Microfabrication of Biocompatible Stimulation Electrode Arrays for Cochlear Implants

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Abstract—A proof of concept to microfabricate an electrode array suitable for use with cochlear implants was successfully manufactured and tested. Thirty microns of photoimageable polyimide was used as a flexible substrate. The array was inserted 20mm into an artificial cochlea filled with a saline and soap solution that simulates intracochlear fluid and hyaluronic acid (used as a lubricant), which is comparable to the performance of current manufactured products.

Index Terms—BioMEMS, Cochlear implant, flexible electronics, polytronics.

I. INTRODUCTION

The financial office of the Dartmouth-Hitchcock Medical Center lists the cost of a cochlear implant at $26,950, and the cost to the patient at twice that. Much of this expense is related to manufacturing because the electrode arrays are put together by hand. The current manufacturing method is high cost, has a low throughput, a low yield, and is difficult to scale. If an electrode array can be microfabricated, possibly using the same processes used to fabricate modern flexible electronics, the manufacturing cost could fall by orders of magnitude. Microfabrication offers financial and technical advantages. Mass production will lower the cost, increase the throughput, and increase the yield. Also, it is easier to scale using microlithography than with tweezers and a microscope. Finally, microfabrication can place additional devices on the array such as position sensors and drug-delivery microfluidic channels.

II. THEORY

A. Physiology of the Cochlea

The human ear is divided into three segments: the outer, middle, and inner ear. Figure 1 illustrates these three divisions. Sound waves are collected by the outer ear, which funnels the vibrations against the ear drum. The sound energy is then amplified by the three ear bones in the middle ear and transferred into the hearing canal of the inner ear. The hearing canal is spiraled in on itself and forms the structure known as the cochlea.

Fig. 1. The outer, middle, and inner ear. [1]
The organ of Corti is located on the basilar membrane and consists of the tectorial membrane and the inner and outer hair cells. In a functioning cochlea, the warping of the basilar membrane stimulates the hair cells in a shearing motion; Figure 4 illustrates this motion.

Fig. 4. Hair cell shearing mechanism: (a) basilar membrane at rest (b) warped basilar membrane. [4]

It is the shearing of the hair cells that causes an electric signal to be sent along the nerve fibers from the hair cells to the spiral ganglia of the cochlear neurons, all three of which are illustrated in Figure 2. The cochlear neurons then relay the signals to the brain where they are interpreted as sound.

B. Pathophysiology of Hearing Loss
Birth defects, disease, and exposure to loud noise can result in a loss of hair cells; this loss of hair cells prevents a transfer of acoustic energy into a neural impulse. A small loss can be managed with a hearing aid which amplifies soft sounds to stimulate the remaining hair cells. When the hair cells are all but gone, sensitivity to entire frequency ranges may be destroyed, and amplified noise will have no effect because the wave traveling down the basilar membrane has nothing to stimulate.

Hair cell loss is often accompanied by a loss of the nerve fibers that run between the hair cells and the spiral ganglia.

C. Hearing from Cochlear Implant Simulation
To enable the perception of sound in someone with a profound hearing loss, an electrode implanted in the scala tympani, illustrated in Figure 2, can be used to directly stimulate the remaining neural structures. Because of the loss of hair cells and neural fibers connecting the hair cells to the cochlear neurons,
electrical stimulation must be targeted at the spiral ganglia of the cochlear neurons, which are left intact. The electrode array of a cochlear implant replaces the hair cells and neural fibers; the spiral ganglia receive a signal directly from the electrode array.

Figure 5 shows the cross section of a cochlea that was inserted with a modern stimulation electrode array before being dissected. The array was implanted in the scala tympani and was designed to hug the inside wall of the cochlea, which is the location closest to the spiral ganglia.

III. PLANNED FABRICATION PROCEDURE

Microfabrication is performed on 100mm polished wafers of no specific sheet resistance. 2µm of TEOS is deposited via PECVD. 1µm of aluminum is then sputter deposited, followed by the first lithography layer and aluminum etch to form the electrode and contact pads. About 3µm of photoimageable polyimide is then spin-coated to insulate the wires from the electrode and contact pads and exposed to open vias. 2µm of aluminum is sputter deposited to fill the vias and the third lithography layer followed by an aluminum etch forms wires connecting the electrode and contact pads. After an acetone photoresist strip, about 30µm of photoimageable polyimide is spin-coated in two layers and exposed to provide the appropriate array stiffness. Finally, a pad etch is used to undercut the TEOS and lift the arrays off the wafer. Figures 6 and 7 illustrate the topology and layout.

