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# Is Cataract Surgery Cost-Effective Among Older Patients With a Low Predicted Probability for Improvement in Reported Visual Functioning?

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**Introduction:** Although cataract surgery has been demonstrated to be effective and cost-effective, 5% to 20% of patients do not benefit functionally from the procedure. This study examines the cost-effectiveness of cataract surgery versus watchful waiting in a subgroup of patients who had less than a 30% predicted probability of reporting improvements in visual function after surgery.

**Methods:** Randomized trial (first eye surgery vs. watchful waiting) of 250 patients who based on a cataract surgery index (CSI) were felt to have less than a 30% probability of reporting improvements in visual functioning after surgery. Cost was estimated using monthly resource utilization surveys and Medicare billing and payment data. Effectiveness was evaluated at 6 months using the Activities of Daily Vision Scale (ADVS) and the Health Utilities Index, Mark 3 (HUI3).

**Results:** In terms of overall utility, the incremental cost-effectiveness of surgery was \$38,288/QALY. In the subgroup of patients with a CSI score >11 (<20% probability of improvement), the cost-effectiveness of cataract surgery was \$53,500/QALY. Sensitivity analysis demonstrated that often this population of patients may not derive a utility benefit with surgery.

**Conclusion:** Cataract surgery is cost-effective even in a subpopulation of patient with a lower, <30%, predicted probability of reporting improved visual functioning after surgery. There may be a subgroup of patients, CSI >11, for whom a strategy of watchful waiting may be equally effective and considerably less expensive.

**Key Words:** cataract surgery, cost-effectiveness, visual functioning, randomized trial

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Age-related cataracts are a leading cause of visual impairment among older persons.<sup>1</sup> The most common treatment of cataract is surgical removal of the lens and replacement with an artificial intraocular lens. This procedure is the most common outpatient surgery performed in the United States, and the volume of cataract surgery has increased 4-fold from 1982–1988<sup>2,3</sup> and cost more than 2 billion dollars annually by 1998.<sup>4,5</sup> Moreover, the cost of cataract surgery to society will increase as the number of older Americans increases dramatically during the next 30 years.<sup>6</sup> Although the reimbursement for cataract surgery has been reduced, it is estimated that 1.6 million cataract surgeries will be performed each year, resulting in 3 billion dollars in Medicare expenditures. In an effort to provide high-quality care that is also cost-efficient, there has been a growing demand for evidence-based support to guide the use of cataract surgery. Current guidelines state that cataract surgery should be performed only when there are sufficient visual symptoms that affect a patient's lifestyle.<sup>7</sup>

Even though cataract surgery is a low-risk intervention with high success rates, between 5% to 20% of patients do not improve.<sup>8–11</sup> The cost-effectiveness ratio for the entire population has been estimated at \$2000 to \$4000 per quality adjusted year.<sup>9,12,13</sup> Several studies have attempted to develop prediction rules to identify older persons who are less likely to benefit from cataract surgery.<sup>14–17</sup> Informing such patients that they have a lower probability of reporting functional improvement after surgery might lead to fewer procedures. However, whether this reduction is desirable remains unknown because the expected benefits and cost-effectiveness of surgery for these persons has not been studied.

In a companion study, we evaluated the health benefit of immediate first eye surgery compared with watchful waiting for older persons with cataracts who had <30% predicted probability of benefiting from the procedure by a randomized clinical trial.<sup>18,19</sup> The study demonstrated that early surgery resulted in better visual function as measured by Activities of Daily Vision Scale (ADVS) scores at 6 months.<sup>18,19</sup> The goal

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of the current study was to evaluate the cost-effectiveness of first eye cataract surgery in this population and to determine whether any subgroup based on the CSI could be identified for whom the costs of surgery would outweigh the health benefits.

## METHODS

The study was a randomized clinical trial of 250 older persons with bilateral cataracts who were recruited from community-based ophthalmologist's offices in greater Los Angeles area. The study was approved by the University of California, Los Angeles Institutional Review Board.

