Softer, thinner and more compliant implants*

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***Abstract*— Tissue irritation is caused by two main reasons – chemical and mechanical. In recent years, material chemical biocompatibility has been much improved but most implants used in soft tissue still have low compliance. This is especially severe in the brain, where the tissue often has a compliance of a soft hydrogel and ordinary silicone materials like PDMS have an elastic modulus up to 1,000 times higher, *i.e.* like a wooden stick irritating your skin. Starting from the remaining challenges of the highly successful Cochlear Implants and recent work on stretchable electronics this review conclude on the merits with soft stretchable printed circuitboards, with components of fluids, gels, and sprinkled with a smart dust of small chips.**

I. Introduction

Incapacitating hearing loss severely affects human communication, psychosocial welfare and quality of life. In 2015, it was calculated that approximately half a billion people had disabling hearing loss, which is 7% of the world's population [1]. According to WHO, it includes 7.5 million children less than 5 years of age. Hearing loss is the 4th leading cause of years lived with disability in the Global Burden of Disease Study, higher than chronic diseases such as diabetes, dementia, and chronic obstructive pulmonary disease [1]. With an ageing population and increased noise pollution, the problem is increasing fast.

With the introduction of cochlear implants (CIs) ear surgery reached the age of the inner ear [2]. CI has revolutionized hearing aid technology with new possibilities to restore hearing in patients with severe/profound sensorineural hearing loss; both in children and adults. CI is the most successful neural prosthesis developed until date, in terms of restoration of function. Essential are inner ear atraumaticity and hearing preservation. The complex fine structure of the cochlea and especially its long, winding and narrow scala tympani, with its fragile basilar membrane and thin soft tissue (10 – 100 µm), demands more delicate implants to limit trauma. Hence, CIs need to be soft and flexible, and all clinical implants are made in silicone. However, their electrodes are stiff, they fill up much of the tract and they are not as softy and flexible that they could be, having a truncated conical geometry, Figure 1.

There is a need for forwarding the understanding and application know-how of the stress transfer between small and soft devices and systems and tissue. Recent years it has

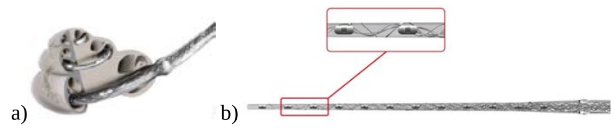

Figure 1. a) Illustration on an electrode array of a cochlear implant inserted into the scala tympani tract. b) A three centimeter long electrode array, conical with 0.5 mm truncated end. (from MED-EL)

become apparent that mechanics drives many biological processes and hence, tuning device rheology and load-deformation relations are crucial to the function or failure. This holds especially true for implants that are interacting with soft tissue.

An implant interacts with the extra cellular matrix, *i.e.* not with the cells directly, in the soft tissue. There are in principle three means to affect the stress distribution around an implant. These are (i) biological/chemical adhesion of tissue to implant; (ii) mechanical adhesion via surface topography and compliance; and (iii) elastic modulus of implant.

Our vision is that softer, thinner and more compliant CI electrode arrays made by microfluidic stretchable printed circuit board (PCB) technology will reduce irritation and improve remaining hearing at the same time as they provide better stimulation of the cochlear nerve. Automated PCB technology would also reduce the handicraft, which should reduce costs as well as variability.

Ultra-thin silicone based smart implants have recently created excitement in medical technology. In much, their promise comes from being unobtrusive in similar manner as contact lenses are compared to eyeglasses. Also, they have intrinsic advantages in their compliancy and direct contact to the organ. Recent work on implanted soft neuroprobes show good promise. [3] Still, most soft microsystems are too stiff, with elastic moduli in the order of 1 MPa. For example, the average modulus brain tissue is in the order of 1,000 times lower, *i.e.* around 1 kPa, Figure 2, [4]. Damage or irritation will create trauma and hearing loss. For the CI of today, the largest mismatch is between the Pt electrodes and the soft tissue of the lateral wall. The complex system in the cochlea that the CI interacts with involves the lateral wall soft tissue where the endocohlear potential (essential for hair cell function) is generated, the basilar membrane and the medial wall. A softer and more miniaturized electrode array may improve the future functional outcome.

The interest of compliant intelligence was initiated from

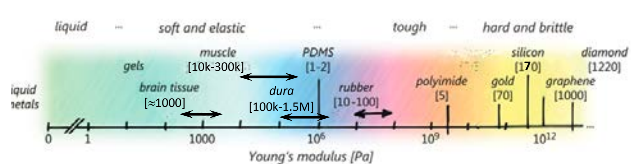

Figure 2. Stiffness of engineering materials and tissue.

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the pioneering work of Rogers *et al.* at Univ. Illinois, Urban Campaign, with advanced integrated circuits (ICs) on elastomers, based on transfer printing of integrated thin-film and silicon-on-insulator (SOI) circuits. [5] Their disruptive technology was demonstrated with, *e.g.*, epidermal electronic tattoos, intelligent dilatation balloons, and compliant neurological electrodes for epileptic seizures. [6] However, just like in rigid electronics, at lower series or larger area electronics printed circuit boards are often preferred with their modular construction, larger cross-sections and lower costs per area. Unfortunately, although meandering metallic circuits can provide elastic behavior at stretching, they are either very thin (and electrically resistive) or less compliant. Also, at repeated large strains they are prone to contact failure with integrated rigid or flexible modules.

As an alternative, our group initiated the use of liquid alloys for stretchable RF-electronics [7]. Our objective was to provide large cross-sections with high compliancy for low resistance also in larger areas and components needed in high quality RF-circuits. In addition, the liquid alloy provided a sliding contact to embedded rigid modules and with that the contact became robust against large strains. More recently, we have introduced a very compliant and adhesive PDMS elastomer (named S3-PDMS for soft, stretchable and sticky PDMS), which not only allowed for better contact to the skin but also increased the adhesion between the embedded modules and the elastomer [8]. Together, these features allow for hybrid integration of small rigid chips from ordinary IC and optoelectronic production, as sprinkled smart dust in the elastomer. Like other PCB technologies, our technology is built on batch-wise production with modular integration of components and good prospects for medium-sized series. Our self-alignment technique by wetting control patterns [9] has good potential to ease high throughput pick'n place surface mounting technology on slightly skewed or stretched soft and stretchable carriers.

To forward the microfluidic stretchable electronics, more use of liquids and gels are needed. Not only liquid alloys but any fluid-based component shows an ultimate compliance. Today, a great number of passive components have been made by combining elastomers and fluids, *e.g.*, neural and ECG electrodes; bio-mechanical measurands; pumps, valves and mixers; as well as batteries and energy harvesters [10]. In addition, insulating silicone gels and conductive hydrogels provide miniaturized systems with very high compliance, *e.g.*, for electronic skin [11]. Hence, most larger components and interconnects should be possible to make by fluids and soft elastomeric materials.

Apart from the obvious impact on CI, the research has significance to the research on neuroprobes and the development of seamless, bidirectional interfaces between humans and machines [12]. Neural probes, and especially auditory brainstem implants [13], should be improved with softer and more compliant arrays.

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