“The benefit of repairing the deltoid ligament in unstable ankle fractures: *Patient-reported functional outcome and radiological stability measurements.”*

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1. Introduction

Ankle fractures occur in 1 out of 800 persons a year and are among the most frequent orthopaedic injuries. Post-traumatic arthritis occurs after fractures and sprains and causes persistent stiffness and pain in your affected joints. The risk of developing posttraumatic arthritis is linked to the severity of the fracture and joint stability after treatment. Posttraumatic arthritis of the ankle is quite common, and since arthroplasty in this joint is far less successful compared to hip and knee, prevention will be preferable to treatment of established arthritis.

Repairing the deltoid ligament is an adjunct to already established practice. We see a great potential in this additional ligament repair. It is shown to restore joint stability experimentally in fracture models. If this can increase joint stability and functional outcome after surgical treatment of unstable ankle fractures, it may also mitigate the risk of posttraumatic ankle joint arthritis in unstable ankle fractures. It is already known that this additional procedure has a role for optimal function in cases where medial ankle instability is evident.

There is a need for a better surgical treatment for unstable ankle fractures for these patients' preservation of function and prevention of pain. We aim to show whether deltoid ligament suture gives a clinically significant superior result than solely osteosynthesis of the lateral malleolus in unstable ankle fractures. This will be performed as a mulitcentre randomized controlled study.

During the last couple of decades less severe ankle fractures have been shown not to need operative treament in general[4,7] and the total number of ankle fracture surgeries has gone down. However, how to treat the more complex fractures is still a challenge. Fractures treated with surgery nowadays are on average more complex than in samples from the three recent decades. There is reason to believe that a more stable repair may be profitable for the patients. The use of weightbearing images in stability assessment in ankle fractures is now more abundant, and increasingly well documented as a main guide in the choice of ankle fracture treatment[1,3]. The understanding of these injuries implies a recognition of the role of the deep deltoid ligament as a main stabilizer of the ankle joint.

Research from Sykehuset Østfold (ØHT) has shown that, as a single procedure, deltoid ligament repair gives more stability than the osteosynthesis of the lateral malleolus[17]. So far, this has only been done in cadaveric studies. **There is reason to believe that operative stabilization beyond plating of the lateral fracture will contribute to a better functional result and may prevent long term osteoarthritis.** This is novel to established treatment, and such a study is in demand worldwide. This deep deltoid ligament repair study will provide knowledge that may change treatment guidelines nationwide and give great attention to research from ØHT and collaborating hospitals in Southern Norway.
Patients sustaining severe ankle fractures have shown a considerable loss of function compared to less severe fractures. The last group on average has a good ADL function, the other has not. Improving outcome for this group may preserve some patients' ability to work and reduce community expenses.

Anatomy of the deltoid ligament and its biomechanical properties

In ankle fractures, partial tears of the deltoid ligament are not rare. What seems to separate lateral ankle fractures that are unstable and need surgery from the rest, is if there is *a complete deltoid ligament injury*. The literature on the deltoid ligament reveals inconsistency in description and interpretation of its anatomy and biomechanics[7-9]. In addition, studies suggest a considerable anatomical variation in the deltoid ligament presentation between individuals. Illustrated under is the deep deltoid ligament which is marked #6, the part of the ligament which is posterior and deep, from the posterior colliculus of the medial malleolus to the medial side of the talar body (Figure 1)[7].

