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Research Article

Pars Plana Vitrectomy and Cataract Surgery in Cases with Macular or Retinal Pathologies Comparing Conventional Phacoemulsification to Femtosecond Laser-Assisted Cataract Surgery: One Year Results of A Randomized Clinical Trial

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Abstract

Introduction: To compare safety and surgical outcomes of combined cataract and vitreoretinal surgery using conventional phacoemulsification or femtosecond laser-assisted cataract removal (FLACS) in eyes with vitreoretinal pathologies undergoing pars plana vitrectomy (PPV). **Methods:** This study included 125 eyes of 122 patients, undergoing PPV in combination with cataract surgery. Prior to PPV, 62 eyes were randomized to FLACS and 63 eyes were randomized to conventional phacoemulsification cataract surgery. Endothelial cell count (ECC), central corneal thickness (CCT), retinal thickness and corrected distance visual acuity (CDVA) were evaluated preoperatively and at intervals up to 12 months post-operatively. Intraoperative and postoperative complications were also recorded. **Results:** At 12 months post-operatively, gains in CDVA were statistically higher in eyes randomized to FLACS. Additionally, ECC loss was significantly lower and significant reductions in corneal pachymetry were observed until the Day 10 postoperative visit. No significant differences in macular thickness parameters were observed. **Discussion:** Vitrectomy combined with FLACS demonstrated significant advantages associated with postoperative improvement in CDVA and endothelial cell loss, with no increased risk of cystoid macular edema.

Keywords: Macular pathology; Femtovitrectomy; FLACS; Phacoemulsification; Sutureless vitrectomy**.**

Introduction

Vitreoretinal pathologies such as macular holes or epiretinal membranes are often associated with reduced reading ability and metamorphopsia. Additionally, a concurrent senile cataract can also negatively affect visual acuity and the ability to visualize retinal pathology during examination. In order to achieve rapid visual improvement for these patients and increase the surgical field of view, a combined approach incorporating cataract removal, followed by pars plana vitrectomy (PPV) is becoming the preferred approach for vitreoretinal surgeons. Combining these procedures minimizes the risk of postoperative PPV cataract development and provides the opportunity to completely fill the vitreous cavity with retinal tamponade. In concurrent cataract and retinal procedures, it is extremely important to confirm stable intraocular lens (IOL) position, prior to initiating PPV. In eyes with a compromised red reflex, the creation of a well-centered continuous curvilinear capsulorhexis can be difficult [1,2]. Any deviation in size or centration of the IOL can cause it to tilt during further surgical manipulation and require repositioning following a fluid-air or gas exchange, which can be challenging. Further manipulation of the IOL postoperatively can lead to complications such as iris-capture and negatively affect visual performance.

Recent publications have provided evidence that cataract surgery combined with Femtosecond laser-assistance (FLACS) is a safe and reliable new surgical approach [3-5]. Intra- and early postoperative results comparing standard phacoemulsification with FLACS in combination with PPV indicated that the laser approach provides a stable IOL position with fewer complications during the first week of postoperative follow-up [6]. Until now, no long term data has been available comparing standard phacoemulsification with FLACS in combination with PPV. The current study has assessed postoperative corrected distance visual acuity (CDVA), postoperative anterior chamber stability and evaluated potential impact of FLACS combined with PPV on endothelial cell loss, corneal thickening and macular thickness over 12 months of follow-up, compared with standard optimized phacoemulsification and PPV.

Methods

Study design and oversight

In this prospective, randomized study, all patients underwent combined cataract surgery and PPV to treat surgery retinal disease, performed by a single surgeon at one clinical site. The study was reviewed and approved by the local Institutional Review Board (reference S-606/2016) and study conduct complied with the Declaration of Helsinki and followed International Conference on Harmonization (ICH) Guidelines for Good Clinical Practice. All participating patients provided written informed consent and understood that study participation was voluntary.

