

First MTP Arthrodesis with the REFLEX[®] HYBRID Nitinol Implant System



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FOOT & ANKLE

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BACKGROUND & INTRODUCTION

Pathology overview: Hallux rigidus

Hallux rigidus is a degenerative arthritis process of the first metatarsophalangeal (MTP) joint and the most common arthritic condition of the foot.¹

Surgery is indicated when conservative measures fail to adequately relieve pain or restore function after a 3–6-month trial. Surgical goals are pain-free function through improved joint mechanics, load redistribution, and/or fusion to eliminate the painful joint. Procedure choice depends on disease severity, activity level, comorbidities, bone quality, and surgeon judgment.²

Grade	Clinical & radiographic findings	Typical surgical approach
Grade 0	Radiographs normal or minimal change; stiffness and pain with activity; no significant dorsiflexion loss	Conservative (orthotics, NSAIDs, physical therapy)
Grade I	Mild dorsal osteophytes, mild joint space narrowing; mild-to-moderate pain and stiffness	Conservative; cheilectomy if refractory
Grade II	Moderate osteophytes with flattening of metatarsal head; ≥50% joint space preserved; moderate loss of motion	Cheilectomy ± moberg osteotomy; early fusion consideration
Grade III	Severe osteophyte formation, <50% joint space preserved; marked stiffness with significant pain throughout ROM	MTP arthrodesis; implant arthroplasty in select patients
Grade IV	Global cartilage loss, complete joint space obliteration; severe rigid deformity with pain at rest	MTP arthrodesis (preferred); total joint replacement

Radiographic and clinical grading of hallux rigidus²

MTP arthrodesis is the most performed surgery for advanced hallux rigidus and the gold standard for Grade III–IV disease, with enduring evidence showing reliable pain relief, durable outcomes, high satisfaction, and predictable long-term function.¹

Evidence and limitations of gold standard construct

Crossed lag screws and dorsal locking plates with a supplemental compression screw account for most contemporary MTP procedures and published evidence.¹ Successful arthrodesis needs both adequate compression for healing and enough rigidity to limit fusion-site motion before consolidation. Gait subjects the first MTP joint to axial loading, dorsiflexion bending, and rotational forces that the construct must resist to avoid malalignment or nonunion. Biomechanical testing has shown that a lag screw with a dorsal locking plate offers a more stable construct than crossed screws alone. Both achieve high union rates in well-selected patients, but plates' superior stability has driven their widespread adoption.

Despite being the gold standard for advanced hallux rigidus, first MTP arthrodesis has notable limitations worth weighing against alternative fixation options. Nonunion is the most significant complication. Contemporary plate fixation has lowered non-union rates to roughly 5%.³ Since revision surgery is more complex than the primary procedure, achieving union initially is the main goal of construct design. Established nonunion carries real costs. Most symptomatic cases require revision, often involving hardware removal, repeat joint prep, bone grafting, and new fixation, with lower union rates than primary fusion, plus more healthcare use, rehab, lost work time, cost, and reduced patient satisfaction and function.

Hardware irritation is the most common secondary complication of plate fixation, since dorsal plates sit beneath high-pressure shoe areas; removal rates run 8–10%.³ Crossed screws avoid this prominence but don't match plates' stability or union rates, making implant choice a tradeoff. Hardware removal itself carries risk including wound complications, nerve irritation, infection, and stress fracture through screw holes, so cost-effectiveness should account for the full episode of care, not just the index implant.

Recovery is also more demanding than with motion-preserving procedures, typically requiring six weeks of protected weight-bearing, a significant burden for patients with standing/walking-heavy jobs, no home support, or bilateral disease needing staged surgery.

These limitations don't diminish arthrodesis as the benchmark treatment but rather define the challenges alternative fixation technologies and motion-preserving procedures aim to address.

