Research Program - Clinical BioMEMS

- MEMS (microelectromechanical systems) for medicine
  - clinician/patient tools
  - “system-on-chip”

- Focus on high impact, unmet clinical needs
  - implantable devices
  - systems integration

- Collaboration and interdisciplinary project teams
  - engineering, clinical, scientific resources
  - QB3, UC-Berkeley, Stanford
  - VC community and medical/biotech industry
What is MEMS?

- **Generic terms**
  - microsystems
  - *micro electromechanical systems (MEMS)*
  - micromachines
- **Size scale**
  - 1 micron = 1/1000 meter
    - hair ~50 micron
    - red blood cell ~10 micron
- **Origins in silicon microelectronics industry**
  - miniature
  - intelligent
  - low cost

Silicon Microfabrication

Leverage the extensive manufacturing infrastructure of the semiconductor industry (Intel, etc.)
**Biomedical MEMS (BioMEMS)**

- Extend MEMS technology to biomedical applications
  - co-locate sense, compute, actuate, control, communicate, power
  - miniaturization, multiplicity, and microelectronics – “3M’s”
- Transitioned beyond silicon technology
  - polymer, glass
  - fluidics, mechanics, optical
- Primary areas of application
  - life sciences research
    - drug discovery and screening
  - clinical tools
    - diagnostic instruments
    - therapeutic aids

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**Organ/Tissue Replacement**

- **Implantable Artificial Kidney**
- **Microtextured Bone Graft**

- **Silicon Nanopore Membrane**
- **3D Multilayer Scaffold**
**In Vivo Diagnostics Tools**

- Coronary Ultrasound Imaging
- Biomechanical Load Monitor

- Wireless Pressure Sensor
- Focused PVDF Transducer

**Targeted Drug Therapy**

- Anti-Restenotic Agent Delivery

- Coronary Artery
- Silicon Microneedles
- Protective Sheath
- Flow Tool
Research Projects

• Wireless pressure microsensors for spine fusion monitoring
  – enabling *in vivo* biomechanics

• Nanoporous membranes for renal replacement therapy
  – development of an implantable bioartificial kidney

• High resolution ultrasonic microtransducers for vulnerable plaque detection
  – towards real-time intravascular ultrasound (IVUS) imaging

Spine Fusion Monitoring System

- Spinal Instrumentation
- Electronics Module
- Strain Gauge
- Antenna
- Pressure Sensor
Challenge in Spine Fusion

Intact

Failure

Working Hypothesis

- eliminate unnecessary revision surgeries
- applicable to other musculoskeletal applications
Wireless Telemetry Principle

LC Tank Circuit Implementation

Pressure Measurement

MEMS Pressure Sensor

Schematic Cross-section

SEM Image
Key Issues

- Significance of pressure measurement
- Safety of MEMS materials
- Performance of telemetry

Pressure Matters!

**Disc**

**Fracture**

Nuclear Load and Pressure in Instrumented Fracture

Loosening and tightening of screws
Pressure Matters! – *In Vivo*

Caprine Investigation

![Graph showing pressure variations](image)

**Pressure Variations: Vertebral Endplate – Bone Graft Interface**

Biocompatibility Assessment

- ISO 10993 Guidelines
  - cytotoxicity
  - acute and chronic irritation
  - hemolysis
  - osmotic fragility
  - coagulation

- Kotzar et al. (Biomaterials, 2002) - *Evaluation of MEMS materials of construction for implantable medical devices*

- Ferrara et al. (Biomedical Microdevices, 2003) – *An in vivo biocompatibility assessment of MEMS materials for spinal fusion monitoring*

- Roy and Fleischman (Sensors and Materials, 2003) – *Cytotoxicity evaluation of microsystems materials using human cells*
Biocompatibility Assessment – 6 Months

Fusion site

Chip location

Caprine Model

Prototype RF Probe (Antenna)

Probe

Sensor

Electrical Circuit

Performance
Commercialization Opportunities

• IDP (intradiscal pressure) monitoring
  – assessment of degenerative disc disease
  – therapy selection for back pain patients

• IOP (intraocular pressure) monitoring
  – risk assessment for glaucoma
  – monitoring of drug adherence

Contact Lens Implementation

Wireless Measurement
# Why MEMS for Medicine Now?

- **Technology ready**
  - fabrication processes and infrastructure
  - wireless implementation

- **Clinical experience**
  - cardiovascular
  - orthopedics and spine
  - cancer

- **Business outlook**
  - aging population
  - healthcare reform