NOTE ***Surgery***

Fixation to the Canine Bone of Artificial Implant with New Surface Structure

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ABSTRACT. Screw and laser (SL) column by making screw threads and forming small holes using laser irradiation on the base metal and conventional beads coating (BC) columns were embedded into the shaft of canine femurs, and compared the implant fixation to the host bone. The interfacial strength in SL columns was almost equivalent as BC columns, and bone-column contact rate was higher than BC columns significantly at twelve weeks after implantation. The newly devised SL surface had almost equivalent bone fixation strength comparable to the conventional BC surface. Also, this surface should provide a useful porous surface for use in artificial joints since there is no risk of surface structure detachment.

KEY WORDS: artificial joint, canine, porous.

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Cementless artificial joints were initially developed to avoid complications associated with cemented artificial joints, such as fibrous tissue formation at the boundary with osseous tissue, cement damage, infection [9], hypotension due to residual harmful monomers, and necrosis of surrounding tissue due to polymerization heat associated with hardening. Cementless artificial joints are porous to allow bone in-growth, and as a result, bone fixation depends largely on the condition of host bones, load transfer in bones, artificial joint materials and surface structures. Many artificial joint designs and materials have been developed since the introduction of artificial joints in the 1980s [9] and cementless artificial joints are now widely applied in clinical medicine. However, there are problems associated with the use of these joints, for example, direct contact between osseous tissue and high strength metal leading to stress shielding and loosening of joints due to subsequent bone resorption [1].

Currently, artificial joints have porous surfaces created by a bead or mesh coating [15], where a porous material is applied by diffusion bonding to the base metal. Since these porous surfaces are made of fine three-dimensional porous structures, osseous tissue can grow into pores over time; however, beads or fiber mesh can become detached due to weight bearing [3, 7].

In an attempt to solve these problems, we created a porous surface on the base metal by making screw threads and forming small holes using laser irradiation on the base metal. As a basic study, to mechanically and histologically observe implant fixation to the host bone, columns with this porous surface and conventional beads coating columns were embedded into the shaft of canine femurs.

Columns were inserted in the femurs of eight healthy beagle dogs, 1 to 3 years old weighing 8 to 12 kg, according to the guidelines established by the Animal Study Committee at Rakuno Gakuen University. Figure 1 shows the configuration of two columns. Screw and laser columns (SL columns) were made by subjecting titanium alloy cylinder (Ti-6Al-4V) with a diameter of 4.5 mm and a length of 13 mm to screw threading followed by laser irradiation to form small holes with a depth of 1 mm and a diameter of 0.3 mm. The porosity index of the SL columns was 33.7%. For comparison, Ti-6Al-4V columns with a diameter of 4.5 mm and a length of 13 mm were coated with beads (diameter: 425–500 μm; BC columns) by diffusion bonding. The porosity index of BC columns was 35%.

Under general anesthesia, the shaft of the left femur was exposed, and four 4.5 mm holes were made 1.5 cm apart to insert SL columns. For comparison, four BC columns were inserted into the shaft of the right femur in the same manner. After surgery, 25 mg/kg of cefazoline sodium (Cefamezin®, Fujisawa Pharmaceutical Co., Osaka, Japan) was administered for seven days, 0.5 mg/kg of ketoprofen (Mejade®,

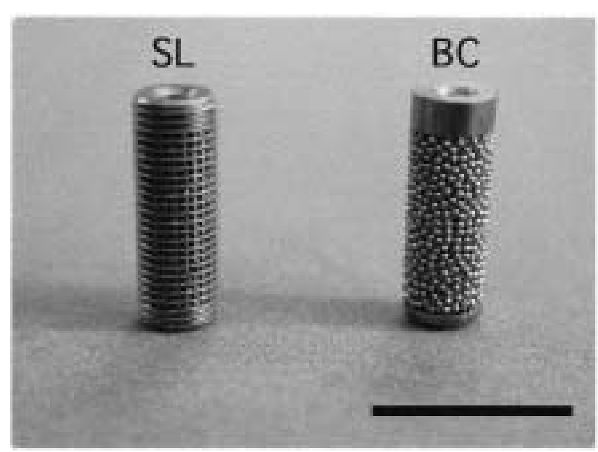

Fig. 1. Photograph of the Screw and laser (SL) and Beads coating (BC) columns. Each column has a diameter of 4.5 mm and a length of 13 mm. Scale bar =10 mm.

