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Comparative study between temporalis fascia graft with and without addittion of cyanoacrylate glue in myringoplasty

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***Abstract*---**Background: Tissue adhesives are often used in myringoplasty because they can hold the graft in place and help the graft absorb by acting as a framework. Aim of the study: The goal is to look at the temporalis fascia graft used in myringoplasty with and without cyanoacrylate glue and compare the two. Patients, and methods: Fifty patients with dry central tympanic membrane perforation were treated with type I tympanoplasty over the course of 1.5 years. In each instance, the autogenous temporalis fascia graft was spot welded and fixed to flaps and the surrounding tissue using glue. Myringoplasty was done on 50 people, and they were randomly put into two groups: those who had cyanoacrylate glue put on the temporalis fascia graft and those who didn't. Results: Each group had 25 cases, and there were no big differences between the groups in terms of age, direction, or size of the tympanic membrane hole. After 6 weeks, there wasn't much difference between the glue group and the control group. In the glue group, 72% had healed and 28% had perforated, while in the control group, 64% had healed and 36% had perforated (p-value 0.544). At 3 months, 88% of the people in the glue group had healed and 3% had perforated, while only 19% of the

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people in the control group had healed and 6% had perforated, which is a difference of 0.463 that is not very important. Post-op, the average ABG was 15.89 in the glue group and 17.18 in the control group. In this case, the 0.321-point gap between the two groups is too small to warrant further investigation. Conclusion: There are many benefits to using cyanoacrylate glue, especially when doing an underlay tympanoplasty with a temporalis fascia graft. The main benefit of glue is that it makes sure the graft is stable because it is spot-welded with it.

***Keywords*---**Myringoplasty, temporalis fascia, Cyanoacrylate, Glue.

Introduction

Several studies report a success rate of 65-85.5 percent when attempting to repair perforations in the tympanic membrane (Dolhi N et al.,2022). Due to its advantageous location and resistance to infection, autogenous temporalis fascia has proven to be the most popular and successful graft material (Abdel Fattah A.A et al.,2020). Even though both the lateral (onlay or overlay) and medial (underlay) surfaces of the temporalis fascia graft have their advantages and disadvantages, the underlay is often employed for type I tympanoplasty (underlay). Bayram A. et al. (2020).

In myringoplasty, the size of the hole makes a significant difference in how rapidly the tympanic membrane (TM) heals (Han JS et al., 2021). Many factors, including the surgeon's visibility, blood supply, Eustachian tube function, and support for the donor material, contribute to the high failure rate in repairs of subtotal TM perforations (Bayram A et al.,2020). Subtotal TM perforations have been treated using a variety of strategies throughout the years. These techniques are derived from the time-honored processes of underlay and overlay grafting. The revolving canal flap, swing door, mediolateral, loop overlay, and anchoring methods are all examples of these. To wit: (Saleh E.M. et al., 2019).

But gelfoam pledgets were always used to keep the graft in the tympanic cavity during these surgeries (Brar S et al.,2022). Even though the risk of serious side effects is low, when it comes to increasing myringoplasty success rates, a novel approach that does not include filling the tympanic cavity is required (Young A Ng M.,2022).
TM perforation is now treated with tissue adhesive-based myringoplasty, which is seen as a cutting-edge method (Azimi B et al., 2021). Since the 1980s, tissue adhesives have been used in ear surgery to hold the graft in place during tympanoplasty, act as scaffolding while vascularization takes place, and keep the area dry to prevent infection (Kaya et al., 2021). Research has shown that tissue adhesives help grafts take hold better (Bansal C et al.,2020).

Aim of the study

The goal is to find out how myringoplasty temporalis fascia grafts made with and without cyanoacrylate adhesive are different from each other.

Patients, and methods

Glue was employed to spot weld and secure the autogenous temporalis fascia graft to the flaps and surrounding tissue in 50 instances of dry central tympanic membrane perforation treated with type I tympanoplasty.

There were no otologic signs or symptoms present, including cholesteatoma, in these individuals. Only conductive hearing loss and a dry central tympanic membrane rupture were present. The ear was completely dry and the infection had been gone for almost six weeks. There was no history of sensorineural hearing loss, prolonged exposure to loud noise, tinnitus, vertigo, or any other otologic disorders, so the preoperative condition would not be misunderstood as a result of the operation or the glue employed. The conductivity-induced hearing loss did not exceed 35 dB at any frequency.

