Mechanical Characterization and Stimulation Solutions for Medical Device Applications


What good is an idea if it remains an idea? Try. Experiment. Iterate. Fail. Try again. Change the world.
- Simon Sinek


The Finals
@NBA
OLDEN STATE


WARRIORS
GOLDEN STATE
KAISER PERMANENTE
DURANT
35


adidas
LOCKER ROOM
AUTHENTICS


Broken
stem

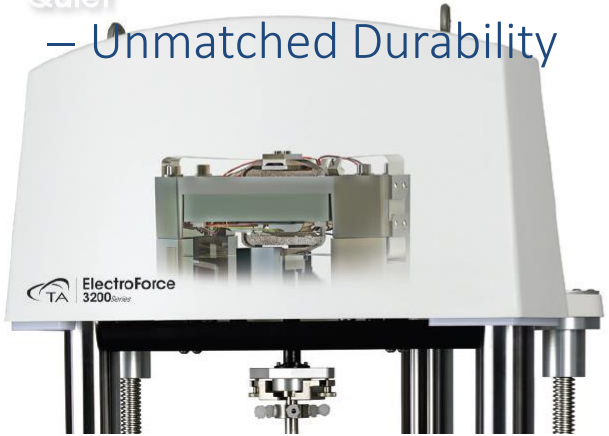
1990 - 2004

2004 - 2015

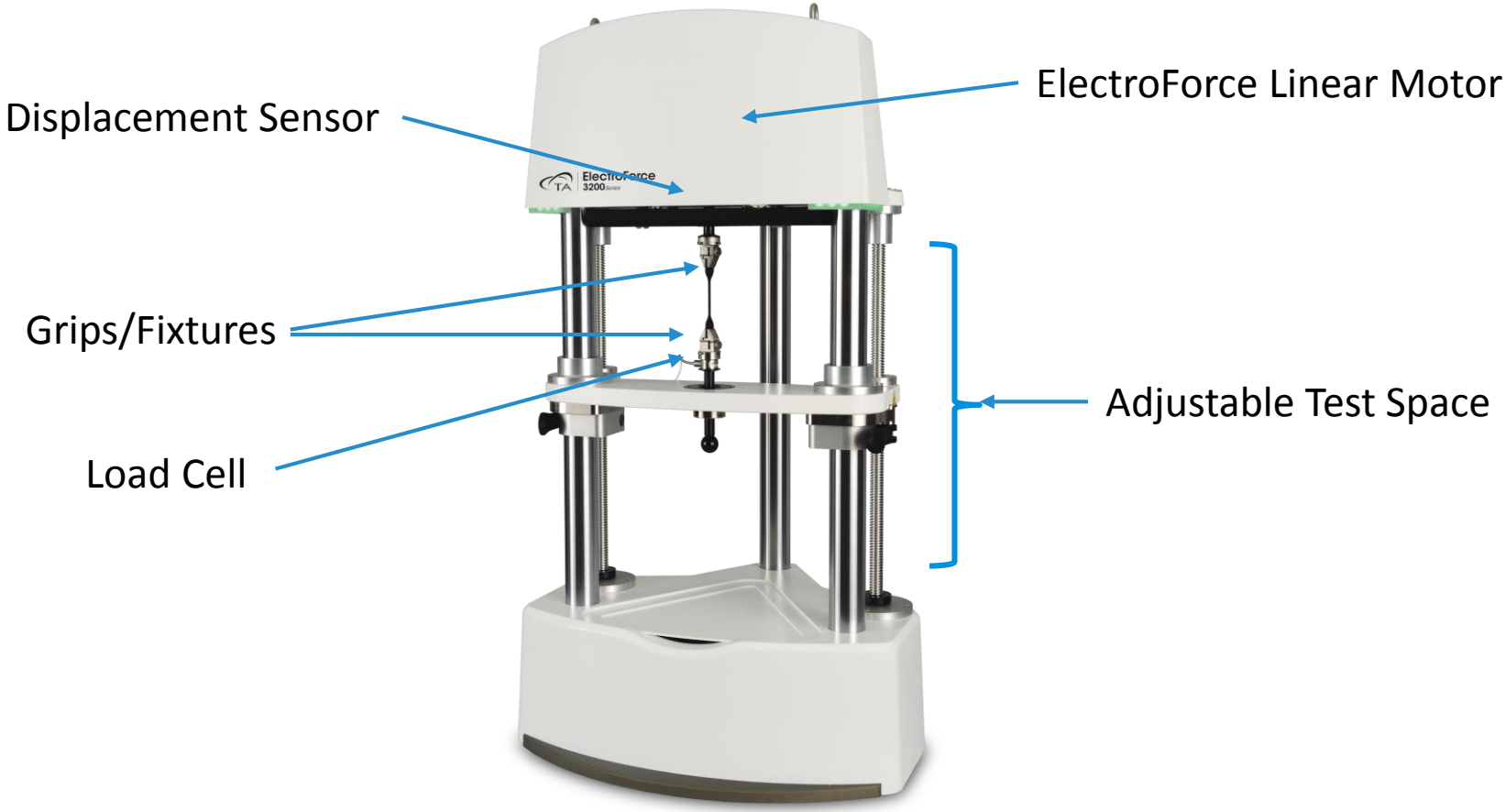
2015 - Present

Linear Motor Technology

- Direct Drive Electromagnetics
  - Highest Accelerations
  - Precise
  - Clean & Quiet
  - Unmatched Durability

