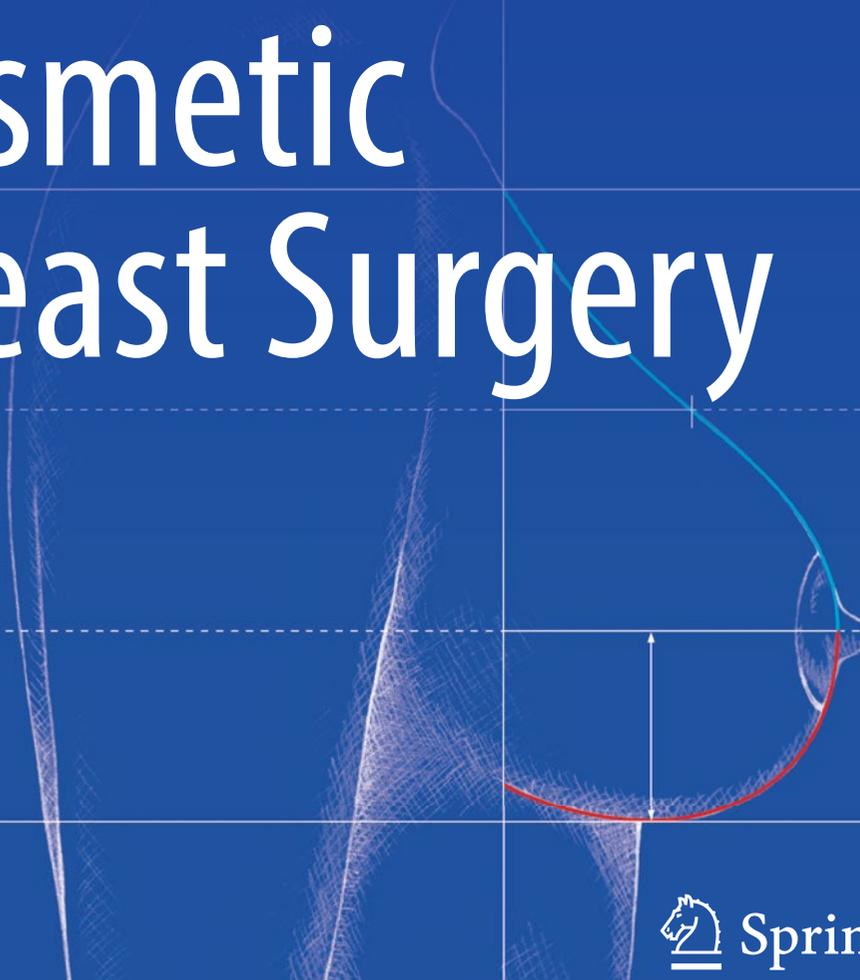


Eric Swanson

# Evidence-Based Cosmetic Breast Surgery



 Springer

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## Preface

Many textbooks are titled some variation of “The Art of Plastic Surgery.” This volume concentrates on the science, relying on data rather than expert opinion. The source material has been published in the major peer-reviewed plastic surgery journals. Many of the conclusions challenge the status quo.

Financial entanglement represents the single biggest problem facing plastic surgery research. Conflicts are not always financial. They can be intellectual, such as being heavily invested professionally in a certain method, such that there is no going back without a loss of credibility (in the author’s mind, anyway). I can think of only a few instances of a surgeon writing, “What I said before is wrong.” My opinion of that author goes up, not down, for correcting the record.

Being in solo private practice frees me from many of the constraints of academic medicine, which is often not as evidence based as one might think. All of my studies are self-funded. The only financial conflict I have is in being a plastic surgeon who believes in the value of, and profits from, performing cosmetic surgery.

As a single-author volume, this book is open to charges that it represents the experience of one surgeon. My methods frequently differ from the way plastic surgery is done at other institutions. My purpose in writing is not to recite the mainstream view but to challenge it. One surgeon, one facility, and one method eliminate many confounders that, well, confound multisurgeon and multicenter studies.

Existing textbooks are composed of many chapters written by well-known contributors describing their “How I do it” methods. One surgeon describes how to perform a breast reduction using the vertical technique, another describes the Wise pattern, and another discusses how to dissect a central breast mound and apply a mesh. This old habit makes for thick textbooks. What is the reader to make of all this often conflicting information? A breast lift is a simple concept. There are not 100 equally valid ways to do it. I use only two operations for almost all of my cosmetic breast surgery patients – implants, a vertical breast lift/reduction, or a combination of the two. Really, only one chapter on mastopexy is needed – the one that stands up to scientific scrutiny. Nonvertical methods may be discarded.

