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A Comparative Study of Full-Thickness Versus Half-Thickness Cartilage Graft in Type I Tympanoplasty

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ABSTRACT

Background & objectives: Tympanic membrane repair using temporalis fascia and perichondrium may show failure as a result of atrophy. Cartilage might be a better alternative. The use of cartilage for tympanoplasty may be associated with some functional impairment due to reduced vibration patterns. Thinning of cartilage can result in acoustic benefits. There is a lack of sufficient evidence to support the use of full thickness or half thickness cartilage graft; therefore, this study was undertaken with the aim of evaluating the outcome of full thickness versus half thickness cartilage graft in Type I tympanoplasty.

Methods: This clinical trial included 60 patients [30 receiving full thickness graft (Group A) & 30 receiving partial thickness graft (Group B)]. Assessment of AB gap, AB gap closure, graft uptake, presence of dry ear, and complications was performed. Data were analysed using SPSS (Statistical Package for Social Sciences) 25.0 version.

Results: The gap closure was significantly greater in Group B compared to Group A at 3 months [5.0 (0.0- 10.0) vs. 4.5 (0.0- 5.25); p-value= .034] and at 6 months [10.0 (5.0-10.325) vs. 5.0 (4.75-10.0); p-value= .031]. Overall, the graft uptake was successful in 95% of the patients. The graft rejection rate was 3.3% and 6.7% in Group A and Group B respectively.

Conclusion: Partial-thickness tragal cartilage grafts in Type I tympanoplasty provide superior audiological outcomes, with better AB gap closure and reduced aural fullness, compared to full-thickness grafts, without compromising the high graft uptake rate.

Keywords: Full thickness cartilage graft, Partial thickness cartilage graft, tympanic membrane, tympanoplasty, perforation.

1. INTRODUCTION

Tympanoplasty is a surgical procedure based on the principles of eradication of the middle ear disease, restoration of sound transmission mechanism, reconstruction of an intact tympanic membrane (TM), and creation of air-containing middle ear space. [1,2] It is commonly used for the management of tympanic membrane perforation (TMP) and has a high success rate of 70-90% in a normally ventilated middle ear.[1]

TMP is prevalent across the globe, with prevalence 2.1% (95% CI, 1.7%-2.6%) and can be seen in any age group with the highest prevalence in older adults (nearly 6.1%) and 0.6% in adolescents and no difference between males and females.[3] The causes of TMP include infection, rapid changes in pressure leading to sudden otorrhea, otalgia, tinnitus, and vertigo or trauma.[4] TMP causes conductive hearing loss due to disruption of sound transmission to the middle ear

ossicles. Chronic suppurative otitis media (CSOM), which is defined by a perforated tympanic membrane (eardrum hole) that allows persistent drainage from the middle ear, is also associated with hearing loss [5] requires tympanoplasty.

TMP repair can be achieved with various materials such as cartilage (Tragal cartilage, conchal or septal cartilage), perichondrium, fat, vein grafts, homologous fascia or dura for the closure of tympanic membrane closure. [1,6,7,8] The most frequently used material is temporalis fascia. However, low elastic modulus of tympanic fascia makes it susceptible to pressure changes in ear.[9] Thus, making it unsuitable for situations like atelectatic ears.[1] Both fascia and perichondrium may fail as a result of atrophy. Findings suggest that Cartilage might be a better alternative to resist the negative middle ear pressure observed in atelectatic ears.[1] Cartilage has a high elastic modulus owing to its thickness and rigidity.[9] Patients with atelectatic ears, subtotal, bilateral, or total perforations, craniofacial abnormalities cholesteatoma, and coexisting revision tympanoplasty are considered to have high risk perforations with higher chances of recurrence. For such patients, cartilage have been found to be beneficial.[2] The rigidity of cartilage prevents its retraction and re-perforation.[1] Apart from this, cartilage shows less anti-inflammatory tissue reaction and becomes well-incorporated with the tympanic membrane. The use of cartilage for tympanoplasty may be associated with some functional impairment due to reduced vibration patterns.[1] However, evidence also suggests that proper preparation and correct placement of cartilage graft provide high success rates and hearing outcomes.[1] The thickness of cartilage graft is critical in determining hearing capacity after tympanoplasty. Some surgeons speculated that thinning of cartilage can result in acoustic benefits,[6] whereas some others have found that partial-thickness cartilage graft have better graft uptake but result in no significant improvement in hearing.[8] Few studies have recommended the use of full thickness cartilage while others recommended partial thickness cartilage. However, there is lack of sufficient evidence to support the use of full thickness or half thickness cartilage graft; therefore, this study was undertaken with the aim of evaluating the outcomes of full thickness versus half thickness cartilage grafts in Type I tympanoplasty.

