Reviewer's report

Title: Adhesive Capsulitis and Dynamic Splinting: a Controlled, Cohort Study

Version: 1 Date: 5 May 2009

Reviewer: Joy C Macdermid

Reviewer's report:

Major comments

I am concerned about the following statement. You cite a case study that suggested early intervention is preferable however this is a controversial point and there are higher quality studies that would suggest that frozen shoulder can be a self-limiting condition. It would be inappropriate to suggest that this single case study is the definitive evidence. While I agree there are limitations in the cohort studies that suggest frozen shoulder is self-limiting these are not refuted by citing a single case study. It is also inappropriate to avoid discussing literature that does not support your position.

The importance of early intervention in treating adhesive capsulitis was discussed by Earley and Shannon [7] in a case study of a 53 year old woman. Upon diagnosis, the patient was immediately enrolled in a therapeutic program which included flexibility training and occupational therapy protocols. They concluded that immediate, conservative treatment was best to prevent the “downward spiral of forced disuse” which may lead to contracture.

The purpose for the four groups compared is unclear and no justification is provided for these in the research question or preceding literature review.

I am concerned about leaving out patients who are noncompliant with therapy from the intervention groups. Please consider an intention to treat analysis. By analyzing only those who followed the splint protocol you are likely overestimating the treatment effects when applied in clinical practice. It is appropriate to perform both an intention to treat and efficacy analysis but I would argue inappropriate to only have the latter in place.

The samples in each treatment arm are exceptionally small. While the authors might argue that lack of power is not at issue given that they found significant results, I would argue that small sample sizes make it more difficult for us to be confident about generalizing the results to other situations. I think it would be important to discuss this limitation. See the comment below concerning the analysis you performed. If you did not perform a between group comparisons analysis and power may remain an issue.
It is unclear whether all groups were provided standardized wear instructions and home programs. How was adherence measured? Was the dosage similar across comparison groups?

There is no discussion of the size of improvement in external Range of motion as compared to that obtained in the previous study cited that use stretching etc..

External range of motion is certainly limited in this condition but is not the most functional range. It is a limitation that this was the only range studied. Surely there must be data on forward flexion for these cases it seems unlikely that it would not have been recorded as it would be standard practice. Why is this data not available?

The allocation procedure is unclear and in fact the lack of randomization is not clear until the conclusions (inappropriate placement of this content). This is a major limitation for the study since there is the possibility for bias in allocation of patients to certain groups.

There is very little discussion of the actual methods used for analysis other than mentioning the software. Please name the specific tests and whether the data fit the underlying assumptions.

When I did a simple t-test using your means and standard deviations to compare the physical therapy group to the group with physical therapy and splinting, I obtained only a 57% probability of difference between the groups (which would clearly fall short of a 95% benchmark). You cite doing repeated measures ANOVA which does provide a more efficient analysis for the within treatment effects. However repeated measures would be inappropriate for the between group comparisons. If you used a statistical procedure that does not allow you to do repeated measures on one factor and group measures on the other (such as generalized linear modeling) then you may have used an inappropriate analysis for your data.

Minor comments

The following is a long run-on sentence with two concepts- please divide

This condition therefore is a serious pathology, which is also known as “Frozen Shoulder” with three phases: 1) The Painful stage is characterized by the gradual onset of diffuse shoulder pain and which usually lasts one to two months; 2) The Frozen stage is characterized by progressive loss of motion (particularly glenohumeral external rotation) which lasts several months to a year or longer [8], and decreased capsular volume in the frozen stage can be visualized with MRI or MRA, for differential diagnosis; 3) The Thawing stage is the final stage
during which range of motion gradually improves over several months to years. Range of motion deficits may continue to be unresolved for more than 3-5 years following the onset of AC. Cont

The following statement sounds information provided by a distributor for a product and does not belong in a scientific paper

Last year 2,500 patients fit with the SDS worldwide, which has been designed to help the patient stretch the shoulder in multiple planes.

The following statement is unclear and needs to be reworded to make it clear what the purpose and specific comparison groups are. The subsequent statement defining the purpose also makes no mention of what constitutes the 4 comparison groups-hence there is not a proper introduction to what the comparison groups are -and why they might be different presented in the introduction.

This study was a three-month prospective, cohort, study examination of the active external rotation of the shoulder, (supine position with humerus abducted to 90°). The null hypothesis was that no change in ROM would be evident for any group or between groups.

New literature is introduced in the conclusions. This is not appropriate in scientific writing.

In studies of specific products it is always important to have full disclosure from the authors about any benefits received for conduct of the research. Please ensure you do so.

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Needs some language corrections before being published

**Statistical review:** Yes, and I have assessed the statistics in my report.