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Search Results – Intramedullary Nailing System

1. F1 Intramedullary Nails - Literature Search Details

The raw search results were initially screened by review of the title and by abstract. Based on this review, applicable literature was selected, and full text versions of each publication were retrieved (where possible) and further reviewed for relevance.

Out of 108 sources identified through targeted searches, 84 articles were excluded based on relevance and data quality. 23 articles were included, each reporting clinical experiences with usable data. Search results and reasons for inclusion/exclusion are shown in Annex 1: Clinical Literature Review Search Results. All full text publications that were appraised are available in Appendix 24.

A PRISMA flow diagram was used to visually represent the search and selection process, including the number of articles at each stage of screening and exclusion. This diagram ensures clarity in the inclusion pathway and provides a transparent overview of decision-making.

No papers on the Austofix F1 Nail were identified during the literature search.

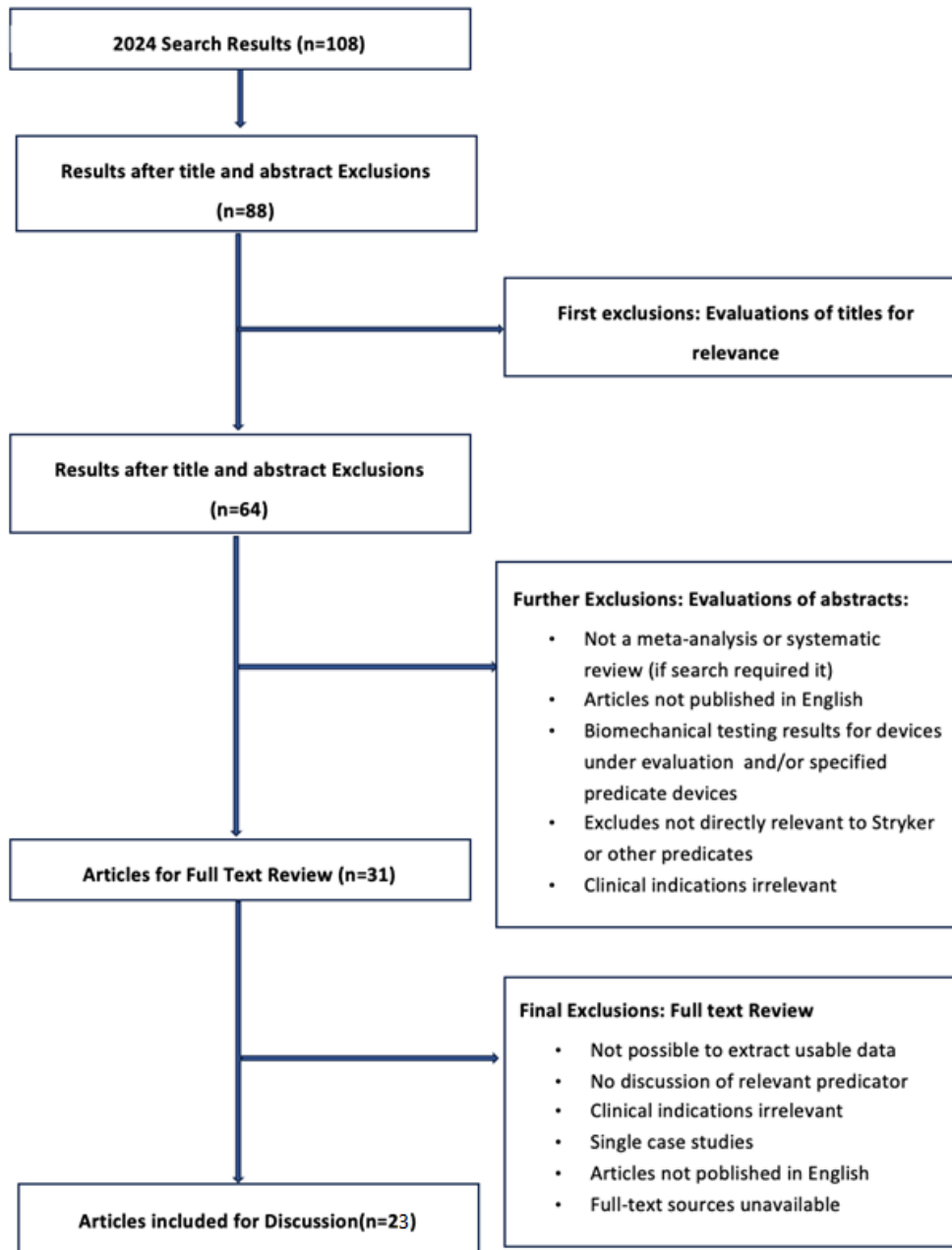


Figure 1 PRISMA Diagram for Quantitative Search

The PubMed search and search hits are shown in Table 1.

Table 1 The PubMed Search Results – Clinical Literature, 2024 review

	Search Terms	Results
PubMed (Published Articles) 2022 to 2024	Gamma3 AND (proximal femoral OR trochanteric)	15 results found. Results not specifically reviewing the Gamma3 femoral nail were excluded. Only full-text sources are included. 5 papers included for full-text review.
	Intertan AND (proximal femoral OR trochanteric)	40 results found. Results not specifically reviewing the Gamma3 femoral nail were excluded. Only full-text sources are included. 13 papers included for full-text review.
	(trochanteric OR Cephalomedullary) AND (Gamma3 OR Intertan OR PFNA) AND (meta-analysis OR systematic review)	8 results found. Results not specifically reviewing the Gamma3 femoral nail were excluded. Only full-text sources are included. 3 papers included for full-text review.
	(Gamma3 OR PFNA OR Intertan) AND (meta-analysis OR systematic review)	45 results found. Results not specifically reviewing the Gamma3 femoral nail were excluded. Only full-text sources are included. 2 papers included for full-text review.

The identified 23 papers were appraised as shown below (Table 2).

Table 2 Literature appraisals – F1 Femoral Nails

Author, Date	Title	Devices Included	Patient Population/ Age		Overview
F1 Femoral Nails – Paper 1					
Panagopoulos et al. (2023)	<i>Study protocol: biomechanical testing, finite element analysis and prospective, randomized, clinical study of single screw Cephalomedullary nailing versus integrated dual interlocking screw fixation for unstable (31A21–3) intertrochanteric fractures in patients >70 years old</i>	Gamma3, Intertan	Total: 194; 97 in Gamma3 and 97 in Intertan Age: Over 70		<p>Summary: A series of biomechanical tests performed to assess the strength and durability of the implant under simulated physiological conditions. The testing includes torsional strength, bending fatigue, and axial compression, ensuring the nail can withstand the mechanical stresses encountered during typical patient activities. The report also compares the F1 nail's performance to that of competitor devices, demonstrating comparable or superior mechanical properties. These findings support the device's safety and reliability for orthopaedic surgical applications.</p> <p>Benefit / Risk Analysis: The Intertan nail provides higher stiffness and load to failure characteristics with less varus collapse in unstable intertrochanteric fractures after cycling loading.</p>
Ranking Criteria			Study	Value	Risk Assessment: No risks or complications were identified in this paper.
Meta-analysis			No	0	Citation Type: Peer reviewed
Prospective/randomised trials			Yes	2	
Relevant predicates			Yes	2	Indication: Cephalomedullary nailing surgery
Appropriate patient group			Yes	2	Same site in body (In compare with F1): Yes
Patient population size			No	0	Material in contact with Human tissue or body fluid: Yes
Usable data on complications			Partial	1	
Minimum 12-month follow-up			No	1	
Ranking Average Total			1.14		

Author, Date	Title	Devices Included	Patient Population/ Age		Overview
F1 Femoral Nails – Paper 2					
Yang et al.(2023)	<i>Dual-screw versus single-screw Cephalomedullary nails for intertrochanteric femoral fractures: a systematic review and meta-analysis</i>	InterTan, PFNA/PFN A-II, Gamma3	Total: 3566 1832 with InterTan, 1734 with PFNA/PFNA-II or Gamma3 Age: Over 71.8 with InterTan, 72.1 with comparator group		Risks/ complication: Summary: This systematic review and meta-analysis compared the efficacy and safety of dual-screw (InterTAN) and single-screw Cephalomedullary nails (PFNA/PFNA-II, Gamma3) in treating intertrochanteric femoral fractures (IFFs). The study found that InterTAN had a significantly reduced risk of implant failures, hip and thigh pain, and all-cause revision or reoperation compared to single screw nails. Patients treated with InterTAN also had significantly higher 1-year Harris Hip Scores and shorter time to union or healing. Femoral neck shortening, time to full bearing, and incidences of non-union, infection, deep venous thrombosis, and mortality were comparable between both groups. The study concluded that InterTAN has superior performance in reducing risks of complications and improving clinical and functional outcomes in the treatment of IFFs.
Ranking Criteria			Study	Value	
Meta-analysis			Yes	2	Benefit / Risk Analysis: Implant failures: InterTan: 4.7% (80/1715), Comparator: 15.1% (241/1597) Hip and thigh pain: InterTan:10.3% (82/797), Comparator: 14.0% (127/908) Revision or reoperation: InterTan: 3.5% (33/944), Comparator: 8.9% (85/952)
Prospective/randomised trials			Yes	2	Risk Assessment: Risks/ complications were identified in this paper.
Relevant predicates			Yes	2	Citation Type: Peer reviewed
Appropriate patient group			Yes	2	
Patient population size			Yes	2	
Usable data on complications			Yes	2	Same site in body (In compare with F1): Yes
Minimum 12-month follow-up			Yes	2	Material in contact with Human tissue or body fluid: Yes
Average Total			2.0		

Author, Date	Title	Devices Included	Patient Population/ age	Overview	
F1 Femoral Nails – Paper 3					
Schemitsch et al.(2023)	<i>Intramedullary Nailing vs Sliding Hip Screw in Trochanteric Fracture Management The INSITE Randomized Clinical Trial</i>	Gamma3, Sliding hip screw devices (SHS)	Total: 850 423 with gamma3, 427 with SHS Age: mean: 78.2	<p>Summary: The INSITE randomized clinical trial by Schematic et al. (2023) compared the effectiveness of intramedullary nails (IMNs) versus sliding hip screws (SHSs) in treating trochanteric hip fractures across 850 patients at 25 international sites. Over a one-year follow-up period, the study found no significant differences in health-related quality of life (HRQOL), fracture healing, mobility, hip function, revision surgery, or adverse events between the two groups. While IMNs showed slightly better mobility and functional scores at 13 and 26 weeks, these differences were not clinically meaningful. Given the higher cost of IMNs and similar outcomes to SHSs, the study concluded that SHSs remain a cost-effective and clinically acceptable option for most patients with trochanteric fractures. Shortening, time to full bearing, and incidences of non-union, infection, deep venous thrombosis, and mortality were comparable between both groups. The study concluded that InterTAN has superior performance in reducing risks of complications and improving clinical and functional outcomes in the treatment of IFFs</p>	
Ranking Criteria			Study		Value
Meta-analysis			No	0	<p>Benefit / Risk Analysis:</p> <p>Implant removal: Gamma: 11, SHS: 11</p> <p>Collapse of fracture and migration of hardware: Gamma: 0, SHS: 1</p> <p>Screw cut out: Gamma: 5,SHS: 3</p> <p>Cutout and screw breakage: Gamma: 0, SHS:1</p> <p>Screw dislocation: Gamma: 0, SHS: 1</p> <p>Screw breakage: Gamma: 2, SHS:5 No significant difference between Gamma and SHS.</p>
Prospective/randomised trials			Yes	2	
Relevant predicates			Yes	2	<p>Risk Assessment:</p> <p>Risks/ complications were identified in this paper.</p>
Appropriate patient group			Yes	2	
Patient population size			partial	1	Citation Type: Peer reviewed
Usable data on complications			Yes	2	Indication: Cephalomedullary nailing surgery
Minimum 12-month follow-up			Yes	2	Same site in body (In compare with F1): Yes
Average Total			1.57		Material in contact with Human tissue or body fluid: Yes

