

# Physical Therapy Versus Watchful Waiting for the Treatment of Adhesive Capsulitis of the Shoulder

## A Prospective Randomized Controlled Trial

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### BACKGROUND

- **Adhesive capsulitis (frozen shoulder)** is a painful condition characterized by<sup>1</sup>
  - capsular contracture and reduced glenohumeral range of motion (ROM)
- Risk factors include<sup>2</sup>
  - diabetes mellitus, thyroid dysfunction, female sex, age
- Affects approximately 2 to 5% of the general population<sup>3</sup>
- Commonly progresses through 3 stages<sup>4</sup>
  - ‘freezing,’ ‘frozen,’ and ‘thawing’
- Most patients experience symptom resolution with more conservative approaches<sup>5-8</sup>
  - operative management occasionally indicated in refractory cases
- Current standard of care includes<sup>9,10</sup>
  - NSAIDs, corticosteroid injections (CSIs), physical therapy (PT)
- Growing evidence suggests CSIs relieve pain and improve ROM in the short term
  - **still a paucity of high-level evidence supporting PT<sup>9,10</sup>**
- Previous studies have evaluated treatment modalities independent of health care costs
  - hinders value-improvement efforts

This study integrated patient-reported outcome measures (PROMs) with health care costs to compare the value achieved through PT vs. watchful waiting (WW).

#### Hypothesis

PT and WW will confer similar improvements in pain and function, but PT will cost significantly more and generate less value

### METHODS

- Patients in this **parallel randomized controlled trial** were randomized 1:1 to:
  - **PT** (standardized protocol involving 1-2 weekly visits for 8-12 weeks)
  - **WW** (i.e., supervised neglect)
    - \*Both cohorts were offered NSAIDs and CSIs as needed
- **Primary outcome**
  - American Shoulder and Elbow Surgeons Score (ASES)
- **Secondary outcomes**
  - Patient Value (12-month ASES score divided by health care costs)
  - Disabilities of the Arm, Shoulder, and Hand (DASH)
  - Visual Analog Scale (VAS) pain scores

Outcomes assessed at baseline, 6 weeks, 3 months, 6 months, and 12 months

- Health care costs were calculated using patient survey responses collected at 12 months, publicly available hospital fees, U.S. Bureau of Labor Statistics wage estimates, and Internal Revenue Service mileage rates.

