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Comparison of Inlay Cartilage Butterfly and Underlay Temporal Fascia Tympanoplasty

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Abstract

Objective. To systematically review the results of inlay cartilage butterfly tympanoplasty and standard underlay temporal fascia tympanoplasty for anatomic and functional end points.

Data Sources. PubMed, Embase, MEDLINE, and Virtual Health Library (VHL/Lilacs) databases were searched from inception through April 2, 2021. No restrictions on language, publication year, or publication status were applied.

Review Methods. The meta-analysis included data from articles that met inclusion criteria and were extracted by 2 authors independently. The PRISMA statement was followed. Risk of Bias 2.0 and Newcastle-Ottawa Scale were used to assess risk of bias. The primary outcome was tympanic membrane closure rate. The secondary outcome was improvement of the air-bone gap.

Results. Ten studies were included, 9 cohort studies and 1 randomized clinical trial, with 577 patients. The graft take rate was 82.8% in the butterfly cartilage inlay tympanoplasty group and 85.2% in the temporal fascia underlay tympanoplasty group (relative risk, 1.01; 95% CI, 0.93-1.11; I^2 = 42%, *P* = .08). The air-bone gap reduction ranged from 6.1 to 11.28 in the butterfly cartilage inlay group and from 5.2 to 12.66 in the temporal fascia underlay group, with a mean difference between groups of −2.08 (95% CI, −3.23 to −0.94; I^2 = 58%, *P* = .04), favoring temporal fascia underlay.

Conclusion. The 2 tympanoplasty techniques analyzed here produced similar results in terms of successful reconstruction of the tympanic membrane and reduction in the air-bone gap. Neither age nor follow-up length of time influenced outcomes.

Keywords

tympanoplasty, tympanic membrane perforation, butterfly cartilage graft, inlay, underlay

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Since the original description of tympanoplasty in the 1950s,[1,2] several access routes, graft placement techniques, and types of grafts have been described. The access routes can be closed (intracanal) or open (retroauricular or endaural). Regarding the graft placement techniques, they are divided into underlay,[3] overlay,[4] inlay,[4] and mixed.[4] Although to date temporal muscle fascia is the most used graft, skin,[2] dura mater, periosteum, areolar tissue, fat, cartilage, and even artificial tissues have been used.[5] The use of cartilage has been reported frequently and used in different techniques (palisade, cartilage island, over or underlay, and inlay/butterfly).[5]

In 1998, Eavey[6] described the technique of tympanoplasty with cartilage inlay, which consists of placing a cartilage graft from the tragus with the shape of the original perforation plus a 2-mm margin. A 1-mm incision is made in the entire circumference of the cartilage, which, by maintaining the traction of the perichondrium on both sides, curls laterally, separating 2 leaflets. Viewed from the side, the graft resembles the wings of a butterfly. The results were confirmed by

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others.[7-13] A randomized clinical trial comparing this technique with underlay fascia tympanoplasty demonstrated similar efficacy in graft take and audiometric outcomes, with advantages of the butterfly in terms of ease and speed of execution and better recovery (instant hearing recovery, less postoperative care, and less pain), making it a cheaper procedure for the health system.[14]

The objective is to carry out a systematic review and meta-analysis of studies that compared the effectiveness of butterfly cartilage inlay tympanoplasty (BCIT) with traditional temporal fascia underlay tympanoplasty (TFUT) and, with the increase in statistical power conferred by this methodology, to identify whether there is a difference in anatomic and/or functional efficacy between the techniques and whether there are predictive factors for success.

Methods

We conducted a systematic review and meta-analysis following the PRISMA statement (Preferred Reporting Items for Systematic Reviews and Meta-analyses).[15] The review protocol was preregistered at the International Prospective Register of Systematic Reviews (PROSPERO: CRD42021277246).

Types of Studies and Interventions

Our planned inclusion criteria were as follows: (1) experimental studies; (2) comparative studies between BCIT and TFUT, regardless if prospective or retrospective; (3) report of at least 1 postoperative outcome (graft take rate and/or difference from pre- to postoperative air-bone gap according to the Committee on Hearing and Equilibrium of the American Academy of Otolaryngology–Head and Neck Surgery[16]); and (4) patients of all ages and clinically diagnosed tympanic membrane perforations. We excluded comparative studies (eg, noncontrolled cohort studies, case series describing just 1 technique), animal studies, duplicate publications, and BCIT in cases with cholesteatoma and ossicular chain disorder. The interventions were BCIT and TFUT.

