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The Cost-Effectiveness of Computer-Assisted Navigation in Total Knee Arthroplasty

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Background: Total knee arthroplasty is one of the most clinically successful and cost-effective interventions in medicine. However, implant malalignment, especially in the coronal plane, is a common cause of early failure following total knee arthroplasty. Computer-assisted surgery has been employed during total knee arthroplasty to improve the precision of component alignment. The purpose of the present study was to evaluate the cost-effectiveness of computer-assisted surgery to determine whether the improved alignment achieved with computer navigation provides a sufficient decrease in failure rates and revisions to justify the added cost.

Methods: A decision-analysis model was used to estimate the cost-effectiveness of computer-assisted surgery in total knee arthroplasty. Model inputs, including costs, effectiveness, and clinical outcome probabilities, were obtained from a review of the literature. Sensitivity analyses were performed to evaluate the impact of component-alignment precision with use of computer-assisted and mechanical alignment guides, total knee arthroplasty failure rates secondary to malalignment, and costs of computer-assisted surgery systems on the cost-effectiveness of computer navigation in total knee arthroplasty.

Results: Computer-assisted surgery is both more effective and more expensive than mechanical alignment systems. Given an additional cost of $1500 per operation, a 14% improvement in coronal alignment precision (within 3° of neutral mechanical axis), and an elevenfold increase in revision rates at fifteen years with coronal malalignment (54% compared with 4.7%), the incremental cost of using computer-assisted surgery is $45,554 per quality-adjusted life-year gained. Cost-savings is achieved if the added cost of computer-assisted surgery is $629 or less per operation. Variability in published clinical outcomes, however, introduces uncertainty in determining the cost-effectiveness.

Conclusions: Computer-assisted surgery is potentially a cost-effective or cost-saving addition to total knee arthroplasty. However, the cost-effectiveness is sensitive to variability in the costs of computer navigation systems, the accuracy of alignment achieved with computer navigation, and the probability of revision total knee arthroplasty with malalignment.

Level of Evidence: Economic and decision analysis, Level I. See Instructions to Authors for a complete description of levels of evidence.

Total knee arthroplasty is one of the most clinically successful and cost-effective interventions in orthopaedics[1-6]. However, implant malalignment is a common cause of failure following total knee arthroplasty[7-12]. A number of studies have examined the accuracy of traditional mechanical alignment guides used for total knee arthroplasty and have demonstrated that while the majority of components are correctly positioned, there are a substantial number of outliers where positioning is outside of the ideal range[13-16].

Recently, computer-assisted surgical navigation systems

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have been developed and employed for total knee arthroplasty. The majority of studies examining computer-assisted surgery have shown more consistent restoration of neutral mechanical alignment, with improved precision of component placement in one or more of the measured anatomic planes, as compared with mechanical guides[17-38]. In particular, most studies have demonstrated consistently better alignment in the coronal plane, with significantly fewer outliers[18,19,23,29,35-38]. Proponents of computer-assisted surgery have argued that the improved consistency of alignment seen in association with computer navigation will improve implant longevity and decrease revision rates. Outcome studies have shown that component alignment in the coronal plane affects both functional success and component longevity. Components placed in a varus or valgus alignment have a higher rate of loosening and revision when compared with components placed in neutral alignment[1,3,5,10,12,14,39-42].

While the initial studies on the use of computer-assisted surgery have demonstrated improvement in postoperative alignment in total knee arthroplasty, to our knowledge the impact on long-term clinical outcomes, revision rates, and overall health-care costs has not been investigated. The purpose of the present study was to evaluate the cost-effectiveness of computer-assisted surgery in total knee arthroplasty.

Materials and Methods

Design

In the present analysis, the cost-effectiveness of total knee arthroplasty with use of computer navigation was compared with that of total knee arthroplasty with use of mechanical alignment guides (the current standard practice). The study population included individuals undergoing primary total knee arthroplasty for the treatment of osteoarthritis. A fifteen-year time-horizon was used on the basis of the available evidence in the literature regarding the impact of implant alignment on long-term implant survival following total knee arthroplasty. The cost-effectiveness ratios for computer-assisted surgery were examined from a health-care-system perspective.