2. MATERIALS & METHODS

2.1 *Study design, study site, study duration*

This non-randomised clinical trial was conducted over a period of 18 months [From August 2023 to January 2025] in the ENT Department of a tertiary care centre in Maharashtra.

2.2 *Study population, sample size, sampling technique*

Study population

The study was conducted among patients undergoing type I tympanoplasty. Patient with Central TMP, subtotal (perforation involving >50% of the total TM area) or total perforation, and those requiring revision tympanoplasty were included in the study. However, patients with history of previous mastoid surgery, ear discharge, those requiring ossicular reconstruction, cholesteatoma, poor cochlear reserve, and Eustachian tube block were excluded from the study.

Sample size

The sample size was calculated using G*power software version 3.1.9.7. The sample size was estimated to achieve a power of 95% at 5% level of significance while detecting a medium effect size (0.25, according to Cohen). The assumption of a medium effect size based on the observations of gap closure at 3 months using full thickness and partial thickness graft as reported in a previous study by Xing C et al. [10] The minimum required total sample size was 54 (27 in each group); however, 60 patients (more than minimum required) were included in the study.

Sampling technique

Eligible subjects who met the inclusion and exclusion criteria were assigned sequentially at enrollment to either Group A or Group B using convenience sampling.

2.3 Primary and secondary outcome

Primary outcome measure

Hearing improvement (AB gap closure) at follow-up and graft acceptance rate and after type I tympanoplasty, comparing full thickness cartilage graft with half thickness cartilage graft.

Secondary outcome measure

Operative time, and postoperative complications, such as graft failure, re-perforation, infection, discharge, or any other procedure-related complication.

2.4 Methodology

Pre-operatively

In both the groups, information regarding age, gender, and presenting symptoms was recorded. Otologic examination was performed to assess the site, size and number of TMPs and to determine if middle ear mucosa was visible. Hearing loss was assessed by performing Rinnie's test, Weber's test and pure tone audiometry (PTA). Rinne's test is performed with 256 Hz, 512 Hz and 1024 Hz tuning forks. During PTA, the air-Bone gap was assessed at 500 Hz, 1000 Hz, 2000 Hz and 3000 Hz was measured and the average of these four frequencies was calculated.

Intra-operatively

The surgery was performed according to the standard protocol followed in the department.

The amount of blood loss was classified as mild, moderate, severe, very severe according to Advanced Trauma Life Support (ATLS) classification.[11] The time required to perform the operative procedure was recorded. The mobility of the ossicular chain was also assessed.

Post-operatively

PTA was performed at 3-month and 6-month follow-up visits. Graft status was assessed by otoscopic examination, and the presence of dry ear was recorded. The presence of complications, if any, was also recorded.

2.5. Statistical analysis plan

Data were analysed using SPSS (Statistical Package for Social Sciences), version 25.0 (IBM, Chicago, IL, USA). Data were analysed for normality using Kolmogorov-Smirnov test. Descriptive statistics were performed. Inter-group comparison of continuous variables was done using independent t-test, Mann-Whitney U test and Kruskal-Wallis test (followed by post hoc analysis). Inter-group comparison of categorical variables was done using Chi-square test or Fisher's exact test. Intra-group comparison of continuous variables was done using Friedman test, followed by post-hoc analysis. P-value<.05 was considered statistically significant.

