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Review

Biomechanical femoral neck fracture experiments—A narrative review

Trude Basso [a,*], Jomar Klaksvik [a], Unni Syversen [b,c], Olav A. Foss [a,d]

[a] Norwegian Orthopaedic Implant Research Unit (NKSOI) Department of Orthopaedic Surgery, St. Olavs Hospital, Trondheim, Norway
[b] Department of Endocrinology, St. Olavs Hospital, Trondheim, Norway
[c] Department of Cancer Research and Molecular Medicine, Norwegian University of Science and Technology (NTNU), Trondheim, Norway
[d] Department of Neuroscience, Norwegian University of Science and Technology (NTNU), Trondheim, Norway

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ABSTRACT

Introduction: Orthopaedic implants can be introduced in clinical practice if equivalency to an already approved implant can be demonstrated. A preclinical laboratory test can in theory provide the required evidence. Due to the lack of consensus on the optimum design of biomechanical experiments, setups vary considerably. This review aims to make femoral neck fracture models more accessible for evaluation to orthopaedic surgeons without any particular background in biomechanics. Additionally, the clinical relevance of the different setups is discussed.
Methods: This is a narrative review based on a non-systematic search in PubMed, Scopus and Cochrane.
Summary: Biomechanical femoral neck fracture experiments should aim at optimizing the recreation of the in vivo situation. The bone quality of the experimental femurs should resemble the hip fracture population, hence cadaveric bones should be preferred to the available synthetic replica. The fracture geometry must be carefully selected to avoid bias. The load applied to the specimen should result in forces within the range of in vivo measured values and the magnitude should be related to the actual weight of the donor.

A well designed biomechanical experiment can prevent harmful devices from being introduced in clinical practice, however, positive results can never exclude the necessity of subsequent clinical studies.

Contents

* Corresponding author at: Norwegian Orthopaedic Implant Research Unit (NKSOI), Department of Orthopaedic Surgery, St. Olavs Hospital, Postbox 3250, 7006 Trondheim, Norway. Tel.: +47 952 41 982; fax: +47 728 26 033.
E-mail address: trude.basso@ntnu.no (T. Basso).

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Introduction

The annual worldwide incidence of hip fractures exceeds 1.7 million.[1] Femoral neck fractures account for 60% of these fractures and mainly occur in the elderly population.[2] With rare exceptions, all femoral neck fractures are treated surgically with either internal fixation or arthroplasty. Today an increasing proportion receives prosthetic replacement.[2] Nevertheless, a significant number of patients still have their proximal fragment fixed using various fixation techniques, and improvement of this treatment modality is therefore of clinical interest.

Clinical outcome after femoral neck fractures (FNF) in patients selected for internal fixation (IF) can be improved by better preoperative selection, optimizing surgical procedures of existing devices and by introducing improved implants and techniques.

Novel orthopaedic devices with similar design as already approved implants may not require level III classification by the U.S Food and Drug Administration (FDA) if equivalency to already approved implants has been demonstrated.[3] New fracture fixation designs are often based on implants already established and are hence likely to fall into this category. Despite obvious limitations, biomechanical laboratory experiments can thus provide sufficient evidence for releasing a novel design.[3]

Evaluation of biomechanical femoral neck fracture experiments is troubled by the variety of the experimental setups used. A basic understanding of the most common setups can prove useful when the clinician evaluates the results and later decides whether to introduce a new device to his practice or not. Biomechanical experiments can also throw light on clinically relevant aspects concerning existing implants.

The most obvious shortcoming of biomechanical laboratory studies is their limitation in describing in vivo bone response to mechanical stimuli. Direct investigation of avascular necrosis, fracture healing, stress shielding and late implant loosening due to local bone necrosis[4] requires response from live bone. Consequently, short-term failures such as early loosening, implant cut-outs and implant breakage can be demonstrated in laboratory experiments, while evaluation of most long-term outcomes cannot. Computerized models, animal experiments and examination of human samples harvested at surgery or postmortem may supply complementary information.

