




# Evaluation of rapid maxillary expansion or alternating rapid maxillary expansion and constriction on Eustachian tube function with audiological tests: A randomized clinical trial

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## Highlights

- The middle ear structures have improved as a result of maxillary expansion.
- Eustachian tube functions improved with RME.
- Middle ear functions improved in both the RME and Alt-RAMEC groups.

## Abstract

### Objectives

Maxillary expansion improves the hearing function. This trial aimed to examine the effects of Eustachian tube function (ETF) with audiological tests in orthodontic patients who underwent rapid maxillary expansion (RME) or alternate rapid maxillary expansion and constriction (Alt-RAMEC) treatment.

### Methods

Forty individuals (mean age=13.35 years) included in the trial had a healthy eardrum, no history of orthodontic treatment, maxillary constriction, mandibular constriction and were not affected by acute or chronic otitis. Patients were randomly assigned to one of two groups (n=20 each): the RME protocol or the Alt-RAMEC protocol. ETF was evaluated using Williams' test at three time points: before expansion (T0), after expansion (T1), and in the 3rd month of retention (T2).

### Results

In the RME group, Eustachian tube dysfunction (ETD) was observed in 18 of 40 ears before expansion (T0). The RME group showed significant improvement in tube function in the 3rd month of retention (T2) (p=0.003). In the Alt-RAMEC group, ETD was observed in 22 of the 40 ears at baseline (T0). Significant improvements in tubal function were observed in the Alt-RAMEC group after expansion (T1) (p=0.008) and in the 3rd month of retention (T2) (p<0.001). In the RME group, 17 of 18 ears recovered, while in the Alt-RAMEC group, 21 of 22 ears recovered.

### Conclusion

Eustachian tube function improved in the RME and Alt-RAMEC groups compared to the pre-expansion period.

### Registration

This trial was not registered.

## Keywords

Palatal expansion technique; Orthodontics; Otolaryngology

## 1. Introduction

Angell described the maxillary expansion procedure in 1860 for situations involving maxillary space shortages and transverse plane inadequacies [1]. A variety of orthodontic appliances and treatment procedures have been devised for maxillary expansion, the most prevalent of which is rapid maxillary expansion (RME) [2].

More than a decade ago, Liou invented the alternating rapid maxillary expansion and constriction (Alt-RAMEC) protocol to provide more forward maxillary movements after maxillary protraction [3]. The screw was opened by 1 mm each day for the first week and closed by 1 mm per day the following week using this technique.

For the first time, the location and function of the Eustachian tube were accurately described in humans in the 19th century by the Italian anatomist Bartolomeo Eustachi. Eustachian tube plays a vital role in ventilation, pressure regulation, and defense of the middle ear cavity, rather than being just a channel connecting the two cavities anatomically [4]. The necessity of having an Eustachian tube that can fulfill its functions for a healthy middle ear and sound transmission is undeniable [5]. When one or more of the three primary functions of the Eustachian tube, ventilation, protection, and clearance, are impaired, this is referred to as Eustachian tube dysfunction (ETD). The ETD plays an essential role in the pathogenesis of middle ear diseases. ETD increases the risk of otitis media and conductive hearing loss. Quantitative or qualitative tests are available to evaluate the functions of the Eustachian tube. The automated Williams' test is a quantitative method used in patients with intact tympanic membranes.

Interest in the entire stomatognathic system has increased in recent years. Another remarkable issue in this field is the treatment of maxillary transverse deficiencies, and thus, improvements in auditory function [6]. Rudolph [7] stated that tubal dysfunction is frequently seen in patients with high palatal vault, and that malformations in the palate and nasopharynx may predispose them to otitis media. ETF is improved by the expansion of the palatal and nasopharyngeal tissues [8]. The relationship between conductive hearing loss and maxillary constriction has been the subject of previous studies [6,9,10]. RME has been shown to improve nasal breathing and normal physiological functions, and prevent upper respiratory tract infections, nasal allergies, respiratory morbidity, and otitis media, which are thought to be the leading causes of conductive hearing loss [11,12]. Micheletti et al. [13] reported that RME did not have a detrimental effect on hearing quality and improved middle ear function in children with posterior crossbite from a one-year perspective.