Nitinol compression staples in foot and ankle arthrodesis

Nitinol compression staples are an increasingly used fixation option in foot and ankle surgery, especially for small-joint arthrodesis. This nickel-titanium alloy's shape-memory and superelastic properties generate continuous compression across the fusion site unlike conventional screws, which provide static compression that can diminish with bone resorption and remodeling. Clinically, union rates run roughly 95% across foot and ankle arthrodesis series, when using a nitinol staple alone or with other implants.⁴

For first MTP arthrodesis specifically, staples are most often used as supplemental fixation with a dorsal plate, or standalone in select patients with good bone quality and lower mechanical demands. Hybrid constructs (lag screw–dorsal plate, lag screw–nitinol plate) are increasingly used to combine compression and stability.

Overall, nitinol staples are best viewed as offering continuous compression, a lower profile, technical simplicity, and versatility in constrained anatomy—not as dramatically superior for fusion outcomes. These attributes may still yield meaningful benefits: less soft-tissue irritation, simpler implantation, and potential cost savings from fewer hardware complications or secondary procedures, ultimately improving outcomes and care value.⁴

REFLEX® HYBRID Nitinol Implant System

The REFLEX HYBRID system is a next-generation nitinol implant designed to merge the dynamic compression of shape-memory staple technology with the mechanical stability of screw-and-plate fixation. Made from nickel-titanium alloy, it uses superelastic, shape-memory properties to sustain compressive force across an arthrodesis or osteotomy site.

The design addresses a known gap in conventional fixation: lag screws deliver strong initial compression that can fade as bone remodels and settles, while standard staples provide dynamic compression but less resistance to rotation and bending than rigid constructs. REFLEX HYBRID aims to combine both strengths — ongoing active compression plus added stability via integrated locking fixation.

The implant pairs a nitinol compression bridge with threaded locking limbs that anchor it in bone. After implantation, the bridge works to return to its preset shape, sustaining compression across the fusion site, while the locking elements create a more rigid bone–implant interface that preserves alignment.

Key features

- **Fully dynamic compression**—continuous, active compression from nitinol shape-memory technology⁵
- **Locking stability**—threaded locking limbs for better resistance to shear and bending forces than conventional plates⁵
- **Low-profile geometry**—minimizes prominence and soft-tissue irritation versus plate constructs
- **Single-implant fixation**—delivers compression and stability without separate compression screws in select applications
- **Bone-preserving design**—less bone removal than many plate-and-screw constructs, useful in smaller joints or revisions
- **Simplified implantation**—insertable through limited exposures while maintaining compression

Biomechanically, REFLEX HYBRID functions as a hybrid construct pairing the biological benefits of dynamic compression with the mechanical benefits of locking plates, maintaining compression while limiting gapping and loosening under cyclic load.⁵

Potential applications include first MTP arthrodesis, Lapidus procedures, midfoot and hindfoot fusion, and osteotomy fixation where both compression and stability matter. As with any fixation technology, outcomes still depend on patient selection, bone quality, surgical technique, and mechanical demands on the fusion site.

Its core value proposition is bridging the traditional divide between dynamic compression staples and rigid locking constructs by offering continuous biologic compression and enhanced mechanical stability in one implant.

Case series

CASE 1

MANAGEMENT OF CHRONIC POST-SURGICAL HALLUX RIGIDUS AND VALGUS DEFORMITY

Patient	K.B.
Age	47
Gender	Female

History of presentation

The patient sought a second opinion for chronic, relentlessly worsening right great toe pain and lesser toe deformities following right foot surgery approximately 1.5 years prior (first MTP joint exploration, second/third interspace neuroma excisions). Since then, her deformity, stiffness, and pain have progressively deteriorated, with pain advancing from activity-related to constant rest pain, accompanied by mounting intolerance to closed-toe shoes.

While she anticipated that surgery would likely be necessary, her primary goal was a procedure offering durable symptom relief while minimizing the risk of further surgical intervention. Despite exhausting nonoperative management, she experienced no meaningful relief, and her condition had become severely disabling, substantially compromising her function, footwear tolerance, and overall quality of life.

