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Is device-assisted reduction prior to semi-extended intramedullary nailing of distal tibial fractures necessary?

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ABSTRACT

Introduction: Traditional methods of nailing distal tibial fractures have an unacceptable risk of mal-alignment due to difficulty in obtaining and maintaining reduction intra-operatively. Methods to obtain and maintain reduction when nailing these fractures, and therefore reducing the risk of Mal-alignment include modified external fixators, distractors and commercial reduction tools. Semi-extended intramedullary nailing of distal tibial fractures via a supra-patellar approach is now being used more commonly. The aim of this study was to assess whether a commercial reduction device (Staffordshire Orthopaedic Reduction Machine – STORM, Intelligent Orthopaedics, Stafffordshire, UK) is necessary to reduce the risk of mal-alignment in patients undergoing semi-extended nailing for distal tibial fractures.
Methodology: A case-control study was conducted in 20 patients who had STORM-assisted reduction of distal tibial fractures prior to intramedullary nailing and 20 controls without STORM. The control group was matched for age, sex, fracture type (AO/OTA), ASA and gender. All patients had an intramedullary nail (IMN) using the semi-extended system. Primary outcome measures were coronal and sagittal mal-alignment. Secondary outcome measure was unplanned return to theatre for complications and problems with fracture healing.
Results: There was no difference in post-operative mal-alignment in both groups. There was no significant difference in time to union in both groups Both groups had equal number of patients requiring unplanned return to theatre. The STORM group was associated with a significantly increased operative time [p = 0.007, 130.3 min (SD 49.4) STORM vs 95.6 mins (SD 22.9) Control].
Conclusion: Intraoperative use of STORM significantly increases operative time with no difference in outcome. The superior orthogonal views and manual control obtained during semi-extended nailing via a supra-patellar approach obviate the need for additional methods: of intraoperative reduction for this fracture group.

Background

The mal-union rate associated with nailing distal tibial fractures is high [1]. This could be the result of difficulty in maintaining reduction against gravity during infra-patellar nailing, especially if the limb is being flexed and extended to enable accurate fluoroscopic imaging [2]. While post-operative loss of reduction, due to the larger diameter of the distal tibia and subsequent loss in interface fit with the IMN is one cause, the problem is usually seen in immediate post-operative radiographs [2].

Supplementary methods to obtain intraoperative reduction and subsequently reduce mal-alignment prior to IMN include blocking screws [3], modified external fixators [4], ankle distractors [5], traction frames [6,7] and commercial reduction tools [8]. The Staffordshire Orthopaedic Reduction Machine (STORM, Intelligent Orthopaedics, Staffordshire, UK [9]) is an intra-operative device that helps reduce and maintain reduction prior to nail insertion and has been advocated in distal tibial fractures to reduce mal-reduction and mal-alignment [8,10].

The semi-extended approach for tibial IMN insertion, can simplify fracture reduction by aligning unstable distal third tibial fractures and allowing the assistant to maintain reduction [2,11–13]. In addition, the full or near –full extension position of the leg can allow for easier fluoroscopic imaging compared to the traditional infra-patellar approach [2,12].

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Table 1
Patient Demographics & Clinical Characteristics (Data are number (%) or mean ± SD).

	Cases (STORM)	Controls (No STORM)	Significance
No of Patients	20	20	p = 1.00
Mean Age	48.4 (15.2)	43.6 (14.7)	p = 0.17
Sex (Male)	18 (90)	12 (60)	p = 0.06
ASA	1.8 (0.83)	1.4 (0.69)	p = 0.19
Mean Operative Time (Min)	130.3 (49.4)	95.6 (22.9)	p = 0.007
General Anaesthetic (GA)	15 (75)	16 (80)	p > 0.99
GA+ Regional Block	5 (25)	4 (20)	p > 0.99
Primary Surgeon Specialist Trainee (%)	12 (60)	17 (85)	p = 0.15
Primary Surgeon Consultant (%)	8 (40)	3 (15)	p = 0.15

This study was designed to determine whether device assisted reduction prior to supra-patellar nailing of distal tibial fractures in a semi-extended position reduced the risk of mal-alignment.

Methodology

A retrospective case control study was conducted in 20 patients with extra-articular distal tibial fracture who had IMN with STORM assisted reduction over a 4-year period (2012–2015) and 20 controls who underwent who underwent IMN without STORM at a single centre. A distal tibial fracture was defined as a fracture that extended no further than 10 cm from the plafond. Fractures in both groups were classified as per the AO/OTA Classification. All patients had a Smith & Nephew Trigen Nail (Smith & Nephew, UK) with a semi-extended approach using standard distal locking with at least 2 distal locking screws.

