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Economic Value of Enhanced Monofocal Intraocular Lenses for Cataract Surgery in Italy

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ABSTRACT

Aim: Cataract is a prevalent health condition, primarily caused by aging, affecting approximately 95 million individuals worldwide. The only effective treatment currently involves surgically removing and replacing the crystalline lens with an artificial intraocular lens (IOL). Various IOLs are available, each with distinct characteristics, costs, and outcomes. This study aimed to assess the value of an enhanced monofocal IOL for cataract surgery, which has been shown to improve intermediate vision and reduce the need for spectacles during intermediate tasks, compared to a conventional monofocal IOL (standard of care), through a cost-utility analysis from both the National Healthcare Service (NHS) and societal perspectives in Italy.

Methods: A cost-utility model was developed incorporating both healthcare and nonhealthcare costs, as well as productivity losses, using data from a socio-economic questionnaire administered at three clinical centers in Italy. The questionnaire included the EuroQol 5D-5L to assess quality of life. National Healthcare Service costs were based on reimbursement tariffs.

Results: Over a 10-year horizon, estimated costs were 15,723 € (16,643 USD) for the standard IOL group and 11,190 € (11,845 USD) for the enhanced monofocal IOL group from the societal perspective. Since no significant differences in patients' quality of life were observed between the two groups, the innovative IOL may be considered a cost-saving option compared to standard monofocal IOL. From the NHS perspective, only the intervention for lens implantation was considered, resulting in costs of 940 € (994.99 USD) and 900 € (952.65 USD) for enhanced monofocal IOL and standard IOL, respectively. In this perspective, enhanced monofocal IOL was dominated (more costly with the same QALYs) by standard IOL.

Conclusions: This study fills a literature gap by evaluating the cost-utility of enhanced monofocal IOLs for cataract surgery compared to standard IOLs. While enhanced monofocal IOL is dominated from the NHS perspective due to slightly higher direct healthcare costs, it is cost-saving from a societal perspective by reducing the overall economic burden with comparable patients' quality of life. The broader benefits, including reduced reliance on corrective measures, visits and exams, formal and informal assistance, emphasize its societal value. This highlights the need for a holistic healthcare approach that balances long-term societal savings with short-term healthcare costs.

Introduction

A cataract is a defect in the clarity of the eye lens, commonly referred to as "clouding," which reduces its ability to transmit light and causes gradual loss of vision—usually in one eye at a time. The most common symptoms include loss of color and contrast sensitivity, reduced night vision, inability to focus, double vision and increased sensitivity to glare.[1]

Cataract is a very common health condition affecting an estimated 95 million people worldwide.[2] The most frequent cause is related to normal aging. Multiple population-based studies have found that its prevalence

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increases from 3.9% at age 55 to 64 years to 92.6% at age 80 years and older.[2] Nonetheless, cataracts can also develop as a consequence of trauma, toxic exposure, intraocular disease, or systemic disease.[3,4] Cataracts are more prevalent in economically developing countries,[5] where they remain a leading cause of blindness. However, the factors leading to cataracts are not yet understood, specifically how much genetics, life habits and diet matter for their formation—although genetic factors are deemed to account for approximately 50% of the variation in their severity.[6]

Loss of vision from cataracts cannot be corrected with eyeglasses. At present, the only available treatment consists of surgically removing the natural lens and substituting it with an artificial intraocular lens (IOL). Cataract surgery is the most frequently performed ophthalmic procedure globally, with over 26 million surgeries conducted each year. Due to demographic shifts and improved access to healthcare services, the number of procedures is increasing at a compound annual growth rate of 3.1%.[7] There is no precise global figure for the total cost of all cataract surgeries worldwide, as the cost varies significantly by region and health system. However, with over 26 million surgeries performed annually, even using an average cost of around $3,000 per eye[8] could suggest an industry worth billions of dollars each year.

An IOL is a medical device consisting of a small artificial lens called "pseudophakic," which serves as a replacement for the natural lens to refract the light rays entering the eye and restore good vision. The conventional lenses used in this intervention have one focusing distance and are known as monofocal IOLs (standard of care). These lenses can be focused either for far-distance or near-distance, and patients will not be able to accommodate after the surgery—ie, to change the focus from one to another. Since monofocal IOLs are typically set to distance vision, most patients require correction for near vision and intermediate distance vision through reading spectacles. As reported by the European Society of Cataract & Refractive Surgeons (ESCRS) Functional Vision working group the achievement of 10/10 vision for far cannot be considered any longer the only aim for the surgery [9]. It is important to consider the day-to-day visual skills that the patient can perform after the surgery as expressed by the functional vision concept.

