

Spinal Device Mechanical Testing

Jonathan Peck, MS

Master Reviewer

Extracolumnar Spinal Devices Team

Katherine Kavlock, PhD

Team Lead

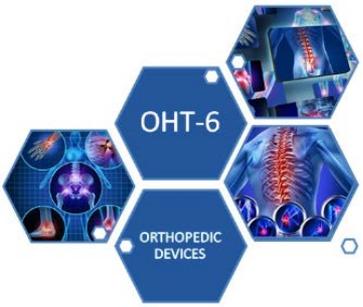
Intracolumnar Spinal Devices Team

DHT6B: Division of Spinal Devices

OHT6: Office of Orthopedic Devices

Office of Product Evaluation and Quality

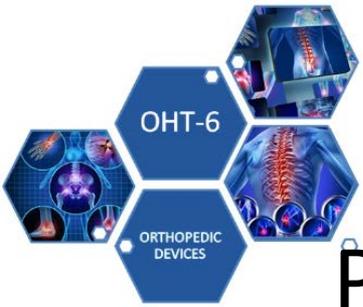
Center for Devices and Radiological Health



Outline

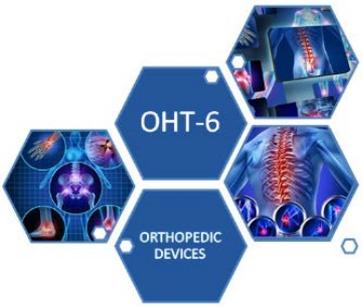


- Performance Testing Section in 510(k) Body
- Test Reports
- AINN Responses
- Other Considerations



Performance Testing Section of 510(k)

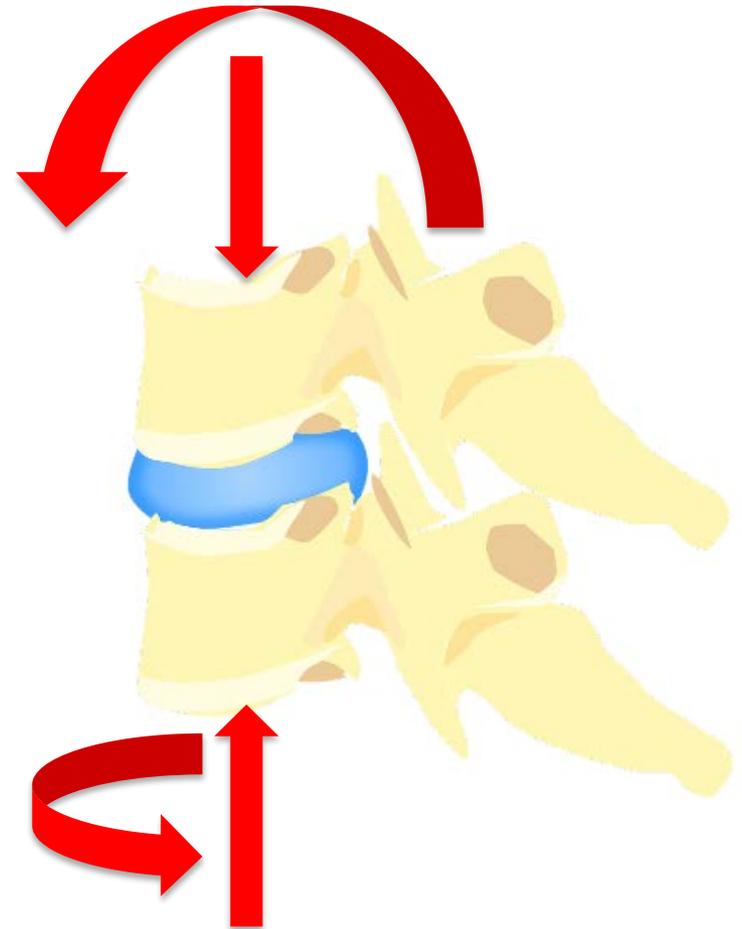
- Test Selection
- Worst-Case Determination
- Acceptance Criteria
- Results Summary
- Substantial Equivalence Conclusions

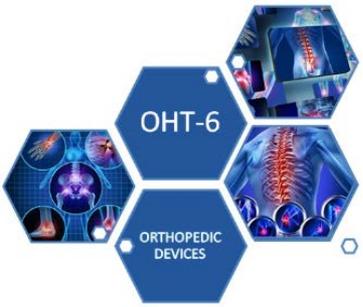


Test Selection



- Spinal device testing is typically based around loading modes, moments, displacements, and angular displacements the devices is expected to experience *in vivo*.

