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BIOPULS™

Solutions for Biomedical Testing

INSTRON®

The difference is measurable™

Solutions for Biomedical Testing

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Longer life expectancy, an increasingly active population and scientific advances are fueling a tremendous demand for new and improved biomedical devices and materials. As technology evolves, researchers and manufacturers face the enduring task of delivering biomaterials and products that combine high quality with life-long performance.

Biomedical testing allows the performance and compatibility of new materials and medical devices to be proven in vitro, without putting patients at risk, and for the evaluation of critical and complex issues in a controlled and repeatable manner. In addition to helping new products meet essential regulations, such as Food and Drug Administration (FDA) compliance, biomedical testing allows the quality of medical products to be verified in a production line, and the development of new and innovative solutions in the laboratory.

This brochure outlines some of the testing challenges facing different sectors of the biomedical community and how they are successfully addressed using Instron®'s BioPuls™ solutions. As you read further, you'll get a sense of how Instron can help you with your research and bring your own products to market and improve the quality of life for the people who use them.

Contents

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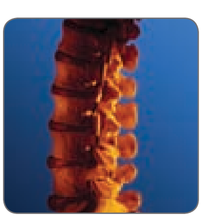
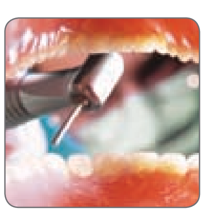
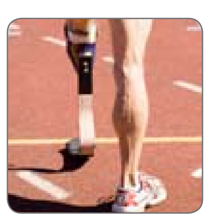




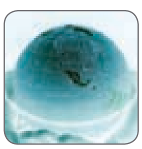


Today, Instron®'s unmatched knowledge and experience are reflected in our BioPuls™ range of application-centric solutions for the biomedical testing industry. These unique testing innovations advance the understanding of material properties and performance across a vast spectrum of biomaterials and medical products.

Instron has engineered the BioPuls range to be the most advanced solution for biomedical testing challenges. With demands as diverse as low force testing on native tissues to complex multi-axial simulation of spinal segments, we have ensured that our products best fit the needs of individual customers and provide many years of superior performance. With no compromises on quality or performance, the BioPuls designs of equipment and accessories reflect Instron's leading product design philosophy, where data integrity, safety and protection of investment are paramount. Whether you are engaged in cutting-edge research or critical quality assurance on the production floor, there is a BioPuls testing solution available from Instron.

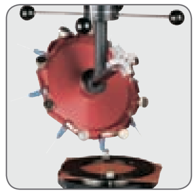
Testing Leadership

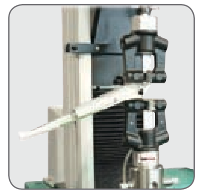
Since 1946, Instron has been the leading provider of testing equipment for every kind of material and structure. For decades, our experience and global perspective has enabled us to be at the forefront of biomedical testing.

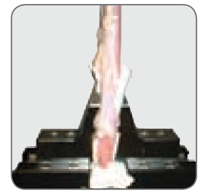


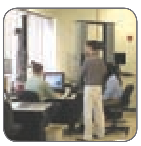
Global Support and Service

Today, Instron has offices in 17 countries and a staff of more than 1200 dedicated professionals who speak more than 20 languages. Instron offers an extensive range of calibration and verification services and is supported by a vast network of field service engineers.









Application Excellence

The Instron® global team of biomedical applications specialists and professional engineers delivers an array of BioPuls™ turnkey solutions for biomaterials, orthopaedics, biomechanics, medical devices and dental testing. Our dedicated Biomedical Applications Team continues to advance their application knowledge and experience through strong customer relationships, active participation on standards committees and conference attendance.

Medical Devices

Regulatory agencies worldwide have set stringent performance standards for nearly every category of medical device. Today, bringing a new medical device to market requires in-depth knowledge of all of its characteristics, from properties of the raw materials to long-term performance under complex service conditions. The testing required to meet the wide variety of standards spans nearly every type of mechanical test, including tension, compression, impact, fatigue and hardness.

For single-use products, testing is particularly important during material selection to maximize the trade-off between performance and cost. For implantable devices, testing protocols ensure that the materials and design will stand up to prolonged use in vivo.

This section provides a glimpse into some of the application solutions Instron® has provided to its medical device customers. You will see how our engineers have addressed a variety of applications, including needles, syringes, tubing and packaging.

Needle Insertion Force

The Challenge

Needle insertion force measurement is a critical parameter for needle developers, as well as in quality control to ensure patient safety. In recent years, researchers and manufacturers have invested significant resources in developing surgical simulation and preoperative planning tools, which require parameters such as needle insertion force. Insertion force is also a key value in characterizing needle geometry and sharpness, and in understanding the effects of velocity, viscosity and frictional force along the needle axis during insertion into soft tissues.

Our Solution

With a wide variety of needles available, fixturing is unique to the objective and application of the tests and results.

Test configurations, such as the BioPuls™ multineedle test fixture, reduce testing time in needle production and quality control processes. Instron® also offers a robust single needle fixture that provides significant advantages for research and development.

▲ The BioPuls™ curved needle tester is used to ensure that the needle is sharp enough to puncture tissue and strong enough to retain its shape during use.

▲ The BioPuls multineedle test fixture (upper) and rotational membrane holder (lower) increase the rate of testing on up to eight needles at multiple penetration points.

▲ A single straight needle fixture (upper) and variable angle membrane holder (lower) are often used in research and development processes for characterizing needle sharpness.

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Plunger Force for Needles and Syringes

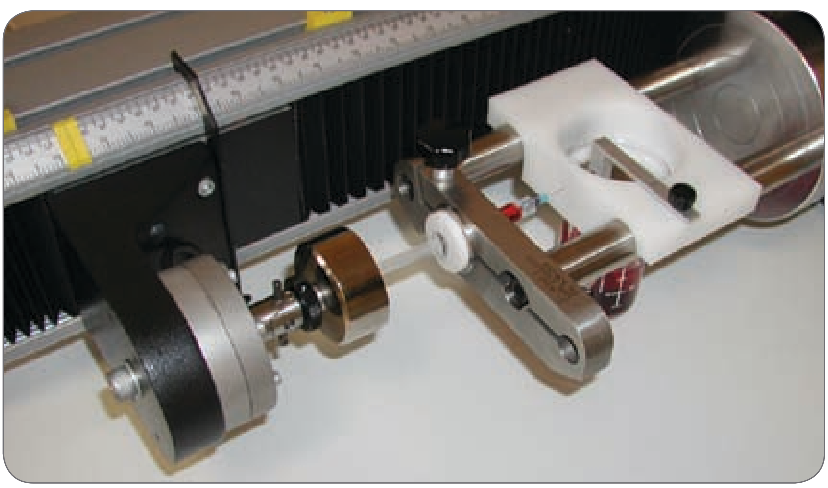
The Challenge

Needles and syringes must be tested to ensure the forces necessary to move the plunger and eject fluid from the barrel are not too high or too low. These forces depend on many factors, including the device materials, viscosity of the liquid, radiation processes used for sterilization, and instrument design. When testing needles, the host tissue (into which the fluid is injected) is another factor influencing device performance.

Our Solution

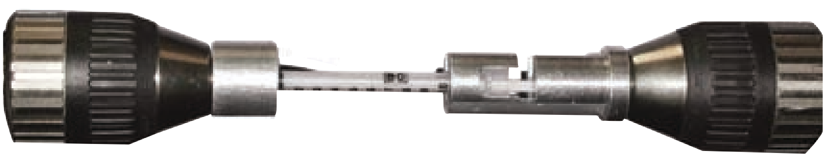
Fixturing specific to the nature and application of the test is usually required. The lower grip is typically designed to hold the barrel, and an upper unit is designed to either eject liquid from the barrel in a compression test or inspire liquid into the barrel in a tensile test.

Instron® universal testing systems can be configured in either an upright or horizontal position to utilize these fixturing options. In some cases, the horizontal configuration is advantageous because it allows accurate simulation of the instrument in its functional position. This configuration may also prevent any sediment in the liquid from clogging the barrel or needle tip during the test.

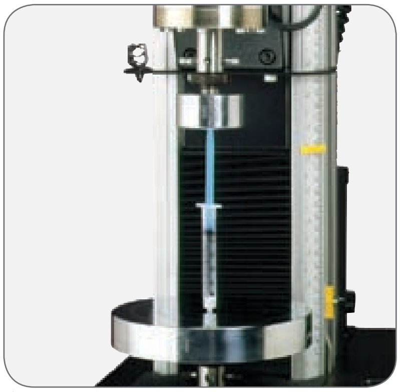


A horizontal 5544 universal testing system with fixturing is used to compare the effect of various medication viscosities on the breakout and sustaining forces required to eject liquid from the barrel.

The fixture shown above is used to measure the ejection forces of fluids from the barrel of a syringe. The fixture uses plastic inserts to hold a variety of different syringe sizes and diameters.



55MT MicroTorsion system for torsion testing conical lock fittings with luer taper for syringes.



A 5544 universal testing system with standard compression platens can be used to evaluate breakout and sustaining forces required to move the needle plunger.

Sutures

The Challenge

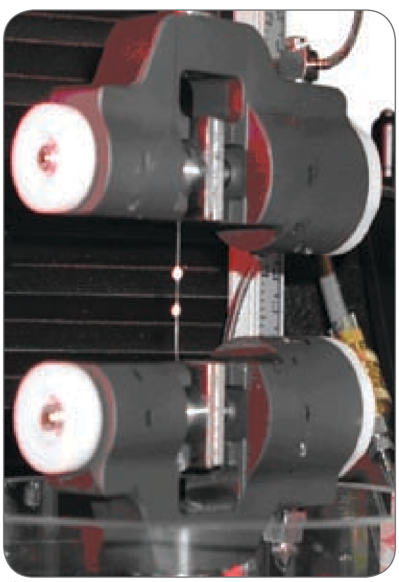
Sutures are manufactured from a variety of resorbable and non-resorbable materials, and may be a single filament or braided with or without coating. Tensile strength and strain are critical measures of performance during and after surgical procedures. The strength of different knotting techniques must also be evaluated. The test method must determine breaking strength and corresponding percent elongation, accurately measure strain without damaging the material, and adhere to FDA guidelines.

