



Minimally invasive surgery for the treatment of hyperacusis: New technique and long term results

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ABSTRACT

Objective: A minimally invasive surgery developed by the senior author has previously been reported to significantly improve sound tolerance after surgery. This report compares the new versus original surgical technique used and long-term results of all patients who have undergone minimally invasive surgery for hyperacusis. **Study design:** A prospective, IRB approved clinical research trial at a single institution with surgery performed by the author (HS).

Setting: All patients were evaluated and treated at a tertiary level otologic referral center.

Subjects and methods: 47 subjects were enrolled from 2014 through 2019, 40 met inclusion criteria including adequate follow-up in the analysis. All subjects underwent oval and round window reinforcement. 20 subjects underwent surgery before 2017 with the original technique of round window reinforcement. 20 subjects underwent new technique with additional oval window and stapes reinforcement.

Results: 80% of subjects who underwent the new surgical technique had improvement in hyperacusis symptoms after surgery compared to 60% of subjects who underwent the original technique. Long term follow-up showed sustained results with both techniques with a mean follow-up of 2 years after surgery.

Conclusions: The most recent, newer technique employed appears to have an 80% success rate in improving sound tolerance with small changes to hearing. The improvement in hyperacusis symptoms after surgery is significant and now found to be sustainable with a mean follow-up of 2 years after initial surgery. Psychological measures of anxiety and depression also were found to be significantly improved after surgery in the newer technique group.

1. Introduction

Hyperacusis, which is characterized by an increased sensitivity and intolerance to normal sound levels, is a challenging condition encountered by otolaryngologists. Baguley and Andersson [1] define hyperacusis as an “experience of inordinate loudness to sound that is well tolerated by most people with an associated component of distress.” In addition to physical symptoms of pain and discomfort, patients also present with social (isolation, limitation in activities), and physical (pain, discomfort) symptoms. Although the mechanism of hyperacusis is not well understood, there is a relationship between hyperacusis and increased central auditory pathway gain secondary to acoustic over-exposure [2]. Hyperacusis can vary between patients with regards to severity, mechanism of onset, and other comorbidities. The reported prevalence of hyperacusis amongst the population can range from 5.9%–17.2% depending on how hyperacusis is defined and if a hearing loss includes/excludes a patient from these statistics [3]. While the

mechanism of hyperacusis is not completely understood, common causes have been identified including, but not limited to, cochlear trauma, head injury, adverse medication reactions, hearing loss, aging, surgery, chronic ear infections, and autoimmune disorders [2]. Prior studies have identified superior semicircular canal dehiscence, perilymphatic fistulas, and third window involving lesions as other potential causes for hyperacusis [4,5]. Stapes hypermobility has been postulated as a possible etiology of hyperacusis in a previous publication by the senior author [6].

Treatment for hyperacusis has been centered upon avoidance of provocative stimuli, cognitive behavioral therapy (CBT), gradual sound exposure, and hearing amplification devices [5,7,8]. Thus far, these treatment options have had varied rates of efficacy. CBT has been shown to improve sensitivity to sound, but published data on this therapy option is limited and would warrant further investigation before being recognized as a definitive and justified treatment option [8]. More recently, a surgical intervention has been developed as a potential

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treatment for hyperacusis patients. This minimally invasive surgery involving reinforcing the oval and round windows and stapes superstructure with temporalis fascia or tragal perichondrium may reduce sound intolerance [7,9,10].

Prior benefits of the surgical management of hyperacusis, along with newly observed stapes hypermobility in select patients, has led the principle investigator to alter the original surgical technique, specifically with increased reinforcement of the oval window as well as adding tissue around the stapes. We present a series of patients who have undergone one of the surgical techniques for treatment of hyperacusis, comparing the outcomes of both the original and new surgical techniques. In this study we aim to present the results of the research study to date with focus on (1) comparing the original versus new surgical techniques, and (2) investigating long-term results to see if the improvements in sound tolerance after surgery are sustainable.

