FOOT AND ANKLE

Should syndesmotic screws be removed after surgical fixation of unstable ankle fractures?

A SYSTEMATIC REVIEW

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Aims
In approximately 20% of patients with ankle fractures, there is a concomitant injury to the syndesmosis which requires stabilisation, usually with one or more syndesmotic screws. The aim of this review is to evaluate whether removal of the syndesmotic screw is required in order for the patient to obtain optimal functional recovery.

Materials and Methods
A literature search was conducted in Medline, Embase and the Cochrane Library for articles in which the syndesmotic screw was retained. Articles describing both removal and retaining of syndesmotic screws were included. Excluded were biomechanical studies, studies not providing patient related outcome measures, case reports, studies on skeletally immature patients and reviews. No restrictions regarding year of publication and language were applied.

Results
A total of 329 studies were identified, of which nine were of interest, and another two articles were added after screening the references. In all, two randomised controlled trials (RCT) and nine case-control series were found. The two RCTs found no difference in functional outcome between routine removal and retaining the syndesmotic screw. All but one of the case-control series found equal or better outcomes when the syndesmotic screw was retained. However, all included studies had substantial methodological flaws.

Conclusions
The currently available literature does not support routine elective removal of syndesmotic screws. However, the literature is of insufficient quality to be able to draw definitive conclusions. Secondary procedures incur a provider and institutional cost and expose the patient to the risk of complications. Therefore, in the absence of high quality evidence there appears to be little justification for routine removal of syndesmotic screws.

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Ankle fractures are common, with an incidence of 100.8 per 100 000 people per year in the United Kingdom. In the Netherlands it is estimated that more than 25 000 people suffer from an ankle fracture each year and the incidence is rising worldwide. In general, younger people are at risk of ankle fractures because of a more active lifestyle while the elderly are also at risk because of poorer bone quality especially when combined with increased physical activity. Approximately half of the patients with an ankle fracture require surgical treatment because of joint instability or incongruence. In about 20% of ankle fractures there is a concomitant injury of the syndesmosis requiring stabilisation. There have been numerous studies regarding the placement of syndesmotic screws, including the optimal number of screws, their diameter, the level of placement and whether they should engage three or four cortices, but the results are inconclusive.

Usually after a period of eight to 12 weeks the syndesmosis is considered to have healed and the screw is no longer necessary. There is however controversy about the best time to remove this screw. During normal walking the fibula rotates and the syndesmosis widens due to the talus being shaped like a truncated cone. The presence of the screw may restrict this motion. Removal after eight to ten weeks has been advocated in order to allow free movement and to minimise the chance of screw breakage. However, several reports have described similar outcomes in patients in whom the syndesmotic screws were either retained or removed.
The aim of this review was to analyse the functional outcomes in adult patients with unstable ankle fractures, for whom syndesmotic screws were inserted and were either subsequently retained or removed.