Author, Date	Title	Devices Included	Patient Population/ Age	Overview
F1 Femoral Nails – Paper 4				
Elbaz et al. (2023)	<i>Reduced cutout for reverse oblique intertrochanteric hip fractures treated with trochanteric fixation advanced (TFN-A) nail compared to the short gamma-3 nail</i>	Gamma3, TFN-A	Total: 203 137 with gamma3, 66 with TFN-A Age: mean: 78.2	Summary: This article is a retrospective study that compares the clinical outcomes of two Cephalomedullary nail systems for the treatment of reverse oblique intertrochanteric hip fractures: the Trochanteric Fixation Nail Advanced (TFN-A) and the Gamma 3 Proximal Femoral Nail (GPFN). The study included 203 patients with reverse oblique fractures (137 in the GPFN group and 66 in the TFNA group). The main finding of the study was that the 235 mm TFN-A nail was associated with significantly lower rates of cutout (a complication where the implant fails to hold the fracture in place) compared to the short GPFN group. There was no significant difference between the two groups in terms of other complications, such as malunion/non-union (where the fracture heals in an abnormal position or doesn't heal at all) or the need for revision surgery. The authors conclude that the 235 mm TFN-A may be a better option than the short GPFN for the treatment of reverse oblique intertrochanteric hip fractures due to the reduced risk of cutout.
Ranking Criteria			Study	Value
Meta-analysis			No	0
Prospective/randomised trials			No	0
Relevant predicates			Yes	2
Appropriate patient group			Yes	2
Patient population size			No	0
Usable data on complications			Yes	2
Minimum 12-month follow-up			Yes	2
Average Total			1.14	
Benefit / Risk Analysis: Orthopaedic complication: TFN-A:19.7%, Gamma3: 13.1 % Non-orthopaedic complication: TFN-A: 21.2%, Gamma3: 23.4%				
Risk Assessment: Risks/ complications were identified in this paper.				
Citation Type: Peer reviewed				
Indication: Cephalomedullary nailing surgery				
Same site in body (In compare with F1): Yes				
Material in contact with Human tissue or body fluid: Yes				

Author, Date	Title	Devices Included	Patient Population/ Age		Overview
F1 Femoral Nails – Paper 5					
Sung et al.(2023)	<i>Treatment outcomes of concomitant ipsilateral neck and trochanteric fractures using Gamma3 nails with U-blade lag screws</i>	Gamma3	Total: 25 Age: mean: 76.3 (61-91)		Summary: This study investigated the outcomes of Gamma3 nails with U-blade lag screws in treating combined femoral neck and trochanteric fractures. The study included 25 patients with a mean age of 76.3 years. Bone union was achieved in 88% of the patients. There were no significant differences between the groups with and without bone union in terms of age, BMD, BMI, operative time, TAD of the lag screw, extent of lag screw migration, and femoral neck-shaft angle. The authors concluded that Gamma3 nails with U-blade lag screws can achieve satisfactory outcomes in treating combined femoral neck and trochanteric fractures.
Ranking Criteria			Study	Value	
Meta-analysis			No	0	Risk Assessment: Risks/ complications were identified in this paper.
Prospective/randomised trials			No	0	
Relevant predicates			Yes	2	Citation Type: Peer reviewed
Appropriate patient group			Yes	2	
Patient population size			No	0	Indication: Cephalomedullary nailing surgery Same site in body (In compare with F1): Yes
Usable data on complications			Yes	2	
Minimum 12-month follow-up			Yes	2	
Total Average			1.14		Material in contact with Human tissue or body fluid: Yes

Author, Date	Title	Devices Included	Patient Population/ Age		Overview
F1 Femoral Nails – Paper 6					
Hongpei et al. (2024)	<i>A Comparative Study of the Early Postoperative Outcome of Three Intramedullary Fixation Modalities in the Treatment of Intertrochanteric Fractures of the Femur in the Elderly</i>	InterTan, PFBN, PFNA	Total patients: 82 PFBN: 22 InterTan: 20 PFNA: 40 Mean age: PFBN: 76.27 InterTan: 80.55 PFNA: 79.15		Summary: This study aimed to compare the early efficacy of PFBN, Inter-TAN, and PFNA procedures for treating intertrochanteric fractures in elderly patients. The researchers found that the PFBN group had longer operative times, more intraoperative fluoroscopy use, and higher blood loss and fluid infusion compared to the Inter-TAN and PFNA groups. However, the PFBN group also had a significantly shorter postoperative weight-bearing time, fracture healing time, and hospital stay. The Inter-TAN group had a shorter postoperative weight-bearing time than the PFNA group. There were no significant differences between the groups in the rate of complications or in functional outcome scores at 6 months postoperatively.
Ranking Criteria			Study	Value	
Meta-analysis			No	0	Benefit / Risk Analysis: Risks/ Complications: Deep vein thrombosis (DVT): InterTan: 1 PFNA: 2
Prospective/randomised trials			No	0	
Relevant predicates			Yes	2	Risk Assessment: Risks/ complications were identified in this paper.
Appropriate patient group			Yes	2	
Patient population size			No	0	Citation Type: Peer reviewed
Usable data on complications			partial	1	Indication: Cephalomedullary nailing surgery
Minimum 12-month follow-up			No	0	Same site in body (In compare with F1): Yes
Average Total			0.71		Material in contact with Human tissue or body fluid: Yes

Author, Date	Title	Devices Included	Patient Population/ Age	Overview
F1 Femoral Nails – Paper 7				
Zhonglian et al. (2024)	<i>A comparison of functional and radiological outcome of combine compression antegrade intertrochanteric nail (InterTan) and proximal femoral nail anti-rotation II (PFNAII) in elderly patients with intertrochanteric fractures</i>	InterTan, PFNA	Total patients: 88 PFBN: 22 InterTan: 20 PFNA: 40 Mean age: 68.72	<p>Summary: This retrospective cohort study compared the clinical outcomes of two intramedullary nail fixation devices—InterTAN and PFNA-II—in elderly patients with intertrochanteric fractures. The study included 88 patients treated at the First Affiliated Hospital of Bengbu Medical College (China) between January 1, 2019, and July 31, 2021. The mean age of the patients was 68.72 years.</p> <p>The key findings were:</p> <ul style="list-style-type: none"> • The PFNA-II group had shorter operation times and less intraoperative blood loss than the InterTAN group. • The InterTAN group had shorter fracture healing time and hospital stays. • The InterTAN group had a lower rate of fracture line widening and postoperative complications. • There was no significant difference between the groups in Harris hip scores at three, six, and 12 months after the operation. <p>The authors concluded that both InterTAN and PFNA-II can effectively promote functional rehabilitation in elderly patients with intertrochanteric fractures. InterTAN may offer advantages in terms of earlier fracture healing and a reduced complication rate.</p>
Ranking Criteria			Study	Value
Meta-analysis			No	0
Prospective/randomised trials			No	0
Relevant predicates			Yes	2
Appropriate patient group			Yes	2
Patient population size			No	0
Usable data on complications			partial	1
Minimum 12-month follow-up			Yes	2
Average Total			1.0	
			Benefit / Risk Analysis: Deep vein thrombosis (DVT): InterTan: 1 PFNA: 2 Risk Assessment: Risks/ complications were identified in this paper. Citation Type: Peer reviewed Indication: Cephalomedullary nailing surgery Same site in body (In compare with F1): Yes Material in contact with Human tissue or body fluid: Yes	

Author, Date	Title	Devices Included	Patient Population/ Mean Age	Overview
F1 Femoral Nails – Paper 8				
Marsillo et al. (2024)	<i>Cephalomedullary nailing for reverse oblique intertrochanteric fractures 31A3 (AO/OTA)</i>	InterTan, Elos Long Nail, Zimmer natural nail system	Total patients: 70 InterTan: 33 patients/ 83.2 years Elos Long Nail: 19 patients/ 83.2 years Zimmer Natural Nail System; 18 patients/ 84.5 years	<p>Summary: This study compared the biomechanical performance of two fixation methods for unstable intertrochanteric femoral fractures with a lateral femoral wall (LFW) fracture: an intramedullary nail combined with a reconstruction plate (ITN/RP) and a single intramedullary nail (ITN).</p> <p>The study found that ITN/RP fixation provided higher axial stiffness and reduced the stress on the implants and femur compared to ITN fixation. Additionally, ITN/RP fixation resulted in less displacement.</p> <p>The authors concluded that the combination of an intramedullary nail and reconstruction plate may be a better option for treating unstable intertrochanteric fractures with LFW fracture.</p>
Ranking Criteria			Study	Value
Meta-analysis			No	0
Prospective/randomised trials			No	0
Relevant predicates			Yes	2
Appropriate patient group			Yes	2
Patient population size			No	0
Usable data on complications			partial	1
Minimum 12-month follow-up			No	0
Average Total			0.71	
			<p>Benefit / Risk Analysis:</p> <p>Screw cut-out: in 2% of the patients</p> <p>Iatrogenic periprosthetic fractures: in 1% of the patients</p> <p>The study found that patients treated with an Intertan nail had the lowest TAD, CALTAD, and TALCALTAD mean radiographic values, and the lowest rate of Hb loss and blood transfusions.</p> <p>Risk Assessment:</p> <p>Risks/ complications were identified in this paper.</p> <p>Citation Type: Peer reviewed</p> <p>Indication: Cephalomedullary nailing surgery</p> <p>Same site in body (In compare with F1): Yes</p> <p>Material in contact with Human tissue or body fluid: Yes</p>	

