

# Differences in gait analysis and clinical outcome after TightRope® or screw fixation in acute syndesmosis rupture: Study protocol for a prospective randomized trial

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## Study protocol

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# Abstract

**Background:** Ankle sprains and fractures are most common injuries in orthopedic and trauma surgery. The concurrent occurrence of syndesmosis ruptures in these injuries represents a more complex problem, as they often remain undetected. A proper and accurate treatment of injuries of the syndesmosis, both isolated and combined with fractures, is necessary to avoid long-term consequences (chronic instability, cartilage damage and post-traumatic osteoarthritis). The most popular treatment option is a static screw fixation and the newly developed dynamic TightRope® (Arthrex, Naples, FL, USA). The aim of this study is to compare monitor ankle range of motion and maximum ankle power in gait as functional outcome parameters of instrumented gait analysis, as well as clinical and radiographic outcome for assessing the stabilization of acute syndesmosis rupture with either a static implant (a 3.5mm metallic screw) or a dynamic device (TightRope®). **Methods:** This prospective, randomized, controlled, clinical trial will be carried out at the Center for Orthopedics, Trauma Surgery and Spinal Cord Injury of the University Hospital Heidelberg. Adult patients, who suffer from an acute syndesmosis rupture, both isolated and in combination with fractures of the lateral malleolus (Weber C and Maisonneuve fractures) and who are undergoing surgery at our trauma center will be included in our study. The patients will be randomized to the different treatment options (screw fixation or “TightRope®”). Subsequent to the surgical treatment, all patients will receive the same standardized follow-up procedures including a gait analysis and MRI of the ankle at 6 months follow-up. The primary endpoint of the study is the successful healing of the syndesmosis and biomechanical investigation with gait analysis. **Discussion:** The results of the gait analysis from the current study will help to impartially and reliably evaluate the clinical and biomechanical outcome of both treatment options of acute syndesmosis ruptures. We hypothesize that the dynamic fixation provides an equivalent or better biomechanical, clinical and radiographic outcome in comparison to the screw fixation.

## Background

Ankle fractures are common injuries in the clinic and operative daily routine of a trauma surgeon (1). Syndesmosis ruptures occur in 13% of these fractures and represents a more complex problem (2). The syndesmosis ligament connects the tibia and the fibula above the ankle joint. It is, among other ligaments, responsible for its stabilization. Isolated injuries of the syndesmosis are extremely rare and often remain undetected in the clinical routine (3). There are several clinical tests (Frick test, squeeze test, cross-leg test, fibula translation test) which confirm the suspicion of injury, but cannot secure it. Although certain syndesmotic injuries may be diagnosed radiographically, these injuries are often missed because of the inability of radiographs to detect them. Tibiofibular clear space greater than 6 mm (diastasis) in AP x-ray view is considered as a radiologic criterion for instability.

Today, magnetic resonance imaging (MRI) is the “gold-standard” for the pretherapeutic evaluation of syndesmotic injury with a sensitivity of 100% and a specificity of 93% (4).

A proper treatment of injuries of the syndesmosis complex is challenging but necessary to avoid malreduction of the syndesmosis that alters tibiofibular joint kinematics and leads to chronic instability, cartilage damage and early osteoarthritic changes of the ankle joint (5, 6). Therefore, accuracy and maintenance of reduction of the syndesmosis are considered essential when treating ankle fractures with concomitant syndesmosis injury.

Even small joint gaps, axis deviations or instabilities lead to considerable dysfunctions and thus increase the risk of post-traumatic arthrosis development (7).

The most popular treatment option of the unstable distal tibiofibular joint is a static 3.5mm screw fixation (FA DePuy Synthes, USA) with one or multiple screws through three or four cortices. Disadvantages of the syndesmosis screws are partial weight-bearing for at least 6 weeks, neglect of the dynamic property of the syndesmosis and an increased risk of chronic instability as well as the potential of late diastasis due to loosening, screw breakage or screw removal. Furthermore, syndesmosis malreduction is reported to occur in up to 50% with syndesmotic screw fixation (8, 9). 6 to 8 weeks after the initial treatment a mandatory implant removal is required to begin weight-bearing at our trauma center. In contrast, some authors prefer to retain the syndesmotic screw in place until she breaks. Whether or not the syndesmotic screw should be removed prior to weight-bearing is still discussed (10).