Hence, more advanced types of lenses, such as i) multifocal and ii) extended-depth-of-focus (EDOF), have been developed to overcome this issue. Generally, they entail additional costs, which in general are not covered by the National Healthcare Service.

Multifocal intraocular lenses are designed to achieve both uncorrected near and distance vision using two or three focal points, as opposed to monofocal IOLs, which have only one. Multifocal IOLs seem to reduce spectacle dependence and improve overall uncorrected visual acuity compared to monofocal IOLs.[10,11] However, multifocal lenses split light into multiple foci, altering natural vision and requiring neuroadaptation.[12] As a result, patients may experience more visual side effects, such as glare and halos.[11]

Contrary to multifocal lenses, EDOF IOLs aim to improve the range of vision by creating a single elongated focal point instead of multiple foci.[13] The objective is to enhance near and intermediate visual performance while reducing photic phenomena, glare and halos, typically associated with multifocal lenses.[13,14] In this context, "enhanced" monofocal IOLs represent a subset of IOLs specifically designed to improve intermediate vision.[14]

The variety of IOL models now available,[15] differing in terms of characteristics, costs and outcomes for patients, makes economic evaluation of technologies in the cataract surgery field desirable, intending to guide actors in charge of health delivery and policy to make evidence-based and value-driven choices for an efficient and transparent use of public healthcare resources. In the field of ophthalmic care, quality has traditionally been anchored to measures of visual acuity.[16] There is now growing recognition that the definition of value should include the perspective of multiple stakeholders and put patients at the center.[17,18] Being the ones who experience the whole episode of care, patients are in a unique position to contribute to the quality of care and value creation[19] and value should be defined around them.[20] Since visual impairment strongly influences quality of life,[21] there is room for consideration of patients' perspectives also in the field of the evaluation of technologies for cataract surgery.

The present study aims at estimating the cost-utility of the enhanced monofocal IOL for cataract surgery (TECNIS EYHANCE IOL, Johnson & Johnson Vision) that has been shown to improve intermediate vision and reduce spectacle dependence for intermediate tasks while minimizing the risk of photic phenomena,[14,22] compared to standard monofocal IOLs. The study adopts both the National Healthcare Service (NHS) and societal perspectives in Italy, not limiting the analysis to the costs sustained by healthcare payers but considering mainly out-of-pocket expenses borne by the patients in the postsurgery period. The Italian Programme for HTA of Medical Devices considers both these perspectives relevant when the introduction of innovative devices is at stake.[23] This research contributes to filling a literature gap since the cost-effectiveness of the innovative TECNIS EYHANCE IOL had never been investigated before and aims to give some consideration to patients' perspectives by using QALYs as a measure of effectiveness.[24]

Methods

The study aimed to investigate the aspects related to the quality of life of patients and the social and economic impact after cataract surgery, comparing monofocal standard versus enhanced monofocal IOLs. Prospective data collection on these aspects was pursued through the administration of questionnaires to patients during the control visit after cataract surgeries in 3 clinical centers in Italy: Eye Clinic, University of Florence, Florence; University Eye Clinic, University of Trieste, Trieste; Morgagni-Pierantoni Hospital, Forlì. These ophthalmologic centers have expertise in delivering advanced eye care, particularly in cataract surgery. They have been selected as they collectively contribute to advancements in ophthalmology, particularly in evaluating and implementing innovative intraocular lenses (eg, enhanced monofocal IOLs) for cataract surgery, while maintaining a balance of clinical care, research, and education.

The study has been approved by the Bocconi Ethics Committee (code FA000459, approval date 25 July 2022) and by the Ethical Committees of the participating clinical centers. Different focus groups were organized in July 2022 involving a few ophthalmologists (MB, GC, EF, RG, RM, GS, LT, DT) to inform the design of the socio-economic questionnaire and for the validation of the model developed to compare the two different types of monofocal IOLs.

Socio-Economic Questionnaire

The consumption of health and nonhealthcare resources that are not routinely collected by hospitals, such as out-of-pocket resources and productivity losses of adults who underwent cataract surgery, has been estimated through a socio-economic questionnaire purposely developed and validated by the clinicians participating in the study. The inclusion criteria for the patients' enrollment were:

- Patients able to provide informed consent for participation;
- Adult individuals (age≥18 years) who underwent cataract intervention with either monofocal standard or enhanced intraocular lenses.