2. Materials and methods

This is an IRB approved, prospective clinical trial enrolling a total of forty-seven patients with a history of hyperacusis who underwent round and oval window reinforcement between May 2014 and April 2019. Institutional Review Board (IRB) approval from Sarasota Memorial Hospital had previously been obtained prior to initiating study-related activities. All patients were enrolled in an ongoing clinical trial to evaluate the effectiveness of round and oval window reinforcement for treatment of hyperacusis. Inclusion criteria have been previously described in a previous publication from our study [10]. Prior to enrollment, subjects underwent a thorough history and physical examination, high resolution CT scan of the temporal bones and an audiometric workup involving an audiogram with pure tone air and bone conduction thresholds, speech discrimination, tympanometry and loudness discomfort level (LDL) testing. Patients were asked to self-report the severity of their hyperacusis on a 0–10 numeric rating scale (H Scale: 10 severe, 0 no symptoms). A hyperacusis self-questionnaire (HQ) was then completed to further assess the patient's hypersensitivity to sound. A self-report inventory Hospital Anxiety and Depression scale (HADS) was used to screen for mood disorders. Hyperacusis questionnaire and audiometric measures were repeated at 1 month following surgery, denoted as short-term results. HQ was then re-taken by mail or online survey completed from March 2019 through May 2019 for long-term results.

Surgery was performed on the self-reported worse ear for hyperacusis. If symptoms were not adequately controlled, patients had the option to undergo surgery on the other ear at earliest 6 weeks after the first surgery.

2.1. Original technique

All procedures were performed by the senior author (HS). The initial surgical technique was employed on all patients from May 2014 through January 2017. This technique included a trans-canal approach and raising of the tympanomeatal flap. Further exposure of the ossicles was performed with a small diamond drill if needed. Temporalis fascia or tragal perichondrium was harvested and cut into 2 mm round pieces using a 2 mm biopsy punch. The oval window was reinforced with one 2 mm piece of tissue, then the round window was reinforced with three pieces of 2 mm tissue as showing Fig. 1. Polyester strip ear canal packing was used for 1 week after surgery.

2.2. New technique

All procedures were performed by the senior author (HS). After January 2017, more extensive reinforcement of the oval window and stapes superstructure was performed. All of these patients underwent trans-canal approach as described in original technique and temporalis fascia was harvested and cut into one 4 mm round piece, and ten 2 mm

round pieces using corresponding punch biopsies. The round window was reinforced using two 2-mm pieces of fascia then covered with a 4 mm piece and gel foam. The oval window was reinforced with the remaining eight 2-mm pieces surrounding the oval window and then draped around the stapes superstructure as shown in Fig. 2. Polyester strip ear canal packing was used for 1 week after surgery.

2.3. Questionnaires

The Hyperacusis Questionnaire (HQ) is a non-validated English adaptation of the German Gerauscherempfindlichkeit (GUF), a German self-report measure for hypersensitivity to sound. It is composed of 15-items, evaluating three dimensions or subscales: cognitive behavior in relation to hyperacusis; somatic behavior or reaction linked to specific situation; and finally, emotional reactions. The total possible score range is 0 to 45, with higher scores indicating higher sound hypersensitivity.

Hyperacusis Numeric Rating Scale (H scale) is an 11-point numeric rating scale which was used to allow patients to score the severity of their hyperacusis from 0 to 10 (10 being most severe).

Overall improvement in hyperacusis (OIH) was devised to be a binary result of improvement in hyperacusis symptoms after surgery based on a reduction in HQ score of 8 or greater and reduction in H scale of > 3 or greater after surgery.

Hospital Anxiety and Depression Scale (HADS) was used to screen for excessive anxiety or depression in study participants. This 14-item questionnaire is composed of two subsets of questions ("a" and "d") designed to score the severity of both anxiety and depression. The possible score range is from 0 to 21 for each subscale. A score of 11 or higher in either subscale is suggestive of the presence of a mood disorder.

2.4. Audiology testing

Pure tone thresholds at 250, 500, 1000, 2000, 3000, 4000, and 8000 Hz were first obtained. 3-tone pure tone average (PTA) (0.5 kHz, 1 kHz and 2 kHz) were then calculated. Loudness discomfort level testing proceeded starting at 60 dB HL and increased in increments of 5 dB HL. As the tone approached the uncomfortable loud level, the step size was decreased in order to determine the LDL with a 1 dB resolution. This process was performed twice at each frequency, and the average of the two LDLs is recorded for each ear separately.

