Orthotek Lab

ISO/ IEC 17025 Accredited

A Third Party Implant Testing Lab

About Orthotek

- Top laboratory in the field of implants and prosthetics
- Organizational member of ILAC, APLAC, whose testing reports are accredited worldwide
- Organizational member of ASTM, TC 110/SC01 (equal to ISO TC 150)
- A third party lab open to orthopedic industry, surgeons and academia worldwide

Orthotek is a third party lab who concentrates on the testing and researching of implants and prosthetics.

The lab offers various testing services, i.e. fatigue, wear, functional tests , FEA and failure analysis services to joint prostheses, spinal implants, osteosynthesis, instruments, etc..

All testing reports are well recognized worldwide FDA, CE, NMPA, AN Visa under the signatory of ILAC, APLAC, etc..

2015

- 2005 Lab established
- A research lab focusing on orthopedic implants
- First hip joint simulator developed

2011

- Accredited by international accreditation service in Asia
- ASTM organizational member & Committeemember of TC 110/SC01 (equal to ISO TC 150)
- More testing facilities equipped, i.e. joint simulators, fatigue frames, bone screw torsion testing apparatus, biomaterial wear frames

Now

- Top testing and academic lab in Orthopedic implants worldwide

Future

Test Scope

ASTM

ASTM F732-00	ASTM F1800	ASTM F2996	ASTM F382	ASTM F543
ASTM F1223	ASTM F1820	ASTM F2267	ASTM G99	ASTM F1717
ASTM F2077	ASTM F2346	ASTM F1612	ASTM F384	ASTM 2345
ASTM F1798	ASTM F2502	ASTM F1160	ASTM F1798	ASTM F1044-05
ASTM F1147-05	ASTM F1541-02	ASTM F897-02	ASTM F2624	ASTM F2706-08
ASTM F564-10	ASTM F1264-16	ASTM F1875-98	ASTM F2052	ASTM F1854-15
ASTM F1829-16	ASTM F2028-14	ASTM F2193-14	ASTM F2423-11	ASTM F561-13
ASTM F2003-02	ASTM F2025-06	ASTM F2132-01e1	ASTM F2183-02	ASTM F2514-08
ASTM F2582-14	ASTM F2606-08	ASTM F2732-13a	ASTM F2722-15	ASTM F2724-08
ASTM F2942-13	ASTM F2979-14	ASTM F3014-14	ASTM F3129-16	ASTM F1714-96

and more ...

ISO

ISO 1424-3	ISO 14242-2	ISO 14879-1	ISO 14242-1	ISO 18192-1
ISO 18192-2	ISO 14801	ISO 12189	ISO 14243-2	ISO 14243-1
ISO 14243-3	ISO 16402	ISO 7206-12	ISO 7206-4	ISO 7206-6
ISO 5833	ISO/TS 13498		ISO /DIS 7206-10	

and more ...

More information， please visit www.orthotek-lab.org, or contact sales@orthotek-lab.org

