Effect of Guselkumab and Golimumab Combination Therapy on Magnetic Resonance Imaging-Detected Inflammation and Damage in Phalangeal Joints of the Hands and Feet and Entheses of the Heels Among Participants With Active Psoriatic Arthritis: Findings From the Phase 2a AFFINITY Study

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Conflicts of Interest

JW, ML, TW, EC, BZ, ER, and LS are employees of Johnson & Johnson; employees may own stock/stock options in Johnson & Johnson.

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Introduction

Psoriatic Arthritis (PsA)

PsA is a complex, multi-pathway inflammatory disease affecting joints, entheses, and skin that leads to functional impairment and reduced health-related quality of life[1]

Rationale for Guselkumab (GUS) + Golimumab (GOL) Combination Therapy

- Combination therapies may enhance efficacy of PsA treatment by modulating complementary immune mechanisms[2,3]

GUS for Active PsA[4]

- Fully human, dual-acting monoclonal antibody that selectively inhibits interleukin (IL)-23 by targeting its p19 subunit and binds CD64 on IL-23-producing inflammatory monocytes[5]

GOL for Active PsA[6]

- Fully human monoclonal antibody targeting tumor necrosis factor alpha (TNFα)

AFFINITY (NCT05071664)

- Phase 2a, randomized, double-blind, active-controlled, proof-of-concept study that evaluated GUS+GOL combination vs GUS monotherapy in adults with active PsA and inadequate TNFα inhibitor response (TNFi-IR)
- GUS+GOL combination showed numerically higher minimal disease activity rates vs GUS monotherapy at W24 (p=0.557)[7]
- Joint disease activity and physical function responses suggested benefit with GUS+GOL combination vs GUS monotherapy for some patients

1. Ritchlin CT, et al. *N Engl J Med*. 2017; 376:957-70. 2. Cuchacovich R. *J Rheumatol*. 2012; 39:187-193. 3. Scher JU, et al. *Arthritis Rheumatol*. 2021; 73:1574-1578. 4. Janssen Biotech, Inc. TREMFYA® (guselkumab) injection, for subcutaneous or intravenous use. Revised 9/2025 (prescribing information). https://www.jnjlabels.com/package-insert/product-monograph/prescribing-information/TREMFYA-pi.pdf. 5. Sachen KL, et al. *Front Immunol*. 2025;16:1532852. 6. Janssen Biotech, Inc. SIMPONI® (golimumab) injection, for subcutaneous use. Revised 10/2025 (prescribing information). https://www.jnjlabels.com/package-insert/product-monograph/prescribing-information/SIMPONI-pi.pdf. 7. Scher JU, et al. *Arthritis Rheumatol*. 2026. doi: 10.1002/art.70152. **W**=Week.

