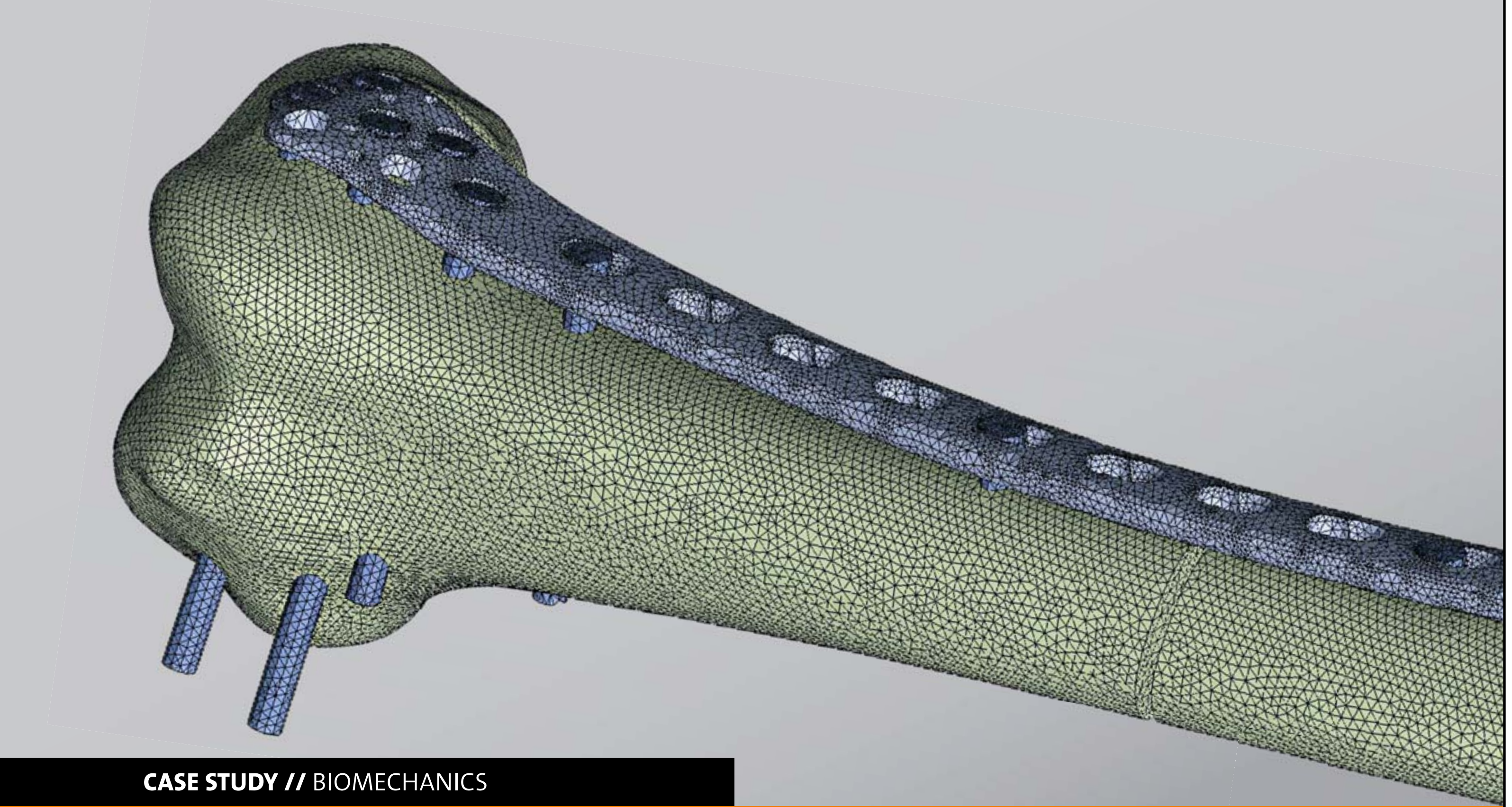

CASE STUDY // BIOMECHANICS

OPTIMIZATION OF FRACTURE TREATMENT

By using optiSLang and ANSYS, the finite element analysis enables surgeons to design and to optimize patient-specific screw arrangements and positions on locking compression plates in diaphyseal fractures of the femur. The analysis and optimization can be conducted within an automated procedure.

