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Surgical and Audiological Outcomes of Wet Versus Dry Temporalis Fascia Graft in Type 1 Tympanoplasty

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Abstract

Objectives: Evaluate the surgical success and postoperative hearing outcome of type 1 tympanoplasty using temporalis fascia graft in its wet versus its dry fashion.

Methods: A prospective randomized comparative study which was conducted in Sulaimanyah otorhinolaryngology & head and neck surgery centre between October 2018 and November 2019 on patients with sign and symptom of tympanic membrane perforation who underwent type 1 tympanoplasty in 2 groups in whom wet graft used in one group, and dry graft used in the other group, these patient followed up after 3 month for graft take and postoperative hearing.

Results: Of the 29 patients included in the study in 15 of them dry graft used and the graft take was 86.7% and in 14 of the wet graft used and the take rate was 78.6%, postoperative mean hearing gain was 14.07 dB in the dry graft group and 12 dB in the wet graft group, all cases in both group had improvement in hearing (*P* value = 0.001), but neither wet or dry was better than the other (*P* value = 0.345). Graft take and hearing gain in different site and size of perforations were not significant, graft take rate was 100% in small size and 50% in subtotal perforation, hearing gain was 14.50 dB for subtotal perforation and 9.50 dB in small size perforation, mean time of wet graft group with 75.36 minutes were shorter significantly than the dry graft with 95 minutes with (*P* value = 0.001).

Conclusion: The nature of the temporalis fascia not affect the outcome type 1 tympanoplasty, and temporalis fascia is a good graft material regarding the success rate and hearing gain, however the wet temporalis fascia graft use may shorten the operation time.

Keywords: Type 1 tympanoplasty, temporalis fascia, chronic suppurative otitis media

Introduction

The tympanic membrane is a structure that forms the medial wall of the external auditory canal and much of the lateral wall of the middle ear space, in other words it separate the external ear from the middle ear, with ossicles it transfer the sound stimulus from the EAC to the fluid of inner ear.[1] Tympanic membrane perforations and its consequences is one of the most common conditions encountered in otorhinolaryngology, most frequent cause of tympanic membrane perforation is infection other less commoner causes are trauma which include penetrating, barotrauma, blast injury and iatrogenic.[2]

Majority of perforations (70%–80%) which caused by infection (acute otitis media) heal spontaneously within a month, with pre-existing tympanosclerosis, malleus injury, infection and large perforations negatively affect spontaneous closure rate, when a perforation becomes chronic, the margin of the perforation can be seen to be stable with squamous epithelial cell grow inside to come in contact with mucosa of middle ear, Permanent perforations may be a symptomatic but the majority of patients present to otorhinolaryngologist due to their symptoms the commonest are: ear discharge and hearing loss.[3]

Myringoplasty can defined as surgical repair of tympanic membrane.[3] Tympanoplasty is a procedure to eradicate middle ear disease and to reconstruct the hearing mechanism.[2] Type 1 tympanoplasty include repair of the tympanic membrane with intact ossicular chain and middle ear is free of disease, granulation tissue and cholesteatoma.[4]

The classical objectives of tympanoplasty have not changed in 50 years and remain: eradication of disease, closure of ear by grafting, hearing rehabilitation, the goals in this order allow for patient counselling and reasonable expectations,[5] the results of tympanoplasty are measured in terms of success or failure of graft-take and hearing improvement.[2]

Three main surgical approaches are used in tympanoplasty these are: trans canal, end aural, and post-auricular, choosing the approach depends on size of the perforation, anatomy of EAC and surgeon's preference, it's important the chosen approach offer full visualization of the perforation.[6] Several types of graft material used from autografts like temporalis fascia, tragal or concha perichondrium, cartilage, fascia lata, vein, periosteum, ear canal or other skin graft and fat all have been used with with ideal material all have their own advantages and disadvantages, allograft like human processed skin and xenograft like equine and bovine pericardium were found to be inferior to temporalis fascia, of the autologous graft material temporalis fascia is the most commonly used one as it's present in large amounts and easy to handle, strong and in the surgical field with success rate of 77–99% in adults.[3] Despite the temporalis fascia being the most commonly used graft in myringoplasty There is not much in the literature about the nature of the temporalis fascia graft (Dry versus wet) effect on the consequence of tympanoplasty and the use of graft dried or wet is controversial.[7]

