Outcome Studies in Plastic Surgery: Knowing the Objectives and Avoiding Pitfalls

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Sir:

After reading the article by Sinno et al,[1] the reader may be confused by a myriad of acronyms and scales, classifications, and esoteric tests, such as the time trade-off. Surely, we are not about to ask patients how many years of life they would be willing to sacrifice to look better. Perhaps it is best to start with the question, what is an "outcome study?"

In general surgery, the outcome of interest may be the removal of a gall bladder without complications. There is little need for patient input. Plastic surgery is quite different. The outcome is usually subjective. Ching et al[2] identified patient satisfaction and improved quality of life as the most important indicators of success in aesthetic surgery. Pusic et al[3] emphasized the importance of the patient's perception. An outcome study evaluates how well we are doing our job as plastic surgeons. It may include questions about the patient's reasons for having surgery, the recovery experience, results, complications, and the psychological impact.[4–7]

Unfortunately, plastic surgeons do not have a particularly good track record when it comes to asking patients for their feedback. Despite the ubiquity of breast augmentation, few studies ask patients for their opinion about their postoperative breast size and the firmness of their breasts.[6] Preoperative breast measurements are recommended as a scientific method to determine implant size,[8] but no supportive patient-reported outcome studies are available. Fat injection of the buttocks has become popular in the last decade. However, there are no published outcome studies. A survey of surgeons[9] recently promoted silicone buttock implants as a "safe and effective procedure with high patient satisfaction" despite a troubling record of complications and no patient-reported outcomes data. Other modalities with a deficiency of patient-reported outcomes data include breast fat injection, breast preexpansion, and cryolipolysis. Even traditional procedures, such as a face lift, liposuction, and abdominoplasty, are rarely subject to outcome studies that evaluate consecutive patients.[4,5] Breast reduction is an exception, at least in terms of measuring functional outcomes. Numerous studies document improvement in back pain and quality of life.[7]

What happens when surgeons attempt to use existing scales (including the Breast-Related Symptoms Questionnaire and Short Form-36, referenced by the authors) to compare mammaplasties? Surprisingly, the authors do not discuss a level 1 study published in 2013 by Thoma et al.[10] This article is relevant because it represents the only publication that uses such scales in a high-level study designed to compare operations—the Wise pattern and vertical reduction mammaplasties. Unfortunately, these instruments were not designed to detect differences in the quality of the aesthetic result. No difference was found. This conclusion does not mean that the techniques are equivalent. The outcome measures were simply not up to the task.[11]

Sinno et al[1] conclude that "outcomes research helps provide evidence for superior treatments." However, the authors do not provide any examples of an outcomes measure that identifies one operation as superior to another in plastic surgery. The authors provide no references at all to outcome studies that use ad hoc questionnaires (ie, surveys that do not use a generally accepted series of questions).[4–7] The criticism that ad hoc studies are "not validated"[12] invites a discussion as to what exactly constitutes validity (a quality that does not depend exclusively on patient interviews, focus groups, field testing, and expert panels).[13] The fact remains: ad hoc questionnaires are the only outcome tools available with sufficient responsiveness to compare surgical techniques.[5,7]

Ad hoc outcome studies provide clinically useful information[4–7] that is sometimes surprising. An example is the finding that breast reductions with resection weights < 300 g per breast provide symptomatic relief.[7] Consequently, insistence on a minimum tissue resection weight is arbitrary. Fortunately, plastic surgeons are quite capable of performing their own outcome studies.[4–7] There is no substitute

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Table 1. Comparison of BREAST-Q and Ad Hoc Surveys

Study Parameter	BREAST-Q	Ad Hoc Surveys
Transparency	Questions concealed	Questions published
Access	Fee	Free
Contract	11-page contract	None
Analysis of data	Outsourced, "QScore"	By investigator
Statistics	Complicated	Standard tests
Number of surveys	Before and after surgery	Postoperative only
Comparisons	Different patients	Same patients
Responsiveness to surgical changes	Overall score, 0–100	Individual, specific
Flexibility	Cannot be modified	Adaptable
Respectful of personal privacy	Includes sexual module	No sex questions
Administration of survey	Mailed, self-written	In-person, verbal
Brevity	Booklet	Single page
Thoroughness of responses	Many responses missing	Almost all questions answered
Proven ability to compare techniques	No publications	Multiple publications
Methodological considerations		
Consecutive patients	Nonconsecutive (selection bias)	Consecutive
Inclusion rate	Low	High
Consideration of confounders	Numerous clinics, surgeons, methods, protocols	Same surgeon, method, protocol
Commercial bias	Receives royalties from licensees and funding from implant manufacturer	None

for rigorous methodology.[14] Such considerations, essential to evidence-based medicine, include consecutive patients, eligibility criteria, the inclusion rate, and consideration of confounders.[14] Outcome studies need not be complicated[4–7] or require psychometric training.[13] It is important to prioritize specific questions of interest to patients.[4–7]

Sinno et al[1] recommend the BREAST-Q[3] although the authors do not report any experience actually using this tool. Drawbacks include a lengthy contract, licensing fee, and outsourcing of data analysis.[15] The survey questions themselves are withheld. The numerous limitations of this device make it an unattractive option (Table 1). The authors also recommend that PROMIS (patient-reported outcome measurement information system) "be further developed for specific health states within plastic surgery." Trying to adapt existing scales related to general health (which is usually not at issue in our specialty) to plastic surgery is unlikely to be productive. Such efforts may represent a distraction from our goal—evaluation of the aesthetic result itself.[16] As the authors recognize,[1] Tracking Operations and Outcomes for Plastic Surgery (TOPS) is a registry, not by itself an outcome tool.

The scientific method helped medicine emerge from the dark ages. However, entrenched ideas (eg, breast autoaugmentation and Wise pattern mammaplasty) exist today just as they did centuries ago (eg, bloodletting). We need to reconsider old methods, evaluate new ones (eg, cryolipolysis), and resist marketing pressures. Patient-reported outcomes and measurements of the aesthetic result[16] are more useful than utility scores, general health scales, or a flawed proprietary device.[3,15] The scientific method, passionless but unprejudiced, serves as our guide.

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