suisselle

beauty ▪ science ▪ innovation

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).

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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

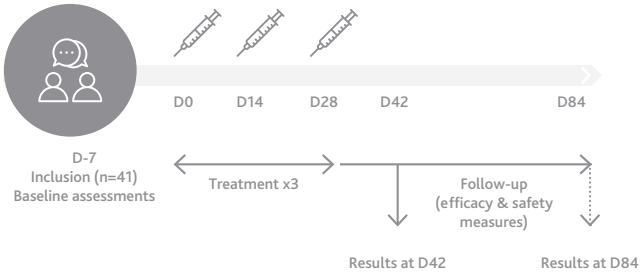
STABILIZED REJUVENATING COMPLEX

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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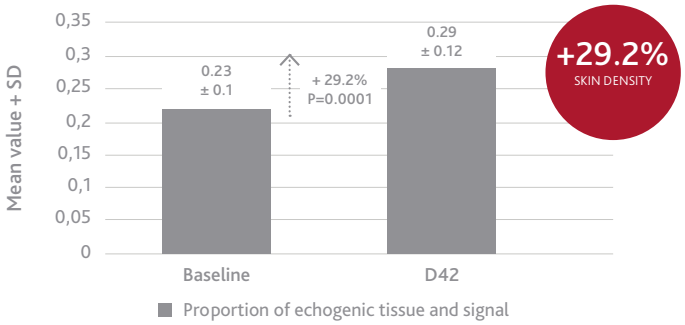
RESULTS AT D42

A significant improvement in skin density

Skin density change *(Dermascan)*

Changes in skin density value between D42 and baseline



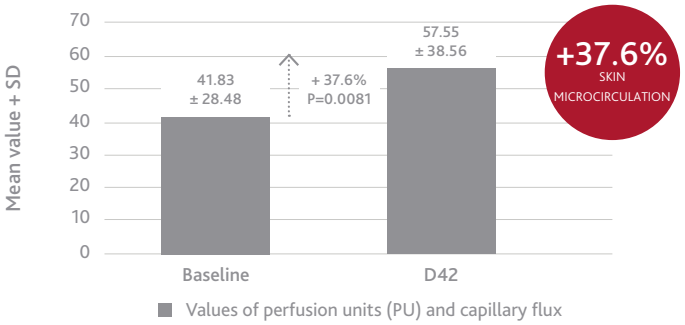
More rejuvenated cells such as fibroblasts => working the skin from the inside!

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!

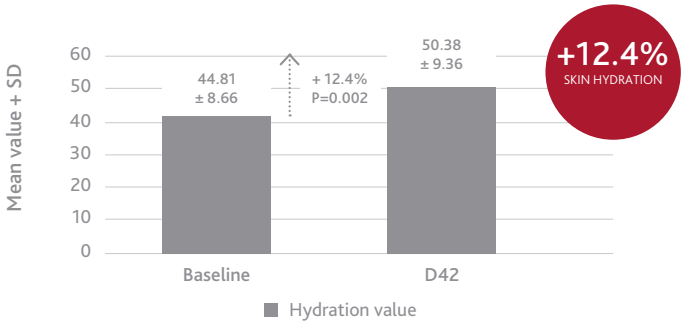
Significant increase in skin microcirculation (perfusion units & capillary flux by >15 units (>37%)) 2 weeks after the last injection

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



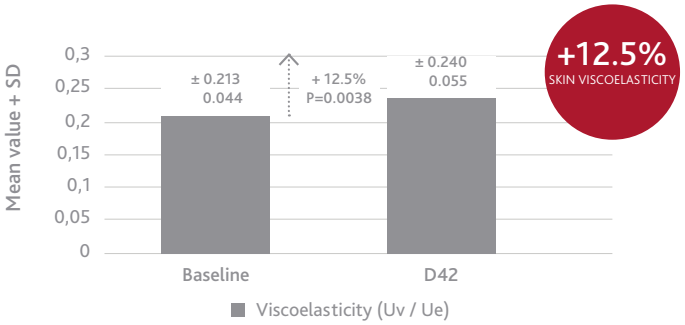
The improvement of skin hydration was statistically superior from 2 (p=0.0286) at D42 (2 weeks after the last injection), which indicates the efficacy of the treatment

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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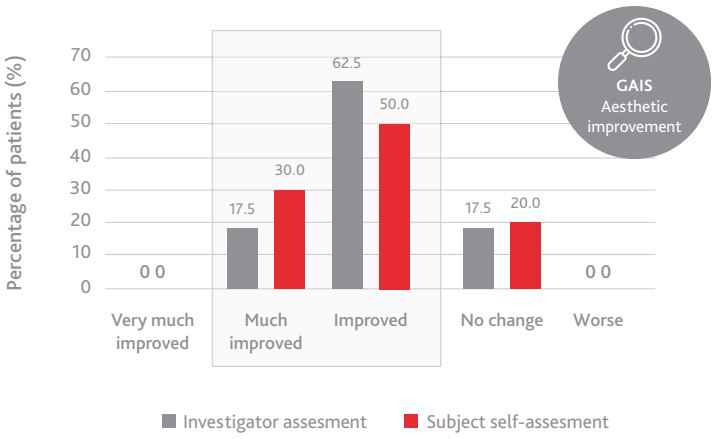
RESULTS AT D42