Some otologists prefer to harvest the temporalis fascia graft after elevating the tympano meatal flap just before graft placement in the middle ear and using it (wet) while others harvest the fascia at the beginning of the operation and use it when it becomes dry.[8] The supporters of using temporalis fascia in its (wet) nature argue that better rate of closure and graft take are achieved using fresh, undried (wet) fascia because its histologically more viable and the greater number of fibroblasts and its survival has a significant role in healing and laying down collagen for the reparative process.[9,10]

On the other hand advocates of (dry) temporalis fascia argue that the fascia serves merely as a frame work for the migration over the epithelium and it's nature not affect the outcome of surgery.[11,12]

In this study we evaluated the surgical success and post-operative hearing outcome of type 1 tympanoplasty using temporalis fascia graft in its wet versus its dry fashion.

Methods and Materials

This prospective randomized comparative study conducted in otorhinolaryngology & Head and Neck surgery centre in Al-Sulaimanyah teaching hospital between October 2018 and November 2019 on 29 patients suffered from signs and symptoms of perforated tympanic membrane seeking treatment. Age of patients were between (15–60) years old, dry temporalis fascia graft used in 15 patients and wet temporalis fascia graft in 14 patients all of them underwent type 1 tympanoplasty in sulaimanyah teaching centre of otorhinolaryngology and head and neck surgery.

Pre checklist was fulfilled after detailed history and clinical examination and necessary radiology and laboratory investigations, and, the checklist involved (Age, gender, cause of perforation, site and size of perforation) and all the patients were exposed to type 1 tympanoplasty by using temporalis fascia either (Wet or Dry) according to blind randomisation. Were informed about the possible rate of success and failure, limitations and complications of the operation, alternative treatment options all are informed about the research (by the researcher).

Inclusion Criteria

1. Central perforation
2. Intact ossicular chain: (determined by preoperative ABG of less than 30 and intraoperative finding, if there discontinuity and erosion of ossicular chain the patient excluded from the study).
3. Inactive COM (for at least 6 weeks)
4. Age more than 8 year

Exclusion Criteria

1. Revision cases
2. Only hearing ear
3. Eustachian tube dysfunction
4. Cases which need additional mastoid surgery
5. Actively discharging ear
6. Diffuse otitis externa

Preoperative Evaluation

History and Examination

A full ENT head and neck history was taken, focus was on key symptoms of the affected side like: otorrhea, hearing loss, tinnitus, otalgia, and vertigo, and previous history.

Examination begin with inspection of the auricle for any scar and signs of infection and microscope and otoscope used to inspect the EAC for any signs of infection or wax impaction, then tympanic membrane inspected for colour, position, land marks, retraction and perforation if present evaluated for site, size, state of middle ear mucosa, ossicles (if could be seen), and examination of the contralateral ear in the above fashion done, all patients submitted to facial nerve examination and fistula test, nasal cavity, oral cavity, oro and naso pharynx all examined according to the complain of the patient to exclude allergy and any septic foci like tonsillitis, rhinosinusitis, and deviated nasal septum and nasal mass.

Hearing Assessment

Hearing of all the included patients assessed by preoperative pure tone audiometry and tuning fork tests (rinne and weber test) absolute bone conduction ABC test.

Surgical Techniques

Harvesting the Temporalis Fascia Graft

In the dry graft group the temporalis fascia harvested at the beginning of the operation and putted on a glass cleared of the soft tissue and muscle and let it to dry, in the wet graft group the temporalis fascia harvested after elevation of the tympano meatal flap and exploring the middle ear and ossicles, then putted directly by underlay technique.

Time of the operation was recorded in both type of graft also type of the graft used is also mentioned.

