## Representative Title

Patient-specific Femoral Implant with Osseointegration

## Contributors

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## Problem Definition

A young 15-year-old lady was diagnosed with a large cancer bone mass in her femur. An alternative to ambulation is the rapid design and insertion of an implant. There is no off-the-shelf implant that can replace the portion of the cancer-infected bone. The implant needs to be patient-specific, designed rapidly, and manufactured swiftly to avoid the spread of cancer.
This implant represents a significant leap forward in medical technology. By harnessing the power of 3D printing, lattice design, and simulation, we've created an implant tailored to an individual patient in form and stiffness. The lattice structure within the implant promotes faster healing, better integration of bone, and improved long-term outcomes. The young lady walks fine a few weeks after the operation.

## Background Perspective

The treatment for a cancerous bone mass in the femur usually involves amputation or surgery to insert locking plates. Sometimes dual-plating of the distal femur is necessary for stable fixation. Surgical fixation using a pre-contoured lateral locking plate develops nonunion and complications in the plate attachment to the bone.
The design of 3D-printed implants is customized to fit a patient's specific needs. A complex lattice geometry is required for the bone to grow into the metal implant, a process called osseointegration. The implant is permanently anchored into the bone through surgery, and the bone then grows into the implant. The torsional brackets, screws, and implant were combined into one printed part, eliminating the possibility of implant misalignment and the need for drilling and screwing the torsional brackets to the implant.

## Technical Overview

This particular femur implant has explicitly been designed for a patient with bone cancer who requires clinical intervention to prevent amputation. The implant has been cut to exact

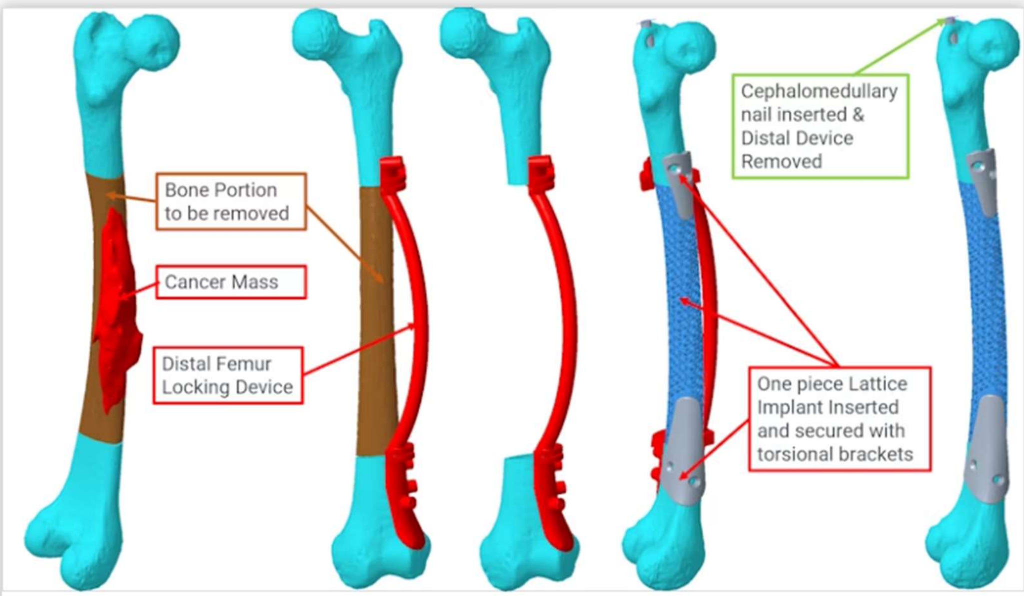
specifications that suit the patient's age, femur geometry, and weight requirements. The implant has been created using Digital Imaging and Communications in Medicine (DICOM) data, which were segmented and used to create both the cutting guide and the implant itself, ensuring a perfect fit for the patient's individual requirements. Advanced Engineering Solutions has designed the implant in partnership with PTC and the Levin Center for 3D Printing and Surgical Innovation at The Tel Aviv Sourasky Medical Center in Israel. The unique lattice design of the implant promotes osseointegration and has been developed using advanced structural simulation to ensure the patient's structural integrity and prevent stiffness discontinuities. The implant includes anti-torsional brackets and is compatible with the FDA-approved Cephalomedullary nailing system. The implant was designed by Dr. Andreas Vlahinos (AES) and Dr. Solomon Dadia (Ichilov Hospital) and using PTC Creo Additive Manufacturing solutions.
The software technologies used were:
The radiology department used medical MRI scans to generate the Digital Imaging and Communications in Medicine (DICOM) data of the leg anatomy.
Materialize Mimics, a visualization, processing, and segmentation software, was used to generate the faceted data for the femur.
PTC's CREO Parametric was utilized to produce high-quality solid models and surfaces from faceted data.
CREO Additive Manufacturing Module was used to generate the parametric TPMS lattice structures with variable thickness.
Based on the patient's weight and literature data, MathCad from PTC was used to generate the structural load cases.
CREO Simulation live powered by ANSYS Discovery was used to optimize the lattice cell size and thickness
The implant was created using laser power bed fusion (L-PBF) technology with an EOS M290.
The post-processing services included removing from the build plate, removing residual debris and metal powder, heat treating, hole drilling, and polishing.
A 3D scanner was used to ensure the dimensional accuracy of the print.

