Title: Effectiveness of formal physical therapy following total shoulder arthroplasty: a systematic review

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ABSTRACT

Background: Physical therapy is considered routine practice following total shoulder arthroplasty (TSA). To date, current regimens are based on clinical opinion, with evidence-based recommendations. The aim of this systematic review was to evaluate the effectiveness of TSA physical therapy programmes with a view to inform current clinical practice, as well as to develop a platform upon which future research might be conducted.

Methods: An electronic search of MEDLINE, EMBASE, CINAHL, and Cochrane Library to March 2018 was complemented by hand and citation-searching. Studies were selected in relation to pre-defined criteria. A narrative synthesis was undertaken.

Results: A total of 506 papers were identified in the electronic database search, with only one study showing moderate evidence of early physical therapy promoting a more rapid return of short-term improvement in function and pain. No studies evaluated the effectiveness of physical therapy programmes in reverse TSA procedures.

Discussion: Restoring ROM and strength following TSA is considered important for patients to obtain a good outcome post-surgery and, when applied early, may offer more rapid recovery. Given the rising incidence of TSAs, especially reverse TSA, there is an urgent need for high-quality, adequately powered RCTs to determine the effectiveness of rehabilitation programmes following these surgeries.

INTRODUCTION

Total shoulder arthroplasty (TSA), including anatomic and reverse TSA, have become more popular, with registry-based studies in Australia, the United States and Europe reporting increasing incidence,[1, 2] with some suggestion of a seven-fold increase over the next 15 years.[3] This increase in incidence is largely on the back of evidence of good clinical outcomes, including reduced pain, increased function and high patient satisfaction,[4-9] and the expanding surgical indications around pathology, such as rotator cuff tear arthropathy (RCTA) and massive rotator cuff tears (MRCT), made possible by reverse TSA.[10-12] Not unlike hip and knee arthroplasty, post-operative physical therapy is considered essential, and indeed routine practice following TSA. Restoration of shoulder strength has shown to be a determinant of functional outcomes, shoulder range of motion (ROM) and satisfaction following TSA.[13, 14] This is considered essential for optimising patient outcomes and best achieved via graduated and progressive physical therapy, consisting of range of motion and strengthening-based exercises.[15]

Despite this apparent importance, the optimal approach to post-operative physical therapy is unknown, as is the quantity and quality of research evidence to inform such clinical decision making. Therefore, the aims of this systematic review were to evaluate the effectiveness of TSA physical therapy programmes with a view to inform current clinical practice, as well as to develop a platform upon which future research might be conducted.

METHODS

Data sources and search strategy

A comprehensive literature search was undertaken via four key databases: MEDLINE via Ovid, EMBASE, CINAHL, and Cochrane Library for all years until March 2018. The MEDLINE search strategy is outlined in Table 1. The electronic search was complemented by searching manually the reference lists of the articles found and previous systematic reviews. All articles were imported to bibliographic software and screened for duplicates (Endnote X7). Two reviewers independently screened the title and abstract of each article using predetermined eligibility criteria (see below). Discrepancies were resolved via discussion and consensus. Full text copies were retrieved for articles that were not excluded based on the title and abstract, and eligibility criteria were applied by the same reviewers. Studies that evaluated a post-surgery physical therapy intervention after TSA, either against another physical therapy intervention or a control group, were included for assessment. Studies reported only as abstracts, or for which we were unable to acquire as full text copies, were excluded from the analyses.

Eligibility criteria

This review included randomised controlled trials (RCTs) investigating post-operative physical therapy for patients having undergone either primary anatomic or reverse TSA. We included any physical therapy or exercise-based intervention that commenced from hospital discharge, which was either supervised by a qualified allied health professional, or self-managed by the patient at home. Clinical outcomes relating to measurements of pain, function and/or strength were assessed. RCTs were excluded if the samples included participants who had undergone a partial shoulder arthroplasty (hemiarthroplasty) or revision shoulder arthroplasty. RCTs written in languages other than English were excluded.

Assessment of risk of bias

The risk of bias of each RCT was assessed by two reviewers (PE/JE) independently using the Physiotherapy Evidence Database (PEDro) scale.[16] The 11 items of the scale were each scored with a 'yes' or 'no'. As the first item of the scale is not included, the maximum score possible is 10; a score of six or more being considered high quality.[17] Results from each reviewer were compared and discrepancies resolved via discussion using the PEDro operational definitions.

