



Radiographic and Patient Reported Outcomes Following Joint Arthrodesis in the Foot Using a Novel, Dynamic Compression Implant System

Results of the SPRINT™ Ambidirectional Multicenter Study

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Introduction

- Results from a 12-month ambidirectional multicenter study to evaluate the use of a novel, titanium dynamic compression implant system for MTP and TMT joint arthrodesis to evaluate:
 - Healing/union rates
 - Outcomes of early weightbearing
 - Patient-reported outcomes



Baseline

12 Month

Study Methods

SPRINT™ Ambidirectional multicenter study
(5 sites and 5 surgeons): 12-month follow-up

Inclusion criteria:

- ≥ 14 years of age
- MTP or TMT joint fixation utilizing compression implant system

Exclusion criteria:

- MTP or TMT joint arthrodesis prior to study procedure
- BMI > 40 kg/m²
- Evidence of peripheral neuropathy
- Untreated moderate-severe osteoarthritis outside the 1st, 2nd, or 3rd TMT or MTP joints
- Use of structural bone graft
- Concomitant procedures altering ability to return to early weightbearing

Radiographic reader: Two independent fellowship trained musculoskeletal radiologist

Outcomes evaluated (12-month follow-up):

- Clinical and radiographic healing
- Return to weightbearing activities
- Pain measured by visual analog scale
- Change in radiographic/angular positional alignment
- Manchester-Oxford Foot Questionnaire (MOxFQ)
- Participant satisfaction
- Clinical complications

Dynamic Compression Implant

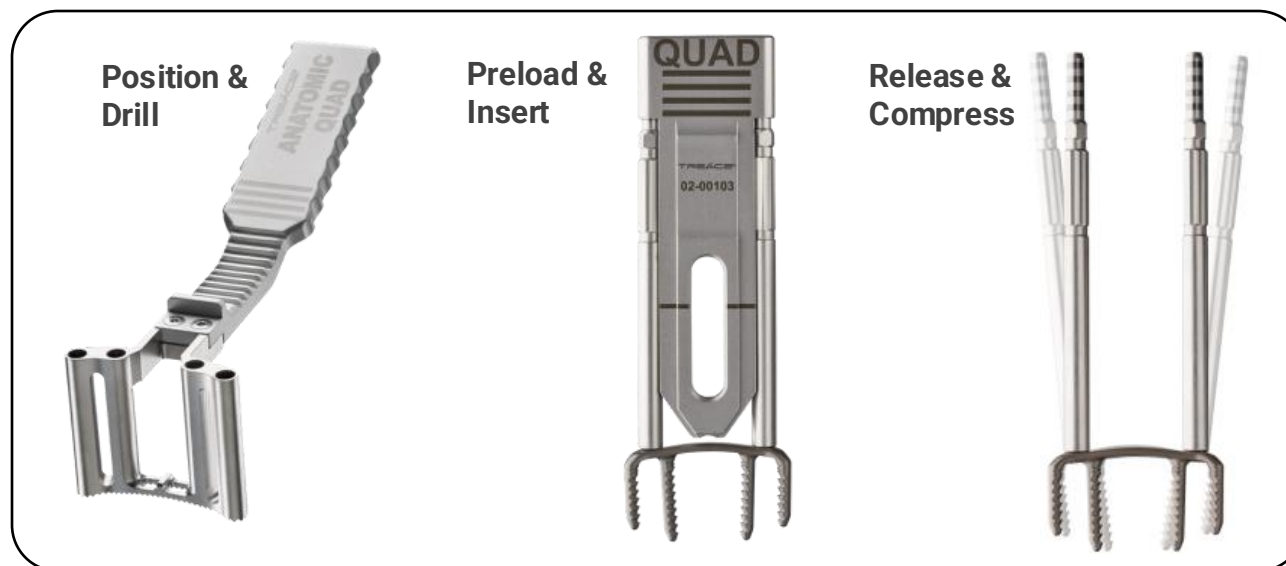
- Novel titanium dynamic compression implant system
- Anatomic configurations for use across multiple applications, including MTP joint and the 1st, 2nd and 3rd TMT joints



Quad
28x13x11mm
28x17x14mm



18mm
18x14mm
18x17mm



Results: Demographics and Baseline Characteristics

- 89/91 (97.8%) patients completed their 12-month follow-up visit

Baseline Characteristics	Category	Patient Population n=91
Age (years), mean (SD)		51.9 (14.2)
Sex, n (%)	Male	11 (12.1%)
	Female	80 (87.9%)
BMI (kg/m ²), mean (SD)		27.2 (5.9)
Index Foot	Left	44 (48.4%)
	Right	47 (51.6%)