Our Solution

Typical tests include a 'straight-pull' test that evaluates the tensile strength and elongation of the suture material itself, and a 'knot-pull' test that evaluates the tensile strength of specific knotting techniques used during surgery. Tests can be conducted in a saline bath to evaluate the strength of suture material under physiological conditions. The fluid environment and body temperature can change material properties, and such changes must be understood before the materials are used in surgery.

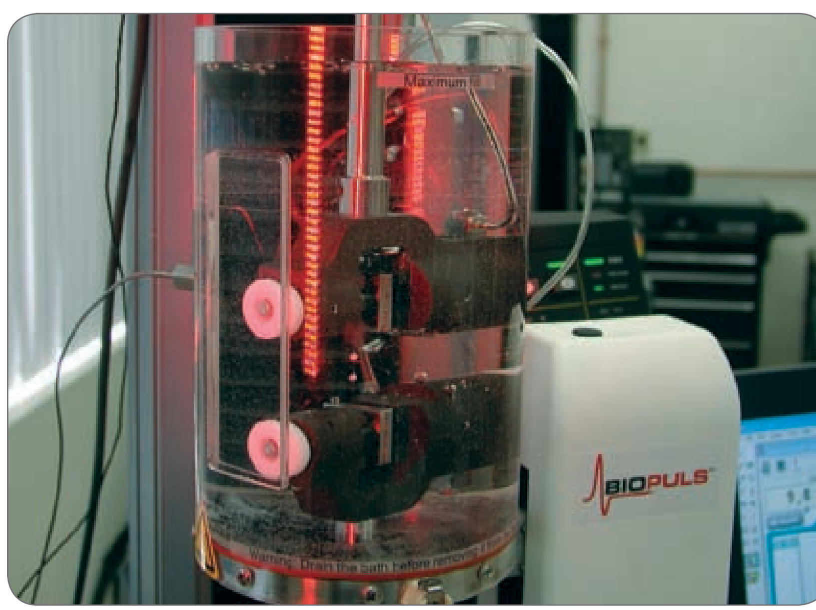
The BioPuls™ pneumatically activated cord and yarn grips, as well as manual capstan grips, are ideal for gripping suture material. Wrapping the material around the mandrel head of the clamp eliminates high stress points that lead to premature failure.

Typical test set ups use a universal testing system. For on-site and quality control testing, the Instron 3300 Series mechanical testing systems combine low cost and ease of use with the precision required for low-force suture testing.



The challenge in measuring strain in a bath with a video extensometer is finding appropriate gauge length marks. In this sutures application, small round pieces of adhesive putty were successful in allowing us to track strain through break.

A 3345 universal testing system, configured with pneumatic cord and yarn grips, is used to perform a knot-pull test on suture material.



The BioPuls Bath, Submersible Pneumatic Grips and SVE are a unique testing solution for evaluating the tensile properties of sutures under physiological conditions. A close up of the specimen with video markers is shown above.

Metallic Wire and Tubing

The Challenge

Metallic wires and tubing are used in the manufacture of a wide variety of medical devices, including stents, needles and guide wires. The engineers developing the materials used for these products or designing the product itself, need to know the strength, stiffness and flexibility of these wires and tubes. For example, in the design of a stent, measuring strain at a particular stress is critical. Too little strain and the stent will not be sufficiently flexible; too much strain and it will not maintain its functional shape.

Our Solution

The primary objective for characterizing most metallic wires and tubes is determining tensile strength and strain at break. For accurate strain measurement, a non-contacting video extensometer is preferred and is the only feasible choice when wire samples will not support the weight of conventional clip-on style strain devices. The video extensometer also prevents premature failure of the wire associated with the knife-edges of clip-on extensometers.

Pneumatic side action grips or screw grips with serrated faces are proven BioPuls™ solutions for gripping this material. When testing metallic tubing, inserts should be used to plug the specimen ends before they are put into the grips. This is helpful in preventing the specimen from collapsing, allowing tensile failure to occur in the gauge area.

A 5569 universal testing system, 5 kN pneumatic side action grips with serrated faces and a video extensometer are ideal for testing stainless steel tubing in tension with high precision strain measurement.

A close-up of the stainless steel tubing specimen shown above. The gripped ends of the tubing are filled with inserts to maintain the tubing geometry and prevent jaw breaks. The 25.4 mm (1 in) gauge length is marked with 2 mm wide black tape wrapped around the diameter of the specimen.

Cord and yarn grips are a unique solution for testing thin wire specimens in tension. The design of the grip prevents jaw breaks that commonly can occur with side acting grips.

ElectroPuls® E1000 performs a high-frequency fatigue test on 300 micron-diamater wire using lightweight collet grips.

Drug Eluting Stents

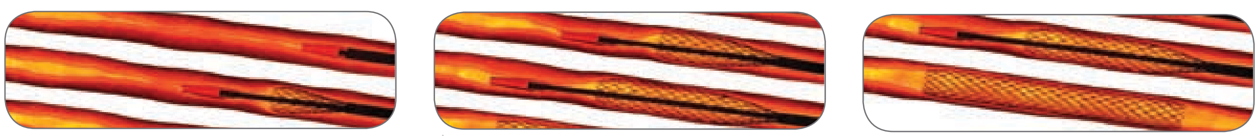
The Challenge

Drug eluting stents (DES) are used in procedures where major arterial blockage is present in coronary arteries. DES are metal stents coated with a drug that elutes over 30-90 days to dramatically reduce restenosis that can occur with bare metal stents. One critical factor in the successful deployment/placement is to make sure the DES is expanded fully to the arterial wall. Under expansion can result in gaps between the stent and wall that could lead to blood clots or sub-acute thrombosis (SAT).

Our Solution

Radial force specifications are critical to the proper selection of DES for particular interventional procedures. The Instron® RX550 can provide highly accurate and repeatable results for radial stiffness and strength for DES. The proprietary segmental compression mechanism of the fixture means that external compliance issues, often found in other radial force measurement techniques, will not be an issue. Also, with stent sizes shrinking to address neural blockages, lower-force load cells can be used to provide results for these sensitive tests. Bluehill® software provides a wide variety of automated calculations for standard results like peak loads, but also more complex measurements like energy.

Instron 5544 RX550 System testing a DES.



Sequence of a DES being deployed in a clogged artery.

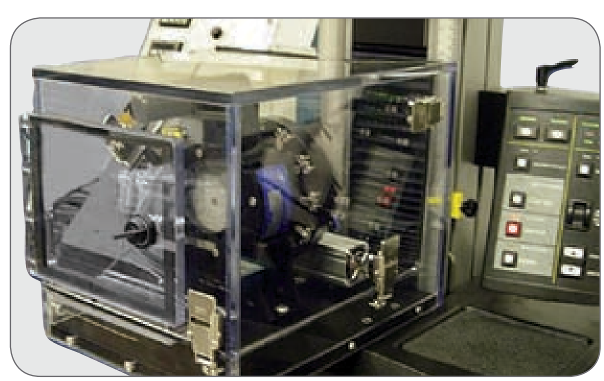
Embolic Filters

The Challenge

Embolic filters are used within a variety of interventional procedures to capture debris resulting from the deployment of a medical device, like a stent. The stent is used to open arterial paths that may be occluded by plaque. Upon placement of the stent, dislodged plaque (or embolic material) can potentially be responsible for heart attacks, strokes, kidney failure or death. Firm placement of the embolic filter is a critical requirement for successful procedures.

Our Solution

One of the most critical parameters for proper utilization of the filter is the radial forces it imparts on the arterial wall. This fit ensures that all material is captured before heading further down the arterial pathways. The Instron® RX550 system has the fidelity to measure the small radial expansion forces of the embolic filter. The small frictional forces of the fixture means that your data will present clean results from the radial tests. Additionally, tensile tests can be performed to evaluate resistance to tearing properties during deployment. Bluehill software will generate standard reports that can be submitted for regulatory submissions.



Instron 5542 RX550 System testing embolic filter at 37°C.

Stent Grafts

The Challenge

Stent grafts are used to treat a wide variety of peripheral arterial issues, as well as abdominal and thoracic aortic pathologic conditions like abdominal aortic aneurysms (AAA). The success of endovascular stent grafts for AAA's has provided motivation to adapt similar technology for descending thoracic aortic aneurysms (TAA's). Survival rates for untreated and traditionally treated (through complex thoracic surgeries) aneurysms are typically quite poor. Advantages of the stent grafts include shorter operative time, avoidance of major thoracic or thoracoabdominal incisions, and significant reductions in morbidity and mortality. For success, the stent graft must be accurately placed and must not move, especially in upper descending thoracic aorta cases.

Our Solution

Typical secure placement for stent grafts are a strong function of the proper selection and sizing since the physiological movements of the aorta can be significant. Additionally, stent grafts have much larger diameters than coronary stents (30+ mm versus 2-3 mm). The Instron® RX650 can accommodate stent grafts that are more than 40 mm in diameter and more than 200 mm in length. Custom sizes can be provided for special specimen types and provide radial strength and stiffness over the entire graft or the securing graft ends. Although room temperature testing can provide excellent comparative results, the system can be configured with a heating chamber to provide body temperature results as well.

Instron 5544 RX650 System testing a stent graft.

Bioabsorbable Drug-Coated Medical Devices

The Challenge

Bioabsorbable drug-coated devices are used to deliver an acute dosage of drugs to specific treatment sites in a manner that prevents systemic drug delivery. This enables clinicians to treat a lesion site with specific drugs that may cause an adverse reaction if delivered systemically. Additionally, the bioabsorbable drug-coated device may speed healing due to more localized high concentration of the drugs. Because the device typically dissolves within 12-18 months, restenosis and clotting could be greatly reduced. This device also eliminates the metal stent interference problem for heart imaging post procedure.

Our Solution

The Instron RX is used to ensure the radial strength of the bioabsorbable devices is great enough to expand and properly seat against the treatment site. In that way, drugs are eluted through the tissue and not the bloodstream. Additionally, data can be generated to determine the length of time the device can maintain its radial strength since this is a critical device requirement. As with all tests on the Instron RX systems, Bluehill® software generates standard reports that can be submitted for regulatory submissions to simplify approval processes.

Loading of a Bioabsorbable stent into a RX550 fixture.

Medical Gloves

The Challenge

Medical gloves can be manufactured from materials, such as latex, nitrile and vinyl; all of which must adhere to performance levels specified by the FDA, as well as international standards (ASTM D6319-00ae3, ASTM D5250-00e4, EN 455-2, ISO 11193-1, ISO/AWI 11193-2). The aging effects of the material must be evaluated to ensure that cross-contamination of the examiner and the patient does not occur. Testing should examine the strength and elongation of the material at break to ensure that measured values fall within normal ranges of use. The main testing difficulty usually involves measuring strain, since traditional strain measurement devices risk damaging the material and causing unwanted failures at the attachment points.