I use only two operations for almost all my cosmetic breast patients – implants, a vertical breast lift/reduction, or a combination of the two.

For generations now, plastic surgeons have described methods to lift the breast tissue using breast tissue rearrangements and “suspending” sutures. These efforts puzzled me. After all, did we not have breast implants at our disposal? Until recently, the combination of implants and a breast lift was perceived to be dangerous and at cross purposes – tightening the breast while simultaneously expanding it. Today we know differently.

It seemed to me that almost everything plastic surgeons “knew” (examples provided in Table 1) was based on clinical impressions alone. Starting in

**Table 1** Things we “know” that are wrong

1. Individual risk stratification (including Caprini scores)
2. Chemoprophylaxis
3. Breast autoaugmentation
4. Textured implants
5. Form-stable implants
6. BREAST-Q
7. Acellular Dermal Matrix for cosmetic breast surgery
8. Implant sizing based on tissue measurements
9. Routine open capsulectomy for capsular contracture
10. General endotracheal anesthesia with paralysis
11. Intraoperative 14-point plan, including nipple shields, to prevent capsular contracture
12. Mosque dome preoperative nipple siting
13. Nonvertical (including inferior pedicle Wise pattern) mammaplasty
14. Nipple grafting
15. Suspension sutures
16. Mesh scaffolds
17. Breast hypertrophy after liposuction (fat redistribution theory)
18. Dual plane dissection to elevate nipple
19. Blocking sutures
20. Controlling/securing the IMF
21. Pectoralis muscle loop
22. Staged augmentation mastopexy
23. Periareolar mastopexy
24. Electrodisssection
25. Ideal breast fuller in lower pole than upper pole (45:55 ratio)
26. One-breast feel
27. No-touch technique
28. Triple antibiotic irrigation
29. 5-centimeter rule to prevent pseudoptosis
30. Nipple as a marker for ptosis
31. Increased risk of combined procedures
32. Accuracy of 3-D computer simulations
33. Randomizing surgical methods
34. Internal bra/laser bra
35. 20° skyward nipple inclination
36. Sub-IMF incision siting, including ICE principle
37. No-vertical-scar breast reduction

(continued)

**Table 1** (continued)

38. 24 h recovery after breast augmentation
39. External volume expansion
40. Tension shielding to improve scars
41. Repeating inverted-T dissection for secondary mammoplasties
42. Nipple transposition as opposed to reposition
43. Unreasonable expectations are more common in breast lift patients
44. Large implant sizes (>400 cc) are unsafe
45. Skin-only mastopexies
46. Cosmetic breast surgery is an art and, by its nature, resistant to scientific evaluation

2002, I launched a battery of clinical, measurement, and outcome studies to learn more. I soon realized that in order to measure results, a breast measurement system was needed, motivating me to develop a two-dimensional measurement system. After evaluating hundreds of published before-and-after photographs, the message was clear – breast autoaugmentation and fascial sutures did not work, despite all of the claims. This was the first of many “emperor wears no clothes” moments that were yet to come.

My outcome studies, based on over 1000 patient surveys, produced unexpected findings. Surgeons for years have warned patients of the dangers of implant sizes that are too large, convinced that large implants would distort the breast and that reoperations would be inevitable. My studies showed otherwise. Women treated with larger implant sizes were more satisfied and experienced no more complications than women with smaller implant sizes. These women did not have a higher reoperation rate after all. Mastopexy patients reported improvements in symptoms of neck, shoulder, and back pain, and exercise tolerance, just as my breast reduction patients did. It became clear that the old, largely insurance-driven, breast lift versus reduction (or form versus function) dichotomy was arbitrary.

Saline implants have long been considered an inferior option compared with silicone gel implants. To the chagrin of plastic surgeons, silicone breast implants were unavailable in the United States from 1992 to 2006, forcing American surgeons to gain experience with saline implants. There was a silver lining to that experience; many surgeons learned that saline implants were not such an inferior choice after all.