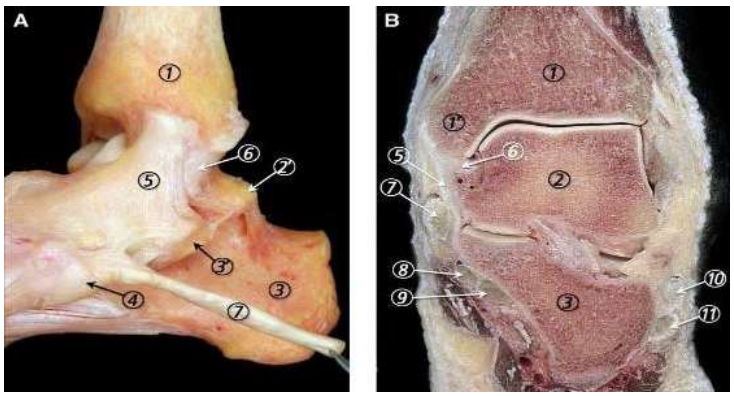

Figure 1 (*A*) Medial view of the ankle joint ligaments showing their typical fanlike morphology. (*B*) Frontal section of the ankle joint where the superficial and deep layers of the MCL (medial collateral ligament) are separated by a small mass of fatty tissue. 1, tibia; 1', medial malleolus; 2, talus; 2', medial talar process; 3, calcaneus; 3', sustentaculum tali; 4, navicular tuberosity; 5, superficial layer of the MCL; 6, deep layer of the MCL; 7, tibialis posterior tendon; 8, flexor digitorum longus tendon; 9, flexor hallucis longus tendon; 10, peroneus brevis tendon; 11, peroneus longus tendon. (Golano et al)

The gold standard in operative treatment of ankle fractures has been plating of the distal fibula and screw fixation of the medial malleolus. Distal fibular fracture in combination with a full deltoid ligament tear has been termed «bimalleolar equivalent ankle fractures». It may seem logical and tempting to fix medial malleolar fractures that are evident on x-rays, and this practice has been less disputed. Peroperatively, when residual instability is found in ankle fractures after fixation of the malleoli, the established strategy has been restabilizing the distal tibiofibular joint/syndesmosis by a transsyndesmotic screw or suture button and/or fixation of avulsed syndesmosis-bearing fragments. Frankly, the rationale of not fixing the deltoid ligament is based on the presumption that this is not necessary, unless the ligament is interposed in the medial gutter and obstructing the reposition of the ankle joint.

Deltoid ligament repair is documented to be a good option to regain ankle joint anatomy from smaller studies. This repair also compensates for syndesmotic injury[11]. The effect of deep deltoid ligament repair in Weber B ankle fractures and its effect on long term function and arthritis is not yet known from clinical studies. Cadaveric studies have shown a better improvement of ankle stability in unstable ankle fractures by deltoid ligament repair alone than from solely plating fractures of the lateral malleolus (results from ØHT/Ålesund Hospital/Norwegian University of Science and Technology (NTNU) research)[17]. Deltoid ligament repair has also been shown to give a more predictable reposition of the tibiofibular syndesmosis than performing a direct transsyndesmotic fixation[2]. The distal tibiofibular syndesmosis and deltoid ligament have a synergistic effect in ankle stability[14]. If they are necessary to fix, which one to fix, or both, is not clear, but to some extent fixing one of them reduces the need of fixing the other.

Pakarinen et al showed that lateral malleolar fractures Weber B SER with a positive external rotation test after bony fixation did not profit on a transsyndesmotic screw[12]. Strømsø et al showed no additional effect of deltoid ligament repair after plating of the lateral malleolus and sometimes a syndesmotic screw[5]. The frequency of use of the syndesmotic screw in their sample was not specified. A major number of fractures treated in these study samples were less severe and would be treated conservatively with current guidelines. This supports the need for studies on fractures still chosen for surgery, a group of more severe fractures than in the samples most research has been done on until now.

Patient reported outcome measures (PROMs)

PROMs are useful in clinical practice, clinical and health services research, economic evaluation, and as national quality indicators. They provide patient-reported data on function [34].
Norwegian validated versions are useful tools in research for evaluation of different treatments and rehabilitation after injury. Ankle Fracture Outcome of Rehabilitation Measure (A-FORM) is a welldeveloped ankle fracture-specific PROM that is free of use[45]. This is until now the best documented Patient Reported Outcome Measure (PROM) in ankle fractures[44]. Most PROMs used in Norway are translated from other languages. Validation of the Norwegian versions is necessary because the validity of each item (question) seems not to be constant between countries and languages. Validation studies are needed to confirm that a new translation of a PROM still has

sufficient measurement properties and that its questions (items) are relevant in the society it will be used[37].

