Evaluating the Impact of Laser-Assisted Lens Capsulotomy

There are two sides to the story.

BY LAURA STRAUB, EDITOR-IN-CHIEF, *CRST EUROPE*

The era of laser cataract surgery seems to be closing in. With a growing number of companies manufacturing femtosecond laser systems for cataract surgery and an abundance of surgeons not only using the technology but also proclaiming their positive results and enhanced postoperative outcomes, all arrows appear to be pointing toward a paradigm shift in the way cataract surgery is performed.

Or are they?

A growing body of evidence shows that a capsulorhexis created with a femtosecond laser can perhaps lead to a more stable refractive result,[1-10] with more precise capsulotomy sizing and centering,[1] better IOL-capsule overlap parameters,[1,2] and less IOL tilt and decentration[3] compared with a manual technique.

In the technology's infancy, He et al[4] suggested that femtosecond lasers for cataract surgery would produce the same advances—improved accuracy, reproducibility, and safety—that they have for refractive surgery. Reggiano-Mello and Krueger proposed that this may be "the most important evolution since the transition to phacoemulsification."[5]

In a more recent study, Hatch and Talamo outlined the benefits of and barriers to laser cataract surgery and concluded that the femtosecond laser "may significantly change the current approach to cataract surgery."[6]

Surgeons have known for many years that, in order to improve refractive outcomes after cataract surgery, they must accurately predict the postoperative lens position,[11,12] and some propose that one of the key determinants of an IOL's position and performance is the size and circularity of the anterior capsulotomy. If it is too small, retained lens epithelial cells (LECs) can cause fibrosis and lead to a hyperopic shift[13]; too large, and tilt, decentration, myopic shift, and posterior capsular opacification (PCO) are possibilities.[14-16] If femtosecond lasers can provide surgeons with the means to create more perfect capsulotomies, it seems as though laser cataract surgery is the wave of the future.

But, there are two sides to every story.

A perfect capsulotomy, which by one definition is a capsulorhexis that is perfectly circular and overlaps the IOL optic by 0.5 mm for 360°,[10] may not be crucial. Some surgeons postulate that, with modern lens designs, good positioning of the lens in the capsular bag is independent of the shape and size of the capsulorhexis.[17,18]

This article aims to present both sides of the story, by summarizing several studies that support or question the value of laser cataract surgery for anterior capsulotomy and by giving surgeons from around the world a platform from which to share their insights and views on the subject.

REVIEWING THE DATA

Introduction. In addition to the capsulotomy, femtosecond laser platforms for cataract surgery can be used to construct corneal wounds, fragment the lens, and perform an astigmatic keratotomy. The studies reviewed in this article concentrate solely on anterior capsulotomy.

Cekic and Batman. In a double-masked, prospective study in 1999, Cekic and Batman determined that a capsulorhexis diameter of 4 mm resulted in a longer postoperative anterior chamber depth (ACD) than a 6-mm capsulorhexis.[12] They used an IOL with an optic diameter of 5 mm in their study and included 51 eyes of 51 consecutive patients who were randomly assigned preoperatively to a capsulorhexis size of 4 (n = 22) or 6 mm (n = 29). Pre-, intra-, and postoperative courses were the same in each group, including surgery with a 3.2-mm clear corneal incision and a divide-and-conquer technique performed by one of two surgeons. In all cases, the incision was enlarged to 5.2 mm for implantation of a 24050 125UT, a PMMA PCIOL with 5° haptic angulation and an A-constant of 118. (Eye Technology, Inc.).[1] Accurate implantation of the IOLs in the capsular bag was confirmed in all cases.

Patients were observed for 90 days, and ACD and axial length (AL) were measured with ultrasonography preoperatively and on postoperative days 1, 7, 30, 60, and 90. On the first postoperative day and with the pupil fully dilated, the size of the capsulorhexis was measured using the slit beam of a slit lamp. According to the authors, a significant increase in ACD and ACD/AL ratios was found in the 6-mm capsulorhexis group on the first day (P = .012 and P = .018). In both groups by day 90, the ACD had increased significantly from preoperative values (4-mm: P = .002; 6-mm: P = .049), and there was a meaningful increase in the ACD/AL ratio (4-mm: P = .002; 6-mm: P = . 019). However, there were statistical differences between the ACD and the ACD/AL ratios in the 4- and 6-mm groups (3.73 ±0.32 mm vs 3.50 ±0.33 mm, P = .028 and 0.152 ±0.01 vs 0.142 ±0.01, P = .004, respectively).

"The refractive error changes followed the ACD changes and showed meaningful differences between the first and 90th days postoperative values of each group," the study's authors concluded.

Norrby. In a ray-tracing study with the aim of identifying and quantifying sources of error in the refractive outcome of cataract surgery, Norrby concluded, "improvement in refractive outcome requires better methods for predicting the postoperative IOL position."[11]

From a literature search, Norrby identified means and standard deviations of 16 parameters that can influence refractive outcomes of cataract surgery in a normal eye and calculated the numerical partial derivative of each parameter with respect to spectacle refraction. He found that the largest sources of refractive errors were preoperative estimation of postoperative IOL position (35%), postoperative refraction determination (27%), and preoperative AL measurement (17%). The result would be a mean absolute error of 0.60 D for an eye of average dimensions. "Reducing these three major error sources with means available today reduces the [mean absolute error] to 0.40 D," he concluded.

Nagy et al. Comparing manual and laser-assisted capsulotomy in cataract eyes, Nagy et al determined that the capsulorhexes were more regularly shaped, resulted in better IOL centration, and showed better IOL-capsule overlap with the laser-assisted technique than with manual creation.[2]

Zoltan Z. Nagy, MD, PhD, performed laser-assisted capsulotomy in 54 eyes of 53 patients and manual capsulotomy with a cystotome and capsulorehxis forceps in 57 eyes of 52 patients. All laser capsulotomies were performed in a designated laser room, and patients were brought into the OR for the remainder of the procedure. With either method of creation, the capsulorhexes were 4.5 mm in diameter; a three-piece acrylic IOL (MA60AC; Alcon Laboratories, Inc.) was implanted in every case, and no intra- or postoperative complications occurred. Additionally, the authors noted that the area of all capsulotomies was smaller than the optical zone of the IOL.

