EOTTS

Extra-Osseous TaloTarsal Stabilization

Comprehensive Clinical Evidence Summary

Phoenix Sinus Tarsi Stent | Astra OrthoMed, Inc. | FDA 510(k) K251382

81	3,500+	10 yrs	+32 pts	4–6%	92%
Published studies 1999–2026	Patient feet pooled	Longest follow-up	Avg AOFAS gain	Type II removal (stand-alone)	Satisfaction at 10 years

This document synthesizes 81 published studies spanning cadaveric biomechanics, retrospective and prospective clinical series, comparative trials, and systematic reviews — representing the most comprehensive body of evidence supporting the EOTTS procedure. Studies span 1999–2026 and include pediatric, adult, and special populations across six continents.

1. Procedure Overview

What is EOTTS?

Extra-Osseous TaloTarsal Stabilization (EOTTS) is a minimally invasive surgical technique that places a stent within the sinus tarsi to internally realign and stabilize the talotarsal joint complex (TTJ). Unlike osseous procedures, EOTTS preserves bone stock, avoids joint arthrodesis, and is fully reversible.

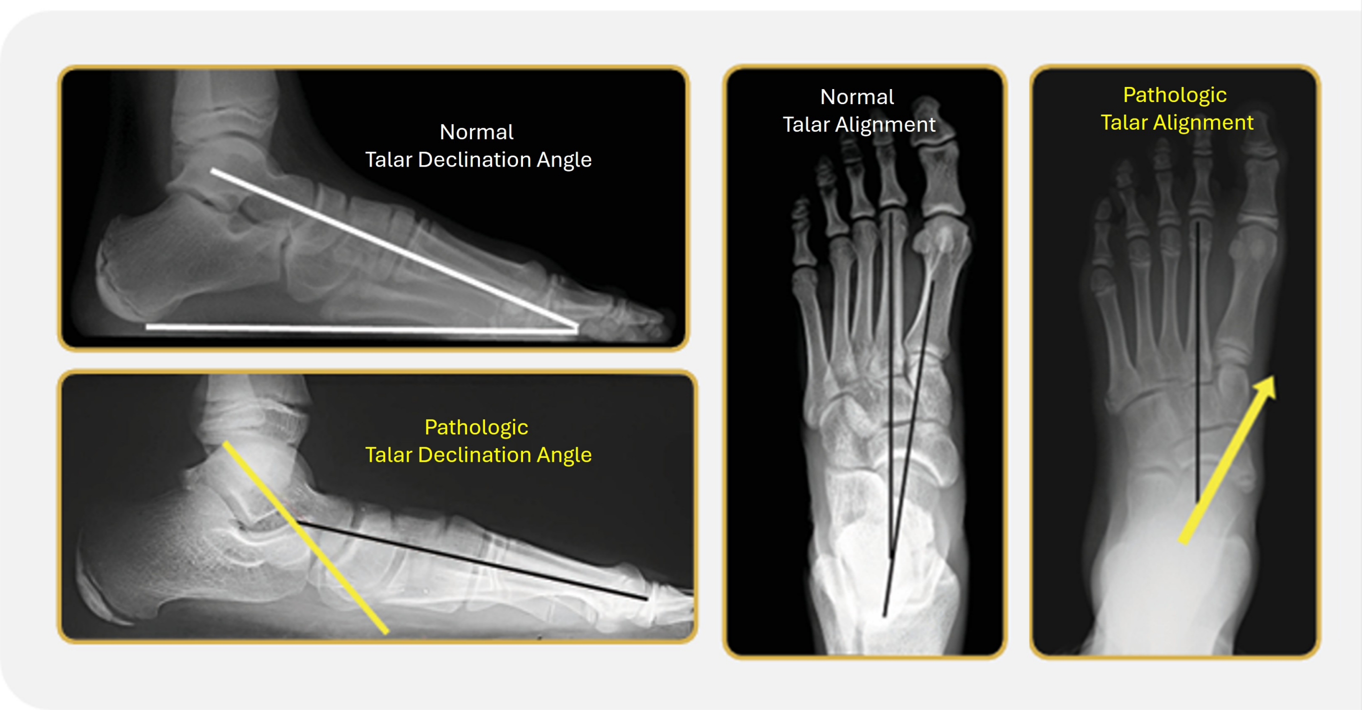
Implant Type	Mechanism	Design	Key Characteristic
Type I (Arthroereisis)	Blocks excessive pronation via mechanical impingement in lateral half of the sinus tarsi	Cylindrical, conical	Abruptly blocks and limits talar pronation on the calcaneus.
Type II (True EOTTS)	Re-centers talus on calcaneus and navicular; stabilizes TTJ while preserving tri-plane motion.	Combination of shapes to naturally fill the sinus tarsi space.	Scientifically proven to be a superior choice over Type I designs.

