

# Sensitivity of selfdynamisable internal fixator to change of bar length and clamp distance

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**Abstract**—Selfdynamisable internal fixator (SIF) is a type of medical device used in internal fixation of long bones. Occasional SIF failure requires an extra surgery, which causes an additional trauma for the patient. To minimize the risk of failure, a methodology was established for optimization of SIF structure and position. It is based on sensitivity studies or structural optimization procedures, performed using finite element method (FEM). Automatic creation of FEM models, for any combination of values of dimensional and positional parameters, is enabled through creation of a robust and flexible CAD model and establishment of bi-directional associativity between CAD and FEM models. This paper focuses on the results of sensitivity study, performed using the defined methodology.

## I. INTRODUCTION

Fractures of long bones typically occur as a consequence of traffic accidents or extreme sports injuries and usually require stabilization by surgery. Selfdynamisable internal fixator (SIF), invented by prof. Mitković, is a type of medical device used in internal fixation of long bones [1]. The structure of SIF is modular (Fig. 1). One of the modules, trochanteric unit with bar, is produced in four different sizes. The number and mutual position of clamps can also be changed, depending on application.

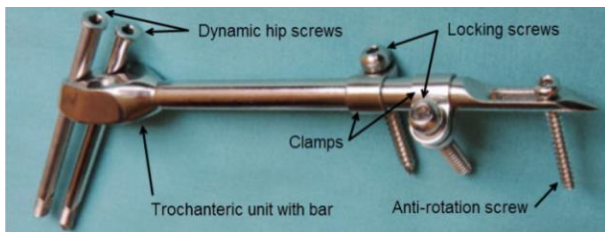


Figure 1. SIF, configured for subtrochanteric femoral fracture treatment

Selfdynamisable internal fixator is designed to allow for the change of axial position of fixated bone parts, which means that the bone parts can get closer over time. In this way, there exists a greater probability of healing process success, thus an extra surgery, which represents an additional discomfort to the patient, is usually avoided [2]. Occasionally a failure occurs in SIF components during

the healing process. In those cases an extra surgery is still required. It is highly desirable to minimize the number of such occurrences.

Failure of SIF components is related to its stress state during the healing process. For each specific patient and type of femoral fracture there exists an optimal configuration and position of SIF components that minimizes component stresses and thus the possibility of failure. In that manner, a research goal was set which aimed to establish a methodology for optimization of SIF configuration and position considering any subject-specific case of femoral fracture. At the same time, the whole optimization process was foreseen to be as robust and fast as possible so it may be used in everyday medical practice.

## II. METHODOLOGY

The defined methodology for optimization of SIF configuration and position consist of four steps, explained below.

1. In the first step, the **subject-specific CAD model of femur** is created. The creation process consists of two stages: the *creation of a polygonal model of the femur* and the *creation of a CAD model of the femur*. Polygonal model is obtained as a result of a pre-defined procedure, which starts with CT scanning of patient's lower extremities. The CAD model is then created from medical images, in a process that includes the extraction of the zone of interest, point cloud creation, triangulation, surface fitting and creation of solid features. In order to obtain the CAD model of femur, it is necessary to remove the segments of the polygonal model that actually don't belong to the femoral bone (parts of the vascular system visible due to insertion of contrast media or surrounding bones). Then the interior of the model is cleaned, whereby the excessive geometry that mainly originates from trabecular bone structure is removed. After the polygonal model is healed and, if required, its smoothness is increased, a closed NURBS surface that represents the outer envelope of the model can be created using surface fitting procedures. By filling the surface with solid geometry, CAD model of femur is created [3], [4].

2. After the CAD model of femur is obtained, a robust **and flexible parametric CAD model** of femur-SIF assembly is created in the next step. The automatic reconfiguration of the model must be possible for any combination of structural parameters (in this case bar length and clamp position). To make this possible, reference geometric entities (RGE's) must be created first, which are crucial in creation of geometric features and definition of assemblies [5]. In this example, the RGE set consisted of specific points, axes and the anatomical curve of femur. Those were created on femur before the assembling of SIF, to identify the most important anatomical landmarks and to mimic the way in which a surgeon describes SIF positioning.
3. The third step represents **the creation of a model for finite element analysis (FEM model)** that is bidirectionally associative with the CAD model. In this way the FE analysis can drive the changes in CAD model configuration, which subsequently drive the changes in FEM model. In this particular case, the bidirectional interface between SolidWorks and ANSYS was used.
4. After the FEM model is created and associated to the CAD model, **parametric studies and structural optimization studies** are performed, which help in identification of optimal SIF configuration.

### III. MODELS/RESULTS/DISCUSSION

The methodology described in previous chapter was tested on an existing subject-specific CAD model of femur, with artificially created simple transverse fracture. This chapter presents the CAD and FEM models of femur-SIF assembly and some of the results of a sensitivity study performed using the established methodology.

CAD model of femur-SIF assembly (Fig. 2) was used as a basis for sensitivity study. The position of SIF on the model and SIF configuration were parameterized. Two driving design parameters were defined in the assembly: the length of trochanteric bar and the distance between clamps. The ability of the model to automatically reconfigure to changes of bar length and clamp position was tested with success [6].

