Evaluation on volunteers, of depigmenting effect on haematomas and oedemas of K Ceutic

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Objective of study

This study consists on the application of **K Ceutic,** in house, after an aesthetic intervention, on the affected area with haematomas and oedemas, during a minimum of 3 weeks up to the total disappearance of the haematomas.

The "depigmenting" effect has been evaluated on 10 volunteers operated on to facial area (Blepharoplasty, Rhinoplasty) and 10 volunteers operated on body area (Liposuction). The evaluations have been carried out using an analogical visual scale by capture of postoperatory photographies every 2, 3 or 4 days.

In parallel, the volunteers have filled a questionnaire in order to evaluate subjectively the cosmetic qualities of the product.

Volunteers

Recruitment principles of the selection and the admission

The included volunteers have been selected from a general panel coming from doctor's patients.

Number of volunteers

20 volunteers have been included in the experiment, 10 for the facial treatment and 10 for the body treatment.

Inclusion criteria

-Recently operated aesthetically on a Blepharoplasty or Liposuction.
-Female or male;
-Age: more than 20 years.
-Skin with haematomas and oedemas marked in the operated zones.

Methodology

Organization of the trial

The study is, opened, intra-individual and comparative across an analogical scale to evaluate, taking into account the photos taken of the volunteers on day D1 of application of the product (some days after the intervention) and of the successive sessions of photos.

This test includes:

1-An initial evaluation that allows verifying the criteria of incorporation and non-incorporation.

2-A period of treatment of 15-21 days in normal conditions of use.

3-Photos in the D1 and in the successive visits to realize the follow-up of the efficiency of the product.

4-Evaluation by the investigator of the intensity of the spots and haematomas by means of an analogical scale from 0 to 5, realizing comparisons that evaluate a maximum intensity of the spots for the D1 (5 in the analogical scale) and 0 it represents the total absence of haematomas in the treated zone.

Evaluation criteria

First criteria
Assessment by the investigator of the intensity of the spots and haematomas in the zone treated across an analogical scale from 0 to 5, as a criteria to detect differences on the intensity of the haematomas by means of the photos taken to the volunteer in the D1 (without application of the product) and the successive sessions in the visits of post operatory control (applying product).

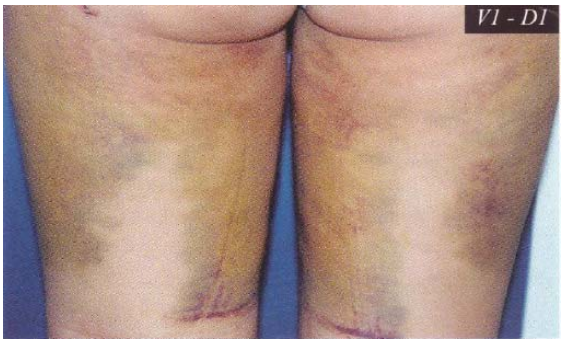
Second criteria
Analysis of the answers of the subjective evaluations of the volunteers after 15-21 days of use to the questionnaire on the efficiency and the organoleptic characteristics of the product.

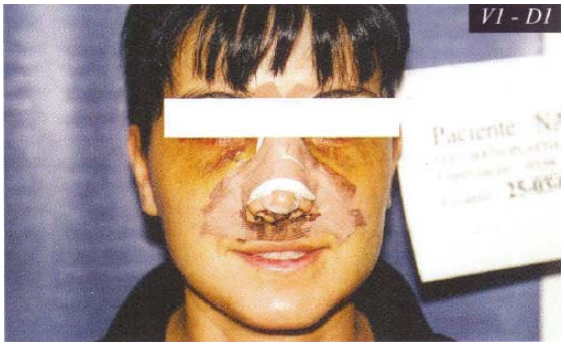
Description of the visits

A- Visit of the day D1:

1- Arrival of the volunteers to the center without having applied any product in the zone affected by the haematomas and post operatory spots.
2- To inform the volunteer about the characteristics of the study, duration and conditions of participation.
3- To take the signed consent of the volunteer.
4- To refill the book of observation with the demographic information (sex, age, ...), the clinical examination of the cutaneous area (destined to receive the product).

