5 YEARS RETROSPECTIVE STYLAGE SATISFACTION SURVEY

T. Thevenet, *Pharm.D*[1]; D. Couchourel, *Ph.D, MBA*[1]

1: Laboratoires VIVACY, 74160 Archamps, France

INTRODUCTION:

Hyaluronic acid (HA) based dermal filler utilization began in 1996. The first clinical studies on soft tissues augmentation were not published until *1997 (Piacquadio et al, 1997; Duranti et al, 1998).* The first available products were manufactured with HA fibers produced from rooster combs . Then, HA fibers were manufactured from bacterial fermentation sources (specific strains of streptococci). HA is a glycosaminoglycan polysaccharide *(Goa KL et al, 1994*) composed of alternating residues of the monosaccharide d-glucuronic acid and N-acetyl d-glucosamine present in the human body that has no species specificity. In theory there is no risk of allergic reaction and the manufacturers suggest that there is no need for skin testing. In fact they do contain some very small amounts of protein (the first batches contained more protein than the current ones), which can cause some reactivity and the stabilization. Nowadays, the raw material degree of purity is extremely high. Thus, and considering the significant industrial progress of all the market recognized manufacturers, relative levels and occurrences of side effects have dramatically dropped. Observed frequencies are now far below levels that could be reasonably detectable in the generally published trials because of the relative small size of the observed cohorts and also because of the generally admitted follow-up duration (usually between 1 year and 1,5 years).
As a result, well designed classical clinical trials should always be completed with large scale surveys, like the present work. Indeed, beside the efficacy data, those results are particularly interesting in term of delayed tolerance data. Indeed, as a major player of this industry, Laboratoires VIVACY considers that side effect frequency should be evaluated as objectively as possible and also communicated to the physicians.

MATERIAL AND METHODS:

A satisfaction survey was carried out between October 2012 and May 2013 with all our prescribing physicians (via our sales teams and local distributors) by sending a detailed retrospective questionnaire. The data collected covered:

- Information on the patient base and medical practices (types of products used, the approximate number of patients monitored for over 2 years or from 1 to 2 years, use of anaesthetics, etc.)
- Performance parameters (ease of injection, quality of aesthetic correction, period of correction etc.) rated on a scale from 1 (Bad/Unsatisfactory) to 10 (Excellent/Extremely satisfactory)
- Information for comparison with competing products (benefits compared to other filler products in terms of volume effect, skin quality, lifting effect, natural look etc.); rated on scales from 1 (Worse than competing products) to 10 (Much better). Only the scores above 5 were considered to be positively in favour of Stylage® in comparison to the competition,
- Information on immediate, (scale from 1 - Very bad immediate tolerance, to 10 - Very good tolerance and open comments) and delayed tolerance (Reply Yes/No to the question “do you have delayed effects?” open description).

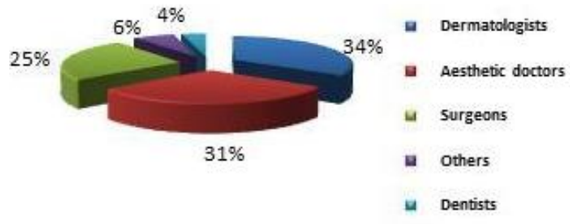
Quantitative data is described by the minimum, maximum, medium 1st and 3rd quartiles, 5th and 95th percentiles, arithmetic mean, 95% confidence interval (Student) and number of missing data according to applicability and relevance. The qualitative data is described by its number, percentage, number of missing data according to their applicability and relevance. The missing data was not replaced. The data was entered and analysed under Excel (V14.0.6024.1000).

RESULTS:

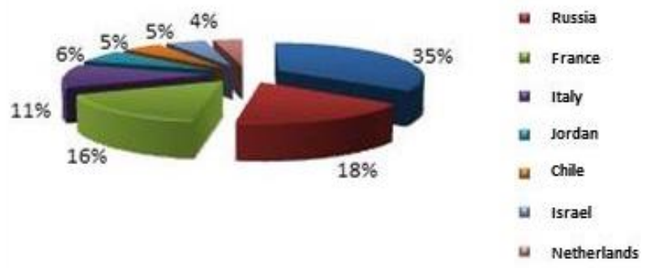
1) Physicians data:

Overall, the questionnaire was completed and returned by 80 doctors. They were mainly dermatologists (n=27), aesthetic plastic doctors (n=25) and surgeons (n=20). 8 nationalities were represented covering all the major geographical zones where Stylage® products are sold (Europe, Asia, Middle East, and South America).

