Dear whom it may concern

April 23, 2018

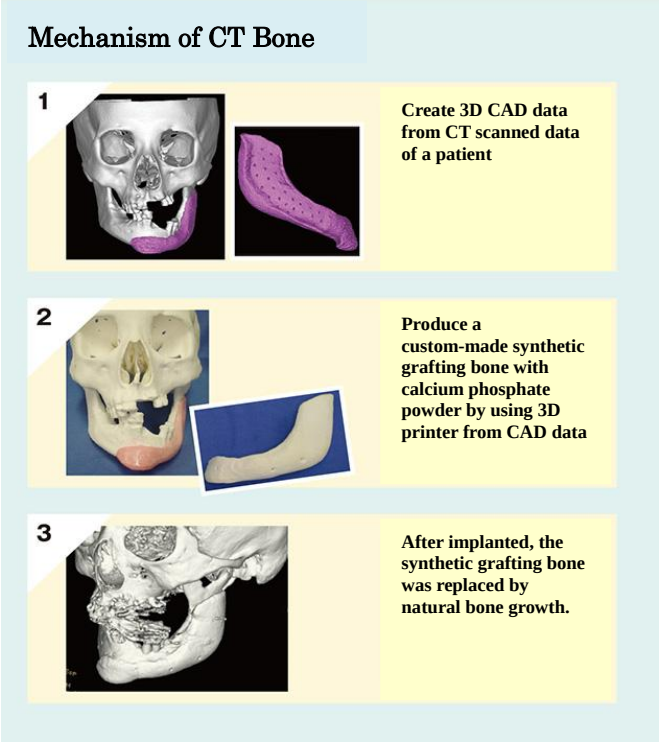
Announces the launch of an epoch-making synthetic bone graft

~Innovation from Japan to the world~

Today, we are pleased to announce our formal approval on May, 2018 for our new technology to produce synthetic bone grafts molded by 3D printer, which can fuse and assimilate into the patient`s bone.
The pre-clinical study for the present project was completed with a subsidy from the New Energy and Industrial Technology Development Organization (NEDO), and the clinical study was performed with support by the National Institute of Biomedical Innovation, Health and Nutrition (NIBIOHN).
In 2001, Next21 K.K. initiated developmental research into this technology in collaboration with RIKEN and the University of Tokyo. In April 17th 2018, We have received an approval for manufacturing and marketing medical devices from The Ministry of Health, Labor and Welfare (MHLW). Also we will simultaneously develop manufacture and selling business toward European market as well as in Japanese market.

Background:

Patients with congenital bone defects, acquired bone deformities, bone defects resulting from excision of malignant tumors, and bone defects resulting from injury require bone-filling treatment.
There are 4 types of bone grafts, Autograft, Allograft, Synthetic Bone graft, and Xenograft.
In the Europe and the United states, Allograft from bone bank is the common transplantation method. On the other hand Autograft is the first and foremost transplantation method operated in Japan.
Autograft requires additional surgery to remove a piece of bone from the patient's own leg or hip bone; therefore it gives an advantage to fuse into our own bone.
However, this entails the patient having to bear the additional invasive procedure, along with the potential risks of infection and physical damage by extended surgical exposure. On the other hand, there is an ethical and infection problems to Allograft, which is harvested from the cadavers.

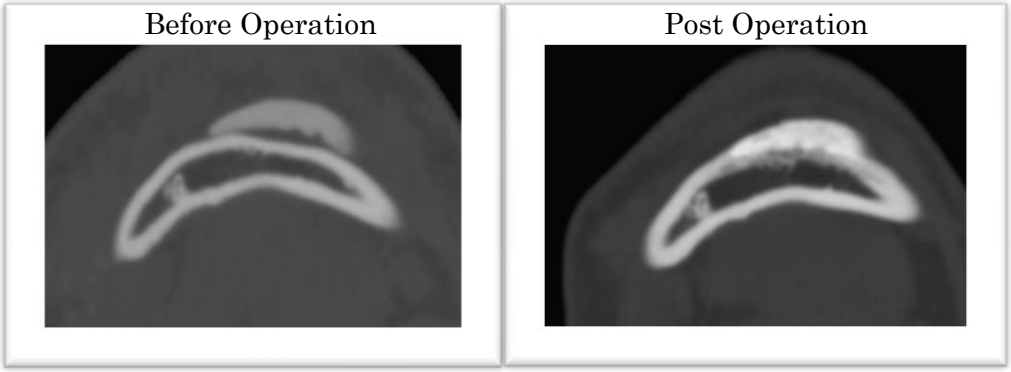


It is also not easy to find an appropriately shaped and sized bone from stock that can be reshaped to match a defect part for successful reconstruction of the patient's original appearance.
Currently available custom-made synthetic graft materials are shaped with machine tools from a heated and sintered block of synthetic bone. This type of synthetic graft material is difficult to be absorbed into natural bone tissue and may separate, potentially leading to inflammation and/or exposure under the skin of the hand or face.
To solve those problems, epoch-making invention of small burdens and faster assimilation with less infection bone graft has been required.

Features of CT-bone

Ct-Bone is molded using 3D printer with its material of calcium-deficient HA, and a new curing treatment method is adopted for optimum recrystallization. With a 3D printer, it is possible to reproduce the shape with an accuracy of 0.1 mm by forming the bone internal structure. Therefore, the manufacturing method with 3D printer is most suitable for molding biomaterial like a bone graft.

One of the features of CT-Bone is that, it does not have a sintering process like any other synthetic bones. Therefore it becomes a physiologically activated, which makes fusion and assimilation quicker into the patient`s bone.



Reference : Yuki Kanno et al. Computed tomographic evaluation of novel custom-made artificial bones, "CT-bone", applied for maxillofacial reconstruction. *Regenerative therapy 5(2016)1-8*

Future business development

In tandem with commercialization in Japan, we will be expanding our sales in Europe

We have already reached into a license agreement with Xilloc Co.(Netherland) concerning the local manufacture and sale of CT-Bone in EU countries.

Regard the Asian market, our plan is to initiate export to Asian countries of product manufactured in Japan.

Please direct inquiry to:

Shigeki Suzuki, Ph.D., President
Next21 K.K.
Tel: +81 3-5840-8830
Mobile: +81 90-6170-3670
Email: suzuki@next21.info

Key words:

1) Autograft: Bones harvested from a healthy part (leg bone or hipbone) of the body to be implanted in another part of the body of the same patient.

2) Synthetic graft: bone-like material created in a laboratory that can be used in bone grafts, to replace human bone that was lost due to servere fractures, disease, etc.

3) Allograft: Grafting with bones of cadaveric origin.

4) Xenograft: A tissue graft or organ transplant from a donor of a different species from the recipient.For example, swine or bovine.