

MARI SUSAN TRUMAN, P.E.
Biomechanical Engineer

BIOMECHANICS AND INJURY EVENT RECONSTRUCTION

The physical principles and methods used in orthopaedic biomechanics are the same as those used to reconstruct injury events. Orthopaedic Biomechanics is a sub-specialty field of biomechanics and biomedical engineering and involves the application of principles of engineering mechanics to understand basic biological processes and mechanisms related to the structure and function of bone and other skeletal tissues, while the broader biomechanics field does the same relative to the structure and function of all living tissues.

Orthopaedic designers compile and use property databases of bone and other tissues. As a result I routinely deal with forces that are applied to the human body during many activities, including impact and injury scenarios. To assure the safety and efficacy of new medical devices, we define clinically relevant performance requirements for their installation and use, and then test to define the product specific performance characteristics.

- Comparison of event forces to injury thresholds
- Motions and forces applied by and to the skeleton/body during physiologic and injury events:
 1. Fall and fall recovery (stumbling)
 2. Projectile impacts
 3. Vehicular collisions
 4. Sports, recreation and occupational overuse or injury
 - sitting
 - walking
 - climbing
 - lifting
 - biking
 - vibration
 - standing
 - jumping
 - jerking
 - pulling
 - hiking
 - bending
 - reclining
 - running
 - throwing
 - pushing
 - repetitive motion
 - helmet impacts
 5. Altered/compensatory mechanics due to injury
 6. Physiologic event reaction times
- 26+ years of product design and development experience, orthopaedic medical devices
- Human joint reconstruction (since 1980)
Implant Examples: Wrist, Ankle, Elbow, Knee, Fingers/Hand, Toes/Foot, Hip, Shoulder, Spine repair
- Skeletal trauma reconstruction (since 1980)
Devices for: Long bones, juxta-articular (near joints), hand, vertebral (spine), sternum, face and skull.

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Implant Examples: Plates, screws, intramedullary nails, external fixation, pins, wires, staples, cables, clamps, anchors, distraction rods

- Tissue reattachment (since 1991)
Implant Examples: Tissue Anchors used for ligament or tendon reattachment - knee, shoulder, wrist, ankle, hand and foot.
- Directed, analyzed and/or completed laboratory evaluations:
 1. Forces on/through normal vs. repaired bones and joints.
 2. In-vivo to in-vitro forces on orthopaedic implants.
 3. Normal (physiologic) vs. injury forces for skeletal tissues.
 4. Bone impact resistance, healthy vs. disease weakened tissues.
 5. Bone cutting efficiency for specific orthopaedic surgical cutting tools.
 6. Documentation of altered gait, joint kinematics or mechanics after injury or orthopaedic repair or reconstruction considering modified injury potential and life style. Quantification of short or long term functional disability.
 7. Range of motion, fatigue and wear endurance characterization of various total joint implant designs for the knee, hip, and wrist, PIP, thumb based CMC joint, and foot MT and DIP joints.
 8. Stability characteristics of joint implant devices and surgical reconstructions, including stability under anticipated physiologic and injury load conditions.
 9. Impact strength and fracture resistance of bone, implants and instruments during surgical reconstruction procedures.
 10. Implant fixation strength and construct stability characterization for various bone fracture repairs using: external fixation, spinal rods screws and hooks, intramedullary nails, bone screws, cannulated bone screws, plates with screws, and k-wires.
 11. Ligament reattachment strength and fixation stability in foam bone model material and animal bone.
 12. Minimally invasive orthopaedic surgical procedure instrument construct stability and accuracy.

MEDICAL DEVICES

- Determination of failure mechanisms, cause of failure.
- Review for device design, manufacturing or warning defects.
- Failure event reconstruction.
- Review of design dossiers and design history files including specifications, clinical performance requirements, test protocols, test results.
- Assist orthopaedic and medical device companies with design, design dossiers, test protocol development, test direction, and test results summary.

Robson Forensic

Engineers, Architects, Scientists & Fire Investigators

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PROFESSIONAL EXPERIENCE

2002 to **Robson Forensic, Inc.**

present *Associate*

Provide technical investigations, analysis, reports, and testimony towards the resolution of commercial and personal injury litigation involving medical devices and/or biomechanical trauma and for failure analysis.

