Massachusetts Institute of Technology
Harvard Medical School
Brigham and Women's Hospital
VA Boston Healthcare System

2.782J/3.961J/BEH.451J/HST524J

DESIGN OF MEDICAL DEVICES/IMPLANTS
Overview

M. Spector, Ph.D.

2.782 Design of Medical Devices/Implants

- Design of a novel implantable device that has a reasonable expectation of working:
  - not an incremental improvement in an existing device
  - no need fabricate the device
  - document should be sufficient for a patent disclosure
- Not to use a thesis topic or a project on which you are already working
- Not a class in writing a "business plan"

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- Description/diagram of the device
  - Dimensions
  - Materials of fabrication
  - A working model is not necessary, but may be possible
  - Computer simulation is not necessary, but may be possible
- Description of how the device is to function
- Diagram of the device in its site of implantation
  - Description of how the implant is to be fixed to the host tissue/organ
  - Instrumentation for implantation (if an essential feature of the device)

2.782 Design of Medical Devices/Implants

Patent Options

- Students are free to pursue a patent on their own (at their own expense)
- Can approach the Patent Office at MIT to determine if the Institute has an interest in obtaining a patent
  - 1/3 to inventor(s)
  - 1/3 to inventors' department
  - 1/3 to Institute

United States Patent **6,034,296**
***Elvin*, et al.** **March 7, 2000**

Implantable bone strain telemetry sensing system and method

Abstract

An implantable self-powered sensing system for a bone fixation device, which includes a self-powered strain sensor mountable on or in a bone fixation device, is disclosed. The sensor is capable of measuring strain in the bone fixation device by generating a strain signal in response to stresses produced thereupon. The system also includes a telemetry unit powered by the generated strain signal and in communication with the sensor. The telemetry unit is activated by the sensor when the strain signal reaches a predetermined value and then transmits the strain signal from the sensor to an external receiver. The sensing system can also include a buffer unit in communication with the sensor and the telemetry unit for collecting and storing the strain signals for transmission by the telemetry unit as a cumulative strain measurement. The method of monitoring healing in a bone and measuring strain in a bone fixation device using the sensing system of the present invention includes the steps of subjecting a patient to a predetermined set of dynamic exercises which vary stresses exerted on the bone fixation device and tests the integrity of the bone fixation device and then measuring the strain resulting from the stresses imposed upon the bone fixation device via the implanted self-powered sensor attached to the bone fixation device, which generates a charge in response to the stresses imposed on the bone fixation device, which then powers the implanted telemetry unit in order to transmit the charge generated by the sensor unit to an external receiver as a corresponding strain measurement signal.

Inventors: **Elvin; Niell** (1110 W. Gate Apartments 550 Memorial Dr., Cambridge, MA 02139); **Elvin; Alex** (1110 W. Gate Apartments 550 Memorial Dr., Cambridge, MA 02139); **Spector; Myron** (921 Seaver St., Brookline, MA 02146)

Appl. No.: **984957**
Filed: **December 4, 1997**

United States Patent **6,699,283**
***Mazzucco*, et al.** **March 2, 2004**

Heart valve with rectangular orifice

Abstract

A mechanical heart valve prosthesis has a generally rectangular orifice and two leaflets that move between a closed position nearly perpendicular to blood flow and an open position nearly parallel to blood flow. Due to the uniform dimension of a rectangle, the leaflets are hinged at the periphery of the orifice, and present a single large central flow region to the blood when opened. The base provides several means of constraining the leaflet rotation during opening and closing.

Inventors: **Mazzucco; Daniel Clarke** (90 Windsor Rd., Medford, MA 02155); **Hartemink; Christopher Allan** (479 Commonwealth Ave., Boston, MA 02215); **Newburg; Seth Owen** (15 Harrington St., Newton, MA 02460-1525)

Appl. No.: **132440**
Filed: **April 25, 2002**

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Exercise in Engineering Design

- Engineering
- Science
- Technology

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Exercise in Engineering Design

- Engineering
  - Making a product for the human good using existing knowledge
- Science
  - Process of acquiring new knowledge
- Technology
  - Means of producing the product

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Approach toward the Design

- Discuss possible design topics in class
  - Personal medical experiences
  - Information from the media
  - Intuit/brainstorm
- Students join to form design teams (3-4/team)
- Consultations with Professors Yannas and Spector
- Consultations with clinicians

2.782 Design of Medical Devices/Implants

- Oral presentations
  - PowerPoint
- Reports
  - Microsoft Word documents

Permanent Replacement Devices/Prostheses

Absorbable Scaffolds for Tissue Engineering/Regeneration

Figures removed due to copyright restrictions.

Permanent Replacement versus Regeneration

Fixation plate and screws

Total hip replacement prosthesis

Biomaterials as Medical Devices

Anorganic trabecular bone as a bone graft substitute material

Multicomponent Medical Devices

Figures removed due to copyright restrictions.

Total knee replacement prosthesis

Collagen-GAG Scaffold

Collagen-GAG Regeneration Templates

Figures removed due to copyright restrictions.

