Innovative regenerative treatment for the tympanic membrane perforation

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Introduction
Chronic tympanic membrane (TM) perforation that is caused by various reasons is a frequent cause of conductive hearing loss and often require surgical repair to restore hearing and prevent recurrent infection. There was no therapy except surgical treatments for the large TM perforation to date. Surgical treatment is not always to succeed and it has various risks.

We developed the new regenerative treatment for the large TM perforation containing total perforation without conventional surgical therapy.

Aim
To establish the new treatment for regeneration of the tympanic membrane (TM) without conventional surgical therapy: tympanoplasty or myringoplasty.

Material and Method
The patients with chronic TM perforation without active inflammation were randomly selected from 53 outpatients. Their ages ranged from 21 to 84, with the average age of 56. Materials for the TM repair were a gelatin sponge with basic fibroblast growth factor (b-FGF) and a fibrin glue.

The effectiveness of this novel therapy for the TM repair was estimated 3 weeks after the procedures.

After creating a mechanical disruption of the TM perforation edge under the microscope, a gelatin sponge immersed in b-FGF was placed over the perforation in contact with the residual TM. Fibrin glue was dripped over it. In case complete closure of the TM perforation was not achieved, the above same treatment was performed repeatedly.

The final estimation was performed 3 months after the treatment.

Results
Complete closure of the TM perforation was achieved in over 98% patients within 4 time treatments. The number/rate of the cases whose the TM perforation were able to close completely by one treatment, 2 times, 3 times and 4 times were 38 (72%), 10 (19%), 2 (4%), and 2 (4%), respectively. Average hearing levels of all patients were improved. No inflammation/infection and no significant sequela were observed in all patients.

Summary
The study demonstrated that the combination of a gelatin sponge and a bFGF was effective for regeneration of the TM. This is the innovative regenerative therapy: easy, simple, cost-effective and non-invasive method for outpatients.

Remarkable advantages of this new regenerative therapy
- No skin incision and no harvest of autologous tissues
- Wide application for various kinds/sizes of the TM perforation
- Only 10 minutes simple/easy procedures for outpatients
- Hearing up immediately after the procedures
- No restrictions of the patient's daily life
- No sequelae and no disadvantages
- Cost-effective