Incomplete overlap occurred in 28% of eyes in the manual capsulorhexis group and 11% in the laser group; this difference was statistically significant (Table 1). There was also a significant correlation between AL and area of capsulotomy, and between average keratometry and area of capsulotomy, in the manual group but not in the laser group. Other significant correlations in the manual group included pupillary area with area of capsulotomy and IOL decentration with AL. There was no correlation between the latter two parameters in the laser group. The study's

TABLE 1. COMPARISON OF LENS DECENTRATION PARAMETERS OF LASER-ASSISTED CAPSULORRHEXIS VERSUS MANUAL CONTINUOUS CURVILINEAR CAPSULORRHEXIS

Median Quartile Range			
Parameter	FS Group	CCC Group	P Value[a]
Axial length, mm	23.78 ±2.46	23.39 ±3.46	> .05
Refractive state, SE	-0.75 ±7.1	-0.75 ±5.5	> .05
Area of capsulotomy, mm^2	16.91 ±1.78	17.78 ±2.8	> .05
Circularity of capsulotomy	0.86 ±0.04	0.85 ±0.03	.032
Complete overlap, %	89	72	.033
Incomplete overlap, %	11	28	.033

Abbreviations: FS, femtosecond; CCC, continuous curvilinear capsulorhexis; SE, spherical equivalent refraction.

[a]Mann-Whitney U test.

TABLE 2. IOL POSITIONING PARAMETERS IN EYES THAT UNDERWENT LASER-ASSISTED AND MANUAL CONTINUOUS CURVILINEAR CAPSULORRHEXIS

Parameter	Manual CCC	Laser CCC	*P* Value
Horizontal tilt, °	2.75 ±1.67	1.53 ±1.08	.007[a]
Vertical tilt, °	4.34 ±2.40	2.15 ±1.41	< .001[a]
Horizontal decentration, µm	270.83 ±190.85	164.25 ±113.78	.034[a]
Vertical decentration, µm	148.40 ±101.59	131.00 ±124.72	> .05
Total decentration, µm	334.91 ±169.67	230.27 ±111.54	.022[a]

Abbreviation: CCC, continuous curvilinear capsulorhexis.
[a]P < .05 between groups using t-test for independent samples.

authors also found statistically better circularity values in the laser group.

"Our results show that capsulorhexis performed with a femtosecond laser is more regularly shaped, does not correlate with pupil size and axial length, and results in a better IOL/capsule overlap and better IOL centration than manual capsulorhexis," the authors concluded.

Kránitz et al. As the first author of two relevant studies,[1,3] Kránitz found not only that better overlap parameters can be achieved with "properly sized, shaped, and centered femtosecond laser capsulotomies" than with manual capsulotomies[1] but that capsulotomies created with a femtosecond laser "resulted in a more stable refractive result and less IOL tilt and decentration."[3]

In the first study,[1] 1-year follow-up of 40 eyes of 40 patients who had undergone laser-assisted capsulotomy (n = 20) and manual capsulotomy (n = 20) was evaluated to compare sizing and positioning parameters and the effects of any differences on IOL centration. All procedures were performed by Dr. Nagy using the same surgical technique except for the method of capsulorhexis creation. In both groups, the capsulotomy was 4.5 mm in diameter. In the laser group, the laser was set to start the capsulotomy at least 100 µm below the anterior capsule and to end it at least 100 µm above; the laser was also used to create a 2.8-mm clear corneal incision. In the manual group, the capsulorhexis was created with a cystotome and capsulorhexis forceps. Eyes were implanted with either a one- or three-piece spherical IOL made of a hydrophobic acrylic material, and the haptics were always situated at the 3- and 9-o'clock positions. IOL power was calculated with the SRK/T formula.

According to the authors, the "capsulotomies were not perfectly round in the postoperative follow-up period in either the [manual capsulorhexis] or [laser] group … ." However, vertical diameter was significantly greater in the manual capsulorhexis group at 1 week and 1 month postoperatively, and statistically significant differences were found in the shortest and longest distances between the edge of the IOL optic and the edge of the capsulorhexis at the same time points.

"Significantly higher values of overlap and circularity showed more regular capsulotomies in the [laser] group," they wrote. "Horizontal decentration of the IOL was also significantly higher in the [manual capsulorhexis] group" at 1 week and 1 year; however, the difference was not statistically significant at 1 month. With respect to vertical diameter, the correlation to the overlap of the capsulorhexis and the IOL was statistically significant at 1 week, 1 month, and 1 year in the manual group but not significant in the laser group.

A limitation of the study, the authors noted, was that the anteroposterior position of the IOL was not evaluated. "It would be interesting and important to examine whether the above described effect of regular femtosecond capsulotomies influences anteroposterior positioning and tilting of the IOL over time," they wrote. "According to the results of our study, potential clinical advantages can be achieved during refractive cataract surgery through effective prevention of optic decentration with precisely controlled shape, size, and centration of capsulotomy with the femtosecond laser."

In the second study,[3] Kránitz and colleagues compared IOL decentration and tilt following circular capsulorhexis creation with the femtosecond laser and manually. They found that those created with the laser resulted in more stable refractive results and less IOL tilt and decentration. A total of 45 eyes were included in the analysis: 20 that underwent laser-assisted capsulotomy and 25 that underwent manual capsulotomy. As in the previous study, Dr. Nagy performed all surgeries, the only difference in surgical technique was the method of capsulorhexis creation, and the size of the capsulorhexis was 4.5 mm. A one-piece AcrySof ReStor IOL (Alcon Laboratories, Inc.) was implanted in all cases, with the haptics placed in the 3- and 9-o'clock positions, and the IOL power was calculated with the SRK/T formula.

Although the difference in distance UCVA between groups was not statistically significant at any time point, the distance BCVA was significantly better in the laser group at 1 month and 1 year postoperatively. Additionally, "significant differences in centration and tilt were noted between the study groups," the authors wrote. "Vertical and horizontal tilt was significantly higher in the manual [capsulorhexis] group than in the laser [capsulorhexis] group."

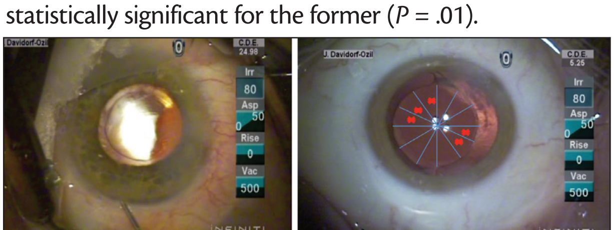
Also, horizontal and total decentration was significantly higher in the manual group (Table 2), as was vertical tilt. The authors further determined that a correlation between the absolute values of total decentration and changes in spherical manifest refraction between 1 month and 1 year postoperatively was significant; however, manifest refraction changes in spherical or cylindrical values did not correlate well with the parameter of IOL tilt.

"In this study, we were able to demonstrate that the use of a femtosecond laser to create an anterior curvilinear capsulotomy results in less IOL decentration and tilt and better [distance BCVA] than the use of a manual [capsulorhexis," they concluded.

