

Multicenter Observational Prospective Unblinded Case-Control Study to Evaluate the Effect of the Distal Targeting System for the Gamma3 Long Nail on Radiation Exposure and Time for Distal Screw Placement

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Purpose: Our objective was to determine if the Distal Targeting System (DTS) for the Gamma3 long nail decreases radiation exposure, fluoroscopy time, and total time for distal screw placement compared to the freehand “perfect circles” technique.

Methods: Between December 2019 and December 2020, 58 consecutive patients with hip/femoral shaft fractures underwent repair with a Gamma3 long nail and were assigned to the DTS (N = 29) or control “perfect circles” cohort (N = 29). An a priori power analysis revealed that 29 patients per cohort were necessary to demonstrate: 40% reduction in radiation exposure and 30% reduction in distal locking time ($\alpha = 0.05$ and power of 0.80). Fracture classifications included AO/OTA 31-A1, 31-A2, 31-A3, 31-B3, and 32-A1. All patients had 2 distal interlocking screws placed. Intraoperative measurements for radiation exposure (mGy), continuous fluoroscopy time (sec), and intraoperative time (sec) between lag screw and final interlocking screw placement were recorded. Mann-Whitney U test was performed to compare differences between these metrics.

Results: The DTS cohort had 76.9% (4.3×) lower radiation exposure, 63.5% (2.7×) lower continuous fluoroscopy time, and 60.0% (1.7×) lower intraoperative time from end of cephalad screw placement to end of distal interlocking screw (P<0.001 for all outcomes). There were no significant differences in patient demographics, injury characteristics, or hospital quality outcome measures (Table 1).

Conclusion: Data suggest that the DTS for the Gamma3 long nail significantly reduces radiation exposure, fluoroscopy time, and intraoperative time for distal screw placement compared to the freehand “perfect circles” technique when used for hip and femur fracture repair.

Intra-operative Measures			
	Control (N=29)	Distal Targeting (N=29)	p-value
Mean Radiation Exposure (mGy)	1.86 ± 1.02	0.43 ± 0.36	<0.001
Mean Continuous Fluoro Time (sec)	35.26 ± 17.68	12.88 ± 5.51	<0.001
Mean Time Between Cephalad & Interlocking Screw (sec)	626.38 ± 210.19	376.03 ± 117.18	<0.001
Demographics			
Mean Age, yrs (±SD)	80.56 (±10.87)	77.05 (±12.24)	0.689
Mean BMI (±SD)	24.83 (±4.47)	27.00 (±7.23)	0.201
Mean CCI, yrs (±SD)	1.62 (±1.88)	1.79 (±1.74)	0.722
Female, %	67.6%	75.0%	0.519
Race, White %	61.8%	62.5%	
Race, Black %	14.7%	12.5%	
Race, Hispanic %	14.7%	0.0%	
Race, Asian %	8.8%	12.5%	
Race, Other %	0.0%	12.5%	
Hospital Quality Outcome Measures			
In-Hospital Complications	9	16	0.309
Minor Complications	11	14	0.437
Major Complications	3	4	0.696
30-Day Readmission	2	2	0.552
90-Day Readmission	0	4	0.258
Surgical Site Infection	0	1	1.000
Hardware Complications	1	1	1.000
Death During Admission	1	1	0.68

TECHNICAL TRICKS AND TIPS

The FDA has stated that it is the responsibility of the physician to determine the FDA clearance status of each drug or medical device he or she wishes to use in clinical practice.