Exponent®

Engineering & Scientific Consulting

Introduction to Exponent

Joy McGrath

Amanda Pentecost, PhD

Presented to Rutgers University

8 January 2020

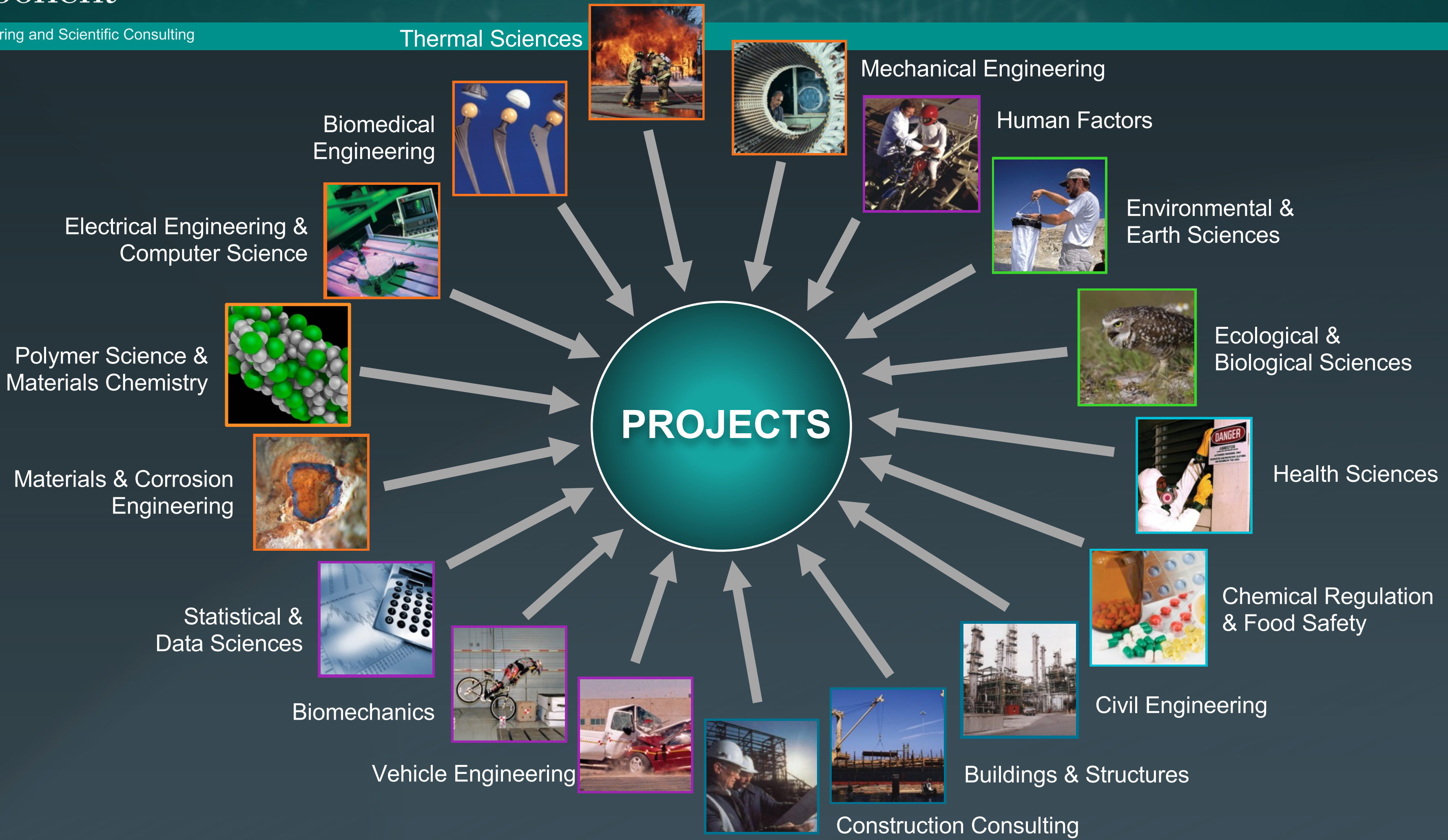
Life Before Exponent

Joy:

- B.S. – Manhattan College Biochemistry
- M.S. – Manhattan College Environmental Engineering
- 22 years at HydroQual/HDR – consulting services
- Started with Exponent in 2017

Amanda:

- B.S. – Drexel University Materials Science and Engineering
- M.S. – Drexel University Biomedical Engineering
- Ph.D. – Drexel University Materials Science and Engineering
- 10 years experience in characterizing nanomaterials for biomedical applications (i.e. drug delivery)
- Started with Exponent right after grad school in 2018


PROJECTS
Thermal Sciences
Mechanical Engineering
Human Factors
Environmental & Earth Sciences
Ecological & Biological Sciences
Health Sciences
Chemical Regulation & Food Safety
Civil Engineering
Buildings & Structures
Construction Consulting
Vehicle Engineering
Biomechanics
Statistical & Data Sciences
Materials & Corrosion Engineering
Polymer Science & Materials Chemistry
Electrical Engineering & Computer Science
Biomedical Engineering
DANGER

Exponent Offices

Environmental Science Practices

Environmental and Earth Sciences

Ecological and Biological Sciences

- Over 80 technical staff
- 13 principals
- Offices
  - Seattle, Boston, Oakland, San Francisco, Irvine, Pasadena, Alexandria, Atlanta, Phoenix, Houston, Washington DC

Recent Hires at Exponent

Dan Hoer

- B.S. – University of North Carolina at Chapel Hill (2009)
  - Environmental Science
  - Began working on a research project that became part of his PhD dissertation
- Ph.D. – University of North Carolina at Chapel Hill (2015)
  - Chemical Oceanography - Biogeochemistry
  - Chemical cycling and ecosystem ecology of Caribbean coral reefs and tropical nearshore waters.
  - Connections formed during side projects, led to a postdoctoral fellowship in a lab at Harvard.
- Postdoctoral Fellow – Harvard University (2015-2018)
  - Organismic and Evolutionary Biology
  - Biogeochemistry of deep sea hydrothermal vents and cold hydrocarbon seeps
- Research Scientist and Engineer – Harvard University (2018-2019)
  - Biogeochemistry and underwater technology development
- Exponent (October 2019)

Sean Ryan

- 2007 B.S., Conservation Biology, San Jose State University, CA
- 2010 M.S., Ecology and Evolution, Bowling Green State Univ, OH
- 2015 Ph.D., Evolution and Ecology, University of Notre Dame, IN
- 2015-2017 Research Geneticist, USDA-ARS, Gainesville, FL
  - Government employee for 3 year position. Applied for and awarded USDA NIFA fellowship
- 2017-2019 USDA-NIFA postdoctoral fellow, dual affiliation: University of Tennessee, Knoxville, TN & North Carolina State University, NC
  - Principle investigator

2019 Exponent

Environmental Strengths: Multiple Disciplines

- Diverse, interlinked portfolio of technical strengths
  - Chemistry
  - Geology/Hydrogeology/Geomorphology
  - Aquatic and terrestrial biology
  - Ecology
  - Toxicology
  - Water resources
  - Veterinary medicine
  - Statistics
  - Modeling
  - Engineering
  - Economics
  - Data visualization and GIS
  - Data optimization
  - Editors/Library science





Types of Projects

Reactive (Litigation)

- Environmental claims (various)
  - Sites
  - Spills
  - Wildfires
- Toxic Tort claims
- Insurance cost recovery claims
- Maritime claims

Proactive (Risk Management)

- Liability estimation
- Product risks and liability
- Water resources
- Ecological asset valuation
- Climate change

Biomedical Engineering

- Over 35 technical staff, including Drexel co-ops
  - Diverse expertise
    - Biology
    - Biomedical Engineering & Sciences
    - Bioengineering
    - Mechanical Engineering
    - Chemical Engineering & Chemistry
    - Materials Science & Engineering
    - Electrical Engineering
    - Modeling
    - Physics
    - Veterinary medicine
- Primarily **engineering** focused compared to Health Sciences & Environmental/Ecological/ Biological Sciences practices
- 5 principals
- Offices
  - **Philadelphia, Menlo Park**, Austin, Chicago/Warrenville, Detroit