Decision Model

Decision-analysis software (TreeAge Pro 2005, Williamstown, Massachusetts) was used to create a model for the treatment of osteoarthritis of the knee with total knee arthroplasty (Fig. 1). The decision tree begins with total knee arthroplasty with use of either traditional mechanical alignment guides or computer-assisted surgical navigation. The initial surgical outcomes are neutral alignment or malalignment (defined as >3° of varus or valgus mechanical alignment). The long-term outcomes are revision surgery with neutral alignment or malalignment.

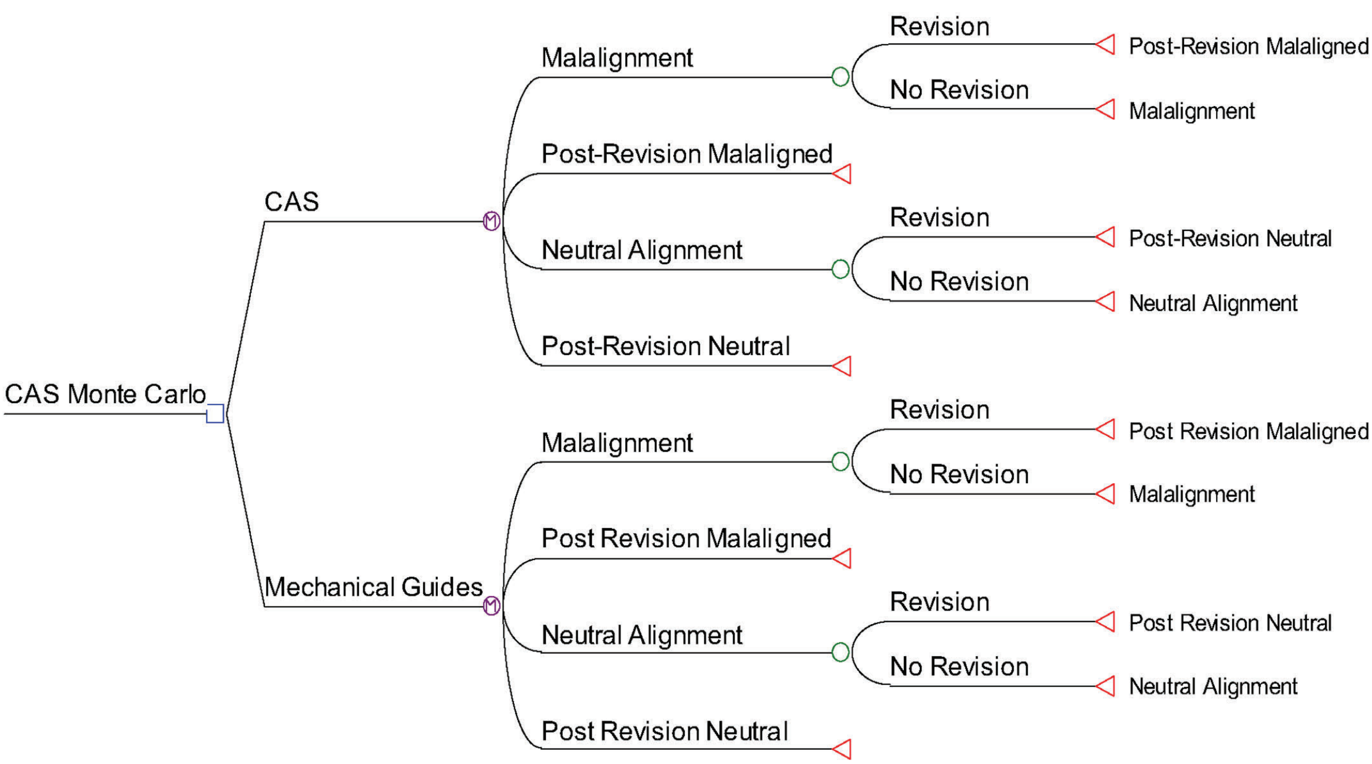

Fig. 1

Decision tree used in the cost-effectiveness analysis. Note that computer-assisted surgery (CAS) and mechanical guides (represented by the circle with the letter "M") are Markov nodes, with four states (Malalignment, Post-Revision Malaligned, Neutral Alignment, and Post-Revision Neutral) that represent the patient's status during each year of follow-up. Patients may make transitions each year from Malalignment to Post-Revision Malaligned or stay in the Malaligned state. Similarly patients may make transitions each year from Neutral Alignment to Post-Revision Neutral or stay in the Neutral Alignment state. The transition probabilities for computer-assisted surgery and for mechanical guides vary by year of follow-up.

