

## Level of evidence of plastic surgery clinical research in Saudi Arabia

Osama A. Samargandi, MD, Asim M. Makhdom, MSc (c), MD,  
Manraj Kaur, MSc, Basim A. Awan, MD, FRCSC,  
Achilleas Thoma, MSc, MD.

Over the last 3 decades, there has been growing awareness and acceptance of the practice of evidence-based surgery.<sup>1</sup> However, arguably not all clinical research is performed in a methodologically rigorous manner that could be translated to everyday practice. Level of evidence (LOE) is used to classify the studies based on their methodological characteristics and quality.<sup>1,2</sup> We set out to examine the LOE of published surgical literature in the Kingdom of Saudi Arabia (KSA), which was specific to plastic surgery. Subsequently, we aimed to further compare our results to the LOE of plastic surgery in North American and European journals. We also aimed to compare our results to the LOE of orthopedic surgery in KSA.

An electronic search was conducted in June 2012 to retrieve plastic surgery-related clinical studies published by authors affiliated with the academic and government institutions within KSA. A list of all Saudi plastic surgeons that were affiliated with the main universities and hospitals in KSA was obtained. Afterwards, a manual search tracking the names and institutions of the surgeons was conducted in the PubMed database for all studies published by Saudi plastic surgeons between January 1990 and May 2012 was performed. The inclusion criteria were studies co-authored by plastic surgeons affiliated to institutions (academic/private) in KSA. Studies published in a language other than English were excluded. Two independent reviewers scanned titles and abstracts of the retrieved studies for their eligibility. Full text of the article was obtained, and in case of discrepancy, the conflict was resolved by discussion. The included articles were categorized according to their study design. Basic science studies (that is, bench work, animal and cadaveric studies), instructional course lectures, editorial correspondence (including discussions, and letters to the editor) were

excluded from the final review. The Oxford Centre for Evidence-Based Medicine (CEBM) - Levels of Evidence scale ([http://www.cebm.net/level\\_of\\_evidence.asp](http://www.cebm.net/level_of_evidence.asp)) was used to determine the LOE in the studies included in the review. A head-to-head comparison of the LOE of plastic surgery articles originating in KSA was performed to the LOE in 4 major plastic surgery journals in North America and Europe with similar exclusion criteria.<sup>3</sup>

Similarly, we compared the results of our study to the LOE of Saudi orthopedic publications over the last 2 decades using similar eligibility criteria.<sup>4</sup> The frequencies of different study designs and the LOE in different plastic surgery journals were determined. The weighted average of the LOE was calculated. The difference in the means was compared using unpaired t test, while chi-square test was used to compare between proportions. A  $p < 0.05$  and confidence interval of 95% were considered statistically significant. A kappa statistic was calculated to provide an estimate of agreement between reviewers. The data were analyzed using the Statistical Package for the Social Sciences version 16 (SPSS Inc, Chicago, IL, USA).

Three hundred and three studies published by 29 plastic surgeons in KSA between January 1990 and May 2012 were retrieved. Of these, 246 (81%) studies met the inclusion criteria and were included in the LOE evaluation. The level of agreement between the 2 reviewers was excellent (kappa=0.893). The most common type of study design was case series (41.9%), followed by case reports (38.6%), and retrospective studies (9.8%). Cross-sectional studies, genetic screening, epidemiological studies, and prospective cohort studies made up the remainder. No randomized controlled trials or meta-analyses were found in our search. Level IV studies make up 91% of the total publications, followed by level III (5.6%), and level II (2.4%). The average level of evidence was 3.89. Sixty-five studies were published from 1990 to 2000, and 181 studies were published from 2001 to May 2012. The average LOE in the studies published between 1990 and 2000 was 3.92, and 3.89 in the studies published between 2001 and May 2012. There was no statistically significant difference when comparing the average LOE between the last 2 decades ( $p=0.55$ ). Furthermore, the LOE in plastic surgery studies published in KSA was found to have lower proportions of level I, level II, and level III, compared with the results of the review by Sinno et al<sup>3</sup> (Table 1). In contrast, no statistically significant difference between the LOE of plastic and orthopedic literature in KSA was noted<sup>4</sup> (Table 1).