Procedures Performed

- Patients had MTP and/or TMT joint fixation using at least one rapid compression implant during the surgical procedure
 - Other concomitant procedures were allowed including, but not limited to, medial eminence resection, bone graft harvest, use of allograft/autograft, and akin osteotomy
- Inclusion of single- and multi-joint arthrodesis highlights system versatility across a range of clinical indications and treatment needs

Procedure Type, n (%)	Patient Population n=91
1 st TMT only	61 (67.0%)
MTP only	15 (16.5%)
1 st , 2 nd , 3 rd TMT (triple)	8 (8.8%)
MTP and 1 st TMT (double)	4 (4.4%)
MTP, 1 st , 2 nd , and 3 rd TMT (quad)	1 (1.1%)
2 nd and 3 rd TMT	1 (1.1%)
2 nd TMT only	1 (1.1%)

Results: Return to Weightbearing

Early weightbearing and activity progression achieved safely
without compromising healing/union

- Return to early, protected weightbearing: mean of 9.0 days (SD=9.3)
- Return to weightbearing in a shoe: mean of 6.5 weeks (SD=1.8)
- Return to full, unrestricted activity: mean of 4.4 months (SD=2.5)

Results: Clinical & Radiographic Healing

- 84/87¹ (96.6%) were clinically and radiographically healed at 12 months
- 3/87¹ (3.4%) patients experienced a symptomatic non-union² at 12 months
 - Non-union was at 1st TMT in all patients
 - One patient required a re-operation to correct the non-union³



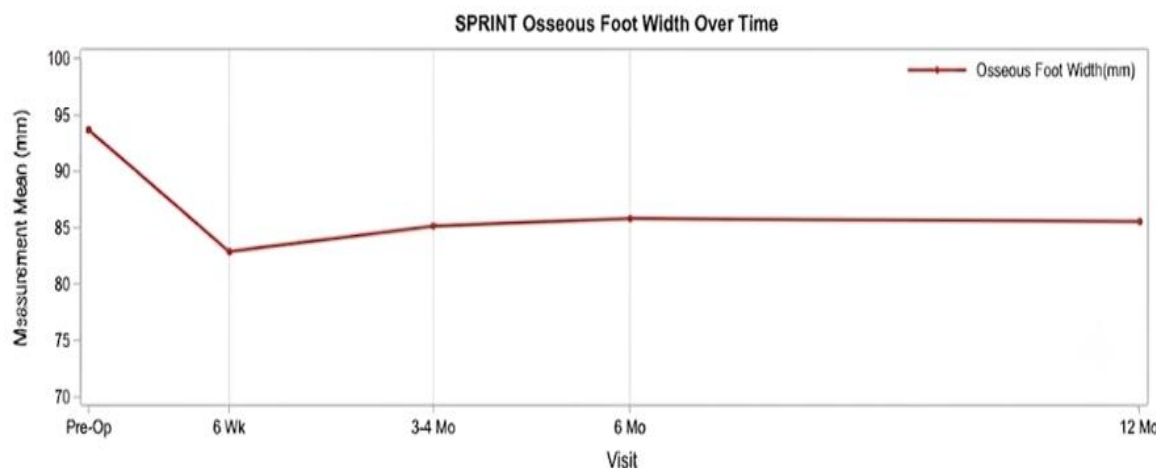
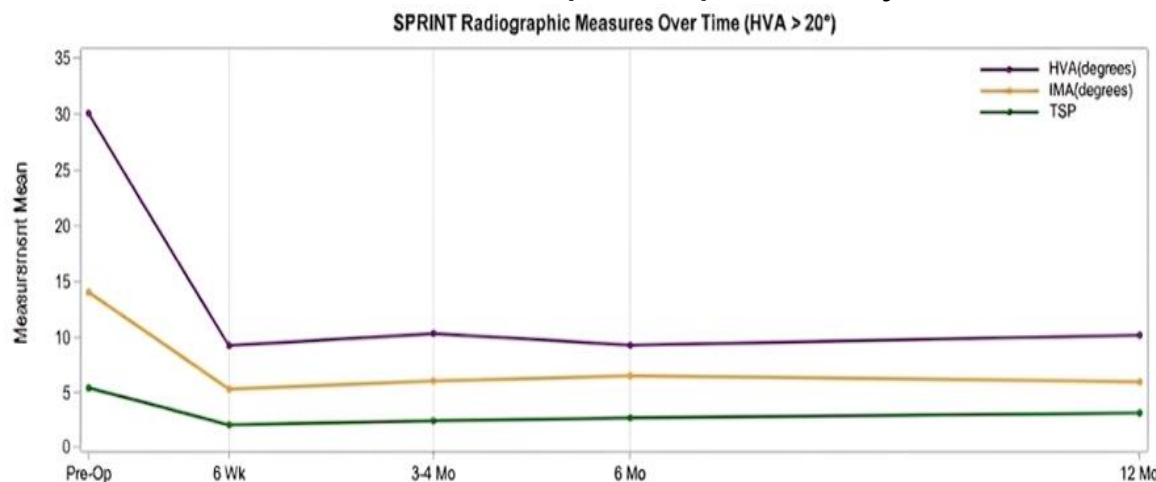
¹87 patients had an x-ray for evaluation at 12 months

