Septal Extension Graft Augmentation with Osteomesh for Nasal Tip Plasty in Asians

Background

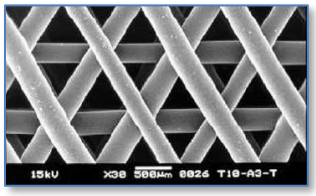
Septal Extension Graft (SEG) is an effective method for nasal tip control and nasal lengthening. SEG is commonly performed in Asians, especially those with higher skin thickness and weak lower lateral cartilage. However, a common complication of SEG is tip drooping or bending of the graft, which may occur due to insecure fixation.[1] Therefore, augmentation graft materials to the SEG may be considered to further enhance the outcome of this procedure.

In the past 4-5 years, Polycaprolactone (PCL) has emerged as the preferred choice of biomaterial for SEG augmentation due to its excellent biocompatibility, gentle degradation profile, and good mechanical compliance. 3D printing is used as the manufacturing technique, which allows an interconnected microarchitecture to be created to facilitate tissue ingrowth. In addition, the stiffness may be tuned to meet the needs of the patient.

Osteopore has combined PCL and 3D printing to create a Regenerative Implant for the treatment of various craniofacial deformities since obtaining US FDA 510(k) clearance more than 10 years ago. International peer-reviewed publications with more than 10 years of retrospective clinical follow-up further confirm the safety and effectiveness of the Regenerative Implant.

The Science: Regeneration vs. Inflammation

Osteomesh under microscopy



Most bioabsorbable polymers are hydrolyzed into the body through the metabolic cycle. However, the importance lies in the rate of absorption, which is related to the choice of polymer and its associated chemistry. Polycaprolactone is a widely studied polymer that had been evaluated as a drug delivery vehicle for contraceptive purposes.[2] It has a stable degradation profile that encourage tissue regeneration. Earlier authors have described the competing relationship between inflammation and regeneration, and that a more neutral pH during degradation is preferential for tissue regeneration.[3]

The PCL used in our Regenerative Implant is carefully curated through a careful study of literature, in vitro and in vivo experimentation, before human application. Careful considerations are made in terms of polymer molecular weight, crystallinity, as well as sterilization technique, as each of them may impact its mechanical strength and ability to support SEG augmentation.

The Technique: Open Rhinoplasty

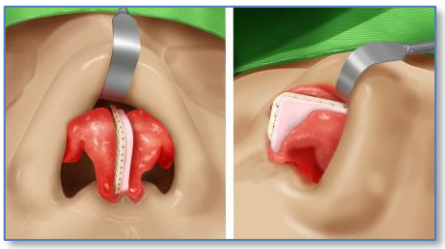
Cartilage graft + Osteomesh:

One hundred and ninety five (195) patients underwent open rhinoplasty with this technique.[4] In this approach, the Regenerative Implant was combined with autologous cartilage graft and inserted into the mucoperichondrial pocket of the septum and fixed to the septum. The degree of the septal extension was dependent on the tip projection and rotation but generally consisted of a 10 – 15 mm intraoperative projection.

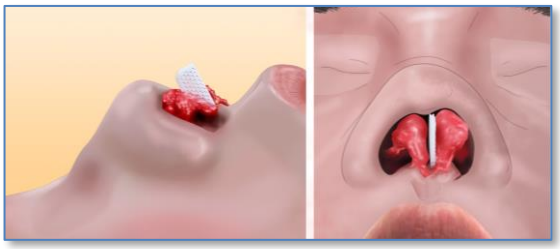
Osteocartilaginous graft + Osteomesh:

Thirty (30) patients underwent open rhinoplasty with this technique.[5] In this approach, the Regenerative Implant was combined with bone and septal cartilage. The strong base portion, containing bone and bilateral arms of cartilage, anchors directly posterior to the anterior nasal spine (ANS), where the septal cartilage is thickest and strongest. It differs from the conventional SEG that the graft anchors at the caudal septum.

Cartilage graft + Osteomesh[4]



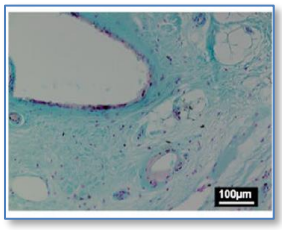
Osteocartilaginous graft + Osteomesh[5]



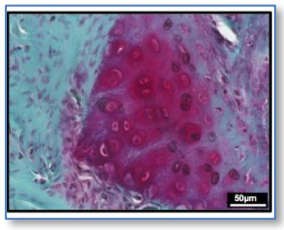
The Evidence

Initial animal study:

Regenerative Implant shows cartilage tissue ingrowth in 6 month animal study[6]



