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### Abstract

**Purpose:** To assess results of the intraoperative regulation of the position of the eye muscle onto the sclera during strabismus surgery under topical anaesthesia, and to evaluate predictors of clinical success versus standard surgery under general anaesthesia.

**Methods:** Comparative case series. A total of 649 surgical procedures were performed in 565 patients. 451 (69.5%) corrections were under topical anaesthesia and 198 (30.5%) under general. The residual angle of deviation was analysed 6 months after surgery as:

- a. 'Very good' (< 4 prism dioptres,  $\Delta$ )
- b. 'Good' (4-10 Δ)
- c. 'Sufficient' (11-20 ∆)
- d. 'Insufficient' (>  $20 \Delta$ )

Classification in the 'very good' and 'good' groups reflected successful outcome, while in 'sufficient' and 'insufficient' indicated failure of the procedure. Chi-square test and multivariable logistic regression were applied in the analysis.

**Results:** intraoperative adjustable surgery under topical anaesthesia was associated with satisfactory results in 372 (82.5%) cases and general anaesthesia in 127 (64.1%) (P < 0.001). In restrictive and paretic strabismus, 44 (67.7%) and 85 (75.2%) patients achieved satisfactory results under topical anaesthesia, respectively, and 9 (32.1%) and 16 (53.3%) patients under general anaesthesia, respectively (P < 0.001 and P < 0.01). Statistically significant correlation with satisfactory results was related to topical anaesthesia (P < 0.001), male gender (P = 0.017), pre-operative potential stereopsis (P = 0.002), and procedure of weakening (P = 0.001).

**Conclusions:** This study demonstrates the advantages of adjustable strabismus surgery by intraoperative suture adjustment under topical anaesthesia over standard strabismus surgery under general anaesthesia, particularly in less predictable cases.

Keywords: Strabismus; Topical Anaesthesia; Adjustable Strabismus Surgery; Intraoperative Suture Adjustment

#### Introduction

Modern-day local anaesthesia began in 1884 with a discovery by Carl Koller, a young ophthalmologist from Vienna who placed a cocaine solution on the cornea, thus producing temporarily insensibility to pain [1]. His discovery opened the door to a new era in ophthalmic surgery, and topical anaesthesia in ocular surgery was adopted, besides the development of synthetic local anesthetics.

During the '60s of the last century, topical anaesthesia started to be applied also in surgery for esotropia [2]. Although promptly displaced by general anaesthesia in subsequent years because of complexities in surgery dosage for squint correction. This reason also led to the adoption of alternative non-surgical procedures for strabismus, for example through the pharmacological action of botulin toxin, and actually very few publications reported the use of topical anaesthesia in strabismus surgery.

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With the introduction of the adjustable sutures [3]. The application of topical anaesthesia has been reconsidered as a key aspect for success [4-6]. In fact, topical anaesthesia has several key advantages, along with the absence of risks related to regional and general anaesthesia. In particular, the value of performing strabismus surgery under topical anaesthesia resides in the higher intraoperative comprehension of the mechanics of ocular muscles, which can allow for a concurrent adjustment in the surgery dosage in order to gain the expected result, thus avoiding the requirement of further surgery [7-8].

Nevertheless, the intraoperative adjustment of the position of the eye muscle onto the sclera (i.e. one-stage adjustable strabismus surgery) under topical anaesthesia is not free from weaknesses, which could restrain ophthalmologists from adopting this technique. Actually, the adoption of topical anaesthesia requires a fully experienced surgeon which completes the procedure in the shortest possible time, as patient is maintained in conscious sedation and is required to collaborate [9].

Moreover, the application of adjustable sutures is not widespread amongst surgeons. This may be due either to the lack of evidence that the considerable investment in extra-time for intraoperative or postoperative suture adjustment is beneficial, or because not all training programs adequately teach this approach [10].

Much of the published literature reports retrospective results from non-randomized studies, which showed no advantages of adjustable sutures over the traditional sutures [11-14]. And data on intraoperative adjustable squint surgery under topical anaesthesia are lacking.

In the present study we compared the clinical results of intraoperative adjustable strabismus surgery under topical anaesthesia in respect to standard surgery under general anaesthesia, and characterized variables related to successful outcomes after 6-month.

#### **Materials and Methods**

The medical records of 565 patients (649 surgical procedures), who had undergone surgery for strabismus in the Ophthalmic Unit of San Bortolo Hospital between January 1996 and January 2010, were retrospectively reviewed. Patients' medical records were consecutively appraised, and those with at least six months of follow-up were included in the analysis, independently from the type of anaesthesia there had received. Institutional Review Board (IRB) approval was obtained to carry out this study. The study was conducted in adherence to the tenets of the Declaration of Helsinki.

