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Developing an International Framework for Informed Consent in Plastic Surgery: A Focus on Cosmetic Breast Augmentation

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Background: Informed consent is a fundamental pillar of patient rights and is an essential part of good clinical practice. In 2019, the International Confederation of Plastic Surgery Societies launched a survey to collect feedback on informed consent practices, with an aim to develop an international guideline for cosmetic surgery

Methods: A 15-question survey was sent to delegates of the International Confederation of Plastic Surgery Societies for dissemination to their national society members. The survey comprised a range of quantitative and qualitative questions. Descriptive and thematic analysis was performed.

Results: There were 364 respondents. Over half of the respondents reported no local informed consent policy, whereas others noted national society, specialist college, or government policies. The majority of respondents believed that the performing surgeon should be responsible for obtaining informed consent with at least two face-to-face consultations. Most respondents agreed with a cooling-off period (duration based on procedure type and use of high-risk devices). Regarding cosmetic breast augmentation, the majority of respondents felt that the performing surgeon should be responsible for postoperative management, including cases that occur as part of surgical tourism. Some respondents incorporate financial consent as part of their informed consent practice. Most supported the development of an international informed consent guideline.

Conclusions: Informed consent should result from face-to-face consultations with the performing surgeon. There should be a minimum cooling-off period. Postoperative surveillance should be available in all settings. The findings of this survey will help inform an international standardized informed consent guideline for cosmetic surgery. *(Plast Reconstr Surg Glob Open 2023; 11:e5371; doi: 10.1097/GOX.0000000000005371; Published online 9 November 2023.)*

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INTRODUCTION

The field of plastic surgery and, in particular, cosmetic surgery continues to expand globally. Once a specialty confined to higher income countries, it has now become more readily accessible, more affordable, and socially acceptable.[1–4] Because increasing numbers of patients undergo plastic surgery in their home country and surgical tourism destinations,[5–12] the issue of informed consent requires closer scrutiny. This is particularly so for cosmetic tourism facilities with business models that favor rapid turnover of cases and minimal timing between patients' initial face-to-face consultation with their surgeon and their procedure. Although some countries may have specific guidelines, standards, or statements of principle,[13,14]

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there is no international consensus or framework for obtaining informed consent, especially in the setting of elective cosmetic surgery.

The informed consent process is an essential part of good clinical practice and a fundamental pillar of patients' rights.[15] Within the field of plastic surgery and, in particular, surgical tourism, the informed consent process can vary substantially in terms of the number of and interval between consultations, who performs the consultations, the modality (face-to-face versus internet), and the type of information provided.[8,16–18]

In 2016, the Medical Board of Australia published guidelines for cosmetic medical and surgical procedures. These guidelines stipulate that informed consent be obtained by the medical practitioner performing the procedure and recommend a two-staged consent process comprising a preoperative consultation at least 7 days before the surgery (analogous to a cooling-off period) and again on the day of the procedure.[11] This is similar to the "period of reflection" outlined in the Medical Council of New Zealand 2011 statement on cosmetic procedures.[19]

The Australian guidelines and Medical Council of New Zealand statement closely reflect the Royal College of Surgeons (RCS) Professional Standards for Cosmetic Surgery.[13] The RCS standards were produced in 2016 in response to a United Kingdom (UK) Department of Health review regarding the regulation of cosmetic interventions.[20] These standards recommend a minimum cooling-off period of 2 weeks between the two stages of consent.[13]

In relation to staging consent, the Royal Australasian College of Surgeons revised a position article in 2017, emphasizing that informed consent is a process rather than a single event and may require more than one consultation. It also highlighted that written information can aid the process but does not constitute informed consent. Ideally, written information should supplement a patient-tailored discussion with the surgeon performing the procedure.[21]

In contrast to countries where formal guidelines or standards specifically address the issue of informed consent, some surgical tourism destinations have no such guidance.[8,15–17] This problem, however, is not isolated to surgical tourism. A 2014 UK study found that while 90% of local cosmetic surgeons were involved in the initial consultation, none were reported to engage in a two-staged signed consent process. Further, only 38% stipulated a two-week cooling-off period.[22] This highlights the global inconsistencies in obtaining informed consent and supports the need for an international framework. Many studies have shown that although documentation of the process may be completed, the patient's knowledge of risk and benefit of a proposed medical treatment and the ability of the patient to withdraw consent for the intervention at any time were not well understood.[23] Ingelfinger wrote in 1972 that "the trouble with informed consent is that it is not educated consent."[24] In cosmetic surgery and medicine, the stakes are raised higher, as the proposed treatments are both elective and discretionary.