Data synthesis

Data were synthesised using a rating system for levels of evidence.[18] This rating system, displayed in Table 2, was used to summarise the results in which the quality and outcomes of individual RCTs are taken into account.

RESULTS

Study selection

A total of 506 papers were identified in the electronic database search, with an additional two publications included for evaluation after manually searching through the reference lists of retrieved papers and existing systematic reviews (Figure 1). After removing duplicates, screening all titles and abstracts, and omitting 12 narrative reviews and clinical commentaries describing post-operative rehabilitation protocols, 19 publications were subsequently assessed in full. After removing a further 18 publications that did not satisfy the selection criteria, only one publication was included for full quality appraisal.

Quality appraisal and risk of bias assessment

The results of the quality appraisal for the single RCT included in this analysis is shown in Table 3. This study, an RCT by Denard and Ladermann,[19] was regarded as high quality according to the PEDro appraisal (Appendix 2), adhering to specification of eligibility, the items of random allocation, participant and assessor blinding, similarity of baseline patient characteristics, measure of variability, and obtained at least one key outcome for more than 85% of participants. It did not meet the item of therapist blinding, which was expected given the trial involved exercise prescription.

Study characteristics

A summary of the characteristics of the included RCT, along with the main results is shown in Table 4. This study included participants having undergone anatomic TSA for glenohumeral osteoarthritis.

Outcomes

Outcomes employed in this study included the Visual Analogue Scale (VAS) to measure pain, the American Shoulder and Elbow Surgeons Shoulder Index Score (ASES), the Single Assessment Numeric Evaluation (SANE) and the Simple Shoulder Test (SST) to assess function, and ROM variables of forward flexion (FF), internal rotation (IR) and external rotation (ER).

Intervention - immediate versus delayed ROM exercises

There is moderate evidence from one high quality RCT[19] that the early initiation of physical therapy promotes a significantly more rapid return of function and improvement in pain in the short term (8 weeks) ($p<0.05$). However, at no time point did ROM significantly differ between the two groups. In this study, immediate ROM consisted of passive external rotation and passive

to active-assisted ROM from 1-4 weeks post-surgery, followed by active ROM until 8 weeks, versus a delayed protocol of passive to active-assisted ROM from 4-8 weeks post-surgery, followed by active ROM until 12 weeks. At 3, 6 and 12-month post-operative follow-up time points, however, no differences were observed in pain, function or ROM variables.

DISCUSSION

This systematic review evaluated the effectiveness of physical therapy programmes following TSA. Previous reviews have summarised the elements of rehabilitation protocols from all the available literature, to draw evidence-based conclusions of rehabilitation following TSA, and have included non-randomised studies and narrative reviews.[20] This systematic review is the first of its kind to evaluate the quantity and quality of RCTs evaluating physical therapy programmes following TSA.

After screening over 500 studies for this systematic review, only one RCT met the inclusion criteria, thereby demonstrating the paucity of high quality research describing and evaluating physical therapy programmes following TSA. This is in stark contrast to the volume of RCTs evaluating rehabilitation interventions following total hip arthroplasty (THA) and total knee arthroplasty (TKA). Henderson et al. [21] evaluated 12 RCTs comparing active interventions following TKA, Artz et al.[22] evaluated 18 RCTs looking at the effectiveness of post-discharge physiotherapy exercise in patients after primary TKA, and Wijnen et al.[23] evaluated 20 RCTs on physiotherapy interventions following THA. Given that TSA procedures are becoming more common, especially reverse TSAs[1], high-quality RCTs evaluating post-operative rehabilitation are needed.

The findings from this study suggest that immediate provision of passive and active-assisted ROM exercises provide short-term benefits in pain and function, when compared to a delayed approach, and at a longer-term follow-up, these benefits are no longer present. These findings, albeit from only one RCT, are consistent with evidence of rehabilitation from other shoulder surgeries and those undergoing hip and knee arthroplasty. In a systematic review and meta-analysis evaluating outcomes between non-supervised home-based exercise versus individualised and supervised programs delivered in clinic-based settings after primary TKA,[24] 12 RCTs of moderate quality demonstrated no difference in short-term improvements in physical function and knee ROM. In a systematic review of early versus delayed motion following rotator cuff repair,[25] rehabilitation involving early motion resulted in initial improvements in ROM and function, but ultimately at one year, both groups displayed similar clinical outcomes.