All the cases discharged several hour after surgery at the same day after monitoring facial nerve function, nystagmus and general condition on oral antibiotic (Amoxiclav tablet 1 gm and ciprofloxacin tablet 750 twice daily for 7 days after excluding drug allergy and interaction). Instruction has been given to all patients to not lift heavy weight, and not sleep on the side of surgery, also to not swim and caution during bathing, wound dressing changed the next day, stiches and the wick in EAC were removed 7 day after operation, and hearing of the patient tested by tuning fork test. The remaining gel foam, blood and serosanguinous fluid sucked from the external auditory canal under microscope after 1 month, and assessed for graft take and residual perforation, all cases had pure tone audiogram 3 months after operation, audiological success was evaluated by comparing mean Air Bone Gap which was measured at the frequencies (500, 1000, 2000, 4000) Hz pre and post operatively in both type of graft. Also hearing gain was measured by subtraction of mean postoperative ABG from the mean preoperative ABG in both types of graft (as seen in Figure 1). Successful surgery considered when the ear was dry, the graft was taken, and there was no residual perforation (as shown in Figure 2) and hearing improved.

Ethical Consideration

Research proposal was fully discussed and approved by the ethical and scientific committee of Iraqi board of otorhinolaryngology & Head and Neck surgery.

The agreement of health authority in of otorhinolaryngology & Head and Neck surgery in Al-Sulaimanyah teaching hospital is granted before starting data collection.

Written consent was taken from each patient after full exploration of the Aim of study and ensuring the confidentiality of the collected data which will not be used for any purpose other than scientific research.

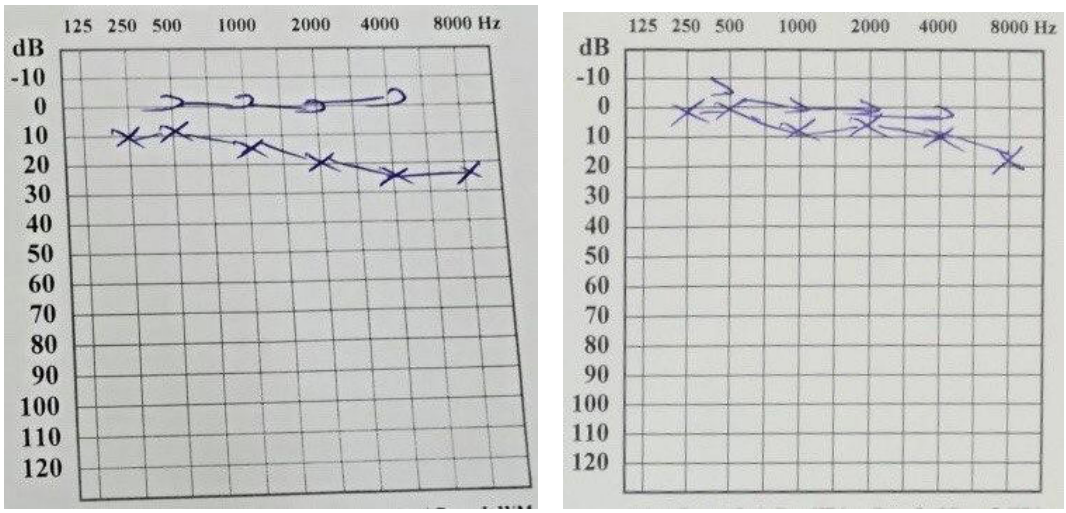

Fig. 1 **A. Pre-operative PTA shows 17 dB ABG, B. Postoperative PTA shows closure of the ABG to about 6 dB hence hearing gain of 11 dB.**

