USE OF LIYOFILIZED HUMAN AMNIOTIC MEMBRANE AS LINING THE TYMPANIC CAVITIES

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SUMMARY: Lyofilized amniotic membrane in 33 patients and teflon sheet in 20 patients was used as lining in tympanic cavities. Only the patients whose contralateral ears were normal were included in the study and these contralateral ears served as control group. The patients were reexplored 1 year later and the newly formed mucosa examined histologically. The middle ear pressures of the amnion lined and teflon lined ears were measured and compared statistically with each other and with the control group. Our experience shows a normal appearing mucosa in amnion lined group on reexploration 1 year later compared to the thick, less vascularised mucosa in teflon lined group. The mobility of the tympanic membrane was better in amnion lined ears (66.6%) than teflon lined ears (60%) although the difference was not found significant statistically. In the light of these findings it can be said that liofilized human amnion membrane is a good biologic material which can be used for lining the tympanic cativies.

Key Words: Human amniotic membrane-tympanic cavities.

INTRODUCTION

One of the main purpose of tympanoplasty operation is to create a middle ear space which contains air. The synthetic materials such as silastic and teflon sheets have some problems of extrusion, infection and adhesions. Human amniotic membrane has been used with good results as temporary or long-term wound dressing, vaginal epitelization, replacement of mucosa, arthroplasty since Davis first reported the use of fetal membrane in skin transplantation in 1910 (2,4,9,10,11). Therefore human aminotic membrane was used to determine its usefulness as lining in tympanic cavities and the problems it may cause. The amniotic mesenchyme is derived from the primary extraembriyonic mesoderm of the blastocyst and is formed by delamination from the undersurface of the trophoblast. Amniotic membrane is a single layer of cuboidal, epidermis-like cells on a base of scattered fibroblasts in a collagen matrix (1,6,11).

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MATERIALS AND METHODS

This study was carried out on 53 patients who was operated by the same group at the ENT Clinic of Hacettepe Medical Faculty. Only the patients whose contralateral ear needed no surgical treatment were included in the study in order to evaluate the ears in a biologic medium. The contralateral ears of these patients served as control group. Liyofilized amnion membrane was used in 33 ears and teflon sheet in 20 ears. The operation methods are shown in Table 1. After the pathology in the tympanic and mastoid cavity was cleaned, amniotic membrane or

Table 1: The operation methods in patients with amnion membrane lined middle ears.

Operation method	No of the pationts	%
Radical mastoidectomy + Posterior wall reconst + cavity obliteration	27	81.8
Atticoantrotomi	1	3
Atticotomy	4	12.2
Combined approach	1	3
Total	33	100.0

teflon sheet was replaced instead of pathologic mucosa. Temporal muscle fascia graft was used in reconstruction of tympanic membrane. The complete audiological examination was performed before and after the operation using Viennatane M142 audiometer and impedansmeter measurements 1 year later after the operation using Interacoustics AZ 3 Electro acoustic impedansmeter in IAC standard silent rooms.

The following criteria were used in the evaluation of the result:

Pressure between 0, -75 mm H_2O Normal

Pressure between -75, -300 mm H_2O Eustachian tube dysfunction

Pressure between -300, -400 mm H_2O Adhesion, mass effect in the middle ear.

The results of the middle ear pressure measured from the operated ears were compared with the normal ears and each operation group with each other using t-test statistically. 10 patients whose middle ear was covered with amniotic membrane and 4 patients with teflon sheet were reexplored 1 year later. The appearance of middle ear mucosa was recorded and the newly formed mucosa was taken for histologic examination.

Table 2: Operation methods in patients with teflon sheet lined ears.

Operation method	Number of the patients	%
Radical mastoidectomy + posterior wall reconst + cavity obliteration	6	30
Atticoantrotomi	3	15
Atticotomi	5	25
Combined	6	30
Total	20	100

Table 3: Middle ear pressure values of the amnion membrane lined middle ears and contralateral normal ears.

Middle ear pressure (mm H_20)	Operated ear		Normal ear	
	Number of patients	%	Number of patients	%
0, -75	13	39.3	22	66.6
-75, -300	7	21.4	4	12.0
-300, -400	13	39.3	7	21.4
Total	33	100.0	33	100.0

RESULTS

A) Clinical exam: No graft failure or reaction to either amniotic membrane or teflon sheet observed. On control exams after the operations the grafts was well vascularized.

