

COMPARISON OF RECENTLY USED PHACOEMULSIFICATION SYSTEMS USING A HEALTH TECHNOLOGY ASSESSMENT METHOD

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Objectives: To compare the recently used phacoemulsification systems using a health technology assessment (HTA) model.

Methods: A self-administered questionnaire, which included questions to gauge on the opinions of the recently used phacoemulsification systems, was distributed to the chief cataract surgeons in the departments of ophthalmology of eighteen tertiary hospitals in Shanghai, China. A series of senile cataract patients undergoing phacoemulsification surgery were enrolled in the study. The surgical results and the average costs related to their surgeries were all recorded and compared for the recently used phacoemulsification systems.

Results: The four phacoemulsification systems currently used in Shanghai are the Infiniti Vision, Centurion Vision, WhiteStar Signature, and Stellaris Vision Enhancement systems. All of the doctors confirmed that the systems they used would help cataract patients recover vision. A total of 150 cataract patients who underwent phacoemulsification surgery were enrolled in the present study. A significant difference was found among the four groups in cumulative dissipated energy, with the lowest value found in the Centurion group. No serious complications were observed and a positive trend in visual acuity was found in all four groups after cataract surgery. The highest total cost of surgery was associated with procedures conducted using the Centurion Vision system, and significant differences between systems were mainly because of the cost of the consumables used in the different surgeries.

Conclusions: This HTA comparison of four recently used phacoemulsification systems found that each of system offers a satisfactory vision recovery outcome, but differs in surgical efficacy and costs.

Keywords: Health technology assessment, Phacoemulsification, Cataract, Cost, Visual acuity

Cataracts are the leading cause of blindness worldwide, and it has been estimated that more than 20 million surgical procedures are conducted every year to remove cataracts, with phacoemulsification being the surgical method of choice (1). This procedure can effectively remove the lens through a nonsutureless incision in a few minutes without severe complications. Therefore, when tertiary hospitals purchase surgical equipment for cataract surgery, phacoemulsification systems are currently the first choice. However, in most hospitals in developing countries, such as China, when the administration of a hospital determines whether to purchase a new phacoemulsification system, the scientific opinion of the clinicians is not the only

determining factor because the cost of these systems, consumables used, and time of the doctors required for the surgery represent critical factors. Because the City Medical Insurance system in Shanghai only permits limited reimbursement for phacoemulsification surgery (2), it is important for hospitals to know the cost-effectiveness of these systems based on published evidence. However, until now, there was no such evidence available that could be used for decision-making regarding the investment in a phacoemulsification system.

Health technology assessment (HTA) is a multidisciplinary field bridging scientific evidence and policy making and is increasingly used worldwide to support decision making concerning the uptake of new medical equipment and devices (3). Hospital managers and physicians subconsciously follow the trends to invest in the latest and most complex, but also more expensive, medical devices. The benefits of a new medical device are almost always overestimated, while the risks are underestimated. HTA not only highlights medical devices that would be too costly relative to their benefits but can also identify potentially ineffective technologies.

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Hospitals increasingly use local HTA models with respect to purchasing new and expensive health technologies (4). The local HTA model used in the present study is a mini-HTA, which is popular because of its capacity to integrate the views of end-users more effectively into hospital policy actions (5;6). The mini-HTA is usually performed by professionals, often by those who are participating in the assessment process, collecting data at the hospital level to inform decision makers. The studies from Ehlers and Folkersen both showed that the use of a mini-HTA could ease the burden of stakeholders to acquire a better understanding of new technologies and build a greater level of contact between doctors and administrative staff as well as improve the relationships between health professionals and economists. It was reported that 77 percent of the respondents were satisfied with the mini-HTA method (6–8).

In the present study, we compared four recently used phacoemulsification systems using a three-part analysis: (i) an investigation of the systems used by the ophthalmic specialists at Shanghai tertiary hospitals with a self-administered questionnaire; (ii) an assessment of the 3-month postoperative outcomes in terms of the visual acuity and the rate of complications after phacoemulsification surgery using these different systems; and (iii) the cost of the phacoemulsification surgery using these systems. The results of the present study may provide comprehensive data regarding the systems to aid in decision making for the purchase of a phacoemulsification system.