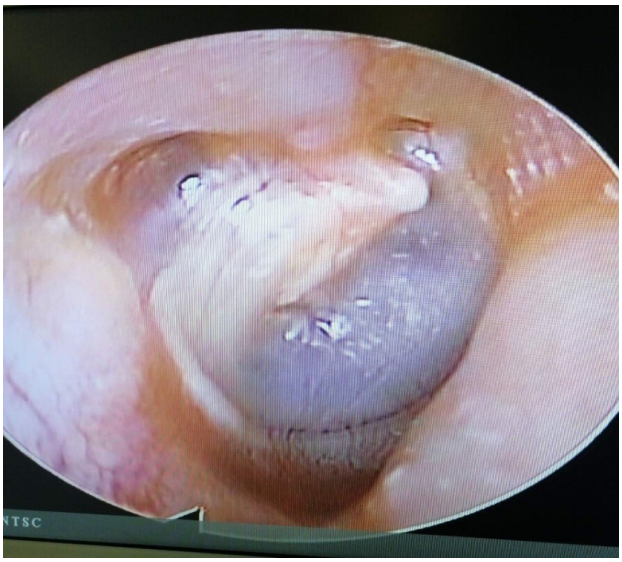

Fig. 2 **Postoperative view of healed temporalis fascia graft.**

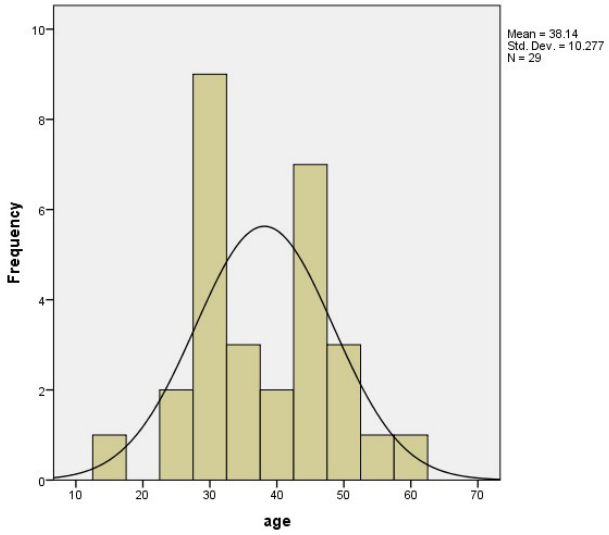

Fig. 3 **Distribution of studied cases according to age.**

Statistical Analysis

Data were introduced into SPSS version 26 statistical program. Descriptive statistics were presented using tables and graphs.

Chi square test was used to find out associations between categorical variables, *t* test and one way ANOVA test were used to find out significance of differences between means of numerical variables.

P value < 0.05 was considered as cut-off point of significance.

Results

The results of this prospective cohort study shows that age of the included patients in this study was between (15–60) the mean age of the studied patients was (Mean ± SD = 38.13 ± 10.27) year and most of the patients were in their 4th decade as showed in Figure 3.

Studied patient was distributed as 15 (52%) of patients exposed to operation by dry TF graft and 14 (48%) of patient exposed to operation by wet TF graft as shown in Figure 4.

Table 1 shows that there was no significant difference between mean age of the patients exposed to dry graft and mean of age of patient exposed to wet graft according to two sample *T*-test, *P* value = 0.212. There was no significant difference between mean age of the male and female patient, *P* value = 0.957.

There was no significant difference between mean age of the patient who took the graft successfully and those who failed to take the graft, *P* value = 0.492.

The mean age of patient exposed to trauma as a cause of TM perforation was not significantly differs than those who the cause of perforation was infection, *P* value = 0.901.

There was no significant difference between mean age of patient according to site and size of perforation, *P* value = 0.103, and 0.084 respectively.

Figure 5 shows no significant correlation between age of patient and hearing gain (r = 0.022, P value = 0.909).

Figure 6 shows that (52%) of patients were males and (52%) exposed to operation by Dry TF graft.

(74%) of patients exposed to operation successfully took the graft.

(59%) of patients got perforation at anterior part of TM, 28% at posterior and 19% got subtotal perforation.

Large size perforations were found in 35% of patients while 57% and 14% of patients got medium and small size perforations respectively, 24% of patients got perforation because of trauma while infection found to be the cause of perforation in 74% of the cases.

Table 2 shows time needed by the surgeon to complete dry graft was found to be significantly longer than wet graft time, P value = 0.001, otherwise no significant difference between mean age, pre ABG, post ABG, hearing gain and duration of disease and type of operation, P value = 0.212, 0.751, 0.315, and 0.197 respectively.