Author, Date	Title	Devices Included	Patient Population/ Mean Age	Overview	
F1 Femoral Nails – Paper 9					
Duan et al. (2024)	<i>Research Progress on the Treatment of Geriatric Intertrochanteric Femur Fractures with Proximal Femur Bionic Nails (PFBNs)</i>	PFBN, PFNA, InterTan	PFBN: 20-55 patients/ 70.4 - 81.4 years PFNA: 24-55 patients/ 73.0 - 83.9 years InterTan; 26-46 patients/ 74.81 - 81.0 years	<p>Summary: This study is a literature review on the use of Proximal Femur Bionic Nails (PFBNs) in treating intertrochanteric femur fractures in elderly patients. The review covers the structural characteristics, dynamic analysis, and clinical trials of PFBNs.</p> <p>The study highlights that PFBNs offer several advantages over traditional fixation methods like PFNA and InterTan, including better fracture stability, reduced stress concentration, and lower risk of complications such as screw cut-out and nail back-out. Clinical trials suggest that PFBNs are associated with faster recovery of hip joint function, shorter non-weight-bearing time, and faster fracture healing.</p> <p>However, the study also notes that PFBNs require more precise surgical techniques, which can lead to longer operating times. The authors conclude that PFBNs offer a promising treatment option for intertrochanteric femur fractures in elderly patients and encourage further research in this area.</p>	
Ranking Criteria			Study	Value	Benefit / Risk Analysis: Operation Time: PFBN longer operation time Blood loss: No significant difference
Meta-analysis			No	0	Risk Assessment: No risks or complications were identified in this paper.
Prospective/randomised trials			No	0	Citation Type: Peer reviewed
Relevant predicates			Yes	2	Indication: Cephalomedullary nailing surgery
Appropriate patient group			Yes	2	Same site in body (In compare with F1): Yes
Patient population size			No	0	Material in contact with Human tissue or body fluid: Yes
Usable data on complications			partial	1	
Minimum 12-month follow-up			No	0	
Average Total			0.71		

Author, Date	Title	Devices Included	Patient Population/ Mean Age	Overview
F1 Femoral Nails – Paper 10				
Jing et al. (2024)	<i>Comparison of postoperative pain between InterTan and proximal femoral nail anti-rotation in femoral intertrochanteric fractures: a retrospective study</i>	PFNA, InterTan	PFNA: 26 patients/ 86.50 ± 3.94 years InterTan: 26 patients/ 85.12 ± 3.66 years	Summary: This study compared postoperative pain in elderly patients with unstable trochanteric fractures treated with either PFNA or InterTan Nail. 40 patients over 80 years old were included in the study, with 26 patients in the PFNA Nail group (Group A) and 26 patients in the InterTan Nail group (Group B). The main observational indicators, including VAS for pain, implant position changes, blood loss, fixation failures, and Harris Hip Scores (HHS), were not significantly different between the two groups. Both groups showed significant improvement in HHS post-surgery. However, early postoperative pain scores were significantly lower in Group B compared to Group A. The study concluded that both implants provided consistent and reliable outcomes, with no significant differences in postoperative functional recovery, mortality, or complications.
Ranking Criteria			Study	Value
Meta-analysis			No	0
Prospective/randomised trials			No	0
Relevant predicates			Yes	2
Appropriate patient group			Yes	2
Patient population size			No	0
Usable data on complications			partial	1
Minimum 12-month follow-up			Yes	2
Average Total			1.0	
Benefit / Risk Analysis:				
Infection:				
PFNA: 2				
InterTan: 2				
No sig. difference between PFNA and InterTan for pneumonia, thrombosis, or postoperative delirium				
Risk Assessment:				
Risks/ complications were identified in this paper.				
Citation Type: Peer reviewed				
Indication: Cephalomedullary nailing surgery				
Same site in body (In compare with F1): Yes				
Material in contact with Human tissue or body fluid: Yes				

Author, Date	Title	Devices Included	Patient Population/ Mean Age	Overview
F1 Femoral Nails – Paper 11				
Yalin et al. (2023)	<i>Interochanteric Femoral Fractures: A comparison of clinical and radiographic results with the proximal femoral intramedullary nail (PROFIN). The antirotation proximal femoral nail (A-PFN) and the Inter TAN nail.</i>	A-PFN, PROFIN, InterTAN	A-PFN: 107/ 77.81 ± 6.64 years PROFIN: 98/ 76.6 ± 9.64 years InterTAN: 104/ 77.55 ± 7.57 years	Summary: This study retrospectively evaluated the clinical and radiographic outcomes of three different proximal femoral nails (PFNs) used for closed reduction and internal fixation of intertrochanteric femoral fractures (IFFs). The study included 309 patients who underwent surgery for IFFs between January 2018 and January 2021. The PFNs used were the A-PFN, PROFIN, and InterTAN. The study found that the A-PFN had longer surgical and fluoroscopy durations, lower Harris Hip Score (HHS) values, and lower Katz Index of Independence in Activities of Daily Living (ADL) values compared to the other two PFNs. The InterTAN nail had the best clinical outcomes, with high HHS and Katz ADL Index scores, no chance of the Z-effect, and a low rate of the V-effect.
Ranking Criteria			Study	Value
Meta-analysis			No	0
Prospective/randomised trials			No	0
Relevant predicates			Yes	2
Appropriate patient group			Yes	2
Patient population size			No	0
Usable data on complications			partial	1
Minimum 12-month follow-up			Yes	2
Average Total			1.0	Benefit / Risk Analysis: Infection: PFNA: 2 InterTan: 2 No sig. difference between PFNA and InterTan for pneumonia, thrombosis, or postoperative delirium Risk Assessment: Risks/ complications were identified in this paper. Citation Type: Peer reviewed Indication: Cephalomedullary nailing surgery Same site in body (In compare with F1): Yes Material in contact with Human tissue or body fluid: Yes

Author, Date	Title	Devices Included	Patient Population/ Mean Age	Overview	
F1 Femoral Nails – Paper 12					
Zhang et al. (2024)	<i>Is Sliding Compression Necessary for Intramedullary Nailing Fixation of AO/OTA Type A3.3 Intertrochanteric Fracture?</i>	PFNA, InterTAN	PFNA: 34/ 73.18 ± 7.15 years InterTAN: 42/ 70.95 ± 5.31 years	Summary: This study investigated whether sliding compression is necessary for treating unstable AO/OTA type A3.3 intertrochanteric fractures. The study compared two approaches: InterTAN alone and PFNA combined with lateral wall reconstruction. A retrospective analysis was conducted on patients who underwent intramedullary nailing fixation for AO/OTA type A3.3 intertrochanteric fractures. The study found that PFNA with lateral wall reconstruction resulted in shorter weight-bearing time and fracture healing time, higher HHS and PPMS scores, and a lower incidence of complications compared to InterTAN. The authors concluded that sliding compression may be required for intramedullary nailing treatment of A3.3 intertrochanteric fractures.	
Ranking Criteria			Study	Value	Benefit / Risk Analysis: PFNA: Harris hip score: 91.71 ± 7.37 InterTan: Harris hip score: 84.33 ± 8.63 PFNA: Parker-Palmer mobility score: 8.53 ± 1.71 InterTan: Parker-Palmer mobility score: 7.66 ± 1.52, p=0.002
					Risk Assessment: No risks or complications were identified in this paper.
Meta-analysis	No	0	Citation Type: Peer reviewed		
Prospective/randomised trials	No	0	Indication: Cephalomedullary nailing surgery		
Relevant predicates	Yes	2	Same site in body (In compare with F1): Yes		
Appropriate patient group	Yes	2	Material in contact with Human tissue or body fluid: Yes		
Patient population size	No	0			
Usable data on complications	Yes	2			
Minimum 12-month follow-up	Yes	2			
Average Total	1.0				

Author, Date	Title	Devices Included	Patient Population/ Mean Age	Overview
F1 Femoral Nails – Paper 13				
Johnson et al. (2023)	MECHANICAL GAINS ASSOCIATED WITH VIRTUAL PROPHYLACTIC INTRAMEDULLARY NAIL FIXATION IN FEMURS WITH METASTATIC DISEASE	InterTAN	InterTAN: 48/64 years	Summary: This study investigates the mechanical benefits of virtual prophylactic intramedullary nailing (IMN) in femurs with metastatic bone disease (MBD) using patient-specific finite element (FE) models. IMN fixation resulted in a modest 10% increase in femur strength and a 7% reduction in fracture risk, with greater benefits seen when the hardware spanned a larger portion of metastatic lesions, particularly lytic and diffuse types. While IMN provided mechanical improvements, its impact was limited in cases with lower baseline fracture risk, suggesting it is most effective for femurs with severe lesions. The findings offer insights to guide surgeons in selecting appropriate interventions for patients with MBD.
Ranking Criteria			Study	Value
Meta-analysis			No	0
Prospective/randomised trials			No	0
Relevant predicates			Yes	2
Appropriate patient group			Yes	2
Patient population size			No	0
Usable data on complications			No	0
Minimum 12-month follow-up			No	0
Average Total			0.71	
			Benefit / Risk Analysis: IMN 10% increase in mechanical strength, 7% reduction in fracture risk. Femurs with lytic (10%) and diffuse (9%) metastases tended to have greater reductions in fracture risk compared to femurs with blastic (5%) and mixed (4%) metastases.	
			Risk Assessment: No risks or complications were identified in this paper.	
			Citation Type: Peer reviewed	
			Indication: Cephalomedullary nailing surgery	
			Same site in body (In compare with F1): Yes	
			Material in contact with Human tissue or body fluid: Yes	

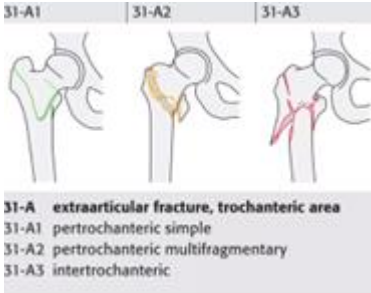
Author, Date	Title	Devices Included	Patient Population/ Mean Age	Overview
F1 Femoral Nails – Paper 14				
McAleese et al. (2024)	Mechanical outcomes of the TFNA, InterTAN and IMHS intramedullary nailing systems for the fixation of proximal femur fractures	InterTAN, TFNA, IMHS	InterTAN: 379/ 64 years TFNA: 183/ 82.1 years IMHS: 241	Summary: This study compared the rate of implant fractures and other mechanical complications among three intramedullary nailing systems used for the fixation of proximal femur fractures: TFNA, InterTAN, and IMHS. The study included 803 patients who underwent surgery between 2008 and 2021. The overall implant fracture rate was 3.1%, with no significant difference between the three devices. The TFNA had the lowest rate of all mechanical complications (4.9%) compared to InterTAN (12.9%) and IMHS (17%). The study identified non-union and increasing lag screw length as risk factors for complications. The cumulative survival rates without revision for TFNA, InterTAN, and IMHS were 97.8%, 95.5%, and 87.9%, respectively, at 2.5 years. The authors concluded that the TFNA system provides effective fixation with a traditional screw and is associated with fewer mechanical complications.
Ranking Criteria			Study	Value
Meta-analysis			No	0
Prospective/randomised trials			No	0
Relevant predicates			Yes	2
Appropriate patient group			Yes	2
Patient population size			yes	2
Usable data on complications			Yes	2
Minimum 12-month follow-up			Yes	2
Average Total			1.42	Benefit / Risk Analysis: Overall implant fracture: No sig. difference Mechanical complication: TFNA: 4.9%/ InterTan: 12.9%/ IMHS: 17% cumulative survival rates without revision surgery: TFNA: 97.8% at 2.5 years InterTAN: 95.5% at 2.5 years, 95.3% at 3.5 years IMHS: 87.9% at 2.5 years, 87.1% at 3.5 years Risk Assessment: Risks/ complications were identified in this paper. Citation Type: Peer reviewed Indication: Cephalomedullary nailing surgery Same site in body (In compare with F1): Yes Material in contact with Human tissue or body fluid: Yes