Types of Outcome Measures

The primary outcome measure was the tympanic membrane closure rate, measured as a percentage of success with correspondent standard deviations. The secondary outcome was audiometric result, measured as the mean improvement of the air-bone gap (difference in the post- minus preoperative air-bone gap) with standard deviation.

Search Strategy

No restrictions on language, publication year, or publication status were applied. The date of the last search was April 2, 2021. We searched all studies from PubMed, Embase, MEDLINE, and Virtual Health Library (VHL/Lilacs). The search syntax for the databases was as follows:

> ((Tympanoplasty[mh] OR Myringoplasty[mh] OR Tympano plast*[tw] OR Myringoplast*[tw]) AND (Cartilage/transplantation[mh] OR (Cartilag*[tw] AND (transplant*[tw] OR graft*[tw])) OR Butterfl*[tw])) OR Transcanal cartilage butterfly inlay technic*[tw] OR Minimally invasive inlay tympanoplast*[tw] OR Cartilage button tympanoplast*[tw] OR cartilage button technique*[tw].

Through these searches, we selected only those studies that compared the efficacies of both tympanoplasties. We also searched the Clinical Trials Register for ongoing trials. Finally, we searched for additional relevant manuscripts from the references of studies, and authors were not contacted for additional information.

Selection of Studies

Two authors (J.F.L.N. and J.P.N.L.) independently performed data extraction applying the inclusion and exclusion criteria after reading the full texts; any discrepancies were resolved by consensus.

Data Extraction and Management

Two authors (J.F.L.N. and J.P.N.L.) independently performed data extraction; any discrepancies were resolved by consensus. For each selected article, the following information was noted in a template built for this study: author, year of publication, number of patients in each comparative group, mean (SD) age of each comparative group, mean (SD) follow-up period in each group (in months), number of success cases in both groups, and mean (SD) difference between the pre- and postoperative air-bone gap in each group.

Assessment of Risk of Bias and Quality in Studies

Two authors (J.F.L.N. and A.K.S.) independently assessed the study quality. For the randomized controlled trial, we used the Risk of Bias 2.0 tool recommended by the Cochrane Collaboration.[17] For nonrandomized studies, we followed the Newcastle-Ottawa Scale.[18]

Measures of Treatment Effect

For categorical data, we calculated relative risk (RR) with 95% CI in the meta-analysis. For continuous data, we calculated the mean differences and 95% CI between groups for analysis.

Statistical Analysis

We performed direct meta-analyses and calculated the RR for the primary outcome: difference in graft take rate. We also conducted direct meta-analysis for the secondary outcome mean—difference in pre- and postoperative air-bone gap—and calculated the mean difference between the post- and preoperative period in the intervention and control groups. To analyze the influence of age in outcomes, we carried out meta-regression using the mean age of study participants as a covariate. Further on, we performed meta-regression using duration of follow-up as a covariate. Heterogeneity was assessed by the Cochran Q test ($P = .1$ was considered statistically significant) and the I^2 test (>50% indicated elevated statistical heterogeneity). The analyses were done with R version 4.0.3, ''Bunny-Wunnies Freak Out'' (R Foundation for Statistical Computing). We conducted further analysis to