Pathology Addressed: Recurrent TaloTarsal Joint Dislocation (RTTJD)

RTTJD — also described as hyperpronation, talotarsal instability, and progressive collapsing foot deformity (PCFD) — creates a cascade of biomechanical dysfunction. EOTTS addresses the root cause rather than downstream symptoms:

- Excessive medial, plantar, and anterior subluxation of the talus on the calcaneus
- Collapse of the medial longitudinal arch and forefoot abduction
- Increased strain on the posterior tibial tendon, plantar fascia, and posterior tibial nerve
- Elevated tarsal tunnel and porta pedis compartment pressure
- Abnormal proximal joint loading (knee, hip) — upstream biomechanical consequence

Key differentiator: In a single minimally invasive procedure, EOTTS simultaneously reduces strain on the posterior tibial tendon, plantar fascia, posterior tibial nerve, and tarsal tunnel — while decreasing medial knee compartment forces by nearly one-third. No single downstream intervention achieves this.



2. Biomechanical & Cadaveric Evidence

Multiple cadaveric studies by Graham et al. (2011) and Kolodziej et al. (2019) established the biomechanical rationale for EOTTS. These six findings demonstrate measurable strain and pressure reduction across multiple tissue systems simultaneously — a result unmatched by soft tissue procedures alone.

Study	Tissue / System	n	Pre-EOTTS	Post-EOTTS	Reduction	p-value
Graham et al. 2011 J Foot Ankle Surg	Posterior tibial tendon elongation	9 cadavers 27 meas.	6.23 ± 2.07 mm	3.04 ± 1.85 mm	**51%**	<0.001
Graham et al. 2011 J Foot Ankle Surg	Posterior tibial nerve elongation	9 cadavers 27 meas.	5.91 ± 0.91 mm	3.38 ± 1.20 mm	**43%**	n/r
Graham et al. 2011 J Foot Ankle Surg	Plantar fascia elongation/strain	6 cadavers 18 meas.	3.62% ± 1.17%	2.42% ± 0.88%	**33%**	n/r
Graham et al. 2011 J Foot Ankle Surg	Tarsal tunnel compartment pressure	9 cadavers	32 ± 16 mmHg	21 ± 10 mmHg	**34%**	<0.001
Kolodziej et al. 2019 PLoS ONE	Medial knee compartment force (in vivo)	10 cadavers	842 ± 247 N	565 ± 260 N	**32.8%**	<0.05
Wong et al. 2020 J Orthop Translat (FEA)	Subtalar joint force distribution	1 FE model	359 N	93 N	**74%**	FEA
Graham et al. 2011 J Am Podiatr Med Assoc	Axial load distribution across subtalar facets	5 cadavers	Concentrated, medial bias	Distributed across facets	**Normalized**	Cadaveric

Clinical implication: EOTTS resolves tarsal tunnel syndrome, posterior tibial tendonopathy, and plantar fasciitis through a single biomechanical correction — eliminating the need for multiple targeted soft tissue procedures. The proximal joint benefit (32.8% medial knee force reduction) was confirmed clinically at 8.6-year follow-up: 40% of adult EOTTS patients reported elimination or reduction of knee and hip pain (Kolodziej et al. 2023).