In 2016, the International Confederation of Plastic Surgery Societies (ICOPLAST) identified key priorities upon which to base their strategic framework.[25] Patient safety was ranked highly, with standardization of care, protecting patients from unscrupulous and under-qualified practitioners, and alerting governments to the risks and cost burden of surgical tourism considered as important initiatives.[25] Given that informed consent is at the core of these initiatives, ICOPLAST designed a survey to collect member feedback on their informed consent practices and the development of an international guideline for cosmetic surgery procedures.

Takeaways

Question: Informed consent processes vary substantially internationally, so a consensus on best practice is needed for patients, especially those undergoing surgical tourism breast augmentation.

Findings: Best practice informed consent for breast augmentation should involve a "cooling-off" period of reflection of at least 10, preferably 14, days between the operating surgeon consultations.

Meaning: Two face-to-face preoperative consultations 10–14 days apart for breast augmentation is optimal surgical safe practice.

METHODS

A 15-question anonymous survey was designed using the secure online Qualtrics platform. The survey contained a mix of qualitative and quantitative questions. (**See appendix, Supplemental Digital Content 1,** which displays the 15-question anonymous survey. **http://links.lww.com/PRSGO/C842**.) The survey was generated in five languages (English, Arabic, Japanese, Korean, and Spanish). These language choices reflected the main regions represented by ICOPLAST delegates.

Inclusion criteria comprised surgeons who were members of their national plastic surgery society and linked to ICOPLAST via their national delegates. Exclusion criteria included those not engaged in clinical practice or associated with their local plastic surgery society. ICOPLAST hierarchy approved the distribution of the survey, and individual respondents provided informed consent.

The survey was launched in February 2019. An email was sent to ICOPLAST delegates for further dissemination to their respective national plastic surgery society members. The email contained an online link to the survey. Two reminder emails were sent before the survey closed in August 2019.

Descriptive statistics were used to analyze the quantitative data. The qualitative data were used for thematic analysis. The Monash University Human Research Ethics Committee granted approval in July 2018 (project ID: 15115). The study adhered to the National Statement on Ethical Conduct in Human Research.[26]

RESULTS

There were 364 participants who completed the survey. The number of responses varied for each question, with some respondents not answering all questions and

Table 1. Number of Responses per Survey Question

Question	No. Responses, n = 364 (%)	Question	No. Responses, n = 364 (%)
1	358 (98.4)	9	348 (95.6)
2	280 (76.9)	10	354 (97.3)
3	354 (97.3)	11	327 (89.8)
4	359 (98.6)	12	336 (92.3)
5	359 (98.6)	13	355 (97.5)
6	356 (97.8)	14	418*
7	459*	15	347 (95.3)
8	293 (80.5)		

*More than one response option available.

others appropriately selecting more than one option when required (Table 1). As such, the proportion of respondents reported throughout this article relates to individual questions.

There were 183 respondents (51.1%) who reported no local informed consent policy. For those who reported the existence of a local policy, 104 (37.1%) identified a national society policy; 92 (32.9%), a specialist college policy; and 84 (30.0%), a government policy (Fig. 1). Respondents identified a range of organizations that had an informed consent guideline, policy, or template (Table 2).

There were 328 respondents (91.4%) who believed that the performing surgeon should be responsible for obtaining informed consent from the patient. Thirteen (3.6%) respondents thought that this role should be delegated to an administrator; 10 (2.8%), to a nurse; and six (1.7%), to someone else (role not specified). Informed consent was not routinely obtained by two (0.6%) respondents.

