



THE BOTULINIC TOXIN

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Information delivered to :

Cachet du Médecin :

Patient's name :

Date :

This document has been conceived under the authority of the French Society of Plastic Reconstructive and Aesthetic surgery (Société Française de Chirurgie Plastique Reconstructrice et Esthétique - SOFCPRE) to complete the information that you received in your first consultation with your Plastic Surgeon. It aims to answer all the questions that you might ask, if you decide to undertake botulinic toxin.

The aim of this document is to give you all the essential information you need in order to make an informed decision, with full knowledge of the facts related to this procedure. Consequently, we strongly advise you to read it carefully.

• DEFINITION, AIMS AND PRINCIPLES

The botulinic toxin is a substance which decreases the muscle contraction by acting at the level of the neuro-muscular junction (myorelaxing action).

Since 1975, the physicians are using the botulinic toxin to correct child strabism, facial tics and spontaneous eye blinking.

In France, the first official licence ("AMM") dates from 1990 concerning certain pathologies in ophthalmology, ENT, fonctionnal physiotherapy and neurology.

Concerning aesthetical medicin, Doctor CARRUTHERS, a canadian ophthalmologist, is the first noticing that patients treated with botulinic toxin have less wrinkles around the eye than the others. In 1990, a more observing female patient asked him to balance the other eye : the aesthetical indication is born so.

The botulinic toxin, under the name of "BOTOX" received, in USA, the Food and Drug Administration (FDA) authorization in 2002 for its use to treat the wrinkles in between the two eyebrows.

In february 2003, for the first time, the french administration, in charge of medicine controls, gave an official licence (AMM) for aesthetical purpose to the botulinic toxin, under the name of VISTABEL (Allergan laboratory). This licence concerns the botulinic toxin use for the treatment of the glabella wrinkles under certain conditions of competency from the physician and of using modalities.

If botulinic toxin injections are done outside this anatomical area, they would be done "out AMM"

In practice, the more usual indications for botulinic toxin aesthetical injections are the wrinkles between the two eyebrows, the frontal lines and the crow-feet wrinkles.

The principle of botulinic toxin consists of using its muscular release properties.

The main goal, we want to reach, is to obtain a decreased muscular action at the level of the forehead and the eyebrows , in order to decrease either the horizontal wrinkles and the vertical ones, done by muscles contraction.

Such a use allows to smooth the skin reliefs and so to get a rejuvenative effect due to the muscular tension release.

From a more global point of view, we must know that the brow position is fixed by the balance of two opposite forces, one corresponding to lowering muscles (located around the eyebrow) and the other one corresponding to one elevating muscle (the frontalis muscle).

The horizontal wrinkles are due to the contraction of the frontalis muscle, and the vertical ones are due to the contraction of the lowering muscles.

This treatment main goal is to improve wrinkles and fine lines, when in a resting position and not to avoid muscle contraction. So, the result will be judge especially on the wrinkles aspect of a quiet face.

Concerning the balance between the lowering and elevating muscles, the botulinic toxin, by reducing the action of one muscles group, decrease the wrinkles related to these muscles and free, at the same time, the action the opposed muscles : our aim is to treat the muscular balance, in order to obtain so a facial harmony.

The botulinic toxin treatment must be done and think with time : so, it is recommand, at the time of the first session, to treat progressively and to avoid the risk of "doing too much".

We should prefer a moderately efficient first session then a too efficient one : so, we don't think, it is suitable to target an optimum as soon as the first injection. In certain cases, it can be necessary to practice several sessions before adapting, for the best, this treatment potentialities, in respect with patient particularities.

• BEFORE INJECTING

No need for special preparation.

The day of injection, you don't need to be fasting. For women, it is recommended to come without any make-up or to remove it just before the injection.

It is very important to minimize the bleeding risk, at the treated areas, by avoiding aspirin for 15 days before and after the session.

