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TENSION BAND VERSUS LOCKING PLATE FIXATION FOR THE TREATMENT OF PATELLA FRACTURE

- a High Quality, Multicenter, Randomized Clinical Trial

STUDY PROTOCOL

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Problem: Approximately 700 patients sustain a patella fracture each year in Demark. Treatment of displaced patella fractures with tension band wiring has become the treatment of choice. However, the outcome following this surgical procedure is commonly reported with knee pain, restriction in joint motion, limitations in activity of daily living and decreased quality of life (QOL).

Potential solution: Locking plate fixation has recently been introduced for patella fractures but has not been tested against standard treatment with tension band fixation. Biomechanical testing has demonstrated more stable fixation of the fractures compared to tension band wiring. However, only few small-scale clinical studies and case series have reported on the patient-reported outcome, functional outcome and safety of locking plate fixation for patella fractures. Performing a high quality independent randomized controlled trial is essential to investigate the effect and safety of tension band wiring versus locking plate fixation to provide high quality evidence and to investigate the economic consequences.

@ this study is organized by the Lower Extremity Research Group (LERG), Department of Orthopedic Surgery - Aalborg University Hospital.

INTRODUCTION

Fractures of the patella are recently reported with an overall incidence of 13.1/100,000/year [1] - representing almost 0,5% of all bone fractures.[2]

The primary aim when treating a patella fractures is to restore the knee extensor mechanism and the patella articular surface. The acute management of patella fractures can be surgical or conservative, depending on fracture classification, and impairment of the extensor mechanism.[3,4] Fractures with a dislocation of maximum 2-3 mm and preserved extensor function are suitable for conservative management.[5,6] Other fractures are indicated for surgical treatment.[5–7] The standard surgical procedure includes tension band wiring for transverse fractures and for comminuted fractures. Screws and Kirshner wires are commonly used in combination with tension band wiring.[8,9]

Following patella fractures, patients commonly report pain, restrictions in range of joint motion, muscle weakness, difficulties with weight-bearing tasks such as walking and climbing stairs and restrictions in quality of life.[9–16] Furthermore, outcomes following patella fractures are reported with high re-operation rates[17] and increased risk in the development of posttraumatic knee osteoarthrosis.[11,18,19]

Recently a locking plat system for surgical management of patella fractures have been introduced. Biomechanical testing has demonstrated mores stable fixation of the fractures using locking plates compared to tension band wiring.[20] However, only few small-scale cohort studies and case series have reported on the clinical, functional and safety outcome of locking plate fixation for patella fractures.[21–28] To date, no studies have tested tension band wiring against locking plate fixation in a randomized and well-powered design in patients with patella fractures.

HYPOTHESIS AND OBJECTIVES

Hypothesis

Locking plate fixation of patella fractures are superior in patient-reported outcome compared to usual care tension band fixation 1 year after surgery.

Primary objective

The overall objective of the study is to compare the 1-year patient-reported Knee Injury and Osteoarthritis Outcome Score ($KOOS_5$)[29] after standard tension band fixation with locking plat fixation for patients with patella fractures.

Secondary objectives

Several other analyses are of interest and are planned but are not objectives of this study. Therefore, these analyses will, for the major part, hypothesis-generating. Analyses of this type include, but are not limited to harms, muscle atrophy, pain, general health, gait function, time to return to work and economical consequences between the two groups.

METHODS

Study design

This study is a pragmatic, prospective, assessor-blinded, randomized independent clinical trial in which we compare locking plate fixation to standard tension band fixation in patients with patella fractures.

The study protocol was developed using the PREPARE trial guide[30] and conforms with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT).[31] The reporting of results will adhere to the Consolidated Standards of Reporting Trials (CONSORT) statement for reporting RCTs.[32]

The study will be registered at ClinicalTrials.gov in May 2021 (NCTXXXXXXX, URL: XXXXX). Enrolment of the first patient will be in September 2021. Enrolment is expected to finalize in December 2022.

Study setting and patients

This study is a multicenter design. Patients will be included from the Department of Orthopedic Surgery, Aalborg University Hospital, Denmark, Department of Orthopedic Surgery, Hjoerring Hospital, Denmark, Department of Orthopedic Surgery, Randers Hospital, Denmark, Department of Orthopedic Surgery, Kolding Hospital, Denmark and Department of Orthopedic Surgery, Viborg Hospital, Denmark and Department of Orthopedic Surgery, Aarhus University Hospital, Denmark.

Participants will be assessed for eligibility by consecutive sampling. A patient will be asked for participation if he/she has met all of the inclusion criteria and has not met any of the exclusion criteria specified below.

A patient will be eligible for study participation if he/she meets the following criteria:

- Above 18 years of age
- Patella fracture suitable for surgically treatment, with both surgical methods
- AO classification 34-B, 34-C

A patient will be excluded from the study if he/she meets any of the following criteria:

- Open patella fracture above Gustillo grade 2
- Bilateral patella fracture
- Total knee replacement in the affected extremity
- Other fractures of the affected extremity within the previous 12 months.
- Other reasons for exclusion (unable to understand Danish, mentally unable to participate, etc).
- Prior ipsilateral patella fracture.

