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CLINICAL STUDY

Modelling lifetime cost consequences of ReSTOR® for presbyopia in four European countries

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Abstract

Aims **To compare the lifetime cost consequences, in France, Italy, Germany and Spain, of liberating presbyopic patients from spectacles by implanting the multifocal intraocular lens ReSTOR®.**

Methods **A Markov model was created to compare a patient cohort implanted with ReSTOR at age 45 years, with a cohort using spectacles, until death or age 100 years. Prevalence rates of patients not requiring spectacles after surgery were obtained from clinical trials. Resource utilisation included implant surgery, spectacles, visits to ophthalmologists and optic centres, transport and time lost by patients. Economic perspectives were those of society and sickness funds. Mortality rates were introduced into the model. Cataract surgery was allowed just for the spectacles-only cohort.**

Results **Rate of spectacle independence was fixed at 80% for ReSTOR. When time spent to care for refraction was not taken into account, lifelong ReSTOR cost was higher than spectacles in all countries (€293; €1013), according to the societal perspective. When time was included, cost saving was observed in Italy (−€136) and the incremental cost to be free of spectacles comprised between €11 and €816. According to the NHS perspective, ReSTOR is a cost saving strategy (−€274; −€605).**

Conclusions **At a 3% discount rate, savings achieved by liberating patients from spectacles counterbalanced partially the initially higher cost of ReSTOR according to the society perspective. ReSTOR could be considered as cost-effective in the four countries provided that the willingness to pay of patients to be free of spectacles would be lower than €23.65/year.**

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Keywords: presbyopia; spectacle freedom; cost minimisation; multifocal intraocular lens

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Introduction

Almost everyone experiences some degree of presbyopia after reaching middle age.[1] Most people begin to notice a visual deficit during their early to middle forties, but symptoms can become apparent during the late thirties. In fact, compared with the accommodation of a young person (ie, 20 D, focusing at 5.0 cm), accommodation has decreased by 25 years (10 D) and continues to decline until about 60 years, when it reaches a plateau (0.5–1.0 D, focusing at 1–2 m).

Reading spectacles and contact lenses are the usual means to correct presbyopia. However, it has now become possible to correct presbyopia with a wider range of procedures, depending upon a person's age, lifestyle, occupation, and the presence of other eye conditions.[2–9] If the sole problem is to focus on close objects (eg, reading) a pair of standard spectacles may be sufficient. Furthermore, difficulty with focusing on both near and distant objects may be corrected by bifocal lenses or two pairs of spectacles. An alternative treatment option is 'monovision', with one eye corrected for distant objects and the other for near objects, which may be performed by contact lenses, refractive surgery, or implanted intraocular lenses. In the latter case, the eye's crystalline lens is removed and replaced by an artificial intraocular lens (IOL). Unlike other surgical techniques that alter the shape of the cornea, an intraocular lens

corrects vision by means of its focusing power. With a monovision strategy one eye may be implanted with an IOL for distance vision and the other with an IOL for near vision, to obviate the need for spectacles.

To enable focusing at different distances and simultaneously achieve greater spectacle independence, a multifocal intraocular lens (MFIOL) implant provides two primary focal points. This can be a solution for presbyopic patients who also require distance correction. Multifocal IOLs are currently used in just this way for cataract surgery patients where they offer an alternative to spectacles for older patients requiring distance vision and presbyopia correction. According to a multinational clinical trial, 41% of subjects ceased to wear spectacles after MFIOL implants.[10] Indeed, it is now possible to implant MFIOLs into both eyes so as to preserve binocular vision, while correcting presbyopia. Thus Pineda-Fernández *et al*. implanted, bilateral, AMO ARRAY Multifocal IOLs into 35 patients and 3 months later found that 31% no longer wore spectacles.[11] However, the disadvantage of MFIOLs is a loss of accommodation, but this may not be important to presbyopic patients, and wearers of reading or bifocal spectacles, as their range of accommodation is already very limited before surgery.

The most recent, and most complex, innovation in lens implant technology is the AcrySof RESTOR® Apodized Diffractive Intraocular Lens.[12,13] Its apodized diffractive optic serves to distribute light between near and distant vision, thereby accommodating vision over a range of distances.[14]

Results with the AcrySof ReSTOR in a clinical study were better than those of all previously published multifocal implant trials, achieving spectacle independence for distance and near vision in 88.0 and 84.6% of subjects, respectively.

