Vitrectomy with and without encircling band for pseudophakic retinal detachment: VIPER Study Report No 2—main results

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ABSTRACT

Background It is unclear whether or not an additional encircling band improves outcome in vitrectomy for pseudophakic retinal detachment (PRD). Also unclear is whether small gauge transconjunctival trocar-guided vitrectomy is as successful as conventional 20 gauge (G) vitrectomy.

Methods 257 adult patients with uncomplicated PRD were enrolled in 14 vitreoretinal centres across Germany. Contingent on availability of qualified surgeons, eligible patients were randomly assigned either (i) with ratio 1:1 to 20 G vitrectomy plus encircling band (group E1) or 20 G vitrectomy without any buckle (group C) or (ii) with ratios 1:1:1 to group E1, C or 23/25 G vitrectomy without any buckle (group E2). Treatment success was defined as no indication for any retina reattaching procedure during the follow-up of 6 months.

Results Success was reached in 79.0% (79/100, group E1) versus 73.5% (72/98, group C) (p=0.558, OR 1.32, 95% CI 0.65 to 2.65. In group E2 87.7% (50/57) of patients reached success compared with 78.7% (48/61) in group C, demonstrating non-inferiority of E2 to C regarding the prespecified margin of 0.8 (OR scale; p=0.05, OR 2.17, 95% CI 0.80 to 5.89). Best corrected visual acuity significantly increased after surgery independent of technique, that is, on average −0.7 (from 1.0 to 0.3) logMAR. Patients suffered from a shift in spherical refraction of −1.0 D in group E1 compared with −0.1 D in group C. Similarly, intraoperative complications (15.2% vs 8.8% of patients) and serious adverse events (30.3% vs 22.5% of patients) were more frequent in group E1.

Conclusions Vitrectomy with gas is an efficient and safe treatment for uncomplicated PRD. An additional encircling band does not significantly reduce the risk for any second procedure necessary to reattach the retina in 20 G vitrectomy. Small gauge transconjunctival vitrectomy is not inferior to the conventional 20 G technique.

Trial registration number: DKRS 00003158, Results.

INTRODUCTION

To date high-level evidence is lacking regarding the question whether an encircling band in addition to vitrectomy in the treatment of pseudophakic retinal detachment (PRD) improves outcome. While several retrospective or non-randomised studies reported almost complete success of combined surgery,1–12 other studies found no benefit of an additional encircling band compared with vitrectomy alone.13–15 An ancillary analysis of the randomised SPR study (Scleral buckling versus primary vitrectomy in rhegmatogenous retinal detachment study) which compared vitrectomy and scleral buckling in the treatment of patients with retinal detachment of medium complexity showed that in pseudophakic patients treated with vitrectomy the use of an additional buckle resulted in a significantly lower redetachment rate of 11.4% vs 40.9% in patients who were treated by vitrectomy alone.6 In contrast an analysis of survey data on 4179 patients with retinal detachments showed a slightly higher failure rate for combined surgery versus vitrectomy alone,7 though selection bias, for example, due to favoring an additional buckle in difficult situations, cannot be ruled out.

The Vitrectomy with and without encircling band in the treatment of pseudophakic retinal detachment (VIPER) Study was set up to answer whether the increased invasivity and operation time, the effect on postoperative refraction and blood circulation of the eye8 and potential specific complications such as buckle migration and infection due to an additional encircling band is justified by lower redetachment rates compared with vitrectomy with gas endotamponade alone.

With 23, 25 or even 27 gauge (G) transconjunctival vitrectomy comparable anatomical results were reported in case series, chart reviews9–11 and in non-randomised comparative studies.12–14 However, since high level evidence is again lacking to date, the VIPER Study was designed to test non-inferiority of transconjunctival vitrectomy to 20 G vitrectomy with gas and without encircling band in the treatment of PRD.