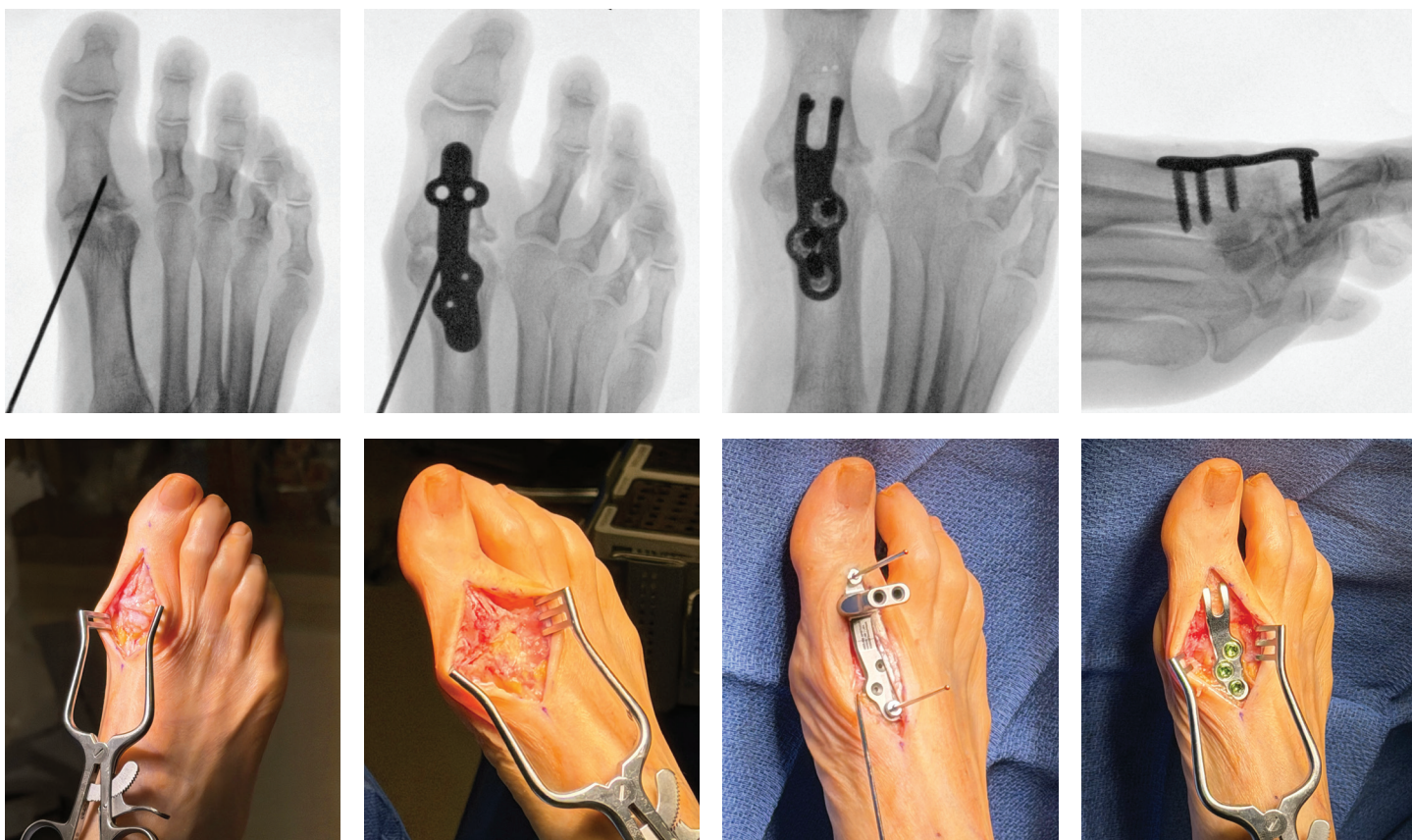
Preoperative clinical exam and imaging

Partially correctable hallux valgus deformity, painful with attempted passive correction. Prominent dorsal hallux MTP spurs were noted, with a positive hallux MTP grind test.



