

# OE ORIGINAL

## Surgery versus Physical Therapy for Rotator Cuff Tear: Insights from OE MIND

### How to Cite

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## Highlights

- OE MIND contains data from 7,500 orthopaedic and physiotherapy RCTs with over 6 million patients and 75 million data points, and is a powerful and efficient tool to auto generate evidence reports regarding a clinical topic.
- Our database contains over 125,000 patients across 623 studies reported for shoulder conditions in OE MIND. Of this, nearly 38,000 patients across 243 studies are for rotator cuff conditions, with 153 treatments studied for rotator cuff tears, and 47 outcome measures reported for studies investigating effectiveness of rotator cuff repair compared to physical therapy alone.
- Patients who underwent surgical repair demonstrated superior outcomes in Constant Shoulder Score and pain compared with those who received physiotherapy treatment at 1 year of follow-up. The effects were statistically significant, but the 95% CI of both outcomes did not exceed the recommended minimally important difference.
- We didn't identify any new ongoing studies comparing surgery versus physiotherapy for rotator cuff tears using OE MIND. There are, however, 10 planned studies aiming to recruit 363 patients currently ongoing for the surgical intervention of rotator cuff repair.
- OE MIND data from 2007, suggests that manufacturers that have published the most research associated with rotator cuff repair are Arthrex, Smith & Nephew, DePuy, Mitek and Linvatec.

OrthoEvidence (OE) M.I.N.D.(Machine Learning Insights Database) tools provide a platform of high quality, comprehensive and timely data analytics, evidence generation and knowledge translation dedicated to better serving orthopaedic and relevant fields. The OE MIND generated results provide clarity from a growing database of insights from the best available evidence and user behaviour. These complex analytics will inform algorithms for machine learning technologies to provide automated reports, self-updating analyses that refresh with new evidence, and much more.

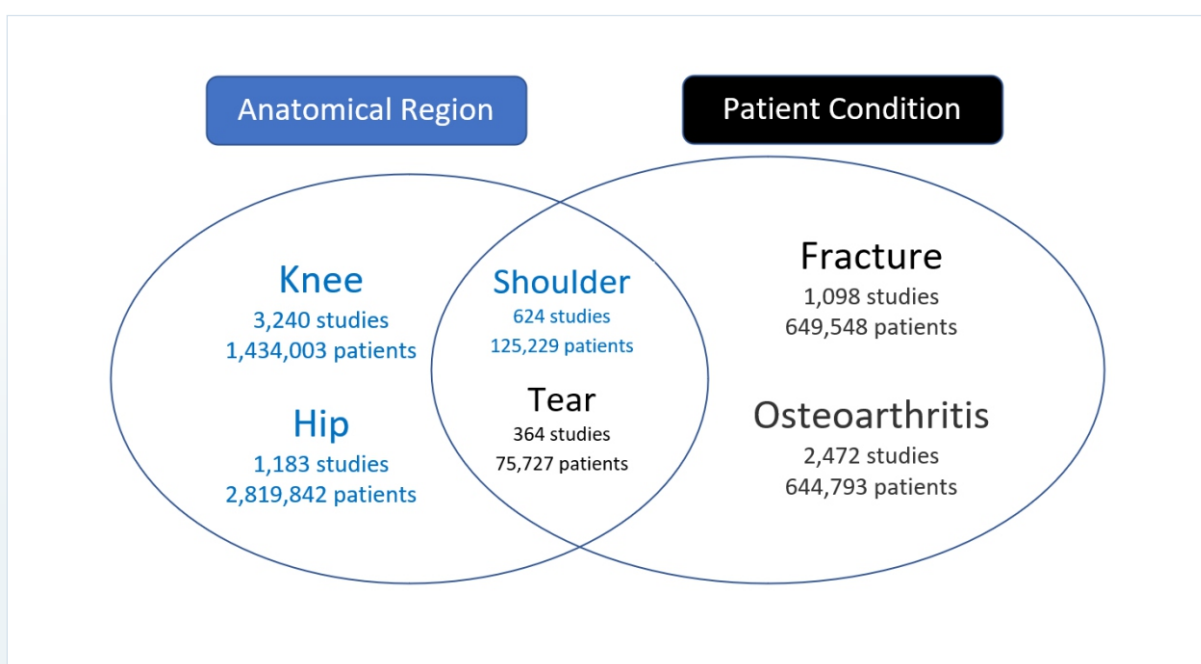
In this OE Original, we present some of the key functions and features of the OE MIND tools using one of the most read topics in the OE community, effectiveness of surgery

versus physical therapy among patients with rotator cuff tears. The analytics include the annual and cumulative numbers of publications and views, a scoping review of published studies, meta-analysis results and quality of evidence for the head to head comparison, cumulative evidence synthesized by time, and a profile of ongoing trials and market analytic features for this clinical topic. All of the data were extracted from randomized controlled trials (RCTs) by experienced medical literature reviewers and validated by the OE team. OE MIND updates the data on a daily basis, with new trials and data being constantly added. The results in this OE Original were based on the operation conducted on January 28, 2021.

