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# Animal Experiment on *In vivo* Galvanic Corrosion of SUS316L and Ti-6Al-4V

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## Abstract

Generally, the combination use of difference metals occurs galvanic corrosion. Therefore, the combination use of SUS316L (SUS) and Ti-6Al-4V(Ti64) is supposed to be prohibited in human body. However, there are necessary cases of the combination use in clinical orthopedics.

In order to investigate the *in-vivo* galvanic corrosion, the plates and screws made of SUS and Ti64 were implanted into the proximal tibia of the rabbits for 52 weeks. The plate and screws were implanted in 4 different combinations of pairing up in different metals and identical metals.

By means of X-ray follow-up and Contact Micro Radiography (CMR), new bone formation around the implants was investigated. And cytopathological observation was performed on the surrounding tissue. Regarding to the implants, microscopic observation was performed on the removed implants surface. Furthermore, metal element analysis was carried out to investigate chromium ion release as a sign of the galvanic corrosion.

In X-ray follow-up and CMR, the bone tissue under the plates became thin and porous like as concellous bone in all the combinations, which is supposedly due to the stress shielding and the disturbance of periosteal blood flow by the implantation. In the surrounding soft tissue and bone tissue, no remarkable findings were obtained in the cytopathological observation.

Regarding to microscopic observation of the implants, short striations with metallic luster in SUS implants, and short striations with metallic luster or dark brown color in Ti64 implant were confirmed. However these are supposedly caused by the scratching or frictional damage during the screw fixation.

In metal element analysis, the Cr element elution was confirmed around the SUS plates. However, there is no significant difference between SUS screw (identical metals) and Ti64 screw (different metals).

As the results, the *in-vivo* galvanic corrosion and related changes were not confirmed in all investigations at 52 weeks.

**Keywords:** Galvanic corrosion; *in-vivo*; Animal experiment; Titanium; Stainless steel

## Introduction

Because of the risk of galvanic corrosion, combination use of different metals is supposed to be prohibited in *in-vivo* environment. Ti-6Al-4V (Ti64) has been use for biomaterials due to its good biocompatibility [1-3]. Therefore, the combination use with the conventional stainless steel of SUS316L (SUS) is increasing due to accidental misuse in emergency cases or necessary choice of stainless wire to tie up bone fragments in complicated fracture and femoral mid shaft fracture after Total Hip Arthroplasty. Ideally, these high quality implant metals of SUS and Ti64 will avoid even galvanic corrosion due to the very stable oxide film [4]. However, the combination use of different implant metal is prohibited by instruction manuals of the medical devices.

There are some reports for *in-vitro* galvanic corrosion [5-7]. Okazaki reported that galvanic corrosion was occurred when the corrosion potential difference of materials is more than 600 mV vs. SCE [8]. The corrosion potential difference of SUS and Ti64 is smaller than that value. On the other hand, there have been few reports for *in-vivo* galvanic corrosion [9].

The purpose of this study is to investigate whether *in-vivo* galvanic corrosion occurs, and the influence of that on the tissue by animal experiment with the fracture fixation devices of the plate and the screw made of SUS and Ti64.

## Material and Methods

Mini DC plates with 6 screw holes (32×5×1.2 mm) and cortex screws (2×12 mm) made of SUS and Ti64 were subjected to this study. These implants were commarcial products for the finger fracture fixation from Synthes GmbH, solothurm, Swizerland. The Mini DC plates were cut in half (31×5×1.2 mm), and implanted with the 3 cortex screws in 4 different combinations (Table 1).

As experimental animals, 6 mature New Zealand white rabbits were used for this *in-vivo* study. As general anesthesia, the mixture liquid of Ketalar (Ketamine) 150mg and Celactal (Xylazine Hydrochloride) 6mg was subcutaneosly injected at the back of neck. As additional

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| Plate | Screw |
|---|---|
| SUS316L | SUS316L |
| SUS316L | Ti-6Al-4V |
| Ti-6Al-4V | Ti-6Al-4V |
| Ti-6Al-4V | SUS316L |

**Table 1:** Implant combinations.

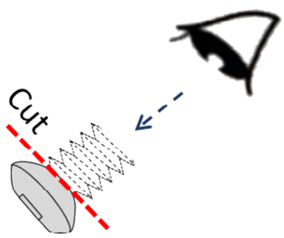



**Figure 1:** The direction of observation.

local anesthesia of the surgical site, Xylocaine 1% with Epinephrine was subcutaneously injected and sprinkled to the exposed soft tissue. Subsequently, the plate was placed at the medial aspect of proximal tibia, and fixed by 3 cortex screws in the specific combination.

