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Article *in* Journal of Refractive Surgery · January 2022

DOI: 10.3928/1081597X-20211007-01

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ABSTRACT

PURPOSE: To describe and compare the cost-effectiveness of small incision lenticule extraction (SMILE), femtosecond laser–assisted in situ keratomileusis (FS-LASIK), and photorefractive keratectomy (PRK) for treating myopia and myopic astigmatism in a private eye center.

METHODS: The perspectives for this cost-effectiveness analysis were for the payer and the health care sector. For the payer's perspective, a decision tree model was made, with a time period of 30 years, and the average weighted utility values and quality-adjusted life years (QALY) were computed for each procedure. The average weighted costs were derived for each procedure and divided by the QALY to obtain the incremental cost-effectiveness ratios (ICER). For the health care sector's perspective, the direct and indirect costs of acquiring the equipment and maintaining the facilities—including consumables and personnel salaries—were obtained to compute the minimum number of patients treated per year.

RESULTS: The weighted utility values were 0.8 for SMILE and PRK and 0.77 for FS-LASIK. The weighted QALYs were 24 for SMILE and PRK, and 23.1 for FS-LASIK. The average weighted costs were 335.45, 443, and 346.96€, respectively. The resulting incremental cost-effectiveness ratios were 13.98 €/QALY for SMILE, 18.46 €/QALY for PRK, and 15.02 €/QALY for FS-LASIK. There was a negative correlation between the ICER and the time (in years) after the surgery. To achieve a profit, the minimum number of patients treated per year is 155 for SMILE, 136 for PRK, and 155 for FS-LASIK.

CONCLUSIONS: Laser corneal refractive surgery is cost-effective for a person desirous of refractive correction for myopia. SMILE had the lowest ICER, followed by FS-LASIK and PRK. This trend was noted at all time periods. The cost of investing in laser refractive surgery facilities is outweighed by the potential income in high-volume eye centers.

[*J Refract Surg*. 2022;38(1):21-26.]

Refractive errors are among the most common causes of correctable visual impairment[1] and the increasing prevalence of myopia may have significant economic implications. The potential global productivity loss due to vision impairment from uncorrected myopia is estimated to be 244 billion US$ (220 billion euros).[2] The lifetime per capita cost of treatment for a person diagnosed as having myopia ranges from 9,300 to 17,020 US$ (range: 8,463 to 15,488 euros). A large part of these costs is due to the cost of spectacles, contact lenses, and eye care services.[3,4] Corneal refractive or keratorefractive surgery, such as photorefractive keratectomy (PRK), femtosecond laser–assisted in situ keratomileusis (FS-LASIK), or small incision lenticule extraction (SMILE), neutralize myopia by surgically remodeling the cornea to lessen its refractive power. Higher up-front costs for these procedures, which have been reported to be 3,851 US$ (3,504€) per patient,[3] may deter patients from opting for corneal refractive surgery. However, refractive surgery has been shown to be more cost-effective than either contact lens or spectacle use for patients with

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Submitted: September 25, 2020; Accepted: September 21, 2021

Disclosure: The authors have no financial or proprietary interest in the materials presented herein.

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doi:10.3928/1081597X-20211007-01

myopia when its costs are prorated in all years with benefit from the procedure.[4] Our study aimed to compare the cost-effectiveness of three corneal refractive procedures (PRK, FS-LASIK, and SMILE) for treating myopia and myopic astigmatism.

METHODS

The perspectives for this cost-effectiveness analysis were those of the payer (the patient), and the eye center or the health care system; as such, this cost-effectiveness analysis only included direct costs to the patient and the eye center. The currency used was the euros (2020) A cost-effectiveness analysis was conducted based on the guidelines and recommendations of the Second Panel on Cost-effectiveness of Health in Medicine.[5]

Cost-Effectiveness Analysis From the Payer's Perspective

A review was made of published data on outcomes and characteristics of patients with myopia and myopic astigmatism who underwent SMILE, FS-LASIK, or PRK. Full data from this review are available from the authors. From this, a reference case was made of a patient with myopia who is desirous of being free of spectacles or contact lens use and is an equally good candidate for either SMILE, FS-LASIK, or PRK. The patient's age was set at 30 years, based on the published average age that refractive surgery was performed in our reference studies. For the reference case, the following assumptions were made: there was no underlying ocular disease or comorbidity, there were no contraindications for the performance of the three modalities of refractive surgery on the patient, the cost for the complications incurred after the procedure would be shouldered by the patient, and benefit from the procedure prior to the onset of age-related conditions would be 30 years. The keratorefractive surgery was assumed to be bilateral, and the complications were assumed to be unilateral. We used a time period of 30 years for the projection of outcomes and accompanying costs was 30 years, with a discount rate of 3%. Outcomes for the perspective of the payer included average weighted costs, average weighted utility values, quality adjusted life years (QALY), and cost per QALY (incremental cost-effectiveness ratio [ICER]).[5] For the health care system's perspective, the outcomes obtained were the income from the procedures (in euros), and the costs (in euros) to the health center.