METHODS

Study design

The VIPER Study was designed as a multicentre, randomised clinical trial. The study was registered in the German Register for Clinical Trials under DRKS 00003158 (http://www.germanctr.de). The design of the study was described in detail in the VIPER Study Report No 1.15 In brief, 14 clinical sites across Germany participated. All centres were experienced in conducting clinical trials according to good clinical practice. The study protocol was approved by each local ethics committee. The tenets of the Declaration of Helsinki were adhered to. Altogether, 34 vitreoretinal surgeons were eligible for this study according to their surgical logs, either for 20 G procedures alone or for both 20 G and 23/25 G procedures depending on the number...
of already performed procedures per surgeon. Patients were randomised to one of the following groups: experimental group 1 (E1): 20 G vitrectomy with gas endotamponade with an additional encircling band. Control group (C): 20 G vitrectomy with gas endotamponade alone. Experimental group 2 (E2): 23 or 25 G vitrectomy with gas endotamponade alone. Patients were randomised either with ratio 1:1 between E1 and C, or with ratios 1:1:1 between E1, C and E2 dependent on the certification of the individual surgeon. Our primary working hypotheses were that (i) treatment success over 6 months would be achieved more frequently in group E1 than in group C (superiority hypothesis) and (ii) the proportion of failures over 6 months is not higher for group E2 than for group C (non-inferiority hypothesis). The follow-up was over 26 weeks with interim assessments after 6 and 12 weeks.

**Primary endpoint**

Success was defined as no indication for any procedure to reattach the retina during the follow-up of 26 weeks. Additional procedures (failure) included any buckling surgery, vitrectomy or tamponade such as reinjection of gas or air or any silicone oil filling. Relevant clinical data (including fundus drawings and photographs) were evaluated by a clinical endpoint committee.

**Key secondary endpoints** included best corrected visual acuity determined with ETDRS charts, refractive status, adverse events such as the new proliferative vitreoretinopathy (PVR), pucker formation and duration of surgery.

**Interventions**

In all three treatment groups the procedure was as standardised as possible for a surgical trial across the participating centres as described in the VIPER Study Report No 1. In brief, all kinds of encircling bands could be used in group E1. All kinds of gas endotamponades were allowed in all treatment groups. Wide field viewing systems were used. Primary use of silicone, circumferential prophylactic laser coagulation or cryopexy was not allowed in any of the treatment groups. Laser coagulation or cryopexy was allowed only to treat breaks or high risk degenerations.

**Eligibility criteria**

Patients were included if they presented with PRD at least 3 months after cataract surgery, following informed consent. Patients were excluded in cases of a giant retinal tear, PVR grade 3 months after cataract surgery, following informed consent. Patients were included if they presented with PRD at least 3 months after cataract surgery, following informed consent. Patients were excluded in cases of a giant retinal tear, PVR grade 3 or tamponade such as reinjection of gas or air or any silicone oil filling. Relevant clinical data (including fundus drawings and photographs) were evaluated by a clinical endpoint committee.

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reattaching procedure (8.8% vs 13.1%). In most cases an additional vitrectomy was performed (E2: 4/57; C: 7/61). In some cases other procedures were done or combined with the additional vitrectomy (see table 2).

The comparison of E2 and C resulted in a pooled OR of 2.17 (95% CI 0.80 to 5.89). The asymptotic p value for the test of the common OR against the prespecified non-inferiority bound of 0.8 was just p=0.05, that is, non-inferiority of E2 was confirmed. The (stratified) absolute risk reduction of E2 versus C was 10.2%, 95% CI 4.0% to 16.9%. The cumulative incidence of detected indications of a reattaching procedure over time is shown in figure 2B (Kaplan-Meier curves; HR 0.65, 95% CI 0.21 to 1.97).

The results of ITT analysis for both comparisons were supported by PP analysis. However, the precision of estimates was lower due to smaller sample size in the PP set (see online supplementary table S3; pooled ORs with 95% CI: E1 vs C 1.07, 0.48 to 2.38; E2 vs C 2.10, 0.51 to 8.61).

Secondary endpoints
Mean visual acuity (in logMAR) equally improved in all groups from baseline to week 26 (between −0.6 and −0.8, see table 3 and online supplementary table S4). Mean spherical refraction (in D) in group E1 changed significantly by −1.0 (from 0.1 at baseline to −0.9 after 26 weeks), whereas in group C no significant change was observed during follow-up (−0.1 at baseline, −0.2 after 26 weeks; E1 vs C −0.8 (−1.2 to −0.3), p=0.001); no relevant difference was observed between groups E2 and C. The proportions of patients with PVR grade C at week 26 were similar in all groups, that is, between 2.1% and 4.1%.