The Ti6Al4V alloy is a popular choice for bone implants because it has both biological and mechanical properties. Titanium was chosen for the implant material due to its ability to fuse with bone and living tissue. The high-strength properties of the alloy allowed us to use a lightweight lattice structure. As there is no ready-made implant that can replace the cancer-infected bone, the cost of creating a custom implant was still less than the cost of using a typical collection of off-the-shelf brackets.
3D printing has improved the implant design by allowing for custom-made implants that perfectly fit a patient's defective space. When it comes to replacing cancer-infected bone, there is no off-the-shelf implant that can do the job. The implant's design was created in the USA, and the operation was done in Israel. The 3D printing technology allowed for rapid on-site production of the implant, saving both time and money for the hospital.

Osseointegration is a process that requires complex geometries to allow the bone to grow into a metal implant. The implant is permanently surgically anchored into the bone, and then the bone grows into the implant. 3D printing can manufacture these complex geometries, which are impossible to create with other production technologies. The 3D-printed implants can enable faster and less invasive procedures, leading to quicker recovery and better health outcomes.

## Reflections

The processes used in this case were designed to quickly generate implants' design and manufacturing for patients who require immediate clinical intervention. Medical scans, such as ultrasounds and MRIs, generate the Digital Imaging and Communications in Medicine (DICOM) data. These data are then used to build patient-specific 3D anatomical models and cutting guides that will be used in surgical planning. In this case, the DICOM data was also used to generate the solid modeling geometry of a customized implant for orthopedic surgery The lattice porosity for osseointegration was determined based on guidance from Dr. Dadia Solomon, a world-renowned surgeon. Analyzing triple periodic minimal surface (TPMS) lattices is challenging since the implicit or voxel geometry cannot be exported as traditional CAD geometry. The team used an innovative approach that used voxel-based real-time simulations to determine the lattice unit cell size. Additionally, a simulation-driven lattice accommodates the considerable stress between the torsional bracket and the implant. Thanks to this approach, the operation was successful, and the young lady was able to walk normally.