3. RESULTS

Pre-operative findings

The affected ear showed a higher proportion of right-sided involvement in Group A (56.7%) and left-sided involvement in Group B (66.7%); however, this difference was not statistically significant (p-value= 0.069). The distribution of TMP site and perforation size was comparable between the groups (p-value= 0.658 and p-value= 0.689, respectively), with moderate-sized perforations being the most common in both groups (60.0% in Group A and 53.3% in Group B). Middle ear mucosal status was also similar, with normal mucosa observed in most participants (90.0% in Group A and 93.3% in Group B; p-value= 0.640). [Table 1]

Rinne's test at 256 Hz was negative in all participants, while the test at 1024 Hz was positive in all participants. At 512 Hz, a significantly higher proportion of patients in Group B had a positive Rinne's test (100.0%) than in Group A (70.0%) (p-value= 0.001). Weber test lateralization did not differ significantly between the groups (p-value= 0.069). A significant difference was observed in the side of diagnosis, with right inactive mucosal chronic otitis media being more

common in Group A (60.0%) and left inactive mucosal chronic otitis media being more common in Group B (66.7%) (p-value= 0.038). Overall, except for the Rinne's test at 512 Hz and the side of diagnosis, the two groups were well matched with respect to baseline demographic and clinical characteristics. [Table 1]

Table 1. Inter-group comparison of baseline (pre-operative) characteristics of patients.

Variable		Statistics	Group A (n=30)	Group B (n=30)	p-value
Age (in years)		Mean ± SD	35.6 ± 14.940	32.2 ± 10.073	.310$^{\infty}$
Gender$^{\#}$	Male	Number (%)	13 (43.3%)	16 (53.3%)	.438
	Female	Number (%)	17 (56.7%)	14 (46.7%)	
Affected ear$^{\#}$	Right	Number (%)	17 (56.7%)	10 (33.3%)	.069
	Left	Number (%)	13 (43.3%)	20 (66.7%)	
Site of TM perforation (quadrant)$^{\Omega}$	Anterior	Number (%)	15 (50.0%)	16 (53.3%)	.658
	Posterior	Number (%)	6 (20.0%)	7 (23.3%)	
	Inferior	Number (%)	1 (3.3%)	0 (0.0%)	
	Anteroinferior	Number (%)	3 (10.0%)	5 (16.7%)	
	Posteroinferior	Number (%)	4 (13.3%)	2 (6.7%)	
	Posterosuperior	Number (%)	1 (3.3%)	0 (0.0%)	
Size of TM perforation$^{\Omega}$	Small	Number (%)	9 (30.0%)	12 (40.0%)	.689
	Moderate	Number (%)	18 (60.0%)	16 (53.3%)	
	Large	Number (%)	3 (10.0%)	2 (6.7%)	
Middle ear mucosa$^{\Omega}$	Right	Number (%)	27 (90.0%)	28 (93.3%)	.640
	Left	Number (%)	3 (10.0%)	2 (6.7%)	
Rinnie's test at 256 Hz	Positive	Number (%)	0 (0.0%)	0 (0.0%)	-
	Negative	Number (%)	30 (100.0%)	30 (100.0%)	
Rinnie's test at 512 Hz$^{\Omega}$	Positive	Number (%)	21 (70.0%)	30 (100.0%)	.001*
	Negative	Number (%)	9 (30.0%)	0 (0.0%)	
Rinnie's test at 1024 Hz	Positive	Number (%)	30 (100.0%)	30 (100.0%)	-
	Negative	Number (%)	0 (0.0%)	0 (0.0%)	
Weber test$^{\#}$	Lateralised to right	Number (%)	17 (56.7%)	10 (33.3%)	.069
	Lateralised to left	Number (%)	13 (43.3%)	20 (66.7%)	
Diagnosis$^{\#}$	Right inactive mucosa COM	Number (%)	18 (60.0%)	10 (33.3%)	.038*
	Left inactive mucosa COM	Number (%)	12 (40.0%)	20 (66.7%)	

SD- Standard deviation. $^{\infty}$Independent t test. $^{\#}$Chi-square test. $^{\Omega}$Fisher's exact test.
*Statistically significant.

The pre-operative AB gap was comparable between the two groups (p-value= 0.294). At both 3 and 6 months postoperatively, Group B had a significantly lower AB gap than Group A (p-value < 0.001 for both). Group B also showed significantly greater AB gap closure at 3 months (p-value= 0.034) and 6 months (p-value= 0.031), indicating superior postoperative hearing improvement compared with Group A. [Table 2]

Table 2. Inter-group comparison of AB gap and AB gap closure.

