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CLINICAL STUDY

Outcomes of macular hole surgery: implications for surgical management and clinical governance

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Abstract

Purpose **The optimal method and timing of the surgical treatment for idiopathic macular holes remains unknown. The aim of this retrospective study was to identify factors associated with anatomical and visual success in macular hole surgery.**

Methods **Case records of 55 patients undergoing macular hole surgery at three units in the 2-year period up to July 2002 were reviewed to identify factors associated with anatomical and visual success. The following potential prognosticators were evaluated: patient age, hole stage, hole latency prior to surgery, preoperative acuity, simultaneous phacoemulsification, and intraocular lens implantation, internal limiting membrane peeling with and/or without indocyanine green, and postoperative posturing.**

Results **The duration of preoperative symptoms, indocyanine green-assisted internal limiting membrane peeling, hole stage, and better preoperative visual acuity were associated with both anatomical success and regaining a postoperative visual acuity of 6/12 or better.**

Discussion **The closure rate in patients undergoing surgery within 1 year of onset was 94.0%, and in those waiting 1 year or more it was 47.4%. Clinical governance and quality issues should dictate that NHS macular hole surgery is available to all within 1 year of onset. This study showed no adverse effect of ICG dye retinal staining. The results support the use of a 'patient-friendly' approach of simultaneous cataract surgery with no prone postoperative posturing.**

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Keywords: macular hole; audit; clinical governance; duration; ICG; ILM

Introduction

The aim of this retrospective study was to identify factors associated with anatomical and visual success in macular hole surgery. The optimal method and timing of the surgical treatment for idiopathic macular holes remain unknown. The traditional technique has been to perform a vitrectomy, induce a posterior vitreous detachment, instil a long-acting gas tamponade and require the patient to posture in a prone position for up to 2 weeks. More recently it has been suggested that prone posturing may not be required and shorter-acting tamponade agents have also been used.[1]

The recent increase in use of preoperative internal limiting membrane (ILM) peeling has been associated with an increased rate of success in macular hole surgery.[2] This manoeuvre is greatly facilitated by the use of indocyanine green (ICG) dye;[3] there are, however, reports of adverse functional outcome when this dye has been used.[4–10] Nuclear sclerotic cataract is a very common complication of macular hole surgery, as a consequence of which some surgeons perform simultaneous 'prophylactic' clear lens extraction with lens implantation.

In this retrospective study, we have reviewed the results of a multisurgeon series of macular hole procedures performed in a 2-year period. All of the treatment variations described above have been employed on this population. The aim was to investigate for factors and techniques associated with adverse or beneficial anatomical and visual outcome.

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Materials and methods

Case records of all patients undergoing macular hole surgery at three units in the 2-year period up to July 2002 were reviewed. The following potential factors were identified as being of interest: patient age, Gass classification hole stage,[11] latency between hole development and surgery (the time from the onset of symptoms to surgery, was estimated from the patient's history, as the time from which they had noticed a change in their vision), preoperative acuity, simultaneous cataract surgery, ILM peeling with and without ICG dye, ILM peeling with ICG, and postoperative prone posturing.

The first eye of all patients for whom complete data were available regarding potential prognosticators, surgical complications, and both anatomical and visual outcome 3 months postoperatively were included. Visual acuities (VAs) were recorded on a Snellen chart as the best spectacle VA with the patient's up-to-date habitual refraction or pinhole. When necessary for the statistical analysis, data were transformed to logMAR format.

Logistic regression was performed to identify factors associated with anatomical closure of macular holes and postoperative VA of 6/12 Snellen or better. Multiple variable logistic regression was employed to assess for confounding.

The standard surgical technique was a three-port vitrectomy using a wide-angle viewing system and a Bausch and Lomb Millenium or Alcon Accurus light source, posterior vitreous detachment was induced in stage two and three holes followed in all cases by an internal search with retinopexy to any breaks and subsequent fluid gas exchange. In variable proportions of patients, the following techniques were also performed: cataract surgery by clear corneal phacoemulsification with insertion of a foldable intraocular lens, ILM peeling with end-gripping forceps, ICG-enhanced ILM peeling with instillation onto the macula, and immediate aspiration of 0.2 mls of 0.5 mg/ml (0.05%) ICG dye with minimal contact time; use of 30% SF_6 as opposed to 16% C_3F_8 gas tamponade, and prone posturing. Patients who prone postured did so for 50 min/h day and night. Patients who did not posture were allowed to maintain a normal erect daytime posture and were asked to sleep horizontally with one or other ear on a single pillow.

