

Ibrahim MI, Johnson AJ, Pivec R, and et al. Treatment of Adhesive Capsulitis of the Shoulder with a Static Progressive Stretch Device: A Prospective, Randomized Study. Journal of Long-Term Effects of Medical Implants 2012; 22(4): 281-291.

Reviewer: Linda Metzger 3-14-14

Design: Randomized controlled trial

Objective: To compare the effects of standard physical therapy alone (control) to physical therapy used together with a static progressive stretch device (intervention) on range of motion (ROM), function, and pain in subjects with shoulder adhesive capsulitis.

Reasons not to cite as evidence:

- Several outcomes are reported: Visual Analog Scale (VAS) for pain, Disabilities of the Arm, Shoulder, and Hand questionnaire (DASH) for function, and three outcomes measuring range of motion (ROM) (passive and active abduction, and passive external rotation), and follow-up measurements at 4,12, and 24 weeks.
- The designation of a primary outcome was not clear.
- The main author was the assessor who performed all outcome measurements and was by the study's design, blinded to the treatment group of each patient. However, protocol violations did occur (how many are not reported), and the assessor inadvertently discovered the treatment group when patients did not keep this information confidential. This is a threat to the internal validity of the study and the outcome measurements would be at high risk of bias.
- Baseline characteristics did not differ between the two groups, but were rather suspiciously similar. The mean baseline DASH score was 73 for both groups and the standard deviations were 3 and 5 for the 2 groups. Typical standard deviations from 3 other studies for baseline DASH scores ranged from 10 to 25. The extremely small standard deviations reported in this study showed 3 to 5 times less variation in the distributions than is typically observed and are uncanny and very suspicious.
- No information was provided on how the participants were recruited or referred into the study.
- The presentation of the outcome data was insufficient. In order to understand the long-term outcomes of interventions, it is important to evaluate the longest follow-up data. However, follow-up data for 12 and 24 weeks including means and standard errors of the mean as actual numbers in tables was not provided. Only simple graphs were presented and did not include any actual means or standard errors of the mean.
- No attempt was made to evaluate or report adherence to the in-home exercises, and so compliance differences between groups could not be assessed.
- Patients in the intervention group were given a daily log to record compliance with the use of the static progressive stretch device. However, no compliance data was reported.
- Both groups showed huge improvements in DASH scores, VAS scores, and ROM at the end of the 4 week intervention. The physical therapy exercise program appears to be effective in reducing pain and increasing function in patients with adhesive capsulitis. While the experimental group appeared to level off or continue to improve

at the 12 and 24 week follow-ups, the control group experienced decreases in improvements in all outcome measurements at the 12 and 24 week follow-ups. Some of the improvements seen may in part be attributed to the natural recovery of the condition over time.

- The mean DASH score decreased in the experimental group from 73 to 5 (68 points) in the control group from 73 to 15 (58 points) at 4 weeks. Both groups showed vast functional improvements that were statistically significant. The small DASH difference observed (10 points) between the groups was statistically significant, but was not clinically significant. Fifteen points represents the difference in score to be considered clinically significant.
- All static progressive stretch devices were provided at no charge by the manufacturer of the device. To rent these devices for 60 people for 4 weeks each would have cost \$30,000. No other external funding was provided. This amount of financial support from the manufacturer lends itself to some mistrust of the integrity of the study.
- There were too many issues to make any evidence recommendations and the author's conclusions were also too weak for evidence.

Interesting Observations:

The authors did report huge improvements in all 3 range of motion measurements in both groups, but a significantly greater increase in the intervention group compared to the control group. The mean increase after 4 weeks in active abduction was 76° vs 46° , in passive abduction 64° vs 37° , and in external rotation 53° vs 30° . Static progressive stretch devices appear to have the potential to restore joint range of motion faster than physical therapy alone.