

WHITE PAPER

Apex Tibial Nailing System

Early Healing in High-Risk Fractures
Following Apex Micromotion Fixation

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KEY TAKEAWAYS

- ✓ Nonunion is a well-known complication that occurs in 7-19% of all tibial fractures treated in Level I trauma centers.
- ✓ Nonunion fractures are associated with a prolonged period of pain and disability and typically require multiple surgical interventions and an average of 20 months to heal.
- ✓ Known risk factors for delayed healing and nonunion include open fracture, smoking, and systemic comorbidities such as diabetes and rheumatoid arthritis.
- ✓ Case reports of high-risk fractures treated with Apex micromotion fixation show excellent early healing, with patients achieving callus bridging by 12 weeks and rapid uncomplicated clinical union.

BURDEN OF DELAYED & NONUNION FRACTURE CARE

Tibial fractures treated by reamed intramedullary (IM) nailing have an expected median time to clinical union of 18 weeks.¹ However, delayed healing and nonunion of tibial fractures remains an important clinical problem. Tibial nonunions are reported to occur at a rate of 7-19% based on data from North American Level I trauma centers.²⁻⁶ Patients who experience this condition may require multiple surgeries over a protracted period of care. Tibial fractures that are designated as nonunions finally heal at an average of 20 months after injury.⁷

Compared to patients healing normally, nonunion patients have significantly higher pain and duration of opioid use, higher rates of depression requiring treatment, and more lost earned income.⁸ Less than 60% of tibial fracture nonunion patients are able to return to work within one year.⁹ The socioeconomic burdens of nonunion are also disproportionately borne by lower-wage workers due to difficulty in returning to jobs with higher physical demands.¹⁰ Care for these patients also burdens the health care system, with nonunions having more than double the direct medical care costs compared to normally healing fractures.⁸

RISK FACTORS FOR DELAYED & NONUNION

Nonunion is a complex condition with multi-factorial origins. Known independent risk factors for nonunion include:

- ✓ **Injury characteristics**—high energy injury, open fracture, extensive soft tissue disruption, bone loss, infection, compartment syndrome, and polytrauma.
- ✓ **Comorbidities**—diabetes, obesity, immune deficiency, rheumatoid arthritis, chronic disease, genetic disease, and other meta-bolic or endocrine conditions.
- ✓ **Behavioral risks**—smoking, alcohol abuse, opioid and other substance abuse.
- ✓ **Surgery-related factors**—malreduction, lack of cortical continuity, fixation instability.

Due to their heterogeneous etiology, nonunions are difficult to predict and clinical trials focused on prevention and treatment are large and complex to design. However, in routine practice, orthopaedic surgeons treat high-risk fractures that give cause for concern for potentially difficult or slow healing from the time of surgery.

APEX MICROMOTION FIXATION

All fractures were treated using the OrthoXel® Apex Tibial Nailing System. The Apex Tibial Nail is the first and only implant to target optimized fracture fixation biomechanics in the early healing period using a proximal gliding insert that produces controlled axial micromotion with high torsional stability (see Figure 1).

The Apex Tibial Nail has FDA 510(k) clearance in the United States and is intended for use in a wide variety of tibial shaft fractures.

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.



PATIENTS, SURGEONS, AND SETTING

All cases were completed at Cork University Hospital, a Level I trauma center located in southwest Ireland. Following product introduction in early 2018, cases have been completed by multiple surgeons in this single center, ranging from highly experienced senior Consultants to supervised junior trainees. Cases included open and closed tibial shaft fractures and a mixture of high- and low-energy injuries. Comorbidities included insulin-dependent brittle diabetes, rheumatoid arthritis, fibromyalgia, cigarette smoking, alcoholism, and other substance abuse.

