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Scleral buckling versus primary vitrectomy in rhegmatogenous retinal detachment (SPR Study): Design issues and implications

SPR Study Report No. 1

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The authors wrote this report on behalf of the SPR Study Group. A complete list of participants is given in the Appendix.

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Abstract *Background*: In patients with more complex rhegmatogenous retinal detachments (RRD) not complicated by proliferative vitreoretinopathy (PVR), the most appropriate operating method is controversial, and different surgeons use different techniques. The Scleral Buckling Versus Primary Vitrectomy in Rhegmatogenous Retinal Detachments Study (SPR Study) is designed to compare primary vitrectomy and scleral buckling techniques in these patients. *Methods*: The SPR Study is a multicentre, randomised, controlled clinical trial stratified by lens status. Patients with RRD which is not complicated by PVR grade B or C and which cannot be treated with a single meridional sponge are randomised to either scleral buckling or pars plana vitrectomy as first surgical intervention. Four hundred consecutive patients are to be recruited per subtrial (phakic and aphakic/pseudophakic patients), and followed up for 1 year. The primary endpoint (functional outcome) is the change in visual acuity. Secondary endpoints (anatomical outcome) include postoperative PVR, retinal reattachment and the number of reoperations necessary to achieve retinal reattachment. Twenty-seven institutions (49 surgeons) in six European countries have been recruited for participation in the study. *Conclusion*: The SPR Study is the first randomised prospective clinical trial to compare scleral buckling and primary vitrectomy in patients with RRD. The results of this study should enable vitreoretinal surgeons to improve the surgical therapy of patients with the more complicated manifestations of RRD.

Introduction

Rhegmatogenous retinal detachment (RRD) is defined as a separation of the neuro-retina from the retinal pigment epithelium, which is caused by a retinal break with subsequent shift of intraocular fluid and liquified vitreous into the subretinal space. If untreated, most RRD will progress to a complete detachment and result in loss of vision of the affected eye. The annual incidence of RRD is about 10 per 100,000 people [34, 37]; the most important risk factors for its development are a history of RRD in the fellow eye, myopia, history of cataract or other intraocular surgery and history of ocular trauma [37]. The proportion of aphakic/pseudophakic patients with RRD has increased to 30% during the past decade [1], due to the increasing numbers of cataract operations performed.

RRD can be treated with different surgical procedures. On the one hand, uncomplicated situations – i.e.

those with good visibility of the fundus, single breaks and/or a limited retinal detachment – are usually treated with scleral buckling techniques or pneumatic retinopexy [2, 7]. In approximately 90–95% of patients with uncomplicated RRD, final retinal reattachment can be achieved with these techniques [1, 2]. On the other hand, in complicated RRD – i.e. those with giant retinal tears, vitreous haemorrhage, breaks at the posterior pole or proliferative vitreoretinopathy (PVR) – pars plana vitrectomy with endotamponade, as established in 1971 by Machemer, is indicated [28, 29].

Between these two groups of RRD in which most surgeons would agree on the method for surgical repair, a large grey zone exists, where there is great controversy about the preferable operating method. These cases are typically RRD with multiple, large or unusually shaped breaks, breaks central to the equator or RRD in pseudophakic patients, in whom no break can be detected preoperatively. Therefore, RRD patients with near-identical pre-operative situations are currently treated using completely differing methods, the choice of which is dependent on the surgeon's individual preferences. As Wilkinson concluded in an editorial on this topic in 1998: "The best method of repairing a particular detachment will remain a matter of speculation and bias until more appropriate data are acquired" [43]. Presented here is the study design of the Scleral Buckling Versus Primary Vitrectomy in Rhegmatogenous Retinal Detachments Study (SPR Study), which aims to compare primary vitrectomy and scleral buckling techniques in patients with RRD not complicated by PVR.

Patients and methods

Objectives

In the SPR Study, a randomised prospective comparison of scleral buckling techniques and primary vitrectomy will be carried out in patients with RRD. The goal of the clinical trial is the improvement of the surgical therapy of RRD with regard to functional as well as anatomical success.

