Z 8 Reasons why low energy FEMTO LDV Z8 FLACS is the best fit for your practice

Scientific literature review of the 8 unique features and 8 clinical performance pillars of FEMTO LDV Z8 FLACS

I. Introduction

The field of ophthalmology has experienced tremendous advancements in the past few decades, particularly in the area of laser-assisted eye surgery. Ophthalmic surgeries of all kinds have become more precise and easier to perform. In corneal surgery, femtosecond lasers have been used for over 20 years and are still the most common, yet sophisticated tool for correcting vision through refractive surgery.[1,2,3] The use of ultrafast pulses translates into lower energy per pulse compared to longer pulse durations and thus improves the quality of incisions and diminishes collateral damage.[4,5] Mode of action of femtosecond lasers may by described in the following manner:a pulse of energy with a pulse duration in the femtosecond range is created by the laser and delivered in a tightly focused spotfashion to the tissue, causing a process called photodisruption, which transforms the tissue in the focal region into a plasma.[6] This plasma then rapidly expands to create micro-cavitation bubbles, which separate the tissue, resulting in an incision after repeated pulse firing across an area.[4,6] The use of ultrafast pulses translates into lower energy per pulse compared to longer pulse durations and thus improves the quality of incisions and diminishes collateral damage.[4,7] However, not all femtosecond lasers are alike. Per pulse energy and pulse spacing parameters differ between various laser systems and are both critical factors in crafting a minimally invasive, smooth resections, most importantly capsulotomy in the context of Femtosecond Laser Assisted Cataract Surgery (FLACS). The quality of the incision can be enhanced with stronger focusing, since this enables even lower pulse energies and therefore a smaller cavitation bubble.[5] Thanks to strong focusing optics (high numerical aperture NA), the Ziemer FEMTO LDV Z8 is the only laser used in laser eye surgery that can provide low pulse energies in the nanojoule (nJ) range. Figure 1. illustrates how the cutting process in a high pulse energy laser is driven by mechanical forces resulting from expanding bubbles. These bubbles cause tissue disruption at a wider radius than the plasma produced at the laser focus, as depicted in Figure 1. A. In contrast, a low pulse energy laser uses spot separations smaller than the spot sizes, resulting in plasma interaction regions that overlap spatially. Tissue evaporation within the plasma volume separates tissue without the need for secondary mechanical tearing effects, as shown in Figure 1[b]. Applying high pulse frequencies in the MHz range results in similar cutting speeds to those achieved with a high-energy laser.

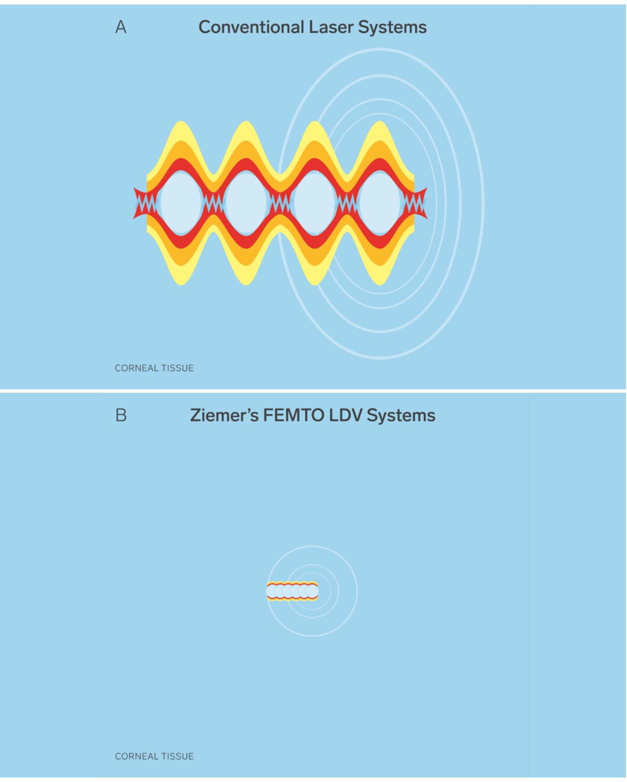


Figure 1. A. High pulse energy, low pulse frequency (large spot separation). The color gradings symbolize the strain levels in the tissue surrounding the induced bubbles; B. low pulse energy, high pulse frequency (small spot separation, overlapping plasma interaction zones). Copyright© Ziemer Ophthalmic Systems AG

When applied in femtosecond laser cataract surgery, the FEMTO LDV Z8 is used to perform following steps of cataract surgery: clear corneal incisions, capsulotomy, lens fragmentation, as well as arcuate incisions to correct astigmatism at the time of cataract surgery. The FEMTO LDV Z8 is equipped with a spectral domain OCT and a color top view camera, based on which the device automatically recognizes the anatomical structures and suggests positions of the cuts. After visual check and confirmation by the operator, the laser proceeds with execution of desired steps of laser cataract surgery, where either all of the above mentioned or certain desired steps can be selected. The FEMTO LDV Z8 uses liquid patient interface, known to be the optimal interface with the regard to IOP increase during the laser treatment.8 The liquid interface facilitates cornea that is free of posterior folds and maintains a state of relaxation and absence of deformation. This prevents any disturbances in the laser beam's trajectory and focal quality, ensuring an ideal resection procedure that includes complete capsulotomies.[8] The FEMTO LDV Z8 is the only femto cataract system with a handheld handpiece attached to an articulated arm, which allows for a lot of flexibility in patient`s positioning and engagement with the patient. Vacuum levels are monitored by the device throughout all duration of suction by means of highly sensitive vacuum sensors, so that the laser emission is immediately stopped in case of loss of vacuum contact. The FEMTO LDV Z8 can be used in sterile and semi-sterile conditions, for temporal and superior approaches, in various operating theatre set-ups, with different phaco-emulsification platforms and, last but not least, without the need for patient`s transfer after the laser pre-treatment.
In addition, the FEMTO LDV Z8 is a versatile platform: it is the only device that can perform not only all aspects of cataract surgery, but additionally corneal and refractive surgeries (LASIK surgery, refractive lenticule extraction, lamellar keratoplasty, penetrating keratoplasty or other treatment requiring lamellar resection of the cornea at a varying depth with respect to the corneal surface) eliminating the need for multiple expensive and cumbersome devices in a single surgical practice. For cataract surgery application, the FEMTO LDV Z8 has been CE marked since 2014, FDA approved since 2015 and after a successful multicenter randomized clinical trial in China received an NMPA market approval in 2022. We will discuss unique features and benefits of the advanced technology of FEMTO LDV Z8, its clinical performance, explore the clinical evidence supporting its use as well as its limitations and potential complications.

II. Z 8 reasons to choose the low energy FEMTO LDV Z8 FLACS: unique features and benefits

1. Low-energy technology

Undoubtedly, the FEMTO LDV Z8's distinct features lie in its utilization of advanced low pulse energy high-frequency technology. This cutting-edge technology provides direct and consequential clinical advantages. Figure 2 once again highlights differences between high and low pulse energy as demonstrated by the phenomenon of creating cavitation bubbles in water. While the technical features have been described earlier, our present focus will remain centered upon the clinical benefits.

