

Informed consent and failure to disclose – legal perspectives for aesthetic surgeons

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As litigation and legal claims in aesthetic surgery and medicine continue to rise, informed consent is not only a legal imperative but also essential in protecting yourself and your business. **Lee Seng Khoo** and **Francesco Mazzarone**, from the world-renowned Ivo Pitanguy Institute in Brazil, provide a comprehensive guide to how to obtain a truly informed consent.

Informed consent is a fundamental legal obligation for all medical procedures including surgical interventions. Essentially, consenting a patient means entering a contractual obligation with a duty of care to the patient [1]. However, there are far more intricacies involved in obtaining informed consent in aesthetic surgery. Aesthetic surgery is an elective procedure that is performed to meet social and psychological desires. It is not carried out to alleviate pain or prevent death. Furthermore, most aesthetic surgeries are carried out in the private sector with monetary reimbursement being given directly to the surgeon. Many aesthetic surgeons aggressively market their services and some even employ sales ‘consultants’ to rope in patients, giving monetary incentives to sales staff who ‘seal the deal’ [2]. With the advent of the digital era and widespread information (or misinformation) available on the internet, patients often arrive at the consultation office with preconceived ideas, expectations and information that may not resonate with the surgeon [2].

This subject matter of obtaining consent is a controversial one. Some downplay the risks involved [3] while aggrandising the improvements the procedure may bring for the patient. There are also surgeons who cite the competitive marketplace as a reason to withhold information such as rare complications, which may result from even a well-executed procedure or surgery, in order not to scare the patient away. While this was once more often the exception than the rule, the reverse possibly holds true today. This is reflected in the ever rising litigation and legal claims in aesthetic surgery

worldwide [4]. The surgeon may be held negligent for not disclosing the consequences of treatment and / or the alternatives available to them in obtaining their consent.

Many surgeons erroneously believe that giving as little information of potential complications and long-term results will lead to a less anxious patient [1]. It can be extremely difficult to balance the legal requirements, patients’ expectations and common sense required to not lose a patient during a consult. In this era, medical paternalism of ‘doctor knows best’ may truly be a misnomer [5].

As aesthetic surgeons, we have often seen patients who are happy with mediocre results and also patients who are unhappy with what we (and our colleagues) would perceive as an excellent result. The patient-doctor relationship begins even before the actual consultation and it is this consult that is often the deal breaker to a happy relationship and eventual outcome. It is better to under-promise and over-deliver than to over-promise and under-deliver. If the patient’s expectations are unrealistic or they do not accept or acknowledge any potential complications, it is indeed better to say no. It is the duty of the surgeon to elicit those desires of the patient and clarify if he / she can fulfill them. It is also the

duty of the surgeon to warn the patient of all material risks and complications associated with the procedure. This approach may not win patients overnight but rest assured, there will be more happy and satisfied patients in one’s clinical practice.

The Bolam test

What happens in reality may have more far reaching implications when clinicians choose to withhold information that will otherwise cause the patient to rethink their decision. Many of us are familiar with the Bolam test developed through a series of English cases culminating in Bolam vs. Friern Hospital Management Committee in 1957 [6]. The Bolam test is testament to medical paternalism presiding over a patients’ autonomy.

The claimant John Hector Bolam was undergoing electro convulsive therapy (ECT) as treatment for his mental depression. The doctor did not give any muscle relaxant drugs and the claimant suffered serious hip fractures. There was divided opinion amongst professionals as to whether relaxant drugs should be given. If they are given there is a very small risk of death; if they are not given there is a small risk of fractures (the risk of fracture was 1 in 10,000). Bolam testified that he was not given any warning as to risks, nor asked whether he would decline treatment due to the risk involved (which was compounded by the fact that no muscle relaxants were used during treatment). The House of Lords formulated the Bolam test as such: “a medical professional is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art . . .”.

“The patient-doctor relationship begins even before the actual consultation”

Putting it simpler terms, the doctor is not negligent, if he / she is acting in accordance with such a practice, merely because there is a body of opinion who would take a contrary view. In this case, the doctor was found to be innocent of any wrongdoing based on the Bolam test.