- Both costs and patient value were normalized to protect confidentiality

### RESULTS

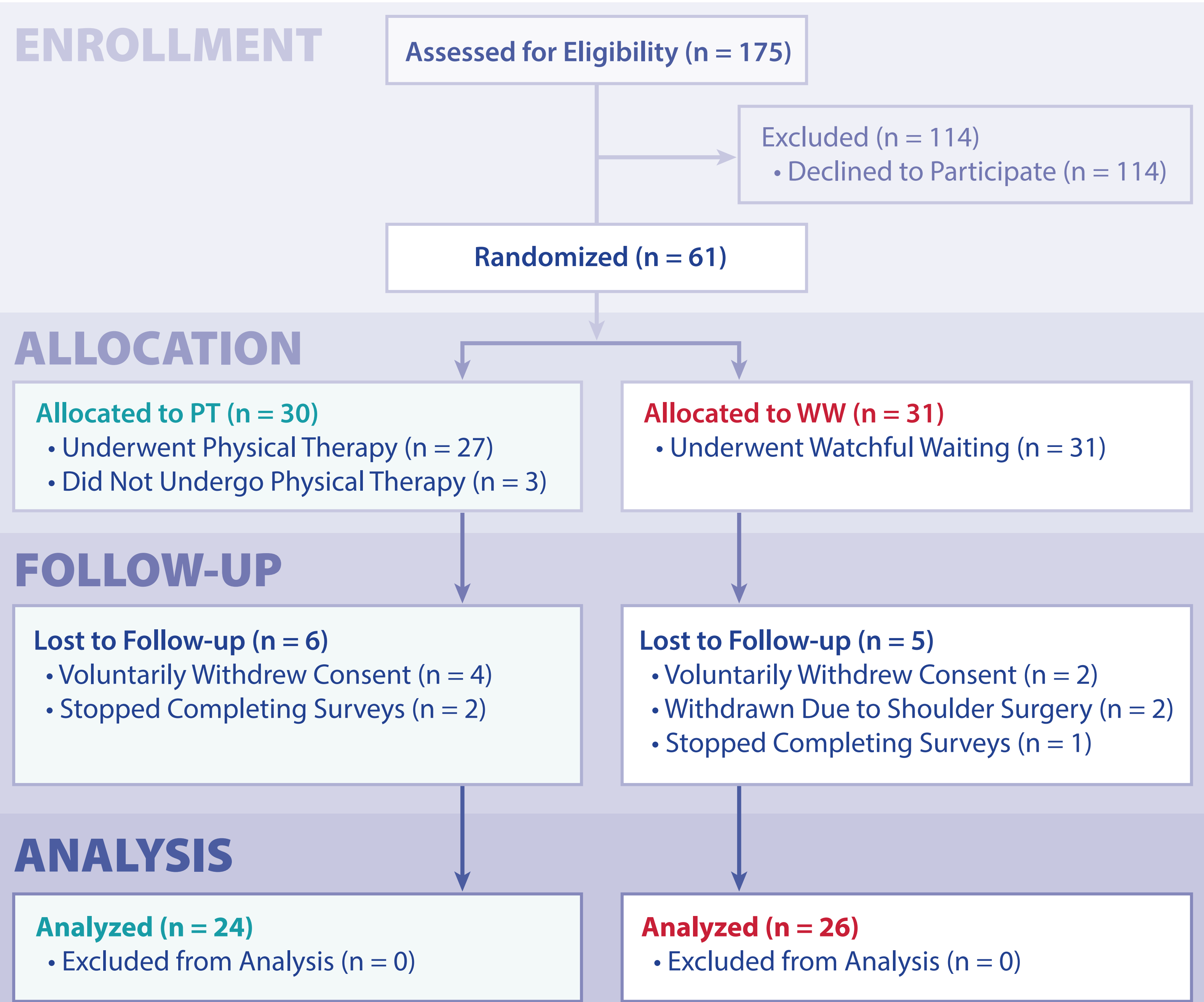
- Between Nov. 2014 and Nov. 2022, we screened 175 patients and enrolled 61 patients (34.9%) (**TABLE 1, FIGURE 1**)

TABLE 1. \*Baseline Patient Characteristics

	Total n = 50	Physical therapy n = 24	Watchful waiting n = 26	P Value†
Age	56.1 (9.6)	56.7 (10.2)	55.5 (9.2)	0.68
Body mass index (kg/m2)	27.8 (5.1)	27.0 (4.8)	28.5 (5.4)	0.33
Gender				0.14
Female	33 (66.0)	13 (54.2)	20 (76.9)	
Male	17 (34.0)	11 (45.8)	6 (23.1)	
Race				0.85
Asian	7 (14.0)	4 (16.7)	3 (11.5)	
Black or African American	1 (2.0)	0 (0.0)	1 (3.8)	
White	42 (84.0)	20 (83.3)	22 (84.6)	
Ethnicity				1.00
Hispanic or Latino	1 (2.0)	0 (0.0)	1 (3.8)	
Not Hispanic or Latino	49 (98.0)	24 (100.0)	25 (96.2)	
Corticosteroid injections				0.29
0	3 (6.0)	3 (11.5)	0 (0.0)	
1	33 (66.0)	14 (53.8)	19 (73.1)	
2	11 (22.0)	6 (23.1)	5 (19.2)	
3	3 (6.0)	1 (3.8)	2 (7.7)	

\*Data are reported as mean (SD) or No. of patients (%). †P values were calculated using Chi-square or Fisher’s exact test for categorical variables and t-tests for continuous variables.

