Transactions on Additive Manufacturing Meets Medicine
Trans. AMMM, Vol 3, No 1, 2021, Article ID 561

Infinite Science | Publishing

Osteointegration of 3D-printed bone plates

L. Yan[1], A. Kostadinov[1*], M. Y. Xie[2], G. K. O'Neill[1,3]

[1] Department of Mechanical Engineering, National University of Singapore, Singapore, Singapore
[2] School of Dentistry, China Medical University, Taichung City, Taiwan
[3] Department of Orthopaedic Surgery, National University Hospital, Singapore, Singapore
[*] Corresponding author, email: bieak@nus.edu.sg

Abstract: Additively manufactured fixation plates can reduce the presence of stress-shielding and induce a better recovery of bone fractures. This is achieved by replacing the stiff, solid material with a more flexible lattice structure. Interestingly, the employment of porous structures within orthopedic implants can induce osteointegration which could further improve the recovery. In this study, we investigate four different lattice designs to detect the presence of osteointegration. The bone regeneration process was examined through histological analysis of a femoral defect remedied with five different fixation plates. The results indicate various amounts of osteointegration which signifies an additional design improvement of 3D-printed fixation plates over conventional, solid bone plates.

I. Introduction

I.I. Background

The design of standardized orthopedic plates has not been greatly changed over the past 50 years due to the limitation of mass fabrication methods, i.e. subtractive Computer Numerical Control (CNC) machining of metals. Solid commercial bone plates have a higher Young's modulus (YM) than cortical bone which leads to so-called stress-shielding. As a result, clinical applications suffer from delayed healing or non-union of fractures [1].

I.II. The new design concept

A new concept of customizable lattice-based bone plates was developed by our team, aiming to reduce YM of implants while maintaining sufficient bending stiffness to support the fracture healing process [2]. Several different prototypes were developed and tested. Our previous field work demonstrated that it is possible to design plates that can serve a multitude of purposes and can be easily adjusted to suit a particular patients' anatomy while simultaneously providing optimized biomechanical properties to support the fracture, allowing ambulation, and improving the healing process [3]. To take this theoretical concept to the next phase of development it is necessary to obtain the relevant certifications and demonstrate the biological benefits of this improved concept in an animal model.

II. Material and methods

II.I. 3D Printing

The design space of the bone plate, based on the CT scanning of the animals, has been confined within a maximum length of 55 mm. Further refining of the internal lattices were conducted to match the animal models selected in this study (Figure 1). The stainless steel 316L samples were printed using a commercial printer (Reinshaw RenAM400) [4] with the standard parameters provided by the manufacturer.

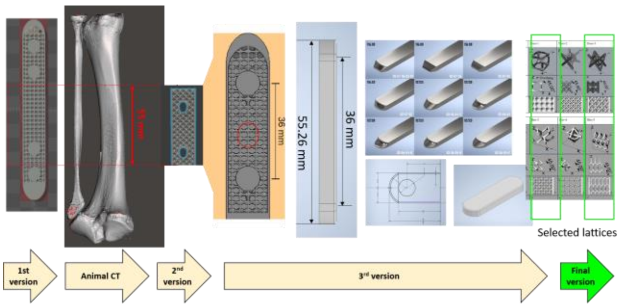

Figure 1: Demonstration of the prototype refining process.

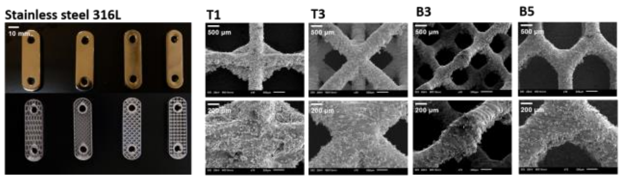

Figure 2: The printed bone plates and SEM images of the internal lattices.

II.II. Biocompatibility test

The biocompatibility of the 3D-printed stainless steel 316L plates was evaluated using test standard of ISO10993-5 cytotoxicity test, ISO10993-10 intracutaneous irritation test, ISO10993-11 acute systemic toxicity test, and USP151 progen test. The results show that there were no significant clinical signs of cytotoxicity in either the control or the treatment group. Furthermore, no mortality was found in any of tested groups.

II.III. Mechanical test

The static and dynamic 4-point bending tests followed the ASTM F382 standard specification and test method for metallic bone plates. All samples have shown no damage after one million cycles of fatigue test while exhibiting a mechanical performance (40–140 GPa) closer to that of bone material (20 GPa) than commercial steel bone plates (200 GPa).

DOI: 10.18416/AMMM.2021.2109561

II.V. Animal test

For the experiment, first, a femoral defect was created on the test animals, in this case five Lanyu pigs (28-30 kg), by milling a section of the femur and tibia with a cylindrical tool. Thereafter, the 3D-printed plates and the commercial bone plates were implanted at the defect sites to evaluate the impact of the implants on the bone regeneration process (Figure 3). After the implantation, the periosteum and related tissues were closed. The animals were kept under close examination until they recovered from the anesthesia. After the surgery, all animals had free access to food and water during the period of observation. Eight-weeks after the implantation, the pigs were sacrificed. The plates and bone specimens of the pigs were harvested and subsequently fixed using 10% formalin (Figure 4).

