The effect of femtosecond laser assisted capsulotomies on the results of cataract surgery

PhD thesis

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Introduction

The pathogenesis of cataract is multifactorial however its aetiology has not been cleared adequately. Although no effective method has been known to prevent or slow its progression, cataract surgery is one of the most cost-effective health interventions.

Before the introduction of femtolasers to intraocular surgery the most significant innovation in the history of cataract surgery has been phacoemulsification, introduced by Kelman in 1967. Thanks to the development of the surgical technique and the technology of implanted intraocular lenses (IOL), cataract surgery nowadays can be performed at an early stage, even in the case of full visual acuity to correct refractive errors and presbyopia (clear lens extraction).

A well performed capsulorhexis is one of the key steps of cataract surgery. Precise refractive results can be achieved if the size and position of the capsulorhexis is ideal resulting in a perfect overlap between the anterior capsule and the rim of the IOL's optic. In this case due to the symmetric contractile forces of the capsular bag, displacement of the IOL, postoperative refractive changes, anterior and posterior capsule opacification can be significantly reduced.

Femtosecond laser provides a new, innovative technology in the field of cataract surgery. Femtosecond lasers utilize photodisruption to cut tissues. A strongly focused laser beam with ultra short pulse duration (400-800 fs) generates hot plasma, that expands as a shock wave, then loses energy and the cooling plasma vaporizes a small volume of tissue, forming a cavitation bubble. Incisions are created by coalescing cavitation bubbles that are formed side by side. Due to the low per pulse energy settings, no collateral tissue damage occurs.

The application of femtosecond laser during cataract surgery through individually planned and precisely implemented operative steps meets more precise pre- and intraoperative measurements .

As the anterior chamber depth and lens thickness are different in each case, an imaging method is needed to visualize the target tissue, i.e. the anterior lens capsule in the case of capsulotomy. The most of the femtosecond lasers on the market, similarly to the Alcon-LenSx platform, use anterior segment OCT to image lens position. The software automatically positions all cuts, then a cross-sectional image of the anterior segment appears on the display, showing the position of the incisions. After checking the settings, the surgeon may change them if necessary. The advantage of the method is that the size, plane and the position of all incisions can be modified.

The capsulotomy can be centred to the limbus, to the pupil centre or it can be placed anywhere in the area of the dilated pupil.

Its size can be varied freely taking into consideration the type of the implanted IOL or the diameter of its optic.

Regarding the extensive application of premium IOLs, judging postoperative IOL position parameters has become more important.

Retroillumination photographs taken by video slit lamp allow to measure IOL decentration from the centre of the dilated pupil with micrometer precision.

Using the diameter of the IOL optic as an intraocular reference marker, optical distortion effects due to the corneal and anatomical differences of the anterior chamber can be eliminated. With the aid of vector analysis not only the size but also the direction of decentration can be calculated. Using reference points, IOL rotation can be also measured. However, IOL tilt can not be evaluated with this method.

IOL tilt and decentration can be measured using Scheimpflug-images. During the Scheimpflug-imaging the plane of the object, the film and the objective are not parallel, that allows documentation of the entire anterior segment of the eye with good depth of focus. Diagnostic devices using Scheimpflug-principle (Pentacam, Galilei) take 25-100 pictures with monochromatic blue light in a few seconds rotating around the optical axis of the eye.

In the Scheimpflug-images the plane of the IOL, the centre of the IOL optic and its horizontal and vertical misalignment compared to the reference axis can be determined.

Determining the difference between perpendicular and the axis between the IOL optic and the reference plane, IOL tilt can be calculated along the x- and y- axis.

Purpose

The study series (A and B studies) aimed to examine the accuracy of femtolaser assisted capsulotomy, its effect on IOL position parameters and on the results of refractive cataract surgery.

A) Evaluation of femtolaser assisted capsulotomies and continuous curvilinear capsulorhexis (CCC) parameters and their effect on IOL centration.