There were 227 respondents (63.2%) who confirmed that their informed consent process involved personally performing two face-to-face consultations and physical examination before the cosmetic surgery procedure. There were 112 (31.2%) respondents who revealed that their practice involved one face-to-face consultation and physical examination before the procedure. No respondents reported obtaining informed consent via the internet without a physical examination, although 20 (5.6%) claimed that they obtained consent via other means, including obtaining consent on the day of surgery, via the internet with a separate physical examination, or during a third face-to-face consultation.

There were 281 respondents (78.9%) who felt that a cooling-off period should exist and that the duration should vary based on the type of procedure. Body site was considered an important theme with longer cooling-off periods suggested for facial and breast procedures. Other key themes to support a prolonged cooling-off period included greater procedural complexity, use of general anesthetic, level of invasiveness, use of new or high-risk medical devices, and combined procedures.

In addition to an increased cooling-off duration for patients with metabolic, cardiovascular, and bleeding disorders, other common themes included additional face-to-face consultations for high-risk patients and those with a psychiatric diagnosis, and addressing modifiable risk factors such as smoking cessation and anticoagulation therapy before surgery.

"No cooling-off period" was a recurring theme when considering minor cosmetic procedures involving the use of injectable products and laser therapy. There was a wide variation in the proposed duration of cooling-off periods for surgical tourism procedures, with some noting it as unnecessary or suggesting a shorter duration would suffice; more flexibility in duration was also mentioned given the potential geographical and language barriers. Others felt that the same cooling-off periods should apply to both local and surgical tourism patients to optimize patient safety and to promote best practice.

In relation to an optimum cooling-off period for procedures that do not involve implantation of high-risk (class

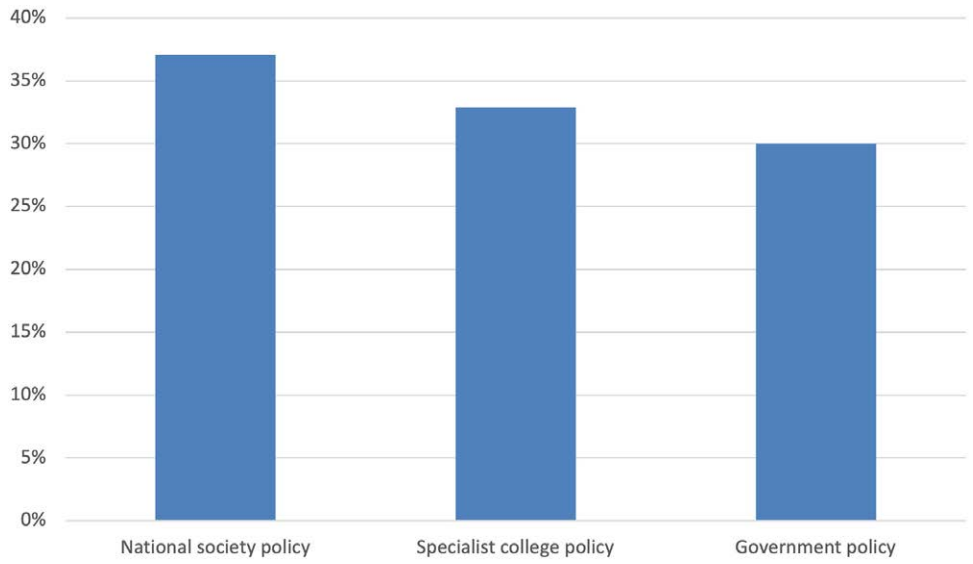

Fig. 1. Type of local informed consent policies (n = 280).