2.5. Statistical analysis

For analyses, the demographic variables were expressed as means, and 95% confidence intervals. Comparison of categorical data was performed using Fischer exact, and comparing means was performed using two-tailed *t*-test. Linear and multiple logistic regression analyses were performed. All statistical calculations were performed using R Core Team (2018). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL <https://www.R-project.org/>.

3. Results

3.1. Short-term results

Overall forty-seven subjects were enrolled and underwent surgery for hyperacusis from May 2014 through April 2019. Seven subjects were excluded: four due to lack of post-operative follow-up and three who recently underwent surgery and are awaiting post-operative evaluation. Twenty subjects underwent surgery with the original technique and twenty with the new technique. Demographics and clinical information overall and grouped by surgical technique are displayed in Table 1. Nine subjects, all in the original technique group, underwent

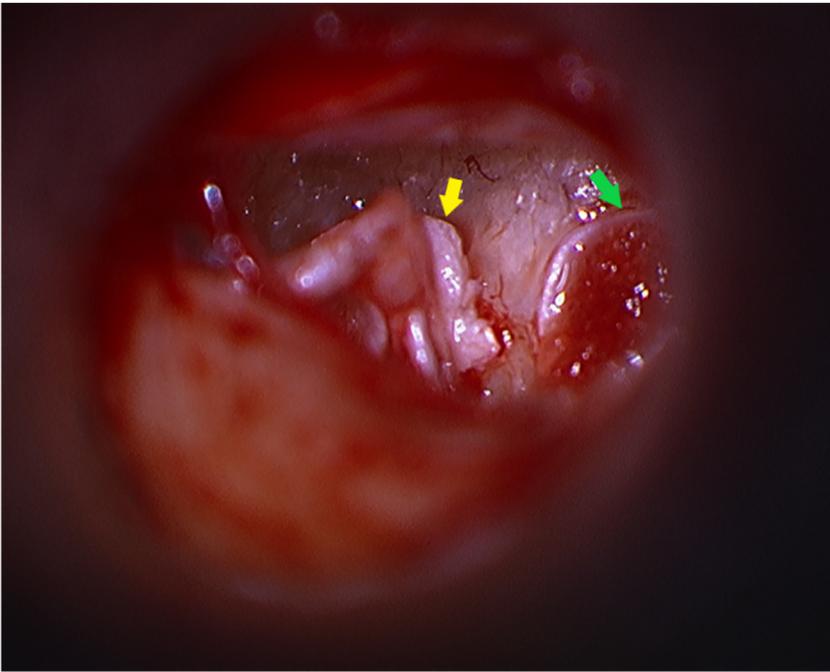


Fig. 1. Original surgical technique – Green arrow showing 4 mm diameter temporalis fascia placed over round window niche. Yellow arrow showing one 2 mm diameter temporalis fascia placed over oval window. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