Patients not satisfying inclusion criteria were excluded from the analysis.

The questionnaire included different sections (see Supplementary materials for the full questionnaire):

1. Informed consent and introduction to the aims of the questionnaire;
2. Personal data (age, occupational status) and information on vision problems and cataract surgery (type of IOL implanted and date of intervention);
3. Need for formal or informal assistance in everyday life and monthly paid assistance;

4. Number of control visits/examinations since cataract surgery, mean time lost per visit/examination, mean out-of-pocket cost per visit/examination (ticket or expense if performed privately, expense for transportation, meals away from home);
5. One-time expenses in the postsurgical period (from surgery to the control visit) for the purchase of eyeglasses/lenses and drugs; monthly expenses for the purchase of contact lenses, eye drops or other related products;
6. Time off for vision-related problems.

Questionnaire for the Evaluation of Patients' Quality of Life

Information regarding the quality of life was gathered using the EuroQol 5D-5L questionnaire (Registration ID: 49969), a standardized instrument for assessing respondents' health status and overall quality of life.[25]

The questionnaire, which assesses five key health dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression), utilizes an algorithm to compute a final score (utility coefficient, ranging from 0 to 1) determined by assigning weights to each answer. A higher score indicates better health. The Visual Analogue Scale (VAS), in the EuroQol questionnaire, measures a patient's self-rated overall health on a scale from 0 (worst imaginable health) to 100 (best imaginable health). The VAS is quick and straightforward, complementing the EQ-5D's descriptive system.

The inclusion criteria for this assessment were identical to those applied to the socio-economic questionnaire.

Questionnaire Implementation and Administration

The Qualtrics platform was utilized to collect both socio-economic questionnaires and EuroQol responses. The questionnaires were administered to patients during the control visit after cataract surgery, generally performed 1 to 3 months after the intervention. The patients completed the questionnaires using a computer at the clinician's office. Before the administration of the questionnaires, respondents were presented with an informed consent form. To provide consent, respondents must click on a dedicated single-choice field (choosing between "I give informed consent" or "I do not give informed consent"). If consent is granted, the respondent gains access to the questionnaire section; otherwise, no questionnaires are presented, and the survey is concluded. It is important to note that online questionnaires do not gather data that can disclose the identity of the respondents. To enhance accuracy and minimize input errors, coded fields were implemented wherever possible, and for text inputs, controls on data types (such as allowing only numbers) were applied when applicable.

The administration of the questionnaires started in October 2023 and ended in September 2024. A sample size of 50 questionnaires was requested for each involved center.

Cost-Effectiveness Analysis (CEA) Model

A cost-utility Markov model was designed to compare standard and enhanced monofocal IOLs from both NHS and societal perspectives in Italy. The analysis followed the Consolidated Health Economic Evaluation Reporting Standards (CHEERS).[26,27]

The model, which considered patients who underwent cataract surgery, projected costs and QALYs to evaluate the incremental cost-utility ratio (ICUR). The mean age of participants in the data collection was 75 years (see Results section for details on data collected), therefore, this mean age was used in the model to ensure representativeness of the analyzed sample. Given the relatively advanced age of the model population, a 10-year time horizon was considered appropriate to represent the patients' follow-up period.

The model (Figure 1) considered two health states, "Postsurgery" and "Death." A Markov cycle of 1 month has been applied. The process

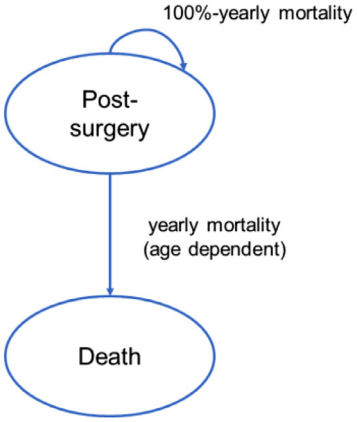

Figure 1. Markov model representation.

starts in the "Postsurgery" health state. Death state represents general mortality for the Italian population.[28] A discount rate of 3% has been applied to QALYs and costs.[29]

The lack of consensus on the appropriate methodology for estimating the willingness-to-pay (WTP) threshold, coupled with the absence of a universally accepted value, complicates the interpretation of cost-effectiveness studies. Globally, WTP thresholds vary widely, ranging from 15,000 € to 80,000 €.[30,31] In Italy, thresholds typically fall within the range of 25,000 to 60,000 €.[32–34] As the higher extreme has been applied in Italy in value-based procurement of medical devices of consolidate use, that value has been considered for the analyses.