While fundamentally different procedures, the clinical management between TSA and rotator cuff repair are indeed similar, with the same initial protection and caution around shoulder soft tissue generally applied in both surgery types, with most published programs simply protocols of specific exercises progressed at specific timelines from passive to active ROM, then to eventual strengthening.[26] To gain exposure to the glenohumeral joint during a TSA, a standard deltopectoral surgical approach is commonly used, involving the release and subsequent repair of the subscapularis tendon, with adequate post-operative protection during rehabilitation essential, particularly external rotation.[26] However, extrapolating the same rehabilitation logic from TSA to RSA may not be appropriate for a few reasons. Firstly, it's important to consider the change in joint biomechanics in RSAs; in particular, the shift in moment arms and muscular length-tension relationships, particularly the deltoid, and the likely absent posterior rotator cuff.[27] Secondly, in reverse procedures it's important for clinicians to ascertain whether the

subscapularis has been repaired, or non-repaired. Clinical outcomes between non-repaired and repaired subscapularis tendons have previously demonstrated no differences[28], however it's important for clinicians to abide by soft-tissue precautions in case a repair has been performed. Thirdly, it's important that clinicians acknowledge the while uncommon, but nevertheless unique, risks of RSA, particularly around early-stage dislocation[29], which may prevent accelerated mobilisation of the shoulder joint to the same degree as TSA. With no clinical trials to date on physical therapy and rate of shoulder mobilization post-operatively, this is an important area of further research.

Implications for clinical practice and future research

Since the development of the first anatomic shoulder replacement by Neer in the 1950s, shoulder joint prostheses have continued to evolve, making it a more than a viable option for the management of severe osteoarthritis. Indeed, more recently, reverse shoulder designs have demonstrated good success in alleviating pain and poor function in patients with primary indications of rotator cuff tear arthropathy, and massive rotator cuff tears with and without OA.[30] However, post-operative rehabilitation, considered by many to be an essential component of patient satisfaction and functional recovery,[15] does not yet have a strong evidence base. The limited available evidence suggests that structured rehabilitation programs, applied by qualified therapists, help guide patients through the various recovery periods after TSA, advancing patients' recovery and improving their final functional gain.[31]

This review demonstrated that immediate initiation of ROM and rehabilitation exercises may be necessary to provide a more rapid return of function following TSA. Early ROM has been a major tenet of rehabilitation following TSA for many years, with most protocols emphasising

immediate passive ROM.[26] However, Mulieri et al.[32] retrospectively reviewed 81 TSA patients who followed either an immediate passive ROM program supervised by a therapist, or 6 weeks of immobilisation with pendular exercises, followed by a home exercise program. No significant differences were reported for forward flexion and abduction ROM at 3, 6 and 12 months post-surgery between the home-based group and the patients receiving formalised physical therapy. Furthermore, the physical component scores for the 36-item Short Form Health Survey were statistically superior for the home-based exercise group compared to the formalised physical therapy group at final follow-up (52 months). Therefore, it appears that immediate post-surgery shoulder mobilisation does not affect the final outcome of TSA.

While the longer term outcomes may not be significantly different for patients receiving an immediate versus delayed rehabilitation protocol , a more rapid return to function could enhance patient satisfaction. Together with treatment efficacy, these are considered strong factors when patients refer to the success of TSA.[33] However, given that this was the result from only one high quality RCT, these results should be taken cautiously, until more high quality RCTs are published.

Furthermore, no RCTs in this review were found directly investigating rehabilitation in patients following a reverse TSA design. Reverse TSA surgeries are becoming more common, having increased from 42% in 2009 to 69% in 2016; overtaking anatomic TSAs as the preferred prosthesis design.[1] Of the available studies that evaluated outcomes before and after reverse TSA, detailed descriptions of post-operative rehabilitation protocols are limited, but when they have been reported, they include a mix of clinic-based and home-based rehabilitation. Since muscular strength has previously been indicated as an important factor in facilitating ROM, patient satisfaction and return to sports following reverse TSA,[13, 14, 34] future research should

investigate the role of post-operative rehabilitation, either structured or home-based to improve this physical capacity.