1.1 Needs description

The trial presented in this research application is crucial to gain knowledge on whether deltoid ligament repair preserves function after ankle fractures better than the established treatment**.** There is reason to believe that operative stabilization beyond plating of the lateral fracture will contribute to a better functional result and may prevent long term osteoarthritis. Patients with posttraumatic arthritis of the ankle experience loss of function, pain and loss of capacity to work and general quality of life. There is potential for savings in society expenses due to less surgical procedures and better maintenance of working capacity among patients. Whether classical x-ray methods can give an impression of deltoid ligament patency after injury, joint stability and development of secondary ankle arthritis, will also be investigated. We will try to show if anatomy is reestabilished after surgical treatment of unstable Weber B ankle fractures. Gravity test images[16] might tell us something about patency of the deltoid ligament after the supposed healing time of one year. Signs of postfracture arthritis is another important outcome, and whether the additional stability of deltoid ligament repair in ankle fracture treatment can help us avoid this, is a key question.

Our translation and validation study on A-FORM and other relevant PROMs will be useful in further clinical work, research and other reports on ankle fractures. The Norwegian translation will be available as a free tool. Based on our findings we can suggest which of these PROMs to use further. Our Norwegian validated translation will be used in ankle fracture clinics and scientific work in Norway and quoted in future Norwegian publications.

This research project should be supportable as a standardized approach to improve treatment for a common and quite severe injury. There is already a high-level scientific cooperation between hospitals and research groups in Southern Norway on methods of treating ankle fractures, and this study will be a continuum and extension of that.

2. Hypothesis, aims and objectives

The overall aim of this project is to restore ankle joint anatomy and ligamentous stability and function. This may mitigate the risk of posttraumatic ankle joint arthritis. The trial will have a special focus on the benefit of repairing the deltoid ligament in unstable ankle fractures. We also investigate whether x-rays can tell us something about stability after treatment and maybe aid a prognosis about secondary arthritis risk. This study will validate PROMs specific for use after treatment of ankle fractures in Norwegian translations. The work will be conducted through three work packages (WPs) separate with aims, hypotheses and objectives.

WP1

Aims and objectives: We expect that additional deltoid ligament suture is superior to solely plating of the lateral malleolus when taking minimal important difference (MID) into consideration.

Hypothesis: «Patient reported function in OMAS score after additional deltoid ligament suture will be clinically superior to after only plating of lateral malleolar fractures in Lauge Hansen SER 4b fractures one year after surgery»

Main end points: Patient-reported function in OMAS score after lateral malleolar plating only versus additional deltoid ligament suture at 1 and 2 years
Secondary end points: Function reported by A-FORM, MOxFQ, SEFAS, EFAS and VAS and EQ-5D5L Infection and reoperation rate and delayed/non-union will be recorded.
Side effects: Implementing e-mail-based electronical systems for patient scoring during follow up.

WP2

Aims and objectives: Medial clear space (MCS) is measured on WBXRs as an inclusion criterion for operative intervention for SER4 fracture. We will check whether there is a difference at group level in medial clear space on WBXRs or gravity test images after surgery with or without deltoid ligament repair.

Hypothesis: "Medial clear space measurements of injured side compared to non-injured on weightbearing x-rays will not be statistically significant between groups".
and
"Medial clear space difference between weightbearing x-rays and gravity test images of injured side will be statistically significant between groups".

Main end points: Differences in MCS (Figure 2[1]) on WBXR or Gravity test (Figure 3[16]) at group level.
Secondary end point: Arthritis will be reported according to Kellgren Lawrence Scale[46].

WP3

Aims and objectives: The main purpose of WP3 is to perform a validation of the A-FORM. We shall evaluate the measurement properties of A-FORM and the other named PROMs; reliability, validity and responsiveness, in accordance with current international standards like the COSMIN checklist[36,37]. Based on our findings we can suggest which of these PROMs to use further.

Hypothesis: It is hypothesized that scores for the foot and ankle specific instruments will be highly correlated, over 0.7. High levels of correlation are expected between these PROMs for several items, given the overlap in content[22]. The specific instruments include items that overlap with two or more EQ-5D items and hence high levels of correlation are expected for EQ-5D-5L index scores and the EQ-5D mobility item. Moderate levels of correlation in the range 0.5 to 0.7 are expected for the EQ-5D usual activities and pain items. Lower levels of correlation in the range 0.3 to 0.5 are expected for the EQ-5D self-care and anxiety/depression items.

