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 (2nd Assessment/cycle 2):

November 2012

Surveillance Report (3rd Assessment/cycle 3):

February 2014

Key Findings (1st 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 1st 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- KQ2: Possibly out of date (1 quantitative and 2 qualitative signals)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

Key Findings (Cumulative: 1st, 2nd, and 3rd assessment/cycle 1-3)

Changed from the 2nd assessment:

- KQ1, KQ3, and KQ4 are up to date
- KQ2: Probably out of date (9 qualitative signals)
- KQ5: Possibly out of date (2 qualitative signals)
- KQ6: Possibly out of date (4 qualitative signals)
- There are no new safety concerns

Summary Decision:

This CER's priority for updating is **Low**

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None of the investigators have any affiliation or financial involvement that conflicts with material presented in this report

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Comparative Effectiveness of Nonoperative and Operative Treatments for Rotator Cuff Tears

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),[1] 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. The second assessment was completed in November 2012. This third assessment was completed in February 2014.

This third surveillance report included 31 studies (one systematic review, two meta-analyses, nine randomized controlled trials (RCTs) and 19 prospective and retrospective cohort studies) identified by using searches through January 2014, and addressed six key questions to evaluate the effectiveness and safety of non-operative 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.[1]

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, probably out of date, 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.[2-4]

2.1 Literature Searches

Cycle 3 (3rd assessment)

The same search strategy for MEDLINE as the 2nd assessment (cycle 2) that appears in the CER's Appendix A[1] was used, but with different search dates (March 16, 2009 to January 15, 2014). EMBASE, Cochrane Central Register of Controlled Trials (2011 – 2012), and CINAHL were not included in this assessment.

Cycle 2 (2nd 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.[1]

Cycle 1 (1st 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; 4th Quarter 2011), and CINAHL (January 01, 2009 - January 10, 2012) as per the original search strategies appearing in the CER's Appendix A.[1] 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.

2.3 Expert Opinion

Cycle 3 (3rd assessment)

We contact one CER-specific expert. We also contacted one expert involved with a Future Research Needs assessment completed for AHRQ on this topic.[73]

Cycle 2 (2nd assessment)

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

Cycle 1 (1st 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 signals(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.[2,3]

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 3 (3rd assessment)

A total of 430 bibliographic records were identified after de-duping. Of the 430 records, 56 were passed on to full text screening. The full text screening of these records resulted in 31 included unique studies.[5-36] Of those 31 studies, nine where included in the previous update, cycle 2 assessment. We also reviewed a Future Research Needs assessment completed for AHRQ on this topic.[73]

Cycle 2 (2nd 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.[37-47]

Cycle 1 (1st assessment)

A total of 15 studies were included in the report.[48-62]

3.2 Signals for Updating in Newly Identified Studies [Cycle 3]

3.2.1 Study overview

The study, population, treatment characteristics, and results for the 31 studies (identified in this 3rd assessment),[5-36] the 11 included studies[37-47] (identified in the 2nd assessment) and the 15 included studies[48-62] (identified in the 1st assessment) are presented in Appendix C (Evidence Table [Cycle 3]).

In brief, participants across the 31 studies included studies (3rd 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 31 studies, one was a systematic review,[6] two were meta-analyses,[12,13] nine were RCTs[5,7,11,15,16,19,20,21,24] and 19 were observational comparative studies.[6,8-10,14,17,18,22,23,25-35] No additional analysis was completed to determine if the RCTs were pivotal (see Appendix B). The sample size of the RCTs ranged from 40[19] to 95.[5]

The sample size for the included cohort studies ranged from 36[9] to 272.[29] The majority of included studies compared either different operative approaches (e.g., open, mini-open, debridement, arthroscopic with or without acromioplasty, arthroscopic with or without biceps tenotomy, biceps tenotomy, biceps tenodesis)[5-10] or techniques of cuff tear repair (e.g., single-row, double-row, bioabsorbable cork screw, metal suture anchor, mattress locking, simple stitch).[6,11-22] Two studies compared arthroscopic cuff tear repair with and without augmentation.[23,24] Three comparative cohort studies reported on complications of operative therapies, including Popeye deformity, stiffness, and glenohumeral arthritis.[8,25,26] One RCT and nine cohort studies found evidence supporting known and new risk factors.[16,25,27-35]

The reported outcomes across the included studies were pain (visual analogue scale),[5,7,18,20,29,30,35] range of motion (ROM; internal, external, forward rotation; abduction),[5,16,19] muscle strength,[16,19] function (Constant score),[5,7,8,11-14,19-21,23,24,26,29,30,32] and cuff integrity (e.g., no re-tear/re-tear rates).[6,17,23,27,33] Most studies reported the use of multi-dimensional tools to measure the domains of function, pain, strength, motion, and satisfaction: Disabilities of the Arm, Shoulder, and Hand (DASH),5,21 University of California Los Angeles (UCLA) score,[7,9-13,16,18,19,21,24,30,32,33] the American Shoulder and Elbow Surgeons score (ASES),[7,8,9,11-13,15,16,18,19,23,24,29-31,33-35] Simple Shoulder Test (SST),[9,26,29,30,33,35] Subjective shoulder value (SSV),[14] and Western Ontario Rotator Cuff Index (WORC).[14,15,19]

3.2.2 Qualitative signals [Cycles 1, 2, and 3]

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

Key question #1

Comparison of early and late surgery

No new evidence was identified in any of the searches. **No Signal**

Key question #2

Comparison of operative approaches

To summarize the evidence found in the previous two searches, there were two new studies comparing operative approaches; one RCT[39] and one cohort study.[37] These study findings agree with the CER results. More specifically, the RCT[39] did not report significant differences between treatment groups receiving acriomoplasty versus not receiving acriomoplasty for rotator cuff repair outcomes. Furthermore, the cohort study[37] did not find significant differences between the complete and partial repair groups. **No Signal**

In cycle 3, there were six new studies comparing operative approaches; one systematic review,[5] two RCTS,[6,7] and three comparative studies.[8-10] A majority of these studies' findings agree with the original CER results. More, specifically, one systematic review and one randomized controlled trial (RCT) suggest that surgical approach has no significant effect on retear rate.[5,6] One RCT suggests that clinical outcomes do not differ significantly among patients with small- to medium-sized rotator cuff tears and no acromial spurs.[7] One comparative cohort study found no statistically significant difference in postoperative outcomes between partial or complete repair.[10] **No Signal**

On the other hand, one comparative cohort study suggests that suture anchor tenodesis of the long head of the biceps tendon leads to less Popeye deformity than tenotomy[8] and another comparative cohort study suggests that among patients with concomitant type II SLAP lesions and large to massive rotator cuff tears, outcomes of simultaneous arthroscopic SLAP and rotator cuff repair are inferior to those of arthroscopic biceps tenotomy.[9] **Two Signals**

Comparison of operative techniques

In the previous two searches, none of the newly identified studies, including three RCTs[9,11,12] and two cohort studies[40,42] showed a significant difference in any of the parameters of rotator cuff between the double- and single-row treatment groups. **No Signal**

In cycle 3, eight of the 11 newly identified studies found no difference in outcomes by operative technique, including double- and single-row suture techniques. More specifically, two meta-analyses,[12,13] two RCTs,[15,19] and four comparative cohort studies[14,17,18,20] found no difference in functional outcomes between techniques.

The remaining three studies reported a difference in function outcomes between double- and single-row suture techniques. A systematic review found a significant difference in retear rates in favor of the double-row technique for larger tears (>1 cm).[6] One RCT found a difference in shoulder strength in favor of double-row fixation for patients with larger tear size (> 3 cm)[16] and another RCT found a difference in favor of single-row fixation for patients with remnant tendons <10 mm in length.[11] **Three Signals**

Additionally, one RCT did not find a significant difference between arthroscopic repair of full-thickness rotator cuff tears with metal biodegradable suture anchor and biodegradable suture anchor.[21] **No Signal**

One comparative cohort study concluded that clinical outcomes between the massive cuff stitch (MCS) and simple stitch were not significantly different.[22] **No Signal**

Comparison of operative augmentation

No conclusions were drawn from the previous two searches.

In cycle 3, one RCT and one comparative cohort study concluded that patch graft/augmentation leads to more intact repairs compared to the nonaugmented group.[23,24] **Two Signals**

Comparison of operative augmentation

The following conclusions were draw from the previous two searches. 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[44] 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 demonstrated a significantly higher re-tear rate in the group that received augmentation vs. no augmentation group (56% vs. 38%, p=0.024).[45] **One Signal**

In cycle 3, one RCT and one comparative cohort study concluded that patch graft/augmentation leads to more intact repairs compared to the nonaugmented group.[23,24] **Two Signals**

Comparison of postoperative rehabilitation

In the previous two searches, one RCT[46] 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**

No new evidence was identified in cycle 3. No Signal

Key question # 3

Comparison of nonoperative interventions

No new evidence was identified in any of the searches. No Signal

Key question #4

Comparison of operative and nonoperative interventions

No new evidence was identified in any of the searches. No Signal

Key question #5

Adverse events or potential harms associated with operative and nonoperative interventions

In the previous two searches, no new evidence was identified. **No Signal**

In cycle 3, three comparative cohort studies reported on complications of operative therapies, including Popeye deformity, stiffness, and glenohumeral arthritis. One study reported that Popeye deformity occurred in 9% of patients that underwent tenodesis and in 27% of patients that underwent tenotomy. A second study addressing stiffness from arthroscopic rotator cuff repair found that one third of patients experienced stiffness, and larger tear size is correlated with stiffness.[8,25] **Two Signals**

In agreement with the original CER, a third study on arthroscopically-treated patients reported that complications were rare and typically consisted of glenohumeral arthritis and stiffness.[26] **No Signal**

Key question #6

Important prognostic factors of outcomes following operative and nonoperative interventions

In the previous 2 searches, no new evidence was identified. **No Signal**

In cycle 3, one RCT and 10 cohort studies found evidence that tear size, age, extent of preoperative symptoms, sex, workers' compensation status, bone mineral density, diabetes mellitus, psuedoparalysis, multiple tendon involvement, concomitant biceps, acromioclavicular joint procedures, and fatty infiltration of the supraspinatus, infraspinatus, and subscapularis significantly modify outcomes.