²Non-union is defined as radiographic lucency and clinical pain of the same joint (1st, 2nd, and/or 3rd TMT or MTP)

³Patient hardware removed and replaced 10 months post-operatively.

Results: Radiographic Measurements

- Subgroup analysis (n=66) performed on hallux valgus patients (HVA >20°)
- Statistically significant improvements in angular radiographic measurements were observed 6-weeks post-operatively and maintained through 12 months



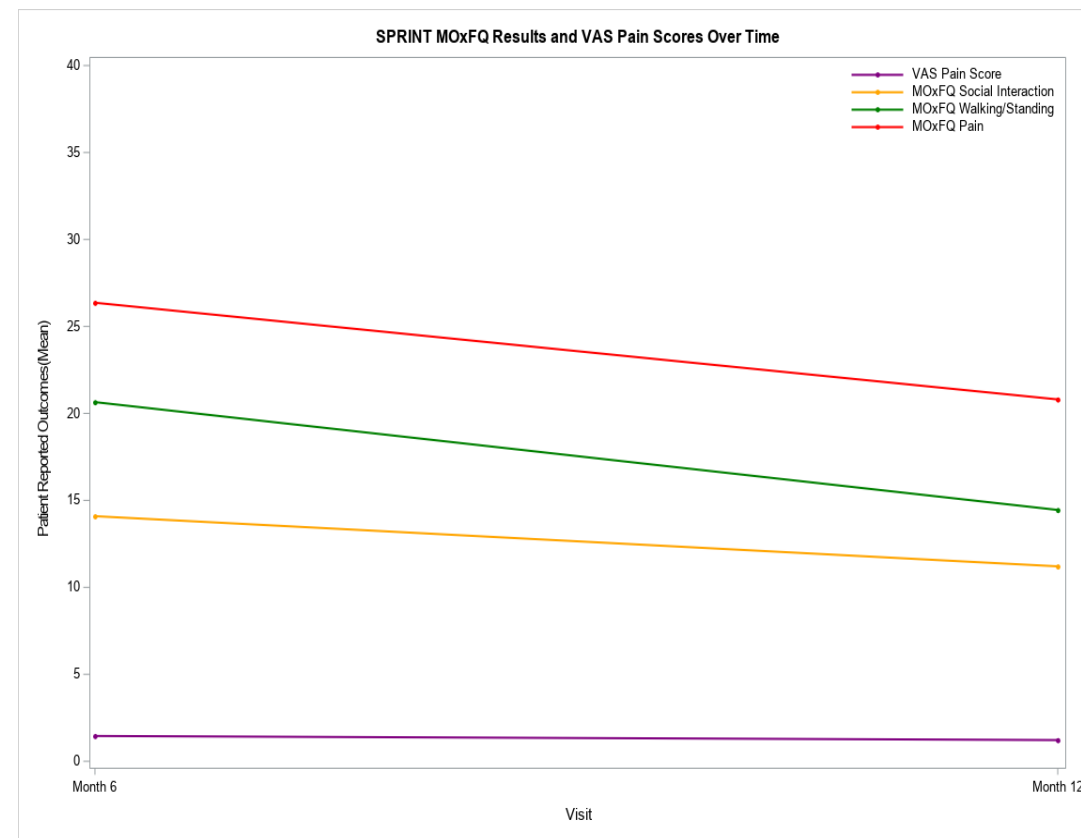
Radiographic measures, Mean (95% CI)

Visit	HVA°	IMA°	TSP	OFW* (mm)
Baseline (N=66)	30.1 (28.4, 31.8)	14.0 (13.2, 14.7)	5.4 (5.1, 5.7)	93.6 (92.0, 95.3)
6 week (N=59)	9.2 (7.5, 10.8)	5.4 (4.4, 6.4)	2.2 (1.8, 2.5)	82.8 (80.9, 84.8)
3-4 month (N=60)	10.3 (8.7, 11.9)	6.2 (5.2, 7.1)	2.5 (2.2, 2.9)	85.1 (83.4, 86.9)
6 month (N=51)	9.4 (7.6, 11.2)	6.6 (5.4, 7.8)	2.8 (2.4, 3.2)	85.8 (83.8, 87.7)
12 month (N=62)	10.2 (8.4, 12.0)	6.2 (5.2, 7.1)	3.0 (2.7, 3.4)	85.6 (83.8, 87.4)