## 1. OE MIND user view reporting tool --- Top read categories

Of about 5,500 Advanced Clinical Evidence (ACE) reports published on the [OE site](#) over the past eight years, osteoarthritis, fracture, pain and tear in anatomical regions of knee, hip and shoulder are most read by the OE members (Figure 1).

**Figure 1. Top read categories of OE ACE reports**

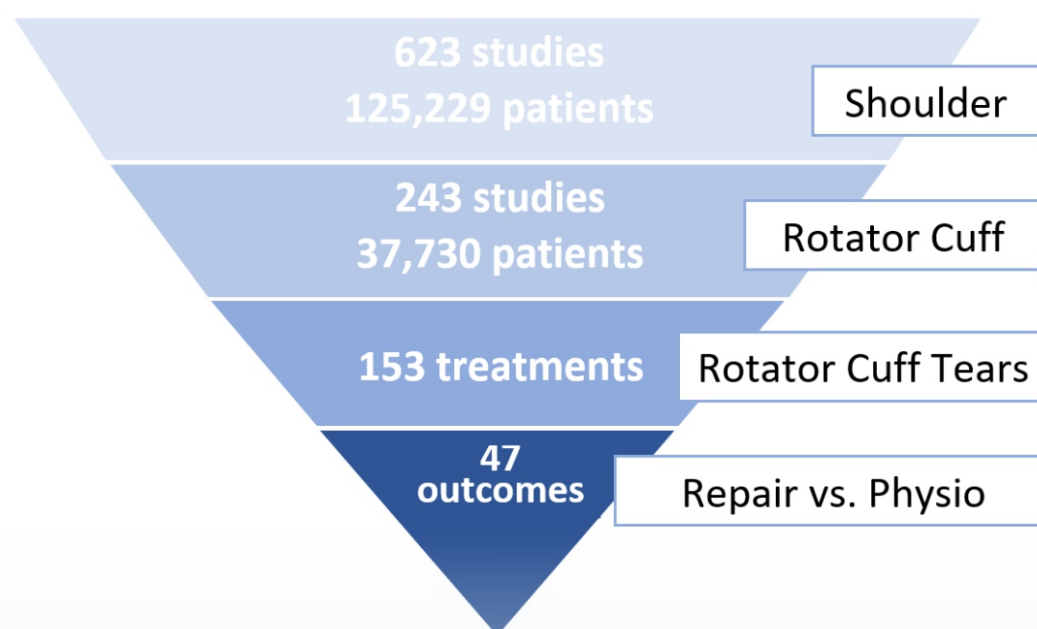


## 2. OE Meta-Analysis Clinical Research Tool

### 2.1 Overview of the available evidence

Over 125,000 patients across 623 studies were reported for shoulder conditions. Of these, nearly 38,000 patients across 243 studies examined rotator cuff conditions. There are 153 treatments that were studied for rotator cuff tears, and 47 outcome measures were reported at various follow-up durations evaluating effectiveness and adverse events of rotator cuff repair compared to physical therapy alone (Figure 2).

**Figure 2. Summary data of research topic according to anatomical region, condition and treatment**



### 2.2 Effectiveness of treatments

We identified 4 articles that reported 3 RCTs comparing the effectiveness of rotator cuff repair to physical therapy alone for patients with rotator cuff tears (Kukkonen et al., 2015; Moosmayer et al., 2010, 2014; Ranebo et al., 2020). The characteristics of the RCTs included in meta-analysis are presented in Table 1.

**Table 1. Characteristics of RCTs included in meta-analysis (Patients' condition: Rotator cuff tear)**

Author, Year	Country	Country	# of patients	Surgical repair	Physiotherapy alone
Kukkonen et al., 2015	Finland	Multiple not-for-profit organizations*	160	A single-row technique was used for $\leq$ tears, otherwise a double-row technique was used.	Patients followed the physiotherapist's instructions and performed a standardized exercise protocol at home for up to 6 months.
Moosmayer et al., 2010, 2014	Norway	South-Eastern Norway Regional Health Authority	103	Patients underwent tendon repair in a standardized manner, either by an open approach or by a mini-open approach.	Patients participated in an outpatient rehabilitation program consisting of twice weekly exercises for the first 12 weeks and with increasing intervals for the next 6 to 12 weeks.
Ranebo et al., 2020	Sweden	Not reported	58	Arthroscopically-assisted rotator cuff repair via an mini-open approach	Patients underwent a progressive 3 phase rehabilitation program, with supervised sessions held weekly for the first 4 weeks and bi-weekly for the next 12 weeks. In between supervised sessions, patients performed home-exercises.

