

Efficacy of the Supramaximal Technique in the Correction of Palpebral ptosis. Randomized Surgical Trial

C. María Cáceres Toledo¹, Odalys Cáceres Toledo², María Eva Saavedra Saavedra³

¹Second Degree Specialist in Ophthalmology. Doctor of Medical Sciences. Professor and Principal Investigator.

²First Degree Specialist in Ophthalmology and MGI. Assistant Professor.

³Resident of third year of Ophthalmology.

Corresponding Author: María Cáceres Toledo, Second Degree Specialist in Ophthalmology. Doctor of Medical Sciences. Professor and Principal Investigator, Cuba, **Email:** alvaca@infomed.sld.cu

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ABSTRACT

Introduction: The palpebral ptosis is defined as the fall of higher eyelid. According the millimeters of this type of fall it is classified in slight, moderate and severe.

Objective: To assess the effectiveness of the Supramaximal technique in the repair of moderate and severe palpebral ptosis.

Material and Methods: 95 patients were studied in a first cut, receiving treatment with the Supramaximal or Suspension to frontal. To determine the therapeutically effectiveness a simple-blind randomized clinical trial was made. The effectiveness was assessed as regards fall of high eyelid, height of palpebral fold, distance of border reflex and satisfaction of the patient. Results: The mean age was of 59, 35 years old. There was an average of female sex and of white race. The 51.6% of study patients have a severe ptosis. The therapeutically effectiveness of the Supramaximal was higher to Suspension to frontal (96.7% y 86.2%) respectively.

Conclusions: The Supramaximal as a surgical technique is more efficacious than the Suspension one to frontal in the correction of moderate and severe higher palpebral ptosis.

KEYWORDS

Ptosis; Supramaximal; Suspension to frontal; Therapeutically Effectiveness.

INTRODUCTION

The Ptosis or drooping of the eyelid, constitutes a health problem, from the antiquity until our days, due to the affectation that it causes on the vision, and the facial aesthetics, mainly in the women, which predominate in almost all the published series [1-12].

The treatment of ptosis is surgical. Several techniques have been used for their correction, which go back to ancient times. Egyptian doctors burned the skin of the upper eyelid with hot gold plates so that the scar retraction would elevate it [1-3]. In modernity and with the introduction of technological advances such as the surgical microscope and the cutting and coagulation equipment, new techniques have been used with good results, among them the Supramaxim [1, 2-11].

Suspension to frontal with autologous fascia lata, has been the most used technique in moderate and severe palpebral ptosis, reason why it is considered the golden rule in its surgical correction [4, 5, 12].

However, for its realization a graft is required, which replaces the physiological mechanism of the palpebral opening and is not without complications.

It is considered that Supramaxim is a therapeutic alternative for cases with poor EPS function, which avoids the risk of infection and extrusion of the graft, does not require the extraction of the fascia lata, so it eliminates a scar and decreases the surgical time [1-14].

In the reviewed literature, the therapeutic results obtained with one or other of these techniques are known separately [1-3, 8-11, 14] but until now, no study has been published to determine which is the most effective. The above is a controversial issue not yet resolved by the scientific community.

In the present investigation, a randomized clinical trial has been designed to demonstrate the aforementioned.

The main objective is: To evaluate the efficacy of the supra-maximal surgical technique in the correction of moderate and severe upper palpebral ptosis.

METHODOLOGICAL DESIGN

A simple blind randomized surgical trial was performed, in which patients from the outpatient clinic of Ophthalmology of the Hermanos Ameijeiras Hospital (HHA) participated. It was carried out from February 2016 to November of the year 2017.

UNIVERSE. All patients with palpebral ptosis of moderate to severe and who meet the selection criteria.

Only cases with this type of ptosis are selected, because both techniques are indicated in their surgical correction.

SAMPLE. It was calculated by the CTM program version 1.1 (See Annex 1).

Patients who attended the Neurophthalmology clinic of the HHA, from February 2016 to November 2017, who met the selection criteria were included. The assignment to each treatment group was carried out randomly and blindly, because it is not possible to “pick up” the surgeon, because of the evidence that the wounds represent, on the patient’s forehead, in one of the techniques.

The sample was composed of 95 patients, 48 were performed Supramáxima technique and 47 suspension to the frontal.