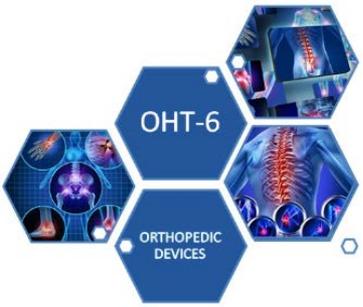




Test Selection: High Volume Device Areas



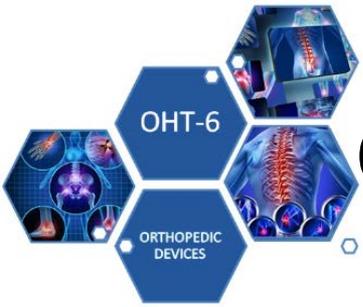
- Guidance documents provide recommended testing regimens for our highest volume device areas.
- Consult the relevant guidance document and provide justification for any tests *not* performed that are recommended by a relevant guidance document
- Certain device features may warrant additional testing to established substantially equivalent mechanical performance



Guidance Documents



- *Guidance for Industry and FDA Staff – Spinal System 510(k)s*
 - Thoracolumbosacral Pedicle Screw Systems
 - Posterior Cervical Screw Systems
 - Cervical and Thoracolumbar Anterior Plating Systems
 - Vertebral Body Replacements
- *Intervertebral Body Fusion Device – Class II Special Controls Guidance for Industry and FDA Staff*
 - Cervical and Lumbar Intervertebral Body Fusion Devices
- *DRAFT Spinal Plating Systems – Performance Criteria for Safety and Performance Based Pathway*
 - Cervical and Thoracolumbar Anterior Plating Systems

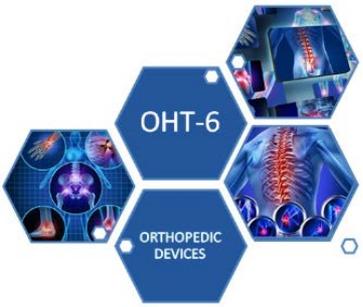


Commonly Utilized Test Standards



- Pedicle screw and anterior plating systems:
 - ASTM F1717 – Cervical and Lumbar Construct Testing
 - ASTM F2706 – Occipital-Cervical Construct Testing
 - ASTM F1798 – Interconnection Testing
 - ASTM F2193 – Component-level Testing

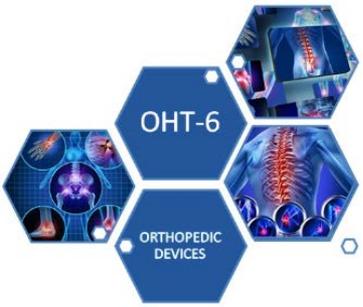
- Intervertebral body fusion devices and vertebral body replacements:
 - ASTM F2077 – Structural Integrity Testing
 - ASTM F2267 – Subsidence Testing



Test Selection: Low Volume Device Areas



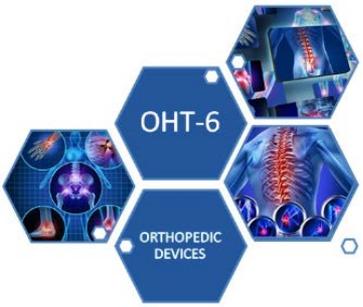
- Devices without guidance and/or standard test methods
 - Provide justification for the test methods selected
 - Predicate device 510(k) Summaries can provide useful insights
 - Include discussion of any applicable literature used to develop testing regimen



