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Xenograft *versus* autograft in tympanoplasty

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Abstract

This retrospective study compares the tympanoplasty success rate when using a xenograft (Zenoderm) or an autograft (temporalis fascia).

Fifty-three ears were operated on over a three-year period. All the tympanoplasty operations were performed by the same surgeon. There were 43 ears in the temporalis fascia autograft group and 10 ears in the Zenoderm xenograft group. Both groups were similar with respect to patient age, type of tympanoplasty, area of tympanic membrane perforation and condition of the contralateral ear.

The tympanoplasty success rate in the temporalis fascia autograft group was 95 per cent. The tympanoplasty success rate in the Zenoderm xenograft group was only 40 per cent. All Zenoderm tympanoplasty failures were regrafted with temporalis fascia autograft. There was a 100 per cent success rate with this salvage surgery.

In conclusion, we suggest that Zenoderm is not a suitable graft material for tympanoplasty.

Key words: Fascia, temporalis; Tympanoplasty; Xenograft; Autograft

Introduction

This clinical study examines the tympanoplasty success rate when using a xenograft (Zenoderm: Ethicon Ltd., Edinburgh, Scotland) in comparison to an autograft (temporalis fascia).

Autografts are tissues transplanted from one part of the body to another in the same individual. Full thickness skin grafts were used originally when the procedure of tympanoplasty was being developed. Berthold (1878) in Germany successfully repaired the tympanic membrane with full thickness skin and called the operation 'myringoplastik'. Modern tympanic grafting began with the original works of Zöllner (1955) and Wullstein (1956) who used split- and full-thickness skin from the arm, leg, and post-auricular areas. However, skin grafts were unsuitable, 11 per cent of the grafts perforated and graft cholesteatoma complicated three per cent of cases (Guilford, 1962; Wright, 1963) (Table I).

The introduction of materials other than thick skin for tympanic grafts such as vein (Shea, 1960), autologous temporalis fascia (Heerman, 1960), and tragal perichondrium (Goodhill *et al.*, 1964), represented a forward step in the progress of tympanic membrane grafting. Such tissues as vein, temporalis fascia, and perichondrium supply a support for the migration of skin, native to the area, over the surface of a newly reconstructed membrane. These supporting materials are especially suitable for the purpose, since they all have a low metabolic rate and can survive with relatively slight change in structure until incorporated into the newly formed membrane (Guilford, 1962).

The term allograft refers to tissue transplanted between genetically non-identical members of the same species. Examples include human cadaveric tympanic membrane with or without attached ossicles (Minatogowa *et al.*, 1990) and allograft human dura mater (Albrite and Leigh, 1966).

The term xenograft refers to tissue transplanted between members of different species. Materials in use include treated porcine dermis (Zenoderm), porcine dura mater, and bovine calf jugular vein (Sanna *et al.*, 1985). The rationale for the use of xenograft material is the availability of a sterile, packaged, ready-to-use material which can be used extensively in the surgery of chronic ear disease.

Ironside (1982) reported some early success when using Zenoderm in tympanoplasty. However, there are no reported clinical trials assessing the efficacy of this xeno-

TABLE I
TRANSPLANTATION TERMINOLOGY

Graft material	Donor	Substance
Autograft	Self	Skin Temporalis fascia Tragal perichondrium Fascia lata Periosteum Vein Fat
Allograft	Man	Tympanic membrane Dura mater
Xenograft	Foreign species	Porcine skin Porcine dura Bovine jugular vein

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TABLE II
TYMPANOPLASTY SUCCESS RATE

Tympanoplasty graft material	Success rate
Temporalis fascia autograft	41/43 (95%)
Zenoderm xenograft	4/10 (40%)
Repeat tympanoplasty using temporalis fascia autograft on Zenoderm failures	6/6 (100%)

graft. Therefore, it was decided to review the patients that underwent tympanoplasty in our University Department using Zenoderm as a graft material and compare them with another group of patients in which temporalis fascia autograft was used.

Patients and methods

This was a retrospective trial. Fifty-three ears were operated on over a three-year period. There were 43 ears in the temporalis fascia autograft group and 10 ears in the Zenoderm xenograft group. All the tympanoplasty operations were performed by the same surgeon. Temporalis fascia autografts were harvested via a post-auricular incision. All tympanic membrane grafts were underlaid medial to the handle of the malleus.

Comparison of the tympanoplasty success rate of both groups showed a large difference between them. Several other aspects of the two groups were also analysed, to see if there were any other differences that might explain this observation. The temporalis fascia autograft group was followed-up for a mean average of 10.5 months (range 2 to 28 months). The Zenoderm xenograft group was followed-up for a mean average of 9.6 months (range 2 to 32 months).

Results

Tympanoplasty success rate

The tympanoplasty success rate for temporalis fascia autograft was 95 per cent. The success rate for Zenoderm xenograft however was only 40 per cent. The six Zenoderm xenograft failures were regrafted with temporalis fascia autografts and all six healed successfully (Table II).

