

Informed Consent in Refractive Eye Surgery: Learning from Patients and the Courts

Abstract:

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Abstract

Refractive eye laser surgery involves ablation of the cornea using excimer laser to correct short or long sightedness and thus negate the need for glasses and/or contact lenses. With the doctrine of informed consent often central to claims of medical negligence in this area, we examine the attitudes, understanding and recall of patients to consent for refractive surgery and outline the relevant law. 102 patients undergoing first time refractive surgery were analysed to examine their understanding and recall of the consenting process. Only 2 patients remembered all 5 risks outlined preoperatively, while 11 remembered no risks at all. 65% of patients consulted the internet to learn more about the operation. Our study demonstrates that patient understanding and recall remains poor. A signed consent form is not, of itself a full defence to allegations of uninformed consent, and the consent process must be comprehensive.

Introduction

Refractive eye laser surgery involves altering the shape of the cornea to correct long or short sightedness. There are 2 main types of surgery; LASIK (laser-assisted in situ keratomileusis) which involves cutting a flap with a keratome or a femtosecond laser approximately 120 microns into the cornea, opening the flap, applying excimer laser to the stroma of the cornea and then closing the flap, and LASEK (laser assisted sub-epithelial keratectomy) comprising of debriding the corneal epithelium, applying excimer laser and allowing the epithelium to heal. These procedures are the most commonly performed surgeries in the world with approximately 1.4 million LASIK operations performed in 2006 in the United States (US) alone. Although usually successful, and with potentially remarkable visual outcomes, this surgery is not without complications.

It is incumbent upon the surgeon to advise and to seek to educate patients preoperatively about their treatment options, potential complications and to seek to identify, and where possible moderate, any unrealistic expectations. The National Institute for Health and Clinical Excellence (NICE) in the UK demands that surgeons ensure that patients fully understand the benefits and potential risks of the procedure, and provide them with clear written information, such as that published by NICE. The objective of our study was to assess patient understanding, recall, and satisfaction with the informed consent process in our refractive laser practice.

Methods

One hundred and two patients undergoing first time LASIK or laser sub epithelial keratomileusis (LASEK) surgery were randomly asked to complete an anonymous page questionnaire pertaining to their preoperative education and consenting process. This form was designed to examine patient understanding and recall of the operation and risks, and was divided into 3 parts assessing: patient satisfaction regarding their preoperative assessment; what was understood about the surgical procedure itself; and finally, their appreciation of post operative issues and potential complications/side effects. This form was filled in prior to surgery on the day of the procedure itself. All relevant patients had been preoperatively reviewed and assessed at least 1 week prior to surgery and at that stage were given an option of either treatment.

At the preoperative assessment, the factual details, benefits and risks of both procedures were explained in detail by 1 surgeon to all patients using diagrams and ocular models. This surgeon performed all 102 surgeries. Specifically patients were told that LASIK involved cutting a flap into the cornea, was more invasive than LASEK, possessed more risks intraoperatively, was associated with a greater risk dry eyes postoperatively, but would result in a quicker visual improvement and was less painful postoperatively. They were also informed that LASEK held less risks than LASIK intraoperatively, was a superficial surface treatment involving scraping of the epithelium (skin) and application of laser to the cornea. They were told their eyes would be sore for a few days, visual improvement would take days to weeks. All patients were specifically told of 5 possible complications (and rates of occurrence) that might occur postoperatively including corneal inflammation, infection, dry eyes, night vision problems (specifically including glare, haloes and starburst effect) and visual loss. All patients were additionally told that spectacles may be required postoperatively.

After this assessment patients were given a specific consent form to bring home and to return with it read. It was to be signed on the day of surgery. The education sessions and the consent forms are particular for either LASIK or LASEK. They require to be initialled at various points of significance throughout the form, and to be signed by both the doctor and patient. These forms outline the nature of the procedure, risks/complications and emphasise the lack of guaranteed outcomes. It was stressed that patients had to read and consider the form extremely carefully and to then decide if they wanted to return for surgery.

Figure 1: Number of risks recalled. Histogram indicating that the average number of risks recalled was 2, with 11 patients unable to recall any risk, and only 2 recalling all 5 potential complications outlined.