Study treatment

The details of the surgical techniques, diagnostic procedures, inclusion criteria and intraoperative and early postoperative complications have been described previously [6]. Eyes meeting the inclusion criteria were randomized (1:1) to undergo FLACS or conventional phacoemulsification cataract surgery prior to PPV. Randomization was performed using a computer-generated sequence (provided from the institutional IT-service).

Following randomization, those eyes in the conventional phacoemulsification group (n = 66) underwent cataract removal with Stellaris Elite (Bausch & Lomb, USA). For those randomized to FLACS (n = 65 eyes) the femtosecond laser procedure was performed with Catalys Precision Laser System (Johnson & Johnson, USA) to create the capsulotomy and perform lens fragmentation [6]. A monofocal, single-piece IOL (TECNIS PCB00, Johnson & Johnson) was implanted in all eyes prior to proceeding to PPV. A 23-gauge PPV was performed in all eyes, using the Stellaris Elite platform. According to the underlying retinal pathology, membrane peeling, removal of the ILM, fluid-air exchange and gas endotamponade was performed.

To ensure comparability between treatment groups, the volume of irrigation fluid used during lens removal for each group was recorded. Following surgery, the unused fluid volume was measured and subtracted from the original 500ml balanced salt solution (BSS) bottle volume. The fluid volume used for priming of the phacoemulsification machine prior to surgery is constant and had not to be calculated separately. Additionally, the surgical time for the phacoemulsification procedure without PPV was documented. For this study cohort, effective phacoemulsification time (EPT), additional surgical steps required to regain stable IOL-position, intra- and early postoperative overlap of capsulorhexis/capsulotomy and IOL optics have been previously published [6].

Study assessments

The primary outcome of the study was the change in corrected distance visual acuity from baseline (pre-operatively) to 12 months postoperatively. Secondary outcomes included changes in corneal pachymetry and corneal endothelial cell counts, anterior chamber and macular parameters, as well as anterior and posterior segment intra- and postoperative complications. Study assessments were performed preoperatively and postoperatively by one of two masked physicians at Day 10, Month 1, Month 3, Month 6, and Month 12 follow-up visits. Best-corrected distance visual acuity was measured using Early Treatment of Diabetic Retinopathy Study (ETDRS) charts. Heidelberg Spectralis optical coherence tomography (OCT) (1.8.6.0, Heidelberg Engineering, Germany) was used to assess macular parameters, including mean retinal thickness, central macular thickness (6.0 mm macular zone) as well as central foveal thickness (1.0 mm diameter central circle), per parameters based on ETDRS. Endothelial cell count (ECC) and corneal thickness were measured preoperatively, and 1 day and 3-4 days postoperatively (only pachymetry), 7-10 days, 50-

60 days, 90-100 days and one year postoperatively by one of two masked physicians. The Sea Eagle endothelial non-contact computer-assisted specular microscope (Rhine-Tec, Germany) was used to objectively assess ECCs. Scheimpflug cross-sectioning anterior segment imaging (Pentacam HR, Oculus, Germany) was performed to provide corneal pachymetry data. This allowed for calculation of absolute hexagonal cell values in addition to the percentage loss in ECC, using the previously published formula [7].

Statistical Analysis

The planned enrollment was based on the statistical power calculation of the previous study [7], which would provide >80% statistical power to detect a statistically significant difference between groups, by means of a 2-sample Wilcoxon test at a 5% significance level. Descriptive statistics were used to summarize all participant characteristics and pre-operative and post-operative assessment data, as well as changes over the study period. Results for each treatment group were depicted in box plots or presented in tables containing mean, standard deviation (SD), median, minimum and maximum values. T-tests were used to compare sample means and P-values less than 0.05 were considered to be statistically significant. Analyses was performed using SPSS Version 27.0 (SPSS Inc., USA).