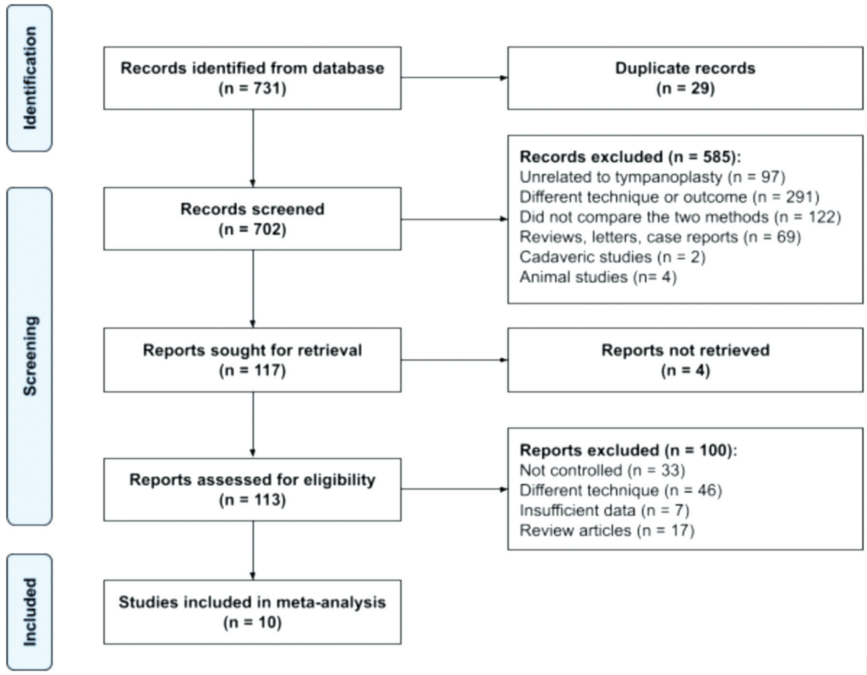

Figure 1. PRISMA flowchart from the initial 731 studies to the 10 included in the meta-analysis.

exclude publication bias, and funnel plots were calculated for the graft take rate and audiologic result. To analyze the presence of publication bias, we did a ''trim and fill'' by creating a funnel plot and estimating the true center after (1) trimming studies causing asymmetries and (2) filling the plot with omitted studies and their missing counterparts around the plot's center.

Results

There were 731 articles identified from the database. After 721 reports were excluded according to different criteria (**Figure 1**), 10 eligible studies were included in the meta-analysis.

Included Studies

Nine studies were cohort studies: 1 prospective cohort and 8 retrospective cohorts. Just 1 of the 10 studies was a randomized clinical trial.

The total number of patients in the meta-analysis was 577. However, the number of patients did not always match the number of ears, since some authors analyzed >1 surgical procedure in each patient. The total number of ears analyzed was 598. Of these, 308 underwent BCIT and 290 TFUT. Two studies included only children in their cohorts,[19,20] 5 consisted of adults and children,[11,13,14,21,22] and 3 studies did not provide enough information about the age range.[10,23,24]

All studies included data regarding the graft take rate in the control and intervention groups, and 6 studies provided data about air-bone gap improvement in both groups[10,13,23,24] (**Table 1**). Two studies did not provide mean age data, just the age range,[13,14] and 1 study did not report follow-up information.[20]

Risk of Bias Assessment

The randomized clinical trial was assessed by the Risk of Bias 2.0 (**Table 2**). We classified all domains as ''low risk'' with the exception of the ''bias due to deviations from intended interventions,'' which we classified as ''moderate risk'' because caregivers and people delivering the interventions were aware of participants' assigned intervention during the trial, although we believe that this is an inherent characteristic of surgical studies. Cohort studies were evaluated by the Newcastle-Ottawa Scale (**Table 3**). Each article was assessed in 3 main domains (selection, comparability, and outcome) and given a total score that could range from 0 to 9. Greater scores mean more reliability for the study. The reasons that the studies did not score in some criteria were as follows: studies consisted of pediatric patients only, thus compromising the representativeness of the cohort; studies did not adjust the analysis for the size of perforation between groups; studies did not adjust the analysis for the perforation location, presence of tympanosclerosis, or patient comorbidities; and studies did not cite the number of patients who were lost to follow-up. We considered the ideal follow-up length as 1 year. Six studies included patients who had undergone previous ear surgery (tympanoplasty or mastoidectomy). In 4 studies, the total number of patients with a history of ear surgery was small, and the authors properly controlled the groups, with no statistical difference between them.[14,19,22,23] Just 1 study showed a statistical difference between groups regarding operation history, with many more patients with this history in the TFUT group,[24] which might have affected the outcomes. One of the studies analyzed just patients undergoing revision tympanoplasty; therefore, all patients of both groups had undergone at least 1 previous tympanoplasty.[10]

Table 1. Characteristics of Included Studies Comparing the BCIT and TFUT Groups.[a]

