The Dynamic Locking Blade Plate;

innovation in the treatment of femoral neck fractures
The Dynamic Locking Blade Plate;
innovation in the treatment of femoral neck fractures

The Dynamic Locking Blade Plate;
innovatie in de behandeling van mediale collum fracturen

(met een samenvatting in het Nederlands)

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Chapter 1

Intracapsular femoral neck fractures

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**Introduction**

A fracture of the hip is a common injury. In 2004, in the Netherlands, with a population of about 16 million, 18,212 patients older than 65 years were treated for a hip fracture. In Sweden, with a population of about 9 million, almost 19,000 people now suffer from a hip fracture each year. Three quarters of these patients are women and the mean age was 81 years in 2000. The incidence increased from 13.2/1000 in 1966 to 25.5/1000 in 1986 in patients older than 80 years of age. Due to the proportional increase of the ageing population the incidence of hip fractures will continue to rise. Bearing in mind that only about 50% of these patients will return to their home and the other half will be discharged to a nursing facility, rehabilitation unit or sheltered housing one can expect that hip fractures will put a larger burden on social and health care resources in the coming years.

Hip fracture is a general description for a number of different types of fractures in the proximal part of the femur. The two main types are intracapsular (femoral neck) and extracapsular (pertrochanteric or intertrochanteric) fractures. Intracapsular hip fractures consist of fractures of the femoral neck proximal to the insertion of the joint capsule. Intracapsular femoral neck fractures can further be divided into displaced and undisplaced fractures. According to the Swedish National Hip Fracture Register, intracapsular fractures of the femoral neck constitute 53% of all hip fractures of which 33% is undisplaced and 67% is displaced. These intracapsular fractures are responsible for the most significant clinical implications. First, the fracture is, except for the varus impacted type, unstable due to the orientation of the fracture line and the direction of all combined forces acting on the hip. Secondly, at the intra-articular site of the fracture there is no cambium layer at the bone cortex, which is indispensable for periostal callus formation. Moreover, in case of an intracapsular fracture, the blood supply to the femoral head, which runs mainly subsynovial on the surface of the femoral neck, is compromised with risk of avascular necrosis of the femoral head. This is especially the case in displaced intracapsular fractures. The rate of avascular femoral head necrosis varies from 11% to 40%.
Intracapsular femoral neck fractures are generally treated surgically, either by means of internal fixation using various implants and thereby preserving the femoral head, or by replacing the femoral head with a prosthesis. The main goal of treatment is to mobilise the patient and restore the hip function as quickly as possible without causing associated morbidity.

The rationale for operative treatment by means of internal fixation is to reduce the risk of secondary displacement for undisplaced fractures, and to maintain fracture reduction for displaced fractures. The main reasons for failing of internal fixation are avascular necrosis and non-union. Avascular necrosis is a result of the compromised vascularisation of the femoral head following a fracture whereas non-union is mostly due to an inadequate fracture reduction or an inadequate osteosynthesis. Of course avascular necrosis and non-union interact and are not entirely separate entities. Failing of internal fixation leads to a reintervention rate of 35% with decreased function and increased morbidity as demonstrated by a meta-analysis performed by Lu Yao 65.

Replacement of the femoral head and neck with a prosthesis offers a way to prevent all possible complications of internal fixation and is therefore an attractive alternative in the biologically elderly patient.

In a Cochrane review of thirteen trials involving 2091 patients, analysing internal fixation versus arthroplasty for intracapsular fractures, no differences for hospital stay, mortality, or regain of same residential state were found 69. Internal fixation had a shorter duration of surgery, less operative blood loss or need for blood transfusion and a reduced risk of deep wound infection. Arthroplasty had a lower reintervention rate in comparison to internal fixation. According to these authors no definite conclusion can be made for differences in pain and residual disability after internal fixation or arthroplasty.

However, according to a recently published international survey, surgeons in North America and Europe have reached consensus with regard to the treatment of intracapsular hip fractures 34,60. It was concluded that undisplaced fractures are treated by internal fixation with preservation of the femoral head. Moreover, most surgeons believe that internal fixation is the procedure of choice in patients less than sixty years old with a displaced fracture. They also agree on patients over
eighty years old with a displaced fracture. In spite of lack of evidence, almost all surgeons prefer arthroplasty. There is however no consensus on how to treat patients with a displaced intracapsular fracture between sixty and eighty years old. It is therefore, and because of the poor clinical results, that the displaced intracapsular fracture is referred to as “the unsolved fracture” 74,123.

When an intracapsular femoral neck fracture is treated by internal fixation there are numerous implants for the surgeon at hand. The sliding hip screw systems (SHS) and multiple parallel screws or pins techniques are the only implants that have been thoroughly evaluated. The advantages of the SHS include good angular stability by firm fixation to the femoral shaft, dynamisation allowing controlled impaction of the fracture and the good fixation in the femoral head. The disadvantages of the SHS implants include the lack of rotational stability at the time of surgery and thereafter, the large frontal area and volume of the implant, increasing the risk of disimpaction during surgery and impairing the vascularity of the femoral head.

The advantages of the multiple parallel screws or pins include the dynamic fixation of the femoral neck fracture and the minimal invasive operation technique. The disadvantages include the limited angular and rotational stability of this fixation technique. The differences in clinical results between the various implants are small. At the present time it is not possible to choose the optimal implant for internal fixation of intracapsular hip fractures based on the available evidence within randomised trials 83.

**Anatomy and Physiology**

* Skeletal anatomy
  The femur is the longest and heaviest bone of the human body. It exists of the femoral head, the medially directed femoral neck and a strong shaft with at the distal end both femoral condyles. The femoral head is, with exception of the fovea capita femora, covered with cartilage. The diameter of the femoral head varies from 40 to 60 mm 118. Within the fovea the ligament teres is attached to the femoral
head. The femoral neck and femoral shaft form an angle of about 135° which varies through life. In newborns the angle is about 150°, but due to the axial load and permanent bone conversion the angle between femoral neck and shaft decreases. The femoral neck is antverted with respect to the femoral shaft with an angle of 10.4° ± 6.7° in healthy individuals. There is no difference between the genders

Between the femoral neck and femoral shaft exists the cranio-lateral placed greater trochanter and the medial-dorsal placed lesser trochanter. On the ventral side the trochanters are connected through the intertrochanteric line and on the dorsal side through the intertrochanteric crista. This is considered as the border between the femoral neck and shaft.

The hip joint or articulatio coxae is the joint between the femoral head and the acetabulum. It forms a ball-and-socket joint and is a so-called enarthrosis which means that more than half of the femoral head is covered by the acetabulum socket.

The proximal femur consists of cancellous bone with an internal trabecular system. The internal trabecular system was first described by Ward. The orientation of the internal trabecular system is along lines of stress. Along these lines cancellous bone is being formed. The final architecture of the trabecular pattern is in such a way that the bone can resist a maximum of forces with a minimum of bone mass. The presence of osteoporosis is important, especially in patients being considered for internal fixation, because the chance of cut out of an internal fixation device is thought to be increased in osteoporotic bone.

The proximal joint capsule is attached to the edge of the acetabulum and the transverse acetabulum ligament. The distal joint capsule is attached to the femoral neck, on the ventral side at the intertrochanteric line and on the dorsal side 1 to 1.5 cm proximal of the intertrochanteric crista. The thick membrana fibrosa of the joint capsule is enforced by three ligaments, the ligamentum iliofemorale, the ligamentum pubofemorale and the ligamentum ischiofemorale. Due to the above mentioned bony and ligamental structures the hip joint is a very stable joint and movement is restricted in the following directions: anteflexion 120°, retroflexion 15°, abduction 45°, adduction 10°, endorotation 35° and exorotation 15°. Luxation is rare and almost always occurs to the dorsal side as the dorsal part of the joint capsule is not enforced by these ligaments.
Vascular anatomy
Many investigators have studied the arterial blood supply of the femoral head. As a consequence a detailed description of the arterial blood supply to the femoral head with many different anatomical definitions exists. The description used in this text is based on the studies by Crock and the anatomical nomenclature used in Rockwood and Green’s “Fractures in Adults”.

The two main arterial sources of the femoral head are the medial and lateral femoral circumflex artery originating from the femoral profunda artery. Other contributors to the arterial blood supply of the femoral head are the foveal artery, originating from the obturator artery or medial circumflex artery, and intraosseous branches of the superior nutrient artery system comming from the medullary cavity.

The medial and lateral femoral circumflex artery form an extracapsular ring at the base of the femoral neck. Ascending cervical branches on the surface of the femoral neck arise from this extracapsular ring and penetrate the hip joint running upward underneath the synovial membrane. They are also known as the subsynovial vessels or retinacular vessels. Because these arteries lie on the surface of the femoral neck they are especially vulnerable to a fracture of the femoral neck. The ascending cervical branches form a second arterial ring at the border of the articular cartilage of the femoral head, the intracapsular subsynovial arterial ring. Blood vessels originate from the intracapsular subsynovial arterial ring and enter the femoral head at this point. As soon as they penetrate the femoral head they are named epiphyseal vessels. Claffey demonstrated that when a fracture line runs through the point of entry of the lateral epiphyseal vessels into the femoral head, avascular necrosis always occurred. Thus, the main source of blood supply to the femoral head runs through the lateral epiphyseal vessels.

The foveal artery, also named medial epiphyseal vessel, enters the femoral head through the ligamentum teres. Although it takes part in the subsynovial circulation, the contribution of the foveal artery to the blood supply of the femoral head is extremely variable. Arnoldi showed that if the retinacular vessels are torn the foveal artery is able to maintain a pulsatile pressure in the femoral head in only about 4% of elderly patients. In addition, Claffey showed that the femoral head cannot survive on the arteries of the ligamentum teres alone.
In conclusion, the arterial blood supply to the femoral head arises from three sources. The foveal artery of the ligamentum teres (medial epiphyseal vessels), the intraosseous vessels comming from the medular cavity and, chiefly, the retinacular vessels, branches of the extracapsular arterial ring, running along the femoral neck beneath the synovium. It is important to realise that when an intracapsular femoral neck fracture occurs the intraosseous vessels are disrupted and the retinacular vessels are seriously damaged. The viability of the femoral head is then dependent on the extent of damage to the retinacular vessels and the limited ability of the foveal artery to supply the femoral head.

**Bone healing**

In general, bone healing is divided into direct and indirect bone healing. Direct, or primary bone healing skips the intermediate steps of tissue differentiation and bone resorption and progresses directly to the final internal remodelling of the Haversian system. Direct bone healing follows stable fixation and compression. Indirect, or secondary bone healing consists of the sequential steps of tissue differentiation, bone resorption and uniting of the fracture fragments by external callus. Finally, the fracture undergoes long-lasting internal remodelling.

The goal of internal fixation of an intracapsular femoral neck fracture is a stable fixation with compression over the fracture fragments. If a stable fixation is achieved we can expect direct bone healing to take place. However, primary bone healing of an intracapsular femoral neck fracture is potentially compromised because of several reasons:

First, the nature of the fracture e.g. the fact that it is an intracapsular fracture makes it more vulnerable to non-union. Synovial fluid prevents clot formation thereby eliminating a factor contributing to bone healing. In addition, the intracapsular part of the neck of the femur has no periostal layer to participate in the bone healing process. Therefore, bone healing in the femoral neck is dependent on endosteal union alone.

Second, primary bone healing requires absolute stability and anatomical alingment of the fracture and the margins are small. Given an optimal vascular supply bone
healing mainly depends on the interfragmentary movement determined by the applied load and the stability of the fixation. According to the interfragmentary strain theory, bone can only heal if the interfragmentary strain is less than the strain tolerance. Different tissues have different strain tolerances before they give way and fail. Bone has a strain tolerance of 2%. Strain tolerance (ε) is defined as the interfragmentary movement (ΔL) divided by the length of the fracture gap (L): ε = ΔL / L. This means that in case of a fracture gap of 1 mm and a desired strain less than 2%, the interfragmentary movement at the fracture gap must be less than 0.02 mm. This requires an absolute stable fixation.

Last, as mentioned before, the arterial blood supply to the femoral head is seriously compromised following an intracapsular femoral neck fracture with risk of avascular necrosis. Union of the fracture can still occur, but in the presence of bone ischemia the incidence of nonunion is increased. The viability of the femoral head after a femoral neck fracture is dependent on preservation of the remaining vascular supply and on revascularisation and repair of the necrotic areas before collapse of the necrotic bone segment can occur. Revascularisation takes place as vessels grow into the necrotic areas from three sources. First, in cases of partial necrosis, ingrowth can occur from the remaining vital portions of the head, such as the subfoveal area. Second, vascular ingrowth can occur across the unifying fracture line from the femoral neck fragment. This is a slower process than ingrowth from the subfoveal area. It is important to remember that these tender vascular buds can be torn repeatedly if there is persistent motion at the fracture site as a result of poor fracture stabilisation. Finally, some vascular ingrowth can occur from tissue over the part of the femoral head that is not covered by articular cartilage.

Anatomical reduction and stable fixation are the major factors that help preserve the remaining blood supply and provide stability necessary for the vascular buds to grow into the area of necrosis. This was confirmed by a study from Arnoldi, who demonstrated that proper fracture reduction with extensive contact between the bone surfaces and stable fixation seemed to offer the best circumstances for restoration of transosseous blood flow across the fracture line. In addition, Moore demonstrated that in a poor reduction, the surface area for blood vessels to grow...
up the remaining neck is decreased so that the incidence of necrosis is increased when the fracture is poorly reduced 73. If the joint capsule remains intact, which may even occur in the presence of displaced fracture fragments, several authors believe that intracapsular pressures exceed the pressure of venous drainage and retinacular vessels thereby inducing femoral head necrosis 18,29,110. Although several experimental studies demonstrated improved femoral head vascularisation after joint decompression 97,113 these results are not yet confirmed by clinical studies 35,69,70. In most cases, intracapsular pressure values in the antalgic position are below the diastolic blood pressure, and the amount of the hemarthros aspirated is very low. In addition, Maruenda et al. demonstrated that hip traction in the antalgic position produced a greater reduction of intracapsular pressure than aspiration of the hemarthros in displaced and undisplaced fractures 68. Therefore, routine evacuation of the intracapsular hematoma in order to prevent femoral head necrosis should not be recommended.

