Study protocol:

Femoral neck fractures treated with pins with or without plate

Coworkers:

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Introduction

Hip fractures represent a considerable burden of disease worldwide. Although the incidence seem to be declining, at least in western Europe and North America [1], the number of fractures will increase the coming decades due to an increased elderly population. Femoral neck fractures represent about half of the hip fractures (with trochanteric fractures as the other half), and can further be subdivided into displaced and (essentially) undisplaced fractures. Femoral neck fractures are generally treated surgically, undisplaced fractures by fixing the fracture using screws or pins with or without additional plates, and displaced fractures by a prosthesis [2]. However, there is an ongoing debate on what is the appropriate implant to use for internal fixation of femoral neck fractures. [3]. In biomechanical studies the evidence seems to be in favour of multiple pins or screws. [4],

To improve healing rates after femoral neck fracture fixation a new implant design was developed by Swemac Innovation AB. While the original implant consisted of 2 isolated hook pins with and outer pin and an inner sliding tounge to allow anchorage in the femoral head, the novel implant consists of 3 titanium hook pins interlocked in an aluminum plate. Interlocking is a new principle of implant design and ensures stable fixation with 9 point contact and therefore allows controlled parallel continuous compression and prevents posterior tilting. The additional third pin enables firm anchorage in the femoral head. This novel implant is designed to minimize micromotion, enhance revascularization of the femoral head, i.e. increase stability and promote primary fracture healing

In a Finite Element analysis Pinloc shows improved stability [5-6]. Biomechanical studies at Oslo University Hospital confirms this finding. [7-8], The use of interlocking in a lateral plate (Pinloc) is introduced in some regions (e.g. Norway, Sweden and Japan). The role of Pinloc so far is unclear because little has been published on it's use, even though it is believed to be an contributor of stability to the fixation of femoral neck fractures with pins [5-8].

A study is now planned at Oslo University Hospital in collaboration with Diakonhjemmet Hospital in hope to further clarify choice of implant.

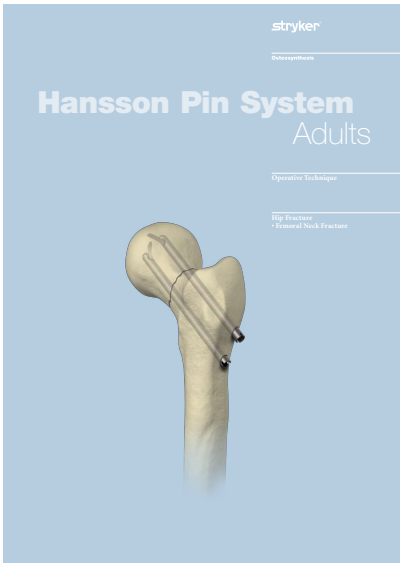

Illustration1 The original Hansson pin.

Illustration 2 Hansson Pinloc System.

Background

Epidemiological data show that the incidence of hip fractures is increasing on a world basis. It has been estimated that by 2050 an annual incidence of 6.26 million annual fractures is expected, compared to 1.66 million in 1990 [9]. This is accredited mainly to the growth of the elderly population outside North-America and Europe.
A hip fracture may have a major impact on the quality of life [10]. The majority of patients are elderly and an acute trauma and subsequent operation and rehabilitation is a physiological and mental strain, and increased morbidity and mortality follow a hip fracture. The societal costs of treating these patients are considerable.
Femoral neck fractures are mainly caused by a fall from own height in the elderly. The fractures are most often classified as displaced or not, using the simplified Garden classification[11]. Several other classification systems also exist, but these have not been shown to be of reliable clinical usefulness [12]. The ideal classification system should be easily applicable, reliable, and aid in treatment decision making and prognosis.

The treatment of femoral neck fractures comprise perioperative and operative modalities. The perioperative modalities consist among others of medical optimalization preoperatively, early rehabilitation and prevention of new fractures by treating osteoporosis and preventing new falls. The main scope of the current study will, however, be the operative modalities.

Surgery for undisplaced femoral neck fractures is performed mainly with fracture reduction on a traction table and internal fixation, using either pins, screws or a sliding hip screw (SHS), both available in various designs from different manufacturers. The latest Cochrane review did not conclude on which implant is the superior[3].

