Chapter 8

Development of Patient-Specific Scaffold and Prosthesis (Morphologically Controlled) for Large Bone Defects

8.1 Introduction

The last objective of this study was to computationally design a patient-specific implant (PSI) for the treatment of large segmental bone defect. Here a direct approach was presented for the creation of implants with specifically matched patient anatomy. For this, two scenarios were presented. First deals with the real-life scenario of the patient having tumour for which the defected bone was resected with virtual surgical planning. The resected portion was fixed with traditionally developed PSI. The second scenario demonstrates the incorporation of porous structures on the previously designed traditional PSI to develop a novel conceptual porous mapped implant, virtually replacing the traditional large implants in the femur bone. Mapping with porous unit cells converts the solid structure into a porous lightweight structure suitable for reducing stress shielding as well for promoting bone ingrowth and nutrient transportation. The porous PSI is expected to provide outstanding performances when implemented in vivo.

8.2 Virtual treatment protocol and rationale

Employing a patient-specific customized titanium implant including modern treatment approach provides unique approach to completely utilize advantages of virtual planning surgery. This treatment procedure can be advised for post-traumatic or pathological bone abnormalities in adult that are typically longer than 8 cm depending on modest expertise and a few other reported articles. (Hamid et al. 2016, Hsu and Ellington 2015). It is preferable to place the implant in the meta-diaphyseal (distal femoral) area, especially if the residual bone is smaller than 2 cm in length. Such a custom-made implant can be used in deficient host where spontaneous bone formation becomes difficult to repair the defect, effectively. A substantial portion of bone graft or replacement volume must be used in the reconstruction to bridge the gap between undamaged proximal and distal host bone and repair the deficiency. Following the second stage, physiotherapy is administered, which includes exercises that immediately allow for full range of motion (ROM) and a persistence to full weight bearing (FWB) over a period of 4-6 weeks. To monitor graft integration and establish the restoration of skeletal continuity, routine clinical reviews should be carried out at regular intervals using plain radiographs and often computed tomography (CT) examination at least every six months.

While inserting the implant into the bone defect, the surgeon must be conscious of space constraints and understand the significance of geometry in 3D. The original fixation must also be totally preserved because this is the most restrictive scenario. The final outcome of this strategy will greatly depend on the implant design. The initial structure might be regarded as less limited if the fixation is being significantly altered (for example, by removing a screw). There is a negotiation between the flexibility obtained and the possible full loss of orientation, even if entirely modifying the original orientation might often be an appealing alternative. Maintaining the correct location of the bone segments in context to each another can be quite challenging when implant removal or revision is desired. It might also be challenging to determine if the implants have effectively developed the anatomic integration of bone segments to their natural position because the virtual process was performed utilising certain predefined parameters.

In order to fully finish the reconstruction, patient-specific 3D printed porous implants must be supplied with bone grafts. As the implant is being loaded with bone grafts, a centralized phantom can be introduced to replace the IM nail as this area would eventually be covered by the nail and would not essentially be occupied. The implant's pore volume and strut volume are dependent on the implant's size and shape. Therefore, the pore volume is the volume needed to entirely remove any air from the area the implant occupies. This is a highly significant concern for large segmental defects, and substantial bone grafts are required when considering final surgery as a second step.

