User Manual for Anterior Vertebral Body Tethering Devices – Method for Assessing Mechanical Durability

Tool Reference

RST Reference Number: RST26OP08.01

Date of Publication: 05/05/2026

Recommended Citation: U.S. Food and Drug Administration. (2026). *Method for Assessing the Mechanical Durability of Anterior Vertebral Body Tethering Devices* (RST26OP08.01). https://cdrh-rst.fda.gov/method-assessing-mechanical-durability-anterior-vertebral-body-tethering-devices

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User Manual for Anterior Vertebral Body Tethering Devices – Method for Assessing Mechanical Durability

1. General Information

This Regulatory Science Tool (RST) provides a method for assessing mechanical durability of anterior vertebral body tethering (AVBT) devices. Specifically, this tool describes the methods to assess mechanical durability of the AVBT device construct under different loading conditions through both static and dynamic testing. This tool describes three different loading condition parameters including (1) Screw Angulation, (2) Tether Gauge Length, and (3) Setscrew Reinsertion and Retightening.

2. Scope

This test method is designed for AVBT devices that feature a tether cord, vertebral screws, and setscrews.

3. Materials and Equipment

A. The following items are needed for assembling the AVBT constructs:
- AVBT device (Vertebral screws, tether cord, setscrews, and associated components based on the manufacturers recommendation)
- Test blocks made of ultra-high-molecular-weight polyethylene (UHMWPE) material (tensile breaking strength equal to 40 ± 3 MPa).
    - Two test blocks with the angle of the screw in relation to the test block at 0° each.
    - Two additional test blocks with the angle of the screw in relation to the test block at 20° each (40° total).
    - See Appendix 1 for final dimensions of the test blocks.
    - Other materials and designs may be used as long as equivalent performance is demonstrated.
- Vise for holding the test blocks while implanting vertebral screws and setscrews
- Insertion torque measuring system (e.g., handheld torque measuring system from IMADA, Northbrook, IL, USA) to measure setscrew insertion torque
- Appropriate setscrew driver bit and torque wrench

B. The following items are needed to perform the loading sequence:
- Mechanical testing system with capacity ~5 kN
- ASTM F1717 Fixtures including
    - 2 hinge pins (see ASTM F1717 Section 6.2 [1])

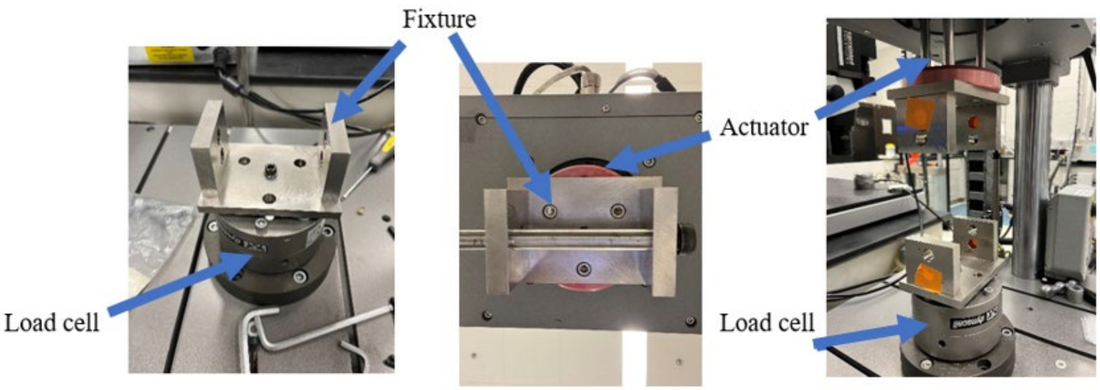


Figure 2: ASTM F1717 fixtures and their attachment to a load frame

4. Recommended Sample Size

The sample size is not prescribed here but should consider the needs of any planned statistical analyses.

5. Test Specimen Assembly

The first step of the test method is to assemble the test specimen constructs. The assembly of the construct is shown below using mock devices [2]:

a. Slowly close the vise jaws such that compression is gently applied to the test blocks for them to be in position for implantation.
b.

