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Nail fixation of unstable trochanteric fractures with or without cement augmentation: A cost-utility analysis in the United States Cost-utility of cement augmentation

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ABSTRACT

Objectives: Recent clinical studies have shown favorable outcomes for cement augmentation for fixation of trochanteric fracture. We assessed the cost-utility of cement augmentation for fixation of closed unstable trochanteric fractures from the US payer's perspective.

Methods: The cost-utility model comprised a decision tree to simulate clinical events over 1 year after the index fixation surgery, and a Markov model to extrapolate clinical events over patients' lifetime, using a cohort of 1,000 patients with demographic and clinical characteristics similar to that of a published randomized controlled trial (age ≥75 years, 83 % female). Model outputs were discounted costs, quality-adjusted life years (QALYs), and incremental cost-effectiveness ratio (ICER) over a lifetime. Deterministic and probabilistic sensitivity analyses were performed to assess the impact of parameter uncertainty on results.

Results: Fixation with augmentation reduced per-patient costs by $754.8 and had similar per-patient QALYs, compared to fixation without augmentation, resulting in an ICER of −$130,765/QALY. The ICER was most sensitive to the utility of revision surgery, mortality risk ratio after the second revision surgery, mortality risk ratio after successful index surgery, and mortality rate in the decision tree model. The probability that fixation with augmentation was cost-effective compared with no augmentation was 63.4 %, 58.2 %, and 56.4 %, given a maximum acceptable ceiling ratio of $50,000, $100,000, and $150,000 per QALY gained, respectively.

Conclusion: Fixation with cement augmentation was the dominant strategy, driven mainly by reduced costs. These results may support surgeons in evidence-based clinical decision making and may be informative for policy makers regarding coverage and reimbursement.

Introduction

Trochanteric hip fractures account for 42 % of all hip fracture types [1]. Compared with femoral neck fractures, trochanteric fractures are associated with older age, osteoporosis, multiple comorbidities, longer hospital stay, poorer function, and higher mortality [2–4]. In the United States (US), trochanteric hip fractures account for 44 % of total healthcare costs for all hip fracture types, with most costs being incurred during the first 90 days following fracture for inpatient hospitalization and skilled nursing facility services [1,2].

Treatment choice for trochanteric hip fracture is open reduction and internal fixation with sliding hip screw systems or intramedullary nailing devices [5]. Despite modifications and improvement of osteosynthesis devices, unstable trochanteric fracture still poses significant

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challenges, with rates of cut out or cut through requiring reoperations from 4.9 % to 9.8 % [6–9]. One solution may be cement augmentation. Several biomechanical studies have demonstrated that cement augmentation improved stability and cut-out/pull-out strength of the construct stability [10–13]. Recent clinical studies reported an overall complication rate of cement augmentation around 3 % or less for trochanteric fractures [14–16]. In a randomized controlled trial (RCT) of closed unstable trochanteric fractures, Kammerlander et al [17] reported six (4.4 %) implant-related reoperations in the non-augmented group, three each due to mechanical failure and symptomatic implant migration, compared with no implant-related reoperations in the augmented group. Nonetheless, causes for concern about cement augmentation for fracture fixation include thermal necrosis and difficulty in removing implant during revision surgery [18].

With the growing emphasis on healthcare costs and value-based medicine in the US, it is important to determine whether additional clinical benefit and therewith associated costs are well balanced. The objective of this cost-utility analysis was to determine whether fixation with cement augmentation was cost-effective versus fixation without augmentation for closed unstable trochanteric fractures from the US healthcare payer's perspective.

Methods

Model cohort and model structure

Details of the cost-utility model have been published elsewhere [19, 20]. The model cohort comprised 1,000 patients whose demographics and clinical characteristics were similar to those of the RCT by Kammerlander et al. [17], i.e., adults aged ≥75 years, 83 % female, closed unstable trochanteric fracture due to a low-energy trauma, and an indication for fixation with Proximal Femoral Nail Antirotation™ (PFNA – DePuy Synthes, West Chester, PA – USA). The model cohort underwent two strategies, i.e., index surgeries: fixation with TRAUMACEM™ V+ Injectable Bone Cement augmentation (a polymethyl methacrylate bone cement) and fixation without cement augmentation. Because the current study is a cost-utility modeling and not a clinical study, an ethics approval was not necessary.

