# Stability of silicone band frontalis suspension for the treatment of severe unilateral upper eyelid ptosis in infants

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PURPOSE. *To address the efficacy, safety, and stability of frontalis suspension of the upper eyelid with a silicone band for the treatment of severe congenital ptosis in infants.*
METHODS. *Data from 22 pediatric patients undergoing unilateral frontalis suspension with silicone band were retrospectively reviewed with a follow-up ranging from 18 to 30 months. The margin-reflex distance (MRD) and the corneal staining had been evaluated at each pre- and postoperative visit. Data were analyzed by analysis of variance and t test for paired data.*
RESULTS. *MRD was absent before surgery in all cases: it ranged from –1 mm to –4 mm (–2.4±0.8 mm). Immediately after surgery, it increased to 2.9±0.3 mm, and then progressively reduced by 0.6 mm within the first 3 months (p=0.001); a further reduction of 0.2 mm, occurring between 3 and 12 months after surgery, was not statistically significant. After the 12-month visit, no changes in MRD were found at follow-up for any patient. Corneal staining, which was present in five patients over the first 2 postoperative weeks, recovered without sequelae. Complications occurred in three eyes: overcorrection and corneal ulcer in one case requiring removal of the silicone band, one granuloma, and one extrusion of the silicone band from the upper frontal incision.*
CONCLUSIONS. *During the study period, the frontalis suspension with a silicone band was an effective and safe procedure. MRD values were stable between month 3 and the end of follow-up, although this series does not preclude the possible occurrence of blepharoptosis at longer time intervals. (Eur J Ophthalmol 2008; 18: 723-7)*

KEY WORDS. *Congenital ptosis, Frontalis suspension, Silicone band, Amblyopia*

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## INTRODUCTION

Both eyelids may be ptotic, but the term “blepharoptosis” or “ptosis” is generally used for the upper eyelid. In children, this condition can be idiopathic or inherited, unilateral or bilateral, congenital or acquired. Correct diagnosis, treatment, and follow-up of pediatric patients are extremely important to prevent the possibility of amblyopia.
Surgical management of ptosis in childhood has been explored in the literature. Frontalis suspension of the upper eyelids, introduced in the second decade of the last century by Hess and by Lexer (1) and then refined by other authors, is the technique of choice in patients with poor or absent elevator function. Currently, there are little data available on early treatment of severe ptosis in infants, and on the stability of surgical results using a silicone sling as the suspensor material. The purpose of the present study was to evaluate these two topics.

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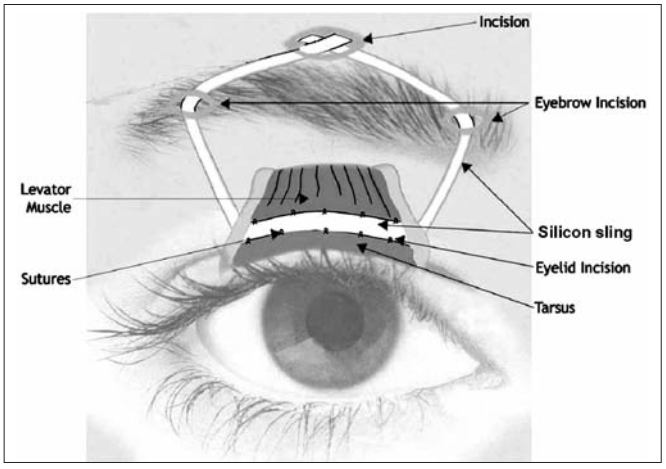


**Fig. 1 -** *Diagram of the silicone sling placement.*

## METHODS

This study was conducted at the Eye Clinic of San Paolo Hospital, Milano, Italy, after approval of the local Ethics Committee; it respected the tenets of the Declaration of Helsinki; informed consent was obtained from all participants.

We retrospectively analyzed the charts of 22 consecutive patients with severe congenital, unilateral ptosis at birth requiring surgical treatment. Two cases had neurogenic ptosis, while 20 had myogenic ptosis.

A complete ophthalmic assessment was done before surgery. In all cases, the margin-reflex distance (MRD, the distance from corneal light reflex to upper lid margin in the primary position) was absent; preoperatively, such a distance was measured and expressed as a negative value (e.g., an eyelid 2 mm below the center of the pupil had an MDR of –2 mm). Bell's phenomenon was present in all cases.

Ptosis was corrected between the fifth and the sixth week of life for all patients. Surgery was performed under general anesthesia by one surgeon (P.N.) using a modified Fox pentagon procedure (2) for the frontalis suspension with a silicone sling. Briefly, the technique consists of a skin incision at the same height of the crease of the fellow eye, and three stab incisions above the eyebrow. After exposure of the tarsus, the silicone sling is fixed to the tarsus and the levator muscle using from 3 to 5 Prolene 6-0 sutures each. The sling is then passed through the orbicular and frontalis muscles using an 18-gauge epidural anesthesia needle (3). A scheme of the correct positioning of the band is given in Figure 1. The sling is tightened in order to align the eyelid 1 mm above desired level (i.e., if an MRD of +2.0 is desired, then a level of +3.0 is the intraoperative goal), as suggested by Chen et al for patients with levator function <2 mm (4). The silicone band is then tied upon itself (4 knots) and buried into the frontalis muscle. The skin is finally closed using a Vicryl 6-0 suture.