In agreement with the original CER, one RCT and six cohort studies found that tear size, age, and extent of preoperative symptoms predict outcomes. [27,28,16,30,31,32,25] **No Signal**

One cohort study found that for patients who underwent arthroscopic repair the failure rate was significantly higher in patients with lower BMD ($p<0.001$); female gender ($p=0.03$); higher grade of fatty infiltration (FI) of the supraspinatus, infraspinatus, and subscapularis (all $p<0$ .001); DM ($p=0.02$); shorter acromiohumeral distance ($p<.001$); and associated biceps procedure ($p<0.001$).[29] **One Signal**

A second cohort study found that larger tears (3.5 vs 2.8 cm) were associated with failure ($p=0.01$), as well as more advanced fatty infiltration (Goutallier 1.3 vs 0.3, $p=0.01$).[33] **One Signal**

A third cohort study found that gender, tear size, and acromioclavicular joint involvement have a significant effect on ASES score.[34] **One Signal**

A fourth cohort study found that the Work Comp group, regardless of compliance with shoulder immobilization and physical therapy, had less improvement in preoperative to postoperative outcome scores for the ASES score (40.4 to 60.1), SST score (3.9 to 6.0) and VAS for pain (7.0 to 3.5) compared to the non-Work Comp group (ASES, 41.7 to 89.2; SST, 4.3 to 10.7; VAS, 6.2 to 0.35; $p<0.0001$).[35] **One Signal**

3.2.3 Quantitative signals [Cycles 1, 2, and 3]

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

Key question #1

Comparison of early and late surgery

No new evidence. **No Signal**

Key question #2

Comparison of operative approaches

We found six new studies, including two RCTS. However, a meta-analysis was not performed to check for quantitative signals for this comparison.

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). In cycle 2 this analysis was updated by incorporating three newly identified RCTs, one from cycle 1 (RR=1.29, 955 CI: 0.72, 2.31)[17] and two from cycle 2 (RR=1.17, 95% CI: 0.91, 1.52[9] and RR=1.22, 95% CI: 0.85, 1.74[11]). 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. This pooled estimate was not updated with the new data found in cycle 3. **One Signal**

This pooled estimate was not updated with the new data found in cycle 3. **No 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

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

Key question #6

Important prognostic factors of outcomes following operative and nonoperative interventions

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

3.3 Safety surveillance alerts [Cycle 3]

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

3.4 Expert opinion [Cycle 3]

One clinical expert provided responses/feedback in the matrix table (Appendix D). A second expert felt that there is new information available on the topic and a literature review needed to be completed to identify that information. One expert felt that there was no new evidence on key question #4. Neither expert commented specifically on key question #1 and #6.

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: New evidence

Experts: None of the experts commented specifically on this key question.

FDA/Health Canada/MHRAsurveillance alerts: None

1st Assessment Conclusion: **Up to date**

2nd Assessment Conclusion: **Up to date**

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

Key Questions #2

Signals from studies identified through the update search: New evidence. **Nine Signals**

Experts: One expert felt that there was new evidence.

FDA/Health Canada/MHRAsurveillance alerts: None

1st Assessment Conclusion: **Up to date**

2nd Assessment Conclusion: **Up to date**

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

Key Question #3

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

Experts: One expert felt that there was new evidence.

FDA/Health Canada/MHRAsurveillance alerts: None

1st Assessment Conclusion: **Up to date**

2nd 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: One expert felt that there was no new evidence.

FDA surveillance alerts: None

1st Assessment Conclusion: **Up to date**

2nd Assessment Conclusion: **Up to date**

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

Key Question #5

Signals from studies identified through the update search: New evidence. **Two Signals**

Experts: One expert felt that there was new evidence.

FDA surveillance alerts: None

1st Assessment Conclusion: **Up to date**

2nd Assessment Conclusion: **Up to date**

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

Key Question #6

Signals from studies identified through the update search: New evidence. **Four signals**.

Experts: None of the experts commented specifically on this key question.

FDA surveillance alerts: **None**

1st Assessment Conclusion: **Up to date**

2nd Assessment Conclusion: **Up to date**

Total (cumulative) Assessments Conclusion: **Possibly out of 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**	**Cycles 1-3 (total cumulative) assessment**
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?								
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.	**Cycle 3 (February 2014)**					Up to date	Up to date	Up to date
	No new evidence	N/A	N/A	None	None of the experts comented specifically on this question			
	Cycle 2 (November 2012)							
	No new evidence	N/A	N/A	None	Both experts agreed that there is no evidence sufficient to invalidate the findings of CER thereby rendering this CER conclusion still valid.			
	Cycle 1 (February 2012)							

	No new evidence	N/A	N/A	None	Both experts agreed that there is no evidence sufficient to invalidate the findings of CER thereby rendering this CER conclusion still valid.			
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?								
Operative approaches	**Cycle 3 (February 2014)**					Up to date	Up to date	Possibly out of date

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. Studies assessing operative treatments	2 cohort[8,9]	**2 Signals** one comparative cohort study suggests that suture anchor tenodesis of the long head of the biceps tendon leads to less Popeye deformity than tenotomy[8] and another comparative cohort study suggests that among patients with concomitant type II SLAP lesions and large to massive rotator cuff tears, outcomes of simultaneous arthroscopic SLAP and rotator cuff repair are inferior to those of arthroscopic biceps tenotomy.[9]	None	None	One expert felt that there is new evidence available.			
	Cycle 2 (November 2012)							

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.	1 RCT[39] 2 cohort studies[37,38]	**No Signal** In agreement with CER results, the new RCT[39] also did not find significant differences between acriomoplasty versus without acriomoplasty for rotator cuff repair outcomes. Likewise one cohort study[37], comparing complete versus partial rotator cuff repair did not find significant difference between the groups.	None	None	Both experts agreed with this conclusion. One expert provided an additional reference[38] to support this conclusion which was already included in this report.			
	Cycle 1 (February 2012)							

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	1 RCT[59] 3 non-RCTs[53,55,58]	**No Signal** In agreement with CER results, 2 newly identified studies comparing open RCR to arthroscopic RCR[58] and biceps tenotomy to tenodesis[53] found no significant differences between the operative approaches in post-operative pain, function, and/or ADL. (ASES score, Oxford Shoulder Questionnaire, Constant score). **No Signal** 1 RCT[59] and 1 cohort study[55] were conducted in patients with concomitant rotator cuff and SLAP tears. In the RCT,[59] 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	**No Signal** 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. **No Signal** None of the MAs of CER could be updated using data from 2 studies[55,59] due to differences in compared	None	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)[67] and the other review's (Coghlan et al. 2008)[66] last date for which the search was done was March 2006.			

study design, the sample size of the study, or the type of outcome measure used.		score). In the cohort study,[55] 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.	interventions and their combinations between MA and the 2 studies.					
Operative techniques	**Cycle 3 (February 2014)**					Up to date	Up to date	Probably out of date

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.	1 systematic review[6] and 2 RCTs[11,16]	**3 Signals** a systematic review found a significant difference in retear rates in favor of the double-row technique for larger tears (>1 cm).[6] One RCT found difference in shoulder strength in favor of double-row fixation for patients with larger tear size (> 3 cm)[16] and another RCT found a difference in favor of single-row fixation for patients with remnant tendons <10 mm in length.[11]	N/A	None	One expert felt that there is new evidence available.			
	Cycle 2 (November 2012)							

	3 RCTs [41,43,44] 2 cohort studies[40,42]	**No Signal** In agreement with the CER, none of the newly identified studies (3 RCTs[41,43,44] and 2 cohort studies[40,42]) showed a significant difference in any of the parameters of rotator cuff function between the double- and single-row treatment groups	**1 Signal** 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[41,43,49] for cuff integrity. Of the 3 RCTs, one was found in cycle 1 (RR=1.29, 955 CI: 0.72, 2.31)[49] and two in cycle 2 (RR=1.17, 95% CI: 0.91, 1.52)[41] and RR=1.22, 95% CI: 0.85, 1.74[44]) The updated pooled RR estimate for cuff integrity was statistically significant in favor of double-row repair.	None	Both experts agreed that there is no evidence sufficient to invalidate the findings of CER thereby rendering this CER conclusion still valid.			