There are limited studies on the functions of the Eustachian tube in patients with maxillary constriction. The effects of the RME and Alt-RAMEC protocols on tubal function were not compared. The aim of this trial was to evaluate ETF with audiological tests in patients treated with the RME and Alt-RAMEC protocols. The null hypothesis of this trial was that there would be no difference between the two protocols.

## 2. Methods

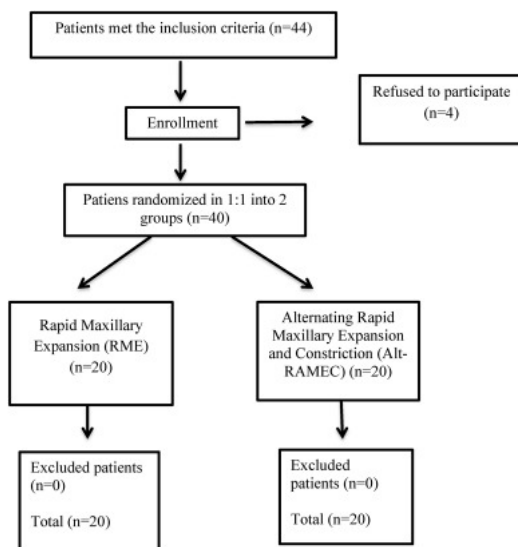
Written and verbal consent were obtained from the patients and their legal guardians separately, and approval was obtained from the Clinical Research Ethics Committee of Sivas Cumhuriyet University (Ethics Committee Decision No: 2020-06/01).

### 2.1. Trial design, registration, and any changes after trial commencement

The patients were divided into two groups: those who received the RME protocol and those who received Alt-RAMEC therapy (Table 1). The Consolidated Standards of Reporting Trials statement was followed during the trial. No adjustments were made at the beginning of the trial.

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Table 1. Participants' flow diagram.



## 2.2. Participants, eligibility criteria, and settings

Forty-four patients who visited the Faculty of Dentistry Orthodontic Clinic at Sivas Cumhuriyet University between June and September 2020 were included in the trial. The inclusion criteria were maxillary constriction in the transverse plane, bilateral posterior crossbite, no history of orthodontic treatment, and healthy eardrums without acute or chronic otitis. Exclusion criteria were patients with a complete plug in of the external auditory canal, active ear infections, and perforated eardrums. According to the cervical vertebral maturation approach, all the patients were in the active growth period. Twenty-four patients were in stage C3, and sixteen were in stage C4.

## 2.3. Interventions

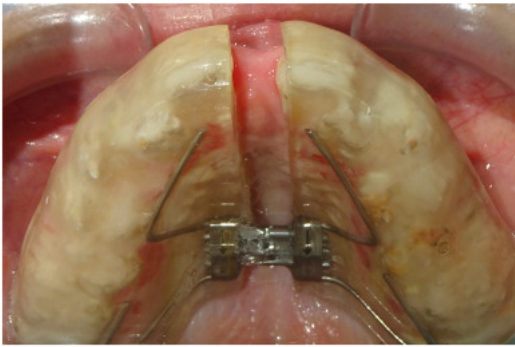
A full acrylic bonded RME appliance with a hyrax screw (Dentaurum, Pforzheim, Germany) was used in the first group, with 0.5 mm/day (two turns per day) expansion ([Fig. 1](#), [Fig. 2](#)). A full acrylic bonded appliance with a Hyrax screw (Dentaurum, Pforzheim, Germany) was applied to the Alt-RAMEC group, with expansion in the first week and constriction in the second; the same application was continued in the following weeks, and the screw was rotated so that the expansion occurred in the ninth week. Expansion and constriction occurred at a rate of 0.5 mm every day. Expansion continued until the conclusion of the ninth week, depending on the amount of construction. When the palatal tubercles of the upper molars touched the vestibule tubercles of the lower molars, the expansion process was complete in both groups. The screw was secured with a 0.014-inch ligature wire once the expansion was complete. To minimize patient discomfort, the appliance was removed 15 days after the expansion was completed, and the Hawley's plate was used during the retention period for 6 months. Patients in the Alt-RAMEC group did not undergo maxillary protraction.