1. To measure and compare sizing and positioning parameters of femtosecond laser capsulotomy with manual continuous curvilinear capsulorrhexis (CCC) and to evaluate the effect of these parameters on anterior capsule - IOL optic overlap.

2. To evaluate anterior capsule - IOL optic overlap after femtolaser assisted and continuous curvilinear capsulorhexis and its effect on postoperative IOL misalignment using retroillumination photographs.

B) Evaluation of IOL tilt and decentration following femtolaser assisted and continuous curvilinear capsulorhexis using Scheimpflug-camera.

3. To compare IOL decentration and tilt following femtolaser assisted and continuous curvilinear capsulorhexis using Scheimpflug-camera.

4. To evaluate IOL tilt and decentration following femtolaser assisted and continuous curvilinear capsulorhexis on postoperative refraction and visual acuity.

Methods

Patients

Patient examinations and surgeries were carried out in the Ophthalmology Department of Semmelweis University between 2009 and 2010. All patients went through a thoroughful ophthalmic examination before surgery. Patients with previous ocular surgery, trauma or active ocular disease, with non dilating pupils or with weak zonules were excluded from the studies.

The study was conducted in compliance with the Declaration of Helsinki, as well as with applicable country and local requirements regarding ethics committee/institutional review boards and other statutes or regulations regarding protection of the rights and welfare of human subjects participating in biomedical research (TUKEB number: 62/2008). A written informed consent was obtained prior to surgery from every patient.

A) Femtolaser assisted capsulotomy was performed in 20 eyes from 20 patients and a manual CCC was performed in 20 eyes from 20 other patients.

B) Femtolaser assisted capsulotomy was performed in 25 eyes from 25 patients and a manual CCC was performed in 20 eyes from 20 other patients.

Surgical technique

All surgeries were performed by the same experienced surgeon. The surgical technique was standardized in each patient, except for the method of capsulorrhexis. Randomization was done using computer-generated tables (Microsoft Excel; Microsoft Corp, Redmond, Washington). After pupillary dilation (1 drop of tropicamide 0.5% every 15 minutes X3) and instillation of topical anaesthetics (proparacaine HCl 0.5%), the laser was docked to the eye using a curved contact lens to applanate the cornea. The location of the crystalline lens surface was determined with an integrated optical coherence tomography imaging system. A 4.5-mm diameter capsulotomy procedure was performed by scanning a cylindrical pattern with 15 15 μJoule energy, starting at least 100 μm below the anterior capsule and ending at least 100 μm above the capsule.

A 4.5-mm capsulorrhexis, also centered on the dilated pupil, was attempted in the manual CCC group and per- formed with the aid of a cystotome and capsulorrhexis forceps. A marker was not used.

Corneal incisions and phacoemulsification were performed conventionally.
Incisions were done with a disposable keratome (Alcon Laboratories Inc, Ft Worth, Texas) in both groups, the main incision was performed superotemporally at 120 degrees. After hydrodissection, phacoemulsification of the nucleus and aspiration of the residual cortex was performed using the Accurus phacoemulsification machine (Alcon Laboratories Inc).
Hydrophobic acrylic IOLs were folded and implanted in the capsular bag with the aid of an injection cartridge through the corneal wound. Lens haptics were placed in the same position (at 3 and 9 o'clock).
As viscoelastic material cohesive, high molecular weight hyaluronate (ProVisc®, Alcon Laboratories Inc.) was used during the surgeries.
During the first study (A) one- and three- piece spherical IOLs (28/12), during the second study one-piece aspheric IOLs (SA60AT, Alcon Laboratories Inc) were used.
After IOL implantation, the viscoelastic material was removed from the anterior chamber and capsular bag by irrigation/aspiration. All incisions were left sutureless.
Intraocular lens power was calculated using the SRK-T formula
No intra- or post- operative complications occurred.
During the first 10 days, all patients received a combination of antibiotic and steroid eye drops (dexamethasone and tobramycin).