Variable	Time interval	Group A (n=30)		Group B (n=30)		Z-value	p-value
		Median (IQR)	Mean rank	Median (IQR)	Mean rank		
AB gap	Pre-operative	25.0 (24.75- 30.00)	32.78	25.0 (23.225- 26.0)	28.22	-1.049	.294
	Post-operative 3 months	20.0 (20.0- 25.0)	42.27	15.0 (15.0- 20.0)	18.73	-5.583	<.001*
	Post-operative 6 months	20.0 (15.0- 20.0)	41.15	15.0 (10.0- 15.0)	19.85	-4.955	<.001*

AB gap closure	Post-operative 3 months	4.5 (0.0- 5.25)	25.88	5.0 (0.0- 10.0)	35.12	-2.115	.034*
	Post-operative 6 months	5.0 (4.75- 10.0)	25.80	10 (5.0- 10.325)	35.20	-2.159	.031*

IQR- inter-quartile range. Mann-Whitney U test. *Statistically significant.

Intra-operative findings

All patients had mild blood loss. Operative time showed no significant difference between Group A and Group B (p-value= 0.598). Most patients in both groups (63.3% in A and 60.0% in B) underwent procedures lasting 1.5-hour. This suggests similar surgical complexity and efficiency for both the full thickness and half thickness cartilage graft techniques in type I tympanoplasty. [Table 3]

Table 3. Inter-group comparison of intra-operative findings.

Variable		Statistics	Group A (n=30)	Group B (n=30)	p-value
Blood loss	Mild	Number (%)	30 (100.0%)	30 (100.0%)	-
	Moderate	Number (%)	0 (0.0%)	0 (0.0%)	
	Severe	Number (%)	0 (0.0%)	0 (0.0%)	
	Very severe	Number (%)	0 (0.0%)	0 (0.0%)	
Operative time$^{\Omega}$	1.5-hours	Number (%)	19 (63.3%)	18 (60.0%)	0.598
	2-hours	Number (%)	11 (36.7%)	11 (36.7%)	
	2.5hours	Number (%)	0 (0.0)	1 (0.3%)	

Fisher's exact test.

Post-operative findings

At 3 and 6 months, post-operatively, the average AB gap was significantly more in Group A than in Group B (p-value<.05). [Table 2] AB gap closure at both 3 and 6 months post-operatively was significantly greater in Group B than in Group A (p-value<.05). [Table 2] Intra-group comparison showed that AB gap closure at 6 months was significantly greater than that at 3 months in both Group A [Z-value= -4.243, p-value<.001] as well as Group B [Z-value= -4.287, p-value <.001], indicating improvement over time.

Graft uptake was successful in 95.0% of the patients. The graft rejection rate was 3.3% and 6.7% in Group A and Group B respectively. The difference in the graft rejection rates between the groups was statistically non-significant (p-value>.05). [Figure 1]

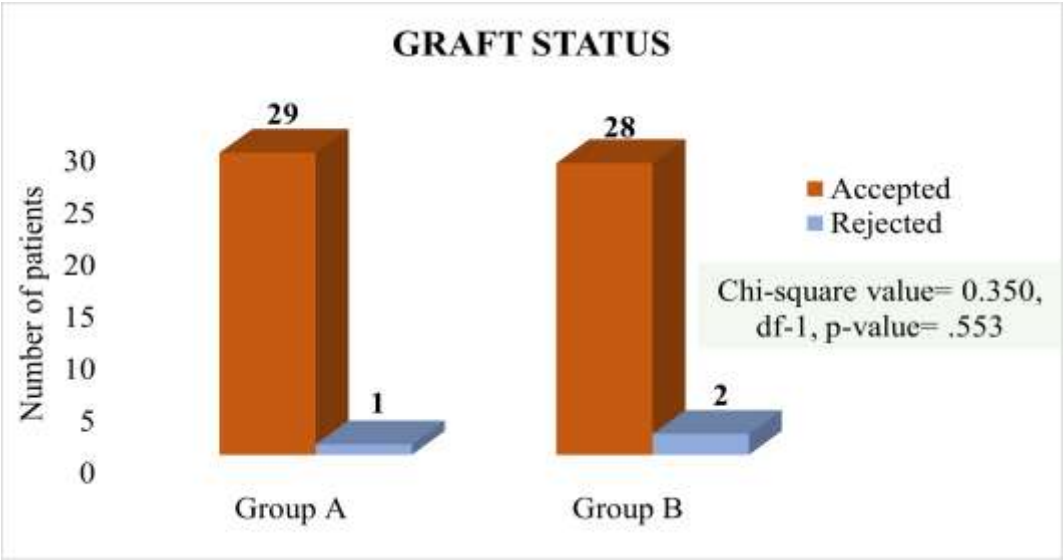

Figure 1. Graft status in Group A and Group B.

