


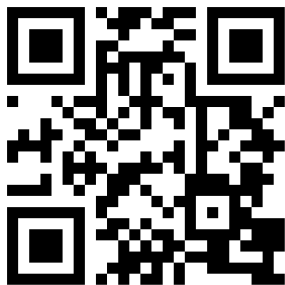
# The Latest Evidence with Regards to Femtosecond Laser-Assisted Cataract Surgery and Its Use Post 2020

This article was published in the following Dove Press journal:  
*Clinical Ophthalmology*

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**Abstract:** Femtosecond laser-assisted cataract surgery (FLACS) was introduced with the hope of making cataract surgery safer and making the refractive result more predictable. It is only in the last four years that level 1 prospective randomised controlled trials (RCT) using current technology have been published. These, along with a meta-analysis of recent studies have shown that there seems to be little long-term visual benefit when using FLACS with monofocal lenses. The promised decrease in ultrasound energy required to remove a cataract has not been consistently demonstrated. There is level one evidence that the rate of posterior capsular rupture is less with FLACS using modern software. The round capsulotomy may be of increasing importance with the uptake of toric, multifocal and extended depth of focus lenses where a predictable capsulotomy size and precise placement of the lens becomes more important.

**Keywords:** femtosecond laser-assisted cataract surgery; conventional cataract surgery; posterior capsular rupture; extended depth of focus intraocular lenses; pseudophakic cystoid macular oedema

## Introduction

Femtosecond laser-assisted cataract surgery (FLACS) or laser cataract surgery (LCS) was introduced with the intention of making cataract surgery refractive results more predictable.<sup>1</sup> It was suggested that it would improve wound architecture, increase the accuracy of the anterior capsulotomy and ensure a more predictable position of the intraocular lens.<sup>2</sup> It was thought that it would be part of the natural evolution of cataract surgery with laser replacing some of the steps previously performed by hand.

An early editorial in 2011 heralded the arrival of the technology.<sup>3</sup> It was suggested that the efficacy and safety of the new technology would have to be addressed in future peer-reviewed studies. At the time, reports of the use of FLACS were only just beginning to find their way into the ophthalmic literature. The editorial predicted that only time would tell if this technology would be adapted into standard ophthalmic practice.<sup>3</sup> A further editorial in 2017 questioned the role of FLACS.<sup>4</sup> It was stated that the proposed benefits of the femtosecond laser were theoretical without there being current conclusive evidence of clinical benefit in terms of visual outcomes.<sup>4</sup> During the last four years, concrete evidence has started to emerge in order to answer the question as to whether FLACS has a future in cataract surgery.

The first report of a human having their cataract removed using FLACS was reported in 2009.<sup>5</sup> During the last 11 years the evidence with regards to the benefit, or lack thereof has emerged. The evidence has risen through the levels of evidence from small case reports, to case series, large multi-centre reviews and the occasional randomised controlled trial (RCT). The first prospective randomised trial using current technology was recently published in 2019.<sup>6</sup> The “Femtosecond laser-assisted cataract surgery versus phacoemulsification cataract surgery” (FACT) study was published in 2020 using current technology with the option of toric intra-ocular lenses (IOL).<sup>7</sup> In 2020 a meta-analysis of the previous RCTs was published looking at the comparison between FLACS and conventional cataract surgery (CCS) since December 2017.<sup>8</sup> This review looks at how both primary interventional and secondary filtered level 1 evidence taken from studies published within the last 4 years, or whose recruitment started in 2016 or later, will allow us to answer the questions as to whether there is a benefit in offering FLACS to our patients.

