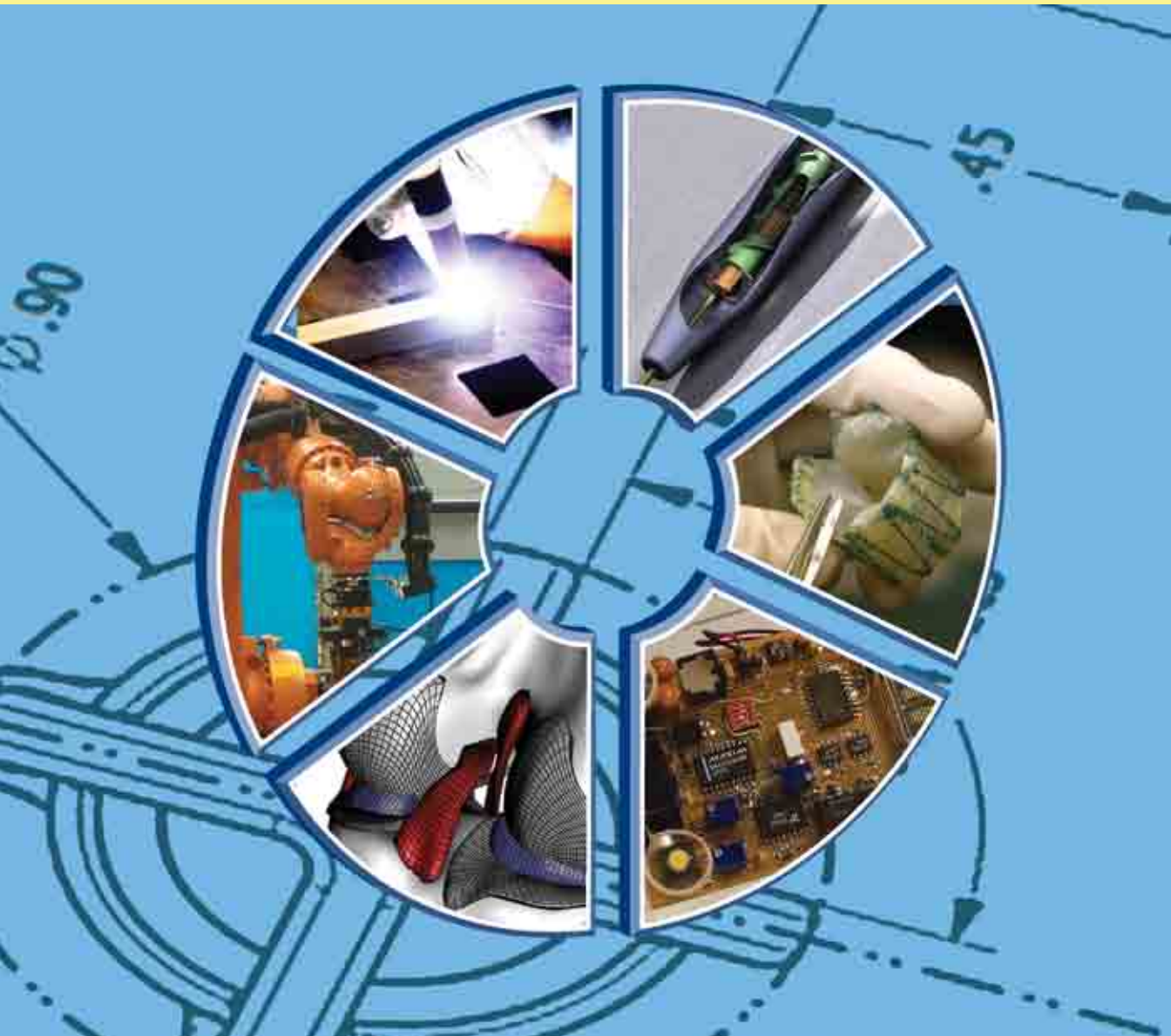
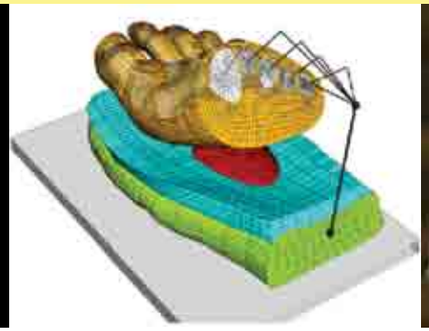
Cleveland Clinic
Lerner Research Institute

Medical Device Solutions



Core Mission



Our Mission:

"To promote the development of innovative medical devices that will advance patient care."

