CEN

WORKSHOP

AGREEMENT

CWA 18131

July 2024

ICS 11.040.99; 35.240.80

English version

Workflow from medical images towards optimal personalized implant designs

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Ref. No.:CWA 18131:2024 E

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European foreword

This CEN Workshop Agreement (CWA 18131:2024) has been developed in accordance with the CEN-CENELEC Guide 29 "CEN/CENELEC Workshop Agreements – A rapid prototyping to standardization" and with the relevant provisions of CEN/CENELEC Internal Regulations — Part 2. It was approved by a Workshop of representatives of interested parties on 2024-05-31, the constitution of which was supported by CEN following the public call for participation made on 2023-10-30. However, this CEN Workshop Agreement does not necessarily include all relevant stakeholders.

The final text of this CEN Workshop Agreement was provided to CEN for publication on 2024-07-03-27. Results incorporated in this CWA received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement N° 953134.

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Introduction

Various methods and variations exist for designing personalized implants, mostly relying on bioengineering principles, but still encompassing to a various degree arbitrary choices, like the position of abutments or screwholes, that render the standardization of the design process difficult. The challenges for a personalized implant design are related to the necessary communication between the clinician (usually a surgeon) and a designer (usually an engineer) to translate a set of medical needs and requirements that have to be met in order for the implant to fulfil its supporting/restoring/regenerating function. This communication may typically result in a time-delay between medical image and the designed implant, furthermore a dependence on designer choices, even when this is conducted by designers at the same level of proficiency and experience, that lead to different implant design outcomes. A final challenge for the design of personalized implants is the dependence on the possibilities and constraints of the manufacturing processes that have to be included in the design towards the final implant.

The goal of this document is to define a design workflow for additively manufacturable implants, particularly those intended for bone replacement and regeneration, even towards a workflow that can be generalizable to other types of implants. For implants the design needs to incorporate advanced design features such as porosity or lattice structures or even surface structures that facilitate native tissue integration (hereby called scaffold implants). If load-bearing elements are present, their mechanical integrity must be ensured. Furthermore, using modern design techniques, this process should be as automated as possible, requiring only a few human inputs from trained and specialized personnel.

This document outlines the design steps starting from clinical patient data, which typically undergoes digital reconstruction and segmentation, to an additively manufacturable file ready to be processed.

1 Scope

This document defines a workflow to design scaffold implants from patient clinical imaging (such as CT-scans). In this workflow the different requirements for the involved steps in implant creation (such as image scan properties, software operations, systematic inclusion of clinicians input, considerations about manufacturability) shall allow repeatability and designer-independent results.

This document is intended to be used by clinicians, implant designers and implant manufacturers. The considered implants are primarily intended to address pathologies of musculo-skeletal structures.

This document is not intended to be used for the design of soft-tissue implants.

2 Roles

Clinician – the treating medical doctor in charge of the patient, usually a surgeon.

Designer – technician in charge to create a 3d printable implant design, usually an engineer.

