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## Initial Experience Using A Femtosecond Laser Cataract Surgery System At A UK National Health Service Cataract Surgery Day Care Centre.

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**Abstract:****Objectives:**

To investigate the operative learning curve following installation of a cataract surgery laser system.

**Setting:**

National Health Service Cataract surgery day care unit in North London, UK.

**Participants:**

One hundred and fifty-eight eyes of 150 patients undergoing laser assisted cataract surgery.

**Interventions:**

Laser assisted cataract surgery using the AMO Catalys femtosecond laser platform.

**Primary and secondary outcome measures:**

Primary outcome measure: intraoperative complications including anterior and posterior capsule tears. Secondary outcome measures: docking to the laser platform, successful treatment delivery, postoperative visual acuities.

**Results:**

Mean case age was  $67.7 \pm 10.8$  years (range 29-88 years). Docking was successful in 148/158 cases (93.7%), of which the laser procedure was completed in 142/148 (95.9% cases). Laser delivery was aborted in 4% of cases due to patient movement. A total of 32 surgeons, of grades from junior trainee to Consultant, performed the surgeries. Median case number per surgeon was 3 (range from 1-20). There were 3 cases with posterior capsule rupture requiring anterior vitrectomy and 1 with zonular dialysis requiring anterior vitrectomy (4/148 eyes, 2.7%). These 4 cases were performed by trainee surgeons, and were either their first laser assisted cataract surgery (2 surgeons) or their first and second laser assisted cataract surgeries (1 surgeon).

**Conclusions:**

The learning curve for laser assisted cataract surgery appears short, with complications predominately confined to trainee surgeons on their initial cases. Whilst all patients went on to have cataract surgery, docking to the laser was not being possible in over 6% cases and 4% patients were unable to remain sufficiently still for complete laser delivery.

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54 **Strengths and limitations of this study:**

- 55 • The main strength of this study is that it reports real-world outcomes following  
56 installation of a femtosecond laser platform for cataract surgery and so the results may  
57 be more generalizable than data obtained from a controlled trial.
- 58 • The main limitations of this study are its retrospective design with reliance on surgeons  
59 to faithfully record their complications on the electronic medical records system used,  
60 and also the relatively small case series size.

64 **Introduction.**

65 Femtosecond laser assisted cataract surgery offers many potential advantages over manual  
66 phacoemulsification cataract surgery including consistent capsulotomy creation,<sup>1</sup> reduced  
67 effective phacoemulsification time and femtosecond laser AK. To date there is minimal data  
68 on outcomes from randomised controlled trials (RCTs), with that limited to large  
69 comparative case series. A number of large RCTs are currently in progress including the UK  
70 National Institute for Health Research (NIHR) funded FACT trial (Femto Assisted Cataract  
71 Trial, ISRCTN77602616)<sup>2</sup> and the French FEMCAT study.<sup>3</sup>

72 There is limited data on the learning curve associated with transition to laser assisted  
73 cataract surgery, with outcomes varying by platform and year of development.<sup>4,5</sup> The  
74 Moorfields at St Ann’s Hospital cataract surgery facility is the main site of the FACT trial, and  
75 is a high volume National Health Service (NHS) cataract day care unit. The aim of this work is  
76 to describe the initial operative learning curve following installation of a cataract surgery  
77 femtosecond laser system at St Ann’s Hospital prior to the start of the FACT trial.

79 **Methods.**

80 This was a retrospective review of cases performed following installation of the Catalys  
81 Precision Laser system (Abbott Medical Optics, USA), for cataract surgery at Moorfields Eye  
82 Unit at St Ann’s Hospital, London. Cases were identified from an electronic medical records

system (OpenEyes) and the laser usage log book, and all were performed between February 2015 and April 2015 prior to the start of the FACT trial. During this period training was available on the Catalys platform by AMO trainers for those who had not used the system before. All surgeons had access to the platform and training, with surgeon grades varying from trainees (Ophthalmology Specialist Trainee years 3-6), fellows, independent non-Consultant surgeons and Consultants. Specialist trainees were supervised by a Consultant Ophthalmologist for all cases. The outcomes investigated were successful patient docking to the laser system, completion of the planned laser delivery and intraoperative complications. All postoperative visual acuities were recorded as Snellen and converted to logMAR, with values for counting fingers (CF), hand movements (HM) and perception of light (PL) substituted with 2.10, 2.40 and 2.70 logMAR respectively.<sup>6</sup>

The study was approved by the Clinical Audit unit, Research and Development department at Moorfields Eye Hospital. Analyses of this type do not require individual ethical permission as they are viewed as audit (see <http://www.hra.nhs.uk/research-community/before-you-apply/determine-whether-your-study-is-research/>). The study was conducted in accordance with the Declaration of Helsinki, and the UK Data Protection Act.