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Fig. 1. Clinical photograph of RME before expansion.



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Fig. 2. Clinical photograph of RME after expansion.

The mean number of screw turns was 35.8 in the RME and 36.2 in the Alt-RAMEC group, respectively.

#### 2.4. Automatic Williams' test (ETF test)

**Tympanogram:** As a result of systematic changes in air pressure in the external ear canal (EEC), the method of graphically recording the flexibility and mobility of the EEC, eardrum, and middle ear structures is called tympanometry, and the results obtained using this method are called tympanograms [14]. Measuring middle ear pressure using a tympanogram while the tympanic membrane is intact provides important information for evaluating ETF.

**Toynbee test:** The patient is asked to swallow repeatedly while his mouth and nostrils are closed in this test. The negative pressure created by the swallowing movement causes the pressure in the middle ear cavity to decrease when the Eustachian tube opens.

**Valsalva maneuver:** In this maneuver, the patient tries to make a forced expiration while his mouth and nostrils are closed. With this maneuver, positive pressure is created in the nasopharynx. When the Eustachian tube is opened, air passes into the tympanic cavity owing to the increased pressure, and the middle ear pressure increases.

The Williams' test was performed under standard conditions in a quiet room using an impedance meter (MAICO Diagnostic GmbH Salzufer 13/14 D-10587 Berlin) (Fig. 3).



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Fig. 3. Impedance meter used in Eustachian tube function test.

In the Williams' test, the middle ear pressure was tested in three conditions:

1. With the first test, a basal tympanogram was taken, and middle ear pressure was recorded (P1).
2. In the second test, middle ear pressure was obtained during swallowing by closing the mouth and nostrils (Toynbee test) (P2).
3. In the third test, middle ear pressure was obtained during a forced expiration by closing the mouth and nostrils (Valsalva maneuver) (P3).

A 3-minute break was subsequently taken, and the same procedure was applied to the other ear. During the test, the pressures corresponding to the peaks of the graph obtained for all the three cases were recorded numerically (P1, P2, and P3). The P1–P2 pressure difference, and the difference between the highest and lowest pressures (Pmax–Pmin), were determined. On the test side, ETF was

considered normal if the pressure difference between P1 and P2 was greater than 10daPa or the pressure difference between Pmax and Pmin was greater than 15daPa (Fig. 4). Ears with the same P1, P2, and P3 pressure values had either permanent or temporary ETD (Fig. 5). Ears with ETD were scored as 0, and ears with functional Eustachian tubes were scored as 1.

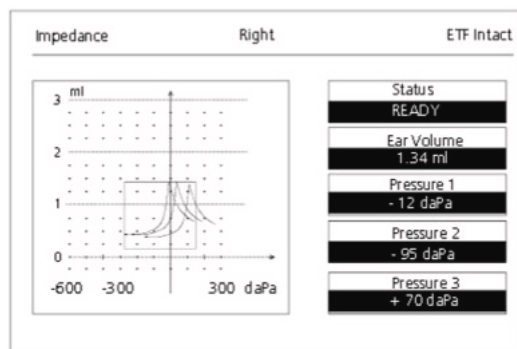


Figure 32 The ETF screen after third test cycle (Pressure 3)

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Fig. 4. Screen view of Williams' test of an ear with functional Eustachian tube.



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Fig. 5. Screen view of Williams' test of an ear with dysfunctional Eustachian tube.

ETF was evaluated using the Williams' test before expansion (T0), after expansion (T1), and in the 3rd month of retention (T2).