In contrast to screw fixation, the flexible, dynamic TightRope® (Arthrex, Naples, FL, USA) suture-button device was developed for physiological stabilization of the distal tibia and fibula. The use of this dynamic suture-button device has increased rapidly over the last years. Theoretically, this suture-button device allows physiological motion of the syndesmosis without need for implant removal, which may reduce the risk of recurrent syndesmotic diastasis as described after syndesmosis screw removal (11, 12).

Biomechanical investigations have demonstrated that the strength of TightRope® device is comparable to a tricortical 3.5mm syndesmotic screw. Several recent studies assessed syndesmosis stabilization with the suture-button device and comparative studies reported equivalent or better functional results in comparison to the syndesmotic screw (3, 13, 14).

Instrumented gait analysis is a well-established procedure at our trauma center, which allows objective quantification of gait deviations in the context of conservative and surgical treatment in the lower extremity. For assessment, the patient is equipped with skin-based markers and asked to walk repeatedly along a 5-10m long walkway at self-selected speed for monitoring joint motion via optical motion tracking. Floor mounted force plates allow for determining ground reaction forces when walking across them. This so called "standard clinical instrumented 3D gait analysis" is a modern in-vivo analysis, which allows for analyzing joint motion and joint kinetics of the major lower limb joints (15, 16).

To date, no study has yet compared both treatment options in terms of biomechanical outcome with kinetic, kinematic changes and compensation mechanisms.

The majority of earlier studies of syndesmosis fixation, which demonstrated the equality of both treatment options, used only standardized questionnaires and plain radiographs to assess syndesmosis reduction and clinical outcome.

Therefore, the purpose of this prospective randomized controlled single-center study was to assess the functional outcome namely by ankle range of motion as well as maximum ankle power as obtained via gait analysis and to rate the clinical and radiologic outcome by monitoring the stabilization of acute syndesmosis rupture with either a static implant (a 3.5mm metallic screw through three cortices) or a dynamic device (TightRope®).

In this study, we expect that dynamic fixation would provide an equivalent or better clinical and radiologic outcome as well as a similar or better function of the ankle, i.e. larger range of ankle motion within the gait cycle and a larger maximum plantar flexion power at pre-swing. It can be assumed that when the maximum ankle performance normalizes, there is sufficient healing.

This study focusses mainly on the treatment of syndesmosis rupture, but it also aims to gain insights into patients' satisfaction in correlation to functional outcome and surgical technique. Additionally, the study targets to show how risk factors, different therapeutic modalities and/or treatment strategies influence this outcome. In future, the risk of long-term consequences and complications should be minimized by analyzing the new and already existing data, the clinical-functional follow-up examination and the subjective result.

The study protocol for this study is described in the present manuscript.

## **Study Design/methods**

### *Objectives and hypotheses*

The objective of this prospective randomized controlled single-center study is the comparison of gait analysis, clinical and radiographic outcome after stabilization of an acute syndesmosis rupture with either a static implant (a 3.5mm metallic screw through three cortices) or a dynamic device (TightRope®).

The following hypotheses will be tested:

H0: The biomechanical (regarding ankle range of motion and maximum plantar flexion power in the gait analysis), clinical (study questionnaire, SF-12, OM, VAS, FAOS) and radiological outcome is different in both treatment options.

H1: The biomechanical (regarding ankle range of motion and maximum plantar flexion power in the gait analysis), clinical (study questionnaire, SF-12, OM, VAS, FAOS) and radiological outcome is equal in both treatment options.

Patients with acute syndesmosis rupture (isolated or combined), suitable according to the study protocol, will be randomized to the two different treatment options (screw fixation or TightRope®).

Syndesmosis reduction will be assessed using CT/3D imaging intraoperatively with ISO C 3D or CIOS Spin (Siemens Healthineers GmbH, Erlangen, Germany) as a part of our standard procedure.

6 Months after the initial treatment, the patients will receive an additional gait analysis and a MRI in the follow-up examination at our outpatient clinic.

### *Study design, registration and ethics*

The study protocol was conducted according to the Declaration of Helsinki and approved by the local ethical committee of our hospital (S-454/2017). Furthermore, it was registered at the German Clinical Trials Register (DRKS00013562).

This study is a registered, clinical, prospective, randomized, controlled, single-center, two-arm, parallel group trial with a one-year follow-up, carried out at a level 1 trauma center.

