

# Density-Based Topology Optimization for a Defined External State of Stress in Individualized Endoprosthesis

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#### Abstract

Endoprosthesis are exposed to the risk of aseptic loosening. The design of the prosthesis shaft to achieve physiological force application is therefore of great importance. Additive manufacturing offers the potential to fabricate highly variable topologies, but challenges the designer with a large number of design variables. In this work, a method is developed to determine an optimized density topology that approximates a given mechanical stress state in the bone after implantation. For this purpose, a topology optimization of the density distribution of the implant is performed.

Keywords: healthcare design, additive manufacturing, topological optimisation, effect engineering, individualised hip endoprosthesis

# 1. Introduction

Joint replacement occupies an essential part of medical technology-based treatments, which provide significant socioeconomic costs (Jerosch et al., 2017). For example, an estimated 450,000 endoprosthetic procedures were performed in Germany in 2019, primarily on the hip and knee (Grimberg et al., 2020). Hip-joint prosthesis are expected to last an average of 15-20 years. A common cause for the necessary revision of the still predominantly used standard shaft prosthesis is the aseptic loosening of the implant due to a non-physiological stress state in the bone after implantation. This so-called stress-shielding effect occurs when the metallic implant shields the remaining bone from the stress it requires to not degrade (Roth and Winzer, 2002).

It is expected that the number of revisions will steadily increase as the average age for initial implantation decreases and thus the expected demands increase. In addition, the life expectancy of patients is increasing, therefore necessitating a longer implant life (Arabnejad et al., 2017; Al-Tamimi et al., 2017). Currently, 50.000 revisional procedures are performed annually in Germany (Grimberg et al., 2020). In addition to the costs incurred, a significant additional burden is associated with revision surgery for the patient. In the future, it will consequently be more necessary than ever to reduce the complication rate and increase the service life of implants. Bone anchored implants are made using additive-manufacturing technologies in which weight and mechanical properties are integral to implant function. Latticed titanium structures have been used in orthopaedic applications, for example an optimized lattice structure for spinal interbody fusion cages and dental implants (Xiong et al., 2019; Choy et al., 2017). Additive manufacturing of metals offers the possibility of producing density-graded implants, which have the potential to adjust the preoperative physiological stress state in the bone even in the postoperative state, so that the remaining healthy bone ideally does not notice that an implant is anchored in it. However, the variety of design options for the density topology complicates or slows down the development and design process.

This work presents an approach to reduce these options using computational optimization techniques as applied to structural mechanics. Therefore, this work presents a method for topology optimization of an endoprosthesis, regardless of the position in the body such as shoulder, knee, hip or even fingers, to approximate the stress state in the postoperative bone to the preoperative physiological state.

For this purpose, a case study is conducted in which a femur is derived from a CT scan of a human patient, virtually implanted with an individualized endoprosthesis and numerically optimized. The goal is an optimized density topology of an individualized hip endoprosthesis generated with Computational Design Synthesis based on the CT scans alone.

This paper is organized as follows: Section 2 presents the theoretical background and related work for the optimization of the specific strain energy and defines the research questions. The methodological approach and specification for the density-based topology optimization for a defined external state of stress in individualized endoprosthesis is presented and applied in Section 3. Then, in Section 4, the method is tested in a case study with an individualized hip endoprosthesis, discussed and the results are validated. The method is then summarized in Section 5.