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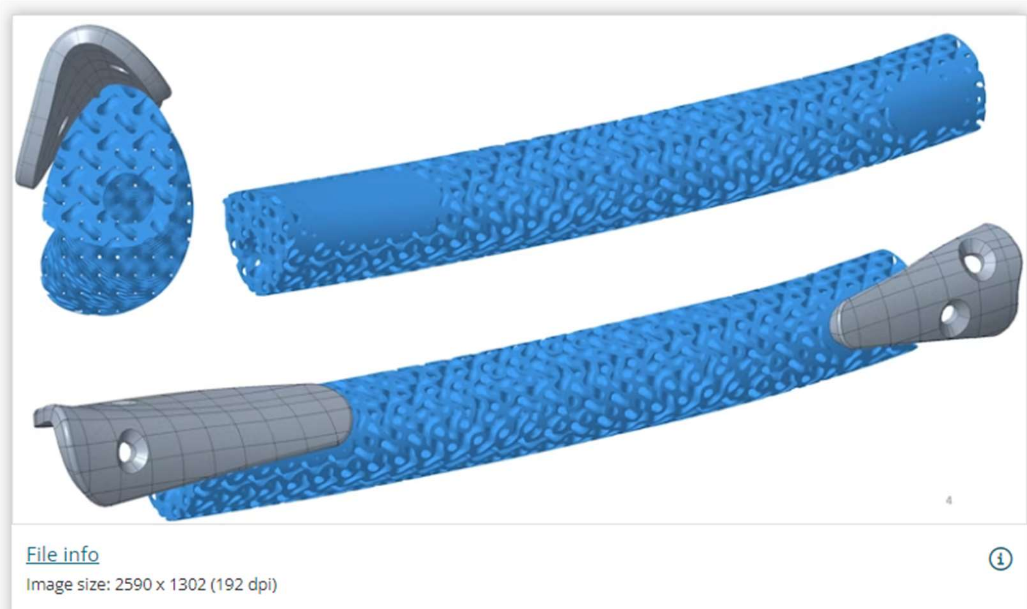
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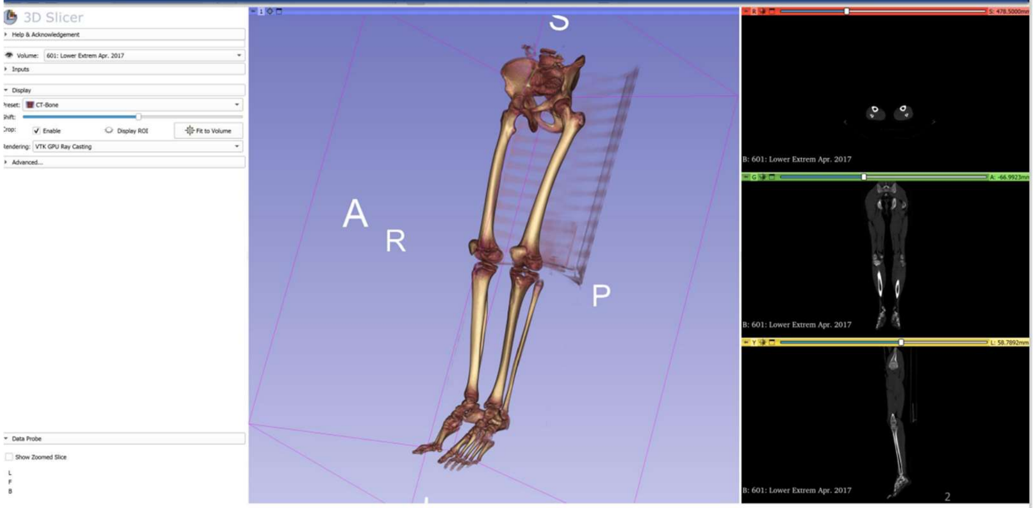
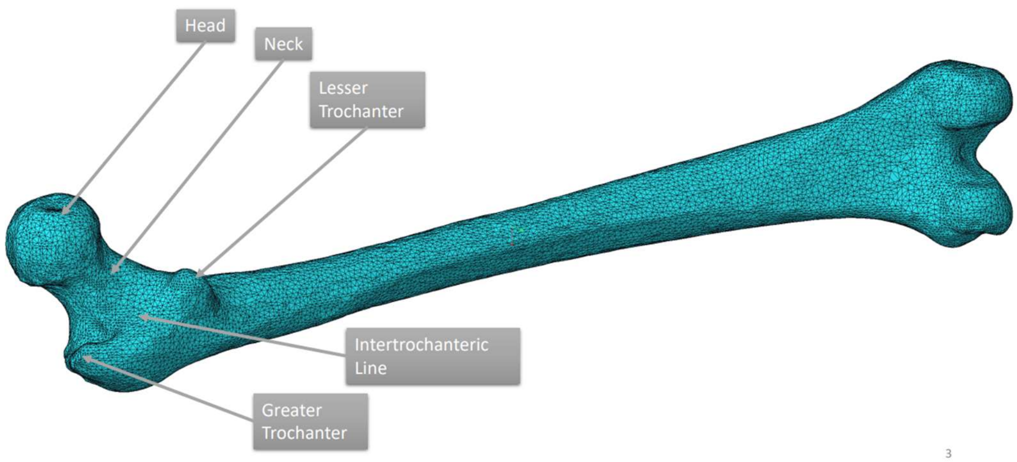
# Digital Imaging and Communications in Medicine (DICOM)

