Fixation methods for acute syndesmotic injury – A systematic review and meta-analysis

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DECLARATION

I, Tom Gieroba, certify that this work contains no material that has been accepted for the award of any other degree or diploma in any university or any other tertiary institution, and, to the best of my knowledge and belief, contains no material previously published or written by any other person, except where due reference has been made in the text. In addition, I certify that no part of this work will, in the future, be used in a submission for any other degree or diploma in any university or other tertiary institution without the prior approval of the University of Adelaide and where applicable, any partner institution responsible for the joint-award of this degree.

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Dr Tom Gieroba
December 6th 2017

SUMMARY

The distal tibiofibular joint is a syndesmotic articulation between the tibia and fibula at the ankle. It is stabilised by a number of ligaments. It is a dynamic articulation which allows fibular motion to accommodate the talus through ankle range of motion. Injuries to the ankle syndesmosis are common and usually occur with an associated ankle fracture. An unstable syndesmosis leads to pain and instability in the short term and posttraumatic osteoarthritis in the long term. As such, surgical stabilisation is recommended for unstable syndesmotic injuries.

Various fixation methods exist for stabilisation of these injuries. Metal syndesmotic screws placed in a lateral to medial direction through the fibula into the tibia are considered the current gold standard. The number of screws, their location, the number of cortices engaged, the screw diameter and whether they are removed or retained once the syndesmosis has healed remain controversial and practice depends on surgeon and institutional preference rather than evidence. More recent developments include bioabsorbable screws and suture button fixation with perceived benefits being no requirement for implant removal and in the case of suture button fixation, a dynamic fixation which more closely approximates the normal motion through an uninjured syndesmosis.

Published and unpublished studies in English were sought in the CINAHL, Embase, PubMed/Medline, Scopus, Web of Science and other databases. A total of 4493 citations were screened for suitability and 79 articles were read and assessed for eligibility. Fifty-three studies were included in final analysis. Two reviewers using the Joanna Briggs Institute - Meta Analysis of Statistics, Assessment & Review Instrument, assessed the quality of the studies.

The effectiveness of syndesmotic injury stabilisation using metal screws, suture button fixation and bioabsorbable fixation was assessed and compared. Composite outcome measures (such as the Olerud-Molander Ankle Score (OMAS) and the American Orthopedic Foot and Ankle Society ankle-hindfoot score (AOFAS), range of motion, pain as measured by visual-analogue scale (VAS), radiological measurements of the syndesmosis, complications and other outcomes were analysed. Single group analysis was performed for all metal screw, suture button or bioabsorbable screw studies where appropriate outcome measures and variance were reported. This analysis was possible for OMAS, AOFAS, VAS, complications

and radiological parameters.

This review includes 24 descriptive studies, 19 cohort studies, 9 RCTs and 1 quasi-experimental study. Bioabsorbable implants featured in 8 studies, metal screws in 29 and suture button constructs in 20 studies. A total of 3,088 subjects are assessed across the included studies. Five studies were included in meta-analysis.

There were no major differences in outcomes across the various fixation methods. All yielded good results with an acceptable complication profile. This review further adds to the assertion that between metal screws, suture button constructs or bioabsorbable screws, there is no significant difference in outcomes following stabilisation of acute syndesmotic injury. The same holds true for the various strategies using metal screws; screw size, number of cortices, screw location, screw number and screw removal have little effect on the final outcome.

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CHAPTER ONE: INTRODUCTION

1.1 Context of the review

Syndesmotic injuries requiring fixation are common. Multiple treatment strategies exist but significant debate remains regarding fixation techniques, implants and the need for removal of implants.

1.1.1 The syndesmosis

In the ankle, the distal tibiofibular joint is a syndesmotic articulation without articular cartilage. It is stabilised by the anterior inferior and posterior inferior tibiofibular ligaments (AITFL, PITFL), the inferior transverse ligament (ITL) and the interosseous ligament (IOL); [1] together referred to as the syndesmotic ligaments or simply the syndesmosis. The AITFL has its origin at the anterolateral (Chaput's) tubercle of the tibia and inserts on the anterior (Le Forte's or Wagstaffe's) tubercle of the fibula. The PITFL originates from the posterior (Volkmann's) tubercle of the tibia and inserts at the posterior edge of the lateral malleolus. The ITL is occasionally considered part of the PITFL (and called the deep part of the PITFL) and forms its deep distal extent. The IOL is a localised thickening of the distal aspect of the interosseous membrane. The AITFL provides 35% of ligamentous stability, followed by the ITL at 33%, the IOL at 22% and the superficial PITFL providing 9% of syndesmotic stability.[2]

The fibula rotates, translates and migrates within its groove; the incisura fibularis tibiae in the tibia to maintain congruence with the wedge shaped talus through talocrural range of motion.[3,4] Subtle motion of the fibula at this joint is important for ankle congruity to allow normal ankle motion and prevent joint degeneration.[5]

1.1.2 Mechanisms of injury

Injuries to the distal tibiofibular syndesmosis are common, occurring in 5-10% of ankle sprains and 23% of ankle fractures.[3] Rotational mechanisms of injury are most common with external rotation and hyper-dorsiflexion responsible for the majority of syndesmotic injury, however other rotational mechanisms have also been described.[6] External rotation can cause isolated syndesmotic injury or one with an associated

fibular fracture. The talus is rotated within the mortise and forces the fibula laterally. In the same way, hyper-dorsiflexion forces the anterior part of the talus into the mortise, displacing the fibula laterally in relation to the tibia. The anterior talar dome is on average 4.2mm wider than the central talus and with sufficient force can rupture the syndesmotic ligaments. [7] More commonly, syndesmotic injuries are associated with fractures. Lauge-Hansen classified ankle fractures based on mechanism of injury and noted that pronation-external rotation fractures and supination-external rotation fractures were most often associated with syndesmotic injury.[8] The Weber classification is based on the location of the fibula fracture and its relationship to the syndesmosis.[9] Weber C fractures occur above the level of the syndesmosis and are associated with syndesmotic injury requiring fixation in 80% of cases, while Weber B fractures occur at the level of the syndesmosis and require syndesmotic stabilisation in 40% of cases.[10] Maisonneuve in 1840 observed proximal fibula fractures associated with syndesmotic injury and interosseous membrane tear caused by external rotation of the foot, an injury which still bears his name.[11]

1.1.3 Presentation

An unstable syndesmosis leads to pain and ankle instability.[3] This manifests itself as rest or use-related ankle pain, symptomatic instability and difficulty mobilising; especially high demand tasks such as pushing off for jumping and running, squatting, ascending or descending stairs and walking on uneven ground. Other complaints include stiffness, limp and swelling.[12] Patients with syndesmotic injury may present with anterolateral ankle pain exacerbated by dorsiflexion. The anterolateral ankle in the region of the AITLF may be tender. Various special clinical tests exist for diagnosis of acute syndesmotic injury but are of limited use in the acute setting when associated with fracture. The *external rotation stress test* involves holding the knee at 90° of flexion and the ankle in a plantigrade position with the examiner passively externally rotating the foot. A positive test results in pain over the distal syndesmosis.[6,13,14] The *squeeze test* is positive when compression of the proximal fibula against the tibia causes pain over the syndesmosis distally.[14,15] A variant of this test can be performed in the seated position – the *crossed-leg test*.[16] The affected leg is crossed over the contralateral knee. Medial sided pressure on the knee of the affected side compresses the fibula against the tibia at the fulcrum where the leg is perched over the contralateral knee. Pain over the syndesmosis represents a positive test. No single test however has been shown to be able to identify

syndesmotic injury with certainty.[17]

1.1.4 Diagnosis

In addition to history and physical examination findings, syndesmotic injury can be diagnosed radiologically. A suspicious fracture pattern as identified above should alert the clinician to potential syndesmotic injury. There are three common plain X-Ray (XR) findings that suggest syndesmotic instability.[18-20] The *tibiofibular overlap (TFO)* varies with positioning. As measured 1cm above the plafond it should measure >6mm on the antero-posterior (AP) and >1mm on the mortise views. The *tibiofibular clear space* (TFCS) is measured 1cm above the plafond and is the distance between the lateral edge of the incisura and the medial edge of the fibula; it should measure less than 6mm on the AP and mortise views. The *medial clear space (MCS)* is the gap medially between the medial malleolus and the talus. It should be no wider than the space between the superior talar dome and the plafond. The tibiofibular clear space measurement is clinically the most useful as it is minimally affected by positioning and rotation.[19] Weight bearing films where tolerated can unmask latent syndesmotic instability and in any suspicious cases comparison should be performed with the contralateral limb. For diastasis less than 2mm, computed tomography (CT) is a more sensitive imaging modality.[21] Comparison scans of the other ankle can be obtained to assess fibular translation, rotation and shortening.[4] Weight bearing CT is a recent development which assists in diagnosing latent syndesmotic instability.[22] Magnetic resonance imaging (MRI) can diagnose injury to the syndesmotic ligaments even in the absence of bony diastasis and has a reported accuracy of 97-100%.[23]

Syndesmotic injury associated with fracture is not always reliably diagnosed with the aforementioned XR parameters owing to bony displacement.[24] It should be tested for intra-operatively with any suspicious fracture pattern but only after anatomic reduction and fixation of fractures. Two commonly used tests are the *external rotation* (ER) *stress test* and the *hook test (Cotton test)*. Both have good interobserver reliability and specificity (0.96 and 0.98 respectively) but have poor sensitivity (0.58 and 0.25).[25] The ER stress test involves stabilising the tibia and externally rotating the foot. Widened medial clear space on fluoroscopy represents a positive test. For the hook test a bone hook or retractor (such as a small Langenbeck) is placed around the medial side of the fibula and a lateral force applied

with the tibia stabilised, with 100Nm as a suggested sufficient force.[3] Lateral movement of the fibula on direct visualisation or fluoroscopy represents a positive test.

1.1.5 Sequelae

In the acute setting, patients with syndesmotic instability present with pain, instability and impaired functional outcomes[26]. Untreated syndesmotic injuries at arthroscopy can demonstrate no healing of the ligament, scar tissue and synovitis in the ankle, a healed functional ligament or a ligament which heals in a non-anatomic or elongated fashion.[27] The ankle is a small and highly congruent joint with a small contact area of around 350mm^2, only one third that of the knee or hip.[28] As such, small changes cause large magnitude abnormalities; even a 1mm talar shift decreases contact area by 42-50% in cadaveric ankle models.[29,30] Diastasis of 1mm in the distal tibiofibular joint increases joint volume by 42%.[31] The articular cartilage at 1-2mm is also relatively thin.[32] A cadaveric model found articular contact pressures with simulated bodyweight in the mid-lateral and postero-lateral talus increased by 45% and 40% respectively with only 2mm of talar shift.[33] This replicates where degenerative changes are first seen in post-traumatic ankle osteoarthritis (OA). Trauma is the most common aetiological factor in ankle arthritis representing 70% of cases.[34] Usually occurring after fracture, it can also be seen after recurrent instability, or occasionally a single sprain episode with ongoing pain. Anatomical syndesmotic stabilisation reduced the progression to post-traumatic OA in ankle fracture with syndesmotic injury.[35]

1.1.6 Treatment

An unstable syndesmosis on imaging, direct visual inspection or at arthroscopy is an indication for surgical stabilisation. [20,26,36-39] Various treatment strategies to stabilise the syndesmosis exist and vary between institutions and surgeons. Usually this is direct stabilisation with an implant across the syndesmosis. Occasionally stabilisation is also achieved indirectly via fixation of associated fractures, the deltoid ligament or a direct syndesmotic ligament repair.[36,38,40] The current recognised gold standard of treatment is:[3] following fixation of associated fractures and reduction of the syndesmosis with a clamp, one or two 3.5mm (small fragment/small frag) or 4.5mm

(large fragment/large frag) diameter screws are placed between the fibula and tibia 1.5 to 2cm proximal to the joint surface, penetrating thee or four cortices of bone.[1,3] Fixation with 2 screws is biomechanically stronger than single screw fixation.[41] Aftercare and timing of weight bearing depend on the pattern and stability of the associated fracture, as well as the stability of fixation. Some series however suggest that syndesmotic fixation is performed unnecessarily in 15-60% of cases, usually if syndesmotic instability is assumed based on fracture pattern rather than an examination of the syndesmosis itself.[36,40]

Practice regarding removal of syndesmotic screws varies.[42] Intact syndesmotic screws limit normal fibular translation and may cause limited range of motion and suboptimal joint function.[43] It is this normal motion that may lead to screw breakage once weight bearing resumes, occurring in 7-29% of cases,[3] with 3.5mm diameter screws more likely to break than 4.0 or 4.5mm screws.[44,45] Screws may be removed routinely at 6 to 12 weeks post operatively to avoid screw breakage and restore normal motion at the syndesmosis. This requires further surgery and exposes the patient to a risk of complications, occupies valuable operating theatre time and presents an economic cost to the health system.

A recent development is suture-button fixation. The most commonly used is the TightRope™ (Arthrex, Naples, FL, USA). It is made of a #5 UHMWPE (Ultra-high molecular weight polyethylene – FiberWire™) suture, which is passed through a 4mm tunnel in the tibia and fibula. When tensioned and secured between two metallic buttons and placed against the outer cortices it provides physiologic stabilization of the ankle mortise. It is a less rigid fixation than screw fixation but allows dynamic stabilisation with more normal motion and does not require routine removal.[46] Similar devices have been developed for other areas where dynamic stabilisation is desirable such as for Lisfranc injuries and anterior cruciate ligament (ACL) ruptures. The Biomet ZipTight™ implant (Biomet Sports Medicine, Warsaw, IN, USA) is another similar product. For this review, suture-button fixation is referred to as TightRope fixation as this is by far the most common implant of this type.

Additionally, an evolution of the syndesmotic screw is the bioabsorbable screw. Traditional screws are made of stainless steel or titanium, while bioabsorbable screws are made of polyglycolic (PGA) or polylactic/polylevolactic (PLA/PLLA) acid. They are weaker than metal screws with PLA screws stronger and slower to resorb than PGA.[47] They have the benefit of not needing removal; eventually losing integrity to allow normal tibiofibular motion.[48]

1.1.7 Outcome Measures

There are a number of outcome measures encountered in foot and ankle literature. The most commonly encountered are the American Orthopedic Foot and Ankle Society ankle-hindfoot score[49] (AOFAS) and Olerud-Molander Ankle Score[50] (OMAS). Button[51] assessed 49 different foot and ankle outcome scales in a systematic review which included AFOAS and OMAS. They concluded that there is not one best score.

The AOFAS was developed in 1994.[52] It has 9 items with both subjective questions relating to pain and function and objective questions regarding range of motion and instability rated by an examiner. The score is out of 100 with a higher score representing better function. It is one of the more widely used foot and ankle outcome measures.[53,54] There is no published data about minimum clinical difference.[55] The OTA (Orthopaedic and Trauma Associatin) score is a slight modification of the AOFAS score with a similar scoring system.[52]

Olerud and Molander[50] developed their score in 1984. It includes symptoms of pain, stiffness, swelling and limitations with stair climbing, running, jumping, squatting, restrictions in work and activities of daily living (ADLs) and use of supports. It is validated for use in ankle fracture and a minimum clinical difference has been suggested as 15 points. It is scored out of 100 points with higher scores representing better function.

SF-12 and 36 scores are patient reported outcome measures of global health and are not specific to the foot and ankle.[56] They have been shown to have moderate to strong correlation with the AOFAS score.[53] A higher score represents better function.

The Bray ankle evaluation score was developed in 1989[57] to follow up a group of patients with open ankle fractures. It is a clinician measured score consisting of assessment of pain, function, ROM (range of motion) and swelling. The score is out of 100 points with higher scores representing better function.

The Baird and Jackson score[58] developed in 1987 to follow up a group of ankle fracture patients consists of subjective symptom evaluation and objective examination of range of motion. It is scored out of 100 with a higher score representing better function.

The Lower Extremity Measure[59] is a patient rated measure of difficulty with ADLs. It is scored out of 100 with greater scores representing better function.

The Foot and Ankle Disability Index was developed in 1999.[60] It is a patient reported outcome measure assessing restrictions associated with ADLs and sport. It is scored out of 100 with a higher score presenting greater disability.

The Short Musculoskeletal Functional Assessment (SMFA) was developed by Swiontkowski in 1999.[61] It is a 46 item patient answered questionnaire measuring function and bother. It has been shown to have moderate to strong correlation with the AOFAS score.[53] A maximum score of 100 represent complete disability.

The Total Ankle Score is not a formal outcome measure. It was developed by Kennedy[62] for a single study and is a modified Baird and Jackson score with radiological criteria included.

1.1.8 Why a systematic review is needed

In clinical practice the question remains as to which fixation method – metal screws, bioabsorbable screws or suture button fixation has the best outcomes. Even with the most commonly used implant (metal screws) questions remain regarding diameter, number, position and number of cortices engaged. Whether or not the screws should be removed also is unclear.

A preliminary search of PubMed, the Cochrane library and the Joanna Briggs Institute (JBI) databases found a single 2007 systematic review of syndesmotic injuries which included only 2 patients who had surgery[63] and no meta-analyses. The scope of the review was limited to studies on syndesmotic injury without fracture and only prospective studies. As a result, only six studies were included with only two patients who were managed with surgery.

The modern era of evidence-based health care relies on the presence of good evidence to guide treatment. The body of research literature is expanding rapidly but correct interpretation and synthesis of this data is important to make correct decisions.[64] The availability of multiple resources with sometimes conflicting evidence can make decision making difficult. Systematic review is a type of secondary research built around synthesis of multiple high-quality studies to combine data and present it in an efficient way.[65] The aim is to pool all available literature to

produce recommendations to guide practice or future research. Meta-analysis can be used to provide a quantitative synthesis of pooled data using additional statistical techniques and analyses.

A systematic review needs to answer a clear question, rather than providing a general summary of available research.[66] Eligibility criteria for included studies or populations need to be determined prior to searching, as do relevant outcomes. Development of a protocol prior to commencing the search, ideally according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines focuses the search strategy and minimises the risk of bias in selecting studies.[67] The protocol can be published for review in databases such as PROSPERO.[68] The search needs to be sensitive, specific and systematic, searching multiple databases. The quality of identified studies needs to be evaluated, ideally with a validated appraisal instrument and multiple reviewers. Results should be present clearly, meta-analysis used where possible and adjuncts such as forest plots or Grading of Recommendations Assessment, Development and Evaluation (GRADE)[69] tables be used to aid interpretation.

The field of surgery, including orthopaedic surgery, does not tend to lend itself well to randomised controlled studies especially when evaluating surgical techniques.[66] Therefore, it is important to pool available data from other study types. Systematic review lends itself to this process.

1.2 Review methodology

This systematic review examines the comparative effectiveness of the commonly encountered syndesmotic stabilisation tools – metal screws, absorbable screws and suture button fixation. A scoping search conducted during the development of the review protocol identified a small number of randomised control trials (RCTs) and cohort studies with descriptive studies making up the bulk of the literature. Despite lower validity than true RCTs, these lower level studies are important especially in surgical research comparing treatments.[70]

1.3 Review question

The aim of this review is to compare the effectiveness of metal screw, bioabsorbable screw and suture button fixation on patient outcomes following acute syndesmotic injury. Additionally, this review has a particular focus on metal screws (the gold standard) and the effect of number, diameter, location, number of cortices and routine removal of metal screws.

The specific review question is: which syndesmotic stabilisation method is the most effective in terms of patient outcomes?

CHAPTER 2: SYSTEMATIC REVIEW

Chapter 2 presents an overview of the systematic review methods. The a priori protocol as published is in Appendix 1.[71]

2.1 Types of participants

This review considers studies that include adult patients (over 18 years) with acute syndesmotic injuries requiring surgical stabilisation (with or without associated fracture). As classified by the Association for Osteosynthesis fracture classification system[72] malleolar region fractures (44-A, B and C) will be included as these are the ankle fractures most commonly associated with syndesmotic injury.

Patients with other associated ankle fractures including tibial plafond and other long bone fractures are excluded as these patients' outcomes are likely to be affected by their other injuries. Chronic syndesmotic injuries (>6 weeks old) are excluded as these have different management strategies and may have worse outcomes.[73] The search is limited to publications in English.

2.2 Types of intervention

This review considers studies that evaluate fixation of acute syndesmotic injuries with metal screws, suture button or bioabsorbable screws. The fixation should occur within six weeks of the injury in the acute hospital setting. Studies which compare two or more fixation methods will be sought preferentially, but studies with any comparator or control group will be included in order to maximise the number of included studies.

2.3 Outcomes

The primary outcomes of interest are: composite functional scores such as the OMAS[50] and the AOFAS[49], range of motion, pain as measured by visual-analogue scale (VAS), radiological measurements of the syndesmosis and complications.

2.4 Study types

Both experimental and epidemiological study designs including randomised controlled trials, non-randomised controlled trials, quasi-experimental, before and after studies, prospective and retrospective cohort studies, case control studies and analytical cross-sectional studies were considered for inclusion. Descriptive epidemiological study designs including case series, individual case reports and descriptive-cross sectional studies with or without a control group were considered for inclusion to maximise the number of patients captured by this review.

2.5 Review Methods

2.5.1 **Search strategy**

Joanna Briggs Institute standard searching methods were followed. The search strategy aimed to find both published and unpublished studies. A three-step search strategy was used. An initial limited search of MEDLINE and CINAHL was undertaken followed by analysis of the text words contained in the title and abstract, and of the index terms used to describe article. A second search using all identified keywords and index terms was then undertaken across all included databases. Thirdly, the reference list of all identified reports and articles was searched for additional studies. Studies published in English were included and no time limits were set on the search.

The list of databases searched is in Table 2.1. In order to keep results as inclusive as possible, a text word only search was performed on all databases. Keywords included syndesmosis and all derivative terms, distal tibiofibular joint (and variations) and high ankle sprain (and variations). A complete search strategy can be found in Appendix 2. Thomson Reuters Endnote x7 software was used to store and read results.

After the initial search in February 2016, the search was repeated again 14 months later in April 2017 after a number of new studies were published. This led to the inclusion of 5 further papers.

Table 2.1 – Databases searched and dates

Database	Date	Results
CINAHL	17/02/2016	396
Cochrane Central Trials Register	17/02/2016	47
EMBASE	17/02/2016	1445
Libraries Australia	17/02/2016	0
Mednar	17/02/2016	432
Open Grey	17/02/2016	2
Proquest	17/02/2016	8
PubMed/MEDLINE	17/02/2016	1225
Scopus	17/02/2016	3402
Web of Science	17/02/2016	1958

2.5.2 **Assessment of methodological quality**

Papers selected for retrieval were assessed by two independent reviewers for methodological validity prior to inclusion in the review using standardised critical appraisal instruments from the Joanna Briggs Institute Meta Analysis of Statistics Assessment and Review Instrument (JBI-MAStARI) (Appendix 3). The instrument consists of 9 or 10 'yes/no/unclear' questions regarding different aspects of the included papers aiming to assess the quality of the papers and reduce the risk of bias. Discrepancies arising between the primary reviewer (TG) and secondary reviewer (NEH) were identified and then resolved through discussion.

2.5.3 **Data collection and synthesis**

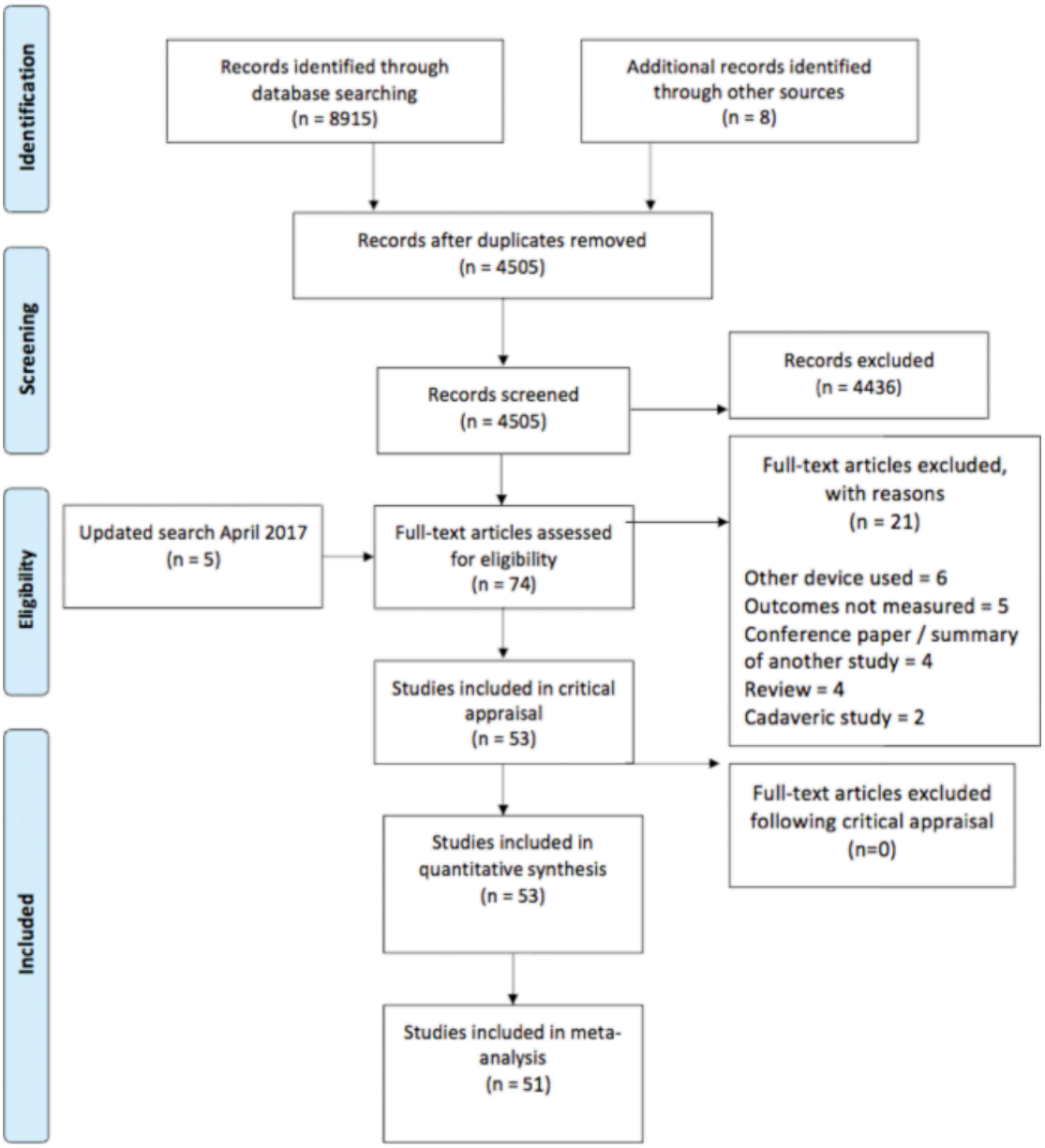
Results were extracted from the included papers and summarised in a spreadsheet (Microsoft Excel for Mac 2011). Specific details about interventions, populations, methods and outcomes were extracted and summarised in text form. For pairwise comparisons RevMan 5.3 software (Cochrane) was used to perform meta-analysis from randomised control trial (RCT) results where possible. Effect sizes are expressed as odds ratios (for categorical data) and their 95% confidence intervals (95% CI) were calculated for analysis. Heterogeneity was assessed statistically using the standard Chi-squared and I^2 tests. For single group meta-analysis, OpenMeta[Analyst] 10.12 (Brown University, Providence, RI, USA) was used to generate Forest plots using weighted means for continuous data and proportional meta-analysis for dichotomous data. Final findings are summarised in GRADE summary of findings tables created using GRADEpro GDT (McMaster University, 2015)

CHAPTER 3: RESULTS

3.1 Search results

Figure 3.1 presents a flow diagram of search results and the review process. Appendix 5 presents details on the excluded studies and reasons for exclusion.

Figure 3.1 – Flow diagram of search results and review process (PRISMA 2009)[67]



3.2 Description of included studies

Tables 3.1-3.3 summarise the included studies, divided by study design. Each study is identified, research methods and follow-up are noted. The number of participants, setting and inclusion criteria are given. The intervention and control are stated with the relevant comparison underlined. In the case of a comparison of one fixation device to another (for example screw to TightRope) the device is underlined. Where two screw types are being compared, the difference between the screws used in the study groups is underlined. The outcomes measured are stated along with the results. When provided in the study reports, 95% CIs and p-values were extracted and included in the table with significant p-values in bold. Finally, notes are given on each study.

Included are 24 descriptive studies, 19 cohort studies, 9 RCTs and 1 quasi-experimental study. Bioabsorbable implants featured in 8 studies, metal screws in 29 and Suture button constructs in 20 studies. A total of 3,088 subjects are assessed across the included studies. Follow-up ranged from 85 days to 8.4 years.

Table 3.1 – Summary of included RCTs and quasi-experimental studies; statistically significant p values in bold.

Study	Methods	Participants/Setting	Intervention/Control	Outcome Measures	Results	Notes
Coetzee 2009[74]	**Randomisation** Not stated **Follow-up** 27 months	**Participants** Total n=24 Intervention n=12 Control n=12 **Setting** Trauma Hospital, Minneapolis, USA **Inclusion Criteria** Acute syndesmotic injury with/without ankle fracture	**Intervention** Syndesmotic stabilisation with 2 TightRopes **Control** Syndesmotic stabilisation with metal screws – 2, 4 cortices, 4/4.5/6.5mm, retained	AOFAS final Dorsiflexion ROM (Range of motion) Plantarflexion ROM Complications	AOFAS mean (range) = 94 (82-100) vs 87 (80-100) - p=0.149 ROM Dorsiflexion degrees mean (range) = 11 (4-20) vs 8 (2-20) – p=0.054 ROM Plantarflexion degrees mean (range) = 53 (37-80) vs 43 (28-70) – p=0.054 Complications (%) = 1/12 (8.3%) vs 1/12 (8.3%)	2 TightRopes vs 2 metal screws. AOFAS and ROM better but not significant Study specifically used syndesmotic screws in compression mode TightRope complication – 1 deep infection requiring removal Screw complication – 1 prominent screw removed

Hoiness 2004[75]	**Randomisation** Closed randomly selected envelopes **Follow-up** 1 year	**Participants** Total n=64 Intervention n=34 Control n=30 **Setting** Trauma Hospital, Oslo, Norway **Inclusion Criteria** Ankle fracture with acute syndesmotic injury	**Intervention** Syndesmotic stabilisation with metal screws - 2, 3 cortex, 3.5mm, retained **Control** Syndesmotic stabilisation with metal screws – 1, 4 cortex, 4.5mm, removed	OMAS at 1 year OMAS at 3 months ROM (Range of motion) at 3 months ROM (Range of motion) at 1 year Complications	OMAS 1yr mean (SD) = 88.8 (14.6) vs 83.3 (8.6) – (95% CI 2.8-13.8); p=0.19 OMAS 3m mean (SD) = 77 (16.1) vs 66.3 (20.1) – (95% CI 1.4-20.0); p=**0.025** ROM Dorsiflexion degrees 1yr mean (SD) = 33.8 (6.8) vs 35.5 (7.9) – p=0.493 ROM Dorsiflexion degrees 3m mean (SD) = 28 (7.9) vs 29.2 (8.7) - p=0.296 Complications (%) = 17/34 (50%) vs 19/30 (63.3%)	2 small frag vs 1 large frag screw. Small frag screws planned retention unless symptoms, large frag planned removal. Small frag screws better functionally at 3 months, not significant at 12 months. ROM same. Very high reported complication rate due to broad inclusions. For 3.5mm screws – 1 loss of position, 1 deep infection, 1 malreduction, 1 screw too long, 1 foot drop, 4 OA, 3 broken screws, 2 removed screws, 2 all metal removed. For 4.5mm screws – 5 loss of reduction, 3 deep infections, 1 malreduction, 2 superficial infection, 5 OA, 3 all metal removed

Kaukonen 2005[76]	**Randomisation** Sealed envelope **Follow-up** 35 months	**Participants** Total n=38 Intervention n=20 Control n=18 **Setting** Trauma Hospital, Helsinki, Finland **Inclusion Criteria** Ankle fracture with acute syndesmotic injury	**Intervention** Syndesmotic stabilisation with a 4.5mm PLA screw **Control** Syndesmotic stabilisation with metal screws – 1, 4 cortices, 4.5mm, removed	ROM Complications Operation time	ROM Dorsiflexion degrees 35 months mean (SD) = 22.2 (10) vs 25.2 (13.4) – (95%CI -5.8-11.7);p=0.490 ROM Plantarflexion degrees 35 months mean (SD) = 45.9 (8.4) vs 45.4 (6.4) (95% CI -6.0-5.0);p=0.854 Complications (%) = 3/20 (15%) vs 1/18 (5.5%) Operation time minutes mean (range) = 79 (40-119) vs 64 (19-96) (95%CI -1.2 - -28.9); **p=0.033**	1 PLA screw vs 1 metal screw. PLA screws equal ROM, more implant related complications. Absorbable screw complication – 3 prominent heads requiring removal Metal screw complication – 1 septic arthritis after screw removal
Khan 2008 [77]	**Randomisation** Randomisation table **Follow-up** 12 months	**Participants** Total n=17 Intervention n=9 Control n=8 **Setting** Military Hospital, Karachi, Pakistan **Inclusion Criteria** Weber C ankle fracture with acute syndesmotic injury	**Intervention** Syndesmotic stabilisation with metal screws – 1, 4 cortices, 3.5mm, retained **Control** Syndesmotic stabilisation with metal screws – 1, 4 cortices, 4.5mm, retained	OMAS at 12 months Broken screws	OMAS at 12 months mean = 84 vs 91 – p=0.805 Broken screws (%) = 0/9 (0%) vs 1/8 (12.5%)	1 3.5mm vs 1 4.5mm screw. All patients subjectively fine. XRs acceptable. No OA.