Davidorf. In a study presented at the 2012 American Academy of Ophthalmology Meeting, Davidorf looked at the effects of capsulorhexis morphology on the predictability of IOL power calculations.[18] This retrospective, observer-masked study included a review of 175 consecutive cataract surgery videos in which the author performed a 2.4-mm clear corneal incision (sutureless), manual capsulorhexis with a capsulorhexis forceps, phacoemulsification with the Infiniti System (Alcon Laboratories, Inc.), and implantation of a foldable IOL.

The presumed ideal capsulorhexis morphology was 360º overlap of the IOL by 0.25 mm to 0.75 mm of capsule. Capsulorhexis morphology in relation to IOL position was graded (Figure 1), and eyes were graded on number of clock hours of (1) perfect overlap, (2) excessive overlap (greater than 0.75 mm), or (3) insufficient overlap (less than 0.25 mm).

Of the selected videos, the analysis included 112 that met the inclusion criteria. Of these, 48 were in the ideal overlap group, 11 were in the insufficient overlap group, and one was in the excessive overlap group. Because only one eye qualified for inclusion in the excessive overlap group, statistical comparisons were presented between the ideal and insufficient overlap groups. Dr. Davidorf concluded that the lowest mean prediction error (Table 3) and the lowest standard deviation were seen in the insufficient overlap group; however, the difference was only statistically significant for the former (P = .01).



(Courtesy of Jonathan Davidorf, MD.)

Figure 1. Capsulorhexis grading.

Findl. At the European Society of Cataract and Refractive Surgeons Annual Meeting in October 2013, Oliver Findl, MD, MBA, FEBOphth, presented a study showing that capsulorhexis size and shape did not have a significant influence on postoperative IOL tilt, decentration, or ACD.[17] This continuous cohort study included screening the of 635 consecutive surgeries performed by nine surgeons ranging in skill from experienced consultants to trainees. Three modern acrylic IOL models were implanted, and preliminary results of the first 254 eyes were reported. There were no inclusion or exclusion criteria; any patient presenting for cataract surgery was included in the study.

During an interview with *CRST Europe*, Dr. Findl said that the definition of the perfect capsulorhexis used in this study was one that had "a complete overlap with the capsulorhexis and the IOL and was 4.5 to 5.5 mm in size."

In all cases, retroillumination photographs were taken 1 hour after standard cataract surgery, along with partial coherence interferometry measurements of ACD with the AC Master (Carl Zeiss Meditec, Inc.), a research device that is not on the market. The opening of each capsulorhexis was also classified at this time as having an ideal size and position or as too large, too small, or eccentric. Eyes that had a perfect capsulorhexis composed the control group; the study group included eyes with capsulorhexes that were too small, too large, or eccentric.

The measurements were repeated 3 months postoperatively in all eyes in the study group and in approximately the same number of eyes randomly selected from the control group.

Measurements of tilt and decentration with a Purkinje meter were also taken at this time. For each retroillumination image, the capsulorhexis shape factor (RSF)—which is defined as the standard deviation of 50 consecutive distances, 7.2º apart, from the IOL's rim to the capsulorhexis' edge—was assessed with the Automated Quantification of After-cataract software devised by Dr. Findl's group.

The mean tilt was 3.8 ±2.1º, and the mean decentration was 0.4 ±0.2 mm. One hour postoperatively, the mean capsulorhexis diameter was 4.76 ±0.5 mm, and at 3 months, it was 4.89 ±0.48 mm. According to Dr. Findl, the change in the mean RSF from 1 hour to 3 months postoperatively (0.27 ±0.13 mm vs 0.24 ±0.10 mm, respectively) was statistically significant (P = .046), and a weak correlation was seen between the RSF and IOL tilt (relative risk = 0.02 and relative risk = 0.04, respectively).

Except for a small difference (0.08 mm) in mean decentration in the large eccentric capsulorhexis group, Dr. Findl found no difference in IOL tilt and decentration between the worst (eccentric) and best (ideal overlap) capsulotomies. He also found no difference in axial eye position or change in axial eye position from immediately postoperatively to 3 months postoperatively and no difference in refraction. Additionally, the spread of data in standard deviations was comparable in all groups, even when including the eccentric group, and the group with complete overlap showed almost identical results in mean and standard deviations as the control group.

Dr. Findl concluded that, with modern IOL designs, good postoperative capsular bag positioning "appears to be relatively independent of the shape and size of the capsulorhexis' opening."

VIEWS FROM THE EXPERTS: QUESTIONING THE IMPORTANCE

Jonathan M. Davidorf, MD

The discussion about capsulorhexis morphology is not new, but the topic has come nearer center stage with the arrival of the femtosecond laser. If surgeons had been convinced that precise capsulorhexis morphology has a big impact on outcomes, why did capsulorhexis markers not gain more popularity over the years? The use of these markers is simple, inexpensive, and low risk. More likely than not, surgeons have been unconvinced that any significant relationship exists.

With laser cataract surgery comes the potential for a perfect capsulorhexis. Faced with this new technology, I had a keen interest in knowing the impact of capsulorhexis morphology on refractive outcomes. There had been a lot of discussion about the subject when the Crystalens (Bausch + Lomb) was first introduced, and surgeon's solutions ranged from making the capsulorhexis large to making it small to making it oval. Our surgical outcomes had been very good, but if we could improve our accuracy, that would be compelling.

Copious claims in the forms of personal communication and published data suggest that a perfect capsulorhexis improves outcomes.[4,9,14,19] The forgoing, however, prompts the question: Does a perfect or near-perfect capsulorhexis translate into better refractive outcomes than a less-perfect capsulorhexis?

Therefore, I studied the effects of capsulorhexis morphology on predictability of IOL power calculations by selecting 175 random videos of cataract surgery in which an acrylic IOL was implanted.[18] The results of my study were outlined earlier. In short, the lowest mean prediction error was seen in the group of capsulorhexes that had the worst construction (ie, insufficient overlap); however, no statistically significant difference in results could be identified between the worst and ideal capsulorhexis groups.

In this comparison of eyes with little to no overlap of the IOL and capsulorhexis versus eyes with ideal morphology, there was no difference in IOL power calculation predictability. It is possible that a difference would present if larger numbers of eyes with longer follow-up were studied; however, if a statistically significant difference can be found only in a cohort larger than 112 eyes (the number included in my analysis that met the inclusion criteria), one has to ask whether creating an ideal capsulorhexis is even clinically relevant. On the other hand, it is possible that the assumptions of ideal capsulorhexis morphology that were used in this study are wrong. We did, however, use a commonly accepted definition: 360° overlap of the IOL by 0.25 to 0.75 mm (Figure 1).

Some cases in this study that seemed to have a perfectly sized and centered capsulorhexis actually had less than ideal overlap of the capsulorhexis and IOL. Therefore, simply because a capsulorhexis looks perfect prior to lens removal, this does not necessarily translate to the center of the IOL's aligning with the center of the seemingly perfect capsulorhexis. This issue can be expected whether the continuous curvilinear capsulorhexis is created manually or with a femtosecond laser.