Figure 1 Flow of participants. G, gauge; ITT, intention-to-treat; PP, per-protocol.

*Inclusive 2 patients who did not receive any surgery
**Patient with change of trial arm had an additional protocol violation
***One patient with three different protocol violations
Regarding anatomical success, defined as retina fully attached at week 26, all groups reached percentages of about 95% (ie, between 93.4% and 96.0%, see table 3).

Subgroup analysis by sex
As expected, we found no indication of any differential efficacy or safety in women and men. Specifically, regarding the primary endpoint, the OR in men for E1 versus C is 1.26 (95% CI 0.55 to 2.88) and for E2 versus C 1.91 (0.60 to 6.14). In women the OR in men for E1 versus C is 1.26 (95% CI 0.55 to 2.88) and for E2 versus C 1.91 (0.60 to 6.14). In women the OR in men for E1 versus C is 1.26 (95% CI 0.55 to 2.88) and for E2 versus C 1.91 (0.60 to 6.14). In women the OR in men for E1 versus C is 1.26 (95% CI 0.55 to 2.88) and for E2 versus C 1.91 (0.60 to 6.14). In women the OR in men for E1 versus C is 1.26 (95% CI 0.55 to 2.88) and for E2 versus C 1.91 (0.60 to 6.14). In women the OR in men for E1 versus C is 1.26 (95% CI 0.55 to 2.88) and for E2 versus C 1.91 (0.60 to 6.14). In women the OR in men for E1 versus C is 1.26 (95% CI 0.55 to 2.88) and for E2 versus C 1.91 (0.60 to 6.14). In women the OR in men for E1 versus C is 1.26 (95% CI 0.55 to 2.88) and for E2 versus C 1.91 (0.60 to 6.14). In women the OR in men for E1 versus C is 1.26 (95% CI 0.55 to 2.88) and for E2 versus C 1.91 (0.60 to 6.14).

Intraoperative complications
Thirty-one patients were affected by intraoperative complications (see online supplementary table S1). Most events occurred after 20 G vitrectomy with encircling band (E1, 15.2%, 15 of 99 patients) followed by 23/25 G vitrectomy (E2, 13%=7/54). The lowest proportion of intraoperative complications were found after standard surgery (20 G vitrectomy without encircling band, C, 8.8%=9/102). Intracocular breaks were the most frequently occurring complications during surgery, none in group C (E1: 6.1%=6/99, E2: 9.3%=5/54, C: 0%=0/102; p=0.014). The most frequent complication during standard surgery was intraocular vitreous haemorrhage (C: 2.9%=3/102, none in E1 and E2).

Table 1 Description of preoperative characteristics (intention-to-treat set)

| Characteristic    | Summary statistics | Summary statistics | Summary statistics |
|-------------------|--------------------|--------------------|--------------------|
| Sex, male         | 70 (70.0%)         | 43 (75.4%)         | 71 (72.4%)         |
| Age, years        | 65±10              | 66±9               | 64±10              |
| Study eye, right* | 51 (51.0%)         | 20 (35.1%)         | 55 (56.1%)         |
| Sphere, dioptre†  | 0.00 (–0.25 to 0.75)| 0.00 (–0.50 to 0.25)| 0.00 (–0.75 to 0.63)|
| Cylinder, dioptre†| –0.50 (–1.25 to 0.00)| –0.25 (–0.75 to 0.00)| –0.50 (–1.13 to 0.00)|
| Axis, degree‡    | 76 (0 to 128)      | 45 (0 to 120)      | 54 (0 to 112)      |
| Intraocular pressure, mm Hg‡ | 14 (12 to 16) | 15 (12 to 18) | 15 (12 to 17) |
| Visual acuity, logMAR‡ | 1.1 (0.3 to 1.7) | 1.0 (0.5 to 1.7) | 0.8 (0.3 to 1.7) |
| Vitreous situation at start of surgery |                         |                    |                    |
| Fully attached    | 6 (6.0%)           | 5 (8.8%)           | 9 (9.2%)           |
| Partly attached   | 37 (37.0%)         | 22 (38.6%)         | 41 (41.9%)         |
| Fully detached    | 56 (56.0%)         | 30 (52.6%)         | 44 (44.9%)         |
| Haemorrhage       | 0 (0.0%)           | 0 (0.0%)           | 1 (1.0%)           |
| Other             | 1 (1.0%)           | 0 (0.0%)           | 3 (3.1%)           |
| Cataract surgery uneventful, yes‡ | 89 (89.0%) | 48 (84.2%) | 89 (91.8%) |
| Laser, yes        | 4 (4.0%)           | 7 (12.3%)          | 8 (8.2%)           |
| Cryocoagulation, yes | 1 (1.0%)         | 0 (0.0%)           | 1 (1.0%)           |
| Gas injection, yes| 0 (0.0%)           | 0 (0.0%)           | 0 (0.0%)           |
| Anti-VEGF injection, yes | 0 (0.0%) | 0 (0.0%) | 1 (1.0%) |