#### Surgical technique

All surgeries were performed under topical or general anaesthesia by a single surgeon (MP). The procedures involved the recession or advancement of lateral and medial recti, resection or duplication of lateral and medial recti, desagittalization of the inferior oblique and tucking of the superior oblique. Topical anaesthesia was obtained with 2% lidocaine eye gel, administered 15 minutes prior to surgery. Additional lidocaine drops were instilled during the incision of conjunctiva and Tenon's capsule, or during surgery according to the level of patient discomfort. Analgesia was achieved by  $1-2 \mu g/kg$  intravenous fentanyl, 10 minutes after the start of the surgery, and by 0.5 mg atropine sulphate. In case of pain, a 0.5  $\mu$ g fentanyl booster was administered.

In patients under topical anaesthesia, intraoperative pain was assessed using a 5-point Verbal Description Scale (0 = no pain, 1 = mild pain, 2 = moderate pain, 3 = severe pain, and 5 = very severe pain) [15]. And intraoperative ocular motility evaluated, with the patient inclined in the operative chair, by fixing a penlight at 5 meters and at 30 cm. Position of the eye muscle onto the sclera was adjust intraoperative as required, and suture knots tied permanently, on the basis of the results of cover tests performed with prisms.

General anaesthesia was induced by intravenous administration of propofol (3-5 mg/kg) in patients pre-operatively sedated with midazolam (1-2 mg), and maintained by propofol infusion (3-5 mg/kg/h). Analgesia was obtained by fentanyl (100  $\mu$ g, bolus). Oculo-cardiac reflex was blocked with atropine (20  $\mu$ g/kg) administered during the induction of general anaesthesia or in case of bradicardia.

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#### **Evaluation of surgery**

Surgical results were classified in consensus with a second surgeon (CS, masking to type of anaesthesia) using a 4-point scale, depending on the residual angle deviation measured 6 months after surgery, as follows: 'very good' (angle deviation < 4 prism dioptres ( $\Delta$ )), 'good' (angle deviation within 4 and 10  $\Delta$ ), 'sufficient' (angle deviation within 11 and 20  $\Delta$ ), and 'insufficient' (angle deviation > 20  $\Delta$ ). Procedures classified in the 'very good' and 'good' groups reflected complete satisfaction of the surgeon for the clinical outcome; i.e., success of the procedure, while classifications of 'sufficient' and 'insufficient' indicated the surgeon's disappointment for the clinically obtained results; i.e., failure of the procedure.

#### Statistical analysis

Results of descriptive analyses are expressed in terms of mean and standard deviation (SD) for quantitative variables and as counts and percentages for categorical variables, unless otherwise specified. Chi-square test was used to examine sub-groups of patients in relation to results of intervention, with p > 0.05 considered statistically significant. Multinomial logistic analysis was used to identify demographic, medical or surgical-related variables that could affect the clinical results of the surgical procedures. All procedures, including those repeated in the same eye and those in the contralateral eye, were considered in the analysis. Multivariate logistic regression model was then performed to determine if any of the variables were related to the satisfaction of the clinical outcome. Results of surgical procedures were treated as a dichotomous dependent variable; i.e., 'satisfactory' and 'disappointing', corresponding to classifications of 'very good' and 'good', and to 'sufficient' and 'insufficient', respectively. The model was adjusted for the identified variables.

Variables that could be modified during the observational period were treated as dichotomous variables and considered present when the predictor was detected pre-intervention. The analysis considered the intra-patient correlations, as a patient may have received more than one surgical procedure in the same eye. Values of p < 0.05 were accepted as statistically significant. Data management and analyses were conducted with STATA Intercooler version 8.0 (STATA Corp., College Station, TX) and with SAS version 9.2 (SAS Institute Inc., Cary, NC) statistical software.

#### Results

A total of 649 consecutive surgical procedures performed in 565 patients, 360 (63.7%) males and 205 (36.3%) females were included in the analyses. Demographic data for the 565 patients are reported in Table 1. Topical anaesthesia was used for 451 squint corrections in 383 patients, and general anaesthesia for 198 interventions in 182 patients. In all cases, non-adjustable sutures were utilized. Patients operated under topical anaesthesia showed a median age of 44.0 years (range, 13 to 87 years) whereas patients who underwent general anaesthesia showed a median age of 35.5 years (range, 14 to 88 years). Surgery in both eyes was performed in 49 (12.8%) patients of the topical group in a single session and 23 (6.0%) patients in two separate sessions. In the general group, 58 (31.9%) and 5 (2.7%) patients underwent surgery for both eyes with the aforementioned timings. Additional surgery was required by 113 patients, 80 in the group that underwent topical anaesthesia and 33 in the general anaesthesia group, with an incidence of re-surgical procedure of 20.9% and 18.1%, respectively.