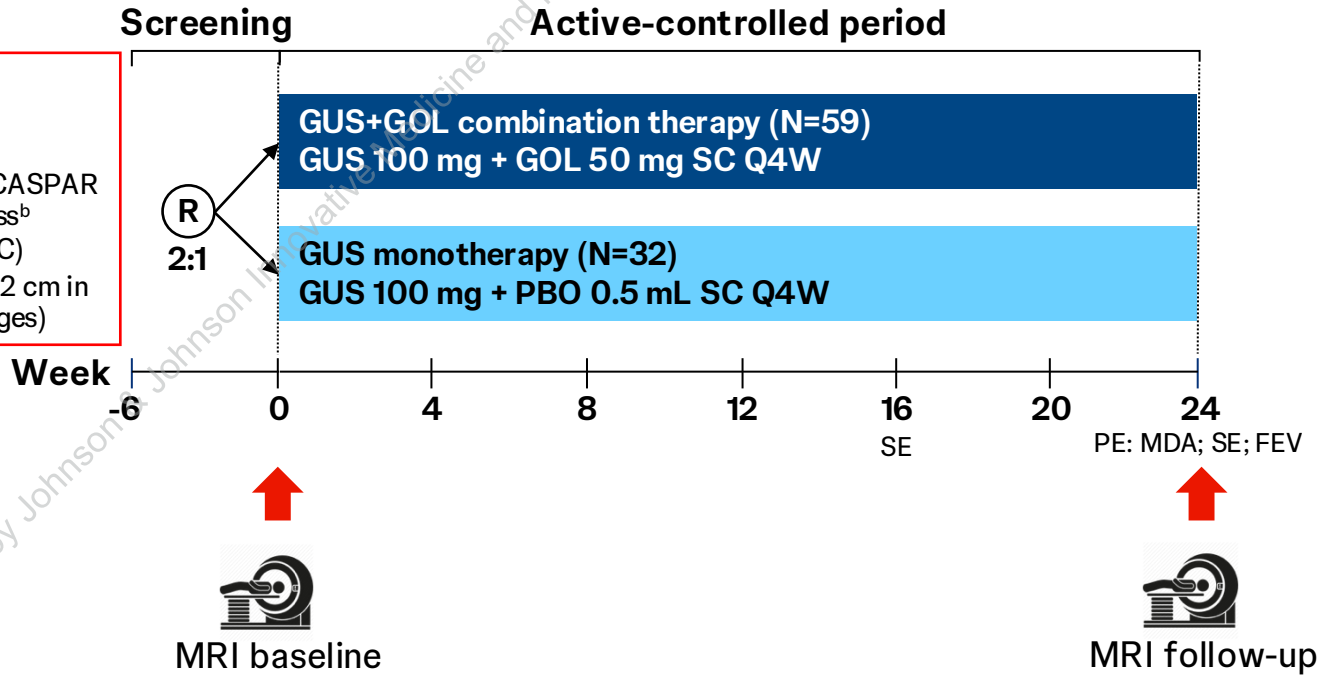
AFFINITY - Study Design & Objectives

Objectives

- Report exploratory magnetic resonance imaging (MRI) assessments from the AFFINITY study
- Evaluate GUS+GOL combination vs GUS monotherapy effects on inflammation and structural damage of the:
  - Hand
  - Forefoot
  - Heel entheses

Key Inclusion Criteria

- Adults ≥18 to ≤65 years
- TNFi-IR[a]
- PsA diagnosis for ≥6 months; CASPAR criteria met; ≥1 PsA subset class[b]
- Active PsA (≥3 TJC and ≥3 SJC)
- Active plaque PsO (≥1 plaque ≥2 cm in diameter or psoriatic nail changes)



Current Analysis: Complete Case Analysis
participants with available data at both baseline and W24 for hand, forefoot, and/or heel

A protocol amendment removed screening high sensitivity CRP ≥0.3 mg/dL criterion and expanded IR to prior TNFi from 1 to 2. [a]IR defined as lack of benefit in response to TNFi after ≥12 weeks of etanercept, adalimumab, certolizumab pegol (or their biosimilars), or ≥14 weeks of infliximab/biosimilars, with last TNFi dose administered >5 half-lives prior to starting study treatment. [b]Subset classification including distal interphalangeal joint involvement, polyarticular arthritis without rheumatoid nodules, asymmetric peripheral arthritis, or spondylitis with peripheral arthritis.
CASPAR=CIASsification criteria for Psoriatic ARthritis, **CRP**=C-reactive protein, **FEV**=final efficacy visit, **GOL**=golimumab, **GUS**=guselkumab, **IR**=inadequate response, **MDA**=minimal disease activity, **PBO**=placebo, **PsA**=psoriatic arthritis, **PsO**=psoriasis, **PE**=primary endpoint, **Q4W**=every 4 weeks, **R**=randomization, **SC**=subcutaneous, **SE**=secondary endpoint, **SJC**=swollen joint count, **TJC**=tender joint count, **TNFi**=tumor necrosis factor inhibitor, **W**=Week.