Age

The mean average age of the temporalis fascia autograft group was 23 years and the mean average age of the Zenoderm xenograft group was 26 years. There was no statistical difference between the two groups ($p > 0.05$).

The Mann–Whitney U test of significance of difference was used to estimate probability. This test is applicable to unpaired samples of unequal size (Bourke *et al.*, 1985).

TABLE III
TYPE OF TYMPANOPLASTY

Type of tympanoplasty	Temporalis fascia autograft	Zenoderm xenograft
Type I	34 (79%)	10 (100%)
Type I + Ossiculoplasty	3 (7%)	0
Type II	2 (5%)	0
Type III	4 (9%)	0
Total	43 (100%)	10 (100%)

Type of tympanoplasty

All 10 of the ears in the Zenoderm xenograft group underwent Type I tympanoplasty via the trans-canal route (Table III).

In the temporalis fascia autograft group 79 per cent (34/43) of the ears underwent Type I tympanoplasty. Also in this group, summation of (a) Type I tympanoplasty procedures (34/43) and (b) Type I tympanoplasty plus Ossiculoplasty procedures (3/43), showed that 86 per cent, i.e. 37/43 of these ears underwent Type I tympanoplasty.

Area of tympanic membrane perforation

A comparison of the area of tympanic membrane perforation, as estimated at the time of operation was also made. The majority of both groups had moderate sized perforations of between 26 to 50 per cent. There was no significant difference between the two groups ($p > 0.05$).

Condition of the contralateral ear

The condition of the contralateral ear in both groups was also compared (Table IV). Seventy-seven per cent of the contralateral ears were otoscopically normal in the temporalis fascia autograft group. Sixty per cent (6/10) of the contralateral ears were otoscopically normal in the Zenoderm xenograft group.

Conduction threshold

Pure tone audiometry was measured at 0.5, 1, 2 and 4 kHz for air and bone conduction in both groups. Preoperative air and bone conduction were similar in the two groups.

In the temporalis fascia autograft group there was a statistically significant ($p < 0.05$), improvement of 12 dB in air conduction. This resulted in an improvement of the air–bone gap from 27 dB pre-operatively, to 15 dB post-operatively. In the Zenoderm xenograft groups there was no significant improvement in air conduction. Bone conduction in the two groups was not significantly affected by surgery.

TABLE IV
CONDITION OF CONTRALATERAL EAR

Condition of contralateral ear	Temporalis fascia autograft	Zenoderm xenograft
Otoscopically normal	33 (77%)	6 (60%)
Perforation	4 (9%)	1 (10%)
Tympanosclerosis	2 (5%)	2 (20%)
CSOM	1 (2%)	0 (0%)
Not recorded	3 (7%)	1 (10%)
Total	43 (100%)	10 (100%)

Discussion

Zenoderm is derived from porcine dermis treated by proteolytic enzyme digestion to remove non-collagenous elements and glutaraldehyde immersion to retard absorption and reduce antigenicity by cross-linking of the collagen molecules. The collagen matrix is lyophilized and sterilized by gamma radiation before use. Zenoderm is marketed in thicknesses varying from 0.1 to 0.6 mm (Eth-

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icon Ltd., 1982). The finished product, when reconstituted in 0.9 per cent saline has been used to repair inguinal hernias (Holl-Allen, 1984b), oro-antral fistulae (Mitchell and Lamb, 1983) and as a dural substitute in neurosurgery (O'Neill and Booth, 1984).

There are several adverse reports of the use of Zenoderm xenograft in the literature.

Zenoderm has been used experimentally for microsurgical reconstruction of tracheae in rats. Post-operatively, progressive distortion and narrowing of the tracheae was noted. Over a six-month period the gradual development of stenosis from 21.8 to 58.5 per cent of the cross-sectional area of the trachea was observed (Moussa and French, 1985).

Adverse effects of Zenoderm implantation into laminectomy sites in rabbits has also been documented. Zenoderm was unlikely to prevent adhesions forming after lumbar surgery (Boot and Hughes, 1984).

After inguinal hernia repair, contraction of the implant site by 10 to 15 per cent was noted in two patients who required exploration three to four months after their initial surgery. On histological examination the implants were seen to be fragmented (Holl-Allen, 1984a).

Contraction or fragmentation of the Zenoderm xenograft as the healing process evolves may be responsible for the disappointing success rate when this foreign material is used in tympanoplasty.

Conclusion

This study has shown that the Zenoderm xenograft and the temporalis fascia autograft groups were similar with respect to patient age, type of tympanoplasty, tympanic membrane perforation area and condition of the contralateral ear. Nevertheless, the Zenoderm xenograft group tympanoplasty success rate was only 40 per cent, compared to a 95 per cent success rate when temporalis fascia autograft was used.

On this basis we conclude that Zenoderm is not a suitable material for tympanoplasty.

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