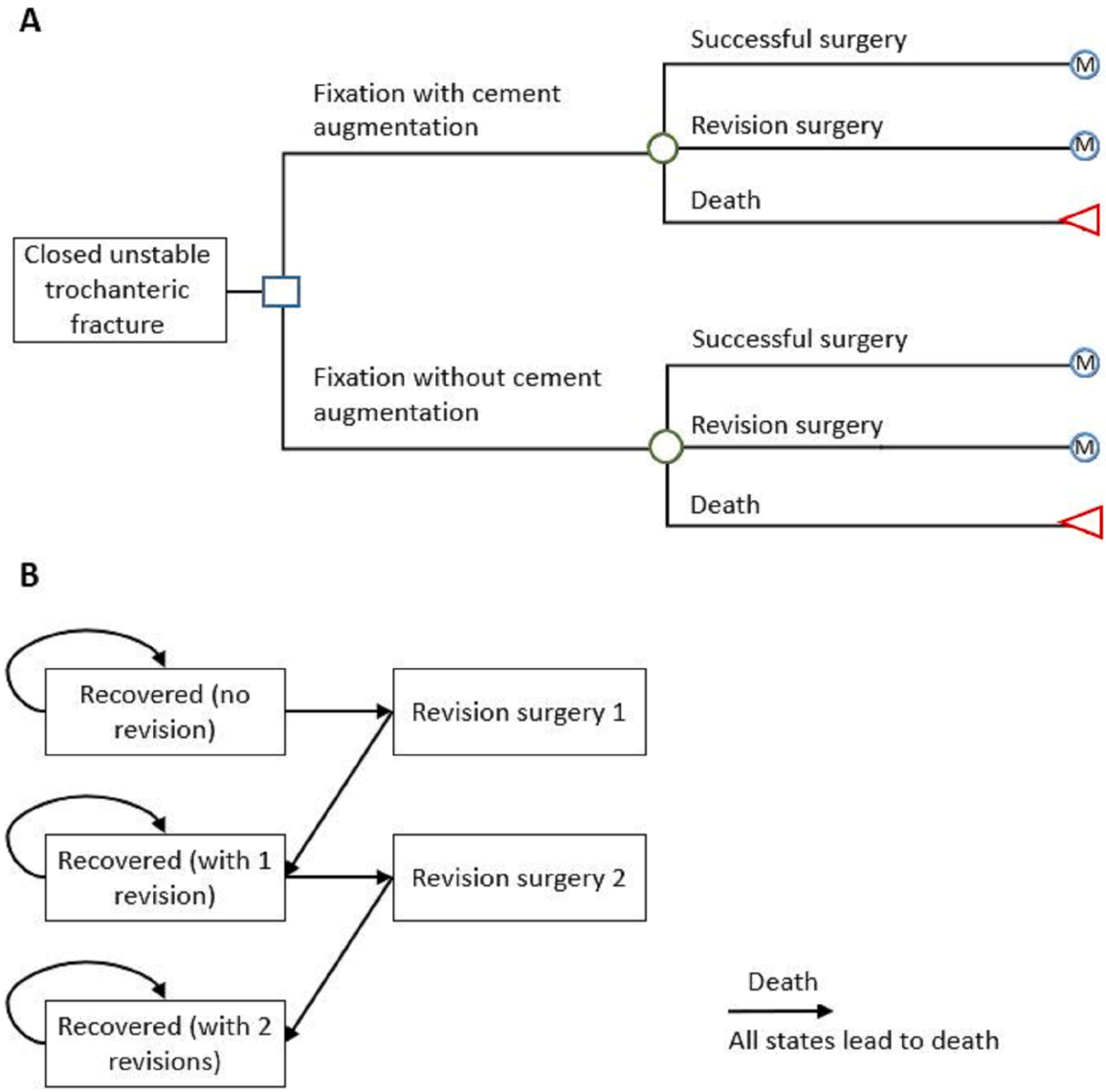

Fig. 1. Model structure.
The two-stage model consisted of a short-term decision tree model (A, one year after the index surgery) and a long-term Markov state-transition model (B, from the second year after the index surgery to lifetime). Adapted from Cost-Effectiveness of Cement Augmentation Versus No Augmentation for the Fixation of Unstable Trochanteric Fractures [19] (open access under CCBY-NC-ND 4.0)

The cost-utility model had two stages, a short-term decision tree model and a time heterogeneous Markov model [19,20]. Three clinical events (successful surgery [requiring no revision surgeries], implant-related revision surgery, and death) [17] and their associated costs and utilities over the first year after the index surgery were simulated in the decision tree model [19,20] (Fig. 1A). The Markov model extrapolated clinical events, costs, and utilities from 1 year after the index surgery to lifetime. In the Markov model, surviving patients were assumed to transition into either "recovered with no revision" or "recovered with one revision" (Fig. 1B). Patients either remained in these states or transitioned to death or additional revision surgery (all-cause ipsilateral revision). A maximum of two revisions surgeries were allowed in the Markov model. The Markov model had a cycle length of 1 year and reflected a lifetime horizon. Tunnel states were implemented to consider the increased mortality rates at 1 year and 2 years after successful index surgery if revision surgeries had been performed [19]. Half-cycle correction was included since patients could transition from one state to another at any time during the cycle duration [19].

Model assumptions and input parameters

Based on the current literature [17,19,21], the model assumed that other clinical events or complications were balanced between strategies; therefore, these events were not considered. Cement-related complications such as toxicity, leakage or pulmonary embolism were also not simulated because they were very rare in trochanteric fracture fixation [21–25], particularly with the routinely performed leakage test before augmentation, and because data on disutility associated with cement-related complications in fracture care were not available [19]. Because of the lack of long-term data on the effect of augmentation on revision surgery rate and mortality rate following revision surgery, the model assumed that these rates were the same between the two strategies [19].