## 2. Optimization of the specific strain energy

Structural optimization involves finding the optimal load path for a specific load and boundary condition, fulfilling imposed requirements for stiffness, weight, or volume reduction (Sigmund and Maute, 2013). The various design possibilities of additive manufacturing for the production of graded implants offer potential for the use of optimization methods (Chang et al., 2012; Iqbal et al., 2019; Bagge, 2000; Deng et al., 2016; Arabnejad et al., 2017). The optimization of implant topologies is mostly methodically instantiated in hip arthroplasty. For this reason, this part deals mainly with implants anchored in the femur. The most common approach is topological optimization with the aim of minimizing the compliance of the implant. The basic idea is that the bone remodeling process aims at minimizing the strain energy in relation to the bone mass. The deformation energy corresponds to the work applied for elastic deformation. A detailed definition with respect to the finite element method can be found in Bagge (2000) and Deng et al. (2016). On this basis, different optimization methods for the design of orthopedic implants can be derived. Thus, Deng et al. (2016) developed an optimization process of an artificial femur. The femur was built as an FE model and the strain energy in each optimization iteration was determined from finite element analysis (FEA). Consequently, the optimization parameter was the compliance of the implant, which was minimized. At the same time, geometric constraints were placed on the optimization to ensure similarity to the physiological femur. The level set method, which is one of the mathematical programming methods, was used as the solution algorithm. However, the optimization model was built only in two dimensions, so this optimization cannot represent the complex relationship of three-dimensional implant design. The three-dimensional case was studied by Sutradhar et al. (2010) in the optimization of implants for facial bone reconstruction. By minimizing the compliance of the implant, they determined the topology of the implants. The goal here was to use as little material as possible with sufficient strength while achieving the most physiological integration with healthy tissue. Arabnejad et al. (2017), as well as Quevedo Gonzalez (2012) took the idea of deformation energy optimization further to address the problem of bone resorption. From the deformation state in the preoperative as well as postoperative femur, they derived a three-dimensional model to represent bone resorption. For this purpose, the deformation energy in the preoperative femur is set in relation to the deformation energy in the implanted state. An optimization function could then be derived from the ratio of the energies, which can be minimized. The reference values for the deformation energy of the intact femur were determined here from optical deformation measurements of a femur. In addition, Arabnejad et al. (2012) integrated a failure criterion to prevent structural weakness of the implant by automatically increasing the density at points of insufficient strength. Heuristic evolution algorithms were used to solve the minimization problem. In this approach, although an FE model of the implanted femur was built, the reference values of the femur were determined from a single experimental trial. The advantage of this multi-objective optimization is a three-dimensional FE model from which a density distribution can be taken, which also accounts for the required strength. Disadvantage is the use of empirical reference values, which can only ever represent a section of the individual patient anatomy.

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For this purpose, the following research questions have been identified:

- a) How can the physiological individual state of stress of the affected bone be taken into account in the postoperative state?
- b) How can the real material parameters of the individual bone for FEA be implemented in the models to optimize the topology of the implanted endoprosthesis based on them?
- c) How can the results of topology optimization be transferred to manufacturable components?

# 3. Method of Density-Based Topology Optimization for a Defined External State of Stress in Individualized Endosprothesis Using the Hip as an Example

In the first step, an optimization procedure must be developed which can be processed constructionally and numerically using computer-aided methods. In the following, the femur and the associated endoprosthesis are used as a representative example for all individualized and osseointegrative endoprosthesis.

One basis of this method is the generation and use of two models, which can be considered as one control loop and is shown schematically for the hip in Figure 1. The models for this topology optimization can be generated from any CT scan and are independent of its origin.

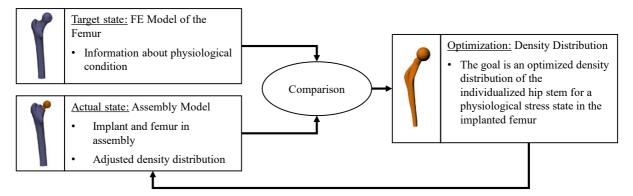


Figure 1. Control principle of the optimization process using the hip as an example.

The first model, the femur model, represents the physiological femur of the patient in its current state and contains the target information. The second model, referred to as the assembly model, models the femur with the inserted patient-specific implant and represents the actual condition. This implant is individually designed using Computation Design Synthesis. The advantages of this individualization in terms of topolgy optimization are a complete preservation of the crotical bone as well as a correct and defined reconstruction of the patient's anatomy (Müller et al., 2021a). Consequently, the initial variables of the model generation are two FE models representing the actual and target state. The second step consists of the optimization procedure, which should bring the actual state into the target state of the physiological femur. Properties of each optimization are the target formulation, the boundary conditions and the constraint of the boundary conditions.

#### 3.1. Three-dimensional optimization procedure

Figure 2 shows an overview of the general procedure of the three-dimensional optimization method unsing the hip as an example.