This paper does not fully describe the complexity of hip biomechanics. The aim is to provide background information necessary to comprehend biomechanical femoral neck fracture models and evaluate their results. By doing so, we hope to make interpretation of laboratory femoral neck fracture-research more accessible to clinicians with no particular background in biomechanics. Important factors like loading conditions, fracture morphology and clinically relevant endpoints are reviewed. The strengths and weaknesses of the different models are discussed.

Background

Basic biomechanics of the hip

Intuitively, weight-bearing during, e.g. walking, compresses the length axis of the femur. The spatial position of the femoral head is located medial and anterior with respect to the anatomical axis of the diaphysis. Therefore weight-bearing also causes an additional bending of the femur. Surrounding soft tissues tend to minimize this bending. Nevertheless, tension on the lateral aspect is still present in vivo.[5] In the stance phase of gait the femoral head is loaded with the femur condyles coupled to the ground. Inward rotation due to femoral anteversion is restricted by this coupling and causes a torsional force to act on the femur. Consequently, stress acting on the femur following human locomotion results in compressive, tensile and torsional strains. Strain distribution found in biomechanical experiments is dependent on the choice of biomechanical setup.

Hip joint loading during various levels of weight-bearing

The joint resultant force (JRF) of the hip is mainly determined by two contributors: body weight and muscular forces. The body weight minus the weight of the supporting leg, acts on the femoral head through a lever arm from the centre of gravity. In addition, the abductor muscles add considerable loads to the JRF. The resultant abductor force in early phase of gait has been calculated to 1–2 times body weight.[6,7] In vivo, JRF has been measured using telemetric prosthesis to approximately 2–3 times body weight during normal walking. Torsion increases during anterior loading as in stair climbing, reaching 2.2% body weight (Newton)-metre.[8] These measurements are based on only four subjects, but the values correspond well with previous calculations[7,9] and are widely used as reference values in current biomechanical publications.[10,11]

During one leg stance, muscles of the non-weight bearing hip act to stabilize the pelvis by counteracting the weight of the hanging leg. This results in a considerable joint force even on the non-weight bearing side.[8,12] Limited touchdown weight-bearing transfers some of this load to the ground and helps balancing the pelvis and might actually reduce the hip joint force compared to the non-weight bearing, straight leg situation. Using a walker resulted in a JRF of 1 times body weight during walking in one patient.[12] Crutches or canes also reduce the joint load during partial weight-bearing, but rarely below 60–65% body weight.[12,13] Elderly patients with femoral neck fractures are often not physically capable to follow instructions on reduced weight-bearing. Nevertheless, when allowed weight-bearing as tolerated, these patients limited their weight-bearing to 50% compared to the uninjured leg 1 week post-operatively, gradually increasing to 85% after 12 weeks.[14]

Fracture geometry

Typically, the fracture geometry varies with the patient's age and the level of energy involved in the trauma. The mean age for patients suffering from hip fractures is approximately 80 years and 70% occur in women.[15] Moreover, the often preceding low-energy trauma clearly indicates impaired bone strength in the majority of patients.

Intracapsular femoral neck fractures in the elderly show a remarkable homogeneity. They initiate at the superior aspect of the lateral collum and follow the cartilage-bone junction in an inferior direction (Fig. 1).[16,17] Somewhere cranial to the inferior buttress of the neck, the fracture-line moves laterally along the trabeculae, leaving 2–5 cm of the inferior subcapital region attached to the head. 14–50% of the displaced fractures have a posterior comminution.[17,18] A true variation in obliquity is only found occasionally, and the radiological variation seen is usually a result of fragment displacement and rotation.[16,17] In patients younger than 60 years, high-energy trauma to an abducted hip is usually the cause of a FNF. The fracture line then run more vertical and lateral, thus making these fractures highly unstable.[19] These fractures account for only 3% of the hip fractures[20] and are often referred to as transcervical fractures. True extracapsular femoral neck fractures are also rare, affecting less than 2% of the hip fracture population.[21]