Preoperative weight-bearing radiographs demonstrating hallux valgus and MTP joint changes.

Intraoperative and postoperative imaging



Intraoperative fluoroscopic and photographic images demonstrating preparation and implant application of REFLEX HYBRID fixation.



Postoperative radiographs confirming deformity correction, hardware position and arthrodesis union.

CASE 2

MANAGEMENT OF A RIGID PLANTARFLEXED HALLUX MTP DEFORMITY IN A PATIENT WITH RHEUMATOID ARTHRITIS

Patient	C.M.
Age	26
Gender	Female

History of presentation

The patient has a history of stable rheumatoid arthritis, managed medically with methotrexate/ Enbrel, and presents with progressively worsening bilateral foot deformities, more severe on the left. She reports chronic, worsening deformities primarily involving the bilateral hallux, with pain centered over the dorsal hallux MTP joint. On the left, she describes significant, escalating disability with shoe wear due to persistent rubbing over the prominent area, with deformity and pain steadily worsening over the past year.

Despite exhausting conservative measures including activity and shoe wear modification, orthotics, and over-the-counter medications, she has experienced no meaningful relief. She feels these issues are severely compromising her ability to perform desired activities and overall ADLs (activities of daily living) and presents today to urgently discuss definitive treatment options.

Preoperative clinical exam and imaging

Rigid pes planovalgus deformity. Moderate, minimally reducible plantar flexion deformity of the hallux MTP joint, with a dorsal bony prominence at the first metatarsal head and overlying callus and chronic skin irritation. Tenderness noted over the dorsal hallux MTP joint. No active hallux extension. NVI.



Preoperative weight-bearing radiographs demonstrating rigid pes planovalgus and plantarflexed hallux MTP deformity.

Postoperative imaging

At 4'11" with a BMI of 18, the patient was small in stature with dysmorphic, small bone anatomy, which posed some challenges in centering the REFLEX HYBRID system across the MTP joint. Despite this, fixation was excellent and ultimately stable.



Postoperative radiographs confirming deformity correction and hardware position.

CASE 3

MANAGEMENT OF PROGRESSIVE HALLUX RIGIDUS AND VALGUS DEFORMITY REFRACTORY TO CONSERVATIVE CARE

Patient	T.M.
Age	56
Gender	Female

History of presentation

The patient presents with progressively debilitating right foot pain, marked deformity, and significant joint-related discomfort during activity, along with a worsening dorsal great toe prominence from spurs. Her symptoms, though activity-dependent and partially relieved with rest, have shown a longstanding pattern of relentless progression in intensity, frequency, and severity, increasingly limiting her function.

Despite exhausting conservative measures including activity and footwear modification and both oral and topical anti-inflammatories, she has experienced no meaningful relief, even after repeated footwear changes. Given the persistent and worsening nature of her condition, she presented to establish care and pursue definitive treatment options.