Focus Areas: "Reactive" Work

- Primarily litigation based; work with medical device companies and their attorneys to analyze claims regarding specific medical devices

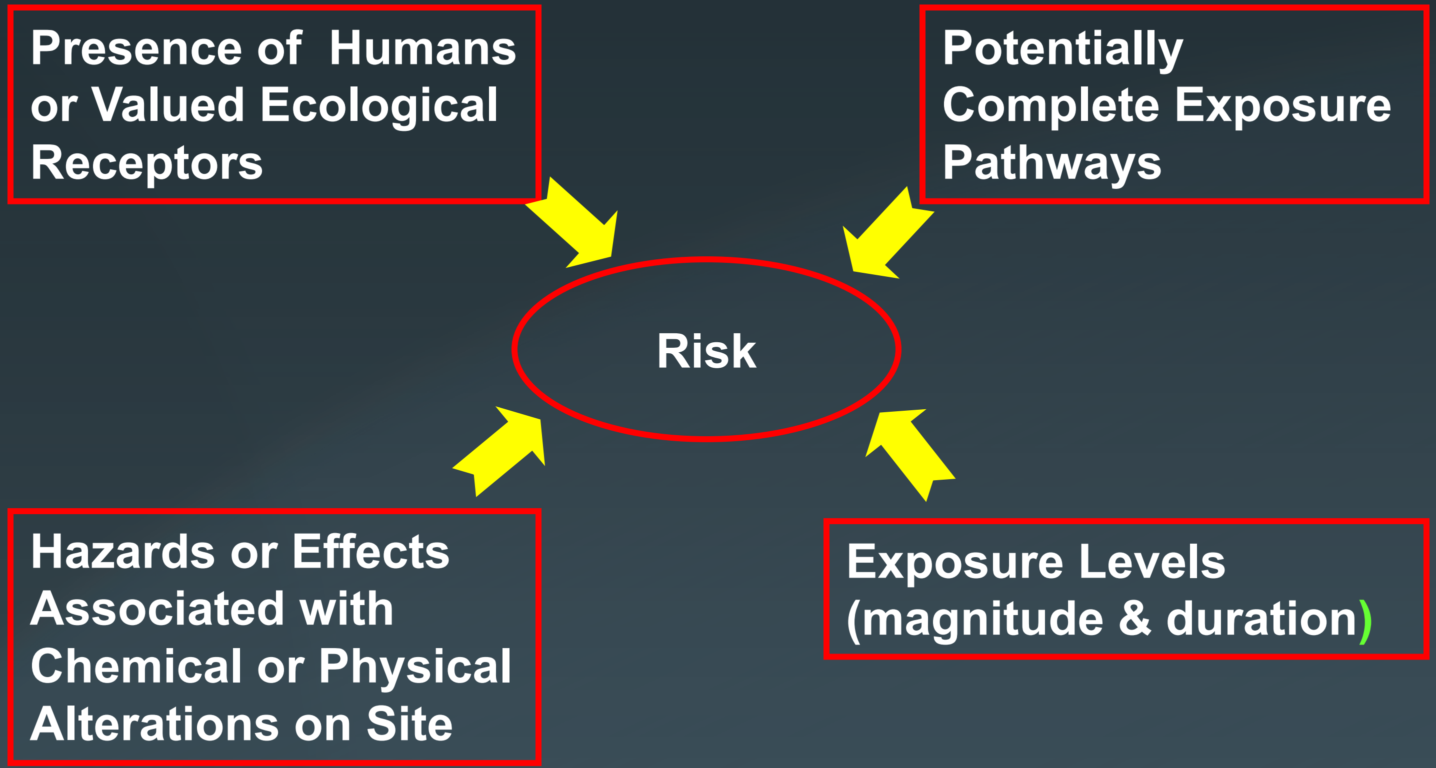
- Examples
  - Failure analysis of medical devices (Product liability)
  - Intellectual property litigation

Focus Areas: “Proactive” Work

- Perform nonclinical testing according to different standards and FDA guidances under GLP conditions for submission to national and international regulatory bodies
- Focused on evaluation of medical devices (occasionally pharmaceutics)
- Examples
  - Mechanical testing of medical devices and tissue-engineered constructs
  - MRI compatibility testing
  - Dissolution and solubility testing
  - Shelf life/stability testing
  - Materials characterization of biomaterials (SEM, FTIR, DSC, microCT, etc.)
  - Wear analysis of implants