Author, Date	Title	Devices Included	Patient Population/ Mean Age	Overview
F1 Femoral Nails – Paper 15				
Li et al. (2024)	Comparison of InterTAN and PFNA internal fixation for elderly patients with intertrochanteric fracture: A retrospective cohort study	InterTAN, PFNA	InterTan: 73 PFNA: 78 Mean age: 68.26±5.05 years.	Summary: This retrospective cohort study compared the clinical outcomes of InterTAN and PFNA internal fixation for intertrochanteric fractures in elderly patients. The study included 151 patients who underwent surgery between October 2019 and December 2021. The PFNA group had shorter operation time, incision length, and intraoperative bleeding, but longer fracture healing time. The InterTAN group had significantly higher Harris hip joint scores at 1, 6, and 12 months after the operation. Both InterTAN and PFNA internal fixation have their own advantages and disadvantages. InterTAN has better postoperative recovery results, while PFNA has less perioperative trauma. The choice of implant should be based on the specific conditions of each patient.
Ranking Criteria			Study	Value
				Benefit / Risk Analysis: InterTAN: Coxa Vara: 1 (1.4%) Incision infection: 1 (1.4%) Delayed union of fracture: 1 (1.4%) PFNA: Coxa Vara: 1 (1.3%) Incision infection: 1 (1.3%) Delayed union of fracture: 1 (1.3%) Loose and broken internal parts: 1 (1.3%)
				Risk Assessment: Risks/ complications were identified in this paper.
Meta-analysis			No	0
Prospective/randomised trials			No	0
Relevant predicates			Yes	2
Appropriate patient group			Yes	2
Patient population size			No	0
Usable data on complications			Yes	2
Minimum 12-month follow-up			Yes	2
Average Total			1.14	
				Citation Type: Peer reviewed
				Indication: Cephalomedullary nailing surgery
				Same site in body (In compare with F1): Yes
				Material in contact with Human tissue or body fluid: Yes

Author, Date	Title	Devices Included	Patient Population/ Mean Age		Overview
F1 Femoral Nails – Paper 16					
Amariel et al. (2024)	Predictive value of tip-apex distance and calcar-referenced tip apex distance for cutout in 398 femoral intertrochanteric fractures treated in a private practice with dynamic intramedullary nailing	Trigen InterTAN	Trigen InterTAN: 398/ 78.6 years		<p>Summary: This retrospective study analysed 398 intertrochanteric hip fractures treated with dynamic intramedullary nailing (Trigen Intertan short nail) in a single private hospital by the same surgeon.</p> <p>The study aimed to determine the predictive value of tip-apex distance (TAD) and calcar-referenced tip-apex distance (CaITAD) for cut-out, a common complication in these fractures. The overall cut-out rate was 2.3% (9/398). Univariate analysis showed significant relationships between cut-out and AO fracture type, quality of fracture reduction, TAD, and CaITAD. However, multivariate analysis revealed that only TAD had an independent significant relationship with cut-out.</p> <p>The study concluded that ensuring stable fixation with TAD >25 mm reduced the occurrence of cut-out after dynamic intramedullary nailing of intertrochanteric fractures. The authors suggest that careful attention to fracture reduction and optimal TAD can significantly decrease the risk of this complication.</p>
Ranking Criteria			Study	Value	Benefit / Risk Analysis:
					Lag-screw cut-out: 2.3% Varus displacement: 7.5%
Meta-analysis			No	0	Risk Assessment: Risks/ complications were identified in this paper.
Prospective/randomised trials			No	0	Citation Type: Peer reviewed
Relevant predicates			Yes	2	Indication: Cephalomedullary nailing surgery
Appropriate patient group			Yes	2	Same site in body (In compare with F1): Yes
Patient population size			No	0	Material in contact with Human tissue or body fluid: Yes
Usable data on complications			Yes	2	
Minimum 12-month follow-up			Yes	2	
Average Total			1.14		

Author, Date	Title	Devices Included	Patient Population/ Mean Age	Overview
F1 Femoral Nails – Paper 17				
Polat et al. (2022)	The effect of bone morphology on fracture type and treatment result in patients with intertrochanteric femur fracture aged over 65 years	InterTan, PFNA	InterTAN: 144/64 years PFNA: 65 Mean age: 81.6 years	Summary: This retrospective cohort study investigated the effect of bone morphology on fracture type and treatment outcomes in patients over 65 years old with intertrochanteric femur fractures (IFFs) treated with intramedullary nailing (IMN). The study included 209 patients with a mean age of 81.6 years. The authors found that unstable IFFs had a significantly higher failure rate than stable IFFs. They also found that the fractured femur had lower bone quality than the unaffected femur. The authors concluded that bone morphology is an important factor to consider when treating IFFs in elderly patients.
Ranking Criteria			Study	Value
Meta-analysis			No	0
Prospective/randomised trials			No	0
Relevant predicates			Yes	2
Appropriate patient group			Yes	2
Patient population size			No	0
Usable data on complications			partial	1
Minimum 12-month follow-up			No	0
Average Total			0.71	Benefit / Risk Analysis: Non-stable IFF in compare with stable FF: Screw/blade prominence: 13.9% Risk Assessment: No risks or complications were identified in this paper. Citation Type: Peer reviewed Indication: Cephalomedullary nailing surgery Same site in body (In compare with F1): Yes Material in contact with Human tissue or body fluid: Yes

Author, Date	Title	Devices Included	Patient Population/ Mean Age	Overview
F1 Femoral Nails – Paper 18				
MéndezOjeda et al. (2024)	Treatment of Trochanteric Hip Fractures with Cephalomedullary Nails: Single Head Screw vs. Dual Integrated Compression Screw Systems	Gamma3, InterTan	Gamma: 262 InterTan: 125 Mean age: 81.6 years	Summary: This retrospective cohort study compared single head screw nails (Gamma3) to dual integrated compression screw nails (InterTAN) for the treatment of extracapsular hip fractures in 387 patients. The study found that the reoperation rate was significantly higher in the InterTAN group (8.8%) compared to the Gamma3 group (2.3%). The authors concluded that despite the potential biomechanical benefits of using two screws with the InterTAN nail, they could not recommend it over the Gamma3 nail due to the increased risk of reoperation.
Ranking Criteria			Study	Value
Meta-analysis			No	0
Prospective/randomised trials			No	0
Relevant predicates			Yes	2
Appropriate patient group			Yes	2
Patient population size			No	0
Usable data on complications			Yes	2
Minimum 12-month follow-up			Yes	2
Average Total			1.14	
			Material in contact with Human tissue or body fluid: Yes	
			Risk Assessment: Risks/ complications were identified in this paper.	
			Benefit / Risk Analysis: Cut out: Gamma: 0.8% InterTan: 4.8% Peri-implant fracture: Gamma: 0.8% InterTan: 3.2% Nail tear: Gamma: 0.4%, InterTan: 1.6% Infection: Gamma: 0.4% InterTan: 0%	
			Citation Type: Peer reviewed	
			Indication: Cephalomedullary nailing surgery	
			Same site in body (In compare with F1): Yes	

Author, Date	Title	Devices Included	Patient Population/ Mean Age	Overview
F1 Femoral Nails – Paper 19				
Quartley et al. (2022)	Stabilisation of AO OTA 31-A unstable proximal femoral fractures: Does the choice of intramedullary nail affect the incidence of post-operative complications? A systematic literature review and meta-analysis	InterTan, PFNA, TFNA, Gamma 3	Total patient population: 3427 Mean age: between 70 to 80.	<p>Summary: The article is a systematic literature review and meta-analysis that investigates whether the choice of intramedullary (IM) nail affects the incidence of postoperative complications in treating unstable AO OTA 31-A trochanteric fractures. The analysis included 23 studies, with 17 focusing on unstable fractures. It compared the INTERTAN IM nail with other designs, revealing that INTERTAN significantly reduced the risk of revision or reoperation, implant failure, and hip/thigh pain without affecting clinical and functional outcomes. No significant differences were found for infection rates, non-union, or healing time. The results suggest that INTERTAN's design, which includes dual interlocking screws and a trapezoidal shape for stability, may contribute to these benefits.</p>  <p>31-A1 31-A2 31-A3</p> <p>31-A extraarticular fracture, trochanteric area 31-A1 pertrochanteric simple 31-A2 pertrochanteric multifragmentary 31-A3 intertrochanteric</p>
Ranking Criteria			Study	Value
Meta-analysis			Yes	2
Prospective/randomised trials			Yes	2
Relevant predicates			Yes	2
Appropriate patient group			Yes	2
Patient population size			Yes	2
Usable data on complications			Yes	2
Minimum 12-month follow-up			Yes	2
Average Total			2	
				<p>Benefit / Risk Analysis:</p> <p>HHS, Non-union, Infection: No sig. difference Reoperation, Varus collapse, screw cut-out, Implant failure: InterTan favoured</p> <p>Risk Assessment:</p> <p>No risks or complications were identified in this paper.</p> <p>Citation Type: Peer reviewed</p> <p>Indication: Cephalomedullary nailing surgery</p> <p>Same site in body (In compare with F1): Yes</p> <p>Material in contact with Human tissue or body fluid: Yes</p>

Author, Date	Title	Devices Included	Patient Population/ Mean Age	Overview
F1 Femoral Nails – Paper 20				
DAI et al. (2023)	Proximal femoral nail anti-rotation vs dynamic hip screws decrease the incidence of surgical site infections in patients with intertrochanteric fractures: Meta-analysis	PFNA DHS	PFNA: 1574 DHS: 1584 Age: between 60 to 80	Summary: This meta-analysis examines the effectiveness of PFNA compared to DHS in treating intertrochanteric hip fractures, focusing on the incidence of postoperative surgical site infections (SSI). The study analysed data from 30 studies, including 3158 patients, and found that PFNA significantly reduced the occurrence of SSI, superficial SSI, and deep SSI compared to DHS. The authors conclude that PFNA is a more effective treatment option for reducing the risk of SSI in patients with intertrochanteric hip fractures.
Ranking Criteria			Study	Value
Meta-analysis			yes	2
Prospective/randomised trials			Yes	2
Relevant predicates			Yes	2
Appropriate patient group			Yes	2
Patient population size			Yes	2
Usable data on complications			partial	1
Minimum 12-month follow-up			Yes	2
Average Total			1.85	Benefit / Risk Analysis: SSI: PFNA favoured vs. DHS Reoperation: No significant difference Risk Assessment: No risks or complications were identified in this paper. Citation Type: Peer reviewed Indication: Cephalomedullary nailing surgery Same site in body (In compare with F1): Yes Material in contact with Human tissue or body fluid: Yes

