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Evaluation of a hub-and-spoke model for the delivery of femtosecond laser assisted cataract surgery within the context of a large randomized controlled trial

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Synopsis

A femtosecond laser can improve cataract theatre efficiency by adopting a hub-and-spoke model with one laser supplying patients to multiple independent operating rooms running in parallel.

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Abstract

Aims:

To test a hypothesis that cataract operating room (OR) productivity can be improved with a femtosecond-laser (FL) using a hub-and-spoke model and whether any increase in productivity can offset additional costs relating to the FL.

Methods

400 eyes of 400 patients were enrolled in a randomised-controlled trial comparing FL-assisted-cataract-surgery (FLACS) with conventional-phacoemulsification-surgery (CPS). 299/400 operations were performed on designated high volume theatre lists (FLACS=134,CPS=165), whereby a hub-and-spoke FLACS model (1xFL,2xORs = 2:1) was compared to independent CPS theatre lists. Details of operative timings and OR utilisation were recorded. Differences in productivity between hub-and-spoke FLACS and CPS sessions were compared using an economic model including testing hypothetical 3:1 and 4:1 models.

Results

The duration of the operation itself was 12.04±4.89 minutes(min) for FLACS compared with CPS of 14.54±6.1min(p<0.001). Total patient time in the OR was reduced from 23.39±6.89min with CPS to 20.34±5.82min with FLACS(p<0.001)(reduction of 3.05min per case). There was no difference in OR turnaround time between the models. Average number of patients treated per theatre list was 9 for FLACS and 8 for CPS. OR utilisation was 92.08% for FLACS and 95.83% for CPS (p<0.001). Using a previously established economic model, the FLACS service cost £144.60 more than CPS per case. This difference would be £131 and £125 for 3:1 and 4:1 models respectively.

Conclusion

The FLACS hub-and-spoke model was significantly faster than CPS, with patients spending less time in the OR. This enabled a improvement in productivity, but insufficient to meaningfully offset the additional costs relating to FLACS.

Abstract word count: 250

Introduction

Over the past decade, Femtosecond lasers (FLs) have been introduced into the field of cataract surgery to try to automate the procedure and more importantly improve both efficacy and safety¹. Multiple prospective case series have been published which appear to support its potential in cataract surgery and more surgeons are adopting this new technology¹⁻⁶. A meta-analysis of FLACS vs CPS performed by Chen et al, identified 9 randomised controlled trials (RCTs)⁷⁻¹⁷. Overall, they found that FLACS significantly reduced effective phacoemulsification time (EPT) compared to CPS. This did not translate into a difference in central corneal thickness or endothelial cell count at one week or beyond. The rates of surgical complications were similar. The post-operative corrected visual acuity was statistically superior in FLACS at 1 week and 6 months post operative but not at 1-3 months. There was no statistically significant difference in uncorrected visual acuity at any time point. A recent Cochrane Review of 16 RCTS including 1638 eyes concluded, 'There is currently not enough evidence to determine the benefits and harms of laser-assisted cataract surgery compared with standard ultrasound cataract surgery. The evidence is uncertain because current studies have not been large enough to provide a reliable answer to this question'¹⁸.

Until good quality evidence is available describing better clinical outcomes it is not possible to currently support the widespread introduction of FLACS within public healthcare organisations such as the National Health Service (NHS). This is especially pertinent as by the very nature of its complex technology, FLACS has significant associated financial costs, including initial purchase costs of the laser itself, servicing, depreciation and the individual patient interfaces (PI). These costs seriously question its financial viability, especially in healthcare systems funded by the state. In addition, current published studies with FLACS report increased total surgical time and therefore reduced patient turnover and productivity¹⁹⁻²¹. This is because the operating surgeon in these studies is typically performing both the FL treatment as well as the subsequent lens extraction within the operating room (OR). This reduction in productivity, is highly important within the public health sector, where high volume surgical models are necessary to meet the both the increasing numbers of patients requiring cataract surgery and economic limitations. It is of note that, the current published literature on the economics of FLACS mainly originates from healthcare systems within the private sector, where supplementary costs of advanced technologies may to a certain extent be passed onto the patient in the form of a co-payment system^{19,22,23}. However, even in such healthcare models, the literature advocates that FLACS at this time is not cost-effective.