## Results

Over the 10 week period prior to start of the FACT trial, laser assisted cataract surgery was attempted on 158 eyes of 150 patients. Mean case age was  $67.7 \pm 10.8$  years. Sixty-seven cases (42%) had ocular co-pathology. Docking was successful in 148/158 cases (93.7%), of which the planned laser procedure was completed in 142/148 (95.9% cases). Where docking was not possible, patients underwent manual phacoemulsification and IOL implantation with appropriate anaesthesia (n=10; 6.3%). Laser delivery was aborted in 4% of patients due to patient movement. All surgeries were single procedures (phacoemulsification and IOL insertion), except 1 case which was combined phacoemulsification, IOL insertion and trabeculectomy.

A total of 32 surgeons, of grades from junior trainee to Consultant, performed the surgeries. Median case number per surgeon during the study period was 3 (range 1-20). Three surgeons had previous experience of using the platform.

Intraoperative problems of any severity were recorded for 15 cases (10.1%). The anterior capsulotomy was complete in 99.3% of cases. For the 1 case where it was incomplete, this was in an eye with white/ hypermature cataract and required manual completion with capsulorrhexis forceps. Overall, there were no anterior capsule tears. There were 3 cases with posterior capsule rupture requiring anterior vitrectomy and 1 with zonular dialysis requiring anterior vitrectomy (4/148 eyes, 2.7%). These 4 cases were performed by trainee surgeons and were either their first laser assisted cataract surgery (2 surgeons) or their first and second laser assisted cataract surgeries (1 surgeon). Table 1 shows the specific details for each case.

Mean postoperative UDVA was 0.26 logMAR (SD 0.34) and postoperative best measured visual acuity was 0.14 logMAR (SD 0.31) at mean 26 days follow-up. Thirty-one percent of cases achieved 0.0 logMAR or better UDVA.

**Table 1: Intraoperative problems**

Complication	Number	Case specific details
Incomplete anterior capsulotomy	1 (0.7%)	1 incomplete in white/ hypermature cataract, completed with forceps.
Anterior capsule tear	0 (0%)	-
Posterior capsule tear with vitreous loss	3 (2.0%)	1 (0.7%): senior trainee surgeon, dense cataract with small pupil, anterior capsulotomy intact, sulcus IOL.  2 (1.4%): junior trainee surgeon, PC rent during lens fragment removal, anterior vitrectomy, anterior capsulotomy intact, sulcus IOL.
Posterior capsule tear, no vitreous loss	0 (0%)	-
Zonular dialysis with	1 (0.7%)	Senior trainee surgeon, anterior vitrectomy,

vitreous loss		IOL to sulcus
Zonular dialysis, no vitreous loss	0 (0%)	-
IOL issues	1 (0.7%)	IOL scratch seen post IOL injection into capsular bag
Iris problems	7 (4.7%)	3 (2.0%): intraoperative floppy iris syndrome associated with alpha-blocker use. 4 (2.7%): pupil down during procedure, requiring iris hooks in 3 cases.
Phacoemulsification platform issues	1 (0.7%)	Hand piece fault, swapped during case

## Discussion.

In this study, 42% of cases had ocular co-pathology using definitions similar to those in the National Ophthalmology Database (NOD) analyses,<sup>6,7</sup> and postoperative best-measured visual acuity of 0.0 logMAR or better was achieved in 31% of eyes overall. Comparable values from the NOD were 37% of cases had ocular co-pathology and best measured visual acuity of 0.0 logMAR or better post-operatively was achieved in 24% eyes overall. Whilst all patients went on to have cataract extraction, we found that docking was not possible in 6% of cases due to insufficient patient co-operation. Whilst this value would be expected to be lower outside of the learning curve with better patient selection, it highlights that laser assisted cataract surgery may not be appropriate in a significant proportion of patients. The 4% of cases where laser delivery was abandoned part way during delivery again further supports this.

There is limited data on the surgical learning curve for laser assisted cataract surgery, with that published showing higher complication rates even for experienced surgeons.<sup>4</sup> This manuscript details the surgical complications following installation of the AMO Catalys femtosecond laser cataract surgery platform in a UK National Health Service (NHS) Cataract Surgery Day Care Unit and includes surgeons of all grades. Overall we found 99.7% of