Introduction

The incidence of femoral shaft fractures is reported as being 1 fracture per 10,000 people. This rate increases to 3 fractures per 10,000 people for male individuals younger than 25 years and elderly patients, especially women, above the age of 65 years. The causes for the fractures of young males mainly include traffic or sports accidents. The increase in femoral fractures among elderly patients is due to an increase in osteoporosis and often results from low-energy trauma, such as falls from standing height at home. With an increase in life expectancy, the overall number of femoral fractures among elderly patients due to osteoporosis is expected to rise. Regarding these patients, an adequate treatment of femoral fractures which takes the material properties of osteoporotic bone into account, is important for a fast remobilization of the patients.

The focus of this study was the treatment of femoral shaft fractures which are commonly treated with plate osteosynthesis. The plate osteosynthesis involves bringing the ends of a fractured bone together and fastening them with a metal plate and screws. Although there are a variety of different plate types, locking compression plates have been widely applied in recent years. Among patients with osteoporosis, the stable fixation of the plate is a big challenge for the surgeon since the bone often lacks the desired stability. This may lead to a high complication rate due to the loosening of screws or breakage of the plate.

The aim of this study was to support surgeons to decide where to place the screws in order to achieve an optimal fracture healing and to prevent implant failure after a femoral shaft fracture. For this purpose, hundreds of different screw arrangements were evaluated and optimized using optiSLang controlling an automated workflow. The procedure involved:

- the use of computed tomography data for patient-specific modeling of the inhomogeneous material properties of the bone
- the evaluation of biomechanical parameters with finite element analysis
- the optimization of the screw arrangement under given constraints

The constraints for the optimization included the number of screws, the inter-fragmentary movement, the distance between plate and bone as well as the yield material properties of bone, plate and screws.

The automation of this process offered a whole new perspective compared to currently used approaches for investigating the influence of position and number of screws on fracture healing. Without an automated process, only a small number of different layouts could be compared to each other. With the proposed system, however, it was possible to select the best layout of hundreds of designs with reasonable effort.

Background

The process of fracture healing is a complex procedure which depends on a multitude of biological and mechanical factors. The process has been well studied in vitro and in vivo experiments. Based on these experiments, advanced treatment methods for bone fractures utilizing techniques such as plate osteosynthesis have been developed. In addition to in vivo and in vitro experiments, computational methods can also lead to new insights concerning the biomechanics of fracture treatment. For example, finite element analysis has proven to be a powerful tool in the evaluation of deformations and stress distributions under load.

Although “flexible internal fixation” is now regarded as the standard approach for the treatment of long bone fractures, there is still disagreement about the conditions for optimal fracture healing. Many research projects focus on defining parameters for fracture treatment both in vivo and in vitro. The healing of a fracture is influenced by biological (e.g. supply with blood) and biomechanical (e.g. interfragmentary movement) parameters. In addition, implants should not fail under the applied load.

The total number of screws influences the stability of a fracture treatment using a plate as an implant for the bone. If too little screws are used, the construct will be unstable. However, screws damage bone tissue, so, their usage should be kept to a minimum. *Stoffel et al.* suggested that for fractures of the lower extremities, two or three screws on either side of the fracture should be sufficient.

Interfragmentary movement is the relative movement of two pre-defined points on opposite sides of a bone fracture. The formation of solid bone tissue is only possible under stable conditions. Too much movement can cause pseudarthrosis, i.e. non-union, of a fracture. Prohibition of any movement can also lead to delayed healing or non-union of the fracture, since the natural formation of callus is prevented. Therefore, a certain interfragmentary movement is needed to induce fracture healing.

According to these studies, interfragmentary movement between 0.5 mm and 1 mm can be considered optimal. Traditional locking screws face the problem that due to a rigid plate-screw connection, the motion at the fracture gap directly beneath the plate is limited. This side of the bone is referred to as “near cortex”. The opposite side of the bone facing away from the plate is referred to as “far cortex”. Due to the elasticity of the plate, a bending motion can occur under load. This leads to a higher interfragmentary movement on the far cortex compared to the near cortex. This can cause unequal callus formation on opposite sides of the bone, which results in faster healing on the far cortex compared to the near cortex (Fig. 1).