Medical specialities



Countries



Physicians experience

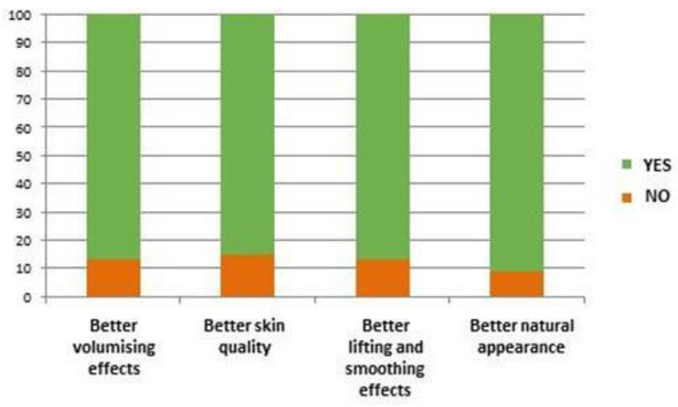
n	**71**
Median value	3 years
Max	5 years
Min	0,83 years
Quartile 75	4 years
Quartile 25	2 years
Centile 95	5 years
Centile 5	1 year

2) Patients data

The practitioners who replied to this questionnaire had an average patient base of around 148 patients who had been followed up for more than 2 years (IC95% [80 - 214]), to which were added around 124 patients who had been followed up for between 1 and 2 years (IC95% [59 – 194]). Overall, the practitioners who answered this survey had over **14,000 patients, with around 8,000 having been followed up for more than 2 years and around 6,000 for between 1 and 2 years.**

3) Comparative satisfaction data

The 2013 global satisfaction profile for the Stylage® range is based on scores from individual satisfaction data (easy to inject, easy to sculpt, aesthetic quality of the correction and duration of the correction), comparative satisfaction scores compared to other products on the market (a better volumising effect, better skin quality, better lifting/smoothing effect, better natural look) and the score for immediate tolerance.



Better volumising effect: The average score awarded by the practitioners who replied is 7.55 out of 10 (IC95% [7.17 – 7.93]); 87% said that Stylage products had a better volumising effect than competing products (score strictly above 5/10); and 56% gave a score of 8/10 or more to our range.

Better skin quality: The average score awarded by the practitioners who replied is 7.67 out of 10 (IC95% [7.27 – 8.06]); 85% said that Stylage® products enabled a better quality of skin to be obtained, than for competing products (score strictly above 5/10); and 56% gave our range a score of 8/10 or above.

Better lifting/smoothing effect: This involved establishing whether the products in the Stylage® range allowed a better lifting/smoothing effect to be obtained compared to the competing products available on the market, i.e., supporting and tightening the skin whilst hugging the contours of wrinkles and anatomical traits sufficiently to avoid creating unattractive visible roughness. The average score awarded by the practitioners who replied is 7.65 out of 10 (IC95% [7.28 – 8.03]); 87% said that Stylage® products enabled a better lifting/smoothing effect to be obtained than competing products (score higher than 5/10); and 61% gave our range a score of 8/10 or higher.

Better skin quality: The average score awarded by the practitioners who replied is 7.67 out of 10 (IC95% [7.27 – 8.06]); 85% said that Stylage® products enabled a better quality of skin to be obtained, than for competing products (score strictly above 5/10); and 56% gave our range a score of 8/10 or above.

4) Delayed tolerance data

After analysing the types of delayed undesirable effects indicated and their appearance, there was an average global prevalence of undesirable delayed effect of **0.25 for 1,000 patients** monitored **(0.025%)** and **0.07 per doctor** who replied to the question. When compared to the average number of years of using the products in the Stylage® range, this represents around:

- **0.08 of delayed undesirable effects for 1,000 patients per year**
- **0.022 cases per doctor per year.**

The delayed undesirable effects reported during the survey are mainly chronic inflammatory nodules and cutaneous conditions occurring several weeks to several months after the injection and diminishing after treatment .

CONCLUSION

80 practitioners from 8 different nationalities with an average of 3 years’ experience replied to our satisfaction survey concerning products in the Stylage® range. In a similar and representative way to what is seen at the global sales level, 51% of practitioners who replied to this survey use all the products in the Stylage® range, with a more frequent use of M, L, and XL products, respectively. In comparison to the competing products on the market, 91% of the practitioners who replied to the survey considered that the products in the Stylage® range allowed a more natural result to be obtained, 87% considered that they enabled both a better volumising effect and a better lifting/smoothing effect and 85% that they also enabled a better skin quality to be obtained.

To conclude, this representative survey of our market and sales once again highlights our customers’ high level of satisfaction and the effectiveness and tolerance of the products in the Stylage® range, in accordance with the previous data set out in the clinical documentation.

REFERENCES

- Piacquadio D, Jarcho M, Goltz R. Evaluation of hylan b gel as a soft tissue augmentation implant material. J Am Acad Dermatol 1997; 36: 544–549.
- Duranti F, Salti G, Bovani Bet al. Injectable hyaluronic acid gel for soft tissue augmentation: a clinical and histological study. Dermatol Surg 1998; 24: 1317–1325.
- Goa KL, Benfield P. Hyaluronic acid. A review of its pharmacology and use as a surgical aid in ophthalmology, and its therapeutic potential in joint disease and wound healing. Drugs 1994; 47: 536–566.