



Efficacy of Percutaneous Cryoneurolysis for Wrist or Hand/Finger Spasticity

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DISCLOSURES

Paul Winston declares that he has had educational grants and has acted on advisory boards and as a consultant for Pacira BioSciences, Inc.; AbbVie; Merz Therapeutics; and Ipsen.

Mahdis Hashemi has received honoraria from Pacira BioSciences, Inc.

Eve Boissonnault declares that she has received educational grants from AbbVie and has acted on advisory boards and as a consultant for AbbVie, Ipsen, Merz Therapeutics, and Pacira BioSciences, Inc.

Daniel Vincent declares that he has acted as a consultant for Pacira BioSciences, Inc. and received funding per session from Island Health.

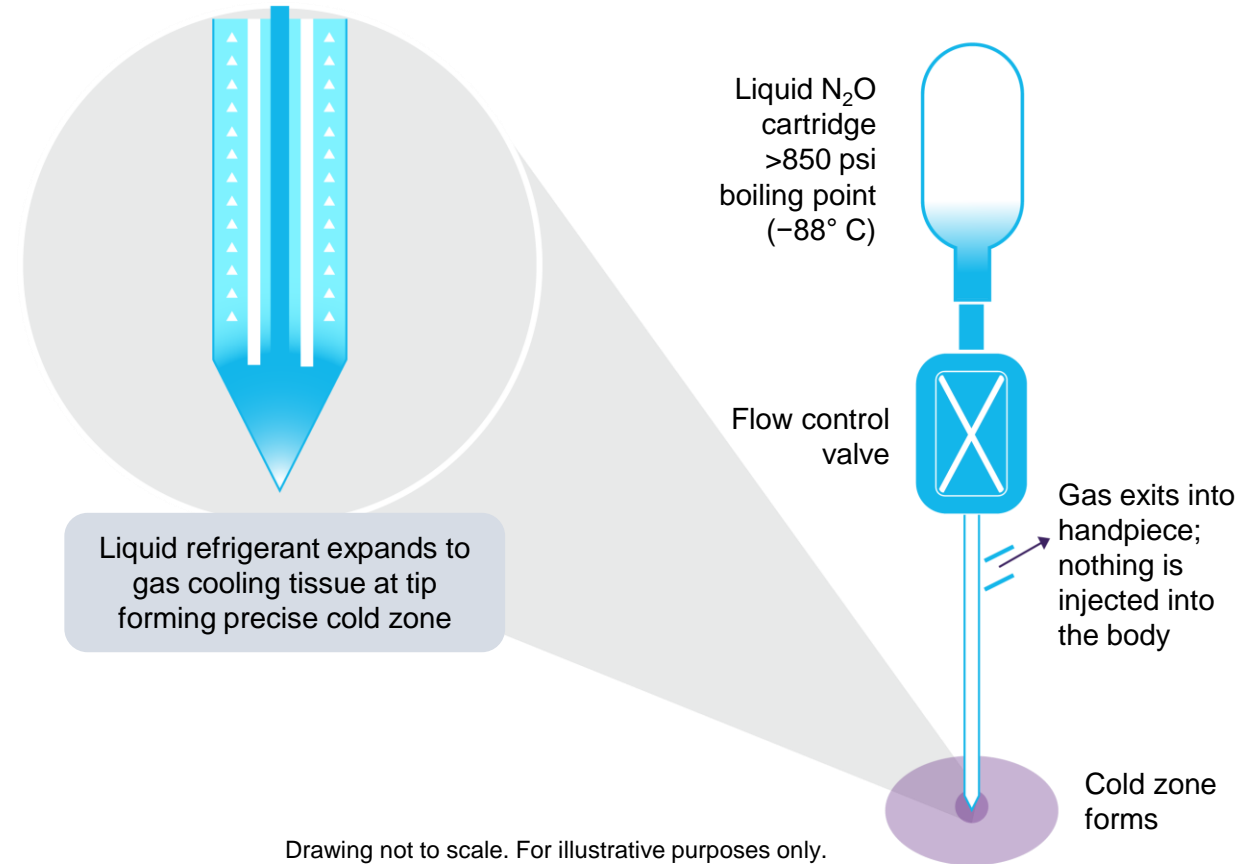
Fraser MacRae has received honoraria from Pacira BioSciences, Inc.