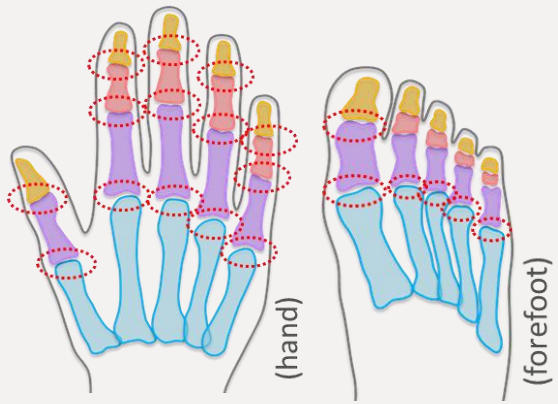
MRI Assessments

Complete Case Analyses

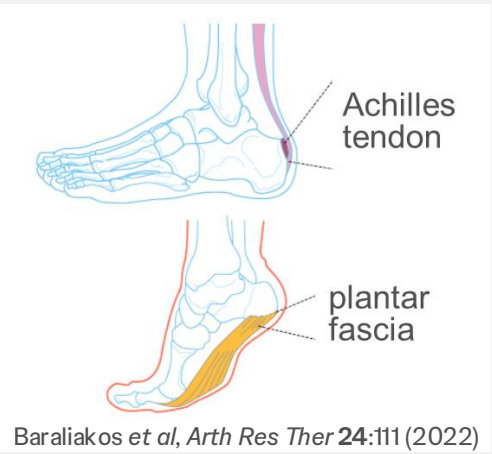
- MRI at **W0** and **W24**
  - 2 blinded central readers
  - Readers scores averaged
- Composite indices of inflammatory burden and structural damage
- Summation of feature scores[1,2]
- ANCOVA of LSM change from baseline for GUS+GOL combination vs GUS monotherapy at W24

OMERACT Scoring Frameworks for Assessment of Inflammation and Structural Damage: PsAMRIS and HEMRIS

PsAMRIS[3] of finger and toe joints	
Inflammatory features	**Structural damage features**
• Synovitis • Tenosynovitis • Periarticular inflammation • Osteitis (bone edema)	• Bone erosion • Bone proliferation



HEMRIS[1] of calcaneal entheses	
Inflammatory features	**Structural damage features**
• Tendinitis (intratendon hypersignal) • Peritendinitis (peri-tendon hypersignal) • Osteitis (bone edema) • Retrocalcaneal bursitis (Achilles only)	• Tendon thickening • Calcaneal enthesophyte (bone spur) • Calcaneal bone erosion



Baraliakos *et al*, *Arth Res Ther* **24**:111 (2022)

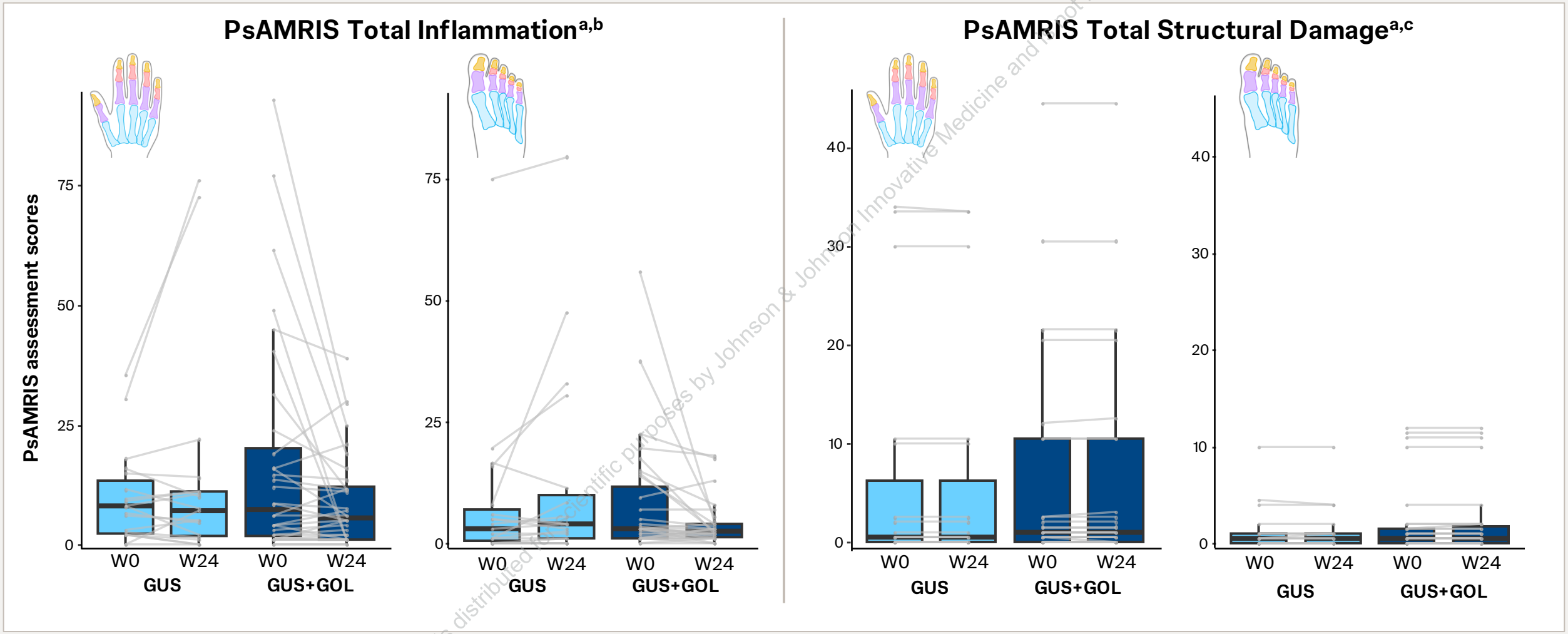
1. Mathew AJ, et al. *J Rheumatol.* 2019;46:1232-8. 2. www.clinicaltrials.gov/study/NCT03783026 (2025). 3. Østergaard M, et al. *J Rheumatol* 2009;36:1816-24. **ANCOVA**=analysis of covariance, **GOL**=golimumab, **GUS**=guselkumab, **HEMRIS**=Heel Enthesitis Magnetic Resonance Imaging Score, **LSM**=least squares mean, **MRI**=magnetic resonance imaging, **OMERACT**=Outcome Measures in Rheumatology, **PsAMRIS**=Psoriatic Arthritis Magnetic Resonance Imaging Score, **W**=Week.