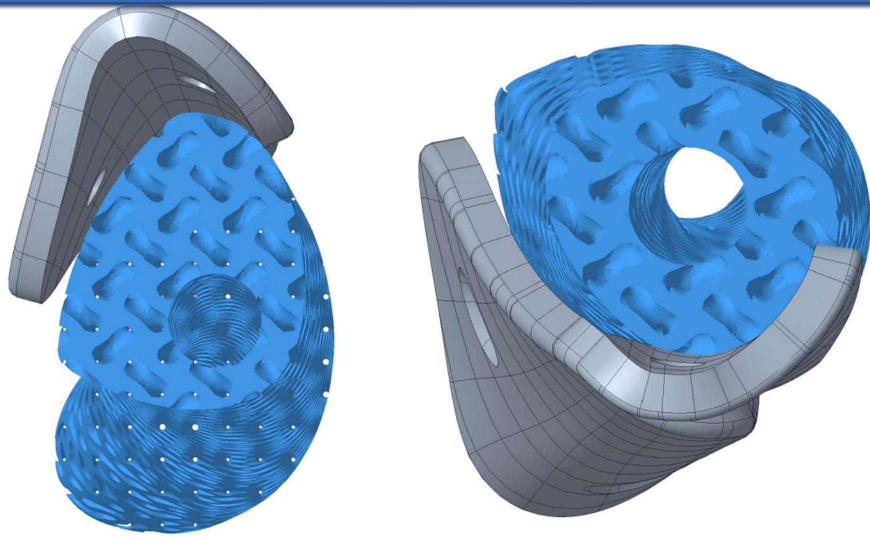





# Segmentation of Femur Bone



## Gyroid Femur Implant with Torsional Brackets and Nail Cavity



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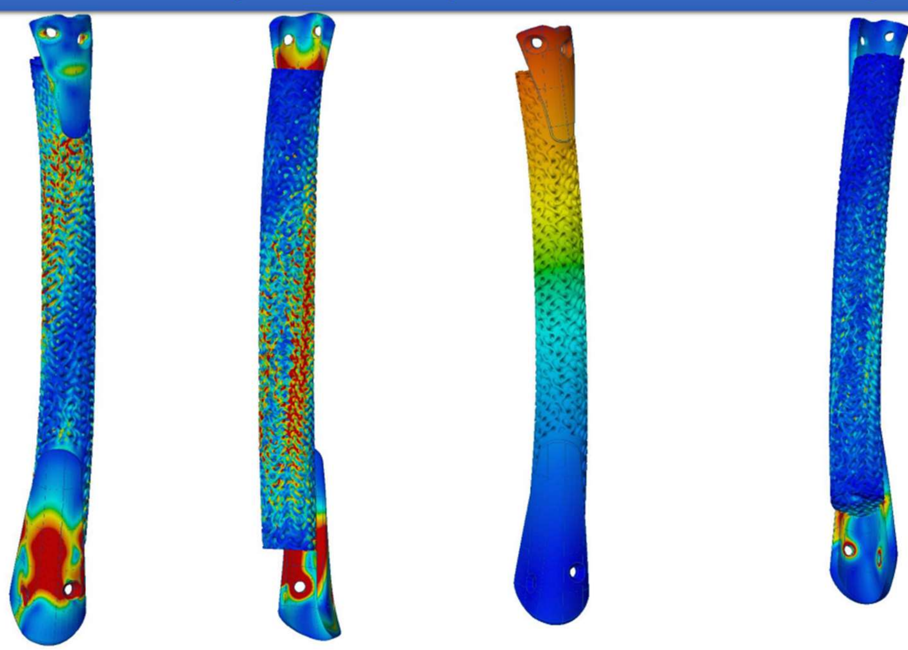
## Stress Analyses of Implant based on Body Weight



