CHAC technology

CELLBOOSTER®

LIFT

CLINICAL STUDY

A prospective, open study on the safety and effectiveness of CELLBOOSTER® LIFT (stabilized booster complex using CHAC technology) on healthy subjects.
Study conducted by EUROFINS in collaboration with Dr. Patricia Morel Mandrino (France) and Dr. Gabriel Siquier (Spain).
Study led by Eurofins, independent laboratory (France).

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CE 0373

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CELLBOOSTER® LIFT

CLINICAL STUDY

INDICATIONS:

- Moderate skin depression, loss of firmness or laxity (facial tissue & contours)
- Fine lines & wrinkles
- Dehydrated skin
- Visible dryness
- Loss of skin tone & microcirculation
- Atrophic scars, post acne, striae
- Couperose.

TREATMENT AREAS:

Epidermis and dermis of:

- Face
- Neck
- Decollete area
- Back of the hands
- Internal face of the arms
- Body

- ✓ Lifts & Smoothes Wrinkles
- ✓ Skin Redensification
- ✓ Skin Tone & Microcirculation Improvement

COMPOSITION:

Stabilized
HYALURONIC ACID 18 mg

VITAMINS
- Riboflavin (B2)
- Sodium Ascobyl Phosphate (C)
- Tocopherol (E)
- Biotin

AMINO ACIDS
- Arginine
- Glycine
- Lysine
- Proline
- Valine

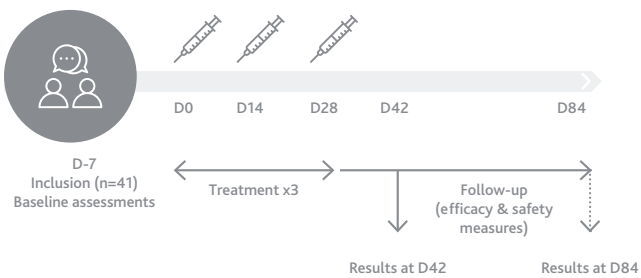
STABILIZED REJUVENATING COMPLEX

METHODOLOGY:

Study design:

Prospective, monocentric, open, non comparative, post-marketing study designed to investigate the efficacy and safety of CELLBOOSTER® Lift on healthy female and male subjects (n=41) aged between 36 and 55 years old, with signs of cutaneous dryness on cheekbones and cutaneous aging on the face (wrinkles, skin laxity and dull skin).

Patient treatments and follow-up



- EMLA CREAM 5%
- 3ml CELLBOOSTER Lift / Session
- Intradermal injection (papula)
- Same injection technique and depth for every patients (whole face excepted forehead)

Patient inclusion & disposition

- ✓ 41 healthy patients aged from 36 to 55 years old (mean 47.8 ± 4.95 yrs, 37 female and 4 male subjects) were included in the study to receive injections of CELLBOOSTER® Lift.
- ✓ All subjects included had hydration values (measured by Corneometer® at baseline) <60AU (mean ± SD = 44.81 ± 8.66 AU).

Objectives:

Primary:
- To evaluate CELLBOOSTER® Lift **effectiveness on skin hydration improvement** 2 weeks after the last treatment (considering a clinically relevant improvement with a change from baseline higher than 2 AU).

Secundary:
- To evaluate **effectiveness on the improvement of skin quality** by objective measurement of skin biomechanical parameters, density, hydration, microcirculation, wrinkles and colour, 2 and 8 weeks after the last treatment.
- To evaluate **effectiveness on clinical Global Aesthetic Improvement**, using the Global Aesthetic Improvement Scale (GAIS), **evaluated by the investigator** 2 and 8 weeks after the last treatment.
- To evaluate **effectiveness on clinical Global Aesthetic Improvement**, using the GAIS, **evaluated by the subject** 2 and 8 weeks after the last treatment.
- To evaluate the **satisfaction of the injectors and the subjects** using a subjective evaluation questionnaire 2 and 8 weeks after the last treatment.
- To illustrate **aesthetic effect through 2D photography** throughout the study period.
- To evaluate **safety throughout the study period by Injection Site Reactions (ISRs) and adverse events (AEs)** collection.

Assessments/endpoints

Primary:

Moisture *(corneometer)* — Change from baseline of epidermis hydration (>2AU*) at D42 — *Arbitrary Unit.

Functional measures

Secondary:
- Hydration *(corneometer)*
- Skin microcirculation *(Laser Doppler)*
- Skin parameters *(cutometer)*
- Skin density *(Dermascan)*
- Skin color *(photographies)*
- Skin wrinkles parameters *(Fringe projection system)*

Change at D42/84 vs. baseline

Subjective measures
- Aesthetic effect *(photographies)*
- GAIS score ≥ "improved" *(investigator & subjects)*
- Degree of satisfaction *(subjective questionnaire – Investigator & subjects)*

Safety — Injection site reactions (ISRs) and adverse events (AEs) collection – Investigator & subjects

Statistical analyses & populations

- FAS (Full Analysis Set): n=41 (any subject included in the study with at least a post-basal value)
- PP (Per Protocol) population: n=39 (any subject included in the study without major deviation)
- Safety population: n=41 (any subject having used the tested device).