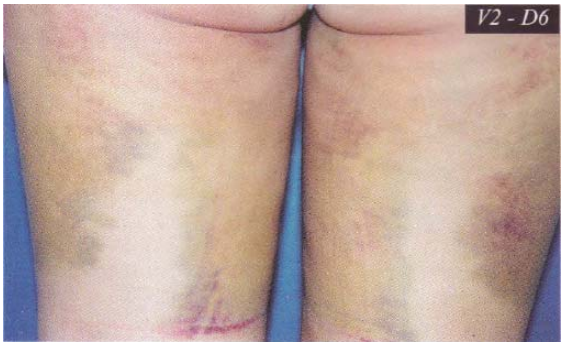
5- To verify the respect of the criteria of inclusion and no-inclusion.
6- To assign a number to the volunteer consecutively according to the order of his (her) arrival in the study.
7- To remind to the volunteers the requirements of the study.
8- To determine the spots to treat for the product.
9- Capture of photos D1 for every volunteer of the zone affected by haematomas.
10- Distribution of the product to the volunteers for an application for 15-21 days up to complete disappearance of the haematomas.

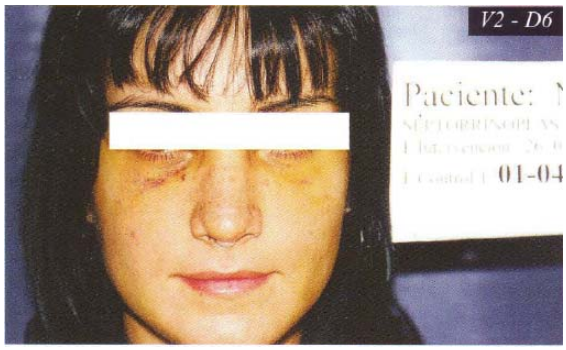




B- Post operatory check-up visits:

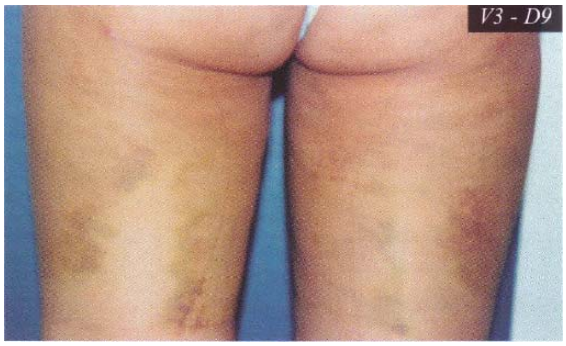
1- The volunteers return to the clinic for the post operatory control of follow-up by the surgeon.
2- Capture of photos D2 in forward, for every volunteer of the zone affected by haematomas.

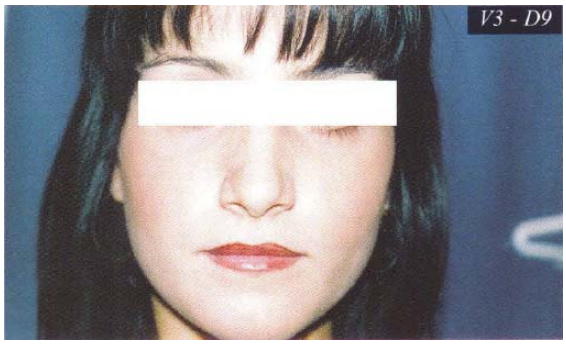




C- Visit at the last day:

1- The volunteers return to the clinic for the last post operatory visit of follow-up with the surgeon.
2- Capture of final photos, for every volunteer of the zone affected by haematomas.
3- The volunteers refill a subjective detailed questionnaire approved by the promoter, on the characteristics of the product studied.
4- End of the study and analysis of the obtained information.