Worst Case Justification



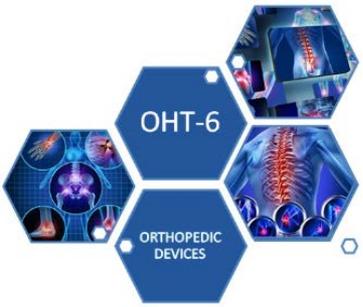
- Common methods used to determine worst case:
 - Engineering Analysis, for example:
 - Smallest diameter pedicle screws and rods
 - Smallest footprint intervertebral body fusion device
 - Finite Element Analysis:
 - Most useful for to justify worst case for single-piece interbody fusion device designs
 - Pilot Testing



Worst Case Justification cont.



- The same construct or device may not be worst case for all test modes
 - Example: Pedicle screw constructs are often tested with cross-connector in compression bending, but without cross-connector for torsion
- Multiple potential worst case constructs of devices may need to be evaluated if a definitive worst case cannot be determined



Worst Case Justification cont.



- Testing should be conducted on final, finished device or provide justification for differences between tested device and final, finished device
 - Example: If steam sterilization is not expected to impact mechanical properties of device, it may be acceptable to test unsterilized device
- If testing done on prototype device, explain why the results are relevant to the final, finished device you intend to market.



Acceptance Criteria



- Acceptance criteria for each test should be listed for each relevant parameter for each test. For example,
 - Yield load
 - Stiffness
 - Runout loads
- Acceptance criteria are typically based on:
 - Side-by-side testing of legally marketed predicate device owned or obtained by the company
 - Valid sources of predicate testing including literature, guidance documents, and standards



Acceptance Criteria Sources



Contents lists available at [ScienceDirect](#)

Journal of Biomechanics

journal homepage: www.elsevier.com/locate/jbiomech
www.JBiomech.com



Mechanical performance of cervical intervertebral body fusion devices:
A systematic analysis of data submitted to the Food and Drug
Administration



Jonathan H. Peck ^{a,*}, David C. Sing ^{b,c,1}, Srinidhi Nagaraja ^c, Deepa G. Peck ^d, Jeffrey C. Lotz ^b,
Anton E. Dmitriev ^c



Contents lists available at [ScienceDirect](#)

Journal of Biomechanics

journal homepage: www.elsevier.com/locate/jbiomech
www.JBiomech.com



Mechanical performance of lumbar intervertebral body fusion devices:
An analysis of data submitted to the Food and Drug Administration



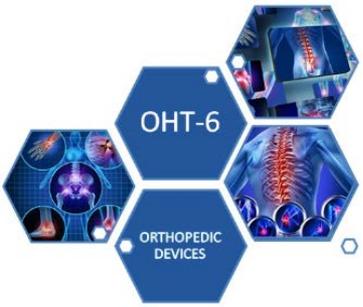
Jonathan H. Peck ^{a,*}, Katherine D. Kavlock ^a, Brent L. Showalter ^a, Brittany M. Ferrell ^a, Deepa G. Peck ^b,
Anton E. Dmitriev ^c

GUIDANCE DOCUMENT

Spinal Plating Systems - Performance Criteria for Safety and Performance Based Pathway

Draft Guidance for Industry and Food and Drug Administration Staff

SEPTEMBER 2019

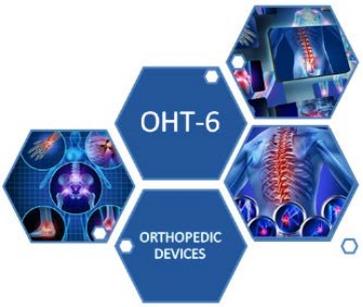


Results Summary



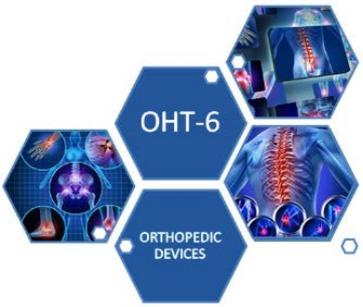
- A test results summary should be provided that compares the subject device performance to acceptance criteria.

