

CUSTOM IMPLANT DEVELOPMENT AND DESIGN PROCESS



ORTHO-DESIGN

ORTHOPAEDIC INNOVATION

At Ortho-design™ we strive to create innovative medical devices and implants that allow medical professionals to provide optimum patient care. Ortho-design™ aims at bridging the gap between innovation, ease of use and affordability in the rapidly evolving medical field. Our team of specialised engineers work alongside surgeons to create modern and effective health care products for all types of patients.

Our **mission** is aligned with South Africa's need for quality, locally manufactured products that perform at the highest standards. Using interdisciplinary skills, from medical professionals to certified manufacturers, we provide our costumers with the ultimate solution.

Ortho-design™ is focused on using inter-disciplinary knowledge to create the most innovative, efficient and feasible medical solutions.

All our products are designed in conjunction with surgeons specialised in the particular field. Our R&D department provides several consulting partnerships with medical professionals to create an innovative engineered, yet user friendly biomedical devices.

Benefits

- **Solving Complex Cases:**
Custom implants allow surgeons to solve problems that were treated conservatively in the past.
- **Better Anatomic Fit:**
Custom implants will be designed to perfectly fit the patients actual anatomy.
- **Unlimited Design Features:**
The 3D additive manufacturing method allows the implant to be virtually any shape and size.
- **Reduced Cost:**
Pre-operative planning reduces valuable time spent in theatre.
- **Reduced Patient Trauma:**
Shorter time in theatre decreases patient load.
- **Sterilizable Models:**
Sterilizable models and implants allows surgeons to construct bone grafts, implant configurations, etc. in theatre before going in-vivo.



Step 1 – Patient data acquisition

The complete CT scan file (in DICOM - .dcm format) should be sent to the Ortho-design team or uploaded onto the website before development can commence.

Option A (preferred option)

1. Patient injury data: The CT scan of the fracture received by Ortho-Design is imported into Ortho-Design's modeling software for post-processing.
2. Additional patient information: A CT scan of a similar bone structure from the same patient should be sent to Ortho-Design to be imported into Ortho-Design's modeling software for post-processing. This is used to design the custom plate to ultimately repair the injury back to the patient's natural anatomy. In the case of a left and a right-hand bone structure, the opposite side is used. If the structure is central, for example, a vertebra, a similar size (top or bottom) is used.

Option B

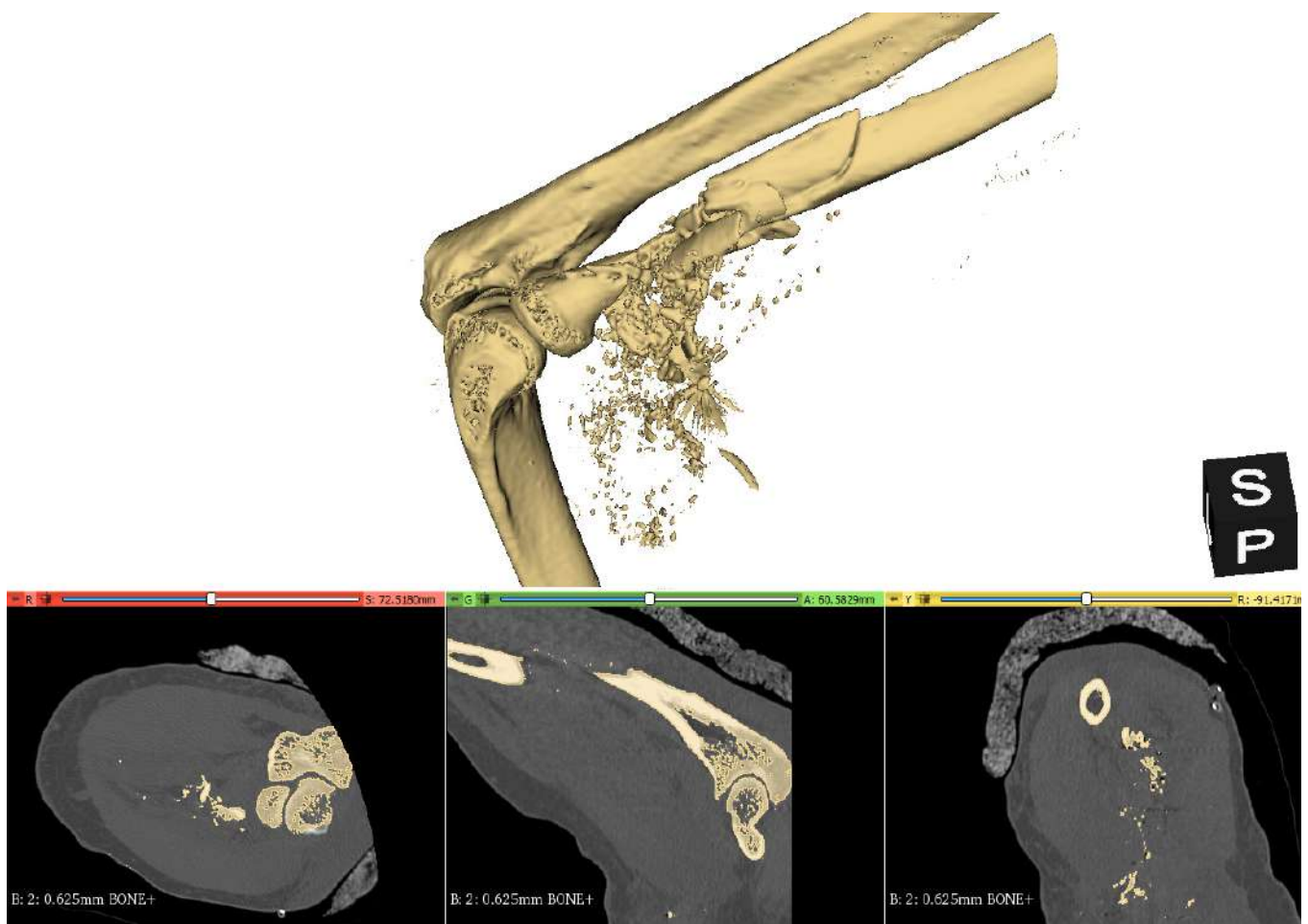
1. Patient injury data: The CT scan of the fracture received by Ortho-Design is imported into Ortho-Design's modeling software for post-processing.
2. Generic human anatomy: A generic model of the specific bone, present in the fracture, is imported into Ortho-Design's modeling software for post-processing. This is used to design the custom plate to ultimately repair the injury back to generic natural anatomy.