Topical anaesthesia was associated with a higher percentage of 'very good' outcomes compared to general anaesthesia (P < 0.001) (Table 2). Considering that the diagnosis of strabismus, in which the result of surgery is largely unpredictable, we found that 44 (67.7%) patients with diagnosis of restrictive squint were assessed as 'very good' and 'good' after surgery under topical anaesthesia and 9 (32.1%) of those under general (P < 0.001). Likewise, 85 (75.2%) and 16 (53.3%) of patients with paretic squint showed 'very good' and 'good' results after surgery under topical or general anaesthesia, respectively (P < 0.01).

Diplopia was resolved with surgery in 150 (68.8%) and 33 (45.8%) of patients under topical and general anaesthesia, respectively (P < 0.0005). Moreover, we found that 48 (60.0%) and 12 (37.7%) of patients that had already undergone surgery for strabismus (prior to this present study, N = 113), were evaluated as 'very good' and 'good', after interventions under topical or general anaesthesia, respectively.

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Multivariate logistic regression analysis (Table 3) evaluating all procedures, showed that the type of anaesthesia, gender, and preoperative potential stereopsis were significantly associated with a 'satisfactory' clinical result after 6 months. In particular, the odds of having 'satisfactory' results increased by three-fold in patients under topical anaesthesia, in patients with potential stereopsis vision at baseline, and in procedures for weakening, while the odds almost doubled for males.

No serious intraoperative or postoperative complications were reported. None of the procedures under topical anaesthesia were converted to general anaesthesia. Pain was effectively controlled with all patients in the topical group scoring between 0 or 1 (no pain and mild pain, respectively). No patients complained due to discomfort or other reasons.

### Discussion

Our findings showed that intraoperative adjustable strabismus surgery under topical anaesthesia yielded better outcomes than general anaesthesia, and highlight surgical and patient variables related to long-term clinical success. In our opinion, intraoperative adjustment of suture represents a successful approach, since this technique increases the optimization of the intraoperative surgery dosage, particularly in patients in which success of the procedure is less predictable. Although the reliability of this technique is primarily based on surgical skills, the efficiency of the combination of topical anaesthesia and sedative infusion is essential to assure effective anaesthetic and sedative actions, without prejudicing the arrangement of the surgical procedure [16]. Moreover, in our practice, the approach to the surgery of strabismus has frequently been a compromise between the expectation of obtaining the best clinical results (i.e., stereopsis) and the baseline condition of the patient (e.g. presence of amblyopia, type and grade of deviation, etc.). Consequently, we usually plan our surgery in view of the pre-operative aim of the surgical procedure and not exclusively of the residual angle of deviation we wish to obtain.

As expected, this study shows that topical anaesthesia is particularly promising in those patients in which the feasibility of orthotropic were pre-operatively predictable, and for the correction of diplopia, that was obtained more frequently in patients who underwent topical anaesthesia than in those in general. The likelihood of evaluating the result of surgical procedure during surgery is a determining factor for the overall efficacy of the procedure, especially in patients in which anatomical disorders can reduce the possibility of accurately scheduling the type of intervention. The superior results we found in restrictive and paretic squint with topical anaesthesia indicated the unpredictability of general anaesthesia, and supported the use of topical anaesthesia in the surgical treatment of incomitant strabismus [17].

In fact, restrictive and paretic squints required an accurate planning of the surgical program and the dosage of surgery, in order to avoid the risk of post-operative diplopia and the regression of surgical results. A further important aspect that presents a challenge that must be overcome for a successful procedure is the potential binocular vision. We found that the occurrence of potential stere-opsis pre-operatively was significantly related to satisfactory results, as expected for the interdependence among motor and sensory mechanisms of ocular alignment [18]. Moreover, we found that the type of procedure affects the final results. Basically, interventions of weakening were significantly related to successful results in our series, although these findings could be a limitation of our study. In fact, interventions of recession were executed whenever possible, because of the feasibility of obtaining a functionally successful weakening of the muscle, and for the reversibility of the technique, and not just to obtain a satisfactory result in patients who presented a more complicated strabismus.

Although these results should be confirmed through further prospective study, our study suggests that the evaluation of ocular motility during surgery under topical anaesthesia is associated with better results in respect to surgery under general anaesthesia, and that intraoperative adjustable surgery under topical anaesthesia should be primarily considered especially in cases of incomitant strabismus. The findings of such good results should encourage to clinicians considering this option for the surgical correction of squint.