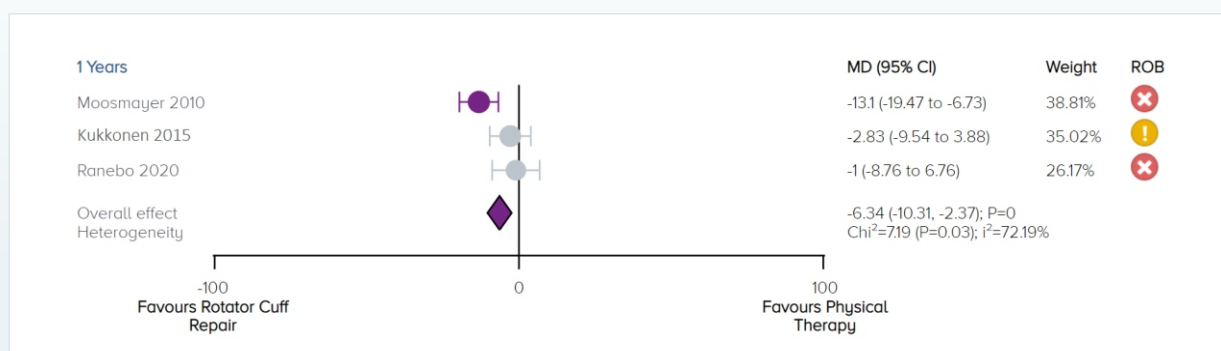
Note: \* Kuopio University Hospital Research Funds, Finnish Medical Foundation, the Turku University Hospital, & the European Society for Surgery of the Shoulder and Elbow.

We are presenting the meta-analysis results of primary outcomes, function measured with Constant Shoulder Score and pain on a 0 to 100 converted scale measured with numeric rating scale (NRS) or visual analogue scale (VAS) at 1 year follow-up.

## 2.2.1 Constant Shoulder Score (0 to 100, a higher score indicates better function)

In the comparison of rotator cuff repair versus physical therapy for the outcome of Constant Shoulder Score at 1 year, a total of 161 patients from 3 studies published between 2010 to 2020 are included in the analysis. One study favours rotator cuff repair (Moosmayer et al., 2010), and 2 studies show no difference between treatments (Kukkonen et al., 2015; Ranebo et al., 2020). The overall effect demonstrates that rotator cuff repair results in a significant improvement in Constant Shoulder Score with patients experiencing, on average, a 6.34 [2.37 to 10.31 95% confidence interval (CI)] point improvement compared to physical therapy alone. The effect and 95% CI did not exceed the recommended minimally important difference (MID) of 8.3 points on the 0 to 100 Constant Shoulder Score for shoulder condition (Hao et al., 2019). The certainty of the evidence by **GRADE** assessment was rated as very low due to serious risk of bias, inconsistency and imprecision (Figure 3).

**Figure 3. Forest plot of Constant Shoulder Score**



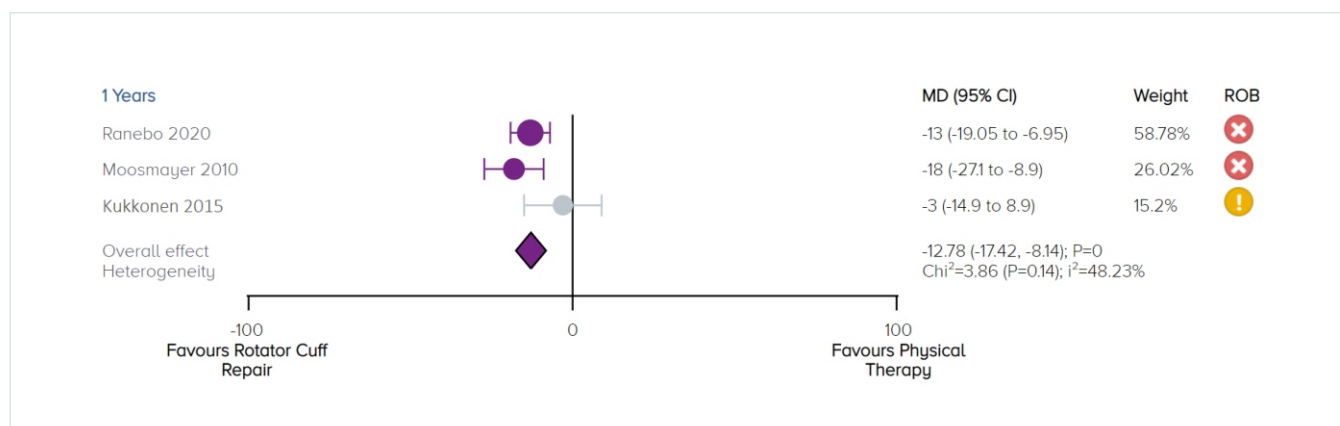
**Notes:** ROB = risk of bias; red circle with a cross mark = high risk of bias; yellow circle with an exclamation mark = have some concerns.