Both probabilistic and deterministic sensitivity analyses (PSA, DSA) have been conducted to evaluate the robustness of the model results. For the former, 10,000 Monte Carlo simulations have been performed by extracting parameters from distributions (gamma for costs and beta for utilities). Ninety-five per cent confidence intervals (95% CI) were applied for PSA and DSA to estimate model parameters variations.

CEA Model Inputs

Healthcare Resource Consumption and Costs

A total of 150 patients, aged 75 years on average (range 49–91 years), responded to the e-survey, with 50 participants from each clinical center involved in the study. Forty percent of the patients (N = 60) underwent surgical intervention with an enhanced monofocal IOL. Twenty-one patients did not provide information on the type of IOL implanted and were excluded from the analyses, while the remaining patients (N = 69) received a standard IOL. The mean time from surgery and questionnaire administration (corresponding to the postprocedural period) was 96 days (range 1–355 days). Among respondents receiving the two lenses under investigation, the majority were retired (N = 109, 84%), followed by workers (N = 11, 9%) and housewives (N = 8, 6%). For one participant the occupation was not reported.

Regarding the visits, the average time lost for each visit was about 1.8 h across both groups. The mean number of visits in the postsurgical period was 1.31 in both groups. Productivity losses were assessed according to the human capital approach.[35] Each working hour lost was quantified based on the average hourly income associated with the professional category considered. In the case of one day lost, eight lost working hours were counted. Productivity losses were not considered for nonprofessional categories like retirees and unemployed. Since housewives typically do not receive formal wages for their work, the human capital approach estimates their economic value by considering the market value of the services they provide, such as childcare, cooking, and cleaning. This has been done by calculating the cost of performing these tasks.[36]

Table I
Summary of costs borne by the patients or their caregivers for the two types of IOLs

Cost item	Standard monofocal IOL	Enhanced monofocal IOL
Mean total expense in the postsurgical period* for:		
- Eye drops/treatments	60.22 € (63.70 USD)	70.85 € (74.94 USD)
- Glasses/lenses	34.93 € (36.93 USD)	22.53 € (23.82 USD)
- Visits/exams (including transportation, meals out of home)	112.27 € (118.66 USD)	63.93 € (67.63 USD)
Productivity loss for visits in the postsurgical period*	9.64 € (10.19 USD)	6.59 € (6.97 USD)
Total cost postsurgical period*	**217.06 € (229.78 USD) (CI 95% 32–661 €, 34–699 USD)**	**163.90 € (173.56 USD) (CI 95% 0–502 €, 0–531 USD)**
Monthly expense for eye drops, products for glasses cleaning, or periodic contact lenses	0.68 € (0.72 USD)	0 € (0 USD)**
Monthly productivity loss for vision problems	74.01 € (78.28 USD)	84.23 € (89.03 USD)
Monthly expense for paid assistance	28.99 € (30.64 USD)	10.00 € (10.58 USD)
Monthly cost for informal assistance	105.71 € (111.76 USD)	50.36 € (53.18 USD)
Total monthly cost	**209.39 € (221.63 USD) (CI 95% 0–1,625 €, 0–1,720 USD)**	**144.59 € (152.35 USD) (CI 95% 0–902 €, 0–954 USD)**

* Period between the surgical intervention and the control visit.
** Data reported only by one patient.

For estimating the economic impact of informal care, the replacement cost approach was employed. This method assesses the value of informal care by applying the same economic rates (eg, wages and salaries) that are typically attributed to professionals providing similar services in the market (eg, nurses and caregivers).[37] For each day of informal care received by patients, 8 h of care were considered. Supplemental Table I presents the unit costs and resource consumption used to estimate productivity losses and the cost of informal care.

Globally, patients with standard IOLs incurred in the postsurgical period a total cost of 217.06 € (229.78 USD) (CI 95% 32–661 €, 34–699 USD) and a monthly cost of 209.39 € (221.63 USD) (CI 95% 0–1,625 €, 0–1,720 USD). For the enhanced monofocal IOLs group, these costs were lower and equal to 163.90 € (173.56 USD) (CI 95% 0–502 €, 0–531 USD) and 144.59 € (152.35 USD) (CI 95% 0–902 €, 0–954 USD), respectively.

Table I reports the detailed costs borne by the patients or their caregivers for the two types of IOLs.

