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Health Technology Assessment (HTA)

HTA Report

Title	Subacromial decompression as a primary/isolated intervention to treat subacromial pain
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Technology	Subacromial decompression (e.g. acromioplasty and/or bursectomy)
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Type of Technology	Surgical procedure

Conflicts of Interest:

The authors have no financial, academic, personal or any other conflicts of interest to declare in relation to this project.

EXECUTIVE SUMMARY

The objective of this report was to evaluate the clinical and economic effectiveness of subacromial decompression as a primary intervention to treat subacromial pain compared to conservative management, no treatment and placebo, and to consider legal, social, ethical and organisational issues associated with limiting access to the procedure.

Clinical evaluation

An existing Cochrane review by Karjalainen was included and critiqued. The meta-analyses performed in the Cochrane review were replicated, and analyses that could not be replicated were produced independently using novel data inputs. The clinical evaluation of efficacy outcomes was informed by 8 randomised controlled trials (RCTs); the clinical evaluation of safety outcomes was informed by 2 RCTs, 7 non-randomised trials and 12 single-arm trials. Effects reported in this executive summary are summarised at 12 months using new analyses replicated from the Cochrane review for pain, function and health-related quality of life (HRQoL), and reported in the Cochrane review for return to work, return to leisure activities and further progression of subacromial pain.

Subacromial decompression versus conservative treatment

Six RCTs compared subacromial decompression to conservative treatment (n=614). At 12 months there were no statistically significant differences reported for pain (low certainty evidence), function (very low certainty evidence), health-related quality of life (HRQoL) (low certainty evidence), return to work (very low certainty evidence), return to leisure activities (very low certainty evidence), progression of subacromial pain (very low certainty evidence). The main reason the evidence was downgraded was due to the risk of detection and performance bias, as participants were not blinded to their treatment allocations.

Subacromial decompression versus placebo (sham surgery)

Three RCTs compared subacromial decompression to placebo (n=406). At 12 months there were no statistically significant differences reported for pain (high certainty evidence), function (high certainty evidence), HRQoL (high certainty evidence), return to work (moderate certainty evidence), return to leisure activities (moderate certainty evidence). Progression of subacromial pain was not reported. The analyses in this section were at a low risk of bias, with some outcomes scored down due to imprecision.

Subacromial decompression versus no treatment

One RCT compared subacromial decompression to no treatment (n=210). At 12 months, there was a statistically significant difference in pain (MD=-1.2, 95% CI -2.04, -0.36, moderate certainty evidence), and a clinically important difference in function (MD=9.5, 95% CI: 2.66, 16.34, moderate certainty evidence) favouring decompression, but no difference for HRQoL (moderate certainty evidence), further progression of subacromial pain (moderate certainty evidence). Other outcomes were not reported. The outcomes in this section were scored down due to risk of detection bias, as participants were not blinded to their treatment allocation.

Safety

There were no statistically significant differences in the number of adverse events recorded for subacromial decompression and non-operative treatments (moderate certainty evidence). Serious adverse events were not reported in the selected RCTs (moderate certainty evidence).

Costs and cost-effectiveness

As the clinical evaluation found no clinically significant improvement in short-term HRQoL for subacromial decompression compared to placebo and conservative management, a cost comparison was conducted. The inpatient cost of subacromial decompression surgery of CHF8,633 was higher than the estimated conservative management cost of CHF1,350 (15 physiotherapy sessions at CHF90 per session). The outpatient delivery of subacromial decompression had a cost of CHF3,972, comprising CHF1,161 for TARMED 24.0710 arthroscopy and 24.0750 decompression; anaesthesia CHF750; and medicines, consumables and overheads CHF2,061. This cost was also higher than the cost of conservative management. Subacromial decompression has no clinical benefit, but has a higher cost, compared to the designated comparator (conservative management), so offers no economic advantage.

A decision analytic model was developed to quantify the cost-effectiveness of subacromial decompression for inpatient-delivered rotator cuff disease compared to no treatment using incremental quality-adjusted life years (QALY). An incremental cost-effectiveness ratio (ICER) of CHF98,102 per QALY gained was estimated at 12 months for surgery compared to no treatment using results of the Can Shoulder Arthroscopy Work (CSAW) trial when no adjustment was made to uneven baseline utilities. With adjustment to these values, the ICER was estimated to be CHF107,913 per QALY gained. Probabilistic sensitivity analyses (PSA) determined with 49% probability that subacromial decompression was more cost-effective compared to no treatment using a hypothetical willingness-to-pay threshold of CHF100,000 per QALY gained. Univariate

sensitivity analyses indicated the ICERs were most impacted by high and low QALY gained estimates, diagnosis-related group (DRG) cost variations and inclusion of costs for the intervention from the tariff system for outpatient medical services.

A budget impact analysis using four substitution scenarios (in which subacromial decompression was substituted with no treatment and physiotherapy at different rates) was used to determine the financial implications of delisting the procedure for the payer. If subacromial decompression is delisted and half of all patients substitute to physiotherapy, then a net cost saving of CHF10.0 million would occur in 2020. This saving decreased to CHF9.6 million if 75% of subacromial decompression patients substituted to physiotherapy in this year, and CHF9.1 million when all patients substitute to physiotherapy. The saving from subacromial decompression delisting decreases as more patients are assumed to substitute to alternate treatments.

Social, legal, ethical, organisational issues

Limiting the use of subacromial decompression as a primary intervention to treat subacromial pain could impact workflow and utilisation of services, due to a likely increase in demand for physiotherapy services. Additionally, issues are related to how depression and anxiety could impact patient recovery, as well as how health communication affects a patient's approach to undergoing physiotherapy. The final issue related to the possible limitation of subacromial decompression as a primary intervention, was ensuring that patients from specific population groups (e.g. the elderly) could access physiotherapy.

Conclusion

The evidence base provides limited to no evidence of clinically important benefits in support of the use of subacromial decompression as a primary or isolated intervention to treat subacromial pain compared to conservative treatment, placebo (sham surgery) or no treatment. Delisting the procedure would result in net cost savings – with the impact sensitive to the proportion of patients who would substitute to other treatments (physiotherapy) or resort to no treatment.

EXECUTIVE SUMMARY (D)

Das Ziel dieses Berichts bestand darin, die klinische und ökonomische Effektivität der subakromialen Dekompression als primäre Intervention zur Behandlung subakromialer Schmerzen im Vergleich zu konservativer Behandlung, keiner Behandlung und Placebo zu bewerten und rechtliche, soziale, ethische und organisatorische Probleme im Zusammenhang mit der Einschränkung des Zugangs zu diesem Verfahren zu berücksichtigen.

Klinische Beurteilung

Ein vorliegendes Cochrane-Review von Karjalainen wurde einbezogen und kritisch bewertet. Die im Cochrane-Review durchgeführten Metaanalysen wurden repliziert, und Analysen, die nicht repliziert werden konnten, wurden mit neuen Dateninputs unabhängig erstellt. Die klinische Beurteilung der Wirksamkeitsergebnisse wurde anhand von 8 randomisierten kontrollierten Studien (RCTs) vorgenommen. Die klinische Beurteilung der Sicherheit erfolgte basierend auf 2 RCTs, 7 nicht-randomisierten Studien und 12 einarmigen Studien. Die in diesem Executive Summary genannten Effekte nach 12 Monaten wurden unter Verwendung neuer, aus dem Cochrane-Review replizierter Analysen bezüglich Schmerzen, Funktion und gesundheitsbezogene Lebensqualität (HRQoL) und der Analysen bezüglich der Rückkehr zur Arbeit, der Rückkehr zu Freizeitaktivitäten sowie des weiteren Fortschreitens von subakromialen Schmerzen, über die im Cochrane-Review berichtet wurde, zusammengefasst.

<u>Subakromiale Dekompression versus konservative Behandlung</u>

Sechs RCTs verglichen die subakromiale Dekompression mit einer konservativen Behandlung (n=614). Nach zwölf Monaten lagen keine statistisch signifikanten Unterschiede betreffend Schmerzen (geringe Sicherheit der Evidenz), Funktion (sehr geringe Sicherheit der Evidenz), gesundheitsbezogene Lebensqualität (HRQoL) (geringe Sicherheit der Evidenz), Rückkehr zur Arbeit (sehr geringe Sicherheit der Evidenz), Rückkehr zu Freizeitaktivitäten (sehr geringe Sicherheit der Evidenz) sowie Fortschreiten des subakromialen Schmerzes (sehr geringe Sicherheit der Evidenz) vor. Der wichtigste Grund für die Herabstufung der Evidenz war das Risiko eines Detektions- und Performance-Bias, da die Teilnehmer und Teilnehmerinnen hinsichtlich ihrer Behandlungszuweisung nicht verblindet waren.

<u>Subakromiale Dekompression versus Placebo (Scheinoperation)</u>

Drei RCTs verglichen die subakromiale Dekompression mit einem Placebo (n=406). Nach 12 Monaten wurden keine statistisch signifikanten Unterschiede in Bezug auf Schmerzen (hohe

Sicherheit der Evidenz), Funktion (hohe Sicherheit der Evidenz), HRQoL (hohe Sicherheit der Evidenz), Rückkehr zur Arbeit (mittlere Sicherheit der Evidenz) sowie Rückkehr zu Freizeitaktivitäten (mittlere Sicherheit der Evidenz) festgestellt. Eine Progression der subakromialen Schmerzen wurde nicht berichtet. Die Analysen in diesem Abschnitt wiesen ein geringes Bias-Risiko auf, wobei einige Ergebnisse aufgrund der Ungenauigkeit niedriger bewertet wurden.

Subakromiale Dekompression versus keine Behandlung

Eine RCT verglich die subakromiale Dekompression mit keiner Behandlung (n=210). Nach 12 Monaten wurde ein statistisch signifikanter Unterschied hinsichtlich der Schmerzen (MD=-1,2, 95%-KI -2,04, -0,36, mittlere Sicherheit der Evidenz) sowie ein klinisch bedeutsamer Unterschied bei der Funktion (MD=9,5, 95%-KI: 2,66, 16,34, mittlere Sicherheit der Evidenz) zugunsten der Dekompression, aber kein Unterschied bei der HRQoL (mittlere Sicherheit der Evidenz) und der weiteren Progression der subakromialen Schmerzen (mittlere Sicherheit der Evidenz) festgestellt. Weitere Ergebnisse wurden nicht berichtet. Die Ergebnisse in diesem Abschnitt wurden aufgrund des Risikos des Detektions-Bias herabgestuft, da die Teilnehmer und Teilnehmer hinsichtlich ihrer Behandlungszuweisung nicht verblindet waren.

Sicherheit

Es wurden keine statistisch signifikanten Unterschiede hinsichtlich der Anzahl berichteter unerwünschter Ereignisse für die subakromiale Dekompression und die nicht-chirurgischen Behandlungen (mittlere Sicherheit der Evidenz) festgestellt. Schwerwiegende unerwünschte Ereignisse wurden in den ausgewählten RCTs nicht berichtet (mittlere Sicherheit der Evidenz).

Kosten und Kosteneffektivität

Da im Rahmen der klinischen Beurteilung keine klinisch signifikante Verbesserung der kurzfristigen HRQoL für die subakromiale Dekompression im Vergleich zu Placebo und zu konservativer Behandlung festgestellt werden konnte, wurde ein Kostenvergleich vorgenommen. Die Kosten für die stationäre Durchführung des operativen Eingriffs zur subakromialen Dekompression von 8'633 Franken lagen über den geschätzten Kosten der konservativen Behandlung von 1'350 Franken (15 Physiotherapiesitzungen zu 90 Franken pro Sitzung). Die Kosten für die ambulante Durchführung der subakromialen Dekompression beliefen sich auf 3'972 Franken, davon 1'161 Franken für TARMED 24.0710 Arthroskopie und 24.0750 Dekompression, 750 Franken für die Anästhesie sowie 2'061 Franken für Medikamente, Verbrauchsmaterial sowie Overhead-Kosten. Diese Kosten lagen ebenfalls über den Kosten der konservativen Behandlung. Die subakromiale Dekompression

weist im Vergleich zum vorgesehenen Komparator (konservative Behandlung) keinen klinischen Nutzen, jedoch höhere Kosten auf. Somit bietet sie keinen wirtschaftlichen Vorteil.

Es wurde ein entscheidungsanalytisches Modell entwickelt, um die Kosteneffektivität der subakromialen Dekompression bei stationär behandelter Erkrankung der Rotatorenmanschette im Vergleich zu keiner Behandlung anhand inkrementeller qualitätsadjustierter Lebensjahre (QALY) zu quantifizieren. Ein inkrementelles Kosten-Effektivitäts-Verhältnis (ICER) von 98’102 Franken pro gewonnenem QALY wurde nach 12 Monaten unter Verwendung der Ergebnisse der CSAW-Studie (Can Shoulder Arthroscopy Work) für den chirurgischen Eingriff im Vergleich zu keiner Behandlung geschätzt, sofern keine Anpassung an ungleichgewichtete Baseline-Nutzwerte vorgenommen wurde. Nach Anpassung an diese Werte wurde die ICER auf 107’913 Franken pro gewonnenem QALY geschätzt. Probabilistische Sensitivitätsanalysen (PSA) ermittelten unter der Annahme eines hypothetischen WTP-Grenzwerts (Zahlungsbereitschaft) von 100'000 Franken pro gewonnenem QALY eine Wahrscheinlichkeit von 49 Prozent für die Kosteneffektivität der subakromialen Dekompression im Vergleich zu keiner Behandlung. Univariate Sensitivitätsanalysen haben aufgezeigt, dass die ICERs durch hohe und niedrige QALY-abgeleitete Schätzungen, diagnosebezogene Fallgruppen (DRG) und die Einbeziehung der Kosten für die Intervention aus dem Tarifsystem für ambulante medizinische Leistungen am stärksten beeinflusst wurden.

Eine auf der Verwendung von vier Substitutionsszenarien (in denen die subakromiale Dekompression durch keine Behandlung und Physiotherapie zu unterschiedlichen Sätzen ersetzt wurde) basierende Ausgaben-Einfluss-Analyse wurde verwendet, um die finanziellen Auswirkungen der Streichung des Verfahrens für den Kostenträger zu bestimmen. Die Streichung der subakromialen Dekompression aus der Liste und der Ersatz durch Physiotherapie für die Hälfte aller Patienten hätten im Jahr 2020 zu einer Nettokosteneinsparung von 10,0 Millionen Franken geführt. Diese Einsparung hätte sich auf 9,6 Millionen Franken verringert, wenn 75 Prozent der Patienten statt subakromialer Dekompression in diesem Jahr eine Physiotherapie erhalten hätten, und auf 9,1 Millionen Franken, wenn alle Patienten mittels Physiotherapie behandelt worden wären. Die Einsparung durch die Streichung der subakromialen Dekompression verringert sich zunehmend, wenn mehr Patienten auf alternative Behandlungen umgestellt werden.

Soziale, rechtliche, ethische und organisatorische Probleme

Die Einschränkung des Einsatzes der subakromialen Dekompression als primäre Intervention zur Behandlung von subakromialen Schmerzen könnte sich auf den Arbeitsablauf und die Inanspruchnahme von Leistungen auswirken, da es vermutlich zu einer Steigerung der Nachfrage

nach physiotherapeutischen Leistungen kommen würde. Fraglich ist zudem, wie sich Depressionen und Angstzustände auf die Genesung des Patienten auswirken können und wie die Gesundheitskommunikation die Einstellung des Patienten zur Physiotherapie beeinflusst. Die letzte Problematik, die mit der möglichen Einschränkung der subakromialen Dekompression als primäre Intervention im Zusammenhang steht, war die Sicherstellung des Zugangs zur Physiotherapie für Patienten aus bestimmten Bevölkerungsgruppen (beispielsweise ältere Personen).

Fazit

Die Evidenzbasis liefert begrenzte bis keine Hinweise auf klinisch bedeutsame Vorteile für die Anwendung der subakromialen Dekompression als primäre oder isolierte Intervention zur Behandlung subakromialer Schmerzen im Vergleich zu einer konservativen Behandlung, Placebo (Scheinoperation) oder keiner Behandlung. Die Streichung des Verfahrens würde zu einer Netto-Kosteneinsparung führen, wobei diese empfindlich gegenüber dem Anteil der Patienten ist, die auf andere Behandlungen (Physiotherapie) ausweichen oder auf eine Behandlung verzichten würden.

EXECUTIVE SUMMARY (F)

L'objectif de ce rapport était d'évaluer l'efficacité clinique et économique de la décompression sous-acromiale en tant qu'intervention primaire pour traiter la douleur sous-acromiale par rapport au traitement conservateur, à l'absence de traitement et au placebo, et d'examiner les questions juridiques, sociales, éthiques et organisationnelles associées à la limitation de l'accès à la procédure.

Évaluation clinique

Une revue Cochrane de Karjalainen a été incluse et critiquée. Les méta-analyses effectuées dans la revue Cochrane ont été reproduites, et les analyses qui n'ont pas pu être répliquées ont été réalisées indépendamment en utilisant de nouvelles données. L'évaluation clinique des résultats d'efficacité s'est fondée sur 8 essais contrôlés randomisés (ECR) ; l'évaluation clinique des résultats de la sécurité s'est fondée sur 2 ECR, 7 essais non randomisés et 12 essais à un seul bras. Les effets reportés dans ce résumé sont résumés à 12 mois en utilisant de nouvelles analyses reproduites de la revue Cochrane pour la douleur, la fonction et la qualité de vie liée à la santé (QVLS), et reportés dans la revue Cochrane pour le retour au travail, aux activités de loisir et la poursuite de la progression de la douleur sous-acromiale.

Décompression sous-acromiale versus traitement conservateur

Six ECR ont comparé la décompression sous-acromiale au traitement conservateur (n=614). À 12 mois, aucune différence statistiquement significative n'a été signalée en ce qui concerne la douleur (preuve de faible certitude), la fonction (preuve de très faible certitude), la qualité de vie liée à la santé (QVLS) (preuve de faible certitude), le retour au travail (preuve de très faible certitude), le retour aux activités de loisirs (preuve de très faible certitude), la progression de la douleur sous-acromiale (preuve de très faible certitude). La principale raison pour laquelle la preuve a été déclassée est le risque de biais de détection et de performance, car les participants n'ont pas été informés en aveugle de l'attribution des traitements.

Décompression sous-acromiale versus placebo (chirurgie fictive)

Trois ECR ont comparé la décompression sous-acromiale au placebo (n=406). À 12 mois, aucune différence statistiquement significative n'a été signalée pour la douleur (preuve de certitude élevée), la fonction (preuve de certitude élevée), la QVLS (preuve de certitude élevée), le retour au travail (preuve de certitude modérée), le retour aux activités de loisirs (preuve de certitude modérée). Il n'a pas été reporté de progression de la douleur sous-acromiale. Les analyses de cette section

présentaient un faible risque de biais, certains résultats ayant été déclassés en raison de leur imprécision.

Décompression sous-acromiale versus absence de traitement

Une ECR a comparé la décompression sous-acromiale à l'absence de traitement (n=210). À 12 mois, on a constaté une différence statistiquement significative au niveau de la douleur (MD = -1,2, CI à 95 % : -2,04, -0,36, preuve de certitude modérée) et une différence cliniquement importante au niveau de la fonction (MD = 9,5, CI à 95 % : 2,66, 16,34, preuve de certitude modérée) en faveur de la décompression, mais aucune différence en ce qui concerne la QVLS (preuve de certitude modérée) et la progression de la douleur sous-acromiale (preuve de certitude modérée). Les autres résultats n'ont pas été reportés. Les résultats de cette section ont été déclassés en raison du biais du risque de détection, les participants n'ayant pas été informés en aveugle de l'attribution des traitements.

Sécurité

Aucune différence statistiquement significative n'a été constatée dans le nombre d'événements indésirables enregistrés pour la décompression sous-acromiale et les traitements non opératoires (preuve de certitude modérée). Aucun événement indésirable grave n'a été signalé dans les ECR sélectionnés (preuve de certitude modérée).

Coûts et rapport coût-efficacité

L'évaluation clinique n'ayant révélé aucune amélioration cliniquement significative de la QVLS à court terme pour la décompression sous-acromiale par rapport au placebo et au traitement conservateur, une comparaison des coûts a été effectuée. Le coût stationnaire de la chirurgie de décompression sous-acromiale, s'élevant à 8633 francs, était plus élevé que le coût estimé du traitement conservateur de 1350 francs (15 séances de physiothérapie à 90 francs par séance). La prestation ambulatoire de décompression sous-acromiale a coûté 3972 francs, dont 1161 francs pour l'arthroscopie TARMED 24.0710 et la décompression 24.0750, 750 francs d'anesthésie et 2061 francs de médicaments, de consommables et de frais généraux. Ce coût était également plus élevé que le coût d'une gestion conservatrice. La décompression sous-acromiale ne présente aucun avantage clinique, mais son coût est plus élevé que celui du comparateur désigné (traitement conservateur), ce qui ne présente donc aucun avantage économique.

Un modèle d'analyse décisionnelle a été mis au point pour quantifier le rapport coût-efficacité de la décompression sous-acromiale dans le traitement de la maladie de la coiffe des rotateurs par

rapport à l'absence de traitement en utilisant les années de vie supplémentaires ajustées sur la qualité (QALY). Un rapport coût-efficacité différentiel (RCED) de 98 102 francs par QALY gagnée a été estimé à 12 mois pour la chirurgie par rapport à l'absence de traitement en utilisant les résultats de l'essai Can Shoulder Arthroscopy Work (CSAW), sans ajustement des utilités de base inégales. En ajustant ces valeurs, le RCED a été estimé à 107 913 francs par QALY gagnée. Les analyses de sensibilité probabilistes (ASP) ont déterminé avec une probabilité de 49 % que la décompression sous-acromiale était plus rentable que l'absence de traitement en utilisant un seuil hypothétique de volonté de payer de 100 000 francs par QALY gagnée. Les analyses de sensibilité univariées ont indiqué que les RCED étaient les plus affectés par les estimations élevées et faibles des QALY gagnées, les variations des coûts des groupes liés au diagnostic (DRG) et l'inclusion des coûts de l'intervention dans le système de tarification des services médicaux ambulatoires.

Une analyse d'impact budgétaire utilisant quatre scénarios de substitution (dans lesquels la décompression sous-acromiale a été remplacée par l'absence de traitement et la physiothérapie à des taux différents) a été utilisée pour déterminer les implications financières du retrait de la procédure pour le payeur. Si la décompression sous-acromiale est supprimée et que la moitié des patients se substituent à la physiothérapie, une économie nette de 10 millions de francs serait réalisée en 2020. Cette économie descend à 9,6 millions de francs si 75 % des patients ayant subi une décompression sous-acromiale passent à la physiothérapie cette année-là, et à 9,1 millions de francs si tous les patients passent à la physiothérapie. Les économies réalisées grâce au déremboursement de la décompression sous-acromiale diminuent à mesure que l'on suppose que davantage de patients se substituent à d'autres traitements.

Questions sociales, juridiques, éthiques et organisationnelles

Limiter l'utilisation de la décompression sous-acromiale comme intervention primaire pour traiter les douleurs sous-acromiales pourrait avoir un impact sur le flux de travail et l'utilisation des services, en raison d'une augmentation probable de la demande de services de physiothérapie. En outre, des questions sont liées à la façon dont la dépression et l'anxiété pourraient avoir un impact sur le rétablissement du patient, ainsi qu'à la façon dont la communication en matière de santé affecte l'approche du patient à l'égard de la physiothérapie. La dernière question liée à la limitation possible de la décompression sous-acromiale en tant qu'intervention primaire était de s'assurer que les patients de groupes de population spécifiques (par exemple les personnes âgées) puissent accéder à la physiothérapie.

Conclusion

Les preuves des données probantes concernant des avantages cliniquement importants à l'appui de l'utilisation de la décompression sous-acromiale comme intervention primaire ou isolée pour traiter la douleur sous-acromiale par rapport au traitement conservateur, au placebo (chirurgie fictive) ou à l'absence de traitement sont limitées ou inexistantes. Le retrait de la procédure entraînerait des économies nettes - l'impact étant lié à la proportion de patients qui se tourneraient vers d'autres traitements (physiothérapie) ou ne suivraient aucun traitement.

EXECUTIVE SUMMARY (I)

L'obiettivo di questo rapporto era valutare l'efficacia clinica ed economica della decompressione subacromiale quale intervento primario per il trattamento del dolore subacromiale rispetto alla gestione conservativa, a nessun trattamento e al placebo, e di indagare le questioni legali, sociali, etiche e organizzative legate alle restrizioni di accesso alla procedura.

Valutazione clinica

Nel rapporto è stata inclusa una revisione Cochrane esistente, prodotta da Karjalainen, e sottoposta a un giudizio critico. Le meta-analisi condotte nella revisione Cochrane sono state replicate, mentre le analisi che non hanno potuto essere replicate sono state prodotte in modo autonomo a partire da nuovi dati. La valutazione clinica dei risultati sull'efficacia è stata informata da 8 studi controllati randomizzati (RCT); la valutazione clinica dei risultati sulla sicurezza è stata informata da 2 RCT, 7 studi non randomizzati e 12 studi a braccio singolo. Gli effetti riportati in questa sintesi sono riassunti a 12 mesi utilizzando nuove analisi replicate dalla revisione Cochrane per il dolore, la funzione e la qualità della vita relativa alla salute (HRQoL), e riportati nella revisione Cochrane per il ritorno al lavoro, il ritorno alle attività ricreative e l'ulteriore progressione del dolore subacromiale.

<u>Decompressione subacromiale rispetto al trattamento conservativo</u>

Sei RCT hanno confrontato la decompressione subacromiale con il trattamento conservativo (n=614). A 12 mesi non sono state registrate differenze statisticamente significative per il dolore (evidenza di bassa certezza), la funzione (evidenza di certezza molto bassa), la qualità della vita relativa alla salute (HRQoL, evidenza di bassa certezza), il ritorno al lavoro (evidenza di certezza molto bassa), il ritorno alle attività ricreative (evidenza di certezza molto bassa) e la progressione del dolore subacromiale (evidenza di certezza molto bassa). La ragione principale per cui l'evidenza è risultata bassa è legata al rischio di bias di rilevamento e di performance, in quanto i partecipanti non erano in cieco rispetto all'assegnazione del trattamento.

<u>Decompressione subacromiale rispetto al placebo (sham surgery)</u>

Tre RCT hanno confrontato la decompressione subacromiale con il placebo (n=406). A 12 mesi non sono state registrate differenze statisticamente significative per il dolore (evidenza di alta certezza), la funzione (evidenza di alta certezza), la qualità della vita relativa alla salute (HRQoL, evidenza di alta certezza), il ritorno al lavoro (evidenza di certezza moderata), il ritorno alle attività ricreative (evidenza di certezza moderata). Non sono stati riportati casi di progressione del dolore

subacromiale. Le analisi di questa sezione presentavano un basso rischio di bias; alcuni risultati hanno ottenuto un punteggio inferiore a causa di imprecisioni.

Decompressione subacromiale rispetto a nessun trattamento

Un RCT ha confrontato la decompressione subacromiale con nessun trattamento (n=210). A 12 mesi si è registrata una differenza statisticamente significativa nel dolore (MD=-1,2, 95% CI -2,04, -0,36, evidenza di certezza moderata) e una differenza clinicamente rilevante nella funzione (MD=9,5, 95% CI: 2,66, 16,34, evidenza di certezza moderata) in favore della decompressione, mentre non si è registrata nessuna differenza nella HRQoL (evidenza di certezza moderata) e nella progressione del dolore subacromiale (evidenza di certezza moderata). Non sono stati riportati altri risultati. Gli esiti di questa sezione hanno ottenuto un punteggio inferiore a causa del rischio di bias di rilevamento, in quanto i partecipanti non erano in cieco rispetto all'assegnazione del trattamento.

Sicurezza

Non sono state registrate differenze statisticamente significative nel numero di eventi avversi per la decompressione subacromiale e i trattamenti non operatori (evidenza di certezza moderata). Gli eventi avversi gravi non sono stati riportati negli RCT selezionati (evidenza di certezza moderata).

Costi e rapporto costo-efficacia

Poiché la valutazione clinica non ha riscontrato alcun miglioramento clinicamente significativo della qualità della vita relativa alla salute (HRQoL) a breve termine nella decompressione subacromiale rispetto al placebo e alla gestione conservativa, è stato condotto un confronto a livello di costi. I costi ospedalieri per un intervento di decompressione subacromiale, pari a 8633 franchi, si rivelano superiori ai costi stimati per una gestione conservativa, pari a 1350 franchi (15 sessioni di fisioterapia da 90 franchi ciascuna). La procedura di decompressione subacromiale in regime ambulatoriale ha avuto un costo di 3972 franchi, comprendente 1161 franchi per artroscopia TARMED 24.0710 e decompressione 24.0750; 750 franchi per l'anestesia; 2061 franchi per farmaci, materiale di consumo e spese generali. Anche questi costi superano quelli di una gestione conservativa. La decompressione subacromiale non ha alcun beneficio clinico, ma comporta costi più elevati rispetto al suo comparatore (gestione conservativa). Di conseguenza, non presenta alcun vantaggio in termini economici.

È stato sviluppato un modello analitico decisionale per quantificare il rapporto costo-efficacia della decompressione subacromiale per la malattia della cuffia dei rotatori in regime di ricovero rispetto a nessun trattamento utilizzando anni di vita incrementali ponderati per la qualità della vita (QALY).

Per il trattamento chirurgico, a 12 mesi è stato stimato un rapporto incrementale costo-efficacia (ICER) pari a 98 102 franchi per ogni QALY guadagnato rispetto a nessun trattamento, con l'utilizzo dei risultati dello studio Can Shoulder Arthroscopy Work (CSAW) quando non sono stati fatti adattamenti per uniformare servizi di base ineguali . Con l'adattamento a questi valori, l'ICER è stato stimato a 107 913 franchi per ogni QALY guadagnato. Le analisi di sensibilità probabilistiche (PSA) hanno determinato il 49 per cento di probabilità che la decompressione subacromiale sia più conveniente in termini di costo-efficacia, rispetto a nessun trattamento, utilizzando un'ipotetica soglia di disponibilità al pagamento pari a 100 000 franchi per QALY guadagnato. Le analisi di sensibilità univariate hanno indicato che gli ICER sono stati maggiormente influenzati da stime di guadagno QALY alte e basse, dalle variazioni dei costi dei gruppi di diagnosi (DRG) e dall'inclusione dei costi dell'intervento dal sistema tariffario per i servizi medici ambulatoriali.

Un'analisi dell'impatto sul bilancio, effettuata utilizzando quattro scenari di sostituzione (in cui la decompressione subacromiale è stata sostituita da nessun trattamento e dalla fisioterapia a tassi diversi), è stata utilizzata per determinare le implicazioni finanziarie della cancellazione della procedura per il pagatore. Se la decompressione subacromiale fosse stata cancellata e la metà dei pazienti la avesse sostituita con la fisioterapia, nel 2020 si sarebbe ottenuto un risparmio netto di 10 milioni di franchi. Questo risparmio passerebbe a 9,6 milioni di franchi se il 75 per cento dei pazienti con decompressione subacromiale passasse alla fisioterapia quest'anno, e a 9,1 milioni di franchi se tutti i pazienti passassero alla fisioterapia. Il risparmio derivante dalla cancellazione della decompressione subacromiale diminuisce man mano che si suppone che più pazienti passeranno a trattamenti alternativi.

Questioni sociali, legali, etiche e organizzative

Limitare il ricorso alla decompressione subacromiale quale intervento primario per il trattamento del dolore subacromiale potrebbe incidere sul flusso di lavoro e sull'utilizzo dei servizi, a causa di un prevedibile aumento della domanda dei servizi di fisioterapia. Altre questioni sono inoltre legate a come la depressione e l'ansia possono influire sul recupero del paziente, nonché a come la comunicazione sanitaria influisce sulla propensione del paziente a sottoporsi a fisioterapia. Un'ultima questione relativa alla possibile limitazione della decompressione subacromiale quale intervento primario riguarda la garanzia che i pazienti appartenenti a gruppi specifici della popolazione (ad es. gli anziani) possano accedere alla fisioterapia.

Conclusione

La base di evidenze fornisce evidenze scientifiche minime o nulle riguardo ai benefici clinicamente rilevanti a sostegno del ricorso alla decompressione subacromiale quale intervento primario o isolato per il trattamento del dolore subacromiale, rispetto al trattamento conservativo, al placebo (sham surgery) o a nessun trattamento. La cancellazione della procedura comporterebbe un risparmio netto sui costi, con un impatto sensibile sulla proporzione di pazienti disposti a sottoporsi ad altri trattamenti (fisioterapia) o a non ricorrere ad alcun trattamento.

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Tables

Figures

Abbreviations and acronyms

15D	15 dimensions
AE	Adverse events
AMSTAR 2	Assessing the Methodological Quality of Systematic Reviews 2
ASD	Arthroscopic subacromial decompression
CAL	Coracoacromial ligament
CHF	Swiss franc
CINAHL	Cumulative Index of Nursing and Allied Health Literature
CSAW	Can Shoulder Arthroscopy Work
CT	Computed tomography
DASH	Disability of the Arm Shoulder and Hand questionnaire
DRG	Diagnosis-related group
EAE	Effectiveness, appropriateness, economic efficiency
EQ VAS	EuroQol visual analogue scale
EQ-5D	EuroQol 5 dimensions questionnaire
EQ-5D-3L	EuroQol 5 dimensions 3-level questionnaire
EUnetHTA	European Network for Health Technology Assessment
FOPH	Federal Office of Public Health
FTT	Full-thickness tear
GRADE	Grading of Recommendations, Assessment, Development and Evaluation
HADS	Hospital Anxiety and Depression Scale
HRQoL	Health-related quality of life
HTA	Health technology assessment
ICER	Incremental cost-effectiveness ratio
IHE	Institute of Health Economics
MCID	Minimum clinically important difference
MCII	Minimal clinically important improvement
MIC	Minimum important change
MID	Minimal important difference
MRI	Magnetic resonance imaging
N/A	Not applicable
NHS	National Health Service
NOT	Non-operative treatment
NR	Not reported

NRS	Numeric rating scale
NSAID	Non-steroidal anti-inflammatory drug
OSD	Open subacromial decompression
OSS	Oxford Shoulder Score
PICO	Population, intervention, comparator, outcome
PSA	Probabilistic sensitivity analyses
PTT	Partial-thickness tear
QALY	Quality-adjusted life years
QoL	Quality of life
RCT	Randomised controlled trial
ROBINS-1	Risk-of-bias tool for non-randomised studies version 1
SD	Standard deviation
SF-36	Short form-36
SIS	Subacromial impingement syndrome
SLAP	Superior labral tear from anterior to posterior
SPADI	Shoulder Pain and Disability Index
SSRS	Subjective Shoulder Rating Scale
UK	United Kingdom
USA	United States of America
VAS	Visual analogue scale
WHO	World Health Organization

Objective of the HTA report

The objective of a health technology assessment (HTA) is to generate a focused assessment of various aspects of a health technology. The analytic methods applied to assess the value of using a health technology are described. The analytical process is comparative, systematic, transparent and involves multiple stakeholders. The domains covered in an HTA report include clinical efficacy and safety, costs, cost-effectiveness and budget impact, and legal, social, ethical and organisational issues. The purpose is to inform health policy and decision-making to promote an efficient, sustainable, equitable and high-quality health system.

1 Policy question and context

Rotator cuff disease is a term used to encapsulate a range of syndromes including rotator cuff tendinopathy/tendinitis, partial-thickness tears (PTT), full-thickness tears (FTT), calcific tendinitis, subacromial impingement syndrome (SIS) and subacromial bursitis.[1] These syndromes lead to subacromial pain, which can be treated by a surgical procedure named subacromial decompression. In recent years, an increase of this procedure has been observed.[1] Historically, clinical studies on the efficacy of this intervention have not been of very high quality, and the suggested benefits of the procedure have thus been questioned. Recently, studies with more robust designs have been published. This HTA report aims to incorporate recent findings into the existing body of evidence and determine whether the efficacy, appropriateness, economic efficiency (EAE) criteria required for coverage via mandatory health insurance in Switzerland are met (see Article 32 of the Federal Law on Health Insurance: Bundesgesetz über die Krankenversicherung, KVG; SR 832.10). If the EAE criteria are shown to be unmet, it is possible to impose limitations on these surgical treatments or remove them from coverage in Switzerland.

2 Research question

This HTA report aims to address the following research questions:

1. What are the benefits and harms of subacromial decompression surgery as primary intervention compared to non-surgical interventions in patients with subacromial pain?
2. How cost-effective is subacromial decompression compared to alternative therapies performed in Switzerland?
3. What is the yearly budget impact of subacromial decompression surgery in Switzerland?
4. Are there any social, legal, ethical and organisational issues associated with subacromial decompression for the treatment of subacromial pain?

Research questions are operationalised in more detail in ***Section 6***.

3 Medical background

3.1 Medical context, disease description, and natural course

3.1.1 Medical context

The rotator cuff is a group of tendons and muscles that forms part of the glenohumeral joint in the shoulder. The muscles connect the upper portions of the arm (i.e. the head of the humerus) to the shallow socket of the shoulder joint (i.e. the glenoid cavity) (***Figure 1***). The rotator cuff dynamically stabilises the joint, permitting dynamic movement.[1-4]

Rotator cuff disease is a common condition that affects the shoulder joint. The disease is common in people who are over 60 years of age and/or frequently repeat specific motions with their shoulder(s). The repetitive motions responsible for rotator cuff disease can occur during occupational or leisure activities.[2 4-8]

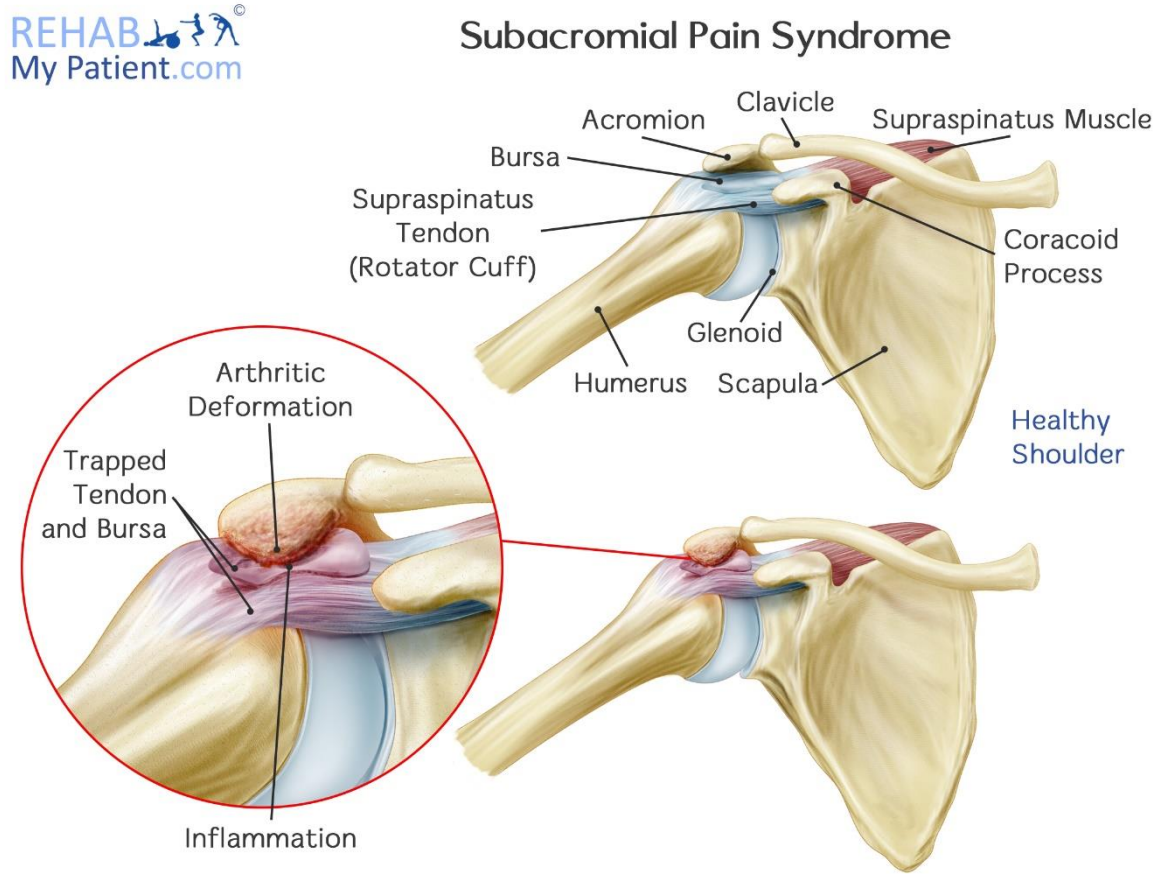

Figure 1 Anatomic representation of shoulder impingement

Source:
REHAB MY Patient.[9] Printed with permission.

