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# Causes of cataract surgery malpractice claims in England 1995–2008 – Source link

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Title:

# Causes of cataract surgery malpractice claims in England 1995-2008

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## ABSTRACT

**Aims**: To analyse the causes of malpractice claims related specifically to cataract surgery in the National Health Service in England from 1995-2008.

**Methods**: All the malpractice claims related to cataract surgery from 1995-2008 from the National Health Service Litigation Authority were analysed. Claims were classified according to causative problem. Total numbers of claims, total value of damages, mean level damages and paid:closed ratio (a measure of the likelihood of a claim resulting in payment of damages) were determined for each cause.

**Results**: Over the 14 year period there were 324 cataract surgery claims with total damages of £1.97 million and mean damages for a paid claim of £19,900. Negligent surgery (including posterior capsule tear and dropped nucleus) was the most frequent cause for claims, while reduced vision accounted for the highest total and mean damages. Claims relating to biometry errors/ wrong intra-ocular lens power were the second most frequent cause of claims and result in payment of damages in 62% of closed cases. The claims with the highest paid:closed ratio were inadequate anaesthetic (75%) and complications of anaesthetic injections including globe perforation (67%).

**Conclusions**: Claims from cataract surgery in the NHS are extremely infrequent. Consent, though essential, may not prevent a claim arising or resulting in damages. Refractive accuracy has significant medicolegal impact. Endophthalmitis can lead to successful claims if there is delay in diagnosis. Claims relating to inadequate anaesthesia or anaesthetic injection complications are particularly hard to defend.

### BACKGROUND

Cataract surgery is the commonest operation undertaken in England with around 300,000 operations performed every year in the National Health Service (NHS)<sup>1,2</sup>. Although the risk of an adverse event is low compared with many other operations, cataract surgery has a significant medicolegal impact due to its high volume<sup>3</sup>. Both in USA and UK, cataract surgery has been found to contribute the largest share of malpractice claims out of the ophthalmic subspecialties<sup>4-7</sup>. In a recent study comparing ophthalmic subspecialty negligence claims in the NHS, we found that cataract surgery was responsible for the highest number of claims and the highest total damages in ophthalmology<sup>8</sup>.

It is therefore surprising that there has been little attention in the literature directed at the *causes* of litigation in modern cataract surgery. Such analysis might provide useful information to improve safety and reduce the burden of claims. The reports prior to 1990 are concerned with the pre-phacoemulsification era and do not relate to the risk profile of current surgical practice<sup>4,5</sup>. For the period following the widespread introduction of phacoemulsification in the mid-1990s, we were able to identify two studies which focus on causes of cataract claims. The first examined 168 claims from 1987 to 1997 in USA<sup>3</sup>. The second study analysed 96 claims from 1990 to 1999 arising from private practice in the UK<sup>9</sup>. However, the independent sector differs in many regards from the context of cataract surgery in the NHS: the number of operations is far fewer; surgery is performed only by consultants; and patient demographics and expectations are different. Furthermore it has been identified that, outside of USA, there is a lack of specific guidance on the emerging issues of ophthalmic malpractice and medical litigation at a national level<sup>10</sup>. There is therefore a need for a systematic evaluation of the causes of negligence claims related to mainstream cataract surgery in the setting of the NHS.

Since 1995, medical malpractice claims in the NHS in England have been handled by a central body, the NHS litigation authority (NHSLA). The NHSLA has maintained a comprehensive database of claims since its inception. Apart from the first year, 1995-96 (when ascertainment was estimated to be 90%), the capture of claims by the database is considered to be complete, due to the procedural requirement of claims to be referred to the NHSLA. For each claim, the database includes a brief case description with details of damages where awarded. Using raw data obtained from the NHSLA database, this study aims to analyse the causes of malpractice claims in cataract surgery in England from 1995-2008.

### METHODS

An online data-request form was submitted to the NHSLA requesting data on all claims arising from the specialty of ophthalmology from 1995 to 2008. We then analysed, claim by claim, the tabulated raw data provided and classified claims according to standard ophthalmic subspecialty divisions. All the claims for cataract surgery were reviewed and grouped according to causative problem. The number of ongoing claims ("open"), completed claims ("closed"), and claims with payment of damages ("paid") were determined. The total and mean level of damages were calculated for each category of cause. For causes where there were at least 3 claims, the paid:closed ratio was also calculated (which indicates the likelihood of a claim resulting in payment of damages).