Concerning NHS costs, cataract surgery in Italy is included in the Essential Levels of Assistance (LEAs); this means that care providers offering such service are remunerated according to Diagnosis Related Groups (DRGs) or ambulatory tariffs. The cost of cataract treatment from the perspective of the payer was considered to be equal to the ambulatory tariff, as most surgeries are executed in the ambulatory setting.[38]

According to the most recent update to reimbursement tariffs (30th December 2024),[39] the fee amounts to 900 € (952.65 USD) and is intended to cover surgery, the cost of the IOL implanted, as well as preoperative and follow-up visits (one should be programmed in the 72 h following surgery and another one to three weeks after, following the guidelines by Società Oftalmologica Italiana[38]). The ophthalmologists involved in the focus group reported that the patient pathway is identical for the implantation of TECNIS EYHANCE IOL and the conventional IOL and that there are no differences in resource consumption, except for the price of the device implanted. No mechanism is foreseen to remunerate the use of technologically advanced and costly IOL options, which may be purchased directly by the clinical centers or paid by the patients in case of co-payment (available in a few Italian Regions). It was thus assumed that the tariff reflects the cost of purchasing a standard monofocal lens and that an extra cost must be faced when choosing to implant a costlier IOL. The cost of the two technologies was provided by the clinical centers involved in the study: it was set to 95 € (100.56 USD) for the standard IOL (TECNIS ZCB00 IOL) and 135 € (142.76 USD) for TECNIS EYHANCE IOL, VAT excluded (4%). In the model, we thus considered a hospital total cost of 900 € (952.65 USD) in the case of the TECNIS ZCB00 implant and 940 € (994.99 USD) for the TECNIS EYHANCE IOL implant, adjusting the value for the "premium" price of TECNIS EYHANCE IOL. Among the regions analyzed, only Emilia Romagna implements a co-payment system. When hospital funds allocated for the purchase of enhanced monofocal IOLs are depleted, patients can opt to cover the cost difference between a standard IOL and an enhanced monofocal IOL (40 €) as an out-of-pocket expense. The latter scenario falls within the societal perspective, as the co-payment is made by the patient.

Supplemental Table II summarizes the parameters used to populate the CEA model with related sources and information on distributions applied in the probabilistic sensitivity analysis.

Quality of Life

EuroQol-5D-5L responses have been analyzed and transformed into utility values by applying the algorithm specific for Italy.[40] The utility values estimated were 0.886 and 0.874 for patients with standard and enhanced monofocal IOLs, respectively, with a slight advantage for the former group. Conversely, patients who underwent implantation of the enhanced monofocal IOL showed a slightly better self-reported quality of life through the VAS compared to the standard IOL group (78 versus 80, $P = 0.46$). Considering the nonstatistically significant differences between the two groups, the same utility value (0.880), corresponding to the average, has been applied to both strategies.

Results

From the societal perspective, the model estimated over a horizon of 10 years a mean cost of 15,723 € (16,643 USD) for a patient with standard monofocal IOL. On the other hand, a patient who underwent cataract surgery with enhanced monofocal IOL showed a social cost of 11,190 € (11,845 USD). The estimated QALYs for the two groups were 5.173. According to the results obtained, the use of an enhanced monofocal IOL may be considered a dominant option (less costly with the same QALYs) compared to the use of a standard monofocal IOL.

From the NHS perspective, only the intervention for lens implantation was considered, resulting in costs of 940 € (994.99 USD) and 900 € (952.65 USD) for enhanced monofocal IOL and standard IOL, respectively. In this perspective, enhanced monofocal IOL was dominated (more costly with the same QALYs) by standard IOL. When the co-payment is considered (the patient covers the cost difference between

Table II
Cost-effectiveness deterministic results

Perspective	Expected outcomes (discounted)	Enhanced monofocal IOL	Standard monofocal IOL	Difference	ICUR(enhanced monofocal IOL vs standard monofocal IOL)
NHS	Costs	940 € (994.99 USD)	900 € (952.65 USD)	40 € (42.34 USD)	Dominated
	QALYs	5.173	5.173	-	
Societal	Costs	11,190 € (11,845 USD)	15,723 € (16,643 USD)	4,533 € (4,792 USD)	Dominant
	QALYs	5.173	5.173	-	

