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## Study and Analyses Plan

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## **Study and Analyses Plan**

**Are patella fractures associated with an increased risk of early knee arthroplasty? A matched cohort study of X000 patella fractures with an average of XX<sup>1</sup> years follow-up**

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<sup>1</sup> The average follow-up period will be calculated when data is available.

## ***Background***

Patella fractures are rare and constitutes 0.7-1% of all fractures (1–3). The incidence of patella fractures has only been reported in a small number of studies and range from 9.5 to 10.7/100,000/year (1,4,5). A recent study by Larsen et al. (6) reported an overall incidence of 13.1/100,000/year with an increase in incidence with increasing age. Larsen et al. (6) reported that men have the highest incidence when they are between 10 and 19 years of age (15.4/100.000/year) while women have the highest incidence when they are between 60 and 80 years of age (36.0/100.000/year).

Knee pain, joint stiffness, symptomatic hardware, arthrofibrosis, non-union, infection, posttraumatic arthritis and limitations in activity of daily living and quality of life are all common complaints after patella fracture (7–9). Boström A. (2) reported that only 49% of patients are pain free at 8.9 years follow-up.

Traumatic knee injuries increase the risk of arthritis. Petrie et al. (7) reported that the force applied to the chondral surfaces during the injury may explain the development of posttraumatic arthritis. Moreover, factors such as fracture comminution, mode of injury, the quality of articular surface reduction and the choice of treatment method, have all been suggested to influence the risk of posttraumatic arthritis following a patella fracture (7,9). Scarce evidence supports the notion that the consequences of patella fracture may be more severe than previously anticipated. In a retrospective study of 64 patients with a follow-up period ranging from 10 to 30 years Sorensen et al (8) discovered that 70% showed patellofemoral arthritis in the ipsilateral knee compared to 31% on the contralateral and uninjured knees. These results were later extended by Mehdi et al.(9) who reported that 8.5% of patients with patella fracture developed patellofemoral osteoarthritis within 6 years. A retrospective analysis by Houdek et al. (10) showed that 0.5% of all patients treated with a TKR reported a previous history of a patella fracture. Collectively, these small and retrospective studies suggest that patellar fracture increase the risk of a TKR years later.

To the authors knowledge the literature lacks recent and adequately powered studies with the aim to systematically examine the association between a patella fracture and the secondary treatment of TKR or arthroscopic procedures.

The primary aim of the study is to report the cumulative incidence of ipsilateral TKR at xx years following patella fractures and compare this to the cumulative incidence of ipsilateral TKR in an age and gender matched non-exposed

group without a prior patella fracture.

The secondary aim of the study is to report the cumulative incidence of ipsilateral arthroscopy, contralateral TKR and contralateral arthroscopy of the knee at xx years following a patella fracture compared to the cumulative incidence of ipsilateral arthroscopy, contralateral TKR and contralateral arthroscopy of the knee in an age and gender matched non-exposed group without a prior patella fracture. Furthermore, the third aim of the study is to compare the time to ipsilateral and contralateral TKR and arthroscopy of the knee following a patella fracture compared to that of an age and gender matched non-exposed group.

The primary hypothesis of the study is that the cumulative incidence after xx years of ipsilateral TKR following a patella fracture is higher compared to an age and gender matched non-exposed group without prior patella fractures.

### ***Patients and methods***

The study is designed as a matched cohort study. All patients who sustained a patella fracture in Demark between the 1th. January 1996 and the 31th. of December 2000, are included as exposed and followed until 2015 with regards to development of posttraumatic osteoarthritis requiring treatment in terms of TKR or arthroscopic procedures.

The primary outcome is ipsilateral TKR (yes/no) within the follow-up period. The secondary outcomes are ipsilateral arthroscopy of the knee (yes/no) and contralateral TKR/arthroscopy of the knee.

The study is undertaken in Denmark, which has a population of 5,699,220 as of December 31th. 2015. Danish law requires that all patient contacts with hospital and outpatient clinics in Denmark are registered in the Danish National Patient Registry(LPR)(11). The Civil Registration Number is given to all residents of Denmark and registered in the Civil Registration System. Hospital identification, date and time of activity, and patient's municipality (among other characteristics) are registered(12). This system enables researchers a complete registration of all health-related issues on an individual- and population-based level.

