

# ***AHRQ Comparative Effectiveness Review***

## ***Surveillance Program***

### **CER # 22:**

Comparative Effectiveness of Nonoperative and Operative Treatments for Rotator Cuff Tears

### **Original release date:**

July 5, 2010

### **Surveillance Report (1st Assessment/cycle 1):**

February 2012

### **Surveillance Report (2<sup>nd</sup> Assessment/cycle 2):**

November 2012

### **Key Findings (1<sup>st</sup> Assessment/cycle1):**

- KQ1, KQ2, KQ3, KQ4, KQ5, and KQ6 are up to date
- Expert opinion: conclusions for KQ1-6 still valid
- There are no new significant safety concerns

### **Key Findings (Cumulative: 1st and 2nd assessment/cycle 1-2)**

Changed from the 1<sup>st</sup> assessment:

- KQ1, KQ3, KQ4, KQ5, and KQ6 are up to date
- KQ2: Possibly out of date (1 quantitative and 2 qualitative signals)
- There are no new safety concerns

### **Summary Decision:**

This CER's priority for updating is **Low** (unchanged from the first assessment)

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# 1. Introduction

The purpose of this mini-report is to apply the methodologies developed by the Ottawa and RAND Evidence-based Practice Centers and to determine whether the Comparative Effectiveness Review (CER) No. 22 (Comparative Effectiveness of Nonoperative and Operative Treatments for Rotator Cuff Tears),<sup>1</sup> is in need of updating. This CER was originally released in July, 2010. The first surveillance assessment report of this CER was submitted to the AHRQ in February 2012. This second assessment was completed in November 2012.

This CER included 137 studies (27 trials, 39 cohort studies, and 71 uncontrolled studies) identified by using searches through January 2009, and addressed six key questions to evaluate the effectiveness and safety of nonoperative and operative treatments for rotator cuff tears.

The key questions found in the Executive Summary of the original CER are as follows:

**Key Question # 1:** Does early surgical repair compared to late surgical repair (i.e., nonoperative intervention followed by surgery) lead to improved health-related quality of life, decreased disability, reduced time to return to work/activities, higher rate of cuff integrity, less shoulder pain, and increased range of motion and/or strength?

**Key question # 2:** What is the comparative effectiveness of operative approaches (e.g., open surgery, miniopen surgery, and arthroscopy) and postoperative rehabilitation on improved health related quality of life, decreased disability, reduced time to return to work/activities, higher rate of cuff integrity, less shoulder pain, and increased range of motion and/or strength?

**Key question # 3:** What is the comparative effectiveness of nonoperative interventions on improved health-related quality of life, decreased disability, reduced time to return to work/activities, higher rate of cuff integrity, less shoulder pain, and increased range of motion and/or strength? Nonoperative interventions include, but are not limited to, exercise, manual therapy, cortisone injections, acupuncture, and treatments and modalities typically delivered by physical therapists, osteopaths, and chiropractors.

**Key question # 4:** Does operative repair compared with nonoperative treatment lead to improved health-related quality of life, decreased disability, reduced time to return to work/activities, higher rate of cuff integrity, less shoulder pain, and increased range of motion and/or strength?

**Key question # 5:** What are the associated risks, adverse effects, and potential harms of nonoperative and operative therapies?

**Key question # 6:** Which demographic (e.g., age, gender, ethnicity, comorbidities, workers' compensation claims) and clinical (e.g., size/severity of tear, duration of injury, fatty infiltration of muscle) prognostic factors predict better outcomes following nonoperative and operative treatment? Which (if any) demographic and clinical factors account for potential differences in surgical outcomes between patients who undergo early versus delayed surgical treatment?

The conclusion(s) for each key question are found in the executive summary of the CER report.<sup>1</sup>

## 2. Methods

We followed *a priori* formulated protocol to search and screen literature, extract relevant data, and assess signals for updating. The identification of an updating signal (qualitative or quantitative) would be an indication that the CER might need to be updated. The Food and Drug Administration (FDA), Health Canada, and Medicines and Healthcare products Regulatory Agency (MHRA) surveillance alerts were examined for any relevant material for the present CER. We also sought the opinions of clinical experts. All of this evidence was taken into consideration leading to a consensus-based decision on whether any given conclusion warrants updating (up to date, possibly out of date, or out of date). Based on this assessment, the CER was categorized into one of the three updating priority groups: high priority, medium priority, or low priority. Further details on the Ottawa EPC and RAND methods used for this project are found elsewhere.<sup>2-4</sup>

### 2.1 Literature Searches

#### Cycle 2 (2<sup>nd</sup> assessment)

The same search strategy as the 1st assessment (cycle 1) was used but with different search dates for MEDLINE (July 1, 2011 to August 28, 2012), EMBASE (2011 Week 1 to 2012 Week 34), Cochrane Central Register of Controlled Trials (2011 – 2012), and CINAHL (using EBSCOhost) from July 1 2011 to August 28 2012, as per the original search strategies appearing in the CER's Appendix A.<sup>1</sup>

#### Cycle 1 (1<sup>st</sup> assessment)

The CER search strategies were reconstructed in MEDLINE (January 01, 2009-January 10, 2012), Embase (2009 Week 1 to 2012 Week 1), the Cochrane Central Register of Controlled Trials (CENTRAL; 4<sup>th</sup> Quarter 2011), and CINAHL (January 01, 2009 - January 10, 2012) as per the original search strategies appearing in the CER's Appendix A.<sup>1</sup> The syntax and vocabulary which include both controlled subject headings (e.g., MeSH) and keywords were applied according to the databases indicated in the appendix and in the search strategy section of the CER report. The MEDLINE search was limited to five general medical journals (Annals of Internal Medicine, BMJ, JAMA, Lancet, and New England Journal of Medicine) and five specialty journals (The Journal of Arthroscopy & Related Surgery, Journal of Bone and Joint Surgery, Journal of Shoulder and Elbow Surgery, American Journal of Sports Medicine, and Clinical Orthopaedics and Related Research). Restricting by journal title was not possible in the Cochrane search and pertinent citations were instead selected from the results. Study design filters were not applied to the Cochrane search since the Cochrane Central Register only contains randomized or controlled clinical trials. Further details on the search strategies are provided in the Appendix A of this mini-report.

## 2.2 Study Selection

All identified bibliographic records were screened using the same inclusion/exclusion criteria as described in the original CER. Uncontrolled before-after studies were excluded unless they reported serious harms.

## 2.3 Expert Opinion

### Cycle 2 (2<sup>nd</sup> assessment)

We contacted the three experts (Two CER-specific and one local) that had responded to the first assessment.

### Cycle 1 (1<sup>st</sup> assessment)

In total, 9 experts (6 CER-specific: lead author, clinical content experts, and technical expert panel members and 3 local clinical content experts) were requested to provide their opinion/feedback in a pre-specified matrix table on whether or not the conclusions outlined in the Executive Summary of the original CER were still valid.

## 2.4 Check for Qualitative and Quantitative Signals

All relevant reports eligible for inclusion in the CER were examined for the presence of qualitative and quantitative signals using the Ottawa EPC method (see more details in Appendix B). CERs with no meta-analysis were examined for qualitative signals only. For any CER that includes a meta-analysis, we first assess for qualitative signal(s) and if no qualitative signal(s) are found, we then assess for quantitative signal(s). The identification of an updating signal (qualitative or quantitative) would indicate that the CER might require updating. The definition and categories of updating signals are presented in Appendix B and in these publications.<sup>2,3</sup>

## 2.5 Compilation of Findings and Conclusions

All of the information obtained during the updating process (i.e., data on qualitative/quantitative signals, the expert opinions, and safety surveillance alerts) was collated, summarized and presented in to a table. We determined whether the conclusions of the CER warranted updating using a four category scheme:

- Original conclusion is still **up to date** and this portion of CER does not need updating
- Original conclusion is **possibly out of date** and this portion of CER may need updating
- Original conclusion is **probably out of date** and this portion of CER may need updating
- Original conclusion is **out of date** and this portion of CER is in need of updating

We used the following factors when making our assessments to categorize the CER conclusions:

- If we found no new evidence or only confirmatory evidence and all responding experts assessed the CER conclusion as still valid, we classified the CER conclusion as still up to date.
- If we found some new evidence that might change the CER conclusion, and /or a minority of responding experts assessed the CER conclusion as having new evidence that might change the conclusion, then we classified the CER conclusion as possibly out of date.
- If we found substantial new evidence that might change the CER conclusion, and/or a majority of responding experts assessed the CER conclusion as having new evidence that might change the conclusion, then we classified the CER conclusion as probably out of date.
- If we found new evidence that rendered the CER conclusion out of date or no longer applicable, we classified the CER conclusion as out of date. Recognizing that our literature searches were limited, we reserved this category only for situations where a limited search would produce prima facie evidence that a conclusion was out of date, such as the withdrawal of a drug or surgical device from the market, a black box warning from FDA, etc.

## **2.6 Determining Priority for Updating**

Determination of priority groups (i.e., Low, Medium, and High) for updating any given CER is based on the following two criteria:

- How many conclusions of the CER are up to date, possibly out of date, or certainly out of date?
- How out of date are conclusions (e.g., consideration of magnitude/direction of changes in estimates, potential changes in practice or therapy preference, safety issue including withdrawn from the market drugs/black box warning, availability of a new treatment)

## 3. Results

### 3.1 Update Literature Searches and Study Selection

#### Cycle 2 (2<sup>nd</sup> assessment)

A total of 198 bibliographic records were identified (MEDLINE=143, Embase=54, CENTRAL=1, and CINAHL=0). After de-duping, there were 197 records (MEDLINE=143, Embase=53, CENTRAL=1, and CINAHL=0). Of the 197 records, 87 were passed on to full text screening. The full text screening of these records resulted in 11 included unique studies.<sup>5-15</sup>

#### Cycle 1 (1<sup>st</sup> assessment)

A total of 15 studies were included in the report.<sup>16-30</sup>

### 3.2 Signals for Updating in Newly Identified Studies [Cycle 2]

#### 3.2.1 Study overview

The study, population, treatment characteristics, and results for the 11 studies<sup>5-15</sup> (identified in the 2<sup>nd</sup> assessment) and the 15 included studies<sup>16-30</sup> (identified in 1<sup>st</sup> assessment) are presented in Appendix C (Evidence Table).

In brief, participants across 11 studies included studies (2<sup>nd</sup> assessment) were diagnosed with rotator cuff tears (or disease) of different severity (e.g., full-thickness tears, rotator cuff lesions without complete tearing, massive rotator cuff tears). Of the 11 studies, six were RCTs<sup>7,9,11-13,15</sup> and five were observational comparative studies.<sup>5,6,8,10,14</sup> None of the RCTs were pivotal (see Appendix B). The sample size of the RCTs ranged from 42<sup>13</sup> to 120.<sup>7</sup> The sample size for the included cohort studies ranged from 37<sup>14</sup> to 190.<sup>8</sup> The majority of included studies compared either different operative approaches (complete vs. partial repair, with/without acromioplasty)<sup>5-7</sup> or techniques of cuff tear repair (e.g., single-row, double-row, transtendon techniques).<sup>8-12</sup> Two studies compared arthroscopic cuff tear repair with and without augmentation,<sup>13,14</sup> and one study assessed the benefit of post-operative rehabilitation.<sup>15</sup>

The reported outcomes across the included studies were pain (visual analogue scale),<sup>7,10,12,15</sup> range of motion (ROM; internal, external, forward rotation; abduction),<sup>7,12,15</sup> muscle strength,<sup>9,11,15</sup> function (Constant score),<sup>6,7,9,10,12-14</sup> and cuff integrity (e.g., no re-tear/re-tear rates).<sup>7-11,14,15</sup> Most studies reported the use of multi-dimensional tools to measure the domains of function, pain, strength, motion, and satisfaction: University of California Los Angeles (UCLA) score<sup>5-8,10,11,13-15</sup> and the American Shoulder and Elbow Surgeons score (ASES).<sup>6-14</sup>

### 3.2.2 Qualitative signals

See also Table 1 (Summary Table), Appendix B, and Evidence Table (Appendix C).