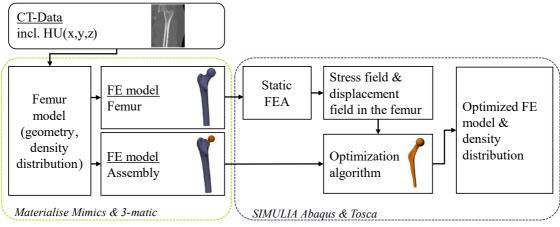


Figure 2. Overview of the method using the hip as an example.

The input variable of the optimization method is the volume data of the patient. These contain the location-dependent density distribution in Houndsfield units (HU) and originate from medical imaging procedures, such as CT-Data. In order to be used the patient data for numerical optimization, they must be converted into a file format for use in FEA programs. To do this, a CAD model is first created from the density distribution, which is then meshed.

To finalize the FE model for further processing, material properties are assigned to the FE model based on the density information. The aim of this method is to achieve a physiological stress distribution in the implanted state. For this purpose, two models are built in the Software Mimics and 3-matic. One is a model of the physiological femur and the other is an assembly model of the osteotomized femur and the individual implant. An FEA of the physiological femur is then used to determine the mechanical stress state. This stress state is then specified as the objective of the optimization of the assembly model.

The optimization also takes place in Abaqus or rather the integrated optimization module Tosca Structure. Finally, the output of the this procedure is an optimized assembly model with an optimized density distribution of the implant in order to minimize stress shielding.

### 3.2. Formulation of Objectives and Constraints

#### 3.2.1. Objective Criterion and Material interpolation

The aim is to minimize the physical quantity used, which is usually the compliance of all elements. Since the optimization procedure is based on the finite element method, the basic FEA equation must first be solved in each optimization step. For the static analysis, this is

$$\boldsymbol{K}\,\boldsymbol{\vec{x}}\,=\,\boldsymbol{\vec{f}}\,.$$

Here,  $\mathbf{K}$  is the stiffness matrix containing the element stiffnesses,  $\vec{u}$  is the vector of displacements and  $\vec{f}$  is the vector of boundary conditions. The compliance can be represented, among other things, by the strain energy *c*. This is given by the sum over all elements with

$$c = \sum u^T \mathbf{K} \, \vec{u} \,. \tag{2}$$

Depending on the boundary conditions, the compliance behaves differently during optimization: if only external forces are applied, the strain energy must be minimized. The optimization objective then results with P as the matrix of external loads to

$$\min\left(\frac{P\bar{u}}{2}\right).$$
(3)

On the other hand, if displacements  $\overrightarrow{u_a}$  are imposed externally, the strain energy should be maximized, so that the optimization objective with **R** as the reaction forces at the nodes displaced by  $\overrightarrow{u_a}$  results in

 $max\left(\frac{R\overline{u}a}{2}\right).$ (4)

The combination of both boundary conditions would result from the addition of both terms. However, since this would yield non-optimal results when minimizing or maximizing only, Abaqus provides the "Energy Stiffness Measure". This no longer corresponds to the physical strain energy and is

$$min\left(\frac{P\vec{u}}{2} - \frac{R\vec{u}_{a}}{2}\right).$$
(5)

This has the advantage of minimizing the target quantity and bringing both boundary conditions in the optimal direction.

To represent the material behavior of the density-reduced elements, the "solid isotropic material with penalization" scheme (*SIMP*), with the material equation

$$E = E_0 \rho^p, \tag{6}$$

was used.  $E_0$  describes the Young's modulus of the solid material,  $\rho$  the density of the material and p the penalty factor, which was chosen to be p = 3 according to the recommendation of the Abaqus documentation. The SIMP scheme is one of the most popular interpolation schemes of optimization methods and is mainly used for static problems. Since only static loads are present in this method, the SIMP scheme was used.