The model was populated with data from the previous RCT [17], published literature [26–28], and supplemental clinical and administrative claims data (Table 1). Recommended by the Panel on Cost-Effectiveness in Health and Medicine [29], both costs and utilities were discounted at a rate of 3 % per year to incorporate the "time preference" where costs and benefits in the future were valued less than those that were immediately realized [29,30].

Probabilities of events in the decision tree model were obtained from the RCT data [17]. For the Markov model, background mortality rates were obtained from the US national life tables [31,32], and rates of revision surgery and mortality were estimated from survival analyses (Cox semi-parametric model) of patient cohorts with hip fracture and nail implantation procedures between 2000 and 2020 from the US Medicare Standard Analytical File (SAF) database, matched to the RCT population by age, sex, and Charlson Comorbidity Index [19,33]. The mortality rate was assumed to be elevated for the first 2 years after a successful index procedure or after a revision procedure in both treatment groups [19].

Costs were considered from the US healthcare payer's perspective and inflated to 2020 US dollars using the consumer price index obtained from the US Bureau of Labor Statistics [34]. Costs of healthcare resource utilizations due to revision surgery, including costs of physician visits, home health agency, skilled nursing facility, inpatient rehabilitation facility, and outpatient hospitals, were included in the model and obtained from published literature [27]. For the augmentation strategy, the costs related to cement augmentation, including the costs of the procedure itself and costs of the required leakage test, were obtained from the Premier Healthcare Database [35]. The augmentation strategy was estimated to increase the surgical time by 5 minutes based on the RCT results [17], and the additional operating room time was calculated using a minute rate of $16.2 [28]. For both treatment groups, costs in conjunction with the index procedure or other complications were concluded to be identical and were therefore not considered.

Table 1
Model parameters.