Table 2 Evaluation of primary outcome, that is, absence of indication for reattaching procedure, based on ITT set (ITT; results for PP set, see online supplementary material)

| E1 20 G vitrectomy with EB (n=100) | C 20 G vitrectomy without EB (n=98) | E1 vs C OR (95% CI) | E2 23/25 G vitrectomy without EB (n=57) | C 20 G vitrectomy without EB (n=61) | E2 vs C OR (95% CI) |
|-----------------------------------|-------------------------------------|---------------------|------------------------------------------|-------------------------------------|---------------------|
| Absence of indication for reattaching procedure | 79 (79.0%) | 72 (73.5%) | 1.32† | 50 (87.7%) | 48 (78.7%) | 2.17†† |
| Additional vitrectomy             | 15 (15.0%) | 18 (18.4%) | –     | 4 (7.0%)  | 7 (11.5%) | –     |
| Additional buckle                 | 1 (1.0%)  | 8 (8.2%)  | –     | 3 (5.3%)  | 4 (6.6%)  | –     |
| Other procedure                   | 5 (5.0%)  | 4 (4.1%)  | –     | 1 (1.8%)  | 2 (3.3%)  | –     |
| Follow-up <23 weeks§              | 4 (4.0%)  | 7 (7.1%)  | 2 (3.5%) | 5 (8.2%)  | –     | –     |

* p≤0.05, ** p≤0.01, *** p≤0.001.
† Breslow-Day test of homogeneity of ORs over surgeons, p=0.386 (0.071).
‡ Asymptotic p value for the test of the common OR against 0.8 (non-inferiority bound): p=0.05.
§ And no indication for reattaching procedure during follow-up.
EB, encircling band; G, gauge; ITT, intention-to-treat; PP, per-protocol.
the eye and may entail specific complications such as buckle migration and infection. In our study the operation duration was significantly longer in the combined surgery of 20 G vitrectomy with additional encircling band (median 63 min) than in 20 G vitrectomy alone (47 min) and 23/25 G vitrectomy (38 min). This longer operation duration may explain a higher stress on the corneal epithelium which made an abrasion necessary in 4 vs 1 cases in the combined surgery group compared with the 20 G vitrectomy alone group (23/25 G vitrectomy: none). In three cases the sclera was perforated during the fixation of the encircling band. Moreover patients experienced a mean myopisation of $-1.0$ D in the combined surgery group versus $-0.1$ D in both other groups ($p<0.001$).

The literature is inconclusive regarding the question whether these costs of the additional buckle are associated with increased anatomical or functional success (we have provided an overview on existing retrospective and non-randomised prospective studies in the VIPER Study Report No 1).15

For the primary comparison of vitrectomy plus encircling band group (E1) versus vitrectomy alone (C) we found a (stratified) absolute risk reduction of 5% (95% CI $-9.2\%$ to 14.5%) in favour of E1, albeit not statistically significant. In arm E1 79% (79/100) of patients showed no indication for any retina reattaching procedure compared with 73.5% (72/98) in arm C (Mantel-Haenszel test, stratified by surgeon: $p=0.558$; pooled OR 1.32, 95% CI 0.65 to 2.65), see table 2. Thus, apart from the direction of effect, the large absolute 29.5% advantage for E1 seen in the SPR trial could not be replicated. The encircling band as an additional means combined with vitrectomy and gas endotamponade does not consistently reduce the risk for any intervention to reattach the retina during a 6-month follow-up. The design of the study implies that the results cannot be merely applied to phakic patients or patients with advanced PVR. However, in phakic retinal detachment primary vitrectomy only one approach besides buckling and combined cataract surgery and vitrectomy.20 It is unclear if a possible difference in the pathophysiology of PRDs affects conclusions regarding the benefit of additional buckling in these patients.

