



# Endolymphatic Duct and Sac Decompression: A New Life for an Old Technique

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**BACKGROUND:** Ménière's disease is an inner ear disorder causing recurrent vertigo, hearing loss, and tinnitus. Diagnosis is based on the variability of the symptoms over time and absence of radiological abnormalities. Medical therapy is effective only in a small percentage of patients. Surgical strategies remain controversial. In this article, we revisit a surgical technique neglected over the years: endolymphatic sac surgery.

**METHODS:** Fifty-four patients affected by Ménière's disease underwent endolymphatic duct and sac decompression. According to the American Academy of Otolaryngology–Head and Neck Surgery criteria, vertigo control was evaluated with follow-up at 6 months, 1 year, and 2 years from the intervention. Hearing results were evaluated before the surgery and at 2 years of follow-up using the pure tone average. The results were compared with similar techniques of endolymphatic sac surgery described in the literature.

**RESULTS:** According to the American Academy of Otolaryngology–Head and Neck Surgery criteria classification, 2 years after surgery, 87% patients achieved complete control of vertigo (class A). The hearing remained stable in 93.5% of patients. The results appear compatible with other publications data regarding endolymphatic sac surgeries.

**CONCLUSION:** The duct and endolymphatic sac decompression allows the control of vertigo and preserves hearing from the pathological effects of Ménière's disease. The revised technique allows the functional restoration of endolymphatic homeostasis.

KEYWORDS: Endolymphatic hydrops, Meniere's disease, vertigo, tinnitus

### INTRODUCTION

Ménière's disease is a pathology of the inner ear discovered by the French doctor Prosper Ménière; it is a condition characterized by recurrent dizziness, hearing loss, tinnitus, and fullness. Symptoms go through a crisis, and the times between one crisis and another can be very variable. The symptoms described also have a variable presentation: vertigo can last from 30 minutes to 8 consecutive hours. In the first stage, the disease is characterized by symptoms fluctuation, and the most recent guidelines are based on this feature for the correct diagnosis.<sup>1</sup>

The pathology occurs with greater frequency in the fourth and fifth decade of life, and is more common in females than in males. The pathology has a genetic and an autoimmune basis; positive familiar anamnesis was found in 10% of cases.<sup>2,3</sup>

The first approach is based on the use of betahistine, antiemetics, oral steroids, diuretics, and lifestyle changes (low-sodium diet and high intake of water).

When pharmacological options do not control the symptoms, then other interventional therapies including intratympanic steroids and gentamicin are not infrequently considered. Surgical options include endolymphatic sac surgery (ELSS), vestibular neurectomy (VN), and labyrinthectomy. In this study, the authors describe the results of duct and endolymphatic sac decompression, which we

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consider is an improvement of the ELSS first described by Portman in 1923.

#### MATERIAL AND METHODS

Retrospective observational study was conducted at the ear–nose–throat (ENT) department of University Hospital Foundation Campus Bio-Medico. Data of 54 patients diagnosed with Ménière's disease using the criteria described by the Bárány Society¹ were collected.

Exclusion criteria included infectious middle ear pathologies, profound deafness, migraine associated vertigo, borderline vestibular disturbances, and other unrelated vestibular pathologies. Positional vertigo was not considered an exclusion criteria when present in association. Patients with bilateral Ménière's disease were excluded from this study. Vertigo control was assessed by comparing the number of pre- vs. postoperative episodes of vertigo. Patients with bilateral Ménière's disease often pose difficulty knowing which side is symptomatic for their vertigo.

From the patient's clinical history, there were several unsuccessful attempts with pharmaceutical management associated with differing dosages in some. All patients in the study underwent pro re nata therapy, for at least 6 months, with diuretics and betahistine at onset of minor symptoms (fullness, intrusive tinnitus, dizziness), while betahistine, corticosteroids, thiethylperazine were given during vertigo attacks. All patients went on a diet based on a high water intake and a low concentration of salt and caffeine. Upon failure of medical therapy, patients underwent surgery of decompression of duct and endolymphatic sac [duct and sac decompression (DASD)] under general anesthesia with an average hospitalization of 2 days.

Patients were evaluated before the surgery, and after 6-12 and 24 months of follow-up.