Variables	Value	Reference/source
Population characteristics		
Cohort size	1,000	-
Mean age at the first surgery, years	85	17
Male sex, %	17.0 %	17
Decision tree model (1st year after index surgery)		
Probabilities		
Revision surgery, without augmentation	4.4 %	17
Successful surgery*, without augmentation	85.2 %	17
Death, without augmentation†	10.4 %	17
Revision surgery, with augmentation	0 %	17
Successful surgery*, with augmentation	89.6 %	17
Death, with augmentation†	10.4 %	17
Utilities		
Successful surgery after fixation	0.708	17
Disutility (multiplier) of revision surgery	0.85	17
Markov model (2nd year after index surgery to lifetime)		
Probabilities of revision surgery		
1st revision surgery given a successful index surgery	Time dependent	Survival analyses‡
1 year after successful index surgery	0.43 %	
2 years after successful index surgery	0.30 %	
≥3 years after successful index surgery	0.40 %	
2nd revision surgery	2.36 %	Survival analyses‡
Probability of death		
Mortality given a successful index surgery, year 2 (relative risk)†	1.57	Survival analyses‡
Mortality given a successful index surgery, year ≥3†	Background mortality	31, 32
Mortality after revision, year 1 (relative risk)	2.13	Survival analyses‡
Mortality after revision, year 2 (relative risk)	1.57	Survival analyses‡
Background mortality	-	31, 32
Utilities		
Successful surgery (SE)	0.754 (0.004)	26
Disutility (multiplier) of revision surgery	0.85	17
Costs and use of healthcare resources		
Total cement augmentation costs	$1,134	
Cement augmentation costs	$1,053	35
Increased OR time (5 minutes, $16.2/minute)	$81	17, 28
Leakage test costs	$82	35
Costs of healthcare resource utilization due to revision surgery		
First revision surgery costs	$16,129	US Medicare SAF database
Second revision surgery costs	$31,400	US Medicare SAF database
Physicians visit	$4,602.0	27
Home health agency	$1,835.37	27
Skilled nursing facility	$7,858.59	27
Inpatient rehab facility	$7,068.77	27
Outpatient hospital	$2,179.36	27

Refer to Appendix for the probability distributions of model parameters used in the sensitivity analyses.
OR indicates operating room; SAF, Standard Analytical File; SE, standard error; US, United States.
* Successful surgery refers to successful index surgery with no revision surgeries needed.
† Increased mortality was considered post successful index surgery for two years. The mortality parameter from trial data (for year 1 post index surgery) was used in the decision tree. Relative risk calculated based on survival analyses was used in the Markov model (for year 2 post index surgery). Baseline background mortality was assumed in year 3 onwards.
‡ Survival analyses using the US Medicare SAF database.

Effectiveness was measured in quality-adjusted life years (QALYs). QALYs were calculated by estimating the remaining years of life after the index surgery and weighing each year with a utility score anchored on a 0 (death) to 1 (perfect health) scale. One QALY equates to a year of perfect health, whereas <1 QALY equates to one year of less-than-perfect health; the severity of the health state impacts the size of the reduction. Utility of successful index surgery (for the decision tree model) and disutility of revision surgery (for both decision tree and Markov models) were estimated based on the RCT results [17,19,20] of the five EuroQol-5D-3L dimensions [36] using the US time trade-off value set provided by the EuroQoL group [37]. Utility of successful surgery for the Markov model was estimated from published literature [26]. Disutility due to revision surgery was assumed to impact patients' utility only in the cycle in which it occurred. Utility values reported over the model time horizon were aggregated to QALYs.

Analyses

In the base-case analysis, the incremental cost-effectiveness ratio (ICER) was the average cost per additional QALY gain ($/QALY) for fixation with augmentation compared with no augmentation.