## 2.2.2 Pain score (0 to 100, a higher score indicates worse pain)

In the comparison of rotator cuff repair versus physical therapy for the outcome of pain at 1 year, a total of 161 patients from 3 studies published between 2010 to 2020 are included in the analysis. Two studies favour rotator cuff repair (Moosmayer et al., 2010; Ranebo et al., 2020), and one study shows no difference between treatments (Kukkonen et al., 2015). The overall effect demonstrates that rotator cuff repair results in a significant

improvement in pain with patients experiencing, on average, a 12.78 (8.14 to 17.42 95% CI) point improvement compared to physical therapy alone, with very low certainty of the evidence. The effect and 95% CI did not exceed the MID of 1.5 points on the 0 to 10 pain VAS, i.e., 15 points on a 0 to 100 pain scale after conversion, for patients with shoulder condition (Hao et al., 2019) (Figure 4).

**Figure 4. Forest plot of pain on 0-100 score**



**Notes:** ROB = risk of bias; red circle with a cross mark, at high risk of bias; yellow circle with an exclamation mark, have some concerns.

## 3. OE MIND Sequential Meta-Analysis Research Tool

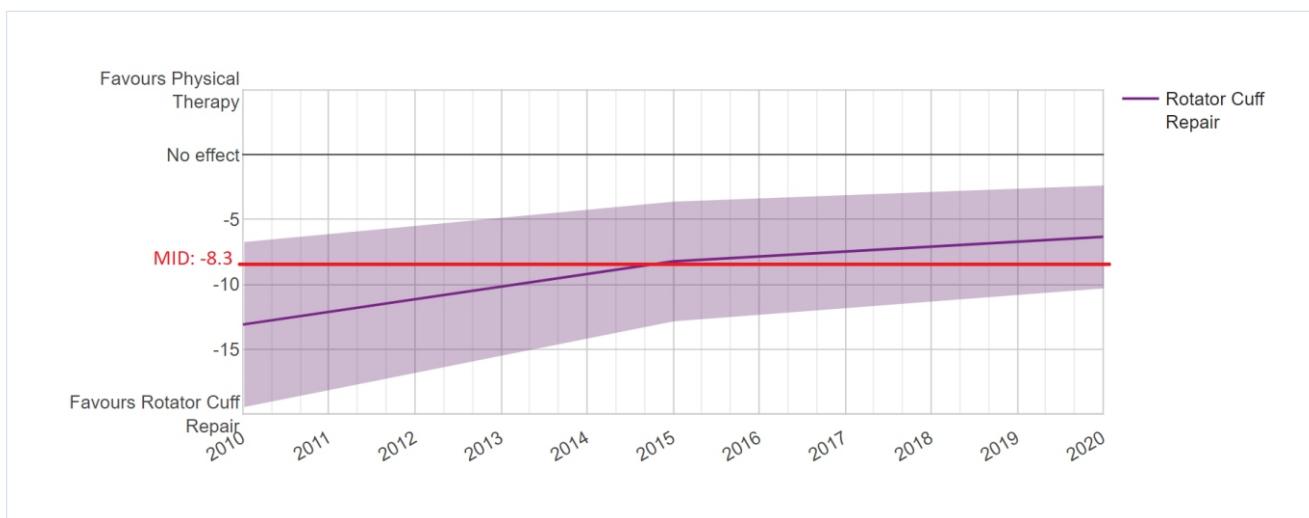
The OE MIND sequential meta-analysis research tool provides meta-analysis results on a certain clinical research topic for any studied outcomes and can reflect the trends of treatment effects over time. When new RCTs are reported, their data are incorporated into its prior effects. These are all presented in one easy-to-understand figure and can help us predict the true effects if more patients are included in further trials, based on available evidence instead of from assumption alone. This not only allows the visualization of trending evidence, but this tool also plays a unique role in assisting researchers to justify their hypothesis and better estimate sample size when they plan a clinical research study.

### 3.1 Constant Shoulder Score

Of the 3 studies in OE MIND evaluating the effect of rotator cuff repair versus physical therapy on function measured with Constant Shoulder Score at 1 year follow-up, the treatment effect started with the first reported study published in 2010 favouring rotator cuff repair, with patients experiencing, on average, a 13.1 point (95% CI 6.73 to 19.47) improvement compared to physical therapy alone. After examining all of the evidence over time up to 2020, the final treatment effect favoured rotator cuff repair, with patients experiencing, on average, a 6.34 point (95% CI 2.37 to 10.31) improvement.

We can see from Figure 5 that the point estimate of effects has been moving toward the “No effect” line when we compare rotator cuff repair versus physical therapy for patients with rotator cuff repair. The 95% CI (the shaded area around the trending solid line in the figure) has yet to cross the “No effect” threshold. This indicates that with the addition of future studies, there is a chance of the effect and confidence interval reaching the no-effect line, and more studies are needed in order to determine the true effect.