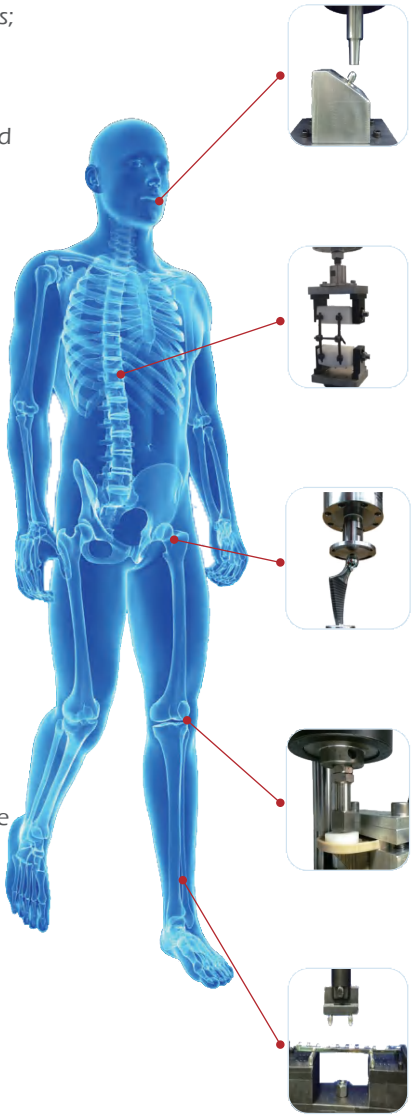
Orthopedic Implants Fatigue Testing

Introduction

- Fatigue is a key factor of the reliability of orthopedic implants, i.e. artificial joints;
- Fatigue testing is an important evaluation of orthopedic implants , and is a required testing item in their premarket notification (CFDA,FDA, CE etc.);
- Support various testing requirements, i.e. hip/knee joint, bone plate, dental implant, spinal implant , acrylic resin cement etc.

Capability and Scope

ASTM F382	Standard Specification and Test Method for Metallic Bone Plates;
ASTM F384	Standard Specifications and Test Methods for Metallic Angled Orthopedic Fracture Fixation Devices;
ASTM F1612	Standard Practice for Cyclic Fatigue Testing of Metallic Stemmed Hip Arthroplasty Femoral Components with Torsion;
ASTM F1717	Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model;
ASTM F1800	Standard Practice for Cyclic Fatigue Testing of Metal Tibial Tray Components of Total Knee Joint Replacements;
ASTM F2077	Test Methods For Intervertebral Body Fusion Devices;
ASTM F2345	Standard Test Methods for Determination of Static and Cyclic Fatigue Strength of Ceramic Modular Femoral Heads;
ASTM F2346	Characterization and Fatigue Testing of Spinal Intervertebral Disc Prostheses;
ASTM F1798	Standard Test Method for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants;
ISO 14801	Dentistry — Implants — Dynamic fatigue test for endosseous dental implants;
ISO 7206-4	Implants for surgery — Partial and total hip joint prostheses Part4: Determination of endurance properties and performance of stemmed femoral components;
ISO 7206-6	Implants for surgery — Partial and total hip joint prostheses — Part 6: Endurance properties testing and performance requirements of neck region of stemmed femoral components;
ISO 7206-10	Implants for surgery — Partial and total hip-joint prostheses — Part 10: Determination of resistance to static load of modular femoral heads;
ISO 5833	Implants for surgery—Acrylic resin cements;
ISO 16402	Implants for surgery — Acrylic resin cement — Flexural fatigue testing of acrylic resin cements used in orthopedics.



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In Vitro Wear Testing

Joint Wear Simulator

- Wear is a key factor affecting the long-term performance of the orthopaedic implants, acknowledged as a required testing item of orthopaedic products by FDA, CE, etc.;
- Joint simulator, serves for product-level wear tests of artificial joints, can reproduce the human natural joint motions in accordance with each standards;
- Simulator can represent the motions, boundary conditions (Loading, Setting Parameters) in accordance with each standards;
- Methodologies of measurement and data processing are calibrated and accredited.

Implants Material Wear Testing

- The wear of implant products can be predicted by the material wear results; Batch tests with multi-stations can be performed to distinguish or select desired materials;
- Compared with product-level test, material test is of high efficiency, low cost.

Capability and Scope

- Perform batch tests for Hip/Knee/intervertebral/shoulder joint prosthesis in all series and implants materials of variety and large amount, with high confidence interval;
- Testing results like wear rate , debris ,etc., agree with the clinical retrieval findings;
- Establish results database, aware of the products development and able to predict;
- Simulate various human in vivo environments (i.e. mechanics, kinematics or lubrication) for different joints; Provide services for customization;
- Test report can be issued both in Chinese and English, and is mutual. recognized among WTO members (including C-FDA, US-FDA, CE etc.) ;

