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#### ORIGINAL ARTICLE

### Primary myringoplasties. Results after a 2 year follow-up period

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#### **KEYWORDS**

Myringoplasty; Tympanic membrane; Perforation; Outcomes; Follow-up

#### **Abstract**

Introduction and goals: The goals of myringoplasty are closure of the perforation in the tympanic membrane and improvement in hearing levels, with varying results in the published literature. Our aim was to determine the results of this procedure at our centre and compare them with the literature. Methods: Retrospective analysis of 217 primary myringoplasties carried out in the Otorhinolaryngology Department of the Hospital Universitario Ramón y Cajal between 1998 and 2003, describing the characteristics of the perforations, surgical technique, and post-operative results (perforation closure and hearing improvement).

Results: The majority were adults with perforations secondary to recurrent middle ear infections (91%). Most were less than sub-total (64%) and did not involve the tympanic annulus (79%). Grafts were inserted using lateral (45%), mixed (29%), and medial (26%) techniques, using retroauricular (66%) and endaural (34%) approaches. Temporal muscle fascia was the graft most frequently used (87%). Perforation closure was achieved in between 78% and 91% of cases throughout the 24-month follow-up period, with an overall closure value of 78% after 2 years of follow-up. Hearing improvement, established as an air bone gap difference of less than 20 dB, was seen in proximately 56% of cases.

Conclusions: At our centre, myringoplasty achieves anatomical (78%) and functional (56%) success comparable to the results described in the literature. We consider medium-term follow-up to be of the utmost importance because of reperforation phenomena, which may occur as much as 2 years or more after surgery.

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#### PALABRAS CLAVE

Miringoplastia; Membrana timpánica; Perforación; Pesultados; Seguimiento

#### Miringoplastias primarias. Resultados a los 2 años de seguimiento

#### Regimen

Introducción y objetivos: La miringoplastia tiene como finalidad el cierre de la perforación timpánica y mejorar la audición, con resultados variables en la literatura. Nuestro objetivo fue saber cuál es la realidad de esta cirugía en nuestro centro y compararla con la publicada.

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Métodos: Análisis retrospectivo de 217 miringoplastias primarias efectuadas en el Servicio de Otorrinolaringología del Hospital Universitario Ramón y Cajal entre los años 1998 y 2003, con descripción de las características de perforación, técnica quirúrgica y resultados postoperatorios (cierre de la perforación y mejoría de la audición).

Resultados: En su mayoría eran adultos y la etiología principal fue la secuela otorreica (91%). Predominaron perforaciones menores a subtotal en tamaño (64%) que no afectaban al anillo timpánico (79%). La técnica de colocación del injerto respecto al resto timpánico fue lateral (45%), mixta (29%) y medial (26%); se utilizó el abordaj e retroauricular (66%) y endoaural (34%). La fascia de músculo temporal fue el injerto más utilizado (87%). El cierre de la perforación se consiguió entre un 78 y un 91% de los casos a lo largo de los 24 meses de seguimiento, con un valor final del 78% a los 2 años de seguimiento. La mejora de la audición, reflejada como un umbral diferencial audiométrico menor de 20 dB, se observó en aproximadamente el 56% de los casos

Conclusiones: La miringoplastia en nuestro centro alcanza cifras de éxito anatómico (78%) y funcional (56%) comparables con las de la literatura. Consideramos fundamental el seguimiento a medio plazo de los pacientes por el fenómeno de reperforación, que puede ocurrir hasta pasados 2 años o más.

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#### Introduction

Myringoplasty is defined as the surgical procedure in which the reconstructive procedure is limited to the repair of a perforation of the tympanic membrane via a skin graft, without further action in the middle ear.<sup>1</sup>

More than 300 years have passed since Banzer in 1640, tried to close a tympanic perforation using a piece of elk horn coated in pig bladder. Much progress has been made since then, and today we use autologous skin grafts. The technique itself has also been improved and there are presently multiple alternatives for each surgery.