In 2012 and 2013, form-stable “gummy bear” implants were finally introduced to the American marketplace, having been used for decades already in Europe. Supportive studies were funded by the manufacturer, and consultants were very highly paid. (According to the Sunshine Act website, one lead author of a core study received \$4.6 million in royalties in 2015.) These shaped implants were promoted as offering a more natural tear-drop shape. After all, who wants a round breast? But these implants were much firmer than their predecessors. They had to be to resist gravitational deformation, like a gummy bear. Advertisements showed a portion of the implant cut out like a piece of pie. It appeared that the material was solid and would resist forming folds and leaks. In time, magnetic resonance studies would prove otherwise. Some operators, including the author, were never impressed with

gummy bear implants. My outcome study revealed that 23% of women thought their saline and less cohesive silicone gel implants were already too firm. Why would women want even firmer implants that can rotate? What about the attractive jiggle quality of less cohesive implants?

In the last decade, we have learned that textured implants, especially the Biocell (Allergan Inc., Irvine, CA) type, are linked to a form of lymphoma that is not as rare as we first thought. Rather than implicating texturing as the cause, corporate-funded researchers promote an infectious etiology and insist that surgeons adopt a laundry list of measures to avoid infection at surgery – as if infection acquired at surgery could cause Anaplastic Large Cell Lymphoma (ALCL) to develop, on average, 8 years later. An infectious etiology has much different implications than a faulty product. The surgeon is blamed for this problem rather than the product. The causal link is obvious. After all, this problem was never reported before textured implants became available in the 1990s, and it occurs exclusively in women with textured implants.

Manufacturers do not promote saline implants for one reason – they are not as profitable as silicone gel implants, which cost two or three times as much. Silicone gel implants would likely be a historical relic if saline implants were the more profitable option.

Acellular dermal matrix, or ADM (i.e., skin that is shaved off cadavers and then processed to remove the donor cells), is widely promoted today. Some surgeons insert Alloderm (Lifecell Corp., Branchburg, NJ) at the time of a capsulectomy in an effort to prevent capsular contracture. Almost all investigators receive corporate funding and discounted products. Combining capsulectomy and ADM greatly increases patient morbidity and cost. Insertion of a second avascular product increases the potential for complications. A much simpler, inexpensive, and at least equally effective, alternative is overlooked – open capsulotomy. Its success (recurrence rate 23%) speaks against the infected biofilm theory of capsular contracture.

Recapitulating history, some plastic surgeons are experimenting with a mesh that is supposed to act as an internal bra. This 30-year-old concept has never been shown to be effective. In fact, the author's measurement study found it ineffective. The manufacturer pays its consultants, who promote the product on TV and the Internet, and funds scientific publications that blur the line between science and marketing.

Caprini scores are supposed to identify individuals who are likely to suffer a venous thromboembolism (VTE). These scores are then used to justify the use of anticoagulants (yes, Caprini received funding from virtually all the anticoagulant manufacturers) after surgery. The subtext is, if surgeons fail to follow risk stratification guidelines, they will be defenseless in court. Uninformed expert testimony compounds the tragedy of a fatal pulmonary embolus. The more I investigated risk stratification and chemoprophylaxis, the more I learned that the whole concept – the ethics, efficacy, and safety – is flawed. It was another “emperor wears no clothes” moment, but there was another silver lining. I soon learned how to reduce risk and identify affected individuals (after surgery, not before) using a superior anesthesia method and ultrasound technology.

Alarming, many of the concepts and recommendations that have been published in our literature are wrong (Table 1). More of what we think we know may be wrong rather than right. These shibboleths will be challenged in the chapters that follow.

“When we meet a fact which contradicts a prevailing theory, we must accept the fact and abandon the theory, even when the theory is supported by great names and generally accepted.” - Claude Bernard 1865.

A disregard of the scientific method has real consequences that affect patient care and in some cases their lives. Even the plastic surgeon’s life can be devastated by wrong assumptions (in the case of VTE prevention). When it comes to evidence-based medicine, we need to walk the walk, not just talk the talk. Proper methodology is not complicated. It starts with consecutive patients, a reasonable inclusion rate, and an objective measuring device. Patient-reported outcome studies are needed, and not ones that are outsourced (i.e., the BREAST-Q).