Kortekangas 2015 [78]	**Randomisation** Computer generated randomisation list. Block size variable 4/6/8. Sealed envelopes opened by nurse in operating theatre **Follow-up** 2 years	**Participants** Total n=40 Intervention n=21 Control n=19 **Setting** University Hospital, Oulu, Finland **Inclusion Criteria** Weber C ankle fracture with acute syndesmotic injury	**Intervention** Syndesmotic stabilisation with TightRope **Control** Syndesmotic stabilisation with metal screws – 1, 3 cortices, 3.5mm, retained	OMAS at 2 years VAS at 2 years ROM (arc of dorsi/plantarflexion) Complications OA (in the absence of contralateral OA) Malreduction on CT (computed tomography) >2mm	OMAS at 2 years mean = 82 vs 84 – p=n.s. VAS at 2 years mean = 1.2 vs 1.2 – p=0.57 ROM degrees mean (SD) = 83 (10) vs 82 (9) – p=0.81 Complications (%) = 1/21 (4.8%) vs 3/19 (15.8%) OA (%) = 13/21 (62.0%) vs 11/19 (57.9%) – p=0.9 Malreduction on CT (%) = 1/21 (4.8%) vs 3/19 (15.8%) – p=0.33	TightRope vs 1 small frag screw. No significant difference in malreduction, OA, ROM, OMAS, VAS. 1 TightRope infected in patient with diabetes – washed out and revision fixation 3 Metal screws broke

Laflamme 2015[79]	**Randomisation** Sealed envelope, computer randomised **Follow-up** 12 months	**Participants** Total n=65 Intervention n=33 Control n=32 **Setting** Multiple Trauma Hospitals, Canada **Inclusion Criteria** Weber C ankle fracture with acute syndesmotic injury	**Intervention** Syndesmotic stabilisation with 1 TightRope **Control** Syndesmotic stabilisation with metal screws – 1, 3.5mm, 4 cortex	OMAS AOFAS VAS ROM Plantarflexion ROM Dorsiflexion Implant removal MCS on XR (X-Ray) Loss of MCS position TFCS on XR Loss of TFCS position	OMAS mean (SD) = 93.3 (9.3) vs 87.7 (12.2) **– p=0.046** AOFAS mean (SD) = 93.1 (8.3) vs 89.9 (12.7) – p=0.255 VAS mean (Range) = 0.6 (0-3) vs 1.1 (0-5) – p=0.12 ROM Dorsiflexion degrees mean (SD) = 13.6 (4.5) vs 14.8 (7.6) – p=0.43 ROM Plantarflexion degrees mean (SD) = 33.6 (7.3) vs 32 (9.8) – p=0.27 Implant removal (%) = 1/33 (3.0%) vs 11/32 (34.4%) MCS mm mean (SD) = 2.9 (0.5) vs 3.1 (0.6) – p=0.38 Loss of MCS mm mean (SD) = 0.05 (0.32) vs 0.41 (0.37) – **p=0.02** TFCS mm mean (SD) = 3.9 (0.9) vs 4.8 (1.5) – **p=0.008**	TightRope vs metal screw. Better clinical outcome on one scoring system, less hardware issues. Better reduction and maintenance of reduction on XR. 1 TightRope was removed for infection, 11 screws removed for irritation Loss of TFCS mm mean (SD) = 0.32 (1.34) vs 1.34 (1.36) **– p=0.0005**

Sun 2014 [80]	**Randomisation** Sealed envelope, block size 4 **Follow-up** 4 years	**Participants** Total n=188 Intervention n=86 Control n=82 **Setting** Trauma Hospital, Shanghai, China **Inclusion Criteria** Ankle fracture with acute syndesmotic injury	**Intervention** Syndesmotic stabilisation with 1 4.5mm PLLA screw, 3 cortices **Control** Syndesmotic stabilisation with metal screws – 1, 3 cortices, 4.5mm, removed	Baird and Jackson ankle score at 4 years ROM Dorsiflexion at 4 years ROM Plantarflexion at 4 years Foreign body reaction Heterotrophic Ossification (HO)	Baird and Jackson mean (range) = 90 (77-100) vs 97 (80-100) – p=0.095 Dorsiflexion degrees mean (range) = 26 (23-28) vs 18 (15-24) – **p=0.011** Plantarflexion degrees mean (range) = 40 (36-45) vs 35 (33-40) – **p<0.001** Foreign body reaction (%) = 29/86 (33.7%) vs 4/82 (4.9%) – **p=0.001** Heterotrophic Ossification (%) = 3/86 (3.5%) vs 0/82 (0%) – p=0.246	1 4.5mm 3 cortex PLLA screw vs large frag screw. No significant difference in Baird and Jackson score or HO. Significantly better ROM in PLLA screw group. Much higher incidence of foreign body reaction with PLLA screws. 5 PLLA screws with significant foreign body reaction requiring debridement. The remainder resolved with wound care
Thordarson 2001 [81]	**Randomisation** Sealed envelope **Follow-up** 11 months	**Participants** Total n=32 Intervention n=17 Control n=15 **Setting** Trauma Hospital, Los Angeles, USA **Inclusion Criteria** Pronation-lateral rotation ankle fracture with acute syndesmotic injury	**Intervention** Syndesmotic stabilisation with 1 4.5mm PLA screw, 4 cortices **Control** Syndesmotic stabilisation with metal screws – 1, 4 cortices, 4.5mm, removed	ROM Dorsiflexion ROM Plantarflexion FB reaction Infections MCS on XR	ROM Dorsiflexion degrees mean = 10 vs 8 ROM Plantarflexion degrees mean = 38 vs 45 FB reaction (%) = 0/17 (0%) vs 0/15 (0%) Infection (%) = 1/17 (5.9%) vs 2/15 (13.3%) MCS mm mean = 3.2 vs 3.3	Absorbable screw versus metal screw. No difference in ROM, XR parameters or foreign body reaction. 1 Deep infection requiring removal of metal in each group, 1 additional superficial infection in metal screw group treated with antibiotics.

Wikeroy 2010 [82]	**Randomisation** Sealed envelope **Follow-up** 8.4 years	**Participants** Total n=48 Intervention n=25 Control n=23 **Setting** Trauma Hospital, Oslo, Norway **Inclusion Criteria** Ankle fracture with acute syndesmotic injury	**Intervention** Syndesmotic stabilisation with metal screws – 2, 3 cortex, 3.5mm, retained **Control** Syndesmotic stabilisation with metal screws – 1, 4.5mm 4 cortex, removed	OMAS Orthopaedic Trauma Association score (OTA) Short-form 36 questionnaire (SF-36) VAS ROM Dorsiflexion Articular Height on XR CT syndesmotic width	OMAS mean (SD) = 82.3 (19.4) vs 82.8 (19.9) – p=0.9 OTA mean (SD) = 88.5 (11.6) vs 84.4 (13.3) – p=0.2 SF-36 mean (SD) = 104 (10.3) vs 102 (9.4) – p=0.41 VAS mean (SD) = 4.9 (6.7) vs 4.5 (7.2) – p=0.8 ROM Dorsiflexion degrees mean (SD) = 26.7 (9.7) vs 34.3 (14.9) – **p=0.03** Articular height mean mm = 2.8 vs 3.3 – **p=0.02** CT syndesmotic width mean mm = 3.2 vs 4.3 – **p=0.025**	This is the long term follow-up of Hoiness 2004.[75] Two small frag removed screws vs 1 large frag retained screw. No significant difference in outcome scores. Minor difference in radiological parameters. ROM better with removed screw.

Moore 2006[83]	**Methodology** Quasi-experimental. Surgeon randomised at time of surgery **Follow-up** 5 months	**Participants** Total n=120 Intervention n=59 Control n=61 **Setting** Trauma Hospital, Bend, Oregon, USA **Inclusion Criteria** Ankle fracture with syndesmotic injury	**Intervention** Syndesmotic stabilisation with 1 or 2 3.5mm screws through 3 cortices with planned retention **Control** Syndesmotic stabilisation with 1 or 2 3.5mm screws through 4 cortices with planned retention	Broken screw Screw removal Loss of reduction Infection Lucency	Broken screw (%) = 5/59 (8.5%) vs 4/61 (6.6%) – p=0.689 Screw removal (%) = 4/59 (6.8%) vs 4/61 (6.6%) – p=0.731 Loss of reduction (%) = 3/59 (5.1%) vs 0/61 (0%) – p=0.871 Infection (%) = 2/59 (3.4%) vs 0/61 (0%) Lucency = 31/59 (52.5%) vs 36/61 (59.0%)	Quasi-experimental (surgeon randomised) study comparing 3 cortical to 4 cortical fixation with no difference in clinical or radiological complications.

Table 3.2 – Summary of included cohort studies; statistically significant p values in bold.

Study	Methods	Participants/Setting	Intervention/Control	Outcome Measures	Results	Notes
Bell 2006[84]	**Methodology** Retrospective observation **Follow-up** 15 months	**Participants** Total n=30 Intervention n=23 Control n=7 **Setting** Trauma Hospital, Singapore **Inclusion Criteria** Weber C Ankle fracture with acute syndesmotic injury fixed with 1, unspecified size 3 cortex metal screw	**Intervention** Screw removal between 6-12 weeks **Control** Screw retention	Baird and Jackson score Pain free patients ROM deficit Flexion/ Extension ROM deficit Inversion/ Eversion Complications Screw breakage XR Instability (secondary shift or displacement) Return to work at final follow-up no restrictions	Baird and Jackson mean (SD) = 88 (5.5) vs 86 (7.46) – p=0.79 Pain free (%) = 11/23 (47.8%) vs 2/7 (28.6%) – p=n.s. Flexion/Extension deficit degrees mean (SD) = 11.5 (5.08) vs 12.1 (6.2) – p=n.s. Inversion/Eversion deficit degrees mean (SD) = 10.4 (3.67) vs 10.0 (6.45) – p=n.s. Complications (%) = 1/23 (4.3%) vs. 1/7 (14.2%) – p=n.s. Screw breakage (%) = 0/23 vs 2/7 (28.6%) **– p=0.025** XR unstable (%) = 0/23 (0%) vs 0/7 (0%)	Study comparing screw removal to screw retention. Screw breakage more likely in retained screw group, functional outcomes equivalent One patient in each group had superficial wound infection Return to work (%) = 13/23 (56.5%) vs 4/7 (57.1%) – p=n.s.

Cottom 2009[85]	**Methodology** Retrospective observation **Follow-up** 10 months	**Participants** Total n=50 Intervention n=25 Control n=25 **Setting** Foot and Ankle Hospital, Sarasota, Florida, USA **Inclusion Criteria** Syndesmotic injury with or without fracture	**Intervention** Syndesmotic stabilisation with 1 or 2 TightRopes **Control** Syndesmotic stabilisation with metal screws (not further characterised)	Modified AOFAS (/63) Short-Form 12 (SF-12) physical and mental performance score Complications MCS on XR TFO on XR TFCS on XR	AOFAS Modified (/63) mean (range) = 50.64 (30-63) vs 53.5 (25-63) SF-12 mean (physical/mental) = 47.02/55.34 vs 46.87/54.69 Complications (%) = 0/25 (0%) vs 12/25 (48%) XR MCS mm mean (range) = 3.00 (3-4) vs 3.08 (2-4) – p=0.7634 XR TFO mm mean (range) = 6.88 (4-11) vs 7.96 (4-11) – p=0.1602 XR TFC mm mean (range) = 3.8 (3-5) vs 2.76 (4-8) – **p=0.0187**	Comparison of TightRopes to 2 metal screws (not further characterised) No significant differences in outcomes Screw loosening or breakage were considered complications (5 and 7 respectively). Study used a modified AOFAS score (max score 63).

Hsu 2011[86]	**Methodology** Retrospective observation **Follow-up** 19 months	**Participants** Total n=52 Group 1 n=19 Group 2 n=20 Group 3 n=13 **Setting** Trauma Hospital, Taiwan **Inclusion Criteria** Ankle fracture with syndesmotic injury treated with 1 3.5mm 3 cortex metal screw	**Intervention** Syndesmotic stabilisation with 1 3.5mm 3 cortex metal screw **Group 1** Screw removal at 6 weeks **Group 2** Screw removed or broken between 6 weeks and 12 weeks **Group 3** Screw removed or broken after 12 weeks	Bray score >75 Screw breakage Recurrent instability on XR	Bray score >75 (%) = 16/19 (84.2%) vs 16/20 (80%) vs 11/13 (84.6%) – p=0.191 Screw breakage (%) = 0/19 (0%) vs 3/20 (15%) vs 2/13 (15.4%) – **p=0.034** Recurrent instability on XR (%) = 3/19 (15.8%) vs 3/20 (15%) vs 0/13 (0%) – p=0.054	Comparison of screw removal early against retention and failure or late removal No major differences although a retained screw is more likely to break than a screw removed early

Naqvi & Cunningham 2012[46]	**Methodology** Retrospective observation **Follow-up** 30 months	**Participants** Total n=46 Intervention n=23 Control n=23 **Setting** Trauma Hospital, Drogheda, Ireland **Inclusion Criteria** Ankle fracture with syndesmotic injury treated with 1 3.5mm 3 cortex metal screw	**Intervention** Syndesmotic stabilisation with 1 or 2 TightRopes **Control** Syndesmotic stabilisation with 1 or 2, 3.5 or 4.5mm, 4 cortex metal screw	AOFAS FADI (Foot and Ankle Disability Index) MCS TFC TFO CT malreduction >2mm Time to Full Weight Bearing (FWB)	AOFAS mean (SD) = 89.6 (8.6) vs 86.5 (9.6) – (95% CI = 82.34-90.7); p=0.26 FADI mean (SD) = 82.4 (11.2) vs 81.2 (15.6) – (95% CI = 74.46-87.97); p=0.76 MCS mm mean (SD) = 3.36 (0.5) vs 3.23 (0.6) – p=0.48 TFC mm mean (SD) = 4.04 (0.8) vs 5.0 (1.8) – **p<0.05** TFO mm mean (SD) = 8.21 (2.0) vs 7.47 (2.0) – p=0.22 CT malreduction >2mm (%) = 0/23 (0%) vs 5/23 (21.7%) – **p<0.05** Time to FWB weeks mean (SD) = 8 (1.2) vs 9.1 (1.8) – p=0.11	Study comparing TightRope to screws. Outcomes similar, minor differences in TFC on XR. Significantly less malreduction on CT with TightRope Study also concluded on regression analysis that syndesmotic malreduction is strongest predictor of poor outcome (AOFAS) – OR -12.39 (95% CI = -22.7 - -2.09)

Thornes 2005[87]	**Methodology** Prospective observation with retrospective comparison to control group **Follow-up** 12 months	**Participants** Total n=32 Intervention n=16 Control n=16 **Setting** Trauma Hospital, Limerick, Ireland **Inclusion Criteria** Ankle fracture with syndesmotic injury	**Intervention** Syndesmotic stabilisation with 1 TightRope style implant (made from #5 polyester and 2 endobuttons) **Control** Syndesmotic stabilisation with metal screws not further classified	AOFAS Implant removal Time of return to work	AOFAS mean = 93 vs 83 - **p=0.04** Implant removal (%) = 0/16 (0%) vs 12/16 (75%) – **p=0.001** Time of return to work mean weeks = 2.8 vs 4.6 – **p=0.02**	Study comparing TightRope type implant (made by the surgeon) to a metal screw Statistically significant better AOFAS score and quicker return to work. No need for implant removal.
Kim 2016[88]	**Methodology** Retrospective observation **Follow-up** 12 months	**Participants** Total n=44 Intervention n=20 Control n=24 **Setting** Trauma Hospital, Busan, South Korea **Inclusion Criteria** Ankle fracture with syndesmotic injury	**Intervention** Syndesmotic stabilisation with 1 TightRope **Control** Syndesmotic stabilisation with 1 or 2 3.5mm 3 cortex metal screws	AOFAS VAS Implant breakage MCS TFC TFO	AOFAS mean (range) = 88.1 (79-95) vs 86.6 (75-96) – p=0.663 VAS mean (range) = 1.4 (0-3) vs 1.5 (0-3) – p=0.795 Implant breakage (%) = 0/20 (0%) vs 5/24 (20.8%) MCS mean mm (range) = 4.25 (2.97-5.71) vs 4.32 (1.98-6.57) – p=0.858 TFC mean mm (range) = 5.15 (2.93-7.30) vs 4.95 (2.72-9.08) – p=0.663 TFO mean mm (range) = 7.21 (2.15-10.30) vs 6.29 (0-10.37) – p=0.235	Study comparing TightRope to metal screw. No statistically significant differences in XR outcomes, AOFAS or VAS.

Kocadal 2016[89]	**Methodology** Retrospective observation **Follow-up** 16 months	**Participants** Total n=52 Intervention n=26 Control n=26 **Setting** Trauma Hospital, Ankara, Turkey **Inclusion Criteria** Ankle fracture with syndesmotic injury	**Intervention** Syndesmotic stabilisation with 1 ZipTight **Control** Syndesmotic stabilisation with 1 3.5mm 4 cortex metal screws retained unless symptomatic	AOFAS Implant removal Infection Implant breakage	AOFAS mean (range) = 88.4 (9.2) vs 86.1 (14) – p=0.4 Implant removal (%) = 1/26 (3.8%) vs 10/26 (38.5%) Infection (%) = 1/26 (3.8%) vs 0/26 (0%) Implant breakage= 0/26 (0%) vs 1/26 (3.8%)	Study comparing ZipTight implant to metal screw. No statistically significant differences in AOFAS. Higher incidence of implant failure and removal in the screw group.
Kaftandziev 2015[90]	**Methodology** Retrospective observation **Follow-up** 12 months	**Participants** Total n=82 Group 1 n=46 Group 2 n=23 Group 3 n=13 **Setting** Trauma Hospital, Skopje, Macedonia **Inclusion Criteria** Ankle fracture with syndesmotic injury	**Intervention** Syndesmotic stabilisation with 1 or 2, 3.5mm 3 or 4 cortex metal screws **Group 1** Screws intact **Group 2** Screw removed at 8-12 weeks **Group 3** Screws broken	AOFAS VAS Displacement	AOFAS mean (SD) = 83 (12.2) vs 85.5 (11.6) vs 92.5 (6.05) – **p= 0.0496** VAS mean (SD) = 1.57 (1.2) vs 1.22 (1.0) vs 1.08 (1.1) – p=0.34 Displacement (%) = 0/46 (0%) vs 0/23 (0%) vs 0/13 (0%)	Study comparing patients with an intact metal screw, a planned removed screw and a broken screw. AOFAS was better in the broken screw group. VAS and displacement were no different There was a note of radiolucency around the screw in 39 of the 59 patients with an intact screw. AOFAS and VAS were no different in this group.

Karapinar 2007[91]	**Methodology** Retrospective observation **Follow-up** 12 months	**Participants** Total n=46 Group 1 n=24 Group 2 n=22 **Setting** Trauma Hospital, Izmir, Turkey **Inclusion Criteria** Ankle fracture with syndesmotic injury	**Intervention** Syndesmotic stabilisation with 1, size not specified metal screws **Group 1** 4 cortical fixation **Group 2** 3 cortical fixation	OMAS Dorsiflexion ROM Plantarflexion ROM Synostosis on XR Synostosis on MRI not seen on XR	OMAS overall mean (range) = 83 (80-95). ROM Dorsiflexion overall degrees mean (range) = 19 (10-40) ROM Plantarflexion overall degrees mean (range) = 37 (20-55) Synostosis XR (%) = 3/24 (12.5%) vs 0/22 (0%) – **p<0.005** Synostosis MRI (%) = 8/24 (33.3%) vs 2/22 (9.1%) – **p<0.005**	Study comparing the rate of synostosis on XR and MRI comparing 3 to 4 cortical fixation with significantly less synostosis in the 3 cortex group. Overall OMAS and ROM reported but not further divided by group.
Kukreti 2005[92]	**Methodology** Retrospective observation **Follow-up** 35 months	**Participants** Total n=36 Group 1 n=19 Group 2 n=17 **Setting** Trauma Hospital, Hull, UK **Inclusion Criteria** Ankle fracture with syndesmotic injury	**Intervention** Syndesmotic stabilisation with 1, 3.5mm 3 or 4 cortical metal screw, removed at 8 weeks **Group 1** Suprasyndesmotic fixation **Group 2** Transsyndesmotic fixation	Full ROM Synostosis Talar displacement OA	Full ROM (%) = 6/19 (31.6%) vs 4/17 (23.5%) – p=n.s. Synostosis (%) = 5/19 (26.3%) vs 8/17 (47.1%) – p=0.34 Talar displacement (%)= 3/19 (5.3%) vs 5/17 (29.4%) – p=n.s. OA (%) = 4/19 (21.1%) vs 4/17 (23.5%) p=1.00	Study comparing metal screw fixation with 1 3.5mm screw either through or above the syndesmosis with no significant differences in ROM or radiological complications.

Maempel 2014[93]	**Methodology** Retrospective observation **Follow-up** 12 weeks	**Participants** Total n=35 Intervention n=12 Control n=23 **Setting** Trauma Hospital, Bristol, UK **Inclusion Criteria** Ankle fracture with syndesmotic injury	**Intervention** Syndesmotic stabilisation with 1 TightRope **Control** Syndesmotic stabilisation with metal screw with planned removal (not further characterised)	Stitch abscess Infection Wound dehiscence Recurrent diastasis	Stitch abscess (%) = 1/12 (8.3%) vs 0/23 (0%) Infection (%) = 0/12 (0%) vs 1/23 (4.3%) Wound dehiscence (%) = 0/12 (0%) vs 1/23 (4.3%) Recurrent diastasis (%) = 0/12 (0%) vs 1/23 (4.3%)	Study comparing the short term complications of metal screw fixation to TightRope fixation with a higher complication rate in the metal screw group
Manjoo 2010[94]	**Methodology** Retrospective observation **Follow-up** 23 months	**Participants** Total n=76 Group 1 = 20 Group 2 = 44 Group 3 = 12 **Setting** Trauma Hospital, London, Ontario, Canada **Inclusion Criteria** Ankle fracture with syndesmotic injury	**Intervention** Syndesmotic stabilisation with metal screws (not further characterised) **Group 1** Intact screws **Group 2** Broken or loose screws **Group 3** Removed screws	Lower Extremity Measure (LEM) OMAS MCS TFC TFO	LEM mean (SD) = 70.3 (6.3) vs 83.3 (3.0) vs 88.1 (4.8) – **p=0.01** OMAS mean (SD) = 46.5 (7.9) vs 62.2 (4.9) vs 66.8 (6.7) – **p=0.04** MCS mean mm (SD) = 3.1 (0.2) vs 3.1 (0.1) vs 3.1 (0.2) – p=0.9 TFC mean mm (SD) = 3.2 (0.2) vs 4.1 (0.2) vs 4.1 (0.3) – **p=0.005** TFO mean mm (SD) = 7.1 (0.3) vs 6.7 (0.4) vs 7.3 (0.6) – p=0.69	Study comparing metal screws that were retained and intact, broken or loose and removed Intact screws had poorer LEM and OMAS scores as compared to removed or loose/broken screws. No significant difference between broken/loose and surgically removed screws No significant difference comparing 3.5mm to 4.5mm screws and no significant difference between tricortical and quadricortical fixation.

Schepers 2014[95]	**Methodology** Retrospective observation **Follow-up** 51 months	**Participants** Total n=93 **Comparison 1** n= 24 vs 49 vs 19 **Comparison 2** n= 77 vs 16 **Comparison 3** n= 81 vs 12 **Comparison 4** n= 84 vs 9 **Comparison 5** n= 37 vs 44 vs 12 **Setting** Trauma Hospital, Amsterdam, The Netherlands **Inclusion Criteria** Ankle fracture with acute syndesmotic injury	**Intervention** Syndesmotic stabilisation with metal screws – varying characteristics **Comparison 1** Low screws vs transsyndesmotic screws vs suprasyndesmotic screws **Comparison 2** 1 screw vs 2 screws **Comparison 3** 3 cortex vs 4 cortex **Comparison 4** 3.5mm vs 4.5mm screws **Comparison 5** Early removal (<8 weeks) vs late removal vs retention	Overall AOFAS Overall OMAS Overall VAS Wound complications CRPS (Complex regional pain syndrome)	AOFAS mean (SD) = 92 (14) OMAS mean (SD) = 77 (24) VAS mean (SD) = 1.8 (1.5) Wound complications = 6/93 (6.5%) CRPS = 1/93 (1.1%)	Detailed study of 93 patients with metal screw fixation. Through subgroup analysis looking at screw location, screw number, screw size, number of cortices, number of screws and timing of removal. Study reports VAS as pain free satisfaction (i.e. 10 is perfect outcome). This has been inverted to match other studies (i.e. 0 is perfect outcome)

Seyhan 2015[96]	**Methodology** Retrospective observation **Follow-up** 12 months	**Participants** Total n=32 Intervention n=15 Control n=17 **Setting** Trauma Hospital, Istanbul, Turkey **Inclusion Criteria** Ankle fracture with syndesmotic injury	**Intervention** Syndesmotic stabilisation with 1 TightRope **Control** Syndesmotic stabilisation with 1 4.5mm 4 cortical metal screw removed at 3 months	AOFAS Dorsiflexion deficit compared to uninjured side Plantarflexion deficit compared to uninjured side Hardware removal for prominence	Mean AOFAS (SD) = 93.7 (7.38) vs 93.4 (6.93) – p=0.889 Mean dorsiflexion deficit degrees (SD) = 1.4 (1.14) vs 3.65 (1.54) – **p=0.001** Mean plantarflexion deficit degrees (SD) = 2.67 (1.49) vs 8.41 (2.63) – **p=0.001** Hardware removal for prominence (SD) = 6/15 (40%) vs 4/17 (23.5%)	Study comparing TightRope to 4.5mm 4 cortical metal screw AOFAS no different, statistically significant better ROM in TightRope group High rate of hardware removal for TightRope
Sinisaari 2002[97]	**Methodology** Retrospective observation **Follow-up** 12 months	**Participants** Total n=32 Intervention n=20 Control n=12 **Setting** Trauma Hospital, Sairaalantie, Finland **Inclusion Criteria** Ankle fracture with syndesmotic injury	**Intervention** Syndesmotic stabilisation with 1 4 cortex 4.5mm PLLA screw **Control** Syndesmotic stabilisation with 1 3.2mm 4 cortical metal screw	OMAS Complications TFC TFO CT syndesmotic width Sick leave days	Mean OMAS (range) = 82 (25-100) vs 90 (70-100) – p=0.93 Complications = 0/20 (0%) vs 0/12 (0%) TFC mm mean (range) = 5.7 (3.6-8.1) vs 5.0 (2.8-8.0) – p=0.42 TFO mm mean (range) = 6.0 (1.5-12.5) vs 6.8 (1.4-13.9) – p=0.77 CT syndesmotic width mm mean (range) = 4.4 (2.8-6.5) vs 4.0 (1.6-6.3) – p=0.47	Study comparing a 4.5mm PLLA screw to a 3.2mm 4 cortical metal screw. No differences in syndesmotic reduction on XR, complications, sick leave duration or OMAS. Sick leave days mean (range) = 78 (42-212) vs 64 (42-95) – p=0.28

Stuart 2011[98]	**Methodology** Retrospective observation **Follow-up** 12 months	**Participants** Total n=137 **Comparison 1** n= 118 vs 19 **Comparison 2** n= 62 vs 63 vs 12 **Comparison 3** n= 120 vs 17 **Setting** Trauma Hospital, Galveston, Texas, USA **Inclusion Criteria** Ankle fracture with syndesmotic injury	**Intervention** Syndesmotic stabilisation with 1, 2 or 3 metal screws with optional removal (42%) at a mean of 4.8 months **Comparison 1** Transsyndesmotic vs suprasyndesmotic **Comparison 2** 3.5mm vs 4.0mm vs 4.5mm **Comparison 3** 3 cortex vs 4 cortex	Implant breakage Implant loosening Loss of reduction	Overall implant breakage = 14/137 (10.2%) Overall implant loosening = 13/137 (9.5%) Overall loss of reduction = 8/137 (5.8%)	Study assessing complications of metal screw fixation with 137 patients and subgroup analyses comparing screw location, diameter and number of cortices.

Tucker 2013[99]	**Methodology** Retrospective observation **Follow-up** 31 months	**Participants** Total n=63 Intervention n=43 Control n=20 **Setting** Trauma Hospital, Belfast, Northern Ireland, UK **Inclusion Criteria** Ankle fracture with syndesmotic injury stabilised with metal screws (varying diameter, number, position and cortices)	**Intervention** Screw removal at a mean of 12 weeks **Control** Screw retention	OMAS	OMAS mean (SD) = 75 (12.9) vs 81.5 (19.3) - p=0.251	Study comparing screw removal to screw retention. No difference in OMAS.
Hamid 2009[100]	**Methodology** Retrospective observation **Follow-up** 12 months	**Participants** Total n=52 Group 1 = 27 Group 2 = 10 Group 3 = 15 **Setting** Trauma Hospital, Charlotte, North Carolina, USA **Inclusion Criteria** Ankle fracture with syndesmotic injury stabilised with metal screws (1 3.5mm, 3 or 4 cortices)	**Group 1** Screw intact **Group 2** Screw broken **Group 3** Screw removed at a mean of 9.7 weeks	Overall AOFAS Overall VAS Overall TFC	AOFAS mean (range) = 85.2 (55-100) VAS mean (range) = 1.6 (0-8.4) TFC mm mean (range) = 4.1 (3.2-5.5)	Study comparing the outcome of metal screws in patients with intact, broken and removed screws. No significant difference seen between the groups

Weening 2005[101]	**Methodology** Retrospective observation **Follow-up** 18.1 months	**Participants** Total n= 39 Group 1 = 31 Group 2 = 8 **Setting** University Hospital, Hamilton, Ontario, Canada **Inclusion Criteria** Ankle fracture with syndesmotic injury stabilised with metal screws (1 or 2, 3.5/4.0/4.5mm, 3 or four cortices, optional removal)	**Group 1** Syndesmosis reduced **Group 2** Syndesmosis not reduced	Overall OMAS Overall Short Musculoskeletal Functional Assessment (SMFA) function index Overall SMFA emotional index Overall SMFA bother index Overall VAS Overall Screw breakage Overall Screw loosening	OMAS mean (SD) = 74.1 (23.4) SMFA function mean (SD) = 11.4 (10.6) SMFA emotional mean (SD) = 16.5 (17.8) SMFA bother mean (SD) = 13.5 (13.1) VAS mean (SD) = 3.4 (3.8) Screw breakage = 2/39 (5.1%) Screw loosening = 3/39 (7.6%)	Study assessing various strategies of metal screw syndesmotic treatment. VAS reported out of 5, so scores doubled to match other studies. Unreduced syndesmoses do worse on some outcomes.

Table 3.3 – Summary of included descriptive studies; statistically significant p values in bold.

Study	Methods	Participants/Setting	Intervention/Control	Outcome Measures	Results	Notes
Kennedy 2000[62]	**Methodology** Retrospective observation **Follow-up** 2.9 years	**Participants** Total n= 45 Group 1 = 26 Group 2 = 19 **Setting** University Hospital, Dublin, Ireland **Inclusion Criteria** Ankle fracture requiring surgical fixation	**Group 1** Syndesmosis stabilised with metal screws (not further specified) **Group 2** Syndesmosis not stabilised (outcomes not included – not part of review question)	Total Ankle Score	Total Ankle Score mean = 62.81	Study comparing patients with and without a syndesmotic injury. There was no overall difference in functional score (Total Ankle Score)
Ahmad 2009[102]	**Methodology** Retrospective observation **Follow-up** 32.5 months	**Participants** Total n= 70 **Setting** University Hospital, Philadelphia, Pennsylvania, USA **Inclusion Criteria** Ankle fracture with syndesmotic injury stabilised with a 4 cortical 4.5mm PLA screw	**Intervention** Ankle fracture with syndesmotic injury stabilised with a 4 cortical 4.5mm PLA screw	AOFAS VAS Prominent hardware Instability clinical Instability radiological	AOFAS mean (range) = 90 (44-100) VAS mean (range) = 1.8 (0-10) Prominent hardware = 2/75 (2.9%) Instability clinical = 0/70 (0%) Instability radiological = 0/70 (0%)	Study of PLA screw fixation of syndesmotic injury. Outcome scores favourable, low complication rate. Trimalleolar fractures did worse on AOFAS and VAS.

Anand 2017[103]	**Methodology** Retrospective observation **Follow-up** 14 months	**Participants** Total n= 36 **Setting** Trauma Hospital, London, UK **Inclusion Criteria** Weber C ankle fracture with syndesmotic injury treated with a TightRope	**Intervention** Weber C ankle fracture with syndesmotic injury treated with one or two TightRopes	AOFAS OMAS MCS TFO Implant breakage Hardware irritation	AOFAS mean (range) = 88.8 (67-98) OMAS mean (range) = 85 (70-100) MCS mm mean (range) = 3.0 (2.7-3.6) TFO mm mean (range) = 10.1 (2.5-12.2) Implant breakage (%) = 1/36 (2.8%) Hardware irritation (%) = 1/36 (2.8%)	Study of TightRope fixation for Weber C ankle fractures. Outcome scores favourable, low complication rate.
Bondi 2016[104]	**Methodology** Retrospective observation **Follow-up** 28 months	**Participants** Total n= 36 **Setting** Trauma Hospital, Mantova, Italy **Inclusion Criteria** Ankle fracture with syndesmotic injury treated with a TightRope	**Intervention** Ankle fracture with acute syndesmotic injury treated with one TightRope	AOFAS FADI Implant removal MCS TFO TFC	AOFAS mean (SD) = 93.11 (4.38) FADI mean (SD) = 130.11 (2.52) Implant removal (%) = 1/32 (3.1%) MCS mm mean (SD) = 4.0 (0.8) TFO mean (SD) = 7.1 (0.8) TFC mean (SD) = 4.6 (1.1)	Retrospective analysis of syndesmotic injuries treated with 1 TightRope. Good functional and radiological results with low complication rate.