Jia Song and **Sandy Shi** are employees of Pacira BioSciences, Inc.



INTRODUCTION

- Upper extremity spasticity can result in deformities of the wrist, hand, and fingers that may require surgical intervention^{1,2}
- Percutaneous cryoneurolysis is a minimally invasive technique that can be used to treat upper extremity spasticity^{3*}
 - The probe cools to between -60°C and -88°C near the targeted nerve³⁻⁵
 - Cooling causes secondary axonotmesis and Wallerian degeneration, allowing for axonal regrowth^{6,7}
- Effects can be prolonged for 3 months in pain treatment studies⁸
 - Previous case reports have found that improvements in upper extremity spasticity may be maintained for up to 17 months after cryoneurolysis^{3,4}
- However, data for changes in spasticity after cryoneurolysis treatment for the wrist, hand, and fingers are limited



Objective:

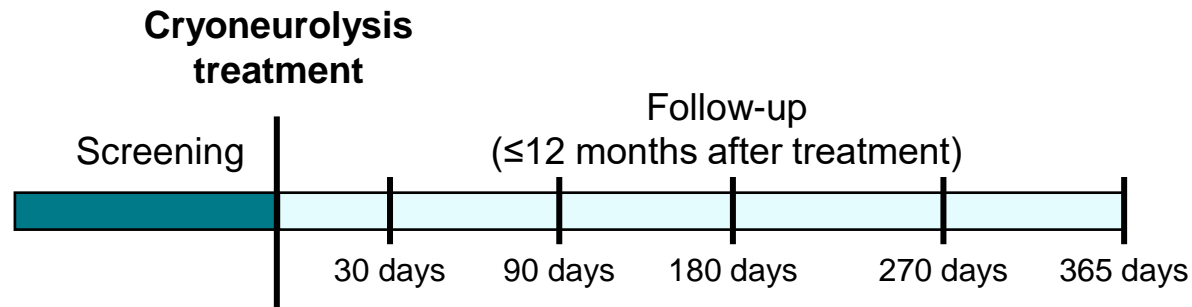
This pilot study evaluated changes in range of motion, spasticity, and wrist, hand, and finger function after cryoneurolysis of the wrist or wrist, hand, and fingers

*Treatment of spasticity is not a currently approved use of the cryoneurolysis device used in this study.

1. Hefter H et al. *Int J Rehabil Res*. 2012;35(3):227-233; 2. Rhee P et al. *J Hand Surg Am*. 2019;44(3):223-235; 3. Winston P et al. *Arch Rehabil Res Clin Transl*. 2019;1(3-4):100030; 4. Rubenstein J et al. *Am J Phys Med Rehabil*. 2021;100:e65; 5. Shaffer JP et al. *Orthop J Sports Med*. 2022;10(5):23259671221096095; 6. Ilfeld BM et al. *Expert Rev Med Devices*. 2016;13(8):713-725; 7. Sunderland S. Nerves and Nerve Injuries. United Kingdom: Churchill Livingstone; 1968:18; 8. Radnovich R et al. *Osteoarthritis Cartilage*. 2017;25(8):1247-1256.

METHODS: STUDY DESIGN

- This repeated-measures pilot study (NCT04670783) included adults who had refractory spasticity with less than full ROM in the wrist or the hand and fingers
 - Percutaneous cryoneurolysis was applied either to the mixed motor sensory trunk of the median and/or ulnar nerve or to the individual muscle branches or intramuscular branches
 - Some participants received cryoneurolysis for multiple sites, including the shoulder and elbow



Outcome	Measure*
AROM	AROM during extension
MAS score	Muscle tone during extension
V1	Maximal passive stretch during extension
Manual dexterity	Box and block test
Hand function	House Functional scale
Thumb deformity	House Classification
Upper extremity function	DASH scores

*Each was measured at 30, 90, 180, 270, and 365 days.

AROM, active range of motion; DASH, Disabilities of the Arm, Shoulder, and Hand; MAS, modified Ashworth scale; ROM, range of motion; V1, maximal passive stretch.