Uncertainty of the model results was evaluated using sensitivity analyses (Appendix). Probabilities of the events, utilities of the event, cost data, and the discount rate were the model parameters that were included in the sensitivity analyses. To identify which parameters significantly influenced the costs, QALYs, and ICER of the base-case scenario, one-way deterministic sensitivity analyses were conducted by varying only a single parameter in their 95 % confidence interval where available or using baseline values ± 15 % while all others remained unchanged [19]. Results of deterministic sensitivity analyses were presented in tornado diagrams, showing the impact of the uncertainty of each model parameter on the ICER, cost difference, and QALY difference. Probabilistic sensitivity analyses were conducted using a parametric Monte Carlo simulation with 10,000 iterations by varying all model parameters simultaneously using their respective probability distributions. Results of the probabilistic sensitivity analyses were presented in cost-effectiveness scatterplots and cost-effectiveness acceptability curves (CEACs), showing the amount of uncertainty of choosing one strategy over the other when accounting for the cumulative uncertainty of all model parameters. The CEACs plotted a range of willingness-to-pay (WTP) thresholds from $0 to $150,000 per QALY on the horizontal axis against the probability of fixation with augmentation being cost-effective compared to no augmentation at that threshold on the vertical axis.

Because the rates of revision surgery assumed in the base-case analysis were lower than previous studies [38–40], the results might be a conservative estimate of the cost-utility of fixation with augmentation. Rates in the base-case analysis may have been lower because the original RCT was carried out in tertiary trauma centers with experienced and skilled orthopedic surgeons [17]. A scenario analysis was therefore conducted to provide more generalized estimates of the cost-utility of fixation with augmentation using rates of revision surgery obtained from a meta-analysis by Rompen et al [25] (1.6 % for fixation with augmentation and 7.4 % for fixation without augmentation, $p = 0.009$) in the decision tree model.

Results

Base-case analyses

Fixation with augmentation dominated no augmentation, i.e., it was associated with lower costs per patient ($1,961.6 versus $2,716.4) and similar QALYs per patient (3.816 versus 3.811). The ICER was −130,765 $/QALY (Table 2).

Sensitivity analyses

The four most influential parameters on the model of ICER were, in rank order, the utility of revision surgery, mortality risk ratio after the second revision surgery, mortality risk ratio after successful index surgery, and mortality rate in the decision tree model (Fig. 2). For the cost difference between the two strategies, greatest result variabilities were related to revision surgery rates in the decision tree model and costs of augmentation (Appendix B, Fig. S1). For the QALY difference, the most influential parameters were mortality rates in the decision tree model, utility of revision surgery, mortality risk ratio after the second revision surgery, and mortality risk ratio after successful index surgery (Appendix C, Fig. S2).

The incremental cost-effectiveness scatterplot showed more robustness of fixation with augmentation being associated with lower costs than it being associated with increased QALYs (99.7 % vs 52.7 % of the 10,000 simulations, Fig. 3). Regardless of the willingness-to-pay threshold, fixation with augmentation was more likely to be cost-effective than no augmentation (Fig. 4). The probability that fixation with augmentation was cost-effective compared with no augmentation, given the observed data, was 63.4 %, 58.2 %, and 56.4 % at WTP thresholds of $50,000, $100,000, and $150,000 per QALY, respectively.

Scenario analyses

Compared with base-case analyses, the scenario analyses showed that surgical fixation with augmentation was associated with greater cost savings (incremental costs: −1,382.0 $/patient), while gains in QALYs remained unchanged (incremental QALYs: 0.01 per patient). The ICER in the scenario analyses was −181,618$/QALY (Table 2).

Discussion

Results from this study showed that the reduced risk of implant-related revision surgery with cement augmentation may translate into

Table 2
Results of the base-case and scenario analyses.

	Costs ($)	QALYs	Incremental costs* ($)	Incremental QALY*	ICER ($/QALY)
Base-case analysis					
Augmentation	1,961.6	3.816	-754.8	0.01	-130,765 (Dominant)
No augmentation	2,716.4	3.811	-	-	-
Scenario analysis†					
Augmentation	2,678.3	3.814	-1,382.0	0.01	-181,618 (Dominant)
No augmentation	4,060.3	3.807	-	-	-

Results are shown as costs or QALY(s) per patient. ICER indicates incremental cost-effectiveness ratio; QALYs, quality-adjusted life years.