FIGURE 1. CONSORT (Consolidated Standards of Reporting Trials) flow diagram



- In the primary as-treated analysis, there were **no differences in ASES, DASH, or VAS pain scores** between patients assigned WW versus PT over the study period (**TABLE 2, FIGURE 2**)

- Relative to baseline scores, **patients from both cohorts improved significantly** at each time point and for all PROMs

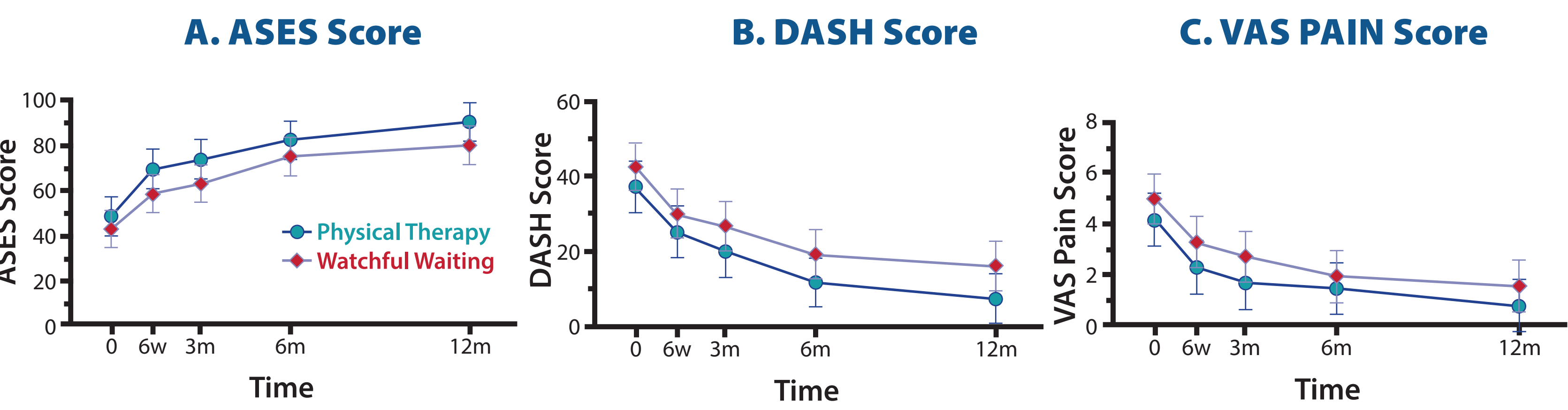
- All results persisted in nonlinear and as-treated sensitivity analyses

TABLE 2. Impact of treatment arm and time on PROMs\*

Predictor variable	Treatment effect	P Value†
<b>ASES</b>		
Physical therapy	8.73 (-1.91, 19.41)	0.11
Time (weeks)	0.66 (0.50, 0.82)	<b>&lt;0.001</b>
Treatment arm x time interaction	0.02 (-0.21, 0.24)	0.89
<b>DASH</b>		
Physical therapy	-6.04 (-14.09, 1.97)	0.15
Time (weeks)	-0.46 (-0.59, -0.34)	<b>&lt;0.001</b>
Treatment arm x time interaction	-0.05 (-0.22, 0.13)	0.60
<b>VAS</b>		
Physical therapy	-0.93 (-2.20, 0.34)	0.16
Time (weeks)	-0.06 (-0.08, -0.04)	<b>&lt;0.001</b>
Treatment arm x time interaction	0.01 (-0.02, 0.03)	0.66

\*Data are reported as average treatment effect (95% confidence interval). Positive (negative) ASES (DASH and VAS) scores indicate superior outcomes. †Boldface: statistical significance.