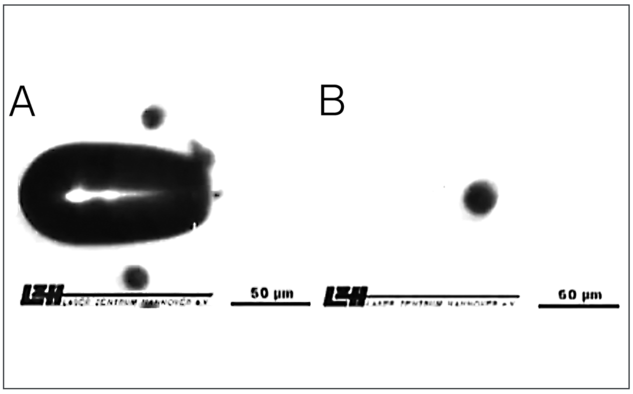


Figure 2. Transient cavitation bubbles in water created by A. high-energy laser pulse (1.35 micro-joules) and B. low energy laser pulse (100 nano-joules) of same duration. A much wider bubble radius is seen for the high-energy micro-joules laser (A). Image property H. Lubatchowski

Why low energy matters:

- Healthier resection edge and reduction in cellular apoptosis: The utilization of low pulse energy in capsulotomy during femtosecond laser-assisted cataract surgery leads to a reduction in cellular loss, diminishes peripheral damage along the capsulotomy edge, and promotes a healthier resection edge. This approach limits the inflammatory response and cellular apoptosis, which tend to intensify with increasing energy levels.[9,10]
- Smooth capsulotomy: A smooth capsulotomy, without grooves and irregularities and most importantly tissue bridges, resembling manual capsulorhexis can be achieved thanks to the high repetition rate and overlapping spots, as shown on Figure 3.

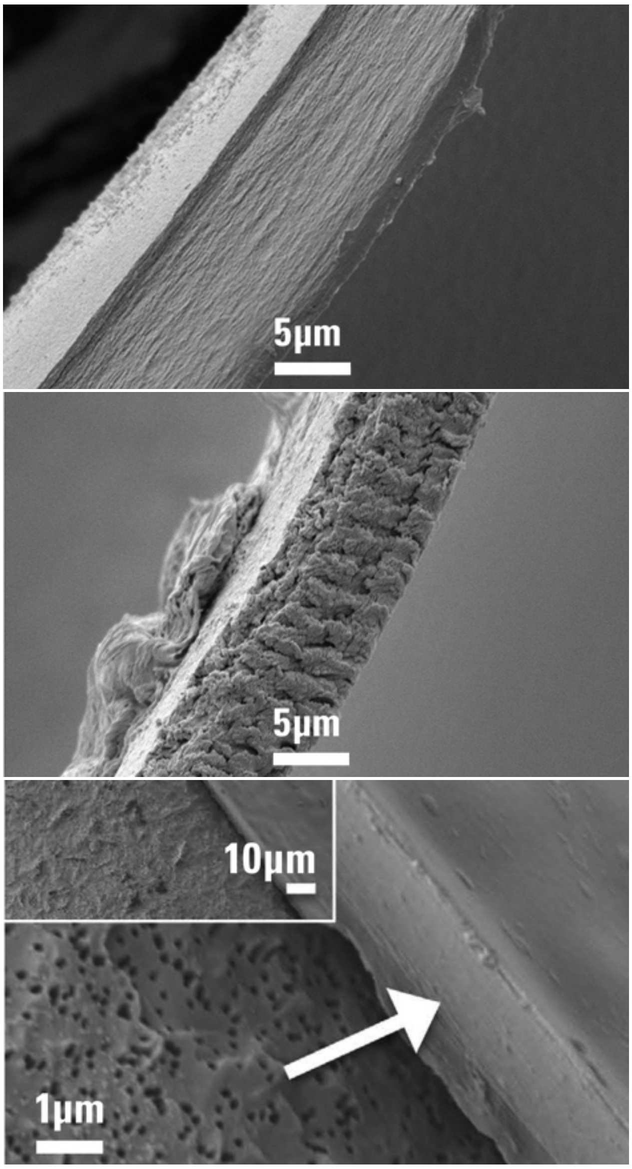


Figure 3. Human capsulotomy edges with manual capsulorhexis (A)[11] and high-energy femtosecond laser (B)[11], compared to low-energy FEMTO LDV Z8 (C)[12]

Tags and irregularities can weaken the rim of the capsule and increase the likelihood of tears in the anterior capsule. Conversely, smoother capsulotomy edges (as shown with the FEMTO LDV Z8) can better withstand greater applied force.

- Strong capsulotomy: The influence of rim quality and the energy applied on capsule strength is supported by a basic research, where Friedman at al.[13] showed that the strength of laser capsulotomies (porcine subgroup) decreased with increasing pulse energy: 152 +/- 21 mN for 3 μJ, 121 +/- 16 mN for 6 μJ, and 113 +/- 23 mN for 10 μJ. The strength of the manual capsulorhexes was 65 +/- 21 mN. This shows how low energy is positively impacting the strength of the capsule rim. Consequently, low energy appears to be the critical factor in achieving both a smooth and robust capsulotomy.
- Midriasis maintained throughout surgery: Pupil size changes occurring due to laser treatment with high-energy lasers are of high clinical significance because small pupil size is generally considered to be a challenge, potentially leading to a higher incidence or severity of complications in cataract surgery. Research with high-energy lasers systems[14,15,16] reports "laser-induced miosis" resulting from prostaglandin release due to ciliary body irritation by laser-created bubbles and thus prompts for application of Non Steroidal Anti-inflammatory Drops (NSAIDs) in combination with mydriatics prior to femto cataract surgery. In contrast to this, studies with the low energy FEMTO LDV Z8 found no differences in pupil diameter or area change[17, 18], as shown in the Figure 4.

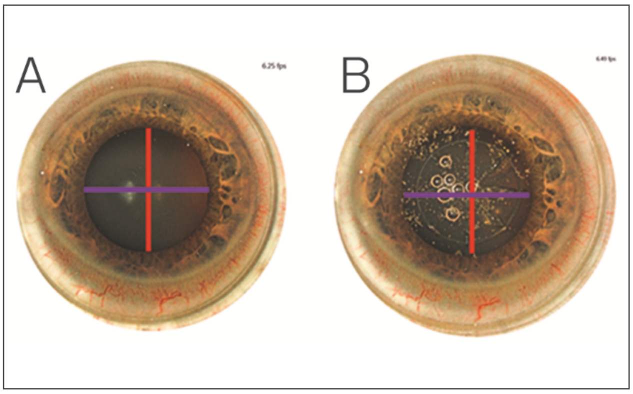


Figure 4. Pupil diameter A. before laser pre-treatment (after patient interface docking) and B. after laser pre-treatment remains unchanged. Copyright© Ziemer Ophthalmic Systems AG

In a study where performance of low energy FEMTO LDV Z8 was compared to a high-energy laser, no miosis was reported in a Z8 group, whereas 19% of patients treated with high-energy laser experienced miosis.[19]

In addition, due to its mobility and versatility, when using the FEMTO LDV Z8, the surgery can be continued immediately after the completion of laser pre-treatment, whilst for other lasers, patients must be transferred to another surgical table or theater in order to continue the surgery. The extended time lapse between laser pre-treatment and further surgical steps may be an additional factor for much more frequent incidences of intraoperative miosis in these cases.[14,16] Absence of miosis observed with the FEMTO LDV Z8 will contribute to more straightforward and safer surgery.