## 2.5. Distortion product otoacoustic emissions

Distortion product otoacoustic emissions (DPOAE) occur when two pure tones, f1 and f2, at different frequencies are introduced into the cochlea and are widely used in the diagnosis and research to assess the functional status of the cochlea [15]. A small earpiece or probe is placed in the ear. The probe transmits sound to the ear and measures the returning sound. Talking during the test was not allowed (hearing was considered normal when a response was received from a sound sent to the cochlea). All measurements were made with the same otoacoustic emission device (ERO-SCAN OAE Test Systems, 70-71, 10,553, Germany).

All individuals underwent DPOAE before expansion, and hearing was normal in all ears.

## 2.6. Objectives (primary and secondary)

The primary aim of this trial was to determine the impact of RME and Alt-RAMEC treatments on ETF. The secondary aim was to determine the relationship between ETF and age and sex.

## 2.7. Sample size calculation

The sample size was calculated based on tympanometric measurements obtained from a pilot study of six patients (three in each group). The mean difference between the groups was 0.53 and the standard deviation was 0.5. The sample size was calculated using G\*Power 3.1. When the alpha value was 0.05, the effect size was 0.9112, the statistical power was 0.801, and 40 patients (20 in each group) were determined. Considering the possible loss during the follow-up period, we decided to recruit another 10% of patients, and the number of patients was 44. Patients who participated in the pilot study were excluded from the trial.

## 2.8. Interim analyses and stopping guidelines

Not applicable.

## 2.9. Randomization and blinding

Patients were randomly assigned to groups with a 1:1 allocation ratio using sealed, opaque envelopes. Each patient was asked to select previously shuffled envelopes that maintained the assignment order at the time of the allocation. Thus, a selection bias was avoided.

The outcome assessor was blinded, and the trial was blinded. Each participant's therapeutic procedures and outcomes were documented in different forms and were discussed following statistical analysis.

## 2.10. Statistical analysis

A statistical analysis was performed using SPSS (Statistical Package for Social Sciences) for Windows version 25.0 package program (SPSS Inc., Chicago, Illinois). Descriptive statistics are presented as frequency (n), percentage (%), mean values (M), standard deviations (SDs), and lower (min) and upper (max) limits. To compare mean ages by group, the Mann-Whitney *U* test was used. The Wilcoxon signed-rank test was used for intragroup comparison. Differences were considered statistically significant at  $p < 0.05$ .

## 3. Results

### 3.1. Participant flow

In accordance with the power analysis performed in this trial, 20 patients with RME and 20 with Alt-RAMEC were recruited. The mean age of the patients in the RME group was  $13.05 \pm 1.14$  (min: 11, max: 15) years, and the mean age of the patients in the Alt-RAMEC group was  $13.70 \pm 0.57$  (min: 12, max: 14) years. The RME group included 75.0% (n=15) female patients and 25.0% (n=5) male patients. 65.0% (n=13) of the patients in the Alt-RAMEC group were female, and 35.0% (n=7) were male. In terms of sex, there were no significant differences between the groups ( $p=0.366$ ). There was no significant difference in age between the groups ( $p=0.156$ ).

## 4. Numbers analyzed for each outcome

The numbers of ears and patients with functional and dysfunctional Eustachian tubes at T0, T1, and T2 are presented in [Table 2](#), [Table 3](#), respectively. The intragroup comparisons are shown in [Table 2](#).

Table 2. The Number of Ears With Functional And Dysfunctional Eustachian Tubes at T0, T1, and T2 as Determined by the Automatic Williams Test, as well as the Results of Within Group Comparisons.

