July 12, 2016

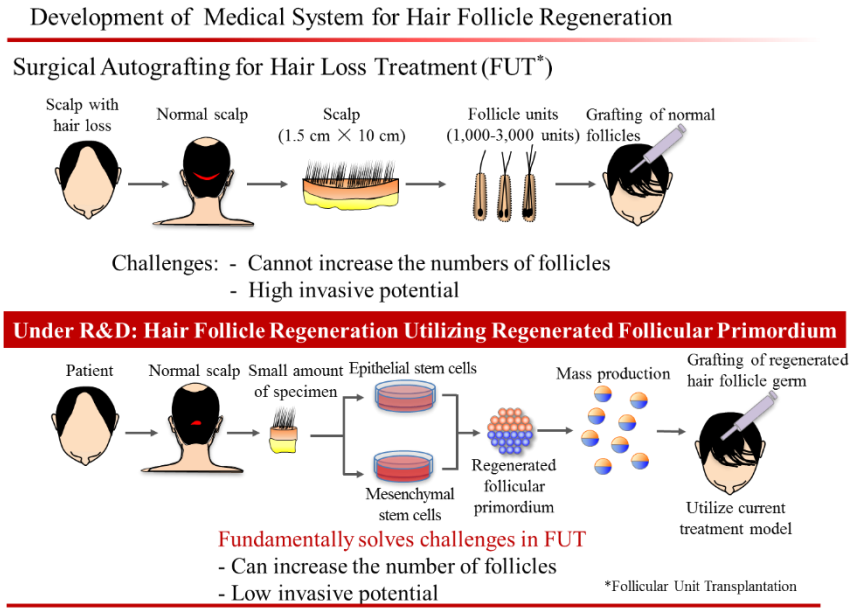
KYOCERA, RIKEN and Organ Technologies Launch Joint Research in Regenerative Medicine to Treat Hair Loss

Organ regeneration technology shows promise for regenerating hair follicles

Kyocera Corporation (President: Goro Yamaguchi), RIKEN national science institute (President: Hiroshi Matsumoto) and Organ Technologies Inc. (President: Yasuhiro Sugimura) announced today a partnership to develop technologies and products for treating alopecia (hair loss) through the regeneration of hair follicles. The companies aim to put the technologies into practical use in 2020.

Background

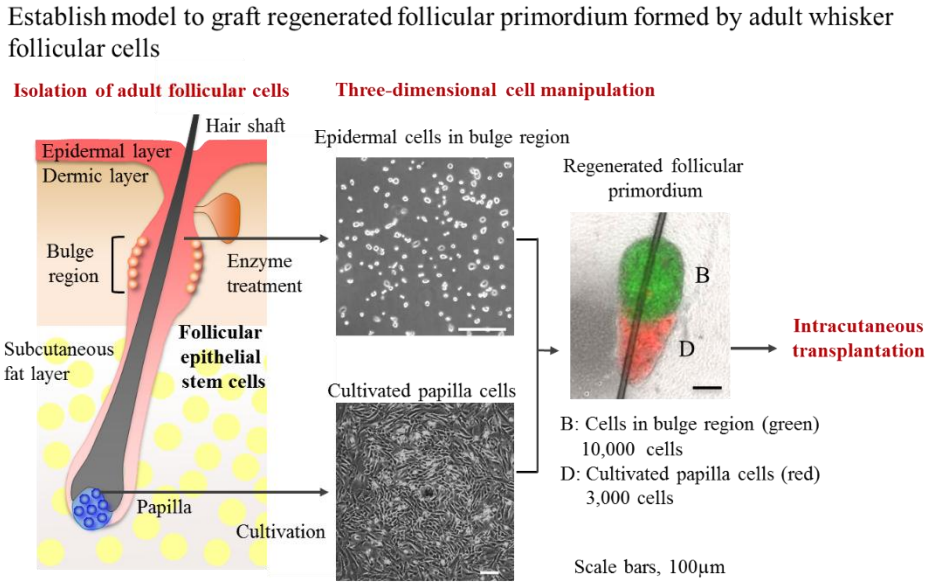
Common types of hair loss include androgenic alopecia, congenital alopecia, cicatricial or "scarring" alopecia, and telogen effluvium alopecia among women. Currently, it is said that there are more than 18 million patients with alopecia in Japan alone[*1]. Because alopecia can influence the quality of life, many diverse treatments, including hair growth formulas, hair loss inhibitors and autografting of individual hair follicles[*2], have been utilized with mixed results. Because no existing treatment — not even surgical autografting — can increase the number of hair follicles, any viable method of regenerating hair follicles has great potential to succeed where other methods fail.



Success of Hair Follicle Regeneration in Mice

The Laboratory for Organ Regeneration (Team Leader: Takashi Tsuji) of the RIKEN Center for Developmental Biology (CDB) has demonstrated that the regeneration of many organs, including teeth, hair follicles and secretory glands, is functionally possible. The hair follicle is the only organ known to regenerate repeatedly after birth (hair cycles[*3]). In 2012, the research team isolated epithelial stem cells and follicle dermal papilla cells (mesenchymal stem cells)[*4] from the follicles of mature mouse whiskers and body hair and used them to develop a technology for the regeneration of follicular primordium by utilizing an "organ primordium technology[*5]" previously developed by the same team. Transplanting the regenerated follicular primordium into hairless mice results in the growth of regenerative follicles, thus demonstrating the feasibility of hair shaft regeneration. The transplanted primordium also forms connections with surrounding tissues (arrector pili muscle and nerves) and repeats normal hair cycles. Furthermore, this method allows control of the hair color by adding pigment stem cells, and the number of hair follicles regenerated, elevating its potential for the aesthetic treatment of alopecia. In addition, the RIKEN research team has succeeded in using iPS cells[*6] to regenerate functional skin organ systems[*7] in mice, including all follicles, sebaceous glands, and skin tissues, thus leading the world in organ regeneration technology[*].