- Negligible inflammation

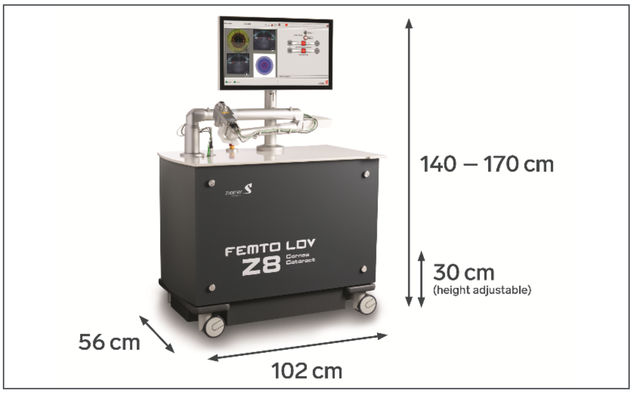
Peri- and post-operative inflammation and the intraocular effects, caused by surgical trauma, remain important issues in cataract surgery. A number of factors are known to be inducers of inflammatory responses, both in manual and femto-cataract surgery. Surgical trauma, ultrasound waves, intra-ocular manipulations, laser cavitation bubbles, and suction induce irritation of ciliary body. The ciliary body reacts by producing prostaglandins and other inflammatory mediators.[20,21] Peri-operatively, the prostaglandins cause pupil miosis and lead to potential difficulties during the course of operation.[20,21] Postoperatively, the inflammation causes pain[22] and slows down patients' return to everyday activities. Anterior chamber flare and corneal swelling are known to influence visual recovery.[23] Macular swelling being a remote effect of inflammatory mediator release in the anterior segment[24] also impacts patients` recovery. This becomes more important than ever before, as younger patients are now also undergoing cataract surgery for refractive reasons.

No changes in IL -1 β and IL – 6 concentrations 5 minutes after femtosecond laser treatment were found with the FEMTO LDV Z8 group in a prospective randomized controlled study comparing the inflammatory impact of low-pulse energy FLACS and conventional cataract surgery.[25] Regarding total prostaglandins (PG) levels (responsible for miosis), an elevation to a mean concentration of 19.86 pg/mL in the low-energy Z8 group compared with 15.6 pg/mL in the CS eyes was detected, which was only a 1.27-fold increase above the baseline. This is in strike contrast with reports using a high-energy laser, where the total PG increase was shown to be 17.5 - fold. 21 The mean concentrations of 25.6 pg/mL IL - 1β and 24.6 pg/mL IL - 6 in aqueous humor for high pulse energy laser pre-treatment reported with another laser system[26] by far exceed those of traces of IL - 1β and 0.45 pg/mL of IL - 6, found in this study.[25] A statistically significantly higher value of 57.6 pg/mL IL - 6 was also found in aqueous humor after using a different high-pulse energy laser pretreatment.[27] In addition to general inflammatory mediators comparison between low-energy FLACS and CS, results of which were in line with the above findings, Liu, Y.C. et al.[28] evaluated changes in aqueous Malondialdehyde (MDA) levels, which reflect the oxidative stress. The oxidative stress, induced during phacoemulsification, strongly correlated with effective EPT, but not with the type of surgery. Thus production of inflammatory mediators with the low-energy FEMTO LDV Z8 is the lowest reported in the literature among all systems on the market. CME can also serve as an indicator of inflammatory reaction resulting from laser pre-treatment. While reports with high-energy lasers noted an increase of post-operative CME29, the laser pretreatment with a low-energy laser including the capsulotomy had no negative impact on this sensitive intraocular structure, even without NSAIDs administration.[24] Furthermore, the mean change in Central Macular Thickness (CMT) and occurrence of postoperative CME was lower in the low-energy FLACS group than the standard-phacoemulsification group in another study; even though this difference was not statistically significant.[30] This indicates negligible inflammatory reaction to the low-energy FEMTO LDV Z8 pretreatment and will have a positive effect on both intra-operative and post-operative periods.

2. Mobility

FEMTO LDV Z8 is completely mobile. This means that it can be rolled in and out of rooms, down hallways and even shared between practices in the same day. In addition FEMTO LDV Z8 has the smallest clinical footprint (its dimensions are shown in Figure 5) of all femtosecond lasers and through a patented self-calibration system, automatically re-adjusts itself upon startup to correct for any small movements that may have occurred during transport. No other laser on the market is truly mobile.

Figure 5. Dimensions of the FEMTO LDV Z8. Copyright© Ziemer Ophthalmic Systems AG



Why mobility matters:

- Ethics:
  - The patient doesn't need to be transferred during the procedure (laser to patient)
  - Patient safety, comfort and satisfaction
  - Absence of transfer is crucial in pediatric setting where surgeries are performed under general anesthesia

- Clinical outcomes:
  - Sterility not compromised
  - No time for pupil size alteration as no time for transfer required
  - Possibility of performing capsulotomy in pediatric patients under sterile conditions and under as short as possible general anesthesia
- Economics:
  - Share the laser with other (Operating Rooms) ORs or clinics
  - One platform, multiple uses in multiple occasions
- Infrastructure:
  - No additional laser theater needed
  - Fits in small theaters and can be stored elsewhere
  - Can be used with any phaco-emulsification device

3. Effective workflow integration

As already mentioned, the FEMTO LDV Z8 can be flexibly used with any phaco-emulsification device desired without any infrastructure changes. It can be used in sterile and semi-sterile conditions. Furthermore different patient approaches, such as superior or temporal (Figure 6) can be adopted. No intra-operative patient transfer needed. Thanks to absence of patient transfer, the FEMTO LDV Z8 is perfectly suitable for bilateral surgeries.

