Copyright © by The Journal of Bone and Joint Surgery, Incorporated Nyholm et al. Time to Surgery Is Associated with Thirty-Day and Ninety-Day Mortality After Proximal Femoral Fracture http://dx.doi.org/10.2106/JBJS.O.00029 Page 1 of 3

#### Protocol

*Title of Project* Association Between Surgical Delay and Mortality in Patients with a Femoral Fracture

#### Introduction

Femoral fractures are divided into three groups according to the classification system developed by Müller and the AO Foundation: (1) proximal femoral fractures (OTA/AO31), (2) shaft fractures (OTA/AO32), and (3) distal femoral fractures (OTA/AO33). A common trait for femoral fractures is the following immobilization due to pain and loss of function of the lower limb.

The most common femoral fractures are the proximal fractures (AO31). They occur predominantly in elderly patients with osteoporosis who fall with trauma directly on the hip<sup>1,2</sup>. The main goal in treatment of these fractures is to establish a stable and pain-free lower limb as soon as possible. The optimal treatment is surgery as non-surgical regimes (traction and bandaging) have been shown to lead to an increased length of stay in hospital, an increased risk of nonunion, and a reduced likelihood of return to the pre-fracture level of function<sup>3,4</sup>.

Whether to spend time optimizing patients before surgery or to perform surgery as soon as possible is a question still not fully answered. Previous studies have shown a correlation between increasing waiting time before surgery (delay of surgery [DOS]) and a longer admission to the hospital<sup>5-9</sup> and a higher risk of complications such as decubitus<sup>5,6,8,10-12</sup>. The association between DOS and mortality is less clear. In spite of extensive research, no clear conclusion has been reached. Some studies have shown a correlation between short DOS and a reduced risk of mortality<sup>12-28</sup>, while others have found no correlation<sup>5,6,9-11,29-33</sup>. So far, no studies have shown a harmful effect of DOS<sup>34</sup>. Based on this evidence, the Danish Reference Program for Hip Fractures recommends surgery within twenty-four hours of admission<sup>35</sup>.

The limit of twenty-four hours is arbitrarily defined and has been up for discussion. Most studies have examined surgical delay of forty-eight hours or less compared with more than forty-eight hours<sup>32,36,37</sup>. One previous study tried to illuminate the effect of ultra-early surgery (delay of less than twelve hours) on early mortality and found a significant reduction in the risk of in-hospital mortality with short delay<sup>18</sup>.

Other factors have been identified to affect the risk of mortality following hip fracture: sex<sup>38,39</sup>, age<sup>38,39</sup>, American Society of Anesthesiology (ASA) score (an estimate of the overall health of the patient)<sup>38</sup>, the experience level of the surgeon<sup>40</sup>, the pre-fracture level of function<sup>24,38,39,41</sup>, the type of hospital (university hospital compared with district hospital)<sup>12</sup>, and the type of fracture<sup>41-43</sup>. The correlation between perioperative blood loss and mortality in hip fractures has not previously been investigated.

So far, only a few studies have investigated the effect of DOS in shaft fractures (OTA/AO32) or distal femoral fractures (OTA/AO33). Due to the clinical similarities with immobilization and loss of function of the affected lower limb, we suggest there might be a similar correlation between DOS and risk of mortality. Streubel et al. showed that surgery within forty-eight hours of admission compared with surgery after ninety-six hours significantly reduces the risk of mortality in distal femoral fractures (OTA/AO33)<sup>44</sup>.

Today we have no recommendations related to early surgery of femoral shaft fractures (OTA/AO32) or distal femoral fractures (OTA/AO33). We believe these patients would benefit from early surgery.

The Danish Fracture Database (DFDB) was established as a web-based database in November 2011. Its primary purpose is prospective, systematic data collection and quality assessment of fracture-related surgery. The DFDB has since been implemented in sixteen departments, covering an estimated 3,700,000 citizens by January 2014. Data are entered into the DFDB by the surgeon immediately after the surgical procedure and consists of patient, fracture, and surgery-related data. The DFDB is approved by the Danish Data Protection Agency, journal nr. 2007-58-0015.

The DFDB was validated in March 2013, finding an acceptable completeness and a high data validity<sup>45</sup>. All types of fractures, including femoral fractures, are registered in the DFDB along with information on time of diagnosis, onset of surgery, type of fracture, type of surgery, educational level of surgeon and supervisor, and the patient's overall state of health.

## Aims

Our aim is to investigate:

- the correlation between DOS and mortality in femoral fractures (proximal femoral fractures, shaft fractures, and distal femoral fractures) in a Danish population;
- if an ideal limit of DOS can be identified in patients with femoral fractures;
- if correlation between DOS and mortality is present and the same for different types of femoral fractures (proximal femoral fractures);
- in a separate study, the effect of the perioperative blood loss in proximal femoral fractures.

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# **Data and Methods**

DOS is indirectly registered in the DFDB as time from diagnosis of fracture (x-ray) until time of onset of surgery.

From the DFDB, we evaluate all registered procedures for OTA/AO31, OTA/AO32, and OTA/AO33 and select adequate patients with regard to inclusion and exclusion criteria.

For selected patients, we will collect data on mortality from the Danish Civil Registration System.

Mortality will be registered at day 30, day 90, and day 365 following surgery.

Surgeries will be divided into groups according to DOS: zero to twelve hours, more than twelve hours to twenty-four hours, more than twenty-four hours to thirty-six hours, more than thirty-six hours to forty-eight hours, more than forty-eight hours to seventy-two hours, and more than seventy-two hours. We intend to compare risk of mortality between groups of DOS for each fracture and then later compare the effect of DOS in different types of femoral fracture.

Previous studies have shown an effect of several other factors on mortality following surgery for a femoral fracture and we intend to adjust for these in the statistical analysis. These factors include sex, ASA score, type of fracture, type of surgery, educational level of the surgeon or supervisor, type of hospital, and occurrence of reoperations.

The correlation between perioperative blood loss and mortality has not previously been investigated in a larger setup and we plan to investigate this in a separate study. We will use data from our local surgery database (Orbit) and from the Danish Civil Registration System. Mortality will be evaluated at day 30, day 90, and day 365 following surgery.

# Inclusion Criteria

All surgeries for a femoral fracture registered in the DFDB (OTA/OA 31-33).

## **Exclusion** Criteria

High-energy trauma (assembly of specialized trauma team upon arrival to the emergency room)

Age less than fifty years

Missing data

Surgery performed at a hospital with less than fifty registered procedures

Unusual type of surgery (fixation methods not commonly used in femoral fractures, such as external fixation for proximal femoral fractures)

## Statistical Methods

Logistical regression analysis will be used to evaluate the correlation between the different groups with calculation of odds ratios (OR). Survival will be estimated using Kaplan-Meier curves.

## **Ethical Considerations**

This is a retrospective observational study with no intervention. Patients and their relatives will not be contacted in relation to this study. No further information will be collected than what is registered in the patients' medical records, in the DFDB, or in the Danish Civil Register. Therefore, we have no ethical issues to consider in relation to this study.

## **Putting Our Work in Context**

Proximal femoral fractures are the most common fractures treated in orthopaedic departments and mortality is very high; as many as 25% of patients die within the first year following fracture. In this study, we plan to examine the correlation between delay of surgery and survival with regard to not only proximal femoral fractures but also other femoral fractures that occur in a type of patients resembling patients with proximal femoral fractures and are also correlated to a high risk of mortality following fracture.

By investigating this correlation, we hope to create a basis for optimization of the treatment of femoral fractures, which in the future hopefully will lead to a decrease in the risk of mortality in these patients.

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