Our Solution

BioPuls™ pneumatic grips are ideal for gripping delicate materials without tearing or causing slippage. The grips allow for adjustable gripping pressure and a choice of face dimensions and surfaces, such as rubber-coated, serrated, wave-profile or flat metallic. Instron®'s long travel extensometer and video extensometers are well suited for providing accurate measures of strain in these typically high-elongation materials. While the long travel extensometer was designed specifically for this type of application, providing a cost-effective easy to use solution, the video extensometer utilizes the most advanced technology for tracking marks on the specimen that eliminate pre-mature failure, which may result from contact points.

A 5544 universal testing system configured with side action screw grips and rubber-coated faces can be used for evaluating the tensile strength of medical gloves.

Medical Packaging

The Challenge

The medical device industry is moving toward prepackaged disposable devices, such as surgical instruments and syringes. The tensile strength of the adhesives used for such packaging must be assessed according to ASTM F 88 to ensure sterilization of instruments during shipment and during storage at the customer site.

Our Solution

Tear, Peel, Friction (TPF) software module contains preconfigured methods for conducting three different peel tests: T-peel, 90° peel and 180° peel. Using a high data acquisition rate to ensure the peel profile is accurately characterized, the strength of the adhesive bond is evaluated using the basic calculation of maximum force on an absolute peak, or using more advanced calculations such as the average of a specific number of peaks, troughs or combination of both. Users have great flexibility in specifying where measurement begins and ends, enabling the software to calculate a broad range of results.

A 3342 universal testing system with 250 N capacity pneumatic side action grips and line contact faces is used to grip disposable syringe packaging in a T-peel test. Such tests allow quality personnel to investigate the seal strength of their packaging methods and to ensure the sterility of the devices after delivery.

Surgical Tubing, Fittings and Catheters

The Challenge

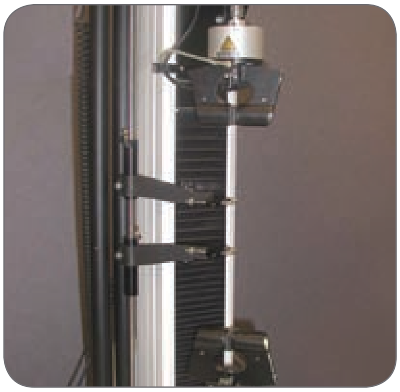
Surgical tubing is used in a wide range of applications, such as drains, feeding tubes, irrigation and surgical procedures. The tubing comes in many shapes and sizes with dozens of possible interconnections and fittings. The mechanical performance of these items is critical, as failure could seriously endanger patients. Testing requirements include failure of the material, failure at joints, and simulation of physiological parameters. In more advanced cases, tortuosity tests may be used to evaluate frictional forces experienced within catheters as they are fed through arterial vessels.

Our Solution

In all testing applications, whether evaluating the mechanical properties of the tubing itself- or assessing the strength of the connection between the tubing and the fittings, correct gripping of the tubing is essential to obtaining accurate measurements. BioPuls™ pneumatically activated cord and yarn grips or manual capstan grips are designed to securely grip surgical tubing while ensuring that test specimens fall within the gauge area.

For modulus and yield calculations, a non-contacting strain measurement device is necessary to accurately measure elongation and prevent failures due to knife-edges or clip-on extensometers. Our video extensometer enables precise strain measurement without damaging the tubing. An Instron® universal testing system is ideal for these testing requirements. For more advanced applications, such as evaluating the frictional force of surgical tubing in tortuosity tests, a horizontal test configuration may be necessary. Using the horizontal testing frame, tubing developers and quality control specialists design their own test method for measuring various frictional, insertion and removal forces of all types of tubing. For both the upright and horizontal test frames, an environmental bath can easily be added to the test space to ensure measurements are taken under physiological conditions.

A 5545 universal testing system configured with side action screw grips and serrated faces is used to compare the strength of a fitting with the ultimate strength of the tubing material.



Tensile strength, strain at break and elastic modulus measurements are acquired for thin-wall tubing specimens using a 3345 universal testing system, pneumatic side action grips and a long travel extensometer.

55MT MicroTorsion system with micro grip chucks for multi-turn torsion testing of surgical tubing.

Breast Implants

The Challenge

Breast augmentation and reconstruction are common operations for women who have undergone a mastectomy or for cosmetic purposes. Implants are manufactured with an outer shell, usually made of an elastomer (like silicone) and filled with either silicone or saline. The shape and size of the implant designs vary to accommodate patient preferences. The mechanical characteristics of these devices must be evaluated, following standards EN 12180 and ISO 14607, to ensure patient safety over time.

Our Solution

Breast implant testing is conducted to evaluate the performance of the design or material of a specific implant, and also for comparison with others on the market. A compression-fatigue test is used to evaluate the strength and life of the implant over time. With the implant mounted between compression platens, the testing system must allow for cyclic compression of the implant for 2 million cycles at 200 cycles per minute. An Instron® fatigue testing systems provides excellent accuracy and waveform fidelity when performing such fatigue tests in either load or position control. WaveMatrix™ software allows easy set up of these straightforward cyclic tests, with variable data collection rates to optimize data storage and ensure that important data from events, such as yield or failure, is collected. Fatigue testing systems can be run at higher frequencies to reduce test time without compromising the integrity of the test.

An impact resistance test is performed to ensure that the implant does not fail under sudden force. This test involves dropping a specified mass vertically onto the implant. In order to accurately control velocity and acceleration of the mass, as well as collect maximum impact load and deformation values, a Dynatup® drop tower is highly recommended. The 9250HV with Impulse™ machine control and data acquisition system accurately delivers a repeatable impact to the specimen while collecting load, time and energy data.

An 8872 fatigue testing system with compression platens evaluates the fatigue properties of a breast implant.

The Dynatup 9250HV drop tower is used to evaluate the strength of the implant under impact.

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Bandages

The Challenge

Bandages are a commonly used product whose materials and designs are characterized by their ability to carry a tensile load - i.e., how much force they can withstand before failure occurs in tension. Measurement of mechanical properties allows evaluation of bandage performance while providing insight for manufacturing processes and quality control.

Our Solution

A standard tensile test is used to evaluate tensile strength and elongation at break, two important parameters in product development and quality control. However, special consideration must be given to testing these materials without causing unwanted failures. BioPuls™ elastomeric grips and pneumatic grips are suitable for testing multi-stranded woven materials used in bandages without causing premature failure at the jaw faces.

Elastomeric grips are used to evaluate the strength of bandages in tension.

Disability Aids: Hip Protector

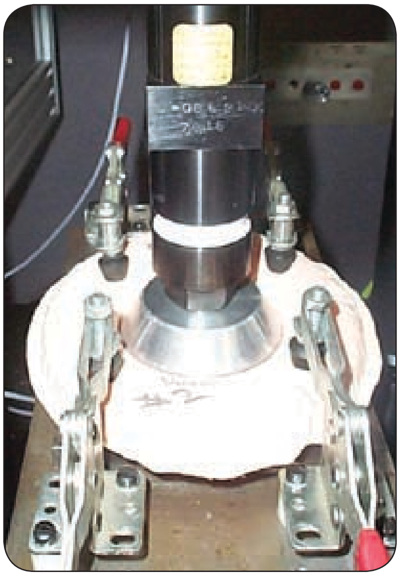
The Challenge

Accidental falls are a leading cause of injury among elderly people. Specifically, hip fractures are the largest single injury resulting from falls in patients aged 65 to 74 years. Biomechanical analysis shows that the maximum force on the hip when falling approaches three times the body weight. This can be reduced by about a third using a protective device. The device must be able to absorb and dissipate impact energy and be comfortable enough to wear on a daily basis.

Our Solution

Evaluation of the performance of a hip protector is conducted by simulating a fall using an impact testing system. By specifying crosshead weight, drop height, velocity and acceleration, test configurations are designed to accurately reproduce forces produced during a fall.

The Dynatup® 9250HV impact testing system allows for all of these configurations, and the Impulse™ machine control and data acquisition system simplifies measurements of maximum load, time to max load, time to failure, total time, impact energy and energy to max load. Results from such tests assist researchers and engineers in the design of protective devices, and help physicians properly prescribe these devices to prevent patient injury.



The impact resistance of a hip protector is evaluated using a Dynatup 9250HV impact testing system.

Biological Tissues

Injury, the aging process, and disease are contributing factors to the irreversible changes in human tissue that lead to pain, discomfort and immobility in a person over time. As researchers and engineers work to develop replacement tissues, perfect surgical techniques, and learn to accurately diagnose these changes in tissue physiology and mechanics, a crucial step is to evaluate the natural tissues they are attempting to simulate. Further, mechanical understanding of healthy tissue is used to diagnose diseased or damaged tissue during the procedure or in the surgeon's office.

The following section provides for an overview of the most common tissue testing applications. Not only do the Instron® biomedical applications specialists have a selection of standard products and accessories, but also the experience and breadth of knowledge to help create a customized solution that meets your individual testing requirements.

Soft Tissues: Low Force

The Challenge

Many soft tissues, such as skin or collagen, are delicate specimens with low ultimate strength values.
An ensuring system should be highly sensitive to low force measurements and small displacements in tension, compression, flexure and fatigue.
The in vivo conditions must also be preserved, ensuring the mechanical properties of natural tissues are maintained and that bio-engineered tissues are tested in their working environment.

Our Solution

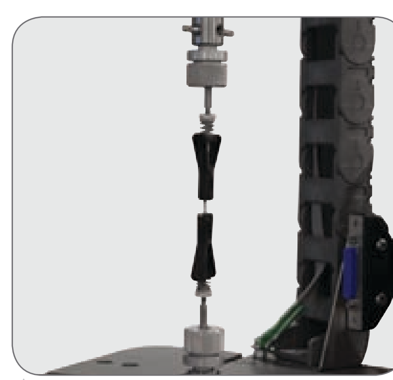
Instron®'s ElectroPuls® and MicroTester™ systems offer the precision necessary for low-force testing of tissues and biomaterials in tension, compression, flexure and fatigue. With the correct selection of a load cell and lightweight grips, these systems have an exceptional capability to run very low-force tests.

