its base case value.

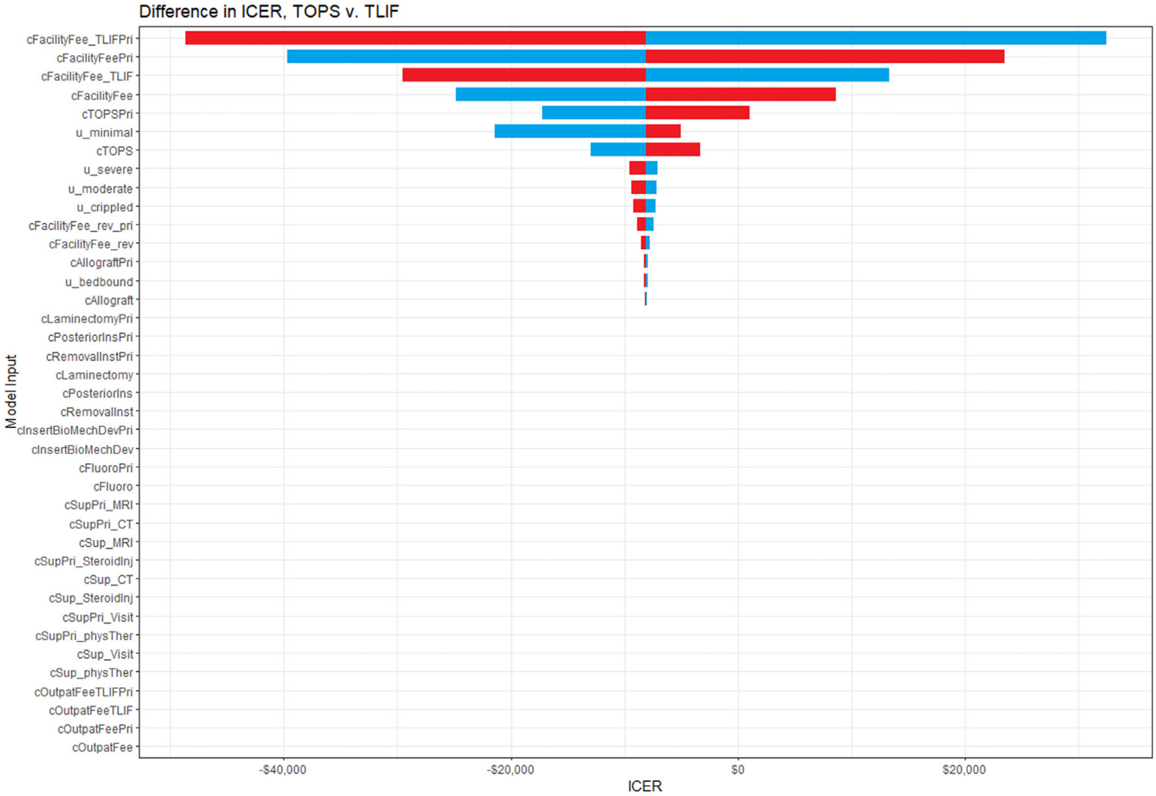


Fig. 4. OWSA results for incremental cost-effectiveness ratio of TOPS vs control. Each parameter is varied by ±20% of its base case value.