### Clinical Trial Protocol

The selection of data sites, trial structure, recruitment, inclusion and exclusion criteria, and randomization have been reported elsewhere.<sup>20</sup> Patients older than 64 years with a diagnosis of bilateral age-related cataracts, with and without other chronic eye diseases, who were candidates for first eye surgery and with a cataract surgery index (CSI) score<sup>17</sup> of 10 or more (which indicates a less than 30% probability of predicted improvement in reported visual functioning) were eligible for enrollment in the study.

### CSI Score

The CSI is a point scheme for predicting improvement in reported visual function. It is derived from 5 factors that represent either good current visual functioning, or other factors that might lead to poor visual functioning. The scoring is as follows:

$$\begin{aligned} \text{CSI} = & 0.1 [\text{preoperation ADVS}] + \text{Points for Age} \\ & + 1[\text{Macular Degeneration}] + 2 [\text{Diabetes Mellitus}] \\ & - 1 [\text{Posterior Subcapsular}] \end{aligned}$$

Expressed in words, the preoperative ADVS<sup>21</sup> score is multiplied by 0.1 and, for patients ages 65–74 years, 1 point is added, 2 points if the person's age is between 75 and 84 years, and 3 points added if the person's age is between 85 and 94, etc; a point is added if there is evidence of macular degeneration in the operative eye; and 2 points are added if the patient has diabetes mellitus regardless of whether retinopathy is present. One point is subtracted if patients have preoperative evidence of a posterior subcapsular cataract. A higher score is associated with less expected improvement. In an observational study, patients with a CSI score of 10 had a 30% probability of predicted improvement, whereas those with scores 11 or higher had between a 5% to 20% probability of predicted improvement.<sup>17</sup>

### ADVS Score

Visual disability was assessed with the ADVS.<sup>21,22</sup> The ADVS used in this study contained 22 items, each of which examines the patient's ability to perform an activity and is scored on a scale of 0–100 (0 indicates no visual functioning, and 100 indicates perfect visual functioning). These activities include driving at night, seeing moving objects with night driving, oncoming headlights, daytime driving, reading signs

at night, reading signs during the day, using public transport, walking downstairs in daylight, walking downstairs in dim light, recognizing faces, seeing the television, reading any writing on television, reading newspapers, reading medicine bottles, reading food cans, writing checks, threading a needle, using a tap measure, using a screwdriver, preparing meals, and playing cards. Patients are assessed as to whether they engage in the activity, have difficulty with the activity, or are unable to perform the activity because of poor vision.

### Clinical Data

Clinical examination results were performed by the ophthalmologists performing the surgery and included best-corrected Snellen acuity and pinhole acuity for vision worse than 20/100; the presence of nuclear, cortical, or posterior subcapsular cataract; any previous ocular surgeries (noncataract); and the presence of any other ocular disease. The severity of cataract was not graded. Participants in the randomized trial were encouraged to see their ophthalmologist 6 and 12 months after enrollment or after surgery on a schedule set by the treating ophthalmologist for postoperative care. Follow-up clinical information was abstracted from the medical records of the treating ophthalmologist.

### Questionnaires

The ADVS,<sup>21</sup> SF-12,<sup>23</sup> Charlson Comorbidity Scale,<sup>24</sup> and Health Utilities Inc. 3 (HUI3)<sup>25</sup> were administered at baseline and 6 months. The 6-month follow-up interview was conducted via telephone.

The HUI Mark3<sup>25</sup> is composed of 40 questions that measure 8 health attributes (vision, hearing, speech, ambulation, dexterity, emotion, cognition, and pain) and one question that measures overall self-assessed health status. The HUI3 includes categorical information in the form of attribute levels (best score for level = 1.00, score for most disabled = 6.00). These attribute scores can then be converted to single attribute utility scores, ranging from 0 to 1. For example, the single attribute vision utility ranges from 1.00, representing perfect vision, to 0.00, representing a blind state. Furthermore, a weighted-scoring algorithm is applied to combine the scores for each attribute to derive a value between 0 and 1 to represent utility of the overall health state (perfect health = 1.00, deceased = 0.00). Missing data on specific questions within each attribute were imputed using a strategy previously developed.<sup>20</sup>

