GLODERM 20L
CLINICAL EVALUATION

Dr. Ivona Igerc
Croatia

Title of Study:

'To assess the safety and performance of Dermal Fillers (GLODERM 20L) in Patients with facial wrinkles(Glabellar Lines).'

Objective: To Assess the safety and performance of GLODERM 20L in subjects with facial wrinkle improvement(Glabellar Lines) and incidence of all adverse events at 6months and any systemic adverse event.

Method:

- GLODERM 20L evaluation is designed as prospective, single center, single arm, open label evaluation .
- The evaluation device will be evaluated in the treatment of patients with wrinkle's assessing the Glabellar Lines and evaluate the Full Face Global Aesthetic Improvement from day of treatment to follow up at 3 and 6 Months.

Eligibiltiy Criteria

Inclusion criteria :

- The patient must be ≥ 18 and ≤ 75 years of age.
- The patient must be willing to comply with the requirement of the Evaluation.
- The patient is willing and able to comply with the evaluation protocol.
- The patient is seeking soft tissue augmentation treatment on the face.
- The patient with Glabellar lines.
- The patient has a pre-treatment Wrinkle Severity Score (WSS) ≥ 2 for bilateral NLF to be treated
- The patient agrees to follow-up examinations out to 6 months post final treatment.

Eligibility Criteria

Exclusion Criteria

- At risk in term of precautions, warnings and contra-indication referred in the package insert of the evaluation devices,
- Who underwent previous injection of permanent filler in the injected area.
- Pregnant/lactating women
- Subjects who have an allergy to lidocaine, prilocaine or other amide-type anesthetic
- Had a chemical peel at the NLF area within 4 weeks prior to evaluation entry. In addition, subjects were restricted from undergoing chemical peels at the NLF area for the duration of the evaluation.
- Had any treatment with Botox® injections:
- in the upper 1/3 of the face within 2 weeks prior to entry into the evaluation, or
- in the lower 2/3 of the face within 24 weeks prior to entry. In addition, subjects were restricted from receiving Botox injections in the face for the duration of the evaluation.

Exclusion Criteria(Cont..)

- Had a history of hypo- or hyperpigmentation of the skin.
- Tolerance to antibiotics or corticosteroids.
- Had any infection, unhealed wound, or active inflammatory process (e.g., skin eruptions such as cysts, pimples, rashes, or hives) at the injection site(s).
- A known history of keloids or bleeding disorders.
- Leukoderma (vitiligo) or a family history of leukoderma or other pigmentary disorders. Patient on Medication with blood thinners.
- Severe physical, neurological or mental disease.
- Excessive facial hair that might interfere with the evaluation of the wrinkle assessments.

Sample Size

- This is a single arm evaluation conducted with target of 18 subjects at single center treated with GLODERM 20L for face with Lines and wrinkles.
- The entire subject participated in evaluation and treated with GLODERM 20L will be followed at 3 and 6 Months with assessment of Glabellar lines and Global Aesthetic Improvement scale by using photograph at all the visits for comparison.

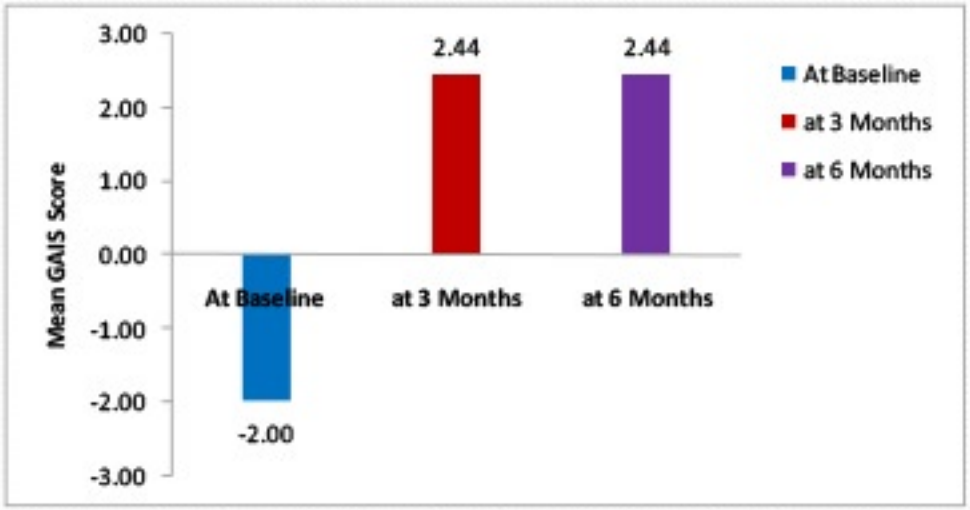
Study Schedule

Event	Screening /Baseline	Procedure	Post –Procedure Day 0	FU 1 3 Months	FU 2 6 Months
Type of contact				Hospital Visit	Hospital Visit
Inclusion/ exclusion Criteria	X				
Physical examination	X				
Medical History	X				
Photograph	X		X	X	X
GAIS Assessment	X		X	X	X
Malar Area	X		X	X	X
Nasolabial fold assessment	X		X	X	X
Perioral and lip line area assessment	X		X	X	X
Marionette lines severity assessment	X		X	X	X
Jaw line severity assessment	X		X	X	X
Adverse Events and Serious Adverse Event Monitoring		X	X	X	X

Results

- **GLOBAL AESTHETIC IMPROVEMENT ASSESSMENT**

Visit	GAIS Score (mean value)
Baseline	-2
3 month follow up	2.44
6 month follow up	2.44



Glabellar severity score (mean value)

Visits	Glabellar severity score (Mean ±S.D.)
Baseline	2.17 ± 0.79
3 month follow up	1.61 ± 0.61
6 month follow up	1.61 ± 0.61

CONCLUSION

- GLODERM 20L is found safe and well tolerable.
- In present evaluation, single dose administration of GLODERM 20L is found effective in treatment of facial wrinkles (Glabellar lines) and safe with good device palatability till 6 months follow up.
- An efficacy evaluation result of GLODERM 20L makes it suitable for use in patients with facial wrinkles.