Case in point: what can we learn from litigation?

Biometry and IOL choice errors

In the next instalment of this series I focus on problems associated with biometry and intraocular lens (IOL) selection for cataract surgery. I have taken previous medicolegal cases I have dealt with and tried to extract some learning points and tips. These are not designed to be proscriptive recommendations but rather brief points for reflection. I hope this article will reinforce practices which should be endemic across the NHS but nevertheless seem to show up as clinical errors which can leave you facing litigation and potential adverse findings related to your clinical practice.

Back in 1950, Harold Ridley implanted the first IOL, following an earlier extracapsular cataract extraction. Postoperatively, the patient's refraction was -24.0/+6.0 x 30 degrees which is not ideal to say the least.

In modern practice we hope to do slightly better and our biometry practice and IOL choices are all designed to allow us to get as close to emmetropia as possible. Thankfully for our high street optometry colleagues we do not achieve this target in every case.

An error in biometry or IOL selection can leave a patient extremely unhappy. If a myope is left hypermetropic they suddenly find they have no clear vision at any distance. If it is the patient's second eye then it can be even worse, leaving the patient anisometropic and necessitating running the gauntlet of an IOL exchange.

If mistakes happen then you owe the patient a duty of candour to let them know about it and explain how it can be rectified. Furthermore, patients like to hear that changes have been made to avoid the same error happening again.

Litigation is about restoring the claimant to their original state. Clearly in cases of visual loss this is not always possible and financial remuneration is the proxy.

There is no motive and no malice in the harm we can potentially cause our patients and we owe it to them and ourselves to try and put as many barriers up as possible to prevent these errors.

If an incorrect lens choice is made and IOL exchange is required, ego has to be put aside. If you are not comfortable with the technical challenges of IOL exchange ask a colleague to assist you. Consider a soft shell technique to minimise the risk of corneal decompensation and give prophylactic postoperative nonsteroidal anti-inflammatory drugs (NSAIDs) to prevent cystoid macular oedema. Have an appropriate sulcus lens of the correct power (usually reduced by 0.5D) ready for use if needed. If you do rupture the posterior capsule during your IOL exchange check the retina carefully to ensure there are no iatrogenic retinal breaks. Try to get in and get in and exchange the IOL as early as possible before the capsule has sealed it in place. The vast majority of claims relate to patients who have had complications after IOL exchange and end up with poor vision. Ensure the patient ends up with good vision and they are unlikely to proceed to complaint or litigation.

How to avoid errors?

1. **Actively ask about laser refractive surgery**
   Patients do not always actively volunteer the fact that they have had previous laser treatment. This is particularly true if they had it many years ago. They often cannot recognise the need to make us aware of this and it is our duty to question them directly. Often, the corneal flap is not visible or easily missed. Clearly in patients who have had previous refractive surgery the ordinary formulae are not applicable and a formula such as the Haigis-L should be used or the IOL power calculated by other methods. Patients accept the risk of a refractive surprise due to their previous laser if they are made aware of it. They do not accept the fact that they had incorrect biometry done for their eye when the previous laser is not recognised and acted upon by their surgeon.
2. **Watch the biometry print out**
   We work at different places with different measurement devices and different print outs. Make sure you check the biometry to ensure that the appropriate formula is being used and the right and left eye print outs are where you think they are. Figure 1 shows a print out with the right and left eyes split vertically,

OD right

AL: 24.18 mm (SNR = 4.3)
K1: 41.67 D / 8.10 mm @ 92°
K2: 42.19 D / 8.00 mm @ 2°
R / SE: 8.05 mm / 41.93 dpt
Cyl.: -0.52 D @ 92°

Eye Status: phakic

OS left

AL: 24.21 mm (SNR = 183.0)
K1: 41.21 D / 8.19 mm @ 105°
K2: 41.98 D / 8.04 mm @ 15°
R / SE: 8.11 mm / 41.59 dpt
Cyl.: -0.77 D @ 105°