Galileo would never have discovered that objects fall at the same rate, propelled by gravity regardless of mass, if he did not use a clock (actually an hourglass). Four hundred years later, measurements have not reached the mainstream in our discipline. Not only do plastic surgeons not measure their results, many do not wish to measure their results. They would prefer to engage in thought experiments and punditry. I call this nonscientific purgatory. Measurements are the missing link in objective analysis. In many ways, evidence-based medicine is measurement-based medicine. It is time to right the ship, for the sake of our patients and ourselves.

In many ways, evidence-based medicine is measurement-based medicine.

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## Author



Dr. Eric Swanson completed medical school and a residency in plastic and reconstructive surgery at the University of Toronto before starting private practice in Kansas City in 1989. Dr. Swanson is an outspoken advocate for evidence-based medicine. Dr. Swanson's self-funded clinical research has culminated in over 100 publications in the top peer-reviewed plastic surgery journals, including numerous articles and letters that challenge the conventional wisdom and offer science-based alternatives.

Dr. Swanson is a frequent lecturer and panelist at national and international meetings, and regularly provides instructional courses in cosmetic breast surgery. Dr. Swanson is a member of the American Society of Plastic Surgeons, the American Society for Aesthetic Plastic Surgery, and the American Association of Plastic Surgeons.

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## Abstract

Cosmetic breast surgery is popularly perceived as artistic. Unfortunately, this notion has allowed nonscientific concepts to persist, without proper scrutiny to establish validity. Without measurements, there is no means to test the effectiveness of surgical methods.

Existing level of evidence scales benefit from modification to include important methodological considerations. Randomization is impractical for elective surgery. However, well-done observational studies can be just as useful. Consecutive patients are needed to avoid selection bias. Prospective studies are initiated before the data are collected, not after. A prospective study among consecutive patients meeting eligibility criteria, with a reported inclusion rate, the use of contemporaneous controls when indicated, and consideration of confounders, is a realistic goal. Such measures are likely to improve study quality. Commercial bias is an endemic problem in medicine. A plastic surgeon may function as a highly paid consultant or as an impartial investigator, but not both.

Patient-reported outcomes are essential in plastic surgery because patient satisfaction is the most important determinant of surgical success. Unfortunately, plastic surgeons are not in the habit of soliciting their patients' opinion regarding the result. A proprietary psychometric test, known as the BREAST-Q, has limited clinical usefulness. Ad hoc surveys provide useful clinical information that can be used to compare operations. There is no better education than performing outcome studies on one's patients.

It is almost taken for granted today that plastic surgeons are artists [1]. Our textbooks are often titled "The Art of Plastic Surgery." Plastic surgery offices may resemble fine art galleries. With some hubris, plastic surgeons cultivate the public perception that we are artists [2]. Goldwyn [2], longtime former editor of *Plastic and Reconstructive Surgery*, joked about wishing he were wearing a beret and a paint-

spotted frock when asked by a patient if he paints in his spare time.

A recent editorial asks plastic surgeons: which type of artist are you, Michelangelo or Da Vinci? [3]. In reality, the talents of these Renaissance artists might not have been well suited for surgery, which is an empirically based discipline with little use for Neo-Platonism. Being one with

a universal force is of limited practical use when it comes to deciding how far to undermine a flap or how much fat to inject. No doubt these legends would have lacked humility, a quality bestowed by the hard experience of surgery, which imposes its own set of limitations and unpredictability on the outcome.

Importantly, neither Michelangelo nor Da Vinci was trained in the scientific method. Michelangelo rejected schooling [4]. Guided by a mystical Neo-Platonic philosophy that was in vogue in Florence at the time, Michelangelo famously claimed that he was releasing the beings captured within the stone [5]. Great as he was, few surgeons would want Michelangelo to be their surgeon, chipping away and trying to liberate a human form in their body, believing he was uniquely touched by genius and divinely inspired [1]. It is not reassuring that Michelangelo had no use for measurements, perhaps explaining why David's hands, particularly the right hand, are disproportionately large, or perhaps that was intentional (at least that is the contemporary spin) [6]. Unfortunately, by considering themselves artists, plastic surgeons may think that evidence-based medicine does not apply to aesthetic surgery. They may believe, if Michelangelo did not measure his results, why should I? [7]

Galileo, a century later, would finally decouple religion and science, famously saying that God would not have given him the capacity for reason if not for him to use it. In doing so, he helped create the scientific method. Remarkably, Galileo had the insight to reject institutional authority, the humility to subject his ideas to experiments, the diligence to see them through, and the courage to risk his life defending unorthodox findings [1]. Galileo revealed the limitations of intuition. For example, it seemed clear to everyone that a heavier object would fall to the ground faster than a light one. Galileo's experiments disproved that popular notion [8].