Results

In all, 55 eyes of 55 patients were included: 22 were male and 33 female. The mean age was 65.6 years with a range of 30–81 years. There were 26 right eyes and 29 left eyes. The median duration of hole latency to surgery in the 52 patients for whom it had been recorded was 8 months. The shortest time to surgery was 1 month, the maximum recorded was 48 months and the interquartile range was from 4.5 to 16.5 months. In all, 31 eyes underwent simultaneous 'prophylactic' clear lens phacoemulsification with lens implantation, 18 eyes did not and six eyes were already pseudophakic at the time of surgery. C_3F_8 gas was employed in 39 eyes, in 13 eyes SF_6 was used and in three eyes the intraoperative gas type used was not recorded. Table 1 shows the rates of

Table 1 Rates of success in percentages with numbers (shown in brackets) in terms of anatomical closure and postoperative VA for seven study factors: stage, duration, preoperative VA, simultaneous phacoemulsification and lens implant, ILM peel with or without the use of ICG (ILM peel ± ICG), ILM peel with the use of ICG (ILM peel + ICG) and postoperative prone posturing

Study factor		*Number*	*Anatomical closure rate (%)*	*Postoperative VA of 6/12 Snellen or better (%)*
Stage	Stage 2	25	24 (96.0)	16 (64.0)
	Stage 3	9	2 (22.2)	1 (11.1)
	Stage 4	17	13 (76.5)	4 (23.5)
Duration	⩽6 months	21	20 (95.2)	11 (52.4)
	6–12 months	12	11 (91.7)	8 (66.7)
	>12 months	19	9 (47.4)	3 (15.8)
Preoperative VA	6/36 Snellen or better	34	31 (91.2)	21 (61.8)
	Less than 6/36 Snellen	21	12 (57.1)	3 (14.3)
Simultaneous phacoemusification and lens implant	No	18	13 (72.2)	5 (27.8)
	Yes	31	24 (77.4)	16 (51.6)
ILM peel ± ICG	No	7	4 (57.1)	0 (0.0)
	Yes	48	39 (81.2)	24 (50.0)
ILM peel + ICG	No	19	11 (57.9)	4 (21.0)
	Yes	36	32 (88.9)	20 (55.6)
Postoperative prone posturing	No	22	18 (81.8)	10 (45.4)
	Yes	33	25 (75.8)	14 (42.4)

Table 2 Logistic regression to identify factors associated with anatomical closure and a VA of 6/12 Snellen or better assessing 11 study factors: age, sex, eye, duration, stage, simultaneous phacoemulsification and lens implant, ILM peel with or without the use of ICG (ILM peel ± ICG), ILM peel with the use of ICG (ILM peel + ICG), intraoperative gas used, postoperative prone posturing, and preoperative VA

		Logistic regression to identify factors associated with anatomical closure		*Logistic regression to identify factors associated with post-operative VA of 6/12 Snellen or better*	
Study factor		Crude OR (95% CI)	*P*-value	Crude OR (95% CI)	*P*-value
Age	Per year	0.93 (0.85, 1.02)	0.14	0.96 (0.89, 1.02)	0.203
Sex	Female	1	0.60	1	0.82
	Male	1.44 (0.38, 5.52)		1.13 (0.38, 3.35)	
Eye	Left	1	0.39	1	0.465
	Right	0.57 (0.15, 2.07)		0.67 (0.23, 1.96)	
Duration	Per month	0.94 (0.89, 1.00)	0.03	0.46 (0.23, 0.91)	0.026
Stage	Stage 2	1		1	
	Stage 3	0.01 (0.0, 0.15)	0.001	0.07 (0.007, 0.66)	0.02
	Stage 4	0.13 (0.01, 1.34)	0.09	0.17 (0.04, 0.69)	0.013
Simultaneous	No	1	0.69	1	0.109
phacoemulsification	Yes	1.32 (0.35, 5.00)		2.88 (0.89, 9.67)	
ILM peel ± ICG	No	1	0.165	1	0.037
	Yes	3.25 (0.616, 17.15)		∞ (1.12, ∞)	
ILM peel + ICG	No	1	0.013	1	0.018
	Yes	5.82 (1.46, 23.17)		4.69 (1.30, 16.9)	
Intraoperative gas	C_3F_8	1	0.45	1	0.265
	SF_6	0.58 (0.14, 2.38)		0.47 (0.12, 1.78)	
Postoperative	No	1	0.60	1	0.824
prone posture	Yes	0.69 (0.18, 2.66)		0.88 (0.30, 2.62)	
Preoperative VA	Per unit increase	0.09 (0.02, 0.46)	0.004	0.006 (0.00, 0.15)	0.002

success in terms of anatomical closure and VA for the seven study factors: stage, duration, preoperative VA, simultaneous phacoemulsification and lens implant, ILM peel with or without the use of ICG, ILM peel with the use of ICG and postoperative prone posturing.