*Osseous Foot Width at Baseline is N=64, Week 6 N=58, 3-4 months N=59

Results: Patient-Reported Outcomes and Satisfaction

- Patient reported post-operative pain (VAS) was 1.5 and 1.2 at 6 and 12 months, respectively
 - In studies^{1, 2} with similar patient populations, a baseline VAS of 3.5 and 4.7 was reported
- Improvements in MOxFQ domains were seen from 6 months to 12 months
 - In studies^{1, 2} with similar patient populations, a baseline MOxFQ scored ranged from 42.7 - 44.9 (Social Interaction), 41.2 - 46.2 (Walking/Standing) and 50.2 - 55.1 (Pain) was reported
- 95.4% of patients reported that they would recommend the procedure to friends



Complications

- 11 (12.1%) of the 91 patients required non-elective reoperation due to the situations listed below
- 1 (1.1%) patient requested hardware removal without medical indication or complication.
- 10 (11.0%) patients experienced one adverse event not requiring surgical intervention.
- 3 (3.2%) patients experienced a hardware failure (no AE/no hardware removal).
- 3 (3.4%) patients experience a symptomatic non-union (radiographic lucency and clinical pain at the same joint) at 12 months; 1 patient required re-operation to correct the non-union^b

Complications Requiring Surgical Intervention ^a	N (%) n=91	Complications Not Requiring Surgical Intervention ^d	N (%) n=91
Hardware removal:		Infection (incision)	5 (5.5%)
• Due to pain - hardware/incision	5 (5.5%)	Wound complication (wound healing)	1 (1.1%)
• Due to allergic reaction to implant materials	1 (1.1%)	Pain due to:	
• Due to malunion	1 (1.1%)	• Non-union	2 (2.2%)
• Due to pain/non-union (1 st TMT) ^b	1 (1.1%)	• Hardware and non-union	1 (1.1%)
Reoperation due to:		• Nerve pain (related to surgery)	1 (1.1%)
• Wound complication	1 (1.1%)	Hardware failures ^e (no adverse event/hardware not removed)	3 (3.2%)
• Infection (incision)	1 (1.1%)	Non-union ^f – 1 st TMT	2 (2.3%)
• Pain due to 2 nd metatarsal stress fracture	1 (1.1%)	^d All complications resolved by 12 months except for one pain due to non-union	
<i>Hardware removal per patient request^c</i>	1 (1.1%)	^e Broken M1-C1 screw (n=1); dorsal plate at 1 st TMT backing out (n=1); broken tine, 1 st TMT (n=1) – none were associated with a non-union	
<i>Note: pain reported in this table is not pain at MTP/TMT joint.</i>		^f Patients are also represented in 1 “pain due to non-union” and 1 “pain due to hardware/non-union”. The second “pain due to non-union” was resolved (both pain and non-union) by 12 months	
^a All complications were resolved post intervention			
^b Patient hardware removed and replaced 10 months post-operatively. At time of study exit, patient’s pain had resolved and progressive fill-in of 1 st TMT noted.			
^c Not considered a complication of procedure/implant			

Discussion

- First dynamic titanium fixation system used for arthrodesis procedures, expanding beyond nitinol-based implants.
- Favorable outcomes across diverse case complexities, including multi-joint and combined procedures.
- Early protected weightbearing achieved without compromising healing.
- High union rates with minimally significant clinical complications.
- Excellent anatomic correction in patients with hallux valgus maintained through 12 months.
- Multicenter results support real-world applicability across a range of midfoot and forefoot arthrodesis procedures.

Limitations

- Single arm study without a control or comparison group.
- Ambidirectional study design makes direct evaluation of patient improvement challenging.
- Study sites included surgeons experienced with the compression implant system for MTP and TMT joint arthrodesis.

Conclusions

- Arthrodesis with a novel titanium compression construct demonstrated favorable healing rates.
- Early protected weightbearing in average of 9.0 days.
- Statistically significant improvements in radiographic measurements (IMA, HVA, TSP and OSF) were observed 6-weeks post-operatively and maintained through 12 months in patients with hallux valgus (HVA $>20^{\circ}$).
- Patient reported outcomes at 12 months (VAS and MOxFQ) compare favorably with literature.

References

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