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# Effect of high intensity focused ultrasound on abdominal skin laxity post sleeve gastrectomy

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## Abstract

The incidence of skin laxity is reported as complications of bariatric surgery. Redundant skin following significant weight loss is a common occurrence affecting up to 96% of patients who undergo bariatric surgery, negatively impacting physical and psychosocial health and detracting from activities of daily living. The purpose of the study was to examine the therapeutic impact of High intensity focused ultrasound (HIFU) in treatment of abdominal skin laxity post sleeve gastrectomy. Eighty-six female patients who had abdominal skin laxity post sleeve gastrectomy participated in the study. They aged from 30 to 45 years. They were recruited from El Kasr El Aini hospital and randomized into two groups of the same number, group (A) includes 43 patients who had abdominal skin laxity post sleeve gastrectomy and who received high intensity focused ultrasound plus medical topical firming creams patients received one session per month for 40 minutes per session with frequency 7-2MH, focal depth 1.5-9 mm, energy 1.0-1.5 J, and group (B) includes 43 patients who had abdominal skin laxity post sleeve gastrectomy and who received medical topical firming creams, improvement in skin laxity appearance was done by using Investigator Global Aesthetic Improvement Scale (IGAIS). And assessment of abdominal skin laxity by improvement in skin tone was done using the modified tissue tonometer. All measurements were collected pre and post treatment. The mean ±SD Abdominal skin laxity post treatment of the group (A) was 7.52±1.22 and that of the group (B) was 4.12±0.31. The mean difference among both groups was 3.4. There was a *statistically* significant difference improvement in the Abdominal skin laxity of the group (A) in comparison with that of group (B) post treatment ($P < 0.001$). HIFU is beneficial in treatment of abdominal skin laxity.

**Keywords:** High intensity focused ultrasound, skin laxity, sleeve gastrectomy, weight loss, sagging skin.

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## 1. Introduction

Among the most common modern bariatric procedures, sleeve gastrectomy, was originally the first part of a two-stage surgery called biliopancreatic diversion along with duodenal switch that was carried out in 1990. Laparoscopic sleeve gastrectomy was initially carried out in 1999. In patients with excessive obesity (BMI>60), sleeve gastrectomy was initially indicated to cause weight loss for the purpose of performing the 2nd stage of biliopancreatic diversion with greater safety via duodenal switch [1]. The sleeve gastrectomy is among the most popular weight loss operation in the United States because it is technically simpler and has fewer morbidity than other weight loss treatments [2]. Significant weight reduction is the loss of half or more of an individual's additional body weight. Many people who have lost a significant amount of weight through bariatric surgery are unsatisfied with the loose, redundant skin and contour drawbacks that have been left. [3-4]. The occurrence of sagging skin is an identified complication associated with operations aimed at reducing body weight. The sudden alteration in body mass index (BMI) subsequent to rapid weight reduction diminishes skin elasticity and induces insufficient retraction of excessive soft tissue, hence causing the presence of redundant skin. [5]. The most typical areas for skin surplus to accumulate are the stomach, upper arms, inner thighs, as well as back. Women are more likely than men to have excess skin on their upper arms, thighs, as well as flanks, according to research by Biörserud et al conservative treatments are preferred by patients because they require less time in recovery and involve fewer hazards than surgical procedures [6]. Abdominal skin laxity is a common side effect of massive weight loss after sleeve gastrectomy. This is caused by a combination of factors, including epidermal thinning, dermal connective tissue loss, as well as atrophy/redistribution of subcutaneous fat. [7] Skin laxity is

a common side effect of bariatric weight loss, and it may necessitate plastic surgery to correct. [8] Effects on tissue from HIFU. There are both non-Thermal along with Thermal physiological and biological impacts of HIFU. Ultrasounds can have damaging thermal effects on tissue, including raising the temperature above 42 degrees Celsius, which may improve blood flow and improve the extensibility of collagen fibers. Repair of fibroblasts and collagen formation can be shown in vitro owing to the non-thermal effects of localized ultrasounds, which cause a realignment of fibroblasts through acoustic micro streaming-induced alterations in pressure in tissue fluids. When the pressure in the desired tissue changes, a phenomenon known as acoustic micro streaming develops, in which fluids travel in just one direction through cell membranes. Consequently, the tissue oxygenation improves [9]

This study may provide a safe, effective and non-invasive treatment modality for abdominal skin laxity post sleeve gastrectomy, in an attempt to avoid invasive modalities and surgical interventions that have another sedation and recovery time.