Groups	T0		T1		T2		Within Group Comparisons		
	Ears With Functioning Eustachian Tube	Ears With Eustachian Tube Dysfunction	Ears With Improved or Functioning Eustachian Tube	Ears With Eustachian Tube Dysfunction	Ears With Improved or Functioning Eustachian Tube	Ears With Eustachian Tube Dysfunction	T1-T0	T2-T0	T2-T1
<b>RME (20 patients 40 ears)</b>	22(55%)	18(45%)	29(72.5%)	11(27.5%)	39(97.5%)	1(2.5%)	.058	.003*	.008*
<b>Alt-RAMEC (20 patients 40 ears)</b>	18(45%)	22(55%)	30(75%)	10(25%)	39(97.5%)	1(2.5%)	.008*	<001*	.008*

Note. RME, Rapid maxillary expansion; Alt-RAMEC, Alternating rapid maxillary expansion and constriction; T<sub>0</sub>, before expansion; T<sub>1</sub>, after expansion; T<sub>2</sub>, 3rd month of retention.



\*Wilcoxon Signed Rank Test,  $p < 0.05$ .

Table 3. The number of patients with functional and dysfunctional eustachian tubes at T0, T1, and T2 as determined by the automatic williams test.

Groups	T0		T1		T2	
	Functioning Eustachian Tube	Eustachian Tube Dysfunction	Functioning Eustachian Tube	Eustachian Tube Dysfunction	Functioning Eustachian Tube	Eustachian Tube Dysfunction
<b>RME (20 patients)</b>	6(30%)	14(70%)	12(60%)	8(40%)	19(95%)	1(5%)
<b>Alt-RAMEC (20 patients)</b>	5(25%)	15(75%)	12(60%)	8(40%)	19(95%)	1(5%)

Note. RME, Rapid maxillary expansion; Alt-RAMEC, Alternating rapid maxillary expansion and constriction; T<sub>0</sub>, before expansion; T<sub>1</sub>, after expansion; T<sub>2</sub>, 3rd month of retention.

In the RME group, functional Eustachian tubes were observed in 22 ears and dysfunctional Eustachian tubes were observed in 18 ears at T0. After RME (T1), the number of ears with functional Eustachian tubes increased to 29, but this was not statistically significant ( $p > 0.05$ ). There were 39 ears with functional Eustachian tubes at T2 ( $P < 0.05$ ) (Table 2). Dysfunctional Eustachian tubes were observed in 22 ears in the Alt-RAMEC group, and statistically significant improvements in tubal function were observed after expansion (T1) ( $p < 0.05$ ) and in the 3rd month of retention (T2) period ( $p < 0.001$ ) (Table 2). According to Cohen's criteria [16], the effect size in the Alt-RAMEC group was very small ( $r = -0.59$ ) at T1.

Finally, 17 of 18 ears with a dysfunctional Eustachian tube in the RME group and 21 of 22 ears in the Alt-RAMEC group showed improvements at T2.

#### 4.1. Harms

No serious harm was observed.

### 5. Discussion

Impaired ETF can lead to pathological alterations in the middle ear, resulting in [conductive hearing loss](#) or otitis media [11]. [Impedance audiometry](#) is a precise and useful technique for testing ETF [in patients](#) with perforated and non-perforated [eardrums](#) [17]. Similar to the study by Kilic et al. [18], the ETD was assessed in this trial using an impedance meter with the Williams' test.

[DPOAE](#) was used in the study because it detects pathologies in the cochlea and the effects on high frequency hearing. Before expansion, all participants underwent DPOAE, and all ears' hearing was normal. Tubal dysfunction may be observed in individuals with normal hearing [19]. Eustachian dysfunction does not always affect hearing and may manifest as ear fullness and tinnitus [20,21].