Progress in these areas enables us to assume an improvement in the success rate of the surgery, but although it is becoming more effective, in reviewing the literature we can find widely differing results and follow-up periods. In turn, there are certain variations in the technique which are defined as superior and more in vogue in recent years.

Myringoplasty is the most frequently performed otologic surgery in our centre after the placement of transtympanic drainage tubes. The objective of the present work is to learn the reality of this surgery in our environment, comparing the results obtained with those published and thus suggest actions for improvement.

#### Patients and methods

We designed a retrospective study in which we made a critical analysis of the primary myringoplasties carried out between 1998 and 2003 at the Hospital Universitario Ramón y Cajal. We analyzed ears with tympanic membrane perforations operated on for the first time, and we established the following as exclusion criteria: subsequent operations, actions on the ossicular chain or the middle ear (tympanoplasty), mastoidectomies, or ears with cholest eatoma.

We collected 500 case histories from which, after applying the exclusion criteria, we obtained 217 primary

myringoplasties carried out over 6 years. We collected data relative to age, aetiology of the perforation, pre-operative findings, and surgical and post-operative complications.

The aim of this study was to analyze the anatomical and functional results of surgery. The anatomical outcome was defined as the condition of the eardrum at post-operative follow-up: complete or perforated. The functional outcome was post-operative hearing, specifically the differential audiometric threshold (DAT)² between the air track and the post-operative bone track, which was grouped in 10 dB intervals. Hearing was expressed as an average hearing threshold (AHT),³ established as the average in decibels for the frequencies 500, 1000, and 2000 Hz. Information was collected on the condition of the eardrum and audiometries reflected in the medical history from the first consultation until the last post-operative review. The cut-off points for the analysis of post-operative results were 1, 3, 6, 12, and 24 months.

In addition to this, the anatomical characteristics of the tympanic perforation and the surgical technique were defined. The location of the perforations was defined as anterior, posterior, inferior, subtotal (3 quadrants), and complete (no tympanum). The size of the perforation was defined as greater than or less than subtotal. Depending on whether they affected the tympanic ring or not, they were categorized as central or marginal. Pegarding the surgical technique, the approach and the type of graft used, as well as the need to grind the external auditory canal, were examined. The placement of the graft was defined as medial or lateral to the tympanic rest, and mixed if it included the 2 options.

Data collection was carried out using a questionnaire designed for the Internet through the "e-encuesta" (e-survey) programme, which was applied to each medical record reviewed, preserving confidentiality. The database was exported to the SPSS program for statistical analysis, through which the  $^2$  and Student t statistical tests were applied; a value of P<.05 was considered as statistically significant.

#### Results

Of the 217 patients undergoing primary myringoplasty, 91% were adults with a mean (standard deviation) age of 38 (17.8) years, with an interval of 7-77 years. The ear more often operated on was the left by a small majority (56%vs 44%). The predominant aetiology of the perforation was otorrheic sequela (91%), distantly followed by the placement of transtympanic drainage tubes (5%), trauma (3%), and after stapedectomy (1%).

The location of the perforation was distributed uniformly in general; inferior perforations were the most frequent (31%, followed by posterior (27%, anterior (20%, subtotal (18%, and complete perforations (4%). They affected the tympanic ring (marginal) in 21% and did not (central) in 79% of cases. With regard to the size of the perforation, 36% were subtotal and 64% less than subtotal. The most relevant pre-operative finding was myringosclerosis, observed in 63% of the ears.

The data concerning the surgery are summarized in Table. The retroauricular surgical approach almost doubled (66%) the endaural (34%). Temporalis muscle fascia (87%) and tragus perichondrium (13%) were used as graft. The most common technique used to affix the graft was the lateral (45%), followed by the mixed (29%) and medial (26%) to the tympanic rest. It was only necessary to grind the conduit in 8% of cases.

We recorded 14% of post-operative complications. The most frequent was cholesteatoma pearl in the eardrum in 11 cases, followed by 5 lateralized grafts, 3 retracted grafts, 3 cases of cholesteatoma in the middle ear, 3 cases of retroauricular haematoma, and 2 cases of blunting.