Medical Device Solutions (MDS) was created to act as a bridge between clinical ideas and licensed medical devices. Our experience in medical device development can quickly and efficiently transform your promising new device ideas into functional prototypes.

Such functional prototypes are needed to demonstrate the technical feasibility and clinical utility of a new concept. These are both key points when establishing a new product's commercial viability.

We use our engineering expertise, in-house mechanical and 3D rapid prototyping capabilities, state-of-the-art equipment, and our new Nitinol Commercialization Center to create the next generation of medical devices.

MDS is staffed with a multi-disciplinary team of professionals who have extensive experience in medical device design, prototyping and product development. Our staff also has commercial experience, including project management and design for manufacturability.

MDS strives to develop strong collaborations throughout Cleveland Clinic, forming teams to advance new technologies. We work closely with Cleveland Clinic Innovations and outside medical device companies. All of our work is kept strictly confidential.

To stay on the cutting edge of medical technology, we remain active in Cleveland Clinic research and product development programs.

Six technical specialty groups form the integrated MDS Core:

- BioRobotics
- Computational Biomodeling
- Electronics
- Engineering & Design
- Mechanical Prototype
- Polymers

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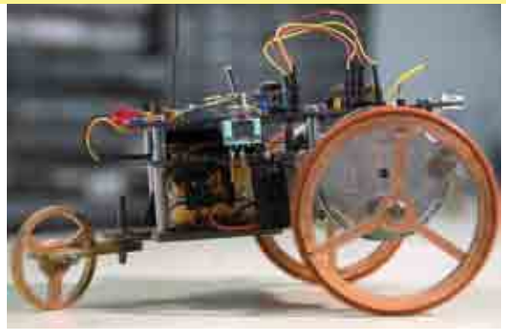


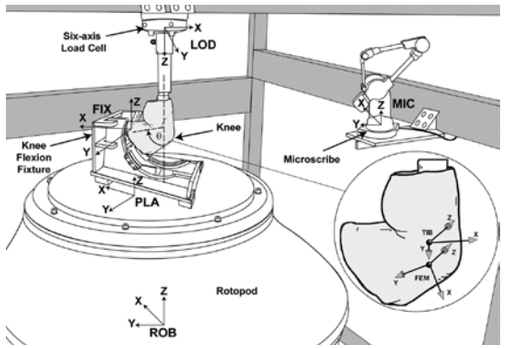
BioRobotics and Mechanical Testing Core (BRMTC) is a fee-for-service facility providing a center of excellence for biomechanical testing of biological structures and biomaterials.

Our mission is to employ world class facilities to allow investigators to conduct high quality research of the mechanical properties of existing biological structures and constructs, as well as to quantify the potential for new technologies and clinical advancements.

The BMRTC provides testing capabilities for a wide range of biomechanical modalities and will offer expert advice and support for development of new test protocols, as well as innovative techniques for instrumentation and data collection. Modalities include tissues, joints, and multi-articular units, such as foot or spine segments.

Robotic Universal Musculoskeletal Simulator (UMS) Testing Systems:

- Knee
- Hip
- Spine
- Shoulder
- Foot/ankle complex

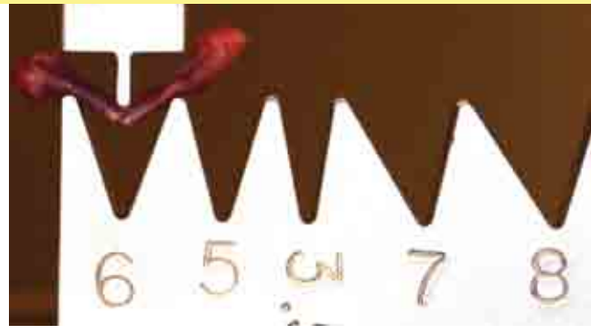


The UMS allows researchers to simulate loading conditions on cadaveric joints by using actuators to simulate muscle forces and simultaneously contact the joint with an external load. Applications of this type of testing are numerous and can be used to provide insights into orthopedics, tissue engineering, fracture healing and treatment, joint kinematics, surgical techniques, disease pathologies, and many others.

Uniaxial and Biaxial Testing Systems:

- Tendons & Ligaments
- Bone & Cartilage
- Skin & Muscles
- Cornea & Sclera
- Implants, Orthotics & Limbs

BioRobotics



Biomechanical Phenotyping Of Genetically Altered Animal Models Can Provide Insights Into:

- Orthopedics
- Tissue engineering
- Fracture healing and treatment
- Joint kinematics
- Surgical techniques
- Disease pathologies

The BMRTC also specializes in biomechanical phenotyping of genetically altered animal models. Biomechanical testing methodologies can be used to study the roles that certain deleted or altered genes play in specific differentiation pathways, or the influence specific proteins have on the mechanical properties of tissue.