Table 2. Organizations Identified as Having an Informed Consent Guideline, Policy or Template

American Academy of Cosmetic Surgery
American Society of Plastic Surgeons
Asociacion Mexicana de Cirugia Plastica, Estetica y Reconstructiva
Australasian Society of Aesthetic Plastic Surgeons
Australian Health Practitioner Regulation Agency
Australian Society of Plastic Surgeons
Australian State and Territory Governments
Avant (medical indemnity insurance provider)
Digimed
Diomed
German Society of Surgery
Good Manufacturing Practice
International Confederation of Plastic Surgery Societies
Irish Medical Council
International Society of Aesthetic Plastic Surgery
Joint Commission International Accreditation
Local hospital guidelines
Medical Council of New Zealand
Medical liability company (generic)
National Scientific Society
Nederlandse Vereniging voor Plastische Chirurgie
Osakidetza
Residency training programs
Royal Australasian College of Surgeons
Royal College of Surgeons (United Kingdom)
Sociedad Argentina de Cirugia Plastica, Estetica y Reparadora
Sociedad Dominicana de Cirugia Plastica Reconstructiva y Estetica
Sociedad Espanola de Cirugia Plastica, Reparadora y Estetica
Societe Francaise de Chirurgie Plastique Reconstructice et Esthetique
The Doctors Company
Thieme Compliance
United States of America—State Medical Boards

III) breast devices, 125 respondents (42.7%) believed that a 7-day duration was appropriate. A 14-day cooling-off period was cited by 91 respondents (31.1%), followed by 18 (6.1%) who felt a 10-day duration was sufficient (Fig. 2). A further 59 respondents (20.1%) selected the "other" option and specified durations ranging from no cooling-off period to 3 months.

In regard to implantation of high-risk (class III) breast devices, 135 respondents (38.8%) thought that a 14-day cooling-off period was appropriate; 113 (32.5%) and 23 (6.6%) believed a 7 and 10-day cooling-off period would be adequate, respectively (Fig. 2). Again, the "other" options ranged from no cooling-off period to 3 months.

In regard to cosmetic breast augmentation, 340 respondents (96.0%) believed that the surgeon who performs the procedure should be responsible for a minimum period of postoperative management. Figure 3 outlines the duration of postoperative management deemed adequate by the respondents.

Responses varied regarding whether a different duration of postoperative management was required for cosmetic breast augmentation performed as part of surgical tourism. There were 195 respondents (58.0%) who did not believe that the duration should differ. For those who thought it should, 123 (36.6%) believed that the duration of postoperative management should be longer, and 18 (5.4%) believed that it should be reduced (Fig. 4).

There were 232 respondents (65.4%) who confirmed that they include financial consent as part of their current informed consent practice for cosmetic surgery procedures. Respondents also reported that they have a "what if" clause that outlines the potential for additional costs secondary to complications and/or that associated with patient dissatisfaction.

There were 191 respondents (55.0%) who believed that an international standardized informed consent guideline was required for cosmetic surgery procedures. Common themes included optimizing patient education and safety, protecting the surgeon, promoting best practice, and benchmarking. Other key aspects included providing guidance for those countries without any formal consent processes, improving postoperative management

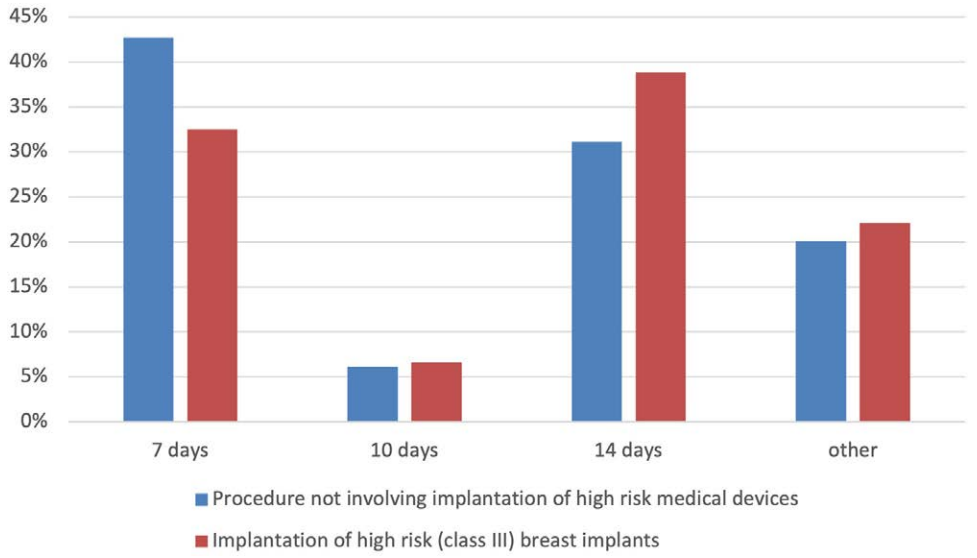

Fig. 2. Proposed cooling-off period including duration for high-risk (class III) breast devices.