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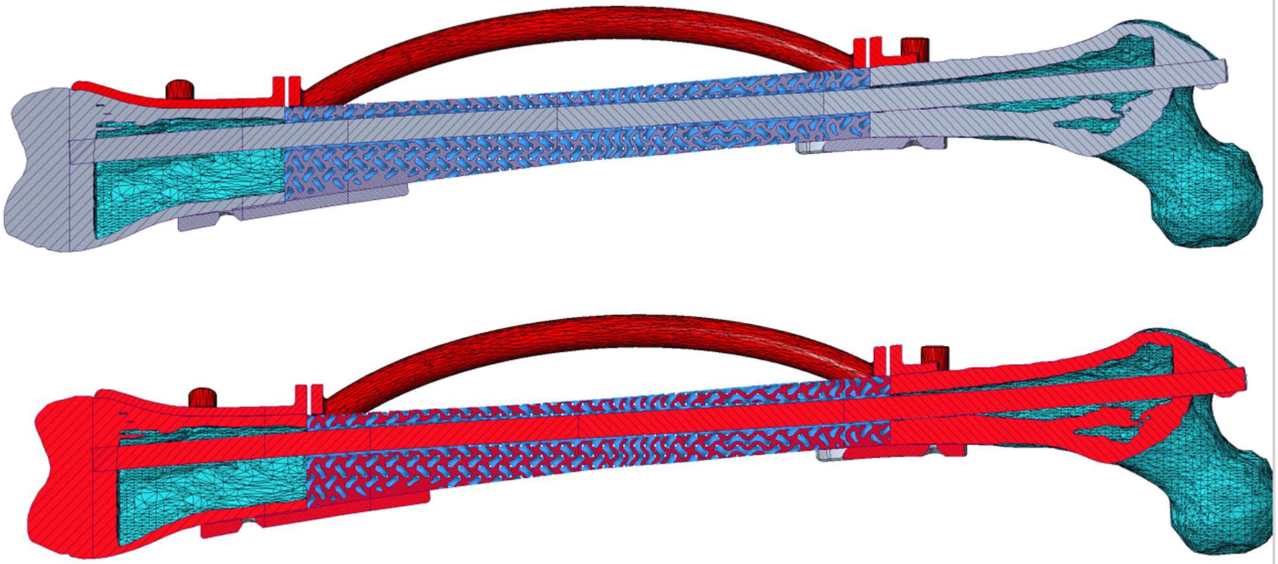
## Sections of the Femur with Gyroid Implant





## Gamma3 Long Nail is intended for fixation of stable and unstable femoral fractures

# Digital Imaging of Femur Implant after Operation


Operation | Operation | 2 weeks post-op | 6 weeks post-op