

Preliminary Results with the Shape Memory Nail: A Self-contained Distal Locking Mechanism for Diaphyseal Femur Fractures

Nando Ferreira¹, Luan Nieuwoudt²

ABSTRACT

Distal interlocking of intramedullary nails can be challenging if not done regularly and can be associated with a prolonged operating time and excessive radiation exposure. Multiple techniques have been developed to overcome these problems but all still rely on conventional distal locking methods. Between December 2011 and March 2013, 18 patients with diaphyseal femur fractures were treated with the shape memory nail (Orthofix, Verona, Italy). These nails use self-contained nitinol memory metal 'wings' at the distal aspect of the nail to provide rotational and longitudinal stability. We observed fracture union in all 18 cases with no non-unions, rotational malalignments or peri-prosthetic infections. Median theatre time was 35 (18–71) minutes and median total radiation time was 50 (20–209) seconds. The shape memory nail (Orthofix, Verona, Italy) is an attractive alternative to conventional interlocking femoral nails. It provides sufficient stability to allow fracture union while decreasing theatre time and limiting radiation exposure.

Keywords: Distal locking, Femur fracture, Intramedullary nail, Memory metal, Nitinol.

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INTRODUCTION

Interlocked intramedullary nails are a gold standard in the operative management of adult diaphyseal femur fractures.¹ These nails rely on interlocking screws to provide rotational and longitudinal stability during fracture healing. Inserting these distal interlocking screws can be technically demanding if not done regularly, and can be associated with prolonged operative time and increased radiation exposure.²

Traditional distal locking screw insertion relies on intraoperative X-ray imaging to guide placement of these screws. Although the design of intramedullary nails has improved significantly, most still rely on traditional interlocking screws for rotational and longitudinal stability.

Multiple techniques and devices have been developed to assist with distal locking including free-hand techniques, nail mounted guides, image intensifier mounted guides and computer assisted techniques.^{3–10} Keenan et al. described the McIndoe scissor technique to help locate both distal locking holes simultaneously.¹¹ Owen et al. evaluated a K-wire and cannulated drill technique and found no benefit when compared to the free-hand technique.⁶ Rohilla et al. and Soni et al. described the nail-over-nail technique to simplify distal locking and decrease radiation exposure.^{7,12} Nail mounted jig techniques have been developed by multiple companies, including Orthofix (Verona, Italy), Stryker (Kalamazoo, Michigan), Synthes (Zuchwil, Switzerland) and the surgical implant generation network (SIGN) nail.^{13–18} The inherent problem with these nail-mounted techniques is the slight deformation that femoral nails undergo during insertion into the intramedullary canal.¹⁹ Goodall et al. and Goulet et al. described image intensifier mounted lasers that allow aiming of the drill through the hole.^{8,20} The Trigen Sureshot (Smith and Nephew, Memphis, Tennessee) relies on electromagnetic computer-assisted navigation to insert distal locking screws.^{3,21} More recently, robot navigation systems have been developed to assist with distal locking.^{22,23} All of these

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techniques, however, still rely on conventional interlocking screws to provide rotational and longitudinal stability.

We report our preliminary results of diaphyseal femur fractures treated with the Orthofix Shape Memory Nail (Orthofix, Verona, Italy). This nail contains Nitinol memory metal 'wings' to provide rotational and longitudinal stability instead of conventional interlocking screws.

MATERIALS AND METHODS

Between December 2011 and March 2013 all patients who presented with isolated diaphyseal femur fractures and were treated with the Orthofix Shape Memory Nail (SMN) were eligible for inclusion. Patients were excluded if they did not complete at least 12 months of follow-up after the index procedure. Institutional ethics committee approval was obtained for this study.

All patients were operated on a fracture table and with the use of a fluoroscopic C-arm. An incision proximal to the greater

trochanter allowed access to the tip of the greater trochanter. After proximal entry reaming, a guide wire was inserted and used to measure the appropriate nail length. The ideal nail depth was measured to be 20 mm from the intercondylar notch. Femoral canal preparation followed with reaming up to size 13 reamers.