Osteoporosis

Osteoporosis is a common disorder among the elderly characterised by a reduction in bone mass. Peak bone mass occurs at about age 30, thereafter resorption dominates formation with progressive loss of bone. Both sexes are affected, but the loss is greater in women than in men because bone resorption significantly increases following the menopause. There is no clear line separating normal age-related bone loss from abnormal pathological loss. In the past, Singh and colleagues used the trabecular pattern seen on x-rays of the upper end of the femur as an index for the diagnosis and grading of osteoporosis 104. This system is based on the presence or absence of the five normal groups of trabeculae in the proximal femur, as described by Ward 125. However, the Singh index seems to be a poor predictor of osteoporosis. In a study performed by Koot et al, a large interobserver variation was noted. Only three of 72 radiographs were given the same classification by all six observers and the kappa values ranged from 0.15 to 0.54 56. There was also no correlation between the Singh classification and the bone mineral density as measured by Dual energy X-ray Absorptiometry (DXA scan). At present, DXA scan is the golden standard in measuring osteoporosis.
Osteoporosis is defined as a bone density of more than 2.5 standard deviations below the peak value. Osteoporosis is prevalent in 16%-18% of women and 3-6% of men in the United States. Osteopenia (defined as a bone density between 1 and 2.5 standard deviations below the peak value) is prevalent in 37%-50% of women and 28%-47% of men in the United States.

The femoral neck fracture, mainly affecting older women, is considered to be an osteoporotic fracture. Many studies have identified a correlation between bone density of the femoral neck and the intrinsic stability of fracture fixation. It is generally assumed that osteoporosis has a negative influence on the stability of internal fracture fixation and is therefore responsible for a higher failure fixation rate. However, a recent study performed by Heetveld and colleagues demonstrated otherwise. They measured bone density with a DXA scan in 111 active patients above 60 years, with a displaced femoral neck fracture, prior to surgery. After a two year follow-up they found no differences in the rate of secondary instability between the patients with osteopenia and osteoporosis. They concluded that clinical outcome of internal fixation for displaced femoral neck fractures does not depend on bone density.

Classification

Several systems exist in order to classify intracapsular femoral neck fractures with the classifications according to Pauwels and Garden being the most widely used.

Pauwels' classification of intracapsular femoral neck fractures is based on the angle the fracture line forms with the horizontal plane seen on a frontal radiograph. In type I the fracture line forms an angle of 30° with the horizontal plane, in type II 50° and in type III 70°. Theoretically, as the steepness of the fracture line increases so do the shear forces, making it a more unstable fracture. The Pauwels classification system however has no prognostic value and is therefore not universally accepted.
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The Garden classification is the most commonly accepted system. It is based on the degree of displacement of the fracture as seen on a frontal radiograph. Type I is an incomplete valgus impacted fracture, Type II is a complete fracture without displacement, Type III is a complete fracture with partial displacement and Type IV is a completely displaced fracture with less than 50% contact between the two fragments. The Garden classification however has also been questioned. Studies by Barnes et al. and Frandsen and Andersen showed no significant difference in the incidence of avascular necrosis between the Garden grade of the fracture. Parker demonstrated in a series of 186 patients with displaced femoral neck fractures that neither the quality of reduction nor the incidence of non-union was influenced by the Garden grade of the fracture. Furthermore, Frandsen showed that the Garden classification suffers from a considerable inter-observer variation. Eight observers classified only 22 cases identically out of 100 randomly chosen femoral neck fractures.

As the number of Garden II fractures is very small and there are no relevant clinical consequences related to the division between Garden III and IV fractures, it is now advocated to classify femoral neck fractures into undisplaced and displaced femoral neck fractures.

The AO Comprehensive Classification of Fractures of the femoral neck divides these into three groups, based on the level of the fracture in the neck, stability of the fracture and its displacement. Thus, B1 are neck fractures, subcapital, with slight displacement, B2 are transcervical fractures, and B3 are subcapital fractures with marked displacement. Blundell et al. reported a very poor intra- and interobserver reliability and found the AO Comprehensive Classification to be of limited predictive use for the outcome of treatment.

Schatzker believes that the AO Comprehensive Classification of femoral neck fractures in its detailed characterisation of the fracture morphology is useful for research purposes. In clinical practice however, even Schatzker relies on the classification of femoral neck fractures simply as undisplaced and displaced.
Treatment modalities

Conservative treatment

Today almost all femoral neck fractures in the western world are treated with internal fixation or a prosthesis. Conservative treatment is considered only in the case of an impacted fracture with inherent stability, or if the patient is medically unfit for surgery.

In impacted femoral neck fractures, the femoral head is driven into the cortex of the femoral neck in a valgus position. This type of fracture is usually classified as a Garden I type fracture and constitutes about 15 to 20% of all femoral neck fractures. Most patients with a Garden I type fracture suffer little pain and there is no deformity with shortening of the leg and external rotation. Therefore one could argue that there is no need for surgery. The main complication of conservative treatment is secondary displacement. Raaymakers and Marti reported 14% secondary displacement of impacted femoral neck fractures following conservative treatment in 1991 and 31% secondary displacement in a study published in 2002. However, in patients over 70 years of age secondary displacement occurred in 41% of the patients. This is in concordance with a recent report of 105 impacted femoral neck fractures treated without surgery. In this study 46% of the patients with a mean age of 78 years required an operation because of secondary displacement. Although secondary displacement is not a rare complication, Raaymakers also noted that delayed surgery following secondary displacement caused no increase in the rate of mortality, nonunion or avascular necrosis. Moreover, the overall mortality rate after conservative treatment is lower (16%) than after operative treatment (26%). Therefore these authors state that conservative treatment for impacted femoral neck fractures is justified. Nevertheless, many surgeons favor internal fixation of impacted femoral neck fractures. On the one hand because of the need for absolute patient cooperation in conservative treatment, and on the other hand because of the ability to reduce the rate of secondary displacement with internal fixation to between 0% and 3%.

In the past displaced femoral neck fractures (Garden III and IV) were treated with longitudinal and lateral traction during 8 weeks followed by a non-weight
bearing period for up to 6 months. Later closed reduction and immobilisation in a spica cast was introduced in order to improve results. However, these forms of conservative treatment resulted in high rates of non-union and deformity. Moreover, the long period of immobilisation itself, in a mostly elderly group of patients, led to serious and sometimes fatal complications. Nonoperative treatment of displaced femoral neck fractures is therefore rarely indicated. Even in severely compromised patients closed reduction and additional fracture stability can be reached under local anesthesia. In the few cases where this is not possible there are several nonoperative or palliative treatment options at hand.

**Arthroplasty**

The first hemiarthroplasty was introduced in 1940 by Moore and Bohlman after removal of giant cell tumor of the femoral head. Since then it has also been used for the treatment of displaced femoral neck fractures. What patient group with a displaced femoral neck fracture is better of with a hemiarthroplasty than with internal fixation is still under debate. The surgical trauma in order to insert a hemiarthroplasty is more extensive, with an increased length of surgery, more operative blood loss and need for blood transfusion, and a higher risk of deep wound infections. On the other hand, a hemiarthroplasty is a more definitive solution and the surgical reintervention rate is lower after a hemiarthroplasty in comparison with internal fixation. No definite conclusion could be drawn for differences in pain and residual disability after internal fixation or arthroplasty in a meta-analysis from the Cochrane Database in 2006. Interestingly, another recent meta-analysis of 14 randomized studies with 2,289 patients drew another conclusion, namely that primary arthroplasty is better than internal fixation of displaced femoral neck fractures. There was no significant difference in mortality between the two groups but primary arthroplasty led to significant fewer complications and reinterventions as compared to internal fixation. The reintervention rate after primary arthroplasty varied from 0%-24% as compared to 14%-53% reintervention rate following internal fixation. Most surgeons today plead for a more patient-centered approach. Even the elderly patients with displaced femoral neck fractures are a heterogenic group
of patients ranging from the active, independent patient to the immobilised and cognitively impaired patient. Blomfeldt et al, recognizing the patient-centered approach, performed a randomised study comparing internal fixation with hemiarthroplasty in severe cognitive impaired patients. The amount of general complications and the mortality did not differ between the groups at two years follow up. Furthermore, there was no difference in the total number of surgical interventions required between the two groups. The health-related quality of life was significantly worse in the hemiarthroplasty group. Therefore, they concluded that there was little in favor of a hemiarthroplasty compared with internal fixation, in patients with severe cognitive dysfunction.

Heetveld et al tried to reduce the re-intervention rate by applying a physiological status score (PSS). Although it did not improve overall decision making they did succeed in reducing the re-intervention rate to 3% in patients selected for hemiarthroplasty.

The recently developed guideline in the Netherlands now recommends arthroplasty for displaced femoral neck fractures in all patients older than 65 years in whom reduction is not optimal and in all patients above 80 years of age, unless minimal invasive surgery for palliation is considered.

**Internal fixation**

Numerous implants have been developed over time for the internal fixation of femoral neck fractures. Tronzo identified over a 100 in 1974. These implants are inserted with the help of X-ray guidance using either an open or closed procedure. Implants may be divided into pins and screws. The type of threads used on screws may vary from narrow to wide and deep. In addition, the proportion of the screw which is threaded may vary from the tip only, to the entire length. The number of pins or screws inserted across the fracture can vary from one to an excess of ten, depending on the size of the implant used. Screws and pins may also be connected to a side plate which is then fixed with screws to the lateral cortex of the femur. Another variation in implant design is a small metal ‘hook’ which is pushed out of the tip of a nail into the subchondral bone of the femur.
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Examples of single nails are the Smith-Petersen nail, the Thornton nail and the Rydell four-flanged nail. Examples of a single nail with a side plate are the Holt nail, the Jewett nail plate, the Massie nail, the McLaughlin nail plate, the Pugh nail and, more recently, the Twin hook. Examples of a single screw with a side plate are the sliding hip screw systems (SHS) such as the Dynamic Hip Screw or Omega. These implant all have the capacity for sliding at the screw/plate junction, allowing for collapse at the fracture site. Examples of implants of which normally three are inserted are AO screws, Nystrom nails and Scand screws.

**Internal fixation: pins and screws**

The fixation of the femoral head by multiple parallel screws or pins allows for impaction at the fracture site and claims rotational stability. However, Frankel has demonstrated that the cancellous bone in the femoral head is a limiting factor in the strength of an internal fixation system. Subsequently, biomechanical testing has shown that a large threaded screw provides better internal fixation than does a nail. This was confirmed by a meta-analysis from Parker which showed that implants with a screw thread are preferable to pins. The clinical relevance of the number of screws used is unclear. There seems to be, however, consensus over the positioning of the screws in the femoral neck and head. Elmerson et al. recommended avoiding the superior part of the femoral head, while Rehnberg and Olerud advised central placement on the lateral view. Barnes et al. also recommended central placement of the screws. Parker concluded, after conducting a prospective study of 185 femoral neck fractures, that the screws should be centrally or inferiorly placed on the anteroposterior view and centrally on the lateral view. However, in a more recent report they found no relationship between nonunion of the fracture and the position of the screws on the anteroposterior radiograph. Because the lateral cortex of the femur frequently is thin and inadequate to provide good fixation for the screws or pins, no angular- nor rotational stability is achieved by screws or pins in femoral neck fractures. The lack of stability may lead to varus displacement of the femoral head. This may contribute to the higher fixation failure of the parallel screws or pins compared to the sliding hip screw system (SHS). The advantage of
multiple parallel screws or pins is the minimal invasive operation technique. This allows the procedure to even take place under local anaesthesia, which is in favor of the elderly compromised patient.

**Internal fixation: sliding hip screw (SHS)**

The principle of a sliding nail is said to have been introduced in the 1940s by Henry Briggs. The advantages of a sliding hip screw include improved fixation in the femoral head, firm fixation to the femoral shaft, and continuous impaction at the fracture site while lessening the chance of a screw penetration through or cutting out of the femoral head. A disadvantage of the SHS is that the screw has the potential to rotate the femoral head during its insertion, a factor that may increase the incidence of avascular necrosis. Smith demonstrated that excessive rotation about the longitudinal axis, or excessive valgus displacement at the time of reduction, can obstruct the remaining blood supply in the ligamentum teres. Lowell found that insertion of a screw for fixation can rotate the femoral head fragment, thereby compromising the remaining blood supply in the capsule and ligamentum teres. Placing an accessory pin in the femoral head above the screw or in an extraosseous location to stabilize the fracture before screw insertion prevents rotation of the femoral head during insertion of the screw. Fixation of the sliding hip screw however, is not improved when supplemented by a proximal cancellous screw. These authors believe that this is because the distance between the sliding hip screw and the lag screw is smaller than the distance between three lag screws. Another disadvantage of the SHS, is the high implant volume and larger frontal area of these devices which may increase the risk of disimpaction at surgery.

As with the parallel pins and screws, the ideal location for placement of the nail in the femoral head has been the subject of much controversy. Bonfiglio suggested central placement on the anteroposterior and lateral radiographs to provide favorable conditions for settling of the fracture. He argued that eccentrically placed nails would put the head into a poor position for proper settling. The depth of nail placement also is critical in obtaining femoral head fixation. Current recommendations are that, for best fixation, the tip to apex distance should be less
than 20 mm. The tip to apex distance being defined as the sum of the distance of the tip of the lag screw to the apex of the femoral head on the AP and lateral X-rays. Recently, a new SHS system has been introduced known as the percutaneous compression plate (PCCP). It was developed by Gotfried as a double axis, minimally invasive implant, providing rotational stability and allowing immediate full weight bearing. Designed originally for extracapsular hip fractures it is now being tested biomechanically in intracapsular hip fractures. According to the biomechanical analysis performed by Brandt and colleagues the PCCP resisted a significantly higher combined axial and torque load than the standard SHS osteosynthesis. However, clinical studies are needed to establish the use of the PCCP for intracapsular femoral neck fractures.

Results of internal fixation of femoral neck fractures

At the present time the multiple parallel screw technique and the sliding hip screw systems are the treatments of choice for internal fixation of intracapsular femoral neck fractures. According to Parker, because of the small differences in failure rates between the numerous implants, the incidence of avascular necrosis and non-union are the main distinctive criteria to be considered. Other lesser criteria to take into account are the ease of insertion, degree of surgical trauma and residual pain and costs.

Avascular necrosis

Avascular necrosis of the femoral head after femoral neck fracture is one of the two major complications of this injury (non-union being the other). The reported incidence of avascular necrosis after femoral neck fractures varies from 11% to 40%. In a histological study of femoral heads after a femoral neck fracture that were obtained from necropsy studies or operations, Catto even found 83% total or partial femoral head necrosis after 13 days in 109 cases. Associated vascular damage also was observed. Fielding and colleagues believe that no method of
therapy for femoral neck fractures will result in less than 11% avascular necrosis, because this is the incidence noted in nondisplaced femoral neck fractures 39. Avascular necrosis is the result of damage to the vascular supply of the femoral head after a femoral neck fracture. When an intracapsular femoral neck fracture occurs the intraosseous vessels are disrupted and the retinacular vessels are seriously damaged. The viability of the femoral head is then dependent on the extent of damage to the retinacular vessels and the limited ability of the foveal artery to supply the femoral head. Stable fixation and anatomical reduction are a prerequisite for revascularization to take place. Persistent motion at the fracture site can torn the tender revascularization buds during vascular ingrowth across the unifying fracture line, which can result in avascular necrosis.

