

Title:

Should ankle syndesmosis screws be removed? Medium term follow up of a randomised controlled trial comparing screw retention with screw removal following ankle fracture fixation.

Short Title:

ASSET Study - Ankle Syndesmosis Screw Extended Term Follow-up Study

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Study Locations:

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1. Study Aim

The purpose of this study is to retrospectively review a cohort of prospectively enrolled patients from a previously published randomised controlled study. The aim is to ascertain whether removal of an ankle syndesmosis screw has an effect on patients' clinical and radiological outcomes after a minimum of 5 years.

2. Hypothesis

Removal of ankle syndesmosis screws does not affect ankle function in the medium term.

3. Background and significance

Certain ankle fractures require surgical fixation, with a subset of these ankle fractures also requiring screw fixation of syndesmotous ligamentous injuries. Screw stabilisation of the disrupted ankle syndesmosis maintains reduction as healing of the distal tibiofibular ligaments

occurs. It has previously been thought that syndesmosis screws may contribute to ankle dysfunction by restricting the normal motion between the tibia and fibula.^{1,2} Screw removal, breakage, or loosening may restore motion but can permit loss of reduction if these occur before complete ligamentous healing.²⁻⁴

In 2014, we published a “Game Changer” article in the Bone and Joint Journal, demonstrating that there is no difference in removing or retaining ankle syndesmosis screws at one-year follow-up. At the time of publication, our study, entitled “*Removal of the syndesmotic screw after the surgical treatment of a fracture of the ankle in adult patients does not affect one-year outcomes*”, was voted by the American Academy of Orthopaedic Surgeons (AAOS) as one of the top 15 studies (from a cohort of 856 studies) most likely to impact Orthopaedic Surgeons’ practice in the world.⁵

One of the limitations in our initial study was the short duration of follow-up of one year. The aim of this current study is to review the patients who participated in the initial study and assess the medium-term outcomes in these patients. At the time of follow-up, we will have a minimum of five years follow-up results from this patient cohort.

4. Research design and methods

Patients who participated in the initial randomised controlled trial (Boyle et al. BJJ. 2014) will be invited to return to outpatient clinics for review.

Study Population

Patients will be identified from the previous study database and invited by telephone to return for follow-up.

Primary Outcome

Olerud-Molander ankle score (OMAS)⁶

The Olerud-Molander scoring scale (100 point scale) was chosen in our initial study because it is a validated⁷ outcome instrument that adequately represents the ankle performance following surgery for ankle trauma. It comprises nine functional parameters which are concerned with primary complaints, the ability to perform simple tasks, and everyday life activities.

Secondary Outcomes

1. American Orthopaedic Foot and Ankle Society (AOFAS) score of hindfoot⁸

This score is a widely accepted and validated⁹ clinician-based evaluation of function (7 criteria), alignment (1 criteria) and pain (1 criteria), for a maximum of 100 points.

2. American Academy of Orthopaedic Surgeons foot and ankle core score (AAOSFACS)¹⁰

This score is a validated¹⁷ patient-reported outcome score related to pain, function, stiffness and swelling, and giving way, for a maximum of 100 points.

3. Pain on visual analogue scale (VAS)

Pain is described with the widely accepted VAS, which ranges from 1 to 10.

4. Range of motion

With a goniometer, dorsi-flexion and plantar-flexion will be measured.

5. Muscular trophicity measure of the leg (Calf girth)

This measure will be taken with a metric band 15 cm under the inferior patellar pole and will be compared to normal side. A ratio of injured side/normal side will be calculated.

6. Radiological loss of reduction

Adequate reduction of the syndesmosis will be evaluated using plain radiographs in the anteroposterior (AP) and mortise views; the "clear space" will be defined as the distance between the medial side of fibula and the incisural surface of tibia (1 cm above tibial pilon). Loss of reduction will be defined as greater than 6mm clear space. Rate of loss of reduction and the range of this loss over 6 mm will be calculated for each group.

7. Implant failure

Rate of implant failure (e.g. screw breakage or loosening, with or without a second surgery for removal) will be measured for each group. Broken screws will be defined as those in which there is a fracture of the screw. Loosened screws will be defined as those surrounded by a radiolucent zone 1 mm in width extending the length of threads in either the fibula or tibia.

8. Rate of secondary surgery

To measure the rate of secondary surgery due to infection or implant removal. Every secondary surgery during the follow up period counts, even for the same patient.

Statistical considerations

Power and sample size calculations

The difference in Olerud-Molander ankle score between the two groups that has been assumed to be of clinical interest is 10 points. Power calculations indicate that in order to detect a 10 point difference in the Olerud-Molander ankle score between groups (assuming mean 87, SD 12), with an 90% power, we will require 31 patients in each group (a total of 62 patients). Nevertheless, we will endeavour to recall as many patients are possible for follow-up outcome measures.

Data storage

Patient information and outcomes will be stored securely by the Principle Investigator. Study information will be stored for a period of ten years and then will be destroyed. Patient confidentiality will be protected at all times; only the Principle Investigator will have access to study information and results.

5. Risks and adverse events

The study poses no additional risks to patients, above the risks associated with usual patient care.

6. References

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