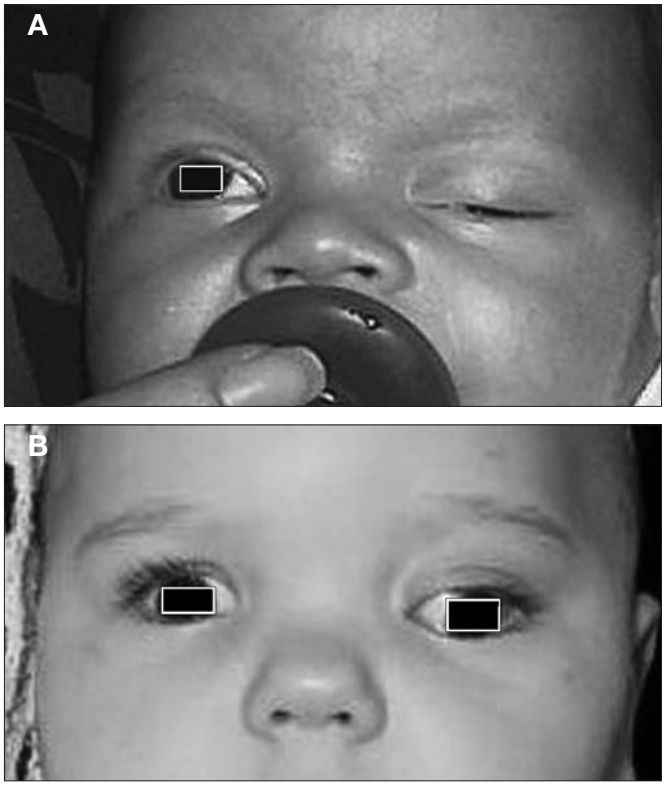


**Fig. 2 -** *A 5-week-old patient with severe unilateral ptosis with no levator function.* **(A)** *preoperative and* **(B)** *2-month postoperative views.*

Postoperative follow-up visits were performed at days 1, 7, and 14, at months 1, 3, 6, 12, and 18, and, for the patients with the longest follow-up, at months 24 and 30. At each visit, the MRD was measured and corneal staining was graded as follows: 0, no staining; 1, punctuate epithelial defects; 2, epithelium loss; 3, corneal ulcer.

Data of operated eyes were analyzed by means of analysis of variance and the two-tailed *t*-test for paired data.

## RESULTS

Mean age at surgery was 5.5±0.5 weeks; right and left eyes were equally affected. Fourteen patients were male and eight were female. The mean follow-up period was 22±4 months (range: 18–30 months).

Results of the study are summarized in Table I and a case is shown in Figure 2.

Preoperatively, MRD was absent in all cases: it was –2.4±0.8 mm, with a range from –1 to –4 mm. Corneal staining was negative in all patients.

Surgery resulted in an improvement of MRD, which peaked at 2.9±0.3 mm at day 1 and then progressively decreased by 0.4 mm during the first 3 months (p=0.001, analysis of variance [ANOVA]); thereafter, it was maintained stably for the remainder of the study (p=0.61, ANOVA). No changes in MRD occurred in any case after month 12.

At all timepoints, the MRD ranged between 2 and 3 mm, with the exception of one patient who had 4 mm of MRD at day 14. Considering the group of 19 patients who had an MRD of 3 mm the day after surgery, at month 1 it reduced to 2 mm in 47% of cases, at month 3 in 58%, and at month 12 in 84%.

Corneal involvement occurred between the first and the second postoperative week in 5 patients (23%) and they were treated with topical antibiotics and lubricating ointments. At week 1, four patients had punctate staining and one de-epithelization; at week 2, two had punctate defects, another two had de-epithelization, and one had corneal ulcer.

Complications occurred in 3/22 cases. One patient had a 4-mm MRD and developed a corneal ulcer at week 2. His family refused to use any medication and required the removal of the silicone band. This patient did not attend follow-up visits and he was therefore excluded from the analysis after week 2. Minor complications occurred in two cases: granuloma at the upper frontal incision (month 3; it was resolved by means of incision and injection of local antibiotics and steroids) and extrusion of the silicone band from the upper frontal incision with no infection (month 1; resolved with repositioning).