What many may not be familiar with is the fact that the Bolam test has come under increased opposition, especially from the USA [7,8], Canada [9], Australia [10] and now even in the UK [11]. In some American states a patient's consent is vitiated if full information of a procedure is not given [7,8] but it remains difficult to ascertain just how such comprehensive information could and should be imparted.

Two 1972 cases in the USA, *Canterbury vs. Spence* [7] and *Cobbs vs. Grant* [8], shifted the paradigm of the inquiry from doctor to patient by creating a 'lay' or 'patient' standard. According to this standard, allegations of failure to disclose are to be judged according to jury assessments of what a reasonable patient in the plaintiff's position would expect to be informed of prior to making a decision about treatment. Judge Robinson said, "It is the prerogative of the patient, not the physician, to determine for himself the direction in which his interests seem to lie [7]."

The *Canterbury* and *Cobbs* decisions have exerted their influence beyond the United States. Appellate courts in Australia [12], Malaysia [13], New Zealand [14], Ireland [15], Germany [16] and Canada [17] have now embraced the patient standard. Singapore [18] remains one of the last legal bastions that subscribes to the Bolam test, rejecting the patient standard in lieu of a professional one. Brazil (where the authors practice) adheres to a patient standard with regards to risk disclosure in informed consent [19].

In the landmark case of *Rogers vs. Whitaker* (1992), the question to be decided by the Australian High Court was whether an ophthalmic surgeon should have warned his patient of the one in 14,000 probability of a complication, sympathetic ophthalmia and subsequent risk of blindness, arising from a proposed surgery [10]. The defendant, Dr Christopher Rogers, was sued for a negligent failure to warn of the risks. Many medical experts were called to testify in court on whether the surgeon ought to have warned the patient of the risk involved, and opinions were divided. If the Australian

High Court had utilised the Bolam test, the surgeon would not have been found guilty for the failure to disclose. The High Court disapproved the principle stated in Bolam and affirmed that a finding of medical negligence may be made even though the conduct of the doctor was in accordance with practice accepted at the time as proper by a responsible body of medical opinion.

In *Montgomery vs. Lanarkshire Health Board* in 2015, a gynaecologist was successfully sued and found guilty of negligence for failing to disclose to the plaintiff the small risk (0.1%) of shoulder dystocia with subsequent hypoxia and brain damage in perusing normal vaginal delivery in diabetic mothers [11]. The gynaecologist stated that she did not disclose this risk to the patient as her clinical experience showed that the risk was a very small one and that, by disclosing such information, all mothers would opt for caesarean section. It was her opinion that "it is not in the maternal interests of women to have caesarean sections."

These landmark cases should force all aesthetic surgeons to be even more hypervigilant in disclosing risks, complications and possible long-term financial implications. For example, how many doctors inform their prospective clientele that the risk of injecting soft tissue fillers in the facial region may result in irreversible blindness via central retinal artery occlusion [20]? A recent survey conducted by The Consulting Room UK states that few practitioners (less than 75%) inform their prospective patients of this rare but real risk [21].

Risks and complications

In the authors' own practice, it is standard operating protocol to first determine what the patients' expectations are and weigh that in with what can be done to improve the condition. It is vital that the surgeon focuses on the aesthetic desire of the patient and not what the surgeon wants or thinks is best. Nonetheless, if what the patient requests could lead to potential adverse trade offs (for example, very large breast implants may give rise to chest wall deformities, back pain and glandular tissue atrophy) then the patient needs to know of the repercussions of their request. In particular, what further surgery will be required in the near future and what will that surgery cost? The US Food and Drug Administration (FDA) recommends that all women who receive breast

implants receive MRI screening for rupture detection three years after the procedure and every two years thereafter [22]. Breast implants may also obscure breast tumour detection during routine mammograms [22]. Such information must always be disclosed to patients as they have both financial and health implications in the long run.

In 1998, the English Court of Appeal (*O'Keefe vs. Harvey-Kemble*) held a surgeon liable for negligence for failure to disclose the risk of capsular contracture prior to performing breast augmentation surgery [23]. The court was of the opinion that it was more than likely that the patient would have chosen not to undergo the breast augmentation had she been made fully aware of the risks.