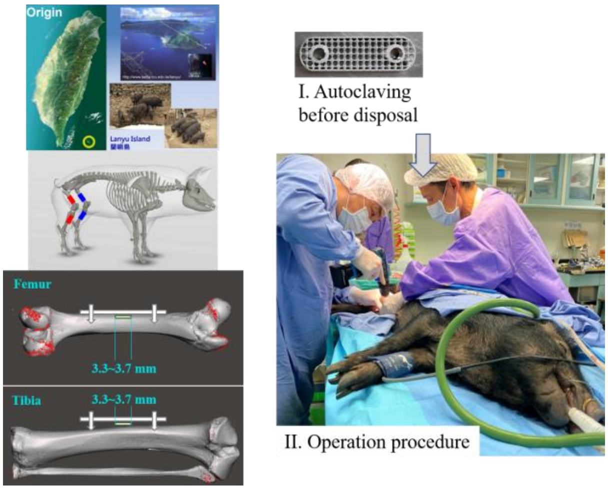

Figure 3: Demonstration of the in-vivo animal study procedures.

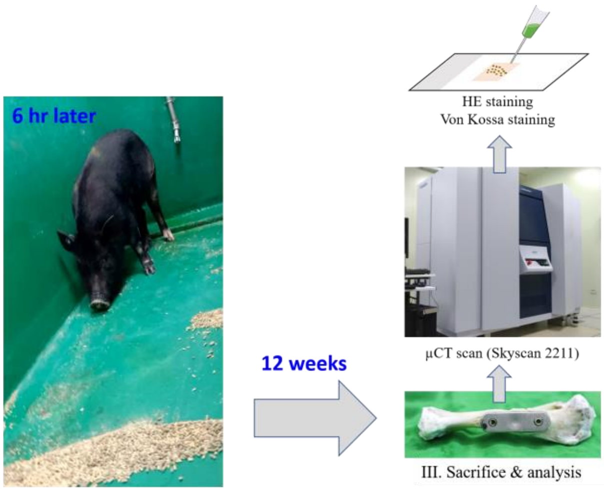

Figure 4: Demonstration of the animal sample harvesting process.

III. Results and discussion

Osteointegration of the 3D-printed bone plates was observed as shown in Figure 5, indicating a high stability and better fitting of the implants during the healing process. In contrast, the commercial bone plates detached from the bone immediately after being unscrewed.

To further validate the osteointegration properties of the lattices, the Von Kossa staining was analyzed. The test results showed that the untreated bone tissue has a horizontally arranged structure, while the newly grown bone material at the defect site has a more irregular appearance, denoted as red circle on Figure 5. Moreover, the VK staining of new bone tissue was darker compared to the natural bone. The rugged and uneven new bone structure shown in the VK staining proves that the bone tissue has grown into the lattices, which is a direct indication of osteointegration.

A comparison between the four selected lattice designs shows that T1 and T3 have a higher amount of implant-integrated bone tissue (see Figure 5) than B3 and B5. This might be due to the high nodal connectivity and rectangular geometry which provides better anchoring and guidance for cell ingrowth. On the other hand, no bone tissue ingrowth was observed underneath the solid commercial bone plates.

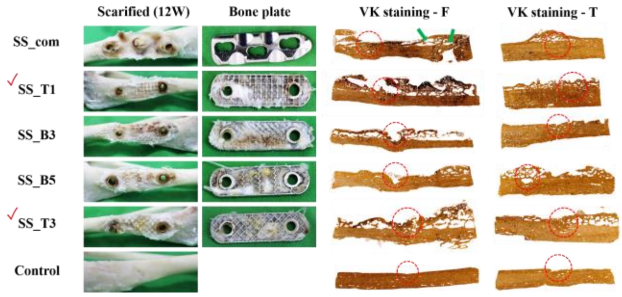

Fig. 5: The osteointegration of the examined 3D printed stainless steel 316L fixation plates. Left side: The regenerated bones and fixation plates showing ingrown tissue; Right side: Longitudinal histologic section with former bone defect geometry (red circle) and regenerated bone material within and above the defect location.

IV. Conclusions

In this work, the functionality of lattice-based bone plates was systematically evaluated. Several 3D-printed plate designs were compared to solid commercial bone plates. The results suggest that our 3D-printed plates can offer several benefits through (1) adjustment of young's modulus, (2) customizability of shape and size, and, most importantly, (3) osteointegration. The combination of these advantages can likely facilitate the fracture healing process and, thus, improve the patient's intervention experience.

Acknowledgments

This work was supported by the National Additive Manufacturing Innovation Cluster (NAMIC), Singapore [grant number 2016013 and 2019023].

Author's statement

Conflict of interest: Authors state no conflict of interest.

References

[1] R. Huiskes, H. Weinans, B. Van Rietbergen, The relationship between stress shielding and bone resorption around total hip stems and the effects of flexible materials, Clinical Orthopaedics and Related Research, vol. 274, pp. 124-134, 1992.

[2] Yan, L., Lim, J.L., Lee, J.W., Hao, T.C.S. and YR, C.D., 2020. Finite element analysis of bone and implant stresses for customized 3D-printed orthopaedic implants in fracture fixation. Medical and Biological Engineering and Computing, 58(5), pp.921-931.

[3] Yan, L., & O'Neill, G. K. (2020). Mechanical performances of lightweight structures for orthopaedic implants. Transactions on Additive Manufacturing Meets Medicine, 2(1).

[4] Yan, L., Zhao, L. P., & O'Neill, G. K. (2020). Dimensional consistency of SLM printed orthopaedic implants designed using lightweight structures. Transactions on Additive Manufacturing Meets Medicine, 2(1).