

Spectacle independence and subjective satisfaction of ReSTOR[®] multifocal intraocular lens after cataract or presbyopia surgery in two European countries

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Purpose: To determine the percentage of patients implanted bilaterally with ReSTOR[®] requiring spectacles at 18 months, the patient satisfaction, and factors that predict spectacles independence.

Methods: The medical and surgical data were collected from patient records. The 'Freedom from Spectacles Value Scale' (FGVS) was used to rank their experiences via telephone interview. A Bayesian network was used to predict postoperative spectacles use.

Results: 304 patients (65.6 years) were included. Postoperative visual acuity was ≥ 0.8 in 93.3% of patients for near vision and in 88.6% of patients for distance vision. After surgery, 87.2% of the patients were spectacles free. 88.2% of the patients rated their vision as being better following the surgery and 93.1% thought that surgery resulted in a positive change. FGVS mean scores (5 the most favorable rating) were: 'Practical Advantages' 3.8, 'Psychological Advantages' 3.8, 'Evaluation of the Result' 4.5, 'Feelings' 4.4, and 'Global Judgement' 4.4. Patients who stated that spectacles wear was particularly bothersome and those who thought that their appearance was more favorable without spectacles were 3 times more likely not to wear spectacles postoperatively.

Conclusion: ReSTOR[®] provides patients with good distance and near vision, a high rate of spectacles independence, and a high degree of patient satisfaction.

Keywords: cataract surgery, multifocal intraocular lens, patient satisfaction, spectacles independence

Introduction

The restoration of functional distance and near vision, independent of any additional refractive correction, remains an ultimate goal for many cataract surgeons. Multifocal intraocular lenses (IOLs) use the principle of simultaneous vision to allow functional vision at all distances.¹ Clinical experience with multifocal IOLs show that they do, indeed, provide patients with the ability to see without spectacles at all distances with an acceptable level of satisfaction.²

The AcrySof[®] ReSTOR[®] multifocal intraocular lens is a foldable, single-piece, biconvex IOL made of a soft acrylic material of high refractive index. The central part of its anterior surface comprises an apodized diffractive region that distributes light to allow a full range of vision.³ The efficacy and safety of the ReSTOR[®] IOL has been reported in numerous publications⁴⁻¹⁶ and has been shown to provide a lifelong, cost-effective alternative to spectacles.^{17,18}

Health authorities now increasingly consider the impact on patient-reported outcomes (PROs) and health-related quality of life (HRQoL) issues from both a clinical

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and economic perspective.^{19–22} Indeed, the replication and validation of results achieved in clinical trials is an important public health issue when considering use of such products within the public sector. At the time of this study the ReSTOR® IOL had been available to the study surgeons for more than 2 years; several thousand IOLs had been successfully implanted and the clinical data of these patients were readily available in patient record files.

The aim of this study was three-fold: 1) to estimate the percentage of patients bilaterally implanted with the ReSTOR® IOL who remained dependent upon spectacles 18 months postoperatively; 2) to determine the degree of satisfaction patients experienced with their IOLs, and 3) To identify the psychological factors most likely to predict postoperative spectacles independence.

Patients and methods

This cross-sectional, multicenter, noncomparative study was conducted in France and Spain, between June 2007 and January 2008. All procedures conformed to the tenets of The Declaration of Helsinki and were in accordance with the European Directive 2001/20/CE. No local Ethics Committee approval was required.

Patient inclusion

Centers were selected from each country in which surgeons were experienced ReSTOR® users and had implanted numerous lenses in the preceding 18 months. All patients recruited had undergone bilateral cataract surgery and ReSTOR® implantation. At the time of the survey, SA60D3, SN60D3, and SN6AD3 were available for surgery.

Inclusion criteria specified that patients should be ≥50 years old, were treated for bilateral presbyopia or age-related cataract using phaco-emulsification and bilateral implantation of the ReSTOR® IOL resulting in postoperative emmetropia, and had at least 1 year elapse since the operation to the second eye.

Exclusion criteria included any patient implanted with the ReSTOR® IOL as part of a clinical trial, any surgical complications necessitating a refractive correction (refractive procedures during surgery were allowed), a postsurgical infection, any history of previous refractive surgery (ie, before ReSTOR® implantation), any ocular disease that might have seriously compromised visual acuity after cataract surgery, a prognosis of deteriorating visual acuity, or an inability (eg, deafness or cognitive impairment) to engage personally in a telephone interview.

