

Autologous Cultured Cartilage JACC: Progress in Clinical Trial aimed at Expanding Indication for Knee Osteoarthritis

Japan Tissue Engineering Co., Ltd. (Headquarters: Gamagori, Aichi Prefecture; President and CEO: Ken-ichiro Hata) is seeking an expansion of indication^{*1} for the regenerative medical product "Autologous Cultured Cartilage JACC[®]" (hereinafter JACC), which is used to treat traumatic cartilage defects or osteochondritis dissecans of the knee.

We have recently notified the Pharmaceuticals and Medical Devices Agency (PMDA) of the completion of our clinical trial for expanding indications (hereinafter referred to as "the Trial"). The progress of the Trial is as follows.

1. Overview of the Trial

The purpose of the Trial is to verify the efficacy and safety of JACC by multicenter, parallel-group clinical trial compared with intra-articular injection of sodium hyaluronate (HA) in patients with knee osteoarthritis^{*2}. The target number of patients in the Trial was set at 58, and patients were randomly assigned to receive either transplantation of JACC or intra-articular injection of HA. Treatment for the final case as well as follow-up observation for all cases have been completed. We have fixed the data obtained through the Trial concerning the cases and conducted a data analysis with regard to efficacy and safety. The results are outlined below.

2. Key analysis results

I Primary outcomes

It was statistically shown that, in terms of change in WOMAC score between pre and post treatment, JACC group improved significantly compared to HA group. ($P < 0.0001$ Student's t-test)

WOMAC (Western Ontario and McMaster Universities Osteoarthritis Index) score: Evaluation score based on patient's clinical symptoms.

I Key secondary outcomes

The presence or absence of repair with hyaline cartilage-like tissue (HCT) , which is one of the key secondary evaluation items, was determined comprehensively by the independent data monitoring committee (IDMC), based on the results of MRI examinations, arthroscopic examinations, and histological evaluations. As a result, 97.4% of the cartilage defect sites evaluated in JACC group showed repair with HCT at 52 weeks post treatment.

I Regarding safety, no adverse events of concern were observed.

In addition to showing a statistically significant improvement in clinical symptoms compared to the HA group, it is of a great significance that the transplantation of JACC repairs cartilage defects caused by knee osteoarthritis with HCT.

[Comment from President Ken-ichiro Hata]

With the vision of “Creating a Future for Regenerative Medicine,” we have been striving to provide more patients with regenerative medical products using patients' own cells. We believe the results of the Trial are extremely important as they suggest the regeneration of damaged knee joints with hyaline cartilage. We would like to express our deepest gratitude to the doctors at the medical institutions who conducted the Trial, as well as the patients who participated. We will swiftly compile data and prepare for manufacturing and sales applications, and continuously work towards the development of regenerative medicine in Japan.

*1 Expansion of indication: To expand the scope of application of a drug for which marketing approval has already been obtained (add diseases treatable with the drug)

*2 Knee osteoarthritis: A disease that causes pain as the cartilage gradually wears away and deforms. In some cases, the cause is not clear while, in other cases, it is possible to identify the cause such as sports- or accident-related trauma. Aging and obesity lead to symptom progression. Currently, knee osteoarthritis is treated symptomatically by administering analgesics with anti-inflammatory properties to alleviate pain and other clinical symptoms, while retarding symptom progression is difficult. The methods to treat severe symptoms are limited to a few options such as high tibial osteotomy in which the angle of the knee is adjusted by cutting the tibia and artificial joint replacement.

About autologous cultured cartilage

Autologous cultured cartilage (brand name: “JACC”), based on technology developed by Professor Mitsuo Ochi (currently President of Hiroshima University) during his research at Shimane Medical University, is Japan's first regenerative medical product in the field of orthopedics.

“JACC” is made by harvesting the patient's own cartilage tissue and mixing it with gel-form atelocollagen to mold it into a three-dimensional form that is then transplanted at the site of cartilage defects in the patient's knee. “JACC” was approved in July 2012, and it has been covered by public health insurance programs since April 2013 in Japan.

In 2019, aiming to further reduce the invasiveness in regards to the patient's body in treatment with JACC, we introduced the method of using an artificial collagen membrane instead of the periosteum harvested from the patient's tibia for transplantation. This reduced the physical burden on patients, as well as simplifying the transplanting procedure for doctors.

Transplantation of autologous cultured cartilage (knee-joint)



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