

## **Clinical Trials of Induced Bone Regeneration Devices to Begin**

**–Aiming for Commercialization as a Next-Generation Bone Reconstruction Material–**

**Osaka, Japan, April 13, 2015** - Tohoku University (located in Sendai, Miyagi Prefecture, President: Susumu Satomi) has been developing induced bone regeneration devices based on an octacalcium phosphate-collagen complex (hereinafter, OCP/Collagen). This is a next-generation bone reconstruction material that is injected into the damaged portion of bones and induces new bone growth.

Toyobo has been working toward the commercialization of OCP/Collagen, and clinical trials for use of this material in dental and oral surgery domains will begin in early June 2015.

### **1. Background**

When portions of bones are lost or fractured (including cracks, appearance of holes, loss of bone mass, or other cases) due to illness, injury, or aging, this may impair patients' ability to live normal lives. For example, in the dental and oral surgery domain, when the bones that support the teeth or the jawbone become defective, patients may experience disabilities, such as losing their ability to chew and pronounce words correctly. In addition, when dental implant treatments are performed, the regeneration of the alveolar bone that supports the teeth may be needed in some cases. The method in general use for regenerating defective bones, known as autologous bone grafting, involves removing a portion of healthy bone tissue from another part of the patient's body, such as the ilium (part of the pelvis), and then, transfer it to the defective bone. At present, this method is regarded as the most-reliable method of therapy, but it requires hospitalization of the patient, and, in some cases, damages the bone from which the graft is taken and may cause lingering pain. Therefore, to lessen the burden on patients, new technologies and materials for therapy are needed.

### **2. Developments Leading to Clinical Trials**

Toyobo believes that the OCP/Collagen induced bone regeneration device that Tohoku University has been developing can be used in such therapy as an alternative to the bone grafting method. Beginning in 2013, in collaboration with Tohoku University, Toyobo has conducted tests of this material on animals as well as various safety tests and nonclinical tests.

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Since preparations have been completed for clinical trials, the decision has been made to start clinical trials, mainly for the reconstruction of bone for dental implants. These trials will be conducted as multicenter clinical trials at several facilities including Tohoku University, which will be the primary trial facility.



### **3. About OCP/Collagen**

OCP/Collagen is made using octacalcium phosphate in powder form and medical-grade collagen and is then processed into a sponge disc. It is imbedded in the defective portion of the bone and in places where the bone tissue has broken or become thinner. The octacalcium phosphate uses collagen as a scaffold as it turns itself into newly created bone tissue conducting bone regeneration.

OCP/Collagen has the following special properties:

- (1) The neonatal bone is expected to show the same properties as a patient's original bone.
- (2) The imbedded device dissolves and is absorbed, but does not remain inside the body.
- (3) There is no need to remove healthy bone tissue from another part of the patient's body, and, even in the case of dental implant treatments, there is no need to hospitalize the patient. This greatly reduces the burden on the patient and is expected to contribute to improving the patient's quality of life.

### **4. Outlook Going Forward**

After the conducting of clinical trials in the dental and oral surgery domains, Toyobo will assess the effectiveness and safety of this treatment method. After clinical trials are completed, Toyobo will immediately submit an application for manufacturing and marketing to Japanese Ministry of Health, Labor and Welfare (JMHLW). We will aim for the commencement of sales beginning in fiscal 2018.

In addition, we will consider applications in other areas where there are medical needs, including the orthopedic and brain surgery domains. Following on from its development of Nerbridge<sup>TM</sup>, a nerve bridging device for peripheral nerve regeneration, Toyobo will commercialize this new treatment material in the field of regenerative medicine.

For more information, contact:

Toyobo Co., Ltd

Corporate Communication Office, Public Relations Group

[pr\\_g@toyobo.jp](mailto:pr_g@toyobo.jp)