Results

A total of 111 eyes were enrolled and randomized into the study. During the 12 month study, three eyes of three patients in both groups were lost to follow-up, did not complete their final follow-up visit, and were therefore excluded from the final analyses. At the end of the study, 63 eyes of 62 patients received conventional phacoemulsification followed by PPV, and 62 eyes of 60 patients were treated by FLACS combined with PPV, completed their 12 month follow-up visit.

Participant demographics, baseline characteristics and retinal pathologies are presented in Table 1. No significant differences were observed between groups. At 12 month follow-up visit mean decimal DCVA was 0.70 (SD 0.27; median 0.63; 0.1 to 1.0) in the FLACS group in comparison to 0.65 (SD 0.27; median 0.80; 0.05 to 1.0) in the conventional phacoemulsification group. The changes in CDVA are presented in Figure 1. One eye of the conventional phacoemulsification, that underwent PPV for retinal detachment lost one line of CDVA, while all other eyes remained stable or gained lines in visual acuity at one year follow-up in comparison to assessed preoperative CDVA. Postoperatively, cystoid macular edema (CME) occurred in three eyes in the FLACS group (1 eye with a macula involved retinal detachment, 2 eyes with macular pucker) and five eyes in the conventional phacoemulsification group (2 eyes with retinal detachment, 1 eye with macular hole, 1 eye with macular pucker, 1 eye with vitreous haemorrhage associated with proliferative diabetic retinopathy).

	FLACS* group	**Standard** group**
Number (of eyes)	62	63
Number of patients	60	62
Age (years)	65.4 +/- 9.6 median: 67.6	63.0 +/- 10.8 median: 64.3
Gender (male / female)	30/32	32/31
Eyes of a female patient (%)	52	49
CDVA (Decimal)	0.26 ± 0.21 median: 0.25 (0.00 - 0.63)	0.27 ± 0.20 Median: 0.28 (0.00 - 0.63)
Axial Length (mm)	23.68 mm ± 1.08 median: 23.73 (21.83 - 27.05 mm)	23.59 mm ± 1.09 median: 23.71 (21.88 - 27.13 mm)

Pentacam Nucleus Staging	1.1 +/- 0.8 (median: 1.0)	1.1 +/- 0.9 (median: 1.0)
Pentacam Nucleus Density 1 (%)	10.9 +/- 2.0 (median: 10.7)	10.8 +/- 2.3 (median: 10.6)
Pentacam Nucleus Density 2 (%)	10.7 +/- 3.3 (median: 10.2)	10.5+/- 1.9 (median: 10.0)
Macular pucker / hole	24 (39%) / 12 (19%)	21 (33%) / 13 (21%)
Vitreous hemorrhage	11 (18%)	12 (19%)
Retinal detachment	15 (24%)	17 (27%)
OCT analysed eyes	54 (87%)	55 (87%)
Macular pucker / hole	24/12	21/13
Vitreous haemorrhage	5	7
Retinal detachment with “macula-on”	13	14

Table 1: Demographics and Baseline Ocular Characteristics; *FLACS - femtosecond laser-assisted cataract surgery; ** Standard - conventional phacoemulsification.

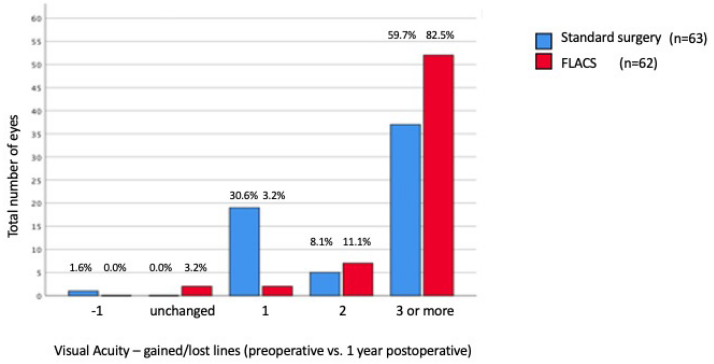

Figure 1: Safety - preoperative vs one year postoperative CDVA in the FLACS group and in the standard group.