FIGURE 2. PROMs over time for patients assigned PT vs. WW



- On average, **patients assigned PT incurred 10x higher costs** than those assigned WW
- Correspondingly, **WW resulted in 5.9x higher patient value** than PT (**TABLE 3**)

- **All differences in costs and value expanded nominally in the as-treated sensitivity analysis**

TABLE 3. Normalized health care costs and value associated with watchful waiting versus physical therapy\*

Economic outcome	Total	Watchful waiting	Physical therapy	Mean difference	P value†
Patient cost‡	1,000 (602 - 1,398)	182 (119 - 245)	1,818 (1,170 - 2,466)	1,636 (967 - 2,304)	<b>&lt;0.001</b>
Economic burden§	4,470 (3,340 - 5,601)	2,025 (1,644 - 2,405)	6,916 (5,160 - 8,670)	4,892 (3,047 - 6,737)	<b>&lt;0.001</b>
Patient value§	100.00 (63.63 - 136.37)	176.83 (118.28 - 235.37)	29.86 (12.50 - 47.21)	-146.97 (-207.47 - [-86.47])	<b>&lt;0.001</b>

\*Costs and value are reported as mean (95% confidence interval). †Boldface denotes statistical significance. ‡Cost values were normalized such that the average cost (across both groups) equaled 1,000. §Patient value was normalized to set the study average equal to 100.

### CONCLUSIONS

- **In this study, patients randomized to PT reported similar PROMs but significantly higher costs than those undergoing WW, demonstrating WW as the higher value treatment modality for the management of adhesive capsulitis**

- **Our findings that patients in both groups achieved similar, substantial improvements in shoulder pain and function align with recent meta-analyses and systematic reviews indicating that PT does not influence the long-term progression of adhesive capsulitis<sup>10-12</sup>**

- **Notably, our analysis did not capture non-pecuniary opportunity costs or how attending PT for frozen shoulder may limit PT access for other patients/conditions, both of which would likely further favor WW over PT**

#### Limitations

- reduced sample size, infeasibility of blinding, and limited racial/ethnic diversity

### REFERENCES

1. Neviaser, A.S. & Hannafin, J.A. Adhesive capsulitis: A review of current treatment. Am. J. Sports Med. 38, 2346–2356 (2010). 2. Wang, K. et al. Risk factors in idio-pathic adhesive capsulitis: a case control study. J. Shoulder Elbow Surg. 22, e24–e29 (2013). 3. Sarasua, S.M. et al. The epidemiology and etiology of adhesive capsulitis in the U.S. Medicare population. BMC Musculoskelet. Disord. 22, 1–12 (2021). 4. Hsu, J.E. et al. Current review of adhesive capsulitis. J. Shoulder Elbow Surg. 20, 502–514 (2011). 5. Warner, J.J.P. et al. Arthroscopic Release for Chronic, Refractory Adhesive Capsulitis of the Shoulder. J. Bone Jt. Surg. 78, 1808–16 (1996). 6. Elhassan, B. et al. Arthroscopic capsular release for refractory shoulder stiffness: a critical analysis of effectiveness in specific etiologies. J. Shoulder Elbow Surg. 19, 580–587 (2010). 7. Hand, C. et al. Long-term outcome of frozen shoulder. J. Shoulder Elbow Surg. 17, 231–236 (2008). 8. Levine, W.N. et al. Nonoperative management of idiopathic adhesive capsulitis. J. Shoulder Elbow Surg. 16, 569–573 (2007). 9. Ahn, J.H. et al. Early Intra-articular Corticosteroid Injection Improves Pain and Function in Adhesive Capsulitis of the Shoulder: 1-Year Retrospective Longitudinal Study. PM R 10, 19–27 (2018). 10. Yip, M. et al. Treatment of Adhesive Capsulitis of the Shoulder: A Critical Analysis Review. JBJS Rev. 6, e5–e5 (2018). 11. Page, M.J. et al. Manual therapy and exercise for adhesive capsulitis (frozen shoulder). Cochrane Database Syst. Rev. 2014, (2014). 12. Handley, N. & Hollander, J.E. Opportunity Cost: The Hidden Toll of Seeking Health Care. Health Aff. Forefr. (2019)

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