Test Parameter	Subject Anterior Cervical Plating System	Performance Criteria for Safety and Performance Based Pathway – Cervical Plates
<i>Static compression bending stiffness (N/mm)</i>	15 ± 1.5 N/mm	9.6 N/mm
<i>Static compression bending yield load (N)</i>	120 ± 10 N	75 N
<i>Static torsional stiffness (N-m/deg)</i>	2.0 ± 0.1 N-m/deg	0.9 N-m/deg
<i>Static torsional yield torque (N-m)</i>	7.5 ± 0.5 N-m	4.7 N-m
<i>Dynamic compression bending – Runout load at 5 Mc (N)</i>	60 N	40 N



Results Summary: Common Problems

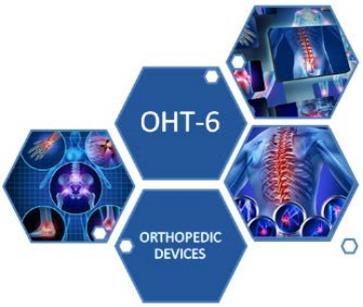
- Static results with high standard deviation
 - Discussion needed to ensure confidence in comparison to acceptance criteria, for example:
 - all test samples meet or exceed the acceptance criteria;
OR
 - the calculated average of all test samples meet or exceed the criteria with a standard deviation of $\leq 10\%$ of the average.



Results Summary: Common Problems



- Fatigue testing with insufficient precision or inconsistent results
 - Adequate precision ensures runout load is representative of actual device fatigue strength, for example:
 - ASTM F2077: 1.5x
 - ASTM F1717: 1.25x
- Failure modes of the subject device not described or not comparable to predicate
 - All failure modes are not created equal
 - Most cracking considered a failure

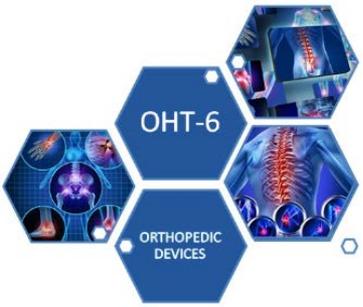


Conclusions



- Provide overall conclusions for how the test results demonstrate substantially equivalent mechanical performance, for example:

The subject plating system performed as well or better than the predicates cited in all relevant comparative parameters, and failure modes between the subject and predicate or reference devices were similar. Therefore, substantially equivalent mechanical performance of the subject device has been demonstrated.



Test Report Recommendations

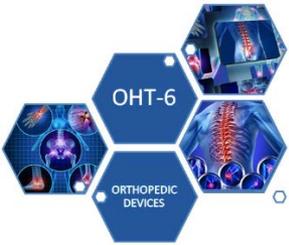


- Device identification
- Test Construct Assembly
- Apparatus
- Procedure
- Deviations from standard methods
- Results



Test Report Recommendations

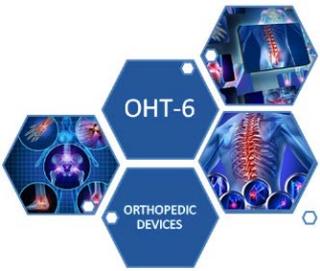
- Each standard test method has reporting requirements listed in the standard
- The guidance documents listed also have some recommendations for test reports as well
- ASTM F2077 does a particularly good job of providing guidance for the contents of a test report



Device Identification



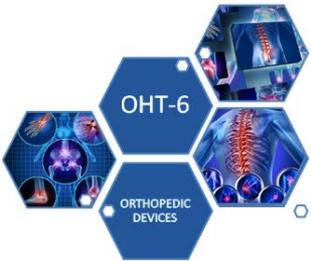
- Please explain if device name changed between testing and 510(k) submission
- To make parts easily identifiable, please provide test device component descriptors, such as
 - Device or component name
 - Materials
 - Nominal dimensions
 - Part/Lot numbers
- Representative pre-test device images from relevant angles (e.g., sagittal, frontal, top)



