Gorgeous
GOURI

Clinical Safety And Efficacy Data

DEXLEVO

INTRODUCTION

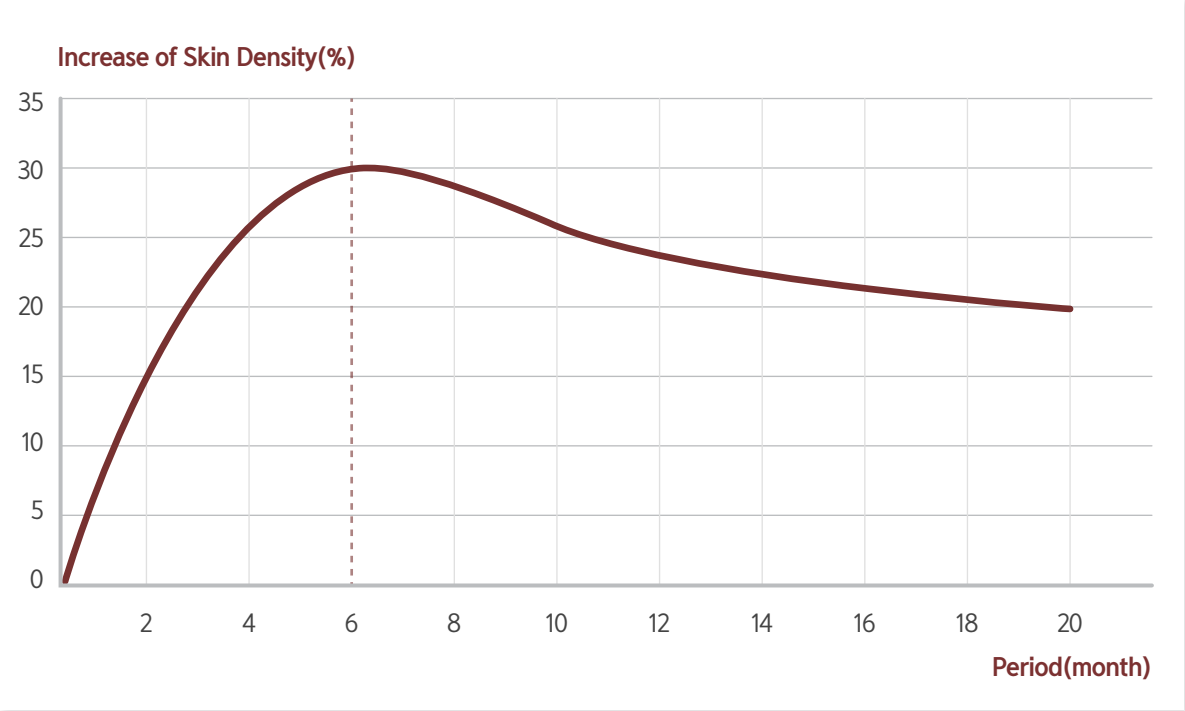
There are lots of Hyaluronic Acid-based dermal fillers and polymer products in the market.
But they are mainly focused on localized part for volumizing effect.
Furthermore, we cannot overlook the possibility of side effects by blocking blood vessel or pressing it.

GOURI is a new type of injectable based on fully solubilized biocompatible and biodegradable PCL which spreads naturally into the extensive part of the skin.
Thanks to DEXLEVO's unique CESABP Technology, you can apply GOURI safely and easily for the entire FACE LIFT.

CESABP(Collagenesis-Enabled Solubilized Active and Biodegradable Polymer) is DEXLEVO's patented technology for natural skin collagen synthesis.