Regeneration and Sympatric Regeneration of Follicular Primordium through Cell Manipulation



*RIKEN Press Release "Growing skin in the lab" http://www.riken.jp/en/pr/press/2016/20160402_1/

Joint Partnership Aims for New Treatment in 2020

Kyocera, RIKEN and Organ Technologies plan to establish cell culture and transplant technologies and develop devices for transplantation, aiming to put the technologies into practical use for the treatment of human alopecia in 2020 in Japan. The RIKEN Integrated Innovation Building*8 (Kobe City, Hyogo Prefecture) will serve as a base for this joint research.

Kyocera will lead technical aspects such as the development of cell processing devices, by utilizing its microfabrication and manufacturing technologies which have been cultivated for over 50 years. RIKEN and Organ Technologies will be responsible for the development of follicle-derived stem cell culture / amplification technologies and cell manipulation technologies for clinical application in humans, establishment of production processes, implementation of preclinical studies and other roles.

Major roles of participating companies

Kyocera	Development of cell processing devices, etc.
RIKEN and Organ Technologies	Development of stem cell culture / amplification technologies, development of cell manipulation technologies, establishment of production processes, implementation of preclinical studies, etc.

Outline of Business Model

Follicular regenerative medicine will focus on the collection of stem cells from the patient's own hair follicles, followed by the processing of these follicles and autografting on the same patient. For the treatment of androgenic alopecia (the most common type), a small number of hair follicles will be collected, from which stem cells will be isolated, cultured and amplified to produce hair follicle germ by the established organ primordium method. The regenerated hair follicle germ will be packaged and delivered to a medical facility for use in transplantation therapy for the patient.

With the goal of Kyocera becoming the commissioned manufacturer for this method through cooperation with Organ Technologies, the joint research partnership plans to pave the way for commercial viability within a research period of two years, followed by the materialization of the business model of commissioned manufacturing.

*1 Source: Guideline for Medical Care on Androgenic Alopecia 2010

*2 The skin is collected from the occipital region of a patient with androgenic alopecia, and the follicle unit is isolated from this skin sample. The follicle unit is transplanted to the site affected by androgenic alopecia for treatment.

*3 In the hair cycle, the hair follicle repeats cycles of regression and growth at certain intervals, resulting in the renewal of the hair shaft. The follicle formed during the fetal period undergoes regression due to apoptosis, and the follicle dermal papilla cell interacts with the epithelial stem cell, resulting in the regeneration of the variable part of the follicle (hair bulb). The hair cycle of human hair on the head spans 3-7 years.

*4 Most organs are formed from a primordial organ, an organ or tissue in its earliest recognizable stage of development following interactions between epithelial stem cells and mesenchymal stem cells during the fetal period. Because organogenesis occurs during the fetal period, the epithelial / mesenchymal stem cells that have the potential for creating organs are considered to be present only during the fetal period, except for the hair follicle.

*5 Organ primordium technology is a three-dimensional cell manipulation technology for the regeneration of an organ primordium developed in 2007 by Takashi Tsuji and his research group. In this technology, an organ primordium is regenerated by the high-density segmentation of epithelial and mesenchymal stem cells and their subsequent reconstitution within collagen gel.

*6 Induced pluripotent stem cells.

*7 The skin organ system is the largest organ system in human body and is composed of follicles, sebaceous glands, sweat glands, epidermal tissue, dermal tissue, and subcutaneous fat tissue.

*8 RIKEN constructed this facility to enable industry-government-academia cooperative research. Located in Kobe City, Japan, operation began in 2015.

About KYOCERA

Kyocera Corporation (NYSE:KYO)(TOKYO:6971), the parent and global headquarters of the Kyocera Group, was founded in 1959 as a producer of fine ceramics (“advanced ceramics”). Kyocera has become a leading supplier of electronic components, printers, copiers, solar power generating systems, mobile phones, semiconductor packages, cutting tools and industrial ceramics with net sales totaling 1.48 trillion yen (approx. USD13.1 billion).

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About RIKEN

RIKEN is Japan's largest research institute for basic and applied research. Over 2500 papers by RIKEN researchers are published every year in leading scientific and technology journals covering a broad spectrum of disciplines including physics, chemistry, biology, engineering, and medical science. RIKEN's research environment and strong emphasis on interdisciplinary collaboration and globalization has earned a worldwide reputation for scientific excellence.

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About Organ Technologies

Organ Technologies Inc. was established in 2008 in order to contribute to human health and welfare by developing organ regeneration technologies through our innovative 3D cell processing technologies. We will not only contribute to people throughout the world who are suffering from illnesses, but will also realize industrial revolution in regenerative medicine from Japan in the near future.

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