Inclusion criteria. Patients over 18 years of age, with moderate and severe upper palpebral ptosis.

Exclusion criteria. Patients with dry eye, in the decompensated of systemic diseases such as Diabetes Mellitus and Myasthenia Gravis. Patients with ptosis of mechanical cause due to allergic conjunctivitis and tumors

The ophthalmological examination was performed, the measurement of the EPS muscle function, the palpebral fissure and the DMR. The degree of clinical involvement of ptosis (moderate or severe) was based on the classification of Salcedo et al [1].

The data obtained will be recorded in the data dump template.

OPERATION OF THE VARIABLES.

Main response variable

Combined results

Satisfactory

When after the surgical techniques used in the patients decrease the millimeters (mm) or return to the palpebral physiological level with respect to the preoperative values of the following variables: upper eyelid drop, margin-reflex distance (DMR), height of the fold palpebral orbital and in which the satisfaction of the patient is obtained.

Not satisfactory

When after the surgical techniques used in the patients do not improve one or more of the above-mentioned parameters and the patient’s dissatisfaction.

DESCRIPTION OF SURGICAL TECHNIQUES

Surgical Technique Supra Máxima

By cutaneous route access to the aponeurosis of the elevator until reaching the “Whitnall” ligament which is fixed to the tarsus with nonabsorbable suture, the height of the eyelid is checked and the skin is sutured

Surgical Technique Frontal Suspension with Fascia Autologous can

In the frontal region at supraciliary level 3 incisions of 5 mm are made. In the tarsus the fascia lata is fixed with absorbable suture, and its ends are directed by means of the fascia needle towards the previously made incisions, crossing the muscles: orbicular and frontal, both are joined and knotted in the medial incision. The eyelid height is checked and the skin is sutured.

The data was processed using the Epidat 3.1 and SPSS version 20 programs. The Chi-square test was applied to find differences between the results of both techniques. The Relative Risk was calculated with the 95% confidence interval.

ETHICAL ASPECTS

The Universal Declaration on Bioethics and Human Rights (2005) [15] was complied with and with the current legislation in Cuba, in accordance with the provisions of the National Health System, established in Law No.41.

RESULTS

In the series studied, the average age was 59.35 years. There was a predominance of female sex (56.8%) and white skin (75.8%). 51.6 %% of the patients studied have severe ptosis.

Table 1 shows the results combined with both techniques. They were satisfactory in 91.5% of the patients, with a higher percentage in the Supramaxim technique compared to the frontal suspension: 96.7% and 86.2% respectively, however the difference between the two was not significant ($p = 0.051$).

Table 1: Therapeutic efficacy according to groups and combined results. Average of operated eyes.

Combined results	Supramaxim	Suspension to the frontal	Total	Significance (p)
Satisfactory	58 (96.7%)	50 (86.2%)	108 (91.5%)	0.051*
Not Satisfactory	2 (3.3%)	8 (13.8%)	10 (8.5%)	
Total	60	59	119	

*Chi square test.

The correction of the ptosis improves the visual quality, because the visual axis is free and the astigmatism is corrected by the drop of the eyelid that covers the pupillary area.

Table 2: Therapeutic efficacy according to groups and related variables.

Variables	Supramaxim	Suspension to the frontal	Total	Significance (p)*
Upper eyelid droop				
satisfactory	60 (100.0%)	51 (87.9%)	111 (93.3%)	0.006*
Not satisfactory	0 (0.0%)	8 (13.8%)	8 (6.7%)	
Reflection margin distance				
satisfactory	59 (98.3%)	52 (88.1%)	111 (93.3%)	0.032*
Not satisfactory	1 (1.7%)	7 (11.9%)	8 (6.7%)	
Height of the orbito-palpebral fold				
Satisfactory	59 (98.3%)	51 (87.9%)	110 (93.2%)	0.031*
Not Satisfactory	1 (1.7%)	8 (13.8%)	9 (7.6%)	
Eyelid cleft				
satisfactory	59 (98.3%)	52 (88.1%)	111 (93.3%)	0.032*
No satisfactory	1 (1.7%)	7 (11.9%)	8 (6.7%)	
Muscle function				
satisfactory	59 (98.3%)	51 (87.9%)	110 (93.2%)	0.031*
Not satisfactory	1 (1.7%)	8 (13.8%)	9 (7.6%)	
Total	60	59	119	

Table 2 shows that the correction of upper eyelid drooping and reflex margin distance was satisfactory in all patients in whom the Supramaxim technique was used. This result was

significantly greater with respect to the frontal suspension, ($p = 0.006$).