#### Key question #1

##### *Comparison of early and late surgery*

No new evidence was identified. **No Signal**

#### Key question #2

##### *Comparison of operative approaches*

There were two new studies comparing operative approaches; one RCT<sup>7</sup> and one cohort study.<sup>5</sup> These study findings agree with the CER results. More specifically, the RCT<sup>7</sup> did not report significant differences between treatment groups receiving acromioplasty versus not receiving acromioplasty for rotator cuff repair outcomes. Furthermore, the cohort study<sup>5</sup> did not find significant differences between the complete and partial repair groups. **No Signal**

##### *Comparison of operative techniques*

In agreement with the CER results, none of the newly identified three RCTs<sup>9,11,12</sup> and two cohort studies<sup>8,10</sup> showed a significant difference in any of the parameters of rotator cuff between the double- and single-row treatment groups. **No Signal**

##### *Comparison of operative augmentation*

The treatment group differences in three studies from the original CER were not significant rendering the results inconclusive due to low quality and small sample sizes of these studies. However, new evidence from the RCT<sup>13</sup> showed significant improvements in the ASES (98.9 vs. 94.8,  $p=0.035$ ) and Constant score (91.9 vs. 85.3,  $p=0.008$ ) favoring the group receiving augmentation treatment over the group not receiving augmentation. However, no difference was measured in the UCLA score between the two groups. **One Signal**

In addition, one cohort study<sup>14</sup> demonstrated a significantly higher re-tear rate in the group that received augmentation vs. no augmentation group (56% vs. 38%,  $p=0.024$ )<sup>14</sup>. **One Signal**

##### *Comparison of postoperative rehabilitation*

In agreement with the CER results, one RCT<sup>15</sup> showed no clinically or significant difference between the rehabilitation and no rehabilitation treatment groups in post-operative rehabilitation pain (0-10 score: 0.23 vs. 0.15,  $p=0.382$ ), ROM-EF (degrees: 155.3 vs. 153.0,  $p=0.729$ ), muscle

strength-elevation (kg: 7.76 vs. 7.33,  $p=0.227$ ), UCLA score ( $p=0.158$ ) or cuff healing rate (76.7% vs. 91.2%,  $p=0.106$ ). **No Signal**

Key question # 3

*Comparison of nonoperative interventions*

No new evidence was identified. **No Signal**

Key question # 4

*Comparison of operative and nonoperative interventions*

No new evidence was identified. **No Signal**

Key question # 5

*Adverse events or potential harms associated with operative and nonoperative interventions*

No new evidence was identified. **No Signal**

Key question # 6

*Important prognostic factors of outcomes following operative and nonoperative interventions*

No new evidence was identified. **No Signal**

### **3.2.3 Quantitative signals**

See also Table 1 (Summary Table), Appendix B, and Evidence Table (Appendix C)

Key question #1

*Comparison of early and late surgery*

No new evidence. **No Signal**

## Key question #2

### *Comparison of operative approaches.*

There was no data for meta-analysis available to check for quantitative signals for this comparison. **No Signal**

### *Comparison of operative techniques.*

The original CER included one meta-analysis which compared double-row technique to single-row technique showing no significant difference between the two groups in cuff integrity (pooled RR=1.20, 95% CI: 0.86, 1.68). We updated this pooled estimate by incorporating newly identified three RCTs, one was from cycle 1 (RR=1.29, 95% CI: 0.72, 2.31)<sup>17</sup> and two from cycle 2 (RR=1.17, 95% CI: 0.91, 1.52)<sup>9</sup> and RR=1.22, 95% CI: 0.85, 1.74<sup>11</sup>). The updated pooled RR indicated a marginally statistically significant difference with respect to cuff integrity in favor of double-row vs. single-row repair technique (RR=1.20, 95% CI: 1.016, 1.42). **One Signal**

### *Comparison of operative augmentation*

There was no data for meta-analysis available to check for quantitative signals for this comparison. **No Signal**

### *Comparison of postoperative rehabilitation*

There was no data for meta-analysis available to check for quantitative signals for this comparison. **No Signal**

## Key question # 3

### *Comparison of nonoperative interventions*

No new evidence. **No Signal**

## Key question # 4

### *Comparison of operative and nonoperative interventions*

No new evidence. **No Signal**

## Key question # 5

*Adverse events or potential harms associated with operative and nonoperative interventions*

No new evidence. **No Signal**

Key question # 6

*Important prognostic factors of outcomes following operative and nonoperative interventions*

No new evidence. **No Signal**

### **3.3 Safety surveillance alerts [Cycle 2]**

There were no safety surveillance alerts relevant to treatments used for rotator cuff tears identified.

### **3.4 Expert opinion [Cycle 2]**

Two of the 3 contacted clinical experts provided their responses/feedback in the matrix table (Appendix D). In general, there was agreement among the experts. One of the experts thought that the conclusions for key question #3 would change based on new evidence<sup>31,32</sup> but the studies suggested were excluded from this review. In addition, a few other studies for key questions #2,<sup>31</sup> and #4,<sup>33</sup> were suggested and all were excluded from this review except for one study.<sup>6</sup>

## 4. Conclusion

Summary results and conclusions according to the information collated from different sources (updating signals from studies identified through the update search, safety surveillance alerts, and expert opinion) are provided in Table 1 (Summary Table). Based on the assessments, this CER is categorized in **Low** priority group for updating.

### Key Question # 1

Signals from studies identified through the update search: No new evidence. **No Signal**

Experts: All experts stated that the conclusions in the key question #1 are still valid.

FDA surveillance alerts: None

1<sup>st</sup> Assessment Conclusion: **Up to date**

Total (cumulative) Assessments Conclusion: **Up to date**

### Key Questions # 2

Signals from studies identified through the update search: Two qualitative signals and one quantitative signal were present. **Three Signals**

Experts: All experts stated that the conclusions in the key question #2 are still valid.

FDA surveillance alerts: None

1<sup>st</sup> Assessment Conclusion: **Up to date**

Total (cumulative) Assessments Conclusion: **Possibly out of date**

### Key Question # 3

Signals from studies identified through the update search: No new evidence. **No Signal.**

Experts: One expert stated that the conclusions in the key question #3 are still valid. The other expert stated that there was new evidence to change the conclusions for key question #3 but these studies were excluded.

FDA surveillance alerts: None

1<sup>st</sup> Assessment Conclusion: **Up to date**

Total (cumulative) Assessments Conclusion: **Up to date**

#### **Key Question # 4**

Signals from studies identified through the update search: No new evidence. **No Signal.**

Experts: All experts stated that the conclusions in the key question #4 are still valid.

FDA surveillance alerts: None

1<sup>st</sup> Assessment Conclusion: **Up to date**

Total (cumulative) Assessments Conclusion: **Up to date**

#### **Key Question # 5**

Signals from studies identified through the update search: No new evidence. **No Signal**

Experts: All experts stated that the conclusions in the key question #5 are still valid.

FDA surveillance alerts: None

1<sup>st</sup> Assessment Conclusion: **Up to date**

Total (cumulative) Assessments Conclusion: **Up to date**

#### **Key Question # 6**

Signals from studies identified through the update search: No new evidence. **No Signal.**

Experts: All experts stated that the conclusions in the key question #6 are still valid.

FDA surveillance alerts: None

1<sup>st</sup> Assessment Conclusion: **Up to date**

Total (cumulative) Assessments Conclusion: **Up to date**

**Table 1. Summary Table**

Conclusions from CER's Executive Summary	Update literature search results	Signals for updating		Safety surveillance alerts	Expert opinion	Validity of CER conclusions	
		Qualitative	Quantitative			Cycle 1 assessment	Cycles 1-2 (total cumulative) assessment
<b>Key Question 1:</b> Does early surgical repair compared to late surgical repair (i.e., nonoperative intervention followed by surgery) lead to improved health-related quality of life, decreased disability, reduced time to return to work/activities, higher rate of cuff integrity, less shoulder pain, and increased range of motion and/or strength?							
One study compared early surgical repair versus late surgical repair after failed nonoperative treatment. Patients receiving early surgery had superior function compared with the delayed surgical group; however, the level of significance was not reported.	<b>Cycle 2 (November 2012)</b>					Up to date	Up to date
	No new evidence	NA	NA	None	Both experts agreed that there is no evidence sufficient to invalidate the findings of CER thereby rendering this CER conclusion still valid.		
	<b>Cycle 1 (February 2012)</b>						
	No new evidence	NA	NA	None	Both experts agreed that there is no evidence sufficient to invalidate the findings of CER thereby rendering this CER conclusion still valid.		
<b>Key question 2:</b> What is the comparative effectiveness of operative approaches (e.g., open surgery, miniopen surgery, and arthroscopy) and postoperative rehabilitation on improved health related quality of life, decreased disability, reduced time to return to work/activities, higher rate of cuff integrity, less shoulder pain, and increased range of motion and/or strength?							
<b>Operative approaches</b> A total of 113 studies examined the effectiveness of operative interventions, while 11 studies evaluated postoperative rehabilitation protocols following surgery. A median of 55 patients (IQR: 34 to 95) with a median age of 58.6 years (IQR: 55.5 to 61.7) were included in the operative studies. Males comprised an	<b>Cycle 2 (November 2012)</b>					Up to date	Up to date
	1 RCT <sup>7</sup> 2 cohort studies <sup>5,6</sup>	<b>No Signal</b> In agreement with CER results, the new RCT <sup>7</sup> also did not find significant differences between acromioplasty versus without acromioplasty for rotator cuff repair outcomes. Likewise one cohort study <sup>5</sup> , comparing complete versus partial rotator cuff repair did not find significant difference	None	None	Both experts agreed with this conclusion. One expert provided an additional reference <sup>6</sup> to support this conclusion which was already included in this report.		

<p>average of 64.6 percent of study participants. For postoperative rehabilitation, studies included a median of 61 participants (IQR: 36 to 79.5) with a median age of 58.0 years (IQR: 56.3 to 60.8). Males comprised an average of 58.9 percent of study participants.</p> <p>Studies assessing operative treatments were categorized as focusing on an operative approach (e.g., open, mini-open, arthroscopic, and debridement), technique (i.e., suture or anchor type or configuration) or augmentation for RC repair. The majority of surgical studies (32 comparative studies and 58 uncontrolled studies) evaluated operative approaches. The comparative studies provided moderate evidence indicating no statistical or clinically important differences in function between open and mini-open repairs; however, there was some evidence suggesting an earlier return to work by approximately 1 month for mini-open repairs. Similarly, there was moderate evidence demonstrating no difference in function between mini-open and arthroscopic repair and arthroscopic repair with and without acromioplasty. There was moderate evidence for greater improvement in function for open repairs compared with arthroscopic debridement. The</p>		between the groups.				
	<b>Cycle 1 (February 2012)</b>					
	<p>1 RCT<sup>27</sup></p> <p>3 non-RCTs 21,23,26</p>	<p><b>No Signal</b> In agreement with CER results, 2 newly identified studies comparing open RCR to arthroscopic RCR<sup>26</sup> and biceps tenotomy to tenodesis<sup>21</sup> found no significant differences between the operative approaches in post-operative pain, function, and/or ADL. (ASES score, Oxford Shoulder Questionnaire, Constant score).</p> <p><b>No Signal</b> 1 RCT<sup>27</sup> and 1 cohort study<sup>23</sup> were conducted in patients with concomitant rotator cuff and SLAP tears. In the RCT,<sup>27</sup> SLAP debridement was compared with SLAP repair in patients undergoing arthroscopic RCR, where debridement was found to significantly improve disability, pain, and range of motion compared to repair (UCLA score). In the cohort study,<sup>23</sup> arthroscopic RCR alone was compared with arthroscopic RCR plus SLAP tear repair. The combination group had significantly improved constant score (function), but not ASES score.</p>	<p><b>No Signal</b> 1 MA in CER included 3 non-RCTs (cohort studies) which compared open RCR to arthroscopic RCR for function as an outcome. The pooled standardized mean difference was not statistically significant (-0.49, 95% CI: -1.12, 0.13). Due to limited interpretability of standardized means, there was no attempt to update this MA.</p> <p><b>No Signal</b> None of the MAs of CER could be updated using data from 2 studies<sup>23,27</sup> due to differences in compared interventions and their combinations between MA and the 2 studies.</p>	None	<p>One expert considered this CER conclusion still valid; the other expert provided references to 2 Cochrane reviews, both of which were deemed as outdated. One review was withdrawn (Ejnisman et al. 2009; last assessed in 2003)<sup>35</sup> and the other review's (Coghlan et al. 2008)<sup>34</sup> last date for which the search was done was March 2006.</p>	