Blue stain (Alcian Blue) showing GAG formation



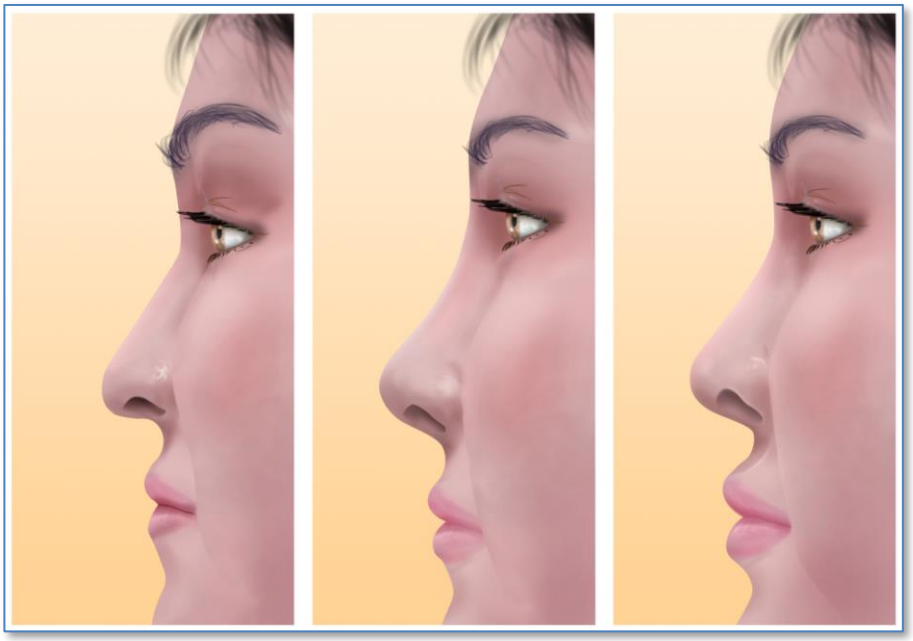
Intense red stain (Safranin-O) showing GAG formation

Osteopore developed the Regenerative Implant for SEG augmentation following a successful animal study. The 6-month in vivo study demonstrated stable augmentation with almost no unwanted changes in contour.[6] In addition, histological evidence suggest that cartilaginous tissue formed in and around our PCL implant.

Human study:

Two human studies were conducted (Study 1: 195 patients, of which forty three (43) were included in the study as they had complete follow-up information with a follow-up period of up to 1 year[4]; Study 2: 30 patients[5]). Based on the combined evidence, majority of patients were satisfied with their outcome (Study 1: 90.7%, Study 2: 96.7%). Only one of the patients required revision surgery. Nasolabial angles were maintained throughout the 1 year of follow-up.

Example of no tip drooping
Left: Pre-operative **Middle**: 3 month post-operative **Right**: 1 year post-operative



Example of slight tip drooping
Left: Pre-operative **Middle:** 3 month post-operative **Right:** 1 year post-operative

Discussion

Safety:

The Regenerative Implant Osteomesh has proven to be a safe augmentation graft material to stabilize SEG for Asians. The PCL biomaterial used in these implants have undergone strict quality control in a GMP certified manufacturing facility. The sterilization method is effective in maintaining sterility while not adversely affecting the mechanical properties of the implant.

Tissue regeneration:

Pre-clinical and clinical outcomes confirm that tip augmentation is maintained in ~90%-95% of cases, while the nasolabial angle is effectively maintained in all cases. The pre-clinical results strongly suggest that cartilage tissue is incorporated into the interconnected pore structure and eventually replaces the bioresorbable biomaterial – no foreign material will remain in the body eventually, eliminating late post-operative complications.

Commitment to continuous improvement:

In the 5% of cases where severe tip drooping is observed (although no revision surgery is required), suturing technique may be further developed and studied to improve the fixation of the Regenerative Implant to the existing septal cartilage, which may further improve outcomes.

Prepared by:

Dr. Lim Jing, PhD

Dr. Philip Yeung, MBBS

Ong Xin Min

References

1. Kim, M.-H., Choi, J.-H., Kim, M.-S., Kim, S.-K. & Lee, K.-C. An introduction to the septal extension graft. *Arch. Plast. Surg.* **41**, 29–34 (2014).
2. Ory, S. J., Hammond, C. B., Yancy, S. G., Wayne Hendren, R. & Pitt, C. G. The effect of a biodegradable contraceptive capsule (Capronor) containing levonorgestrel on gonadotropin, estrogen, and progesterone levels. *Am. J. Obstet. Gynecol.* **145**, 600–605 (1983).
3. Young, S. M. *et al.* Use of bioresorbable implants for orbital fracture reconstruction. *Br. J. Ophthalmol.* **101**, 1080 LP – 1085 (2017).
4. Kim, S. H. & Choi, J. Y. Surgical outcomes and complications of septal extension graft supported by 3D printed polycaprolactone plate. *Laryngoscope* **130**, 1680–1685 (2020).
5. Ahn, T., Heo, C.-Y. & Ahn, K. A Compound Osteocartilaginous Graft with Polycaprolactone (PCL) Mesh in Asian Rhinoplasty. *J. Plast. Reconstr. Aesthetic Surg.* (2020) doi:10.1016/j.bjps.2020.05.098.
6. Wiggenhauser, P. S., Balmayor, E. R., Rotter, N. & Schantz, J. T. In vivo evaluation of a regenerative approach to nasal dorsum augmentation with a polycaprolactone-based implant. *Eur. J. Med. Res.* **24**, 6 (2019).