The anatomical results are shown in Figure 1. The closure of the perforation was achieved in 78%91% of cases during subsequent post-operative controls after 24 months of follow-up. The rate of closure of the perforation was higher after a month (91%) and lower after 24 months (78%). At 12 months follow-up the closure of the perforation was observed in 82% of cases.

The pre-operative hearing of patients is given in Figure 2. They presented an AHT of 43 dB in air with a DAT of 27 dB. In bone, the AHT figure was 16 dB. As a general functional result, it was observed that 56% of patients presented a DAT <20 dB on average over successive controls (Figure 3): thirty percent after a month, 75% after 3 months, 55% after 6 months, 61% after 12 months, and 56% after 24 months. These results are also grouped in intervals of 10 dB in Figure 4.

The improvement in post-operative DAT with respect to the pre-operative DAT was as follows: after 12 months' follow-up, patients who had a post-operative DAT <20 dB reduced their DAT by 26% (7 dB) compared to the pre-operative condition. In patients where the DAT was <10 dB after a year, the reduction was 63%(17 dB).

#### Discussion

The main objective of myringoplasty has traditionally been the closure of the tympanic perforation to prevent chronic infection of the middle ear and to improve hearing, all conducive to improving quality of life. This can be

Table 1 Surgical technique Approach (n=188) **Retroauricular** 66% Endaural 34% Grinding of the conduit (n=199) No 92% Yes 8% Graft (n=188) Fascia of temporalis muscle 87% Tragus perichondrium 13% Technique (n=175) Lateral 45% Mixed 29% Medial 26%

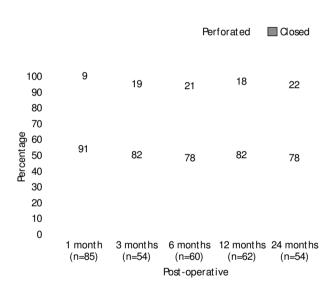
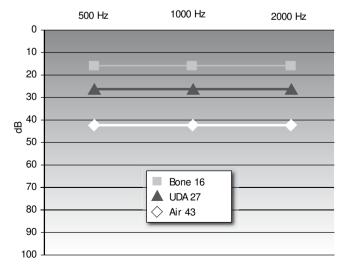
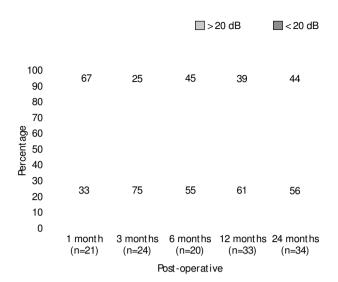


Figure 1 Anatomical results.

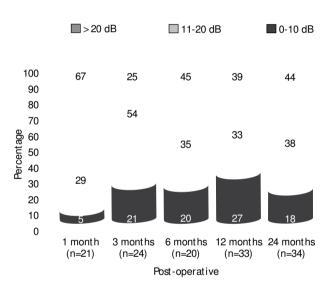


**Figure 2** Pre-operative audiometry: average hearing threshold (AHT).

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**Figure 3** First post-operative differential audiometric threshold (DAT) I.



**Figure 4** Second post-operative differential audiometric threshold (DAT) II.

established by observing the condition of the eardrum and through audiometry in post-operative controls.<sup>4</sup>

In our study we observed an anatomical success rate of 78% after 2 years of follow-up. This figure falls within the wide variability of successful closure of the perforation described in the literature (66%91%). 4-10 Our results worsen as the monitoring time progresses, as reflected by the high rate of closure of 91% after 1 month compared to 78% after 24 months. This phenomenon has been described in previous studies which also conducted a post-operative follow-up with different time intervals. This is explained by the rate of reperforation of the eardrum, which is estimated at between 7% and 27% 11 It is likely that the results of some series reported with high closure figures and short-term follow-up, lower than 6-12 months, 8.9, 12 would decrease if they continued for longer. Other studies claim that the higher incidence of reperforation occurs within the first

3 months and then stabilizes with time.<sup>11</sup> We agree with other authors<sup>5</sup> on the need for a prolonged period of post-operative follow-up, no less than 24 months, to assess the real ability to maintain a long-term closed eardrum.