METHODS: ELIGIBILITY CRITERIA

Inclusion criteria

- Adults who had refractory spasticity with less than full ROM in the wrist or the hand and fingers
- Clinical examination demonstrated that further ROM in the muscle may be possible
- Muscle had reducible spasticity as measured by an ultrasound-guided e-stimulation diagnostic nerve block
- Participants were offered a cryoneurolytic procedure and consented to undergo the procedure

Exclusion criteria

- Being unable to attend the treatment schedule
- Prior neurolytic procedure to the nerve such as phenol or cryoneurolysis in the past 2 years

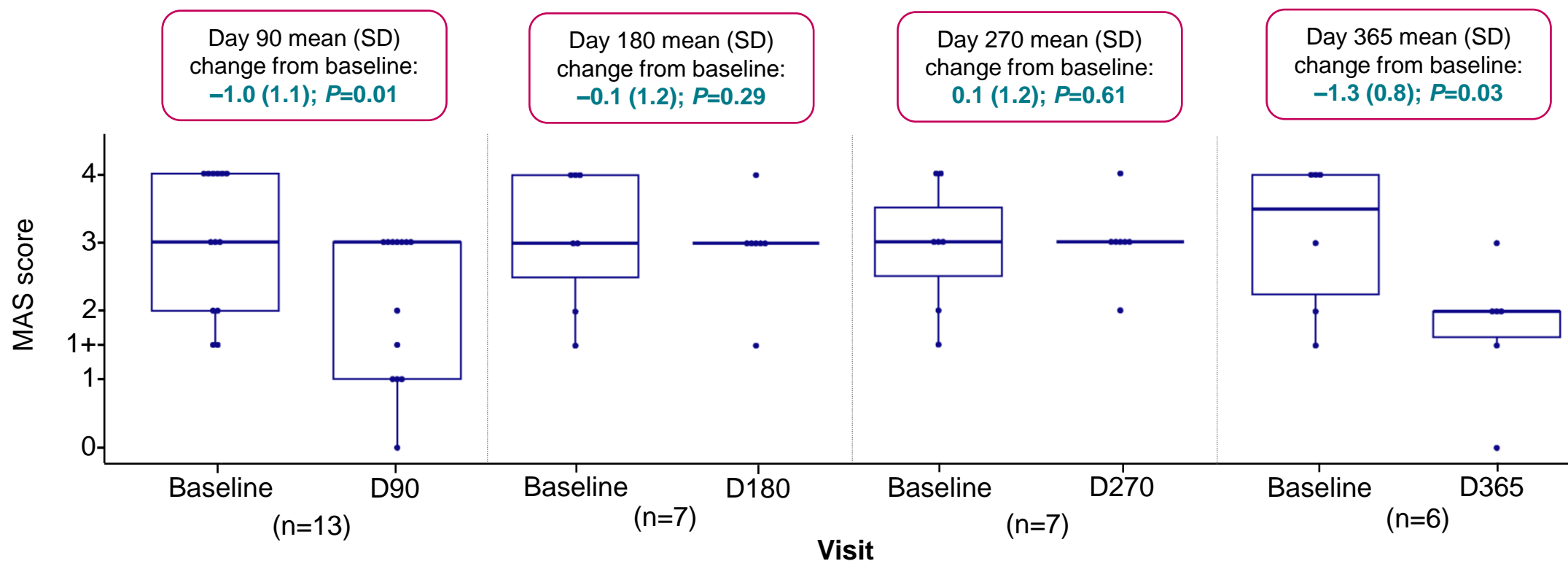
RESULTS: BASELINE CHARACTERISTICS

- 29 participants received cryoneurolysis for hand/finger flexor muscles, and 18 of these participants also received cryoneurolysis for wrist flexor muscles
- At baseline, mean AROM and V1 were low, the mean wrist extension MAS score was high, and most participants had thumb deformity and low upper extremity function

Outcome	Value
Demographic and baseline characteristics	
Age, mean (SD), y [n]	59.7 (16.8) [29]
Sex, n (%)	
Male	14 (48.3)
Female	15 (51.7)
Wrist Extension AROM, mean (SD) [n]	22.9° (27.1°) [7]
Wrist Extension MAS score, mean (SD) [n]	3.0 (1.0) [17]
Wrist Extension V1, mean (SD) [n]	37.5° (37.7°) [17]
Hand function, mean (SD) [n]	0.68 (1.5) [25]
House functional scale score, n	
Type I	9
Type II	7
Type III	1
Type IV	7
Box and block test, mean (SD), blocks/min, [n]	2.6 (4.0) [21]
DASH score, mean (SD)	62.8 (22.0)

