

I am not sure why the words for the article's title were chosen to be, "Is Stapedectomy Ever Ethical?" I think there are better formats for this complex subject than one person's opinion that will forever be in print in this journal. Personally, I strongly believe that stapes surgery is neither ethical nor unethical, but rather it is the surgeon who is ethical or unethical. The real tragedy would be the elimination of stapes surgery without insurers covering the costs of hearing aids, because then many people would have no help for their hearing loss.

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### Never Say "Ever"

*To the Editor:* As a practicing general otolaryngologist, who refers candidates for stapedectomy to competent otologists, I wish to comment on the editorial and response to "Is Stapedectomy Ever Ethical?" from the September 1998 issue of *The American Journal of Otolaryngology*.

Mr. Matthew Howard's essay is a responsible analysis of the stapedectomy question. I agree for the most part with his statement that "stapedectomy is ethical only where the patient has both given a fully informed consent and determined to proceed with surgery after a reasonable trial of hearing aid use." However, is Mr. Howard not aware that most insurance plans do not cover the cost of hearing aids, whereas stapedectomy is fully covered? Would not an ethical situation demand that the patient have similar cost and benefit for both options? Is it ethical that only the rich can afford the low-risk option of hearing aids?

I fully agree with Dr. Shea that stapedectomy "is a great operation" "when it works". I am however very disappointed by his resistance to allowing patients to experience for themselves the immediate benefits of a simple hearing aid trial. It is highly arrogant to believe that patients, "when they consult you for advice", "have made up their minds" "and do not want to try a hearing aid." Dr. Shea admits that: "Of course, I am biased". Patients expect and depend on their physician for wisdom, not personal bias.

No, stapedectomy is *not* "always ethical", even in the "right hands".

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### Is Stapedectomy Ever Ethical?—Faulty Premise, Faulty Conclusion

*To the Editor:* In response to Dr. Howard's recent editorial entitled "Is Stapedectomy Ever Ethical" (1), we would like to offer this reply. Some Otologists have argued on our Internet discussion group that the argument put forth in this editorial is not legitimate or too ridiculous to warrant reply. Although we can certainly commiserate with their feelings, we feel compelled to respond because silence is often misconstrued as meaning agreement.

Like most arguments with faulty conclusions, the usual problem is a faulty premise. This is evidenced in

Dr. Howard's editorial. Below are a list of premises that Dr. Howard asserts to make his argument and conclusion. (The premises enumerated are not direct quotations, but rather summaries of his comments.)

*Premise #1: Hypothetical procedure A, for completely cosmetic purposes, has a mortality rate of 100% and is therefore unethical to perform.* Dr. Howard confuses medical judgment with medical ethics. Such a procedure is more of an issue of surgical stupidity than medical ethics. Although ethical considerations are definitely present, the main issue is concern for medical judgment. Dr. Howard's comments on the issue of amputation versus limb preservation afford more of an example of progression of medical science than ethical changes in thinking or behavior.

*Premise #2: Cosmetic surgery has no medical or psychosocial benefit and consequently should only be performed if it is absolutely free of any complications.* Although he does not come out and directly say this, Dr. Howard implies that cosmetic surgery is something that has no benefit and should not be performed unless there is a guarantee of no complications. People with disabilities are discriminated against on a regular basis. If a paraplegic patient could hide the fact that he was wheelchair bound, we don't doubt that he would be a more successful candidate for a job or have less trouble finding a date. This is not possible for the paraplegic, but the hearing loss patient who suffers from otosclerosis can not only hide their disability, but also completely eliminate it. Cosmetic surgery has more benefits other than pure appearance. It has the psychosocial effects of how society views the patient and how the patients view themselves as well as all the echoing repercussions from this.

*Premise #3: Stapedectomy is a cosmetic operation.* Stapedectomy does not change the appearance of the patient and it is a procedure designed solely for the functional purpose of improving hearing. Saying stapedectomy is a cosmetic procedure is like saying surgical fixation of a femur fracture is cosmetic because it allows the patient to be seen without a wheelchair or crutch.

*Premise #4: Hearing aids are an equal alternative to a successful stapedectomy.* Hearing aids are not an equivalent to a successful stapedectomy. The quality of sound produced by a hearing aid is not equivalent to normal hearing. A successful stapedectomy patient never has trouble with acoustic feedback, never runs out of batteries, never has to take a hearing aid out to take a bath, swim, or shower, and never has to take his hearing device out for any reason. A successful stapedectomy patient has much less problems with cerumen impactions, otitis externa, and word discrimination with background noise.