### Cost/Utilization Estimates

Cost estimates for this study took a societal perspective and were derived from several sources over a 6-month time horizon. Health care utilization and the direct and indirect costs from the standpoint of the patient were derived from monthly surveys over 6 months. Each monthly survey asked the following: 1) the number of doctor visits and the out-of-pocket cost of each visit; 2) the transportation costs and amount spent on the trip; 3) lost days from work among caregivers; 4) other eye procedures performed and associated out-of-pocket costs; 5) obtaining new glasses and cost of the glasses; 6) the use of eye medications and medication costs;

and 7) the use of formal home care as a result of decreased vision and associated cost.

To reduce the missing information in these monthly surveys, we employed the following imputation strategy. Because expenses and utilization were correlated ( $\rho = 0.32$ ) among patients with complete records, the imputation method used for missing monthly data was to use the value of the expenditures and utilization in the prior month. This imputation method was compared with other strategies, such as mean substitution<sup>26,27</sup> and hot decking<sup>28–30</sup> and performed better on the complete data with months removed at random. The cost of cataract surgery was divided into 4 major components: 1) perioperative medical care; 2) anesthesia care; 3) surgery; and 4) facilities. Cost data for these services were determined using previously published articles and summaries from Medicare billing data from the Health Care Financing Administration, HCFA.<sup>31,32</sup> Cost estimates for items such as glasses, medications, and doctor visits, in addition to the cost of other eye procedures were estimated using 2001 Average Medicare Payment Information.<sup>33</sup> The effects of these estimated costs were further analyzed using sensitivity analysis.

### Statistical Analysis

Participants were compared on baseline demographic variables and clinical characteristics to study-eligible persons who refused to be randomized; similarly, participants in each treatment arms were compared on these characteristics.

General linear models, using STATA 7.0 software (STATA Corp; College Station, TX), were used to assess differences between treatment arms on HUI scores controlling for baseline HUI score, CSI components (age, diabetes, posterior subcapsular cataract, and macular degeneration), gender, number of medical comorbidities, SF-12 physical and mental health summary scores, and visual acuity in both eyes. The CSI components were included as covariates to adjust for effects that might be due to clinical severity related to cataracts, whereas the medical comorbidities and SF-12 scores were included to adjust for general health status. Gender was included as an adjuster to control for the tendency of women to self-report slightly worse health on quality of life surveys.<sup>34</sup>

Although the trial population was restricted to individuals with a CSI score equal to or greater than 10 (representing a less than 30% overall probability of reporting improvement in visual functioning after surgery) the study population was still heterogeneous because those with higher CSI scores had lower predicted probabilities of improvement. Accordingly, the data were also analyzed for 3 subgroups based on CSI score ( $=10, 11, >11$ ), accounting for 26%, 39%, and 35% of the study population, respectively. The analysis was performed using an intention-to-treat model with crossovers included in their original assigned study arm.

### Cost-Effectiveness Analysis

We followed the reference case recommendations for cost-effectiveness from U.S. Public Health Service Cost-effectiveness Panel.<sup>35</sup> The outcome and cost data were used to derive a cost per quality of life year (Cost/QALY) ratio. Cost differences were compared between the 2 treatment arms. Two horizons of benefit were evaluated. A conservative

horizon for the benefit from cataract surgery of 1 year initially was chosen to reflect the expectation that many in the watchful waiting arm would have surgery within 1 year. A second horizon of benefit reflecting life expectancy (assuming initial differences persisted over the remaining lifetime) was used in sensitivity analysis. Data were extrapolated for both horizons of benefit because our trial data outcome point was at 6 months. The cost-effectiveness analysis was performed on the intention-to-treat model and the treatment-received model. The subgroup analysis using the 3 CSI categories was performed in both models.