RESULTS: WRIST EXTENSION MAS SCORES

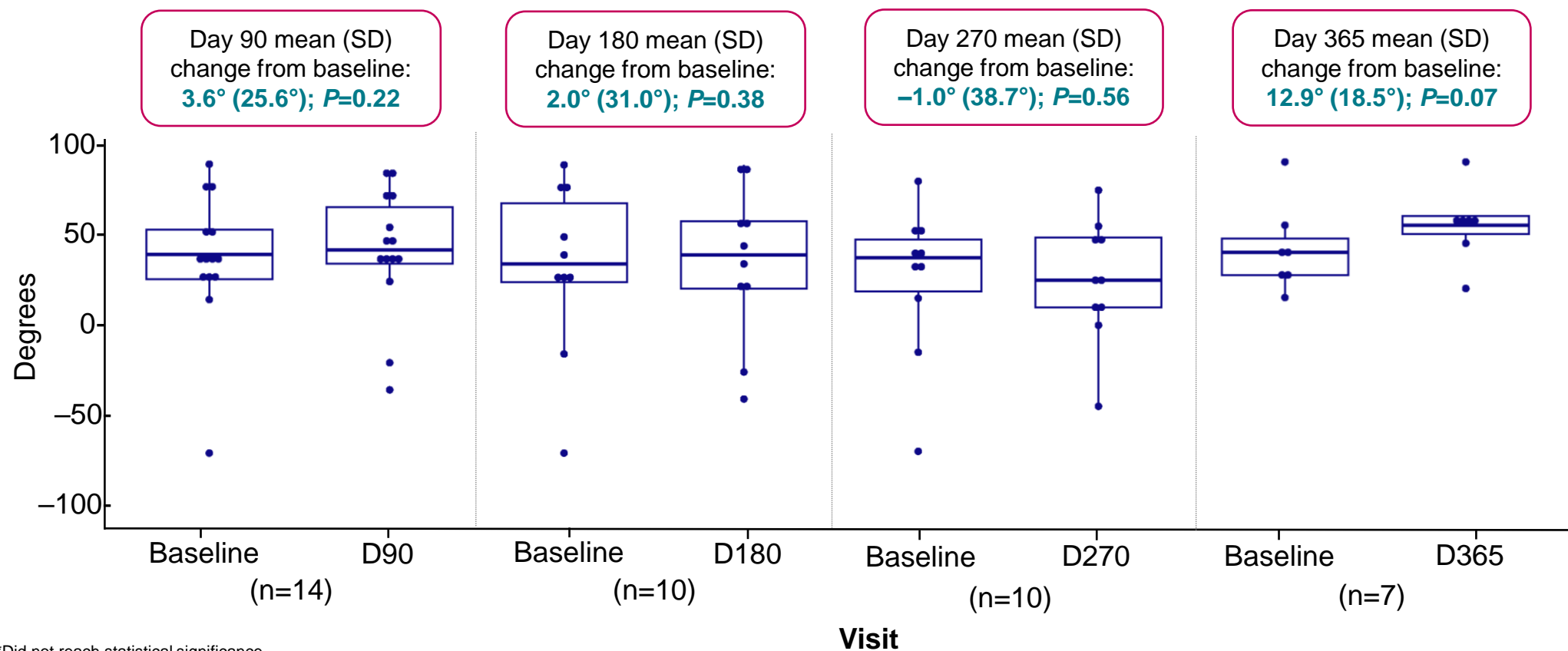
- MAS scores numerically decreased at Day 180 compared with baseline*
- MAS scores significantly decreased at Day 90 and 365 compared with baseline



*Did not reach statistical significance.
MAS, Modified Ashworth scale; SD, standard deviation.