Rotator cuff disease is a term used to encapsulate all symptomatic disorders of the rotator cuff that can result in pain, weakness and instability in the shoulder joint.[1 2] This includes all symptomatic disorders of the rotator cuff, which can be caused by inflammation, acute injury (trauma) or degeneration. Conditions classified as rotator disease include tendinopathy/tendinitis, PTT, FTT, rotator cuff tear arthropathy, calcific tendinitis, bursitis and SIS.[1-5 7 8 10-14] This report focuses specifically on subacromial pain syndrome, otherwise known as SIS.

The main risk factors for subacromial pain include age (≥60 years), family history, occupation (e.g. painters, construction workers, carpenters), and certain sports (e.g. sports with repetitive shoulder strain such as swimming, tennis, baseball).[2-6 13]

3.1.2 Signs and symptoms

Common signs and symptoms of rotator cuff disease include shoulder pain, difficulty doing overhead activities due to pain (i.e. shoulder abduction between 60°–120°), shoulder weakness, pain in the deltoid and/or forearm, loss in shoulder active range of motion and sleep disturbance (due to shoulder pain).[1-3 5 6 8] Other subacromial pain symptoms include, but are not limited to weakness and pain during any of the following tests: Gerber's test (for tendonitis or tear in the subscapularis tendon), the belly-press test (for tear in the subscapularis tendon), and Neer impingement test and/or Hawkins impingement test (to determine if shoulder pain is caused by shoulder impingement).

3.1.3 Diagnosis

Under specific circumstances, a clinician diagnosing subacromial pain may order medical imaging on the affected shoulder in order to identify any signs of pathology.[15] The imaging may include X-ray, ultrasound, computed tomography (CT) scan or magnetic resonance imaging (MRI). X-ray imaging is ordered to visualise bone spurs (i.e. osteophytes) or arthritis, while ultrasound imaging is used to visualise the soft tissue structures (e.g. muscle, tendons, bursa) in the affected shoulder or to assess the width of the subacromial space. MRI and CT enable all structures of the shoulder to be visualised.[4 15]

3.1.4 Natural course of the disease

Subacromial pain is thought to be the result of interactions between intrinsic (i.e. biological) and extrinsic (i.e. mechanistic) influences that can cause narrowing of the subacromial space.[1 16 17] Shoulder impingement occurs when an inflamed bursa and/or tendon, due for example to repetitive overhead activity, compress the tendons and muscles in the joint between the acromion, the humerus and the glenoid, resulting in pain and movement limitation (***Figure 1***). The intrinsic factors of SIS can result in

attritional tears and concurrent joint degeneration when there is a thickening of the subacromial bursa and oedema.[8] This can advance into inflammatory changes and the development of fibrosis.[1-4 6] Furthermore, histological studies have associated extracellular and cellular changes with damage affecting the structure and integrity of rotator cuff tendons.[1 10]

The extrinsic theory of subacromial pain relates to contact between the section of the shoulder blade (i.e. scapula) that extends over the edge of the shoulder joint (i.e. acromion) and the surrounding rotator cuff tendons.[18] It is suggested that impingement can also be caused by bone spurs (i.e. osteophytes) on the under-surface of the acromion and/or the distal part of the clavicle being in contact with the overlapping rotator cuff tendons.[17-21] When narrowing of the subacromial space results in discomfort and pain during shoulder abduction between 60º–120º it is referred to as the painful arc.[19 19 20] The coracoacromial ligament (CAL), which connects two protruding sections of bone (acromion and coracoid) in the scapula to one another, is thought to be a contributor to the pain felt by people suffering from subacromial pain. This is because CAL stiffening increases the contact pressure of the ligament with the nearby rotator cuff tendons. Various rotator cuff tendon pathologies, such as tears, can contribute to CAL stiffening. This contact pressure can cause the degeneration of both the rotator cuff and the CAL.[22-24]

Subacromial pain can cause significant disability due to chronic pain, extensive weakness and loss of motion in the shoulder.[1 3 4 6 14] The weakness and loss of motion is generally the result of stiffness of the joint due to pain and/or tears. Shoulder stiffness occurring over prolonged periods of time can result in severe contraction of the surrounding tissue.[3 4 6] Joint stiffness can still occur post-surgery, if patients fail to move their shoulders.[3 4 6 14]

3.1.5 Prevalence of the condition

There is limited published information on the prevalence and burden of disease related to subacromial pain in Switzerland; however, there are statistics on shoulder, neck, and arm pain, which currently represent the third most common cause of physical discomfort in the Swiss population, affecting around 32% (2018) of men and 44.8% (2018) of women.[25-27]

Medstat data[A] on shoulder diagnosis and intervention provided by the Federal Office of Public Health (FOPH) indicated that approximately 1,873[B] patients were diagnosed with subacromial pain as the primary diagnosis in 2018 in Switzerland.[28] This corresponds to the following diagnoses: impingement syndrome of the shoulder, bursitis in the shoulder area, joint pain in the shoulder region, osteophyte in the shoulder region, other bursal cyst in the shoulder region and pain in the shoulder region.

3.2 Treatment pathway

Most accepted guidelines on rotator cuff disease (including SIS) focus on the treatment of rotator cuff tears (i.e. PTT or FTT), and do not provide a treatment pathway specific to the management of SIS. Two different guidelines provide treatment pathways for SIS including surgical and non-surgical interventions.[29 30] The guidelines of the Cheshire and Wirral partnership – National Health Service (NHS) Foundation Trust (2016) in the United Kingdom (UK) suggest a non-surgical intervention as an alternative to surgical interventions.[29] In contrast, Diercks et al. from the Dutch Orthopaedic Society (2014) recommend that a surgical intervention follows non-surgical interventions as the final step in the treatment pathway for SIS.[30]

Figure 2 shows a treatment pathway for SIS based on these two guidelines. A treatment pathway for SIS is dependent on a variety of factors (e.g. age, occupation, level of activity, comorbidities). In general, the first step in the treatment pathway is the prescription of non-steroidal anti-inflammatory drugs (NSAIDs) for a period of up to two to four weeks.[16 17 23 29-32] If the pain does not subside, the patient will then undergo physiotherapy. If there is no improvement and symptoms persist (i.e. longer than 3 months) the patient can receive a subacromial corticosteroid injection.[30 32] If the symptoms do not subside after this injection, the patient may receive a surgical intervention and undergo subacromial decompression.[1 16 17 23 29-34] Clinical experts have suggested that some orthopaedic surgeons may choose to repeat corticosteroid injections if the first attempt was unsuccessful, instead of proceeding to surgery systematically. To be eligible for subacromial decompression surgery a patient generally has

[A] In Switzerland hospital inpatient diagnoses and treatments are routinely registered within the Medstat Database following the *International Statistical Classification of Disease (ICD-10)* and *Swiss Classification of Surgical Interventions (CHOP)* codes.

[B] From a dataset of approximately 15,000 patients that had specific shoulder complaints, or underwent a limited number of procedures; not every patient was classified under an ICD-10 or CHOP code.

to have suspected SIS (i.e. positive Neer and/or Hawkins impingement test), have experienced a minimum of three months of subacromial pain, and experienced no relief from conservative therapy.[1 16 17 29 30 32] The surgery is usually followed up with postoperative physiotherapy and exercises before the patient is discharged from the treatment pathway.[1 16 17 23 29-34]

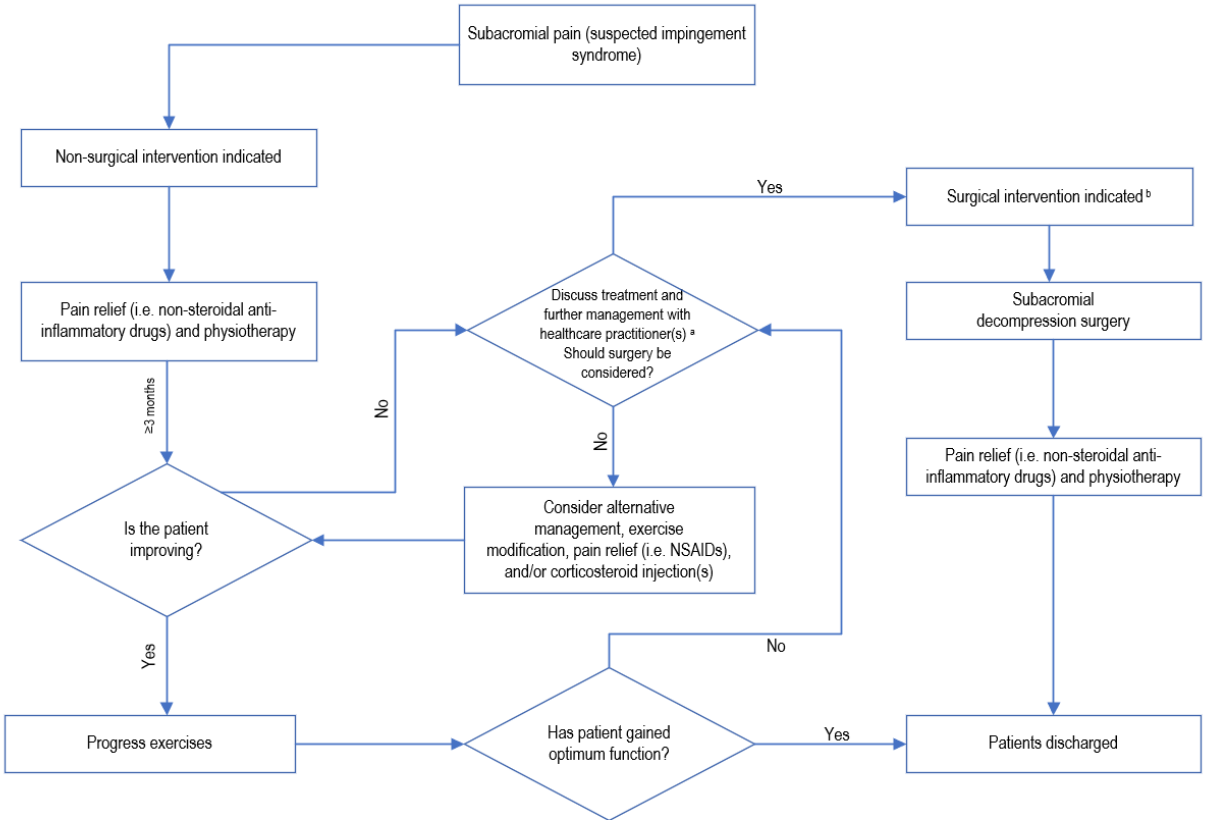

Figure 2 Treatment pathway for shoulder impingement syndrome

Notes:

[a] If a patient does not improve while undergoing non-surgical treatment then a review of treatment with a physiotherapist and/or clinician is considered.

[b] Surgical intervention is only considered after 3 months of conservative treatment without symptom relief.

Source:

Based on treatment pathways outlined by Cheshire and Wirral Partnership – NHS Foundation Trust and Diercks 2014.[29 30]

4 Technology

4.1 Technology description

4.1.1 Overview of subacromial decompression

Subacromial decompression was first described by Neer in 1972.[35] The term is used to describe a variety of surgical procedures conducted on the shoulder joint that aim to widen the subacromial space.[23 36 37] A subacromial decompression can include acromioplasty and/or bursectomy and/or CAL resection. Additionally, under specific circumstances, the procedure can also include coplaning. These surgeries can be done as standalone procedures or in combination with one another. For example, if a patient undergoes an acromioplasty and bursectomy with a CAL arthroscopy and coplaning, it is considered a subacromial decompression.[1 17 22 23 36 37] If a patient just has an arthroscopic acromioplasty, it is still defined as a subacromial decompression. The individual procedures are described as follows:

- **Acromioplasty** is the resection of the undersurface of the section of the scapula that extends over the edge of the shoulder joint (anterior acromion). By resecting a part of the bone with a motorised burr remover or oscillating saw, the surgery increases the space within the joint, accommodating the inflamed bursa and tendons. This procedure can be done either as an open surgery or arthroscopically.[22 35 38]
- **Bursectomy** is the resection or debridement (i.e. removal of injured or damaged tissue) of the subacromial bursa, generally using electrocautery. This procedure aims to reduce the size of the bursa to make space for the joint tendons and muscles. The debridement can be done in an open or arthroscopic intervention.[19 22 23 39-41]
- **CAL release** involves the release (cutting) or resection of the ligament. The resection is conducted using a shaver inserted in the subacromial space and can be done arthroscopically or as an open or mini-open surgery.[19 22 23 35 37 42]
- **Coplaning** involves the resection and/or smoothing of bone spurs (osteophytes) that occur on the underside of the acromion and/or the distal section of the clavicle. This procedure can be conducted arthroscopically or through a mini-open approach.[22 23 43 44] This can, but is not often, done as part of a subacromial decompression procedure.

This assessment only focuses on populations who undergo a standalone subacromial decompression procedure. For this assessment any populations that underwent a subacromial decompression alongside acromioclavicular (AC) joint resection and/or FTT repairs were excluded.

All of these procedures are conducted by an orthopedic surgeon under general anesthesia.[45-47] Subacromial decompression can be conducted as an ambulant procedure or in a hospital setting with subsequent hospitalisation. Whether a patient requires hospitalisation largely depends on the way the surgery is executed (i.e. arthroscopic vs open decompression), the condition of the patient and personal preference.

Like any other surgery, subacromial decompression is contraindicated in cases of allergy to anesthetics. Arthroscopic decompression is also contraindicated in young patients with rotator cuff tear associated with instability and secondary impingement, in patients with isolated acromioclavicular pathologies, or if the anterior part of the acromion of the deltoid muscle needs to be preserved.[48]

The 2018 Medstat data for inpatient hospital separations related to DRG I29C (Complex procedures on scapula, clavicula, ribs or shoulder) suggested that 75% (n=1,045/1,385) of patients with subacromial pain as the primary diagnosis underwent a subacromial decompression as the primary intervention.[28] In total, 1,215 patients in Switzerland (2018) with either impingement syndrome of the shoulder, bursitis in the shoulder area, joint pain in the shoulder region, osteophyte in the shoulder region, bursal cysts or shoulder pain, were treated with subacromial decompression as the primary form of intervention.[28] In 2017, 84% (n=504/599) of all shoulder arthroscopies conducted in outpatient facilities and invoiced to mandatory insurers were decompressions. The nature of the outpatient database does not allow identification of the proportion of decompressions conducted for the treatment of SIS, as primary or isolated treatment.[49] Detailed tables describing the Medstat data for procedures and diagnoses coded under DRG I29C are outlined in ***Table 1***.

Table 1 Primary diagnosis and intervention codes related to subacromial decompression coded under Swiss DRG I29C in 2018

Diagnostic codes (primary)	**Total (n)**
cHD_M754 Impingement syndrome of the shoulder	1635
cHD_M755 Bursitis in the shoulder area	89
cHD_M2551 Joint pain: shoulder region	121
cHD_72571 Osteophyte: shoulder region	6
cHD_M7131 Other bursal cyst: shoulder region	4
cHD_M7961 Pain in the extremities: shoulder region	18
Intervention codes (primary)	**Total (n)**
cHB_818333 Expansion of the subacromial space, arthroscopically	1560
cHB_835X11 Bursectomy, shoulder and axilla	64
cHB_818344 Acromioplasty with division of the coracoacromial ligament, open surgical	79
Combinations of diagnostic and intervention codes	**Total (n)**
Paitents with primary subacromial pain	1873
Patients with primary shoulder pain that could NOT be subacromial pain	143
Patients treated with subacromial decompression as the primary intervention	1703
Paitents with secondary subacromial pain	7121
Patients treated with subacromial decompression as the secondary intervention	7249
Paitents with subacromial pain	8346
Patients treated with subacromial decompression the as the intervention	8336
Subacromial pain (*cHD_M754 code only*) as primary diagnosis AND expansion of subacromial space as the primary intervention (*cHB_818333 code only*)	1080
Patients with non-primary subacromial pain	13640
Patients treated with non-primary subacromial decompression	13810
Non-primary subacromial painv AND subacromial decompression as the primary intervention	488
Subacromial pain as the primary diagnosis AND subacromial decompression was NOT the primary intervention	658
Subacromial pain as primary diagnosis AND subacromial decompression as primary intervention	1215

4.1.2 Duration of treatment

The duration of treatment for subacromial pain can depend greatly on individual patient experience with the condition.[1 22 29 30] Subacromial decompression is generally completed in a single session of surgery. Under these conditions, the dressings covering the incisions can be removed three days post-surgery, while sutures are generally removed after five to 14 days. Typically, if the procedure was conducted without other surgical steps such as biceps tenodesis or rotator cuff repair, a patient will be able to move their arm to shoulder height or above, two to four weeks post-surgery. Full movement of the shoulder joint can be gained within three to eight weeks post-surgery. The complete benefits of surgery can be realised anywhere from a few months to a year.[33 36 50 51]

Post-surgery, it is common for patients to undergo physiotherapy. How long patients undergo physiotherapy, and when the full benefit of the surgical intervention is realised, is highly dependent on their compliance with their treatment plan.[33 36 51]

4.1.3 Risks/safety concerns related to subacromial decompression

Subacromial decompression surgery has a low risk of adverse events (AEs), with a reported occurrence of around 3%.[1 19] Frozen shoulder (adhesive capsulitis) is the most frequently reported AE associated with subacromial decompression. Frozen shoulder can result in further surgery, and/or corticosteroid injections. Other temporary minor complications include transient swelling from post-brachial plexus block and infection.[1 52 53] Serious AEs observed within 30 days post-surgery are rare (0.6%). Serious AEs include pulmonary embolism, nerve injury, deep infection, venous thromboembolism and death.[1 50] It is unclear if pulmonary embolism and venous thromboembolism are related to the procedure or to the anesthesia.

4.2 Alternative technologies

Conservative therapy is the main alternative to subacromial decompression. Traditionally, conservative therapy is the first line of treatment for subacromial pain, with subacromial decompression only being considered if conservative therapy fails. Should subacromial decompression be disinvested, conservative therapy will remain the next-best alternative for patients with subacromial pain. For the purposes of this HTA, conservative therapy has been defined as the main comparator.

The first stages include pain relief (e.g. NSAIDs) for a period of two to four weeks, followed by physiotherapy and exercises. If symptoms do not improve, patients can receive a subacromial corticosteroid injection followed by further physiotherapy and exercises.[16 23 29 31 32]

4.3 Regulatory status / provider

Currently, decompression is reimbursed under mandatory health insurance. Typically, subacromial decompression is conducted by an accredited orthopaedic surgeon. In Switzerland, future orthopaedic surgeons are trained by starting their internship with a year in general surgery or general medicine before proceeding with five years of specialisation.[54] Official recognition is accomplished by registering with the Swiss College of Surgeons and/or the Swiss Orthopaedics society, which provide training, scholarships and fellowships.[55 56] Additionally, a pilot project for a bureau of extrajudicial expertise (bureau d'expertises judiciaires du Foederatio Medicorum Helveticorum) was created.[57] Its role is to provide an extrajudicial process of support and information to patients during and after the procedure, especially in case of complications.[57]

5 PICO

5.1 PICO box

Table 2 PICO criteria

P:	Patients with subacromial pain (sometimes diagnosed as SIS) *Subgroups:* • *Older patients (≥60 years of age), manual labourers, smokers,[58 59] athletes* *Exclusion criteria:* • *Patients undergoing surgery for benign/malignant tumours, adhesive capsulitis, shoulder instability/dislocation, joint replacement, fracture or full thickness rotator cuff tear*
I:	Surgical intervention to widen the subacromial space surrounding the tendon, i.e. subacromial decompression, acromioplasty, bursectomy, coracoacromial ligament resection
C:	Placebo/sham procedures, conservative therapy (e.g. physiotherapy, injections)[a], no intervention
O:	**Efficacy:** – Shoulder pain (e.g. mean change measured by numerical/categorical scale) – Shoulder function (e.g. mean change measured via SPADI, OSS, DASH etc.) – Health-related quality of life (HRQoL) (e.g. mean change measured with SF-36, EQ-5D, etc.) – Ability to return to work (e.g. patient-reported ability to do usual occupation) – Return to leisure activities – Further progression of subacromial pain (i.e. treatment failure)[b] **Safety:** – AEs – Serious AEs (i.e. mortality, life-threatening, requiring intervention or author-defined)

Abbreviations
AE = adverse event, **DASH** = Disabilities of the Arm Shoulder and Hand, **EQ-5D** = EuroQol 5-dimensions questionnaire, **HRQoL** = Health-related quality of life, **OSS** = Oxford Shoulder Score, **SF-36** = Short form-36, **SIS** = subacromial impingement syndrome, **SPADI** = Shoulder Pain and Disability Index.
Explanatory notes
[a] Non-operative treatments may include non-steroidal anti-inflammatory drugs, intra-articular or subacromial glucocorticosteroid injections, physiotherapy.
[b] Patients crossing to the surgery arm of the trial or patients undergoing additional subacromial decompression

The study population of interest is patients with subacromial shoulder pain, also known as SIS. Patients are excluded if they had benign or malignant tumours, adhesive capsulitis, shoulder instability or dislocation, joint replacement, fracture or full thickness rotator cuff tear. These populations have been excluded because treatment for subacromial pain in these groups requires additional treatments that can confound the effects of subacromial decompression. No limitations were placed on how long patients had to have experienced subacromial pain.

5.2 Intervention

The intervention under investigation is the surgical procedure of subacromial decompression, with specific focus on isolated and primary treatments. The intervention can consist of three different procedures: acromioplasty, bursectomy and CAL resection. Acromioplasty may occur in combination with bursectomy and/or CAL resection. Furthermore, a subacromial decompression can, under specific circumstances, include a procedure called coplaning. When used as part of a subacromial decompression, coplaning is always performed alongside acromioplasty, bursectomy or CAL release, never as a standalone procedure.

5.3 Comparator

The comparators to subacromial decompression include placebo/sham procedures (e.g. diagnostic and/or therapeutic arthroscopy), conservative therapy (e.g. oral NSAIDs, steroid injections, physiotherapy), and no intervention. Additional details about the proposed comparators are presented in ***Section 4.2***. It is noted that placebo/sham procedures are not used in clinical practice, but rather represent relevant comparators to determine the efficacy of subacromial decompression under trial conditions.

5.4 Outcomes

5.4.1 Efficacy outcomes

Shoulder pain and shoulder function are critical outcomes. Pain and function are important indicators used to diagnose and assess the severity of subacromial pain and SIS. Shoulder pain can be estimated using numerical and/or categorical scales such as the visual analogue scale (VAS). Similarly, shoulder function can be measured using a variety of numerical and/or categorical scales such as the Shoulder Pain and Disability Index (SPADI), the Oxford Shoulder Score (OSS), the disability of the arm shoulder and hand questionnaire (DASH), the University of California – Los Angeles shoulder score and the

Constant-Murley score. The degree to which pain increases or decreases indicates whether treatment improved the patient's condition, or if the **treatment failed**.

The effect of subacromial pain on **quality of life** (QoL) is also a critical outcome. QoL can be measured using a self-reported assessment of patient physical and mental health. Tools that can be used to measure QoL include questionnaires such as the short form-36 (SF-36) and the EuroQoL 5-dimensions questionnaire form (EQ-5D-3L). In brief, these tools require patients to assess their current health status across multiple dimensions (e.g. mobility, self-care, usual activities, pain/discomfort).

The ability to **return to work and/or leisure activities** (i.e. sport) is an important outcome. A patient's ability to return to specific work or leisure activities indicates whether the intervention under investigation is effective because the main risk factors for subacromial pain include repetitive overhead movements during leisure activities or occupation.

A **minimal clinically important difference (MCID)** is the smallest difference in a specific outcome measure that would warrant a change in patient management, as a result of patient perceived an improvement. Other metrics used to determine the smallest change in an outcome(s) measurement that translates to a patient feeling better, as well as changes in physiological and anatomical function, include the minimally important difference (MID), minimally important change (MIC), and minimal clinically important improvement (MCII).[60-62] The MCIDs for the outcomes described above are detailed in ***Appendix C***.

5.4.2 Safety

Serious AEs are critical safety outcomes, whereas **total AEs** are important outcomes. These outcomes reflect if a patient has been harmed during or due to the surgical procedure. Potential AEs and serious AEs associated with subacromial decompression are described in ***Section 4.1.3.***

6 HTA key questions

For the evaluation of the technology the following key questions covering the central HTA domains, as designated by the European Network for Health Technology Assessment (EUnetHTA) Core Model (efficacy, safety, costs, cost-effectiveness, budget impact, and legal, social, ethical and organisational aspects), are addressed:

1. Is subacromial decompression as a primary intervention efficacious compared to conservative therapy, placebo and no treatment?

2. Is subacromial decompression as a primary intervention safe compared to conservative therapy, placebo and no treatment?

3. What are the costs associated with subacromial decompression?

4. How cost-effective is subacromial decompression compared to conservative therapy and no treatment?

5. What is the budget impact of subacromial decompression?

6. Are there legal, social or ethical issues related to subacromial decompression?

7. Are there organisational issues related to subacromial decompression?

6.1 Additional questions

1. Are there subpopulations (e.g. people over 60 years of age, manual labourers, smokers, athletes) that benefit from subacromial decompression?
2. Are there subpopulations (e.g. smokers) that do not benefit from subacromial decompression?
3. Is there a difference in the efficacy of subacromial decompression compared to conservative treatment, placebo (sham surgery), or no treatment, when acromioplasty and/or bursectomy and/or coplaning, are performed with or without CAL release?

7 Efficacy, and safety

7.1 Methodology efficacy, and safety

7.1.1 Databases and search strategy

A systematic literature search was used to identify and collate all literature related to efficacy, effectiveness, safety, cost-effectiveness, budgetary impact, and social, legal, organisational and ethical aspects of treating SIS with subacromial decompression. The search was conducted in eight bibliographic biomedical databases (PubMed, Embase, Cochrane Library, Cumulative Index of Nursing and Allied Health Literature (CINAHL), EconLit, York Centre for Reviews and Dissemination, Ethicsweb, PsychInfo) from inception to 13 August 2020. The search was not restricted by publication year or study design. Key search terms related to the population and intervention were combined and run through these databases. This systematic search was an update to a scoping search performed on 9 January 2020. (The complete methodology for the scoping search is available from *Scoping report: Subacromial decompression for rotator cuff disease*).[63] Details of the bibliographic databases and the full search strategy for each are reported in ***Appendix A***. Unlike the scoping report, methodological filters were not used to refine the search output to answer specific research questions. This was done to increase the sensitivity of the search.

Searches were conducted to identify ongoing clinical trials related to subacromial decompression (***Table 36***). Six clinical trials databases were searched (ClinicalTrals.gov, Cochrane Central Register of Controlled Trials, EU Clinical Trials Registry, World Health Organization (WHO) International Clinical Trials Registry Platform, Current Controlled Trials MetaRegister and Australian New Zealand Clinical Trials Registry).

Websites of HTA agencies and clinical practice guideline databases were also searched to identify relevant HTA reports that included cost-effectiveness analyses (***Table 24***).

7.1.2 Other sources

Grey literature searches were conducted on specialty websites (***Table 25, Appendix A***) to highlight any relevant literature that may not have been otherwise identified. The keywords used to search clinical trial registries are detailed in ***Table 36***, ***Appendix A.***

7.1.3 Study selection

Results from the literature search were imported into Rayyan (bibliographic management software).[64] Rayyan functions similarly to EndNote but allows for easy blinding of reviewers and management of

study inclusion conflicts. Study selection was limited to English, French, German and Italian language studies. French, German and Italian are three of the four official languages of Switzerland. The fourth language of Romansh was not included due to the limited amount of publications available in the language. Relevant studies in other languages were identified to estimate the likelihood of language bias in the search results. Only studies meeting the population, intervention, comparator, and outcome (PICO) criteria were considered eligible for inclusion. Moreover, studies based in countries outside of WHO – Mortality Stratum A[C] were excluded during full-text screening as the cause of death and burden of disease are not comparable to those in Switzerland.[65 66] There was no minimum follow-up period for safety outcomes.

Study selection was conducted independently by two reviewers, in duplicate, in two phases. All records were screened by title and abstract. Conflicts between reviewers on study inclusion were settled via consensus. If consensus could not be reached, a third reviewer decided whether to include or exclude the citation. Articles deemed potentially relevant were then reviewed in full text by both reviewers independently, with disagreements settled via the same procedure of consensus.

7.1.3.1 Study design

Different types of publications and study designs were considered for selection. Systematic reviews and randomised controlled trials (RCTs) that met the PICO criteria were included to assess the safety and efficacy of subacromial decompression as a primary and isolated surgical procedure.

Due to the limited amount of evidence available for the safety of subacromial decompression, systematic reviews, RCTs, non-RCTs and single-arm studies that met the population, intervention, and AE outcomes were included.

Study characteristics were extracted for the included RCTs (e.g. author details, country of publication, year, setting, length of follow-up, population, intervention, comparator, outcomes, sample size) using preformed extraction templates. The extraction templates for non-randomised and single-arm trials did

[C] WHO – Mortality Stratum A countries include: Andorra, Australia, Belgium, Brunei, Canada, Croatia, Cuba, Cyprus, Czech Republic (Czechia), Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Israel, Italy, Japan, Luxembourg, Malta, Monaco, The Netherlands, New Zealand, Norway, Portugal, San Marino, Singapore, Slovenia, Spain, Sweden, Switzerland, UK, and USA. For more information see the WHO website (https://www.who.int/choice/demography/mortality_strata/en/)

not include a sections for a comparator. All data extractions were completed by one reviewer, then checked by a second reviewer for accuracy.

7.1.4 Assessment of quality of evidence

Only the articles that assessed the safety and efficacy outcomes (***Section 5***) underwent the critical appraisal. The appraisal of the quality of evidence was performed using two researchers independently. Any differences were settled via consensus. If consensus could not be reached, a third reviewer was consulted.

The critical appraisal tools used to review each study were dependent on the study design. The Assessing the Methodological Quality of Systematic Reviews 2 (AMSTAR 2) tool was used to appraise the quality of included systematic reviews.[67] To align with Karjalainen et al., RCTs not reported in the any included systematic reviews were appraised using the Cochrane risk-of-bias tool for randomised trials version 1.0.[1] This was a deviation from the scoping report, where the Cochrane risk-of-bias tool for randomised trials version 2.0 was the preferred critical appraisal tool for RCT.[68] The RCT summary was reproduced in *R studio* using the 'robvis' package. The non-randomised trials were appraised using the Cochrane risk-of-bias tool for non-randomised studies version 1 (ROBINS-I).[69] Single-arm trials were appraised using the Institute of Health Economics (IHE) quality appraisal checklist for case series studies.[70]

The Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach was used to appraise the quality of evidence.[71 72] GRADEpro GDT was used to construct the summary of tables (SoF).[73] The time points presented in the SoF table (i.e. 12 months) were decisions made posteriori.

If a systematic review was included in the evidence base to assess clinical outcomes, the quality appraisal performed (i.e. risk of bias and/or GRADE) in that review was summarised in the HTA.

7.1.5 Data analyses of efficacy and safety

7.1.5.1 Analysis of systematic reviews

Where existing systematic reviews were identified that met the inclusion criteria of this HTA, the relevant results were summarised narratively. The results of existing reviews were data checked against the full-text publications of the primary studies included in the review, and when necessary, the analysis was re-run to ensure reproducibility. If any inconsistency arose between the existing review and the primary studies, an analysis (meta-analysis or narrative analysis) was updated or re-run. Similarly, if the same outcomes were analysed in the included systematic review and this HTA but how the outcomes were

defined differed, the analysis (i.e. meta-analysis, narrative analysis) was re-run and updated with the additional data from the relevant RCT(s). In situations where the outcome was not assessed in the systematic review but was included in this HTA protocol, the data was extracted and a novel analysis (i.e. meta-analysis, narrative analysis) was conducted.

7.1.5.2 Meta-analysis methods

Dichotomous outcomes were meta-analysed using Review Manager version 5.4 (Cochrane Collaboration) when at least two RCTs were available.[74] The meta-analysis was performed using random-effects models with the Mantel-Haenszel statistical model. Results were reported as risk ratios (RR) with 95% confidence intervals (CI).

Continuous outcomes were meta-analysed using Review Manager version 5.4 (Cochrane Collaboration) when at least two RCTs were available.[74] The meta-analysis was performed using random-effects models with the inverse variance method. Analysed continuous outcomes were reported both as mean difference (MD) and standardised mean differences (SMD), which were used to account for differences in the measurement scales reported for outcomes across included studies. When extracted, continuous data were accompanied by a standard deviation and/or a 95% CI. The MDs were interpreted as clinically important following the MCIDs summaries in ***Appendix C***. The SMDs were interpreted following the recommendations detailed in the *Cochrane Handbook for Systematic Reviews of Interventions (version 5.1.0)*, whereby a SMD of 0.2 represents a small effect, 0.5 a moderate effect, and 0.8 a large effect.[75]

Random-effects models were used in order to account for any variations in the individual surgical procedures that are considered part of a subacromial decompression (***Section 5***) as well as the differences in conservative therapy techniques (e.g. physiotherapy techniques, dose of NSAIDs etc.). The random-effects model was also used to account for variations in population-based factors and discrepancies in how the intervention and comparators were delivered in the included trials.

Dichotomous and continuous outcome data were pooled at specific time points and not based on the longest follow-up of individual trials, as the follow-up durations were too different across trials.

7.1.5.3 Assessment of heterogeneity

Meta-analysis results were illustrated using forest plots, as they provide a visual representation of the reported effect sizes and uncertainty across the included studies. Heterogeneity and inconsistency were also assessed statistically. The statistical methods used to measure heterogeneity in meta-analyses of continuous outcomes were Tau^2 and I^2. Statistical methods used to measure heterogeneity in meta-analyses of continuous outcomes were the χ^2 test ($p < 0.10$ indicated significant heterogeneity) and I^2.

The significance of I^2 was dependent on the strength of the evidence for heterogeneity (i.e. Tau^2 and χ^2) as well as direction and size of the measured effect. It was interpreted in accordance with the *Cochrane Handbook for Systematic Reviews of Interventions (version 6.1)*.[75] An I^2 of 0–40% is low (i.e. may not be important), 30–60% is moderate, 50–90% is substantial and 75–100% is considerable heterogeneity.[75]

7.1.5.4 Subgroup analysis

Subgroup analyses outlined *a priori* in the scoping report included patients over 60 years of age, manual labourers, smokers and non-smokers, and athletes. In addition, a number of *post hoc* analyses were recommended by independent reviewers and stakeholders, including decompression procedures with or without a CAL resection, duration / type of symptoms, diagnosis, underlying pathologies, preoperative therapies, type or combinations of interventions, accompanying - and subsequent therapies. There was insufficient data to investigate any of these subgroups.

7.1.5.5 Assessment of publication bias

The risk of publication bias was not assessed by testing funnel plot asymmetry, as this requires a minimum of 10 studies included in the analysis.[71] A narrative inspection of publication bias was performed by searching clinical trial registries in order to identify any unpublished trials.

7.1.5.6 Missing values

Missing standard deviations (SD) were obtained from available means, sample sizes, standard errors and 95% CI or 99% CI using formulae detailed in the *Cochrane Handbook for Systematic Reviews of Interventions (version 6.1)*.[75] The formulae used are detailed below.

$$SD = \sqrt{N}\ x\ (upper\ limit - lower\ limit)/X$$

Where *X* is a fixed value established at 3.29 for 90% CIs, 3.92 for 95% CIs, and 5.15 for 99% CIs.

Where continuous values needed to be combined, the formulae detailed in the *Cochrane Handbook for Systematic Reviews of Interventions (version 6.1)* was used.[75] The formulae used are detailed below.

$$Sample\ size = N_1 + N_2$$

$$Mean = \frac{N_1 M_1 + N_2 M_2}{N_1 + N_2}$$

$$SD = \sqrt{\frac{(N_1 - 1)SD_1^2 + (N_2 - 1)SD_2^2 + \frac{N_1 N_2}{N_1 + N_2}(M_1^2 + M_2^2 - 2M_1 M_2)}{N_1 + N_2 - 1}}$$

Where a continuous value needed to be converted from one scale to another, the following formula was used.

$$Value\ in\ scale\ 2 = \left(\frac{((Value\ in\ scale\ 1 - Scale\ 1\ minimum) \times (Scale\ 2\ maximum - Scale\ 2\ minimum))}{(Scale\ 1\ maximum - Scale\ 1\ minimum)}\right) + Scale\ 2\ minimum$$

For studies that reported outcomes graphically, *Graphreader.com* was used to convert the graph points into numerical values.[76]

Where results were communicated in change from baseline and not a value, the following formula was used for conversion.

$$Value\ in\ scale = baseline\ value + change\ value$$

If data was not available to calculate an SD, it was imputed using the 'impute_SD' function in the *R* (version 1.4) package 'metagear', following the imputation methods described by Bracken.[77] [78] When a time point was represented either by a single study with missing SDs or two studies including one with missing SDs, the study with missing information was omitted to avoid bias in the imputation.

7.1.5.7 Safety outcome assessment

The assessment of the harm posed by a subacromial decompression as a primary and isolated procedure was addressed using results from RCTs, non-randomised trials and single-arm trials. Safety outcomes considered for the present assessment of subacromial decompression for the treatment of SIS were surgery-related AEs and serious AEs. Due to the lack of details and the common under-reporting of AEs, advice from the International Council for Harmonisation of Technical Requirement for Pharmaceuticals for Human Use could not be applied retrospectively.[79] Instead, severe AEs were defined using the given study definition. It is important to note that the lack of standardization of AEs could limit the findings related to safety, for example, the true effect of the surgical procedure could be over- or under-estimated.

7.1.5.8 Time points

The main time points were determined *post-hoc*. The eight time points included: 3 months; 6 months; 12 months; 18 months; 24 months; 30 months; 48 months; 60 months; and 120 months.

7.2 Results efficacy, effectiveness and safety

7.2.1 PRISMA Flow Diagram

The results of the literature searches are summarised in ***Figure 3***. The bibliographic database searches and pearling returned a total of 19,089 articles (Results from individual database searches are listed in ***Table 27***). A total of 3,729 duplicate citations were removed and 15,360 title and abstracts were screened, leaving 136 publications for review by full text. A total of 42 publications were included that assessed safety and/or efficacy/effectiveness of subacromial decompression to treat SIS. From these 42 publications, there was 1 systematic review,[1] 8 RCTs (k=17 publications),[19 44-47 52 80-90] 7 non-randomised trials (k=7 publication),[38 53 91-95] and 12 single-arm trials (k=12 publications).[96-107] Additionally, one publication assessed the cost-effectiveness of the surgical procedure. Four publications assessed ethical (k=1), organisational (k=3), or social (k=3) considerations.

A comprehensive list of all excluded publications (k=94) is available in ***Appendix D***.

7.2.2 Evidence base pertaining to efficacy, effectiveness and safety

All of the RCTs identified in the systematic literature search were also included in Karjalainen et al. in the 2019 Cochrane review (***Table 3***).[1] As such, the Cochrane review was used as the basis for the evaluation of efficacy, effectiveness and safety of subacromial decompression. The results of the Cochrane review have been summarised and critiqued; where necessary (e.g. due to data discrepancies or differences in the definition of outcomes between this HTA and the Cochrane review), analyses have been re-run.