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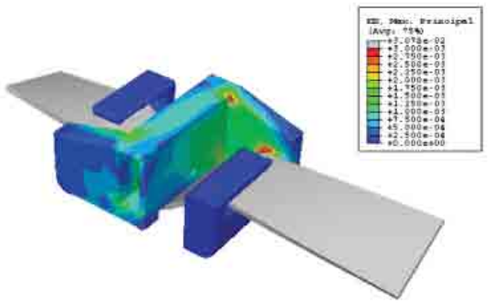


Computational Biomodeling (CoBi) provides solutions for physics-based computer simulations of biological systems. In computational modeling, one searches for the representation of the essential aspects of the biological system in a usable form. While description of the system with mathematical equations provides this form, a.k.a. model, useful information is extracted by solving these equations numerically, a.k.a. simulation.

Successful realization of the modeling & simulation process establishes virtual test beds to explore the system. CoBi Core provides services for application specific model development and simulation platforms to complement experimental approaches. Our ultimate goals are to enrich our understanding of biological systems and to promote simulation based medicine.

Our expertise helps formulation of the biological system, including multilevel interactions among cells, tissues and organs, and simulate its response as it interacts with the environment and other systems. Along this direction, our capabilities include providing the know-how for:

Numerical analysis

- Finite element analysis
- Optimization

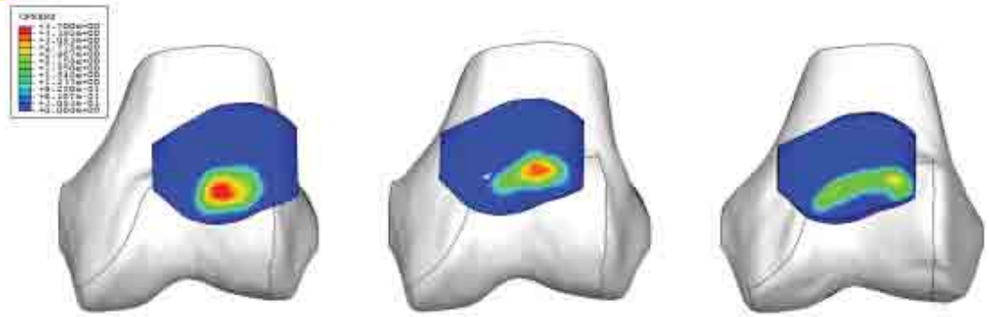
Research support

- Musculoskeletal biomechanics
- Tissue mechanics
- Predictive simulations of musculoskeletal movements
- Quantification of tissue deformations
- Concurrent simulation of multiple pyhsiological domains
- Multiscale coupling in tissue mechanics
- Coupling of numerical analysis approaches

Translational investigations

- Interface development for massive and or expedited modeling & simulation
- Patient-specific/specimen-specific modeling

Computational Biomodeling



- Inverse analysis for in situ characterization of tissues
- Simulation-based evaluation of surgical procedures
- Assessment of therapeutic interventions
- Virtual prototyping for medical device design

CoBi Core follows many national and international initiatives for biomedical computation and modeling, e.g. SimTK, Physiome, Living Human, and contributes to these efforts when possible.

We utilize the latest state-of-the-art approaches among a variety of disciplines: engineering, physiology, and computer science.

Our team is interested in discussion with the investigators of diverse biological disciplines to explore potential collaboration paths, or simply to enjoy the excitement of scientific discovery through modeling and experimentation.

Photo Images:

Top left:
CoBi Core utilized finite element analysis to develop a buckle transducer for harness force measurements. The device is currently used by NASA at the International Space Station to record loading of the shoulders and hips of the astronauts during exercise countermeasures.

Top Right:
Computational modeling provides a platform for a-priori testing of the performance of surgical procedures. In orthopedics, such investigations can be used to predict the outcome of trochlear osteotomy targeted for the correction of patellofemoral instability but may also confirm that undesirable contact pressures in corrected joints do not exist.

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Electronics

Electronics

The **Electronics** facility is an electronic design, fabrication and repair laboratory that specializes in custom electronics, electro-mechanical systems, transducers and optics for biomedical applications.

We have extensive experience in all aspects of medical research instrumentation. Our specialties include:

- Low-power circuits & telemetry
- Bio-electric signal amplification and processing
- Ultrasound, motion control & spectroscopy
- Imaging & data acquisition
- Sensors for pressure, flow, temperature, force, displacement, and gas concentration

We have developed systems for many different biomedical disciplines including, cardiology, orthopedics, neurology, gastroenterology and otolaryngology.