3. Methodology

Patients will be included by written consent after written and oral information. Patients will be included from the area of Sykehuset Levanger, Trondheim University Hospital, Sykehuset Innlandet, Haukeland University Hospital, Ålesund Hospital and Sykehuset Østfold. Outpatient visits and x-ray surveys will be arranged by named co-authors in collaborating hospitals, and electronical PROM-surveys by the PhD-candidate through the main hosting hospital.
Statistics form our surgical departments suggest that there will be between 80 and 100 candidates a year prone for inclusion in our recruitment districts altogether. Surgery should be performed within 2 weeks after injury. Treatment in both arms of randomisation must be performed by equally experienced surgeons, a consultant or fellowship-trained orthopaedic surgeon taking part in the procedure, preferably a foot and ankle surgeon or experienced trauma surgeon performing at least 10 ankle fractures a year. Randomization will be performed after consent before surgery.
Preoperative CT should be performed as a general routine in cases of posterior malleolar fragments or suspicion of other additional injuries like for instance Chaput-Tillaux-injuries.

3.1 Project arrangements, method selection and analyses

We want to examine the additional effect of deltoid ligament repair in unstable SER 4b fractures. Samples consisting of both SER 4a- and b- fractures already show good-excellent results after plating of the lateral malleolus only; Olerud-Molander Score (OMAS) one year after fixation in SER ankle fractures was about 80 on average[9,15] Because the fractures in our sample are more severe, their scores on average will be lower. We expect that additional deltoid ligament suture is superior to solely plating of the lateral malleolus when taking minimal important difference (MID) into consideration.

Another question is whether additional deltoid ligament repair leads to a significant difference in radiological findings within a follow-up of two years. We will use standing x-rays in the mortise projection and measurement of medial clear space (MCS) (Figure 2). Supplementary gravity test X-rays (Figure 3) for evaluation of deltoid ligament integrity at 1 year. Arthritis according to Kellgren Lawrence Scale will also be reported. Results after 5 years will be reported in later publications. Gravity test (Figure 3) is a more dynamic survey testing talar tilt, when increased suggests partial deltoid ligament insufficiency. WBXR is at given times of follow up. We will use gravity test at 1 and 5 years to see whether there is a difference in gravity test.

Surgical technique (WP1 and WP2): The lateral malleolus shall be fixed with a modern anatomic plate, and no additional testing performed. For patients randomized to deltoid ligament repair: Deltoid ligament repair is done by a curved incision following the path of the posterior tibial tendon from just posterior to the malleolus till past the anterior tip. The medial surface of the malleolus is identified, and the tendon retinaculum is incised in the direction of the tendon. The tendon is lifted out of its sheath and held proximally. Because the ligament most often is torn on its talar end, the routine repair will be suturing the deep deltoid ligament fibres to a bone anchor in the talus. We recommend temporary pin placement and fluoroscopy in at least one projection (AP) to confirm correct positioning prior to anchor placement. A modern bone anchor must be used. The ankle is held in slight inversion and 10-15 degrees of plantar flexion when tightening and tying the sutures. We close more superficial and anterior parts of the ligament tear before putting the tendon back into its retinaculum, which is closed with a resorbable # 1 suture or stronger.
Aftertreatment: Up to 2 weeks in a cast or walker orthosis when loading max 20 kg. Thereafter free movement with or without orthosis from 2 weeks, weightbearing as tolerated.

Inclusion criteria (WP1, 2 and 3):
- isolated Weber type B fractures.
- Initial medial clear space (MCS)>=7mm or weightbearing x-ray evaluated as unstable or primary reposition after fracture dislocation
- 18-70 years of age.
- Pre-injury walking ability without aids.

Exclusion criteria (WP1, 2 and 3):
- assumed not compliant (drug use, cognitive- and/or psychiatric disorders).
- previous history of ipsilateral ankle fracture.
- previous history of ipsilateral major ankle-/foot surgery.
- open fx Gustillo Anderson II or more, multi-trauma and pathologic fracture.
- neuropathies and generalized joint disease such as Rheumatoid Arthritis
- other more severe condition in same extremity
- posterior malleolus fragment > ¼ of sagittal diametre or fixation of tibial fragment
- syndesmotic screw or suture button

Design (WP 1 and 2): Randomized controlled trial (computerized); clinical superiority design, multicentre, follow up at 6 weeks, 3 months, 1, 2 and 5 years.