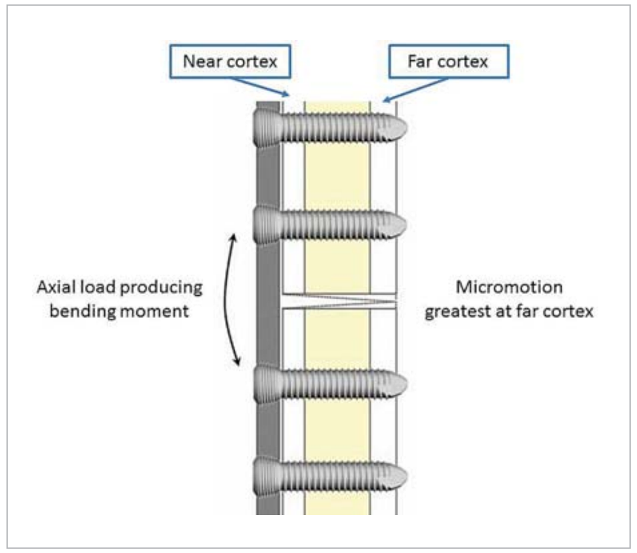

Fig. 1: Fracture movement on the near cortex is limited compared to the far cortex

Objective

The treatment of fractures is a complex process. To ensure an optimal healing process, several biomechanical factors such as the interfragmentary movement have to be considered. The influence of these factors on the healing process has been extensively researched. Currently, it is not possible to guarantee an optimal setting of these parameters during surgery. Surgeons normally base their decision of where to place a screw on experience and general guidelines. However, the structure and shape of the bone of every patient is different. In particular, patients with osteoporotic bones need special attention to prevent bone damage which may lead to implant failure.

This work aims to develop a tool which supports the surgeon in deciding where to place screws during plate osteosynthesis in order to provide optimal healing conditions. For this purpose, an automatic workflow has to be developed which determines the best screw configuration under given constraints. In this workflow, biomechanical parameters, e.g. displacement, stress and strain, on bone and implant have to be evaluated for a multitude of designs. FEA is used for the assessment of these factors. These parameters are used as parameters for optimizing the screw configuration. The optimization procedure produces one patient specific layouts which satisfies all constraints and offers the best-known healing prospects for the fracture.

To enable use in a clinical setting, the need for user input should be kept to a minimum so that non-specialists are also able to use this tool. In addition, to minimize costs for hospitals, existing software packages should be used. Automation of the whole workflow and an efficient computation time are especially important to ensure quick delivery of results which is essential in a clinical environment

Materials and Methods

A partly automated workflow (Fig. 2) was developed to select the best screw arrangement and position for plate osteosynthesis. Some tasks had to be executed manually for every patient. These tasks included bone segmentation, repositioning of bone fragments as well as the initial positioning of the plate. The majority of tasks, however, were controlled by optiSLang (DYNARDO GmbH, Weimar, Germany) and automatically performed. These tasks included the mesh generation, the assignment of material properties and boundary conditions, the finite element analysis and the optimization. The model consisted of bone fragments, a locking compression plate and a varying number of screws. These objects were either generated or adapted for use in a FEA.