		No. of ears		No. of patients		Male:female		Age, y, mean ± SD		Follow-up, mo, mean ± SD		Take rate, %		ABG improvement, mean ± SD	
Study	Design	BCIT	TFUT	BCIT	TFUT	BCIT	TFUT	BCIT	TFUT	BCIT	TFUT	BCIT	TFUT	BCIT	TFUT
Effat[21]	RC	28	23	21	23	13:8	11:12	24.5	27	23[b]		43	83		
Couloigner[19]	RC	59	29	51	26	25:26	16:10	9.9 ± 3.4	10.9 ± 2.3	26.6 ± 19.9	21.8 ± 17.1	71	83		
Dave[10]	PC	5	12	5	12	3:2	7:5	33 ± 9.65[b]		15.6	15.22	80	83.4	6.75 ± 5.24	9.14 ± 5.6
Haksever[13]	RC	29	43	29	43	16:13	19:24			12[b]		96.5	90.7	6.9	10.3
Kim[23]	RC	56	56	56	56	19:37	18:38	56.5 ± 13.8	50.5 ± 15.8	10.6 ± 3.1	10.2 ± 3.6	96.4	91.1	7.9 ± 2.2	8.9 ± 3.2
Kim[24]	RC	23	13	22	13	10:12	6:7	47.9 ± 15.7	50.3 ± 19.6	10.0 ± 7.3	12.5 ± 12.2	91.3	76.9	6.1 ± 8.2	5.2 ± 10.3
Ference[20]	RC	21	41	21	41			13.4	13.5			85.7	75.6		
Mauri[14]	RCT	34	36	34	36	13:21	14:22			7.61 ± 4.1	7.4 ± 3.6	88.2	86.1		
Ulku[11]	RC	25	17	25	17	9:16	9:8	32.0	32.4	27.4	29.1	92.0	88.2	11.28	12.66
Wang[22]	RC	28	20	26	20	10:16	7:13	56.0 ± 15.3	54.2 ± 15.5	11.2 ± 2.7	15.9 ± 3.4	82.1	85	6.3 ± 2.5	9.3 ± 3.2

Abbreviations: ABG, air-bone gap; BCIT, butterfly cartilage inlay tympanoplasty; PC, prospective cohort; RC, retrospective cohort; RCT, randomized clinical trial; TFUT, temporal fascia underlay tympanoplasty.
[a]Blank cells indicate *not available*.
[b]Single value represents data for both groups combined.

Table 2. Risk of Bias Assessment for the Randomized Clinical Trial Included.[a]

Study: Mauri[14]	Assessment
Bias arising from the randomization process	Low risk
Bias due to deviations from intended interventions	Some concerns
Bias due to missing outcome data	Low risk
Bias in measurement of the outcome	Low risk
Bias in selection of the reported results	Low risk
Overall assessment	Some concerns

[a]Based on the Risk of Bias 2.0.[17]

Another singular feature of this study is that all patients in the TFUT group were submitted to mastoidectomy at the same time, which was not seen in any other study in this systematic review. None of the studies compared the outcomes between patients submitted to primary tympanoplasty and patients with a history of ear surgery. Furthermore, the studies did not provide enough raw data, making it unfeasible to us to estimate the effect of previous surgery on take rate or air-bone gap closure.

Effects of Interventions

Tympanic Membrane Closure Rates. The general graft take rate was 82.8% in the BCIT group and 85.2% in the TFUT group. The meta-analysis for the graft take rate did not show differences between the techniques (RR, 1.01; 95% CI, 0.93-1.11; I^2 = 42%, P = .08, for heterogeneity; **Figure 2**).

We performed meta-regression for the primary endpoint using age (Supplemental Figure S1, available online), considering 8 studies where these data were present (P = .6229), and meta-regression for the primary end point using follow-up (Supplemental Figure S2), considering 9 studies (P = .4823), as previously planned.

Reduction in the Air-Bone Gap. Only 6 of the 10 studies presented sufficient data to calculate air-bone gap improvement after surgery. Air-bone gap reduction ranged from 6.1 to 11.28 in the BCIT group and from 5.2 to 12.66 in the TFUT group, with a mean difference of −2.08 (95% CI, −3.23 to −0.94), favoring the TFUT group (**Figure 3**).

Effect of the Publication Bias. Funnel plots were calculated for the graft take rate and for the audiologic result to analyze the risk of publication bias. As we can see in Supplemental Figures S3 and S4 (available online), there was no publication bias for any of the outcomes; therefore, there was no need to ''trim and fill.''

Discussion

In the studies in the meta-analysis, the graft take rate varied from 43% to 96.5% in BCIT and from 75.6% to 91.1% in TFUT, which did not reach statistical significance (RR, 1.01; 95% CI, 0.93-1.11; **Table 1**). This finding aligns with that of the single randomized clinical trial comparing the techniques, which did not demonstrate any difference between the graft take rates of 85.3% for BCIT and 86.1% for TFUT.[14] There was 1 outlier study in terms of graft take results,[21] as illustrated in **Figure 2**; however, the author did not provide any information about the perforation's size.

Conversely, cartilage performed better than fascia in the study of van Stekelenburg and Aarts.[25] There were at least 5 meta-analyses[26-30] and 1 systematic review[31] comparing cartilage and fascia as grafts for tympanoplasties. Only 3 included BCIT.[26,27,31] The studies demonstrated a degree of superiority in the cartilage group in terms of successful closure of the perforation.