The aim of this economic analysis was to model the lifetime costs and consequences of wearing spectacles *vs* implantation of ReSTOR (a multifocal IOL) with reference to other MFIOLs, in the treatment of presbyopia.

Materials and methods

This economic study used a Markov model to estimate the lifetime cost consequences for society and sick funds in four European countries (France, Germany, Italy and Spain) after bilateral lens replacement with ReSTOR implants, as compared with traditional spectacles. TreeAge software version 4.0 was used to build a Markov model simulating cohorts of patients with lenses replaced by bilateral ReSTOR implants at age 45 years and followed up until death or age 100 years. Immediately after surgery, operated patients progressed to one of two possible visual states: spectacles not needed, or spectacles needed and purchased. The frequency of spectacles not needed was derived from controlled clinical trials of ReSTOR. During all subsequent Markov cycles patients progressed to one of three possible states: spectacles not needed, spectacles needed and purchased, or dead (Figure 1). The duration of a cycle was 1 month and patients were eliminated at death or when they reached 100 years. National mortality statistics were used for life expectancy.[15–18] In the 'spectacle control group' (not operated) patients wore spectacles and replaced them at the same frequency, every 3 years, as patients requiring spectacles after surgery. However, they could also experience cataract and be operated upon for that purpose. Patients with ReSTOR did not suffer from cataract.

The base–case analysis compared two groups of patients, that is, patients implanted bilaterally with ReSTOR *vs* patients using spectacles, only, followed by possible cataract surgery from age 70 years with a cataract rate similar to that of the national population.

A three-way sensitivity analysis was performed on the primary sensitive parameters, that is, discount rates (0, 3 and 5%), multifocal IOL premiums (€0, €250 and €500), and prevalence rates of spectacle independence (20, 40, 60 and 80%), to estimate possible cost consequences of other MFIOLs.

Efficacy and resource utilisation

In a clinical study ReSTOR achieved higher rates of spectacle independence for both distance (88.0%) and near vision (84.6%) than those reported for previous multifocal intraocular implants. ReSTOR also provided qualitatively better visual acuity with tolerable unwanted photic phenomena[13,19] from both a clinical and a patient perspective. Consequently, in the base–case analysis, the overall rate of spectacle independence was fixed at 80% for ReSTOR hence 20% of the patients will require spectacles.

A survey was carried out across four countries to estimate the costs of wearing spectacles after surgery. The patient sample[20] was recruited by ophthalmologists given a questionnaire to answer. Resources consumed and costs associated with surgery were itemised as follows: (1) surgical procedure (both eyes); (2) two intraocular implants (ReSTOR); (3) time spent on surgery (including transport); and (4) other transport to the clinic. Resources consumed by patients needing spectacles were itemised, as follows: (1) ophthalmologist or optometrist consultations for prescriptions; (2) transport and time related to the visit; (3) visits to optical centres; (4) time spent in choosing and collecting spectacles; and (5)