Outcome measures

The outcome of retinal detachment surgery will be evaluated using six main endpoint criteria: (1) Change in visual acuity (VA; logMAR scale) from the initial examination to visit 4 using letter-by-letter scoring on ETDRS charts [17], irrespective of any intermediate cataract surgery. Should a cataract be present at visit 4, cataract surgery is recommended and the VA 6 weeks after immediate cataract surgery is used. (2) Postoperative occurrence of PVR grade B or C, irrespective of any reoperation. (3) Retinal reattachment after 1 year without any "retina-affecting reoperation", defined as any manipulation that reattaches the retina or ensures its attachment (prophylaxis). "Retinal reattachment" refers to attachment of the retina central to the equator. (4) Retinal reattachment after 1 year (any kind of reoperation permitted). (5) Development of cataract in phakic eyes using the lens opacity classification system LOCS-III [11]. 'Development of cataract' means an increase of at least 1.0 on any of the LOCS-III grading scales from initial examination to visit 4. (6) Number of retina-affecting reoperations (see definition of endpoint 3). Endpoints 2, 3 and 4 will be assessed by the endpoint committee using photodocumentation.

Every patient has to be examined at four scheduled follow-up visits: within the 1st week after surgery; 8 weeks after surgery; 6 months after surgery; and 1 year after surgery. Additional examinations will be performed in the case of reoperations or at any additional unscheduled visit (e.g. because of concomitant therapy or adverse event).

Trial design

Due to differences in the preoperative pathological situations in phakic versus aphakic/pseudophakic patients [38] as well as in their postoperative course [36], this study is divided into two separately conducted parallel trials. The phakic trial has a fixed sample size parallel group design, while the aphakic/pseudophakic trial has a parallel group design with an adaptive interim analysis allowing the use of internal as well as external information (e.g. variance estimates from the first phase of the aphakic/pseudopakic trial phase and the completed phakic trial, respectively) in order to plan the second trial phase.

The trials will be carried out as randomised, controlled clinical prospective studies. In order to compare the two operating methods, the patients will be randomly assigned to one of two parallel groups (Fig. 1).

