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II. Use of a grading system in the evaluation of complications in a randomised controlled trial on cataract surgery

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SUMMARY A randomised controlled trial in progress for more than five years assessed 333 eyes by three methods of cataract surgery. These were (A) intracapsular extraction and contact lens usage; (B) intracapsular extraction and implantation of an iris supported lens (Federov I); and (C) extracapsular extraction and implantation of an iridocapsular lens (Binkhorst 2-loop). This paper reports the use of a weighting scale for rank scoring complications which are dissimilar or are mutually exclusive (for example, capsular versus contact lens problems) to allow the use of non-parametric statistics for comparing disparate features. Thus we found that group B did significantly worse in terms of the number and severity of postoperative complications, a trend in accordance with visual results. This method may serve as a useful model for similar studies.

The surgery of cataract extraction is linked to the manner of aphakic correction. For 30 years when spectacles were the treatment of choice the aim was to remove the entire cataract within its capsule. This certainty has disappeared with the advent of modern extracapsular surgery and intraocular lens implantation.

Hitherto intraocular lens surgery could be done either with intra- or extracapsular lens extraction, the choice depending on the style of intraocular lens that one believed would give the best results. Another method of aphakic correction was by means of contact lenses which, when well tolerated, could give as good results as those produced by the use of intraocular lenses. What was in doubt was the method of cataract extraction and aphakic correction which would give the best visual results and the least complications.

To try to answer this question we started a randomised controlled trial in 1980 assigning eligible patients to one of three treatments current at that time: group (A) intracapsular extraction (IC) and contact lens; group (B) intracapsular extraction (IC) and iris-supported lens implant; and group (C) extracapsular extraction (EC) and iridocapsular lens implant.

The main aim of the study was to compare (i) visual outcome and (ii) complication rate.

When complications were being considered, comparison between groups was not possible in some instances, because some complications occurring in one group were not expected to occur in the others. Thus contact lens complications were not expected in the other two groups, nor were complications unique to implants, such as dislocation, expected in the contact lens group. Likewise capsulotomies would be expected after extracapsular but not intracapsular extractions. The fact that some of these complications differed in nature and seriousness presented the problem of making valid comparisons.

The purpose of this paper is to report the use of a

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grading system to allow widely differing events to be compared. The system has been applied to the assessment of complications occurring in the three treatment groups.

Material and methods

METHOD OF CLINICAL TRIAL

The method of the trial has been reported in detail.[1] It was fully developed in a 'manual of operations' which was approved by a peer review committee set up by the National Eye Institute.

METHOD OF DEVISING THE WEIGHTING SCALE

A list of all the complications was given to six independent observers, two of whom were ophthalmologists working in the United States. The others were from the United Kingdom and were involved with the study either as reviewers or assessors or were directly engaged in data collection.

Each was asked to grade the complications and assign a score of 1–3 according to seriousness. Grading was done by the following rules:

Grade I=Unlikely to need operation.

(Score 1) or unlikely to lead to a drop in visual acuity (VA) by two lines of Snellen chart or more.

Grade II=May need treatment.

(Score 2) or may lead to some loss of vision (by two lines or more) but not suddenly.

Grade III=Needs further treatment.

(Score 3) or needs emergency action; or leads to loss of VA by two lines or more; or leads to loss of VA by two lines or more if no emergency action is taken.

A numerical scale of 1–13 was obtained by adding the scores and subtracting 5 (Table 1). Although only three grades were used, the numerical scale gave a range of values to those events which have varying degrees of seriousness.

Results

Three hundred and thirty-three eyes in 327 patients were the subject of the trial. All eyes have been followed up for at least a year. Apart from death there was no loss to follow-up. There were 111 eyes in group A, 110 in group B, and 112 in group C. The age distribution of the patients has been reported,[1] and the mean age was 72 years.

Table 2 lists all the complications which occurred in the first year of follow-up for every patient as well as in the whole period of the study containing patients with different lengths of follow-up (one to five years). A more detailed description of the complications has been presented in a separate paper.[1] Table 3 shows the number of eyes suffering no complications and those that suffered one or more.

RESULTS OF THE SCORING BY MEANS OF THE WEIGHTING SCALE

There was surprisingly close agreement between observers in their scoring of the 39 events (Table 1). In only three instances (choroidal effusion, iris in wound, repositioning of implant) was there an overlap between the Serious (grade 3) and the Trivial (grade 1), where the scoring contained all three grades.

There was complete or 5/6 agreement in 20 events and 2/3 or better agreement in 30 events (Table 4).

