

Comparative Effectiveness Research Review Disposition of Comments Report

Research Review Title: *Comparative Effectiveness of Nonoperative and Operative Treatment for Rotator Cuff Tears*

Draft review available for public comment from November 10, 2009 to December 8, 2009

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Comments to Research Review

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Comments on draft reviews and the authors' responses to the comments are posted for public viewing on the EHC Program Web site approximately 3 months after the final research review is published. Comments are not edited for spelling, grammar, or other content errors.

The tables below include the responses by the authors of the review to each comment that was submitted for this draft review. The responses to comments in this disposition report are those of the authors, who are responsible for its contents, and do not necessarily represent the views of the Agency for Healthcare Research and Quality.

Section	Comment	Response
Introduction	The clinical examination is also used tyo determine IF there is a RC tear as well (not just the size of the tear). This evidence should be reveiwed briefly for the reader.	The following statement describes the use of clinical examination in determining the presence of an RC tear (page 14): “Diagnosis of an RC tear involves a complete history, appropriate clinical examination, and a comparison of the involved shoulder to the uninjured side.” Although clinical assessment is part of the diagnostic work-up, the literature indicates that clinical tests have poor accuracy. The following statement has been revised to reflect this (page 14): “Since most clinical tests for rotator cuff pathology have been shown to have poor diagnostic accuracy{Hughes, 2008 8223 /id} and give poor estimates of cuff tear size,{Bryant, 2002 1041 /id} diagnostic imaging should be employed as part of the preliminary work-up for chronic shoulder pain.”
Introduction	Subacromial decompression does not always involve the removal of the CA ligament. Suggest changing to "may" involve removal of CA ligament.	Thank you for this observation. We have revised the statement as follows (page 15): “Subacromial decompression combines an acromioplasty with the removal of the subacromial bursa and, in some cases, removal of the coracoacromial ligament.”
Introduction	DASH measure is commonly used in studies	The DASH is listed in the summary of frequently reported outcome measures of Table 1 (page 17). The names of the nine commonly used functional scales were not listed in the text in order to reduce redundancy with the accompanying table.

Introduction	<p>1. Outcome tools chart: Scaling column: not all scales have indicated the Range of the scale (Ex: SST is 0-12 points). For each scale, it would be helpful to indicate the exact value that indicates better shoulder function (Ex: SST 12=full function).</p> <p>2. Evidence for outcome tools is not up to date.</p> <ul style="list-style-type: none"> - PENN reference is Leggin BL, et al, JOSPT, 2006. - ASES, DASH, SST, SPADI psychometric properties: more references (see RoyJS et al, Arthritis Rheum, 2009) <p>3. Please delete ref #42, replace with Leggin et al. as the original reference.</p> <p>4. The authors suggest for future research for consensus for the clinical important change/ differences. There is currently information for the presented outcome tools for the MCID / MCIC. The outcome tools chart may benefit from this currently known psychometrics.</p>	<p>We have revised the outcome measures summary table (see table 1, page 17) to include information on the MCID for the scales whenever possible and have updated the references for the psychometric properties of the scales based on the citations provided. In addition, for each scale, we have specified the number of items, the overall scale and indicated which score represent best and/or worst outcomes. Thank you for this feedback.</p>
Introduction	<p>Diagram does not appear to match Key Question #6: there is no arrow from the pt/ clinical factors to the outcome for non-operative, which is part of Q#6.</p>	<p>Thank you for this observation. As reflected by the key question, the arrow was intended to refer to outcomes for all interventions. We have rearranged the diagram to clarify this.</p>
Introduction	<p>In the executive summary, write KQ number next to each title when summarizing results.]</p>	<p>The key question number has been added before each title in the executive summary results section.</p>
Introduction	<p>List target population and audience under objectives.</p>	<p>We have added the following statement to our objectives (page 20): “The report is intended for a broad audience, including professional societies developing clinical practice guidelines, patients and their care providers, as well as researchers conducting studies on treatments of this condition.”</p>
Introduction	<p>Really appreciated the outcome measures table - referenced it several times throughout the text</p>	<p>Thank you for this feedback. We are happy to hear that the outcome measures table was helpful in reading and interpreting the report.</p>
Introduction	<p>No comments. Very clear</p>	<p>Thank you for this kind comment.</p>
Introduction	<p>[The problem and the questions were articulated clearly</p>	<p>Thank you for this kind comment.</p>