*Premise #5: Hearing aids are complication free.* We have never known of a patient who has lost a job because of a successful stapedectomy, but one of us (GG) witnessed a patient lose his job because of discrimination caused by his hearing impairment. If this patient had an option to restore his hearing with surgery, he would have done it in an instant. Discrimination against people with hearing impairment, even those "corrected" by hearing aids, is a real entity. In our society, like it or not, wearing

hearing aids is like wearing a sign that says "I am hearing-impaired." The uninformed public also often incorrectly interprets this to mean not just hearing impaired, but also mentally impaired.

*Premise #6: Breast implants were pulled off the market for ethical reasons.* Breast implants were taken off the market because of political reasons—not scientific or ethical reasons. In fact, breast augmentation is now sometimes done with a higher risk procedure (autologous augmentation) because the silicone implants are no longer available.

*Premise #7: Stapedectomy produces a significant rate of complications in 0% to 7% of patients.* What is a significant rate of complications? This is a subjective question that can only be answered by the patient who has been well advised by a competent physician. For some patients a significant rate of complications would be anything higher than 0%, but for other patients anything less than 10% would seem insignificant.

Dr. Howard's editorial also includes inappropriate studies regarding complication rates in stapedectomy. Including the rate of sensorineural hearing loss (SNHL) after gelfoam closure of the oval window in stapedectomy is like saying acoustic neuromas should never be removed because there was a 78% mortality rate for the procedure in 1913 (2). The technology of stapedectomy has changed over the past 40 years. We have recognized that there are some patients who should not have stapedectomy (patients with congenital inner ear deformities) because they are at high risk for developing gushers (3,4). We have also learned that covering the oval window with a tissue graft or using a small fenestra technique reduces the chance of a perilymphatic fistula and SNHL (5–7). The laser has dramatically reduced the risk of hearing loss during revision stapedectomy, with no additional risks to the inner ear (8,9). These have all contributed to much lower complication rates. It is our opinion that profound SNHL as a complication from stapes surgery should be less than 2%. Recent review of stapes surgery at our two institutions found a rate of profound sensorineural hearing loss to be 0.6% (6 in 924 procedures) for primary stapedectomy/stapedotomy and 1.9% (6 in 304 procedures) for revision stapedectomy (10). If a surgeon has a 7% rate of profound SNHL after stapedectomy, this may have been acceptable in the early 1970's, but it is not acceptable today.

Additionally Dr. Howard's reasoning regarding informed consent in his editorial is faulty. He seems to feel that because some physicians do not obtain a truly informed consent, then the entire surgical procedure of stapedectomy is unethical. We contend that physicians who do not inform their patients of reasonable risks of any surgical procedure are acting unethically. A truly informed consent will not be possible until all patients attend medical school. However, it is possible to advise patients of the most commonly encountered complications, the incidence of occurrence, and our own personal experience with the procedure. A truly informed consent is not possible, but an adequately informed consent is possible. Hearing aids should be presented as an alternative to stapedectomy and profound hearing loss should always be discussed as a possible complication of surgery. Just because some physicians

are unethical or incomplete with informed consent does not mean all or even most are.

Applying Dr. Howard's argument to other surgical or medical procedures produces some interesting situations. Because wheelchairs are "complication free," it would be unethical to perform any knee or hip surgery. Almost any surgical procedure for a nonlife-threatening condition becomes unethical, because general anesthesia has a "significant" mortality rate. Because antibiotics can cause life-threatening allergic reactions, then they should never be prescribed for anything except for life-threatening infections. We know that hearing aids result in a higher incidence of cerumen impactions and otitis externa, and these can lead to malignant otitis externa (MOE) in diabetic and AIDS patients. And because MOE has a very high mortality rate (and we can all agree that dying is worse than hearing loss), is it unethical to prescribe hearing aids to diabetic and HIV patients because there is a definable mortality rate associated with their use? What about the patients who develop diabetes and use hearing aids—should we now take away their hearing aids to save their lives?

The dogmatic nature of Dr. Howard's editorial raises the vision of postmodern paternalism. This is particularly expressed in his unilateral forcing of a patient to undergo a hearing aid trial before stapedectomy. Such an action violates the patient's right to have a significant voice in the decision-making process of his or her health care. Although Dr. Howard may feel it is unethical to offer a patient the option of stapedectomy, we feel it is unethical to withhold this option. Given treatment option "A", which has a negligible complication rate, and treatment option "B", which has a complication rate of 10%, we, as physicians, are obligated to point out the differing complication rates to the patient. But it is up to the patient to decide which option is the correct one for his or her own given situation, giving due consideration to economic realities and limitations.