All patients who were implanted with Apex Tibial Nails, including both low-risk cases and the high-risk cases featured here, were offered an opportunity to provide written informed consent to participate in an observational clinical study designed to quantitatively assess fracture healing using radiographic and patient-reported outcomes measures according to a previously-published study protocol.^{11,12}

This whitepaper features case reports of patients who were considered high risk for compromised fracture healing based on their injury characteristics or comorbidities and who achieved successful uncomplicated clinical union following Apex micromotion fixation.

SURGERIES & FOLLOW-UPS

All fractures were treated by reamed implantation of an Apex Tibial Nail in micromotion locking mode with two mediolateral proximal screws and at least two distal screws. Patients were advised to begin early mobilization and progressed quickly to full weight bearing unless clinically contraindicated (e.g. intra-articular fracture extension). Follow-ups were completed according to a set protocol for the observational study in which patients consented to participate, which included X-rays and clinical exams occurring at least at 6, 12, 18, and 24 weeks, or more if needed. In all cases, clinical union was achieved prior to the 24-week follow-up, but X-rays continued to 24 weeks as specified in the observational protocol.

All patients had a low-dose CT scan at 12 weeks, which was used to assess the callus present according to a published methodology.¹¹ Briefly, this assessment included virtual torsional testing of 3D models reconstructed from the CT scans. Each fracture was also digitally reconstructed to allow virtual torsion testing of the intact limb. Each model (fractured and intact) produced a measurement of structural integrity known as torsional rigidity.

These torsional rigidities were then normalized to produce a ratio (fractured/ intact) that can be used as a summary indicator of healing progress. This ratio, known as normalized virtual torsional rigidity (VTR), takes a value of 0 if the fracture is completely unhealed (no callus bridging) and progresses to a value around 1 as the fractured limb regains rigidity equivalent to the patient's own intact anatomy. Published data for low-risk tibial fractures indicates that they can be expected to achieve a normalized VTR value of around 1 by 12 weeks after injury.^{11,12}

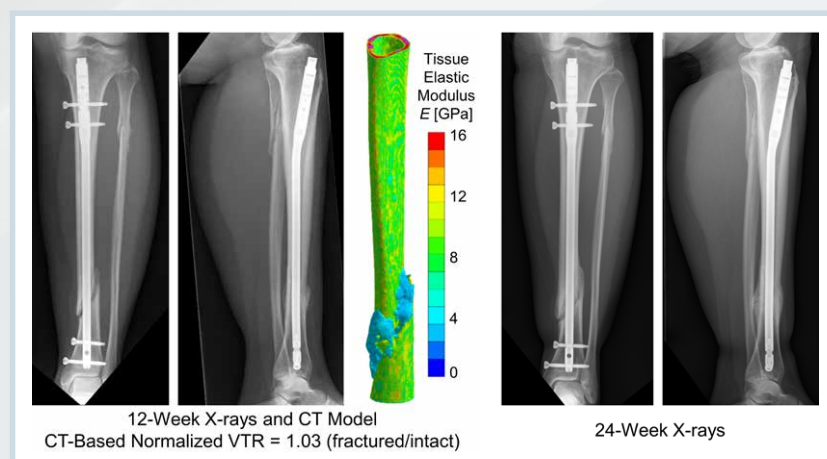
In all cases, radiographic union was defined as RUST score ≥ 10 , with consensus between the three authors.

ROBUST HEALING IN HIGH-RISK CASES

Case A (Figure 2): Female, age 46, insulin-dependent brittle diabetes with poorly controlled blood sugar (elevated HbA1c). Fall from standing height resulted in a closed tibial fracture, OTA/AO 42-A1. The patient was slow to weight-bear for two weeks despite encouragement, but was compliant thereafter.

RUST scores at 6 and 12 weeks were 9 and 11. On the 12-week CT scan, the callus was clearly bridged and the limb had achieved a normalized virtual torsional rigidity, VTR = 1.03 (fractured/intact), which indicates that healing had progressed to equivalence with the structural rigidity of the intact limb. Clinical union occurred by 12 weeks and the patient had no pain and returned to all activities with no restrictions. Given that insulin-dependent diabetes is associated with a documented statistically significant increase in the risk of nonunion⁷¹³ and delayed union⁷¹⁴, this is an excellent healing result.