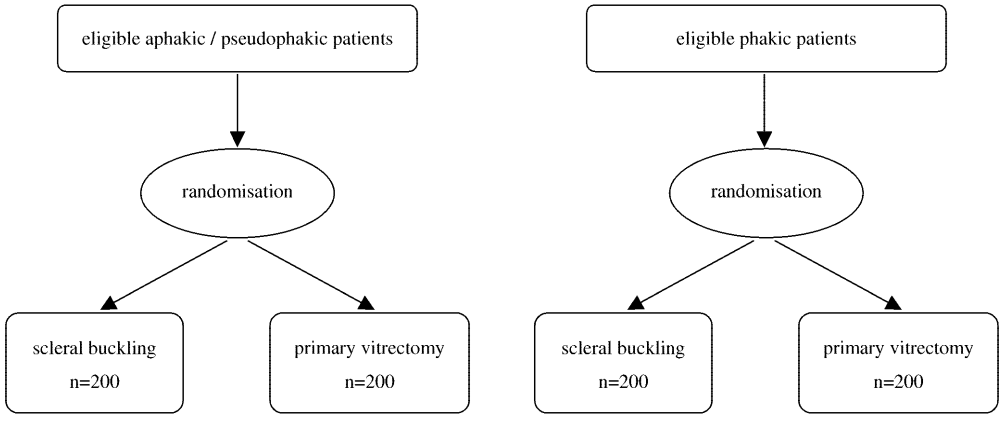

Fig. 1 Treatment strategy

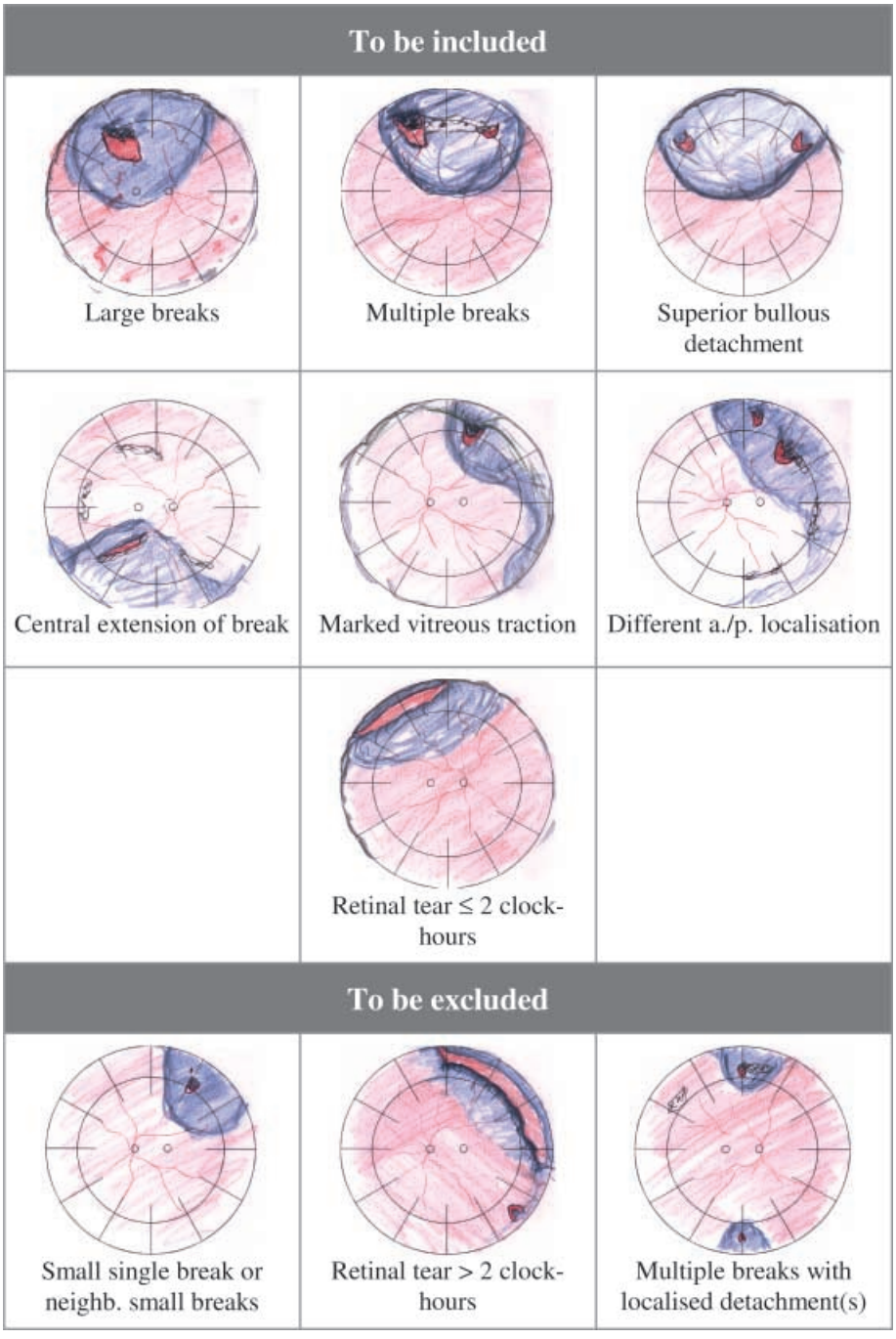

Fig. 2 Fundus drawings

Inclusion criteria

Preoperatively, "unclear hole situations" are present in a higher proportion of aphakic/pseudophakic patients than of phakic patients. Therefore, "unclear hole situations" have been included into the aphakia/pseudophakia group; they will be excluded from the phakic group. In the aphakia/pseudophakia group, only cataract operations without any damage to the posterior capsule or zonular dialysis are permitted; secondary YAG laser capsulotomy, however, can be performed. Patients with a history of cryotherapy or photocoagulation for retinal breaks can be included in both subtrials. The validity of inclusion criteria (Fig. 2, Table 1) will be checked by the acknowledged study surgeons and will be reviewed by the Endpoint Committee.

All patients with RRD presenting to the departments of ophthalmology performing this clinical trial are documented to support monitoring activities. After verification of eligibility criteria (including informed consent), randomisation (opening of prepared sealed envelopes) will take place immediately before surgery.