Baseline characteristics of the MRI Complete Case subset were comparable across treatment groups and the overall AFFINITY population

Baseline Characteristics	GUS + GOL MRI subset N = 30	GUS mono MRI subset N = 17	Total MRI subset N = 47	Overall study population N = 91
Demographics				
Age, years	48.6 (10.7)	46.1 (10.1)	47.7 (10.5)	49.4 (10.5)
Female, %	57%	65%	60%	62%
BMI, kg/m^2	30.6 (7.1)	29.9 (6.9)	30.4 (7.0)	31.1 (6.6)[a]
PsA Characteristics				
PsA duration, years	6.8 (6.2)	5.3 (4.7)	6.2 (5.7)	7.8 (7.0)
SJC (0-66), median (range)	8.0 (3; 50)	8.0 (3; 37)	8.0 (3; 50)	8.0 (3; 50)
TJC (0-68), median (range)	13.5 (3; 54)	12.0 (6; 57)	13.0 (3; 57)	13.0 (3; 66)
HAQ-DI (0-3)	1.2 (0.6)	1.0 (0.7)	1.2 (0.6)	1.2 (0.6)
SF-36 PCS (US norm=50)	32.6 (8.8)	31.7 (9.2)	32.3 (8.9)	32.1 (8.6)
Screening CRP, %				
<0.1 mg/dL	10%	0%	6%	10%
≥0.1 and <0.3 mg/dL	27%	29%	28%	22%
≥0.3 mg/dL	63%	71%	66%	68%
Enthesitis / Dactylitis, %	63% / 23%	65% / 24%	64% / 23%	62% / 23%
Mean LEI (1-6) / **DSS** (1-60)	2.8 / 12.6	1.9 / 12.8	2.5 / 12.6	2.7 / 9.4
PsO Characteristics				
PsO duration, years	9.7 (8.2)[b]	10.2 (7.0)	9.9 (7.7)[c]	12.2 (10.5)[d]
PsO % BSA, median (range)	2.0 (0; 40)	5.0 (0; 51)	4.0 (0; 51)	3.0 (0; 51)
≥3% BSA and IGA ≥2, %	33%	59%	43%	38%
PASI (0-72), median (range)	5.5 (2.7; 28.4)	5.0 (0.5; 48.2)	5.5 (0.5; 48.2)	4.8 (1; 48)