Ortho-Design's interactive website makes the transfer of CT data effortless. The patient data is then used to create a custom implant that allows the surgeon to return, as

Step 2 – Fracture Modelling from Patient Data

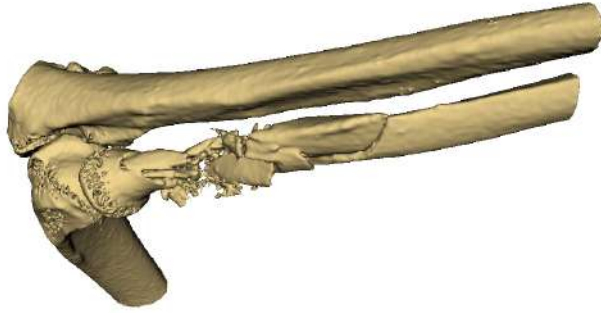
The CT scanned data is imported into Ortho-Design's modeling software to post-process and convert into usable data.

- The scanned data is uploaded to the software and transformed into a 3D model.



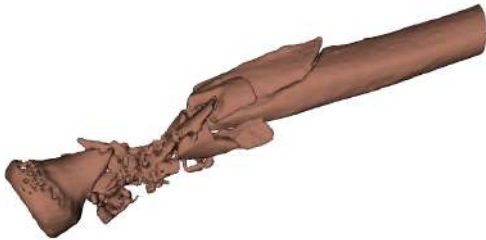
- The scan is then manipulated into a model used for fitting.





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- The 3D model is then further processed to isolate the fracture.



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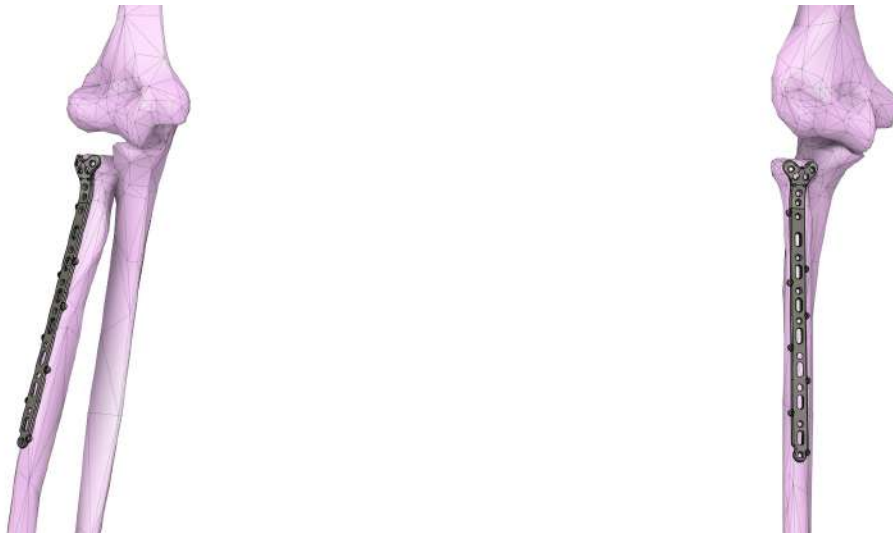
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- The 3D model is then exported into readable CAD format for the fitting of a custom prosthesis.