All patients completed a questionnaire for epidemiological purposes, summarized in Table 1. The questions asked to the patient were chosen based on the literature and on clinical experience.<sup>4</sup> In the preoperative period, for the vestibular evaluation, the majority of patients underwent a video head impulse test. The ratio between the number of vertigo attacks before and at 6, 12, and 24 months after the DASD was evaluated according to the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) criteria; for vertigo control, the results were catalogued as follows: 0 = A, complete control; 1-41 = B, substantial control; 41-80 = C, limited control; 81-120 = D, insignificant control; >120 = E, worsening control; F, for patients using secondary treatment. The audiological evaluation was performed with a pure tone audiometry at frequencies of 500-1000-2000-4000 Hz. Only bone conduction was considered, while air conduction was not taken into consideration in order to reduce variability. The preoperative and the postoperative audiometric examinations were assessed using the 4-pure tone average (PTA). According

#### **MAIN POINTS**

- The duct and the endolymphatic sac as a morpho-functional unit.
- Endolymphatic duct and sac surgery in Meniere's disease.
- Epidemiology in Meniere Disease.

Table 1. Epidemiology of the Patients Considered

Table 1. Epidermology of the Fatients considered	
Data of Patients	289
Male : female	30:24
Right : left	23:31
Age (average)	52.4
Familiarity for vertigo disease	14.8%
Familiarity for autoimmune disease	5.5%
Positive testing for autoimmune disease	5.5%
Head trauma experience	16.6%
Migraine diagnosis	16.6%
Worsening of crisis during premenstrual period	9.2%
Tumarkin attack experience (feeling of being pushed on the ground)	31.5%
Lermoyez syndrome experience (hearing improvement during vertigo crisis)	11.1%
Worsening of crisis during change of season	50%
Worsening of crisis during warm temperature	26%
Worsening of crisis during cold temperature	18.5%
Worsening of crisis during with dry weather	5.5%
Worsening of crisis during humid weather	16.6%
Worsening of crisis during coffee assumption	22.2%
Stress-induced crisis	66.6%
Head turning-induced crisis	4.2%
Height-induced crisis	22.2%
Bilateral symptoms	11.1%
First symptom age	40 ± 14
First crisis age	44 ± 12

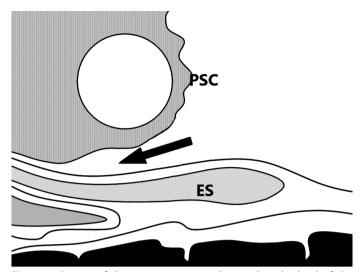
to the AAO-HNS criteria for the hearing level assessment, a change  $\leq$ 10 dB was considered nonsignificant. The intrusiveness of tinnitus and ear fullness were examined considering the stability, improvement, or worsening of the symptoms with a follow-up of 24 months. The authors compared vertigo control and auditory outcomes with the results from previous endolymphatic sac interventions.<sup>5</sup>

Statistical analysis was performed using software STATA 16.1 software (StataCorp LT, College Station, Tex, USA). The authors calculated the absolute and relative frequencies of the subjects in the "response" classes and the hearing variation classes. Clopper Pearson's exact 95% CI was calculated for the percentage of subjects with total recovery.

The authors assert that this work comply with the ethical standards. Campus Bio-Medico Ethics Committee approved this study, approval no: 67.22. The authors obtained written consent from all 54 participants.

## **Surgical Technique**

After mastoidectomy, the surgeon visualizes the lateral and posterior semicircular canal prominence, then proceeds to the identification and exposure of the sigmoid sinus and identification of the dura mater of the middle and posterior cranial fossa. The surgeon carries on to the skeletonization of the dura mater which appears thickened in correspondence of the endolymphatic duct and sac. Bone pâté



**Figure 1.** Section of the posterior semicircular canal at the level of the endolymphatic sac. The bone pâté is placed on one side of the sac. The arrow shows the bone pâté placement. ES, endolymphatic sac; PSC, posterior semicircular canal.

and Tissucol are placed below the posterior semicircular canal, near a thicker and paler pink dura, in order to decompress the duct and sac (Figure 1).<sup>6</sup> The authors describe the detachment of the bone from the meninges. The dura detachment occurs through the fibrillar (Surgicel<sup>TM</sup>) and its decompression through the bone pâté.