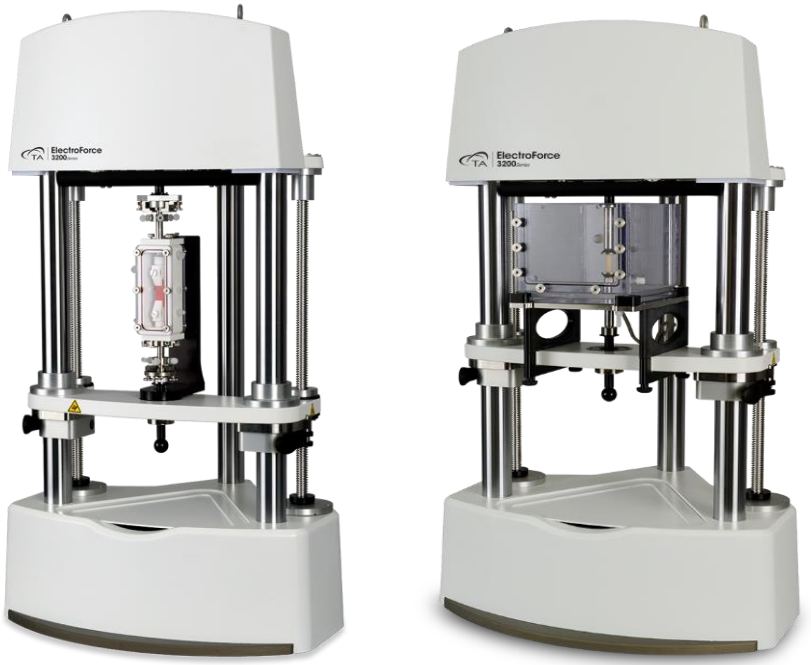


ElectroForce Load Frame Architecture

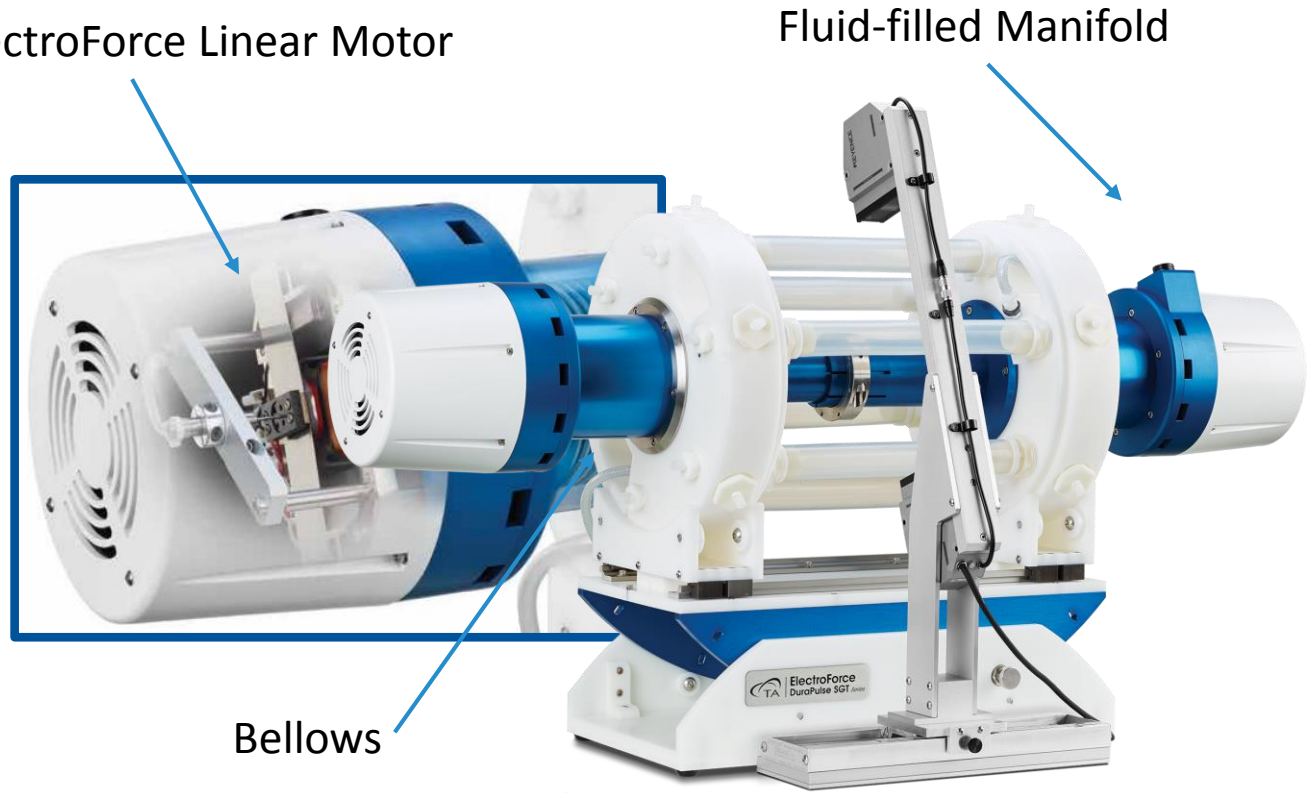


ElectroForce Load Frame Accessories

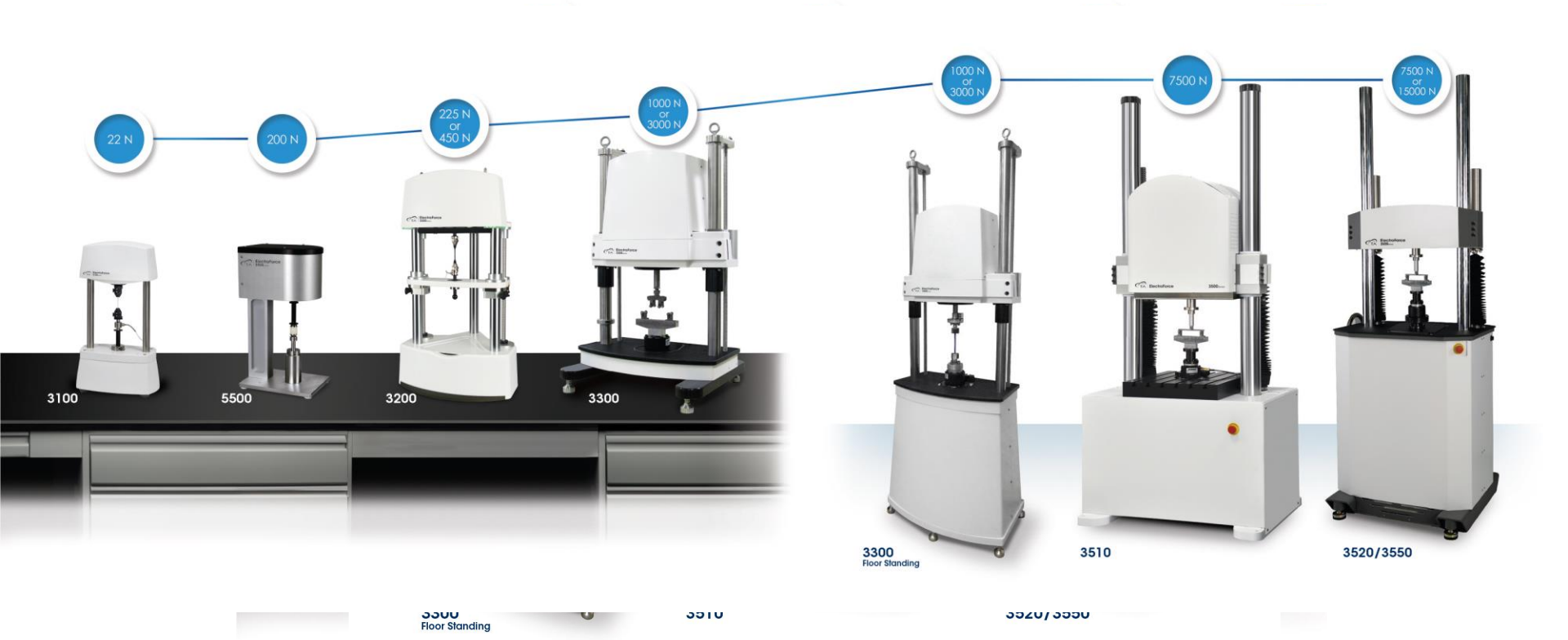
- Torsion motors
- Extended Stroke (ES) Motor
- Heated saline bath
- Sterile BioDynamic chamber
- Hot/Cold chambers
- Digital Video Extensometer (DVE)
- Tensile grips, TEC grips, compression platens, bend fixtures
- Multi-specimen fatigue fixture
- Low force/torque sensors, extensometers



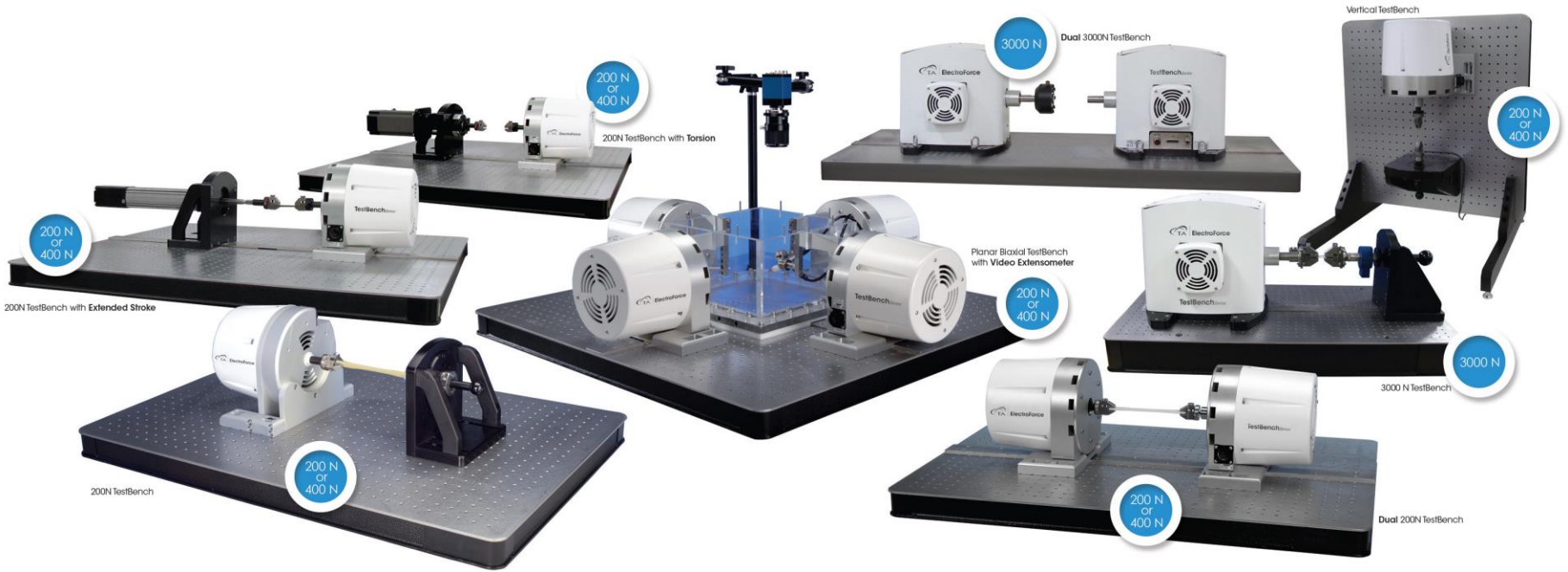
ElectroForce Stent Graft Test Instrument Architecture