### *Inclusion and exclusion criteria*

Patients older than 18 years who suffer from acute syndesmosis rupture and who are undergoing surgery for a syndesmotic rupture at our Center for orthopedics and trauma surgery will be included in this study after giving their informed consent.

Exclusion criteria are pregnancy, the disability for approval, congenital deformities of the lower extremities, missing informed consent or refusal of participation. Patients with any known contraindications for MRI examination will be excluded as well.

### *Study setting and population*

Study patients pass a follow-up over one year with clinical and radiologic examinations one day before and after the initial operation as well as 6, 12, 26 and 52 weeks after treatment in our outpatient clinic. In this study there is no need for additional clinical examinations for the patients, with the exception of an additional motion analysis and a MRI 6 months after initial treatment to evaluate the biomechanical outcome and the healing status of the syndesmosis ligament.

Surgery and examinations will be performed by an experienced orthopedic and trauma surgery consultant.

The patients will be randomized to the different treatment options (screw fixation or TightRope®).

The following questionnaires will be used for clinical and psychosocial evaluation:

"study questionnaire screw vs. TightRope"

"SF-12 – Health survey"

"Score of Olerud und Molander (OMAS)"

"pain on a VAS"

"Foot and ankle outcome score (FAOS)"

In the following, the procedure of this study is described and additionally illustrated in

figure 1:

- Diagnosis of an acute syndesmosis rupture (isolated or combined) and indication of surgical treatment in our clinic
- Informed consent and inclusion
- Randomization 1:1 to the different treatment options (screw fixation or TightRope®)
- Preoperative clinical and radiologic examinations
- Preoperative clinical and psychosocial evaluations with questionnaires above-mentioned
- Surgery with screw fixation or TightRope®
- Standardized intraoperative CT/3D imaging with ISO C 3D or CIOS Spin (Siemens Healthineers GmbH, Erlangen, Germany) for assessment of syndesmosis reduction
- Postoperative clinical and radiologic examinations with x-ray of foot and ankle
- Clinical and radiologic follow-up (6 weeks, 3, 6, 12 months) postoperatively + abovementioned questionnaires
- additional standard clinical instrumented 3D gait analysis to evaluate the biomechanical outcome (duration: 30 minutes) 6 months after the operation
- additional MRI of the ankle joint to evaluate the healing status of the syndesmosis ligament (duration: 30 minutes) 6 months after the operation

### *Participants and consent*

All patients assigned for surgical treatment of acute syndesmosis rupture at our level 1 trauma center can be involved in our study. Patients must be at least 18 years of age without any exclusion criteria and provide their written consent before any study-relevant intervention. Before participation, each patient, suitable to the study protocol, will be fully informed by informed consent about the scientific purpose and risks associated with the procedures. The participation is voluntary and every participant is able to withdraw their consent to participate in the trial at any time without giving reasons.

Informed consent takes place in an one-to-one appointment at trauma center with an experienced orthopedic and trauma surgeon. A full verbal explanation of the study, a written patient information sheet and informed consent form will be provided before inclusion.

## *Randomization*

Patients will be randomly assigned to one of two groups (intervention or control) using a computer-generated random block assignment in a 1:1 ratio using nQuery Advisor v7.0 software (Statsols, Cork, Ireland). This method helps in maintaining the balance of treatment assignment while reducing the potential for selection bias. Patients, researchers performing the follow-up examination and the trial statistician will be blinded to the group allocation. If the treatment of syndesmosis rupture is not accomplished after randomization due to an intraoperatively observed missing acute syndesmosis rupture with no need of stabilization, the patient will be excluded from final analysis. At the date of screw removal 6 to 8 weeks after the operation, a blinding of the patients will no longer be possible.

## *Surgical treatment*

The fractures will be fixed within 8 days of the initial trauma in both groups using standard AO (Arbeitsgemeinschaft für Osteosynthesefragen) (17) principles. Antibiotic prophylaxis will be given perioperatively. Open reduction and internal fixation (ORIF) of fibula fractures will be treated either with a 1/3 tubular plate with or without lag screws or in high fibula fractures with syndesmosis fixation only. Additional fractures of medial and/or posterior malleolus will be treated according to standard principles before stabilizing the syndesmosis. The distal tibio-fibular joint will be reduced without direct visualization of the syndesmosis and held at its anatomical position by a reduction clamp. The ankle joint will be positioned at an angle of 90° between the tibial shaft and the foot during syndesmosis fixation in accordance with the randomization (cortical screw or TightRope®).