There are several ways to create fractures in experimental setups. Methods include weakening of the neck by using a saw[22] or drilling multiple holes[23] through the cortex followed by mallet blows to the head. In this way, the naturally occurring rough

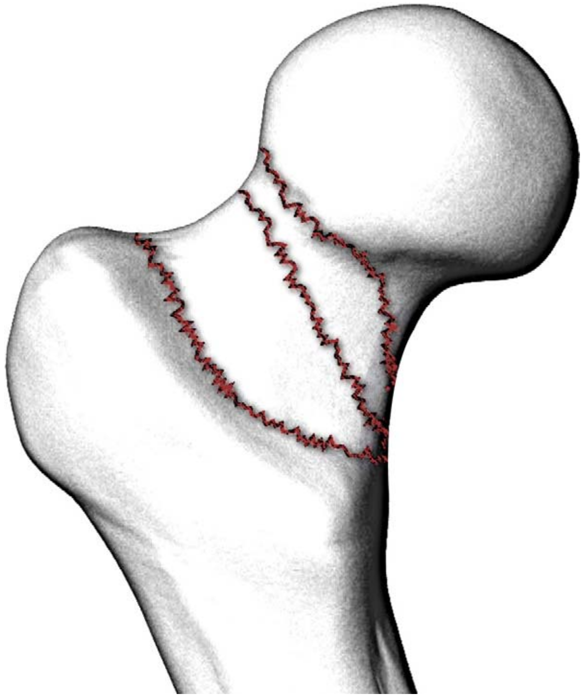

Fig. 1. Posterior view of three clinically relevant fracture lines: subcapital, transcervical and extracapsular.

surface, which contributes to stabilize the fracture in vivo, can be created. An osteotomy at a defined angle is another alternative.[24] Posterior comminution can be simulated by removing a posterior wedge.[10] Mid-cervical fractures are frequently created despite being unusual in vivo.[10,23,25]

The experimental specimen

The use of human cadaveric femurs in laboratory tests is still regarded as the gold standard by most researchers.[10,25–28] They show a unique resemblance to the in vivo situation with vast intersubjective variations in terms of strength and geometry. Human bone also enables re-creation of a realistic rough fracture surface. Limited access to donors and strict ethical regulations has made the use of femur analogues more common.[29,30] Fourth generation composite femurs (Sawbones®, Pacific Research Laboratories, Wa. USA) consist of glass-fibre reinforced epoxy and polyurethane foam to resemble cortical and cancellous tissue. The composition does not contain a trabecular structure and the very small femoral neck anteversion does not mirror the in vivo mean of 15°. The replica therefore represents a simplification of human bone (Fig. 2). This particular composite femur replicates healthy bone found in male subjects <80 years.[31]

The jig

In vitro FNF experiments most often employ a testing machine with some kind of jig fitted (Fig. 3). The simplest setup consists of a fixed distal diaphysis with a head-enclosing device to mimic the acetabulum through which a force is applied (Fig. 4a).[22,24] The orientation of the femur then determines the degree of bending of the femur and the magnitude of the torsional moment. By adding simulated abductor muscles or a lateral tension band,[10,25,27] the bending of the femur becomes more physiological correct. This setup requires distal anchorage of the diaphysis that allows angulations and rotation and makes separate application of torsional forces possible. It is important to recognize that the applied load no longer equal the JRF in the hip. The effect of the simulated abductor resultant or tension-band is rather small if the load is applied close to the head (Fig. 4b),[10] but increases considerably if applied through a lever arm (Fig. 4c).[25]

Loading

The materials testing machine can be programmed to apply loads in a static manner or dynamically, the latter commonly referred to as cyclic loading. One cycle is made up of a single or combined force delivered with varying magnitude.[24,26] Sometimes effort is made to experimentally imitate the alternating forces found during a normal walking cycle.[32]