#### RESULTS

1132 claims for the whole of ophthalmology in the period 1995-2008 were studied. Of these, 324 (29%) were related to cataract surgery, 225 (69%) of which closed. For cataract surgery claims, the paid:closed ratio was 44%, with total damages of £1.97 million and mean damages for a paid claim of £19,900.

Table 1 shows the breakdown of claims by causes, with related causes grouped into areas. For convenience, Table 2 shows the top five ranking problems for each of the parameters determined (total claims, total damages, mean damages, paid:closed ratio).

# Table1: Breakdown of claims by causes

Area	Problem	Total	Closed	Paid	Paid to	Total	Mean
		Claims	claims	claims	closed %	damages £	damages £
Pre-operative	Delay in treatment	4	3	0	-	0	0
assessment	Operation not indicated	3	1	1	-	5,000	5,000
	Inadequate consent	6	1	1	-	12,500	12,500
Biometry/IOL	Biometry error/ wrong IOL power/	64	45	28	62%	302,006	10,786
	post-op refractive error						
	Defective IOL (including opacity)	9	6	0	0%	0	0
	IOL not available in theatre	1	1	1	-	7,000	7,000
Anaesthetic	Complication of injection (including globe perforation)	8	6	4	67%	115,000	28,875
	Inadequate anaesthetic	5	4	3	75%	77,000	25,666
Surgery	Wrong side	1	0	-	-	-	-
	Negligent surgery (including PC tear, dropped nucleus)	77	58	14	25%	247,885	17,705
	Globe perforation (from antibiotic injection)	4	2	2	-	51,316	25,658
	Corneal damage	4	1	1	-	17,500	17,500
	Equipment failure	18	13	7	54%	98,077	14,346
	Expulsive haemorrhage	4	3	1	-	13,058	13,058
Post-operative	Reduced vision	40	26	13	50%	607,000	46,692
	Endophthalmitis (including delay in diagnosing)	26	17	7	41%	113,833	16,262
	Retinal detachment	13	12	5	42%	177,671	35,534

	Suture complications (including	5	5	2	40%	28,500	14,250
	abcess)						
	Inadequate post-op management	10	6	1	17%	25,000	25,000
	(including follow-up)						
	Post-op glaucoma	3	2	1	-	7,000	7,000
	Posterior capsule opacification	2	2	2	-	3,587	1,794
	Drop/ ocular surface problems	4	3	1	-	500	500
	Diplopia	1	0	-	-	-	-
	Orbital cellulitis	1	0	-	-	-	-
	CRVO	1	0	-	-	-	-
Miscellaneous	Indeterminate	9	8	4	50%	62,324	10,387
	Injured by another patient	1	0	-	-	-	-
Total		324	225	99	44%	1,971,757	19,916

Rank	Total claims	Total damages	Mean damages	Paid:closed ratio
1	negligent surgery	reduced vision	reduced vision	inadequate anaesthetic
2	biometry error/wrong	biometry error/wrong	post-op retinal	complication of local
	IOL power/ post-op	IOL power/post-op	detachment	anaesthetic injection
	refractive error	refractive error		
3	reduced vision	negligent surgery	complication of local	biometry error/wrong
			anaesthetic injection	IOL power
4	post-op endophthalmitis	post-op retinal	inadequate anaesthetic	equipment failure
		detachment		
5	equipment failure	complication of local	inadequate post-	post-operative reduced
		anaesthetic injection	operative management	vision
			(including follow-up)	

# Table 2: Top five ranking causes for each parameter

## DISCUSSION

This is the most comprehensive factually-based national study to date that directly compares the causes and outcomes of the medicolegal activity associated with modern cataract surgery. It is also the largest published series of cataract claims in the world, and one of very few such studies since the introduction of phacoemulsification. It serves to focus our attention on the areas of our practice where there is room for improvement and provides an evidence base for the development of ophthalmic medicolegal guidance.

Nevertheless the study has some drawbacks. The data supplied by the NHSLA are in summary form and often details about the events surrounding the claim are limited. It is therefore not always possible to assign the claim to a causative problem (the 9 indeterminate claims.) The claims are anonymised so no

information regarding geographical spread or individual hotspot units can be discerned. In addition, the data are confined to England and no claims from private practice or general practice (eg delayed referrals from primary care) are included. From a risk management perspective, it is also important to recognise that negligence claims represent just the tip of the risk iceberg. Near-misses, undetected adverse events, cases in which patients do not take matters further, and resolution of complaints by local or national non-legal bodies represent a large pool of clinical incidents, most of which never reach the NHSLA. Further work would be needed to see if the risk profile suggested by claims matches that of these other sources of data.