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3 147 anterior capsulotomies to be complete, there were no cases of anterior capsule tears and  
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5 148 there was a 2.7% vitreous loss rate. Expected posterior capsule rupture and/ or vitreous loss  
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7 149 rates from the UK NOD report of outcomes from 28 NHS Hospital Trusts are 1.95% overall  
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9 150 and 2.51% for cases with any ocular co-pathology.<sup>6</sup> Additionally as posterior capsule rupture  
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11 151 is associated with surgeon training grade,<sup>8</sup> the rate in this series appears in line with that  
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13 152 expected. While it is not possible to separate out complications that are directly  
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15 153 attributable to the use of the laser platform, based on the intraoperative stages at which  
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17 154 these occurred, they appear unlikely to be directly related to the use of the Catalys system  
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19 155 as all cases had previously reported co-pathology risk factors for posterior capsule rupture.<sup>8</sup>  
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21 156 Of note, the 4 cases with vitreous loss were either trainees' first laser assisted cataract  
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23 157 surgery (2 surgeons), or their first and second laser assisted cataract surgeries (1 surgeon)  
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25 158 and consequently other factors such as increased anxiety due to change in surgical  
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27 159 technique may have played a role. A large case series of 1852 operations using the AMO  
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29 160 Catalys platform report an anterior capsule tear rate of 1.84% and posterior capsule tear  
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31 161 rate of 0.43%.<sup>9</sup> For trainee surgeons, intraoperative and postoperative complication rates of  
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33 162 laser assisted cataract surgery are thought to be similar to those of manual cataract  
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35 163 extraction.<sup>10</sup> Data from a small series on trainee surgeons' initial supervised use of the Alcon  
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37 164 LenSx platform reported a successful docking rate of 97.6% and posterior capsule tear rate  
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39 165 of 0% (0/62 cases).<sup>11</sup>  
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41 166 Interestingly we found the vast majority of intraoperative complications to be iris problems,  
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43 167 with the pupil coming down in 3 (2.0%) cases such that iris hooks were required to complete  
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45 168 the respective cases. A recent comparative series investigating pupil diameter before and  
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47 169 after laser assisted cataract surgery reported that laser pre-treatment induced significant  
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49 170 pupillary miosis with the pupil diameter falling below 5mm in 4.0% of cases.<sup>12</sup> It is possible  
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51 171 that different dilation regimes such as additional doses after laser pre-treatment or use of  
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53 172 mydriatic devices (eg. Mydriaserit, BENAC, France) may be preferable in laser assisted  
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55 173 cataract surgery procedures.  
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57 174 The main limitations of this study are its retrospective design with reliance on surgeons to  
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59 175 faithfully record their complications on the electronic medical records system used, and also  
60 176 the relatively small case series size. Despite this, the learning curve for the AMO Catalys

platform appears limited, and the manufacturer's recommendation of 10 initial supervised cases with a trainer appears satisfactory.

In conclusion, the learning curve for femtosecond laser assisted cataract surgery appears to be short, with complications predominately confined to trainee surgeons on their initial cases.

**Contributorship statement:**

ACD was responsible for the study concept. All authors made substantial contributions to the design of the study. ACD drafted the manuscript and all authors provided critical review and approved the final manuscript.

**Competing interests:**

There are no conflicts of interest to disclose.

**Funding statement:**

ACD was supported by the National Institute for Health Research (NIHR) Biomedical Research Centre based at Moorfields Eye Hospital NHS Foundation Trust and UCL Institute of Ophthalmology.

**Data sharing statement:**

No additional data are available.

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# BMJ Open

## Initial Experience Using A Femtosecond Laser Cataract Surgery System At A UK National Health Service Cataract Surgery Day Care Centre.

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Complete List of Authors:	Day, Alexander; UCL Institute of Ophthalmology; Moorfields Eye Hospital, Cataract Service Dhallu, Sandeep; Moorfields Eye Hospital, Cataract Service Maurino, Vincenzo; Moorfields Eye Hospital, Cataract Service Wilkins, Mark; Moorfields Eye Hospital, Cornea
<b>Primary Subject Heading</b>:	Ophthalmology
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Keywords:	Cataract and refractive surgery < OPHTHALMOLOGY, OPHTHALMOLOGY, Corneal and external diseases < OPHTHALMOLOGY

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**Funding statement:**

ACD was supported by the National Institute for Health Research (NIHR) Biomedical Research Centre based at Moorfields Eye Hospital NHS Foundation Trust and UCL Institute of Ophthalmology.

**Data sharing statement:**

No additional data are available.

For peer review only

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**Abstract:**

**Objectives:**

To describe the initial outcomes following installation of a cataract surgery laser system.

**Setting:**

National Health Service Cataract surgery day care unit in North London, UK.

**Participants:**

One hundred and fifty-eight eyes of 150 patients undergoing laser assisted cataract surgery.

**Interventions:**

Laser cataract surgery using the AMO Catalys femtosecond laser platform.

**Primary and secondary outcome measures:**

Primary outcome measure: intraoperative complications including anterior and posterior capsule tears. Secondary outcome measures: docking to the laser platform, successful treatment delivery, postoperative visual acuities.

**Results:**

Mean case age was 67.7 ± 10.8 years (range 29-88 years). Docking was successful in 94% (148/158 cases), and in 4% (6/148 cases) of these, the laser delivery was aborted part way during delivery due to patient movement. A total of 32 surgeons, of grades from junior trainee to Consultant, performed the surgeries. Median case number per surgeon was 3 (range from 1-20). The anterior capsulotomy was complete in 99.3% of cases, there were no anterior capsule tears (0%). There were 3 cases with posterior capsule rupture requiring anterior vitrectomy and 1 with zonular dialysis requiring anterior vitrectomy (4/148 eyes, 2.7%). These 4 cases were performed by trainee surgeons, and were either their first laser cataract surgery (2 surgeons) or their first and second laser cataract surgeries (1 surgeon).

**Conclusions:**

Complications were confined to trainee surgeons on their initial cases. There were a small number of cases where docking to the laser and complete laser delivery were not possible. Whilst these numbers will be lower outside of the learning curve, it suggests that laser cataract surgery may not be appropriate for every patient.