Despite these considerations, FLACS does offer the promise to automate a number of the component parts of cataract surgery so that they do not need to be undertaken by an appropriately trained ophthalmic surgeon within the OR. Surgical steps such as corneal incisions, arcuate keratotomies, capsulotomies and nuclear lens division can be undertaken with FL by a doctor in training or suitably accredited and trained nurse/technician in a clean room. This has the potential to reduced the amount of time each individual patient spends in the OR with the ophthalmic surgeon. As a result, the efficiency of cataract surgery might be improved by increasing the number of surgical cases undertaken in a given time period. This potential efficiency is increased if a "hub and spoke" model is utilized, with a single FL treating and then feeding patients into several operating ORs for completion of surgery. Potentially, if the number of cases per theatre session can be increased sufficiently then the additional costs associated with FL technology might be offset. In a previous publication, we have previously explored this possibility using a hypothetical model based on real world financial data²⁴. We reported that in order to break even, there would need to be, for example, a 43% increase in the number of operations performed per theatre list accompanied by a need to discount the cost of the PIs by at least 52% by the manufacturers².

As yet, there are no publications looking at the efficacy, safety and additionally the economics of FLACS compared to CPS, within a 'hub-and-spoke' model, as described above, in a real world

1 public health sector setting, where both trainee and fully accredited surgeons undertake surgery,
2 with all the constraints that can be associated with the Public Health Sector, such as limited
3 financial resources, OR space and resistance to change in formalized working practices In order to
4 investigate some of these issues, we undertook an RCT comparing FLACS with CPS, in which we
5 delivered our FLACS service using a hub-and-spoke model. Surgeries were performed by 3 cataract
6 surgeons of differing levels of experience (one fully accredited with twenty years experience, one
7 newly accredited and one specialist registrar). Two hundred and ninety-nine of the 400 cases were
8 performed on designated high volume theatre lists, whereby a hub-and-spoke FLACS model (with
9 one femtosecond laser and two ORs) was compared to independent CPS theatre lists. Details of
10 operative timings and OR utilisation within these lists were recorded. Our aims were to provide the
11 best quality evidence to date on whether FLACS can improve productivity in cataract surgery in the
12 public health sector while maintaining safety and efficacy and what models of FLACS delivery
13 might offset its associated addition costs.
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Methods

Randomised Controlled Trial

This analysis of relative productivity of FLACS delivered by hub-and-spoke model vs CPS was performed as a secondary outcome of a prospective randomised interventional case-controlled study at a single University Hospital (Guy's & St Thomas' Hospital NHS Foundation Trust, London, UK) to compare the clinical outcomes of FLACS with CPS (Clinicaltrials.gov registration number NCT02825693). The study was approved by local Research & Development and Cambridge South Research Ethics Committee (reference 16/EE/0180). This study adhered to the tenets of the declaration of Helsinki.

Patients were screened, recruited and consented from routine cataract clinics by members of the trial team (HR, VW) as per the trial protocol (Version 2.0, 18/05/2016) (Table 1).

Inclusion Criteria:
<ul style="list-style-type: none"> Patients must have reduced visual acuity or visual symptoms attributed to the presence of cataract in one or both eyes by the examining ophthalmologist or else must require cataract surgery on clinical grounds other than visual symptoms.
<ul style="list-style-type: none"> Patients must be willing to attend for follow-up at 3-4 weeks after cataract surgery.
<ul style="list-style-type: none"> Patients must have sufficient English language for informed consent and completion of the patient reported outcome questionnaires.
Exclusion Criteria:
<ul style="list-style-type: none"> Children below the age of 18
<ul style="list-style-type: none"> Already enrolled in another study
<ul style="list-style-type: none"> Clinical contraindications for FLACS, such as: <ul style="list-style-type: none"> Significant corneal opacities Small pupils (<4mm) following pharmacological dilatation Patients unable to lie sufficiently flat so as to be positioned underneath the laser machine.

Table 1. Inclusion and exclusion criteria for enrolment into the study

Cataract Surgery Delivery Models

General Model, Staff-duties and Patient Flow

Cataract operations were performed during 4 hour theatre sessions, either in the morning or afternoon. Patients for cataract surgery were admitted on a staggered arrival basis to an ophthalmic day care unit (ODCU) which staffed by a receptionist and a mixture of ophthalmic technicians (OTs) and ophthalmic nurses (ONs) (Table 4).

After electronic registration by the receptionist, the patients were prepared for the OR by the ON/OTs. This included a series of medical observations, such as blood pressure and blood sugar (if diabetic), and administration of mydriatic therapy. Mydriatic therapy used in this study included a Mydriaserit implant (Thea Laboratories, Clermont-Ferrand, France) and two drops of topical diclofenac sodium 0.1% to reduce the risk of intraoperative miosis^{25,26}. The ward ON/OTs brought and collected the patients to and from the OR, which were adjacent to the ODCU, after being telephoned by one of the OR nurses (TNs). After surgery was completed the ON/OTs performed further medical observations, gave advice about aftercare, dispensed medication, discharged the patients and arranged follow-up.