In order to investigate the bone formation around the implants, X-ray pictures were taken at 0, 24 and 52 weeks after implantation. At 52 weeks, tibia bones were harvested with the implants. During harvesting, tissue reaction was carefully inspected every soft tissue layer. Bone tissue formed on the implants was carefully detached, and the screws were removed. After that, the screws were cut near the screw head and the plate and the back surface of screw heads were observed by stereoscopic microscope (Figure 1). Furthermore, the tibia bones with the metal plates were cut into thick slice and dehydrated, then embedded in polymethyl methacrylate (PMMA). And thin specimens were made for Contact Micro Radiogram (CMR), and cytological observation.

By means of Electron probe Micro Analyzer (EPMA-1720H, Shimazu, Kyoto), Additional Element mapping analysis was performed on the thin specimens with SUS plates, in which Chromium (Cr) was selected as an marker element of the anodic dissolution due to the galvanic corrosion because the standard electrode potential of SUS is lower than that of Ti64, SUS is accordingly supposed to be corroded.

This animal study was performed at the animal experiment center of Aichi Medical University, which was approved by the animal experiment ethics committee of Aichi Medical University in compliance with an act of Welfare and Management of Animals enacted by The Ministry of the Environment in Japan according to International Guiding Principles for Biomedical Research Involving Animals announced by the Council for International Organizations of Medical Sciences 1985.

## Results and Discussion

### X-ray photograph (X-P) follow-up

At 24 weeks after implantation, new bone formation was observed around the implanted plates in all the combination. Especially at Ti64 plate, the bone formation was active showing double-layer structure of original cortical bone and newly formed bone at the plate edges.

At 52 weeks, all the plates were covered by bone tissue, but the cortical bone under the plates became thin in all the combinations. It is considered as the results of the stress shielding and the disturbance of periosteal blood flow due to the implanted metal plates [10,11]. No abnormal findings such as osteolysis and malformation to be possibly caused by the galvanic corrosion were observed in Figure 2.

### Visual observation during harvesting

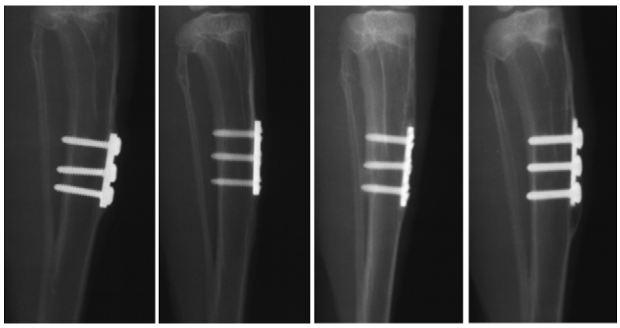
In order to observe the influence of the galvanic corrosion on the surrounding soft tissue, the outer skin, subcraneous and muscular tissues were carefully removed layer by layer. No discoloration was confirmed in the exposed subctaneous tissue and the fascia. Swelling and necrosis were not observed in muscles and periosteum. And the implants were mostly covered by newly formed bone tissue (Figure 3).

In general, foreign body reaction derived from metal corrosion and wear is known as metallosis involving tissue necrosis and absorption due to continuous and chronic inflammation, generation of granulation tissue, and the dark brown discoloration of surrounding tissue.

From the findings, no abnormal tissue reaction was observed in surrounding tissue and the tibia bone. Therefore, no influence of the galvanic corrosion was confirmed.

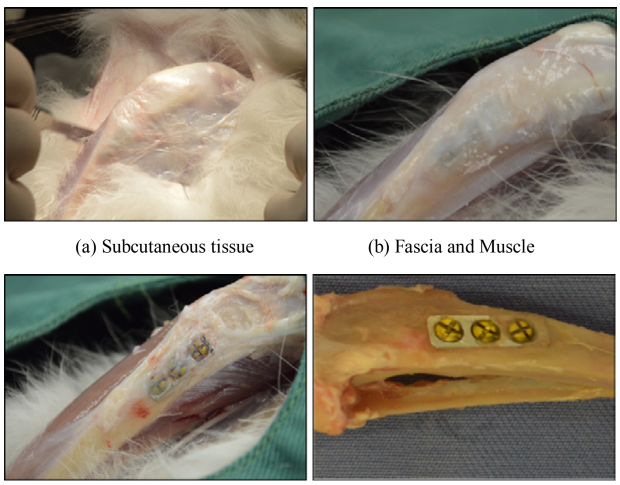
### Cytopathological observation

In the soft tissue sampled from directly over the implants, connective tissue consists of muscular tissue, fat tissue and collagen