As shown in (Table 3) there was no significant association between gender of patient and type of TF graft used according to Chi-square test, P value = 0.096.

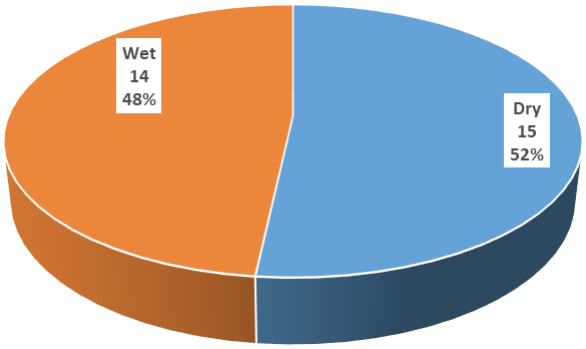

Fig. 4 **Distribution of studied cases according to type of operation.**

No significant association were noticed between site, size and cause of perforation and type of TF graft used (P = 0.608, 0.617, 0.682) respectively.

Table 4 shows that 86.7% of patients who took the graft successfully had been exposed to dry TF graft, in comparison with 78.6% who had been operated on using wet TF graft.

There was no significant association between type of graft and outcome of operation, P value = 0.651.

No significant association were noticed between sex of patient, site, size of lesion, cause of perforation and outcome of operation, P value = 0.465, 0.174, 0.344 and 0.347 respectively.

Table 5 shows that the post-operative ABG was significantly lower than the preoperative ABG in dry TF graft, P value = 0.001.

Post-operative ABG was also found to be significantly lower at postoperative measurements than the preoperative ABG, in wet type operation, P value = 0.001.

Table 6 shows that the mean of hearing gain in successful graft group was significantly better than that of failed graft, P value = 0.001.

Discussion

Although temporalis fascia is the most common graft material used for closing perforations of the tympanic membrane with considerable successful results there is still debate on the technique of surgery and nature and preparation of the temporalis fascia graft used, in this study tympanoplasty type 1 procedure done in 29 patients by underlay technique in a group of 15 patients dry TF graft used and in the second group 14 patients wet TF graft has been used and different factor analysed that may affect the outcome.

In dry TF group successful closure of perforation achieved in 86.7% and in wet TF graft take was 78.6% and results were statistically not significant, our results were close to results of those studies that studied the effect of the nature of the TF on the outcome of surgery, which they showed no

Table 1. **Difference between mean age of patients according to studied variables**

		N	Mean	Std. deviation	*P* value
0peration	Dry	15	40.47	9.141	0.212
	Wet	14	35.64	11.160	
Gender	Male	15	38.60	9.334	0.957
	Female	14	37.64	11.540	
Outcome	Graft taken	24	38.75	10.916	0.492
	Graft not taken	5	35.20	6.419	
Cause	Trauma	7	38.57	12.095	0.901
	Infection	22	38.00	9.947	
Site	Anterior	17	41.53	9.900	0.103
	Posterior	8	33.13	11.077	
	Subtotal	4	33.75	4.349	
Size	Large	10	33.60	8.922	0.084
	Medium	15	42.20	10.345	
	Small	4	34.25	8.732	

effect of the nature of TF graft on the graft take. In his study Alkan S et al.[8] showed 91.4% complete graft take in the wet and 88.6% in the dry graft group which was not significant statistically, also results of Singh GB et al.[13] showed no significant difference in closure rate in both groups, In a related study Loock JW et al.[9] showed slight higher success rate of dried fascia more than wet and dried then re-hydrated fascia but also the difference in his study was not significant.