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3 Patients were treated on either all-FLACS or all-CPS theatre lists. All cataract operations were
4 performed under local anaesthetic. All were unilateral and no other additional procedures planned,
5 other than arcuate keratotomies for reduction of corneal astigmatism.
6

7 The duties of the ophthalmologist inside the OR included: helping positioning the patient on the
8 operating table, the scribing of patient details onto the whiteboard, the removing of the Mydriasept
9 implant, the marking of the forehead above the eye for cataract surgery prior to the World Health
10 Organization (WHO) checklist²⁷, scrubbing and gowning, leading the WHO checklist, preparation
11 and draping of the eye for surgery, operating, writing the operation notes, and scanning the paper
12 WHO checklist into the hospital's electronic patient record software.
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15 **FLACS Hub and Spoke Delivery Model**

16 FLACS theatre lists were run as a hub-and-spoke model (figure 1). A LenSx femtosecond laser
17 (Alcon Inc, Fort Worth, Tx, USA) was installed in the anaesthetic room of one of the ORs, hereafter
18 referred to as the laser suite (LS), and was used to feed patients into two adjacent ophthalmic ORs
19 which were running in parallel. The femtosecond laser was operated by an ophthalmologist (HR,
20 VW). The model required an additional OT who supervised patients waiting in the corridor outside
21 the LS (Table 4). There was a maximum of 4 patients seated in the theatre corridor at any one time
22 (2 patients waiting for laser treatment, 2 patients waiting to enter OR). In the FLACS model, the
23 ophthalmologist performing the femtosecond laser treatment was responsible for marking the
24 patients' eyes before laser, delivering laser treatment, removing the Mydriasept implant, and
25 instilling additional topical phenylephrine 10%. Performing laser treatment included preparing the
26 patient interface, entering patient details into the FL, selecting the planned treatment profile,
27 positioning the patient on the laser bed, instilling topical anaesthetic in to the operative eye,
28 inserting the lid speculum, docking the patient interface to the eye, performing Optical Coherence
29 Tomography (OCT) of the anterior segment, choosing the treatment parameters, and delivering the
30 laser treatment. If completion of FL treatment was not possible for any reason, this and the reason
31 why was recorded and the patient proceeded to the OR for CPS.
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35 The number of patients booked to each 4 hour theatre list were decided in advance of each theatre
36 list. The intention was to attempt to always maximize the number of patients treated during the
37 allotted theatre time with reference to the levels of nursing and para-medical staffing. Initial targets
38 were chosen based on existing experience of CPS and FLACS at our institution and titrated as the
39 trial progressed, according to whether theatre lists were finishing early or over-running.
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42 **Operating Room Timings**

43 Two hundred and ninety-nine of the 400 cases were performed on designated high volume theatre
44 lists, whereby patients were randomized to either hub-and-spoke FLACS model (with one FL and
45 two ORs) or CPS only theatre lists. Various timings of OR utilization were undertaken by a TN and
46 included the time taken for the patient to enter the OR, duration of cataract surgery, time taken for
47 the patient to exit the OR after completion of surgery, the total individual patient time in the OR, the
48 time the OR was empty between patients, over and under-runs of allotted OR time, etc
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51 Timings of patient entry to the OR, start of operation, end of operation and patient exit from the OR
52 were recorded contemporaneously by TNs using the existing theatre management software (Galaxy
53 Theatre Management System, iSOFT, DXC Technology, Virginia, US). Accuracy of timings was
54 ensured by a trained observer (IJMM). Timings of patient entry and exit from the LS were recorded
55 by the ophthalmologist performing the laser treatment. Start of operation and end of operation were
56 defined as application of antiseptic solution to the eye and skin, and removal of eyelid speculum.
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Economic Model

The results from this were used as inputs for a hypothetical economic model, reported in a previous publication, to determine an estimation of the costs of cataract surgery²⁴. This financial model has been described in greater detail in the previous publication but was based on averaged costs/values from 5 different NHS foundation trusts and 4 femtosecond laser manufacturers. This model was used to provide an estimation of the difference in cost per case of running a FLACS service as compared with a traditional cataract service. Furthermore if the results supported that a hub and spoke model could be run with more than two ORs, these iterations were also tested using the model.

Statistics

For the purposes of this study, the first two CPS and FLACS theatre lists each were excluded from analysis as they were scheduled with reduced patient numbers in order to allow theatre staff to familiarize with the models. The final four theatre sessions of the study were run as mixed lists in order to facilitate the scheduling of the remaining research participants and to avoid under utilised theatre sessions. These final mixed lists were also excluded from analysis.

The primary outcome as per the study protocol were the relative costs of FLACS and CPS. However in light of inherent difficulties in accurate recordings of costs within a large tertiary ophthalmology service, it was determined that this would be replaced with the number of cases on FLACS and CPS lists and the duration of the operations. This current study study of 299 patients had a power of 99% to detect an effect size (d) of 0.5 for the numbers of participants included in this analysis with regards to duration of surgery with $\alpha=0.05$ and a two tailed analysis.