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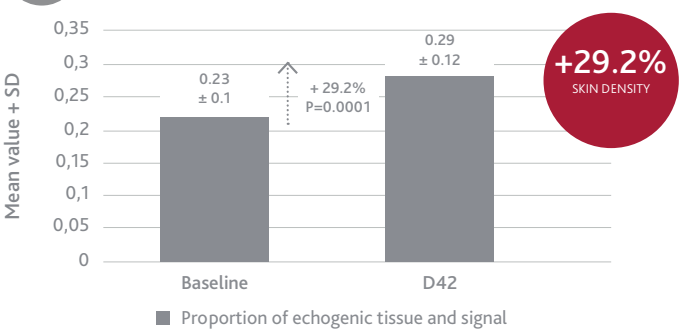
RESULTS AT D42

A significant improvement in skin density

Skin density change *(Dermascan)*

Changes in skin density value between D42 and baseline



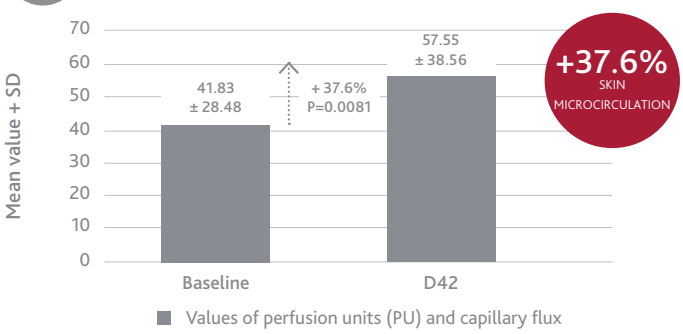
More rejuvenated cells such as fibroblasts => working the skin from the inside!

Significant increase in the proportion of echogenic signal (+0.06, +30%) 2 weeks after the last injection

A significant improvement in skin microcirculation

Skin microcirculation *Laser Doppler*

A significant improvement in skin microcirculation and capillary flux



A better blood flow, and thus more oxygen & energy for the tissue!

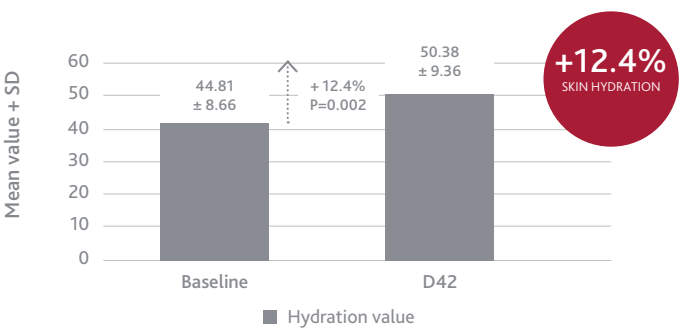
Significant increase in skin microcirculation (perfusion units & capillary flux by >15 units (>37%)) 2 weeks after the last injection

A significant improvement in skin hydration (primary endpoint)

Moisture change *(Corneometer®)*

A significant improvement in skin moisture/hydration 2 weeks after the last injection

Changes in hydration value between D42 and baseline



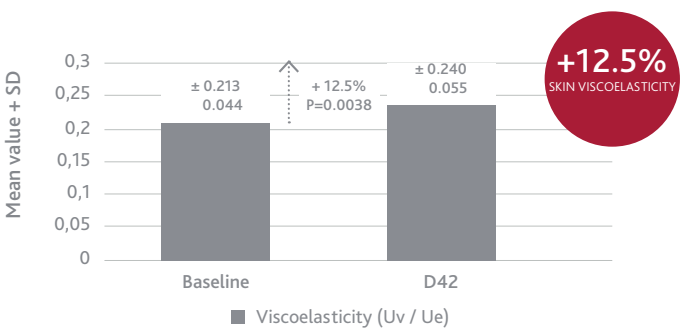
The improvement of skin hydration was statistically superior from 2 (p=0.0286) at D42 (2 weeks after the last injection), which indicates the efficacy of the treatment

A significant improvement in skin viscoelasticity parameter

Viscoelasticity change *(Cutometer®)*

A significant improvement in skin viscoelasticity 2 weeks after the last injection

Changes in skin viscoelasticity value between D42 and baseline



Statistically significant increase (+12.5%) in skin viscoelasticity (p=0.0038) two weeks after the last injection

