Research into the mechanical causes of higher rates of hip implant failure in women

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Functional Performance and Device Use Laboratory

Health of Women Workshop – 25 June 2013
Background

• Lab objective

To investigate where patient factors and behavior can induce adverse outcomes from regulated medical devices

• Staff Expertise
  • Clinical kinematic and gait analysis
  • Computational modeling and image analysis
  • Human factors
  • Neuro-prosthetics and neuro-ergonomics
Outline

• Brief introduction
  • Patient population
  • Clinical symptoms

• Current Research
  • Research Avenues
  • Findings

• Female-specific research
Patient population

• Per year\(^1\)
  • Over 430,000 hip replacements in 2009
  • Generally favorable outcomes\(^2\)

• Younger and more active patients\(^1\) (1990-2009)
  • 160% increase for ages 45-64
  • 50% increase for ages 65-85

• New technologies developed

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1 National Center for Health Statistics. Health, United States, 2011
3 Photo: www.nevadahomebuy.com
Clinical Symptoms

- Adverse Reactions to Metal Debris (ARMD)
  
- Bearing wear and taper wear / corrosion

1 Matthies AK, et al. CORR 2012; 470(7):1895-906
4 Goldberg et al. CORR. 2002 401:149
Research Avenues

• Biological and Histological
  • Pseudotumors
  • Immune reaction

• Patient reported outcomes
  • Pain Scale
  • Function indices

• Metal ions
  • Systemic effects
  • Serum
  • Urine

• Corrosion
  • Chemical environment
  • Interaction between materials

• Lubrication
  • Type (boundary, fluid film)
  • Changes

• Mechanical
  • Design parameters
  • Positioning Accuracy
  • Patient activity
Potential Factors - Femoral Component

Design parameters

- Angular mismatch$^{2,5}$
- Contact length$^{3-5}$
- Head diameter & offset$^{3-5}$
- Cup features$^6$


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Femoral Component Results

- Coefficient of friction
- Angular mismatch
- Taper thickness
- Trunnion diameter
- Trunnion contact length
- Head center offset

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Potential Factors - People-based

Surgical and Patient variables

- Body weight
- Positioning
- Size
- Activities
- Anatomy

Langton, 2011
Potential Factors - Positioning

• Often outside safe zone\(^1\)

• Anatomic differences

• Complications

\(^1\)Saxler 2004
Positioning Results

- Edge loading\(^1,2\)
- Micro-separation\(^3\)
- Compromised lubrication\(^4\)
- Increased metal ion concentrations\(^5\)
- Larger heads less affected by position\(^5\)

\(^1\)De Haan JBJS Br 2008; \(^2\)Campell CORR 2010; \(^3\)Sariali JoB 2012; \(^4\)Bishop JOR 2012; \(^5\)Langton JBJS Br 2008
Research Gap

• Implants fail at higher rate in women\(^1\)

• Size may be an issue - Doesn’t explain it \(^2,3,4\)
  • Multivatiable retrospective studies
  • Controlling for size, sex is still a significant factor

\(^1\)Latteier 2011, \(^2\)Glyn-Jones 2009, \(^3\)Hinsch 2011, \(^4\)Kordas 2012
Research Gap

• Sex-based analysis from retrieval data
  • Unknown usage patterns
  • Secondary factors

• Laboratory studies are idealized

• Computational models use “generic” geometries or often male bones and muscles
Female anatomic models

- Leverage existing collaboration with the Foundation for Research on Information Technologies in Society (IT'IS)
- Bones and tendon insertions
- May include ligaments
Human data acquisition

• System components
  • 3-D motion from video-based infrared cameras

• Force platforms

• Surface Electromyography (muscle activity)

• Accelerometry

• Eye gaze tracking
Movement and muscle data
Analyzing Subject Movements

- Anybody Modeling System
- Utilize custom geometry and muscle locations
- Calculate forces on implant
- Several purposes
  - Inputs to a device-based computational model
  - Vary parameters, analyze change in muscle force
  - Analyze effort of different activities
Mechanical testing

- **Class II Special Controls Guidance Document:**
  Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis

- Wear simulator
  - Gait based: cyclic
  - Ideal orientation
  - 5-10 million cycles

- Taper junctions
  - Guidance Document for Testing Non-Articulating, 'Mechanically Locked', Modular Implant Components

**INTERNATIONAL STANDARD**
ISO 14242-1

Designation: F 1814 – 97a (Reapproved 2009)
Future Mechanical Testing - ASTM

• WK38566 – Standard Method for Measuring Metal Ions in Retrieved Fluid Samples from Total Joint Arthroplasty

• WK24686 – Guide for Hard on Hard Hip Devices


• WK34813 – Guide for High Demand Hard on Hard Hip Simulator Testing
Acknowledgements

• Funding
  • Office Women’s Health
  • Critical Path

• FDA Machine Shop

• Metal-on-Metal Workgroup members
Questions