Two eyes of the FLACS group received additional panretinal laser coagulation (1 eye with retinal detachment, 1 eye with proliferative diabetic retinopathy) and one eye in the conventional phacoemulsification group with preoperative complete retinal traction detachment underwent a second surgery due to re-detachment of the retina four months after the initial surgery. Preoperative OCT could only be performed in eyes without retinal detachment of the macular area or dense vitreous hemorrhage. Although preoperative data was missing, these eyes were included in analysis of postoperative CME. Mean central retinal thickness and central foveal thickness values are illustrated in Figures 2 and 3. Preoperatively mean central retinal thickness was 388 µm (SD 84) in the FLACS group and 414 µm (SD 107) in the conventional phacoemulsification group. One month postoperatively, the mean central retinal thickness in the FLACS group was 357 µm (SD 72), 351 µm (SD 65) at three months, 339 µm (SD 61) at six months and 327 µm (SD 60) at the 12 month follow-

up. In the conventional phacoemulsification group mean central retinal thickness was 379 µm (SD 96) one month postoperatively, 369 µm (SD 80) at three months, 357 µm (SD 75) at six months and 343 µm (SD 74) at 12 months. Mean central retinal thickness and central foveal thickness were not significantly different between groups at each follow-up visit.

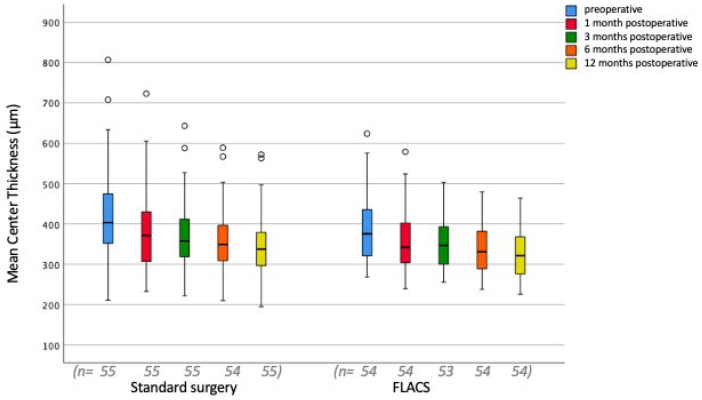

Figure 2: Boxplot of retinal mean center thickness from preoperative values over one year follow up time. The bottom and top of the box are the 25th and 75th percentiles, respectively, and the band near the center is the 50th percentile (median). The bars outside the box indicate the maximum and minimum of all data. A minor outlier (denoted by a small circle) is an observation 1.5 x interquartile range outside the central box; The change is statistically significant not different over the whole postoperative period ($p<0.001$).

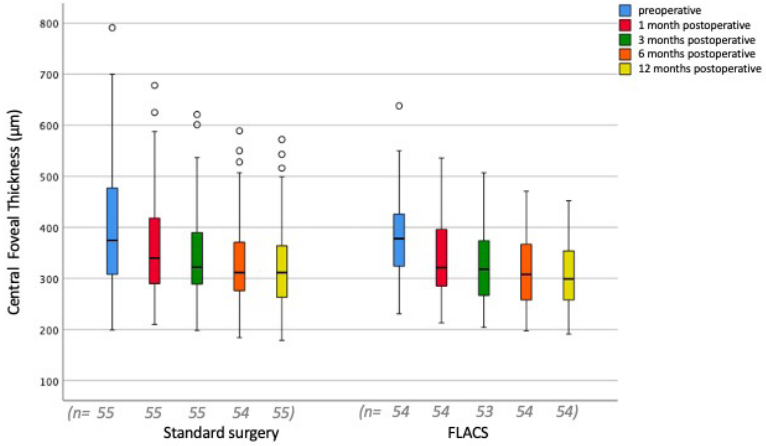

Figure 3: Boxplot of retinal central foveal thickness from preoperative values over one year follow up time. The bottom and top of the box are the 25th and 75th percentiles, respectively, and the band near the center is the 50th percentile (median). The bars outside the box indicate the maximum and minimum of all data. A minor outlier (denoted by a small circle) is an observation 1.5 x interquartile range outside the central box; The change is not statistically significant different over the whole postoperative period ($p<0.001$).