2003 to **Mari S. Truman, OrthoBioMech LLC**

Present *Consultant*

Orthopaedic device development offering design and development services for the orthopaedic and medical device industry. Recent projects include soft tissue repair, trauma, spine, hip and knee implant system design and development.

2005 to **Small Bone Innovations, Inc., (SBI)**

2005 *Senior Product Development Engineer*

Principal engineer for upper and lower extremity trauma product systems.

2002 to **GE Medical Systems Navigation and Visualization, Inc.**

2003 *Mechanical Engineer, Orthopaedic Applications*

Design and development of mechanical tools to facilitate image guided, minimally invasive orthopaedic surgical procedures.

1999 to **Seabrook International, LLC (DBA G&G Machine Technologies, LLC) and**

2002 **Nelson & Small Manufacturing Management**

Vice President of Product Development / Director, Midwest Region

- Founder and director of Seabrook's mid-west based design center offering design and development services for the orthopaedic and medical device industry.
- Providing general project management, design, and Design Dossier services for several new orthopaedic product systems for multiple orthopaedic companies. Recent product development projects include: Acetabular cups, knee implants and instruments, intramedullary nail implants and instruments, spinal implants and instruments, tools for less invasive surgical procedures, soft tissue attachment and a sternotomy repair system.
- Implemented and use of multiple CAD/CAE software and communication tools including Unigraphics, Pro/E, Algor, SDRC IDEAS Artisan, and Solid Works.
- Medical device technical sales support for Seabrook International, LLC.
- Invention, invention refinement and patent application on new designs in conjunction with customers.

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1998 to 1999 **Othy Inc, a division of Symmetry Medical Inc.**

Design Engineer

- Created custom and standard-line generic instrumentation for primary total knee, total hip, and endoscopic procedures, including a few unique/patentable inventions.
- Implemented company-wide participation in ISO 9001 level, team-oriented product development practices.
- Drafted and implemented “Fast Track” Design Control forms and protocols, to bring R&D practices into compliance with ISO & FDA regulations while making efficient use of existing R&D resources.
- Created engineering databases and spreadsheet programs for traditional closed form stress analyses.

1993 to 1998 **ArthroMotion LLC**

President and Founder

- Provided product design, development, and engineering services in orthopaedics.
- Completed several turnkey system development projects from inception through launch, in compliance with ISO & FDA design control regulations.
- Co-authored papers and talks with surgeons/researchers/engineering associates.
- Participated in collaborative research projects with several major biomechanics laboratories and orthopaedic teaching institutions.
- Named as an inventor on three Orthopaedic product device patents. Invented several other unique devices/concepts, which were patentable.
- Assisted with 8 patent applications, awarded three patents.

1991 to 1993 **Zimmer, a division of Bristol-Myers Squibb Company**

Senior Development Engineer, Fracture Management Division

- Completed unique fracture fixation biomechanical analyses and initiated cutting tool efficiency analyses.
- Assisted in the redesign and launch of the Herbert/Whipple Bone Screw System. Facilitated design and launch of the Herbert Mini Bone screws and the Herbert cannulated bone screw systems.
- Functioned as both project designer and project manager for these systems. Completed all design assurance documentation.
- Helped sales training department develop effective educational tools for the Herbert family products.

1991 **Biomet Inc.**

Senior Engineer, Patient Matched Implants (PMI)

- Worked on methods to automate the production of implants utilizing 3D CT scan reconstructions.

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- Supervision of radiology technologist whose duties ranged from completing 3D CT Scan reconstructions, writing field communications, giving tours, definition of CT scan parameters, and QC evaluation of composite plastic materials via CT scans.
- Design of custom prostheses and instruments to match patient and surgeon needs via CT scans or x-rays.
- Wrote and edited drafts of the surgical technique for patient matched hip implants (written and videotaped version).
- Conceptualized a unique, low cost, flexible sterilization case system.
- Designed a modular custom reamer and gage system.

1980 to
1991

DePuy, a division of Boehringer Mannheim Corporation

Sr. Product Development Engineer: 1989-1991

(Total Knee Implants and Instrumentation)

- Planned and started development of a new total knee implant and instrumentation system.
- Wrote surgical techniques, design rationales, and design assurance plans.
- Led project teams and coordinated research, planning, testing, design & development programs. Completed projects: AMK all-poly tibial tray, AMK Universal Femoral components, Tibial IM Alignment Guide.
- Planned educational sessions and spoke at sales training sessions both in-house and at national sales meetings.
- Frequently spoke to surgeon tour groups covering various contemporary orthopaedic topics.