Table 1 *Grading of postoperative complications and events (arranged in alphabetical order)*

Complication	*Individual scores of six graders (A-F)*						*Score on derived scale*
	A	*B*	*C*	*D*	*E*	*F*	
Blepharitis	1	1	1	1	1	1	1
Bullous keratopathy	3	3	3	3	3	3	13
Capsule opacities	2	2	3	3	3	3	11
Choroiditis	2	2	2	2	2	1	6
Choroidal effusion	2	3*	2	2	1	1	6
Conjunctival bleb	2	2	1	1	2	1	4
Corneal abrasion	1	2	1	1	1	1	2
Corneal abscess	2	3	3	2	3	3	11
Corneal oedema	3	2	2	3	3	2	10
Corneal ulcer (infected)	3	3	3	2	2	3	11
Cystoid macular oedema	2	2	3	3	3	3	11
Dislocated implant	3	3	3	3	3	3	13
Displaced pupil	2	1	1	2	2	1	4
Endophthalmitis	3	3	3	3	3	3	13
Episcleritis (prolonged)	2	2	1	1	2	2	5
Excess lens matter	2	2	2	1	1	1	4
Excess deposits on implant	2	2	2	1	1	1	4
Hyphaema	2	2	2	1	1	2	5
Hypopyon	2	3	3	3	3	3	12
Implant removal	3	3	3	3	3	3	13
Intermittent implant/ endothelial touch	3	3	3	3	3	3	13
Iris cyst	2	1	1	1	1	1	2
Iris in wound	2	1	3*	2	2	2	7
Low tension glaucoma	2	2	2	2	2	2	7
Marginal keratitis	2	1	1	1	2	1	4
Positioning of implant	2	1	2	3*	2	2	7
Pupil block glaucoma	3	3	3	3	3	2	12
Raised intraocular pressure	2	3	2	2	2	2	8
Retinal detachment	3	3	3	3	3	3	13
Shallow anterior chamber	2	2	3	2	3	3	10
Subluxed implant	2	2	2	3	2	2	8
Suture reaction	1	2	2	1	1	1	3
Suture removal	1	1	1	1	1	1	1
Tear in Descemet's membrane	2	1	2	2	2	1	5
Traumatic extrusion of implant	3	3	3	3	3	3	13
Uveitis (severe)	2	2	2	1	1	2	5
Vein occlusion	3	2	3	3	3	3	12
Vitreous opacity	2	1	1	1	1	1	2
Vitreous to section	2	2	3	2	2	2	8

The scale is derived by adding all the scores and subtracting 5.
*Denotes overlap with grade 1.

Table 2 *Postoperative complications and events*

Complications or events	*Groups*					
	A		*B*		*C*	
	1 Yr	*AGG*	*1 Yr*	*AGG*	*1 Yr*	*AGG*
Raised pressure	18	19	37	38	16	16
Cystoid macular oedema	9	10	20	24(23)	14	16
Capsule opacity					4	19
Suture removal	12(10)	15(13)	11	13	17	19
Uveitis (severe)	2	3	12	13	7(6)	7(6)
Subluxed implant			8(5)	10(5)	3	3
Shallow anterior chamber	1	1	9	9	1	1
Hypopyon	2	2	7	8(7)	2	3
Hyphaema	7	7	5	5	4(3)	6(4)
Blepharitis	2	10	1	3	1	3
Corneal abrasion	3	7(5)	0	1	0	4(3)
Corneal abscess	3	6	1	1	0	2(1)
Marginal keratitis	2	6(4)				
Bullous keratopathy			0	3	0	4
Conjunctival bleb	3	3	1	1		
Vitreous to section	3	3				
Excess remaining lens matter					3	3
Excess deposits on implant			3	3		
Dislocated implant			2	3		
Vein occlusion	1	3	0	1	1	1
Retinal detachment	1	1	0	2	2	2
Suture reaction			1	2	2	2
Pupil block glaucoma			2	2	2	2
Corneal oedema	1	1	0	0	2	0
Episcleritis prolonged	2	2	2(1)	2(1)		
Implant removal and anterior vitrectomy			2	2		
Choroidal effusion					1	1
Iris in wound	1	1				
Endophthalmitis	1	1				
Infected corneal ulcer	0	1				
Displaced pupil	1	1				
Choroiditis	1	1	1	1		
Positioning of implant			1	1		
Tear in Descement's membrane			1	1		
Intracapsular implant/ endothelial touch			1	1		
Traumatic rupture of section and implant extrusion			1	1		
Low-tension glaucoma			1	1		
Vitreous opacities					0	1
Iris cyst					1	1

AGG=Aggregate episodes for five years. Where an eye had more than one episode of a complication the number of eyes affected are shown in parentheses.
Group A=intracapsular extraction+contact lens (IC+CL).
Group B=intracapsular extraction+Fedcrov I implant (IC+Fcd).
Group C=extracapsular extraction+iridocapsular implant (EC+I-C).