## 2. MATERIALS AND METHODS

### *2.1 Study design*

All aspects of the study were disclosed and informed consent was obtained. The patients were randomly assigned into two equal groups via the envelope mode. After patients' agreement to participate in the study, cards with either "HIFU group" or "control group" recorded on them were closed in envelopes; then a blinded physical therapist was asked to select one envelope. According to the selected card, patients were assigned to their corresponding group. Dates for starting the allocated therapy were regulated and the therapy began after the first week of randomization. The examiner physical therapist was not included in randomization procedures and was unaware of the therapy allocation. Patients were asked not to disclose their therapy allocation to the physical therapist during assessment. The participants were informed to report any harmful effects throughout the treatment period.

### *2.2 Sample size determination*

Sample size calculation was performed using G*POWER statistical software (version 3.1.9.2; Franz Faul, Universitat Kiel, Germany) and revealed that the required sample size for this study was 43 subjects per group. Calculations were made using $\alpha$=0.05, power = 90% and effect size =0.74and allocation ratio N2/N1 =1.

### *2.3 Subjects*

Eighty-six female patients who had post sleeve gastrectomy abdominal skin laxity participated in this study. They were aged from 30 to 45 years. The individuals were recruited from El Kasr El Aini hospital and randomly distributed into two equal groups. Patients were enrolled in the trial if they met the following criteria: (1) Female gender with age range between 30 to 45 years participated in this study. (2) All patients had post sleeve gastrectomy abdominal skin laxity mild to moderate degree based on skin laxity scale. Patients were excluded if they had acute viral diseases, acute tuberculosis, and mental disorders. The elderly, especially those with advanced photoaging and severe skin laxity. Skin lesions at the desired location. A severe case of acne, maybe with cysts. metallic implants within the treated area. Genetic disease Skin infectious diseases. Sociological diseases. Pregnant.

### *2.4 Outcome measures*

#### *2.4.1 Investigator Global Aesthetic Improvement Scale (IGAIS)*

IGAIS was used for assessing the improvement in skin laxity appearance post treatment period, which lasted for 4 weeks. The scale ranges from 0 to 3 as 0 = No change, 1 = Mild improvement, 2 = Moderate improvement, 3 = Significant improvement.

#### *2.4.2 The modified tissue tonometer (MTT)*

MTT was utilized before the beginning of treatment and again following the 4-week period. Mark multiple points to be measured. Include an equivalent normal skin point(s). Prepare patient template taking particular care to record permanent bony surface points. Apply the MTT baseplate directly to the tissue through the holes in the template. Hold MTT vertically, with bubble of spirit level centered. Ensure no extra downward pressure is applied while resting the device on the tissue. Record the depression of the plunger in millimeters after 6 seconds. The patient must be able to remain immobile when the MTT is in contact. Repeat each point three times with at least 2 minutes' "rest" between attempts. Recalibrate the device to zero on a solid surface between each set of measures. To determine longitudinal change in measures, comparison of averaged score for individual points is appropriate and/or analysis of the change of individual sagging points difference from normal skin control point(s).

#### *2.4.3 Intervention*

A total of 86 patients were randomized into 2 groups of the same number. All participants in both groups were given a verbal explanation of the study's purpose, significance, and methodology. Prior to starting the study, every participant provided written informed consent.

**Group (A)** This group includes 43 patients who had abdominal skin laxity post sleeve gastrectomy and who received high intensity focused ultrasound. Plus, medical topical firming creams patients received one session per month for one month; the time of session is 40 minutes.

**Group(b)** This group includes 43 patients who had abdominal skin laxity post sleeve gastrectomy and who received medical topical firming creams.