Nisshin Pharmaceutical Co., Yamagata, Japan) and 0.01 mg/kg of buprenorphine hydrochloride (Lepetan®, Otsuka Pharmaceutical Co., Tokyo, Japan) was administered for three days, and then 2.2 mg/kg of carprofen (Rimadyl®, Pfizer Japan Inc., Tokyo, Japan) was administered for seven days.

The columns were removed from four dogs at six weeks and from four at twelve weeks after implantation. Under general anesthesia, the shaft of the femur was exposed and 2 cm semi-columnar specimens were removed using a sagittal saw and bone chisel.

Each column specimen was subjected to a push-out test [2, 5, 9] using Instron Universal Testing Instrument Model 1130 (Instron Co., Canton, ND, U.S.A.) to assess fixation between the femur and the column. In this test, the cross head was pushed out at a rate of 0.5 mm/min until the applied load peaked and started to decrease. Shear strength was calculated using the following formulae [11].

Shear strength (mega pascal, MPa) = load at failure / contact area (mm^2)

Contact area (mm^2) = $\pi \times$ column diameter $\times$ average cortical thickness

In the push-out test, the mean ± standard deviation for shear strength was calculated, and a Student's *t*-test was used to statistically compare the two groups. P values less than 0.05 were considered significant.

Bone in-growth was analyzed on the specimens used for the push-out test by light microscopy. Each specimen was fixed in 10% neutral buffered formalin, dehydrated using ethanol, embedded in polymethylmethacrylate, sliced into 100 μm sections, and stained using toluidine blue O stain.

After histological observation, the bone-column contact rate (%) for six and twelve weeks were calculated using the free software, NIH image 1.62 (National Institute of Health, Bethesda, U.S.A. available on the Internet at http://rsb.info.nih.gov/nih-image/) on Macintosh personal computer system. It was calculated the length of contact part on bone and column deviated by the total length of column. One slice of one column was measured for calculation. Thus, twelve slices were analyzed for each type of column at each implantation time. The mean ± standard deviation for contact rate was calculated, and a Student's *t*-test was used to statistically compare the two groups. P values less than 0.05 were considered significant.

Figure 2 shows the results of the push-out test. Six weeks after implantation, the shear strength for SL columns and BC columns was 13.7 ± 4.7 and 14.0 ± 3.7 MPa, respectively, with no significant difference between the two groups. Twelve weeks after implantation, the shear strength for SL columns increased slightly to 15.1 ± 5.3 MPa, while that for BC columns decreased slightly to 13.7 ± 4.5 MPa, but with no significant difference between the two groups.

Figure 3 shows histology of two columns after six weeks. The contact between the SL columns and the bone was incomplete in some areas, bone in-growth was observed to reach the bottom of the holes in most areas. However, bone in-growth for the BC columns was observed, it did not reach

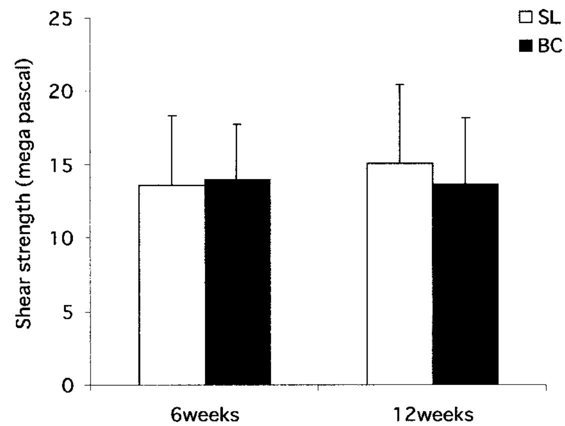

Fig. 2. Results of push-out test. The error bar indicates standard deviation for the twelve columns in each group. There was no significant difference between the two groups. SL; Screw and laser column, BC; Beads coating column.