After selection of the appropriate length nail, the nail was attached to the jig and the nitinol wings closed as per the described surgical technique. Nail insertion to the appropriate depth was followed by controlled deployment of the Nitinol 'wings' (Fig. 1). Two proximal interlocking screws and a nail end cap completed the surgical procedure. After wound closure, the patient was returned to the ward and received 24 hours of prophylactic antibiotics (1 g Cephazolin 8 hourly). Surgical time from skin incision to skin closure was recorded for all surgeries. The radiation exposure, in seconds, for each case was read from the fluoroscopy machine and

recorded. Total radiation exposure during nail insertion, Nitinol wing deployment, and proximal screw placement was recorded separately.

Functional rehabilitation was encouraged under the guidance of a physiotherapist with a program focussing on early mobilisation and weight bearing followed by normalisation of gait pattern and functional use. No period of restricted weight bearing was used. Outpatient follow-up was scheduled at 6 weeks; 3 months, 6 months and 12 months after nail insertion. Nail removal was considered after 12 months and after radiographic evidence of fracture union. Nail removal was performed with patients in the lateral position. The proximal end of the nail was exposed followed by end cap and proximal locking screw removal. The nail removal jig was attached to facilitate closure of the Nitinol wings followed by removal of the nail. After nail removal, patients were allowed to continue functional use of the limb without any period of restricted activity.



Fig. 1: AP and lateral radiographs showing deployment of Nitinol 'wings'

RESULTS

Eighteen patients met the inclusion criteria. No patients were excluded. The cohort comprised 14 men and four women with a mean age of 29.7 years (range 18–56, SD 10.4) (Table 1). Mean follow-up was 13.4 months (range 12–18). In total, 11 fractures were classified as AO 32A, six OA 32B and one AO 32C.

Medical co-morbidities were identified in four patients (27%). These four patients were all HIV positive with cluster of differentiation 4 (CD4) counts ranging from 192 to 584 cells/mm³ (mean = 381.5 cells/mm³). All four patients were on highly active anti-retroviral (HAART) treatment. Four patients (27%) were active smokers.

Surgical time ranged from 18 to 71 minutes (median = 35, SD 18) and showed a significant variance between different surgeons. Additionally, a gradual reduction in operative time was observed with subsequent surgeries indicating the learning curve associated with the use of a new device (Fig. 2).