3 Overview

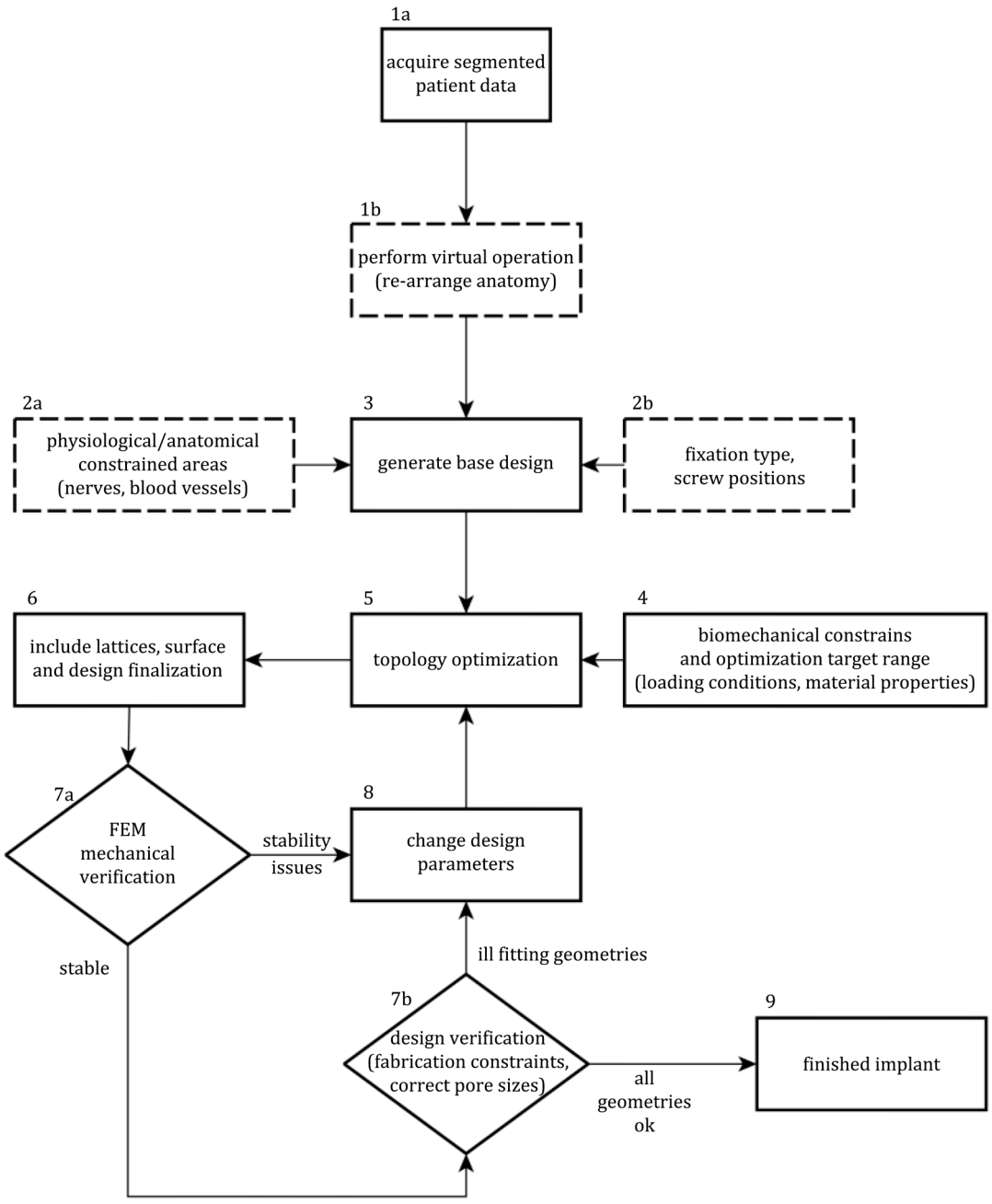

Figure 1 — Overview of the design process with influencing factors. Boxes with dashed boarders are inputs required from the treating clinicians

An overview of the process is depicted in Figure 1. In principle, a basic design is created by processing information about geometrical boundary conditions (from imaging data) as well as specific clinical and anatomical relevant information (e.g. “protected” zones because of anatomical structures not visible in the patient imaging, as nerves or blood vessels) and information about the way the implant and the native tissue shall be connected including virtual operation outcome.

Parameters required from a technical perspective should be as standardized as possible, facilitating an automated process. The initial generation of parameter ranges including biomechanical constraints and properties should be derived from literature and the clinician’s expertise. The designer is in charge of

creating a base design. Also, the designer shall implement the biomechanical model, with defined and documentable biomechanical conditions from literature. Scaling factors to comply with measurements from the patient or parameter-dependent load models (including, weight, age, etc.) may be included. Employing this biomechanical model, the designer shall perform topology optimization. In the next step, the designer might add lattices or implant surface structures, to target specific optimization criteria (e.g. lightweight design, tissue-elasticity match, cell/tissue integration, convective nutrients requirements) or as the results of the topology optimization.