<p>strength of evidence was low for the remaining comparisons and outcomes examined in the studies, precluding any conclusions regarding their comparative effectiveness. The uncontrolled studies consistently reported functional improvement from preoperative to postoperative scores, regardless of the type of approach used (open, mini-open, or arthroscopic), the study design, the sample size of the study, or the type of outcome measure used.</p>							
<p><b>Operative techniques</b> Operative techniques were examined in 15 comparative studies. Six studies compared single-row versus double-row fixation of repairs, providing moderate evidence of no clinically significant difference in function and no difference in cuff integrity. There was moderate evidence for no difference in cuff integrity between mattress locking and simple stitch. The evidence was too limited to make conclusions about the other techniques.</p>	<b>Cycle 2 (November 2012)</b>					Up to date	Possibly out of date
	<p>3 RCTs<sup>9,11,12</sup> 2 cohort studies<sup>8,10</sup></p>	<p><b>No Signal</b> In agreement with the CER, none of the newly identified studies (3 RCTs<sup>9,11,12</sup> and 2 cohort studies<sup>8,10</sup>) showed a significant difference in any of the parameters of rotator cuff function between the double- and single-row treatment groups</p>	<p><b>1 Signal</b> 1 MA in CER comparing double-row vs. single-row repair for cuff integrity (pooled RR=1.20, 95% CI: 0.86, 1.68) was updated by incorporating data from 3RCTs<sup>9,11,17</sup> for cuff integrity. Of the 3 RCTs, one was found in cycle 1 (RR=1.29, 95% CI: 0.72, 2.31)<sup>17</sup> and two in cycle 2 (RR=1.17, 95% CI: 0.91, 1.52)<sup>9</sup> and RR=1.22, 95% CI: 0.85, 1.74<sup>11</sup>)  The updated pooled RR estimate for cuff integrity was statistically significant in favor of double-row repair. (RR=1.20, 95% CI: 1.016, 1.42</p>	None	Both experts agreed that there is no evidence sufficient to invalidate the findings of CER thereby rendering this CER conclusion still valid.		
	<b>Cycle 1 (February 2012)</b>						
<p>3 RCTs<sup>17,20,22</sup> 2 non-</p>	<p><b>No Signal</b> In agreement with CER results, 2 RCTs<sup>17,22</sup> and 1 non-RCT<sup>19</sup> showed no difference</p>	<p><b>No Signal</b> 1 MA in CER comparing double-row vs. single-row repair for cuff integrity</p>	None	Both experts agreed that there is no evidence sufficient to invalidate the findings			

	RCTs <sup>19,25</sup>	between single-row and double-row techniques in post-operative pain, <sup>17,19</sup> function, <sup>17,19,22</sup> range of motion, <sup>17,19</sup> satisfaction, <sup>17,19</sup> and cuff integrity. <sup>17</sup> One non-RCT <sup>19</sup> showed improved healing rate for double-row vs. single-row technique for tears between 2.5-3.5 cm. In 1 RCT, <sup>20</sup> there was no difference between RCR techniques employing metal vs. biodegradable anchors in disability (DASH score) and function (Constant score); in 1 non-RCT, <sup>25</sup> suture bridge was shown to improve cuff integrity (but not pain, function, range of motion, or strength) compared to single-row technique.	(pooled RR=1.20, 95% CI: 0.86, 1.68) was updated by incorporating data from 1 RCT <sup>17</sup> with a RR of 1.70 (95% CI: 0.95, 3.05) for cuff integrity. The updated pooled RR (95% CI) was 1.30 (0.97, 1.75). The statistically non-significant difference was maintained as well as the change in the effect size or the width of the 95% CI was less than 50%.		of CER thereby rendering this CER conclusion still valid.		
<b>Cycle 2 (November 2012)</b>							
<b>Operative augmentations</b> Eight studies, including three comparative and five uncontrolled studies, assessed augmentations for operative repair. The three comparative studies were relatively small and no overall conclusions were possible. Although the five uncontrolled studies evaluated different types of augmentation, they all indicated improvement in functional score from baseline to final follow-up.	1 RCT <sup>13</sup> 1 cohort study <sup>14</sup>	<b>2 Signals</b> The treatment group differences in 3 studies from the original CER were not significant thereby rendering the conclusions as inconclusive due to low quality and small sample size of these studies. However, new evidence from one small RCT <sup>13</sup> showed significant differences in ASES (98.9 vs. 94.8, p=0.035) and Constant score (91.9 vs. 85.3, p=0.008) favoring the augmentation treatment groups over no augmentation.  Moreover, one cohort study demonstrated a significantly higher re-tear rate in the	None	None	Both experts agreed that there is no evidence sufficient to invalidate the findings of CER thereby rendering this CER conclusion still valid.	Up to date	Possibly out of date

		augmentation vs. no augmentation group (56% vs. 38%, p=0.024). <sup>14</sup>						
<b>Cycle 1 (February 2012)</b>								
	1 RCT <sup>18</sup>  2 non-RCTs <sup>28,29</sup>	<b>No Signal</b> In general, 3 newly identified studies, 1 RCT <sup>18</sup> and 2 non-RCTs <sup>28,29</sup> showed no difference between RCR alone vs. RCR with augmentation in post-operative pain, ADL, range of motion, and function. Note that, in two observational studies, the use of augmentation was associated with improved cuff integrity <sup>28,29</sup> or muscle strength. <sup>28</sup>	None	None	Both experts agreed that there is no evidence sufficient to invalidate the findings of CER thereby rendering this CER conclusion still valid.			
<b>Postoperative rehabilitation</b>	<b>Cycle 2 (November 2012)</b>							
Of the 11 postoperative rehabilitation studies (10 comparative, 1 uncontrolled), 3 compared continuous passive motion with physical therapy versus physical therapy alone. These three studies provided moderate evidence of no clinically important or statistically significant difference in function, but some evidence for earlier return to work with continuous passive motion. Each of the remaining studies examined different rehabilitation protocols; therefore, the evidence was too limited to make any conclusions regarding their comparative effectiveness.	1 RCT <sup>15</sup>	<b>No Signal</b> In agreement with CER, the RCT showed no clinically or significant difference between the rehabilitation and no rehabilitation treatment groups.	None	None	Both experts agree with these conclusions. One expert provided an additional study <sup>31</sup> to be reviewed but it was excluded from this report.	Up to date	Up to date	
<b>Cycle 1 (February 2012)</b>								
	No new evidence	None	None	None	Both experts agreed that there is no evidence sufficient to invalidate the findings of CER thereby rendering this CER conclusion still valid.			
<b>Key question 3:</b> What is the comparative effectiveness of nonoperative interventions on improved health-related quality of life, decreased disability, reduced time to return to work/activities, higher rate of cuff integrity, less shoulder pain, and increased range of motion and/or strength? Nonoperative interventions include, but are not limited to, exercise, manual therapy, cortisone injections, acupuncture, and treatments and modalities typically delivered by physical therapists, osteopaths, and chiropractors.								
Nonoperative interventions	<b>Cycle 2 (November 2012)</b>					Up to date	Up to date	

<p>were examined in three comparative and seven uncontrolled studies. The studies included a median of 42 patients (IQR: 25.3 to 73.3), with a median age of 61 years (IQR: 60.4 to 61.5). Males comprised an average of 50 percent of participants. Each of the comparative studies assessed different interventions, including: sodium hyaluronate versus dexamethasone; rehabilitation versus no rehabilitation (not otherwise specified); and physical therapy, oral medications, and steroid injection versus physical therapy, oral medications, and no steroid injection. The limited evidence precludes conclusions of comparative effectiveness. The degree of improvement in functional outcome scores varied considerably across the uncontrolled studies.</p>	No new evidence	None	None	None	One expert considered this CER conclusion still valid; One expert did not agree with the conclusions and provided two additional studies <sup>31,36</sup> to invalidate the conclusions but both studies were excluded from this report.			
	<b>Cycle 1 (February 2012)</b>							
	2 RCTs <sup>24,30</sup>	<p><b>No Signal</b> In 1 RCT,<sup>24</sup> patients with rotator cuff lesions without complete tear receiving sodium hyaluronate had improved function (Constant score) and pain (VAS) compared to patients on placebo 6 weeks after treatment.</p> <p>In 1 RCT,<sup>30</sup> patients with chronic rotator cuff disease who received manual therapy and exercise had improved shoulder disability and pain (SPADI score) but not global change compared to patients receiving ultrasound and inert gel.</p>	None	None	One expert considered this CER conclusion still valid; the other expert provided reference to 1 Cochrane review (Green et al. 2003) <sup>37</sup> , which was deemed as outdated, because the last date for which the search was done was June 2002.			
<b>Key question 4:</b> Does operative repair compared with nonoperative treatment lead to improved health-related quality of life, decreased disability, reduced time to return to work/activities, higher rate of cuff integrity, less shoulder pain, and increased range of motion and/or strength?								
<p>Five studies compared nonoperative to operative treatments, with a median sample size of 103 (IQR: 40 to 108). The mean ages in the studies ranged from 46.8 to 64.8 years. Males represented 55 percent of study</p>	<b>Cycle 2 (November 2012)</b>							
	No new evidence	None	None	None	Both experts considered this conclusion still valid. One expert provided an additional study <sup>33</sup> that was not relevant to this review.	Up to date	Up to date	
<b>Cycle 1 (February 2012)</b>								

participants. The interventions varied across studies, but generally the nonoperative arms included components such as steroid injection, stretching, and strengthening and were compared with open repair or debridement. The evidence was too limited to make conclusions regarding the comparative effectiveness of the interventions.	No new evidence	None	None	None	One expert considered this CER conclusion still valid; the other expert provided reference to 1 Cochrane review (Buchbinder et al. 2003) <sup>38</sup> , which was deemed as outdated, because the last date for which the search was done was June 2002 (last assessed in November 2002).		
<b>Key question 5: What are the associated risks, adverse effects, and potential harms of nonoperative and operative therapies?</b>							
A total of 85 studies provided data on 34 different complications of nonoperative, operative, and ostoperative rehabilitation interventions. Complications were poorly reported, with studies providing limited information on how complications were defined and assessed. In 21 studies, it was reported that no complications occurred during the course of the study. In general, the rates of complication were low and the majority of complications were not deemed to be clinically important or were reported in few studies.	<b>Cycle 2 (November 2012)</b>					Up to date	Up to date
	No new evidence	None	None	None	Both experts agreed that there is no evidence sufficient to invalidate the findings of CER thereby rendering this CER conclusion still valid.		
	<b>Cycle 1 (February 2012)</b>						
	1 RCT <sup>24</sup>  1 non-RCT <sup>28</sup>	<b>No Signal</b> Only two studies reported any information on harms. <sup>24,28</sup> The RCT <sup>24</sup> which compared non-operative treatments (sodium hyaluronate vs. placebo) stated that there were no complications. The other study of cohort design <sup>28</sup> comparing RCR with and without augmentation reported zero peri-operative complications and three patients with popeye deformity	None	None	One expert considered this CER conclusion still valid; the other expert provided the reference for the outdated and withdrawn review (Ejnisman et al. 2009). <sup>35</sup>		
<b>Key question 6: Which demographic (e.g., age, gender, ethnicity, comorbidities, workers' compensation claims) and clinical (e.g., size/severity of tear, duration of injury, fatty infiltration of muscle) prognostic factors predict better outcomes following nonoperative and operative treatment? Which (if any) demographic and clinical factors account for potential differences in surgical outcomes between patients who undergo early versus delayed surgical treatment?</b>							
Overall, 72 of the 137 studies examined the impact of prognostic factors on patient outcomes. General conclusions	<b>Cycle 2 (November 2012)</b>					Up to date	Up to date
	No new evidence	None	None	None	Both experts agreed that there is no evidence sufficient to		