TABLE I Variables in Markov Model

Variable	Value	Low Range	High Range	References
Probability				
Alignment with computer-assisted surgery	0.90	0.82	1	18,19,23,29,35-38
Alignment with mechanical guides	0.76	0.65	1	13-16,18,19,23,29,35-38
Revision with malalignment (cumulative probability at 15 years)	0.54*	0.15	0.80	3,10,14,39,41
Revision with neutral alignment (cumulative probability at 15 years)	0.047†	0	0.20	3,10,14,39,41
Utility (quality of life)				
Primary total knee arthroplasty	0.92	0.82	1	48,57,58
Revision total knee arthroplasty	0.80	0.60	0.90	48,57,58
Cost				
Incremental cost of computer-assisted surgery	$1500	$650	$4000	44-46
Primary total knee arthroplasty with mechanical guides	$11,018‡	$8000	$20,000	
Revision total knee arthroplasty with mechanical guides	$13,922‡	$10,000	$30,000	
Discount rate	3%	0%	5%	
Years of follow-up	15	5	15	

*Annual probability = 0.0080 at Years 0 to 9 and 0.1094 at Years 10 to 15[41]. †Annual probability = 0 at years 0 to 5 and 0.0048 at Years 6 to 15[41]. ‡Derived from 2006 Medicare reimbursement values.

Component Alignment and Implant Survival

The literature was reviewed to determine possible clinical outcomes and their probabilities. A review of the literature with use of the PubMed database (www.pubmed.gov) involving searches for the keywords "knee arthroplasty," "alignment," and "computer" was performed to identify studies examining implant alignment in the coronal plane with use of mechanical cutting guides and computer-assisted surgery. Reference lists from the retrieved articles also were examined to identify any additional studies of interest. The literature search identified four studies that exclusively examined postoperative alignment after total knee arthroplasty with mechanical cutting guides[13-16] and eight studies that compared mechanical cutting guides with computer-assisted surgery[18,19,23,29,35-38]. The baseline estimate used in the cost-effectiveness analysis for alignment was calculated by taking a weighted average based on the total number of patients evaluated in each of the studies (Table I).

A review of the literature with use of the PubMed database involving searches for the keywords "knee arthroplasty," "outcome," and "alignment" was also performed to identify studies examining implant longevity as it relates to component alignment. Five studies were identified that provided sufficient data to calculate the failure rates for each group[3,10,14,39,41]. The duration of follow-up ranged from two months to fifteen years, although all studies included some patients with at least eight years of follow-up. The baseline estimate for the fifteen-year cumulative incidence of revision surgery used in the analysis was determined by taking a weighted average based on the total number of patients evaluated in each of the studies. The annual probability of revision surgery was estimated from the fifteen-year cumulative incidence of revision surgery and the pattern of revision surgery over the fifteen-year period. For revision after neutral alignment, the annual rate of revision surgery was assumed to be zero for Years 0 to 5 and then constant for Years 5 to 15 to yield the cumulative incidence of 0.047 at Year 15. For revision after malalignment, the annual rate for Years 0 to 9 was calculated to produce a cumulative incidence of revision of 0.07 at nine years. A second annual probability of revision surgery was calculated for Years 10 to 15 to produce a fifteen year cumulative incidence of revision of 0.54 at fifteen years (Table I).

Cost Determination

The costs for primary and revision total knee arthroplasty were based on 2006 Medicare reimbursement for primary (Diagnosis Related Group 544) and revision (Diagnosis Related Group 545) total knee arthroplasty[43]. The cost estimates for start-up and incremental costs associated with computer-assisted surgical navigation equipment were obtained from published industry sources with a total of eight different vendors representing five different navigation equipment manufacturers surveyed[44]. Both fee-per-use and capital investment models were considered. These values were consistent with costs outlined in a report on image-guided surgical systems published by the Millennium Research Group, a health-care technology consulting firm, and a report published by the Ontario Ministry of Health and Long-Term Care[45,46]. Costs per patient varied with the total volume of procedures performed at a given institution, with per-case costs decreasing as the total number of cases per year increased. Costs also varied by region, type of contract, and navigation system used. Cost estimates included both fixed and variable costs associated with the surgical navigation equipment as well as direct and indirect costs incurred in the operating room due to additional operating-room time associated with computer-assisted surgery.