Inclusion criteria:
- Age over 18
- chronic suppuratve otitis media safe type
- For the last three months, you've had stable, dry TM perforations with no ear drainage.

The exclusion criteria
- The presence of a cholesteatoma
– Prior middle ear surgery or the installation of a ventilation tube in the affected ear.
- Ossicular chain anomalies, previous cleft palate or pharyngeal surgery,
- Mental retardation, and other medically-recognized cognitive disorders all qualify as ossicular anomalies.
- Any history of pharmacological, chemical, biological, or synthetic material sensitivity or allergy.

Randomization
The patients didn't know what kind of surgery they were going to have. After the people were chosen, a computer picked a number at random. Depending on whether the number was even or odd, the people took part in either the glue group or the control group.

Methods
The full medical history of each patient is written down. An otolaryngologist may do an otoscopic exam under a microscope to find out more about the size, type, and condition of the middle ear mucosa. Investigations include routine blood tests, hearing tests, and checks to see if a person is fit for anaesthesia.

Surgical technique
The underlay technique and an autogenous temporalis fascia graft were used during surgery on the patients, who were given either local or general anaesthesia. The external auditory canal (the opening behind the ear) was numbed locally with xylocaine 2% and epinephrine 1:100,000, and the temporalis fascia graft area. As usual, the patients were cleaned, made ready, and covered.

They used the postauricular method. The harvested, dried temporalis fascia graft was put into an incision made behind the ear.
After the meatotomy, the pinna moved back and the flaps of periosteum went up. The tympanic membrane was looked at, and the outer edge of the hole was cleaned all the way around. After the cuts were made in the canal skin, a flap of skin from the back of the canal was lifted. The first of these cuts was made on the side of the tympanic annulus, from 6 to 12 o'clock, transversely along the posterior bone canal wall.

Then, two long cuts were made that started at the top and bottom of the transverse cut and ended a few millimetres from the meatus. After that, the remaining upper and lower edges of the skin canal and skin flaps with an anterior base were made. When the posterior tympanic annulus was lifted, it was easier to see the tympanic membrane. It was found that the chorda tympani nerve, the ossicles, and the middle ear cavity were all healthy and moving. After that, antibiotic eardrops were put in the opening of the eustachian tube and in the middle ear gelfoam.

The graft was cut and used to close the hole before it was carefully put in between the annulus and the ring. To hide the fascia graft, skin flaps were put back where they came from. At this point, an insulin syringe was used to coat the graft under the flap's edges and any leftover pieces of tympanic membrane with glue. Two hours after removing the cyanoacrylate glue (Fig. 1) from refrigeration at 4 degrees Celsius, it was allowed to warm to room temperature. The 1 mL of glue in the sterile single-dose vial was placed onto the operating table in a sterile field after the packaging was opened and the glue's clarity and flow were confirmed.
After that, an insulin syringe and a clean, 4-5 cm needle were used to get the single-dose bottle of glue open. The glue was slowly injected into the skin, one drop at a time, using the same syringe and a 16-G IV (fig 2). Without putting anything in the tympanic cavity, glue was put on the edges of the remaining tympanic membrane, drop by drop, to connect the graft to the malleus.