Patients meeting the inclusion criteria were selected randomly from an exhaustive list of cases. Letters were sent to each patient explaining the purpose of the research and requesting their participation. Agreement was made through the signing of an informed consent form and a subsequent telephone interview. All necessary medical data were collected from the patient records.

The objective of the study was to survey a total of 300 patients (30 patients from each center – 5 centers from France and 5 from Spain). Previous studies indicate that bilateral implantation of the ReSTOR® IOL results in at least 80% of patients not needing spectacles 1 year postoperatively. Power analysis of the data indicated that a cohort of 300 patients should provide sufficient power (95% confidence interval 75% to 85%) to estimate spectacles independence, the primary endpoint of this study.

Outcome measures

Medical data comprising socio-demographic variables (age, gender, job status), clinical characteristics before surgery (general and ocular co-morbidities), eye characteristics at surgery, and visual acuity (before and after surgery) were collected retrospectively from the patient medical records. Patient satisfaction and factors contributing to postoperative spectacles independence were assessed prospectively by a direct telephone interview. This interview covered aspects relating to the patient's socio-occupational status, spectacles dependence before and after ReSTOR® IOL implantation, subjective evaluation of the quality of their postsurgical vision without spectacles, details on their private health insurance coverage, and any change in their ocular and general health since surgery that may negatively affect the patient's perspective of the performance of the lens.

Patient satisfaction was assessed using a new, specific 21-item tool ('Freedom from Spectacles Value Scale': FGVS) that was administered during the telephone interview.^{23–26} The FGVS includes 'Global Evaluation' and 'Advantages' dimensions that are self-rated from 1 ('No, not at all') to 5 ('Yes, absolutely'). The 'Global Evaluation' dimension includes three subdimensions ('Evaluation of the Result', 'Feelings' and 'Global Judgment'). The 'Advantages' dimension has two subdimensions, 'Practical Advantages' and 'Psychological Advantages', that ask questions relating to the benefits that freedom from spectacles offers. The 'Practical Advantages' subdimension covers the patient's perception of how troublesome spectacles wear is, eg, 'Do you find it is a bother to wear spectacles?' rated from 1 ('No, not at all') to 5 ('Yes, absolutely'), with 5 being the most unfavorable score.

Other practical related questions included those pertaining to condensation, heaviness, movement on nose, restrictions in vision, cleaning, loss and breakage. The 'Psychological Advantages' subdimension includes items relating to 'Self-image' and 'Other people's perceptions', eg, 'Do other people prefer your appearance without or with spectacles?' rated from 1 ('Definitely better without spectacles') to 5 ('Definitely better with spectacles').

Statistical analysis

Statistical analysis was performed using SASTM statistical software (SAS Institute; North Carolina, USA) for all patients

enrolled. Comparisons across countries were performed using a Chi-square test for categorical variables and Student t-tests for continuous variables.

A Bayesian network was constructed to predict post-operative spectacles use as specified from FGVS scores, age, sex and country. The network was constructed with Bayesialab software, release 4.6.1 (Bayesia, Mayenne, France), that uses an unsupervised learning paradigm to reveal the entire set of probabilistic relationships existing within a database.

A Bayesian network is a probabilistic graphical model that represents a set of random variables and their conditional independencies via a directed acyclic graph. Our Bayesian