**Materials and Methods**

This systematic review was conducted on the 22 December 2015 using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines. The following databases were searched: Medline (PubMed), Embase and the Cochrane library. Search-terms used were: Ankle fractures; Ankle injuries; Bone screws; Syndesmo*; Transsyn-desmos*; Device removal; Reten*; Retain*; Hold*; Preserve*. (Full search strings are available online in the supplementary material). No restrictions regarding year of publication or language were applied. Any article in a foreign language in which none of the authors was proficient was translated. All titles and abstracts were reviewed by two independent readers (SD, TS) using Covidence. An article was found eligible when it concerned ankle fractures, syndesmosis injuries, placement of a syndesmotic screw and the removal and retention of the syndesmotic screw. Based on the title and abstract, a list of full text articles was created. These articles were further evaluated and were excluded if they were biomechanical studies, had no patient related outcome measure (PROM), were case reports, were on skeletally immature patients, or were reviews. When there was any discrepancy between the two reviewers consensus was reached after discussion. Subsequently the references of all included articles were examined to search for additional relevant studies. The Oxford Level of Evidence criteria were used to assess the level of evidence. To evaluate the methodological quality of the randomised controlled trials (RCT), the Cochrane tool was applied. Using this tool, studies are screened on seven domains. The reviewer can award three levels of bias to each domain for each study; low risk of bias, high risk of bias or unclear risk of bias. Studies where the first three domains have a low risk of bias and no important concerns related to the last four domains are classified as low risk of bias studies. In studies where a maximum of two domains are scored as high risk of bias or unclear risk of bias, are classified as studies with moderate risk of bias. In the case of three domains or more scoring a high risk of bias or
unclear risk of bias, studies are classified as having a high risk of bias. For the assessment of non-randomised studies we have used the MINORS criteria as proposed by Slim et al.\textsuperscript{28} Using this classification, studies are scored on 12 different domains. For each domain studies can receive; 0 points (not reported), 1 point (reported but inadequate) or 2 points (reported and adequate). The lower the number of points a study is awarded, the lower the methodological quality of the study and vice versa. When necessary, groups of patients within studies were combined (i.e. patients with broken/loose screws and patients with in situ intact screws) and new weighted means and standard deviations (SD) were calculated using Review Manager (Cochrane Collaboration, version 5.2, London, United Kingdom). The independent \( t \)-test was used to compare the new groups. A \( p \)-value < 0.05 was considered statistically significant.

**Results**

The search produced a total of 457 articles, of which 128 were duplicates and were removed. A total of 329 articles remained to be reviewed for title and abstract, after which 303 articles were eliminated. Of the remaining 26 articles, another 17 were excluded after reading the full text (Fig. 1). Reasons for exclusion were; biomechanical studies,\textsuperscript{29,30} no PROMs reported,\textsuperscript{31-41} case reports,\textsuperscript{42} reviews,\textsuperscript{43,44} After screening the references of the included articles, two articles were added,\textsuperscript{20,45} leaving a total of 11 articles to be included in this systematic review.

Of the 11 articles found there were two RCTs\textsuperscript{45,46} and nine non-randomised studies.\textsuperscript{6,16,20,21,24,47-49} The two RCTs were level of evidence IIb (low-quality RCTs) and the remaining nine studies were level of evidence level IV (case series, poor quality cohort and case-control studies) (Table I). In the RCT by Boyle et al\textsuperscript{46} patients were randomised between routine removal and the retaining of the syndesmotic screw after fixation of an unstable ankle fracture. A total of 51 patients were included and the primary outcome measure was the Olerud-Molander score (OMAS).\textsuperscript{50} Secondary outcome measures were the American Orthopaedic Foot and Ankle Society Hindfoot scale (AOFAS),\textsuperscript{51} pain, range of movement and loss of reduction. All patients included had one 4.0 mm quadricortical screw which was then removed at three months post-operatively (in the case of routine removals). At follow-up one year post-operatively, no outcome measure significantly differed between the two groups (routine removal versus retaining the syndesmotic screw: mean OMAS 85.8 (SD 13.2) versus 83.5 (SD 19.8); \( p = 0.631 \), independent \( t \)-test). There were concerns regarding the methodological quality of the data (Fig. 2). A total of 21 (29.2\%) of the randomised patients were not available for follow-up which might have introduced selection bias. Furthermore a post hoc power analysis revealed that at least 35 patients were needed in each group to demonstrate non-inferiority between the two groups, which was not reached (Fig. 2). A RCT by Hoiness and Strømsøe\textsuperscript{45} of 64 patients divided into those receiving one 4.5 mm quadricortical screw followed by routine removal, and those who had two 3.5 mm tricortical screws which were retained. Using the primary endpoint of the OMAS and the secondary endpoints as range of movement and loss of reduction after one year revealed no significant difference in the mean OMAS after one year (routine removal versus retaining the syndesmotic screw; 83.3 (SD 18.6) versus 88.8 (SD 14.6); \( p = 0.192 \), independent \( t \)-test). There are concerns regarding the methodological quality of the study. First of all, the two groups did not receive the same initial treatment which may represent a confounding bias. In addition, the randomisation process was not adequately reported (Fig. 2). The results of the non-randomised trials are shown in Table I. Most of the papers demonstrated an equal\textsuperscript{6,16,20,24,47-49} or better\textsuperscript{21} functional outcome following retaining the syndesmotic screw, but there were also concerns regarding the methodological quality of this study (Fig. 3). A meta-analysis considering the PROMs was deemed not possible due to the heterogeneity of the data.