Analysis

A relatively conservative estimate of $1500 (in 2006 United States dollars) per procedure was chosen for the baseline case, with a broad range of cost estimates examined in the sensitivity analyses to incorporate multiple scenarios based on differences in geographic region, hospital procedure volume, and type of navigation equipment (ig I). As derived from the literature, the probability of neutral alignment with use of both mechanical guides (76%) and computer-assisted surgery (90%), and the probability of revision at fifteen years with neutral alignment (4.7%) and malalignment (54%) were used in the model. A discount rate of 3% annually was used with regard to costs and health outcomes, as recommended by the United States Panel on Cost-Effectiveness in Health and Medicine[47]. An incremental cost-effectiveness ratio was calculated from the incremental discounted fifteen-year costs of computer-assisted surgery as compared with mechanical guides and the incremental discounted fifteen-year quality-adjusted life-years for computer-assisted surgery as compared with mechanical guides.

Sensitivity Analysis

One-way sensitivity analyses were performed for each of the independent variables in Table I. In these analyses, each variable was individually varied over the ranges shown in Table I, and the incremental costs, incremental quality-adjusted life-years, and incremental cost-effectiveness ratios were calculated to identify thresholds for the independent variable at which computer-assisted surgery would be considered to result in cost-savings as compared with mechanical guides as well as thresholds at which computer-assisted surgery would be considered to be cost-effective based on an incremental cost per quality-adjusted life-year gained of $50,000.

A Monte Carlo sensitivity analysis was performed to evaluate the combined impact of all of the individual independent variables jointly in the incremental costs, incremental quality-adjusted life-years gained, and incremental cost-effectiveness ratios. In this analysis, each variable was represented as a probability distribution (Table II) and a random sample for each variable was drawn from its probability distribution and was entered into the model. The incremental costs, incremental quality-adjusted life-years gained, and incremental cost-effectiveness ratios and their 95% confidence intervals were calculated from a Monte Carlo simulation using 1000 samples.

Results

Cost-Effectiveness Ratio

In the base case analysis, computer-assisted surgery as compared with traditional mechanical alignment guides had an incremental cost of $871 and an incremental gain of 0.019 quality-adjusted life-year, yielding an incremental cost-effectiveness ratio of $45,554 per quality-adjusted life-year.

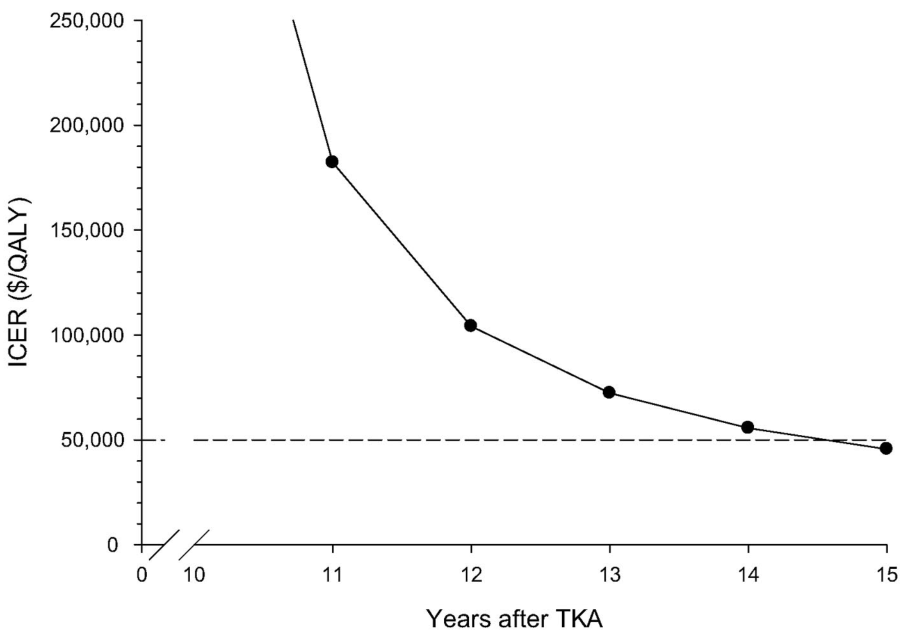

Fig. 2

One-way sensitivity analysis of incremental cost-effectiveness ratio (ICER) of computer-assisted surgery compared with mechanical guides by years of follow-up after total knee arthroplasty (TKA). The incremental cost-effectiveness ratio crosses $100,000 per quality-adjusted life-year (QALY) at 12.13 years and crosses $50,000 per quality-adjusted life-year at 14.56 years.