<p>are limited, due to the varied methodologies across studies, particularly the different outcomes for which prognostic factors were evaluated. There is some evidence that tear size, age, and extent of preoperative symptoms may modify outcomes; while, workers' compensation board (WCB) status, sex, and duration of symptoms generally showed no significant impact.</p>					invalidate the findings of CER thereby rendering this CER conclusion still valid.		
	<b>Cycle 1 (February 2012)</b>						
	No new evidence	None	None	None	Both experts considered this CER conclusion still valid; one expert mentioned 'fatty infiltration' as a prognostic factor, which had already been covered in CER. The other expert provided a reference for a study (Zumstein et al. 2008 <sup>39</sup> which had already been included in the CER.		
<p>pts=patients; d=day(s); yr(s)=years; mo=month(s); NR=not reported; SLAP= superior labral anterior posterior; RCR=rotator cuff repair; CER=comparative effectiveness review; RCT=randomized controlled trial; AE=adverse event; FU=follow-up; SR=systematic review; MA=meta-analysis; PL=placebo; FDA=food and drug administration; ADL=activities of daily living; SPADI=shoulder pain and disability index; ASES=American Shoulder and Elbow Surgeons score; DASH=Disabilities of the Arm, Shoulder and Hand questionnaire; VAS=visual analogue scale</p>							

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## Appendix A: Search Methodology

All MEDLINE, CENTRAL, and Embase searches were limited to the following journals:

**General biomedical** – Annals of Internal Medicine, BMJ, JAMA, Lancet, and New England Journal of Medicine

**Specialty journals** – The Journal of Arthroscopy & Related Surgery, Journal of Bone and Joint Surgery, Journal of Shoulder and Elbow Surgery, American Journal of Sports Medicine, and Clinical Orthopaedics and Related Research

Database: Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) <July 1, 2011 to August 28, 2012>, EBM Reviews - Cochrane Central Register of Controlled Trials <2011 – August 28 2012>, Embase <2011 Week 1 to 2012 Week 34> Search Strategy:

- 
- 1 exp rotator cuff/in (2919)
  - 2 ((rotator cuff\* or rotator interval\* or supraspin?tus or infraspin?tus or "teres minor" or subscapularis or anterosuperior or posterosuperior) adj5 (tear or tears or tore or torn or lesion\* or rupture\* or avuls\* or injur\* or repair\* or debride\*)).mp. (11259)
  - 3 exp tendon injuries/ (27748)
  - 4 exp Muscles/in (9734)
  - 5 ((tendon or tendons or muscle\* or muscular) adj5 (tear or tears or tore or torn or lesion\* or rupture\* or avuls\* or injur\* or repair\* or debride\*)).mp. (79491)
  - 6 ((full or partial) adj4 (thick\$ or tear or tears)).ti,ab. (33441)
  - 7 or/3-6 (121790)
  - 8 exp Shoulder/ or exp Shoulder Joint/ (40313)
  - 9 (shoulder or glenohumeral).mp. (103420)
  - 10 (rotator cuff\* or rotator interval\* or supraspin?tus or infraspin?tus or "teres minor" or subscapularis or anterosuperior or posterosuperior).mp. (20777)
  - 11 or/8-10 (109065)
  - 12 7 and 11 (12281)
  - 13 or/1-2,12 (15201)
  - 14 randomized controlled trial.pt. (646236)
  - 15 controlled clinical trial.pt. (166666)
  - 16 exp randomized controlled trials as topic/ (108167)
  - 17 exp Random Allocation/ (155079)
  - 18 exp Double-Blind Method/ (323102)
  - 19 exp Single-Blind Method/ (43309)
  - 20 clinical trial.pt. (749302)
  - 21 exp clinical trials as topic/ (339047)
  - 22 (clin\$ adj25 (trial\$ or study or studies or design)).ti,ab. (1802432)
  - 23 ((singl\$ or doubl\$ or trebl\$ or tripl\$) adj25 (blind\$ or mask\$)).ti,ab. (397660)
  - 24 exp placebos/ (255317)
  - 25 placebo\$.ti,ab. (438535)
  - 26 random\$.ti,ab. (1664467)
  - 27 exp research design/ (3464504)
  - 28 comparative study/ (2282068)

29 exp evaluation studies/ (350477)  
 30 exp follow-up studies/ (1128731)  
 31 ((follow\$ or observational or compar\$) adj3 (trial\$ or study or studies or design)).ti,ab. (901094)  
 32 exp prospective studies/ (596447)  
 33 exp epidemiologic studies/ (3200762)  
 34 exp causality/ (2173154)  
 35 exp Epidemiologic Factors/ (2719235)  
 36 (effect\$ or outcome\$ or allocat\$ or control\$ or assign\$ or compar\$ or experiment\$ or analys\$ or  
 analys\$).mp. (24412408)  
 37 ((control\$ or prospectiv\$ or volunteer\$ or participant\$) adj5 (trial\$ or study or studies or  
 design)).mp. (5766091)  
 38 (group or groups).ti,ab. (5089046)  
 39 cohort\$.ti,ab. (519492)  
 40 case-control\$.ti,ab. (148346)  
 41 cross sectional.ti,ab. (298943)  
 42 (case adj (comparison or referent\$ or series)).ti,ab. (65511)  
 43 longitudinal.ti,ab. (262726)  
 44 (causation or causal\$.ti,ab. (140840)  
 45 (analytic adj (study or studies)).mp. (3534)  
 46 "single subject".ti,ab. (4117)  
 47 SSRD.ti,ab. (21)  
 48 "n-of-1".ti,ab. (90898)  
 49 baseline.ti,ab. (721494)  
 50 "before after".ti,ab. (5347)  
 51 or/14-50 (27621404)  
 52 animals/ not humans/ (5017953)  
 53 51 not 52 (24167680)  
 54 13 and 53 (10458)  
 55 limit 54 to ("all adult (19 plus years)" or "middle age (45 to 64 years)" or "middle aged (45 plus  
 years)" or "all aged (65 and over)" or "aged (80 and over)") [Limit not valid in CCTR,Embase; records  
 were retained] (9278)  
 56 ("annals of internal medicine" or bmj or jama or lancet or "new england journal of medicine").jn.  
 (551963)  
 57 (arthroscopy or "journal of bone & joint surgery american volume" or "journal of bone & joint  
 surgery british volume" or "journal of shoulder & elbow surgery" or "american journal of sports  
 medicine" or "clinical orthopaedics & related research").jn. (75305)  
 58 56 or 57 (627268)  
 59 55 and 58 (1656)  
 60 (201107\* or 201108\* or 201109\* or 201110\* or 201111\* or 201112\* or 2012\*).ed. (1129438)  
 61 59 and 60 (149)  
 62 61 use prmz (149)  
 63 exp rotator cuff rupture/ (3406)  
 64 ((rotator cuff\* or rotator interval\* or supraspin?us or infraspin?us or "teres minor" or subscapularis  
 or anterosuperior or posterosuperior) adj5 (tear or tears or tore or torn or lesion\* or rupture\* or avuls\* or  
 injur\* or repair\* or debride\*)).mp. (11259)  
 65 exp tendon injury/ or exp tendon rupture/ or exp ligament rupture/ (34503)  
 66 exp muscle injury/ (6595)  
 67 ((tendon or tendons or muscle\* or muscular) adj5 (tear or tears or tore or torn or lesion\* or rupture\*  
 or avuls\* or injur\* or repair\* or debride\*)).mp. (79491)  
 68 ((full or partial) adj4 (thick\$ or tear or tears)).ti,ab. (33441)  
 69 or/65-68 (122590)

70 exp Shoulder/ or exp Rotator Cuff/ (33826)  
71 (shoulder or glenohumeral).mp. (103420)  
72 (rotator cuff\* or rotator interval\* or supraspin?tus or infraspin?tus or "teres minor" or subscapularis  
or anterosuperior or posterosuperior).mp. (20777)  
73 or/70-72 (109065)  
74 69 and 73 (10998)  
75 or/63-64,74 (14816)  
76 exp randomized controlled trial/ or exp "randomized controlled trial (topic)"/ (681874)  
77 exp randomization/ (155079)  
78 exp controlled clinical trial/ (543156)  
79 (clin\$ adj25 (trial\$ or study or studies or design)).ti,ab. (1802432)  
80 ((singl\$ or doubl\$ or trebl\$ or tripl\$) adj25 (blind\$ or mask\$)).ti,ab. (397660)  
81 exp placebo/ (203536)  
82 placebo\$.ti,ab. (438535)  
83 random\$.ti,ab. (1664467)  
84 (ae or co or ct or do or th).fs. (7524282)  
85 exp methodology/ (3046208)  
86 exp "types of study"/ (18842649)  
87 exp "evaluation and follow up"/ (1208079)  
88 ((follow\$ or observational or compar\$) adj3 (trial\$ or study or studies or design)).ti,ab. (901094)  
89 (effect\$ or outcome\$ or allocat\$ or control\$ or assign\$ or compar\$ or experiment\$ or analys\$ or  
analyz\$).mp. (24412408)  
90 ((control\$ or prospectiv\$ or volunteer\$ or participant\$) adj5 (trial\$ or study or studies or  
design)).mp. (5766091)  
91 (group or groups).ti,ab. (5089046)  
92 cohort\$.ti,ab. (519492)  
93 case-control\$.ti,ab. (148346)  
94 cross sectional.ti,ab. (298943)  
95 (case adj (comparison or referent\$ or series)).ti,ab. (65511)  
96 longitudinal.ti,ab. (262726)  
97 (causation or causal\$.ti,ab. (140840)  
98 (analytic adj (study or studies)).mp. (3534)  
99 (epidemiologic\$ adj (study or studies)).ti,ab. (121649)  
100 "single subject".ti,ab. (4117)  
101 SSRD.ti,ab. (21)  
102 "n-of-1".ti,ab. (90898)  
103 baseline.ti,ab. (721494)  
104 "before after".ti,ab. (5347)  
105 or/76-104 (34590164)  
106 (animal/ or nonhuman/) not human/ (8162930)  
107 105 not 106 (27899358)  
108 75 and 107 (12546)  
109 limit 108 to (adult <18 to 64 years> or aged <65+ years>) [Limit not valid in Ovid  
MEDLINE(R),Ovid MEDLINE(R) In-Process,CCTR; records were retained] (8726)  
110 ("annals of internal medicine" or bmj or bmj clinical research ed or "jama journal of the american  
medical association" or "jama the journal of the american medical association" or lancet or "new england  
journal of medicine").jn. (564337)  
111 ("arthroscopy journal of arthroscopic and related surgery" or "arthroscopy the journal of  
arthroscopic related surgery official publication of the arthroscopy association of north america and the  
international arthroscopy association").jn. (3155)