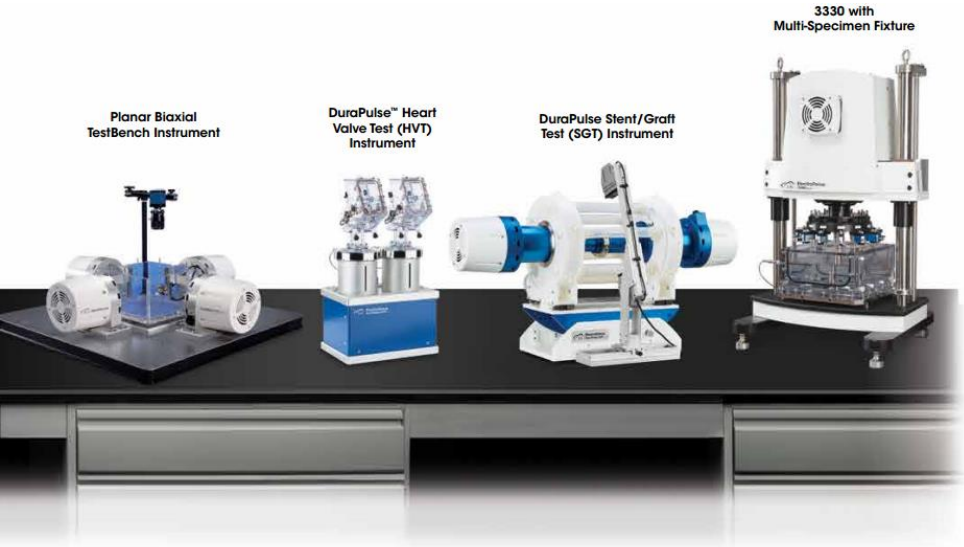
Load Frame Instruments



TestBench Instruments



Cardiovascular Device Instruments



3510 Axial Drug-Eluting
Stent Test Instrument

9210 Pulsatile Drug-Eluting
Stent Test Instrument

9400 Multi-Axial Peripheral
Stent (MAPS) Test Instrument

Key Technology Benefits

Performance

Responsive

Controllability

Versatile

Reliability

Unmatched Warranty

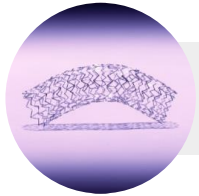
Durable

Environment

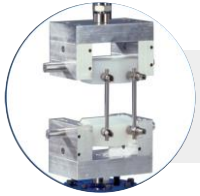
Energy Efficient

Clean

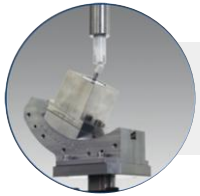
Application Examples



Cardiovascular Devices

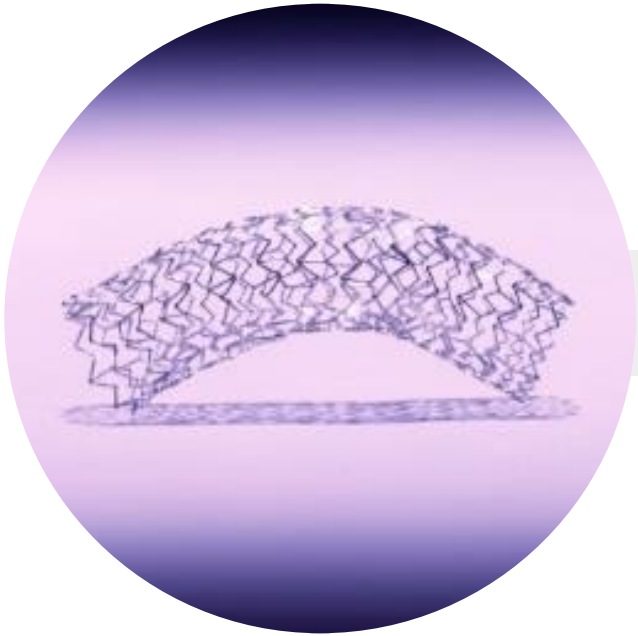


Orthopaedic Devices



Dental

Other Devices



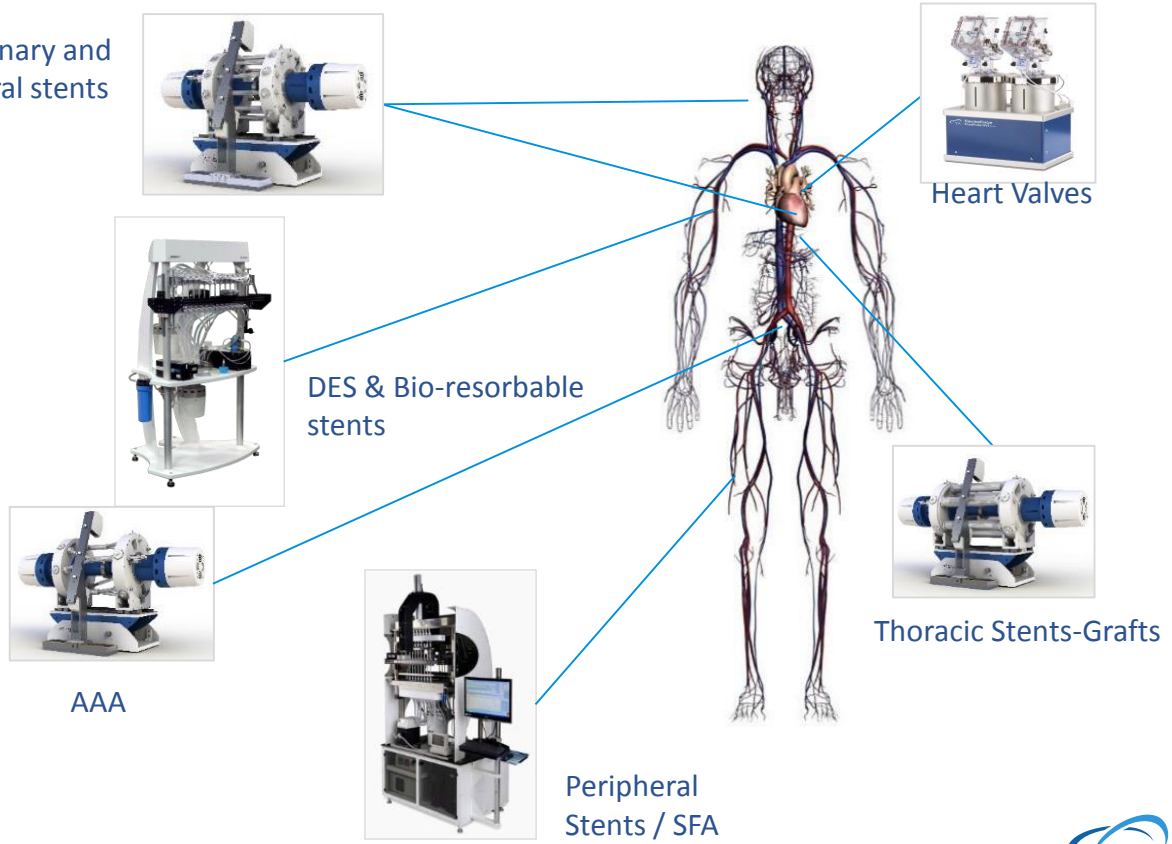
Cardiovascular Devices

ElectroForce Cardiovascular Instruments

You design the devices, we design the

BEST CARDIOVASCULAR FATIGUE INSTRUMENTS

to test them



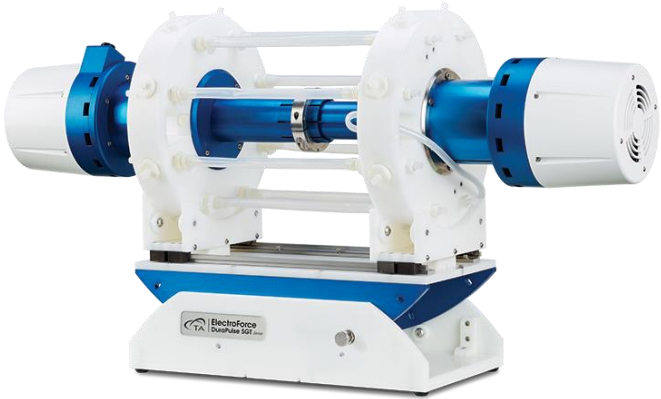
Pulsatile Fatigue of bare metal stents

Industry Need:
Simulate 10-year life cycle of bare metal stents

Research Need:
Pulsatile fatigue testing of bare metal stents at accelerated frequencies and reducing the time to market

ElectroForce Application:
A Stent/Graft Tester (SGT) running at accelerated frequencies, establishing and measuring clinical radial distensions using an optimal micrometer while testing using physiological or non-physiological silicone mock arteries

(ISO 25539-2 and ASTM 2477)



DuraPulse™ Stent/Graft Test (SGT) Instrument

Dual linear motor configuration provides industry-leading dynamic performance

Radial strain and pressure control for physiologically-relevant test methods

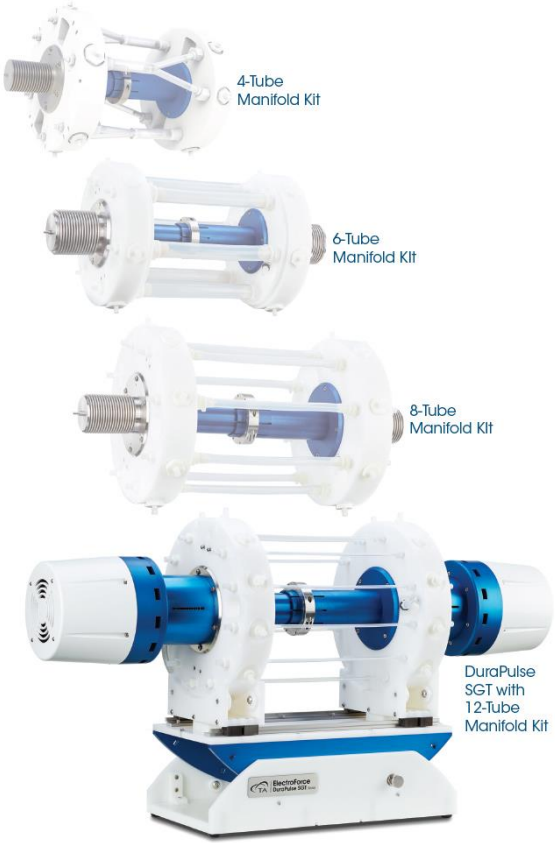
Modular manifold assemblies for testing various device sizes

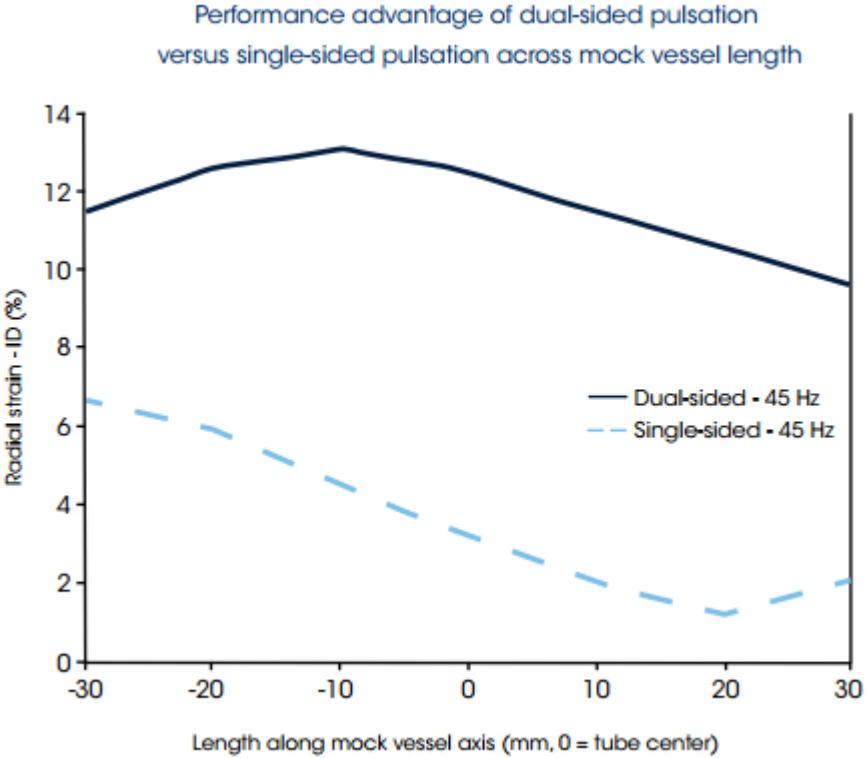
Tilting, rotating and length adjustment cradle base for varying test setups

Industry's only 10-year motor warranty offers unparalleled reliability!