Due to the inability to separate the population data in each RCT, the research questions relating to the subpopulations outlined in ***Section 6*** could not be addressed.

There was limited information published on subacromial decompression-related AEs and serious AEs in the Cochrane systematic review and included RCTs.[1] Consequently, in addition to the Karjalainen et al. review, seven non-randomised trials and twelve single-arm studies were included to further evaluate the safety of subacromial decompression.[1 38 53 91-107]

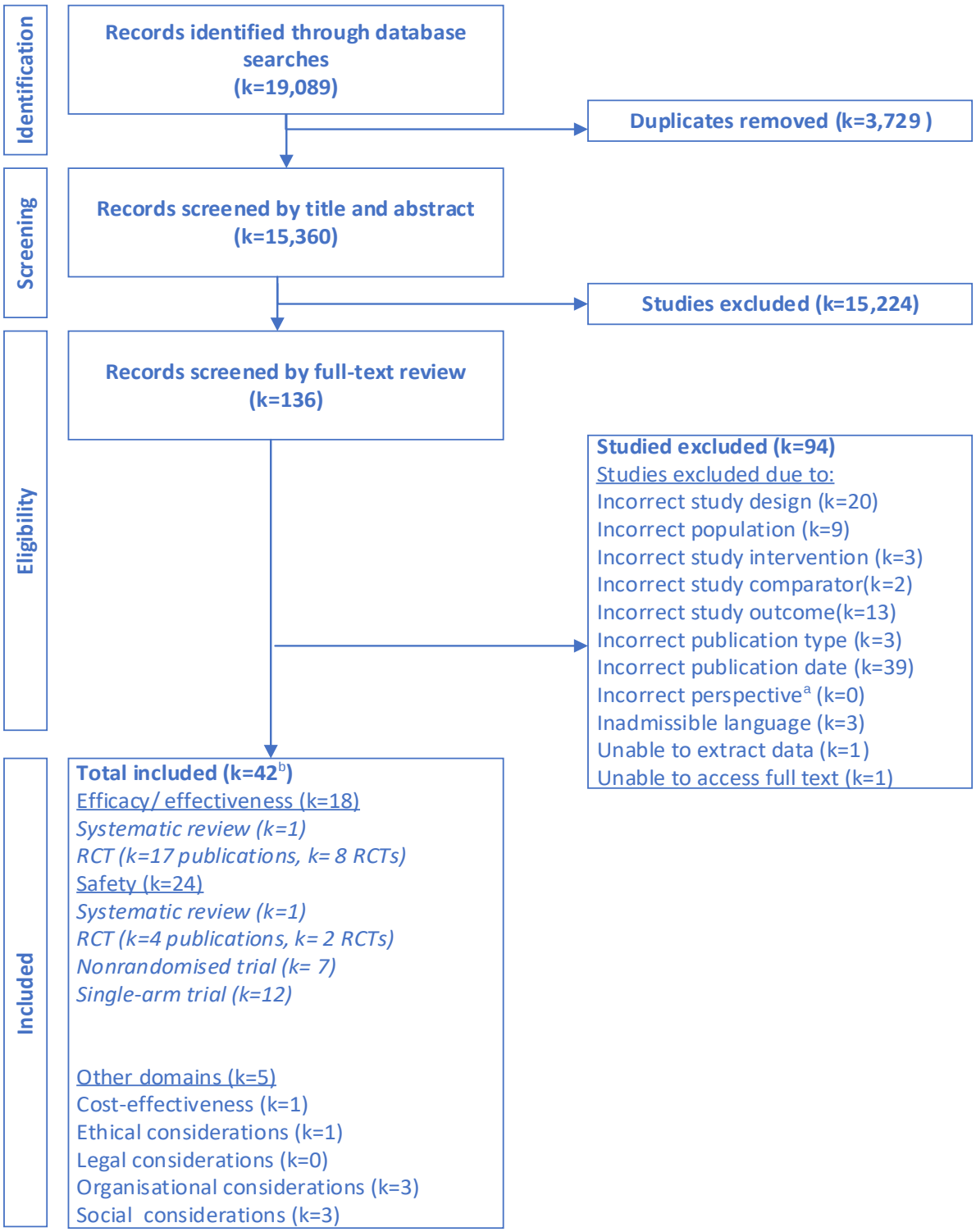

Figure 3 PRISMA flow chart

Abbreviations:
RCT = Randomised control trial
Notes:
a Articles that addressed auxiliary considerations from an investment standpoint instead of disinvestment.
B Some articles are included in multiple domains

7.2.3 Study characteristics

7.2.3.1 Systematic reviews

The Karjalainen et al. review assessed similar outcomes as detailed in the PICO criteria (***Section 5***).[1] These outcomes included shoulder pain, shoulder function, HRQoL, AEs and serious AEs, participation (recreation and work), and treatment failure (e.g. progression to full thickness tear). The single outcome that was not assessed in this HTA (***Section 5***) but was included in Karjalainen et al. was global assessment of treatment success.[1] Some of the metrics and tools used to measure the predetermined outcomes differed between this HTA and the review by Karjalainen et al. For example, treatment failure in Karjalainen et al. was defined as progression to rotator cuff tear, whereas in this HTA it has been defined as further progression of disease (e.g. patients crossing to the surgery arm of the trial, patients undergoing additional subacromial decompression). In cases where this occurred, the analysis was updated using the methods previously described (***Section 7.1.5.1***).

7.2.3.2 Randomised control trials

Of the eight included RCTs, three were placebo-controlled[19 44 52 80 81 88] and five were active-controlled (i.e. compared subacromial decompression to conservative therapy).[45-47 82-87 89 90] It is important to note that three of the included RCTs had both a placebo and an active comparator.[19 44 52 80 81 88]

While all the included RCTs (k=8) were conducted in Western Europe (Sweden, Norway, Finland, UK, Germany, Denmark), none were performed in Switzerland. The patients (some with PTT) included across the RCTs totalled 1,079, with 648 of these being included in the placebo-controlled trials.[19 44-47 52 80-90] Most trials were conducted at a single centre (k=4).[46 80 81 83 89 90] A third (k=3) of the studies had a follow-up period of 2 to 2.5 years.[45 52 80-82 88] Follow-up duration ranged from immediate postoperative care for safety outcomes and from 12 months up to 10 years for outcomes.[19 44-47 52 80-90]

The study characteristics of each RCT are reported in ***Table 3*****.**

Table 3 Characteristics of included RCTs for efficacy of subacromial decompression

First author; year; country; trial ID	Inclusion criteria; Sample size	Design; Setting; Follow-up	Intervention; Comparator	Outcomes
Beard 2018 [19 44] UK NCT01623011	Subacromial pain ≥3 months (tendinopathy and PTT) Clinical diagnosis of tendinopathic pain or PTT (by radiography, MRI or ultrasound) Age up to 75 years Resistant to conservative treatment n=313	RCT, partial blinding, cross over Multicentre (32 hospital sites) 12 months	Arthroscopic subacromial decompression (acromioplasty + coracoacromial ligament release) Investigational arthroscopy (placebo) No treatment	*Pain* - Pain on activity (pain DETECT) *Function* - Constant-Murley score *Quality of life* - EQ-5D *Further progression of disease* - Treatment failure
Brox 1999 [80 81] Norway NR	Shoulder pain ≥3 months Clinical diagnosis of rotator cuff disease, including positive impingement sign and test (no imaging) Age up to 66 years Resistant to conservative treatment n=125	RCT, partial blinding Single centre 30 months	Arthroscopic subacromial decompression (bursectomy + acromioplasty + resection of the coracoacromial ligament) Detuned laser treatment (placebo) Physiotherapy (supervised)	*Pain* -Pain on activity *Function* - Neer shoulder score *Further progression of disease* -Percentage of patients receiving pain medication post-operatively. *Return to work* - Percentage of shoulder-related absence from work compared to baseline
Farfaras 2016 [45 82] Sweden NR	Subacromial pain ≥6 months with intact rotator cuff (verified by ultrasound) n=87	RCT, partial blinding NR Mean 29.7 to 31.6 months depending on treatment arm, range 23.6 to 37.5 months	Arthroscopic acromioplasty + bursectomy Open acromioplasty Physiotherapy	*Function* - Constant-Murley score *Quality of life* - SF-36 *Further progression of disease* - Treatment failure

First author; year; country; trial ID	Inclusion criteria; Sample size	Design; Setting; Follow-up	Intervention; Comparator	Outcomes
Haahr 2005 [46 83] Denmark NR	Subacromial pain for 6 months to 3 years Clinical diagnosis of impingement syndrome (no imaging) Normal passive glenohumeral movement Age up to 55 years n=90	RCT, blinding NR Single centre Range 48 to 96 months	Arthroscopic subacromial decompression + coracoacromial ligament resection Physiotherapy	*Function* - Constant-Murley score *Quality of life* - Marginalisation index *Ability to return to work* - Sick leave index *Further progression of disease* - Treatment failure
Ketola 2009 [47 84-87] Finland NR	Shoulder impingement syndrome ≥3 months (diagnosed by radiography or MRI, Neer test) Age up to 60 years Resistant to conservative treatment n=140	RCT, partial blinding Multicentre 24 months	Arthroscopic acromioplasty + physiotherapy Physiotherapy	*Pain* - Pain on activity (VAS) *Function* - Shoulder disability questionnaire score *Ability to return to work* - Working ability (VAS) *Further progression of disease* - Treatment failure
Paavola 2018 [52 88] Finland NCT00428870	Subacromial pain ≥3 months Clinical diagnosis of impingement syndrome (MRI to exclude rotator cuff tear) Age up to 65 years Resistant to conservative treatment n=210	RCT, double blind Multicentre (n=3) 24 months	Arthroscopic subacromial decompression (bursectomy + acromioplasty) Diagnostic arthroscopy (placebo) Physiotherapy	*Pain* - Pain on activity (VAS) *Function* - Constant-Murley score *Quality of life* - 15D questionnaire *Ability to return to work* - mentioned in the protocol but these results are yet to be published

First author; year; country; trial ID	Inclusion criteria; Sample size	Design; Setting; Follow-up	Intervention; Comparator	Outcomes
				Ability to return to leisure activity - Proportion of participants able to return to leisure activities *Further progression of disease* - Treatment failure
Peters 1997 [89] Germany NR	Subacromial impingement Clinical diagnosis of impingement syndrome (radiography, ultrasound, Neer test or Hawkins impingement test) Age up to 78 years n=72	RCT, blinding NR Single centre 48 months	Arthroscopic subacromial decompression or acromioplasty Open subacromial decompression (surgeon preference) Conservative treatment (physiotherapy + NSAIDs)	*Function* - SSRS *Further progression of disease* - Treatment failure
Rahme 1998 [90] Sweden NR	Subacromial impingement syndrome Subacromial pain for at least 12 months Age up to 63 years n=42	RCT, blinding NR Single centre 12 months	Acromioplasty Physiotherapy	*Further progression of disease* - Treatment failure

Notes:
[A] All outcomes reported are relevant to the PICO described in ***Section 5.***
Abbreviations:
15D = 15 dimensions, **EQ-5D** = EuroQol 5-dimensions questionnaire, **MRI** = magnetic resonance imaging, **NR** = not reported, **NSAID** = non-steroidal anti-inflammatory drug, **PTT** = partial thickness tear, **RCT** = randomised controlled trial, **SF-36** = Short-form 36, **SSRS** = Subjective Shoulder Rating Scale, **VAS:** visual analogue scale.

7.2.3.3 Non-randomised trials

Study characteristics of the included non-randomised trials are outlined in ***Table 38*** (***Appendix B***). The observational studies included for safety outcomes (k=7) were conducted across Western Europe (Norway, Germany, France, Finland, The Netherlands, the UK) and North America (United States of America (USA)).[38 53 91-95] There were 915 patients included across the observational studies. Most of the studies did not report the centres in which they were conducted (k=5).[38 53 93-95] The other two publications correspond to single-centre studies.[91 92] The follow-up period for the included observational studies ranged from immediate postoperative care for safety outcomes and from 8 months up to 120 months (10 years) for outcomes, with a mean follow-up time ranging from 18 months to 90 months (7.5 years).[38 53 91-95]

The patient indications varied between studies. All studies required patients to be diagnosed with SIS. Three studies evaluated rotator cuff tears alongside SIS.[38 92 95] Over half of the studies included patients diagnosed by Neer and/or Hawkins-Kennedy tests (k=4).[38 92 93 95] Four studies also required patients to have experienced subacromial pain for a specific amount of time before they could undergo subacromial decompression.[53 92-94] The amount of time patients were required to have had subacromial pain differed between studies (i.e. 3 months (k=1)[92] or 6 months (k=3)[53 93 94]). Five of these studies included patients for whom conservative treatment had failed (i.e. physiotherapy and/or NSAIDs).[53 92-95] The median follow-up time for these studies was 32.5 months.

7.2.3.4 Single-arm trials

Study characteristics of the included single-arm trials are outlined in ***Table 39*** (***Appendix B***). The single-arm studies included for the safety evaluation (k=12) were performed across Western Europe (Belgium, France, Finland, Germany, Norway and the UK), North America (Canada and USA) and South-East Asia (Singapore), while one study was a collaboration between the UK and Australia. A total of 1,022 patients were evaluated during these studies.[96-107] One multicentre study did not report on the institutions where the trial was conducted.[106] The remaining studies all reported the single centre where they were performed.[96-105 107] The follow-up period for the included single-arm studies ranged from immediate postoperative care for safety outcomes and from 3 months up to 180 months (15 years) for outcomes, with the mean follow-up time ranging from 14.6 months to 108 months, with a median of 15 months.[96-107]

As in the non-randomised studies, patient diagnosis varied also between single-arm trials. For most studies, a SIS diagnostic was necessary for inclusion (k=10).[97-101 103-107] Two of them evaluated patients presenting SIS and rotator cuff tears,[97 104] while one study evaluated patients with rotator cuff pain accompanied by tendinopathy,[96] and one study did not require a particular diagnosis for inclusion.[102]

Four studies used the Neer and/or Hawkins-Kennedy tests to diagnose impingement.[97-99 103] Five studies required participants to have experienced pain for a certain period of time prior to intervention.[97 99 101 104 105] The amount of time that patients had to experience pain before study inclusion was either a minimum of 3 months,[97] or a minimum of 6 months.[99 104 105] Five studies recruited participants who received unsuccessful conservative treatment.[98 99 101 104 105]

7.2.4 Risk of bias

7.2.4.1 Systematic reviews

The review by Karjalainen et al. was appraised using AMSTAR 2 (***Table 4***).[1 67] The overall confidence in the systematic review was high. Therefore, it can be concluded that the systematic review accurately and comprehensively summarised the results from all available studies.

Table 4 Summary of AMSTAR results

Question	Yes/No
Did the study include a PICO?	**Yes**
Were the methods established a priori and deviations reported?	**Yes**
Were the study design selection criteria explained appropriately?	**Yes**
Was a comprehensive literature search strategy used?	**Yes**
Was study selection performed in duplicate?	**Yes**
Was data extraction performed in duplicate?	**Yes**
Were excluded studies listed with justification for exclusion?	**Yes**
Were included studies described in adequate detail?	**Yes**
Was risk of bias assessed appropriately for RCTs?	**Yes**
Was risk of bias assessed appropriately for NRSIs?	**Yes**
Were sources of funding reported for included studies?	**Yes**
If MA was performed, was the method appropriate?	**Yes**
If MA was performed, was the impact of bias assessed?	**Yes**
Was bias accounted for when interpreting/discussing the results?	**Yes**
Were sources of heterogeneity discussed?	**Yes**
Was publication bias assessed?	**Yes**
Were sources of conflicts of interest declared by the authors?	**Yes**
Overall quality	**High**

Abbreviations:
MA = meta-analysis, **NRSI** = non-randomised studies of intervention, **PICO** = population, intervention, comparator, outcome, **RCT** = randomised controlled trial.
Source :
Karjalainen et al. 2019[1]

7.2.4.2 Randomised control trials

According to Karjalainen et al., two of the placebo-controlled trials by Beard et al. and Paavola et al. met the criteria of low risk of bias.[1 19 44 52 88] The other six trials had a number of sources of bias related to performance and detection bias caused by inadequate blinding of personnel and participants.[1 45-47 52 80-90] The summary of the risk of bias assessment performed by Karjalainen et al. is presented in ***Figure 4***.[1]

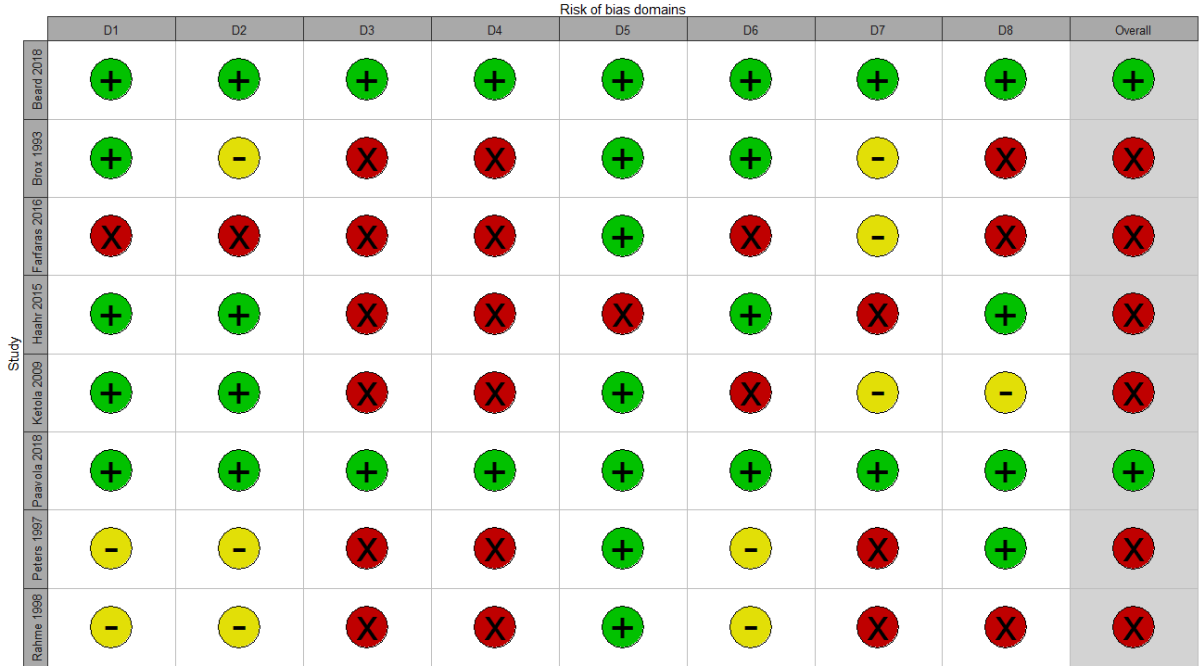

Figure 4 RCT risk of bias summary

Notes:
D1: Random sequence generation (selection bias)
D2: Allocation concealment (selection bias)
D3: Blinding of participants and personnel (performance bias)
D4: Blinding of outcome assessment for self-reported outcomes (detection bias)
D5: Blinding of outcome assessment for outcomes assessors (detection bias)
D6: Incomplete outcome data (attrition bias)
D7: Selective reporting (reporting bias)
D8: Other bias
Green = low level of bias, Yellow = moderate risk of bias, Red = high risk pf bias
Source:
Karjalainen et al. [1]

Treatment allocation

The Karjalainen et al. systematic review detailed that four of the included trials were deemed to have a low risk of selection bias. This was reported as appropriate allocation concealment and adequate random sequence generation.[1 19 44 46 47 52 83-88] Two trials were considered to have an unclear risk of selection bias due to the failure of the relevant publications to appropriately report the methods used to conceal treatment allocation and randomise participants.[1 89 90] Similarly, a trial by Brox et al., was

considered to have an unclear risk of selection bias because it did not explicitly report allocation concealment.[1 80 81] However, the trial probably did adequately use random sequence generation for patient allocation into trial arms.[1 80 81] Finally, the study by Farfaras et al., was deemed to have a high risk of bias for the domains of random sequence generation and allocation concealment.[1 45 82] It was concluded that this trial presented a high risk of selection bias.

Blinding

The Karjalainen et al. systematic review suggested that only the three-armed trials by Beard et al. and Paavola et al. presented a low risk of performance and detection bias.[1 19 44 52 88] This was because the placebo-controlled arms of the trials by Beard et al. and Paavola et al. blinded all personnel and participants aside from the staff present in the operating theatre.[1 19 44 52 88] Contrastingly, the study participants in the conservative treatment arm could not be blinded to the non-operative intervention they received. This resulted in the comparator arms of the trials by Beard et al. and Paavola et al. presenting a high risk of performance and detection bias.[1 19 44 52 88] The inability to blind the participants could have resulted in an over-valued benefit of surgery compared to no treatment (Beard et al.) and conservative therapy (Paavola et al.).[1 19 44 52 88]

The other six active-control trials were considered to have a high risk of performance and detection bias.[1 45-47 80-87 89 90] This was because the participants in the respective trials were aware of their treatment allocation. Due to the majority of critical outcomes being subjective, Karjalainen et al. also assigned high risk to trials where personnel were blinded.[1 45-47 80-87 89 90]

Incomplete outcome data

Karjalainen et al. reported a low risk of attrition bias in four of the included trials.[1 19 44 46 52 80 81 83 88] These trials had comparable losses to follow-up or missing data across all of the reported outcomes and across all of the trial arms. The reasons for the loss of participants were also reported.[1 19 44 46 52 80 81 83 88]

The study by Beard et al., was considered to present a low risk of attrition bias as the number of participants lost to follow-up was similar in all trial arms at six months (surgery 15% (16/106), placebo 9% (9/103)) and 12 months (surgery 17%, (18/106), placebo 10% (10/103)).[1 19 44] Similarly, the study by Brox et al., was deemed to present a low risk of attrition bias.[1 80 81] The proportion of participants lost to follow-up was similar in both arms of the trial at six months (surgery 9% (4/45), conservative therapy 2% (1/50)) and 30 months (surgery 13% (6/45), conservative therapy 10% (5/50)).[1 80 81]

Losses to follow reported by Haahr et al. were almost comparable in both trial arms at the 12-month time point (surgery 9% (4/45), conservative therapy 4% (2/45)).[1 46 83] The study by Paavola et al. was also determined to have a low risk of attrition bias, as the number of patients lost to follow-up or with

missing data was comparable across the three arms of the trial.[1 52 88] For the pain and function outcomes in the surgery arm at 24 months, 0% (0) to 7% (4/57) of participants were lost to follow-up or had missing data reported. For the pain and function outcomes in the placebo arm at 24 months, 3% (2/66) to 11% (7/64) of participants had missing data or were lost to follow-up. Lastly, for the pain and function outcomes in the conservative treatment arm of the trial, 4% (3/75) to 10% (7/70) of participants had missing data or were lost to follow-up at 24 months.[1 52 88]

Karjalainen et al. determined that two of the trials presented an unclear risk of attrition bias.[1 89 90] The study by Rahme et al. was deemed to present an unclear risk of bias because 14% (3/21) of trial participants were lost to follow-up with no reported reason why.[1 90] Likewise, the study by Peters et al. was deemed to present an unclear risk of attrition bias because it reported an imbalance in follow-up across the trial arms (surgery 19% (6/32), conservative therapy 10% (4/40)) without providing any explanation.[1 89]

Karjalainen et al. stated that the studies by Ketola et al. and Farfaras et al. presented a high risk of attrition bias.[1 45 47 82 84-87] The study by Ketola et al. had a large amount of missing data and losses to follow-up in the surgery arm of the trial at 3 months and 6 months, compared to the conservative treatment arm.[1 47 84-87] At the 3-month time point, 39% (27/70) of the participants were missing from the surgery arm, compared to 19% (13/70) in the conservative treatment arm.[1 47 84-87] Likewise, at the 6-month time point, 37% (26/70) of participants were missing from the surgery arm, while 20% (14/70) were lost to follow-up in the conservative treatment arm.[1 45 82] Losses to follow-up and missing data were equal across the trial arms at the 12-month follow-up, with 27% (19/70) in the surgery arm and 26% (18/70) in the conservative treatment arm.[1 45 82]

Farfaras et al. reported a per-protocol analysis.[1 45 82] The analysis was missing 37.5% (9/24) of data points from the first surgery arm (open acromioplasty), 42% (10/29) of data points from the second surgery arm (arthroscopic acromioplasty), and 11% (3/21) of data points from the conservative treatment arm of the trial.[1 45 82]

Selective reporting

Karjalainen et al. reported that two trials by Paavola et al. and Beard et al. presented a low risk of reporting bias.[19 44 52 88] An unclear risk of reporting bias was presented by Brox et al., Farfaras et al. and Ketola et al..[45 47 80-82 84-87] The three remaining trials by Haahr et al., Peters et al. and Rahme et al. presented a high chance of reporting bias.[1 46 83 89 90]

The trial by Farfaras et al. was rated by Karjalainen et al. as presenting an unclear risk of reporting bias because it did not report the critical outcomes of pain and AEs and it did not have a published protocol.[1]

[45 82] The study by Ketola et al., was also deemed to present an unclear risk of reporting bias because AEs were only reported for participants in the surgery arm of the trial and some predetermined outcomes (i.e. passive movement and strength) were not reported.[1 47 84-87] The study by Brox et al. was considered to present an unclear risk of reporting bias because it did not have a published protocol or trial registration.[1 80 81] Additionally, two of the five trial population subsets reported participation in work. However, it is important to note that this study was published prior to mandatory trial protocol registrations.[1 80 81]

The study by Haahr et al. was considered to present a high risk of reporting bias by Karjalainen et al. because there was no trial registration or protocol.[1 46 83] Additionally, some outcomes were incompletely reported and were added post-hoc.[1 46 83] Similarly, the study by Peters et al. was considered to present a high risk of reporting bias because it did not report a trial registration or protocol.[1 89] This meant it was impossible to confirm if other outcomes besides the subjective shoulder rating score were meant to be assessed.[1 89] Whereas, Rahme et al. deemed to present a high risk of reporting bias as not all outcomes were reported at the predetermined time points.[1 90]

Other potential sources of bias

Of the eight included trials, Karjalainen et al. considered four to have additional potential sources of bias.[1 19 44 46 52 83 88 89] The study by Ketola et al. was considered to have an unclear risk of other bias,[47 84-87] while the studies by Brox et al., Farfaras et al. and Rahme et al. presented a high risk of other bias.[1 45 80-82 90]

The study by Ketola et al. was deemed to present an unclear risk of other bias because 13% (n=9) of participants in the surgery arm had unintended labral repair during the subacromial decompression.[1 47 84-87] This additional procedure to treat a different condition may have biased the results in favour of surgery.[1 47 84-87] Additionally, participants in both trial arms had glucocorticoid steroid injections, which may have biased the trial estimates.[1 47 84-87]

The study by Brox et al. was determined by Karjalainen et al. to present a high risk of other bias due to the fact that at six months, recruitment for the placebo arm was terminated (at 68 participants from a projected 125) after an unintended interim analysis indicated no benefit.[1 80 81] Farfaras et al. also terminated recruitment early, resulting in a significant imbalance in participant allocation into the three trial arms.[1 45 82] Finally, 57% (12/21) of participants in the conservative treatment arm of the trial by Rahme et al. crossed over to the surgery arm at the 6-month time point.[1 90]

7.2.4.3 Non-randomised trials

Due to the nature of their design, non-randomised studies present a higher risk of bias than RCTs. The risk of bias in the seven non-randomised studies included for the evaluation of the safety of subacromial decompression as a primary and isolated intervention for the treatment of SIS was evaluated using ROBINS-I. Overall ROBINS-I scores represent the highest risk of bias identified in each domain for individual studies (***Table 5***). Most studies (k=5) presented a critical level of bias,[53 91-93 95] while two were judged to have a serious level of bias.[38 94]

Confounding

Most studies scored poorly in the confounding domain.[38 53 93-95] The main confounding factors across trials were obvious differences in mean age and/or gender ratio between study groups. One study did not control for differences in preoperative physiotherapy between groups, which may have had an impact on postoperative health outcomes.[38] Similarly, in one study the difference between treatment groups was the experience of the surgeon conducting the subacromial decompression.[94] Confounding may have greatly impacted safety outcomes.

Selection

All studies scored well for the selection domain. None of the studies based the selection of participants on postoperative characteristics. As these studies were only included for the evaluation of safety outcomes, it was considered that follow-up started as soon as the intervention was conducted.

Classification of intervention

Most studies presented a low to moderate risk of bias for the classification of intervention domain.[38 53 91-94] In three studies, the classification of the intervention status could have affected the knowledge of the outcome or the risk of the outcome.[93-95] Groups were selected on the basis of a different diagnosis (i.e. presence of rotator cuff tears or different number of impingement symptoms) or on a difference in surgeon operative experience.

Deviation from intervention

Most studies presented a low to moderate risk of bias for the deviation from intervention domain.[38 53 92-95] Important co-interventions, such as physiotherapy, were not balanced between arms in three studies, which could have affected effectiveness and safety outcomes.[38 53 91]

Incomplete outcome data

Outcome data were available for all participants in most of the included studies.[38 53 92-95] The study by Connor et al. failed to report the results for two patients in one of the treatment groups. No justification for the missing data was provided.[91]

Measurement of outcomes

Most studies scored a high risk of bias in the outcome measurement domain.[38 53 91-94] In these studies, assessors were not blinded to interventions and co-interventions, which may have impacted the assessment of safety outcomes.

Selection of reported results

Most studies presented a low risk of bias in terms of reported result selection.[38 53 91-94] The safety results displayed in the study by Soyer et al. could have been influenced by the difference in rotator cuff disease between the groups.[95]

Table 5 Non-randomised studies risk of bias appraisal summary

Study	Confounding	Selection	Classification of intervention	Deviation from intervention	Missing data	Measurement of outcomes	Selection of reported results	ROBINS- I overall score
Connor 2000[91]								
Inderhaug 2018[92]								
Järvelä 2010[53]								
Machner 2001[38]								
Magaji 2012[93]								
Schröder 2001[94]								
Soyer 2003[95]								

Abbreviations:
ROBINS- I: risk of bias tool for non-randomised studies version 1
Notes:
Scores were based on answers to the ROBINS-I tool questionnaire.
Overall scores reflect the worst level of bias found in any domain.
Low (green): comparable to a well-performed randomised trial.
Moderate (yellow): sound for a non-randomised study but not comparable to a rigorous randomised trial
Serious (orange): presence of important bias
Critical (red): the bias is too important to provide useful evidence on the effect of the intervention.

7.2.4.4 Single-arm trials

By design, single-arm trials have an inherent higher risk of bias compared to RCTs and non-randomised studies. One of the studies included as a single-arm trial in the present assessment was initially an RCT. It compared the efficacy and safety of open vs arthroscopic subacromial decompression.[99] As both arms performed decompression, this trial was evaluated along with other selected single-arm studies. The IHE tool was used to establish the risk of bias in the twelve single-arm studies included for the safety evaluation of subacromial decompression for the treatment of SIS. Overall IHE scores correspond to the highest risk of bias identified in any given domain for each study. The majority of studies presented a serious level of bias (k=9),[96-99 102 104-107] while three studies presented a critical level of bias.[100 101 103] For most studies, the determining factor for assigning a critical or serious risk of bias was the quality of study design.

Study design

Most studies were conducted in a single centre,[96-105 107] and several trials did not indicate whether patients were recruited consecutively.[100-103 105] Three studies were retrospective,[96 100 101] and two did not report whether they were conducted under a prospective design.[98 103] When recruitment is not done consecutively and when trials are retrospective, there is a greater chance for patient selection to be biased (e.g. selection of patients with a certain degree of disease), which in turn can impact efficacy and safety outcomes.

Study population

Most studies presented a serious level of bias for the study population domain,[96-99 101 102 104-107] while two trials were critically biased.[100 103] Patients either entered the trial at a different point in the disease or this information was not provided. If patients presented with different degrees of severity of impingement or rotator cuff tear, it would impact efficacy and safety outcomes by adding inconsistency. Three studies also did not provide clear inclusion or exclusion criteria.[100 102 103]

Intervention and co-intervention

Most studies showed a low to moderate risk of bias for the intervention and co-intervention domains.[96-102 104-106] Two trials presented a serious risk of bias due to partial descriptions of either the intervention, co-interventions or both.[103 107]

Outcome measure

Except for the trial conducted by Husby et al.,[99] which was originally designed as an RCT, all studies were unblinded for surgery and follow-up assessment. This could induce a bias in the evaluation of adverse and serious adverse events in studies that compared two types of subacromial decompression (i.e. open vs arthroscopic decompression).

Results and conclusions

Most studies presented a low/moderate risk of bias for the results and conclusion domain.[97-107] The study conducted by Billaud et al. did not provide information about loss to follow-up.[96] This can be indicative of selective reporting and may bias the overall effect of surgery. AEs could have been intentionally hidden through this omission.

Competing interest and sources of support

Most studies either partially reported competitive interests and funding sources,[96 100] or did not provide this information.[98 99 101-103 105-107]

Table 6 Single-arm studies risk of bias appraisal summary

Study	Study design	Study population	Intervention and co-intervention	Outcome measure	Results and conclusions	Competing interest and sources of support	Overall score
Billaud 2019[96]							
Eid 2012[97]							
Frieman 1995[98]							
Husby2003[99]							
Hyvönen 1998[100]							
Lim 2007[101]							
Luyckx 2011[102]							
Machner 2000[103]							
McKee 2000[104]							
Petré 1998[105]							
Pillai 2012[106]							
Rao 2006[107]							

Notes:
Scores were based on answers to the IHE tool questionnaire.
Overall scores reflect the worst level of bias found in any domain.
Low/moderate (green):no important study design flaws detected.
Serious (orange): important study design flaws detected.
Critical (red):critical study design flaws detected.
Partial information (blank circled in orange): only competing interest or sources of support were provided.
No information (blank circled in red): no information was given on competing interest or sources of support.

7.2.5 Applicability of evidence to Switzerland

It was not possible to compare the population characteristics of the included trials (k=8) to the Swiss populations in detail, as there is limited demographic information available on Swiss patients that suffer exclusively from subacromial pain. A brief comparison of the population demographics was conducted as part of the economic analysis (***Section 8.2.1***). However, this analysis was not limited to subacromial pain, as it included data related to other complex shoulder pathologies. The applicability of the evidence to Swiss practice is uncertain.

7.2.6 Findings: Efficacy of subacromial decompression versus conservative treatment

7.2.6.1 Shoulder pain

Summary of the Cochrane review by Karjalainen et al.[1]

The review by Karjalainen et al. included four RCTs in the meta-analysis.[1] The analysis ranked shoulder pain on a scale of 0 to 10. At the 3- and 6-month time points, all 4 RCTs were included in the meta-analysis.[46 47 52 80 81 83-88] Whereas, at 12 months and 24 months 3 RCTs were included[46 47 52 83-88] and at 60 months 2 RCTs were included.[46 47 83-87]

The analysis conducted by Karjalainen et al. was replicated using data published in the literature (***Appendix B***, ***Figure 15***). Some of the data varied due to rounding, without changing the outcome of the analysis. No statistically significant differences occurred between conservative treatment and subacromial decompression at 3 months (MD=-0.55; 95% CI: -1.24, 0.14, p=0.12), 24 months (MD=-0.44; 95% CI: -1.37, 0.49; p=0.07) and 60 months (MD=0.36; 95% CI: -1.17, 1.89; p=0.65). Heterogeneity and inconsistency for these subtotals were moderate to high at 24 months (χ^2=5.43, I^2=63.17%) and 60 months (χ^2=3.76, I^2=73.37%), and low at 3 months (χ^2=5.64, I^2=46.79%).

There were statistically significant differences in favour of subacromial decompression over conservative treatment at 6 months (MD=-0.56, 95% CI: -1.09, -0.02, p=0.04) and 12 months (MD=-1.01, 95% CI: -1.60, -0.42, p=0.38), but these were not clinically important. The heterogeneity and inconsistencies for these subtotals were low at 6 months (χ^2=3.79, I^2=20.82%) and 12 months (χ^2=1.95, I^2=0%).

Appraisal of the Cochrane review by Karjalainen et al.[1]

Data checking and appraisal of the meta-analysis confirmed the main findings summarised above, with some differences noted.[1] The method used in this HTA to impute the SDs from Brox et al. 1993 provided different values to those published in Karjalainen et al. (***Figure 5***).[1 80 81] In addition, Haahr et al. used a different scale for the pain outcome compared to the other included studies, where the minimum (min=0) was considered to be the worst pain outcome and the maximum (max=15) to be the best outcome.[46 83] The pain scores were converted from a scale from 15 to 0 to a scale from 0 to 10 to align with the other included studies. Due to the change in the direction of effect for the Haahr et al. publication, the significance of the 3-month and 6-month time points changed compared to the Cochrane review. In the updated analysis, a significant but not clinically important difference favouring surgery was observed at 3 months. The heterogeneity and inconsistency at the 12-month time point were low.

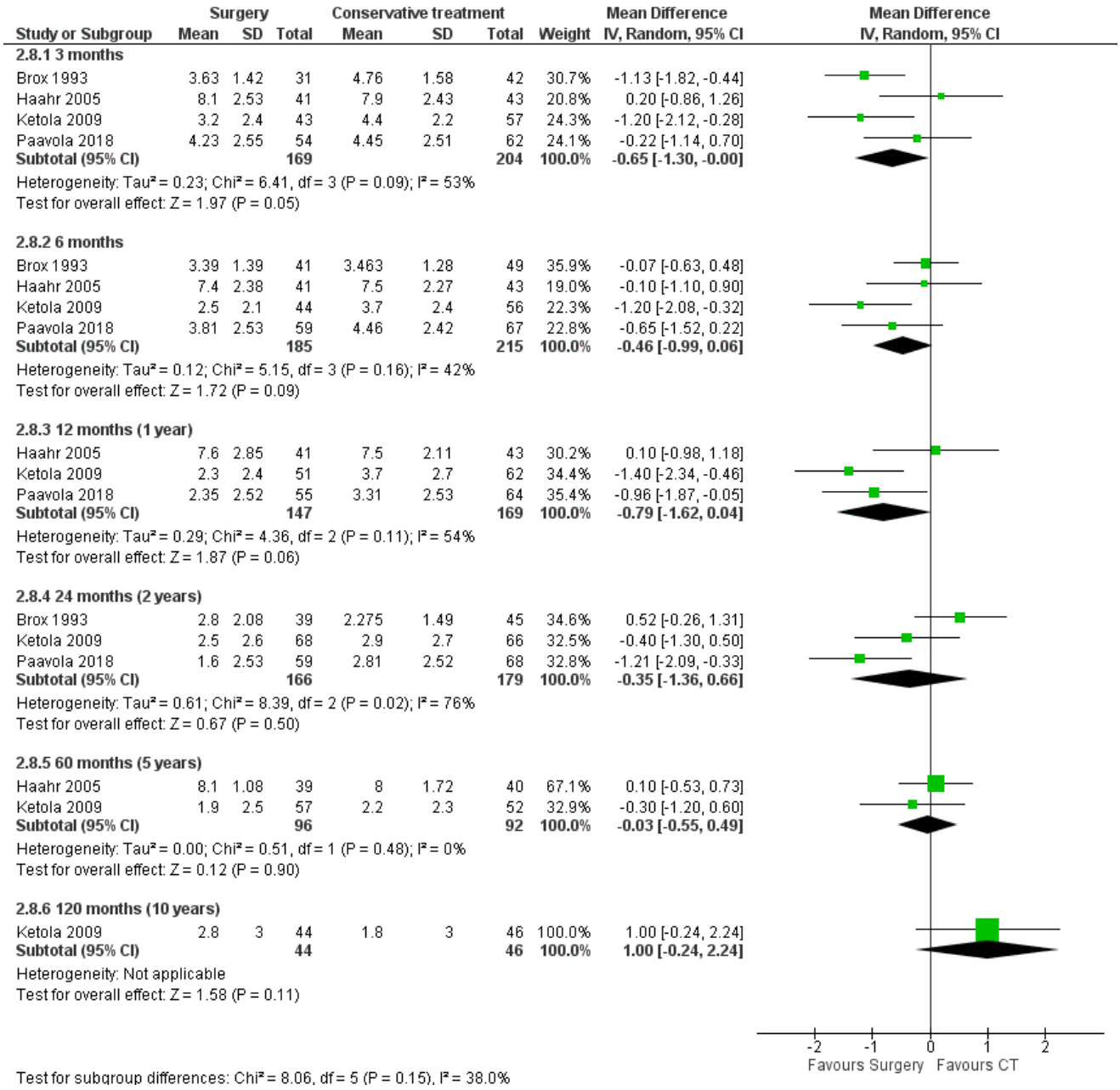

Figure 5 Forest plot indicating the mean difference in pain for subacromial decompression compared to conservative treatment from 3 months to 120 months with newly imputed SDs

Abbreviations:
CI = confidence interval, **CT** = conservative treatment, **SD** = standard deviation.
Notes:
Scores were adjusted to fit 0–10 scale.
Missing SDs from Brox 1993 were imputed using the Bracken 1992 method in the metagear R package.[77 80 81]

7.2.6.2 Shoulder function

Summary of the Cochrane review by Karjalainen et al.[1]

The meta-analysis by Karjalainen et al. included a total of six RCTs for shoulder function comparing subacromial decompression and conservative treatment.[1 45-47 52 80-89]

The analysis conducted by Karjalainen et al. was replicated using data published in the literature. Some of the data varied due to rounding without changing the outcome of the analysis. Before the 24-month mark, subacromial decompression did not improve shoulder function in patients with subacromial pain compared to conservative treatment. The 95% CI included zero, at three different time points in the meta-analysis: 3 months (MD=6.11, 95% CI: -5.57, 17.79, p=0.31), 6 months (MD=3.66, 95% CI:-2.25, 9.58, p=0.23) and 12 months (MD=3.24, 95% CI: -8.08, 14.55, p=0.57) (***Appendix B***, ***Figure 16***). Three RCTs were included in the analysis at 3 months,[46 47 80 81 83-87] 3 were included at 12 months,[46 47 83-87 89] and 4 were included in the 6-month analysis.[46 47 52 80 81 83-88] Heterogeneity and inconsistencies in the meta-analyses ranged from substantial to considerable at 3 months (χ^2=10.78, I^2=81.45%), 6 months (χ^2=7.10, I^2=57.76) and 12 months (χ^2=8.39, I^2=76%). It is important to note that the study by Ketola et al. appears to heavily favour surgery at 3, 6 and 12 months.[47 84-87]

Statistically significant differences occurred at time points from 24 months to 120 months. Compared to conservative treatment, subacromial decompression improved shoulder function at 24 months by 4.94 points (95% CI: 0.77, 9.11, p=0.02), at 60 months by 7.63 points (95% CI: 0.17, 15.09, p=0.04), and at 120 months by 9.54 points (95% CI:1.93, 17.15, p=0.01). The difference at 120 months was clinically important.[1] The meta-analysis included 5 RCTs at 24 months,[45 47 52 80-82 84-89] and 2 RCTs at 60 months[47 84-87 89] and 120 months.[45 47 82 84-87] Heterogeneity and inconsistency at 24 months (χ^2=5.34, I^2=25%), 60 months (χ^2=0.37, I^2=0%) and 120 months (χ^2=0.97, I^2=0%) were low.