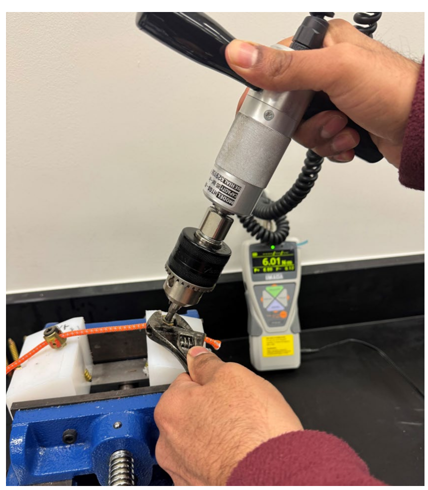


Figure 3: Test blocks held in vise and setscrews being inserted to lock tether cord into the screw head using a handheld torque measuring system

c. Insert the vertebral screws into the test blocks through the appropriate pilot hole to the desired depth.
d. Make sure the distance between both the test blocks (screws - center to center) is at the appropriate gauge length (76 mm or 25 mm)
e. Hold the vise position and insert the tether cord into the screw heads as per the manufacturer's recommendation.
f. Insert the setscrews to lock the tether cord position by tightening the setscrews to the appropriate torque (as per the manufacturer's recommendation).
g. Record the maximum torque applied to each setscrew.

6. AVBT construct configurations for mechanical testing.

A. Screw Angulation

- Two different screw angulation configurations (0° & 40°) should be assessed to evaluate the influence of screw angulation on the mechanical performance of the AVBT construct.
- 0° screw angulation represents a test construct with no angulation between the two vertebral levels, and 40° screw angulation represents an extreme post-op cobb angle between the two vertebral levels (post-op cobb angle based on the literature [3,4]).

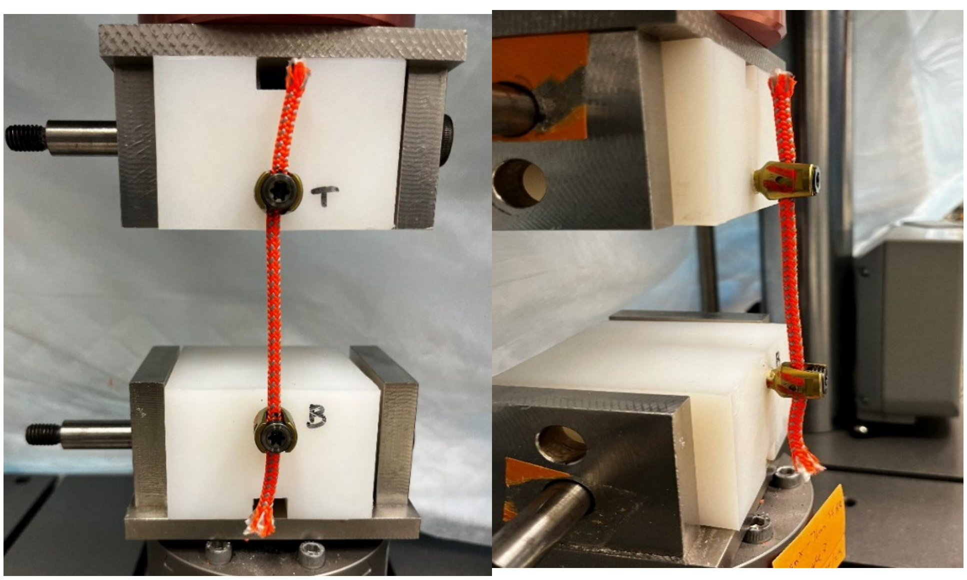


Figure 3: A mock AVBT construct in 0° screw angulation configuration.