**TABLE I -** MEAN RESULTS OF THE STUDY

| Time of visit | Patients (n) | Grade of corneal involvement (% of patients) | Margin-reflex distance |
|---|---|---|---|
| Preoperative | 22 | 0 (100) | –2.4±0.8 |
| Day 1 | 22 | 0 (100) | 2.9±0.3 |
| Day 7 | 22 | 0 (77) | |
| | | 1 (18) | |
| | | 2 (5) | 2.6±0.5 |
| Day 14 | 22 | 0 (77) | |
| | | 1 (9) | |
| | | 2 (9) | |
| | | 3 (5) | 2.6±0.6 |
| Month 1 | 21 | 0 (100) | 2.5±0.5 |
| Month 3 | 21 | 0 (100) | 2.3±0.5 |
| Month 6 | 21 | 0 (100) | 2.3±0.4 |
| Month 12 | 21 | 0 (100) | 2.1±0.4 |
| Month 18 | 19 | 0 (100) | 2.1±0.4 |
| Month 24 | 12 | 0 (100) | 2.2±0.5 |
| Month 30 | 10 | 0 (100) | 2.1±0.6 |

## CONCLUSIONS

Although surgery is the first treatment choice for ptosis, a consensus on techniques, indications, and timing is still lacking. This may be due to a limited predictability of outcome, even in the presence of a thoughtful clinical assessment and no complications (5), but also to the surgeon's experience and preference.

Lambert et al (6) demonstrated that, in the cases of congenital cataract, the developmental delay leading to the impairment of integrative visual functions and determining amblyopia occurs within the first 6 weeks of life. It is likely that the timing may be very similar for congenital, severe, ptosis. In their animal study, Langford et al induced a severe unilateral ptosis on chicks at birth and, after 30 days, they showed that ptosis was associated with increased axial length (7). The rationale for early surgery is therefore to restore a correct visual maturation as soon as possible: if we delay surgery after the sixth week of life, we could restore eyelid alignment without improving amblyopia. Further follow-up of these patients with data on visual acuities (compared to untreated or late-treated patients) may allow confirmation of this hypothesis. In our dataset, symmetry between eyelids and other aesthetic issues were not considered.

This is the first study reporting data on ptosis surgery in infants, though the efficacy and safety of eyelid suspension for congenital ptosis have already been described for children under 3 years of age (8-10). Our results confirm the safety of the procedure in neonates, since complications, which occurred in 3/22 cases, can be successfully managed: they were not serious in two eyes and even the patient that had overcorrection and corneal ulcer showed resolution of this problem after removal of the band.

Silicone proved to be a suitable material for frontalis suspension of the superior eyelid. The behavior of this mater-

ial was highly predictable, with a small but significant reduction of MRD within the first 3 months (about 0.6 mm) and a good stability (0.2 mm, which was not statistically significant) for the remainder of the study. Hence, we confirmed that some postoperative fall is expected with silicone as has been described by other authors (9, 11).

Our data suggest that, to achieve optimal stable results after 1-year follow-up, an overcorrection of about 0.5 mm might be desirable during surgery, which may be easily achieved by positioning patients' eyelids at about 1.5 mm over the desired postoperative level. In any case, this extrapolation derives from retrospective data; only a prospective study (possibly with randomization between correction and overcorrection) may adequately answer this question. Moreover, if this overcorrection was achieved, it is extremely likely to induce more exposure-related problems (i.e., MRD of 4 or more for at least the first postoperative months).

The use of a silicone sling has been retrospectively addressed by Carter et al on 25 lids of 14 children under 3 years of age (mean age 18 months) with severe ptosis with poor levator function (9). Surgery achieved good functional results; postoperative corneal exposure was constant during the first weeks and 8% required sling revision. Silicone was particularly indicated in patients with a poor Bell's phenomenon, as the elasticity of this material, compared to fascia, allows the patients to close their upper lids with greater ease.

Among the other materials, autogenous fascia lata is probably the most popular option, as it is a simple and effective procedure with few complications (10-12). Nevertheless, in children, autogenous fascia lata may be difficult to harvest (13). It also requires a longer operative time (14) and a longer postoperative recovery period (14), results in scarring on the thigh (14), and may be associated with infection (15) and hernia (16) at the donor site. Moreover, due to its inelasticity, fascia lata may counteract the action of the orbicularis muscle, making palpebral closure more difficult. Since conclusive data comparing fascia lata and silicone sling in large, prospective, multicenter studies are lacking, the superiority of one material over the other has yet to be demonstrated (17).

Other materials have also been proposed, in particular temporal fasciae complex (12) and palmaris longus tendon (18, 19); the use of banked human fascia lata (20) may be limited by costs and difficult availability. Meshes (Mersilene, nylon, polytetrafluoroethylene, polypropylene) are effective, but they are associated with a high rate of recurrences (about 30%) (21, 22) and complications, such as suture granulomas and the "cheese-wire" effect (8, 23).

Our study is limited by a relatively short follow-up, which does not preclude the possible occurrence of blepharoptosis at longer time intervals, and by the small number of patients. Data on fellow eyes were not collected and therefore an evaluation of symmetry between eyes was not possible. It is also possible that a bilateral asymmetric ptosis was present and was not addressed, as this study focused on unilateral ptosis repair. Finally, this study does not verify the hypothesis that early treatment of ptosis, as for congenital cataract, is effective in reducing the risk of amblyopia. This topic needs to be investigated on the basis of prospective data on visual acuities (which are still missing in our cohort of patients), possibly comparing early treatment vs late treatment of severe ptosis.

Nevertheless, our results suggest that frontalis suspension of the upper eyelid with a silicone band is a relatively safe, easy, and effective procedure for the treatment of severe congenital ptosis in infants.

*The authors have no financial or proprietary interest in any product mentioned herein.*

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