Additionally, it would be interesting to examine how consistently a surgeon could achieve ideal capsulorhexis morphology using a manual technique, if the surgeon were to consciously strive to achieve that goal. Presumably, it could be achieved more often than 43%, the percentage of times ideal morphology was achieved in this study. Although optical zone markers or calipers can be used to guide construction of the capsulorhexis,

TABLE 3. COMPARISON OF MEAN PREDICTION ERRORS

	Haigis	SRK-T
Total cohort	+0.24 ±0.50 D	+0.25 ±0.47 D
Ideal CCC (n = 48)	+0.28 ±0.44 D	+0.26 ±0.41 D
Worst (insufficient overlap) CCC (n = 11)	-0.03 ±0.35 D	+0.06 ±0.52 D
P value (Student's t-test)	*P* = .01	*P* = .24
ANOVA (F-test)	*P* = .46	*P* = .28

Abbreviations: CCC, continuous curvilinear capsulorhexis; ANOVA, analysis of variance.

(Courtesy of Jonathan Davidorf, MD.)

the study's results do not make a compelling argument in favor of taking extra steps in an attempt to improve IOL calculation predictability, as others have suggested.[20]

Our study suggests that there is no relationship between capsulorhexis morphology, lens decentration and tilt, and refractive outcomes in cataract surgery. Because no differences were evident between the ideal and worst groups in this study, if differences do exist, they may be subtle. Additionally, if an experienced surgeon prospectively sets out to create an ideal capsulotomy manually, he or she should be able to avoid an eccentric capsulotomy more than 90% of the time. In other words, we could anticipate a less than 10% incidence of creating a problem that is not a problem.

I found Dr. Findl's study both interesting and well done; it provides a good description of what occurs physiologically with different capsulotomy shapes. His results support the idea that capsulotomy shape—even when considering the most eccentric shapes—has little to no impact on IOL position. Although there was essentially no difference in the mean and standard deviations between the groups in Dr. Findl's study for both tilt and decentration, it would be interesting to see if there is any clinically identifiable difference in actual visual outcomes between the eccentric eyes and the control group. Would that 0.08 mm difference in mean decentration have any visual impact on potentially less forgiving eyes, such as those receiving a multifocal IOL? Would a hypothetical multifocal patient have no problems with rings and halos if his or her IOL were decentered 0.35 mm (control group mean) but have noticeable problems at 0.43 mm of decentration (eccentric group mean)?

Dr. Findl's data suggest that a small amount of IOL decentration is common, regardless of the capsulorhexis' size and shape. He also found a much higher percentage of eyes with eccentric capsulotomies (33.2%) than was seen in my study (10%); perhaps his definition of eccentric was less rigid than the definition in my study. Alternatively, the high rate may have occurred because of the inclusion of the results of trainee surgeons in Dr. Findl's data set. Notably, both of our studies were retrospective. It stands to reason that, if both studies were repeated prospectively, with experienced surgeons attempting to create the supposedly ideal capsulorhexis, the percentage of eyes with eccentric capsulotomies would fall precipitously in both studies—and the percentage of ideal capsulotomies would rise.

If our goal is to improve IOL centration or refractive outcomes, it appears that we may be illogically focusing on capsulorhexis size and shape. Similarly, if the goal is to find key data that demonstrate clinical relevance (ie, identifiable visual benefit for the patient) of the femtosecond laser for cataract surgery, my conclusion would be to look elsewhere.

Incidentally, as the proposed benefits of a laser-assisted capsulorhexis appear to wane, the tide is shifting toward the potential benefits of reduced phaco energy that the femtosecond laser can achieve. The subject is important to investigate; however, for the experienced cataract surgeon operating on a moderately dense cataract, regardless of the selected IOL type, current phaco machines permit the procedure to be done with only minimal amounts of ultrasound energy and without endothelial cell loss.

The femtosecond laser's real benefit for patients may rest not with the standard case, regardless of IOL design, but with more niche cases, such as surgery in eyes with dense, white, and posterior polar cataracts and perhaps in patients with zonulopathy. It may also be beneficial for patients having surgery performed by surgeons in training, for whom the risk of an errant capsulorhexis or an overdose of phaco power may be more likely.

My capsulorhexis morphology study was relatively easy to perform, and I would encourage other surgeons to do the same in order to answer the question for themselves. Perhaps they will find something different.

Oliver Findl, MD, MBA

I have always been interested in how capsulorhexis size and centration affect IOL positioning in the capsular bag. As we know, axial positioning is important for refractive outcomes, and it is also important for IOL decentration and tilt. As laser cataract surgery gains momentum, now is a good time to evaluate such parameters and decide whether additional technologies are warranted to enhance outcomes.

There are a few points I would like to make regarding our study.[17] First, we objectively measured decentration and tilt of IOLs using a prototypic Purkinje meter developed by Pablo Artal, PhD. We did not use slit-lamp grading, but actual measurements. Second, we categorized capsulorhexes postoperatively, and therefore, the ones that were included in the perfect capsulotomy group were perhaps even more perfect than laser capsulotomies; just because a capsulotomy is perfectly created does not mean the lens will center on that capsulotomy due to an asymmetric capsular bag or other factors. Third, is a 0.08 mm difference in mean decentration—the difference I found in the large eccentric capsulorhexis group compared with the ideal overlap group—clinically relevant? Obviously, there are some outliers, and you could therefore argue that there are a few eyes in this population that could have done a little better if they had undergone a laser capsulotomy. However, I have also seen several examples of eyes that had perfect alignment—as they would with a laser—but the IOL still decentered because of asymmetric contraction of the capsule.

The bottom line is that a perfect capsulorhexis with a nice IOL overlap at the end of surgery does not guarantee perfect centration or mean that decentration will never occur. The implication our study has for patients is that the femtosecond laser probably makes little difference to their outcomes. There are still many questions that we have as surgeons. Do you center the capsulorhexis on the pupil? On the corneal center? We know that the answer differs from eye to eye.

Another thing to consider is study protocols. Some studies that showed a correlation between perfect capsulotomies and better refractive outcomes had small sample sizes. Additionally, the measurement techniques used in the studies might not have been as precise as those used in our study. For example, Scheimpflug imaging has poor reproducibility for measuring the decentration and tilt of an IOL. Personally, I do not put faith in the results of these small, nonrandomized trials.

I think that the femtosecond laser is a fascinating technology for cataract surgery, and its use can perhaps bring increased safety and reduce endothelial cell loss. However, in the context of the capsulotomy, it seems to have a very small effect on postoperative outcomes, with little evidence to support claims otherwise.