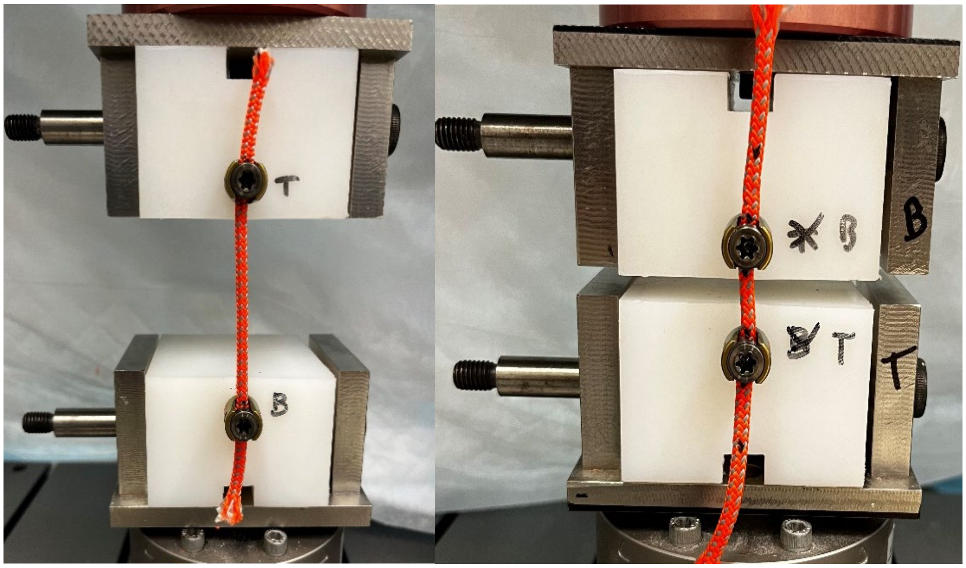


Figure 5: A mock AVBT construct in 76 mm (left) and 25 mm (right) gauge length configurations.

B. Setscrew reinsertion and retightening

- During the surgical procedure of AVBT device implantation, a surgeon may need to tension or potentially reinsert the setscrew while adjusting the tether cord through multiple vertebral levels. This loading should be assessed to evaluate the influence of setscrew reinsertion and retightening.

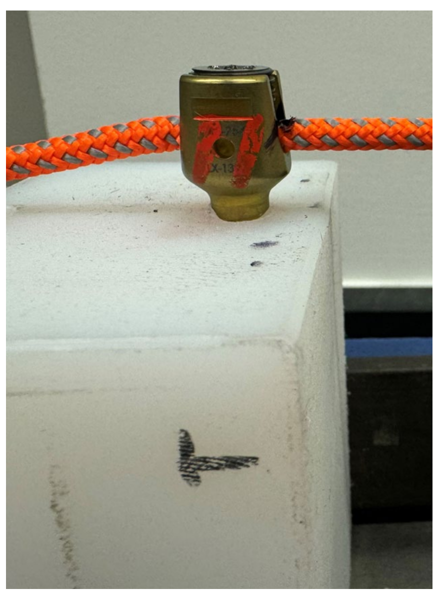


Figure 6a: A mock AVBT construct where setscrew is tightened onto the tether cord with manufacturer recommended torque.

Figure 6b: Setscrew is loosened until the torque reading becomes negligible on the torque measuring system.

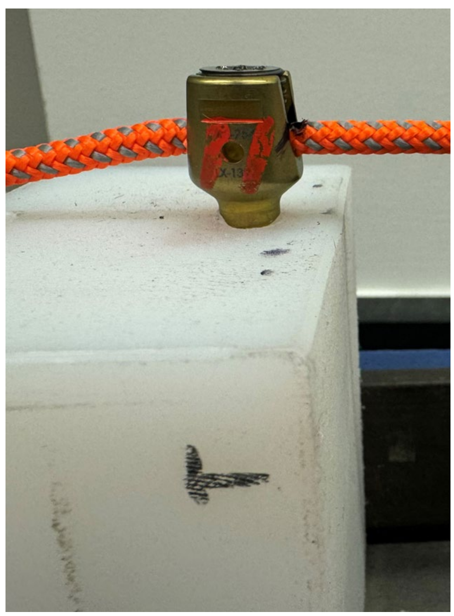


Figure 6c: Setscrew is retightened onto the tether cord at the same location with manufacturer recommended torque.