**Discussion**

The literature shows that there is no significant difference in functional outcome between patients undergoing routine syndesmotic screw removal and those in whom a syndesmotic screw is left in situ or only removed on request. We have identified two RCTs which both showed no significant difference in functional outcome between the two treatment strategies.\textsuperscript{43,46} Furthermore, we found nine case control-series, of which all but one did not report any significant benefit in terms of functional outcome following removal of the screw.\textsuperscript{6,16,20,21,24,47-49}

The quality of the studies included in the analysis is however imperfect and the results should be interpreted with caution. The two RCTs were found to have flaws. Boyle et al\textsuperscript{46} study was possibly underpowered and a large number of patients were lost to follow-up. In the study by Hoiness and Strømsøe,\textsuperscript{45} the two groups were not comparable as different sizes and numbers of screws were used. Neither of these two randomised studies showed any clinical difference between routine removal and retained screws. Moreover, almost all of the case-control series showed no clinical difference or better outcomes in patients with retained screws. Manjoo et al\textsuperscript{53} have though reported a potential benefit of routine removal of the screw. However, they compared 20 intact screws with 44 loose or broken screws in 12 patients in whom the screws were removed, which was different to the groupings described in other studies. Based on this report it not possible to draw any conclusion as to whether routine removal is beneficial as broken or loose screws are reported to have done just as well.

There was one study which compared functional outcome before and after removal of syndesmotic screws and a significant benefit of screw removal was reported.\textsuperscript{19} Interpreting the results of this study was difficult though,
Table I. Overview of included studies