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**Table 1** - The level of evidence (LOE) of Saudi plastic studies compared with the LOE of major journals in plastic surgery in 2007,<sup>3</sup> and LOE of Saudi orthopedic studies<sup>4</sup> over the last 2 decades.

Level of evidence	LOE in the current study	LOE in Sinno et al study <sup>3</sup>	P-value	95% confidence interval	LOE in Makhdom et al study <sup>4</sup>	P-value	95% confidence interval
I	0 (0.0)	16 (3.0)	N/A	N/A	4 (3.0)	N/A	N/A
II	6 (2.4)	118 (16.0)	<0.0001	0.0983 - 0.1708	9 (6.0)	0.214	-0.0097 - 0.0856
III	14 (5.6)	301 (41.0)	<0.0001	0.3048 - 0.4018	8 (5.0)	0.853	-0.0488 - 0.0537
IV	226 (91.0)	291 (40.0)	<0.0001	0.4611 - 0.5643	138 (86.0)	0.700	-0.0219 - 0.1148

n (%), NA - not applicable

The most important finding from this review was that most of the studies published by plastic surgeons affiliated with Saudi Arabian institutions belonged to low level evidence (level IV), and the most common type of study was case series (41.9%). Interestingly, these findings do not deviate from the overall state of evidence in plastic surgery.<sup>1-3</sup> Randomized controlled-trials (RCTs) are the highest quality study designs, that aim to measure the real efficacy of an intervention by eliminating confounders and other intruding factors. If RCTs are conducted in high quality design, they will be ranked at the top of the hierarchy of evidence. However, such RCTs are fraught with numerous challenges in surgery.<sup>5</sup> It is difficult and sometimes unethical to assign patients into control group due to the unnecessarily associated morbidity.<sup>5</sup> The rarity of certain congenital conditions encountered may result in low sample sizes, resulting in the study being underpowered.<sup>2</sup> In such circumstances, the only option available to the academic surgeons is to conduct retrospective studies. Orthopedic surgery is known to have relatively higher LOE studies compared with plastic surgery.<sup>3</sup> However, we found no statistically significant difference when the LOE of plastic studies was compared to the LOE of orthopedic studies in KSA.<sup>4</sup> This highlights the limitations in terms of research methodology education programs and funding in KSA. Makhdom et al<sup>4</sup> proposed that the lack of interest in conducting RCTs in KSA might be attributed to lack of financial support, availability of trained support personnel, and relative absence of research incentives (research grants or awards) as the reasons for the persistent low quality orthopedic evidence. These factors along with the amount of planning and methodological considerations that go into designing RCTs play a major role in the low level of evidence research.

Our study has some limitations. During our online search to track surgeons' names and institutions in KSA, we restricted our search to PubMed database, we might have missed studies that are not indexed in PubMed. Nevertheless, as there are no dedicated

plastic surgery journals in KSA, there was no alternative efficient method to avoid this problem. Moreover, our comparison to the LOE of orthopedic Saudi studies might not reflect the overall LOE of the other surgical specialties in KSA. However, to date there are no published surgical LOE studies in KSA that were indexed in PubMed other than Makhdom et al study.<sup>4</sup>

In conclusion, low level of evidence has dominated the plastic surgery literature for the last 2 decades in KSA. Surveying the surgical staff, faculty, and residents should be designed to assess the perceived local barrier to high quality research and strategies to overcome these barriers should be implemented.

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From the Division of Plastic and Reconstructive Surgery, Department of Surgery (Samargandi, Awan), Faculty of Medicine, the Department of Orthopedic Surgery (Makhdom), King Abdulaziz University, Jeddah, Kingdom of Saudi Arabia, and the Division of Orthopedic Surgery (Makhdom), McGill University Health Center, Montreal, Quebec, and the Department of Surgery (Kaur), the Division of Plastic Surgery (Thoma), Surgical Outcomes Research Centre (SOURCE), Department of Surgery, Department of Clinical Epidemiology & Biostatistics, McMaster University, Ontario, Canada. Address correspondence and reprints request to: Dr. Osama A. Samargandi, Division of Plastic and Reconstructive Surgery, Department of Surgery, Faculty of Medicine, King Abdulaziz University, PO Box 80215, Jeddah, Kingdom of Saudi Arabia. Tel: +966 (12) 6408346. E-mail: Osamargandi@gmail.com

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