Prophylactic scleral buckle for prevention of retinal detachment following vitrectomy for macular hole


Abstract

Aim—To review the rate of retinal detachment after macular hole surgery in patients who received vitrectomy and scleral buckle versus those who had vitrectomy alone.

Methods—All patient charts and hospital records were examined for patients who underwent vitrectomy surgery for macular hole between September 1993 and June 1997. A total of 326 patients were identified and all were followed for a minimum of 6 months. Clinical records were examined for details of the surgical procedure, visual acuity, hole closure status, adjuvant therapies used, and postoperative retinal attachment status. Relative risks (the ratio of the incidence rate in the exposed to that in the unexposed) with 95% confidence intervals and χ² tests were calculated to determine which variables were associated with retinal detachment. The primary outcome measure in this review was retinal attachment status.

Results—Of 326 eyes which underwent surgery for macular hole during the study period, scleral buckles were utilised in 152 (46.6%) patients. Analysis revealed a detachment rate of 13.2% in patients who did not receive a scleral buckle compared with 5.9% detachment rate in those who did. Analysis of these results indicated a 2.42 times greater risk of developing a retinal detachment in patients without a scleral buckle. Complications related to the use of scleral buckles occurred in two of 152 cases (1.3%).

Conclusions—A reduction in the rate of retinal detachment was noted in patients receiving prophylactic scleral buckles. Those finding suggest a possible beneficial effect of this adjunctive procedure in preventing postoperative retinal detachments. The authors are currently preparing a multicentred, prospective, clinical trial to further study this hypothesis.

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Macular hole is an idiopathic condition that typically affects individuals in their sixth to seventh decade of life. In 1988, Gass postulated the role of tangential vitreous traction in the development of idiopathic macular hole. Since that time, several clinical trials have substantiated the efficacy of vitrectomy for the treatment of patients with idiopathic macular hole. Currently, the success rate for patients undergoing vitrectomy for macular hole ranges from 70% to 90%. With these results, surgical intervention has become the standard of care for patients with this condition.

In two of the earlier series, the complication rates following macular hole surgery were reported to be quite low. Wendel et al reported a 1% detachment rate in a retrospective review of 170 eyes undergoing macular hole surgery. Smiddy and co-workers reported a 2% detachment rate in 90 eyes undergoing macular hole surgery with transforming growth factor β (TGF-β) adjuvant therapy. These statistics are in keeping with the suggested retinal detachment rates following vitrectomy surgery for epiretinal membranes. In a more recent study Park et al reported a much higher complication rate. In that article the authors noted a 14% rate of retinal detachment. The detachment rate was corroborated by the results from a prospective multicentred trial, which reported an 11% incidence of retinal detachment.

Prophylactic scleral buckles have been suggested to be of benefit in selected cases of complex vitrectomies. Rosner et al and Ahmadieh et al have reported a reduction in the rate of retinal detachment after vitrectomy for penetrating ocular trauma. In these cases the detachment rates in the non-buckled group are significantly higher than those seen for conventional elective vitrectomy surgery. The role of circumferential traction and subsequent proliferative changes occurring after penetrating trauma are suspected to contribute to a 60–80% detachment rate postoperatively. The higher complication rate in this disease group (that is, penetrating trauma) facilitates a statistical advantage in adjunctive therapy. To the best of the authors’ knowledge, there have been no studies to date investigating the potential beneficial effect of prophylactic scleral buckles in patients undergoing macular hole surgery.

In our centre, historical preferences have developed that have encouraged the use of prophylactic scleral buckles in selected cases. One of our surgeons in particular performs this adjunctive procedure on all vitrectomies for macular hole surgery. The role of circumferential traction and subsequent proliferative changes occurring after penetrating trauma are suspected to contribute to a 60–80% detachment rate postoperatively. The higher complication rate in this disease group (that is, penetrating trauma) facilitates a statistical advantage in adjunctive therapy. To the best of the authors’ knowledge, there have been no studies to date investigating the potential beneficial effect of prophylactic scleral buckles in patients undergoing macular hole surgery.
We report a review of 326 consecutive patients with macular holes from a hospital-based clinic of five retinal specialists, their rate of retinal detachment postoperative vitrectomy, and scleral buckle versus vitrectomy alone.

