A NEW EXTERNAL FIXATION SYSTEM FOR TIBIAL SHAFT FRACTURES

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(FDA: IOS external fixator 510(k) K070724)

Purpose

In a new external fixation system for tibial fractures, accurate reduction was achieved with a complex temporary device, the Staffordshire Orthopaedic Reduction Machine (STORM) following which the fracture was fixed using a simple but mechanically sophisticated fixator (IOS). The fixator is designed to allow controlled bending to optimise movement at the fracture site for callus growth. Ideal mechanical properties are approached: elastic return is to the reduced position; epicentric placement minimises shear and distraction on weightbearing; integral healing assessment measures bending stiffness. The device is single-use.

Fig 1
Fixator applied epicentrically.

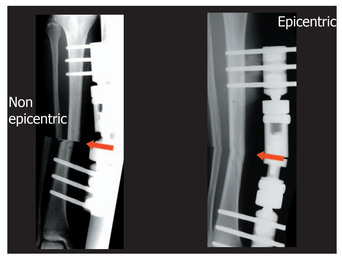


Fig 2
Non-epicentric placement causes shear.

Methods

Closed unstable tibial shaft fractures in 60 patients were externally fixed using the STORM in the operating theatre to reduce the fracture prior to application of an IOS fixator. Immediate full weight-bearing was encouraged. Bending characteristics of the fixator allowed 1mm of axial movement for 20 kg loading. Fixator removal time was determined by fracture stiffness measurements against which the integral IOS stiffness measurement was compared.

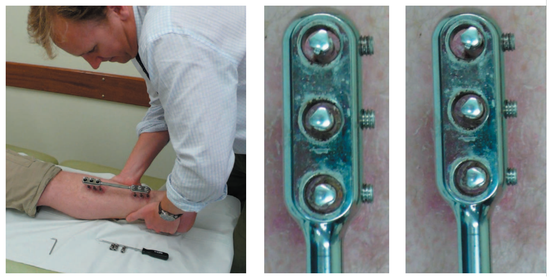


Fig 3 Fracture stiffness meaurement in clinic.
The circular gap is 2mm.
2mm of movement = 1° off bending
1° of manual bending = 15Nm/degree

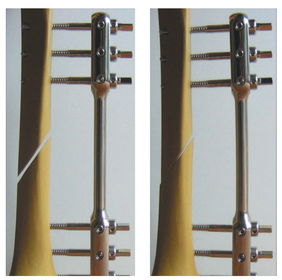


Fig 4 Fracture site movement under loading.

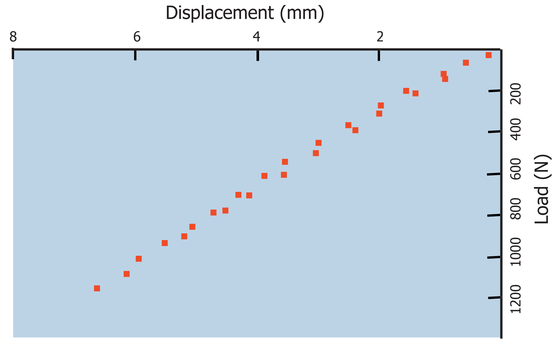


Fig 5 Stiffness of IOS
1mm of movement for every 20kg of loading.

Fig 6 IOS applied as definitive fixation after reduction using STORM.

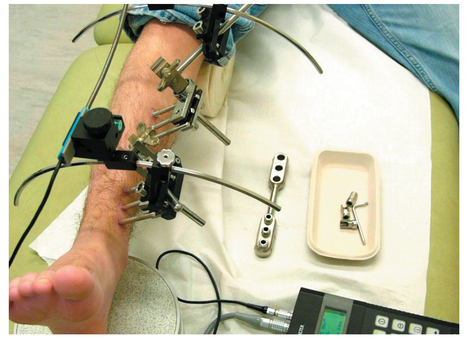


Fig 7 1° of bending validated against stiffness of 15 Nm/degree using the Orthofix Orthometer.

Results

Mean healing time was 18.1 weeks; 4 patients healed in under 9 weeks. The shortest time was 8 weeks 3 days. The healing endpoint was fixator removal at a bending stiffness of 15Nm/deg in two orthogonal axes. There was no subsequent creep or re-fracture. Good reduction, defined as less than 3 deg of maximum angulation and less than 3mm of maximum translation, was achieved and maintained.

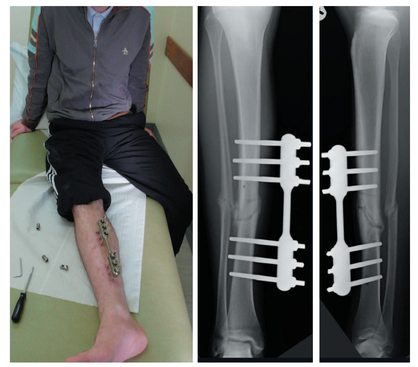
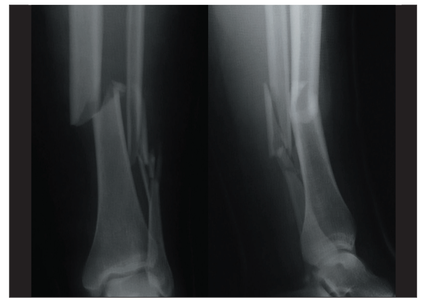
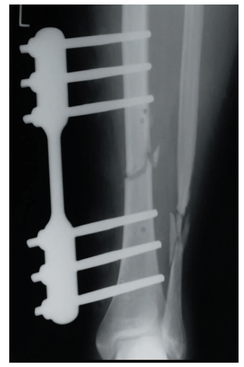


Fig 8 Healed 8 weeks 3 days from injury.





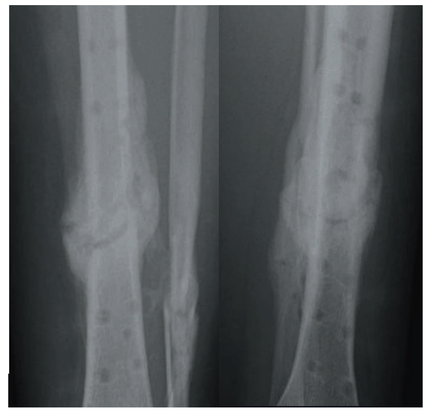


Fig 9 107kg patient.
Fully weight bearing from week 3.
Healed 13 weeks 4 days from injury.

Conclusion

The IOS/STORM system allows safe and effective treatment of tibial shaft fractures. With the fracture reduced on STORM, the external fixator screws can be placed in optimum positions. Good reductions were achieved and maintained. The IOS bending characteristics appear to approach the optimum for callus growth. The simple integral fracture stiffness measurement method has been validated against current more complex measurement devices.