For the static syndesmotic screw fixation, a 2.5 mm hole will be drilled under fluoroscopic guidance, approximately 2 cm above and parallel to the distal tibial joint line from lateral to medial. If plating of the fibular fracture is necessary, the hole will be drilled through an empty screw hole. Three cortices will be drilled through and a 3.5 mm screw will be tightened.

For the dynamic fixation of the Syndesmosis by means of TightRope® a 3.5 mm hole will be

drilled under fluoroscopic guidance, approximately 2 cm above and parallel to the distal tibial joint line (through a hole of the plate if present) from lateral to medial. A guide needle will be inserted from lateral to medial through the drill hole to position the oblong button over

the medial tibial cortex and confirmed by x-ray. Afterwards, the assembly will be tensioned by pulling the free ends of the FiberWire on the lateral side. These will be hand-tied with a surgical knot and the round button will be firmly applied on the lateral cortex of the fibula (or onto the plate if present). After achieving an adequate syndesmotic fixation by either technique, the reduction clamp will be removed and the stability controlled under fluoroscopy.

After syndesmosis fixation, intraoperative CT/3D imaging with ISO C 3D or CIOS Spin (Siemens Healthineers GmbH, Deutschland) will be performed to evaluate syndesmosis reduction.

The post-operative treatment protocol is similar in both groups. The ankle will be immobilized in a below-the-knee cast with the ankle joint at 90° for 6 weeks with partial weight-bearing. Between the 6<sup>th</sup> and 8<sup>th</sup> week, only the static syndesmosis screw will be removed in a standardized outpatient surgery. The dynamic fixation of the syndesmosis by means of TightRope® needs no removal postoperatively. Afterwards, weight-bearing can be gradually increased with approximately 20 kilograms per week until full weight-bearing is achieved.

### *Follow-up*

Subsequent to surgery, all patients will receive similar follow-up procedures. Follow-up at our trauma center is standardized, based on a well-established protocol, and all procedures and diagnostics are based solely on medical indications. First radiological and clinical evaluation of the surgical treatment will be performed on day two after surgery. Discharge from hospital will be realized as soon as general health conditions (soft tissue conditions, patient mobility and pain level) allow it. Afterwards, patients will receive physiotherapy and manual lymphatic drainage. Further clinical and radiographic evaluations are planned for 6 weeks, 3, 6 and 12 months after surgery following our standardized procedure for fracture patients treated in our hospital (tab. 1). There are no additional follow-up appointments or x-ray examinations necessary for the study. Merely the gait analysis and MRI control of the syndesmosis will be performed 6 months postoperatively during the regular follow-up appointment.

MRI images will be assessed by a senior radiologist for degenerative changes of the tibio-talar joint and the syndesmosis structure (unaffected, hyperintense signal alteration on T2, partial tear, complete tear), widening and calcification. By using questionnaires preoperatively and postoperatively after 6 weeks, 3, 6, and 12 months during the appointments, patients can provide information on pain, mobility of foot and ankle and quality of life (SF-12) (18) during the course of treatment. General patient data, including age, profession, Body Mass Index (BMI), risk factors, medication, concomitant diseases, previous surgeries and details of the accident will be documented preoperatively.

At 25 weeks postoperatively, patients also receive a gait analysis and MRI is performed to assess motion anomalies and the healing process of the syndesmosis.

The planned study will run over two years. Patients will be admitted over a period of one year. Each patient will be treated and followed-up over a twelve-month period.

All data will be stored and monitored using pseudonyms. The data of all patients will be analyzed statistically and compared at the end of the two years (tab. 1).

Furthermore, all data of the participating patients will be carefully assessed, and all adverse events and complications of the treatment will be reported at the end of this trial. The harms will be categorized according to their degree of severity in either serious or non-serious.