Refraction: -0.50 D +1.75 D x 175°

Eye Status: Pseudophakic Acrylate

AMO Tecnis ZCB00		Alcon SA60AT		AMO Tecnis ZCB00		Alcon SA60AT	
SF:	2.03	SF:	1.65	SF:	2.03	SF:	1.65
IOL (D)	REF (D)	IOL (D)	REF (D)	IOL (D)	REF (D)	IOL (D)	REF (D)
23.0	-1.06	22.0	-0.89	23.5	-1.20	22.5	-1.04
22.5	-0.71	21.5	-0.54	23.0	-0.85	22.0	-0.68
22.0	-0.37	21.0	-0.19	22.5	-0.50	21.5	-0.33
21.5	**-0.03**	**20.5**	**0.16**	**22.0**	**-0.16**	**21.0**	0.02
21.0	0.30	20.0	0.50	21.5	0.18	20.5	0.37
20.5	0.63	19.5	0.84	21.0	0.51	20.0	0.71
20.0	0.96	19.0	1.17	20.5	0.84	19.5	1.05
Emme. IOL: 21.45		Emme. IOL: 20.73		Emme. IOL: 21.77		Emme. IOL: 21.03	
Alcon AcrySof MA60AC		**Alcon SN6CWS**		**Alcon AcrySof MA60AC**		**Alcon SN6CWS**	
SF:	1.9	SF:	1.84	SF:	1.9	SF:	1.84
IOL (D)	REF (D)	IOL (D)	REF (D)	IOL (D)	REF (D)	IOL (D)	REF (D)
22.5	-0.90	22.5	-0.98	23.0	-1.03	23.0	-1.12
22.0	-0.55	22.0	-0.63	22.5	-0.68	22.5	-0.77
21.5	-0.20	21.5	-0.28	22.0	-0.34	22.0	-0.42
21.0	**0.14**	**21.0**	**0.06**	**21.5**	**0.01**	**21.5**	**-0.07**
20.5	0.47	20.5	0.40	21.0	0.35	21.0	0.27
20.0	0.80	20.0	0.73	20.5	0.68	20.5	0.61
19.5	1.13	19.5	1.06	20.0	1.01	20.0	0.94
Emme. IOL: 21.20		Emme. IOL: 21.09		Emme. IOL: 21.51		Emme. IOL: 21.39	

Figure 1: A print out with the right and left eyes split vertically.

Preoperative Data:
AL: **23.67 mm (!) (SD = 0.03 mm, SNR = 3.8)**
K1: **41.77 D / 8.08 mm @ 110°**
K2: **42.56 D / 7.93 mm @ 20°**
SE: **42.17 D**
Cyl.: **-0.79 D @ 110°**
R: **8.01 mm (SD = 0.00 mm)**

Target Ref.: **plano**
opt. ACD: **2.62 mm**
Visual Acuity:
Refraction:
Eye Status: **phakic**

OD right

Alcon AcrySof MA60AC		Alcon SN60WF		AMO Tecnis 1 ZCB00		Rayner C-Flex 570 C	
A Const:	119.2	A Const:	119	A Const:	119.3	A Const:	118.8
IOL (D)	REF (D)	IOL (D)	REF (D)	IOL (D)	REF (D)	IOL (D)	REF (D)
24.0	-1.10	23.5	-0.93	24.0	-1.00	23.5	-1.12
23.5	-0.74	23.0	-0.57	23.5	-0.65	23.0	-0.76
23.0	-0.39	22.5	-0.22	23.0	-0.30	22.5	-0.40
22.5	**-0.04**	**22.0**	**0.13**	**22.5**	**0.05**	**22.0**	**-0.05**
22.0	0.30	21.5	0.47	22.0	0.39	21.5	0.30
21.5	0.64	21.0	0.82	21.5	0.73	21.0	0.65
21.0	0.98	20.5	1.15	21.0	1.06	20.5	0.99

Preoperative Data:
AL: **23.89 mm (SD = 0.02 mm, SNR = 13.1)**
K1: **42.35 D / 7.97 mm @ 114°**
K2: **42.51 D / 7.94 mm @ 24°**
SE: **42.43 D**
Cyl.: **-0.16 D @ 114°**
R: **7.96 mm (SD = 0.01 mm)**

Target Ref.: **plano**
opt. ACD: **2.59 mm**
Visual Acuity:
Refraction:
Eye Status: **phakic**

OS left

Alcon AcrySof MA60AC		Alcon SN60WF		AMO Tecnis 1 ZCB00		Rayner C-Flex 570 C	
A Const:	119.2	A Const:	119	A Const:	119.3	A Const:	118.8
IOL (D)	REF (D)	IOL (D)	REF (D)	IOL (D)	REF (D)	IOL (D)	REF (D)
23.0	-1.06	22.5	-0.88	23.0	-0.96	22.5	-1.06
22.5	-0.70	22.0	-0.53	22.5	-0.61	22.0	-0.71
22.0	-0.36	21.5	-0.18	22.0	-0.27	21.5	-0.35
21.5	**-0.01**	**21.0**	**0.16**	**21.5**	**0.07**	**21.0**	**0.00**
21.0	0.33	20.5	0.50	21.0	0.41	20.5	0.34
20.5	0.66	20.0	0.84	20.5	0.74	20.0	0.69
20.0	0.99	19.5	1.17	20.0	1.07	19.5	1.02

Figure 2: A print out with the right eye above the left.