The Karjalainen et al. meta-analysis did not provide an overall score for the experience of shoulder function in patients who received subacromial decompression compared to conservative treatment.[1]

Appraisal of the Cochrane review by Karjalainen et al.[1]

The appraisal of the meta-analysis suggested a few potential issues with the review by Karjalainen et al.[1] The first issue identified during data checking was that SDs imputed in order to meta-analyse the studies by Ketola et al. and Peters and Kohn could not be verified.[1 47 84-87 89] The second issue was that Peters and Kohn did not report a shoulder function outcome at 60 months.[89] The RCT did report shoulder function results for 36 and 48 months but these were not reported in the meta-analysis by Karjalainen et al.[1 89] The 60-month outcome could not be verified. For these reasons, the meta-analysis was replicated with newly imputed SDs for the studies by Ketola et al. and Peters and Kohn, as well as

the addition of the 36-month and 48-month time points and removal of the 60-month time point.[47 84-87 89] In the analysis shoulder function was measured using a 0-100 scale; however, the metrics included were not limited to the Constant-Murley Score.

The updated meta-analysis (***Figure 6***) verifies most of the results of the review by Karjalainen et al.[1] In the newly computed meta-analysis, there were no statistical differences observed at the 3-month, 6-month ,and 12-month time points . Heterogeneity and inconsistencies at the 6-month time point remained moderate between the two analyses. Heterogeneity and inconsistencies at 3 months and 12 months remained substantial for both time points.

The mean differences observed at the 24-month and 120-month time points were statistically significant, but only the differences observed at 120 months were clinically important. These results suggest that subacromial decompression improved shoulder function in patients with subacromial pain, compared to conservative treatment. This analysis had low heterogeneity and inconsistencies at 24 months and 120 months.

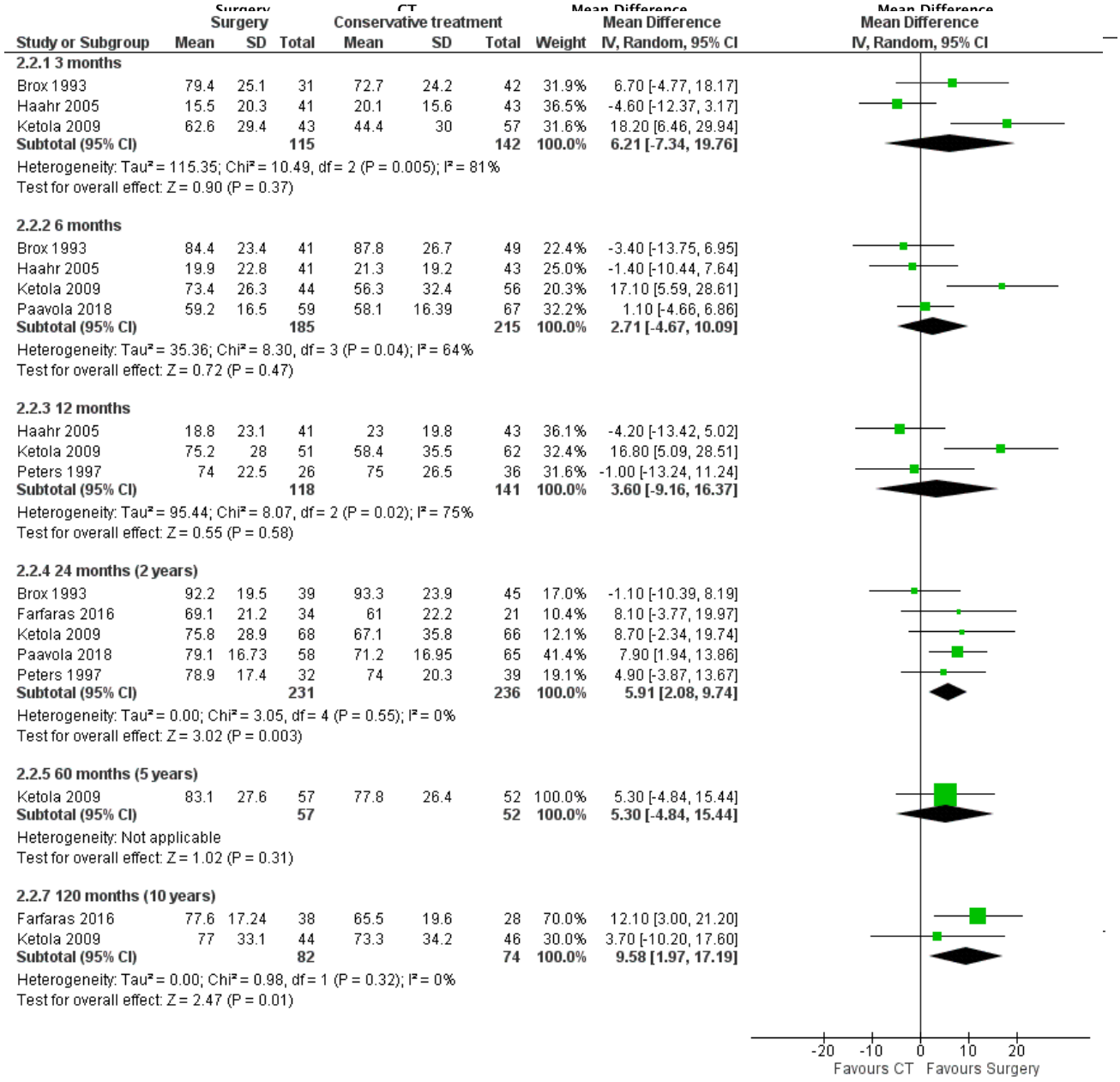

Figure 6 Forest plot indicating the mean difference in shoulder function for subacromial decompression compared to conservative treatment from 3 to 120 months with newly imputed SDs

Abbreviations:
CI = confidence interval, **CT** = conservative treatment, **SD** = standard deviation.
Notes:
Scores were adjusted to fit 0–100 scale.
Missing SDs from Brox 1993 and Peters 1997 were imputed using the Bracken 1992 method in the metagear R package.[77 80 81 89] Peters et al. provided data at 3 years and 4 years but was omitted for these time points as only one or no other study was available to impute the missing SD.[89] Brox et al. provided data at 2.5 years but was omitted for the same reason.[80 81]

7.2.6.3 Health-related quality of life

Summary of the Cochrane review by Karjalainen et al.[1]

The Karjalainen et al. meta-analysis included three RCTs for HRQoL comparing subacromial decompression and conservative treatment.[45 47 52 82 84-88] The meta-analysis was performed using SMD because Paavola et al. and Ketola et al. reported HRQoL using 15 dimensions (15D) (scale 0–1), and Farfaras et al. used SF-36 (scale 0–100).[45 47 52 82 84-88]

The analysis conducted by Karjalainen et al. was replicated using data published in the literature (***Appendix B***, ***Figure 17***). There were no statistically significant differences reported at any time point, ranging from 3 months to 120 months. Heterogeneity at both the 24-month (χ^2=1.29, I^2=22.23%) and 120-month (χ^2=0.12, I^2=0%) timepoints were low.

Appraisal of the Cochrane review by Karjalainen et al.[1]

Appraisal of the Karjalainen et al. meta-analysis identified a potential issue.[1] This issue related to the inability to verify SD imputed from Paavola et al. at the 3-month, 6-month and 12-month time points in the meta-analysis by Karjalainen et al., probably due to rounding in the figure presented.[1]

The meta-analysis (***Figure 7***) was updated by using the SD values imputed (formula described in ***Section 7.1.5.6***) from Paavola et al. at the 3-month, 6-month, 12-month and 24-month time points.

The updated meta-analysis results for the 24-month time point suggests no effect, as the result was not statistically significant.[52 88] The pooled result for the 12-month time point was not estimable due to the outcomes published by Paavola et al.[52 88] Heterogeneity and inconsistency at the 24-month time point was moderate.

In contrast with the Karjalainen et al. analysis, the new analysis showed a statistically significant and clinically important difference in HRQoL at 120 months favouring decompression, with low heterogeneity and inconsistencies (***Figure 7***).

Individual RCTs were included in the analysis at 3 months, 6 months, 24 months, 36 months, 48 months and 60 months. None of these time points reported statistically significant results.

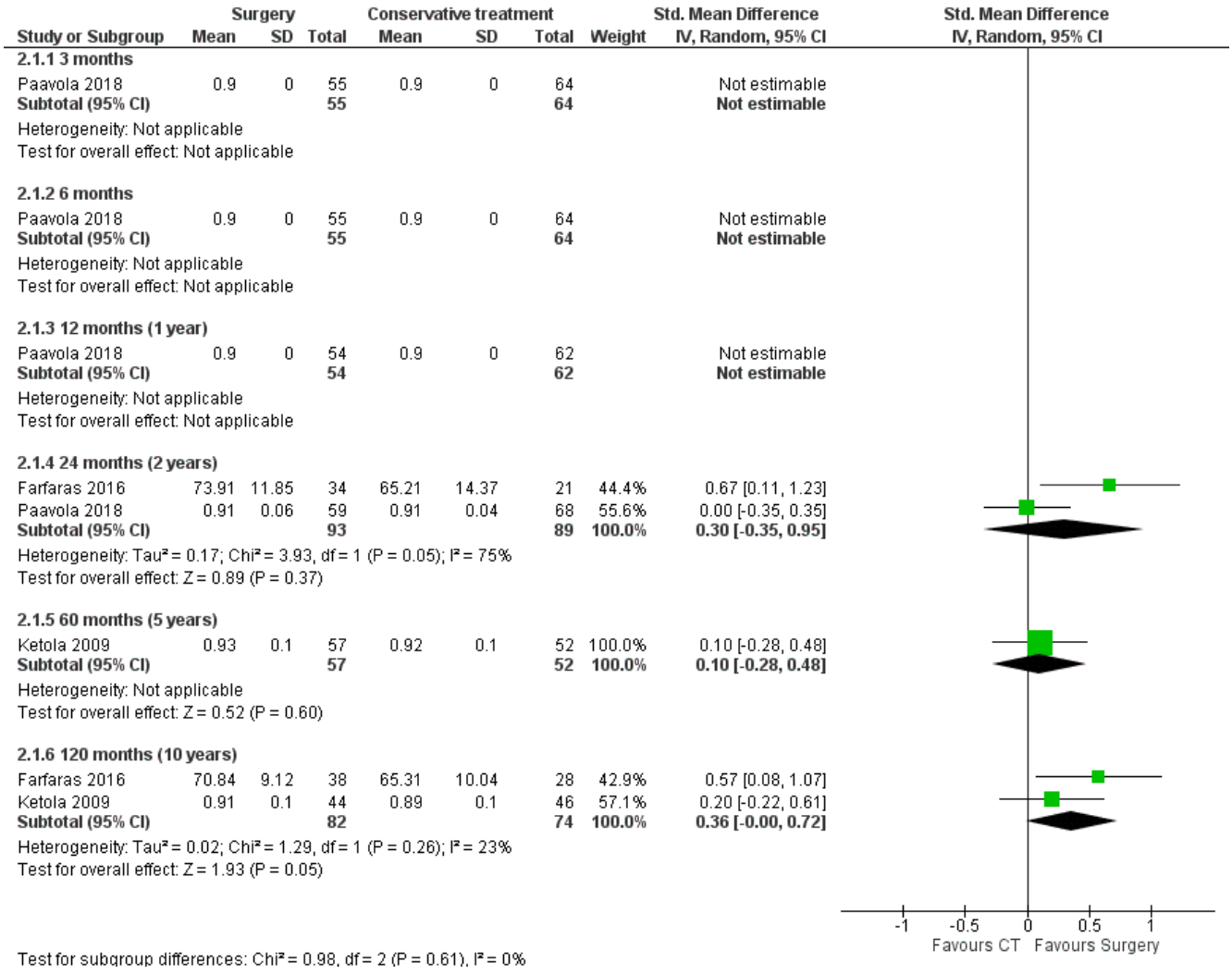

Figure 7 Forest plot indicating the standardised mean difference in HRQoL for subacromial decompression compared to conservative treatment from 3 to 120 months with newly imputed SDs

Abbreviations:
CI = confidence interval, **CT** = conservative treatment, **HRQoL** = health-related quality of life, **SD** = standard deviation.
Notes:
SDs were calculated using means and 95% CIs and the formula provided in section ***7.1.5.6***.

7.2.6.4 Ability to return to work

Summary of the Cochrane review by Karjalainen et al.[1]

The Karjalainen et al. meta-analysis included four RCTs examining ability to return to work for patients after subacromial decompression compared to conservative treatment for subacromial pain. [1 46 47 52 80 81 83-88]

The analysis reported six time points, of which three included more than one RCT. No statistically significant differences were reported at 6 months (RR=1.05, 95% CI: 0.81, 1.36, p=0.7), 24 months (RR=0.87, 95% CI: 0.7, 1.07, p=0.19) or 60 months (RR=1.13, 95% CI: 0.97, 1.32, p=0.11).[1 46 47 52 80 81 83-88] Heterogeneity and inconsistency between these time points ranged from low to moderate, with 6 months (χ^2=1.84, I^2=45.62%) and 24 months (χ^2=1.63, I^2=38.69%) reporting moderate heterogeneity, and 60 months recording low heterogeneity (χ^2= 0.69, I^2=0%).

The 3-month (RR=0.96, 95% CI: 0.75, 1.22), 12-month (RR=0.98, 95% CI: 0.85, 1.13) and 120-month (RR=1.07, 95% CI: 0.97, 1.18) time points included single RCTs and did not indicate any statistically significant differences.[1 47 52 84-88] Given that single studies were included at these time points, heterogeneity and inconsistency could not be calculated.

The Karjalainen et al. meta-analysis did not provide an overall estimate for ability to return to work after subacromial decompression compared to conservative treatment for people with subacromial pain.[1]

Appraisal of the Cochrane review by Karjalainen et al. 2019[1]

When comparing subacromial decompression to conservative treatment for the ability to return to work, the appraisal of the meta-analysis could not be validated or re-analysed. The only trial and time point that could be verified was the Haahr et al. study at the 5-year time point.[46 83]

There were two main issues identified. The first issue was that the publications related to the study by Paavola et al.[52 88] do not detail any data related to patients' ability to work or return to work following subacromial decompression. However, this does not exclude the possibility that data used in the meta-analysis was provided to Karjalainen et al. by Paavola et al.[1 52 88] The second issue is that the numerators could not be confirmed as they appear to have been imputed from the trial data extracted from the respective publications.

7.2.6.5 Ability to return to leisure activities

Summary of the Cochrane review by Karjalainen et al.[1]

The systematic review by Karjalainen et al. identified one RCT (Paavola et al.) that reported on ability to return to leisure activities after subacromial decompression compared to conservative treatment.[52 88] The Karjalainen et al. meta-analysis did not report any statistically significant differences at the four reported time points: 3 months (RR=1.31, 95% CI: 0.91, p=015), 6 months (RR=1.12, 95% CI: 0.83, 1.50, p=0.47), 12 months (RR= 1.08, 95% CI: 0.88, 1.33, p=0.46) and 24 months (RR=1.06, 95% CI: 0.88, 1.27, p=0.64). Since the meta-analysis was based on a single study for each time point, heterogeneity and inconsistency could not be calculated.

Appraisal of the Cochrane review by Karjalainen et al. 2019[1]

The appraisal could not confirm all of the results of the Karjalainen et al.[1] review summarised above. The publications associated with Paavola et al., could confirm the risk ratio reported at 24 months but not for the other time points.[52 88] This does not exclude the possibility that data used in the meta-analysis was provided to Karjalainen et al. by Paavola et al.[1 52 88]

7.2.6.6 Further progression of subacromial pain

Summary of the Cochrane review by Karjalainen et al.[1]

The Karjalainen et al. review included two RCTs that assessed treatment failure in patients with subacromial pain.[1 45 47 82 84-87] Karjalainen et al. defined treatment failure as tears during the trial follow-up time periods.[1] The meta-analysis reported results from single RCTs, which found no statistically significant differences at 60 months (5 years) (RR=1, 95% CI: 0.40, 2.52, p=1.00) and 156 months (13 years) (RR=0.37, 95% CI: 0.07, 1.87, p=0.23). Since individual RCTs were included at each time point in the meta-analysis, heterogeneity and inconsistency could not be calculated.

Appraisal of the Cochrane review by Karjalainen et al.[1]

The appraisal of the Karjalainen et al. systematic review confirms the findings summarised above.[1]

7.2.7 Findings: Efficacy of subacromial decompression versus placebo (sham procedure)

7.2.7.1 Shoulder pain

Summary of the Cochrane review by Karjalainen et al.[1]

The Karjalainen et al. systematic review included two RCTs in the analysis.[1 19 44 52 88] The analysis ranked shoulder pain on a scale of 0 to 10. There were no statistically significant differences reported up to 12 months (***Appendix B***, ***Figure 18***). One study was included at 24 months, which reported a significant difference favouring decompression (MD=0.9, 95% CI: -1.79, -0.01, p=0.05), but this difference was not clinically significant.

The systematic review and meta-analysis did not provide an overall estimate for experience of shoulder pain in patients who underwent subacromial decompression compared to placebo (sham surgery).[1]

Appraisal of the Cochrane review authored by Karjalainen et al.[1]

The appraisal of the meta-analysis, indicated that one study (Brox et al. 1993) was missing from the review by Karjalainen et al.[1 80 81] Brox et al. reported pain on activity on a scale of 1 to 9; however it was converted to a 0-to-10 scale using the formula in ***Section 7.1.5.6***.[80 81]

The meta-analysis was replicated and the additional study with data for pain on activity was added. Missing SDs from Brox et al. were calculated using the Bracken 1993 methods from the metagear package in R (***Figure 8***).[77 80 81] The addition of the study by Brox et al. to the 6-months comparison did not change the results.[80 81] There was a noticeable change to heterogeneity and inconsistency between the present analysis and that of Karjalainen, which were considerable. Similarly, to the replicated meta-analysis, this new analysis found a statistically significant but not clinically important difference in shoulder pain at 24 months, where subacromial decompression improved the pain experienced by patients.

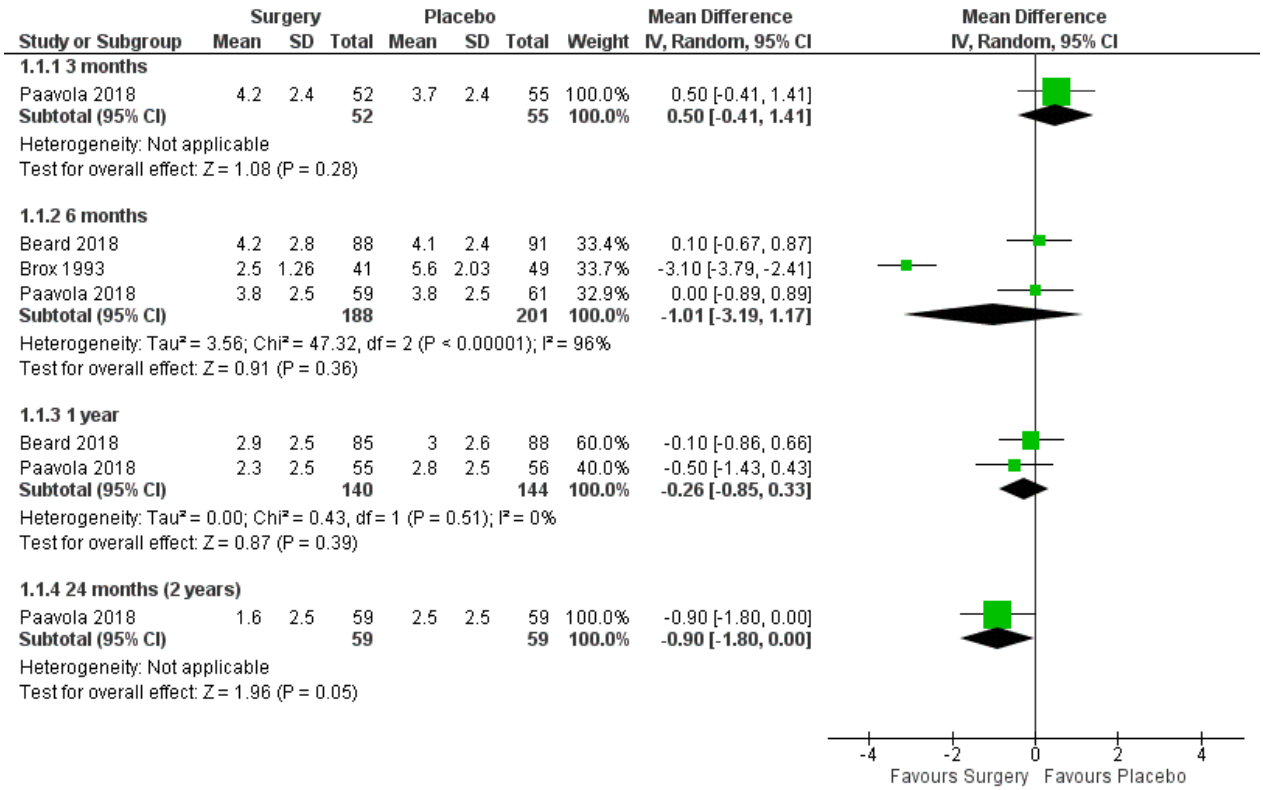

Figure 8 Forest plot indicating the mean difference in shoulder pain for subacromial decompression compared to placebo (sham surgery) from 3 to 24 months, with newly imputed SDs

Abbreviations:
CI = confidence interval, **SD** = standard deviation.
Notes:
Scores were adjusted to fit 0–10 scale. Missing SDs from Brox 1993 were imputed using the Bracken 1992 method in the metagear R package.[77 80 81] Brox et al. provided data at 2.5 years but was omitted for this time point as no other study was available to impute the missing SD.[80 81]

7.2.7.2 Shoulder function

Summary of the Cochrane review by Karjalainen et al.[1]

Karjalainen et al. included two RCTs for shoulder function comparing subacromial decompression to placebo in the meta-analysis at 6 months and 12 months.[1 19 44 52 88] Additionally, one RCT was included in the meta-analysis at 24 months.[52 88] The analysis ranked shoulder function on a scale 0 to 100.[1] The analysis reported no statistically significant differences at 6 (MD=-3.72, 95% CI: -8.72, 1.28, p=0.14), 12 (MD=2.76, 95% CI: -1.36, 6.87, p=0.19) or 24 months (MD=4.2, 95% CI: -1.61, 10.01) (***Appendix B, Figure 19***). Heterogeneity and inconsistencies in both meta-analyses were low with I^2= 29.5% (χ^2=1.42) at 6 months and I^2 = 0% (χ^2=0.48) at 12 months.

Appraisal of the Cochrane review by Karjalainen et al.[1]

Appraisal of the Karjalainen et al. meta-analysis identified two potential issues.[1] The first related to the 12-month time point: Karjalainen et al.[1] reported that Paavola et al. listed a shoulder function score (Constant-Murley score); however the publication by Paavola et al. listed the score as unavailable at that time point (Paavola et al., supplementary appendix 2).[52] The second concern was that one study (Brox et al.) was missing from the Karjalainen et al. review.[1 80 81]

The meta-analysis was updated (***Figure 9***) with the addition of the Brox et al. study (6 months) and the removal of the Paavola et al. study (12 months).[52 80 81 88] Brox et al. reported shoulder function using the Neer score (scale 10–100[80 81]), which was converted to a 0–100 scale using the formula in ***Section 7.1.5.6***. Missing SDs from Brox et al. were imputed using the Bracken method in the metagear R package.[77 80 81] The meta-analysis below ranked shoulder function on a scale of 0 to 100, with 100 being the best. The updated analysis did not alter the findings of the Karjalainen et al review, reporting no statistically significant at any time point.

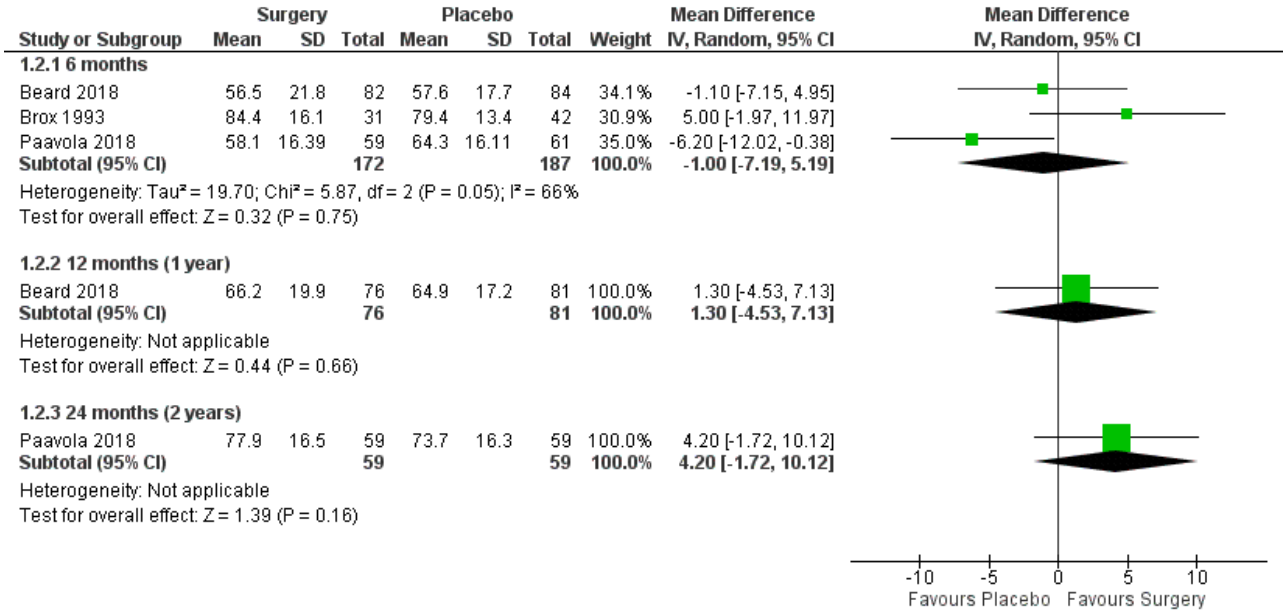

Figure 9 Forest plot indicating the mean difference in shoulder function for subacromial decompression compared to placebo (sham surgery) from 6 to 30 months, with newly imputed SDs

Abbreviations:
CI = confidence interval, **SD** = standard deviation.
Notes:
Scores were adjusted to fit 0–100 scale. Missing SDs from Brox 1993 were imputed using the Bracken 1992 method in the metagear R package.[77 80 81] Brox et al. provided data at 5 years but was omitted for these time points as no other study was available to impute the missing SD.[80 81]

7.2.7.3 Health-related quality of life

Summary of the Cochrane review by Karjalainen et al.[1]

The Karjalainen et al. meta-analysis included two RCTs for HRQoL outcomes comparing subacromial decompression and placebo (sham surgery).[1 19 44 52 88] The meta-analysis was performed using SMDs because Paavola et al. reported HRQoL using 15D (0–1) and Beard et al. used EuroQoL 5-dimensions 3-level questionnaire form (EQ-5D).[19 44 52 88]

The analysis conducted by Karjalainen et al. was replicated using data published in the literature.[1] (***Appendix B***, ***Figure 20***).The published meta-analysis indicated that there were no significant differences at any time point from 3 to 24 months.

Appraisal of the Cochrane review by Karjalainen et al.[1]

Appraisal of the meta-analysis with updated SDs confirmed the main findings summarised above;[1] no statistically significant differences were observed (***Figure 10***).

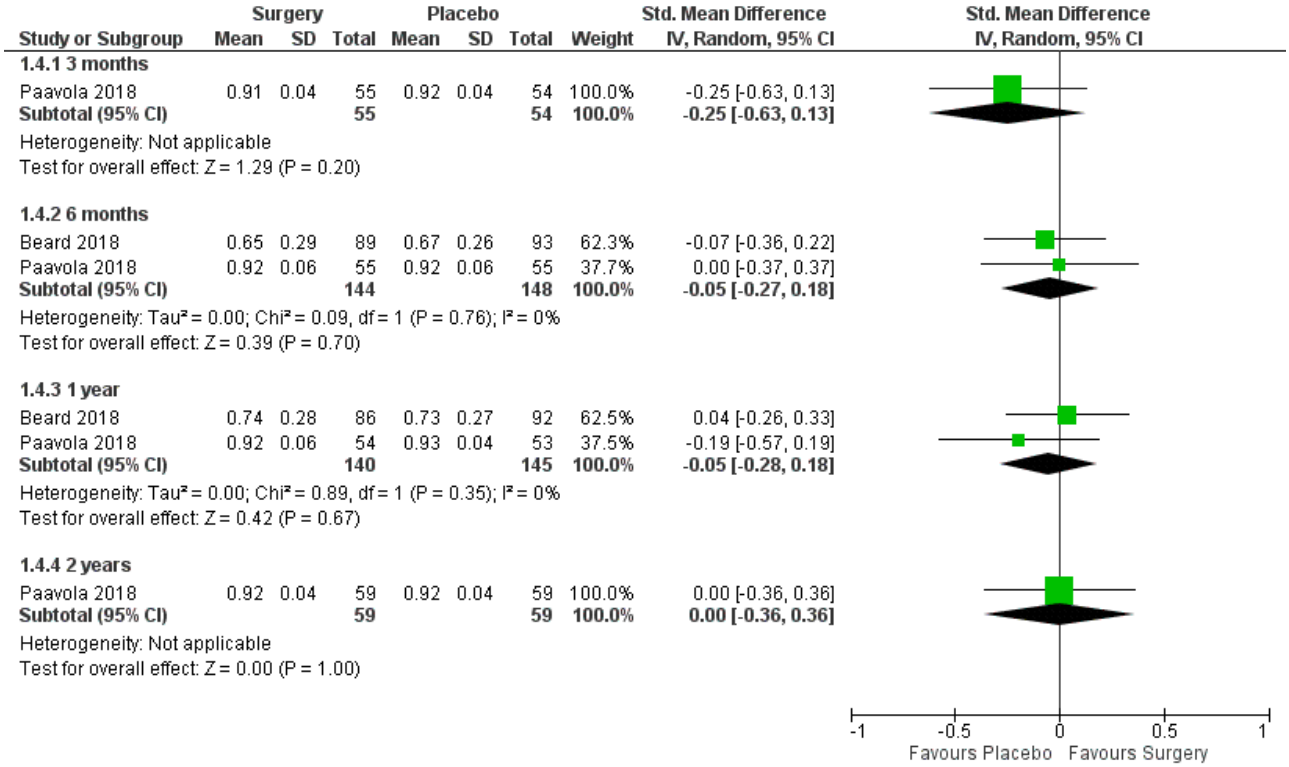

Figure 10 Forest plot indicating the standardised mean difference in HRQoL for subacromial decompression compared to placebo from 3 months to 24 months with newly calculated SDs

Abbreviations:
CI = confidence interval, **HRQoL** = health-related quality of life, **SD** = standard deviation.
Notes:
SDs were calculated using means and 95% CIs and the formula provided in section ***7.1.5.6***.

7.2.7.4 Ability to return to work

Summary of the Cochrane review by Karjalainen et al.[1]

According to Karjalainen et al., one RCT (Paavola et al.) reported how subacromial decompression to treat subacromial pain could affect a patient's ability to work.[1 52 88] The meta-analysis did not report any statistically significant results at 3 months (RR=0.94, 95% CI: 0.74, 1.21, p=0.65), 6 months (RR=1.08, 95% CI: 0.91, 1.28, p=0.37), 12 months (RR=1.05, 95% CI: 0.89, 1.23, p=0.58) or 24 months (RR=0.98, 95% CI: 0.83, 1.15, p=0.79). Given that the meta-analysis included one study by Paavola et al., heterogeneity and inconsistency could not be calculated.[52 88]

Appraisal of the Cochrane review by Karjalainen et al.[1]

Appraisal of the meta-analysis could not confirm the findings detailed in the review by Karjalainen et al. summarised above.[1] This was because the publications related to the study by Paavola et al. did not report any data related to ability to work or return to work. This does not exclude the possibility that data used in the meta-analysis was provided to Karjalainen et al. by Paavola et al.[1 52 88] An additional issue identified was that the study by Brox et al. was not included in the meta-analysis even though the trial reported data on shoulder-related absences from work at 6 months and 30 months.[80 81]

7.2.7.5 Ability to return to leisure activities

Summary of the Cochrane review by Karjalainen et al.[1]

The Karjalainen et al. meta-analysis included one RCT (Paavola et al.) that reported return to leisure activities compared to placebo (sham procedure).[1 52 88] The meta-analysis did not report any statistically significant differences at the four included time points of 3 months (RR=0.82, 95% CI: 0.62, 1.1, p=0.19), 6 months (RR=0.94, 95% CI: 0.71, 1.23, p=0.64), 12 months (RR= 0.95, 95% CI: 0.79, 1.15, 0.60) and 24 months (RR= 1.05, 95% CI: 0.87, 1.26, p=0.63). Given that the meta-analysis included a single study by Paavola et al., heterogeneity and inconsistency could not be calculated.[52 88]

Appraisal of the Cochrane review by Karjalainen et al.[1]

Appraisal of the meta-analysis could not confirm all of the findings detailed in the review by Karjalainen et al.[1] summarised above. The publications associated with the study by Paavola et al. could confirm the risk ratio reported at 24 months but not for other time points.[52 88] This does not exclude the possibility that data used in the meta-analysis was provided to Karjalainen et al. by Paavola et al.[1 52 88]

7.2.7.6 Further progression of subacromial pain

Summary of the Cochrane review by Karjalainen et al.[1]

The Karjalainen et al. systematic review does not include any RCTs that assessed the further progression of subacromial pain (treatment failure) after subacromial decompression compared to placebo (sham surgery).

Appraisal of the Cochrane review by Karjalainen et al.[1]

The appraisal of the Karjalainen et al. systematic review confirms the findings summarised above.[1]

7.2.8 Findings: Efficacy of subacromial decompression versus no treatment

7.2.8.1 Shoulder pain

Summary of the Cochrane review by Karjalainen et al.[1]

One RCT, by Beard et al., examined shoulder pain (numeric rating scale (NRS) scale 1–10) experienced by patients who underwent subacromial decompression compared to patients who had no treatment.[1 19 44] The study published two time points and found that at 6 months subacromial decompression improved shoulder pain by 0.80 points (MD=-0.80 95% CI: -1.6, 0.00, p=0.05) and at 12 months shoulder pain improved by 1.2 points (MD= -1.20, 95% CI: -2.04,0.36, p=0.005) compared to no treatment (***Figure 21***). Even though the results where statistically significant at both time points, the differences between subacromial decompression and no treatment were not clinically important. Since a single study was included at each time point, heterogeneity and inconsistency could not be calculated.

The review by Karjalainen et al. did not provide an overall estimate for experience of shoulder pain in patients who underwent subacromial decompression compared to no treatment.[1]

Appraisal of the Cochrane review by Karjalainen et al.[1]

The appraisal of the meta-analysis confirmed the findings summarised above.[1]

7.2.8.2 Shoulder function

Summary of the Cochrane review by Karjalainen et al.[1]

A single RCT by Beard et al. examined shoulder function (Constant-Murley score, 1–100 scale) of patients who underwent subacromial decompression compared to patients who had no treatment.[1 19 44] Clinically important differences favouring subacromial decompression over no treatment were reported at 6 (MD=11.10, 95% CI: 4.52, 17.68, p<0.001) and 12 months (MD= 9.50, 95% CI: 2.66, 16.34, p=0.007) (***Figure 22***). Given that a single study was included at each time point, heterogeneity and inconsistency could not be calculated.

Appraisal of the Cochrane review by Karjalainen et al.[1]

The appraisal of the meta-analysis confirmed the overall findings summarised above.[1]

7.2.8.3 Health-related quality of life

Summary of the Cochrane review by Karjalainen et al.[1]

One RCT was included in the Karjalainen et al review.[1] The trial by Beard et al. examined QoL using EQ-5D in patients that underwent subacromial decompression, compared to patients who had no treatment.[19 44] Two time points (6 months and 12 months) were published. The results at 6 months reported a statistically significant and clinically important difference (MD=0.13, 95% CI: 0.03, 0.23, p<0.001) favouring subacromial decompression over no treatment (***Figure 23***). In contrast, at 12 months the analysis indicated that subacromial decompression does not affect HRQoL (SMD=0.08, 95% CI: -0.01, 0.17, p=1.00) compared to no treatment. Since one study was included, heterogeneity and inconsistency could not be calculated.

Karjalainen et al. did not provide an overall estimate of HRQoL outcomes for patients who underwent subacromial decompression compared to no treatment.[1]

Appraisal of the Cochrane review by Karjalainen et al.[1]

Appraisal of the meta-analysis confirmed the findings summarised above.[1]

7.2.8.4 Ability to return to work

Summary of the Cochrane review by Karjalainen et al.[1]

The systematic review by Karjalainen et al. did not include any RCTs that assessed the ability of patients with subacromial pain to return to work after subacromial decompression, compared with no treatment.