Baseline characteristics were summarised for each treatment arm. Results were analysed primarily as per intention to treat. Continuous data was reported using means and standard deviations if data appear Gaussian, or medians and inter-quartile ranges if not. Binary data was reported as frequencies and percentages and evaluated with Fischer's exact test. Student's t-tests were used for parametric data and the Mann Whitney U test for non-parametric. All statistical tests used a two-sided p value of $\alpha=0.05$ unless otherwise specified. Intra-operative complications were defined as any event that involved unintentional trauma to an ocular structure, requiring additional treatment, or havin a negative effect on participants' eyesight.

Results

A total of 427 patients (427 eyes) were recruited for the study and randomized to receive FLACS or CPS. Twenty-seven were excluded or withdrew in advance of surgery. For the purpose of this study comparing FLACS in a hub and spoke model with dual CPS theatre lists 299 of 400 operations were included for analysis (Figure 2). Excluded patients included 57 patients who had had surgery on the first 2 of each theatre sessions for FLACS/CPS and 44 patients treated on mixed (CPS and FLACS) theatre lists. There were no significant differences between patients included and excluded for this analysis other than those excluded were on average 3 years older ($p=0.01$) and had shallower anterior chambers by 0.17mm ($p<0.01$) (Table 2). Of the 299 eyes included in this analysis, 134 patients had received FLACS, and 165 patients underwent CPS. Baseline demographics for the FLACS and CPS groups are seen in Table 3. The only significant difference at baseline was the FLACS group had a longer axial length by 0.39mm ($p=0.02$). 5 patients due to receive FLACS were treated with CPS due to the following reasons: palpebral aperture too narrow for patient interface ($n=3$, 2.2%), patient lack of compliance ($n=1$, 0.7%), administrative error ($n=1$, 0.7%).

	High volume theatre list participants	Patients not treated on designated high volume theatre lists	p
Male/female	140/159	41/60	0.30
1 st Eye/2 nd Eye	243/56	87/14	0.29
Right Eye/Left Eye	164/135	55/46	1
Age (years)	69.45 ± 10.81	72.42 ± 8.6	0.01
Pre-operative best corrected distance visual acuity (logMAR)	0.60 ± 0.51	0.51 ± 0.36	0.10
Spherical equivalent refractive error diopters (D)	-0.50 ± 4.32	-0.38 ± 3.52	0.80
Axial length (mm)	23.78 ± 1.39	23.67 ± 1.56	0.51
Anterior chamber depth (mm)	3.27 ± 0.38	3.10 ± 0.55	<0.01
Average predicted PCR risk ²⁸	1.63 % ± 1.24	1.63 % ± 0.71 %	1

Table 2. Demographics of patients included and excluded from the hub-and-spoke model analysis demonstrating equivalence between the two groups

The 139 patients undergoing FLACS were treated during 8 hub-and-spoke sessions, involving 16 four hour theatre sessions. The 160 patients randomized to CPS were treated on 20 cataract theatre lists. The average OR utilisation of a hub-and-spoke session was 221mins ± 21 (92.05%±8.71) with a median of 9 patients treated in each OR, while the average duration of a CPS list was 230± 22 min (95.81%±9.17) ($p<0.001$) with a median of 8 patients treated per list. Patients receiving FLACS spent, a mean time of 5.85±1.99 min in the LS. 25% of FLACS theatre sessions over-ran the allotted 4 hours compared with 30% of CPS lists. Average theatre over-run was 5±2.16 min for FLACS and 13.67±8.76 mins for CPS ($p=0.09$).

	FLACS	CPS	p
Male/female	62/72	78/87	0.90
1 st Eye/2 nd Eye	111/23	132/33	0.55
Right Eye/Left Eye	70/64	94/71	0.42
Age (years)	69.07 ± 11.55	69.78 ± 10.14	0.57
Pre-operative best corrected distance visual acuity (logMAR)	0.65 ± 0.52	0.57 ± 0.50	0.18
Spherical equivalent refractive error diopters (D)	-0.58±5.34	-0.42 ± 3.15	0.75
Axial length (mm)	23.99 ± 1.44	23.60 ± 1.33	0.02
Anterior chamber depth (mm)	3.31 ± 0.38	3.23 ± 0.37	0.07
Average predicted PCR risk ²⁸	1.64% ± 0.99%	1.62% ± 1.43 %	0.89

Table 3. Patient demographics for the two treatment arms

Staffing levels for both models can be seen in Table 4. The hub-and-spoke model required one additional OT to be present compared with the CPS. A comparison of the average times associated with each operation can be seen in Table 5 and Table 6.

