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RETINAL DISORDERS

Scleral buckling versus primary vitrectomy in rhegmatogenous retinal detachment study (SPR Study): predictive factors for functional outcome. Study report no. 6

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Abstract
Purpose To identify risk factors associated with best-corrected visual acuity (BCVA) 1 year after initial surgery following primary vitrectomy (PV) and scleral buckling surgery (SB) for rhegmatogenous retinal detachment (RRD).
Methods Relating the final BCVA at the 1-year follow-up visit to pre- and intraoperative findings in the "randomized, prospective, multicenter clinical trial comparing scleral buckling versus primary vitrectomy for repair of rhegmatogenous retinal detachment" (SPR Study) using multivariate statistical methods.
Results In the phakic subtrial, final BCVA is associated with the number of breaks (p=0.0259), duration of symptoms (p=0.0476), baseline BCVA (p=0.0002), retinal detachment central to major vessels arcades (p=0.0088), total detachment (p=0.0027), and chain formation of breaks (p=0.0129). In the pseudophakic/aphakic subtrial, final BCVA is related to the number of retinal breaks (p=0.0010), secondary cataract or central capsular fibrosis (p=0.0141),

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Ralf-Dieter Hilgers has full access to the data in the study, and takes responsibility for the integrity of the data and accuracy of the data analysis. We agree to allow Graefe's Archive for Clinical and Experimental Ophthalmology to review our data upon request.

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intraoperative laser photocoagulation (p=0.0373), and inferior detachment with breaks below the 4 and 8 o'clock positions (p=0.0173).
Conclusion Final BCVA is the most important outcome for patients undergoing RRD surgery. Our results demonstrate that the final BCVA is related to a higher preoperative number of breaks in both subtrials. Additional risk factors varied between phakic and pseudophakic subgroups.

Keywords RRD surgery · Primary vitrectomy · Scleral buckling · BCVA

Introduction

The "Scleral buckling versus primary vitrectomy in rhegmatogenous retinal detachment study" (SPR Study) was designed to compare scleral buckling (SB) versus primary vitrectomy (PV) in rhegmatogenous retinal detachment (RRD) of medium complexity [1–3]. Although well-formulated inclusion and exclusion criteria were used, the definition of "medium complexity" covers a wide range of preoperative findings [3]. Retinal surgeons must determine whether the functional and anatomical outcome after retinal detachment surgery depends on preoperative findings. Many groups have tried to identify some prognostic factors for visual and anatomical results after retinal detachment surgery. The most commonly identified preoperative factors are macular detachment, baseline best-corrected visual acuity (BCVA), patient age, preoperative proliferative vitreoretinopathy (PVR), and duration of retinal detachment, all of which seem to influence functional and anatomical outcome [4–7].

The SPR Study was a prospective, randomised multicentre clinical trial in which numerous pre-, intra- and postoperative characteristics were documented according to the study protocol. In this study, we analysed this comprehensive dataset to generate a secondary analysis of predictive factors.

The novel aspect of our analysis is the simultaneous assessment of pre- and intraoperative findings for predicting functional outcome on a well-defined disease such as primary RRD. In addition, our analysis distinguishes between phakic and pseudophakic patients according to the study design in two separate study subgroups.

Materials and methods

SPR Study design

The SPR Study was designed to compare SB and PV in patients with a primary RRD of medium complexity [3]. Institutional Review Board (IRB)/Ethics Committee approval was obtained at all participating centres. Between August 1998 and June 2003, 45 surgeons in 25 centres in five European countries recruited a total of 416 phakic (209 SB/207 PV) and 265 pseudophakic (133 SB/132 PV) patients. Informed consent was obtained from each patient.

According to the definition of the full analysis set [8], one patient was excluded from analysis because of missing post-randomisation data. The study design and general data collection (e.g., inclusion criteria, follow-up time, etc.) have previously been published [2, 3]. For this analysis, we used information regarding the pre- and intraoperative findings from the case report forms of the study, as detailed in Table 1.

Additional evaluation

Additional information was extracted from the fundus drawings within the CRF and the surgical notes. Due to individual differences in recording fundus drawings and surgical notes, all drawings and notes were reviewed and classified by three vitreoretinal surgeons (H. H., N. F., P. W.) with regard to pre- and intraoperative characteristics (Table 2, 3). In cases in which the reviewers' results disagreed, a majority vote (2:1) was adopted.