Post-operatively, a dry ear was seen in 95.0% of the patients. The incidence of a dry ear did not differ significantly between the groups (p-value>.05). The incidence of aural fullness was significantly greater in Group A than in Group B [20% vs. 0%] (p-value<.05). [Table 4]

Table 4. Inter-group comparison of dry ear and complications.

Variable		Statistics	Group A (n=30)	Group B (n=30)	p-value
Dry ear$^{\Omega}$	Yes	Number (%)	29 (96.7%)	28 (93.3%)	.554
	No	Number (%)	1 (3.3%)	2 (6.7%)	
Complications$^{\Omega}$	Aural fullness	Number (%)	6 (20.0%)	0 (0.0%)	.033*
	Residual perforation	Number (%)	1 (3.3%)	2 (6.7%)	
	None	Number (%)	23 (76.7%)	28 (93.3%)	

$^{\Omega}$Fisher's exact test. *Statistically significant.

4. DISCUSSON

Poor audiological outcome can be a concern in type I tympanoplasty when performed using cartilage. The properties of cartilage graft, such as rigidity and stiffness, help in effective healing of TM. However, these properties are believed to result in compromised hearing outcomes. It has been assumed theoretically and found experimentally that cartilage slicing could attain hearing outcomes comparable to those of fascia. However, this has not been established clinically; therefore, this study was undertaken with the aim to study the outcome of full thickness versus half thickness cartilage graft in Type I tympanoplasty.

In the present study, the mean age of the patients in Groups A and B was 35.6 ± 14.94 years and 32.2 ± 10.07 years respectively, with no significant difference. These findings closely match those of *Xing C et al*. who reported similar mean ages of 39.91 ± 11.06 and 41.17 ± 11.83 years, respectively, in the two group.[10] However, the mean age of the patients was comparatively lower in the studies by *Sayed MS et al*. (24.30 ± 9.59 & 25.70 ± 6.26 years) [12], *Elfouly MS* (23-42 & 11-49 years) [13], and *Sabaa MA et al*. (17-36 vs 13-49 years) [14]. This is possibly due of regional demographic variations or differences in the inclusion criteria among the various studies. The non-significant difference between the groups made them comparable. The gender distribution in our study showed slight female preponderance, with 51.7% females and 48.3% males. Group A and Group B did not differ significantly with respect to gender distribution. Thus, the two groups were comparable with respect to gender also.

There is evidence that size and site of perforation, along with the involvement of multiple sites, have an impact on pre-operative hearing loss, post-operative graft uptake. and residual perforations.[8] The literature also suggests that the functional success rate of tympanoplasty is influenced by mucosal conditions (presence of edema).[15] The mobility of the ossicular chain is essential for sound transmission and is important for normal hearing.[16] In the present study, mobility of ossicular chain was present in all the patients in both groups.

Non-significant differences between the groups with respect to age, gender, affected ear, size, site, and number of perforations, and mobility of ossicular made these two groups comparable.

In the present study, tympanoplasty using a full-thickness graft required slightly less operative time than a partial-thickness graft (1.68 ± 0.245 hours vs. 1.71 ± 0.284 hours). However, this difference was not statistically significant, indicating that although partial-thickness grafting may require additional effort and technical precision, it does not significantly increase the overall operative time.