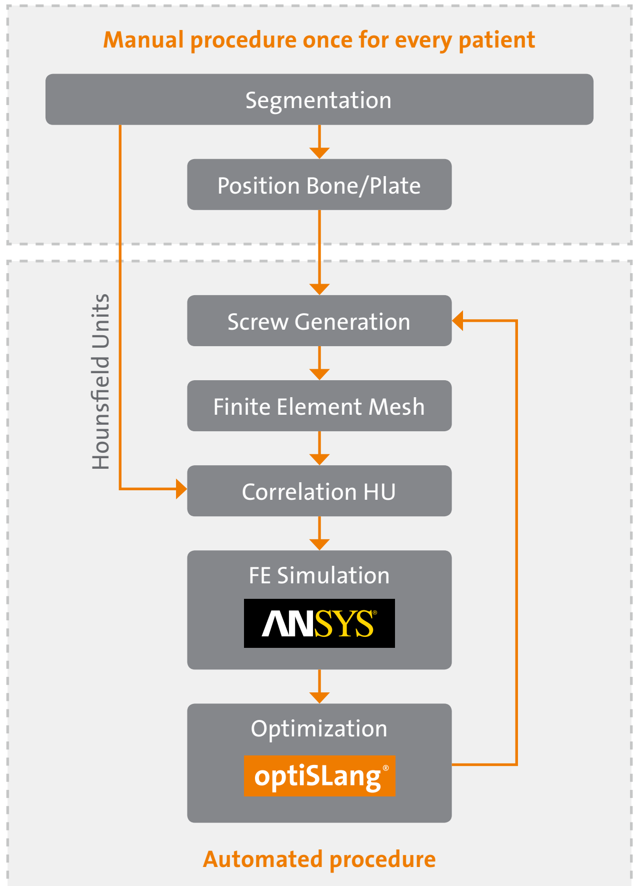

Fig. 2: Procedure for the optimization of fracture treatment

The CT dataset of a 22-year old female was supplied by the Department of Radiology at the Technische Universität München. The software Mimics (Materialise, Leuven, Belgium) was used for the segmentation of the three-dimensional CT data sets. Finally, a three-dimensional geometry of the femur was created. The surface of the bone was smoothed and any small holes, tunnels or peaks on the surface were removed with the software Geomagic (Research Triangle Park, North Carolina, USA). In this study, a healthy femur was used as an example and an artificial transverse fracture with a fracture gap of 3 mm was created using the software Blender Version 2.67 (Blender Foundation, Amsterdam, The Netherlands) (Fig. 3).

Fig. 3: A transverse fracture with a fracture gap of 3 mm was artificially added to a segmented femoral bone

In this simulation, a Locking Compression Plate (LCP, article number: 422 258) manufactured by the company Synthes (Zuchwill, Schweiz) was used. This plate was designed for the treatment of distal femoral fractures. The compression plate had seven screw holes on the distal end and 13 screw holes for the fixation along the bone shaft. The plate was designed to match the mean shape of femoral bones of a cohort and allowed secure attachment. The plate was positioned relative to the femur following the recommendations of surgeons. The screws were automatically generated using the software Blender at the beginning of each optimization loop. An input file contained information about each screw as a discrete variable. The file was generated automatically by the software optiSLang. The value “0” represented the state “no screw”, “1” a monocortical screw and “2” a bicortical screw. To demonstrate the functionality of this model, four screw designs were chosen. The layouts differed with respect to the bridging length, which is the distance between fracture gap and the first screw on either side of the fracture. The bridging length is known to have a large influence on the stability of the plate-bone construct. Four different designs were evaluated: In design a, the screws were placed directly next to the fracture. In design b and c, the bridging length were comprised of two or five unoccupied screws holes respectively. Design d had the largest bridging length with ten empty screw holes (Fig. 4).

The finite element mesh was created with the mesh generation software ANSYS ICEM CFD (ANSYS Inc., Canonsburg, USA).

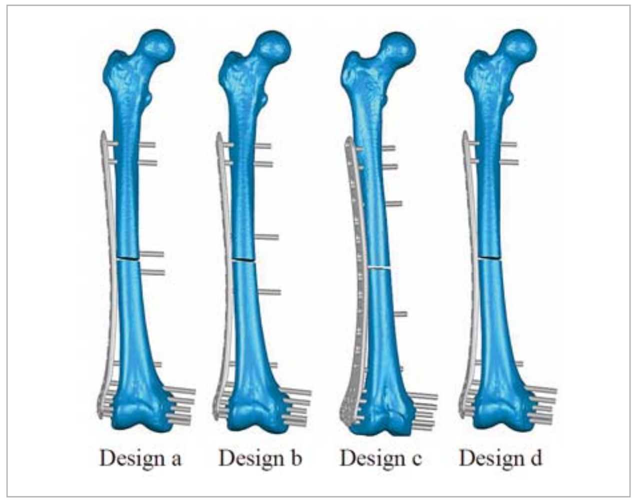

Fig. 4: Four screw layouts with varying bridging length. The bridging length is the distance between fracture gap and the first screw on either side of the fracture

Fig. 5: Meshed bone with plate and screws

The mesh was generated (Fig. 5) automatically reading a script in the programming language tcl (Tool Command Language) using the following procedure:

- Import of stl files
- Create intersection lines and intersection points between objects
- Create material points
- Mesh generation
- Smoothing of mesh surface
- Export of data as input file for ANSYS Classic

Since the arrangement of screws was different for every optimization run, the tcl file was re-generated during every optimization run by a Python program.