#### 3.2.2. Constraints

Two options are available to apply the constraints. First, the existing stress values from the static FEA of the bone can be used directly. The von Mises stress is used as the physical quantity. The elements in the bone surrounding the implant serve as the area of constraint. The choice of von Mises stress eliminates the information about the direction of loading. However, since constraints are placed along the entire contact area between the implant and the bome, it is assumed that a physiological stress state is present when the plurality of constraints is satisfied. Another approach, which indirectly maps the stresses present, is to constrain the strains. Since the elastic modulus of the bone remains constant during optimization and the temperature does not change, the stresses follow directly from the strains. Here, the direction. At the beginning of the first three-dimensional optimization experiments, both displacements and stresses were used as constraints. However, as the work progressed, the stress constraint was chosen because both optimization approaches produced qualitatively similar results and the displacement constraint required a larger number of constraints due to the different spatial directions.

## 4. Case Study: Individualized endoprosthesis of a human hip

### 4.1. Numerical investigations of the optimization and results

In order to investigate the behavior of the optimization process, an individualized short-shaft endoprosthesis with a length of 149 mm was derived using CT scans of a human hip and the Computational Design Synthesis. The models and boundary conditions were created according to the structure in Section 3.2 and the physiological stress state in the real femur was determined. Figure 3 presents a summary of the three-dimensional model setup and the optimization procedure for the hip.

Surface Load 2 N/mm <sup>2</sup> (≙ 400 N)	Optimization goal	Minimization of the Energy Stiffness Measure, which represents compliance.
	Constraints	Von Mises stresses in interface between implant and femur.
	Topology variation	Edge densities of the implant from 100 % - 40 %.

Figure 3. Three-dimensional model structure and optimization procedure of the hip endoprosthesis with objectives and constraints.

Furthermore, the topology of the implant margin is varied to ensure a periodic margin for osseointegration. For this purpose, the margin of the implant is fabricated in different densities between 100 % and 40 %. The results of previous work have shown that a defined outer layer is necessary to maximize bone ingrowth (Müller et al., 2021b). To this end, all elements that share a common node with the interface set are defined in an element set, which is then locked for optimization. It should be emphasized at this point that the following validations represent only a small part of the factors influencing the optimization, since the focus of this work is on the fundamental development of the method.

For the quantitative evaluation of the results, different parameters were introduced, which compare the pre- and postoperative state. At this point, the main parameter is the efficiency  $\eta_g$ , which describes the relative reduction of all stress deviations of the optimized endoprosthesis compared to the unoptimized one. However, the informational value of the averaged stress deviations alone is limited, which is why a local assessment is also performed to identify areas of increased and thus critical deviation. For this purpose, point clouds are created which show the stress deviation in color-coded form. Figure 4 shows the von Mises stress in the preoperative state at the top and in the postoperative state with an unoptimized shaft prosthesis at the bottom. It can be seen that the greatest differences occur on the medial side of the femur. After implantation, stresses are reduced in the proximal metaphysis and diaphysis. While stresses of between 12 and 20 N/mm<sup>2</sup> are present in the physiological femur, these are reduced to about 5 N/mm<sup>2</sup> after implantation. At the same time, an increase in stress occurs postoperatively in the diaphysis below the implant.

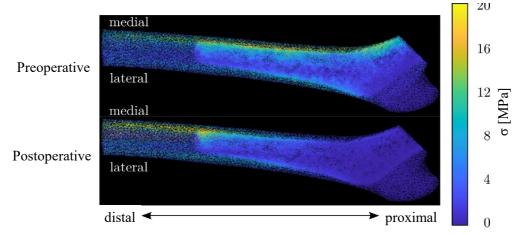


Figure 4. Distribution of von mises stress in the preoperative and the unoptimized postoperative states.

The stresses are increased here from about 10 N/mm<sup>2</sup> to up to 25 N/mm<sup>2</sup>. Furthermore, the stresses in the physiological femur are generally increased in the marginal region of the implant. Preoperatively these are about 8 N/mm<sup>2</sup>, postoperatively up to 5 N/mm<sup>2</sup>.

