Cosmetic use of tricalcium phosphate in hyaluronic acid

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Introduction

Reduction of facial volume, both in patients afferent to aesthetic medicine and patients afferent to dentistry, has been one of the problems due to its great impact for the last few years. In fact with the advent of new dental techniques, more and more patients after having gone from mobile prosthesis to fixed prosthesization especially through bony implants, have problems in the reduction of volume of perioral tissues. In this field, bio-restructuring medicines increased exponentially. Tricalcium phosphate (βTCP) is a rather new material in aesthetic medicine and presents the fundamental advantage to be ready to use, since it is already dispersed in hyaluronic acid with a stable preparation for a certain period of time. It is part of a category of bio restructuring medicines which are coverage that obtain a reaction from the organism through a mechanism of insult, lesion, both this insult is thermal, as in laser, or the insult comes from an extraneous body as happens for polylactic and tricalcium phosphate: a mechanism of reaction and reparation that will give as the result occurs. So, it allows the formation of a fibrous collagen, particularly useful in case of atony of tissues and for the restitution of not important volumes. The progenitor of bio restructuring medicines remains the polylactic acid, already on the market for almost 10 years. According to the author, tricalcium phosphate is half the way between polylactic and reabsorbable fillers, since it has a less volumetric impact compared to polylactic acid, it has indications very close to more tick and lasting reabsorbable fillers, but with a better duration of results compared to the last ones. This publication is not supported in any way from the manufacturer and it is the result of the experience independent from the authors. These pages are an update of the preliminary publication. (7)

Materials

Beta Tricalcium Phosphate (βTCP). βTCP, (chemical formula: Ca3(PO4)2) produced by the French ABR Developement, is a medical dispositive in class III. It has the trademark CE. The exact composition is:

- Tricalcium phosphate: 70mg (7%)
- Hyaluronic acid: 18mg (1,8%)
- Sodic caramellosis: 8mg (0,8%)
- Saline Solution: 1ml

It is a completely reabsorbable material. It is composed of microparticles of synthetic ceramic, biocompatible, biodegradable, immunologically inert, with a diameter of 40 micron. The study of the ceramic inert started with the French CNR back in the '60s, but a dedicated and better-aimed research was done in the '90s. These particles are dispersed in a gel of hyaluronate of pure sodium, not cross-linked, with a very high molecular weight. These are products produced by synthesis in laboratory and there is not any risk of bacterial contamination. These ceramic microparticles belong to the family of calcium phosphate and foresee a slow reabsorption, but absolutely complete, as demonstrated by numerous histological preparations. Reabsorption occurs due to phagocytes thank

to the macrophages, to extracellular dissolution and cellular degradation, to transformation in ions of Calcium and Phosphate and to elimination by chemical hydrolysis (due to hydration) without the enzymatic intervention through natural ways. The total reabsorption occurs in about a year. The product is sold in prefilled syringes of 1 ml ready for the use.
The **SODIUM HYALURONATE** contained in the commercialized product derives from bacterial extraction and presents a rather high molecular weight, from 2 to 3.000.000 Daltons that assure a not so quick reabsorption.

Mechanism of action

The mechanism of action is not completely cleared, even if it follows the footsteps of other bio restructuring medicines. Volumes increased for a mild reaction to tricalcium phosphate with a formation of fibrotic collagen. This reaction is normally cold. The hyaluronic acid in which it is dispersed the βTCP is, "according to the author", a double action: it allows an initial volumetric filling with a discreet duration that allows the patient to appreciate the immediate result. Besides, the hyaluronic acid has a very interesting reparative reaction that allows limiting to the minimum the spots of injection. Besides, it well helps the injection of the product. The mechanism of action and the rational use recommend a very prudential and gradual approach to the patient.

Contraindications and indications
Let us immediately say that patient with remarkable depletions of the under skin are not indicated: the product would not have an acceptable cost-benefit rate. Besides, the districts with high facial expression as forehead, wrinkles of the lateral canthus or the code bar wrinkles are still contraindicated. Even the zones with very thin skin, as for instance décolleté and neck, are still contraindicated. Instead the correction of nasogenian furrows and also important cutaneous folds is excellent. The product can be massaged and distributed very well and even in the cheeks' folds where the facial expression is important, it can be advantageous and remained natural. Even the patient with a ptosis of the malar region and the mandibular edge are indicated. The result on the depress scars is excellent, if they are enough soft and do not have too defined edges.

Preparation

All the patients have been largely informed about the obtainable aesthetic possibilities and about the characteristics of materials. A complete informed consent has been always signed up. All the patients have been photographed according to the standardized guidelines of the author, always respecting the plan of Frankfort. (Fig.1)

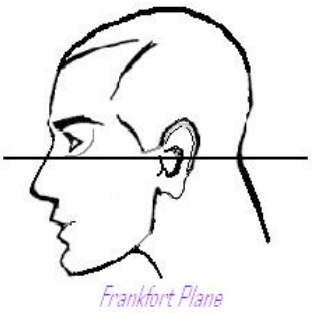

Fig. 1: Plan of Frankfort

Pictures are taken in A-P, at 45° and also picture of the right and left profile. Patients are marked,

especially the first times, to decide exactly how to distribute the material. For this purpose, eyeliner for make up is used because it can be easily removed. Then, the patients are anaesthetized with lotion made of prilocaine and lidocaine for at least 30 minutes. Plastic wrap keeps the lotion in occlusion. Lately a new anesthetic galenic lotion, prepared by an expert pharmacist with lidocaine at 15%, has been tested. We will inform you when an adequate experience will occur.