Table I Socio-demographic data

Country	France	Spain	Total
N	152	152	304
Sex (% male)	36.2	32.2	34.2
Age (year),			
Mean \pm SD	64.9 \pm 7.5	66.4 \pm 8.9	65.6 \pm 8.3
Range	50.5 to 79.3	50.8 to 83.0	50.5 to 83.0
Retired patients (%)	77.0	63.2	70.1
Current job status or before retirement (%)			
Legislative, public administrative high grade profession, managers	6.6	13.2	9.9
Intellectual and scientific profession	6.6	4.6	5.6
Intermediate-grade profession	13.8	31.6	22.7
Administrative employees	31.6	4.0	17.8
Salesperson or services profession	7.9	0	3.9
Farmers, forestry and fishing profession	4.6	0.4	2.6
Artisans, craft workers	11.8	0.4	6.3
Truck drivers, building site workers	2.6	0	1.3
Non-qualified employees and workers	5.3	10.5	7.9
Professional army	1.3	0	0.7
Others jobs	7.9	34.9	21.4
Co-morbidities before surgery (%)			
Cardiovascular system	19.7	14.5	17.1
Psychiatry	0.7	2.6	1.6
Respiratory system	1.3	2.0	1.6
Skeleton and muscles	2.6	7.2	4.9
Urogenital system	0.7	3.9	2.3
Digestive system	1.3	2.0	1.6
Cancer	1.3	0.7	1.0
Immune system	2.6	9.2	5.9
ENT (ear nose throat)	0	1.3	0.7
Central nervous system	1.3	3.3	2.3
Skin and dermoskeleton	2.0	0	1.0
Metabolic disorders	17.8	4.6	11.2
Others	0.7	5.3	3.0
Health care insurance coverage (%)			
Public health insurance only	25.0	42.8	33.9
Public health insurance and private insurance	75.0	57.2	66.1

network represents the probabilistic relationships between FGVS scores and spectacles independence. Given FGVS scores, the network can be used to compute the probability of wearing spectacles.

To estimate the Bayesian network we used the Taboo Order (using 'Tabu Search')²⁷ algorithm. Taboo Order is a Bayesian network learning algorithm quantified by a 'Minimum Description Length' (MDL) score.²⁸

Results

Socio-demographics data

A total of 490 eligible patients were selected and contacted from the randomized lists provided (France: 194; Spain: 296). Replies were received from 89% of the contacted individuals in France (161 positive: 94%) and 59% in Spain (163 positive: 94%). Successful follow-on telephone interviews were conducted with 155 individuals from France and 161 from Spain. From these patients full medical record analysis was carried out on 152 patients from each country for a total of 304 patients.

The socio-demographic data are presented in Table 1. The mean age of patients was 65.6 ± 8.3 years with no significant national differences. 70.1% of these patients were retired and the majority of them (65.8%) were female. Of those patients who are employed, 40.5% classed themselves as having administrative to intermediate-grade professional jobs. The most common co-morbidities were cardiovascular diseases (17.1%) and of the cohort examined, 66.1% had private health insurance.

Visual characteristics of patients before surgery

Prior to surgery, 28% of the patients were myopic, 68% were hypermetropic and 50% were astigmatic. The proportions of astigmatic and myopic patients were significantly higher in Spain ($P < 0.05$), whereas the proportion of hypermetropic patients was significantly higher in France ($P < 0.05$). Early glaucoma affected 3% of patients, and 2% had concomitant macular or optical nerve pathology with the potential to impair vision. Finally, 5.3% of patients received medication for ocular hypertension.

Table 2 provides details of the Snellen decimal distance visual acuity. Pre-operatively 62.5% of patients had a visual acuity of 0.8 or better and there was a statistically significant ($P < 0.05$) differential between the countries, with more patients attaining this score in France (73.3%) than in Spain (52.0%).

Table 2 Snellen decimal distance visual acuity of the best eye before surgery

Variable	France (n = 146)	Spain (n = 150)	Total (n = 296)
Visual acuity (decimal)			
Mean \pm SD	0.85 ± 0.19	0.72 ± 0.25	0.78 ± 0.23
Median	0.9	0.8	0.8
Range	0.3 to 1.2	0.05 to 1.0	0.05 to 1.2
Patients \geq 0.8 (%)	73.3	52.0	62.5

Notes: Distance visual acuity was not collected in 8 (France: 6; Spain: 2) patient charts.

Surgical features

Table 3 indicated that the main motivating factor for ReSTOR® implantation was presence of cataract rather than presbyopia and this was especially true in Spain. The mean time interval between the first and second eye operations was approximately 15.7 days and the average time since the second eye operation to the time of this study was 2.0 years. The mean power of the ReSTOR® IOL implanted was $21.1 \text{ D} \pm 3.6 \text{ D}$.

Visual characteristics of patients after surgery

In both countries more than 90% of patients did not undergo further refractive surgery following ReSTOR® implantation. Postoperative refraction results are given in Table 4. For near vision the mean uncorrected best eye visual acuity (decimal) was 0.96, while for distance vision the figure was 0.90. Moreover, postoperative visual acuity was ≥ 0.8 for near vision in 93.3% of patients; for distance vision in the value was 88.6%.

