



Study Design and Hierarchy of Evidence for Surgical Decision Making

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- Historical perspective
- Systematic reviews and meta-analyses
- Randomized controlled trials
- Observational studies: cohort studies and case-controlled studies
- Case reports and series
- Basic science or physiologic studies
- Limitations of using the hierarchy of evidence
- Grading the strength of a body of evidence
- Evidence-based plastic surgery
- Summary
- References

Surgical therapy decisions have historically been based on existing surgical dogma, personal experience, recommendations of surgical authorities, and thoughtful application of surgical basic sciences [1]. As plastic surgeons strive to offer their patients the surgical techniques and procedures that maximize benefit and minimize harm, many different factors may influence their clinical decision-making, including the clinical state of the patient, the clinical setting (academic versus private practices, rural versus urban settings), circumstances (emergency versus elective surgery), patient preferences, and the plastic surgeon's expertise (Fig. 1). The availability of health care resources may also have an impact on surgical decisions; for example, academic centers may have ample technologic

resources that are lacking in rural settings, where only basic technology exists.

In addition to these considerations, research evidence also plays a significant role in clinical decisions. It is often challenging to decide which parts of the existing or growing body of clinical research evidence to consider, and how to apply these research findings when making surgical decisions for specific patients. A literature search to address a particular plastic surgery question using an electronic database, such as Medline, may provide a multitude of articles with conflicting recommendations.

The introduction of evidence-based clinical practice [2] in the last two decades has provided direction on how to identify the best available

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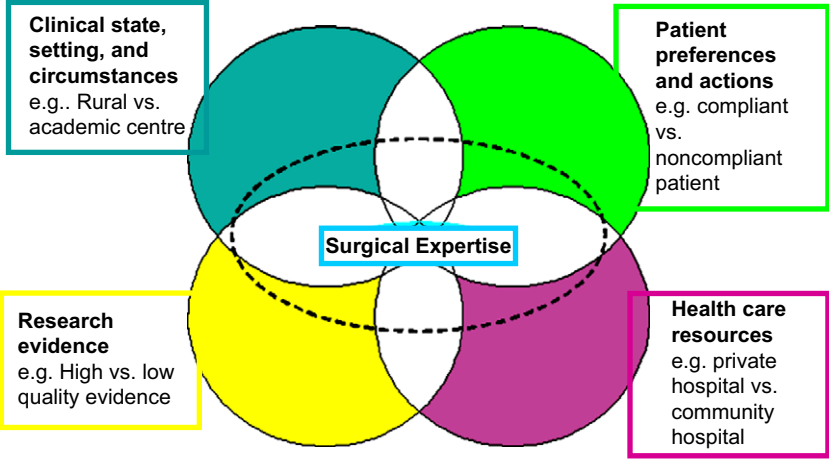


Fig. 1. Factors in making decisions in plastic surgery.

evidence. Evidence-based clinical practice can be defined as the integration of the best research evidence with clinical expertise, while factoring patient values into clinical decision making [2]. In contrast to the traditional approach to plastic surgical practice, the evidence-based plastic surgery approach acknowledges that intuition, unsystematic clinical experience, and pathophysiologic rationale are insufficient grounds for clinical decision-making. It also stresses the importance of examining the evidence from clinical research. It is important for plastic surgeons to apply principles of evidence-based plastic surgery when deciding which of the competing surgical techniques and procedures to use on their patients [3].

Not all research evidence is judged to be of equal value. That is, different research designs have different strengths and, therefore, different levels of value in the decision making process [4]. For surgeons, the integration of research evidence into daily practice requires an understanding of what constitutes high and low quality evidence. Before making a clinical decision, a plastic surgeon must be aware of the strength of the available evidence, and therefore the degree of confidence associated with a decision based on that evidence. The hierarchy of evidence is often represented by a pyramid, in which studies that represent the best evidence are placed at the top, and those representing low quality evidence are placed at the bottom (Fig. 2). When facing a patient with a particular problem, plastic surgeons should seek answers by looking at the best available evidence. For studies evaluating the best surgical treatment in descending order, the authors recommend the following hierarchy of evidence: meta-analysis and systematic reviews of high quality randomized controlled trials, randomized

controlled trials, cohort studies, case-controlled studies, case series, expert opinions, and in vitro and animal studies (see Fig. 2). This ranking has an evolutionary order, moving from simple observational methods at the bottom of the pyramid, through to increasingly sophisticated and statistically refined study designs at the top of the pyramid. Unfortunately, many of the publications in the plastic surgery literature fall into the lower levels of the evidence pyramid.

The purpose of this article is to provide a historical overview of the hierarchy of evidence and discuss key study designs in the hierarchy of evidence, including meta-analyses, randomized controlled trials, and observational studies, including cohort studies and case controlled studies, case series and case reports, and basic science studies. Several systems to rate the strength of

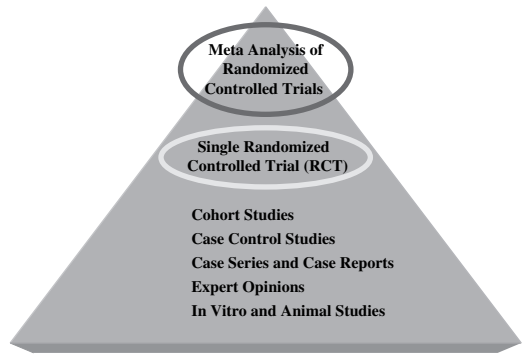


Fig. 2. Hierarchy of evidence pyramid. The meta-analysis of randomized controlled trials (RCT) is considered the best evidence, followed by a large RCT with a narrow confidence interval.

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