Apex Tibial Nailing System

Enhanced Construct Fatigue Life with Apex Micromotion Fixation

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Key Takeaways

- ✓ *In high-risk fractures, delayed bony union is associated with prolonged mechanical loading of the implant construct and can lead to fatigue failures including screw breakage.*
- ✓ *The OrthoXel® Apex Tibial Nailing System features a gliding insert system that reduces mechanical stress in the proximal screws and extends construct fatigue life.*

Introduction

Patients who may be at risk for compromised bone healing require special attention in surgical planning and construct selection. Known risk factors for delayed healing and nonunion include open fracture, infection, high-energy injury, diabetes, and smoking, among others. These injuries are associated with a longer expected timeframe for healing[1] and a greater risk of screw breakage and reoperation.[2]

In cases of delayed healing, the absent or mechanically insufficient callus does not support structural loading across the fracture site and implant fatigue failures are natural concomitants of prolonged cyclic loading of the construct.

Knowing that this scenario may arise, the surgeon may wish to select an implant construct based on factors including the anticipated fatigue life. Accordingly, the purpose of this investigation was to test the performance of the Apex Tibial Nailing System under mechanical loading conditions representative of prolonged physiological weight-bearing with absent bony bridging.

Materials and Methods

Standard testing requirements (ASTM F1264) for intramedullary nailing construct components include tests that induce pure bending loading of the working length of the nail with no load transmission via screws and separate pure bending testing of the screws themselves.[3] These tests have been considered the industry-standard benchmark for construct mechanical performance for nearly two decades, but they do not represent clinically relevant physiological loading.

This approach is particularly deficient as a predictor of screw life in clinical use because the pure bending tests do not replicate the physical interaction between the screw, bone, and implant.

For fatigue testing, the following comparable implant systems were tested:

- OrthoXel™ Apex Tibial Nailing System (Ø 13 mm nail with Ø 5 mm locking screws) –micromotion locking mode
- Zimmer® Natural Nail™ System (Ø 13 mm nail with Ø 5 mm locking screws) – static locking mode

Figure 1: *Micromotion locking with the Apex Tibial Nailing System allows 1 mm of controlled cyclic axial compression during weightbearing by means of a preassembled proximal stem insert.*

All constructs were assembled for testing in identical clinical configurations, with two proximal and two distal locking screws, all in the mediolateral orientation. For the Zimmer system, this produced a standard static locking construct. For the OrthoXel™ system, this produced micromotion fixation with about 1 mm of allowable axial compression in the proximal nail body, constrained by the preassembled gliding insert system (*see Figure 1*).

The mechanical test setup for both implant systems was identical and was developed to recreate functional weightbearing loads. A schematic of the test setup is shown in *Figure 2*.

Briefly, this fixture was designed to represent bony fixation without allowing any possibility of screw loosening during prolonged cyclic testing. The proximal and distal screws were mounted in two 40-mm diameter aluminum tubes with 3-mm wall thickness that were filled with 20 PCF foam, a material commonly used for testing orthopaedic screw fixation.[4] The specific grade of foam was chosen to mimic the approximate range of ultimate strength of cancellous bone for a young individual,[5] reflecting the expected median age of tibial fracture patients.[1] Force transmission from the load frame to the implant was directed through proximal and distal ball mounts, which were designed to provide an angular offset of the proximal nail stem as dictated by the Herzog bend of the implant.

The cyclic loading pattern was based on a published protocol for a modified staircase test.[6] Cyclic loading commenced for each construct at 1200N. If the construct withstood 500,000 cycles (representative of walking 3 miles a day, 7 days a week, for 16 weeks[7]), the load was increased by 200 N and a new construct tested. If a construct failed prior to 500,000 cycles, the next construct was tested at 200 N less. The fatigue life was defined as the staircase load at which the construct withstood 500,000 cycles, confirmed with observations of failure at a higher load and replicate survival at the limit load. All loads were applied at 5 Hz, based on test standards and published recommendations for titanium alloy implants.

[3,8] All testing was carried out by Endolab GmbH. an accredited (DAkkS O-PL-18838-02-00) and certified (ZLG-P-944.98.07) test laboratory according to DIN EN ISO/IEC 17025 and 93/42/EWG for biomechanical testing.

Figure 2: *Samples were presented in the fatigue test fixture using composite tubes and ball mounts.*

Results

The modified staircase protocol was completed for both the OrthoXel™ Apex and Zimmer® Natural Nail™ constructs. The mode of failure in both constructs was the same – fatigue fracture in the most-distal proximal-end screw. No nail failures were observed in either construct. Test results and fatigue limits for both constructs are shown in Table 1.

Table 1: Fatigue test results for all constructs		
Axial Load	**Apex Nail Micromotion Locking**	**Natural Nail™ Static Locking**
1200 N	500,000 cycles no failure	500,000 cycles no failure
1400 N	500,000 cycles no failure	500,000 cycles screw bending **Fatigue Limit**
1600 N	500,000 cycles no failure **Fatigue Limit**	screw fatigue failure
1800 N	screw fatigue failure	not tested

Comparing the two constructs, fatigue testing under identical loading conditions showed that the Apex Nail with proximal micromotion fixation had superior fatigue life compared to the Natural Nail™ with static fixation. Full reports of test results and post-failure inspection findings are held on file.[9]

Discussion and Conclusions

Construct fatigue life is an important consideration in the care of patients who have known risk factors for delayed bone healing or nonunion. From the initiation of partial weight-bearing, the device biomechanics should promote mechanoregulated bone healing. In cases when bony bridging is expected to be slow, the mechanical demands on the construct will be prolonged. In these tests, **the higher fatigue limit (delayed proximal screw breakage) in the Apex system indicates that the proximal insert design reduces screw stresses.**

For difficult fractures, increased fatigue life increases the survivability of the construct and may help delay or prevent secondary procedures including removal of hardware. In summary, based on the results of physiological biomechanical testing, **the Apex Tibial Nailing System offers a clear advantage for the treatment of high-risk fractures – micromotion fixation with superior construct fatigue life.**

References

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