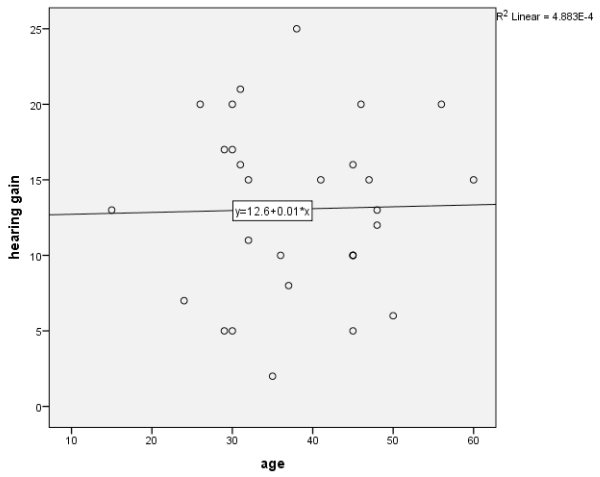

Fig. 5 **Distribution of hearing gain according to age.**

Regarding dry temporalis fascia some authors like England RJ et al.[14] and Wormald PJ et al.[15] postulated that when a dry graft put in a wet environment it will shrink and lost contact with remnant of tympanic membrane. Indorewala.[16] also observed shrinkage and thickening of temporalis fascia in a study conducted on dogs, authors like Chow et al.[17] advocate that a large size graft be harvested as a result of this shrinkage of temporalis fascia.

Effect of age on the graft take is studied, some studies consider graft take is affected by age and it's lower in children than adults.[18] And this due to immature functioning of Eustachian tube and recurrent upper respiratory tract infection and under developed immune system.[19] Because of that cases included in this study were above 8 years old, there was no difference in the mean age of the included patients in the two groups; however in our study age was not a significant factor on the graft take and hearing outcome and it was similar to other studies.[20]

Of the 29 patient in this study (15 = 52%) was male and (14 = 48% was female, there is no difference in rate of graft take in both sexes this is similar to results of study done by Naderpour M et al.[21]

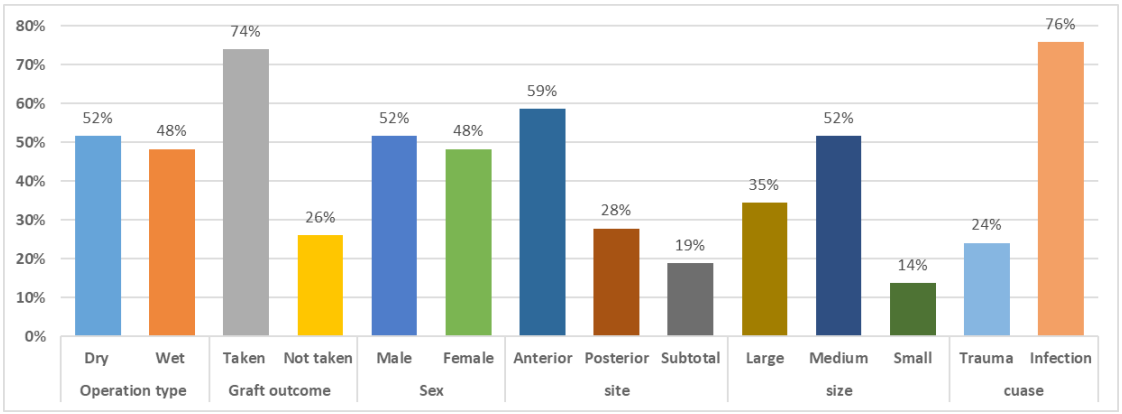

Fig. 6 **Distribution of studied cases according to essential characteristics.**

Table 2. **Two sample *t* test, differences between means of numerical dependent variables according to studied variables**

		N	Mean	Std. deviation	*P* value
Age	Dry	15	40.47	9.141	0.212
	Wet	14	35.64	11.160	
pre ABG	Dry	15	21.47	6.739	0.751
	Wet	14	22.29	7.021	
Time	Dry	15	95.00	12.392	0.001
	Wet	14	75.36	11.843	
Post ABG	Dry	15	7.40	6.685	0.315
	Wet	14	10.29	9.539	
Hearing gain	Dry	15	14.07	5.612	0.315
	Wet	14	12.00	5.961	
Duration	Dry	15	5.07	2.404	0.197
	Wet	14	8.64	10.180	

