

# Endolymphatic Sac Surgery for Ménière's Disease

## Long-term Results After Primary and Revision Surgery

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**Objective:** To analyze the results of primary and revision endolymphatic sac surgery for the treatment of Ménière's disease in patients who failed medical therapy.

**Design:** Retrospective medical chart review.

**Setting:** Tertiary referral center.

**Patients:** Fifty-one adult patients with Ménière's disease who failed medical therapy.

**Interventions:** Endolymphatic sac to mastoid shunts were performed. Revision sac procedures were performed in patients who developed clinically significant recurrent vertiginous spells 5 months or longer after their original procedure.

**Main Outcome Measures:** Frequency of major vertiginous episodes measured by the standards listed in the 1995 American Academy of Otolaryngology guidelines for evaluation of therapy in Ménière's disease.

**Results:** Twenty-four months after primary sac surgery, 27 patients (53%) exhibited class A results (no vertigo), and 12 (24%) exhibited class B results (1%-40% of baseline). In 14 patients undergoing revision sac surgery, 5 (36%) showed class A results and 4 (29%) showed class B results. Patients who failed treatment with sac surgery more than 24 months after their primary procedure obtained better results than those who failed treatment less than 24 months after their initial sac procedure. In the 37 patients who had long-term follow-up (mean duration of follow-up, 88 months) after their last sac procedure, 57% exhibited class A results (21 cases) and 35% exhibited class B results (13 cases).

**Conclusions:** Endolymphatic sac surgery provided improvement in major spells of vertigo in 77% of patients at 24 months after surgery. Revision surgery provided improvement in 65% of cases. Results of revision surgery were better in those patients who developed recurrent symptoms more than 24 months after their original procedure compared with those of patients who failed treatment earlier.

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**M**ÉNIÈRE'S DISEASE IS ONE of the more common causes of otologic dizziness. Symptoms include episodic dizzy spells lasting 20 minutes to 24 hours, tinnitus, a full sensation in the ear(s), and sensorineural hearing loss. The complete constellation of symptoms is not present in every patient. Guidelines for the diagnosis and evaluation of treatment were published in 1972,<sup>1</sup> 1985,<sup>2</sup> and 1995<sup>3</sup> by the American Academy of Otolaryngology Committee on Hearing and Equilibrium (AAO). The purpose of the guidelines was to help establish the diagnosis and to provide consistent recordings of results of treatment.

Although the pathophysiologic characteristics of Ménière's disease is not completely understood, most clinicians suggest medical treatment as the first line of therapy. A low-sodium diet and a diuretic are considered the mainstays of treatment, although some clinicians feel that allergy management is important. For patients who continue to have frequent major dizzy spells despite adequate medical

therapy, a variety of other types of interventions are available, including intermittent pressure therapy using the Meniett device,<sup>4,5</sup> intratympanic injections of drugs (eg, corticosteroids<sup>6</sup> and gentamicin sulfate),<sup>7,8</sup> endolymphatic sac procedures, labyrinthectomy, and resection of the vestibular portion of cranial nerve VIII. Endolymphatic sac surgery has been an important treatment modality for many years. Although sac surgery is an operative procedure, it is nondestructive to the patient's hearing and balance organs and can usually be performed on an outpatient basis.

The ideal design for a study of sac surgery would be a randomized double-blind process that includes a sham surgical procedure,<sup>9</sup> but even such a study provoked controversy.<sup>10,11</sup> Currently, repeating such a study is not feasible. Most reported series of sac surgery do not contain a control arm.

Although the literature contains numerous reports of the results of sac surgery, there are not many publications of series of cases performed by 1 surgeon with good follow-up over 2 or more years using the 1995 AAO guidelines.<sup>3</sup> The current se-

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**Table 1. Staging of Ménière's Disease**

Stage	4-Tone Hearing Level, Mean, dB <sup>a</sup>	Cases, %
1	≤25	14
2	26-40	18
3	41-70	60
4	>70	8

<sup>a</sup>Mean of 0.5, 1, 2, and 3 kHz.

ries provides data on both primary sac surgery and revision sac surgery.