Antero-posterior and lateral radiographs of the tibial shaft were obtained post operatively and in subsequent clinic visits to determine union. Data on patient demographics, comorbidities, level of operating surgeon (consultant v trainee), ASA grade, presence or absence of a fibular fracture, level of fibular fracture, associated fibular fixation, time to union, complications and return to theatre were collected from electronic health records. Carestream PACS was used to determine the coronal and sagittal plane deformity in immediate post-operative antero-posterior and lateral radiographs in both the case and control groups. Measurements on angulation and translation were measured using standard methods [14]. Union was determined based on the presence or absence of bridging callus in 3 out of 4 cortices in post-operative radiographs using the validated radiological union score of the tibia (RUST) [15]. Failure to achieve bridging callus in 3 out of 4 cortices in 6 months was defined as a non-union.

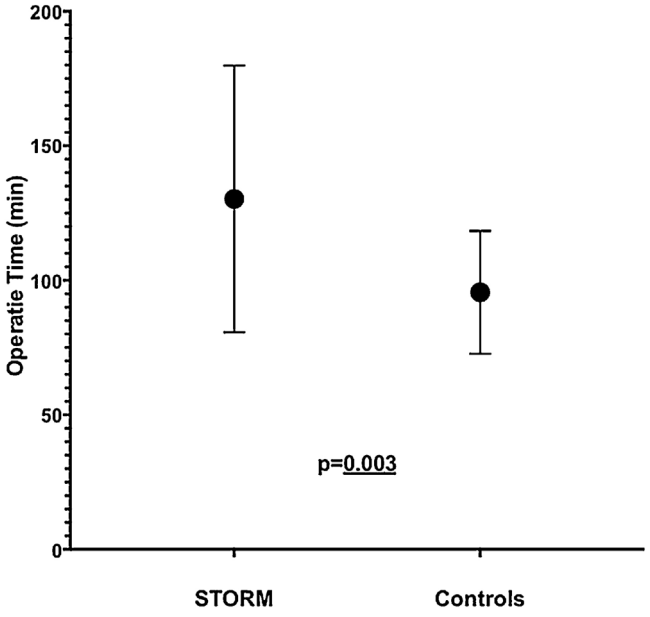

Fig. 1. Mean Operative Time in Patients Treated with STORM & Controls.

Primary Outcome measures included the radiographic determination of alignment. Secondary outcome measures included need for return to theatre for implant complications of fracture healing. Statistical analysis was performed using GraphPad Prism Version 7 (GraphPad Software Inc. California, USA). Fisher's exact test was used for independent categorical data; Mann–U Whitney for continuous nonparametric data and Chi Squared for continuous parametric data. Ordinary ANOVA was used when comparing two or more continuous variables. Statistical significance was set at $p < 0.05$.

Results

40 Patients were included in this study out of which 20 patients had STORM assisted reduction with supra-patellar IMN (cases) and

Table 2
Fracture Characteristics, Alignment, Union and Return to Theatre in STORM & Control Group (Data are number (%) or mean ± SD).

	Cases STORM	Control No STORM	Significance
AO/OTA 43- A1	9 (45)	10 (50)	p > 0.99
AO/OTA 43- A2	1 (5)	1 (5)	p = 1.00
AO/OTA 43- A3	10 (50)	9 (45)	p > 0.99
Distance of Fracture from Joint (cm)	7.3 (1.2)	7.3 (1.6)	p = 0.89
Fibular Fracture			
Proximal (n)	10 (50)	10 (50)	p = 1.00
Same Level (n)	8 (40)	6 (30)	p = 0.74
Distal (n)	2 (10)	2 (10)	p = 1.00
Segmental (n)	0 (0)	1 (5)	p = 1.00
No Fracture (n)	0 (0)	1 (5)	p > 0.99
Fibular Fracture Fixation	3 (15)	2 (10)	p > 0.99
Mean Coronal Plane Alignment (degrees)	0.85 (0.90)	2.2 (0.94)	p < 0.0001
Mean Sagittal Plane Alignment (degrees)	1.3 (1.2)	1.6 (1.5)	p = 0.68
Time to Union (Days)	180 (89.7)	228.7 (119.9)	p = 0.311
Delayed Union (n)	3 (15)	4 (20)	p > 0.99
Non Union (n)	0 (0)	3 (15)	p = 0.23
RUST	9.3 (1.8)	8.5 (1.1)	p = 0.24
Mean Time of RUST Score Calculation (Months)	7.4 (3.2)	7.7 (2.6)	p = 0.55
Unplanned return to theatre (n)	5 (25)	6 (30)	p > 0.99