Methods	Since there are limited head to head trials, perhaps network meta analysis can be utilized to answer some of the questions or clarify some of the issues.]	We were unable to conduct network meta-analyses in this review. In order to conduct network analysis to indirectly compare interventions A and B, there need to be sufficient studies that directly compare a third intervention (C) with both A and B. Such analyses would be best suited for interventions that are discrete and standardized across studies, e.g., comparisons of drugs A, B, and C. In our review, interventions were highly complex, consisted of many and varying components and were poorly described. Also, for most interventions, evidence was sparse. Therefore, we felt it was inappropriate to attempt combining studies through indirect comparison.
Methods	Sorry if I missed this - was looking for info on how minimal clinical important difference was calculated or method usedI felt comparatively that the statistical methods could have been elaborated on a bit more.	Minimal clinical importance difference was defined as a difference exceeding 10% on a given scale (e.g. 10-point differences on the 100-point CMS). This decision was based on precedents set in the rotator cuff literature for visual analogue scales (see Tashjian RZ et al 2009). A statement describing the MCID has been added to the statistical methods section on page 27: “Statistically significant results were considered to be clinically relevant if they exceeded a minimal clinically important difference of ten percent on any given scale.{Tashjian, 2009 14995 /id}”
Methods	Methodlogy is well described	Thank you for this kind comment.
Methods	[described clearly	Thank you for this kind comment.
Results	correction: "one" should be changed to "two". There are two studies (#168, and #145) comparing nonoperative treatments. Study #145 compares nonoperative and operative treatments as well, so should be included in the last part of the sentence as well.	The sentence now reads: “Three studies (one RCT{Shibata, 2001 1154 /id} and two retrospective cohort studies{Leroux, 1993 3849 /id;Vad, 2002 1050 /id}) compared the effectiveness of nonoperative treatments in patients with RC tears.”
Results	reference source not found	Thank you. The reference source has now been identified.
Results	add: "... in addition to home exercise 'versus home exercise' and found no"	The sentence has been revised as follows (page 104): “One RCT evaluated individualized physical therapy in addition to home exercise versus home exercise alone”

Results	Rehav versus no rehab (Leroux et al, #168) used the outcome tool named the 'scapular functional index'. I am not sure that this is actually an outcome tool. Might it be a measure of scapular position? I could not find the article by Leroux, nor any reference of the scapular functional index. Please define this measure, and clarify that this is a measure of function / disability.	The Scapular functional index is a measure of function that was used in only this one study. We have add a brief description of the scale in the paragraph outlining the Leroux study (page 132): "Patients were evaluated using the Scapular functional index, a 100-point functional scale with five components (pain, motility, function, power and stability)"
Results	Please define location of the steroid injection for non-operative treatments: was the steroid injected into the GH joint or subacromial space?	We have defined the location of the steroid injection whenever the studies specified this information. In cases where no indication of injection site was provided, we have stated that the location was not described.
Results	Galatz et al paper 21 page 348 excluded because of the authors statement of not having baseline data which is not accurate as the same cohort was studied 10 years earlier and cited in JBJS Iannotti paper 92 which was included. The Galatz study is the only prospective longitudinal chort study in the literature.	Thank you for bringing this issue to our attention. The Galatz et al (2001) paper was excluded since this publication did not report baseline data (only 2 and 10 year followup data); however we recognize that the baseline scores were presented in the earlier publication of the same study (Iannotti et al 1996). We have addressed this issue by considering the Galatz paper a multiple publication of the earlier study, and have added the 10-year followup data in our results. In addition, we have cited the Galatz publication alongside the Iannotti 1996 publication in the evidence tables.
Results	Harryman paper on cuff integrity was excluded for not having baseline data yet this was not a study that required this information of the intent of validity of the study. It was a study to evaluate cuff integrity post operatively as associated with final outcome and the size of the tear at the time of surgery.	We apologize for the confusion regarding the eligibility of this study. Cuff integrity was not initially identified as an outcome of interest at the study onset; instead, a post-hoc decision was made to extract data on this outcome in the studies that had been included in the review (see page 26). In other words, a study with cuff integrity data had to report on one of the other 6 outcomes in order to be included in the review. In Harryman et al (2003), endpoint data is presented for the SST, however the baseline data for this functional measure is not given. Therefore, the study was excluded due to lack of baseline data.

