The Next Generation in Articular Cartilage Regeneration

ProChon Biotech, a privately held medical device company, has developed an orthobiologic implant that leverages a patient’s own healthy tissue to repair cartilage cells in the patient’s knee. ProChon’s BioCart™ Cartilage Regeneration System utilizes Chondrocyte Preservation Technology™ (CPT), which includes a proprietary fibroblast growth factor (FGF2) variant—a key regulator of cellular processes involved in blood vessel formation, wound healing and the remodeling of bone and cartilage.

**The Next Generation Autologous Chondrocyte Implant (ACI)**

For patients with symptomatic hyaline cartilage injuries that do not respond to conservative therapy, surgical intervention may be necessary. The microfracture procedure, a first line treatment for chondral injuries, is common but offers only limited degrees of success and has a long rehabilitation period. First generation ACI has created the ability to grow native cartilage, but has numerous limitations. In comparison, this new technology provides high quality chondrocyte proliferation through a minimally invasive, two-step procedure for both safe and anticipated long-term cartilage regeneration.

**The FGF Technology**

One of the largest and most versatile growth factor systems in our body is the FGF system. These proteins, their receptors and signaling networks serve as key regulators of cellular processes involved in blood vessel formation, wound healing and the remodeling of bone and cartilage.

The growth and development of human tissue as well as the mechanisms by which our bodies can heal and repair are under the delicate control of signaling molecules that act as communication networks between cells. These signaling molecules, or growth factors, are secreted by cells to influence the behavior of other cells that receive the signals through special receptors embedded in their surfaces. It is believed that a deeper understanding of these signaling networks will ultimately enable the control of direct tissue growth and repair, thereby enhancing the body’s natural capacity to heal. The FGF2 variant protects against chondrocyte de-differentiation, yet accelerates cell proliferation and guarantees a cell yield from small biopsies during cell culture expansion.
Biological Scaffold

To effectively deliver quality cells directly to the defect site, a three-dimensional biological scaffold has been developed that is suited for cartilage regeneration using a proprietary position in fibrin and hyaluronic acid based formulations. The scaffold consists of an inter-connected, open pore structure that enables even and random distribution of chondrocytes, mimicking the natural spatial distribution of chondrocytes within their extra-cellular matrix and supporting the growth of chondrocytes once implanted into native cartilage. The scaffold can be thought of as a biologic sponge. The hydrogel nature of the scaffold allows for transmission of mechanical forces that are known to stimulate chondrocytes. These two factors lead to rapid fill of the implant at the defect site, thus stimulating the production of hyaline-type cartilage, which functions comparable to normal cartilage. In addition, the structural composition of the scaffold is such that it better protects chondrocytes (vs. non-scaffold ACI systems) from the deleterious effects of external mechanical forces, allowing for an accelerated rehab protocol.

The System Process

A small sample of healthy cartilage is removed arthroscopically from a non-weight bearing area of the subject’s knee and is sent to ProChon’s laboratories. Scientists then separate the chondrocytes (cartilage cells) from the biopsy and grow these cells in a solution that is enhanced with its FGF2 variant that accelerates the proliferation of high-quality articular cartilage cells. The use of the patient’s own tissue and blood in the proliferation process reduces the risk of rejection and potential disease transmission.

After approximately two weeks, the necessary number of cartilage cells are obtained and seeded into a proprietary biologic scaffold. (With traditional ACI, the time between biopsy and implant is approximately six to eight weeks.) The chondrocyte-seeded scaffold is then sent back to the hospital for implantation in the patient’s knee. As part of the minimally invasive procedure, the scaffold implant is custom cut to precisely match and fill the cartilage defect, and secured peripherally with biologic glue. Unlike traditional ACI, which requires suturing of a cover (periosteum or a biologic membrane) over the defect before injecting a solution of cells, the hyaluronate and fibrin of the BioCart scaffold have intrinsic adhesive properties, precluding the need for suturing or harvesting periosteal tissue. This property greatly reduces operative time.

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The BioCart System is commercially available in Israel and Greece and is undergoing a Phase II multicenter clinical study in the U.S. To date, over 80 patients have undergone implantation with some patients now more than five years post-implantation.

References


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