INJECTION OF A NEW HYALURONIC ACID (HA) IN THE PERI-OCULAR AREA TO REDUCE TEAR TROUGH DEFORMITIES AND SUNKEN EYES: RETROSPECTIVE STUDY BASED ON 120 CASES

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BACKGROUND

Tear trough deformity occurs with age and is characterised by a sunken appearance that make the individual look tired and aged. However, volume replacement in the peri-ocular complex is highly challenging due to the delicate nature of the area that means even small lumps are visible. A detailed understanding of the underlying anatomy is also needed to avoid inadvertent intravascular injection that can lead to blindness.

Juvéderm® Volbella™ with lidocaine (referred hereafter as Volbella) is an injectable HA gel that is smooth, non-particulate and cohesive. It comprises both short and long chain HA. This combination allows for minimal gel swelling and has a long duration of effect. Thus it is a possible optimal candidate for use in the tear tough area.

OBJECTIVE

To assess a new HA injectable gel (Volbella) for the treatment of peri-ocular deformity such as tear trough and sunken eye. Secondary objectives were to assess product safety, assess the effects of Volbella combined with Juvéderm® Voluma® with lidocaine (referred hereafter as Voluma) treatment on overall midface and peri-ocular rejuvenation, and assess the influence of injection technique (i.e. depth of injection; cannula or needle).

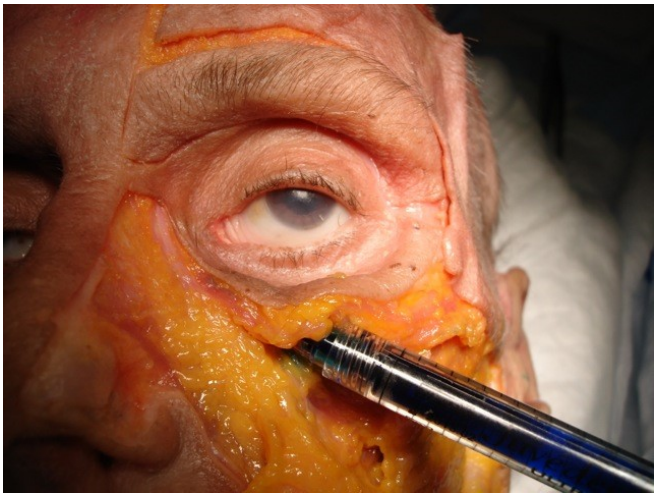
PATIENTS AND METHODS

120 volunteers aged ≥18 years presenting with tear trough and/or sunken eyes were included. Patients were clinically scored by the physician pre- and post-injection. After injection, patients assessed efficacy and pain (0: no pain to 10: severe pain) and completed a patient questionnaire. The physician assessed efficacy and completed a physician questionnaire. Adverse events (AEs) were recorded.

RESULTS

90 patients were analysed (30 were excluded since they were not followed up for long enough). 89 patients were injected on both sides and 1 patient was injected on the right side only, so data from 179 injections were pooled for analysis. Injections were performed mostly on the sub-palpebral pre-periosteal region and injection technique was the same for both eyes, comprising either cannula or needle (Figure 1). Patients with Grade 2 or 3 on the baseline scores were injected, before the Volbella injection, with Voluma into the deep malar fat pad to re-create midface convexity.

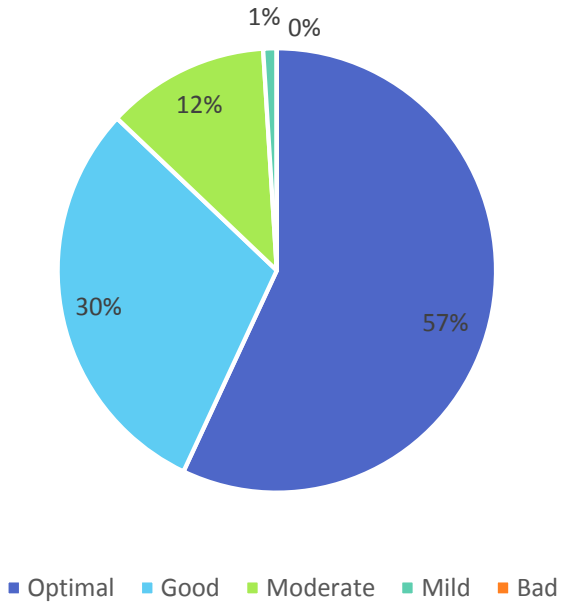
Figure 1: Safe injection of Volbella pre-periosteal, strictly under the orbicular muscle (shown on a cadaver)



Patient Assessment: Following Volbella injection, patient assessment showed 94% would recommend treatment, 96% found it beneficial, and 79% felt more attractive. Patient pain assessment was <4 in all cases, with 36% of patients feeling no pain. Post-injection, 63% of patients felt no pain.