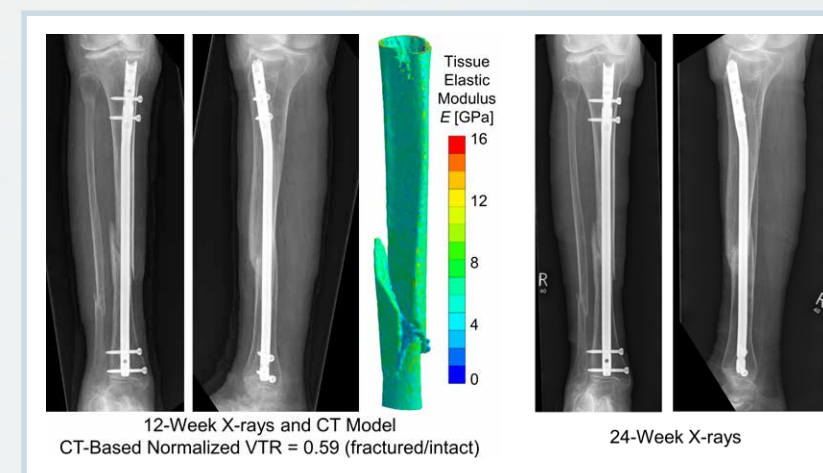
Figure 2: Case A Female, age 46, insulin-dependent brittle diabetes, closed 42-A1, achieved robust structural healing on 12-week X-rays and CT and uncomplicated clinical union.



Case B (Figure 3): Female, age 74, rheumatoid arthritis treated with methotrexate, osteopenia with pronounced cortical thinning. Mechanical fall from less than standing height resulted in an open (Gustilo-Anderson II) tibial fracture, OTA/ AO 42-B3. Fracture reduction was difficult due to poor bone quality.

RUST scores at 6 and 12 weeks were 6 and 10. On the 12-week X-rays and CT scan, callus formation was well underway and the limb had achieved a normalized virtual torsional rigidity, VTR = 0.59 (fractured/intact), which indicates that significant structural healing had already taken place. At 12 weeks, the patient had no pain, reported outstanding health, and had regained full mobility. Given that rheumatoid arthritis is associated with a documented statistically significant increase in the risk of nonunion^{13,15}, and this elderly osteoporotic patient also had a compound wound and did not suspend the use of antimetabolite medication, this is an excellent result.

Figure 3: Case B Female, age 74, rheumatoid arthritis and osteopenia with pronounced cortical thinning, open (II) 42-B3, achieved partial union on 12-week X-rays and CT and uncomplicated clinical union.



Case C (Figure 4): Male, age 45, heavy smoker, alcoholic, unemployed with suspected poly-substance abuse. Bike accident resulted in a closed tibial fracture, OTA/AO 42-A1.

The RUST score at 12 weeks was 12. On the 12-week CT scan, the callus was clearly bridged and the limb had achieved a normalized virtual torsional rigidity, VTR = 0.95 (fractured/intact), which indicates that healing had progressed to near equivalence with the structural rigidity of the intact limb. Clinical union occurred by 12 weeks and the patient had full functional recovery and reported good health. Heavy smoking has been frequently reported as a statistically significant risk factor for delayed union and nonunion. Substance abuse including opioid exposure prior to injury is also associated with a significant increase in nonunion risk.¹⁶ Given the fracture healing risks in this patient, the fact that clinical union was achieved at a routine 12 weeks is an excellent healing result.

Figure 4: Case C Male, age 45, heavy smoker, alcoholic, suspected poly-substance abuse, closed 42-A1, achieved robust structural healing on 12-week X-rays and CT and uncomplicated clinical union.