The bone pâté is positioned as a spacer between the dura mater and the bone by the side of the duct and endolymphatic sac to avoid the subsequent ascent of the dura. Its autologous and soft material does not tear the meninges and allows dural scarring, moving the endolymphatic duct and sac in a new position. The Tissucol (Tisseel) is used to fix the structure. The temporalis muscle fascia and rotation flap of the sternocleidomastoid muscle is aimed to avoid the regrowth of bone in the mastoid and the treated area.

The authors have already described how to decompress both the duct and the endolymphatic sac using bone pâté and named DASD, meaning duct and sac decompression.<sup>7</sup>

## **RESULTS**

Among the 54 subjects analyzed, 7 were classified as class F and 47 as class A. The percentage of subjects who had a total recovery at 12 months is equal to 87% (95% CI: 75.1%-94.6%). At 24 months, the percentage of subjects with total recovery is 86.7%, but 1 patient was lost (Table 2).

Seven patients (class F) underwent vestibular nerve section as second surgery and 1 patient was lost during the course of follow-up, and they were not considered for the auditory evaluation. After 24

Table 2. Vertigo Control at 6, 12, and 24 Months

	Class A		Class F		Total
	n	%	n	%	n
6 months	47	87.04	7	12.96	54
12 months	47	87.04	7	12.96	54
24 months	46	86.79	7	13.21	53

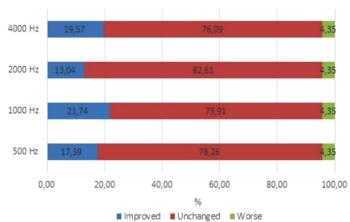


Figure 2. Improved, unchanged, worse of hearing frequency at 24 months ( $\pm 10$  db).

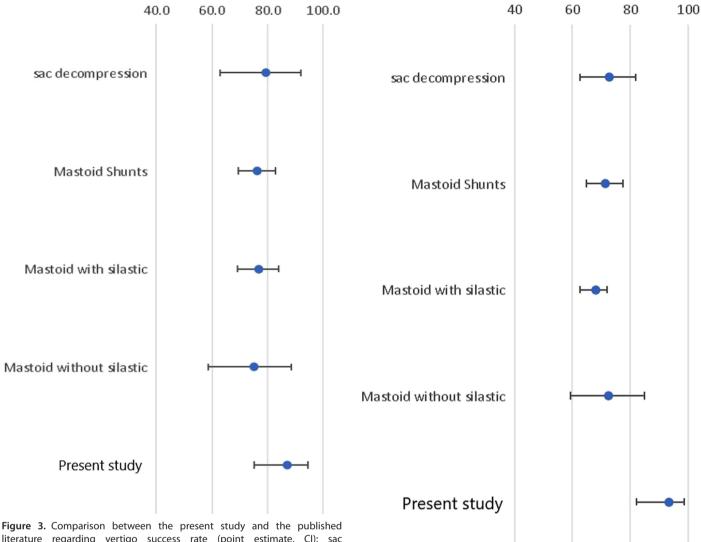
months, the pure tone average (PTA) was calculated at the frequencies of 500 Hz, 1000 Hz, 2000 Hz, and 4000 Hz, and the comparison between preoperative and postoperative results was calculated for each individual patient. A change >10 dB in PTA was considered significant. Pure tone average worsened in 6.5% of patients (>10 dB). For each of the frequencies (500 Hz, 1000 Hz, 2000 Hz, and 4000 Hz), improvement, worsening, and hearing stability were calculated (Figure 2).

The percentages of stability, improvement, and worsening of tinnitus at 24 months after intervention in the remaining 46 patients were 56.5%, 37%, and 6.5% respectively. Ear fullness was stable in 26.1%, improved in 65.2%, and worsened in 8.7%.

The authors compared the value of patients in class A with the confidence interval (class A–B) obtained in different papers grouped in a meta-analysis (ELSS studies). The prevalence of vertigo control is higher than that in other studies, but the Cls overlap. Therefore, the results of our surgical technique appear to be similar to the data obtained previously (Figure 3). The percentages of improved or stable PTA are better to a Cl for the same data obtained from the meta-analysis (average variation:  $-3.5 \pm 9.6$ ) (Figure 4). We report 2 cases of cerebrospinal fluid leak during surgery (to be settled with the insertion of the Surgicel) and 1 case of surgical wound dehiscence.