Figure 6. FEMTO LDV Z8 in superior (A) and temporal (B) approaches used in sterile conditions

4. Handheld handpiece

High precision mechanics and optics are integrated in the handpiece, which allows working very close to the eye. The Ziemer LDV Z8 is the only femto cataract system with a handheld eye interface (handpiece). The handpiece allows surgeons to engage with their patients directly; once docked, the handpiece moves with the patient, ensuring a perfect capsulotomy even if movement such as coughing occurs during laser treatment. Because the LDV Z8 handpiece with the patient interface is on an articulating arm (Figure 7), the many docking angles are possible and docking can be successfully performed on any size of patient or at any orientation (e.g. spine abnormalities or obesity). All other lasers are restricted to a precise 90° angle, fixed mechanical docking position leading to vacuum breaks and aborted cases if there is any patient movement.
In addition holding the handpiece in surgeon's hands allows to establish a contact between the surgeon and his patient, helping patients to feel more secure "in surgeon's hands".

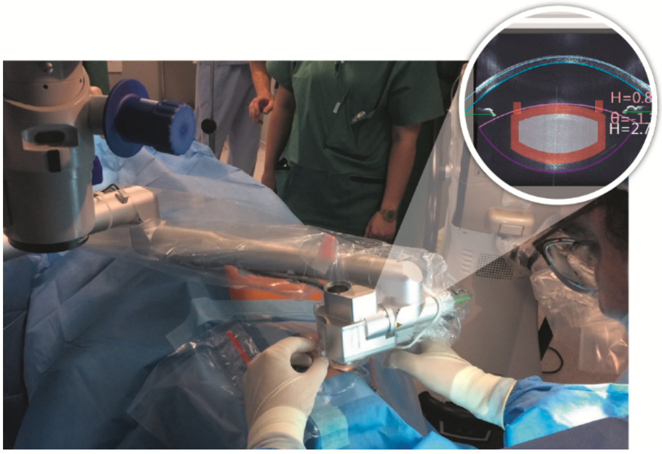


Figure 7. Articulating arm and the handpiece in the hands of the surgeon. Copyright© Ziemer Ophthalmic Systems AG

5. Sterile technique and its benefits

Because the FEMTO LDV Z8 can move freely into and out of the OR, sterility of the laser surfaces that are near the patient are maintained thanks to a disposable draping system. With each sterile procedure pack, the sterile draping system is included and can be affixed to the device within approximately 1 minute.
One of the primary criticisms of femtosecond lasers has been their disruption of the surgical workflow. Because of their size, lasers are often too large to fit into the OR. To accommodate this, surgeons will perform laser pre-treatment in a non-sterile room and then move the patient into the OR to finish the procedure. The FEMTO LDV Z8 is the only laser that is completely mobile and can be moved in or out of the OR within minutes. The FEMTO LDV Z8 FLACS is generally performed in the sterile OR which enhances patient`s experience as no room changes are required.

6. Visualization possibilities

The Z-CATARACT application uses intra-operative OCT imaging and machine learning algorithms for automated edge detections and cut placements. High resolution in house-developed intra-operative OCT and Top-View imaging allow for planning and visual control during the laser part of the surgery.

7. CE mark for use in pediatric cataract setting

- → FEMTO LDV Z8 is the only CE marked device approved for pediatric cataract surgery
- → Mobility and small footprint of the FEMTO LDV Z8 allow to place it inside any sterile OR. Ability to maintain sterile environment is a necessary prerequisite in case of surgery on pediatric surgery
- → Space for the anesthesiologist as well as for their equipment is given thanks to the small footprint of the FEMTO LDV Z8, which will ensure seamless integration in the workflow when the surgery is performed under general anesthesia
- → Patient transfer is not needed with the FEMTO LDV Z8 and in unfeasible in pediatric setting
- → FEMTO LDV Z8 published evidence: Largest sample published to date with femtosecond laser is with the FEMTO LDV Z8 (51) eyes)[31]
- → Published evidence in complex pediatric cases, where surgery with the FEMTO LDV Z8 was shorter than the manual, most valuably shortening the general anesthesia time[32]
- → Naturally all benefits of capsulotomy precision as in adult cataract surgery are applicable in pediatric setting, however important to consider capsule elasticity and its dependence on age

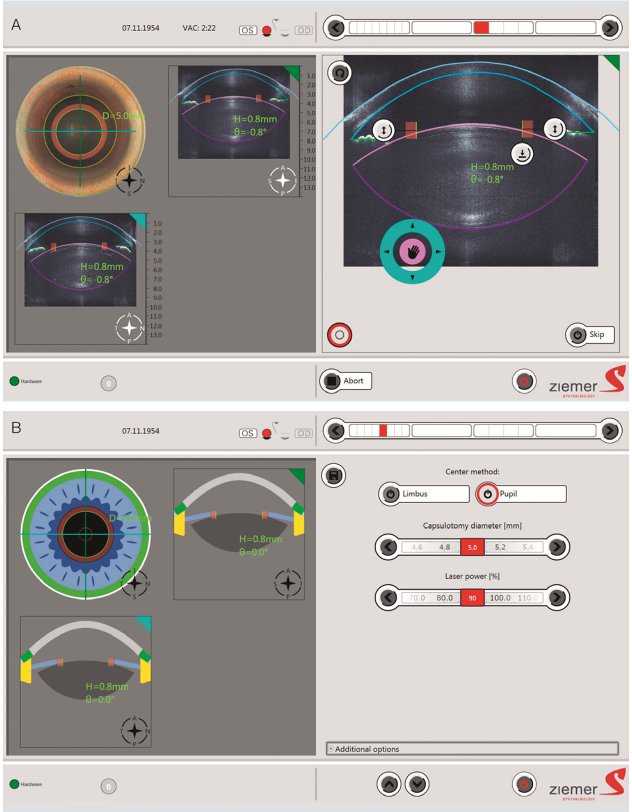
8. Constant innovation and applications à la carte

Swiss technology, designed in-house to further facilitate rapid innovation, constantly developing new features allowing choice of applications à la carte. The FEMTO Z8 femtosecond laser offers multiple applications that can be customized for your surgical needs and it grows as your practice and technology advances.

III. Z 8 pillars of clinical performance of low energy FEMTO LDV Z8 FLACS (Peer-reviewed literature review)

1. Low-energy capsulotomy

FEMTO LDV Z8 capsulotomy is customizeable in diameter, position and depth and can be centered according to surgeons' preferences. As with all steps of the FLACS surgery, the capsulotomy is placed automatically by the laser based on the OCT and color Top View images (Figure 8) and executed after visual control and confirmation by the operator.



