Thermal-sprayed
Silver-containing Hydroxyapatite Coating in a Rat Femoral Model: Analysis of the Initial Fixation

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Disclosures:

Introduction:
The degree of osseointegration determines the long-term survival and favorable outcomes of orthopedic implant use. Initial fixation is influenced by a number of factors. Hydroxyapatite (HA) coating has a good osteoconductive property and sealing effect on peri implant migration of particles that lead to osteolysis. Furthermore, HA-coated implants show desirable midterm clinical results. Infection prevention is another important factor that influences long-term results. Postoperative infections sometimes occur despite systemic prophylaxis, necessitating surgical treatment. This complication is not only difficult for patients and surgeons but also increases medical costs. Thus, the availability of an implant that has both osteoconductive and antibacterial properties is required. We previously developed an antibacterial coating with Ag-containing HA (Ag-HA) that releases Ag ions to achieve high antibacterial activity and low cytotoxicity in vitro [1]. Antibacterial activity against methicillin-resistant Staphylococcus aureus (MRSA) has been shown in vitro [2], in a subcutaneous rat model [3], and in a rat tibia model [4]. In addition, the Ag-HA coating has properties of both Ag and HA and shows good biocompatibility and osteoconductivity in rat tibiae [5]. However, a direct mechanical assessment has not been performed to date. Thus, the aim of this study is to evaluate the initial fixation of Ag-HA coating on titanium (Ti) in terms of shear strength.

Methods:
We prepared Ag-HA- and HA-coated implants using commercially pure titanium rods (length, 12 mm; diameter, 2 mm). The Ag-HA and HA coatings covered a 7-mm portion of the implant length, while 5 mm of the implant length was left uncoated. Each implant had a hole (diameter, 1 mm) for mechanical testing purposes on the uncoated side. We prepared three types of implants as follows: i) Ti; ii) HA coating on Ti; and iii) 3% Ag-HA coating on Ti. Twenty-one 15-week-old male Sprague-Dawley rats were used in this study. The femoral intercondylar fossa was exposed through the medial parapatellar approach. The distal femoral intramedullary canal was reamed through the intercondylar fossa with a stainless steel drill to create a hole that was 2.2 mm in diameter. Each implant was inserted into the reamed medullary canal. The rats were divided into three groups of seven according to the inserted implant. After four or 12 weeks, the rats were killed and the femora of the bilateral hind legs were excised. The radiographs were assessed for possible aseptic loosening, osteolysis, and the formation of heterotopic bone. The distal condyles of the femora were cut to expose the non-coated portions of the implants. Each femur was fixed to the instrument with cement. A stainless steel wire was passed through the hole in the
non-coated portion of the implant and the wire was fixed by a machine. The implant was pulled upwards by a jig connected to the wire until the implant was pulled out from the femur while the load was kept parallel to the long axis of the implant at a constant displacement of 2 mm/min (Fig. 1). The strongest tensile force recorded during the extraction was defined as the bone-implant shear strength (N, Newton).

Results:
At four and 12 weeks after implantation, the radiographs confirmed that the implants had been inserted correctly into the femora. There was no evidence of aseptic loosening, osteolysis, or the formation of heterotopic bone (Fig. 2). The bone-implant shear strengths of the Ti, HA, and 3% Ag-HA coating groups were 8.1 ± 4.6 N, 199.1 ± 48.4 N, and 196.5 ± 55.1 N, respectively, at four weeks and 22.8 ± 16.3 N, 324.1 ± 70.4 N, and 335.3 ± 33.2 N, respectively, at 12 weeks (Fig. 3). The value in the Ti group was significantly different from that in the HA and 3% Ag-HA groups at both four and 12 weeks (p < 0.01). No significant difference was found between the HA and 3% Ag-HA groups. After the pull out test, some bone tissue remained adhered to the surface of the HA and 3% Ag-HA implants. However, no bone tissue was seen on the surface of the pulled out Ti implants.

Discussion:
No studies in vivo have performed a direct mechanical assessment of the Ag-HA coating. The results of this study demonstrate that the 3% Ag-HA coating has the same effect on bone-implant shear strength as the HA coating. The 3% Ag-HA coating was shown to have an equal initial fixing property to that of the HA coating in the rat femora. Yonekura et al. [5] evaluated the affinity indices in the rat tibiae and described the percentage of bone formation and bone contact. They reported that the affinity indices of the 3% Ag-HA coating were the same as those of the HA coating. This finding supports this result of the direct mechanical assessment described here and shows that the effect of HA will not be subtracted if low-dose silver is employed. Ag toxicity depends on the dose. The content of Ag₂O including 3% Ag-HA was approximately 0.3% by weight after spraying compared to 3% by weight before spraying. The low dose of Ag in the Ag-HA coating does not inhibit bone regeneration. Thus, the Ag-HA coating, which has properties of both HA and Ag, is useful for orthopedic implants. Thus, 3% Ag-HA coating on implants may be a biologically safe antibacterial biomaterial that may be used to reduce the incidence of implantation-related surgical-site infections.

Significance:
Ag-HA coating on implants may facilitate good osseointegration and be a biologically safe antibacterial biomaterial. Its use may be of value for reducing the incidence of surgical-site infections related to implantation.

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References:

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Figure 1  Diagram showing the apparatus for the push-out test.
Figure 2  X-rays of the right femur with implant at four weeks after implantation.  
(A) A-P view  
(B) Lateral view

Figure 3  Bar graph showing mean shear strength of each groups at 4 and 12 weeks after implantation.  *  p<0.001

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