Devices developed in Electronics:

- Algorithms and hardware
- Control and data system for Continuous Flow Total Artificial Heart
- Radio controlled, programmable, actively steerable guide wire
- Portable data recorder for NASA astronaut bone loss study
- Implantable system for long-term telemetry of in vivo Oxygen tension in bone
- Computer controlled system for plating radioisotopes onto coronary stents
- Highly programmable coupled pacing pacemaker with telemetry
- Wheelchair with wireless eye-blink control system

Design expertise:

- Analog, digital, mixed signal
- Laser and optical systems
- Ultrasonic imaging
- Microcontrollers, SBC's
- Ultra-low-power and implantable circuits
- Wireless data acquisition and control (RF, RFID, IrDA, Blue Tooth)
- Motor controller/driver and motion control
- Sensor-based systems
- GUI, PC interface, and custom control
- LabVIEW programming and support
- PCB design and manufacturing

Data acquisition system design:

- We offer consultation on transducer selection, as well as strain gauge application and custom transducer design
- Computer operated or stand-alone systems
- Design and setup of data capture and storage systems

Laboratory and office equipment repair:

- We are able to repair most electronic or electro-mechanical equipment at rates that are comparable to outside vendors
- Many instruments are available for short-term loan while your equipment is being serviced

Resources include:

- LPKF Protolaser S system for rapid high resolution PCB production
- Rayproof™ high performance shielded room
- Two printed circuit board rapid prototyping systems
- LPKF Protomat S100 circuit board milling machine
- T-Tech Quick Circuit 7000 circuit board milling machine
- Lindgren radio-frequency shielded room
- Agilent 4-channel 2GS/s oscilloscope
- Orcad and Protel electronic design automation schematic capture and printed circuit board (PCB) layout software
- Surface mount PCB assembly stations
- Integrated calibration system & HP precision LCR meter
- HP precision arbitrary waveform generator

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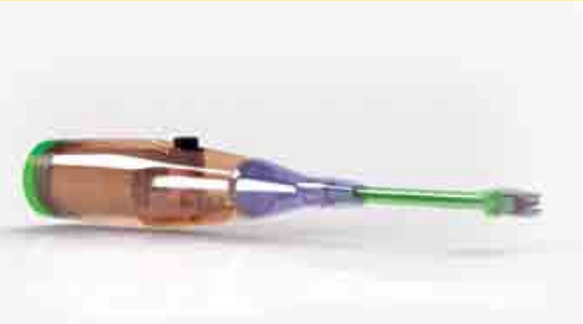
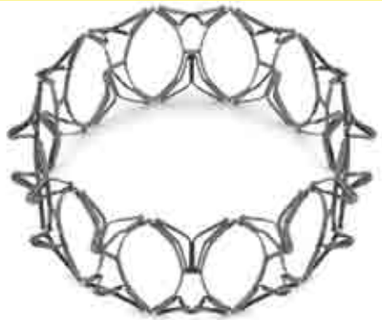
Engineering & Design

Engineering & Design





The **Engineering & Design** group consists of mechanical and biomedical engineers who focus on research and development related to new medical devices. Our team combines years of experience in the medical device field with state-of-the-art tools, including computer-aided design software, finite element analysis, digital anatomic reconstruction and rapid prototyping to develop new medical devices.

We have the resources to evaluate technology designed by groups external to the Cleveland Clinic. We can perform device testing through clinical trials or by bench testing, animal model testing, and surgical testing in the operating room.

We serve as subcontractors on Small Business Innovation Research (SBIR) grants sponsored by the National Institutes of Health. In addition, we have taken the lead role on state, federal and foundation research projects.

Our experience includes:

- Initial conceptual design
- Device development using Nitinol
- SolidWorks, Pro/ENGINEER & Solid Edge CAD software
- Mimics, Magics and TeraRecon digital anatomic reconstruction software
- Prototype fabrication
- Prototype testing and refinement
- Process development
- Modeling analysis
- *In vitro* and *in vivo* testing
- Rapid Prototyping (3D printing, SLA)

Our design group also has commercialization experience, including project management and design for manufacturability. Partnerships between Cleveland Clinic investigators, physicians and outside firms extends our capabilities.

We work extensively with the other MDS groups as needed to make each project a success.

MDS designed and developed the Instrumented Harness Buckle for NASA (as shown below). The harness will be used by astronauts while exercising in space and was tested on the International Space Station. **Top photo:** buckle prototype; **Bottom photo:** harness strap with functional prototyped buckle.