The absolute endothelial cell counts did not demonstrate any statistically significant differences over time. In the FLACS group the absolute endothelial cell values changed from 2431 cells/mm^2 (SD 312; range 1743 to 3152) preoperatively, to postoperatively, 2336 cells/mm^2 (SD 295) at one week, 2362 cells/mm^2 (SD 301) at three months, 2401 cells/mm^2 (SD 310) at six months and 2394 cells/mm^2 (SD 313; range 1702 to 3111) at 12 months. In the conventional phacoemulsification group, absolute endothelial cell values (Figure 4) changed from 2612 cells/mm^2 (SD 239; range 1980 to 2109) preoperatively, to 2361 cells/mm^2 (SD 256) at one week, 2358 cells/mm^2 (SD 251) at three months, 2349 cells/mm^2 (SD 245) at six months and 2366 cells/mm^2 (SD 260, range 1763 to 2801) at twelve months postoperatively.

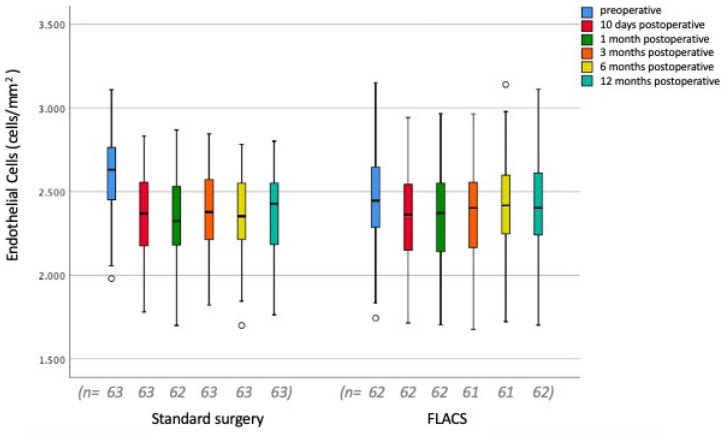

Figure 4: Boxplot of absolute central endothelial cell count over twelve months follow-up time; The bottom and top of the box are the 25th and 75th percentiles, respectively, and the band near the center is the 50th percentile (median). The bars outside the box indicate the maximum and minimum of all data. A minor outlier (denoted by a small circle) is an observation 1.5 x interquartile range outside the central box; The change is not statistically significant different over the whole postoperative period ($p<0.001$).

Relative change in corneal endothelial cell loss demonstrated significant differences between groups at all examination points and showed positive correlation with intraoperative EPT. Relative change in corneal endothelial cell loss from the preoperative evaluation (Figure 5) to one week postoperatively was 3.8 % (SD 3.2), 2.8 % (SD 2.7) after three months, 1.2% (SD 1.7) after six months and 1.5% (SD 3.5) at twelve months postoperatively in the FLACS group, compared to the conventional phacoemulsification group, which showed 9.6 % (SD 4.7) relative change in corneal endothelial cells loss at one week, 9.7 % (SD 4.7) after three months, 10.0 % (SD 4.8) after six months and 9.5 % (SD 5.2) at twelve months postoperatively. Corneal thickness was only significant different between groups at Day 1, Day 3, and Day 10, but not at any later time points (Figure 6).