Another mechanism which may cause avascular necrosis is the tamponade effect. When the capsule remains intact intracapsular pressures can exceed the diastolic and venous blood pressure and obstruct the blood supply to the femoral head. However, as mentioned before, there are no clinical studies which demonstrate that evacuation of the hemarthros prevents avascular necrosis.

Avascular necrosis precedes late segmental collapse but may stay asymptomatic for a long time 4. It is important therefore to distinguish between avascular necrosis and late segmental collapse. Avascular necrosis, the actual death of bone secondary to ischemia, is an early phenomenon after a fracture of the femoral neck 3,10. Late segmental collapse is the collapse of the subchondral bone and articular cartilage that overlies the ischemic bone. This collapse results in joint incongruity, pain, and eventually post traumatic arthritis. This collapse occurs late in the sequence of the ischemic event and is recognised as a clinical entity. It may occur several years later, however development takes place within 2 years after fracture in most cases 4. Necrotic bone retains its mechanical properties, and may function adequately without ever collapsing, particularly when proper internal fixation is in place. Therefore, not all patients with avascular necrosis will have late segmental collapse 11,22,45. Moreover, femoral heads with partial necrosis may revascularise and repair before late segmental collapse of the ischemic area will occur.
Chapter 1

Symptoms usually develop later than 6 months after surgery, and patients report pain in the groin, gluteal area, or proximal femur. Radiography does not allow diagnostic reliability until 6 months after fracture and usually 1 or 2 years later. When there is a suspicion of avascular necrosis bone scintigraphy often will be required. In patients in whom revascularisation occurs, this test will show an image of central low isotope uptake within an area of high isotope uptake. This is caused by an avascular necrotic area where nuclides cannot be captured, surrounded by revascularised tissue uptaking the isotope.

Nowadays, nonferromagnetic materials are increasingly being used which makes the use of an MRI, with a high diagnostic output, possible. The presence of a low signal intensity band away from the fracture line in T1-weighted images clearly delimits the necrotic area. Once segmental collapse has developed, the diagnosis becomes simple using plain radiographs.

Non-union
The rate of non-union after nondisplaced fractures is low but increases with the age of the patient and as a result of functional treatment. Non-union occurs in 20% to 40% of displaced fractures. Some authors report non-union rates of less than 5%. However, most series report union rates of 80% to 95% after reduction and internal fixation of displaced femoral neck fractures.

Many factors, such as operative technique, vascularity, and comminution, have been identified as causes of non-union after femoral neck fractures. According to Alberts et al and Toh et al, the quality of reduction and the positioning of the screws have the greatest influence on the union rate after femoral neck fractures. Toh, in contrast to the study performed by Alberts, also found that as patient age advances, the rate of union decreases. Either inadequate reduction or poor internal fixation technique was present in all cases of non-union in the series reported by Fielding and associates. Parker also noted a relationship between poor reduction and internal fixation and the incidence of non-union. In addition, Barnes and colleagues reported that the quality of reduction directly affect union. Although union can occur in the presence of avascular necrosis, many authors have noted a marked increase in non-union in patients with avascular necrosis of the femoral head.
Comminution at the fracture site, especially posteriorly, was noted by Banks to be present in more than 60% of patients in whom non-union eventually developed. Scheck also noted the relationship between posterior comminution and non-union.

Barnes reported that the percentage of union decreases as the patient’s age and the degree of osteoporosis increases. This is in contradiction with the results of a more recent study of 111 active elderly patients, performed by Heetveld, who measured bone density pre-operatively with a DXA scan. He concluded that bone density does not affect clinical outcome of internal fixation.

**Pins and screws**

There are many studies on the results of internal fixation of many different pins and screws. Parker and colleagues offered a summary of all previously undertaken randomised trials comparing different kinds of implants.

One randomised trial was found for the following implants: double divergent pins, Hessel pins and Nystrom nails. In all three trials about 30%-50% of the internal fixations failed. There were no notable differences between the implants and therefore no conclusions could be drawn on the potential advantages of these implants. A single Thornton nail has been evaluated in a randomised trial against three cancellous screws. The cancellous screws showed a tendency to lower risk of fracture healing complications. Fourteen out of 31 (50%) patients with a Thornton nail needed a reintervention.

The Rydell four-flanged nail has a hook, which is extruded from its tip once placed within the femoral head. The nail is canulated and only one nail is used to fix the fracture. It has been evaluated in five randomised studies, two against Gouffon pins and three studies against Hansson pins. None of these studies when combined demonstrated any notable difference in the risk of fracture healing complications between groups. Hansson hook pins are smooth pins with a hook extruded from their tip. Normally two pins are used. They have been compared with other pins in seven randomised trials. In three of these they were compared with the Rydell nail as mentioned before.

Three studies compared Hansson pins with Uppsala screws and one with two AO screws. In summary, there were no significant differences in fracture healing complications between implants.
Chapter 1

**Sliding hip screw (SHS)**
The sliding hip screw (SHS) has been evaluated within eleven randomised studies. A similar incidence of fracture healing complications was seen with double divergent pins, fixed nail plate and two Hansson pins. Seven studies compared the SHS with different type of cancellous bone screws. Summation of these seven studies gave a trend to a higher fixation failure rate with the cancellous screws and a higher risk of deep wound infection for the SHS, but none of these outcomes reached statistical significance. Operative blood loss and operative time were increased for the SHS. Overall re-intervention rate for arthroplasty was similar for both types of implants.

**Conclusion**
Fracture reduction and implant positioning are of great importance in preventing fracture healing complications such as avascular necrosis and non-union. There is little difference between implants with regard to the incidence of fracture healing complications. Thus, given an adequate fracture reduction and implant positioning it is only with dramatic improvement of the characteristics of the implant that we can positively influence the failure rate of internal fixation of femoral neck fractures.
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Intracapsular femoral neck fractures


Intracapsular femoral neck fractures


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Intracapsular femoral neck fractures
Chapter 2

Internal fixation of displaced intracapsular hip fractures in active elderly patients: long term results

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Submitted
Chapter 2

Abstract

Internal fixation of displaced intracapsular hip fractures in the active elderly patient remains debatable. The rate of failure of fixation and the need for revision surgery are important factors in the decision for either internal fixation or an endoprosthesis. Equally important but less known are the long-term functional outcome and mortality rates. The purpose of this study was to investigate the rate of failure of fixation, long-term functional outcome and long-term mortality in a cohort of active elderly patients.

A prospective study of 34 patients between 60 and 90 years old with a high physiological status score and a displaced intracapsular hip fracture treated by internal fixation was performed. Seven years after surgery the rate of failure of fixation, functional outcome and the mortality rate were determined.

Failure of fixation occurred in 13 out of the 34 patients (38%). An inadequate internal fixation was noted in 8 out of the 13 patients with failure of fixation. The functional outcome after one year was fair and did not decline during the seven years of follow-up. Five-years mortality rate was higher in the studied patient group when compared to an age-matched control population.

This study demonstrates a high rate of failure of fixation following internal fixation in active elderly patients. An inadequate internal fixation is an important contributor to failure of fixation. A satisfactory functional outcome is sustained in the surviving patients. Long-term mortality is high.
Introduction

According to a recent survey among surgeons from North America and Europe, internal fixation (IF) of a displaced intracapsular hip fracture in patients between sixty and eighty years old remains subject of debate. Advantages of IF include preservation of the femoral head, shorter duration of surgery, lower risk of deep infections, less blood loss, less need for blood transfusion and possibly an initial lower mortality. A disadvantage of IF is the high risk of failure and the need for revision surgery. Results from level 2 studies comparing IF versus arthroplasty in elderly patients reported rates of secondary surgery ranging from 33% to 47% following internal fixation.

Failure of fixation is mainly caused by avascular necrosis (AVN) and non-union leading to cutting out of the implant. AVN is caused by damage to the retinacular vessels, insufficient reduction of the fracture or lack of stability of the internal fixation. Non-union and implant failure may also be caused by either insufficient reduction and/or inadequate placement of the implant, which is sometimes due to lack of surgeon experience.

AVN and non-union occur mostly in the first year after surgery. AVN may even become evident in the second year postoperatively. Most studies have a two-year follow-up for this reason and hence little has been published on IF results in the long term (i.e. > 5 years).

Primary research questions to be answered in this study were: what is the rate of failure of fixation in a cohort of relatively healthy and active patients? What most likely caused the fixation to fail? What is the long-term (5-7 year) function and mortality rate in this group of active elderly patients?

Patients and Methods

From 2000 to 2001 our hospital participated in the PSS (Physiological Status Score) Hip trial. For the purpose of this trial, prospective data of patients between 60 and 90 years old presenting at the emergency ward with a displaced intracapsular hip fracture were collected. All patients with a high physiological status score
(PSS > 20) were included and treated by internal fixation with a dynamic hip screw (DHS) (Figure 1) 13. Surgical residents in their last year of surgical training performed the procedures.

An adequate reduction was defined as a Garden Index of 160°-180° on the Anterior-Posterior view (AP view) and a maximum of 10° retro- or anteversion on the lateral view. All patients were treated with a fixed angle sliding hip screw system (dynamic hip screw) with an anti-rotation K-wire peroperatively or placement of a second screw to prevent rotation of the femoral head.

Placement of the hip screw in the centre or lower half of the femoral head on the AP view and in the centre or slightly dorsal half of the femoral head on the lateral view was protocolled. If the above described requirements were not achieved, the procedure was considered technically inadequate.

From the first day postoperatively patients were mobilised under supervision of a physiotherapist and allowed partial weight bearing according to pain. To assess clinical outcome, the Harris Hip Score was determined at one year and, for the purpose of this study, at more than five years follow-up 12. Conventional radiographs were performed at each follow-up interval and the occurrence of non-union or AVN was noted. Patients were seen 8 weeks postoperatively, 1 year, 2 years and 7 years after internal fixation.

Failure of fixation was defined as secondary displacement of the fracture with cutting out of the implant or a revision to arthroplasty because of AVN or non-union.

Using a 1-sided binomial test the mortality rate of the studied patient group was compared to the mortality rate of an age-matched Dutch control population. Information on the five-years mortality rate of an age-matched Dutch control population was delivered by the Central Bureau of Statistics of the Netherlands (CBS).

Using the Fisher exact test, we examined if a technically inadequate procedure had an effect on the risk of failure of fixation. A P-value of < 0.05 was considered significant.

This study has been conducted according to the principles established in Helsinki in 1964 and revised in 2000. All patients gave their informed consent prior to their inclusion in the study.

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Figure 1. Internal fixation of an intracapsular hip fracture with a DHS

Results

A total of 34 patients, 14 men and 20 women with a high physiologic status, were included in the study. The mean age was 77 years (range: 60-89 years). Seven years after surgery 14 patients were still alive and available for follow up.

All 34 patients suffered a displaced intracapsular hip fracture and were treated with a DHS with a 2 hole barreled side plate. The mean time between the sustaining of the fracture and surgery was 18 hours (range: 3-49 hours), 29 out of 34 patients were operated on within 24 hours. Mean duration of surgery, including positioning the patient and reduction of the fracture, was 63 minutes (range: 30-120 minutes). In 11 patients the result of the internal fixation did not meet the formulated demands and was considered technically inadequate (Table 1).

Failure of fixation occurred in 13 out of the 34 patients (38%) (Table 1). In 8 of these patients the internal fixation was technically inadequate (Table 1). The relative risk (RR) of failure of fixation in case of a technically inadequate procedure is 3.35 when compared to a sufficient IF $P = 0.008$ [CI 95% 1.42-7.87; Fisher’s exact
test] (Table 1). Non-union was the cause of failure of fixation in 6 patients and AVN with collapse of the femoral head and the need for a revision occurred in 3 patients. Cutting out of the implant was noted in 5 patients. Clinical outcome after one year, as assessed by the Harris Hip Score (HHS), was fair (mean 76 range: 47-94, n = 23). After 7 years the HHS was again determined in 10 patients with successful IF out of the 14 surviving patients, and the clinical outcome was fair (mean 71 range: 67-91). The calculated 5-year mortality rate of the studied patient group is 47%. According to the CBS of the Netherlands the 5-year mortality rate of an age-matched control population is 28.4%. When comparing the 5-year mortality rate of our patient group with the age-matched control population using a 1-sided binomial test, an excess mortality following a hip fracture is observed, \( P = 0.016 \) [CI 95% 29.8 - 64.9].

Table 1. The relation between a technically inadequate procedure and failure of fixation.

<table>
<thead>
<tr>
<th></th>
<th>Failure of fixation</th>
<th>Successful bone union</th>
</tr>
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<tbody>
<tr>
<td>Technically inadequate</td>
<td>8</td>
<td>3</td>
</tr>
<tr>
<td>Sufficient internal fixation</td>
<td>5</td>
<td>18</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>13</strong></td>
<td><strong>21</strong></td>
</tr>
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</table>

Failure after a technically inadequate internal fixation = \( 8/11 = 72.7\% \)

Failure after a sufficient internal fixation = \( 5/23 = 21.7\% \)

Discussion

A rate of failure of fixation of 38% (13 out of 34 patients) can be depicted as high but is in concordance with the literature \(^4, 10, 13, 16, 18, 25, 26\). As morbidity increases with the delay to surgery and in an attempt to prevent the occurrence of avascular necrosis we strive for performing surgery within 24 hours post-trauma \(^2, 8, 19, 21\). This was achieved in 29 out of 34 patients.

Inadequate reduction and inadequate placement of the hip screw, occurring in 8 out of the 13 patients with failure of fixation, should not be accepted and can necessitate the conversion to a prosthesis in the elderly patients \(^26\). However,
Internal fixation in active elderly patients

during the first procedure no arthroplasty was performed in this study. Based on the high rate of technically inadequate procedures (11/34) we now reserve the femoral head preserving internal fixation for members of the trauma surgery staff only. Furthermore, we anticipate on the placing of a prosthesis in case of an inadequate reduction.

The relative risk of failure of fixation in case of a technically inadequate procedure is 3.35 in this study when compared to a sufficient IF. This implies that failure to perform an adequate reduction or adequate placement of the hip screw is largely responsible for failure of fixation. There have been many reports on the influence of an inadequate reduction of the fracture or inadequate placement of the hip screw on the outcome of bone healing in hip fractures. In a prospective multicenter 2 year follow-up study Heetvedt found a correlation between failure of IF and rating of overall technique and fracture reduction. Schep described a failure rate of 53% in a group of patients with an inadequate reduction and fixation score after IF of femoral neck fractures with Hansson hook pins or cannulated screws. They stated that the importance of adequate fracture reduction is indisputable and that it is the first and most important step in the IF of displaced intracapsular hip fractures.

The position of the hip screw has also been the subject of many studies. Amongst others, Parker advised to place the hip screw centrally or inferiorly on the AP view and centrally on the lateral view after statically evaluating 25 patients with cut-out against 200 patients without cut-out. In addition, Parmar stressed the importance of knowledge of the concept of the tip apex distance to surgeons.