3. Clinical Outcomes

3.1 Pain Relief

Consistent VAS pain reduction is documented across study designs, implant types, populations, and geographic regions:

Study	n (feet)	Pain metric	Pre-op	Post-op	Follow-up
Bresnahan et al. 2013	46	% foot pain change	—	–36.97%	>12 months
Merçun et al. 2022	123	VAS	5.5	2.2	30 months
García Bistolfi et al. 2022	19	VAS	7.05	0.77	68 months
Yang et al. 2025	85	VAS	5.2	1.1	38.8 months
Shi et al. 2023	50	VAS	5.56	0.60	30 months
Fang et al. 2023	40	VAS	5.28	1.72	17 months
Chen et al. 2026 (Taiwan)	20	VAS	7.2	2.6	25.8 months
Vogt et al. 2021	113	Complete pain relief	—	90% (102/113)	29 months
Kolodziej et al. 2023 (8.6 yr)	61	Multi-scale pain	Baseline	–18.6%; knee/hip reduced in 40%	8.6 years
Gu et al. 2025	18	VAS	5	0	>12 months

3.2 Functional Outcomes — AOFAS Score

Consistent improvements of 25–42 points documented across diverse populations:

Study	Population	Pre-op	Post-op	Gain	Context
Garras et al. 2012	Pediatric (n=23)	53	95	**+42**	Kidner + SA
Bresnahan et al. 2013	Mixed (n=46)	69.5	89.2	**+19.7**	Type II stand-alone
Juanto & Kolodziej 2020	CP Pediatric (n=20)	62.8	87.8	**+25**	Type II stand-alone
Jain et al. 2021	Adult (n=20)	67.3	95.5	**+28.2**	EOTTS vs. non-surg. (76.2→68.4)
Wang et al. 2021	Pediatric (n=46)	55.5	86.3	**+30.8**	Type I, alone & adjunctive
Herdea et al. 2022	Pediatric (n=66)	37.4	98.8	**+61.4**	All EOTTS types
Moraca et al. 2025	Pediatric (n=74)	—	94.5	**—**	10-year F/U; 92% satisfaction
Xu et al. 2026	Adolescent (n=21)	68.3	95.5	**+27.2**	8.2-yr post-implant removal
Elhalawany et al. 2026	Young adult (n=32)	62.7	94.2	**+31.5**	MDCO+SA; 39-month F/U
Gu et al. 2025	Pediatric (n=18)	51.1	90.1	**+39**	Coalition+EOTTS

Critical data point: Jain et al. (2021) is the only controlled comparison in the literature. EOTTS patients improved from 67.3 to 95.5 on the functional scale while the non-surgical group declined from 76.2 to 68.4. This directly demonstrates that EOTTS changes the natural history of talotarsal instability.

3.3 Long-Term Durability

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Graham et al. 2012	5 years	117	Excellent satisfaction; 6% removal rate; stand-alone Type II

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Kolodziej et al. 2023	8.6 years	61	MFS 98; LEFS 88.6; 40% proximal joint pain relief
Agnew et al. 2023	7.9 yrs (up to 12.7)	67	4.5% removal rate; effective long-term in select patients
Moraca et al. 2025	10 years	74	AOFAS 94.5; FFI 9.1; 92% satisfaction; no joint degeneration;
Xu et al. 2026	8.2 yrs post-removal	21	AOFAS 95.5; mild arch recurrence only

4. Radiographic Correction

Radiographic improvement is consistently documented across angular measurements in both AP and lateral planes. Graham et al. (2012) confirmed that post-operative talar declination and talar 2nd metatarsal angles were reduced to values consistent with published norms for healthy feet — confirming anatomic, not merely partial, correction.