### Sensitivity Analysis

Sensitivity analysis was performed varying both the horizon of benefit and generating an acceptability of the intervention.<sup>36</sup> The acceptability curve gives an estimate of the proportion of the sampling distribution of the costs and effects that lie below the price line of a specific cost-effectiveness plane, the price being the maximum willingness to pay for a gained effect unit.<sup>37</sup> To model a lifetime horizon of benefit, we used life tables from the National Center of Health Statistics.<sup>38</sup> The undiscounted life expectancies of each patient were transformed to discounted (at 3%) life expectancy using an error function approximation.<sup>39</sup> The discounted life expectancy was then multiplied by the utility gain to derive a discounted cumulative QALY gain for the lifetime of each patient. Future costs and benefits of second eye cataract surgery were not modeled.

In addition, sensitivity analysis was also performed by bootstrapping the following 4 samples 10,000 times each: (a) total sample with a 1 year horizon benefit, (b) patients with CSI  $>11$  with a 1-year horizon benefit, (c) total sample with a lifetime horizon benefit, (d) patients with CSI  $>11$  with a lifetime horizon benefit.<sup>40</sup> Each bootstrapped sample was then used to model the gain in utility and the cost, adjusting for all the covariates resulting in incremental effectiveness and cost.<sup>37</sup> These results were then used to generate joint densities and acceptability curves following standard techniques.<sup>41,42</sup>

## RESULTS

### Surgery Versus Watchful Waiting Arms

Participants were predominantly women (62%) and white (87%), with an average age of 78 years. Baseline ADVS and HUI scores were 85 (SD 11) and 0.74 (SD = 0.26), respectively. Of the 250 RCT participants, 133 were assigned to the surgery arm, and 117 were assigned to the watchful waiting arm. At baseline, there were no significant differences between the trial arms on measures of demographic, clinical, and outcome variables (data not shown). By 6 months, 16 participants in the surgery arm withdrew and 17 participants in the watchful waiting arm withdrew (Fig. 1). Thus, the sample sizes in the surgery arm and watchful waiting arm were 117 and 100 participants respectively at 6 months. A total of 32 participants crossed over during the trial (20 from the surgery arm did not get surgery, and 12 from the watchful waiting arm did get surgery in the 6 months of the trial).

Pepper Trial Consort Table

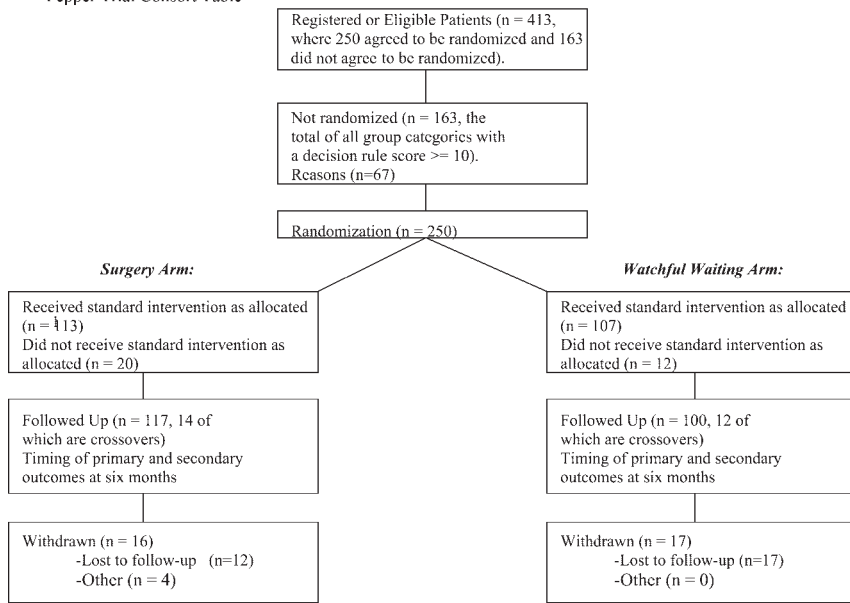


FIGURE 1. Clinical trial consort table.