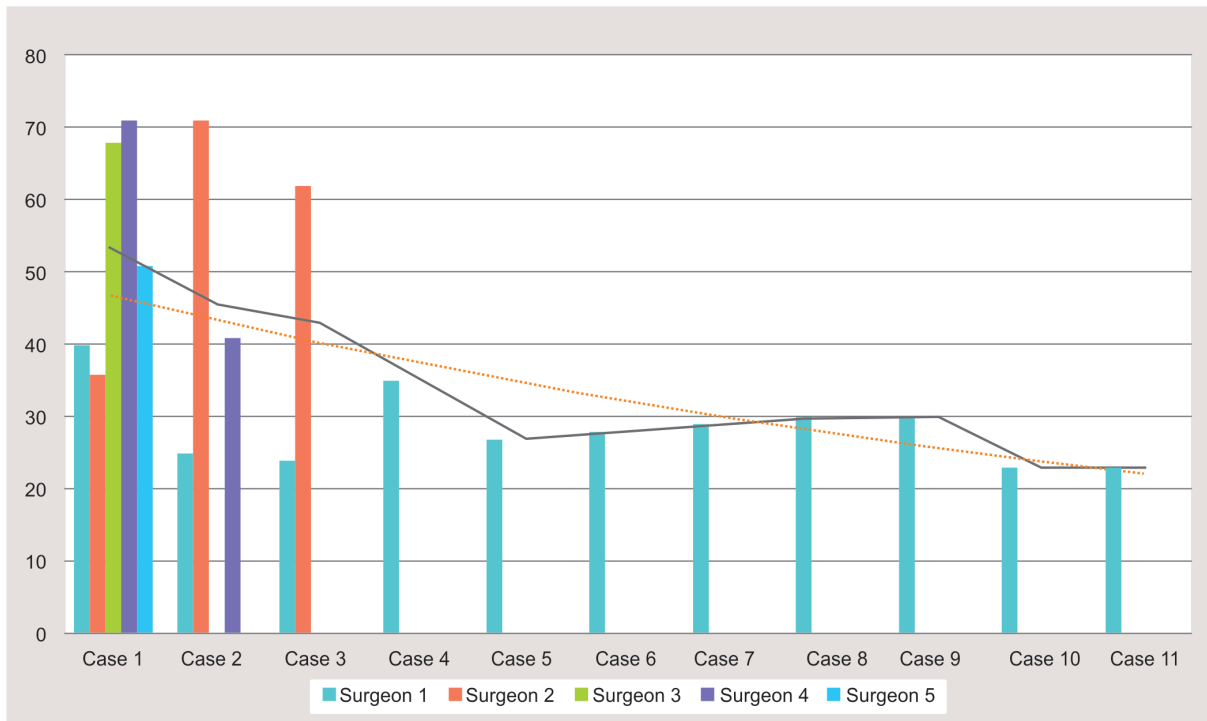


Fig. 2: Time (minutes) per case for each surgeon

Table 1: Details of results

<i>Patient</i>	<i>Age</i>	<i>Gender</i>	<i>AO</i>	<i>Nail length</i>	<i>Surgical time (min)</i>	<i>Radiation time: nail insertion (seconds)</i>	<i>Radiation time: wings opening (seconds)</i>	<i>Radiation time: proximal screws (seconds)</i>	<i>Radiation time: total (seconds)</i>	<i>Callus</i>
1	39	M	32A	395	40	16	4	4	30	Hypertrophic
2	18	M	32A	410	25	23	4	9	45	Hypertrophic
3	56	M	32B	350	24	14	4	5	43	Hypertrophic
4	19	M	32A	410	35	14	1	6	54	Hypertrophic
5	30	M	32B	395	27	35	1	9	45	Normotrophic
6	32	M	32B	395	28	17	1	9	34	Normotrophic
7	20	M	32A	410	68	24	3	7	203	Normotrophic
8	30	F	32C	380	29	21	3	6	51	Hypertrophic
9	32	F	32A	395	36	18	8	10	117	Hypertrophic
10	19	M	32A	395	30	25	4	8	58	Hypertrophic
11	35	M	32A	380	71	14	11	7	135	Normotrophic
12	33	M	32A	380	62	9	9	2	114	Normotrophic
13	22	F	32B	380	30	25	3	4	32	Normotrophic
14	20	M	32A	410	71	63	2	13	78	Normotrophic
15	19	M	32A	395	41	39	8	3	50	Normotrophic
16	46	F	32A	380	51	25	5	5	41	Hypertrophic
17	32	M	32B	395	23	10	1	7	20	Normotrophic
18	33	M	32B	395	18	12	1	6	25	Normotrophic
Median	30				35	19.5	3.5	6.5	50	
Mean	29.7				39.4	22	4	7	65	
STDEV	10.4				18	13	3	3	48	
Range	18–56				18–71	9–63	1–11	3–13	20–135	