Radiographic parameter	Pre-op (mean)	Post-op (mean)	Correction	Representative study
Talar declination angle (lateral)	25.1 ± 0.7°	19.4 ± 0.5°	–5.7°	Graham et al. 2012
Lateral Meary's angle (T2M)	24.8 ± 1.0°	5.8 ± 0.9°	–19.0°	Graham et al. 2012
Calcaneal inclination (normalized)	21.0 ± 0.7°	21.8 ± 0.7°	Normalized	Graham et al. 2012
Lateral talo-calcaneal angle	40.2 ± 8.5°	25.4 ± 4.4°	–14.8°	Wang et al. 2021
Lateral talar 2nd metatarsal	24.4 ± 10.4°	5.3 ± 5.5°	–19.1°	Wang et al. 2021
AP talar 2nd metatarsal	17 ± 6°	11 ± 4°	–6°	Chen et al. 2022
TaloNavicular coverage angle	33.1°	12.7°	–20.4°	Le Gall et al. 2024
Calcaneal inclination	14.8°	23.6°	+8.8° (restored)	Xie et al. 2023
Talar declination (adolescent)	41.0 ± 4.4°	25.2 ± 7.1°	–15.8°	Alkhatatba et al. 2024
Lateral Meary's (adolescent)	22.4 ± 6.1°	7.5 ± 3.7°	–14.9°	Alkhatatba et al. 2024
Navicular-cuboid distance	19 ± 6 mm	24 ± 5 mm	+5 mm	Graham et al. 2011

5. Special Populations & Expanded Indications

Adult Acquired Flatfoot / PCFD (Stage I–IIb)

- Lewis et al. (2024) — 212 feet, stage I flexible PCFD: 95.5% patient satisfaction (52.3% 'very satisfied' + 43.2% 'satisfied'); significant improvement in FAOS, FADI, EQ-5D-5L ($p<0.05$)
- Needleman (2006) — 78% patient satisfaction; AOFAS 52→87; adjunctive with soft tissue reconstruction
- Viladot et al. (2018) — Stage IIA PTTD: favorable results at 47.5-month follow-up
- Chen et al. (2026) — Four-in-one standardized PCFD protocol: VAS 7.2→2.6, AOFAS 48.5→78.4; alignment maintained after removal

Cerebral Palsy

- Juanto & Kolodziej (2020) — Ambulant CP (GMFCS I-II): AOFAS 62.8→87.8; 0% serious complications; delays or avoids more aggressive surgery
- Lin et al. (2024, meta-analysis) — EOTTS and lateral column lengthening produce comparable functional results; EOTTS has fewer postoperative complications

Tarsal Coalition

- Gu et al. (2025) — Coalition resection + EOTTS: AOFAS 51.1→90.1; VAS 5→0 at 1 year; 93.8% return to sport at median 3 months; zero wound complications
- Peretto et al. (2025) — Up to 9-year follow-up; synthetic membrane + EOTTS: excellent results; no recurrence

Hallux Valgus + Flatfoot

- Yang et al. (2025) — Simultaneous Scarf osteotomy + EOTTS: VAS 5.2→1.1; AOFAS 73.0→91.1 at 38.8 months; sustained forefoot and hindfoot correction

Accessory Navicular + Flatfoot

- Shi et al. (2023) — Kidner + EOTTS: VAS 5.56→0.60; AOFAS 53.4→91.1; minimal wound; rapid recovery
- Fang et al. (2023) — Modified Kidner + EOTTS: VAS 5.28→1.72; AOFAS 47.4→82.8; 0% STP; 0% removal
- Gan et al. (2023) — SA alone may be sufficient: correcting flatfoot relieves AN pain in most cases without Kidner

Osteogenesis Imperfecta (Type I)

- Hsu et al. (2021) — First published data in pediatric type I OI: AOFAS 68→95; maintained correction at 55 months; no significant complications

Neuropathic / Diabetic Flatfoot

- Martucci et al. (2020) — EOTTS in neuropathic pes planus: minimally invasive approach to offloading and healing medial column ulcerations

6. Comparative Evidence

Multiple studies directly compare EOTTS to other surgical approaches, consistently demonstrating equivalent or superior outcomes with lower morbidity:

Study	Comparison	n	Key finding	Verdict
Chong et al. 2015 J Pediatr Orthop B	SA vs. lateral column lengthening (pediatric)	24 feet	No difference in outcomes; both significantly improved hindfoot motion;	Equivalent; SA preserved ROM
Silva et al. 2021 Foot Ankle Surg	EOTTS vs. lateral column osteotomy	34 feet	AOFAS 50.3→81.6; EOTTS 'comparable outcomes and relatively more straightforward and less invasive.	
Jain et al. 2021 Indian J Orthop	EOTTS vs. non-surgical	20 feet	EOTTS: MFS 67.3→95.5 vs. non-surgical: 76.2→68.4	EOTTS clearly superior
Lin et al. 2024 Front Pediatr (meta)	SA vs. LCL in cerebral palsy	Multi-study	LCL achieved greater radiograpic correction. EOTTS had fewer complications	Patient selection criteria is important.
Vogt et al. 2021 Children (Basel)	Three different SA implant types	113 feet	Compared Type I arthroereisis with calcaneo-stop and bioabsorbable devices	Long-term correction depends on the the type of implant.