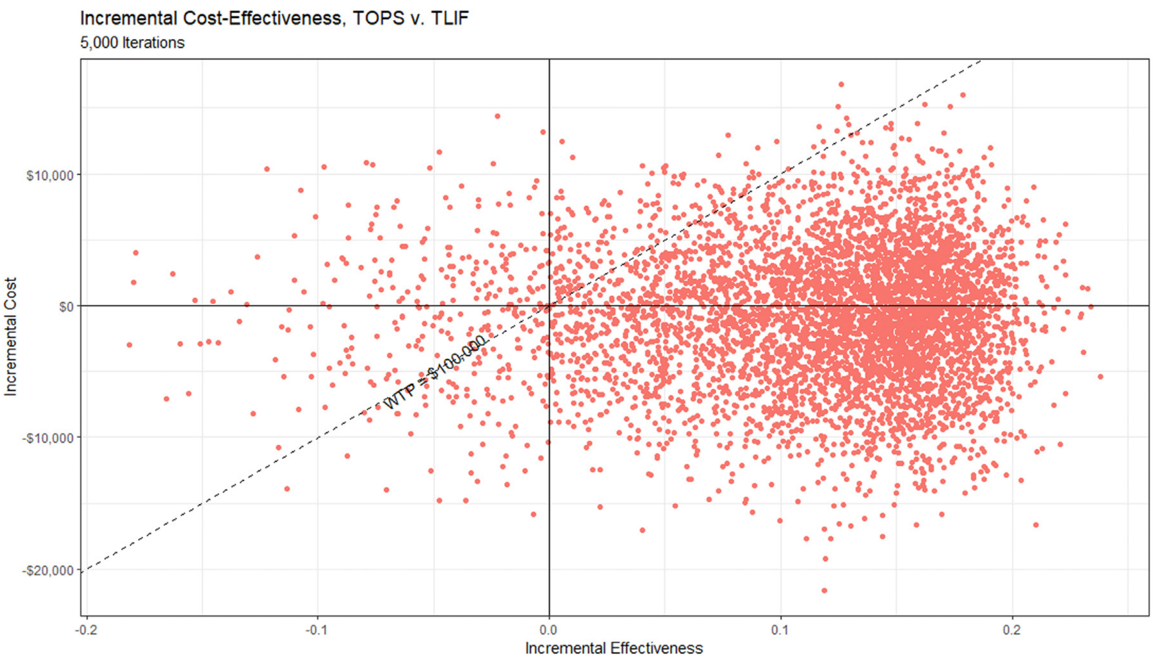


Fig. 5. Cost-effectiveness scatter plot. The control strategy, TLIF, is on the point of origin. All other points are simulation results. Each other point is in reference to the control strategy, meaning that points to the right of origin are "more effective" and below the origin, "less expensive."

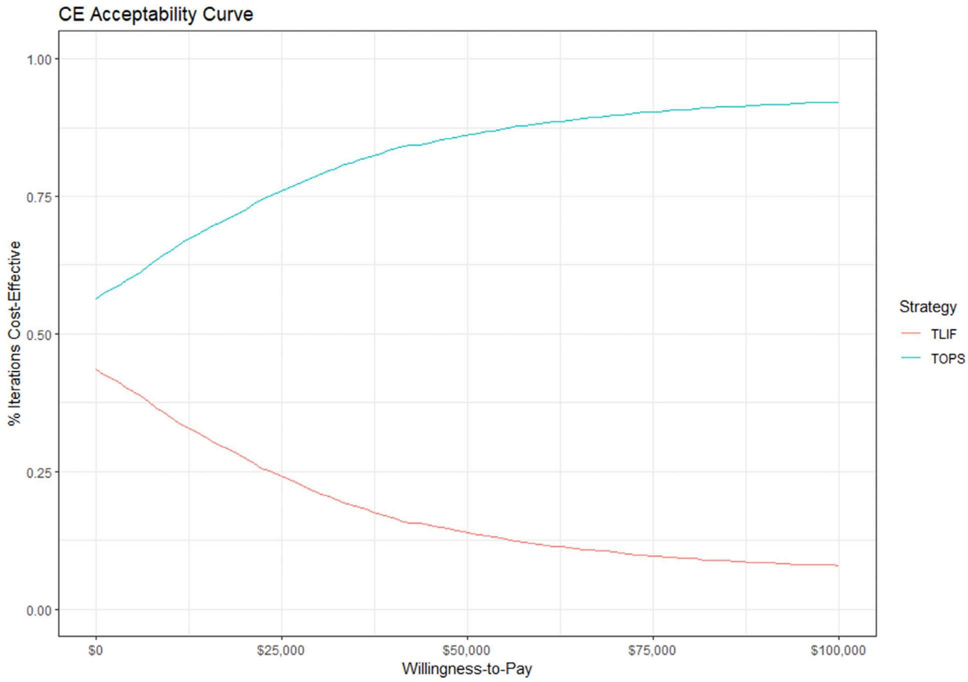


Fig. 6. Cost-effectiveness acceptability curves. The y-axis indicates the percentage of the 5,000 iterations in which the strategy is considered cost-effective given a specific WTP threshold. For example, the probability for TOPS at the WTP of $100,000 per QALY gain is about 92.5%, meaning that TOPS is the more cost-effective strategy in around ~4,627 (5,000*92.5%) iterations.