The material properties for bone, plate and screws were set in the pre-processor in ANSYS. Plate and screws were considered as homogeneous materials either made of the titanium alloy Ti-6Al-7Nb or stainless steel 316L. Bone was modeled as an inhomogeneous material consisting of 72 different materials depending on the HU value of the element. Cortical bone properties were chosen as the material property for the homogeneous bone to assess the difference between modeling the bone as a homogeneous object compared to an inhomogeneous object. All materials were assumed to be linear elastic and isotropic. Patient-specific bone material properties, such as Young’s modulus, were derived from Hounsfield Units contained in CT data. The mechanical properties were mapped onto the mesh using an algorithm programmed in Python.

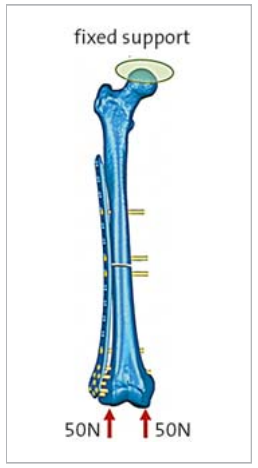

Fig. 6: Physiological loading case - Force application from distal

A number of studies have looked into the physiological loading of femoral bone. However, opinions about the loading vary greatly which might be caused by the complexity of the loading cases. In particular, loading cases shortly after surgery have yet to be researched. Following surgery, patients should put a maximum weight of 10 to 15 kg on the injured leg. At the beginning of the rehabilitation process, patients learn not to put more than a weight of 15 kg on the injured leg. This weight is equal to the ground reaction force (GRF), which is the force exerted by the ground in response to a body being in contact with it. The combined weight force of foot and lower leg added up to approximately 50 N for an average total body weight of 70 kg. The maximum force on the distal end of the femur would be 100 N under the assumption the patient puts a maximum weight force of 150 N on the injured leg (Fig. 6). Half of the force was put on each femur condyle to ensure physiological application of the force. The forces were represented as a vector

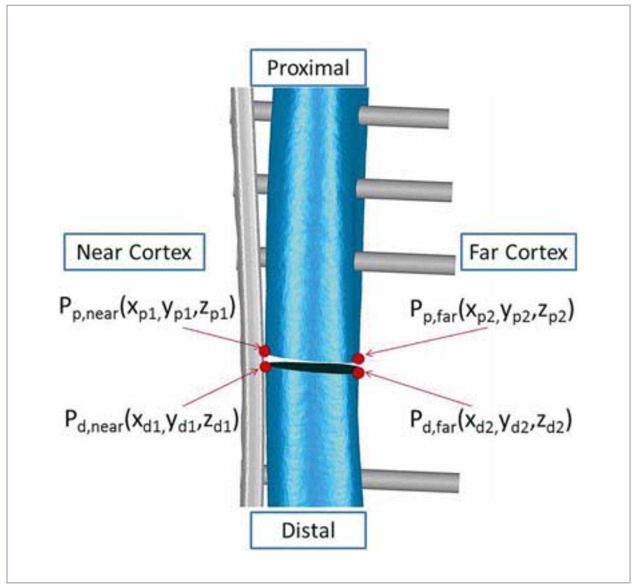

Fig. 7: Determination of interfragmentary movement using the relative displacement of two points on the far cortex and on the near cortex of the bone. (Pp,xxx = Displacement of node on proximal bone fragment, Pd,xxx = Displacement of node on distal bone fragment, d = Relative displacement between two points)