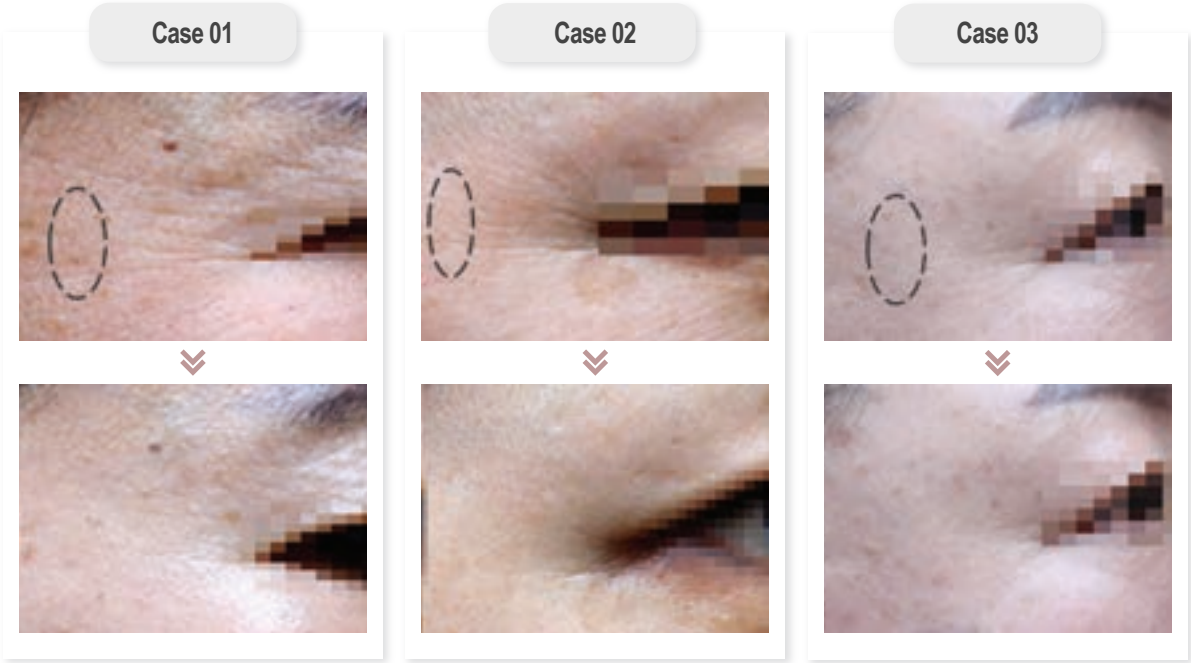
CHANGE OF DENSITY

The increasing rate of skin density is significantly getting higher until 6 months after application by neo-collagenesis. It starts deceasing after 6 months and remains consistently.



SPREADABILITY

We applied 0.7ml of GOURI injecting just one point around eyes to see how it spreads.
Each of the around eye was photographed at 12 weeks after application.
Around the eye such as eye crow's feet and elasticity of each patients was improved by only one point application. Since the fully solubilized liquid PCL of GOURI spreads smoothly and widely into the skin.



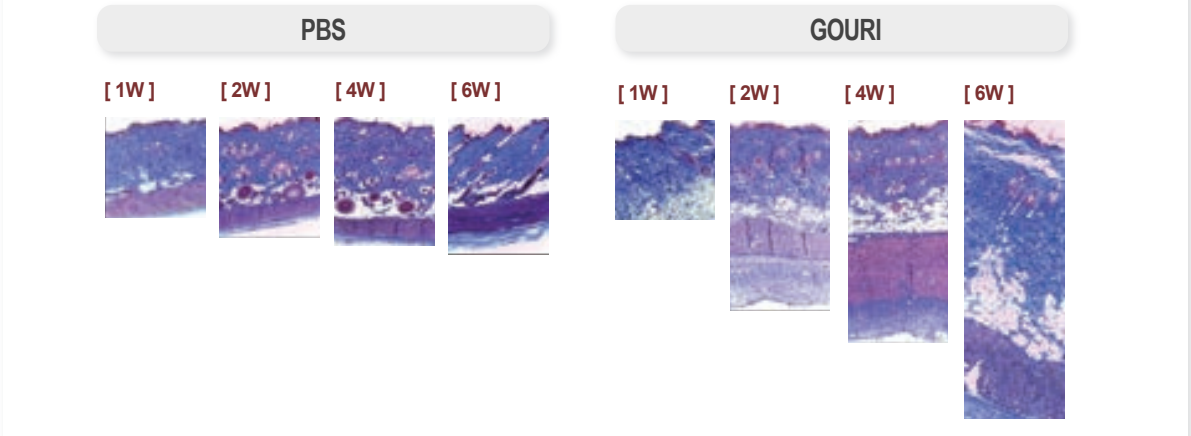
[Figure1] Around the eyes at 12 weeks after application (◌ Injection Point)

COLLAGENESIS

To evaluate neocollagenesis, biopsy specimens of 6 week-old female Sprague Dawley rat were obtained at 1,2,4, and 6 weeks after the filler injection.

