STYLAGE XXL: 18 MONTHS CLINICAL FOLLOW-UP

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INTRODUCTION:

Facial volume loss because of lipoatrophy is one of the most visible sign of ageing (Ascher et al, 2006). Beside the surgical techniques, those volumes can be replenished. By performing these injections, physicians can partially correct ageing signs and patients facial rejuvenation can be evaluated *(Greco et al, 2012)*

Several methods are currently available: surgically, fat autografts (lipofilling) are commonly used (Metzinger et al, 2012). Non-surgical procedures have also been developed with non-degradable products (L-polylactic acid, polyacrylamid, calcium hydroxyapatite) *(Duracinsky et al, 2013; Lafaurie et al, 2013; Carruthers et al, 2008*), and with degradable products (hyaluronic acid *(Hoffman, 2009; Pignatti et al, 2012; Muhn et al, 2012; Callan et al, 2013)*

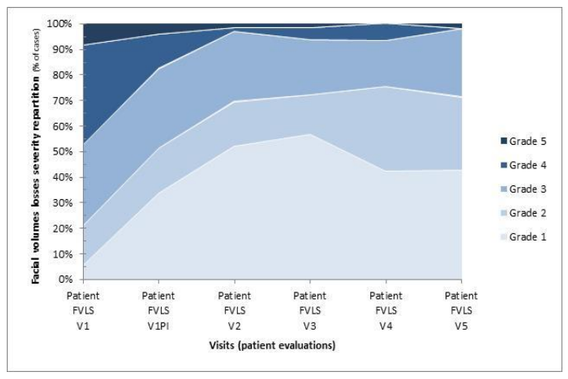
In order to complete the existing STYLAGE hyaluronic acid products, VIVACY has developed a new viscous, cohesive and elastic volumizing product, based on patented IPN-Like technology. STYLAGE XXL typical indications are facial volume losses and localized lipoatrophies. In this post-marketing clinical survey, efficacy and safety of this new product have been evaluated in France and in Poland.

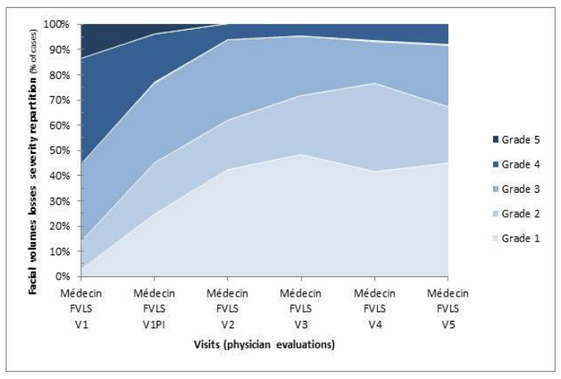
MATERIAL & METHODS:

- Baseline data analysis: age, gender, smoking habits
- Injections parameter analysis: injection sites, needle/cannula usage and injected volumes
- Clinical parameters efficacy analysis: Facial Volume Loss Scale (FVLS) (*Ascher et al, 2006*). Grade 1 to grade 5 (the most severe). Global Aesthetic Improvement Scale (4 levels: worst, no change, slightly improved, improved, highly improved). The follow-up was performed at 1-3 months, 6 months, 12 months and 18 months post-injection
- Easiness of injection evaluation
- Physician and patient satisfaction evaluation
- Side effects evaluation and analysis

RESULTS: EFFICACY OF THE TREATMENT

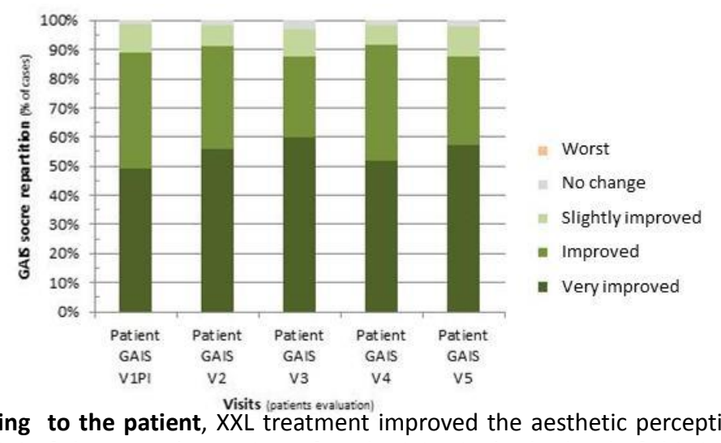
74 patients have been followed. Women: 84% (n=62). Men: 11% (n=8). ND: 5% (n=4). 65% of the patients were treated in France and 36% in Poland. Drop-off rate was 5%, 12%, 18% and 34% for 1-3 months, 6 months, 12 months and 18 months visits, respectively.