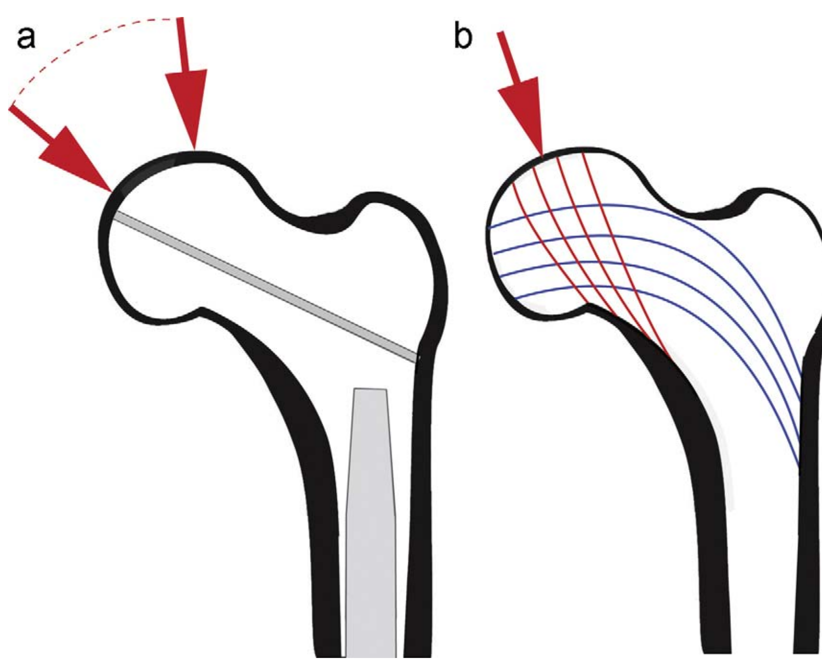

Fig. 2. Schematic cross-section showing optimum loading direction of a synthetic (a) and a human (b) proximal femur.

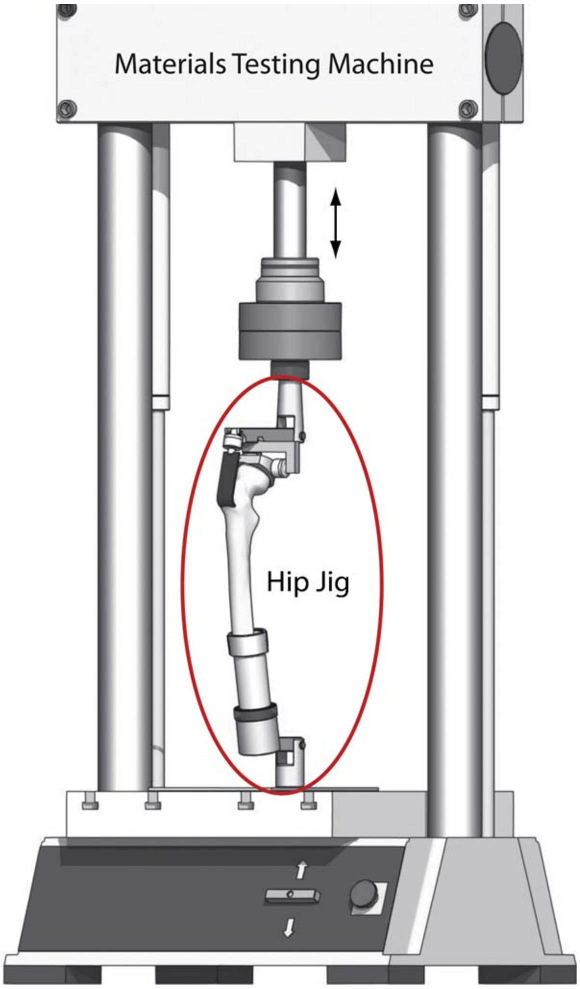

Fig. 3. A hip simulator typically consists of a materials testing machine applying programmed loads to a femur mounted in a passive jig.