			(RR=1.20, 95% CI: 1.016, 1.42.					
	Cycle 1 (February 2012)							

	3 RCTs [49,52,54] 2 non-RCTs [51,56]	**No Signal** In agreement with CER results, 2 RCTs[49,54] and 1 non-RCT[51] showed no difference between single-row and double-row techniques in post-operative pain,[49,51] function,[49,51,54] range of motion,[49,51] satisfaction,[49,51] and cuff integrity.[49] One non-RCT[51] showed improved healing rate for double-row vs. single-row technique for tears between 2.5-3.5 cm. In 1 RCT,[52] there was no difference between RCR techniques employing metal vs. biodegradable anchors in disability (DASH score) and function (Constant score); in 1 non-RCT,[56] suture bridge was shown to improve cuff integrity (but not pain, function, range of motion, or strength) compared to single-row technique.	**No Signal** 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 1 RCT[49] 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%.	None	Both experts agreed that there is no evidence sufficient to invalidate the findings of CER thereby rendering this CER conclusion still valid.			

Operative augmentations Eight studies, including three comparative and five uncontrolled studies, assessed augmentations for operative repair. The three comparative studies were relatively small and no overall	**Cycle 3 (February 2014)**					Up to date	Up to date	Possibly out of date
	No new evidence	**2 Signals** One RCT and one comparative cohort study concluded that patch graft/augmentation leads to more intact repairs compared to the nonaugmented group.[61,62]	N/A	None	One expert felt that there is new evidence available.			
	Cycle 2 (November 2012)							

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[45] 1 cohort study[46]	**2 Signals** 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[45] 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 augmentation vs. no augmentation group (56% vs. 38%, p=0.024).[46]	None	None	Both experts agreed that there is no evidence sufficient to invalidate the findings of CER thereby rendering this CER conclusion still valid.			
	Cycle 1 (February 2012)							

	1 RCT [50] 2 non-RCTs [60,61]	**No Signal** In general, 3 newly identified studies, 1 RCT[50] and 2 non-RCTs[60,61] 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[60,61] or muscle strength.[60]	None	None	Both experts agreed that there is no evidence sufficient to invalidate the findings of CER thereby rendering this CER conclusion still valid.			
Postoperative rehabilitation 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	**Cycle 3 (February 2014)**					Up to date	Up to date	Up to date
	No new evidence	N/A	N/A	None	One expert felt that there is new evidence available.			
	Cycle 2 (November 2012)							
	1 RCT [47]	**No Signal** 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[63] to be reviewed but it was excluded from this report.			
	Cycle 1 (February 2012)							

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.	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.			
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.								
One study compared early surgical repair versus late surgical repair after failed	**Cycle 3 (February 2014)**					Up to date	Up to date	Up to date
	No new evidence	N/A	N/A	None	One expert felt that there is some new evidence.			
	Cycle 2 (November 2012)							

nonoperative treatment. Patients receiving early surgery had superior function compared with the delayed surgical group; however, the level of significance was not reported.	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[31,36] to invalidate the conclusions but both studies were excluded from this report.			
	Cycle 1 (February 2012)							

	2 RCTs [56,62]	No Signal In 1 RCT,[56] 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. In 1 RCT,[62] 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.	None	None	One expert considered this CER conclusion still valid; the other expert provided reference to 1 Cochrane review (Green et al. 2003)[69], which was deemed as outdated, because the last date for which the search was done was June 2002.			
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?								
One study compared early surgical repair versus late surgical repair after failed nonoperative treatment.	**Cycle 3 (February 2014)**					Up to date	Up to date	Up to date
	No new evidence	N/A	N/A	None	One expert felt that this is an area where more evidence is needed.			
	Cycle 2 (November 2012)							

Patients receiving early surgery had superior function compared with the delayed surgical group; however, the level of significance was not reported.	No new evidence	None	None	None	Both experts considered this conclusion still valid. One expert provided an additional study[65] that was not relevant to this review.			
	Cycle 1 (February 2012)							
	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)[70], which was deemed as outdated, because the last date for which the search was done was June 2002 (last assessed in November 2002).			
Key question 5: What are the associated risks, adverse effects, and potential harms of nonoperative and operative therapies?								
One study compared early	**Cycle 3 (February 2014)**					Up to date	Up to date	Possibly ouft of date

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.	2 Cohort studies	**2 Signals** One study reported that Popeye deformity occurred in 9% of patients that underwent tenodesis and in 27% of patients that underwent tenotomy. A second study addressing stiffness from arthroscopic rotator cuff repair found that one third of patients experienced stiffness, and larger tear size is correlated with stiffness.[8,25]	N/A	None	One expert felt that there is new evidence.			
	Cycle 2 (November 2012)							

	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.			
	Cycle 1 (February 2012)							
	1 RCT[56] 1 non-RCT[60]	**No Signal** Only two studies reported any information on harms.[56,60] The RCT[56] which compared non-operative treatments (sodium hyaluronate vs. placebo) stated that there were no complications. The other study of cohort design[60] 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).[67]			
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?								
One study	**Cycle 3 (February 2014)**					Up to date	Up to date	Possibly out of

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.	1 RCT and 10 Cohort studies[16,25,27-,35]	**4 Signals** In agreement with the original CER, one RCT and six cohort studies found that tear size, age, and extent of preoperative symptoms predict outcomes.[27,28,16,30,31,32,25] One cohort study found that for patients who underwent arthroscopic repair the failure rate was significantly higher in patients with lower BMD (p<0.001); female gender (p=0.03); higher grade of fatty infiltration (FI) of the supraspinatus, infraspinatus, and subscapularis (all p<0 .001); DM (p=0.02); shorter acromiohumeral distance (p<.001); and associated biceps procedure (p<0.001).[29] A second cohort study found that larger tears (3.5 vs 2.8 cm) were associated with failure (p=0.01), as	N/A	None	None of the experts commented specifically on this question.			date

		well as more advanced fatty infiltration (Goutallier 1.3 vs 0.3, p=0.01).[33] A third cohort study found that gender, tear size, and acromioclavicular joint involvement have a significant effect on ASES score.[34] A fourth cohort study found that the Work Comp group, regardless of compliance with shoulder immobilization and physical therapy, had less improvement in preoperative to postoperative outcome scores for the ASES score (40.4 to 60.1), SST score (3.9 to 6.0) and VAS for pain (7.0 to 3.5) compared to the non-Work Comp group (ASES, 41.7 to 89.2; SST, 4.3 to 10.7; VAS, 6.2 to 0.35; p<0.0001).[35]						
	Cycle 2 (November 2012)							

	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.			
	Cycle 1 (February 2012)							
	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[71] which had already been included in the CER.			

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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:

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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$)).ti,ab. (397660)
24 exp placebos/ (255317)
25 25 placebo$.ti,ab. (438535)
26 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 analyz$).mp. (24412408)
37 ((control$ 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$).ti,ab. (140840)
45 (analytic adj (study or studies)).mp. (3534)
46 "single subject".ti,ab. (4117)
47 SSRD.ti,ab. (21)
48 "n-of-1".ti,ab. (90898)
49 baseline.ti,ab. (721494)
50 "before after".ti,ab. (5347)
51 or/14-50 (27621404)
52 animals/ not humans/(5017953)
53 51 not 52 (24167680)
54 13 and 53 (10458)
55 limit 54 to ("all adult (19 plus years)" or "middle age (45 to 64 years)" or "middle aged (45 plus years)" or "all aged (65 and over)" or "aged (80 and over)") [Limit not valid in CCTR,Embase; records were retained] (9278)
56 ("annals of internal medicine" or bmj or jama or lancet or "new england journal of medicine").jn. (551963)
57 (arthroscopy or "journal of bone & joint surgery american volume" or "journal of bone & joint surgery british volume" or "journal of shoulder & elbow surgery" or "american journal of sports medicine" or "clinical orthopaedics & related research").jn. (75305)
58 56 or 57 (627268)
59 55 and 58 (1656)
60 (201107* or 201108* or 201109* or 201110* or 201111* or 201112* or 2012*).ed. (1129438)
61 59 and 60 (149)
62 61 use prmz (149)
63 exp rotator cuff rupture/ (3406)
64 ((rotator cuff* or rotator interval* or supraspin?tus or infraspin?tus or "teres minor" or subscapularis or anterosuperior or posterosuperior) adj5 (tear or tears or tore or torn or lesion* or rupture* or avuls* or injur* or repair* or debride*)).mp. (11259)
65 exp tendon injury/ or exp tendon rupture/ or exp ligament rupture/ (34503)
66 exp muscle injury/ (6595)
67 ((tendon or tendons or muscle* or muscular) adj5 (tear or tears or tore or torn or lesion* or rupture* or avuls* or injur* or repair* or debride*)).mp. (79491)
68 ((full or partial) adj4 (thick$ 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

#	Query	Limiters/Expanders	Last Run Via	Results
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 pediatr* or paediatr*) OR SU (child* or pediatr* 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	

#	Query	Limiters/Expanders	Last Run Via	Results
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[3] 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.

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 <=0.5 or RRR new / RRR old >=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 <=0.5 or RD new / RD old >=1.5).