## Strengths and limitations of this study:

- The main strength of this study is that it reports real-world outcomes following installation of a femtosecond laser platform for cataract surgery and so the results may be more generalizable than data obtained from a controlled trial.
- The main limitations of this study are its retrospective design with reliance on surgeons to faithfully record their complications on the electronic medical records system used, and also the relatively small case series size.

## Introduction.

Femtosecond laser assisted cataract surgery offers many potential advantages over manual phacoemulsification cataract surgery including consistent capsulotomy creation,<sup>1–3</sup> reduced effective phacoemulsification time,<sup>4</sup> lower endothelial cell loss,<sup>4,5</sup> and femtosecond laser astigmatic keratotomy.<sup>6,7</sup> To date there is limited data on visual outcomes and surgical complication rates for laser cataract surgery from randomised controlled trials (RCTs),<sup>2,5,8–10</sup> with that available being predominantly from large comparative case series.<sup>11–13</sup> A number of large RCTs are currently in progress including the UK National Institute for Health Research (NIHR) funded FACT trial (Femto Assisted Cataract Trial, ISRCTN77602616)<sup>14</sup> and the French FEMCAT study.<sup>15</sup>

There is little data on the learning curve associated with transition to laser assisted cataract surgery, with outcomes varying by platform and year of development.<sup>16,17</sup> The Moorfields at St Ann's Hospital cataract surgery facility is the main site of the FACT trial, and is a high volume National Health Service (NHS) cataract day care unit. The aim of this work is to describe the initial outcomes following installation of a cataract surgery femtosecond laser system at St Ann's Hospital prior to the start of the FACT trial.

## Methods.

This was a retrospective review of cases performed following installation of the Catalys Precision Laser system (Abbott Medical Optics, USA), for cataract surgery at Moorfields Eye Unit at St Ann's Hospital, London. Cases were identified from an electronic medical records

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99 system (OpenEyes) and the laser usage log book, and all were performed between February  
100 2015 and April 2015 prior to the start of the FACT trial. During this period training was  
101 available on the Catalys platform by AMO trainers. All surgeons had access to the platform  
102 and training, with surgeon grades varying from trainees (Ophthalmology Specialist Trainee  
103 years 3-6), fellows, independent non-Consultant surgeons and Consultants. Specialist  
104 trainees were supervised by a Consultant Ophthalmologist for all cases. The outcomes  
105 investigated were successful patient docking to the laser system, completion of the planned  
106 laser delivery and intraoperative complications. All postoperative visual acuities were  
107 recorded as Snellen and converted to logMAR, with values for counting fingers (CF), hand  
108 movements (HM) and perception of light (PL) substituted with 2.10, 2.40 and 2.70 logMAR  
109 respectively.<sup>18</sup>

110 The study was approved by the Clinical Audit unit, Research and Development department  
111 at Moorfields Eye Hospital. Analyses of this type do not require individual ethical permission  
112 as they are viewed as audit (see <http://www.hra.nhs.uk/research-community/before-you-apply/determine-whether-your-study-is-research/>). The study was conducted in accordance  
113 with the Declaration of Helsinki, and the UK Data Protection Act.  
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115  
116 **Results**

117 Over the 10 week period prior to start of the FACT trial, laser cataract surgery was  
118 attempted on 158 eyes of 150 patients. Mean case age was 67.7 ± 10.8 years. Sixty-seven  
119 cases (42%) had ocular co-pathology. Docking was successful in 94% (148/158 cases), and in  
120 4% (6/148 cases) of these, the laser delivery was aborted part way during delivery due to  
121 patient movement. Where docking was not possible, patients underwent manual  
122 phacoemulsification and IOL implantation with appropriate anaesthesia (n=10; 6.3%). Laser  
123 delivery was aborted in 4% of patients due to patient movement. All surgeries were single  
124 procedures (phacoemulsification and IOL insertion), except 1 case which was combined  
125 phacoemulsification, IOL insertion and trabeculectomy.

126 A total of 32 surgeons, of grades from junior trainee to Consultant, performed the surgeries.  
127 Median case number per surgeon during the study period was 3 (range 1-20). Two surgeons  
128 (5 and 2 surgical cases in this series) had previously performed >200 laser cataract surgery  
129 procedures.

Intraoperative problems of any severity were recorded for 14 cases (9.6%). The anterior capsulotomy was complete in 99.3% of cases. For the 1 case where it was incomplete, this was in an eye with white/ hypermature cataract and required manual completion with capsulorrhexis forceps. Overall, there were no anterior capsule tears. There were 3 cases with posterior capsule rupture requiring anterior vitrectomy and 1 with zonular dialysis requiring anterior vitrectomy (4/148 eyes, 2.7%). These 4 cases were performed by trainee surgeons and were either their first laser cataract surgery (2 surgeons who performed a total of 2 and 12 laser cataract surgeries in this series); or their first and second laser cataract surgeries (1 surgeon who performed a total of 6 laser cataract surgeries in this series). Table 1 shows the specific details for each case.