In the authors' practice options, including non-invasive treatment, surgical treatment and no treatment, are discussed in depth with the patient. Photographs of the surgeons' previous work, showing pre and post results (both satisfactory and unsatisfactory), are shown to the prospective patients. Photographs of postoperative complications such as keloids, poor scarring, wound dehiscence, necrosis, infection, haematoma, lid ectropion, asymmetry, capsular contractures, etc. are shown to the patient with regards to the specific procedure requested. Without a doubt, such an approach may literally 'scare' a patient who wants the surgery but is unprepared to accept any unforeseen complications that may occur, even in the best of hands. Surgical cases are only booked if the patient willingly gives an informed consent, having understood all the details of the procedure and accepting the risk of incurring any of the complications. The fact that there is a signed consent form alone does not mean that the patient has fully understood or accepted the treatment proposed [24]. For a consent to be deemed valid, the patient's decision must be voluntary, and the person consenting must understand the information relayed by the doctor and have the capacity to make the decision [4].

If there is compelling evidence to suggest that the procedure was carried out below a reasonably competent standard, then legal action may still be brought by the patient, whether or not informed consent can be proven. In the authors' experience, patients very rarely file a legal complaint regarding complications, provided the treating doctor has explicitly explained



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possible complications prior to surgery. The surgeon should also discuss the following in the adverse event of complications occurring: How will the condition be dealt with and, in the case of an unsatisfactory result requiring re-operative surgery, will the surgeon be performing revision surgery with a fee waiver? And if so, does that waiver include clinic and anaesthetic fees? A formal written agreement should be drafted to avoid any misunderstanding in the postoperative period. Withholding or downplaying these vital pieces of information is a surefire recipe for inviting lawsuits in aesthetic surgery.

Importance of a ‘cooling’ off period

While sales people in other sectors like to force a person to make a purchase then and there leaving no room for ‘buyer’s remorse’, the same cannot be applied to the practice of aesthetic surgery. The *Good Medical Practice in Cosmetic Surgery* issued by the Independent Healthcare Advisory Services UK states, “You should not normally admit any patient for a procedure to be carried out sooner than two weeks after the initial consultation

in order to allow the patient adequate time for reflection [25].” The English National Minimum Standards further states that no patient should be admitted for the procedure on the same day as the initial consultation [26]. This is to allow a fair amount of time for the patient to digest the information provided and make an educated decision rather than being forced to make a decision on the spot. A UK-based cosmetic surgeon was found guilty in 2012 for coercing a patient to sign up for liposuction by offering a discounted price if she agreed to do the surgery as soon as possible with her two other friends who were present during consultation [27]. Another cosmetic surgeon was struck off by the General Medical Council (GMC) in 2014 for “subordinating his proper responsibilities as a doctor to the pursuit of a commercial enterprise [28].” Among the allegations were the claims that the doctor took a deposit on the first consultation and committed vulnerable patients to surgery without a ‘cooling off’ period. A recent study of 50 cosmetic surgery providers in the UK in 2014 revealed that the majority offered free consultations (54%) and

promotional deals (52%), of which 27% were time-limited clearly violating the national regulations [2].

Preoperative photography is mandatory and any existing asymmetries or pre-existing defects pointed out to the patient (again preoperatively). This is because the patient may only notice a particular asymmetry or defect postoperatively and attribute this to the surgery. If any complications develop, it is important to keep a record of all encounters noting the progress and to take photographs to document the evolution of treatment. In court, this is the only admissible defense on the behalf of the surgeon and it is imperative that this matter be taken very seriously. The surgeon should not ‘abandon’ the patient and instead should see the patient more frequently, demonstrating concern and allaying fears. The majority of complications are, thankfully, short-lived and easily rectified. The key to patient satisfaction is having a surgeon who demonstrates empathy and takes extreme ownership of the complications.

The surgeon should have clear, easily understandable postoperative instructions formally printed on the practice’s letterhead. Such professionalism impresses the patient and also serves as formal evidence that information has been relayed to the patient for postoperative care. Seeing the patient on the following morning after surgery is mandatory and the surgeon should perform the dressing change. A follow-up check in 7 to 14 days further solidifies the patient-doctor experience and can be timed for suture removal and formal photography. Depending on the type of surgery, it is wise to see the patient again at three to four months and again at 12 months to document the surgical result and maintain patient contact. A happy, satisfied patient can be a source of referral and growth to the practice.