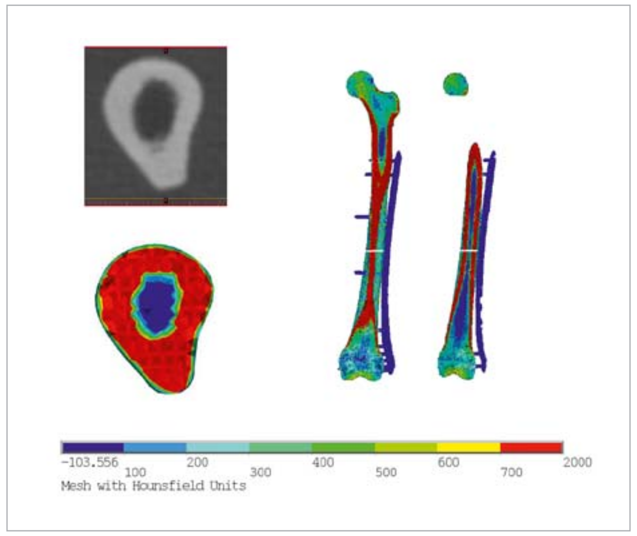

Fig. 8: Assigning HU as temperatures on the finite element model of bone. Left side: CT scan (top) and finite element model with HU distribution (bottom) of femoral shaft bone. Right side: Two parallel longitudinal sections of the finite element model of femoral bone. Cortical bone (red) was mainly located along the bone shaft. The femoral epiphyses primarily consisted of cancellous bone (green). The dark blue array of the bone indicated the bone marrow. No HU were assigned to the plate and screws.

field rather than two single vectors. This led to smoother changes in the internal forces and moments.

Elderly people particularly have problems maintaining a maximum weight of 15 kg on the injured leg. In light of this, the applied force was increased threefold to 300 N to simulate an accidental overload situation.

The relative displacements of two nodes on the near cortex and far cortex were determined for the evaluation of the interfragmentary movement (Fig. 7). These nodes were already defined during the mesh generation stage. HU values were successfully assigned to the elements of the finite element model of the bone (Fig. 8). The bone shaft consisted mainly of cortical bone with HU larger than 700. Cancellous bone was the main material of the femoral epiphyses with HU below 600. Negative HU were assigned to elements of the medullary space. On average, more than 30% of femoral bone was classified as cortical bone.

The elements of the outermost layer were assigned slightly lower HU values than the next inner element layers. This was caused by averaging the HU of bone and the surrounding soft tissue which possessed HU values below that of bone.

Optimization

The sensitivity analysis and optimization were performed using the software optiSLang v4 (Fig 9). New designs were created using an evolutionary algorithm. The objective of the optimization was to minimize the number of screws. The parametric model consisted of 21 design parameters. 20 design parameters were responsible for generating the screws. These parameters could take on one of three discrete states: 0 representing no screw, 1 representing a monocortical screw and 2 representing a bicortical screw. As the subject bone showed no signs of osteoporosis, the same outcomes would be expected no matter if monocortical or bicortical screws were applied. Therefore, only two discrete states were permitted (0 = no screw, 2 = bicortical screw). The remaining design parameter represented the distance between plate and bone. This parameter could take on a continuous value between 0 mm and 5 mm.

The constraints of the optimization were chosen according to findings from the literature. To maintain a stable attachment of the plate to the bone fragments, at least two screws had to be placed in every fragment. The interfragmentary movement was considered an important boundary condition for optimizing the number of screws and their position. Due to the bending load, the interfragmentary movement on the near cortex was generally smaller than on the far cortex. Two constraints were specified to take this behavior into account. To prevent failure of the implant under overload the stress levels in the bone, plate and screws had to remain below the yield stress for the corresponding material. Overload was defined as three times the recommended load. An overview of the parameters and their corresponding values can be found in Table 1.

Parameter	Value	Loading
Number of screws per fragment	n ≥ 2	n.a.
Interfragmentary Movement – near cortex	dnc < 0.7 mm	Normal load
Interfragmentary Movement – far cortex	dfc < 1.7 mm	Normal load
Maximum stress (titanium alloy)	σ < 800 MPa	Overload (threefold)
Maximum stress (stainless steel)	σ < 690 MPa	Overload (threefold)
Maximum stress (bone)	σ < 100 MPa	Overload (threefold)