Figure 1. The Cyanoacrylate Glue used

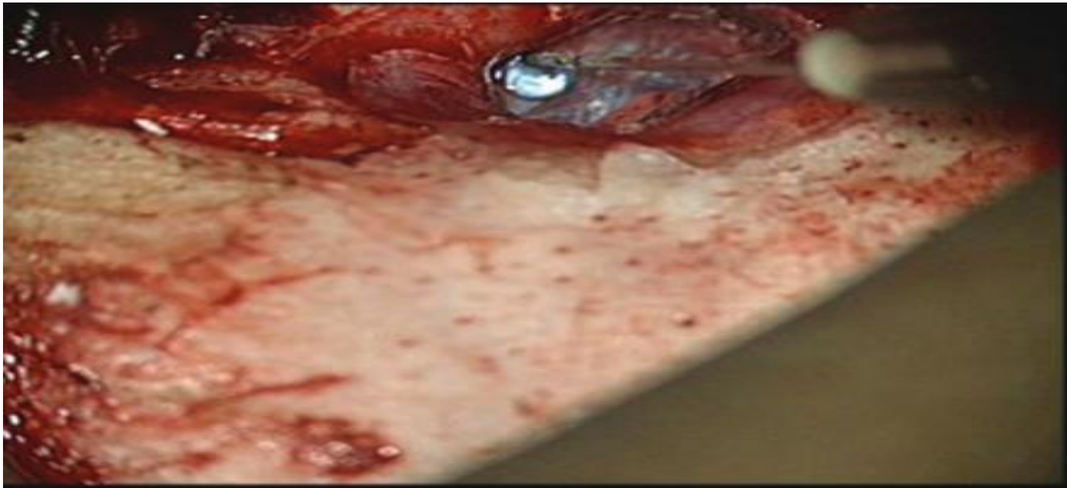

Figure 2. Image captured intraoperatively depicting the process of glueing the temporalis fascia graft in place

For the glue to harden, blood or tissue must touch the needle or cannula. As little glue as possible was polymerized to make a thin layer of glue. To reach this goal, you couldn't put more than one drop in the same spot.

During the first 5–6 seconds after the glue was put on, the extra glue was taken off with a dry Gelfoam swab.The canal was filled in three to five minutes, and while Silastic was recommended by the manufacturer, it was not utilised. Gelfoam soaked in ear-safe antibacterial eardrops was used to fill the canal. The wound was closed with two rows of stitches. There are claims that a comparable surgical operation may be carried out without the use of adhesive.

Postoperative Care

The mastoid dressing was left on for a week after surgery. The patients were given the usual advice about how to take care of themselves in the bath, how to avoid raising the pressure in the middle ear, warning signs, allergies, and harmful effects. First, the patients were checked a week after surgery, and their bandages were taken off. This was done with the help of forceps and suction under otomicroscopy. During the 6-week visit, patients were checked to see how well they were healing, and any granulations or holes that didn't heal were written down.

The mastoid dressing was still on a week after surgery. The patients got the usual advice about how to take a bath, how to avoid raising the pressure in the middle ear, warning signs, allergies, and dangerous side effects. One week after surgery, patients had their first checkup and their bandages were taken off. Suction and forceps were used during otomicroscopy. At the 6-week checkup, the patients' progress was looked at, and any persistent granulations or holes were written down.

Statistical analysis of the data

The IBM SPSS software programme, version 20.0, was used to look at the data that came from the computer. IBM Corporation is based in Armonk, New York. The information about the categories was shown as percentages and numbers. A Chi-square test was used to compare two groups. The Fisher Exact correction test was used instead when more than 20% of the cells had expected counts of less than 5. The Monte Carlo correction test was run when more than 20% of the cells had expected counts of less than 5. The Shapiro-Wilk test was used to find out if continuous data were normal. To show quantitative data, range (minimum and maximum), mean, standard deviation, and median were used. A Student t-test was used to compare two groups with quantitative variables that were spread out in a regular way. The Mann-Whitney test was used to compare two groups when the numbers weren't spread out in a normal way. The 5% level was used to figure out how important the data was.

Result

Each group had 25 cases, and there were no big differences between the groups in terms of demographics, side, and size of tympanic membrane perforation, as shown in Table 1 and Figure 3.

Table (1): Comparison between glue group, and control group according to demographic data, side, and perforation size

	Glue group (n= 25)	Control group (n= 25)	Test of sig.	p
Age(years)				
Mean ± SD.	27.20 ± 5.35	26.28 ± 5.33	t=0.609	0.545
Median (Min. – Max.)	24.0 (19.0 – 34.0)	24.0 (19.0 – 34.0)		
Sex				
Male	16 (64.0%)	16 (64.0%)	χ^2=0.0	1.000
Female	9 (36.0%)	9 (36.0%)		
Side				
Right	13 (52.0%)	14 (56.0%)	χ^2=0.081	0.777
Left	12 (48.0%)	11 (44.0%)		
Perforation size				
Large central perforation	10 (40.0%)	9 (36.0%)	χ^2=0.585	^{MC}p= 0.946
Medium sized perforation	7 (28.0%)	9 (36.0%)		
Small sized perforation	2 (8.0%)	2 (8.0%)		
Subtotal perforation	6 (24.0%)	5 (20.0%)		