Author, Date	Title	Devices Included	Patient Population/ Mean Age	Overview
F1 Femoral Nails – Paper 21				
Xu et al. (2022)	Comparative effectiveness research on proximal femoral nail versus dynamic hip screw in patients with trochanteric fractures: a systematic review and meta-analysis of randomized trials	PFN, DHS	PFN: 934 DHS: 955 Mean age: between 70 to 80	Summary: This systematic review and meta-analysis compared the effectiveness of proximal femoral nail (PFN) and dynamic hip screw (DHS) for the treatment of trochanteric fractures. The study included twelve randomized controlled trials (RCTs) with a total of 1889 patients. The authors found that PFN had shorter operative time and less intraoperative blood loss but needed more intraoperative fluoroscopy time compared to DHS. There was no difference between the two devices in terms of postoperative complications like non-union, implant failure, and revision surgery.
Ranking Criteria			Study	Value
				Benefit / Risk Analysis: Non-union. PFN: 1.7%, DHS: 2% Implant failure: PFN: 2.5%, DHS: 3.5% Revision surgery: PFN: 2.2%, DHS: 2.9%
				Risk Assessment: Risks/ complications were identified in this paper.
Meta-analysis			Yes	2
Prospective/randomised trials			Yes	2
Relevant predicates			Yes	2
Appropriate patient group			Yes	2
Patient population size			Yes	2
Usable data on complications			Yes	2
Minimum 12-month follow-up			Yes	2
Average Total			2	

Author, Date	Title	Devices Included	Patient Population/ Mean Age	Overview
F1 Femoral Nails – Paper 22				
Wu et al.(2024)	Meta-analysis of the clinical efficacy of the Gamma3 nail vs Gamma3U-blade system in the treatment of intertrochanteric fractures	Gamma 3 nail, Gamma3U-blade system	Gamma 3 nail: 404 Gamma3U-blade system: 391 Mean age: Gamma 3 nail: 70 years Gamma3U-blade system: 72 years	Summary: This meta-analysis compared the clinical efficacy of two surgical methods for treating intertrochanteric fractures: the Gamma3 nail and the Gamma3U-blade system. The study found that the Gamma3U-blade system, which is a newer generation of the Gamma3 nail, has several advantages, including enhanced fixation stability and a lower risk of cutting out. However, the study also found that the Gamma3U-blade system has a longer surgical time than the Gamma3 nail. The study concluded that both surgical methods are safe and effective for treating intertrochanteric fractures. However, the Gamma3 nail may be a better option for patients who cannot tolerate lengthy surgery.
Ranking Criteria			Study	Value
				Benefit / Risk Analysis: Harris Hip score: No significant difference. Fixation stability: Gamma3 U-blade system favoured vs. Gamma3 nail. Cutting out: Gamma3U-blade system favoured vs. Gamma3 nail. Surgical time: Gamma3 nail favoured vs. Gamma3 U-blade system.
				Risk Assessment: No risks or complications were identified in this paper.
Meta-analysis			Yes	2
Prospective/randomised trials			No	0
Relevant predicates			Yes	2
Appropriate patient group			Yes	2
Patient population size			Partial	1
Usable data on complications			yes	2
Minimum 12-month follow-up			Yes	2
Average Total			1.57	
				Citation Type: Peer reviewed
				Indication: Cephalomedullary nailing surgery
				Same site in body (In compare with F1): Yes
				Material in contact with Human tissue or body fluid: Yes

Author, Date	Title	Devices Included	Patient Population/ Mean Age	Overview
F1 Femoral Nails – Paper 23				
Liao et al. (2024)	Proximal femoral nail antirotation versus InterTan nail for the treatment of intertrochanteric fractures: A systematic review and meta-analysis	InterTan, PFNA	Total patient population: NA 15 articles were reviewed	Summary: The article is a systematic literature review and meta-analysis that investigates whether the choice of intramedullary (IM) nail affects the incidence of postoperative complications in treating unstable AO OTA 31-A trochanteric fractures. The analysis included 23 studies, with 17 focusing on unstable fractures. It compared the INTERTAN IM nail with other designs, revealing that INTERTAN significantly reduced the risk of revision or reoperation, implant failure, and hip/thigh pain without affecting clinical and functional outcomes. No significant differences were found for infection rates, non-union, or healing time. The results suggest that INTERTAN's design, which includes dual interlocking screws and a trapezoidal shape for stability, may contribute to these benefit.
Ranking Criteria			Study	Value
Meta-analysis			No	2
Prospective/randomised trials			No	2
Relevant predicates			Yes	2
Appropriate patient group			Yes	2
Patient population size			NA	NA
Usable data on complications			Yes	2
Minimum 12-month follow-up			Yes	2
Average Total			1.71	Benefit / Risk Analysis: Blood loss, surgical duration and fluoroscopy time: PFNA favoured vs. InterTan Postoperative complications: InterTan favoured vs. PFNA Risk Assessment: No risks or complications were identified in this paper. Citation Type: Peer reviewed Indication: Cephalomedullary nailing surgery Same site in body (In compare with F1): Yes Material in contact with Human tissue or body fluid: Yes

Table 3 Literature Review Risk Summary

Study	Harris Hip Score	Blood loss	Reoperation	Varus Collapse	Screw cut-out	Non-union	Infection	Implant failure
Panagopoulos et al. (2023)	Gamma vs. IT: no sig. difference	Gamma vs. IT: no sig. difference	Gamma vs. IT: IT favoured	Gamma vs. IT: no sig. difference	Gamma vs. IT: IT favoured	Gamma vs. IT: no sig. difference	NA	N Gamma vs. IT: no sig. difference
Yang et al.(2023)	InterTan vs. PFNA/PFNA-II, Gamma3: InterTan favoured	InterTan vs. PFNA/PFNA-II, Gamma3: mean difference 18.19 ml, comparator favoured	InterTan: 33 out of 944 patients, competitor 85 out of 952	InterTan vs. PFNA/PFNA-II, Gamma3: InterTan favoured	70% lower in InterTan in compare with competitors	InterTan vs. PFNA/PFNA-II, Gamma3: no sig. difference	InterTan: 37 out of 944 patients, competitor 28 out of 952	InterTan: 4.7% or 80 out of 1715 cases Competator: 15.1% or 241 out of 1597 cases
Schemitsch et al. (2023)	Gamma3 vs. SHS: no sig. difference	Gamma3 vs. SHS: no sig. difference	Gamma3: 3.6% SHS: 5.2%	NA	Gamma3 vs. SHS: no sig. difference	Gamma3: 10.4% PFNA: 15.9%	NA	Gamma: 3.6% SHS: 5.2%
Elbaz et al.(2023)	NA	Gamma: 2.8 g/dL TFN-A: 2.7 g/dL	Gamma vs. TFN-A: no sig. difference	NA	Gamma vs TFN-A: TFN-A favoured	Gamma: 2%, TFN-A: 1.5%	NA	NA
Sung et al.(2023)	NA	NA	NA	NA	NA	NA	NA	3 of 25 patients
Hongpei et al.(2024)	NA	Higher blood loss in PFBN group	NA	NA	NA	NA	NA	NA
Zhonglian et al.(2024)	NA	Higher blood loss in the InterTan group	NA	NA	NA	NA	NA	NA
Marsillo et al.(2024)	NA	InterTan: 0.8 g/dl Elos: 1 g/dl ZNN: 0 g/dl	NA	NA	2% of total patients	NA	NA	2% of total patients according to screw cut-out

Study	Harris Hip Score	Blood loss	Reoperation	Varus Collapse	Screw cut-out	Non-union	Infection	Implant failure
Duan et al. (2024)	PFBN and InterTan favoured vs. PFNA	PFNA, PFBN and InterTan: No sig. difference	NA	NA	NA	NA	NA	PFBN favoured vs. InterTan and PFNA
Jing et al. (2024)	PFNA, InterTan: No sig. difference	PFNA, InterTan: No sig. difference	NA	NA	NA	NA	PFNA, InterTan: No sig. difference	NA
Yalin et al. (2023)	A-PFN favoured vs. PROFIN and InterTan	A-PFN, PROFIN, InterTan: No sig. difference	A-PFN, PROFIN, InterTan: No sig. difference	A-PFN, PROFIN, InterTan: No sig. difference	A-PFN, PROFIN, InterTan: No sig. difference	A-PFN, PROFIN, InterTan: No sig. difference	A-PFN, PROFIN, InterTan: No sig. difference	A-PFN, PROFIN, InterTan: No sig. difference
Zhang et al. (2024)	PFN favoured vs. InterTan	NA	NA	NA	NA	NA	NA	NA
Johnson et al. (2023)	InterTan	NA	NA	NA	NA	NA	NA	NA
McAleese et al. (2023)	NA	NA	IMHS: 12.9%	NA	TFNA:0% InterTan;0.8% IMHS: 2.5%	TFNA: 1.6% InterTan:1.1% IMHS: 2.5%	TFNA: 0% InterTan: 0.3% IMHS: 1.2%	TFNA: 3.1%. InterTan: 2.2% IMHS: 2.1%
Li et al. (2024)	InterTan vs. PFNA: InterTan favoured	InterTan: 164 PFNA: 125	NA	InterTan vs PFNA: no sig. difference	NA	InterTan vs PFNA: no sig. difference	InterTan vs PFNA: no sig. difference	NA
Amariel et al. (2024)	NA	NA	NA	7.5%	2.3%	NA	NA	NA
Polat et al. (2023)	NA	NA	Non-stable IFF in compare with stable FF: 2.4%	Non-stable IFF in compare with stable FF: 14.4%	Non-stable IFF in compare with stable FF: 13.9%	NA	NA	Non-stable IFF in compare with stable FF: 7.7%

Study	Harris Hip Score	Blood loss	Reoperation	Varus Collapse	Screw cut-out	Non-union	Infection	Implant failure
Méndez-Ojeda et al. (2024)	NA	NA	Gamma: 2.1% InterTan: 8.7%	NA	Gamma: 0.8% InterTan: 4.8%	NA	Gamma: 0.4% InterTan: 0%	NA
Xu et al. (2022)	NA	PFNA vs. DHS: PFNA favoured	PFN: 2.2%, DHS: 2.9%	NA	NA	PFN: 1.7%, DHS: 2%	NA	PFN: 2.5%, DHS: 3.5%
DAI et al. (2023)	NA	NA	PFNA vs. InterTan: No sig. difference	NA	NA	NA	PFNA favoured vs. DHS	
Quartley et al. (2022)	IntertAN vs. other nails: No sig. difference	IntertAN vs. other nails: No sig. difference	IntertAN vs. other nails: InterTan reduce by 64%	IntertAN vs. other nails: InterTan reduce by 62%	IntertAN vs. other nails: InterTan reduce by 62%	IntertAN vs. other nails: No sig. difference	IntertAN vs. other nails: No sig. difference	IntertAN vs. other nails: InterTan reduce by 62%
Wu et al. (2024)	Gamma 3 nail vs. Gamma3U-blade system: No Sig. difference.	NA	NA	NA	Gamma3U-blade system favoured vs. Gamma3 nail.	NA	NA	Gamma3U-blade system favoured vs. Gamma3 nail.
Liao et al.	NA	PFNA favoured vs. InterTan	NA	InterTan favoured vs. PFNA	InterTan favoured vs. PFNA	InterTan favoured vs. PFNA	NA	NA

1.2. F1 Literature Overview

The literature review evaluates different orthopaedic devices, particularly focusing on the Gamma3 intramedullary nail and its alternatives, such as Smith & Nephew InterTan, PFNA, and sliding hip screws.