Results	The Iannotti 93 study quoted no difference in outcome (PENN scores and Cuff integrity) between RCR +/- augmentation. This is true but the authors failed to disclose that the study was aborted due to a high complication rate of hypersensitivity reaction to the graft material in 3/15 patients in the augmentation group. In the complication section paper 93 is cited but only for complications that did not occur in the categories selected by the authors so summarize. Hypersensitive reaction should be cited as a complication and can be listed under seroma or as other complication category. The Walton article in 2007 JBJS not cited showed the same problem with this graft material in RCR. This finding was also demonstrated in other smaller single cohort studies not included that do not meet inclusion criteria for this review. Why was the Walton et al study of Restore JBJS 2007 not cited.	We have inserted the following statement to clarify that the Iannotti et al 2006 study was aborted early (page 97): "The study authors suggest that the lack of statistically significant difference between the groups is attributable to the small sample size; this study was aborted early since it appeared that augmentation would not improve the rates of cuff integrity, the primary study outcome." Also, the three hypersensitivity reactions occurring in the augmentation group have now been added to the complications sections under the seroma category. Thank you for drawing our attention to the Walton et al (2007) study. We have included this study in the operative augmentation section (page 97) and have also reported on the inflammatory reaction events in the complications section.
Results	Add references under summary sections in results under each key question. Some folks will just read the summary and make it helpful to read.	We appreciate your suggestion. We have added references to the summary sections in order to provide more clarity for the reader.
Results	Minor typo - "The mean age of study participants WAS 41.2 to 80 years.	Thank you for catching this typo. The change has been made.
Results	Typo - format of footnote - parentheses	Thank you.
Results	Typo - "A retrospective cohort STUDY..."	The change has been incorporated.
Results	typo - rotation, not rotator	The change has been incorporated.
Results	Consider listing what the "among others" were to be consistent with previous sections	We have omitted "among others" from this sentence since the list includes all the main types of interventions used in the studies. The statement now reads (page 118): "Various types of interventions were examined across the individual studies, including stretching and strengthening, steroid injections, oral medications."

Results	Results are disappointing because of lack of level I and II literature , unfortunate but not unexpected.]	As you have observed, the vast majority of studies on this topic are low level of evidence, precluding definitive conclusions on which treatments are most effective. We hope that authors will find the recommendations for future research helpful in guiding the design and conduct of future studies, in order to address this gap in the evidence.
Results	described clearly and objectively]	Thank you for this kind comment.
Discussion	In various places, the authors state that 'objective' outcome measures should be used in future research (p.20, 163, 165...). The authors describe patient-rated outcome tools as subjective (p.28-29), thus it appears that the overall recommendation is to use objective tools a primary measure or deemed equal to patient-rated measures for outcome assessment. The needs for future research need clarification; it is critical to use patient-rated measures, with the addition of objective measures as appropriate, dependent upon the study. The relationship between impairments (objective measures) and patient-rated outcomes (function / disability) are moderate in shoulder disorders, indicating that improvement in function / pt satisfaction / HRQOL, and pain may be achieved without improvements in impairments.	We apologize for the confusion, and agree that patient-rated measures are critical in the assessment of treatment outcomes in this clinical area. We have rephrased the statements regarding recommendations of outcomes measures for future research, such that they now read as follows (e.g., page 177): "Future research should seek to minimize bias by blinding outcome assessors, using validated and standardized outcome assessment instruments, adequately concealing allocation (where applicable), and handling and reporting missing data appropriately"
Discussion	Typo - "The result is that there IS..."	The change has been incorporated.
Discussion	"Physical therapists" instead of "therapists"	The change has been incorporated.
Discussion	The implications of the major findings were clearly stated but I was looking for some comments beyond the methodological flaws of the literature to explain the lack of clear support for any one intervention. ?diverse pathology presentation	Diverse pathological presentation was certainly a factor influencing the lack of consistency across studies. We have added the following statements to the discussion section (page 176): "Lack of consistency across studies may also be attributable to the variation in pathological presentation of rotator cuff disease. While the majority of patients had full-thickness tears, the size and configuration of the tears, degree of fatty infiltration, and number and type of comorbidities varied widely across the studies included in the review."