SD: Standard deviation χ^2: Chi square testMC: Monte Carlot: Student t-test
p: p value for comparison between the studied categories

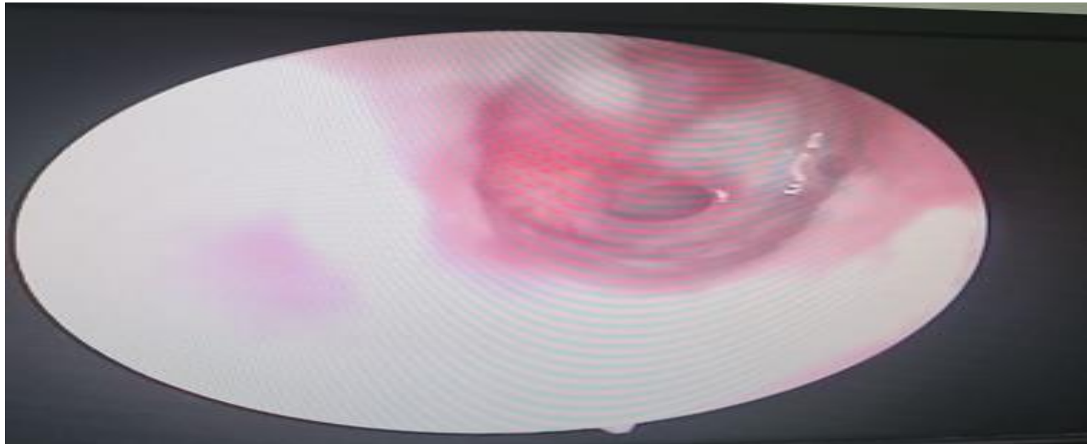

Figure 3. Tympanic membrane perforation

As far as the amount of air in the bone before surgery, there was no difference between the two groups (p-value = 0.318). The graft success rate was higher in the glue group (88% vs. 76%) than in the control group (76%), but there was no difference (p-value = 0.463).

Table (2): Comparison between glue group ,and control group according to Preoperative data ABG ,and Graft intake success rate

Preoperative data	Glue group (n= 25)	Control group (n= 25)	Test of sig.	p
ABG				
Mean ± SD.	21.32 ± 2.67	22.14 ± 3.01	t=1.009	0.318
Median (Min. – Max.)	21.50 (17.80 – 28.90)	21.50 (17.80 – 28.90)		
Graft intake success rate				
No	3 (12.0%)	6 (24.0%)	χ^2=1.220	^{FE}p=0.463
Yes	22 (88.0%)	19 (76.0%)		

χ^2: Chi square test MC: Monte Carlo FE: Fisher Exact
t: Student t-testU: Mann Whitney test
p: p value for comparison between the studied categories

TM status 6 weeks after surgery was better in the glue group than in the control group. In the glue group, 72% of the wounds were healed and 28% were still open. In the control group, 64% of the wounds were healed and 36% were still open, which was not a big difference (p-value = 0.544). At 3 months, 88% of the people in the glue group were healed and 3% had holes. In the control group, only 19% were healed and 6% had holes, which isn't a big difference. The glue group had a mean ABG of 15.89 after surgery, while the control group had a mean ABG of 17.18. The difference between the two groups was not significant, at 0.321.

In the glue group, 84.4% of cases had no complications, but 8% had retraction, 4% had infections, and 4% had myringitis. In the control group, 76% of cases had no complications. 4% had an infection, 4% had tinnitus, and 4% had myringitis, but the differences were not important, as shown in table 3 and figure 4.

Table (3): Comparison between glue group, and control group according to post-operative

Post-operative	Glue group (n= 25)	Control group (n= 25)	Test of sig.	p
T.M status 6 wks				
Healed	18 (72.0%)	16 (64.0%)	χ^2=0.368	0.544
Perforated	7 (28.0%)	9 (36.0%)		
T.M status3 mn				
Healed	22 (88.0%)	19 (76.0%)	χ^2=1.220	^{FE}p=0.463
Perforated	3 (12.0%)	6 (24.0%)		
ABG				
Mean ± SD.	15.89 ± 3.98	17.18 ± 5.01	t=1.003	0.321
Median (Min. – Max.)	15.60 (12.30 – 26.60)	15.60 (12.30 – 26.60)		
Complications				
No	21 (84.0%)	19 (76.0%)	χ^2=1.783	^{MC}p=0.914
Retractions	2 (8.0%)	3 (12.0%)		
Infections	1 (4.0%)	1 (4.0%)		
Tinnitus	0 (0.0%)	1 (4.0%)		
Myringitis	1 (4.0%)	1 (4.0%)		

