Response to: Additional Thoughts on a Topical Body Firming Moisturizer for Upper Arm Rejuvenation

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We thank the letter's author for his/her knowledgeable comments regarding our study, which was registered with clinicaltrials.gov and can be found under the following ID: NCT04065035.[1-3] The Consolidated Standards of Reporting Trials is intended to "improve the reporting of parallel-group randomized controlled trial, enabling readers to understand a trial's design, conduct, analysis and interpretation, and to assess the validity of its results."[4] Although we did not specifically employ the Consolidated Standards of Reporting Trials reporting tool, we believe we met the scientific rigor of those standards and certainly did not intentionally deviate from them.

The primary outcome measure is the outcome an investigator considers most important in a studys.[5] Our objective was to evaluate the efficacy and tolerability of the topical body firming moisturizer (TBFM) for upper arm firming and rejuvenation. Because efficacy and tolerability cannot be measured by the same primary outcome, our study included several outcomes to determine efficacy and tolerability of TBFM. These outcomes are delineated in our Methods, including an efficacy evaluation for all patients performed by an experienced and blinded clinical grader at several time points; a self-assessment questionnaire at 2 time points; objective tolerability evaluations by an experienced and blinded clinical grader at several time points; a subjective tolerability self-assessment questionnaire at several time points; measurements of the upper arm circumference with measuring tape and via 3-dimensional imaging; corneometer measurement of skin hydration; ultrasound measurements of skin density; clinical photography assessment; immunohistochemical scoring; epidermal thickness measurements; and elastin-stained biopsies.

We understand the concern regarding our split-body study being paired, rather than randomized, due to possible systemic bioavailability of the active ingredients in TBFM. We believe that the efficacy of topically applied products is through signaling pathways. Our studies on fat cells were performed in an in vitro setting to elucidate the mechanism of action of the adipose-targeting pathways of the ingredients. We were interested in understanding if the adipocyte size would be affected, and therefore, in vitro testing was appropriate. Consequently, the split-body study was more appropriate for this clinical design.

Our study showed that TBFM demonstrates both efficacy and tolerability for upper arm firming and rejuvenation. To our knowledge, this is the first such study designed to evaluate TBFM. We welcome any clinical scientist to replicate our results.

Disclosures

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