The exposed group is conducted with a retrospective review of all patients diagnosed with a patella fracture between the 1th of January 1996 and 31th. of December 2000. All patients are followed from the time of patella fracture until 2015 with regards to surgery with TKR or arthroscopic surgery of the knees. Patients are

censored in case of emigration from the country. Death and receiving a TKR on the side of the patella fracture is considered a competing event.

The non-exposed group will consist of individuals identified from the Civil Registration System matched to the exposed group on age (year of birth) and gender. For each exposed 10 non-exposed are selected who had not experienced a patella fracture on the same side as the injured knee of the corresponding exposed patient on the date of the fracture. Non-exposed are hence considered side-specific. Both exposed and non-exposed are censored in case of emigration from the country or at the end of follow-up.

This study is conducted in accordance with the ethical standards of the responsible committee and with the ethical principles of the 1975 Declaration of Helsinki. The Local Ethics Committee was asked to approve the study and answered the study design does not need notification. The study is approved by the Danish Data Protection Agency (J. nr. 2008-58-0028, Id: 2016-176). The reporting of the study complies with the 'The REporting of studies Conducted using Observational Routinely-collected health Data (RECORD) Statement (13).

### ***Data retrieval***

All patients who are registered regardless of contact type with the ICD-10 diagnose code patella fracture (DS82.0) between the 1th of January 1996 and 31th. of December 2000 are identified in the LPR (Danish National Patient Registry) and basic characteristics; age, gender, age at the time of diagnose and side of fracture is obtained (exposed). Patients are included at the time of first contact with a patella fracture in the LPR. Patients with prior patella fractures and patients with prior TKR are excluded from the study. Side specific information about TKR, arthroscopy and patella fractures are then obtained from the LPR if occurred between the time of inclusion and 31th. of December 2015.

All identified patients with a patella fracture are matched by age (year of birth), gender, side of fracture at the time of fracture with a ratio of 1 to 10 from the CPR (Civil registration number) (non-exposed) and specifically matched to the exposed on the fracture date. Non-exposed with TKR or patella fracture on the same

side as the matched exposed prior to the inclusion date are excluded (LPR). Non-exposed are identified in the LPR regarding surgery related to arthroscopy of the knees, TKR and patella fracture from the date of inclusion until 31th. December 2015.

### *Statistics*

Baseline characteristics of the study population will be reported in a descriptive table with separate information for the two groups. This will include medians and interquartile ranges for continuous variables and frequencies and percentages for categorical variables.

The primary outcome is the cumulative incidence reported yearly in the entire observational period of ipsilateral TKR in the two groups. We will estimate the relative difference between the two groups yearly during the entire observational period. Death will be considered as a competing event.

The time to event will be counted from the date of patella fracture diagnosis for the exposed group and the corresponding matching date for population non-exposed. Event times will be censored at the date of emigration from the country or end of the study follow-up by 31th of December 2015 and death will be considered as a competing event. We will perform the analysis evaluating the effect of patella fracture on ipsilateral TKR using a Cox proportional hazards regression model comparing exposed to non-exposed. We will report the effect estimate from this analysis as a hazard ratio with corresponding 95% confidence interval to estimate the incidence rate ratio. We will report results from the crude analysis without adjustments. Furthermore, we will repeat the analysis stratified by age-groups (0-50, 51+) and gender. To investigate the assumption of proportional hazards we will divide the follow-up time into 1-year periods.

We will perform additional analyses to investigate the effect of patella fracture on the secondary outcomes (ipsilateral and contralateral arthroscopy of the knees and contralateral TKR) following the same methods as for the main analysis except that we will also consider TKR as a competing event for arthroscopy in the same side. All analyses will be performed using Stata statistical software (StataCorp LP) and the significance level for analyses ( $\alpha$ ) will be set to 0.05. All analyses will be performed by an experienced statistician.

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