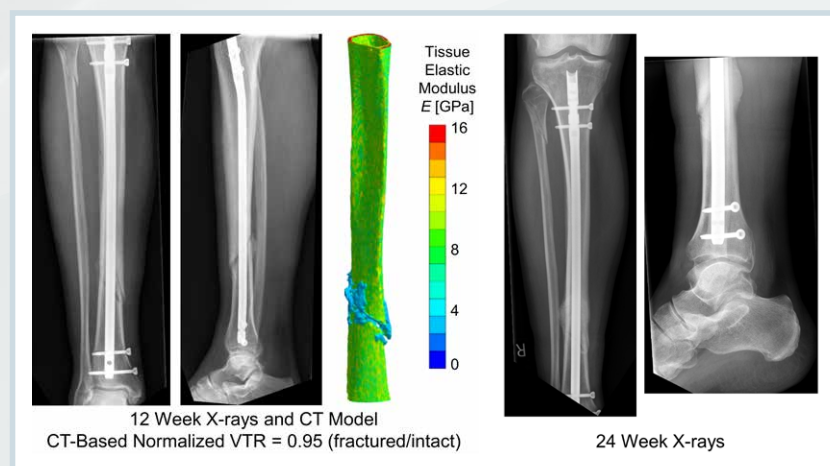
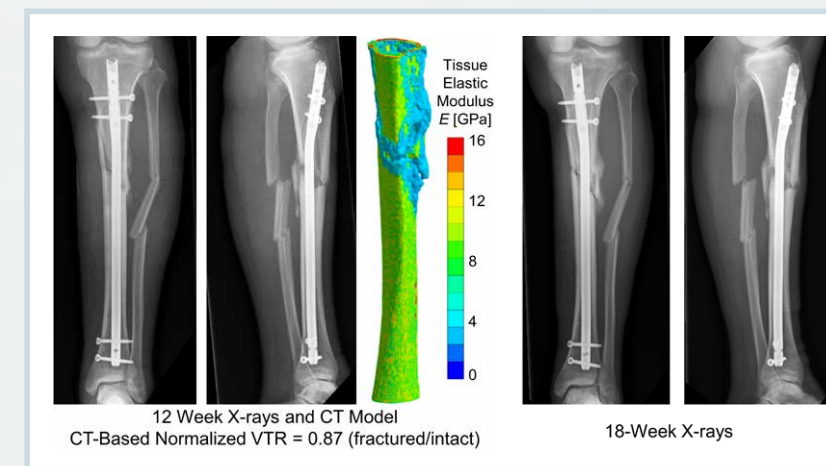


Figure 5: Case D Male, age 55, open (IIIB) 42-C3 with degloving and muscle loss, required debridement and flap coverage, achieved robust structural healing on 12-week X-rays and CT and uncomplicated clinical union.



Case D (Figure 5): Male, age 55, crushed between two vehicles and sustained an open (Gustilo-Anderson IIIB) tibial fracture, OTA/AO 42-C3. Soft tissue injury was extensive with degloving and muscle loss, but no arterial damage. Primary fixation by reamed nailing was undertaken with debridement and flap coverage by a plastic surgery team.

RUST scores at 6 and 12 weeks were 8 and 12. Proliferative callus was observed on the 12-week CT scan and the limb had achieved a normalized virtual torsional rigidity, VTR = 0.87 (fractured/intact), which indicates that surprisingly advanced structural healing had already taken place, given the severity of the soft tissue injury. Clinical union was achieved by 12 weeks and the patient continued with no sign of infection, no additional procedures, and good functional recovery with minimal pain. Given the high-energy injury in combination with the degree of communication and soft tissue loss, to achieve robust callus bridging at 12 weeks is an exemplary healing result.

CONCLUSIONS

In this pilot case series of four high-risk tibial fractures treated with the Apex Tibial Nailing system, all four patients demonstrated outstanding healing results. These patients were enrolled in a larger ongoing observational study to assess healing with Apex micromotion fixation in a broad range of tibial fractures, including both low- and high-risk cases. In all these high-risk cases, patients achieved rapid uncomplicated union, despite having comorbidities and injury patterns known to significantly increase the risk of delayed or nonunion.