AVN, as seen on the conventional X-ray, with segmental collapse of the femoral head leading to a failure of fixation occurred in 3 out of the 34 patients, which is similar to rates found in the literature. It is well established that displaced fractures have a higher incidence of AVN when compared to undisplaced fractures. On the other hand, elderly patients have a lower incidence of AVN following IF of a displaced intracapsular hip fracture.

The functional outcome after one year, reflected by a mean HHS of 76 (range: 47-94), is in line with previous reports. The mean HHS of the surviving patients with successful bone healing seven years after internal fixation was 71 (range: 67-
91). Functional outcome achieved after one year therefore does not decline in the years thereafter.

The 5-years mortality rate reported after a hip fracture in the elderly differs between 34.7% and 55.3% depending on the age, comorbidity and distribution of gender in the studied population 7, 11, 15, 24, 27. In our relatively healthy patient group we observed a 5-year mortality rate of 47% which is in line with the above mentioned previous reports but demonstrates an excess mortality when compared to an age-matched Dutch control population. This high mortality rate combined with the high risk of revision surgery must be taken into account when considering internal fixation in the active elderly patient. Although this was still under debate at the time this study was undertaken in 2000, the national level 2 guideline in The Netherlands on the treatment of intracapsular hip fractures now recommends endoprosthesis treatment in patients older than 80 years of age with a displaced intracapsular hip fracture 1.

Conclusions

An adequate reduction and adequate position of the internal fixation device are the cornerstones of management in displaced intracapsular hip fractures. The outcome of this study shows a high rate of failure of fixation following technically inadequate DHS fixation. If satisfactory-good functional outcome is achieved at 1 year, this is sustained even after several years in surviving patients. Long term mortality, even in a relatively healthy cohort, is high.
References


Chapter 3

Twin hook fixation for intracapsular hip fractures

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Submitted
Chapter 3

Abstract

The aim of this study was to investigate the performance of the Twin hook in the internal fixation of intracapsular hip fractures. Twenty-one patients aged 43 to 75 (mean 59) years with an intracapsular hip fracture treated by internal fixation with a Twin hook were retrospectively analysed. During follow-up radiological outcome was assessed by conventional radiographs and functional outcome by the Harris Hip Score. Failure of fixation was defined as the need for revision surgery due to cut out, non-union or avascular necrosis.

After a mean follow up of 13 months we noted 3 fixation failures. All 3 fixation failures were preceded by inadequate reductions. Functional results, assessed by the Harris Hip Score, were good.

In conclusion, the Twin hook seems to be an attractive alternative for the fixation of intracapsular hip fractures. However, an adequate reduction remains a prerequisite for a favourable outcome.
Introduction

The internal fixation of intracapsular hip fractures remains a challenging problem. The use of screws or a sliding hip screw system (SHS) for the fixation of intracapsular hip fractures has been the subject of many clinical trials. From these trials we have learned that up till now there is no evidence for a difference in clinical outcome between the SHS or screws. The results of the FAITH trial will probably solve this issue.

A relative new device for the fixation of proximal femoral fractures is the Twin hook (Stryker Osteosynthesis; Selzach, Switzerland). It combines the advantages of the early Hansson pin and a side plate while improving the fixation strength within the femoral head. Two biomechanical studies so far demonstrated superior rotational stability in artificial bone. In addition, four clinical studies with the Twin hook have been undertaken. Surprisingly, only trochanteric fractures where studied. The Twin hook however has some features which, in our opinion, makes it especially suitable for the fixation of intracapsular hip fractures.

First of all, internal fixation with a Twin hook is a simple and straightforward procedure. Secondly, the side plate provides angular stability which prevents varus displacement as opposed to internal fixation with screws. Thirdly, no rotational force is required during insertion of the hook pin. Finally, by deploying the apical hooks the Twin hook provides fixation strength within the femoral head comparable to the lag screw but with improved rotational stability.

As a result of the above described features we assumed that the use of the Twin hook will result in a lower rate of fixation failure. The purpose of this study was to investigate the results of internal fixation of intracapsular hip fractures with the Twin hook and compare them with the results mentioned in the international orthopaedic literature.
Materials and methods

The present study is a retrospective analysis of all patients with an intracapsular hip fracture treated with internal fixation by means of a Twin hook in 2008. Patients with pathological fractures or patients with previous surgery on the ipsilateral hip were excluded.

The fractures were classified as displaced or undisplaced. Patients younger than 75 years of age with an intracapsular hip fracture, in whom the risk of revision surgery was acceptable and who choose internal fixation after informed consent were eligible for internal fixation. An adequate fracture reduction was defined as a Garden’s angle of 160°-180° on the Anterior-Posterior view (AP view) and a maximum of 10° retroversion or 5° anteverision on the lateral view. Furthermore, to rule out shortening of the hip, the medial cortex of the femur had to be in alignment with the femoral head. The Garden’s angle is defined as the angle between the medial shaft of the femur and the weight bearing medial trabeculae of the femoral head (fig 1). It is used as a measure for the extent of the varus or valgus dislocation.

Figure 1. The Garden angle.
Placement of the pin in the centre of the femoral head on the AP view and in the centre or slightly dorsal half of the femoral head on the lateral view was demanded. Surgery was performed by members of the trauma staff with experience in hip surgery. If the above described requirements with respect to the reduction of the fracture and placement of the pin were, according to the authors, not reached, it was considered a technical failure.

The Twin hook consists out of an 8.9 mm pin with two apical hooks and a keyed barrel plate comparable to a side plate of a standard SHS. The hooks are deployed in the subchondral bone of the femoral head with a maximum span of 31 mm (fig 2).

![Figure 2a and b. Twin hook fixation of an intracapsular hip fracture.](image)

In order to perform an internal fixation with the Twin hook the patient is placed in a supine position on the extension table and care is taken for an adequate reduction of the fracture. A 2.8 mm guide pin is inserted in the right position and reaming of the femoral head and neck over the guide pin with an 8.86 mm reamer is performed. The guide pin is removed and the keyed barrel plate is placed against the lateral femoral shaft. The Twin hook is then assembled on the introcer and
inserted through the plate and pushed into the reamed channel. The introducer can be used as a joystick to seat the plate. After verifying the central position of the Twin hook the hooks are deployed by turning the introducer. Finally, the plate is fixed against the lateral femoral cortex with two cortical screws.

Postoperative, patients were allowed partial weight bearing with the help of a physiotherapist. Follow-up was at 2 weeks, 6 weeks, 3 months, 6 months and 1 and 2 years. To assess clinical outcome the Harris Hip Score (HHS) was determined. Conventional radiographs were performed at 6 weeks and at each follow-up interval thereafter. Patients underwent a bone scintigraphy when there was suspicion of avascular necrosis on clinical or radiological grounds. During the follow-up cut out, avascular necrosis and non-union were noted. If these complications lead to revision surgery, it was defined as failure of fixation.

Results

A total of 21 patients (11 women and 10 men) with an intracapsular hip fracture were treated by internal fixation with a Twin hook. The mean age was 59 years (range: 43-75 years). The mean time between the sustaining of the fracture and surgery was 20 hours (range: 2-60 hours). Ten fractures were undisplaced and 11 were classified as displaced. One patient died of an unrelated cause. All other patients were available for follow-up. Failure of fixation occurred in none of the undisplaced fractures and in 3 of the displaced fractures. Thus, in total 3 out of the 21 patients (14%) suffered a failure of fixation. The failure rate of 3/21 (14%) was compared with an a-priori estimated failure rate from the literature of 35% with a binomial test. The difference was significant (one-sided p-value 0.033).

In all 3 patients with failure of fixation there was a matter of suboptimal reduction or inadequate placement of the pin. In the 18 patients with successful bone union only one patient suffered an inadequate reduction. Avascular necrosis, confirmed by bone scintigraphy, occurred in 2 patients. As mentioned above, in one patient this lead to a failure of fixation. The other patient, despite the avascular necrosis, did not suffer a segmental collapse and eventually
experienced successful bone union. Cutting out of the Twin hook did not occur. Clinical outcome after a mean follow-up of 13 months (range: 6-24 months), as assessed by the HHS, was good (mean: 81.5 range 57-97).

Discussion

Whatever internal fixation device is used, the results are disappointing. Meta-analysis and clinical trials suggest failure of fixation in 21% to 57% of cases depending on the type of fracture and the age of the patient. Compared to the outcome reported in the above mentioned studies, a failure of fixation in 3 out of the 21 patients presented in this study, can be depicted as low. Limitations however are the small number of patients and of course the retrospective nature of the study.

Half of the patients suffered a displaced hip fracture. It has been well established that displaced fractures are more likely to fail than undisplaced. The extent of the damage to the vascularisation of the femoral head is more severe in displaced fractures and displaced fractures are more difficult to reduce and are more unstable. It is therefore striking to note that the three fixation failures reported in this study all concerned displaced fractures. Moreover, in the three reported fixation failures the reduction was suboptimal and/or the placement of the pin was inadequate. On the other hand, in the remaining 18 patients where internal fixation with a Twin hook was successful, only one patient suffered an inadequate reduction and there was no malplacement of the Twin hook.

The improved rotational stability of the Twin hook as demonstrated in two separate biomechanical studies is of special interest in the fixation of intracapsular hip fractures. These types of hip fractures are especially vulnerable to rotational forces due to the damaged joint capsule and the intrinsic rotational instability. If these forces are not neutralised by a stable internal fixation device it will lead to movement at the fracture site and to unfavourable conditions for the primary endosteal bone healing of the femoral neck and revascularisation of the femoral head. Also, the fact that no rotational force is required during insertion of
the hook pin will prevent rotation of the femoral head during the introduction of the hook pin. This will help to preserve the vascularisation of the femoral head in the remaining joint capsule. Another practical advantage is that no second anti-rotational K-wire or screw is needed. Removal of the Twin hook is simple and requires only a small incision as the pin may be removed without removing the plate. The fact that the Twin hook is not inserted by means of a cannulated technique brings about the risk of making a ‘false route’ and displacing the fracture. In practice this problem was not encountered in the present series. Another potential disadvantage of the Twin hook is the shape of the apical hooks when compared to the spherical shape of the femoral head. Placing the Twin hook just beneath the surface of the femoral head, where the highest bone density exists, will allow only partial deployment of the hooks. This could have a negative effect on the rotational stability of the Twin hook since the resistance against torsion loads is mainly dependent on the hooks of the Twin hook 20. On the other hand, there is no difference in rotational stability in either the clockwise or counter-clockwise direction as is with the SHS 15.

Clinical outcome, as assessed by the HHS, was good and most patients were satisfied with the result. This is in concordance with the functional results reported by others following internal fixation with screws or a SHS 6, 9, 10, 25.

Conclusion
In conclusion, the Twin hook seems to be a feasible alternative for the internal fixation of intracapsular hip fractures. In addition, this study underlines once again the importance of an adequate reduction and fixation in this type of fracture.
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Chapter 4

The Dynamic Locking Blade Plate, a new implant for intracapsular hip fractures: Biomechanical comparison with the Sliding Hip Screw and Twin Hook

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Chapter 4

Abstract

Internal fixation of intracapsular hip fractures results in a high failure rate with non-union and avascular necrosis being the two most important complications. In order to prevent these possible complications treatment should consist of an anatomical reduction and stable fixation by insertion of a low volume, dynamic implant, providing angular and rotational stability to the femoral head. According to these principles a new implant, the Dynamic Locking Blade Plate (DLBP) was designed for the fixation of intracapsular hip fractures. We performed a biomechanical analysis in synthetic bone to compare the rotational stability and cut out resistance of the DLBP with a conventional sliding hip screw (SHS) and the more recently developed Twin Hook. The rotational stability of the DLBP proved to be three times higher than the rotational stability of a SHS and two times higher than the Twin Hook. There was no major difference in cut out resistance between the different implants. The design of the DLBP and possible advantages with regard to the healing of an intracapsular hip fracture are discussed.
Introduction

The treatment of an intracapsular hip fracture is still under debate. There is consensus regarding the biologically young and elderly patient. Young patients are treated with internal fixation in order to preserve the femoral head and regain full function of the hip. Elderly patients are treated with an arthroplasty in order to limit the period of immobilisation and to prevent revision surgery. The treatment of the intracapsular hip fracture in patients aged sixty to eighty years remains controversial and is therefore referred to as “the unsolved fracture”.

The results of internal fixation, especially in the elderly, are disappointing. A revision rate with decreased function and increased morbidity of 35% and up to 48% are reported in two large meta-analysis performed by respectively Lu Yao and Bhandari.

As an illustration of the poor clinical results there are many implants available for the use of internal fixation of an intracapsular hip fracture. Parker concluded from his meta-analysis of randomised trials that there is little difference in failure rate between these different implants. However, the meta-analysis performed by Bhandari et al. demonstrated better results for screw and side-plate constructs than multiple screws. The sliding hip screw (SHS) is one of the most commonly used screw and side-plate constructs with reported failure rates of 12-41%. The Twin Hook (Stryker, Geneva, Switzerland) has recently been developed as an alternative to the conventional side-plate with lag screw constructs. It consists of a side-plate with a sliding nail from which two oppositely directed apical hooks are deployed. To our knowledge there are no clinical studies available on the use of the Twin Hook in intracapsular hip fractures.

Non-union is a major cause of failure of internal fixation of an intracapsular hip fracture. It is therefore important to realise that healing of an intracapsular femoral neck fracture is potentially compromised because of several reasons. First, the intracapsular part of the neck of the femur has no periostal layer to participate in the bone healing process. Therefore, bone healing in the femoral neck is dependent on endosteal union alone without the formation of peripheral callus. Secondly, primary bone healing requires, according to the interfragmentary strain
theory, absolute stability and anatomical alignment \textsuperscript{22}. In order to prevent non-union of a femoral neck fracture a device for internal fixation should therefore preserve the endosteal layer of the femoral neck and provide the required stability. Another major cause of failure of internal fixation is avascular necrosis \textsuperscript{28}. The viability of the femoral head after a femoral neck fracture is dependent on the preservation of the remaining vascular supply and on the occurrence of revascularisation. Again, stable fixation and anatomical alignment are a prerequisite for this process to take place. Persistent motion at the fracture site can torn the tender, so called, revascularisation buds during vascular ingrowth and cause avascular necrosis. Also increasing the volume of the implant within the femoral head may be deleterious to femoral head viability \textsuperscript{11,27}.