# DISCUSSION

The decompression of the endolymphatic sac was proposed in France in the 1920s and was based on the concept of pressure relief with consequent release of the endolymphatic sac. The decompression took place simply with the removal of the mastoid bone, and the results, depending on the study, ranged between 60% and 90% therapeutic success (category A-B).<sup>5</sup> In 1960, House introduced first the subarachnoid shunt, followed by the mastoid shunt with Silastic placement. Even with this technique, the control of vertigo was achieved in 75% of cases. The shunt without Silastic positioning appeared to provide the same results as the original technique in vertigo control. Hearing improvement rates appear to be in favor of the Silastic-free procedure.<sup>5</sup> In 1976, Paparella introduced the T-tube insertion as a valve in the endolymphatic duct; he described vertigo control in 94% of cases and an improvement in the hearing threshold in 30% of cases.8 However, neither the use of the T-tube nor the subarachnoid shunt is currently employed.



**Figure 3.** Comparison between the present study and the published literature regarding vertigo success rate (point estimate, CI): sac decompression, 79.3% (95% CI: 62.9-91.9); mastoid shunt, 76.4% (95% CI: 69.5-82.7); mastoid with Silastic, 76.9% (95% CI: 69.1-83.9); mastoid without Silastic, 75% (95% CI 58.6-83.5); present study, 87% (95% CI, 75.1-94.6).

The purpose of these techniques is the functional restoration of the endolymph discharge valve. Histopathological studies of the temporal bones have highlighted structural alterations in patients with Ménière's disease. These modifications could be consequent to infections in pediatric age, head trauma, or chronic insult of an autoimmune nature.

Periductal fibrosis, hypoplasia of the vestibular aqueduct, and atrophy of the endolymphatic sac are some of the the alterations described that may cause an incorrect channeling of the duct and endolymphatic sac. 9.10 Symptom severity is not always directly related to failure to control symptoms. The severity of the structural changes could be due to the ELSS failure. According to microstructural studies, the duct and the endolymphatic sac represent a morphofunctional unit; the periductal channels that surround it could play a role in the reabsorption of endolymph, and these are structurally similar to the cells of the cochlea spiral ligament which are responsible for potassium recirculation. 11 Nordstrom et al 12 in support of this hypothesis investigated the vascular plexus around the endolymphatic duct and highlighted the role of it in endolymphatic resorption. In

**Figure 4.** Comparison between the present study and published literature regarding pure tone average (500-1000-2000-4000 Hz) (point estimate, CI): sac decompression, 72% (95% CI: 62.5-81.9); mastoid shunt, 71.4% (95% CI: 64.9-77.5); mastoid with Silastic 68% (95% CI: 62.7-72.1); mastoid without Silastic 72.5% (95% CI: 59.4-84.9); present study, 93.5% (95% CI: 82.1-98.6).

the animal model, the duct and endolymphatic sac obliteration also caused hydrops. <sup>13</sup> The authors hypothesize that the improvement in flow may improve perilymph uptake, almost like placing a stent, but with an ab-extrinsic improvement. Removal of bone in the intraosseous portion and decompression may facilitate distension of the duct and endolymphatic sac.

Among other therapies in patients with intractable Ménière's, 1 recent study has demonstrated increased vertigo control when combining intratympanic steroids and highdose betahistine. The role for intratympanic gentamicin (ITG) therapy remains controversial in light of its risk for causing further hearing impairment. Stokroos, among the randomized controlled trial studies, observed the control of vertigo with a low risk for hearing by performing the injections 6 weeks apart; Postema demonstrated hearing impairment by performing the injections of gentamicin 1 week apart due to the cumulative effect of gentamicin, and the follow-up was performed for 1

year. Wu-Minor showed a hearing loss in 17% of cases with weekly administration intervals even after a follow-up of 24 months. The injections were interrupted with the onset of spontaneous nystagmus. 15,16 The enormous interindividual variability in the inner ear sensitivity does not allow performing a safe gentamicin treatment for all patients. In the literature, the dosage of the drug to be used to preserve the cochlea remains variable. The advantages of this therapeutic strategy are the ease of execution and replicability. Silverstein in his international surveys confirmed that gentamicin administration was preferred for its convenience to ELSS.<sup>17</sup> In our opinion, it is not feasible to perform ELSS study with a nonsurgical control or a double-blind study in order to demonstrate the real efficacy of ELSS technique. One of the few studies performed with a placebo surgical control is the Thomson study, which raised the question of the placebo effect of ELSS.<sup>18</sup> However, the study results were questioned years later.19