### Intention-to-Treat Model of Outcome Variables ADVS and HUI3 at 6 Months

After case-mix adjustments, those individuals in the surgery arm had a mean improvement in ADVS score of 6.51 points compared with those in the watchful waiting arm ( $P < 0.0001$ ; Table 1). The subgroup analysis based on CSI categories ( $= 10, = 11, >11$ ), participants with a CSI score equal to 10 or 11 had significant improvement in

ADVS scores (data not shown) and those participants with CSI scores greater than 11 benefited less (Table 1). The gain in mean visual utility of 0.031 ( $P < 0.035$ ) was significant (Table 1), but the mean gain in overall utility, HUI3 score, of 0.041 of surgery over watchful waiting was not. The point estimate of incremental overall utility for those patients with a CSI  $>11$  was lower at 0.024 and not significant.

TABLE 1. Results from Intention-to-Treat Analysis Multivariate Regression Models Testing for Differences Between Trial Arms on 6-Mo Endpoint Measures

Variable	Baseline	Follow-Up at 6 Mo	Difference	Adjusted Impact of Surgery* Mean (SD)*	P*
ADVS (n = 209)				6.51 (1.64)	<0.0001
Watchful waiting	85.8	82.3	-3.5		
Surgery	84.0	88.6	4.6		
ADVS (CSI >11; n = 72)				1.48 (2.95)	0.617
Watchful waiting	90.2	87.2	-3.0		
Surgery	89.5	88.8	-0.7		
Visual utility (n = 209)				0.031 (0.014)	0.035
Watchful waiting	0.92	0.92	0.0		
Surgery	0.927	0.954	0.027		
HUI (n = 209)				0.041 (0.029)	0.156
Watchful waiting	0.754	0.723	-0.031		
Surgery	0.744	0.760	0.016		
HUI (CSI >11; n = 74)				0.024 (0.053)	0.657
Watchful waiting	0.788	0.710	-0.078		
Surgery	0.783	0.733	-0.05		

\*Control variables in the ADVS analysis were baselines ADVS, age diabetes, PSC, AMD, gender, baseline PCS 12, baseline MCS 12, and medical comorbidities. Control variables in the HUI analysis were baseline HUI, age, diabetes, PSC, AMD, gender, baseline PCS 12, baseline MCS 12, and medical comorbidities.

The mean difference between the control arm and the cataract surgery arm.

Derived using a general linear multivariate model.

AMD indicates age-related macular degeneration; MCS, Mental Composite Score; PSC, posterior subcapsular cataract.



### Cost and Resource Utilization Differences between Trial Arms Over the Course of 6 Months

Participants in the surgical arm had: (a) more visits to ophthalmologists with a higher mean cost, \$208 versus \$14; (b) more glasses ordered with a higher mean cost, \$14 versus \$4; and (c) higher copayment fees for Visits, \$30 versus \$6, compared with those in the watchful waiting group (Table 2). Mileage costs associated with travel also were higher for surgery patients (mean cost of \$10 vs. \$2). Surgical procedures, other than the initial first eye cataract surgery, also were greater in the surgery group (5 second-eye cataract surgeries vs. none in the watchful waiting group during the 6-month follow-up period). Among the watchful waiting arm there were 3 tear duct procedures, whereas there were none in the surgical arm. These costs include 12 patients in the watchful waiting arm who received cataract surgery and 20 in the surgery arm who did not. Cost was also determined for subgroups based on CSI score. The cost differences between treatment groups were as follows: \$1803 for a CSI = 10, \$1639 for a CSI = 11, and \$1284 for a CSI >11. The variation in cost difference between arms based

on CSI subgroups was caused largely by less crossover to no operations in the subgroups more likely to benefit.

Cost and resource utilization analysis was performed for the 6-month period. The costs were partitioned into 4 nonoverlapping groups: nonsurgery costs, non-health care costs, patient copays, and surgical costs (Table 2). There were statistically significant differences between the randomized arms in all 4 cost groups. The average cost of cataract surgery was \$1975 for those in the surgery arm compared with \$407 in the watchful waiting arm, a difference of \$1567 ( $P < 0.0001$ ), driven mainly by the surgical cost of first eye cataracts. (Overall, the cost per participant receiving the operation was \$2047 more than those not having the operation.)