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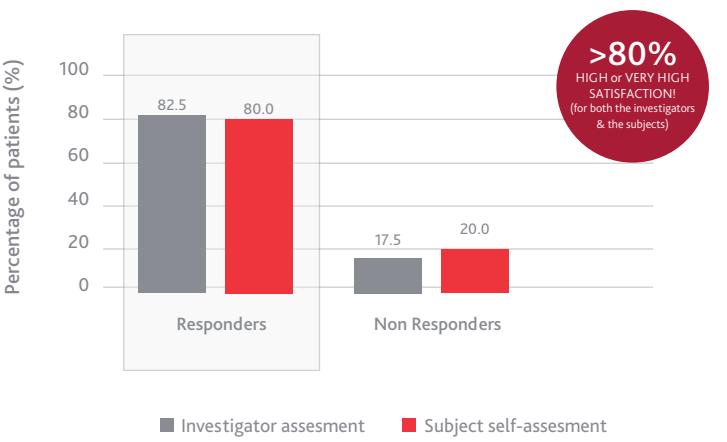
RESULTS AT D42

A significant improvement in aesthetic rating

A significant improvement in skin microcirculation and capillary flux

Aesthetic change - GAIS
as measured by investigators and subjects

Responders rates
as measured by investigators and subjects

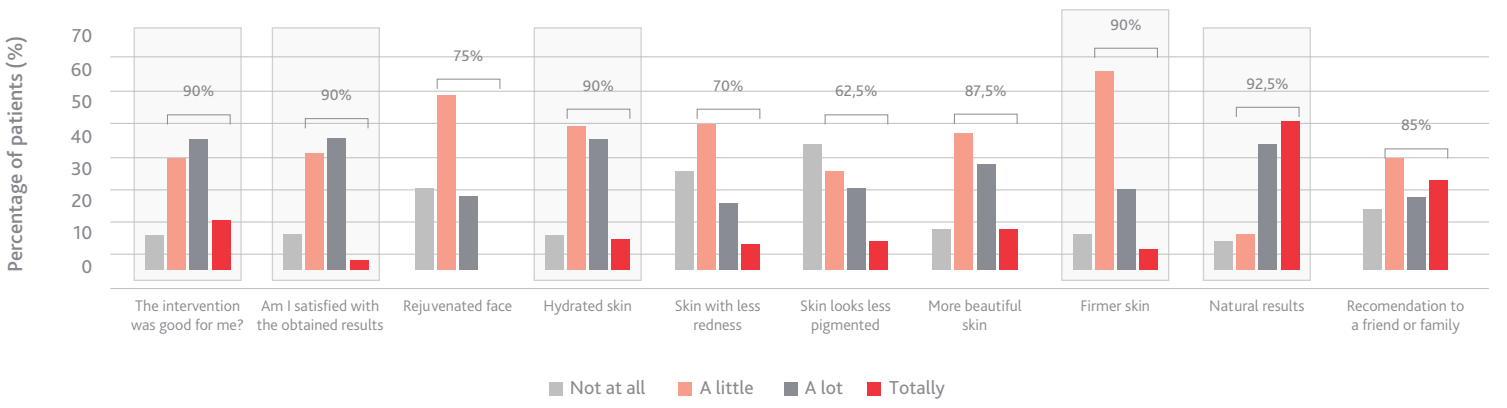


A very high satisfaction and a statistically significant responder rate as rated by the investigators and the subjects 2 weeks after the last injection

CELLBOOSTER® Lift: a significant improvement in aesthetic rating

Very high satisfaction rates among included patients

Patient satisfaction and agreement regarding the improvement of their skin



A very high satisfaction of the subjects 2 weeks after the last injection

Subject Satisfaction

>90% HIGH or VERY HIGH Patients SATISFACTION!

« The treatment is good »
« Obtained results »

>60% Patients SATISFACTION on all parameters!

« Hydrated skin »
« Firmer skin »

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A high satisfaction during injection sessions

Injectors appraisal on product features
during the 3 injections

100% HIGH or VERY HIGH SATISFACTION at D0, D14 & D28!

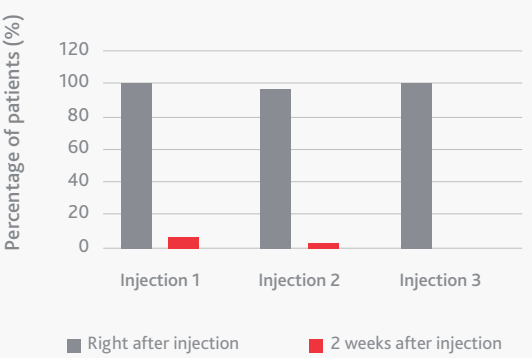
- ✓ EASE OF INJECTION
- ✓ EASE OF VIAL MANIPULATION
- ✓ EASE OF PRODUCT POSITIONING
- ✓ EASE OF TURBIDITY DETECTION

CELLBOOSTER® Lift: Injection Site Reactions (ISRs) and Adverse Events (AEs) appraisal

Injection site reactions* as reported by the investigators and the subjects

Safety endpoint - ISRs
Investigators and subject report
(ISRs collection)

Proportion of patients presenting at least one sign of ISR during the clinical trial



- ✓ Most of the ISRs observed by the investigators and subjects were judged as being mild.
- ✓ None of the reported ISRs were considered as severe whatever the injection point.
- ✓ All ISRs reported by the subjects lasted from 1 to 3 days & disappeared 2 weeks after each injection session.