Mean postoperative UDVA was 0.26 logMAR (SD 0.34) and postoperative best measured visual acuity (better of UDVA or pinhole) was 0.14 logMAR (SD 0.31) at mean 26 days follow-up. Thirty-one percent of cases achieved 0.0 logMAR or better UDVA.

**Table 1: Intraoperative problems**

Complication	Number	Case specific details
Incomplete anterior capsulotomy	1 (0.7%)	1 incomplete in white/ hypermature cataract, completed with forceps.
Anterior capsule tear	0 (0%)	-
Posterior capsule tear with vitreous loss	3 (2.0%)	1 (0.7%): Trainee surgeon, dense cataract with small pupil, anterior capsulotomy intact, sulcus IOL.  2 (1.4%): Trainee surgeon, PC rent during lens fragment removal, anterior vitrectomy, anterior capsulotomy intact, sulcus IOL.
Posterior capsule tear, no vitreous loss	0 (0%)	-
Zonular dialysis with	1 (0.7%)	Trainee surgeon, anterior vitrectomy, IOL to

vitreous loss		sulcus
Zonular dialysis, no vitreous loss	0 (0%)	-
IOL issues	1 (0.7%)	IOL scratch seen post IOL injection into capsular bag
Iris problems	7 (4.7%)	3 (2.0%): intraoperative floppy iris syndrome associated with alpha-blocker use. 4 (2.7%): pupil down during procedure, requiring iris hooks in 3 cases.
Phacoemulsification platform issues	1 (0.7%)	Hand piece fault, swapped during case

**Discussion.**

In this study, 42% of cases had ocular co-pathology using definitions similar to those in the Royal College of Ophthalmologists' National Ophthalmology Database (RCOphth NOD) analyses,<sup>18,19</sup> and postoperative best-measured visual acuity of 0.0 logMAR or better was achieved in 31% of eyes overall. Comparable values from the NOD were 37% of cases had ocular co-pathology and best measured visual acuity of 0.0 logMAR or better post-operatively was achieved in 24% eyes overall. Whilst all patients went on to have cataract extraction, we found that docking was not possible in 6% of cases due to insufficient patient co-operation. Although this value will be lower outside of the learning curve, it suggests that laser cataract surgery may not be appropriate for every patient. The 4% of cases where laser delivery was abandoned part way during delivery further supports this.

There is limited data on the surgical learning curve for laser cataract surgery,<sup>11,12,20,21</sup> with laser platforms having also undergone considerable software and hardware development over the past few years.<sup>22,23</sup> This manuscript details the surgical complications following installation of the AMO Catalys femtosecond laser cataract surgery platform in a UK National Health Service (NHS) Cataract Surgery Day Care Unit and includes surgeons of all grades. Overall we found 99.3% of anterior capsulotomies to be complete, there were no

cases of anterior capsule tears and there was a 2.7% vitreous loss rate. Expected posterior capsule rupture and/ or vitreous loss rates from the UK RCOphth National Ophthalmology Database report of outcomes from 28 NHS Hospital Trusts were 1.95% overall and 2.51% for cases with any ocular co-pathology.<sup>18</sup> Of note the ocular co-pathology rate was higher in our series than in the recent RCOphth NOD analysis and so this may in part explain the higher complication rate in addition to that due to the surgical learning curve for transition to laser cataract surgery. While it is not possible to separate out complications that are directly attributable to the use of the laser platform, based on the intraoperative stages at which these occurred, they appear unlikely to be directly related to the use of the Catalys system as, for example there were no posterior capsule tears resulting from an anterior capsule rip. Furthermore, all cases in which a posterior capsule tear/ vitreous loss did occur, were higher than average risk cases due to the presence of one or more independent risk factors for posterior capsule rupture.<sup>24</sup>

Of note, the 4 cases with vitreous loss were either trainees' first laser assisted cataract surgery (2 surgeons), or their first and second laser assisted cataract surgeries (1 surgeon). A large case series of 1852 operations using the AMO Catalys platform report an anterior capsule tear rate of 1.84% and posterior capsule tear rate of 0.43%.<sup>13</sup> For trainee surgeons, intraoperative and postoperative complication rates of laser assisted cataract surgery are thought to be similar to those of manual cataract extraction.<sup>21</sup> Data from a small series on trainee surgeons' initial supervised use of the Alcon LenSx platform reported a successful docking rate of 97.6% and posterior capsule tear rate of 0% (0/62 cases).<sup>20</sup> In a recent report of the first 2 years of experience using the Bausch and Lomb Victus platform, the posterior capsule tear rate was low even within the learning curve (0.3%, 3/1105 events overall).<sup>11</sup>

Interestingly we found the vast majority of intraoperative complications to be iris problems, with the pupil coming down in 3 (2.0%) cases such that iris hooks were required to complete the respective cases. A recent comparative series investigating pupil diameter before and after laser cataract surgery reported that laser pre-treatment induced significant pupillary miosis with the pupil diameter falling below 5mm in 4.0% of cases.<sup>25</sup> In a series of 1500 laser cataract operations, the intraoperative pupil constriction rate was reduced from 9.5% in the first 200 cases to 1.2% for the latter 1300 cases when an additional 1 drop of 10% phenylephrine was given after the laser procedure.<sup>12</sup> The authors also noted that factors

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such as platform evolution, which shortened overall procedure time and more efficient scanning patterns that reduced the required delivered energy may too have been partly attributable.<sup>12</sup>

The main limitations of this study are its retrospective design with reliance on surgeons to faithfully record their complications on the electronic medical records system used, and also the relatively small case series size.