Recent engineering projects include:

- Custom otoscope device with laser beam to diagnose pediatric middle ear effusion
- Novel mitral stent-valve replacement device with percutaneous delivery
- Mechanical design, development and testing for above the knee amputee prosthetic device
- Tonsil massaging device to treat tonsil stones
- Adjustable inflow cannula for ventricular assist device heart pumps
- Novel head-rest support device with three degrees-of-freedom
- Pulsatile tissue culture bio-reactor
- Developed 50 unique iliac models for large medical device company

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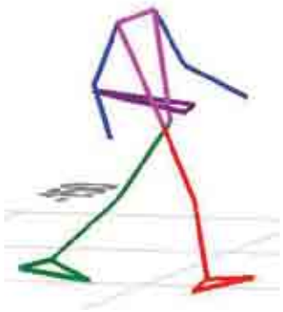
Gait Lab



The **Gait Lab** primarily works with patients who have neurological conditions that affect their ability to walk or maintain postural stability. We can perform data analysis on their gait and posture by using a variety of high-tech equipment and software.

We have worked with amputees completing a variety of activities of normal daily living to help in designing a prosthetic knee device.

What the Gait Lab can provide:

- Motion capture data for various activities (gait, activities of daily living, etc.)
- Temporal and Spatial Data for gait analysis – cadence, velocity, step stride length, step width, etc.
- Kinematic Data – various joint angles (focus on lower extremity)
- Kinetic Data – joint forces, moments, and powers in addition to ground reaction forces (focus on lower extremity)
- Kistler Force Plate provides a postural stability assessment and calculates the path of the center of pressure while standing still for a length of time.
- Instrumented treadmill provides ground reaction forces for both feet simultaneously in X-, Y-, and Z-directions for a continuous walk at various speeds.
- Typical gait analysis lasts approximately one hour per patient and data analysis usually can be completed within a week after data collection (usually a couple days).

Equipment:

Motion Capture System:

- 8 infrared Eagle Digital RealTime System (Motion Analysis Corporation cameras mounted on the walls to collect motion capture data.
- EVaRT and Cortex software: Under a single software environment we can set up, calibrate, capture motion in real-time, capture motion for post processing, edit and save data in the format of your choice.
- OrthoTrak software: OrthoTrak is a fully automated, three-dimensional, clinical gait measurement, evaluation and database management system. OrthoTrak allows the clinician to easily record the patient's physical measurement data with the gait report, and quickly compile technical data into simple, easy to read, charts and graphs.
- Adhere reflective markers to the body at specific anatomical locations and record various motions in the center of the lab (gait, activities of daily living, sports, etc.)

AMTI Force Plates: Two small force plates and one large force plate in the ground to provide kinetic data.

Kistler Force Plate: Another force plate used for measuring center of pressure and postural stability. Collect and analyze data with BioWare software.

Head Accelerometer: A head accelerometer test may be combine while performing the postural stability analysis on the Kistler force plate.

Instrumented Treadmill: A dual-belt dynamometric treadmill for the continuous dynamic measurement on each leg, and recording of the 3 spatial components (3D) of the ground reaction forces while walking.

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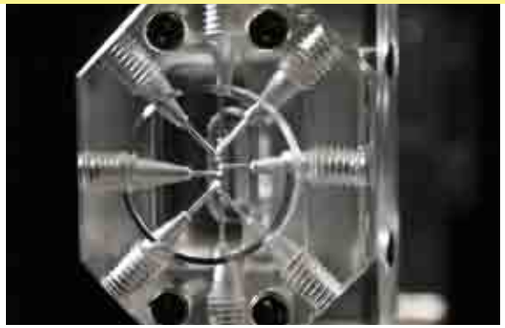
Gait Lab

Recent Studies in the Gait Lab:

- Normal Pressure Hydrocephalus Study – gait analysis, instrumented treadmill, center of pressure force plate, accelerometer
- Multiple Sclerosis Study – gait analysis, and Hip Flexion Assist Orthosis Study with MS patients
- Cerebral Palsy patients – gait analysis
- Third Frontier Prosthetic Knee Project – gait analysis, activities of daily living
- Parkinson's DBS Research – center of pressure force plate
- Throw Right – baseball pitching biomechanical analysis
- Golf Study – golf swing biomechanical analysis and EMG
- NASA Instrumented Harness Study – instrumented treadmill
- Exotendon Research Study – gait analysis, instrumented treadmill, and EMG

Mechanical Prototype

Mechanical Prototype



The **Mechanical Prototype** staff is highly skilled in a variety of fabrication, customization and repair services for mechanical devices and equipment.

We are proficient in precision machining of metals and plastics, welding of structural and exotic metals, instrument refurbishing and mechanical repair.