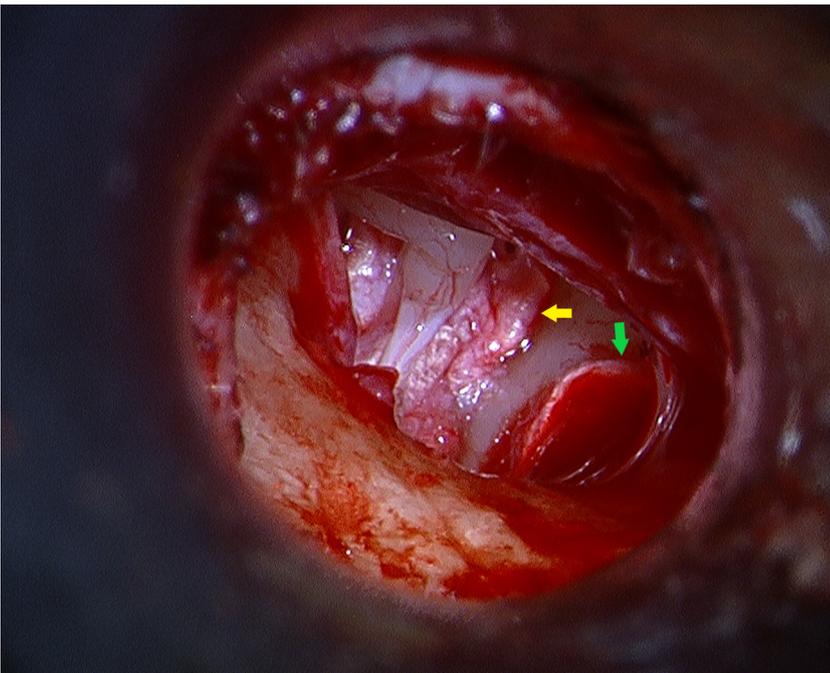


Fig. 2. Newer surgical technique – Green arrow showing 4 mm diameter temporalis fascia placed over round window niche. Yellow arrow showing 8 × 2 mm pieces of diameter temporalis fascia placed over oval window and stapes superstructure. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

bilateral surgery.

Short-term surgical results for all forty patients are displayed in [Table 2](#). When comparing to the original versus new techniques, the new technique had a higher percentage of subjects with improvement in hyperacusis symptoms (OIH) (80% in the new group, 60% in the original technique group). Statistical analysis showed no significant difference in the OIH between groups ($p = .3$). Improvements in HADS anxiety and depression scores were found in the new technique group ($p < .05$). The new technique has greater improvements in LDL, HQ score, H scale than the original group but statistical analysis did not prove significance ($p > .05$).

Multiple logistic regression analysis was performed analyzing the effects on overall improvement in hyperacusis symptoms (OIH) in all subjects combined using the following variables: age, sex, duration of

symptoms, laterality of symptoms (bilateral or unilateral), history of acoustic or head trauma, hearing loss complaints, tinnitus complaints, history of anxiety, history of depression, surgery on one or both ears, and surgical technique (original or new). Age was the only statistically significant factor with older patients having more improvement ($p = .04$).

3.2. Long-term results

Twenty subjects were included in the long-term data, seven from the original technique group and 13 from the new technique group. The other twenty excluded for lack of follow-up. Mean long-term follow-up was 41.2 months (range 32.4 to 50.0) in the original technique group, and 15.1 months (range 9.8 to 20.4) in the new technique group. [Fig. 3](#)

Table 1
Demographics.

	Overall		Original technique		New technique	
	n or mean	%	n or mean	%	n or mean	%
Patients	40		20		20	
Age (years)	61.9 [58.4,65.4]		61.6 [55.8,67.4]		62.2 [57.6,66.8]	
Sex						
Male	16		7	35	9	45
Female	24		13	65	11	55
Hyperacusis Symptoms						
Unilateral	15		4	20	11	55
Bilateral	25		16	80	9	45
Duration of Hyperacusis (years)	8.1 [5.2,11.0]		10.3 [6.0,14.6]		5.9 [1.9,9.9]	
Tinnitus						
None	7	17	5	25	2	10
Unilateral	5	12		0		0
Bilateral	28	70	15	75	18	90
Complaint of Hearing Loss	21	52	8	40	13	65
Acoustic or Head Trauma	10	25	3	15	7	35
History of Anxiety	22	55	11	55	11	55
History of Depression	12	30	7	35	5	25
Hyperacusis Surgery						
Unilateral	31	77	11	55	20	100
Bilateral	9	22	9	45	0	0

Demographics of all patients. [,] : CI 95%–95% confidence interval.

Table 2
Short-term surgical outcomes grouped by surgical techniques original versus newer technique.

All subjects (n = 40)	Preop	Postop	Postop - Preop	p
HQ Score	30.7	15.9	-14.8	0.00000001
H Scale (1–10)	9	4.7	-4.3	0.00000001
LDL	70.8	84.1	13.3	0.00006
HADS Anxiety	8.4	5.9	-2.5	0.02
HADS Depression	6.2	4.6	-1.6	0.09

Original technique (n = 20)	Preop	Postop	Postop - Preop	p
HQ Score	30.5	18.6	-11.9	0.0007
H scale	8.7	4.9	-3.8	0.00003
Pre-op LDL (dB)	73.3	82.1	8.8	0.028
HADS Anxiety	7.7	6.5	-1.2	0.51
HADS Depression	5.7	5.4	-0.3	0.82