## Visual Acuity

Visual and refractive results are the most important endpoints for patient satisfaction.<sup>8</sup> Three prospective randomized controlled studies found that there was no long-term visual advantage when using FLACS.<sup>6,7,9</sup> The latest meta-analysis published in 2020 showed that subgroup analysis of RCTs pointed to better uncorrected distance visual acuity in the FLACS group in the medium term (six months), but there was no difference in visual outcome in the long term of 6 months or more.<sup>8</sup> [Table 1]

The difficulty with reporting visual results was underscored by the FACT study in which the surgeon could

decide on whether patients were to have a non-toric lens, toric lens or astigmatic keratotomies.<sup>7</sup> Previous studies did not always comment on the use of toric lenses and allowed each participating center to use their own brand of intra-ocular lens.<sup>9</sup> A large retrospective study of 1838 eyes found that the strongest predictor of refractive success was found in those eyes receiving a toric IOL, having less corneal astigmatism and those with an axial length of between 22 and 24.8 mm, rather than whether the patient had FLACS or CCS.<sup>10</sup> Any improvement or even comparison in vision, therefore, is hard to demonstrate due to variations in case mix, follow-up times corneal astigmatism and the use of toric or non-toric lenses.<sup>11</sup>

It was suggested that by having a complete circular capsulotomy there would be less lens tilt or decentration which would then translate into better vision.<sup>12</sup> The recent meta-analysis stated that there were distinct advantages of FLACS regarding surgical endpoints with regards to better capsulotomy circularity.<sup>8</sup> The circularity did not result in better long-term vision though. Furthermore, having less capsular shrinkage post FLACS may not have made a lasting difference to vision in the past but may do so in the future. In 2012, an RCT used Scheimpflug imaging to show that FLACS led to better lens centration and less tilt 1 year after surgery.<sup>13</sup> In late 2020, a more reliable way than Scheimpflug photography or Purkinje images was used to measure and report the tilt and decentration of lenses.<sup>14</sup> The Casia2 (Tomey GmbH) anterior segment optical coherence tomographer (AS-OCT) measurements showed that incomplete capsular optic overlap did not lead to increased tilt, but did lead to increased decentration.<sup>14</sup> This may have an influence on multifocal lenses, extended depth of focus (EDOF) lenses and toric lenses which rely

**Table 1** Significant Difference Between FLACS and Conventional Cataract Surgery Variables in Level I RCTs or Meta-Analysis Literature 2016–2020

First Author	Year	Cohort	Visual Acuity At 3 Months	Corneal Recovery at 1 Month	Ultrasound Power	Cystoid Macular Edema
Roberts et al <sup>6</sup>	2019	Multiple surgeons RCT	No difference	No difference	No difference	–
Day et al <sup>7</sup>	2020	Multiple surgeons RCT	No difference	–	–	–
Kolb et al <sup>8</sup>	2020	Meta-analysis	No difference	-	Yes (FLACS advantage)	None
Schweitzer et al <sup>9</sup>	2020 Recruitment prior to 2016	Multiple surgeons RCT	No difference	None	None	

on the precise placement of the IOL and where decentration could lead to image degradation. The decreased tilt may explain the decreased YAG capsulotomy rates associated with FLACS when compared to CCS.<sup>15</sup> Another advantage of having a precise predetermined capsulotomy is that it allows for anterior optic capture with haptics positioned in the ciliary sulcus if needed.<sup>16</sup>

It is perhaps a combination of the above which would prompt an experienced surgeon to use FLACS when performing surgery to introduce a new EDOF lens for the first time rather than rely on a manual capsulotomy.<sup>17</sup>

## Corneal Recovery

The question of whether FLACS results in a quicker corneal recovery has not been conclusively answered. Two recent studies suggest that there is no benefit with regards to corneal swelling post-operatively measured at one-month post-op.<sup>6,9</sup> The latest meta-analysis suggests that less ultrasound energy leads to less injury to corneal tissue, which is especially important in the long term.<sup>8</sup> A recent prospective study has shown that FLACS is safer in eyes with shallow anterior chambers of less than 2mm.<sup>18</sup>

## Ultrasound Power

It was suggested that FLACS would decrease the power needed to remove the nucleus.<sup>19</sup> Previously, two prospective RCTs have suggested that this may not always be the case and that the energy used is similar.<sup>6,9</sup> More recent meta-analysis, however, showed less energy needed in the FLACS group and suggests “a distinct advantage of FLACS regarding surgical endpoints such as CDE [cumulated dissipated energy]”.<sup>8</sup> Different and evolving surgical techniques between surgeons will probably make this question unanswerable, especially as techniques may change depending on the complexity of each operation.