8.2.1 Development of conceptual patient specific implant to treat tumorized femur bone

The implant's form must be anatomically correct and resemble the original bone structure. In this tumor case as shown in Figure 8.1 two proximal and distal transverse planes were created to resect the tumor region which was measured as 148.52 mm (Figure 8.1 left). As every patient-specific implant shape primarily determines the type of defect treatment that is to be accomplished, the shape of the customised implant design plays a significant role. To achieve a successful response, the implant design must consider a wide range of essential factors. Aspects that are particular to each situation include mechanical, anatomical, and functional characteristics. MIMICS was used to mask the ROI of mid-resected bone to illustrate this. In order to obtain a 3D structure that is anatomically accurate, this procedure is carried out. Its design must be capable of being properly placed through the specified surgical exposures and consider the limitations imposed by the local anatomy or any existing implants. Consideration must be focussed on the stabilization of implants for enabling osseointegration and thereby permitting quick recovery and mobility as well as secured load bearing when the overall sizes, shapes, and contour of these implants are customized to accurately resemble actual bone physiology (Figure 8.1). This may be prepared along with the surgeon who will be doing the procedure since they are aware of the potential outcomes as well as the precise plan for stabilisation that includes cerclage cables, IM nails, plates, and screws. Juxta-articular implants for long bone defects include metaphyseal flares (Figure 8.2 (c) upper portion), whereas diaphyseal implants have a more cylindrical shape (Figure 8.2 (c) bottom section). In addition to allowing for maximum muscular activity and sustaining mechanical interactions across the entire limbs, both parts are specifically tailored to reduce the possibility of soft tissue interference. They are also simple to install and remove.

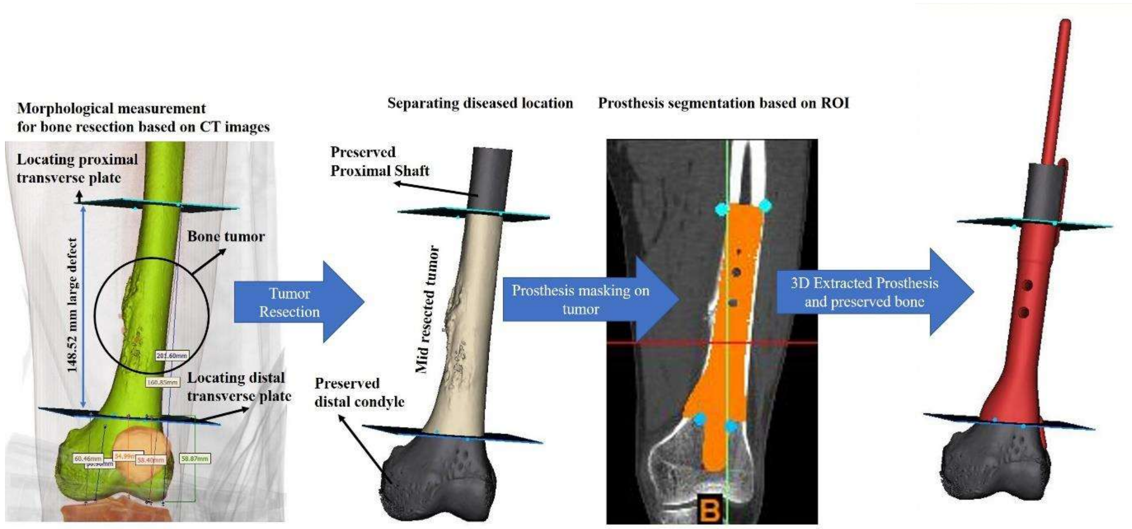

Figure 8.1: Sequence of steps in prosthesis extraction accounting specific anatomy.