Tab. 1: Boundary constraints for optimization

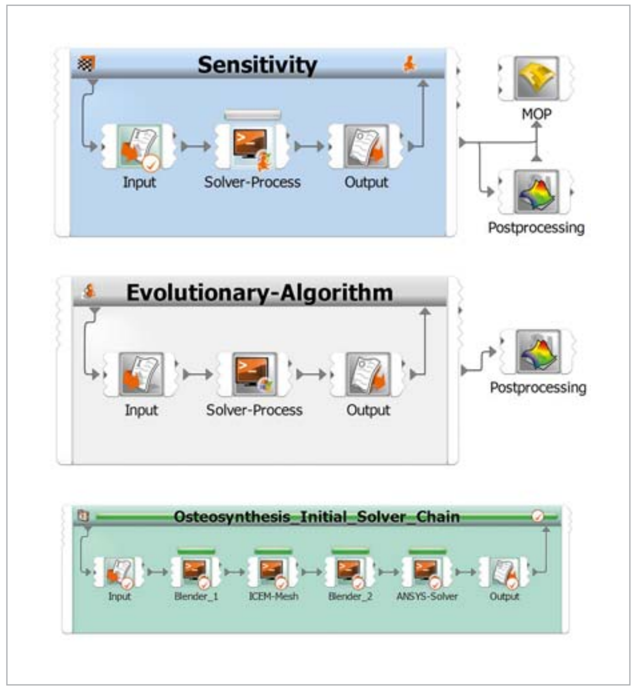

Fig 9: Upper panel: sensitivity work flow with meta modelling; middle panel: optimization work flow; lower panel: solver-chain

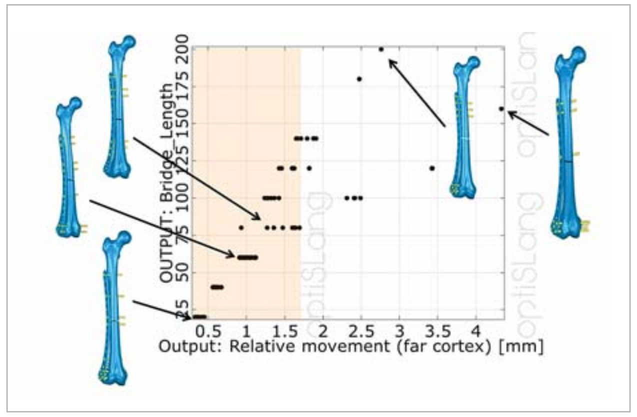

Fig 10: Relationship between bridging length and interfragmentary movement on the far cortex. A linear correlation between the bridging length and the relative movement of the far cortex was observed

The bridging length had a significant impact on the interfragmentary movement. A larger bridging length resulted in a linear increase in relative movement on the near cortex (Fig. 10). A positive linear relationship between bridging length and relative movement was observed on the far cortex.

The objective of the optimization was to minimize the total number of screws. A design with four screws was selected as the optimal design by the evolutionary optimization algorithm (Fig 11). The design had a medium bridging length of four unoccupied screw holes which equaled a distance of 100 mm. There was a 0.5 mm distance between plate and bone. 180 designs were evaluated in order to select the best design. Designs with up to 16 screws were evaluated during the random sampling period. Primarily designs with four screws were tested towards the end of the optimization.

Discussion

This study developed a general procedure for the optimization of fracture treatment. The aim was to improve the healing process by determining the optimal screw configuration under certain biomechanical constraints. The developed workflow enabled the selection of an optimal screw layout out of several thousand possible arrangements. For this purpose, the finite element mesh generation and the finite element analysis were successfully automated. It is the first procedure which allows for more than the comparison between individual FEAs of different plate osteosynthesis.