* Incremental costs/QALYs per patient calculated as costs/QALYs per patient of augmentation minus costs/QALYs per patient of no augmentation.

† In the scenario analysis, higher rates of revision surgery (1.6 % for augmentation and 7.4 % for no augmentation) were assumed in the decision tree model. These rates were based on the meta-analysis by Rompen et al [6].

Fig. 2. Tornado diagram showing the influence of each model parameter on the incremental costs-effectiveness ratio.
ICER: incremental cost-effectiveness ratio; DT: decision tree.

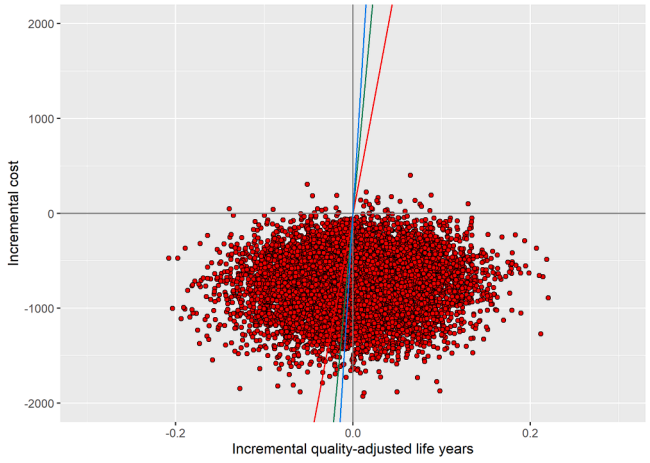

Fig. 3. Incremental cost-effectiveness scatterplot comparing fixation with cement augmentation versus fixation without augmentation.
The scatterplot shows willingness-to-pay thresholds at $50,000 (red line), $100,000 (green line), and $150,000 (blue line) per quality-adjusted life year (QALY). Each point represents an incremental cost-effect pair. Each quadrant corresponds with increased/decreased costs or improved/reduced QALYs. Fixation with cement augmentation was associated with lower costs and increased QALYs in 99.7 % and 52.7 % of the 10,000 iterations, respectively.

lower costs in the long term from the US healthcare payers' perspective. In the base-case analysis, fixation with augmentation dominated fixation with no augmentation, driven mainly by reduced costs. Probabilistic sensitivity analyses showed more robustness of cost savings than of QALY gains, which was expected because augmentation was not expected to have significant impact on patients' length of life. At the three commonly used WTP thresholds [41], the probabilities of cement augmentation being cost-effective ranged from 56.4 % to 63.4 %. This indicates that cement augmentation is the superior strategy most of the times, but uncertainty around model parameter values used in this study precludes us from concluding the superiority of cement augmentation in all cases. This uncertainty needs to be addressed when long-term data are available. Findings from this study are consistent with those from a previous one from the German healthcare payer's perspective [19], but cost reduction is greater and more robust (99.7 % vs 66.4 % of 10,000 simulations) in this study. The two analyses have the same model structure, with the decision tree model built on the RCT results [17], while background mortality rates, costs, and utilities are country specific [19].

The results favored the use of cement augmentation with respect to cost reduction when assuming low rates of revision surgery without augmentation (4.4 %) [17]. When assuming higher rates of revision surgery within the first year in non-augmented cases (7.4 %), cement augmentation was associated with even greater cost savings. The higher rates of revision surgery were based on a meta-analysis [25], which included various fixation devices to compare cement augmentation with no augmentation for the fixation of trochanteric fracture in patients >65 years old. Results from the scenario analyses may, therefore, represent an upper boundary of the cost-utility of cement augmentation. Overall, this might indicate that in patients at an even higher risk of revision surgery, such as those at older age or with poor bone quality [42,43], fixation with augmentation might be even more cost-effective. However, this warrants future studies to confirm.