We must also respect the following **contra-indications** :

- Certain neuromuscular diseases, like myasthenia
- Pregnancy and breast feeding : even if pregnant only for few days pregnancy, you must reschedule the injections after your pregnancy and breast feeding, eventually. So, it is advisable to perform any necessary exam, if you are in doubt and to inform, by giving the results to your physician.
- Known hypersensitivity to botulinic neurotoxin A or to serum-albumin
- Present treatment with antibiotics from the aminosid group (Amiklin, Gentallin)

We must also respect a certain number of **precautions** :

- If you are treated, on the other hand, by botulinic toxin injections, for pathological spasms, if you had an episode of facial paralysis, if you suffer of neuromuscular disease or of clotting failures, you must tell your physician who should do your aesthetic botulinic toxin injections. He will judge himself, after contacting your GP, if it is advisable or not to perform these injections and how to do it.
- If before injections, you take medicine, like anti-coagulating drugs or aspirin or antibiotics or if you have any health problem (like infection, flu, dental abscess ...) you must imperatively tell your physician before injections.
- From a general point of view, don't hesitate to mention your physician all even lesser health problem, you had to allow him to see if these injections are advisable. With the same idea, you must tell all your interrogations and mention all the treatments, you.

• TYPE OF ANESTHESIA

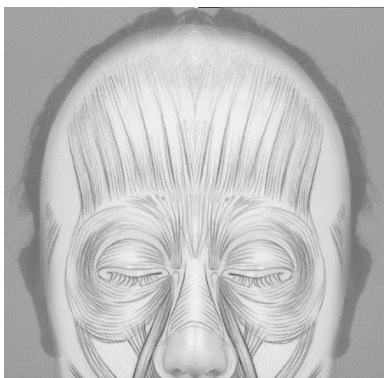
No anaesthesia is needed

• INJECTIONS PERFORMANCE

The treatment is done in the doctor's office or in an hospital, depending on your doctor's choice and habits.

This treatment consists on a serie of facial injections. The needle is fine and the injections are usually less painful.

The time treatment is a few minutes.



• AFTER THE OPERATION : THE FOLLOW-UP

During the two hours following the injections, it is advised not doing intense sport and not lying down. It is also advised to avoid facial manipulation or massage for 24 hours following the session.

It is very important to minimize the risks of bruises or bleeding at the treated area, for 15 days before and after injections, in order to avoid the injected substance to run away to muscles around what could produce undesirable side effects.

On the other hand, during the three days following injections, it is suitable to strongly contract the injected muscles, three times a day, during about 5 seconds per muscle.

Usually, the after injection is light. Some slightly swollen marks may stay for 20 to 30 minutes before disappearing. The patients can go back to their normal life after the injections. Some rare undesirable but transitory effects may occur like :

- Redness at the injected points, rarely persisting more than 3 to 6 days
- Ecchymosis (bruises), rarely observed and may stay a couple of days
- Edema : a swelling, more often around the eyes, may appear progressively within 4 to 5 days and then decrease within a few days or weeks.
- Sensibility failure : an impression of tension or fixity of the forehead, mouth or neck, depending on the treated area, as well as a modified sensibility, related to the feeling of a "cardboard" skin, may stay for a few days.
- Ocular or facial fugacious pains : such pains have been described in the treated region but remain exceptional

Whatever, if you have any worry in the post injection period, don't hesitate to contact your physician.

• THE RESULT

The expected result consists of wrinkles decreasing with small motions keeping; it is obtained within 3 to 15 days following the injections.

Effects : you can see the result after a few days, but for about 15 days, the effects on the face may be variable (even sometimes possibly asymmetrical) before ending to stabilize.

The result obtained after the first session stays 3 to 6 months averagely, after what the injection can be renewed.

Injection frequency : the injections have to be done several times, with space of 3 to 6 months, before getting a quite stable result.

Starting after the second injection, the results may stay longer (6 to 8 months). It is then suitable to repeat the injections every 3 to 6 months.