Steven G. Safran, MD

I do not use a femtosecond laser, as I feel it adds time, expense, complexity, and potential risk to cataract surgery, with no real benefits to offset those considerations. Additionally, I have little difficulty making a capsulorhexis in the size and shape I want with a manual technique, and I know many other surgeons who also consider the manual fashioning of a capsulorhexis to be a basic step in cataract surgery that they can perform effectively and that requires no particular assistance.

Theoretically, it makes little sense to assume that the capsulorhexis plays any role in the effective lens position (ELP). The lens optic goes where the haptics take it, and the haptics are ideally positioned in the capsular bag equator. The capsulorhexis has no influence on the position of the capsular bag equator and, thus, has virtually no influence on the position of the lens haptics. The capsulorhexis may only influence the position of the lens optic to the extent that its presence has an effect on capsular contraction forces over time such that enough significant asymmetric forces are created that may lead to a distortion of the IOL's optic-haptic structural relationship. Most IOLs have a set optic-haptic relationship by design, and the amount that this can be changed by capsular contraction forces is likely minimal, especially with modern one-piece IOLs with robust haptics and broad haptic-optic junctions. Even with the Crystalens, which has a variable optic-haptic relationship, there is little agreement on the ideal capsulorhexis size and questionable influence of capsulorhexis size and shape on refractive outcomes.

What I have learned clinically is that the capsulorhexis can become relevant only through capsular contraction forces—forces that are mediated by the presence of remaining LECs that undergo metaplastic transformation into myofibroblast-like cells, laying down connective tissue with contractile elements. This LEC behavior over time is the underlying cause of problems with phimosis, asymmetric contraction, and lens dislocation within the capsular bag, when it occasionally occurs. The capsulorhexis matters only to the extent that the remaining LECs make it relevant. By focusing attention on the removal of LECs, one can have a far more positive impact on refractive outcomes than by obsessing over a perfect capsulorhexis.

Once a capsulorhexis overlaps the lens optic 360º and its diameter is reasonable in size (eg, more than 4 mm), its geometric shape becomes irrelevant; whether it is round, elliptical, or shaped like Mickey Mouse's head does not really matter. Additionally, it matters less once the LECs are carefully removed, and even less when using modern one-piece IOLs.

Dr. Findl's study confirms what I have been saying for years based on my clinical experience: The capsulorhexis' shape is irrelevant to the refractive outcomes of cataract surgery. Removal of residual cortex and LECs, on the other hand, I believe to be an important component of obtaining reproducibly excellent results, especially with the Crystalens, which is more affected by these factors. Removing all the cortical remnants and LECs will minimize capsular contraction forces, eliminate capsular phimosis, prevent Z syndromes, and make the size and the shape of the capsulorhexis virtually irrelevant.

An investigation using scanning electron microscopy (SEM)[21] showed that capsulorhexes made with a femtosecond laser resembled a micro-can opener, with a zipper or jagged edge. In contrast, manual tears resulted in a completely smooth edge. Aberrant pulses, pits, tags, and a demarcation line indicative of damage to surrounding tissue were seen on SEM, all of which can be associated with an increased risk of radial tears that can extend posteriorly and lead to complications. In this multicenter study, there was a 16-fold higher radial tear-out rate with laser capsulorhexes than with those created manually; this was consistent at all three participating centers.

Taken collectively, it appears that the jagged edge of a laser capsulorhexis makes it more prone to tear out with surgical manipulation.

I have heard surgeons comment that the use of the laser is associated with intraoperative miosis and more difficult cortical clean-up. I wonder, with a jagged laser capsulorhexis edge, how much more difficult would it be to clear the edge of LECs, compared with the smooth edge created with a manual tear? I suspect that phimosis and capsular contraction issues will prove to be more likely over time with laser anterior capsulotomies than with manual capsulotomies.

If a surgeon has difficulty making a capsulorhexis and wants to use the Fugo Plasma Blade (Medisurg Research & Management Corp.) or a laser to help, that is fine, but I do not feel that patients should be charged extra as a result. I certainly do not feel that these patients should be told that the perfectly round capsulorhexis from a femtosecond laser is better or safer or more likely to provide an excellent refractive outcome than what many other surgeons and I can do faster, cheaper, and just as reliably by hand.

There is no study that shows a significant difference in refractive outcomes between a laser anterior capsulotomy and a manual technique; nor would there be any reason to suspect this. Most surgeons I speak with report little difficulty in creating a reliable capsulorhexis by hand, and I know of many surgeons besides myself who cannot remember the last radial tear-out they had. If a surgeon has little difficulty making the incisions, performing the capsulorhexis, and chopping the lens nucleus effectively and efficiently with his or her manual technique, I do not see the benefit of a femtosecond laser—for the surgeon or for his or her patients.

Richard Schulze Jr, MD, MPhil (Oxon)

Dr. Findl's findings confirm what many of us have long suspected: the capsulorhexis, while important, is less important with regard to refractive outcomes than industry would have us believe. I have studied Dr. Findl's results and communicated them to my American colleagues on the American Society of Cataract and Refractive Surgery (ASCRS) EyeMail online chat group.

Dr. Findl, however, is not the only one to report this, as there are at least two other studies of which I am aware that have come to the same conclusion: (1) Dr. Davidorf's study of 175 eyes[18] and (2) a study of 2,000 eyes by James A. Davison, MD, which won a best paper of session award at the 2012 ASCRS annual meeting.[22] Dr. Davison found that "imperfection of optic overlap had no anatomic or refractive clinical significance." As I understand, this paper is being prepared for publication.

Following are some of the comments I made on the ASCRS group recently.

Aesthetically, most surgeons like to see round, well-centered capsulorhexes with complete overlap of the optic, whether we produce our capsulorhexis manually or with a femtosecond laser. This is one of the main factors I look at when I judge the quality of my own surgical performance. Industry would have us believe that a well-centered, round capsulorhexis with complete optic overlap is a necessary precondition of predictable refractive outcomes and is heavily invested in convincing surgeons to purchase lasers to achieve this. However, Findl,[17] Davidorf,[18] and Davison[21] come to the opposite conclusion, finding that the capsulorhexis is not the determining factor in refractive outcomes.

Additionally, a prospective randomized comparison of refractive outcomes with laser-assisted versus manual phacoemulsification by Lawless et al[23] showed that attempted versus achieved refractive outcomes with manual phacoemulsification were slightly better than outcomes with the femtosecond laser; the difference, however, was not statistically significant.

A forthcoming publication in *Ophthalmology* includes several SEM images of laser capsulotomies.[21] Although I cannot share them here due to copyright laws, they are available to that journal's subscribers at http://tinyurl.com/kykux85. I cannot help but be reminded of the old can opener capsulotomies we used to do with extracapsular procedures many years ago; there is a reason why we switched to a capsulorhexis.