Table 2 shows the estimates of the odds ratios (OR) associated with each study factor together with 95% confidence intervals (CI). It can be seen that the duration of preoperative symptoms, hole stage, ICG-assisted ILM peeling and better preoperative VA were associated with both anatomical success and a good postoperative VA of 6/12 Snellen or better at univariate level. There is evidence also that ILM peeling with or without ICG dye use was associated with regaining this level of postoperative acuity.

Multiple variable logistic regression was used to try to identify whether the association between successful outcome and use of ICG might be due to confounding by other factors. Adjustment for preoperative VA led to a reduction in the OR estimates, but patients with ICG were still more likely to be successful than those without (OR : 3.84, 95% CI (0.85, 17.29) $P = 0.08$). Adjustment for duration had little influence on the OR estimate for ICG and stratification by hole type showed higher success rates in patients with ICG for all hole types. Adjustment for preoperative VA led to a reduction in the influence of duration. Thus, the association between duration and successful outcome may well be the case because duration is associated with reduction in VA.

There were no cases of retinal detachment, endophthalmitis, or any other sight-threatening complication in this series.

Discussion

The aim of macular hole surgery is to improve the patients' vision and prevent further visual deterioration; this is achieved by closing the hole. In most series, the outcome measures applied are closure rate and proportion of patients undergoing surgery who achieve a final corrected acuity of 20/50 or better. There is no 6/15 equivalent to the 20/50 line on a British Snellen chart. Accordingly, we have chosen a higher standard of 6/12 (20/40) or better as our index of visual outcome.

Macular hole closure rates and visual outcome have improved considerably over the last decade. It has, however, been recognised that the latency between hole onset and also the anatomical hole and stage are important prognosticators.[12,13] Reported closure rates therefore vary depending on the cases included in each series. This point is illustrated by data from a meta-analysis of factors influencing the outcome of 389

macular hole procedures reported by Kang *et al*. The authors found an anatomical closure rate for stage 2 holes of less than 4 months duration of 97.6% compared to 88.9% with holes of 4 or more months preoperative latency. The percentage of patients in Kang *et al*'s series with a postoperative VA of 6/12 or better in these two latency groups were 78.6 and 55.6%, respectively. For stage 3 and 4 holes, they reported anatomical closure rates for holes of up to 4 months preoperative latency of 82.5%, and found closure rates of 77.8 and 63.6%, respectively, for holes present for 4–6 months and 6–12 months; the percentage of patients with a postoperative VA of 6/12 or better in these three groups were 33.3, 29.6, and 18.2%.

We report a similar trend and comparable overall closure rates with better anatomical closure rates and postoperative VA in macular holes of shorter duration. Kang *et al* report that overall less than 40% of cases achieved a postoperative acuity of 6/12 or better; in our series this was 43.6%. Our closure rate was 95.2% for macular holes of less than 6 months duration, 91.7% for those from 6 to 12 months duration, and 47.4% for those greater than 1 year.

Other operative and demographic factors may also beneficially or adversely affect outcome, with areas of ongoing contention and debate including potential ICG dye toxicity, the need for postoperative prone posture and the potential value of simultaneous 'prophylactic' clear lens surgery. In order to inform our clinical practice, we have investigated the anatomical and visual outcome associated with eight such potentially important factors. The nonrandom application of these differing techniques may have introduced bias into our results. We have attempted to control for such bias(es) by performing multiple variable analysis. In such a multifactorial environment, our data present evidence suggestive of association between outcome and factor and we acknowledge that randomised trials would be required to rigorously investigate links between prognosticators and success. Age, gender, and laterality were found not to be associated with outcome and are not further discussed.

Preoperative VA

The most significant predictor of both anatomical- and visual outcome success in this series was good preoperative acuity. In those with a preoperative acuity of 6/36 or better, the closure rate was 91.2 and 61.8% achieved 6/12 Snellen or better. By comparison, those with a preoperative acuity of less than 6/36 Snellen had a closure rate of 57.1% and only 14.3% achieved 6/12 Snellen or better. The difference is statistically significant using a signrank test ($P = < 0.001$).

Acuity is known to decline with both hole chronicity and hole stage, however, it is clinically recognised that hole stage and chronicity are also colinear with chronic holes typically being stage 3 or 4. The process of delivering macular hole surgery in the British National Health Service can result in long waiting list delays and this was the case for many patients included in this series. Of the three factors of acuity, hole chronicity, and hole stage, only the chronicity of the hole is potentially controllable in a waiting list environment. Our overall closure rate was 78.2 and 43.6% of all patients undergoing surgery achieved a postoperative acuity of 6/12 Snellen or better. When holes of 12 months or less duration are considered, the closure rate was 94.0% with 57.6% achieving 6/12 or better. This contrasted greatly with the corresponding results of 47.4 and 15.8% in those with a latency between onset and surgery of more than 12 months. These data suggest that NHS services should be configured in such a way as to be able to deliver macular hole surgery in less than 12 months from onset.