7. Safety Profile & Complication Analysis

7.1 Sinus Tarsi Pain & Removal Rates

Sinus tarsi pain (STP) is the most commonly reported adverse event. It is generally transient, manageable, and resolves with implant removal in virtually all cases. Rates vary substantially by implant type and use context:

Study	n (feet)	Implant / Use	STP rate	Removal rate	Notes
Graham et al. 2012 (5-year)	117	Type II stand-alone	—	**6%**	Long-term benchmark; 5-year follow-up
Agnew et al. 2023 (7.9-year)	67	Type II	—	**4.5%**	Longest U.S. Type II follow-up
Bresnahan et al. 2013	46	Type II stand-alone	—	**4.35%**	Multicenter prospective
Fu et al. 2025 (n=1,008)	1,008	Type II (HyProCure)	Peds 3.8% Adult 25.4%	Peds 1% Adult 15.3%	Largest series; all removals w/o adverse effects
Merçun et al. 2022	123	Type II stand-alone vs. combined	11%	15%	Lower rates as stand-alone vs. conjoined
Wang et al. 2021	46	Type I pediatric	13%	2.2%	Implant depth = key modifiable risk factor
García Bistolfi 2022	19	Type I pediatric	0%	**0%**	5-year F/U; zero complications
Fang et al. 2023	40	Type II + Kidner	0%	**0%**	17-month F/U; adolescent
Needleman 2006	28	Type I adjunctive adult	39%	**39%**	All resolved with removal; early series
Lewis et al. 2024	212	Type I adjunctive PCFD	—	**48.1%**	Elective removal protocol; correction maintained
Saxena et al. 2016	104	Type I adult stand-alone	—	22.1%	11mm implants most frequently removed
Fu et al. 2025 (risk)	236	Type II PCFD	25.4%	15.3%	88% satisfied; 94% would recommend
Moraca et al. 2025 (10-year)	74	Metallic endosinotarsal	—	—	No joint degeneration; intact bony surfaces at 10 years

Key insight: Type II stand-alone EOTTS consistently demonstrates 4–6% removal rates at 5–8 years — among the lowest in any foot and ankle implant category. Higher rates in some series reflect Type I implants, adjunctive use in complex deformities, or adult populations — not an inherent limitation of the EOTTS procedure.

7.2 Reversibility — What the Data Shows

Finding	Supporting evidence
Complication resolution on implant removal — ~100%	Across all studies reporting resolution, STP resolves in essentially 100% of cases. No permanent nerve or joint damage attributable to the implant is documented in any study.
Correction maintained after removal	Xu et al. (2026): 8.2 years post-removal — radiographic correction substantially maintained vs. preoperative. Garras et al.: no subtalar arthritis after removal. Lewis et al. & Chen et al. (2026): structural alignment preserved after elective removal.
No joint degeneration	Moraca et al. (2025) — 10-year follow-up: intact bony surfaces adjacent to implants; no degenerative changes. Garras et al.: extra-articular plug did not lead to subtalar arthritis.

Finding	Supporting evidence
Implant depth is the modifiable risk factor	Fu et al. (2025, n=236): minimizing insertion depth significantly reduces STP and removal rates. Wang et al. (2021): each additional mm from tail to lateral calcaneal wall = 38.8% greater odds of STP. Proper sizing and seating are critical.