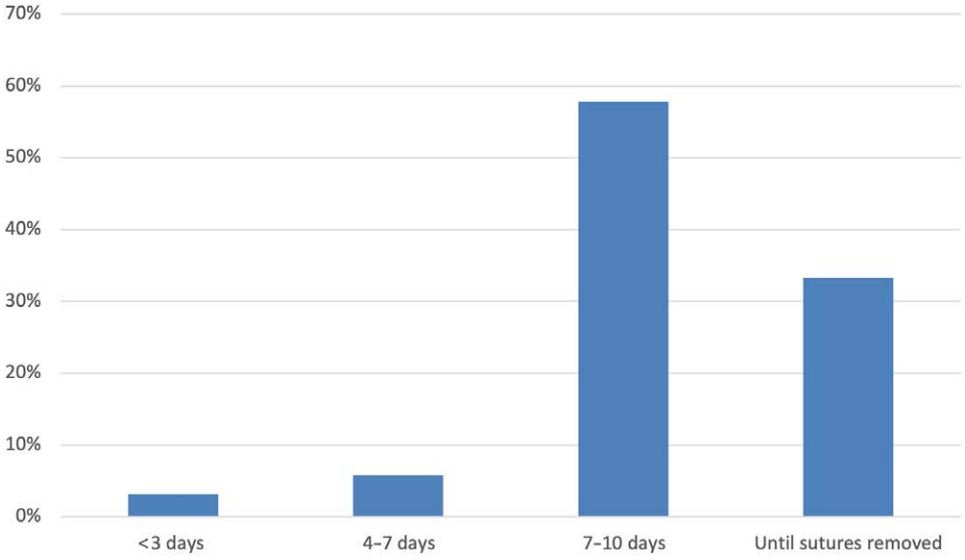

Fig. 3. Duration of postoperative management proposed after cosmetic breast augmentation.

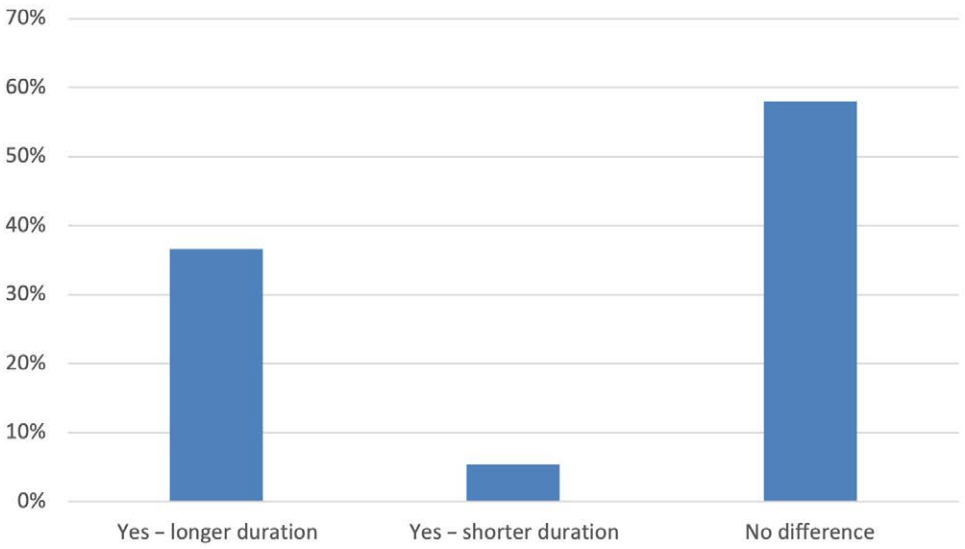

Fig. 4. Duration of postoperative management considered appropriate post cosmetic breast augmentation as part of surgical tourism.

and consistency of care between regions, and reducing the burden on home country health systems after suboptimal surgical tourism outcomes.