Manager of Implant Technology – Hips & Knees: 1988-1989

LCS Knee System Marketing Product Manager

- Produced technical write-ups on topics such as Titanium, Titanium wear, Poly Wear, Competitive analyses of TKA systems, and TKA instrumentation.
- Re-wrote and updated LCS knee surgical technique, wall chart, planned LCS knee system modernization, line extension possibilities, held surgeon user focus meeting, ran LCS knee sales training meetings, and helped run dinner meetings (mini-courses).
- Created strategic planning documents for TKA, extremity and hip systems.
- Ran LCS knee sales training sessions, presented patellar kinematics and patello-femoral kinematics & competitive overview at DePuy's National Sales Meetings.

Marketing Product Manager Reconstructive II: 1986-1988

Total Knees & Extremity Joints

- Planned and executed the launch of DePuy's AMK TKA systems.
- Responsible for the marketing/sales results for the total knee and extremity joint products, with emphasis on new product development and promotion.

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- Coordinated creation of sales promotional programs, sales aids (audiovisual aids, advertisements, brochures, surgical techniques, design rationales, reference literature), and new product launch plans.
- Ran mini bioskills courses for surgeons, aided customer service, supplied financial justification of projects, submitted long and short term product line plans and budget proposals.

Manager, New Product Coordination: 1985-1986

- Reduced lead time and improved efficiency for new product development, production and introduction.
- Creation of refined new product development protocol, project timelines, project teams. Also responsible for new product production, “trouble-shooting.”

Development Engineer, Product Development Engineer: 1980-1985

- Responsibilities included product design, project management, and product line maintenance for multiple trauma, spine and extremity joint product areas.

EDUCATION

Biomedical Engineering; B.S.E. - The Catholic University of America, Washington D.C., 1980, Magna Cum Laude.

Course Highlights: Core curriculum met requirements for M.E. & Pre-Med majors. Including drafting, mechanical design, materials, 6 semesters’ physics, 8 semesters’ math, 8 semesters’ chemistry, computer science, biomedical design, and biomedical instrumentation.

Masters Courses Completed: Actively enrolled as a Mechanical Engineer graduate student at University of Illinois, Urbana Champaign Campus.

University of Toledo (UT): (1) Management of Projects & Technology Innovation; (2) Applications of Engineering Analysis

University of Illinois at Chicago (UIC): (1) Numerical Methods in Mechanical Engineering; (2) Dynamic Systems Analysis I; (3) Spine Biomechanics

University of Illinois at Urbana-Champaign: (1) Probability Theory I; (2) Legal Issues in Entrepreneurship; (4) Lectures in Entrepreneurship; (5) Introduction to Finite Element Analysis; (5) Quality Engineering, Six Sigma; (6) Decision Making with Multiattribute Utility Analysis ; (7) Failure Analysis of Mechanical Components; (8) Technology Innovation and Strategy; (9) Managing Advanced Technology in Industry; (10) Fracture Resistant Design; (11) Corrosion of Metals.

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Continuing Education:

Annually attended a minimum of 4 continuing education courses for orthopaedic surgeons between 1980 and 1990. A partial list of orthopaedic related continuing education courses attended:

Complex Case Controversies in Primary and Revision Total Knee Arthroplasty
Revision Total Hip Arthroplasty: How to Plan and How to Remove Components
Injuries of the Distal Radioulnar Joint
Spondylolysis and Spondylolisthesis
Arthroscopic Meniscal Repair
Tibial Nonunions: Current Treatment Concepts
Wrist Arthroscopy
Stable Internal Fixation for Fractures: Upper Extremity
Thoracolumbar Fractures
Deformity Correction Using External and Internal Fixation
Shoulder Arthroplasty: Current Techniques
Operative Management of Rotator Cuff Tears
Intramedullary Nailing of Upper Extremity Fractures
Physiology of Bone... Formation, Regeneration & Repair
Wrist Instabilities
External Fixation of High Energy Distal Tibial Fractures
Controversies in the Management of Open Fractures
Intramedullary Nailing of the Femur
Cervical Spine Trauma
Intra-Articular Fractures of the Distal Radius and Ulna
Management of Phalangeal and Metacarpal Fractures
Primary Total Hip Arthroplasty
Primary Total Knee Arthroplasty
Upper Extremity Injuries in the Young Athlete
Lumbar Spine: The Herniated Disc
Current Concepts in Joint Replacement

Put together course agendas for DePuy sponsored Total Knee Arthroplasty (TKA) orthopaedic surgeon continuing education meetings in 1987, 1988, and part of 1989. Attended AAOS meetings annually from 1981 to 2002.

