

Fortélis Extra Resorbable and Non-surgical Volumising Implant of Swiss Conception

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SUMMARY

Fortélis Extra is a non-surgical cohesive polydensified monophasic implant. It is obtained from pharmaceutical-grade hyaluronan of biotechnological origin with a very high molecular mass. Dosed at 25.5 mg/ml of HA, it is cross-linked via butane diol diglycidyl ether (BDDE).

It is exclusively injected into the mid- to deep reticular dermis, as well as sub-periosteum, with a 27G needle. It is exclusively intended for the volumetry of the face and deep wrinkles and folds. It is not indicated for the treatment of fine lines.

We present below our first year of follow-up on the first 28 patients treated.

INTRODUCTION

Today, the treatment of the ageing face can no longer be limited to wrinkle filling. Ageing is also the result of the loss of volumes, sometimes their displacement, of the loss of fat, even muscle and bone, and a certain cutaneous sagging.¹

Apart from the various surgical techniques available (such as facelifts, lipofilling, thread lifting), patients now wish to have less heavy, more discreet procedures that do not require hospitalisation or professional and/or social isolation. Filling implant manufacturers have therefore tried to design a gel with properties that are more volumising than smoothing.

Fortélis Extra is a non-surgical cohesive polydensified monophasic implant, from injectable hyaluronan of biotechnological origin. The hyaluronan used for its creation is pharmaceutical-grade and of very high molecular mass.

It is presented in a 1ml glass syringe, dosed at 25.5 mg/ml of HA, and is injected into the mid to deep reticular dermis, as well as sub-periosteum, with a 27G needle. It is exclusively intended for the volumetry and deep folds of the face as well as for the increase in lip volume. It is not intended for the filling of fine lines and shallow wrinkles.

MANUFACTURING PROCESS

The manufacturing process uses a technology similar to that of Esthélis, namely, a dynamic

cross-linking process of a high molecular weight hyaluronan.^{2,3,4,5}

However, unlike CPM, in which the hyaluronan is distributed and infiltrates in between the collagen fibrils, the Fortélis Extra manufacturing process enables an elasticity capable of pushing out the extra-cellular matrix and the conjunctive tissues to be developed.

This specific process, which makes the product more resistant to deformation, with a high elasticity module close to the elasticity module of a solid, is called EVE, for Extra Volumising Elasticity. This particular technology therefore favours elasticity, to decrease the impact of the viscosity (or flow) component.

The reticulation rate of Fortélis Extra is higher than that of Esthélis Basic.

CHEMICAL CHARACTERISTICS

Manufacturer's data, Anteis SA:

- pH: 6.8-7.4
- Osmolarity: 280-330
- Proteins: <50 ppm
- Endotoxins: <0.5 EU/ml.

VISCO-ELASTIC CHARACTERISTICS

What is elasticity?

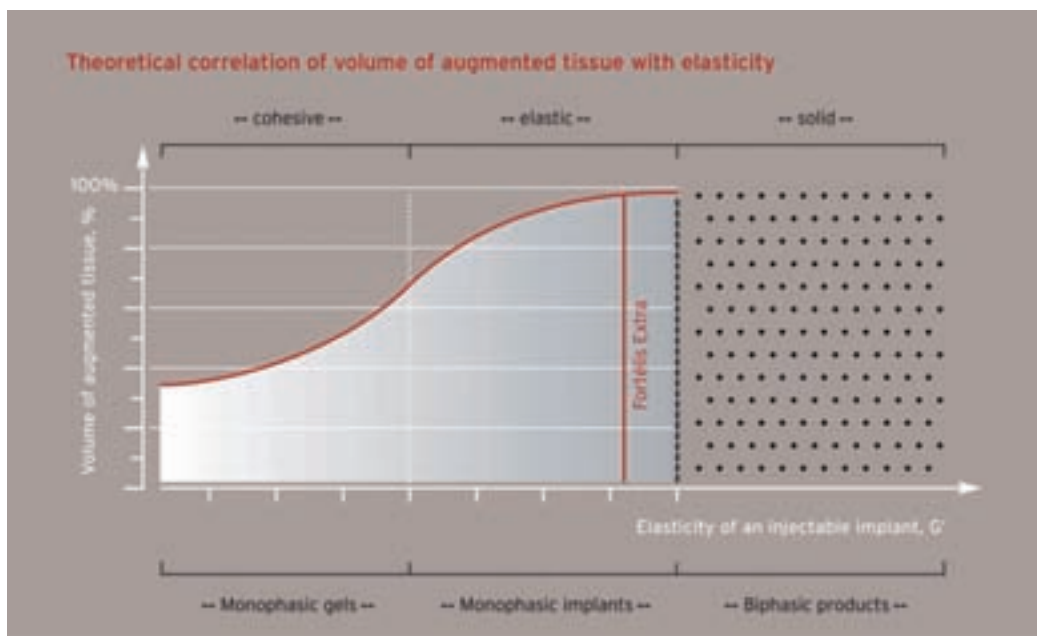
Elasticity is the capacity that a substance has to recover its initial shape when the exterior forces exerted on it are interrupted. It is a physical idea that is different from the common idea of extensibility, erroneously called elasticity.

