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#### ABSTRACT

*Objective:* Grommets may be considered as the treatment of choice for otitis media with effusion (OME) in children born with a cleft. But the timing and precise indications to use them are not well established. The aim of the study is to compare the results of hearing and speech controls at three and six year-old in children born with total cleft or cleft palate in the presence or not of grommets.

*Methods:* This retrospective study concerns non syndromic children born between 1994 and 2006 and operated for a unilateral cleft lip palate (UCLP) or a cleft palate (CP) alone, by one surgeon with the same schedule of operations (Malek procedure). We compared the results of clinical observation, tympanometry, audiometry and nasometry at three and six year-old. The Borel-Maisonny classification was used to evaluate the velar insufficiency. None of the children had preventive grommets. The Fisher Exact Test was used for statistical analysis with p < 0.05 considered as significant.

*Results:* Seventy-seven patients were analyzed in both groups. Abnormal hearing status was statistically more frequent in children with UCLP compared to children with CP, at three and six years (respectively, 80-64%, p < 0.03 and 78-60%, p < 0.02), with the use of grommets at six years in 43% of cases in both groups. Improvement of hearing status between three and six year-old was present in 5% of children with UCLP and 9% with CP, without the use of grommets.

*Conclusion:* The use of grommets between three and six year-old was not associated to any improvement of hearing status or speech results children with UCLP or with CP, with a low risk of tympanosclerosis. These results favor the use of grommets before the age of three, taking into account the risk of long term tympanosclerosis.

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## 1. Introduction

Normal hearing during the early phase of infancy is critical in order to develop language, speech and cognitive development. Intelligible speech must be acquired as early as possible for good social integration [1,2]. Due in part to velopharyngeal dysfunction and earing problems such as otitis media with effusion (OME), children born with a cleft lip and palate (UCLP) or a cleft palate (CP)

\* Results presented at the 12th International congress on Cleft lip/Palate and related craniofacial anomalies, May 5–10, 2013, Orlando, Florida, USA. *Abbreviations:* OME, otitis media with effusion; UCLP, cleft lip palate; CP, cleft

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http://dx.doi.org/10.1016/j.ijporl.2015.10.012 0165-5876/© 2015 Elsevier Ireland Ltd. All rights reserved. have significantly more speech and hearing problems than children born without a cleft [3–5]. Therefore, an increased prevalence of OME with an associated hearing loss may affect the development of speech and language and lead to lower verbal activity [6,7].

The true incidence of OME in the cleft palate children remains obscure, especially in young children. It has been demonstrated that children with CP present OME often present within the first six months of life [8,9]. It is also well known that children with CP have a risk of OME even after five years of age, although the prevalence of the otitis is supposed to be present between four and six years of age [10]. The incidence of OME seems to be very high, until 90%, even after cleft repair [8,11].

The surgical insertion of a tympanostomy/ventilation tube (grommets) can provide aeration and equalization of pressure to

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the middle ear cavity and thus allow the fluid to drain and decrease secretion from the mucosa. Therefore, insertion of ventilation tube in children with OME is considered the treatment of choice in most studies even if surgery does not to change the incidence of OME.

In most studies, timing to perform routine or selective insertion of grommets in children with a cleft are not well defined. For selective insertion of grommets, decision and indications are also not so well defined. Indications are normally based on clinical observation and evolution on tympanometry and the use of grommets in prevention for better hearing is still not proved [12]. These may be inserted routinely at the time of the palatoplasty, that means preventively or selectively before that clinical examination and tympanogram are positive for an OME. In contrast, a conservative approach by the insertion of grommets in symptomatic patients is motivated by the early well known complications and not always previsible of their insertions such as atelectasis, perforation, tympanic membrane tympanosclerosis (tympanosclerosis) and chronic otitis media. These results favor therefore a conservative approach with an indication of surgery principally based on careful hearing examination and tympanometry [13].

The aim of the study is to compare the evolution of hearing and speech status at three and six years of age and the utility of using grommets.

# 2. Materials and methods

This retrospective study compares hearing and speech status at three and six years of age for children operated for a UCLP or a CP without associated anomalies and born between 1994 and 2006. Children born with bilateral cleft, associated malformations, chromosome abnormalities or not operated by our surgeon were excluded from the study.