Measurements

A) To document capsulotomies, digital retroillumination photographs were taken 1 week, 1 month, and 1 year after surgery. Photographs were imported into Adobe Photoshop (Adobe Systems Inc, San Jose, California) for measuring IOL decentration and the following capsulotomy parameters: vertical and horizontal diameter, circularity, and the shortest and longest distance between the edge of capsulorrhexis and the IOL optic edge (distance min, distance max) along an elongated radius of capsulorrhexis. The diameter of the implanted IOL was used as a scale to eliminate the magnification effect of the cornea.
Intraocular lens decentration was evaluated according to Becker et al. The previously described method was altered by changing the reference point to the center of the pupil, because both the femtosecond capsulotomies and the manual procedures were aligned at the pupil center. To eliminate the effect of mydriatic drops on changing the position of the pupil center, the same amount and type of mydriatic drops were used to dilate patients' pupils before surgery and before taking the photographs.

Adobe Photoshop gives a vector (determined by its length and angle to the horizontal plane) between the pupil center and center of the IOL. The length of the vector shows the total IOL decentration. Horizontal and vertical decentration were calculated using trigonometry analysis. To determine the magnitude of horizontal and vertical decentration without reference to nasal/ temporal or up/down orientation, the absolute values of the above-mentioned parameters were counted.

Circularity is a parameter used for determining the regularity of capsulotomy shape according to the following formula: $circularity = 4\Pi\ (area/perimeter^2)$.

The quotient of the shortest and longest distance between the edge of the capsulorrhexis and the edge of the IOL optic was calculated to determine capsule–IOL overlap:

overlap=distance min/distance max.

Circularity and overlap values of 1.0 indicate a perfect circle and an absolute regularly overlapping anterior capsule on the optic of the implanted IOL, respectively.

Shifting of the visual axis from the pupil center was determined with a Lenstar biometer (Haag-Streit, Koeniz, Switzerland) in all eyes before and 1 year after cataract surgery.

B) A Scheimpflug imaging system (Pentacam; Oculus Optikgeräte GmbH, Wetzlar, Germany) was used to evaluate IOL tilt and decentration. Lens decentration and tilt were measured according to de Castro et al. as follows: IOL decentration is obtained from the distance between the IOL center and pupillary axis. Positive horizontal coordinates stand for nasal in the right eye and temporal in the left eye. Positive vertical coordinates stand for superior decentration, and negative for inferior ones. By eliminating positive and negative signs, the magnitude of horizontal and vertical decentration could be determined without reference to nasal/temporal and superior/inferior orientation, respectively. Total decentration, determined by trigonometry analysis, shows the magnitude of the result vector of horizontal and vertical decentration.

Regarding IOL tilt, positive tilt around the x-axis indicates that the superior edge of the IOL is moved forward, and vice versa for negative tilt. Positive tilt around the y-axis shows, in the right eye, nasal tilt and indicates that the nasal edge of the IOL is moved backward and vice versa for a negative tilt around the y-axis in right eyes. A positive tilt around the y-axis stands for temporal tilt (nasal edge of the IOL moves forward) in left eyes. By eliminating positive and negative signs, the magnitude of horizontal and vertical tilt could be determined without reference to any orientation.

Statistical analysis

Statistical analyses were performed with SPSS 16.0 (SPSS Inc, Chicago, Illinois). Departure from normal distribution assumption was tested by the Shapiro- Wilks W test.
Significance level was set at $p < 0.05$ in all statistical analyses.

A) Differences between the two groups of capsulorrhexis parameters were analysed using repeated measures analysis of variance (ANOVA) test with Newman- Keuls test.
To determine predictors of IOL decentration, logistic regression analyses were performed via univariable general estimating equation (GEE) models.
Chi-square test of homogeneity was applied to compare the distribution of dichotomized horizontal decentration values at 0.4 mm between the two study groups.
Correlations between vertical diameter and overlap parameters were analysed with Spearman rank correlation.