Artists rely on their intuition as a guide. Scientists are trained to question it, aware that the road to ruin is paved with good intuitions. The famed seventeenth-century mathematician and philosopher René Descartes famously commented that doubt is the origin of wisdom [9]. For example,

it may be intuitive that manipulating breast tissue can improve upper pole fullness. Only measurements can prove otherwise [10]. Clinical decision-making based on intuition and first principles remains common today, and the need for scientific validation is no less than it was four centuries ago. Ultimately, intuition must give way to the facts.

Turning to one's inner psyche for guidance in surgery is dangerous and in fact bound to fail, humans being inherently imperfect. We need the scientific method to guide the way. Just as we want our pilots to have good instincts, we also want them to have an altimeter. It is sobering to review our literature and consider how many surgical techniques that were conceived in creative bursts remain grounded because of a lack of scientific validation. In mammoplasty, the number exceeds 100 [10]. Apathy toward science, or a willingness to let the science be outsourced, has real consequences for patients.

Art and science may not be mutually exclusive, but there is an essential difference. An artist uses a medium as a form of self-expression. A scientist seeks to uncover knowledge (and arguably beauty) that already exists, while imparting none of his or her own prejudices regarding what that should be [1]. Plastic surgeons are not really sculptors; we do not fashion marble into an artistic rendering. Our job is to model tissues to improve upon an existing template (cosmetic surgery) or to reconstruct one that has been made deficient through birth, disease, or trauma (reconstructive surgery). We are renovators, not creators. Plastic surgeons may have more in common with the restorers of the Sistine Chapel ceiling than with its creator [1]. Most of us would prefer our surgeon to be respectful of the innate beauty of the human form and not to be inspired to stamp his or her signature on it. Few people would like their nose to be recognized as the work of a particular surgeon [1].

As a product of creativity and imagination, innovation is celebrated [11]. New or popularized techniques find an audience at meetings. So what is missing? *Measurements*. Without measurements, no rejuvenation concept is ever proved and none is disproved either, a sort of therapeutic purgatory.

Without measurements, no rejuvenation concept is ever proved and none is disproved either, a sort of therapeutic purgatory.

Saying that numerous techniques can deliver the same result is a familiar throwaway line at meetings. As scientists, we do not really believe that, do we? Perhaps it is more accurate to say that without measurements there is no way to ever know. Often the less scientific merit for a claim, the more passionate the proponent. Such claims often follow the lead-in, “I’m a firm believer that...” [1]

Some plastic surgeons suggest that our specialty is too subjective to permit scientific evaluation [12]. In truth, there is always a way of measuring if one puts one’s mind to it. Claiming that because plastic surgery is an art, or because it is aesthetic, evidence-based medicine does not apply is no excuse for not measuring. The old axiom applies: what we measure, we improve (and the opposite is true too) [1]. Fortunately, computer imaging has made photographic standardization and measurements easy to perform. Gillies, who reportedly said that the camera was the most important advance in the history of plastic surgery [13], might feel the same way about the computer if he were with us today. Examining one’s *consecutive*, standardized photographs is an educational experience for which there is no substitute. After doing so, plastic surgeons might be less inclined to promote a “natural breast implant” or an “internal bra.”

Plastic surgeons attend medical school, and not a fine arts academy, for a reason [6, 7]. We need to rededicate ourselves to the scientific method. We need to use a ruler (or its computerized analog) along with a scalpel [6].

Certainly, innovation gives us a competitive advantage [11]. However, so does our professionalism. A commitment to the truth and a resistance to marketing pressures help distinguish plastic surgeons from the wannabes. If we insist on being artists, we risk separating ourselves

further from the medical mainstream [14]. No, it is not time to reconsider plastic surgery as a fine art. Cross-training is fine; the importance of an appreciation for aesthetics is unquestioned. But let us not forget our medical foundation.

