



# C l o s i n g the Gap

## The Kanemaru Tissue Engineered Tympanic Membrane

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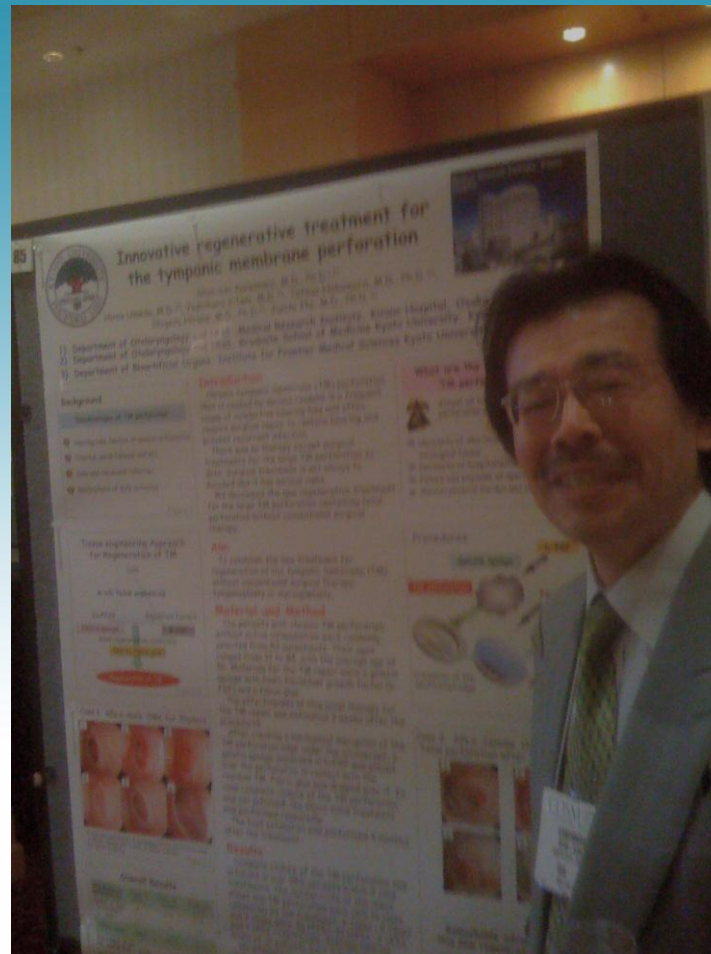


## Conflict of Interest Statement:

This presentation will not include discussion on any commercial products or services and the author has no real or potential financial gain from research and / or financial links or affiliations with the medical supply industry



# Triological Society, Scottsdale 2 April 2009





# Concept

- To safely bioengineer a new tympanic membrane in patients with chronic perforations
- To reproduce nature's three layer tympanic membrane



# Methodology

- b- FGF
  - Basic Fibroblastic Growth Factor engineered from E.coli
- “Tisseel”
  - Fibrin glue derived from plasma of screened patients



# Safety

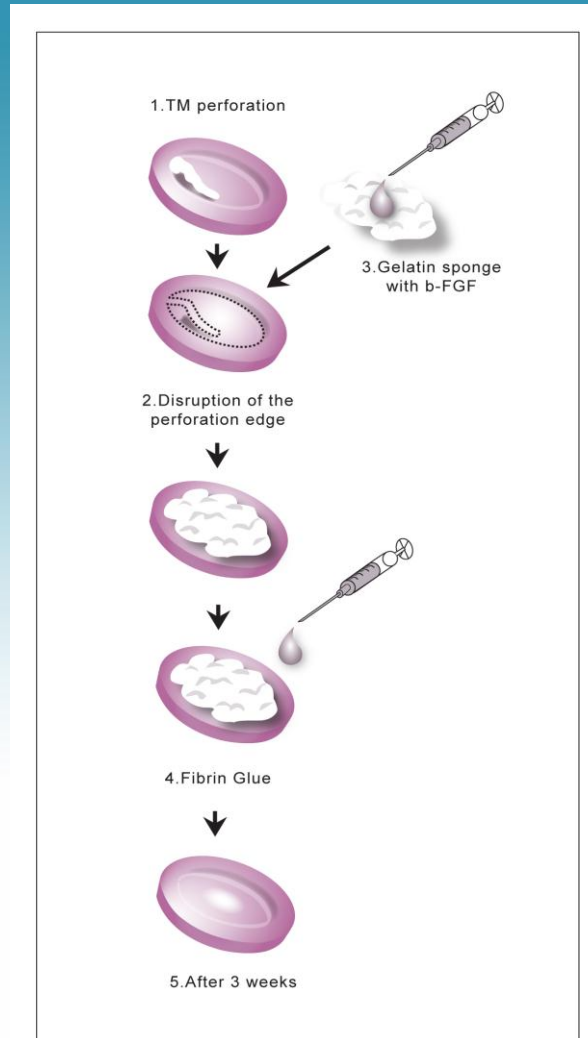
- b-FGF derived from genetically engineered E.coli human DNA.
- “Tisseel” safely used in over 5 million applications without serious disease transmission



# Why a tissue engineered TM?

- 106,000(estimated) Australians with CSOM or tympanic membrane perforations
  - *Highly represented in ATSI children populations*
  - Easy
  - Safe
  - Time saving procedure (3-4/hour instead of 1/hour)

## Kanemaru Tissue Engineering Procedure







## *Regenerative Treatment for Tympanic Membrane Perforation*

*Kanemaru, S. Umeda, H. Nakamura, SH. et al.*

*Otology & Neurotology 32:1218-1223 2011*

- Study
- 56 patients with 63 chronic perforations
  - 53 b-FGF group
  - 10 controls (saline)
  - 10-85 years (M=55 yrs)



# Results

- Complete closure TM perforation in 98%
- Control group 10%



# Tissue Engineering elements

- Cells - perforation edge
- Scaffolds - gelfoam
- Regulatory factors - b-FGF



# b-FGF

- Polypeptide mitogen - stimulates proliferation of epidermal and connective tissue cells.
- Gelfoam acts as sustained release substrate for b-FGF.



# Treatment numbers

1. - 41 (77.4%)

2. - 7 (13.2%)

3. - 3 (1.9%)

4. - 1 (1.9%)

*Failure 1 (1.9%)*



# Concerns

- Cholesteatoma formation
- Oncogenic?



# Advantages

- Avoids invasive incisions
- All size perforations
- Easy/15 minute procedure
- No sequelae noted so far
- High success rate
- Fully regenerated TM morphology
- Cost effective







# “A Regenerative Method of Tympanic Membrane Repair Could Be the Greatest Advance in Otology Since the Cochlear Implant”

Robert K Jackler M.D.

Otology & Neurootology

April 2012