### Patients and methods

Clinical records from five members of a full-time academic retina division were reviewed in a consecutive manner. All patient charts and hospital records were examined for patients who underwent vitrectomy surgery for macular hole between September 1993 and June 1997. Patients with previous history of retinal detachment or repair on the operative eye were excluded. In patients with bilateral disease or multiple surgeries, only data from the first procedure (in the designated study period) were used. Specific data retrieved included preoperative and postoperative visual acuity, patient demographics, retinal attachment status, lens status and refraction preoperatively, presence or absence of scleral buckle, type of buckle used, presence or absence of intraretinal cryopexy or laser, time to retinal detachment, number and location of retinal tears, and hole closure rates. Preoperative and postoperative refraction and visual acuity during follow-up were performed in some cases by the referring ophthalmologist.

Relative risks (the ratio of the incidence rate in the exposed to that in the unexposed) with 95% confidence intervals and $\chi^2$ test were calculated to determine which variables were associated with retinal detachment.

### Results

A total of 326 consecutive patients underwent surgical treatment for macular hole during the...
study period. All patients were followed for a minimum of 6 months (range 6–48 months) with a mean of 17 months. The mean age of patients was 67 (SD 9.51) years (range 16–102 years). Of the patients treated for this condition, 112 (34%) were male and 214 (66%) were female (Table 1). Patients with previous surgery on the affected eye represented 19% (65/326). Of these, cataract surgery alone constituted 69%, vitrectomy alone 7.6%, vitrectomy with IOL 9%, and 1.2% had a previous trabeculectomy.

Scleral buckles were utilised in 152 (46.6%) of the 326 cases. Demographics such as age and sex did not vary between the buckled and non-buckled groups (Table 2). The buckle element most commonly employed was the Mira No 240 band (121 of 152 eyes, 79%). Other buckle elements employed were the Mira No 41 band (15.7%), Mira No 287 tire (2.6%), Mira No 286 tire (1.3%), and Libiatric No 20 tire (0.6%). Intraoperative cryopexy was performed in 178 of 326 (54.8%) cases. In individuals who underwent cryopexy treatment, the therapy was placed posterior to the scleromembranes in a prophylactic manner. The decision to perform this or not was once again related to surgeon preference.

Of those patients who developed detachments, specific data regarding buckle type, time to and location of detachment, adjuvant therapies, and visual outcome are included in Table 3. Patients developing intraoperative detachments were excluded from this analysis. Time to retinal detachment varied between 1 week and 18 months (average 9 weeks) with the majority (62%) occurring by 8 weeks. Of the retinal detachments that developed, 16 of 32 (50%) were inferior, seven were superior, one was temporal, and seven were total. Retinal tear development was evenly distributed between all four quadrants. At the time of repair 40% of the detachments were noted to be macula off and 60% macula on.

Overall, visual acuity improved by one or more lines in 71% of patients, remained the same in 12%, and worsened by one or more lines in 16%. No statistically significant difference existed between hole closure rates for buckled versus non-buckled patients (Table 4).

Analysis revealed three factors associated with higher rates of postoperative retinal detachment: presence of scleral buckle, concomitant cryopexy use, and type of intraocular tamponade (Table 5). The rate of postoperative retinal detachment among all patients who received prophylactic scleral buckles was 5.9% compared with 13.2% in the non-buckled group (p=0.02). The group treated with retinocryopexy exhibited a 6.7% detachment rate, compared with 13.6% in those who were not (p=0.03). Subgroup analysis, however, showed a strong preference for cryopexy use in the surgeons who carried out the majority of prophylactic scleral buckles (Table 6). Multivariate analysis was not feasible as the use of buckle and cryopexy were not evenly distributed among surgeons.

Complications associated with the use of scleral buckles were experienced in two patients, consisting of one infected and one extruded buckle hardware. Endpoint analysis indicated that neither case sustained decreased visual acuity as a result of these complications. 

**Discussion**

In 1991, a pilot series of macular hole patients was reported by Kelly and Wendel and they
documented the efficacy of surgical repair using vitrectomy techniques. Since that time a number of retrospective surgical series, as well as a randomised prospective clinical trials have reached similar conclusions. It is now recognised that vitrectomy techniques can anatomically close macular holes and result in improved visual acuity in a majority of individuals.