New technique (n = 20)	Preop	Postop	Postop - Preop	p
HQ Score	31.5	12.6	18.9	0.000003
H scale	9.4	4.5	-4.9	0.00002
LDL (dB)	68.3	86.6	18.3	0.0006
HADS Anxiety	9.1	5.3	-3.8	0.008
HADS Depression	6.7	4	-2.7	0.03

Preop: Pre-operative means, Postop: Short term post-operative means, Postop - Preop - Difference in post-operative means minus pre-operative means. p: t-test p values, bolded p-values were statistically significant p < .05. HQ: Hyperacusis questionnaire scores (1–45), H: Hyperacusis grade (1–10), LDL – Loudness discomfort level (dB). HADS: Hospital anxiety and depression score.

shows mean HQ scores pre-operatively 32.0, short-term post-operatively 16.1, and long-term post-operatively 18.0. Divided by groups, the mean HQ scores in the new group were 30.2 pre-operatively, 10.8 short-term post-operatively, and 12.4 long-term. The original group

mean HQ scores were 35.3 pre-operatively, 26.0 1 short-term, and 28.6 long term. The pre-operative to post-operative improvements both short and long term were statistically significant in all patients combined and in the new technique group (all p < .01). When comparing the post-operative HQ means short-term versus long term, there were no statistically significant difference in all patients combined and divided by new and original surgical groups (p > .05). Individual subject data of all twenty patients is displayed on Fig. 4.

3.3. Audiological results

There were thirty-four patients who had pre and post-operative pure tone audiometry. The six patients who did not have post-operative audiometry were in the new technique group. Results also show statistically significant improvement in loudness discomfort levels (LDL) after surgery (70.8 dB pre-operatively and 84.1 dB after surgery). The rise in post-operative LDL was higher in the new technique compared to old technique groups (18.3 and 8.8 respectively) but were not statistically different (p = .39).

Overall the mean pre-operative air conduction PTA was 25.3 and post-operatively 31.6 (p = .19). The subject's post-operative audiological results including changes to air conduction PTA and word recognition scores are displayed on Fig. 5. In comparing the new and original technique groups, the mean increase in air conductive PTA in the new group was 6.5 dB, and 4.0 dB in the original technique group, both statistically insignificant (p > .05). There were 4 patients we found to have a rise in PTA > 10, three of in the original technique group and one from the new technique group. Word recognition testing showed a slight increase in mean score in both groups (0.1 in original, 1.5 in new) although not statistically significant. There was one patient who had a reduction in word recognition of > 10, who was in the original technique group.

3.4. Complications

One patient had a drop in air conductive PTA of 30 dB, mostly in the high frequencies after surgery without evidence of air-bone gap. This subject had no complaints of hearing loss after surgery. There were no reported complications of dizziness, tympanic membrane perforations, or post-operative infections.

4. Discussion

This project is an overview of a research study involving a minimally invasive surgical treatment for hyperacusis. In 2015, Silverstein et al. has reported patients with hyperacusis who underwent surgical treatment including oval and round window reinforcement with tissue [9]. Results show that most patients experienced improvement in sound tolerance after surgery with minimal changes to hearing [6,9,10]. In 2017, the surgical technique was modified to place additional reinforcement of tissue around the oval window and stapes. The rationale for change was initiated after a series of patients with operative findings of stapes hypermobility. This was studied in the most recent article and was proposed as a possible etiology for hyperacusis in some patients [6]. Since the newer technique has been employed, the results have shown continued success. In the authors' opinion, patients are having better outcomes compared to those who underwent the original technique.

Short term results in this study have shown 80% improvement in overall hyperacusis symptoms with the new technique versus 60% improvement with the original technique. The surgical outcome of hyperacusis improvement was measured by both the hyperacusis questionnaire (HQ) and the hyperacusis rating numeric scale (H scale), which had statistically significant improvements after surgery overall and in both new and original technique groups. In comparing the two groups, the new technique showed higher improvement in hyperacusis