Efficacy analysis

Analogical scale for the evaluation

After the localization of the zones with spots and haematomas, the capture of photos of the selected area is done in order to allow its good visualization for its posterior evaluation by the Investigator.
At the day D1, very close to the intervention on the facial or corporal level, the intensity of the spots are considered to be at the maximum intensity, being assigned the maximum value of the analogical scale: 5. In the different visits of postoperatory

control, we proceeds to photograph the same zones, in order to evaluate the intensity of the haematomas in the zones treated with K Ceutic.

Clinical evaluation of the spots

VI, V2, V3 and V4 represents the days of visit of the patients for the capture of the photos, after the intervention:

The post operatory visit V1: between 3-4 days after the facial and corporal intervention.

The post operatory visit V2: between 5-7 days after the facial and corporal intervention.

The post operatory visit V3: between 8-10 days after the facial intervention and 8-14 days after corporal intervention.

The postoperatory visit V4: between 10 - 14 days after the facial and corporal and 14-21 days after corporal intervention.

Intensity of the spots	
VERY MARKED	5 +++++
MARKED	4 ++++
MODERATED	3 +++
SLIGHT	2 ++
VERY LIGHT	1 +
NONE	0

Development of the analysis

The analysis is realized in 2 stages:

1- Evaluation according to the analogical scale of 0 (no haematomas) to 5 (haematomas very intense, D1), by means of the detailed observation of the photos of each one of the volunteers at the different visits.

2- Analysis of the obtained results that allow to verify a more rapid disappearance of the haematomas in the affected zones, by means of the determination of %DH (% Disappearance of Haematomas) and of the average time of recovery, which is the time (in days) from the D1 (beginning of application of the product) with decrease to the half of the haematomas initial intensity is observed.

Results

Results of depigmenting efficacy

In the following table are detailed the results obtained after the analysis of the photographies taken in every session from the day D1.

Facial Treatment	V1	V2	V3	V4
Average of the scores	5,0	2,1	0,7	-
% Disappeared haematomas	-	58%	85,7%	-

Corporal Treatment	V1	V2	V3	V4
Average of the scores	4,9	2,1	1,0	0,3
% Disappeared haematomas	-	57,5%	79,4%	95%

The results show that the treated zones with the product K Ceutic, either on facial or corporal spots, it was appreciated a notable decrease in the intensity of the haematomas, which demonstrate the depigmenting potential of the product.

From these results it outstanding that the disappearance of the haematomas is notable from the first applications of the product (5° to 7° post operatory day).

Synthesis and interpretation

Determination of the average time of disappearance of 50% of haematomas (t50) after the pos toperatory daily application of the product K Ceutic.

Facial treatment: 4,2
Corporal treatment: 5,5

This information shows that the major intensity of the haematomas is eliminated in the first 4-5 days of post operatory application of the K Ceutic, either at facial or corporal level.

Discussion - Conclusion

ln the experimental conditions adopted, the evaluation of the depigmenting potential of the cosmetic product K Ceutic has been assessed, in a group of 20 adult volunteers, in treatment of the postoperatory aesthetic haematomas (blepharoplasty, rhinoplasty and liposuction) and applied from 10 to 21 days. The obtained results indicate that:

1- The major intensity of the haematomas fade out rapidly in the first 4 to 5 days of post operatory application of the K Ceutic, either in facial or corporal treatment,

2- 100 % of the volunteers shows a reduction in haematomas intensity up to 85% in the 5 to 7 days of use of the product either in facial or corporal treatment.

3- Clinically, no reaction of cutaneous intolerance has been detected

4- Subjectively, evaluated by the volunteers:

• The acceptability of the product is satisfactory with 85 % of favorable impression
• The efficiency is satisfactory for 100 % of the volunteers

This information allows concluding that the product K Ceutic has a good depigmenting potential, a good cutaneous tolerance and a good cosmetic acceptability.