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	Topical anesthesia N = 383 No. (%)	General anesthesia N = 182 No. (%)	
Sex			
Male	217 (56.7)	143 (78.6)	
Female	166 (43.3)	39 (21.4)	
Age (yrs)			
Mean ± SD	$43.6 \pm 14.5$	38.1 ± 15.7	
Diagnosis			
Paretic	113 (29.4)	30 (16.5)	
Infantile Exotropia	69 (18.0)	38 (20.9)	
Restrictive	65 (17.0)	28 (15.4)	
Essential Infantile Esotropia	52 (13.6)	41 (22.5)	
Secondary Esotropia	47 (12.3)	22 (12.1)	
Secondary Exotropia	37 (9.7)	23 (12.6)	
Onset			
Infancy	132 (34.5)	82 (45.0)	
Infancy/Decompensated	26 (6.8)	10 (5.5)	
Late infancy	27 (7.0)	14 (7.7)	
Adulthood	198 (51.7)	76 (41.8)	
Reoperations			
No	303 (79.1)	149 (81.9)	
Yes	80 (20.9)	33 (18.1)	
Diplopia			
No	165 (43.1)	110 (60.4)	
Yes	218 (56.9)	72 (39.6)	
Potential binocular vision			
No	137 (35.8%)	92 (50.5%)	
Yes	246 (64.2%)	90 (49.5%)	
Angle of deviation $(\Delta)^*$			
0	0 (-)	0 (-)	
1-4	4 (1.0)	0 (-)	
5-10	17 (4.5)	15 (8.2)	
11-20	110 (28.7)	34 (18.7)	
≥ 21	252 (65.8)	133 (73.1)	

**Table 1:** Patient demography and baseline clinical characteristics (N = 565 patients)SD: Standard deviation; No: Number;  $\Delta$ : Prism diopter.\* Measured for distance

\* Measured for distance.

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Type of anesthesia	No. of procedures	Clinical results N (%)			
		Very good <sup>1</sup>	Good <sup>2</sup>	Sufficient <sup>3</sup>	Insufficient <sup>4</sup>
Topical	451	295 (65.4)	77 (17.1)	39 (8.6)	40 (8.9)
General	198	83 (41.9)	44 (22.2)	29 (14.7)	42 (21.2)

*Table 2:* Distribution of clinical outcomes with respect to the type of anesthesia (N = 649 yes)

Δ: prism diopter; No: number;

<sup>1</sup>*Very good = angle deviation < 4*  $\Delta$ *;* 

<sup>2</sup>Good = angle deviation between 4 and 10  $\Delta$ ;

<sup>3</sup>Sufficient = angle deviation between 11 and 20  $\Delta$ ;

<sup>4</sup>Insufficient = angle deviation >  $20 \Delta$ .

Predictor	No.	OR	95% CI	Р
Type of anesthesia				
General	198	1.00		< 0.001
Topical	451	3.24	2.09-5.03	
Sex				
Females	246	1.00		0.017
Males	403	1.66	1.09-2.52	
Age				
1-year increments	649	0.99	0.98-1.01	0.913
Previous surgeries				
No	491	1.00		0.098
Yes	158	1.24	0.90-3.46	]
Onset				
Infancy	233	1.00		
Infancy/decompensated	40	1.07	0.768-2.03	0.369
Late infancy	44	0.87	0.349-3.27	0.905
Adulthood	332	0.66	0.354-2.14	0.764
Type of squint <sup>1</sup>				
Vertical				
No	369	1.00		0.269
Yes	280	0.75	0.449-1.249	
Divergent				]
No	395	1.00		0.126
Yes	254	0.60	0.308-1.156	
Convergent				
No	381	1.00		0.108
Yes	268	0.57	0.288-1.130	
Diplopia at baseline				
No	294	1.00		0.123
Yes	355	0.57	0.275-1.166	

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Potential binocular vision at baseline				
No	251	1.00		0.002
Yes	398	3.15	1.546-6.402	
Type of surgery – <i>weakening</i> <sup>2</sup>				0.001
No	105	1.00		
Yes	544	2.89	1.546-5.400	
Type of surgery – <i>reinforcement</i> <sup>2</sup>				
No	404	1.00		0.435
Yes	245	1.24	0.724-2.115	
Surgery in the right eye <sup>3</sup>				
No	278	1.00		0.545
Yes	371	1.20	0.653-2.237	
Surgery in left eye <sup>3</sup>				
No	260	1.00		0.141
Yes	389	1.56	0.862-2.834	

**Table 3:** Likelihood of satisfactory clinical outcome (N = 649 eyes) OR: Odds Ratio; No: number;

<sup>1</sup>No. = 153 (32.6%) squints were combined

<sup>2</sup>No. = 140 (21.6%) procedures performed both for weakening and reinforcement

<sup>3</sup>No. = 111 (17.1%) procedures affected both eyes

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