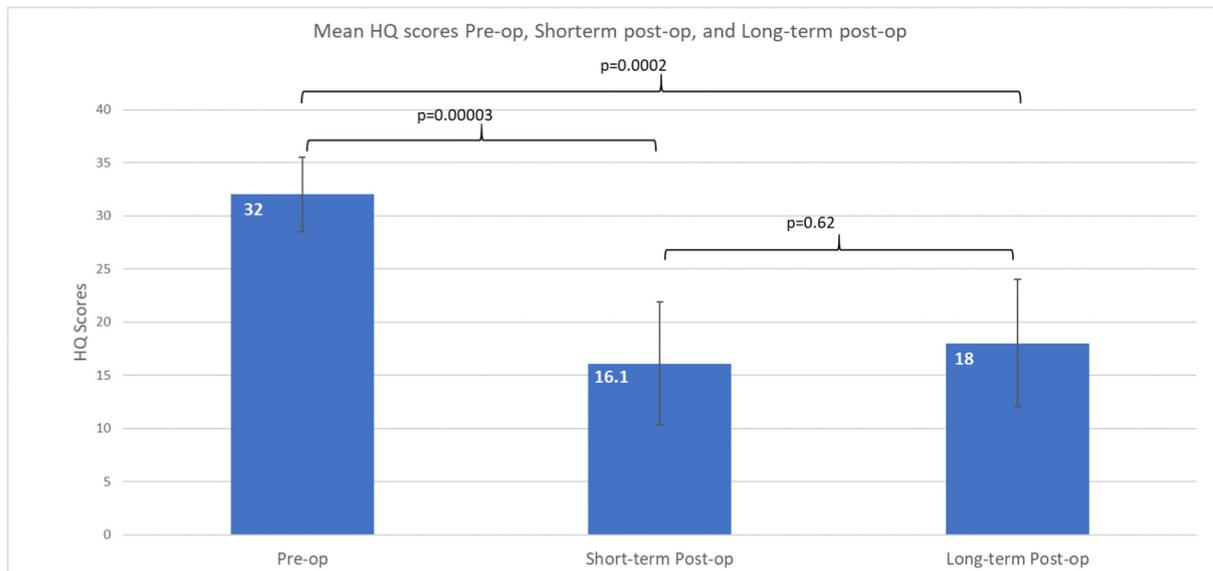


Fig. 3. Mean hyperacusis questionnaire (HQ) scores, all subjects, pre-operatively, 1 month post-operatively, and long term post-operatively. Statistical analysis by t-test displayed by p-values.