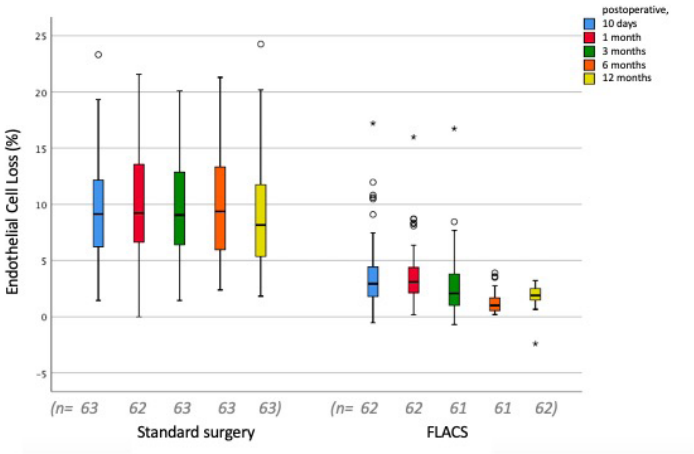

Figure 5: Boxplot of corneal endothelial cell loss (%) from preoperative values over twelve months follow-up time; The bottom and top of the box are the 25th and 75th percentiles, respectively, and the band near the center is the 50th percentile (median). The bars outside the box indicate the maximum and minimum of all data; A minor outlier (denoted by a small circle) is an observation 1.5 x interquartile range outside the central box; A major outlier (denoted by a *) is an observation 3.0 x interquartile range outside the central box; The change is not statistically significant different over the whole postoperative period ($p<0.001$).

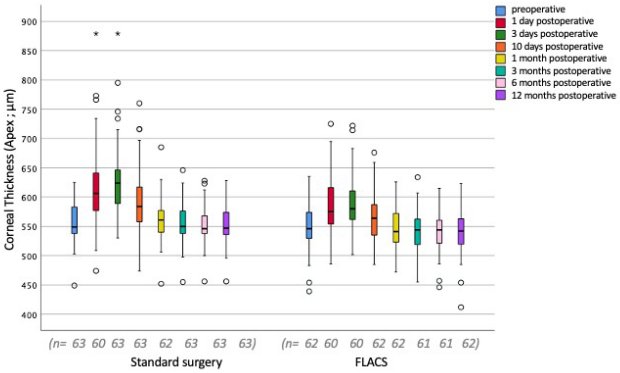

Figure 6: Boxplot of the corneal thickness (apex) from preoperative values over twelve months follow-up time; The bottom and top of the box are the 25th and 75th percentiles, respectively, and the band near the center is the 50th percentile (median); The bars outside the box indicate the maximum and minimum of all data; A minor outlier (denoted by a small circle) is an observation 1.5 x interquartile range outside the central box; A major outlier (denoted by a*) is an observation 3.0 x interquartile range outside the central box; The change is statistically significant different at 1 day, 3 days and 10 days follow-up, but not later on over the whole postoperative period ($p<0.001$).

EPT was significantly different (FLACS 0.21 ± 0.11 seconds (s) versus the conventional phacoemulsification group 1.39 s ± 1.15). Mean cataract surgery time was not significantly different, with 415 s ± 0.29 (341 s to 459 s) in the FLACS group and 407 s ± 0.25 (332 s to 465 s) in the conventional phacoemulsification group. There were also no significant differences in mean irrigation fluid volume, 97 ml ± 16 (74 ml to 121 ml) in the FLACS group and 94 ml ± 13 (72 ml to 115 ml) in the conventional phacoemulsification group.

Complications

All conventional phacoemulsification and FLACS procedures were uneventful. No intraoperative capsule complications occurred during phacoemulsification or IOL-implantation in either group. Elevated intraocular pressure (IOP) was observed in four eyes in the conventional phacoemulsification group (1 eye with retinal detachment: 25 mmHg, 3 eyes with macular pucker: 26 mmHg, 27 mmHg, 28 mmHg) at the Day 3 postoperative visit and in one eye at the Month 1 follow-up (vitreoretinal traction syndrome: 37 mmHg; steroid responder). Elevated IOP only occurred in one eye of the FLACS group at the Month 1 follow-up (macular pucker: 32 mmHg; steroid responder).