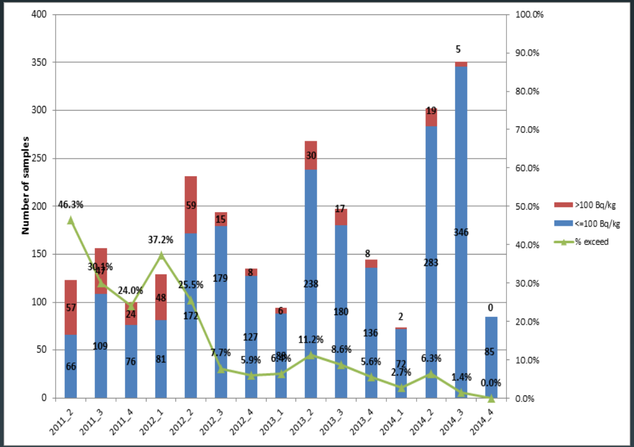
Project Examples

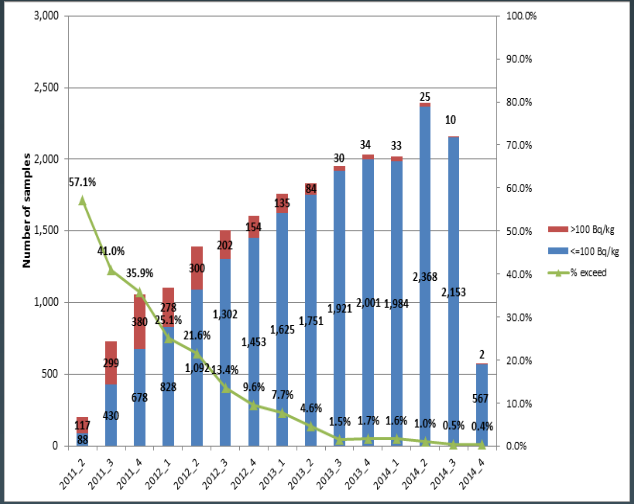
What is Risk Assessment?



Japan v. Korea Seafood Safety

- Great East Japan Earthquake and tsunami – March 11, 2011
- Caused nuclear accident at the Tokyo Electric Power Plant
- Emission of Cs-134 and Cs-137 (8-37 PBq)
- Seafood safety Cs - 100 Bq/kg
- From 2011-2014 – collected over 60,000 marine and freshwater samples
  - 17 highest priority samples – 99% of population <100 Bq/kg





Case Study – "Paintshop Pond"

Site History

- Henry Wood's Son Paint Factory manufactured dry paint pigments (1848~1920s)
- Wellesley College purchased the land in 1932 and demolished all buildings
- Colorful red, yellow, orange, green soils around the pond were obvious
- 1903, health officials noted high levels of lead Lake Waban
- In 1970 DEP and environmental groups sampled soils around lake and pond noting high levels of lead, chromate (Cr(VI))
- Wellesley College covered the colored soils with a tarp, fenced it off and put signs up.
- Added 600 tons of clean sand to swimming areas of the lake annually
- 3000 tons of soil near paintshop pond were excavated
- College wanted to distance itself from responsibility for Lake Waban
- In 1982 environmental assessment began (Lake Waban, The Pond, Wetlands, Upland environments)

Initial protective step?

Things to Consider?


Wellesley College
Wzly
D
C
A
E
B
C
© 2010 Google
Image MassGIS, Commonwealth of Massachusetts EOEA
©2007 Google
Pointer lat 42.288358° lon -71.313005° elev 179 ft
Streaming 100%
Eye alt 5910 ft

Soil Data for A

Compounds	# Analyzed	# Detected	Min	Max	Average
Total Metals (mg/kg dry wt.)					
Arsenic, Total	183	174	2.2	16	8
Cadmium, Total	145	88	0.045	5	1.27
Chromium, Total	394	394	2.15	110,000	2,883
Copper, Total	117	117	2.7	282	27
Lead, Total	378	373	2.1	214,000	5,433
Mercury, Total	16	9	0.1	28	2.01
Nickel, Total	142	141	3.2	4,900	124
Silver, Total	132	40	0.023	2	1
Chromium III	394	394	2.15	61,600	1,753
Chromium VI	310	310	0	48,400	1,436