In conclusion, failure to disclose risks of a procedure makes an informed consent invalid and quite often indefensible in the court of law. It is therefore imperative that all aesthetic surgeons pre-empt this by disclosing all material risk (no matter how rare) to the patients. All aesthetic surgeons should also remember that, even though there is pressure to increase revenue and turnover to maintain a practice, it is important to allow an adequate ‘cooling off’ period to allow the patient to change their mind and avoid ‘buyer’s

remorse'. It is always better to bring the expectations of the patient down while aiming to over-deliver the intended results. The Bolam test is gradually being phased out, marking an end of medical paternalism in favour of greater patient autonomy. Aesthetic surgeons must take note of the changing legal trends in medical law that will affect their practice.

References

- Meisel A, Kuczewski M. Legal and ethical myths about informed consent. *Archives of Intern Med* 1996;**156**(22):2521-6.
- Rufai SR, Davis CR. Aesthetic surgery and Google – ubiquitous, unregulated and enticing websites for patients considering cosmetic surgery. *J Plast, Reconstr and Aesthet Surg* 2014;**67**(5):640-3.
- <http://newyorkcity.legalexaminer.com/medical-practice/plastic-surgery-organizations-tell-doctors-to-downplay-risks-of-breast-implant-related-cancer/>
- Mavroforou A, Giannoukas A, Michalodimitrakis E. Medical litigation in cosmetic surgery. *Med Law* 2004;**23**(3):479-88.
- Gilbert M. Agreements, coercion, and obligation. *Ethics* 1993;**103**(4):679-706.
- Bolam v Friern Barnet Hospital Management Committee [1957] 1 WLR 582; [1957] 2 All ER 118 (QBD).
- Canterbury v. Spence, 464 F.2d 772, 1972.
- Cobbs v. Grant, 8 Cal. 3d 229, 1972.
- Bauer v. Seager et al. 2000 MBQB 113. 23.
- Rogers v. Whitaker (1992) 175 CLR 479.
- Montgomery v. Lanarkshire Health Board [2015] UKSC 11, [2015] All ER (D) 113 (Mar).
- Naxakis v. Western Gen. Hosp. (1999) 73A.L.J.R. 782.
- Hong Chuan Lay v. Dr. Eddie Soo Fook Mun (1998) 5 C.L.J. 251; Kamalam v. Eastern Plantation Agency (1996) 4 M.L.J. 674.
- B v. Medical Council (High Court, Auckland HC11/1996, 8 July 1996).
- Geoghegan v. Harris, [2000] I.R. 536.
- Fenher H. Informed consent in aesthetic plastic surgery. *Handchir Mikrochir Plast Chir* 2006;**38**(1):64-7.
- Reihl v. Hughes, [1980] 2 S.C.R. 880.
- Shanmugam K. Testing the Bolam Test: consequences of recent developments. *Singapore Med J* 2002;**43**(1):7-11.
- Gerson Luiz Carlos Branco. Responsabilidade Civil por Erro Medico: Aspectos [Liability for Medical Error: Aspects]. *Revista Sintese De Direito Civil E Processual Civil* 2000;128-151.
- Lazzeri D, Agostini T, Figus M, et al. Blindness following cosmetic injections of the face. *Plast Reconstr Surg* 2012;**129**(4):995-1012.
- <http://www.bodylanguage.net/all-eyes-on-fillers/>
- Kaunitz A. Breast Implants, MRI, and the FDA: How to Advise Our Patients? *Medscape* 2011.
- O'Keefe v. Harvey-Kemble Court of Appeal (Civil Division) 24 April 1998 (1998) EWCA Civ 701.
- Epstein M. Why effective consent presupposes autonomous authorisation: a counterorthodox argument. *Journal of Medical Ethics* 2006;**32**:342-4.
- Association of Independent Healthcare Organisations. *Good Medical Practice in Cosmetic Surgery*. 2006 (revised 2014).
- Department of Health. Review of the Regulation of Cosmetic Interventions. 2013.
- General Medical Council (GMC UK). Fitness to Practice Hearing & Decision - 17 May 2012 to 1 June 2012. Reference number 312843.
- Dyer C. Cosmetic surgeon is struck off for putting commercial interests ahead of his patients. *BMJ* 2014;**349**(7972):4.



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