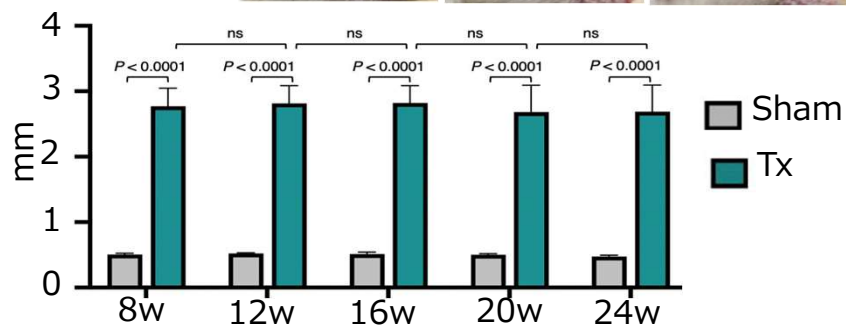


再生医療

小児患者に笑顔を！

世界初、 ヒト弾性軟骨デバイスによる 顔面醜形修復治療

Long term observation in vivo



Long term stability in vivo



EPELCATM: Ear Perichondrium-Derived Elastic Cartilage

ヒト弾性軟骨デバイスを用いた
小児顔面醜形に対する新規治療法の開発

The University of Tokyo

Hideki TANIGUCHI

東京大学

教授・谷口 英樹

The issue to be addressed / Unmet Medical Needs

Unmet Medical Needs:

No minimally invasive, scaffold-free, and long-term morphologically stable cartilage regeneration therapy is currently available for craniofacial reconstruction.

Current Treatment Challenges

- Highly invasive rib cartilage harvesting
- Risk of postoperative pain and pulmonary complications
- Limited availability of autologous cartilage tissue
- Poor elasticity leading to stiffness and fracture risk

Market Opportunity

The target patient population exceeds 10 million patients worldwide.

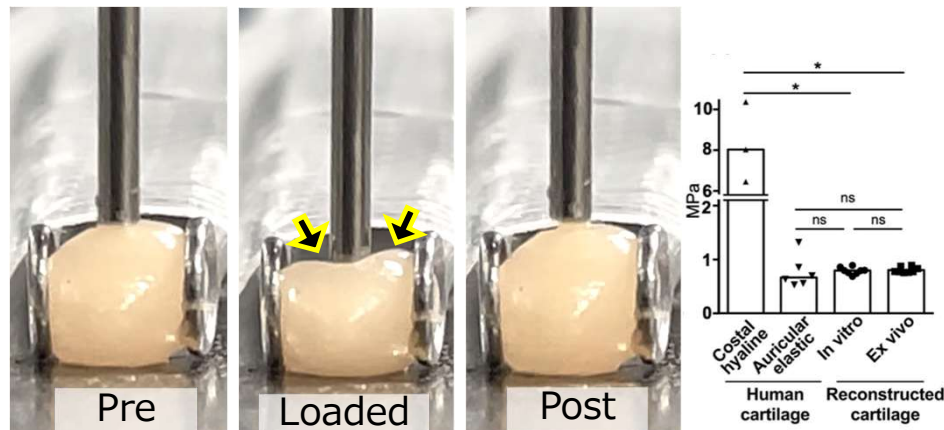
- Nasal deformation is caused by congenital nasal deformity, post-traumatic nasal deformity, tumor resection, tissue defects associated with autoimmune disease
- Congenital nasal deformities : 4.6 million patients worldwide
- Post-traumatic nasal deformities : 5 million patients worldwide
- Nasal defects after tumor resection : 1 million new patients/year globally
- Granulomatosis with polyangiitis (GPA) : 0.8 million patients worldwide

Our Solution

World's first ear perichondrium-derived scaffold-free elastic cartilage product,

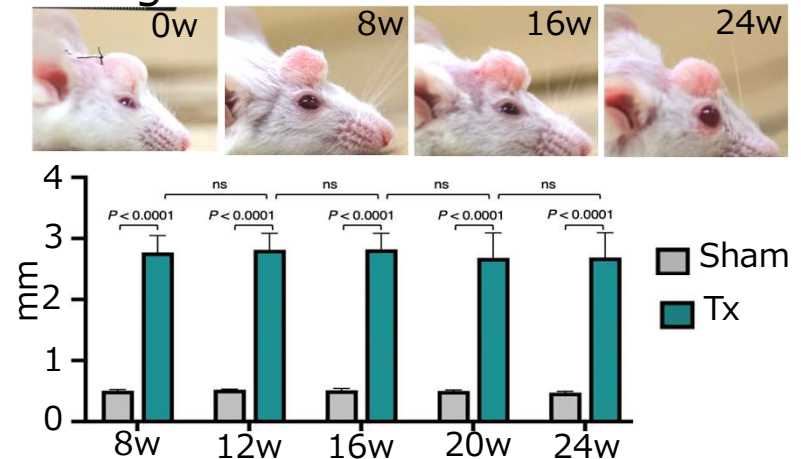
- Exhibits elasticity similar to native elastic cartilage
- Maintains the subcutaneous lift effect in vivo under long term observation
- Uses ear perichondrial cells, enabling a minimally invasive treatment approach.
- Scaffold-free, thereby avoiding scaffold-associated inflammatory responses.