While the expression level of collagen upon MT staining in the PBS-injected group increased only slightly over time, the GOURI injected group showed a marked increase during the first 6 weeks.

THe degree of dermal thickening of PBS injected group did not induce clinical distinction, compared to GOURI.



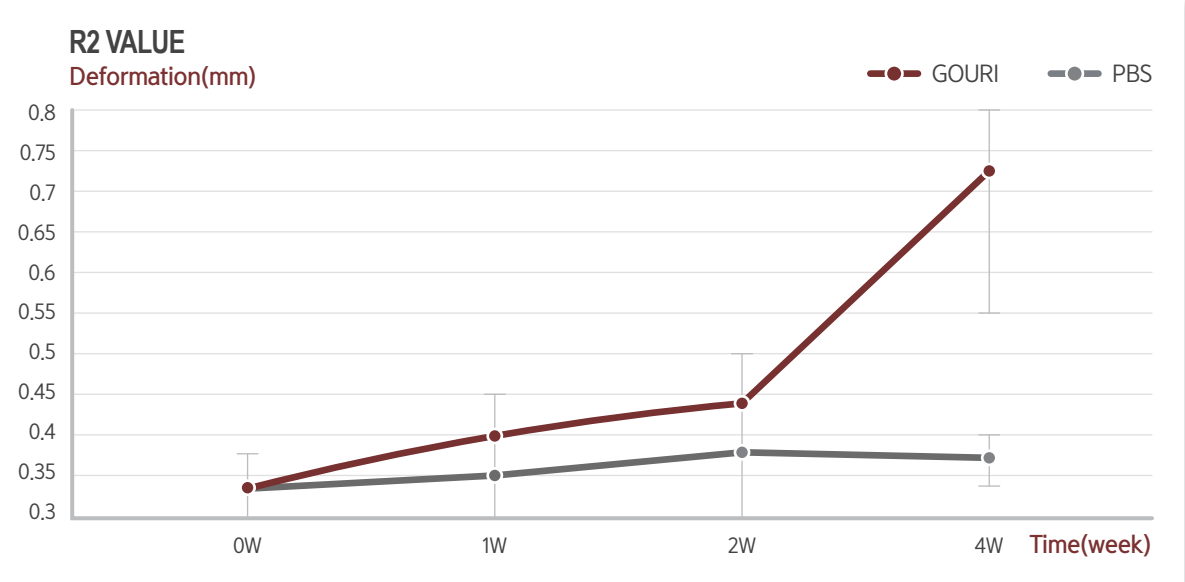
[Figure2] Histological changes over 6 weeks after filler. It shows more densely pakced and increased dermal collagen in the GOURI injected tissue, demonstrating that the maximal dermal thickness at week 6 may be attributed to neocollagnesis. PBS, phosphate-buffered saline

Biopsy specimens from the GOURI showed increased thickness of the dermis since the first week, sparing that of the subcutaneous fat. PCL microspheres seemed to act as nuclei for new collagen formation with the activation of fibroblasts by volume expansion and stretching. Besides, it is worth considering that an intradermal injection of the PCL filler may achieve higher collagen regeneration than subdermal or subcutaneous injections.

SKIN ELASTICITY

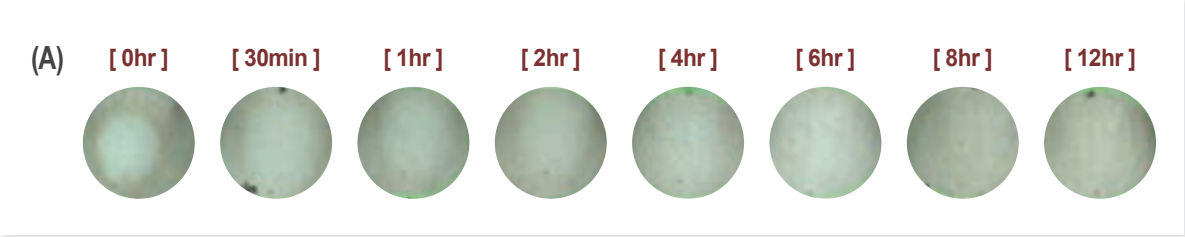
Skin elasticity at the injected site of 6 week-old female Sprague Dawley rat was calculated using R2, R5, and R7 values measured by Custometer CM580 immediately after 1, 2, and 4 weeks after injection. R2 value, defined as Ua/UF, is considered as the most important parameter reflecting gross elasticity.