However, indirect evidence suggest that there are less treatment failures when three screws are used in the femoral neck compared to two screws[13-14]. The evidence for this is, however, weak and the Cochrane review also concludes that the role of the number of pins or screws remains unclear.

In our studies we hope to further evaluate the role of the number of pins and interlocking in a plate when treating femoral neck fractures.

Radiostereometry (RSA) is the most precise and accurate method to measure motion in vivo between different segments in orthopaedic research[15]. To do so, radiopaque tantalum markers are implanted into the bone defining different segments. Stereoradiographs are performed over time to detect movement and monitor the healing or lack thereof. This movement can be calculated both as translations and rotations. They are ideal to describe and compare the stability of fracture systems. RSA has been used successfully in earlier studies on fracture healing[16]. Due to the high acccuracy and precision, RSA yield reliable results with relatively small study-groups. We plan to use RSA to measure fracture dislocation and time to healing in our studies

Earlier fracture studies with RSA include fractures of the ankle, radius, tibial plateau, femoral neck and trochanteric hip fractures[15, 16]. Mattsson et al used RSA in a study on SHS with cement augmentation[16]. Ragnarsson et al used RSA in several studies on femoral neck fractures[17-20]. In one study, spontaneous compression of the femoral neck fractures was recorded between operation and mobilization of the patients[20].

Aim of studies

The study will be on the function of adding of a 3rd nail and interlocking of nails in a plate and it´s ability to prevent secondary dislocation. We will utilize RSA for measurements during follow-up.
0-Hypothesis: The addition of Pinloc with 3 pins prevents secondary dislocation compared to treatment with 2 Hansson pins alone.

1-Hypothesis: The addition of Pinloc and a 3rd nail does not provide additional stability.

In addition we will record clinical data related to, pain, satisfaction and function.

Study design

We are planning a randomized controlled trial on femoral neck fractures to evaluate the role of the Pinloc in the undislocated fractures. The first 6 patients will be used as cohort to establish the method for implanting the tantalum markers After these patients the method will be evaluated and adjusted if necessary before the remaining patients will be included.

Patients and methods:
We plan to include 30 patients recruited from Oslo University Hospital. Inclusion will be performed by the orthopaedic surgeon on call.

Inclusion criteria will be any patient with a femoral neck fracture that fits the following criteria:
- undisplaced
- above the age of 50
- able to walk independently, aids such as crutches or walker allowed
- able to consent
- fit for surgery with pins with or without interlocking in a plate.

Exclusion criteria:
- not willing or able to attain follow up
- previous fracture or surgery with retained metal work in the same hip
- concomitant disease that will shorten life expectancy

Fractures will be classified using the Gardens classification[11]. Patients will be randomized to either 2 Hansson pins or 3 pins with an interlocking plate. Surgery will be performed on a traction table. Tantalum markers will be implanted peroperatively according to a predetermined pattern. Markers in the femoral head will be implanted through the reaming canal for the nails and through the fracture gap when possible. Markers in the femoral shaft will be implanted through the lateral cortex using drillholes or a surgical awl. The fractures will be fixed using the 2 Hansson pins with or without an interlocking plate depending on the randomization.

Follow-up:
The patients will be followed for 52 weeks. During the hospital stay RSA-images will be obtained as soon as possible after surgery, preferably before mobilization and then again after mobilization before discharge. After discharge RSA-images will be obtained at 4, 8, 12 and 24 weeks or until healing is observed. At the same time points a clinical evaluation will be performed.

Statistical power

Modern RSA studies of the hip performed at our institution have achieved a precision of 0.1-0.2 mm translation and 0.2 – 0.6 degree rotation[21, 22]. The accuracy deteced with a phantom study is between 12 – 65 microns for translation and 0.025 – 0.051 degrees[23].

Larsson et al[16] found 0.6 mm as the smallest significant angulation in the frontal plane. In the out of plane movement we find the lowest precision with 0.58 degrees. We intend to detect mean differences in movement between the groups of 2.0 mm with a power of 80 %, as this probably is less than a clinically relevant difference. This results in a group of 8 patients each. Translation movement can easily be detected with a precision of 0.3 mm[21] and does therefore not deteriorate the power.

To encounter problems with inferior radiographs and uncompliant patients we suggest a group size of 15 patients each.

End points

RSA
- Fracture displacement with a mean of more than 0.31 mm translation and 0,6 degrees angulation (rotation).