Discussion	[Objective and clearly stated - did not exceed the limitations of the studies	Thank you for this kind comment.
Discussion	While the future research section is clear and concise; this is one area where I felt it may be helpful to offer more explicit examples of specific studies and comparisons that are needed. One of the main features of a comprehensive review such as this is to identify gaps. Both researchers and funding panels could benefit from more specific examples of comparisons and study designs that are most desirable.	Thank you for this critical feedback. We have expanded the future research section to provide more specific information on the types of comparisons that are priorities for advancing research in this field. Further, we have identified specific methodological considerations for future research, and have referred readers to several checklists (CONSORT and STROBE) as well as an example of a well-designed study that was included in our review (please see page 177).
Discussion	[The report is thoughtfully constructed and well-presented, but will probably have relatively little impact on clinical practice because its conclusions are so weak. The authors attribute the inability to draw firm conclusions to the deficiencies in the literature and leave it at that. But this is of little help to current patients and providers who must make treatment choices today. Can the authors provide recommendations for how to select a therapy, even in the absence of firm evidence? For example, can evidence from other types of surgery plausibly be brought to bear? If so, what are the strengths and weaknesses of the resulting inference?]	The purpose of AHRQ comparative effectiveness reviews is to identify, evaluate and synthesize the available evidence on a given topic. Specific recommendations for treatment fall beyond the scope of this report and care providers should refer to current clinical practice guidelines for direction on selecting treatments in the absence of solid evidence from the literature. Similarly, an investigation of other types of surgery is beyond the scope of this review.
Discussion	[The section on future research provides sound advice on general principles of study design. However, such statements of general principles seem to have had little impact on the quality of the research studies in this field. Perhaps the authors should be more specific. In particular, an appendix would be helpful within which the design of one or more ideal studies are described in detail. Such an appendix could then be used by professional societies and others to make more specific recommendations regarding future research.]	This is a good observation. In lieu of an appendix, we have provided a reference to an example of a well-conducted randomized controlled trial comparing operative versus nonoperative treatments, as well as references of guidelines for conducting and reporting on various study designs (CONSORT and STROBE). The specific design elements of future studies will vary depending on the research questions being investigated; however authors may find these resources helpful in designing and conducting studies to minimize the risk of bias.
Figures	Results: SMD = -1.32, but in Figure 29 the Std Mean Diff is -1.34. Please correct one of the values.	We have corrected the value in the text, which should have read -1.34. Thank you for identifying this typo.