- 112 ("journal of bone and joint surgery series a" or "journal of bone and joint surgery series b").jn. (18158)
- 113 ("journal of shoulder and elbow surgery" or "journal of shoulder and elbow surgery american shoulder and elbow surgeons et al").jn. (5618)
- 114 "american journal of sports medicine".jn. (10520)
- 115 "clinical orthopaedics and related research".jn. (41722)
- 116 or/110-115 (643510)
- 117 109 and 116 (2246)
- 118 (2011\* or 2012\*).em. (3518244)
- 119 117 and 118 (324)
- 120 119 use emez (153)
- 121 exp rotator cuff/in (2919)
- 122 ((rotator cuff\* or rotator interval\* or supraspin?tus or infraspin?tus or "teres minor" or subscapularis or anterosuperior or posterosuperior) adj5 (tear or tears or tore or torn or lesion\* or rupture\* or avuls\* or injur\* or repair\* or debride\*)).mp. (11259)
- 123 exp tendon injuries/ or exp ligaments/in (39809)
- 124 exp muscles/in (9734)
- 125 ((tendon or tendons or muscle\* or muscular) adj5 (tear or tears or tore or torn or lesion\* or rupture\* or avuls\* or injur\* or repair\* or debride\*)).mp. (79491)
- 126 ((full or partial) adj4 (thick\$ or tear or tears)).ti,ab. (33441)
- 127 or/123-126 (132957)
- 128 exp Shoulder/ or exp Shoulder Joint/ or exp Rotator Cuff/ (44827)
- 129 (shoulder or glenohumeral).mp. (103420)
- 130 (rotator cuff\* or rotator interval\* or supraspin?tus or infraspin?tus or "teres minor" or subscapularis or anterosuperior or posterosuperior).mp. (20777)
- 131 or/128-130 (109065)
- 132 127 and 131 (12560)
- 133 or/121-122,132 (15460)
- 134 133 (15460)
- 135 limit 134 to yr="2011 -Current" (1917)
- 136 135 use cctr (18)
- 137 62 or 120 or 136 (320)
- 138 remove duplicates from 137 (208)
- 139 remove duplicates from 137 (208)
- 140 139 use prmz (143)
- 141 139 use emez (54)
- 142 139 use cctr (11)

CINAHL (August 28, 2012)

#	Query	Limiters/Expanders	Last Run Via	Results
S10	S6 and S7	Limiters - Exclude MEDLINE records Expanders - Apply related words Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL	30

S9	S6 and S7	Expanders - Apply related words Narrow by SubjectAge: - aged, 80 and over Narrow by SubjectAge: - aged: 65+ years Narrow by SubjectAge: - all adult Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL	70
S8	S6 and S7	Expanders - Apply related words Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL	130
S7	EM 201107-20121231	Expanders - Apply related words Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL	231648
S6	S4 not S5	Expanders - Apply related words Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL	1268
S5	TI ( child* or pediater* or paediatr* ) OR SU ( child* or pediater* or paediatr* )	Expanders - Apply related words Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL	284905
S4	(S1 or S2) and S3	Expanders - Apply related words Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL	1288
S3	(tear or tears or tore or torn or lesion* or rupture* or avuls* or repair* or debride* or	Expanders - Apply related words	Interface - EBSCOhost	54468

	full-thickness or partial-thickness or thickness)	Search modes - Boolean/Phrase	Search Screen - Advanced Search Database - CINAHL	
S2	(MH "Glenohumeral Joint/IN")	Expanders - Apply related words Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL	44
S1	"rotator cuff*" OR DE ("rotator cuff" OR "shoulder joint") OR (MH "Shoulder Joint+") OR (supraspinatus OR infraspinatus OR "teres minor" OR subscapularis OR anterosuperior OR posterosuperior)	Expanders - Apply related words Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL	3477

The CINAHL results (30 records) were screened based on the journal names at the time of searching and none were retained

## Appendix B: Updating Signals

### Qualitative signals\*

#### Potentially invalidating change in evidence

This category of signals (A1-A3) specifies findings from a pivotal trial\*\*, meta-analysis (with at least one new trial), practice guideline (from major specialty organization or published in peer-reviewed journal), or recent textbook (e.g., *UpToDate*):

- Opposing findings (e.g., effective vs. ineffective) – **A1**
- Substantial harm (e.g., the risk of harm outweighs the benefits) – **A2**
- A superior new treatment (e.g., new treatment that is significantly superior to the one assessed in the original CER) – **A3**

#### Major change in evidence

This category of signals (A4-A7) refers to situations in which there is a clear potential for the new evidence to affect the clinical decision making. These signals, except for one (A7), specify findings from a pivotal trial, meta-analysis (with at least one new trial), practice guideline (from major specialty organization or published in peer-reviewed journal), or recent textbook (e.g., *UpToDate*):

- Important changes in effectiveness short of “opposing findings” – **A4**
- Clinically important expansion of treatment (e.g., to new subgroups of subjects) – **A5**
- Clinically important caveat – **A6**
- Opposing findings from meta-analysis (in relation to a meta-analysis in the original CER) or non-pivotal trial – **A7**

\* Please, see Shojania et al. 2007<sup>3</sup> for further definitions and details

\*\*A pivotal trial is defined as: 1) a trial published in top 5 general medical journals such as: Lancet, JAMA, Annals of Intern Med, BMJ, and NEJM. Or 2) a trial not published in the above top 5 journals but have a sample size of at least triple the size of the previous largest trial in the original CER.

## Appendix B: Updating Signals (Continued)

### Quantitative signals (B1-B2)\*

#### Change in statistical significance (B1)

Refers to a situation in which a statistically significant result in the original CER is now NOT statistically significant or vice versa- that is a previously non-significant result become statistically significant. For the ‘borderline’ changes in statistical significance, at least one of the reports (the original CER or new updated meta-analysis) must have a p-value outside the range of border line (0.04 to 0.06) to be considered as a quantitative signal for updating.

#### Change in effect size of at least 50% (B2)

Refers to a situation in which the new result indicates a relative change in effect size of at least 50%. For example, if relative risk reduction (RRR) new / RRR old  $\leq 0.5$  or RRR new / RRR old  $\geq 1.5$ . Thus, if the original review has found RR=0.70 for mortality, this implies RRR of 0.3. If the updated meta-analytic result for mortality were 0.90, then the updated RRR would be 0.10, which is less than 50% of the previous RRR. In other words the reduction in the risk of death has moved from 30% to 10%. The same criterion applied for odds ratios (e.g., if previous OR=0.70 and updated result were OR=0.90, then the new reduction in odds of death (0.10) would be less 50% of the magnitude of the previous reduction in odds (0.30). For risk differences and weighted mean differences, we applied the criterion directly to the previous and updated results (e.g., RD new / RD old  $\leq 0.5$  or RD new / RD old  $\geq 1.5$ ).

\* Please, see Shojania et al. 2007<sup>3</sup> for further definitions and details

## Appendix C: Evidence Table

Author year Study name (if applicable)	Study design	Subjects	Treatment groups (n; dose)	Treatment duration	Outcomes and findings
<b>Key Question # 1:</b> Does early surgical repair compared to late surgical repair (i.e., nonoperative intervention followed by surgery) lead to improved health-related quality of life, decreased disability, reduced time to return to work/activities, higher rate of cuff integrity, less shoulder pain, and increased range of motion and/or strength?					
<b>Cycle 2</b>					
No new relevant evidence was identified	NA	NA	NA	NA	NA
<b>Cycle 1</b>					
No new relevant evidence was identified	NA	NA	NA	NA	NA
<b>Key question # 2:</b> What is the comparative effectiveness of operative approaches (e.g., open surgery, miniopen surgery, and arthroscopy) and postoperative rehabilitation on improved health related quality of life, decreased disability, reduced time to return to work/activities, higher rate of cuff integrity, less shoulder pain, and increased range of motion and/or strength?					
<b>Cycle 2</b>					
<b>Operative approach</b>					
Iagulli 2012 <sup>5</sup>	Cohort study	97 pts with massive rotator cuff tear (diameter ≤ 30 cm) mean age: 63.4 - 64.5 years; male%: NR	Complete repair (n=52, dose: NA) vs. partial repair (n=45, dose: NA)	NA	<u>Complete repair vs. partial repair (FU=2 yrs post-operation)</u> <b>UCLA score:</b> 29.64±4.92 vs. 29.49±5.90, p=0.89
Jo 2011 <sup>6</sup>	Cohort study	42 pts with full-thickness rotator cuff tear mean age: 59.8 – 61.8 years; male%: 36	RCR with PRP (n=19, dose: NA) vs. RCR without PRP (n=23, dose: NA)	NA	<u>PRP vs. without PRP (FU=16 months post-operation)</u> <b>UCLA score:</b> 31.78±6.15 vs. 30.83±4.96, p=0.579 <b>ASES index:</b> 87.61±24.83 vs. 89.92±17.03, p=0.744 <b>Constant score:</b> 79.12±13.42 vs. 82.00±13.02, p=0.476 <b>DASH:</b> 13.19±25.45 vs. 8.48±14.05, p=0.473 <b>SST:</b> 9.83±3.31 vs. 10.57±1.73, p=0.355 <b>SPADI:</b> 12.03±24.96 vs. 10.08±16.32, p=0.673

Author year Study name (if applicable)	Study design	Subjects	Treatment groups (n; dose)	Treatment duration	Outcomes and findings
Shin 2012 <sup>7</sup>	RCT	120 pts with small to medium sized rotator cuff tear mean age: 55.8 – 57.8 years; male%: 56	RCR with acromioplasty technique (n=60, dose: NA) vs. RCR without acromioplasty (n=60, dose: NA)	NA	<u>RCR with acromioplasty vs. RCR without acromioplasty (FU=24 mo)</u> <b>UCLA score:</b> 33.4±3.3 vs. 32.3±3.5, p>0.05 <b>ASES index:</b> 90.7±13.1 vs. 87.5±12.0, p>0.05 <b>Constant score:</b> 85.0±11.3 vs. 83.3±13.0, p>0.05 <b>ROM-FF (mean degrees):</b> 173.8±14.8 vs. 170.8±19.4, p>0.05 <b>ROM-ER at side (mean degrees):</b> 67.1±14.4 vs. 69.2±12.4, p>0.05 <b>IR (spine level):</b> 8.2±2.4 vs. 8.4±1.1, p>0.05 <b>Pain (VAS score):</b> 1.1±0.9 vs. 1.3±1.4, p>0.05 <b>Retear rate (%):</b> 17 vs. 20, p=0.475
<b>Operative technique</b>					
Mihata 2011 <sup>8</sup>	Cohort study	190 pts with full-thickness rotator cuff tear (any diameter) mean age: 62 years; male%: 53	Single-row (n=63, dose: NA) vs. double-row (n=22, dose: NA) vs. compression double-row (combined double-row and suture-bridge; n=105, dose: NA)	NA	<u>Single-row vs. double-row vs. compression double-row (FU=2 yrs)</u> <b>Retear rate (%):</b> 7/65 (10.8%) vs. 6/23 (26.1%) vs. 5/104 (4.7%), p>0.05 <b>ASES index:</b> 95.6±11.1 vs. 94.7±15.2 vs. 97.4±9.1, p>0.05 <b>UCLA score:</b> 34.0±3.9 vs. 33.5±5.3 vs. 34.2±3.5, p>0.05
Lapner 2012 <sup>9</sup>	RCT	90 pts with full-thickness rotator cuff tear (any diameter) mean age: 56.8 years; male%: 71	Single-row (n=48, dose: NA) vs. double-row (n=42, dose: NA)	NA	<u>Single-row vs. double-row (FU=2 yrs post-operation)</u> <b>ASES index:</b> 87.9±16.9 vs. 89.3±17.5, p=0.74 <b>Constant score:</b> 86.6±14 vs. 86.3±14.2, p=0.84 <b>WORC score:</b> 84.4±21.3 vs. 81.7±20.9, p=0.60 <b>Muscle strength (in kg):</b> 8.0±6.0 vs. 7.3±3.2, p=0.56 <b>Healing rate (%):</b> 32 (67%) vs. 33 (78%), p=0.254
Kim 2012 <sup>10</sup>	Cohort study	52 pts with full-thickness rotator cuff tear (diameter 1-4 cm) mean age: 58 years; male%: 57	Double-row (n=26, dose: NA) vs. suture-bridge (n=26, dose: NA)	NA	<u>Double-row vs. suture-bridge (FU=2 yrs post-operation)</u> <b>UCLA score:</b> 32.25±2.17 vs. 30.58±5.87, p=0.185 <b>ASES index:</b> 90.50±10.12 vs. 88.46±15.67, p=0.585 <b>Constant score:</b> 80.71±7.38 vs. 73.96±15.39, p=0.053 <b>Pain (VAS score):</b> 2.08±0.88 vs. 1.80±2.27, p>0.05