### Cost-Effectiveness Analysis

The incremental cost-effectiveness of cataract surgery for a 1 year time horizon of benefit was \$38,228 per quality-adjusted life year (QALY) based on the aforementioned costs and a gain of 0.041 utility points in participants receiving surgery. Even in patients with a CSI score >11, there was

**TABLE 2.** Results from Intention-to-Treat Analysis of Utilization and Cost Over a 6-Mo Horizon

	Watchful Waiting (n = 117)				Surgery (n = 133)				P
	Mean*	Price	Mean Cost†	SD	Mean*	Price	Mean Cost†	SD	
Nonsurgery costs (excluding co-pay)									
New doctor visit	1.00	91.00	\$91.00		1.00	91.00	\$91.00		
Follow-up doctor visits	1.03	47.44	\$48.96		2.46	47.44	\$116.89		
Total doctor visits	2.03		\$139.96	11.01	3.46		\$207.89	16.40	0.001
Glasses	0.08	55.05	\$4.64	2.28	0.26	55.05	\$14.48	2.91	0.01
Medications	0.37	30.30	\$11.15	2.57	0.44	30.30	\$13.21	2.45	0.55
Total utilization cost			\$155.74	14.18			\$235.58	19.35	0.0015
Nonhealth care costs									
Mileage	8.29	0.30	\$2.49	0.75	31.95	0.30	\$9.58	3.03	0.037
Other travel costs	0.77		\$0.77	0.57	1.08		\$1.08	0.47	0.67
Lost work days	0.01	50.00	\$0.25	0.26	0.08	50.00	\$3.95	3.11	0.28
Total nonhealth care costs			\$3.51	1.01			\$14.61	4.69	0.035
All patient co-pays									
Visit co-pay	4.71		\$4.71	1.94	7.95		\$7.95	3.40	0.43
Surgery co-pay	0.58		\$1.18	0.58	1.18		\$1.18	0.71	0.52
Glasses co-pay	5.70		\$5.70	2.75	30.15		\$30.15	7.55	0.005
Medication co-pay	6.13		\$6.13	2.30	4.28		\$4.28	1.31	0.46
Total co-pays			\$17.72	6.18			\$43.56	10.95	0.005
Surgery cost (excluding co-pay)									
First eye cataract	0.13	1761.00	\$221.89	60.34	0.90	1761.00	\$1591.94	48.91	<0.0001
Second eye cataract	0.00		\$0.00	0.00	0.04	1761.00	\$77.48	33.92	0.04
Tear duct surgery	0.03	260.54	\$8.34	4.70	0.00	261.00	\$0.00	0.00	0.056
Glaucoma surgery	0.00		\$0.00	0.00	0.01	720.02	\$6.31	6.32	0.36
Retained lens material	0.00		\$0.00	0.00	0.01	573.11	\$5.03	5.03	0.36
Total surgical cost			\$230.22	60.20			\$1680.77	62.12	<0.0001
Total cost			\$407	76.16			\$1975	73.78	<0.0001
Difference in cost (surgery-watchful waiting)		Mean	\$1567						
		SD	\$0						

\*Mean number of procedures per patient.  
†Mean per patient cost.

**TABLE 3.** Incremental Cost-Effectiveness of Cataract Surgery Over Watchful Waiting Based on Intention to Treat

Group	Utility Gain*	Cost	Cost/QALY
1-year time horizon			
Entire sample	0.041	\$1567	\$38,228
CSI >11	0.024	\$1284	\$53,500
Lifetime time horizon			
Entire sample	0.261	\$1567	\$6004
CSI >11	0.229	\$1284	\$5607

\*Utility Gain is calculated here using multi-attribute weights for the Health Utilities Index 3.

some health benefit leading to an incremental cost-effectiveness ratio relative to patients on the waiting arm of \$53,500/QALY (Table 3). Sensitivity analysis was performed based on extending the first 6-month benefit over the life expectancy of each of the participants. The incremental cost-effectiveness of cataract surgery for a lifetime time horizon was \$6004/QALY in the entire sample, and \$5607/QALY for those with a CSI >11 (Table 3).