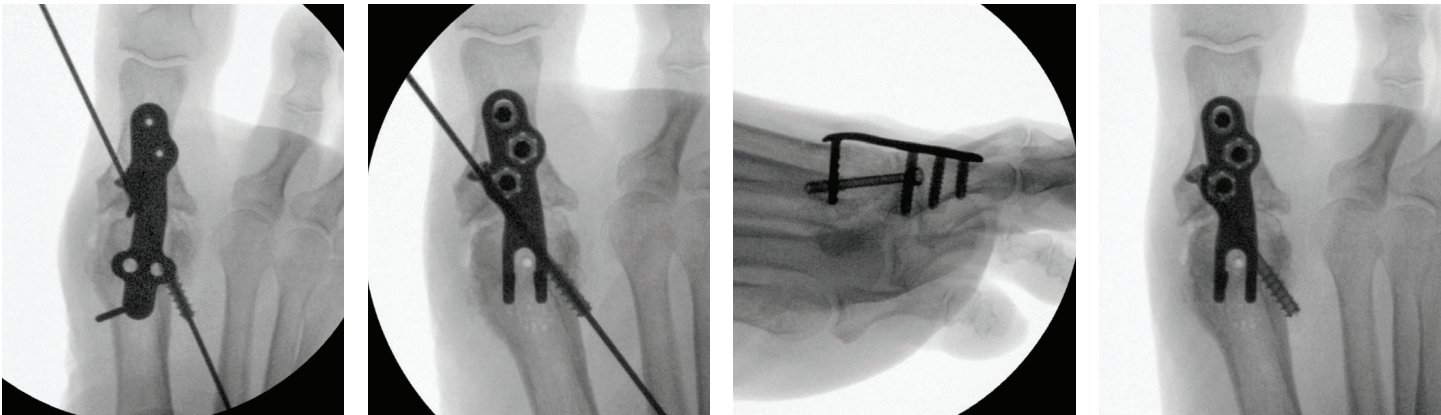
Preoperative clinical exam and imaging

Hallux valgus deformity with prominence over the dorsal hallux MTP joint. Notably decreased range of motion compared to the contralateral side, with a positive hallux MTP grind test. NVI.



Preoperative weight-bearing radiographs demonstrating hallux valgus and MTP joint changes.

Intraoperative and postoperative imaging



Intraoperative fluoroscopic images demonstrating joint preparation and REFLEX HYBRID fixation.



Postoperative radiographs confirming deformity correction and hardware position.

CASE 4

MANAGEMENT OF CHRONIC HALLUX RIGIDUS AND VALGUS DEFORMITY REFRACTORY TO CONSERVATIVE CARE

Patient	L.S.
Age	54
Gender	Female

History of presentation

The patient presents with progressive, worsening chronic pain over the dorsal hallux MTP joint that has failed to respond to extensive conservative management, including activity modification, footwear adjustments, oral and topical anti-inflammatories, and a prior steroid injection—none of which provided meaningful relief. Given the relentless progression of her symptoms and their mounting, significant impact on her quality of life, she presents today to establish care and urgently discuss the indication for surgical management.

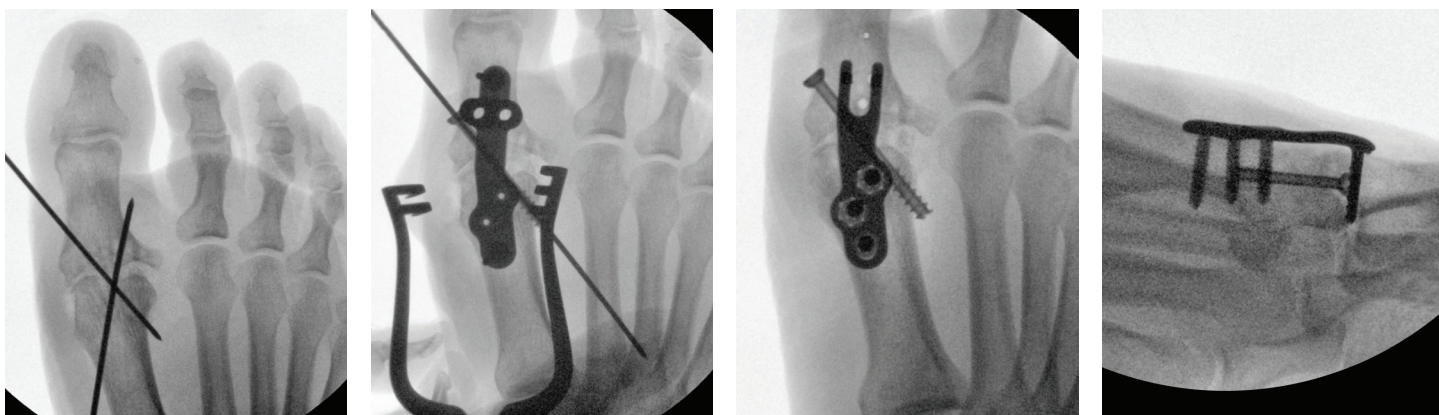
Preoperative clinical exam and imaging

Hallux valgus deformity with mild swelling at the hallux MTP joint. Hallux MTP motion is notably reduced, with pain throughout the arc of motion and a positive grind test. Tenderness is noted over the hallux MTP joint, along with a palpable spur prominence. NVI.