Computing for Cost-Effectiveness From the Payer's Perspective

A decision tree model (**Figure A**, available in the online version of this article) was used. In keratorefractive surgery, whether it involves lenticule extraction or corneal ablation, corneal stromal tissue is permanently removed. The decision tree model shows the procedure followed by all patients who undergo laser refractive surgery and their postoperative course. The probabilities for obtaining specific utility values after SMILE, FS-LASIK, and PRK, as well as the management and outcomes of their complications, were outlined in the model. These were derived from textbooks and published journal articles evaluating the effectiveness of the three procedures, and our own database. The study was only limited to the most reported or the most visually threatening postoperative complications. The details of the references used to create the decision tree model are included in the supplemental material. **Table A** (available in the online version of this article) describes the probabilities for each of the outcomes and lists in detail, along with the references, the resulting utility value from each branch of the decision tree.

Medical Costs

Direct costs pertaining to the three corneal refractive procedures, and the management of any possible complication that might occur, were used for the cost-effectiveness analysis from the payer's perspective. This analysis did not include the indirect costs of undergoing the procedure, such as transportation to and from the eye center for the procedure and the revisions, or absenteeism from work for the patient and a companion. The costs associated with corneal refractive surgery and its complications were taken from multiple sources: institutional or facility costs as set by our eye center and the standard retail prices of medications in Spain or other European countries. Annual costs reflect the total cost projected per component of the procedure, from the initial consultation to the total cost of management options of each complication. Certain management options for the complications are not required for every patient; these include penetrating keratoplasty for corneal infections or corneal ectasia, or Nd:YAG for epithelial ingrowth. To avoid overestimating the projected costs, we multiplied the cost by the frequency that it is performed for such indications, as shown in the published literature or based on the authors' experience. The average for all weighted costs (average weighted costs) was computed and then multiplied by the incidence percentage of each complication. Discounted lifetime costs were computed for treatments that are foreseen to last more than 1 year. To be specific, discounted lifetime costs were computed for the lifetime use of contact lenses for corneal ectasia or the use of topical lubricants for chronic dry eye over a period of 3 years. The defined time period for this cost-effectiveness analysis was 30 years, and a 3% annual discount rate was applied in management options where prolonged or lifetime treatment is required.[5] The discounted lifetime costs were multiplied by the frequency or probability of a complication happening to obtain the weighted discounted lifetime costs.

We computed for the total gain from undergoing any of the above procedures or the QALYs using the formula of Prieto and Sacristán.[6] The utility values were solely obtained from the visual acuity outcomes of each procedure and were based on the study by Brown et al.[7] Utility values are a reflection of patient preference and evaluate how patients are able to function in their activities of daily life. These give an objective assessment or quantification of the quality of life associated with a health or disease state. The utility values used for this study are standardized time trade-off vision utilities solely based on bilateral visual acuity and unaffected by the cause of vision loss, age, sex, or any comorbidity. The closer the utility value is to 1.0, the better the visual acuity and the implied quality of life. Time trade-off vision utilities are obtained by asking patients how long they are expected to live, and how many of those remaining years of life would the patient be willing to trade in return for a therapy that would allow the current vision in each eye to be perfect vision bilaterally.[8] **Table A** shows the utility values based on the visual acuity outcomes for each procedure. The average weighted utility value was obtained from the utility value per branch of the decision tree model multiplied by the probability of said outcome. This was then multiplied by 30, the assumed number of years with benefit from the procedure, to obtain the QALY. The weighted average cost per procedure was computed and subsequently divided by the QALY to get the ICER or the cost per QALY gained.[5] Sensitivity analysis was performed by varying the average weighted utility values, average weighted costs, and QALYs by 25%. We then performed cost-effectiveness analyses at different time periods (1,5, 10, 15, 25, 35, and 45 years) following the procedure described above. A correlational analysis was performed using Excel software (Microsoft Corporation) to compare the relationship of the ICER to different time periods after the procedure.

Computing for Cost-Effectiveness From the Eye Center's Perspective

According to previous research on this topic,[9,10] the following formula was used to compute the cost-effectiveness analysis:

Clients × Payment > Am + M + Cp + Ci – (Ceq × Ci) + G where Am = annual amortization (Ceq-Vr)/Vu, Ceq = financing mode of the equipment, Vr = residual value, Vu = useful life, M = annual maintenance (including consumables), Cp = costs of personnel, Ci = indirect costs, and G = patents/marketing.

The information for amortization, financing, and maintenance of the equipment and personnel and indirect costs was obtained from several sources, mainly the eye center and the standard or recommended costs in similar institutions in Spain or Europe. For the purposes of this article, personnel costs refers only to the salary of the personnel who interact with a patient from the preoperative phase up to the keratorefractive procedure and the postoperative follow-up visits—an ophthalmologist, an optometrist, and a nurse. The equipment's useful life was set at 5 years. The amount paid by patients per eye was provided by the eye center.

