Invited Discussion on “Body Contouring using a Combination of Pulsed Ultrasound and Unipolar Radiofrequency: A Prospective Pilot Study”

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Although plastic surgery procedures for aesthetic purposes decreased by nearly an 11% overall in 2020, due to temporary closure of private practice centers during the COVID-19 pandemic, liposuction remains, after breast augmentation, the second most common aesthetic procedure, representing 15.1% of all procedures worldwide.

This demand for body contouring is rapidly increasing, and interest in noninvasive approaches has also grown. In fact, non-surgical fat reduction is among the five non-surgical procedures representing nearly the 4% of all them [1].

There are many devices that use radiofrequency to reduce the localized subcutaneous adipose tissue [3]. Accent (Alma Lasers, Buffalo Grove, IL) is another unipolar radiofrequency device. In a study conducted by Emilia del Pino et al in 2006, the results revealed that 68% of patients had a volume contraction of 20% in thighs and buttocks (EBM IV) after two treatment sessions 15 days apart [4]. Following this line, Goldberg et al performed 6 fortnightly treatment sessions in 2008, concluding that 27 of the 30 patients showed improvement, and the mean reduction in thigh circumference was 2.45 cm [5].

While using another non-surgical fat reduction procedure like cryolipolysis, the complications reported from the published series in 2009 and 2012 revealed relatively few long-term sequelae. The main reported side effects were transient erythema and sensory changes that resolved reasonably quickly [6–8]. Nevertheless, more than 3 years from its introduction in the market, the first published cases of paradoxical adipose hyperplasia associated with cryolipolysis [9] appeared.

Renuvion/J-Plasma devices use RF energy and helium to create plasma to cut, coagulate and eliminate soft tissue with heat during surgery. While in 2019 Renuvion had
promised as a safe and effective method for skin rejuvenation and deep soft tissue contraction [10], in March 2022 FDA warned against the use of Renuvion. The FDA received reports describing serious adverse events (SAEs) when the device is used directly on the skin and potentially life-threatening adverse events (AEs) when it was used under the skin. The AEs reported were second- and third-degree burns, infection, change in skin color, scars, nerve damage, significant bleeding, and air or gas accumulation under the skin, in body cavities, and in blood vessels causing admissions to the intensive care unit in some patients.

This new device (Alma prime X) is the first device, up to date and to our knowledge, in combining pulsed non-focused ultrasound and unipolar radiofrequency to improve results in inducing apoptosis in subcutaneous adipose cells and reducing the fat thickness with mild posttreatment symptoms, with no added down-time and or adverse events [11]. This study seems to offer positive and promising results in reducing the thickness of the adipose tissue layer with a total absence of adverse events but the follow-up is certainly too short (3 months), warranting a cautious attitude.

We have also missed a comparison of the results between the group of men and women as it is well known the gender differences in the adipose tissue metabolism. The following differences may play a role in the variation in net regional fat storage between men and women. There is evidence of a more pronounced difference in catecholamine-mediated lipolysis between upper body and lower body fat depots in women than in men. Free fatty acid release by the upper body subcutaneous fat depots is higher in men than in women, indicating a higher resistance to the antilipolytic effect of meal ingestion in the upper body fat depots in men. Also, there is a higher fat storage in women due to lower basal fat oxidation in females as compared to males. Finally, postprandial fat storage may be higher in subcutaneous adipose tissue in women than in men, whereas storage in visceral adipose tissue has been hypothesized to be higher in men [12].

The noninvasive device market needs further controlled, randomized and prospective studies to evaluate the long-term effectivity and, mostly, the safety of these devices. We also need these studies to compare devices to identify which technology provides the higher benefit in terms of outcomes, safety and lack of paradoxical events for patients given the previous experience with novel and apparently innocuous devices.

**Declarations**

**Conflict of interest** The authors declare that they have no conflicts of interest to disclose.

**Human and Animal Rights** This article does not contain any studies with human participants or animals performed by any of the authors.

**Informed Consent** For this type of study, informed consent is not required.

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