## Evidence-Based Cosmetic Breast Surgery

Until now, no publication has been published with the words “evidence based” and “cosmetic breast surgery” in the same title. The problem is, “evidence based” has become a cliché. “Evidence-based medicine” is a phrase coined by Guyatt in 1991 [15]. Sackett et al. [16] defined evidence-based medicine as “the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients through integrating clinical expertise with the best available external clinical evidence from systematic research and the patient’s values.” This definition is subject to interpretation as to what exactly constitutes the best available clinical evidence.

In reviewing the plastic surgery literature, it would appear that evidence-based medicine was introduced to plastic surgery in about 2009 [17, 18]. However, physicians have known about the importance of rigorous methodology and study design for decades. These are not new concepts. They have simply been neglected. For example, Brody and Latts [19], in 1981, wrote “established techniques for the conduct of drug trials are well-described in the literature, but none of our plastic surgery writing on this subject betrays any familiarity with a controlled study.” In discussing the etiology of capsular contracture, the authors [19] called for prospective studies, concurrent controls, and reproducible diagnostic criteria. They emphasized the need for “well-established, scientifically valid analysis rather than artistic ‘impressionism’” (i.e., conclusions based on clinical impressions) [19].

Scientific study of cosmetic breast surgery has suffered from a lack of accepted definitions and terms relating to breast shape, and a practical

measurement system. There has been a noticeable reluctance to use measurements, or even to standardize photographs [20]. As I took my seat after a presentation at the 2016 meeting of the American Society of Plastic Surgeons, a senior co-panelist leaned to me and whispered, “too scientific.” The irony is that I do not make detailed measurements that I follow precisely in surgery. I rarely adhere exactly to my preoperative markings. My final decision regarding nipple placement is made in surgery. I do not use tissue measurements to determine implant size. The time I spend making markings is just a few minutes. The system I developed is used *after* surgery, for comparison of before-and-after photographs using the same reference plane [21]. It is a means to evaluate and quantify surgical changes later, when I have an opportunity in my office to match photographs and make the measurements. This analysis is the foundation of my work to scientifically evaluate cosmetic breast surgery (Fig. 1.1). In many ways, evidence-based cosmetic breast surgery is measurement-based cosmetic breast surgery.

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## Levels of Evidence

The lack of science in plastic surgery is well recognized [17, 22–25]. Efforts to incorporate evidence-based medicine [15, 26] in plastic surgery are justified. Both the Level of Evidence [27] and Grade [23] concepts originated in a seminal Canadian Task Force Report published in 1979 [28]. Evidence-based medicine challenges traditional clinical practice based on unsystematic clinical observations, basic principles, common sense, experience, and expert opinions [16, 26, 29, 30]. Ironically, the Level of Evidence classification [27] itself is a product of experience and expert opinion. Evidence-based medicine is not intended to be static, but rather a dynamic, lifelong process [30, 31] that recognizes the need to evolve [16]. There is no grand-

father clause that shields it from scientific scrutiny [32]. When analyzed, medical practice guidelines often fall short in meeting methodological standards [32]. About half the guidelines are outdated in 6 years [33].

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## Evaluating Evidence-Based Medicine in Plastic Surgery

In 2013, the author used the components of evidence-based medicine [24, 30], including “tracking down the best evidence” and “critically appraising that evidence” to investigate evidence-based medicine in plastic surgery [34]. A 2-year period of cosmetic surgery publications in the *Journal of Plastic and Reconstructive Surgery*, July 2011 through June 2013, was retrospectively evaluated. All articles with a Level of Evidence rating published in the Cosmetic Section were included. Each paper was designated a quality rating by the author using a new Cosmetic Level of Evidence And Recommendation (CLEAR) scale (Table 1.1). This classification modifies the traditional Level of Evidence ranking [7] and grade of recommendation (Table 1.2) [17, 23–25]. Table 1.3 and Fig. 1.2 compare the classifications. Table 1.4 summarizes the findings.

Forty-eight studies (55%) were designated a Level 4 using the *Journal of Plastic and Reconstructive Surgery*’s Level of Evidence rating. Three articles were assigned a Level 1. Forty-one articles (48%) evaluated consecutive patients or consecutive patients subject to inclusion criteria. Thirty-five studies (40%) consisted of chart reviews and a recording of complication and reoperation rates. Twenty-five studies (29%) reported physical measurements on patients or images. An equal number of studies (29%) featured subjective evaluations of the result by the investigators. Patient-derived data were collected in 18 studies (21%).