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Novel implant for peri-prosthetic proximal tibia fractures

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ABSTRACT

Background: Repair of peri-prosthetic proximal tibia fractures is very challenging in patients with a total knee replacement or arthroplasty. The tibial component of the knee implant severely restricts the fixation points of the tibial implant to repair peri-prosthetic fractures. A novel implant has been designed with an extended flange over the anterior of tibial condyle to provide additional points of fixation, overcoming limitations of existing generic locking plates used for proximal tibia fractures. Furthermore, the screws fixed through the extended flange provide additional support to prevent the problem of subsidence of tibial component of knee implant.
Methods: The design methodology involved extraction of bone data from CT scans into a flexible CAD format, implant design and structural evaluation and optimisation using FEM as well as prototype development and manufacture by selective laser melting 3D printing technology with Ti6Al4 V powder.
Results: A prototype tibia implant was developed based on a patient-specific bone structure, which was regenerated from the CT images of patient's tibia. The design is described in detail and being applied to fit up to 80% of patients, for both left and right sides based on the average dimensions and shape of the bone structure from a wide range of CT images.
Conclusion: A novel tibial implant has been developed to repair peri-prosthetic proximal tibia fractures which overcomes significant constraints from the tibial component of existing knee implant.

Introduction

The increase in human life expectancy and aging world population have led to a rapid increase in musculoskeletal conditions and diseases such as osteoarthritis, osteonecrosis, rheumatoid and osteosarcoma in the healthcare system [1–3]. Degenerative conditions at the joints, especially at the knee, have been increasing in recent times [4,5]. Generally, both total knee arthroplasty and unicondylar knee arthroplasty are the most common and successful treatments to reduce pain and restore physical functions of the knee. However, many patients suffer peri-prosthetic fractures of tibia following the knee arthroplasties as most of them are advanced in age and have osteoarthritis [6–8].

The proximal tibia consists of an exterior of cortical bone and an interior of cancellous bone. Cortical bone is a denser bone and has higher elastic modulus than that of cancellous bone. In knee arthroplasties, the tibial component of knee implant consists of a central stem, which is implemented into the interior of proximal tibia. Therefore, the tibial component of knee implant is mainly supported by cancellous bone. As knee implants are normally manufactured by either stainless steel or titanium alloy, which has elastic modulus much higher than both cancellous bone and cortical bone in tibia, stress shielding and bone resorption are likely to occur [9,10]. According to this, stress fractures without any trauma is the common cause of peri-prosthetic fractures of tibia following the knee arthroplasties [7,11,12]. Felix et al. [12] classified several common peri-prosthetic fractures of tibia associated with the presence of knee implant on the basis of anatomical location and the status of prosthetic fixation (Fig. 1). Fractures occurred at the tibial plateau are known as Type I and fractures occurred adjacent to tibial stem are known as Type II. Type III fractures are classified as fractures at the distal tibial shaft, and those fractures occurred at the tibial tubercle are known as Type IV. For different types of peri-prosthetic fractures of tibia, different treatment options, which depend on the fracture site and the status of prosthesis, are available [7,12].

One of the most common treatment options is to apply locking plates with several locking screws inserted around the proximal tibial condylar and on the tibial shaft [13]. Fig. 2(a) shows one of the commercial generic locking plates currently used in surgical treatment of proximal tibia fractures in Australia. It is a lateral

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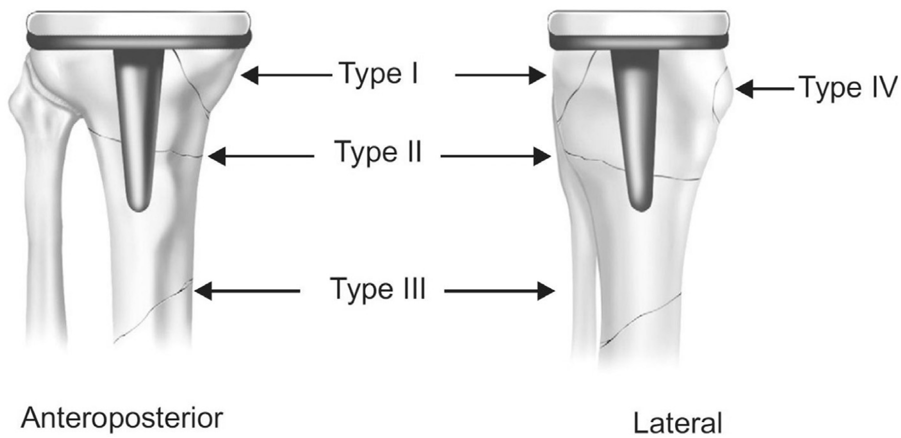