RESULTS

Cost-Effectiveness From the Payer's Perspective

The average baseline utility value for patients with myopia prior to undergoing refractive surgery was 0.61. The average weighted utility values were 0.8 for SMILE and PRK, and 0.77 for FS-LASIK. The corresponding QALYs were 24 for SMILE and PRK, and 23.1 for FS-LASIK. **Table B** (available in the online version of this article) gives the breakdown of the costs for undergoing SMILE, PRK, or FS-LASIK, and for managing the complications of each of the procedures. The projected total lifetime costs (with a time period of 30 years) were 25,853.8€ for SMILE, 22,443.65€ for PRK, and 25,889.47€ for FS-LASIK. When the probability of each complication was taken into consideration, the projected total weighted lifetime costs were 3,019.082€ for SMILE, 3,101.1€ for PRK, and 3,122.63€ for FS-LASIK. The averages of these weighted lifetime costs were 335.45, 443, and 346.96€, respectively. The resulting incremental cost-effectiveness ratios were 13.98 €/QALY for SMILE, 18.46 €/QALY for PRK, and 15.02 €/QALY for FS-LASIK (**Table 1**). With sensitivity analysis, the ICER for SMILE ranged from 8.39 to 18.64 €/QALY, the ICER for PRK ranged from 11.08 to 30.76 €/QALY, and the ICER for FS-LASIK ranged from 9.01 to 25.04 €/QALY.

Annual costs (in 2020 euros) reflect the total cost projected per component of the procedure, from the initial consultation to the total cost of management options of each complication. In certain treatments where not all patients will undergo a management option, such as corneal transplant for corneal ectasia, the cost was multiplied by the frequency by which patients would undergo these procedures as presented in the published literature. Discounted lifetime costs were computed for treatments that go beyond 1 year

TABLE 1

Total and Average Weighted Cost, Weighted Utility Value, Weighted QALY, and ICER Per Procedure for a 30-Year Time Period

Group	Total Weighted Cost (€)	Average Weighted Cost (€)	Weighted Utility Value	Weighted QALY	ICER (€/QALY)
SMILE	3,019.08	355.45	0.8	24	13.98
PRK	3,101.1	443	0.8	24	18.46
FS-LASIK	3,122.63	346.96	0.77	23.1	15.02

QALY = quality adjusted life year; ICER = incremental cost effectiveness ratio; SMILE = small incision lenticule extraction; PRK = photorefractive keratectomy; FS-LASIK = femtosecond laser–assisted laser in situ keratomileusis

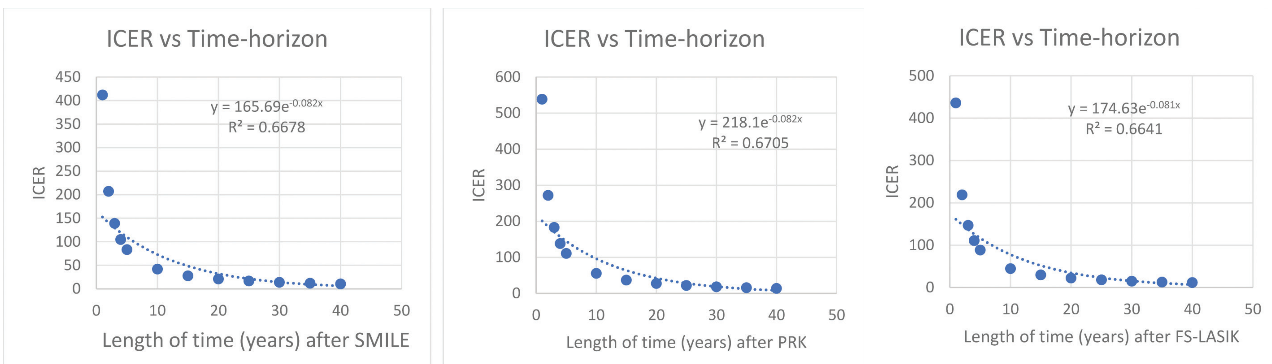

Figure 1. Scatter plots of the incremental cost-effectiveness ratio (ICER) versus the time period for small incision lenticule extraction (SMILE), femtosecond laser–assisted in situ keratomileusis (FS-LASIK), and photorefractive keratectomy (PRK).

or foreseen to last the patient's lifetime, such as 3 to 4 years of artificial tears for chronic dry eye or lifetime use of contact lenses for corneal ectasia. The average discounted lifetime costs for postoperative complications were multiplied by the corresponding frequency of the complication to derive the weighted discounted lifetime costs. The values for the frequency rates and the references from which they were derived are listed in **Table A**.

We computed the average weighted costs, weighted QALY, and ICER for SMILE, PRK, and FS-LASIK at different time periods. **Table C** (available in the online version of this article) summarizes these values for all three procedures. There was a moderately strong negative correlation between the ICER and the QALY for SMILE (R = -0.79), PRK (R = 0.79), and FS-LASIK (R = 0.68). This is illustrated in **Figure 1**.

Cost-Effectiveness From the Eye Center's Perspective

Table 2 shows the yearly direct and indirect costs for the eye center (in euros). The useful life of the equipment was assumed to be 5 years. In our center, the annual costs of maintaining and operating facilities for keratorefractive surgery are 403,000€ for SMILE, 353,000€ for PRK, and 403,000€ for LASIK. All of our patients pay 2,600€ for bilateral keratorefractive surgery regardless of the procedure. With that in mind, the minimum number of patients undergoing SMILE, FS-LASIK, and PRK needed per year to achieve a profit would be 155, 155, and 136 patients, respectively.

