Authors' reply to comments by Sharma et al. on the article by Su JC et al.: Shape memory Ni-Ti alloy swan-like bone connector for treatment of humeral shaft nonunion

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Thank you very much for your questions concerning the article entitled "Shape memory Ni-Ti alloy swan-like bone connector for treatment of humeral shaft nonunion" [1]. These questions, are very interesting thoughtful and represent concerns of many researchers. I want to thank the editor for providing this platform, through which scholars can learn about the design and application of medical appliances based on shape memory alloy. Our response to your queries is as follows:

1. Sterilisation of the implant and the influence of routine autoclaving on material properties:

As with the other internal fixation materials, such as stainless steel and titanium alloy, shape memory alloy requires routine autoclaving, which has no impact on shape memory property, because Ni-Ti alloy transforms under low temperature and returns to the previous shape under high temperature. This phenomenon, in which transformation only occurs during heating, is called one-way memory effect. It has been reported that routine autoclaving has little impact on alloy fatigue [2].

2. Radial nerve injury:

Indeed, the radial nerve is at risk in the middle and lower part of the humerus. However, the main fixation position of SMC is at the anterior and lateral

aspect of the humerus, while the radial nerve is posterior of the middle and lower part of the shaft. Only partial exposure is enough for SMC implantation. Previous reports on radial nerve injury indicate they mainly occur near the nonunion in the middle and lower shaft after too much exposure. Nevertheless, with the improved implantation method and proficient technique, radial nerve exposure can be avoided, resulting in a very low injury rate.

3. Implant removal:

This is a good question. The SMC is removed with a specific tool. First, the SMC is immersed in sterilised ice saline at 0–4°C, then the embracing arms are braced with specific tools and the "neck" of the SMC is separated with a needle holder. Usually, the SMC can be removed this way. For some patients, the substance of bone embraced by the SMC shrinks and callus develops rapidly around the SMC. Therefore, the callus should be removed prior to SMC removal. SMC removal is not difficult, but the surgeon requires training to understand the structure and properties of the SMC.

4. Blood circulation blockage by the SMC, size selection of the SMC and postoperative supplementary stabilisation.

The SMC holds the bone in a embracing fashion. The embracing arms form a standard circle and the main plate is hollow. Therefore, the total surface area is small. Point contact is formed when the SMC meets the irregular surface of the bone, which will not influence microvascular blood flow of the bone cortex and favours revascularisation. Carbon black-ink microangiogram and radioactive microspheres were employed to observe the influence of fixation in two groups on revascularisation and local microcirculation of the cortical substance of bone. Results

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demonstrated that due to its special spatial configuration and material properties, the SMC cannot only form secure fixation but does less damage to the blood supply of the shaft, which is favourable for cortex revascularisation.

Therefore, as the surgical procedure described in the article shows, only a small exposure around the nonunion is needed to ensure the success of SMC implantation. Relatively speaking, the SMC is protective of blood supply compared with steel-plate fixation, which is much longer. SMC size is based on full consideration of the humeral bone anatomy and biomechanical features, with a diameter/axial length ratio of around 1:6 [3, 4]. Generally, postoperative supplementary stabilisation is not needed.

5. SMC application to femur and forearm nonunions and fresh fractures:

The SMC was designed based on the anatomical and biomechanical features of limb shafts. It is absolutely applicable to femur and forearm nonunions. For fresh fractures, the SMC is not recommended because of the disruption of the surrounding tissues. In these circumstances, steel-plate mini-invasive biological fixation is recommended. However, whether the SMC is suitable for fresh fractures needs further experimental and clinical evidence.

6. Histocompatibility of Ni-Ti alloy:

With its specific physical and chemical features, Ni-Ti alloy has been applied to many clinical areas. Its excellent biocompatibility in some aspects exceeds pure Ti. Without compromising its physical and chemical features, the surface condition is improved and dissolved Ni within the body is reduced, which improves its biocompatibility. The erosive behaviour of Ni-Ti alloy, selective attachment of Ni to plasma proteins as well as erosion resistance of the Ni-Ti alloy are the main targets of our research group in the next phase.

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