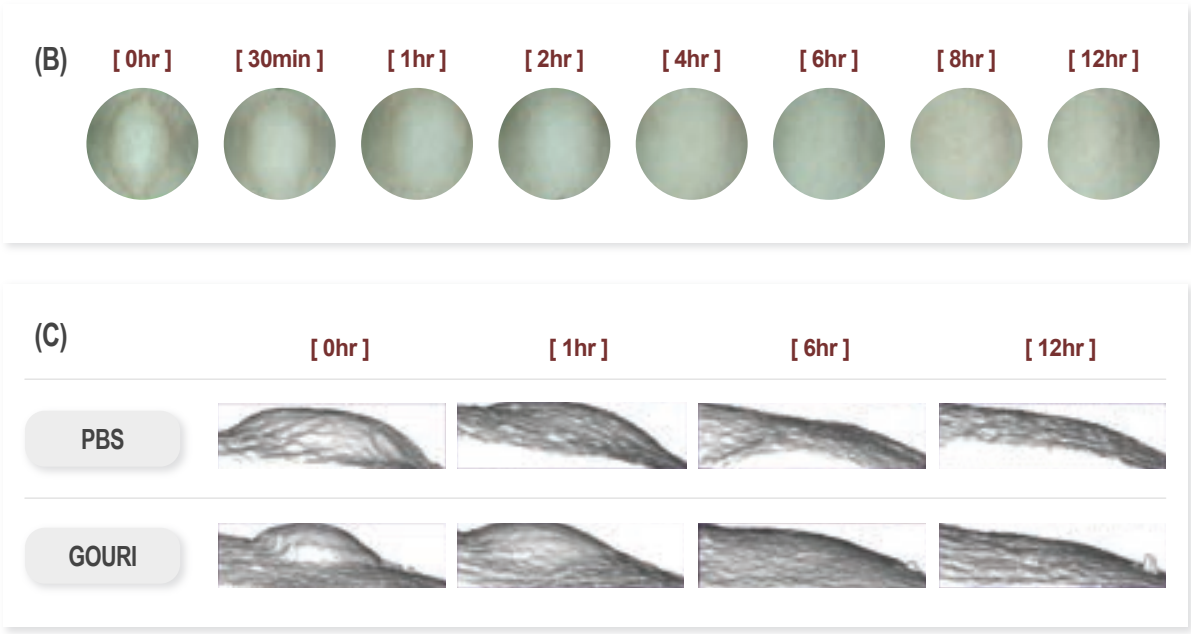
Custometer evaluation data and histological evaluation in rat skin support that dermal rejuvenation can be achieved by increasing skin elasticitiy and dermal collagen with GOURI The increased dermal thickness was not enough to fill skin folds and lift depressed areas, but sufficient to induce rejuvenation.



[Figure3] Chronological change of skin elasticity as measured by a Cutometer.
R2 value reflecting dermal elasticity showed a gradual elevation until week 4.

MORPHOLOGICAL CHANGE OF NODULE AFTER INJECTION





[Figure4] Morphological changes observed over time with a Folliscope and PRIMOS LITE. 3D-reconstruction images. A,B Folliscope images for the PBS group and GOURI. In the GOURI injected area, the injection volume decreased more gradually than the volume of the PBS-injected region for the first 2 hours. After 8 hours, no gap in height was observed. C. PRIMOS LITE 3D-reconstruction images for the PBS and GOURI groups.

The change of nodule was analyzed by photography with Folliscope and a three-dimensional profiling system. The skin surface of 6 week-old female Sprague Dawley rat was evaluated immediately at 0.5, 1, 2, 4, 6, and 12 hours after the injection.