Power, group size (WP1 and 2): To detect a defined minimal clinically important difference of between 8 and 10 (slightly more than half of the standard deviation (SD), or 9,7 as referred[44]) in OlerudMolander ankle score between the study-groups, expected SD 14 points (Pakarinen et al found 13 and 15 in their groups[12]. Molund et al had a SD of 12 on average[15]), significance level α = 0.05, Power 0,8, and estimated 20% drop out (two-sided t-test, clinical superiority design) we will include 60 patients in each group to ensure sufficient power after expected drop out [26,30].

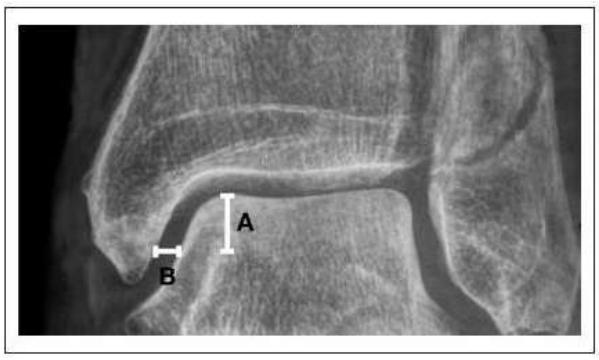

Figure 2. The figure demonstrates the method for obtaining medial clear space measurements from mortise view projections in weightbearing radiographs. First, we marked a 5.0-mm distance starting at the talar dome and caudally (line A). Then, the medial clear space was measured as the distance between the medial border of the talus and the lateral border of the medial malleolus on a line parallel to and 5.0 mm below the talar dome (line B).

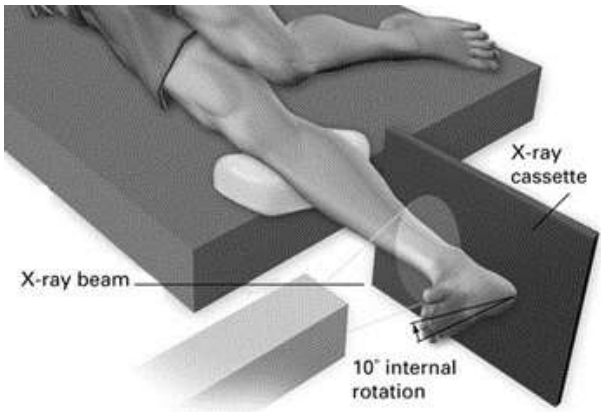

Figure 3: Gravity test after Schock &al

Method selection, design and group size WP3: We will perform a systematic translation of the A-FORM according to COSMIN guidelines. This survey has its origin in Australia and is until now the best documented Patient Reported Outcome Measure (PROM) in ankle fractures and is specific to this kind of injury. A-FORM will be used as one of the outcome measures after treatment of ankle fractures in WP1. Patient enrollment will be the same as for for the rest of this project; 120 patients who are randomized to different surgical treatments for Weber B ankle fractures. The self-completed questionnaires will include OMAS, A-FORM, EQ 5D- 5L, European Foot and Ankle Society, (EFAS) Score, Self-Reported Foot and Ankle Score (SEFAS), Manchester Oxford Foot- and Ankle Questionnaire (MOxFQ), and VAS pain. We also include EQ-5D-5L, which has general relevance, irrespective of any underlying health problem, also called generic, and tells us about people's general health.
Date of surgery is registered. In order to calculate responsiveness, we will use observations from 6 months and 1 year postoperatively. Reliability will be based on a retest 2-4 weeks from the score at one year.

A-FORM has 15 items. Number of patients included is based on a rules-of-thumb from 4 to 10 subjects per variable, with a minimum number of 100 subjects fulfilling out of 120 patients included will ensure stability of the variance covariance matrix[28,33,41]Our largest scoring system to be evaluated is MOxFQ, consisting of 16 items. Inclusion will start in 2024.