To prevent these possible complications of internal fixation, in our opinion, properties of a new improved implant should include: good angular and rotational stability, good femoral head fixation, a small frontal area and low implant volume and the possibility of applying dynamic compression over the fracture. Therefore, in an attempt to solve the “unsolved fracture” we designed the dynamic locking blade plate (DLBP) (BAAT medical engineering, Hengelo, The Netherlands), a new implant which claims the above named characteristics. The objective of this study was to determine the biomechanical characteristics of the DLBP and compare them with the characteristics of the SHS and Twin Hook. For this purpose the rotational stability of the DLBP, SHS and Twin Hook were determined in synthetic bone. Furthermore, a cut out test procedure with dynamic axial load testing was performed \textsuperscript{1}.

**Materials and Methods**

The DLBP consists of a barrelled side-plate combined with a cannulated locking blade. A guide pin is inserted and the femoral head and neck are reamed with an adjustable reamer. The blade and plate are assembled together with the introducer as one device. The cannulated blade with the attached plate is then pushed over the guide pin into the femoral head. Note that this does not require a rotational
force. The plate is fixed to the lateral cortex with two self-tapping screws. The blade is locked subchondrally in the femoral head by deploying the impactions anchors (Figure 1).

![Dynamic Locking Blade Plate (DLBP)](image)

**Figure 1.** Illustration of the Dynamic Locking Blade Plate (DLBP).

The SHS is a side-plate combined with a conventional lag screw and the Twin Hook is a side-plate combined with a nail from which apical hooks are deployed. The implants were inserted into pre-drilled bone substitute material to a defined
depth following the surgical technique. Beforehand the proportions of the different implants were determined (Table 1).

A solid rigid polyurethane foam with a density of 15 pcf and 20 pcf (Sawbones, Malmö, Sweden) was used as a bone substitute material to simulate the cancellous bone in the femoral head. Both foams comply with ASTM F1839. We chose polyurethane foam as test medium in order to obtain comparable results instead of absolute clinically relevant data. The 15 pcf foam has material properties similar to osteoporotic cancellous bone, the 20 pcf foam simulates healthy bone. Both foams provide a distinctly lower variability in their mechanical properties compared to human bone specimens.

Table 1. Proportions of the DLBP, Twin Hook and Lag Screw.

<table>
<thead>
<tr>
<th>Implant</th>
<th>Volume (mm³)</th>
<th>Frontal area (mm²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>DLBP</td>
<td>920</td>
<td>31</td>
</tr>
<tr>
<td>Twin Hook</td>
<td>1500</td>
<td>50</td>
</tr>
<tr>
<td>Lag Screw</td>
<td>1975</td>
<td>133</td>
</tr>
</tbody>
</table>

**Torsion test**

Figure 2 illustrates the test setup of the torsion test. The implants are rotated with a constant angular velocity while the torque is being measured. The implant is only loaded with a torque around the axis of the blade. The implant is rotated over 45° with an angular speed of 1°/second. Failure is defined as 20° of implant rotation. Rotational resistance is the torque at 20° of rotation.

Four samples of the DLBP, two of the Twin Hook and three of the SHS were tested in 15 pcf and 20 pcf foam.
**Figure 2.** Setup for the torsion test of the DLBP.

_Cut out test_

Figure 3 illustrates the test setup for the cut out test. The test procedure is identical to the Stryker Twin Hook Cut Out test procedure. The inserted implants were placed in a steel cup and clamped to the test device. The hooks of the Twin Hook were basically orientated and the blades of the DLBP were placed in a transverse direction. As a result the impaction anchors of the DLBP are orientated in a sagital plane. Free length of implant out of the set up is 55 mm.

The specimen are loaded with a sinusoidal multistage load according to the following description (Figure 4):

- The set up is preloaded with 30N. At this load the position $S_{\text{start}}$ is taken as reference position.
- The start load is $F_{\text{upper}} = 600$N at a load ratio of $F_{\text{upper}}/F_{\text{lower}} = 10:1$.
- After each 700 cycles the load is increased by $\Delta F_{\text{upper}} = 50$N.
- The force and the movement $S$ of the screw in the foam is determined after each 100 load cycles.
- After each load stage the piston is unloaded to 30N and the plastic deformation is determined as the difference between $S_{\text{end}}$ and $S_{\text{start}}$.
- Test frequency: 2Hz.
Cut out value was defined as the load where the total movement $S$ in the foam exceeds a value of 2 mm or more than 1 mm in one load stage. This criteria is similar to the criteria used in the cut out tests performed by Nonomiya. This value was chosen since a migration of 2 mm in the femoral head can already be identified on a postoperative radiograph and might cause a change in the treatment of the patient. Three samples of the DLBP and two of the Twin Hook were tested. Cut out test values of the SHS were derived from the data published by Nonomiya.

![Figure 3. Setup for the cut out test.](image)

![Figure 4. Schematic drawing of the setup for the cut out test.](image)
Anchor expansion test
The impaction anchors of the DLBP are deployed by turning a screw inside the implant. This requires a rotational force. The required rotational force, and whether or not the impaction anchors expanded, was tested in air, 15 pcf foam and 20 pcf foam.

Results

Torsion test
The results are shown in Table 2. The Twin Hook shows a strong increase in rotation resistance in the first 2° in the 15 pcf foam after which the resistance stays at a maximum independent of the angle of rotation. In the 20 pcf foam there is a reproducible rotational resistance increase at 10° after which the torque stabilises again.

The DLBP shows a similar strong increase of rotational resistance over a rotation of approximately 10° but does not stabilise. The rotational resistance keeps slowly increasing during further rotation.

Table 2. Mean rotational resistance at 20° of rotation.

<table>
<thead>
<tr>
<th>Foam density (pcf)</th>
<th>DLBP (Nm)</th>
<th>Twin Hook (Nm)</th>
<th>SHS (Nm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>15</td>
<td>9.0</td>
<td>4.5</td>
<td>3.8</td>
</tr>
<tr>
<td>20</td>
<td>15.1</td>
<td>7.2</td>
<td>4.8</td>
</tr>
</tbody>
</table>

Cut out test
The cut out value of 2 mm total displacement was reached in all tests before the deformation per loadstage exceeded 1 mm. Table 3. shows a summary of the results. The results of the cut out tests of the different implants are all within 10% of each other.

The cut out behaviour of the DLBP was similar to that of the Twin Hook. Both implants show a continuous increasing cut out displacement during the test.
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Table 3. The mean cut out resistance expressed as the cut out load at 2 mm of femoral head displacement.

<table>
<thead>
<tr>
<th>Foam (pcf)</th>
<th>DLBP (N)</th>
<th>Twin Hook (N)</th>
<th>SHS (N) (*)</th>
</tr>
</thead>
<tbody>
<tr>
<td>15</td>
<td>1133</td>
<td>1200</td>
<td>1178</td>
</tr>
<tr>
<td>20</td>
<td>2000</td>
<td>2025</td>
<td>1802</td>
</tr>
</tbody>
</table>

(*) Data derived from the Stryker cut out test by Nonomiya H and Bauer C.

Anchor expansion test

The results of the measured maximum rotational force are shown in Table 4. In all performed tests there where no technical failures while expanding the impaction anchors.

Table 4. Maximum torque (nM) while expanding the impaction anchors.

<table>
<thead>
<tr>
<th>Material</th>
<th>Maximum torque (Nm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>air</td>
<td>1,5</td>
</tr>
<tr>
<td>15 pcf</td>
<td>1,8</td>
</tr>
<tr>
<td>20 pcf</td>
<td>2,2</td>
</tr>
</tbody>
</table>

Discussion

The DLBP, SHS and the Twin Hook follow the principals of a sliding implant with side-plate construct: fixation within the femoral head and on the lateral cortex of the femur with the possibility of dynamic compression over the fracture. One of the main differences is the insertion technique. All three implants require a guide wire and predrilling. Insertion of the lag screw of the SHS then requires a rotational force with the risk of rotating the femoral head and thereby damaging the already compromised vascular supply of the femoral head. An anti-rotation K-wire or second screw is needed as a precautionary measure. On the contrary, the DLBP being a blade, and the Twin Hook being a nail, are pushed into the femoral head, not requiring a rotational force.

After insertion of the DLBP the impaction anchors are expanded in order to lock the blade within the femoral head and provide additional rotational stability.
Rotational stability of the DLBP is mainly based on the design of the blade and the two side wings. From the Twin Hook, apical hooks are deployed to gain fixation within the femoral head and to provide rotational stability. The anchor expansion tests demonstrated that it requires a minimum of force from the surgeon to expand the impaction anchors of the DLBP. Moreover, the impaction anchors never failed to expand in any material in any of the tests.

The presently performed tests demonstrated that when the implants are rotated 20° in 20 pcf sawbone a maximum momentum of 4.75 Nm for the SHS, 7.2 Nm for the Twin Hook and 15.1 Nm for the DLBP is measured. This means the design of the DLBP has succeeded in providing a three times higher rotational stability compared to the SHS and two times higher rotational stability compared to the Twin Hook. These results are in concordance with the data published by Nonomiya and Bauer on the torsion resistance tests of the Twin Hook. They measured a maximum momentum of 6.59 Nm at 20° of rotation in 20 pcf foam which is 9% lower than that of the current tests. This can be explained by the slight difference in test setup. Figure 5 gives a comparison of results from Nonomiya and Bauer and the current tests. As illustrated the DLBP is far more superior in rotational stability than the Twin Hook and the SHS.

![Torsion resistance in 20 pcf foam](image)

**Figure 5.** Comparison of the torsional resistance results in this test and the data of Nonomiya.
The capacity to resist high torsion loads is particularly important in intracapsular hip fractures. Hip joint contact forces are about 2.7 times body weight. This means that for a person of 95 kg forces acting on the hip will reach 2500N. Therefore a small misalignment of the implant in the femoral head will lead to high torsion moments. For example, with a axial force of 2500 N and a misalignment of 3 mm an additional rotation moment of 7.5 Nm will be generated as shown in Figure 6. Because of it's ability to resist high rotation moments the DLBP is more forgiving with respect to proper placing of the implant in the centre of the femoral head. In contrast, placing of the conventional lag screw comes very precise. Superior or peripheral positioning is associated with an increased occurrence of cut out.

![Figure 6. Additional torsion moment due to a small misalignment.](image)

Overall, the cut out behaviour of the Twin Hook and the DLBP show a high level of similarity. Because of the shape of the anchors of the DLBP it is possible to place the DLBP just beneath the surface of the femoral head, where the highest bone density exists as shown in Figure 7. This would also be possible with the Twin Hook, but only if the hooks are partially deployed. However, this could have a negative effect on the rotational stability of the Twin Hook since the resistance against torsion loads is mainly depended on the hooks of the Twin Hook.

Although the cut out test procedure provides us with useful and valid data it is not a true reflection of clinical practice. Normally, the surgeon would strive for an optimal reposition of the fracture which will result in bony support between the femoral head and the trochanteric region. Therefore, a great part of the axial force acting on the hip will be diverted through the bone. Thus, in clinical practice, when care is taken with the reposition of the fracture, cut out resistance will be far more higher.
Another striking difference is the proportion of the DLBP and Twin Hook when compared to the SHS. The frontal area of the DLBP is 4.3 times smaller than that of the SHS. The volume of the DLBP is 47 % and the Twin Hook 76 % of that of the SHS. The latter will therefore remove a greater proportion of cancellous bone. This may have adverse consequences on the stability of the fracture and the endosteal bone healing of the femoral neck, as well as on the viability of the femoral head. As mentioned in the introduction, bone healing in the femoral neck is dependent on endosteal union alone 24. Furthermore, the rotational stability of the fracture is indispensable for the preservation of the remaining blood supply and revascularisation of the femoral head 25.

![Diagram of DLBP and Twin Hook](image.png)

**Figure 7.** Schematic comparison of a DLBP and a Twin Hook when fully deployed subchondral in a femoral head.
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Conclusions
The DLBP has a far better rotational stability than the Twin Hook and SHS. Further more the DLBP has a smaller volume and smaller frontal area than the SHS. There are no significant differences in cut out values between the DLBP, Twin Hook and SHS.

The superior rotational stability of the DLBP may provide the right conditions for primary bone healing of the femoral neck and revascularisation of the femoral head. It’s minimal invasive characteristics may help to preserve the remaining vascular supply and respects the biology of bone healing of the femoral neck. We therefore hypothesize that the DLBP is a more biological and stable implant than the SHS and the Twin Hook leading to less avascular necrosis and a lower failure rate after internal fixation of an intracapsular hip fracture. A prospective clinical trial with the DLBP to verify this hypothesis is now being performed.
References


Chapter 5

Initial promising results of the Dynamic Locking Blade Plate, a new implant for the fixation of intracapsular hip fractures: results of a pilot study

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Abstract

The osteosynthesis of intracapsular hip fractures results in a 19%-48% failure rate. Only when the anatomical reduction is secured by stable fixation, revascularisation of the femoral head can take place and the fracture can heal by primary osteonal reconstruction. The common implants lack rotational and/or angular stability. Also the relative large volume of the implants within the femoral head compromises the (re)vascularisation. The combination of an anatomical reduction and a low volume, dynamic implant, providing angular and rotational stability seem to be crucial factors in the treatment of intracapsular hip fractures. This assumption formed the starting point for the development of the Dynamic Locking Blade Plate (DLBP), a new implant for the internal fixation of intracapsular hip fractures. This report describes the first clinical results of the new implant.

Internal fixation with the DLBP was performed in 25 consecutive patients with an intracapsular hip fracture within 24 hours from admission. Failure of fixation, due to non-union, avascular necrosis, implant failure or secondary displacement of the fracture, was the primary outcome measure. Functional outcome was assessed by the Harris Hip Score.

Following internal fixation of intracapsular hip fractures with the DLBP a failure rate of 2 out of 25 patients and excellent functional results were seen after a follow up of more than two years.

The initial clinical results of the DLBP are promising and justify the start of a randomised controlled trial.
Introduction

Proximal femoral fractures can be classified into intracapsular- and extracapsular hip fractures. Intracapsular hip fractures can be further classified into those which are displaced and those which are essentially undisplaced. Many other classification methods exist for the intracapsular hip fractures but these have not shown to be of reliable clinical usefulness.\textsuperscript{1, 3, 8, 16} Non-operative treatment of intracapsular hip fractures is unpredictable and leads to high failure rates (46\%)\textsuperscript{15}. Intracapsular hip fractures are therefore generally managed surgically, either by internal fixation of the fracture using various implants and thereby preserving the femoral head, or by hip replacement with an endoprosthesis. Concerning the first option, three main complications may follow internal fixation: avascular necrosis, non-union and implant failure. A meta-analysis performed by Lu Yao and, more recent, Bhandari showed a reintervention rate of respectively 35\% and up to 48\% due to the complications as mentioned above after internal fixation of displaced intracapsular hip fractures\textsuperscript{2–7}. Studies on the internal fixation of intracapsular hip fractures that also include undisplaced fractures report better results. Parker reported an incidence of non-union of 8.5\% following internal fixation of undisplaced intracapsular fractures versus 30.1\% for displaced fractures. The overall incidence of non-union was 19.3\%\textsuperscript{9}.