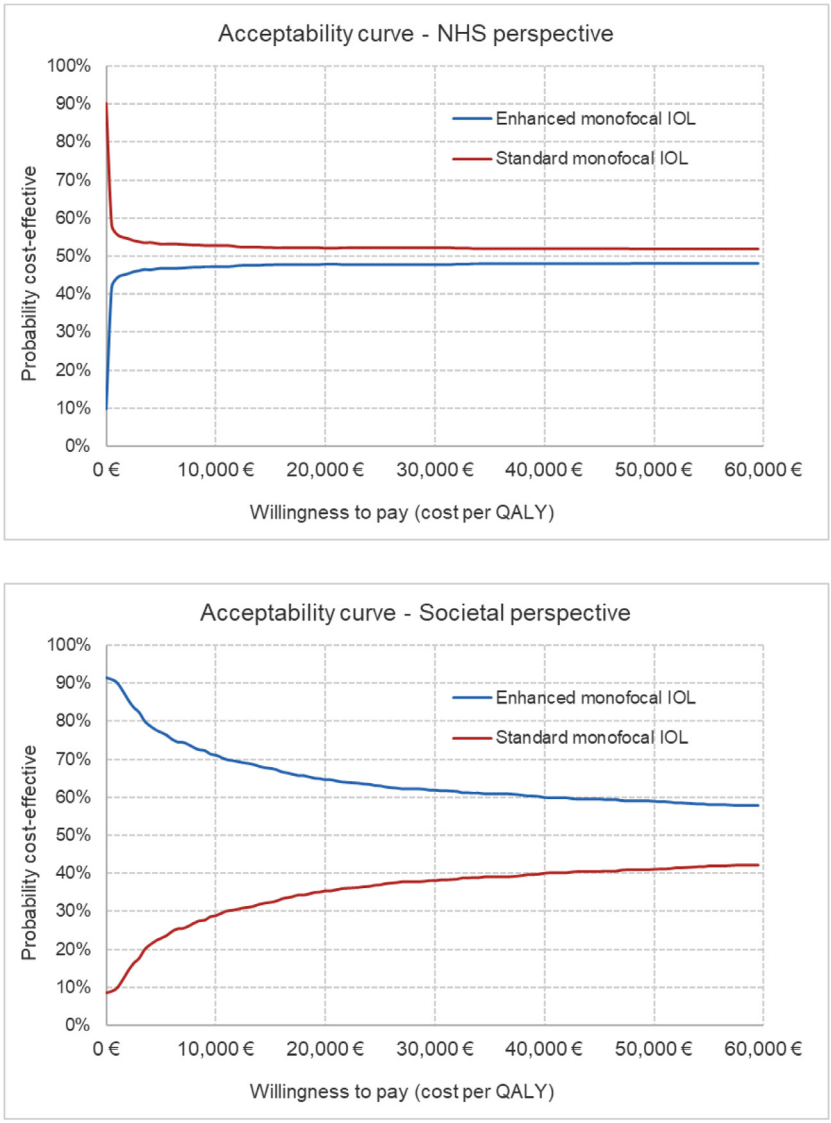

Figure 2. PSA results (acceptability curves for the ICUR) for both NHS and societal perspectives.

the two types of lenses), the two options become essentially equivalent from the NHS perspective, with identical costs and QALYs.

Cost-effectiveness results are reported in Table II. The probabilistic sensitivity analysis showed that enhanced monofocal IOLs are cost-effective in 59.60% of the simulations considering the societal perspective and a WTP threshold of 60,000€/QALY; in contrast, from the NHS perspective, standard IOLs are cost-effective in 51.90% of simulations at the same WTP threshold (Figure 2).

Considering the societal perspective, one-way sensitivity analyses confirmed the dominance of enhanced monofocal IOLs across all parameter variations except for utility values. In the case of the lower bound utility value for the enhanced monofocal IOL (u = 0.700), the standard IOL becomes cost-effective, with an ICUR of 4,284 € (4,529 USD)/QALY (standard IOL versus enhanced IOL). Similarly, when considering the upper bound utility value for the standard IOL (u = 1.000), the cost-effectiveness of the standard IOL is further confirmed, with an ICUR of 6,426 € (6,805 USD)/QALY (standard IOL versus enhanced IOL). From the NHS perspective, utility values remain the most impactful parameters, while variations in other parameters do not alter the outcome. When the utility value for the standard IOL is set at 0.700, the ICUR decreases to 38.66 € (40.92 USD)/QALY, making the enhanced monofocal IOL cost-effective. Similarly, when the utility value for the en-

hanced monofocal IOL is set at 1.000, the ICUR becomes 56.70 € (60.02 USD)/QALY, also supporting the cost-effectiveness of enhanced monofocal IOLs.