B) Audiological exam: The results of postoperative middle ear impedansmetric measurements of amniotic membrane lined ears, teflon sheet lined ears and normal ears are shown respectively in Tables 2, 3 and 4. The difference between normal ears and the amnion membrane lined ears was found statistically significant ($t=2.093$, $p<0.05$). The difference between normal ears and teflon sheet lined ears was found statistically significant ($t=2.982$, $p<0.01$). The difference between the amnion membrane and teflon sheet lined ears was not found significant statistically ($t=0.865$, $p>0.05$). However, the percentage of the mobile ears postoperatively was higher in amnion lined ears when compared to teflon sheet lined ears.

C) Reexploration findings:

1) Findings of the middle ear mucosa covered with amniotic membrane:

Table 4: Middle ear pressure values of the teflon sheet lined middle ears and contralateral normal ear.

Middle ear pressure (mm H_20)	Operated ear		Normal ear	
	Number of patients	%	Number of patients	%
0, -75	8	40	12	60
-75, -300	-	-	3	15
-300, -400	12	60	5	25
Total	20	100	20	100

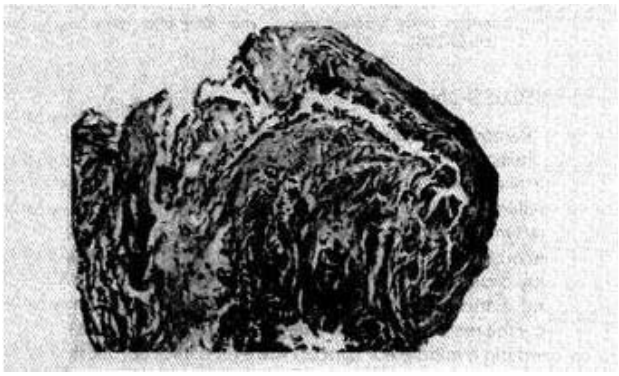

Figure 1: Normal mucosa is seen 1 year later after amnion membrane use (H+EX230).

Table 5: Results of statistical analysis.

Groups	Sd	x (Operation) - X (Normal)	t	Tablet		Result
				0.05	0.01	
O (amnion) - Normal	32	91.66	2.093	2.04	2.75	p<0.05
O (Teflon) - Normal	19	139.75	2.982	2.09	2.85	p<0.01
O (amnion) - (Teflon)	51	44.33	0.065	2.00	2.66	p>0.05

The middle ear was covered with a thin and well vascularized mucosa. Round window nische can be seen easily. The histologic examination showed mucosa which contains small capillaries in a loose connective tissue (Figure 1).

2) Findings of the middle ear mucosa covered with teflon sheets:

The middle ear was covered with a thick, slightly vascularised mucosa. In a patient the thick mucosa obstructed the round window niche. A thick fibrotic tissue which has very little vascularization and foreign body reaction was seen on histologic exam (Figure 2).

DISCUSSION

Removal or disturbance of tympanic mucosa results in adhesions. To prevent these adhesions and to have an air filled middle ear space, various materials such as Gelfilm, silastic and teflon sheets have been used to line the tympanic cavity. The gel film has been abandoned because it does not prevent adhesions (3,5). Silastic sheet may cause secondary tympanic membrane perforations and extrusions (3). According to our experience until now the results with teflon sheet are better than silastic in creating a middle ear space. However, a thick fibrotic tissue with minor degree of vascularization was found on histologic examination of the mucosa with teflon sheet. In a few patients it was seen on reexploration that this thick fibrotic tissue obstructed the round window niche. Some authors (7,8) recommend the removal of these synthetic materials. However, it is rejected by some patients, because of the necessity for a second operation.

Figure 2: A thick fibrotic tissue which has very little vascularisation and foreign body reaction seen 1 year later after teflon use (H+EX230).

Therefore it was thought to cover the tympanic cavity with human amniotic membrane instead of synthetic materials. It was shown that antigenicity of the amnion appears to be very low and no evidence of rejection after transplantation was reported (9,10,11). Amniotic membranes have been shown to have the ability to decrease bacterial growth (10). Human amniotic membrane is readily available, easily stored and inexpensive. It was used with good results as wound dressing for burns, vaginal epithelization, replacement of nasal mucosa in hereditary hemorrhagic telengiectasia, arthroplasty and in ear surgery to close the small tympanic membrane perforations and as lining in mastoid cavities (2,4,9,10,11). Although measurements of middle ear pressures do not show any significant difference between amnion membrane and teflon sheet lined ears, the histologic examination of the mucosa in the amnion membrane lined ears showed almost nearly normal mucosa compared to the thick and little vascularised mucosa of the teflon sheet lined ears.

In the light of these finding it can be said that human amniotic membrane is a biologic material which might be used in lining the tympanic cavities.

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