In terms of audiologic result, our meta-analysis revealed that TFUT was slightly but significantly superior to BCIT in terms of reduction of the air-bone gap. In a previous randomized clinical trial, the air-bone gap closure was greater in the fascia graft, although not statistically significant.[14] Since the introduction of cartilage in tympanoplasty reconstruction,

Table 3. Risk of Bias Assessment for Cohort Studies.[a]

	Selection				Comparability		Outcome			
Study	Representativeness of exposed cohort	Selection of nonexposed cohort	Ascertainment of exposure	Demonstration that outcome of interest was not present at start of study	Adjust for the most important risk factors	Adjust for other risk factors	Assessment of outcome	Follow-up length	Loss to follow-up rate	Score
Effat[21]	1	1	1	1	0	0	1	1	0	6
Couloigner[19]	0	1	1	1	1	1	1	1	0	7
Dave[10]	1	1	1	1	0	0	1	1	1	7
Haksever[13]	1	1	1	1	0	0	1	1	1	7
Kim[23]	1	1	1	1	1	1	1	0	0	7
Kim[24]	1	1	1	1	0	0	1	0	0	5
Ference[20]	0	1	1	1	0	1	1	0	0	5
Ulku[11]	1	1	1	1	0	0	1	1	0	6
Wang[22]	1	1	1	1	0	0	1	0	0	5

[a]Based on the Newcastle-Ottawa Scale.[18]

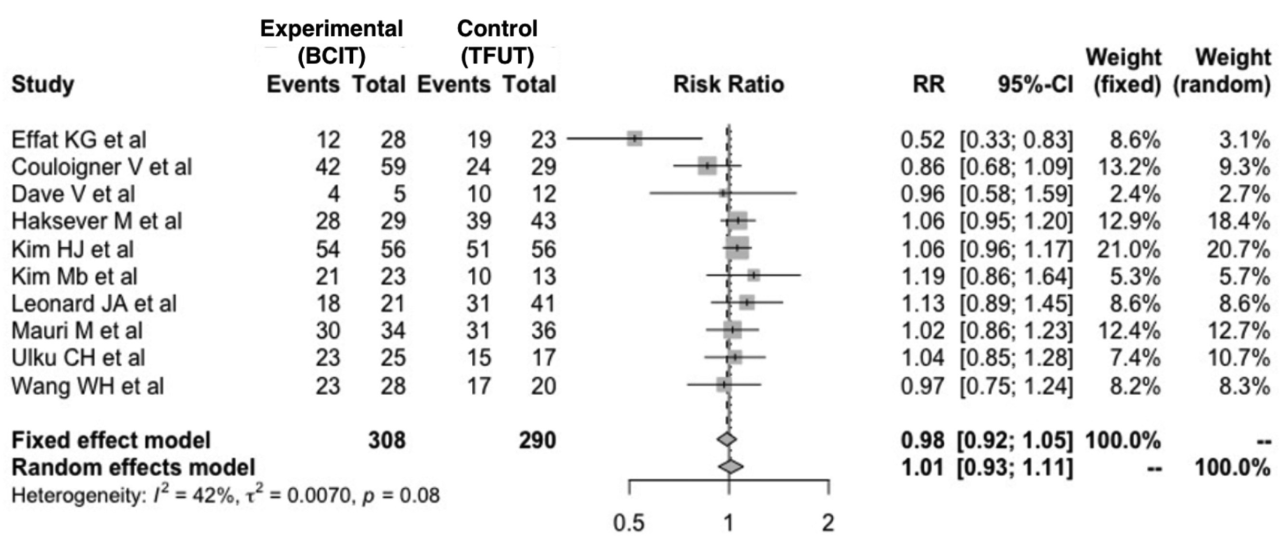

Figure 2. Forest plot of the meta-analysis of anatomic success: graft take rate. BCIT, butterfly cartilage inlay tympanoplasty; TFUT, temporal fascia underlay tympanoplasty.