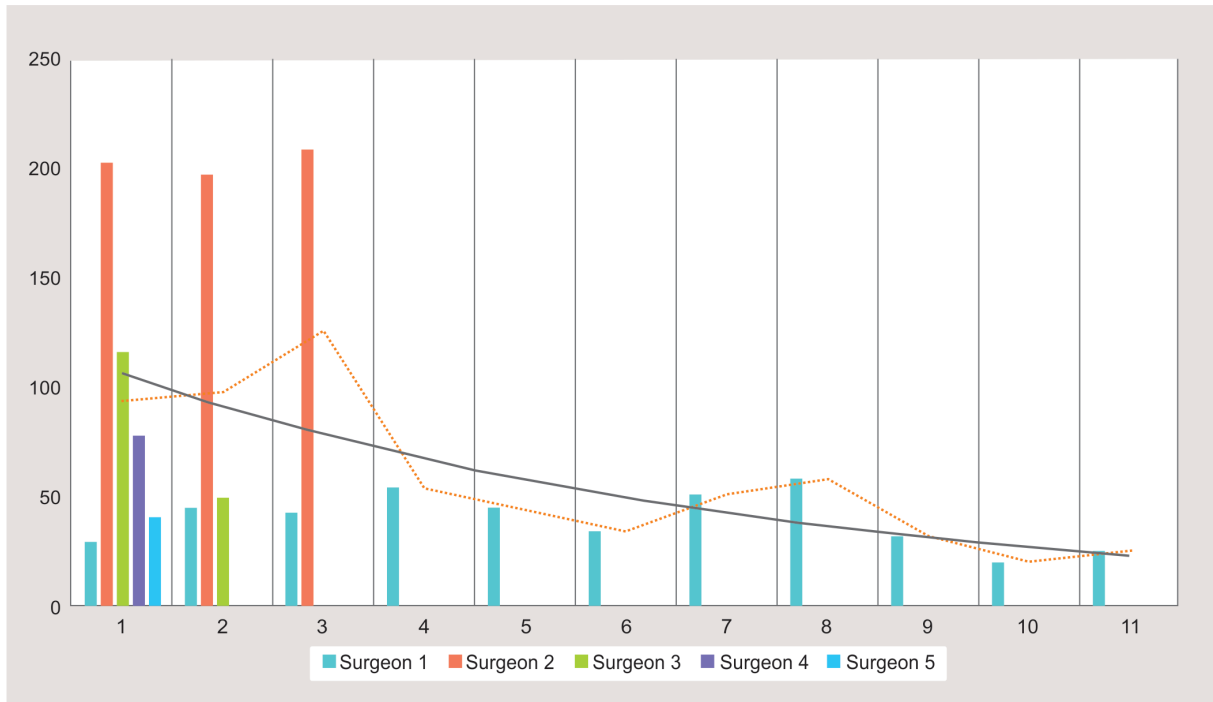


Fig. 3: Radiation time (seconds) per case for each surgeon

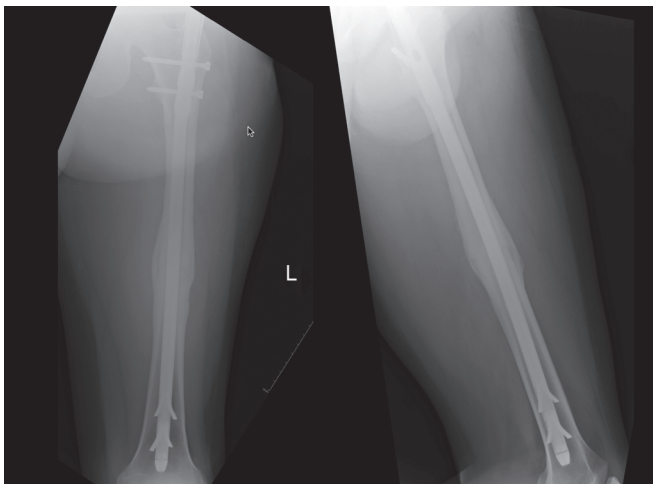


Fig. 4: AP and lateral radiographs showing union of a midshaft femur fracture 12 months after nail insertion



Fig. 5: AP and lateral radiographs showing hypertrophic callus formation 6 weeks after nail insertion

Total fluoroscopic screening time, similarly, showed a significant variance between surgeons. Screening time ranged from 20 seconds to 209 seconds (median = 50, SD 63). Here too, screening time tended to decrease with subsequent cases, though not as marked as seen with surgical time (Fig. 3). The mean screening time for distal locking through opening of the Nitinol wings were 4 seconds and ranged from 1 to 11 seconds.

All 18 fractures united without any additional surgeries or adjuvant therapies. Sixteen of the 18 fractures (88.9%) were clinically and radiologically united at the 3-month follow-up. The two remaining patient's fractures were confirmed to be united at their 6-month follow-up. Ten patients (55.6%) united with normotrophic callus (Fig. 4) while the remaining eight patients (44.4%) had hypertrophic callus (Fig. 5) evident on follow-up radiographs.

No superficial or deep infection developed. No malunions occurred and no patient reported distal femur pain.

Six patients agreed to elective nail removal (Fig. 6). Four patients refused removal and the remaining eight patients never returned after their 12-month follow-up. The removals were performed according to the described surgical technique and were accomplished without incident.

DISCUSSION

The aim of this study was to present our initial experience of diaphyseal femur fractures treated with the Orthofix Shape Memory Nail (Orthofix, Verona, Italy). The unique Nitinol memory metal distal locking mechanism provided an alternative to conventional distal interlocking screws.