TABLE II Variables for Monte Carlo Sensitivity Analysis

Variable	Distribution	α	β	Mean	Standard Deviation
Probability of revision					
Malalignment after total knee arthroplasty	Beta	102.859	89.042	0.536	0.036
Neutral alignment after total knee arthroplasty	Beta	58.477	1185.717	0.047	0.006
Cost of computer-assisted surgery	Gamma	4	0.00266667	1500	750
Probability of alignment					
Computer-assisted surgery	Beta	82.969	9.014	0.902	0.031
Mechanical guides	Beta	175.704	54.275	0.764	0.028
Quality of life					
Primary total knee arthroplasty	Beta	42.32	3.68	0.92	0.04
Revision total knee arthroplasty	Beta	51.2	12.8	0.80	0.05
Cost					
Revision total knee arthroplasty	Gamma	7.752883	0.00055688	13,922	5000
Primary total knee arthroplasty	Gamma	13.48848	0.00122422	11,018	3000

Sensitivity Analysis

The results of the one-way sensitivity analyses to identify thresholds for cost-savings and thresholds for cost-effectiveness (based on an incremental cost-effectiveness ratio of <$50,000 per quality-adjusted life-year) are summarized in Table III. The relationship between the likelihood of neutral alignment with computer-assisted surgery and the incremental cost-effectiveness ratio as it relates to the incremental cost of computer-assisted surgery is shown in the Appendix. As the cost of computer-assisted surgery increases, a higher probability of neutral alignment with computer-assisted surgery would be required to produce cost-savings (see Appendix). Furthermore, as the probability of neutral alignment with computer-assisted surgery increases, cost-savings would be achieved at a lower threshold of the probability of revision with malalignment (see Appendix). The model is based on a fifteen-year time-horizon. At shorter time-points, there is less of a differential between the rates of failure between neutral and malaligned implants, and, accordingly, the incremental cost-effectiveness ratio is higher. The incremental cost-effectiveness ratio of computer-assisted surgery as compared with mechanical guides crosses the $100,000 per quality-adjusted life-year threshold at 12.13 years after total knee arthroplasty and the $50,000 per quality-adjusted life-year threshold at 14.56 years (Fig. 2). The variables and distributions for the Monte Carlo sensitivity analysis are shown in Table II. In the Monte Carlo sensitivity analysis, computer-assisted surgery as compared with mechanical guides had an incremental cost of $871 (95% confidence interval, $445 to $2909) and an incremental effectiveness of 0.0192 quality-adjusted life-year (95% confidence interval, –0.002 to 0.0473). The relationship between cost and effectiveness in the probability analysis, also referred to as the cost-effectiveness space, is shown in Figure 3 as a scatter plot. The relatively large distribution of potential incremental costs and associated effectiveness within the 95% confidence interval ellipse provides a visual depiction of the magnitude of uncertainty in the estimates of the incremental costs and incremental effectiveness. Although computer-assisted surgery was more effective in 97% of the samples in the simulation and was more expensive in 84.5%, the scatter plot and the 95% confidence intervals reveal that, in many of the simulations, the incremental cost-effectiveness ratio would be calcu-

TABLE III Thresholds for Base Case Determined in One-Way Sensitivity Analysis

	Threshold	
	"Cost-effective" (Incremental Cost-Effectiveness Ratio <$50,000/Quality-Adjusted Life-Year)	Cost Savings (Incremental Costs <$0)
Additional cost of computer-assisted surgery	$1585	$629
Cost of revision total knee arthroplasty	$12,043	$33,190
Probability of neutral alignment with mechanical guides	0.77	0.57
Probability of neutral alignment with computer-assisted surgery	0.90	No threshold
Probability of revision with neutral alignment at 15 years	0.069	No threshold
Probability of revision with malalignment at 15 years	0.509	No threshold