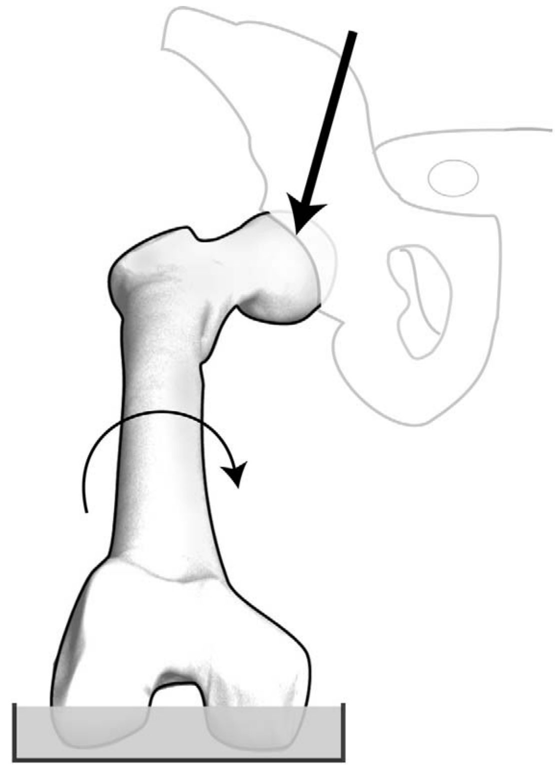

Fig. 5. Putting weight on a flexed hip, as occurs during stair climbing, increases the posteriorly directed torsional force in the upper femur.

Application of a single force on the anterior aspect of the femoral head by tilting the proximal femur posteriorly, results in a combined compressive, tensile and torsional load simulating stresses during stair-climbing (Fig. 5).[33] The force seeks to rotate the proximal femur posteriorly while the distal femur is relatively constricted by the distal embedding. Alternatively, torsion can be applied directly to the femoral head[23,28] or to the distal diaphysis.[34]

Until recently, forces applied to the specimen have been standardized making all specimens subjected to the same amount

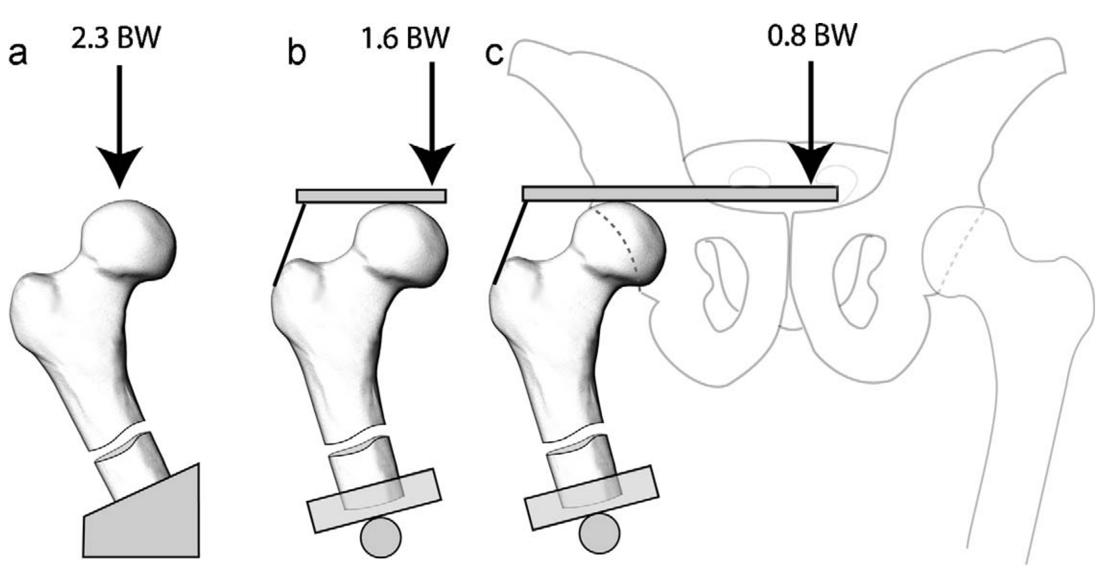

Fig. 4. Examples of single leg stance setups resulting in identical hip joint resultant forces. BW = body weight. (a) A distally fixed femur is subject to a single force acting directly on the femoral head. (b) A more physiological constraining allows movement of the femur during loading, enabling a passive simulated lateral muscle force. (c) A lever arm delivers bodyweight from a simulated centre axis of body mass to the femoral head and the construct is levelled by a passive simulated lateral muscle force.

