Sharp.AI: Longitudinal AI-Based Evaluation of Radiographic Progression in PsA

Zijun Gao[1†], Darshana Govind[1†], Dimitri Kessler[1], Chaitanya Parmar[1], Kenneth Broos[1], Nicholas Fountoulakis[1], Xiaoqin Tang[1], Luiza Gabriel[1], Elizabeth Hsia[1], Gabriela Oana Cula[1], Lenore Noonan[1], Philip Murphy[1], Anna Beutler[1], Terence Rooney[1], Michael Deman[1], Peter Ory[2], Kristopher Standish[1*], Robert Janiczek[1*]

[1]Johnson & Johnson, Spring House, PA, USA. [2]Virginia Mason Franciscan Health-St. Anne Hospital, WA, USA

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Background

Accurate radiographic assessment is essential for monitoring **disease progression and treatment efficacy** in PsA clinical trials. While PsA-modified van der Heijde Sharp (vdHS) scoring remains the gold standard, its labor-intensive nature and limited sensitivity to subtle longitudinal change motivate the need for **scalable AI-based approaches with ability to capture progression over short trial intervals.**

Objective

To develop and evaluate **Sharp.AI**, an end-to-end deep learning pipeline for cross-sectional and longitudinal radiographic assessment.

Method

• Data & Study Design

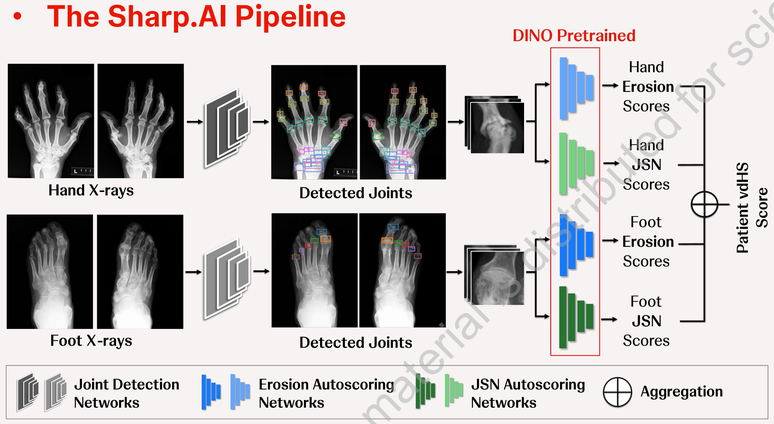
- Longitudinal PsA and RA clinical trial X-rays
- Multiple timepoints (baseline → follow-up)
- Expert reader panel as reference
- Multi-site data spanning hundreds of sites: PsA (19 countries) and RA (31 countries).

Table 1. Demographic of (a).PsA and (b).RA Dataset

a. PsA Data		Missing	Overall	Training	Validation	Holdout Test
N			1401	840	211	350
Age, Median [Q1,Q3]			48.0 [39.0,55.0]	48.0 [38.0,56.0]	46.0 [36.0,53.0]	48.0 [40.2,56.0]
Sex, n (%)	Female		679 (48.5)	380 (45.2)	100 (47.4)	199 (56.9)
	Male		722 (51.5)	460 (54.8)	111 (52.6)	151 (43.1)
BMI, Mean (Std)		2	30.2 (7.0)	30.5 (7.2)	29.3 (7.0)	30.0 (6.6)
PsA-modified vdHS, median [Q1,Q3]		13	12.5 [3.5, 34.2]	12.0 [3.5, 34.1]	13.0 [4.0, 36.2]	12.8 [3.6, 33.5]

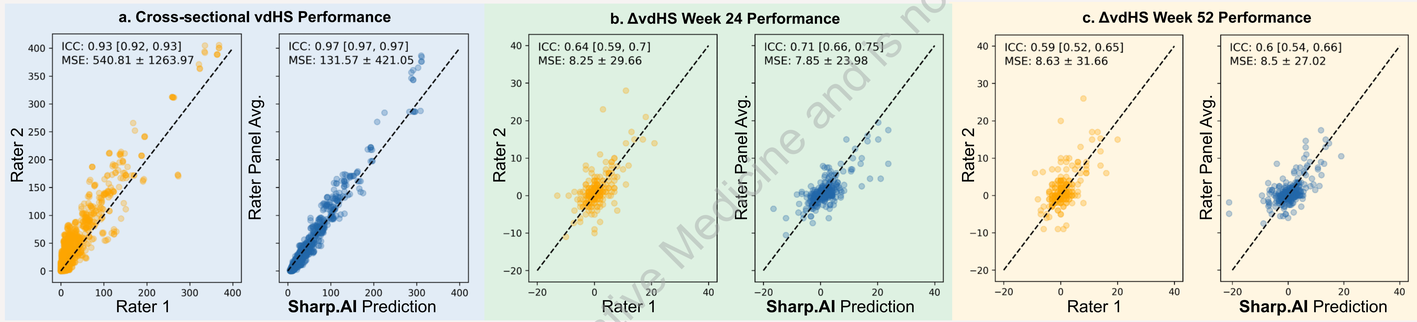
b. RA Data		Missing	Overall	Training	Holdout Test
N			2749	2153	596
Age, Median [Q1,Q3]			53.0 [44.0,60.0]	52.0 [44.0,60.0]	54.0 [45.0,62.0]
Sex, n (%)	Female		2219 (80.7)	1737 (80.7)	482 (80.9)
	Male		530 (19.3)	416 (19.3)	114 (19.1)
BMI, Mean (Std)		4	27.2 (6.1)	27.1 (6.0)	27.6 (6.5)
vdHS, median [Q1,Q3]		27	16.5 [4.5,49.4]	16.5 [4.5,49.0]	16.5 [4.5,51.0]