Center method: Pupil

Capsulotomy diameter [mm]: 4.6 4.8 5.0 5.2 5.4

Laser power [%]: 70.0 80.0 90 100.0 110.0

Figure 8. Graphic User Interface of FEMTO LDV Z8 displaying capsulotomy planning screen, showing: A. color Top View image, horizontal and vertical OCT sections and enlarged active screen with the current planning. B. Settings example. Copyright© Ziemer Ophthalmic Systems AG

Considerations in judging the success of capsulotomy include consistency in size, position, circularity and strength. Femtosecond laser capsulotomy offers several advantages over manual capsulorhexis, including increased precision, reproducibility, and consistency.[33, 34] In a randomized controlled trial[34], where FEMTO LDV Z8's capsulotomies were compared to conventional surgery (CS) and the target capsulotomy diameter was 5.0 mm, the achieved capsulotomy diameter in the Z8 group was 5.0 ± 0.12 mm (range: 4.6–5.4 mm), median 5.0 mm, and in the conventional cataract surgery group 4.7 ± 0.36 mm (range: 4.0–5.6 mm), median 4.7 mm. The observed difference was statistically significant ($p < 0.001$) and indicates high precision and reproducibility of the FEMTO LDV Z8's capsulotomy diameter.
In addition, capsule strength and edge quality were investigated in laboratory setting, where the capsulotomies performed using the FEMTO LDV Z8 produced smooth profile with no induration or tags and resistant to rupture capsulotomies.[12] Earlier literature describing higher energy FLACS platforms suggested a higher rate

of anterior tags at higher energy settings.[35] Although the full implications of edge smoothness for resistance to rupture have yet to be established, smoother edge without tags and irregularities is expected to be less prone to ruptures, as irregularities may create weaker points on the capsule rim. These findings are clinically supported by a direct comparison of the FEMTO LDV Z8 with a high energy laser in a retrospective comparative analysis, where the number of free-floating capsulotottmies was significantly higher ($p=0.03$) in FEMTO LDV Z8 group, as compared to the LenSx group, i.e. 100% vs 94%, respectively.[19]

Very low occurrence of anterior capsule tears using FEMTO LDV Z8 was reported in a large real world case series, where among 1,806 eyes of 1,131 patients only 5 eyes experienced complications, 3 of which were anterior capsule tears (0.17%) and two posterior ruptures (0.11%). No other complications occurred in this study.36 In their meta-analysis Kolb et al.[37] reported 1% of anterior capsule tears and 0.43% of posterior capsule ruptures for high-energy lasers, whereas Wang et al. presented 1.77% and 0.62% respectively. Thus, the occurrence of capsule tears reported in the literature with the low-energy FEMTO LDV Z8 is the lowest and indicates high safety of the procedure.

The effect of the laser resection on the capsule rim may contribute to its quality and such properties as smoothness and rupture resistance. It has been shown, that cell death reaction also depends on the laser pulse energy settings and can be reduced to the level observed in a manual capsulorhexis, when lower pulse energies are applied.[9,38] Excessive cell death may cause inflammatory response, however it is not known, if moderate cellular apoptosis may contribute to slowing the posterior capsule opacification (PCO) development. Many studies have been conducted so far in order to define which factors may influence development of PCO, including IOL design, administration of therapeutic agents, surgical technique itself, and other surgical procedures to clean the posterior capsule. A study with the low energy FEMTO LDV Z8 found significantly lower Evaluation of Posterior Capsular Opacification (EPCO) scores in the FLACS group when compared to CS at 18 months (0.050 ± 0.081 vs 0.122 ± 0.239, respectively ($p = 0.03$)).[39]

In this study capsulotomy shape presented higher stability and circularity in the FEMTO LDV Z8 group over the 18-month observation period. In another retrospective study, over the 24-month postoperative period, PCO requiring neodymium-doped yttrium aluminum garnet (Nd:YAG) capsulotomy was performed in 38% of eyes following FLACS and in 58% of eyes following CS ($p> 0.05$). FEMTO LDV Z8 FLACS group demonstrated a significantly reduced incidence of PCO requiring Nd:YAG.[40] Thus, a balance between the cell death, capsule diameter precision and stability coupled with application of the low energy FLACS may explain a positive effect of the PCO occurrence in FEMTO LDV Z8 FLACS.

2. Low-energy lens fragmentation

Numerous lens fragmentation patterns are possible with the FEMTO LDV Z8. According to preferred techniques, cataract hardness or its specific characteristics, one can adapt the depth or diameter of fragmentation and select either several segments (from 4 to 16 segments), or rings, or their combination, as shown in the Figure 9 below:

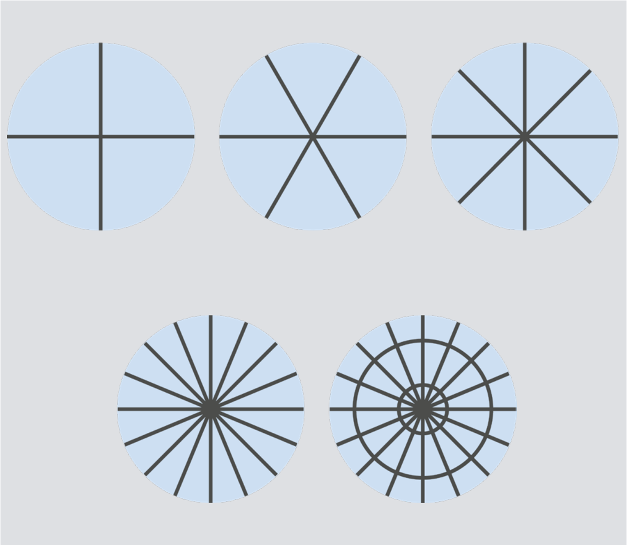
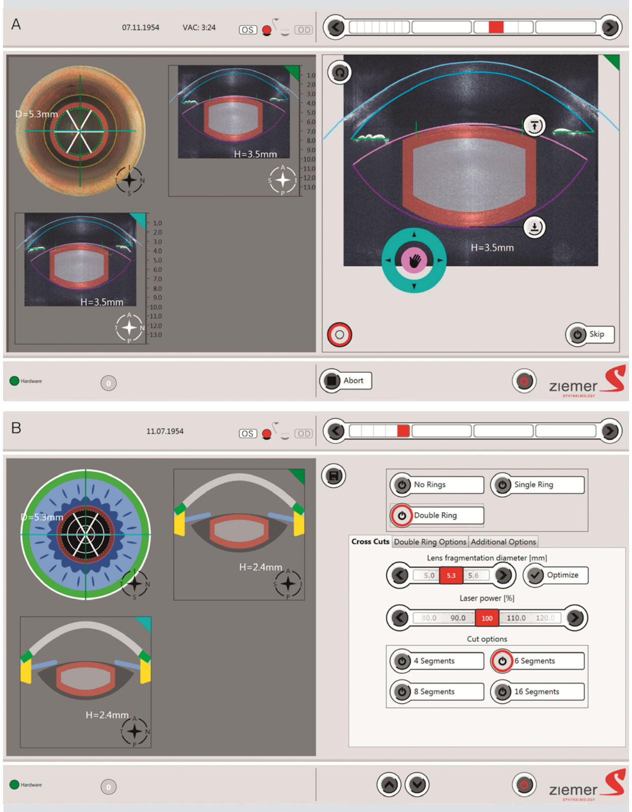


Figure 9. Various possible lens fragmentation patterns. Copyright© Ziemer Ophthalmic Systems. Example of the lens fragmentation is shown in the Figure 10. Copyright© Ziemer Ophthalmic Systems AG