IV. PLANNED TESTING PROCEDURE

An artificial cochlea is placed in a petri dish filled with a solution of saline and soap to simulate intracochlear fluid and hyaluronic acid (used as a lubricant). A syringe is used to fill the artificial cochlea with the solution. Tweezers are used to grip the array and insert it into the cavity of the artificial cochlea. The test setup is pictured in Figure 10.
During insertion, it is important to see if the array takes the shape of the outside wall of the cochlea. A "V" shaped bend will induce trauma in the tissue of the cochlea during insertion and indicates that the array is too stiff.

After full insertion, the tweezers are placed at the cavity opening and the array is removed. Using the position of the tweezers as a reference, the insertion depth is measured.

V. Fabrication Challenges

The first metal layer was deposited via evaporation instead of sputter deposition to serve the interest of time. The evaporated metal suffered from bulging nodules of metal that shorted out some electrode channels and disrupted following topology. The second metal layer was sputter deposited and did not add further film aberrations.

The pad etch used to undercut the TEOS also etched the aluminum. An implantable device will replace the aluminum with a biocompatible metal, and so this issue may be resolved after this requirement is met.

The photoresist used to define the wires in the third lithography layer was not easily stripped with acetone. Harsher chemistry or oxygen plasma can not be used because they will damage the underlying layer of polyimide. A photoresist that is hard baked at a lower temperature will be more responsive to acetone stripping.

After lift off, stress from metal deposition and polyimide solvent evaporation curls the array in the direction opposite what is desired for insertion. However, it is not difficult to manually reshape the electrode array.

The final thick layer of polyimide will prematurely curl off the wafer at temperatures over 100°C. If the wafer is gradually ramped up to temperatures over 100°C the problem is avoided.

VI. Data and Analysis

It was anticipated that the two metal layers might not achieve electrical contact due to either polyimide residue or metal 2 breakage over the edge of the via through the insulator. Scanning Electron Microscopy (SEM) was performed on a cleaved sample to verify the cross sectional topology. Figure 11 shows photoresist on top of metal 2, on top of polyimide 1, on top of metal 1, on top of TEOS on silicon.

The via through the polyimide has very gradual sidewall angles; this is characteristic of an aqueous developed photoimageable polyimide. There is no apparent breakage of metal 2, but because of the damage to the aluminum from the lift-off pad etch, electrical contact could not be verified.

During testing, the lifted-off electrode arrays were consistently inserted 20mm into the saline and soap-filled artificial cochlea. Figure 12 depicts one such insertion.
A 20mm insertion is close to the performance of currently available electrode arrays, which feature 22mm to 25mm insertion depths.

The array appears to bend smoothly up until the tip, where the cochlea’s radius of curvature begins to decrease. This indicates that the array is slightly too stiff. Conversely, after an insertion depth of 20mm was reached, further attempts to advance the array would cause it to buckle, which prevents deeper insertion, which indicates that the array is too flexible. Figure 13 depicts this action.

In order to achieve a deeper insertion depth while minimizing trauma to the cochlea, the array must maintain flexibility at its tip while being stiff enough to resist buckling. A design with a tiered thickness, which is possible with additional lithography steps, could provide this function.

Because polyimide is an elastic material, if sufficient depth is not achieved during insertion, the array will attempt to return to its original shape, and in doing so, will force itself out of the cochlea. A tiered thickness may also reduce this tendency by promoting a deeper insertion depth.

VII. CONCLUSION

Microfabrication is a viable cochlear implant electrode array manufacturing alternative to hand assembly. Polyimide offers structural qualities that enable an insertion depth near what current technology offers.

An additional lithography layer would allow for a tapered design that is more flexible toward the apical curve of the cochlea and stiffer toward the base of the cochlea; this tiered thickness may grant buckle resistance during insertion and increased flexibility in smaller radius curves, all of which increases insertion depth and reduces trauma to the patient.

Along with deposition and patterning of a biocompatible metal, extension of this work may cover use of additional materials such as photoimageable silicone and a parylene coating.

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REFERENCES


BIOGRAPHY
Ward A. Johnson was born and raised in Hanover, New Hampshire, in the United States of America. Ward expects to receive a Bachelor of Science degree in Microelectronic Engineering from the Rochester Institute of Technology, Rochester, NY, in May 2006. In the Fall of 2006 Ward hopes to pursue a Master of Science in Microelectronic Engineering from the Rochester Institute of Technology and continue applying microfabrication techniques to biomedical devices.

He has worked in a co-op capacity for Eastman Kodak Company in Rochester, New York, as a plasma process engineer, Med-El Corporation in Innsbruck, Austria, as a research and development engineer, and Advanced MicroSensors in Shrewsbury, Massachusetts, as a photolithography engineer.