

Comments on “Double-Blind Comparison of Ultrasonic and Conventional Osteotomy in Terms of Early Postoperative Edema and Ecchymosis”

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I read the manuscript by Ilhan et al¹ with great interest. The authors performed a randomized study comparing two types of osteotomy in rhinoplasty: ultrasonic and conventional osteotomy. They found that ultrasonic osteotomy results in less edema and ecchymosis. Their patients were blind to the study and not informed about which osteotomy technique was applied to them. The same surgeon performed both types of surgery and was not blinded. The postoperative evaluation of the surgical results was performed by blinded examiners. Although the authors called their study a “double-blinded” comparison, I do not agree with them.

I agree that blinding of the examiners was important, because their attitude about the technique might affect their assessment. I did not understand how a contribution was expected from patient blindness in this study. Although they did not discuss the effect of the patient blindness on the study, I hope that such an effect is minimal. On the other hand, the blinding of surgeon, evaluator, and biostatistician might be important in this clinical trial to overcome transfer of their attitudes toward or against an intervention during the study. In a “double-blinded” study like this the readers probably expect that the surgeon and evaluators are blinded, not the patients.

The authors considered their study double-blinded because the patients and evaluators were blinded. I prefer that the surgeon instead of the patient is blinded in a “double-blinded” study because unblinded clinicians may transfer their attitude to the treatment.² However, I am aware that it is impossible to design a study with surgeon blindness. Two options are available in such cases: the lack of the surgeon’s blindness and the resultant potential bias may be discussed in the paper, or the study may be performed

using an expertise-based design. In an expertise-based design, the patients are randomized to paired surgeons with expertise in only one procedure.³ The expertise-based design is advised to overcome transfer of the surgeon’s attitude toward or against an intervention during the surgery. I agree that it is difficult to randomize patients who initially presented to a particular aesthetic surgeon. In this situation, a double-blind study is not required. If a double-blind study is still desired, it is possible to carry out but the drawbacks of the study must be addressed in the Discussion section.

Randomization is important because it eliminates selection bias. All persons associated with the study (participants, surgeons, data collectors, outcome adjudicators, and data analysts) should be blinded as much as possible.² The term “double-blinded” should be avoided in surgical trials.³ Its meaning changes according to the individual using it. It is more meaningful to define the persons who are blinded to the study in the Methods section instead of calling the study “double-blinded.”³

Disclosures

The author declared no potential conflicts of interest with respect to the research, authorship, and publication of this article.

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