

# Clinical evaluation of the safety and performance of a novel hyaluronic acid filler in correction of mid-face age-related volume deficit

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## OBJECTIVES

Hyaluronic acid (HA) is the most commonly used soft-tissue filler for facial rejuvenation<sup>1</sup> and it has challenged the use of more invasive aesthetic surgical procedures<sup>2</sup>. This clinical study evaluated performance and safety of a soft tissue filler (HA filler cross-linked with BDDE, produced with XTR™ Technology) for facial volume restoration/augmentation of mid-face age-related volume deficit.

## MATERIALS AND METHODS

This was a prospective, non-comparative, single center study on 50 healthy women aged 40-60 and thus crossing three generations (Millennials, X Generation, and Baby Boomers) with volume deficit on malar area. At visit 1 each side of the face was treated with supraperiosteal boluses in this sequence: zygomatic arch (2 boluses in line, 0.2-0.3 ml each), malar area (3 boluses, lateral SOOF, medial SOOF, deep malar fat pad, 0.3-0.4 ml each), deep pyriform fossa (1 bolus, 0.3-0.4 ml).

## RESULTS

Assessment of safety and performance were made at M1, M3 and M6. At M1 all subjects achieved an improvement in GAIS (Global Aesthetic Improvement Score, Fig.1) and in the FVLS (Face Volume Loss Score, Fig.2) as assessed by the investigator. 3D pictures (Fig.3) were used to calculate instrumentally cheekbone volume variation, showing a significant increase at M1 which persisted until M6 (Fig.4). Significant improvement in skin quality was also observed. Moreover, subjects' and injector's satisfaction were very good and no adverse device effects and no device deficiency occurred.

## CONCLUSIONS

The novel HA filler injected in subjects with mild to moderate mid-face volume deficit induced a global aesthetic improvement on all subjects until 6 months after first injection, as confirmed by both clinical and subjective evaluations. Objective instrumental measurements also highlighted a significant increase of cheekbone volume, skin density, thickness and firmness. This study confirmed the device safety, tolerability, and clinical performance.

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2. Prasetyo A, et al. Hyaluronic acid fillers with cohesive polydensified matrix for soft-tissue augmentation and rejuvenation: a literature review. *Clinical, Cosmetic and Investigational Dermatology*. 2016; 9: 257-280