	FLACS (BOTH ORS)	CPS (BOTH ORS)
OPERATING ROOMS (ORS)		
OPHTHALMOLOGISTS	3	3
OR NURSES	6.5	6.5
OPHTHALMIC DAY CARE UNIT		
OPHTHALMIC TECHNICIANS	3	2
OPHTHALMIC NURSES	2	2
RECEPTIONIST	1	1

Table 4. Staffing levels associated with delivery of hub-and-spoke FLACS and CPS services. ORs = Ophthalmic Operating Rooms

	FLACS (N=139)	CPS (N=160)	T TEST (P VALUE)
TIME FROM ENTERING OR TO START OF OPERATION	5.83 ± 2.58	6.25 ± 2.91	0.19
DURATION OF OPERATION	12.04 ± 4.89	14.54 ± 6.19	<0.001
TIME FROM END OF OPERATION TO EXITING OR	2.47 ± 0.66	2.6 ± 1.02	0.20
TOTAL TIME IN OR	20.34 ± 5.82	23.39 ± 6.89	<0.001
OR EMPTY	5.27 ± 3.25	5.23 ± 3.28	0.92

Table 5. Comparison of OR timings (in minutes) between hub-and-spoke FLACS and CPS based on intention to treat analysis. OR = Ophthalmic Operating Room

	FLACS (N=134)	CPS (N=165)	T TEST (p value)	FLACS CONVERTED TO CPS (N=5)
TIME FROM ENTERING OR TO START OF OPERATION	5.82 ± 2.62	6.24 ± 2.87	0.19	6 ± 1.58
DURATION OF OPERATION	11.73±3.53	14.71 ± 6.76	<0.001	20.40 ± 17.87
TIME FROM END OF OPERATION TO EXITING OR	2.47 ±0.66	2.59 ± 1.02	0.24	2.4 ± 0.89
TOTAL TIME IN OR	20.2 ±4.59	23.55 ± 7.47	<0.001	28.8 ± 19.33
OR EMPTY	5.79±3.9	5.27 ± 3.25	0.21	6.4 ± 1.95

Table 6. Comparison of OR timings (in minutes) between hub-and-spoke FLACS and CPS based on actual operation performed.

Complications

The overall rate of intraoperative complications were similar between the two groups 3.54% vs 3.76% however there was a noticeable difference in the rates of vitreous loss (0% with FLACS compared to 1.88% in CPS) (Table 7).

COMPLICATIONS	FLACS	CPS	RR	P
ANTERIOR CAPSULAR TEAR	3 (2.16%)	3 (1.88%)	1.15 (95% CI 0.24-5.6)	0.86
POSTERIOR CAPSULE TEAR WITH VITREOUS LOSS	0 (0%)	3 (1.88%)	0.16 (95% CI 0.01 -3.15)	0.23
DM TEAR	1 (0.72%)	0 (0%)	3.45 (95% CI 0.14 – 84.0)	0.45
SUPRACHOROIDAL HAEMORRHAGE	1 (0.72%)*	0 (0%)	3.45 (95% CI 0.14 – 84.0)	0.45
ABANDONED - EXTREME ZONULAR WEAKNESS	0 (0%)	1 (0.63%)	0.38 (95% CI 0.01-9.34)	0.56
TOTAL COMPLICATION RATE	3.54%	3.76%	0.95 (95% CI 0.30-3.07)	0.94

Table 7. Incidence of complications between the two treatment arms based on intention to treat analysis. *This patient was allocated to FLACS but was unable to undergo this procedure and the patient underwent CPS (RR = Relative Risk).

Economic Modelling

Based on our OR timings, using a hub-and-spoke model, we achieved a mean reduction of total time in the OR per patient of 3.05min. This allowed us to undertake one extra FLACS case per 4 hour theatre list compared to our CPS only lists. The average number of cases on using our operative models were were 8 for CPS and 9 for FLACS, which represented an average 12.5% increase in productivity. We applied these results to our economic model. Based on these results, the average cost for each cataract operation was £355.42 for CPS and £500.02 for FLACS (figure 3).

A bivariate sensitivity analysis examining the number of cases/week and the cost of the patient interface (PI) was performed, reporting the additional cost per case of a FLACS service (Table 8).

		NUMBER OF CATARACT OPERATIONS PERFORMED PER WEEK			
COST PER LASER PATIENT INTERFACE (£)		20	40	60	80
COST PER LASER PATIENT INTERFACE (£)	40	£72.75	£46.51	£37.76	£33.39
	70	£102.75	£76.51	£67.76	£63.39
	100	£132.75	£106.51	£97.76	£93.39
	130	£162.75	£136.51	£127.76	£123.39

Table 8. Bivariate sensitivity analysis comparing effects of cost of patient interface and number of operations performed per week on the additional cost of FLACS compared with CPS within a 2:1 hub-and-spoke FLACS model.