Fig. 1. Classification of common peri-prosthetic fracture of the tibia associated with the presence of knee implant. [7,12].

locking plate, which consists of buttress head for fixation over the lateral condyle of tibia and stem for fixation over the lateral side of tibial shaft. Although this generic implant has been commonly used as one of the treatment options for Type II and III fractures, it was found that there are several limitations of applying this lateral locking plate to patients with existing total knee arthroplasty. Firstly, this lateral locking plate cannot be used for Type I and IV fractures. Secondly, the design of this lateral locking plate does not provide sufficient support around the proximal tibial condyle. This can lead to further fracture around the tibial condyle. Thirdly, the lateral fixation of this locking plate severely restricts the fixation points for fixing the implant onto tibia due to the presence of the central stem of the tibial component of knee implant. Fig. 2(b) shows a computed tomography slice of the fixation of this lateral locking plate onto the tibia of a patient with total knee arthroplasty [14]. The presence of the metallic central stem of the tibial component of knee implant severely restricts the lateral fixation of the locking plate onto the tibial condyle. In some situations, drilling holes on the tibial component of knee implant may be required in order to fix the buttress head of the implant onto the lateral tibial condyle which can significantly extend the operation time of the surgery and increase the risks of complications. Furthermore, fixations of this lateral locking plate onto existing tibial component of knee implant can make operation procedure more complicated and challenging if revision of total knee arthroplasty is required in the future.

A novel implant has been designed with an extended flange over the anterior of tibial condyle to provide additional points of fixation, overcoming limitations of existing generic locking plates used for proximal tibia fractures. Furthermore, the screws fixed through the extended flange provide additional support to prevent the problem of subsidence of tibial component of knee implant.

The design methodology involving extraction of bone data from CT scans into a flexible CAD format, implant design and structural evaluation and optimisation using FEM as well as prototype development and manufacture by selective laser melting 3D printing technology with Ti6Al4 V powder, followed by physical testing and use in patients are discussed in this paper.

Methods

In the current study, a conceptual design of tibial implant was developed for a 74 years old woman who suffered fractures on both tibia and fibula of her right leg following the total knee arthroplasty in Australia. A CT-based 3D printing research and development system for implant design was developed, as shown in Fig. 3, and applied to design an implant for proximal tibia fracture associated with total knee arthroplasty.

CT scans on the right leg of the patient were taken obtain details of the fracture in tibia using a Philips iCT 256 Slice CT Scanner (a current of 442 mAs and energy of 120 kVp). The slice thickness was set as 0.8 mm with pixel spacing of 0.195. Fig. 4(a)–(c) show the CT images around the fractured regions of the patient's right tibia. A stack of CT slices obtained in DICOM's file's format were then imported into a commercial software package, MIMICS, which was specially developed for medical image processing.

Before carrying out any segmentation on the CT slices, a three-dimensional model was directly generated based on the raw data in the CT slices (Fig. 5) to provide useful information of the fracture for precise planning of the segmentations required to obtain an accurate three-dimensional bone model. Fig. 5 shows fractures were found around the tibial neck (highlighted by the red circle), between the medial condyle of tibia and the tibial shaft. The presence of metallic material causes poor quality images or "noise" which can be seen as highlighted in green circles around tibial condyle.

The "noise" needs to be removed to generate a precise three-dimensional bone model of tibia for the design of implant. The bones and the metallic implant were first distinguished from the CT image based on the threshold value of Hounsfield Units (HU). HU values are commonly used for measurements of the level of attenuation in CT images. HU are a normalised scale of the attenuation coefficient measurement in which the HI values of the radiodensity of air and distilled water at standard temperature and pressure are -1000 and 0 HU, respectively. The HU value of a structure also depends on its density. Generally, the HU value of a bone lies between 200 and 3000 [15] while the HU value of titanium is about 2921 ± 218 [16]. According to this, the minimum and maximum threshold values were set at 2901 and 3071, respectively to extract the metallic implant from the CT images while the minimum and maximum threshold values for capturing the bony structure were set at 226 and 2900, respectively, in the current study.

After the threshold values were set, two masks were created. One is for the bony structure while the other one is for the metallic implant. Segmentation was then conducted on the mask for the bony structure in order to capture the tibia only. The mask on every single CT image was edited in order to remove the regions for the fibula and to ensure all the regions of interest are included in the masks. In the meantime, the noise, which have the HU values lower than 2901, around the tibial condyle due to the presence of the metallic tibial component of knee implant were also removed.