**Sensitivity Analysis**

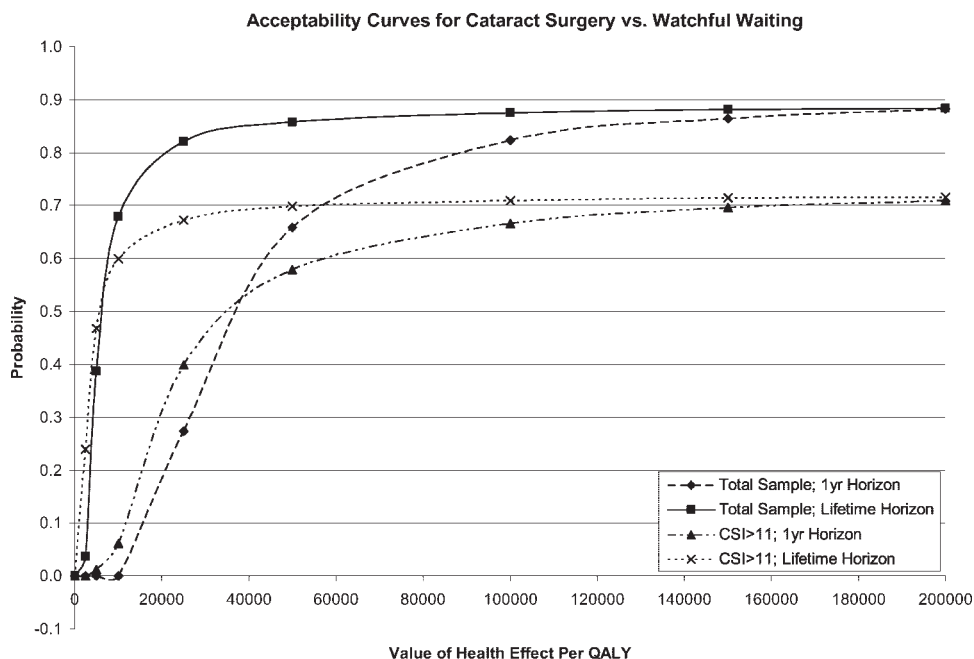
We generated acceptability curves for 4 cases: (a) Entire Sample—1 year horizon, (b) CSI >11—1 year horizon, (c) Entire Sample—lifetime horizon, and (d) CSI >11—lifetime horizon (Fig. 2). In all 4 cases, surgery was more costly than watchful waiting in each bootstrapped sample. However, there were cases where surgery was less effective. Because there were no cases in which surgery was cost saving, the acceptability curves cut the y-axis at 0. The acceptability curves all rise asymptotically to a value less than 1 because not all simulated trials resulted in a health

gain. In the total sample only 88% of the simulated trials resulted in a health benefit, whereas in the subgroup of patients with a CSI >11 only 70% of the simulated trials yielded a health benefit. Using a lifetime horizon shifted the curves to the left indicating they are more cost-effective but does not change the upper asymptote. A decrease in the cost of surgery would shift the curves to the left whereas an increase would shift the curves to the right (data not shown), but neither would change the upper asymptote.

**DISCUSSION**

Although the cost-effectiveness of cataract surgery, in general, has been demonstrated,<sup>9,12,13,43</sup> this study shows that it is also cost-effective for 75% of patients who were previously estimated to have a small probability (<30%) of benefiting from the procedure. Nevertheless, we were able to identify a subgroup (those with CSI >11) for whom the costs would exceed \$50,000 per QALY. Such participants can be easily identified preoperatively by the prediction rule using the ADVS instrument and basic information.<sup>17</sup> The absolute percentage of those with age-related cataracts who meet this threshold is small (an estimated 5–10% of all persons who currently undergo cataract surgery).<sup>11,17</sup> By using a watchful waiting strategy with a CSI >11, comparable outcomes can be achieved at less expense. In fact, if this subgroup could be managed without surgery, Medicare could potentially save \$10 to \$20 million dollars annually.