Table 4 Summary of Recent Evidence of Intramedullary Nails for Intertrochanteric Femoral Fractures

Category	Key Findings
Insights from Recent Studies	Fracture instability was the most significant predictor of device failure and mortality. Unreamed nails had higher reoperation rates (4.9%).
Biomechanical Performance of Devices	InterTAN showed superior rotational stability, faster healing, and fewer complications than PFNA-II in unstable fractures. PFNA with lateral wall reconstruction improved outcomes in AO/OTA A3.3 fractures.
Implications for Device Selection	InterTAN preferred for unstable fractures; Gamma3 suitable for less complex cases. Long nails advised subtrochanteric fractures. Surgical technique and screw positioning are crucial.
Analysis of Blades and Screws	Failures were more frequent with helical blades, primarily due to medial migration and cut-out.
Updated Findings from Recent Studies	Helical blades showed fewer cut-outs than lag screws, but optimal TAD is critical. InterTAN group had fewer complications and better healing vs. PFNA-II. Lag screws had better functional outcomes and fewer complications than helical blades.
Clinical Performance and New Evidence	F1 nails resolved previous complications (e.g., Z-effect). H2 and F1 nails showed no major complications, reduced stress at distal tip.
Comparative Insights from Recent Studies	Short Gamma nails associated with higher femoral shaft fracture risk (2%). Unlocked nails effective for stable fractures but distal locking necessary for unstable ones.
Introduction	Intertrochanteric fractures common in elderly; InterTAN emerges as key treatment.
Key Advantages and Features	InterTAN's dual screw offers superior fixation, reduces complications, improves healing and function.
Comparative Performance	F1 shows better outcomes and lower complications than PFNA and Gamma3. Shorter surgical time noted for Gamma3, but F1 offers better stability.
Current Research and Future Directions	Research focuses on TAD, bone morphology, and F1 efficacy in complex fracture types.

Conclusion

F1 is a leading option for IFF due to its biomechanical strength and low complication rate. Ongoing research continues to validate its use.

1.3. Clinical Outcomes (Gamma3 vs. InterTan)

(Berger-Groch et al., 2016)

- InterTan showed slightly better clinical results, with shorter hospital stays and operation times.
- Gamma3 had better lag screw positioning but higher neck impaction rates.
- Full weight-bearing was achieved earlier with InterTan, but the difference was minimal.
- The study had limitations due to small sample size and high mortality at a five-year follow-up (Berger-Groch et al., 2016)

Table 5 Clinical Results, Gamma3 vs. InterTan

	IT + G3 n=104	IT n=55	G3 n=49	Statistics (p) IT vs G3
Male	24	12	12	0.74
Female	80	43	37	
Age (years)	81.8±9.2	81.6±9.4	82.0±9.2	0.86
ASA	2.7±0.5	2.7±0.6	2.7±0.5	0.86
OTA/AO A1.1-1.3	28	14	14	1
OTA/AO A2.1-3.3	62	31	31	1
Subtrochanteric Fracture	14	7	7	1
Time to surgery (hours)	20.4 ± 15.9	22.3 ± 16.7	18.4 ± 14.9	0.21
Surgery time (minutes)	50 ± 16	48 ± 28	51 ± 20	0.52
X-ray (sec)	131 ± 91	135 ± 106	126 ± 71	0.61
Transfused pat.	57	29	28	0.84
ICU stay (days)	3.3 ± 2.3	3.4 ± 2.4	3.0 ± 2.8	0.85
Hospital stays (days)	11.6 ± 5.6	10.3 ± 2.9	12.9 ± 0.7	0.03
Mortality (5 years)	63	33	30	0.76

Table 6 Summary of Clinical Findings (Gamma3 vs. InterTan)

Parameter	Findings
Surgery Time	InterTan had slightly shorter surgery time than Gamma3
Hospital Stay	InterTan group had shorter hospital stay
Full Weight-Bearing	Achieved slightly earlier in InterTan group
Radiographic Review	Gamma3 had better lag screw positioning but higher neck impaction rate
Study Limitation	Small sample size, 5 year follow-up in study was restricted due to high mortality rate

1.4. Proximal Femoral Shortening

- A common complication of internal fixation with intramedullary nails.
- The Gamma3 showed incidences of shortening >5mm in 29 patients and >10mm in 8 patients.
- Despite shortening, fixation success was high (45 out of 48 cases). (Gilat et al. 2017)

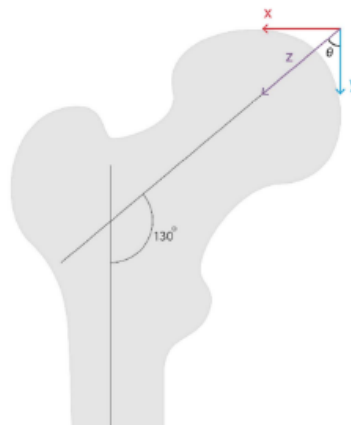


Figure 2 Overall Shortening Vector Calculation – $z = y \times \sin\theta + x \times \cos\theta$

Table 7 Incidence of shortening

Shortening/No. of Cases	x Vector (Abductor Lever Arm)	y Vector (Femur Vertical Length)	z Vector (Overall PFS)*
Less than 1 mm	4 (8.5%)	3 (6.5%)	1 (2%)
1-4.9 mm	26 (54%)	25 (52%)	18 (37.5%)
5-9.9 mm	13 (27%)	14 (29%)	21 (43.5%)
10 mm or greater	5 (10.5%)	6 (12.5%)	8 (17%)
Mean ± SD	4.5 ± 3.7	5.5 ± 4.4	7 ± 4.8
Median	3.4	4.4	5.6
Range	0-17.8	0-21.9	0-23.8

*z is the vector calculated using the x and y values and the corresponding angle (θ) to the NSA (Fig. 2).

Table 8 Summary of Proximal Femoral Shortening Findings

Parameter	Findings
Shortening Incidence	Common in internal fixation methods, including Gamma3
Cases of >5mm Shortening	29 out of 48 patients
Cases of >10mm Shortening	8 out of 48 patients
Fixation Success	45 out of 48 patients
Study Conclusion	Shortening is common and needs to be addressed in femoral nailing

1.5. Screw Cut-Out & Failure Risk

- Gamma3 had a higher risk of cut-out than earlier-generation devices, confirmed by some studies.
- Tip-apex distance (TAD) and surgical technique were critical factors in reducing cut-out risks.
- Some studies found no significant differences in failure rates between Gamma3 and competing devices. (Pascarella et al. 2016b)(Mingo-Robinet et al. 2015a)(Tsai et al. 2017a)



Figure 3 Lag Screw Cutout 40 Days Post-Surgery

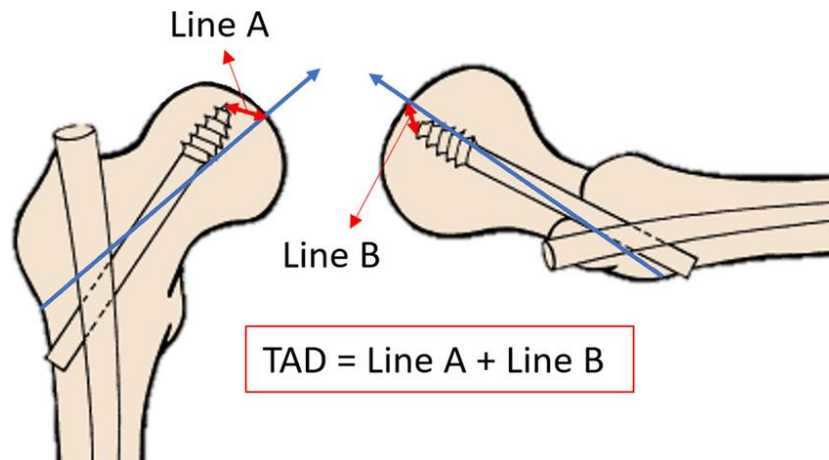


Figure 4 Tip-Apex Distance (TAD)

Table 9 Effect of Variables on Cutout Risk

Variable	n/N	%	RR (95% CI)	P*
Intramedullar device				
TGN	5/153	3.27	1 (1)	<0.01
G3	10/65	15.38	4.71 (1.67–13.23)	
Sex				
Female	12/182	6.59	1 (1)	0.71
Male	3/36	8.33	1.26 (0.38–4.25)	
AO pattern				
Stable	4/115	3.48	1 (1)	0.04
Unstable	11/103	10.68	3.07 (1.01–9.35)	
Distraction				
≤5 mm	9/147	6.12	1 (1)	0.52
>5 mm	6/71	8.45	1.38 (0.51–3.73)	
TAD				
≤25 mm	9/152	5.92	1 (1)	0.40
>25 mm	6/66	9.09	1.54 (0.57–4.14)	
Varus–valgus cervical angle (degrees)				
125–135	7/145	4.83	1 (1)	0.09
<125 or ≥136	8/73	10.96	2.27 (0.86–6.02)	

*Pearson χ^2 test.

Table 10 Effect of type of Intramedullary Device on Cutout Risk by Fracture Pattern and Postoperative Distraction

Fracture Pattern	Intramedullary Device	n/N	Cutout %	Cutout RR (95% CI)	P*	P†	
Unstable	TGN	3/79	3.80	1 (1)	<0.01	<0.17	
	G3	8/24	33.33	8.78 (2.53–30.51)			
Stable	TGN	2/74	2.70	1 (1)	0.54		
	G3	2/41	4.88	1.80 (0.26–12.34)			
Distraction	>5 mm	TGN	2/60	3.33	1 (1)	<0.01	<0.27
		G3	4/11	36.36	10.91 (2.27–52.49)		
	≤5 mm	TGN	3/93	3.23	1 (1)	0.05	
		G3	6/54	11.11	3.44 (0.90–13.22)		

*Pearson χ^2 test.
†Cochran-Mantel-Haenszel test.

Table 11 Summary of Screw Cutout Risk Factors

Risk Factor	Effect on Cutout Risk
Tip-Apex Distance (TAD)	Major predictor, especially in females
Fracture Type	Stable fractures had lower cut-out risk
Surgical Technique	Critical for reducing failures
Device Type	Gamma3 had higher cut-out risk than other devices

1.6. Fixation and Implant Performance

- Gamma3 outperformed its predecessors in reducing the need for reintervention.
- Other failure risks, like nail breakage, femoral fractures, and non-union, were lower with Gamma3 compared to other devices. (Marie et al. 2016b) (Yu et al. 2015).