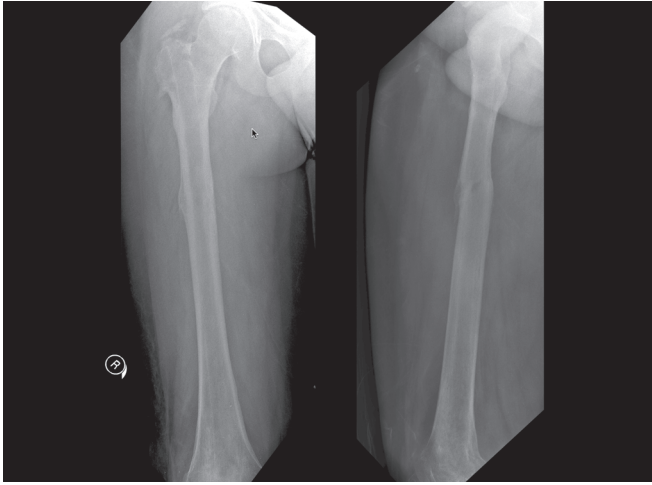


Fig. 6: AP and lateral radiographs of femur after removal of nail

Nitinol stands for nickel (Ni), titanium (Ti) and Naval Ordnance Laboratory (NOL) where it was discovered in the early 1960s and used in medical devices since the 1970s.^{24–27} It is the generic trade name for the nickel and titanium alloy where the two metals are present in near equal anatomic percentages. Nitinol exhibits two unique properties namely shape memory effect and superelasticity. The shape memory effect refers to the alloys ability to be deformed at certain temperatures ranges and then return to its original shape when heated. It is this property that is frequently exploited for medical purposes as is the case in the shape memory nail (Orthofix, Verona, Italy).

In addition to the Nitinol distal locking mechanism in the SMN by Orthofix, several other companies have developed solutions to assist surgeons to achieve length and rotational stability following long-bone intramedullary nailing. Expandable self-locking nails have shown initial promise but reports of implant failure and limb shortening have curtailed their use.^{28–33} The electromagnetic computer-assisted Trigen Sureshot (Smith and Nephew, Memphis, Tennessee) system retains the traditional interlocking screws but uses real-time three-dimensional ‘navigation’ to assist with distal locking without the need for fluoroscopic radiation.^{3,21}

In addition to finding solutions to simplify distal locking, strategies to reduce radiation exposure during distal locking is also a priority. Krettek et al. compared the use of a targeting device for distal locking with the free hand technique.⁵ They reported that although the targeting device was slower than the free-hand technique for distal locking (6.6 ± 2.4 minutes vs 4.8 ± 1.5 minutes), total radiation time was significantly less with use of the targeting device (23 ± 17 seconds vs 69 ± 34 seconds). The authors reported total radiation time for distal locking only using the free-hand technique to be 37 ± 15.5 seconds.⁵ Hoffmann et al. reported a median time benefit of 244 seconds without using ionising radiation when comparing distal locking with conventional fluoroscopic guidance and Sureshot (Smith and Nephew, Memphis, Tennessee) electromagnetic-guided methods in 50 cadavers.³ Similarly, Horn et al. reported a significant reduction in radiation exposure ($230.54 \mu\text{Gy}$ vs $690.27 \mu\text{Gy}$) when comparing Sureshot with free-hand distal locking.³⁴ Theoretically, apart from screening for confirmation, no fluoroscopic imaging is required during the deployment of the Nitinol distal locking ‘wings’. This was illustrated in our findings

with a mean time for fluoroscopic screening during deployment being 4 seconds, but being as low as 1 second in multiple cases.

The low number of cases enrolled during this pilot study is a clear limitation. The fact that only six nails were removed during the study period is also a concern; although all of these removals were uneventful, the ability to close the Nitinol wings for extraction need more rigorous testing.

CONCLUSION

The Orthofix Shape Memory Nail is an attractive alternative to conventional interlocking femoral nails. The nitinol memory metal distal locking ‘wings’ provide sufficient rotational and longitudinal stability to allow fracture union while limiting radiation exposure.

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