With the increase in the number of surgeries being performed for macular hole, more information has also been obtained regarding the rates of complications. These complications include cystoid macular oedema, cataract, visual field defects, photic retinopathy, endophthalmitis, retinal pigment epithelium disruption, hole enlargement, retinal vascular occlusion, elevated intraocular pressure, and retinal tears and detachments. The latter two complications were the focus of this study.

At present, a discrepancy occurs in the literature regarding the rate of retinal detachment following macular hole surgery (Table 7). As mentioned previously, the earlier retrospective studies suggested an incidence rate close to that seen in vitreectomies performed for epiretinal membranes (1–7%). Two more recent reports, however, have noted a much higher rate of retinal detachment, the latter of which arose from the results of a randomised prospective multicentred trial (11–14%). Of interest, the original report from the randomised clinical trial described a 6.2% detachment rate in the treatment arm of the study at the 6 month follow up period. The subsequent manuscript, reporting findings after 12 months follow up, noted an 11% detachment rate.

Any discussion of postoperative complications rates that are as disparate as those mentioned above will clearly lead to controversy as to the mechanisms/surgical methodology leading to the higher detachment rates. We would like to state that, although our detachment rate was higher than normally seen for conventional vitrectomy surgery, this retrospective review does not allow us to generate hypotheses as to why this may be the case.

The principal outcome examined in this review however, was the effect that prophylactic scleral buckling had on the formation of postoperative retinal detachments. This retrospective comparison was made possible owing to the strong surgeon preference where prophylactic buckles were concerned. In particular, the surgeons selected patients for prophylactic scleral buckle whom they thought would be most likely to develop a retinal detachment. This is referred to as a conservative bias; that is to say, absence of this bias may have shown an even greater beneficial effect for this adjunctive procedure. To our knowledge we know of no other surgeon biases that led to the decision to perform a prophylactic scleral buckle.

In our review, the primary outcome of the association between prophylactic scleral buckling and the rate of retinal detachment was shown to be statistically significant (p=0.027). We subsequently investigated the roles of any additional factors that could have contributed to this difference. We were able to identify two additional variables—use of adjuvant retinocryopexy and the type of intraocular tamponade (silicone oil versus gas). We preface the reporting of these results by stating that these were secondary outcome measures.

An association between the rate of retinal detachment and the use of retinocryopexy was found (p=0.038). This could partially be explained by the surgeon preference in this technique. The two surgeons with the highest proportion of “buckled” patients also accounted for the majority of patients in which retinocryopexy was used (Table 6). This confounding variable cannot be completely controlled for and as such adds support to the need for a prospective randomised trial.

A higher than expected retinal detachment rate was identified with patients who had silicone oil for intraocular tamponade. The sample size for this subgroup was small (n=6) does not allow for adequate statistical analysis or for conclusions to be derived. All six patients had silicone oil used as a result of geographic difficulties in transportation. Our hospital serves as a regional referral centre for the province and, on occasion, patients referred to our centre may live in places that require travel through high mountain passes. No difference in detachment rates was noted between patients receiving SF6 tamponade versus C3F8.

The use of TGF-β in the treatment of macular holes remains controversial. Although the original trial suggested a 100% anatomical success rate with adjunctive TGF-β therapy, a more recent prospective double masked randomised study did not show a significant difference in the treatment arms. Among the participating surgeons in our review, a strong preference also existed regarding use of TGF-β. Overall, the macular hole closure rate of our series (84.6%) is in keeping with that suggested in literature. No statistically significant correlation regarding the use of TGF-β and either hole closure or rate of retinal detachment was identified in our series.

The recent publication by Akduman et al presented a case series of four patients with retinal detachments after macular hole surgery. All four were suspected to be serous in nature and resolved spontaneously without medical or surgical intervention. Considering this, an unbiased observer re-examined the operative reports and charts of our detached patients. Of 32 postoperative detachments, 30 were definitively rhegmatogenous (that is, causative break identified). In two cases, no retinal breaks were identified suggesting the possibility that these patients may have had serous retinal detachments.