DISCUSSION

Cost-effectiveness analysis is a form of economic evaluation that assesses health outcomes and costs of interventions designed to improve health. The ICER gives the prorated cost in the years with projected benefit from the procedure, taking into account the possible cost from complications associated with the procedure. This value shows, for one intervention compared with another, the cost of achieving an additional unit of health.[5] Thus, the ICER for SMILE means that a patient who undergoes the procedure will have spent 13.98€ per year over 30 years with good vision. Likewise, for FS-LASIK and PRK, a patient will have spent 15.02 and 18.46€ per year, respectively, over 30 years with good vision. Cost-effectiveness is indicated when an ICER is lower than the cost-effectiveness threshold for a country. The cost-effectiveness threshold for Spain is between 22,000 and 25,000€,[11] and the ICER values of all three procedures at all time periods are below the cost-effectiveness threshold. Given that a statistical analysis could not be performed between these values, we cannot conclude that one procedure is more cost-effective than the other. However, SMILE, PRK, and FS-LASIK are all cost-effective from the payer's perspective when done between the ages of 20 and 60 years.

The ICERs for SMILE, PRK, and FS-LASIK were obtained at different time periods and analyzed. It is interesting to note the exponential and moderately negative correlation between the ICER and the time period for all three. The ICER is highest 1 year after SMILE, PRK, or FS-LASIK is performed. At 10 to 20 years after the procedure, there is a more significant exponential decrease in ICER, with less steep changes in the ICER beyond that. Alternatively, we can say that the earlier a corneal refractive procedure is performed, meaning the longer the time period, the lower the ICER becomes and the more cost-effective it is. This is a trend we noted for SMILE, PRK, and FS-LASIK, and is probably due to the effect induced by the QALYs that can be experienced with good vision over a longer time period when a procedure is performed at an earlier age. Similar studies that compare cost-effectiveness and the timing of treatment are mostly focused on cataract surgery,[12-14] but to our knowledge, there are none pertaining to corneal refractive procedures.

Cost is a significant consideration for patients who are contemplating undergoing keratorefractive procedures. These procedures are mostly not covered by health insurance policies. However, they have been shown to be more cost-effective than lifetime use of spectacles or contact lenses for the correction of ammetropia.[4,15] Mohammadi et al[4] have shown that correction with refractive surgery entails an annual and lifetime cost of 19.1 US$ and 568.1 US$. This is opposed to the respective annual and lifetime cost for spectacle correction of 342.5 US$ and 9,373 US$ and for contact lenses at 198.3 US$ and 5,203.1 US$. Lamparter et al[16] reported in 2005 expected costs of 518.51€ per gained refractive benefit unit for myopic LASIK. Although our model was different, our results mirror those of Mohammadi et al and we surmise that the expected lower costs for myopic corneal refractive surgery in our study would be due to the improvements in the technology and machines, hence a lower incidence of complications and associated costs. Most of the value-based studies pertaining to cost-effectiveness, cost-benefit, or cost-utility in ophthalmic procedures or conditions pertain to cataract surgery. **Table D** (available in the online version of this article) lists the results of similar value-based studies on cataract surgery, other ophthalmic interventions, and a few non-ophthalmic interventions. Our ICER values (ranging from 10.47 to 538.47 €/QALY for all three procedures at all time periods) are lower than the values of these studies and we suppose that this is due to the chronic, recurrent, lifelong, and visually debilitating nature of these ophthalmic conditions. The non-ophthalmic interventions in the table are also described for chronic, recurrent, potentially life-threatening or life-altering conditions, and it is difficult to compare quality adjusted life years and the definition of utility of an intervention between ophthalmology studies and those of other specialties because of the varying measures of utility and quality of life or health status. There have been motions to standardize the procedure for performing cost-effectiveness analyses, and this is affected by the existence of a multitude of variables that may affect the analysis, from the assignment of utility to determine the impact of the intervention to the determination of which cost to include. However, these would be interesting to pursue, especially in the field of corneal refractive surgery, because the outcomes of these studies could potentially aid in decision-making for a prospective patient or in a setting with limited resources.

TABLE 2

Direct and Indirect Costs for Obtaining and Maintaining the Facilities for Laser Corneal Refractive Surgery

Item	Cost (€)
Cost of the femtosecond laser (VisuMax; Carl Zeiss Meditec AG)	250,000
Annual amortization of the femtosecond laser	50,000
Cost of the excimer laser (Schwind Amaris 750S; SCHWIND eye-tech-solutions)	250,000
Annual amortization of the excimer laser	50,000
Annual maintenance/consumables	48,000
Personnel costs	135,000
Indirect costs	60,000
Marketing costs	60,000

With regard to the health care sector perspective, SMILE, FS-LASIK, and PRK are not widely available in more eye centers because of the direct and indirect costs associated with purchasing of the equipment needed and other expenses (eg, the consumable materials in the operating room or the maintenance and storage expenses for the lasers) to ensure the continuous availability of these services. We have found that, at least for high-volume centers such as ours, the cost of investing in these laser refractive surgery facilities is outweighed by the potential income.