According to the patient, the medium improvement was 0,9 grades at V1 (IC95% : [0,7 – 1,2]), 1,4 grades at V2 (IC95% : [1,1 – 1,8]), 1,5 grades at V3 (IC95% : [1,1 – 1,8]), 1,4 grades at V4 (IC95% : [1,1 – 1,8]) and 1,4 grades at V5 (IC95% : [1,0 – 1,9]). **According to the physician**, medium improvement of the treatment was 1,0 grade at V1 (IC95% : [0,7 – 1,3]), 1,6 grades at V2 (IC95% : [1,3 – 1,9]), 1,7 grades at V3 (IC95% : [1,4 – 2,0]), 1,7 grades at V4 (IC95% : [1,4 – 2,1]) , and 1,8 grades at V5 (IC95% : [1,4 – 2,1]). (Friedman and Wilcoxon tests, performed against pre-injection data.)

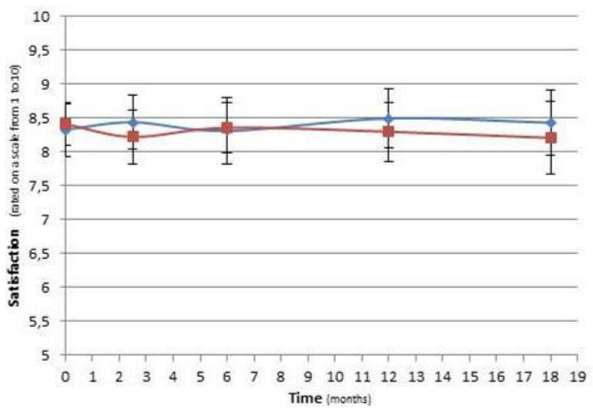
During the whole follow-up period, the differences observed regarding the severity grades repartition were statistically significant when compared to baseline (patients and physicians) (p<0,0001)



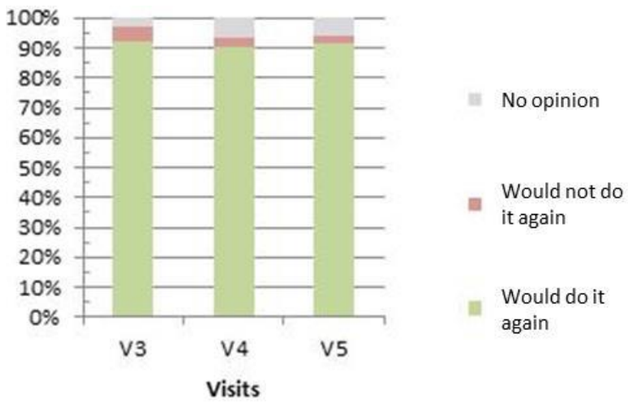
According to the patient, XXL treatment improved the aesthetic perception in more than 90% of the cases (V1P1, just after the injection). The level of this improvement was maintained at a similar level until 18 months after injection (V5). 1 patient mentioned no change in her aesthetic perception.

n	Standard deviation	Mean value	Median value	1st Quartile	3rd Quartile
64	2,42	7,88	9	7	10

Easiness of injection. Notation out of 10. Mean value is 7,88 (IC95% : [7,28 – 8,47]).



According to the patients and to the physicians, **the mean satisfaction of the treatments is ranging from 7,5 to 9 out of 10,** between 1 month and 18 months after injection.



Patients contentment. Roughly, **90% of the patients would go again for the same treatment** after 6, 12 and 18 months post-injection.

RESULTS: ADVERSE REACTIONS REPORTING

	Oedema	Hematoma	Redness	Induration	Discoloration	Product migration	Pain during injection	Pain during massage
Weak (n)	12	12	17	3	3	1	19	23
% of included patients	16,2%	16,2%	23,0%	4,1%	4,1%	1,4%	25,7%	31,1%
Moderate	4	7	2	1	0	0	9	6
% of included patients	5,4%	9,5%	2,7%	1,4%	0,0%	0,0%	12,2%	8,1%
Severe	0	1	0	0	0	0	1	1
% of included patients	0,0%	1,4%	0,0%	0,0%	0,0%	0,0%	1,4%	1,4%
TOTAL	21,6%	27,1%	25,7%	5,5%	4,1%	1,4%	39,3%	40,6%

Repartition and severity of adverse reactions recorded in the studied population

CONCLUSION

This follow-up was designed to evaluate the efficacy and the safety of STYLAGE XXL on 74 patients treated by 11 physicians, either in France and in Poland.

FVLS was improved from 1 to 4 grades in 80% of the patients (mean of 1,5 grades). The first results were obtained immediately after the injection. Optimal results were obtained 1 to 3 months after injection and the volumetric replenishment improvement was still statistically significant 18 months after the treatment (p<0,0001). The aesthetic consequences were correlated with the FVLS evolution and were also dramatically improved.

Regarding the tolerance data, one should keep in mind that the test product is the most volumising product of the STYLAGE product range. XXL figures are completely in the line with other available comparable biodegradable products on the market *(Callan et al, 2013; Hoffman, 2009)*.

This work exhibits also some limitations. First, the 'grade 0' was absent from the FVLS scale. One of the consequences was the artificial limitation of amplitude of the scale. Secondly, in the tolerance data set, no data were recorded concerning the onset of adverse reactions and their durations.

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