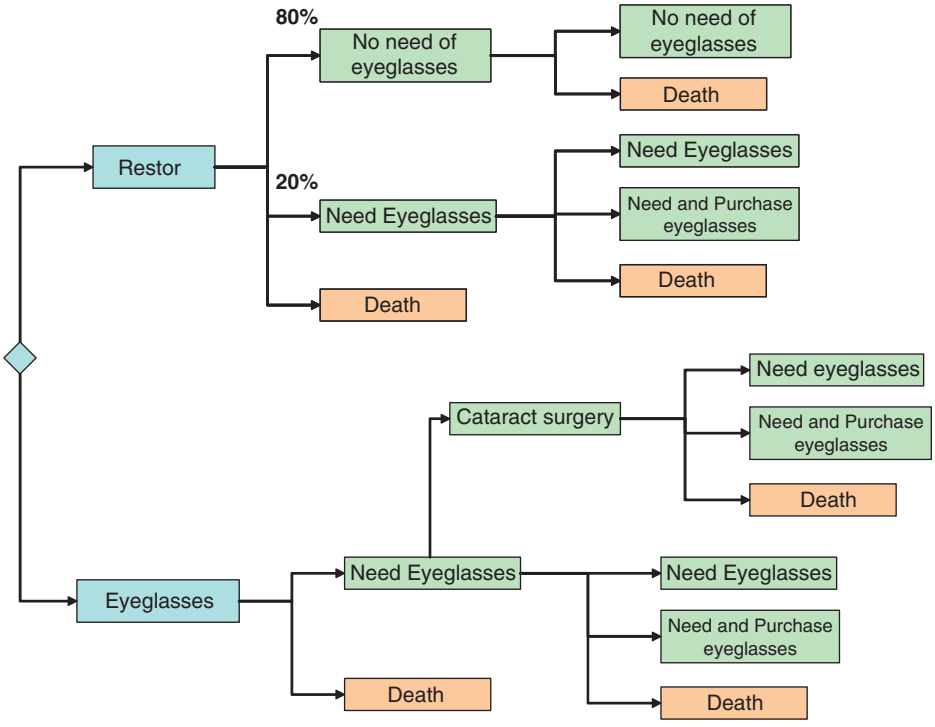

Figure 1 Model schema.

transport to an optical centre. An annual rate for spectacle replacement was also estimated.

For control patients whose only intervention was spectacles, the probability of cataract surgery was estimated from national statistics.

In addition to costs incorporated in the model, the following resources were consumed periodically by patients wearing spectacles: (1) visits to an optical centre for frame maintenance; (2) time spent on the visit; (3) cleaning devices purchased; and (4) transport to an optical centre.

Costing

Results are expressed in 2006 euros. A discount rate of 3% was fixed for the base–case analysis. The following national tariffs and available sources were used to estimate the unit costs of medical resources consumed (Table 1):

(a) According to a European survey[20] most people spent from €200 to €400 for a pair of spectacles, except in France where the majority paid more than €500. Spectacle costs were not reimbursed except in France.[35] French national health service (NHS) tariffs varied according to age (above or below 18 years) and the degree of optical correction. For persons above 18 years, reimbursement was 65% for lenses and 65% for frames.

(b) The average cost of cataract surgery varied from €1050 in Spain to €1250 in Germany, including the cost of a monofocal intraocular implant.[21,25,26,36]

(c) From the societal perspective an arbitrary €500 was added to the cost of cataract surgery with ReSTOR as a premium for the MFIOL.

(d) Ophthalmologists' consultation fees varied from €25 in France to €100 in Italy, with optometrists' costs influenced by official regulations, that is, in Italy and Germany optometry is not a recognised profession and many optometrists do not charge for a visit, whereas in Spain optometrists' costs are regulated at €40 without NHS reimbursements.[22–24,25,27]

(e) Spectacle cleaning materials costs varied widely, according to package size, brand and type of accessories (sprays, cloths) and supplier; hence an approximate average cost of €3 was applied to the present analysis.

(f) As costs per kilometre and type of transportation differed between countries (taxis from €0.9 in France to €1.80 in Spain, with subway and bus costs similar at about €0.20–€0.30, depending on the ticket and distance covered) different internet sources [28,29,30,37] were solicited to obtain an approximated average cost of €0.40 per kilometre weighted by the

Table 1 Unit costs by country and type of resource consumed (2006 €)

Item	France		*Germany*		*Italy*		*Spain*	
	SOCIETY	*NHS*	*SOCIETY*	*NHS*	*SOCIETY*	*NHS*	*SOCIETY*	*NHS*
Cataract surgery								
• Surgery[21–24]	1145.9	1145.9	1250	1250	1106	1106	1050	1050
• ReSTOR premium[a]	500	0	500	0	500	0	500	0
• Monofocal IOLs for cataract	In DRG	In DRG	In DRG	In DRG	In DRG	In DRG	In DRG	In DRG
• Other multifocal IOLs[b]	[0–500]	0	[0–500]	0	[0–500]	0	[0–500]	0
Spectacles[25,26]	578.9	19.71	387.6	0	310.5	0	230.2	0
Cost of cleaning	3		3		3		3	
Visit[25,27–29]								
• Ophthalmologist	25	16.50	57.78	23.75	100	12.91	60	60
• Optometrist	—	—	0	0	0	0	40	0
Mean cost per km[30–33]								
• Visit/implant	0.39	—	0.27	—	0.31	—	0.46	—
• Optical centre	0.31	—	0.23	—	0.31	—	0.45	—
Cost of work/hour[34]	24.7	—	26.22	—	21.39	—	14.75	—