Both groups received topical firming cream treatment for 1 month. The experimental group (High intensity focused ultrasound group) additionally received HIFU. pre-treatment preparation and applied a topical anesthetic cream to all treated areas of the abdomen, we would use a HIFU device transducer for body skin tightening with a frequency of 2 MHZ and focal depth of 7-9 mm, Ultrasound gel would be applied to the treated area and the transducer of HIFU was pressed perpendicularly, uniformly, and firmly to the skin surface. Treatment exposure would be initiated with a line of individual ultrasound pulses. The pulse duration for each exposure ranged from 25 to 40 milliseconds. The energy per ultrasound pulse would range from 1.0 to 1.5 J. If patients reported feeling pain, we would reduce exposures to 0.1–0.3 J per time, and we would not increase exposures up to 1.5 J.

The time required for complete HIFU treatment of the abdomen would be from 20- 40 minutes**.** All patients would be followed up at 4 weeks after treatment**.**

### *2.5 Statistical analysis*

Unpaired t-test was conducted for comparison of age between groups The Mann-Whitney test was employed to compare the variables of Age, Abdominal skin laxity (pressure), as well as skin laxity (appearance) among the two groups prior to and following treatment. Normal distribution of data was checked using the Shapiro-Wilk test. The Wilcoxon test was conducted for comparison between pre-treatment and post-treatment measurements of Abdominal skin laxity in group B. The level of significance for all statistical tests was set at P. value < 0.05.

## 3. Results and Discussion

### *3.1 Subject characteristics*

Eighty-six patients with abdominal skin laxity post sleeve gastrectomy participated in this study.

Table (1) showed patient's demographic data (age), the mean ±SD age of group (A) was 41.42±4.09 years, with minimum value of 33 years and maximum value of 45 years. The mean ±SD age of group (B) was 40.28±3.53 years, with minimum value of 33 years and maximum value of 45 years. There was no significant difference in the mean age values between both groups (P =0.09).

### *3.2 Pre-treatment mean values of Abdominal skin pressure of both groups (A and B)*

Prior to treatment, both groups had mean SD Abdominal skin laxity values of 4.23±0.42 and 4.10±0.23, respectively. The mean difference between the two groups was 0.13. When comparing group, A and group B before treatment, abdominal skin pressure did not differ significantly which means there is no different in both group skin laxity (P = 0.27). (Table 2).

### *3.3 Pre and post treatment mean values of Abdominal skin pressure of group A*

Group A had a pretreatment mean SD of 4.23±0.42 for abdominal skin pressure , whereas group B had a post-treatment mean SD of 7.521.22. There was a -78% increase in the mean difference to -3.29. Abdominal skin pressure was significantly higher in Group A after treatment compared to Pre-treatment so there is significant increase in skin tightness and significant decrease in skin laxity (P< 0.001). (Table 3)

### *3.4 Pre and post treatment mean values of Abdominal skin pressure of group B*

Prior to treatment, group B had a mean of 4.10±0.23 in abdominal skin pressure , and following treatment it was 4.12±0.31. The change percentage was 0.49%, whereas the mean difference was 0.02%. In group B, there was no statistically significant difference between pre- and post-treatment scores for abdominal skin pressure so there is no significant change in abdominal skin laxity (P= 0.65). (Table 4).

### *3.5 Post treatment mean values of Abdominal skin pressure of both groups (A and B)*

After treatment, group (A) had a mean of 7.52±1.22 mmhg of abdominal skin pressure , while group (B) had a mean of 4.12±0.31 mmhg. The mean difference among the groups was 3.4. After treatment, a statistically significant difference has been detected between groups (A) and (B) in terms of abdominal skin pressure which means significant difference improvement in group A skin laxity (P< 0.001). (Table 5).

### *3.6 Post treatment distribution of skin laxity improvement of both groups (A and B)*

As revealed in table (6), group (A) showed that in terms of skin laxity , there was a statistically significant (P<0.001) difference among the two groups.

### *3.7 Ethical approval*

The research related to human use has complied with all the relevant national regulations and institutional policies; this trial was assented by the Ethical Committee of the Faculty of Physical Therapy, Cairo University. The study was retrospectively registered in the Clinical Trials Registry approval (No.: (NCT05994079).