Our study showed found that, at 3 months and 6 months, post-operatively, the mean AB gap was significantly more in Group A than in Group B (p-value<.05). AB gap closure at 3 and 6 months post-operatively was

significantly greater in Group B than in Group A (p-value<.05), indicating that partial thickness cartilage grafts provide better acoustic outcomes than full thickness cartilage grafts. These findings align with the trends seen in previous studies by *Guindi SS et al*., who reported AB gap closure of 19.48 ± 5.93 and 9.71 ± 0.52 with partial and full thickness graft respectively.[17] Similarly, *Xing C et al*. reported greater AB gap closure of 15.81 ± 4.12 with partial thickness and 13.20 ± 3.96 with full thickness graft.[10] In the study conducted by *Sabaa MA et al.,* AB gap closure achieved with partial thickness graft was 16.03 ± 2.09 and with full thickness graft was 8.40 ± 3.40.[14]

In the present study, the rate of graft uptake rate was 95.0%. Graft rejection was seen in 3.3% and 6.7% of the patients in Group A and Group B respectively. The graft uptake did not differ significantly between groups (p-value>.05). Similar to the present study, previous studies have also reported a high graft uptake rate with both partial and full thickness graft. *Vadiya S et al*. reported an uptake rate of 97% and 100.0% with FTG and PTG respectively.[8] *Sayed MS et al.* reported graft uptake rate of 85% and 80% with FTG and PTG respectively.[12] Similarly, according to *Sabaa MA et al.* the graft uptake was observed in 85% and 80% of the patients in FTG and PTG group.[14] *Xing C et al.* noted equal graft uptake rate of 96.7% with both the techniques.[10] The variation in graft uptake rates among different studies may be attributed to several factors such as differences in surgical technique, surgeon experience, type and thickness of graft used, size and site of tympanic membrane perforation, condition of the middle ear mucosa, Eustachian tube function, presence of infection at the time of surgery, and duration of follow-up. Patient-related factors such as age, smoking, and comorbidities may also influence graft healing. Additionally, some studies included only dry ears while others included wet ears, which can further affect graft uptake rates. Variations in sample size and study design may also contribute to the differences reported across studies.

In the present study, the presence of dry ear (95%) was consistent with the graft uptake rate. A dry ear after tympanoplasty typically represents a successful outcome as the primary goal of surgery in chronic otitis media is to eradicate infection and achieve a stable, non-discharging ear. Additionally, postoperative packing (e.g., Gelfoam) temporarily occludes the canal, and once removed, the healed ear may remain unusually dry due to altered middle ear aeration.[18]

Aural fullness after tympanoplasty is a recognized postoperative symptom, often transient and occurring in 10-20% of cases within 3-6 months, primarily due to Eustachian tube dysfunction (ETD) that impairs middle ear ventilation post-grafting.[19] In the present study, the incidence of aural fullness was significantly higher in Group A than in Group B [20% vs. 0%; p-value<.05]. Residual perforation was seen in 3.3% and 6.7% of patients in Group A and Group B respectively. Previous study *Sayed M et al.* did not observe the development of aural fullness or residual perforation but observed that otorrhea developed more frequently in the partial-thickness group than in the full-thickness group (20% vs. 5%).[12] *Xing C et al.* recorded infection to be slightly more frequent with full thickness than partial thickness graft.[10]

Overall, the findings of this non-randomized clinical trial establish that partial-thickness tragal cartilage grafts in Type I tympanoplasty yield superior audiological outcomes, with significantly better AB gap closure at 3 and 6 months (p-value<0.05) than full-thickness grafts, despite the latter's theoretical advantages in rigidity and stiffness for TM healing. While operative times were comparable (1.68 ± 0.245 vs. 1.71 ± 0.284 hours, p>0.05) and overall graft uptake remained high (95%) without significant intergroup differences, full-thickness grafts were associated with a higher aural fullness (20% vs. 0%, p-

value<0.05), likely due to bulkier mass effect impeding middle ear ventilation and ossicular mobility, in contrast to the enhanced acoustic properties of partial-thickness grafts resulting from reduced impedance and preserved perichondrial flexibility.

Limitations of the study

1. In the present study, a significant baseline difference in Rinne's test suggests the groups may not have had the same degree of hearing loss before surgery, which can affect the outcome interpretation. Because Rinne reflects conductive hearing status, the group with a worse baseline result may show different postoperative hearing gain simply due to starting from a poorer hearing level, not necessarily because of the graft type.
2. This was a single centre study; therefore, the results of the study lack generalizability.
3. Due to time constraint, follow up period was short.
4. Although, sample size included was based on sample size estimation, it was a relatively small sample size.

CONCLUSION

Partial-thickness tragal cartilage grafts in type I tympanoplasty provide superior audiological outcomes with better AB gap closure and reduced aural fullness compared to full-thickness grafts, without compromising high graft uptake rates.

Declaration by Authors

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