Appraisal of the Cochrane review by Karjalainen et al.[1]

Appraisal of the systematic review by Karjalainen et al. confirms the findings summarised above.[1]

7.2.8.5 Ability to return to leisure activities

Summary of the Cochrane review by Karjalainen et al.[1]

The Karjalainen et al. systematic review did not include any RCTs that assessed the ability of a patient with subacromial pain to return to leisure activities after subacromial decompression, compared to no treatment.

Appraisal of the Cochrane review by Karjalainen et al.[1]

Appraisal of the Karjalainen et al.[1] systematic review confirmed the findings summarised above.

7.2.8.6 Further progression of subacromial pain

Summary of the Cochrane review by Karjalainen et al.[1]

The Karjalainen et al. systematic review did not include any RCTs that assessed further progression of subacromial pain (treatment failure) after subacromial decompression compared to no treatment.

Appraisal of the Cochrane review by Karjalainen et al.[1]

Appraisal of the Karjalainen et al.[1] systematic review confirms the findings summarised above.

7.2.9 Findings safety

Evidence pertaining to safety obtained from RCTs

Summary of the Cochrane review by Karjalainen et al.[1]

In terms of safety outcomes, the Cochrane review authored by Karjalainen et al., included two RCTs for the comparison of subacromial decompression and placebo or subacromial decompression and non-operative conservative treatment (***Table 7, Table 37***).[1 19 52] The meta-analysis published in the Cochrane review concluded that there was no clinically important difference in the incidence of total AEs between study arms (***Figure 24***).[1] Due to very low event occurrence, the authors cautioned that this effect could not be entirely confirmed and they narratively summarised the main outcomes.[1]

In short, AEs were observed in 3% of participants across treatment arms.[1] Frozen shoulder or transient minor complications of surgery such as temporary swelling in the brachial area, were reported in 34 per 1,000 patients who received subacromial decompression compared to 37 per 1,000 patients who received placebo or conservative treatment (RR=0.91, 95% CI: 0.31, 2.65, p=0.86).[1] There were no serious AEs reported in the selected RCTs.

Appraisal of the Cochrane review by Karjalainen et al.[1]

Appraisal of the meta-analysis from Karjalainen et al. could not confirm the reported outcomes.[1] The present analysis differed slightly due to a different total population recorded in the non-operative group, combining placebo (i.e. arthroscopy) and no treatment arms (***Figure 11***). This updated meta-analysis does not change the outcome of the analysis and does not affect the final conclusion of the report regarding safety outcomes. It does change the overall AE estimate for patients who received placebo or conservative treatment to 18 per 1,000 patients (n=6/164), while the present extraction reports an AE occurrence of 30 per 1,000 patients (n=5/165) who received a decompression. Heterogeneity and inconsistency for the updated meta-analysis remained low.

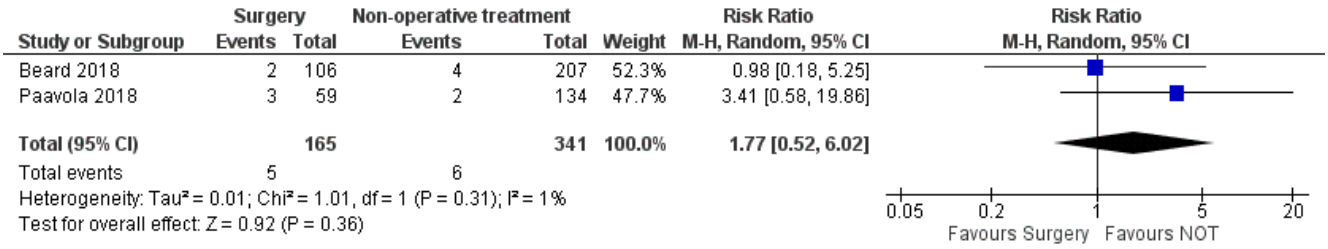

Figure 11 Forest plot indicating the total risk ratio for total adverse events for subacromial decompression compared to non-operative treatment

Abbreviations:
CI: confidence interval, **NOT**: non-operative treatment.
Notes:
Non-operative treatment in this case refers to placebo and conservative treatment; surgery corresponds to subacromial decompression.

Table 7 Summary of the evidence pertaining to safety obtained from RCTs

Study ID	Population	Follow-up	Intervention	Comparator	Adverse events	Serious adverse events
CSAW [19 44] (UK)	Total: n=313 ASD: n=106 Investigative arthroscopy (placebo): n=103 Conservative treatment: n=104	6, 12 months	ASD	Placebo (sham) Conservative treatment (active monitoring with specialist reassessment)	Frozen shoulder: Total: 2.5% (n=6) ASD: 2.8% (n=2) Placebo: 3.1% (n=2) Conservative treatment: 3.1% (n=2)	None observed
FIMPACT [52 88] (Finland)	Total: n=193 ASD: n=59 Placebo: n=63 Conservative treatment: n=71	24 months	ASD	Placebo (sham) Conservative treatment	Temporary swelling in the brachial area related to a brachial plexus block: Total: 0.8% (n=1) Placebo: 1.6% (n=1) Frozen shoulder: Total: 3.3% (n=4) ASD: 5.1% (n=3) Placebo: 1.6% (n=1) Conservative treatment: 2.8% (n=2)	None observed

Abbreviations:
ASD = arthroscopic subacromial decompression, **CSAW** = can shoulder arthroscopy work, **FIMPACT** = Finnish shoulder impingement arthroscopy controlled trial, **UK**: United Kingdom.

Evidence pertaining to safety obtained from non-randomised studies

In addition to the two RCTs presented in the Cochrane review, seven non-randomised studies were added to the present safety assessment of subacromial decompression for the treatment of subacromial pain, which represented a total cohort of 915 patients (***Table 8***, ***Table 38***).[1 38 53 91-95 108]

In five of these studies, no peri- or post-operative AEs were observed.[38 53 91 93 95] Two studies reported surgery-related AEs.[92 94] Some patients who received an arthroscopic subacromial decompression (ASD) experienced postoperative stiffness (4.9%, n=14/287), deep infections (0.3%, n=1/287), or temporary frozen shoulder (1.1%, n=2/181).[92 94] Open subacromial decompressions (OSDs) led to complications in a few patients, such as superficial wound infections (2.5%, n=2/80), haematoma (1.3%, n=1/80) or temporary frozen shoulder (3.8%, n=3/80).[94] Globally, subacromial decompression generated infections in 0.9% (n=5/548) of patients and temporary frozen shoulders in 1.9% (n=5/261) of patients who participated in studies where AEs were detected.[92 94] AEs were observed in 2.8% (n=26/915) of subacromial decompression surgeries with 1.5% (n=14/915) of the total cohort experiencing postoperative stiffness, 0.1% (n=1/915) of patients presenting with haematoma, 0.8% (n=8/915) of patients treated for postoperative infections and 0.5% (n=5/915) of patients presenting with temporary frozen shoulder symptoms.[92 94]

The review by Karjalainen et al. also evaluated observational studies for safety outcomes. In these observational studies serious AEs measured within 30 days of surgery occurred in 5 or 6 per 1,000 patients and included deep infection, pulmonary embolism, nerve injury and death.[1] The authors reported that in the absence of precise estimates, the risk of serious AEs was less than 1%, based on moderate-certainty evidence, downgraded due to imprecision.[1] In the current evaluation, serious AEs were observed in one of the included non-randomised studies.[92] Inderhaug et al. considered that a total of 10% of patients (n=15 per 140 patients or 107 per 1,000 patients treated by subacromial decompression only) presented with serious AEs that resulted in re-operations.[92] Eight patients (5.7%, n=8/140) had to receive a revision acromioclavicular resection, five received a second subacromial decompression (3.6%, n=5/140), one received a capsulotomy for a frozen shoulder (0.7%, n=1/140) and one patient underwent a superior-labral tear from anterior to posterior (SLAP) repair (0.7%, n=1/140).[92]

Table 8 Summary of the evidence pertaining to safety obtained from non-randomised studies

Study ID	Population	Follow-up	Intervention	Adverse events	Serious adverse events
Connor 2000 [91]	Total: n=36 Group I: n=18 Group II: n=18	Mean: 21 months (range: 8–57) Mean: 18 months (range: 19–61) Mean: 23.7 months (range: 12–57)	OSD (n=16) ASD (n=16)	None observed	None observed
Inderhaug 2018 [92]	Total: n=287 Group A: n=140 Group B: n=147	Mean: 90 months	ASD ASD + RC repair (debridement)	Postoperative stiffness (4.9%, n=14) Infection (0.3%, n=1) Deep infection (0.3%, n=1)	Total of Serious AEs leading to re-operation: 10% (n=15 of 140) Acromioclavicular resection (5.7%, n=8) New subacromial decompression (3.6%, n=5) Capsulotomy for frozen shoulder (0.7%, n=1) SLAP repair (0.7%, n=1)
Järvelä 2010 [53]	Total : n=80 Outpatients : n=40 Inpatients : n=40	Mean: 33 months (range: 24–59) Mean: 32 months ± 6 SD Mean: 34 months ± 11 SD	ASD	None observed	None observed
Machner 2001 [38]	Total: n=152 Group I: n=22 Group II: n=69 Group IIIa: n=27 Group IIIb: n=34 (groups reflect severity of impingement)	Mean: 32.5 months (range: 8–72)	Arthroscopic bursectomy (n=22) ASD (n=62) OSD (n=7) ASD + RC repair (n=12) OSD + RC repair (n=15) Arthroscopic debridement (n=12) Open debridement (n=22)	None observed	None observed

Study ID	Population	Follow-up	Intervention	Adverse events	Serious adverse events
Magaji 2012 [93]	Total: n=83 Group A (4 symptoms): n=51 Group B (3 symptoms): n=21 Group C (2 symptoms): n=11	Mean: 28.8 months (range: 12–60)	ASD + subacromial steroid injection	None observed	None observed
Schröder 2001 [94]	Total: n=238 (261 surgeries) Open: n=80 Arthroscopy ≤10 surgeries: n=64 Arthroscopy 11–20 surgeries: n=21 Arthroscopy >20 surgeries: n=96	Mean 30 months (range: 12–120)	OSD (n=80) ASD (n=181)	Open cohort: Superficial wound infection (2.5%, n=2) Haematoma (1.3%, n=1) Temporarily frozen shoulder (3.8%, n=3) Arthroscopic cohort: Temporarily frozen shoulder (1.1%, n=2)	None observed
Soyer 2003 [95]	Total: n=39	Mean: 37 months (range: 12–48)	ASD	None observed	None observed

Abbreviations:
AE = adverse event, **ASD** = arthroscopic subacromial decompression, **OSD** = open subacromial decompression, **RC** = rotator cuff, **SLAP** = superior labral tear from anterior to posterior, **SD** = standard deviation.

Evidence pertaining to safety obtained from single-arm studies

There were twelve single-arm studies included in the present safety assessment of subacromial decompression for the treatment of subacromial pain, which represented a total cohort of 891 patients (***Table 9***, ***Table 39***).[96-107] There were no peri- or post-operative complications observed in six of the selected studies. [96 97 99 103 105 106]

AEs were reported in five single-arm studies and one study reported on the lack of satisfaction for the scar.[98 100-102 104 107] AEs were observed in 4.3% (n=38/891) of all patients treated with subacromial decompression. Across the cohort evaluated herein, infections were observed in 0.2% (n=2/891) of patients, 0.9% (n=8/891) of patients experienced temporary shoulder stiffness, 0.1% (n=1/891) of patients experienced a shoulder sinus near the portal site or adhesive capsulitis, 1.7% (n=15/891) of patients presented a frozen shoulder and 0.2% (n=2/891) of patients were not satisfied with the scar.

Serious AEs were observed in two of the selected single-arm studies and were related to OSDs.[98 104] The surgery-related serious AEs reported corresponded to wound infections that needed drainage, which occurred in 2 patients out of 145 (1.4%).[98 104]

Table 9 Summary of the evidence pertaining to safety obtained from single arm studies

Study ID	Population	Follow-up	Intervention	Adverse events	Serious adverse events
Billaud 2019 [96]	n=90	Not specified	Arthroscopic acromioplasty (7%, n=3) Arthroscopic acromioplasty + RC repair (93%, n=87)	None observed	None observed
Eid 2012 [97]	n=80	Mean: 71.9 months (range: 53.7–82.6)	ASD	None observed	None observed
Frieman 1995 [98]	n=74	Mean: 19.6 months (range: 12–48)	Open acromioplasty	Superficial wound infection (1.3%, n=1)	Deep wound infection leading to drainage and parenteral antibiotic treatment (1.4%, n=1)
Husby 2003 [99]	n=39	3, 6, 12, 96 months	ASD OSD	None observed	None observed
Hyvönen 1998 [100]	n=93	Mean: 108 months (range: 72–180)	Open acromioplasty	Total: 9.7% (n=9) Wound infection (1.1%, n=1) Temporary stiffness (8.6%, n=8)	None observed
Lim 2007 [101]	n=42	Mean: 14.6 months (range: 12–30)	ASD	Total: 4.7% (n=2) Shoulder sinus near portal site that healed within three weeks of dressing (2.4%, n=1) Adhesive capsulitis that resolved through intensive physical therapy within 6 months (2.4%, n=1)	None observed
Luyckx 2011 [102]	n=272	Mean: 15 months (minimum of 12 months)	ASD	Frozen shoulder (9%, n=15)	None observed
Machner 2000 [103]	n=103	Mean: 30 months (range: 7–84)	Arthroscopic acromioplasty	None observed	None observed
McKee 2000 [104]	n=71	6, 12, 18, 24 months postoperative	Open acromioplasty	Total (8.5%, n=6)	Wound infection requiring drainage and debridement (1.4%, n=1)
Petré 1998 [105]	n=40	Not specified	ASD	None observed	None observed
Pillai 2012	n=96	Mean: 16 months (range: 12–	OSD as a revision surgery following	None observed	None observed

Study ID	Population	Follow-up	Intervention	Adverse events	Serious adverse events
[106]	(unsatisfied patients: n=11)	26)	arthroscopic acromioplasty		
Rao 2005 [107]	n=22	1.5 months postoperative, then range: 6–24 months	Subacromial decompression	None observed Patients unsatisfied with the scar (one hypertrophic and one unsightly scar formation) (9.1%, n=2)	None observed

Abbreviations:
ASD = arthroscopic subacromial decompression, **OSD** = open subacromial decompression, **RC** = rotator cuff.

7.2.10 GRADE summary of findings

The GRADE findings for the three different comparators (i.e. placebo (sham surgery), conservative treatment and no treatment) included in the PICO criteria (***Section 5***) have been summarised in ***Table 10, Table 11*** and ***Table 12***. Additionally, when it was deemed relevant, findings reported in the Karjalainen et al.[1] review were also summarised in the respective tables. Any evidence analysed narratively was not summarised in the GRADE tables to minimise the risk of misinterpreting unweighted evidence.

Following the GRADE approach, seven outcomes are reported in each of the summary of findings tables.[72] These outcomes are detailed in the PICO criteria (***Section 5***). The GRADE score aligned with that detailed in the Karjalainen et al. review unless the meta-analysis was updated in ***Section 7.2.5***.[1] The updated outcomes detailed in the GRADE summary tables are those that are weighted most heavily in the updated meta-analysis in ***Section 7.2.5***.

According to the GRADE approach,[72] the quality of evidence that supports each outcome is defined as follows:

- **High certainty**: We are very confident that the true effect lies close to that of the estimate of the effect.
- **Moderate certainty**: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
- **Low certainty**: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.
- **Very low certainty**: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.

Table 10 GRADE summary of findings table, subacromial decompression compared to conservative treatment

Outcomes	Anticipated absolute effects[1] (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with conservative treatment	Risk with subacromial decompression				
Shoulder pain Scale: 0 to 10 follow-up: 12 months	Mean 6.09 points	**MD 0.79 points lower** (1.62 points lower to 0.04 points higher)	-	345 (3 RCTs)	⊕⊕◯◯ LOW	Subacromial decompression may improve shoulder pain but the evidence is very uncertain.[2]
Shoulder function Scale: 0 to 100 follow-up: 12 months	Mean 47.8 points	**MD 3.6 points higher** (9.16 points lower to 16.37 points higher)	-	259 (3 RCTs)	⊕◯◯◯ VERY LOW	Subacromial decompression may result no difference in shoulder function.
HRQoL follow-up: 12 months	-	**SMD 0.16 SD higher** (0.21 lower to 0.52 higher)	-	116 (1 RCTs)	⊕⊕◯◯ LOW	Subacromial decompression may result no difference in HRQoL.
Ability to return to work follow-up: 60 months	674 per 1,000	762 per 1,000 (654 to 890)	RR 1.13 (0.97 to 1.32)	188 (2 RCTs)	⊕◯◯◯ VERY LOW	The evidence is very uncertain about the effect of subacromial decompression on a patient's ability to return to work.
Further progression of subacromial pain follow-up: 60 months	167 per 1,000	167per 1,000 (67to 420)	RR 1.00 (0.40 to 2.52)	90 (1 RCTs)	⊕◯◯◯ VERY LOW	Subacromial decompression may have little to no effect on further progression of subacromial pain, but the evidence is very uncertain.
AE follow-up: 12 to 24 months *	18 per 1,000	31 per 1,000 (9 to 106)	RR 1.77 (0.52 to 6.02)	506 (2 RCTs)	⊕⊕⊕◯ MODERATE	Subacromial decompression probably does not increase AEs.
Serious AE follow-up: 12 to 24 months *	No events			340 (2 RCTs)	⊕⊕⊕◯ MODERATE	Serious adverse rates in observational studies are reported as less than 1%.2

Abbreviations:
AE: Adverse event, **CI:** confidence interval, **EQ-5D-3L** = EuroQol 5 dimensions questionnaire, **HRQoL** = health-related quality of life, **NRS** = numeric rating scale, **SD** = standard deviation, **SMD** = standardised mean difference. **MD** = mean difference, **MIC** = minimal important change, **MID** = minimal important difference, **RCT** = randomised controlled trial, **RR** = risk ratio, **VAS** = visual analogue scale, **15D** = 15 dimensions.
Notes:
[1] **The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
[2] **Source:** Karjalainen et al. 2019[1]
***Adverse event data is for all non-operative treatments.**

Table 11 GRADE summary of findings table, subacromial decompression compared to placebo (sham surgery)

Outcomes	Anticipated absolute effects1 (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with placebo (sham surgery)	Risk with subacromial decompression				
Shoulder pain Scale: 0 to 10 follow-up: 12 months	Mean 2.92 points	**MD 0.26 points lower** (0.85 lower to 0.33 higher)	-	284 (2 RCTs)	⊕⊕⊕⊕ HIGH	Subacromial decompression probably does not reduce subacromial pain.
Shoulder function Scale: 0 to 100 follow-up: 12 months	Mean 64.9 points	**MD 1.3 points higher** (4.53 points lower to 7.13 points higher)	-	157 (1 RCTs)	⊕⊕⊕⊕ HIGH	The evidence suggests that subacromial decompression does not improve shoulder function.
HRQoL follow-up: 12 months	-	**SMD 0.05 SD fewer** (0.28 lower to 0.18 higher)	-	285 (2 RCTs)	⊕⊕⊕⊕ HIGH	Subacromial decompression results in little to no difference in HRQoL.
Ability to return to work follow-up: 12 months	818 per 1,000	859 per 1,000 (728 to 1,000)	RR 1.05 (0.89 to 1.23)	111 (1 RCT)	⊕⊕⊕◯ MODERATE	Subacromial decompression results in little to no difference in a patient's ability to return to work.
Further progression of subacromial pain follow-up: 12 months	No events		-	361 (3 RCTs)	⊕⊕⊕◯ MODERATE	No events were reported.
AE follow-up: 12 to 24 months*	18 per 1,000	31 per 1,000 (9 to 106)	RR 1.77 (0.52 to 6.02)	506 (2 RCTs)	⊕⊕⊕◯ MODERATE	Subacromial decompression probably does not increase AEs.
Serious AEs*	No events		-	331 (2 RCTs)	⊕⊕⊕◯ MODERATE	Serious AEs in observational studies are reported as less than 1%.[2]

Abbreviations:
AE: Adverse event, **CI** = confidence interval, **HRQoL** = health-related quality of life, **SD** = standard deviation, **SMD** = standardised mean difference, **MD** = mean difference, **RCT**= randomised controlled trial**, RR** = risk ratio
Explanatory notes:
[1] **The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
[2] **Source:** Karjalainen et al. 2019[1]
***Adverse event data is for all non-operative treatments.**

Table 12 GRADE summary of findings table, subacromial decompression compared to no treatment

Outcomes	Anticipated absolute effects[1] (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with no treatment	Risk with subacromial decompression				
Shoulder pain assessed with: numerical rating scale Scale: 0 to 10 follow-up: 12 months	Mean score 4.1 points	**MD 1.2 points lower** (2.04 lower to 0.36 lower)	-	166 (1 RCT)	⊕⊕⊕◯ MODERATE	Subacromial decompression probably results in little to no difference in shoulder pain.[2]
Shoulder function assessed with: Constant score Scale: 0 to 100 follow-up: 12 months	Mean score 56.7 points	**MD 9.5 points higher** (2.66 points higher to 16.34 points higher)	-	146 (1 RCT)	⊕⊕⊕◯ MODERATE	Subacromial decompression likely results in a slight increase in shoulder function.[2] The difference is clinically important (MID=8.3).
HRQoL assessed with EQ-5D-3L follow-up: 12 months	Mean score 0.66 points	**MD 0.08 higher** (0.01 points lower to 0.17 points higher)	-	178 (1 RCT)	⊕⊕⊕⊕ HIGH	Subacromial decompression probably results in a slight increase in HRQoL.[2]
Ability to return to work	Not reported		-	210 (1 RCT)	⊕⊕⊕◯ MODERATE	N/A
Further progression of subacromial pain follow-up	No events		-	210 (1 RCT)	⊕⊕⊕◯ MODERATE	Precise estimates are unknown.

Abbreviations:
AE: Adverse event, **CI** = Confidence interval, **HRQoL** = health-related quality of life, **SD** = standard deviation, **SMD** = Standardised mean difference, **MD** = Mean difference, **RR** = Risk ratio

Explanatory notes
[1] **The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
[2] **Source:** Karjalainen et al. 2019[1]

7.3 Summary statement clinical efficacy and safety

Subacromial decompression versus conservative treatment

Six RCTs compared subacromial decompression to conservative treatment (n=614). At 12 months there were no statistically significant differences reported for pain (low certainty evidence), function (low certainty evidence), health-related quality of life (HRQoL) (low certainty evidence), return to work (very low certainty evidence), return to leisure activities (very low certainty evidence), progression of subacromial pain (very low certainty evidence).

Subacromial decompression versus placebo (sham surgery)

Three RCTs compared subacromial decompression to placebo (n=406). At 12 months there were no statistically significant differences reported for pain (high certainty evidence), function (high certainty evidence), HRQoL (high certainty evidence), return to work (moderate certainty evidence), return to leisure activities (moderate certainty evidence). Progression of subacromial pain was not reported.

Subacromial decompression versus no treatment

One RCT compared subacromial decompression to no treatment (n=210). At 12 months, there was a statistically significant difference in pain (MD=-1.2, 95% CI -2.04, -0.36, moderate certainty evidence) and function (MD=9.5, 95% CI: 2.66, 16.34, moderate certainty evidence), but not for HRQoL (moderate certainty evidence), further progression of subacromial pain (moderate certainty evidence). Other outcomes were not reported.

Safety

There were no statistically significant differences in numbers of total adverse events between subacromial decompression and non-operative treatments.

8 Costs, cost-effectiveness and budget impact

8.1 Methodology costs, cost-effectiveness and budget impact

Subacromial decompression as a primary and isolated intervention was not found to have superior efficacy to conservative management or placebo in the clinical evaluation. In such cases, economic analyses are generally limited to cost minimisation assessment. The costs of subacromial decompression are compared to conservative management in the costs section of this report.

The Can Shoulder Arthroscopy Work (CSAW) trial reported improved short-term health outcome improvements for surgery over no treatment.[19] A decision analytic model was developed to quantify the cost-effectiveness of subacromial decompression for rotator cuff disease compared to no treatment using incremental QALYs. The model was developed in TreeAge Pro (TreeAge Software, Inc, One Bank Street Williamstown, MA, 01267 USA) and health outcome assumptions were derived from the CSAW trial.

PSA was performed to account for uncertainty in the input parameters (See ***Table 14*** for assumptions). The analysis involved 10,000 iterations used to calculate 95% CI for costs and effectiveness. The probability of the ICER being cost-effective was estimated using a hypothetical willingness-to-pay threshold of CHF100,000.

The annual cost for subacromial decompression as an isolated intervention was taken from Swiss DRG (diagnosis-related group) costs for inpatient delivery.[109] ICERs were calculated using base case unit costs and health outcomes reported at 6 and 12 months in a decision model. Utility differences were based on results of the CSAW trial that reported EQ-5D.[19] Sensitivity analyses were included to account for outpatient delivery, which was costed using TARMED costs, and utility outcomes calculated using per-protocol analysis.

8.1.1 Economic modelling background

8.1.1.1 Review of economic literature

The systematic searches reported in ***Section 7*** identified one relevant economic analysis by Rombach et al.,[110] which was a trial-based economic evaluation utilising data from the CSAW trial.[19] The analysis compared subacromial decompression, arthroscopy (sham) or no treatment using the EQ-5D-3L questionnaire to quantify QoL. The baseline to 6 months and baseline to 12 months subacromial decompression ICERs against no treatment were £52,100 and £21,138, respectively, while the sham comparison ICERs were -£266,000 and £46,833.

It was noted in the scoping report that the 2015 cost base for the analysis and UK NHS perspective may limit the applicability of the results to the Swiss health system. No economic studies were found where physiotherapy was included as a comparator. The clinical evaluation found no significant clinical benefit for this comparison in relation to quality of life, therefore a cost-utility analysis was deemed inappropriate for subacromial decompression against physiotherapy.

8.1.1.2 Overview of economic model

A decision analytic model (summarised in ***Table 13***) was developed to estimate the expected costs and QALYs associated with surgical intervention to widen the subacromial space surrounding the tendon (i.e. subacromial decompression, acromioplasty, bursectomy, CAL resection) compared with no treatment for an average patient with subacromial pain.

Table 13 Summary of the economic evaluation

Perspective	Swiss payer
Patient population	Patients with subacromial pain
Intervention	Surgical intervention to widen the subacromial space surrounding the tendon, i.e. subacromial decompression, acromioplasty, bursectomy, coracoacromial ligament resection
Comparator	No treatment
Type of economic evaluation	Cost-utility analysis
Sources of evidence	CSAW trial, Swiss DRG costs
Time horizon	1-year, 6 months
Outcomes	Quality-adjusted life years/life-years gained
Methods	Decision model
Software packages used	Tree Age Pro

Abbreviations:
CSAW = Can Shoulder Arthroscopy Work, **DRG** = diagnosis-related group.

8.1.1.3 Intervention and comparator

Patients in the CSAW trial were treated across 32 hospitals in the UK.[19] A standard decompression procedure using arthroscopic keyholes was employed and general anesthetic provided. Patients underwent standardised postoperative care and exercise therapy of one to four routine treatment sessions. The economic model uses the Swiss DRG I29C (Complex procedures involving scapula, clavicle, ribs or shoulder weight) for estimating the payer cost of the decompression procedure in Switzerland.[111]

Conservative therapy is the first line of treatment for subacromial pain, with subacromial decompression being delivered if conservative therapy is ineffective. Should subacromial decompression be disinvested, conservative therapy will remain the next-best alternative. As noted, conservative therapy was found to have similar health outcomes to subacromial decompression in the clinical evaluation. Correspondingly, the cost-effectiveness model is limited to a comparison of subacromial decompression with no treatment. No treatment was assumed to entail no cost. Patients in the CSAW no-treatment group had no prescribed physiotherapy or steroid injections, however, a range of hospital visits and other follow-up medical services were used after the initial procedure. This cost difference is included in a sensitivity analysis.

8.1.1.4 Methods used to generate results

The economic analysis took a payer perspective. Health service costs were using mean Swiss DRG items reported on Datenspiegel. High and low utility values for the univariate analysis were taken from the 95% confidence interval for QALYs gained in the CSAW trial.[19 44] Surgery costs were varied using the standard deviation of Swiss DRG costs, along with outpatient delivery costs specified using TARMED. The probabilistic sensitivity analysis was based on parameters and distribution assumptions included in ***Table 14***. Cost assumptions were included as normal distributions, while utility estimates were included as beta distributions.

8.2 Evidence table

Model assumptions were derived for costs and utility health outcomes and are summarised in ***Table 14*** along with sources and the derivation of each assumption.

Table 14 Summary of evidence for the economic evaluation

Assumption	**Value**			**Source of Evidence and Comments**
Cost				
Decompression	**Weight**	**Cost (CHF)**	**SD (CHF)**	
Surgery DRG weight in the base case	0.829	8,633	3,297	The base case uses the DRG I29C – Complex procedures involving scapula, clavicle, ribs or shoulder weight from https://datenspiegel100.swissdrg.org/drgs. accessed 24 November 2020. The mean and SD are included as a normal distribution in the PSA.
No treatment				
Weight in the base case	0.000	-	-	The base case includes no costs for the no-treatment comparator.
Utility outcome for base analysis				
Decompression surgery	**Base**	**Standard error**		

Assumption	Value		Source of Evidence and Comments
Baseline	0.517	0.029	EQ-5D estimates and standard errors were taken from Rombach et al. (2019)[110] Standard errors were converted to standard deviations and included as beta distributions for the PSA.
6 months	0.654	0.03	
12 months	0.735	0.03	
No treatment			
Baseline	0.499	0.032	EQ-5D estimates and standard errors were taken from Rombach et al. (2019)[110] Standard errors were converted to standard deviations and included as beta distributions for the PSA.
6 months	0.526	0.036	
12 months	0.658	0.034	
Incremental QALYs based on adjusted baseline utilities			
Decompression versus no treatment	**Mean**	**Confidence interval**	
Baseline to 6 months (ITT)	0.03	0.010 to 0.050) p = 0.007	Taken from Rombach 2019, Table III, p. 59. The authors noted QALYs were based on EQ-5D-3L values adjusted for baseline differences.
Baseline to 12months (ITT)	0.08	0.030 to 0.130) p = 0.002)	Taken from Rombach 2019, Table III, p. 59. As above, the authors adjusted baseline values.
Baseline to 12 months (PP)	0.09	(0.040 to 0.140) p = 0.001	Taken from Rombach 2019, Table vi (Supplementary file). As above, the authors adjusted baseline values.

Abbreviations:
CHF = Swiss franc, **DRG** = diagnosis-related group, **EQ-5D** = EuroQol 5-dimensions questionnaire, ITT= intention-to-treat, PP= per protocol**, PSA** = probabilistic sensitivity analysis, QALY= quality adjusted life years, **SD** = standard deviation.
Sources:
Rombach et al. 2019.[110]

8.2.1 Applicability of trials

Characteristics of patients comprising the clinical evidence (summarised in ***Table 15***) are compared with circumstances of use in Switzerland.

Table 15 Features of patient population in the CSAW trial

Parameter	Value	Sources/Comments
Demographics	53 years 50% women	Participants in the CSAW trial had average ages of 52.9 to 53.7 years across the three arms of the trial and around half of trial participants were women.
Clinical characteristics	Confirmed by a consultant surgeon	Diagnosis of subacromial shoulder pain in the CSAW trial was confirmed by a consultant surgeon (using local pathways of diagnosis, which may include X-rays, magnetic resonance imaging scans or ultrasounds). Patients needed to be eligible for arthroscopic surgery and to have completed conservative treatment, including physiotherapy that includes a remedial exercise regimen and at least one cortisone injection
Surgical setting	Hospital	32 hospitals in the UK with 51 surgeons

Abbreviations:
CSAW = Can Shoulder Arthroscopy Work, **UK** = United Kingdom.

8.2.1.1 Demographics (age and gender)

The CSAW trial included patients of around 53 years of age, half of whom were women. Age and gender profiles for the key trial used for estimating health outcomes in the economic analysis were similar to what could be expected in Switzerland. The Swiss DRG I29C (Complex procedures involving scapula, clavicle, ribs or shoulder) had utilisation of 20.3% for 40–49-year-olds, 30.9% for 50–59-year-olds and 18.2% for 60–69-year-olds.[111] Of these procedures, 65.1% were used by men and 34.9% by women.

8.2.1.2 Clinical characteristics

Inclusion criteria for CSAW included a diagnosis of subacromial shoulder pain by a consultant surgeon (using local pathways of diagnosis, which may include X-rays, MRI scans or ultrasounds). Patients needed to be eligible for arthroscopic surgery and to have completed conservative treatment, including physiotherapy that includes a remedial exercise regimen and at least one cortisone injection.

Participants were excluded for full-thickness tear of the rotator cuff tendons or calcific tendonitis evident on routine imaging, other shoulder pathology (non-impingement related) identified on MRI or ultrasound, or for having undergone ASD, cuff repair, joint replacement or glenohumeral joint surgery in the past three years. Exclusions also covered rheumatoid arthritis or any other inflammatory disorder of the joints, symptomatic cervical spine pathology, septic arthritis and age older than 75 years. There are no limitations placed on how long patients had to have experienced subacromial pain to be eligible for subacromial decompression in Switzerland.

8.2.2 Utility measures

The scoping report noted that full movement of the shoulder joint can be gained within three to eight weeks post-surgery and complete benefits of surgery can be realised anywhere between a few months to a year.[33 36 50 51] The CSAW trial measured health outcomes at 6 and 12 months after randomisation, with patients in the no-treatment group having an additional reassessment 3 months after randomisation. Outcomes included the Oxford Shoulder Score (OSS) at 12 months, the modified Constant-Murley score, Pain-DETECT, Quantitative Sensory Testing, the Hospital Anxiety and Depression Scale (HADS), EuroQol visual analogue scale (EQ VAS) and EQ-5D-3L score [UK tariff]. Effectiveness benefits of surgical intervention versus no treatment were captured in the economic model as incremental QALYs using EQ-5D-3L index scores.

Effectiveness benefits of surgical intervention versus no treatment were captured in the economic model as incremental QALYs using EQ-5D-3L index scores. Utilities were taken from Rombach.[110] The authors noted "*outcomes were analyzed as randomized, regardless of compliance with the randomized procedure (intention to treat (ITT) approach)*." (p. 56). Intention-to-treat results are included in the base

economic analysis presented in ***Table 16*** of this report. Supplementary analyses undertaken by Rombach and colleagues included a per-protocol analysis. The incremental QALY result of this approach is included as a sensitivity analysis. The authors also calculated QALYs by adjusting EQ-5D-3L values to account for baseline differences using linear regression. Economic model results are presented with and without this adjustment in the base case.

8.2.3 Costs inputs for surgery and no treatment

The costs included in this report were calculated using Swiss DRG costs (***Table 14***). The DRG weight in the base case was 0.829 (using the Swiss DRG I29C – Complex procedures involving scapula, clavicle, ribs or shoulder weight and average cost of CHF8,633). The average length of stay associated with this DRG was 2.7 days. For the 1,215 patients that had subacromial pain as the primary diagnosis, and who received a subacromial decompression as the primary procedure, the average length of stay was 2.4 days. No treatment was assumed to entail zero costs in the base analysis.

Follow-up costs after the initial procedure were not included for decompression or no treatment. This simplifying assumption may understate cost differences as only the initial procedural cost for decompressions is included in the base economic model analysis. Rombach and colleagues estimated decompression costs to be £1380 (excluding the procedure itself) over the 12 months following the initial procedure and no treatment costs to be £915 over the same period, or a difference of £465 (CHF565) in their UK study.[110] This additional follow-up cost difference is included in the decompression procedure cost as a univariate sensitivity analysis.

Conservative management for subacromial pain in Switzerland encompasses a number of stages, including pain relief, physiotherapy and corticosteroid injection. The trial by Paavola compared subacromial decompression with an exercise therapy intervention involving daily home exercises along with 15 visits to an independent physiotherapist.[112] This number of physiotherapist visits is combined with a cost of CHF90 per session to generate a conservative management cost of CHF1,350.

The inpatient cost of subacromial decompression surgery of CHF8,633 is CHF7,283 higher than that of CHF1,350 for conservative management.[111] The outpatient delivery of subacromial decompression was estimated to have a cost of CHF3,972, which comprised CHF1,161 for TARMED 24.0710 arthroscopy and 24.0750 decompression, anaesthesia CHF750, medicines, consumables, and overheads CHF2,061. This cost is CHF2,622 greater than conservative management. Given subacromial decompression surgery was not found to have superior efficacy to conservative management in the clinical evaluation, this comparison is not included in the economic model. The cost is used in the budget impact analysis that follows cost-effectiveness results of the subacromial decompression surgery versus no treatment comparison.

8.3 Results: Cost-effectiveness

The incremental costs and effectiveness of the surgery versus no treatment comparisons at 6 and 12 months are presented. The ICER for surgery was less than a hypothetical willingness-to-pay of CHF100,000 at 1 year, but not at 6 months when unadjusted baseline utilities were used to estimate incremental QALYs. ICERs were CHF98,102 at 12 months and CHF233,324 per incremental QALY at 6 months. Rombach[110] presented incremental QALYs based on adjustments to utility values to account for baseline differences. At 12 months, the ICER was estimated to be CHF107,913 per incremental QALY with this adjustment.

Table 16 Incremental cost-effectiveness of surgery compared to no treatment

	Cost in CHF	Incremental cost	QALYs	Incremental QALYs	ICER
No adjustment to baseline utility values					
6 months					
Surgery	8,633	8,633	0.29	0.04	233,324
No treatment	0	0	0.26		
12 months					
Surgery	8,633	8,633	0.64	0.09	98,102
No treatment	0		0.55		
Rombach adjustment to baseline utility values					
6 months					
Surgery	8,633	8,633	NS	0.03	287,767
No treatment	0	0	NS		
12 months					
Surgery	8,633	8,633	NS	0.08	107,913
No treatment	0	0	NS		

Abbreviations:
CHF = Swiss franc, **ICER** = incremental cost-effectiveness ratio, **QALY** = quality-adjusted life year.

8.3.1.1 Univariate sensitivity analysis

Sensitivity of the results to different model assumptions was explored in univariate sensitivity analysis. A tornado graph for surgery compared to no treatment at 12 months is presented in ***Figure 12***. Analyses included calculating incremental utility gain over baseline, per protocol estimation of QALY gain (0.09 QALYS over 12 months), high and low utility gains based on 95% confidence intervals reported in the Rombach study, inclusion of follow-up costs, variations in DRG costs based on confidence intervals reported on Datenspiegel, and outpatient delivery of surgery. ICER estimates were most affected by the inclusion of the 95% confidence interval range for QALY gains from Rombach (0.03–0.13),[110]

delivery of surgery in an outpatient setting, which was estimated to cost CHF3,972 per procedure, and variation in the Swiss DRG costs for decompression surgery by reported standard deviation.

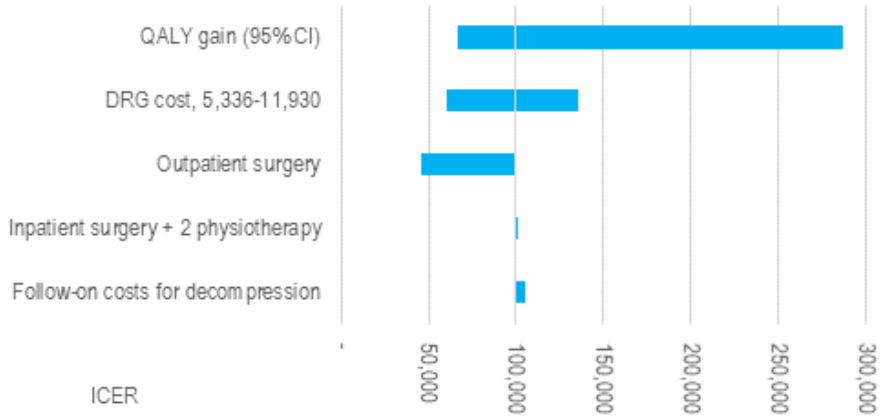

Figure 12 Surgery compared to no treatment: incremental 12-month cost-effectiveness tornado graph

Abbreviations:
CI = confidence interval, **DRG** = diagnosis-related group, **ICER** = incremental cost-effectiveness ratio, **QALY** = quality-adjusted life year.