DuraPulse SGT Instrument

Accessories





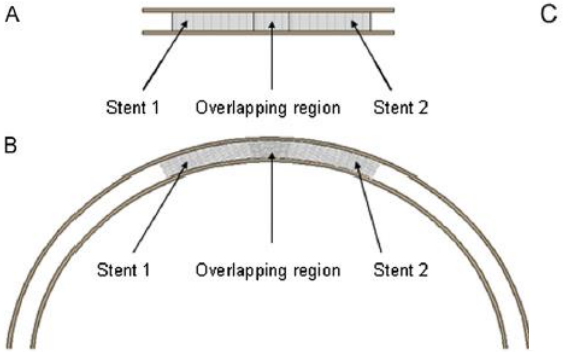
Pulsatile Fatigue of bare metal stents

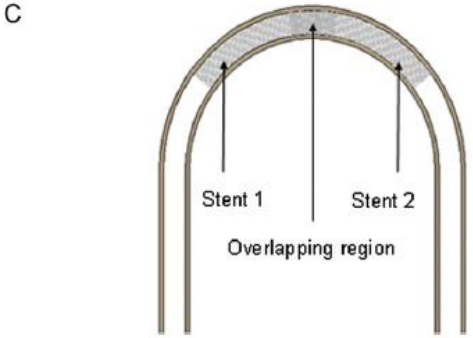
Research Need:

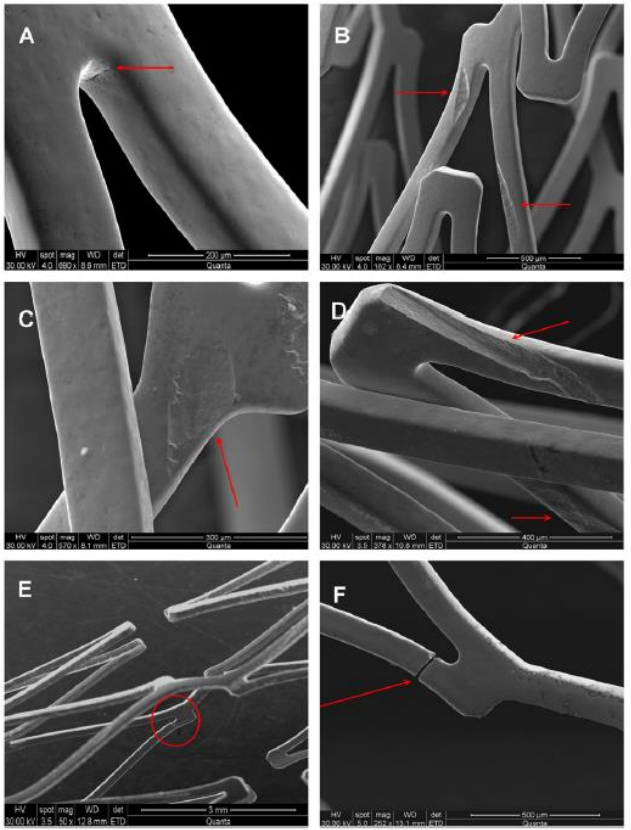
Explore effects of radius of curvature and overlapping on stent failure

ElectroForce Application:

Utilize SGT to characterize fatigue of overlapped (30%) Nitinol, CoCr, and SS stents in straight and curved (2 cm and 4 cm radius of curvature). Testing frequency of 50 – 60 Hz over 21 days (100 million cycles or 2.5 years of simulated use).







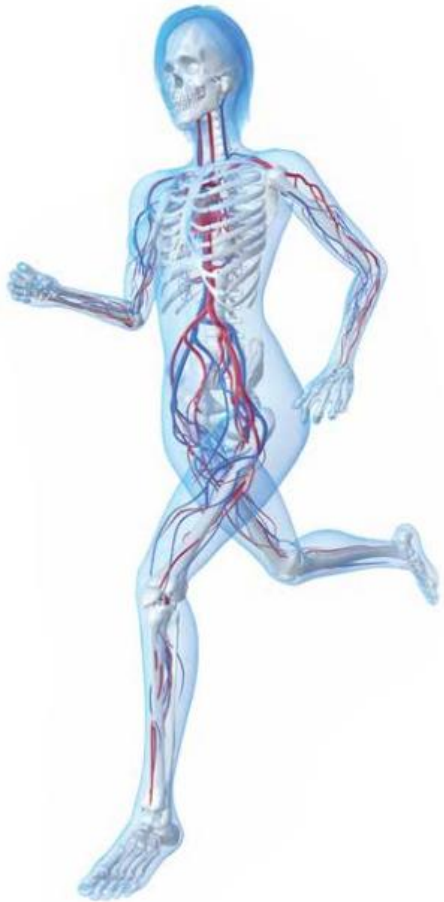
Kapnisis et al., Stent overlapping and geometric curvature influence the Structural integrity and surface characteristics of coronary nitinol stents, *Journal of the Mechanical Behavior of Biomedical Materials,* 2013, 227-236

Multi-Axis Fatigue

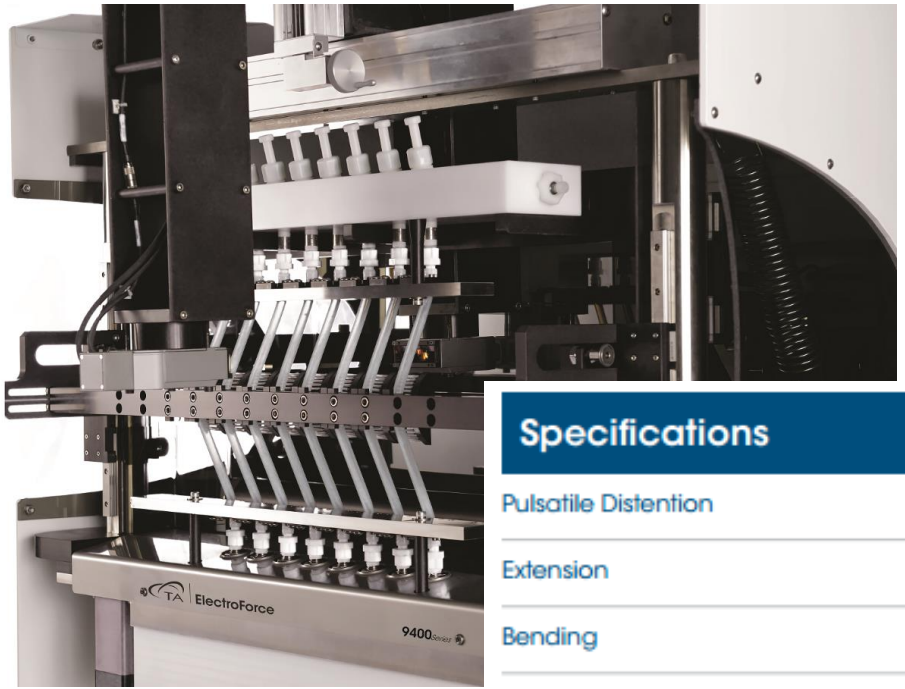
Peripheral Stent

Simulation of multi-mode biomechanical conditions found in peripheral arteries including:

- Renal arteries
- Carotid arteries
- Femoral-popliteal arteries



ElectroForce 9400 Multi-Axis Peripheral Stent



Specifications	Range of Motion	Maximum Frequency
Pulsatile Distention	0 - 5% Strain	60 Hz
Extension	0 - 20% Strain	2.25 Hz [1]
Bending	0 - 90 Degrees	2.25 Hz [1]
Rotation	0 - 60 Degrees	4.5 Hz [1]

[1] When bending, extension, and rotation motions are combined, equivalent waveform frequency is 1.5 Hz.

Pulsatile Fatigue

Drug Eluting Stents (DES)

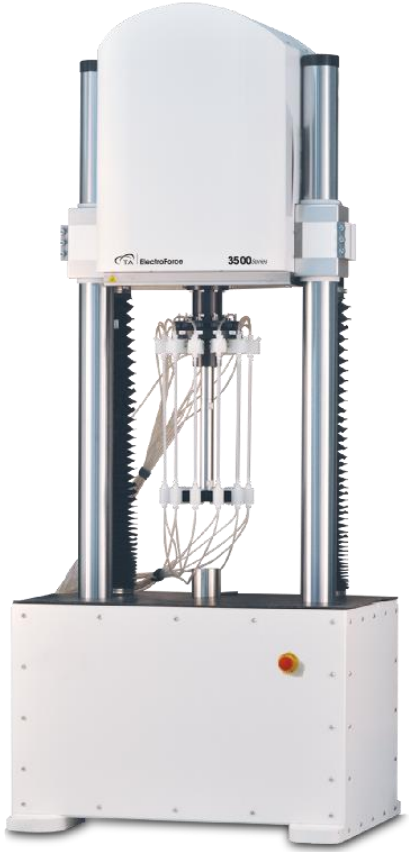
- Combine pulsatile loading with particulate capture and/or counting
- Independent flow loops to ensure proper analysis of particulate elution
- Up to 12 mock arteries per test, 2-14mm diameter

- Particulate Options:
  - Capture: Automated dual-filter design for continuous particle capture
  - Counting: Interfaces with third-party real-time particle counters
- Meets or exceeds international standards such as ISO 25539 and ASTM 2477 as well as FDA guidance documents

Multi-Specimen Axial DES Fatigue

- **Industry Need:** Evaluating coating or bioresorbing stent integrity during axial motion
- **Research Need:** Quantify particulate shedding during axial extension of stents in vessels
- **ElectroForce Application:** Stents deployed in mock vessels are cycled in longitudinal extension while flow through individual devices are measure for particulate size and rate. Test is performed with an ElectroForce 3510 with Multi-specimen DES Fixture and particulate-fluid is individually ported to third party counters.