The height of the orbito-palpebral fold, the palpebral fissure and the function of the levator palpebrae superior muscle were also satisfactory in a significantly higher percentage with the Supramaxim technique.

Figure 1. Surgical results with both techniques. Before and after surgery 1-a and 1-b with the Supramaxim, 1-c and 1-d with the Suspension to the Frontal.

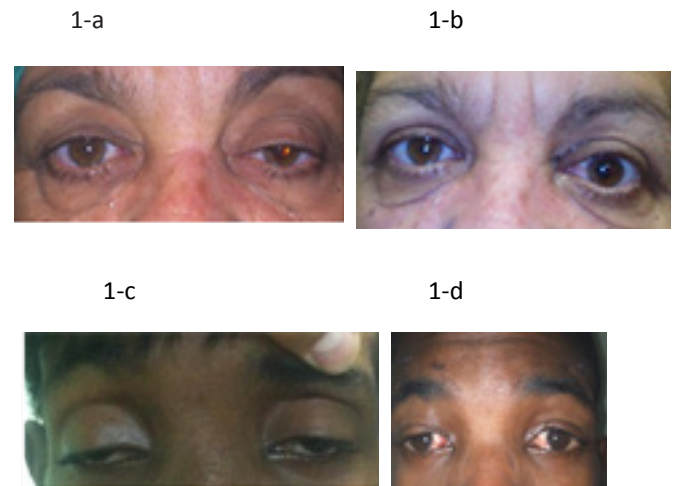


Table 3 shows the degree of satisfaction, which was higher with the Supramaxim (97.9%), but the difference between the two was not significant ($p = 0.111$).

Table 3: Therapeutic efficacy according to groups and patient satisfaction.

Patient satisfaction	Supramaxim	Suspension to the frontal	Total	Significance (p)
Satisfactory	47 (97.9%)	42 (89.4%)	89 (93.7%)	0.111*
Not Satisfactory	1 (2.1%)	5 (10.6%)	6 (6.3%)	
Total	48	47	95	

* Chi square test.

DISCUSSION

Most authors agree that the most used techniques for moderate and severe palpebral ptosis are the Suspension to the frontal and the Supramaxim [1-14, 16-20].

With the Supramaxim surgical technique, a greater percentage of satisfactory results was achieved compared to the frontal suspension. Similar results have been reported by other authors, [5-11] which consider that with the Supramaxim the action of the EPS is reinforced and the physiological mechanism of ocular opening is conserved, however, with the Suspension to the Frontal, this mechanism is replaced by a tissue

inserted between the tarsus and the frontal muscle.

In the Cáceres and cols 7 series, excellent therapeutic results were obtained with the frontal suspension with autologous fascia lata and in the two cases operated with the maximum reinforcement of the EPS.

Negrin-Cáceres et al [11] have obtained similar results with Supramaxim in 95 operated cases.

In the report by Nagaraju et al, [14] both techniques were compared. The frontal suspension was performed at 60% of the eyes and the Supramaxim on the remaining 40%. Optimal correction was achieved in 56% of the patients without significant differences between the two comparison groups.

In Japan, [17] good results have been reported with frontal suspension surgery, since all patients achieved satisfactory functional results. In a study carried out in China, [18] satisfactory results were obtained in 92% of the 55 patients (75 eyes) operated on with the Frontal Suspension technique with severe congenital ptosis. These results exceed those achieved in the present. clinical trial; However, Gómez et al [19] report an 81% success rate with the same technique, which is lower than that obtained for the two techniques evaluated in our trial.

In studies conducted in Cuba, Jerez et al, [20] managed to correct 29 eyes (87.87%) with the Suspension to the frontal and although three cases were hypocorrected, it was suggested that the surgical technique was satisfactory, as they were mostly null or poor excursion of the eyelid lift muscle.

Patient satisfaction was achieved with both techniques, although it was higher in Supramaxim. This parameter is closely related to the quality of life, which is a pillar of medicine in Cuba. In the literature consulted [1-20], no data are collected that assess the post-operative satisfaction of patients with eyelid ptosis, which reinforces the aforementioned.

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