8.3.1.2 Probabilistic sensitivity analysis

Inputs were specified as distributions for costs and effectiveness (***Table 14***). A mean cost difference for surgery versus no treatment of CHF8,611 (95% CI, from PSA, CHF-2,120, CHF15,146) was estimated, and incremental effectiveness of 0.083 (95% CI, from PSA, -0.5, 0.63), generating an ICER of CHF103,747. Using a hypothetical willingness-to-pay threshold of CHF100,000 per QALY (***Figure 13***), surgery had a 49% probability of being cost-effective when compared with no treatment.

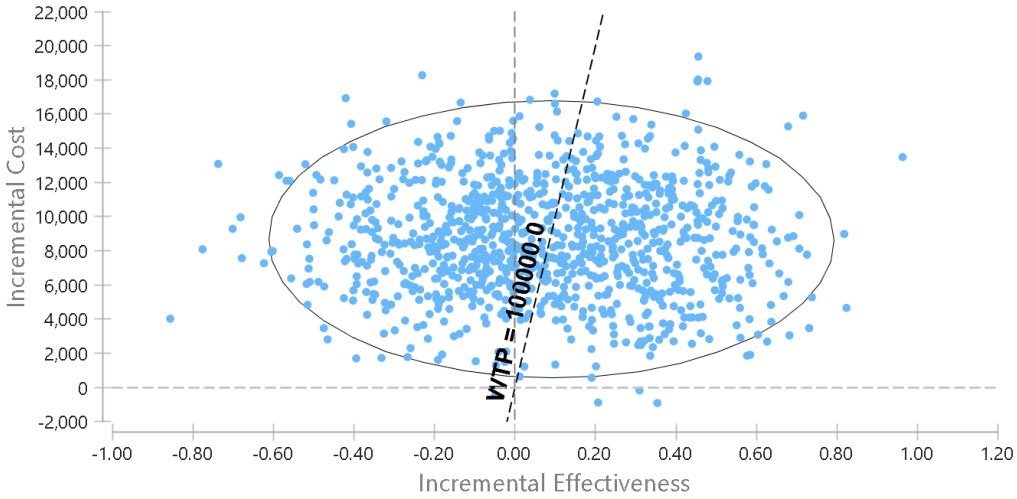

Figure 13 Cost-effectiveness plane at 12 months for surgery compared to no treatment

Abbreviations:
WTP = willingness-to-pay (CHF).

A cost-effectiveness acceptability curve is presented in ***Figure 14***. The graph presents the probability that surgery will be cost-effective against the willingness-to-pay thresholds on the horizontal axis. It is evident that surgery has a more than 49% chance of being cost-effective at willingness-to-pay thresholds of greater than CHF100,000.

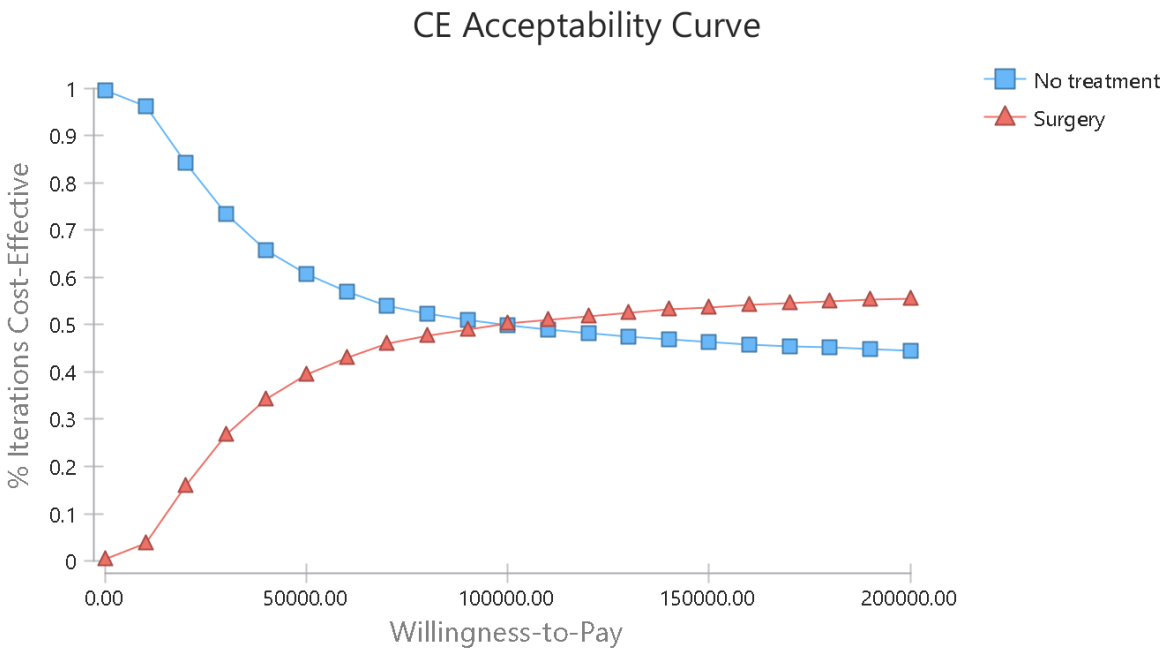

Figure 14 Cost-effectiveness acceptability curve

Abbreviations:
WTP = willingness-to-pay (CHF).

8.4 Results: Budget impact

The financial implications of delisting decompression surgery as a primary and isolated procedure were examined using budget impact analysis from a payer's perspective. Decompression surgery was assumed to have a payer cost of CHF8,633 (cost of Swiss DRG) for inpatient delivery and outpatient cost of CHF3,972 per procedure.

Four scenarios of physiotherapy and no treatment substituting for decompression surgery are presented. In the first scenario, it was assumed 100% of current decompression surgery procedures will be substituted by additional physiotherapy. Physiotherapy is assumed to have a cost of CHF1,350, equivalent to 15 sessions at CHF90 per session. This number of sessions was included in the Paavola trial.[112] The second and third scenarios assumed that 75% and 50% of decompression surgery procedures will be substituted by physiotherapy, and the last scenario assumed 100% of current decompression surgery will be substituted by no treatment.

8.4.1 Assumptions in the budgetary impact analysis

A total of 1,215 procedures, where patients had subacromial pain as the primary diagnosis and subacromial decompression as the primary intervention were delivered in hospitals. These estimates are increased by the Swiss national population growth rate of 0.7% for 2019.[109] Estimates for 2020–2024 are presented in ***Table 17***.

FOPH advised that 504 outpatient decompression surgery procedures (TARMED codes) were invoiced to mandatory health insurers in 2017. This procedural number is reduced to reflect the proportion of subacromial decompressions that were performed as a primary intervention. In the absence of outpatient data, it is assumed that the proportion of subacromial decompressions performed as a primary intervention among inpatients (20.4%) would be similar in the outpatient setting. It is thus assumed that 103 outpatient subacromial decompressions performed as a primary intervention will be performed in 2020.

It is estimated there will be 1,355 inpatient and outpatient decompression surgeries in 2024 (1,249 and 106 and procedures combined, respectively). The estimated payer cost of decompression in Switzerland will increase from CHF10.9 million in 2020 to CHF11.2 million in 2024. The cost in 2020 is estimated as 103 outpatient procedures multiplied by the TARMED cost of CHF3,972 per procedure, plus 1,215 multiplied by the inpatient per procedure Swiss-DRG cost of CHF8,633. There is uncertainty around this projection as the proportion of surgeries that are outpatient-delivered could increase from the current proportion of 8%. If this proportion increased to 20% by 2024, then the total cost would decrease from CHF11.2 million to CHF10.5 million in 2024.

Table 17 Swiss decompression surgery as primary procedure projections, 2020-2024

Description	2020	2021	2022	2023	2024	Source
Decompression treatment projections						
Outpatient decompression procedures	103	104	104	105	106	FOPH and primary proportion assumption
Outpatient decompression cost (CHF)	408,385	411,244	414,123	417,021	419,941	TARMED cost (CHF3,972) x procedures
Inpatient decompression procedures	1,215	1,224	1,232	1,241	1,249	Database and primary proportion assumption
Inpatient Decompression cost (CHF)	10,489,095	10,562,519	10,636,456	10,710,911	10,785,888	CHF8,633 x inpatient procedures
Total decompression procedures	1,318	1,327	1,336	1,346	1,355	Inpatient + outpatient procedures
Total cost of decompression as primary procedure	10,897,480	10,973,763	11,050,579	11,127,933	11,205,828	**Inpatient + outpatient costs**

Abbreviations:
CHF = Swiss franc, **FOPH** = Federal Office of Public Health.

8.4.2 Financial Implications

The five-year budget impact of delisting decompression as a primary surgery from a payer perspective is presented in ***Table 18***. In the event that 100% of surgery patients substituted to physiotherapy, an annual cost saving of CHF9.1 million would be realised in 2020 and CHF9.4 million by 2024. If 75% of patients substituted to physiotherapy, then a cost saving of CHF9.6 million would be realised in 2020 (CHF10.9 million for inpatient and outpatient decompression procedures less CHF1.3 million for additional physiotherapy), increasing to CHF9.8 million by 2024. If 50% of surgical patients used physiotherapy in the event of delisting, the payer saving would increase to CHF10 million in 2020. If current surgery patients substituted to no treatment, the current expenditure of CHF10.9 million would be saved. There is uncertainty around the estimated outpatient unit cost of decompression of CHF3,972. However, if this unit cost were to vary by 10%, the payer net saving from delisting would vary by 0.4%, given the small number of outpatient-delivered decompression procedures in Switzerland. There is considerable variation associated with the average DRG cost per inpatient-delivered surgery, due to differences in hospital tariffs and other factors. Varying the average cost of DRG I29C (CHF8,633) by the standard deviation (CHF3,297) results in the cost saving ranging from CHF5.3 million to CHF13.5 million in 2024 for the scenario in which 100% of surgery patients substituted to physiotherapy, and CHF7.1 million to CHF15.3 million in 2024 for the scenario in which 100% of current surgery patients receive no treatment.

Table 18 Treatment costs in Switzerland, 2020–2024

	Units	2020	2021	2022	2023	2024	Source
100% of current surgery patients receiving physiotherapy							
0% of current patients receiving surgery	Number	0	0	0	0	0	Scenario applied to current procedures
100% of patients receiving physiotherapy	Number	1,318	1,327	1,336	1,346	1,355	Scenario applied to current procedures
Patients receiving surgery	CHF	0	0	0	0	0	Surgery procedures x no cost for delisted procedure
Patients receiving physiotherapy	CHF	1,779,052	1,791,505	1,804,045	1,816,674	1,829,391	Procedures x TARMED cost
Total	**CHF**	1,779,052	1,791,505	1,804,045	1,816,674	1,829,391	**Sum of surgery and physiotherapy**
Payer saving	**CHF**	**9,118,429**	**9,182,258**	**9,246,533**	**9,311,259**	**9,376,438**	Payer surgery cost less physiotherapy cost
75% of current surgery patients receiving physiotherapy							
25% of current patients receiving surgery	Number	329	332	334	336	339	Scenario applied to current procedures
75% of patients receiving physiotherapy	Number	988	995	1,002	1,009	1,016	Scenario applied to current procedures
Patients receiving surgery	CHF	0	0	0	0	0	Surgery procedures x no cost for delisted procedure
Patients receiving physiotherapy	CHF	1,334,289	1,343,629	1,353,034	1,362,505	1,372,043	Procedures x TARMED cost
Total	**CHF**	1,334,289	1,343,629	1,353,034	1,362,505	1,372,043	**Sum of surgery and physiotherapy**
Payer saving	**CHF**	**9,563,191**	**9,630,134**	**9,697,545**	**9,765,428**	**9,833,786**	Payer surgery cost less physiotherapy cost
50% of current surgery patients receiving physiotherapy							
50% of current patients receiving surgery	Number	659	664	668	673	678	Scenario applied to current procedures
50% of patients receiving physiotherapy	Number	659	664	668	673	678	Scenario applied to current procedures
Patients receiving surgery	CHF	0	0	0	0	0	Surgery procedures x no cost for delisted procedure
Patients receiving physiotherapy	CHF	889,526	895,752	902,023	908,337	914,695	Procedures x TARMED cost
Total	**CHF**	889,526	895,752	902,023	908,337	914,695	**Sum of surgery and physiotherapy**
Payer saving	**CHF**	**10,007,954**	**10,078,010**	**10,148,556**	**10,219,596**	**10,291,133**	Payer surgery cost less physiotherapy cost
100% of current surgery patients receiving no treatment							
No current patients receiving surgery	Number	0	0	0	0	0	Scenario applied to current procedures
100% of patients receiving no treatment	Number	1,318	1,327	1,336	1,346	1,355	Scenario applied to current procedures
Patients receiving surgery	CHF	0	0	0	0	0	Surgery procedures x no cost for delisted procedure
Patients receiving no treatment	CHF	0	0	0	0	0	No treatment costs

	Units	2020	2021	2022	2023	2024	Source
Total	**CHF**	0	0	0	0	0	**Sum of surgery and no treatment**
Payer saving	**CHF**	**10,897,480**	**10,973,763**	**11,050,579**	**11,127,933**	**11,205,828**	Payer surgery cost less physiotherapy cost

Abbreviations:
CHF = Swiss franc.

8.5 Summary statement costs, cost-effectiveness, and budget impact

The clinical evaluation found subacromial decompression as a primary and isolated intervention did not improve quality of life outcomes for people with subacromial shoulder pain compared to placebo and conservative management. The inpatient cost of subacromial decompression surgery of CHF8,633 (Datenspiegel SwissDRG 10.0) was higher than the estimated conservative management cost of CHF1,350 (15 physiotherapy sessions at CHF90 per session). Correspondingly, it is evident that subacromial decompression is costlier and has no significant clinical improvement over its main comparator (conservative management), therefore offers no economic advantage.

A decision-analytic model was developed to quantify the cost-effectiveness of inpatient-delivered subacromial decompression for rotator cuff disease compared to no treatment using incremental quality-adjusted life years (QALY) as most surgery in Switzerland is delivered in this setting. An incremental cost-effectiveness ratio (ICER) of CHF98,102 per QALY gained was estimated at 12 months for surgery compared to no treatment when utility values were not adjusted for baseline differences. When utilities were adjusted to account for baseline differences, an ICER of CHF107,913 per QALY gained was estimated at 12 months. Probabilistic sensitivity analyses (PSA) determined with 49% probability that subacromial decompression was cost-effective compared to no treatment using a hypothetical willingness-to-pay threshold of CHF100,000 per QALY gained.

A budget impact analysis using four substitution scenarios (in which subacromial decompression was substituted with no treatment and physiotherapy at different rates) was conducted. If subacromial decompression is delisted and half of patients substitute to physiotherapy, then a net cost saving of CHF10.0 million would occur in 2021. This saving decreased to CHF9.6 million if 75% of subacromial decompression patients substituted to physiotherapy in this year and CHF9.1 million if all substituted to physiotherapy. The saving from subacromial decompression delisting decreases as more patients are assumed to substitute to alternate treatments.

9 Legal, social and ethical issues

9.1 Methodology legal, social and ethical issues

The evidence base for legal, social and ethical issues was identified from both systematic and non-systematic searches. The search terms and systematic search strategies are outlined in ***Section 7.1.1***, ***Section 7.1.2*** and ***Appendix A: Sources of literature (databases)***. The non-systematic searches included searches of Google and PubMed using terms such as shoulder, rotator, pain, ethical, morals, legal, patient experience, and patient attitudes. The non-systematic searches were conducted by a single reviewer.

Many study designs were included in this narrative assessment of legal, social and ethical issues. The study designs included, but were not limited to, systematic reviews, literature reviews, RCTs, non-RCTs, single-arm studies, ethnographic studies, phenomenological studies, narrative research and case studies.

Results for this section were analysed and summarised narratively.

9.2 Results legal, social and ethical issues

9.2.1 PRISMA flow diagram

A total of five (k=5) publications were identified and included in the narrative synthesis.[113-117] The majority of these (k=3) were identified through the systematic search (see ***Figure 3***).[113-115] Three publications assessed social considerations and one publication evaluated ethical considerations.[113-115] The targeted searches identified two publications that appraised social considerations.[116 117] Neither the systematic search nor the targeted searches identified any publications addressing legal issues related to using subacromial decompression to treat subacromial pain. A PRISMA diagram was not included in this section given that both systematic and non-systematic searches were conducted.

9.2.2 Evidence table

The five included publications (***Table 19***) are broadly applicable to the Swiss healthcare context as they were conducted in WHO – Mortality Stratum A countries in Europe and North America.[113-117] Four were conducted in European countries, being the UK (k=2), Denmark (k=1), and Sweden (k=1).[113-116] The North American publication (k=1) was conducted in the USA.[117]

All included publications (k=5) were primary research studies that took place in hospital settings. Four were prospective studies[113 114 116 117] and one was retrospective.[115] Three of the studies were case-

series (single-arm trials),[113 116 117] one was a cross-section qualitative study[114] and the other was a retrospective case-series.[115]

Most of the included publications (k=4) focused on treating patients with subacromial pain with subacromial decompression.[114-117] One publication focused on a wider range of shoulder pathologies and surgical interventions.[113] Additionally, one publication focused on young athletes (age <40 years) with subacromial pain.[117]

The total population in the included publications totalled n=57,544 (***Table 19***),[113-116] including a small number of young athletes (n=33).[117]

Follow-up time within the included publications ranged from 6 months to 11 years.[113 115-117] It is important to note that since the study by Cuff and Littlewood was a cross-sectional study, there was no follow-up time point.[114]

Table 19 Characteristics of included studies for social and ethical issues

First author, year; country	Indication; sample size	Design; follow-up; setting	Outcomes
Christiansen 2016[113] Denmark	Patients with: - Rotator cuff syndrome - Tendinitis (i.e. bicipital calcific) - Subacromial pain - Bursitis - Shoulder lesions - Unspecified lesions n=57,311	Prospective case series 1 year (52 weeks) Hospital setting	Social Patient attitude Ethics Access
Cuff 2017[114] UK	Patients with subacromial pain n=9	Cross-sectional qualitative study – semi-structured interview N/A Hospital setting	Social Patient attitude
Dekker 2016[115] UK	Patients with subacromial pain n=86	Retrospective case-series 6 months Hospital setting	Social Psychological aspects
Klintberg 2011 [116] Sweden	Patients with subacromial pain n=105	Prospective case series 8–11 years Hospital setting	Social Patient expectation
Tibone 1985[117] USA	Athletes (age <40 years) with subacromial pain n=33	Prospective case-series 18–27 months Hospital setting	Social Patient expectation

Abbreviations:
N/A = not applicable, **UK** = United Kingdom, **USA** = United States of America

9.2.3 Findings: legal issues

The searches did not identify any literature related to the legal implications of limiting the use of subacromial decompression to treat subacromial pain.

9.2.4 Findings: social issues

The evidence on social issues associated with limiting the use of subacromial decompression to treat subacromial pain related to psychological considerations and patient attitudes and expectations.

9.2.4.1 Psychological aspects

The psychological state of the patient can affect the outcome of surgery. A retrospective case-control study based in the UK indicated that a diagnosis of depression and anxiety (HADS score) prior to subacromial decompression to treat subacromial pain can negatively affect the pain (i.e. VAS) and function (i.e. OSS) outcomes six months post-surgery.[115] Patients with higher levels of anxiety and depression when undergoing ASD experienced lower postoperative improvements in pain and function.[115] The study stated that depression and anxiety were strongly positively correlated with pain (R=-0.508, p=0.01) and negatively correlated with function (R=-0.626, p=0.01).[115] It is unclear how depression and anxiety affect the outcomes of the comparator interventions.

9.2.4.2 Patient attitude

Patients' attitudes towards surgery and the benefits of physiotherapy can be affected by a clinician's language. A key finding of a qualitative study from the UK was that the language used by clinicians to explain subacromial pain and treatment options can affect patients' engagement and opinions towards non-surgical interventions such as conservative therapy.[118] This is because the language clinicians use to explain the biological model behind subacromial pain, and to positively explain how a surgical intervention (i.e. subacromial decompression) can improve pain and function, differs from the language used to describe conservative treatment.[118] Clinicians should inform and encourage patients towards musculoskeletal pain management in the form of conservative treatment and educate patients about the positive outcomes of the intervention.[118] In order to challenge unhelpful beliefs in musculoskeletal pain management by conservative treatment, positive educational materials such as infographics that highlight benefits of this treatment in neutral language should be targeted at patients.[118] If subacromial decompression is to be limited, it is important that a patients' attitudes towards physiotherapy can be influenced by their clinicians' language and recommendations. Moreover, patients' attitudes towards adopting physiotherapy as a treatment for shoulder pain can be influenced by other factors aside from language.

Patient attitude towards the adoption of physiotherapy before and after shoulder surgery to treat pain differs between genders.[113] One prospective case series in Denmark suggested that gender can affect the likelihood of a patient with shoulder pathologies adopting physiotherapy 26 weeks before the first hospital contact or within 26 weeks after any surgical intervention.[113] Women (RR_{crude}=1.22) were more likely to adopt physiotherapy 26 weeks before the first hospital contact than were men (RR_{crude}=1.00).[113] Similarly, women (RR_{crude}=1.07) were more likely than men (RR_{crude}=1.00) to use physiotherapy services within 26 weeks post-surgical intervention.[113] Therefore, if subacromial decompression to treat subacromial pain is limited, additional attention would need to be provided to men to ensure that they adopt physiotherapy as a treatment.

9.2.4.3 Patient expectation

Patient expectations of, and satisfaction with, the benefits of undergoing subacromial decompression to treat subacromial pain can differ between population subgroups.[116 117] A Swedish prospective case series indicated that 16.1% (n=17) of patients aged 50 years and over with subacromial pain were dissatisfied with their shoulder function after subacromial decompression.[116] An American prospective case series found that approximately 57% (n=20) of athletes with subacromial pain were dissatisfied with their shoulder function post-subacromial decompression, with 76% of them being unable to regain their throwing or overhead sports ability.[117] If subacromial decompression to treat subacromial pain is to be limited, consideration would need to be given to the satisfaction the overall patient population has in the procedure, as well as how different sub-populations perceive the procedure.

9.2.5 Findings: ethical issues

The evidence on ethical issues associated with limiting the use of subacromial decompression related to ensuring that population subgroups have access to suitable alternatives.[113] A Danish study highlighted potential concerns in patients undergoing a variety of shoulder surgeries to treat joint pain regarding particular populations being able to access physiotherapy prior to surgical or hospital contact.[113] The older population (56–65 years of age) was less likely to adopt physiotherapy (RR_{crude}= 0.85) 26 weeks before first hospital contact.[113] Nevertheless, 26 weeks post-surgical intervention adoption of physiotherapy among the older population (RR_{crude}= 1.06) had increased.[113] Likewise, patients with a lower level of education (i.e. no higher education or vocational training) had lower use of physiotherapy (RR_{crude}=0.97) 26 weeks before first hospital contact.[113] By 26 weeks after surgical intervention, this socioeconomic gap had disappeared.[113] Consequently, if subacromial decompression to treat subacromial pain is limited, additional attention would need to be given to ensuring that vulnerable population subgroups are able to adopt physiotherapy as a treatment.

An additional study identified during the systematic searches described experience with informed consent and shoulder surgery in an Italian healthcare context.[119] Because informed consent is not a consideration for disinvestment, this study was not included in this HTA analysis.

9.3 Summary statement legal, social and ethical issues

An evidence base was identified for social and ethical issues related to limiting the use of subacromial decompression as a primary and isolated intervention for patients with subacromial pain. No information was identified relating to potential legal issues associated with limiting use of the procedure. The identified evidence base on associated social issues related to psychological aspects, patient attitudes and patient expectations. The evidence-base highlighted that access was the ethical issue associated with the possible limitation of the treatment option.

10 Organisational issues

10.1 Methodology: organisational issues

The evidence base for organisational issues was identified from both systematic and non-systematic searches. The search terms and systematic search strategies are outlined in ***Section 7.1.1***, ***Section 7.1.2*** and ***Appendix A***. The non-systematic searches included searches of Google and PubMed using terms such as shoulder, rotator, pain, work-flow, system structure, and sustainability. The non-systematic searches were conducted by a single reviewer.

Many study designs were included in this narrative assessment of organisational issues. The study designs included, but were not limited to, systematic reviews, literature reviews, RCTs, non-RCTs, single-arm studies, ethnographic studies, phenomenological studies, narrative research and case studies. Results for this section were analysed and summarised narratively.

10.2 Results: organisational issues

10.2.1 PRISMA flow diagram

The total of three publications were identified and included in the narrative synthesis of organisational issues, identified through the systematic search.[32 113 114] No relevant articles were found through the targeted searches. A PRISMA diagram was not included in this section given that both systematic and non-systematic searches were conducted.

10.2.2 Evidence table

The three included publications (***Table 20***), all appeared to be applicable to the Swiss healthcare context as they were all conducted in WHO – Mortality Stratum A countries.[32 66 113 114] The two primary research publications were conducted in the UK and Demark.[113 114] The secondary research publication was a rapid review that included data from WHO – Mortality Stratum A countries.[32 66] All the data provided by the three publications occurred in a hospital-based setting, either inpatient or outpatient.[32 113 114] Two of the three included publications limited the population solely to patients suffering from subacromial pain who were treated with subacromial decompression as a primary intervention and/or conservative treatment.[32 114] The remaining publication considered patients with around-shoulder pathology who were treated with a range of shoulder-focused surgical procedures.[113]

The sample size for both the primary studies (k=2) totalled n=57,320, with one study including the majority of the cohort (n=57,311),(Christiansen 2016) and one study including 9 patients.(Cuff 2017)[113 114] Sample size for the rapid review totalled n=1,014.[32] The follow-up period for the case series was one

year.[113] Given that the study by Cuff and Littlewood was a cross-sectional qualitative study, there was no follow-up time.[114] The rapid review included data sets that had follow-up periods ranging from 1 to 14 years.[32]

Regarding the individual publications, the first study by Cuff and Littlewood examined the effect of the language doctors used to explain subacromial pain on patients' opinions toward and adoption of conservative treatment options.[118] Christiansen et al. (2016) investigated the utilisation of physiotherapy (i.e. conservative treatment) in patients with subacromial pain as part of a non-surgical intervention, or after subacromial decompression.[113] Finally, the rapid review by Vandvik et al. was a detailed clinical practice guideline for the treatment of subacromial pain.[32]

Table 20 Characteristics of included studies for organisational issues

Study; country	Indication; sample size	Design; follow-up; setting	Outcomes
Cuff 2017[114] UK	Patients with subacromial pain n=9	Cross-sectional qualitative study – semi-structured interview Not applicable Hospital setting	Organisational Practitioner education
Christiansen 2016[113] Denmark	Patients with: • Rotator cuff syndrome • Tendinitis (i.e. bicipital calcific) • Subacromial pain • Bursitis • Shoulder lesions • Unspecified lesions n=57,311	Prospective case series 1 year Hospital setting	Organisational Utilisation
Vandvik 2019[32] Not applicable	Patients with subacromial pain n=1,014	Rapid review (k=7) 1–14 years Hospital outpatient setting	Organisational Workflow

Abbreviations:
UK = United Kingdom.

10.2.3 Findings: organisational issues

Three organisational issues were identified in the literature that could occur if the use of subacromial decompression as a primary intervention to treat subacromial pain is limited. These issues relate to how the treatment options would change workflow, conservative treatment utilisation and practitioner education.

If patients with subacromial pain have limited surgical options, the main treatment pathway would be continuation of conservative treatment.[32] This would result in changes to workflow for healthcare practitioners including orthopaedic surgeons, general practitioners and physiotherapists (further

explained in ***Section 4.2***). These changes in workflow would mean that clinicians would need to be educated on the new clinical pathway for patients with subacromial pain, which focuses on non-surgical conservative treatment instead of subacromial decompression.[32] Clinicians would need to be educated in how to best assist patients with improving their understanding of the condition and the importance of maintaining their treatment regimen.[32 118]

As discussed above in ***Section 9.2.4***, an important finding of Cuff and Littlewood was that a clinician's language can substantially change patients' acceptance of, and opinions towards, non-surgical interventions such as conservative therapy.[118] This is likely due to how a clinician explains the biological model behind subacromial pain and the benefits of subacromial decompression, but does not ascribe any positive connotations to conservative treatment.[118] Changing patient perceptions of the alternatives will likely be needed to enable optimal uptake. This was highlighted by that fact that in Denmark patients with subacromial pain were more likely to utilise and accept physiotherapy (i.e. conservative treatment) after undergoing decompression, with 80% of patients using the rehabilitation service postoperatively;[113] whereas, 45% of patients with subacromial pain utilised physiotherapy prior to undergoing the surgical procedure.[113]

The publications highlighted that when patients pursued conservative therapy instead of subacromial decompression to treat subacromial pain, more practitioner education to assist with their understanding of the treatment was needed.[118] To address this matter in the event that limitations are placed on the use of subacromial decompression to treat subacromial pain, clinicians will need to be educated and their understanding of conservative treatment for musculoskeletal pain and function management increased, so they can inform their patients on positive outcomes of the intervention.[118]

10.3 Summary statement organisational issues

There was limited available evidence to substantiate potential organisational issues associated with changes to the reimbursement of subacromial decompression. Potential issues relate to (i) changes in workflow for healthcare practitioners, resulting in a shift in resource utilisation from surgery to physiotherapy and other conservative management options; (ii) additional training requirements for clinicians on the optimal application of conservative management as an option for treating subacromial pain; and (iii) changes to patient perception and utilisation of conservative management as an option for treating subacromial pain.

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11 Additional issues

11.1 Clinical practice position statements and guidelines

Five clinical practice position statements and guidelines were identified through the systematic search and targeted searches (***Table 21***).[29 30 32 120 121] Three of these were clinical practice guidelines[29 30 32] and two were positions statements.[120 121] The issuing organisations were from the UK (k=2),[29 120] the Netherlands (k=1)[30] and Australia (k=1).[121] One of the guidelines did not have an applicable jurisdiction.[32]

There was some disagreement in the literature regarding the clinical utility of subacromial decompression as a primary intervention to treat patients with subacromial pain.[29 30 32 120 121] Four of the clinical practice position statements and guidelines (i.e. orthopaedic opinions and investigation) recommended the use of subacromial decompression to treat patients with subacromial pain under specific circumstances, such as multiple failed cycles of conservative treatment and worsening symptoms.[29 30 120 121] A single clinical guideline, by Vandvik et al. strongly recommended against the use of subacromial decompression in favour of conservative treatment.[32]

Table 21 Summary of clinical guidelines and recommendations regarding subacromial decompression

Author; Country	Recommendation	Strength of recommendation
Guidelines [a]		
Cheshire Wirral Partnership NHS Foundation Trust, 2016 [29] UK	Conservative treatment is recommended for the management of subacromial pain. Pathway for orthopaedic opinions and/or investigations is included in the clinical management algorithm.	NR NR
Dutch Orthopaedic Association, 2014 [30] The Netherlands	Conservative treatment is recommended as the preferred management of subacromial pain: - Glucocorticosteroid injection - Physiotherapy - NSAIDs The recommendation for a patient with subacromial pain to undergo an arthroscopic subacromial decompression is dependent on: - Symptomatic rotator cuff tear - Condition of muscles - Age - Activity level	Level 1* Level 1–2 Level 3 Level 2–3
Vandvik, 2019 [32] NR	Recommends against subacromial decompression to treat patients with subacromial pain in favour of conservative treatment.	Strong [b]
Position statements [c]		

Author; Country	Recommendation	Strength of recommendation
Shoulder and Elbow Society of Australia (SESA)—a subsidiary of the Australian Orthopaedic Association (AOA), 2017 [121] Australia	Arthroscopic decompression should only be performed on patients with subacromial pain who have significant and persistent symptoms that have not responded to conservative treatment.	NR
British Elbow & Shoulder Society (BESS) and British Orthopaedic Association (BOA), 2017 [120] UK	Informed decision-making on use of arthroscopic subacromial decompression in patients with subacromial pain. [d]	NR

Abbreviations:

NHS = National Health Service, **NR** = not reported, **NSAIDs** = non-steroidal anti-inflammatory drugs, **UK** = United Kingdom.

Notes:

Conservative treatment: Non-operative treatments may include NSAIDs, intra-articular or subacromial glucocorticosteroid injections, physiotherapy

***Strength of Recommendation level:** 1 = High-quality studies, 2 = Moderate-quality studies, 3 = low-quality studies, 4 = very-low-quality studies.[30]

[a] Clinical practice guidelines

[b] Evidence quality per outcome: Pain = High, Function = High, HRQoL= High, Return to work = Low, Serious harms = Moderate.[32]

[c] A statement addressing the association's and/or organisation's position on the publication of Beard et al.[19]

[d] Until guidelines are updated[120]

12 Discussion

The main objective of this HTA was to evaluate the clinical and economic impact of subacromial decompression as a primary and isolated intervention to treat subacromial pain and give consideration to the legal, social, ethical and organisational issues associated with limiting access to the surgical procedure.

12.1 Comparison to previous reviews

Three other reviews evaluated the clinical efficacy of subacromial decompression to treat patients with subacromial pain.[17 122 123] The review by Lähdeoja et al.,[17] compared subacromial decompression to both conservative treatment and placebo, and was prepared by the same authors as the recent Cochrane review by Karjalainen et al. The other two[122 123] compared subacromial decompression to conservative treatment.

The findings of these three reviews are generally in accordance with the findings of this HTA.[17 122 123] All three HTAs concluded that subacromial decompression has no significant clinical benefit over conservative treatment when treating patients with subacromial pain.[17 122 123] Similarly, Lähdeoja et al. found that subacromial decompression does not have a significant clinical benefit over placebo (sham surgery) when used to treat patients suffering from subacromial pain.[17]

Two additional reviews were identified.[1 124] Both were published by the Cochrane Collaboration, with the HTA by Karjalainen et al. being an update of that by Coghlan et al.[1 124] Given that Karjalainen et al.[1] formed part of the evidence base of the clinical evaluation section of this HTA, it has not been listed as a comparison HTA.

12.2 Limitations in the HTA methods

There are several limitations related to the methodology employed to conduct this HTA. The first limitation is the risk of publication bias because fewer than ten trials were included (Grey literature searches were conducted to limit the risk of publication bias). Secondly, all available evidence was not included in the HTA because the inclusion criteria was limited to countries in WHO – Mortality Stratum A to ensure the evidence was applicable to the Swiss healthcare context; this may have excluded additional non-randomised and single arm studies, but it is important to note that there were no additional RCTs that were excluded from the report. In addition, MCIDs could not be defined for all identified predetermined outcomes (***Table 40***). This meant that there was no way to determine if a statistically significant difference for these outcomes (i.e. ability to return to work, ability to return to

leisure activities, and further progression of disease) was clinically important or not. The final limitation to this HTA was that not all research questions could be answered due to the lack of evidence (e.g. optimal subgroups for decompression).

12.3 Limitations in the Cochrane review

The confidence in the systematic review by Karjalainen et al. was high as it comprehensively summarised the results from all available trials.[1] Quality of the evidence-base for this systematic review ranged from high to low.[1]

From the eight included RCTs the risk of bias ranged from low to high. Out of these studies, two of the placebo-controlled trials met the criteria of low risk of bias,[1 19 44 52 88] whereas the other six trials were rated as high risk due to a number of sources of bias. In six of the trials the bias was related to detection and performance bias caused by inadequate blinding of trial personnel and participants.[1 45-47 52 80-90] Three of the trials had a high risk of reporting bias resulting from selective reporting caused by the lack of a published protocol and not publishing outcomes at predetermined time points.[1 46 83 89 90] A single trial presented a high risk of selection bias because of inadequate sequence generation and allocation concealment.[1 45 82]

The review by Karjalainen et al. did not define some of the predetermined outcomes and time points the same way as this HTA or did not impute conservative SDs.[1] To address this the meta-analyses were re-run or updated when necessary. Finally, the authors of the Karjalainen et al. were not transparent about which unpublished outcome data was provided to them directly from the trial investigators.

The systematic review by Karjalainen et al. was well executed and of high quality.[1] The evidence base comprised RCTs with varying risks of bias and this was taken into account in the conclusion and recommendations.[1] However, some of the analysis had to be updated or re-run as the outcomes were defined differently in Karjalainen et al. than they were in the PICO criteria for this HTA.[1]

12.4 Limitations in the primary studies

The quality of the included evidence for each outcome (***Table 10***) when subacromial decompression as a primary intervention is compared to conservative therapy ranged from moderate to very low. Where necessary, the evidence for specific outcomes was downgraded due to the risk of detection and performance bias in the included RCTs because participants were aware of their treatment allocations. Additional reasons for downgrading the quality of the outcomes were inconsistency, imprecision and publication bias.

Evidence quality for the outcomes (***Table 11***) when subacromial decompression as a primary intervention is compared to placebo (sham surgery) ranged from high to moderate. Specific outcomes were downgraded when necessary due to the risk of bias (i.e. detection and performance bias), imprecision and inconsistency.

Evidence quality for the included outcomes (***Table 12***) when subacromial decompression as a primary intervention is compared to no treatment was moderate.

12.5 Summary of heterogeneity and inconsistency

Overall, heterogeneity and inconsistency with the various meta-analyses performed in ***Section 7*** ranged from low to considerable. Moderate to considerable heterogeneity was most prevalent in the meta-analyses in which conservative treatment was the comparator. The higher levels of heterogeneity were likely caused by small numbers of patients in the trials, imbalances of patient numbers between trial arms, and risks of detection and performance bias.[1 45-47 80-87 89 90] The high risk of detection and performance bias was likely caused by the participants being aware of their treatment allocations in the included RCTs.[1 45-47 80-87 89 90] Heterogeneity in meta-analyses where placebo (sham surgery) was the comparator was low (I^2=0% to 21%). This was likely due to two of the three trials presenting a low risk of bias and having a balanced number of patients in all trial arms.[1 19 44 52 88] Compared to other time points and outcomes, shoulder function at the 6-month time point returned substantial heterogeneity (χ^2=5.28, I^2=62%), most probably caused by the trial by Brox et al. having a small number of patients, an imbalance of patients between the trial arms, and a high risk of detection and performance bias caused by inadequate blinding.[80 81 99] Calculating heterogeneity in the meta-analyses comparing subacromial decompression to no treatment was not possible because a single trial was included at two time points.[19 44]

12.6 Limitations of the economic analyses

This health economic analysis has some limitations. The cost of subacromial decompression included in the economic model was limited to the cost of the procedure itself. Follow-up medical services and medicines costs may differ between subacromial decompression, no treatment and conservative management. Follow-up costs were included in a sensitivity analysis, although cost differences were based on the UK study of Rombach[110] and care pathways could differ in Switzerland. This study was also the sole source of health outcome data used to compare subacromial decompression and no treatment in the economic model.

The budget impact analysis comprised three scenarios to calculate the payer cost implications of subacromial decompression procedure delisting. These included potential subacromial decompression patients resorting to no treatment if the procedure were to be delisted, plus proportions (50% and 75%) substituting to physiotherapy. Physiotherapy is a first-line conservative treatment option for subacromial pain, with subacromial decompression being considered if conservative treatment provides limited benefit. A more accurate calculation of net payer cost implications involves estimating the proportion of Swiss subacromial decompression patients who would benefit from increased utilisation of physiotherapy in the event that surgery was delisted. It is unclear what proportion of current patients this subpopulation represents, so broad 50% and 75% substitution rates were included to gauge cost impacts.