ATB Class, 2004 Users Conference

Pro/E Parametric Design/Modeling

SDRC IDEAS Parametric Design/Modeling & FEM/FEA Training

Introduction to FEM/FEA using Algor Software (1996, at Algor)

GMP Regulations

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ISO 9000/9001/European Community (EC) Essential Requirements Regulation Status
Total Quality Management
IV-Tech Course on Machining (1982-83)
University of Wisconsin course Designing for Manufacturability (1981)
Dale Carnegie Course (1980)

PROFESSIONAL REGISTRATIONS

Professional Engineer: Ohio

PROFESSIONAL MEMBERSHIPS and RECOGNITION

Ohio Society of Professional Engineers (OSPE)
American Society of Mechanical Engineers (ASME)
American Materials Society (AMS)
American Society for Testing and Materials (ASTM)
International Society of Biomechanics (ISB)
American Society of Biomechanics (ASB)
American College of Sports Medicine (ACSM)
North American Spine Society (NASS)
Tau Beta Pi Engineering Honor Society, elected into membership 1979
Society of Automotive Engineers (SAE)
National Society of Professional Engineers (NSPE)
Orthopedic Research Society (ORS)

Sterling Who's Who Executive Edition, 1994/95
Mechanical Engineering Dept., C.C. Chang Award, Biomedical Engineering, 1980

PATENTS

5935128 Orthopaedic template system including a joint locator
5853413 Wrist fusion plate
5549690 Prosthetic thumb joint and method of manufacture
Pending: (1) Orthopaedic surgical tool (assigned to J&J); (2-4) Three patents for Locking and flexible fasteners for orthopedic reconstruction (5) Toe fusion device; (6) Tendon repair system

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BIOENGINEERING RELATED PRESENTATIONS, AUTHORSHIP/COAUTHORSHIP

1. Bodell, L., Hollister, A., Truman, M. and Focht, L.: **A New Implant and Procedure for Thumb Based Carpometacarpal Joint Reconstruction.** Presented at the 6th Congress of the International Federation of the Societies of for Surgery of the Hand, Helsinki, Finland, July 3-7, 1995.
2. Hollister, A., Truman, M. and Focht, L.: **Creation of a Thumb Carpometacarpal Joint Implant Saddle Shape with Surfaces of Revolution for Offset Axes of Rotation.** Presented at the 6th Congress of the International Federation of the Societies of for Surgery of the Hand, Helsinki, Finland, July 3-7, 1995.
3. Hollister, A., Truman, M., and Focht, L.: **Computer Model of the Knee with Two Fixed Offset Revolutes for Tibiofemoral Motion.** Presented at the XVth Congress of the International Society of Biomechanics, Jyvaskyla, Finland, July 2-6, 1995.
4. Hollister, A., Truman, M., and Focht, L.: **Computer Aided Design Model of the Knee with Two Fixed Offset Axes.** Abstracts - 14th Annual Meeting of the Arthroscopy Association of America, San Francisco, CA, May 4-7, 1995.
5. Truman, M., Hollister, A., and Focht, L.: **Thumb Carpometacarpal Surface Replacement Arthroplasty with an Asymmetric Saddle.** Poster - American Society for Surgery of the Hand, 49th Meeting, Cincinnati, OH, October 26-29, 1994.
6. Truman, M., Hollister, A., and Focht, L.: **Prosthetic Joint Replacement Using Surfaces of Revolution for Two Offset Axes of Rotation.** Abstract ME '94 - International Congress - ASME Winter Annual Meeting, Chicago, IL, November 11, 1994.
7. Truman, M., Hollister, A., and Focht, L.: **Prosthetic Joint Replacement Design Methods to Restore Kinematics and Stability while Preventing Material Overload.** Proceedings - 14th Southern Biomedical Engineering Conference, Shreveport, LA, April 7-9, 1995.
8. Truman, M, and Hollister, A.: **Simulation of Thumb Carpometacarpal Joint Saddle Shape with Surfaces of Revolution for Offset Axes of Rotation.** Talk and Computer Demonstration Presented at the Vth Symposium on Computer Simulation in Biomechanics, Jyvaskyla, Finland, June 28-30, 1995.
9. Truman, M, and Hollister, A. **Mathematical Modeling of Joint Surface Shapes Using Surfaces of Revolution About Offset Revolutes.** Presented at Vth Symposium on Computer Simulation in Biomechanics, Jyvaskyla, Finland, June 28-30, 1995.
10. Truman, M, Hollister, A., and Focht, L.: **Simulation of Thumb Carpometacarpal Joint Saddle Shape with Surfaces of Revolution for Offset Axes of Rotation.** Presented at the XVth Congress of the International Society of Biomechanics, Jyvaskyla, Finland, July 2-6, 1995.
11. Truman, M, Hollister, A., and Focht, L.: **Simulation of Thumb Carpometacarpal Joint Saddle Shape with Surfaces of Revolution for Offset Axes of Rotation.** Presented at the International Hand and Wrist Biomechanics Symposium, September 10-11, 1995, San Francisco, CA.