ICG-assisted ILM peeling

ILM peeling has been reported to be associated with significantly improved visual and anatomical success in all types of acute and chronic macular holes, as well as in holes that have either reopened or failed the initial surgery.

ICG dye selectively stains the vitreomacular interface providing good contrast between the ILM and underlying unstained retina, thereby allowing easier and safer removal of the ILM;[3] such dye staining allows nontraumatic complete ILM peeling to be performed in almost all cases.

Many published clinical series suggest that good anatomical and visual outcome may be achieved with ICG use.[14–24] However, there appears little doubt that in some circumstances ICG ILM peeling may be toxic to the retina with impaired acuity outcome, RPE pigmentary change and visual field defects being reported.[4–10,25] Factors that have been considered to be important in this toxicity include dye concentration, tonicity, contact time, and a photodynamic action associated with long wavelength endoillumination. We have used the dye at a concentration of 0.5 mg/ml (0.05%) diluted in 5 mg/ml in aqueous solvent and then one in 10 in BSS, with the shortest possible retinal contact time and use of a Bausch and Lomb Millenium or Alcon Accurus light source.

Of the 55 patients, 48 (87.3%) underwent ILM peeling and in 36 (65.5%) cases, this peeling was enhanced by ICG dye. The closure rate and percentage achieving Snellen 6/12 or better in those with no peeling was 57.1 and 0%; in those undergoing ILM peeling $\pm$ ICG

was 51.2 and 50.0%; and in those undergoing ICG-assisted ILM peeling was 88.9 and 55.6%, respectively.

The data that we present suggest that ICG retinal staining at a concentration of 0.5 mg/ml (0.05%) was associated with both enhanced rates of hole closure and improved visual outcome and as such do not support the hypothesis that the dye is retinotoxic when used at this concentration and contact time.

Simultaneous phacoemulsification

Nuclear sclerotic is a common complication of macular hole surgery with almost ubiquitous progression to subsequent cataract surgery. In Brooke's recent series, 97% of patients were pseudophakic at the time of final follow-up.[26] The 'one-stop' approach of prophylactic combined clear lens phacovitrectomy removes the need for a second subsequent procedure. There may also be nonsocial theoretical benefits to such prophylactic simultaneous cataract surgery. Performing phacoemulsification in vitrectomised eyes is more difficult and presents a higher incidence of complications than in nonvitrectomised eyes. The most important features proposed for this difference are the lack of vitreous support and possible damage to the posterior capsule or zonular fibres.[27] In addition, reducing the total number of hospital consultations and individual operations reduces the financial costs incurred.

No eye developed clinically significant cataract by the 3-month postoperative visit in those that did not have simultaneous cataract surgery; accordingly, we do not think that the VA results in the phakic postoperative group have been adversely influenced by cataract. The closure rate in eyes undergoing simultaneous lens surgery was 77.4% compared to 72.2% in those who did not; the corresponding figures for the rate of achievement of 6/12 or better were 51.6 and 27.8%.

Postoperative posturing

In this series, 81.8% of patients who did not posture and 75.8% of those who did had successful anatomical closure of macular holes; postoperative VA was 6/12 Snellen or better in 45.4% of the no posture group and 42.4% in the posture group.

Face-down posturing 50 min/h is difficult and unpopular; as a result of this the compliance must be questionable. It has, however, been considered to be a crucial part of macular hole surgery, especially when short-acting gases are used. Our retrospective series found no evidence to support the need for posturing. The success rate when we used shorter SF_6 acting gas was also comparable to that with C_3F_8, with 79.5% of patients who had C_3F_8 and 69.2% of patients who had SF_6 had successful anatomical closure of macular holes. Postoperative VA was 6/12 or better in 48.7% of the C_3F_8 and 38.5% in the SF_6 group. No patients, however, had SF_6 tamponade and no posture.

Conclusion

Macular hole closure was found in 43 of 55 cases (overall 78. 1% success). Univariate analysis showed preoperative symptom duration, better preoperative acuity, use of ICG at a concentration of 0.5 mg/ml (0.05%) and hole stage to be associated with improved anatomical outcome and postoperative VA. In our series, ILM peeling with ICG, with the shortest possible retinal contact time, improved both the rate of closure and the rate of recovery of 6/12 acuity. We found no evidence suggestive of ICG retinotoxicity.

Stopping prone posturing and the performance of simultaneous cataract surgery were not associated with adverse outcome. Macular hole surgery might reasonably be made more 'user-friendly' with no postoperative posturing and simultaneous cataract surgery. The closure rate in patients undergoing surgery within 1 year of the onset of symptoms was 94%, and in those waiting 1 year or more it was 47.4%. Clinical governance and quality issues should dictate that NHS macular hole surgery is available to all within 1 year of onset.

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