In summary, we believe Dr. Howard's editorial comments make two major errors. He confuses medical decision making with ethical reasoning and he attempts to create ethical conclusions based mainly on economic considerations. Because economics and ethics are not synonymous, his activity falls short of justification. In his opening paragraph he hints at the concept of distributive justice, a noble enterprise. However, our pluralistic society has not yet concluded its struggle with health care economics in an explicit and public fashion.

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## An Audiologist Replies

*To the Editor:* I found the interchange between Drs. Howard and Shea in Vol. 19 of *The American Journal of Otolaryngology* of interest. Let me first explain "where I am coming from." I am not a physician, but an audiologist with more than 40 years of experience directing Audiology programs in Departments of Otolaryngology. Currently, I am Professor of Audiology at New York University and Chair of the New York City Department of Health Communicative Disorders Advisory Committee.

Dr. Howard's title "Is Stapedectomy Ever Ethical" comes as a surprise because this highly physiologic procedure, performed on tens of thousands of otosclerotic patients throughout the world, has clearly stood the test of time. As an Audiologist who spends a significant portion of his time teaching about (with some dispensing) hearing aids, I have always advised patients who are good surgical candidates of their options which include amplification as an alternate to surgery. With a large air-bone gap, good to excellent word recognition scores, and good cochlear reserve, I have "tilted" my recommendation in favor of surgery because if I were otosclerotic, surgery would be the direction I would elect to go. My experience with a variety of otologic surgeons at a variety of institutions and locations has been extremely satisfactory and satisfying.

Stapedectomy is hardly classifiable as cosmetic. Along with other audiosurgical procedures, it represents the "golden age" of surgical rehabilitation. No longer is surgery aimed only at control of sepsis, e.g., mastoidectomy, which I had performed on me by Kopetsky more than 65 years ago; otology has successfully conquered infectious disease and has been able to turn its attention to elective surgical correction of otosclerosis and other noninfectious disease. The "significant rate of complications" to which Howard refers from stapedectomy is not how I interpret the reported results. Certainly not 0%, but is there any surgical or nonsurgical procedure which is

totally free of complications? Patients do not consult with otologists for a procedure that is more cosmetically acceptable than hearing aids. Rather, they consult in an effort to determine what forms of treatment are available to them for treatment of their otologic disease. Hearing aids today can be fitted so that they are essentially inconspicuous or even invisible. Eighty percent of hearing aids purchased today are worn in-the-ear or in-the-canal, and the completely in-the-canal style has captured a significant part of the market. So stapes surgery is now selected for reasons other than the unacceptable cosmetic aspects of ear-worn amplification.

Failure to inform prospective patients of the possibility that they may sustain further hearing loss or even lose all hearing on the operated ear is a violation of the concept and practice of informed consent. Even if all otologists in a particular community are withholding information about this complication, at some point in time the courts will rule this gap in information is unacceptable. Statistics should be quoted based upon the complication rate of the specific otologist and the national complication rate when both agree. Howard is correct when he states that "concealment of the risk of hearing loss . . . does not make such concealment ethical."

Howard considers a requirement that patients not undergo stapedectomy "until they have failed a trial of hearing aid use" as "eminently practical." This argument confuses me entirely. Total deafness in the operated ear occurs in 1% to 2% of stapedectomized ears (1). An incidence of 1% to 3% of patients with immediate or delayed sensorineural hearing loss has been reported (2). Because the overwhelming majority of surgical candidates will do *equally well* with successful surgery as with a hearing aid(s), we would expect candidates for stapedectomy to use hearing aids successfully.

I find myself in almost complete agreement with John Shea's response to the Howard editorial. This master innovator and surgeon prepares his stapedectomy patients well from both a professional and legal point of view. However, his comparison of the difficulties with hearing aids that he has experienced with those of patients with conductive loss is incorrect. He suffers from a high frequency sensorineural hearing loss probably associated with reduced word recognition, narrowed range of comfortable loudness, problems of temporal and frequency resolution, etc., etc. He probably should try a fully digital instrument, although the ability to hear well in noisy situations is far from resolved. His problems with amplification are *very* different from those experienced by conductives whose adjustment to small (inconspicuous) hearing aids is, with few exceptions, rapid and uphill. The otosclerotic patient who is a good candidate for stapes surgery has a large air-bone gap, good to excellent word recognition scores, excellent tolerance for amplified sound, etc. In short, all of the factors which make for successful use of hearing aids.

Is stapedectomy ever unethical? Yes, from this Audiologist's point of view. It is unethical: 1. when performed on persons with significant sensorineural hearing loss; 2. when performed on those with mixed losses who will be