Cottom 2008[105]	**Methodology** Retrospective observation **Follow-up** 10.8 months	**Participants** Total n=25 **Setting** Foot and Ankle Hospital, Sarasota, Florida, USA **Inclusion Criteria** Ankle fracture with syndesmotic injury treated with a TightRope	**Intervention** Ankle fracture with acute syndesmotic injury treated with one or two TightRopes	Modified AOFAS (/63) Short-Form 12 (SF-12) physical and mental performance score Complications MCS TFO TFCS	AOFAS Modified (/63) mean (range) = 50.64 (30-63) SF-12 mean (physical/mental) = 47.02/55.34 Complications (%) = 0/25 (0%) XR MCS mm mean (SD) = 3.12 (0.33) XR TFO mm mean (SD) = 7.12 (1.71) XR TFC mm mean (SD) = 3.88 (0.83)	Retrospective analysis of 25 patients treated with 1 or 2 Tightropes. Study used a modified AOFAS (max score 63). Good clinical and radiological results. Possibly the same TightRope patient cohort as Cottom 2009[85] as the overall outcome measures are identical but with slightly different XR measurements.

DeGroot 2011[106]	**Methodology** Retrospective observation **Follow-up** 20 months	**Participants** Total n=24 **Setting** Trauma hospital, Newton, Massachusetts, USA **Inclusion Criteria** Ankle fracture with syndesmotic injury treated with a TightRope	**Intervention** Ankle fracture with acute syndesmotic injury treated with one, two or three TightRopes	AOFAS Removal Infections Button subsidence HO MCS TFO TFC	AOFAS mean (range) = 94.17 (71-100) Removal (%) = 6/24 (25%) Infection (%) = 0/24 (0%) Button subsidence (%) = 4/24 (16.7%) Heterotrophic ossification (%) = 3/24 (12.5%) MCS mm mean (SD) = 3.8 (0.39) TFO mm mean (SD) = 7.9 (1.2) TFC mm mean (SD) = 3.3 (0.7)	Study of patients treated with one, two or three (n=1) TightRopes. Good radiological and clinical outcomes but high removal rate. HO and subsidence were not associated with worse outcomes.
Gennis 2015[107]	**Methodology** Retrospective observation **Follow-up** 4 months	**Participants** Total n=166 **Setting** Trauma hospital, Boston, Massachusetts, USA **Inclusion Criteria** Ankle fracture with syndesmotic injury treated with metal screws	**Intervention** Ankle fracture with acute syndesmotic injury treated with one or two 3.5mm 3 or 4 cortical metal screws	Broken screw Screw removal MCS TFO TFC	Broken screw (%) = 91/166 (54.8%) Screw removal (%) = 58/166 (34.9%) MCS mm mean = 2.0 TFO mm mean = 7.3 TFC mm mean = 4.0	Study assessing the outcomes of syndesmoses fixed with metal 3.5mm screws. No difference in radiological outcomes for intact/ broken/ loose/ removed screws or with fracture pattern.

Hovis 2002[108]	**Methodology** Retrospective observation **Follow-up** 34 months	**Participants** Total n=23 **Setting** Trauma hospitals, Dallas, Texas, USA **Inclusion Criteria** Ankle fracture with syndesmotic injury treated with 4.5mm PLLA screw	**Intervention** Ankle fracture with acute syndesmotic injury treated with one or two 4.5mm 4 cortical PLLA screws	OMAS ROM Dorsiflexion ROM Plantarflexion Complications	OMAS mean (SD) = 93.9 (6.6) ROM Dorsiflexion degrees mean (SD) = 17.4 (10.2) ROM Plantarflexion degrees mean (SD) = 40.2 (12.2) Complications (0%) = 0/23 (0%)	Study following the outcomes of syndesmotic stabilisation with PLLA screws. Good outcomes clinically with no complications. Individual patient data given allowing calculation of SD (range only given in paper).
Jones 2015[109]	**Methodology** Retrospective observation **Follow-up** 60 months	**Participants** Total n=27 Group 1 n=15 Group 2 n=12 **Setting** University hospital, Durham, North Carolina, USA **Inclusion Criteria** Lauge-Hansen SER-IV type ankle fracture with syndesmotic injury	**Group 1** Syndesmotic stabilisation with metal screw (not otherwise specified) with planned removal **Group 2** Syndesmosis stabilised indirectly with deltoid ligament repair (not included in analysis – not part of review question)	AOFAS FADI VAS Loss of reduction	AOFAS mean (SD) = 95 (5.77) FADI mean (SD) = 96.4 (5.86) VAS mean (SD) = 0.2 (0.45) Loss of reduction (%) = 1/15 (6.7%)	Comparison of metal screw syndesmotic stabilisation to indirect stabilisation with deltoid ligament repair. No significant difference between the groups. Good results in the metal screw patients.

Kaye 1989[110]	**Methodology** Retrospective observation **Follow-up** 6.3 months	**Participants** Total n=31 **Setting** Trauma hospital, San Jose, California, USA **Inclusion Criteria** Ankle fracture with syndesmotic injury	**Intervention** Syndesmotic stabilisation with 1, 3.5, 4.0, 4.5 or 6.5mm 3 or 4 cortical metal screw with planned removal	ROM Dorsiflexion ROM Plantarflexion Malreduction Screw malposition HO	ROM Dorsiflexion degrees mean = 9 ROM Plantarflexion degrees mean = 38 Malreduction (%) = 1/31 (3.2%) Screw malposition (%) = 2/31 (6.5%) HO (%) = 7/31 (22.6%)	Study assessing outcome of metal screw syndesmotic fixation. Good results clinically.
Korkala 1999[111]	**Methodology** Retrospective observation **Follow-up** 12 months	**Participants** Total n=7 **Setting** Trauma hospital, Lahti, Finland **Inclusion Criteria** Ankle fracture with syndesmotic injury stabilised with 1 or 2 4.5mm 4 cortical PGA screws	**Intervention** Syndesmotic stabilisation with 1 or 2 4.5mm 4 cortical PGA screws	Soft tissue reaction Stiffness	Soft tissue reaction (%) = 1/7 (14.3%) Stiffness (%) = 1/7 (14.3%)	Small study (n=7) assessing outcomes of PGA screws.

Kwaadu 2015[112]	**Methodology** Retrospective observation **Follow-up** 35 months	**Participants** Total n= 31 **Setting** Trauma hospital, Philadelphia, Pennsylvania, USA **Inclusion Criteria** Acute syndesmotic injury with or without ankle fracture stabilised with metal screw (not otherwise characterised)	**Intervention** Syndesmotic injury stabilised with tri or quadricortical metal screw (not otherwise characterised) in lagged mode with planned retention	AOFAS Stiffness Hardware removal Delayed union Lucency OA	AOFAS mean (SD) = 88.4 (13) Stiffness (%) = 0/31 (0%) Hardware removal (%) = 2/31 (6.5%) Delayed union (%) = 1/31 (3.2%) Lucency (%) = 1/31 (3.2%) OA (%) = 1/31 (3.2%)	Study examining lagged syndesmotic fixation. Good outcomes and low complication rate.
Miller 2002[113]	**Methodology** Retrospective observation **Follow-up** 15 months	**Participants** Total n= 4 **Setting** Trauma hospital, Baltimore, Maryland, USA **Inclusion Criteria** Ankle fracture with acute syndesmotic injury stabilised with a bioabsorbable screw	**Intervention** Syndesmotic injury stabilised with 1 or 2 5mm tricortical PGA/PLA co-polymer screw	Osteolysis Irritation	Osteolysis (%) = 0/4 (0%) Irritation (%) = 2/4	Small study (n=4) examining complications associated with bioabsorbable screws. No osteolysis, 2 prominent screw heads.

Naqvi & Shafqat 2012[114]	**Methodology** Retrospective observation **Follow-up** 6 months	**Participants** Total n= 49 **Setting** Trauma hospital, Drogheda, Ireland **Inclusion Criteria** Acute syndesmotic injury with or without ankle fracture, stabilised with a TightRope	**Intervention** Syndesmotic injury stabilised with 1 or 2 TightRopes	AOFAS FADI Removal MCS TFO TFC Time to full weight bearing	AOFAS mean (SD) = 85.57 (16.71) – 95%CI 77.96-93.16 FADI mean (SD) = 81.20 (16.11) – 95%CI 73.86-88.53 Removal (%) = 3/49 (6.1%) MCS mean mm (SD) = 3.33 (0.63) TFO mean mm (SD) = 8.88 (1.60) TFC mean mm (SD) = 4.37 (0.67) Time to full weight bearing weeks mean (SD) = 7.76 (1.16)	Study of 49 TightRope patients. Good clinical and radiological results with low complication rate.

Peterson 2015[115]	**Methodology** Retrospective observation **Follow-up** 5 months	**Participants** Total n= 56 **Setting** Orthopaedic hospital, Bartlett, Illinois, USA **Inclusion Criteria** Acute syndesmotic injury with or without ankle fracture, stabilised with a ZipTight implant	**Intervention** Syndesmotic injury stabilised with 1 or 2 ZipTight implants	Infection Removal Osteolysis MCS TFO TFC	Infection (%) = 1/56 (1.8%) Removal (%) = 3/56 (5.4%) Osteolysis (%) = 0/56 (0%) MCS mean mm (SD) = 3.1 (0.7) TFO mean mm (SD) = 7.4 (2.6) TFC mean mm (SD) = 4.3 (1.4)	Study of radiological outcomes and complications assessing ZipTight implant. Good radiological results with low complication rate.
Qamar 2011[116]	**Methodology** Retrospective observation **Follow-up** 2 years	**Participants** Total n= 16 **Setting** Trauma hospital, Gomersall, UK **Inclusion Criteria** Ankle fracture with syndesmotic injury stabilised with a TightRope	**Intervention** Syndesmotic injury stabilised with 1 TightRope	AOFAS Superficial infection Implant removal Time to full weight bearing	AOFAS mean (range) = 86 (48-100) Superficial infection (%) = 2/16 (12.5%) Implant removal (%) = 1/16 (6.3%) Time to full weight bearing weeks mean (range) = 4.5 (4-6)	Study of TightRope fixation. Good clinical outcomes, low complication rate.

Rigby 2013[117]	**Methodology** Retrospective observation **Follow-up** 23.6 months	**Participants** Total n= 37 **Setting** Foot and ankle hospital, Sarasota, Florida, USA **Inclusion Criteria** Acute syndesmotic injury with or without ankle fracture, stabilised with a TightRope	**Intervention** Acute syndesmotic injury with or without ankle fracture, stabilised with 1 or 2 TightRopes	AOFAS MCS TFO TFC Prominent knot Removal Infection	AOFAS mean (range) = 97 (90-100) MCS mm mean (SD) = 3.0 (0.5) TFO mm mean (SD) = 7.4 (2.8) TFC mm mean (SD) = 4.2 (1.3) Prominent knot (%) = 7/37 (18.9%) Removal (%) = 4/37 (10.8%) Infection (%) = 3/37 (8.1%)	Study assessing outcomes of TightRope patients. Good clinical and radiological outcomes. Higher incidence of hardware complications.

Storey 2012[118]	**Methodology** Retrospective observation **Follow-up** 85 days	**Participants** Total n= 102 **Setting** Trauma hospital, Sheffield, UK **Inclusion Criteria** Ankle fracture with syndesmotic injury stabilised with a TightRope	**Intervention** Ankle fracture with syndesmotic injury stabilised with one or two TightRopes	Implant removal Superficial Infection Osteomyelitis Osteolysis Migration Malposition VTE	Implant removal (%) = 8/102 (7.8%) Superficial Infection (%) = 3/102 (2.9%) Osteomyelitis (%) = 3/102 (2.9%) Osteolysis (%) = 2/102 (1.9%) Migration (%) = 3/102 (2.9%) Malposition (%) = 3/102 (2.9%) VTE (%) = 4/102 (3.9%)	Study of TightRope complications. Low rate of problems. Modified technique for suture burial also described.
van den Bekerom 2013[119]	**Methodology** Retrospective observation **Follow-up** 3.4 years	**Participants** Total n= 236 **Setting** Trauma hospital, Amsterdam, The Netherlands **Inclusion Criteria** Ankle fracture with syndesmotic injury stabilised with metal screws	**Intervention** Ankle fracture with syndesmotic injury stabilised with 1 or 2, 3.5 or 4.5mm, 3 or 4 cortical metal screws with planned removal at 6-12 weeks	Implant breakage Recurrent diastasis Loosening Synostosis	Implant breakage (%) = 4/236 (1.7%) Recurrent diastasis (%) = 1/236 (0.4%) Loosening (%) = 0/236 (0%) Synostosis (%) = 11/236 (4.7%)	Study of complications with metal screw fixation. Low overall rate.

van Vlijmen 2015[120]	**Methodology** Retrospective observation **Follow-up** 5 years	**Participants** Total n= 43 **Setting** Trauma hospital, Bedford Park, South Australia, Australia **Inclusion Criteria** Ankle fracture with syndesmotic injury stabilised with metal screws	**Intervention** Ankle fracture with syndesmotic injury stabilised with 1 or 2, 3.5 or 4.5mm, 3 or 4 cortical metal screws with planned removal at 2 or 3 months	Loss of dorsiflexion/plantarflexion compared to uninjured side Loss of inversion/eversion compared to uninjured side Broken screw Decreased TFO OA Calf diameter loss compared to uninjured side Ankle diameter difference compared to uninjured side	Loss of dorsiflexion/plantarflexion degrees mean (SD) = 3.3 (16.8) Loss of inversion/eversion = 6.4 (16.8) Broken screw (%) = 2/43 (4.7%) Decreased TFO (%) = 22/43 (51.2%) OA (%) = 11/43 (35.6%) Calf diameter loss cm mean (SD) = 0.0 (1.79) Ankle diameter difference cm mean (SD) = 1.0 (0.98)	Study assessing outcomes of patients treated with metal screws. High incidence of OA noted.

Walker 2015[121]	**Methodology** Retrospective observation **Follow-up** Not stated	**Participants** Total n= 36 **Setting** Trauma hospital, Wellington, New Zealand **Inclusion Criteria** Weber C ankle fracture with syndesmotic injury stabilised with metal screws	**Intervention** Syndesmotic stabilisation with 1 or 2, 3.5 or 4.5mm, 3 or 4 cortical metal screws with optional removal	Implant breakage Removal Loosening Recurrent diastasis Infection Stiffness	Implant breakage (%) = 9/36 (25%) Removal (%) = 30/36 (83.3%) Loosening (%) = 8/36 (22.2%) Recurrent diastasis (%) = 1/36 (2.8%) Infection (%) = 2/36 (5.6%) Stiffness (%) = 1/36 (2.8%)	Study assessing complications following metal screw syndesmosis stabilisation.
Willmott 2009[122]	**Methodology** Retrospective observation **Follow-up** 5.3 months	**Participants** Total n= 6 **Setting** Trauma hospital, Kent, UK **Inclusion Criteria** Syndesmotic injury with or without ankle fracture, stabilised with TightRope	**Intervention** Syndesmotic stabilisation with 1 or 2 TightRopes	Removal/ Irritation MCS TFO TFC Time to full weight bearing	Removal/Irritation (%) = 2/6 (33.3%) MCS mm mean (SD) = 2.6 (0.9) TFO mm mean (SD) = 3.6 (1.68) TFC mm mean (SD) = 3.8 (0.97) Time to full weight bearing weeks mean (range) = 6 (4-8)	Small series (n=6) of syndesmotic stabilisation with TightRope.

Jordan 2011[123]	**Methodology** Retrospective observation **Follow-up** Not specified, minimum 16 weeks	**Participants** Total n= 86 **Setting** Trauma hospital, San Francisco, California, USA **Inclusion Criteria** Ankle fracture with acute syndesmotic injury treated with 1, 2 or 3 4.5mm 4 cortex metal screws	**Intervention** Screw removal at 11-16 weeks post operatively	MCS pre-removal TFO pre-removal TFC pre-removal	MCS mm mean (SD) = 2.990 (0.6140) TFO mm mean (SD) = 5.830 (2.5403) TFC mm mean (SD) = 4.725 (1.5769)	Study of metal screw removal comparing radiological parameters before and after removal

Pakarinen 2011[124]	**Methodology** RCT **Randomisation** Randomisation list with randomly changing block sizes of 4 and 6 with sealed envelopes **Follow-up** 12 months	**Participants** Total n= 24 Intervention n=13 Comparator n=11 **Setting** Trauma hospital, Oulu, Finland **Inclusion Criteria** Lauge-Hansen SER ankle fracture with acute syndesmotic injury	**Intervention** Syndesmotic stabilisation with 1 3.5mm tricortical metal screw with planned retention **Comparator** No syndesmotic stabilisation (results not included in analysis – not part of review question)	OMAS Rand-36 (physical function) Rand-36 (pain) VAS (pain) ROM Dorsiflexion ROM Plantarflexion MCS TFC VAS (function)	OMAS mean (SD) = 79.6 (15.5) Rand-36 (physical function) mean (SD) = 0.9 (0.2) Rand-36 (pain) mean (SD) = 0.9 (0.4) VAS (pain) mean (SD) = 2.55 (2.54) ROM Dorsiflexion degrees mean (SD) = 22 (5.8) ROM Plantarflexion degrees mean (SD) = 41 (8.0) MCS mean mm = 3.5 TFC mean mm = 5.4 VAS (function) mean (SD) = 2.26 (2.46)	RCT comparing syndesmotic stabilisation with metal screws to no stabilisation. No stabilisation group excluded from analysis, therefore this RCT is analysed as a single group descriptive study.

3.3 Methodological quality

Included studies scored between 4 and 10 on the critical appraisal question. Tables 3.4-3.6 include scores, divided by study design. Of note, the newest RCT (Laflamme)[125] was the only paper to score full points. Many of the RCTs lost points on blinding. The nature of orthopaedic research for example has the surgeon aware of the technique being used and also has the review of XR imaging aware of which implant has been used.

Some initial differences were found between the primary and secondary reviewer, but both reviewers agreed upon the papers included in final analysis and were able to achieve a consensus, thus a third reviewer was not required.

Table 3.4 – Critical appraisal scores for included RCTs and Quasi-experimental studies – Questions in appendix 3. Y = Yes, N = No, N/A = Not applicable, U = Unknown

RCT	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Total
Coetzee 2009[74]	U	N	U	N	U	Y	Y	Y	Y	Y	5
Hoiness 2004[75]	Y	N	Y	Y	N	Y	Y	Y	Y	Y	8
Kaukonen 2005[76]	Y	Y	Y	N	N	Y	Y	Y	Y	Y	8
Khan 2008[77]	Y	Y	U	N/A	N	Y	Y	Y	Y	Y	7
Kortekangas 2015[78]	Y	N	Y	Y	N	Y	Y	Y	Y	Y	8
Sun 2014[80]	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	9
Thordarson 2001[81]	Y	Y	U	N	N	Y	Y	Y	Y	Y	7
Wikeroy 2010[82]	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	9
Laflamme 2015[79]	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	10
Quasi-experimental	**Q1**	**Q2**	**Q3**	**Q4**	**Q5**	**Q6**	**Q7**	**Q8**	**Q9**	**Q10**	**Total**
Moore 2006[83]	N	Y	N	N	U	Y	Y	Y	Y	Y	6

Table 3.5 – Critical appraisal scores for included cohort studies – Questions in appendix 3. Y = Yes, N = No, N/A = Not applicable, U = Unknown

Cohort Study	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Total
Bell 2006[84]	Y	Y	Y	Y	Y	Y	Y	Y	Y	9
Cottom 2009[85]	Y	Y	Y	N	Y	Y	N	Y	Y	7
Hsu 2011[86]	Y	Y	Y	N	Y	Y	N	Y	Y	7
Naqvi & Cunningham 2012 [46]	Y	Y	Y	Y	Y	Y	N	Y	Y	8
Thornes 2005[87]	Y	Y	Y	N	Y	Y	N	Y	Y	7
Kim 2016[88]	Y	Y	Y	N	Y	Y	N	Y	Y	7
Kocadal 2016[89]	Y	Y	Y	N	Y	Y	N	Y	Y	7
Kaftandziev 2015[90]	Y	Y	Y	Y	Y	Y	N	Y	Y	8
Karapinar 2007[91]	Y	Y	Y	N	Y	Y	N	Y	Y	7
Kukreti 2005[92]	Y	Y	Y	N	Y	Y	Y	Y	Y	8
Maempel 2014[93]	Y	Y	Y	N	N	Y	N	N	Y	5
Manjoo 2010[94]	Y	Y	Y	Y	Y	Y	N	Y	Y	8
Schepers 2014[95]	Y	Y	Y	Y	Y	Y	Y	Y	Y	9
Seyhan 2015[96]	Y	Y	Y	Y	Y	Y	Y	Y	Y	9
Sinisaari 2002[97]	Y	Y	Y	Y	Y	Y	N	Y	Y	8
Stuart 2011[98]	Y	Y	Y	Y	Y	Y	N	Y	Y	8
Tucker 2013[99]	Y	Y	Y	Y	Y	Y	N	Y	Y	8
Hamid 2009[100]	Y	Y	Y	Y	Y	Y	N	Y	Y	8
Weening 2005[101]	Y	Y	Y	Y	Y	Y	N	Y	Y	8

Table 3.6 – Critical appraisal scores for included descriptive studies – Questions in appendix 3. Y = Yes, N = No, N/A = Not applicable, U = Unknown

Descriptive Study	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Total
Kennedy 2000[62]	N	Y	Y	Y	N/A	Y	N	Y	Y	6
Ahmad 2009[102]	N	Y	Y	Y	N/A	Y	N	Y	Y	6
Anand 2017[103]	N	Y	Y	Y	N/A	Y	N	Y	Y	6
Bondi 2016[104]	N	Y	Y	Y	N/A	Y	N	Y	Y	6
Cottom 2008[105]	N	Y	N	Y	N/A	Y	N/A	Y	Y	5
DeGroot 2011[106]	N	Y	Y	Y	N/A	Y	N	Y	Y	6
Gennis 2015[107]	N	Y	Y	Y	N/A	Y	Y	Y	Y	7
Hovis 2002[108]	N	Y	Y	Y	Y	Y	Y	Y	Y	8
Jones 2015[109]	N	Y	Y	Y	N/A	Y	N	Y	Y	6
Kaye 1989[110]	N	Y	N	Y	N/A	Y	N	Y	Y	5
Korkala 1999[111]	N	Y	Y	Y	N/A	Y	Y	Y	Y	7
Kwaadu 2015[112]	N	Y	N	Y	N/A	Y	N	N	Y	4
Miller 2002[113]	N	Y	N	Y	N/A	Y	N	Y	Y	5
Naqvi & Shafqat 2012[114]	N	Y	Y	Y	N/A	Y	N	Y	Y	6
Peterson 2015[115]	N	Y	Y	Y	N/A	Y	N	Y	Y	6
Qamar 2011[116]	N	Y	Y	Y	N/A	Y	N	Y	Y	6
Rigby 2013[117]	N	Y	Y	Y	N/A	Y	N	Y	Y	6
Storey 2012[118]	Y	Y	Y	Y	Y	Y	N	Y	Y	8
van den Bekerom 2013[119]	Y	Y	Y	Y	Y	Y	N	Y	Y	8
van Vlijmen 2015[120]	Y	Y	Y	Y	Y	U	N	Y	Y	7
Walker 2015[121]	Y	Y	N	Y	N/A	Y	N	Y	Y	6
Willmott 2009[122]	N	Y	Y	Y	Y	Y	N	Y	Y	7
Jordan 2011[123]	N	Y	N	Y	N/A	Y	N	Y	Y	5
Pakarinen 2011[124]	Y	Y	Y	Y	Y	Y	N	Y	Y	8

3.4 Results

Results below are presented structured as intervention, comparator then outcomes separated by study design. Where meta-analysis was possible results are presented first, followed by the other RCT results and finally results from other study designs. When results are given in the body of the text, the intervention group is presented first followed by the control group. All results are means or proportions. Variance figures are given where available; a single number in parenthesis represents an SD and where two figures are given this represents range. Wherever available, p values and 95% CIs are given.

3.4.1 Metal Screws

3.4.1.1 METAL SCREWS COMPARED TO METAL SCREWS

3.4.1.1.1 DESCRIPTION OF INCLUDED STUDIES

3.4.1.1.1.1 DESCRIPTION OF RCTs AND QUASI-EXPERIMENTAL STUDIES

Three RCTs compared metal screws to other metal screws. Meta-analysis was not possible for the RCTs comparing metal screws. The study by Wikeroy[82] is the long-term follow up (8 years) of Hoiness' study[75] (3 and 12 months). Both compared 1 4.5mm 4 cortex screw which was removed to 2 3.5mm 3 cortex screws which were retained. The patients had various ankle fractures with syndesmotic injury. The remaining study by Khan[77] compared a single 4 cortex 3.5mm to a single 4 cortex 4.5mm screw both of which were removed with follow-up at 12 months. These patients all had Weber C ankle fractures with syndesmotic injury. The studies were deemed too different to warrant meta-analysis.

Moore[83] performed a 'surgeon randomised' quasi-experimental study comparing syndesmotic fixation utilising 1 or 2 3.5mm retained screws engaging either 3 or 4 cortices with planned screw retention. There was no further elaboration as to the randomisation method given. All patients had Weber C ankle fractures with a mean follow-up of 5 months.

3.4.1.1.1.2 DESCRIPTION OF COHORT STUDIES

General

Schepers[95] performed a detailed retrospective analysis of 93 consecutive ankle fractures with syndesmotic injury treated with metal screws over a 7 year period with 51 month follow-up. They reported overall outcomes for the entire group and performed subgroup analysis assessing screw location, number of screws, number of cortices, screw size and timing of removal or retention. Stuart[98] performed a similar study with 137 consecutive patients over 4 years with 12 month follow-up. Their subgroups assessed screw location, diameter and number of cortices.

Weening[101] assessed a cohort of 39 patients fixed with various metal screws with 18.1 month follow-up and also performed a comparison of patients with reduced vs not reduced syndesmoses.

Screw removal vs screw retention

Bell[84] performed a retrospective analysis of screw retention vs screw removal. All patients had Weber C ankle fracture with acute syndesmotic injury treated with a single unspecified size 3 cortex metal screw. The intervention group had the screw removed at 6-12 weeks.

Hsu[86] compared three groups after syndesmotic fixation with a single 3.5mm 3 cortex screw; screw removal at 6 weeks, screw retention with removal or breakage at 6-12 weeks and screw removal or breakage after 3 months.

Kaftandziev[90] compared 3 groups of patients treated with 1 or 2 3.5mm 3 or 4 cortex metal screws; those with intact screws, those with planned screw removal between 8 and 12 weeks and those with a broken screw. Manjoo[94] compared the same 3 groups; intact screws, removed screws (at average 9 months, range 4-21 months) and broken or loose screws with 23 months follow-up. They also performed subgroup analysis comparing 3.5mm to 4.5mm screws and tricortical to quadricortical fixation.

Tucker[99] assessed OMAS in patients with various metal screws comparing removal to screw retention with 31 month follow-up and mean screw removal at 12 weeks.

Hamid [100] reported the outcomes of 52 patients with metal screw syndesmotic stabilisation with 12 month follow-up and compared the results of patients with

broken screws, intact screws and removed screws (according to surgeon preference, at a mean of 9.7 weeks).

Tricortical vs quadricortical fixation

Karapinar[91] compared the outcomes of patients treated with 1 metal screw of unspecified size, removed at 5 months engaging either 3 or 4 cortices. They reported only pooled outcomes of OMAS and ROM but compared the incidence of synostosis of the syndesmosis between groups.

Suprasyndesmotic vs transsyndesmotic fixation

Kukreti [92] compared the outcomes of patients treated with a single 3.5mm 3 or 4 cortex screw either through the syndesmosis of above the syndesmosis and reported on ROM and radiological complications.

3.4.1.1.2 OUTCOMES

3.4.1.1.2.1 OUTCOME SCORES

3.4.1.1.2.1.1 RESULTS FROM RCTs

All RCTs reported on composite outcome scores. Hoiness[75] comparing 2, 3 cortex, 3.5mm, retained screws with 1, 4 cortices, 4.5mm, removed screws found a significant difference OMAS at 3 months of 77 (16.1) vs 66.3 (20.1) (95% CI 1.4-20.0); p=0.025. but no significant difference at 1 year - 88.8 (14.6) vs 83.3 (8.6) – (95% CI 2.8-13.8); p=0.19. Wikeroy[82] in the same patient group at 8.4 years found no significant difference between the groups in OMAS (82.3 (19.4) vs 82.8 (19.9) – p=0.9). They also included other outcome measures with no significant differences; OTA score (88.5 (11.6) vs 84.4 (13.3) – p=0.2) and SF-36 (104 (10.3) vs 102 (9.4) – p=0.41). Khan[77] comparing a single retained 4 cortex 3.5mm screw to a single 4 cortex 4.5mm screw found a non-significant difference in OMAS at 12 months of 84 vs 91 – p=0.805.

3.4.1.1.2.1.2 RESULTS FROM COHORT STUDIES

General

Karapinar[91] reported pooled results for OMAS in their metal screw group. Mean (range) OMAS was 83 (80-95). Overall AOFAS and OMAS for Schepers'[95] patients were 92 (14) and 77 (24). Hamid[100] reported the overall outcomes of their metal screw patients. Mean AOFAS was 85.2 (range 55-100). Weening[101] reported overall outcome measures for 39 patients with various metal screws. Mean SMFA emotional index (SD) was 16.5 (17.8), functional index 11.4 (10.6), bother index 13.5 (13.1) and OMAS 74.1 (23.4).

Screw removal vs screw retention

Bell[84] reported Baird and Jackson score at final follow-up. There was no significant difference – 88 (5.5) vs 86 (7.46) – p=0.79.

Hsu[86] reported the proportion of patients with a Bray score of more than 75. There were no significant differences between screw removal at 6 weeks vs removal or breakage at 6-12 weeks vs removal or breakage beyond 3 months (16/19 (84.2%) versus 16/20 (80%) vs 11/13 (84.6%) – p=0.191).

Kaftandziev[90] found a higher mean AOFAS (SD) in those patients with broken screws (92.5 (6.05)) as compared to patients with intact screws (83.0 (12.2)) and patients post screw removal at 8-12 weeks (85.5 (11.6)); p=0.0496. Manjoo[94] found worse mean LEM (SD) scores and mean OMAS (SD) in patients with intact screws (70.3 (6.3) and 46.5 (7.9)) as compared to broken/loose screws (83.3 (3.0) and 62.2 (4.9)) and removed screws (88.1 (4.8) and 66.8 (6.7)); p= 0.01 and 0.04. There was no significant difference between broken/loose and surgically removed screws (LEM p=0.66, OMAS p=0.24, MCS=0.54, TFC p=0.12, TFO p=0.34).

Schepers[95] performed subgroup analysis in their overall patient cohort comparing screws removed before 8 weeks, after 8 weeks and retained screws. Mean (SD) AOFAS scores were not significantly different (94 (4.6) vs 90 (17) vs 92 (10); p=n.s.), nor were OMAS scores (82 (20) vs 73 (27) vs 73 (20); p=n.s.).

Tucker[99] studied patients with various metal screws and compared. There was no significant difference in OMAS (75 (12.9) vs 81.5 (19.3); p=0.251)

Hamid[100] reported AFOAS comparing patients with intact, broken and removed screws. Mean AOFAS (SD) was highest in the broken screw group; 83.07 (13.59) vs 92.4 (12.69) VS 85.8 (11.33) P=0.0466. Patients with lucency around their screw had no difference in AOFAS (p=0.639)

Weening's[101] patients had no significant difference between removed and retained screws.

Tricortical vs quadricortical fixation

Manjoo's[94] study of screw removal performed subgroup analysis and found no significant difference in outcome scores between tricortical and quadricortical screws. Weening's[101] patients had no significant difference between three and four cortical fixation and Hamid[100] reported no difference in AOFAS in patients with 3 or 4 cortical fixation.

Schepers[95] performed subgroup analysis in his overall patient cohort comparing tricortical screws to quadricortical screws. Mean (SD) AOFAS scores were not significantly different (91 (14) vs 92 (12); p=n.s.), nor were OMAS scores (77 (24) vs 74 (26); p=n.s.).

Screw diameter

Manjoo's[94] study of screw removal performed subgroup analysis and found no significant difference between 3.5mm and 4.5mm screws (LEM p=0.5, OMAS p=0.33)

Schepers[95] found no difference comparing 3.5 to 4.5mm screws in either mean AOFAS (SD) or mean OMAS (SD) (92 (14) vs 91 (10); p=n.s. and 76 (26) vs 80 (21); p=n.s.).

One vs two screws

Schepers[95] compared fixation with 1 or two screws. There was no difference in mean AOFAS (SD) ((91(14) vs 93 (11); p=n.s.) although there was a significant difference in OMAS (75 (25) vs 85 (16); p=0.043).