What is an elasticity module?

The elasticity module of a gel represents its "solid" component, its resistance to external deformation forces, the gel recovering its initial form when the stress stops.

To retain its volumising character, a gel must have a high elasticity module after its injection into the dermis. The gel then permits the face's volumes to be modelled.

An insufficiently elastic gel will not permit the modelling of the face's volumes because it will not present enough resistance to the stress exerted by the tissues and will tend to favour a flowing behavior. However, these less elastic but more cohesive gels permit, through



Graph 1: Theoretical representation of the elasticity module of different forms of wrinkle filling gels (Courtesy Anteis SA).

their perfect bio-integration, a very natural correction of fine lines and wrinkles.

A too elastic gel becomes a solid. Its fragmentation inevitably entails the formation of particles (case of biphasic gels).⁶

The elasticity of the Fortélis Extra gel is very close to the elasticity of solids, while still retaining enough cohesiveness to remain a monophasic gel. (Graph 1)⁷

The Fortélis Extra gel can be compared with a cluster of small springs, connected to each other in the three dimensions of space. Once implanted into the reticular dermis or sub-periosteum, the “springs” develop an elasticity capable of pushing out the surrounding tissues and maintaining this increase in volume over the course of time.

INDICATIONS

During our first year of injection, we tried the Fortélis Extra gel in the following zones:

- Deep nasolabial grooves
- Deep frown lines
- Lips, as much for contour as for volume
- Hollow cheeks
- Cheekbones
- Chin
- Oval of the face
- Ring hollow with groove under the eyes

INJECTION

The injection is done with a Kendall-type 27G needle, in the mid- to deep dermis. The preferred technique is retrograde tunnelling or,

to create a volume, a slow local infiltration.

For the correction of folds, the implant, using the retrograde tunnelling technique, must be done in the deep, even mid-reticular dermis.

The superficial reticular dermis must be absolutely avoided. A risk of visible cords could, in fact, exist.^{3,8,9}

For the volumising effect, for example for the cheekbones, but also the chin, the injection can, indeed must, be done against the periosteum, the needle being introduced perpendicularly to the cutaneous plane. The product can be felt spreading under the fingertips during the injection. An injection using the fanning technique may be performed. A few clusters of gel may also be done. Once implanted, the gel can be delicately modelled after injection.

To fill hollow cheeks, the gel must be injected into the mid, even deep reticular dermis, possibly with a sandwich positioning.

To give the lips volume, the injection of a very small quantity of Fortélis Extra into the vermillion along the virtual channel is recommended to redefine the lips. Next, the implant is injected into the muscle using the retrograde tunnelling technique.

DISTRIBUTION OF THE GEL IN THE DERMIS

In theory, contrary to Esthélis, Fortélis Extra is not diffused into the dermis horizontally and vertically, but in the form of a cluster where it is deposited. It therefore has a volumising effect. Its visco-elastic characteristics permit

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the gel to be compared to “gummy bears” (jelly candies) or to an auricular protection “Ohropax”. (Figure 1)⁷

The gel undergoes pressure and major deformation as it moves through the needle. The structure of the matrix slowly recovers its geometry at the implant site.

It then therefore exerts, through its elastic component, pressure on the surrounding dermis, consequently permitting the correction of folds and deep wrinkles, providing volume in the exact proportion of the volume injected.