B) Differences between the two study groups in visual acuity and IOL tilt and decentration values were tested with t test for independent samples.
The chi-square test of homogeneity was applied to compare the distribution of dichotomized tilt and decentration values of 5° and 0.4 mm, respectively, between the study groups.
Due to non-normal distribution of values representing spherical equivalent changes postoperatively, correlation between IOL total decentration and spherical equivalent changes was analysed with Spearman rank correlation.
Linear regression analysis was performed to determine correlation between the absolute value of IOL vertical tilt and distance visual acuity.

Results

A) No statistically significant differences were noted between the femtosecond and CCC groups in regards to age and gender distribution, refractive status, and axial length (p›0.05).

Differences between the two groups of capsulorrhexis parameters were analysed using repeated measures analysis of variance (ANOVA) test with Newman- Keuls test.

Although capsulotomies were not perfectly round in the postoperative follow-up period in either the CCC or FS group, the femtolaser-assisted capsulotomies proved to be significantly more regular (0,86±0,01) compared to CCCs (0,83±0,02).

The vertical diameter of CCCs was significantly larger compared to the vertical diameter of femtolaser assisted capsulotomies 1 week (CCC vs. femto. caps.: 4,79±0,36 vs. 4,51±0,11) and 1 month (CCC vs. femto. caps.: 4,62±0,34 vs. 4,47±0,21) after surgery.

Statistically significant differences were observed in the shortest and longest distance between the edge of the IOL optic and the edge of the capsulorrhexis 1 week and 1 month after surgery (Distance min: CCC vs. femto. caps.: 1 week: 0,17±0,21 vs. 0,42±0,16; 1 month: 0,26 ±0,24 vs. 0,47±0,19; 1 year: 0,12±0,18vs. 0,46±0,16; Distance max: CCC vs. femto. caps.: 1 week: 1,09±0,21 vs. 0,95±0,17; 1 month: 1,12±0,17vs. 0,96±0,23; 1 year: 1,09±0,14 vs. 1,00±0,24).

Significantly higher values of overlap showed more regular capsulotomies in the femtosecond laser assisted capsulotomy group: CCC vs femto. caps.: 1 week: 0,17±0,19 vs. 0,47±0,24; 1 month: 0,24 ±0,23 vs. 0,53±0,25; 1 year: 0,13±0,19 vs. 0,54±0,31).

Horizontal decentration of the IOL was also significantly higher in the CCC group during the first year. **(**CCC vs femto. caps.: 1 week: 0,28±0,16 vs. 0,12±0,11; 1 month: 0,26±0,14 vs. 0,13±0,09; 1 year: 0,30±0,16 vs. 0,15±0,12).

The type of capsulorrhexis was found to be a significant predictor of horizontal decentration in the univariable GEE model (odds ratio [OR]: 5.95, 95% confidence limit [CL]: 1.58-22.22, P‹0.01). When predictors of horizontal IOL decentration were explored, only capsulorrhexis overlap showed a significant effect (P=.002) among all capsulorrhexis parameters. Decentration was not influenced by type of implanted IOL according to a GEE model (p›0.05).

No statistically significant differences in decentration values were noted between one-piece and three-piece IOLs according to repeated measurements ANOVA test with Newman- Keuls test (p›0.05).

The ratios of ›0.4 mm and ‹0.4 mm horizontal decentration values were 4/16, 3/17, and 5/15 eyes in the CCC group 1 week, 1 month, and 1 year after surgery, respectively. Horizontal decentration did not exceed 0.4 mm in any eye in the femtolaser assisted capsulotomy group (0/20 at all time points). Chi-square test of homogeneity was applied to compare the distribution of dichotomized horizontal decentration values at 0.4 mm between the two study groups. A statistically significant difference was found between groups at 1 week and 1 year postoperatively (p=0.035 and 0.016, respectively).
Vertical diameter demonstrated a statistically significant correlation to the overlap in the CCC group at all three time points (1 week: r=-0.91, p‹0.01; 1 month: r=-0.76, p‹0.01; and 1 year: r=-0.62, p‹0.01), whereas no significant correlation was noted between the two parameters in the femtosecond laser assisted capsulotomy group (p›0.05).