TOPS™ cohort. The PSA was similarly significant in that 92.5% of scenarios favored TOPS™ compared to 63.1% in our previous analysis.

It is important to acknowledge the limitations of this analysis. Cost assessment in healthcare is an intricate process and calculations have inherent variability [22,23]. This is further confounded by the fact that costs can fluctuate regionally. As a result, national averages were used and can theoretically skew the data in any one direction. It is reassuring that significant regional differences in outcomes were not appreciated in the clinical manuscript. Also, Markov Models are conditional to present health states, with the past and future states acting independently. It would be conceivable that a patient's health state trajectory is dependent on previous health states. Moreover, the Markov Model assumes that populations begin in similar health states. This seems reasonable considering the data was abstracted from an RCT but pragmatically we acknowledge that is unlikely to be true. Highly salient to all cost-effectiveness analyses are challenges in capturing true productivity loss. This study was similarly limited and unable to account for elements such as transportation and caregiver costs. To mitigate the limitations, our report utilized a myriad of complex sensitivity analyses. Despite accounting for model uncertainty and variances, TOPS™ was overwhelmingly cost-effective compared to TLIF. Lastly, this research was supported by Premia Spine. While this can undoubtedly create implicit bias, the authors all adhere to the highest ethical standards. The data was abstracted from the ongoing FDA IDE clinical trial data set and Premia Spine was not involved in the decisions, analysis, or creation of this manuscript.

This study not only reaffirms our prior conclusion but suggests a continued longitudinal improvement in cost-effectiveness over time. These current ICER values for TOPS™ compared to TLIF is based on a more complete dataset from the IDE trial and should theoretically inform a more robust and accurate model. The TOPS™ device appears to be overwhelmingly cost-effective compared to TLIF and should be considered a highly viable option for appropriate patients. Innovative interventions tend to be considerably more costly than the current standards they seek to replace. A series of complex analyses and processes tend to follow for the 'system' to determine if this is a sustainable and meaningful alternative. It is exceedingly uncommon for novel technology, such as the TOPS ™ System, to provide improved quality of life at a lower long-term cost. Although still early, this certainly appears to be a healthcare economic discovery. The authors suggest that the data be followed closely and updated periodically alongside the IDE study. In an effort to identify similar technologies and economic trends in the future, it is paramount that we continue to monitor the complex and longitudinal components of cost-effectiveness following early analyses and extrapolations.

## Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

## CRediT authorship contribution statement

**Jared D. Ament:** Writing − review & editing, Writing − original draft, Visualization, Validation, Supervision, Software, Resources, Project administration, Methodology, Funding acquisition, Formal analysis, Conceptualization. **Jack Petros:** Writing − original draft, Visualization, Validation, Project administration, Methodology, Formal analysis. **Tina Zabehi:** Writing − original draft, Visualization, Methodology, Investigation, Formal analysis, Conceptualization. **Randy Yee:** Writing − original draft, Visualization, Validation, Supervision, Software, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **J. Patrick Johnson:** Writing − review & editing, Supervision, Resources, Project administration, Formal analysis. **Amir Vokshoor:** Writing − review & editing, Supervision, Software, Resources, Project administration, Formal analysis.

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## Supplementary materials

Supplementary material associated with this article can be found in the online version at https://doi.org/10.1016/j.spinee.2024.01.004.

## References

[1] Ravindra Vijay M, Senglaub Steven S, Rattani Abbas, Dewan Michael C, Härtl Roger, Bisson Erica, et al. Degenerative Lumbar Spine Disease: Estimating Global Incidence and Worldwide Volume. Global Spine J 2018 Dec;8(8):784–94. https://doi.org/10.1177/2192568218770769. Epub 2018 Apr 24. PMID: 30560029; PMCID: PMC6293435.