Table 3. **Association between categorical studied variables and type of operation**

		Operation type				
		Dry		Wet		
		Count	Row *N* %	Count	Row *N* %	*P* value
Sex	Male	10	66.7%	5	33.3%	0.096
	Female	5	35.7%	9	64.3%	
Site	Anterior	10	58.8%	7	41.2%	0.608
	Posterior	3	37.5%	5	62.5%	
	Subtotal	2	50.0%	2	50.0%	
Size	Large	4	40.0%	6	60.0%	0.617
	Medium	9	60.0%	6	40.0%	
	Small	2	50.0%	2	50.0%	
Cause	Trauma	3	42.9%	4	57.1%	0.682*
	Infection	12	54.5%	10	45.5%	

Table 4. **Association between studied categorical variables and outcome**

		Graft taken				
		Graft taken		Graft not taken		*P* value
		Count	Row *N* %	Count	Row *N* %	
Operation type	Dry	13	86.7%	2	13.3%	0.651
	Wet	11	78.6%	3	21.4%	
Sex	Male	13	86.7%	2	13.3%	0.465
	Female	11	78.6%	3	21.4%	
Site	Anterior	15	88.2%	2	11.8%	0.174
	Posterior	7	87.5%	1	12.5%	
	Subtotal	2	50.0%	2	50.0%	
Size	Large	7	70.0%	3	30.0%	0.344
	Medium	13	86.7%	2	13.3%	
	Small	4	100.0%	0	0.0%	
Cause	Trauma	5	71.4%	2	28.6%	0.347
	Infection	19	86.4%	3	13.6%	

Table 5. **Paired sample *t* test, difference between means of ABG measured preoperatively and 3 months after operation according to type of operation**

		Mean	*N*	Std. deviation	*P* value
Dry	pre ABG	21.47	15	6.739	0.001
	post ABG	7.40	15	6.685	
Wet	pre ABG	22.29	14	7.021	0.001
	post ABG	10.29	14	9.539	

Regarding the cause of perforation in 76% of cases (22 patients) the cause was infective, and in 14% (7) the cause was traumatic, and graft take was slightly higher in cases of infection as a cause of perforation but the results were not significant, authors like Sheehy JL et al.[4] reported close outcome.

The effect of perforation site is also addressed on the outcome of surgery results showed higher rate of failure in and subtotal perforations (50%) but close success rate in anterior and posterior perforations, effect of site on graft take was statistically not significant (*P* value = 0.174). Effect of the perforation size on the success rate of graft take is also studied; all cases of small size perforation took the graft successfully while 30.0% of the large and 13.3% of the medium sized perforation failed to take the graft. Although the results were statistically not significant but we notice from the results that there was higher rate of failure in the subtotal and large sized perforations.

Table 6. **Independent 2 samples *t* test, differences between means of hearing gain according to studied variables**

		N	Mean	Std. deviation	*P* value
Gender	Male	15	13.67	5.381	0.573
	Female	14	12.43	6.309	
Operation	Dry	15	14.07	5.612	0.345
	Wet	14	12.00	5.961	
Outcome	Graft taken	24	14.75	4.766	0.001
	Graft not taken	5	5.00	2.121	
Cause	Trauma	7	12.71	7.204	0.859
	Infection	22	13.18	5.439	
Size	Large	10	13.60	7.321	0.427
	Medium	15	13.67	5.233	
	Small	4	9.50	1.732	
Site	Anterior	17	13.29	5.720	0.750
	Posterior	8	11.88	4.086	
	Subtotal	4	14.50	9.539	

Higher rate of failure in the subtotal perforations could be due to the effect of graft shrinkage.[16] Or improper placement of the graft or inadequate support of the graft in the anterior half, due to higher rate of malleus handle erosion and inadequate access to anterior margin of the perforation and also there is studies reported similar outcome of Myringoplasty operation in subtotal perforations similar to other perforation's size.[22] There is some studies in the literature that show higher success rate in the posterior type of perforation and lower success in the anterior type due to the fact that the posterior half of the tympanic membrane has better blood supply than the anterior half, which supplied by branches of mallear artery while anterior half is infused by branches of annular ring.[23] Or could be due to the effect of graft shrinkage.[16]