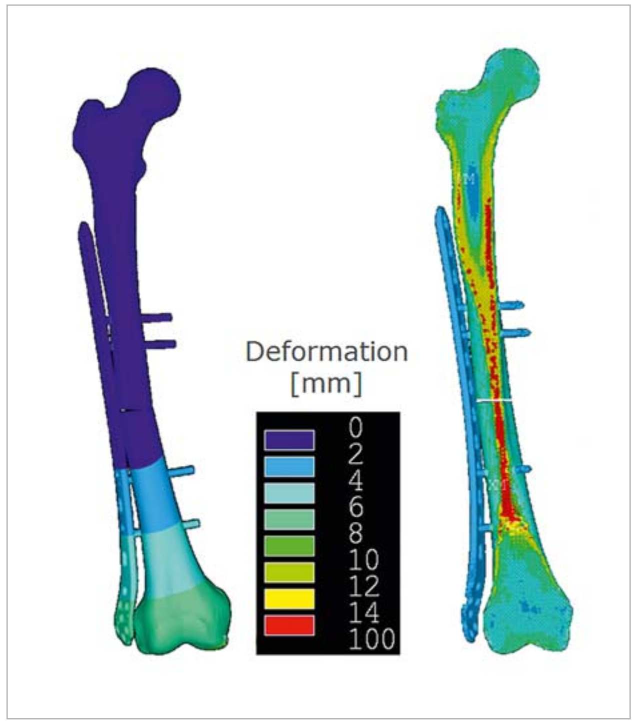

Fig 11: Optimal design after optimization under pre-defined constraints. The optimal design consisted of four screws in total, two screws on the distal segment and two screws on the proximal segment. The bridging length measured 100 mm

The optimization process required minimal user input. The user only needed to segment the bone, position the plate relative to the bone and select a couple of specific points on the model. These points included the material points of bone and plate, the measurement points for the interfragmentary movement as well as the points for force application and constraints. In the future, the user input may be further reduced by an automated segmentation procedure.

The rest of the procedure was performed automatically through a batch file. The selection of an optimal design, based on more than 150 other designs, using an evolutionary algorithm was completed within 24 hours. Further parallelization of the computation process might be able to decrease the computation time.

An improvement to the model might be the integration of more joint and muscle forces in order to make the model more realistic. Integration of a full muscoskeletal model in the simulation model may be achieved using the software AnyBody (AnyBody Technology A/S, Aalborg, Denmark) in the future. This software consists of a detailed model of the femur during gait. It is able to simulate a whole gait and models can be customized, for example the maximum ground reaction force could be adjusted not to exceed 150 N during walking. An interface has already been developed which could map the muscle insertion points from AnyBody's model femur onto the mesh of the individual patient's femur. Since all forces and moments would be in equilibrium, there would be no need to constrain some parts of the model.

Optimal conditions for fracture healing regarding the interfragmentary movement were based on the recommended loading case of 100 N. The overload case was defined with 300 N which is equal to putting around half of the body weight on the injured leg. This value was selected as it represented a considerable increase in force. Furthermore, a much higher force would have probably led to extreme pain for the patient. Another possible extreme scenario could be the simulation of stumbling or even falling.
The integration of anisotropic material properties of bone into a finite element model is challenging and requires high resolution CT data. The alignment of the trabeculae can be used to derive a stiffness tensor which incorporates the anisotropic material properties.

In this work, a bonded interface was selected between bone and defeatured screws. This allowed faster computation. It should be considered that even if the interface has a major influence on the area around the screws, it has almost no influence on the global load deformation behavior such as the interfragmentary movement.

The selected optimum screw arrangement consisted of only four screws. This was the minimum possible number of screws since at least two screws had to be placed in each bone fragment. The selection of a design at the lower end of the design space demonstrated that a minimum number of screws could provide optimal healing conditions. However, the implant construct would fail if only one screw failed. Screws at the distal end of the bone did not affect the simulation outcome and were therefore omitted. However, some surgeons consider them important since they improve the pull-out strength of the screws.

The interfragmentary movement on the near cortex was only 0.22 mm. This movement was considered too small for fracture healing and therefore the selected design cannot be considered "optimal". A constraint which only allows interfragmentary movements larger than 0.3 mm would need to be added to the optimization to avoid insufficient movements. The movement on the far cortex was approximately five times higher compared to the near cortex. This resulted in very different healing conditions on both sides of the bone which may cause non-union. Therefore, the proportion of near cortex movement to far cortex movement should be added as a second objective to the optimization. The healing would be more regular on both sides of the bone with the value being close to 1. An automated workflow has been established, which can be easily adapted for femur geometries from other patients. More patient specific data which also includes osteoporotic bone should be evaluated in order to generate a greater data base. Furthermore, other types of fractures such as diagonal or spiral fractures should be examined. Also a robustness evaluation of the optimal design would be one of the next steps.

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