(a) SUS-SUS (b) SUS-Ti64 (c) Ti64-Ti64 (d) Ti64-SUS

**Figure 2:** Bone formation around implant (Plate-Screw).



(a) Subcutaneous tissue (b) Fascia and Muscle (c) Periosteum (d) Tibia bone and Implants

**Figure 3:** Visual observation (Plate: SUS, Screw: Ti64).

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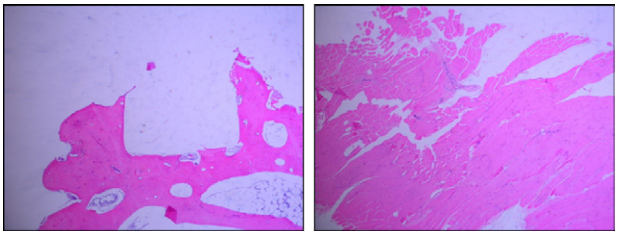
fibers was observed, but no granulation tissue was confirmed. In the surrounding bone tissue, normal osteocytes and bone marrow cells were observed, but macrophages as the immune system cells and the cellular necrosis were not confirmed.

In general, the process of cellular repair shows the inflammatory cell infiltration and the granulation tissue [12]. However, no remarkable findings were obtained in the cytopathological observation (Figure 4), which suggests no influence of the galvanic corrosion in the surrounding tissue.

### CMR observation of bone tissue

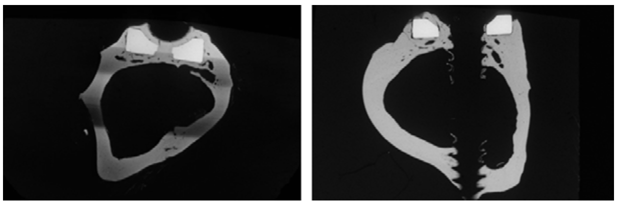
In the specimens harvested at 52 weeks, bone formation covering the implanted plate and also getting into the narrow gap of the implants was observed in all the combination. Consequently all the plates were almost buried in the cortical bone. And the bone tissue under the implanted plates became thin and porous like as concellous bone in all the combinations (Figure 5).

These findings are almost the same as the results of X-P follow-up, which is also considered as the results of the stress shielding and the disturbance of periosteal blood flow due to the implanted metal plates, but not due to the galvanic corrosion.



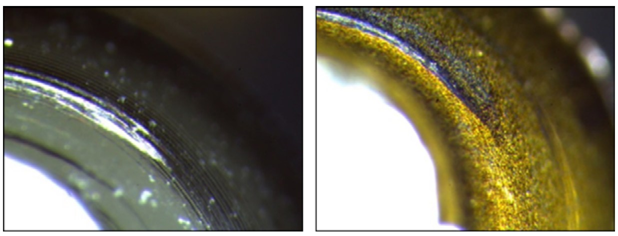
(a) Bone tissue (b) Soft tissue over the plate

**Figure 4:** Cytological observation (Plate: SUS, Screw: Ti64).



(a) SUS-SUS (b) SUS-Ti64

**Figure 5:** CMR of cross section (Plate-Screw).



(a) Plate: SUS, Screw: SUS (b) Plate: SUS, Screw: Ti64

**Figure 6:** Microscopic observation of bottom of screw head.

### Microscopic observation of implant surface

Regardless of the implant combination, SUS implants showed circumferential short striations at the inner surface of the screw hole and the bottom surface of the screw head (Figure 6). However, the short striations maintained the metallic luster with no discolorations.

Therefore, the short striations were probably caused by not the corrosion, but by the concentric friction during tightening the screws.

On the other hand, in Ti64 implants, the circumferential short striations with metallic luster or dark brown color were observed on the implant surfaces of yellowish brown color. It is well known that the color change of the Titanium system alloy depends on the thickness of the oxide film [13]. The Ti64 implants subjected to this study is colored yellowish brown by the anode oxidation. Therefore the short striations with metallic luster or dark brown color were probably caused by the scratching or frictional damage of the oxide film. Although it is confirmed that the oxide film of the implant surfaces will be damaged by the scratching or friction during the screw fixation, the oxide film will be repaired soon in the open field of operation. Accordingly the high corrosion resistance will be maintained in those anti-corrosion metals.

### The element mapping analysis

Assuming Chromium element elusion due to the galvanic corrosion, Element mapping analysis targeting Cr(Cr-Kα) was executed on the thin specimens with the SUS plates in the different combinations of the SUS screws(identical metal) or the Ti64 screws (different metal).

As the background of mapping analysis, Cr elements were almost evenly detected at the bone tissue because the very small amount of Cr is physiologically contained in human body with the rate of 28.5 ng/kg [14,15].