<table>
<thead>
<tr>
<th>Author/year of publication</th>
<th>Type of study</th>
<th>OLOE</th>
<th>Mean follow-up time (mths)</th>
<th>Control (n)</th>
<th>Intervention (n)</th>
<th>Mean outcome</th>
<th>Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bell et al 2006</td>
<td>Prospective cohort</td>
<td>4</td>
<td>Removal after 6 to 12 weeks (n = 23)</td>
<td>Retaining the syndesmotic screw (n = 7); Broken (n = 2); Intact (n = 5)</td>
<td>Baird and Jackson score52 88 vs 86 (p = 0.79)</td>
<td>No difference in functional outcome between the two groups</td>
<td></td>
</tr>
<tr>
<td>Boyle et al 2014</td>
<td>RCT</td>
<td>2b</td>
<td>Removal after 12 weeks (n = 26)</td>
<td>Retaining the syndesmotic screw (n = 25); Broken (n = 9); Intact (n = 16)</td>
<td>OMAS 86.7 vs 82.4 (p = 0.367)</td>
<td>Removal of a syndesmotic screw produces no significant functional, clinical or radiological benefit</td>
<td></td>
</tr>
<tr>
<td>Egoi et al 2010</td>
<td>Retrospective cohort</td>
<td>4</td>
<td>Removal after 12 weeks (n = 11)</td>
<td>Retaining the syndesmotic screw (n = 68); Broken (n = 15); Intact (n = 53)</td>
<td>AOAS NP (p = 0.82)</td>
<td>No statistical difference in outcome between patients with removed or broken screws and intact screws</td>
<td></td>
</tr>
<tr>
<td>Hamid et al 2009</td>
<td>Cross-sectional cohort</td>
<td>4</td>
<td>Removal after 11 to 20 weeks (n = 15)</td>
<td>Retaining the syndesmotic screw (n = 37); Broken (n = 10); Intact (n = 27)</td>
<td>AOAS 85.80 vs 85.59 (p = 0.96)</td>
<td>No statistical difference in clinical outcome of patients who had their syndesmosis screw removed and those who did not. Patients with broken screws seemed to fare the best</td>
<td></td>
</tr>
<tr>
<td>Heiness and Stramsae 2004</td>
<td>Quasi-RCT</td>
<td>2b</td>
<td>Routine removal of quadri cortical screws after 9.5 weeks (n = 30)</td>
<td>Retaining the two tricortical syndesmosis screws (n = 34); Broken (n = 3); Intact (n = 31)</td>
<td>OMAS 83.3 vs 88.8 (p = 0.192)</td>
<td>No difference in functional outcome between routinely removed single quadrilateral and retained two tricortical screws</td>
<td></td>
</tr>
<tr>
<td>Kaftandziev et al 2015</td>
<td>Cross-sectional cohort</td>
<td>4</td>
<td>Minimum of 12 weeks (n = 23)</td>
<td>Retaining the screw (n = 59); Broken (n = 13); Intact (n = 46)</td>
<td>AOAS 83 vs 88.03 (p = 0.043)</td>
<td>Patients with retained screw did significantly better than patients in whom the screw was routinely removed, this was mainly because of patients with an broken screw</td>
<td></td>
</tr>
<tr>
<td>Kolodziej et al 2010</td>
<td>Cross-sectional cohort</td>
<td>4</td>
<td>Removal after 7 to 22 weeks (n = 13)</td>
<td>Retaining the screw (n = 20); Broken (n = 8); Intact (n = 12)</td>
<td>AOAS 89 vs 86.2 (p = NP)</td>
<td>Removal of the syndesmotic screw does not significantly improve functional outcome</td>
<td></td>
</tr>
<tr>
<td>Manjoo et al 2010</td>
<td>Cross-sectional cohort</td>
<td>4</td>
<td>Removal after 40 weeks (n = 12)</td>
<td>Retaining the screw (n = 64); Broken (n = 44); Intact (n = 20)</td>
<td>OMAS 66.80 vs 51.29 (p &lt; 0.001)</td>
<td>Patients with intact screw have significant worse clinical or radiological outcome compared to patients with removed or broken screws</td>
<td></td>
</tr>
<tr>
<td>Schepers et al 2014</td>
<td>Cross-sectional cohort</td>
<td>4</td>
<td>Removal after 8 to 12 weeks (n = 44)</td>
<td>Retaining the screw (n = 12); Broken: NP; (p = 0.971) Intact: NP</td>
<td>OMAS 73.22 vs 72.92 (p = 0.821)</td>
<td>No difference in OMAS between removal and retaining group</td>
<td></td>
</tr>
<tr>
<td>Tucker et al 2013</td>
<td>Cross-sectional cohort</td>
<td>4</td>
<td>Removal after 10 to 12 weeks (n = 43)</td>
<td>Retaining the screw (n = 12); Broken: NP; (p = 0.107) Intact: NP</td>
<td>OMAS 75 vs 81.5 (p &lt; 0.001)</td>
<td>Routine removal does not improve outcome and should not be performed</td>
<td></td>
</tr>
<tr>
<td>Weening and Bhandari 2005</td>
<td>Cross-sectional cohort</td>
<td>4</td>
<td>Removal after 9 weeks (n = 30)</td>
<td>Retaining the screw (n = 20); Broken: NP; Intact: NP</td>
<td>OMAS NP</td>
<td>Removal had no influence on OMAS in multivariable model</td>
<td></td>
</tr>
</tbody>
</table>