RESULTS: WRIST EXTENSION V1

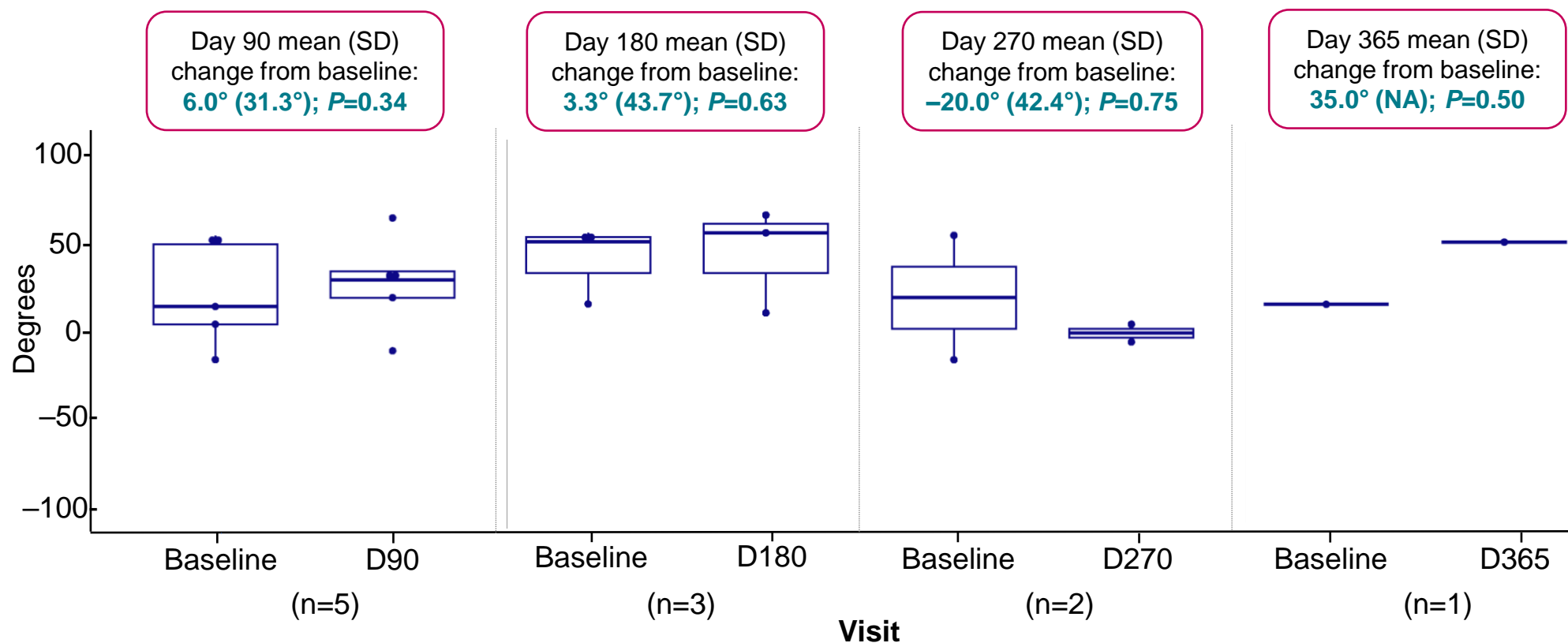
- V1 increased at Day 90, 180, and 365 compared with baseline*



*Did not reach statistical significance.
V1, maximal passive stretch.

RESULTS: WRIST EXTENSION AROM

- Change in wrist extension AROM from baseline was evaluated for participants with active movement at baseline (n=7)
- AROM increased at Day 90, 180, and 365 compared with baseline*



*Did not reach statistical significance.

AROM, active range of motion; NA, not available; SD, standard deviation.

RESULTS: CHANGE IN V1, AROM, AND MAS FROM BASELINE

Outcome	Mean (SD) change from baseline	P value
Wrist extension MAS		
Day 90	−1.0 (1.1)	0.01
Day 180	−0.1 (1.2)	0.29
Day 270	0.1 (1.2)	0.61
Day 365	−1.3 (0.8)	0.03
Wrist extension V1		
Day 90	3.6° (25.6°)	0.22
Day 180	2.0° (31.0°)	0.38
Day 270	−1.0° (38.7°)	0.56
Day 365	12.9° (18.5°)	0.07
Wrist extension AROM		
Day 90	6.0° (31.3°)	0.34
Day 180	3.3° (43.7°)	0.63
Day 270	−20.0° (42.4°)	0.75
Day 365	35.0° (NA)	0.50