METHODS

Surgeon's Opinions/Expert Opinions

A self-administered questionnaire was prepared by the study group. It included two parts: (i) Introductions and Perspectives about the recently used phacoemulsification system; and (ii) a self-administered 15-item questionnaire, as shown in Table 1. The mini-HTA was based on a checklist designed for a rapid assessment of four aspects: technology, patient, organization and economy (3). The original mini-HTA model was a 13-item form. Our self-administered questionnaire principally relied on ophthalmic physicians. In January 2016, a pilot study was performed in the authors' hospitals (Shanghai General Hospital and Shanghai Eye Hospital) to confirm that the questionnaire was easy to understand. Then, the chief cataract surgeons in the Department of Ophthalmology at another eighteen tertiary hospitals in Shanghai were invited to fill in the questionnaire between February 2016 to March 2016. In terms of quality, the ophthalmic specialists had to ensure that they completed the forms correctly. Finally, the forms were collected and summarized to produce a comprehensive report.

Based on the questionnaire, there were four types of phacoemulsification systems currently being used in the eighteen Shanghai tertiary hospitals: the Infiniti Vision system (Alcon, Fort Worth, TX), Centurion Vision system (Alcon, Fort Worth,

TX), WhiteStar Signature system (Advanced Medical Optics, Santa Ana, CA), and Stellaris Vision Enhancement system (Bausch & Lomb, Rochester, NY). The characteristics of these four systems are listed in Table 2. All four of these systems are available in the authors' hospitals (Shanghai General Hospital and Shanghai Eye Hospital). The Infiniti Vision system and the Centurion system are both manufactured by Alcon company. The Infiniti Vision system was released in 2003 and provided an upgraded torsional ultrasound mode, which was reported to result in less heat production, a reduced surgical time and fewer postoperative complications compared with the traditional longitudinal mode (9). The Centurion system was released in 2013 and is the newest of the four phacoemulsification systems compared in the present study. The Centurion Vision system uses an Active Fluidics system with a compressive irrigation bag, which can provide a variable infusion pressure to ensure better stability of the surgical intraocular pressure. It also uses an In-trepid Balanced ultrasound tip for better surgical efficacy (10).

Clinical Outcomes and Safety of the Phacoemulsification Surgery

From January 2016 to March 2016, eligible cataract patients who underwent phacoemulsification surgery in the authors' hospitals were enrolled in the present study. Because each patient had a unique case series code in the authors' hospital, we used the simple random sampling method to allocate the patient into the eye surgery room which is equipped with different types of phacoemulsification system. The inclusion criteria were set as: (i) Patients with an explicit diagnosis of cataract in the operated eye with nuclear (N) lens opacities classified as N0 to NIII by the Lens Opacities Classification System II (LOCS II) (11); (ii) patients who could understand and cooperate in this study and were willing to undergo ophthalmic examinations and provide written informed consent; (iii) patients without other eye diseases, such as keratopathy, glaucoma, dacrycystitis, uveitis, ocular trauma, and age-related macular degeneration, and so on; and (iv) patients who could be followed-up within 90 days (3 months) after surgery. The purpose and the risks of the surgery were fully explained to all of the patients.

All of the patients underwent a successful phacoemulsification procedure with foldable posterior chamber intraocular lens implantation through clear corneal incisions under local anesthesia. All of the surgical procedures were conducted by a skilled surgeon (H.Z.) who has conducted more than ten thousand phacoemulsification surgeries during the past 10 years and who was helped by one assistant and one nurse. Written informed consent was provided by all of the participants, and the study was approved by the ethics committee of Shanghai General Hospital, Shanghai Jiao Tong University and was conducted according to the Declaration of Helsinki.

The clinical variables and demographics of the patients were recorded based on the clinical charts and surgical reports. All patients came back to the hospital 1 month and 3 months

Table 1. Responses to the Modified Mini-HTA form Received from Eighteen Tertiary Hospitals in Shanghai