Anchor based methods evaluate how a change in the total score of a PROM relates to an external criterion (anchor). The anchor commonly consists of a patient global assessment (PGA) rating scale, in which the patients are asked, in a single question at follow-up: "Have you improved during the last 9 months?". The 7 possible responses to the question were (1) completely recovered/very much better, (2) much better, (3) a little better, (4) unchanged, and (5) a little worse (6) much worse and (7) a very much worse. We evaluated the relationship between the PGA scales and changes in total PROM score from before surgery to 6 and 12 months after surgery[40]. In follow up we supplemented with patient acceptable symptom state (PASS) values "Taking into account all the activities you have during your daily life, your level of pain, and also your functional impairment, do you consider that your current state is satisfactory?" (yes/no)[42,44].

Statistical analysis (WP1 and WP2): Descriptive data will be presented as means with standard deviations, medians with range or frequencies, and percentages when appropriate. T-test will be used to analyze differences between groups for the primary outcomes. Non-parametric test will be used if data are skewed. Data will be analyzed using the IBM SPSS Statistics. The significance level is set to 5%. All statistical analysis will be performed in cooperation with the statistician at ØHT.

Statistical analysis (WP3)
The measurement properties tested and related terminology follow the COSMIN checklist[28]. Levels of missing data will be assessed at the item and scale level with the latter also including imputation for missing data according to author guidelines; for example, where half or more item responses are present.
Confirmatory factor analysis (CFA) with weighted least squares estimation will be used to assess structural validity. Model fit will be assessed with the comparative fit index (CFI), Tucker-Lewis Index (TLI) and root mean square error of approximation (RMSEA) [29-31]. The CFI and TLI should be greater than 0.90 and RMSEA between 0.06 and 0.08 for acceptable fit[31,32].

Internal consistency and Cronbach's alpha will be assessed, the intraclass correlation coefficient will be used for estimating reliability within a two-way mixed effects model with absolute agreement. Weighted kappa will be used for assessing individual item reliability[32]. The standard error of measurement (SEM) and smallest detectable change (SDC) will be estimated[33]. Hypothesis testing will be used to assess the validity of the three foot and ankle instrument scores through comparisons of those for the EQ-5D-5L and clinical variables. LISREL will be used for the CFA and PASW Statistics 18. 0 will be used for the remainder of the statistical analysis.

3.2 Participants, organization and collaborations
Project leader and co- supervisor: Frede Frihagen, MD, PhD, consultant orthopaedic surgeon, Østfold Hospital Trust and professor at Oslo University Hospital. Professor Frihagen has vast research experience.
Main supervisor: Marius Molund, MD, PhD, consultant orthopaedic surgeon, Department of orthopaedic surgery, ØHT. Marius has extensive clinical and research experience. He has experience in supervising PhD students, and is a reviewer of Foot and Ankle International, the most renown journal of foot and ankle surgery.
Co-supervisor: Andrew M. Garratt, PhD, Senior researcher, PhD, Norwegian Health Institute (FHI). Dr. Garratt has several publications on psychometry (PROMS and measurement properties). He is also supervising the ongoing PROM-validation study, and is responsible for EQ-5D in Norway, which is an important generic health score.
Co-supervisor: Aksel Paulsen, MD, PhD consultant orthopaedic surgeon and head of research, Orthopaedic dept., Stavanger University Hospital (SUS) Prof. Paulsen has insight in PROM translation and research.
PhD candidate: Esten Konstad Haanæs, consultant orthopaedic surgeon, Sykehuset Levanger and PhD candidate in Department of orthopaedic surgery, ØHT,
will be responsible for the day-to-day management of the RCT, coordinating the collaborating sites, the recruitment of patients, to conduct analyses and write manuscripts.
Collaborations: Innlandet Hospital Trust, Haukeland University Hospital, Sykehuset Levanger, Ålesund Sykehus and Trondheim University hospital and Stavanger university hospital is willing to take part. Örebro University hospital has also been invited. The network will be strong and maybe international.
Håvard Furunes, MD, PhD, consultant orthopaedic surgeon, SI, Gjøvik.
Henning Klasen Hansen, consultant orthopaedic surgeon, SI, Elverum
Øystein Bakke Larsen, orhopaedic surgeon, Trondheim University Hospital (St. Olav's).
Conflicts of interest: We claim no conflict of interest for the applicants.