VIEWS FROM THE EXPERTS: IN FAVOR OF LASER CAPSULOTOMY

Arun C. Gulani, MD

Practicing at a center for a global population of premium cataract patients referred by their surgeons for the correction of complications, second opinions, or assistance with undesirable outcomes, I would like to say that I have seen both sides of this debate regarding the impact of the capsulorhexis on lens centration: I have seen patients, both with well- and poorly seated lenses, who may be unhappy with their refractive outcomes.

However, I think the bigger discussion is the question, what are we aiming for? As surgeons, our tolerance of anything less than perfect is now very low. For this reason, the appeal of femtosecond lasers, premium IOLs, and secondary laser enhancements is magnified. Additionally, as our tolerance decreases, so do the tolerances of our patients and of lens technologies. Gone are the days of implanting a monofocal IOL and not worrying about a little postoperative movement. Now, we must prevent the lens from shifting in the capsular bag by using an array of tactics, including a perfectly formed capsulorhexis, in our endeavor toward premium cataract surgery.

Our high standards come to bear on this discussion of lens decentration in the capsular bag, but we cannot focus simply on different positions of the IOL with regard to capsulorhexis morphology. Two of the commonest things I see in unhappy patients that are referred to me are a retained ophthalmic viscosurgical device and residual cortex in the capsular bag. A retained ophthalmic viscosurgical device can change the refractive power, because the lens rests more anteriorly than predicted. Retained cortex causes improper fitting of the lens and induces capsular contraction, which can trigger IOL movement (eg, tilt) that affects visual acuity. In some cases, it can even affect ACD. All of these factors can surely influence refractive outcomes and, as a result, patients' satisfaction.

The IOL's haptics will ensure perfect centration whether the capsular bag is oval or round. More important are (1) uniform, circumferential overlap of the lens by the capsular opening and (2) proper seating of the lens, even if the capsule later contracts. Here lies the femtosecond laser's advantage; it is not about a better-fashioned capsulorhexis (ie, laser vs manual) but about the laser's ability to consistently create a capsulorhexis with a predictable size and shape.[24,25] In fact, I am a proponent of not forcing femtosecond laser-assisted surgery on all patients. In certain cases, however, I do feel that the laser could be a necessity, especially when the capsulorhexis is the Achilles' heel of those cases. Three such examples are eyes with a mature cataract, eyes with pseudoexfoliation syndrome (Figure 2), and eyes with a subluxated cataract (Figure 3).

eyetube.net

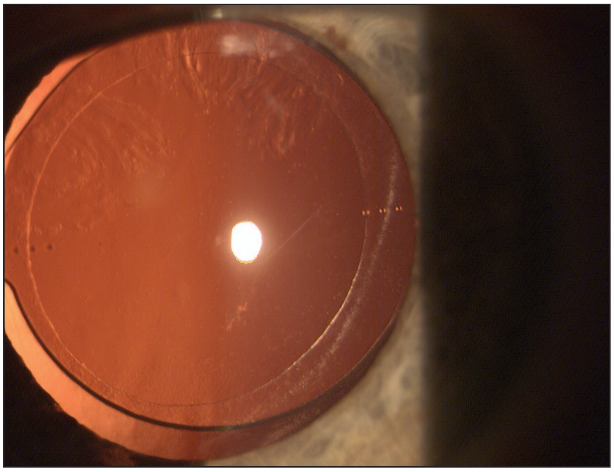
eyetube.net/?v=gepoo/

Today, while we debate about IOL centration and capsular impact on vision, the fact is that a perfectly round and well-centered capsulorhexis is the hallmark of a surgeon's aesthetic skills. Just like we took already successful LASIK outcomes from 20/20 to beyond 20/20 by chasing wavefront aberrations, every aspect of cataract surgery today is under scrutiny in our quest to deliver premium outcomes to our patients. In that direction, then, we should pursue a consistent, centered, and circular capsulorhexis irrespective of what the final data will prove on visual impact.

In the recent past, we used to look at our continuous capsulorhexis and think it was gorgeous. Now, we look at it and say, "I planned 5 mm but ended up with 5.5 mm" or "It is not a perfect circle but a slight oval." We all know that both capsulorhexes are still acceptable, but today, you look at your patient the next day and think, "I could have done better."

Kathryn M. Hatch, MD

Capsulotomy is one of the most delicate and essential steps of cataract surgery. For decades, surgeons have tried to achieve the perfect formation.



(Courtesy of Arun C. Gulani, MD.)

Figure 2. An eye with pseudoexfoliation and high astigmatism was treated with laser cataract surgery.

What is a perfect capsulotomy, and why is it important? Not only does the size of the capsulotomy matter for use of space in the eye during nuclear disassembly, but overlap of the edge of the IOL optic is also desirable. We know that the capsule fibroses after surgery, and this process may affect ELP and has a large influence on refractive results. So the question remains: Do capsulotomy size and shape affect ELP?

I see several issues with Dr. Findl's study. First, it evaluates results at only 3 months postoperatively, whereas capsular healing can continue thereafter and affect the ELP. Second, it does not take into account the patients' ALs, which could have significant effects on ELP. Third, it does not compare manual capsulorhexes with those created with a femtosecond laser. Caution should be exercised when making assumptions about the comparisons of ELP with a so-called perfect manual capsulorhexis of 4.5 to 5 mm with a laser-assisted capsulorhexis. Friedman et al[14] showed that a laser-assisted capsulotomy is more than 10 times as precise of intended size compared with a manually created one by the best of surgeons.

If one is trying to decide whether the laser-assisted capsulotomy with optic capture has better refractive results and more predictable ELP compared with manual surgery, a more prudent study would be one that compares refractive results and ELP in eyes with similar ALs at least 9 to 12 months postoperatively in the following groups: (1) laser-assisted 5-mm capsulotomies with optic capture, (2) manually created 5-mm capsulotomies with optic capture, and (3) manually created, eccentrically shaped capulotomies without optic capture.