Table 1 Inclusion criteria

Aphakic/pseudophakic subtrial	Phakic subtrial
1. Aphakia/pseudophakia	1. Phakia
2. Unclear hole situation	2. Clear hole situation
3. One or more retinal holes which cannot be treated sufficiently with a single 7.5×2.75 mm Silastic sponge (e.g. large holes, multiple holes, multiple holes of varying anterior–posterior localisation, massive traction)	
4. Absence of breaks at or posterior to the vessel arcades	
5. Absence of PVR stage B or C according to Machemer et al. [29]	
6. Absence of other eye diseases that may significantly influence VA	
7. Absence of other intraocular operations apart from cataract surgery without implantation of an intraocular lens or with implantation of an intracapsular intraocular lens	7. Absence of intraocular operations
8. Absence of myopia of more than –7.0 diopters	
9. Absence of severe systemic disease that may alter the postoperative course of the healing process	
10. Absence of pregnancy	
11. Age ≥18 years	
12. Written consent	
13. Willingness and ability of the patient to participate in all follow-up examinations	
14. No participation of the patient in other studies	

Table 2 Operating procedures

Scleral buckling procedure	Primary vitrectomy procedure
1. Use of silicone sponges and/or silicone encircling bands or a combination of both according to the surgeon's choice	1. Standard three-port pars plana vitrectomy
2. Treatment of retinal breaks using cryopexy	2. Use of an encircling band based on the surgeon's decision (surgeons should apply their routine technique throughout the study, i.e. always use an additional encircling band or never)
3. Intraocular tamponade with injection of BSS, air or SF_6 (optional, no other gases permitted), if necessary	3. Removal of the flap of the retinal tear to reduce persistent traction on the break (optional)
4. Drainage of subretinal fluid with a needle or using electrolysis (optional)	4. Use of PFCL (optional)
5. Puncture of the anterior chamber (optional)	5. Treatment of the retinal break with cryotherapy or endolaser coagulation
	6. Intraocular tamponade with a 20–40% SF_6/air mixture (air, C_3F_8 or silicone oil not permitted as an initial tamponade)
	7. Draining retinotomies if needed

Surgical procedures

Two operating methods will be compared in this study. Study surgeons differ in their opinion about the necessity of an additional encircling band in primary vitrectomy. On the one hand, the encircling band is used as an ancillary tool to create scleral indentation for removal of the peripheral vitreous and/or for the support of equatorial and preequatorial breaks and/or to reduce tractional forces of peripheral vitreous remnants. On the other hand, some surgeons are of the opinion that an additional encircling band would not improve the results of primary vitrectomy. Therefore, according to the individual surgeon's standard protocol, an encircling band should either always or never be used in this study when performing primary vitrectomy. As a result, this study should also obtain adequate data to evaluate the necessity of an additional encircling band in primary vitrectomy. The operating procedures fixed in the study protocol are described in Table 2.

Reoperations and other medical interventions can be performed at any time depending on the surgeon's decision and on the patient's consent. The surgeon is allowed to use any additional tool or method if anatomical success cannot be achieved with the assigned procedure alone (e.g. performing an additional vitrectomy if anatomical success cannot be achieved with scleral buckling alone during the first intervention). The possible effect of treatment crossovers, i.e. primary vitrectomy following scleral buckling, or vice versa, will be assessed and contingently incorporated into the statistical model for analysis of the primary endpoint.

Study centres and surgeons

The study protocol was approved by the ethics committees responsible for the 27 participating centres in Austria, France, Germany, UK, Sweden and Switzerland, with 49 surgeons participating in this trial. In order to participate in the study, a surgeon had to have performed a minimum of 100 scleral buckling procedures and 100 vitrectomies according to his/her own documented operating catalogue. Randomisation and statistical analysis will be performed stratified by surgeon. Data regarding surgeons with fewer than 10 patients recruited per subtrial will be collapsed for statistical analysis.