Our study has several limitations. It only considered the payer and health care sector perspectives such that certain costs related to productivity, potential disability, or work absenteeism of the patient and companion were not included in this analysis. We used a simple decision tree model and did not include other outcomes or other complications to prevent our data from having too much information to the point of it being impractical or unwieldy. One of the further limitations of our model is that, to account for the evidence-based treatment modalities for managing certain complications of laser refractive surgery, it may overestimate the total costs of treating complications. These were considered and corrected for by multiplying the cost of the procedure with the frequency by which it is done, as described in the Methods section. Costs entailed from both the payer and eye center's perspective may be biased because these reflect the costs used in the setting of our eye center and in Spain, which may be lower than those in other countries. Our data are based on an eye center with a high volume of refractive procedures performed and a long history of providing said procedures, and we advise caution when extrapolating our data for the use of other eye centers because it may not be reflective of others' experiences. Future long-term data, especially regarding the complication rates and outcomes for each of the three procedures with the development of new laser platforms and surgical techniques, may affect similar studies on cost-effectiveness from the payer's perspective and even a societal perspective. It would also be interesting to compare the cost-effectiveness of the three procedures for treating hyperopia. Another interesting future study could involve subgroup analysis and comparison of cost-effectiveness between different stages of severity of myopia, or between extremes of age groups.

AUTHOR CONTRIBUTIONS

Study concept and design (MJTDB, DPP, JLA); data collection (MJTDB); analysis and interpretation of data (MJTDB, DPP, MC-C, JA); writing the manuscript (MJTDB, MC-C); critical revision of the manuscript (DPP, JA, JLA); statistical expertise (MC-C); administrative, technical, or material support (JLA); supervision (DPP, JA, JLA)

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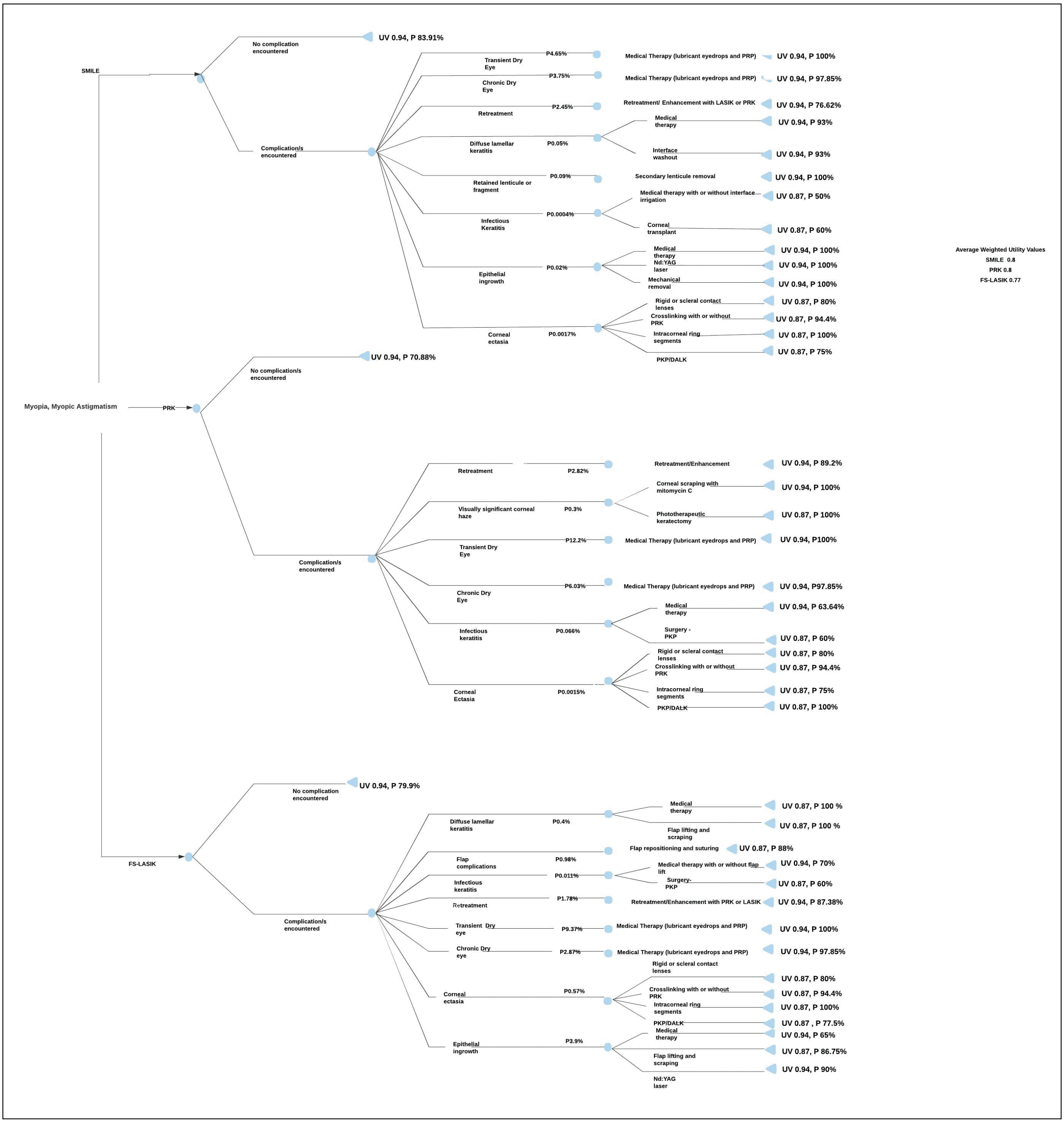

Figure A. The decision tree model for a patient with myopia who is eligible for either small incision lenticule extraction (SMILE), femtosecond laser–assisted in situ keratomileusis (FS-LASIK), or photorefractive keratectomy (PRK). Outcomes and their probabilities (P) are designated by a circle. Squares designate the evidence-based management options for the complications. The utility values (UV) based on the end visual acuity outcomes, and their probabilities (P) are to the right of the triangles.