The improvement in hearing reflects the functional success of the myringoplasty, which we define in our study as a post-operative DAT <20 dB, and which we observe, in general, in 56% of cases. We chose this value based on previous studies8,10 and on the belief that a reduction in DAT is the most reliable way of expressing the improvement in a patient's hearing. Figures have been published for improvement of hearing up to 91% in patients, but this figure, when the follow-up is at least 12 months, ranges between 52% and 67% 6,7,10 It should be pointed out that the improvement in hearing in our study increased with time. which can be explained by the gradual process of healing and post-operative stabilization of the neotympanum and middle ear. On the other hand, our audiometric improvement results do not represent reality completely, since the number of audiometries available in the histories was low. Probably, the average results in our series could be slightly better due to the fact that we included the control audiometries from the first month after the operation, which have worse hearing figures, in the calculation of the overall improvement in hearing.

Most studies arbitrarily define the improvement of hearing as a cut-off point or mean of audiometric parameters with very different values and times, therefore we must be very careful when assessing these figures. There are recommendations from international committees³ for these assessments which enable a comparison between different series.

Multiple studies have attempted to define the possible prognostic factors for this surgery. Aggarwal<sup>5</sup> discusses them in his review of the literature. According to available data, in our series we observed a higher percentage of closure after 12 months using a retroauricular surgical approach compared with the endaural (91% vs 72%). although these differences were not statistically significant (P=.07). This might be explained by a lack of sample size that prevents statistical significance from being reached. since this correlation has been observed by Albera et al11 as a prognostic factor. It is true that other studies do not observe this relationship and do not take it into account, as it would depend on the characteristics of the perforation. 8,12 Notwithstanding the foregoing, Albera et al11 achieved results similar to their overall average of success for perforations with worse prognosis using the retroauricular approach. Therefore they conclude that the retroauricular approach is the most decisive factor in the outcome of the surgery, citing the improved visualization of the perforation and more comfortable placement of the graft. This does not preclude the use of the endaural approach for small posterior perforations that are completely definable. This approach also allows this procedure to be effected, in a greater proportion, on an out-patient basis. 11,13

The main difficulty we have encountered in conducting this study has been the lack of data reflected in the case histories and the loss of patients during follow-up. This alleged loss of patients can be explained by several reasons. As we are a tertiary hospital without a defined protocol for follow-up, patients are variably monitored in the hospital and later at the specialist centre of their health care area. There are

also different criteria and times for considering a patient as discharged. The lack of data is one of the major drawbacks associated with the preparation of retrospective studies with the review of medical records. The establishment of protocols for prospective studies and the definition of thematic care units are possible solutions to this problem.

There will always be variability in the surgical outcome as this is inherent to the patient's characteristics, the surgeon's ability and the details of the technique. But it is also true that, insofar as parameters are standardized and protocols are created based on scientific evidence, comparisons between different centres will lead to an average that will better reflect reality. The way to determine the results obtained through a surgical technique in our hands and how to improve them is by a critical review over an appropriate period. All this will help us both to know how we are managing the situation and to offer the patient realistic expectations of the operation, since the success of a procedure is not only based on reaching its goal but also on maintaining the results over time.

#### Conclusions

At our centre, myringoplasty is a procedure that achieves anatomical (78%) and functional (56%) success figures comparable to those in the literature. We believe it should be indicated both for the closure of the perforation and to improve hearing, in view of the different success rates for each of these parameters. We consider the mediumterm monitoring of patients to be fundamental due to the reperforation phenomenon which can take place even after 2 years or more.

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#### Conflict of interests

The authors have declared there is no conflict of interest.

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