Outcome variables

All pre- and intraoperative characteristics were investigated in relation to the secondary study endpoint "functional success", measured as "best-corrected visual acuity" (BCVA) on the logarithm of the minimum angle of resolution (logMAR) scale at the 1-year visit. In contrast to the trial's primary endpoint (change in BCVA), we used the final BCVA, as this reflects the patient overall benefit and function after treatment.

Statistical methods

Continuous variables were summarised by means and corresponding standard deviations (SD). Categorical data were presented by frequencies and percentages. According to clinical practise, missing values documented for some of the categorical variables were assessed as non-occurrence of a clinical finding. In addition, we used the last observation carried forward principle to substitute missing 1-year BCVA observations.

For model building, we followed the selection strategy proposed by Ulm et al. [9]. In brief, all exploratory variables were studied univariately and in a corresponding multivariate analysis of variance model, with surgical procedure and surgeon as immanent factors. Exploratory

Table 1 Surgery-related findings collected from the case report forms

Lens status	Phakic	Pseudophakic/aphakic
General data	Age	Age
Presence of symptoms prior to surgery	deterioration in visual acuity	deterioration in visual acuity
	visual field defect	visual field defect
	photopsia	photopsia
	mouches volantes	mouches volantes
	duration of symptoms >1 week	duration of symptoms >1 week
Previous treatment prior to surgery	cryotherapy	cryotherapy
		photocoagulation
		cataract surgery
		capsulotomy during cataract surgery
		YAG capsulotomy
Pathologic findings anterior segment	secondary cataract/capsular fibrosis	secondary cataract/capsular fibrosis
Pathologic findings posterior segment	vitreous opacity/haemorrhage	vitreous opacity/haemorrhage
	macula attached/detached	macula attached/detached
	number of breaks in the retina	number of breaks in the retina
	break extension >1 clock hour	break extension >1 clock hour
	break with elevated flap	break with elevated flap
	break with irregular edges	break with irregular edges
	retinal detachment central to vessel arcades	retinal detachment central to vessel arcades
		posterior capsule damaged
Other Preoperative findings	visual acuity category (≥1.0 logMAR or <1.0 logMAR)	visual acuity category (≥1.0 logMAR or <1.0 logMAR)
	LOCS III values	
Intraoperative findings	additional breaks found	additional breaks found
	subretinal hemorrhage during surgery	subretinal hemorrhage during surgery
	incomplete drainage of subretinal fluid	incomplete drainage of subretinal fluid
	iatrogenic breaks	iatrogenic breaks
	subretinal gas	subretinal gas
	subretinal heavy fluid	subretinal heavy fluid
		retinal incarceration during surgery
	lens touch during surgery	

factors were assessed as relevant to be mutually included in our final model if the *p*-value was below 10%. Relevant effects in either analysis were studied further for treatment interaction. In doing so, we used the significance margin of 10% (0.1). Finally, we defined a model which consists of the former relevant exploratory factors and relevant interactions to treatment. The resulting model based on the aforementioned selection process was adapted to accommodate the data to discover those factors or interactions contributing significant information (*p*-value falls below the 5% margin) for predicting functional outcome. All test results are reported as degrees of freedom (df), value of the F-statistic (F), and *p*-value (*p*).

All analyses were done using SAS® statistical software, V9.1.3 procedure GLM (SAS Institute, Cary, NC, USA) under Windows XP.

Results

The evaluation is based on fundus drawings and surgical reports of all 680 SPR patients.

Phakic subtrial

Our final model is described in Table 4. The following factors showed a statistically significant relation with BCVA at the 1-year follow-up visit: Number of breaks (df=1, F=5.00, p=0.0259), duration of symptoms (df=1, F=3.95, p=0.0476), preoperative BCVA (df=1, F=13.77, p=0.0002), retinal detachment central to vessels arcades (df=1, F=6.94, p=0.0088), total detachment (df=1, F=9.10, p=0.0027), and chain formation of breaks (df=1, F=6.24, p=0.0129).

