Biocompatible MEMS Fabrication Method for In Vivo Force Measurement Within Implanted Joints

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INTRODUCTION:
Microelectromechanical systems (MEMS) offer the possibility of miniaturizing many types of biosensors for in vivo use. Two scenarios are available for in vivo operation of MEMS devices: 1.) use of standard MEMS techniques and implementation of a hermetic seal for biological use or 2.) utilization of biocompatible materials for design fabrication. For orthopaedic applications, MEMS can provide high force resolution and high spatial resolution to map contact areas and forces across joints in vivo.

A few researchers have turned to the second option of direct fabrication from biocompatible materials. In cases where mechanical loading may cause surface wear, such as arthroplasty, surface materials must also show sufficient fatigue strength to determine that undue wear does not occur. The coefficient of friction is a factor in wear consideration, and all layers must be biocompatible so that any wear debris that may be released is not additionally irritating to the body. In addition, many traditional MEMS materials such as silicon are brittle and unsuitable to undergo loading in the body and could thus cause stress shielding or stress concentrations. This could lead to inaccurate measurements and premature failure.

Strain gauges have been used in implants for in vivo load measurement, but are always completely contained within a metal component implant. By fabricating microsensors on implant-grade ultra-high molecular weight polyethylene (UHMWPE) and using bio-friendly gold and titanium for decoration of sensor electrodes, the sensors are bioinert. They can be embedded within bulk polyethylene in a total joint replacement for in vivo measurement of weight-bearing loads with wireless transmission. The direct measurement within polyethylene also allows calculation of stress concentrations on the articulating surface which may be correlated to implant wear. However, UHMWPE has a very low surface energy, which endows it with low friction but also makes it difficult to incorporate in electrical devices, since metal will not adhere to the bare polyethylene surface.

This paper focuses on the fabrication process of MEMS sensor arrays out of all-biocompatible materials, using standard semiconductor processing equipment available in most cleanroom fabrication facilities. This method is presented with the recognition that the fabrication processes here may be applied to other types of bioMEMS devices where low-surface energy biomaterials are present.

METHODS:
A capacitive sensing cell comprised of six sensors per cell is designed to measure axial, shear, and in-plane forces when embedded within polyethylene within a total joint replacement. The change in capacitance due to strain when the material undergoes load is measured and output to calculate stress within the material.

UHMWPE film (extruded) and compression molded UHMWPE disks were used as a substrate, and all processing was performed in a cleanroom environment. Few film and twenty disk samples were used, which includes 10 samples of 1040 Substrates underwent an initial rinse with acetone, followed by methyl alcohol, and a final ethyl alcohol rinse. Following the primary cleaning, substrates were exposed to oxygen plasma, nitrogen plasma, or both for 30 seconds at 100W power. After plasma treatment, substrates were examined via light microscopy, atomic force microscopy, and contact angle measurement (deionized water) to examine the effects of the plasma treatment.

The UHMWPE samples were then mounted on silicon wafers for handling purposes and electrodes were patterned on the surface using modified photolithography techniques. Increased bake times were necessary for proper photolithic curing, and patterns were then metallized via electron-beam evaporation with approximately 300 nm gold with a titanium seed layer with subsequent liftoff. A parylene layer was deposited via room-temperature vacuum vapor deposition was used as a dielectric between electrode layers. Reactive ion etching was used to pattern vias in the parylene layer when necessary to allow access to bottom electrodes.

RESULTS:
Prior to activation of the surface, no material remained on the polyethylene samples following metal deposition and lift-off. The oxygen/nitrogen combination treatment showed the best results, yielding an increase in the energy of the polyethylene surface. A critical dimension of 2 micrometers was achieved using this process. The chemical changes and nanoroughening of the polyethylene surface is supported by the decreased contact angles (higher wettability) for the oxygen/nitrogen treatment group, which demonstrates an increase in surface energy. Microscopy of the treated samples also shows mechanical roughening, which may help lock the thin metal coatings onto the polyethylene surface.

DISCUSSION:
Plasma treatment of the UHMWPE surface sufficiently improved its adhesion characteristics to allow the direct fabrication of MEMS devices on the polyethylene surface. The surface of the polymer is activated when some of the polymer chains are broken or some of the hydrogen atoms are lost from the polymer backbone. These sites are locations where oxygen atoms and nitrogen atoms and hydroxyl, amine, and other groups may attach to functionalize the surface. The presence of more polarized atoms on the surface increases the surface energy and greatly improves adhesion of deposited materials during lithography steps.

With successful fabrication on the polyethylene surface, the sensors will next undergo mechanical testing and embedding in bulk polyethylene orthopaedic components. The effects of additional compression molding (e.g. placing the sensors in the mold with the powder) and the heat of steam sterilization have yet to be investigated.

We are currently developing application-specific integrated circuits (ASICs) to measure the small changes in capacitance produced by these sensors. It is promising that even the readout circuitry could be printed using these fabrication techniques. This diminishes the impact of the sensors and circuits on the implant performance, and can give real-time, patient-specific information on postoperative loading and wear.

CONCLUSION:
Biosensors for orthopaedic implants are evolving to allow an enhanced view of the complex loading of total joint replacements, and can be made out of biomaterials without significant modification to the implant itself. A novel fabrication method has been designed to enable processing of biocompatible substrates with semiconductor cleanroom equipment. A sensor array has been designed that will allow for the full characterization of stress and strain in three dimensions in a force map and the sensors have been fabricated using fully-biocompatible materials. These smart sensing systems can give researchers a better understanding of the kinetics and kinematics of orthopaedic implants and enhance their performance both globally in design and individually through patient-specific in vivo evaluation.