

Central Iwate-Kamaishi Area

Development of "New" Nickelless Co-Cr-Mo Alloy with Enhanced Functionality and High Biocompatibility to Be Applied to Medical Devices

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Project Promotion

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Major Participating Research Organizations

Industry...Nittetsu Fine Products Co., Ltd., Dowa Forging Co., Ltd., Ferrotec Corporation, TOHOKU NIPPATSU CO.,LTD., MIKUNI CORP, TOKOSHA CO., LTD., TOKYO WIRE WORKS, LTD., and other 14 participating organizations, which totals 21 organizations
Academia...Iwate University, Iwate Prefectural University, Iwate Medical University, Tokyo Medical and Dental University, Kobe University
Government...Iwate Institute Research Center, National Institute for Material Science, Kamaishi Otsuchi Industrial Research Development and Training Center

Core Research Organization

Iwate University

Aim of research and development

The most of medical equipment are imported from Europe and the United States in Japan though the market scale of medical equipment is increasing due to the arrival of a graying society. Moreover, a metallic allergy caused by the nickel is a serious problem in Europe recently, and the voice to request the non-magnetic material corresponding to opening MRI etc. has become clamorous on the medical treatment site. Therefore, the development of the creation of a specific and quality metallic material (biomaterial) in various functionalities demanded for the medical treatment, which should be safe, and strong. Medical application device that uses are also in a pressing need.

From the above-mentioned viewpoint, "the high performance nickel-less alloy for medical use" that is original seeds of Department of Engineering at the University of Iwate, and the technologies of the prefecture known as "town of iron" for the city of Kamaishi were combined for research and development by industries, academia and government. It aims at strengthening the intellectual foundation for the metal system biomaterial and the creation of the high-value-added type metal for the biomaterial industry though the study to achieve a higher functionality of the material and the high biocompatibility.

Contents of research

1. Creation of excellent medical application Co-Cr-Mo alloy with durability, safety, and functionality

The artificial joint replacement operations are in the elevational trend as the only surgical treatment for a lot of bone diseases seen by the senior citizen every year. However, some problems have surfaced along with it. It is a necessity of the non-magnetic material that corresponds to a diagnostic device such as MRI where has the strong magnetic field, as well as a concern of allergic problems for some people due to nickel contained in biomaterials of metal. Moreover, there are some problems of durability like the fatigue of the components as well as potential risk of bone melting due to a large amount of debris from sliding surfaces of the artificial joints.

Based on the above-mentioned background and in this research, a further improvement of durability, safety, and the functionality (non-magnetism) are requested for biomaterials of "nickel-less" for medical use with high performance Co-Cr-Mo alloy". That is original seeds of Department of Engineering at The University of Iwate. Therefore, it is aims at establishment of the superplastic forming technology that enables the processing into a free shape of the materials.



Vacuum melting furnace which is vital for alloy manufacturing in Kamaishi Area

2. Creation of high biocompatible frame type Co-Cr-Mo alloy

The developed alloy needs to be improved to have more adaptability with the bones to the artificial joint for practical use. This is because it becomes easy to cause the uncomformability happens to the distortion by contacting of bones and the metal in the bone. It could cause movement or deformation of bones. Therefore, it is important to consider the proper way to anchor the bones and the artificial joints. If it has no interfacial adaptability in spite of comparable dynamic adaptability, it could cause an early loosening of the artificial joints.

Thus, it aims at a biocompatible improvement of nickel-less Co-Cr-Mo alloy in this research.

3. Creation of Co-Cr-Mo alloy for blood and circulatory organs for medical use

Recently, the stent treatment that uses the catheter technology is rapidly increasing for the diseases of circulatory organ systems as a treatment method that require no surgery to open chest or abdomen. In this term, as the stent that is a small cylinder of the reticulation of the metal wire would remain in the intravascular for a long term, it may become the factor of excessive defensive reactions of human body. Moreover, there is a problem of the nickel allergy mentioned above. In this research, it aims at the establishment of the method of controlling the excessive defensive reaction.



Cytotoxic tests for new alloy

The main study results

1. Development of bridging nickel-less Co-Cr-Mo artificial joint made of Mo alloy and in

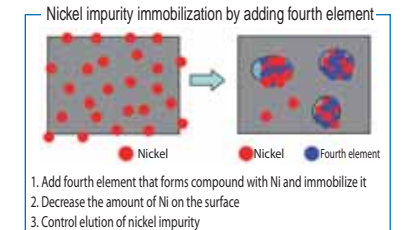
The superplasticity technology that enables improvement of durability by the microstructure control, a biocompatibility, and the arbitrary shape is accomplished, and it aims at the practical use of a variety of medical application devices that use nickel-less Co-Cr-Mo alloy. In particular, bridging products are developed for artificial hip joints or knees etc, and artificial joint product inside the bones for fixation of its fracture.



Photo of a lecture for actual examples of artificial hip prosthesis by orthopedic clinicians

2. Achievement of substance innocuous process of nickel impurity inevitably contained in nickel-less Co-Cr-Mo alloy

As for nickel-less Co-Cr-Mo alloy, a small amount of nickel is inevitably contained in the alloy as cobalt impurities that are the raw materials. Department of Engineering at the University of Iwate has a seed of solution that makes the plastic working without the nickel addition for the first time in the world, which was said to be impossible. While the substance innocuous process of the nickel impurity was achieved, and further nickel allergic measures method was established.



Establishing the method of immobilizing nickel impurity in alloy by adding fourth element

3. Development of nickel-less Co-Cr-Mo alloy non-magnetic device material for good compatibility of blood

When the diagnostic unit that uses the strong magnetic field such as MRI is used, the magnetic substance in human body could affect diagnostic images. The origin of the paramagnetic susceptibility of nickel-less Co-Cr-Mo alloy is controlled for the solution, for development of non-magnetic device material is accomplished with it. Non-magnetic device materials are used for medical application scissors and the surgery apparatus, other than medical application devices such as the cerebral artery bump clips.

4. Development of excellent nickel-less Co-Cr-Mo alloy blood vessel system device material in blood compatibility

With an aim to make a practical use of nickel-less Co-Cr-Mo alloy for the blood vessel system medical application device such as stents, a method to control an excessive defensive reaction of human body is still developed.