Tab. 1: Overview of clinical and radiologic follow-up

	PreOP	intraOP	2nd day post OP	6 weeks post OP	3 months post OP	6 months post OP	12 months post OP
Informed consent	×	-	-	-	-	-	-
Clinical examination	×	×	×	×	×	×	×
X-ray	×	×	×	×	×	×	×
CT/3D imaging	-	×	(X)	-	-	-	-
screw removal	-	-	-	×	-	-	-
MRI	-	-	-	-	-	×	-
gait analysis	-	-	-	-	-	×	-
<b>Questionnaires</b>							
SF-12	×	-	-	×	×	×	×
"Screw fixation vs TightRope"	×	-	-	×	×	×	×
Olerud und Molander	-	-	-	×	×	×	×
VAS pain	-	-	-	×	×	×	×
Foot and ankle outcome score	-	-	-	×	×	×	×

CT - computed tomography, MRI - magnetic resonance imaging, SF-12 - 12-item Short Form health survey, VAS pain - Visual Analog Scale for Pain

### *Criteria that lead to termination of study*

Every participant is able to withdraw their consent to participate in the trial at any time without giving reasons. Thereby the recorded study data may be destroyed immediately upon request or with the consent of the participant, can still be included in the evaluation.

If initial data indicates either impossible realization due to technical difficulties or an increased risk for the participants that is potentially harmful, the study will be terminated immediately.

### *Sample size calculation and statistical analyses*

Formal sample size determination is not possible as potential effects are not yet known. Data from previous studies were utilized to determine the necessary sample size (19-21). We plan a sample size of 25 patients, who will be treated with the cortical screw fixation and 25 patients, who will be treated with the dynamic TightRope® system within two years. The patients will be randomized to the two different treatment options. The randomization will be independent of the surgeon and the doctor who will do the examinations and the questionnaires.

Standard unpaired Student's t-test and ANOVA-test to detect significant changes between the two groups will be conducted.

The empirical distribution of continuous data and scores will be reported and calculated with means, standard deviation (SD), median, minimum, maximum values and with absolute and relative frequencies for categoric data as well as unpaired t-test p-values to depict a significant difference between the different groups. An independent senior statistician of the Institute of Medical Biometry and Informatics of our university will perform the analysis.

The analysis and illustrations will be carried out by use of SPSS version 25.0 for 135 Windows (IBM Corp., Armonk, New York, USA) and GraphPad Prism version 6.00 for Windows (GraphPad Software, San Diego, California, USA). Categorical variables will be examined for differences using the chi-square test. Possible differences for continuous data and scores between groups will be evaluated with the Wilcoxon U-test. For the representation of statistical relationships, the Pearson correlation coefficient will be used. The final details of the statistical analysis will be established in a statistical analysis plan, which will be completed before the closing of the database (before the end of data collection). A p-value of  $\leq .05$  will be used to indicate statistical significance.

#### *Primary outcome measures*

The primary endpoint of this study is a successful healing of the syndesmosis 6 months after surgery by evaluation of MRIs of the ankle (22). MRI scanning in the plain of the syndesmotic ligaments is the investigation of choice to evaluate syndesmosis healing. MRI images will be evaluated for degenerative changes of the cartilage of the ankle, appearance (unaffected, hyperintense signal alteration on T2, partial/complete tear), widening and calcification of the syndesmosis. If these evaluations are ordinary, successful healing can be assumed.

Another primary outcome measurement of this study is the gait analysis 6 months postoperatively to detect biomechanical differences between both treatment groups.

Due to the pilot study character, it remains to be clarified which are the most suitable parameters to depict potential effects and differences.

#### *Secondary outcome measures*

Secondary endpoints and measurements will be recorded 6 weeks, 3, 6 and 12 months postoperatively. The measurements include different questionnaires mentioned above with subjective evaluation of the quality of life (assessed by the 12-item Short Form health survey [SF-12] questionnaire) (18), pain (Visual Analog Scale [VAS]). In addition, a self-designed questionnaire as well as the "Score of Olerud und Molander (OMAS)" (23) and "Foot and ankle outcome score (FAOS)" (24) will be used to evaluate the range of motion, deficits in daily life, symptoms after ankle fractures and after surgical treatment and socioeconomic factors (period of time, returning back to work and time of recovery).

## Discussion

The objective of this prospective randomized controlled single-center study is the comparison of the gait analysis, clinical and radiographic outcome after stabilization of an acute syndesmosis rupture with either a static implant (a 3.5mm metallic screw through three cortices) or a dynamic device (TightRope®).

The study aims to investigate the the clinical, biomechanical and radiographic outcome of TightRope® as a dynamic stabilization device compared to the gold-standard, the static screw device after acute syndesmosis ruptures of the ankle.