χ^2: Chi square test MC: Monte Carlo FE: Fisher Exactt: Student t-test
p: p value for comparison between the studied categories

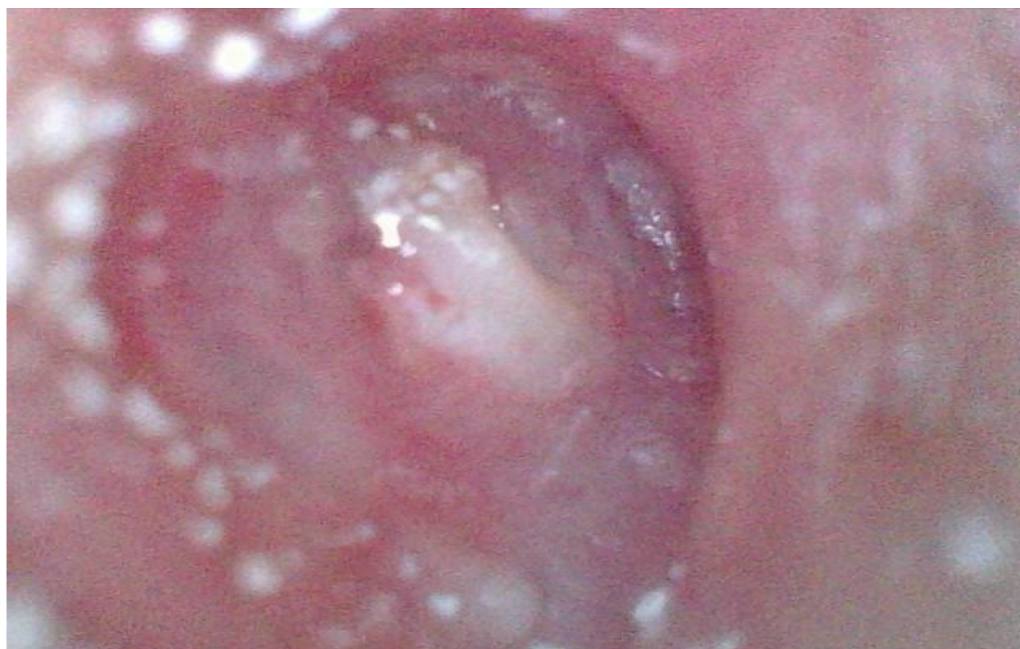

Figure 4. Postoperative Photograph Showing healed Graft

As regard mean ABG in glue group preoperative was 21.32 which decreased to 15.89 post operative with significant differences as shown in table4

Table (4): Comparison between pre-operative, and post-operative according to ABG in glue group (n= 25)

ABG	Pre-operative	Post-operative	t	p
Mean ± SD.	21.32 ± 2.67	15.89 ± 3.98	13.385*	<0.001*
Median (Min. – Max.)	21.50 (17.80 – 28.90)	15.60 (12.30 – 26.60)		

t: Paired t-test
p: p value for comparison between pre-operative ,and post-operative
*: Statistically significant at p ≤ 0.05

As regard mean ABG in control group preoperative was 22.14 which decreased to 17.16 post operative with significant differences as shown in table5

Table (5): Comparison between pre-operative, and post-operative according to ABG in control group (n= 25)

ABG	Pre-operative	Post-operative	t	p
Mean ± SD.	22.14 ± 3.01	17.18 ± 5.01	9.947*	<0.001*
Median (Min. – Max.)	21.50 (17.80 – 28.90)	15.60 (12.30 – 26.60)		

t: Paired t-test
p: p value for comparison between pre-operative ,and post-operative
*: Statistically significant at p ≤ 0.05

Discussion

The graft absorption rate in our research was 88% in the glue group and 76% in the control group. We observed a greater incidence than this in medical records (82 percent). When doing an underlay tympanoplasty with a temporalis fascia graft, using cyanoacrylate adhesive offers several advantages. One major advantage is that the glue's adhesive qualities guarantee the graft's stability in respect to the many skin flaps and the permanent bone components. By doing so, the graft won't shift, and the resulting wound won't become worse (Sandeep K et al.,2017). No statistically significant differences were found between the glue group and the control group (p = 0.463), however the glue group had a greater graft success rate.