12.7 Ongoing clinical trials

Ongoing and unpublished clinical trials (k=4) that met the PICO criteria (***Section 5***) are summarised in ***Table 41*** (***Appendix E***). All trials are registered in continental Europe, with two in Denmark, one in Finland and one in The Netherlands. One of the included clinical trials is currently recruiting and is expected to be completed by March 2021. This trial aims to assess the efficacy of subacromial decompression in a single-arm trial. Another trial, which has not started recruiting, has been recently registered (November 2020) and is expected to be completed by June 2025. This RCT compares subacromial decompression to placebo (sham surgery) in order to determine the efficacy of the procedure in treating patients with subacromial pain. Both of the two remaining clinical trials are RCTs; one comparing subacromial decompression to physiotherapy and the other comparing it to usual care. These RCTs are not actively recruiting and were completed in 2008 and 2018, although the results are yet to be published.

13 Conclusions

The clinical efficacy and safety of subacromial decompression as primary and isolated treatment of subacromial pain were informed by a systematic review published by the Cochrane Collaboration, and the 8 RCTs included within it. The safety evaluation was supplemented by non-randomised and single-arm studies. The literature provided limited or no evidence of clinically important benefits of subacromial decompression compared to conservative treatment, placebo (sham surgery) or no treatment. The overall quality of evidence for safety and efficacy outcomes, as inferred by GRADE, ranged from high to very low. The major source of bias encountered in the included RCTs was inadequate blinding of personnel and participants. Non-randomised and single-arm studies presented a risk of bias from moderate to critical.

Compared to no treatment, an ICER of CHF98,102 per QALY gained was estimated at 12 months for surgery, without adjustment to baseline utility values and CHF107,913 per QALY gained with adjustment to baseline utility. These estimates are similar to a hypothetical willingness to pay figure of CHF100,000. Delisting the procedure would result in net cost savings – with the impact sensitive to the proportions of patients who would substitute to other treatments (physiotherapy) or resort to no treatment.

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15 Appendix A: Sources of literature (databases)

15.1 Literature sources

Table 22 Biomedical bibliographic databases

Source	Results
PubMed	https://www.ncbi.nlm.nih.gov/pubmed/
Embase	https://www.embase.com/
The Cochrane Library (inc. CENTRAL)	https://www.cochranelibrary.com/
CINAHL	https://www.ebscohost.com/nursing/products/cinahl-databases/cinahl-complete
York CRD	https://www.crd.york.ac.uk/CRDWeb/
Econlit	https://www.aeaweb.org/econlit/
PsychInfo	https://www.apa.org/pubs/databases/psycinfo/
ETHMED	http://www.idem.uni-goettingen.de/en/database-ethmed.html

Table 23 Clinical trial registries

Source	Website
ClinicalTrals.gov	https://clinicaltrials.gov/
Cochrane Central Register of Controlled Trials	https://www.cochranelibrary.com/central
EU Clinical Trials Registry	https://www.clinicaltrialsregister.eu/
World Health Organization (WHO), International Clinical Trials Registry Platform	https://www.who.int/ictrp/en/
Australian New Zealand Clinical Trials Registry	http://www.anzctr.org.au/

Table 24 HTA agency websites

HTA Websites	
International	
National Information Centre of Health Services Research and Health Care Technology (NICHSR)	https://www.nlm.nih.gov/hsrph.html
National Library of Medicine Health Services/Technology Assessment Texts (HSTAT)	https://www.ncbi.nlm.nih.gov/books/NBK16710/
International Information Network on New and Emerging Health Technologies (EuroScan International Network)	https://www.euroscan-network.global/index.php/en/47-public-features/761-database-home
Australia	
Adelaide Health Technology Assessment (AHTA)	https://www.adelaide.edu.au/ahta/pubs/
Centre for Clinical Effectiveness, Monash University	http://monashhealth.org/health-professionals/cce/

Centre for Health Economics, Monash University	https://www.monash.edu/business/che
National Health and Medical Research Council	https://www.nhmrc.gov.au/
Australian Safety and Efficacy Register of New Interventional Procedures—Surgical (ASERNIP-S)	https://www.surgeons.org/research-audit/research-evaluation-inc-asernips
Australia & New Zealand	
Health Technology Reference Group (HTRG)	https://www.coaghealthcouncil.gov.au/AHMAC/Health-Technology-Reference-Group
Austria	
Institute of Technology Assessment / HTA unit	https://www.oeaw.ac.at/ita/publikationen/
Ludwig Boltzmann Institute for Health Technology Assessment (LBI-HTA)	https://hta.lbg.ac.at/page/publikationen/en
Gesundheit Österreich GmbH (GOG)	http://www.goeg.at
Hauptverband der Österreichischen Sozialversicherungsträger (HVB)	http://www.sozialversicherung.at
University for Health Sciences, Medical Informatics and Technology	https://www.umit.at
Argentina	
Institute for Clinical Effectiveness and Health Policy (IECS)	http://www.iecs.org.ar
Belgium	
Scientific Institute of Public Health (IPH)	https://www.wiv-isp.be/en
Belgian Health Care Knowledge Centre (KCE)	http://kce.fgov.be
Rijksinstituut voor Ziekte- en Invaliditeitsverzekering (RIZIV-INAMI)	https://www.inami.fgov.be/
Bulgaria	
National Center of Public Health Analyses (NCPHA)	http://ncpha.government.bg/index.php?lang=en
Brazil	
National Committee for Technology Incorporation (CONITEC)	http://conitec.gov.br/en/
Canada	
Institute of Health Economics (IHE)	http://www.ihe.ca
Institut National d'Excellence en Santé et en Services (INESSS)	https://www.inesss.qc.ca/en/home.html
The Canadian Agency for Drugs and Technologies in Health (CADTH)	http://www.cadth.ca/
The Canadian Association for Health Services and Policy Research (CAHSPR)	https://www.cahspr.ca/
Centre for Health Economics and Policy Analysis (CHEPA), McMaster University	http://www.chepa.org/
Centre for Health Services and Policy Research (CAHSPR), University of British Columbia	http://www.chspr.ubc.ca/
Institute for Clinical and Evaluative Studies (ICES)	http://www.ices.on.ca/
Saskatchewan Health Quality Council (Canada)	http://www.hqc.sk.ca/
Evidence Development and Standards Branch (HQO)	http://www.hqontario.ca
Croatia	
Ministry of Health of the Republic of Croatia (MIZ)	https://www.miz.hr
Croatian Health Insurance Fund (CHIF)	https://www.hzzo.hr
Croatian Institute of Public Health (CIPH)	https://www.hzjz.hr/english/
Colombia	
Instituto de Evaluación Tecnológica en Salud (IETS)	http://www.iets.org.co

Cyprus	
Ministry of Health Cyprus (MoH Cyprus)	https://www.eunethta.eu/moh-cyprus
Republic of Cyprus Pharmaceutical Services	https://www.moh.gov.cy/moh/phs/phs.nsf/dmlindex_en/dmlindex_en?opendocument
Czech Republic	
Ministry of Health Czech Republic (MoH Czech)	https://www.mzcr.cz/en
State Institute for Drug Control (SUKL)	https://www.sukl.eu
Denmark	
Danish National Institute of Public Health	https://www.sdu.dk/en/sif/forskning
Social & Health Services and Labour Market (DEFACTUM)	http://www.defactum.net
Estonia	
Institute of Family Medicine and Public Health (UTA)	https://www.tervis.ut.ee
Finland	
National Institute for Health and Welfare (THL)	https://www.thl.fi
Finnish Coordinating Center for Health Technology Assessment (FinCCHTA)	https://www.ppshp.fi/Tutkimus-ja-opetus/FinCCHTA/Sivut/HTA-julkaisuja.aspx
Finnish Medicines Agency (FIMEA)	http://www.fimea.fi
France	
French National Authority for Health (Haute Autorité de Santé; HAS)	http://www.has-sante.fr/
Comité d'Evaluation et de Diffusion des Innovations Technologiques (CEDIT)	http://cedit.aphp.fr/
Germany	
German Institute for Medical Documentation and Information (DIMDI)	https://www.dimdi.de/
Institute for Quality and Efficiency in Health Care (IQWiG)	http://www.iqwig.de
Federal Joint Committee (Gemeinsamer Bundesausschuss; G-BA)	https://www.g-ba.de/english/
Greece	
Institute of Pharmaceutical Research and Technology (IFET)	http://www.ifet.gr/english_site/
National and Kapodistrian University of Athens (EKAPTY-NKUA)	http://en.phs.uoa.gr/
National Evaluation Centre of Quality and Technology in S.A-EKAPTY	http://www.ekapty.gr/
National Organization for Medicines (EOF)	http://www.eof.gr
National Organisation for Healthcare Provision (EOPYY)	http://www.eopyy.gov.gr
Onassis Cardiac Surgery Centre (OCSC)	http://www.onasseio.gr/
Hungary	
Health Services Management Training Center (SU)	http://www.semmelweis.hu/emk/en/
National Institute of Pharmacy and Nutrition (NIPN)	http://www.ogyei.gov.hu/main_page/
Ireland	
Health Information and Quality Authority (HIQA)	http://www.hiqa.ie
National Centre for Pharmacoeconomics, St James Hospital (NCPE)	http://www.ncpe.ie
Italy	
Agenzia Sanitaria e Sociale Regionale (ASSR)	http://www.inahta.org/members/assr/
Centro Regionale Unico sul Farmaca del Veneta (CRUF/AOUIVR)	http://www.ospedaleuniverona.it/ecm/home
HTA Unit in A. Gemelli Teaching Hospital (UVT)	https://www.policlinicogemelli.it/

Italian Medicines Agency (AIFA)	http://www.agenziafarmaco.gov.it
National Agency for Regional Health services (Agenas)	http://www.agenas.it
Regione Del Veneto – Area Sanita E' Sociale (Veneto/CRUF)	http://www.ospedaleuniverona.it/ecm/home
Regione Emilia-Romagna (RER)	http://www.regione.emilia-romagna.it/
Sede del Ministro – Ministero della salute (DGFDM IT)	http://www.salute.gov.it
University Hospital A. Gemelli (UCSC GEMELLI)	http://www.roma.unicatt.it/
Unita di Valutazione Technology Assessment (UVTA/AOP)	http://www.sanita.padova.it
Kazakhstan	
Ministry of Public Health of the Republic of Kazakhstan, Republican Centre for Health Development (RCHD)	http://www.rcrz.kz
Korea	
National Evidence-based healthcare Collaborating Agency (NECA)	www.neca.re.kr/eng
Latvia	
National Health Service (NVD)	http://www.vmnvd.gov.lv/
Lithuania	
The Institute of Hygiene (HI)	http://www.hi.lt
State Health Care Accreditation Agency (VASPVT)	http://www.vaspvt.gov.lt
Luxembourg	
Inspection Générale de la Sécurité Sociale (IGSS), Cellule d'Expertise Médicale (CEM)	http://www.mss.public.lu/publications/index.html
Malaysia	
Health Technology Assessment Section, Ministry of Health Malaysia (MaHTAS)	http://www.moh.gov.my
Malta	
Directorate for Pharmaceutical Affairs (DPA/MoH Malta)	http://www.health.gov.mt/en/pharmaceutical/Pages/pharmaceutical-affairs.aspx
Mexico	
Centro Nacional de Excelencia Tecnológica en Salud (CENETEC)	www.cenetec.gob.mx
The Netherlands	
Erasmus Universiteit Rotterdam (EUR)	http://www.eur.nl/
Health Council of The Netherlands (Gezondheidsraad)	https://www.gezondheidsraad.nl/
The Netherlands Organisation for Health Research and Development (ZonMw)	http://www.zonmw.nl
Zorginstituut Nederland (ZIN)	https://www.zorginstituutnederland.nl/
Utrecht University (UU)	http://www.uu.nl
Norway	
The Norwegian Institute of Public Health (NIPHNO)	http://www.fhi.no/
Norwegian Directorate of Health (Hdir)	http://helsedirektoratet.no/english
Norwegian Medicines Agency (NOMA)	http://www.legemiddelverket.no
Poland	
Agency for Health Technology Assessment and Tariff System (AOTMiT)	http://www.aotm.gov.pl
Portugal	
Administração Central do Sistema de Saúde, I.P. (ACSS IP)	http://www.acss.min-saude.pt
National Authority of Medicines and Health Products (INFARMED)	http://www.infarmed.pt

Republic of China, Taiwan	
Center for Drug Evaluation (CDE)	http://www.cde.org.tw
Romania	
Babes-bolayi University, Cluj School of Public Health (UBB)	http://publichealth.ro/
Institutu National De Sanatate Publica (INSP/NIPHB)	https://www.insp.gov.ro/
National School of Public Health, Management and Professional Development (NSPHMPDB)	http://www.snspms.ro
Singapore	
Agency for Care Effectiveness(ACE)	Agency for Care Effectiveness (ACE) (ace-hta.gov.sg)
Slovakia	
Comenius University in Bratslava (UniBA FOF)	https://uniba.sk/en/
Ministry of Health of the Slovak Republic (MoH Slovak Republic)	http://www.health.gov.sk
Slovenia	
Ministry of Health of the Republic of Slovenia (MoH Slovenia)	http://www.mz.gov.si/en/
National institute of Public Health (NIJZ)	http://www.nijz.si
Public Agency of the Republic of Slovenia for Medical Products and Medical Devices (JAZMP)	http://www.jazmp.si/en/
South Africa	
Charlotte Maxeke Research Consortium (CMeRC)	http://www.cmerc.org
Spain	
Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)	http://www.aemps.gob.es
Agencia de Evaluación de Tecnologias Sanitarias, Instituto de Salud “Carlos III”I / Health Technology Assessment Agency (AETS)	http://publicaciones.isciii.es/
Agency for Health Quality and Assessment of Catalonia (AQuAS)	http://aquas.gencat.cat
Andalusian HTA Agency	http://www.aetsa.org/
Basque Foundation for Health Innovation and Research (BIOEF)	http://www.bioef.org/
Basque Office for Health Technology Assessment (OSTEBA)	http://www.euskadi.eus/web01-a2ikeost/en/
Directorate General for Pharmacy and Health Care Products (DGFPS MSPSI)	website not provided
Evaluation AND Planning Unit – Directorate of the Canary Islands Health Service (SESCS)	https://funcanis.es/
Fundación Canaria de Investigación Sanitaria (Funcanis)	http://www.funcanis.org/
Fundacion Profesor Novoa Santos (AVALIA FNS)	http://www.fundacionprofesornovoasantos.org/es/
Fundación Pública Andaluza Progreso y Salud (FPS)	http://www.juntadeandalucia.es/fundacionprogresoysalud/
Galician Agency for Health Technology Assessment (AVALIA-T)	http://acis.sergas.es
Health Sciences Institute in Aragon (IACS)	http://www.iacs.es/
The Instituto De Salud Carlos III (AETS-ISCIIIS)	https://eng.isciii.es/eng.isciii.es/Paginas/Inicio.html
Sweden	
Center for Medical Health Technology Assessment	http://www.cmt.liu.se/?l=en&sc=true
Dental and Pharmaceutical Benefits Agency (TLV)	http://www.tlv.se
Medical Products Agency (MPA)	http://www.lakemedelsverket.se

Swedish Council on Technology Assessment in Health Care (SBU)	http://www.sbu.se/en/
Switzerland	
Swiss Federal Office of Public Health (SFOPH)	http://www.bag.admin.ch/hta
Swiss Network on Health Technology Assessment (SNHTA)	http://www.snhta.ch/
Tunisia	
INEAS – National Authority for Assessment and Accreditation in Healthcare, TUNISIA	http://www.ineas.tn/fr
United Kingdom	
All Wales Therapeutics and Toxicity Centre (AWTTC)	http://awttc.org
Healthcare Improvement Scotland (HIS)	http://www.healthcareimprovementscotland.org
National Health Service Health Technology Assessment (UK) / National Coordinating Centre for Health Technology Assessment (NCCHTA)	https://www.nihr.ac.uk/
NHS Quality Improvement Scotland	http://www.nhshealthquality.org/
National Institute for Clinical Excellence (NICE)	http://www.nice.org.uk/
Health Technology Wales (HTW)	http://www.healthtechnology.wales
National Institute for Health Research (NIHR), including HTA programme	http://www.nets.nihr.ac.uk/programmes/hta
United States	
Agency for Healthcare Research and Quality (AHRQ)	https://www.ahrq.gov/research/findings/index.html
Harvard School of Public Health	http://www.hsph.harvard.edu/
Institute for Clinical and Economic Review (ICER)	http://www.icer-review.org/
Institute for Clinical Systems Improvement (ICSI)	http://www.icsi.org
Minnesota Department of Health (US)	http://www.health.state.mn.us/
Office of Health Technology Assessment Archive (US)	http://ota.fas.org/
U.S. Blue Cross / Blue Shield Association Technology Evaluation Center (Tec)	https://www.bcbs.com/news/press-releases/blue-cross-blue-shield-association-launches-evidence-street-website-streamline
Veteran's Affairs Research and Development Technology Assessment Program (US)	http://www.research.va.gov/default.cfm
Uruguay	
Health Assessment Division, Ministry of Public Health, (HAD)	http://www.msp.gub.uy

Source:
Based on the INAHTA members list [125]

Table 25 Specialty websites

Specialty websites	
Geneva Medical Association	https://www.amge.ch/
American Association for Surgery of Trauma	aast.org/Default.aspx
American Association of Orthopaedic Surgeons	http://www.aaos.org/
American College of Sports Medicine	https://www.acsm.org/

American College of Surgeons	http://www.facs.org/
American Orthopaedic Association	https://www.aoassn.org/aoaimis/aoanew
American Orthopaedic Society for Sports Medicine	https://www.sportsmed.org/aossmimis
American Shoulder and Elbow Surgeons (ASES)	https://www.ases-assn.org/
American Sports Medicine Institute	http://www.asmi.org/
Arbeitsgemeinschaft fur Osteosynthesefragen	http://www.aofoundation.org/wps/portal/
Association of Orthopaedic and Trauma surgeons of Russian Federation	http://www.rniito.org/
Association of Surgeons of Great Britain and Ireland	http://www.asgbi.org.uk/
Australian Orthopaedic Association	https://www.aoa.org.au/
Australian Specialty Orthopaedic Meetings	http://www.aoa.org.au/Content/NavigationMenu/Events/Subspecialties/default.htm
Austrian Orthopaedic Association	http://www.orthopaedics.or.at/
Austrian Orthopaedic Society	http://www.unfallchirurgen.at/index.php
Arbeitsgemeinschaft wissenschaflicher Fachgesellschaften (AWMF)	https://www.awmf.org
Belgian Orthopaedic and Trauma Society	http://www.bvot.be/index.php
British Association of Sports and Exercise Medicine	http://www.basem.co.uk/
British Elbow and Shoulder Society	http://www.bess.org.uk/
British Orthopaedic Association	http://www.boa.ac.uk/
British Orthopaedic Research Society	http://www.borsoc.org.uk/
British Orthopaedic Specialists Association	https://www.bosa.org.uk/
British Orthopaedic Sports Trauma Association	http://www.bosta.ac.uk/
British Trauma Society	http://www.bts-org.co.uk/
Bulgarian Orthopaedics and Traumatology Association (BOTA)	http://www.bulortho.org/ENG/index.htm
Canadian Orthopaedic Association	http://www.coa-aco.org/
Combined meeting of Orthopaedic Research Societies	http://www.eors.eu/
Dansk Ortopaedisk Selskab (DOS) - Denmark	http://barneortopaedi.dk/
Dutch Orthopaedic Association	http://www.orthopeden.org/m_home
Dutch Orthopaedic Society	http://www.trauma.nl/
Eastern Orthopaedic Association	http://eoa-assn.org/
European Federation of National Associations of Orthopaedics and Traumatology	https://www.efort.org/
European Federation of Societies for Microsurgery	http://www.efsm.eu/
European Orthopaedic Research Society	https://www.eors.info/
European Society for Movement Analysis in Adults and Children	http://www.esmac.org/
European Society for Surgery of Shoulder and Elbow	https://www.eusser.org/
European Society for Trauma and Emergency Surgery	http://www.estesonline.org/
Finnish Orthopaedic Association	http://www.soy.fi/
German Society for Orthopaedic and Trauma	https://dgou.de/en/home/
German Orthopaedic Society	http://www.bvou.net/fe/index.php
Greek Orthopaedic Association	http://www.eexot.gr/
Hungarian Orthopaedic Association	http://www.ortopedtarsasag.hu/info.aspx?sp=100
Icelandic Orthopaedic Association	http://www.lis.is/
International Congress of Shoulder and Elbow Surgery	http://www.icses.org/

International Federation of Sports Medicine	https://www.fims.org/
International Society of Orthopaedic Surgery and Traumatology (Belgian)	http://www.sicot.org/
International Society of Physical and Rehabilitation Medicine	http://www.isprm.org/
International Sports Medicine Science and Performance	http://www.leedsmet.ac.uk/conferences/sportsmedicine/index_conference_details.htm
Internet Society of Orthopaedic Surgery and Trauma	http://www.isost.net/
International combined meeting of orthopedic research societies	https://i-cors.org/
Irish Orthopaedic Association	http://www.ioa.ie/
Mid-American Orthopaedic Association	http://www.maoa.org/
National Association of Orthopaedic Technologists	http://www.naot.org/
Nederlandse Orthopaedische Vereniging	https://www.orthopeden.org/
New Zealand Orthopaedic Association	http://www.nzoa.org.nz/
Nordic Orthopaedic Federation	http://www.norf.org/?Home
Norwegian Orthopaedic Association Norwegian Medical Association	https://beta.legeforeningen.no/om-oss/english/
Orthopaedic Research and Education Foundation	https://www.oref.org/
Orthopaedic Research Society	https://www.ors.org/
Orthopaedic Trauma Association	https://ota.org/
Polish Orthopaedic Association	http://www.ptoitr.org.pl/
Polish Orthopaedic Society	http://www.ortopedia.biz.pl/
Romanian Orthopaedic Association	http://www.sorot.ro/
Russian Orthopaedic Society	http://www.rniito.org/
Ruth Jackson Orthopaedic Society	http://www.rjos.org/web/index.html
Societa Italiana di Ortopedia e Traumatologia	http://www.siot.it/pagine/index.html
Society of Orthopaedics and Traumatology of the East	http://www.sotest.org/
Société Française de Chirurgie Orthopédique et Traumatologique	http://www.sofcot.fr/
Society of Military Orthopaedic Surgeons	https://www.somos.org/
Southern Orthopaedic Association	http://soaassn.org/
Spanish Orthopaedic Society	http://www.secot.es/
Sports and Exercise Medicine UK	http://www.uksem.org/
Faculty of sports and exercise medicine UK	https://www.fsem.ac.uk/
Swedish Orthopaedic Association	http://www.ortopedi.se/index1.asp?siteid=1&pageid=1
Swiss Orthopaedic Association	http://www.swissorthopaedics.ch/de/
Turkish Orthopaedic Association	http://www.totbid.org.tr/
Vereinigung Süddeutscher Orthopäden und Unfallchirurgen Association of South German Orthopaedic Surgeons	https://www.vsou.de/home/
Washington State Orthopaedic Association	https://wsoa.org/
Wenckebach Instituut (Netherlands)	http://www.wenckebachinstituut.nl/documenten/algemeen/International%20conferences.htm
Western Orthopaedic Association	http://woa-assn.org/index.cfm
World Orthopaedic Concern (United Kingdom)	http://www.wocuk.org/
IOC world conference on prevention of injury & illness in sport	https://ioc-preventionconference.org/

Table 26 Clinical practice guidelines

Clinical practice guidelines	
Guidelines International Network (GIN)	https://www.g-i-n.net/library/international-guidelines-library
Association of Scientific Medical Societies (AWMF)	https://www.awmf.org/awmf-online-das-portal-der-wissenschaftlichen-medizin/awmf-aktuell.html
National Guideline Clearinghouse	https://www.ahrq.gov/gam/index.html
Scottish Intercollegiate Guidelines Network	https://www.sign.ac.uk/
Swiss Medical Weekly	https://smw.ch/en/
TRIP Database	http://www.tripdatabase.com/

15.2 Search results

Table 27 Summary of biomedical bibliographic database search results

Source	Results
PubMed	9,170
Embase	5,671
The Cochrane Library (inc. CENTRAL)	17
CINAHL	3,752
York CRD	20
Econlit	457
PsychInfo	0
ETHMED	2
Total	19,089

Table 28 Search strategy – PubMed [13 August 2020]

No.	Query	Hits
1	Rotator cuff [tw]	13,356
2	Shoulder [tw]	77,977
3	Subacromial [tw]	2,863
4	Glenohumeral [tw]	6,576
5	1 OR 2 OR 3 OR 4	81,550
6	Shoulder impingement syndrome [mh]	1,770
7	Shoulder pain [tw]	9,187
9	Subacromial bursitis [tw]	121
10	Bursitis [mh]	4,769
11	Bursit* [tw]	4,757
12	Impingemen* [tw]	10,887
13	Rotator cuff disease [tw]	507
14	Rotator cuff injuries [mh]	5,764
15	Rotator cuff injur* [tw]	5,993
16	Tendinopathy [mh]	12,236
17	Tendin* [tw]	18,937
18	6 OR 7 OR 8 OR 9 OR 10 OR 11 OR 12 OR 13 OR 14 OR 15 OR 16 OR 17	50,607
19	General Surgery [mh]	38,845
20	Surgery [tw]	2,647,931
21	Operati*[tw]	966,395
22	Bursectom* [tw]	685
23	Acromioplast* [tw]	599
24	Decompress* [tw]	52,382
25	Decompression, surgical [mh]	30,709

26	Arthroscopy [mh]	23,902
27	Arthroscop* [tw]	36,494
28	Repair [tw]	334,343
29	Debridement [tw]	32,908
30	19 OR 20 OR 21 OR 22 OR 23 OR 24 OR 25 OR 26 OR 27 OR 28 OR 29 OR 30	3,373,432
31	5 AND 18 AND 30	9,170

Table 29 Search strategy – Embase (OVID) [13 August 2020]

No.	Query	Results
1	exp Rotator cuff/	8,609
2	exp Shoulder/	66,767
3	Subacromial.ti,ab,kw.	3,3387
4	Glenohumeral.ti,ab,kw.	7,359
5	**Or/1-4**	**70,666**
6	exp Shoulder impingement syndrome/	2,839
7	Shoulder pain.ti,ab,kw.	9,288
9	Subacromial bursitis.ti,ab,kw.	153
10	exp Bursitis/	4,691
11	Bursit*.ti,ab,kw.	3,498
12	Impingemen*.ti,ab,kw.	12,784
13	Rotator cuff disease.ti,ab,kw.	607
14	exp Rotator cuff injuries/	11,702
15	Rotator cuff injur*.ti,ab,kw.	579
16	exp Tendinopathy/	17,060
17	Tendin*.ti,ab,kw.	19,488
18	Degenerati*.ti,ab,kw.	253,361
19	**Or /5-18**	**311,239**
20	exp General Surgery/	15,508
21	Surgery.ti,ab,kw.	1,670,842
22	Bursectom*.ti,ab,kw.	641
23	Acromioplast*.ti,ab,kw.	701
24	Decompress*.ti,ab,kw.	59,195
25	exp Arthroscopy/	31,600
26	Arthroscop*.ti,ab,kw.	39,355
27	Repair.ti,ab,kw.	418,821
28	Debridement.ti,ab,kw.	31,235
29	**Or/20-28**	**2,110,035**
30	**5 AND 19 AND 29**	**5,671**

Table 30 Search strategy – CINAHL [11 August 2020]

No.	Query	Results
1	MH ”Rotator cuff+”	3,011
2	MH “Shoulder+”	6,492
3	TX “Subacromial”	1,894
4	TX “Glenohumeral”	4,011
5	**1 OR 2 OR 3 OR 4**	**12,935**
6	MH “Shoulder impingement syndrome+”	1,352
7	TX “Shoulder pain”	8,647
8	MH “Pain+”	204,712
9	TX “Subacromial bursitis”	95
10	MH “Bursitis+”	1,713
11	TX “Bursit*”	2,153
12	TX “Impingemen*”	7,214
13	TX “Rotator cuff disease”	386
14	MH “Rotator cuff injuries+”	2,899
15	TX “Rotator cuff injur*”	3,106
16	MH “Tendinopathy+”	4,669
17	TX “Tendin*”	12,227
18	TX “Degenerati*”	46,900
19	TX “Calci*”	91,689
20	**5 OR 6 OR 7 OR 8 OR 9 OR 10 OR 11 OR 12 OR 13 OR 14 OR 15 OR 16 OR 17 OR 18 OR 19**	**352,703**
21	TX “Surger*”	871,049
22	TX “Surgi*”	390,934
23	TX “Operati*”	357,548
24	TX “Bursectom*”	93
25	TX “Arthroplast*”	48,516
26	TX “Acromioplast*”	262
27	TX “Decompress*”	13,825
28	MH “Arthroscopy+”	11,680
29	TX “Arthroscop*”	25,873
30	TX “Repair”	77,176
31	TX “Debridement”	15,618
32	(TX “calci*” AND TX “remov*”)	12,442
33	**20 OR 21 OR 22 OR 23 OR 24 OR 25 OR 26 OR 27 OR 28 OR 29 OR 30 OR 31 OR 32**	**1,232,379**
34	**5 AND 20 AND 33**	**3,752**

Table 31 Search strategy -- Cochrane Library [11 August 2020]

No.	Query	Results
1	(rotator cuff):ti,ab,kw (Word variations have been searched)	1,646
2	(Shoulder):ti,ab,kw	10,844
3	(Subacromial):ti,ab,kw	806
4	**#1 OR #2 OR #3**	**11,273**
5	(pain):ti,ab,kw	174,555
6	(bursit*):ti,ab,kw	498
7	(impingemen*):ti,ab,kw	1,039
8	(injur*):ti,ab,kw	57,808
9	(tendinopathy):ti,ab,kw	993
10	(tendin*):ti,ab,kw	1,802
11	(degenerat*):ti,ab,kw	9,208
12	(calci*):ti,ab,kw	36,102
13	**#5 #6 OR #7 #8 OR #9 OR #10 OR #11 OR #12**	**46,972**
14	(surgery):ti,ab,kw	205,008
15	(surgi*):ti,ab,kw	97,912
16	(operati*):ti,ab,kw	85,259
17	(bursectom*):ti,ab,kw	35
18	(arthroplast*):ti,ab,kw	11,670
19	(acromioplast*):ti,ab,kw	118
20	(decompress*)	3,411
21	(arthroscop*)	5,214
22	(repair)	15,733
23	(debridement)	3,078
24	(calci* AND remov*):ti,ab,kw	865
25	**#14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24**	**272,590**
Filtered		
26	**#4 AND #13 AND #25 in Cochrane Reviews**	**17**
27	**#4 AND #13 AND #25 in Trials**	**354**

Table 32 Search strategy – PsycINFO [11 August 2020]

No.	Query	Results
1	exp Shoulder/	580
2	Subacromial.ti,ab.	50
3	glenohumeral.ti,ab.	50
4	**Or/1-3**	**634**
5	Shoulder pain.ti,ab.	461
6	Exp Pain/	57,564
7	Bursit*.ti,ab.	29
8	Impingemen*.ti,ab.	296
9	Rotator cuff disease.ti,ab.	4
10	Rotator cuff injur*.ti,ab.	12
11	Tendin*.ti,ab.	2,276
12	Degenerati*.ti,ab.	17,940
13	Calci*.ti,ab.	16,315
14	**Or/5-13**	**92,791**
15	Surger*.ti,ab.	28,350
16	Surgi*.ti,ab.	20,894
17	Operati*.ti,ab.	107,969
18	Bursectom*.ti,ab.	1
19	Arthroplast*.ti,ab.	439
20	Acromioplast*.ti,ab.	1
21	Decompress*.ti,ab.	930
22	Arthroscop*.ti,ab.	79
23	Repair.ti,ab.	8,197
24	Debridement.ti,ab.	77
25	(calci* AND remov).ti,ab	**0**
26	**Or/16-25**	**154,244**
27	**4 AND 14 AND 26**	**35**

Table 33 Search strategy – York CRD [11 August 2020]

Number	Query	Results
1	Subacromial impingement	12
2	Subacromial decompression	11
3	**1 OR 2**	**20**

Table 34 Search strategy – EconLit [11 August 2020]

Number	Query	Results
1	TX shoulder	4,785
2	TX rotator cuff	9
3	**1 OR 2**	**4,790**
4	TX impingement	80
5	TX pain	131,392
6	TX bursitis	15
7	TX tendin*	1,499
8	TX degenerate*	6,416
9	TX calci*	1,146
10	**4 OR 5 OR 6 OR 7 OR 8 OR 9**	**27,574**
11	TX surgery	4,616
12	TX surgical	3,513
13	TX operati*	240,913
14	TX arthroplasty*	76
15	TX decompress*	132
16	TX repair	15,244
17	TX debridement	11
18	**11 OR 12 OR 13 OR 14 OR 15 OR 16 OR 17**	**248,830**
19	**4 AND 10 AND 18**	**457**

Table 35 Search strategy – ETHMED [11 August 2020]

Search Terms	Results
Glenohumeral	0
Subacromial	0
Shoulder	1
Subacromial decompression	0
Decompression	0
Subacromial impingement	1
Total	**2**

Table 36 Clinical trial registries search results [27 November 2020]

Source	Search terms	Results
Australian New Zealand Clinical Trials Registry	Subacromial	1
ClinicalTrals.gov	Subacromial AND decompression	20
Cochrane Central Register of Controlled Trials	Subacromial decompression	139
EU Clinical Trials Registry	Subacromial	8
International Clinical Trials Registry Platform, Current Controlled Trials MetaRegister (ISRCTN)	Subacromial	25
World Health Organization (WHO), International Clinical Trials Registry Platform	Not searched, database undergoing maintenance	

16 Appendix B: Evidence pertaining to effectiveness, efficacy and safety outcomes

16.1 Validated analyses from the Karjalainen et al review

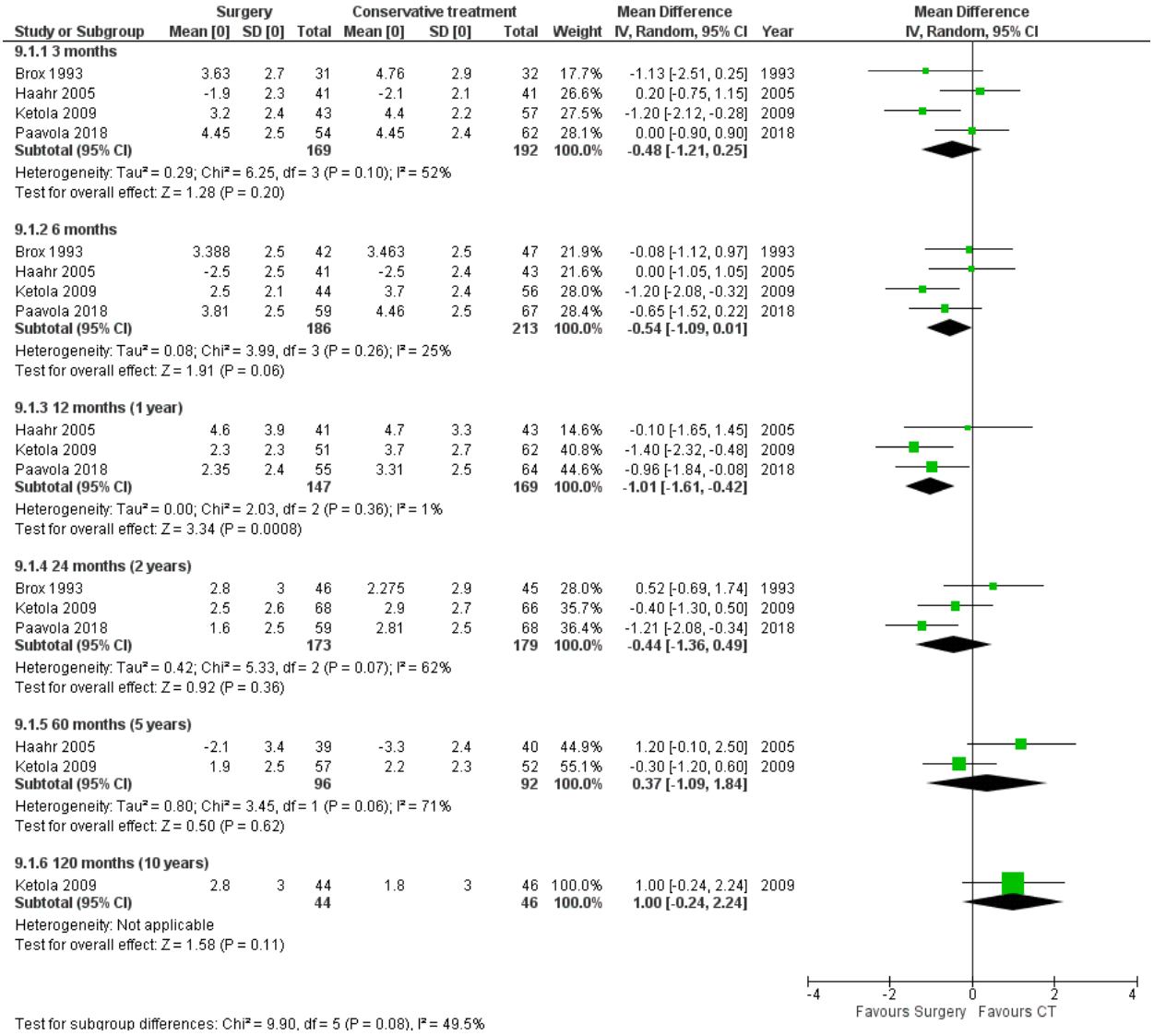

Figure 15 Forest plot indicating the mean difference in shoulder pain for subacromial decompression compared to conservative treatment from 3 to 120 months replicated from Karjalainen et al

Abbreviations:
CI = confidence interval, **CT** = conservative treatment, **SD** = standard deviation.

Notes:
Scores were adjusted to fit 0–10 scale.
This analysis was computed in Revman using the same data sources as Karjalainen et al.[174]

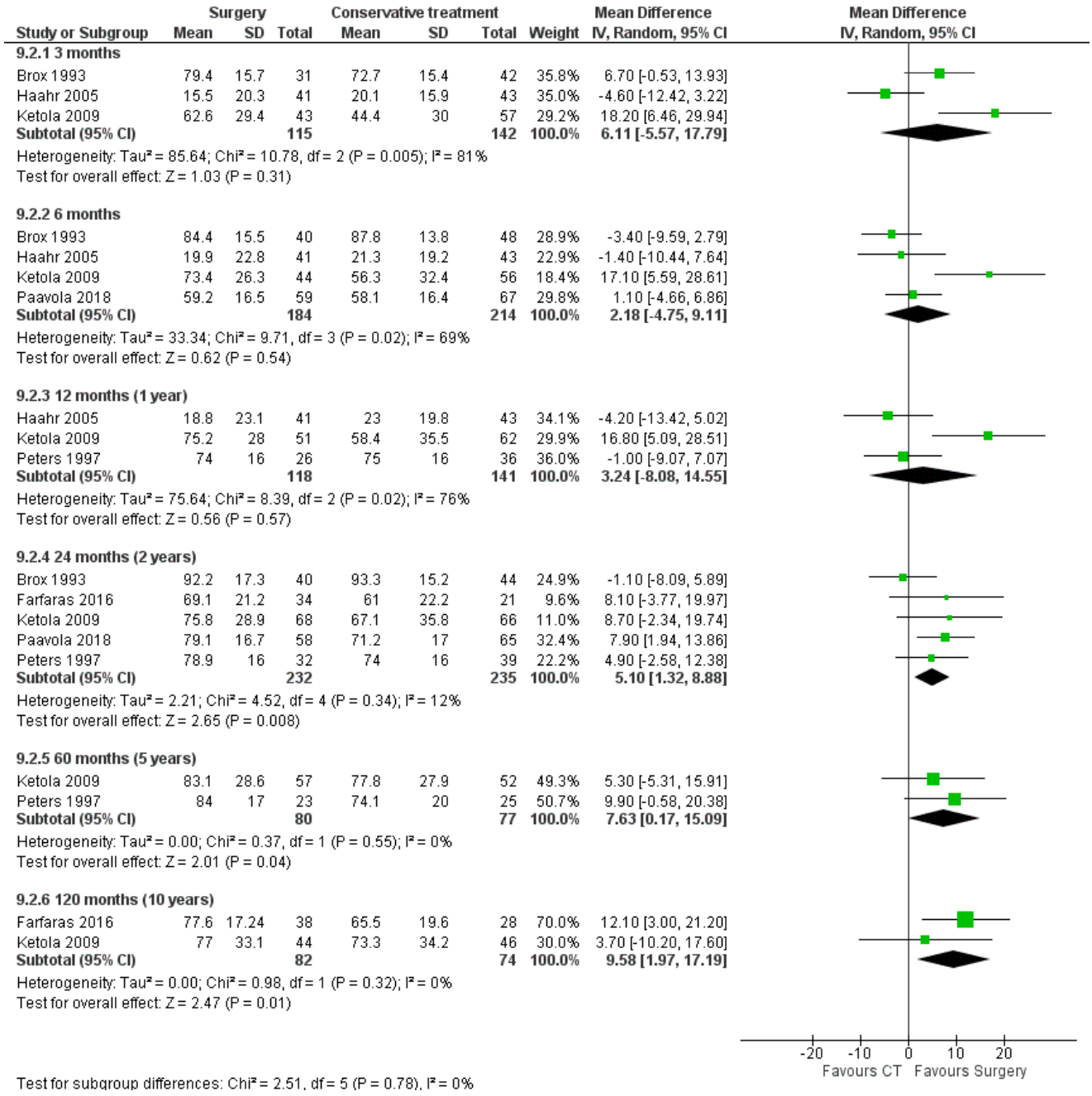

Figure 16 Forest plot indicating the mean difference in shoulder function for subacromial decompression compared to conservative treatment from 3 to 120 months replicated from Karjalainen et al.

