Discrepancies between Registered and Published Primary and Secondary Outcomes in Randomized Controlled Trials within the Plastic Surgery Literature

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BACKGROUND: Recent studies have identified an alarmingly high incidence of discrepancy between registered and published outcomes in registered medical and surgical randomized controlled trials. This has not yet been studied in the plastic surgery literature.

METHODS: The authors systematically assessed plastic surgery randomized controlled trials (RCTs) published between 2012–2016, in seven high impact plastic surgery journals. Data was collected from the registration website and published manuscript using a standardized data extraction form.

RESULTS: 145 RCTs were identified, of which fifty-seven RCTs were registered (39%). Forty-nine RCTs were included in the final analysis. Forty-three of trials (88%) had a discrepancy between registered and published outcomes - 23 trials (47%) for primary outcome(s), and 37 trials (76%) for secondary outcome(s). The prevalence of unreported registered outcomes was 13% (primary) and 38% (secondary). Registered primary outcomes were published as secondary outcomes in 30% of trials. Publishing new non-registered secondary outcomes (65%) and changing the assessment timing of published primary outcomes (61%) were the most common types of discrepancies. Discrepancies favored a statistically significant positive outcome in nineteen of the forty-three trials (44%) with an outcome discrepancy.

CONCLUSION: Similar to studies of trials in other medical and surgical areas of the literature, the field of plastic surgery has high rates of discrepancies between registered and published trial outcomes. Outcome reporting discrepancy is even more problematic secondary outcomes, an area of analysis that has previously been poorly studied in other areas. This study also identified biasing practices such as outcome discrepancies favoring a statistically significant result.

A Critical Assessment of Surveys in Plastic and Reconstructive Surgery: A Systematic Review

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PURPOSE: Surveys are one of the fundamental approaches used to assess patient preferences and current practice patterns in plastic surgery. In contrast with other surgical specialties, plastic surgery procedures emphasize quality of life outcomes. Therefore, understanding factors that influence the attitudes of patients and physicians are important to achieve successful outcomes. Despite the prevalent use of surveys in Medicine, researchers have identified inherent biases in surveys used in medical research. It is uncertain how prevalent and the magnitude of these problems in plastic surgery surveys. Our specific aims are to (1) determine the extent to which survey instruments in plastic and reconstructive surgery contain inherent biases and (2) identify areas of improvement for developing survey instruments.

METHODS: We searched four databases (Embase, PsychInfo, Medline and PubMed) for articles in plastic surgery that contain a survey. We identified studies published from 1997 to 2017 that had some measurement of physician/patient attitudes as a key theme. Validated or outcome instruments were excluded. Two trained reviewers assessed the articles using specific inclusion and exclusion criteria. A modified checklist from Choi et al. was used to examine the biases in these surveys.

RESULTS: Of the 4,768 articles captured by the search, 200 articles were included in the final review. The number of questions in a survey ranged from 2 to 82 (mean, 14
questions). The mean percentage of biased questions in a survey questionnaire was 19%. Flaws that could have a considerable impact on responses, such as leading questions (0.3%) and double-barreled questions (0.7%), were negligible. Conversely, relatively minor flaws, such as forced choice (8.9%) and end-aversion (4.3%), were more common. When performing a multivariable analysis, we observed no significant differences in the percentage of bias among later years or longer surveys.

CONCLUSION: Overall, surveys in plastic surgery do not contain inherent flaws that impact survey results. This critical review revealed areas of improvement for survey research in this specialty. Given the policy implications of data collected with surveys in measuring physician/patient attitudes, the Plastic Surgery specialty has performed remarkably well in delivering carefully structured surveys that captured attitudes of plastic surgery practices. Alerting Plastic Surgery researchers in the biases in past surveys assures an even more robust application of this essential survey tool.

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Textbook Versus Digital Simulation for Cleft Surgery Education: A Prospective, Randomized, Blinded Trial

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BACKGROUND: Digital and online resources play a major role in surgical education. However, the educational value and effectiveness of these resources have not been critically evaluated in the field of cleft surgery. We present a prospective, randomized, blinded trial comparing the educational efficacy of a textbook versus digital simulation in teaching novice learners the surgical markings for cleft lip repair.

METHODS: Novice learners (N = 35) were asked to draw cleft lip repair markings on a standardized patient photograph of a cleft deformity (Pretest). Subjects were then randomized to one of two educational tools for cleft markings: textbook (n=17) or digital simulation (n=18). Participants were given 20 minutes of study, and then asked to draw cleft lip repair markings a second time on the same standardized photograph (Posttest). They were then exposed to the educational tool provided to the other study group and asked to complete a validated survey comparing the educational value of both resources. Cleft lip markings were graded in a blinded fashion twice, using a 10-point scale created by two senior cleft surgeons. Paired and independent t-tests were used to compare differences between groups. Inter and Intra-rater reliability was evaluated using intra-class correlation coefficients (ICC).

RESULTS: Intra-rater reliability was excellent for both pretest (ICC = 0.94; p<0.001) and posttest (ICC = 0.95; p<0.001) grading. Pretest performances between the textbook and simulator groups were comparable (0.82 ± 1.17 vs. 0.64 ± 0.95; p=0.31). There was significant improvement in posttest performance compared to pretest in both the textbook (3.50 ± 1.62 vs. 0.82 ± 1.17; p<0.001) and simulator (6.44 ± 2.03 vs. 0.64 ± 0.95; p<0.001) groups. However, significantly greater improvement was demonstrated by the simulator group when compared to the textbook group (5.81 ± 2.01 vs. 2.68 ± 1.49; p<0.001). Participants thought the simulator increased interest (3.91 ± 1.01 vs. 2.31 ± 1.21; p<0.001), allowed learning (3.83 ± 0.95 vs. 2.17 ± 1.20; p<0.001), was stimulating (3.74 ± 0.98 vs. 1.69 ± 0.87; p<0.001), clearer (3.66 ± 1.08 vs. 2.17 ± 1.22; p<0.001), effective in teaching (4.14 ± 0.94 vs. 2.31 ± 1.21; p<0.001) and likely to be recommended to others (4.00 ± 1.11 vs. 2.14 ± 1.19; p<0.001) more than the textbook.

CONCLUSION: A prospective, randomized, blinded trial demonstrates superior cleft lip repair markings education though digital simulation compared to textbook. Participants subjectively found digital simulation to be a superior educational platform. Our findings highlight the need to invest in these digital resources to teach the next generation of cleft surgeons.