3:1 and 4:1 Hub and spoke model

Although the duration of FL application to the eye is usually between 25 and 45 seconds, patient time inside the laser room was 5.85mins \pm 1.99. In our model, the laser operator is an ophthalmologist working unassisted, and therefore the majority of time spent is on preparing the patient and setting up the laser. Based on our results, we recommend that the maximum number of ORs which could be run (in order to maximize the utility of a femtosecond laser) in a hub-and-spoke model would be four (average total patient time in OR + turnaround time 25.12mins \pm 5.25). Adding a third OR to our economic modelling of the costs of cataract surgery reduced the cost per case from £500.02 to £477.28 and adding a fourth reduced it to £465.91. Performing the same bivariate analyses on a 3:1 and 4:1 hub-and-spoke models as above shows that the difference in cost could be reduced further if the hospital was performing greater numbers of cataract surgery and received a significant discount in the cost of the patient interface from the manufacturer (Table 9). However in order to break even, our financial modelling shows the manufacturers would need to offer between 78-99% discount on the cost of the PIs (Table 10 Error! Reference source not found.).

		Number of operations performed per week				
		40	60	80	100	
Cost per patient interface	3:1 Model	40	£33.40	£24.65	£20.28	£17.65
		70	£63.40	£54.65	£50.28	£47.65
		100	£93.40	£84.65	£80.28	£77.65
		130	£123.40	£114.65	£110.28	£107.65
			Number of operations performed per week			
	4:1 model	40	£26.84	£18.10	£13.72	£11.10
		70	£56.84	£48.10	£43.72	£41.10
		100	£86.84	£78.10	£73.72	£71.10
130		£116.84	£108.10	£103.72	£101.10	

Table 9. Bivariate sensitivity analyses demonstrating the additional cost of FLACS compared with CPS within a theoretical 3:1 and 4:1 hub-and-spoke FLACS model when the cost of the patient interface and the number of operations per week are varied.

NUMBER OF CATARACT OPERATIONS/YEAR

% DISCOUNT ON COST OF PI		2000	3000	4000	5000	6000
	4:1 model	91	84	81	79	78
	3:1 model	96	89	86	84	82
	2:1 model	n/a	99	95	93	92

Table 10. Break even points for hub-and-spoke FLACS with CPS services calculated for the % discount of the patient interface based on the number of ORs concurrently run and the number of operations performed per year

Cases unable to undergo FLACS

Five (3.6%) patients randomised to FLACS did not receive femtosecond laser treatment. This is consistent with reported rates of unsuccessful attempts at FLACS between 2.3-6.3%²⁹⁻³¹. In our experience, the most common reason was that the palpebral aperture was too narrow to permit the 16mm patient interface to appanate with the cornea. Four of these patients underwent uneventful CPS, with one suffering a suprachoroidal haemorrhage. This patient was considered at increased risk for this rare complication with an axial length of 19.66mm.

Discussion

We have conducted a large randomised controlled trial comparing FLACS with CPS, by reporting the clinical outcomes and testing the efficiency of FL-centric methods of running cataract theatre lists. When FLACS is performed within traditional models featuring one surgeon, or installing the FL in the OR, productivity may be adversely affected, leading to incurring additional indirect costs¹⁹⁻²¹. Evaluating new models of delivering cataract surgery (such as a hub-and-spoke model) within a RCT, where patients are prospectively randomised to CPS or FLACS, allows us to test the model within a rigorous framework, rather than performing a case-control study where bias may be inherent.

By deploying a FL in the anaesthetic room adjacent to the OR and using a hub-and-spoke model, we have found that surgical time and patient time in OR are shorter for FLACS than CPS. Reducing patient time in OR by 3.05minutes for FLACS ($p<0.001$) led to an average of one extra operation per OR operating list of FLACS (median 9 cases per list) than CPS (median 8 cases per list), resulting in a 12.5% improvement in productivity (overall 2 more operations per session). Furthermore, despite the additional cases, the FLACS lists were shorter than the CPS lists, and more CPS sessions overran. Our method of titrating the numbers of patients scheduled for surgery to maximise the number of operations within the four hour session resulted in extremely high levels of OR utilisation. Our ambition resulted in a number of theatre sessions overrunning (25% FLACS vs 30% CPS), especially when unforeseen complications had occurred. Theatre list overruns may incur financial penalty at some NHS/public hospitals, however, our greater concern was to test the limits of our models.

There were some differences between the 299 patients included for this analysis and the 101 excluded, namely that the excluded group were 3 years older on average, with a corresponding shallower ACD by 0.17mm. It is unlikely that these differences are clinically significant and would have had a material effect on the timings of the theatre list²⁸. Importantly, the prospectively calculated risk of PCR were equivalent between the two groups.