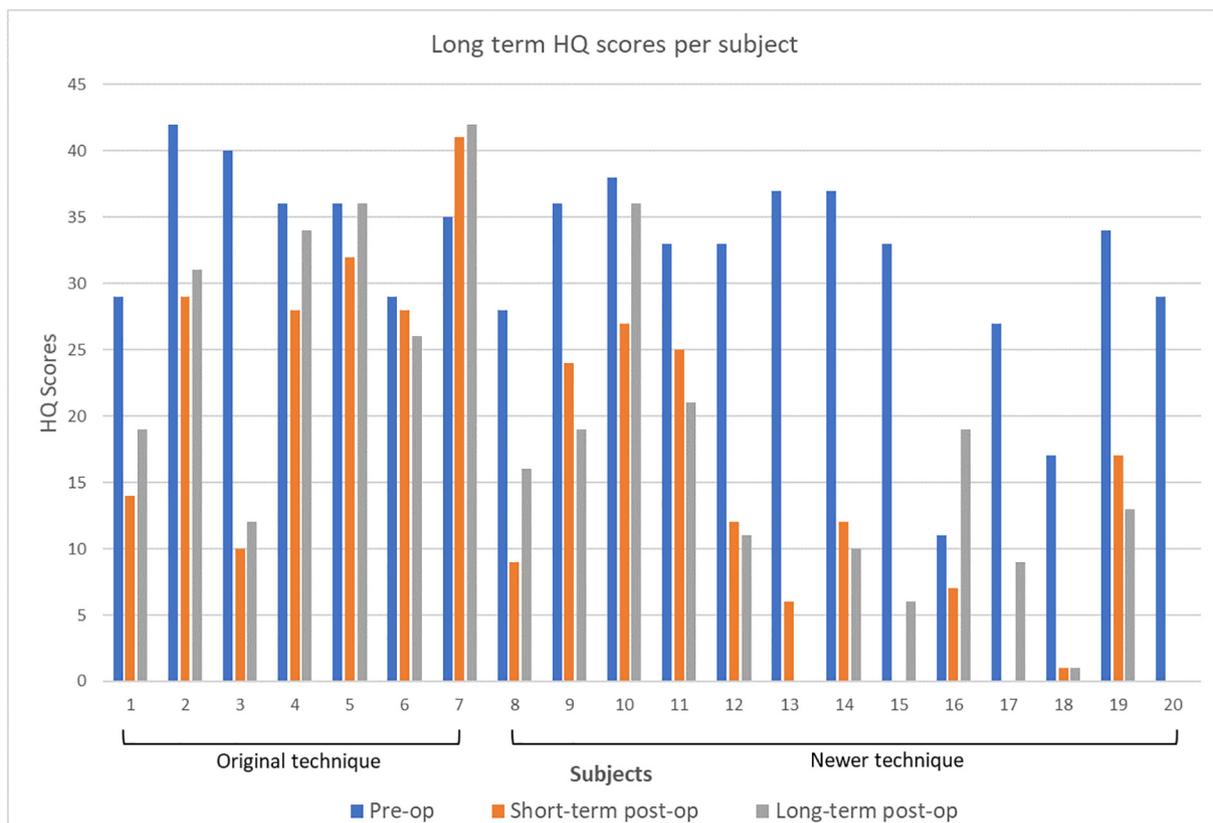


Fig. 4. Long term hyperacusis questionnaire (HQ) scores, all subjects, pre-operatively, short-term post-operatively, and long term post-operatively. Subjects displayed in chronological order. The first seven subjects in the original technique group and the last thirteen subjects in the newer technique group.

symptoms with HQ and H Scale but were not statistically significant. Long term data was able to be obtained from twenty of the forty patients presented mainly in the source of hyperacusis questionnaire scores. Results were encouraging that improvements in HQ survey post-operatively appear to be stable over time with a mean follow-up for all patients of two years. There was no statistically significant change in HQ scores from short-term to long-term scores. Although most of the patients (13/20) were from the new technique group, Fig. 4 shows that

those with improvement shortly after surgery kept improvement long term, and those who did not improve maintained similar HQ scores long term. The improvements seen post-operatively appear to be long lasting. This eliminates the effect of a temporary short-term improvement caused by post-operative changes to the tympanic membrane and/or middle ear.

When analyzing the audiological results, there was a statistically significant improvement in loudness discomfort levels (LDL) after