In conclusion, the learning curve for femtosecond laser cataract surgery appears to be short, with complications predominately confined to trainee surgeons on their initial cases.

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# BMJ Open

## Initial Experience Using A Femtosecond Laser Cataract Surgery System At A UK National Health Service Cataract Surgery Day Care Centre.

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Date Submitted by the Author:	22-Jun-2016
Complete List of Authors:	Day, Alexander; UCL Institute of Ophthalmology; Moorfields Eye Hospital, Cataract Service Dhallu, Sandeep; Moorfields Eye Hospital, Cataract Service Maurino, Vincenzo; Moorfields Eye Hospital, Cataract Service Wilkins, Mark; Moorfields Eye Hospital, Cornea
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Keywords:	Cataract and refractive surgery < OPHTHALMOLOGY, OPHTHALMOLOGY, Corneal and external diseases < OPHTHALMOLOGY

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Manuscripts



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**Data sharing statement:**

No additional data are available.

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**Abstract:**

**Objectives:**

To describe the initial outcomes following installation of a cataract surgery laser system.

**Setting:**

National Health Service Cataract surgery day care unit in North London, UK.

**Participants:**

One hundred and fifty-eight eyes of 150 patients undergoing laser assisted cataract surgery.

**Interventions:**

Laser cataract surgery using the AMO Catalys femtosecond laser platform.

**Primary and secondary outcome measures:**

Primary outcome measure: intraoperative complications including anterior and posterior capsule tears. Secondary outcome measures: docking to the laser platform, successful treatment delivery, postoperative visual acuities.

**Results:**

Mean case age was 67.7 ± 10.8 years (range 29-88 years). Docking was successful in 94% (148/158 cases), and in 4% (6/148 cases) of these, the laser delivery was aborted part way during delivery due to patient movement. A total of 32 surgeons, of grades from junior trainee to Consultant, performed the surgeries. Median case number per surgeon was 3 (range from 1-20). The anterior capsulotomy was complete in 99.3% of cases, there were no anterior capsule tears (0%). There were 3 cases with posterior capsule rupture requiring anterior vitrectomy and 1 with zonular dialysis requiring anterior vitrectomy (4/148 eyes, 2.7%). These 4 cases were performed by trainee surgeons, and were either their first laser cataract surgery (2 surgeons) or their first and second laser cataract surgeries (1 surgeon).

**Conclusions:**

Despite the learning curve, docking and laser delivery were successfully performed in almost all cases, and surgical complication rates and visual outcomes were similar to those expected based on national data. Complications were predominately confined to trainee surgeons, and with the exception of intraoperative pupil constriction appeared unrelated to the laser performed steps.

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**Strengths and limitations of this study:**

- The main strength of this study is that it reports real-world outcomes following installation of a femtosecond laser platform for cataract surgery and so the results may be more generalizable than data obtained from a controlled trial.
- The main limitations of this study are its retrospective design with reliance on surgeons to faithfully record their complications on the electronic medical records system used, and also the relatively small case series size.

**Introduction.**

Femtosecond laser assisted cataract surgery offers many potential advantages over manual phacoemulsification cataract surgery including consistent capsulotomy creation,<sup>1-3</sup> reduced effective phacoemulsification time,<sup>4</sup> lower endothelial cell loss,<sup>4,5</sup> and femtosecond laser astigmatic keratotomy.<sup>6,7</sup> To date there is limited data on visual outcomes and surgical complication rates for laser cataract surgery from randomised controlled trials (RCTs),<sup>2,5,8-10</sup> with that available being predominantly from large comparative case series.<sup>11-13</sup> A number of large RCTs are currently in progress including the UK National Institute for Health Research (NIHR) funded FACT trial (Femto Assisted Cataract Trial, ISRCTN77602616)<sup>14</sup> and the French FEMCAT study.<sup>15</sup>

A number of studies have provided data on the surgical learning curve for laser cataract surgery,<sup>11,12,16-18</sup> with outcomes varying by platform and year of development.<sup>19,20</sup> The Moorfields at St Ann's Hospital cataract surgery facility is the main site of the FACT trial, and is a high volume National Health Service (NHS) cataract day care unit. The aim of this work is to describe the initial outcomes following installation of a cataract surgery femtosecond laser system at St Ann's Hospital prior to the start of the FACT trial.