Postoperatively the patients will be fitted with a knee stabilizing brace. Initially the brace will be set to 0 degrees ROM for 2 weeks, followed by 2 weeks with ROM 0-60 degrees and 2 weeks of ROM 0-90. A Standardized physiotherapy regime will be offered for all patients from week 2 postoperatively.

Recruitment

Medical staff at the Departments of Orthopedic Surgery on participating sites, will take part in the recruitment procedure. Oral and written information about the study will be provided to the patient. Patients are recommended to take at least 2 hours to consider and discuss participation with a relative before deciding on participation in the study. Before planning surgery patients will be asked whether they are willing to participate in the study. If patients agree to participate in the study written informed consent will be obtained. If patients disagree to participate in the study standard surgery will be offered and patients will not be included in the study.

Randomization

After baseline assessment the patients fulfilling eligibility criteria and who are willing to participate will be randomized to locking plate fixation VS standard care tension band fixation. Randomization will be performed after the patient has been anesthetized. To ensure that the number of participants receiving the two interventions is closely balanced within each stratum a computer-generated randomization schedule in random-sized permuted blocks of three patients stratified by hospital and gender will be used. For each stratum (female, male), the allocation ratio will be 1:1. Computer-generated randomization lists will be used.

Blinding

At the 3-,6- and 12-months follow-ups, blinded outcome assessments will be performed by a physiotherapist/nurse. All assessors involved in the study on all sites will receive extensive training regarding outcome assessment for the trial. Masking the implant towards the patient will be obtained by standardized surgical reports regardless of type of implant used.

Before unblinding the trial, an independent statistician (MBJ) will perform the analyzes. Results from the analyzes will be presented to all authors prior to unblinding the randomization code. With the group allocation masked all authors agree on two written interpretations of results before unblinding the randomization code.

DATA COLLECTION AND OUTCOME

Data from all patients will be collected at baseline and at 3-, 6- and 12-months follow-ups.

Baseline characteristics

Age, gender, height, weight and BMI will be collected. Furthermore, co-morbidity, smoking, diabetic, trauma mechanism and fracture classification (CT-based) will be obtained. Socioeconomic status measured by job status and education level will be obtained by interview.

Primary outcome

One-year Knee Injury and Osteoarthritis Outcome Score – ($KOOS_5$).[29]

The Knee Injury and Osteoarthritis Outcome Score (KOOS) [29] is a standardised patient-reported questionnaire developed to evaluate knee problems. The questionnaire includes five subscales: pain, ADL, symptoms, sport and QOL and an overall score $KOOS_5$ can be calculated. A total score of 100 indicates no symptoms, and 0 indicates major symptoms. KOOS reference data are available. [34]

Secondary outcomes

Knee Injury and Osteoarthritis Outcome Score – subscales: pain, ADL, symptoms, sport and QOL. KOOS outcome will be measured at 3-, 6- and 12-months follow-ups.

General health will be assessed using EQ-5D-5L questionnaire (5-level version), both the descriptive index and the EQ-VAS. This will also allow for a later cost-effectiveness analysis. It consists of five dimensions: Mobility, self-care, usual activities, pain/discomfort and anxiety/depression, and a self-rated health scale on a 20 cm vertical, visual analogue scale with endpoints labelled 'the best health you can imagine' and 'the worst health you can imagine'. An Eq5d-5L index of 1.0 indicated full health, 0 death, and -0.59 denoted a condition worse than death. General health will be measured at 3-, 6- and 12-months follow-ups.

Knee pain and neuropathic pain will be assessed using the "PainDETECT" questionnaire. The "PainDETECT" screening questionnaire uses a scoring method between 1-38. Pain will be measured at 3-,6- and 12-months follow-ups.

Bone union, will be evaluated on standard AP and side X-rays of the fractured patella. The evaluation of bone union will be defined as: i) visible callus formation, diminished no visible fracture line and no pain from the fracture site at weight-bearing and at clinical examination. Will be measured at 3-,6- and 12-months follow-up.

Maximum isometric knee-flexion and extension strength at 60 degrees knee flexion measured as Nm/kg body mass. Will be measured bilaterally by a strap-mounted dynamometer attached to the wall (Mecmesin AFG2500, Mecmesin Ltd, West Sussex, UK). Measures will be performed at 12-months follow-up.

Knee range of motion. *W*ith the patient supine on an examination table the full range of passive motion in both knee joints will be measured using a standard goniometer. Measures will be performed preoperatively and at 3- 6- and 12-months follow-ups.