### *3.8 Informed consent*

Informed consent has been obtained from all individuals included in this study. The main findings of the current study indicated considerable differences in the obtained data for abdominal skin laxity pre and post treatment application (in the group of HIFU) the skin of individuals who have lost weight due to bariatric surgery. [11]. Loss of collagen, breakdown of elastin fibers, and dehydration contribute to the dermal atrophy seen in sagging skin. [12]. Morbid obesity is associated with chronic inflammation, which has severe impacts on the skin. Massive weight loss following bariatric surgery can reduce or halt metabolic syndrome damage, but it may additionally aggravate the skin's clinical condition. Skin laxity after bariatric surgery creates significant challenges for cosmetic surgeons [13]. In young individuals with proper wound healing as well as BMI of fewer than 30 kg/m2, HIFU has been demonstrated to be an effective treatment for mild to moderate skin laxity. As the clinical outcome is partly tied to collagen neo-synthesis, nevertheless, older patients with extremely high levels of skin laxity or photoaging are not considered the fair candidates and should not be provided this treatment option. [14]. A total of 32 Korean patients with facial, abdominal, as well as thigh skin laxity were chosen for the study by Ko E.J. et al., [15]. who concluded that HIFU safely and successfully enhances skin elasticity as well as clinical contouring of both the face and the body. The hospital's ethics committee at Chung-Ang University gave their approval to the study. All patients gave their informed consent. Patient exclusion criteria included a history of infection or inflammation of the skin, pregnancy, skin illnesses that may disrupt wound healing, open wounds, as well as scarring across the treatment region, as well as any previous cosmetic or surgical procedures (such as laser, RF, surgical lifting, filler infusions). Both cheeks, the lower belly, and the back of the thigh were anesthetized before the procedure began with a topical anesthetic lotion.