Step 3 – Initial Design of Implant

A custom plate is then designed using Ortho-Design's CAD software. The plate is strategically designed in phases to ultimately create the best solution.

- The process starts with the design of a generic plate according to the patient's anatomy (healthy) acquired in step 1. Following an iterative process, a plate is designed to fit the generic anatomy, whether it is a healthy bone from the patient or a generic model.



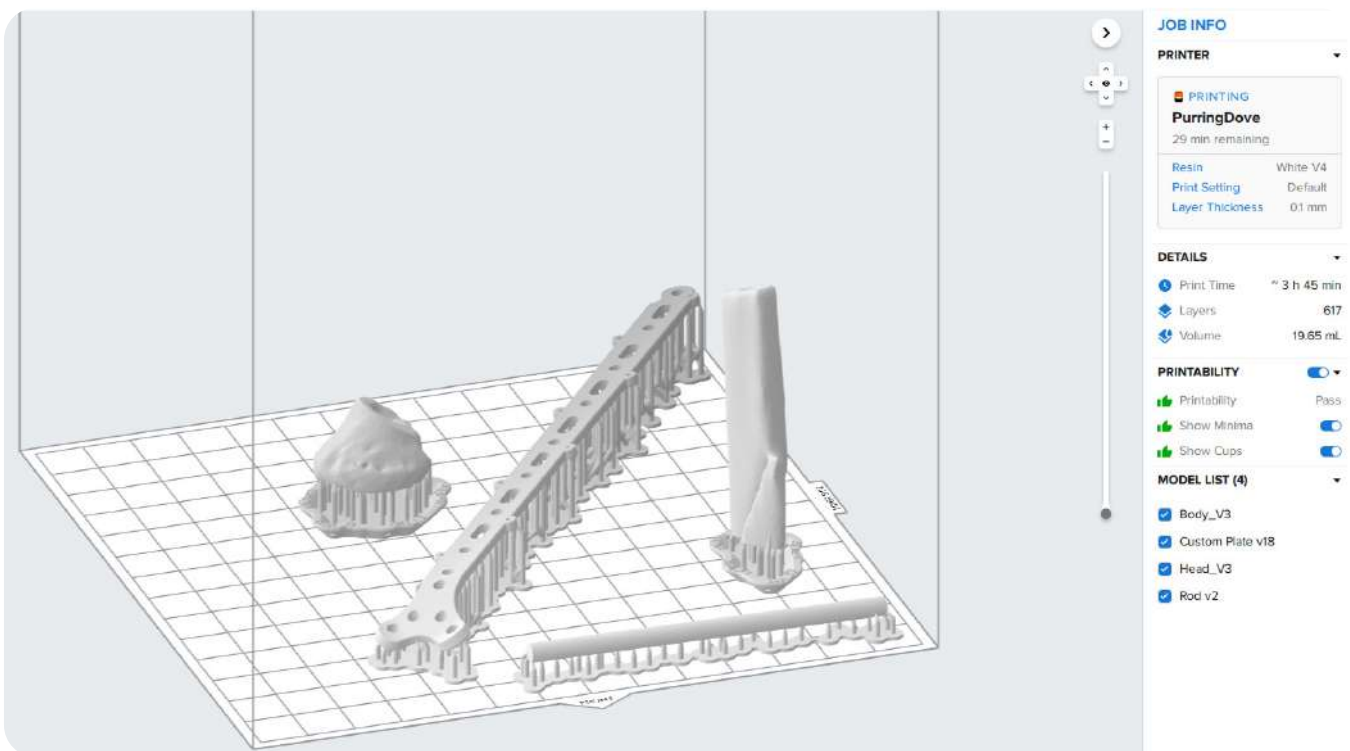
- The model of the injured anatomy is then added to the generic plate where the design is adapted to ensure ultimate fixation.



Step 4 – Custom Implant Fitting

The fracture fixation points and the custom plate is then 3D printed for actual fitting.

- The bone that will be fixated, as well as the custom-designed plate, is then 3D printed for final fitting. The accuracy of this fitting is up to 25µm.