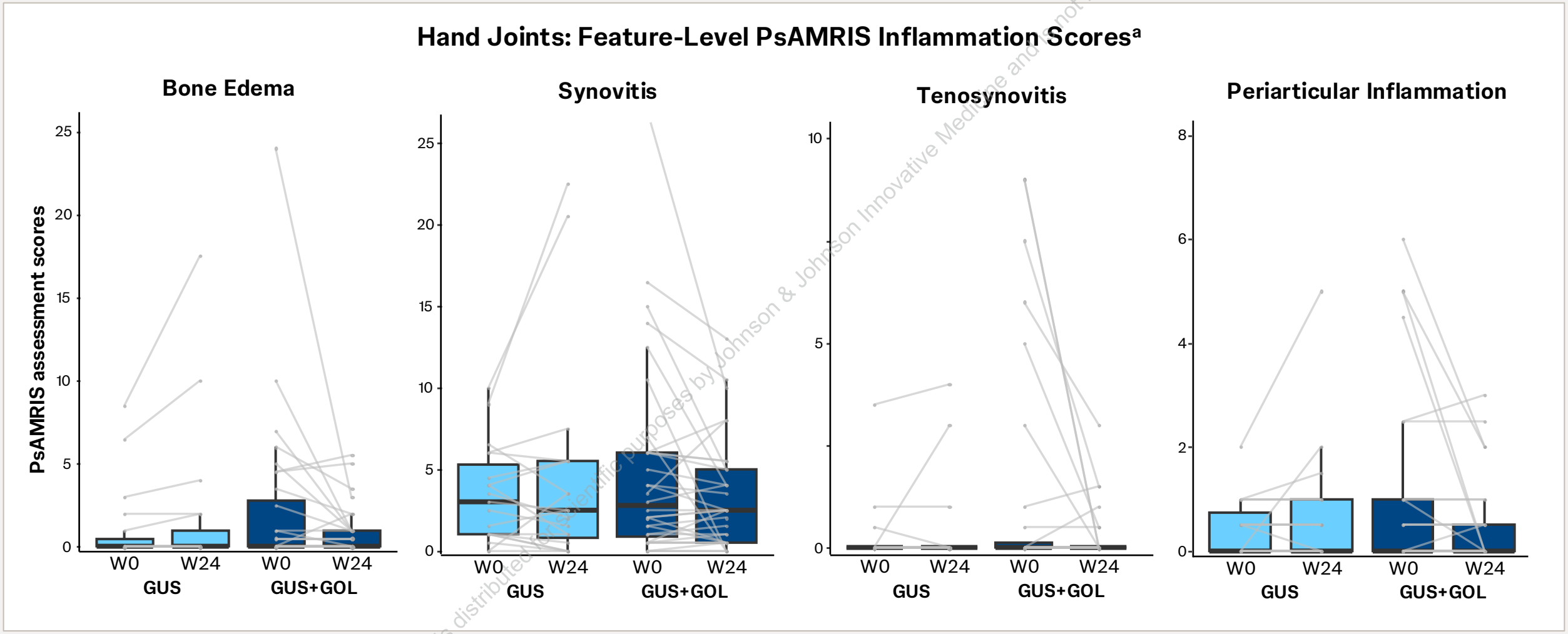
Data are mean (SD) unless otherwise noted. [a]N=90. [b]N=28. [c]N=45. [d]N=89. **BMI**=body mass index, **BSA**=body surface area, **CRP**=C-reactive protein, **DSS**=Dactylitis Severity Score, **GOL**=golimumab, **GUS**=guselkumab, **HAQ-DI**=heath assessment questionnaire disability index, **IGA**=Investigator's Global Assessment, **LEI**=Leeds Enthesitis Index, **MRI**=magnetic resonance imaging, **PASI**=psoriasis area severity index, **PsA**=psoriatic arthritis, **PsO**=psoriasis, **SD**=standard deviation, **SF-36 PCS**=short form-36 physical component summary, **SJC**=swollen joint count, **TJC**=tender joint count.