Table 2 Recording of additional findings extracted from surgical notes and pre-, intra- and postoperative fundus drawings. All characteristics were classified as present or not present

Characteristic	Finding
Clarity of optical media	- adequate visualisation of retinal periphery
	- vitreous haemorrhage
Extension of RRD	- superior RRD with breaks between 10 and 2 o'clock positions
	- inferior RRD with breaks between 4 and 8 o'clock positions
	- bullous detachment
	- RRD confined to one quadrant
	- total detachment
Break characteristics	- central breaks
	- unusual breaks
	- multiple breaks, involved area ≥3 clock hours
	- chain formation of breaks
	- unclear break situation
Additional parameters	- lattice degeneration
	- localisation of retinal detachment
Surgery	- use of lasertherapy
	- use of cryotherapy
	- drainage of subretinal fluid
	- tamponade

A higher number of breaks were associated with lower BCVA. In addition, patients with symptoms for more than 1 week and patients with a preoperative BCVA ≥1.0 (logMAR) had a worse functional outcome. Patients with a preoperative BCVA ≥1.0 (logMAR) had a mean final BCVA of 0.55 (logMAR/ SD 0.46) compared to those with a baseline BCVA <1.0 and a final BCVA of 0.28 (SD 0.30). In patients with a postoperative retinal detachment central to vessel arcades, or total detachment, visual acuity 1 year after initial surgery worsened. If breaks were configured in a chain formation, visual acuity was better compared to patients without this feature.

Pseudophakic/ aphakic subtrial

The results for the final model in pseudophakic/aphakic eyes are summarized in Table 5. Final BCVA is significantly related to the number of retinal breaks in this model (df=1, F=11.03, p=0.0010), secondary cataract or central capsular fibrosis (df=1, F=6.12, p=0.0141), intraoperative laser photocoagulation (df=1, F=4.39, p=0.0373) and inferior detachment with breaks below the 4 and 8 o'clock positions (df=1, F=5.75, p=0.0173). We also observed significant interaction between inferior detachment and the surgical method df=1, F=4.69, p=0.0314).

Patients with a higher number of retinal breaks, with secondary cataract or central capsular fibrosis have a lower final BCVA. However, the intraoperative use of laser is associated with a better functional outcome. Patients with inferior detachment and breaks below the 4 and 8 o'clock positions had a lower BCVA, most notably in the SB group.

Our model including the covariates leads to significant progress in clarifying variability (model fit) in the data. For

Table 3 Description of additional findings based on fundus drawings in the case report forms and surgical notes

	Phakic patients (N=415)		Pseudophakic patients (N=265)	
	SB (N=209)	PV (N= 206)	SB (N=133)	PV (N=132)
Adequate visualisation of retinal periphery	2% (5)	4% (8)	8% (11)	5% (7)
Vitreous haemorrhage	8% (17)	8% (16)	3% (4)	2% (3)
Intraoperative use of laser photocoagulation	3% (6)	43% (89)	4% (5)	48% (63)
Intraoperative use of cryotherapy	98% (205)	75% (155)	89% (119)	65% (86)
Subretinal fluid drainage	66% (137)	0.5% (1)	68% (91)	2% (2)
Intraocular tamponade	52% (109)	96% (197)	45% (60)	97% (128)
Bullous detachment	35% (74)	26% (54)	17% (23)	22% (29)
Inferior detachment with breaks below the 4 and 8 o´clock positions	3% (6)	5% (10)	7% (9)	5% (7)
Localized detachment (one quadrant only affected)	15% (31)	12% (25)	6% (8)	11% (14)
Unusual breaks	42% (88)	41% (84)	23% (30)	20%(26)
Multiple breaks over ≥3 clock hours	22% (45)	23% (66)	9% (12)	11% (14)
Unclear break situation	1% (2)	2% (4)	37% (49)	37% (49)
Central breaks	14% (30)	20% (42)	11% (15)	6% (9)
Superior detachment with breaks above the 10 and 2 o´clock positions	46% (97)	33% (68)	25% (33)	27% (35)
Total detachment	4% (9)	5% (10)	4% (5)	9% (12)
Lattice degeneration	18% (38)	21% (44)	10% (13)	11% (14)
Chain formation of breaks	37% (77)	42% (86)	14% (19)	17% (22)