ElectroForce 3510 with Multi-Specimen DES Fixture



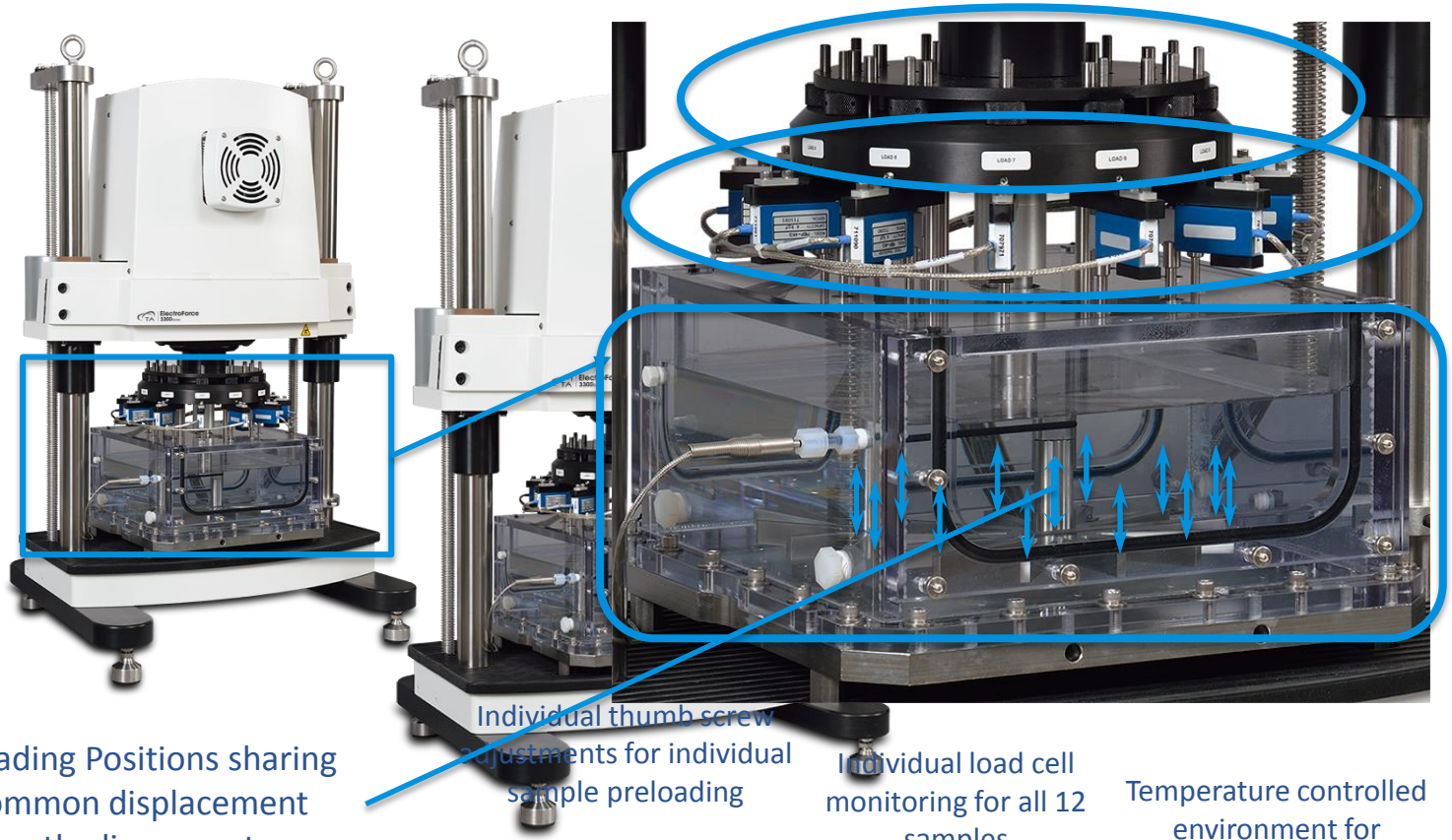
- 12 mock vessel fixture in ElectroForce 3510
- 300 mm mock vessel length
- 50 mm dynamic displacement range
- Up to 100Hz operation
- 37 deg C temperature
- 55 ml/min flow rate to particulate counters

Multi-Specimen Fatigue (MSF) Test Instruments

Other Applications

- Septal Closure Devices
- Vena Cava Filters
- Occluder struts
- Stent Compression
- Decellularized Tissue
- Delivery catheters

Multi-Specimen Fatigue (MSF) Test Instrument



12 Loading Positions sharing a common displacement from the linear motor

Individual thumb screw adjustments for individual sample preloading

Individual load cell monitoring for all 12 samples

Temperature controlled environment for physiological testing

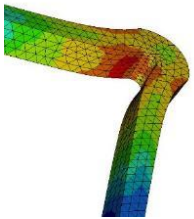
Axial Fatigue of Stent Material

Purpose of Study

- Characterize specific stent material and geometry to determine acceptable stress levels for stent design

Material & Geometry

- NiTi Superalloy
- “Diamond” shape, designed to simulate critical apex in stent design

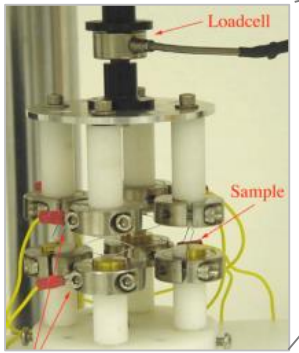


Test Mode

- Displacement (Strain) Control
- 50Hz Sinusoidal Waveform
- Varied Strain Amplitude and Mean

Instrument

- ElectroForce 3220 (225 N)
- Multi-Specimen Fixture with failure detection

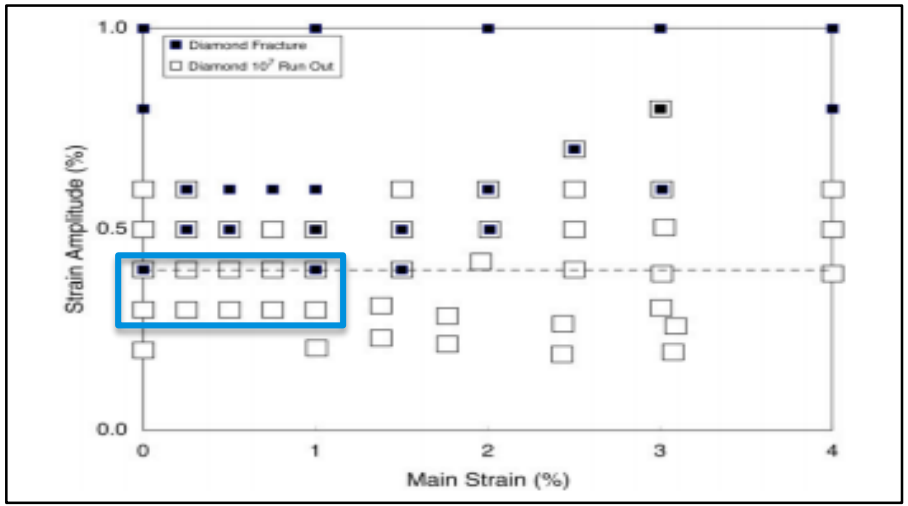


A.R. Pelton et al., Fatigue and durability of Nitinol stents, *Journal of Mechanical Behavior of Biomedical Materials,* 2008, 153-164

Results

Stent Wire

- Fatigue failures above 0.4%
- Life improves with Main (mean) Strain above 1.5%
- Hypothesis: the stress-induced martensite transformation leads to improved fatigue life (desirable)
- These results enable stent designers to design more durable devices which increase patient safety



A.R. Pelton et al., *"Fatigue and durability of Nitinol stents," Journal of Mechanical Behavior of Biomedical Materials, 2008, 153-164*

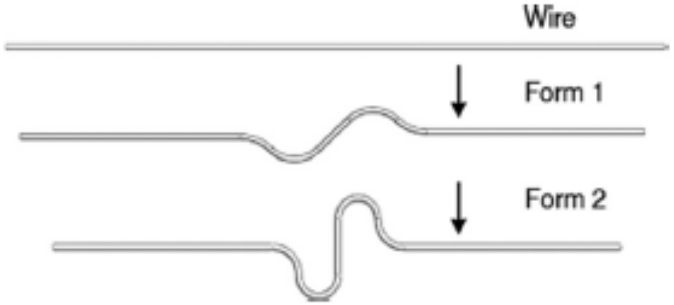
Improving Axial Fatigue

Purpose of Study

- Compare the fatigue properties of Standard versus High Purity Nitinol towards improved fatigue performance

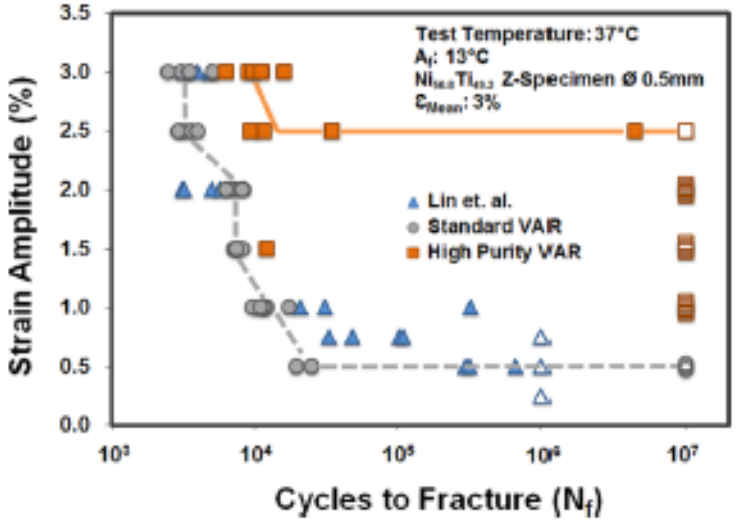
Material & Geometry

- Z-specimen geometry
- Finished wire diameter of 0.05 mm
- Key difference is oxygen + nitrogen content



Test Mode

- ElectroForce 3330 MSF-12
- Displacement (Strain) Control
- Constant 3% mean with Variable Amplitude
- 20Hz Sinusoidal Waveform



Robertson et al., Influence of microstructural purity on the bending fatigue behavior of VAR-melted superelastic Nitinol, *Journal of Mechanical Behavior of Biomedical Materials,* 2014, 181-186

Axial Fatigue of Pacemaker Leads

- **Industry Need:**
  Simulate life cycle of pacemaker leads. There is an increased focus due to recent failures with commercially available devices

- **Research Need:**
  Accelerated axial fatigue testing of lead wires, measuring forces and conductivity, understanding when failures occur

- **ElectroForce Application:**
  The ElectroForce® 3230 and 3330 Multi-Specimen test instrument provides the ability for users to test multiple samples at once at accelerated frequencies, minimizing test time and reducing time to market.