Author year Study name (if applicable)	Study design	Subjects	Treatment groups (n; dose)	Treatment duration	Outcomes and findings
					<b>Retear rate (%)</b> : 6/25 (24%) vs. 5/25 (20%), p=0.733
Ma 2012 <sup>11</sup>	RCT	53 pts with full-thickness rotator cuff tear (> 1cm diameter) mean age: 61 years; male%: 55	Single-row (n=27, dose: NA) vs. double-row (n=26, dose: NA)	NA	<u>Single-row vs. double-row (FU=2 yrs post-operation)</u> <b>UCLA score</b> : 31.40±3.34 vs. 31.53±3.40, p=0.89 <b>ASES index</b> : 91.25±2.36 vs. 91.38±2.36, p=0.85 <b>Abduction strength (kg)</b> : 4.91±0.8 vs. 5.01±0.62, p=0.63 <b>ER strength (kg)</b> : 6.86±0.84 vs. 7.03±0.78, p=0.46 <b>Intact cuff (%)</b> : 17 (63%) vs. 20 (77%), p=0.63 <b>Partial tear (%)</b> : 4 (14.83%) vs. 3 (11.5%), p=0.63 <b>Complete tear (%)</b> : 6 (22.2%) vs. 3 (11.5%), p=0.63
Shin 2012 <sup>12</sup>	RCT	48 pts with symptomatic partial-thickness articular-sided rotator cuff tear (> 50% of the tendon thickness) mean age: 55 years; male%: 48	RCR with transtendon technique (n=24, dose: NA) vs. RCR after tear completion (n=24, dose: NA)	NA	<u>RCR transtendon technique vs. RCR tear completion (FU=32 mo)</u> <b>Pain (VAS score)</b> : 1.4±0.4 vs. 1.1±0.2, p=0.207 <b>ASES index</b> : 89.1±2.1 vs. 86.2±3.2, p>0.05 <b>Constant score</b> : 84.8±2.7 vs. 87.1±2.4, p>0.05 <b>ROM-FF (mean degrees)</b> : 167.8±5 vs. 170.4±3.2, p>0.05 <b>ROM-ER at side (mean degrees)</b> : 65.2±4.4 vs. 66.6±2.0, p>0.05 <b>IR (spine level)</b> : L1/T12 vs. L1/T12, p>0.05
<b>Operative augmentation</b>					
Barber <sup>13</sup>	RCT	42 pts with 2-tendon rotator cuff tears measuring greater than 3Com. Mean age: 56 years. Male%: 74	RCR with augmentation (n=56, dose: NA) vs. RCR without augmentation (n=56, dose: NA)	NA	<u>RCR with augmentation vs. RCR without augmentation (FU=24 mo)</u> <b>UCLA score</b> : 28.2±2.1 vs. 28.3±3.0, p=0.43 <b>ASES index</b> : 98.9±4.2 vs. 94.8±14.2, p=0.035 <b>Constant score</b> : 91.9±9.2 vs. 85.3±11.0, p=0.008
Bergeson <sup>14</sup>	Cohort study	37 pts with full-thickness rotator cuff tear (diameter at least 2 cm) mean age: 65 years; male%: NR	RCR with augmentation (n=16, dose: NA) vs. RCR without augmentation (n=21, dose: NA)	NA	<u>RCR with augmentation vs. RCR without augmentation (FU=1 yr post-operation)</u> <b>Retear rate (%)</b> : 9/16 (56%) vs. 8/21 (38%) p=0.024 <b>Retear rate (single row repairs) (%)</b> : 8/13 (62%) vs. 8/20 (40%), p=0.022

Author year Study name (if applicable)	Study design	Subjects	Treatment groups (n; dose)	Treatment duration	Outcomes and findings
					<b>ASES index:</b> 87 vs. 84, p=0.65 <b>UCLA score:</b> 29 vs. 29, p=0.55 <b>Constant score:</b> 73 vs. 76, p=0.58 <b>WORC score:</b> 80 vs. 82, p=0.66 <b>SANE score:</b> 89 vs. 87, p=0.92
<b>Post-operative rehabilitation</b>					
Lee 2012 <sup>15</sup>	RCT	85 patients with medium-large rotator cuff tear who had undergone single-row RCR; mean age: 55 years; male%: 64	Aggressive passive rehabilitation (n=43; manual therapy 2 x day) vs. Limited passive rehabilitation (n=42; continuous passive motion exercise, self-passive exercise)	6 weeks	<u>Aggressive group vs. Limited group (FU=1 yr post-operation)</u> <b>Pain at rest (0-10):</b> 0.23 (range 0-3) vs. 0.15 (range 0-3), p=0.382 <b>Pain at motion (0-10):</b> 1.47 (range 0-5) vs. 1.53 (range 0-5), p=0.808 <b>ROM-FF (mean degrees):</b> 155.3±13.0 vs. 153.0±12.2, p=0.729 <b>ROM-ER at side (mean degrees):</b> 53.0±11.6 vs. 48.1±13.9, p=0.078 <b>Abduction (mean degrees):</b> 167.8±12.8 vs. 161.8±27.3, p=0.884 <b>Muscle strength-elevation (in kg):</b> 7.76 vs. 7.33, p=0.227 <b>Muscle strength-external rotation (in kg):</b> 7.94 vs. 7.62, p=0.542 <b>Muscle strength-internal rotation (in kg):</b> 8.90 vs. 8.44, p=0.450 <b>UCLA score:</b> NR (p=0.158) <b>Percent of excellent cases:</b> 16 (47.1%) vs. 15 (50%), p=0.341 <b>Healing rate (%):</b> 23 (76.7%) vs. 31 (91.2%), p=0.106
<b>Cycle 1</b>					
<b>Operative approach</b>					
Abbot 2009 <sup>27</sup>	RCT	48 pts with concomitant rotator cuff and type II SLAP lesion tears; mean age: 52 yrs;	RCR + SLAP tears debridement (n=24; dose: NA) vs. RCR + SLAP tears repair (n=24; dose: NA)	NA	<u>RCR + SLAP tears debridement vs. RCR + SLAP tears repair (FU=2 yrs)</u> <b>UCLA score (max=35):</b> 34±2.1 vs. 31±2.7, p<0.001 <b>Pain (max=10):</b> 9.6±0.8 vs. 7.7±1.4, p<0.001 <b>Functional improvement (max=10):</b> 5.5±1.1 vs.

Author year Study name (if applicable)	Study design	Subjects	Treatment groups (n; dose)	Treatment duration	Outcomes and findings
		male%: NR			3.8±1.9, p<0.001 <b>Forward flexion</b> (max=5): 4.9±0.3 vs. 4.8±0.4, p=0.27 <b>Strength</b> (max=5): 4.9±0.3 vs. 4.7±0.5, p=0.08 <b>Satisfaction</b> (max=5): 5±0 vs. 5±0, p=NR <b>ROM-IR:</b> 69.8±11.8 vs. 37.8±23.8, p<0.001 <b>ROM-ER:</b> 84.8±9.0 vs. 69.7±12.5, p<0.001 <b>ROM-FF:</b> 166.5±4.9 vs. 163.1±10.0, p=0.08
Forsythe 2010 <sup>23,40</sup>	Non-RCT	62 pts with concomitant symptomatic full-thickness rotator cuff and SLAP lesion tears who failed initial conservative treatment; mean age: 56.9 yrs; male%: 58	RCR + SLAP tears repair (n=34; dose: NA) vs. RCR (n=28; dose: NA)	NA	<u>RCR + SLAP tears repair vs. RCR (FU=41-43 mo)</u> <b>ASES score:</b> 96.4±9.2 vs. 92.3±12.1, p=0.137 <b>Function (Constant score):</b> 91.0±8.0 vs. 85.0±6.5, p=0.002 <b>Abduction:</b> 161.6±9.6 vs. 158.2±17.2, p=0.329 <b>ROM-FF:</b> 164.6±7.4 vs. 162.5±14.4, p=0.472 <b>ROM-ER:</b> 68.1±9.9 vs. 68.9±11.1, p=753
Adla 2010 <sup>26</sup>	Non-RCT	30 pts with symptomatic moderately sized rotator cuff tears; mean age: 54-57 yrs; male%: 69.2	RCR [arthroscopic] (n=15; dose: NA) vs. RCR [open] (n=15; dose: NA)	NA	<u>RCR [arthroscopic] vs. RCR [open] (FU=12 mo)</u> <b>Oxford shoulder questionnaire (mean change):</b> 24.9±6.7 vs. 25.5±7, p=0.70 (95% CI: -6.0, 6.0) <b>Function (Constant score):</b> 82.0 vs. 78.0, p=NR
Koh 2010 <sup>21</sup>	Non-RCT	90 pts aged 55 yrs or older with rotator cuff tears combined with biceps lesion, subluxation, dislocation, or degenerative type II SLAP lesion; mean age: 65-66 yrs; male%: 29.7	Biceps tenodesis (n=45; dose: NA) vs. Biceps tenotomy (n=45; dose: NA)	NA	<u>Biceps tenodesis vs. Biceps tenotomy (FU=27 mo post-operation)</u> <b>ASES score:</b> 84.7±13.58 vs. 79.64±15.76, p=0.176 <b>Function (Constant score):</b> 82.91±13.49 vs. 78.27±14.08, p=0.193 <b>Arm cramping pain:</b> 2/43 (4.65%) vs. 4/41 (9.75%), p=0.427
<b>Operative technique</b>					

Author year Study name (if applicable)	Study design	Subjects	Treatment groups (n; dose)	Treatment duration	Outcomes and findings
Cho 2010 <sup>25</sup>	Non-RCT	46 pts who had arthroscopic rotator cuff tear repair and subsequent retear; mean age: 57.8 yrs; male%: 63.0	Single-row (n=19; dose: NA) vs. Suture bridge [transosseous-equivalent] (n=27; dose: NA)	NA	<p><u>Single-row vs. Suture bridge (FU=7.5 mo post-operation)</u>  <b>Pain (VAS)-rest:</b> 0.3 (range: 0-3) vs. 0.2 (range: 0-1), p=0.431  <b>Pain (VAS)-motion:</b> 2.4 (range: 0-6) vs. 2.0 (range: 0-5), p=0.472  <b>ROM-FF:</b> 148.3 (range: 80-170) vs. 147.3 (range: 20-170), p=0.923  <b>ROM-ER:</b> 40.9 (range: 6-70) vs. 40.9 (range: 0-90), p=0.991  <b>ROM-IR:</b> T12 (range: T4-L4) vs. L1 (range: T7-S1), p=0.204  <b>Muscle strength in kg (FF):</b> 4.94 vs. 5.6, p=0.164  <b>Muscle strength in kg (ER):</b> 6.56 vs. 6.9, p=0.701  <b>Muscle strength in kg (IR):</b> 7.26 vs. 7.7, p=669  <b>Function (Constant score):</b> 77.40 vs. 76.20, p=0.672  <b>UCLA score:</b> 30.4 vs. 29.2, p=0.311  <b>Retear (type 1):</b> n=14 (73.7%) vs. n=7 (25.9%), p=0.049  <b>Retear (type 2):</b> n=5 (26.3%) vs. n=20 (74.1%), p=0.049</p>
Aydin 2010 <sup>22</sup>	RCT	68 pts with symptomatic full-thickness rotator cuff tear; mean age: 58.0 yrs; male%: NR	Single-row (n=34; dose: NA) vs. Double-row (n=34; dose: NA)	NA	<p><u>Single-row vs. Double-row (FU=36 mo)</u>  <b>Function (Constant score):</b> 82.2 (range: 72-96) vs. 78.8 (range: 68-94), p&gt;0.05</p>
Koh 2011 <sup>17</sup>	RCT	62 pts with full-thickness 2-4 cm rotator cuff tear; mean age: 61.3 yrs; male%: 32.2	Single-row (n=31; dose: NA) vs. Double-row (n=31; dose: NA)	NA	<p><u>Single-row vs. Double-row (FU=27.5 mo post-operation)</u>  <b>Retear (full-thickness):</b> 4/24 (16.6%) vs. 6/23 (26.0%), p=0.999  <b>Retear (full or partial):</b> 15/24 (62.5%) vs. 7/23 (30.4%), p=0.124  <b>No tear:</b> 9/24 (37.5%) vs. 16/23 (69.6%), p=NR  <b>Pain (VAS):</b> 1.8 ± 2.0 vs. 1.9 ± 2.5, p=0.973</p>