ISO 14242	Wear of total hip-joint prostheses
ISO 14243	Wear of total knee-joint prostheses
ISO 18192	Wear of total intervertebral spinal disc prostheses
ASTM F732	Standard Test Method for W ear Testing of Polymeric Materials

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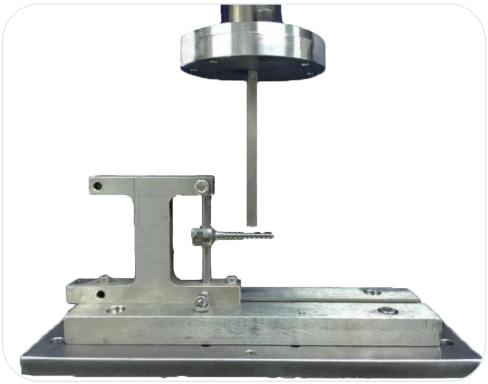
Static mechanical testing

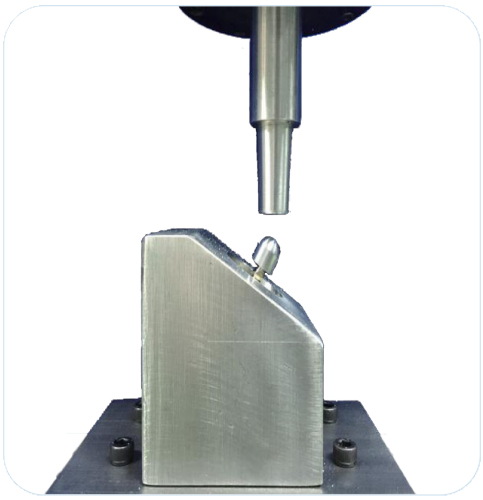
Mechanical Testing

- Static mechanical property, i.e. tension, compression, are the key characteristic of orthopedic implants and biomaterials;
- A key analysis method in R&D of implant products and a required testing item in their premarket notification(CFDA, FDA, CE etc.);
- Orthotek static mechanical testing machine is a highly integrated equipment, providing specified jig and fixture tools, which can support various static tests of different implant products, i.e. four-point bend testing, insert push in/out testing etc.



Capability and Scope

ASTM F1820	Standard Test Method for Determining the Forces for Disassembly of Modular Acetabular Devices
ASTM F2267	Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression
ASTM F382	Standard Specification and Test Method for Metallic Bone Plates
ASTM F384	Standard Specifications and Test Methods for Metallic Angled Orthopedic Fracture Fixation Devices
ASTM F2345	Standard Test Methods for Determination of Static and Cyclic Fatigue Strength of Ceramic Modular Femoral Heads
ASTM F1717	Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model
ISO 16402	Implants for surgery – Acrylic resin cement – Flexural fatigue testing of acrylic resin cements used in orthopedics
ISO 12189	Implants for surgery – Mechanical testing of implant-able spinal devices – Fatigue test method for spinal implant assemblies using an anterior support



Finite Element Analysis in Orthopedics

Finite Element Simulation

- Analysis on biomechanical performance of complicated bone model, i.e. Pelvis, spine;
- Worst case selection among different specifications of implants;
- Provided customized simulation according to requirements;
- 3D digital design optimization for the products. Utilize the method of FEA to evaluate the reliability of each prosthesis, and optimize the product according to the results.

Case Introduction

1、Worst Case Selection

Simulation ISO standard test methods to select of the worst case of hip stem for fatigue testing and analysis.

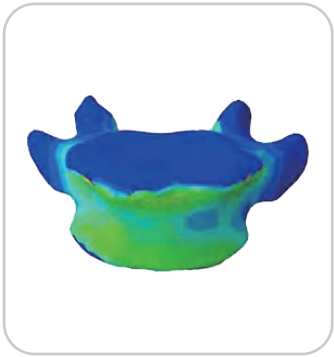
2、The Biomechanical Analysis of the Geometry-Complicated Bionic

Design customization hemipelvis prosthesis, including the simulation of the stress, strain, stiffness and fatigue life of the prosthesis, providing safety-check and suggestions on optimizations.