	Response 1 (no. of hospitals)	Response 2 (no. of hospitals)
Introduction		
How long have you used this system?	<3 years (6)	≥3 years (12)
How many surgeries have you conducted with this system?	500 to 1000 (6)	> 1000(12)
Would you recommend the system to other doctors?	Yes (15)	No (3)
Technology		
Was an assessment of the literature carried out before purchase of the system (by the department or by others)?	Yes (16)	No (2)
Is the system associated with any risks, adverse effects?	Yes (4)	No (14)
Has the system been recommended by academic organizations, such as medical associations, etc.?	Yes(16)	No(2)
Has the department previously, on any other occasion, applied for introduction of the system?	Yes (17)	No (1)
Patient		
Does the system require any special ethical or psychological considerations?	Yes (18)	No
Is the system expected to influence the patients' quality of life, social or employment situation?	Yes (18)	No
Organization		
Are any positive effects of the system expected for the staff in terms of information, training, or working environment?	Yes (16)	No (2)
Are special accommodations to the physical setting required before installing the system?	Yes(18)	No
Will the system affect other departments or service functions in the hospital?	Yes(3)	No(15)
Economy		
Compared to the previously used system, are there any costs saved per patient?	Yes (12)	No (6)
Compared to the previously used system, are there cost savings for the hospital?	Yes (12)	No (6)
Are there additional costs that can be expected for other hospitals, in other sectors, etc.?	Yes (1)	No (17)

Note. The system: the phacoemulsification system most recently used in the hospital.

Table 2. Characteristics of the Four Phacoemulsification Systems Compared in the Present Study

	Infiniti	Centurion	Signature	Stellaris
Manufacturer	Alcon	Alcon	AMO	Bausch & Lomb
Submodes	Continuous, Pulse, Burst	Continuous, Pulse, Burst	Continuous, Pulse, Burst	Continuous, Pulse, Burst
Resonant frequency	38.0±1.9kHz	30 to 60kHz	38 to 40kHz	28.5kHz
Pulse rate range	0-100pps	1-250pps	1-14pps	2-600pps
Burst length	5 to 600 ms	2-500 ms	50-150 ms	2-600 ms
Vacuum range				
Phacoemulsification	0-650 mmHg	0-700 mmHg	0-650 mmHg	0-650 mmHg
Irrigation/aspiration	0-650 mmHg	0-700 mmHg	0-650 mmHg	0-650 mmHg
IV pole height range	13 to 110 cm	20 to 110 cm	to 107 cm	30 to 140 cm
Consumable used	Active Fluidics packs	Intrepid Plus gravity packs	OP070 tubing packs	BL5111 Venturi packs
Purchase cost in the 20 Shanghai tertiary hospitals ^a	RMB 520,000 to 780,000 Or USD 74,927 to 112,391	RMB 1,000,000 to 1,200,000 Or USD 144,092 to 172,911	RMB 650,000 to 750,000 Or USD 93,660 to 108,069	RMB 610,000 to 850,000 Or USD 87,896 to 122,478

^aUsing the exchange rate in March 2016 as RMB yuan: US dollar = 6.94: 1.

after surgery and underwent a standardized follow-up. Visual acuity before and 3 months after surgery were recorded. The intraoperative and postoperative complications that occurred were all recorded.

Costs Related to the Phacoemulsification Surgery

The average cost related to the phacoemulsification surgery of the aforementioned patients were derived from the medical and financial records. The time required for the phacoemulsification surgery was calculated. The calculated costs included three parts: staff costs, consumable costs, and operating room costs. The staff costs were calculated based on the average length of the phacoemulsification procedure and the cost per hour for the doctors and nurses. These were provided by the human resources department of the hospital. The cost of the consumables, including surgical kits, perfusion fluid, and so on, were provided by the supplies purchasing department. The costs of the operating room were provided by the general logistics department.

For Chinese hospitals, all four types of phacoemulsification systems are imported from abroad, and the original purchase costs are far more expensive than the costs of the consumables. In China, medical system purchases are made individually by the hospitals, either through agents or directly from the manufacturer, so the costs of the systems differ significantly between hospitals, even for the same systems, as shown in [Table 2](#). Therefore, the purchase costs of the systems from the authors' hospital were not included in this study because they did not represent the purchase costs in other hospitals.

Statistics

Descriptive data are shown as absolute values and frequencies (in percentages) for categorical data and as the means and standard deviations for continuous variables. One-way analysis of variance (ANOVA) was used to check the statistical significance of the differences between variables. A two-tailed p value of $< .05$ was considered to be significant for all analyses, which were carried out using the SPSS version 10.0 Statistical package (Chicago, IL).