[2] Wang Yi Xiang J, Káplár Zoltán, Deng Min, Leung Jason C S. Lumbar Degenerative Spondylolisthesis Epidemiology: A Systematic Review with a Focus on Gender-Specific and Age-Specific Prevalence. J Orthop Translat 2017;11:39–52. https://doi.org/10.1016/j.jot.2016.11.001.

[3] Martin Brook I, Mirza Sohail K, Spina Nicholas, Spiker William R, Lawrence Brandon, Brodke Darrel S. Trends in Lumbar Fusion Procedure Rates and Associated Hospital Costs for Degenerative Spinal Diseases in the United States, 2004 to 2015. Spine (Phila Pa 1976) 2019 Mar 1;44(5):369–76 PMID: 30074971. https://doi.org/10.1097/BRS.0000000000002822.

[4] Schneider Nicole, Fisher Charles, Glennie Andrew, Urquhart Jennifer, Street John, Dvorak Marcel, et al. Lumbar Degenerative Spondylolisthesis: Factors Associated with the Decision to Fuse. Spine J 2021;21(5):821–8. https://doi.org/10.1016/j.spinee.2020.11.010.

[5] Lubelski Daniel MD, Williams Seth KMD‡, O'Rourke Colin MS†;, et al. Differences in the Surgical Treatment of Lower Back Pain Among Spine Surgeons in the United States. Spine (Phila Pa 1976) June 1, 2016;41(11):978–86. https://doi.org/10.1097/BRS.0000000000001396.

[6] Austevoll Ivar Magne, Gjestad Rolf, Solberg Tore, Storheim Kjersti, Brox Jens Ivar, Hermansen Erland, et al. Comparative Effectiveness of Microdecompression Alone vs Decompression Plus Instrumented Fusion in Lumbar Degenerative Spondylolisthesis. JAMA Netw Open 2020;3(9): e2015015. https://doi.org/10.1001/jamanetworkopen.2020.15015.

[7] Kaiser Radek, Kantorová Lucia, Langaufová Alena, Slezáková Simona, Tučková Dagmar, Klugar Miloslav, et al. Decompression alone versus decompression with instrumented fusion in the treatment of lumbar degenerative spondylolisthesis: a systematic review and meta-analysis of randomised trials. J Neurol Neurosurg Psychiatry 2023 Aug;94(8):657–66. https://doi.org/10.1136/jnnp-2022-330158.

[8] Joaquim AF, Milano JB, Ghizoni E, Patel AA. Is There a Role for Decompression Alone for Treating Symptomatic Degenerative Lumbar Spondylolisthesis?: A Systematic Review. Clin Spine Surg 2016 Jun;29(5):191–202 PMID: 26710187. https://doi.org/10.1097/BSD.0000000000000357.

[9] Azizpour Kayoumars, Schutte Pieter J, Arts Mark P, Pondaag Willem, Bouma Gerrit J, Coppes Maarten, et al. Clinical outcome in decompression alone versus decompression and instrumented fusion in patients with isthmic spondylolisthesis: a prospective cohort study. J Neurosurg Spine 2023 Feb 3;38(5):573–84 PMID: 36738462. https://doi.org/10.3171/2022.12.SPINE22808.

[10] Pinter Zachariah W, Freedman Brett A, Nassr Ahmad, Sebastian Arjun S, Coric Domagoj, Welch William C, et al. A Prospective Study of Lumbar Facet Arthroplasty in the Treatment of Degenerative Spondylolisthesis and Stenosis: Results from the Total Posterior Spine System (TOPS) IDE Study. Clin Spine Surg March 2023;36 (2):E59–69. https://doi.org/10.1097/BSD.0000000000001365.