**Figure 5. Sequential meta-analysis result for Constant Shoulder Score at 1 year follow-up**



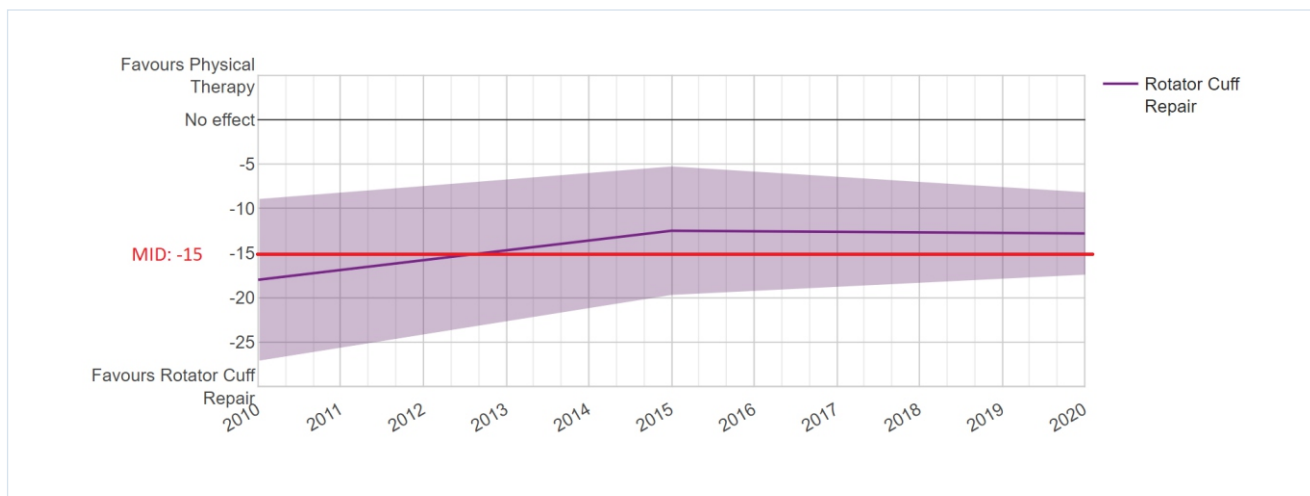
### 3.2 Pain score

Similarly, the sequential meta-analysis of pain measured with NRS or VAS at 1 year follow-up showed that the point effect and its 95% CI moved toward the “No effect” line, and the trend became flattened. The most updated evidence showed a superior effect of repair compared to physical therapy alone for pain (Figure 6).

The treatment effect started with the first reported study published in 2010 favouring rotator cuff repair, with patients experiencing, on average, a 18.0 point (95% CI 8.9 to 27.1) improvement for pain. In 2015, the pooled mean difference between the two treatments was 12.5 point (95% CI 5.2 to 19.7) for pain. After examining all of the evidence over time up to 2020, the final treatment effect favoured rotator cuff repair, with patients experiencing, on average, a 12.78 (95% CI 8.14 to 17.42) improvement for pain (Figure 6). The flattening of the trend line means that the addition of future studies may not drastically change the effect estimate, and this may be close to the true effect seen.



