Facial Line Outcomes (FLO-11) and Facial Line Satisfaction Questionnaire (FLSQ) Meet FDA Patient-Reported Outcome Guidance

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The recent article by Dr Ascher and colleagues titled "Significantly Increased Patient Satisfaction Following Liquid Formulation AbobotulinumtoxinA Treatment in Glabellar Lines: FACE-Q Outcomes From a Phase 3 Clinical Trial" highlights the importance of patient-reported outcome (PRO) measures in facial aesthetic clinical trials.[1] Although we completely agree with the importance of PROs in assessing aesthetic conditions and treatments, we noted inaccurate claims that 2 PRO measures used for assessing outcomes with botulinum toxin type A (BoNTA), the Facial Line Outcomes (FLO) Questionnaire and the Facial Line Satisfaction Questionnaire (FLSQ), are not in alignment with FDA PRO guidance. Specifically, the authors stated:

> Existing measures include the Facial Line Treatment Satisfaction Questionnaire [FTS], the Facial Lines Outcome Questionnaire [sic; Facial Line Outcomes], and the Facial Line Satisfaction Questionnaire [FLSQ]. However, reviews of PRO measures in cosmetic surgical procedures and nonsurgical facial rejuvenation, including BoNTA injections, conclude that many of these current outcome measures are not aligned to recommendations for the development and validation of PRO measures, or they do not meet US Food and Drug Association [sic; Food and Drug Administration] (FDA) criteria. In fact, only three PRO measures have been identified as meeting all current recommendations and FDA criteria for PRO measures … Of these, only the FACE-Q is appropriate for reporting outcomes from aesthetic facial procedures.

Regrettably, the authors cited outdated versions of the FTS (which has been replaced by the FLSQ) and the FLO (the 7-item FLO-7, which has been replaced by the 11-item FLO-11). Moreover, the guidance cited by the authors is not from the US FDA, but from a report to the UK Department of Health.[2]

To be clear, the current versions of both the FLSQ and FLO-11 were developed in accordance with FDA PRO guidance.[3] In particular, Section D of this guidance describes how to obtain patient input for content validation of a new instrument as well as for an existing instrument in a new patient population.[3] An update to the FLO-11 was recently published in *ASJ Open Forum*,[4] and it may therefore benefit readers to be aware of the following:

1. FLO-11 was developed with input from subjects with crow's feet lines (CFLs) and upper facial lines (UFLs), resulting in its verification as a valid tool to assess the impact of UFLs.[5] Dayan et al[4] studied the psychological impact of forehead lines (FHLs) and UFLs (FHLs + CFLs + glabellar lines), and concluded that FLO-11 is a content-valid and comprehensive instrument for measuring the impacts of all these facial lines.

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2. Pompilus et al[6] updated the FLSQ for use in adults with UFLs, and concluded it was a valid questionnaire for assessing treatment expectations, satisfaction, impact, and preference in this population.
3. Recent publication of two 12-month, phase 3 studies of toxin-naive subjects receiving onabotulinumtoxinA or placebo for treatment of FHLs noted that the current versions of these questionnaires meet the FDA PRO guidance.[7] In these phase 3 studies, subject-reported satisfaction and impact of treatment were prespecified secondary endpoints collected from FLSQ and FLO-11.[7] Based on the evidence from these studies, the FDA approved FLSQ satisfaction data in the product labeling for onabotulinumtoxinA treatment of FHLs.[7]

The assertation made by Ascher et al that the FACE-Q is the only appropriate PRO measure for reporting aesthetic facial outcomes is inaccurate, as both the FLO-11 and FLSQ PRO measures were developed to meet FDA PRO guidance. We hope that the information in this letter apprises the authors and your readers of the rigorous work undertaken to develop these PRO measures and highlights the importance of these measures in facial aesthetic clinical trials.

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