A lot of studies investigated the equality of both treatment options with numerous advantages of the suture-button device over the screw fixation (25). Zhang et al. described in their review that both devices had similar functional outcomes and postoperative complication rates. Furthermore, TightRope® device leads to a better range of motion and earlier return to work, compared to the screw fixation. Besides, TightRope® fixation groups had lower rates of implant removal, implant failure and malreduction.

Actually, there is no human study with focus on objective biomechanical outcome measurements by using a gait analysis. Former biomechanical studies have demonstrated the advantages of the dynamic fixation of the syndesmosis only in animals or models (13, 26-28).

In the current study we use the OM score, as it is the only validated assessment tool for ankle fractures. It detects clinical differences between treatment groups with a higher sensitivity and specificity as other scores (29).

In our study, weight-bearing is allowed after 6 weeks in both groups and only after screw removal in the intervention group, although many studies have proposed earlier weight-bearing with the dynamic fixation on the one hand (14, 30). On the other hand, the static screw fixation prohibits early weight-bearing especially because of a high risk of screw breakage. These studies show that early weight-bearing is associated with a shorter recovery time as well as a quicker return to main activities.

Furthermore, the need and timing for postoperative routine syndesmotic screw removal are still subject to controversial discussions. In accordance with AO principles, elective routine screw removal prior to the beginning of full weight-bearing is carried out in our trauma center between the 6<sup>th</sup> and 8<sup>th</sup> week after surgery.

Unfortunately, a second operation for implant removal involves the risk of potential infections, increased costs for the patient, missed work days, a longer recovery time or other complications (31). The higher material costs of the TightRope® are largely surpassed by the reoperation costs (32).

Furthermore, other studies have demonstrated that early screw removal before syndesmosis healing increases the risk of developing a syndesmotic diastasis (33). Schepers et al. demonstrated in their review that there was no better outcome when routinely removing syndesmotic screws (10).

The number of screws, screw size, and number of cortices are still subject to controversial discussions as well. According to the standard AO principles and depending on the injury we use one or two 3.5 mm tricortical trans-syndesmotic screws as well as one or two TightRope® suture button devices.

Up to 30% of patients with an ankle fracture complain of residual symptoms such as pain, swelling and movement restrictions. Clinical and radiological investigations cannot clearly identify the causes for these complaints. Additional objective information about the clinical outcome during postoperative follow-up examination are necessary and can be provided by modern investigation techniques such as gait analysis (34). However, these modern investigation tools have not yet been used in the literature so far to compare the outcome of TightRope® and screw fixation patients.

Clinical gait analysis helps to identify the level of ground reaction forces, ankle loads and reasons of incorrect loads or overloads. It is possible to determine parameters, like cadence (steps per minute), stride length, gait speed or walking distance as well as parameters of the gait symmetry and the variability of the gait pattern. An incorrect marker placement on the body, the soft tissue's variability as well as other adjacent joint pathologies or deformities can lead to systematic measurement errors (35).

The primary strength of this study is its prospective randomized controlled and well-established design and follow-up examination protocol. All outcome measures and tools were validated. CT/3D scan will be performed to assess the quality of ankle reduction.

The large number of 50 patients is also remarkable. Moreover, only experienced orthopedic trauma surgeons will perform all surgical procedures which improves good external validity. The objective biomechanical outcome measurements with the aid of gait analysis is a unique characteristic which can show kinematics and functions of the ankle joint.

Limitations of the study include the diversity of ankle injury and fracture types, that can bias the outcome. To minimize bias, all included patients will follow the same postoperative weight-bearing pattern.

We only perform CT/3D imaging on the fracture site. A bilateral CT investigation to detect possible anatomical variations will not be performed. A one-year follow-up involves the danger of not being able to detect long-term complications as degenerative changes or osteolysis that could be a result of either a malreduced syndesmosis or an initially unreported osteochondral lesion. Therefore, a longer follow-up period would be interesting to observe such possible changes in the ankle mortise (widening, osteolysis or osteoarthritis).

Our hypothesis is that TightRope® will provide the same biomechanical, clinical and radiological outcome with a similar or better postoperative function of the ankle in the gait analysis. Furthermore, we assume that the recovery time and the time required to return to work is shorter in the TightRope® cohort than in the static screw control group.

The results of the study should, in biomechanical terms, therefore help to demonstrate the comparability of different treatment methods by using the gait analysis as an objective and modern measurement method.

