Medical Device Development and Entrepreneurship

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Introduction

• Overview
• Medical Device Development
• Device Startups
• Consulting
Some Device Fields...

- Cardiovascular
- Orthopaedic
- Sleep disturbances
- Vascular closure
- Cosmetic
- Etc.
AAA Devices
Abdominal Aortic Aneurysm
AAA Device
Coronary Artery Disease

- Stents are used as scaffolds to hold open the artery
Finite Element Analysis (FEA)

- Design
- Life prediction
- FDA requirements
- Can shorten the design cycle
FEA & Testing

• Finite element analysis (FEA) and physical testing are complementary
• A comprehensive program needs to include both components
• With judicious experimental validation, FEA can be used to reduce the amount of physical testing that is needed and shorten the design cycle
The Challenge for Medical Device Development

• Reduce development time
• Increase confidence of success
• Avoid surprises and delays
Prototype Development

• Physical prototype
  • Cost and lead time is often a limitation
  • Essential for animal testing and determining needed characteristics
  • Want to reduce the number of design iterations that are prototyped

• Virtual prototype
  • Assess more design options
  • Compare alternatives
Testing Is Essential for:

- Detailed characterization of the material; Getting data needed for the analysis
- Fatigue testing taking into account surface finish, processing steps
- Validation
Nitinol Stent FEA
Stent FEA
Stent FEA

• Rolldown

Expansion
Stent FEA

- Rolldown
  - time = 4.1000E+00
  - fringes of eff. stress (v-m)
  - min=4.667E+02 in element 3802
  - max=5.873E+04 in element 6747
  - ref. surface values for shells

- Expansion
  - time = 6.0500E+00
  - fringes of eff. stress (v-m)
  - min=1.205E+03 in element 13087
  - max=1.059E+05 in element 14091
  - ref. surface values for shells
Creative Strategies in Medical Devices
510(K) vs PMA?

• 510(K)
  ▪ Concept of equivalence
  ▪ May 28, 1976 Medical Devices Amendments to the FDA
  ▪ Pro’s
    • Speed
    • Lower risk
  ▪ Con’s
    • Low barriers to entry
    • 510(K) with clinical trials

• PMA – Pre Market Approval
  ▪ Clinical trials for safety and efficacy of device
  ▪ Pro’s – barriers to entry
  ▪ Con’s – time, expense and risk
Medical Device Development

- Needs Assessment
- Research
- Intellectual property
- Biomedical ethics
- Brainstorming
- Assessing Clinical and Market Potential
- Developing patent strategies
- Prototyping
Value of Execution

- Ref: Rich Ferrari
Consulting Implications

• Reduced fees for equity?
  ▪ Incentive
  ▪ Upside potential

• Need some assessment of the company
  ▪ Capitalization
  ▪ Burn rate
Resources

Startups & Business

• SVEBP  www.siliconvalleypace.com
• Stanford BUS16  continuingstudies.stanford.edu
• TVC  www.techventures.org
• TEN  www.tensv.org
• Girvan Institute  www.girvan.org
Medical Device

- Stanford Biodesign [innovation.stanford.edu](http://innovation.stanford.edu)
- BioDesign Network [mdn.stanford.edu](http://mdn.stanford.edu)
- NanoBioConvergence [www.nanobioconvergence.org](http://www.nanobioconvergence.org)
- DeviceLink [www.devicelink.com/mddi](http://www.devicelink.com/mddi)
- TCT [www.tctmd.com](http://www.tctmd.com)
- Vulnerable Plaque [www.vp.org](http://www.vp.org)
- Vascular News [www.CXvascular.com](http://www.CXvascular.com)
Summary

• Many opportunities in medical devices
  ▪ Entrepreneurs
  ▪ Consultants
• Increasingly multi-disciplinary
• Technology can be applied to advantage