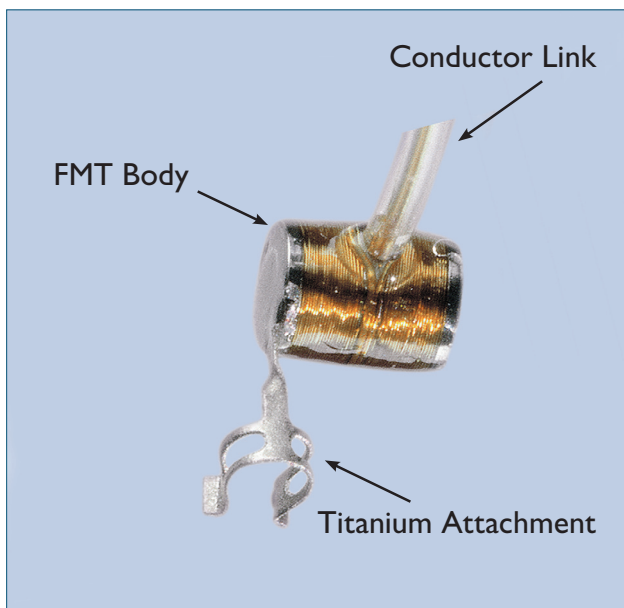


# A journey through the VIBRANT SOUNDBRIDGE®

The Vibrant Soundbridge® Middle Ear Prosthesis was developed by Geoff Ball, an engineer with hearing loss, who is now a bilateral user of the prosthesis. Ball felt that the key to the Vibrant Soundbridge (VSB) was the method accomplishing a Direct Drive solution. He developed a unique, patented solution, called the Floating Mass Transducer (FMT).



Before the FMT could be realized there were several key developments that needed to occur. The understanding of the biomechanical operation of the human ear had to be characterized. The first system that was used at Stanford was the VMS (video stroboscopic measurement system).

Although limited, the system provided data indicative of small micron amounts of volume displacement of the inner ear leading to the delivery of significant sound pressure levels in the cochlea.

Unhappy with the limited range of the VMS, Ball developed a Laser Doppler Vibrometry (LDV) system that was capable of making measurements in temporal bones down to nanometer levels and also validated the temporal bone test method by replicating the results for 100 live human ears.

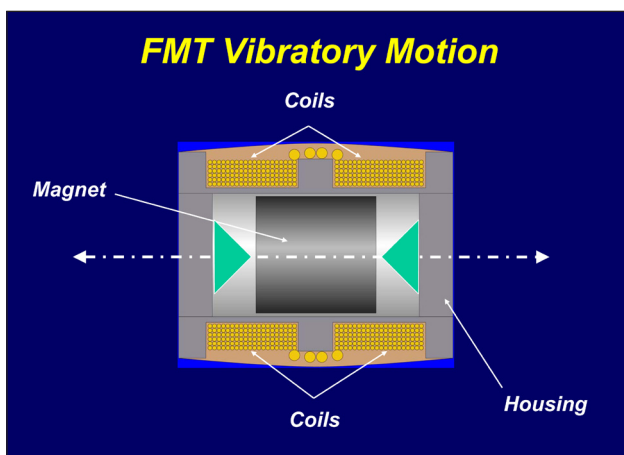
The LDV was also the perfect tool for measuring micro-transducers on the bench and in vivo. In 1990, after two years of studying all middle ear transducers in depth and reviewing the advancements in the field at the time, such as piezo-electric solutions, Ball had an important realization. All the devices conceived operated under the optimization theory of engineering, and they all applied this theory to the concept of "direct drive" in largely the same and consistent way. All the existing designs were variations of two common themes: plunger design and/or remote magnet design. These two approaches failed in either transducer efficiency, surgical feasibility, long term stability, or all three.

Ball became increasingly interested in linear programming. Linear programming teaches that a problem generally has a set of inputs and outputs that must be either maximized or minimized in order to optimize the best possible result that the constraints allow. In attempting to build a linear programming model for the middle ear implant (MEI) transducer problem, the light bulb went on.

After his time working with the VMS and LDV, Ball recognized that few people truly understood how little the middle ear actually needed to move for significant sound levels to be appreciated by the target structure, the cochlea.

“The ear moves about as much as the heartbeat of an ant”, Ball explained. “The most important concept is that a transducer only needs to move a few microns to achieve the desired effect with as little input power consumption as possible.” He discovered that only 1 milliamp of input was sufficient to result in 110 dB of sound pressure level (SPL) to the cochlea.

Ball also realized that the transducer needed to be small. He found that a small device weighing only 25 milligrams would not significantly affect the middle ear structures in terms of mass loading, as the ossicular chain and tympanic membrane (TM) already weighed well over 100 milligrams.



With these realizations, Ball discarded all the previous ideas that he had developed or that were previously published. He started with a clean slate with the goal of creating a completely new solution.

This new transducer would need to be:

- 1) sized as small as possible,
- 2) attached without bone screws and using only one attachment point,
- 3) implanted without a micropositioner,
- 4) capable of producing 1 micron of motion at 1kHz for a 50 microwatt input,
- 5) manufactured with a minimum of parts and the ability to last for years of operation,
- 6) surgically achievable by an “average” otologist in 2 hours or less,

- 7) resistant to static pressures and translocation potential and
- 8) highly likely to preserve hearing.

Persons familiar with the actual implementation of linear programming are aware that the output is often non-intuitive or perhaps even counter-intuitive. They will also recognize that the actual output from the model, at least for complicated multi-dimensional problems such as the MEI problem, is very hard to ascertain. Perhaps the greatest and undervalued aspect of linear programming as applied to complex problems is the value that comes from the actual identification of the constraints and outputs required.