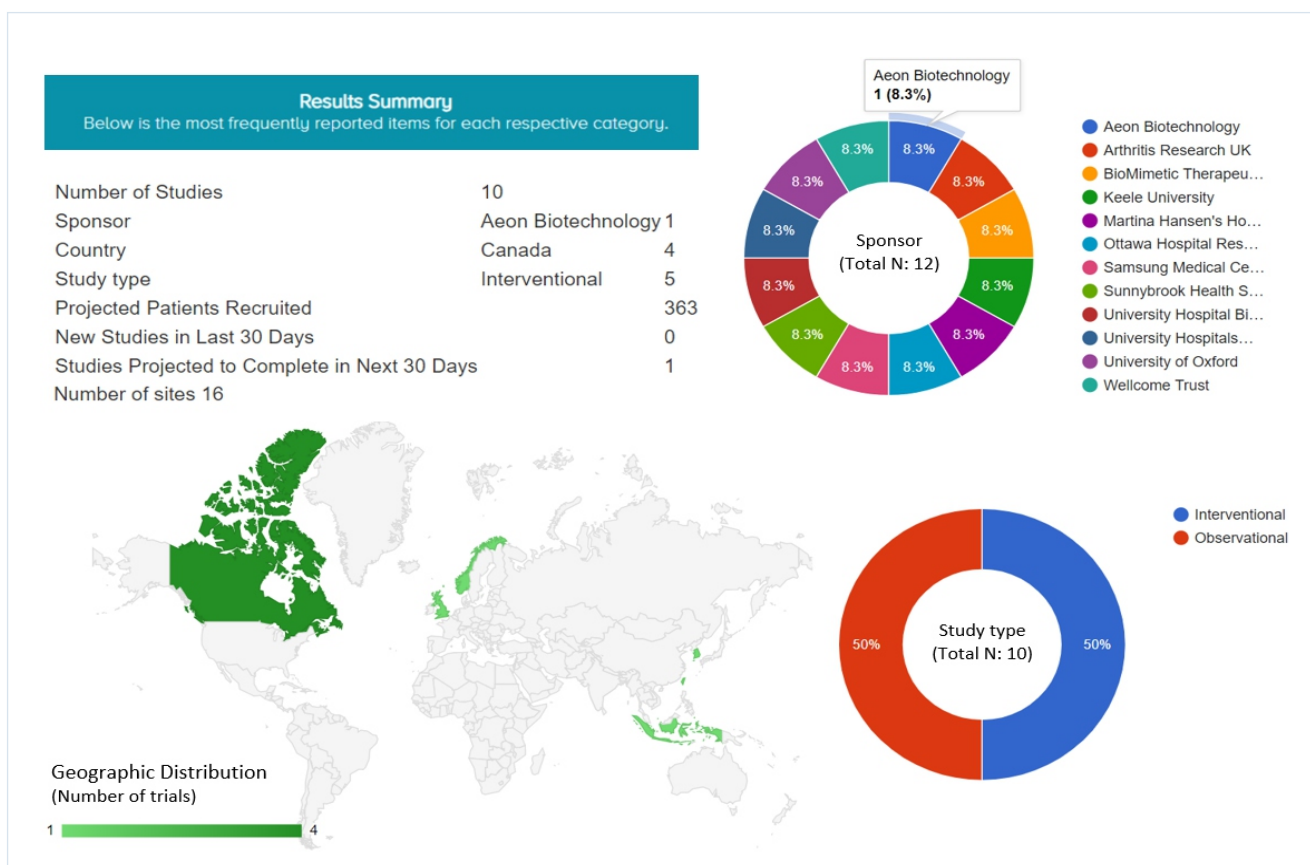
**Figure 6. Sequential meta-analysis result for pain at 1 year follow-up**



## 4. OE MIND Ongoing Trials Tool

Our ongoing trials tool uses a unique interface to harness data from the clinicaltrials.gov registry. We did not find any registered, ongoing studies that investigated the effects of rotator cuff repair versus physical therapy alone. For a surgical intervention compared to another non-physio treatment for rotator cuff repair, a total of 10 studies were found to be currently ongoing around the world, aiming to recruit 363 patients (Figure 7).