Sediment Data for E

Compounds	# Analyzed	# Detected	Min	Max	Average
Total Metals (mg/kg dry wt.)					
Arsenic, Total	30	30	2.2	8	6
Cadmium, Total	30	30	0.045	3	4
Chromium, Total	30	30	800	10500	2883
Copper, Total	30	30	50	200	70
Lead, Total	30	30	600	15000	6000
Mercury, Total	30	30	0.1	1	0.8
Nickel, Total	30	30	50	3000	1500
Silver, Total	30	30	0.023	2	1
Chromium III	30	30	800	10500	2883
Chromium VI	30	30	ND	ND	

Reference Data for Soil and Sediment

Metal	Local Background for Soil (mg/kg)	Local Reference for Sediment (mg/kg)
Arsenic	2–16	3–8
Cadmium	1–5	1–4
Chromium total	20–40	15–30
Copper	10–25	15–40
Lead	20–45	30–50
Mercury	0.1–1	0.1–1
Nickel	10–35	5–45
Silver	0.02–3	0.01–3

Our Screening Identified Key Metals

- Lead
- Chromium
- Arsenic

Other things to consider?

- What do we know about the toxicity of these chemicals?
- Receptors at site


Wellesley College
Wzly
School
Recreation on Land
Swim and Fish
Fish and Wildlife
• Waterfowl
• Upland birds
• Mammals
• Amphibians
• Fish
Homes
© 2010 Google
Image MassGIS, Commonwealth of Massachusetts EOEA
©2007 Google

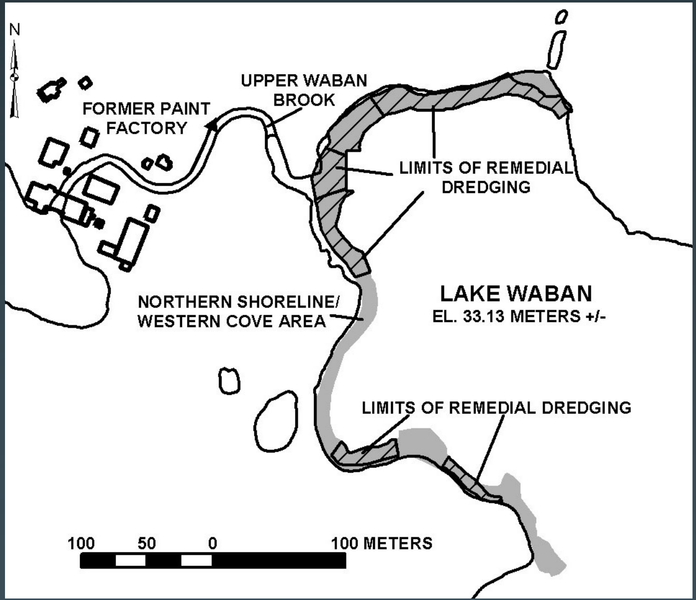
The data indicated….

- Lake Waban
  - Fish populations are sustained (only growth effects)
  - Metal exceedances of WQC
  - Food chain modeling indicated wildlife not impacted by metals
  - No significant risk found
- Paintshop Pond
  - WQC exceeded for Al (not site related)
  - Risks to benthos, fish and wildlife were low
  - No significant risk found
- Wetlands
  - Number and types of plants similar to references
  - Number and species of birds and wildlife similar to reference areas
  - Very few amphibians
  - Metals in the waters and soils are bioavailable
  - Wetland functions maybe comprised, some risk found
- Upland
  - Vegetation is stress
  - Food chain modeling indicated birds and mammals at risk
  - Visual observations
  - Risk is found

How might the risk be reduced?