RESULTS

Surgeon's Opinions/Expert Opinion

Among the eighteen tertiary hospitals, the different phacoemulsification systems used at the time of the HTA were the Infiniti Vision system in seven hospitals (38.89 percent), Centurion Vision system in five hospitals (27.78 percent), WhiteStar Signature system in four hospitals (22.22 percent), and Stellaris Vision Enhancement system in two hospitals (11.12 percent).

The Centurion Vision system is the newest system, and in the five hospitals using the system, the surgeons had used the system for approximately 1 year and in more than 500 pha-

coemulsification surgeries. The majority (83.3 percent) of the surgeons who filled out the self-administered questionnaire recommended their recently used systems, and only three doctors did not recommend their system: with one surgeon not recommending either of the Infiniti, Signature, and Stellaris systems. Most of the surgeons had reviewed the literature or had received recommendations about the system before it was purchased. Only four doctors knew about disadvantage associated with the systems, all of which were for the Centurion Vision system, and the adverse effect mentioned was the high cost of the consumables.

All of the surgeons confirmed that the system would help cataract patients recover their vision. Most agreed that the system would provide the staff with more information about the phacoemulsification system. Fifteen of the surgeons considered that the system only affected the service function of the Department of Ophthalmology, while three surgeons considered that the system affected the service of the logistic support department in their hospital. Two-thirds of the surgeons reported that the cost per patient was lower compared with their previously used system because there were fewer surgical complications when using the new system even though the cost of consumables was higher. Two-thirds of the surgeons also considered that the costs for the hospital were decreased because the time required for the surgery is much shorter with the new system, and, therefore, the costs associated with the staff and operating room are saved. Most of the surgeons agreed that the costs only affected the Department of Ophthalmology and did not affect other departments in the hospital.

In summary, all the four phacoemulsification systems were recommended by most of the experts, because they considered that comparing to their previously used system, each of the recently used systems facilitates better vision recovery, and less costs of the patient and the hospital. In summary, these systems were considered to be effective and informative and did not interfere with other departments of the hospital. Most of the surgeons considered that the phacoemulsification surgery conducted using these systems was much safer than their previously used system and indicated that the technique saved more money for the patient

Clinical Outcomes and Safety of the Phacoemulsification Surgery

A total of 150 cataract patients were enrolled in the present study, each of whom underwent phacoemulsification surgery combined with intraocular lens implantation in one eye. The Infiniti system was used on thirty-five eyes (23.33 percent), the Centurion system on sixty-one eyes (40.67 percent), the Signature system on twenty-five eyes (16.67 percent), and the Stellaris system was used on twenty-nine eyes (19.33 percent). The demographics and preoperative characteristics were similar in the four groups ([Table 3](#)). The surgical parameters are shown in [Table 3](#). A significant difference was found among

Table 3. Baseline Characteristics, Surgery Parameters, and Postoperative Complications of the Patients

	Infiniti (<i>n</i> = 35)	Centurion (<i>n</i> = 61)	Signature (<i>n</i> = 25)	Stellaris (<i>n</i> = 29)	F-Value ^a	<i>p</i> -Value
Male gender (%)	15 (42.9)	26 (42.6)	11 (44.0)	12 (41.4)	0.04	0.98
Mean age, years (SD)	71.54(10.8)	67.79(11.8)	72.04(8.3)	67.83(11.9)	1.54	0.21
Left eye (%)	15 (42.9)	30 (49.2)	10 (40.0)	12 (41.4)	0.29	0.83
Preoperative LogMAR visual acuity	0.95 (0.41)	1.07 (0.55)	1.00 (0.46)	1.00 (0.48)	0.44	0.72
Cumulative dissipated energy, percent-seconds	9.94 (3.1)	7.20 (2.4)	11.12(2.5)	10.74 (3.3)	18.05	<0.01
Total length of surgery, minutes, (SD)	8.79 (2.4)	8.50 (1.7)	9.22 (3.1)	9.82 (2.6)	2.29	0.08
Postoperative LogMAR visual acuity	0.45 (0.19)	0.43 (0.15)	0.45 (0.15)	0.43 (0.11)	0.17	0.92
Postoperative complications at the end of one month						
Corneal edema (%)	3(8.6)	2(3.3)	2 (8.0)	3(10.3)	0.67	0.57
Hypertension (%)	4(11.4)	4(6.6)	3 (12.0)	3(10.3)	0.32	0.81

^aOne-way ANOVA.

the four groups in the cumulative dissipated energy, with the lowest value found in the Centurion group, followed by the Infiniti group. However, no significant differences were found in the duration of the surgery.

