Response to "Facial Line Outcomes (FLO-11) and Facial Line Satisfaction Questionnaire (FLSQ) Meet FDA PRO Guidance"

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A recent Letter to the Editor by Dr Patel and colleagues, entitled "Facial Lines Outcomes (FLO-11) and Facial Line Satisfaction Questionnaire (FLSQ) Meet FDA PRO Guidance"[1] noted an inaccuracy in a statement in the introduction of our paper entitled, "Significantly Increased Patient Satisfaction Following Liquid Formulation AbobotulinumtoxinA Treatment in Glabellar Lines: FACE-Q Outcomes From a Phase 3 Clinical Trial."[2] In our introduction, we reference 2 review articles by Morley et al[3] and Kosowski et al,[4] both of which note that very few patient-reported outcome (PRO) measures for aesthetic procedures are aligned with the recommendations for the development and validation of PRO measures defined in each review. As an example, we had referred to the US Food and Drug Administration (FDA) criteria for PRO measures, as discussed by Morley et al.[3] Dr Patel and colleagues have highlighted that both of these reviews[3,4] in fact refer to the previous versions of these 2 measures, which have since been updated and developed in accordance with FDA PRO guidance. These PRO measures were the Facial Line Satisfaction Questionnaire (FLSQ; published in 2015)[5] and the Facial Line Outcomes questionnaire (FLO-11; published in 2014),[6] previously named the Facial Line Treatment Satisfaction Questionnaire and the FLO-7 questionnaire, respectively. We would also take this opportunity to refer readers to a recent systematic review of PRO measures for botulinum toxin type A in cosmetic indications for further information.

As noted in the methodology section of our paper, the FACE-Q results are tertiary endpoints from a phase 3 study conducted between January 2015 and August 2015. The protocol of this study was finalized in July 2014 and, as such, predates the validation of the current versions

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of the FLO-11 or the FLSQ. Thus, it holds true that the FACE-Q "was developed specifically to address the lack of available PRO measures." That said, the availability of the FLO-11 and FLSQ would not have altered the decision to use scales from the FACE-Q as outcome measures in our study. In fact, ours was the first to use FACE-Q scales in a large phase 3 study. Based on the validated FACE-Q scales for satisfaction with facial appearance, psychological well-being, and perception of aging, we were able to provide an in-depth analysis of patients' experience and satisfaction with glabellar line appearance across the 6-month follow-up period following injection with liquid formulation abobotulinumtoxinA. In addition to achieving high levels of patient satisfaction on each FACE-Q scale in patients receiving active treatment, our study demonstrated significant correlations between improvements on both the FACE-Q satisfaction with facial appearance and psychological well-being scales and improvements in primary and secondary endpoints of the study (investigators' live assessment and patient self-assessment of glabellar line severity at day 29). These results highlight the clinical relevance of the FACE-Q PROs and demonstrate the suitability of these patient-centric measures for use in future clinical trials and in clinical practice.

We also note that the quotation of our paper in the letter from Dr Patel and colleagues is misleading in that the following sentences are replaced with an ellipsis: "In fact, only 3 PRO measures have been identified as meeting all current recommendations and US Food and Drug Administration criteria for PRO measures. These are the BREAST-Q, FACE-Q Satisfaction with Facial Appearance Scale, and Skindex," referencing the Morley et al review.[3] Thus, the statement cited, "Of these, only the FACE-Q is appropriate for reporting outcomes from aesthetic facial procedures," is taken out of context as we are in fact referring to these 3 PROs as meeting the criteria set out in the recommendations. Furthermore, although the FDA criteria for PROs were given as an example to highlight for US readers that the FACE-Q does meet these criteria, we would note that our study was conducted in European countries and as such there was no obligation to align to this guidance.

Overall, we acknowledge the remarks from Dr Patel and colleagues that the current versions of the FLSQ and FLO-11 may also be appropriate PRO measures for reporting aesthetic facial outcomes, and echo their sentiments on the importance of employing PRO measures in aesthetic clinical trials.

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