There are many implants available for the internal fixation of intracapsular hip fractures. However, a Cochrane review, performed by Parker and Stockton, concluded that none of the implants tested were found to be significantly superior for any of the outcome measures related to fracture healing complications or mortality\textsuperscript{10}. Parker and Stockton also concluded that the sliding hip screw systems (SHS) and multiple parallel screw techniques are the only methods that have been comprehensively evaluated\textsuperscript{10}.

Disappointed by the results achieved with the current implants we designed and developed a new implant specifically for the internal fixation of intracapsular hip fractures. It bears the working name “dynamic locking blade plate (DLBP)” and will soon be available as the Gannet\textsuperscript{8} (Pro-Motion Medical, Zwijndrecht, The Netherlands). In march 2009 we reported on the results of the biomechanical tests of this new implant\textsuperscript{13}. Characteristics of the DLBP are it’s low implant volume,
the firm fixation within the femoral head, the superior rotational stability when compared to the SHS and twin hook \(^{13}\), the angular stability and it’s simple use. An illustration and description of the DLBP can be seen in Figure 1. In this report the first clinical results of the DLBP after two years of follow up are demonstrated.

![DLBP illustration](image)

**Figure 1.** The dynamic locking blade plate (DLBP).

The implant consists of:

1. *dynamic winged locking blade* including two impaction anchors
2. barrelled side plate (similar to the SHS)
3. two cortical screws

**Surgical technique**

Based on the specific type of bone healing and the specific vascularisation of the femoral head, the backbone of operative treatment of intracapsular hip fractures is an anatomical reduction and firm fixation of the femoral head allowing dynamic compression \(^{11,12,14}\). After anatomical reduction of the fracture a 3.0 mm 135° guide wire is placed centrally in the femoral head followed by cannulated reaming up to 5mm in the femoral head. Then the locking blade together with a two hole side plate is mounted on the introducer (Fig. 2). The complete implant is introduced over the guide wire and gently tapped in while the mounted side plate functions as a rotational guide. After the side plate is seated along the lateral cortex, the introducer is released and the locking blade further tapped in the femoral head up to 5mm subchondrally. Next the side plate is fixed with two cortical screws. By turning the set screw clockwise in the shaft of the locking blade, the impaction anchors are expanded by which the blade is locked within the femoral head (Fig 3 and 4).
Figure 2. Assembly of the DLBP.

Figure 3. Expanding the impaction anchors.
Initial promising results of the Dynamic Locking Blade Plate

**Figure 4.** (a) Preoperative radiographs of a displaced intracapsular hip fracture and (b) after reduction of the fracture. (c) The DLBP is inserted and the impaction anchors are expanded. (d) One year postoperative the fracture has healed with slight shortening of the femoral neck.

**Notes on the surgical technique**

Aimed is for an anatomical reduction and not for a valgus reduction to prevent vascular damage by kinking of the lateral retinacular vessels. The guide wire is placed centrally in the femoral head because this is the rotational neutral point and in this position the risk of avascular necrosis is further reduced. Unlike the introduction of sliding hip screw devices, no torque force at all is exerted on the femoral head. Rotational stability is provided by the side-winged tip of the locking blade and is further improved by the two impaction anchors \(^{13}\). No perioperative antirotational pin nor an extra antirotational screw is necessary. Also, no pre-tapping for the locking blade is needed. The inner diameter of the pre-drilling in the femoral head relative to the outer diameter of the shaft of the locking blade is as such that no disimpaction of the fracture will occur, hereby avoiding strain on the remaining intact capsular vessels, when inserting the implant in the femoral head. The cutting time is reduced by inserting the mounted blade and plate as
one single unit. The barrelled side plate provides angular stability combined with dynamic axial compression of the fracture. The impaction anchors lock the blade in the femoral head and prevent perforation and backing out of the implant. Furthermore, dynamic testing showed augmented rotational stability by the impaction anchors when compared to the SHS and Twin hook \(^5\). The holding power of the expanded anchors is improved by impaction of the cancellous bone.

On removal, the impaction anchors are pulled in by turning the setscrew anti clockwise. During the biomechanical tests the impaction anchors never failed to withdraw \(^5\). After removal of the cortical screws the locking blade together with the side plate is tapped out by means of an extractor mounted on the locking blade.

**Patients and methods**

Based on the international orthopaedic literature it seems reasonable to set the failure rate of the common implants on 35%. Assuming a failure rate of 12%, a sample size of 26 would be needed to achieve a power of 80%. The target significance level is 5%. Based on this power assessment and the fact that it concerned a new implant, the Medical Ethics Committee allowed the inclusion of 25 patients for the first clinical DLBP trial. After getting approval we conducted a prospective, non-randomised, monocentre, observational pilot study on the clinical results of a cohort of consecutive patients with an intracapsular hip fracture treated by internal fixation with a DLBP at our institute. Included were patients from 18-75 years of age with an undisplaced or displaced intracapsular hip fracture (Comprehensive Classification of Fractures type 31-B), Garden I-IV. The patients should be able to give informed consent and were mobilised without aids before trauma. Excluded were patients who suffered a hip fracture more than 12 hours before admission, patients with former operations on the same hip, patients with other fractures of the lower extremities and patients with symptomatic disease of the same hip or patients unable to attend the follow-up. The procedures were performed within 24 hours from admission \(^4\). Two surgeons participated in the trial and performed the surgical procedures. The standardized
follow-up, including functional and radiological examination, was performed at 6 weeks, 3, 6, 12 and 24 months. The mean follow-up by now is more than two years. The primary outcome measure was failure of fixation due to avascular necrosis, non-union, implant failure, secondary displacement of the fracture or migration of the implant. Secondary outcome measures of the study were the mean operation time, per- and postoperative complications, the moment of full weight bearing, and the functional outcome by the Harris Hip Score.

Results

From February 2006 till July 2007 51 patients younger than 76 years of age with an intracapsular hip fracture presented at our institute. Thirteen of these patients suffered from pre-existent symptomatic disease of the hip and were treated with an endoprosthesis. Another 13 patients were treated with an alternative form of internal fixation (SHS or Twin hook) because of the lack of informed consent or because the participating surgeons were not available. 25 patients (14 women, 11 men) with an intracapsular hip fracture were treated with the DLBP. The mean age of these patients was 60 years (range: 39-75 years). Eight fractures were undisplaced (6 Garden I, 2 Garden II) and 17 were displaced (14 Garden III, 3 Garden IV). There were no peri- or postoperative complications. The mean operation time, including positioning of the patient and reposition of the fracture, was 40 minutes, decreasing from 53 minutes (range: 45-75 minutes) in the first 5 patients to an average of 26 minutes (range: 20-30 minutes) in the last 5 patients. The difference in mean operation time between the first 5 patients and the last 5 patients is statistically significant (P=0.008) using a Wilcoxon rank sum test. The average time to full weight bearing was 6 weeks post trauma.

After a follow-up of 2 years, in 23 out of 25 patients the bone healing was uncomplicated. One patient (ASA3, Garden IV) developed an avascular necrosis and collapse of the femoral head treated by a hemiarthroplasty (Fig 5). In another patient (ASA2, Garden III) a non-union was diagnosed more than half a year postoperatively and this patient was treated by a total hip arthroplasty. The failure rate of 2/25 (8%) was compared with an a-priori estimated failure rate from the
literature of 35% with a binomial test. The difference was significant (1-sided P
value 0.002). When comparing the failure rate of only the displaced hip fractures
2/17 (12%) the difference remains significant (P = 0.033).
Two male patients with a nearly anatomical reduction on the radiographs after
6 months and an excellent result according to the Harris Hip Score were lost to
follow-up after 6 months. During the 2 year follow-up 2 patients died of unrelated
causes. No secondary displacement was noted. Migration of the DLBP, determined
by measuring the tip-apex distance corrected for magnification in both frontal
and lateral views, was not noted. The functional outcome showed an average
Harris Hip Score after one year follow-up of 92 (range: 76-100) and after two years
follow-up 93 (range: 73-100).
Initial promising results of the Dynamic Locking Blade Plate
Figure 5. Avascular necrosis and collapse of the femoral head. (a) Preoperative radiograph of a displaced intracapsular hip fracture. (b) Fracture reduction and internal fixation with a DLBP. (c) Three months postoperative: segmental collapse of the femoral head; the patient is eligible for hip replacement surgery. (d) Three weeks later the patient presents at the emergency department with a total collapse of the femoral head.

Discussion

The results of internal fixation of intracapsular hip fractures with the DLBP or Gannet® are, at least, promising. Internal fixation of intracapsular hip fractures with the DLBP resulted in a re-intervention rate of 2 out of 25 (8%) patients, compared to a 19%-48% re-intervention rate for the SHS and the multiple screws/pins fixation reported in the literature. When we only consider the displaced hip fractures, the result, 2 failures out of 17 displaced hip fractures (12%) would still mean a substantial improvement compared to the literature reporting on only displaced hip fractures.

The patient that developed an avascular necrosis suffered from a disabling chronic obstructive pulmonary disease (COPD), obesity and a nicotine addiction which
made it very likely for this patient to develop an avascular necrosis. Thus, when considering the preoperative morbidity of this patient, and although the patient was mobilised without aids before sustaining an intracapsular hip fracture, this patient should not have been treated by internal fixation. The patient that developed a non-union suffered from a stroke one week after surgery due to an aneurysm of the cerebral medial artery with a partial paralysis as a consequence. It is well established that the chance of developing a non-union increases with age and preoperative morbidity. Under these circumstances and for the same reasons as mentioned above, this patient would also not have been treated by internal fixation.

Nevertheless, 2 failures out of 25 patients after a follow-up of 2 years remains an excellent result when compared to the international literature. This study however has its limitations. As the patient group is small, the study design nonrandomised and, regarding the fact that one of the co-developers of the DLBP is involved in this study, a certain bias should be anticipated. However, the difference in outcome of this study as compared to the results mentioned in the international literature is such that it cannot be explained by bias alone and it seems likely that some implant related effects of the DLBP are responsible. The combination of an anatomical reduction and a low volume, dynamic implant fixed within the femoral head providing angular and rotational stability are crucial factors in the treatment of intracapsular hip fractures.

**Conclusion**

The initial clinical results of the DLBP in the internal fixation of undisplaced and displaced intracapsular hip fractures are promising. The very low re-intervention rate after a follow-up of two years justifies the start of a prospective, randomised multicentre trial.

**Acknowledgments**

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References


Discussion, integration and conclusion

W.H. Roerdink

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What is the problem?

A patient with a hip fracture is a common encounter on our emergency wards. In 2004 18,212 patients older than 65 years were treated for a hip fracture in the Netherlands and the number of patients increases with about 230 hip fractures a year. It is expected that hip fractures will continue to increase their burden on health care and socio-economic systems in the near future.

Hip fractures can be divided into intracapsular (femoral neck) and extracapsular (trochanteric) hip fractures. About half of the hip fractures constitute intracapsular or femoral neck fractures. There is still much controversy on the treatment of these kinds of fractures. The controversy comes down to two unanswered questions. Firstly, which patient do we treat with an endoprosthesis (EP) and which patient do we treat with internal fixation (IF)? This controversy mainly exists in the age group between 60 and 80 years old. Young patients (< 60 years) are treated with IF and older patients (> 80 years) are treated with an EP because of the high risk of fixation failure in the elderly. An exception are very old patients at the end of their lives, confined to bed, and who sustain an intracapsular hip fracture. They are best treated by “palliative IF” through a minimal invasive approach. The aim is to make these patients pain free and allow for them to be nursed with a minimum of “collateral damage”. Once we have chosen to treat the patient with IF, the second controversy appears: What implant are we going to use to perform the IF with? It is this controversy which gave rise to this thesis.

How are we dealing with it?

Before the era of modern surgical orthopaedics most patients with a hip fracture were treated by bed rest or by traction with huge splints or with a plaster cast. However, most femoral neck fractures did not unite and mortality was high. In 1850 Von Langebeck placed the first pin in a non-united femoral neck fracture. Although later his patient died of sepsis it was marked as the beginning of the surgical treatment of hip fractures. While hip surgery was not without risk for
patients in the 19th century, the IF of hip fractures meant a huge step forward. It prevented serious deformities and patients were no longer confined to their bed during the bony healing process. Since then many different implants have been developed and used for the fixation of hip fractures. Tronzo identified over a 100 in 1974. Most implants are made of a pin or screw or a variant of one of these modalities. For example, the Hansson pin, which consists out of a pin from which two hooks can be extruded from the tip. In some of the implants used a side plate can be connected providing extra resistance against the axial load thereby preventing a varus deformity of the femoral head and neck. In the sliding hip screw systems (SHS) the screw has the capacity for sliding at the screw-plate junction allowing compression at the fracture site during axial loading. Pins were also combined with plates, the Twin hook is a fine illustration of this feature. Although many implants are available they all have in common that they perform poorly when it comes to the IF of displaced intracapsular hip fractures. Meta-analysis performed by Lu Yao and Bhandari demonstrated a reintervention rate of respectively 35% and up to 48% after internal fixation of displaced intracapsular hip fractures. Studies on the internal fixation of intracapsular hip fractures that also include non-displaced fractures report better results. Parker reported an incidence of non-union of 8.5% following internal fixation of non-displaced intracapsular fractures versus 30.1% for displaced fractures. The overall incidence of non-union was 19.3%.

Of the implants used for the IF of intracapsular hip fractures the sliding hip screw systems (SHS) and the parallel screws are the most widely used and most thoroughly investigated. A Cochrane review, performed by Parker and Stockton, concluded that the SHS and parallel screws were not significantly superior to one and other when fracture healing complications and mortality were compared.
What is the solution?

At Medisch Spectrum Twente, the Dynamic Hip Screw (DHS), a sliding hip screw system, has been the implant of choice for the fixation of intracapsular hip fractures during the last three decades. The results evaluated in the PSS hip trial and described in chapter 2 of this thesis are disappointing. With the annotation that it concerned a relatively old patient population and 1/3 of the fracture reductions were not optimal we noted 40% fixation failures. To us this was unacceptable and from then on the reduction of the fracture was more appreciated, residents were no longer allowed to perform an internal fixation of an intracapsular hip fracture without direct supervision and IF was limited to patients younger than about 80 years of age. Besides these measures we went looking for an alternative implant. First we sought a superior alternative in the existing implants. We already used the Twin hook for trochanteric fractures, which the implant was originally designed for. However, the Twin hook has some features that makes it especially suitable for the fixation of intracapsular hip fractures.