Discussion

Currently, various IOL options are available for the surgical treatment of cataract patients. In this context, enhanced monofocal IOLs should be considered as a potential option, taking into account the clinical benefits reported in the published literature.[41]

While randomized controlled trials (RCTs) are generally regarded as the gold standard for establishing the efficacy of new healthcare technologies compared to the standard of care, the unique features of medical device-based technologies (such as a small eligible patient population, challenges in recruitment, inability to blind clinicians and patients, choice of a comparator group, and a learning curve) may present obstacles to conducting a traditional RCT. In response to these challenges, alternative approaches like real-world studies have been suggested to mitigate the impact of these issues.[23,42–44] In the current study, we conducted a cost-effectiveness analysis that compared enhanced monofocal IOLs to standard monofocal IOLs, considering both the NHS and societal perspectives in Italy and relying on real-world data.

Considering a time horizon of 10 years, the analyses from the NHS perspective showed that the standard IOL may be the preferred choice for the management of patients with cataract as it is less costly with the same health benefits. Conversely, when the perspective was extended to the whole society, enhanced monofocal IOLs showed to be a cost-saving option compared to standard monofocal IOLs. Considering the societal perspective, for standard IOLs, the primary cost driver in the postsurgical period was attributed to follow-up visits and exams, while informal care constituted the main component of the monthly costs in the follow-up. For the enhanced monofocal IOLs group, these items were the cost of eye drops/treatments and productivity losses for vision problems, respectively. The analysis from the NHS perspective was based solely on the cost of the intervention involving a lens implant. Since the cost was similar for both IOLs, this was reflected in the comparable cost-effectiveness probabilities observed in the probabilistic sensitivity analysis. Anyway, extending the cost-effectiveness analysis to a societal perspective provides a more comprehensive view of economic and social benefits. This helps in making better-informed healthcare decisions, improving patient outcomes, and optimizing resource allocation beyond just the NHS, aligning to the so-called value-based healthcare paradigm.[20] In particular, this study has the merit of incorporating the patient perspective, going beyond the consideration of purely medical outcomes. Indeed, clinical endpoints represent a too-narrow conceptualization of value that doesn't necessarily reflect the quality of life experienced by patients. Despite persistent calls for incorporating the patient perspective into HTA, efforts to do so appear to be lagging.[45] Further research in this direction is needed also in the field of IOLs for cataract surgery, as most of the outcomes analyzed in the literature are purely clinical.

The current study presents a few limitations. Limitations are both related to the cost-utility and QALY elicitation methodologies and to the limited availability of data on TECNIS EYHANCE IOL which is a relatively new technology.

While the EQ-5D system is widely used across various health conditions, it is not specifically tailored to assess some conditions, such as conditions affecting sensory functions like vision. It is likely that for this reason, the EuroQol questionnaire was not able to discriminate patients' quality of life between the two different types of monofocal IOLs. Recently, additional dimensions, also called "bolt-ons," have been proposed to extend the EQ-5D to address this issue. The vision bolt-on EQ-5D appears to be more discriminative than the standard EQ-5D in the measurement of vision problems. Future studies should investigate the extent to which the vision bolt-on item can increase the sensitivity of the EQ-5D to vision change in interventional studies.

Another consideration pertains to complications following cataract surgery, which were not incorporated into the model. Since the surgical procedure and follow-up care are consistent for both types of lenses, this factor was not expected to influence the overall outcomes of the analysis.

In estimating healthcare and nonhealthcare resource utilization from a societal perspective, it is important to recognize that self-reported data may be susceptible to recall bias and limited generalizability. For instance, respondents reported higher costs for informal care after cataract surgery with standard IOLs compared to enhanced ones, despite no significant differences in quality of life between the two lens types. Although the questions explicitly instructed respondents to focus on vision-related issues, it remains unclear whether patients required assistance for other problems and whether this influenced their responses. To strengthen the validity of the current model, collecting data through prospective, multicenter observational studies would provide more reliable and comprehensive information. Such studies would also enable a more accurate assessment of potential differences between IOL types and the impact of patients' comorbidities on final outcomes.