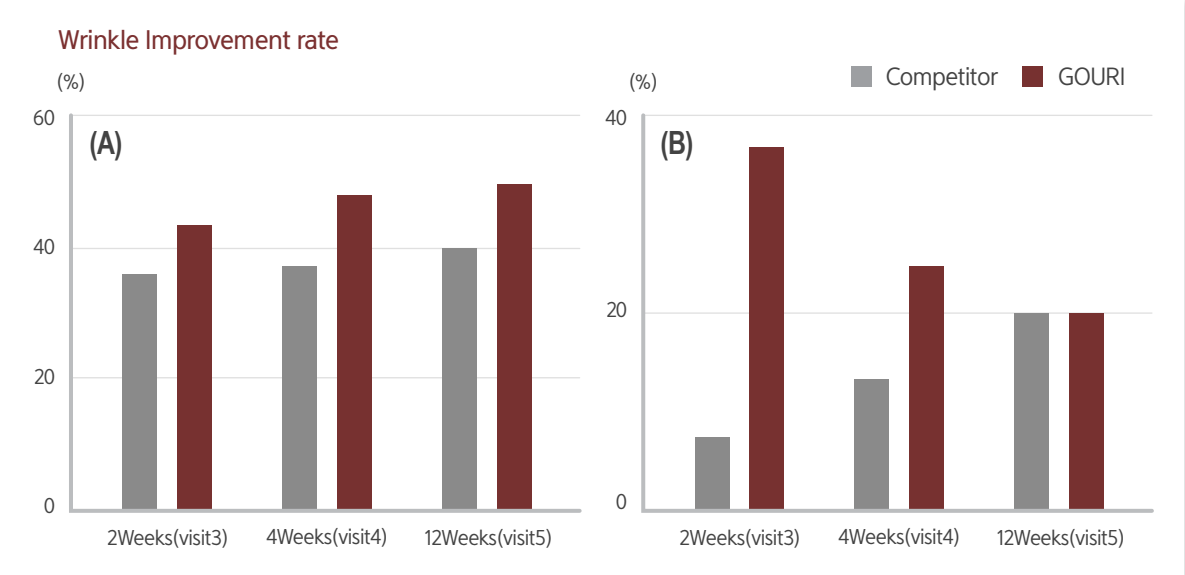
We observed that compared with the PBS-treated group, GOURI group showed slower and more gradual dispersion in the first 2 hours. The GOURI-injected area demonstrated no difference from surrounding at up to 8 hours.

Three-dimensional images contructed using PRIMOS LITE showed that the GOURI-injected nodules exhibited a more cohesive and spherical appearance than the dull and relatively more dispersed nodules in the PBS-injected group upon preliminary examination(Figure3. C)

WRINKLE IMRPOVEMENT

Injection of up to 1ml was injected into the intramuscular cavity of 29 subjects to evaluate wrinkle improvement. Independent evaluators and testers assessed the CFGS(Crow's Feet Grading Scale) for each of the application areas of GOURI and competitor at 2 weeks, 4 weeks, and 12 weeks after the final application.

Scale	Detail	Scale	Detail
0	No wrinkles	3	Moderate wrinkles
1	Very fine wrinkles	4	Severe wrinkles
2	Fine wrinkles		

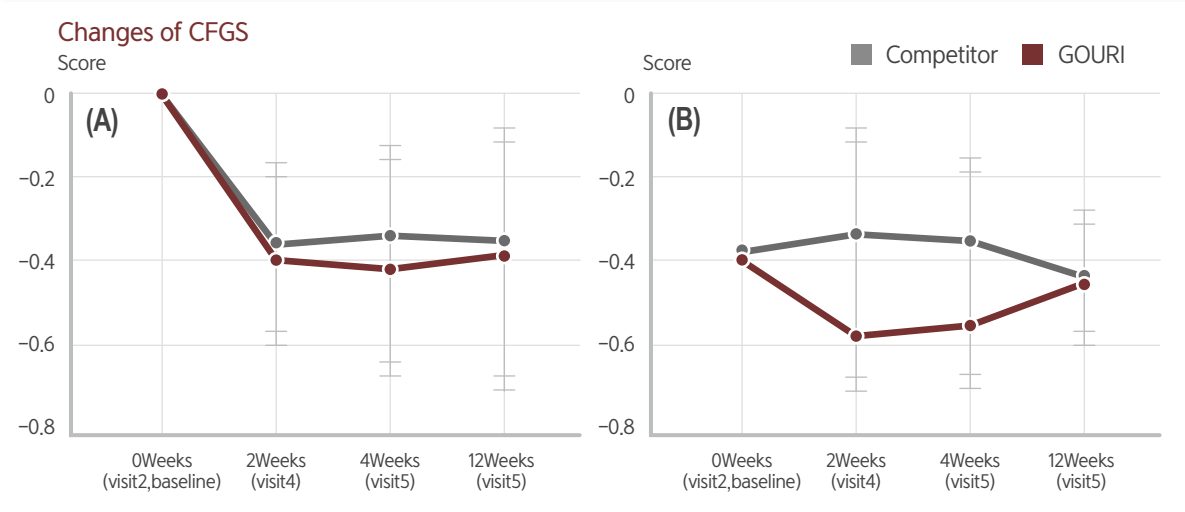


[Figure5] Wrinkle improvement rate accroding to CFGS(Crow's Feet Grade Scale) when resting(A) and when laughing(B) was evaluated by independent evaluators after final application.