In order to vary the starting solution, the material properties of the titanium alloy Ti-6Al-4V with a density of 100 %, 80 %, 60 % and 40 % are assigned to the edge of the implant. Figure 5a) shows the evaluation of the deviations of the von Mises stresses for the shaft prosthesis with 100 % edge density. The blue histogram shows the deviation before optimization, the red one the deviations after optimization. Globally, the mean stress deviation was reduced by 7.2 % from 2.61 N/mm<sup>2</sup> to 2.42 N/mm<sup>2</sup>. Above 5 N/mm<sup>2</sup>, a degree of optimization of 1.4 % was achieved. Figure 5b) shows the spatial distribution of the stress deviations at the top before and at the bottom after optimization. It can be seen that the largest deviations from the femur are in the region of the medial margin of the proximal dia- and metaphysis. Laterally, the area of stress deviation is smaller. However, deviation of up to 15 N/mm<sup>2</sup> occurs in both areas. At locations of the higher deviations, no or hardly any reduction due to optimization can be seen.

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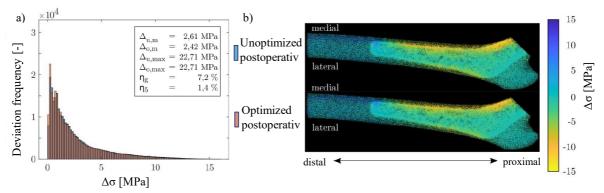


Figure 5. a) Histogram and characteristics of the optimization of the shaft prosthesis with 100 % edge density, b) Spatial distribution of the stress deviation before and after the optimization of the shaft prosthesis with 100 % edge density.

If the density of the implant margin is reduced, the optimization result improves with regard to the fact that the optimization levels are increased.

Figure 6a) shows the histogram of the optimization of the shaft prosthesis with 40 % margin density, and Figure 6b) shows the corresponding spatial distribution. For this edge density, the greatest optimization success is shown for the hip endoprosthesis. With a global optimization level of 42.6 %, the average stress was reduced from 2.19 to 1.26 N/mm<sup>2</sup>. Above 5 N/mm<sup>2</sup>, an optimization degree of 13.58 % was achieved. The success of the optimization is also clearly visible in the spatial representation. The deviations in metaphysis and diaphysis of up to 15 N/mm<sup>2</sup> were almost completely reduced to below 1 N/mm<sup>2</sup>. The remaining higher deviations are localized in the transition from metaphysis to diaphysis. The stress deviation in the distal diaphysis remains.

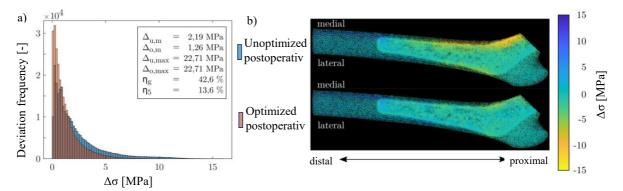


Figure 6. a) Histogram and characteristics of the optimization of the shaft prosthesis with 40 % edge density, b) Spatial distribution of the stress deviation before and after the optimization of the shaft prosthesis with 40 % edge density.

#### 4.2. Discussion and transferability of the results to manufacturable models

Looking at the density of the optimized assembly models, the considered optimizations show a common behavior. The optimization aims at a hollow structure inside the implant. Figure 7 shows such a density distribution as an example for a shaft optimization with 80 % edge density. Two areas are present: The red outer area, which retains the original density, and the blue area, in which the density assumes the minimum of the specified lower limit of 20 %. This behavior appears reasonable from an anatomical point of view. In the blue region in the physiological femur is the medullary canal located. The optimization model thus strives for an anatomical approximation under the given boundary conditions and starting designs. A noticeable feature in the density distribution are islands of material with high density. These appear inside the implant. Due to the irregular shape and the different positions in which they are localized, it can be assumed that they are artifacts of optimization. If a hollow structure is to be derived from the density distribution, these material islands should be reduced. In the subsequent processing it seems reasonable to filter the density distribution to avoid these structures.

#### DESIGN SUPPORT TOOLS AND METHODS

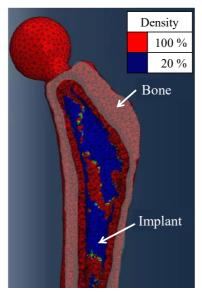


Figure 7. Density distribution of the shaft endoprosthesis optimization at 80 % edge density.