Discussion

FLACS has established advantages in cataract and refractive surgery procedures due to its reduced ultrasound energy, lower rates of postoperative inflammation and preservation of endothelial cells [8-13]. In the current prospective, randomized clinical trial we compared conventional phacoemulsification and FLACS in combination with PPV in eyes with retinal pathologies to determine if these noted advantages similarly translate into combined surgeries. All evaluated safety parameters such as visual acuity, endothelial cell count and corneal pachymetry and macular parameters over 12 months of follow-up revealed either equivalence or superiority in favor of the FLACS procedure.

The first, intra- and early postoperative, results of our study [6] focused on early IOL-dislocation and validated the advantage of creating an optimal capsular bag opening [14,15] providing a stable position for the IOL. This study also focused on changes in the anterior as well as posterior segment with regards to macular thickness changes, edema and visual recovery in both study groups. Despite the statement of Vote et al. [3], who noted that over time, the clinical indications for FLACS have become quite narrow, we conversely found benefits in all our cases where cataract surgery was to be combined with PPV. The benefits of FLACS for non-routine cataract surgery were confirmed by Alio et al. [5] and O´Brart et al. [16], but despite the costs of this promising and new technology, the advantages for its application in routine cataract cases was not clear. In eyes with both retinal pathology and cataract, whose combined surgeries are both intra- and postoperatively challenging, FLACS has been indicated in a variety of situations and therefore performed frequently. Jung et al. [1] and Gómez-Resa et al. [2] observed within their trials the distinct advantages of IOL stability and positioning, as well as efficacy of FLACS when combined with vitrectomy.

In our study analysis of CDVA analysis as a safety outcome, we were not able to compare the absolute ETDRS letter values, due to the presence of existing macular pathologies. Therefore, we evaluated the loss or gain of acuity lines after surgery and were able to demonstrate that both procedures were safe without any statistically significant differences postoperative. It is not uncommon for corneal changes to be observed following an uneventful anterior segment surgery with manipulation in the anterior chamber. Features such as thickening of stromal layers or endothelial changes can therefore contribute to longer duration of visual recovery in these eyes. The current study found that endothelial cell loss was less, in favor of those treated with FLACS, as many study groups have previously reported within the past decade [17]. Others that have compared conventional phacoemulsification and FLACS, e.g. Kelkar et al. [18]. reported similar and equal endothelial cell loss of less than 10% at 6 months postoperatively. Rates of postoperative macular changes and retinal complications in both groups were found to be equal, until the last follow-up visit. This highlights potential a limitation of the current study, by restricting the follow-up period to only 12 months.

Furthermore, preoperative OCT parameters could only be obtained in eyes without retinal detachment or vitreous hemorrhages, resulting in the exclusion of these eyes from the overall analysis of macular thickness data. Our reported macular thickness analysis

represents data from a smaller subgroup of each study arm with epiretinal membranes, macular holes or diabetic macular pathology, respectively. As such, strong conclusions cannot be made, but rather a limited statement on changes in macular thickness values over time is possible.

Within the current study, FLACS in combination with PPV in eyes with retinal disease and/or pathology has demonstrated not only intra- and early postoperative benefits, but also revealed advantages in long-term outcomes. This is evidenced by the change of visual acuity, reduced corneal endothelial cell loss, and corneal pachymetry until the 10th day postoperatively. It is important to note that in the current study no macular complications were associated with the FLACS procedure, within the short or long-term follow-up period.

In conclusion, FLACS provided a more reliably stable anterior segment in eyes requiring combined cataract and vitreoretinal surgery, without any disadvantages observed in long-term patient outcomes.

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Ethical consideration and informed consent statements

Consent to participate: written informed consent; Ethical approval S-606/2016 Heidelberg University.

Declaration of conflicting interest

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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