Response of PsAMRIS composite indices within treatment groups



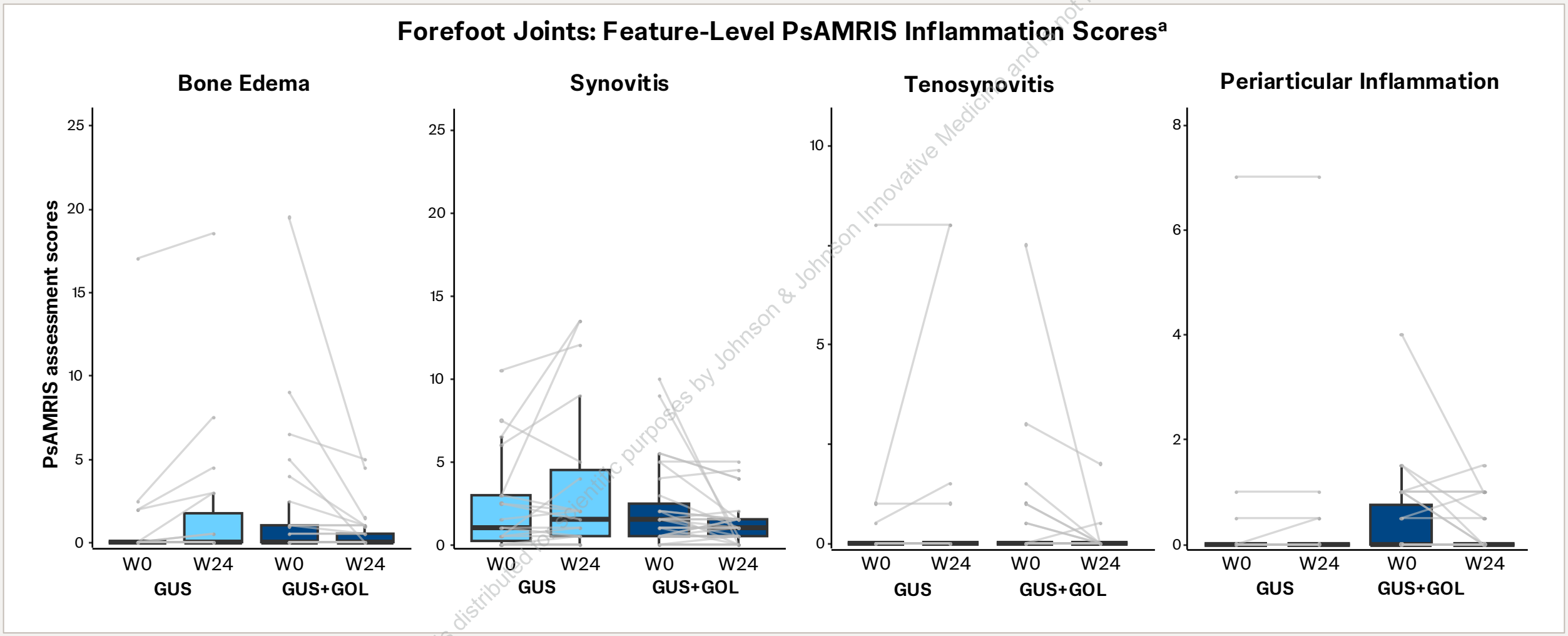
[a]Lines connecting W0 and W24 depict each participant's trajectory over time and boxplots show the distribution of the measurements (median [middle line] IQR [box] ± 1.5*IQR [whiskers]). [b]Summation of 1x bone marrow edema, 2x synovitis, 2x tenosynovitis, and 3x periarticular inflammation. [c]Summation of 1x bone erosion and 20x bone proliferation. **GOL**=golimumab, **GUS**=guselkumab, **IQR**=interquartile range, **PsAMRIS**=Psoriatic Arthritis Magnetic Resonance Imaging Score, **W**=Week.

Numerically greater reductions in hand inflammation with GUS+GOL combination vs GUS monotherapy at W24



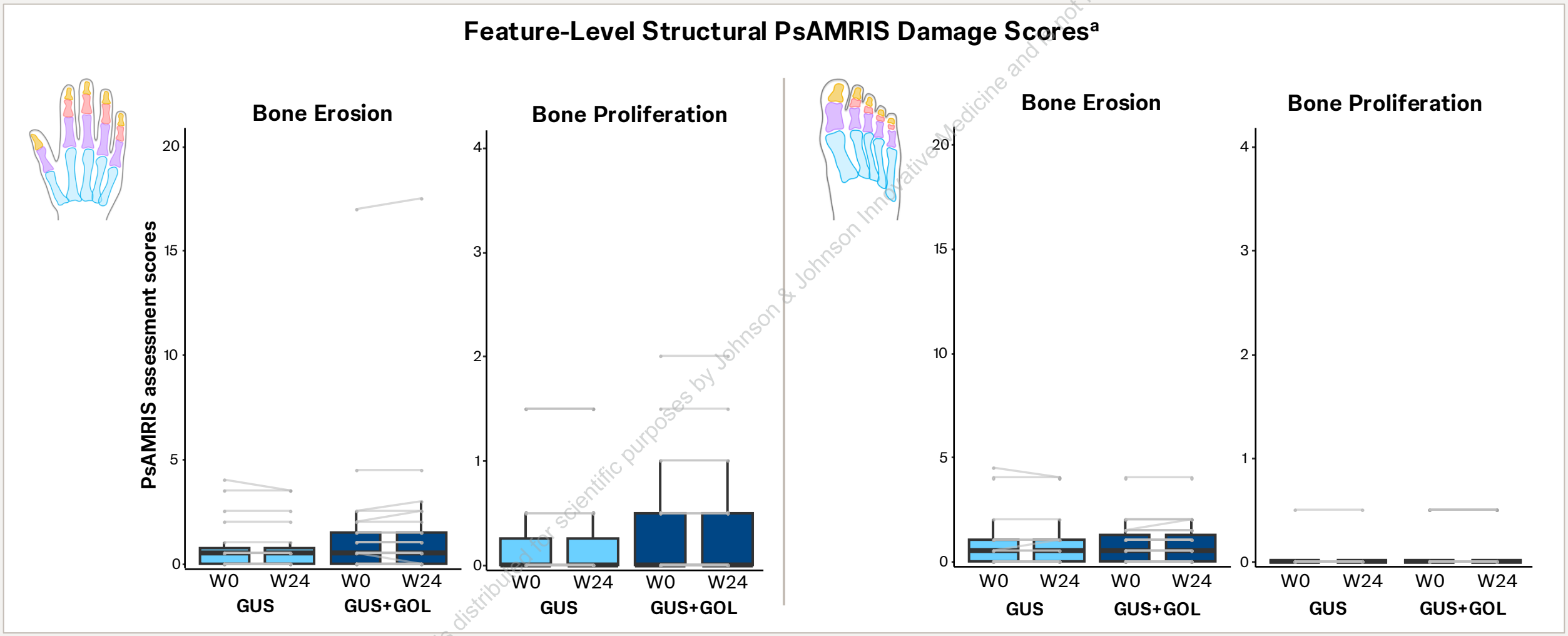
[a]Lines connecting W0 and W24 depict each participant's trajectory over time and boxplots show the distribution of the measurements (median [middle line] IQR [box] ± 1.5*IQR [whiskers]).
GOL=golimumab, **GUS**=guselkumab, **IQR**=interquartile range, **PsAMRIS**=Psoriatic Arthritis Magnetic Resonance Imaging Score, **W**=Week.