7. Load the Test Specimens to Failure

a. Place the test construct between one of the ASTM F1717 test fixtures and insert a hinge pin.
b. Carefully align the actuator so the second hinge pin can be inserted without loading the test specimen.
c. Tare the test system's load and displacement sensors.

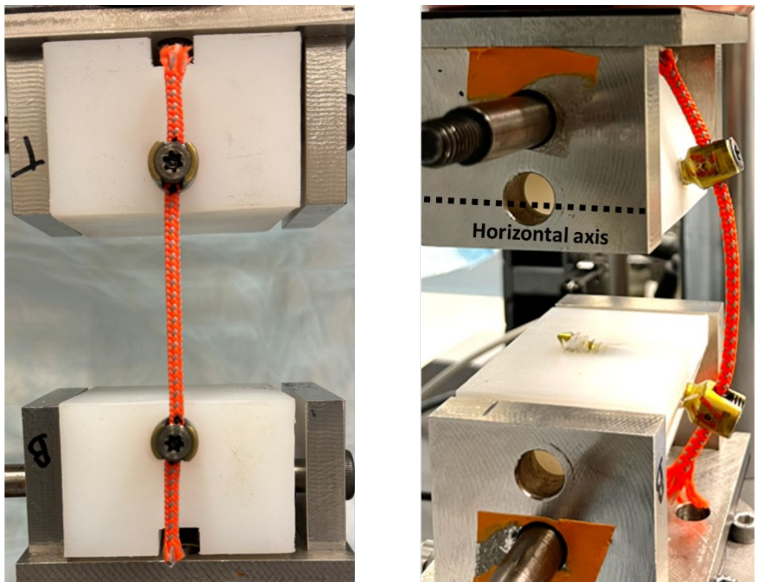


Figure 4: Example of test specimens (Mock AVBT construct) loaded using ASTM F1717 fixtures: 0° screw angulation construct (Left) and 40° screw angulation construct (Right)

A. Static Testing

a. Tension the test specimen at a loading rate of 15.2 mm/min while collecting time, load, and displacement data.
b. Stop the actuator after test specimen failure, such as cord fracture, or a large drop in force (e.g., 50%).
c. Unload the test specimen if necessary and remove it.
d. Repeat through all test specimens.

B. Dynamic Testing

a. Tension the test specimen under load control using a sinusoidal waveform cycling between a minimum and maximum load, with a load ratio of R=10 and at a constant frequency of 6 Hz (or lower).
b. The dynamic tension loading should be applied until failure or a maximum of 1.25 million cycles while collecting time, number of cycles, load (maximum and minimum), displacement at minimum load and maximum load data. Note: Dynamic tests may need to run for longer durations (10 million cycles) to establish runout loads and fatigue curves.

c. Failure of the construct should be identified based on the following criteria:
    i. Evident slippage of the tether cord or deviation in the programmed peak to peak load value.
    ii. Evident fracture, failure, or damage of any component in the construct.
    iii. Deviation of ≥ 3 mm in the displacement at maximum load values.

d. Unload the test specimen if necessary and remove it.

e. Repeat through all test specimens.

f. The initial dynamic load will be based on the yield load data obtained from the static testing of that specific construct configuration. Loads for remaining specimens will be determined from the outcome of the previous specimen(s).

8. Analysis

1. Analysis for static testing
    I. Plot all specimen data as load vs. displacement plots.
    II. Determine a best-fit straight line of the elastic zone of each plot, biasing selection toward the beginning of the data, but omitting initial nonlinear regions where the specimen and fixtures may have settled. See ASTM E3076 or RST24OP06.01.
    III. Record the slope of the linear elastic zone as the stiffness of the construct in terms of load/displacement.
    IV. Offset the elastic zone best-fit line by 1% of the gauge length (0.76 mm for 76 mm) and determine the intersection of this new line with the data. Report the load at this intersection as the 1% yield load as shown in the example image below.
    V. Determine and report the ultimate load for each specimen.