### 2.1. Organization and surgery

All children born with unilateral UCLP had velar repair performed at three months, and anterior hard palate and lip closure at six months, following the Malek procedure [14]. A vomer-flap was used to reconstruct the nasal layer of the velum. In children born with CP, closure was performed at five to six months. Surgery was done by the same surgeon and with the same procedure from 1994 to 2006. All children born with a cleft in the palate were fitted with a removable palatal appliance before one week of age and were bottle fed with a normal teat and expressed breast milk.

Clinical evaluations were organized in a single institution by the same surgeon and team following the same schedule. All children were assessed before and after surgery, six months later and once a year until the age of three by the pediatric surgeon and the speech therapist. A paediatrician followed the children to evaluate their psychomotor development and risk of OME. Pediatricians were instructed in the special care needed to diagnose OME and the risk of hearing loss in their cleft patients. They were asked to perform routine otoscopy, tympanometry and check for glue ear.

As of age three, the child was evaluated by a multidisciplinary team. The multidisciplinary cleft team is composed of the pediatric surgeon, two pediatric ENT specialists, a craniofacial surgeon, an orthodontist, two speech therapists and a psychologist. The child and its parents were seen depending on the child's needs, usually annually or biannually.

# 2.2. Hearing evaluation

Children did not undergo preventive tympanostomy. They were under rigorous medical follow-up and examined frequently and carefully. Physicians were asked to perform routine otoscopy, tympanometry and glue ear controls. The hearing status was considered abnormal when they presented any of the following complications: OME, tympanic membrane retraction or perforation or cholesteatoma. They were then sent to our ENT specialist to organize a clinical control, a tympanometry, an audiometry and a nasometry. The same controls were done at three and six years of age by the paediatric otolaryngologist of our team. Our clinical indications to perform tympanostomy and insert grommets were chronic episodes of OME, abnormal tympanometry and audiometry with a hearing loss of more than 30 dB in one ear in conjunction with hearing loss reported by the parents and disorder in speech acquisition.

### 2.2.1. Otomicroscopy

Children presenting OME were seen by the team upon referral by the otolaryngologist specialist (ENT). A paediatric otolaryngologist, specialized in the treatment of children with cleft lip and palate, performed otomicroscopy at each visit. Air conduction was measured and recorded.

#### 2.2.2. Tympanometry and audiometry

Hearing evaluation was reported in a reproducible manner based on impedance tympanograms using a Grason-Stadler GSI-28A tympanometer, and on total audiograms using a Grason-Stadler GSI-16 earphone audiometer (Grason-Stadler, Littleton, MA, USA). These completed the ENT's clinical examination and were performed on the same day as the speech evaluation. Hearing assessment was performed at variable ages and in response to individual needs over the following years. The hearing loss was reported if it was conductive, but sensori-neural or mixed hearing loss were excluded.

The children who were diagnosed with OME based on the results of otomicroscopy and tympanometry received tympanostomy tubes after an average of three months of OME without improvement under medical treatment. OME was considered persistent if it lasted more than three months, especially after the summer. We put short-term grommets in gold or metal under microscope view. The insertions were realized with a microsurgical knife, ideally in the lower internal quadrant. Follow-up was done by the same paediatric otolaryngologist. Grommets removal was realized either spontaneously or after routine controls. Then, children were seen three months later to check the anatomy. Indications and time to extraction were dependant on each children and based on clinical examination and improvement of hearing.

# 2.3. Speech evaluation

Perceptual speech evaluation by gualified speech pathologists experienced in cleft pathology is the mainstay of speech control in our institution. At the age of three, the first speech evaluation was performed using video recordings. Velopharyngeal insufficiency (VPI) or nasal air emission was evaluated according to the Borel-Maisonny classification (Table 1) [15]. A simplified classification was used to analyze our results: (A) good phonation; (B) Phonation with continuous air emission; (C) bad phonation; and (D) no intelligibility. Hyper-nasality, hypo-nasality, audible nasal emission, voice quality, misarticulations associated with VPI, and intelligibility were assessed. Nasal emission on separate phonemes was measured using a 622 Kay Electronics nasometer (Kay Elemetrics, Pine Brook, NJ, USA). Fluoroscopic velopharyngeal evaluations were not considered. Clinical perceptual speech evaluations and nasometry were performed by the same two therapists before and after operations. Concerning speech, parents were provided with strategies to encourage babbling and early verbal communication as of one year of age.

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