## METHODS

This study was approved by the institutional review board at West Virginia University School of Medicine (Morgantown). A retrospective medical chart review was performed over the 18-year period of August 1988 through July 2006. Eighty-three cases of endolymphatic sac surgery performed from October 1989 through October 2004 were identified. Twelve cases with follow-up of less than 24 months were excluded. Four cases of surgery (in 2 patients) were excluded because the patients had diseases other than Ménière's disease. The study group consisted of 51 patients who underwent primary endolymphatic sac surgery for definite Ménière's disease and 16 subjects who underwent revision sac surgery for recurrent disabling Ménière's disease.

To collect data, I used a data sheet in a prospective fashion that utilized the criteria mentioned in the 1995 AAO guidelines<sup>3</sup> after they were published. An additional sheet of paper listing the functional levels described by the 1995 AAO guidelines<sup>3</sup> was handed to the patients at each office visit, and the patients identified the level that best described their impairment produced by Ménière's disease. I also kept a computerized list of all patients with Ménière's disease seen during the study period.

### SURGICAL TECHNIQUE FOR PRIMARY SAC SURGERY

After I performed a complete mastoidectomy, I removed bone to expose the posterior fossa dura from the mastoid tip inferiorly almost to the tegmen mastoideum superiorly and from the posterior semicircular canal to the sigmoid sinus. The endolymphatic sac was identified as a thickened portion of the dura, usually beginning just inferior to a line extending from the lateral semicircular canal bisecting the posterior semicircular canal (Donaldson line). A right-angled pick was used to make an opening in the lumen of the sac. A blunt needle was inserted into the lumen to confirm the presence of a lumen. An arrow-shaped piece of Silastic (Dow Corning, Midland, Michigan) was inserted into the sac with the tail of the arrow extending into the mastoid cavity.

### SURGICAL TECHNIQUE FOR REVISION SAC SURGERY

After opening the mastoid, mucosa, new bone, and fibrous scar tissue were removed from the area of the endolymphatic sac and a new opening was made into the lumen of the sac. Another Silastic arrow was inserted after removing the original piece of Silastic.

## RESULTS

Forty-nine patients underwent 51 primary endolymphatic sac operations; 2 men underwent endolymphatic

**Table 2. Control of Vertigo in 51 Cases 24 Months After Primary Endolymphatic Sac Surgery**

Numerical Score	Class	Control, %	Cases, No.
0	A	53	27
1-40	B	24	12
41-80	C	0	0
81-120	D	2	1
>120	E	0	0
Secondary treatment <sup>a</sup>	F	22	11

<sup>a</sup>Initiated owing to disability from vertigo.

sac surgery in both ears, sequentially, after developing Ménière's disease in the contralateral ear that was unresponsive to medical therapy. The patients ranged in age from 20 to 84 years (mean age, 45 years). Twenty-eight right ears and 23 left ears were treated surgically. The male to female ratio was 27:22. These 49 patients were among the more than 400 patients with Ménière's disease whom I saw during the study period. I encountered a cerebrospinal fluid leak in 2 cases. In 1 case the leak was located at the edge of the sac, and a tiny plug of fat was inserted that stopped the leak; a Silastic arrow was placed in the sac. In the other case, that of an 84-year-old woman, the leak was sealed by packing an abdominal fat graft in the mastoid space with fibrin glue without using a Silastic arrow; this patient did not experience another spell of vertigo during 48 months of follow-up.

The 1995 AAO guidelines<sup>3</sup> describe staging of Ménière's disease by the degree of hearing loss. The most frequent stage for patients undergoing endolymphatic sac surgery was stage 3 (**Table 1**). The 1995 AAO guidelines<sup>3</sup> recommend comparing the frequency of definitive attacks of vertigo in the 6 months prior to treatment with the frequency in the interval of 18 to 24 months after treatment. For example, if the patient experienced 10 major dizzy spells per month prior to treatment but only 1 major spell per month in the 18-24 month period after treatment, the patient would have a numerical score of 10 and would be placed in class B in **Table 2**. The control rate of vertigo in the 51 cases of primary endolymphatic sac surgery was 53% in class A and 24% in class B (**Table 2**). Among the 11 patients in class F, 2 underwent vestibular nerve section and 9 underwent revision sac surgery.