One of the striking findings for most readers is likely to be the low total number of claims. There were only 324 claims over a fourteen year period, equivalent to 23 per year. Given that hundreds of thousands of cataract operations are performed in the NHS per year, only a tiny fraction will lead to a claim. This is probably due to the inherent low risk of the surgery and the fact that there are many alternative routes available to complainants (mentioned above) that prevent most events ever converting into claims.

We found that reduced vision after surgery and negligent surgery (including posterior capsule tears and dropped nuclei) together make up over one third of the claims and 43% of the damages. These claims result in damages being paid in 32% of closed cases. This is of interest as it is part of routine consent for cataract surgery to warn of the risk of the standard intra-operative complications and post-operative reduced vision. Nevertheless, this does not prevent claims arising, nor from being successful in many cases. This highlights the fact that, just because a complication is known to occur on a regular basis and is consented for, does not imply that there is no fault attributable in the individual case. It also highlights the need for surgeons to take every precaution available to reduce the chance of the predictable complications of cataract surgery. In addition, it is necessary to discuss pre-operatively with patients potentially

unavoidable complications which may occur without surgery being negligent (eg dropped nucleus in a posterior polar cataract with pre-existing posterior capsule defect).

Biometry or intra-ocular lens (IOL) power errors are also a major cause of claims and, more often than not, lead to payment of damages (paid:closed ratio of 62%). This is despite the fact that visual outcomes may be excellent<sup>3</sup>. This underlines the critical importance of accurate biometry and the need for robust systems for ensuring the biometry data in the notes match the patient, the power of the IOL inserted matches that documented in the notes, and that any pre-operative anomalies or concerns are flagged up and acted upon. This may be facilitated by using a tailored version of the recently introduced WHO Surgical Safety Checklist. As patients' expectations of the refractive outcomes of cataract surgery rise, this area of litigation may well increase.

The claims with the highest paid:closed ratio represent the ones that are hardest to defend. It would have been difficult to predict that inadequate anaesthetic would be the highest ranking on this measure. The psychological distress caused to a patient who suffered pain while awake during an operation clearly has a strong resonance in a sympathetic court of law. This is a pertinent finding as there is a trend towards lighter forms of ocular anaesthesia, such as topical only. However, perhaps we should welcome this trend since the second most likely cause to result in damages is globe perforation from anaesthetic injection, a well-described medicolegal scenario<sup>11</sup>.

Endophthalmitis has an incidence of between 0.05% and 0.25%<sup>12</sup>, yet it accounted for 4% of claims. Part of this may reflect the devastating nature of the condition and the affected patient's feeling of the need for compensation. There is also heightened public awareness about the risk of hospital-acquired infections. But it is a complication that is universally consented for and is rarely attributable to a specific fault at the level of the surgeon or the Trust. In several of the claims, it was explicitly stated that it was the *delay* in

diagnosis of endophthalmitis which was the prime cause of the claim. This might be reduced by better education of front-line staff, ophthalmic or non-ophthalmic, to whom these cases first present.

There is now a universal consent form for cataract surgery, based on the Royal College of Ophthalmologists guidelines, which is freely downloadable<sup>13</sup>. It includes most of the complications highlighted by this study. However as discussed above, consent, though essential, does not necessarily prevent a claim. The factors that motivate patients to sue centre more around behaviour than around clinical competence. There are *predisposing* factors to litigation (eg rudeness, delays, inattentiveness, miscommunication and apathy) as well as *precipitating* factors (eg adverse outcomes, iatrogenic injuries, failure to provide adequate care, mistakes and systems errors). In practice it appears that precipitating factors are unlikely in themselves to lead to litigation in the absence of predisposing factors<sup>14</sup>. It has also been demonstrated that 70% of litigation is related to poor communication after an adverse outcome, where patients feel that they have been deserted, devalued, poorly informed or have been misunderstood<sup>15</sup>. It therefore behoves us to make friends with our mistakes. After any adverse event, what most patients require is a sympathetic apology that it has happened (which has no legal standing as an admission of liability) and a clear explanation. People are reluctant to sue someone that they like<sup>16</sup>.

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# **Competing interests**

None declared

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