The model in this study had several major assumptions. First, it assumed that implant-related revision surgery was the major clinical event that led to the differences in costs and effectiveness, and that the difference in revision surgery rate was restricted to the first year after the index surgery [19]. These conservative assumptions were largely based on the findings from the RCT [17], given the lack of long-term literature on the clinical outcomes of cement augmentation; however, augmentation may most likely have its greater impact in early stages of healing. Second, mortality rate was also assumed to be balanced between the two strategies, which was supported by the current literature that cement augmentation did not influence the mortality after fixation [17,21–23,25]. Finally, no other clinical events including other general complications were simulated in the model as they were considered balanced between the two strategies. Cement-related complications include mainly cement leakage into the joint and bone cement

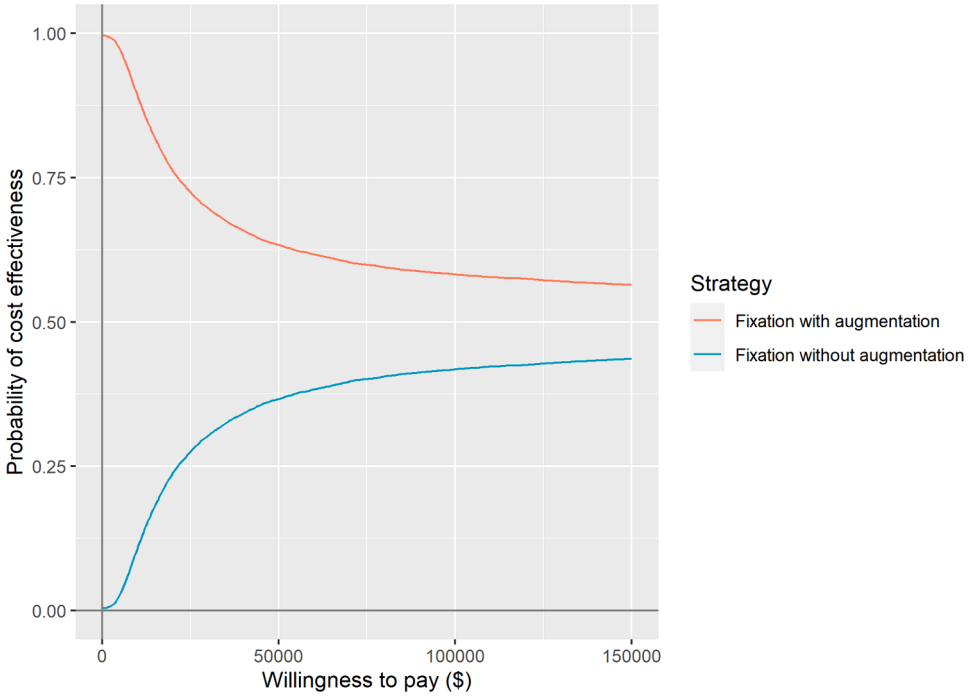

Fig. 4. Cost-effectiveness acceptability curves (CEACs).
The curves show the probabilities of fixation with cement augmentation and fixation without augmentation being cost-effective over a range of willingness-to-pay thresholds. The CEACs demonstrated a 63.4 %, 58.2 %, and 56.4 % certainty of PFNA with augmentation being cost-effective at willingness-to-pay thresholds of $50,000, $100,000, and $150,000 per QALY, respectively.

implantation syndrome. The former can be prevented by performing the required leakage test prior to injecting the bone cement [21], which represents a minimal impact on cost. Based on current literature, only two intraoperative complications of minor cement leakage into the joint have been reported from two studies [17,44]; in neither case did the leakage result in clinical problems for the patients or require additional intervention, hence no significant implications on costs or effectiveness. Bone cement implantation syndrome is rare in trochanteric fracture fixation but a more common concern for joint arthroplasty [45–47], where a greater volume of cement is implanted in a bone cavity with higher pressure resulting in higher risk of embolization of fat, bone marrow, and cement [48]. Nevertheless, future long-term data from large studies on the safety of cement augmentation in fracture fixation, should they be published, might lead to modification of this assumption and affect the model findings.