Gait assessment. Walking ability and gait asymmetries in the two groups will be measured while patients walking on a pressure-sensitive mat (GAITRite System®).[35] The mat registers footprints, gait speed, and cadence, as well as temporal and spatial parameters of the gait cycle.
Gait speed and cadence represented the general characteristics of the gait pattern. Gait characteristics for the injured and the non-injured leg were evaluated with respect to single-support and step-length. The asymmetry between the injured and the non-injured leg was reported as percentage asymmetry.[36] Furthermore, the variability of the gait cycles was reported as the coefficient of variance (CV) of stance time. Will be measured at 3-, 6- and 12-months follow-up. Gait assessment will only be performed for patients included on the site of Aalborg University Hospital.

Time to return to work. Measure the time from surgery to end of sick leave measured in days.

Harms: Adverse events, defined as any negative or unwanted reactions to the two groups will be recorded. Based on previous reports we will focus on: infection, DVT and re-operation. Patients are continuously requested to report any suspicion of a potential AE. Furthermore, adverse events (AE) will be recorded at 3-, 6- and 12-months follow-up by asking patients about potential AEs using open-probe questioning to ensure that all AEs are recorded. Furthermore, medical records will be checked at the primary endpoint (12 months) for all AEs occurring from inclusion until the 12 months follow-up. An AE is defined as any undesirable experience during follow-up leading to contact with the healthcare system (general practitioner or hospital). If an AE result in hospitalization, prolonged inpatient hospital care, result in re-surgery, or if an AE is life-threatening, result in death, permanent disability or damage, they will be categorized as serious adverse events (SAEs).

DATA MANAGEMENT, ETHICS AND MONITORING

The Danish Data Protection Agency have approved the study (N- 20210022). Before, during and after the trial, all personal data will be stored securely in order to protect confidentiality. The study will be approved by the Danish Committee on Health Research Ethics (N-2021-0022) and will be conducted in agreement with the Helsinki declaration. All participants will give a written informed content. A data monitoring committee evaluating any adverse events between all included sites will be established. The data monitoring committee will consist of the primary investigator on all sites and the first and last author of this paper. Both main data and adverse event data will be entered into and managed in a RedCAP solution managed by Aalborg University Hospital.

STATISTICS

Sample size calculation

The study will be powered to detect a 10-point difference between groups in $KOOS_5$ at the primary endpoint - 12 months follow (power of 80 % and significance level at 0.05 (two sided). The calculation of the sample size is based on previous study from Aalborg University Hospital reporting the long-term KOOS outcome following patella fractures treated with standard care tension band fixation.[12] With a reported standard deviation of 18 calculation showed that 51 patients will be required in each group.

The drop-out rate was set to 20 % and therefore, a total of 122 participants will be randomized.

Disposition of patients

The number of patients either completing or permanently discontinuing the study will be summarized using counts and percentages.

Study population definitions

The Intention to treat (ITT) population consists of all randomized patients irrespective of whether the patients actually received study intervention or their compliance with the study protocol, in the treatment group to which the participant was assigned at randomization. A patient will be considered randomized as soon as a treatment is assigned according to the allocation sequence.

General statistical approach: For continuous variables we will calculate mean, standard deviation, median, range (minimum and maximum), as well as number of missing data (if relevant). Summary tables for quantitative variables included in publication are expected to include at least mean and standard deviation by treatment group, but other descriptors may be displayed as well.

All summary tables for categorical variables will display counts, percentages and number of missing data (if relevant) by treatment group.

Handling of missing data: Multiple imputation will be used.

Primary analysis: The primary analysis will be done on the ITT population. The main statistical comparison will be performed using the un-paired *t* test. In case of clear deviations from the assumption of normally distributed values, the analysis will be supplemented by a bootstrap approach.

Superiority will be claimed if the between-group difference in $KOOS_5$ at 12 months has a significant magnitude of at least 10 KOOS point. In order to assess the robustness of the primary analysis, the main analysis will be repeated on the As-Observed population.

Secondary analyses: Between-group comparisons at 12 months follow-up in the secondary continuous outcomes will be analyzed utilizing the same statistical methods as the primary outcome.

Adverse events will be compared between groups at 12 months follow-up using a Poisson model.

A detailed statistical analysis plan will be made publicly available before the last patient is included in the study.

DISSEMINATION

Results will be submitted for publication to an international, peer-reviewed journal, regardless of whether the results are positive, negative or inconclusive in relation to the study hypothesis. Authorship eligibility will be based on the recommendations from the International Committee of Medical Journal Editors (ICMJE). The order of the authors in the publications will be identical to this protocol, conditioned on the inclusion of patient by the site represented by the author. Furthermore, a full list of all collaborators on the different sites will be published together with the above list of authors if the publishing journal support collaborators listing.

PERSPECTIVES

This trial is expected to add new knowledge concerning the surgically treatment of patella fractures. To the authors knowledge this study is the first to add randomized knowledge of locking plate fixation VS standard care tension band fixation to patients with patella fractures.

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