Remedy

- Cleanup level of 600 ppm lead in sediment to protect water fowl
- Cleared 30 acres of trees
- Water drained from Paintshop Pond
- 1200 fish were moved to Lake Waban
- 20,000 yd^3 soil treated on site
- 36,000 yd^3 excavated
- Soil buried under protective barrier to prevent spread of contamination
- Athletic fields built on top of protective barrier



Exponent®

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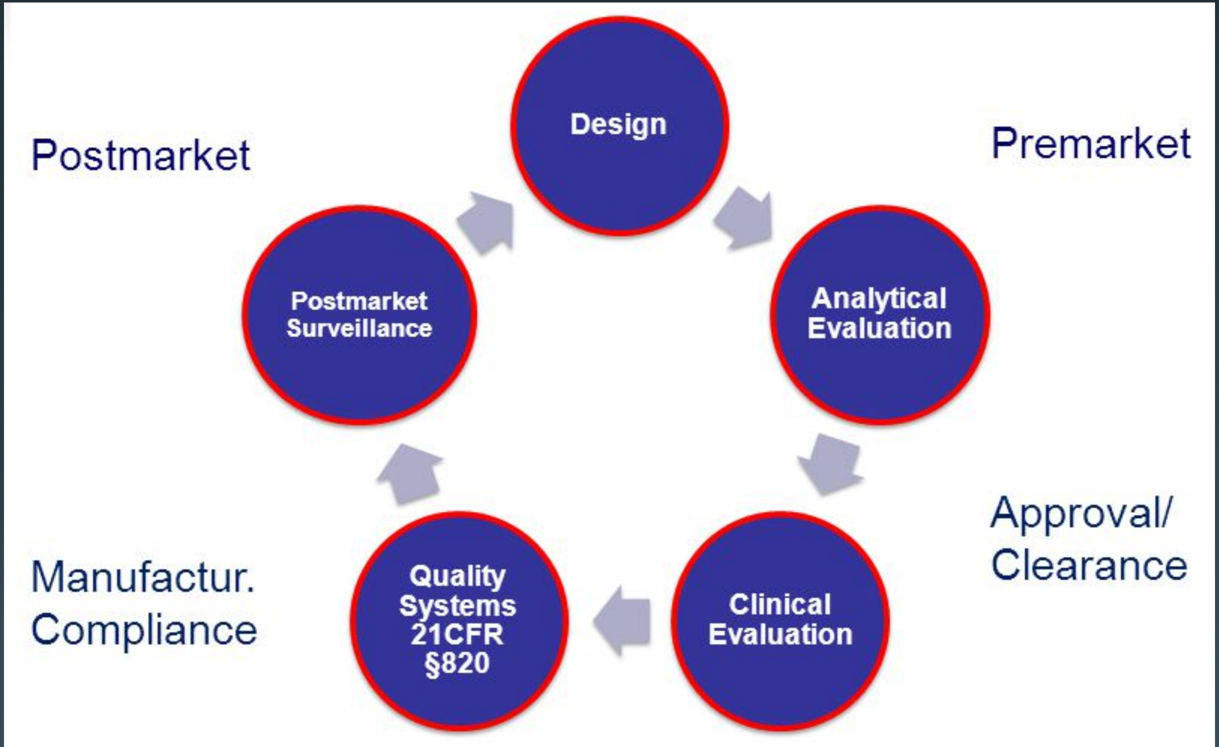
The End Result