Themes of concern included how to implement an international guideline and whether surgeons would be expected to follow local laws or customary practices. Some highlighted that an international guideline cannot be enforced or that there could be different interpretations, which in turn could lead to inconsistent practices between regions. Another concern was about the uptake of an international guideline, particularly in the surgical tourism setting where unscrupulous practice can occur in an effort to meet unrealistic patient expectations and to minimize postoperative responsibility.

In response to survey question 15 about whether an international standardized informed consent guideline is required, there were 28 free text responses, all of which were written in Spanish. There were some recurring positive themes in relation to why an international standardized informed consent guideline is required. These themes included:

- It would help standardize consenting criteria
- It will provide legal certainty and protection
- It would be consistent with universal ethical principles, and
- It would make our profession more credible and stronger

Less common responses included:

- It could help standardize clinical management of patients (to be overseen by each country's medical society), and
- It could place more onus on patients to understand and assume risks associated with surgery.

DISCUSSION

Informed consent is an ethical pillar of communication between medical professionals and patients and therefore needs to be rigorous and inclusive. Interestingly, more than half of the survey respondents (51.1%) had no set policy for informed consent; this underpins the need for a framework in which to assemble a robust policy. Proper and fully informed consent in a contemporary surgical practice is a pillar of the relationship of trust and collaboration ("shared decision-making") and allows patients to comprehend the proposed procedure and decide whether to accept or reject a treatment plan.[27]

The informed consent process should implement the principle of patient autonomy, including the fundamental right to make a decision based on their understanding of the procedure, benefits and alternatives. This is in contrast to commonly delivered information about procedural risks, which suggests an emphasis on malpractice risk reduction for the surgeon over patient autonomy.[28] For many surgical interventions, the information provided to patients is relatively straightforward and easily understood; this is particularly so for nonelective surgery where a patient presents with an obvious diagnosis and the intended surgical procedure is curative.

For many elective plastic surgery procedures, and specifically cosmetic breast augmentations, there are a plethora of considerations to be made by the patient. These include implant choice, surgical placement, risks and complications, and financial implications if expectations are not met. There are also longer-term issues of capsular contractures, development of anaplastic large cell lymphoma or breast implant illness, ongoing surveillance of breast parenchyma and implants, predicted in situ lifespan of the implants, the effect of pregnancy, lactation and weight loss/gain, the need for future surgical exchange or explantation, and any adjunctive procedural alternatives.[29]

All of these aspects need to be absorbed by the patient. As such, at least two preoperative consultations are recommended because such a thorough coverage can usurp a patient's concentration during a single consultation, particularly when they have preconceived ideas about the procedure from social media posts and internet sites. Indeed, the rising healthcare consumerism engendered by alternative internet sources can confound patients when told that their expectations are unrealistic.[22] Some patients require lengthy discussions to unpack their preconceived ideas; all of this absorbs consultation time and highlights the need for follow-up consultations. Indeed, evidence suggests that in many medical settings, patients often have limited recall and come away with a poor comprehension of information provided to them.[30]

To fully understand all of these fundamental informed consent components, which are essential to the ethical viability of plastic surgical interventions, most surgeons provide patient decision-aids to reinforce the information from the surgical consultation. These are helpful but do not replace further face-to-face consultation with their treating surgeon.[27] In fact, noninteractive interventions such as written information for patients to read independently has been shown to be less likely to improve patient comprehension than active bidirectional communication.[28,31] Nor does an internet consultation serve as an appropriate surrogate, because the treating surgeon needs to physically examine the patient, and this should involve the taking of accurate measurements.

Notwithstanding the foregoing, and the recognized importance of informed consent, there is a justifiable need for a cooling-off period for procedures where high-risk (class III) devices are to be implanted. The question is how long should this period be? According to the UK RCS Professional Standards for Cosmetic Surgery,[13] any cooling-off period depends on several factors: "These include the invasiveness, complexity, permanence, and risks of the intervention, how many intervention options the patient is considering and how much information they have already considered about a proposed intervention."