Author year Study name (if applicable)	Study design	Subjects	Treatment groups (n; dose)	Treatment duration	Outcomes and findings
					<p><b>Function (Constant score):</b> 85.5 ± 12.7 vs. 85.7 ± 20.2, p=0.416</p> <p><b>ASES score:</b> 84.3 ± 15.50 vs. 84.60 ± 22.00, p=0.481</p> <p><b>UCLA score:</b> 29.5 ± 4.4 vs. 30.1 ± 6.5, p=0.267</p> <p><b>ROM-FF:</b> 150.3 ± 13.5 vs. 151.0 ± 16.2 (range: 20-170), p=0.507</p> <p><b>ROM-IR:</b> T8 vs. T9, p=0.053</p> <p><b>ROM-ER:</b> 33.2 ± 15.4 vs. 30.8 ± 13.4, p=0.547</p> <p><b>Satisfaction (good to excellent):</b> 25 (80.6%) vs. 27 (87.0%), p=NR</p>
Pennington 2010 <sup>19</sup>	Non-RCT	132 pts with rotator cuff tear; mean age: 55 yrs; male%: NR	Single-row (n=78; dose: NA) vs. Double-row (n=54; dose: NA)	NA	<p><u>Single-row vs. Double-row (FU=24 mo post-operation)</u></p> <p><b>Healing rate (grade 1-3):</b> n=35/44 (79.5%) vs. n=25/37 (67.5%), p&lt;0.017 [total population]</p> <p><b>Healing rate (grade 1-3):</b> n=13/18 (72%) vs. n=19/25 (76%), p&lt;0.03 [tears between 2.5-3.5 cm]</p> <p><b>ASES score:</b> 86.9 vs. 91.6, p&gt;0.05</p> <p><b>Pain (VAS):</b> 1.1 vs. 0.4, p&gt;0.05</p> <p><b>UCLA score:</b> 29.6 vs. 29.3, p&gt;0.05</p> <p><b>ROM-FF:</b> 160 vs. 167, p&gt;0.05</p> <p><b>ROM-ER:</b> 82 vs. 88, p&gt;0.05</p> <p><b>ROM-IR:</b> 74 vs. 81, p&gt;0.05</p> <p><b>Abduction:</b> 157 vs. 161, p&gt;0.05</p> <p><b>Satisfaction:</b> 95% vs. 92%, p=NR</p>
Milano 2010 <sup>20</sup>	RCT	110 pts with symptomatic full-thickness rotator cuff tear; mean age: 61.6 yrs; male%: 65	RCR-metal anchors (n=55; dose: NA) vs. RCR-biodegradable anchors (n=55; dose: NA)	NA	<p><u>RCR-metal anchors vs. RCR-biodegradable anchors (FU=24 mo)</u></p> <p><b>DASH score (0-100):</b> 17.6 ± 17.2 vs. 22.8 ± 19.9, 95% CI: -13.80, 0.40</p> <p><b>Work-DASH score:</b> 24.9 ± 28.1 vs. 22.5 ± 24.1, 95% CI: -8.50, 12.82</p> <p><b>Constant score:</b> 104 ± 20.5 vs. 98.6 ± 14.3, 95% CI: -1.48, 12.27</p>
<b>Operative augmentation</b>					
Castricini 2011 <sup>18</sup>	RCT	88 pts with rotator cuff tear; mean age:	RCR (n=45; dose: NA) vs. RCR + Augmentation with PRFM (n=43;	NA	<p><u>RCR vs. RCR + Augmentation with PRFM (FU=20.2 mo)</u></p>

Author year Study name (if applicable)	Study design	Subjects	Treatment groups (n; dose)	Treatment duration	Outcomes and findings
		55 yrs; male%: 45.4	dose: NA)		<p><b>Constant score</b>  <b>Shoulder pain:</b> 14.3 (10-15) vs. 14.3 (10-15), p&gt;0.05  <b>ADL:</b> 18.8 (14-20) vs. 19.3 (16-20), p&gt;0.05  <b>ROM:</b> 38.8 (26-40) vs. 39.1 (36-40), p&gt;0.05  <b>Strength:</b> 16.5 (4-25) vs. 15.7 (40-24), p&gt;0.05  <b>Total score:</b> 88.4 (54-100) vs. 88.4 (72-99), p=0.44</p> <p><b>Tendon thickness</b>  Normal: 17/38 (44.7%) vs. 27/40 (67.5%), p=0.181</p>
Cho 2009 <sup>28</sup>	Non-RCT	68 pts with massive rotator cuff tears; mean age: 59.5 yrs; male%: 45.6	RCR (n=31; dose: NA) vs. RCR + Augmentation of biceps (n=37; dose: NA)	NA	<p><u>RCR vs. RCR + Augmentation (FU=15 mo post-operation)</u>  <b>Pain (VAS)-rest:</b> 0.13 (range: 0-1) vs. 0.15 (range: 0-1), p=0.524  <b>Pain (VAS)-motion:</b> 2.03 (range: 0-7) vs. 2.7 (range: 0-8), p=0.317</p> <p><b>ROM-FF (degrees):</b> 159.1 vs. 156.2, p=0.35  <b>ROM-ER (degrees):</b> 40 vs. 47, p=0.094  <b>ROM-IR:</b> L1 vs. T11, p=0.053  <b>Abduction (degrees):</b> 168 vs. 162, p=0.202</p> <p><b>Muscle strength-FF (kg):</b> 5.4 vs. 7.27, p=0.017  <b>Muscle strength-ER (kg):</b> 6.8 vs. 8.62, p=0.001  <b>Muscle strength-IR (kg):</b> 7.5 vs. 9.9, p&lt;0.001  <b>Muscle strength-abduction (kg):</b> 4.6 vs. 6.5, p=0.26</p> <p><b>Re-tear rate:</b> 14/19 (73.7%) vs. 10/24 (41.7%), p=0.036</p> <p><b>Constant score:</b> 81 (range: 55-96) vs. 82.6 (range: 69-96), p=0.412  <b>UCLA score:</b> 30.3 (range: 20-35) vs. 32.6 (range: 22-35), p=0.198  <b>Satisfaction (excellent):</b> 5 (16.1%) vs. 18 (48.7%), p=NR</p>

Author year Study name (if applicable)	Study design	Subjects	Treatment groups (n; dose)	Treatment duration	Outcomes and findings
Barber 2011 <sup>29</sup>	Non-RCT	40 pts with clinically significant symptomatic full-thickness rotator cuff tear (10-50 mm in width); mean age: 57 yrs; male%: 67.5	RCR (n=20; dose: NA) vs. RCR + Augmentation with PRFM (n=20; dose: NA)	NA	<u>RCR vs. RCR + Augmentation with PRFM (FU=31 mo)</u> <b>Re-tear rate:</b> 12/20 (60%) vs. 6/20 (30%), p=0.03 <b>Healing rate (tears &lt; 3 cm length):</b> 7/14 (50%) vs. 12/14 (86%), p<0.05 <b>Healing rate (tears ≥ 3 cm length):</b> 1/6 (16.6%) vs. 2/6 (33%), p<0.07 <b>ASES score:</b> 94.7 vs. 95.7, p=0.35 <b>Constant score:</b> 84.7 vs. 88.1, p=0.19 <b>SANE score:</b> 93.7 vs. 94.5, p=0.37 <b>SST score:</b> 11.4 vs. 11.3, p=0.41
Randelli 2011 <sup>16</sup>	RCT	53 pts with complete rotator cuff tear; mean age: 60 yrs; male%: 40	RCR (n=27; dose: NA) vs. RCR + Augmentation with PRP (n=26; dose: NA)	NA	<u>RCR vs. RCR + Augmentation with PRP (FU=24 mo post-treatment)</u> <b>Re-tear rate:</b> 12/23 (52%) vs. 9/22 (41%), p=0.40 <b>UCLA score:</b> 31.3 ± 4.1 vs. 33.3 ± 2.2, p=0.06 <b>Constant score:</b> 78.7 ± 10.0 vs. 82.4 ± 6.3, p=0.10 <b>SST score:</b> 10.9 ± 1.4 vs. 11.3 ± 0.9, p=0.30
<b>Post-operative rehabilitation</b>					
No new relevant evidence was identified	NA	NA	NA	NA	NA
<b>Key question # 3:</b> What is the comparative effectiveness of nonoperative interventions on improved health-related quality of life, decreased disability, reduced time to return to work/activities, higher rate of cuff integrity, less shoulder pain, and increased range of motion and/or strength? Nonoperative interventions include, but are not limited to, exercise, manual therapy, cortisone injections, acupuncture, and treatments and modalities typically delivered by physical therapists, osteopaths, and chiropractors.					
<b>Cycle 2</b>					
No new relevant evidence was identified	NA	NA	NA	NA	NA
<b>Cycle 1</b>					
Chou 2010 <sup>24</sup>	RCT	51 pts who had rotator cuff lesions without complete tearing refractory to	Sodium hyaluronate (n=25; 25 mg/wk) vs. PL (n=26; 2.5 mL/wk normal saline)	5 wks	<u>Sodium hyaluronate vs. PL (1 week post-treatment)</u> <b>Constant score:</b> 72.48 ± 16.46 vs. 72.42 ± 11.75, p=0.9887 <b>Pain (VAS):</b> 4.20 ± 1.76 vs. 4.77 ± 1.75, p=0.252

Author year Study name (if applicable)	Study design	Subjects	Treatment groups (n; dose)	Treatment duration	Outcomes and findings
		previous conservative therapy or rehabilitation for 3 mo or longer; mean age: 52 yrs; male%: 37.2			<p><b>Global improvement</b> (physician-assessed): NS (p=0.272)  <b>Global improvement</b> (patient-assessed): NS (p=0.164)</p> <p><u>Sodium hyaluronate vs. PL (6 weeks post-treatment)</u>  <b>Constant score:</b> 79.24 ± 13.09 vs. 69.07 ± 13.29, p=0.0095  <b>Pain (VAS):</b> 3.04 ± 2.03 vs. 5.12 ± 2.42, p=0.0018</p>
Bennell 2010 <sup>30</sup>	RCT	120 pts with chronic rotator cuff disease; mean age: 60 yrs; male%: 53	MT + exercise (n=59; 10 sessions of soft tissue massage, joint/spine mobilization, postural taping, and home exercise) vs. PL (ultrasound + inert gel; n=61; 10 sessions)	MT (10 wks), exercise (22 wks), PL (10 wks) followed by no treatment for 12 wks	<p><u>MT + exercise vs. PL (22 wks post-baseline)</u>  <b>SPADI total score (0-100):</b> 22.4 ± 22.0 vs. 15.6 ± 17.8  MD (95% CI): 7.1 (0.3, 13.9)</p> <p><b>SPADI pain score (0-100):</b> 24.8 ± 23.7 vs. 17.3 ± 19.6  MD (95% CI): 7.1 (0.3, 13.9)</p> <p><b>SPADI function score (0-100):</b> 19.6 ± 20.7 vs. 11.6 ± 16.6  MD (95% CI): 7.6 (1.8, 13.4)</p> <p><b>VAS-motion (pain score):</b> 2.6 ± 2.9 vs. 1.6 ± 2.4  MD (95% CI): 0.9 (-0.03, 1.7)</p> <p><b>VAS-rest (pain score):</b> 1.3 ± 2.5 vs. 0.4 ± 2.5  MD (95% CI): 0.7 (-0.1, 1.4)</p> <p><b>SF-36 physical score (0-100):</b> 10.8 ± 25.0 vs. 4.7 ± 22.3  MD (95% CI): 6.3 (-2.0, 14.5)</p> <p><b>AQoL (-0.4-1.0):</b> 0.0 ± 0.2 vs. 0.0 ± 0.1  MD (95% CI): 0.0 (0.04, 0.1)</p> <p><b>Muscle strength-abduction (kg):</b> 1.1 ± 4.4 vs. 0.4 ±</p>