Numerically greater reductions in forefoot inflammation with GUS+GOL combination vs GUS monotherapy at W24



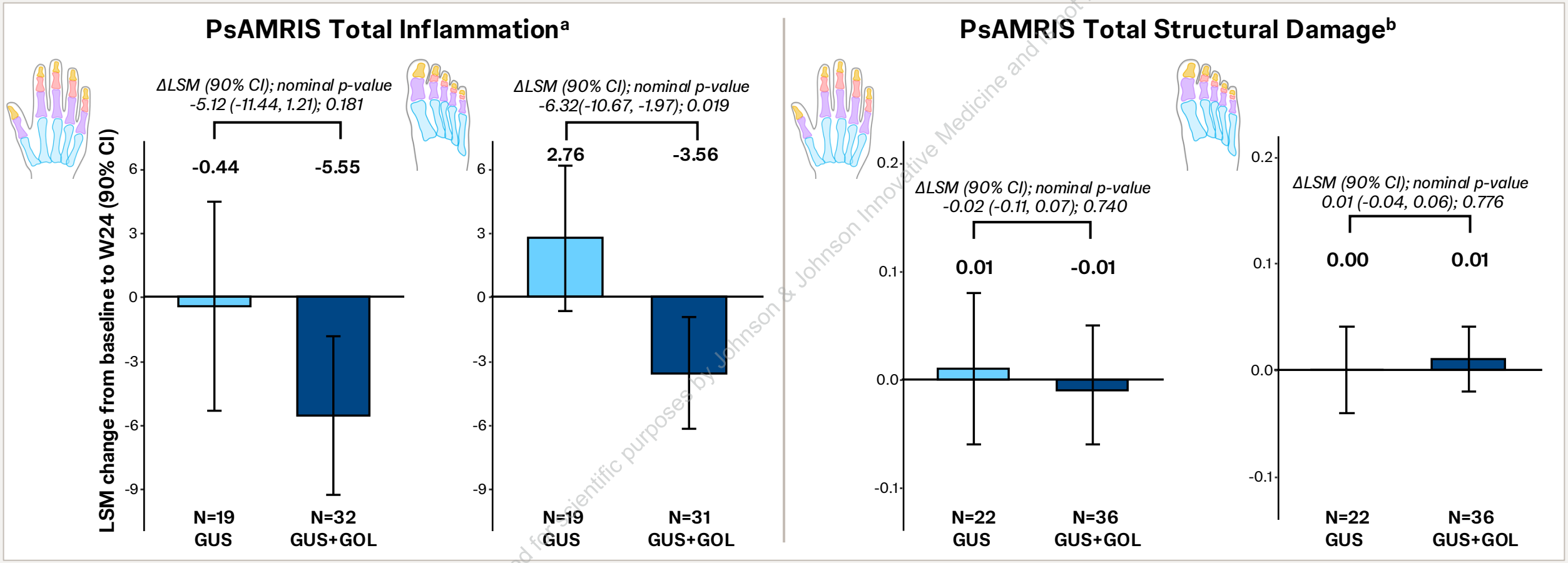
[a]Lines connecting W0 and W24 depict each participant's trajectory over time and boxplots show the distribution of the measurements (median [middle line] IQR [box] ± 1.5*IQR [whiskers]).
GOL=golimumab, **GUS**=guselkumab, **IQR**=interquartile range, **PsAMRIS**=Psoriatic Arthritis Magnetic Resonance Imaging Score, **W**=Week.