Table 4 Results of the ANCOVA analysis in the phakic subtrial. Significance is given if $p \leq 0.05$

	DF	Type III SS	Mean square	F value	Pr>F
Surgeon	18	2.55392065	0.14188448	1.12	0.3278
OP	1	0.35297133	0.35297133	2.79	0.0956
Age	1	0.00018642	0.00018642	0.00	0.9694
Number of breaks	1	0.63248292	0.63248292	5.00	0.0259
LOCS III grading (total)	1	0.07378468	0.07378468	0.58	0.4454
Symptomatic visual loss	1	0.13781600	0.13781600	1.09	0.2971
Duration of symptoms >1 week	1	0.49954112	0.49954112	3.95	0.0476
Macula on/off	1	0.13556367	0.13556367	1.07	0.3011
Category of visual acuity	1	1.74028833	1.74028833	13.77	0.0002
Retinal detachment central to vessel arcades	1	0.87771868	0.87771868	6.94	0.0088
Iatrogenic breaks during surgery	1	0.39029824	0.39029824	3.09	0.0797
Localisation of retinal detachment	1	0.27546747	0.27546747	2.18	0.1408
Intraoperative laser photocoagulation	1	0.16555874	0.16555874	1.31	0.2532
Subretinal drainage	1	0.00234609	0.00234609	0.02	0.8917
Tamponade	1	0.01411486	0.01411486	0.11	0.7385
One quadrant detachment	1	0.01931206	0.01931206	0.15	0.6961
Superior detachment	1	0.26144752	0.26144752	2.07	0.1513
Total detachment	1	1.15061508	1.15061508	9.10	0.0027
Central breaks	1	0.34944060	0.34944060	2.76	0.0973
Chain formation of breaks	1	0.78899098	0.78899098	6.24	0.0129
OP* number of breaks	1	0.12879619	0.12879619	1.02	0.3135
OP* category of visual acuity	1	0.10338068	0.10338068	0.82	0.3664
OP* retinal detachment cenral to vessel arcade	1	0.20187004	0.20187004	1.60	0.2072
OP* localisation of visual acuity	1	0.34421294	0.34421294	2.72	0.0998
OP* superior detachment	1	0.40469845	0.40469845	3.20	0.0744
OP* total detachment	1	0.46859707	0.46859707	3.71	0.0550
OP* chain formation of breaks	1	0.09523902	0.09523902	0.75	0.3860

instance, our model in the pseudophakic group revealed an adjusted R-square of 0.3297, which corresponds to a nearly fourfold increase compared to the model without covariates (only surgery and surgeon remained), with an adjusted R-square of 0.0873. The corresponding values for the models in the phakic trial are 0.2894 (compared to 0.0925 for the reduced model).

Discussion

The main outcomes of the SPR Study were that in patients with RRD of medium complexity, the choice of surgical technique has a significant impact on the outcome. In phakic patients, better functional success could be achieved with SBS, whereas in pseudophakic patients, better anatomical outcomes were achieved with primary vitrectomy [2, 3]. The purpose of this study was to identify pre- and intraoperative risk factors that were associated with the functional outcome in all study subgroups of this prospective randomized trial. In the SPR Study, the surgical procedures PV and SB were standardised according to the surgeon techniques; however, individual differences still occurred, for example the intraoperative use of laser- or cryotherapy. These variations were included into this risk factor analysis. Several studies have investigated the association between pre- and intraoperative findings and functional outcome after retinal detachment surgery. The most relevant preoperative factors that have been associated with a better functional outcome in several studies are attached macula, better BCVA, younger age, no PVR, and shorter duration of retinal detachment [4–7]. But most studies used a retrospective multivariate analysis of consecutive, non-randomised case series. Although the SPR Study was not designed to evaluate prognostic factors for functional outcome, the prospective study offers detailed information from patients' medical history and intraoperative findings, which may facilitate the identification of novel predictive factors in the treatment of RRD patients. Another characteristic of the SPR Study was its exclusion of patients with preoperative PVR, which leads to a relatively homogenous cohort with RRD of medium complexity.