No Rings
Single Ring
Double Ring
Cross Cuts | Double Ring Options | Additional Options
Lens fragmentation diameter [mm] 5.0 5.3 5.6
Optimize
Laser power [%] 80.0 90.0 100 110.0 120.0
Cut options
4 Segments
6 Segments
8 Segments
16 Segments

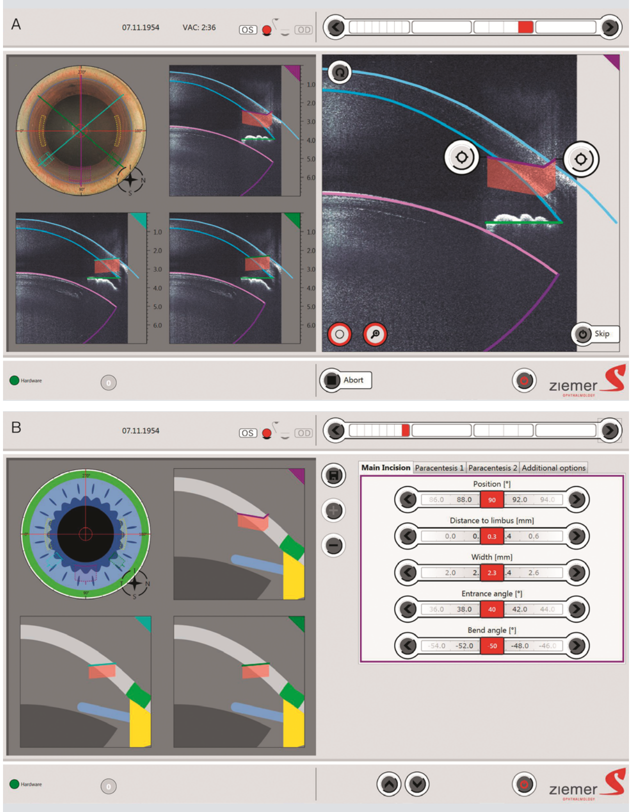
Figure 10. Graphic User Interface of FEMTO LDV Z8 displaying lens fragmentation planning screen showing: A. color Top View image, horizontal and vertical OCT sections and enlarged active screen with the current planning. B. Settings example. Copyright© Ziemer Ophthalmic Systems AG

3. Low energy and endothelial cell protection

In line with all reports dedicated to FLACS in general the FEMTO LDV Z8 FLACS as well, has been shown to reduce the phacoemulsification time and effective phacoemulsification time (EPT),[39,41,42] thereby diminishing the corneal endothelial injury.43 The reduction of phacoemulsification time and endothelial cell protection were found in different cataract densities. Schroeter at al.[43] reported notably shorter EPT ($p = 0.007$) and significantly better endothelial cell counts ($p = 0.048$) in FLACS group compared to CS in patients with grade II cataract in a prospective randomized controlled study. At the same time Ou et al.[42] conducted a retrospective case–control study and found decrease in phacoemulsification energy consumption ($p < 0.001$) and reduction of endothelial loss ($p < 0.001$) in FLACS group compared to CS in patients with harder cataracts (grades IV-VI). Three surgeons with different experience levels and using different surgical approaches participated in the latter study, however the decrease in energy consumption as well as endothelial cells protective effect of low energy FLACS were not different between the surgeons. In a public teaching hospital setting similar results were found, where the total phacoemulsification power (TPP) was significantly less in FLACS compared to CS ($p = 0.031$).[44] Thus, the decreased energy consumption and endothelial preservation when using FEMTO LDV Z8 are reported for different cataract densities, in addition this effect was shown to be independent of surgeons` experiences or techniques.

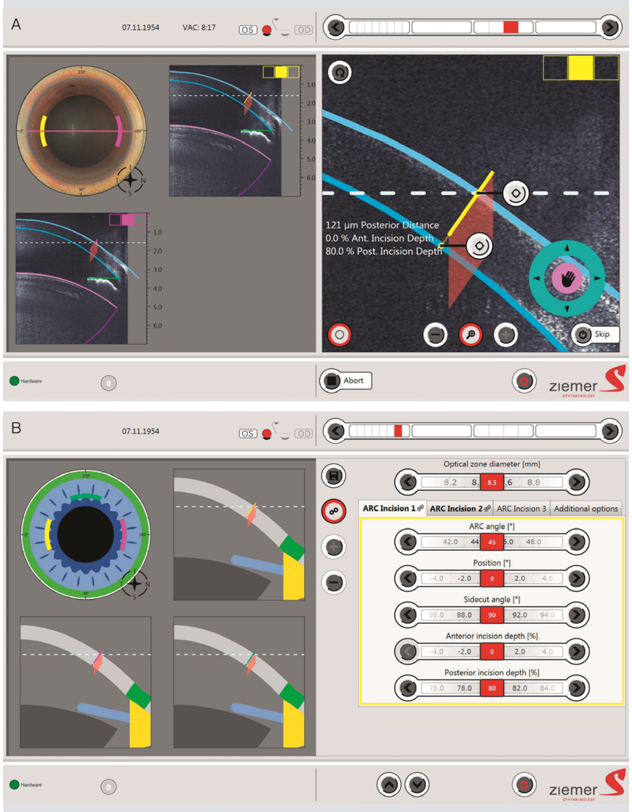
4. Low-energy corneal incisions

When discussing laser corneal incisions using the low-energy FEMTO LDV Z8, it is impossible not to recall the extensive research on low energy usage in corneal procedures spanning several decades. Low energy was demonstrated to induce minimal collateral damage and inflammation, resulting in a highly favorable healing in the cornea, manifested by minimal wound healing reaction and apoptotic cells along the incision plane.[45] The FEMTO LDV Z8 can perform up to 3 corneal incisions of customizeable width and shape, which can be used as desired as a main incision and paracenthesis, either all at once or as many as needed Arcuate (ARC) incisions can also be administered to patients with astigmatism of up to 3D and can serve as an alternative for costly toric IOLs in some cases. Below are examples of planning screens and settings or different incisions (Figures 11 and 12).



Main Incision | Paracentesis 1 | Paracentesis 2 | Additional options
Position [°] 86.0 88.0 90 92.0 94.0
Distance to limbus [mm] 0.0 0. 0.3 .4 0.6
Width [mm] 2.0 2. 2.3 .4 2.6
Entrance angle [°] 36.0 38.0 40 42.0 44.0
Bend angle [°] -54.0 -52.0 -50 -48.0 -46.0

Figure 11. Graphic User Interface of FEMTO LDV Z8 displaying CCI planning screen showing: A. color Top View image, horizontal and vertical OCT sections and enlarged active screen with the current planning. B. Settings example. Copyright© Ziemer Ophthalmic Systems AG



121 µm Posterior Distance
0.0 % Ant. Incision Depth
80.0 % Post. Incision Depth

Optical zone diameter [mm]: 8.5
ARC Incision 1 | ARC Incision 2 | ARC Incision 3 | Additional options
ARC angle [°]: 45
Position [°]: 0
Sidecut angle [°]: 90
Anterior incision depth [%]: 0
Posterior incision depth [%]: 80

Figure 12. Graphic User Interface of FEMTO LFV Z8 displaying ARC incisions planning screen showing A. color Top View image, horizontal and vertical OCT sections and enlarged active screen with the current planning. B. Settings example. Copyright© Ziemer Ophthalmic Systems.