* Please, see Shojania et al. 2007[3] for further definitions and details

Appendix C: Evidence Table (Cycle 3/3rd Assessment)

Author	Year	Title	Participants	Intervention groups	Primary outcome	Findings
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?						
Operative approaches: Open or mini-open RCR vs. arthroscopic RCR						
van der Zwaal P, et al.[5]	2013	Clinical outcome in all-arthroscopic versus mini-open rotator cuff repair in small to medium-sized tears: a randomized controlled trial in 100 patients with 1-year follow-up.	95 patients with full-thickness small to medium-sized tears: 47 all-arthroscopic rotator cuff repairs and 48 mini open repairs	All-arthroscopic versus mini-open rotator cuff repair	Functional outcomes measured by Disabilities of the Arm, Shoulder, and Hand (DASH) score as a primary outcome score and the Constant-Murley score Clinical outcomes measured with a visual analog scale - pain/impairment score, and measurement of active forward flexion/external rotation as secondary outcome measures	Functional outcome, pain, range of motion, and complications did not significantly differ between patients treated with all-arthroscopic repair and those treated with mini-open repair in the first year after surgery.
Duquin TR, et al.[6]	2010	Which method of rotator cuff repair leads to the highest rate of structural healing? A systematic review.	23 Cohort studies and RCTs on 1252 rotator cuff repairs	Transosseous (TO), single-row suture anchor (SA), double-row suture anchor (DA), and suture bridge (SB) repair methods, as well as for open (O), miniopen (MO), and arthroscopic (A) approaches	Retear rate	There was no difference between arthroscopic and nonarthroscopic approaches (O + MO) in retear rate.

Author	Year	Title	Participants	Intervention groups	Primary outcome	Findings
Operative approaches: Arthroscopic RCR with acromioplasty vs. without acromioplasty						
Shin SJ, et al.[7]	2012	The efficacy of acromioplasty in the arthroscopic repair of small- to medium-sized rotator cuff tears without acromial spur: prospective comparative study.	120 patients who had small- to medium-sized rotator cuff tears and various types of acromions without spurs: 60 underwent arthroscopic rotator cuff repair with acromioplasty and 60 arthroscopic rotator cuff repair without acromioplasty	Arthroscopic rotator cuff repair with or without acromioplasty	Functional outcomes measured by American Shoulder and Elbow Surgeons (ASES), and Constant and University of California, Los Angeles (UCLA) scores Clinical outcomes of pain intensity and patient satisfaction with the surgery by use of a visual analog scale	Clinical and functional outcomes were not significantly different, and acromioplasty may not be necessary in the operative treatment of patients with small- to medium-sized rotator cuff tears in the absence of acromial spurs.
Operative approaches: Biceps tenotomy vs. tenodesis						
Koh KH, et al.[8]	2010	Treatment of biceps tendon lesions in the setting of rotator cuff tears: prospective cohort study of tenotomy versus tenodesis.	90 patients with rotator cuff tear and biceps tendon lesion: 45 underwent bicep tenotomy and 45 underwent suture anchor tenodesis	Bicep tenotomy and suture anchor tenodesis	Overall shoulder function was assessed with ASES score and the Constant score	Clinical evaluations showed no differences between the 2 groups: P = .1766 for ASES scores (power = 71%) and P = .1933 for Constant scores (power = 73%).
Operative approaches: Arthroscopic RCR with SLAP repair vs. arthroscopic RCR with biceps tenotomy						
Kim SJ, et al.[9]	2012	Arthroscopic repair of concomitant type II SLAP lesions in large to massive rotator cuff tears: comparison with biceps tenotomy.	36 patients with concomitant type II SLAP lesions and large to massive rotator cuff tears: 16 combined SLAP and rotator cuff repairs and 26 arthroscopic tenotomy and rotator cuff repairs	Combined SLAP and rotator cuff repair or tenotomy and rotator cuff repair	Range of motion, Simple Shoulder Test (SST), ASES score, and UCLA score	For patients with concomitant type II SLAP lesions and large to massive rotator cuff tears, the outcomes of simultaneous arthroscopic SLAP and rotator cuff repair were inferior to those of arthroscopic biceps tenotomy and cuff repair in terms of functional shoulder scores and range of motion.

Author	Year	Title	Participants	Intervention groups	Primary outcome	Findings
Operative approaches: Complete open RCR vs. partial open RCR vs. debridement						
Iagulli ND, et al.[10]	2012	Comparison of partial versus complete arthroscopic repair of massive rotator cuff tears.	97 patients with a massive rotator cuff tear (30 cm^2 or greater): 47 underwent partial repair and 52 underwent complete repair	Partial or complete arthroscopic rotator cuff repair	UCLA shoulder scores	No statistically significant differences in postoperative outcomes were noted when the 2 groups, partial or complete repair, were compared with one another (P = .89).
Operative techniques: Single-row (SR) vs. double-row (DR) suture anchor fixation						
Kim YK, et al.[11]	2013	Treatment outcomes of single- versus double-row repair for larger than medium-sized rotator cuff tears: the effect of preoperative remnant tendon length.	78 patients with larger than medium-sized rotator cuff tears	SR and DR suture bridge (SB) methods	UCLA, Constant, and ASES scores	SR technique provided better rotator cuff integrity when remnant tendons are less than10mm in length, while DR-SB technique provided better rotator cuff integrity when remnant tendons are greater than or equal to 10mm in length. The UCLA and Constant scores were significantly higher in patients with tendons <10mm in length who underwent SR repair (P = .02 and P = .029, respectively), and the UCLA and ASES scores were significantly higher in patients with tendons ≥10mm in length who underwent DR-SB repair (P<.001 and P = .001, respectively).
Chen M, et al.[12]	2013	Outcomes of single-row versus double-row arthroscopic rotator cuff repair: a systematic review and meta-analysis of current evidence.	6 RCTs on 476 patients needing arthroscopic rotator cuff repair	DR and SR rotator cuff repair	Constant scores, UCLA, and ASES scores	DR repair provided a significantly higher rate of intact tendon healing than does SR repair in patients with large or massive tears, but, there was no difference in functional outcomes.
Sheibani-Rad S, et al.[13]	2013	Arthroscopic single-row versus double-row rotator cuff repair: a meta-analysis of the randomized clinical trials.	5 RCTs on 349 patients	SR and DR rotator cuff repair	Constant scores, UCLA, and ASES scores	There was no significant difference in clinical outcomes between SR and DR rotator cuff repair.

Author	Year	Title	Participants	Intervention groups	Primary outcome	Findings
Gerhardt C, et al.[14]	2012	Arthroscopic single-row modified mason-allen repair versus double-row suture bridge reconstruction for supraspinatus tendon tears: a matched-pair analysis.	40 patients with rotator cuff tear: 20 received SR modified Mason-Allen stitch and 20 received a modified suture bridge DR repair	Arthroscopic SR modified Mason-Allen stitch or a modified suture bridge DR repair	Subjective shoulder value (SSV), Constant-Murley score (CS), and Western Ontario Rotator Cuff Index (WORC)	Modified Mason-Allen SR did not demonstrate significant differences in outcomes compared to modified suture bridge DR in a matched patient cohort.
Lapner PL, et al.[15]	2012	A multicenter randomized controlled trial comparing single-row with double-row fixation in arthroscopic rotator cuff repair.	90 patients undergoing arthroscopic rotator cuff repair: 48 SR repairs and 42 DR repairs	SR or a DR repair	Primary objective to compare the Western Ontario rotator cuff index (WORC) score at twenty-four months. Secondary objectives included comparison of ASES scores and strength between groups	No significant differences in functional or quality-of-life outcomes were identified between SR and DR fixation techniques.
Ma HL, et al.[16]	2012	Clinical outcome and imaging of arthroscopic single-row and double-row rotator cuff repair: a prospective randomized trial.	53 patients requiring rotator cuff repair: 27 SR rotator cuff repairs and 26 DR repairs	SR or DR rotator cuff repair	Clinical and imaging outcomes using UCLA score and the ASES index and assessing muscle strength in abduction and external rotation	Arthroscopic rotator cuff repair with DR fixation showed better shoulder strength in patients with larger tear size (> 3 cm) in comparison to SR fixation. However, the imaging results showed no significant difference in cuff integrity in both groups in patients with any tear size at 6-month and minimum 2-year follow-up.
Mihata T, et al.[17]	2011	Functional and structural outcomes of single-row versus double-row versus combined double-row and suture-bridge repair for rotator cuff tears.	patients with full-thickness rotator cuff tears: 65 shoulders in 63 patients in the SR group and 23 shoulders in 22 patients in the DR group	SR, DR, and compression double-row techniques	Retear rate	For small and large and massive tears, the retear rate in the DR group did not differ from that in the SR group.