• The Sharp.AI Pipeline



Results

• Patient-level Performance on PsA Test Set



End-to-end **Patient-level**	Rater 1 vs. Rater 2		**Sharp.AI** vs. Rater Panel Avg.	
Task (Evaluated Samples #)	ICC [95% CI]	MSE (Mean ± Std.)	ICC [95% CI]	MSE (Mean ± Std.)
a. Cross-sectional vdHS (1,575)	0.93 [0.92, 0.93]	540.81 ± 1263.97	**0.97 [0.97, 0.97]**	**131.57 ± 421.05**
b. ΔvdHS Week 24 (420)	0.59 [0.52, 0.65]	8.63 ± 31.66	**0.6 [0.54, 0.66]**	**8.5 ± 27.02**
c. ΔvdHS Week 52 (424)	0.64 [0.59, 0.7]	8.25 ± 29.66	**0.71 [0.66, 0.75]**	**7.85 ± 23.98**
ΔvdHS Week 100 (123)	**0.88 [0.83, 0.91]**	**11.27 ± 38.76**	0.86 [0.80, 0.90]	15.07 ± 41.36

Q1: 25th percentile. Q3: 75th percentile. MSE: mean squared error; Std.: Standard deviation; ICC: intraclass correlation coefficients; CI: Confidence Interval

• Joint-level Performance on PsA Holdout Test Set

End-to-end **Joint-level**	Rater 1 vs. Rater 2		**Sharp.AI** vs. Rater Panel Avg.	
Task (Evaluated Joints #)	ICC [95% CI]	MSE (Mean ± Std.)	ICC [95% CI]	MSE (Mean ± Std.)
Foot BE (13,014)	0.87 [0.85, 0.88]	0.86 ± 5.49	**0.94 [0.94, 0.95]**	**0.39 ± 2.1**
Foot JSN (13,014)	0.91 [0.9, 0.92]	0.23 ± 0.81	**0.97 [0.97, 0.98]**	**0.08 ± 0.24**
Hand BE (43,187)	0.87 [0.86, 0.88]	0.3 ± 1.2	**0.9 [0.89, 0.91]**	**0.15 ± 0.72**
Hand JSN (43,185)	0.91 [0.9, 0.91]	0.23 ± 0.85	**0.97 [0.97, 0.97]**	**0.08 ± 0.31**

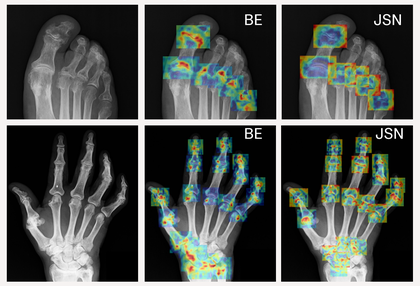
• Patient-level Performance on RA Holdout Test Set

End-to-end **Patient-level**	Rater 1 vs. Rater 2		**Sharp.AI** vs. Rater Panel Avg.	
Task (Evaluated Samples #)	ICC [95% CI]	MSE (Mean ± Std.)	ICC [95% CI]	MSE (Mean ± Std.)
Cross-sectional vdHS (2,883)	**0.96 [0.96, 0.96]**	**164.41 ± 352.43**	0.95 [0.95, 0.96]	179.76 ± 344.71
ΔvdHS ≤ Week 24 (377)	0.64 [0.57, 0.69]	8.21 ± 34.42	**0.65 [0.59, 0.71]**	**10.19 ± 26.45**
ΔvdHS Week 52 (685)	**0.66 [0.61, 0.7]**	**9.1 ± 29.03**	0.64 [0.59, 0.68]	14.63 ± 36.95
ΔvdHS Week 104 (685)	**0.79 [0.75, 0.82]**	**11.93 ± 39.49**	0.73 [0.68, 0.77]	19.71 ± 75.86
ΔvdHS ≥ Week 208 (230)	0.64 [0.56, 0.71]	23.17 ± 77.33	**0.66 [0.58, 0.73]**	**32.02 ± 81.82**

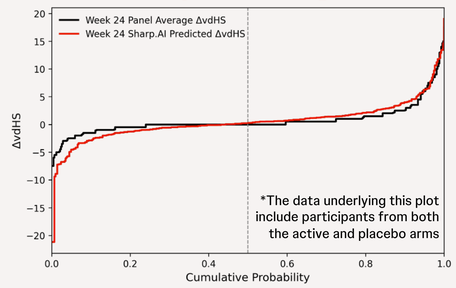
Conclusions

- Sharp.AI provides **accurate cross-sectional patient-level vdHS** estimates.
- The derived **longitudinal measures** align with expert-annotated structural progression.
- Sharp.AI **generalizes well to RA** scoring despite not being trained on RA data.
- The Sharp.AI pipeline provides a **scalable, objective** alternative to manual scoring, with the potential to **accelerate clinical trial workflows** and **improve consistency** in monitoring structural joint damage.
- Future work includes performing **analytical validation** on a **hold out test dataset** to enable regulatory discussion on the potential for Sharp.AI to support and/or **replace a central reader panel** for radiographic analyses endpoints.

• Explainability - Attention Map



• Sensitivity to Change*



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Acknowledgements

Acknowledgement to the **AutoPiX** project supported by the Innovative Health Initiative Joint Undertaking and its members, and other contributing partners under grant agreement No.101194766.

Contact Information

Corresponding author emails:
kstandis@its.jnj.com; rjanicze@its.jnj.com

Conflict of Interest

Authors who are employees of Johnson & Johnson may own stock or stock options in the company. Anna Beutler has previously received consulting fees from Kiniksa Pharmaceuticals and Boston Pharmaceuticals.

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