## **Trial Status**

The RCT trial is ongoing (study protocol version 1.0 02.08.2017, S-454/2017), patient recruitment and surgical treatment began in December 2017. Recruitment is expected to be completed in December 2019. The follow-up is conducted over a twelve-month period for each patient included. Data analysis will only be performed after complete one-year follow-up. Thereafter, the final results will be published.

## **List Of Abbreviations**

AO: "Arbeitsgemeinschaft für Osteosynthesefragen"

BMI: Body Mass Index

CT: computed tomography

MRI: magnetic resonance imaging

OMAS: Score of Olerud und Molander

ORIF: open reduction and internal fixation

SF-12: 12-item Short Form health survey

VAS pain: Visual Analog Scale for Pain

## **Declarations**

### **Study beginning**

The acquisition of study participants started after receiving the approval of the trial protocol by the local ethics committee.

### *Ethics approval and consent to participate*

Ethical approval was obtained by the Ethics Committee of the University of Heidelberg Medical Faculty prior to the beginning of the study (Ethikkommission I der Medizinischen Fakultät Heidelberg, S-454/2017).

This trial was registered in the German Clinical Trials Register (DRKS) in Freiburg, a primary registry within the WHO Registry Network, Germany, on 07 December 2017 with the trial registration number DRKS00013562.

The trial will be conducted at our Center for Orthopedics and Trauma Surgery in the context of Good Clinical Practice and in accordance with the Declaration of Helsinki.

The Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) Checklist for the implementation of study protocols was followed (Fig. 2 and Additional file 1) (36, 37).

Written informed consent will be obtained from each patient. In the event that a patient's physical or mental health becomes jeopardized because of participation in the present study, the patient will be dismissed immediately and excluded from the study. All protocol modifications will be registered with the DRKS, published in the final paper and communicated to the participants. Before inclusion into the trial, participants will be informed both orally and in writing about all relevant aspects of the trial (e.g. aims, methods, anticipated benefits, potential risks of the study and possibly entailed discomfort). Participants must be at least 18 years of age and provide written informed consent. They have to be able to understand the character and individual consequences of the clinical trial. The participants' free decision to participate will be documented by signature on the informed consent form.

All patient-related information is subject to medical confidentiality and to medical secrecy, the European General Data Protection Regulation (DSGVO – Datenschutz-

Grundverordnung), the Federal Data Protection Act (Bundesdatenschutzgesetz) and the State Data Protection Act (Landesdatenschutzgesetz). Third parties will not have any insight into original data.

#### *Consent for publication*

Not applicable. This manuscript does not contain data from any individual person.

#### *Availability of data and materials*

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

#### *Competing interests*

The authors declare that they have no competing interests in this section.

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#### *Authors' contributions*

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Study conception and design: JD, SW, GS, SIW, CF.

Acquisition of data: JD, SW, GS, SIW, CF.

Data monitoring and statistical analysis: JD, SW, TB, GS, SIW, CF.

Analysis and interpretation of data: JD, SW, TB, GS, SIW, CF.

Drafting of manuscript: JD, SW, GS, SIW, CF.

Critical revision: JD, SW, TB, GS, SIW, CF.

All authors read and approved the final version of this manuscript. Authorship eligibility guidelines according to the ICMJE were followed. The use of professional writers is not intended.

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## Additional File Information

Additional file 1: Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2013 Checklist: recommended items to address in a clinical trial protocol and related documents. (JPEG 109 kb)