Author year Study name (if applicable)	Study design	Subjects	Treatment groups (n; dose)	Treatment duration	Outcomes and findings
					2.5 MD (95% CI): 1.2 (0.1, 2.3)  <b>Muscle strength-ER (kg):</b> 0.3 ± 4.3 vs. -0.1 ± 1.9 MD (95% CI): 0.9 (-0.1, 1.9)  <b>Muscle strength-IR (kg):</b> 1.3 ± 3.4 vs. 0.0 ± 2.7 MD (95% CI): 1.5 (0.4, 2.5)  <b>Global change overall ('much better'):</b> 31 (57%) vs. 24 (41%) RR (95% CI): 1.39 (0.94, 2.03)
<b>Key question # 4:</b> Does operative repair compared with nonoperative treatment lead to improved health-related quality of life, decreased disability, reduced time to return to work/activities, higher rate of cuff integrity, less shoulder pain, and increased range of motion and/or strength?					
<b>Cycle 2</b>					
No new relevant evidence was identified	NA	NA	NA	NA	NA
<b>Cycle 1</b>					
No new relevant evidence was identified	NA	NA	NA	NA	NA
<b>Key question # 5:</b> What are the associated risks, adverse effects, and potential harms of nonoperative and operative therapies?					
<b>Cycle 2</b>					
No new relevant evidence was identified	NA	NA	NA	NA	NA
<b>Cycle 1</b>					
Chou 2010 <sup>24</sup>	RCT	51 pts who had rotator cuff lesions without complete tearing refractory to previous	Sodium hyaluronate (n=25; 25 mg/wk) vs. PL (n=26; 2.5 mL/wk normal saline)	5 wks	<u>Sodium hyaluronate vs. PL (during 5 wk treatment)</u> <b>Complications:</b> None

Author year Study name (if applicable)	Study design	Subjects	Treatment groups (n; dose)	Treatment duration	Outcomes and findings
		conservative therapy or rehabilitation for 3 mo or longer; mean age: 52 yrs; male%: 37.2			
Cho 2009 <sup>28</sup>	Non-RCT	68 pts with massive rotator cuff tears; mean age: 59.5 yrs; male%: 45.6	RCR (n=31; dose: NA) vs. RCR + Augmentation of biceps (n=37; dose: NA)	NA	RCR vs. RCR + Augmentation (FU=15 mo post-operation) <b>Post-operative complications (immediate):</b> None <b>Post-operative complications (pop-eye deformity):</b> n=2 vs. n=1
Randelli 2011 <sup>16</sup>	RCT	53 pts with complete rotator cuff tear; mean age: 60 yrs; male%: 40	RCR (n=27; dose: NA) vs. RCR + Augmentation with PRP (n=26; dose: NA)	NA	RCR vs. RCR + Augmentation with PRP (FU=24 mo post-treatment) <b>Complications:</b> 1 pt in the RCR group had failure of cuff repair
<b>Key question # 6:</b> Which demographic (e.g., age, gender, ethnicity, comorbidities, workers' compensation claims) and clinical (e.g., size/severity of tear, duration of injury, fatty infiltration of muscle) prognostic factors predict better outcomes following nonoperative and operative treatment? Which (if any) demographic and clinical factors account for potential differences in surgical outcomes between patients who undergo early versus delayed surgical treatment?					
<b>Cycle 2</b>					
No new relevant evidence was identified	NA	NA	NA	NA	NA
<b>Cycle 1</b>					
No new relevant evidence was identified	NA	NA	NA	NA	NA
pts=patients; d=day(s); yr(s)=years; mo=month(s); NR=not reported; vs.=versus RCT=randomized controlled trial; CER=comparative effectiveness review; SLAP=superior labral anterior posterior; RCR=rotator cuff repair; FU=follow-up; SR=systematic review; NA=not applicable; VAS=visual analogue scale; UCLA=University of California Los Angeles; ROM=range of motion; IR=internal rotation; ER=external rotation; FF=forward flexion; ASES=American Shoulder and Elbow Surgeons score; kg=kilogram; DASH=Disabilities of the Arm, Shoulder and Hand questionnaire; PRFM=platelet rich fibrin matrix; SANE=single assessment numeric evaluation; SST=simple shoulder test; PL=placebo; MT>manual therapy; MD=mean difference; 95% CI= 95 percent confidence interval; SF=short form; RR=relative risk; AqoL=assessment of quality of life; SPADI=shoulder pain and disability index; PRP=platelet rich plasma; WORC=Western Ontario Rotator Cuff Index					

## Appendix D: Questionnaire Matrix

### Comparative Effectiveness of Nonoperative and Operative Treatments for Rotator Cuff Tears

AHRQ Publication No. 10-EHC050-EF July 2010

Access to full report: <http://www.effectivehealthcare.ahrq.gov/ehc/products/67/474/Rotator%20Cuff%20Exec%20Summ.pdf>

Clinical expert name:

Conclusions from CER (executive summary)	Is the conclusion(s) in this CER still valid? (Yes/No/Don't know)	Are you aware of any new evidence that is sufficient to invalidate the finding(s) in CER? (Yes/No/Don't know) If yes, please provide references	Comments
<b>Key Question 1.</b> Does early surgical repair compared to late surgical repair (i.e., nonoperative intervention followed by surgery) lead to improved health-related quality of life, decreased disability, reduced time to return to work/activities, higher rate of cuff integrity, less shoulder pain, and increased range of motion and/or strength?			
One study compared early surgical repair versus late surgical repair after failed nonoperative treatment. Patients receiving early surgery had superior function compared with the delayed surgical group; however, the level of significance was not reported.			
<b>Key Question 2.</b> What is the comparative effectiveness of operative approaches (e.g., open surgery, miniopen surgery, and arthroscopy) and postoperative rehabilitation on improved health related quality of life, decreased disability, reduced time to return to work/activities, higher rate of cuff integrity, less shoulder pain, and increased range of motion and/or strength?			

<p>A total of 113 studies examined the effectiveness of operative interventions, while 11 studies evaluated postoperative rehabilitation protocols following surgery. A median of 55 patients (IQR: 34 to 95) with a median age of 58.6 years (IQR: 55.5 to 61.7) were included in the operative studies. Males comprised an average of 64.6 percent of study participants. For postoperative rehabilitation, studies included a median of 61 participants (IQR: 36 to 79.5) with a median age of 58.0 years (IQR: 56.3 to 60.8). Males comprised an average of 58.9 percent of study participants.</p> <p>Studies assessing operative treatments were categorized as focusing on an operative approach (e.g., open, mini-open, arthroscopic, and debridement), technique (i.e., suture or anchor type or configuration) or augmentation for RC repair. The majority of surgical studies (32 comparative studies and 58 uncontrolled studies) evaluated operative approaches. The comparative studies provided moderate evidence indicating no statistical or clinically important differences in function between open and mini-open repairs; however, there was some evidence suggesting an earlier return to work by approximately 1 month for mini-open repairs. Similarly, there was moderate evidence demonstrating no difference in function between mini-open and arthroscopic repair and arthroscopic repair with and without acromioplasty. There was moderate evidence for greater improvement in function for open repairs compared with arthroscopic debridement. The strength of evidence was low for the remaining comparisons and outcomes examined in the studies, precluding any conclusions regarding their comparative effectiveness. The uncontrolled studies consistently reported functional improvement from preoperative to postoperative scores, regardless of the type of approach used (open, mini-open, or arthroscopic), the study design, the sample size of the study, or the type of outcome measure used.</p> <p>Operative techniques were examined in 15 comparative studies. Six studies compared single-row versus double-row fixation of repairs, providing moderate evidence of no clinically significant difference in function and no difference in cuff integrity. There was moderate evidence for no difference in cuff integrity between mattress locking and simple stitch. The evidence was too limited</p>			
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<p>to make conclusions about the other techniques.</p> <p>Eight studies, including three comparative and five uncontrolled studies, assessed augmentations for operative repair. The three comparative studies were relatively small and no overall conclusions were possible. Although the five uncontrolled studies evaluated different types of augmentation, they all indicated improvement in functional score from baseline to final followup.</p> <p>Of the 11 postoperative rehabilitation studies (10 comparative, 1 uncontrolled), 3 compared continuous passive motion with physical therapy versus physical therapy alone. These three studies provided moderate evidence of no clinically important or statistically significant difference in function, but some evidence for earlier return to work with continuous passive motion. Each of the remaining studies examined different rehabilitation protocols; therefore, the evidence was too limited to make any conclusions regarding their comparative effectiveness.</p>			
<p><b>Key Question 3.</b> What is the comparative effectiveness of nonoperative interventions on improved health-related quality of life, decreased disability, reduced time to return to work/activities, higher rate of cuff integrity, less shoulder pain, and increased range of motion and/or strength? Nonoperative interventions include, but are not limited to, exercise, manual therapy, cortisone injections, acupuncture, and treatments and modalities typically delivered by physical therapists, osteopaths, and chiropractors.</p>			
<p>Nonoperative interventions were examined in three comparative and seven uncontrolled studies. The studies included a median of 42 patients (IQR: 25.3 to 73.3), with a median age of 61 years (IQR: 60.4 to 61.5). Males comprised an average of 50 percent of participants. Each of the comparative studies assessed different interventions, including: sodium hyaluronate versus dexamethasone; rehabilitation versus no rehabilitation (not otherwise specified); and physical therapy, oral medications, and steroid injection versus physical therapy, oral medications, and no steroid injection. The limited evidence precludes conclusions of comparative effectiveness. The degree of improvement in functional outcome scores varied considerably across the uncontrolled studies.</p>			
<p><b>Key Question 4.</b> Does operative repair compared with nonoperative treatment lead to improved health-related quality of life, decreased disability, reduced time to return to work/activities, higher rate of cuff integrity, less shoulder pain, and increased range of motion and/or strength?</p>			

<p>Five studies compared nonoperative to operative treatments, with a median sample size of 103 (IQR: 40 to 108). The mean ages in the studies ranged from 46.8 to 64.8 years. Males represented 55 percent of study participants. The interventions varied across studies, but generally the nonoperative arms included components such as steroid injection, stretching, and strengthening and were compared with open repair or debridement. The evidence was too limited to make conclusions regarding the comparative effectiveness of the interventions.</p>			
<p><b>Key Question 5.</b> What are the associated risks, adverse effects, and potential harms of nonoperative and operative therapies?</p>			
<p>A total of 85 studies provided data on 34 different complications of nonoperative, operative, and ostoperative rehabilitation interventions. Complications were poorly reported, with studies providing limited information on how complications were defined and assessed. In 21 studies, it was reported that no complications occurred during the course of the study. In general, the rates of complication were low and the majority of complications were not deemed to be clinically important or were reported in few studies.</p>			
<p><b>Key Question 6.</b> Which demographic (e.g., age, gender, ethnicity, comorbidities, workers' compensation claims) and clinical (e.g., size/severity of tear, duration of injury, fatty infiltration of muscle) prognostic factors predict better outcomes following nonoperative and operative treatment? Which (if any) demographic and clinical factors account for potential differences in surgical outcomes between patients who undergo early versus delayed surgical treatment?</p>			
<p>Overall, 72 of the 137 studies examined the impact of prognostic factors on patient outcomes. General conclusions are limited, due to the varied methodologies across studies, particularly the different outcomes for which prognostic factors were evaluated. There is some evidence that tear size, age, and extent of preoperative symptoms may modify outcomes; while, workers' compensation board (WCB) status, sex, and duration of symptoms generally showed no significant impact.</p>			
<p>CER=comparative effectiveness review; RCT=randomized controlled trial; IQR=interquartile range</p>			