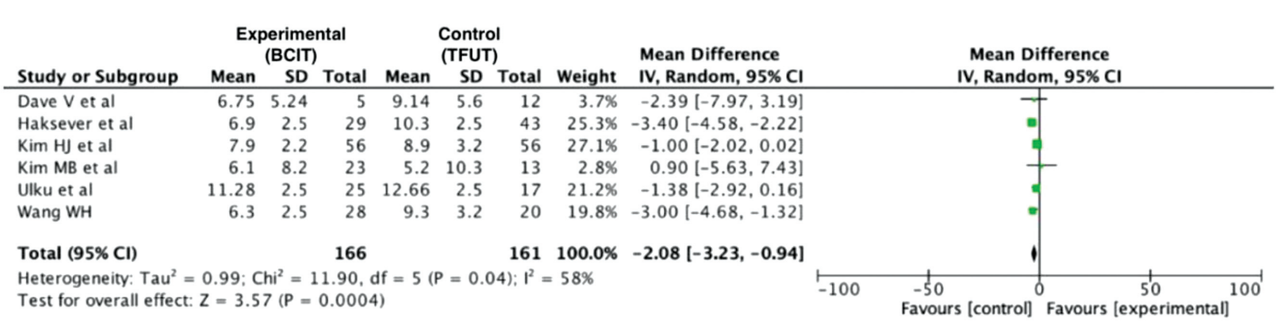

Figure 3. Forest plot of the meta-analysis of functional success: reduction in the air-bone gap. BCIT, butterfly cartilage inlay tympanoplasty; TFUT, temporal fascia underlay tympanoplasty.

acceptance has been hampered by a hypothetical detrimental impact on hearing. Conceptually, one might anticipate significant conductive hearing loss, especially in the lower tones, with a tympanic membrane that is rigid and thick. However, in a separate meta-analysis, the subgroup of full-thickness cartilage grafts revealed a significantly better hearing outcome than the temporalis fascia graft group.[30] Dornhoffer[32] also found no difference in postoperative hearing results when comparing cartilage and perichondrium tympanoplasty. Moreover, there was no difference in postoperative hearing results regarding the size of cartilage used. In a similar article, Gerber et al demonstrated that cartilage does not impede sound transmission.[33] Four meta-analyses[26-30] and the 1 systemic review[31] showed no difference regarding audiometric results.

Age was not predictive for the anatomic and audiologic success of the surgery. The role of the age is still controversial in the literature. A recent article stated that age does not matter for the take rate and air-bone closure.[34] In the meta-analysis by Vrabec et al, interestingly 25 of 30 studies showed no difference in success based on patient's age, but the pooled analysis of the global data found a positive association. They concluded that the greater success in healing of the tympanic membrane following tympanoplasty in children is seen with advancing age.[35]

Length of follow-up did not predict outcomes. The initial studies by pioneers of otology using ear canal skin[36] and vein[37] as grafts reported a high rate of reperforation in the long term due to atrophy or poor resistance to infection, creating the thought that long follow-up would be needed to provide a more realistic guide to patient counseling than short-term results. Although reperforation rates occur with cartilage and fascia, it appears that the long-term rates are more successful.[14,38] Although some authors recommended a minimum follow-up of 2 years, the Committee on Hearing and Equilibrium of the American Academy of Otolaryngology–Head and Neck Surgery suggested that following patients for 1 year is sufficient.[16] Many studies had a follow-up time <1 year. There is evidence indicating improvement in the postoperative gap in the BCIT group over the course of a long follow-up period.[12] This may be due to the decrease in cartilage thickness with the partial absorption of cartilage tissue over time, and it is relevant for large perforations.

Besides the small follow-up period of some studies, our study has limitations. The retrospective nature of all but 1 study is problematic in terms of controlling for selection and allocation bias. We could not control for the influence of perforation position and size in the outcomes—factors that may affect the surgeon's choice of surgical technique (eg, small and anterior perforations may be corrected more easily with BCIT than with TFUT). We also could not control for the presence of previous ear surgery. None of the analyzed studies compared the outcomes between patients submitted to primary tympanoplasty and patients with a history of ear surgery, and the scarcity of raw data presented make this analysis unfeasible to us. Even with the robust statistical techniques used, we must point out that 9 of the 10 studies analyzed have a low quality of evidence (grade C), and our findings should therefore be analyzed with that in mind. Until new prospective randomized controlled multi-institutional clinical trials emerge, however, this is the best evidence available for decision making.

Conclusion

BCIT and TFUT produce similar results in terms of successful reconstruction of the tympanic membrane and a reduction in the air-bone gap. Neither age nor follow-up length influenced outcomes.

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Author Contributions

José Faibes Lubianca Neto, data collection, risk of bias assessment, conduction, analysis, final revision; **Artur Koerig Schuster**, data collection, design, risk of bias assessment, analysis, final revision; **João Pedro Neves Lubianca**, data collection, analysis, final revision; **Roland Douglas Eavey**, analysis, final revision.

Disclosures

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Supplemental Material

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