"The vast majority of claims relate to patients who have had complications after IOL exchange and end up with poor vision. Ensure the patient ends up with good vision and they are unlikely to proceed to complaint or litigation."

whereas Figure 2 shows a print out with the right above the left. This led to a clinical error in IOL selection.

3. **Check the name and check the side**
This seems obvious. Make sure you are picking the lens for the correct side and the biometry filed in the notes is for the correct patient. Often picking the incorrect side does not matter overly (although it is clearly bad practice) and we get away with it as the IOL power for each eye is often very similar and the patient would not know that they had the right eye IOL selection placed into their left eye. Indeed, this may not even be discovered until they return for their second eye. Watch out for amblyopic eyes, which may be a marker of anisometropia meaning that an error of lens selection will have a massive implication for refractive outcomes.
4. **Use the right formula**
Follow the RCOphth recommendations regarding the correct IOL formula to use. Train your staff who do the biometry to recognise when the formula needs to be changed if the IOL master does not do it automatically.
5. **Look for red flags**
Watch out for something out of the ordinary. A difference of more than 0.3mm between the axial length of the two eyes? A chosen lens power of 23.0D in an eye with an axial length of 25mm? Very flat k readings?
6. **Discuss the refractive outcome and the need for second eye**
A lot of angst occurs because patients are not involved in the choice regarding their refractive outcomes. Hypermetropes as usually universally happy at being left emmetropic. Myopes may not be. Particularly low myopes may wish to remain so, as they enjoy reading without spectacles. If the patient is involved in the decision making process, whether they end up happy or not, you have discharged your duty to them. Warn patients with significant ametropia that they will need the second eye doing to balance things up. Furthermore do not leave someone very myopic or hypermetropic to balance their phakic eye without explaining that later when the other cataract gets removed they will have to remain myopic / hypermetropic.
7. **Contact lenses out for biometry**
Patients need to have their contact lenses out before their biometry. These patients are keen to have good spectacle free vision and so will be more attuned to their refractive outcome and recognise when they are not as close to emmetropia as they should be.
8. **Do not have IOL calculations for lenses you do not use on your biometry print out**
There is no reason for having an IOL on the print out which you do not use and is not even available in your theatres. This simply increases the risk of error. This is particularly important for anterior chamber (AC) IOLs. If an AC IOL power is inadvertently picked (which can occur easily on a busy high volume list) then the patient will be left significantly hypermetropic and very unhappy. If you have AC IOLs routinely available in your lens bank then calculating the appropriate lens power from the in-the-bag power is relatively easy even in the stressful situation of complicated surgery. If needed, an aide memoire can be placed on the wall of the operating theatre allowing the lens to be calculated when needed. Having the AC IOL power on the biometry is courting a lens power error.
9. **Make sure they know about presbyopia and residual astigmatism**
Patients are getting more demanding and routinely expect to be spectacle free following cataract surgery. They should be informed that there is some margin of error and that some degree of astigmatism will remain. By assessing our own surgical induced astigmatism, which we should all be measuring, we can endeavour to reduce this but, if there is more than 1.0D, some will persist. Furthermore, younger patients need to be told of the significant presbyopia that will ensue after cataract surgery with a monofocal IOL.
10. **Avoid having all the IOLs out already**
Although this may seem to be an efficient system it can lead to error if the list order is changed or someone puts the IOLs in the wrong order. It encourages the theatre staff to go into autopilot with the inherent risk therein.
11. **Write and circle your lens choice**
Handwriting can be an issue. If you can, circle your IOL choice on your biometry print out and also write it in the clinical notes. This creates another level of check that can be done to ensure the IOL you chose is actually the one given to you.
12. **Use the WHO Surgical Checklist**
Repetition leads to complacency and this is often relegated to a tick box exercise but it remains a vital part of the patient pathway.

No matter how good the system, people will still make mistakes. Some reasons include:

- people in a hurry
- lack of training or accessible guidelines
- inexperienced staff
- depending on others / delegating tasks
- machine error (rare)
- human error (sadly frequent).

We cannot and will not eliminate errors but we owe a duty of care to make sure that we learn and put in place processes which minimise the risk. We need to recognise errors, involve the patient in the process and rectify matters as soon as possible.

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