Each system features a twin-column design and an all-electric actuator, making it ideally suitable for clean room environments. The MicroTester and the ElectroPuls E1000 can be configured vertically or horizontally to fit on any laboratory workbench and for easy mounting of a temperature-controlled environmental bath and optical instruments.

ElectroPuls systems are capable of running slow-speed static tests through to high-frequency dynamic tests, and the MicroTester provides a much higher resolution for measuring extremely low loads, often in the sub gram range.

The MicroTester is extremely versatile for a variety of low-force tissue tests in both vertical and horizontal configurations.

Micro three-point bend fixture with saline tank.



ElectroPuls E1000 system fitted with a low-force Dynacell and fiber clamps allows testing of tissues in the gram range.

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Soft Tissues: Uniaxial

The Challenge

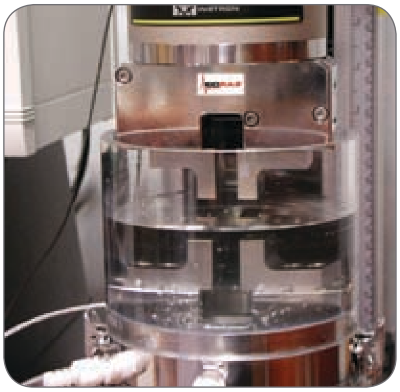
Testing of human tissues, such as ligaments, tendons, the spinal cord and the esophagus is essential to the characterization of their behavior in vivo. Testing is performed to determine material properties used to set design specifications for bio-engineered replacement tissues, and to determine expected values in surgical simulation and modeling tools. In order to accurately replicate tissue behavior during testing, it is essential that the physiological conditions are maintained.

Our Solution

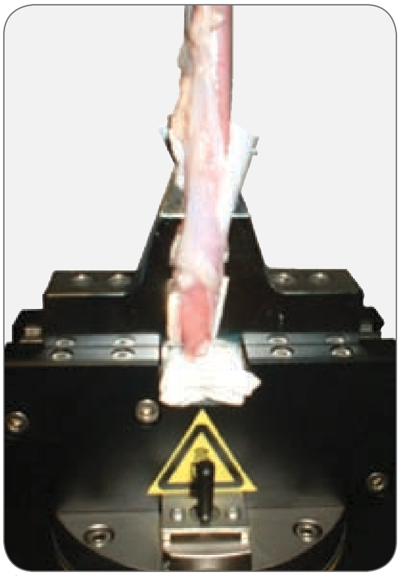
Within the BioPuls™ range there is a wide choice of high and low-capacity fixtures and environmental baths for tensile and fatigue testing of a variety of tissues. These solutions operate with any Instron® testing system that provides advanced electronics for precision, reliability and control.

Alignment is less of a concern with soft tissues than with harder materials, but the problems of gripping are much more severe. The gripping solution is often specific to the characteristics of the specimen material and the conditions of the test. The wide variety of BioPuls options include line contact jaw faces, roughened grip surfaces, interlocking wave profile faces, adhesively bonding of the specimen ends, staples or stitched ends.

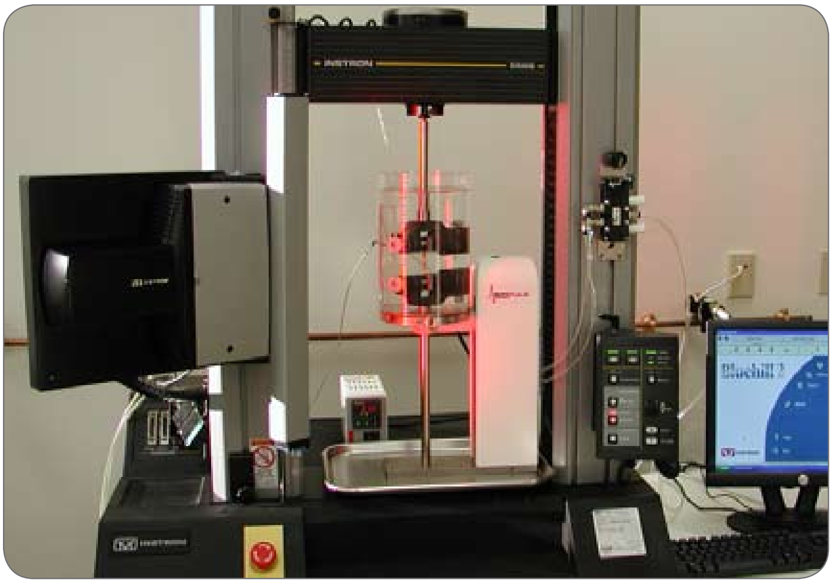
Non-contacting strain measurement techniques are often preferred to eliminate problems associated with local stress concentrations and deformation at the contacting points. A video extensometer is particularly suitable and can be used to offer high accuracy strain measurement, even with specimens tested in environmental baths.



BioPuls submersible versagrips in a quick latch tank are ideal for gripping higher-strength ligaments and tendons, and testing to failure.



Esophagus specimen in BioPuls submersible versa-grips for in vitro tensile testing. The ends of the esophagus specimen are wrapped in paper to aid in gripping.



The BioPuls Bath, Submersible Pneumatic Grips and the Standard Video Extensometer (SVE) create the ideal test configuration for testing a wide variety of soft tissue specimens under physiological conditions and with highly accurate non-contacting strain measurements.

Soft Tissues: Biaxial

The Challenge

Planar biaxial testing of soft tissues is often required to fully characterize the inherent anisotropic properties of the tissue or to set up biaxial stress-strain states to provide more accurate in vivo simulation. With uniaxial testing, fibers may realign along the test axis, altering the mechanical properties of the tissue. In addition, constitutive models cannot be developed based on uniaxial testing alone.

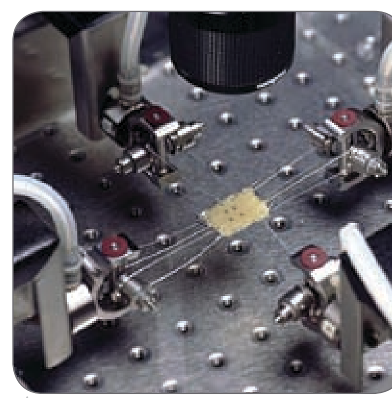
The gripping technique must be capable of securely holding soft tissues without causing damage, and lateral deformations must be unrestricted in order to ensure homogeneous specimen deformation in the gauge area under biaxial loading. In addition to this, strain measurement must not damage the tissue or cause stress concentrations, and be able to account for strain in all directions of loading.

Our Solution

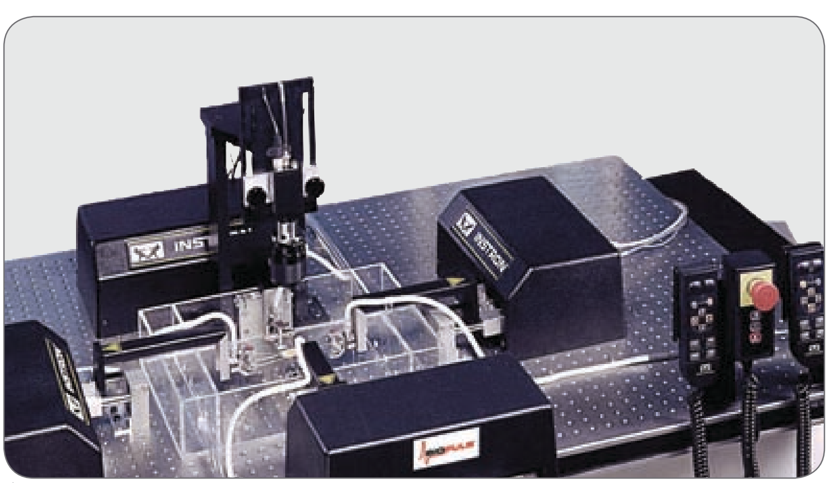
The BioPuls™ low-force planar-biaxial soft tissue system was developed to perform mechanical testing and property analysis of soft planar biomaterials, native tissues and tissue-engineered scaffolds. The configurable system consists of four fatigue-rated actuators mounted to an air-suspended isolation table. The system is capable of running both uniaxial and biaxial tests to offer ultimate flexibility for soft tissue testing.

The 8800 controller is capable of providing true planar-biaxial control, giving both translation and deformation control in both axes. This aids in the ability for highly accurate specimen center-point control, allowing the use of optical instruments mounted above the specimen. The exceptional resolution of the controller ensures accuracy when measuring the extremely low loads associated with many soft tissues.

A simple gripping method based on sutures and pulleys distributes the loading forces equally around the specimen, allowing simultaneous testing along the X and Y axes. The entire system is easily configured with our BioPuls temperature-controlled environmental bath, for simulation of physiological conditions during testing.



Tissue sample with suture grips and unique non-contacting biaxial strain measurement system.



BioPuls planar-biaxial system for soft tissue testing.

BIOPULS

Hard Tissues: Bone

The Challenge

Understanding the mechanical properties and behavior of bone helps researchers develop replacement materials, and for regenerative solutions to treat problems, such as osteoporosis. Additionally, test data on the mechanical behavior of bone under combined loading patterns experienced in vivo helps researchers create accurate models for purposes such as predicting fracture in patients and evaluating fracture treatment protocols.

Bone is a naturally anisotropic material, exhibiting different mechanical properties in different directions. The composition and loading response of hard cortical and spongy cancellous bone differ greatly and therefore require a variety of testing solutions to accurately characterize the tissue in vivo.

There are several items of interest where testing bone is concerned: the fracture line will differ depending on the type and combination of forces applied; the rate of loading; and the moisture content, all of which influence the mechanical properties of bone.

Fixture applies shear loading to the femoral head of a rat femur.

Our Solution

Instron® testing systems provide the ability to perform variable speed tensile, compressive, indentation, flexure and fatigue testing on a variety of different bone specimens, from small sections to intact long bones. With diversity in specimen size and geometry, the BioPuls™ fixturing is often unique to the objective of the test. BioPuls offers a full line of test fixtures including potting, tensile, bend and indentation fixtures, and compression platens for testing of any bone specimen type.

Strain measurement is also dependent upon specimen size and geometry. For flat or round bone specimens, a clip-on extensometer may be mounted directly. For small, delicate specimens or those with irregular geometry, an LVDT may be mounted to the test fixtures. In some cases, a non-contacting video extensometer may also be an appropriate option.