Each eye in each treatment group was given a score according to the type and number of complications it suffered. This was done for the first year of each eye in the study and for the whole duration of the trial (one to five years).

Table 3 *Number of eyes suffering more than one complication at the end of one year*

	Number of events or complications per case					
Treatment group	*0*	*1*	*2*	*3*	*4*	*5*
A	56	37	12	5	0	1
B	36	33	25	11	4	1
C	53	42	10	5	1	1

Group A=IC+CL. Group B=IC+Fcd. Group C=EC+I-C.

Table 4 *Agreement between observers for the 39 events*

Level of agreement	*No. of events scored*
Complete	10
5/6	10
4/6	10
Half	6

Three events had an overlap between grades 3 and 1.

The values were ranked and tested by non-parametric statistics. The Kruskal-Wallis test showed a highly significant variation between the three groups ($p<0.0003$) at one year. The Mann-Whitney U test showed that group B (IC+implant) was significantly worse than groups A (IC) and C (EC+implant), which did not differ significantly from A.

The same tests were applied to the aggregate total, and the relationship between groups was not significantly altered.

Discussion

Although there are limitations to comparing basically dissimilar entities (like apples and pears), there is often a need to make comparisons to arrive at clinical decisions. Cataract surgery is the commonest form of intraocular operation, and it has been estimated that more than 500 000 operations are carried out annually in the United States alone.[2] The use of intraocular lenses has increased steeply in the last decade, and it is important to know whether intraocular lens surgery is acceptably safe and how it compares with current alternatives.

For individual clinicians the choice of surgery is based on experience and belief. The logical process behind decision making is still based on a system of weighing up preferences and probabilities. The proposed weighting scale attempts to make the intuitive process more quantitative and thus more accessible to informed scrutiny.

That there was almost complete agreement between experienced ophthalmologists over grading what was trivial and serious gave such a system some

Table 5 *Rank scores and comparison of treatment groups at 1 year Mann-Whitney U test*

Groups tested	*No. of cases*	*Mean rank*	*Z value (corrected for ties, 2-tailed p)*
Group A vs.	111	96·17	−3·6111
Group B	110	125·96	p<0·0003
Group B vs.	110	125·35	−3·3047
Group C	112	92·89	p<0·001
Group A vs.	111	110·57	−0·353
Group C	112	113·42	p<0·724

Group A=IC+CL. Group B=IC+Fed. Group C=EC+I-C.

validity. That there was extremely good agreement between the observers in the United States and in the United Kingdom lent even more support to the adoption of this method. In only three instances (choroidal effusion, iris in wound, and positioning of implants, each affecting one case in the entire study) did one of the observers give each of them a score of three when all the other observers gave scores of two or one. It was surprising that, when the other events or complications were considered, more overlap did not occur, as many of the events must comprise problems which could vary greatly in severity.

A greater number of grades could have been used, but that would have introduced a different form of arbitrariness. It was comparatively easy to choose between serious, trivial, and intermediate grades, but it would be more difficult to be exact about the level of intermediacy. The derived scale gives intermediate values, which reflects the equivocal attitude of the ophthalmologists to some events that did not always have a serious outcome.

When this system was applied to our three treatment groups, group B scored considerably higher than either group A or C. This confirmed the impression from the table of complications and events (Table 2) that intracapsular extraction with an iris supported lens was more prone to complications, which were additively more serious, than either intracapsular extraction with contact lens or extracapsular extraction with a lens implant. Furthermore, the outcome is in agreement with the results of assessment of visual acuity,[1] thus adding to the validity of the method, and it suggests that vision may be complication-dependent.

If we had applied this method of grading at an earlier stage, we should have obtained significant differences between groups. Such a system could have value in similar studies and will allow valid comparisons to be made even when numbers are small.

As many patients present with cataract in their sixth or seventh decade, a much longer follow-up will be needed to derive a true profile of all the problems which could arise in the three treatment groups. For example, would failure to tolerate a contact lens increase significantly with time, and would increasing numbers of eyes needing capsulotomy after extracapsular extraction lead to greater complications in group C? Our study will be able to answer some of these questions, and we believe our weighting scale will allow existing differences to be validly compared.

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