3、Design of Bone Screw Hole Por Spine Impairment

Formulated the plan of the bone screw implantation for individual patients, i.e. selection of the orientation, depth, size of the bone screws. Evaluate the biomechanical performance of the spine by FEA.

Capability and Scope



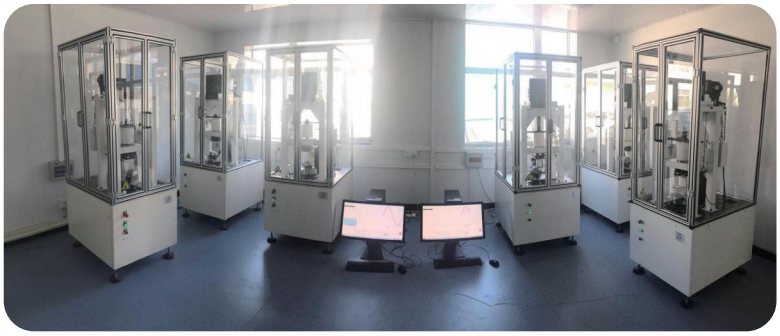
ASTM F2996	Standard practice for finite element analysis (FEA) of non-modular metallic orthopedic hip femoral stems
ASTM F543	Standard specification and test methods for metallic medical bone screws.
ISO 7206-4	Determination of endurance properties and performance of stemmed femoral components
ISO 7206-6	Endurance properties testing and performance requirements of neck region of stemmed femoral components
ISO 14879	Total knee-joint prostheses – Part 1: Determination of endurance properties of knee tibial trays

Lab in Factory: a total solution

Orthotek's 'Industrial Lab Supporting' plan, to have your own lab in the factory

- ISO 17025 qualified lab site layout and functional area design;
- Advanced specified testing apparatus for implants, real low cost and high efficient test solutions;
- ISO 17025 quality system software to run the lab in regulation;
- Professional training program for lab engineers and testing methodology to improve the lab team's capability;
- Long-term improvement in the soft power of the factory, stay close in touch with the latest tendency of the international standard organizations.

- Already built Beijing Innovation Engineering Artificial Joint Lab (CHUNLI Medical Co. Ltd);
- Already built Microport Artificial Joint Wear Testing Lab (Microport Co. Ltd);
- Already built the bone screw testing capability of Medtroinic Kanghui (CNAS accredited);
- Already built the spine implants testing capability of Beijing Fule Medical Co. Ltd;
- .....and more



Note* 'Industrial Lab Supporting' plan only supports the company who passes the testing credit qualification by Orthotek.

Hip Joint/Intervertebral Spinal Disc Wear Simulator

Introduction

- Meeting and going well beyond ISO 14242 and ISO18192 standards on hip and intervertebral spinal disc wear tests;
- Multiple workstation design, independent control, simultaneous testing with control group station;
- High-precision control for high load and large hip joint motions;
- Simple and stable control system, pre-installed ISO standard test program, fully automatic operation;
- Choice of the world's top implant testing laboratory;
- High-precision mechanics, displacement data acquisition with self-calibration function;
- High reliability design, comprehensive security protection;
- Strong guarantee and warranty , professional training.

Motion

Item	Load	Displacement	Accuracy
Axial load	3000N	—	±1%
FE	—	±25°	±1%
Ab/Ad	—	±10°	±1%
IER	—	±10°	±1%
ML	—	±5mm	—
AP	—	±5mm	—

Other Parameters

Item	Parameter
Number of Stations	1 (test station) + 1 (control station)
Dimensions (length x width x height)	900mm×900mm×2140mm
Total Weight	1860kg
Test Frequency	1~1.5Hz/ 0.1Hz
Power Supply	AC 220V /50HZ/25A
Temperature Control	37℃±2℃

Knee Joint Wear Simulator

Introduction

- Meeting and going well beyond ISO 14243 on knee joint wear tests;
- Multiple workstation design, independent control, , simultaneous testing with control
- group station;
- High-precision control for high load and large knee joint motions;
- Simple and stable control system, pre-installed ISO standard test program, fully automat-
- ic operation;
- Choice of the world's top implant testing laboratory;
- High-precision mechanics, displacement data acquisition with self-calibration function;

High reliability design, comprehensive security protection;

Strong guarantee and warranty , professional training.