Our personnel can work from concept sketches to design and fabricate new devices, test research fixtures & equipment.

Documentation of the newly created part or device is also available through two-or three-dimensional computer-aided design (CAD) drawings.

Software used:

- Pro-ENGINEER
- SolidWorks
- AutoCAD software

CAD drawings can be converted into computer-aided manufacturing (CAM) programs that are directly fed into the Computer Numerical Control (CNC) machines or Rapid Prototyping machines to fabricate the desired parts.

What we can do for you:

Fabrication Capabilities:

We have created high-precision devices for a wide variety of clinical and research applications. Examples of devices we produced include:

- Acrylic cranial windows
- Brain tissue environmental chamber
- Myocardium rapid-freezing device
- Mitral valve repair frame

Our expertise allows us to develop custom devices suited for your needs. Some of our machining equipment includes:

CNC Machines

- 5-axis Vertical Machining Center
- 4-axis Turning Center
- 4-axis Wire EDM
- 2 1/2-axis Vertical Mills

Manual Machines:

Vertical Mills

Generates complex geometries. Machinable materials include metals (surgical stainless, implant materials, etc.), polymers (autoclavable, high-impact resistant, load bearing) and ceramics.

Lathes

Three engine lathes of various sizes are specially suited for high precision custom work. Capabilities range from turning large diameters (21”) to holding to high tolerances (0.0002”).

Multiple Welding Disciplines

Our TIG (Tungsten Inert Gas), Oxy-Acetylene and Arc welders allow us to weld a variety of materials including stainless steel, steel, aluminum and titanium.

Precision Surface Grinding

Three types of grinders allow us to machine hardened materials such as chromium cobalt, hardened tool steels, carbides and heat-treated stainless steels to extremely close tolerances.

Surface Finishing

To give devices a good looking outer finish we use either one of our two bead blasting methods. We have aluminum oxide beads that give a slightly dimpled finish, or silicon carbide chips that give a deeper etched finish.

Heat Treating

With our high precision temperature-controlled programmable electrical furnace, we can provide a range of heat treatments for steel items up to 4” x 6” x 12.”

Shears/Breaks

Standard metalworking equipment is available for shearing, bending and forming sheet metal and bar stock.

Plastics shop

Our plastic shop is where most of the fabrication of acrylic, polypropylene, and other plastics is performed. The shop also handles wood in order to make fixtures for various projects.

Instrument Refurbishing

Old, dull and/or damaged instruments can be returned to like-new condition. We sharpen, polish, weld, straighten and make replacements for broken or lost components. Metallic instruments can be uniquely labeled using our etching process.

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Nitinol Commercialization Center

MDS is pleased to announce that Cleveland Clinic's regional **Nitinol Commercialization Center** of expertise is now taking orders.

Nitinol is a relatively new alloy that is being incorporated into commercial applications because of its extraordinary shape memory and superelastic properties.

"Shape memory" means that the alloy can "remember" its shape; after being deformed it returns to its original shape through the application of heat. "Superelasticity" refers to the fact that nitinol has the ability to withstand up to 8% recoverable deformation, which is approximately 40 times greater than typical metals.

Current biomedical applications using nitinol:

- Cardiovascular stents
- Guidewires
- Minimally invasive surgical tools
- Self-locking orthopedic devices
- Orthodontic wires

Nitinol capabilities include:

Build prototypes for medical devices

- Small quantities with a low price
- Quick lead times
- Heat Treatment, Lasercutting, and Shapesetting

Material Processing

- Shape memory
- Bioresorpable polymer
- CoCr, MP35N
- 316LSS

Material Testing

- Radial stiffness
- Pinch compression
- Body temperature and room temperature material properties characterization.

Design Expertise:

- Fixture and medical device design
- CAD (computer aided drawing)
- ProENGINEER and SolidWorks compatible
- Laser programming for complex geometries

Melissa Young, PhD | 216.444.1793 | youngm7@ccf.org

Nitinol Commercialization Center

Athermal Lasercutter:

- Latest Technology: Sub picosecond pulse ionizes the target material that is electrostatically ejected from the substrate. The material ejection occurs much faster than the heat transferred to the surrounding areas, resulting in an athermal process.
- Minimal heat affected zone (HAZ)!
- Straight cuts can be made in a single pass
- Ultra fine kerf < 20 microns
- Wall thicknesses < 0.7mm
- 4 axis for intricate geometries

Lasercut designs from tube or flat sheet

- Tube diameters from 0.3mm up to 10mm
- Sheet dimensions 12"x 12"

Heat Treatment/Shapesetting:

- Detect and set phase transformations
- Austenite (A_f) optimization
- Fluidized bath heat treatment operating temperatures from +50 to 700°C, with accurate temperature stability ±0.2°C

Current Projects:

- Aortic stent grafts
- Ablation stents
- Heart valve support frames
- Sutureless clips
- Orthopedic attachments
- Novel medical products

Polymers



The **Polymer Laboratory** supports research and product development efforts where polymeric and biologic materials are required. The laboratory uses both synthetic and natural polymeric materials such as:

- Polyurethane
- Polyolefin
- Silicone
- Epoxies
- PVC & Natural rubber

Biologic materials include:

- Gelatin
- Hyaluronan
- Pericardial Tissue

After fabricating the materials or devices, we work closely with researchers and clinicians to support the evaluations of the new technology.

We have participated in projects to manufacture items as diverse as components for artificial heart programs including:

- Pump Diaphragms
- Inflow and Outflow Cannulas
- Heart Valves
- Sewing Cuffs
- Casting and ejection molding blood pump housing and fittings
- Blood-compatible internal coatings
- Transparent devices for flow pattern studies
- Implantable parts with pore textured surfaces for optimal cell tissue growth

The 900 square foot Polymer Lab consists of three main areas:

1) A class 100 clean room and transitional gray room for bioprosthetic valve fabrication and biomaterials processing.
2) A main laboratory room for polymer processing equipped with fume hoods, glove box, forced air and vacuum ovens.
3) A molding room equipped with a canopy hood and hydraulic press for compression molding and dip or solution casting, and an injection molding press.

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Polymers



Technical Support & Services:

- Device design and prototyping
- Device testing
- Compression molding & vacuum forming
- Dip and solution casting & mold casting
- Carbon fiber epoxy composite materials manufacturing,
- Bioprosthetic tissue valve fabrication
- Blood compatible polymer surface treatments
- Polymer mold design and fabrication
- Support of biologic and polymeric materials testing
- Polymer procedure & process development
- AutoCAD and Pro/ENGINEER drawing documentation
- Provide polymer and biomaterial process control specifications
- Consulting and technical training

Equipment:

- DYMAX Ultraviolet Light Source Model 5000-EC
- Glass 1000 laminar flow bench
- ONPCO Vacuum Oven Model 5851
- Blue M Oven Model OV-510 A-3
- Wisconsin Oven Model ULE-500
- MINI JECTOR Ejection Machine Model #70, Chromed, with Ventilation System
- P.H.I. Hydraulic Presser Model B-243-M4 with Ventilation System
- LABCONCO Glove Box
- WILD M3Z Dissecting Microscope with camera
- Explosion Proof Refrigerator
- Fume Hoods
- Class 100 clean room

Rapid Prototyping

MDS has two 3D **Rapid Prototyping Printers** from Objet™: an Eden 260 and a Connex 350. These machines are used to build prototype parts for use as models or functional prototypes. Due to the additive nature of the build process, complex parts can be made that sometimes aren't possible with a traditional method of manufacture. Anatomical geometry taken from CT or MRI scans can be built as easily as a designed part. These machines allow us to build parts within hours.

The 3D printers use a technology called "PolyJet" to build part models in very small vertical layers. On each layer the cross-section shape is generated by depositing light-sensitive liquid resin and immediately curing it in place with a UV lamp, thus solidifying the resin.

The tray supporting the part then moves down and the next cross-sectional layer is deposited. The vertical resolution of the machine is 0.0006" (0.016mm) while the horizontal resolutions are 0.017" (0.042mm) x 0.017"(0.42mm). The fine resolution enables building prototype parts with very small detail.

The Objet 3D printers currently have 13 unique materials available, including both rigid and flexible, rubber-like types. The Connex can even blend two discrete materials together, forming what Objet calls "Digital Materials" and enabling an additional 41 materials for selection.

Partial list of materials:

- FullCure 720 - rigid, transparent, yellow
- VeroClear- rigid, transparent, clear
- VeroWhite - rigid, opaque, white (black, blue, gray also available)
- TangoPlus - flexible, translucent, clear (black & gray also available)
- RGD5160-DM - ABS like material (green)
- MED610 - Bio-compatible (rigid, clear)

Applications include:

- Demonstration models
- Anatomical models
- Fuctional prototypes
- Molds for silicone rubber molding
- Building models from CT, MRI or other imaging systems
- Parts can be painted, dyed & machined