B) No statistically significant differences were noted in age, gender distribution, or axial length between the two study groups (p›0.05).
No significant differences were noted between the two groups in regards to UDVA at any postoperative time point (p›0,05). However, CDVA proved to be significantly better in the femtolaser assisted capsulotomy group 1 month and 1 year after surgery (CCC vs. femto. caps.: 1 month: 0,84±0,16 vs. 0,94±0,11 p=0,031; 1 year: 0,92±0,09 vs. 0,97±0,06 p=0,038).

Significant differences in centration and tilt were noted between the study groups:

- vertical and horizontal tilt was significantly higher in the CCC group (CCC vs. femto. caps.: vertical tilt: 4,34±2,40 vs. 2,15±1,41 p<0,001; horizontal tilt: 2,75±1,67 vs. 1,53±1,08 p=0,007).
- horizontal and total decentration was significantly higher in the CCC group as well (CCC vs. femto. caps.: horizontal decentration 270,83±190,85 vs. 164,25±113,78 p=0,034; total decentration: 334,91±169,67 vs. 230,27±111,54 p=0,022).

Applying the chi-square test of homogeneity to compare the distribution of dichotomized tilt and decentration values (at 5° and 0.4 mm, respectively) be-tween the study groups, a significant difference was found in vertical tilt and horizontal and total decentration. The ratios of ›5° and ‹5° vertical tilt values were 10/25 eyes in the CCC group and 1/20 eyes in the femtolaser assisted capsulotomy group (p=0.008). The ratios of ›0.4 mm and ‹0.4 mm horizontal decentration values were 6/25 eyes in the CCC group and 0/20 in the femtolaser assisted capsulotomy group (p=0.017).

A significant correlation was also noted between the absolute value of total decentration and the absolute value of changes in spherical manifest re-fraction between 1 month and 1 year postoperatively (R=0.33, P=0.032). Manifest refraction changes in spherical or cylindrical values did not show a correlation with IOL tilt parameters (P›0.05).
Linear regression analysis showed significant correlation between IOL vertical tilt and CDVA (R^2=0.17, β=-0.41, 95% confidence limit: :-0,69 - -0,1; p=.005).

Conclusions

During refractive cataract surgery significant clinical advantages can be achieved with femtolaser assisted capsulotomy thanks to its regular shape, and well controlled size and position.

1. According to our results, which were first published by our research group in international and national scientific journals, femtolaser assisted capsulotomies proved to be properly sized and significantly more regular compared to conventional manually performed continuous curvilinear capsulorhexis.

2. We have described for the first time, that due to the precise sizing and centration anterior capsule – IOL optic overlap becomes more even in the case of femtosecond laser assisted capsulotomies than manual continuous curvilinear capsulorhexis

3. More stable postoperative IOL positions (regarding IOL decentration and tilt) can be achieved through precise anterior capsule- IOL overlap in the case of femtosecond laser assisted capsulotomies.

4. We described first that clinically significantly less IOL decentration ant tilt can be measured after femtolaser assisted capsulotomies compared to manually performed continuous curvilinear capsulorhexis. We found IOL decentration was six times more likely to occur when capsulorrhexis was performed manually.

5. We were able to demonstrate for the first time, that more stable postoperative IOL position resulted in more stable postoperative refraction and better visual acuity (BCVA) in the case of femtolaser assisted capsulotomies. IOL decentration is responsible for changes in postoperative manifest refraction, while IOL tilt influences postoperative BCVA.

List of publications

List of publications related to the thesis

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