Spectacles independence

Prior to surgery 93.4% of patients wore spectacles; of these 51.8% wore varifocal spectacles and 19.7% wore contact lenses. In addition, 45.1% of these patients reported replacing their spectacles every 3 years, or more, the frequency being higher in France than in Spain. Following surgery 87.2% of patients were

Table 3 Reason for surgery: cataract and/or presbyopia

Reason for surgery	France	Spain	Total
N (%)	112	152	264 (100.0)
Cataract in both eyes	73 (65.2)	144 (94.7)	217 (82.2)
Presbyopia in both eyes	37 (33.0)	6 (3.9)	43 (16.3)
Cataract in one eye and presbyopia in other eye	2 (1.8)	2 (1.3)	4 (1.5)
Not documented	40	—	40

Table 4 Best eye visual acuity after surgery

Variable	France	Spain	Total
Near uncorrected visual acuity (decimal)			
Patients (n)	145	137	282
Mean \pm SD	1.01 \pm 0.05	0.90 \pm 0.19	0.96 \pm 0.15
Median	1.0	1.0	1.0
Range	0.8 to 1.2	0.25 to 1.0	0.25 to 1.2
Patients \geq 0.8 (%)	100	86.1	93.3
Near best corrected visual acuity (decimal)			
Patients (n)	88	87	175
Mean \pm SD	1.00 \pm 0.01	0.89 \pm 0.21	0.95 \pm 0.16
Median	1.0	1.0	1.0
Range	0.9 to 1.0	0.4 to 1.0	0.4 to 1.0
Patients \geq 0.8 (%)	100	79.3	89.7
Distance uncorrected visual acuity (decimal)			
Patients (n)	146	151	297
Mean \pm SD	0.91 \pm 0.13	0.89 \pm 0.13	0.90 \pm 0.13
Median	1.0	0.9	0.9
Range	0.4 to 1.2	0.4 to 1.0	0.4 to 1.2
Patients \geq 0.8 (%)	89.7	87.4	88.6
Distance best corrected visual acuity (decimal)			
Patients (n)	99	94	193
Mean \pm SD	0.96 \pm 0.08	0.96 \pm 0.07	0.96 \pm 0.07
Median	1.0	1.0	1.0
Range	0.7 to 1.0	0.8 to 1.0	0.7 to 1.0
Patients \geq 0.8 (%)	94.9	100	97.4

spectacles free (France: 88.2%; Spain: 86.2%). Of those patients who wore spectacles postoperatively the majority did so only sometimes (61.5%) and in most cases (71.8%) for near vision.

Subjective evaluation of postoperative spectacles independence

The Bayesian network based on FGVS scores, age, sex and country is presented in Figure 1. The network depicts associations (arrows) connecting subscores of 'Global Evaluation' ratings. 'Global Judgment', 'Evaluation of the Result', and 'Feelings' subdimensions were excluded because of items confounded with 'Global Evaluation'. Figure 1 shows that 'Global Evaluation' (benefit) was associated with both practical and psychological benefits, as well as the patient's self-image without spectacles.

More importantly, the Bayesian network evinced two factors that were strong predictors of postoperative spectacles independence. These were. 1) Do you find that it is a bother to wear spectacles?; and 2) Do other people prefer to see you with or without spectacles? Reports of 'bother with

spectacles' were associated with age, 'Global Evaluation' (benefit), and self-image without spectacles.

Figure 2 indicates the proportion of patients who were bothered by various inconveniences of wearing spectacles (condensation on lenses, cleaning, heaviness, slipping down nose, restricted vision, loss, damage, and breakage). Spanish patients were more troubled than French patients by the latter four items.

Patient satisfaction

Following surgery 93.1% of patients noted a global positive change in their vision, 88.2% stated their vision had improved, and 78.0% of patients considered their sight problems to be resolved. Mean scores from the FGVS tool (scaled 1 = bad to 5 = good?) were 'Global Evaluation' = 4.5. Mean subscores were 'Evaluation of the result' = 4.5, 'Feelings' = 4.4, and 'Global Judgment' = 4.5, demonstrating high levels of satisfaction throughout the population. The 'Advantages' score was 3.8. Mean 'Advantages' subscores for spectacles freedom were 'Practical' = 3.8 and 'Psychological' = 3.8.