Preoperative weight-bearing radiographs demonstrating hallux valgus and MTP joint changes.

Intraoperative and postoperative imaging



Intraoperative fluoroscopic images demonstrating joint preparation and REFLEX HYBRID fixation.



Postoperative radiographs confirming deformity correction and hardware position.

Case summaries and key takeaways

Surgical indications

Symptomatic, advanced hallux rigidus (with or without accompanying hallux valgus deformity) refractory to extensive conservative management.

Operative considerations

A standard dorsal approach to the first MTP joint is used, with dissection down to the joint capsule and articular surfaces. Joint preparation is performed with cup-and-cone reamers, followed by deformity correction and bone grafting as needed. The arthrodesis site is compressed, with an optional supplemental lag screw at the surgeon's discretion. Definitive fixation is achieved with the REFLEX HYBRID system, which allows flexible construct configuration by placing the nitinol staple limbs on either the proximal phalanx or first metatarsal side, based on surgeon preference and patient anatomy.

Postoperative clinical course

Postoperatively, the patients remained heel weight-bearing for 2 weeks, then transitioned to flat-foot weight-bearing in a rigid postoperative shoe until 6 weeks, with transition to regular footwear between 6–8 weeks depending on swelling and clinical progress.

At 12-week follow-up, the patients were extremely satisfied with their outcome, reporting complete resolution of preoperative pain, successful return to previously intolerable footwear, maintained deformity correction, and a normalized gait. Overall, they noted markedly improved quality of life and a positive outlook for their long-term function.

Comparative outcomes to precedent techniques/implants

While the postoperative protocol is unchanged, based on the author's experience, recovery and functional progression appear roughly 2–3 weeks faster. The smaller incision likely aids quicker wound and soft-tissue healing, and postoperative swelling tends to be milder throughout recovery, allowing earlier return to footwear and daily activities.

Summary and key takeaways

- The REFLEX HYBRID system provides stable fixation for hallux MTP fusion while delivering prolonged, sustained dynamic compression.
- Application is similar to placing a dorsal plate and screw, but with fewer steps.
- The implant system allows flexible placement based on patient anatomy.
- Based on the author's experience, clinically, patients in this case series tend to heal a bit faster postoperatively, with quicker wound healing, less swelling, and less pain.

Advantages over existing fixation options

Current evidence supports interfragmentary compression combined with dorsal plate fixation as the gold standard for first MTP arthrodesis. The REFLEX HYBRID system builds on these principles, using a nitinol compression element to deliver continuous dynamic compression across the fusion site while providing rotational control and minimizing plantar gapping through its dorsal position. A recent study demonstrates that REFLEX HYBRID has a higher ultimate failure load and higher stiffness when compared to a traditional dorsal plate and screw construct.⁵

In well-selected cases—minimal to no axial-plane deformity—the implant's continuous compression may reduce or eliminate the need for a supplemental lag screw, simplifying application without sacrificing stability. By combining sustained compression with dorsal fixation in one system, REFLEX HYBRID aims to capture the benefits of both lag screw and dorsal plate constructs in a low-profile design.

Technically, REFLEX HYBRID application is at least equivalent to—and often simpler than—traditional lag screw and dorsal plate fixation. Its streamlined technique, smaller exposure, and lower hardware profile may improve operative efficiency and support soft-tissue recovery while preserving the biomechanical principles needed for successful fusion.

Limitations and contraindications

Beyond standard contraindications for any internal fixation—active infection, inadequate soft-tissue coverage, or inability to comply with postoperative restrictions—few absolute contraindications are specific to the REFLEX HYBRID system.