A study by Deenadayal et al. looked at a large series of myringoplasty procedures with 10-year follow-ups and found that the use of cyanoacrylate adhesive significantly enhanced the rate of graft absorption in all kinds of tympanic membrane perforations (Deenadayal DS et al.,2011). Twenty-three ears with subtotal and big central holes were repaired using octyl-2-cyanoacrylate by Gedikli et al. The graft acceptance rate was 91.3%. According to a 2011 study (Gedikli O et al.,2011).

Even though cyanoacrylate glue worked well for fixing grafts in tympanoplasty, Tuzuner et al. showed that it didn't affect graft uptake or hearing recovery in any way (Tuzuner A et al.,2015). All of these trials, though, only looked at how adding

more cyanoacrylate glue to the normal myringoplasty can help. Hung et al. came up with the anterosuperior anchoring method, Consequently, the graft ended up adjacent to the malleus handle and the external auditory canal. This method worked well for both adults and children. (Hung T et al.,2004)

These results were good and matched those found in the research (Primrose WJ et al., 1986;Hung T et al., 2004). The entrance of the Eustachian tube at the tympanic ostium may be blocked by placing gelfoam in the tympanic cavity. which could cause some patients to feel like their ears are full after myringoplasty. When they come in contact with weak bases like water or blood, cyanoacrylates, a type of synthetic glue, quickly harden. In both human and animal studies, cyanoacrylate derivatives have been used to treat myringoplasty successfully. (Gedikli O et al.,2011;Tuzuner A et al.,2015)

In the study by Sandeep K. et al., successful graft uptake was 90%, which was higher than the number that came from medical records (82%). (Sandeep K et al., 2017). Kaushik and Jain did a study in 2017 that looked at 60 cases of COM that were fixed with tissue adhesive. Yuasa and Yuasa (2008) found that underlay myringoplasty with fibrin glue to fix a hole in the tympanic membrane worked 97.3% of the time and decreased the air-bone gap by 10.3 dB. Evandro JP et al. found that tissue glue-assisted myringoplasties worked 80.6% of the time in 31 cases. (2005) Evandro JP et al. The results of our study were about the same.

Deenadayal et al. followed up on hundreds of myringoplasty surgeries over a decade and found that all forms of tympanic membrane perforations treated with cyanoacrylate glue had considerably higher rates of graft absorption (Deenadayal DS et al.,2011). 23 ears with subtotal and big holes in the centre were treated with octyl-2-cyanoacrylate by Gedikli et al. Absorption of the graft was 91.3%. (Gedikli O et al.,2011)

It has been shown by Tuzuner et al. that cyanoacrylate glue has little influence on graft uptake and hearing restoration, despite the fact that it is an effective fixative for tympanoplasty grafts. A. Tuzuner, among others (2015). Mohanty and Kurian (2016) did a study on 33 cases of Type 1 tympanoplasty using fibrin glue. They found that the average PTA before surgery was 34.45 dB, but that it dropped to 24.55 dB 3 months after surgery and to 21.73 dB 6 months after surgery. This shows that fibrin glue is good for hearing after surgery and can be used, especially in people with large perforations. In our study, the AB Gap went from 22.14 to 17.16 after surgery. The results of this study are also similar to those of these other studies.

Each study, however, focused primarily on the potential advantages of augmenting normal myringoplasty with additional cyanoacrylate glue. Instead of using gelfoam for packing the middle ear, this research investigated the use of cyanoacrylate glue. The basic underlay myringoplasty technique is distinct from the myringoplasty technique we used in that it provides support in additional locations. The graft is secured to the malleus, tympanic ring, and manubrium using cyanoacrylate adhesive. Without packing gelfoam in the tympanic cavity, we discovered that cyanoacrylate adhesive was sufficient to maintain the graft in

place. This was evident due to the fact that both groups had the same graft absorption rate, hearing improvement, and difficulties.

Conclusion

There are many benefits to using cyanoacrylate glue, especially when doing an underlay tympanoplasty with a temporalis fascia graft. The main benefit of glue is that it makes sure the graft is stable because it is spot-welded with it.

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