3.3 Budget
ØHT have applied for and been granted 50% employment of the PhD candidate for 6 years, starting at August 1st, 2024 Østfold Hospital Trust will pay for local costs related to radiographic examinations needed for medium- and long-term follow- up, presenting our research at international conferences and open access publishing.
Cooperating centres are asked to cover expenses for extra outpatient clinic costs and supplementary x-rays. If not covered, we will advice and help in the process of applying for local/regional/national research funding. Per patient- costs for x-ray surveys at collaborating hospitals if no other financing source is found.

3.4 Plan for activities, visibility and dissemination

Time schedule WP1, WP2, WP3:

Year	2024	2025	2026	2027	2028	2029
WP1	Patient inclusion	Patient inclusion	Patient inclusion	Follow up	End follow up	Data analysis/ Article
WP2	Patient inclusion	Patient inclusion	Patient inclusion	Follow up	End follow up	Data analysis/ Article
WP3	Patient inclusion	Patient inclusion	Patient inclusion	Inclusion Ending	Data analysis and article	
Statistics, Pedagogics					X	
Writing and submission						X

Dissemination: The PhD fellow will be first author on a minimum of 3 articles published in openaccess, international peer-review medical journals within the field of orthopedic medicine based on the material from these studies. The results will be presented at national and international conferences primarily in the field of orthopaedic surgery, but also in the fields of musculoskeletal and sports medicine. In addition, we aim to communicate the results to the study participants, other patients with ankle fractures and to the public.

3.5 Plan for implementation

Results from the project will be of interest for health care professionals in orthopaedic trauma, foot and ankle surgery and sports medicine. Our findings on deltoid ligament repair may influence treatment of ankle fractures depending on what we find during our study. The results from our trial will add some knowledge to the understanding of unstable ankle fractures. Maybe we can add some improvement to treatment and outcome after ankle fractures. Our validated translation of PROMs will be taken into use rapidly by health professionals as tools communication with patients in clinical and scientific work in Norway and quoted in future publications. Results will be communicated to attending patients, presented in regional media and on international congresses and published in renown journals with a high impact factor.

4. User involvement

WP3**:** Patients have been interviewed on the content in the PROMs and hence contribute to the development of Norwegian translations.

WP1 and 2: We have contacted the consumer board at Østfold Hospital and invited them to participate and provide constructive input on our protocol. We have got feedback before editing our written patient information. The patient representative is invited to have a meeting with the project group for final planning. We will also consult actual patients, who are under treatment to inform the design of the study (written and oral information) and the protocol in general.

5. Ethical considerations

The Regional Committee for Medical and Health Research Ethics (REK Sørøst) have approved WP1 and WP2 (ref. 496556) and application will be sent to the Data Protection Officers at all collaborating hospitals. The clinical trial is registered in clinicaltrials.gov database. Participants will be informed, written and orally, that participation in the studies is voluntary, and that they can withdraw their consent at any time without influencing their further treatment. All data collection and management will be in agreement with terms in approvals.

Regarding WP1, one can expect some side effects from one additional step in a surgical procedure. Side effects can be pain from the posterior tibial tendon or ankle stiffnes or problems from the ankle

or subtalar joint after deltoid ligament suture in case of malplacement of the anchor/ligament suture. Not yet being well established, it might be challenging to perform for other than foot and ankle surgeons or experienced trauma surgeons. Anyway, we do not find it very difficult to teach. We believe that the moderate risk implied by this ligament suture may be outweighed by improved talar reduction, ankle stability and function. We will of course offer collaborating hospitals teaching in our procedure for deep deltoid ligament repair.

Our data safety and monitoring board (DSMB), Are H. Stødle, Oslo University Hospital and Mette Andersen Aleris Tromsø/Vestre Viken HT have a mandate to stop the study if untoward effects are observed. They will look through major surgical complications in the groups after inclusion of the first 30 patients and then after 60 patients and function at follow up of 1 year.

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