Suprasyndesmotic vs transsyndesmotic fixation

Schepers[95] compared fixation levels dividing them as transsyndesmotic (0-20.99mm above the ankle joint or 21-40.99mm above the ankle joint) or suprasyndesmotic (41-60mm above the ankle joint). There was no difference in mean AOFAS (SD) (93 (10) vs 92 (14) vs 88 (15); p=n.s.) or OMAS (74 (24) vs 81 (23) vs 71 (26); p=n.s.).

3.4.1.1.2.2 PAIN

3.4.1.1.2.2.1 RESULTS FROM RCTs

Wikeroy[82] reported on VAS at 8 years. There was no significant difference in pain comparing 2, 3 cortical, 3.5mm, retained screws with 1, 4 cortices, 4.5mm, removed screws (4.9 (6.7) vs 4.5 (7.2) – p=0.8).

3.4.1.1.2.2.2 RESULTS FROM COHORT STUDIES

General

Schepers'[95] reported VAS in an inverse fashion compared to other studies with a score of 10 on their study being a perfect outcome. For the purposes of consistent reporting of results, the VAS have been inverted to match the other studies. Overall the patients had a VAS of 1.8 (1.5).

Hamid[100] reported the overall outcomes of their metal screw patients. Mean VAS was 1.6 (range 0-8.4).

Overall mean VAS (SD) in Weening's[101] cohort of various metal screws was 3.4 (3.8).

Screw removal vs screw retention

Bell[84] reported 11/23 (47.8%) of patients with removed screws had a VAS of 0 at final follow-up with 2/7 (28.6%) of patients in the retained screw group with the same score (p=n.s.)

Kaftandziev[90] noted no differences in mean VAS (SD) comparing intact screws (1.57 (1.2)), removed screws (1.22 (1.0)) and broken screws (1.08) (1.1); p=0.34.

Schepers [95] found no difference in VAS between screw removed early (before 8 weeks), late (after 8 weeks) or retained screws. (1.6 (1.4) vs 1.9 (1.6) vs 1.8 (1.7); p=n.s.).

Hamid[100] compared VAS (SD) in patients with intact screws, broken screws and removed screws. There was no significant difference (2.31 (2.76) vs 0.96 (2.31) vs 0.74 (0.97); p=0.215). Patients with lucency around their screw had no difference in VAS (p=0.537).

Tricortical vs quadricortical fixation

Schepers [95] found no difference in VAS between tricortical and quadricortical screws (1.7 (1.5) vs 2.1 (1.4); p=n.s.)

Screw diameter

Schepers [95] found no difference in VAS between 3.5mm and 4.5mm screws (1.8 (1.5) vs 1.4 (1.6); p=n.s.)

One vs two screws

Schepers [95] compared use of one screw to two screws and found no difference in VAS (1.9 (1.5) vs 1.4 (1.6); p=n.s.)

Suprasyndesmotic vs transsyndesmotic fixation

Schepers[95] compared fixation levels dividing them as transsyndesmotic (0-20.99mm above the ankle joint or 21-40.99mm above the ankle joint) or suprasyndesmotic (41-60mm above the ankle joint). VAS was 1.7 (1.3), 1.5 (1.5) and 2.5 (1.6) in the groups respectively with a statistically higher VAS in the suprasyndesmotic group; p=0.024.

3.4.1.1.2.3 ROM

3.4.1.1.2.3.1 RESULTS FROM RCTs

Hoiness[75] and Wikeroy[82] reported results for dorsiflexion of the same patient group at 3 months,12 months and 8 years comparing 2 3 cortex, 3.5mm, retained screws with 1, 4 cortex, 4.5mm, removed screws. They found no significant differences at 3 months 33.8° (6.8) vs 35.5° (7.9) – p=0.493 and 12 months 28° (7.9) vs 29.2° (8.7) p=0.296, but noted a small difference of 7.6° at 8 years 26.7° (9.7) vs 34.3° (14.9) –

p=0.03.

3.4.1.1.2.3.2 RESULTS FROM COHORT STUDIES

Screw removal vs screw retention

Bell[84] presented ROM figures as deficit compared to the uninjured ankle. There were no significant differences between the groups. Flexion/extension deficit was 11.5° (5.08) vs 12.1° (6.2) – p=n.s. Inversion/eversion deficit was 10.4° (3.67) vs 10.0° (6.45) – p=n.s.

Tricortical vs quadricortical fixation

Karapinar[91] reported pooled results for ROM in their metal screw group. Mean dorsiflexion (range) was 19° (10-40) and plantarflexion 37° (20-55).

Suprasyndesmotic vs transsyndesmotic fixation

Kukreti[92] found no difference in ROM when comparing fixation through or above the syndesmosis. They reported the proportion of patients with full ROM compared to the opposite side (6/19 (31.6%) vs 4/17(23.5%)); p=n.s.

3.4.1.1.2.4 COMPLICATIONS

3.4.1.1.2.4.1 RESULTS FROM RCTs AND QUASI-EXPERIMENTAL STUDIES

Hoiness[75] reported broadly on complications when comparing 3 cortex, 3.5mm, retained screws with 1, 4 cortices, 4.5mm, removed screws. They found a complication rate of 50% (17/34) vs 63.3% (19/30). In the first group; 1 loss of position, 1 deep infection, 1 malreduction, 1 screw too long, 1 foot drop, 4 OA, 3 broken screws, 2 removed screws, 2 removal of all metal. In the second; 5 loss of reduction, 3 deep infections, 1 malreduction, 2 superficial infections, 5 OA, 3 all metal removed. While not further analysed statistically there is a significant difference in infection rate – 0 vs 5.

Khan[77] comparing a single retained 4 cortex 4.5mm screw to a 4 cortex 3.5mm screw reported only on screw breakage as a complication with one occurrence in the

4.5mm group (0/9, 0%) and none in the 3.5mm group (1/8, 12.5%).

Moore[83] compared tricortical to quadricortical fixation using 3.5mm screws with planned retention. There was no significant difference in the rate of screw breakage (5/59 (8.5%) vs 4/61 (6.6%); p=0.689), need for screw removal (4/59 (6.8%) vs 4/61 (6.6%); p=0.731) or infection (2/59 (3.4%) vs 0/61 (0%); p=n.s.).

3.4.1.1.2.4.2 RESULTS FROM COHORT STUDIES

General

Schepers[95] reported overall complications in metal screw patients and noted a wound complication rate of 6/93 (6.5%) and one case of CRPS (1.1%). Stuart[98] noted an overall implant breakage rate of 14/137 (10.2%).

Weening[101] found an overall rate of metal screw breakage of 3/39 (7.6%)

Screw removal vs screw retention

Bell[84] noted a similar infection rate (1/23 (4.3%) vs 1/7 (14.2%) p =n.s.). The broken screw rate was significantly higher as expected in patients with retained screws (0/23 (0%) vs 2/7 (28.6%) – p=0.025).

Hsu[86] compared timing of screw removal and noted a statistically significant higher incidence of screw breakage with screws removed later (0/19 (0%) at 6 weeks vs 3/20 (15%) at 6 weeks to 12 weeks vs 2/13 (15.4%) beyond 12 weeks; p=0.034)

Tricortical vs quadricortical fixation

Stuart[98] compared the incidence of screw breakage between tricortical and quadricortical fixation. They found a higher incidence of screw breakage in the tricortical group (14/120 (11.7%) vs 0/17 (0%)) but it was not statistically significant; p=0.2159.

Hamid[100] noted no difference in screw breakage comparing tricortical to quadricortical fixation.

Screw diameter

Stuart[98] compared 3.5mm, 4.0mm and 4.5mm screws. The rate of screw breakage

was significantly higher in the smaller screw groups (8/62 (12.9%) vs 6/63 (9.5%) vs 0/12 (0%)); p=0.0489.

Suprasyndesmotic vs transsyndesmotic fixation

Stuart[98] noted no difference in screw breakage rates between suprasyndesmotic and transsyndesmotic screws (2/19 (10.5%) vs 12/118 (10.2%)); p=1.

3.4.1.1.2.5 RADIOLOGICAL OUTCOMES

3.4.1.1.2.5.1 RESULTS FROM RCTs AND QUASI-EXPERIMENTAL STUDIES

Wikeroy[82] reported on long-term XR outcomes comparing 3 cortex, 3.5mm, retained screws with 1, 4 cortices, 4.5mm, removed screws. They found a significant difference in articular height 2.8 vs 3.3 – p=0.02 at 8 years with better cartilage preservation in the first group and CT measured syndesmotic width of 3.2mm vs 4.3mm p=0.025 suggesting better reduction.

Moore[83] compared the incidence of loss of reduction and lucency in tricortical and quadricortical small fragment screws with planned retention. There was no significant difference in the rate of loss of reduction (3/59 (5.1%) vs 0/61 (0%); p=0.871) or lucency (31/59 (52.5%) vs 36/61 (59.0%); p=n.s.) between the two groups although the rate does seem rather high.

3.4.1.1.2.5.2 RESULTS FROM COHORT STUDIES

General

Hamid[100] reported the overall outcomes of their metal screw patients. Mean TFC was 4.1mm (range 3.2-5.5).

Weening[101] found an overall rate of metal screw loosening of 2/39 (5.1%)

Screw removal vs screw retention

Bell[84] had no radiological instability in either group. Hsu[86] noted a trend towards

recurrent diastasis with earlier screw removal (3/19 (15.8%) removed at 6 weeks vs 3/20 (15%) removed/broken at 6-12 weeks vs 0/13 (0%) removed/broken after 3 months) but it did not reach statistical significance (p=0.054).

None of Kaftandziev's[90] patient groups had secondary shift (intact screw, removed screw, broken screw).

Manjoo[94] performed radiological analysis of patients with intact screws, loose or broken screws and removed screws. The mean TFC (SD) was significantly lower in patients with intact screws (3.2mm (0.2) vs 4.1mm (0.2) vs 4.1mm (0.3); p=0.005. Mean MCS (SD) (3.1mm (0.2) vs 3.1mm (0.1) vs 3.1mm (0.2); p=0.9) and mean TFO (SD) (7.1 (0.3) vs 6.7 (0.4) vs 7.3 (0.6); p=0.69) were similar.

Hamid[100] reported the incidence of lucency in patients with retained 3.5mm screws, the rate was 25/37 (67.6%).

Tricortical vs quadricortical fixation

Karapinar[91] examined the proportion of patients developing synostosis either evident on XR, or not evident on plain film seen only on MRI. Tricortical fixation had a significantly lower incidence of both gross synostosis evident on XR (0/22 (0%) vs 3/24(12.5%)) and synostosis seen only on MRI (2/22 (9.1%) vs 8/24 (33.3%)) as compared to quadricortical fixation; p<0.005.

Manjoo's[94] study of screw removal performed subgroup analysis and found no significant difference between tricortical and quadricortical screws although loosening was slightly more likely with tricortical screws but not statistically significant (OR 1.3; 95% CI 0.4-3.50).

Stuart[98] compared tricortical and quadricortical fixation. There was no significant difference in screw loosening (10/110 (9.1%) vs 3/17 (17.6%); p=0.369). There was a trend towards a higher rate of loss of reduction with tricortical fixation but it did not reach statistical significance (5/120 (4.2%) vs 3/17 (17.6%); p=0.06).

Screw diameter

Manjoo's[94] study of screw removal performed subgroup analysis and found no significant difference between 3.5mm and 4.5mm screws (MCS p=0.4, TFO p=0.18, TFC 0.47). Relative risk of screw breakage was higher comparing 3.5mm to 4.5mm screws but was not statistically significant - 2.5 (95% CI 0.4-9.9). The same was

noted for loosening (RR=3.0 (95% CI 0.7-9.0)).

Stuart[98] compared 3.5mm to 4.0mm to 4.5mm screws. The incidence of screw loosening was not significantly different (8/62 (12.9%) vs 5/63 (7.9%) vs 0/12 (0%); p=0.374), nor was the rate of loss of reduction (3/62 (4.8%) vs 5/63 (7.9%) vs 0/12 (0%); p=0.653)

Suprasyndesmotic vs transsyndesmotic fixation

Kukreti[92] found no difference in syndesmotic synostosis (5/19 (26.3%) vs 8/17 (47.1%); p=0.34), talar displacement (3/19 (5.3%) vs 5/17 (29.4%); p=n.s.) or OA (4/19 (21.1%) vs 4/17 (23.5%) p=1.00) when comparing fixation through or above the syndesmosis.

Stuart[98] compared suprasyndesmotic to transsyndesmotic fixation and noted no difference in the rates of loss of reduction (1/19 (5.3%) vs 7/118 (5.9%); p=1) and a non-significant trend towards higher rate of loosening in the transsyndesmotic group (0/19 (0%) vs 13/118 (11%); p=0.214).

3.4.1.1.2.6 OTHER OUTCOMES

3.4.1.1.2.6.1 RESULTS FROM RCTs

There are no other outcomes to report from RCTs.

3.4.1.1.2.6.2 RESULTS FROM COHORT STUDIES

General

Schepers[95] performed multivariate regression analysis assessing factors influencing outcome. Trimalleolar fractures had poorer AOFAS (77 (23)), OMAS (60 (22)) and VAS (2.9 (1.2)) than either unimalleolar (95 (10); p=0.034, 83 (19); p=0.001, 1.4 (1.4); p=0.001) or bimalleolar fractures (92 (11); p=n.s., 73 (29); p=n.s., 19 (1.6); p=0.045). The beta for number of malleoli fractured on regression analysis is -7.6 for AOFAS (95% CI = -11.3 - -3.8), -7.6 for OMAS (95% CI = -1.0 - -0.5) and for VAS -0.5 (95% CI = -0.9 - -0.1). Age was also associated with a poorer outcome in all groups on regression analysis. Low energy trauma correlated with a better AOFAS as compared to high energy trauma (Beta 3.2, 95% CI = 0.7-5.7).

Weening[101] compared the outcomes of patients with reduced compared to not

reduced syndesmoses following stabilisation with metal screws. There was no difference in OMAS or SMFA bother and emotional indices (p>0.05) but there was a better (lower) mean score for reduced patients compared to not-reduced on the SMFA functional index (SD) (17.0 (4.4) vs 10.2 (5.9); p=0.04). Non-reduction was also significantly associated with a reduction in running ability (p = 0.05), accounting for 15% of the variance in the Olerud and Molander running subscale.

Screw removal vs screw retention

Bell[84] reported on return to full pre-injury employment. This was possible in 13/23 56.5%) of patients with removed screws and 4/7 (57.1%) of patients in the retained screw group (p=n.s.).

Kaftandziev[90] performed a separate analysis of the 39 of 59 patients with intact screws with radiolucency around their screws on XR. These patients had no difference in AOFAS or VAS compared to those patients without osteolysis.

Stuart[98] performed a power analysis to assess the number of patients needed in a study to see a statistically significant difference based on their observed rates of complications and a p value of 0.05. Screw location would require 59,390 patients, screw diameter between 3.5 and 4.0mm 1,656 patients, screw diameter between 3.5mm and 4.5mm screws 567 patients, screw diameter between 4.0mm and 4.5mm 345 patients and number of cortices 325 patients. These numbers are all higher than any single study included.

3.4.1.2 METAL SCREWS COMPARED TO TIGHTROPE

3.4.1.2.1 DESCRIPTION OF INCLUDED STUDIES

3.4.1.2.1.1 DESCRIPTION OF RCTs

Three RCTs[74,78,79] compared metal screws to TightRopes. While all reported a composite outcome score (OMAS or AOFAS), 2 of the 3 studies did not report standard deviations (Coetzee and Kortekangas).[74,78] It was decided not appropriate to calculate standard deviations from the p values provided given only 3 studies were included and 2 did not provide standard deviation data. ROM and VAS were also not amenable to meta-analysis for the same reason.

Kortekangas[78] compared TightRope fixation to 1 3 cortex 3.5mm retained metal

screw in patients with Weber C fractures and 2 year follow-up. Coetzee[74] compared two TightRopes to 2 4 cortex screws of various sizes (4, 4.5, 6.5mm) in compression mode which were retained; this was in patients with syndesmotic injury with or without fracture and 27 month follow-up. Laflamme[79] compared one TightRope to 1 4 cortex 3.5mm 4 cortex screw in patients with syndesmotic injury associated with ankle fracture and 12 months follow-up.

3.4.1.2.1.2 DESCRIPTION OF COHORT STUDIES

Cottom's 2009 study[85] was a retrospective study comparing tightrope fixation to some sort of metal screw fixation (specifics not given) with a 10 month follow-up.

Naqvi and Cunningham in 2012[46] retrospectively compared 1 or 2 TightRope fixation against 1 or 2, 3.5 or 4.5mm, 4 cortex metal screws with 3 month follow-up. An important conclusion of their study on regression analysis is that malreduced syndesmoses had poorer outcomes on AOFAS (OR -12.39 (95% CI = -22.7 - -2.09)).

Thornes[87] compared a TightRope style implant to metal screw fixation with 12 month follow-up. The suture-button group was observed prospectively and retrospectively compared to a matched control group of patients fixed with metal screws. The implant itself was made by the surgeon by passing a loop of #5 polyester suture through two Endobuttons (Smith & Nephew Inc., Andover, MA. USA) creating a device very similar to a TightRope.

Kim[88] compared a TightRope to 1 or 2 3.5mm 3 cortex metal screws for syndesmotic stabilisation with ankle fracture with one year follow-up.

Kocadal[89] compared a ZipTight to a 3.5mm 4 cortex metal screw. They reported ROM and incidence of hardware removal and hardware related complications with 16 month follow-up.

Maempel[93] analysed short term complications (12 weeks) comparing TightRope fixation to metal screw (not further characterised) fixation.

Seyhan[96] compared TightRope fixation to a 4.5mm 4 cortical metal screw with 12 month follow-up.

3.4.1.2.2 OUTCOMES

3.4.1.2.2.1 OUTCOME SCORES

3.4.1.2.2.1.1 RESULTS FROM RCTs

Laflamme[79] reported a small difference in OMAS (mean (SD) = 93.3 (9.3) vs 87.7 (12.2) – p=0.046) - p=0.046) but no significant difference in AOFAS(mean (SD) = 93.1 (8.3) vs 89.9 (12.7) – p=0.255). Coetzee[74] reported AOFAS at final follow-up and found no significant difference comparing TightRope fixation to metal screws (AOFAS mean (range) = 94 (82-100) vs 87 (80-100) - p=0.149). Similarly, Kortekangas[78] reported OMAS at 2 years with no significant difference (82 vs 84 – p=n.s.).

3.4.1.2.2.1.2 RESULTS FROM COHORT STUDIES

Cottom in 2009[85] reported a modified AOFAS score (out of 63). It did not include the sections on walking surfaces, sagittal motion, hindfoot motion, and ankle-hindfoot stability or the section evaluating alignment. They also reported a SF-12 score. Modified AOFAS was similar (50.64 (30-63) vs 53.5 (25-63)) between the two groups, as was SF-12 on physical and mental outcomes (47.02 vs 46.87 and 55.34 vs 54.69) respectively.

Naqvi and Cunningham in 2012[46] reported AOFAS and FADI scores. There were no significant differences between the groups (AOFAS mean (SD) = 89.6 (8.6) vs 86.5 (9.6) – (95% CI = 82.34-90.7); p=0.26. FADI mean (SD) = 82.4 (11.2) vs 81.2 (15.6) – (95% CI = 74.46-87.97); p=0.76). Thornes[87] noted a statistically significant better AOFAS score in the suture button fixation group (93 vs 83 – p=0.04).

Kim [88] reported AOFAS at 12 months and noted no significant difference between TightRopes (88.1; range 79-95) and metal screws (86.6; range 75-96); p=0.663. Kocadal [89] compared the ZipTight to metal screws and found no significant difference in AOFAS (mean (SD)) 88.4 (9.2) vs 86.1 (14); p=0.4.

Seyhan[96] compared 12 month AOFAS scores for TightRope fixation and metal screw fixation with a 4.5mm 4 cortex single screw removed at 3 months. There was no significant difference (93.7 (7.38) vs 93.4 (6.93); p=0.889).

3.4.1.2.2.2 PAIN

3.4.1.2.2.2.1 RESULTS FROM RCTs

Laflamme[79] reported no significant difference in VAS at final follow-up (VAS mean (Range) = 0.6 (0-3) vs 1.1 (0-5) – p=0.12), nor did Kortekangas[78] (VAS at 2 years mean = 1.2 vs 1.2 – p=0.57).

3.4.1.2.2.2.2 RESULTS FROM COHORT STUDIES

Kim [88] reported VAS and found no difference between TightRope (1.4; range 0-3) and metal screws (1.5; range 0-3), p=0.795.

3.4.1.2.2.3 ROM

3.4.1.2.2.3.1 RESULTS FROM RCTs

Laflamme[79] found no significant difference between groups in dorsiflexion (13.6° (4.5) vs 14.8° (7.6) – p=0.43) or plantarflexion (33.6° (7.3) vs 32° (9.8) – p=0.27). Kortekangas[78] reported an overall arc of motion (sum of dorsiflexion and plantarflexion) and found no significant difference between the groups (83° (10) vs 82° (9) – p=0.81). Coetzee[74] found a trend towards better ROM in the TightRope group (dorsiflexion 11° (4-20) vs 8° (2-20) – p=0.054, plantarflexion 53° (37-80) vs 43° (28-70) – p=0.054) but it did not reach statistical significance.

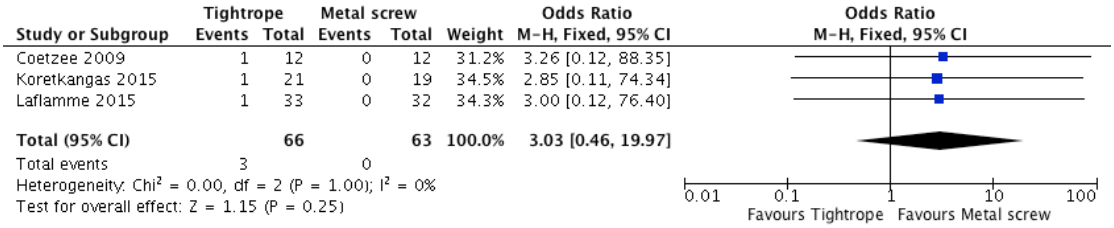
Seyhan[96] recorded the ROM deficit compared to the uninjured side at 12 months for TightRope fixation and metal screw fixation with a 4.5mm 4 cortex single screw removed at 3 months. There was statistically significant better ROM in the TightRope group. Dorsiflexion deficit was 1.4° (1.14) vs 3.65° (1.54); p=0.001 and plantarflexion deficit was 2.67° (1.49) vs 8.41° (2.63); – p=0.001.

3.4.1.2.2.4 COMPLICATIONS

3.4.1.2.2.4.1 RESULTS FROM RCTs

Meta-analysis was possible for the three RCTs for a subset of complications – infections.

Figure 3.2 – Meta-analysis of complications (infections) of RCTs comparing metal screws to TightRope fixation



The studies were homogeneous (I^2=0.00%, Chi^2 p=1). A trend towards lower infections in metal screws was noted (OR 3.03) but it did not reach statistical significance (95% CI 0.46-19.97, p=0.25).

Overall complication numbers were otherwise low. Coetzee[74] found a non-infection complication rate of 1/12 (8.3%) in the screw group (metal prominence requiring screw removal) and no other complications in the TightRope group. Kortekangas[78] reported 3 broken screws (3/19; 15.8%) in the screw group and no non-infection complications in the TightRope group. Laflamme[79] reported a implant irritation rate requiring removal of 1/33 (3%) in the TightRope group and 11/32 (34.4%) in the metal screw group; a significant difference.

3.4.1.2.2.4.2 RESULTS FROM COHORT STUDIES

Cottom's 2009 study[85] reported hardware removal due to loosening or breakage as a complication (5/25 (20%) and 7/25 (28%) respectively) in the metal screw group and no episodes in the TightRope group. There were no other complications reported in either group. Thornes[87] reported an implant removal rate of 0/16 (0%) with suture button fixation vs 12/16 (75%) in the metal screw group – p=0.001). Kim [88] noted a high implant failure rate for 3.5mm screws (5/24 (20.8%)) as compared to TightRopes (0/20). Kocadal [89] reported low incidence of complications in both ZipTight and metal screw groups. Symptomatic implants were removed in 1/26 (3.8%) ZipTight fixations and 10/26 (38.5%) metal screw fixations. The ZipTight group had 1 (3.8%) superficial infection and the metal screw group had 1 (3.8%) broken screw.

Maempel[93] found a higher overall incidence of complications in the metal screw group (1/12 (8.3%) vs 3/23 (12.9%)). There was one suture abscess in the TightRope group and 1 each of infection, wound dehiscence and recurrent diastasis in the metal screw group, all following screw removal.

Seyhan's[96] had moderate levels of prominent hardware necessitating removal in 6/15 (40%) TightRope patients and 4/17 (23.5%) 4.5mm screw patients. Although all metal patients were planned for screw removal, these 4 patients had significant irritations prior to removal. TightRopes were removed for soft tissue irritation.

3.4.1.2.2.5 RADIOLOGICAL OUTCOMES

3.4.1.2.2.5.1 RESULTS FROM RCTs

Kortekangas[78] reported a syndesmotic malreduction (>2mm) rate on CT of 1/21(4.8%) in the TightRope group versus 3/19 (15.8%) in the metal screw group but this did not reach statistical significance – p=0.33. They also reported a CT diagnosed incidence of OA of 13/21 (62%) in the TightRope group and 11/19 (57.9%) in the metal screw group. This is rather high in both groups but does not statistically differ between groups (p=0.9). Laflamme[79] found better radiological outcomes with the TightRope group – MCS (2.9mm (0.5) vs 3.1mm (0.6) – p=0.38), Loss of reduction of MCS 0.05mm (0.32) vs 0.41mm (0.37) **–** p=0.02, TFCS 3.9 (0.9) vs 4.8 (1.5) – p=0.008 and loss of reduction of TFCS 0.32mm (1.34) vs 1.34mm (1.36) – p=0.0005. All were statistically significant aside from MCS.

3.4.1.2.2.5.2 RESULTS FROM COHORT STUDIES

Cottom's 2009 study[85] found MCS was similar; 3.00mm (3-4) vs 3.08mm (2-4); p=0.7634, as was TFO (6.88mm (4-11) vs 7.96mm (4-11); p=0.1602). TFC was statistically better in the TightRope group (3.8mm (3-5) vs 2.76mm (4-8); p=0.0187).

Naqvi and Cunningham in 2012[46] found similar MCS (3.36mm (0.5) vs 3.23mm (0.6) – p=0.48) and TFO (8.21mm (2.0) vs 7.47mm (2.0) – p=0.22), but again TFC was statistically better in the TightRope group (4.04mm (0.8) vs 5.0mm (1.8) – p<0.05). The incidence of malreduction of >2mm as measured by CT was also significantly different; 0/23 vs 5/23 (21.7%) – p<0.05.

Kim [88] observed no statistical differences in XR indices when comparing a Tightrope to a 3.5mm 3 cortex metal screw. MCS (4.25mm (2.97-5.71) vs 4.32mm (1.98-6.57); p=0.858), TFC (5.15mm (2.93-7.30) vs 4.95mm (2.72-9.08); p=0.663) and TFO (7.21mm (2.15-10.30) vs 6.29mm (0-10.37); p=0.235) were all similar.

Kocadal [89] performed detailed bilateral ankle CT analysis of syndesmotic parameters comparing ZipTight implants to metal screws. They compared the normal side to the

post-operative side and reported fibular translation, fibular rotation, syndesmotic area (divided into upper, middle and lower) and syndesmotic volume. All are good markers for syndesmotic reduction and width.[126] Unfortunately, statistical analysis was limited to comparing the normal side to the operated side in each group and no formal comparison was performed for the post-operative sides between the two groups. Fibular translation (mean (SD)) was 1.2mm (1.2) vs 1.7mm (2.0). Fibular rotation (mean (SD)) was 14.4° (8.4) vs 10.9° (6.7). Syndesmotic areas (upper, middle and lower) were (mean (SD)) 88.9mm^2 (27.1) vs 99.0mm^2 (25.2), 79.0mm^2 (23.3) vs 86.2mm^2 (25.9) and 73.2mm^2 (18.2) vs 71.5mm^2 (22.5) respectively. Syndesmotic volume was 1589.2mm^3 (386.0) vs 1677.2mm^3 (406.6).

3.4.1.2.2.6 OTHER OUTCOMES

3.4.1.2.2.6.1 RESULTS FROM RCTs

There were no other outcomes to report on RCT.

3.4.1.2.2.6.2 RESULTS FROM COHORT STUDIES

Naqvi and Cunningham in 2012[46] reported on time to resumption of full weight bearing. There was a small difference between groups of 1 week in favour of TightRope fixation (8 weeks (1.2) vs 9.1 weeks (1.8)) but it was not statistically significant (p=0.11). Thornes[87] reported on time to return to work and noted a significantly shorter time for the suture button group (2.8 weeks vs 4.6 weeks – p=0.02).

3.4.1.3 METAL SCREWS COMPARED TO BIOABSORBABLE SCREWS

3.4.1.3.1 DESCRIPTION OF INCLUDED STUDIES

3.4.1.3.1.1 DESCRIPTION OF RCTs

Three RCTs[76,80,81] compared metal screws to bioabsorbable screws. Kaukonen[76] compared a 4.5mm PLA screw to a metal screw – 1 4 cortex, 4.5mm removed screw in patients with any ankle fracture and a syndesmotic injury with 35 month follow-up. Sun[80] compared a 4.5mm 3 cortex PLLA screw to a 3 cortex 4.5mm removed metal screw in patients with any ankle fracture with syndesmotic injury with 4 year follow-up. Thordarson[81] compared a 4 cortex 4.5mm PLA screw to a 4 cortex 4.5mm

removed metal screw with 11 month follow-up.

Only Sun[80] reported outcome measures. ROM was reported in all three studies but standard deviation data was only available for one. Again, it was decided not to proceed with meta-analysis based on calculated standard deviations given the small number of studies.

3.4.1.3.1.2 DESCRIPTION OF COHORT STUDIES

A single cohort study compared metal screws to bioabsorbable screws. Sinisaari[97] compared a 4.5mm PLLA screw to a 3.2mm metal screw with 12 month follow-up.

3.4.1.3.2 OUTCOMES

3.4.1.3.2.1 OUTCOME SCORES

3.4.1.3.2.1.1 RESULTS FROM RCTs

Sun[80] reported Baird and Jackson scores at final follow-up comparing a bioabsorbable screw to metal screw with scores favouring metal screws but not with statistical significance – 90 (70-100) vs 97 (80-100) p=0.095.

3.4.1.3.2.1.2 RESULTS FROM COHORT STUDIES

Sinisaari[97] reported OMAS comparing a PLLA screw to a 3.2mm 4 cortical metal screw. There was no significant difference (82 (25-100) vs 90 (70-100); p=0.93).

3.4.1.3.2.2 PAIN

None of the included studies reported pain as an outcome.

3.4.1.3.2.3 ROM

3.4.1.3.2.3.1 RESULTS FROM RCTs

All RCTs measured ROM. Sun[80] reported significantly better ROM in the bioabsorbable group; dorsiflexion 26° (23-28) vs 18° (15-24); p=0.011 and plantarflexion 40° (36-45) vs 35° (33-40); p<0.001. Kaukonen[76] reported similar values but not a significant difference between the groups; dorsiflexion 22.2° (10) vs 25.2 (13.4) – (95%CI -5.8-11.7);p=0.490 and plantarflexion 45.9° (8.4) vs 45.4° (6.4) (95% CI -6.0-5.0);p=0.854. Thordarson[81] with earlier follow-up (11 months vs 3-4

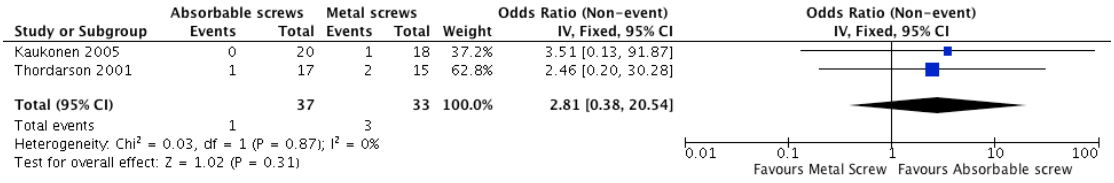
years in the other RCTs) found less dorsiflexion overall (10° vs 8°) with similar plantarflexion (38° vs 45°) and no significant difference between the bioabsorbable and metal screws.

3.4.1.3.2.4 COMPLICATIONS

3.4.1.3.2.4.1 RESULTS FROM RCTs

Analysis of complications was amenable to meta-analysis although only 2 studies reported complications. Inflammatory foreign body reaction as a complication was excluded from meta-analysis as this is a clinical problem unique to bioabsorbable screws, however a meta-analysis of infections was possible.

Figure 3.3 – Meta-analysis of complications (infections) of RCTs comparing metal screws to bioabsorbable screw



The studies were homogeneous (I^2=0.00%, Chi^2 p=0.87).. A trend towards lower infection in bioabsorbable screws was noted (OR 2.81) but it did not reach statistical significance (95% CI 0.38-20.54, p=0.31).

Regarding non-infection complications; Kaukonen[76] also reported 3 prominent screw heads in the bioabsorbable group (3/20 – 15%) and no non-infection complications in the metal screw group. Sun[80] reported 29/86 patients with bioabsorbable screws (33.7%) had symptomatic hardware with 5 significant foreign body reactions requiring debridement. The metal group had 4 cases of symptomatic hardware not requiring intervention. Thordarson[81] reported no foreign body reaction in either group.