The design should undergo numerical simulations (e.g. using the Finite Element Method) for mechanical properties to ensure they meet the specifications, preventing any stresses that could damage the implant. Subsequently, the overall dimensions and lattice sizes should be examined to ensure they fall within an acceptable range and no errors occurred during the file generation. If significant deviations are detected, the implant shall be regenerated with modified parameters and reevaluated. These steps should be performed by the designer.

In the following paragraph a detailed description of the steps is presented.

4 Decision on implant application (Step 1a)

The type of the implant shall be defined by the clinician according to the underlying pathology and the tissue/organ function the implant is going to support/replace/regenerate. The patient data shall be acquired. The relevant structures shall be segmented, in most cases those are the bones, but if needed for the surgery, other required structures shall be segmented as well, for example important nerves, vessels or tumours.

5 Digital surgery (Step 1b)

After segmentation of the structures of interest digital virtual operation, if necessary, should be performed by the clinicians since it reflects the later operation. This step is necessary, when changes on the patient's anatomy are planned, like moving a bone. The digitally planned surgery allows to create patient specific implants, which fit the new, desired anatomical shape. At this stage, it is already advisable to consider which tools will be used during the surgery. This includes not only which screws but also e.g. which cutting tools, as they will influence the cutting surface.

6 Defining physiological/anatomical constrains (Step 2a)

Important key locations for the implant shall be clearly identified by the treating clinicians. Positions of connecting elements between implant and native tissue (e.g. osteotomy plates) shall be marked, if applicable. The clinicians shall further specify locations, where vessels, nerves or defects are placed, where no implant should be placed.

7 Defining surgical constrains (Step 2b)

Clinicians shall decide on important locations and the tools that will be used during the surgery. This includes the positions for fixing devices (screws, sutures, etc.), which may be crucial for the subsequent topology optimization process, among other factors. It further includes the information, which screws (type, diameter, manufacturer) should be used.

8 Generation of base design (Step 3)

8.1 General

These steps should be performed by the designer in order to create a base design, here illustrated using a bone scaffold implant. Starting point for the designer is the type of implant, the clinician decided on in step 1a.

8.2 Identification of volume to be occupied by the implant

If a digital reconstruction of the bone is available, it should be utilized for the implant design. If not, the segmented bone from the patient image data shall be considered. The volume that the implant needs to fill shall be selected based on the specific defect being treated. Critical regions where no implant should be placed shall be excluded. These regions could include nerve or blood vessel pathways, as well as zones of damage identified by the clinician (include inputs from step 2a). The selection of the design volume is done by the designer, considering all the restrictions from the clinician (2a and 2b).

8.3 Inputting structural important locations

If the basic shape of the implant depends on the positions of the fixing elements (e.g. screws, as is typical for bone plates), the order within the workflow should be adjusted accordingly.

If locations are marked where no implant should be placed (e.g. due to nerves, vessels), these positions shall be marked in the design, to prevent the inadvertent creation of implant material there.

8.4 Design considerations for implant insertion

Undercuts shall be eliminated to facilitate the easiest possible insertion of the implant. It is important to consider the direction from which the implant is intended to be inserted, which is determined by the planned surgical access. This is essential to ensure that the implant can be successfully placed. A representative image of an undercut for a hypothetical bone augmentation implant is shown in Figure 2.

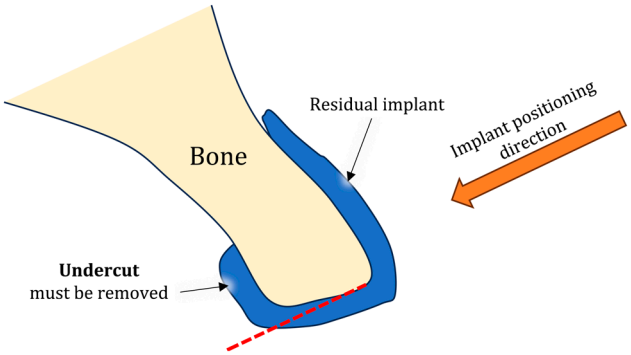

Figure 2 — Schematic of undercut with a residual implant and an undercut portion separated by the red line

9 Developing biomechanical loading model (Step 4)

For the subsequent Finite Element Method (FEM) and topology optimization steps, an appropriate biomechanical model shall be utilized. It is recommended to apply forces to the tissues that correspond in direction and magnitude to the muscles or other surrounding tissue attached to them. It may be helpful to consider multiple loading scenarios defining ranges of operation, with each type of load reflecting a maximum force exerted.