The CFGS(Crow's Feet Grading Scale) when resting and when laughing was evaluated by the independent evaluator at 2, 4, 12 weeks after the final application of GOURI and competitor(other medical device).

Four weeks after the final application of the GOURI, the improvement rate of the restrained CFGS when resting was 48.28% comparing to 41.38% of control group.

The improvement rate of the laughing CFGS, which was evaluated by an independent evaluator at 4 weeks after the final application of the GOURI and competitor was 20.69% and 13.79%.



[Figure6] Changes in CFGS(Crow's Feet Grade Scale) when resting(A) and when laughing(B) was evaluated by independent evaluators after final application.

GOURI at time of week 2 versus 4 weeks and 12 weeks versus baseline(0 weeks) and resting and laughing CFGS values as assessed by independent evaluators changes in CFGS value after final application.
The average of both CFGS values of GOURI when resting and laughing were lower than the values of competitor.

SAFETY

NAMSA, USA

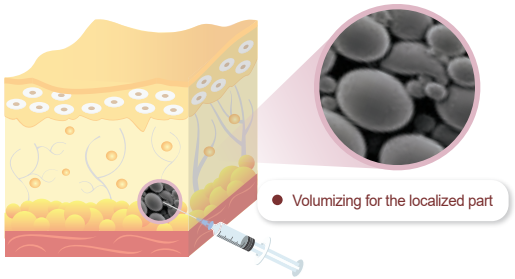
Test Category	Regulation	Study Details	Results
Cytotocxicity	ISO 10993-5	ISO Elution Method	Non-cytotoxic
Pyrogenicity	ISO 10993-11, USP<151>	USP pyrogen Study-Material Mediated	Non-pyrogenic
Sensitization	ISO 10993-10	ISO Guinea Pig Maximization Sensitization Test	No sensitivity
Intracutaneous Irritation	ISO10993-10	ISO Modified Intracutaneous Study In Rabbits	Non-irritant
Acute Systemic Toxicity	ISO 10993-11	Acute Systemic Toxicity Study In Mice	Non-toxic
Subchronic Toxicity	ISO 10993-11	13 Week Systemic Toxicity Study in Rats Following Subcutaneous Implant	Non-toxic
Genotoxicity	ISO 10993-3, OECD guidelines 471	Bacterial Reverse Mutation Study	Non-mutagenic
	OECD guidelines 474	Mouse Peripheral Blood Micronucleus Study	Non-mutagenic
	ISO 10993-3, OECD guidelines 490	Definitive Mouse Lymphoma Assay	Non-mutagenic
Local tolerance	ISO 10993-6	ISO Muscle Implantation Study In Rabbits-4weeks	Non-toxic, Non-irritant
		ISO Muscle Implantation Study In Rabbits-26weeks	Non-toxic, Non-irritant

CONCLUSION

The existing high polymer fillers provide volume for the localized part because the micro size particles don't disperse into the skin.

However, the micro size particles are associated with adverse reactions such as vascular infarction and necrosis, granuloma formation, and skin discolor-ation. Moreover, it can cause technical difficulties during administration because of its particles often block the needle.

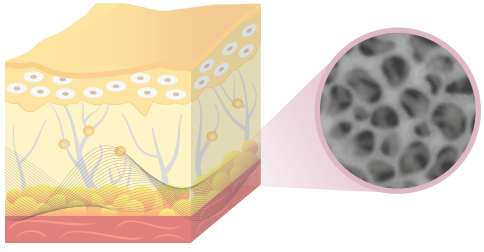
[High polymer products]

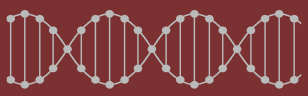


GOURI, However, a new type of injectable based on the world's first Fully Solubilized PCL without micro particle, encourages face lifting and elasticity for entire face by neocollagenesis.

Unlike other existing filler products, it improves entire face safely and effectively without any side effects.

[GOURI]





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