Table 12 Summary of Fixation Performance

Device	Fixation Success
Gamma3	Outperformed predecessors, lower reintervention rate
Previous Generation Gamma	Higher need for reintervention
Other Competing Devices	Comparable success but varied outcomes

Table 13 Post-Operative Complications (TGN v Gamma3)

Parameter	TGN-cohort	G3N-cohort	p-value
Wound hematomas	4 (3,4%)	3 (3%)	0,59†
Abscess	4 (3,4%)	1 (1%)	0,38†
Deep infection	4 (3,4%)	2 (2%)	0,69†
Femoral shaft fracture	0 (0%)	0 (0%)	
Cut-out	4 (3,4%)	2 (2%)	0,69†
Cumulative surgical-related complication rate	13,68%	8%	0,2†
Cardiovascular complications	3 (2,6%)	3 (3%)	0,58†
Pneumonia	3 (2,6%)	1 (1%)	0,63†
Pulmonary oedema	1 (0,9%)	3 (3%)	0,38†
Pulmonary embolism	1 (0,9%)	1 (1%)	0,71†
Death	8 (6,8)	6 (6%)	0,52†

Table 14 Fixation not requiring further intervention

Nail	Fracture healing	%
SGN	196 of 205	95.60
TGN	122 of 131	93.12
Gamma3	673 of 686	98.10

1.7. Blade vs. Screw Fixation

- Lag screws performed better than helical blades in unstable fractures, showing superior functional outcomes and fewer failures. (Ashok S. Gavaskar, et al. 2018) (Stern et al. 2017) (S. Li et al. 2015)

Table 15 Summary of Clinical Findings (Gamma3 vs. InterTan)

Parameter	Findings
Blade Fixation	Higher failure rate, particularly due to medial migration
Lag Screw Fixation	Superior functional outcomes, reduced complications
Study Conclusion	Lag screw is preferred over helical blade for stability

Table 16 Functional results and complication results

TABLE 3. Functional Results

	PFNA Group	InterTan Group	P
HHS	81.29 ± 6.6	84 ± 6.3	0.045
Excellent	6	8	
Good	30	32	
Fair	8	7	
Poor	4	2	
Mobility score			
Pre-injury	7.8 ± 0.9	7.9 ± 0.8	0.42
1 y follow-up	6.55 ± 0.8	7.04 ± 0.9	0.008
Abductor strength, kg	5.57 ± 0.8	6.45 ± 0.86	<0.001
TUG test, s	21 ± 4.02	18.8 ± 3.3	0.002

TABLE 4. Complications

	PFNA Group	InterTan Group	P
Varus collapse	5	1	0.09
Cut-out	2	1	0.55
Medial blade/screw migration	2	0	0.15
Symptomatic	2	0	0.153
Blade/screw back out			
Revision surgeries	6	1	0.049
Hemiarthroplasty	2	1	
Helical blade revision	4	0	

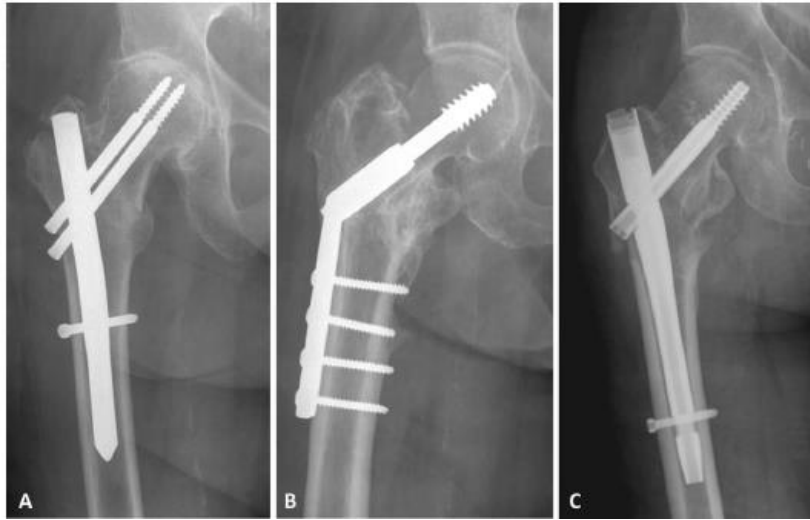


Figure 5 Anteroposterior radiographs showing treatment of fractures with (from left) H2, DHS, Gamma3

1.8. Fracture Stability & Fixation Approaches

- Extramedullary devices (e.g., DHS) were preferred for stable fractures, while intramedullary nails (e.g., Gamma3, PFN) were better for unstable fractures.
- A study with 743 patients confirmed fracture stability as the main factor in early failure and mortality (Figure 19). (Horner et al. 2017) (Caiaffa et al. 2016)

1.9. Distal Screw Location & Peri-Implant Fractures

- The Austofix Short Nailing Range System placed the distal screw more proximally to reduce stress and improve fixation.
- Peri-implant fractures were a concern with short Gamma nails, and studies suggested unlocked nailing for stable fractures to reduce complications. (Horner et al. 2017)



Figure 6 Unlocked short nail completely filling medullary canal.

Table 17 Summary of Distal Screw Location Findings

Parameter	Findings
Austofix F1 Distal Screw	Placed more proximally to reduce stress and improve fixation
Gamma Nail Complications	Higher risk of peri-implant fractures, especially with short nails
Study Recommendation	Long nails preferred for fractures with subtrochanteric extension

Gamma3 and InterTAN nails both show strong clinical performance, with InterTAN offering advantages for unstable fractures due to better biomechanics and fewer complications. Device selection should be tailored to patient needs and surgical goals, balancing operative time and long-term outcomes. Despite design improvements, complications like proximal femoral shortening and screw cut-out remain concerns. These are influenced by implant type, surgical technique, and patient factors like bone density. While newer systems like Gamma3U-blade and InterTAN reduce risks, variability in outcomes across studies emphasizes the need for standardized reporting and further large-scale research

No adverse events or effects from the use of intramedullary nails were reported in any of the papers reviewing the comparable device.

Table 18 Risks from the use of all brand intramedullary femoral nails identified in the literature

Risk	Description / Literature Evidence
Screw Cut-Out	Most frequent complication. Risk can be reduced with proper TAD control and U-blade designs.
Neck Impaction	Higher rate of femoral neck impaction compared to InterTAN, affecting functional outcomes.
Reoperation Risk in Dual-Screw Systems	InterTAN nails show a higher reoperation rate than Gamma3 in some studies.
Longer Surgery with U-Blade Systems	Gamma3U-blade systems provide better fixation but prolong surgical time.
Proximal Femoral Shortening	Can affect leg length and gait, particularly in osteoporotic bone.
Infection and Implant Breakage (Rare)	Rare complications, but possible in certain high-risk populations.
Malunion/Non-union in Complex Fractures	More likely when technique is suboptimal or bone quality is poor.

Table 19 Benefits from the use of intramedullary femoral nails identified in the literature

Benefit	Description / Supporting Evidence
Shorter Operative Time	Gamma3 and similar single-screw systems generally allow quicker surgical procedures—beneficial for elderly patients with comorbidities.
Reduced Blood Loss	Studies highlight that Gamma3 nails result in less intraoperative bleeding compared to dual-screw systems.
Effective Fixation in Unstable Fractures	Intramedullary nails provide reliable fixation in unstable intertrochanteric and subtrochanteric fractures.
Favourable Radiographic Outcomes	Good lag screw positioning and maintenance of fracture reduction were reported with Gamma3 nails.
Low Cut-Out Rates in Advanced Designs	Gamma3U-blade system shows improved resistance to screw cut-out.
Minimized Risk of Implant Failure	IM nails like Gamma3 and InterTAN show lower implant failure rates in large meta-analyses.
Early Mobilization Support	Supports early full weight-bearing post-op in most cases, promoting faster recovery.

1.10 Appraised Comparator Literature

The literature search on femoral nailing systems from leading manufacturers (Stryker, Smith & Nephew, Synthes) highlighted newer models like Gamma3, InterTAN, and PFNA, though many studies lacked clear distinction between short and long nails. The review highlights that intramedullary nails, particularly dual-screw systems like InterTAN, remain a widely accepted and effective treatment for proximal femoral fractures. Recent studies show advantages in stability, complication rates, and recovery outcomes, though trade-offs like longer surgery times persist. (Quartley et al., 2022) (Liao et al., 2024)

Table 20 Literature Review related to Biomechanical and Performance of IMN for Proximal Femoral Fracture

Category	Key Findings	Supporting Studies
Device Performance and Comparisons	Dual-screw systems (e.g., InterTAN) outperform single-screw systems (e.g., Gamma3) in reducing implant failures, hip/thigh pain, and revision surgeries. - InterTAN showed better functional recovery and faster union vs. PFNA. - Gamma3 nails had shorter surgical time and fewer complications (e.g., lag screw migration).	Yang et al., 2023; Méndez-Ojeda et al., 2024; Zhonglian et al., 2024; Wu et al., 2024; Liao et al., 2024
Cut-out and Fixation Stability	Gamma3U-blade improved biomechanical fixation and reduced cut-out risk vs. standard Gamma3, at the cost of longer surgeries. - TFN-A reduced cut-out risk in reverse oblique fractures compared to Gamma3.	Wu et al., 2024; Elbaz et al., 2023
Complications and Functional Outcomes	InterTAN had higher reoperation rates despite biomechanical advantages. - PFNA systems reduced bleeding and surgical time but were less effective for early recovery. - PFBNs showed better fracture stability and lower complication rates, though with longer operating times.	Méndez-Ojeda et al., 2024; Li et al., 2024; Liao et al., 2024; Duan et al., 2024
Clinical and Biomechanical Findings	- InterTAN demonstrated superior axial stiffness and reduced implant stress, especially in unstable fractures. - Gamma3 remained preferred for shorter, less complex surgeries.	McAleese et al., 2024; Zhang et al., 2024; Xu et al., 2022
Future Directions and Limitations	- New designs like PFBNs and nail-plate combinations are promising for complex fractures. - Lack of global trauma registries limits long-term data. - Multicentre trials are needed to refine clinical guidelines.	Marsillo et al., 2024; Dai et al., 2023

Table 21 Qualitative Review of IMN for Proximal Femoral Fracture

Category	Details
Gamma3 Performance	Reduced operative time and blood loss, particularly beneficial for older patients with comorbidities. However, concerns include screw cut-out and neck impaction. (Panagopoulos et al., 2023; Liao et al., 2024)
InterTAN Advantages	Superior biomechanical stability, lower rates of varus collapse and implant failure in unstable fractures. Meta-analysis of 3566 patients showed a lower revision rate (3.5%) compared to Gamma3 (8.9%), and reduced incidences of hip and thigh pain. Supports earlier mobilization and enhanced fixation in osteoporotic bones. (Yang et al., 2023; Zhonglian et al., 2024)
Comparative Findings	Gamma3U-blade shows better fixation stability and lower cut-out rates compared to Gamma3 but requires longer surgical times. (Wu et al., 2024)
Limitations and Recommendations	Patient-specific considerations are crucial, including fracture type, bone quality, and surgeon expertise. Dual-screw designs like InterTAN are preferable for patients with compromised bone density or complex fractures, while Gamma3 is better for cases requiring shorter surgeries.