Construct Assembly



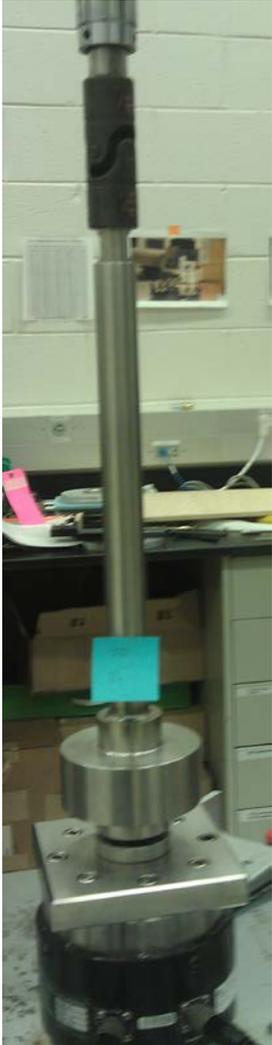
- Provide relevant details regarding assembly of test constructs, for example:
 - Screw and set screw tightening torques
 - Pilot hole diameters
 - Distance between screw tulips and test blocks to allow for polyaxial failure (ASTM F1717 and F2706)
 - Mechanism by which interbody device integrated fixation components are fixed to test blocks

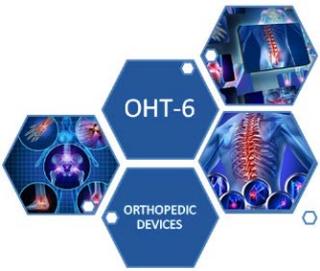


Apparatus

FDA

- Describe the test setup including notable geometries, for example:
 - Active lengths
 - Moment arms
 - Occipital-cervical angle
 - Intradiscal heights (ASTM F2077)
- Describe test blocks, including:
 - Material
 - Dimensions
 - Engineering drawings of test blocks for ASTM F2077 with additional description of details such as pocket depth





Apparatus - Degrees of Freedom



- Describe how the degrees of freedom are restricted or allowed by the physical apparatus and test machine settings:
 - Universal joints
 - X-Y sliding tables
 - Standard specific fixtures (e.g., ASTM F2077)
 - Test machine actuator settings, for example:
 - Locked displacement
 - Free floating
 - Applying constant load/torque

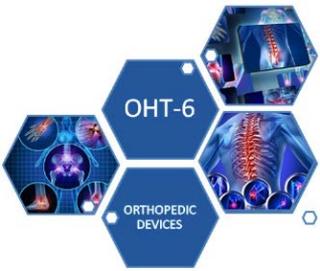


Apparatus



- Describe the test environment
 - Test in solution at 37C if device materials are sensitive to temperature changes in this range
 - Consider testing in solution if wear debris analysis may be desired
 - *ASTM F1877 – Standard Practice for Characterization of Particles*
- Provide test setup images showing:
 - All relevant elements (e.g., universal joints)
 - Closeup of device in fixturing





Procedure



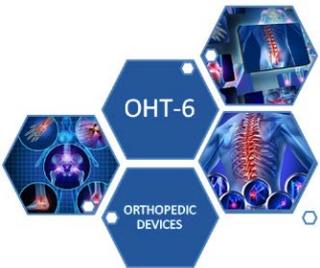
- State pre-loads (e.g., torsion testing) and how those loads are maintained throughout testing
- Describe conditions for termination of test
 - Maximum displacement
 - Load cell limits
- Static tests:
 - Displacement rate or angular displacement rate
 - Torsional direction (i.e., clockwise or counter-clockwise)



Procedure – Fatigue Tests



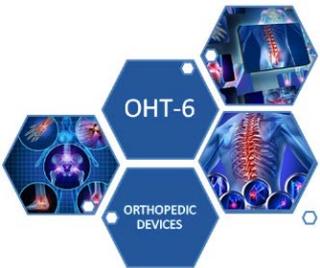
- State notable methods, such as:
 - Test frequency
 - Consider material response and test machine capabilities
 - R-value (ratio of highest to lowest load/torque)
 - Defined by many standards
 - Fatigue precision:
 - Consider increases in load based on adequate fatigue precision as defined by many standards



