Response to "Analysis of spin in the reporting of topical treatments of photoaged skin"

To the Editor: Scientifically rigorous, well-designed clinical studies are important to the authors at NeoStrata Company and dermatologist Dr Patricia Farris. It was, therefore, disappointing to read the article, "Analysis of spin in the reporting of topical treatments of photoaged skin" by Motosko et al,[1] which presented several errors and mischaracterizations of our referenced publications[2,3] and raised serious concerns about the merit of this article. The Motosko article[1] was based on the spin strategies identified by Boutron who evaluated "randomized controlled trials with statistically nonsignificant results for primary outcomes."[4] Our published studies achieved statistically significant results of primary outcomes and, therefore, did not need to employ spin tactics.[2,3] In addition, the authors inaccurately reported results for nasolabial fold improvement in Table III: 1.3% treated versus 0.9% vehicle instead of 10.3% versus 0.9%.[1,3]

Specific examples pertaining to our studies are outlined below on the basis of the top 4 spin strategies presented in the article (Supplemental Table I).[1]

Use of multiple primary outcomes. The referenced articles[2,3] included clinical grading of specific signs of aging as the primary efficacy outcome, which is highly relevant for cosmetic products making comprehensive, appearance-based claims. Because there is no single accepted grading scale that captures multiple signs of skin aging (eg, texture, lines, pigment, laxity), individual parameters were graded and analyzed independently. Results demonstrated that all clinically graded parameters were significantly improved versus vehicle in both clinical studies at the end of the double-blind test period of each study (week 16). As a result, the potential issue of multiplicity had no practical impact for interpretation of these studies and, therefore, should not have been considered a relevant factor for spin.

Inappropriate extrapolation of results from specific outcome to global improvement. Clinically-graded results in dermatology are meaningful only if a patient can appreciate the visible changes of their skin. In accordance, the primary outcome measure in our published studies was clinical grading with results confirmed via self-assessment, which were further supported by photographic and other visualization techniques (eg, surface replicas) to demonstrate (not extrapolate) visible changes. This type of imagery is used in both medical and cosmetic dermatology and should be considered a strength of a well-designed cosmetic clinical study, not a spin tactic.

Focus on within-group comparison. Our publications clearly demonstrated statistically significant ($P < .05$) improvements between treatment groups (treated vs vehicle) and within the treatment group; results were analyzed on the basis of individual scores at each time point and presented as percent change. The criticism regarding use of inappropriate statistical analysis in these articles (Table III) is erroneous.

Focus on interim analyses to give more weight to nonsignificant findings. It appears interim analyses used by Motosko refers to interim data or interim timepoints that are presented. The focus of the referenced NeoStrata publications was the primary outcome, where statistically significant differences were demonstrated at 16 weeks versus vehicle. In addition, predetermined interim timepoints were presented from both studies demonstrating progressive improvement with treatment supporting statistically significant findings during the study and at week 16.[2,3]

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