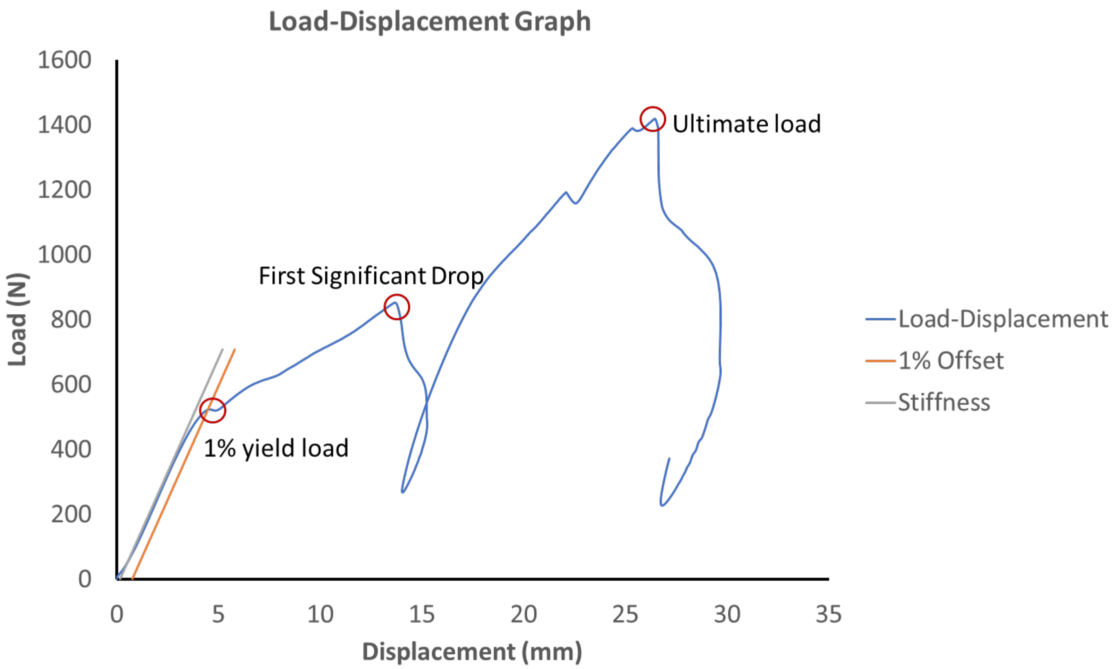


Figure 5: Representative force-displacement curve for the mock device showing yield load (N) at 1% offset, first significant drop (N, first peak where drop in force is more than 100 N), and ultimate load (N).

VI. Overall, stiffness (N/mm), 1% yield load (N), displacement at 1% yield load (mm), ultimate load (N), and displacement at ultimate load (mm) should be recorded.

VII. Means and standard deviations of the above values for each construct configuration should be recorded.

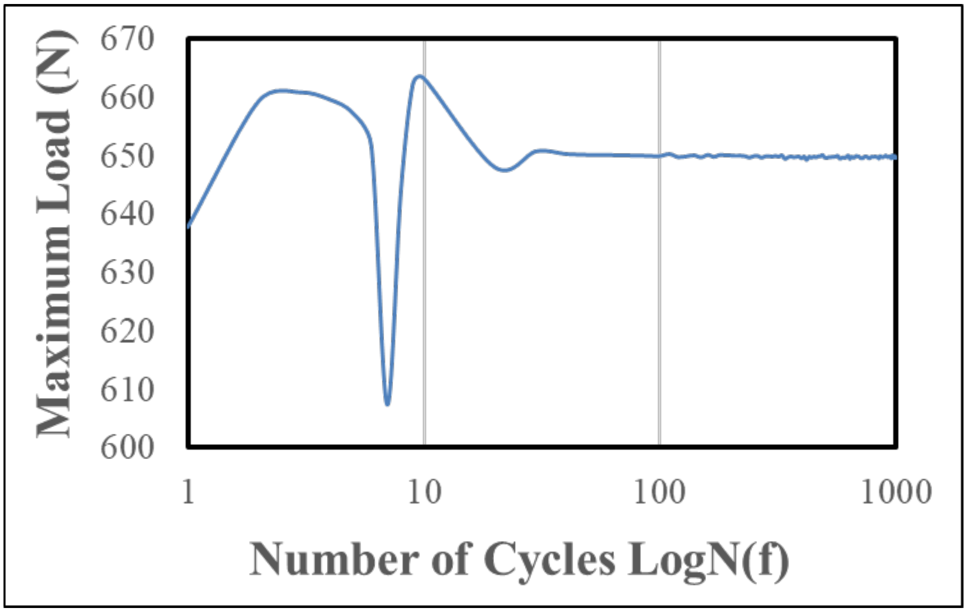
VIII. In the test report, include photographs of at least one example assembled test specimen before testing, one on the test frame, and one post-test for each construct configuration. Provide one photograph for each unique failure mode.