Hearing Outcome

In both groups of patients hearing improved significantly when preoperative and postoperative ABG is compared, in both groups (*P* value = 0.001). Also postoperative hearing gain compared in both groups, mean hearing gain in dry graft group was (14.07 ± 5.6) dB, and the mean postoperative hearing gain in the wet graft group was (12.00 ± 5.9) dB, there is no advantage of one group over the other and the results in both groups were statistically not significant, (*P* value = 0.345). That means despite the nature of the graft (Wet or Dry) there is advantage in using TF as a graft material in type 1 tympanoplasty in regard to hearing gain post operatively. Karela et al.[24] suggested an improvement in hearing in 91.5 percent of cases using TF graft and reported that myringoplasty is a procedure that can be effective in many cases, irrespective of age, gender, location and perforation size.

Although in his study Alkan S et al.[8] the hearing results for wet graft was better with mean hearing gain of 15.25 dB than the dry graft group with 9.75 dB but the results were statistically insignificant, our results were close to the results of a study done by Singh GB et al.[13] which showed comparable hearing results in both groups.

Hearing outcome in different age groups were not significant that indicates age is not a predictive factor on similar to other studies.[21] Hearing outcome according to (size and site) is also addressed, mean hearing gain was higher in large and medium more than the small perforations, but the results were statistically not significant (*P* value = 0.427), despite that our result was insignificant showed a mean hearing gain in small sized perforation of 9.5 dB which is higher than the results of some authors which showed that after myringoplasty for small tympanic membrane perforation (less than 50 percent) of tympanic membrane ABG is a minimum (average 5.5 dB) and higher ABG (average 10.5 dB) is more common after closure of perforations of (more than 50 percent) of TM.[21] About hearing outcome in different sites anterior and subtotal perforations had higher mean hearing gain than the posterior perforations postoperatively also this was statistically not significant (*P* value = 0.750).

Despite that the effect perforations site on hearing outcome is not significant but the post-operative hearing gain was higher in subtotal[25] perforations Yung MW. Concluded that a large central and postero inferior perforations cause high preoperative hearing loss and get most benefit after surgery and his work showed that site of perforation affect the degree of hearing loss and subsequent improvement after surgery, our results were comparable with results of other studies that showed no effect of perforation size on hearing outcome.[24]

Time of Operation

Time of operation observed and it was (95 ± 12.39) minute in the dry graft group and (75.35 ± 11.84) minute in the wet graft group, results were significantly shorter in the wet graft group (*P* value = 0.001), harvesting the graft after elevation of the tympanomeatal flap and placing it directly after cleaning it from the muscles and soft tissue may have a role in decreasing mean operation time in our study, there is two studies in the literature that addressed the time of operation in wet and dry temporalis fascia graft, in his study Singh GB et al.[13] found

difficulty in placing the wet graft under the tympanomeatal flap and tympanic membrane remnant which made the time longer for placement of the graft, our results was similar to results of Alkan S et al.[8] who found that manipulation of the wet graft was easier when placed in the middle ear but he also noticed that wet graft rehydrate more quickly when placed through the middle ear and become thicker and smaller in size and when the time to put the graft is prolonged the graft become thicker and difficult to manipulate so it's better be applied by an experienced surgeon.

Conclusion

Surgical and audiological outcome of type 1 tympanoplasty using TF graft in different site and size perforations is not affected by the nature of the TF whether it's used in dry or wet fashion regardless of the graft nature. Temporalis fascia is an excellent graft material for closing tympanic membrane perforation and regain hearing. And it's a matter of surgeon's preference and experience to choose how to use the graft, however using TF in it's wet form may reduce the time of operation significantly in experienced hands, also we can conclude that large perforations has the highest hearing loss, also subtotal and large anterior perforations may need more attention to surgical details regardless the type of graft used because of higher rate of graft failure.

Conflict of Interest

None.

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