Lin et al. showed a considerable decline in corneal astigmatism and a significant decrease in the percentage of eyes with ±0.5 D and ±1.0 D astigmatism at 3 month using FEMTO LDV Z8 arcuate incisions.[46] Schwarzenbacher et al.[47] showed a significant reduction in anterior and total corneal refractive power astigmatism 1 year after surgery, while posterior corneal curvature showed no significant change. Vector astigmatism analysis indicated stable astigmatism at 1 month, 3 months, and 1 year, and corneal wavefront HOAs significantly improved at all follow-up periods. The study concluded that Femto Arcuate Keratotomy (AK) was an efficient and stable method for reducing corneal astigmatism while preserving corneal optical quality. The “Castrop” nomogram developped by P. Hoffmann was applied in this study[48], however since then a new updated nomogram based on larger number of cases has been published and is recommended for use.[49] Stability is another very important finding, due to posisble regression of the effect of femtosecond corneal relaxing incisions. Most probably, the minimal healing response and negligible collateral damage of the corneal tissue to the low energy laser incisions are supporting stability of the treatment, by preventing regenerative processes, which naturally occur as a reaction to tissue damage. The depth of the incisions was also evaluated and shown to be very precise: the average corneal cut depth corresponded to 79.49% of the total corneal depth, where 80% was planned, demonstrating high precision of the cut, as shown on an example of the OCT taken after the cut on Figure 13.

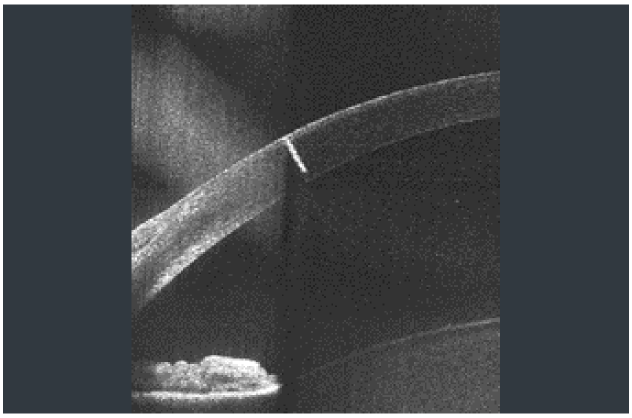


Figure 13. Cross-sectional view of Arcuate Incision on post-cut OCT (human eye). Image property © Ziemer Ophthalmic Systems AG

5. Low-energy FEMTO LDV Z8 applied in difficult cases

While the above presented clinical outcomes were obtained during routine surgeries in uncomplicated cases, FLACS is known for providing benefits in difficult cases. For instance, to perform FLACS in patients with small pupils that either do not achieve adequate preoperative pharmacological mydriasis, or in whom intraoperative miosis occurs, surgeons developed surgical techniques that include the use of mechanical pupil expanders (e.g. Malyugin ring, iris hooks, etc.).[50,51] Ophthalmic viscosurgical devices (OVDs) are used to facilitate insertion of mechanical pupil expanders and to achieve viscomydriasis.[51,52,53] Successful use of the FEMTO LDV Z8 demonstrated and described the technique of FLACS in 2 identical patients with cataracts and small pupils (3.5 mm each) using iris hooks, no intra-operative complications occurred and vision of both patients reached 0 logMAR at 3 months.[54] Similarly, a case series using Malyugin ring combined with the FEMTO LDV Z8 in eyes with ectopia lentis, demonstrated how FLACS in this case has the potential to improve surgical results by allowing the anterior capsulotomy to be created with the femtosecond laser, thus increasing the precision of the capsulotomy and minimizing possible complications in the selected cases. In addition, femtosecond laser capsulotomy and lens prefragmentation in patients with ectopia lentis are known to reduce the mechanical stress on the lens capsule and zonular apparatus caused by cataract extraction.[53]

As the cases mentioned in this section will require the use of OVDs, special attention needs to be paid to the choice of the appropriate in combination with the laser OVD. Mansoor et al.[55] evaluated the effectiveness of

femtosecond laser-assisted anterior capsulotomy done with the Ziemer LDV Z8, in the presence of five different most commonly used OVDs in cataract surgeries in the anterior chamber and under two different energy settings (90% and 150% energy) using fresh porcine eyes. They found that: 1. The refractive index and particularly the viscosity of an OVD influence performance of the femtosecond laser. 2. Use of a higher energy setting in the presence of an OVD in the anterior chamber to enhance the efficacy of laser-assisted anterior capsulotomy is recommended. 3. Selecting an OVD with a refractive index similar to that of the aqueous humor and with a lower viscosity (e.g. Healon and Provisc) is recommended, as far as the intended mechanical purpose of the OVD permits.
Another research was dedicated to the FLACS with the FEMTO LDV Z8 in the presence of corneal edema.[56] In order to achieve consistent and complete capsulotomies in the presence of corneal edema, it is necessary to increase laser energy, as edematous cornea being a non-transparent medium and may hinder the laser delivery however. However, in case of high energy the quality of the capsule rim may be compromised.9 Because of the low energy delivered by the FEMTO LDV Z8, even incremental increases in energy appeared to have minimal effect on lens capsule morphology and strength and negligible influence on cell death. Furthermore, increasing energy appeared to enhance consistency and the ability to complete a capsulotomy in an edematous cornea. This may be particularly useful when performing FLACS in eyes with concurrent corneal pathology such as Fuchs Endothelial Dystrophy, in order to reduce endothelial damage from phacoemulsification energy.

6. Learning curve and potential complications

Although the use of FLACS technique is reported to entail a learning curve, unlike conventional cataract surgery, the learning curve for femtosecond laser-assisted surgery is short. Cavallini et al.[57] observed the following initial learning curve: for the first 60 FLACS cases, the intraoperative complication rate was higher, than for the following 60 FLACS cases. At the same time, no major complications, such as anterior capsule tears, posterior capsule tears, or dropped nuclei occurred during the study evaluating the first experience and first 14 cases operated with the FEMTO LDV Z8.33 In a the large case series by Riemey at al.[36], which reported 0.28% intraoperative complication rate, even if the first 20 operations were included in the analysis, the complication rate would hardly change: 0.28% and 0.38% for two surgeons who participated in the study. The first complication after the learning curve occurred in surgery number 106. This indicates a potentially shorter learning curve with the low-energy FEMTO LDV Z8 laser as opposed to the high-energy technology.
Overall FEMTO LDV Z8 publications report no major complications[33,34], with 0.28% intra-operative capsule complications36 reported in large case series. Two cases of incomplete Clear Corneal Incisions (CCI) and no other complications were reported in a case control study, which included 140 eyes[41], no incomplete capsulotomies or miosis were observed. No intraoperative complications and one case of Cystoid Macular Edema (CME) in the FLACS group and two in the CS group were reported in a randomized Controlled Trial Comparing 1-Year Outcomes of Low-Energy Femtosecond Laser-Assisted Cataract Surgery versus Conventional Phacoemulsification.[58] Also in a learning setting in a public teaching hospital no intraoperative complications were reported in either of the groups, when FEMTO LDV Z8 FLACS was compared to CS in a prospective study which included 90 eyes from 90 patients.[44] The most dreaded complication of of cataract surgery, i.e. posterior capsule rupture was reported only in one study, where among 1806 eyes, two cases were observed.[36] These reports indicate high safety of the low-energy FEMTO LDV Z8.