In older patients with unstable trochanteric fractures, the Gamma3 nail offers benefits such as shorter operation times, reduced blood loss, and shorter hospital stays compared to plating and arthroplasty. However, it carries a higher risk of complications like neck impaction. The Smith & Nephew InterTAN, a two-screw system, addresses some risks of dual-screw designs and shows improved early clinical outcomes, including shorter hospital stays and earlier weight-bearing. A randomized trial with 104 patients showed comparable long-term results for both devices, but the InterTAN group had slightly better early outcomes, while Gamma3 had better screw positioning but higher neck impaction rates.

1.11 F1 Adverse Event/Advisory Notice and Clinical Trial Database Searches

Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE), Therapeutic Goods Administration (TGA) Database of Adverse Event Notifications (DAEN), adverse event and advisory notice databases were interrogated for any adverse event or advisory notice for comparator/similar devices. The following searches were conducted, and the number of hits is listed below. The complete search results are presented in Appendix 23.

Adverse Events/Advisory Notice Database	Search Terms	No of Hits	Relevant Hits Relating only to the device ¹
MAUDE (FDA)	Stryker Gamma 3 System - FDA Product Code: HSB		

¹ Surgical technique /surgeon experience/incorrect positioning of devices adverse events are not considered as direct implant.

Adverse Events/Advisory Notice Database	Search Terms	No Hits	of Relevant Hits Relating only to the device ¹
01/01/2022 – 31/12/2024	2022 - 2024	73	7
	Synthes PFNA - FDA Product Code: HSB		
	2022 - 2024	409	56
	Smith&Nephew Trigen Intertan - FDA Product Code: HSB		
	2022 - 2024	139	54
DAEN (TGA) 2022 – 2024	Stryker Gamma 3 System	2	1
	Synthes PFNA	0	0
	Smith&Nephew Trigen Intertan	8	
Clinicaltrial.gov	Intramedullary Femoral Nails	3	1 – Data not published
	Stryker Gamma 3 System	4	0
	Synthes PFNA	1	1 – Data not published
	Smith&Nephew Trigen Intertan	3	1 – Data not published

The following device problems were extracted from the adverse event reports (MAUDE and DAEN) for all three comparator devices. There was no published data on the trials identified from Clinicaltrials.gov. No adverse events were identified for the Austofix devices.



1.12 Stryker Gamma 3 System MAUDE reported device problems 2022-2024.

Stryker Gamma3 2022 - 2024	Abscess; Necrosis; Osteomyelitis	Discomfort	Embolism/Embolus	Failure of Implant	Failure of Implant; Non-union Bone Fracture	Failure of Implant; Non-union Bone Fracture; Ambulation Difficulties; Implant	Foreign Body In Patient	Hip Fracture	Implant Pain	Insufficient Information	Limb Fracture	Malunion of Bone	Malunion of Bone; Unequal Limb Length	Necrosis	No Clinical Signs, Symptoms or Conditions	Non-union Bone Fracture	Perforation	Thrombosis/Thrombus	Unspecified Infection	Grand Total	
Death			1																		1
Adverse Event Without Identified Device or Use Problem			1																		1
Injury	2	2		15	2	1		3	6	6	1	1	1	2		5	9	5	4	65	
Adverse Event Without Identified Device or Use Problem	2	2						3	6	4	1	1	1	2		5	9	5	4	45	
Break; Fracture				2		1															3
Break; Fracture; Device Damaged by Another Device				2	2																4
Device Dislodged or Dislocated										1											1
Device Dislodged or Dislocated; Migration				4																	4
Malposition of Device				1																	1
Malposition of Device; Device Dislodged or Dislocated				4																	4
Malposition of Device; Migration										1											1
Migration				2																	2
Malfunction							1			1					5						7



Stryker Gamma3 2022 - 2024	Abscess; Necrosis; Osteomyelitis	Discomfort	Embolism/Embolus	Failure of Implant	Failure of Implant; Non-union Bone Fracture	Failure of Implant; Non-union Bone Fracture; Ambulation Difficulties; Implant	Foreign Body In Patient	Hip Fracture	Implant Pain	Insufficient Information	Limb Fracture	Malunion of Bone	Malunion of Bone; Unequal Limb Length	Necrosis	No Clinical Signs, Symptoms or Conditions	Non-union Bone Fracture	Perforation	Thrombosis/Thrombus	Unspecified Infection	Grand Total
Adverse Event Without Identified Device or Use Problem										1										1
Failure to Align							1								4					5
Failure to Align / Miss aligned drilling															1					1
Grand Total	2	2	1	15	2	1	1	3	6	7	1	1	1	2	5	5	9	5	4	73

1.13 Synthes PFNA MAUDE reported device problems 2022-2024.

Note that all events are listed in the table below. Rows highlighted in “green” represent incidents that may be related directly to the device and are not related to surgical technique or surgeon experience or patient related factors.



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Event	Adverse Event Without Identified Device or Use Problem	Adverse Event Without Identified Device or Use Problem; Migration	Appropriate Term/Code Not Available; Migration	Break	Break; Contamination /Decontamination Problem; Device-Device Incompatibility	Break; Device-Device Incompatibility	Break; Entrapment of Device	Break; Entrapment of Device; Device-Device Incompatibility	Break; Migration	Component or Accessory Incompatibility	Detachment of Device or Device Component; Device-Device Incompatibility	Device Slipped	Device Slipped; Improper or Incorrect Procedure or Method	Device-Device Incompatibility	Device-Device Incompatibility; Adverse Event Without Identified Device or Use Problem	Device-Device Incompatibility; Difficult to Advance	Device-Device Incompatibility; Material Twisted/Bent	Device-Device Incompatibility; Mechanical Jam	Device-Device Incompatibility; No Apparent Adverse Event	Entrapment of Device; Device-Device Incompatibility	Improper or Incorrect Procedure or Method; Output Problem	Manufacturing, Packaging or Shipping Problem	Material Deformation	Migration	No Apparent Adverse Event	Off-Label Use	Use of Device Problem	Grand Total
Death	1																											1
Respiratory Failure	1																											1
Injury	148	3		34				3						6	3		1						1	86		1	1	287
Appropriate Clinical Signs, Symptoms, Conditions Term / Code Not Available	2			5																			9					16
Arthritis																							1					1



1.14 Smith&Nephew Intertan MAUDE reported device problems 2022-2024

	Adverse Event Without Identified Device or Use Problem	Break	Break; Fracture; Device Damaged by Another Device	Break; Material Deformation	Delivered as Unsterile Product	Device Dislodged or Dislocated	Failure to Align	Fracture	Fracture; Material Fragmentation; Detachment of Device or Device	Fracture; Separation Failure	Malposition of Device; Migration	Material Twisted/Bent	Migration	Off-Label Use; Adverse Event Without Identified Device or Use	Physical Resistance/Sticking	Positioning Failure	Premature Separation	Grand Total
Death	1																	1
Embolism/Embolus	1																	1
Injury	20	5	2			1		5			1	1	3	1				39
Bone Fracture(s); Failure of Implant; Insufficient Information												1						1
Bone Fracture(s); Implant Pain														1				1



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Bone Fracture(s); Non-union Bone Fracture; Post Operative Wound Infection; Malunion of Bone; Physical Asymmetry													2							2
Failure of Implant	4		1					1												6
Failure of Implant; Foreign Body In Patient		1																		1
Failure of Implant; Limb Fracture; Implant Pain			1																	1
Failure of Implant; Seroma								1												1
Hip Fracture	1																			1
Implant Pain	4																			4
Insufficient Information		2				1						1								4
Limb Fracture	2																			2
Malunion of Bone	1																			1
Malunion of Bone; Unequal Limb Length	1																			1
No Clinical Signs, Symptoms or Conditions								3												3
Non-union Bone Fracture	1																			1
Pain; Loss of Range of Motion; Ambulation Difficulties; Swelling/ Edema													1							1
Pain; Non-union Bone Fracture; Limb Fracture		2																		2
Perforation	2																			2
Thrombosis/Thrombus	3																			3
Unspecified Infection; Non-union Bone Fracture; Malunion of Bone	1																			1
Malfunction		4		1	1		1	2	1	1					1	1	1	1	14	
Insufficient Information		2																		2
No Clinical Signs, Symptoms or Conditions		2		1	1			2	1	1					1	1	1	1	11	
Perforation							1													1
Grand Total	21	9	2	1	1	1	1	7	1	1	1	1	3	1	1	1	1	1	54	

The following types of Device-Related Events were reported for the Intertan System:

- **Mechanical/Physical Issues:**
 - Break, Fracture, Material Deformation, Device Dislodgement, Failure to Align, Malposition/Migration, Material Twisted/Bent, Positioning Failure, Premature Separation, Physical Resistance/Sticking
- **Product Quality Issues:**
 - Delivered as Unsterile Product
- **Off-Label Use:**
 - Adverse event reported without identified device or use problem.

DAEN reported adverse events for:	Event
Stryker Gamma 3 System	<ol style="list-style-type: none"> 1. Report No. 73582: the reported adverse event type is "Activation, Positioning or Separation Problem." Specifically, the event description states that "The screw would not engage into the nail." No injury was reported as the outcome of this adverse event. 2. Report No. 102638: Event Description: Revision due to fracture; Reported Event Outcome: Injury; No further information.
Synthes PFNA	No results
Smith&Nephew Trigen Intertan	<ol style="list-style-type: none"> 1. Device nail fractured (Report number: 75791) - Outcome: Injury; Event type: Material Integrity Problem. 2. Fracture of the femur requiring revision surgery (Report number: 76233) - Outcome: Injury; Event type: Material Integrity Problem. 3. Device broke (Report number: 84797) - Outcome: Injury; Event type: Material Integrity Problem. 4. Unknown complication (Report number: 81730) - Outcome: Injury; Event type: Insufficient Information. 5. Reoperation related to static proximal fixation benefits (Report numbers: 99262, 99264, 99265, 99267) - Outcome: Not specified; Event type: Insufficient Information.

1.15. Summary Table: Device-Specific Adverse Events related to the F1 Femoral Nailing Comparators

Adverse Event Type	Examples/Notes
Break/Fracture of Device or Components	Device nail fractured, device broke
Device Dislodged or Dislocated	Implant moves out of position
Malposition of Device	Device not correctly positioned
Migration of Device or Components	Implant moves within tissue
Material Deformation, Twisting, or Bending	Device bends or deforms
Device-Device Incompatibility	Components do not fit/work together

Adverse Event Type	Examples/Notes
Detachment of Device or Device Component	Part of implant comes loose
Device Slipped	Implant shifts unexpectedly
Failure to Align/Positioning Failure	Device cannot be properly aligned
Premature Separation	Device separates before intended
Physical Resistance/Sticking	Device difficult to move or gets stuck
Activation, Positioning, or Separation Problems	Screw not engaging, activation issue
Material Fragmentation	Device breaks into pieces
Delivered as Unsterile Product	Product not sterile upon receipt
Manufacturing, Packaging, or Shipping Problem	Product defect from production or transport