**Figure 7. Ongoing trials of surgical intervention for rotator cuff repair**

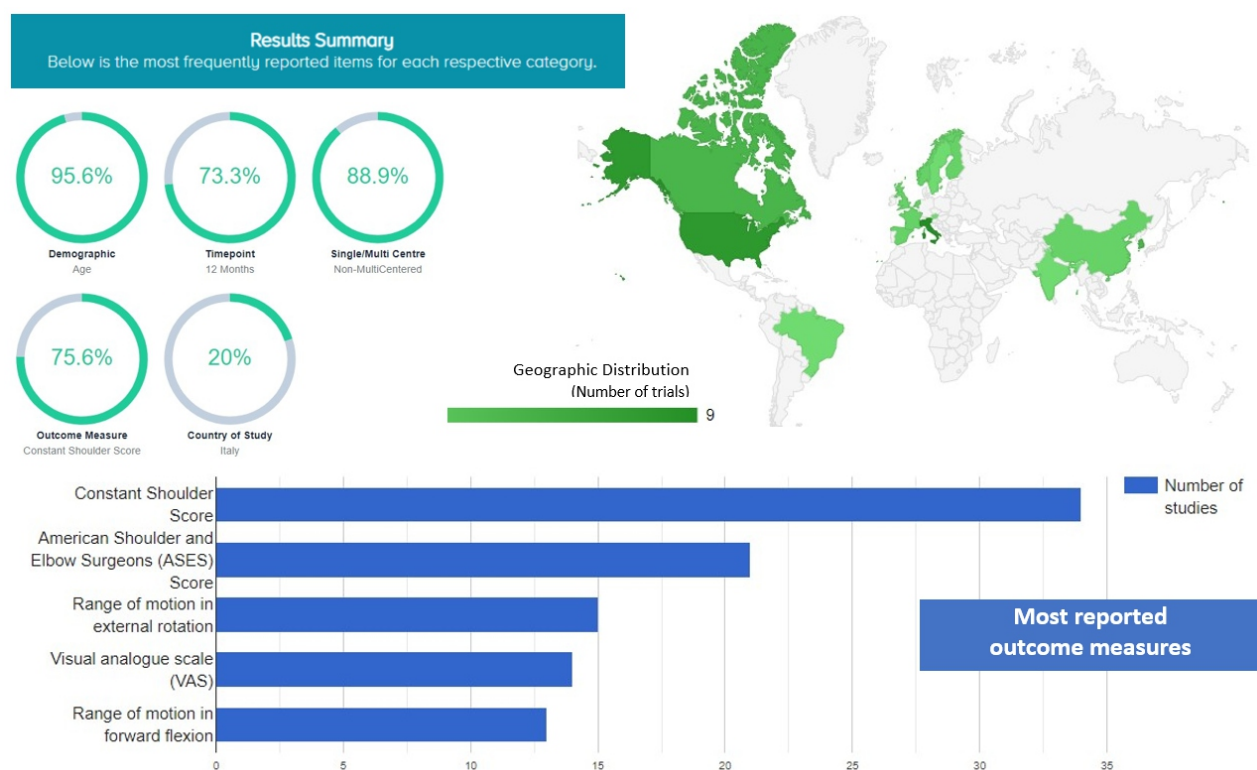


## 5. OE MIND Trial Characteristics Tool ---

### The most frequently reported characteristics in prior studies to plan future studies

It takes knowledge of completed studies to assist in the planning of our own research. The OE MIND Research planning tool provides us with an overview of characteristics of prior RCTs. For rotator cuff repair-related studies, the most frequently reported characteristics include: patient demographics, age (95.6% studies reported age); follow-up time point, 12 months (73.3% studies reported outcomes at 12 months' follow-up); studies conducted at a single center (88.9%); Constant Shoulder Score (75.6%); and the country, Italy (20%, with 9 ongoing studies) (Figure 8).

**Figure 8. The most frequently reported characteristics of relevant studies about rotator cuff repair**





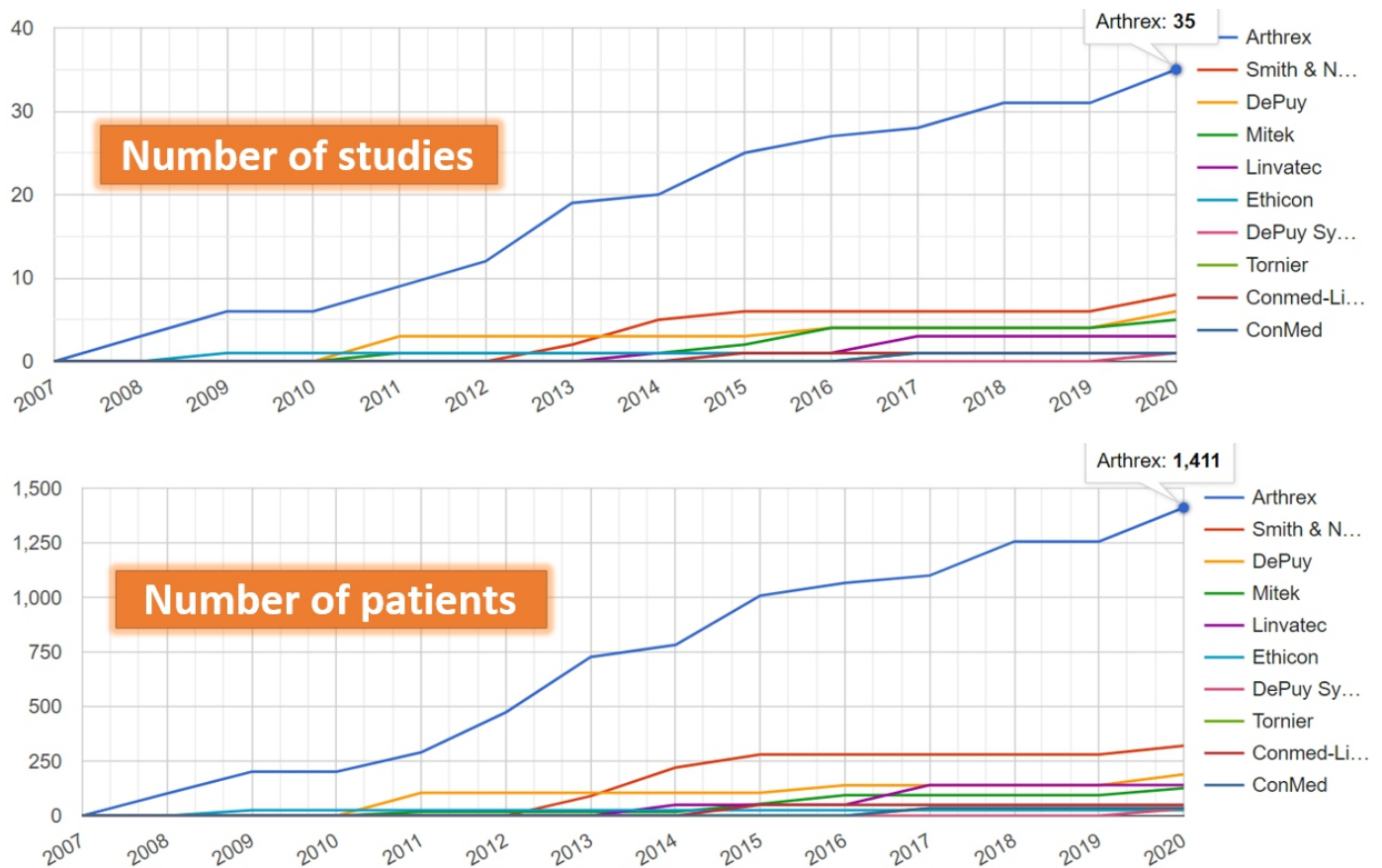
## 6. OE MIND Market Analysis Tool: Who's Sponsoring Research?