**Methods.**

This was a retrospective review of cases performed following installation of the Catalys Precision Laser system (Abbott Medical Optics, USA), for cataract surgery at Moorfields Eye

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Unit at St Ann’s Hospital, London. Cases were identified from an electronic medical records system (OpenEyes) and the laser usage log book, and all were performed between February 2015 and April 2015 prior to the start of the FACT trial. During this period training was available on the Catalys platform by AMO trainers. All surgeons had access to the platform and training, with surgeon grades varying from trainees (Ophthalmology Specialist Trainee years 3-6), fellows, independent non-Consultant surgeons and Consultants. Specialist trainees were supervised by a Consultant Ophthalmologist for all cases. The outcomes investigated were successful patient docking to the laser system, completion of the planned laser delivery and intraoperative complications. All postoperative visual acuities were recorded as Snellen and converted to logMAR, with values for counting fingers (CF), hand movements (HM) and perception of light (PL) substituted with 2.10, 2.40 and 2.70 logMAR respectively.<sup>21</sup>

The study was approved by the Clinical Audit unit, Research and Development department at Moorfields Eye Hospital. Analyses of this type do not require individual ethical permission as they are viewed as audit (see <http://www.hra.nhs.uk/research-community/before-you-apply/determine-whether-your-study-is-research/>). The study was conducted in accordance with the Declaration of Helsinki, and the UK Data Protection Act.

**Results**

Over the 10 week period prior to start of the FACT trial, laser cataract surgery was attempted on 158 eyes of 150 patients. Mean case age was 67.7 ± 10.8 years. Sixty-seven cases (42%) had ocular co-pathology. Docking was successful in 94% (148/158 cases), and in 4% (6/148 cases) of these, the laser delivery was aborted part way during delivery due to patient movement. Where docking was not possible, patients underwent manual phacoemulsification and IOL implantation with appropriate anaesthesia (n=10; 6.3%). Laser delivery was aborted in 4% of patients due to patient movement. All surgeries were single procedures (phacoemulsification and IOL insertion), except 1 case which was combined phacoemulsification, IOL insertion and trabeculectomy.

A total of 32 surgeons, of grades from junior trainee to Consultant, performed the surgeries. Median case number per surgeon during the study period was 3 (range 1-20). Two surgeons

(5 and 2 surgical cases in this series) had previously performed >200 laser cataract surgery procedures.

Intraoperative problems of any severity were recorded for 14 cases (9.6%). The anterior capsulotomy was complete in 99.3% of cases. For the 1 case where it was incomplete, this was in an eye with white/ hypermature cataract and required manual completion with capsulorrhexis forceps. Overall, there were no anterior capsule tears. There were 3 cases with posterior capsule rupture requiring anterior vitrectomy and 1 with zonular dialysis requiring anterior vitrectomy (4/148 eyes, 2.7%). These 4 cases were performed by trainee surgeons and were either their first laser cataract surgery (2 surgeons who performed a total of 2 and 12 laser cataract surgeries in this series); or their first and second laser cataract surgeries (1 surgeon who performed a total of 6 laser cataract surgeries in this series). Table 1 shows the specific details for each case.

Mean postoperative UDVA was 0.26 logMAR (SD 0.34) and postoperative best measured visual acuity (better of UDVA or pinhole) was 0.14 logMAR (SD 0.31) at mean 26 days follow-up. Thirty-one percent of cases achieved 0.0 logMAR or better UDVA.

**Table 1: Intraoperative problems**

Complication	Number	Case specific details
Incomplete anterior capsulotomy	1 (0.7%)	1 incomplete in white/ hypermature cataract, completed with forceps.
Anterior capsule tear	0 (0%)	-
Posterior capsule tear with vitreous loss	3 (2.0%)	1 (0.7%): Trainee surgeon, dense cataract with small pupil, small anterior capsulotomy made and enlarged manually at start of case, PC rent during lens removal.  2 (1.4%): Trainee surgeon, PC rent during lens fragment removal,

Posterior capsule tear, no vitreous loss	0 (0%)	-
Zonular dialysis with vitreous loss	1 (0.7%)	Trainee surgeon, anterior vitrectomy, IOL to sulcus
Zonular dialysis, no vitreous loss	0 (0%)	-
IOL issues	1 (0.7%)	IOL scratch seen post IOL injection into capsular bag
Iris problems	7 (4.7%)	3 (2.0%): intraoperative floppy iris syndrome associated with alpha-blocker use. 4 (2.7%): pupil down during procedure, requiring iris hooks in 3 cases.
Phacoemulsification platform issues	1 (0.7%)	Hand piece fault, swapped during case