Multi-Specimen Load Control Axial Fatigue

- **Industry Need:** Simulate life cycle loading on devices that fatigue significantly different

- **Research Need:** Accelerated axial fatigue testing of medical devices, specifically in a controlled cyclic force (load) environment

- **ElectroForce Application:** The Multi-Station TestBench instrument allows users to test up to 4 samples at once on one set of electronics and software in either displacement or load control, still enabling accelerated frequency testing

Multi-Station TestBench Instruments

Independent Force or Displacement Control for additional flexibility

Up to 4 independent stations on one controller and software package

± 6.5 mm displacement

Compact breadboard and guiderail for test space adjustment

200 N max force

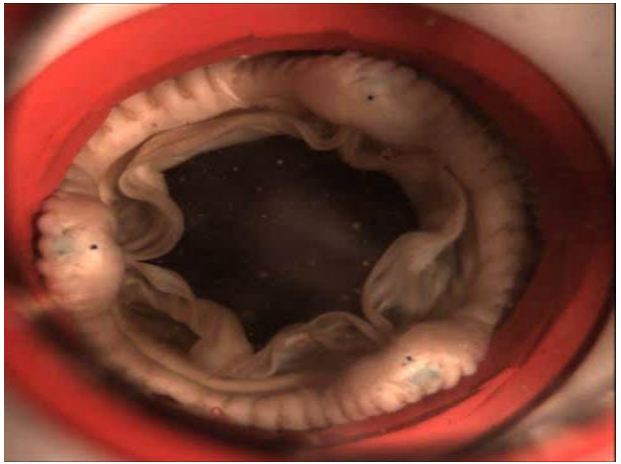
Reaction Bracket with micro test space adjustment

Accelerated Wear Testing of Heart Valve Technologies

- **Industry Need:**
  Simulate life cycle of heart valve technologies

- **Research Need:**
  Accelerated wear testing of heart valve technologies at accelerated frequencies, attaining clinical and physiological pressures with minimal additional fatigue or wear.

- **ElectroForce Application:**
  The DuraPulse™ heart valve durability system provides the capability for users to test heart valve technologies up to 40 mm at accelerated frequencies (15-40 Hz) with precise control and ease of use



Heart Valve Durability

ElectroForce 2-station DuraPulse™ heart valve durability testing instrument

Accelerated wear/durability of heart valve technologies including:

- Mechanical valves
- Bioprosthetic valves
- Aortic valves
- Mitral valves
- Pulmonary valves
- Tricuspid valves
- Pediatric valves

DuraPulse™ Heart Valve Test (HVT) Instrument

**2-Station DuraPulse™ HVT –
heart valve durability testing instrument**

- 2, 4, 6 station configurations
- Capable of testing various sizes and types of valves
- Independent control of each station
- PeakIQ™ algorithm and Closed-loop control for minimizing additional fatigue on valve
- 15-30+ Hz frequency range (valve dependent)
- Full visibility of chamber
- No need for system tuning or bleeding air out
- Fast filing and draining process

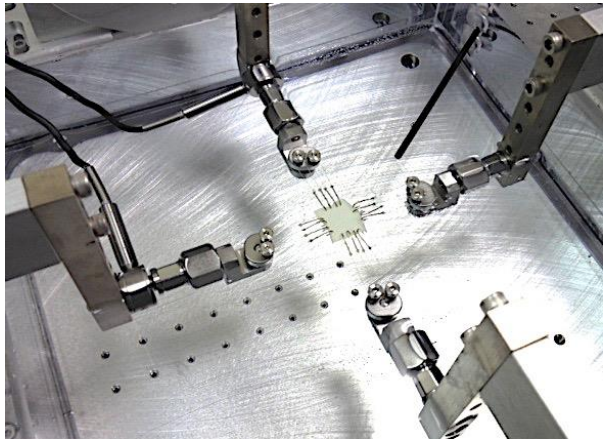
Planar Biaxial Test Instruments

- Planar Test Instrument
- Modular, tabletop system
- 2- or 4-motor configurations
- Dynamic force ranges: ±200 N or ±400 N
- Displacement Range: ±13 mm
- Dynamic Performance: static to 100 Hz
- Optional Digital Video Extensometer for real-time $\varepsilon_{11,}$ $\varepsilon_{22\ and}$ ε_{12} measurements

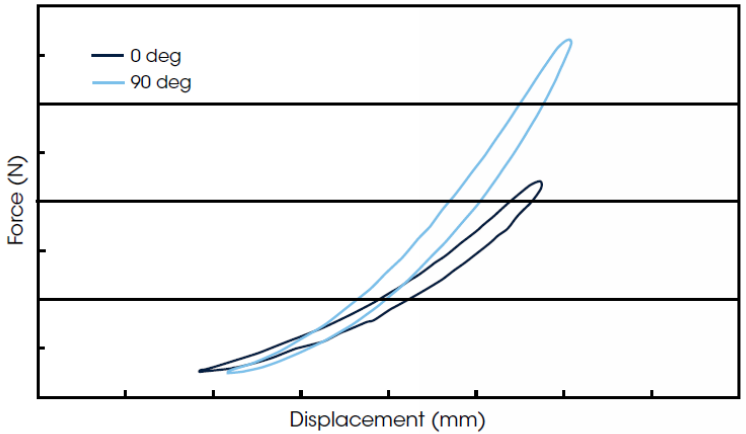
Planar Tissue Characterization

Anisotropic property characterization

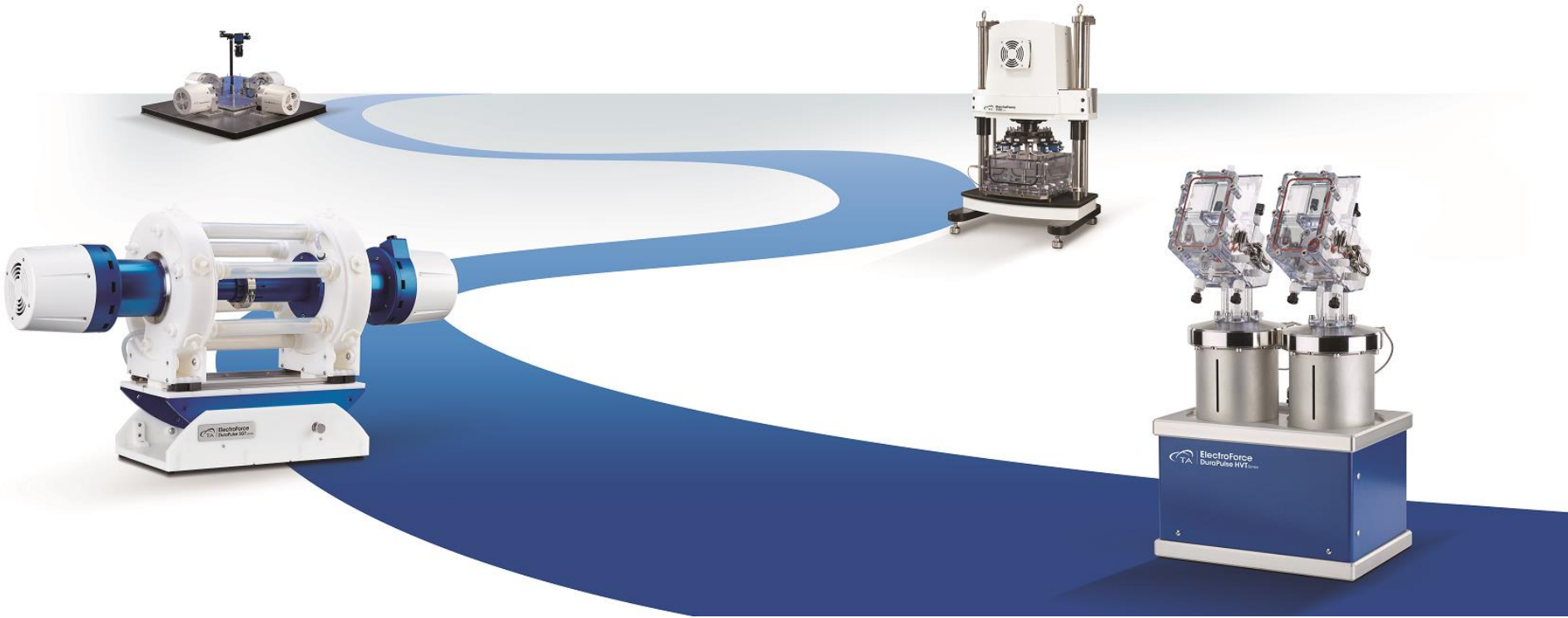
- Pericardium
- Heart valve leaflets
- Blood vessels