Deviations from Standards



- Describe and *justify* any deviations from the standard test methods
- Explain any expected effect the testing deviation may have on test results
 - Example: “Use of epoxy to attach IBFD to test block was necessary to properly apply torsion. This may inflate the measured yield torque and stiffness as compared to testing of device without epoxy.”
- Certain testing deviations may invalidate comparisons to acceptance criteria from literature or guidance documents

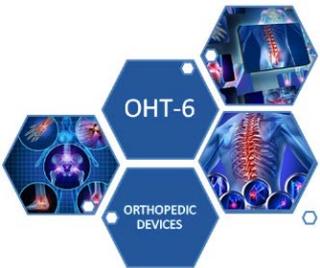


Results – Static Tests



- Provide results for each specimen as well as mean and standard deviation for each

Specimen ID	Stiffness (N/mm)	Yield Displacement (mm)	Yield Load (N)	Ultimate Displacement (mm)	Ultimate Load (N)
AC1	10,925	1.30	10,600	2.25	15,900
AC2	11,345	1.35	11,005	2.15	15,750
AC3	10,900	1.32	10,950	2.05	14,500
AC4	10,775	1.39	11,300	2.15	15,300
AC5	11,525	1.36	11,450	2.20	15,025
AC6	11,200	1.35	10,750	2.25	14,750
Mean	11,112	1.35	11,009	2.18	15,204
St. Dev	291.9	0.03	321.6	0.08	552.4



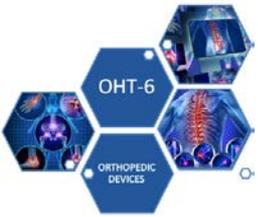
Results – Fatigue Tests



- For each specimen, provide max/min load or torque, number of cycles achieved, and failure mode (if applicable)

Specimen ID	Maximum Load (N)	Minimum Load (N)	Number of Cycles Achieved	Failure Mode
<i>F-AC1</i>	4000	400	5 000 000	No failure detected
<i>F-AC2</i>	6000	600	5 000 000	No failure detected
<i>F-AC3</i>	9000	900	945 487	Fracture
<i>F-AC4</i>	8000	800	3 456 789	Fracture
<i>F-AC5</i>	7000	700	4 345 678	Fracture
<i>F-AC6</i>	6000	600	5 000 000	No failure detected

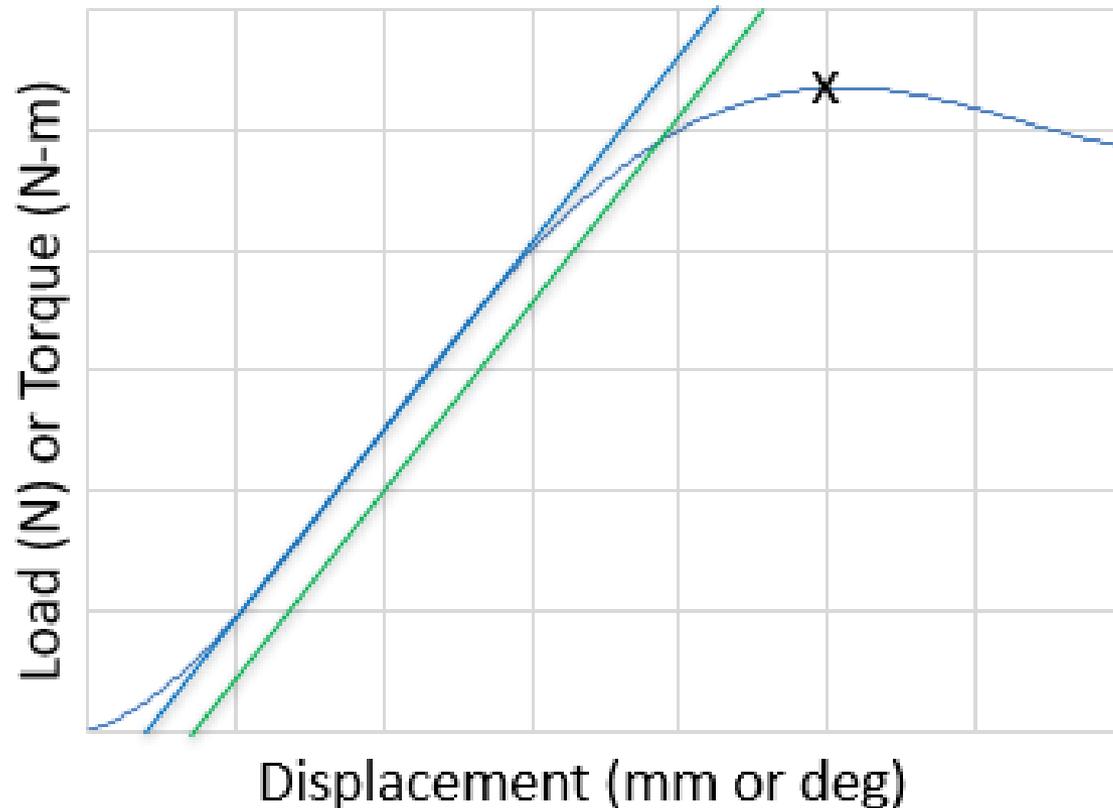
- Consider also supplying a plot of these load vs. number of cycles plot with regression analysis.