Total Product Lifecycle

Reactive

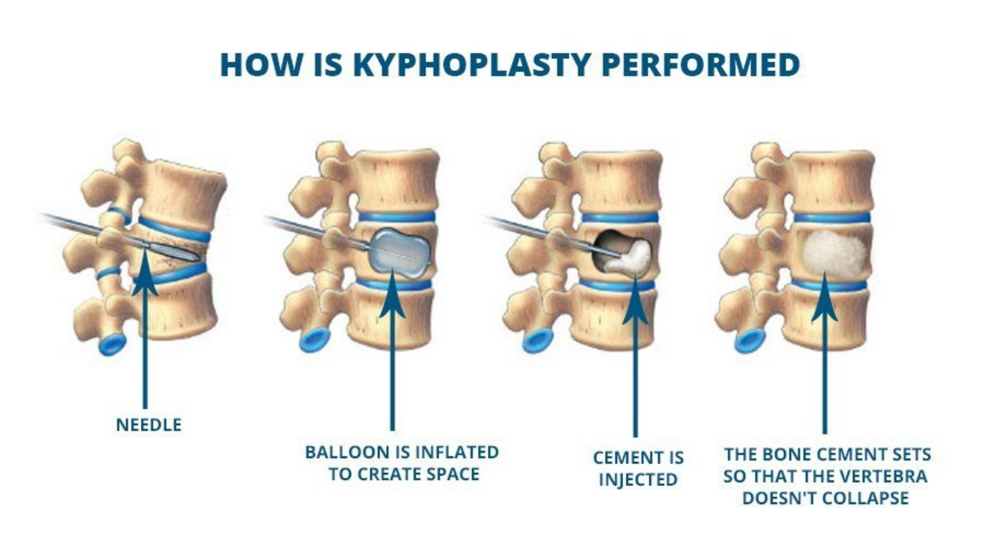


Proactive

FDA.gov

Spinal Repair

- Kyphoplasty
  - Minimally invasive procedure for spinal compression fractures that occur in vertebrae weakened by osteoporosis
  - Aims to reduce pain, stabilize vertebrae, and restore vertebrae to its normal height



Exponent was asked to validate the method to determine mechanical stability

Totalspinebrain.com

Spinal Repair

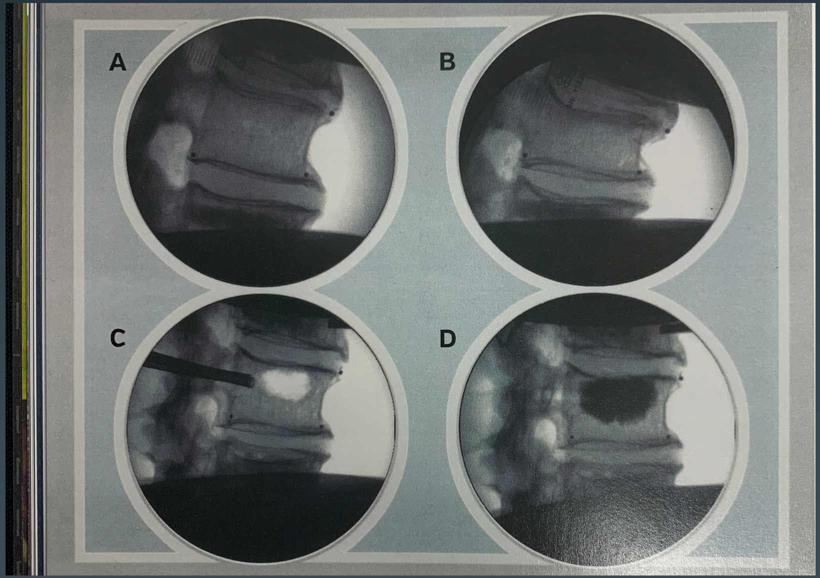
- What can be tested to ensure mechanical stability?
  - Company is also making their own proprietary bone cement
  - Want to restore vertebrae to normal height
  - Want to restore vertebrae function