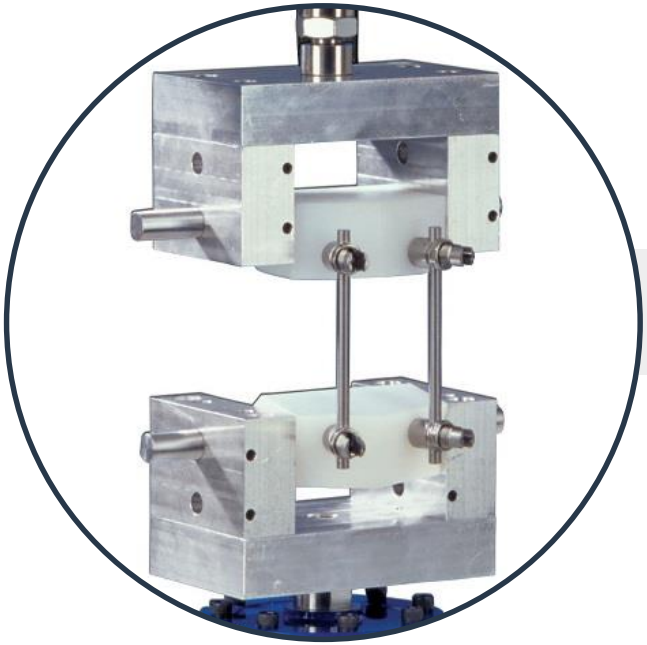


Anisotropic behavior of heart valve leaflet material under equibiaxial stretch



Trusted for Testing along the Entire Development Pathway



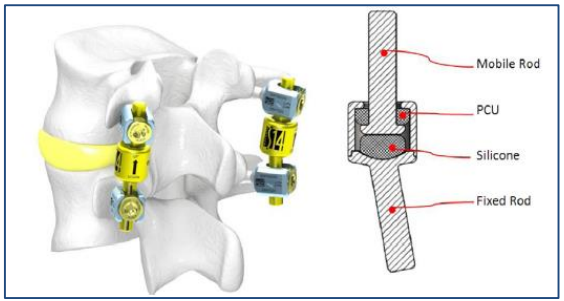


Orthopaedic Devices

Spinal Implant Testing

Clinical Need:
Develop implants to alleviate spinal pain and disc degeneration and characterize implantable materials

ElectroForce application:
Static and dynamic testing protocol (ASTM standards – F1717, F2077, F2346, etc.), both axial and torsion testing, utilizing ElectroForce 3330 and 3510 test instruments

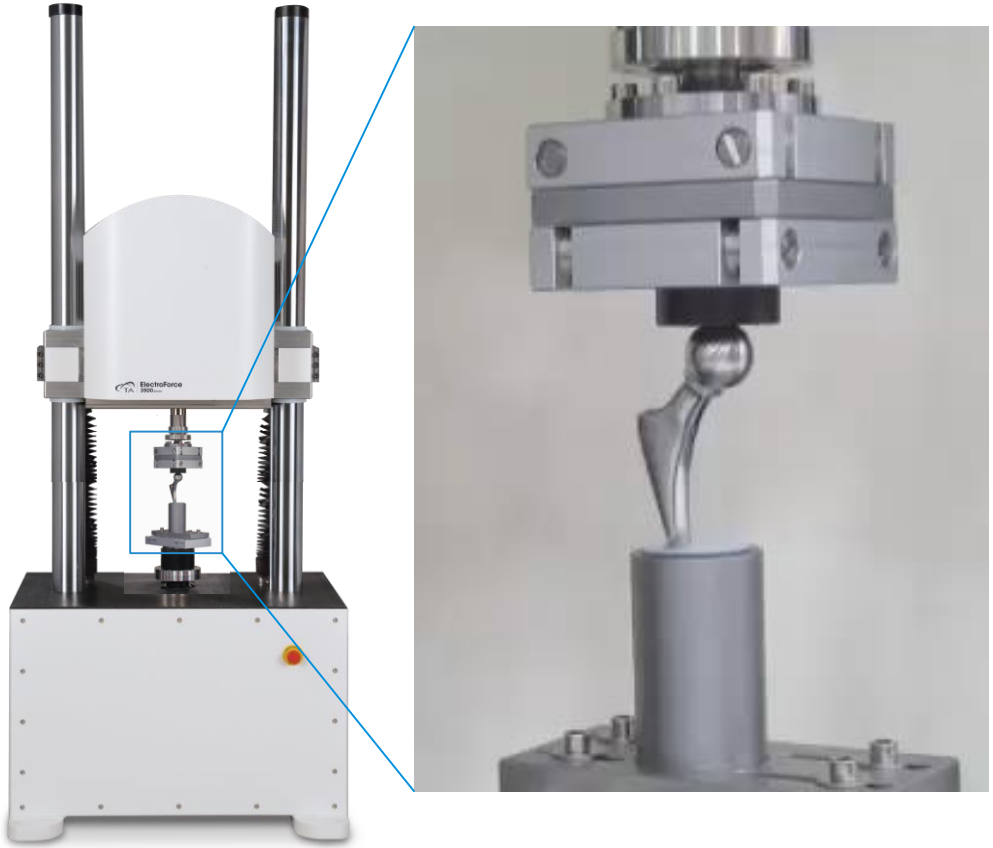


Hip Implant Fatigue

Clinical Need:
Develop hip replacement devices for osteoarthritic hips

Development Need:
Fatigue testing of femoral components of hip replacement devices

ElectroForce application:
Dynamic testing protocol according to ISO 7206, ASTM F1440, and ASTM F1612 using the ElectroForce 3510 in ambient conditions or in a physiologically relevant environmental chamber

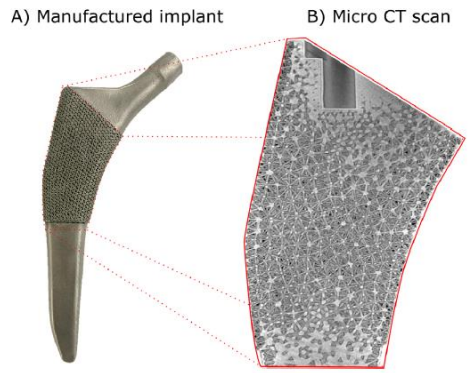


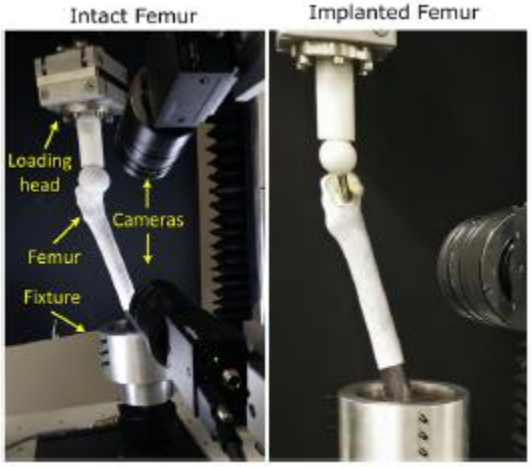
Hip Implant Design

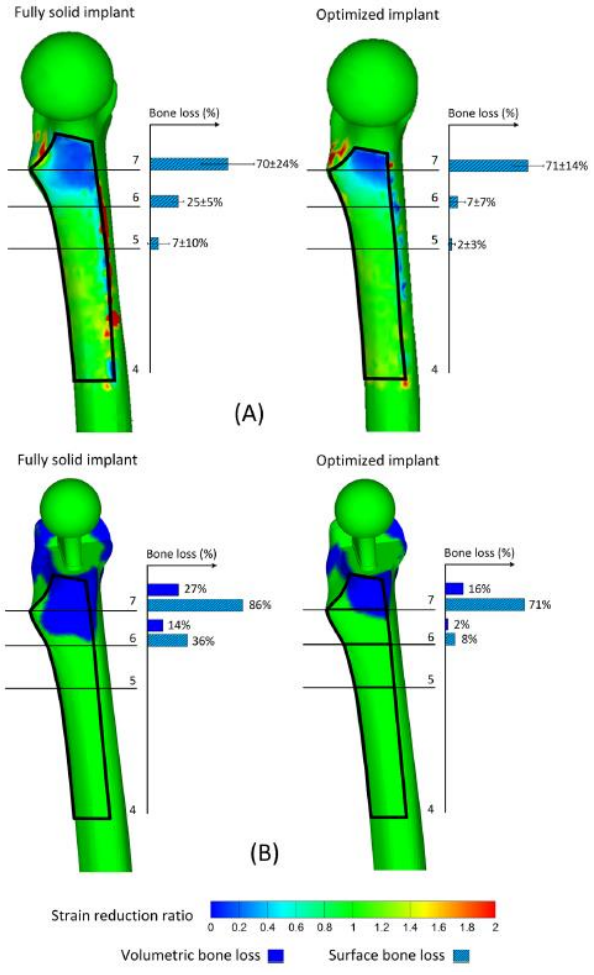
Clinical Need:
Reduce the prevalence of stress-shielding that occurs following hip replacement

Development Need:
A fully-porous, tunable femoral stem that reduces the impact of stress-shielding

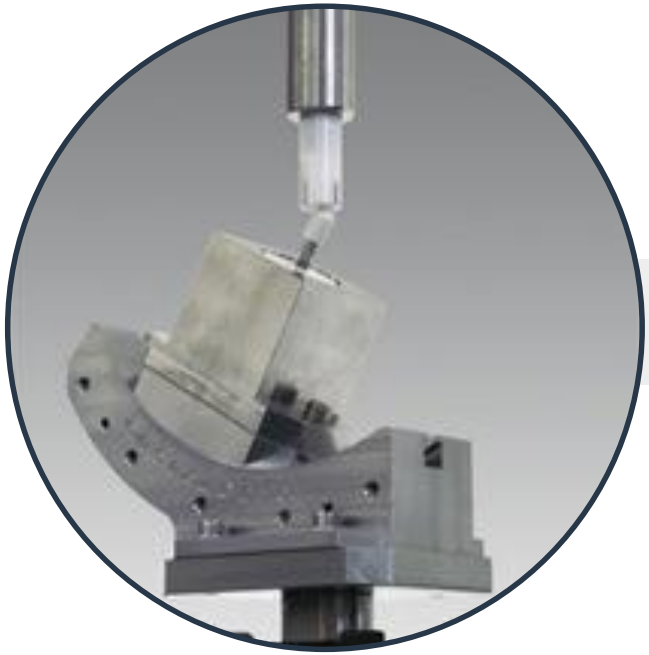
ElectroForce application:
ElectroForce 3510 statically loaded (2300 N) intact composite femur and femur with two implants – solid and porous







Arabnejad et al., Fully Porous 3D Printed Titanium Femoral Stem to Reduce Stress-Shielding Following Total Hip Arthroplasty, *Journal of Orthopaedic Research*, DOI 10.1002/jor.23445.