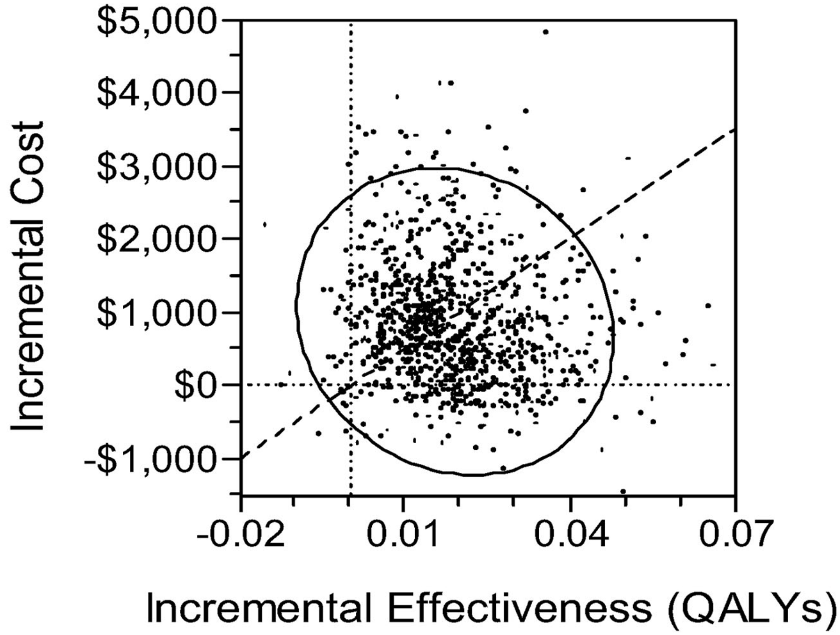

Fig. 3

Scatter plot depicting the incremental cost-effectiveness ratios derived from the Monte Carlo (probabilistic) sensitivity analysis. The ellipse represents the 95% confidence ellipse for the cost-effectiveness ratios. The dashed line denotes the threshold of $50,000 per quality-adjusted life-year (QALY). The vertical dashed line at 0 QALYs represents the incremental effectiveness threshold; positive values indicate increased effectiveness of computer-assisted surgery as compared with mechanical guides. The horizontal dashed line at $0 represents the incremental cost threshold; positive values indicate an increased cost of computer-assisted surgery as compared with mechanical guides. Note both the scatter in the estimates and that approximately half of the cost-effectiveness ratios from the Monte Carlo simulations are above and below the $50,000 per quality-adjusted life-year threshold line.

lated from negative incremental costs or negative incremental effectiveness. In this circumstance, it is more appropriate to summarize the uncertainty in the incremental cost-effectiveness ratio graphically in an acceptability curve. Figure 4 plots the proportion of the Monte Carlo simulations that were cost-effective, defined as an incremental cost-effectiveness ratio below the "willingness to pay" threshold shown on the x axis. Only 54% of simulations had an incremental cost-effectiveness ratio below the $50,000 per quality-adjusted life-year threshold, and 74% were below the $100,000 per quality-adjusted life-year threshold.

Discussion

Computer-assisted surgical navigation in total knee arthroplasty has been reported to result in a higher degree of precision in component placement when compared with traditional mechanical guides and potentially could be a valuable tool in the field of joint replacement[17-34]. As the technology is relatively new, there are no long-term outcome studies in which implant longevity following procedures performed with computer navigation has been compared with that following those performed with use of traditional mechanical guides. The present study provides a useful framework for evaluating the clinical utility of computer-assisted surgery in the context of the existing literature on component alignment and implant survivorship.

In the present study, a Markov decision model was utilized to evaluate the cost-effectiveness of computer-assisted surgery with use of known costs of the technology and procedures as well as outcomes data from a review of the published literature. On the basis of our base case estimates (Table I), computer-assisted surgery could be considered a cost-effective technology with an incremental cost-effectiveness ratio of $45,554 per quality-adjusted life-year, which is below the $50,000 per quality-adjusted life-year threshold, a threshold that is commonly used by policy-makers for defining cost-effectiveness[48-50]. From a public policy viewpoint, given the rising costs associated with total knee arthroplasty procedures, it is also important to consider thresholds for cost-savings associated with the use of new technologies. Our analysis demonstrates that the use of computer-assisted surgery in total knee arthroplasty can be cost-saving over the entire period of care when the initial cost of computer-assisted surgery is $629 or less per operation. Thus, as incremental costs decrease with improvements in the technology, the justification for using computer-assisted surgery increases. Computer navigation could reduce the costs and improve the quality of life associated with total knee arthroplasty when one considers both the initial and downstream costs (for example, revision procedures avoided) over a longer time-horizon. In higher-volume settings, the cost per case for computer-assisted surgery would be lower and cost-savings are readily achievable. While the in-