In other words, the mental exercise of attempting to set up the problem appropriately forces the researcher to disassemble preconceived and/or “mistaken beliefs” and this results in a clearer understanding of the problem. Sometimes this is the best output.

The output from Ball's modeling efforts were essentially these:

- 1) piezo systems were eliminated as a solution because they failed in the area of device longevity and geometric size constraints,
- 2) transducers with component counts of more than 10 were eliminated,
- 3) “plunger” and/or “piston” systems were eliminated as these required “screws” and/or positioners and more than one attachment,
- 4) coil magnet solutions with separation distances of more than 1 mm were eliminated due to the inverse cube law and, therefore, they failed the 50 microwatt requirement. Inertial drive transducers were the only devices that satisfied the majority of the model requirements.

The only issue with inertial drive transducers was that, being small precision-made devices, they were very expensive to build and were beyond the funding capability of university funding levels.

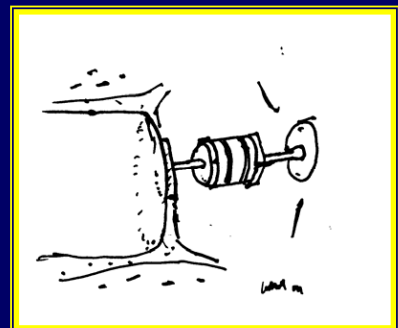
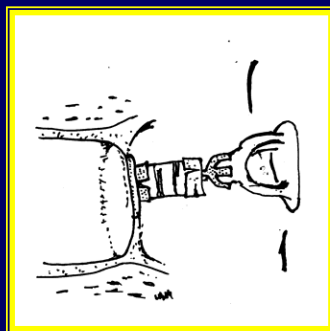
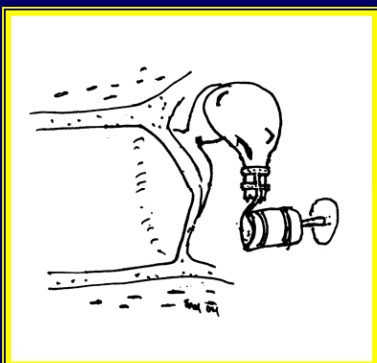
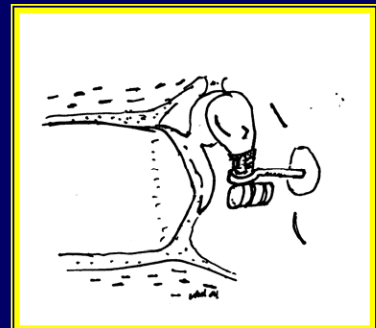
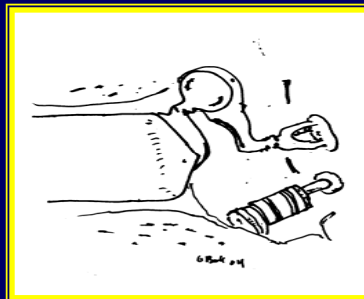
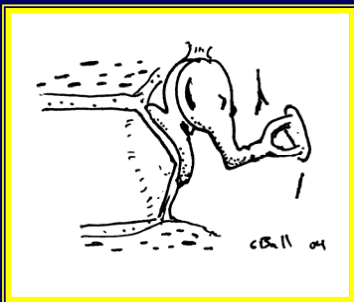
Ball filed his first patents in 1992, and since that time he has initiated 61 filings (both US and International), covering 13 areas - not all related to hearing. The majority of his methods have now been tried, and most of them have been successful. Ball has long believed that the single best place to put any direct drive system is as close to the cochlea as possible, without creation of a fistula.

He constantly thinks of new applications for the system - such as utilizing the transducer in new applications and new positions. This could afford the best opportunity for coupling to the cochlea and in theory could increase output significantly, particularly in cases where driving the mass of the ossicular chain and tympanic membrane is not feasible.

Today the current VSB is one of the most reliable active implantable medical devices. The current system has been employed in thousands of patients in over 20 countries and is the only implantable mechanical direct drive hearing system approved for use in both the US and EU as well as a host of other countries. Adoption of the device is increasing, particularly in patients with chronic ear conditions, where no other medical option, including hearing aids, is available to treat hearing loss.

New speech processors are under development and new applications of the technology are currently being investigated to attempt to treat conductive and mixed hearing losses. Formal clinical trials are ongoing to expand indications for the VSB.

### “Any inertial drive transducer in contact with any vibratory structure of an ear”



*Drawings based on US patent numbers 5,456,654; 5,554,096; 5,624,376; 5,800,336; 5,857,958; and 5,897,486. Alternative placements of the Floating Mass Transducer are not approved for commercial use and are investigational only.*



Geoffrey Ball is the CTO of VIBRANT MED-EL. He has over 26 years of medical device industry experience. He was the founder of Symphonix Devices Inc., Ehos Medical Systems and a founding team member of ReSound Corporation. He worked as a research biomedical engineer at Stanford University and the Department of Veterans Affairs. He has also worked and/or consulted for CooperSonix Medical, LaserScope, NewLase, Collagen Corporation and Attachments International. He had his undergraduate training at University of Oregon and graduate school at University of Southern California.

Mr. Ball was awarded the Engineer of the Year for Best Design in 2000, the Annuzio award in Science and Medicine in 2002 (1st runner up) and was the Sci3 Silicon Valley Entrepreneurship Award winner in 1998.



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