Author	Year	Title	Participants	Intervention groups	Primary outcome	Findings
Pennington WT, et al.[18]	2010	Comparative analysis of single-row versus double-row repair of rotator cuff tears.	132 shoulders of patients who underwent primary arthroscopic rotator cuff repairs: 78 were repaired with an SR arthroscopic Mason-Allen configuration (MAC) repair and 54 with a DR transosseous equivalent repair configuration	DR transosseous-equivalent versus SR-MAC arthroscopic repair techniques	Scoring methods included the modified UCLA shoulder score (0 to 35), ASES shoulder index (0 to 100),and visual analog scale (VAS) (0 to 10)	No clinically significant improvement in outcome scores between DR transosseous-equivalent repair and SR-MAC repair.
Duquin TR, et al.[6]	2010	Which method of rotator cuff repair leads to the highest rate of structural healing? A systematic review.	23 Cohort studies and RCTs on 1252 rotator cuff repairs	Transosseous (TO), single-row suture anchor (SA), double-row suture anchor (DA), and suture bridge (SB) repair methods, as well as for open (O), miniopen (MO), and arthroscopic (A) approaches	Retear rate	Retear rates were significantly lower for double row repairs when compared with transosseous. Retear rate for combined single-row methods (TO + SA, 44%) was significantly higher than the retear rate for combined double-row methods (DA + SB, 24%, P < .002). For smaller tears, retear rate did not differ significantly by method of repair (TO vs SA, P = .94) or surgical approach (O 1 MO vs A, P = .94) for single-row repairs. For larger tears (>1 cm), double-row repair methods lead to significantly lower retear rates when compared with single-row methods. For larger tears, retear rate did not differ significantly by method of repair (TO vs SA, P = .94) or surgical approach (O + MO vs A, P = .94) for single-row methods.

Author	Year	Title	Participants	Intervention groups	Primary outcome	Findings
Burks RT, et al.[19]	2009	A prospective randomized clinical trial comparing arthroscopic single- and double-row rotator cuff repair: magnetic resonance imaging and early clinical evaluation.	40 patients with rotator cuff tear: 20 DR rotator cuff repairs and 20 SR repairs	DR rotator cuff repair compared with SR repair	UCLA, Constant, WORC, Single Assessment Numerical Evaluation (SANE), ASES, range of motion, internal rotation strength, and external rotation strength	No clinical or MRI differences were seen between patients repaired with a SR or DR technique.
Aydin N, et al.[20]	2010	Single-row versus double-row arthroscopic rotator cuff repair in small- to medium-sized tears.	68 patients with a full-thickness rotator cuff tear: 34 SR and 34 DR arthroscopic rotator cuff repairs	SR versus DR arthroscopic rotator cuff repair	Constant score	Results show no difference in functional outcome between DR fixation and SR fixation for small to medium tears.
Operative techniques: Bioabsorbable corkscrews vs. metal suture anchor						
Milano G, et al.[21]	2010	Arthroscopic rotator cuff repair with metal and biodegradable suture anchors: a prospective randomized study.	patients with a full-thickness rotator cuff tear	Metal vs. biodegradable suture anchors	DASH and Work-DASH self-administered questionnaires, as well as the Constant score normalized for age and sex	Differences between arthroscopic repair of full-thickness rotator cuff tears with metal and biodegradable suture anchors were not significant.
Operative techniques: Mattress locking vs. simple stitch						
Ko SH, et al.[22]	2009	A prospective therapeutic comparison of simple suture repairs to massive cuff stitch repairs for treatment of small- and medium-sized rotator cuff tears.	110 patients who underwent arthroscopic repair of full-thickness rotator cuff tears: 55 had a massive cuff stitch (MCS) and 55 had a simple stitch	MCS vs. simple stitch	Visual analog scale for pain, activities of daily living, and UCLA scores	The clinical outcomes between the MCS and simple stitch were not significantly different.

Author	Year	Title	Participants	Intervention groups	Primary outcome	Findings
Operative augmentation: Patch graft vs. no augmentation						
Mori D, et al.[23]	2013	Arthroscopic surgery of irreparable large or massive rotator cuff tears with low-grade Fatty degeneration of the infraspinatus: patch autograft procedure versus partial repair procedure.	57 patients with large or massive rotator cuff tears: 30 had a patch graft procedure and 27 had a partial repair	Patch graft procedure and partial repair in shoulders with low-grade fatty degeneration of the infraspinatus	Constant and ASES scores and retear rate	The patch graft procedure showed an 8.3% retear rate, whereas the partial repair had a retear rate of 41.7% (P=0.015).
Barber FA, et al.[24]	2012	A prospective, randomized evaluation of acellular human dermal matrix augmentation for arthroscopic rotator cuff repair.	42 patients undergoing arthroscopic repair of 2-tendon rotator cuff tears measuring greater than 3 cm: 22 received augmentation and 20 did not	Arthroscopic single-row rotator cuff repair with GraftJacket acellular human dermal matrix augmentation or without augmentation	ASES, Constant, and UCLA scales	Acellular human dermal matrix augmentation of large (3 cm) cuff tears involving 2 tendons showed better ASES and Constant scores and more frequent intact cuffs as determined by gadolinium-enhanced MRI. Intact repairs were found in 85% of the augmented group and 40% of the nonaugmented group (P less than 0.01).
Key Question 5: What are the associated risks, adverse effects, and potential harms of non-operative and operative therapies?						
Koh KH, et al.[8]	2010	Treatment of biceps tendon lesions in the setting of rotator cuff tears: prospective cohort study of tenotomy versus tenodesis.	90 patients with rotator cuff tear and biceps tendon lesion: 45 underwent bicep tenotomy and 45 underwent suture anchor tenodesis	Bicep tenotomy and suture anchor tenodesis	Presence of Popeye deformity (observed or not)	Suture anchor tenodesis of the long head of the biceps tendon lead to less Popeye deformity than tenotomy. In the tenodesis group, 4 (9.3%) patients had Popeye deformity, whereas 11 (26.8%) had Popeye deformity in the tenotomy group, and this difference was significant (P 5 .0360).
Seo SS, et al.[25]	2012	The factors affecting stiffness occurring with rotator cuff tear.	119 patients that underwent arthroscopic rotator cuff repair	Arthroscopic rotator cuff repair	Stiffness (assessed with range of motion) of the shoulder	Among all patients, 39 (32.7%) exhibited stiffness. A statistically significantly higher degree of stiffness was seen for full-thickness tears than for partial-thickness in patients undergoing arthroscopic rotator cuff repair (P

Author	Year	Title	Participants	Intervention groups	Primary outcome	Findings
						= .0187). Posterosuperior cuff tears showed a statistically significantly higher prevalence of stiffness (P =0.0415) than anterosuperior cuff tears. Patients with trauma had a statistically higher prevalence of stiffness (P = .0264).
Porcellini G, et al.[26]	2011	Partial repair of irreparable supraspinatus tendon tears: clinical and radiographic evaluations at long-term follow-up.	67 patients with irreparable rotator cuff tears	Arthroscopic partial suture of the cuff	Pain relief and functional improvement: Simple Shoulder Test and Constant score, and complications	Complications developed related to the index surgery in 6 (9%) of the 67 patients arthroscopically treated with functional repair of the posterior cuff. In general complications were rare and typically consisted of glenohumeral arthritis and stiffness.
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 non-operative and operative treatment?						
Park JY, et al.[27]	2014	Arthroscopic repair of large u-shaped rotator cuff tears without margin convergence versus repair of crescent- or L-shaped tears.	95 consecutive patients with a large-sized rotator cuff tear, crescent- or L-shaped tears	Arthroscopic repair	Retear and tear pattern	Findings did not indicate significant differences in retear rates between the repair of crescent- or L-shaped tears and that of U-shaped tears.
Peters KS, et al.[28]	2012	A comparison of outcomes after arthroscopic repair of partial versus small or medium-sized full-thickness rotator cuff tears.	169 rotator cuff repairs in 166 patients who had a full-thickness tear measuring <3 cm2	Knotless single-row arthroscopic repair	Outcome after repair of partial-thickness rotator cuff tears compared with full-thickness tears	No difference in retear rate and postoperative shoulder stiffness rate was found between patients who had a full-thickness and patients who had a partial-thickness tear.

Author	Year	Title	Participants	Intervention groups	Primary outcome	Findings
Ma HL, et al.[16]	2012	Clinical outcome and imaging of arthroscopic single-row and double-row rotator cuff repair: a prospective randomized trial.	53 patients requiring rotator cuff repair: 27 SR rotator cuff repairs and 26 DR repairs	SR or DR rotator cuff repair	Clinical and imaging outcomes using UCLA score and the ASES index and assessing muscle strength in abduction and external rotation; and the effect of various tear size on repair integrity	Arthroscopic rotator cuff repair with double-row fixation showed better shoulder strength in patients with larger tear size (3 cm) in comparison with single-row fixation. However, the imaging results showed no significant difference in cuff integrity in both groups in patients with any tear size at 2-year follow-up.
Chung SW, et al.[29]	2011	Factors affecting rotator cuff healing after arthroscopic repair: osteoporosis as one of the independent risk factors.	272 patients with arthroscopically repaired full-thickness rotator cuff tears	Arthroscopic repair	For the clinical variables (ASES, SST, Constant, VAS), age, gender, arm dominance, symptom duration and aggravation, smoking, diabetes mellitus (DM), hypertension or any heart disease, steroid injection history on the same shoulder joint, traumatic event, shoulder stiffness, level of sports activity, demand of shoulder activity, and bone mineral density (BMD) were recorded.	For patients who underwent arthroscopic repair the failure rate was significantly higher in patients with lower BMD ($P<.001$); older age ($P<.001$); female gender ($P = .03$); larger tear size ($P<.001$); higher grade of fatty infiltration (FI) of the supraspinatus, infraspinatus, and subscapularis (all $P< .001$); DM ($P = .02$); shorter acromiohumeral distance ($P<.001$); and associated biceps procedure ($P<.001$).
Oh JH, et al.[30]	2011	Outcome of rotator cuff repair in large-to-massive tear with pseudoparalysis: a comparative study with propensity score matching.	58 patients with large-to-massive rotator cuff tears	Rotator cuff repair in patients with active motion deficit may yield inferior outcome.	Functional outcomes (VAS, Constant score, SST, ASES score, UCLA score) and pseudoparalysis after rotator cuff repair and cuff healing	Postoperative function and cuff healing were not different according to the presence of pseudoparalysis after rotator cuff repair.