## Figures

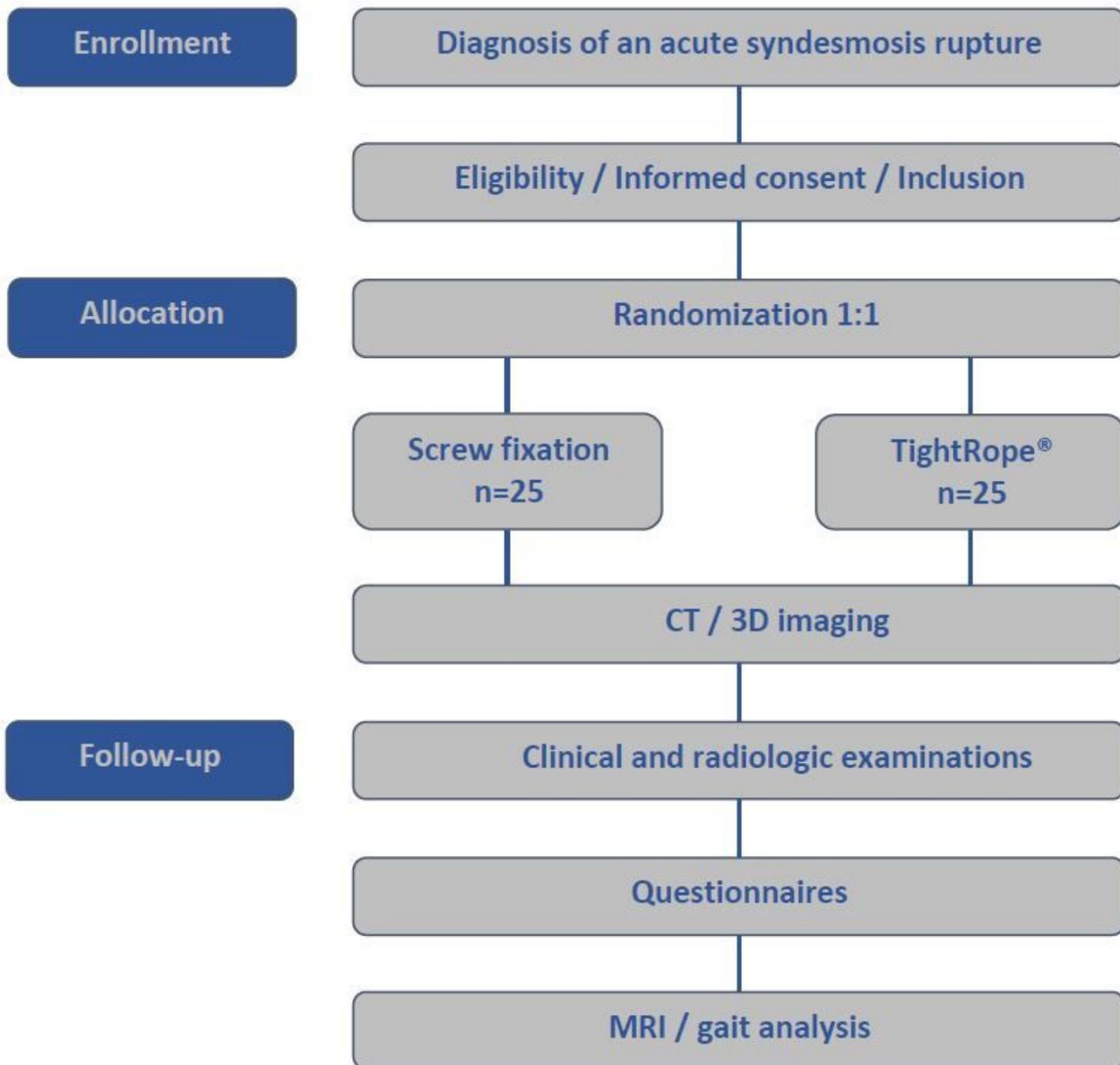


Figure 1

Flowchart of the study protocol

TIMEPOINT**	STUDY PERIOD							
	Enrollment	Allocation	Post-allocation (12/2017-01/2020)					Close-out
	<i>preOP day</i> 12/2017- 12/2019	day of treatment 12/2017- 12/2019	<i>t</i> <sub>1</sub> 2 <sup>nd</sup> D	<i>t</i> <sub>2</sub> 6W	<i>t</i> <sub>3</sub> 3M	<i>t</i> <sub>4</sub> 6M	<i>t</i> <sub>5</sub> 12M	03/2020
<b>ENROLMENT:</b>								
Eligibility screen	X							
Informed consent	X							
<i>Randomization</i>	X	X						
Allocation		X						
<b>INTERVENTIONS:</b>								
<i>Screw fixation</i>		X		X*				
<i>TightRope</i> <sup>®</sup>		X						
<b>ASSESSMENTS:</b>								
<i>Radiologic outcome</i>		X	X	X	X	X	X	
<i>MRI</i>						X		
<i>Gait analysis</i>						X		
<i>Clinical outcome</i>				X	X	X	X	
<i>Subjective outcome</i>				X	X	X	X	

Figure 2

Study process schedule (according to the standard protocol items: recommendations for Interventional Trials (SPIRIT) guidelines)

## Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [Tabelle.JPG](#)
- [SPIRITFillablechecklist15Aug2013.doc](#)
- [EthicalApprovalenglisch.docx](#)