Previous analysis on first eye and second eye cataract surgery in general populations have demonstrated cost-effectiveness ranging from \$2000–\$4500/QALY.<sup>9,12,13,43</sup> Many of the more recent reports are based on models or registry data rather than randomized clinical trials.<sup>13,43</sup> Furthermore, previous studies did not focus on a population with a marginal



**FIGURE 2.** Acceptability curves for cataract surgery versus watchful waiting.

likelihood for benefit from surgery. This study enrolled a greater proportion of patients with either good preoperative visual functioning or with other coexistent eye disease than previous studies. Additionally previous analyses also used a longer time horizon, 10 to 15 years, of benefit significantly greater than our 1-year horizon, but comparable to our lifetime time horizon. Because patients were allowed to have first eye cataract surgery in the watchful waiting arm after 6 months, we choose a short time horizon to evaluate the incremental cost-effectiveness of a strategy of short-term watchful waiting versus upfront cataract surgery. Moreover, analysis of a subset of patients at 12 months (data not shown and not a primary end-point of the trial) indicated that the incremental benefit of cataract surgery over initial watchful waiting had diminished. However, our sensitivity analysis demonstrated that our results would be similar to previous studies if a longer horizon was used for analysis. Finally, although cataract surgery would be more cost-effective if a longer time horizon of benefit were assumed, the uncertainty associated with the benefit of the procedure is independent of time horizon. Our sensitivity analysis demonstrated if this trial were to be repeated numerous times, cataract surgery would fail to show benefit 12% of the time.

The cost-effectiveness of cataract surgery in our trial population is comparable with other interventions, such as combined community outreach program for pneumococcal and influenza vaccine in persons aged 65 and older (\$41,000–\$58,000),<sup>44</sup> use of radiation after breast-conserving surgery (\$38,000),<sup>45</sup> adjuvant chemotherapy for patients 75 years of age with node-negative, estrogen receptor-negative early-stage breast cancer (\$58,000/QALY),<sup>32</sup> and lovastatin for cholesterol reduction (\$46,000/QALY).<sup>46</sup> Moreover, by using a prediction rule and limiting surgery to only those with CSI scores of 11 or less, cataract surgery would be even more cost-effective.

There were several limitations in this study. The decision rule used for entry into the trial was applied to patients considered eligible for cataract surgery by an ophthalmologist. However, many patients with cataracts are never referred to an ophthalmologist. Thus, the study population may not be representative of the general population with cataracts. In addition, only approximately 20% of the ophthalmology practices approached agreed to participate in the trial, which again limited generalizability. Another limitation was the sample size of the trial, which was not powered to evaluate small changes in overall health related utility, of which visual functioning is a small part. Nevertheless, the highly significant change in visual functioning supports the notion that there might have been an overall utility benefit from cataract surgery had this study been designed and powered to test this outcome. We also used alternative approaches for additional validation of our estimated benefit.

In addition to these methodological limitations, there is some uncertainty about the true current costs of surgery. The in-depth cost analysis of cataract surgery by Steinberg et al<sup>47</sup> in 1991 calculated a total cost of cataract surgery at \$2500. However, Medicare reimbursement fees change annually and there has been a substantial reduction in reimbursement for

cataract surgery over the last decade. The cost estimates used in this paper reflect a cross section of outpatient centers that were surveyed in 1998 and costs may have changed since then.

In summary, we have demonstrated that surgery is acceptably cost-effective for most cataract patients but a small percentage of cataract patients for whom surgery is less cost-effective can be easily identified with a simple prediction rule. Managing these patients medically could potentially save Medicare \$10 to \$20 million dollars next year and even more in the future as the number of older persons with cataract increases.

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