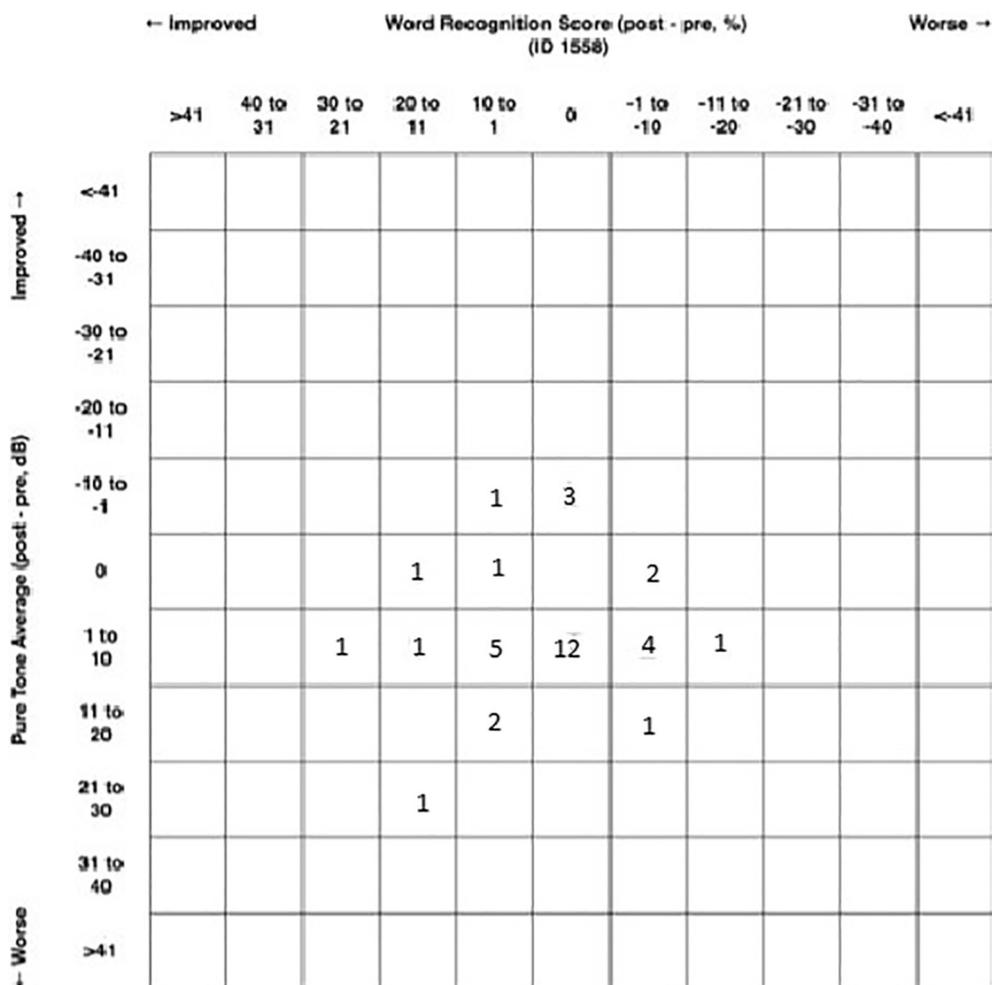


Fig. 5. Postoperative hearing outcomes in all subjects.

surgery. There was also a slight increase in PTA, although statistically insignificant, in all patients combined and in both groups. Despite the additional reinforcement of the stapes and oval window in the new technique group, there does not appear to be a statistically significant rise in PTA compared to the original surgery results.

The results of multiple regression analysis looking at factors influencing improvements in hyperacusis symptoms showed that age was a positive influence on symptomatic improvement. These results were not expected and not well understood. A history of tinnitus before surgery appeared to have a negative influence in symptomatic improvement after surgery although not statistically significant ($p = .06$). In the authors' opinion, subjects with complaints of severe tinnitus before surgery tend to not do as well in controlling symptoms of hyperacusis after surgery as those who present with main complaints of sound intolerance. Previous reports from this research study have shown no significant changes in tinnitus symptoms after surgery [6,9,10]. These findings are counseled to subjects enrolling in the study as our improvements have only been in sound tolerance. Due to these previous findings, tinnitus questionnaire data was chosen not to be included in this report.

The psychological effects of surgery were also analyzed using the HADS anxiety and depression score before and after surgery. We found that roughly 25% of our subjects were previously diagnosed with anxiety disorder and roughly 50% were previously diagnosed with depression. There was a statistically significant improvement in HADS anxiety score after surgery, mostly represented by the new technique group. These results are consistent with previous reports [6,9,10].

Anxiety and depression have been associated with subjects suffering from hyperacusis [11]. These findings support the idea that with improved sound intolerance in these subjects, there are positive psychological effects with reduction in symptoms of anxiety and depression after surgery.

4.1. Limitations

One limitation is the use the meaningful interpretation of subject HQ and H scale scores is limited using non-validated questionnaires. These questionnaires have been used since inception of the study and a newer questionnaire is now being collected [12]. Although the newer technique appears more efficacious in reduction of hyperacusis symptoms, there is not enough to prove statistical significance. The author expects this to change as more subjects undergo this surgery. Another limitation to the study is the lack of comparison to other treatment strategies for hyperacusis or a control group.

5. Conclusion

Minimally invasive surgery for the treatment of hyperacusis involving reinforcement of the oval and round windows with tissue improves sound tolerance in 80% of subjects treated with the new technique in this study. Adding additional tissue to the stapes and oval window appears to increase tolerance of sounds in these subjects more effectively without than the original round window centered approach in the original technique without major changes in hearing. Stapes

hypermobility may explain the increased improvements we are measuring after surgery with the new technique. Audiometry shows a trend to slight rise in pure tone averages after surgery and 1 patient out of 40 had a rise in PTA of > 20 after surgery. As reported in our institutions previous studies on this subject [6,9,10], the improvement after surgery is significant and now found to be sustainable with a mean follow-up of 2 years after initial surgery. This minimally invasive surgical option for hyperacusis appears to be a safe, effective, long term treatment to improve sound tolerance in most of the treated subjects.

Acknowledgments

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