An environmental bath is easily adapted to any of the testing systems and is used to ensure that both hard cortical bone and soft cancellous bone remain moist to provide results indicative of the bone's behavior in the human body.

Software allows for versatility and simple modification of the loading sequences to accurately simulate loading in vivo. In addition, calculations such as elastic modulus, tensile strength and percent strain are simple to set up and modify before or even after the tests have been conducted.

Compression test on a wet bone sample with external strain measurement between platens.

An ElectroPuls® E1000 test instrument performs fatigue testing on a whole bone.

Biomaterials

The successful release of bio-engineered materials to market requires extensive knowledge of how these materials behave under a variety of different mechanical and environmental stresses throughout their lifecycle, including manufacture, sterilization and in vivo loading. For example, metallic, ceramic and polymeric materials must be able to withstand normal wear conditions and high loading profiles. Resorbable materials must combine strength with timely resorption and support of tissue regeneration.

How well a biomaterial replicates the structure and mechanical properties of the natural tissue it is replacing is assessed through mechanical testing and simulation. The innovative BioPuls™ solutions provide the necessary versatility to ascertain the details of these complex relationships. Typical test protocols involve determining tensile, compressive, shear and fatigue properties of a material. Hardness tests or impact loading may also be required to accurately characterize performance.

The following section illustrates how Instron is working with its customers to address the challenges of biomaterials testing.

Hydrogels

The Challenge

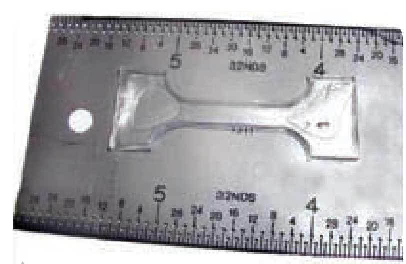
Hydrogels are widely used in the biomedical industry for applications such as coatings for catheters, contact lenses, scaffolds, and wound dressings; these absorbable materials help reduce friction and the risk of infection. Hydrogels are often implanted in the body, so must be tested in a physiological environment. Gripping hydrogels poses many problems as they are slippery and tear easily. The appropriate grips are critical to ensure the specimen does not fail before testing begins. Hydrogels fail at low forces, so highly accurate load and displacement measurements are required. Dehydrated specimens have significantly different properties, so the use of a 37 °C bath to maintain physiological conditions is necessary to ensure proper characterization of hydrogels.

Our Solution

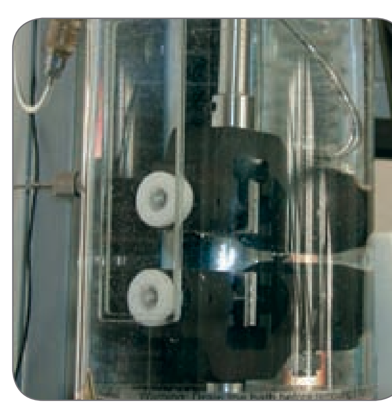
An Instron® model 5544 electromechanical testing frame configured with a 10 N load cell, the Instron BioPuls™ Bath and 250 N capacity submersible pneumatic grips with 25 x 25 mm surfalloy faces are a perfect fit for this test.

The BioPuls Bath provides an in vitro envrionment that keeps the specimen hydrated. These grips use pneumatics to open and close the faces, so the user's hands are free to carefully insert the specimen without damage. Surfalloy faces offer enough friction to grip the specimen, without being too rough and tearing it.

This test configuration can easily handle very small specimens, such as a contact lens, which requires a gauge length of only 5 mm.



Close-up of a hydrogel specimen.



The recommended test configuration for testing hydrogels includes the BioPuls submersible pneumatic grips and temperature-controlled bath.

BIOPULS™

Nickel Titanium (Nitinol)

The Challenge

The shape memory and superelastic characteristics of nitinol make it an extremely desirable material for many medical devices. These include devices include stents, dental wires, internal fracture fixation devices, catheter guide wires and pins, and biopsy forceps.

Nitinol wire is thin, yet very hard, and causes numerous problems with gripping. Unless the correct gripping technique is used, failure of the wire often occurs within the jaw face. When measuring strain, the testing system's position transducer is often insufficient to obtain accurate measurements. Further, contacting extensometry may introduce errors such as those caused by the slippage of knife-edges or local deformation at the contact point.

Our Solution

The BioPuls™ solution for testing nitinol wire conforms to standard ASTM F 2516-05, 'Standard Test Method for Tension Testing of Nickel-Titanium Superelastic Materials'. Pneumatic cord and yarn grips are most effective in obtaining maximum stress at failure in thin wire and tubing by reducing the stress concentration on the specimen at the grip faces and by allowing easy loading and alignment of the specimen. This approach also prevents wear of grip faces due to the hardness of the material. For larger diameter wire and tubing, side-acting and wedge-style grips with serrated or serrated v-faces are often used.

The non-contacting video extensometer allows highly accurate strain measurement, while eliminating failures associated with clip-on extensometers. Markers on the wire allow the video extensometer to track the relative position of markers throughout the test.

Pneumatic cord and yarn grips, and the video extensometer are successfully able to test the ultimate strength of nitinol wire without premature failure of the specimen as a result of gripping or measuring strain.

Elastomeric Materials

The Challenge

Heart valves are a very dynamic component of the human body, opening and closing with every heartbeat. Elastomeric compounds are often an ideal choice as a constituent material in the manufacture of artificial valves, as well as replacement tissues, as they can offer excellent durability and long-term reliability.

Our Solution

Instron®'s 8870 fatigue testing system and ElectroPuls® electrodynamic test instruments are ideal for durability testing of artificial heart valves and the materials used in their production. The systems are capable of running dynamic tests across a wide frequency range of many elastomeric materials. A low-force Dynacell™, combined with lightweight grips, is used to minimize inertial errors in the load reading and to achieve exceptional control accuracy. An environmental bath provides in vivo simulation and determines how biological reactions to the elastomeric material will affect valve stability and life performance.

An 8872 system with wave profile grips for fatigue testing of viscoelastic thin films down to loads less than 10 N in solution.

Orthopaedics

Orthopaedics

Decades of success in using orthopaedic implants for the restoration of normal function to arthritic joints and for post-trauma stabilization and repair, has led to a proliferation of new materials, designs and applications. Dozens of joint replacement products, most commonly for the hip, spine and knee joints, are available on the market. As they represent the most complex mechanical systems in the body, articulating joints provide implant designers with many challenges to overcome. Most notably, designers must apply their knowledge of joint kinematics and loads to their designs to ensure life-long performance. Physiological forces dependent on the patient's body weight and physical activities, motions in up to six degrees-of-freedom, and the need for a near frictionless bearing surface, are all taken into consideration in attempts to replicate the joint. In addition, the effects of stress shielding and wear must be studied and the service life of the implant in vivo must be verified. All this fuels a fast-growing need for more complex and anatomically correct testing protocols.

BioPuls Dual-Station ISO hip simulator.

Instron® in Orthopaedics

Instron has considerable experience testing in orthopaedics: from basic static testing of raw materials, to impact loading of joint components, through to complete simulation for evaluating the fatigue and wear properties in vivo. Through every phase of implant development, Instron's innovative BioPuls™ solutions meet a vast array of demands found within the orthopaedics field. Offerings include the unmatched Dual-Station™ strategy of simulator accessories that significantly reduces testing time when carrying out long-term wear and durability tests.

This section highlights the range of orthopaedic applications Instron is actively involved in with its customers.

BIOPULS™

Modular Hip Implants

The Challenge

After surgery involving modular hip implants, the detachable head must remain immobile on the stem as the patient recovers and returns to normal levels of activity. Motion of ceramic heads will cause wear of the metallic stem, while fretting of metallic heads can cause stress corrosion. Either condition will lead to premature implant failure.

Our Solution

A static test based on ISO 7206-9 characterizes the ability of a femoral head, whether ceramic or metallic, to resist torques normally associated with implant use in vivo. The test takes place in an environmental bath filled with deionized water and maintained at a temperature of +37 °C. While applying a static compressive preload, a transverse torque is ramped until the head begins to rotate.

The BioPuls™ fixture accommodates both metallic and non-metallic hip implants, and is suitable for a wide variety of geometries.

BioPuls axial-torsional grips with quick latch environmental bath.

Hip Implant Fatigue

The Challenge

Following surgery, proximal loosening and stress shielding can occur as a result of normal activity and can lead to abnormal loading profiles. Fatigue testing of hip implants is used to determine the endurance properties by simulating the dynamic loading of the implant during gait.

Our Solution

ISO standards have been established to test for both abnormal and normal fatigue loading.

- The ISO 7206-4 standard simulates loading when proximal loosening has occurred. Loads are applied through the femoral head of the hip implant to induce compressive, bending and torsional stresses.
- The ISO 7206-6 standard examines fatigue of the implant neck, which is more consistent with a correctly fixed implant subjected to normal in vivo loading.

The BioPuls™ femoral fatigue fixture was specifically designed to meet and exceed the requirements of the ISO tests. The fixture includes a low-friction loading head and adapters for mounting to the 8872 fatigue testing system. The fixture can also be easily adapted to suit other testing machines and test setups. The flexible specimen holder is also provided to accommodate a wide variety of hip geometries, offset angles, embedding materials and embedding depths.

The fixture also accommodates an environmental chamber for complete in vivo simulation.

BioPuls femoral fatigue fixture using patented Dynacell™ load cell technology.

The embedding fixture ensures correct implant alignment for the test.

Hip Simulation

The Challenge

Wear of Total Hip Replacements (THR) has been identified as one of the major causes of osteolysis, and consequently, implant failure. ASTM F 1714 'Standard Guide for Gravimetric Wear Assessment of Prosthetic Hip Designs in Simulator Devices' was developed to evaluate the wear properties of ceramic and polymeric materials used as bearing surfaces in hip joint replacement prostheses. It represents a more physiological simulation than basic wear-screening tests such as pin or ring-on-disk.