Motion

Item	Load	Displacement	Accuracy
Axial load	0~5000N	—	±1%
FE	—	0°~90°	—
Ap	-265~110N	0~50mm	±1%
IER	-1~6N·m	±30°	±1%

Other Parameters

Item	Parameter
Number of Stations	1 (test station) +1 (control station)
Dimensions (length x width x height)	800mm×800mm×2400mm
Total Weight	1500kg
Test Frequency	1~1.5Hz/ 0.1Hz
Power Supply	AC 220V /50HZ/45A
Temperature Control	37℃±5℃
Control Method	force/displacement

Fatigue Testing System-Dynamo series

Introduction

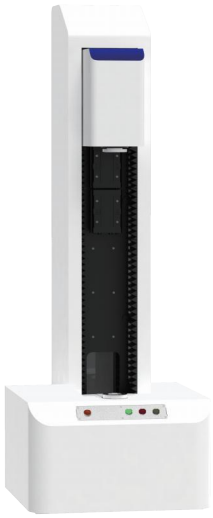
- Patented fatigue tester developed for dynamic tests of orthopedic implants;
- Simple and stable operation system with 'one click' design avoiding of any complicated and redundant programming;
- High reliability and precision system with easy and low maintenance cost;
- Completed testing fixtures for ISO\ASTM\YY standard tests with 'easy user running';
- Strong support in customer own testing capacity setup by the professional testing training and lab on site lecturing.

Compression/tension Fatigue Testing System–Dynamo/FAT

	Parameters	Accuracy
Max. Load	3000N/10000N/15000N	1%
Displacement	0-300mm	0.01mm
Accuracy Grade	Grade 1	—
Frequency	0-15Hz	1%
Power Supply	AC380V 50Hz	—
Total Weight	600kg	—

Torsional Fatigue Testing System–Dynamo/TFT

	Parameters	Accuracy
Axial Load	±3000N	1%
Torsional Load	±20N·m	1%
Displacement	0-700mm	1%
Accuracy Grade	Grade 1	—
Frequency	0-10Hz	1%
Power Supply	AC380V 50Hz	—
Total Weight	300kg	—



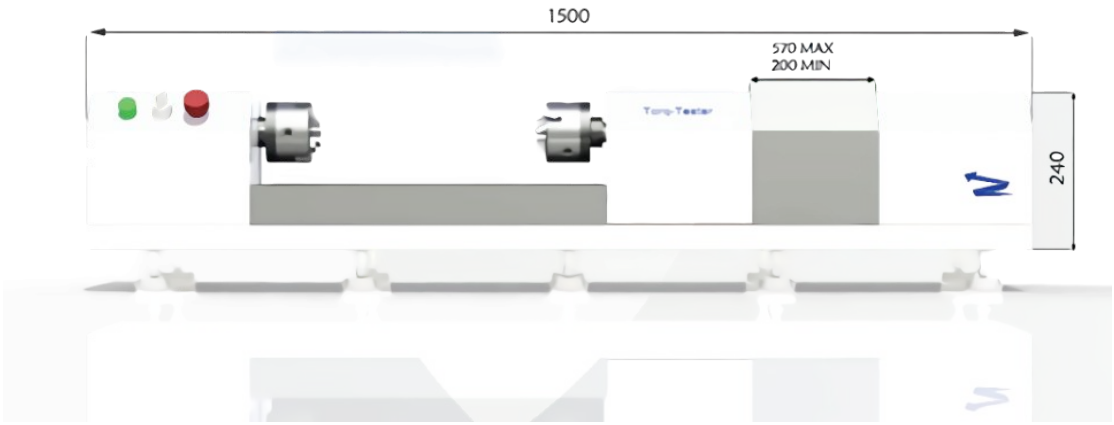
Medical Bone Screw Torsion Tester

Introduction

TorqTester-BonSc543 is a precision instrument developed by Orthotek Laboratory for the testing of the torsion performance of medical bone screws. It supports the testing and research of the torsion, screw-in, pull-out and self-tapping performance of bone screws. The operating system is highly integrated to provide an effective means of testing the performance of bone screws.