3.4.1.3.2.4.2 RESULTS FROM COHORT STUDIES

Sinisaari[97] reported no complications in any of the PLLA screw or metal screw patients.

3.4.1.3.2.5 RADIOLOGICAL OUTCOMES

3.4.1.3.2.5.1 RESULTS FROM RCTs

Sun[80] reported on long-term radiological follow-up (4 years) and noted a higher incidence of HO in the bioabsorbable group (3/86 – 3.5% vs 0/82 – 0% - p=0.246). Thordarson[81] found a similar MCS in the two groups (3.2 vs 3.3mm).

3.4.1.3.2.5.2 RESULTS FROM COHORT STUDIES

Sinisaari[97] reported radiological parameters comparing a 4.5mm PLLA screw to a 3.2mm metal screw. CT syndesmotic width (4.4mm (2.8-6.5) vs 4.0mm (1.6-6.3); p=0.47), TFC (5.7mm (3.6-8.1) vs 5.0mm (2.8-8.0); p=0.42) and TFO (6.0mm (1.5-12.5) vs 6.8mm (1.4-13.9); p=0.77) were not significantly different.

3.4.1.3.2.6 OTHER OUTCOMES

3.4.1.3.2.6.1 RESULTS FROM RCTs

Kaukonen[76] noted a 15.1 minute longer operation time associated with use of a PLLA screw (95% CI -1.2 - -28.9; p=0.033).

3.4.1.3.2.6.2 RESULTS FROM COHORT STUDIES

Sinisaari[97] compared the mean number of sick days taken by patients treated with a PLLA screw as compared to a metal screw. There was no significant difference (78 (42-212) vs 64 (42-95); p=0.28).

3.4.1.4 METAL SCREWS WITH NO COMPARATOR

3.4.1.4.1 DESCRIPTION OF INCLUDED STUDIES

3.4.1.4.1.1 DESCRIPTION OF DESCRIPTIVE STUDIES

Kennedy[62] compared the outcomes of 26 patients with syndesmotic injury with 19 patients without syndesmotic injury with 2.9 year follow-up. They reported an overall composite functional measure (Total Ankle Score) consisting of assessment of swelling, stiffness, ROM, pain, work ability and XR outcomes. The outcomes of the group without syndesmotic injury are not included in this systematic review as this is not part of the review question, although there was no significant difference (p=0.899).

Gennis[107] assessed the radiological outcomes of 166 patients treated with 3.5mm screws with 4 month follow-up and also compared the outcomes based on fracture pattern and screw integrity. They selected 4 month follow-up as the majority of secondary shift and syndesmotic re-displacement occurs within either 4 weeks of fixation or within 4 weeks of screw removal.[123]

Jones[109] compared the outcomes of patients with Lauge-Hansen SER-IV fractures with metal screw syndesmotic fixation to patients with deltoid ligament repair with suture anchor to indirectly stabilise the syndesmosis. Follow-up was 5 years, but only 5 patients in the metal screw group had complete analysis of all measures at final follow-up due to a high rate of non-responders. The outcomes of the latter group are not included in this review as this was not part of the review question, however there were no significant differences.

Kaye[110] assessed the outcomes of 31 metal screw patients at a mean of 6.3 months.

Kwaadu[112] performed lagged syndesmotic fixation (overdrilling of both fibular cortices) with an unspecified diameter, number or tri or quadricortical metal screw.

Van den Bekerom[119] reported on complications in 236 patients treated with various metal screws.

Van Vlijmen[120] followed 43 metal screw patients (treated with various screws and planned removal) for 5 years and reported outcomes and complications.

Walker[121] performed a retrospective audit of 36 patients with Weber C fractures treated with metal screws. Follow-up duration was not specified but was at least 3 months.

Jordan[123] followed the radiological markers of syndesmosis reduction in 86 patients with 4.5mm 4 cortex screw fixation removed at 11-16 weeks and compared pre-operative to post-operative measurements.

Pakarinen[124] performed an RCT comparing syndesmotic fixation with 1 3.5mm tricortical metal screws with no syndesmotic fixation at all in patients with Lauge-Hansen SER (Weber B equivalent) fractures and unstable syndesmosis on screening in theatre post stabilisation of any fractures. The outcomes of the patients who did not undergo syndesmotic fixation were not included as this is not part of the review question.

3.4.1.4.2 OUTCOMES

3.4.1.4.2.1 OUTCOME SCORES

3.4.1.4.2.1.1 RESULTS FROM DESCRIPTIVE STUDIES

Kennedy[62] reported Total Ankle Score on their patients with syndesmotic injury following fixation with metal screws (not further specified). Total Ankle Score (mean) was 62.81.

Jones'[109] metal screw patients had a mean (SD) AOFAS of 95 (5.77) And FADI of 96.4 (5.86).

Kwaadu's[112] mean (SD) AOFAS was 88.4 (13) in patients treated with lagged syndesmotic fixation.

Pakarinen's[124] patients with stabilised syndesmoses had a mean OMAS (SD) of 79.6 (15.5) compared to the patients with no stabilisation – 83.6 (13.1). There was no significant difference; p=0.5, 95% CI -8.2 – 16.3. They also reported mean (SD) SF-36 scores for physical function (0.9 (0.2) vs 1.0 (0.2); p=0.23, 95% CI -0.1 – 0.3) and pain (0.9 (0.4) vs 1.1 (0.2); p=0.32, 95% CI -0.1 – 0.5) and noted no significant difference.

3.4.1.4.2.2 PAIN

3.4.1.4.2.2.1 RESULTS FROM DESCRIPTIVE STUDIES

Jones [109] reported a mean (SD) VAS of 0.2 (0.45) in their metal screw patients.

Pakarinen[124] reported mean (SD) VAS of 2.55 (2.54) in stabilised patients compared to 1.13 (1.25) in unstabilised patients. There was no significant difference; p=0.38, 95% CI -31.2 – 3.3.

3.4.1.4.2.3 ROM

3.4.1.4.2.3.1 RESULTS FROM DESCRIPTIVE STUDIES

Kaye[110] measured ROM in patients treated with a metal screw (varying size and cortices) and noted a dorsiflexion mean ROM of 9° and plantarflexion of 38°.

Van Vlijmen's[120] patients at 5 years had a mean (SD) loss of dorsi/plantarflexion of 3.3° (16.8) and mean (SD) loss of inversion/eversion mean 6.4° (16.8).

Pakarinen's[124] patients with stabilised syndesmoses had mean (SD) dorsiflexion of 22 (5.8°) and plantarflexion 41° (8.0) compared to the patients with no stabilisation – 23° (0.6) and 36° (7.6). There was no significant difference in dorsiflexion (p=0.34, 95% CI -6 – 9) or plantarflexion (p=0.58, 95% CI -13 – 1).

3.4.1.4.2.4 COMPLICATIONS

3.4.1.4.2.4.1 RESULTS FROM DESCRIPTIVE STUDIES

Gennis[107] reported broken screws in 91/166 (54.8%) patients. Screws were removed (mostly electively) in 58/166 (34.9%).

Jones [109] had a single patient experience loss of reduction with metal screw stabilisation (1/15; 6.7%).

One of Kaye's[110] patients had a malreduction (1/31; 3.2%) and 2 had a malpositioned screw (2/31; 6.5%).

None of Kwaadu's[112] patients had stiffness (0/31; 0%). Two patients (2/31; 6.5%) had removal of metal for prominence. One patient experienced delayed union (1/31; 3.2%).

Van den Bekerom's[119] cohort of 236 patients had 4 broken screws (1.7%), recurrent diastasis in 1 patient (0.4%), and no episodes of loosening (0%). 3.5mm screws through 4 cortices were most likely to break although no formal statistical analysis was performed.

Van Vlijmen's[120] patients had 5 broken screws (5/43; 11.6%).

Walker's[121] 36 patients had 9 broken screws (25%), 8 loose screws (22.2%), 1 episode of recurrent diastasis requiring revision (2.8%), 30 screws removed (83.3%), 2 infections (5.6%) (one superficial treated with antibiotics and one deep requiring debridement) and 1 stiffness (2.8%).

3.4.1.4.2.5 RADIOLOGICAL OUTCOMES

3.4.1.4.2.5.1 RESULTS FROM DESCRIPTIVE STUDIES

Gennis[107] reported mean MCS, TFO and TFC at final follow-up of 2.0mm, 7.3mm and 4.0mm respectively. Presence of dislocation, fracture pattern, use of a plate and screw removal were not associated with differences in outcome. An intact screw as compared to a loose, broken or removed screw had no significant difference in measurements. Kaye[110] found an incidence of HO of 7/31 (22.6%).

Kwaadu[112] noted a rate of OA at 25 months of 1/31 (3.2%). One patient had a lucency around the screw (1/31, 3.2%).

Eleven of Van den Bekerom's[119] patients had synostosis on final XR (4.7%).

Van Vlijmen's[120] patients at 5 years had an incidence of OA on XR of 11/43 (25.6%) and a well reduced TFO in 22/43 (51.2%). There was no difference in these outcomes whether the screw(s) were removed at 2 or 3 months.

Jordan's[123] final (12 week) mean (SD) MCS, TFO and TFC were 2.990mm (0.6140), 5.830mm (2.5403) and 4.725mm (1.5769) before screw removal. After removal they measured 3.054mm (0.6556), 5.024mm (2.5250) and 5.529mm (1.4738). There was a significant difference for TFO (p=0.000) and TFC (p=0.000) but not for MCS (p=0.140) suggesting that the talus remains reduced in the mortise despite the slight widening of the syndesmosis. There were no differences in the measurements between fracture types or with different number of screws.

Pakarinen's[124] patients with stabilised syndesmoses were compared to patients without stabilisation. Mean MCS and TFC were not significantly different (3.5mm vs 3.2mm; p=0.34 and 5.4mm vs 5.5mm; p=0.41).

3.4.1.4.2.6 OTHER OUTCOMES

3.4.1.4.2.6.1 RESULTS FROM DESCRIPTIVE STUDIES

Van Vlijmen[120] measured change in calf and ankle diameter of the injured and uninjured extremities at a mean of 5 years post injury. Mean (SD) calf diameter loss was 0cm (1.79cm) and ankle diameter increased by 1cm (0.98).

Walker[121] found no correlation between surgeon experience and number of screws,

diameter or number of cortices engaged (p=0.256, 0.141, 0.102).

Pakarinen[124] also reported a self-rated VAS for function. Mean (SD) scores for stabilised patients were 2.26 (2.46) compared to patients without stabilisation 1.49 (1.50) with no significant difference (p=0.37; 95% CI -25.5 – 9.9)

3.3.4.2 TIGHTROPE

The results of the TightRope studies are presented below. All but one study used the Arthrex brand TightRope implant. The remaining study (Peterson 2015)[115] utilised a Biomet (Biomet Sports Medicine, Warsaw, IN) ZipTight™ implant. Thornes[87] constructed their own TightRope type implant using a #5 braided polyester suture and 2 Endobuttons (Smith and Nephew, Andover, MA, USA).

3.4.2.1 TIGHTROPES WITH NO COMPARATOR

3.4.2.1.1 DESCRIPTION OF INCLUDED STUDIES

3.4.2.1.1.1 DESCRIPTION OF DESCRIPTIVE STUDIES

Anand[103] analysed the results of 36 patients with Weber C ankle fractures treated with one or two TightRopes with follow-up at 14 months. Bondi[104] used 1 TightRope to stabilise the syndesmosis in patients with ankle fracture with 28 month mean follow-up. The mean (SD) distance from the plafond to the TightRope was 1.73cm (0.39). Cottom's 2008[105] study followed 25 patients treated with 1 or 2 TightRopes for 10 months. This was probably the same TightRope group that was compared to metal screws in their 2009 study[85], although this is not explicitly stated. There were minor differences in XR measurements, otherwise outcome scores and complication rates were the same. DeGroot[106] followed 24 patients treated with 1, 2 or 3 TightRopes for 20 months. Naqvi & Shafqat[114] followed 49 TightRope patients (1 or 2) for 6 months. Peterson[115] used one or two ZipTight implants and examined complications and XR outcomes. Qamar[116] followed 16 TightRope patients for 2 years. Rigby[117] followed 37 TightRope patients for almost 2 years. Storey[118] analysed the complications of 102 patients treated with one or two TightRopes. They also described a modified technique in which the sutures are not cut flush with the lateral

button but left 1cm long and buried subperiosteally to reduce soft tissue irritation. Willmott[122] followed a small number (6) patients with TightRopes and analysed radiological indices and complications.

3.4.2.1.2 OUTCOMES

3.4.2.1.2.1 OUTCOME SCORES

3.4.2.1.2.1.1 RESULTS FROM DESCRIPTIVE STUDIES

Anand[103] found a mean (range) AOFAS and OMAS at 14 months of 88.8 (67-98) and 85 (70-100). Bondi's[104] cohort had a mean AOFAS (SD) of 93.11 (4.38) and mean FADI (SD) of 130.11 (2.52). Cottom's 2008[105] patients had a mean (range) AOFAS (modified /63) of 50.64 (30-63) and SF-12 scores of 47.02 and 55.34 for the physical and mental sections respectively. DeGroot[106] noted a mean AOFAS (range) of 94.17 (71-100). Naqvi & Shafqat[114] reported an AOFAS (SD) of 85.57 (16.71); 95%CI 77.96-93.16 and FADI (SD) of 81.2 (16.11); 95% CI 73.86-93.53. Qamar's[116] mean (range) AOFAS was 86 (48-100). Rigby's[117] mean (range) AOFAS was 97 (90-100).

3.4.2.1.2.2 PAIN

3.4.2.1.2.2.1 RESULTS FROM DESCRIPTIVE STUDIES

No studies recorded pain as an outcome.

3.4.2.1.2.3 ROM

3.4.2.1.2.3.1 RESULTS FROM DESCRIPTIVE STUDIES

No studies recorded ROM as an outcome.

3.4.2.1.2.4 COMPLICATIONS

3.4.2.1.2.4.1 RESULTS FROM DESCRIPTIVE STUDIES

Anand[103] had one case of TightRope breakage and failure requiring revision to a screw (1/36; 2.8%) and one case of hardware irritation necessitating removal (1/36; 2.8%). Bondi[104] had one TightRope require removal for knot prominence (1/36; 2.8%). Cottom's 2008[105] group had no complications (0/25; 0%). DeGroot[106] group required removal of TightRope in 4/24 (25%) of patients; 4 for prominence, 1 for pain and ROM restriction and one due to a second injury. Three of Naqvi & Shafqat's[114] patients had removal of TightRope for lateral knot prominence (3/49; 6.1%). They

then modified the technique with burial of the suture ends subperiosteally with no more episodes of knot prominence (p=0.04). Peterson's[115] patients experienced one deep infection (1/56; 1.8%) and 3 implants removed for irritation (3/56; 5.4%). Qamar's[116] patients had a superficial infection rate of 2/16 (12.5%) both treated with oral antibiotics. There was 1 implant removal for prominence (1/16; 6.3%). Seven of Rigby's[117] patients had irritation from the knot (7/37; 18.9%) and 4 (10.8%) of these patients went on to have the implant removed with resolution of symptoms. Three patients had superficial infections treated with oral antibiotics (8.1%). Storey's[118] cohort of 102 patients had 8 implants removed (7.8%), no episodes of implant prominence, 3 superficial infections treated with oral antibiotics (2.9%), 3 cases of osteomyelitis (2.9%), 3 cases of implant migration (2.9%), 3 malpositioned implants (2.9%) and 4 cases of VTE (2 each of DVT and PE) (3.9%). Willmott[122] had 6 TightRope patients, 2 of whom had lateral soft tissue irritation requiring implant removal (2/6; 33.3%).

3.4.2.1.2.5 RADIOLOGICAL OUTCOMES

3.4.2.1.2.5.1 RESULTS FROM DESCRIPTIVE STUDIES

Anand's[103] mean (range) MCS and TFO were 3.0mm (2.7-3.6) and 20.1mm (2.5-12.2) respectively. Bondi's[104] mean (SD) MCS, TFO and TFC were 4.0mm (0.8), 7.1mm (0.8) and 4.6mm (1.1). Cottom[105] measured mean (SD) MCS, TFO and TFC. They were 3.12mm (0.33), 7.12mm (1.71) and 3.88mm (0.83). Naqvi & Shafqat[114] measured mean (SD) MCS, TFO and TFC (3.33mm (0.63), 8.88mm (1.60), and 4.37mm (0.67)). Peterson[115] measured mean (SD) MCS, TFO and TFC (3.1mm (0.7), 7.4mm (2.6), 4.3mm (1.4)). There were no cases of osteolysis (0/56; 0%). Rigby's[117] radiological measures were mean (SD); MCS 3.0mm (0.5), TFO 7.4mm (2.8), TFC 4.2mm (1.3). Storey[118] noted osteolysis in 2 patients (2/102; 1.9%). Willmott's[122] final mean (SD) MCS, TFO and TFC were 2.6mm (0.9), 3.0mm (1.68) and 3.8mm (0.97).

DeGroot's[106] mean (SD) MCS, TFO and TFC were 3.8mm (0.39), 7.9mm (1.2) and 3.3mm (0.7). MCS and TFC increased by an average of 0.1mm and TFO decreased by an average of 0.1mm over the follow-up period. Heterotrophic Ossification was noted in 3/24 (12.5%) patients. The AOFAS scores for these patients were higher than the overall mean. Button subsidence into the cortex of either the tibia or fibula by 2-4mm occurred in 4/24 (16.7%). AOFAS was worse but not significantly different

in this subgroup (89.5 vs 95.1; p=0.231)

3.4.2.1.2.6 OTHER OUTCOMES

3.4.2.1.2.6.1 RESULTS FROM DESCRIPTIVE STUDIES

Cottom's 2008[105] patients had a mean (SD) time to full weight bearing of 5.52 weeks (1.93) and the Maisonneuve subset 4.93 weeks (1.86). DeGroot's[106] patients took a mean (SD) of 5.7 weeks (2.1) to achieve full weight bearing. Naqvi & Shafqat[114] patients took an average (SD) of 7.76 weeks (1.16) to resume full weight bearing. Qamar's[116] patients took a mean of (range) 4.5 weeks (4-6) to commence full weight bearing. Willmott's[122] group had a mean (range) time to full weight bearing 6 weeks (4-8).

Peterson[115] noted a minor but statistically significant difference in the mean (SD) distance between buttons on XR at first follow-up (51.9mm (7.7)) and final follow-up (53.0mm (7.3mm); p<0.001.

Rigby[117] compared first post-operative to final post-operative XR indices (mean (SD)) (MCS 2.9mm (0.5) vs 3.0mm (0.5), TFO 7.2mm (2.7) vs 7.4mm (2.8), TFC 4.1mm (1.1) vs 4.2mm (1.3)). The differences were 0.11mm, 0.53mm and 0.09mm respectively and were not statistically significant (p<0.001, p<0.002, p<0.001).

3.4.3 BIOABSORBABLE SCREWS

3.4.3.1 BIOABSORBABLE SCREWS WITH NO COMPARATOR

3.4.3.1.1 DESCRIPTION OF INCLUDED STUDIES

3.4.3.1.1.1 DESCRIPTION OF DESCRIPTIVE STUDIES

Ahmad[102] assessed a group of 70 patients with syndesmotic injury stabilised with 1 4.5mm 4 cortical PLA screw with 32.5month follow-up. Hovis[108] assessed 23 patients with syndesmotic injury stabilised with 1 or 2 4 cortical 4.5mm PLLA screws with 34 month follow-up. OMAS and ROM were given for each patient allowing calculation of SDs (range given in paper only as measure of variance). Korkala[111] assessed the outcomes of 7 patients treated with 1 or 2 4.5mm 4 cortical PGA screws with 12 month follow-up. Miller [113] described the complications in 4 patients treated with a

PGA/PLA co-polymer 5mm tricortical bioabsorbable screw.

3.4.3.1.2 OUTCOMES

3.4.3.1.2.1 OUTCOME SCORES

3.4.3.1.2.1.1 RESULTS FROM DESCRIPTIVE STUDIES

Ahmad's[102] group of patients with 1 4.5mm 4 cortical PLA screw had a mean AOFAS (range) of 90 (44-100). Hovis'[108] patients had a mean OMAS (SD) of 93.9 (6.6).

3.4.3.1.2.2 PAIN

3.4.3.1.2.2.1 RESULTS FROM DESCRIPTIVE STUDIES

Ahmad's[102] group of patients with 1 4.5mm 4 cortical PLA screw had a mean VAS (range) of 1.8 (0-10)

3.4.3.1.2.3 ROM

3.4.3.1.2.3.1 RESULTS FROM DESCRIPTIVE STUDIES

Hovis' [108] patients had a mean ROM (SD) at final follow-up of 17.3° (10.2) dorsiflexion and 40.2° (12.1) plantarflexion.

3.4.3.1.2.4 COMPLICATIONS

3.4.3.1.2.4.1 RESULTS FROM DESCRIPTIVE STUDIES

Ahmad's[102] 4.5mm PLA screw patients had a symptomatic hardware prominence rate requiring removal of 2/70 (2.9%). There were no cases of clinical instability. Hovis[108] reported no complications in their cohort of 23 patients (0%). Korkala[111] had one patient with a soft tissue reaction requiring dressings (1/7; 14.3%) and one patient with residual stiffness (1/7; 14.3%). Miller[113] noted 2 patients (2/4; 50%) with prominent screw heads not requiring any treatment.

3.4.3.1.2.5 RADIOLOGICAL OUTCOMES

3.4.3.1.2.5.1 RESULTS FROM DESCRIPTIVE STUDIES

Ahmad's[102] 4.5mm PLA screw patients through 4 cortices had no radiological instability. None of Miller's[113] patients had osteolysis (0/4; 0%).

3.4.3.1.2.6 OTHER OUTCOMES

3.4.3.1.2.6.1 RESULTS FROM DESCRIPTIVE STUDIES

Ahmad[102] found that trimalleolar fractures did worse on VAS and AOFAS as compared to the other fracture patterns (bimalleolar, Maisonneuve and dislocations). Mean AOFAS (range) was 78.6 (44-100) and mean VAS (range) was 3.9 (0-10). Compared to the overall scores for the entire study cohort (AOFAS 90, VAS 1.8) there was a significant difference (AOFAS p=0.002, VAS p=0.007).

3.5 Single group analysis

This heterogeneous group of studies with varying designs and surgical techniques with many different results has been summarised in the below single group analyses. Any comparable outcome with results recorded in five or more of the included studies has been included. Outcomes reported fewer than five times among all the studies were not subject to single group analysis to keep the number of analyses reasonable and to ensure that the included analyses has sufficient numbers of patients included. Single group results were extracted from all studies where possible. Means were taken and SD used as a measure of variance. Where no variance measure was included, the study was not included in the analysis. Where range was given instead of SD, the method of Hozo[127] was used to calculate a SD. This method varies based on sample size. A study with 15 or fewer subjects is subject to a formula to calculate SD from ROM, and studies with 15-70 and 70 or more subjects have the range divided by 4 and 6 respectively. While this does have some inherent inaccuracy, it allowed inclusion of the greatest possible number of studies which was our aim in the single group analysis. OpenMeta[Analyst] software (Brown University, Providence, Rhode Island, USA) was used.

Subgroup analysis was performed separating metal screws from TightRopes from bioabsorbable screws. A continuous random-effects analysis method was applied. For continuous variables, a pilot sensitivity analysis was performed for AOFAS scores comparing various random-effects models (Hedges-Olkin, DerSimonian-Laird, Sidik-Jonkman, Maximum likelihood and empirical Bayes). Overall AOFAS score for all included studies varied by 0.086 (range 89.854-89.940) on a 100-point score. Minimum score on 95% CI varied by 0.512 (range 87.957-88.469) and maximum by 0.339 (range 91.412-91.751). With such minor variation, a DerSimonian-Laird model was employed as the simplest and most commonly used.[128] For categorical variables a binary random-effects model was employed. A pilot sensitivity analysis was performed for broken implants comparing the same various random-effects models. Overall rate of broken screws varied by 0.005 (range 0.099-0.104) with minimum 95% CI varying by 0.004 (range 0.054-0.058) and maximum by 0.005 (range 0.140-0.155). Again, a DerSimonian-Laird model was employed.

Single group analyses are available for AOFAS, OMAS, VAS, ROM, Complications and radiological outcomes. Results are present in Forest plot format with subgroup analysis dividing the patient groups into metal, suture-button and bioabsorbable

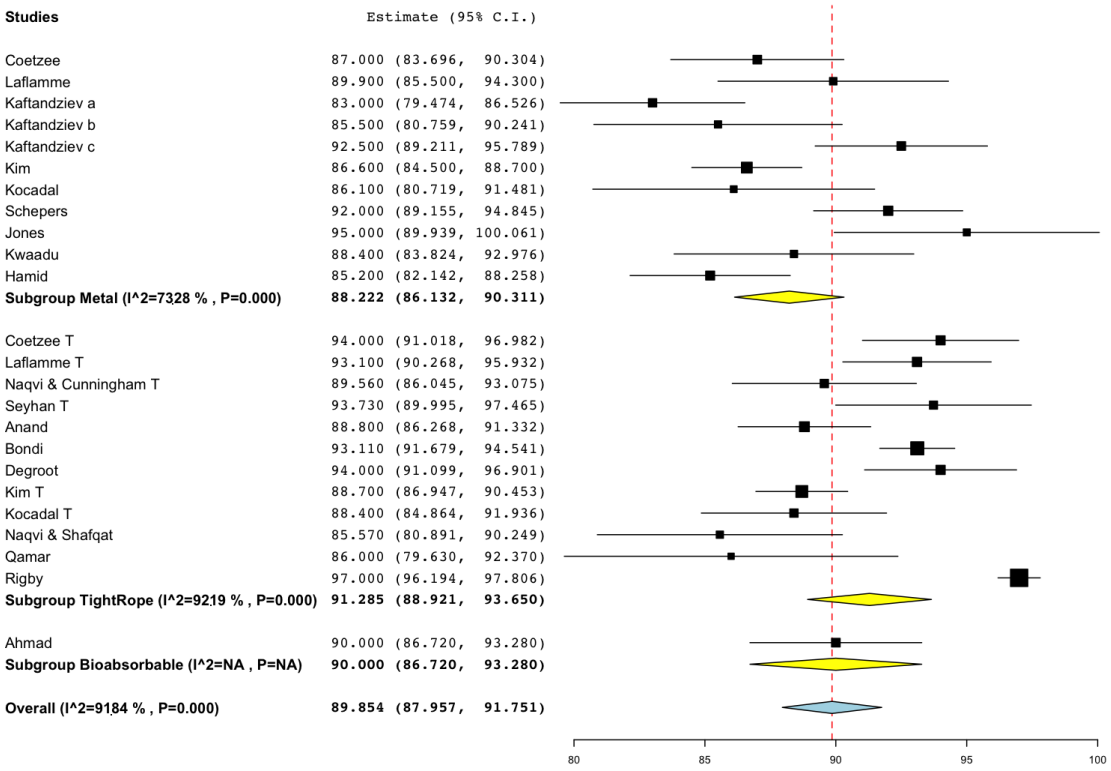
groups.

3.5.1 AOFAS

Single group analysis was performed for AOFAS scores at final follow-up (Figure 3.4). Nine metal screw studies (with 3 groups for Kaftandziev[90]), 12 TightRope studies and one bioabsorbable study were included. Metal screws scored lower overall (88.222, 95% CI 86.132-90.311) with significant heterogeneity (I^2=73.3%, p=0.000). TightRopes had an overall AOFAS of 91.285 (95% CI 88.921 – 93.650) with high heterogeneity (I^2=92.19%, p=0.000) and the one included bioabsorbable study had a mean AOFAS of 90 (95% CI 86.72-93.28).

Overall AOFAS for all fixation methods was 89.854 (95% CI 87.957-91.751); falling within the 95% CI of all subgroups suggesting no significant difference although there was a trend towards higher scores for the TightRope group.

Figure 3.4 – Single group analysis of AOFAS for metal screws, TightRopes and bioabsorbable screws



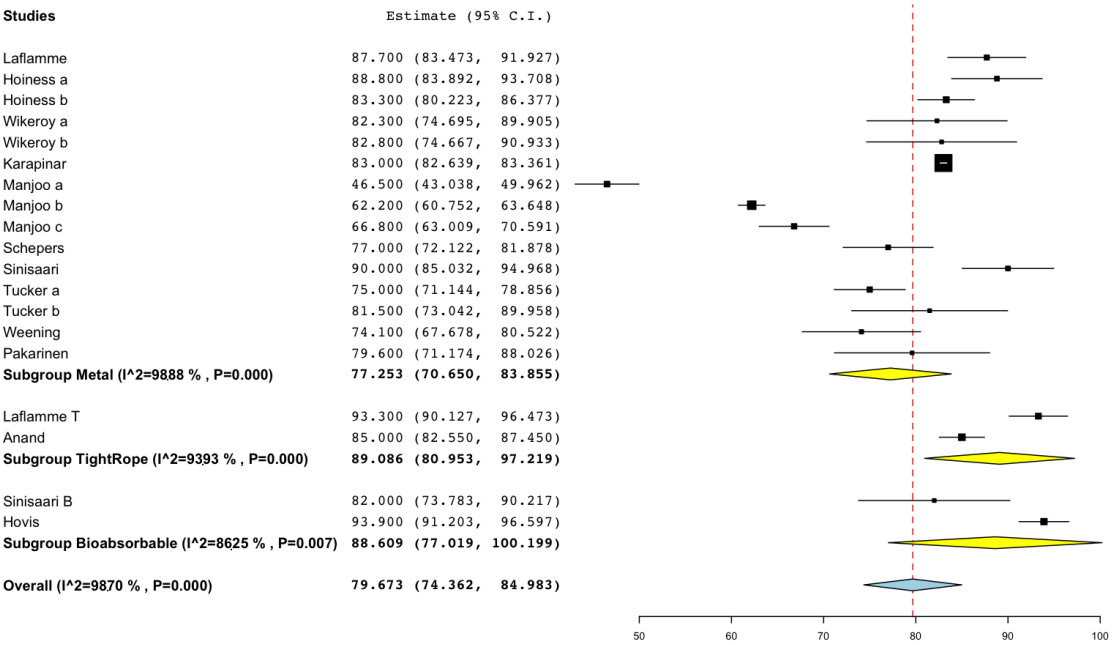
3.5.2 OMAS

Final OMAS was included for single group analysis for 10 metal screw studies (with multiple groups for 4 studies), 2 TightRope studies and two bioabsorbable screw studies (Figure 3.5). Metal screws scored lower overall (77.253, 95% CI 70.650 - 83.855) with high heterogeneity (I^2=98.80%, p=0.000). TightRopes had an overall OMAS of 89.086 (95% CI 80.953 - 97.219) with high heterogeneity I^2=93.93% (p=0.000) and the included bioabsorbable studies had an overall OMAS of 88.609 (95% CI 77.019 - 100.199) with lower but still substantial heterogeneity (I^2 =86.25%, p=0.007).

Overall OMAS for all fixation methods was 79.673 (95% CI 74.362-84.983), (I^2=98.70%, p=0.000); falling within the 95% CI of all subgroups suggesting no significant difference but again TightRopes scored the highest.

Of note, each of Manjoo's[94] groups performed significantly worse than any other metal screw groups. The reason for this is unclear.

Figure 3.5 – Single group analysis of OMAS for metal screws, TightRopes and bioabsorbable screws



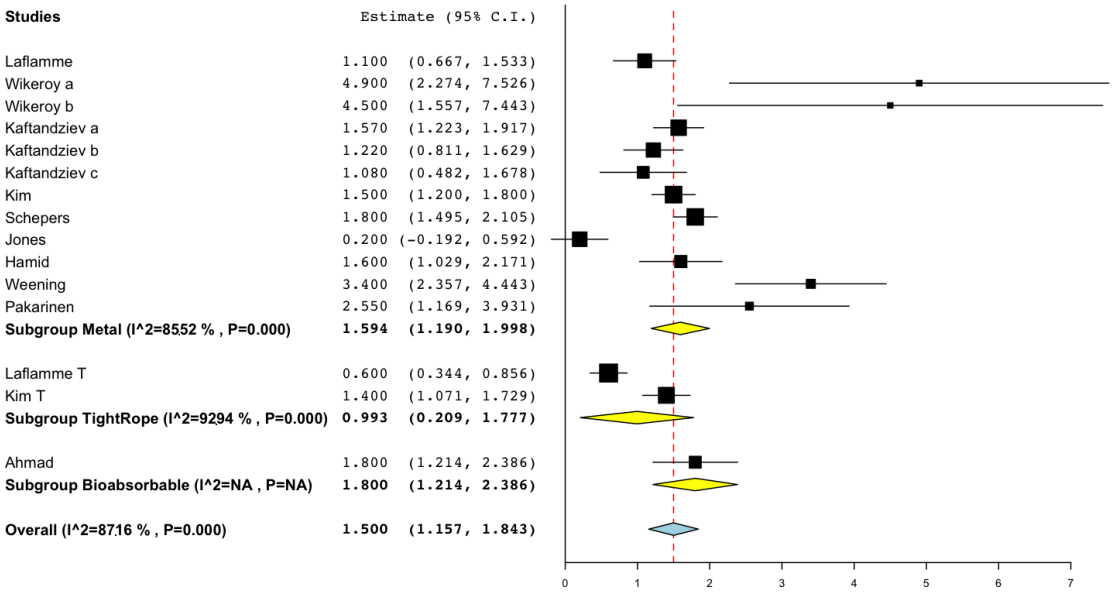
3.5.3 VAS

Final VAS was included for single group analysis for 9 metal screw studies (with multiple groups for 2 studies), 2 TightRope studies and one bioabsorbable screw study (Figure 3.6). Metal screws scored 1.594 (95% CI 1.190 - 1.998) with high heterogeneity (I^2=85.52%, p=0.000). TightRopes had a lower VAS of 0.993 (95% CI 0.209 - 1.777) with high heterogeneity I^2=92.94 (p=0.000) and the included bioabsorbable study had a VAS of 1.800 (95% CI 1.214-2.386).