Around the SUS plates, regardless of the screw materials of SUS or Ti64, Cr elements were detected with the concentration gradient, which is suggested Cr elements elusion from the SUS plates (Figure 7).

However, there is no significant difference between the combinations of SUS screw and Ti64 screw. Consequently, this Cr element elution is considered to be not due to the galvanic corrosion.

### Risk of the galvanic corrosion

In this animal study of 52 weeks after implantation, the *in-vivo* galvanic corrosion due to the different metals of SUS and Ti64 was not confirmed in all investigations. The results suggest no risk of the galvanic corrosion with such high corrosion resistant metals in short term. However, the scratch and friction damages of the oxide film were observed at the contact surface in the screw fixation. Also Cr element elution from the SUS plates with either SUS screws or Ti64 screws was confirmed.

In addition, this animal study is only simulating the contact of different metals in living body, which experiences the temporary inflammation in the healing process of surgical damage, in other words, a secure environment for the galvanic corrosion. Accordingly the risk of the galvanic corrosion still remains in long term, and in more severe corrosion environments such as continuous chronic inflammation due to the infection, the instable fixation of fracture and the implants. Furthermore, other factors can be considered such as the decrease of corrosion resistance, precursory corrosion of Stainless Steel, the friction and wear of the implants, the ratio of the surface areas, etc. It is generally thought that the passive oxide film of the high

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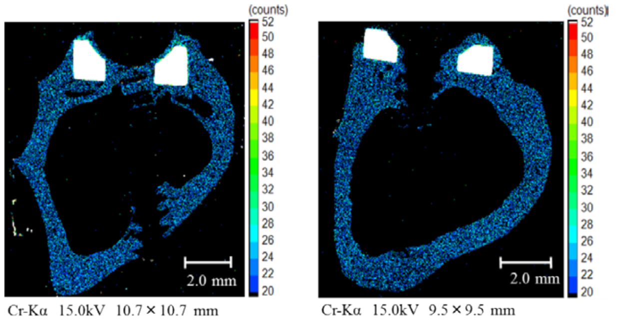


(a) Plate: SUS, Screw: SUS (b) Plate: SUS, Screw: Ti64

**Figure 7:** Cr element mapping analysis on SUS316L plate.

corrosion resistant metals is very stable, and protects the metals from the corrosion. Even if the passive oxide film is damaged by scratching, the film is immediately repaired by reoxidation. However in electrolyte solution and *in-vivo* situation, the passive oxide film repeats the dissociation and reoxidation, where the lack of the dissolved oxygen results in the failure of the passive film repair.

Regarding Stainless Steel, some typical corrosions are well known as pit corrosion due to the perforation of chlorine ion, and crevice corrosion due to inhomogeneous distribution of the dissolved oxygen. These corrosions can be the precursory to the galvanic corrosion. In case of the implants with instable fixation, there exists the friction and wear between implants or between implant and bone tissue. The friction and the wear particles damage the passive oxide film, and the wear particles may induce severe inflammation. Therefore, the friction and wear can be the multiple factors for the galvanic corrosion. It is also well-known that the corrosion potential difference of metal materials depends on not only the standard electrode potentials but also the surface areas ratio of Cathode/Anode. For instance, the combination use of a big Ti64 plate and small SUS screws, or a titanium alloy hip stem and stainless steel wire may induce the galvanic corrosion.

## Conclusions

In order to investigate the *in-vivo* galvanic corrosion, and the influence on the surrounding tissue, the plates and screws made of SUS and Ti64 were implanted into the rabbit tibia for 52 weeks. The plate and screws were paired up in the different metal combination as the *in-vivo* galvanic model, and the identical metal combination as the control.

In X-ray follow-up and Contact Micro Radiography, the bone tissue under the plates became thin and porous like as concellous bone in all the combinations, which is supposedly due to the stress shielding and the disturbance of periosteal blood flow by the implantation.

In the cytopathological observation, no remarkable findings were obtained in the surronding soft tissue and the bone tissue.

In microscopic observation of the metal implants, short striations with metallic luster in SUS implants, and short striations with metallic luster or dark brown color in Ti64 implant were confirmed, which is supposedly caused by the screw fixation. In metal element analysis, the Cr element elution was confirmed around the SUS plates in both the combinations of SUS screw (identical metals) and Ti64 screw (different metals) with no significant difference.

As the results, the *in-vivo* galvanic corrosion and related changes were not confirmed in all investigations. However, the risk of the galvanic corrosion still remains in long term, and in more severe environments. Therefore, further investigations and related research are requested.

### Acknowledgement

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