8. Return to Activity & Quality of Life

- Kolodziej et al. (2023) — 8.6-year follow-up: patients performed moderate-to-strenuous activities with no foot symptoms; MFS 98, LEFS 88.6; 40% reported elimination/reduction of knee and hip pain
- Martinelli et al. (2018) — 45 of 45 pediatric patients returned to sports; duration, frequency, and type of sporting activity unchanged; emotional status and footwear improved
- Gu et al. (2025) — 93.8% return to sport at median 3 months (tarsal coalition + EOTTS cohort)
- Herdea et al. (2022) — AOFAS 37.4→98.8; sports performance, foot aesthetics, and QoL all significantly improved in children and adolescents
- Pardus et al. (2024) — 140 feet: high QoL in all domains (somatic, psychological, social, environmental); less fatigue after sport; reduced need for orthotics post-surgery
- Alsiddiky et al. (2023) — 65 feet: 90.8% improved foot shape; 81.5% improved pain; 76.9% improved ability to walk (patient-reported, multicenter)
- Miraj et al. (2025) — AOFAS 59.1→87.0; OxAFQ-C improved across all domains including school, play, and emotional wellbeing
- Fu et al. (2025, n=236) — 88% satisfied; 94% would recommend to others; 93% would undergo EOTTS on contralateral foot if needed

9. Type II EOTTS — Differentiating Evidence

While both Type I and Type II implants demonstrate clinical benefit, the published literature identifies consistent biomechanical and clinical advantages for Type II (true EOTTS / sinus tarsi stent) in appropriate candidates:

Parameter	Type II EOTTS	Type I arthroereisis (cylindar/cone)
Mechanism	Stabilizes the talus at the axis point of the STJ	Stabilizes the talus lateral to the axis point
Long-term removal rate	4–6% (stand-alone, 5–8 year studies)	11–48% (varies; higher in adjunctive, adult use)
Sinus tarsi pain (pediatric)	3.8% (Fu et al. 2025, n=1,008)	7–13% in comparable studies
Motion preservation	TTJ motion preserved; no impingement-based restriction	Impingement blocking device
Biomechanical data	Significant data published	Limited biomechanical data
FEA comparison (Jin et al. 2025)	Type II generated stronger corrective effect than Type I	
Associated pathology coverage	Multiple studies show positive results to associated tissued damaged by RTTJD	Limited studies to associated tissue patholgy
Stand-alone evidence	Strong: multiple stand-alone studies with excellent long-term results.	Often studied as an adjunctive procedure

10. Synthesized Clinical Takeaways

1. EOTTS treats root cause, not symptoms.

By stabilizing the talotarsal joint, EOTTS simultaneously reduces strain on multiple soft tissue structures (PTT, plantar fascia, posterior tibial nerve, tarsal tunnel) — a mechanism no single downstream intervention achieves.

2. Consistent, clinically meaningful outcomes across 25+ years of evidence.

AOFAS improvements of 25–42 points, VAS reductions of 3–5 points, and radiographic normalization to published norms are replicated in retrospective, prospective, and comparative studies across pediatric, adult, and special populations.

3. Excellent long-term durability.

Studies up to 10 years confirm maintained clinical and radiographic outcomes. Implant removal does not negate correction — structural alignment is preserved even after elective or symptomatic removal.

4. Type II stand-alone EOTTS has the lowest complication and removal rates.

When used as a stand-alone procedure in appropriately selected patients, Type II EOTTS demonstrates 4–6% removal rates at 5–8 years — among the lowest in any foot and ankle implant category.

5. Fully reversible with no permanent sequelae.

Implant removal resolves complications in ~100% of cases. No permanent bone damage, joint arthritis, or irreversible soft tissue injury attributable to EOTTS is documented in any study in the literature.

6. Minimally invasive; ideal for office-based and ASC settings.

EOTTS requires a small lateral incision, no bone cutting, and no permanent hardware. Recovery is rapid; patients return to activity within weeks. This profile supports office-based procedure economics.

7. Proximal joint benefit extends value proposition.

Kolodziej et al. (2019, 2023) document reduction in medial knee compartment forces and patient-reported knee/hip pain relief — extending the clinical benefit beyond the foot and supporting EOTTS as a systemic lower extremity alignment correction.

Appendix: Full Study Reference List (81 Studies)

Studies listed in chronological order. Study IDs correspond to the Master Evidence Extraction database.

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