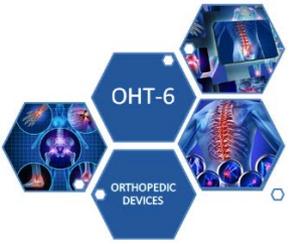


Load-Displacement Plots



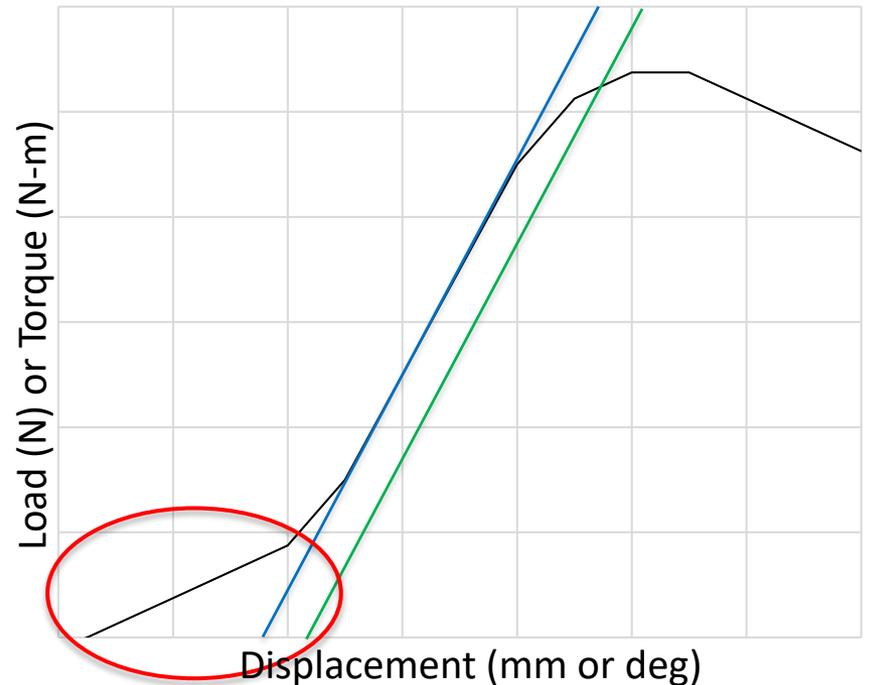
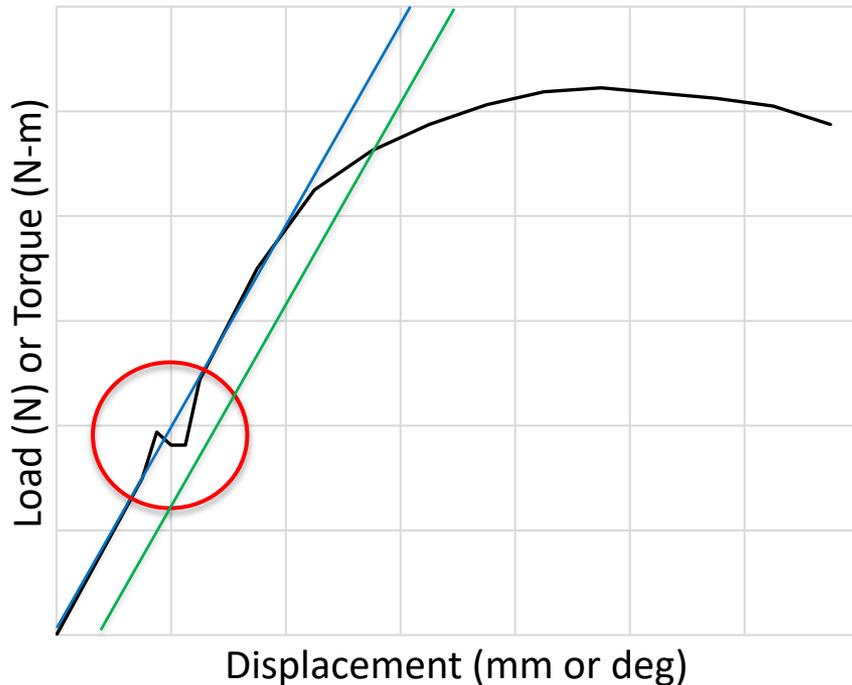
- Provide individual load-displacement curves for each specimen with stiffness line, offset line (used for yield calculation), and ultimate load marking