of force regardless of the weight of the donor. An alternative is to apply force as % BW of the donor.[35] The load force might be increased in a stepwise manner,[26,32] incremented linearly,[35] or held stable during the test period.[28]

Alternative experimental methods

To directly explore the biological response to various aspects of fracture treatment, vital cells are required. Animal models can be applied, but the differences in loading conditions and geometry between humans and animals makes direct clinical inference of results difficult. Regarding testing of new materials, animal studies are important before clinical introduction.

The finite element method is a numerical model in which geometric shapes, in this context that of the femur and implant, are divided in multiple elements creating a mesh. Material properties, boundary conditions and degree of constraint are included in the model. Computerized models constantly improve and today provide complementary information particularly when describing altered stress distribution after various interventions.[11] Attempts have also been made to simulate the fracture healing process.[36] Naturally these computer models can never be better than the input parameters used. Today they provide supplementary information, but cannot yet substitute traditional biomechanical experiments preceding clinical trials.

Outcomes

Stiffness and load-to-failure

A static compression test can reveal the stiffness of a bone-implant construct. The stiffness can be compared to that of intact bone or to a comparable construct. Compression will cause head deflection. This provides data for a load/deflection curve, and stiffness can be calculated from the elastic part of the slope. Further compression will reveal yield load with damage accumulation/micro-fracturing culminating in plastic deformation and eventually failure.[37] Stiffness and load-to-failure are widely used end-points.[25,26]

Stability

Sufficient implant stability and implant-bone fixation are needed to avoid fracture gap opening with possible redisplacement during early weight-bearing. Tests involving cyclic loading are necessary to examine these phenomena. Implant loosening due to failure of the implant-bone interface may only be present after thousands of cycles tested and remains undetected if only a static force is applied to the construct.[32]

Although displacement measured directly by the testing machine is still in use,[33] active or passive markers attached to the femur on both sides of the fracture provide more accurate data when evaluating rigidity and stability.[10] The use of 3D technology provides accurate measurements of the relative movement between the markers. Markers can also be mounted on the implant itself to evaluate screw migration in the femoral head.[32]

Strain

To investigate local strain, strain gauges must be attached to a bone which is later subject to a compression test. Strain in this context can be defined as local stretching or compression of the examined cortex due to applied stress and can theoretically add information related to bone remodelling.[38]

Although rarely done in practice, strain-testing of the femoral cortex using strain-gauges can be included in experimental testing of fracture implants.[39] Likewise, strain on the implant itself can be measured, either by attaching strain-gauges in the implant-lumen or by modifying the implant for this purpose.[40,41] Strain measurements of loaded femurs are often used for validation purposes in computer models.[39,42]

Discussion

A variety of biomechanical setups are used when investigating femoral neck fractures. This opens up the possibility to thoroughly examine this common fracture, but also hampers direct comparison of study results and makes assessment of clinical relevancy difficult. High quality preclinical investigation is essential to secure the patient's welfare, and awareness of the limitations of such studies is essential.

Clinically, failure of internal fixation in femoral neck fractures rarely occurs due to excessive axial loading as observed during load-to-failure axial compression tests. The relevance of such simplified load scenarios must be questioned as the forces applied to the specimen rarely, if ever, occur in real life. Biomechanical experiments should aim at creating physiological setups to reveal possible advantages or disadvantages for the patient and not primarily test the extremes. Neither elderly patients who are allowed weight-bearing[14] nor younger patients with weight-bearing restrictions[19] are fully loading their fixated hip in the fracture healing period. Loading of 80% bodyweight or less seems to be the most realistic scenario to simulate the fracture healing period. Dynamic tests seem more prone to recreate failure following repetitive stress of the implant-bone interface as seen in vivo, than static compression tests. Great discrepancies on outcome were found after static and cyclic loading of the same experimental population, and the authors indicated cyclic loading to be the superior method of the two in terms of clinical relevance.[24]