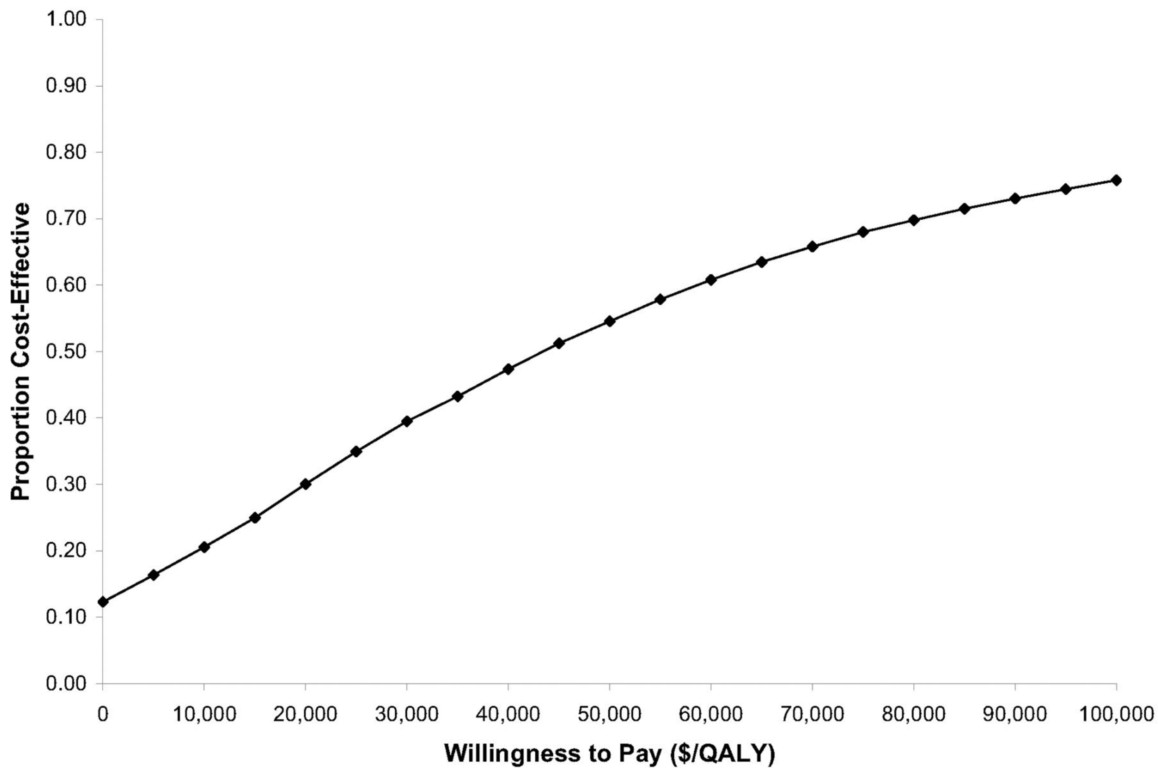

Fig. 4

Acceptability curve depicting the relationship between dollars per quality-adjusted life-year (QALY) on the x axis and the proportion of simulations in the Monte Carlo analysis that are cost-effective on the y axis. Fifty-four percent of simulations had an incremental cost-effectiveness ratio of <$50,000 per quality-adjusted life-year, and 74% had an incremental cost-effectiveness ratio of <$100,000 per quality-adjusted life-year.

cremental costs in our model do include the increased operating room cost associated with the slightly longer operative times, the analysis does not attempt to model changes in the total number of procedures done per day because of operating room time constraints. This depends largely on the hospital, surgeon, practice patterns, and operating room utilization. Importantly, the model assumes a fifteen-year life expectancy of the patient postoperatively to realize the maximum benefit. With shorter time-horizons, there is correspondingly less of a benefit, as shown in Figure 2. Therefore, the cost-effectiveness of computer navigation in total knee arthroplasty will be more favorable when applied to younger patient populations with longer life expectancies.

In addition, we performed Monte Carlo sensitivity analyses to better characterize the extent of uncertainty in the model. The Monte Carlo approach incorporates variation of the individual variables into the cost-effectiveness analysis. This allows a better determination of the range of likely cost-effectiveness ratios, given the underlying uncertainty of the input variables, than the point estimates used in one-way sensitivity analyses. The scatter plot in Figure 3 shows that there is a relatively large range of possible outcomes and consequently considerable uncertainty in the model. An important implication of the probabilistic sensitivity analysis is the need for more precise estimates of the long-term probability of revision total knee arthroplasty as a function of the amount of malalignment in primary total knee arthroplasty.