Firstly, the fact that IF with a Twin hook is a simple procedure. Secondly, no rotational force is required during insertion of the pin. Thirdly, by deploying the apical hooks the Twin hook provides fixation strength within the femoral head comparable to the lag screw but with improved rotational stability. The retrospective analysis of the patients we treated with the Twin hook is described in chapter 3 of this thesis. Although the results were rewarding we are not allowed to compare them with the results achieved with the SHS as described in chapter 2. Both patient groups were very different: the average age of the patients in the Twin hook group was 59 (43-75) years old as compared to the patients in the SHS group with an average age of 77 (60-89) years old. Moreover and even more important is the fact that in the Twin hook group about half of the fractures were displaced whereas in the studied SHS group all fractures were displaced. Of course we also have to take into account the retrospective nature of both studies and the fact that both studies concerned a limited number of patients.

Meanwhile the international orthopaedic trauma community i.e. the International Hip Fracture Research Collaborative (IHFRC) led by Bhandari, also addressed
these long lasting controversies. Amongst others, they designed the FAITH (Fixation Using Alternative Implants for the Treatment of Hip Fractures) trial. It concerns a multi-centre randomized trial comparing SHS and cancellous screws in the treatment of displaced and non-displaced intracapsular hip fractures in patients aged 50 years and older. Primary outcome is revision surgery rates. Secondary outcome measures are quality of life, function and complications including mortality, avascular necrosis, nonunion, implant failure and implant removal after fracture healing to minimize pain and infection. The study started in 2009 and is estimated to complete the enrolment of the planned 2000 patients in 2013. Expectations are that the SHS will perform superior to the cancellous screws. The SHS is easier to place in the desired position, the SHS prevents varus displacement and is able to divert the axial load to the shaft of the femur. So, if the SHS is the superior implant of the two, we are, in 2013, left with an implant that obtained disappointing results in the PSS hip trial as well as in our own patient group as described in chapter 2. Although this tremendous effort by the IHFRC is of great value from a scientific point of view, we did not want to await the results and went back to the basics of the femoral neck fracture.

Back to basics

The aim was to design an implant that possesses the biological and mechanical characteristics to perform superiorly in the IF of intracapsular hip fractures. In order to identify the ideal characteristics of a new implant it is essential to appreciate the vulnerable blood supply to the femoral neck and head and to understand the process of bone healing in the femoral neck as described in chapter 1 of this thesis. Bone healing of the femoral neck is a vulnerable process. The intracapsular part of the femoral neck has no cambium layer and therefore cannot heal by peristomal callus formation. Hence, bone healing of the femoral neck is dependent on endosteal healing alone. This type of bone healing requires absolute stability. Furthermore, if the vascularisation of the femoral head is compromised after a fracture, revascularisation takes place when vessels grow into the devascularised
areas. These tender, so called vascular buds can be torn repeatedly if persistent motion remains at the fracture site as a result of poor fracture stabilisation. Another, in our opinion, compromising factor in the bone healing process is the volume of the implant within the femoral head. A relatively large volume of the implant within the femoral head impairs the vascularity of the femoral head and potentially compromises endosteal bone healing of the femoral neck.

**Solving the unsolved fracture?**

In view of the above described features on healing of the femoral neck it is our firm conviction that a newly designed implant for the fixation of intracapsular hip fractures must fulfil the following demands. The new implant must provide absolute angle- and rotational stability to prevent varus displacement and to promote revascularisation and endosteal bone healing. Furthermore, the volume of the implant within the femoral head must be kept as low as possible for the above outlined arguments.

Bearing in mind the described features we came to design the Dynamic Locking Blade Plate (DLBP). As described in chapter 4 and 5 the DLBP consists of:

- a cannulated blade, with a large bearing area, at the end of a pin to divert the axial load to the shaft of the femur and to provide rotational stability. The pin has a small frontal area to prevent disimpaction of the fracture when inserting the implant in the femoral head.
- a barrelled side plate which provides angular stability thereby preventing varus displacement. It allows controlled axial collapse of the fracture leading to compression at the fracture site.
- two apical impactions anchors to gain fixation within the femoral head and providing additional rotational stability.
Before testing the DLBP in a clinical trial the biomechanical characteristics of the new implant were to be analysed in a laboratory setting. In addition, the implant had to comply with standards defined by the “Notified body” (Kema Quality) before it could be used in patients. For this purpose a cut out test procedure was performed as well as static and dynamic axial load testing according to ASTM (American Society for Testing and Materials) standards. Furthermore, the rotational stability in synthetic bone was determined as well as push in and pull out tests.

The results of the biomechanical analysis are, as far as they are clinically relevant, described in chapter 4. The biomechanical performance of the more common SHS and the Twin hook, which was the implant of choice in Medisch Spectrum Twente at the time, was compared to the DLBP in the exact same tests. The superior rotational resistance (three times the resistance of the SHS) was of course very encouraging. The fact that is was not tested in human bone specimens does not alter the good results of the torsion tests. Moreover, besides the fact that human bone specimens are very expensive, they also vary in their mechanical properties. In order to create as less confounding as possible, when comparing the different implants, it is, in our opinion, necessary to use a test medium with exactly the same density and mechanical properties at each measurement.

Finally, after fulfilling the biomechanical testing and complying with the ASTM standards the DLBP was ready for its first clinical trial.

The first test

Our primary interest was to test the performance of the DLBP in maintaining fracture reduction and preventing revision surgery (failure rate). Important secondary goals of the first clinical trial with the DLBP were to test its safety and the handling of the implant in the operating theatre (per- and postoperative complications and mean operation time).

Assuming a failure rate of 12% in patients treated with a DLBP and a failure rate of 35% in the common implants we would at least need 26 patients to achieve a
power of 80%. Based on this power assessment and the fact that it concerned a new implant, the Medical Ethics Committee (MEC) allowed the inclusion of 25 patients for the first clinical DLBP trial. Although we thought of this as a very small sample size for such a common injury we of course had to comply with the ruling of the MEC. In February 2006 we started with including the first patients and within 1.5 years 25 patients were enrolled in the study. As described in chapter 5 we achieved a failure rate of only 2 out of 25 patients. Although we were encouraged by the result, we are also aware of the fact which Parker so clearly cited: “Clinicians should be wary of drawing definite conclusions from a single study as often the results are not reproduced in later studies”. Therefore a number of limitations of this study have to be taken into account i.e:

- small sample size
- non-randomised observational study
- non-displaced as well as displaced intracapsular hip fractures were included
- only two surgeons in one hospital performed the procedure
- one of the surgeons was involved in the development of the DLBP
- patient follow-up as well as the radiological follow-up was done by the doctors who also performed the surgery

We are very conscious of these limitations but we do not think that the results that we gained with the DLBP can be explained by these limitations or possible bias alone. Of course, it is important and fair to differentiate between the results of displaced and non-displaced fractures. We also think that for this pilot study we could group them together as they form the same clinical challenge with the same expected complications except for the fact that displaced fractures have a worse outcome. In order to accommodate this shortcoming we mentioned the results separately for displaced and non-displaced fractures. Using a binomial test the difference in outcome for displaced fractures is still significant compared to an a priori estimated failure rate of 35%, which in our view is a very realistic failure rate.

Another important finding of this clinical trial was that there were no technical failures or other problems concerning the implant or insertion of the implant. In fact, the DLBP proved to be simple, fast, reliable and a joy to work with.
Chapter 6

Future directions and dreams

The DLBP is now available named as Gannet because of its strong resemblance to this seabird with its wide wingspan. To firmly establish the use of the Gannet (DLBP) and to gather more evidence based support we now started a prospective multicentre trial. If we consider the first clinical trial, described in chapter 5, as a phase I trial this next study can be defined as a phase II trial. In stead of only two surgeons more orthopaedic and trauma surgeons in three different hospitals will perform an IF with the Gannet (DLBP). These surgeons are not involved in the development of the Gannet (DLBP) and will be critical towards the use of the Gannet (DLBP). Since the Gannet (DLPB) now bears a Conformité Européenne (CE)-certificate issued by Kema Quality, permission from the MEC is not provided and we are free to choose a larger patient sample size. All patient data are collected on a secured web-based case report form (CRF) Fig 1.

Meanwhile, the IHFRC started the HEALTH (Hip Fracture Evaluation with Alternatives of Total Hip Arthroplasty versus Hemi-Arthroplasty) trial in 2009. A multi centre randomised clinical trial comparing total hip arthroplasty (THA) and hemi-arthroplasty (HA) in the treatment of displaced intracapsular hip fractures in patients of 50 years and older. The target number of participants is 2500 patients. The anticipated end date is March 2012. The HEALTH trial will learn us which EP is superior in the treatment of displaced intracapsular hip fractures. When the FAITH trial and the HEALTH trial are successfully completed we might still be left with the question whether a displaced intracapsular hip fracture is best treated with an EP or with IF?

Based on the considerations in this thesis we believe the Gannet (DLBP) performs superior to screws or a SHS in the IF of intracapsular hip fractures. If the Gannet (DLBP) holds up it’s fine performance in the present phase II trial it would be very interesting to compare the Gannet (DLBP) in a randomised clinical trial (RCT) against the “winner” of the FAITH trial. We anticipate that the Gannet (DLBP) will obtain superior results in this proposed trial. When this trial is completed we will advise the IHFRC to design a RCT in which the “winner” of the HEALTH trial is compared to the Gannet (DLBP).
Discussion, integration and conclusion

Figure 1. Case Report Form on the secured website

Conclusion
This thesis has taught us that it takes endurance to develop a new implant without the support of large and established companies. We also think, on the basis of this thesis, that we can be optimistic about the future treatment of intracapsular hip fractures because we may have provided surgeons with a superior alternative for the existing internal fixation implants.
Chapter 7

Summary
Summary

The scope of this thesis was to describe the design and development of the Dynamic Locking Blade Plate (DLBP), an improved internal fixation (IF) device, in order to gain more satisfactory results in the IF of intracapsular hip fractures than is currently reported in the international literature.

Chapter 1 describes the magnitude of the increasing number of hip fractures and the clinical dilemmas they pose. In the Netherlands 18,212 hip fractures in patients older than 65 years were registered in 2004. Hip fractures are expected to increase their burden on health care and social resources in the coming decades. In general, two types of hip fractures can be distinguished, i.e. extracapsular hip fractures and intracapsular hip fractures or femoral neck fractures. This thesis focuses on intracapsular hip fractures since the results of current surgical treatment of this type of hip fracture are disappointing and give rise to much controversy.

First, the anatomy and physiology of the hip are described. Especially the vulnerable vascular supply of the femoral head and the specific type of bone healing are emphasized. The different type of classification systems for intracapsular hip fractures are discussed and it is concluded that in clinical practice it is best to simply classify them as displaced or undisplaced. Then an outline of conservative treatment, arthroplasty and internal fixation is given. The rate of revision surgery following arthroplasty for a displaced intracapsular hip fracture varies between 0% and 24%. The rate of revision surgery following an IF technique varies between 14% and 53%. The results following arthroplasty are at the expense of an increased length of surgery, more operative blood loss and need for blood transfusion, a higher risk of deep wound infections, and possibly an increased mortality. Which treatment modality is best for which patient remains under debate.

The two main complications of IF are avascular necrosis and non-union. The importance of fracture reduction and implant positioning in preventing these complications is underlined.

Finally, it is concluded that only with strong improvement of the internal fixation implant we can positively influence the failure rate of IF of femoral neck fractures. Chapter 2 describes a cohort of 34 relatively fit elderly (60-90 years) patients with a displaced intracapsular hip fracture treated by IF with a dynamic hip screw (DHS). We choose the DHS as it is one of the most widely used and accepted
and most extensively researched internal fixation implants. It is known from the literature that failure of fixation and the need for revision surgery following IF is high. The goal of this study was to analyse our own performance and to determine the outcome in terms of the rate of failure of fixation, long-term functional outcome and mortality. After 7 years of follow-up, failure of fixation was observed in 13 out of 34 patients. In the majority of patients who suffered failure of fixation an inadequate IF, due to either incorrect insertion of the screw or an inadequate reduction, was noticed. In patients with successful bone healing the functional outcome was fair and did not worsen in the 7 years thereafter. Five-years mortality rate in the studied patient group was higher then an age-matched control population. Based on these findings and other reports from the international orthopaedic literature we changed our policy with regard to displaced intracapsular hip fractures. Inadequate reductions or placement of the hip screw were no longer accepted. In case of an inadequate reduction IF was abandoned and an arthroplasty was performed. Furthermore, in accordance with the Dutch clinical practice guide line for femoral neck fractures the maximum age for performing an IF was set at 80 years.

In Chapter 3 a retrospective analysis of a small group of patients (11 women and 10 men) with an intracapsular hip fracture (10 undisplaced and 11 displaced) treated by IF with a Twin hook is reported. At the time we considered the Twin hook to be an attractive alternative to the DHS or parallel screws for the fixation of intracapsular hip fractures. Arguments in favour of the Twin hook are (1) the simple and straightforward surgical procedure, (2) the angular stability provided by the side plate, (3) the fact that no rotational force is required during insertion of the pin and finally (4) the improved rotational stability of the Twin hook when compared to the DHS.

The mean age of the studied patient group was 59 years (43-75 years). After a mean follow-up of 13 months 3 out of 21 patients suffered a failure of fixation. In all 3 patients there was a matter of suboptimal reduction or inadequate placement of the pin. In contrast, in the 18 patients with successful bone union only one patient suffered an inadequate reduction. Clinical outcome, assessed with the Harris Hip Score (HHS), was good. Despite the small number of patients and the
retrospective nature of the study we concluded the Twin hook to be an attractive alternative for the IF of intracapsular hip fractures.

Chapter 4 describes the development and testing of the Dynamic Locking Blade Plate (DLBP). Again the typical endosteal bone healing of the femoral neck without the formation of peripheral callus is pointed out. In addition, the vulnerable vascular supply of the femoral head and the process of revascularisation following a femoral neck fracture are described. Disturbance of these processes will respectively lead to non-union and avascular necrosis. It is concluded in the introduction that a stable fixation and anatomical alignment are a prerequisite for an uncomplicated healing of a fractured femoral neck. Properties of a new improved IF device should therefore include: (1) good angular and rotational stability, (2) firm femoral head fixation, (3) a small frontal area and low implant volume and (4) the possibility of dynamic compression over the fracture site. With the design of the DLBP we attempted to incorporate the above named properties into one implant. The objective of the study described in Chapter 4 is to determine the biomechanical characteristics of the DLBP and compare them to the characteristics of the Sliding Hip Screw (SHS) and Twin hook.

The implants were inserted in a solid polyurethane foam (Sawbone®) of two different densities which functioned as a bone substitute. We tested rotational stability, which is of particular importance in femoral neck fractures, and cut out resistance. In addition, we performed an anchor expansion test.

The results of the torsion tests of the DLBP revealed a three times higher rotational resistance when compared to the SHS and two times higher when compared to the Twin hook. There was no major difference in cut out resistance. Moreover, there were no technical failures when expanding the impaction anchors.