Table 5 Results of the ANCOVA analysis in the pseudophakic/ aphakic subtrial. Significance is given if $p \leq 0.05$

	DF	Type III SS	Mean Square	F Value	Pr>F
Surgeon	12	4.67933640	0.38994470	2.15	0.0151
OP	1	0.05524271	0.05524271	0.30	0.5818
Age	1	0.32976923	0.32976923	1.82	0.1791
Number of breaks	1	2.00369825	2.00369825	11.03	0.0010
Symptomatic visual loss	1	0.12815499	0.12815499	0.71	0.4017
Duration of symptoms>1 week	1	0.34312911	0.34312911	1.89	0.1706
Secondary cataract / capsular fibrosis	1	1.11206111	1.11206111	6.12	0.0141
Macula on/off	1	0.18416371	0.18416371	1.01	0.3150
Posterior capsule damage	1	0.43080502	0.43080502	2.37	0.1249
Category of visual acuity	1	0.33179236	0.33179236	1.83	0.1778
Subretinal heamorrhage during surgery	1	0.18941150	0.18941150	1.04	0.3082
Localisation of retinal detachment	1	0.43987277	0.43987277	2.42	0.1210
Intraoperative laser photocoagulation	1	0.79697474	0.79697474	4.39	0.0373
Intraoperative cryotherapy	1	0.03696230	0.03696230	0.20	0.6523
Inferior detachment	1	1.04447684	1.04447684	5.75	0.0173
One quadrant detachment	1	0.17530375	0.17530375	0.97	0.3269
Retinal break with elevated flaps	1	0.22394075	0.22394075	1.23	0.2680
Subretinal drainage	1	0.24221543	0.24221543	1.33	0.2493
OP* number of breaks	1	0.00402833	0.00402833	0.02	0.8817
OP* secondary cataract / capsule fibrosis	1	0.20789589	0.20789589	1.14	0.2858
OP* intraoperative use of lase	1	0.13445714	0.13445714	0.74	0.3904
OP* inferior detachment	1	0.85108534	0.85108534	4.69	0.0314
OP* subretinal draingae	1	0.00592552	0.00592552	0.03	0.8568

1. Visual acuity

In this analysis, we focused on final BCVA and not on changes between pre- and postoperative BCVA (the primary endpoint of the SPR Study). We categorized preoperative visual categories into two groups: BCVA≥1.0 logMAR and <1.0. Patients in both categories experienced remarkable visual improvement, which concurs with the results of Ross et al. [10]. In phakic, but not in pseudophakic or aphakic eyes, these preoperative visual categories are related to final BCVA results. Our results indicate that these categories may facilitate the assessment of final BCVA in phakic eyes from pre- and intraoperative findings, irrespective of the surgical method. Patients with a preoperative BCVA > 1.0 (logMAR) had a mean final visual acuity of 0.55 (logMAR/ SD 0.46), while those with a BCVA≤1.0 (logMAR) achieved a mean BCVA of 0.28 (logMAR/ SD 0.30). An association between functional outcome and preoperative BCVA has been found in other studies [10–21] and some authors have proposed preoperative BCVA as the most important variable related to the final visual result after retinal detachment surgery [22]. However, to the best of our knowledge, no other authors have performed this analysis differentiated according to lens status.

2. RRD extension

Although dissimilar in phakic and pseudophakic/ aphakic eyes, the extent and location of the detached retinal area seem to be a prognostic factor for visual function. In phakic eyes, total preoperative RRD and a retinal detachment central to vessel arcades were significantly associated with final BCVA, whereas an inferior detachment with breaks below the 4 and 8 o'clock positions was identified in pseudophakic/aphakic eyes. Reduced BCVA after total RRD was due to macular detachment, which was most likely associated with reduced visual function. On the other hand, the "macula attached/detached" parameter had no significant negative impact on the BCVA results in our final multivariate model. The correct preoperative assessment of macular status is difficult, as this may vary according to head position, and may be classified differently by several observers. Preoperative BCVA might be a better surrogate of macular status, and this was found to be associated with functional outcome. However, other studies reported the "macula detached" classification to be a relevant prognostic factor for functional outcome [6, 23–28].

Pseudophakic/aphakic eyes with inferior detachment and breaks below the 4 and 8 o'clock positions achieved worse functional results. Although this parameter should

not depend on the lens status, final visual acuity seems to be associated with worse inferior RRD presenting in pseudophakic or aphakic eyes, with breaks between the 4 and 8 o'clock positions.