Elastic modulus of product



Similar elasticity to native elastic cartilage

Long term observation in vivo



Long term stability in vivo

Competitive Positioning

Our product is the only single-stage, scaffold-free elastic cartilage implantation therapy using minimally invasive ear perichondrial cells.

Item	Scaffold combined Cartilage	Two-Stage Cultured Cartilage	Scaffold-Free Elastic Cartilage
Company	Company A	-	Our solution
Cell Source	Ear chondrocytes	Ear Chondrocytes	Ear Perichondrial Cells
Scaffold Material	Porous PLA Scaffold + Atelocollagen	Scaffold-free	Scaffold-free
Transplantation	Single-stage	Two-stage (requires ectopic maturation)	Single-stage
Time to Treatment	7 weeks	8 months or longer	6 weeks
Key Feature / Limitation	Inflammatory response associated with scaffold materials	Highly invasive and prolonged treatment period	Scaffold-free, minimally invasive, and short treatment period

Development Stage/Future Milestones

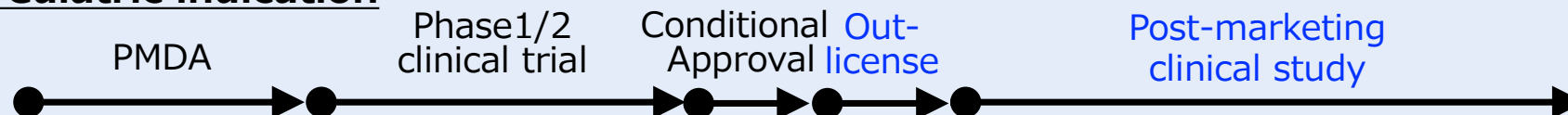
Future milestones include out-licensing and commercialization for both pediatric and adult indications.

- Simplification and automation of the manufacturing process.
- Ongoing non-clinical safety studies using rodents.
- Investigator-initiated Phase 1/2 clinical trial for pediatric nasal deformities ongoing.
- Expansion from pediatric to adult indications is planned.
- Out-licensing to an industry partner is a key commercialization objective.

Adult indication



Pediatric indication



2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036
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PMDA: Pharmaceuticals and Medical Devices Agency

Team

- Hideki Taniguchi, The University of Tokyo, Regenerative Medicine
- Takayoshi Oba, The University of Tokyo, Regenerative Medicine
- Shinji Kobayashi, Kanagawa Children's Medical Center, Plastic Surgery
- Yutaka Inaba, Yokohama City University, Orthopedic Surgery
- Masatoki Watanabe, Japan Tissue Engineering, Bioengineering
- Kenichi Morita, J-Tech Corporation, Bioengineering
- Yasutaka Okita, The University of Osaka Hospital

Key publications

Kobayashi S, Taniguchi H et al. Reconstruction of human elastic cartilage by a CD44+ CD90+ stem cell in the ear perichondrium. ***Proc Natl Acad Sci U S A***. 2011

Takebe T, Kobayashi S, Taniguchi H et al: Transient vascularization of transplanted human adult-derived progenitors promotes self-organizing cartilage. ***Journal of Clinical Investigation***, 2014

Enomura M, Kobayashi S, Oba T, Morita K, Taniguchi H et al. Development of a method for Scaffold-Free Elastic Cartilage Creation. ***Int J Mol Sci***. 2020

Oba T, Kobayashi S, Inaba Y, Taniguchi H et al. In Vitro Elastic Cartilage Reconstruction Using Human Auricular Perichondrial Chondroprogenitor Cell-Derived Micro 3D Spheroids. ***J Tissue Eng***. 2022

WO/2008/091013

(KR1020090104833 EP2119767 US20090324560 CN101657536 JPWO2008091013)

Filled date; Jan 23, 2008

Applicants: Yokohama City University

Title: Ear perichondrium-derived chondroprogenitor cells for elastic cartilage regeneration

WO/2023/032441

(CN117716021 JPWO2023032441 US20260158191)

Filled date: Jun 27, 2022

Applicants: Yokohama City University

Title: Spheroid-based 3D cartilage fabrication technology

Exclusive know-how for large-scale manufacturing and quality control of EPELCA™

Business Opportunity

- Target patient population exceeds 10 million patients worldwide
- High unmet medical need in congenital, post-traumatic, autoimmune, and post-oncologic nasal deformities
- Out-licensing opportunity to regenerative medicine and medical device companies
- Potential expansion to additional indications including auricular reconstruction, craniofacial reconstruction, and soft tissue augmentation
- Scalable manufacturing enabled by ear perichondrial cell banking and scaffold-free production technology

Appendix

Data that Can Be Disclosed After Signing an NDA

- Unpublished efficacy data (Rodents)
- Unpublished efficacy data (cynomolgus monkeys)
- Unpublished safety data
- Preliminary results of the Phase 1/2 clinical trial