In order to be able to classify the influence of the starting solution on these material accumulations, it is also possible to use Bayesian networks to analyze the density configuration at these points (Plappert et al., 2020).

To model the density optimization generated in this way, the volume is homogenized and filled with graded lattice structures. These lattice structures are mathematically homogenized in advance and implemented in the implant after the topology optimization in postprocessing, as shown in Figure 8.

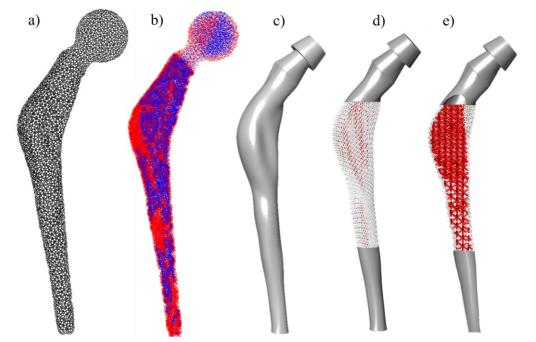


Figure 8. Procedure for implementing topology optimization on a finalizable implant showing a) the point cloud with density values, b) a scatter of the point cloud with associated density values, c) generation of the socket geometry from the CDS, d) transfer of the density values to the lattice structure, and e) a sectional view.

In this case study, the density values from the optimization were read for each center point of the volume element of the mesh. These density values are registered in a visual programming environment as a point cloud with the density information as a scalar and then matched within the full volume of the individualized implant. Using algorithm-based modeling of the mesh structures based on unit cells,

these density values can be interpolated at the center of these unit cells. The result are defined density values for each unit cell, which lead to, with regard to mathematical homogenization, in graded radii for each strut of the lattice structures. The result is a model that can be additively manufactured without any further intermediate step.

# 5. Summary and Outlook

The aim of this work was to develop a method for determining an optimized density topology for endoprosthesis. The optimized topology should approximate the stress state in the bone after implantation to the physiological stress state. To this end, a comparative model was constructed using the finite element method, which first determines the physiological stresses in the preoperative femur simulatively from patient-specific image data and then places these as a condition on an optimization procedure for the implant model. The Tosca Structure module integrated in Simulia Abaqus was used as the solution environment for the optimization problem.

To create the three-dimensional models, an FE model of the femur and an assembly model of bone and the inserted implant were created using the Materialise Mimics and 3-matic software. The model of the bone was created from CT-Scan by meshing a segmented mask of the bone and then assigning material properties based on the contrast values contained in the CT-Scan. For the assembly model, the parametric CAD models of individualized implants were generated externally from the segmented cancellous bone using Computational Design Synthesis and were merged with the osteotomized femur model.

To verify the success of the optimization method, several optimizations were performed varying the starting topology. To vary the topology, the outermost elements of the implant were made with 100, 80, 60, and 40 % of the original material density. To evaluate the optimization results, the deviations of the von Mises stress of the assembly model from the physiological femoral model were considered. Depending on the initial marginal density, the averaged stress deviations for the shaft implant could be reduced by 7.2 to 42.6 % by means of the optimization. The starting topology therefore has an influence on the optimization result. The highest deviations, which are present in the proximal metaphysis and diaphysis, could be almost completely eliminated for an edge density of 40 %. Despite the higher stress deviations in the unoptimized state, good results could be achieved with the optimized shaft prosthesis. These good results are expected to translate into significantly lower bone resorption, as the stress shielding effect can be significantly reduced.

It turns out that this topology optimization can also be performed for all bone-anchored and mechanically loaded implants in humans and animals whose boundary conditions are known and which are susceptible to stress shielding.

With regard to future investigations, a parallel optimization of several starting solutions appears to be useful in order to be able to utilize the influence of the starting topology. The material model for interpolation of the bone and implant as a function of density could also be further detailed to bring the models closer to the real behavior. Furthermore, following processing of the determined density distributions should be considered to improve the producibility of the topology. In conclusion numerical and experimental validations of this approach, in particular of the lattice structures created in this way, are necessary.

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