Results

Of the 102 patients, 39 were male, 63 were female and the average age was 35.33 years. 64 and 34 patients knew they were undergoing LASEK and LASIK, respectively. Four patients were unsure for which procedure they were being consented. All patients reported that the procedure proposed was clearly outlined at the time of assessment and that they were encouraged to ask questions. No patient felt pressurised by the doctor to proceed with surgery. 96 % of respondents felt that bringing home the consent form was a good idea and that they remembered more as a result. Patients advised that the average time they spent reading the form was 7 minutes. The internet was additionally consulted by 65% of patients to learn more about the procedure. Only 23% of this group believed they learned anything extra from doing so. Overall 37% were very satisfied with the consenting procedure, 63% were satisfied and no patient was less than satisfied.

Figure 2: Individual Risks Recalled. Histogram demonstrating that reduced vision was the most commonly remembered risk (85%) while corneal inflammation was the least remembered risk (8%).

With regard to the surgery itself, only 2 patients recalled for what the abbreviations LASIK and LASEK stood. 41% recalled incorrectly that EK possessed more risks intraoperatively, 14% of patients recalled incorrectly that EK involved cutting a flap into the cornea whilst 30% incorrectly interpreted that IK involved removal of corneal epithelium. 28 % of patients considered the surgery a not serious, 18% thought that the actual surgery itself would be painful (with 4 patients unsure). With regard to the postoperative period, the average number of risks recalled was 2 (Figures 1 & 2). 11 patients (11%) remembered none, while only two (2 %) remembered all 5 risks outlined. 18% of patients incorrectly thought that the vision would be perfect 1 day post LASEK. 12% incorrectly thought that LASIK would be more painful post operatively.

Discussion

Refractive surgery accounts for 34% of all ophthalmology claims on the files of the Medical Defence Union indemnity society in the UK. There was a 166% increase in negligence claims relating to laser surgery over a 6 year period up to 2003. In the US, a jury made an award for as much as up to \$7.25 million for LASIK associated medical negligence. analysis appears to demonstrate that, despite a lengthy and detailed consent process, patient understanding and recall of the procedures and risks remained poor. This is similar to the findings of Cheung et al who noted that, despite repetitive explicit counselling, only 39% of patient undergoing cataract surgery knew what a cataract was, 28% knew what surgery entailed and 43% misunderstood that surgery was completely risk free. Informed consent is a process rather than simply signing a form, and should include a detailed outline by the doctor to the patient, setting out treatment options, risks involved and expected outcomes. Hickson et al suggested that the physician's ability to establish rapport with, provide access to and communicate effectively with the patients is as important as technical competence in protecting against litigation. Abbott reported that many claims and lawsuits centred on poor physician relationship and lack of communication with the patient.

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As to what precisely needs to be disclosed in this preoperative consultation is jurisdiction dependent. In the Supreme Court case of *Fitzpatrick v Whyte*, the Irish judiciary favoured a test as to the patient's knowledge, understanding and expectations, and Irish case law precedent appears to now impose a higher standard in consenting for elective procedures which would include laser eye surgery.^{8,9} In Ireland, the courts distinguish between elective and emergency procedures, in that for elective procedures there is an obligation wherever there is a risk- however exceptional or remote- of grave consequence involving severe pain stretching for an appreciable time into the future and involving the possibility of further operative procedures, to warn of that risk in the clearest possible language. In cases not involving a risk of ongoing severe pain, such as laser eye surgery, the obligation to warn is lessened to a significant risk which would affect the judgement of a reasonable patient. As to whether a risk was significant, both the statistical frequency of the risk and the severity of its consequences must first be ascertained. In conclusion, our study indicates that patients understanding and recall of the consent process is poor. Those it is imperative for the surgeon to outline laboriously and in detail the procedure and all potential risks.

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References

1. Market Scope LLC Comprehensive Report of the Refractive Market, 2005.
2. www.nice.org.uk
3. www.mdu.co.uk
4. Slade GD, Krafczek A, Smith S Anatomy of a Lawsuit II: Closing Thoughts Feb 2007. Supplement to *Cataract and Ref Surg Today*
5. Cheung D and Sandramouli S. The consent and counselling of patients for cataract surgery: a prospective audit. *Eye* 2005 19: 963-971
6. Hickson GB and Jenkins AD. Identifying and addressing communication failures as a means of reducing unnecessary malpractice claims *NCMedJ* 2007 68:362-4
7. Abbott RL. Informed Consent in Refractive surgery. *Cur Opin Ophth* 9: 29-34
8. *Geoghan v Harris* [2000] 3IR536
9. *Fitzpatrick V Whyte* (2005) IEHC 479, and (2007) IEHC 479.
10. *Walsh v. Irish Family Planning Ltd* [1992] 1 IR 496 510 Flaherty J