Our Solution

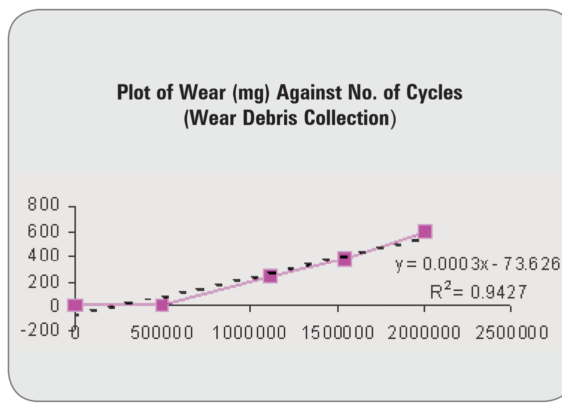
The BioPuls™ Dual-Station™ ASTM hip simulator incorporates the gravimetric method as per the ASTM standard. It provides an accurate and cost-effective solution for four degrees-of-freedom hip wear simulation and is offered as an accessory for the 8874 axial-torsional testing system.

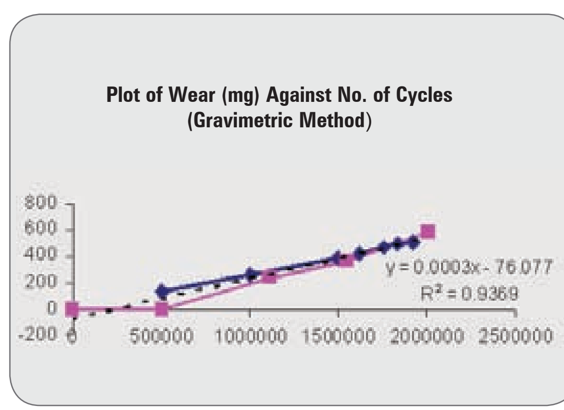
The system applies physiologically accurate loads and motions in axial flexion-extension, abduction-adduction and internal-external rotation on a test specimen maintained under in vivo conditions. Easy system control is enabled through Instron®'s user-friendly interfaces and fatigue software.

To conform to ASTM requirements, hip wear simulators must use two specimens; one test specimen and one control specimen. This strategy is necessary to eliminate possible errors due to fluid absorption into the specimen or those associated with creep of the bearing materials. Instron's unique Dual-Station design enables simultaneous testing of both specimens, a solution whose simplicity and flexibility is unmatched. Without Dual-Station capability, both specimens must either be tested in series, taking over four months to complete a single test, or occupy two testing systems in parallel.

The 8874 is a versatile testing system that, in addition o the long-term wear simulation tests,can be easily reconfigured to accommodate a full range of other biomechanical tests.

The BioPuls Dual-Station ASTM hip simulator on an 8874 system. The axial-torsional actuator, in combination with the fixture, generates four-axis motion in the upper wear station.





Wear results consistent with clinical performance.

The Challenge

With the vast array of differing hip implant designs and materials available in the market, the ISO 14242 standard ‘Implants For Surgery - Wear Of Total Hip Joint Prostheses’ creates a common platform for evaluating wear performance. It details a strict set of testing parameters including load/ motion profiles, implant alignment, the conditions for environmental simulation, as well as a defined test procedure. The standard also specifies clear methods for measurement of implant wear.

Our Solution

The BioPuls™ Dual-Station™ ISO hip simulator was designed to address the more demanding requirements of ISO 14242. The simulator is offered as an accessory for 8870 testing systems, providing a unique approach for hip wear testing that conforms to the requirements of both the ASTM and ISO standards.

Unlike other standards, ISO specifies that the hip motions must be generated by the femoral head, not the acetabular cup, a common failure with other hip simulator designs. Femoral and acetabular components must also be mounted in the physiological position - the femoral head distal to the acetabular cup. This BioPuls simulator system generates physiological load/motion combinations as defined by the ISO standard to permit accurate generation of wear of the hip implant.

The BioPuls ISO simulator was designed around the unmatched strategy of the Instron® Dual-Station, which allows users to increase both productivity and flexibility. Both stations feature environmental baths for accurate simulation of in vivo conditions.

BioPuls Dual-Station ISO simulator with control station and wear test station.

BioPuls ISO hip simulator. The wear test station generates loads and motions within the femoral head.

Knee Testing

The Challenge

Fatigue fracture of knee tibial trays is one of the most commonly reported failure mechanisms of Total Knee Replacements (TKR). It is caused by loss of underlying bone support resulting from biological reactions such as wear-induced osteolysis. Under these conditions, the tibial tray becomes mechanically unstable and cyclic loading imparted by normal walking propagates fatigue cracks, ultimately leading to catastrophic failure.

The ISO 14879 standard 'Determination of Endurance Properties of Knee Tibial Trays' provides a common set of test parameters for determining and validating the fatigue properties of different tibial tray designs.

Our Solution

The unique features of Instron®'s 8870 servo hydraulic and ElectroPuls® electrodynamic testing systems will assist designers, manufacturers and researchers through the product life-cycle process, from deriving fundamental material properties (such as resistance to fatigue crack propagation) to testing the entire tibial tray and beyond.

The BioPuls™ clamping fixture is used to secure one half of the tibial tray, simulating a fully supported condyle. The other unsupported condyle is then subjected to physiologically representative loading. By using Instron's Dynacell™ load cell, dynamic inertial errors (such as those caused by the fixturing and from hydro-dynamics that result when testing in an environmental bath) can be removed, allowing for a more accurate measurement of load being applied to the specimen.

BioPuls tibal tray fatigue fixture.

A 8872 servohydraulic fatigue system with BioPuls tibial tray fixture.

BIOPULS™

The Challenge

Total Knee Replacement (TKR) allows the damaged and degenerated articular surfaces of knee joints to be replaced with prosthetic components. The laxity of the knee joint can be affected by the partial removal of ligaments and other soft tissue constraints. Excess laxity places soft tissue under abnormal strains, causing instability in the joint and ultimately, joint failure. If the knee is too rigid, the patient will not have a normal and comfortable range of motion. An optimum level of knee laxity is desired.

Our Solution

An Instron® axial-torsional 8874 testing system, with the addition of an anterior-posterior actuator, allows researchers to conduct in vitro tests on the internal/external rotation and anterior/posterior translation stability of the knee joint while it is subjected to normal gait loads. The effects of component and ligament misbalance on the passive stability of the knee joint can then be assessed.

The additional actuator and fixturing can be removed from the integral T-slot table to allow other accessories to be used for additional tests. This offers the ultimate in flexibility for biomechanical laboratories that perform a variety of tests.

A reliable mechanical model and testing system that can assess the passive stability and laxity of a knee joint is a valuable tool in the design and selection of the optimum replacement knee. Surgical techniques and instrumentation can also benefit, as these can be refined preoperatively to reduce component misalignment and ligament misbalance.

An 8874 testing vsystem with anterior-posterior actuator studying laxity and tribology.

Knee implant fixture on an 8874 testing system (Photo courtesy of Southampton University, UK).

Spinal Constructs

The Challenge

During normal patient activity, spinal constructs can be subjected to high in vivo loading, which may result in catastrophic failure. Simple static testing must be performed to evaluate the compressive, tensile and torsional loading required to fracture the spinal construct.

Service life testing of spinal constructs is critical as fatigue failure is more common than catastrophic failure. Loading is typically applied with a constant-amplitude, load-controlled sinusoidal waveform, running in excess of five million cycles.

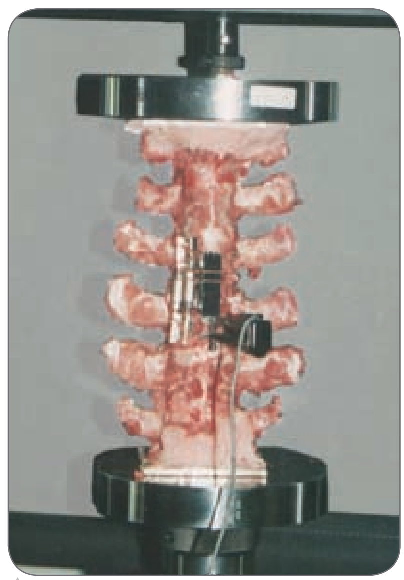
ASTM F 1717 'Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model' specifies methods for both the static and fatigue testing of spinal implant assemblies.

Our Solution

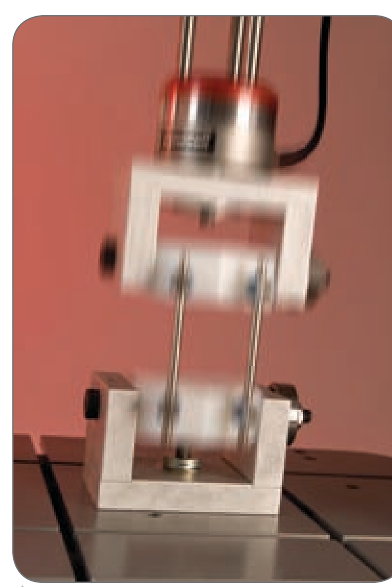
For all spinal construct testing, Ultra High Molecular Weight Polyethylene (UHMWPE) blocks are used, rather than vertebrae, to eliminate the variances that bone properties and geometry may introduce.

Instron® universal testing systems are ideal for static tensile and compressive tests. Static software test packages record load displacement curves and perform calculations required by the ASTM standard. For application of torsional strain, any of Instron's torsion tabletop testing systems are ideal. The 55MT MicroTorsion™ system can be used when multiple revolutions are required.

Instron's 8870 servo hydraulic and ElectroPuls® electrodynamic systems achieve exceptional response and accuracy across the frequency range and are ideal for durability testing of spinal constructs. Using hardware features such as integral inertia compensation from the Dynacell™ load cell, the system response can be optimized in or out of an environmental bath.



A universal testing system determines the compressive load to failure of a spinal instrument. Both the video and clip-on extensometers monitor local displacement of the spine specimen.



An ElectroPuls E1000 system runs a fatigue test on lumbar implants to ASTM F 1717.

Spine Simulation

The Challenge

The spine is the most complex mechanical system in the human body, capable of six degrees-of-freedom motion. Coupled motions have a significant effect on a construct or disc implant that cannot be predicted with simple uniaxial testing. Multiaxial testing helps further the understanding of spine kinematics, aiding in the design of new instruments and implants that allow a more physiological range of motion.

An Instron second generation BioPuls six-axis modular spine testing system.

Our Solution

The BioPuls™ multiaxis modular spine testing system allows load application in up to six axes, supporting mechanical testing of spinal column sections including occipital/cervical, cervical, thoracic and lumbar/sacral. Building on the proven foundations of the SMART spine tester, jointly developed between Instron® and the National University of Singapore, the latest Instron development provides improved simulation of spinal kinematics.