Living bone is a highly dynamic tissue in which bone repair and load-induced adaptation constantly happen. In a patient, initiation of head migration or screw loosening may cause pain and discomfort leading to a pain-induced adjustment to the magnitude of weight-bearing. Following this, fracture healing might resume with resulting improved stability, again increasing the weight-bearing capacity. A biomechanical laboratory experiment cannot reflect this dynamic pain-induced feedback, and during experimental loading of cadaveric bone or synthetic replica, only material breakdown occurs.

By definition, the bending moment increases with increasing distance from applied force. Consequently, increased distance from applied joint force to the fracture surface has been shown to inversely correlate with force to failure in biomechanical tests for hip fracture implants.[43] Likewise, high vertical fracture-lines cause unstable fracture situations under axial loading.[43] Implants chosen for unstable fractures must carry most of the load due to inadequate load-sharing of implant and bone.[44] Stiffer implants, like a sliding hip-screw or intramedullary nail, will therefore show superior qualities in test setups with transcervically and laterally located fracture-lines, particularly when high fracture angles are created. The utility of these studies is significantly reduced if the intention is to provide information on the best treatment of femoral neck fractures in general. This may also explain why the often superior in vitro biomechanical results of stiffer implants have proven difficult to verify clinically.[45] The fracture geometry represented by fracture-line and surface roughness should to the greatest extent possible be standardized and mimic a clinical relevant situation.

Synthetic femurs are easily accessible and easier to handle than cadaver specimen. Their uniform geometry makes optimal standardization possible. For whole-bone mechanics they have proven to be a good substitute.[31,46] Still, the simplification of bone architecture makes extrapolation of biomechanical results from replica into real life somewhat difficult. The load transmission in a reduced femoral neck fracture is shared between the bone itself and the implant.[41] It is a problem that synthetic replica are designed to mirror bone qualities in a healthy male population while the hip fracture population is dominated by elderly women[2] with inferior bone strength. Consequently, we believe human cadaveric femurs where the age and bone-quality of the donor resemble a relevant patient-population should be preferred, at least until proper validation of synthetic replica for use in hip fracture experiments has been made.

Perhaps one of the greatest contributions of well designed biomechanical laboratory experiments is the possibility to prevent potentially harmful devices from being introduced to clinical practice. Strain measurement may identify cortex areas most vulnerable to later failure due to stress risers or stress shielding. A stress riser on the cortex might induce a later fracture around an implant, such as a subtrochanteric fracture, a rare, but well known complication in vivo.[47] Likewise, documentation of inferior implant qualities causing breakage and early loosening can be revealed during experimental testing. Conventional devices and methods will probably be best evaluated through clinical studies and well-designed registers.

It seems inadequate to introduce new implants to general clinical use based on successful results in biomechanical experiments alone. A stepwise introduction has been proposed,[3] suggesting laboratory experiments as a basis for further clinical studies and eventually commercial use if proven successful.

Despite the obvious shortcomings of biomechanical laboratory models for FNF, a better alternative is yet not available. It is tempting to speculate whether the current regulations of clinical introduction of new implants partly explain the vast number of IF devices for femoral neck fractures available on the market, of which none have proven considerably superior to the others.

Conclusions

In our opinion, a well-designed biomechanical FNF model for investigation of internal fixation devices is one that closely mirrors the in vivo situation. Human cadaveric femurs should be preferred instead of synthetic replicates, and the age of the donor and quality of bone should resemble the actual patient population. Standardized fractures should mimic fractures as they present themselves in vivo to avoid bias. The constraining of the femur should mirror the physiological situation as good as possible. Finally, dynamic loading is preferable and patient specific applied load should result in JRF within the range measured in vivo. Preclinical discovery of potential harmful qualities of orthopaedic devices should impede clinical use. Positive experimental findings should lead to further clinical testing.

Conflict of interest statement

All authors state no conflict of interest.

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