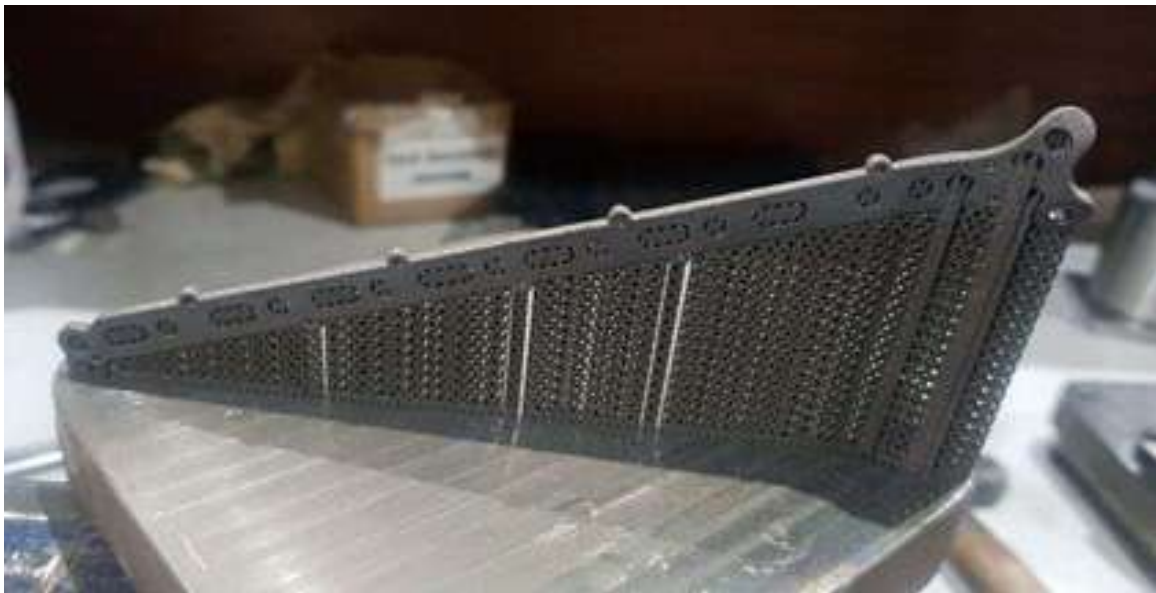


- The physical parts are then fitted and the custom implant is adjusted if necessary.

Step 5 – Custom Implant Manufacturing

The implant is then manufactured according to the specifications.

- The custom implant can be 3D printed using medical-grade materials (Titanium Ti6Al4V, PEEK, etc.) according to the specific design specifications.



- The Custom implant can be manufactured with CMC, drilling, milling, etc. techniques using medical-grade materials (Titanium Ti6Al4V, PEEK, etc.)
- All materials strictly adhere to medical regulations and have all the necessary FDA/CE, ISO, and other certifications.

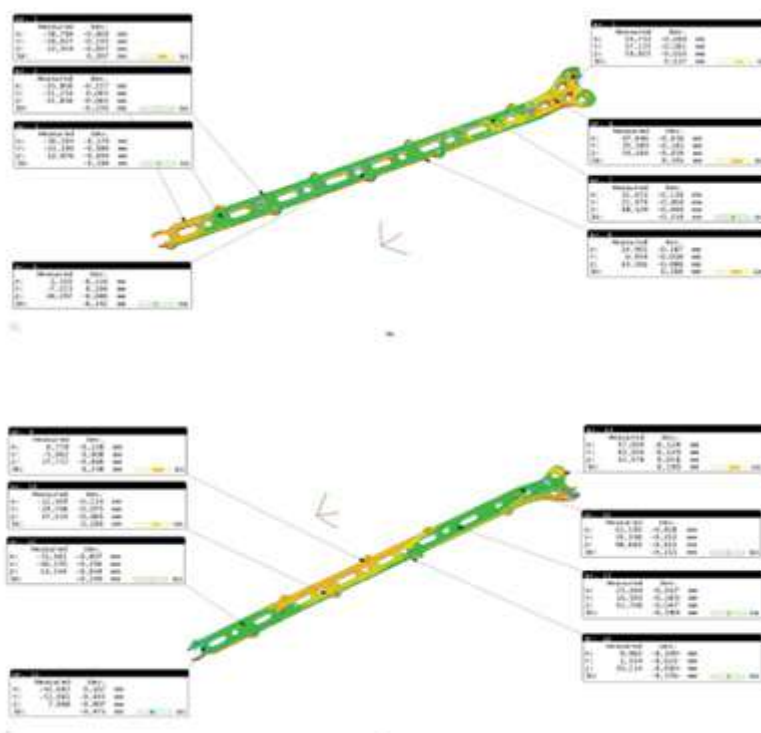
Step 6 – Quality Control

As custom implants are specialized to patients' needs, a precise quality control process is followed.

- The actual and estimated printed conditions are compared and assessed for deviations. The level of oxygen content, material flow and temperature during the final print is measured and should be in accordance with the applicable standards before approval.



- The final dimensions of the critical parts of the plate are then compared to the modelled CAD design. These measurements should be within strict tolerances before approval.





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