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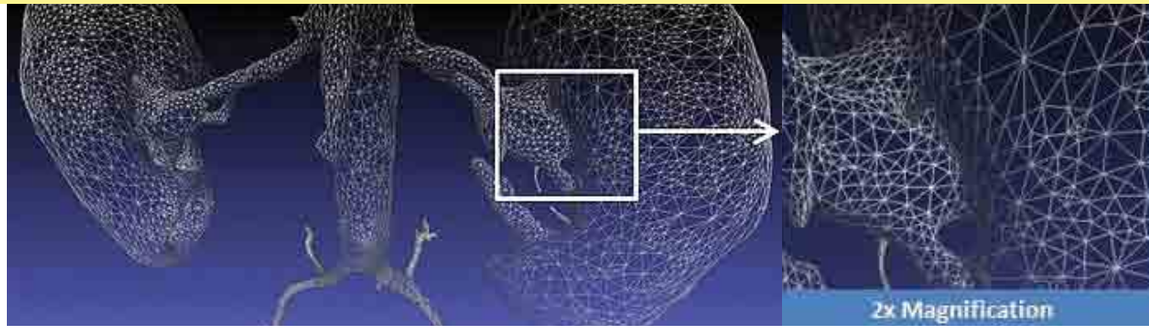
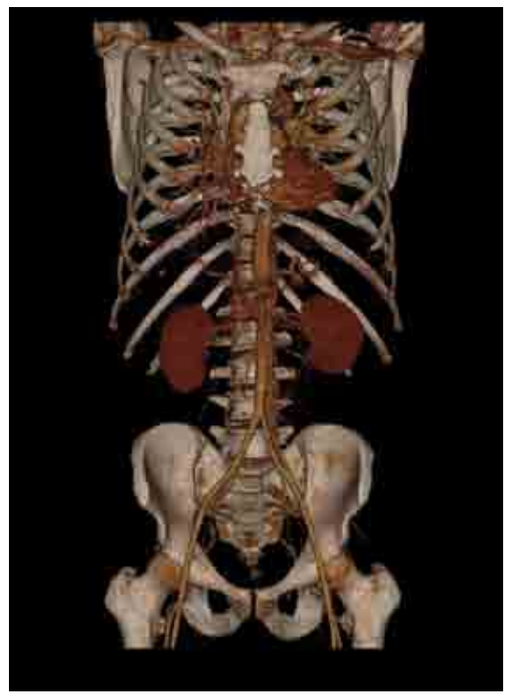
Medical Imaging Analysis



The **Peripheral Vascular Core Lab (PVCL)** has partnered with MDS to offer a medical image post-processing service that provides three dimensional geometries of nearly any anatomical structure. Geometries are obtained from medical imaging (CT or MRI) identified by PVCL that meet predefined anatomic and disease criteria. The required anatomic surface or volume is then converted to a sharable digital format (i.e. STL file) compatible with engineering and modeling software or the Rapid Prototyping Service can use the digital file to create a 3D print.

- Accurate 3D Anatomic Geometry Surfaces and Volumes
- Digital Files generated from our available medical imaging (CT/MRI) or yours
- Any anatomical structure (Cardiovascular, Orthopedic, Oncology…)
- Normal, Diseased, and Device Implanted Anatomy
- Digital files can be used to support engineering, computer modeling, and 3D printing



The PVCL has over 20 years of experience of providing central lab medical imaging analysis for clinical trials in all phases. PVCL image analysis has been utilized to support everything ranging from product R&D to FDA submission.

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CAREN system

The **CAREN system** is a high-tech medical and research system for human balance and locomotion. CAREN (Computer Assisted Rehabilitation Environment) is a hardware and software system for registration, evaluation, and training of functional human behavior.

Subject's are immersed in a true multi-sensory virtual reality (VR) experience pertaining to the Visual, auditory, Vestibular, tactile and proprioceptive systems of the human body.

This system is truly multidisciplinary and will enable collaborative works with rehabilitation experts, orthopedics, occupational therapists, physiotherapists, neurologists, pediatrics, mental health, and research.

The real-time feedback system registers and reacts faster than human perception and faster than any other system.

Applications in clinical analysis:

- Assessment and identification of balance compensation anomalies and related postural stability problems
- Measuring and correcting gait problems arising from inefficient muscle usage
- Early identification of degenerative muscular conditions and dysfunctions
- Identifying neural substrates of task difficulty and cognitive effort
- Identifying and training muscle control on hemi paresis, TBI and neglect patients
- Early detection of muscular dystrophies

Applications in rehabilitation:

- Improving well timed protective extension, reaction to perturbations
- Training of muscle coordination and strength with amputees and joint replacements
- Rehabilitation and training of osteoarthritis patients
- Neurological rehabilitation of spinal cord injuries and diseases, paresis, TBI and neglect
- Prosthetics fitting and alignment

Notes

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