The mean time of each patient undergoing patient preparation for FL and FL application was 5.85 \pm 1.99 mins. Based such results it is easily possible to have a hub-and-spoke model of one FL feeding into 3 or 4 ORs (4:1 or 3:1) rather than 2 (2:1). we recommend that the ideal number of ORs to maximize the utility of a femtosecond laser in a hub-and-spoke model would be four (average total time per patient in OR + turnaround 25.12mins \pm 5.25). We predict that this would result in 3 or 4 more operations performed overall by the FLACS model per session (one for each OR).

Potential issues of having a 3:1 or 4:1 model to attempt to use a femtosecond laser as a tool for high volume surgery is that this requires a suitable and dedicated room within theatres and multiple ORs. This limits the use of such a model to an institution with such facilities already in place or a purpose-built unit. For instance, with a maximum of 2 eye ORs at our institution we are not able to evaluate adding additional ORs to our existing hub-and-spoke model. It is important to incorporate any development costs in the planning process if deciding whether to adopt this technology.

In order to minimize costs of running the hub and spoke model it is important to minimise the additional number of staff needed. Our model required 2 additional members of staff, one ophthalmologist to operate the laser and one OT to chaperone the patients between the LS and ORs. For our CPS lists, the extra OT was not present, however there were 3 ophthalmologists between the two ORs. This may have improved the efficiency of the CPS lists in our study to a degree by allowing the surgeons to rotate.

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3 The financial model demonstrates that the PI is the single most expensive item for the FLACS
4 service. However, thus far FL platforms have tended to be used, and marketed as a premium
5 product (based on reported improved refractive outcomes and stability)³². However it is very likely
6 that a public health care service may be able to negotiate discounts on the costs of FLACS,
7 especially if used within a high-volume service (which further improves affordability) (Table 8 and
8 Table 9). Further cost savings may be made by improved safety which may make cost savings in
9 post-operative management³³. It is important to note therefore that whilst there was no difference in
10 posterior capsular rupture (PCR) and vitreous loss rates in this arm of the present study to
11 investigate comparative high volume hub-and-spoke FLACS and CPS theatres lists (table 7), the
12 results of the overall RCT showed a statistically significant reduction in PCR with FLACS, in a
13 public health setting with different grade of surgeons operating, including those in training
14 (personal communication H. Roberts, D. O'Brart). As such complications incur additional costs, if
15 our findings with respect to PCR rates are replicated by others, then our economic modelling might
16 be more favourably inclined toward a FLACS hub-and-spoke model.
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20 Our investigation of the effects of number of allied health professionals (AHPs) assisting in cataract
21 theatre lists on the overall productivity showed a marked difference in the number of cataract
22 surgeries performed between different institutions, but furthermore that a minimum of 4 AHPs are
23 required to deliver high volume cataract surgery with effective use of theatre time and minimum
24 delays (in submission Manuscript ID bjophthalmol-2017-310452.R1). Our cataract ORs are
25 generally run with 3 AHPs, which precludes further increases in productivity, which is evident in
26 our turnaround time compared with other surgical units. The average time between one operation
27 finishing and the start of the next was 13.57min and 14.08min for FLACS and CPS respectively,
28 meaning that only between 47.0 - 50.8% of OR time is spent engaged in surgery. Our previous time
29 and motion studies showed that patient turnover with 4 AHPs present can be reduced to 9.70mins
30 within NHS units. Including one additional AHP per OR to our unit (at a cost of £70 per session) to
31 facilitate patient turnover could provide a similar overall time saving as this femtosecond laser
32 technology.
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35 36 **Conclusion**

37 In summary, FLACS with a hub-and-spoke model was significantly faster than CPS, with patients
38 spending less time in the OR. This enabled a slight improvement in productivity, but not sufficient
39 to meaningfully offset the additional costs relating to FLACS. Further gains in productivity may
40 have been achieved with a 3:1 or 4:1 hub-and-spoke model.
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Legends for figures in the text

Figure 1. St Thomas' Hospital's 'hub-and-spoke' model for FLACS

Figure 2. CONSORT flowchart of participant numbers through the study.

Figure 3. Comparison of weekly costs of FLACS vs CPS services.