It is concluded that the DLBP has a far better rotational stability than the SHS and Twin hook. The superior rotational stability of the DLBP and its minimal invasive characteristics may provide the right biomechanical and biological conditions for an uncomplicated bone healing of the femoral neck.

In Chapter 5 the first clinical results of the DLBP are presented. The need for an improved internal fixation device is stressed. The DLBP possesses the necessary characteristics: (1) it is a low volume implant, (2) it provides firm fixation within
the femoral head, (3) the rotational stability is superior, (4) fixation to the shaft provides angular stability, (5) no rotational force is applied to the femoral head during insertion, and (6) the use of the DLBP is very simple.

IF with the DLBP was performed in 25 consecutive patients with an intracapsular hip fracture. Eight patients suffered an undisplaced hip fracture and 17 patients suffered a displaced hip fracture. Failure of fixation, due to avascular necrosis, non-union, implant failure, secondary displacement of the fracture or migration of the implant, was the primary outcome measure. Secondary outcome measures were the mean operation time, per- and postoperative complications, the moment of full weight bearing and the functional outcome by the HHS.

After a 2 year follow-up uncomplicated bone healing was observed in 23 out 25 patients. When compared to the failure rate reported in the international orthopaedic literature the difference is significant. The difference remains significant when comparing only the displaced hip fractures. Functional results assessed by the HHS were excellent.

These initial clinical results of the DLBP in the IF of intracapsular hip fractures are promising and justify the start of a larger (randomised) clinical trial.

In Chapter 6 the results described in this thesis are reflected upon. The methods used are critically reviewed and the findings are refined. In the last paragraph future directions are postulated.
Nederlandse samenvatting
Het doel van dit proefschrift is het beschrijven van het ontwerp en de ontwikkeling van de "Dynamic Locking Blade Plate" (DLBP). De DLBP is een nieuw implantaat voor de interne fixatie (IF) van mediale collum fracturen. Met het nieuwe implantaat wordt beoogd betere resultaten te behalen dan die tot nu toe in de internationale literatuur worden vermeld.

**Hoofdstuk 1** In Nederland werden in 2004 18.212 heupfracturen bij mensen ouder dan 65 jaar geregistreerd. Men verwacht dat de behandeling van heupfracturen een toenemend beslag op de gezondheidszorg gaat leggen. Er kunnen over het algemeen twee soorten heupfracturen worden onderscheiden, te weten extracapsulaire heupfracturen en intracapsulaire heupfracturen. De intracapsulaire heupfracturen worden in de klinische praktijk mediale collum fracturen genoemd. Dit proefschrift handelt voornamelijk over de IF van mediale collum fracturen aangezien de resultaten van de IF teleurstellend zijn en aanleiding geven tot veel discussie. Het alternatief voor de IF van mediale collum fracturen is de heupkop te vervangen door een endoprothese, een zogenaamde arthroplastiek. Over de voor- en nadelen van beide behandelmethoden en welke de te verkiezen chirurgische behandeling is voor de mediale collum fractuur bestaat nog een grote controverse.

In hoofdstuk 1 worden de anatomie en fysiologie van de heup beschreven. Hierbij worden de kwetsbare bloedvoorziening van de heupkop en de specifieke botgenezing van de femurhals benadrukt. De verschillende classificatie systemen voor mediale collum fracturen komen eveneens aan de orde. De conclusie is dat voor de klinische praktijk de mediale collum fractuur het beste geclassificeerd kan worden als gedisloceerd of niet-gedisloceerd. Vervolgens worden de verschillende behandelmethoden, i.e. conservatieve behandeling, arthroplastiek en IF beschreven. Het aantal revisieoperaties voor gedisloceerde mediale collum fracturen behandeld met arthroplastiek varieert in de literatuur tussen de 0% en 24%. Het aantal revisieoperaties na een IF techniek daarentegen varieert in de literatuur tussen de 14% en 53%. De betere resultaten na arthroplastiek gaan mogelijk wel ten koste van meer peroperatief bloedverlies, meer diepe infecties en mogelijk een hogere mortaliteit. De twee belangrijkste complicaties van IF zijn avasculaire necrose van de heupkop en het uitblijven van de botgenezing, in de
engelse literatuur geduid als “non-union”. Om deze complicaties te voorkomen is het van groot belang dat een adequate repositie van de fractuur plaatsvindt en het implantaat op de juiste wijze gepositioneerd wordt in de heupkop. Concluderend wordt gesteld dat, gegeven een goede repositie van de fractuur en een juiste positionering van het implantaat, het alleen mogelijk is de resultaten van de IF van mediale collum fracturen te verbeteren door een significante verbetering van de eigenschappen van het implantaat.

_Hoofdstuk 2_ beschrijft een cohort van 34 relatief gezonde oudere (60-90 jaar) patiënten met een gedisloceerde mediale collum fractuur die behandeld zijn middels IF met een dynamische heupschroef (DHS). De keuze voor de DHS is gebaseerd op het feit dat het één van de meest gebruikte en meest onderzochte implantaten voor de IF van mediale collum fracturen is. Uit de literatuur is bekend dat het falen van de IF van mediale collum fracturen hoog is en dus ook het aantal revisieoperaties. Het doel van deze studie is om onze eigen resultaten van de IF van gedisloceerde mediale collum fracturen te analyseren. Hiertoe werd het aantal revisieoperaties na IF, de functionele uitkomst op lange termijn en de mortaliteit bepaald.

Na een follow-up van 7 jaar was er bij 13 van de 34 patiënten een revisieoperatie uitgevoerd. Bij de meerderheid van deze patiënten was sprake van een inadequate IF doordat de heupschroef niet in de juiste positie was geplaatst of omdat er sprake was van een slechte repositie. Bij de patiënten met een succesvolle botgenezing was de functionele uitkomst redelijk en er trad ook geen verslechtering van de functie op in de daarop volgende 7 jaar. De 5-jaars mortaliteit in dit cohort was hoger dan die van een voor de leeftijd gecorrigeerde populatie.

Op basis van deze uitkomsten en gegevens uit de internationale literatuur hebben we ons beleid ten aanzien van de behandeling van gedisloceerde mediale collum fracturen gewijzigd.

Een onvoldoende repositie en een onjuiste positie van de heupschroef worden niet meer geaccepteerd. Indien het niet gelukt een adequate repositie te verkrijgen wordt afgezien van een IF en wordt er geconverteerd naar een arthroplastiek. Bovendien is in overeenstemming met de Nederlandse richtlijn “behandeling van de proximale femurfractuur bij de oudere mens” besloten geen IF meer te verrichten bij patiënten ouder dan 80 jaar.
In **hoofdstuk 3** wordt een retrospectieve analyse beschreven van een kleine groep patiënten (11 vrouwen en 10 mannen) met een mediale collum fractuur (10 niet-gedisloceerd en 11 gedisloceerd) die behandeld werden middels IF met een Twin hook. Destijds beschouwden wij de Twin hook als een goed alternatief voor de IF van mediale collum fractures i.p.v. de DHS of parallelle schroeven. Argumenten ten faveure van de Twin hook zijn (1) de eenvoudige en overzichtelijke procedure, (2) de hoekstabiliteit die geleverd wordt door de femurplaat, (3) het feit dat er geen rotatiekracht vereist is voor het inbrengen van de pen en tenslotte (4) de verbeterde rotatiestabiliteit in vergelijking tot de DHS.

De gemiddelde leeftijd van de bestudeerde patiënten groep was 59 jaar (43-75 jaar). Na een gemiddelde follow-up van 13 maanden was er bij 3 van de 21 patiënten sprake van een falen van de IF. Bij alle 3 deze patiënten was sprake van een suboptimale repositie van de fractuur of een onjuiste positie van de geplaatste pen. Dit in tegenstelling tot de 18 patiënten waarbij een ongecompliceerde botgenezing optrad en waarbij er sprake was van slechts 1 suboptimale repositie. De functionele uitkomst, die werd bepaald aan de hand van de Harris Hip Score (HHS), was goed.

Ondanks het kleine aantal patiënten en de retrospectieve aard van de studie meenden wij te kunnen concluderen dat de Twin hook een aantrekkelijk alternatief is voor de interne fixatie van mediale collum fracturen.

**Hoofdstuk 4** beschrijft het testen en de ontwikkeling van de Dynamic Locking Blade Plate (DLBP). De specifieke endostale botgenezing van de femurhalter zonder de formatie van perifere callus wordt opnieuw benadrukt. Ook de kwetsbare bloedvoorziening van de heupkop en het proces van revascularisatie worden beschreven. Verstoring van deze processen zal leiden tot “non-union” en avasculaire kopnecrose. Een stabiele fixatie en een anatomische repositie zijn om die reden een eerste vereiste voor een ongecompliceerde botgenezing van de mediale collum fractuur. Een nieuw en verbeterd IF implantaat moet dan ook over de volgende vereisten beschikken: (1) een goede hoek- en rotatiestabiliteit, (2) een stevige fixatie van de heupkop, (3) een klein frontaal oppervlak en een laag implantaat volume en (4) de mogelijkheid van dynamische compressie over de fractuurspleet. Met het ontwerp van de DLBP hebben wij getracht de voornoemde vereisten te incorporeren in één implantaat.
Het doel van de studie beschreven in hoofdstuk 4 is de biomechanische karakteristieken van de DLBP te bepalen en deze te vergelijken met de eigenschappen van de glijdende heupschroef (DHS) en de Twin hook. De implantaten werden op de reguliere wijze ingebracht in een vast polyurethaan schuim (Sawbone®) van twee verschillende dichtheden. Het polyurethaan schuim functioneert als botssubstitutie. De uitbraakweerstand en de rotatiestabiliteit van de verschillende implantaten is getest. Daarnaast is het uitdraaien van de impactie ankers getest.

De torsie testen tonen een drie maal hogere rotatieweerstand van de DLBP aan in vergelijking tot de DHS en een twee maal hogere rotatieweerstand in vergelijking tot de Twin hook. Er bestaat geen groot verschil in uitbraakweerstand tussen de verschillende implantaten. Daarnaast deden zich geen technische problemen voor bij het uitdraaien van de impactie ankers.

Geconcludeerd wordt dat de DLBP over een superieure rotatiestabiliteit beschikt in vergelijking tot de DHS en de Twin hook. De superieure rotatiestabiliteit van de DLBP en de minimaal invasieve eigenschappen vormen mogelijk de juiste biomechanische en biologische condities voor een ongecompliceerde botgenezing van de mediale collum fractuur.

In hoofdstuk 5 worden de eerste klinische resultaten van de DLBP gepresenteerd. De noodzaak voor een nieuw en verbeterd IF implantaat wordt nogmaals benadrukt. De DLBP beschikt over de vereiste karakteristieken: (1) het is een klein-volume implantaat, (2) het voorziet in een stevige fixatie van de heupkop, (3) de rotatiestabiliteit is superieur, (4) fixatie aan de femurschacht voorziet in hoekstabiliteit van het implantaat, (5) er wordt geen rotatiekracht uitgeoefend op de heupkop tijdens het inbrengen van het implantaat en (6) het gebruik van het implantaat is eenvoudig.

Er werd een IF verricht met de DLBP bij 25 opeenvolgende patiënten met een mediale collum fractuur. Acht patiënten hadden een niet-gedisloceerde mediale collum fractuur en 17 patiënten hadden een gedisloceerde mediale collum fractuur. De primaire uitkomst maat is het falen van de IF ten gevolge van avasculaire necrose, non-union, implantaat falen, secundaire dislocatie van de fractuur of migratie van het implantaat. Secundaire uitkomst maten zijn de
gemiddelde operatietijd, per- en postoperatieve complicaties, het moment van volledige belasting en de functionele uitkomst bepaald door de HHS. Na een follow-up van 2 jaar is de botgenezing bij 23 van de 25 patiënten ongecompliceerd verlopen. Wanneer we dit resultaat vergelijken met de internationale literatuur is het verschil significant. Het verschil blijft significant wanneer we de resultaten van alleen de gedisloceerde mediale collum fracturen vergelijken. De functionele resultaten zoals bepaald met de HHS zijn uitstekend. De initiële resultaten van de IF van mediale collum fracturen met de DLBP, zoals hierboven beschreven, zijn veelbelovend en rechtvaardigen de start van een grotere (gerandomiseerde) klinische trial. In hoofdstuk 6 vindt een beschouwing plaats van de resultaten die worden beschreven in dit proefschrift. De gebruikte methoden worden kritisch beschouwd en de uitkomsten worden genuanceerd. In de laatste alinea’s worden de ideeën voor de toekomst geschetst.
Dankwoord
Dankwoord
Dankwoord

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Curriculum Vitae
The author was born on June 27, 1970 as son of Frits Roerdink and Jaqueline Michel in the Huize Tavenier maternity clinic just across the Central Station of the city of Groningen. In 1980/1981 he lived with his parents and his brother Wouter in Washington DC and visited the elementary school in Silver Spring, Maryland. He started secondary school in 1982 at the Wessel Gansfort College in Groningen. After finishing his exams in 1989 he spent one year working and travelling in Israel, Egypt and the island of Terschelling. In 1990 and 1991 he fulfilled his national service as a reconnaissance paratrooper with the Korps Commando troepen in Roosendaal. After leaving the army he commenced medical school at the University of Groningen. In 1993 he spent 3 months as an intern together with Annechien Bouman in a rural hospital in Murewa, Zimbabwe. In 1994 and 1995 he participated as a student assistant in the practical anatomy course for medical students. He received his medical degree (M.D.) in 1997 and started working as a resident at the Intensive Care of Medisch Spectrum Twente in the city of Enschede. In 1999 he was accepted as a surgical trainee and spent the first three years of his residency at the Department of Surgery at the University Hospital of Groningen under guidance of Prof. dr. R van Schilfgaarde and Prof. dr. HJ ten Duis. During that time he investigated the local and systemic inflammation of polytrauma patients (supervisor: Prof. dr. HJ ten Duis) and later on the acute phase response following radiofrequency ablation and cryoablation of colorectal liver metastases (supervisor: Dr. KP de Jong). The last three years of his surgical training took place at the Department of Surgery at Medisch Spectrum Twente under the guidance of Prof. dr. PAM Vierhout and his successor Dr WJB Mastboom. Following his registration as a general surgeon in 2005 he started a 2 year trauma fellowship in 2006 under the guidance of Dr ADP van Walsum at Medisch Spectrum Twente which has the disposal of a level I trauma centre with a mobile helicopter unit stationed nearby at Rheine in Germany. In this setting he became involved in the development and research of a new implant for the internal fixation of femoral neck fractures which eventually led to the accomplishment of this thesis. Since 2009 he is a member of staff, working as a general and trauma surgeon at the Department of Surgery of Deventer Hospital. In 2000 he married Annechien Bouman, the love of his life, who now works as a gynaecologist, also as a member of staff at the Deventer Hospital. In 2004 their daughter Anne Roos was born and one and half year later, in 2005, their son Jan Frederik.