RESULTS: HAND FUNCTION AND THUMB DEFORMITY

- There was an improvement in hand function based on House functional classification at Day 180 and 365 compared with baseline*
- Based on thumb-in-palm House classification, improvements in thumb position were observed at Day 180 and Day 365*

Hand functional scale

180 days (n=14) mean (SD) change from baseline **0.1 (1.2); $P=0.43$**

365 days (n=4) mean (SD) change from baseline **0.5 (1.0); $P=0.5$**

Thumb position classification

8 participants exhibited ordinal improvements from baseline to Day 180
Type IV to Type II: n=3
Type IV to Type III: n=1
Type II to Type I: n=4

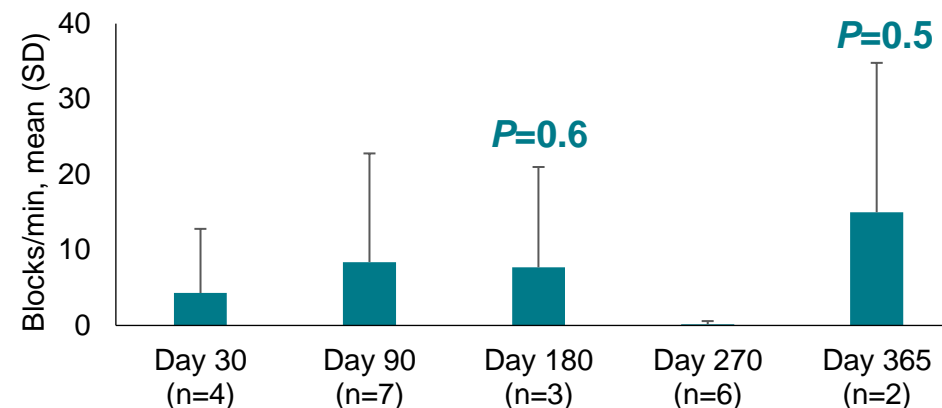
2 participants exhibited ordinal improvements from baseline to Day 365
Type II to Type I: n=1
Type IV to Type II: n=1

*Did not reach statistical significance.
SD, standard deviation.

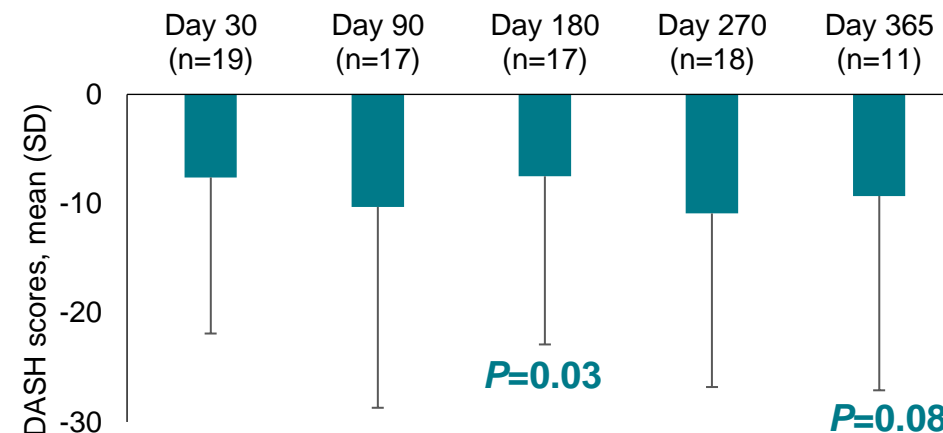
RESULTS: MANUAL DEXTERITY AND UPPER EXTREMITY FUNCTION

- The number of blocks moved by participants at Day 180 and Day 365 were numerically increased compared with baseline*
- DASH scores were significantly reduced at Day 180 compared with baseline
- DASH scores were numerically reduced at Day 365 compared with baseline*

Manual dexterity change from baseline



DASH score change from baseline



*Did not reach statistical significance.

DASH, Disabilities of the Arm, Shoulder, and Hand; SD, standard deviation.

CONCLUSIONS



Percutaneous cryoneurolysis of the wrist and/or hand, finger flexor muscles, or the innervating nerves was associated with improvements in wrist active and passive range of motion and spastic tone 365 days after treatment



There were improvements in thumb-in-palm deformity House classification, House classification for hand function, manual dexterity, and DASH score 365 days after treatment