Table A
Incidence Rates (Inc) of the Selected Complications for SMILE, PRK, and FS-LASIK

	Inc	References	Management	UV	Prob	References	Inc	References	Management	UV	Prob	References	Inc	References	Management	UV	Prob	References
			SMILE	0.94	83.91	1–21			**PRK**	0.94	70.88	2212,13,17,23–34			**FS-LASIK**	0.94	79.9	1,4,18,24,28,35–43
Retreatment or Enhancement	2.45	1–3,5–7,15–19,21,40,44–46	PRK	0.94	80.43	44,45,47–50	2.82	12,13,51–54,17,23,25,27,28,32–34	Repeat PRK	0.87	90.35	55–58	1.78	1,18,28,35,39,59–62	PRK	0.94	91.5	63–65
			LASIK/CIRCLE cap-to-flap conversion	0.94	72.8	45,48–50			LASIK	0.94	88.13	65–67			Flap Lift	0.87	100	64,65,68,69
Diffuse Lamellar Keratitis	0.46	1,2,17–19,21,40,46,70–72,3,5–7,10–12,16	Medical Management	0.94	93	70							0.4	73	Medical Management	0.87	100	74
			Interface washout	0.94	93	70			Table A						Flap lift and interface washout	0.94	93	75
Retained lenticule or lenticule fragment	0.09	1,2,13,15–19,21,40,46,70,3,71,5–7,9–12	Secondary removal	0.94	100	76												
Transient Dry Eye	4.65	10,77–82	Lubricants	0.94	100	83–87	12.2	88–91	Lubricants	0.94	100	83–85,87,88,92	9.37	79,88,90,91,93	Lubricants	0.94	100	83–85,87,88,92
Chronic Dry Eye	3.75	79,94	Lubricants	0.94	97.85	83–85,87,92,95	6.03	88,90,96	Lubricants	0.94	97.85	83–85,87,92,95	2.87	88,90,96	Lubricants	0.94	97.85	83–85,87,92,95
Infectious Keratitis	0.0004	97,98	Medical Management	0.87	50	97	0.066	99	Medical Management	0.94	63.64	99	0.01 1	99	Medical Management	0.94	70	99
			Corneal Transplant	0.87	60	100			Corneal Transplant	0.87	60	100			Corneal Transplant	0.87	60	100
Epithelial Ingrowth	0.02	1,2,13,15–19,21,40,46,70,3,71,5–7,9–12	Medical/Conservative Management	0.94	100	101							3.9	102	Medical/Conservative Management	0.94	65	103
			Nd:YAG Laser	0.94	100	104									Nd:YAG Laser	0.94	90	102,103,105
			Mechanical Removal	0.94	100	104									Flap lift and scraping	0.87	65	103,106
Corneal ectasia	0.0017	107–112	RGP contact lenses	0.87	80	113,114	0.001 5	115–123	RGP contact lenses	0.87	80	113	0.57	124	RGP contact lenses	0.87	80	113
			Collagen Cross-linking	0.87	94.4	108,113,125,126			Collagen Cross-linking	0.87	94.4	113,125–127			Collagen Cross-linking	0.87	94.4	113,125–128
			Intracorneal ring segments	0.87	100	129			Intracorneal ring segments	0.87	100	129			Intracorneal ring segments	0.87	100	129
			Penetrating Keratoplasty	0.87	50	113,130,131			Penetrating Keratoplasty	0.87	55	113,130			Penetrating Keratoplasty	0.87	55	113,130,132
			DALK	0.87	100	133			DALK	0.87	100	133			DALK	0.87	100	131
Corneal Haze								134–153	Corneal scraping with Mitomycin C	0.94	100	154						
							0.3		Phototherapeutic keratectomy	0.87	100	155						
Visually significant flap complications													0.98	156	Flap repositioning and suturing	0.87	88	157

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Table B
Medical Costs (in 2020 Euros) for SMILE, LASIK, and PRK

Medical Costs for SMILE				**Frequency**
	Annual Cost	**Discounted Lifetime Costs**	**Weighted Discounted Lifetime Costs**	
Consultation	100	100		
Screening for refractive surgery	100	100		
Bilateral surgery	2,600	2,600		
Postoperative medications	80	80		
Total	**2,880**	**2,880**	**2,880**	
Transient dry eye				**4.65%**
Consultation	80	80		
Medical treatment: topical lubricants, protein rich plasma eyedrops (full course of two months)	445	445		
Total	**525**	**525**	**24.41**	
Chronic dry eye				**3.75%**
Consultation	80	80		
Medical treatment: topical lubricants, protein rich plasma eyedrops (full course of two months)	445	1,861.71		
Total	**525**	**1,941.71**	**72.81**	
Retreatment				**2.45%**
Consultation	80	80		
Retreatment or enhancement with PRK or LASIK	1,300	1,300		