## Cystoid Macular Edema

The question of cystoid macular edema (CME) seems also to have been answered. Early reports showed that there was no difference between CME between manual and FLACS.<sup>20</sup> These have now been conclusively confirmed.<sup>21</sup>

## Learning Curve

The learning curve with regards to performing FLACS is two pronged in that the surgeon needs to learn how to use the laser and familiarize themselves with the settings, as well as change the way they operate. There are steps that the surgeon needs to be cognizant of as the cortex has been

“amputated” or truncated at the capsulotomy edge and there may also be intra-lenticular or retro-lenticular gas.

Bali et al were the first to publish results with regards to the first 200 eyes undergoing FLACS.<sup>22</sup> The possibility of posterior lens dislocation into the vitreous cavity was noted in 4 cases performed with this technology in 2011. It was realized that vigorous hydrodissection in the presence of retro-lenticular gas in a dense cataract could lead to capsule “blow-out”. The simple maneuver of allowing the gas to escape, or sweeping under the capsule for three clock hours before hydrodissection has eliminated this problem.<sup>23</sup> The same surgeons have not had another case of posterior capsular blow-out in a further 9766 cases. Improved surgical technique and software upgrades has also reduced the PCR from 7% to 0.3%.<sup>24</sup>

The RCT reported by Roberts et al required surgeons to have completed 30 FLACS cases before the trial began.<sup>6</sup> The FACT study required the participants to have undergone 10 supervised FLACS procedures.<sup>7</sup> In both these RCTs, over 95% of patients randomized to receive FLACS actually did receive FLACS and the rate of posterior capsular rupture in the FLACS group was 0% in both groups.<sup>6,7</sup> This would suggest that the learning curve is not as steep as has previously been suggested. This is in stark contrast with the results of the FEMCAT study using previous generation software where the surgeons needed to have completed 10 supervised FLACS procedures, but had a PCR rate of 1.4% which is higher than that found in almost any recent publication.<sup>6,7,9</sup>

The FEMCAT study stopped recruitment in 2015 and the study results, although interesting have not been reproduced in later studies using newer software.<sup>9</sup> Sixteen percent of patients randomized to the FLACS group did not receive FLACS. This was reported as being due to technical laser failure, small pupils or inability to place a suction ring.<sup>9</sup> This number is three times higher than those of later RCT using updated software post 2015.<sup>6,7</sup> It was not stated whether these factors were present both before and after the software upgrade (August 2014) midway into the study period.<sup>9</sup> The FEMCAT selected patients with healthy eyes based on the non-inclusion criteria as well as excluding patients with a history of systemic alpha blockers, zonular instability or with pupils less than 6 mm.<sup>9</sup> These challenging cases are probably the patients who are now thought to derive the greatest benefit from FLACS.<sup>25</sup>

In essence, the FEMCAT study design set a high bar that is difficult to improve upon in a statistically significant way.<sup>9</sup> In

2021, the authors of the latest meta-analysis noted that “even in the first cases of laser surgery, complications rarely occur”.<sup>26</sup>

## Cost

FLACS is undoubtedly more expensive than CCS. The FEMCAT study showed that FLACS was more expensive and did not result in better corrected visual acuity using monofocal lenses. Of note, the study did not explain why their surgeon using FLACS would cost one and a half times more than one performing CCC (€66.8 versus €45.1) and also why their anesthesiologist seeing a patient who was randomized to FLACS would be 1.44 times more expensive than an anesthesiologist seeing a patient having CCS (€57.1 versus €29.1).<sup>9</sup>

On a micro scale the statistically reduced risk of having a PCR reported by Roberts with FLACS needs to be taken into account as the cost of a vitrectomy or secondary procedure would add costs to the patient.<sup>6</sup> This may be an acceptable financial risk calculation statistically as the risks are low with both methods of surgery, but to the individual patient who has an increased risk of cystoid macular edema, retinal detachment or endophthalmitis from a ruptured capsule, it would make a tangible difference. Novel methods of dealing with the increased costs would need to be found to ensure that the FLACS technology continues to be available.