IX. Provide complete descriptions of all the failures and failure modes of the AVBT implant assemblies.

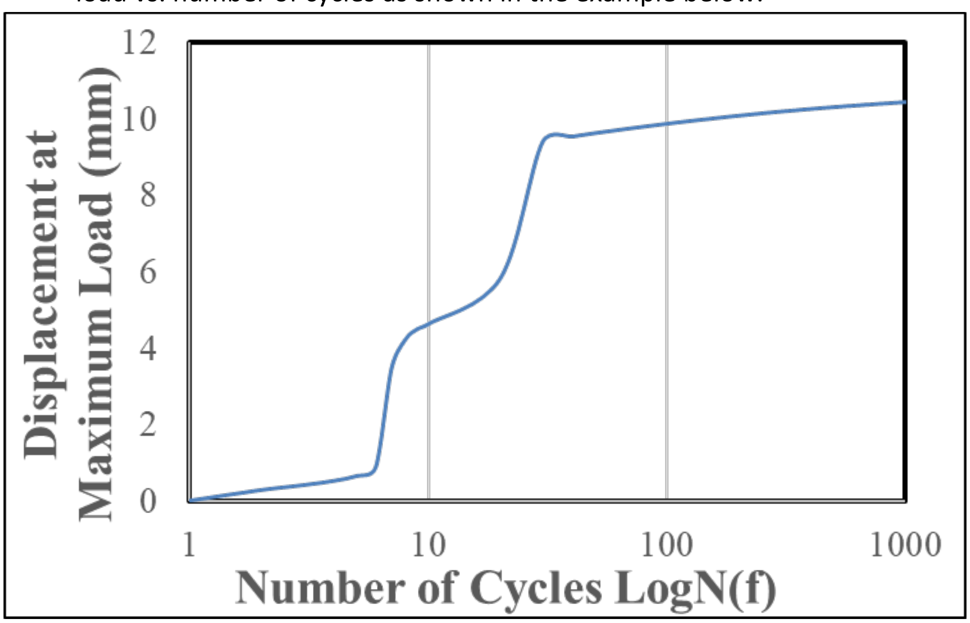
X. Record any deviations to the protocol including changes to the test fixtures or setup.

2. Analysis for dynamic testing

I. Plot all specimen data on a semi-log graph with load vs. number of cycles.



II. Plot all specimen data on a semi-log graph with displacement at maximum load vs. number of cycles as shown in the example below.



III. For each specimen, record the number of cycles (N), failure mode (or runout without a visible failure), load ratio (R), maximum applied load (N), minimum applied load (N), and frequency (f).

IV. In the test report, include photographs of at least one example assembled test specimen before testing, one on the test frame, and one post-test for each construct configuration. Provide one photograph for each unique failure mode and each runout specimen.

V. Provide a complete description of all the failures and failure modes of the AVBT implant assembly.
VI. Record any deviations to the protocol including changes to the test fixtures or setup.