The postoperative clinical and safety findings were the following: (i) a positive trend in visual acuity was found in all four groups after cataract surgery at the end of the follow-up. Comparing with preoperative visual acuity, the postoperative visual acuity increased significantly in the Infiniti system group (paired *t* sample test; *t* = 7.59; *p* < .01), the Centurion system group (paired *t* sample test; *t* = 8.92; *p* < .01), the Signature system group (paired *t* sample test; *t* = 5.50; *p* < .01), and the Stellaris system group (paired *t* sample test; *t* = 4.61; *p* < .01). We found similar final visual acuity results in the four groups after surgery. (ii) No serious ocular adverse events or device deficiencies occurred during the surgeries. Temporary postsurgical complications, such as corneal edema and hypertension, were rare in all four groups. At the end of the 1-month follow-up, corneal edema and hypertension were found in a few patients. Although no significant difference was found among the groups in the co-occurrence rate of these two complications, the patients in the Centurion group had the fewest complications. No persistent complications were found at the end of the 3-month follow-up.

In summary, the Centurion system may provide best surgical efficacy and least surgical complications, and the vision recovery outcomes were all satisfactory in the four phacoemulsification system groups.

Costs Related to the Phacoemulsification Surgery

As shown in Table 4, the cost of surgery was similar between the Infiniti Vision and WhiteStar Signature systems. The significant difference was in cost of surgery using the Centurion system compared with the other systems. The active-fluidics configuration used by the Centurion system included the

0.9-mm 45-degree aspiration bypass system Intrepid Balanced tip and the 0.9-mm Intrepid Ultra infusion sleeve. This configuration is far more expensive than the gravity-fluidics configuration used in the Infiniti Vision system, the tubing packs used in the WhiteStar Signature system, and the Venturi packs used in the Stellaris Vision Enhancement system. The Centurion group had the lowest staff and operating room costs, mainly because the length of the surgery was the shortest in this group. The highest total cost of surgery was for the Centurion Vision system, followed by the Stellaris Vision Enhancement system.

DISCUSSION

It is widely believed that HTA can improve the quality of health care and ensure a high value for monetary investments in medical settings, especially in “resource-poor” or limited budget settings (1;2). However, the HTA method has seldom been implemented in developing countries, such as China as some aspects of the HTA cannot be used in developing countries. In certain circumstances an adapted HTA method should be used to meet the specific needs (12). After searching PubMed and the Chinese Wanfang literature database, we identified a few HTA studies that were previously performed in the field of ophthalmology (13), but we believe that our study is the first to report using the HTA method for health technology assessment in Chinese hospitals. The present results can be used as a recommendation for purchasing phacoemulsification systems in China, and the procedures used in the study can help in other medical settings in developing countries so that they can apply HTA methods when deciding on their investment (14).

In the present study, we modified the original 13-item mini-HTA form to a self-administered 15-item questionnaire, where thirteen of the questions could be answered simply with a “yes” or “no,” to improve the response rate. Chief cataract surgeons who had sufficient experience conducting surgeries with the systems were chosen to fill out the form because their

Table 4. Comparison of the Costs (RMB Yuan or US dollar,^a Average \pm SD) to Use the Four Phacoemulsification Systems

	Infiniti	Centurion	Signature	Stellaris	F-Value ^a	p-Value
Staff	RMB	RMB	RMB	RMB	3.94	0.01
	485.71	469.51	496.40	504.14		
	(53.36)	(44.36)	(53.30)	(50.89)		
	or USD	or USD	or USD	or USD		
Consumables	69.99	67.65	71.53	72.64	378.26	<0.01
	(7.69)	(6.39)	(7.68)	(7.33)		
	RMB	RMB	RMB	RMB		
	591.14	1051.33	563.04	655.45		
Operating room	(58.22)	(86.64)	(80.70)	(89.75)	1.09	0.36
	or USD	or USD	or USD	or USD		
	85.18	151.49	81.13	94.44		
	(8.39)	(12.48)	(11.63)	(12.93)		
Total	RMB	RMB	RMB	RMB	192.38	<0.01
	152.94	146.93	155.08	157.72		
	(31.18)	(28.87)	(30.27)	(26.11)		
	or USD	or USD	or USD	or USD		
	22.04	21.17	22.34	22.73		
	(4.49)	(4.16)	(4.36)	(3.76)		
	RMB	RMB	RMB	RMB		
	1229.80	1667.89	1214.52	1317.31		
	(82.19)	(118.07)	(98.00)	(106.26)		
	or USD	or USD	or USD	or USD		
	177.20	240.33	175.00	189.81		
	(11.84)	(17.01)	(14.12)	(15.31)		