HISTOLOGY

The sole histological study currently available to us is the skin of the thigh of a male subject. (Figure 2)

At Day 0:

- 85% of the surface of the slice is occupied by an Alcian Blue + material and colloidal iron +, separating the collagen fibers.
- The implant is in the deep half of the reticular dermis.
- This image is totally different from the one observed with the CPM® gels of the Esthélis® range. These occupy the dermis along its entire height, excepting the papillary dermis, the gel harmoniously infiltrating between the collagen fibers.

At Day 90:

- 40% of the surface of the slice is occupied by an Alcian Blue + material, separating the collagen fibers.

- The implant is almost totally on the entire height of the reticular dermis with, however, predominance in the mid and deep part.
- The implant is dispersed in the form of pools, diffusing on the edges of these pools.
- There is no inflammatory reaction or fibrosis.

RETENTION OVER TIME

The clinical experience is a little over a year (February 2009) (marketed, CE label, as of November 2007).

Regular follow-up of the patients indicates a retention on the order of nine to 12 months.

The first 28 patients are broken down as follows:

- 28 subjects: average age 53 years old (33-67)
- 8 men: average age 48 years old (33-66)
- 20 women: average age 55 years old (43-67)
- Out of the first 28 subjects injected and followed, it may currently be said that:

At 6 months:

There is a clinical improvement, regardless of the zone treated. It is at the labial level that the product’s retention over time seems to be the lowest.

However it is also true our patients refuse to look like “groupers”. Therefore the quantity of the implant injected was always small.

At more than 10 months:

A distinct improvement of the various zones treated persisted for most of the subjects followed. (Figure 3)



Figure 1: Elasticity-plasticity of ear protection Ohropax®

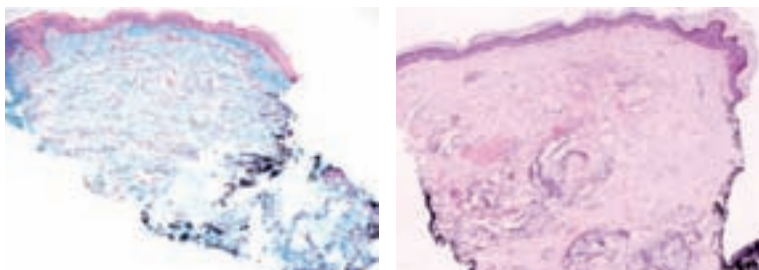


Figure 2: Histology - D0 Colloidal Iron

D90 Hematoxylin-Eosin

SECONDARY EFFECTS

We noted, during our first tests, an erythema and a discreet tumefaction of the soft tissues in a female patient treated for the disappearance of a buccal pad of fat on the right. The erythema remained visible for 48 hours and the tumefaction for six days. Neither of these reactions required treatment other than psychological support. The reaction is probably the result of the injection of too much gel (1 ml) for a small area. (Figure 4)

Following a demonstration injection, we noted a translucent cord, very probably due, as previously mentioned, to an injection that was a little too superficial. (Figure 5)

On the labial level, the result was particularly satisfactory and natural. We should point out, however, that at the level of the lip, the edema can be a little more significant than with the CPM technology gel.³

This edema can persist for three to 8 days, without any serious effects or consequences. The effect can be lessened, if necessary, by the administration of non-steroid anti-inflammatory medication after the implant.

Two patients did not like the result:

- The first because she received too large a quantity of the product in the lip (1.5 ml). (Figure 6)



Figure 3: Results



Figure 4: Side effects

Figure 5: Side effects

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- The second because the injection was slightly asymmetrical, with a slight edema reaction that lasted 48 hours.

DISCUSSION

Among the various volumising implants on the market, we must look at the cohesiveness and elasticity (elasticity module) of the product that we envisage using.

If certain measurements, such as the elasticity module, require more or less sophisticated equipment, it is easy, even in one's office, to do simple physical tests to evaluate the qualities of a gel. (Picture 7)¹⁰

It is the ease of injection of this gel with the EVE technology's dynamic cross-linking that, for non-surgeons, makes it a valuable work tool.

CONCLUSIONS

Fortélis Extra, an injectable implant with polydensified monophasic hyaluronan using the EVE technology, shows itself to be, after a year of use and follow-up, a volumising product for the redefinition of the face and lips, with excellent safety of use and retention over time, even in zones subject to strong mechanical stress.

After 12 months, no delayed inflammatory reaction was reported. It should be noted that

post-injection an erythema and/or edema of the zone treated may persist for 24 to 48 hours.

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Figure 6: Side effects



Figure 7: Comparative elasticity