**Discussion.**

This manuscript describes the outcomes following installation of the AMO Catalys femtosecond laser cataract surgery platform in a UK National Health Service (NHS) Cataract Surgery Day Care Unit and includes surgeons of all grades. Overall we found 99.3% of anterior capsulotomies to be complete, there were no cases of anterior capsule tears and there was a 2.7% vitreous loss rate. Expected posterior capsule rupture and/ or vitreous loss rates from the UK RCOphth National Ophthalmology Database report of outcomes from 28 NHS Hospital Trusts were 1.95% overall and 2.51% for cases with any ocular co-pathology.<sup>21</sup> Of note 42% eyes in our series had ocular co-pathology and this proportion is higher than in the recent RCOphth NOD analysis where the corresponding value was 37%. This may in part explain the higher complication rate, in addition to that due to the surgical learning curve for transition to laser cataract surgery. While it is not possible to separate out complications that are directly attributable to the use of the laser platform, based on the intraoperative stages at which these occurred, they appear unlikely to be directly related to

the use of the Catalys system as, for example there were no posterior capsule tears resulting from an anterior capsule rip. Furthermore, all cases in which a posterior capsule tear/ vitreous loss did occur, were higher than average risk cases due to the presence of one or more independent risk factors for posterior capsule rupture.<sup>22</sup> In this study, 31% eyes achieved a postoperative best-measured visual acuity of 0.0 logMAR or better, and the corresponding value reported in the RCOphth NOD was 24% eyes overall achieved a postoperative best measured visual acuity of 0.0 logMAR or better. Overall, the surgical complication rates and visual outcomes show that the transition to laser assisted cataract surgery in a UK NHS environment appears safe despite the learning curve.

In this series we found that docking was not possible in 6% of cases and that in 4% of cases where successful docking was made, the laser delivery was abandoned part way during delivery. Naturally one would expect these values to be lower outside of the learning curve, however this does emphasize that docking and laser delivery appears acceptable to almost all patients, despite limited previous experience for the vast majority of surgeons within this series.

Of note, the 4 cases with vitreous loss were either trainees' first laser assisted cataract surgery (2 surgeons), or their first and second laser assisted cataract surgeries (1 surgeon). A number of studies have provided data on the surgical learning curve for laser cataract surgery,<sup>11,12,16-18</sup> with laser platforms having also undergone considerable software and hardware development over the past few years.<sup>23,24</sup> A large case series of 1852 operations using the AMO Catalys platform report an anterior capsule tear rate of 1.84% and posterior capsule tear rate of 0.43%.<sup>13</sup> For trainee surgeons, intraoperative and postoperative complication rates of laser assisted cataract surgery are thought to be similar to those of manual cataract extraction.<sup>18</sup> Data from a small series on trainee surgeons' initial supervised use of the Alcon LenSx platform reported a successful docking rate of 97.6% and posterior capsule tear rate of 0% (0/62 cases).<sup>17</sup> In a recent report of the first 2 years of experience using the Bausch and Lomb Victus platform, the posterior capsule tear rate was low even within the learning curve (0.3%, 3/1105 events overall).<sup>11</sup>

Interestingly we found the vast majority of intraoperative complications to be iris problems, with the pupil coming down in 3 (2.0%) cases such that iris hooks were required to complete the respective cases. A recent comparative series investigating pupil diameter before and

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194 after laser cataract surgery reported that laser pre-treatment induced significant pupillary  
195 miosis with the pupil diameter falling below 5mm in 4.0% of cases.<sup>25</sup> In a series of 1500 laser  
196 cataract operations, the intraoperative pupil constriction rate was reduced from 9.5% in the  
197 first 200 cases to 1.2% for the latter 1300 cases when an additional 1 drop of 10%  
198 phenylephrine was given after the laser procedure.<sup>12</sup> The authors also noted that factors  
199 such as platform evolution, which shortened overall procedure time and more efficient  
200 scanning patterns that reduced the required delivered energy may too have been partly  
201 attributable.<sup>12</sup>

202 Based on our experience and the published literature, emphasis on the following changes to  
203 clinical practice appears helpful to facilitate the conversion to laser assisted cataract  
204 surgery:

- 205 1) Careful case selection. This covers multiple areas including expected patient  
206 cooperation<sup>16</sup> to dilated pupil size. For the latter, whilst some lasers have automatic  
207 capsulotomy diameter reduction if the pupil is smaller than that required for the  
208 programmed capsulotomy size, there is little point proceeding to make a  
209 capsulotomy that subsequently needs enlarging at the beginning of the procedure  
210 (with the possible exception of that for intumescent white cataracts where creating  
211 a laser mini-capsulotomy has reported to be effective).<sup>26</sup>
- 212 2) To administer additional mydriatic eye drops following the laser delivery to minimise  
213 the risk of intraoperative pupil constriction.<sup>12</sup>
- 214 3) Confirming the capsulotomy is complete (“free floating”) without any adhesions,  
215 which if present can be successfully managed to prevent extension to a capsular  
216 tear.<sup>27</sup>
- 217 4) Careful hydrodissection to reduce any likelihood of capsular block and associated  
218 posterior capsule rupture.<sup>28</sup>

219 The main limitations of this study are its retrospective design with reliance on surgeons to  
220 faithfully record their complications on the electronic medical records system used, and also  
221 the relatively small case series size.

222 In conclusion, despite the learning curve, docking and laser delivery were successfully  
223 performed in almost all cases, and surgical complication rates and visual outcomes were  
224 similar to those expected based on national data. Complications were predominately

225 confined to trainee surgeons, and with the exception of intraoperative pupil constriction  
226 appeared unrelated to the laser performed steps.

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