Author	Year	Title	Participants	Intervention groups	Primary outcome	Findings
Gulotta LV, et al.[31]	2011	Prospective evaluation of arthroscopic rotator cuff repairs at 5 years: part I--functional outcomes and radiographic healing rates.	193 patients who underwent all-arthroscopic rotator cuff repairs	All-arthroscopic rotator cuff repairs	Pre- or intraoperative variables that were predictive of: Shoulder and Elbow Surgeons (ASES) score, range of motion, manual muscle testing, and ultrasonography	No pre- or intraoperative variables were predictive of an ASES score >90. Factors predictive of a radiographic defect include larger size (OR 1.72, 95% CI 1.04-2.85, P = .03), multiple tendon involvement (OR 5.56, 95% CI 1.23-25.22, P = .02), older age (OR 1.15, 95% CI 1.04-1.28, P = .01), concomitant biceps (OR 16.16, 95% CI 3.01-86.65, P = .001), and acromioclavicular joint procedures (OR 6.70, 95% CI 1.46-30.73, P = .01).
Papadopoulos P, et al.[32]	2011	Functional outcome and structural integrity following mini-open repair of large and massive rotator cuff tears: a 3-5 year follow-up study.	57 patients (62 shoulders) who underwent an arthroscopic subacromial decompression followed by a mini-open rotator cuff repair	Arthroscopic subacromial decompression followed by a mini-open rotator cuff repair	Factors predictive of: Constant-Murley and UCLA scores	Patient age, the size of the initial tear, as well as the size of a potential re-tear are factors that negatively affect the final clinical outcome.
Sethi PM, et al.[33]	2010	Repair results of 2-tendon rotator cuff tears utilizing the transosseous equivalent technique.	40 patients with combined supraspinatus and infraspinatus tendon tears	Arthroscopic repair using transosseous-equivalent (TOE) suture bridge technique	Factors predictive of: Re-tear rate and the overall Constant and UCLA scores, ASES, SST	Larger tears (3.5 vs 2.8 cm) were associated with failure (P = .01), as was more advanced fatty infiltration (Goutallier 1.3 vs 0.3, P = .01).
Nho SJ, et al.[34]	2009	Prospective analysis of arthroscopic rotator cuff repair: subgroup analysis.	193 patients who underwent all-arthroscopic repair of a rotator cuff tear	All-arthroscopic repair of a rotator cuff tear	Patient demographic and rotator cuff characteristics that affect outcomes including ASES score	Gender, tear size, and acromioclavicular joint involvement have a significant effect on ASES score. Rotator cuff characteristics such as tear size, biceps pathology, acromioclavicular joint pathology, and tissue quality have a significant effect on postoperative tendon integrity.

Author	Year	Title	Participants	Intervention groups	Primary outcome	Findings
Cuff DJ, et al.[35]	2012	Prospective evaluation of postoperative compliance and outcomes after rotator cuff repair in patients with and without workers' compensation claims.	42 consecutive patients with Workers' Compensation claims and 50 consecutive patients without a Workers' Compensation claim	A postoperative protocol of shoulder immobilization and physical therapy	Compliance and outcomes after rotator cuff repair in patients with and without Workers' Compensation claims: ASES score, SST score and VAS	The Work Comp group, regardless of compliance with shoulder immobilization and physical therapy, had less improvement in preoperative to postoperative outcome scores for the ASES score (40.4 to 60.1), SST score (3.9 to 6.0) and VAS for pain (7.0 to 3.5) compared to the non-Work Comp group (ASES, 41.7 to 89.2; SST, 4.3 to 10.7; VAS, 6.2 to 0.35; $P < .0001$).
Seo SS, et al.[25]	2012	The factors affecting stiffness occurring with rotator cuff tear.	119 patients that underwent arthroscopic rotator cuff repair	Arthroscopic rotator cuff repair	Stiffness (assessed with range of motion) of the shoulder	Among all patients, 39 (32.7%) exhibited stiffness. A statistically significantly higher degree of stiffness was seen for full-thickness tears than for partial-thickness in patients undergoing arthroscopic rotator cuff repair ($P = .0187$). Posterosuperior cuff tears showed a statistically significantly higher prevalence of stiffness ($P =0.0415$) than anterosuperior cuff tears. Patients with trauma had a statistically higher prevalence of stiffness ($P = .0264$).

Appendix D: Evidence Table (Cycle 1 & 2/1st and 2nd Assessments)

Author year Study name (if applicable)	Study design	Subjects	Treatment groups (n; dose)	Treatment duration	Outcomes and findings
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?					
Cycle 2					
No new relevant evidence was identified	NA	NA	NA	NA	NA
Cycle 1					
No new relevant evidence was identified	NA	NA	NA	NA	NA
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?					
Cycle 2					
Operative approach					
Iagulli 2012[5]	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	Complete repair vs. partial repair (FU=2 yrs post-operation) **UCLA score:** 29.64±4.92 vs. 29.49±5.90, p=0.89
Jo 2011[6]	Cohort study	42 pts with full-thickness rotator cuff tear mean age: 59.8 – 61.8 years; male%:	RCR with PRP (n=19, dose: NA) vs. RCR without PRP (n=23, dose: NA)	NA	PRP vs. without PRP (FU=16 months post-operation) **UCLA score:** 31.78±6.15 vs. 30.83±4.96, p=0.579 **ASES index:** 87.61±24.83 vs. 89.92±17.03, p=0.744

Author year Study name (if applicable)	Study design	Subjects	Treatment groups (n; dose)	Treatment duration	Outcomes and findings
		36			**Constant score:** 79.12±13.42 vs. 82.00±13.02, p=0.476 **DASH:** 13.19±25.45 vs. 8.48±14.05, p=0.473 **SST:** 9.83±3.31 vs. 10.57±1.73, p=0.355 **SPADI:** 12.03±24.96 vs. 10.08±16.32, p=0.673
Shin 2012[7]	RCT	120 pts with small to medium sized rotator cuff tear mean age: 55.8 – 57.8 years; male%: 56	RCR with acriomoplasty technique (n=60, dose: NA) vs. RCR without acriomoplasty (n=60, dose: NA)	NA	RCR with acriomoplasty vs. RCR without acriomoplasty (FU=24 mo) **UCLA score:** 33.4±3.3 vs. 32.3±3.5, p>0.05 **ASES index:** 90.7±13.1 vs. 87.5±12.0, p>0.05 **Constant score:** 85.0±11.3 vs. 83.3±13.0, p>0.05 **ROM-FF (mean degrees):** 173.8±14.8 vs. 170.8±19.4, p>0.05 **ROM-ER at side (mean degrees):** 67.1±14.4 vs. 69.2±12.4, p>0.05 **IR (spine level):** 8.2±2.4 vs. 8.4±1.1, p>0.05 **Pain (VAS score):** 1.1±0.9 vs. 1.3±1.4, p>0.05 **Retear rate (%):** 17 vs. 20, p=0.475
Operative technique					
Mihata 2011[8]	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	Single-row vs. double-row vs. compression double-row (F U=2 yrs) **Retear rate (%):** 7/65 (10.8%) vs. 6/23 (26.1%) vs. 5/104 (4.7%), p>0.05 **ASES index:** 95.6±11.1 vs. 94.7±15.2 vs. 97.4±9.1, p>0.05 **UCLA score:** 34.0±3.9 vs. 33.5±5.3 vs. 34.2±3.5, p>0.05
Lapner 2012[9]	RCT	90 pts with full-thickness rotator cuff tear (any diameter) mean age: 56.8 years; male%:	Single-row (n=48, dose: NA) vs. double-row (n=42, dose: NA)	NA	Single-row vs. double-row (F U=2 yrs post-operation) **ASES index:** 87.9±16.9 vs. 89.3±17.5, p=0.74 **Constant score:** 86.6±14 vs. 86.3±14.2, p=0.84 **WORC score:** 84.4±21.3 vs. 81.7±20.9, p=0.60 **Muscle strength (in kg):** 8.0±6.0 vs. 7.3±3.2,