REFERENCES

1. Dailey HL, Wu KA, Wu P-S, McQueen MM, Court-Brown CM. Tibial fracture nonunion and time to healing following reamed intramedullary nailing: Risk factors based on a single-centre review of 1003 patients. *J Orthop Trauma*. 2018;32(7):e263-269.
2. Bhandari M, Guyatt G, Walter SD, et al. Randomized Trial of Reamed and Unreamed Intramedullary Nailing of Tibial Shaft Fractures. *J Bone Joint Surg - Am Vol*. 2008;90(12):2567-2578.
3. Bhandari M, Tornetta III P, Sprague S, et al. Predictors of reoperation following operative management of fractures of the tibial shaft. *J Orthop Trauma*. 2003;17(5):353-361.
4. Fong K, Truong V, Foote CJ, et al. Predictors of nonunion and reoperation in patients with fractures of the tibia: an observational study. *BMC Musculoskelet Disord*. 2013;14(1):103.
5. Lack WD, Starman JS, Seymour R, et al. Any Cortical Bridging Predicts Healing of Tibial Shaft Fractures. *J Bone Joint Surg - Am Vol*. 2014;96:1066-1072.
6. O'Halloran K, Coale M, Costales T, et al. Will My Tibial Fracture Heal? Predicting Nonunion at the Time of Definitive Fixation Based on Commonly Available Variables. *Clin Orthop Relat Res*. 2016:1-11.
7. Metsemakers WJ, Handojo K, Reynders P, Sermon A, Vanderschot P, Nijs S. Individual risk factors for deep infection and compromised fracture healing after intramedullary nailing of tibial shaft fractures: A single centre experience of 480 patients. *Injury*. 2015;46(4):740-745.
8. Antonova E, Le TK, Burge R, Mershon J. Tibia shaft fractures: costly burden of nonunions. *BMC Musculoskelet Disord*. 2013;14(1):1.
9. Tay WH, De Steiger R, Richardson M, Gruen R, Balogh ZJ. Health outcomes of delayed union and nonunion of femoral and tibial shaft fractures. *Injury*. 2014;45(10):1653-1658.
10. MacKenzie EJ, Morris, Jr. JA, Jurkovich GJ, et al. Return to work following injury: the role of economic, social, and job-related factors. *Am J Public Health*. 1998;88(11):1630-1637.
11. Schwarzenberg P, Maher MM, Harty JA, Dailey HL. Virtual Structural Analysis of Tibial Fracture Healing from Low-Dose Clinical CT Scans. *J Biomech*. 2019;83:49-56.
12. Dailey HL, Schwarzenberg P, Daly CJ, Boran SAM, Maher MM, Harty JA. Virtual Mechanical Testing Based on Low-Dose Computed Tomography Scans for Tibial Fracture: A Pilot Study of Prediction of Time to Union and Comparison with Subjective Outcomes Scoring. *J Bone Joint Surg*. 2019;Accepted In Press.
13. Zura R, Xiong Z, Einhorn T, et al. Epidemiology of Fracture Nonunion in 18 Human Bones. *JAMA Surg*. 2016;151(11):e162775.
14. Aderinto J, Keating JF. Intramedullary nailing of fractures of the tibia in diabetics. *J Bone Joint Surg - Br Vol*. 2008;90(5):638-642.
15. Zura R, Braid-Forbes MJ, Jeray K, et al. Bone fracture nonunion rate decreases with increasing age: A prospective inception cohort study. *Bone*. 2017;95:26-32.
16. Buchheit T, Zura R, Wang Z, Mehta S, Della Rocca CJ, Steen RC. Opioid exposure is associated with nonunion risk in a traumatically injured population: An inception cohort study. *Injury*. 2018;49(7):1266-1271



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