3. Retinal breaks

The final BCVA was lower in eyes with more than one retinal break, irrespective of the lens status. Due to the study entry criteria (one or more retinal hole not treatable with a single 7.5 × 2.75 mm silastic sponge), which was more frequent than the other "large single break" inclusion criterion in the SPR Study patients. We also found "chain formation of breaks" associated with better visual outcome in phakic patients. One could speculate that retinal holes arranged in a chain formation resemble the clinical situation of a single, large retinal hole (e.g., multiple holes within a lattice degeneration). It would therefore be easier to identify and treat such an area compared to a more widespread arrangement of retinal breaks.

Another intraoperative finding was worse functional outcome after iatrogenic retinal holes during surgery in phakic eyes. This could be a retinotomy or an accidentally-induced retinal hole, and should warn the surgeon to prevent any additional breaks if possible. On the other hand, this negative affect on visual function by iatrogenic breaks most probably resembles a complicated retinal situation.

4. Secondary cataract/lens fibrosis

Secondary cataract or lens fibrosis related significantly to impaired functional outcome in the pseudophakic/aphakic subtrial. Reduced visualisation during surgery will naturally affect final results. Secondary cataract or lens fibrosis seems to be more relevant than reduced visualisation by cataract as measured using the LOCS III in phakic patients. As a consequence, particular attention should be paid when removing secondary cataract or lens fibrosis before retinal detachment surgery.

5. Intraoperative laser use

The intraoperative use of laser was associated with better visual outcome in the pseudophakic/aphakic group. We could not evaluate the influence of total laser area on functional outcome, as some surgeons prefer circular laser treatment in retinal detachment therapy. It is likely that extensive laser therapy prevents redetachment, but this criterion must be applied in a prospective clinical trial.

6. Duration of symptoms

In the phakic, but not the pseudophakic/aphakic subtrial, longer duration of symptoms was associated with a poorer functional outcome. We evaluated the two categories of symptoms according to duration≤1 week and >1 week. It seems likely that longer duration is accompanied by more advanced intraretinal changes during the early postoperative phase, as already described by Pastor [6].

Although other factors were discussed in previous studies, we could not confirm the relevance of duration of macular detachment (as it was not recorded in the SPR Study) [6, 23, 25, 26] and patient age [6, 23, 25, 29] to final visual results.

Because the investigation of risk factors associated with the anatomical success is based on completely different statistical methods which can not be given in this paper, we will continue our consideration concerning anatomical success in a forthcoming paper.

7. Limitations of the analysis

The outcome of surgery of RRD is influenced by a multitude of pre-, intra- and postoperative factors. Any analysis of factors and their correlation with the outcome is associated with three major problems. First, several presumably important risk factors can currently not be quantified satisfactorily for analysis in larger trials (for example, "quality" of the surgeon or the surgical intervention, extent of vitreous removal during vitrectomy, nature and strength of vitreoretinal adhesions, etc.). Second, many presumably important risk factors are still unknown (for example, intraretinal changes following retinal detachment that influence photoreceptor death and are likely to have an effect on functional outcome irrespective of the anatomical outcome or other factors). And third, possible but unidentified interactions between the known, unknown or difficult to quantify factors described above. It is, therefore, likely that several important risk factors or confounding factors associated with functional outcome following RRD surgery were not included into this analysis. The reason for this is that we had to limit this research to the quantifiable risk factors that were collected within the SPR Study and were available for statistical analysis. However, we think that this is the most detailed and comprehensive dataset of clinical risk factors collected within the setting of a prospective randomised multicentre trial in RRD surgery to date. We are, therefore, of the opinion that despite the above mentioned limitations, the analysis of factors available for analysis to date is worthwhile and of clinical importance.

Conclusion

In the pseudophakic subtrial, a lower final BCVA was associated with a higher number of breaks, the occurrence of secondary cataract/central capsular fibrosis, no laser treatment, and the occurrence of inferior detachment with breaks below the 4 and 8 o´clock positions.

In the phakic subtrial a lower final BCVA was associated with a higher number of breaks, duration of symptoms more than 1 week, lower preoperative visual acuity, retinal detachment central to vessel arcades, total detachment and no chain formation of breaks.

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