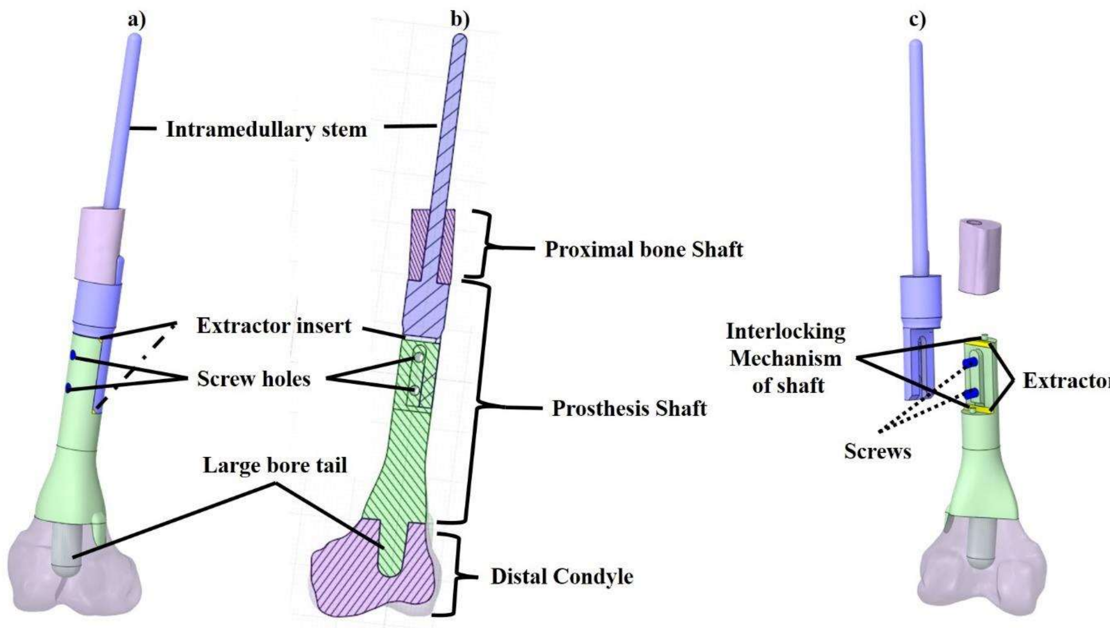

Figure 8.2: Conceptualization of prosthesis (a) 3D view (b) Section view (c) Exploded view.

8.2.2 Pore mapping on patient specific implant

To support the bone grafts and allow space for tissue development, vascularization, and the transport of nutrients from the ECM, these large implants frequently need to have voids (pores) constructed into the structure. It should be noted that in this project only porous implant for large segmental bone defect is proposed which is a representation of virtual planning prior to surgery for manufacturing of anatomically matched implant. The implant is composed of a series of pores, which can be seen in both the components in Figure 8.3 (a) and (b). In this representation only primitive mapping is shown.