According to "International consensus (ICON) on treatment of Ménière's Disease," the first therapeutic step consists in medical treatment and lifestyle changes. The second line of treatment uses intratympanic corticosteroids. The third step is the conservative surgery, like the ELSS; the fourth step consists in a destructive treatment that can be medical or surgical (ITG, VN).<sup>20</sup>

In Italy, a questionnaire-based study showed that the ENT specialist prefers to use intratympanic steroids over treatment with gentamicin, and after the failure of intratympanic therapy, only 6.4% of specialists prescribe ELSS. Vestibular neurectomy is preferred by 58.4% of specialists.<sup>21</sup> In the USA and the UK, the situation is reversed; ELSS is prescribed in 85% and 50% of cases, respectively, and VN is instead rarely recommended.<sup>22,23</sup>

It is known from the epidemiological questionnaire that a high percentage of patients reported an increase in dizziness crises during the change of seasons; stress seems to be an important trigger of the disease. In contrast to what has been described in the literature, there was not a high percentage of migraine patients. Out of 54 patients, 31.5% presented a Tumarkin attack; in this patient series, 11.1% of subjects reported hearing improvement during vertigo as described in Lermoyez syndrome. The onset of vertigo was found for an average of 4 years after the first symptom.

Our study results highlight how the surgical technique (DASD) leads to total vertigo control or complete therapeutic failure without intermediate values. Some patients have experienced different symptoms after surgery: the onset of an acute vertiginous crisis seems to stop and sometimes patients describe a feeling of light-headedness that can be associated with increased tinnitus and initial instability but a not a full rotational vertigo. The hearing results remain stable over time. In the pathological course of the disease, hearing deteriorates progressively during crises. The functional restoration of the endolymphatic outflow allows hearing protection. The comparison with the meta-analysis in the study highlights comparable results with regard to other ELSS techniques. The limitations of this study consist in its retrospective nature, the subjective nature of the complaints, the natural history of Ménière's disease (periods of remission and exacerbation), and the uncertainty of the results stability over a longer follow-up period (>2 years). We also acknowledge that further acceptance of our proposed surgical technique will require other treatment centers to independently confirm these findings in future.

An important consideration worth mentioning is that we are unable to control subsequent healing, which is a possible reason for operative failure in some patients with abnormal scarring/fibrosis. For this reason, the surgeon places the temporalis muscle fascia and the sternocleidomastoid flap, to reduce this eventuality, which remains possible. There may be a selection bias because patients who came to our clinic were already seriously ill.

The pure-tone audiometric examination 2 years after the operation depends on the stage of the disease and the years of the disease, not only on the benefit elicited by the surgery.

According to the results of the surgery proposed in this study, the new structure built in the inner ear allows the reduction of endolymphatic hydrops severity. The simple use of the bone pâté can decompress both the duct and the endolymphatic sac, aiding in the escape of the endolymph. This old surgery should return to use.

Ethics Committee Approval: This study was approved by Ethics Committee of Campus Bio-Medico University (Approval No: 67.22, Date: September 20, 2022).

**Informed Consent:** Written informed consent was obtained from all the patients who agreed to take part in the study.

Peer-review: Externally peer-reviewed.

**Author Contributions:** Concept – F.S., F.B.; Design – V.F., F.B.; Supervision – F.G.; Resources – C.B., M.P.; Materials – M.T.; Data Collection and/or Processing – M.P., C.B.; Analysis and/or Interpretation – F.B., C.B.; Literature Search – M.T.; Writing – F.B., M.T.; Critical Review – F.G., F.S.

**Declaration of Interests:** The authors have no conflict of interest to declare.

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