Using successful clinical models, such as those developed by White and Panjabi, the Instron system follows the 'free-end' approach to spine testing. This approach results in more physiological movement of each vertebra with respect to one another, with each axis of motion independently controlled and measured

The multiaxial spine testing work head can be added to an 8800 series fatigue testing system. This is a cost-effective alternative to purchasing a dedicated spine system. The system also relies on use of multiaxial load cells to fully characterize the loads induced in the specimen. The 8800 controller provides the exceptional control accuracy required for multi-axis testing. WaveMatrix™ software provides power and flexibility, including a generation of complex command waveforms, and optimization of data acquisition and storage.

Instron's Spine testing system can apply loads and motions in all six degrees-of-freedom.

Intervertebral Disc Prostheses

The Challenge

Intervertebral disc replacement is a surgical technique for the treatment of lower back pain related to degenerative disc disease. The advantage of this technique over traditional spinal fusion is that it preserves or restores motion in the spine and has the potential to delay the onset of degeneration of healthy discs at adjacent levels in the spine. Disc prostheses are designed to be load bearing over the physiological range of disc motion and to give years of pain- and trouble-free operation in the body. Understanding the static and dynamic characteristics of a particular device allows manufacturers and designers to ensure their product is proven and accepted.

Current and emerging ASTM standards provide a methodology for characterising the static strength and dynamic fatigue behavior of disc prostheses. The rigorous testing regimes in these standards aim to scientifically validate any prosthesis design.

With a typical test run lasting for 10 million cycles and requiring both axial and torsional loading, it is vital that a system copes with these performance demands and delivers the highest quality of results. The requirement to conduct these tests in a wet environment adds to the complexity of the system.

Our Solution

An Instron® 8874 axial-torsional system, with the addition of Instron's temperature controller and re-circulator unit, allows device manufacturers and contract research laboratories to conduct both static and cyclic testing on a range of implant designs. The bath, in which saline flow and temperature are controlled, provides a stable environment.

With the use of specialized test fixturing, the Instron 8874 system's combined axial-torsional actuator allows for characterization to be conducted in axial compression, compression-shear and compression-torsion test modes for both articulating discs of traditional metal-on-metal, or metal-on-polyethylene design. It's also used for the next generation of protheses, which feature an elastomeric component to give axial compliance under load that mimic the biomechanics of the natural disc. The challenges of developing testing equipment and fixtures that allow for unconstrained six degrees of freedom of motion and satisfy demanding ASTM requirements have been overcome by the Instron 8874 installation at Ranier Technology Limited, Cambridge, UK. It is used for both performance and fatigue characterization of their elastomeric lumbar disc prosthesis – CAdisc-L.

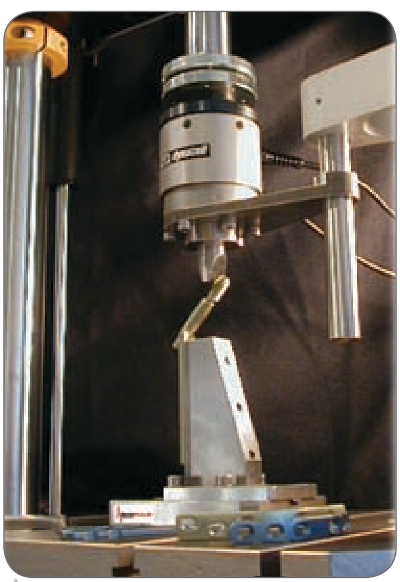
Instron 8874 testing system, and combined temperature controller and recirculation unit, provide a platform for specialized test fixtures to satisfy ASTM standard requirements.

Next generation disc replacement technologies, such as Ranier's CAdisc-L lumbar prosthesis, feature elastomeric components capable of restoring the axial compliance of the natural spine.

Orthopaedic Fixation Devices

The Challenge

Orthopaedic fixation devices are used during reconstructive surgery to treat fractures of bones and soft-tissue injuries normally caused by trauma. Devices, such as bone plates, compression screws and femoral nails, are used to provide stability and maintain the alignment of bone fragments during the healing process. Quantification of important characteristics, such as bending strength or stiffness, can provide surgeons with insight into implant performance, while allowing researchers to compare device materials and designs. The fatigue life of the implant over a specific time period or range of maximum loading must also be determined.



An 8870 fatigue testing system with a Biopuls™ fixture for a hip compression screw.

Our Solution

The flexibility of Instron®'s dynamic systems, such as the ElectroPuls® electrodynamic series or 8870 servo hydraulic series, allow laboratories to investigate a comprehensive range of device characteristics and performance. Normally following ASTM standards, fixtures are often unique to the objective and application of the tests and results.

For instance, to meet ASTM F 382, 'Standard Specification and Test Method for Metallic Bone Plates', a four-point flexure fixture is used to evaluate the static and fatigue bending. The corrosion-resistant construction of these fixtures allows the test to be carried out both in and out of an environmental bath.

Bone plates and a hip compression screw.

An 8874 axial-torsional servo hydraulic system is used to perform a fatigue test on a femoral nail.

A craniomaxillofacial implant is tested on an ElectroPuls® E3000 system at 20 Hz using a low-force Dynacell load cell.

Dental

Understanding the mechanisms of everyday processes, such as eating and cleaning, can help dentists and oral surgeons find the optimal methods for maintaining healthy teeth.

Besides cosmetic considerations, dental restorations, such as crowns, have to last and provide years of pain free and useful service. Evaluating the mechanical behavior of restorative materials is important in establishing their function. Besides the wear behavior of restorative materials, the durability of the adhesives used in restorations is also vital to implant longevity.

Instron®'s range of dental testing solutions encompasses these wide variety of challenges.

Tensile and Shear Adhesion

The Challenge

A key concern for dental restorative materials and adhesives is their tensile and shear bond strength to the tooth enamel. However, alignment errors associated with angularity and concentricity of the specimen can make pure tensile and shear testing difficult. The ISO 11405 and ISO 7405 standards seek to address this problem with fixtures that ensure specimen alignment during test set up.

Our Solution

The BioPuls™ test fixtures meet and exceed the ISO requirements by addressing alignment of the specimen during preparation, as well as preventing loss of alignment during testing.

The specimen preparation accessory follows the ISO recommendations for set up of the specimen prior to test. It comes with a complete set of tools including cups and studs for multiple test specimens.

The tensile and shear adhesion test fixtures are unique testing solutions with self-aligning capability. The solution for tensile testing of dental adhesion is an easy-to-use fixture designed to correct angularity misalignments. The dental adhesion shear test fixture incorporates frictionless bearings to minimize measurement errors, and includes a range of shear tools.

Fixtures enable tensile adhesion strength of dental materials to be evaluated.

BioPuls shear adhesion fixture.

Specimen preparation accessory.

Flexural Strength

The Challenge

ISO 6872 defines the basic requirements for flexural testing of dental materials. To accommodate the small specimen size, a miniature bend fixture with the ability to incorporate different anvil diameters is required.

Our Solution

The BioPuls™ micro three-point bend fixture provides specialized features for testing according to ISO 6872. The fixture addresses the issues of alignment and parallelism that are vital for these tests.

The fixture is engineered to ensure high precision of span distances and centering. The unit features and includes various sized anvils with mounting in a V-slot for high anvil parallelism.

Micro three-point bend fixture for flexural tests.

Implant Fatigue

The Challenge

Dental implants are an alternative to traditional crown and bridge solutions for replacing damaged and missing teeth. These endosseous dental implants are titanium based, and are securely and permanently anchored in the jawbone. This removes the need to grind down the adjacent healthy teeth to support a bridge, and also provides mechanical stimulation to the underlying bone and gum structures to promote healthy tissue growth around the implant.
Current and emerging ISO standards for the dynamic fatigue testing of these endosseous dental implants specify a method for determining the fatigue strength and behavior of dental implants. The standards simulate the functional loading of the implant body under “worse case” conditions.

Our Solution

With the use of specialized test fixtures to clamp the dental implant in the correct angular orientation and to remove any lateral constraints, the Instron® range of dynamic testing systems allows fatigue testing and characterization to be fully conducted to the ISO standards. The capability of the Instron 8874 testing system to conduct compression and torsion testing allows our customers to introduce biaxial testing when required.

The dental implant fatigue fixture can be fitted to a 8870 servo hydraulic system or an ElectroPuls® Electrodynamic system.

An endosseous implant undergoes compression-bending fatigue.

Biomechanics & Kinesiology

The study of biomechanics and kinesiology, a discipline that emerged through the fusion of engineering, materials science and medicine, seeks to understand the human body in motion. This interdisciplinary science examines biological systems from a mechanical perspective and uses the principles of mechanics to understand issues relating to structure and function.

Biomechanics research has helped to enhance athletic performance, provide methods for preventing injury and improve safety in a variety of activities. For example, shoe manufacturers have utilized 'energy return' materials in the soles of athletic footwear to reduce stress and decrease impact energies usually absorbed at the ankle, knee and hip joints. Mechanical testing of protective gear, such as helmets and athletic braces, ensures that potential injury is minimized.

In a clinical setting, an understanding of biomechanics has helped to advance techniques in rehabilitation and physical therapy, as well as in the design and manufacture of prostheses and mobility aids. In many cases, these developments provide freedom to individuals who would otherwise become dependant on the aid of others.

Prosthetic Limbs

The Challenge

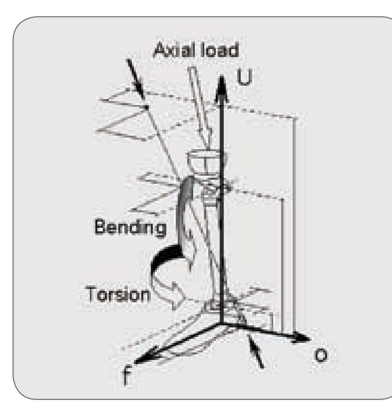
A prosthetic leg should ideally mimic the function of a normal human leg. To prevent failure of the prostheses, both static and cyclic tests are needed to determine strength and fatigue durability. ISO 10328 defines the procedures for static and cyclic strength tests of lower-limb prostheses. In these tests, compound loads are produced that correspond to the peak values that normally occur during the stance phase of walking.

Our Solution

The BioPuls™ prosthetic limb fixturing can be mounted onto an 8870 fatigue testing system. The loading configuration can be adjusted to apply loading at the heel-strike and toe-off phases of the gait cycle. Proof testing, static testing and dynamic testing can all be conducted on the same system.