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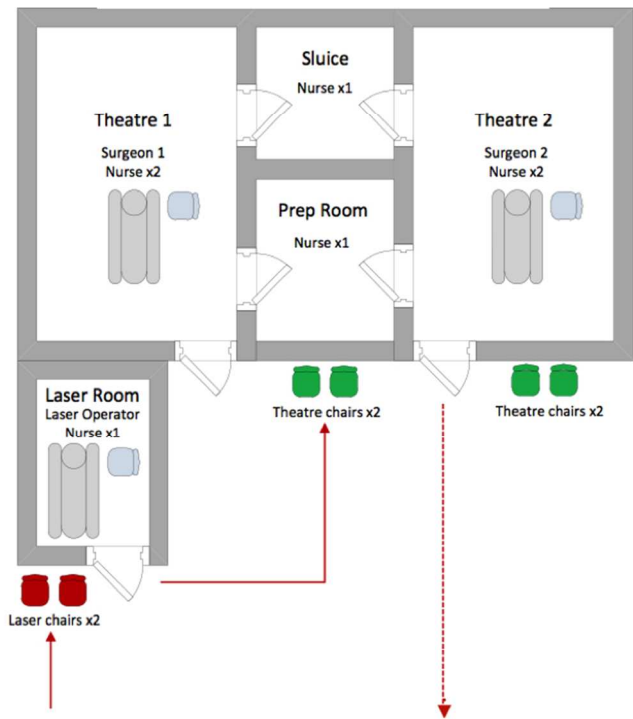


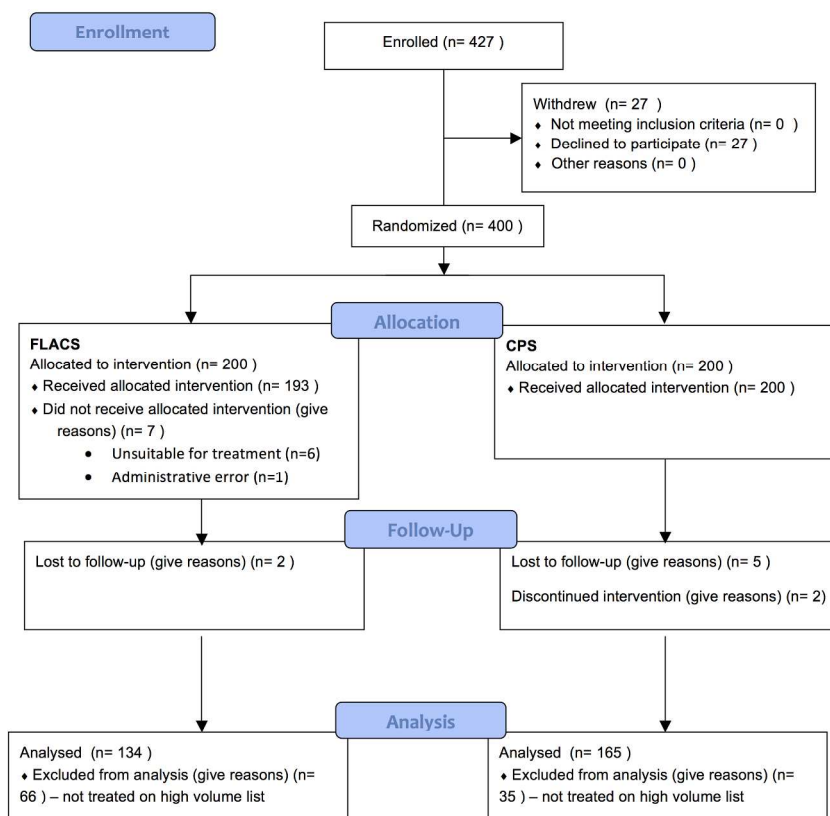
Figure 1. St Thomas' Hospital's 'hub-and-spoke' model for FLACS

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CONSORT 2010 Flow Diagram

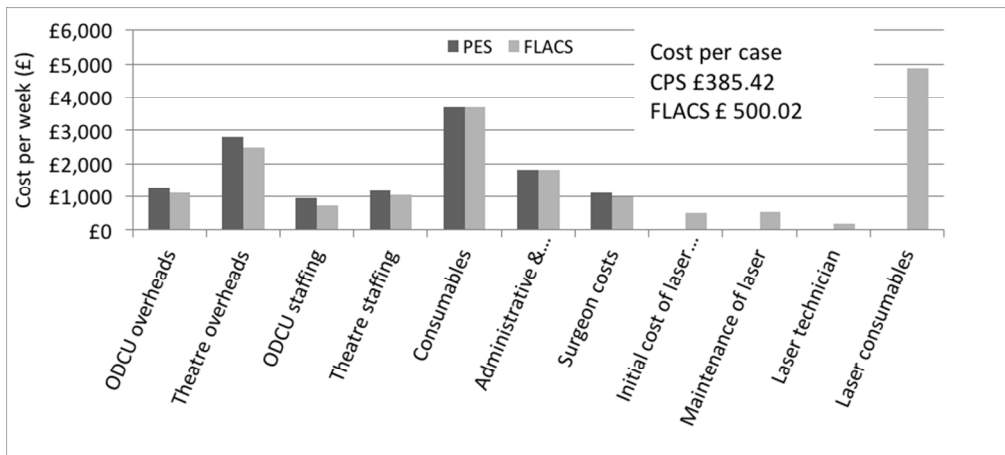


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