Strengths and limitations of this review

In this review, two of the co-authors were responsible for identifying relevant studies, extracting the data, appraising the quality of the evidence and synthesising the findings. This is a clear strength of the review, as is the extensive search strategy employed. Although the results from this review are consistent with evidence across other joint replacements and shoulder surgeries, there are limitations that warrant consideration. Firstly, and most obviously, only one RCT was included for evaluation. The included RCT, which was rated as high quality, did not blind participants, which is considered a common short-coming and widely regarded as typical in pragmatic RCTs of this nature. Secondly, the study did not measure patient compliance with the post-operative rehabilitation protocol among the intervention group. Patient compliance and adherence to a physical therapy program is an important element to measure in a rehabilitation study, and indeed could have influenced the reported outcomes. While difficult to inform clinical practice from only one included study, this review does indeed highlight the need of more evidence-based research in the form of RCTs in rehabilitation following both TSA and, in particular, RSA.

CONCLUSION

Restoring ROM and strength following TSA is considered important for patients to obtain a good outcome post-surgery and, when applied early, may offer more rapid recovery. Despite this, there is a paucity of research evidence to inform clinical practice. Given the rising

incidence of TSAs, especially reverse TSA, this review demonstrates the urgent need for high-quality, adequately powered RCTs to determine the effectiveness of rehabilitation programmes following these surgeries.

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TABLE 1. Search terms in MEDLINE database.

	Search Term
1	shoulder arthroplasty OR shoulder replacement [Title / Abstract]
	AND
2	exercise OR rehabilitation OR physiotherapy OR physical therapy [Title / Abstract]

Table 2. Levels of evidence

Strong evidence	Consistent findings in multiple high quality studies (n>2)
Moderate evidence	Consistent findings among multiple lower quality studies and/or one higher quality study
Limited evidence	Only one relevant low quality study
Conflicting evidence	Inconsistent findings amongst multiple studies
No evidence from trials	No studies