Abbreviations:
CI = confidence interval, **CT** = conservative treatment, **SD** = standard deviation.
Notes:
Scores were adjusted to fit a 0-100 scale.
This analysis was computed in Revman using data published in Karjalainen et al.[1 74]

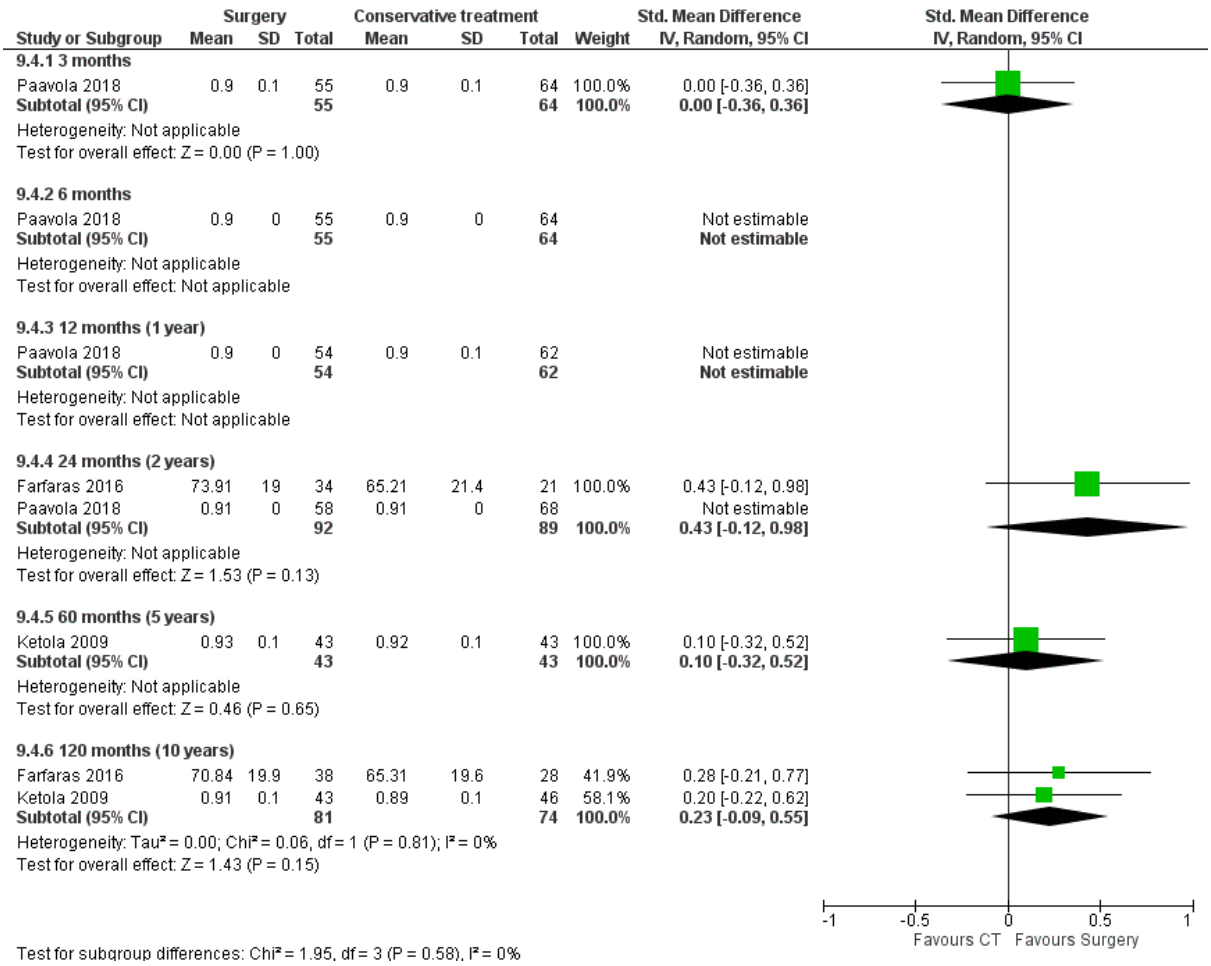

Figure 17 Forest plot indicating the standardised mean differences in HRQoL for subacromial decompression compared to conservative treatment from 3 months to 120 months replicated from Karjalainen et al.

Abbreviations:
CI = confidence interval, **CT** = conservative treatment, **HRQoL** = health-related quality of life, **SD** = standard deviation.
Notes:
This analysis was computed in Revman using data published in Karjalainen et al.[1 74]

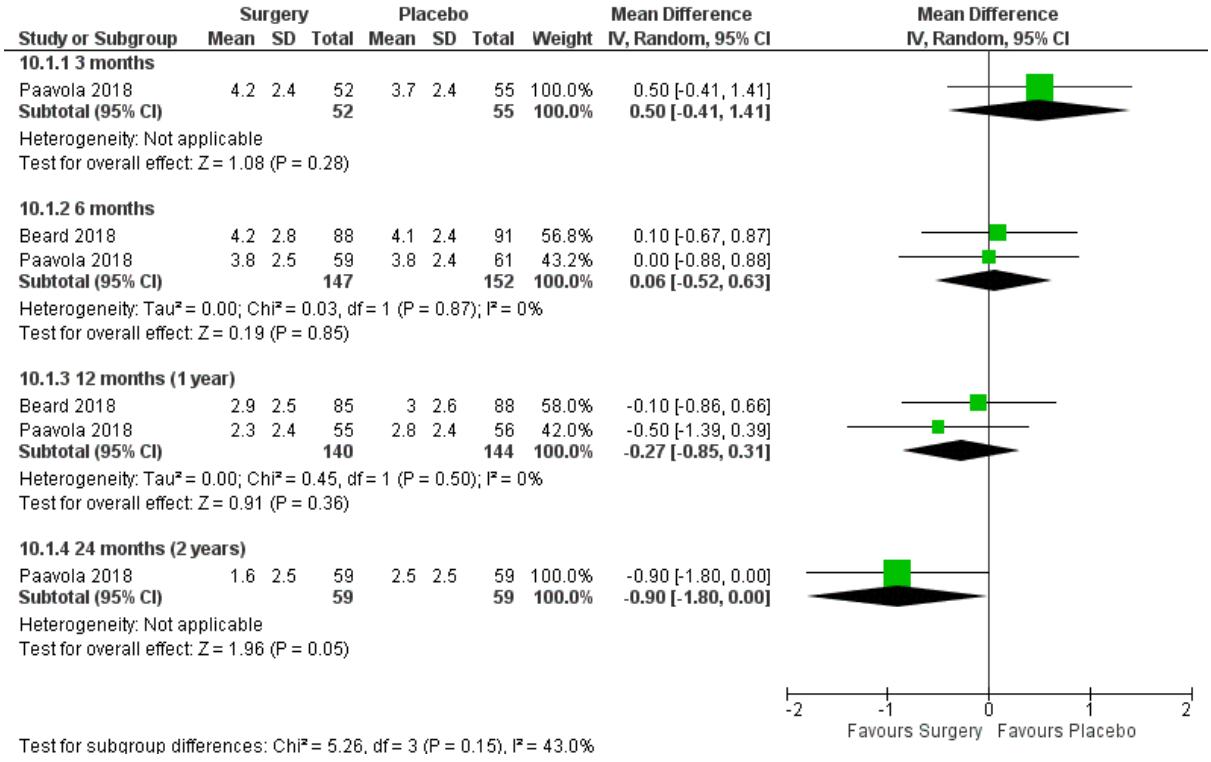

Figure 18 Forest plot indicating the mean difference in shoulder pain for subacromial decompression compared to placebo from 3 months to 24 months replicated from Karjalainen et al.

Abbreviations:
CI = confidence interval, **SD** = standard deviation.
Notes:
This analysis was computed in Revman using the same data sources as Karjalainen et al., and using SDs imputed by Karjalainen et al.[1 74]

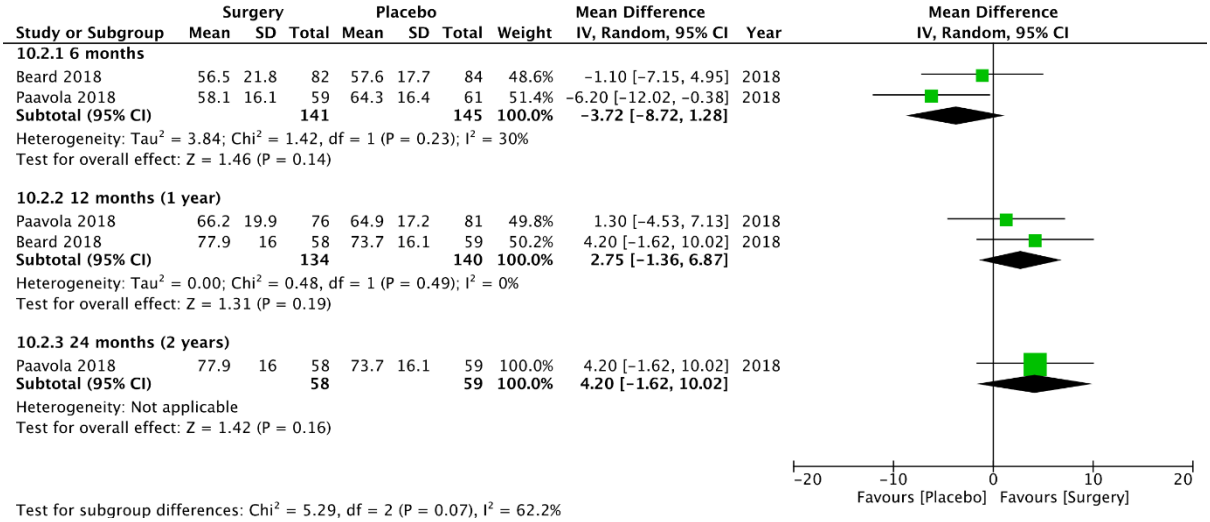

Figure 19 Forest plot indicating the mean difference in shoulder function between subacromial decompression and placebo from 6 months to 24 months replicated from Karjalainen et al.

Abbreviations:
CI = confidence interval, **SD** = standard deviation.
Notes:
This analysis was computed in Revman using data published in Karjalainen et al.[1 74]

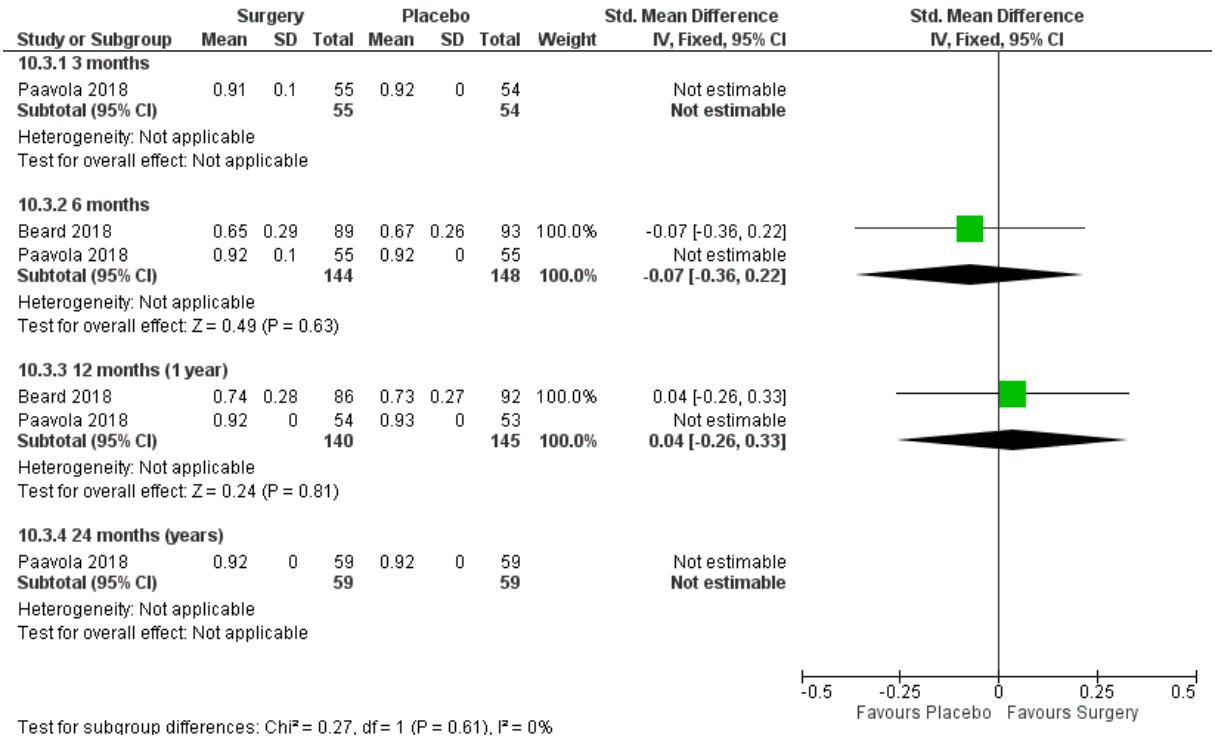

Figure 20 Forest plot indicating the standardised mean difference in HRQoL for subacromial decompression compared to placebo from 3 months to 24 months replicated from Karjalainen et al.

Abbreviations:
CI = confidence interval, **HRQoL** = health-related quality of life, **SD** = standard deviation.
Notes:
This analysis was computed in Revman using data published in Karjalainen et al.[1 74]

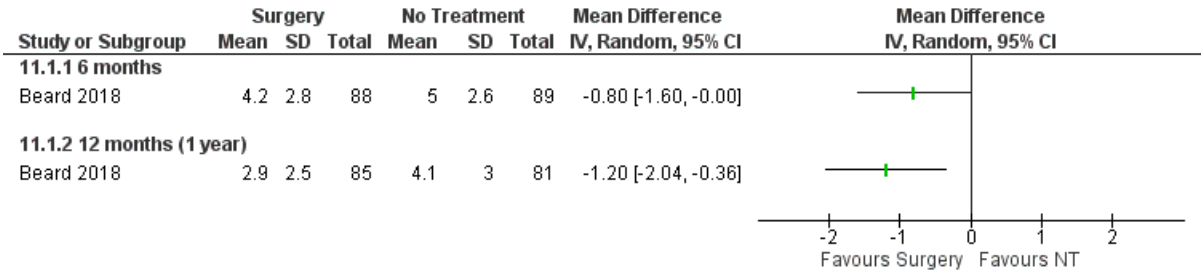

Figure 21 Forest plot indicating the mean difference in shoulder pain for subacromial decompression compared to no treatment from 6 months to 12 months according to data published by Karjalainen et al.

Abbreviations:
CI = confidence interval, **NT** = no treatment.
Notes:
This analysis was computed in Revman using data published in Karjalainen et al.[1 74]

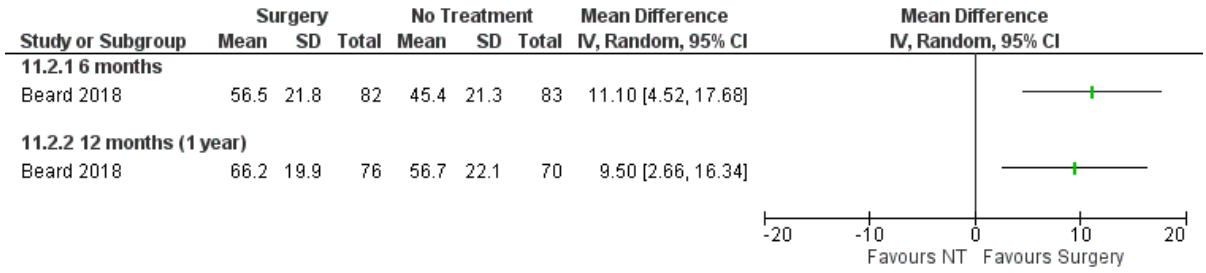

Figure 22 Forest plot indicating the mean difference in shoulder function for subacromial decompression compared to no treatment from 6 months to 12 months according to data published in Karjalainen et al.

Abbreviations:
CI = confidence interval, **NT** = no treatment.
Notes:
This analysis was computed in Revman using the same data sources as Karjalainen et al.[174]

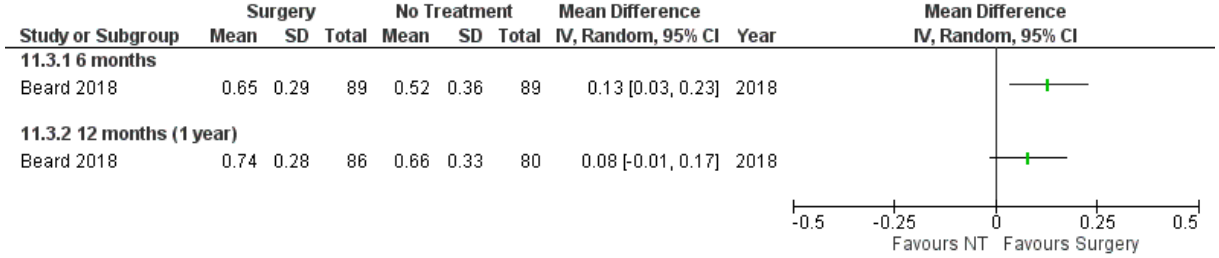

Figure 23 Forest plot indicating the mean difference in HRQoL for subacromial decompression compared to no treatment from 6 months to 12 months according to data published by Karjalainen et al.

Abbreviations:
CI = confidence interval, **HRQoL** = health-related quality of life, **NT** = no treatment.
Notes:
This analysis was computed in Revman using the same data sources as Karjalainen et al.[174]

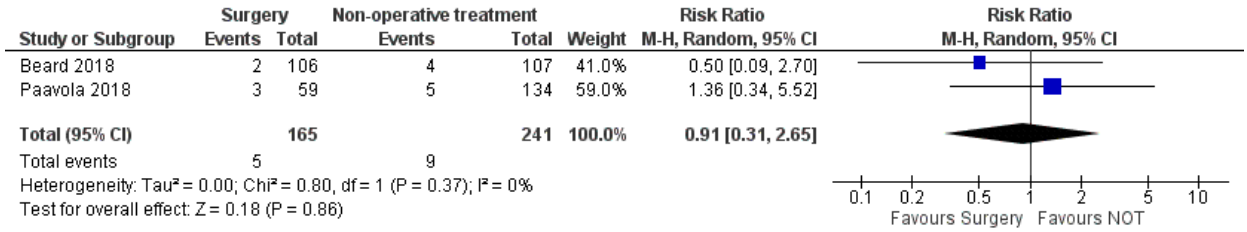

Figure 24 Forest plot indicating the total risk ratio for total adverse events for subacromial decompression compared to non-operative treatment

Abbreviations:
CI: confidence interval, **NOT**: non-operative treatment.

Notes:
Non-operative treatment in this case refers to placebo and conservative treatment; surgery corresponds to subacromial decompression

16.2 Tables presenting data related to safety outcomes

Table 37 Evidence pertaining to safety obtained from RCTs

Trial	Study design	Population	Follow-up	Intervention	Comparator	Adverse events	Serious adverse events
CSAW [19 44] (UK)	Randomised 1:1:1 Double-blind for ASD vs placebo but single blind for other two arms Multicentre (30 hospitals, 38 surgeons) Pragmatic Parallel groups (3) Placebo-controlled	Total: n=313 ASD: n=106, mean age 52.9 years ± 10.3 SD, 49.1% males Investigative arthroscopy (placebo): n=103, 53.7 years ± 10.5 SD, 49.5% males Conservative treatment: n=104, mean age: 53.2 years ± 10.2 SD, 50.0% males	6, 12 months	ASD	Placebo (investigational arthroscopy) Conservative treatment (active monitoring with specialist reassessment)	Frozen shoulder: Total: 2.5% (n=6) ASD: 2.8% (n=2) Placebo: 3.1% (n=2) Conservative treatment: 3.1% (n=2)	None observed.
FIMPACT [52 88] (Finland)	Randomised Double-blind Multicentre Parallel groups (3) Sham-controlled	Total: n=193 ASD: n=59, mean age: 50.5 years ± 7.3 SD, 71.2% males Placebo: n=63, mean age: 50.8 years ±7.6 SD, 73.0% males Conservative treatment: n=71, mean age: 50.4 years ± 6.6 SD, 66.2% males	24 months	ASD	Placebo (diagnostic arthroscopy) Conservative treatment (supervised, progressive individually designed physiotherapy)	Temporary swelling in the brachial area related to a brachial plexus block: Total: 0.8% (n=1) Placebo: 1.6% (n=1) Frozen shoulder: Total: 3.3% (n=4) ASD: 5.1% (n=3) Placebo: 1.6% (n=1)	None observed.

Abbreviations:
ASD = arthroscopic subacromial decompression, **CSAW** = can shoulder arthroscopy work, **FIMPACT** = Finnish shoulder impingement arthroscopy controlled trial, **OSD** = open subacromial decompression, **SD** = standard deviation, **UK** = United Kingdom.

Table 38 Evidence pertaining to safety obtained from non-randomised studies

Study ID, design, country	Population n, age, gender ratio	Follow-up	Intervention	Adverse events	Serious adverse events
Connor 2000[91] Single centre Prospective USA (New York)	Total: n=36, 55.6% males Group I: n=18, mean age: 45 years (range: 29—67), 66.7% males Group II: n=18, mean age: 42 years (range: 19—61), 50.0% males	Mean: 21 months (range: 8—57) Mean: 18 months (range: 19—61) Mean: 23.7 months (range: 12—57)	OSD (n=16) ASD (n=16)	None observed.	None observed.
Inderhaug 2018[92] Single centre Prospective Norway (Bergen)	Total: n=287 Group A: n=140, mean age: 52 years, 40.0% males Group B: n=147, mean age: 58 years, 40.0% males	Mean: 90 months	ASD ASD + RC repair (debridement)	Postoperative stiffness (4.9%, n=14) Infection (0.3%, n=1) Deep infection (0.3%, n=1)	Total or Serious AEs leading to re-operation: 10% (n=15 out of 140) Acromioclavicular resection (5.7%, n=8) New subacromial decompression (3.6%, n=5) Capsulotomy for frozen shoulder (0.7%, n=1) SLAP repair (0.7%, n=1)
Järvelä 2010[53] Single centre Prospective Consecutive recruitment Finland	Total: n=80 Outpatients: n=40, mean age: 48 years ± 9 SD, 56.8% males Inpatients: n=40, mean age: 51 years ± 9 SD, 40.5% males	Mean: 33 months (range: 24—59) Mean: 32 months ± 6 SD Mean: 34 months ± 11 SD	ASD	None observed.	None observed.

Study ID, design, country	Population n, age, gender ratio	Follow-up	Intervention	Adverse events	Serious adverse events
Machner 2001[38] Single centre Prospective Germany	Total: n=152, mean age: 51 years (range: 18—76), 66.4% males Group I: n=22 Group II: n=69 Group IIIa: n=27 Group IIIb: n=34 (groups reflect severity of impingement)	Mean: 32.5 months (range: 8—72)	Arthroscopic bursectomy (n=22) ASD (n=62) OSD (n=7) ASD + RC repair (n=12) OSD + RC repair (n=15) Arthroscopic debridement (n=12) Open debridement (n=22)	None observed.	None observed.
Magaji 2012[93] Single centre Prospective Consecutive recruitment UK	Total: n=83, 56.6% males Group A (4 symptoms): n=51, mean age: 58 years (range: 49—61), 58.8% males Group B (3 symptoms): n=21, mean age: 54 years (range: 52—57), 47.6% males Group C (2 symptoms): n=11, mean age: 51 years, range (49—54), 63.6% males	Mean: 28.8 months (range: 12—60)	ASD + subacromial steroid injection	None observed.	None observed.

Study ID, design, country	Population n, age, gender ratio	Follow-up	Intervention	Adverse events	Serious adverse events
Schröder 2001[94] Single centre Prospective Consecutive recruitment The Netherlands	Total: n=238, mean age: 46 years (range: 17—77), 46.6% males Open: n=80, mean age: 49 years ± 11 SD (range: 23—77) Arthroscopy ≤10 surgeries: n=64, mean age: 42 years ± 10 SD (range: 20—65) Arthroscopy 11–20 surgeries: n=21, mean age: 47 years ± 11 SD (range: 26—62) Arthroscopy >20 surgeries: n=96, mean age: 46 years ± 12 SD (range: 17—76)	Mean 30 months (range: 12—120)	OSD (n=80) ASD (n=181)	Open cohort: Superficial wound infection (2.5%, n=2) Haematoma (1.3%, n=1) Temporarily frozen shoulder (3.8%, n=3) Arthroscopic cohort: Temporarily frozen shoulder (1.1%, n=2)	None observed.
Soyer 2003[95] Single centre Prospective Consecutive recruitment France	Total: n=39 (41 shoulders), mean age: 51 years (range: 37—78), 43.6% males	Mean: 37 months (range: 12—48)	ASD	None observed.	None observed.

Abbreviations:
AE = adverse event, **ASD** = arthroscopic subacromial decompression, **OSD** = open subacromial decompression, **RC** = rotator cuff, **SLAP** = superior labral tear from anterior to posterior, **SD** = standard deviation, **UK** = United Kingdom, **USA** = United States of America.

Notes:
* These numbers were calculated as averages and do not reflect whether some individuals needed more than one re-operation or not.

Table 39 Evidence pertaining to safety obtained from single-arm studies

Study ID, design, country	Population n, age, gender ratio	Follow-up	Intervention	Adverse events	Serious adverse events
Billaud 2019[96] Single centre Retrospective Consecutive recruitment France (Mérignac)	n=90 mean age: 58 years ± 8.3 SD (range: 41—76) 61.1% males	Not specified	Arthroscopic acromioplasty (7%, n=3) Arthroscopic acromioplasty + RC repair (93%, n=87)	None observed.	None observed.
Eid 2012[97] Single centre Consecutive recruitment UK (Yeovil)	n=80 (83 shoulders) mean age: 57.1 years ± 11.9 SD (range: 32—84) 47.5% males	Mean: 71.9 months (range: 53.7—82.6)	ASD	None observed.	None observed.
Frieman 1995[98] Single centre Consecutive recruitment USA (Philadelphia)	n=74 (75 shoulders) mean age: 29.2 years 48.6% males	Mean: 19.6 months (range: 12—48)	Open acromioplasty	Superficial wound infection (1.3%, n=1)	Deep wound infection leading to drainage and parenteral antibiotic treatment (1.3%, n=1)
Husby 2003[99] Randomised Prospective Double blinded only for some outcomes Single centre Norway (Oslo)	Total: n=39 ASD: n=20, mean age: 42 years ± 11 SD (range: 29—61), 46.7% males OSD: n=19, mean age: 45 ± 8.3 SD (range: 27—59), 42.1% males	3, 6, 12, 96 months	ASD OSD	None observed.	None observed.
Hyvönen 1998[100] Single centre Retrospective Finland (Oulu)	n=93 (96 shoulders) mean age: 45 years (range: 26—69) 64.5% males	Mean: 108 months (range: 72—180)	Open acromioplasty	Total: 9.7% (n=9) Wound infection (1.1%, n=1) Temporary stiffness (8.6%, n=8)	None observed.

Study ID, design, country	Population n, age, gender ratio	Follow-up	Intervention	Adverse events	Serious adverse events
Lim 2007[101] Single centre Retrospective Singapore (Singapore)	n=42 mean age: 50 years (range: 38—76) 64.3% males	Mean: 14.6 months (range: 12—30)	ASD	Total: 4.7% (n=2) Shoulder sinus near portal site that healed within three weeks of dressing (2.4%, n=1) Adhesive capsulitis that resolved through intensive physical therapy within 6 months (2.4%, n=1)	None observed.
Luyckx 2011[102] Single centre Prospective Belgium (Leuven)	n=272 mean age: 54 years ± 9.75 SD (range: 22—82) 39.2% males	Mean: 15 months (minimum of 12 months)	ASD	Frozen shoulder (9%, n=15)	None observed.
Machner 2000[103] Single centre Germany (Magdeburg)	n=103 mean age: 80 years 54.2% males	Mean: 30 months (range: 7—84)	Arthroscopic acromioplasty	None observed	None observed
McKee 2000[104] Single centre Prospective Consecutive recruitment Canada (Toronto)	n=71 mean age: 56.1 years (range: 32—75) 70.4% males	6, 12, 18, 24 months postoperative	Open acromioplasty	Total (8.5%, n=6)	Wound infection requiring drainage and debridement (1.4%, n=1)
Petré 1998[105] Single centre Prospective Belgium (Edegem)	n=40 mean age: 50.5 years (range: 32—69) 37.5% males	Not specified	ASD	None observed	None observed

Study ID, design, country	Population n, age, gender ratio	Follow-up	Intervention	Adverse events	Serious adverse events
Pillai 2012[106] Single arm Multicentre Prospective Consecutive recruitment (Australia-Woodville SA and Cairns QLD, UK-Dumfries)	n=96 (unsatisfied patients: n=11) mean age: 57 years (range: 42—75) 63.6% males	Mean: 16 months (range: 12—26)	OSD as a revision surgery following arthroscopic acromioplasty	None observed	None observed
Rao 2005[107] Single centre Prospective Consecutive recruitment UK (Newport)	n=22 (25 shoulders) mean age: 58.5 years (range: 32—80) 77.3% males	1.5 months postoperative, then range: 6—24 months	Subacromial decompression	None observed Patients unsatisfied with the scar (one hypertrophic and one unsightly scar formation) (9.1%, n=2)	None observed

Abbreviations:
ASD = arthroscopic subacromial decompression, **OSD** = open subacromial decompression, **QLD** = Queensland, **RC** = rotator cuff, **SA** = South Australia, **SD** = standard deviation, **UK** = United Kingdom, **USA** = United States of America.

17 Appendix C: Minimum clinically important differences and improvements for outcomes of interest

A non-systematic targeted search was conducted in order to identify minimum clinically important differences (MCIDs), minimum important change (MIC), minimal important differences (MIDs) and minimal clinically important improvement (MCII) related to the outcomes of interest (see ***Section 5***). It was planned to use the identified MCIDs, MIC and MIDs (***Table 40***) as a guide, not as a complete assessment of the literature. The MCIDs generally relate to VAS, NRS, PainDETECT, Constant-Murley score, EQ-5D and 15D. The applicability of these MCIDs, MIC, MID and MCIIs to the current HTA report is currently uncertain. There are differences in population demographics, diagnosis and interventions, so caution must be taken when extrapolating the MCIDs to the outcomes reported.

Table 40 Minimal clinically important differences/improvements for outcomes of interest

Rating information	MIC/MID/MCII/MCID	Study type	Population demographics	Author; Country
Shoulder pain				
VAS Scale: 0–10	1.5 [a] MID	SR	Patients with subacromial pain	Hao 2019 [11] NR
NRS Scale: 0–10	1.5 [a] MID	SR	Patients with subacromial pain	Hao 2019 [11] NR
PainDETECT	NR	NR	NR	NR
Shoulder function				
Constant-Murley score Scale: 0–100	8.3 [a] MID	SR	Patients with subacromial pain	Hao 2019 [11] NR
Shoulder disability questionnaire score	NR	NR	NR	NR
SSRS	NR	NR	NR	NR
Neer score Scale: 10–100	NR	NR	NR	NR
HRQoL				
EQ-5D-3L Scale: -0.59–1	0.07 [a] MID	SR	Patients with subacromial pain	Hao 2019 [11] NR
15D	0.015 [b] MIC	RCT	Diagnosis: 16 different diagnostic groups [c] Age: ≥16 years Mean age: 60 years Duration: 6 months	Alanne 2015 [126] Finland

Rating information	MIC/MID/MCII/MCID	Study type	Population demographics	Author; Country
SF-36 Scale: 0–100	NR	NR	NR	NR
Marginalisation index	NR	NR	NR	NR
Ability to return to work				
Return to work	NR	NR	NR	NR
Return to leisure activities				
Return to leisure activities	NR	NR	NR	NR
Further progression of disease				
Treatment failure	NR	NR	NR	NR

Abbreviations:

EQ-5D = EuroQol 5 dimensions questionnaire, **MID** = minimal important differences, **MIC** = minimum important change, **MCID** = minimum clinically important difference, **MCII** = minimal clinically important improvement, **NRS** = numeric rating scale, **NR** = not reported, **RCT** = randomised control trial, **SR** = systematic review, **SF-36** = Short-form 36, **SSRS** = subjective shoulder rating scale, **VAS**= visual analogue scale, **15D** = 15 dimensions,

Notes:

a = estimates based on literature search

b = mean change is predetermined category of 'slightly better'

c = Diseases include hyperparathyroidism, gastrointestinal symptoms or problems, invasive coronary procedures, coronary artery disease, aortic valve disease, breast cancer, pain, melanoma, liver disease requiring transplantation, prostate cancer, varicose veins, human papilloma virus, hearing problems, tonsillar problems requiring tonsillectomy and depression.

18 Appendix D: List of excluded trials at full text

18.1 Incorrect study design (k=20)

1. Abboud JA, Silverberg D, Pepe M, et al. Surgical treatment of os acromiale with and without associated rotator cuff tears. *J Shoulder Elbow Surg* 2006;15(3):265-70.
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18.2 Incorrect population (i.e. incorrect country, patient demographics) (k=9)

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18.3 Incorrect intervention (k=3)

1. Loh Y, Trail I. Is arthoscopy of the shoulder safe—a study/perspective on arthroscopic subracromial decompression. *J The Medical Journal of Malaysia* 2002;57(2):205-08.
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18.4 Incorrect comparator (k=2)

1. Hawkins RJ, Plancher KD, Saddemi SR, et al. Arthroscopic subacromial decompression. *J Shoulder Elbow Surg* 2001;10(3):225-30.
2. Kolk A, Thomassen BJW, Hund H, et al. Does acromioplasty result in favorable clinical and radiologic outcomes in the management of chronic subacromial pain syndrome? A double-blinded randomized clinical trial with 9 to 14 years' follow-up. *J Journal of Shoulder and Elbow Surgery* 2017;26(8):1407-15.

18.5 Incorrect outcomes (k=13)

1. Biberthaler P, Beirer M, Kirchhoff S, et al. Significant benefit for older patients after arthroscopic subacromial decompression: a long-term follow-up study. *International Orthopaedics* 2013;37(3):457-62.
2. Chelli M, Grimberg J, Lefebvre Y, et al. Internal impingement of the shoulder: An international survey of 261 orthopaedic surgeons. *Orthop Traumatol Surg Res* 2019;105(8S):S207-S12.
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18.6 Incorrect publication type (k=3)

1. Farfaras S, Sernert N, Rostgard-Christensen L, et al. Subacromial Decompression in Patients with Impingement Syndrome Results in Better Clinical Outcome Compared to Physiotherapy in the Long Term. A Prospective Randomised Study. *J Orthopaedic Journal of Sports Medicine* 2017;5(3):1-1.
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3. Rupp S, Rehm S, Tempelhof S, et al. Mid-term results after arthroscopic subacromial decompression (ASD) with special focus on the bias due to an application to social insurance for pension. *Unfallchirurg* 2001;104(10):961-64.

18.7 Incorrect publication date (i.e. published before 1997) (k=39)

1. Adolfsson L, Lysholm J. Results of arthroscopic acromioplasty related to rotator cuff lesions. *Int Orthop* 1993;17(4):228-31.
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18.8 Incorrect perspective (i.e. investment instead of disinvestment)[4] (k=0)

N/A

18.9 Inadmissible language (i.e. not English, German, French, or Italian) (k=3)

1. Nicoletti SJ, Carrera EF, Neto NA, et al. Arthroscopic subacromial bursectomy with and without acromioplasty for treatment of impingement syndrome. Functional results after a 45-month follow-up. *Revista Brasileira de Ortopedia* 1998;33(5):333-37.
2. Pagan Conesa JA, Mas Martinez J, Sanchez Martin A, et al. Prospective analysis of a series of shoulder arthroscopies in the treatment of rotator cuff tears. *J Revista de Ortopedia y Traumatologia* 2003;47(1):16-25.
3. Struzik S, Glinkowski W, Komor A, et al. Arthroscopic treatment of subacromial impingement syndrome. *Ortop Traumatol Rehabil* 2003;5(4):450-6.

18.10 Unable to extract data (k=1)

1. Habernek H, Schmid L, Frauenschuh E. Five-year results of rotator cuff repair. *Br J Sports Med* 1999;33(6):430-3.

18.11 Unable to access full text (k=1)

1. Boileau P, Coste JS, Deprey F, et al. [Arthroscopic treatment of impingement and partial thickness tears of the rotator cuff of the shoulder]. *Rev Chir Orthop Reparatrice Appar Mot* 2004;90(8 Suppl):3S35-48.

[4] Articles that address auxiliary considerations from an investment standpoint instead of disinvestment.

19 Appendix E: Ongoing and recently completed clinical trials

The search results and terms are detailed in ***Table 36*** (***Appendix A***). The ongoing and unpublished clinical trials (k=4) are detailed below in ***Table 41***.

Table 41 Recruiting, active and recently completed clinical trials

Trial registry ID; Country	Indication Sample size	Intervention	Comparator	Primary outcomes	Recruitment status; Expected completion date
ClinicalTrials.gov					
NCT04644042 Denmark	Subacromial pain n=160	Arthroscopic subacromial decompression	Placebo (sham surgery)	*Pain* • NRS *Function* • SPADI • OSS • ROM	Not yet recruiting, June 2025
NCT03815669 Denmark	Subacromial pain n=250	Arthroscopic subacromial decompression	NR	*Pain* • VAS *Function* • ROM • OSS *HRQoL* • EQ-5D • EQ VAS • HADS *Ability to return to work/ leisure* • Return to work	Recruiting, March 2021
NCT00637013 Finland	Subacromial pain n=100	Acromioplasty	Physiotherapy	*Pain and* • VAS *Function* • Constant-Murley score	Active, not recruiting January 2017
International Clinical Trials Registry Platform, Current Controlled Trials MetaRegister (ISRCTN)					
ISRCTN58108023 The Netherlands	Subacromial pain n=70	Arthroscopic subacromial decompression	Usual care	*Function* • Shoulder disability questionnaire	Unknown November 1, 2008

Abbreviations:

EQ-5D = EuroQol 5 dimensions questionnaire, **EQ VAS** = EuroQol visual analogue scale, **HADS** = hospital anxiety and depression scale, **HRQoL**= health-related quality of life, **NR** = not reported, **NRS** = numeric rating scale, **OSS** = Oxford shoulder score, **ROM** = range of motion, **SPADI** = shoulder pain and disability index, **VAS** = Visual analogue scale.