Radiographical healing
- Implant position

Perioperative events
- Time of surgery
- Blood loss
- Postoperative pain (NRS) while in hospital

Postoperative complications
- Surgical complications (reoperations for any reason, infection, peri-implant fractures)
- Medical complications

Clinical results at follow up points
- Eq5d
- Harris Hip Score
- Timed Up and Go (Tug) test
- Pain (NRS)
- Satisfaction with operated hip (NRS)

Primary end point
- Movement during healing as measured by RSA compared between randomization groups

Secondary end points
- Time to union as measured by RSA (cessation of motion) and radiographs
- Clinical scores and measurements

Ethical considerations and patient concerns:

In this study we randomize all fractures to 2 Hansson pins or 3 pins interlocked in a plate. Towards the stable end of the fracture spectrum there may be a concern that the 3 pins interlocked in a plate is used unnecessarily because the fracture will heal in a good position without the 3rd pin and the plate. However, there are still many reoperations after fixation faillure for undisplaced fractures[26]. For fractures that heal shortening and varus collapse is common and are correlated to lower physical functioning[27]. The high rate of late problems with a long-term discomfort in about one-quarter of patients is a new and somewhat surprising finding, especially as orthopaedic surgeons usually consider the undisplaced femoral neck fracture as a less severe hip fracture[28].

The application of the plate does not require a larger skin incision, but some more soft tissue dissection is usually necessary and the procedure will be prolonged by about 10-15 minutes. On the other hand there might be a concern that fractures that traditionally would be operated with a 3 isolated pins in e.g. Britain and United States not will get this within the planned study. The same uncertainty applies on this end, and in many countries in Western Europe, the 3 pins are seldom used.

For the time being there is no clinical documentation on which fractures this device is recommended for. We therefore argue that this study is necessary to provide better evidence on which the choice of implant can be based upon.

Mechanical studies indicates higher stability for Pinloc than the original design. According to Finite Element Analyses Pinloc provides higher torsional rigidity and lower translation compared to two Hansson pins[5]. In addition Pinloc provides higher stiffness and yields higher stresses in the region of the trauma in simulated standing and sitting position [6]. In our biomechanical studies Pinloc demonstrated improved biomechanical parameters in 8/9 parameters compared to two Hansson pins[7-8].

Looking at the fixation related complications in undisplaced fractures, improved stability can potentially prevent both compression and varus collaps and possibly promote primary fracture healing. However, it is also a matter of how this increased stiffness is achieved. Novel angular stable implants like Posterio Lateral Femoral Locking Plate doesn´t allow compression due to divergent screws possibly leading to catastrophic failure, while Targon facilitates

compression intramedullary by individually telescoping screws in the femoral head with corresponding risk of jamming of hardware resulting in cut-out[29-30]. Interlocking is a new design which offers a solution to this problem as controlled compression is allowed and jamming prevented.

Regarding the use of tantalum markers, they have been used in numerous studies and there is no evidence of any morbidity associated with their use[25]. The implantation of the tantalum markers will not increase the surgical trauma as the implantation will be performed through the same incision as the fracture repair. The surgical procedure will be prolonged by five to ten minutes, but no extra damage to the soft tissues or extra bleeding will occur. Clinical studies using RSA have previously been performed at Oslo University Hospital[21-23] without any sideeffects or complications.

There is limited knowledge on when secondary dislocation or loss of reduction occur in these fractures, and the highest accuracy would have been obtained by very frequent radiographic controls to get a detailed description on movement in the fracture by time. This would probably impose an unnecessary burden on these patients by having to participate in a large number of follow ups. It would also probably involve too much consumption of research resources. The number of controls has been chosen based on our own experience and after personal communication with researchers in Sweden and Finland who have performed fracture healing studies using RSA. Hopefully the present study will enable us to target the frequency and total number of RSA radiographs for subsequent studies.

In this study we will only include patients who are able to give informed consent. By this we ensure the patients are informed on whatever risks are present and the extent of the follow-up.

Publication

The study will be published in an international peer reviewed medical journal.

Further plans:

We have already started a similar study on trochanteric fractures. We have planned further studies , including this study on femoral neck fracture fixation, which also will provide the foundation for a PhD project. In Sweden a larger multicentre clinical trial comparing Hansson pins with Pinloc is in preparation.

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