Author year Study name (if applicable)	Study design	Subjects	Treatment groups (n; dose)	Treatment duration	Outcomes and findings
		71			p=0.56 **Healing rate (%):** 32 (67%) vs. 33 (78%), p=0.254
Kim 2012[10]	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	Double-row vs. suture-bridge (FU=2 yrs post-operation) **UCLA score:** 32.25±2.17 vs. 30.58±5.87, p=0.185 **ASES index:** 90.50±10.12 vs. 88.46±15.67, p=0.585 **Constant score:** 80.71±7.38 vs. 73.96±15.39, p=0.053 **Pain (VAS score):** 2.08±0.88 vs. 1.80±2.27, p>0.05 **Retear rate (%):** 6/25 (24%) vs. 5/25 (20%), p=0.733
Ma 2012 [11]	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	Single-row vs. double-row (F U=2 yrs post-operation) **UCLA score:** 31.40±3.34 vs. 31.53±3.40, p=0.89 **ASES index:** 91.25±2.36 vs. 91.38±2.36, p=0.85 **Abduction strength (kg):** 4.91±0.8 vs. 5.01±0.62, p=0.63 **ER strength (kg):** 6.86±0.84 vs. 7.03±0.78, p=0.46 **Intact cuff (%):** 17 (63%) vs. 20 (77%), p=0.63 **Partial tear (%):** 4 (14.83%) vs. 3 (11.5%), p=0.63 **Complete tear (%):** 6 (22.2%) vs. 3 (11.5%), p=0.63
Shin 2012 [12]	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	RCR transtendon technique vs. RCR tear completion (FU=32 mo) **Pain (VAS score):** 1.4±0.4 vs. 1.1±0.2, p=0.207 **ASES index:** 89.1±2.1 vs. 86.2±3.2, p>0.05 **Constant score:** 84.8±2.7 vs. 87.1±2.4, p>0.05 **ROM-FF (mean degrees):** 167.8±5 vs. 170.4±3.2, p>0.05 **ROM-ER at side (mean degrees):** 65.2±4.4 vs.

Author year Study name (if applicable)	Study design	Subjects	Treatment groups (n; dose)	Treatment duration	Outcomes and findings
					66.6±2.0, p>0.05 **IR (spine level):** L1/T12 vs. L1/T12, p>0.05
Operative augmentation					
Barber[13]	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	RCR with augmentation vs. RCR without augmentation (FU=24 mo) **UCLA score:** 28.2±2.1 vs. 28.3±3.0, p=0.43 **ASES index:** 98.9±4.2 vs. 94.8±14.2, p=0.035 **Constant score:** 91.9±9.2 vs. 85.3±11.0, p=0.008
Bergeson[14]	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	RCR with augmentation vs. RCR without augmentation (FU=1 yr post-operation) **Retear rate (%):** 9/16 (56%) vs. 8/21 (38%) p=0.024 **Retear rate (single row repairs) (%):** 8/13 (62%) vs. 8/20 (40%), p=0.022 **ASES index:** 87 vs. 84, p=0.65 **UCLA score:** 29 vs. 29, p=0.55 **Constant score:** 73 vs. 76, p=0.58 **WORC score:** 80 vs. 82, p=0.66 **SANE score:** 89 vs. 87, p=0.92
Post-operative					

Author year Study name (if applicable)	Study design	Subjects	Treatment groups (n; dose)	Treatment duration	Outcomes and findings
Lee 2012[15]	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	Aggressive group vs. Limited group (FU=1 yr post-operation) **Pain at rest** (0-10): 0.23 (range 0-3) vs. 0.15 (range 0-3), p=0.382 **Pain at motion** (0-10): 1.47 (range 0-5) vs. 1.53 (range 0-5), p=0.808 **ROM-FF (mean degrees):** 155.3±13.0 vs. 153.0±12.2, p=0.729 **ROM-ER at side (mean degrees):** 53.0±11.6 vs. 48.1±13.9, p=0.078 **Abduction (mean degrees):** 167.8±12.8 vs. 161.8±27.3, p=0.884 **Muscle strength-elevation (in kg):** 7.76 vs. 7.33, p=0.227 **Muscle strength-external rotation (in kg):** 7.94 vs. 7.62, p=0.542 **Muscle strength-internal rotation (in kg):** 8.90 vs. 8.44, p=0.450 **UCLA score:** NR (p=0.158) **Percent of excellent cases:** 16 (47.1%) vs. 15 (50%), p=0.341 **Healing rate (%):** 23 (76.7%) vs. 31 (91.2%),
Cycle 1					
Operative approach					
Abbot 2009[27]	RCT	48 pts with concomitant rotator cuff and type II SLAP lesion tears;	RCR + SLAP tears debridement (n=24; dose: NA) vs. RCR + SLAP tears repair (n=24; dose: NA)	NA	RCR + SLAP tears debridement vs. RCR + SLAP tears repair (FU=2 yrs) **UCLA score** (max=35): 34±2.1 vs. 31±2.7, p<0.001 **Pain** (max=10): 9.6±0.8 vs. 7.7±1.4, p<0.001

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 **Forward flexion** (max=5): 4.9±0.3 vs. 4.8±0.4, p=0.27 **Strength** (max=5): 4.9±0.3 vs. 4.7±0.5, p=0.08 **Satisfaction** (max=5): 5±0 vs. 5±0, p=NR **ROM-IR:** 69.8±11.8 vs. 37.8±23.8, p<0.001 **ROM-ER:** 84.8±9.0 vs. 69.7±12.5, p<0.001 **ROM-FF:** 166.5±4.9 vs. 163.1±10.0, p=0.08
Forsythe 2010[23,40]	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> **ASES score:** 96.4±9.2 vs. 92.3±12.1, p=0.137 **Function (Constant score):** 91.0±8.0 vs. 85.0±6.5, p=0.002 **Abduction:** 161.6±9.6 vs. 158.2±17.2, p=0.329 **ROM-FF:** 164.6±7.4 vs. 162.5±14.4, p=0.472 **ROM-ER:** 68.1±9.9 vs. 68.9±11.1, p=753
Adla 2010[26]	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> **Oxford shoulder questionnaire (mean change):** 24.9±6.7 vs. 25.5±7, p=0.70 (95% CI: -6.0, 6.0) **Function (Constant score):** 82.0 vs. 78.0, p=NR
Koh 2010[21]	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> **ASES score:** 84.7±13.58 vs. 79.64±15.76, p=0.176 **Function (Constant score):** 82.91±13.49 vs. 78.27±14.08, p=0.193 **Arm cramping pain:** 2/43 (4.65%) vs. 4/41 (9.75%), p=0.427
Operative technique					

Author year Study name (if applicable)	Study design	Subjects	Treatment groups (n; dose)	Treatment duration	Outcomes and findings
Cho 2010[25]	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	Single-row vs. Suture bridge (FU=7.5 mo post-operation) **Pain (VAS)-rest:** 0.3 (range: 0-3) vs. 0.2 (range: 0-1), p=0.431 **Pain (VAS)-motion:** 2.4 (range: 0-6) vs. 2.0 (range: 0-5), p=0.472 **ROM-FF:** 148.3 (range: 80-170) vs. 147.3 (range: 20-170), p=0.923 **ROM-ER:** 40.9 (range: 6-70) vs. 40.9 (range: 0-90), p=0.991 **ROM-IR:** T12 (range: T4-L4) vs. L1 (range: T7-S1), p=0.204 **Muscle strength in kg (FF):** 4.94 vs. 5.6, p=0.164 **Muscle strength in kg (ER):** 6.56 vs. 6.9, p=0.701 **Muscle strength in kg (IR):** 7.26 vs. 7.7, p=669 **Function (Constant score):** 77.40 vs. 76.20, p=0.672 **UCLA score:** 30.4 vs. 29.2, p=0.311 **Retear (type 1):** n=14 (73.7%) vs. n=7 (25.9%), p=0.049 **Retear (type 2):** n=5 (26.3%) vs. n=20 (74.1%), p=0.049
Aydin 2010[22]	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	Single-row vs. Double-row (FU=36 mo) **Function (Constant score):** 82.2 (range: 72-96) vs. 78.8 (range: 68-94), p>0.05
Koh 2011[17]	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	Single-row vs. Double-row (FU=27.5 mo post-operation) **Retear (full-thickness):** 4/24 (16.6%) vs. 6/23 (26.0%), p=0.999 **Retear (full or partial):** 15/24 (62.5%) vs. 7/23 (30.4%), p=0.124 **No tear:** 9/24 (37.5%) vs. 16/23 (69.6%), p=NR **Pain (VAS):** 1.8 ± 2.0 vs. 1.9 ± 2.5, p=0.973