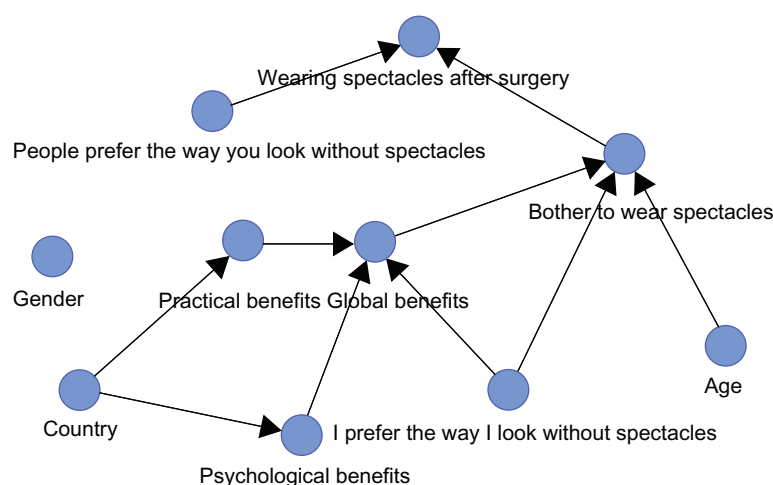


Figure 1 Bayesian network. Each node represents a variable. All continuous variables were dichotomized. Each arrow describes an association between variables. Each arrow is associated with a contingency table (available upon request). With the contingency table set, a posteriori probability could be evaluated. The a posteriori probability to wear spectacles knowing the answers to 'Bother to wear spectacles' and to 'People prefer the way you look without spectacles' are presented in Figure 3.

Further analysis of the psychological score revealed that most patients (70.4%) preferred themselves without spectacles and 50.7% reported that others, too, preferred their appearance without spectacles.

A subgroup of patients ($n = 12$) rated 'bother to wear spectacles' < 5 (they did not answer 'Yes, absolutely' to the question 'Do you find it is a bother to wear spectacles?') and rated self-appearance with spectacles either 4 or 5 (they answered 'Definitively or somewhat better without spectacles' to the question 'Do other people prefer the way you look with or without spectacles?'). Patients who showed little concern over wearing spectacles were more likely (probability: 58%) to wear them following ReSTOR implantation (Figure 3). The probability of wearing spectacles postoperatively in

the total population was 12.8%. The foregoing 12 patients comprised 3.9% of the total population examined. Had they not been offered ReSTOR® lenses the proportion of patients who ultimately wore spectacles would have been reduced, resulting in an overall spectacles freedom rate of 89.0%. Conversely, Figure 3 shows that those patients who were considerably inconvenienced by spectacles and sensitive to the preference of others to see them without spectacles were three times more likely not to wear them postoperatively (probability: 22%).

Discussion

Several clinical trials have confirmed the efficacy and safety of the AcrySof® ReSTOR® IOL.⁴⁻¹⁵ The ReSTOR® IOL has