the base metal. Figure 4 shows histology of two columns after twelve weeks. The bone in-growth was complete for the SL columns. However, while the degree of bone in-growth for the BC columns was greater at twelve than at six weeks after implantation, it did not reach the base metal in some areas. Figure 5 shows the results of the bone-column contact rate. Six weeks after implantation, the contact rate for SL columns and BC columns was 70.8 ± 3.9% and 68.9 ± 2.4%, respectively. There was no significant difference between the two types of columns with the numbers available. Twelve weeks after implantation, the contact rate for SL columns and BC columns was 75.9 ± 2.5% and 73.3 ± 2.6%, respectively. There was significant differences between the two columns ($P<0.05$).

Cementless artificial hip joints were developed to resolve the problems associated with cemented total hip replacement. In recent years, various studies have been conducted and these joints are most commonly used in clinical settings [3, 14]. In the present study, the pore sizes for porous SL and BC were 300 and 425 μm, respectively. It is generally accepted that the pore size needs to be at least 150 μm in order for bone in-growth to develop. When pores are smaller than 100 μm, vascular invasion is poor and osseous tissue cannot grow due to poor blood circulation [4, 6, 12]. However, when pores are too big, stability is reduced by connective tissue invasion. Indeed, the average pore size for human artificial joints is 350 μm (range: 100–500 μm) [13]. Based on these observations and continuous pore formation, we believe that the optimal pore size is 200–400 μm.

Medial bone growth is essential for favorable fixation soon after placement of cementless artificial joints [8]. To achieve long-term stable fixation of an acetabular shell to osseous tissue, sufficient long-term bone in-growth must be achieved solely through the porous surface. For this to occur, the porous surface needs to be of a certain thickness, and at the same time, bonded strongly to the base metal. Hence, we developed an implant with porous base metal

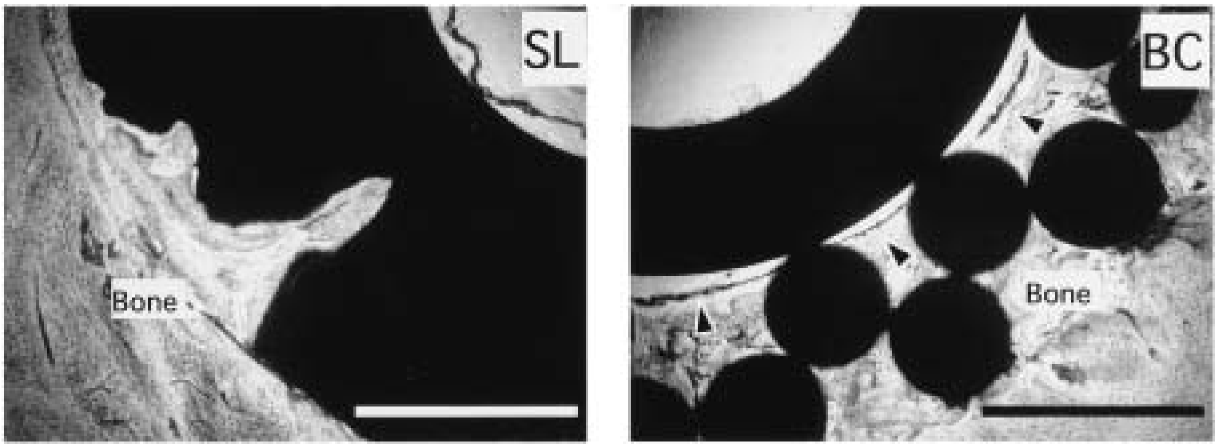

Fig. 3. Toluidine blue staining of undecalcified section at six weeks. SL: Screw and laser column. Bone in-growth was observed to reach the bottom of the holes in most areas. BC: Beads coating column. Bone in-growth was observed, but it did not reach the base metal (arrows). These findings were observed all around the base metal. Scale bar =1 mm.

