Biocompatibility evaluation of Ti-15Mo-1Bi alloy in rabbit femur

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Reported in this presentation is histological evaluation of a newly-developed beta-phase Ti-15wt%Mo-1wt%Bi alloy implanted in rabbit femur. Ti-15Mo-1Bi and Ti-6Al-4V (control) alloys were prepared using a commercial arc-melting vacuum-pressure type casting system (Castmatic, Iwatani Corp., Japan). To fabricate Ti-7.5Mo-1Bi alloy, appropriate amounts of Ti, Mo and Bi, each with 99% in purity, were melted in a U-shaped copper hearth with a tungsten electrode. Ti-6Al-4V alloy was fabricated from re-melting of commercial Ti-6Al-4V (ELI) rods. For animal study, cylindrical pins, 6 mm in length and 2 mm in diameter, were fabricated. The surface of cast alloys was sandblasted with 250 μm alumina powder, etched with HF/HNO3 acid and cleaned with acetone and distilled water.

Twelve 2.5-3 kg adult male New Zealand rabbits were selected for this study. The knee joint region was selected as the implantation site. This region was cleaned and given local anesthetics of atropine, 0.001 mg/kg, through subcutaneous injection. A hand drill with a screw rod of 2 mm in diameter and 7 mm in length was used to drill a hole through cortical bone into bone marrow, which was located at the lateral part of distal femur and about 10 mm proximal to the distal end of femur. The alloy pins were individually pressed into the pre-drilled holes of the left and right femurs of rabbit (n=4). After survival periods of 6, 12, and 26 weeks, the rabbits were sacrificed using intravenous injection of 15% potassium chloride, 1.5 ml/kg, in conjunction with ketamine anesthesia. The distal piece of each femur, which contained the Ti alloy pin, was fixed with 10% neutral buffered formalin at 4°C for 3 days and dehydrated with a series of graded ethanol. Samples were then embedded in methylmethacrylate (MMA) and sliced into six 250 μm thick sections, from lateral to medial, using a Buehler low speed diamond saw. These sections were further polished to a final thickness of about 50 μm, then stained with toluidine blue and photographed using an optical microscope with a digital camera. The areas of new bone tissue surrounding the implant were measured within a 2.5 mm dia. circle, concentric to the implant pin on each section. The areas of new bone growth surrounding the pins were calculated using a computer program (Image Pro). Levels of new bone formation were analyzed and compared among various sections at various post-implantation times as well as between the two alloys using a two-way ANOVA statistical analytic method followed by Tukey's post-hoc comparison.

The results indicate that, at 6, 12 and 26 weeks post-operation, new bone formation was seen around the implanted pins of both alloys. The amount of new bone formation decreased from cortical bone implantation site to marrow cavity site (sections 1-5). The new bone areas measured at section 1 (exterior site) always have the highest values among all sections. The highest cell activity existed near the endosteum side of the cortex. In Ti-6Al-4V system, the new bone area measured in section 1 increased with implantation time. Although increasing in new bone area was found in all inner sections (sections 2-5) between week 6 and week 12, the new bone areas in these sections showed decreases with implantation time between week 12 and week 26. The new bone area in section 2 at week 26 was only about 1/3 that of section 2 at week 12, and the new bone area of section 3 and 5 also showed significant decreases between week 12 and week 26.

In Ti-15Mo-1Bi system, the decrease of new bone area between week 12 and week 26 was not found. In the opposite, new bone areas were found to show continuous increase with implantation time. As a result, at 26 weeks post-implantation, new bone areas found in sections 2-4 were 3 to 4 times higher than that found in Ti-6Al-4V system. This result suggests that Ti-15Mo-1Bi alloy has significantly higher biocompatibility than Ti-6Al-4V.