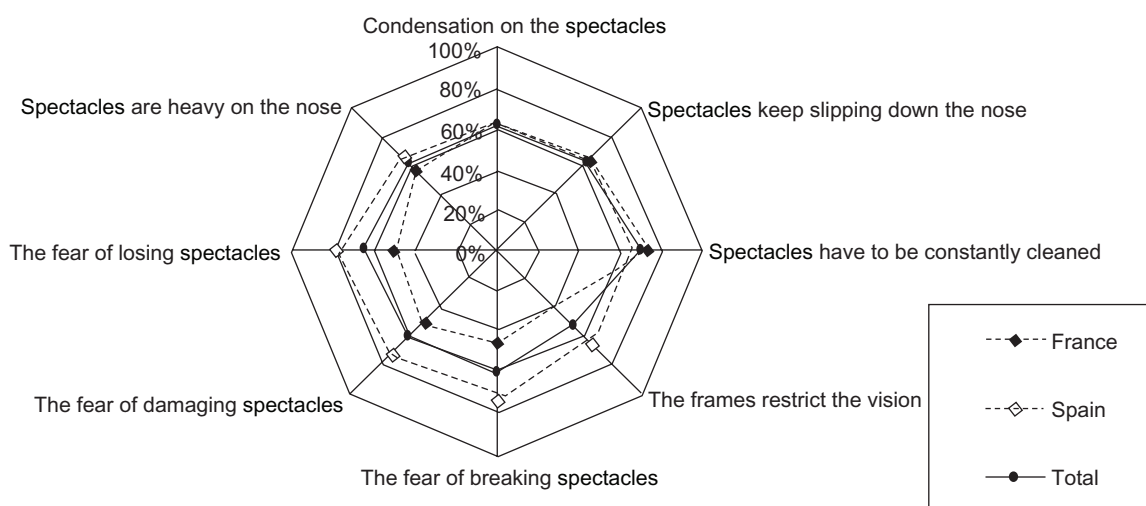


Figure 2 Disadvantages of wearing spectacles as self-rated by patients agreeing 'strongly' or 'somewhat' with the respective items.

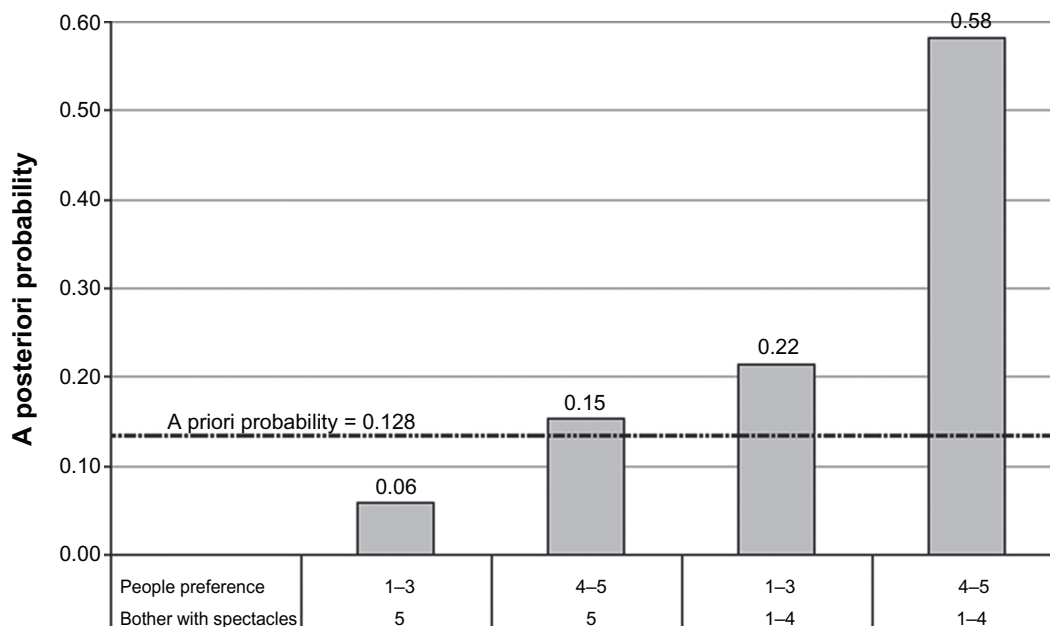


Figure 3 Probabilities of wearing spectacles according to the Bayesian network. A priori probability is presented by the dotted line and equals 12.8%. Vertical bars represent a posteriori probabilities, ie, once the answer to the question is known. The higher the distance between the dotted line and the vertical bar, the more informative the answer.

Questions:

People preference: Do other people prefer the way you look with or without spectacles? 1: Definitely better without spectacles; 2: Somewhat better without spectacles; 3: Indifferent; 4: Somewhat better with spectacles; 5: Definitely better with spectacles.

Bother with spectacles: Do you find that it is a bother to wear spectacles? 1: No, not at all; 2: Not particularly; 3: Can't say either way; 4: Yes, somewhat; 5: Yes, absolutely.

demonstrated good near vision acuity without compromising distance vision, acceptable contrast sensitivity, thus leading to spectacles independence and high patient satisfaction, in most of the patients. To our knowledge no real-life study has been conducted to assess the psychological factors that best predict spectacles independence in bilateral ReSTOR® IOL cataract or presbyopia patients.