But we recommend never reinjecting after a period of time of less than 3 months, to avoid, especially, to create a resistance to the substance, due to like "a vaccination effect".

The result on the face aspect can be stabilized after 3 sessions but, in certain cases, we may need at least 8 to 10 sessions to get a quite stable result.

On the other way, we must remark that if we stop injecting, the treated muscle will go back to its normal function, from before the injections.

• **DISAPPOINTING RESULT**

Localized imperfections

In a few cases, some localized imperfections (persistence of small wrinkles) may be seen without speaking of real complication. They depend to the previous aspect of the skin, already marked with deep indelible “fracture” due to the oldness of the wrinkle.

It may also exist insufficient or even asymmetrical results : they are related to the fact, we have more or less strong muscles and often asymmetrical too.

These imperfections are usually treated with a complementary botulinic toxin injection, a month after the injection.

Concerning this, we must underline that if a localized complementary injection may be indicated to improve the result, it shouldn't be done before 15 days after the session because the balance between the different muscles takes 15 days to set up.

Residual asymmetry

An asymmetry between the two sides of the face as well as more marked wrinkles on one side than the other may most often exist before the injection. On the other hand, the muscle responsible for the wrinkle can be stronger on one side than on the other. This is generally analysed before the injection. In such a case, the injections will be done in an adapted way, it means, slightly differently on one side compared with the other. Nevertheless, a residual asymmetry can persist and eventually profit from a complementary injection.

Aesthetical procedures aim to render the patient happier, in a realistic way. But sometimes, we can miss the goal and the procedure may unfortunately improve pre-existing psychological problems. The post-injection experience can be extremely different from one patient to the other and this even in case of a comparable aesthetical result.

Concerning botulinic toxin, the rejuvenation is obtained with the contrapart of some facial expression decreasing or even disappearing. This aspect of this treatment would have been evaluated with you to avoid disappointment especially if you are acting, presenting

• **POSSIBLE COMPLICATIONS**

The complications are very rare.

The possible complications are the followings :

PERSONAL OBSERVATIONS

Facial complications

- Headache : it can appear after the first injections and disappear within a few hours to a few days
- Eyebrow ptosis : frontal injection may produce a slight drooping of the eyebrows. This is generally due to a previous low position of the eyebrows. It will usually regress within a few weeks.
- Eyelid ptosis : the injection of the glabella region may induce a partial drooping of the upper eyelid which can stay for 4 to 8 weeks. This is quite rare (less than 1% of the cases) and always disappears within a few weeks.
- Smiling and swallowing discomfort : lips injection may induce a smiling discomfort or small abnormal movements. The neck injection may produce swallowing difficulties.
- Eye dryness : due to a decrease in tear secretion, which can produce a keratitis, especially on patients wearing contact lenses (be aware to well hydrate the cornea)
- Paradoxical muscle contraction and mimic disturbance : in the days following injection, the muscles may present some paradoxical movements (spontaneous contraction) without any gravity.

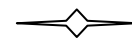
General complications

They are absolutely exceptional.

- Allergic reaction: cutaneous rash, urticaria, general allergic reaction
- Nausea, vertigo
- Tiredness, fever, flu syndrome
- Skin and buccal dryness

All things considered, the risks must not be overestimated, but you must be conscious that an operation, even a minor one, always has some degree of unforeseeable unknown factors.

You can be assured that if you are operated on by a qualified Plastic Surgeon, he will have the experience and skill required to avoid these complications, or to treat them successfully if necessary.



These are the facts which we wish to bring to your attention, to complement what you were told during the consultation.

Our advice is for you to keep this document and to read it and think it over carefully after your consultation.

Once you have done this you will perhaps have further queries, or require additional information.

We are at your disposal should you wish to ask questions during your next consultation, or by telephone, or even on the day of the operation, when we will meet in any case, before the anesthesia.