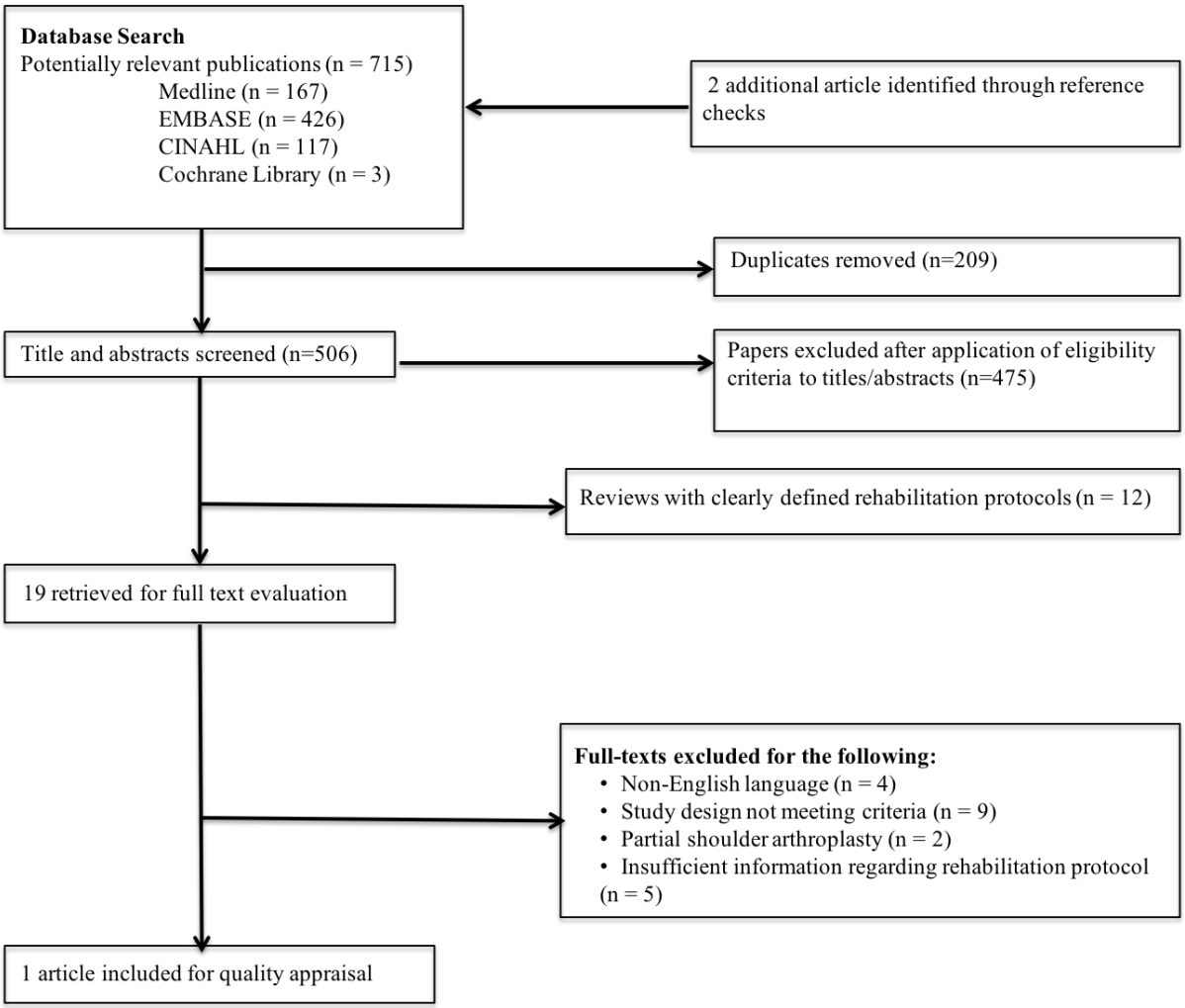

FIGURE 1. A flow chart of the search strategy used in this review.

372 **Table 3.** Completed PEDro quality-appraisal tool

	Eligibility criteria specified	Random allocation	Concealed allocation	Similarity of baseline characteristics	Participant blinding	Therapist blinding	Assessor blinding	<15% dropouts	Treatment, control or intention-to-treat	Between-group statistical comparisons	Point measures	**Total**
Denard & Ladermann[19]	Y	Y	N	Y	N	N	Y	Y	Y	Y	Y	**8**

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374 **TABLE 4**. Characteristics of included studies

Study	Evidence Level	Participants	Intervention	Comparison	Outcome Measures
Denard & Ladermann[19]	Level I, Randomised-controlled trial	60 patients scheduled for TSA with primary glenohumeral OA INT (n = 27), mean age 69.1 years (52 - 85), 56% female, 59% dominant arm. COM (n = 28), mean age 66.9 years (42 - 82), 39% female, 54% dominant arm	Immediate ROM: • Sling worn 4 weeks; • From day 1: PROM in FF, and AAROM overhead rope and pulley; passive ER to 30° with a stick; active hand, wrist, and elbow exercises and active scapular retraction. • From Week 4: sling discontinued, passive ER as tolerated; active FF as tolerated. • From Week 8: commencement of strengthening exercises. • From Week 12: activities as tolerated, no repetitive lifting over 25 lb (11.3 kg).	Delayed ROM: • Sling worn 4 weeks; • From Day 1: active hand, wrist, and elbow exercises, and active scapular retraction exercises. • From Week 4: sling discontinued, PROM in FF and AAROM with overhead rope and pulley and passive ER as tolerated; • From Week 8: active FF as tolerated, commencement of strengthening exercises; • From Week 16: activities as tolerated, no repetitive lifting over 25 lb (11.3 kg).	Pain: VAS Function: ASES, SST, SANE ROM: FF, ER, IR

375 AAROM, active-assisted range of motion; ABD, abduction; ADL, activities of daily living; AROM, active range of motion; ASES, American Shoulder and Elbow Surgeons Score; COM,
376 comparison group; ER, external rotation; FF, forward flexion; INT, intervention group; IR, internal rotation; kg, kilograms; lb, pounds; OA, osteoarthritis; PROM, passive range of motion;
377 ROM, range of motion; SANE, Single Assessment Numeric Evaluation; SST, Simple Shoulder Test; VAS, Visual Analog Scale.