Structural damage scores of finger and toe joints were generally stable with GUS+GOL combination and GUS monotherapy through W24



[a]Lines connecting W0 and W24 depict each participant's trajectory over time and boxplots show the distribution of the measurements (median [middle line] IQR [box] ± 1.5*IQR [whiskers]).
GOL=golimumab, **GUS**=guselkumab, **IQR**=interquartile range, **PsAMRIS**=Psoriatic Arthritis Magnetic Resonance Imaging Score, **W**=Week.

GUS+GOL combination exhibited numerically greater reductions in inflammation of the hand and forefoot vs GUS monotherapy at W24



Structural damage remained stable with both GUS+GOL combination and GUS monotherapy

Data shown are LSM (90% CI) change from baseline to W24 for all participants with available assessments (N; complete case analysis). Data calculated from an ANCOVA model, with randomization arm, baseline endpoint measurement, and baseline stratification factors as the explanatory factors. [a]Summation of 1x bone marrow edema, 2x synovitis, 2x tenosynovitis, and 3x periarticular inflammation. [b]Summation of 1x bone erosion and 20x bone proliferation. **ANCOVA**=analysis of covariance, **CI**=confidence interval, **GOL**=golimumab, **GUS**=guselkumab, **LSM**=least squares mean, **PsAMRIS**=Psoriatic Arthritis Magnetic Resonance Imaging Score, **W**=Week.

Calcaneal entheses: changes in inflammatory and structural damage scores were comparable between treatment groups through W24

HEMRIS assessments	GUS monotherapy	GUS+GOL combination
	LSM change from baseline to W24 (90% CI)	
Inflammatory score	N=21	N=35
Achilles tendon[a]	-0.28 (-0.56, -0.00)	-0.03 (-0.25, 0.18)
Plantar fascia[b]	-0.15 (-0.32, 0.01)	0.00 (-0.13, 0.13)
Structural damage score	N=22	N=35
Achilles tendon[c]	-0.03 (-0.10, 0.04)	0.02 (-0.03, 0.08)
Plantar fascia[d]	-0.02 (-0.05, 0.00)	0.00 (-0.02, 0.02)

Nominal *p*-value ns for GUS+GOL vs GUS for all assessments

Data shown are LSM (90% CI) change from baseline to W24 for all participants with available assessments (N; complete case analysis). Data calculated from an ANCOVA model, with randomization arm, baseline endpoint measurement, and baseline stratification factors as the explanatory factors. [a]Summation of intra-tendon hypersignal, peri-tendon hypersignal, bone marrow edema, and retrocalcaneal bursitis. [b]Summation of intra-fascia hypersignal, peri-fascia hypersignal, and bone marrow edema. [c]Summation of tendon thickening, calcaneal enthesophyte, and calcaneal bone erosion. [d]Summation of fascia thickening, calcaneal enthesophyte, and calcaneal bone erosion. **ANCOVA**=analysis of covariance, **CI**=confidence interval, **GOL**=golimumab, **GUS**=guselkumab, **HEMRIS**=Heel Enthesitis Magnetic Resonance Imaging Score, **LSM**=least squares mean, **ns**=non-significant, **W**=Week.

Key Takeaways

Exploratory MRI assessments from the phase 2a AFFINITY study of participants with PsA and TNFi-IR through W24 indicated:

- ✓ **GUS+GOL combination provided greater reductions in finger and toe joint inflammatory scores vs GUS monotherapy**
- ✓ **Structural damage scores were stable for both treatment groups**
- ✓ **Changes in HEMRIS assessments were comparable between groups**

Findings are consistent with clinical assessments that suggested GUS+GOL combination may provide some patients with additional benefits in joint disease activity and physical function[1]

1. Scher JU, et al. *Arthritis Rheumatol*. 2026. doi: 10.1002/art.70152. **GOL**=golimumab, **GUS**=guselkumab, **HEMRIS**=Heel Enthesitis Magnetic Resonance Imaging Score, **MRI**=magnetic resonance imaging, **PsA**=psoriatic arthritis, **TNFi-IR**= inadequate tumor necrosis factor alpha inhibitor response, **W**=Week.