Physician Assessment: Physician assessment was good/optimal for 87% of patients (Figure 2) and injection was judged as easy/very easy for 92% of patients.

Figure 2: Physician Assessment Of Volbella Injection For Periocular Correction

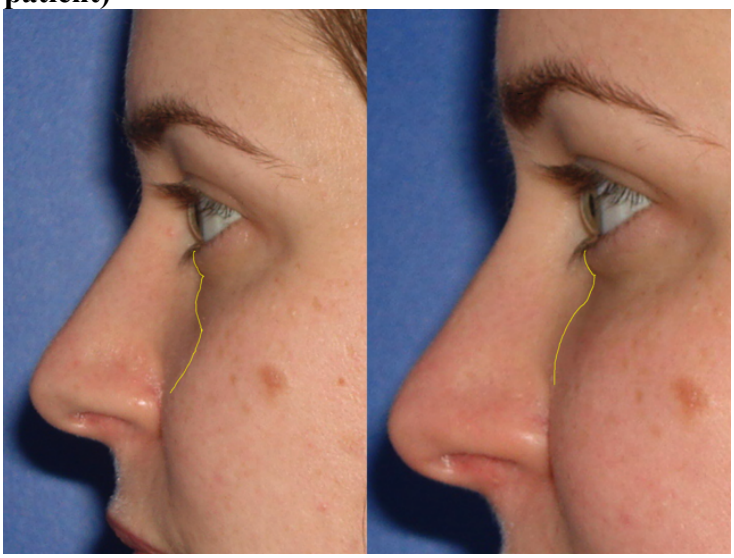


Physican Rating Scales: Patients were assessed at 6, 9, 10 and 12 months post-injection. Only those who had not received further touch-up injections were assessed at each timepoint. The results of the two scales used were as follows:

Hirmand Tear Trough Rating Scale (rated on a scale from 0 to 3): An **improvement of >2 points** was seen for more than **two-thirds of patients**, with highly significant improvements from baseline being observed post-injection at all visits (Wilcoxon test $p<0.0001$).

Midface Volume Deficit Scale (rated on a scale from 5 to 0): Improvements were observed for 89% of patient's post-injection, with the improvement being >2 grades in approximately one-third of patients. The changes from baseline were highly significant at all visits (Wilcoxon test $p<0.0001$). Midface correction was found to be good or optimal for 84% of patients.

Figure 2: Tear Trough (Hirmand Scale 2) Corrected with 0.3cc Volbella per side (25 year-old female patient)



Note: yellow line highlights the contour of the tear trough before and after treatment and clearly shows the reduced depth and size of the sunken area

Figure 3: Tear Trough (Hirmand Scale 3) Corrected with 0.5cc Volbella per side + 1cc Voluma® midface (60 year-old female patient)

Impact of Injection Technique

69% of all injections were performed with a cannula and 31% with needles. The Hirmand Tear Trough Rating Scale showed improvements of >2 scores for >72% of patients injected with a cannula and 53% of patients injected with a needle. However, correction was considered good or optimal whatever the injection mode for at least 93% of patients.

Efficacy of Combined Voluma and Volbella

30 patients received both Voluma and Volbella treatment (i.e. 60/179 injections [34%]). It is difficult to determine the benefits of the combined treatment, although the efficacy scores for those who received both products was notably higher than for those treated with Volbella alone. It may be useful to use a combination approach in more severe cases (i.e. Grades 2-3) (Figure 3).

SAFETY

There were no AEs reported on the right side for 87% of patients or the left for 92% of patients. AEs reported during injection were swelling (8 cases) and ecchymosis (5 cases), and AEs reported after injection were swelling (12 cases), ecchymosis (4 cases) and bruising (3 cases). **No abnormal lumps or nodules** were reported, no patients reported an allergic reaction, **no cases of Tyndall effect** were seen, and there were no cases of long-term swelling.

CONCLUSION

Periocular rejuvenation using injectable fillers can create outstanding clinical results and provide practitioners with less invasive treatment options. This study showed the benefits of Volbella, administered alone or in combination with Voluma, as evidenced by both patient and physician assessments. The duration of effect was prolonged, with highly significant benefits being seen up to 12 months. Both cannula and needle injection techniques resulted in good or optimal efficacy for at least 93% of patients. Treatment was well-tolerated, no severe or long-term AEs reported, and particularly of note, no lumps, nodules nor Tyndall effect were seen.

CONFLICT OF INTEREST STATEMENT

The author received grants from Allergan Europe for this study.