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Protocol Article

Tension band versus locking plate fixation for patella fractures – a protocol of a randomised controlled trial

Rasmus Elsoe[1], Rikke Thorninger[2], Rasmus Severinsen[2], Jens-Christian Beuke[3], Rikke Serritslev[3], Steffen Skov Jensen[4], Morten Kjerri Rasmussen[4], Peter Szephalmi[5], Juozas Petruskevicius[6], Jeppe Barckman[6], Niels Henrik Bruun[7] & Peter Larsen[1, 8]

1) Department of Orthopedic Surgery, Aalborg University Hospital, 2) Department of Orthopedic Surgery, Regional Hospital Randers, 3) Department of Orthopedic Surgery, Regional Hospital Kolding, 4) Department of Orthopedic Surgery, Regional Hospital Viborg, 5) Department of Orthopedic Surgery, Hjoerring Hospital, 6) Department of Orthopedic Surgery, Aarhus University Hospital, 7) Research Data and Biostatistics, Aalborg University Hospital, 8) Department of Occupational Therapy and Physiotherapy, Aalborg University Hospital, Denmark

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ABSTRACT

INTRODUCTION. Following surgical management of patella fractures, patients commonly report pain; difficulties with weight-bearing tasks such as walking, running and climbing stairs; and restrictions in quality of life. Recently, a locking plate system for surgical management of patella fractures has been introduced. To date, no studies have compared standard treatment with tension band wiring with locking plate fixation in a randomised study design. We aim to compare the one-year patient-reported Knee Injury and Osteoarthritis Outcome subscale scores ($KOOS_{5\text{-subscales}}$) after standard care tension band fixation with locking plate fixation for patients with patella fractures.

METHODS. This is a multicentre randomised and prospective clinical trial. A total of 122 patients will be included in the study, and the primary outcome will be the KOOS subscales at 12 months after surgery.

CONCLUSIONS. Findings from the present study are expected to advance our understanding of outcome following surgical treatment of patella fractures.

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Fractures of the patella have recently been reported at an overall annual incidence of 13.1/100,000 - representing almost 0.5% of all bone fractures [1, 2].

The primary aim when treating a patella fracture is to restore the knee extensor mechanism and the patella articular surface. Acute management of patella fractures can be surgical or conservative, depending on fracture classification and impairment of the extensor mechanism. Fractures with a dislocation not exceeding 2-3 mm and preserved extensor function are suitable for conservative management [3]. Other fractures are indicated for surgical treatment. Despite different methods of osteosyntesis of patella fractures, the tension band wiring in combination with Kirshner wires or screws remains a standard surgical procedure in most departments of orthopaedic surgery worldwide [4].

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. [5-9]. Furthermore, outcomes following patella fractures were reported with high rates of complications and re-operations [10] and increased risk of development of post-traumatic knee osteoarthrosis [11].

Recently, a locking plate system for surgical management of patella fractures has been introduced [12]. Biomechanical testing has demonstrated a more stable fixation of the fractures using locking plates than tension band wiring [13]. However, only few small-scale cohort studies and case series (n > 67) have reported on the clinical, functional and safety outcome of locking plate fixation for patella fractures [12-14]. To date, no studies have tested tension band wiring against locking plate fixation in a randomised and well-powered design in patients with patella fractures [15].

The primary objective of the study is to compare the Knee Injury and Osteoarthritis Outcome subscale scores ($KOOS_{5\text{-subscales}}$) [16] after standard care tension band fixation with locking plate fixation for patients with patella fractures one year after surgery.

The secondary objectives are to evaluate the effect of locking plate fixation of patella fractures compared to standard care tension band fixation on the secondary outcomes (**Table 1**).

TABLE 1 Outcomes.

Type	Outcome	Subscale	Measurement follow-up, months
Primary	$KOOS_5$	Pain	12
		ADL	12
		Symptoms	12
		Sports[a]	12
		QOL	12
Secondary	$KOOS_5$	Pain	3, 6
		ADL	3, 6
		Symptoms	3, 6
		Sports	3, 6
		QOL	3, 6
	EQ-5D-5L	Mobility	3, 6, 12
		Self-care	3, 6, 12
		Usual activities	3, 6, 12
		Pain/discomfort	3, 6, 12
		Anxiety/depression	3, 6, 12
		EQ-VAS	3, 6, 12
	Bone union	-	3, 6, 12
	Muscle strength	-	6, 12
	Knee range of motion	-	3, 6, 12
	Pain	-	3, 6, 12
	Patient Acceptable Symptom State	-	3, 6, 12
	Adverse events	-	3, 6, 12
	Time to return to work	-	3, 6, 12

ADL = activities of daily living; EQ VAS = EuroQol visual analogue scale; $KOOS_5$ = Knee Injury and Osteoarthritis Outcome 5 Subscales score; QOL = quality of life.
a) Power calculation.

Our hypothesis is that in KOOS, locking plate fixation of patella fractures are superior to standard care tension band fixation one year after surgery.

METHODS

Study design

This study is a pragmatic, prospective, assessor-blinded, randomised 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 and conforms with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) [17]. The reporting of results will adhere to the Consolidated Standards of Reporting Trials (CONSORT) statement for reporting RCTs [18]. The study is registered

with ClinicalTrials.gov (NCT04891549).

Study setting and patients

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

Participants will be assessed for eligibility by consecutive sampling. A patient will be asked for participation if he/she meets the inclusion criteria and fails to meet any of the exclusion criteria specified below.

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

- Above 18 years of age

- Patella fracture suitable for surgical treatment with both surgical methods

- Arbeitsgemeinschaft für Osteosynthesefragen (AO) classification 34-B, 34-C.