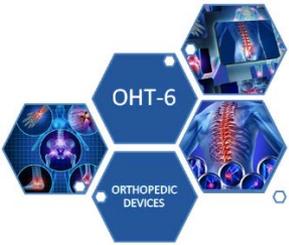




Load-Displacement Plots

- Justify any irregularities in the load-displacement curve that occur prior to calculated yield or stiffness values

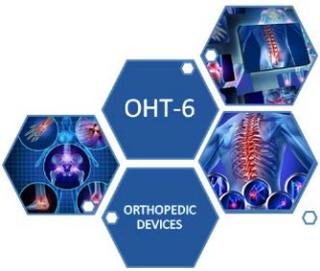




Failure Modes



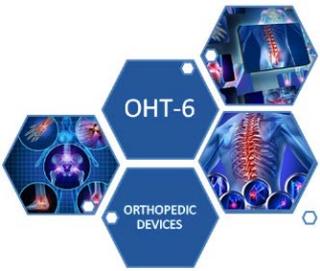
- Provide description of all failure modes for each specimen
- Post-test device images including magnified images of failure modes
 - *ASTM F3292 – Standard Practice for Inspection of Spinal Implants Undergoing Testing* contains recommendations for inspecting spinal implants for failure after testing
- Provide post-test device images for runouts in fatigue testing



Responses to Requests for Additional Information



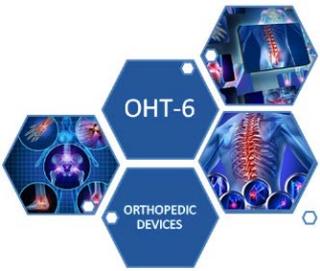
- List each deficiency from FDA verbatim
- Provide narrative responses for each deficiency or subpart of deficiencies. Narrative Responses should:
 - Address all requests in the deficiency
 - Describe any testing performed to address the deficiency
 - Include comparisons to acceptance criteria
 - Summarize literature used to support response to deficiency (and provide copies)



Cadaver Testing



- Cadaver testing can be useful to evaluate questions related to bone-implant interface
- No standardized test methods exist for cadaver evaluations of spinal devices
- Q-submissions are recommended to discuss test methods prior to initiation of these potentially costly, time-consuming studies



510(k) Summary



- Include reference to any applicable testing standards as well as the specific tests conducted.
- Include overall conclusions for how the test results demonstrate substantially equivalent mechanical performance, for example:

“The following tests were conducted on the worst case device: static and dynamic axial compression, and static and dynamic torsion testing per ASTM F2077, and subsidence testing per ASTM F2267. Results of the tests demonstrate substantially equivalent mechanical performance as compared to a legally marketed predicate device.”

Thank You!