*removal was only performed on indication
†median
‡three removed due to prominent hardware
OLOE, Oxford Level of Evidence; RCT, randomised controlled trial; OMAS, Olerud-Molander Score; AOAS, American Orthopaedic Foot and Ankle Society Hindfoot scale; NP, not provided

because there was no control group and a locking screw through a locking plate was used which is a more rigid construct compared with regular syndesmotic screws. In our review, loosening or breakage of the screw occurred in 15% to 69% of the patients with retained screws, although loosening in up to 91% of patients has been reported in the literature.44 This is relevant as several authors have shown that patients in whom the syndesmotic screw had broken or became loose fared best.21,48,50 Interestingly, Song et al55 noted in their study that 36% (nine out of 25) of patients had evidence of a malreduced syndesmosis following fixation and eight out of nine of these malreductions spontaneously reduced following syndesmotic screw removal. It is possible that if a screw breaks or loosens the malreduction is corrected which improves the outcome without the need of screw removal. It is also possible that removal of a screw is only indicated in patients with ankle pain due to a prominent screw or where reduced range of movement or malreduction is attributable to the presence of an intact screw.

Removal of the syndesmotic screw is not straightforward. High rates of complications have been reported following removal of the metalwork,33,51-59 especially in patients who sustained a post-operative wound infection at the initial fixation, as they have been shown to have a worse outcome when compared with patients without infection.60-62 There are two studies which have reported
widening of the tibiofibular space after syndesmotic screw removal, however no detrimental functional effect was demonstrated. 32,35

A number of other devices are currently available to treat a syndesmosis injury but were not part of our evaluation. A total of two RCTs have compared the Tightrope (Arthrex, Naples, Florida) suture button device with regular syndesmotic screws. 63,64 Kortekangas et al 63 compared the accuracy and maintenance of reduction, functional outcome and degree of osteoarthritis (OA) at two year follow-up. They did not find any significant difference in the number of malreduced syndesmoses, functional outcome, the extent of OA or the number of secondary procedures between the two treatment groups. Lafllamme et al 64 reported a statistically significant difference in functional outcome in favour of the Tightrope at a one year follow-up, but the difference was not clinically relevant. However, they did find a significantly higher rate of secondary procedures in the syndesmotic screw group. 64 Schepers 9 reported that the removal rate after the use of a suture button device was around 10%, although others have recorded up to 25% removal rate. 55,66 Schepers 9 also found that the functional outcome in patients treated with a suture button device and those with conventional syndesmotic screws was equal, which has also been reflected in other studies. 63,67,68 Van der Eng, Schep and Schepers 69 failed to show any reduction in the complication rate in patients treated with bioabsorbable screws compared to metallic screws. 69 Furthermore, in a RCT, Sun et al 70 did not find a significant difference in functional outcome between patients treated with metallic screws compared with patients treated with bioabsorbable screws.

There are several limitations to our study. A planned meta-analysis was not possible due to the heterogeneity of the data. It might have been that by pooling studies significant differences would have been found which would have enabled definitive conclusions to be drawn. Also in this systematic review the adult population as a whole was described and it is possible that certain subpopulations (e.g. young active patients with high demands in sporting activities) might benefit from routine removal of the screw.

A financial cost is incurred both at the time of screw removal (mean price of syndesmotic screw removal is €1500 in the Netherlands), and in the course of treating any complications that may arise from this procedure. This is
without any consideration of the cost of the loss of income from elective removal of the screw.

In conclusion, the current literature does not provide any evidence to support routine removal of syndesmotic screws with regard to functional outcome. Moreover, there is a clear evidence of morbidity and financial costs for such a policy. We believe that a study with appropriate power and full cost analysis would be required in order to justify routine screw removal.

**Take home message:**
In the absence of high quality evidence there appears to be little justification for routine removal of the syndesmotic screw following an ankle fracture.

**Supplementary material**
Full search strings are available alongside this paper online at http://www.bjj.boneandjoint.org.uk

**Author contributions:**
S. A. Dingemans: Designing the paper, Data acquisition and analysis, Interpretation of the data, Drafting of the work.
S. Rammelt: Designing the paper, Interpretation of the data, Critically revising the work.
T. O. White: Designing the paper, Interpretation of the data, Critically revising the work.
J. C. Goslings: Designing the paper, Interpretation of the data, Critically revising the work.
T. Schepers: Designing the paper, Data acquisition and analysis, Interpretation of the data, Drafting of the work.

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