ISRs were considered as expected following an injection with a Class III medical device & resolved 2 weeks after the last injection

* ISRs reported by investigators and subjects were considered as expected after a Class III medical device injection and included Redness/Erythema, Pain/tenderness, Induration, Oedema, Lumps/Bumps, Bruising/Hematoma, Itching and Discoloration/Pigmentation.

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CONCLUSION

A strong clinical trial that allows 2 weeks after a 3 injections protocol to observe that CELLBOOSTER® LIFT leads to:

+37.6%
SKIN MICROCIRCULATION

+12.5%
SKIN VISCOELASTICITY

+29.2%
SKIN DENSITY

+12.4%
SKIN HYDRATION

+100%
HIGH OR VERY HIGH
INJECTORS SATISFACTION

>90%
HIGH OR VERY HIGH
PATIENTS SATISFACTION

With a well tolerated treatment

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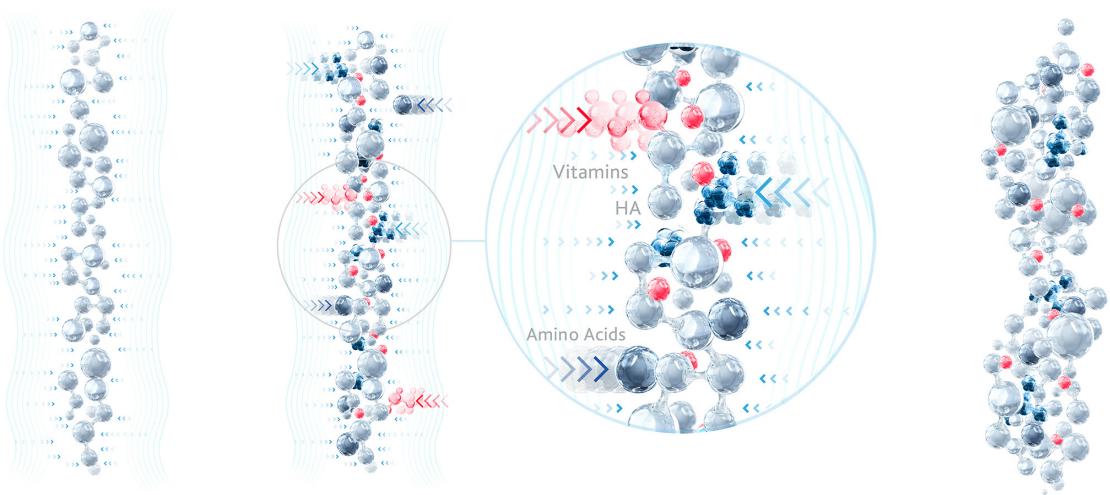
CHAC TECHNOLOGY

CHAC Technology modifies and exploits the natural properties of Hyaluronic Acid (HA) making it an **optimal vehicle** for transporting essential nutrients to the skin, ensuring their **effective delivery** and **long-lasting results.**

This proprietary technology makes it possible to integrate biologically active ingredients onto HA macromolecules under conditions of mechano-stimulated reactions - **simultaneous pressure** and **shear deformation.** Specific bioactive components such as vitamins, and amino acids are **simultaneously integrated** and **uniformly distributed** onto the HA macro chains, **forming a large complex** that in essence represents a **unique macromolecular 'depot'** of biologically active material. As a result, multiple molecular complexes are formed.

These **molecular complexes** are based on supramolecular interaction between bioactive components and functional groups of HA, and unlike bioactive components **cannot be recognized by hyaluronidase.**



STEP 1

FORMING OF A HA MATRIX:

High pressure and **shear deformation** ensures unfolding of the molecules of HA.

STEP 2

FORMING OF LINKED COMPLEX:

Integration of active components into the structure of the HA "matrix" under the influence of pressure and shear deformation with **the formation of links** between HA molecules and active components (amino acids and vitamins).

STEP 3

FORMING THREE-DIMENSIONAL STRUCTURAL CHAC-COMPLEX:

The pressure on molecules reduces resulting in "unfolding" of the HA molecules with **integrated active components.**

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