Overall VAS for all fixation methods was 1.500 (95% CI 1.15 – 1.843); falling within the 95% CI of all subgroups suggesting no significant difference but again TightRopes tended towards having the best scores. (I^2=87.16%, p=0.000)

Wikeroy's[82] patients had the highest (worst) VAS, perhaps because the long follow-up (8 years) allowed complications such as OA to develop and cause symptoms.

Figure 3.6 – Single group analysis of VAS for metal screws, TightRopes and bioabsorbable screws



3.5.4 ROM

ROM (both dorsiflexion and plantarflexion) at final follow-up was included for single group analysis for 8 metal screw studies (with multiple groups for 2 studies), 2 TightRope studies and three bioabsorbable screw studies (Figure 3.7 and 3.8). Metal screw overall dorsiflexion ROM was 23.570° (95% CI 18.739 – 28.402), (I^2=97.90%, p=0.000). Bioabsorbable screw dorsiflexion is 22.113° (95% CI 16.585 – 27.640), (I^2=89.78% p=0.093). TightRope dorsiflexion ROM was significantly lower (12.526°, 95% CI 10.016 - 15.035), and less varied (I^2=64.50%, p=0.093).

Overall dorsiflexion ROM was 21.637° (95% CI 18.469 – 24.805) (I^2=99.39%, p=0.000). Of note, both TightRope studies had lower ROM than the overall mean. Laflamme's[79] TightRope patients had slightly worse dorsiflexion ROM than the metal screw patients in that study, but it was not statistically significant. The opposite was the case in Coetzee's study[74], the TightRope patients had slightly better dorsiflexion but again there was no statistically significant difference.

Fewer metal screw studies (6) reported plantarflexion ROM. Metal screw mean plantarflexion is 38.564° (95% CI 34.831 – 42.290) and heterogeneous (I^2=92.27%, p=0.000). TightRope studies mean plantarflexion is 43.005° (95% CI 24.003 – 62.008). The two studies had very different mean plantarflexion ROM (33.6° and 53°) so heterogeneity is quite high (I^2=96.11%, p-0.000). Bioabsorbable screws had a mean plantarflexion ROM of 41.891° (95% CI 38.028 – 45.755), heterogeneity was lower but still significant (I^2=79.59%, p=0.007).

Overall plantarflexion ROM was 39.085° (95% CI 37.387-42.224) (I^2=98.53%, p=0.000) with no significant difference between groups.

Figure 3.7 – Single group analysis of dorsiflexion ROM° for metal screws, TightRopes and bioabsorbable screws

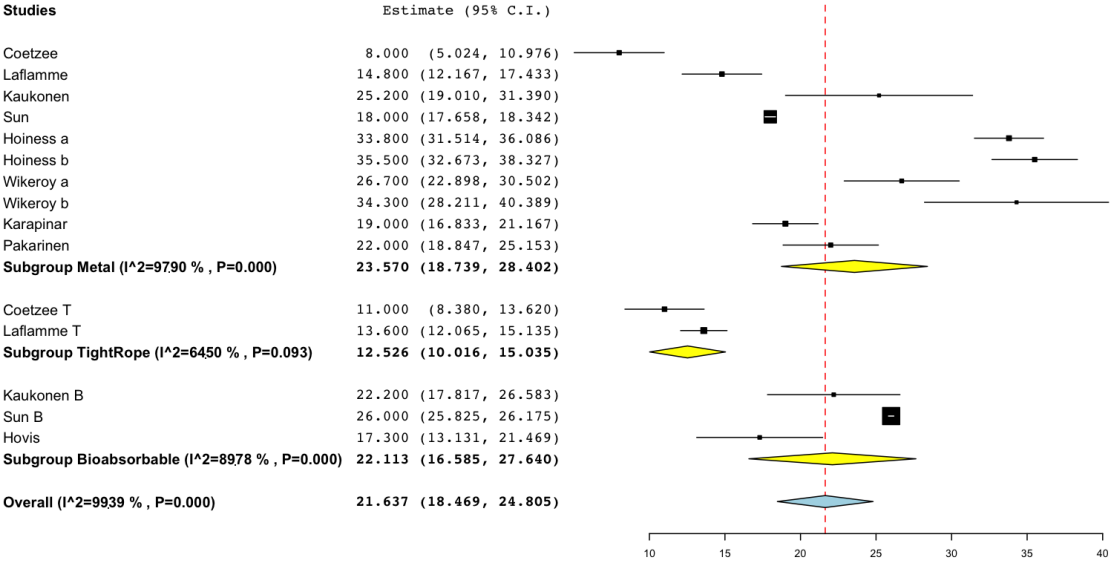
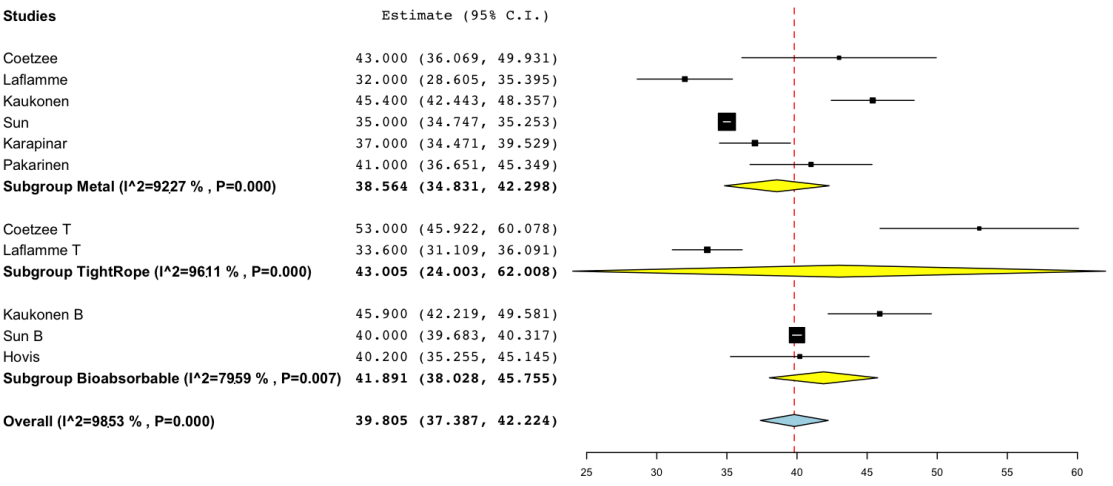


Figure 3.8 – Single group analysis of plantarflexion ROM° for metal screws, TightRopes and bioabsorbable screws



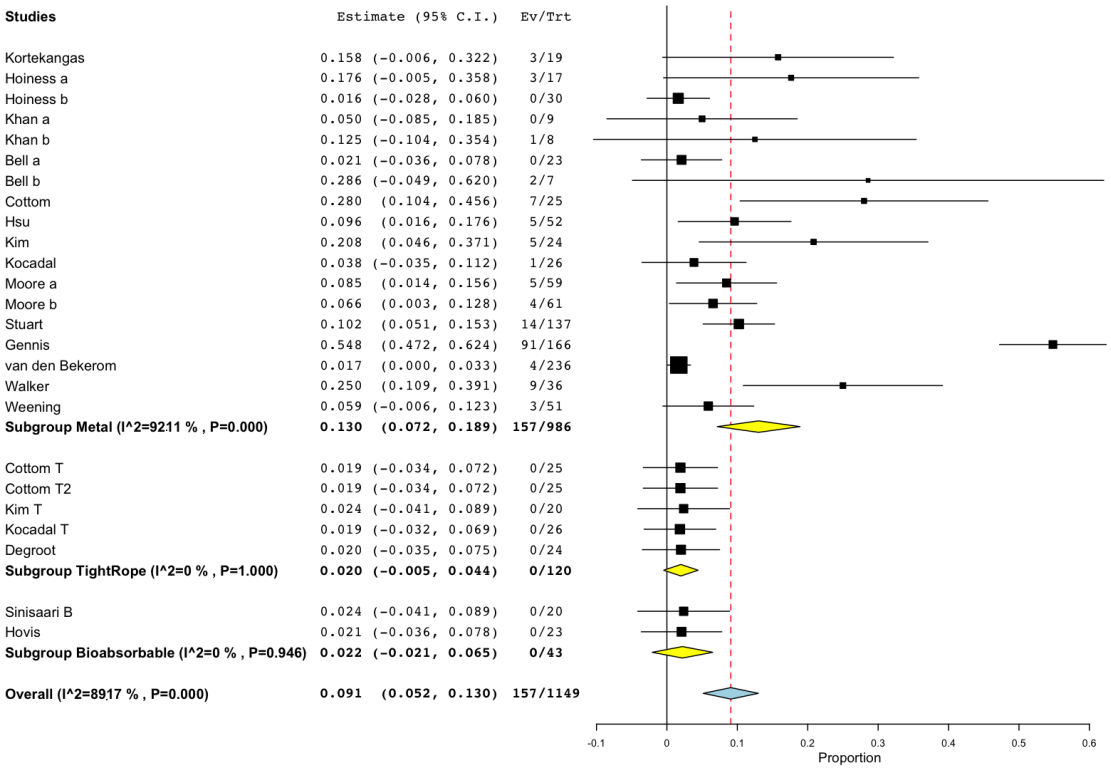
3.5.5 Complications

Single group analysis was performed for implant breakage, implant removal, infection, implant loosening, foreign bony reaction and implant prominence.

3.5.5.1 Implant breakage

Implant breakage was recorded in 14 metal screw studies, 5 TightRope studies and 2 bioabsorbable screw studies (Figure 3.9). The total incidence of implant breakage in metal screws is 157/986 (0.130, 95% CI 0.072 – 0.189). There was a reasonable amount of heterogeneity (I^2=92.11%, p=0.000) which was to be expected as some studies reported screw breakage as a complication while others recorded it as an endpoint. There were no broken implants in the 120 included TightRope and 43 include bioabsorbable screw patients. Overall risk of implant breakage is 0.091 (95% CI 0.052-0.130) (I^2=89.17%, p=0.000). Implant breakage appears to be unique to the metal screw group as a broken bioabsorbable screw would be undetected on XR and a broken TightRope may fail through the radiolucent suture rather than the strong metal button leading to possible under-appreciation of implant breakage.

Figure 3.9 – Single group analysis of implant breakage for metal screws, TightRopes and bioabsorbable screws

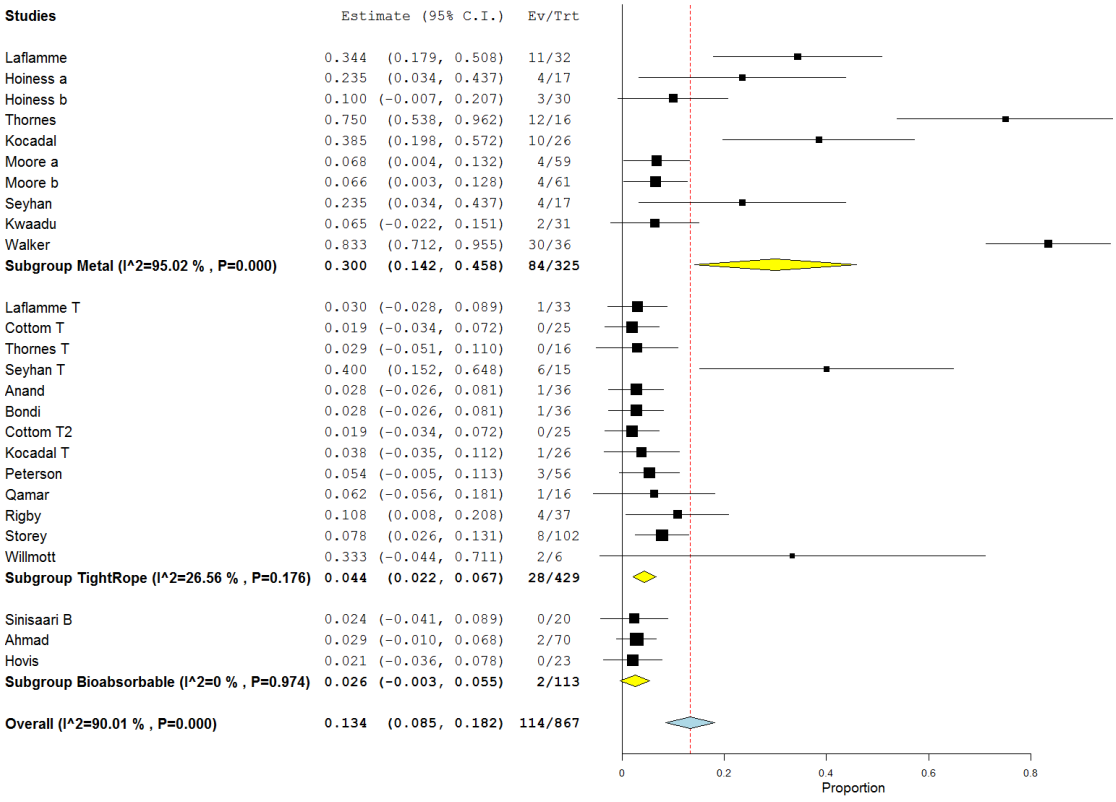


3.5.5.2 Implant removal

Implant removal was recorded in 8 metal studies, 13 TightRope studies and 3 bioabsorbable studies (Figure 3.10). Studies with planned implant removal have been excluded from analysis. The rate of screw removal was significantly highest (84/325, 0.300 95% CI 0.142-0.458) and most varied (I^2=95.02%, p=0.000) in the metal screw studies. TightRopes had a lower (but non-zero) incidence of implant removal (28/429, 0.044, 95% CI 0.022-0.067) with more consistent results (I^2=25.56%, p=0.176) and bioabsorbable screws had the lowest need for implant removal (2/113, 0.023, 95% CI -0.003 – 0.055) with very consistent results (I^2=0%, p=0.974).

The overall incidence of implant removal is 114/867 (0.130, 95% CI 0.085 - 0.182) (I^2=90.01%, p=0.000).

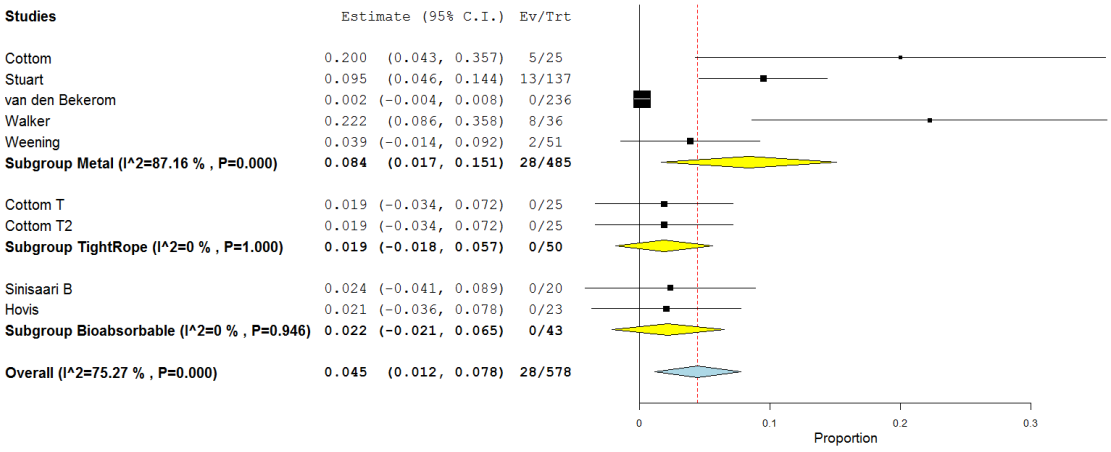
Figure 3.10 – Single group analysis of implant removal for metal screws, TightRopes and bioabsorbable screws



3.5.5.3 Implant loosening

Implant loosening was reported in 5 metal studies, 2 TightRope studies and 2 bioabsorbable studies (Figure 3.11). Incidence was highest in metal screws (28/485, 0.084, 95% CI 0.017-0.151) with high variability (I^2=87.16%, p=0.000). There were no cases of implant loosening in the 50 TightRope and 43 bioabsorbable screw patients although due to low numbers this difference was not statistically significant. Again, implant loosening is not apparent on plain XR with the non-metal screw fixation methods perhaps explaining this difference.

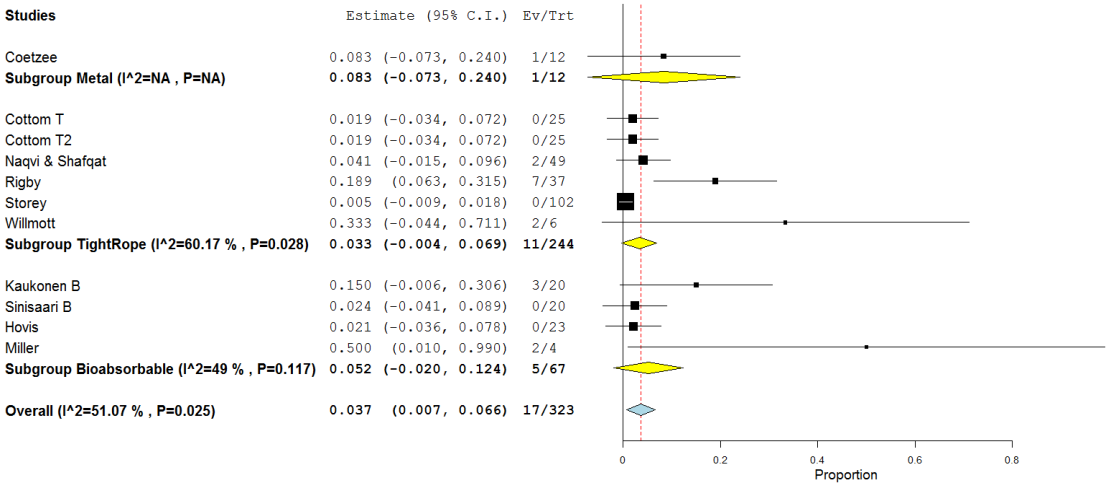
Figure 3.11 – Single group analysis of implant loosening for metal screws, TightRopes and bioabsorbable screws



3.5.5.4 Implant prominence

Implant prominence was reported in 1 metal study, 6 TightRope studies and 4 bioabsorbable studies (Figure 3.12). It is however important to note that most metal studies removed prominent screws (and reported them as implant removal) rather than classifying them as prominent, hence the low number of included metal screw patients in this analysis. Metal screw prominence occurred in 1/12 (0.083, 95% CI -0.073 – 0.240) patients. TightRope patients had a low incidence of prominence (11/244, 0.033, 95% CI -0.004 – 0.069) with some heterogeneity (I^2=60.17%, p=0.028) as did bioabsorbable patients (5/67, 0.052, 95% CI -0.020 – 0.124) with good consistency (I^2=49%, p=0.117). The overall rate of implant prominence is 17/323 (0.037, 95% CI0.007 – 0.066) with moderate heterogeneity (I^2=51.07%, p=0.025).

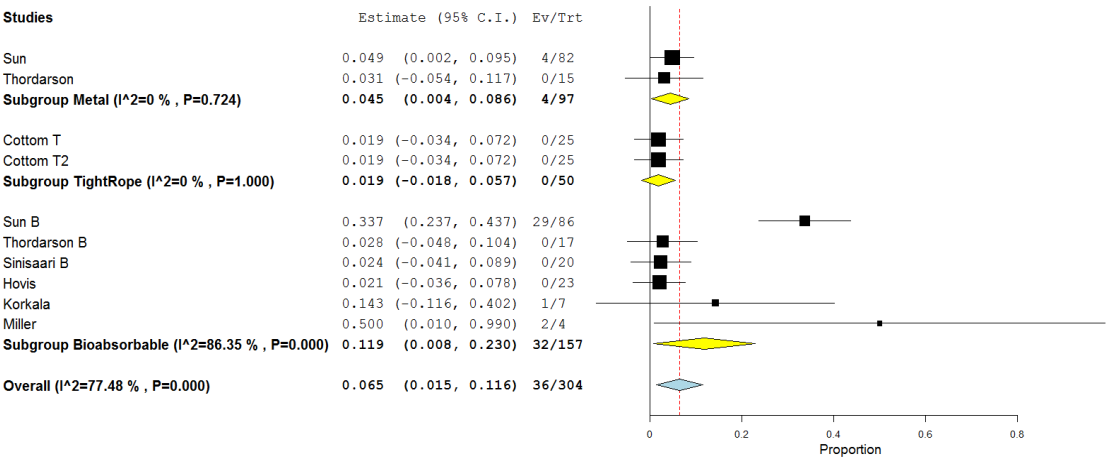
Figure 3.12 – Single group analysis of implant prominence for metal screws, TightRopes and bioabsorbable screws



3.5.5.5 Foreign body reaction

Foreign body reaction was reported on 2 metal studies, 2 TightRope studies and 6 bioabsorbable studies (Figure 3.13). There were no cases in TightRope patients (0/50) and 4 cases in metal screw patients (4/97, 0.045, 95% CI 0.004 – 0.086) with good homogeneity (I^2= 0%, p=0.724). The highest incidence was in the bioabsorbable patients (32/157, 0.119, 95% CI 0.008 – 0.230) with high heterogeneity (I^2=86.35%, p=0.000). It is important to note that foreign body reaction is considered to be unique to bioabsorbable implants or suture implants which generate immunogenic debris so not many studies reported on this complication and the only metal studies reporting on it were RCTs comparing metal screws to bioabsorbable fixation.

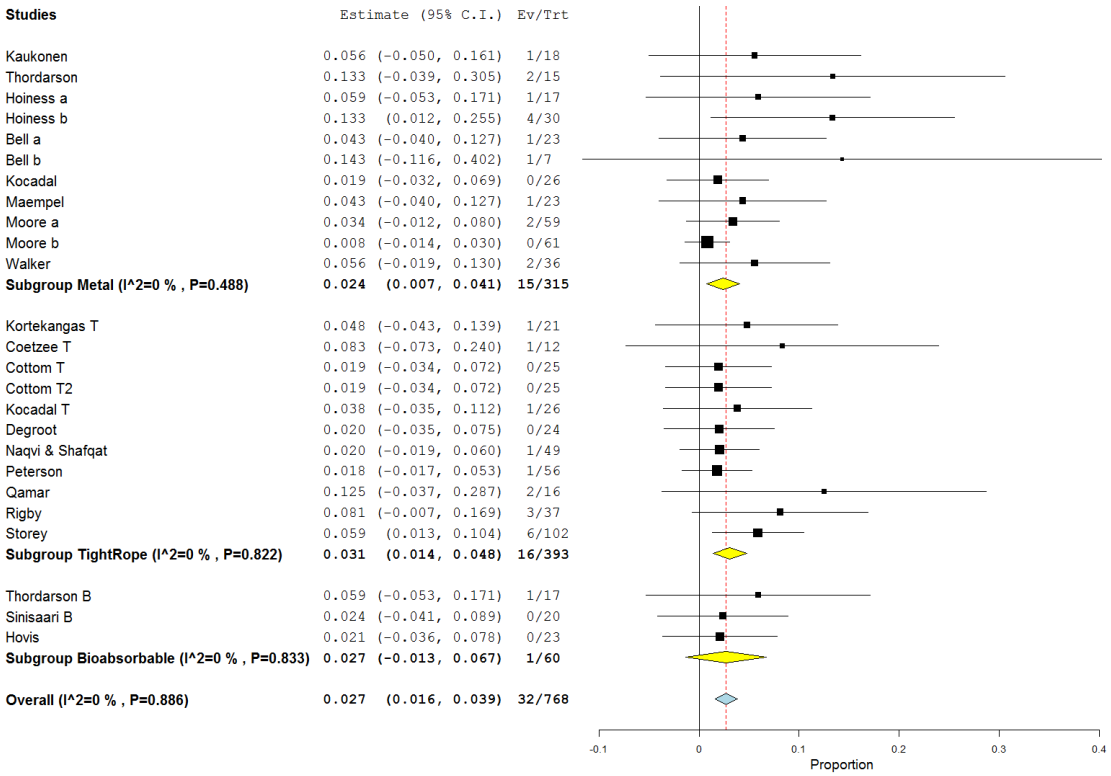
Figure 3.13 – Single group analysis of foreign body reactions for metal screws, TightRopes and bioabsorbable screws



3.5.5.6 Infection

Infection is a commonly reported complication reported by 8 metal, 11 TightRope and 3 bioabsorbable studies (Figure 3.14). The overall infection rate was low 32/768 (0.027, 95% CI 0.016-0.039) with good concordance amongst all groups (I^2=0, p=0.0488; I^2=0, p=0.822; I^2=0, p=0.833) and all included studies overall (I^2=0%, p=0.886). There were no significant differences between the three groups (15/315, 0.024, 95% CI 0.007 – 0.041); (16/393, 0.031, 95% CI 0.014-0.048); and (1/60, 0.027, 95% CI -0.013 – 0.067) respectively.

Figure 3.14 – Single group analysis of infection for metal screws, TightRopes and bioabsorbable screws



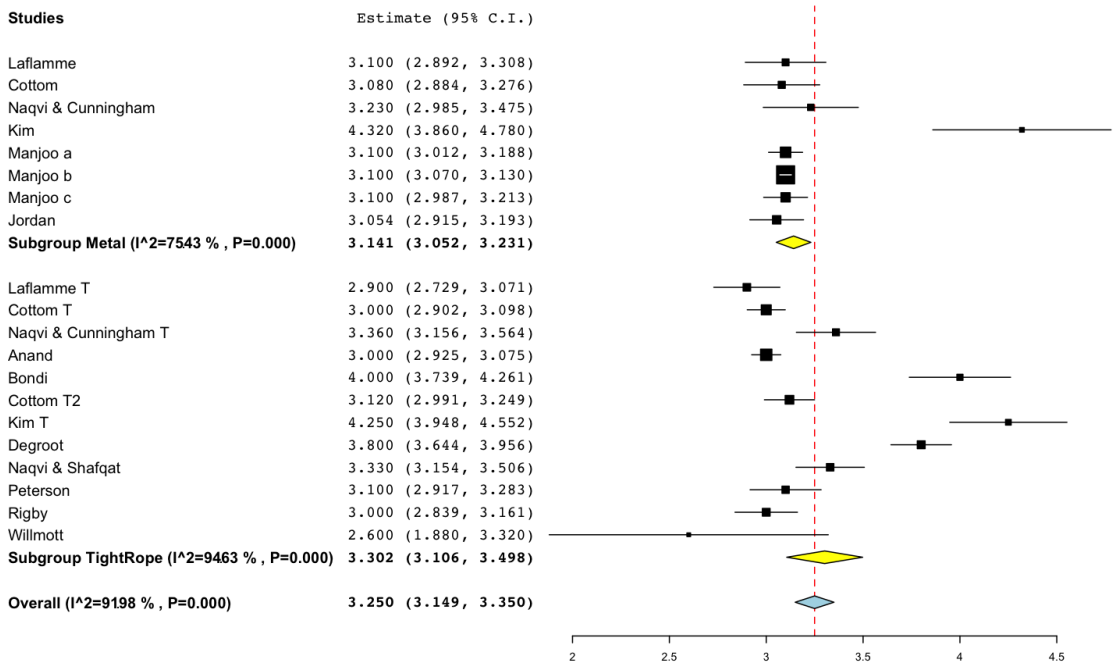
3.5.6 Radiological outcomes

Radiological measurements of syndesmotic reduction were compared (MCS, TFO, TFC). Other radiological outcomes were also compared – loss of reduction, lucency, heterotrophic ossification and osteoarthritis.

3.5.6.1 Medial Clear Space

Medial clear space was recorded in 6 metal and 10 TightRope studies (Figure 3.15). Overall MCS was 3.141mm in the metal group (95% CI 3.052 – 3.231) with most studies being clustered closely aside from Kim, resulting in heterogeneity (I^2=75.43%, p=0.000). Overall TightRope MCS was 3.302mm (95% CI 3.106-3.498) with more spread (I^2=94.63%, p=0.000). There was no significant difference between the groups with overall MCS for all included studies measuring 3.250mm (95% CI 3.149 - 3.350), (I^2=91.98, p=0.000)

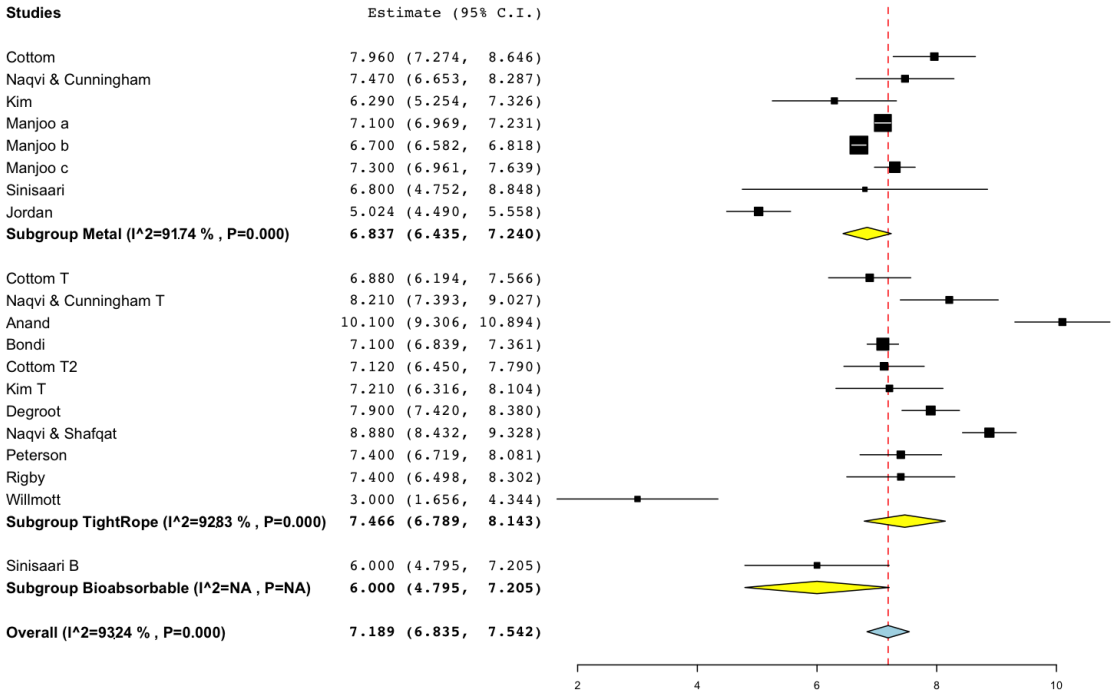
Figure 3.15 – Single group analysis of MCS (mm) for metal screws and TightRopes



3.5.6.2 Tibiofibular overlap

Tibiofibular overlap was recorded in 6 metal studies with a mean of 6.837mm (95% CI 6.435-7.240) (I^2=91.74%, p=0.000), 11 TightRope studies with a mean of 7.466mm (95% CI 6.789 – 8.143), (I2=92.83%, p=0.000) and one bioabsorbable study (6.000mm, 95% CI 4.795 – 7.205) (Figure 3.16). There was no significant difference between the groups, overall mean 7.189mm (95% CI 6.835 – 7.542) with heterogeneity I^2=93.24, p=0.000. Of note, Willmott's study was an outlier with a TFO of only 3.0mm. This may be due to positioning as TFO is the syndesmotic measurement most sensitive to ankle positioning on XR.

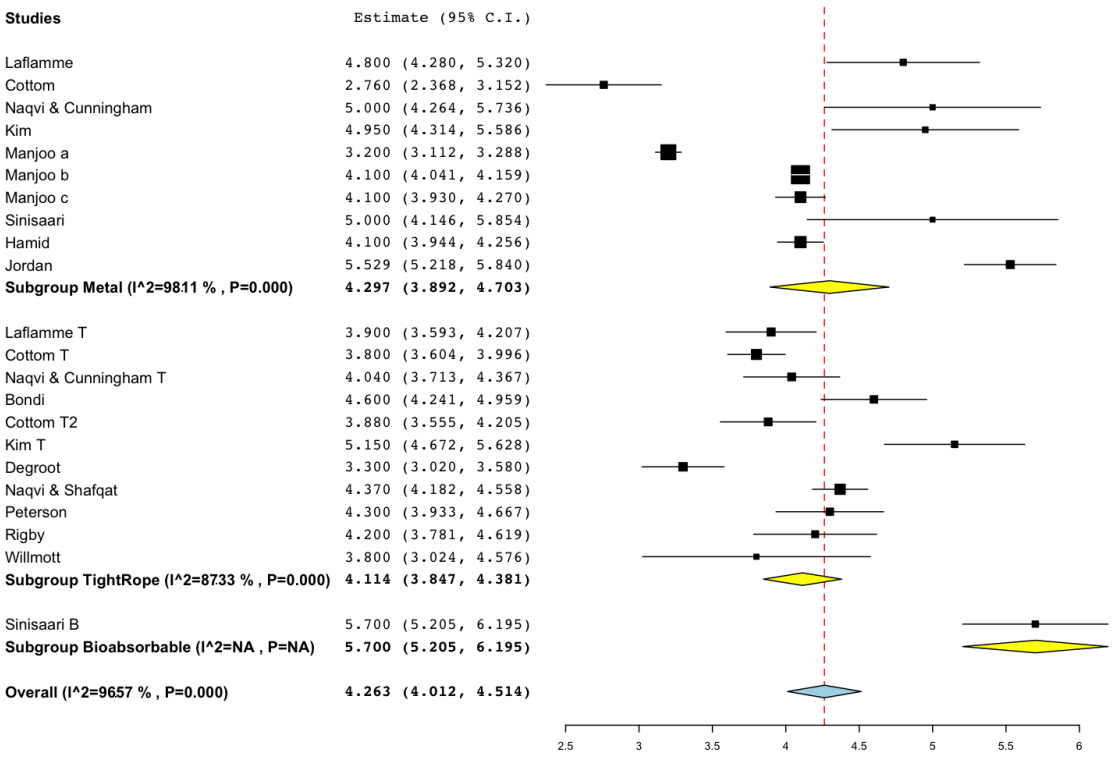
Figure 3.16 – Single group analysis of TFO (mm) for metal screws, TightRopes and bioabsorbable screws



3.5.6.3 Tibiofibular clear space

Tibiofibular clear space was recorded for 8 metal studies with a mean of 4.297mm (95% CI 3.892 - 4.703), (I^2=98.11%, p=0.000), 11 Tightrope studies with a mean of 4.114mm (95% CI 3.847 - 4.381), (I^2=87.33%, p=0.000) and 1 bioabsorbable study (5.700mm, 95% CI 5.205 – 6.195) (Figure 3.17). Overall mean TFC was 4.263mm (95% CI 4.012-4.514) with significant heterogeneity (I^2=96.57%, p=0.000). There were no significant differences between metal screws and TightRopes. The single bioabsorbable study had a significantly higher TFC.

