

VARIODERM®

Post Marketing Safety Data Collection

Methodology

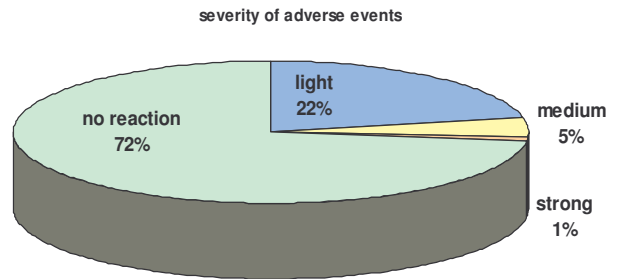
Approximately 100 patients (105 males and females aged between 23 and 73 years) from multicenter will be injected Hyaluronic acid gel to the indicated facial or lip area. Patients will be seen in the clinic to check the patient satisfaction and any adverse events at the following times; month1, month3, month6.

Introduction

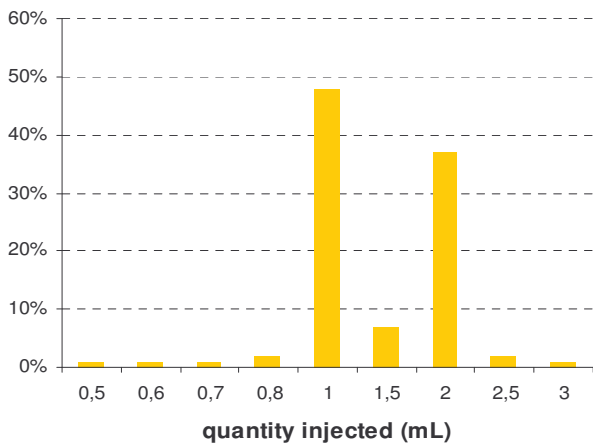
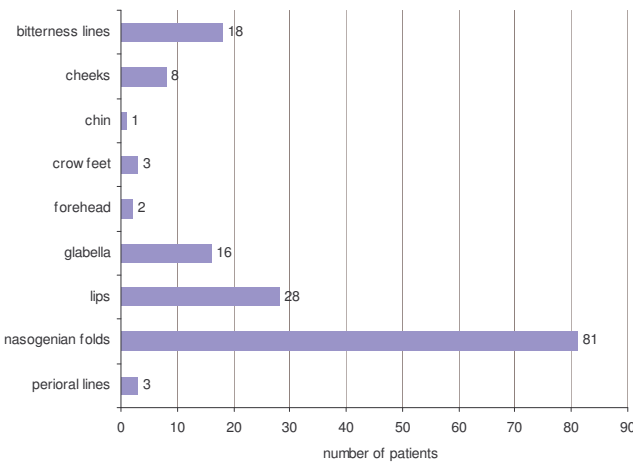
VARIODERM® is a high molecular weight and highly cross-linked hyaluronic acid gel (12mg/ml) that can resist resumption better with time as DVS cross link and slow down the degradation process considerably. Because of its very good viscoelastic and fluid properties, hyaluronic acid is an ideal injectable filler which allows to restore and create volume into the appropriate dermal layers and is indicated for treating medium and deep cutaneous depressions such as wrinkles, folds and other defects in facial contours (cheekbones, chin) and lip contours. The high viscosity of this gel ensures to maintain the volume created in the intercellular matrix. The hyaluronic acid gel is then resorbed according to the same process as for endogenous and exogenous hyaluronic acid metabolism.

VARIODERM® is very well tolerated by the body: it contains highly biocompatible components which are well integrated into the surrounding tissue. Moreover they are non animal origin and do not contain any preservatives nor aesthetics so the risk of allergy and the transmission of parasitosis or prion disease are eliminated.

The safety parameters of the 105 completed procedures were assessed by the participating clinicians and any intolerance symptoms appeared within 8 days following the injection were checked. Most of the patients (72%) did not present any reaction. In case of, were transient and patient complained light redness and swelling for 1 hour to 3 days. These reactions are possibly linked to the patient sensitivity and injected quantity. Only one patient complained of visible swelling up to 6 weeks: inflammatory nodule went away without any problem after two injections of hyaluronidase. Remarkable with this patient was the history of multiple previous treatments. One patient noted a haematoma in the area on the upper lip and one herpes simplex on the upper lip was reported. No reaction or side effect was indicated in the 1, 3, 6 months follow-up reports.



Treated defects

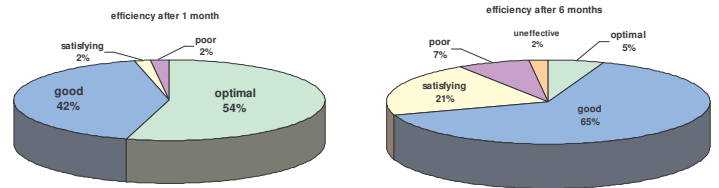


Analysis of safety

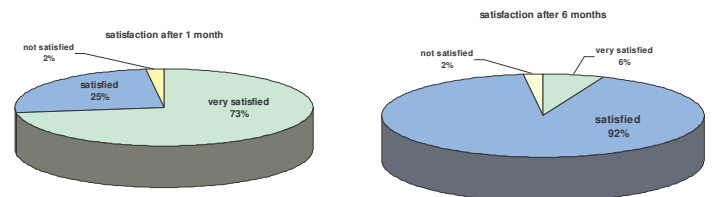
All adverse events were recorded and coded according to standard terms. All reported adverse events were within the anticipated post procedure adverse reactions, were transient and resolved with no further complications.

Analysis of efficacy

Efficiency was assessed by clinicians using five grades: from "optimal" to "ineffective". Filling effect has been described as optimal and good from one week to 6 months. Then it was satisfying until 9 months and decreased after this time.



Satisfaction was graded by patients using three grades: from "very satisfied" to "not satisfied". Almost all patients (98%) satisfied with the result of VARIODERM® injection through the 6 months follow up periods.



Summary and conclusions

The tested VARIODERM® product is easy to apply, accompanied by very mild pain, it seems to be a safe and effective mean to provide with volume and improve contour irregularities on face and lips associated with age.

The follow-up after at least 6 months demonstrated the long duration of VARIODERM® filler in the skin, according to the level of injection and the quantity used. The application was easy to perform.

Immediate reaction as redness, swelling and hardening faded away in about one week. No long term reaction was observed.

All in all, VARIODERM® was tested as a new kind of hyaluronic acid with a good volume effect, a good adaptation to the tissue with a long lasting augmentation and a good level of security.

It is recommended to continue the medical follow-up on long time scale in order to exclude a potential permanent appearance of nodules or a foreign body reaction.