NHS = National Health Service.
[a]Fixed arbitrarily at €500.
[b]Analysed by sensitivity analysis

Table 2 Average resources consumed in the Markov model period (from age 45 years) with either a ReSTOR or spectacle strategy, by country

Item	*France*		*Germany*		*Italy*		*Spain*	
	ReSTOR	*Spectacles*	*ReSTOR*	*Spectacles*	*ReSTOR*	*Spectacles*	*ReSTOR*	*Spectacles*
Number of spectacles	2.96	14.91	3.07	15.44	3.49	17.56	3.37	16.93
Number of units purchased to clean spectacles	13.07	67.50	6.55	33.92	11.21	58.23	6.21	32.24
Visit to ophthalmologist to correct visual acuity	3	15	2.73	13.75	2.90	14.58	2.19	11.01
Visit to optometrist to correct visual acuity	—	—	—	—	0.59	2.98	1.2	5.9
Transportation ophthalmologist (km)	289	867	176	646	408	1548	393	1542
Transportation optical centre (km)	309	1586	153	791	289	1504	220	1144
Time spent to care for visual acuity (h)	62.4	121.0	58.7	98.7	64.3	127.5	54.8	81.6
Cumulative cataract surgery rate (of surviving patients)	0%	56%	0%	38%	0%	37%	0%	52%

Base–case scenario: cost of ReSTOR = €500; discount rate = 3%; patients freed from spectacles = 80% after ReSTOR.

proportion of subjects using the various types of transportation.[20]

(g) Time spent was valued economically using estimated hourly earnings published by the European Union Statistical Office.[31]

Results

According to the Markov model and national mortality statistics, the average additional life expectancy of patients aged 45 years in the four European countries ranged from 34.5 to 37.0 years, reflecting differences in general life expectancy from 78.4 years in Germany to 80.5 years in Spain.[32] The average estimated duration of spectacle wear by unoperated patients was similar to their life expectancy and was more than five times that of patients implanted with ReSTOR (6.9–7.4 years, depending on the country).

Table 2 shows the average resources consumed per patient according to treatment strategy and country. Consistent with the average duration of spectacle dependence, patients with spectacle correction only consumed five times more spectacles, visits to ophthalmologists, transportation and cleaning devices, and devoted about 60 more hours dealing with their visual acuity than patients with ReSTOR implants.

Table 3 Cost consequences (€) with either a ReSTOR or spectacle strategy per country from the societal perspective

Item	*France*		*Germany*		*Italy*		*Spain*	
	ReSTOR	*Spectacles*	*ReSTOR*	*Spectacles*	*ReSTOR*	*Spectacles*	*ReSTOR*	*Spectacles*
Surgery including the MFIOL	3292	0	3500	0	3212	0	3100	0
Spectacles	489	2462	415	2088	377	1898	408	2053
Spectacle cleaning	23	119	12	54	20	104	11	58
Visit to correct visual acuity	45	225	97	490	175	880	108	544
Transportation	142	495	55	218	142	566	184	736
Cost of cataract surgery	0	277	0	216	0	185	0	254
Total without time spent	**3991**	**3578**	**4079**	**3066**	**3925**	**3632**	**3811**	**3645**
Time spent	1325	1727	1356	1545	1174	1603	726	697
Total including time spent	**5316**	**5305**	**5436**	**4611**	**5099**	**5235**	**4537**	**4342**
Difference	+11	Ref	+816	Ref	−136	Ref	+195	Ref

Base–case scenario: cost of ReSTOR = €500; discount rate = 3%; patients freed from spectacles = 80% after ReSTOR.