^aUsing the exchange rate in March 2016 as RMB yuan: US dollar = 6.94: 1.

suggestions are the major determinants of system investments used by the hospital executives in Shanghai. The surgeons can provide references, check legal aspects, and evaluate the safety of the system. They can also assess whether there are additional costs or savings associated with the technology with respect to the previous system used and whether it can be used for the same indications.

As mentioned by Ehlers, the disadvantages of the mini-HTA are typically centered on an insufficient evaluation of the evidence base and a lack of quality control, too much emphasis on financial factors, and difficulty answering financial questions for some hospital staff (7). Apart from these disadvantages, the surgeon's opinions/expert opinions cannot provide a direct comparison among different types of systems. Therefore, in the present study, we specifically compared the surgical outcomes and the cost of the surgery among the four systems used in the authors' hospitals. According to the self-administered questionnaire, most of the chief cataract surgeons highly praised their recently used phacoemulsification systems. The decisions made in many medical settings can easily be influenced by past experience without an evidence base

and by lobbying pressure for new technologies, mainly from commercial organizations, so that medical resources may be disproportionately wasted. However, in the present study, we consider that the recommendations from the surgeons accurately reflected the local values and provided evidence-based local information on the clinical- and cost-effectiveness of the systems.

Scientists and engineers continue to make advances in phacoemulsification systems, including ultrasound tips, sleeves, and fluidics, to improve the surgical efficiency and patient outcomes. Compared with the gravity-fluidics or other configurations used in the other three recently used systems, the active-fluidics configuration used in the Centurion Vision system was proven to have less cumulative energy dissipation, less aspiration fluid used, and a shorter aspiration time (14). In the present study, we also found that the Centurion Vision system had the highest surgical efficiency, the shortest surgery time and the lowest rate of postoperative complications. However, newly developed therapeutic technology is always much more expensive than the existing technology. The high cost of consumables used with the Centurion Vision system should not

be neglected when hospital management decides to invest in a new phacoemulsification system. However, it is also possible that more widespread use of the Centurion Vision system in the future may lead to a decrease in the cost of consumables.

The inherent limitations of the present study should be mentioned. First, this study was a small-sized mini-HTA study performed in an ophthalmic care center. The self-administered questionnaire was modified from previously published mini-HTA form. Because we enrolled a consecutive series of patients with senile cataracts, the limitation in the design of our study is obvious wherein the patients were not randomly selected from all types of cataract, thus limiting the power of the study. Second, the experiences of the chief cataract surgeons differed from each other, which may have led to bias in the evaluation of the different systems. However, because the surgeons had all conducted more than 500 surgeries using the systems, we consider that the learning curve for the surgeons should not have influenced the interpretation of the final data. Third, the results of the present study are only applicable to tertiary centers because the volume of surgery performed and the ability to resolve the more difficult cases are critical to the cost-effectiveness analysis and may not apply to other institutions. For example, in a community-based hospital, it is crucial make an investment for the future in terms of the human resources to be trained and to keep the incidence of complications low. The sustainable costs and clinical efficacy should be balanced with equal access to expensive technologies, especially in these hospitals (15).

In conclusion, each of the recently used phacoemulsification systems can offer satisfactory vision recovery outcomes. The clinical data showed that the Centurion Vision system offers the highest surgical efficacy with less active surgical instrumentation time, as measured by the cumulative dissipated energy. However, the total cost of surgery performed using the Centurion Vision system was the highest. We believe that it is mandatory to provide hospital management with more precise data on the financial considerations, effectiveness, and influence on the hospital and patients to allow them to better decide whether to invest in a new phacoemulsification system. Introduction of the HTA model into the decision-making process of hospitals in developing countries is recommended.

CONFLICTS OF INTEREST

The authors have nothing to declare.

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