The issue of increased cost was also highlighted when surgeons were transitioning from extracapsular surgery to phacoemulsification when best-corrected visual outcome was the end measure.<sup>27</sup> Perseverance with the “new” expensive technology eventually led to operations with reduced post-operative astigmatism and using uncorrected vision as an endpoint. The first phaco machines are primitive compared to those used 30 years later. It may be argued that once the expense of the laser machine and disposables is significantly reduced and accepted into routine practice, it may lead to a new visual refractive endpoint with regards to premium lenses.

## Anterior Capsular Complications

The latest meta-analysis indicated that although anterior capsular tears occurred more with FLACS, the long-term visual outcome was not worse.<sup>8</sup> It went on to state that although capsular tears might cause the need for unplanned vitrectomies, two large studies did not reveal differences among FLACS and CCS.<sup>8</sup>

The high incidence of capsular tears of 1.87% (15/804) experienced in 2014 was initially highlighted in a paper using an immersion-based patient interface.<sup>28</sup> A further study by the same group then claimed an anterior capsular tear rate of 1.84%.<sup>29</sup> It was hypothesized that the “postage stamp” formation of the capsulorhexis with misplaced laser pits would lead to weakness and a possible tear that could extend to the equator. This hypothesis was accepted until an inter-eye prospective non-randomized prospective study compared the capsulotomies of patients who had one eye randomized to FLACS and the other eye to CCS.<sup>30</sup> The breaking force and strain of each capsule was measured and scanning electron microscopy was applied to determine whether imperfections were present. It was found that the capsulotomies created by a femtosecond laser was as strong as a manual capsulorrhexis and similar in appearance.<sup>30</sup> In the same year, another group identified improved cut quality and reduced number of tags in capsulotomies with greater vertical spot separation suggesting that early comparisons may have been limited by existing software and our relative experience with laser settings.<sup>31</sup> More recently, a large retrospective series identified a possible clinical benefit to the revision of laser parameters. Scott and co-authors found that anterior capsule tear rates decreased as vertical spacing was increased (10, 15 and 20µm vertical spacing provided anterior capsule rupture rates of 0.79%, 0.35% and 0.09%, respectively).<sup>32</sup>

A review of the initial studies which initiated the concern with regards to anterior capsular tears showed that a single group had reported 98% (64 of the 65 cases) with regards to anterior capsular tears using a particular make of machine. Inclusive of all laser cohorts, the same group reported 82% (64 of 78) cases of anterior capsular tears reported in studies worldwide.<sup>8</sup> This prompted the authors of the latest meta-analysis to suggest that the increased rate of capsular complications might be related to the settings of a particular unit’s laser settings and that these results could not be generalized to all makes of laser machines.<sup>26</sup>

The most recent meta-analysis performed of the literature from December 2017 to January 2019 was unable to find a statistically significant difference in anterior capsular complication between the two groups.<sup>8</sup>

## Posterior Capsular Complications

Reliable evidence with regards to a possible difference in complication rates started to be reported between 2015 and 2016. In 2015, it was noted that FLACS resulted in a statistically significant decrease in complications when

compared to CCS and that 80% of surgeons had a lower rate of PCC with FLACS (0.7%) than with CCS (1.18%).<sup>33</sup> In 2016, a large study of 7155 patients showed that converting from CCS to FLACS resulted in a decrease in posterior capsular complications.<sup>34</sup> All surgeons who started using FLACS had a decrease in their complication rate regardless of the level of experience with the vitreous loss rate decreasing by 55% from 1.17% to 0.65% in the FLACS group.<sup>34</sup>

