

THE EFFECTS OF Endotelon ON POST OPERATIVE OEDEMAS

Results of a double blind study against a placebo using 36 patients.

RESUME: A study using double blind placebo was done using 32 patients. The research was to study the preventative effects of the active ingredient (OPC) on the constitution of the post-operative oedemas after a face-lift operation. The treatment was administered using 300mg/day during the five days preceding the face-lift and then from the 2nd to the 6th day after the operation. The totality of the patients was homogenous in their average age (56.5 years old, extremes being 44 and 65) and their psychological profiles were all operated upon by the same surgeon using a unique surgical technique and the same anesthetic. The patients were placed into two equal groups drawn by lots. The results were judged using three criteria. Based upon the principle criteria (delay in the disappearance of the oedemas after the operation) a significant difference ($p = 0.01$) was shown to be in favor of the Endotelon: 11.4 days against 15.8 days for the placebo group. The size and volume of the oedemas evaluated by the clinician using an analog scale of Day 2, Day 5 and Day 12 was always less in the Endotelon group than in the placebo group. Finally the overall judgement of the clinician showed itself to be statistically better in the Endotelon group.

Key words: Face lift, post-operative oedemas, flavanoids, preventive treatment
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INTRODUCTION

The procyanidol oligomers (OPC) are of vegetal origins coming from raisin seeds and belonging to flavanol chemical class [3]. In vitro, it has the property of electively attaching itself to collagen and elastin fibers. In vivo, it reinforces the conjunctive structures of the blood vessels, correcting the alterations of capillary resistance observed either spontaneously or after absorbing acetylsalicylic acid [1].

OPC has been sold commercially since 1978 as a “vasculoprotector” in the form of coated pills that dissolve entirely. The dose is 50mg under the ophthalmologic and phlebotomologic indications. The knowledge of these different properties lead us to research the effect of this medication on the oedemas of the face in maxilla-facial surgery and more specifically on oedemas after a face lift.

In effect, this prevention, well standardized in its operative technique, causes in an inevitable fashion no matter what surgical equipment is used, an edema on the face. Since this edema is very voluminous it will aggravate follow up operations and create large tension at the suture points.

It is clear then that in this type of pathology the prevention of oedemas should constitute an essential preoccupation for the surgeon.

The objective of the work presented here is to show the preventive effect of OPC on post face-lift operation oedemas.

PATIENTS AND METHODS

The test was conducted using a double blind against a placebo.

The 2 pills were administered 3 times daily (300mg/day) for 10 days. No other medication was given during the entire time of the test. The treatment was followed from Day 5 to Day 1 and then from Day 2 to Day 6. Day 0 was the day of the face-lift.

Each patient before undergoing a face-lift was included under the condition that they were not undergoing any other therapy.

The results were evaluated with the aid of three criteria:

- The principal criterion was the time it took for the oedemas to disappear expressed in days.
- The other criteria were, on the one hand, the importance of the oedemas evaluated by the clinician, graphed on an analog scale using Day 2, Day 5 and Day 12. On the other hand the overall judgement of the clinician expressed on Day 12 as the patient was leaving in five degrees: Excellent (4), Very Good (3), Good (2), Mediocre (1) and Bad (0).

RESULTS

Thirty-three patients took part in this study. One patient was found not to have followed the prescribed treatment before the operation and was therefore excluded from the study, which in the final analysis included thirty-two patients.

The drawing by lot put these patients into two equal groups:

- Sixteen patients received a placebo (Group P)
- The other sixteen received OPC (or verum) (Group V)

It was a very homogenous society that took part in this study. All of the participants were female with the average age being 56.5 years old (44 and 65 were the extremes). All told we had an average age of Group P of 55.3 and in Group V 57.7.

The anesthesia was the same in both groups (the association being a local plus neuroleptanalgesia). It was the same surgeon who did the face lift an operation without drainage on each patient which has the advantage of eliminating the risk of an eventual "surgical team" effect.

The Effect on the Principal Criteria

The time it took for the oedemas to disappear after the operation was on the average:

- 11.4 days in the Group V
- 15.8 days in the Group P

This difference is statistically significant whether the test is non parametric ($p = 0.007$ using the Mann and Whitney test) or parametric ($p = 0.015$ using the Student test)

The Effect on the Secondary Criteria

Evaluation of the volume of the oedemas

The analog scale gave a measurement varying from 0 to 100mm. The average height of each of these three times and for both groups is shown in Figure 1. We can see that starting from Day 2 the oedemas is judged to be less voluminous by the clinician. The spread between both groups is maintained at each estimation without being significantly different ($p = 0.11$ by variance analysis).

Overall Clinical Judgement

Finally, the global judgement of the clinician expressed on Day 12 varies according to the histogram in Figure 2.

The difference between the two groups here is significant ($p = 0.04$ using the non-parametric Mann & Whitney test).

DISCUSSION

Whatever judgement criteria considered and despite the relatively limited number of observations, the difference in favor of OPC is manifest.

This significance of the tests can explain itself by the constancy of the effect under OPC and by the homogeneity and therefore the weak variability inter-subject of those taking part in the study.

It is also interesting to note that the time in which it takes for the oedemas to disappear is positively correlated to the evaluation of the volume of the oedemas. This correlation being much stronger ($p < 0.01$) in Group V than in Group P ($p < 0.05$), the latter probably underwent stronger fluctuations.

Tolerance to the OPC seemed perfect as not one patient complained of the slightest secondary effects during the test.

CONCLUSION

This test done in a double-blind against a placebo using 32 plastic surgery patients allowed us to show that Endotelon administered in doses of 300mg/day for five days

preceding the operation and two to six days after the operation has a notable preventative effect on post-face lift oedemas.

It lowers the length of the evolution of the oedemas from 15.8 days to 11.4 days. This length is also correlated to the volume and size of the oedemas at Day 2 and evaluated on a graph.

Also, the great homogeneity of the participants studied (same patient profile, same surgeon, same anesthesia) allowed us to show a significant difference between the two groups (treated and non-treated) on two out of three criteria in the retained analysis.

The observations reported here encourage us to use Endotelon before undergoing plastic surgery. The results successively obtained here in this test bear this out.