[11] Centers for Medicare Medicaid Services. *National Health Expenditure Data: Historical*. Accessed September 10, 2021. https://www.cms.go/NationalHealthExpendData/NationalHealthAccountsHistorical

[12] Minemyer Paige. CMS: National Health Spending Grew by 2.7% in 2021 as the COVID-19 Pandemic's Effects Linger. Fierce Healthcare 2022. 14 Dec https://www.fiercehealthcare.com/payers/cms-national-health-spending-grew-27-2021-covid-19-pandemics-effects-linger.

[13] Harrop James S, Hilibrand Alan, Mihalovich Kathryn E, Dettori Joseph R, Chapman Jens. Cost-effectiveness of surgical treatment for degenerative spondylolisthesis and spinal stenosis. Spine (Phila Pa 1976) 2014 Oct 15;39(22 Suppl 1):S75–85 PMID: 25299263. https://doi.org/10.1097/BRS.0000000000000545.

[14] Hoy Damian, March Lyn, Brooks Peter, Blyth Fiona, Woolf Anthony, Bain Christopher, et al. The global burden of low back pain: estimates from the Global Burden of Disease 2010 study. Ann Rheum Dis 2014;73:968–74.

[15] Tosteson Anna N A, Lurie Jon D, Tosteson Tor D, Skinner Jonathan S, Herkowitz Harry, Albert Todd, et al. for the SPORT Investigators. Surgical treatment of spinal stenosis with and without degenerative spondylolisthesis: cost-effectiveness after 2 years. Ann Intern Med 2008;149(12):845–53.

[16] Ament JD, Kim KD. Standardizing cost-utility analysis in neurosurgery. Neurosurg Focus 2012 Jul;33(1):E4. PMID: 22746236. https://doi.org/10.3171/2012.4.FOCUS1288.

[17] Ament JD, Vokshoor A, Badr Y, Lanman T, Kim KD, Johnson JP. A Prospective Study of Lumbar Facet Arthroplasty in the Treatment of Degenerative Spondylolisthesis and Stenosis: Early Cost-effective Assessment from the Total Posterior Spine System (TOPS) IDE Study. J Health Econ Outcomes Res 2022 Mar 25;9(1):82–9 PMID: 35620455; PMCID: PMC9132256. https://doi.org/10.36469/001c.33035.

[18] Summary of Safety and Effectiveness Data. https://www.accessdata.fda.gov/cdrh_docs/pdf22/P220002B.pdf. Accessed 11/1/2023

[19] Sanders Gillian D, Neumann Peter J, Basu Anirban, Brock Dan W, Feeny David, Krahn Murray, et al. Recommendations for Conduct, Methodological Practices, and Reporting of Cost-effectiveness Analyses: Second Panel on Cost-Effectiveness in Health and Medicine. JAMA 2016 Sep 13;316 (10):1093–103 Erratum in: JAMA. 2016 Nov 8;316(18):1924. PMID: 27623463. https://doi.org/10.1001/jama.2016.12195.

[20] Kim Salin, Hedjri Soroush Mortaz, Coyte Peter C, Raja Rampersaud Y. Cost-Utility of Lumbar Decompression with or without Fusion for Patients with Symptomatic Degenerative Lumbar Spondylolisthesis. Spine J 2012;12(1):44–54. https://doi.org/10.1016/j.spinee.2011.10.004.

[21] Chotai Silky, Sivaganesan Ahilan, Parker Scott L, Wick Joseph B, Stonko David P, McGirt Matthew J, et al. Effect of complications within 90 days on cost per quality-adjusted life year gained following elective surgery for degenerative lumbar spine disease. Neurosurgery 2017;64(suppl_1):157–64. https://doi.org/10.1093/neuros/nyx356.

[22] Alvin Matthew D, Miller Jacob A, Lubelski Daniel, Rosenbaum Benjamin P, Abdullah Kalil G, Whitmore Robert G, et al. Variations in cost calculations in spine surgery cost-effectiveness research. Neurosurgical Focus FOC 2014;36(6):1–10 Retrieved May 5, 2023, from. https://doi.org/10.3171/2014.3.FOCUS1447.

[23] Missios S, Bekelis K. Hospitalization cost after spine surgery in the United States of America. J Clin Neurosci 2015;22(10):1632–7.