The definitive answer with regards to level 1 evidence using current technology could only be answered post the publication of two RCTs in 2018 and 2020.<sup>6,8</sup> In an RCT using current software, a “significant reduction in posterior capsular rupture in the femtosecond laser-assisted group” was reported.<sup>6</sup> There were no reported cases of PCR in the FLACS group compared with 3% (6 of 200) in the CCS group. The FACT trial published in 2020, also had no cases of PCR in the FLACS group while reporting a rate of 0.5% (2 of 392) in the CCS group.<sup>7</sup> Combining the results of these two large RCTs shows that there were no PCR in the FLACS group and 8 of 592 in the CCS group.<sup>6,7</sup> It is not surprising therefore that the conclusion of a meta-analysis reported in 2020 stated that

in our subgroup analysis of RCTs ... posterior capsule ruptures seemed less with FLACS, which was of clinical importance even if statistical significance was missed.<sup>8</sup> [Table 2]

The low PCC rate in FLACS found in these recent RCTs validates the fact that the capsular rupture rate is less than 1% in almost every FLACS series where more than 1000 patients were enrolled. These range from 0.27% (n=1105),<sup>35</sup> 0.30% (n=2021),<sup>24</sup> 0.31% (n=1300),<sup>2</sup> 0.43% (n=1852)<sup>29</sup> and 0.77% (n=3371).<sup>34</sup> Posterior capsular rupture rates were also

reported to be less common in eyes operated on by residents (0% vs 3.0%)<sup>36</sup> and (0% vs 3.1%)<sup>37</sup> or in operations on vitrectomized eyes (0% vs 12%).<sup>38</sup>

These figures of less than 1% should be considered as PCR is associated with an increased risk of endophthalmitis (OR 6.33, 95%, CI 4.22~9.49) as well as an increased risk of retinal detachment.<sup>39</sup> Secondary surgery to suture a lens into the sulcus is less than optimal for a multifocal or extended depth of focus lenses and may lead to an unhappy patient, especially one expecting a precise refractive outcome.

In 2021, in response to a letter in JCRS, the authors of the latest meta-analysis of FLACS and CCS stated

in summary, there are noteworthy advantages of FLACS compared with manual cataract surgery, such as higher precision, and less damage to ambient structures. Even better results of laser surgery, especially a reduction in complication rates, might be expected with more clinical experience and further developed laser systems.<sup>26</sup>

## Conclusion

Both level 1 primary interventional studies and a level 1 secondary filtered meta-analysis are now available to answer the questions posed 10 years ago with regards to FLACS. These studies do not show any long-term visual benefit with regards to FLACS with regards to monofocal, non-toric lenses. These studies do show that the PCR of between 0% and 0.6% in cases where current generation FLACS is used has become the norm, while CCS has a reported PCR of greater than 1%. This 40% decrease in posterior capsular complications should play a part in the decision to offer FLACS, especially when tackling difficult cases.

**Table 2** Incidence of Posterior Capsular Complications in FLACS Literature 2016–2020

First Author	Year	Cohort	Evidence Level	FLACS (%)	Manual (%)	Cases (FLACS vs Manual)
Roberts et al <sup>6</sup>	2019	Multiple surgeons	1	0.0%	3.0%	0/200 vs 6/200*
Day et al <sup>7</sup>	2020	Multiple surgeons	1	0.0%	0.5%	0/392 vs 2/393
Scott et al <sup>34</sup>	2016	Multiple surgeons	2	0.65%	1.17%	22/3367 vs 44/3775*
Brunin et al <sup>36</sup>	2017	Registrars	3	0.00%	3.00%	0/76 vs 3/101
Hou et al <sup>37</sup>	2015	Registrars	3	0.00%	3.00%	0/68 vs 4/128
Wang et al <sup>38</sup>	2018	Multiple surgeons (post vitrectomy eyes)	3	0.00%	12.0%	0/25 vs 3/25

**Note:** \*Statistically significant.

## Disclosure

Dr Wendell Scott reports grants from Johnson & Johnson, outside the submitted work. The authors report no other conflicts of interest in this work.

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