Precise laser-assisted capsulotomies with consistent optic capture will allow surgeons to have more predictable ELPs and refractive results. As with many new

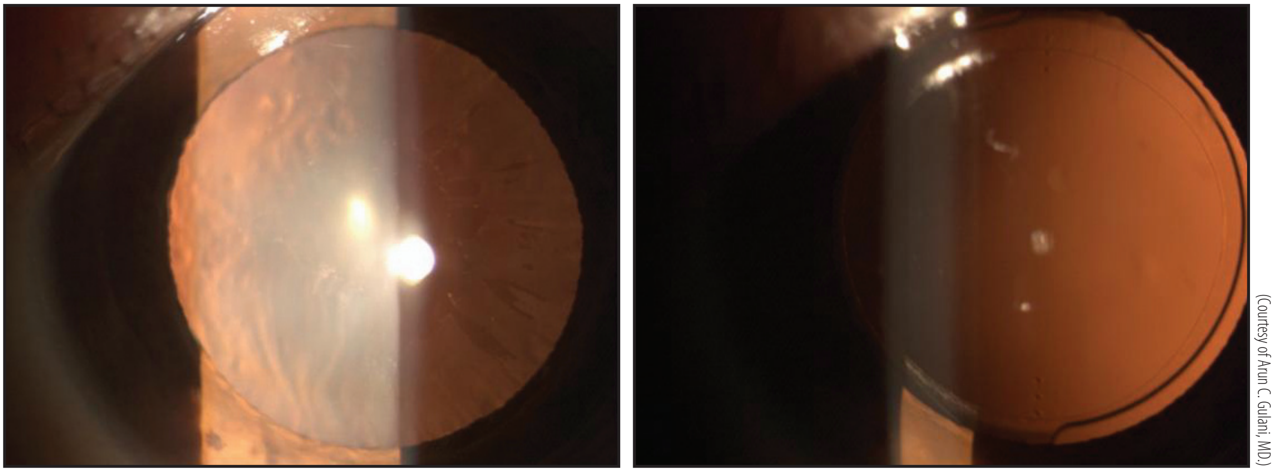


Figure 3. Laser cataract surgery was performed in the presence of a subluxated cataract.

technologies, time, results, and continued research will allow us to see the advantages of the femtosecond laser.

Erik L. Mertens, MD, FEBOphth

As was pointed out by Nagy et al,[3] the size, centration, and circularity of the capsulorhexis does play a role in final IOL position and refractive outcomes. Dr. Findl's study[17] does not disclose which IOLs were used. Nor does it include refractive outcomes.

A 360º overlap of the capsulorhexis and the IOL gives a more stable IOL position, resulting in less tilt and decentration. Multifocal IOLs are very sensitive to this, and more eyes can achieve a stable refractive outcome with less refractive error when the capsulorhexis is perfectly created and positioned. In my experience with the FineVision trifocal IOL (PhysIOL; not available in the United States), the ratio of enhancements I perform dropped from 11.3% to 3.6% in normal cases with no intraoperative complications. The only difference between my current and my previous technique is the use of the femtosecond laser in creating the capsulorhexis.

Mark Packer, MD, CPI

In capsulorhexis and capsulotomy construction, size and shape do matter—although the limits of tolerance vary with IOL design. Basic safety concerns have established the upper and lower limits of size. Complete 360º overlap of the capsule on the IOL optic represents a well-accepted principle for the prevention of PCO[26] and specifies our criteria for maximum diameter and circularity. In this regard, Kranitz et al have demonstrated a benefit of laser-assisted capsulotomy.[1] Prevention of capsular contraction syndrome and the adverse effects of capsular phimosis suggest a minimum capsulorhexis diameter of approximately 4.5 mm.

Within that range, the findings of Cekic and Batman[12] make intuitive sense: a larger opening results in a shallower chamber because the transverse tensile forces in the anterior capsule are reduced.[27] This finding suggests that a more consistent capsulotomy design results in a more consistent postoperative ACD and thus a more predictable ELP and refractive outcome. The study of laser cataract surgery outcomes by Filkorn et al[28] supports this hypothesis.

Davidorf,[18] Davison,[22] and Findl[17] report little if any untoward effects from the decentered or aberrant capsulorhexis. In my experience, however, a capsulorhexis that runs off the edge of the optic can lead to capsular fibrosis, PCO, IOL decentration, and optical side effects. A capsulorhexis that is too small is prone to phimosis, hyperopic shift, and glare; Raviv shares my point of view.[29] Refractive cataract surgery with multifocal, toric, and accommodating IOL designs demands even less tolerance of imperfection in capsulotomy construction.

In my view, the optimal center for the capsulotomy is the optical axis or center of the crystalline lens, as the IOL, with its haptics at the equator, automatically centers itself symmetrically in the capsular bag. The optic comes to rest in the center of the capsule in the X-Y plane. Making the capsulotomy concentric with the optic consistently achieves 360º overlap of the capsule. Imaging and guidance that detect the optical axis are necessary to meet this requirement.

Findl states, "Even in those cases where no rhexis overlap with the IOL was observed (18 cases), tilt and decentration were not significantly different ($P = .564$ and $P = .293$) compared to normal cases."[17]

Should we, therefore, abandon any attempt to achieve

360° overlap of the capsule on the optic? I think not. As Peng et al[30] wrote more than a decade ago, "Our histopathological observations suggest that creating a [continuous curvilinear capsulorhexis] with a diameter slightly smaller than that of the IOL optic allows the capsule edge to adhere to the anterior surface of the optic, enhancing the efficiency of the barrier effect by creating a closed system."

Adequate surgical outcomes are not the same as optimal surgical outcomes. The aesthetic perception of a perfect capsulotomy resonates with the clinical evidence for enhanced outcomes. Constructing that perfect opening remains a worthwhile goal. ■

Jonathan M. Davidorf, MD, is the director of Davidorf Eye Group in Los Angeles, California, and is a clinical assistant professor of ophthalmology at the Jules Stein Eye Institute. Dr. Davidorf may be reached at (818) 883-0112; drj@davidorf.com.

Oliver Findl, MD, MBA, is director of ophthalmology at the Hanusch Hospital, Vienna, Austria, and a consultant ophthalmic surgeon at Moorfields Eye Hospital, London. He is also the founder and head of the Vienna Institute of Research in Ocular Surgery (VIROS), Hanusch Hospital, Department of Ophthalmology, Vienna, Austria. He acknowledged no financial interest in the products or companies he mentioned. Dr. Findl may be reached at oliver@findl.at.

Arun C. Gulani, MD, is the director of the Gulani Vision Institute in Jacksonville, Florida. Dr. Gulani may be reached at (904) 296-7393; gulanivision@gulani.com.

Kathryn M. Hatch, MD, practices corneal, cataract, and refractive surgery at Talamo Hatch Laser Eye Consultants in Waltham, Massachusetts, and is a clinical faculty member at the Alpert Warren Medical School of Brown University in Providence, Rhode Island. Dr. Hatch may be reached at (781) 890-1023; kmasselam@gmail.com.

Erik L. Mertens, MD, FEBOphth, is medical director of Medipolis, Antwerp, Belgium. He is a cochief medical editor of CRST Europe. *He acknowledged no financial interest in the products or companies he mentioned. Dr. Mertens may be reached at +32 3 828 29 49; e.mertens@medipolis.be.*

Mark Packer, MD, CPI, is a clinical associate professor at the Casey Eye Institute, Department of Ophthalmology, Oregon Health & Science University, and president of Mark Packer MD Consulting. He is a consultant to Abbott Medical Optics Inc., Bausch + Lomb, and Lensar. Dr. Packer may be reached at mark@markpackerconsulting.com.