To assess the effects of intermittent vertigo on the patient's activities of daily living, the 1995 AAO guidelines<sup>3</sup> described a 6-point functional scale (**Figure**). The results of this study are as follows. The mean functional level score at baseline was 4.4; at 24-month follow-up, 2.8, and at long-term follow-up, 2.8. Since 1995, the patients in this study had been asked to self-assess their functional level. It was not unusual to observe patients select functional level 2 or 3 even when they stated that they were free of major dizzy spells. Whether they were actually having adjunctive spells or did not completely understand the functional scale is uncertain.

Hearing results were summarized for the 4-frequency mean of 0.5 to 3 kHz. The worst audiogram result in the 6-month period prior to definitive therapy was compared with the worst audiogram result in the 18 to 24 month interval after treatment. The 1995 AAO guide-

Regarding my current state of overall function, not just during attacks (check the ONE that best applies):

- 1. My dizziness has no effect on my activities at all.
- 2. When I am dizzy I have to stop what I am doing for a while, but the dizziness soon passes and I can resume activities. I continue to work, drive, and engage in any activity I choose without restriction. I have not changed any plans or activities to accommodate my dizziness.
- 3. When I am dizzy I have to stop what I am doing for a while, but the dizziness does pass and I can resume activities. I continue to work, drive, and engage in most activities I choose, but I have had to change some plans and make some allowance for my dizziness.
- 4. I am able to work, drive, travel, take care of a family, and engage in most essential activities, but I must exert a great deal of effort to do so. I must constantly make adjustments in my activities and budget my energies. I am barely making it.
- 5. I am unable to work, drive, or take care of a family. I am unable to do most of the active things that I used to. Even essential activities must be limited. I am disabled.
- 6. I have been disabled for 1 year or longer and/or I receive compensation (money) because of my dizziness or balance problem.

**Figure.** The 6-point functional level scale, according to the 1995 guidelines of the American Academy of Otolaryngology Committee on Hearing and Equilibrium.<sup>3</sup>

**Table 3. Hearing Results**

Time	Hearing Threshold, dB <sup>a</sup>	Word Recognition, %
Baseline	48	65
24-month follow-up (n=42)	52	69
Long-term follow-up (n=24)	60	49

<sup>a</sup>Mean of 4 frequencies (0.5, 1, 2, and 3 kHz).

lines<sup>3</sup> also allow for reporting of results at the most recent follow-up. A summary of the hearing results is listed in **Table 3**. The comparisons between baseline and 24-month follow-up, baseline and long-term follow-up, and 24-month and long-term follow-up were statistically significant at  $P < .001$  for both hearing threshold and word recognition scores using the *t* test.

The mean long-term word recognition score had dropped to 49% in the 24 cases with long-term audiograms. Ten of these ears had word recognition scores of 24% or less, but conversely, 8 ears showed word recognition scores between 80% and 100%.

### REVISION ENDOLYMPHATIC SAC SURGERY

Sixteen endolymphatic sac revision procedures (31%) were performed on the 51 ears that had undergone primary endolymphatic sac surgery. Nine of the revisions were performed because of recurrent symptoms of vertigo that recurred prior to 24 months after the original sac surgery. Seven revision cases were performed for recurrence after the 24-month follow-up period. These latter procedures were performed from 28 to 94 months (mean, 50 months) after the primary procedure. As a general rule, I did not offer a revision procedure unless the patient had at least a 6-month period of improvement in frequency of dizziness after the original procedure.

The operative findings in these revision cases showed mucosalization over all areas of previously exposed dura

**Table 4. Control of Vertigo at Revision 24 Months After Surgery in 14 Cases<sup>a</sup>**

Numerical Value	Class	Control, %	Cases, No.
0	A	36	5
1-40	B	29	4
41-80	C	7	1
81-120	D	0	0
>120	E	7	1
Secondary treatment <sup>b</sup>	F	21	3

<sup>a</sup>Two patients were lost to follow-up.

<sup>b</sup>Owing to disability from vertigo.

and the endolymphatic sac. Frequently, the mucosa completely sealed the previously inserted Silastic arrow from the mastoid cavity. On at least 1 occasion, the Silastic arrow had extruded into the mastoid cavity. Many patients exhibited fibrous scarring over the dura, and in most cases partial regrowth of bone covering a portion of the previously exposed dura was noted. This new bone was drilled away using diamond burs. After removing the mucosa, the new bone, and the fibrous scar tissue, if present, a new opening was made into the endolymphatic sac and a new Silastic arrow was inserted. The operative findings were similar between those cases revised less than 24 months after their original sac procedure compared with those cases revised more than 24 months after the original operation.