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12. Truman, M, and Hollister, A: **Simulated Articular Surface Shapes for the Thumb Carpometacarpal Joint.** Presented at the ASME Winter Annual Meeting, San Francisco, CA, November 12-17, 1995.
13. Griffin, A, and Truman, M: **Interfacing Between Rapid Prototyping and CAD,** Presented at the National Manufacturing Week Conference, the McCormick Center, Chicago IL, March 17, 1998.
14. Truman, M.: **Implementation of Effective Design Control Procedures by Development Teams – tips based on historical experiences,** Presented at the Indiana Medical Device Manufacturer's Council (IMDMC) Seminar : Simplification of Process for Design Control: Medical Devices and Software, Indianapolis, IN April, 29, 1998.
15. Truman, M.: **Use of Biomechanics to Explain Injury Mechanics and Reconstruct Events,** *proceedings*, Presented at Forensics for Lawyers, OSBA CLE, Cleveland and Columbus OH, December 2002 & October 2003.
16. Truman, M.: **Avoiding Patient Injury Lawsuits, Design Team Tips** *BoneZone*, Winter 2003 Knowledge Enterprises, Inc, Chagrin Falls, OH.
17. Ferrara, L., Moderator, Shuvo, R and Truman, M, Speakers: **Biomaterials and Future Engineering Considerations: What Do We Really Need?,** *proceedings*, North American Spine Society (NASS) Spring Break, Boca Raton, FL, April 23, 2004.
18. Truman, M., Ferrara, L., Milks, R., and Eckhardt, J.: **Acute Thoracic Vertebral Injury Thresholds.** *Proceedings of IMECE04 2004 ASME International Mechanical Engineering Congress November 13–20, 2004*, Anaheim, California USA.

LECTURES

1. Derian, G, and Truman, M.: Vehicle Collisions, Reconstruction and Injury Biomechanics, Lorman Continuing Legal Education Series, Columbus Ohio, January 26, 2005 & Cleveland Ohio, May 18, 2005.
2. *Several Talks* for the Ohio State Bar Association (OSBA) and Ohio Trial Lawyer (OATL) Continuing Legal Education courses in 2003 and 2004 related to Injury Biomechanics and other Biomechanics Issues in Forensic Reconstructions.
3. Truman, M.: Preparing and Trying the Soft Tissue Case - Biomechanics Expert Reviews, Pennsylvania Bar Institute, Mechanicsburg, PA, July 20, 2006.
4. Truman, M.: Successful Resolution of Medical Equipment and Medical Malpractice Claims, Third Annual Medical Malpractice Insurance Execusummit, New York, NY, November 15, 2007.
5. Truman, M., and Higinbotham, E.: Rebutting Seatbelt Defense, and Preparing and Trying the Soft Tissue Case, Central Ohio Association for Justice (COAJ), Buckeye Hall of fame, Columbus, OH, March 10, 2009.