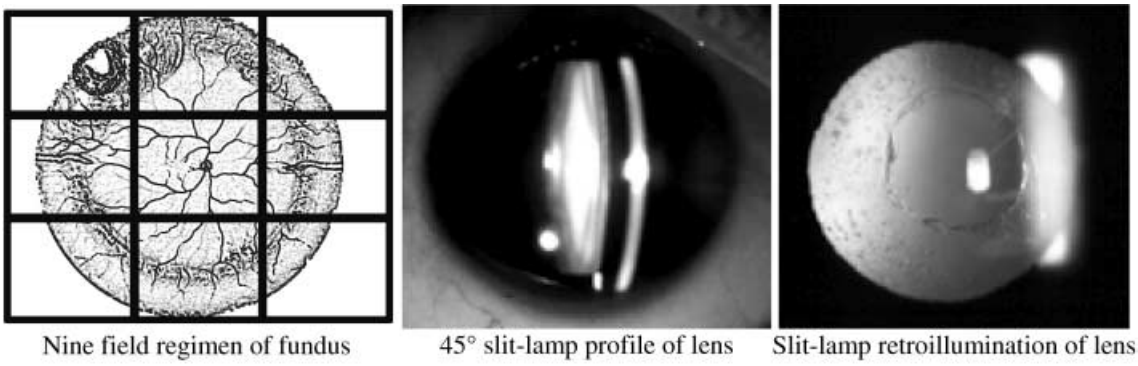

Fig. 3 Example set

Statistical aspects

Sample size

Recent retrospective data regarding the primary endpoint criterion "change of VA" have only been published for the population of aphakic/pseudophakic patients. Based on these data, a mean change in VA (measured as the difference from the preoperative value on logMAR scale) of 0.50 (SD 0.75) is to be expected in the vitrectomy group and of 0.20 (SD 0.85) for the scleral buckling group [4]. This approximately resembles a low (Δ=0.2) to medium (Δ=0.4) effect according to Cohen [12]. Assuming a 10–20% drop-out rate, 200 patients per treatment group are reasonable for comparison of the mean difference in VA between the two groups of patients (Δ=0.35, power=90%). Due to the lack of reliable data regarding the primary endpoint criterion "change of VA" in phakic patients, the same number of patients per treatment group (n=200) will be recruited in the phakic subtrial. Statistical units of the study are the patients. As simultaneous operative treatment of rhegmatogenous ablatio retinae in both eyes is rare, an intraindividual comparison of both operating methods is not indicated. Hence, only one eye per patient will be included in the study. If both eyes of one patient fulfil the inclusion criteria, the surgeon will determine which eye will be used.

Since the recruitment rate in the aphakic/pseudophakic subtrial persistently fell below target during the first recruitment year (August 1998 to July 1999), the inclusion criteria were extended and the trial design was modified (see below). Following randomisation of the 400th phakic patient, both subtrials will be stopped. The phakic subtrial will be evaluated according to fixed sample reasoning, whereas an adaptive interim analysis [5] will be conducted in the aphakic/pseudophakic subtrial. Originally, an adaptive interim analysis was planned in the phakic subtrial, in order to obtain reliable data for power estimation and design of a second trial stage, whilst the aphakic/pseudophakic trial was to be evaluated according to fixed sample reasoning. The exchange became necessary because the recruitment rate of aphakic/pseudophakic patients did not meet the initial expectation.

Randomisation, blinding

Randomisation is carried out in permuted blocks of varying size, stratified by the surgeon, and takes place in the operating theatre following the preoperative fundoscopy, which must be performed for final confirmation of the inclusion criteria.

"Blinding" of the measurement of the main endpoint criterion "change in VA" was not performed for practical reasons, e.g. lack of manpower. However, the endpoint criteria 2–4 see (Outcome measures) will be blindly assessed by the Endpoint Committee.

Statistical analysis

In both subtrials, the two operating methods will be compared based on the differences in VA using separate two-factor analysis of variance models (factor "operation method"; block factor "surgeon"; no interaction). Any missing postoperative VA value will be substituted by the last postoperative value recorded. In the event that no postoperative value is available or the pre-operative value is missing, the corresponding worst case scenario will be adopted. The test of the main effect "operating method" will be performed at the two-sided 5% significance level. While the phakic subtrial will be analysed according to fixed sample reasoning, an adaptive interim analysis will be performed in the aphakic/pseudophakic subtrial (see Trial design) [5,6]. Complete details on statistical analysis of outcome variables will be specified in the statistical analysis plan, a study document to be finalised well before any inspection of study patient data.

Study progress

Monitoring

Standardisation of VA and cataract measurement was realised by training of surgeons at a study meeting. Moreover, the staff of individual centres involved in the trial were intensively instructed during "on site" monitoring in usage of ETDRS charts and LOCS-III. Hereby, illumination of charts (>1000 lux) and examination rooms (<150 lux) was checked. In most centres, the examination rooms were completely darkened. Distance for VA testing was verified to be 4 m.

Evaluation of photodocumentation with examples

Prior to patient recruitment, the quality of the photographic documentation of individual centres was assessed by the Endpoint Committee using specific test slides of the ocular fundus (nine-field regimen), 45° slit-lamp profile, and slit-lamp retroillumination (see Fig. 3). Sample photographs were submitted by 22 centres; of these, 11 sets (50%) were found acceptable and 6 sets (27%) were improved in two revisions. All surgeons with insufficient documentation were urged to improve their standards.