The control of vertigo in the revision patients is listed in **Table 4**, which shows that 65% of patients achieved either class A or B results. Twenty-one percent (3 cases) are listed as having achieved class F results and undergone additional procedures; 2 of these 3 patients underwent vestibular nerve section and 1 underwent labyrinthectomy. All 3 of these patients were in the group that experienced recurrence of symptoms prior to 24 months after the original sac operation.

**Table 5** compares the results in those patients who underwent revision surgery and who presented earlier than 24 months after the primary sac procedure vs the patients who experienced recurrence after 24 months. Two of the 16 patients who underwent revision surgery were lost to follow-up at 24 months after revision, but 1 of these patients returned 70 months postoperatively with class A results. In general, the patients who presented with recurrence more than 24 months after primary endolymphatic sac surgery obtained better results with revision surgery than did patients who experienced recurrence before 24 months.

### LONG-TERM RESULTS AFTER ENDOLYMPHATIC SAC SURGERY

Thirty-seven patients had more than 24 months of follow-up after their last endolymphatic sac surgery. The mean duration of follow-up in this group was 88 months (range, 31-192 months). The results of vertigo control are as follows: class A, 21 cases (57%); class B, 13 cases (35%), class C, 3 cases (8%), and no cases in classes D, E, and F. However, these results do not include patients who underwent vestibular nerve section or labyrinthectomy. None of the patients who had more than 24 months

**Table 5. Revision Sac Surgery: Interval Between Primary and Revision Procedure Compared With Vertigo Control**

Short-term Recurrence			Long-term Recurrence		
Patient	Months, No.	Class	Patient	Months, No.	Class
1	6	E	10	28	A
2	7	F	11	32	B
3	7	A	12	34	B
4	10	A	13	37	B
5	11	A	14	57	Lost <sup>a</sup>
6	13	F	15	71	B
7	13	F	16	94	A
8	14	C			
9	18	Lost			

<sup>a</sup>Lost at 24 months but class A at 70 months.

of follow-up after primary and revision surgery underwent additional surgical procedures for failure of control of vertigo. The long-term vertigo control rate, defined as class A or B results, was 92%.

## COMMENT

### OPERATIVE TECHNIQUE

Various operative procedures have been performed on the endolymphatic sac, including opening the sac to allow drainage into the mastoid or into the subarachnoid space. A variety of devices have been used to try to keep the drainage route patent, but to my knowledge, no studies show superiority of one device over other devices. Brinson et al<sup>12</sup> showed that wide decompression of the endolymphatic sac produces similar results in regard to control of vertigo compared with placement of a drain into the sac. The current report describes use of a small, handcrafted Silastic arrow placed into the lumen of the sac in an attempt to drain the sac into the mastoid cavity. The universal operative finding in the revision cases of mucosa covering the Silastic arrow raises doubts about the long-term patency of the surgically created fistula between the sac and the mastoid cavity in patients who are doing well after primary sac surgery. Information is not available on the status of the shunt device in patients who are doing well in regard to the symptoms of Ménière's disease.

### PRIMARY CASES

Brinson et al<sup>12</sup> reported a series of 94 cases of patients with definite Ménière's disease who underwent either an endolymphatic-mastoid shunt or endolymphatic sac decompression. Using the 1995 AAO guidelines,<sup>3</sup> they reported an identical 66% to 67% class A or B results in both groups at 18 to 24 months of follow-up. Preoperative and postoperative mean pure-tone hearing levels were in the 45- to 50-dB range in both groups. The stage of disease in regard to hearing was similar to the current series.