Figures	Complications: not all re-tears result in pain, loss/ reduction in function and increase in disability. Please clarify this.	We have added the following statement in the complications section to clarify that asymptomatic retears may have remained undetected (page 133): "It should be noted that not all retears are symptomatic (e.g., associated with pain, stiffness, reduced function), therefore some retears may have been undetected in patients who were satisfied with their clinical outcome."
Figures	Comlicated but undrstandable	The tables are complex as there was much information we felt was relevant and should be captured in a tabular format. We are happy to hear that, despite the complexity, the information was presented clearly.
General	Evidence tables (Appendix) Great summary. However, need to add a column stating the quality of the study	Thank you for your suggestion. Summary quality ratings have been added to the first column of the evidence tables for each included study.
General	Small thing - my credentials should include PhD (candidate)	We apologize for the error. Your credentials have been updated.
General	Unfortunately the literature does not give us substantive answers, not an uncommon problem in the medical literature in general and the surgical literature specifically. I am aware that there are a number of studies from the group at Washington U in St Louis that supposedly will answer many of these unanswered questions but since they are not yet published, they obviously cannot be used. I would urge a rapid review of the literature in the near future with a goal of a including this literature base if it is as significant as am led to believe.	Thank you for your suggestion. We similarly identified a number of ongoing studies, in particular several RCTs, which address some of the current gaps in the research evidence. An update of the review may be merited once these studies have been completed and published.
General	The questions were stated clearly, the methodology was sound and transparent, the observations and conclusions were clear, and the future questions are articulated nicely. Unfortunately, this is an area where the questions are clinically important but the existing literature does not allow a comparative assessment of the various interventions.	Thank you for your feedback. We hope that research gaps and methodological issues identified in this report are helpful in directing the course of future research.
General	Exceptionally well done in my opinion. Massive amount of information analyzed and summarized quite well.	Thank you for this kind comment.

General	This is a very thoughtful and well done report. The report authors accurately state what is currently done and why. They carefully and thoughtfully review the scientific literature and appropriately identify its strengths and weaknesses. The questions they addressed in their analysis are the most clinically relevant and their suggestions for future research are also excellent.	Thank you for this feedback. We are pleased that the reviewer found the evidence report to be thorough and transparent.
General	We suggest that the report specifically and explicitly addresses the differences in relatively subjective outcomes, such as return to work, and between substantially different treatments (e.g. repair vs. debridement), which are more suspect when there is a high potential for bias.	Thank you. We have rephrased the description of outcome measures using the terms “patient self-reported” and “clinician-assessed” as opposed to “subjective” and “objective”, in order to provide more clarity on the nature of these assessment scales.
General	This is an excellent review of most of the literature. The non operative section however is not complete and very sparse. In my own personal collection of articles, I have many more than are listed here. I would strongly suggest a more thorough search of the non operative rehabilitation literature (not just injections)	Our literature search was designed by a research librarian and aimed to capture the available evidence on all nonoperative treatments. As noted in our selection criteria, all types of nonoperative interventions were considered for inclusion. However, many nonoperative studies were excluded because they failed to confirm the diagnosis of a rotator cuff tear through use of an imaging modality (or intraoperative findings). Since clinical tests alone are often inaccurate in establishing the diagnosis of a tear, we believe this criterion was necessary to address our research questions (which were specific to tears, not rotator cuff pathology in general) and ensuring the fair comparisons between nonoperative and operative treatments.
General	Also, why are textbooks being cited? Other than that, good job	Hallmark textbooks were occasionally used to support general information in the introduction section of our report, such as the description of various operative and nonoperative treatments. We believe the use of recent textbooks is appropriate for this purpose.