A patient is excluded from participating in 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, tumours, etc.)

- Prior ipsilateral patella fracture.

Recruitment

Medical staff at the departments of orthopaedic surgery of the participating sites will take part in the recruitment procedure. Oral and written information about the study will be provided to patients. Patients are recommended to take at least two hours to consider and discuss participation with a relative before deciding on participation 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.

Randomisation

After baseline assessment, the patients who meet the eligibility criteria and opt in will be randomised to locking plate fixation versus standard care tension band fixation. To ensure that the number of participants receiving the two interventions is closely balanced within each stratum, a computer-generated randomisation 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 randomisation lists will be used.

Blinding

At the three-, six-, and 12-month follow-ups, blinded outcome assessments will be performed by a physiotherapist/nurse. Masking the implant towards the patient will be obtained by standardised surgical reports regardless of type of implant used.

Before unblinding the trial, an independent statistician (NHB) will perform the analyses.

Data collection and outcome

Baseline characteristics

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

Primary outcome

The primary outcome will be the one-year $KOOS_{5\text{-subscales}}$ [16].

Considering a threshold for clinically important differences, conclusion superiority will be claimed if three of the five KOOS subscales have a minimum difference of: ten points for pain, nine points for symptoms, six points for activities of daily living (ADL), ten points for sport/rec. and ten points for quality of life (QOL).

The KOOS is a standardised patient-reported questionnaire developed to evaluate knee problems [16]. The questionnaire includes five subscales: pain, ADL, symptoms, sport and QOL. A total score of 100 indicates no symptoms and 0 indicates major symptoms. KOOS reference data are available [19].

Secondary outcomes

KOOS-subscale scores will be measured at the three- and six-month follow-up.

General health

General health will be assessed using EQ-5D-5L questionnaire (EuroQol, five dimensions, five-level version), both the descriptive index and the EuroQol-visual analogue scale (EQ-VAS) [20]. The scale consists of five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression, and a self-rated health scale rated 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 EQ-5D-5L index of 1.0 indicates full health, 0 death, and –0.59 denotes a condition worse than death. General health will be measured at the three-, six-, and 12-month follow-up.

Bone union

Bone union will be evaluated on standard anterior-posterior and lateral radiographs of the fractured patella. The evaluation of bone union will be defined as diminished or no visible fracture line and no pain from the fracture site at weight-bearing and at clinical examination. Bone union will be measured at the three-, six-, and 12-month follow-up.

Maximum isometric knee flexion and extension

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 the six and 12-month follow-up.

Knee range of motion

With 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 at the three-, six-, and 12-month follow-up.

Pain

Rest pain and worst pain during the past 24 hours will be measured on a numerical rating scale (1-10). The use of pain killers will also be measured. Measures will be performed at the three-, six-, and 12-month follow-up.

Patient Acceptable Symptom State

The Patient Acceptable Symptom State (PASS) is included to express the highest level of symptom beyond which patients consider themselves well. PASS will be collected at the three-, six-, and 12-month follow-up.

Time to return to work

Measures the time from surgery to end of sick leave in days.

Harms

Adverse events (AE), defined as any negative or unwanted reactions to the two groups will be recorded. Based on previous reports, we will focus on infection, deep vein thrombosis and re-operation. Patients are continuously requested to report any suspicion of a potential AE. Furthermore, AE will be recorded at the three-, six-, and 12-month follow-up by asking patients about potential AE using open-probe questioning to ensure that all AE are recorded. Furthermore, medical records will be checked at the primary endpoint (12 months) for all AE occurring from inclusion to the 12-month follow-up.

Data management, ethics and monitoring

The Danish Data Protection Agency approved the study (N-2021-063). Before, during and after the trial, all personal data will be stored securely to ensure confidentiality. The study is approved by the Danish Committee on Health Research Ethics (N-2021-0022) and will be conducted in agreement with the Helsinki Declaration. A data monitoring committee will be established, evaluating any AE between all included sites. The data monitoring committee will consist of the first and last author of this paper. Both main and AE 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 ten-point difference between groups in KOOS Sport/Rec at the primary endpoint – 12-month follow-up (power of 80% and significance level at 0.05 (two sided)) [19]. The calculation of the sample size is based on a previous study reporting the long-term KOOS outcome following patella fractures treated with tension band fixation [7]. With a reported standard deviation of 18, the calculation showed that 51 patients will be required in each group.

The drop-out rate was set to 20%, leading to a total of 122 participants for randomisation.

General statistical approach

In summary tables, we report quantitative baseline variables as the mean and standard deviation. We report categorical baseline variables as counts and percentages.

The analysis will be done on the intention to treat population. To assess the robustness of the primary analysis, the primary analysis will be repeated on the “as-observed” population. Case analysis will be performed to handle missing data.

The difference between the two treatment arms will be estimated by mixed-model regression adjusted for gender and using robust variance estimation. Patients will be considered as random effect and follow-up (at three, six, and 12 months). The treatment arm and interaction will be treated as fixed effect variables. Mean scores, standard deviations, mean differences and 95% confidence intervals (CIs)will be reported in a table.

AE will be compared between groups at the 12-month follow-up using a mixed Poisson model with adjustment

for gender.

Trial registration: ClinicalTrials.gov ID: NCT04891549.

DISCUSSION

This trial is expected to add new knowledge concerning the surgical treatment of patella fractures. To the authors' knowledge, this study is the first to report randomised data on locking plate fixation versus standard care tension band fixation for patients with patella fractures.

Correspondence *Rasmus Elsoe*. E-mail: rae@rn.dk

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Conflicts of interest Potential conflicts of interest have been declared. Disclosure forms provided by the authors are available with the article at ugeskriftet.dk/dmj

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