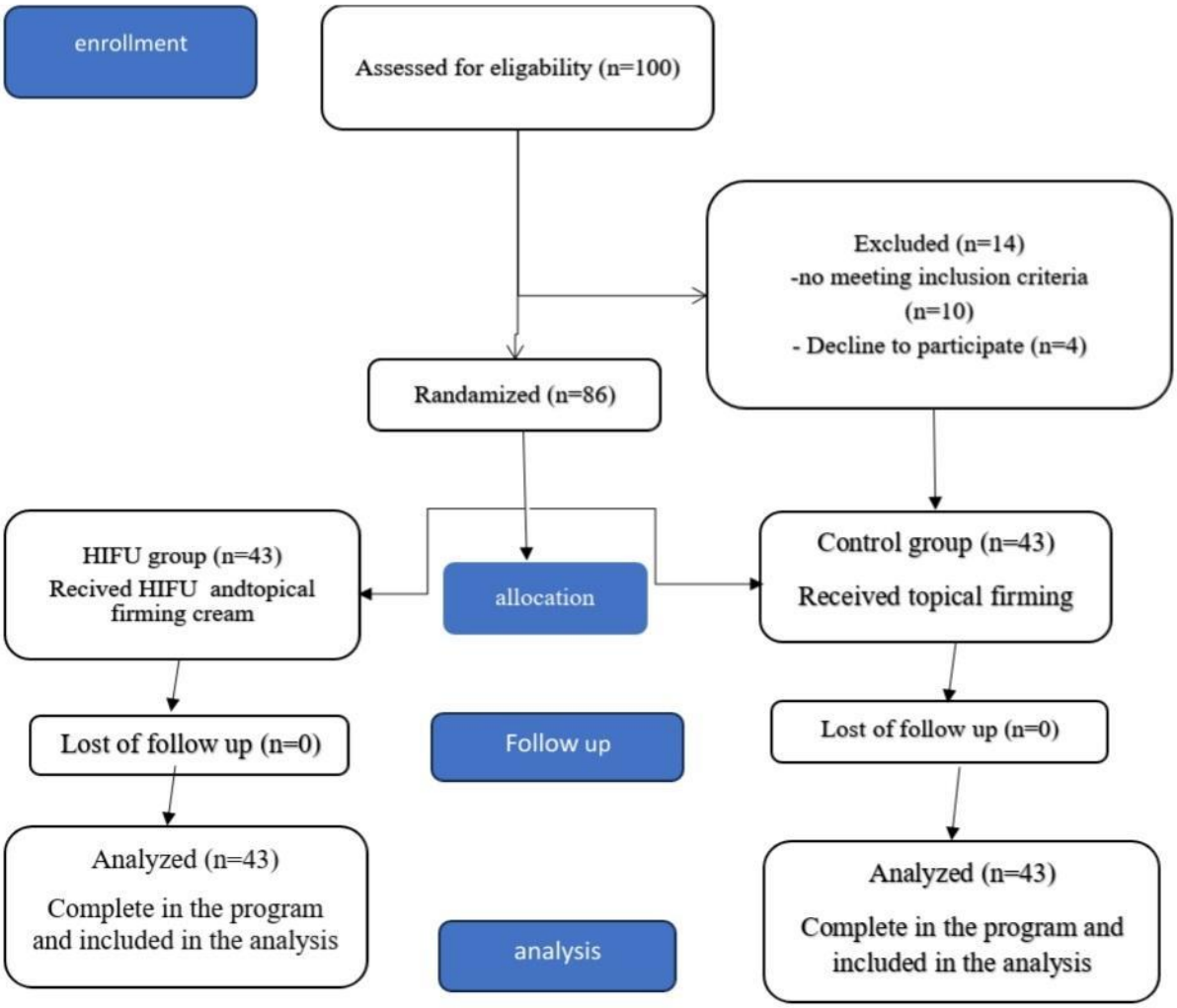


**Fig 1:** Flow chart of the study

**Table 1:** Comparison of mean values of age between the group A and B

| Age | Group A | Group B |
|---|---|---|
| $\overline{X}$ ± SD | 41.42±4.09 | 40.28±3.53 |
| **Minimum** | 33 | 33 |
| **Maximum** | 45 | 45 |
| **U. value** | 728 | |
| **P. value** | 0.09 | |
| **Significance** | NS | |

**x̄: Mean** **SD: Standard deviation** **U.value: Mann-Whitney value**
**P. value: Probability value** **NS: Non-significant**

**Table 2:** Comparison of pre- treatment mean values of Abdominal skin pressure between group A and B

| Abdominal skin pressure | $\overline{X}$ ± SD | MD | U. value | P. value | Sig |
|---|---|---|---|---|---|
| **Group A** | 4.23±0.42 | 0.13 | 824 | 0.27 | NS |
| **Group B** | 4.10±0.23 | | | | |

**x̄: Mean** **SD: Standard deviation** **MD: Mean difference**
**U. value: Mann-Whitney value** **P. value: Probability value** **NS: Non-significant**

**Table 3:** Comparison between pre- and post-treatment mean values of Abdominal skin pressureity of group A

| Abdominal skin pressure | $\overline{X}$ ± SD | MD | % of change | Z. value | P. value | Sig |
|---|---|---|---|---|---|---|
| **Pretreatment** | 4.23±0.42 | -3.29 | 78 | -5.72 | < 0.001 | S |
| **Post treatment** | 7.52±1.22 | | | | | |

**x: Mean** **SD: Standard deviation** **MD: Mean difference**
**Z. value: Wilcoxon value** **P. value: Probability value** **S: Significant**

**Table 4:** Comparison between pre- and post-treatment mean values of Abdominal skin pressure of group B

| Abdominal skin pressure | $\overline{X}$ ± SD | MD | % of change | Z. value | P.value | Sig |
|---|---|---|---|---|---|---|
| **Pretreatment** | 4.10±0.23 | 0.02 | 0.49 | -0.45 | 0.65 | NS |
| **Post treatment** | 4.12±0.31 | | | | | |

**x̄: Mean** **SD: Standard deviation** **MD: Mean difference**
**Z. value: Wilcoxon value** **P. value: Probability value** **NS: Significant**

**Table 5:** Comparison of post treatment mean values of Abdominal skin pressure between group A and B

| Abdominal skin pressure | $\overline{X}$ ± SD | MD | U. value | P. value | Sig |
|---|---|---|---|---|---|
| **Group A** | 7.52±1.22 | 3.4 | 3.5 | < 0.001 | S |
| **Group B** | 4.12±0.31 | | | | |

**x̄: Mean** **SD: Standard deviation** **MD: Mean difference**
**U. value: Mann-Whitney value** **P. value: Probability value** **S: Significant**

**Table 6:** Frequency distribution and comparison of skin laxity Percentile between group A and B

| skin laxity | Group A | Group B | U value | P. value | Sig |
|---|---|---|---|---|---|
| **Grade 0** | 0 (0) % | 43 (100) % | 0.00 | < 0.001 | S |
| **Grade 1** | 8 (18.6) % | 0 (0) % | | | |
| **Grade 2** | 35 (81.4) % | 0 (0) % | | | |