General	Only one orthopedic surgeon (Ken Yamaguchi, MD; St. Louis) was included among the 7 Technical Expert Panel Members. There should be greater inclusion of orthopedic surgeons on this panel.	Care is taken to select a diverse technical expert panel (TEP) which includes primary care providers and specialists, relevant professional organizations, and both content and methods experts. For this particular topic, it was important that there be representation from both orthopedic surgeons and physical therapists. Although there was only one orthopedic surgeon on the TEP, one of the clinical leads of this project is an orthopedic surgeon and a representative from the American Academy for Orthopaedic Surgeons (the topic nominator) was also a consultant for the evidence review.
General	This meta analysis was very strict and selective in the literature included, eliminating all published retrospective studies and those that did not have "base line" data, thereby excluding clinically relevant data of many well regarded studies that were followed longitudinally with retrospective analysis of prospectively collected data. This likely excluded several studies that identified the selection criteria for non vs. operative treatment (1-4,8), the benefits and pitfalls of nonoperative treatment (1-4,8), the early treatment of cuff tears (5), and the benefits of surgical treatment vs. failed non-op treatment (6,7). You can quickly review which manuscripts were accepted or eliminated by reviewing the ends of the manuscript and appendices. Attached additional references that were not included in the manuscript and are cited above with the appropriate reference #.	Retrospective studies were eligible for inclusion in the study if they had a comparison/control group (e.g., retrospective cohort studies were included). However, in consultation with our technical expert panel, the decision was made to exclude retrospective before-and-after studies (i.e., single-arm studies with a pre and post-intervention measure, which analyzed previously collected data), since these studies represent an extremely low level of evidence and are at high risk for bias. Single-arm studies with no baseline data were always excluded, since there was no measure of comparison; i.e., comparisons could not be made across intervention arms, or across time from before to after intervention. Please see our response with regard to the specific references below.
General	ASES would like to opportunity to recommend peer reviewers for this study.	The pubic web-based feedback system is open to all individuals. Comments received through this forum are considered in the same manner as the comments from invited peer reviewers.

<p>General</p>	<p>Additional References not included in manuscript:</p> <ol style="list-style-type: none"> 1. Bokor, D.J., Hawkins, R.J., Huckell, G.H., Angelo, R.L., and Schickendantz, M.S.: Results of Nonoperative Management of Full-Thickness Tears of the Rotator Cuff. Clin. Orthop. 1993; 294: 103 – 110. 2. Goldberg, B.A., Nowinski, D.O., Matsen III, F. A.: Outcome of Nonoperative Management of Full-Thickness Rotator Cuff Tears. CORR, 2001; 382: 99-107. 3. Hawkins, R.H., Dunlop, R.: Nonoperative Treatment of Rotator Cuff Tears. CORR, 1995; 321: 178-188. 4. Itoi, E., Tabata S.: Conservative Treatment of Rotator Cuff Tears. CORR 1992; 275: 165 – 173. 5. Bassett RW, and Cofield RH: Acute tears of the rotator cuff: Timing of surgical repair. Clin. Orthop. 1983;175:18-24. 6. Jost, B., Pfirrmann, C.W., and Gerber, C.: Clinical Outcome After Structural Failure of Rotator Cuff Repairs. J Bone and Joint Surg 2000; 82-A: 304-314. 7. Jost, B., Zumstein, M., Pfirrmann, C.W., Gerber, C.: Long-Term Outcome After Structural Failure of Rotator Cuff Repairs. J Bone and Joint Surg, 2006; 88-A: 472 – 479. 8. Wolfgang, G.L.: Surgical Repairs of Tears of the Rotator Cuff of the Shoulder. Factors Influencing the Result. J Bone and Joint Surg 1974; 56-A: 14-26. 	<p>One of the cited references (Hawkins et al 1995) was actually included in the review. The remaining listed studies were excluded because they did not meet one or more of the study selection criteria (see report page 24). Specifically, they were excluded for the following reasons:</p> <ol style="list-style-type: none"> 1. Boker et al, 1993; this is a retrospective before-and-after (BA) study; only prospectively designed BA studies were considered for inclusion in the review. 2. Goldberg BA et al, 2001; this is a retrospective BA study 3. Hawkins RH et al, 1995; this study was <i>included</i> in the review 4. Itoi E et al, 1992; this is a retrospective BA study 5. Bassett RW et al, 1983; this study was excluded because it was published before the year 1990. The publication date criterion was specified since the intervention procedures have evolved considerably over time. 6. Jost B et al, 2000; this study was not eligible as it focused on treatment of re-ruptures of the rotator cuff following initial repair 7. Jost B et al, 2006; as above, this study was not eligible as it focused on treatment of re-ruptures of the rotator cuff following initial repair 8. Wolfgang GL et al, 1974; excluded because it was published before 1990. <p>We hope this explanation is helpful in clarifying our rationale for excluding these studies.</p>
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