Economic evaluations are only useful to the extent that they are considered in decision-making processes. The present cost-utility analysis suggests that TECNIS EYHANCE IOL has a cost-saving profile compared to the standard of care from the societal perspective, and the ophthalmologists involved in a focus group reported that they believe that monofocal IOLs with enhanced intermediate function should become the standard treatment in patients with cataracts. Yet, this may require both a reorganization of IOL purchasing processes and the implementation of codification and reimbursement systems that keep up with technological advancements. In the Italian context, care pathways and decision-making processes are not always centered around value, which limits the impact that studies such as the present one may have in practice. The lack of appropriate reimbursement as the key determinant of the scarce adoption of technological advancements has been recognized in the cataract surgical field.[46] The reimbursement tariff remunerating cataract surgery has been progressively reduced starting from the year 2000 based on purely economic considerations and the existing tariffs limit the provision of the best possible care in cataract surgery. Thus, it should be further investigated whether an increase in the reimbursement tariff, intended to cover the additional cost of purchasing an enhanced monofocal IOL, would promote a broader adoption of this innovative IOL in standard clinical practice, ultimately enhancing benefits for society as a whole. Considering the high volume of cataract surgeries performed each year in Italy (more than 600,000[47]), even a modest price difference can translate into a significant financial burden at the healthcare system level. Moreover, beyond the absolute cost difference, the lack of a dedicated reimbursement for advanced IOLs removes a direct financial incentive for their adoption, which is a well-documented driver of innovation uptake in surgical fields. While some centers may still offer these lenses, their use remains limited compared to standard IOLs.

In healthcare procurement, traditionally, the lowest price approach has been predominantly employed, particularly for standard and widely available medical devices where there is minimal variation in quality or innovation. Nowadays, the *most economically advantageous tender* approach is becoming more prevalent, particularly for tenders managed by centralized procurement entities or regional purchasing bodies. This approach uses a weighted scoring system that combines technical quality and price to determine the best overall value. This shift aligns with broader efforts to integrate value-based healthcare principles.[48,49] In this context, the present study seeks to shift toward a more strategic, value-based approach to IOL procurement, which should also incorporate a broader set of outcomes to evaluate multiple dimensions of IOL value,[50] avoiding generic tender award criteria, that are unable to discriminate the different level of quality of the competing lenses.

Conclusions

The present study contributes to filling a literature gap related to the cost-utility profile of the enhanced monofocal IOL (TECNIS EYHANCE) for cataract surgery compared to the standard of care, which had never been investigated before. From the NHS perspective, the enhanced monofocal IOL is dominated due to higher direct healthcare costs, making the standard option more favorable in terms of immediate healthcare expenditures. However, from a societal perspective, the enhanced monofocal IOL proves to be cost-saving, reducing the overall economic burden by lowering both direct and indirect costs while maintaining patients' quality of life. These broader benefits, such as reduced dependency on corrective measures, visits and exams, formal and informal assistance, highlight its value to society. This contrast underscores the importance of a holistic approach to healthcare decision-making, where long-term societal savings and patient benefits are considered alongside short-term healthcare costs.

Our findings demonstrate the advantages of this advanced technology while also underscoring the need for further research or registry data, particularly involving diverse IOL types. The evaluation of patients' quality of life highlights the importance of effectively distinguishing between different lenses. Additionally, incorporating new technologies into a structured reimbursement plan with appropriate tariffs is critical for sustainable adoption.

In conclusion, these analyses offer valuable evidence in support of transitioning towards more innovative healthcare technologies for patients, aligning with the ongoing harmonization of health technology assessment (HTA) regulations at the European level.[51] Future randomized controlled trials or registry-based studies could provide stronger recommendations. Moreover, further cost-utility analyses considering different lens types, material expenses, and potential complications would be highly beneficial for clinicians, policymakers, and patients alike.

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Ethics Approval

The study has been approved by the Bocconi Ethics Committee (code FA000459) and by each clinical center that has enrolled patients: Eye Clinic, University of Florence, Florence; University Eye Clinic, University of Trieste, Trieste; Morgagni-Pierantoni Hospital, Forlì.

Data, Materials and Code Availability

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Declaration of competing interest

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

CRediT authorship contribution statement

Carla Rognoni: Writing – original draft, Methodology, Investigation, Formal analysis, Conceptualization. **Ilaria Giabbani:** Writing – review & editing. **Marco Balestrieri:** Writing – review & editing, Resources. **Giacomo Costa:** Writing – review & editing, Resources. **Eleonora Favuzza:** Writing – review & editing, Resources. **Rosa Giglio:** Writing – review & editing, Resources. **Rita Mencucci:** Writing – review & editing, Resources. **Giovanni Staurenghi:** Writing – review & editing, Resources. **Leonardo Taroni:** Writing – review & editing, Resources. **Daniele Tognetto:** Writing – review & editing, Resources. **Rosanna Tarricone:** Writing – review & editing, Supervision, Funding acquisition, Conceptualization.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.clinthera.2025.02.002.

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