The objective of the present study was to address this question with an appropriate study design using a large sample of more than 300 patients in France and Spain, in order to assess the effectiveness of ReSTOR® IOL implantation 2 years postoperatively. The survey confirmed that uncorrected visual acuity dramatically improved from its presurgical state. For spectacles independence, 87.2% of patients (France: 88.2%; Spain: 86.2%) never wore spectacles following implantation of the lens for either near or distance vision. Moreover, the proportion increased to almost 90% of cases when <4% of the patient cohort, who expressed no particular interest in freedom from spectacles, was excluded from the analysis. A concordant finding was high patient satisfaction, 88.2% rating their vision as being better after surgery and 93.1% affirming that surgery had changed their vision positively.

The present observational findings mirror the results obtained through previous clinical trials that address freedom from spectacles wear following ReSTOR® implantation. For

example, Chiam et al^{5,15} reported spectacles dependency in 14% to 15% of patients, while Vingolo et al²⁹ reported 8% and Sallet³⁰ found 0%. A European multicenter study⁸ of 117 patients reported that 74.4% never wore spectacles again after ReSTOR® implantation, with higher rates when distance vision (88.0%) and near vision (84.6%) were considered separately. Alfonso et al³¹ evaluated distance, intermediate, and near vision performance in 325 patients with ReSTOR® IOLs and at 6 months postoperatively found that 98% were free from spectacles for near vision and 96% for intermediate vision. Recently, De Vries et al³² reported a 3-year follow-up study of AcrySof® ReSTOR® implants in 22 cataract patients (44 eyes). Six months after surgery, 83.7% of patients regained complete spectacles independence for distance vision and 81.9% for near vision. At 3 years these proportions were 85.0% and 75.0%, respectively, and patients expressed high satisfaction.

Freedom from spectacles is a major outcome variable for ReSTOR® IOL surgery, not only for overall patient satisfaction and quality of life, but also for spectacles costs for aging people with cataracts or presbyopia. The cost to patients for a pair of spectacles in four European Countries was recently estimated by Cuq et al³³ at between €213 and €316, and from a societal perspective it varied from €214 to €566. Economic models applied to France, Germany, Italy

and Spain showed ReSTOR® IOLs as being a cost-effective alternative to spectacles.^{17,34} The models were applied to data from clinical trials in which spectacles independence rates proved to be a highly sensitive parameter. However, it was important to confirm that the observed effectiveness in clinical trials also applied to routine clinical practice.

Our study has several limitations. First, we chose the study centers and hence national inferences are questionable. This was unavoidable since at the time of the survey ReSTOR® activities were mostly conducted at a few centers. Second, some patients declined to participate in the survey. The response rate was higher in France (161/194 solicited) than Spain (163/296). Nonetheless, this rate was similar at all centers and no association was found between response rates and spectacles independence rates relative to centers. Third, freedom from spectacles was declared by the patients with no verification from other medical sources. This approach was taken because the question was simple and the answer clear to trained interviewers, who were independent of the ophthalmologists. Fourth, patients in both countries underestimated their health insurance coverage compared to the official data. National data for 2006 indicate that 88.7% of the population in France³⁵ and 70% in Spain³⁶ were covered by private health insurance. Thus it is likely that our patients were mostly retired and no longer had access to private insurance paid by employers. Moreover, less ubiquitous insurance coverage in Spain might explain why the fear of losing, damaging, or breaking spectacles was felt more strongly by Spanish than French patients. Fifth, we used a retrospective experimental design. While minimizing the observational bias consequences, the patient psychology might have been affected by the surgery and the association could have been different preoperatively. However, it has to be stated that ‘being bothered by spectacles’ and ‘social appearance without spectacles’ are personality traits that are unlikely to be modified seriously in 1 year. Prospective data collection should be collected to confirm our findings.

Conclusion

This longitudinal analysis of clinical outcomes with the ReSTOR® IOL confirms the results of other prospective clinical trials and investigations. ReSTOR® IOL implantation for the treatment of cataract or presbyopia conferred good distance and near vision, a high rate of spectacle independence, and considerable patient satisfaction. ‘Bother to wear spectacles’ and ‘self-image without spectacles’ are two factors associated with spectacles independence.

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