TorqTester-BonSc543

- Customerized testing parameters input, as well as pre-installed ASTM F543 testing program;
- High precision system for Accurately capture the self-tapping point and screw in/out torque;
- Special bone screw custom fixture covering trauma and Craniofacial screw;
- Operator station ergonomics design.

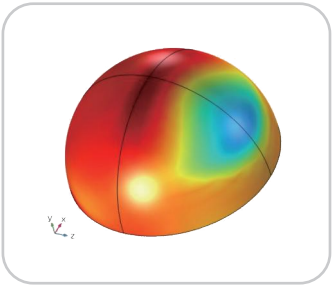


Item	Parameters	Accuracy
Axial Load	±300N	1%
Torque Range	20N · m	1%
Displacement	0-300mm	0.50%
Max. Rotation Speed	40r/min	1%
Power Supply	AC220V 50Hz	—
Total Weight	200kg	—

Wear Modelling and Simulation of Hip Joint Replacements

Finite Element Simulation

- Prediction of the wear performance of hip replacements through computational modelling and simulations which is fast and low-cost. Find out the optimal product across a group of samples to be evaluated, with combination of corresponding physical joint simulator tests;
- Wear analysis in terms of design of parameters, materials, manufacture accuracy etc. Providing advice on optimisation of design;
- Prediction wear under load and motion in various daily activities and for the specific patient (patient groups), combined with finite element analysis;
- Provided customized simulation according to requirements.



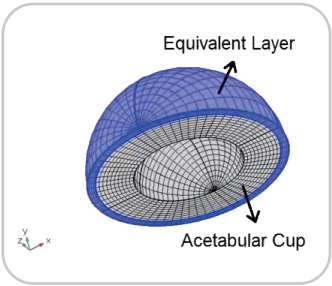
Case Introduction

1、 Worst Case Selection

Simulation ISO standard test methods to select of the best case of artificial hip joint products for wear testing and analysis.

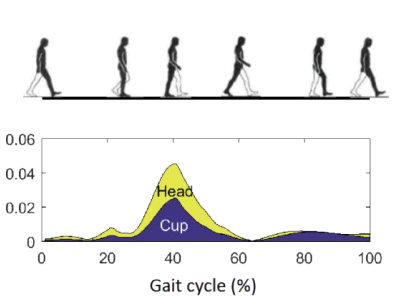
2、Analysis of failure cause & Providing advice on optimisation

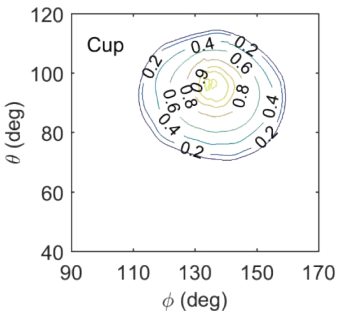
According to the customer's sample of the material and exercise loading, Wear analysis of artificial hip joint sample in terms of parameters, materials, manufacture accuracy etc. Providing advice on optimisation of design.

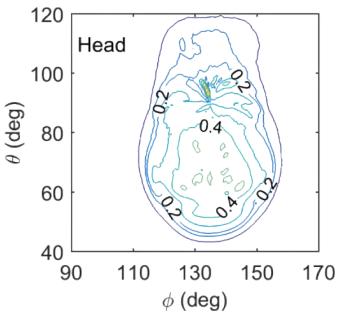


Capability and Scope

ISO 14242 Implants for surgery – Wear of total hip-joint prostheses.







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