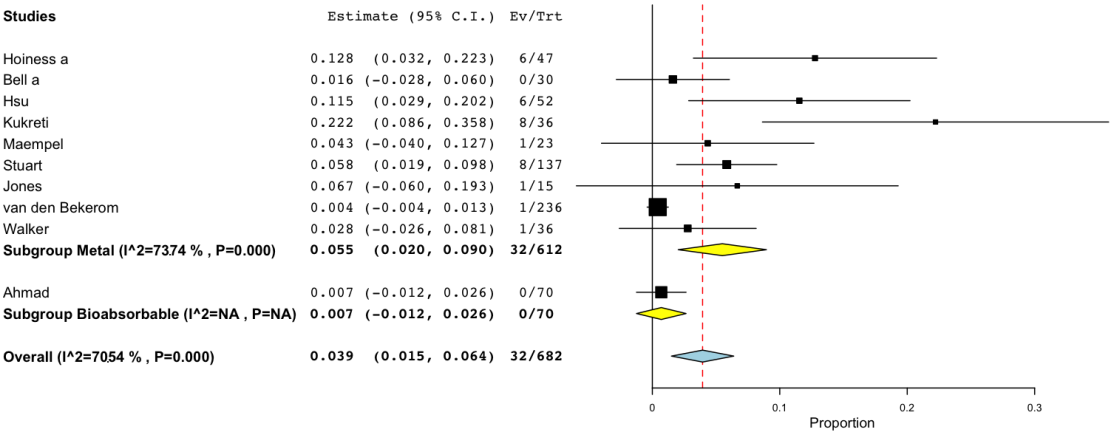
Figure 3.17 – Single group analysis of TFC (mm) for metal screws, TightRopes and bioabsorbable screws



3.5.6.4 Loss of reduction

Loss of reduction was recorded as a radiological complication in 9 metal studies with an incidence of 32/612 (0.055, 95% CI 0.020 – 0.090) and one bioabsorbable study with no cases documented (0/70) (Figure 3.18). No TightRope studies measured this outcome. Given the low numbers, there was no significant difference between metal screws and the single bioabsorbable study. Overall loss of reduction incidence was 32/682 (0.039, 95% CI 0.015 – 0.064).

Figure 3.18 – Single group analysis of loss of reduction for metal screws and bioabsorbable screws

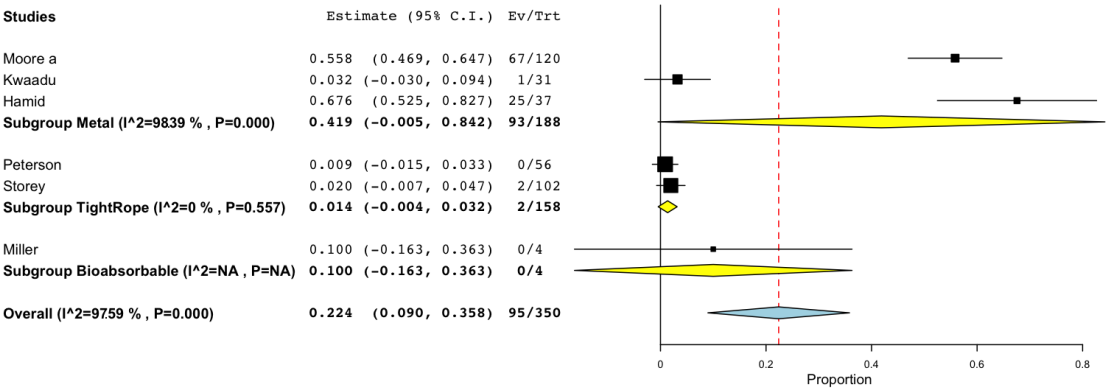


3.5.6.5 Lucency

Radiological lucency was recorded in 3 metal studies, 2 TightRope studies and 1 bioabsorbable study (Figure 3.19). Metal screw lucency incidence was 93/188 (0.419, 95% CI -0.005 – 0.842) with high heterogeneity (I^2=98.39%, p=0.000). Tightrope lucency incidence was 2/158 (0.014, 95% CI -0.004 – 0.842) with low heterogeneity (I^2=0%, p=0.557) and the single bioabsorbable study had 0/4 cases of lucency. The overall incidence of lucency was low (95/350, 0.224, 95% CI 0.090 – 0.358). Given the heterogeneity of the metal screw studies with a lucency rate ranging from 3.2% to 68%, there was no significant difference between the groups.

In subgroup analysis, Hamid[100] and Kaftandziev[52] noted that presence of lucency had no effect of AOFAS or VAS.

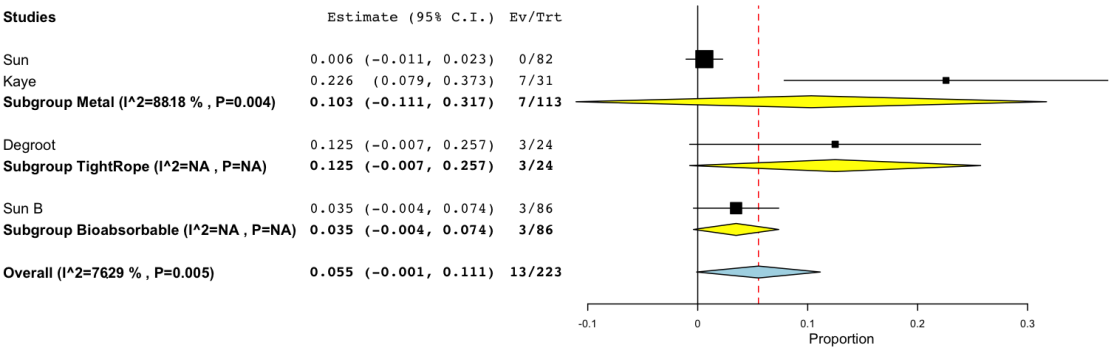
Figure 3.19 – Single group analysis of lucency on XR for metal screws, TightRopes and bioabsorbable screws



3.5.6.6 Heterotrophic ossification

The presence of heterotrophic ossification was documented in 2 metal screw studies, and in 1 each of TightRope and bioabsorbable studies (Figure 3.20). It occurred in 7/113 metal screw patients (0.103, 95% CI -0.111 – 0.317), 3/24 TightRope patients (0.125, 95% CI -0.007 – 0.257) and 3/86 bioabsorbable patients (0.035, 95% CI = -0.004 - 0.074). Overall incidence was low (13/223, 0.055, 95% CI -0.001 – 0.111). Heterogeneity was significant (I^2=76.29%, p=0.005).

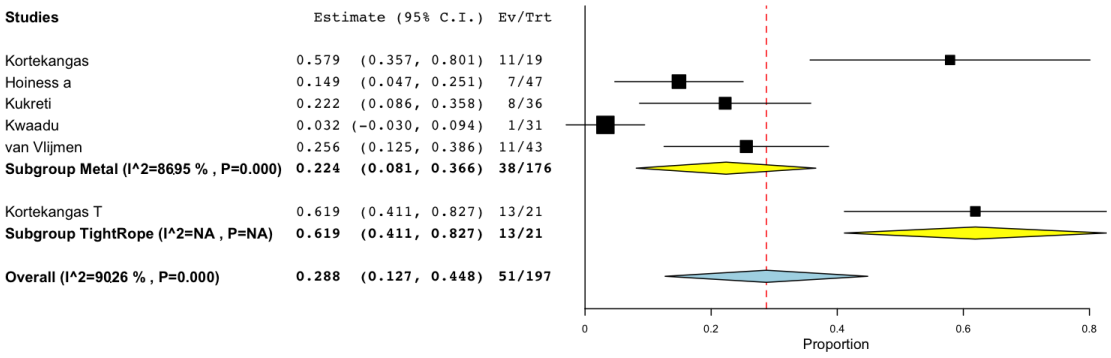
Figure 3.20 – Single group analysis of HO on XR for metal screws, TightRopes and bioabsorbable screws



3.5.6.7 Osteoarthritis

Osteoarthritis on imaging at final follow-up was recorded for 5 metal screw studies and a single TightRope study (Figure 3.21). Metal screw incidence was 38/176 (0.224, 95% CI 0.081 – 0.366) with high heterogeneity (I^2=86.95%, p=0.000). The recorded incidence in TightRope patients was 13/21 (0.619, ,95% CI 0.411 - 0.827) Overall incidence was 51/197 (0.288, 95% CI 0.127 – 0.448) with marked heterogeneity (I^2=90.26, p=0.000). The higher number of studies in the metal screw group reflect the fact that there were more long term studies in patients with metal screws and OA is a long term complication. The high incidence of OA in Kortekangas'[78] patients is due to CT imaging being used for OA diagnosis – a more sensitive modality than XR. As this is the only study included in the TightRope group it skews the analysis.

Figure 3.21 – Single group analysis of OA at final follow-up for metal screws, and TightRopes



CHAPTER 4: DISCUSSION

4.1 Outcome measures

Eleven different outcome measure scales have been used in the included studies. AOFAS and OMAS were the most commonly encountered but the others include OTA score, SF-12, SF-36, Bray score, Baird and Jackson score, LEM, FADI, SMFA and Total ankle score.

All treated syndesmotic injuries had an acceptable AOFAS score. The mean score overall was 89.854 (95% CI 87.957 - 91.751) corresponding to a 'good-excellent' result. The lowest included score was in Kaftandziev's early screw removal group with a mean of 83, corresponding to a 'good' result[52].

OMAS scores were also acceptable with an overall mean score of 79.673 (95% CI 74.362-84.983) corresponding to a 'good' result[50]. The lowest score encountered was in Manjoo's[94] patients with intact metal screws. This score represents a 'fair' result.

4.2 VAS

The overall VAS score was low in all included studies – 1.5 (95% CI 1.157 – 1.843). This corresponds to low pain. The highest score was noted in Wikeroy's[82] metal screw patients with scores of 4.5 and 4.9. This was the study with longest follow-up (8.4 years) and it is possible that these patients started developing significant arthritis or other ankle pathology.

4.3 ROM

ROM results showed variation. Mean dorsiflexion was 21.637° (95% CI 18.469 – 24.085) with a range of 8° to 35.5°. Plantarflexion mean was 39.085° (95% CI 37.387 – 42.224) with a range of 32° to 53°. Normal ankle ROM (range) in adult females age 20-44 is dorsiflexion 13.8° (12.9 – 14.7) and plantarflexion 62.1° (60.3-63.6) and in adult males age 20-44 is dorsiflexion 12.7° (11.6-13.8) and plantarflexion 54.6 (53.2-56.0)[129]. There is some restriction noted in the post injury ankles.

4.4 Complications

The overall complication rate was low. Implant breakage occurred in 9.1% (95% CI 5.2 - 13), implant removal in 13.4% (95% CI 8.5 – 18.2), implant loosening in 4.5% (95% CI 1.2 – 7.8), implant prominence in 3.7% (95% CI 0.7 - 6.6), foreign body reactions in 6.5% (95% CI 1.5 – 11.6), and infection in 2.7% (1.6 – 3.9%).

4.5 Radiological outcomes

Overall syndesmoses were reduced anatomically[18-20]. The mean MCS was 3.25mm (95% CI 3.149 – 3.50), TFO 7.189mm (95% CI 6.835 – 7.542) and TFC 4.263mm (95% CI 4.012 – 4.514). Loss of reduction was uncommon (3.9%, 95% CI 1.5% - 6.4%). Post-traumatic arthritis was common (28.8%, 95% CI 12.7 – 44.8%).

4.6 Specific comparisons

4.6.1 Metal screws vs TightRope

4.6.1.1 Outcome measures

Laflamme[79] noted a slightly higher OMAS in TightRope patients as compared to metal screw patients (mean (SD) = 93.3 (9.3) vs 87.7 (12.2) – p=0.046) - p=0.046). This corresponds to a maximum difference of 5.6 which is not a clinically significant difference. AOFAS in the same study was not different. Thornes[87] noted a statistically significant better AOFAS score in the suture button fixation group (93 vs 83 – p=0.04); a difference of 10 points. The included outcomes measures were not different in Cottom[85], Naqvi & Cunningham[46], Kim[88], Kocadal[89] and Seyhan[96]. Single group analysis found no significant difference overall.

There may be a minor positive effect in outcome measures favouring TightRopes over metal screws.

4.6.1.2 VAS

Laflamme[79], Kim[88] and Kortekangas[78] found no difference in VAS comparing TightRopes to metal screws. Single group analysis found no significant difference overall.

There is no difference in pain between TightRopes and metal screws.

4.6.1.3 ROM

Laflamme[79] and Kortekangas[78] found no difference in ROM comparing TightRopes to metal screws. Coetzee[74] noted a trend towards better ROM in the TightRope group (dorsiflexion 11° (4-20) vs 8° (2-20) – p=0.054, plantarflexion 53° (37-80) vs 43° (28-70) – p=0.054) but it did not reach statistical significance. Seyhan[96] noted less ROM restriction compared to the uninjured side in the TightRope patients. They recorded the ROM deficit compared to the uninjured side at 12 months for TightRope fixation and metal screw fixation with a 4.5mm 4 cortex single screw removed at 3 months. There was statistically significant better ROM in the TightRope group. Dorsiflexion deficit was 1.4° (1.14) vs 3.65° (1.54); p=0.001 and plantarflexion deficit was 2.67° (1.49) vs 8.41° (2.63);

– p=0.001. The two TightRope studies (Laflamme[79] and Coetzee[74]) included in single group analysis had lower dorsiflexion ROM than the other fixation methods overall, but no significant difference in ROM in the internal comparison against metal screws.

TightRopes may allow better range of motion.

4.6.1.4 Complications

Meta-analysis of Laflamme[79], Coetzee[74] and Kortekangas[78] found no difference in infection rate.

Laflamme[79] reported an implant irritation rate requiring removal of 1/33 (3%) in the TightRope group and 11/32 (34.4%) in the metal screw group; a significant difference. Kocadal[89] reported a lower incidence of symptomatic implant removal. It was required in 1/26 (3.8%) ZipTight fixations and 10/26 (38.5%) metal screw fixations. Seyhan[96] had moderate levels of prominent hardware necessitating removal in 6/15 (40%) TightRope patients and 4/17 (23.5%) 4.5mm screw patients. Although all metal patients were planned for screw removal, these 4 patients had significant irritation prior to removal. Thornes[87] reported an implant removal rate of 0/16 (0%) with suture button fixation vs 12/16 (75%) in the metal screw group – p=0.001.

Cottom[85] reported hardware removal due to loosening or breakage as a complication (5/25 (20%) and 7/25 (28%) respectively) in the metal screw group and no episodes in the TightRope group. Kim[88] noted a high implant failure rate for 3.5mm screws (5/24 (20.8%)) as compared to TightRopes (0/20).

Maempel[93] found a higher overall incidence of complications in the metal screw group (1/12 (8.3%) vs 3/23 (12.9%)). There was one suture abscess in the TightRope group and 1 each of infection, wound dehiscence and recurrent diastasis in the metal screw group, all following screw removal.

Single group analysis found a significantly higher incidence for screw breakage in metal screws. The total incidence of implant breakage in metal screws is 157/986 (0.130, 95% CI 0.072 – 0.189). There was high heterogeneity (I2=92.11%, p=0.000) which was to be expected as some studies reported screw breakage as a complication while others recorded it as one of their endpoints. There were no broken implants in the 120 included TightRope. Implant breakage appears to be unique to the metal screw group as a TightRope failure is more likely to be occult on XR. Single group analysis also noted a higher need for removal of hardware for metal screws. The rate of screw removal was significantly highest (84/325, 0.300 95% CI 0.142-0.458) and most varied (I2=95.02%, p=0.000) in the metal screw studies. TightRopes had a lower (but non-zero) incidence of implant removal (28/429, 0.044, 95% CI 0.022-0.067) with more consistent results (I2=25.56%, p=0.176). There was no difference in loosening, implant prominence, foreign body reaction or infection on single group analysis.

It is important to note that metal screws have a higher removal rate. This may be explained by some surgeons removing metal screws routinely and perceived ease of removal of metal screws as compared to the other implants.

TightRopes have a favourable complication profile as compared to metal screws.

4.6.1.5 Radiological outcomes

Kortekangas[78] reported a lower rate of malreduction on CT of 1/21(4.8%) in the TightRope group versus 3/19 (15.8%) in the metal screw group but this did not reach statistical significance – p=0.33. They also reported a CT diagnosed incidence of OA of 31/21 (62%) in the TightRope group and 11/19 (57.9%) in the metal screw group. This is rather high in both groups but does not statistically differ between groups (p=0.9). Laflamme[79] measured a lower TFC in the TightRope patients (TFC 3.9mm (0.9) vs 4.8mm (1.5) – p=0.008), MCS was not different. Cottom[85] found no significant difference in MCS and TFO but TFC was lower in the TightRope group (3.8mm (3-5) vs 2.76mm (4-8); p=0.0187). Naqvi & Cunningham[46] found the same (4.04mm (0.8) vs 5.0mm (1.8) – p<0.05). There was also a significantly lower incidence of malreduction in the TightRope group (0/23 vs 5/23 (21.7%) – p<0.05.). Kim[88] and Kocadal[89] found no radiological differences. Single group analysis noted no difference in MCS, TFO, TFC, loss of reduction, lucency or HO.

Kortekangas[78] and Naqvi & Cunningham[46] conclude that syndesmotic reduction may be more accurate in TightRope fixation as it is a dynamic fixation which allows the fibula to more accurately find its anatomical position in the incisures as compared to rigid fixation with a screw.

TightRopes have a lower incidence of malreduction and equally reduced syndesmotic measurements on XR.

4.6.1.6 Other outcomes

Thornes[87] noted a significantly shorter time for return to work for the suture button group (2.8 weeks vs 4.6 weeks – p=0.02).

4.6.2 Metal screws vs bioabsorbable screws

4.6.2.1 Outcome measures

Sun[80] and Sinisaari[97] found no difference in Baird and Jackson scores and OMAS respectively. Single group analysis found no difference in outcome measures.

4.6.2.2 VAS

No studies comparing metal screws to bioabsorbable screws reported VAS and only a single

descriptive bioabsorbable screw study[102] reported VAS.

4.6.2.3 ROM

Sun[80] reported significantly better ROM in the bioabsorbable group; dorsiflexion 26° (23-28) vs 18° (15-24); p=0.011 and plantarflexion 40° (36-45) vs 35° (33-40); p<0.001. Kaukonen[76] and Thordarson[81] found no difference in ROM. Single group analysis found no difference in ROM.

Bioabsorbable screws may allow better ROM as compared to metal screws.

4.6.2.4 Complications

Meta-analysis of Kaukonen[76] and Thordarson[81] found no difference in infection. Kaukonen[76] also reported 3 prominent screw heads in the bioabsorbable group (3/20 – 15%) and no non-infection complications in the metal screw group. Sun[80] reported 29/86 patients with bioabsorbable screws (33.7%) had symptomatic hardware with 5 significant foreign body reactions requiring debridement. The metal group had 4 cases of symptomatic hardware not requiring intervention. Sinisaari[97] and Thordarson[81] found no difference in complications. Single group analysis found that the total incidence of implant breakage in metal screws is 157/986 (0.130, 95% CI 0.072 – 0.189). There were no broken implants in the 43 included bioabsorbable screw patients. Bioabsorbable screws had a lower need for implant removal as compared to metal screws (2/113, 0.023, 95% CI -0.003 – 0.055) vs (84/325, 0.300 95% CI 0.142-0.458) with very consistent results (I^2=0%, p=0.974). Single group analysis found no difference in loosening, prominence, foreign body reaction and infection.

Bioabsorbable screws have a higher incidence of foreign body reaction but lower incidence of other complications.

4.6.2.5 Radiological outcomes

Sun[80] noted a higher incidence of HO in the bioabsorbable group (3/86 – 3.5% vs 0/82 – 0% - p=0.246). However, DeGroot[106] found that patients with HO did not have worse outcomes on AOFAS. Sinisaari[97] and Thordarson[81] found no difference in radiological outcomes. Single group analysis noted no difference in TFO. TFC was higher in the single included bioabsorbable screw study[97]. TFC was recorded for 8 metal studies with a mean of 4.297mm (95% CI 3.892 - 4.703) and 1 bioabsorbable study (5.700mm, 95% CI 5.205 – 6.195). There was no difference in loss of reduction, lucency or incidence of HO on single group analysis. The remaining measures of syndesmotic reduction were not significantly different.

Bioabsorbable screws may be associated with a greater incidence of HO but no difference in radiological outcomes otherwise.

4.6.2.6 Other outcomes

Kaukonen[76] noted a 15 minute longer operative time with use of a PLLA screw (95% CI -1.2 - -28.9; p=0.033).

4.6.3 Metal screw strategies

4.6.3.1 Outcome measures

Screw removal compared to retention had equivalent outcome measures in studies by Bell[84], Hsu[86], Schepers[95], Tucker[99] and Weening[101]. The patients of Hoiness and Wikeroy[75,82] had equivalent OMAS scores comparing a 3.5mm retained screw to a 4.5mm removed screw. Kaftandziev[90] found a higher mean AOFAS (SD) in those patients with broken screws (92.5 (6.05)) as compared to patients with intact screws (83.0 (12.2)) and patients post screw removal at 8-12 weeks (85.5 (11.6)); p=0.0496. The maximum difference was 9.5. Manjoo[94] found a clinically significant 23.8 higher mean OMAS (SD) in patients with removed screws (66.8 (6.7)) as compared to broken/loose (62.2 (4.9)) screws or intact screws (46.5 (7.9)). Hamid[100] found that AOFAS was best in broken screws over removed or intact screw. Mean AOFAS (SD) was highest in the broken screw group; 83.07 (13.59) vs 92.4 (12.69) VS 85.8 (11.33) P=0.0466. The greatest difference was 9.33.

Screw removal or breakage may improve outcome scores.

Number of cortices engaged had no difference in outcome measures as studied by Manjoo[94], Schepers[95], Hamid[100] and Weening[101].

Screw diameter has no effect on outcome measures as studied by Manjoo[94], Schepers[95] and Khan[77]

Screw number had no clinically significant effect on outcomes scores as measured by Schepers[95]. There was no difference in mean AOFAS (SD) ((91(14) vs 93 (11); p=n.s.) although there was a difference in OMAS (75 (25) vs 85 (16); p=0.043) between one and two screws. A 10 point difference in OMAS is not clinically significant.

Screw location also had no bearing on outcome scores as measured by Schepers[95].

4.6.3.2 VAS

The patients of Hoiness and Wikeroy[75,82] had equivalent VAS comparing a 3.5mm retained screw to a 4.5mm removed screw.

Screw number, diameter or number of cortices engaged had no difference in VAS as measured by

Schepers[95].

VAS was affected by screw location. Schepers[95] compared fixation levels dividing them as transsyndesmotic (0-20.99mm above the ankle joint or 21-40.99mm above the ankle joint) or suprasyndesmotic (41-60mm above the ankle joint). VAS was 1.7 (1.3), 1.5 (1.5) and 2.5 (1.6) in the groups respectively with a statistically higher VAS in the suprasyndesmotic group; p=0.024.

4.6.3.3 ROM

Hoiness[75] and Wikeroy[82] reported results for dorsiflexion of the same patient group at 3 months,12 months and 8 years comparing 3 cortex, 3.5mm, retained screws with 1, 4 cortices, 4.5mm, removed screws. They found no significant differences at 3 months 33.8° (6.8) vs 35.5° (7.9) – p=0.493 and 12 months 28° (7.9) vs 29.2° (8.7) p=0.296, but noted a small difference of 7.6° at 8 years 26.7° (9.7) vs 34.3° (14.9) – p=0.03.

Screw removal had no effect on ROM as measured by Bell[84].

Screw location had no effect on ROM as measured by Kukreti[92].

4.6.3.4 Complications

There was a higher incidence of wound infection following screw removal as measured by Hoiness[75].

Number of cortices engaged had no effect on complications according to Moore[83], Stuart[98] and Hamid[100].

There were no differences in complication rate with screw removal in Bell's[84] study. Hsu[86] noted that screws taken out later were more likely to be broken. There was a statistically significant higher incidence of screw breakage with screws removed later (0/19 (0%) at 6 weeks vs 3/20 (15%) at 6 weeks to 12 weeks vs 2/13 (15.4%) beyond 12 weeks; p=0.034).

Screws removed later are more likely to be broken.

Screw size was not associated with a different complication rate in Khan's study[77]. Smaller screw size was associated with a higher incidence of screw breakage in Stuart's[98] study. They compared 3.5mm, 4.0mm and 4.5mm screws. The rate of screw breakage was significantly higher in the smaller screw groups (8/62 (12.9%) vs 6/63 (9.5%) vs 0/12 (0%)); p=0.0489.

Smaller diameter screws may be associated with a higher incidence of screw breakage.

Screw location had no effect on complications as measured by Stuart[98].

4.6.3.5 Radiological outcomes

Wikeroy[82] compared 3 cortex, 3.5mm, retained screws with 1, 4 cortices, 4.5mm, removed screws. They found a significant difference in articular height 2.8 vs 3.3 – p=0.02 at 8 years with better cartilage preservation in the first group and CT measured syndesmotic width of 3.2mm vs 4.3mm p=0.025 suggesting better reduction.

Intact screws as compared to removed or broken screws had a lower TFC in the study by Manjoo[94] suggesting that intact screws may be able to over-reduce the syndesmosis. The mean TFC (SD) was significantly lower in patients with intact screws (3.2mm (0.2) vs 4.1mm (0.2) vs 4.1mm (0.3); p=0.005. However, MCS and TFO were not different in the study. Screw removal did not affect radiological outcomes in the studies by Bell[84], Hsu[86] and Kaftandziev[90].

Intact screws may be able to cause syndesmotic over-reduction.

There was no difference in radiological outcomes comparing 3 to 4 cortex fixation in studies by Moore[83], Manjoo[94] and Stuart[98]. Four cortical compared to three cortical fixation had a higher rate of synostosis on XR and MRI as measured by Karapinar[91].

Screw size had no effect on radiological outcomes as measured by Manjoo[94] and Stuart[98].

Screw location had no effect on radiological outcomes as measured by Kukreti[92] and Stuart[98].

4.6 Other findings of note

Trimalleolar fractures (as compared to other fracture patterns), increasing age and higher mechanism of injury were found to be associated with poorer AOFAS, OMAS and VAS in Schepers' study[95]. The authors performed a regression analysis and noted that trimalleolar fractures had poorer AOFAS (77 (23)), OMAS (60 (22)) and VAS (2.9 (1.2)) than either unimalleolar (95 (10); p=0.034, 83 (19); p=0.001, 1.4 (1.4); p=0.001) or bimalleolar fractures (92 (11); p=n.s., 73 (29); p=n.s., 19 (1.6); p=0.045). These differences are clinically significant. The beta for number of malleoli fractured on regression analysis is -7.6 for AOFAS (95% CI = -11.3 - -3.8), -7.6 for OMAS (95% CI = -1.0 - -0.5) and for VAS -0.5 (95% CI = -0.9 - -0.1). Ahmad[102] also noted the same findings. Trimalleolar fractures did worse on AOFAS and VAS as compared to the other fracture patterns (bimalleolar, Maisonneuve and dislocations). Mean AOFAS (range) was 78.6 (44-100) and mean VAS (range) was 3.9 (0-10). Compared to the overall scores for the entire study cohort (AOFAS 90, VAS 1.8) there was a significant difference (AOFAS p=0.002, VAS p=0.007). Again, this difference is clinically significant. Age was also associated with a poorer

outcome in all groups on regression analysis. Low energy trauma correlated with a better AOFAS as compared to high energy trauma (Beta 3.2, 95% CI = 0.7-5.7).

Syndesmotic non-or malreduction was associated with worse outcomes. Only two included studies reported on outcomes following malreduction. Weening[101] found a better (lower) mean score for reduced patients compared to not-reduced on the SMFA functional index (SD) (17.0 (4.4) vs 10.2 (5.9); p=0.04). Non-reduction was also significantly associated with a reduction in running ability (p = 0.05), accounting for 15% of the variance in the Olerud and Molander running subscale although the overall OMAS score was not different. Naqvi and Cunningham[46] on regression analysis concluded that malreduced syndesmoses had poorer outcomes on AOFAS (OR -12.39 (95% CI = -22.7 - -2.09)).

Stuart[98] ran a power analysis to assess various complications of different metal screw strategies. With their observed complication rate and an alpha of 0.05, screw location would require 59,390 patients, screw diameter between 3.5 and 4.0mm 1,656 patients, screw diameter between 3.5mm and 4.5mm screws 567 patients, screw diameter between 4.0mm and 4.5mm 345 patients and number of cortices 325 patients to gain a statistically significant results. These numbers are all higher than any single study included.

Hamid[100] and Kaftandziev[90] found that patients with lucency around their screws had no worse AOFAS or VAS.

Jordan[123] found a slight increase in TFO and TFC after screw removal but not MCS suggesting that the talus remains reduced in the mortise despite the slight widening of the syndesmosis.

4.7 Limitations of this review

This review does have some limitations. Due to the pre-existing lack of any strong evidence to guide treatment, a variety of fixation methods and techniques are employed in the included studies. A variable number of screws were used of varying diameter and number of cortices engaged. Some were planned to be removed and others not. Tightrope use varied also; 1 or 2 were used. Bioabsorbable screws were made of varied materials, had variable diameters and engaged varying numbers of cortices. This heterogeneity was evident in the single group analysis where results even in patients with the same types of implants varied significantly. Schepers[42] in 2012 performed a survey of Dutch orthopaedic and trauma surgeons regarding their practice around syndesmotic fixation. Eighty-one percent of surgeons used 1 screw, 9% used 2. Eighty-five percent of surgeons used 3.5mm screws, 11% used 4.5mm screws. Sixty-three percent of surgeons engaged 3 cortices, 31% engaged 4. Eighty-one percent of surgeons placed trans-syndesmotic screws, 16% used suprasyndesmotic screws. This highlights the varying practice

utilising just one type of implant.

Similarly, devices in the suture button implant group vary. A biomechanical cadaveric study compared the TightRope to the ZipTight implant.[130] There were no differences in simulated ROM or diastasis during loading but the load to implant failure was lower.

Complications were also reported broadly and there was wide variability between what studies defined as complications. Some studies for example used removal of screw as an endpoint or had patients with removed screws as one of the treatment groups, whereas other studies considered screw removal a complication. Some surgeons routinely remove metal screws, and metal screw removal may be perceived as easier than removing the other types of implants, perhaps accounting for the higher removal rate in metal screws.

Certain complications such as implant breakage may not be easily apparent for radiolucent implants such as bioabsorbable screws and the suture part of a TightRope so the true incidence of implant failure may be under-reported. However, a cadaveric model of TightRope and ZipTight failure found that the majority of failures (14/15) occurred via fibular fracture or device pull-through rather than loosening (1/15) suggesting that the majority of failures should be apparent on imaging.[130] Importantly, the radiological outcomes in terms of syndesmotic reduction are equal across the groups suggesting that even if these non-metal implants are failing, they are still stabilising the syndesmosis enough to maintain reduction or for long enough to allow syndesmotic healing.

The low number of included RCTs is another limitation of this review. Other studies of perhaps less sound methodology were used although this is the best available evidence at the time.

During study selection, other limitations arose. Only studies published in English were selected. There is likely to be a body of worldwide literature in other languages on the topic.

As this is a topic of ongoing research (nine active studies under the term ‘syndesmosis’ on the Clinical Trials register[131]) this review may need to be updated in the future. However, this is why the search was updated in April of 2017 with 5 new studies included. With 53 studies included, this is the most exhaustive review on the topic that the authors are aware of.

Orthopaedic literature has been known in the past to be subject to publication bias[132] whereby studies with positive findings may be selectively published over studies with negative findings. Another statistical limitation is the low number of studies presenting 95% confidence intervals and measures of variance for their results.