**U.value: Mann-Whitney value** **P. value: Probability value** **S: Significant**

Areas affected were 7.5 x 7.5 centimeters on the lower abdomen and thighs, and 5.0 x 5.0 centimeters on each cheek. One standard transducer (MF1; 7 MHz; 1.5 mm focal depth) was utilized for facial skin tightening up, and 4 newly designed transducers (MF3; 2 MHz; 3 mm focal depth; MF4; 2 MHz; 4.5 mm focal depth; MF6; 2 MHz; 6 mm focal depth; as well as MF9; 2 MHz; 9 mm focal depth) were utilized for body skin tightening up. After applying ultrasound gel to the affected area, the HIFU transducers were placed firmly but uniformly against the skin at a perpendicular angle. The treatment began with a series of ultrasonic pulses. Each exposure had a pulse duration of between 25 and 40 ms. Exposure lines of ultrasonic pulses, each 25 mm in length, were manually administered next to and parallel to each other, with around 3-5 mm between them. Subjects were treated with a variety of transducers suited to different skin depths. The face was treated with three transducers (MF1, 3, and 4), while the other five (MF1, 3, 4, 6, and 9) were administered to the body. Ultrasound pulses typically carry between 1 and 1.5 J of energy. When patients complained of pain, clinicians lowered their exposures to between 0.1 and 0.3 J per session, rather than the maximum of 1.5 J. There was a total of 537.6 J distributed between 120 cheek shots and 450 abdominal as well as thigh shots in the treatment lines. It took longer than 40 minutes for the full HIFU treatment of the face as well as body. Using experimental data collected from dermatologists as well as patients, Saket, P. et al. [16] demonstrated that HIFU seems to be a safe and beneficial technique for treating skin laxity.

Choi SY et al., [17] showed that HIFU can successfully tighten the dermis and subdermal skin without causing any adverse effects.

Frank M. and Saedi N. [18] found that HIFU may effectively tighten the skin in targeted "problem areas" without causing any damage to the surrounding tissue, suggesting that this technique has significant promise for noninvasive body sculpting. Minimal downtime and side effects are associated with less than an hour of treatment. A single treatment is sufficient to produce visible effects. HIFU is a hopeful new method that we are just starting to learn more about. **Shek et al.** [19] reported on a study in which 12 healthy males and females (with BMIs below 30 kg/m2) had 161 J/cm2 applied to their front abdomens. Shalom et al. [20] found that when HIFU was applied to one side of the abdomen as well as a placebo was applied to the other, there was a 2.1-centimeter reduction in waist circumference at 12 weeks among six healthy adults with a mean BMI of 25.5 kg/m2. Before having abdominoplasty, these patients were monitored for efficacy as well as laboratory abnormalities for 28 days following treatment. The surgery did not result in a statistically significant rise in lipids, liver enzymes, or any other measure of clinical chemistry. Histopathology results on skin sent for treatment during abdominoplasty revealed fat necrosis with infiltration of lymphocytes as well as macrophages without causing injury to adjacent tissues. No anesthetics were administered in advance, and pain was rated on a visual analog scale from 0 to 7 throughout the surgery. The mean level of pain was 3. 5 out of 7. Mild erythema or abrasions appeared on four patients (67%), but these resolved within a few hours to a few days.

Solish et al., [21] compared the efficacy of HIFU at varying fluences for fat reduction. In addition, HIFU has been shown to be an effective method for treating skin laxity by Jewell ML et al., [22-23]. Following 3 months of treatment with HIFU using a mean energy level of 134.8 J/cm2, Fatemi and Kane [24] demonstrated that the mean waist circumference decreased by 4.6 cm. In conclusion, Physiotherapists, and other medical practitioners, according to the findings of the present study, should seriously evaluate the effects of HIFU for the management of skin laxity as well as skin tightening. Additional studies are needed, according to the authors of this study note before this can be regarded definitively successful.

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**Disclosure statement**

No author has any financial interest or received any financial benefit from this research.

**Conflict of interest**

No potential conflict of interest relevant to this article was reported.

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