Table 4 Lifetime cost consequences (€) with either a ReSTOR or spectacle strategy per country from NHS perspectives

Item	*France*		*Germany*		*Italy*		*Spain*	
	ReSTOR	*Spectacles*	*ReSTOR*	*Spectacles*	*ReSTOR*	*Spectacles*	*ReSTOR*	*Spectacles*
Surgery including IOL	0	0	0	0	0	0	0	0
Spectacles	35.2	177.10	0	0	0	0	0	0
Visit to correct visual acuity	29.4	148.20	40	202	22.6	113.6	88	443.5
Cataract surgery	0	271.5	0	215.3	0	182.5	0	249.3
Total	**65**	**597**	**40**	**417**	**23**	**296**	**88**	**693**
Difference	−532	Ref	−377	Ref	−274	Ref	−605	Ref

NHS = National health service.
Base–case scenario: cost of ReSTOR = €500; discount rate = 3%; patients free from spectacles = 80% after RESTOR.

Table 3 compares the estimated societal costs of a non-implanted presbyopic patient with the costs of a ReSTOR patient according to our base–case scenario. In almost all countries, the incremental cost of ReSTOR was higher than the savings achieved with spectacle independence, mainly due to discounting. Even though the major saving was directly related to spectacle costs, other costs borne by patients (such as transportation and time spent) remained significant.

Table 4 compares the estimated NHS costs of a patient with spectacles to those of a patient with ReSTOR, according to our base–case scenario. When the table is contrasted to Table 3 it would seem that the NHS funds are not major stakeholders, as their costs represented approximately 10% of the costs borne by society for patients with spectacles, alone, and only 1% for patients with ReSTOR. Nonetheless, savings were realised by the sickness funds of all countries even when they did not reimburse the cost of spectacles.

Tables 5 and 6 summarise three-way sensitivity analyses from the economic perspectives of society and sickness funds, respectively, with the base–case scenario highlighted. From a societal perspective (Table 5) MFIOLs without discounting were economically advantageous in all countries at spectacle independence rates of 60%, or better, irrespective of price. At a 3% discount rate MFIOLs became advantageous in France, Italy and Spain with a spectacle independence rate of 80%, or better, depending on price. In the latter countries it was generally necessary for MFIOLs to exceed a spectacle independence rate of 20% before they became less expensive than spectacles without discounting.

In Germany, when the spectacle independence rate is lower than 40%, a price premium remained even with no discounting. At a 5% discount rate, MFIOLs were always more expensive for society than spectacles except in Italy, where the spectacle independence rate was 80% with no discounting.

From the sickness fund perspective (Table 6), MFIOLS were advantageous at all spectacle independence rates, with or without discounting because the surgery and IOLs would not be covered.

Discussion

This economic analysis estimated the cost consequences until death, or age 100 years, of ReSTOR implant surgery for presbyopia in patients aged 45 years, in four European countries (France, Germany, Italy, and Spain). The economic perspectives were those of societies and

Table 5 Cost differences between spectacles and non-cataract multifocal IOLs (€), including time spent, by spectacle independence rates, discount rates and MFIOL prices (societal perspective)

Spectacle independence rates (down) and IOL Cost →		*Discount rate = 0%*			*Discount rate = 3%*			*Discount rate = 5%*		
		€0	*€250*	*€500*	*€0*	*€250*	*€500*	*€0*	*€250*	*€500*
France										
% spectacle independence after MFIOLs	80%	*−4172*	*−3672*	*−3172*	*−988*	*−488*	11	88	588	1088
	60%	*−2555*	*−2055*	*−1555*	*−22*	478	978	828	1328	1828
	40%	*−938*	*−438*	62	945	1445	1945	1569	2069	2569
	20%	680	1180	1680	1912	2412	2912	2310	2810	3310
Germany										
% spectacle independence after MFIOLs	80%	*−2731*	*−2231*	*−1731*	*−184*	316	816	712	1212	1712
	60%	*−1347*	*−847*	*−347*	665	1165	1665	1368	1868	2368
	40%	37	537	1037	1514	2014	2514	2024	2524	3024
	20%	1421	1921	2421	2362	2862	3362	2681	3181	3681
Italy										
% spectacle independence after MFIOLs	80%	*−4111*	*−3611*	*−3111*	*−1137*	*−637*	*−136*	*−110*	390	890
	60%	*−2478*	*−1978*	*−1478*	*−157*	343	843	640	1140	1640
	40%	*−845*	*−345*	155	822	1322	1822	1390	1890	2390
	20%	788	1288	1788	1802	2302	2802	2140	2640	3140
Spain										
% spectacle independence after MFIOLs	80%	*−3310*	*−2810*	*−2310*	*−807*	*−307*	195	57	557	1057
	60%	*−1996*	*−1496*	*−996*	*−14*	486	986	666	1166	1666
	40%	*−681*	*−181*	319	779	1279	1779	1275	1775	2275
	20%	633	1133	1633	1572	2072	2572	1885	2385	2885