In this trial, 18 of the 40 ears in the RME group were dysfunctional at baseline. By the third month of retention, 17 of the 18 (94.4%) dysfunctional ears had recovered. These findings showed that RME significantly improved tubal dysfunctions in the ears. In patients with transverse maxillary insufficiency and conductive hearing loss, Kilic et al. [6] discovered that RME treatment had a beneficial and statistically significant effect on both hearing and controlling the proper operation of the Eustachian tube. In a [systematic review](#) made in 2017, it was found that there was an improvement in hearing after maxillary expansion in patients with hearing loss, however, it was stated that controlled and randomized studies were needed to investigate this issue further [8]. This trial partially agrees with the findings of Kilic et al. [18]. Improvements in ETF with RME in patients with resistant [otitis media with effusion](#) and maxillary constriction were observed by Kilic et al. [18]. According to their results, 15 of 22 dysfunctional ears healed after the observation period. Villano et al. [22] found improvements in the ETF in all ears, which partially differed from the findings of the current trial. These partial differences could be attributed to different patient selection criteria, patient age, and ETF tests.

The Alt-RAMEC group was administered the 9-weeks open-close regimen proposed by Liou et al. [23] in this trial. Various methods have been used in several studies. Isci et al. [24] (no final expansion), Cantürk and Çelikoğlu [25] (no final expansion), and Maino et al. [26] used an 8, 4, and 5-weeks protocol, respectively. A double-hinged expander was commonly utilized in Alt-RAMEC treatment to improve anterior expansion [27]. However, as there was no requirement for better expansion in the anterior region, a hyrax expander was used in this trial. This type of expander has been used in several studies [24,25]. In this trial, the patients in the Alt-RAMEC group did not undergo maxillary protraction. Only a few studies have used Alt-RAMEC without maxillary protraction [[28], [29], [30]].

To the best of our knowledge, no studies have evaluated the relationship between Alt-RAMEC and ETF. According to the data from this trial, the ETF improved in the Alt-RAMEC group compared to the pre-expansion period. A total of 22 of the 40 ears were dysfunctional at baseline, however, after expansion and the third month of retention, 21 of the 22 (95.4%) dysfunctional ears healed. Simultaneously, unlike the RME group, the improvements observed after expansion in the Alt-RAMEC group were statistically significant, but the effect

size was very small. This statistical difference may be due to the higher number of ears with ETD in the Alt-RAMEC group than in the RME group.

In this study, the percentage of ETD in normal eardrums was high. Asymptomatic Eustachian dysfunction affects a large number of people. Many factors contribute to dysfunction, including missing teeth, unilateral chewing, adenoid tissue, reflux, infections [21,31].

Thus, the null hypothesis was rejected. Improvements in the ETF were observed in both the RME and Alt-RAMEC groups.

## 6. Limitations

ETF improved in the RME and Alt-RAMEC groups, but long-term outcomes were not evaluated. Long-term studies with larger sample sizes are thus required.

Another limitation of this trial was the lack of a control group. There are studies in the literature that compare two groups with no control groups [[32], [33], [34]].

## 7. Generalizability

There may be limitations to the generalization of the trial because only patients in a certain age group living in a region were included in the trial.

## 8. Conclusion

Eustachian tube function improved in the post-expansion period and in the 3rd month of retention compared to the pre-expansion period in the RME.

The Alt-RAMEC group also showed improvements in ETF post-expansion and in the 3rd month of retention.

With both expansion protocols, improvements in the ETF emerged.

## Protocol

The protocol was not published before trial commencement.

## Funding

None.

## Ethics approval

Written and verbal consent were obtained from the patients and their legal guards separately, and approval was obtained from the Clinical Research Ethics Committee of Sivas Cumhuriyet University (ID: 2020-06/01).

## Peer-review

Externally peer-reviewed.

## Authors' contributions

Concept – Z.Ç.B., M.D.; Design – Z.Ç.B., M.D.; Supervision – C.D.; Resources – Z.Ç.B, M.D.; Materials Z.Ç.B., M. D.; Data Collection and/or Processing – Z.Ç.B.,M.D.,V.Y.Ö.; Analysis and/or Interpretation - Z.Ç.B.; Literature Search –Z.Ç.B.; Writing Manuscript - Z.Ç.B; Critical Review - Z.Ç.B., M.D.; Other – Z.Ç.B.

## Declaration of competing interest

The authors have no conflict of interest to declare.

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