By varying the loading configuration, compound loads like bending and torque can be applied to the prosthesis from a single test force, eliminating the need for multiple actuation systems. An integral locator and alignment rod allows parameters like knee and ankle centers to be defined, and the correct physiological loads to be applied.

A 3R80 prosthetic knee joint undergoes a structural strength test according to ISO 10328 condition II.



Loading configuration (heel-strike position).

Athletic Footwear

The Challenge

A person walking will experience loads of up to three times their body weight at the heels and up to eight times their body weight when exercising. Sports footwear seeks to absorb some of this impact loading and prevent it from being transmitted to the body.

Different parts of the sole are tailored to have different properties. The heels of sport shoes are designed to absorb heel impact energy, while the forefoot area can enhance an athlete's performance during push-off by acting like a spring rather than dissipating the energy. Determining the dynamic properties and performance of these complex visco-elastic materials in the sole is vital to producing optimal footwear design.

Our Solution

An ElectroPuls® electrodynamic or a 8870 servohydraulic testing system allows researchers and manufacturers to determine the visco-elastic behavior of different areas of the sole. Fatigue loading tests are used to investigate parameters, like energy absorption and dynamic stiffness, when performing activities such as running and jumping.

Advanced features of our systems include inertial compensation with Dynacell™, trimodal control, and adaptive control (where the control-loop terms adapt as specimen stiffness changes). WaveMatrix™ software can run complex loading profiles, such as a starting ramp to a certain load, a running cycle and a step-response (simulating a jump or a sudden impact).

ElectroPuls E3000 electrodynamic test instrument performing impulse tests on training shoe.

Protective Headgear

The Challenge

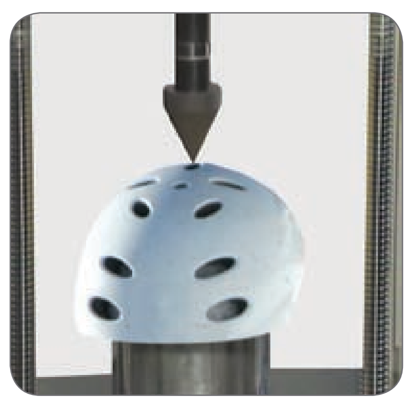
In many sporting activities, such as football, cycling, horseback riding and skiing, a helmet is the only method of protection from sudden impact to the head resulting from a fall or collision. The use of protective headgear and helmets is proven to prevent fatal head injuries and reduce the severity of non-fatal head injuries in comparison to incidents where helmets were not worn.

In order for these protective devices to function properly, a variety of different tests must be performed to ensure their effectiveness. Such testing must determine the impact strength of the outer shell, the inner cushioning of the helmet, and the strength of the strapping material.

Our Solution

Impact testing is the most common method for evaluating the effectiveness of different barrier and cushioning materials used in the manufacture of helmets. The Dynatup® 9250HV drop tower is a versatile instrument with a spring-assisted velocity accelerator for impact velocities up to 20 meters per second, and impact energies up to 1,670 Joules to accommodate a variety of different impact testing methodologies.

For testing of the strap material, an Instron universal testing system may be used with screw action grips, elastomeric roller grips or the preferred pneumatic side action grips, for basic tensile tests to evaluate load to break and tensile strength. Impulse™ software allows the user to easily calculate other results, such as stress at preset strain values or the elastic modulus.



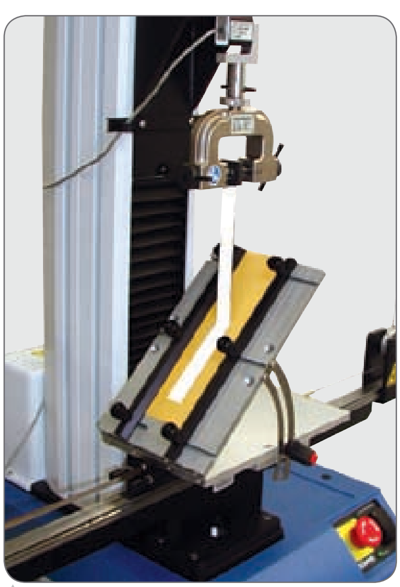
A Dynatup impact testing system is used to determine the impact resistance of a cycling helmet in order to verify that the materials and design are sufficient for use on the playing field.

Instron® Product Range

Static Systems

- Universal, electromechanical testing systems are most commonly used for determining tensile, compressive, and peel strength on a variety of medical devices such as needles, tubing, sutures, gloves, surgical instruments, stents, packaging, and adhesives.
- Multi-turn torsion testers, such as the 55MT series, provide dependable torque testing capabilities for medical devices involving fine wire, bon screws, tubing, Luer-Lok syringes, and surgical instruments.
- Perform in vivo testing of medical devices & biomaterials using the BioPuls™ bath and submersible pneumatic grips.
- Measure radial stiffness and radial strength of interventional devices using Instron RX5500 or RX650 systems.
- Conduct low-force testing of soft tissues using the MicroTesters.

The 55MT series of multi-turn torsion testers provides dependable torsion, axial-torsion and low torque testing capabilities.



Model 3345 single column system performing a peel test on an adhesive material.

Model 5569 testing system with advanced video extensometer, BioPuls bath and submersible grips, and Bluehill software.

Model 5848 with x-y testing stage.

BIOPULS™

Dynamic and Impact Systems

- Servohydraulic and Electrodynamic testing systems are commonly used for determining the fatigue life of implants, devices, tissues and biomaterials. These systems are also ideal for static testing, measuring properties such as tensile strength or strain.

- ElectroPuls® test instruments are all-electric systems that require no special utilities such as 3-phase power, oil, air or water. These clean and low noise systems present flexbility to perform slow-speed static and high-frequency dynamic tests of a variety of biomaterials and medical devices.

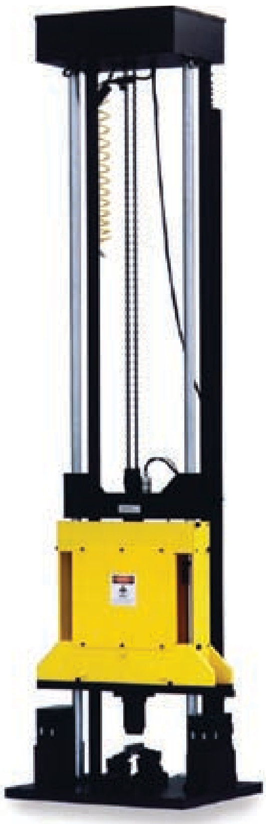
- Use single-axis systems to perform low-force tests or characterize joint replacement materials or components. Axial-torsional, biaxial or multi-axial systems allow more accurate in vivo simulation of materials and implants.

- Perform in vitro testing of medical devices and biomaterials using a range of environmental baths and submersible grips, fixtures and accessories.

- Instrumented Impact testing systems are most commonly used for determining impact resistance on a variety of medical devices such as syringes, medical implants, tools, and packaging.

- Measure energy absorption and force transmission characteristics of protective devices using Dynatup® 9200 or 9250 HT systems.

ElectroPuls® E1000 in horizontal configuration allows optical instruments to be mounted above an environmental bath for soft tissue tests.



Dynatup instrumented impact testing system can perform tests on a variety of medical devices.

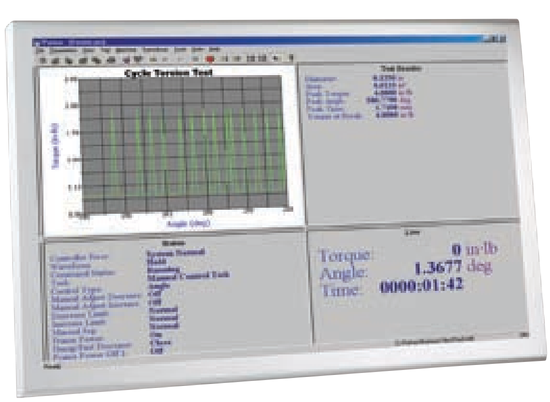
ElectroPuls E3000 is a low noise and clean test instrument for biomaterial and medical device testing.

Instron®'s 8870 range of servohydraulic test systems can perform by static and dynamic testing .

Software for Static & Dynamic Testing

Bluehill® Software for Static Testing

- Designed for single axis testing (tension, compression, flexure, stress-relaxation, creep, peel, tear, friction, etc.) and conformance with a wide variety of international testing standards including ASTM, ISO, EN, and DIN, Bluehill software can be used with all universal, static and dynamic testing systems.
- Provides a wide variety of automated calculations for standard results like peak load, yield strength, modulus and energy, but also allows for more unique and complex results with user-defined calculations.
- Allows the user to automatically generate hard-copy or electronic reports that can be submitted for regulatory submissions to simplify approval processes.
- Ensures that all test methods and data generated are appropriately protected using the software's three levels of security – administrator, manager, and operator.
- 21 CFR § 11 compliancy can be achieved with the ComplianceBuilder (CB) option for Bluehill software. CB includes: electronic signature capture, secure audit trails and report, version restoration and record retention, and secure protection of all data and test methods with time-out features.



Partner™ Software for Torsion Testing

- Partner software works seamlessly with the 55MT MicroTorsion testing system.
- Complex testing routines can be executed with the touch of a single button.
- Observe tests by watching the real-time plot of torque and angle.
- Ensure tests are run safely and correctly by monitoring peak values, measurement rates and live displays.

WaveMatrix™ Software for Dynamic Testing

- WaveMatrix™ is intelligent software designed for single and multi-axis fatigue and dynamic testing of materials and components.
- It can run everything from static ramps, cyclic waveforms, sampled data through to turning point files with multiple steps and with loops.
- The highly visual environment with intergrated tabular screens, clear menu structures, time-based matrix test preview and configurable live test work space is designed to be intuitive and instill confidence.
- The Intelligent data processor uses tools such as data reduction to ensure manageable data file sizes and capturing of the exact data you need.
- An innovative file storage system ensures that all test methods and test data are collated for each test run.
- The peak and trend functions can monitor and detect changes in specimens allowing the user to perfom actions or end the test in a controlled manner.

Impulse™ Software for Impact Testing

- Impulse software is an integrated data acquisition, analysis and visualization package for use with impact testing systems.
- Key features of the software include an innovative data explorer that provides total control in storing, viewing and managing test data; flexible formatting of test curves and result reports; and a vast library of built-in calculations.

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