Our survey confirmed that the majority (78.9%) of respondents endorsed a cooling-off period. With this in mind, and in the pursuit of an international framework to guide safe consenting practices, cooling-off periods between at least two face-to-face consultations need to be aligned with the overall complexity of the proposed intervention. Interestingly, when questioned about the appropriate length of a cooling-off period for routine cosmetic surgery (not involving implants) 42.7% chose 7 days, whereas 31.1% opted for a 14-day period of reflection. However, for breast augmentation, 32.5% chose 7 days, whereas 38.8% were in favor of the 14-day option. Our survey results somewhat mirror the RCS standards whereby the preference trend was for longer cooling-off periods for the more complex invasive procedures involving breast implants.

A safe recommendation, therefore, would be a mandatory minimum of at least 7 days cooling-off for all cosmetic procedures and at least 10 (preferably 14 days) for breast augmentation. These timeframes are at variance to common consenting practices in the surgical tourism industry, where internet consultations precede the overseas travel and patients are likely to only meet their surgeon on the day before surgery.

Postoperative management can also fall well below accepted standards for safe practice. This ICOPLAST survey demonstrated that the vast majority of respondents (96.1%) believe that the surgeon who performs a procedure should provide postoperative management at least until sutures are removed at 7–10 days after the operation. The surgical tourism business model should be considered "less than safe" if our recommended guidelines are compromised. Indeed, our survey results found no reason why tourism patients should have truncated postoperative management, and 36.6% of respondents advocated for even longer periods for breast augmentation patients treated overseas. The complication profile of surgical tourism has been well recorded,[11,32] and for breast augmentation, delayed complications can represent a significant cost burden on the public health system of the patient's country of origin,[33] further aggravating the cost of complications from private sector breast augmentation leading to reparative surgery in public hospitals.[34] Given that breast implants may remain in situ for 10–15 years and

complications can arise at any time, it behooves surgeons to provide fully informed financial consent that outlines several "what if" scenarios to emphasize the potential longer-term risks to patients and to reduce the ever attendant legal challenge to the surgeon for a "failure to disclose" in their informed consent process.[35] Equally important, however, is a treating surgeon's awareness of the possibility of a patient's decisional regret postoperatively if their cosmetic result falls short of their expectations. The best antidote to decisional regret is to ensure the operation's side effects are fully explained; possible complications are listed clearly; and it is clear, in the event of any negative outcome, who will bear the cost.

Future research is needed to correlate patient-reported outcomes with patients' assessments of their consent process. Breast implant registries with the ability to collect patient-reported outcomes are well placed to collect such data over the long-term.[36] To assess the impact of a revised informed consent for both cosmetic and reconstructive surgery, the BREAST-Q system of patient reported outcomes is considered to be of pivotal importance.[37–39] Only with a fully informed consent process will each patient be protected adequately, as it is their fundamental right.

This study has the limitations of all surveys in that it relies on accurate responses from surgeons who are members of the national societies that comprise ICOPLAST. Although the authors took every possible care to develop the survey questions in keeping with best epidemiological practice, it is acknowledged that double determinations to assess the veracity of responses is not possible at a granular level.

CONCLUSIONS

Fully informed consent is a basic right of all surgical patients and should result from face-to-face consultation with their surgeon. For cosmetic patients, a period of reflection of at least 7 days is considered the minimum time for them to arrive at an autonomous decision about whether to proceed. When procedures involve high-risk devices like breast implants, a longer cooling-off period of at least 10 days, but preferably 14 days, is essential for patients to process the operative risks involved and the longer-term issues that might develop. Postoperative surgical surveillance should be available in all operative settings until sutures are removed and, ideally, should continue for the in situ life of any implantable device.

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DISCLOSURES

Prof. Deva is a consultant and research coordinator for Allergan (AbbVie), Mentor (Johnson and Johnson), and KCI (3M). All the authors have no financial interest to declare in relation to the content of this article.

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