9. References

1. ASTM F1717-21, 2021 "Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model" ASTM International, West Conshohocken, PA, 2021, DOI: 10.1520 /F1717-21, www.astm.org
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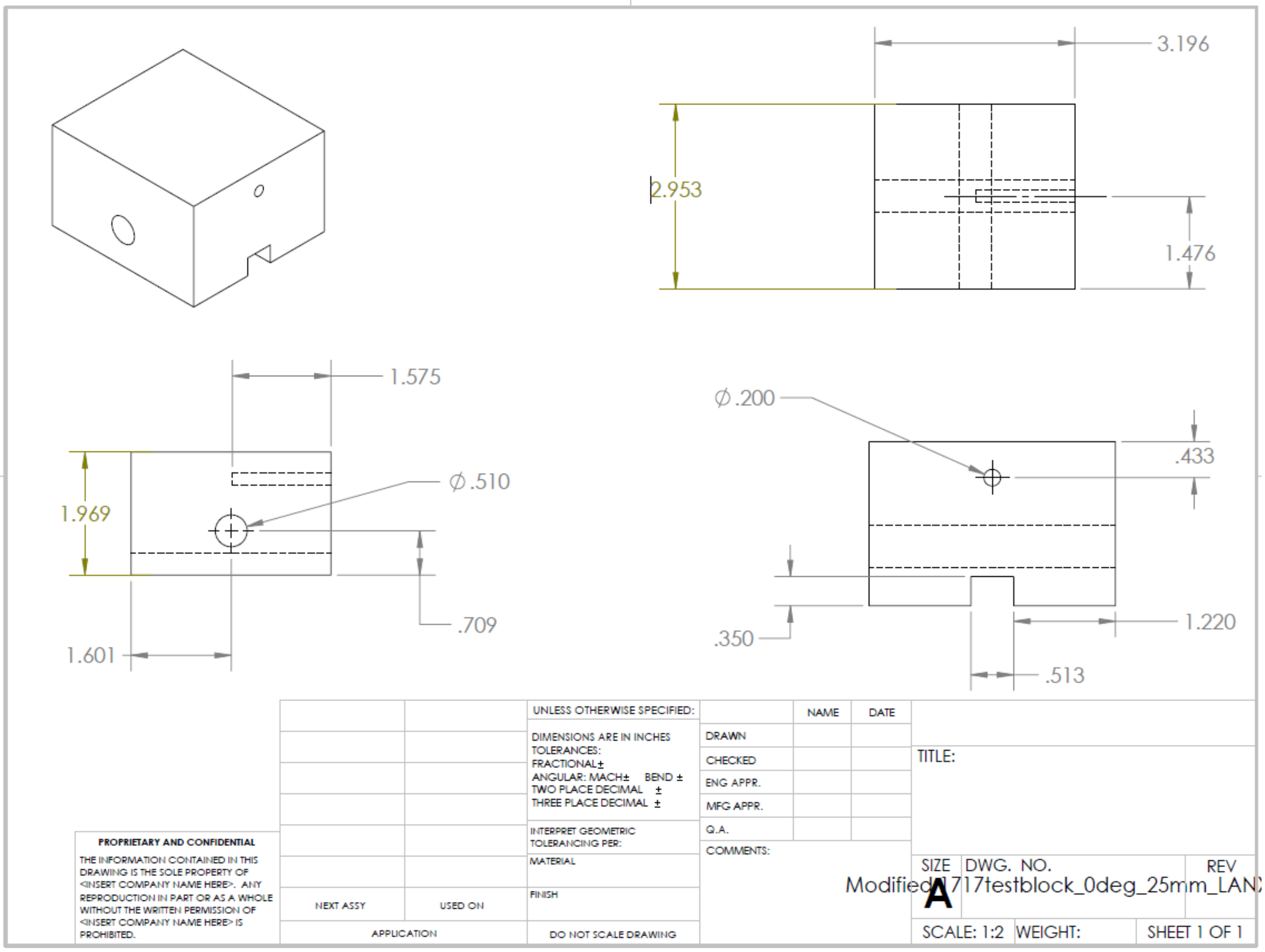
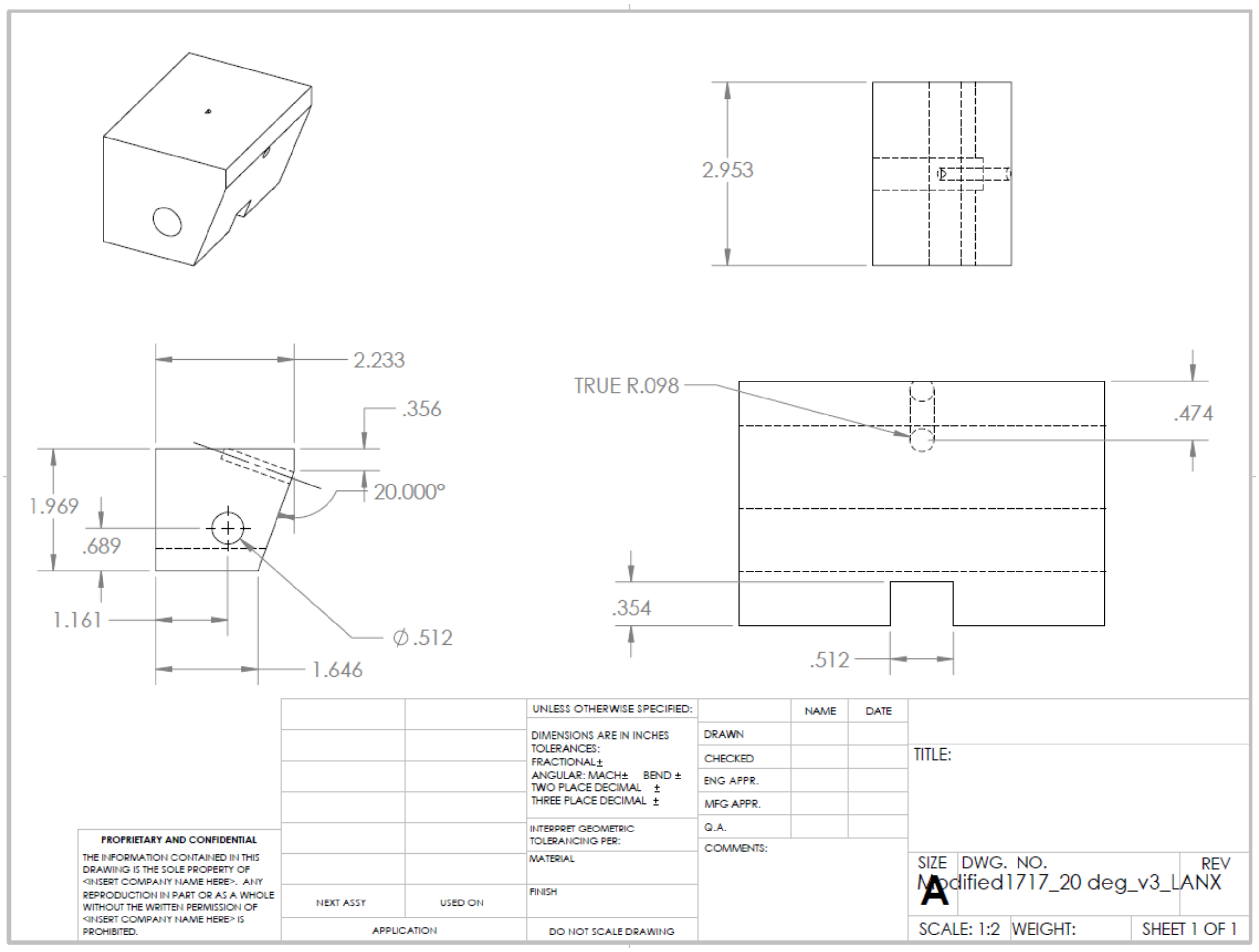
4. Cunningham BW, Sefter JC, Shono Y, McAfee PC. Static and cyclical biomechanical analysis of pedicle screw spinal constructs. Spine 2000;25(6S):1S-12S.
5. Courvoisier A, Baroncini A, Jeandel C, et al. Vertebral Body Tethering in AIS Management—A Preliminary Report. Children 2023;10(2):192.

Appendix 1: Test Block and Fixture Drawings

1. 0° test block



2. 20° test block



ASTM F1717 Side Support Fixture