Postoperative medications	60	60		
Total	**1,440**	**1,440**	**35.28**	
Diffuse lamellar keratitis				**0.46%**
Consultation	80	80		
Interface irrigation	1,000	1,000		
Topical medications	60	60		
Total	**1,140**	**1,140**	**5.24**	
Retained lenticule or lenticule fragment				**0.09%**
Consultation	80	80		
Secondary lenticule removal	1,000	1,000		
Postoperative medications	60	60		
Total	**1,140**	**1,140**	**1.03**	
Infectious keratitis				**0.0004%**
Consultation	80	80		
Interface irrigation	1,000	1,000		
Topical antibiotic or antifungal medication	100	100		
Corneal transplant	263	263		
Postoperative medications	60	60		
Total	***1,502.5***	***1,502.5***	***0.006***	
Epithelial ingrowth				**0.02%**
Consultation	80	80		
Medical treatment – steroid eyedrops	0.23	0.23		
Epithelial scraping and washout	89.3	89.3		
Nd:YAG laser	2.5	2.5		
Postoperative or post-laser medications	60	60		
Total	***232.03***	***232.03***	***0.27***	
Corneal ectasia				**0.0017%**

Consultation	80	80		
Diagnostics	80	80		
Contact lenses (changed every quarter, annual cost)	304	14,462.56		
Crosslinking	36	36		
Intrastromal rings	34	34		
Penetrating keratoplasty/lamellar keratoplasty	300	300		
Postoperative medications	60	60		
Total	**894**	**15,052.56**	**0.26**	
Overall Cost	**9,978.53**	**28,853.8**	**3,019.82**	
Average Cost	**1,108.73**	**2,872.64**	**335.45**	
Medical costs for PRK				
Consultation	100	100		
Screening for refractive surgery	100	100		
Bilateral surgery	2,600	2,600		
Postoperative medications	80	80		
Total	**2,880**	**2,880**	**2880**	
Retreatment				**2.82%**
Consultation	80	80		
Retreatment or enhancement	1,300	1,300		
Total	***1,380***	***1,380***	***38.92***	
Visually significant corneal haze				**0.3%**
Consultation	80	80		
Corneal scraping with mitomycin C	10	10		
Phototherapeutic keratectomy	10	10		
Postoperative medications	60	60		
Total	**160**	**160**	**0.48**	

Transient dry eye				**12.2%**
Consultation	80	80		
Medical treatment: topical lubricants, protein rich plasma eyedrops (full course of two months)	445	445		
Total	***525***	***525***	***64.05***	
Chronic dry eye				**6.03%**
Consultation	80	80		
Medical treatment: topical lubricants, protein rich plasma eyedrops (full course of two months)	445	1,861.71		
Total	**525**	**1,941.71**	**117.09**	
Infectious keratitis				**0.066%**
Consultation	80	80		
Topical antibiotic or antifungal medication	100	100		
Corneal transplant	264.38	264.38		
Postoperative medications	60	60		
Total	**504.38**	**504.38**	**0.33**	
Corneal ectasia				**0.0015%**
Consultation	80	80		
Diagnostics	80	80		
Contact lenses (changed every quarter, annual cost)	304	14,462.56		
Crosslinking	36	36		
Intrastromal rings	34	34		
PKP/DALK	300	300		
Postoperative medications	60	60		

Total	**894**	**15,052.56**	**0.23**	
Overall Cost	**6,868.38**	**22,443,65**	**3,101.1**	
Average	**981.20**	**3,206**	**443**	
Medical costs for LASIK				
Consultation	100	100		
Screening for refractive surgery	100	100		
Bilateral surgery	2,600	2,600		
Postoperative medications	80	80		
Total	***2,880***	***2,880***	***2,880***	
Diffuse lamellar keratitis				**0.4%**
Consultation	80	80		
Medical treatment – steroid eyedrops	60	60		
Flap irrigation and repositioning	1,000	1,000		
Total	**1,140**	**1,140**	**4.56**	
Visually significant flap complications requiring treatment				**0.98%**
Consultation	80	80		
Flap repositioning and/or suturing	1,000	1,000		
Postoperative medication	60	60		
Total	***1,140***	***1,140***	***11.17***	
Infectious keratitis				**0.011%**
Consultation	80	80		
Flap lifting and interface irrigation	1,000	1,000		
Topical antibiotic or antifungal medication	100	100		
Corneal transplant	264.38	264.38		
Postoperative medications	60	60		
Total	**1,504.38**	**1,504.38**	**0.165**	
Retreatment				**1.78**

Consultation	80	80		
Retreatment or enhancement with PRK or LASIK	1,300	1,300		
Postoperative medications	60	60		
Total	**1,440**	**1,440**	**25.63**	
Transient dry eye				***9.37%***
Consultation	80	80		
Medical treatment: topical lubricants, Protein rich plasma eyedrops (full course of two months)	445	445		
Total	***525***	**525**	**49.19**	
Chronic dry eye				**2.87%**
Consultation	80	80		
Medical treatment: topical lubricants, Protein rich plasma eyedrops (full course of two months)	445	1,861.71		
Total	**525**	**1,941.71**	**55.74**	
Corneal ectasia				**0.57%**
Consultation	80	80		
Diagnostics	80	80		
Contact lenses (changed every quarter, annual cost)	304	14,462.56		
Crosslinking	36	36		
Intrastromal rings	34	34		
PKP/DALK	300	300		
Postoperative medications	60	60		
Total	**894**	**15,052.56**	**85.8**	