Spinal Repair

Step 1: Test stability of bone cement

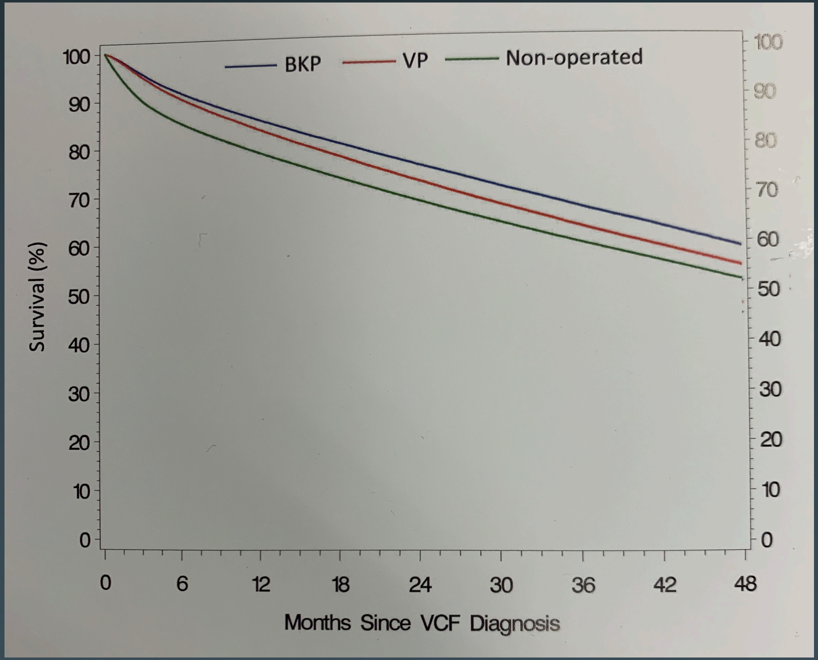
– Under static & fatigue conditions

Step 2: Test the entire procedure in cadaver spines



Spinal Repair

- **Step 3: Survivability**
  - Collaborative effort: Biomedical engineering, biostatistics, and health economics
  - BKP: balloon kyphoplasty; VP: vertebroplasty
  - BKP and VP are cost-effective alternatives to nonsurgical management



Surgical Mesh

Surgical Mesh

- Medical device used to provide additional support when repairing weakened or diseased tissue
- Usually permanently implanted and fixed with sutures or tacks

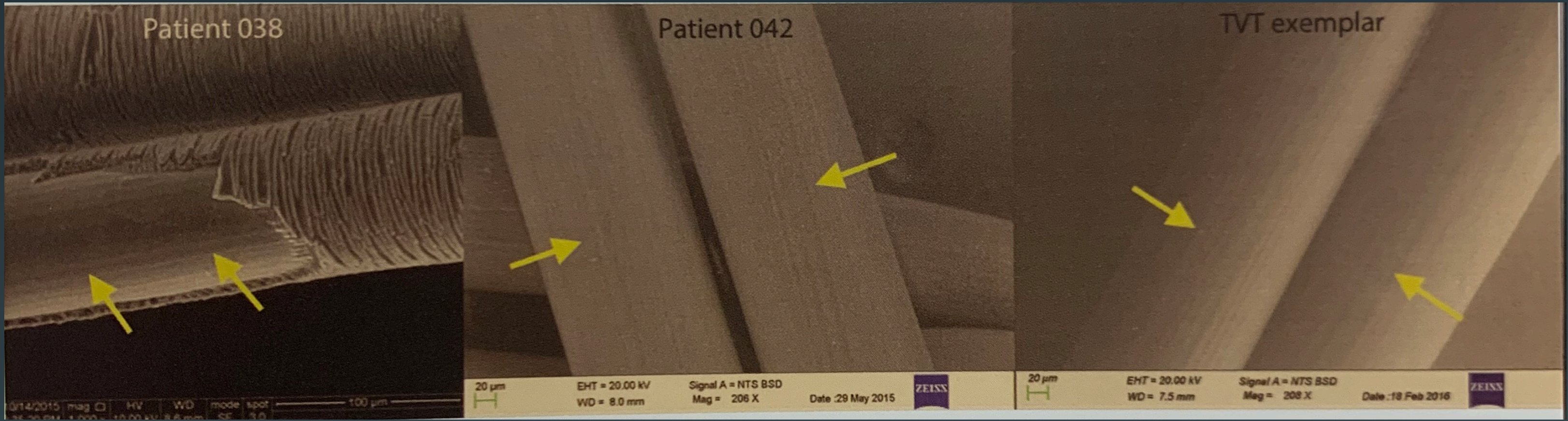
What properties should be tested when designing this biomaterial?

Surgical Mesh

- Lawsuit claims:
  - Mesh degrades *in vivo* and suffers losses in physical performance
- Company asks Exponent to investigate these claims
- What are ways we can characterize the mesh?
  - We receive a small excised piece of the mesh (1” x 1”) from a patient that is surrounded with tissue and fixed in formalin
  - Part of the claim states that these meshes oxidize *in vivo*

Surgical Mesh

Plaintiff alleges that cracking on the mesh fibers indicates oxidation



Exponent showed that this “cracking” effect was caused by tissue adherence, and it could be cleaned to expose an unoxidized, nondegraded surface

Smooth surfaces exposed with no visible ductile damage, and have the same manufacturing extrusion lines

Q & A