Italic: Multifocal IOLs less expensive than spectacles. Shadowed: base–case scenario, that is cost of ReSTOR = €500; discount rate = 3%; patients free from spectacles = 80% after ReSTOR.

the national sickness funds. Although ReSTOR is a new technology approved for cataract patients, it could be used as an alternative to spectacles for presbyopic patients.

Apart from France, where reimbursement rates were low, spectacles were not reimbursed by national health services, whereas all countries financed almost 100% of cataract surgery and visits to ophthalmologists for vision correction.

Our study was based on national data (mortality and prevalence of cataract), clinical trials, and a dedicated survey in the four countries, above. The concomitant use of clinical trials and national survey data provided good guarantees of internal and external validity, as recommended by most health economics guidelines.[33]

The analysis from a societal perspective showed that with a time horizon of up to 55 years, a 3% discount rate and 20% of patients subsequently using spectacles, ReSTOR implantation incurred similar costs in all four countries. At a price of €500 ReSTOR yielded savings in Italy (−€136), and extra costs that were very small in France (€11) and slightly more in Spain (€195) and Germany (€816). Taking into account that the remaining life expectancy in this country was 34.5 years, the patient had to pay €23.65/year to be free of spectacles.

For Sickness Funds, ReSTOR was always the better strategy as it avoided a significant number of visits to ophthalmologists and optometrists, and eliminated cataract surgery. The fact that discount rates significantly modified our results is not surprising as they stemmed from the long-term follow-up built into our model (up to 55 years). Two variables drove the economic benefit of ReSTOR, namely time and spectacle independence.

The risks associated with cataract surgery were not taken into account by our model. First, most cataract surgery complications were associated with very low incidence rates: one inpatient death (0.002%) was reported among the 51 791 cataract operations (age <60 years) performed annually in France[36] in 2006, whereas the probability of toxic anterior segment syndrome (TASS) was about 0.07%,[34] the incidence rate of endophthalmitis incidence was about 0.18%,[38] that of choroidal macular oedema about 0.40%,[39] retinal detachment 0.93%[40] and Nd-YAG laser at 3 years after Acrysof 7.1%.[41] From a National Health System point of view France is an example that supports this discussion, that is, a TASS or endophthalmitis episode costs €4125,[42] a CME €2100,[43] a retinal detachment €3609,[36] and[22] a Nd-YAG laser €84, hence the average cost of cataract surgery complications was about 59€.

Table 6 Cost differences between spectacles and non-cataract multifocal IOLs (€) (multifocals—spectacles) according to different assumptions (Sickness Fund perspectives)

Spectacle independence rates after MFIOLs	*Discount rate*		
	0%	*3%*	*5%*
France			
80%	*−1078*	*−532*	*−362*
60%	*−970*	*−468*	*−312*
40%	*−863*	*−403*	*−263*
20%	*−756*	*−339*	*−238*
Germany			
80%	*−739*	*−377*	*−260*
60%	*−674*	*−337*	*−229*
40%	*−609*	*−297*	*−198*
20%	*−544*	*−257*	*−167*
Italy			
80%	*−560*	*−274*	*−185*
60%	*−523*	*−251*	*−167*
40%	*−485*	*−228*	*−150*
20%	*−448*	*−206*	*−133*
Spain			
80%	*−1136*	*−605*	*−432*
60%	*−991*	*−517*	*−364*
40%	*−845*	*−429*	*−296*
20%	*−700*	*−341*	*−228*

Italic: Multifocal IOLs less expensive than spectacles. Shadowed: base–case scenario, that is, cost of ReSTOR = €500; discount rate = 3%; patients free from spectacles = 80% after ReSTOR.