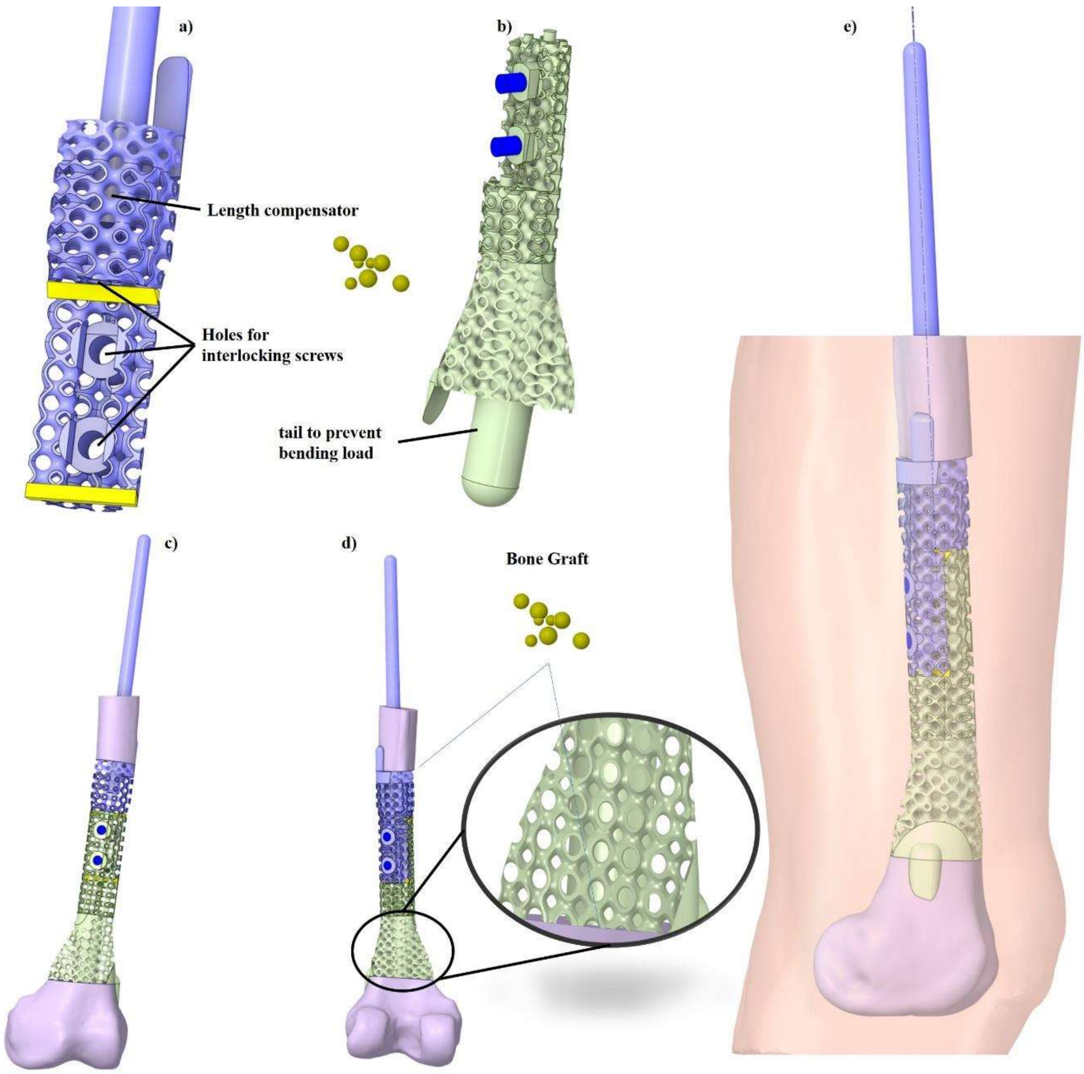

Figure 8.3: Primitive unit cell mapped patient specific implant (a) Upper part illustrating length compensator mechanism to tolerate the micro mismatch of length of implant (b) Lower part of implant illustrating large bore tail and fins to provide resistance to bending and torsional load. (c) Anterior view of complete assembly (d) posterior view of complete assembly (e) 3D view of implanted assembly at anatomical location (thigh)

Similarly, other porous unit cells can also be mapped depending on the morphological and mechanical outcomes. Compared to other forms of therapy, the introduction of pores is a more advanced procedure that offers a far better weight to strength ratio. They are comparable to the powerful yet light and open trusses used in the Eiffel Tower.

8.3 Summary

Designing cutting jigs and drill guides will frequently be helpful to ease the actual surgery (not included in this study) if extra bone has to be removed or if the preclinical proposal calls for inserting "blind" screw inside the structures (Wong et al. 2012). When the region of interest (ROI) of existing location is appropriate, cutting jig and drilling guide could be designed and placed according to particular implants or specific morphological characters. The jigs and guides will be positioned extremely firmly in relation to the skeletal pathologies and can be fastened to the existing implant enabling them to be secured in place as well as let the surgeons drill or resect the bones precisely. The cutting jig and drilling guide must therefore be constructed and placed according to the specific anatomic characteristics, considering the anticipated modification in location in relation to local anatomy, when the existing position of ROI is not appropriately aligned. Virtual planning therefore offers an almost infinite number of options.

The struts at the extremity of the implant have small fins and a big bore tail added to improve rotational control (Figure 8.3(d) and (e)). This reduces the possibility of shear at the bone/implant contact in addition to providing torsional resistance. Pore struts are generally rough and resistant to torsion, but that might be considerably improved by adding microscopic "cleats" or incorporating macro components into the implants that conform to recognized bone flaws. Another option is to create intramedullary tapered truss extensions that, when placed against the bone, can offer torsional stability. The intrinsic shear resistances in bone-implant interfaces might even be greatly increased by leveraging of uneven skeletal shape.

Because the confluence of plate and the porous structures generate stress concentrating focal points and implants might fail in this juncture, no plates are included to increase stability in this custom design. To reduce the possibility of early failure, designing plate elements spanning the whole structure can be recommended. In many cases, it is preferable to have a hole and extractor space in the implants since it allows for compression during mobility restoration while also providing certain movement to facilitate implantation.