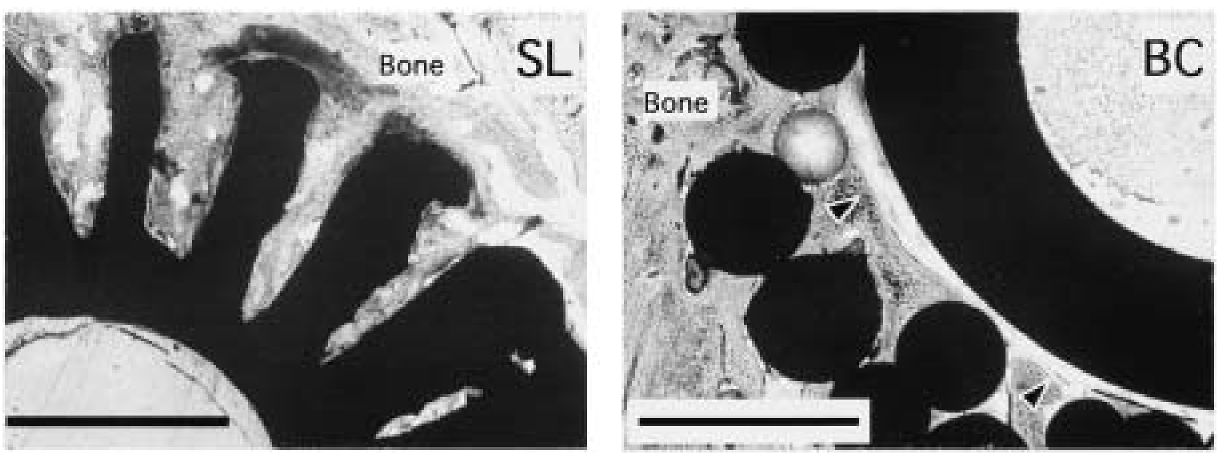

Fig. 4. Toluidine blue staining of undecalcified section at twelve weeks. SL: Screw and laser column. Bone in-growth was completed. BC: Beads coating column. The degree of bone in-growth was greater than that at six weeks after implantation, but it did not reach the base metal (arrows). These findings were observed all around the base metal. Scale bar =1 mm.

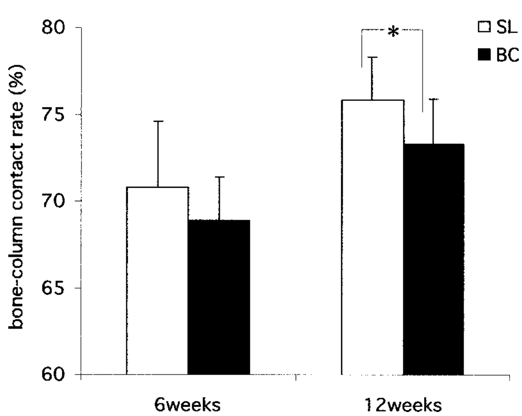

Fig. 5. Results of measurement of bone-column contact rate. The error bar indicates standard deviation for the twelve samples in each group. * represents where P<0.05. SL; Screw and laser column, BC; Beads coating column.

instead of applying porous material to the base metal. When forming a strong bond between bone and implant, bone in-growth is important, and this is reflected in the degree of shear strength [14].

In conclusion, the newly devised SL surface had almost equivalent bone fixation strength comparable to the conventional BC surface in mechanical and histological examinations. It is assumed that the bone in-growth between two types of column will differ for longer observation time, because the bone-column contact rate of SL column in twelve weeks was higher than that of BC column significantly. Also, because the SL surface is created on the base metal, it should be a useful porous surface for use in artificial joints since there is no risk of surface structure detachment.

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