Technique

The packaging is made of 2 fl of product of 1 ml each with 4 26G needles. The product can be easily extruded also through a 27G needle. Injections have to be executed, as already said, very superficially compared to polylactic acid, in the deep derma, and not in the under skin, where the product is lost with rather modest results for acceptable quantities. The first times that it is injected, it is good to be prudent because the injective easiness can easily lead to hypercorrections, even though an accurate massage can reduce this eventual problem. As a rule for almost every materials handled by the author (this remains the golden rule) injections are executed never over the 0,1 ml each and especially well distributed until the attainment of the desired volume. Injections in bolus have always to be avoided, unless it is a cheekbone or the malar zone where the injection is normally deeper. In this case the required quantity of material increases a lot to obtain a visible correction. At the end, a massage is always performed to uniform the implant, even if a distribution is not possible as for many materials diluted in water. In fact, it is a gel that pervades the tissues in a way similar to fillers. The number of injections especially guarantees the uniformity of the implant: it is better to execute more injections with small amount of material rather than fewer injections with lot of material. The hyaluronic acid allows an immediate volumetric result, well accepted by patients, and the number of phials used per session can be even two. The prudence, as already said before, imposes to well evaluate the patient while we are correcting him/her, avoiding hypercorrections. The volume given by the correction of hyaluronic acid tends to decrease after 15, 20 days, while the one due to the neocollagenesis thank to βTCP tends to appear. But the real result is obtained 2 months after the last session. As previously said, a phial is normally used, but it is possible to use even 2 or 3 of them. It is evident that the costs increase. If this is evident and valid for aesthetic medicine, a complex dental rehabilitation, where the costs can be easily damped to have in the end both a perfect mechanical result and a good aesthetic result, can be less important. However, it is better to execute more sessions with a single phial rather than use all material in only one session. This is normally the rule of the author. Following sessions are executed: generally the first sessions are done after 30-40 days, but in some patient even one session can be sufficient. It is possible to superficialized the injections, for example in nasogenian furrows, to have a better volumetric result, but pay always attention not to execute too superficial and so visible implants: a deep implant needs more material but it always looks more natural.

Results and discussion

The technique is very easy: the material is easily handled and gives immediate and easily determined results. The preliminary results already published in a scientific paper (7) confirm the good compliance of patient. The pain of the procedure has always been acceptable. Today, after 1 year and a half from the first experiences, the volumetric result is good after a period of time if the injections remain in the deep derma. One of the best areas, where the results were excellent, is the area of the nasogenian furrows: the result is immediate and very natural. Even the marionette's wrinkles had a good immediate result as good was the result on the mandibular edge. The late result starts to appear after 20 days and it reaches its maximum, according to the first experiences, after about two months. But as it happens for all the bio restructuring medicines, after a period of

time a compaction of the derma and in general a more turgid skin occurs. (Fig.2-3) Even the cheekbone has never been treated superficially, but only to improve the thickness.

Fig. 2: Patient before the treatment

Fig. 3: Patient after the treatment

The collateral effects (Tab. 1) have been overlapped to the ones due to fillers: hematomas, modest edema that last at least 24 hours, local reddening for several hours. Nor reaction of intolerance either the appearance of nodulation right after the procedure or after a period of time occurred.

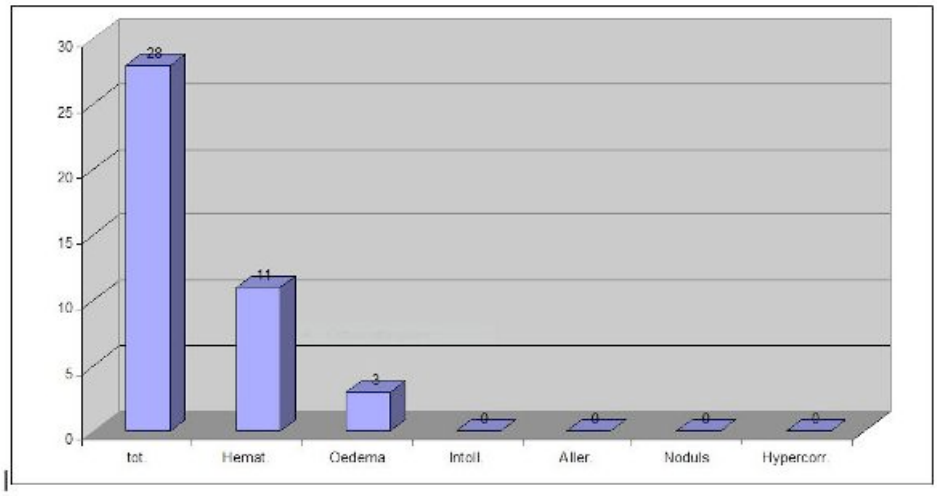

Table 1: Collateral effects

Conclusions

The correction of not important volumes, but especially the correction of facial folds, finds in tricalcium phosphate an innovative product that so far did not give any problems. Doing the math, after a year of using it, the indications are closer to fillers rather than restructuring as polylactic acid. The result after a certain period of time improves compared to common reabsorbable fillers. A

discreet experience is still required and we are all waiting for some independent scientific publications that validate its safety and long lasting results.

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