With the reported data on manufactures of orthopaedic devices or therapeutics used in the clinical studies, this OE MIND tool provides the number of studies and patients, geographical information and list of their according publications for a certain research topic.

For rotator cuff repair-related studies, we found that since 2007, the manufacturers that have published the most research are Arthrex (N of studies=35), Smith & Nephew (N=8), DePuy (N=6), Mitek (N=5) and Linvatec (N=3) (Figure 10).

The manufacturers with the largest cumulative sample size are Arthrex (N of patients=1,411), Smith & Nephew (N=320), DePuy (N=189), Linvatec (N=140) and Mitek (N=126) (Figure 9).

**Figure 9. Manufacturers with most researches for rotator cuff repair**



## Discussion

Rotator cuff tears are a common injury that results in dysfunction and pain of the shoulder. Despite good results using both surgical and conservative treatments such as physiotherapy, each have their own risks of adverse effects. With surgery, postoperative shoulder stiffness and infection remain areas of concern, along with the risk that the tear will not heal. With physiotherapy, leaving the tear unrepaired can leave patients more susceptible to progression and deterioration of their condition, and cause tears which were repairable initially to be possibly unreparable at a later time (Moosmayer et al., 2010, 2014). In our meta-analysis, a low quality of evidence showed that rotator cuff repair was superior to physical therapy alone in function and pain improvement at 1 year follow-up among patients with rotator cuff tears. The effects were statistically significant, but the 95% CI of the Constant Shoulder Score or pain scale did not exceed the recommended MID when reporting treatment effects regarding shoulder condition (Hao et al., 2019). There was not enough data provided in the three trials to evaluate adverse events between the groups in our meta-analysis.

Studies are often seen comparing different surgical approaches (Figures 3,8,10) (Mijares et al, 2020; Nazari et al., 2019) or comparing different post-surgical rehabilitation programs (Li et al., 2018). However, studies comparing the surgical versus non-surgical modalities are lacking. Whether a subgroup effect exists for patients with different sizes of tears (small

to medium-sized tears or large to massive-sized tears) is also unknown. Compared to surgery, conservative treatments may be beneficial in reducing the overall treatment and societal costs (Kukkonen et al., 2015).

One of the major concerns during the evidence quality assessment was the serious risk of bias: all the included RCTs blinded the outcome assessors but were not able to blind participants or research personnel (Guyatt et al., 2011a). Other major concerns were the imprecision and inconsistency. We rated down one level of GRADE assessment for imprecision regarding both outcomes. Although the CIs of the outcomes excluded the no effect line, their CIs crossed the recommended MID values and clinical decisions would differ if the upper boundary versus the lower boundary of the CIs represented the true effect, for patients to achieve a minimally important improvement (Guyatt et al., 2011b). We rated down one level of GRADE quality of assessment for inconsistency based on values of I<sup>2</sup> which was 72.19% for Constant Shoulder Score and 48.23% for pain (Guyatt et al., 2011c).

Additional future research with larger sample sizes and with at least 1 year follow-up is needed to comprehensively evaluate the outcomes and associated cost, and verify the findings of the current meta-analysis results. As of this point in time, however, our analysis reveals no currently ongoing trials in this field.

## Bottom line

Meta-analysis of a limited number of RCTs showed that patients who underwent surgical tendon repair had superior outcomes in Constant Shoulder Score and pain compared with those who received physiotherapy treatment at 1 year of follow-up. The effects were statistically significant, but the 95% CI of both outcomes did not exceed the MID.

OE MIND tools are efficient and able to generate sufficient evidence-based reports to address a clinical topic. We identified one of the topics that interested our OE community members by user views. We presented an overview of the available evidence profile based on RCTs, meta-analysis results of treatments, trend of the effects along the publication of more studies, profile of ongoing studies regarding a patient condition, most reported characteristics of prior studies and manufacturers cited in the published studies.

## Related ACE Reports



Surgery superior to physiotherapy in small and medium rotator cuff tears



Comparison of primary tendon repair vs physiotherapy treatment for rotator cuff tears



Effects of physiotherapy, acromioplasty, and repair for nontraumatic rotator cuff tear



No Difference in 1 Year Clinical Outcomes with RC Repair vs Physiotherapy for Traumatic RC Tear

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