From the patients' point of view the issue is much more difficult as it concerns the topic of vision economic value, as it requires a debatable economic normative approach. Although there was no standard definition of vision status for adverse events following cataract surgery, the probability of 'low vision' was 1.79% after TASS,[44] 55% after endophthalmitis,[45] 22% after CME,[46] 15% after retinal detachment,[47] and 0.25% [48] after Nd-YAG laser. On assuming the hypothesis that adverse events are independent of each other, the probability of an 'altered vision' status because of cataract surgery should not exceed 0.35%. Best eye visual acuity has always been regarded as the main (single?) utility driver,[49–51] however disutility (that is, no quality of life) has never been demonstrated in cases of unilateral vision loss. The probability of bilateral vision loss would require an adverse event affecting both eyes after cataract surgery and the theoretical incidence rate of this would be 0.001%. Assuming a disutility of 0.4 for such a state, the largest value reported by Brown *et al*,[52] over a 30 year duration and a willingness to pay for one QALY of €50 000, the economic value of an adverse event after cataract surgery would be €2. If we were to add some degree of disutility for unilateral blindness the economic value might increase to about €59 per utility centile.

Also, two other matters should be taken into account. First, all costs should be discounted as in the Western countries concerned most patients undergo cataract surgery during their seventies and would necessarily experience similar unwanted events a little later. Therefore, clear lens extraction could be regarded as a predictable expense of cataract surgery. Thus, at a discount rate of 5% over 30 years, all the reported costs should be divided by two. Second, calculation of the expected economic value of very rare expensive goods is associated with high uncertainty (large variance). At a population level these risks are usually mutualised. At a personal level, in-depth patient information requires a legal guarantee of informed consent that is usually confirmed by a signed contract. To conclude, the cost of adverse events following cataract surgery is a small part of the refractive cost, from an NHS point of view. From a patient's point of view the anticipated value of surgery is subject to high variability and reported patient information should follow proper informed consent.

We tried to maintain a very conservative approach. For example, in calculating the mean number of broken spectacles for each country from survey findings[20] we chose the lowest mean rate. Moreover, we assumed comparable non-financial benefits with all treatment strategies, which is not the case. ReSTOR patients value the lens and are willing to pay for the benefit of spectacle independence. Some ReSTOR patients reported broader vision (unrestricted by spectacle frames), feelings of well-being, freedom and youthfulness, and improved socialisation, and so on.[40,53]

Our analysis has the following limitations: (1) a model cannot replace longitudinal data collection, but the feasibility and economics of such an effort can be questioned; (2) we hypothesised that the prevalence rate of spectacle independence remains constant until the end of a patient's life, whereas the current known efficacy of ReSTOR implants does not exceed 3–4 years; (3) the external validity of our survey regarding spectacle costs could be debated, but our cost structure was coherent across countries;[20] (4) we valued the cost savings of avoided refraction visits after ReSTOR fully, which may be disputed as refraction could be a marginal reason for an ophthalmic visit, but visits avoided were not the main driver of ReSTOR savings; and (5) our sensitivity analysis, conducted on the three main drivers of uncertainty, showed that any IOL able to provide a spectacle independence prevalence rate >80% will, on average, always yield cost savings for sickness funds.

Our model showed that savings with ReSTOR achieved in our four European countries were mainly realised by sickness funds and not by patients. This was

explained by the fact that cost shifting occurred entirely to the benefit of national health services which only pay for cataract surgery. For their part, patients avoided the costs related to care and refraction treatment. It is worth noting that the costs met by patients exceeded those of national health services. Hence, our results support the case that patients should be allowed complete freedom to set the budget for refraction correction, according to their own economic circumstances. National health services that would deny them this right may be regarded as economically irrational and unfairly interventionist.

In conclusion, according to our data and model, ReSTOR was always a cost-saving alternative to spectacles in presbyopia when viewed from a sickness fund's perspective. According to the societal perspective, ReSTOR is a cost-effective alternative to spectacles provided that the patient willingness to pay to avoid wearing spectacles is lower than €23.65/year. The results of our sensitivity analysis could be used either to compare MFIOLs or to estimate the costs and consequences of new IOLs aimed at freeing the patient from spectacles.

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