Author year Study name (if applicable)	Study design	Subjects	Treatment groups (n; dose)	Treatment duration	Outcomes and findings
					Function (Constant score): 85.5 ± 12.7 vs. 85.7 ± 20.2, p=0.416 **ASES score:** 84.3 ± 15.50 vs. 84.60 ± 22.00, p=0.481 **UCLA score:** 29.5 ± 4.4 vs. 30.1 ± 6.5, p=0.267 **ROM-FF:** 150.3 ± 13.5 vs. 151.0 ± 16.2 (range: 20-170), p=0.507 **ROM-IR:** T8 vs. T9, p=0.053 **ROM-ER:** 33.2 ± 15.4 vs. 30.8 ± 13.4, p=0.547 **Satisfaction (good to excellent):** 25 (80.6%) vs. 27 (87.0%), p=NR
Pennington 2010[19]	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	<u>Single-row vs. Double-row (FU=24 mo post-operation)</u> **Healing rate (grade 1-3):** n=35/44 (79.5%) vs. n=25/37 (67.5%), p<0.017 [total population] **Healing rate (grade 1-3):** n=13/18 (72%) vs. n=19/25 (76%), p<0.03 [tears between 2.5-3.5 cm] **ASES score:** 86.9 vs. 91.6, p>0.05 **Pain (VAS):** 1.1 vs. 0.4, p>0.05 **UCLA score:** 29.6 vs. 29.3, p>0.05 **ROM-FF:** 160 vs. 167, p>0.05 **ROM-ER:** 82 vs. 88, p>0.05 **ROM-IR:** 74 vs. 81, p>0.05 **Abduction:** 157 vs. 161, p>0.05 **Satisfaction:** 95% vs. 92%, p=NR
Milano 2010[20]	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	<u>RCR-metal anchors vs. RCR-biodegradable anchors (FU=24 mo)</u> **DASH score (0-100):** 17.6 ± 17.2 vs. 22.8 ± 19.9, 95% CI: -13.80, 0.40 **Work-DASH score:** 24.9 ± 28.1 vs. 22.5 ± 24.1, 95% CI: -8.50, 12.82 **Constant score:** 104 ± 20.5 vs. 985.6 ± 14.3, 95% CI: -1.48, 12.27
Operative augmentation					
Castricini 2011[18]	RCT	88 pts with rotator cuff tear; mean age:	RCR (n=45; dose: NA) vs. RCR + Augmentation with PRFM (n=43;	NA	<u>RCR vs. RCR + Augmentation with PRFM (FU=20.2 mo)</u>

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)		**Constant score** **Shoulder pain:** 14.3 (10-15) vs. 14.3 (10-15), p>0.05 **ADL:** 18.8 (14-20) vs. 19.3 (16-20), p>0.05 **ROM:** 38.8 (26-40) vs. 39.1 (36-40), p>0.05 **Strength:** 16.5 (4-25) vs. 15.7 (40-24), p>0.05 **Total score:** 88.4 (54-100) vs. 88.4 (72-99), p=0.44 **Tendon thickness** Normal: 17/38 (44.7%) vs. 27/40 (67.5%), p=0.181

Author year Study name (if applicable)	Study design	Subjects	Treatment groups (n; dose)	Treatment duration	Outcomes and findings
Cho 2009[28]	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) **Pain (VAS)-rest:** 0.13 (range: 0-1) vs. 0.15 (range: 0-1), p=0.524 **Pain (VAS)-motion:** 2.03 (range: 0-7) vs. 2.7 (range: 0-8), p=0.317 **ROM-FF (degrees):** 159.1 vs. 156.2, p=0.35 **ROM-ER (degrees):** 40 vs. 47, p=0.094 **ROM-IR:** L1 vs. T11, p=0.053 **Abduction (degrees):** 168 vs. 162, p=0.202 **Muscle strength-FF (kg):** 5.4 vs. 7.27, p=0.017 **Muscle strength-ER (kg):** 6.8 vs. 8.62, p=0.001 **Muscle strength-IR (kg):** 7.5 vs. 9.9, p<0.001 **Muscle strength-abduction (kg):** 4.6 vs. 6.5, p=0.26 **Re-tear rate**: 14/19 (73.7%) vs. 10/24 (41.7%), p=0.036 **Constant score:** 81 (range: 55-96) vs. 82.6 (range: 69-96), p=0.412 **UCLA score:** 30.3 (range: 20-35) vs. 32.6 (range: 22-35), p=0.198 **Satisfaction (excellent):** 5 (16.1%) vs. 18 (48.7%), p=NR
Barber 2011[29]	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	RCR vs. RCR + Augmentation with PRFM (FU=31 mo) **Re-tear rate**: 12/20 (60%) vs. 6/20 (30%), p=0.03 **Healing rate (tears < 3 cm length):** 7/14 (50%) vs. 12/14 (86%), p<0.05 **Healing rate (tears ≥ 3 cm length):** 1/6 (16.6%) vs. 2/6 (33%), p<0.07 **ASES score:** 94.7 vs. 95.7, p=0.35 **Constant score:** 84.7 vs. 88.1, p=0.19 **SANE score:** 93.7 vs. 94.5, p=0.37 **SST score:** 11.4 vs. 11.3, p=0.41

Author year Study name (if applicable)	Study design	Subjects	Treatment groups (n; dose)	Treatment duration	Outcomes and findings
Randelli 2011 [16]	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) **Re-tear rate**: 12/23 (52%) vs. 9/22 (41%), p=0.40 **UCLA score:** 31.3 ± 4.1 vs. 33.3 ± 2.2, p=0.06 **Constant score:** 78.7 ± 10.0 vs. 82.4 ± 6.3, p=0.10 **SST score: 10**.9 ± 1.4 vs. 11.3 ± 0.9, p=0.30
Post-operative rehabilitation					
No new relevant evidence was identified	NA	NA	NA	NA	NA
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.					
Cycle 2					
No new relevant evidence was identified	NA	NA	NA	NA	NA
Cycle 1					
Chou 2010[24]	RCT	51 pts who had rotator cuff lesions without complete tearing refractory to previous conservative therapy or rehabilitation for 3 mo or longer; mean age: 52 yrs; male%: 37.2	Sodium hyaluronate (n=25; 25 mg/wk) vs. PL (n=26; 2.5 mL/wk normal saline)	5 wks	Sodium hyaluronate vs. PL (1 week post-treatment) **Constant score:** 72.48 ± 16.46 vs. 72.42 ± 11.75, p=0.9887 **Pain (VAS):** 4.20 ± 1.76 vs. 4.77 ± 1.75, p=0.252 **Global improvement** (physician-assessed): NS (p=0.272) **Global improvement** (patient-assessed): NS (p=0.164) Sodium hyaluronate vs. PL (6 weeks post-treatment) **Constant score:** 79.24 ± 13.09 vs. 69.07 ± 13.29, p=0.0095 **Pain (VAS):** 3.04 ± 2.03 vs. 5.12 ± 2.42, p=0.0018

Author year Study name (if applicable)	Study design	Subjects	Treatment groups (n; dose)	Treatment duration	Outcomes and findings
Bennell 2010[30]	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	<u>MT + exercise vs. PL (22 wks post-baseline)</u> **SPADI total score (0-100):** 22.4 ± 22.0 vs. 15.6 ± 17.8 MD (95% CI): 7.1 (0.3, 13.9) **SPADI pain score (0-100):** 24.8 ± 23.7 vs. 17.3 ± 19.6 MD (95% CI): 7.1 (0.3, 13.9) **SPADI function score (0-100):** 19.6 ± 20.7 vs. 11.6 ± 16.6 MD (95% CI): 7.6 (1.8, 13.4) **VAS-motion (pain score):** 2.6 ± 2.9 vs. 1.6 ± 2.4 MD (95% CI): 0.9 (-0.03, 1.7) **VAS-rest (pain score):** 1.3 ± 2.5 vs. 0.4 ± 2.5 MD (95% CI): 0.7 (-0.1, 1.4) **SF-36 physical score (0-100):** 10.8 ± 25.0 vs. 4.7 ± 22.3 MD (95% CI): 6.3 (-2.0, 14.5) **AQoL (-0.4-1.0)**: 0.0 ± 0.2 vs. 0.0 ± 0.1 MD (95% CI): 0.0 (0.04, 0.1) **Muscle strength-abduction (kg):** 1.1 ± 4.4 vs. 0.4 ±

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) **Muscle strength-ER (kg):** 0.3 ± 4.3 vs. -0.1 ± 1.9 MD (95% CI): 0.9 (-0.1, 1.9) **Muscle strength-IR (kg):** 1.3 ± 3.4 vs. 0.0 ± 2.7 MD (95% CI): 1.5 (0.4, 2.5) **Global change overall ('much better'):** 31 (57%) vs. 24 (41%) RR (95% CI): 1.39 (0.94, 2.03)
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?					
Cycle 2					
No new relevant evidence was identified	NA	NA	NA	NA	NA
Cycle 1					
No new relevant evidence was identified	NA	NA	NA	NA	NA
Key question # 5: What are the associated risks, adverse effects, and potential harms of nonoperative and operative therapies?					
Cycle 2					
No new relevant evidence was identified	NA	NA	NA	NA	NA
Cycle 1					
Chou 2010[24]	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	Sodium hyaluronate vs. PL (during 5 wk treatment) **Complications:** 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[28]	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) **Post-operative complications (immediate):** None **Post-operative complications (popeye deformity):** n=2 vs. n=1
Randelli 2011[16]	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) **Complications**: 1 pt in the RCR group had failure of cuff repair
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?					
Cycle 2					
No new relevant evidence was identified	NA	NA	NA	NA	NA
Cycle 1					
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 E: 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**
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?			
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.			
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?			
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).			

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
Males comprised an average of 58.9 percent of study participants. 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. 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 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
conclusions about the other techniques. 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. 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.			
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.			
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 hyaluraonate versus dexamethasone; rehabilitation versus no rehabilitation (not otherwise specified); and physical therapy, oral medications, and steroid injection versus physical therapy, oral medications,			

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
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.			
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?			
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.			
Key Question 5. What are the associated risks, adverse effects, and potential harms of nonoperative and operative therapies?			
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.			
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?			
Overall, 72 of the 137 studies examined the impact of prognostic factors on patient outcomes. General conclusions			

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
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.			
CER=comparative effectiveness review; RCT=randomized controlled trial; IQR=interquartile range			