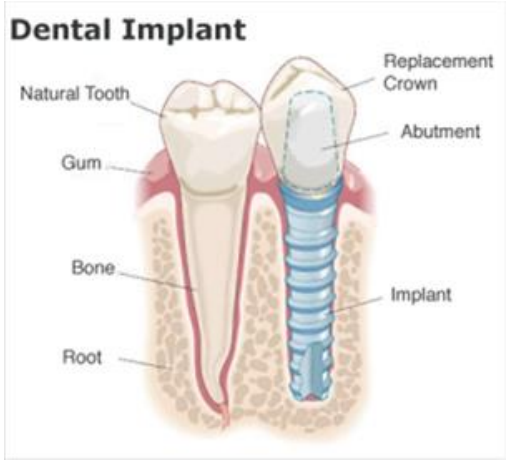
Dental Implants and Devices

Dental Implant Fatigue

Clinical need:
Reliable dental implant designs that can be used in conjunction with replacement crowns

Development need:
Static and fatigue testing of endosseous dental implants (posts) according to ISO test standard (14801). Typical loading regime might be 30 to 300 N compression-compression at frequencies not to exceed 15 Hz.

ElectroForce Application:
ElectroForce 3300 with a dental implant fixture that provides unique solution for degree of freedom, multi-angle base, and zirconia loading surface, and optional saline bath

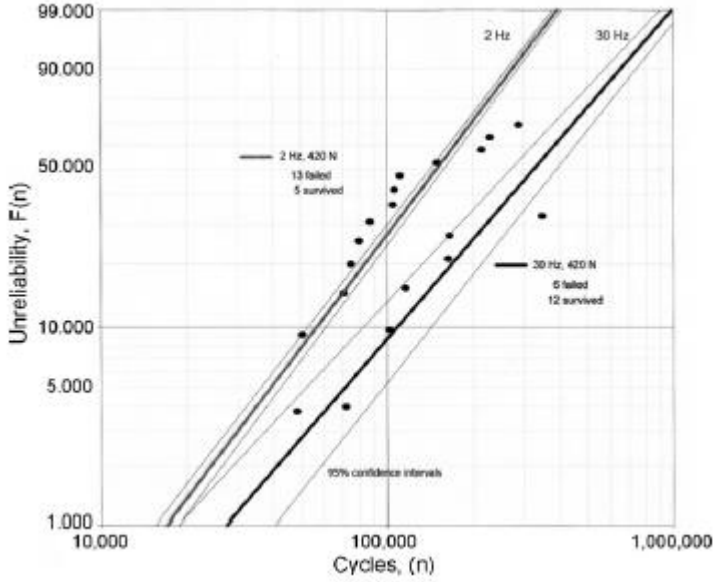


Dental Implant Fatigue

Research need:
Determine the impact of test frequency and associated strain rate on resulting implant failures – is testing faster…better.

ElectroForce Application:
Fatigue testing of dental implants with a 3300 at a peak force of 420 N at frequencies of 2 Hz and 30 Hz

Results:
Fracture probabilities of the selected implants were greater at 2 Hz than 30 Hz. It is hypothesized that the failure mode changes at higher frequencies, however, typical chewing frequencies are less than 2 Hz.

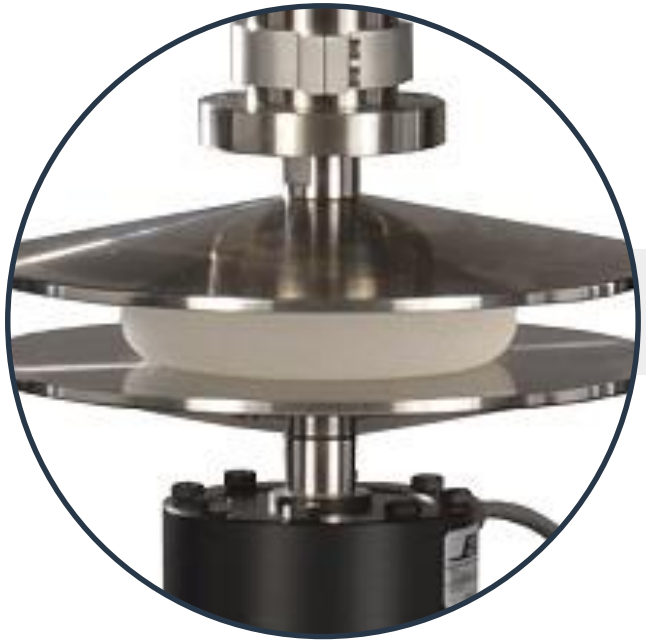


Dental Wear

Clinical need:
Implantable dental restorative materials that will last repetitive forces seen during mastication

Development need:
Understanding the fatigue and wear behaviors of dental composites under various loading conditions over time

ElectroForce Application:
3330 with secondary horizontal actuator to provide gliding phase. System includes translation table and multi-component load cell to measure forces in the X and Z directions.



Other Devices

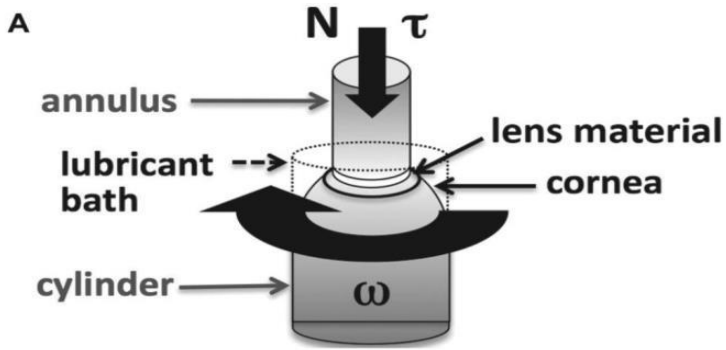
Contact Lens Testing

Dr. Tannin Schmidt
University of Calgary

Clinical Need:
Develop better lubricants (solutions) for ocular applications, such as contact lenses

Research Need:
Determine interface boundary conditions for a lubricant (lubricin) on cornea tissue

ElectroForce Application:
Resected cornea was adhered to the rotational side of an Axial-Torsion 3200 Test System. Lens material was adhered to the axial side and the samples were immersed in a homemade lubricant bath



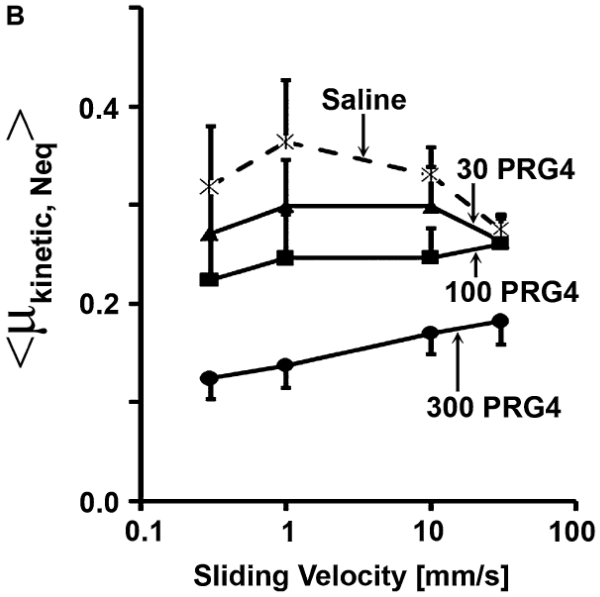
T Schmidt et.al, Eye & Contact Lens 2012;38: 27–35
DOI: 10.1097/ICL.0b013e31823f7041

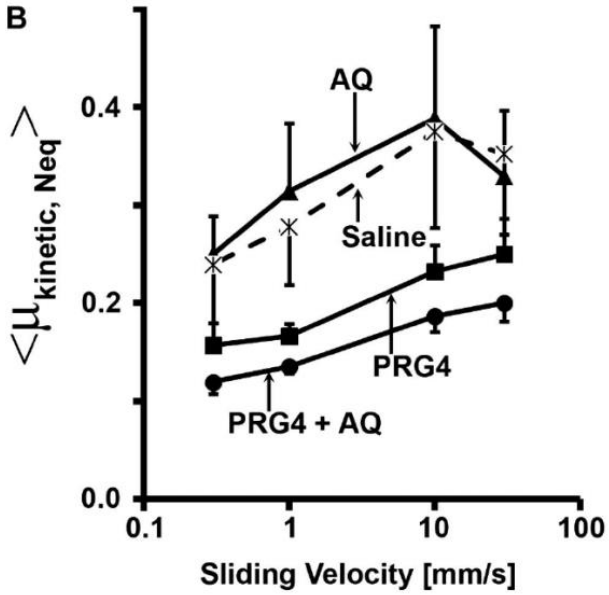
Contact Lens Testing

Results:

Lubricin reduced friction at the cornea-lens interface

- Dose-dependent trend
- Magnified effect when HA was added





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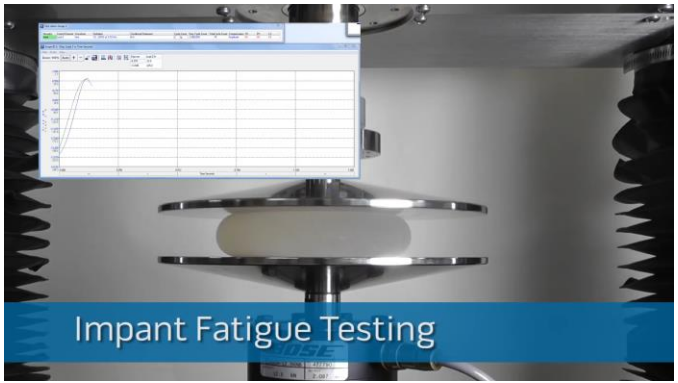
Breast Implant Testing

Clinical Need:
Long-lasting implant materials that closely mimic natural material behavior

ElectroForce Application:
Dynamic characterization of fatigue properties and implant burst pressure with an 3510 Test System used to perform tests (ISO Standard 14607)



THANK YOU