Our conclusions differ somewhat from those of Dong and Buxton, who recently reported the results of a cost-effectiveness analysis of computer-assisted surgery in total knee arthroplasty with use of a Markov model with both deterministic and probabilistic sensitivity analyses[51]. They estimated an incremental cost of computer-assisted surgery per patient of 235 (British pounds) in the British National Health Service, which is substantially less than the estimated costs used in our model. Those authors concluded that computer-assisted surgery was a cost-saving technology, saving 583 per patient, with a modest improvement of 0.014 quality-adjusted life-year over a ten-year period. There are several important differences between these two studies. First, the cost of computer-assisted surgery may be substantially lower in Britain than in the United States, partly because of the involvement of a single government payer. Second, that study assumed a constant annual failure rate resulting from malalignment, which outcome studies generally have shown not to be the case[41]. Finally, the effect of computer-assisted surgery on outcome in their analysis was based on a smaller number of studies and their analysis did not include any studies that looked directly at failure rates associated with malalignment. All of those factors likely cause their model to overestimate the cost-effectiveness of computer-assisted surgery.

In our analysis, we utilized outcome studies examining the effect of alignment on failure rates in an attempt to create a clinically relevant and realistic model for examining the cost-effectiveness of computer-assisted surgery in total knee arthroplasty. Clearly, there are limitations associated with this approach as much of these data necessarily relate to procedures performed ten to twenty years ago when surgical techniques and total knee arthroplasty implants were different. Many of the studies had small numbers and notable heterogeneity, which was subsequently reflected in the uncertainty measurements in the cost-effectiveness analysis. Moreover, our analysis assumed an equal propensity for failure with varus and valgus malalignment. While a number of studies have demonstrated a higher rate of failure with valgus alignment, the absolute numbers of patients with valgus alignment are small, making it difficult to determine whether the different types of malalignment have equivalent failure rates[3,14,39]. Nonetheless, the outcome studies used in our analysis do provide a realistic foundation on which to build our model for evaluating the effectiveness of computer-assisted surgery. Moreover, by including the variability of the outcome data in our probabilistic Monte Carlo analysis, our study provides a more realistic estimate of the true uncertainty of the incremental cost-effectiveness ratio.

The present study did not examine the effect of computer-assisted surgical navigation on short-term complication rates. None of the studies that were included in our analysis demonstrated any major complications resulting from computer-assisted surgery. We also did not examine the effect of computer-assisted surgery on sagittal plane or rotational alignment. Many studies examining computer-assisted surgery have demonstrated improved femoral rotation and sagittal plane alignment of the tibia, although few studies have examined outcomes with respect to alignment in these other planes, making it difficult to quantify long-term benefit[52-56].

The field of surgical navigation is evolving, and navigational strategies and costs will continue to change over time. While the present study examined the cost-effectiveness of current navigational systems, it also can serve as a useful framework for evaluating the cost-effectiveness of future navigational technologies as more data become available.

The key determinant of clinical outcomes and cost-effectiveness is the effect of computer-assisted surgery on implant survival and revision rates. Long-term outcome studies ultimately will provide the answer to this question. In the short term, however, decision-analysis models such as the one presented in the current study provide a valuable tool for identifying the key variables and predicting their impact on the cost-effectiveness of this promising new technology. In the present study, we found the cost-effectiveness of computer-assisted surgery to be very sensitive to the incremental cost of the navigation equipment, the incremental benefit of computer-assisted surgery over mechanical guides in terms of implant alignment, and the impact of implant malalignment on implant survival and revision rates. Additional studies examining the long-term outcomes of total knee arthroplasty with regard to implant alignment are needed. As the costs associated with this technology decrease and the accuracy of computer-guided implant alignment improves, computer-assisted surgery has the potential to become a cost-saving technology while at the same time improving patient outcomes.

Appendix

eA Figures illustrating the sensitivity analyses used in this study are available with the electronic versions of this article, on our web site at jbjs.org (go to the article citation and click on "Supplementary Material") and on our quarterly CD-ROM (call our subscription department, at 781-449-9780, to order the CD-ROM).■

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