Evaluation of extended recruitment list

All patients suffering from a primary retinal detachment are to be documented in an extended recruitment list including reason(s) for exclusion and coloured fundus drawings. Statistical analysis of 645 valid records obtained up to 10 July 10 1999 showed that in 44 of 199 aphakic/pseudophakic eyes, an "unclear hole situation" (exclusion criterion) was present. These eyes had been operated

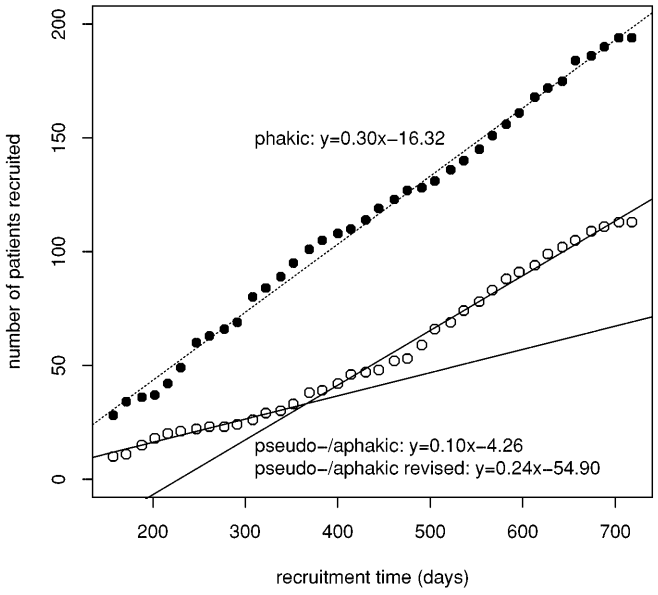

Fig. 4 Study prognosis by 6 July 2000

on using either the scleral buckling technique (21 cases) or vitrectomy (23 cases), demonstrating that neither technique appears superior. Moreover, the analysis results motivated a more specific definition of other eye diseases, systemic diseases and concomitant therapies to be excluded. Collection of recruitment data will be continued until December 2000. The detailed statistical analysis of this epidemiological dataset will be published elsewhere.

Extension of inclusion criteria

Modified inclusion criteria for aphakic/pseudophakic patients to participate in the study are: (1) "Unclear hole situation"; (2) absence of other eye diseases, in particular, retinopathy in diabetic patients; (3) absence of any systemic disease affecting the study eye (NB: diabetic patients without retinopathy are eligible); and (4) absence of therapy with acetazolamide or warfarin. Modifications 2, 3 and 4, plus systemic steroids, have also been adopted for phakic patients.

Prediction of study progress

On 6 July 2000, recruitment time varied from 56 to 708 days per surgeon (mean 570.8, SD 159.1). During this period, a maximum of 8 aphakic/pseudophakic and 19 phakic patients were recruited per surgeon leading to a total of 113 aphakic/pseudophakic and 194 phakic patients. The slope of total recruitment number versus time was nearly constant in the phakic subtrial (0.30) with expected remaining recruitment time of 1.88 years. However, in the aphakic/pseudophakic group of patients, the modified inclusion criteria led to a substantial increase in the slope. Up to the study meeting on 10 July 1999, a slope of 0.10 (recruited patients per day) was observed, whereas the slope on 6 July 2000 was 0.24, leading to a decrease of expected remaining recruitment time (target: 400 patients) from 9.13 years to 3.27 years. The recruitment progress from 29 July 1998 to 6 July 2000 is shown in Fig. 4.

Discussion

Since 1983, the indications for so-called primary vitrectomy (i.e. vitrectomy as the first intraocular surgery) in RRD have expanded to include less complicated situations which would have previously been treated with scleral buckling techniques [24, 40, 41]. During the past 15 years, primary vitrectomy for RRD has rapidly gained popularity, in contrast to the decreasing number of scleral buckling procedures performed [1]. The advantages of vitrectomy include the better intraoperative control of complicated RRD than with scleral buckling surgery and the avoidance of complications typically associated with the latter technique [18, 31]. Further, due to the expanding spectrum of indications, vitreoretinal surgeons currently perform a much greater number of vitrectomies than previously [1, 27]; they are, therefore, more familiar with this technique in more challenging situations than they are with scleral buckling. This is particularly true for vitreoretinal surgeons who started their surgical training in the 1990s.