In cases where forces magnitude and/or directions are not known for the patients, these can be substituted with values from corresponding healthy subjects from relevant literature. If there are scaling models that consider specific patient parameters such as weight, age, and gender, it is advisable to utilize these models.

10 Numerical simulation of structural mechanics including Topology optimization (Step 5)

Topology optimization can serve various purposes, particularly for load-bearing implants, making it an interesting option for distinguishing between regions that should be made from bulk material and those that may consist of less stable lattices. With conventional methods like SIMP (Solid Isotropic Material with Penalization), it is possible to partition the volume into several areas. Structural gradations, such as bulk, solid lattice, weaker lattice with larger pores, and no material at all, can be chosen as needed. The results can also be utilized to introduce gradients into the lattice structures, depending on the requirements.

When applying boundary conditions, it is advisable to designate positions of fixing elements or any other implant regions that must remain unchanged (corresponding to “passive” regions). In most cases, the optimization objective will be to achieve maximum stiffness with minimal volume. For mechanical boundary conditions, it is recommended to apply the forces exerted by the biomechanical system on the bone and transfer them to the implant through the screws using an appropriate contact condition.

Other methods that operate with parametric volumetric bodies, often referred to as field optimization, are also suitable for these processes. In any case, the result of the numerical optimization should be verified with a structural analysis, such as finite elements, as outlined in Chapter 7.

11 Lattices and design finish (Step 6)

Topology optimization alone does not inherently produce appropriate structures. Struts shall be completed to meet minimum manufacturing sizes. The coarse surfaces of optimization meshes should be smoothed. Especially in the case of ceramic components, it is necessary to round parts to prevent part destruction during sintering. The sleeves around screw holes should be appropriately reinforced. Due to the changes that occur during these processes, the implant shall be re-evaluated through simulation.

12 Mechanical design verification (Step 7a)

To prevent fractures and damage to the implant, it is essential to ensure an adequate fracture resistance. For this purpose, a structural analysis is recommended, with the simplest approach being a Finite Element Analysis (FEM). If at any point, stresses exceed a certain material-specific threshold (breaking strength including a safety factor), the regions in question shall be reinforced accordingly. The thresholds for the FEM simulations shall be defined according to real life tests with the corresponding materials, also considering cracking and other common defects. Multiple load cases should be thoroughly examined, and it is advisable to include fatigue testing as well, to ensure long term stability. To achieve this, the necessary parameters should be adjusted during the initial design or topology optimization, and the implant should be regenerated. It is essential to determine suitable simulation parameters for the lattice size by conducting a mesh convergence study.

13 Geometrical design verification (Step 7b)

The geometry of the bone scaffold should be thoroughly examined. Are there enough pores for osseointegration with a suitable size of around ⌀ 0,7 mm[1)]? Are all edges rounded to enable ceramic sintering? Are there overhangs or features with high aspect ratio that cannot be manufactured? In the event of any issues, the design parameters should be appropriately adjusted. If there is abrasive post-processing, such as grinding or polishing, the design must include the appropriate allowance for it.

14 Change of design parameters (Step 8)

This step is not necessary if the implant passes all checks. In case a deficiency is identified, the design parameters must be adjusted so that these issues are addressed in the redesign. The design undergoes these checks once again for verification.

15 Finished Design (Step 9)

After exporting the design into a printable format, the finalized design should be presented to the clinician for review. If there are no objections, the manufacturing process can commence.

1) Ghayor C and Weber FE (2018), Osteoconductive Microarchitecture of Bone Substitutes for Bone Regeneration Revisited. Front. Physiol. 9:960. doi: 10.3389/fphys.2018.00960.