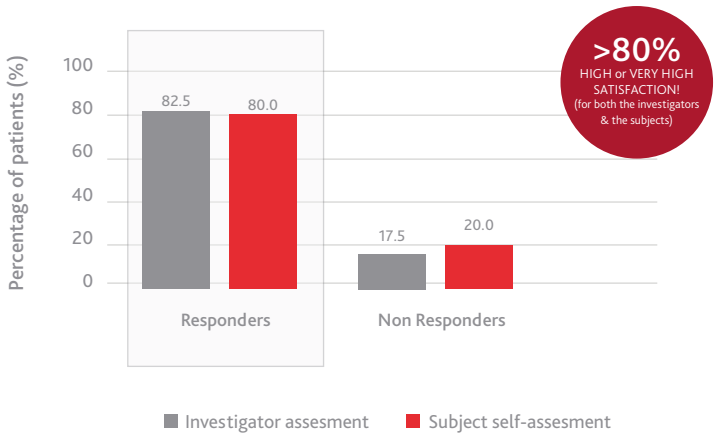
A significant improvement in aesthetic rating

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

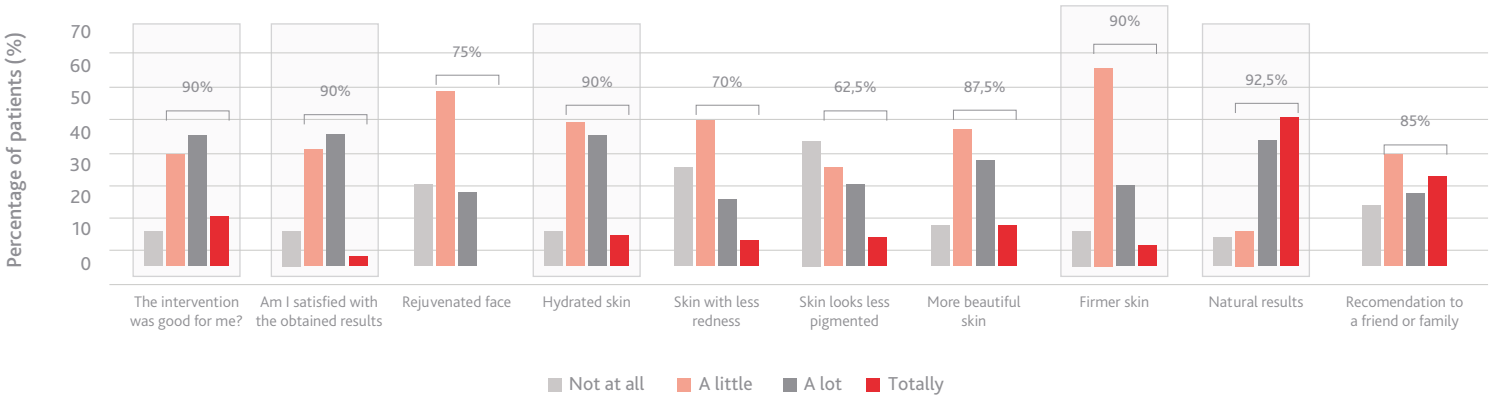


A very high satisfaction and a statistically significant responder rate as rated by the investigators and the subjects 2 weeks after the last injection

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!

>60% Patients SATISFACTION on all parameters!

« The treatment is good »
« Obtained results »
« 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!

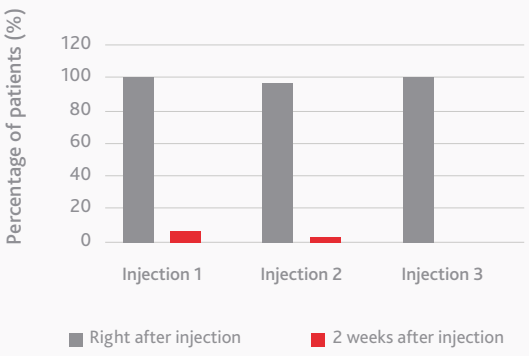
- ✓ EASE OF INJECTION
- ✓ EASE OF VIAL MANIPULATION
- ✓ EASE OF PRODUCT POSITIONING
- ✓ EASE OF TURBIDITY DETECTION

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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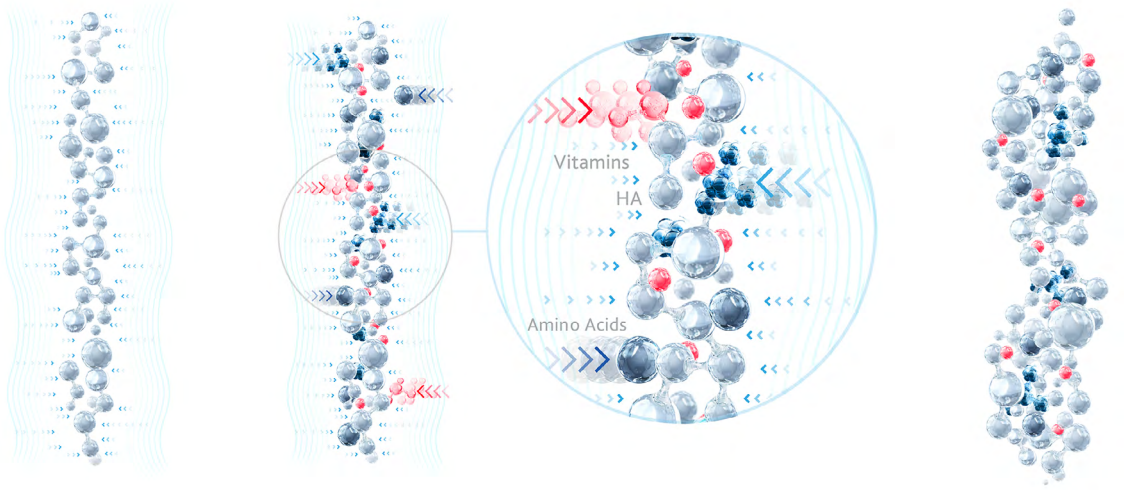
CHAC TECHNOLOGY

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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