7. Low energy FEMTO LDV Z8 combination with premium intraocular lenses

Considering that premium intraocular lenses (IOLs) depend more on precise centration for optimal performance and capsule diameter stability, no fibrosis or tilt development are prerequisites for stable effective lens position (as shown on the drawing below Figure 14), growing body of evidence speaks for a tandem of premium IOLs and FLACS.

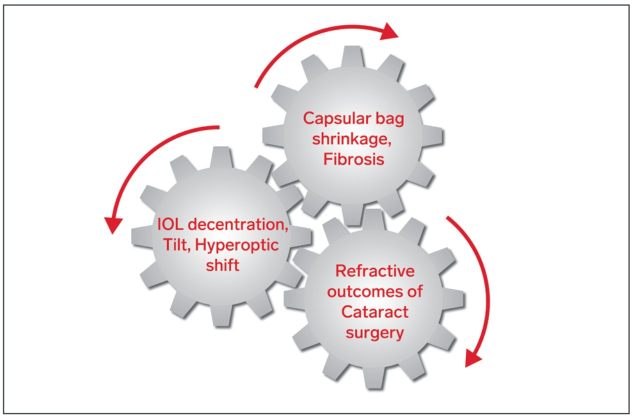


Figure 14. Demonstrates dependencies between capsule fibrosis and shape changes, IOL misplacement resulting in refractive outcome. Copyright© Ziemer Ophthalmic Systems AG

Several scientific works, where FEMTO LDV Z8 in combination with premium IOLs delivered high quality visual outcomes, have been published in recent years.[59,60,61,62] The IC-8 IOL was shown to attain good centration and positional stability up to 3 month postoperatively when combined with FLACS. It enabled both extended depth of focus and tolerance to aberration, making it capable of achieving spectacle independence after surgery.[60]

In another example, patients who underwent a safe bilateral implantation with Intensity IOL achieved a high degree of spectacle independence and satisfaction 6 months after surgery.[62] Lens implants are becoming more advanced requiring increased accuracy and precision in cataract surgery, which FLACS can provide. Technique and equipment has been developing hand in hand with the new IOLs and it is only natural to expect, that further developments of IOLs and FLACS will be occurring in parallel.

8. Low-energy FEMTO LDV Z8 FLACS in pediatric cataract surgery

Pediatric cataracts are rare, but their early management can have a tremendous impact on the quality of life of children. In addition, every pediatric case is unique and differs from routine cataract surgery in adults. Main differences lie in high capsule elasticity, consideration of posterior capsule opacification, very young age of patients and potential comorbidities often manifesting with congenital cataracts. The use of femtosecond lasers in pediatric cataract surgery has been reported with several lasers, however in these cases the lasers were used off-label. To date the FEMTO LDV Z8 is the only femtosecond laser having a CE mark for use in pediatric cataract setting. The FEMTO LDV Z8 was successfully applied in case series including 12 patients with primary persistent hyperplastic primary vitreous (PHPV) syndrome. Successful posterior capsulotomies were achieved and the use of the femtosecond laser allowed for a reduction in the number of intraocular manipulations, which mitigates the risk for complications and shortens the duration of surgery and anesthesia for pediatric patients.[32] The largest number of congenital cataract surgeries using femtosecond laser to date, was published with the FEMTO LDV Z8 and included 51 eyes of 33 pediatric cataract patients. Intra-operative and long-term safety, resulting in significant improvement in visual acuity were demonstrated in this study.[31]

IV. Conclusions

FEMTO LDV Z8 is the latest generation low-pulse energy high frequency laser, which in the context of cataract surgery performs capsulotomy, lens pre-fragmentation, clear corneal incisions and arcuate incisions to treat astigmatism at the time of cataract surgery. It is the only laser used in laser eye surgery that can provide low-pulse energies in the nanojoule (nJ) range. FEMTO LDV Z8 is mobile and can be used in various operating theatre's set-ups with various phaco-emulsification devices and, last but not least, without the need for patient transfer after the laser pre-treatment.

High precision, reproducibility and consistency of the FEMTO LDV Z8's capsulotomies, when compared to SC, are reported in studies. Capsulotomy edge was found to be smooth and rupture resistant. The occurrence of capsule tears reported in the literature with the low-energy FEMTO LDV Z8 is the lowest and indicates high safety of the procedure. A significantly reduced incidence of PCO requiring Nd:YAG treatment in the eyes operated with the FEMTO LDV Z8 supports the high capsulotomy performance and low-energy benefits of the FEMTO LDV Z8. Furthermore, decreased energy consumption and endothelial preservation when using FEMTO LDV Z8 are shown for different cataract densities, in addition this effect was independent of surgeons' experiences or techniques. The low energy incisions are highly precise, furthermore arcuate keratotomies effectively correct astigmatism and maintain correction effect at long term. In complex cases FEMTO LDV Z8 was successfully applied in combination with iris hooks and Malyugin ring, in ectopia lentis patients, with an OVD in the anterior chamber, in cases with concurrent corneal pathology and was shown effective in cases with corneal opacities. It is frequently used in tandem with premium IOLs due to capsulotmy precision, negligible inflammation and low PCO occurrence. FEMTO LDV Z8 is the only laser having a CE mark for use in pediatric cataract setting, supported by large case numbers published in the literature.

Major distinct feature of the FEMTO LDV Z8 is its utilization of advanced low-pulse energy high-frequency technology, which results in: healthier resection edge and reduction in cellular apoptosis, smooth and strong capsulotomies, midriasis maintained throughout the duration of the surgery and negligible inflammation.

In the future, low-energy femtosecond laser cataract surgery is likely to become more widely adopted as the technology becomes more advanced and affordable. Additionally, the use of artificial intelligence (AI) and machine learning may play a role in optimizing surgical planning and improving patient outcomes. For example, AI algorithms could help surgeons determine the optimal surgical parameters for each individual patient based on their unique anatomy and other factors. Overall, the combination of low-energy femtosecond laser cataract surgery and advanced IOL technology is expected to revolutionize cataract treatment in the coming years, leading to improved outcomes and a higher quality of life for patients.

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