See Swerdlow, Joel L. "Unmasking Skin." *National Geographic* (November 2002).

WAITING LIST FOR ORGANS
Sci. Registry of Transplant Recipients

	No. on waiting list as of 6/30/01	No. who died on list 7/1/00-6/30/01
Kidney	49,860	2,837
Liver	18,089	1,799
Pancreas	976	23
Kidney-Pancreas	2,587	220
Heart	4,200	608
Lung	3,798	497
Heart-Lung	222	35
Intestine	170	24
All	79,902	6,043

NY Times, 3/10/02

www.ustransplant.org

ERAS OF (ORTHOPEDIC) SURGERY

1920-1970	Age of Devices
1970-	Age of Biomaterials
2000-	Age of Tissue Engineering
2010 -	Age of Gene Therapy (?)

ERAS OF (ORTHOPEDIC) SURGERY

1920-1970 Age of Devices
- -Fracture fixation
- -Joint replacement
- -Spine instrumentation

1970- Age of Biomaterials
- -Hydroxyapatite coatings for TJA
- -Bone graft substitute materials

ERAS OF (ORTHOPEDIC) SURGERY

2000- **Age of Tissue Engineering**

-Porous absorbable materials to be seeded with cells or implanted alone to be infiltrated with cells *in vivo*

2010 - **Age of Gene Therapy (?)**

-Materials as delivery systems for genes

Medical Device Failures

Articles removed due to copyright restrictions.

Lehr, Dick. "$4.75b Accord Eyed on Breast Implants." *The Boston Globe*, September 10, 1993.

Reisch, Marc. "Jaw impant suit targets Du Pont, Dow Corning." *C&EN*, May 1993.

Newsweek, April 29, 1991

"Small Particle Disease"
Particles Released From Implants

Figures removed due to copyright restrictions.

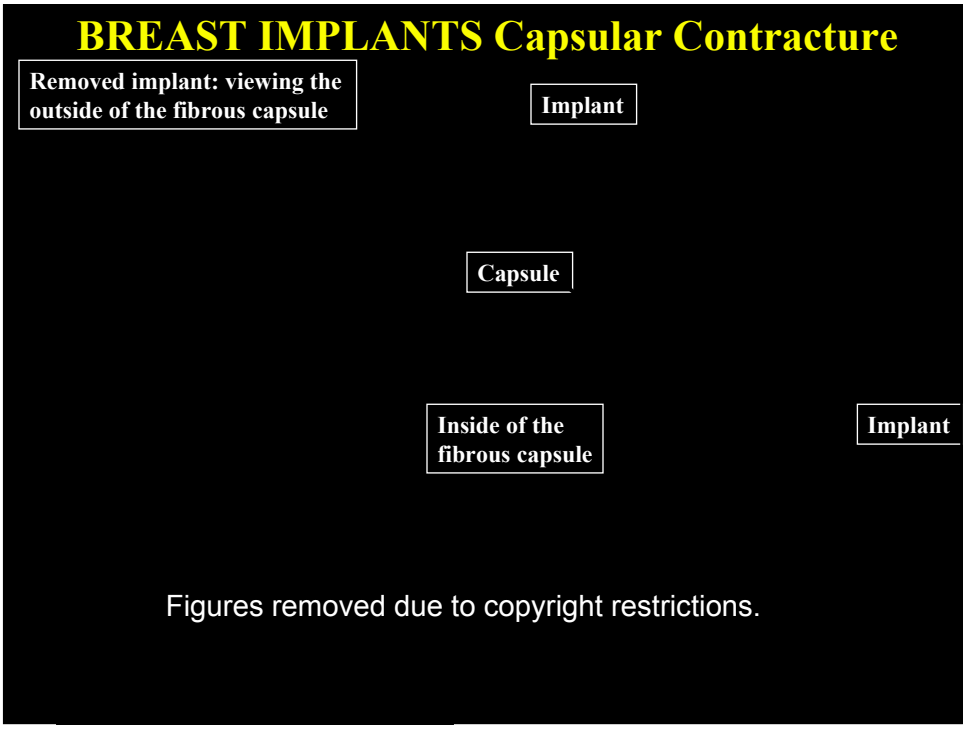
Sci. 295:1994 (2002)

BREAST IMPLANTS
Capsular Contracture

Figures removed due to copyright restrictions.

Photograph shows Grade IV capsular contracture in the right breast of a 29-year-old woman seven years after subglandular (on top of the muscle and under the breast glands) placement of 560cc silicone gel-filled breast implants.

BREAST IMPLANTS Capsular Contracture



Figures removed due to copyright restrictions.

PRIOR YEARS

Examples of Student Projects:

Implantable arterial bloodflow sensor for post-bypass surgery
Nanoparticle-enabled cochlear implant
Scaffolds for repairing heart tissue and synovium
TMJ treatment implant
Small-diameter vascular grafts
Esophageal cancer implant
Stimulator for treating sleep apnea
Implantable lens
Adjustable hip implant to correct leg length discrepancy
Regenerating damaged Fallopian tubes