FEM model was created in ANSYS, which was bidirectionally associative to CAD model (Fig. 3) [7]. The following contact and boundary conditions were defined (as in [8]):

- Frictional contact between the steel parts (fixator, clamps and screws);
- Bonded contact between the screws and femur, to simplify the description of threaded connections;
- Fixed support at the distal end of the femur;
- A force of 883 N applied at femoral head in the direction of the mechanical axis of the femur, to approximate the one-legged stance of a person having the mass of 90 kg.

A sensitivity study was defined, in which 16 design configurations were considered. The configurations were based on different combinations of values of two chosen structural parameters. Bar length took values of 100, 150, 200 and 250 mm, while clamp distance was set at 1, 10, 19 or 28 mm.

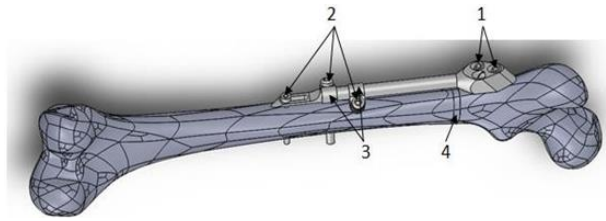


Figure 2. CAD model of SIF mounted on femur with a simple transverse fracture. Trochanteric unit with bar is fixed to the femur using hip screws (1), screws on the distal end of the femur (2) and clamps (3). Fracture zone is modeled as a separate volume inside femur model (4)

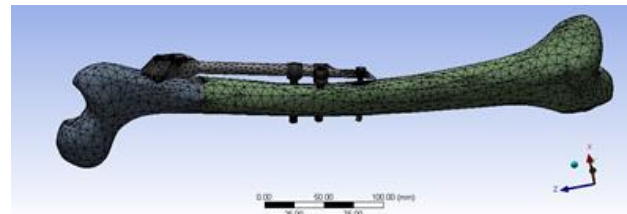


Figure 3. FEM model of SIF-femur assembly

Typical results of a finite element analysis run as a part of sensitivity study are shown in Fig. 4. It was shown that critical stress occurs in SIF and not in the bone, which corresponds to observations from clinical practice according to which SIF failure occurs rather than bone failure [9].

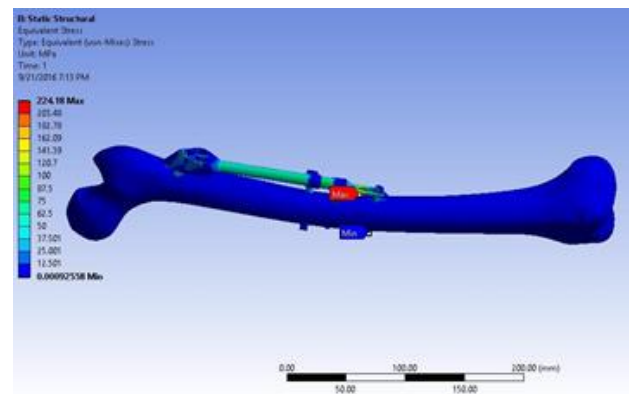


Figure 4. Typical SIF stress field obtained by FEA

As presented in Fig. 5, sensitivity study showed that minimal SIF stress corresponds to maximal trochanteric bar length and clamp distance between 19 and 28 mm. Calculated fixator stresses generally decrease with the increase in length of the trochanteric bar and the increase in mutual clamp distance [6]. The maximum stress for any assembly is far below the yield stress but, having in mind that the real nature of load may be dynamic and that critical stress of SIF material gets lower due to fatigue, from purely mechanical point of view it is recommended that maximal length of the bar and maximal distance between clamps are chosen.

Nevertheless, what also needs to be considered is that the higher the trochanteric unit bar length and the mutual clamp distance are, the surgery will be overall more invasive. Thus, the surgeon may still choose another combination of parameter values, if, in his opinion, it will cause less trauma to the patient [6], [8].

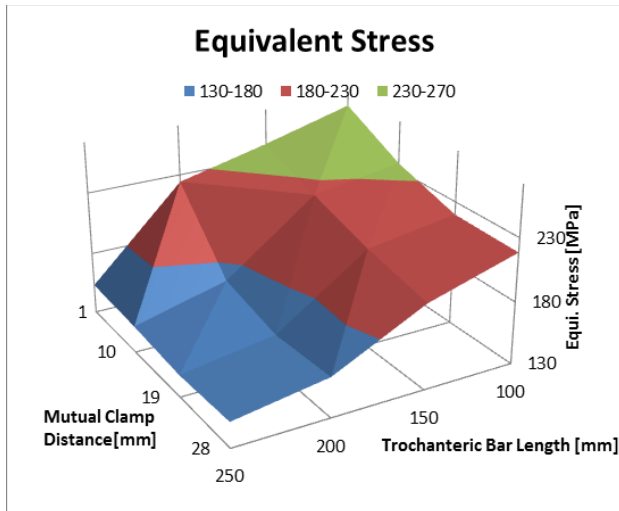


Figure 5. Sensitivity of SIF stress to change of trochanteric bar length and mutual clamp distance

#### CONCLUDING REMARKS

A methodology for optimization of Selfdynamisable internal fixator (SIF), a type of medical device used in internal fixation of long bones, was presented. The obtained results may be used by an orthopedist as a guide for selection of SIF components in given subject-specific case, in combination with other criteria such as minimization of cut length and surrounding tissue trauma.

It is considered that, with slight modifications, the same methodology may be used for optimization of any similar device.

#### ACKNOWLEDGMENT

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