There are several limitations to our study. First, the decision tree model was built heavily based on the results of the RCT which reported a small number of implant-related revision surgeries, and the difference between the augmented and non-augmented group was not statistically significant [17,19,20]. Although this RCT represents the highest level of evidence on the clinical efficacy of cement augmentation, accuracy of the decision tree model parameter is subjected to the risk of bias of the RCT, such as the lack of blinding, imbalanced treatment adherence rate, missing data, and loss to follow-up [17]. Second, we used the analyses of the US Medicare SAF database to estimate the rates of revision surgery and mortality after revision surgery in the Markov model, but the US Medicare SAF database did not specify cement augmentation. Nonetheless, this should not have a major impact on the results because these rates were assumed to be balanced in the Markov model between the two strategies. It could have, however, underestimated the effect of augmentation and thus resulted in a more conservative model. Third, the Markov model assumed balanced probabilities of revision surgery and mortality between strategies because the current literature lacks comprehensive long-term comparative data on outcomes, rates of complications and revision surgery, and mortality rates after cement augmentation versus no augmentation. It is possible that the addition of long-term data could affect our findings. Fourth, cost savings might have been slightly underestimated because costs of a few healthcare resource utilizations, such as diagnostic investigations and medications, were not considered when calculating the costs of revision surgery. Finally, the analyses were performed from the US healthcare payer's perspective; therefore, results may not be generalizable to other healthcare system.

Conclusions

In conclusion, for closed unstable trochanteric fractures, based on an RCT with low revision rates in patients over 75 years old, fixation with cement augmentation was the dominant strategy compared with no augmentation from the US healthcare payer's perspective, mainly driven by cost savings. When assuming higher, potentially more representative, rates of revision surgery, we observed even greater cost savings. The results of this study may support surgeons in their evidence-based clinical decision making and may be informative for policy makers with respect to coverage and reimbursement.

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Role of the Funder/Sponsor

AO Foundation had no role in the design of this study, its execution, analyses, interpretation of the data, or decision to submit results.

CRediT authorship contribution statement

Alexander Joeris: Conceptualization, Data curation, Funding acquisition, Investigation, Methodology, Project administration, Resources, Supervision, Writing – original draft, Writing – review & editing. **Mina Kabiri:** Conceptualization, Data curation, Formal analysis,

Investigation, Methodology, Project administration, Resources, Software, Validation, Visualization, Writing – original draft, Writing – review & editing. **Thibaut Galvain:** Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Resources, Software, Validation, Visualization, Writing – original draft, Writing – review & editing. **Mollie Vanderkarr:** Conceptualization, Data curation, Investigation, Methodology, Project administration, Resources, Validation, Writing – original draft, Writing – review & editing. **Chantal E. Holy:** Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Resources, Software, Validation, Visualization, Writing – original draft, Writing – review & editing. **Javier Quintana Plaza:** Formal analysis, Investigation, Methodology, Resources, Validation, Writing – original draft, Writing – review & editing. **Julia Schneller:** Conceptualization, Methodology, Writing – review & editing. **Christian Kammerlander:** Conceptualization, Methodology, Supervision, Writing – review & editing.

Declaration of competing interest

Dr Joeris has nothing to disclose; Dr Kabiri reports other from Johnson and Johnson MedTech, during the conduct of the study; Dr Galvain reports other from Johnson and Johnson, during the conduct of the study; Ms Vanderkarr reports other from DePuy Synthes, Inc, during the conduct of the study; Dr Holy reports other from Johnson & Johnson, during the conduct of the study; other from Johnson & Johnson, outside the submitted work; and she is an employee of Johnson & Johnson; Dr Quintana Plaza has nothing to disclose; Dr Schneller has nothing to disclose; Dr Kammerlander reports other from DePuy Synthes, Inc, during the conduct of the study.

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Supplementary materials

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