Goin et al<sup>13</sup> reported that the endolymphatic-mastoid shunt procedure did not affect the natural course

**Table 6. Long-term Results of Goldenberg and Justus<sup>a</sup>**

Year	Results, %			
	No Vertigo	Better	Same	Worse
1983	25	54	8	13
1990	54	29	8	8

<sup>a</sup>See study by Goldenberg and Justus.<sup>17</sup>

of hearing loss in Ménière's disease. Using a modification of the 1985 AAO guidelines,<sup>2</sup> they compared 29 patients who underwent sac surgery for intractable vertigo with a control group of 30 patients in whom surgery was recommended but was not performed either because the vertigo improved or because the patient refused surgery. Both the patients who underwent surgery and the control patients showed worsening of the mean pure-tone hearing level and speech discrimination scores over the 24-month follow-up period.

### REVISION CASES

Paparella and Sajjadi<sup>14</sup> reported a series of 26 revision endolymphatic sac surgery cases performed in the period from 1982 to 1986. The indications for revision were vertigo and hearing loss in 22 cases and only hearing loss in 4 cases. All but 1 of the 22 patients saw improvement in vertigo; 12 were free from vertigo, 10 were substantially improved, and 1 was unchanged.

Huang and Lin<sup>15</sup> reported the results of 44 revision sac procedures performed for recurrence of vertigo after primary sac surgery. The interval between primary surgery and recurrence of symptoms ranged from 2 to 60 months with a mean interval of 17 months. The mean length of time between the 2 operations was 26 months. They reported complete control of vertigo in 64% and substantial control in 20% using the 1985 AAO guidelines.<sup>2</sup> Huang and Lin<sup>15</sup> stated that the earlier after primary surgery that the symptoms of vertigo recurred, the worse the prognosis. My study supports this conclusion.

### LONG-TERM RESULTS

#### Vertigo

In 1983 Goldenberg and Justus<sup>16</sup> reported on 48 endolymphatic sac procedures from their Ménière's disease database of 350 cases. In 1990 Goldenberg and Justus<sup>17</sup> published follow-up information on 24 of the original patients showing somewhat improved results over time regarding control of vertigo (**Table 6**).

Quaranta et al<sup>18</sup> reported a series of 38 patients with intractable Ménière's disease with a minimum follow-up of 7 years. Twenty patients underwent endolymphatic sac surgery, but 18 declined surgery. At 2, 4, and 6 years the surgical cases exhibited 65%, 85%, and 85%, respectively, class A or B results compared with 32%, 50%, and 74%, respectively, for the patients who did not undergo surgery. The difference in control of vertigo was statistically significant at 2 and 4 years, but not at 6 years.

Ostrowski and Kartush<sup>19</sup> used the 1995 AAO guidelines to describe the long-term results of 68 patients with classic Ménière's disease who underwent endolymphatic sac-sigmoid sinus decompression surgery. They reported results with a mean (SD) follow-up period of 55 (25) months. Vertigo control results were as follows: class A, 47%; class B, 25%; class C, 9%; class D, 3%; and class F, 16%.

### Hearing Loss

In 1989, Stahle et al<sup>20</sup> reported the long-term results of the natural course of Ménière's disease in a series of 161 patients followed for at least 9 to 12 years. After 5 to 10 years of disease, the hearing loss stopped at a hearing threshold of 50 to 60 dB with speech discrimination of 50% to 60%. After 20 years, 82% of their subjects exhibited a mean hearing loss of 50 dB.

Sixty percent of my cases were stage 3, which means that the 4-frequency (0.5, 1, 2, and 3 kHz) mean pure-tone hearing level was 41 to 70 dB. Although, at 24 months after surgery, the mean word recognition score (Table 3) had improved from 65% to 69%, the long-term follow-up showed that the word recognition score had dropped to 49%. The mean pure-tone hearing level had dropped from 48 dB at baseline, to 52 dB at 24-month follow-up, and down to 60 dB at the long-term follow-up.

In conclusion, these prior studies, as well as the long-term results in the current study, show that patients with Ménière's disease tend to improve over time in regard to major spells of vertigo. Endolymphatic sac surgery seems to be beneficial in regard to decreasing or eliminating major dizzy spells in those patients who continue to have frequent and severe dizzy spells despite maximal medical therapy. For those patients who initially do well after sac surgery but who experience recurrence of symptoms later, revision surgery is often beneficial. The longer the interval between primary endolymphatic sac surgery and the revision procedure, the more likely it is that the patient will obtain a beneficial response from the revision surgery.

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