Epithelial ingrowth				**3.9%**
Consultation	80	80		
Medical treatment – steroid antibiotics	11.52	11.52		
Flap lift, epithelial scraping and washout	89.3	89.3		
Nd:YAG laser	25	25		
Postoperative or post-laser medications	60	60		
Total	**265.82**	**265.82**	**10.37**	
Overall Cost	**10,314.20**	**25.889.47**	**3,122.63**	
Average cost	**1,146.02**	**2,876.61**	**346.96**	

Table C

Comparison of Average Weighted Costs (AWC), Weighted QALY (QALY) and ICER at Different Time Periods

	40 year time period			***35 year time period***			***30 year time period***		
	AWC (€)	***QALY***	***ICER (€/ QALY)***	***AWC (€)***	***QALY***	***ICER (€/ QALY)***	***AWC (€)***	***QALY***	***ICER (€/ QALY)***
SMILE	*335.47*	*32.04*	*10.47*	*335.46*	*28.04*	*11.96*	*335.45*	*24*	*13.98*
PRK	*443*	*32*	*13.84*	*443*	*28*	*15.82*	*443*	*24*	*18.46*
FS-LASIK	*357.07*	*30.8*	*11.59*	*354.19*	*26.95*	*13.14*	*346.96*	*23.1*	*15.02*
	25 year time period			***20 year time period***			***15 year time period***		
	AWC (€)	***QALY***	***ICER (€/ QALY)***	***AWC (€)***	***QALY***	***ICER (€/ QALY)***	***AWC (€)***	***QALY***	***ICER (€/ QALY)***
SMILE	*335.45*	*20.03*	*16.75*	*335.44*	*16.02*	*20.94*	*335.44*	*12.02*	*27.91*
PRK	*443*	*20*	*22.15*	*443*	*16*	*27.69*	*443*	*12*	*36.92*
FS-LASIK	*349.57*	*19.25*	*18.16*	*347.73*	*15.4*	*22.58*	*346.13*	*11.55*	*29.97*
	10 year time period			***5 year time period***			***1 year time period***		
	AWC (€)	***QALY***	***ICER (€/ QALY)***	***AWC (€)***	***QALY***	***ICER (€/ QALY)***	***AWC (€)***	***QALY***	***ICER (€/ QALY)***
SMILE	335.43	8	41.93	335.43	4	83.86	329.54	0.8	411.92
PRK	443	8	55.37	443	4	110.75	431	0.8	538.47
FS-LASIK	344.76	7.7	44.77	340.93	3.85	88.55	335.58	0.77	435.81

Table D

Similar Studies for Other Ophthalmic Procedures and Several Non-ophthalmic Procedures or Devices

Author/s	Procedure	Type of Study Done	Currency/Year	ICER
Brown et al[1]	Ranibizumab for subfoveal neovascular macular degeneration	Cost-utility analysis	US dollars($)/ 2008	50,691/QALY
Kobelt et al[2]	Bilateral cataract surgery (type unspecified)	Cost-effectiveness analysis	US dollars($)/ 2002	4,500/QALY
Brown et al[3]	Silicone oil versus perfluoropropane for severe proliferative vitreoretinopathy without previous vitrectomy	Cost-utility analysis	US dollars($)/ 2002	40,252/QALY
	Perfluoropropane versus silicone oil for severe proliferative vitreoretinopathy with previous vitrectomy		US dollars($)/ 2002	62,383/QALY
Javitt and Aiello[4]	Screening and treatment of eye disease in patients with Diabetes Mellitus	Cost-effectiveness analysis	US dollars($)/ 1996	3,190/QALY
Eye Care Comparative Effectiveness Research Team (ECCERT)[5]	Cataract surgery (type unspecified)	Cost-utility analysis	US dollars($)/2013	2,049/QALY
Busbee et al[6]	Cataract surgery in the second eye (phacoemulsification and extracapsular cataract extraction)	Cost-utility analysis	US dollars($)/2003	2,727/QALY
Brown et al[7]	Unilateral Cataract surgery	Cost-utility analysis	US dollars($)/2013	1,636/QALY
Brown et al[8]	Bilateral Cataract surgery	Cost-utility analysis	US dollars($)/2018	1,514/QALY
	First eye cataract surgery			1,001/QALY
	Second eye cataract surgery			3,101/QALY

Author/s	Procedure	Type of Study Done	Currency/Year	ICER
Brunner-LaRocca et al[9]	Drug eluting stents for patients at high or low risk of cardiac events	Cost-effectiveness analysis	Euros(€)/2007	40,467/QALY
Kumar et al[10]	Risk-targeted lung cancer screening	Cost-effectiveness analysis	US dollars($)/2018	53,000-75,000/QALY
Osnabrugge et al[11]	Coronary artery bypass graft	Cost-effectiveness analysis	Euros(€)/2015	2,967-3,757/QALY

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