It remains unclear, however, whether better anatomical and functional results can be achieved in uncomplicated RRD with primary vitrectomy than with scleral buckling. A review of the current literature disclosed more than 20 series of primary vitrectomy for RRD in which the indications for vitrectomy are similar to the inclusion criteria of the SPR Study [3, 8, 9, 10, 13, 14, 15, 16, 19, 20, 21, 22, 23, 25, 31, 32, 33, 39, 41, 44, 45]. The reattachment rates with one operation vary between 64% [21] and 100% [9, 14]. The rate of final anatomical success varied between 82% [20] and 100% [9, 14, 32]. A VA of 0.4 or better was noted in 32% [15] to 90% [13] of cases. Postoperative PVR occurred in 0% [9, 13, 14, 15, 32, 39] to 20% [20] of cases. Based on these data, a conclusion cannot be drawn concerning the superiority of either technique with regard to anatomical and functional results.

Of further interest is that the techniques used to perform primary vitrectomy vary significantly among as well as within the individual studies. For example, primary vitrectomy followed by additional scleral buckling was either never used at all [8, 10, 21, 23], was performed in some or selected cases [9, 19, 20, 31, 32] or was applied in all cases [3, 14, 41, 44, 45]. It is unclear whether scleral buckling plus primary vitrectomy increases the success rate or adds further complications to the procedure, as comparable success rates have been achieved with and without scleral buckling. Further, four different types of tamponades have been used (air, SF_6, C_3F_8 and silicone oil). This stresses not only the great diversity of indications used for primary vitrectomy but also the differing opinions of experienced vitreoretinal surgeons regarding the technical details of the operating procedure.

A comparison of published results of primary vitrectomy to those of scleral buckling techniques is difficult, as in most series of scleral buckling techniques the indications for surgery do not match those of primary vitrectomy. Irrespective of the initial morphology, retinal reattachment can be achieved with one scleral buckling procedure in about 80% of cases with RRD, and with one or more operations in 90–95% [1, 35]. No major improvements in reattachment rates could be observed during the past decade [35]. Two studies published recently compared scleral buckling techniques with primary vitrectomy in a retrospective manner [8, 32]. Both groups found equivalent reattachment rates between 89% and 92% for each method. This further underlines that, to date, there is no evidence for the supremacy of one of the two operating methods in the situations that have been included in the SPR Study.

In conclusion, primary vitrectomy or scleral buckling techniques, or a combination of both, are used currently in comparable situations of average complexity, with the choice of method depending solely on the individual surgeon's preferences. Since it is unlikely that two different surgical methods result in a comparable anatomical and functional outcome as well as a similar complication rate [43], a randomised prospective clinical trial is required to compare primary vitrectomy and scleral buckling in the treatment of RRD [26, 43]. The SPR Study is designed to prospectively compare scleral buckling and primary vitrectomy in RRD in a randomised fashion. The results of this study will provide adequate data to determine the best method for repairing more complex manifestations of RRD.

Finally, two points need to be stressed. Firstly, it is not astonishing that the 49 participating surgeons differ in their judgement of the clinical situation and, thus, the choice of the surgical procedure to be applied. This may best be expressed by the inclusion criterion "one or more retinal holes which cannot be treated sufficiently with a single 7.5×2.75 mm Silastic sponge". However, the consensus reached over the inclusion criteria is supported by all participating surgeons located in various clinics and countries. Secondly, the operational procedures for randomisation and blindness to the allocated treatment had to be chosen for good practical reasons, but, nevertheless are prone to criticism. These procedures are unlikely to affect the validity of the data, which, in any case, will be cross-checked in various ways. Hence, the study will provide valid data to answer the questions formulated.

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Appendix: Participants

Principal investigators. M.H. Foerster, W. Lehmacher

Study co-ordinator R.-D. Hilgers

Endpoint committee (photographic readers). N. Bornfeld, K.-U. Bartz-Schmidt, H. Heimann, R.-D. Hilgers, M. Hellmich

Advisory board. M.H. Foerster, P. Bauer, K. Lemmen

Biostatisticians and data managers. W. Lehmacher, R.-D. Hilgers, M. Hellmich, H. Christ, K. Schnürer, M. Frackowiak

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