Table 7 Literature review of retinal detachments in macular hole patients

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<thead>
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<th>Author</th>
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<th>Intraop tear</th>
<th>Intraop RD</th>
<th>Postop RD</th>
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<tbody>
<tr>
<td>Smiddy</td>
<td>1993</td>
<td>2.00%</td>
<td>2%</td>
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<tr>
<td>WendeB</td>
<td>1993</td>
<td>2.60%</td>
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<tr>
<td>SaadA</td>
<td>1995</td>
<td>1.10%</td>
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<td>ParkA</td>
<td>1995</td>
<td>14%</td>
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<tr>
<td>Pendergrass</td>
<td>1996</td>
<td>2%</td>
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<td>Banker</td>
<td>1997</td>
<td>11%</td>
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<td>Freeman</td>
<td>1997</td>
<td>6.20%</td>
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</tr>
<tr>
<td>This study</td>
<td>1998</td>
<td>6.20%</td>
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ments as described by Akduman et al. Given the low incidence of these serous detachments there was no effect on the statistical outcomes of this study.

The authors recognise the inherent difficulties in performing prophylactic surgery. A point could be made that even if the true retinal detachment rate for macular hole patients were 15%, up to 85% of patients would receive adjunctive treatment that may not have been necessary. This remains an intrinsic concern in the concept of prophylactic therapy; however, we note that up to one third of patients in the detached group had a macula involving status. Given the variability of the stated retinal detachment rates for this surgical procedure in the literature, the use of prophylactic buckles would increase with a higher complication rate. Further study needs to be addressed in a prospective manner to determine the true retinal detachment rate for patients undergoing macular hole surgery.

The authors acknowledge that there are several limitations regarding this review. The retrospective nature of this study is perhaps the most limiting, as it was necessary to rely on previous charts and operative records for data collection. Two sources of potential systematic error were of particular concern—observer and selection bias. At the onset of this study we identified retinal attachment status as the primary outcome measure. As this was neither a subtle finding nor one that could be overlooked by the surgeon we feel that observer bias would be less of an issue than a more subjective evaluation (that is, visual acuity, hole closure status). One important point that we would like to stress was our insistence on data retrieval for all patients undergoing macular hole surgery during the study period. Deliberate attempts were made to correlate operative logs, surgical booking records, and follow up with referring doctors with that of surgeon’s records to ensure a consecutive series of enrolment and follow up. These efforts were made to limit selection bias (that is, surgeons determining which cases to review). On several occasions retinal detachments were identified in patients and had been referred to another retinal surgeon for the secondary repair. Interestingly, we asked all participating surgeons to estimate their presumed personal detachment rates before disclosing our findings. In each case optimism prevailed and the surgeons underestimated their detachment rates (see Table 8).

One final analogy the authors would like to identify to support our hypothesis involves the decision making that is undertaken when repairing a primary retinal detachment. For example, the principal reason for using an encircling band beyond the area of the retinal breaks or detachment is to support the vitreous base in uninvolved quadrants for the possibility of missed or new breaks. If we assume that vitrectomy for macular hole carries with it a higher detachment rate than that of conventional indications (that is, epiretinal membrane) this logic can be carried forward. Furthermore, the higher the true detachment rate involved with this procedure, the more beneficial the effect will be of this prophylactic measure. Although the retinal detachment rate for macular holes remains highly contentious and may in fact be lower than we describe in our series, this study sheds interesting insight into the concepts of prophylactic buckling for any condition that has a higher than normal detachment rate.

To date, this case control series represents the largest consecutive review of macular hole surgery results that has been published. It is also presents the largest series of retinal detachments as a complication of vitrectomy for macular hole. Although this study supports the possible protective effects of prophylactic scleral buckles, the authors caution against the widespread acceptance of this adjunctive procedure until two facts are clearly established in the literature—a consistently reported rate of postoperative retinal detachments after macular hole surgery and a prospective evaluation of this hypothesis. The authors have received funding and are currently undertaking a prospective randomised trial to help answer these two concerns.

Table 8  Yearly retinal detachment rates

<table>
<thead>
<tr>
<th>Year</th>
<th>Retinal detachments N (%)</th>
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<tbody>
<tr>
<td>1993</td>
<td>0/9 (0)</td>
</tr>
<tr>
<td>1994</td>
<td>6/55 (10.9)</td>
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<tr>
<td>1995</td>
<td>9/109 (8.2)</td>
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<tr>
<td>1996</td>
<td>11/85 (12.9)</td>
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<td>1997</td>
<td>6/68 (8.8)</td>
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p=0.671