Steven G. Safran, MD, PA, is in private practice in Lawrenceville, New Jersey. He is a paid speaker for Bausch + Lomb. Dr. Safran may be reached at safran12@comcast.net.

Richard Schulze Jr, MD, MPhil (Oxon), practices at Schulze Eye & Surgery Center, Savannah, Georgia. Dr. Schulze may be reached at (912) 352-3120; richardschulze@comcast.net.

1. Kránitz K, Takacs A, Miháltz K, et al. Femtosecond laser capsulotomy and manual continuous curvilinear capsulorhexis parameters and their effects on intraocular lens centration. *J Refract Surg*. 2011;27(8):558-563.
2. Nagy ZZ, Kránitz K, Takacs AI, et al. Comparison of intraocular lens decentration parameters after femtosecond and manual capsulotomies. *J Refract Surg*. 2011;27(8):564-569.
3. Kránitz K, Takacs A, Miháltz K, et al. Intraocular lens tilt and decentration measured by Scheimpflug camera following manual or femtosecond laser-created continuous circular capsulotomy. *J Refract Surg*. 2012;28(4):259-263.
4. He L, Sheehy K, Culbertson W. Femtosecond laser-assisted cataract surgery. *Curr Opin Ophthalmol*. 2011;22:43-52.
5. Reggiano-Mello G, Krueger RR. Comparison of commercially available femtosecond lasers in refractive surgery. *Expert Rev Ophthalmol*. 2011;6(1):55-65.
6. Hatch KM, Talamo JH. Laser-assisted cataract surgery: benefits and barriers. *Curr Opin Ophthalmol*. 2014;25(1):54-61.
7. Palanker D, Blumenkranz MS, Andersen D, et al. Femtosecond laser-assisted cataract surgery with integrated optical coherence tomography. *Sci Transl Med*. 2010;2(58):58ra85.
8. Masket S, Sarayba M, Ignacio T, Fram N. Femtosecond laser-assisted cataract incisions: architectural stability and reproducibility. *J Cataract Refract Surg*. 2010;36:1048-1049.
9. Tackman RN, Kuri JV, Nichamin LD, Edwards K. Anterior capsulotomy with an ultrashort pulse laser. *J Cataract Refract Surg*. 2011;37(5):819-824.
10. Yeilding RH, Villar-Kuri J, Naranjo-Tackman R, et al. Evaluation of size and shape of anterior lens capsules after photodisruption laser capsulotomy and continuous curvilinear capsulorhexis. *Invest Ophthalmol Vis Sci*. 2009;50:e-abstract 5394.
11. Norrby S. Sources of error in intraocular lens power calculation. *J Cataract Refract Surg*. 2008;34:368-376.
12. Cekic O, Batman C. The relationship between capsulorhexis size and anterior chamber depth relation. *Ophthalmic Surg Lasers*. 1999;30:185-190.
13. Sanders DR, Higginbotham RW, Opatowsky IE, Confino J. Hyperopic shift in refraction associated with implantation of the single-piece Collamer intraocular lens. *J Cataract Refract Surg*. 2006;32:2110-2112.
14. Friedman NJ, Palanker DV, Schuele G, et al. Femtosecond laser capsulotomy. *J Cataract Refract Surg*. 2011;37:1189-1198.
15. Ravalico G, Tognetto D, Palomba M, et al. Capsulorhexis size and posterior capsule opacification. *J Cataract Refract Surg*. 1996;22(1):98-103.
16. Walkow T, Anders N, Pham DT, Wollensak J. Causes of severe decentration and subluxation of intraocular lenses. *Graefes Arch Clin Exp Ophthalmol*. 1998;236:9-12.
17. Findl O. Influence of rhexis size and shape on postoperative IOL tilt, decentration and anterior chamber depth. Paper presented at: The XXXI Congress of the ESCRS; October 7, 2013; Amsterdam, Netherlands.
18. Davidorf JM. Impact of capsulorhexis morphology on the predictability of IOL power calculations. Paper presented at: The American Academy of Ophthalmology Annual Meeting; November 11, 2012; Chicago, IL.
19. Izak AM, Werner L, Pandey SK, et al. Analysis of the capsule edge after Fugo plasma blade capsulotomy, continuous curvilinear capsulorhexis, and can-opener capsulotomy. *J Cataract Refract Surg*. 2004;30:2606-2611.
20. Tassignon MJ, Rozema JJ, Gobin L. Ring-shaped caliper for better anterior capsulorhexis sizing and centration. *J Cataract Refract Surg*. 2006;32:1253-1255.
21. Abell RG, Davies PE, Phelan D, et al. Anterior capsulotomy integrity after femtosecond laser-assisted cataract surgery [published online ahead of print September 28, 2013]. *Ophthalmology*. doi: 10.1016/j.ophtha.2013.08.013.
22. Davison JA. Intraoperative capsule complications during phacoemulsification and IOL implantation. Paper presented at: The ASCRS 2012 Annual Meeting; April 20-24, 2012; Chicago, IL.
23. Lawless M, Bali SJ, Hodge C, et al. Outcomes of femtosecond laser cataract surgery with a diffractive multifocal IOL. *J Refract Surg*. 2012;28(12):859-864.
24. Donnenfeld E, Gulani AC. Astigmatism correction during cataract surgery. In: Garg H, Alió JL, eds. *Femtosecond Laser: Techniques and Technology*. 1st ed. Miami, FL; JayPee Highlights Medical Publishers; 2012:155-161.
25. Gulani AC. Femtosecond laser in cataract surgery: designer cataract surgery. In: Garg H, Alió JL, eds. *Femtosecond Laser: Techniques and Technology*. 1st ed. Miami, FL; JayPee Highlights Medical Publishers; 2012:152-154.
26. Smith SR, Daynes T, Hinckley M, et al. The effect of lens edge design versus anterior capsule overlap on posterior capsule opacification. *Am J Ophthalmol*. 2004;138:635-636.
27. Danysh BP, Duncan MK. The lens capsule. *Exp Eye Res*. 2009;88(2):151-164.
28. Filkorn T, Kovács I, Takács A, et al. Comparison of IOL power calculation and refractive outcome after laser refractive cataract surgery with a femtosecond laser versus conventional phacoemulsification. *J Refract Surg*. 2012;28(8):540-544.
29. Raviv T. The perfectly sized capsulorhexis. *Cataract & Refractive Surgery Today*. http://www.crstoday.com/PDF%20Articles/0609/CRST0609_08.pdf. Accessed November 22, 2013.
30. Peng Q, Visessook N, Apple DJ, et al. Surgical prevention of posterior capsule opacification. Part 3: Intraocular lens optic barrier effect as a second line of defense. *J Cataract Refract Surg*. 2000;26(2):198-213.