The main considerations involve implant fit and patient anatomy. Given the construct's fixed geometry and relative rigidity, careful preoperative assessment is needed in patients with atypical bone morphology—a narrow or small first metatarsal, short proximal phalanx, or other dysmorphic anatomy—that could limit optimal positioning. Alternative fixation may offer more placement flexibility in these cases.

As with other nitinol implants, known nickel hypersensitivity is a relative contraindication. Surgeons should also use caution with severe bone loss, compromised bone stock, or complex deformities, where alternative methods may allow more versatile correction and fixation.

Ultimately, implant selection should be individualized based on anatomy, bone quality, deformity, and surgeon preference to achieve stable fixation and optimal fusion conditions.

Learning curve and surgical pearls

The learning curve for the REFLEX HYBRID system is modest for surgeons already familiar with first MTP arthrodesis and contemporary dorsal plating, since the core principles—joint preparation, deformity correction, compression, and fixation—remain unchanged. Optimal performance, however, depends on achieving good implant-to-bone fit.

A key technical pearl is careful preparation of the dorsal bony surface. After deformity correction and any lag screw fixation, a microsagittal saw can “feather,” contour, and flatten the dorsal cortex from the proximal phalanx across the arthrodesis site to the distal first metatarsal. This promotes intimate contact between the implant's flat undersurface and the bone, minimizing prominence and optimizing seating.

The placeholder pin and inserter instrumentation help confirm implant position before final deployment. As with standard plate fixation, maintaining the desired fusion position throughout insertion is important. Trial positioning and fluoroscopic assessment before definitive implantation help ensure proper alignment, fit, and staple leg placement.

Economic considerations

The economic impact of the REFLEX HYBRID system depends on facility-specific pricing and contracts, so direct cost comparisons vary by institution. Generally, though, overall implant cost appears comparable to a traditional construct of an interfragmentary lag screw and dorsal locking plate with locking/non-locking screws.

While acquisition costs may be similar, value extends beyond hardware pricing. Streamlined instrumentation, a simpler construct, lower implant profile, and potentially shorter operative time may improve procedural efficiency, while theoretical benefits in soft-tissue preservation, wound healing, and reduced hardware prominence could carry downstream economic benefits.

Ultimately, evaluating the REFLEX HYBRID system should weigh both direct implant costs and the broader procedural and recovery factors that shape overall value for patients, surgeons, and healthcare systems.

OR time and reoperation rates

Early clinical experience suggests the REFLEX HYBRID system may reduce operative time by roughly 15 minutes versus a traditional lag screw and dorsal plate construct, mainly due to a streamlined implantation process and smaller exposure (less dissection and closure time).

This time savings could translate into incremental cost benefits at the facility and surgeon level, though the magnitude will vary by institutional workflow and OR economics.

There's currently insufficient evidence to conclude the REFLEX HYBRID system lowers reoperation rates compared to established fixation methods. Still, its lower-profile design and smaller soft-tissue footprint may theoretically reduce hardware irritation and subsequent removal procedures.

Final thoughts

The REFLEX HYBRID system represents an evolution of established first MTP arthrodesis fixation principles rather than a departure from them. Current evidence and early clinical experience suggest it can achieve fusion rates and outcomes comparable to traditional interfragmentary compression and dorsal plate constructs.

Its potential advantages lie not in superior union rates, but in combining continuous dynamic compression with the rigid fixation and rotational stability needed for successful arthrodesis—merging the biomechanical strengths of dorsal plating with the biologic rationale of sustained compression, something static constructs lack.

Its lower profile, streamlined technique, and reduced soft-tissue disruption may also lower hardware-related symptoms, improve comfort, and speed recovery. These benefits still need validation through long-term comparative studies but represent meaningful potential value for patients and healthcare systems.

Ultimately, REFLEX HYBRID should be viewed as another valuable option in the surgeon's toolkit, preserving proven fixation principles while adding biologically favorable dynamic compression in an efficient, patient-centered construct.



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