Not many included studies had long term follow-up. Three studies[82,109,120] only had follow-up of 5 years or longer. Certain complications, notably post traumatic arthritis take time to develop and the

true incidence of long term complications is not entirely clear from this review.

4.8 Implications for practice

Metal screws and TightRope implants are widely available for use by surgeons. Bioabsorbable screws for ankle fracture fixation are less so, and are not readily available, for example, where the authors work (South Australia). The benefit of this exhaustive review is evidence that in reality there are only minor differences in outcomes between the various fixation methods and strategies. What is important is an anatomical reduction of the syndesmosis and stabilisation with an implant that suits the patient and the surgeon.

Malreduction of the syndesmosis may be common[133]. One study noted a CT malreduction rate of 53% which was only evident on plain XR in 24% of cases. Naqvi and Cunningham[46] noted no cases of malreduction with use of the TightRope. A series of 5,271 patients were followed, of whom 79 underwent early revision[134]. The most common reason for revision (in 59% of patients) was a malreduced syndesmosis. Sagi et al compared patients with reduced to malreduced syndesmoses. A malreduced syndesmosis is associated with significantly poorer functional outcomes at long-term follow-up (2 years) as measured on SMFA Functional Index (12.0 vs 27.0, $p<0.05$) and OMAS (46.3 vs 72.7, $p<0.05$) and a trend (p=n.s.) towards poorer SMFA Bothersome (18.3 vs 30.8) and Emotional (19.7 vs 32.0) indices.[135]

The findings of this review suggest that screw removal is optional. It is not an entirely benign procedure. Andersen[136] followed a series of 161 patients with 1 or 2 metal syndesmotic screws, all 4 cortical 3.5, 4.0 or 4.mm with removal at 10-12 weeks under local anaesthesia with no antibiotic coverage. They reported 8 (5.0%) infections (2 requiring debridement, 1 responding to IV antibiotics and 5 requiring oral antibiotics) and 2 broken screws (1.2%). Schepers[137] followed 76 patients following metal syndesmotic screw removal under various anaesthetic techniques with no prophylactic antibiotics. Seven patients (9.2%) developed infections, 2 were deep requiring surgery. Five screws (6.6%) were broken at the time of removal.

Cost is an important factor for surgeons, hospitals and patients. The current prices (in 2017 Australian dollars) for metal screws around the 40-50mm length commonly used for syndesmotic stabilisation is $27.80 for 3.5mm and $22.60 for 4.5mm screws. The TightRope implant costs $394. However, Neary[138] performed an economic analysis comparing in the US the TightRope to 2 3.5mm metal screws without planned removal. They estimated a TightRope removal rate of 4% and metal screw removal rate of 20% (4.4% and 30% respectively according to this review). They estimated the cost of implants, operating room time, surgeon time, radiology and anaesthesia fees.

The estimated cost (in US dollars) for uncomplicated treatment was $17,969 for 2 3.5mm screws and $18,171 for one TightRope. The cost of a subsequent metal removal procedure was estimated to be $14,768. Although the TightRope is slightly more expensive, they concluded that with the lower rate of hardware removal it is a more cost effective treatment. The estimated cost per Quality Adjusted Life Year (QUALY) was $3,298 for 1 TightRope, $3,445 for 2 TightRopes, $3,576 for 1 3.5mm screw and $3,583 for 2 3.5mm screws.

4.9 Implications for research

There is a low number of good quality RCTs on the topic of syndesmotic fixation. It is not always entirely possible to apply perfect randomisation to a surgical study. Surgery is an art and a truly blinded RCT is not possible as the surgeon will be aware of which implant is being used. As such, reviews are important to pool data from lower quality studies to draw conclusions but obviously this will be limited by the quality of studies being included.

The outcome measures already exist and are validated so this is an area that lends itself to further research. Syndesmotic injuries are common and so the population exists for a large multi-centre RCT comparing syndesmotic fixation methods. This review however demonstrates that differences between methods are minimal and perhaps a large RCT would be a low yield exercise.

Finally, this review is likely to require updating in the future as more research is added to the body of evidence.

4.10 GRADE Summary of findings tables

Table 4.1 – GRADE Summary of findings table for TightRopes versus metal screws

Summary of findings:

TightRopes compared to Metal screws for Adults with acute syndesmotic injury

Patient or population: Adults with acute syndesmotic injury
Setting: Acute care hospital
Intervention: TightRopes
Comparison: Metal screws

Outcome № of participants (studies)	Impact	Certainty
Outcome scores follow up: range 85 days to 8.4 years № of participants: 1292 (29 observational studies)	Single group analysis: AOFAS 91.285 (95% CI 88.921 – 93.650) vs 88.222 (95% CI 86.132-90.311). OMAS 89.086 (95% CI 80.953 - 97.219) vs 77.253 (95% CI 70.650 - 83.855). There may be a minor positive effect in outcome measures favouring TightRopes over metal screws.	⨁◯◯◯ VERY LOW [a,b,c,d]
VAS follow up: range 85 days to 8.4 years № of participants: 438 (9 observational studies)	Single group analysis: VAS 0.993 (95% CI 0.209 - 1.777) vs 1.594 (95% CI 1.190 - 1.998). There is no difference in pain between TightRopes and metal screws.	⨁◯◯◯ VERY LOW [a,b,c,d]
ROM follow up: range 85 days to 8.4 years № of participants: 610 (17 observational studies)	Single group analysis: Dorsiflexion 12.526° (95% CI 10.016 - 15.035) vs 23.570° (95% CI 18.739 – 28.402). Plantarflexion 43.005° (95% CI 24.003 – 62.008) vs 38.564° (95% CI 34.831 – 42.290). Head to head studies: 3 studies no difference, 1 study less ROM restriction. TightRopes may allow better range of motion as compared to metal screws.	⨁◯◯◯ VERY LOW [a,b,c,e]
Complications follow up: range 85 days to 8.4 years № of participants: 1889 (33 observational studies)	Multiple comparisons. Infection: 4 studies no difference. Hardware removal: 3 studies less hardware removal. 1 study no difference. Implant breakage: 1 study less. Single group analysis: Implant breakage 0% vs 13% (95% CI 7.2-18.9%). Hardware removal 4.4% (95% CI 2.2-6.7%) vs 30% (95% CI 14.2-45.8%). TightRopes have a favourable complication profile as compared to metal screws.	⨁◯◯◯ VERY LOW [a,b,c]
Radiological outcomes follow up: range 85 days to 8.4 years № of participants: 1708 (33 observational studies)	Multiple comparisons. Malreduction 4.8% vs 15.8%. MCS: 3 studies no difference. TFC: 3 studies lower. TFO: 2 studies no difference. Single group analysis: MCS 3.302mm (95% CI 3.106-3.498) vs 3.141mm (95% CI 3.052 – 3.231). TFO: 7.466mm (95% CI 6.789 – 8.143) vs 6.837mm (95% CI 6.435-7.240). TFC: 4.114mm (95% CI 3.847 - 4.381) vs 4.297mm (95% CI 3.892 - 4.703). TightRopes have a lower incidence of malreduction and equally reduced syndesmotic measurements on XR.	⨁◯◯◯ VERY LOW [a,b,c,d]

***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).

CI: Confidence interval

GRADE Working Group grades of evidence
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

Explanations

a. Downgraded due to low number of included RCTs
b. Heterogeneity noted in results, but direction of effect is consistent
c. Varying metal screw strategies used as comparator
d. Few 95% CIs given in studies, but single group analysis had relatively narrow 95% CI
e. Few 95% CIs given in studies. Single group analysis had wide 95% CI

Table 4.2 – GRADE Summary of findings table for bioabsorbable versus metal screws

Summary of findings:

Bioabsorbable screws compared to Metal screws for Adults with acute syndesmotic injury

Patient or population: Adults with acute syndesmotic injury
Setting: Acute care hospital
Intervention: Bioabsorbable screws
Comparison: Metal screws

Outcome № of participants (studies)	**Impact**	Certainty
Outcome scores follow up: range 85 days to 8.4 years № of participants: 1123 (28 observational studies)	Head to head: 2 studies no difference. Single group analysis: AOFAS: 90.000 (95% CI 86.72-93.28) vs 88.222 (95% CI 86.132-90.311). OMAS: 88.609 (95% CI 77.019 - 100.199) vs 77.253 (95% CI 70.650 - 83.855) .There is no difference in outcome scores comparing bioabsorbable screws to metal screws.	⨁◯◯◯ VERY LOW a,b,c,d
ROM follow up: range 85 days to 8.4 years № of participants: 663 (17 observational studies)	Head to head: 1 study better ROM, 2 studies no difference. Single group analysis: DF: 22.113° (95% CI 16.585 - 27.640) vs 23.570° (95% CI 18.739 - 28.402). PF 41.891° (95% CI 38.028 - 45.755) vs 38.564° (95% CI 34.831 - 42.290). Bioabsorbable screws may allow better ROM as compared to metal screws.	⨁◯◯◯ VERY LOW a,b,c,d
Complications follow up: range 85 days to 8.4 years № of participants: 1622 (29 observational studies)	Various outcomes. Infection: 2 studies no difference. Prominent implant: 2 studies more prominent implants, 1 study no difference. Foreign body reaction: 1 study more foreign body reactions. Single group analysis: Implant breakage 0% vs 13% (95% CI 7.2 - 18.9%). Implant removal 2.3% (95% CI 0.3 - 5.5%) vs 30% (95% CI 14.2 - 45.8%). Bioabsorbable screws have a higher incidence of foreign body reaction but lower incidence of other complications as compared to metal screws.	⨁◯◯◯ VERY LOW a,b,c,e
Radiological outcomes follow up: range 85 days to 8.4 years № of participants: 1630 (27 observational studies)	Multiple comparisons. Head to head: HO: 1 study higher incidence of HO. Single group analysis: TFO: 6.000mm (95% CI 4.795 - 7.205) vs 6.837mm (95% CI 6.435-7.240). TFC: 5.700mm (95% CI 5.205 - 6.195) vs 4.297mm (95% CI 3.892 - 4.703). Bioabsorbable screws may be associated with a greater incidence of HO but no difference in radiological outcomes otherwise, as compared to metal screws.	⨁◯◯◯ VERY LOW a,b,c,d

***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).

CI: Confidence interval

GRADE Working Group grades of evidence
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

Explanations

a. Downgraded due to low number of included RCTs
b. Heterogeneity noted in results, but direction of effect is consistent
c. Varying metal screw strategies used as comparator
d. Few 95% CIs given in studies. Single group analysis had wide 95% CI
e. Few 95% CIs given in studies, but single group analysis had relatively narrow 95% CI

Table 4.3 – GRADE Summary of findings table for metal screws strategies

Summary of findings:

Any metal screw strategy compared to A different metal screw strategy for Acute syndesmotic injury

Patient or population: Acute syndesmotic injury
Setting: Acute hospital setting
Intervention: Any metal screw strategy
Comparison: A different metal screw strategy

Outcome № of participants (studies)	**Impact**	Certainty
Outcome scores follow up: range 85 days to 8.4 years № of participants: 988 (244 observational studies)	Multiple outcomes. Screw removal: 5 studies no difference. Screw breakage: 3 studies better outcome. Number of cortices: 4 studies no difference. Screw diameter: 3 studies no difference. Screw number: 1 study no difference. Screw location: 1 study no difference. Screw removal or breakage may improve outcome scores. Number of cortices engaged, screw diameter, screw number and screw location do not affect outcome scores.	⨁◯◯◯ VERY LOW a,b,c
VAS follow up: range 85 days to 8.4 years № of participants: 384 (9 observational studies)	Multiple outcomes. Screw number: 1 study no difference. Screw diameter: 1 study no difference. Number of cortices: 1 study no difference. Screw location: 1 study higher VAS with suprasyndesmotic screws. Screw diameter, number or number of cortices engaged does not affect VAS. Suprasyndesmotic screws are associated with higher pain scores.	⨁◯◯◯ VERY LOW a,b,c
ROM follow up: range 85 days to 8.4 years № of participants: 517 (16 observational studies)	Multiple outcomes. Screw removal: 1 study no difference. Screw location: 1 study no difference. Retained screws may reduce ROM on long-term follow-up. Screw location and removal had no effect on ROM.	⨁◯◯◯ VERY LOW a,b,c
Complications follow up: range 85 days to 8.4 years № of participants: 1394 (24 observational studies)	Multiple outcomes. Screw removal: 1 study more infection. Number of cortices: 3 studies no difference. Screw size: 1 study more breakage with smaller screws, 1 study no difference. Screw location: 1 study no difference. Screw removal may be associated with a higher risk of wound infection. Smaller screw size may be associated with a higher risk of screw breakage. Number of cortices and screw location had no effect on complications.	⨁◯◯◯ VERY LOW a,b,c
Radiological outcomes follow up: range 85 days to 8.4 years № of participants: 1443 (26 observational studies)	Multiple outcomes. Screw removal: 3 studies no difference. Number of cortices: 1 study more synostosis, 3 studies no difference. Screw size: 2 studies no difference. Screw location: 2 studies no difference. Intact screws may be able to cause syndesmotic over-reduction. Screw size and location have no effect on radiological outcomes. Four cortical screws may be associated with a greater risk of heterotrophic ossification.	⨁◯◯◯ VERY LOW a,b,c

*__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).

CI: Confidence interval

GRADE Working Group grades of evidence
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

Explanations

a. Downgraded due to low number of included RCTs
b. Heterogeneity noted in results. Varying effects. Multiple outcomes.
c. Various treatment strategies compared

CHAPTER 5: CONCLUSION

Syndesmotic injuries associated with ankle fracture are common. This review identified 53 studies assessing fixation methods of acute syndesmotic injury. There are minor differences between metal screws, TightRopes and bioabsorbable screws. There are also minor differences when comparing the various metal screw strategies. All treatment strategies have acceptable functional outcomes, pain, range of motion, XR parameters and an acceptable complication profile. What is important is recognising the syndesmotic injury and performing anatomical reduction and stabilisation. This review supports the notion that surgeons should continue to use the implant that they are familiar with, gives them good result and is best tailored to the needs of the patient.

CHAPTER 6: REFERENCES

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CHAPTER 7: APPENDICES

APPENDIX I: A PRIORI PROTOCOL

Review title

Fixation methods for acute injuries of the ankle syndesmosis: a systematic review protocol

Reviewers

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Review question/objective

The objective of this review is to compare the effectiveness of several fixation methods for fixation of acute ankle syndesmotic injury. Metal screw fixation, bioabsorbable screw fixation and suture button fixation will be compared in adult patients with acute syndesmotic injuries. Outcomes to be measured include functional outcome measures, range of motion, complications, pain and radiological indices. Subgroup analysis of metal screws will aim to identify the most effective strategy regarding number, diameter and location of screws as well as number of cortices engaged and removal or retention of the screws.

The reviewers seek to critically evaluate the available evidence to provide an evidence-based appraisal of the comparative safety and efficacy of the treatment strategies.

Background

Syndesmotic injuries requiring fixation are common. Multiple treatment strategies exist but significant debate remains regarding fixation techniques, implant type and the need for removal of implants.[1]

In the ankle, the distal tibio-fibular joint is a syndesmotic articulation without articular cartilage. It is stabilized by the anterior and posterior tibiofibular ligaments, the inferior transverse ligament and the interosseous membrane.[2] The fibula rotates, translates and migrates within the incisura to maintain congruence with the wedge shaped talus through talocrural range of motion.[1] Subtle motion of the fibula at this joint is important for ankle congruity to allow normal ankle motion and prevent joint degeneration.[3] The ankle is a highly congruent joint and even a 1mm talar shift decreases contact area by 42%.[4]

Injuries to the distal tibiofibular syndesmosis are common, occurring in 5-10% of ankle sprains and 23% of ankle fractures.[1] An unstable syndesmosis leads to ankle instability and pain.[1] There are various treatment strategies to stabilize the syndesmosis and these vary between institutions and surgeons. Following reduction of the syndesmosis, the current most widely used treatment is placement of one or two 3.5mm, 4.0 or 4.5mm diameter metal screws between the fibula and tibia at 1.5 to 2cm proximal to the joint surface, penetrating three or four cortices of bone.[1,2] Aftercare and weight bearing depend on fracture pattern and stability.

Practice regarding removal of metal syndesmotic screws varies. Intact syndesmotic screws limit normal fibular translation[5] and it is this normal motion that may lead to screw breakage once weight bearing resumes, occurring in 7-29% of cases,[1] with 3.5mm diameter screws more likely to break than 4.0 or 4.5mm screws.[6] Screws may be removed routinely at 6 to 12 weeks post operatively to avoid screw breakage and allow normal motion at the syndesmosis, however this requires further surgery exposing the patient to a risk of complications and an economic cost to the health system.

A recent development is suture button fixation. A non-absorbable suture is passed through a drill tunnel through the tibia and fibula and secured at both ends by buttons. It is a less rigid fixation than screw fixation but allows dynamic stabilization with more normal motion and does not require routine removal.[7]

Additionally, an evolution of the syndesmotic screw is the bioabsorbable screw.

Traditional screws are made of stainless steel or titanium, while bioabsorbable screws are made of polyglycolic (PGA) or polylactic (PLA) acid. They are weaker than metal screws with PLA screws stronger and slower to resorb than PGA.[8] They have the benefit of not needing removal; eventually losing integrity to allow normal tibiofibular motion.[9]

In clinical practice, the question remains as to which fixation method – metal screws, bioabsorbable screws or suture button fixation has the best outcomes. Even with the most commonly used implant (metal screws), questions remain regarding diameter, number, position and number of cortices engaged. Whether or not the screws should be removed also is unclear.

A preliminary search of PubMed, the Cochrane library and the JBI library found a single 2007 systematic review of syndesmotic injuries which included only two patients who had surgery[10] and no meta-analyses. Therefore, there is a need to conduct a systematic review of current approaches to fixation for acute syndesmotic injury to summarize the evidence and provide guidance for clinical practice and research.

Inclusion criteria

Types of participants

This review will consider studies that include adult patients (over 18) with acute syndesmotic injuries requiring surgical stabilization (with or without associated fracture). As classified by the AO (Association for Osteosynthesis) fracture classification system,[11] malleolar region fractures (44-A, B and C) will be included as these are the ankle fractures most commonly associated with syndesmotic injury.

Patients with other associated ankle fractures including tibial plafond and other long bone fractures will be excluded as these patients' outcomes are likely to be affected by their other injuries. Chronic syndesmotic injuries (>6 weeks old) will be excluded as these have different management strategies and may have worse outcomes.[12] Studies in languages other than English without an accessible translation will be excluded.

Types of interventions of interest

This review will consider studies that will evaluate fixation of acute syndesmotic injuries with metal screws, suture button or bioabsorbable screws. The fixation should occur within 6 weeks of the injury in the acute hospital setting and be performed by a surgeon.

Types of outcomes

This review will consider studies that include the following outcome measures: compound functional scores, range of motion, pain as measure by visual-analogue scale or other metrics, radiological measurements of the syndesmosis and complications. Compound functional scores such as the Olerud-Molander[13], the American Orthopedic Foot and Ankle Society ankle-hindfoot score and the American Academy of Orthopedic Surgeons foot and ankle score[14] will be sought where reported. Where algorithms to compare the various scores exist they will be utilized.

Types of studies

This review will consider both experimental and epidemiological study designs including randomized controlled trials, non-randomized controlled trials, quasi-experimental, before and after studies, prospective and retrospective cohort studies, case control studies and analytical cross sectional studies for inclusion. This review will also consider descriptive epidemiological study designs including case series, individual case reports and descriptive cross sectional studies with or without a control group for inclusion.

Search strategy

A comprehensive and exhaustive literature search will be performed. The search strategy aims to find both published and unpublished studies. A three-step search strategy will be utilized in this review. An initial limited search of MEDLINE and CINAHL will be undertaken followed by analysis of the text words contained in the title and abstract, and of the index terms used to describe article. A second search using all identified keywords and index terms will then be undertaken across all included databases. Thirdly, the reference list of all identified reports and articles will be searched for additional studies. Studies published in English will be considered for inclusion in this review. Studies published after 1900 will be considered for inclusion

in this review.

The databases to be searched include: PubMed, Embase, Scopus, The Cochrane Central Register of Controlled Trials, Web of Science.

The search for unpublished studies will include: Scirus, Mednar, ProQuest theses and dissertations, and Grey Source, Index to Theses, Libraries Australia

Initial keywords to be used will be:

syndesmos*[tw] OR syndesmot*[tw] OR (tibiofibular[tw] AND distal[tw]) OR (tibio-fibular[tw] AND distal[tw]) OR (diastasis[tw] AND ankle[tw]) OR ("high ankle"[tw] AND sprain[tw]) OR (high-ankle[tw] AND sprain[tw]) OR AITFL[tw] OR PITFL[tw] OR "anterior inferior tibiofibular ligament"[tw] OR "posterior inferior tibiofibular ligament"[tw] OR "anterior inferior tibio-fibular ligament"[tw] OR "posterior inferior tibio-fibular ligament"[tw]

Assessment of methodological quality

Papers selected for retrieval will be assessed by two independent reviewers for methodological validity prior to inclusion in the review using standardized critical appraisal instruments from the Joanna Briggs Institute Meta Analysis of Statistics Assessment and Review Instrument (JBI-MAStARI). Any disagreements that arise between the reviewers will be resolved through discussion, or with a third reviewer.

Data collection

Data will be extracted from papers included in the review using the standardized data extraction tool from JBI-MAStARI. The data extracted will include specific details about the interventions, populations, study methods and outcomes of significance to the review question and specific objectives.

Data synthesis

Quantitative data will, where possible be pooled in statistical meta-analysis using JBI-MAStARI or RevMan where appropriate. All results will be subject to double data entry. Effect sizes expressed as odds ratio (for categorical data) and weighted mean differences (for continuous data) and their 95% confidence intervals will be calculated for analysis. Heterogeneity will be assessed statistically using the

standard Chi-square and I^2 and also explored using subgroup analyses based on the different study designs included in this review. Where statistical pooling is not possible the findings will be presented in narrative form including tables and figures to aid in data presentation where appropriate. Forest plots and a GRADE Summary of Findings table will aid in the presentation of results.

If sufficient quality data are extracted, subgroup analysis will be performed for metal screws evaluating: screw diameter, number of screws, number of cortices engaged, location relative to syndesmosis and screw removal versus retention.

Conflicts of interest

None to declare

Acknowledgements

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APPENDIX II: SEARCH STRATEGY

Keywords selected:

syndesmos*

syndesmot*

tibiofibular AND distal

tibio-fibular AND distal

diastasis AND ankle

“high ankle” AND sprain

high-ankle AND sprain

Each keyword searched using “OR” Boolean operator. Where available the ‘all fields’ option was selected for all databases.

Database	**Date**	**Hits**	**Strategy**
CINAHL	17/02/2016	396	syndesmos* OR syndesmot* OR (tibiofibular AND distal) OR (tibio-fibular AND distal) OR (Diastasis AND ankle) OR (“high ankle” AND sprain) OR (high-ankle AND sprain)
Cochrane Central Trials Register	17/02/2016	47	syndesmos* OR syndesmot* OR (tibiofibular AND distal) OR (tibio-fibular AND distal) OR (Diastasis AND ankle) OR (“high ankle” AND sprain) OR (high-ankle AND sprain)

EMBASE	17/02/2016	1445	syndesmos* OR syndesmot* OR (tibiofibular AND distal) OR (tibio-fibular AND distal) OR (Diastasis AND ankle) OR (“high ankle” AND sprain) OR (high-ankle AND sprain)
Libraries Australia	17/02/2016	0	syndesmos*[tw] OR syndesmot*[tw] OR (tibiofibular[tw] AND distal[tw]) OR (tibio-fibular[tw] AND distal[tw]) OR (Diastasis[tw] AND ankle[tw]) OR (“high ankle”[tw] AND sprain[tw]) OR (high-ankle[tw] AND sprain[tw])
Mednar	17/02/2016	432	syndesmos*[tw] OR syndesmot*[tw] OR (tibiofibular[tw] AND distal[tw]) OR (tibio-fibular[tw] AND distal[tw]) OR (Diastasis[tw] AND ankle[tw]) OR (“high ankle”[tw] AND sprain[tw]) OR (high-ankle[tw] AND sprain[tw])
Open Grey	17/02/2016	2	syndesmos* OR syndesmot* OR (tibiofibular AND distal) OR (tibio-fibular AND distal) OR (Diastasis AND ankle) OR (“high ankle” AND sprain) OR (high-ankle AND sprain)
Proquest	17/02/2016	8	syndesmos* OR syndesmot* OR (tibiofibular AND distal) OR (tibio-fibular AND distal) OR (Diastasis AND ankle) OR (“high ankle” AND sprain) OR (high-ankle AND sprain)
PubMed/MEDLINE	17/02/2016	1215	syndesmos*[tw] OR syndesmot*[tw] OR (tibiofibular[tw] AND distal[tw]) OR (tibio-fibular[tw] AND distal[tw]) OR (Diastasis[tw] AND ankle[tw]) OR (“high ankle”[tw] AND sprain[tw]) OR (high-ankle[tw] AND

			sprain[tw])
Scopus	17/02/2016	3402	syndesmos* OR syndesmot* OR (tibiofibular AND distal) OR (tibio-fibular AND distal) OR (Diastasis AND ankle) OR (“high ankle” AND sprain) OR (high-ankle AND sprain)
Web of Science	17/02/2016	1958	syndesmos* OR syndesmot* OR (tibiofibular AND distal) OR (tibio-fibular AND distal) OR (Diastasis AND ankle) OR (“high ankle” AND sprain) OR (high-ankle AND sprain)

APPENDIX III - MASTARI APPRAISAL INSTRUMENT

JBI Critical Appraisal Checklist for Randomised Control / Pseudo-randomised Trial

Reviewer _____ Date _____

Author _____ Year _____ Record Number _____

	Yes	No	Unclear	Not Applicable
1. Was the assignment to treatment groups truly random?	☐	☐	☐	☐
2. Were participants blinded to treatment allocation?	☐	☐	☐	☐
3. Was allocation to treatment groups concealed from the allocator?	☐	☐	☐	☐
4. Were the outcomes of people who withdrew described and included in the analysis?	☐	☐	☐	☐
5. Were those assessing outcomes blind to the treatment allocation?	☐	☐	☐	☐
6. Were the control and treatment groups comparable at entry?	☐	☐	☐	☐
7. Were groups treated identically other than for the named interventions	☐	☐	☐	☐
8. Were outcomes measured in the same way for all groups?	☐	☐	☐	☐
9. Were outcomes measured in a reliable way?	☐	☐	☐	☐
10. Was appropriate statistical analysis used?	☐	☐	☐	☐
	☐	☐	☐	☐

Overall appraisal: Include ☐ Exclude ☐ Seek further info. ☐

Comments (Including reason for exclusion)

JBI Critical Appraisal Checklist for Descriptive / Case Series

Reviewer _____ Date _____

Author _____ Year _____ Record Number _____

	Yes	No	Unclear	Not Applicable
1. Was study based on a random or pseudo-random sample?	☐	☐	☐	☐
2. Were the criteria for inclusion in the sample clearly defined?	☐	☐	☐	☐
3. Were confounding factors identified and strategies to deal with them stated?	☐	☐	☐	☐
4. Were outcomes assessed using objective criteria?	☐	☐	☐	☐
5. If comparisons are being made, was there sufficient descriptions of the groups?	☐	☐	☐	☐
6. Was follow up carried out over a sufficient time period?	☐	☐	☐	☐
7. Were the outcomes of people who withdrew described and included in the analysis?	☐	☐	☐	☐
8. Were outcomes measured in a reliable way?	☐	☐	☐	☐
9. Was appropriate statistical analysis used?	☐	☐	☐	☐

Overall appraisal: Include ☐ Exclude ☐ Seek further info ☐

Comments (Including reason for exclusion)

JBI Critical Appraisal Checklist for Comparable Cohort/ Case Control

Reviewer _____ Date _____

Author _____ Year _____ Record Number _____

	Yes	No	Unclear	Not Applicable
1. Is sample representative of patients in the population as a whole?	☐	☐	☐	☐
2. Are the patients at a similar point in the course of their condition/illness?	☐	☐	☐	☐
3. Has bias been minimised in relation to selection of cases and of controls?	☐	☐	☐	☐
4. Are confounding factors identified and strategies to deal with them stated?	☐	☐	☐	☐
5. Are outcomes assessed using objective criteria?	☐	☐	☐	☐
6. Was follow up carried out over a sufficient time period?	☐	☐	☐	☐
7. Were the outcomes of people who withdrew described and included in the analysis?	☐	☐	☐	☐
8. Were outcomes measured in a reliable way?	☐	☐	☐	☐
9. Was appropriate statistical analysis used?	☐	☐	☐	☐

Overall appraisal: Include ☐ Exclude ☐ Seek further info. ☐

Comments (Including reason for exclusion)

APPENDIX IV: EXCLUDED STUDIES

1) Aksu, N., et al. (2013). "A time proven simple physiologic technique: Fixation of syndesmotic ruptures with fibula fractures by ANK nail." Injury 44: S11.

   Conference paper evaluating a different syndesmotic stabilisation device

2) Andersen, M. R., et al. (2015). "High complication rate after syndesmotic screw removal." Injury 46(11): 2283-2287

   Study assessing complications related to screw removal only

3) Bai, X. D., et al. (2006). "Operative treatment for separation of distal tibiofibular syndesmosis." Chinese Journal of Traumatology - English Edition 9(3): 175-180.

   Study included other syndesmotic fixation methods including no treatment, ligament reconstruction and external fixation

4) Buckley, R. (2005). "Tricortical screws were as effective as quadricortical screws in ankle fractures at 1 year." Journal of Bone and Joint Surgery - Series A 87(2): 465.

   A one page summary of one of the included studies (Hoiness 2004)

5) Casillas, M. M. (2006). "Operative treatment of acute syndesmotic injuries with screw fixation and without direct exposure or repair of the syndesmotic ligaments." Techniques in Foot and Ankle Surgery 5(1): 27-33.

   A technique paper with a case series of 2 patients and no outcomes recorded

6) Darwish, H. H., et al. (2012). "Compression Screw Fixation of the Syndesmosis." Foot & Ankle International 33(10): 893-899 897p.

   Cadaveric study

7) De Vil, J., et al. (2009). "Bolt fixation for syndesmotic injuries." Injury 40(11): 1176-1179.

   Syndesmotic stabilisation performed with a barbed metal bolt

8) Dingemans, S. A., et al. (2016). "Should syndesmotic screws be removed after surgical fixation of unstable ankle fractures? a systematic review." (2049-4408 (Electronic)).

   Systematic review of screw removal

9) ElRayes, M. and A. Hammoda (2007). "Screw versus staple in stabilization of diastasis of tibiofibular syndesmosis." Foot and Ankle Surgery 13(1): 5-9.

   Syndesmotic staple fixation evaluated. In screw group, results not reported in a reliable manner.

10) Farhan, M. J. and T. W. D. Smith (1985). "Fixation of diastasis of the inferior tibiofibular joint using the syndesmosis hook." Injury 16(5): 309-311.

    Syndesmotic stabilisation performed with a metal hook passed around the fibula

and fixed to the tibia with a screw.

11) Georgiadis, A. G., et al. (2015). "Suture fixation of the syndesmosis using readily available materials." Foot and Ankle International 36(11): 1378-1383.

Syndesmotic stabilisation with a surgeon made TightRope style implant. Only illustrative cases included.

12) Inge, S. Y., et al. (2016). "A systematic review on dynamic versus static distal tibiofibular fixation." (1879-0267 (Electronic)).

Systematic review comparing metal screws to suture button type constructs

13) Kabukcuoglu, Y., et al. (2000). "The ANK device: a new approach in the treatment of the fractures of the lateral malleolus associated with the rupture of the syndesmosis." Foot Ankle Int. 21(9): 753-758.

Syndesmotic stabilisation with an ANK device – a solid intramedullary fibular wire with a loop passing to the tibia for fixation with a screw

14) Kara, A. N., et al. (1999). "A different approach to the treatment of the lateral malleolar fractures with syndesmosis injury: the ANK nail." J Foot Ankle Surg. 38(6): 394-402.

Study evaluating ANK device

15) Marqueen, T., et al. (2005). "Comparison of the syndesmotic staple to the transsyndesmotic screw: a biomechanical study." Foot & Ankle International 26(3): 224-230 227p.

Cadaveric study

16) Naqvi, G. A., et al. (2011). "Treatment of tibiofibular syndesmotic disruptions with Arthrex TightropeTM." Irish Journal of Medical Science 180: S102-S103.

Conference paper of Naqvi 2012

17) Neary, K. C., et al. (2016). "Suture Button Fixation Versus Syndesmotic Screws in Supination-External Rotation Type 4 Injuries." (1552-3365 (Electronic)).

Systematic review cost effectiveness analysis of suture button

18) Seyhan, M., et al. (2013). "Comparison of screw fixation with elastic fixation methods in the treatment of syndesmosis injuries in ankle fractures." Injury 44: S30-S31.

Conference paper of Seyhan 2015

19) Solan, M. C., et al. (2017). "Syndesmosis Stabilisation: Screws Versus Flexible Fixation." (1558-1934 (Electronic)).

Narrative review of screws vs flexible fixation

20) Tempesta, V., et al. (2013). "Tightrope for the treatment of ankle syndesmosis injuries: A multicentric study." Journal of Orthopaedics and Traumatology 14(1): S53-S54.

Conference paper lacking detailed results

21) van der Elst, M., et al. (2007). "Fixation of syndesmotic disruption using bioresorbable screws." Operative Orthopadie und Traumatologie 19(3): 294-304.
Paper on surgical techniques. No outcomes measured