For the comparison of small gauge transconjunctival vitrectomy (E2) and 20 G vitrectomy with gas alone (C) we demonstrated non-inferiority against the prespecified relative bound of 0.8 (pooled OR 2.17, 95% CI 0.80 to 5.89, $p=0.05$) and, thus, confirmed several retrospective studies who stated ‘similar results’.12 14 18 19 21 The proportion of patients with no indication of a reattaching procedure was slightly higher in E2 (87.7%, 50/57) as compared with C (78.7%, 48/61; see table 2) and the (stratified) absolute risk reduction of E2 versus C was 10.2%, 95% CI $-4.0\%$ to 16.9%. Hence, based on our data, absolute differences larger than $-4.0\%$ in favour of C can be excluded.

The fact that transconjunctival surgery resulted in less redetections may be explained by the use of trocar systems which may reduce the risk of applying perpendicular forces to the vitreous base during insertion of instruments, a reduced risk of vitreous incarcerations compared with sclerotomies and a reduced flow through the cutter resulting in a diminished traction on the vitreous base. Accordingly, less retinal detachments have been observed after transconjunctival vitrectomy for macular surgery.22 23

As a limitation, the follow-up of 6 months may lead to an overestimation of the success rates because possible redetections later than 6 months were not identified. However, it is unlikely that a late redetachment after 6 months is still causally related to the initial condition. Data from large case series suggest that redetachment usually occurs within 6 months. In a series by Lee85% of redetachments were recorded within the first

![Image](https://example.com/image.png)

**Figure 2** Kaplan-Meier curves for the cumulative proportion without indication for reattaching procedure: (A) treatment E1 versus C, (B) treatment E2 versus C (patients with insufficient follow-up, ie, <23 weeks, are censored; intention-to-treat set). G, gauge.

After 20 G with encircling band some additional types of intraoperative complications were observed: corneal oedema (4/15), scleral perforation during buckling and fogged intraocular lens (three in each category). In the other two groups only a few additional individual cases of other types of complications were observed.

**Adverse events**

In total, 78 serious adverse events occurred in 60 patients (see online supplementary table S2). In group E1, almost one-third of the patients was affected (E1: 30.3% = 30/99), whereas the proportions in group E2 and C were lower (E2: 13% = 7/54; C: 22.5% = 23/102). The most frequently observed serious adverse event was retinal detachment. In total, 52 of those events occurred in 41 patients (E1: 16 of 99 patients, E2: 4/54, C: 21/102). Besides, there were some cases of ocular hypertension (3/30 patients in E1, none in E2 and C) and pain (2/30, E1) and several individual cases of various types, most of which occurred in group E1.

**DISCUSSION**

Retinal surgeons expect additional buckling procedures to provide enhanced support of the vitreous base and better visualisation of the periphery. On the other hand, the additional scleral buckle implies increased invasivity and operation time, it affects the postoperative refraction and the blood circulation of...
3 months and 97.7% of failure was seen within the first 6 months after the initial procedure. These results are confirmed by the observations in the VIPER Study: redetachments occurred within 12 weeks after the initial surgery with a small trend towards earlier redetachments when an encircling band occurred within 12 weeks after the initial surgery with a small trend towards earlier redetachments when an encircling band was used (see figure 2A).

Consequently, it appears not necessary to place a 360° buckle in addition to primary vitrectomy with gas endotamponade to successfully treat pseudophakic retinal detachment. The non-inferiority analysis showed that small gauge vitrectomy using transconjunctival techniques is at least equally successful and safe and can be recommended as well as the 20 G technique.

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Contributors PW: conception, design, data acquisition, analysis, interpretation, critical revision. MH, PS: conception, design, analysis, drafting, SB: data acquisition, analysis, interpretation, critical revision. EL: conception, data acquisition, analysis, critical revision. HA, AP, HH, AL, GR: data acquisition, analysis, critical revision. BM: design, data acquisition, analysis, interpretation, drafting. All authors: final approval and accountability for all aspects of the work.

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