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The effects of different surgical procedures on voice before and after treatment of adenoid and tonsil diseases in children

Submission date 14/12/2025	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 22/12/2025	**Overall study status** Ongoing	
Last Edited 18/09/2026	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific, Public, Principal investigator

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Study information

Scientific Title
Evaluation of acoustic parameters before and after different surgical approaches in adenotonsillar pathologies in children: a randomized controlled study

Study objectives
Background and Rationale:
Adenoidectomy with or without tonsillectomy is the most frequently performed surgical procedure in childhood. Postoperative complications include bleeding, pain, and voice changes, with many parents noting alterations in their child's voice. Adenoid and tonsillar tissue can obstruct the airway space, potentially impeding vocal production and altering voice quality.

The current body of evidence primarily focuses on the impact of adenotonsillectomy on subjective speech measures, such as nasality and perceptual-auditory voice parameters. However, it has also been suggested that the significant removal of tissue from the oropharyngeal and nasopharyngeal spaces may lead to phonatory instability, manifesting as objective changes in vocal fold vibration patterns.

To date, few studies have comprehensively assessed both the laryngeal and supralaryngeal aspects of speech production following tonsil surgery, either with or without concomitant adenoidectomy. Furthermore, there is a paucity of research specifically measuring and characterizing voice changes following different surgical techniques.

This study aims to:
1. Document changes in objective and subjective voice parameters before and after adenotonsillectomy.
2. Investigate whether there is a difference in pre- and postoperative voice parameters between two established surgical techniques—bipolar dissection and cold dissection tonsillectomy—both of which are performed safely and are associated with similar complication rates in the literature.

Novelty and Positioning:
While studies evaluating various voice parameters exist, they often employ different designs and frequently do not specify the precise surgical method used. The methodology of this planned study, which directly compares two defined surgical techniques within a randomized controlled framework, represents a novel approach not commonly encountered in the current literature.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 01/08/2025, Izmir Tepecik Training and Research Hospital Clinical Research Ethics Committee (Güney Mah. 1140/1 Sok. No:1 Yenişehir Konak, İzmir, 35170, Türkiye; +90 (0) 2324696969 - (internal no:)1729; iyikliniktepecikeah@gmail.com), ref: Ref-08012025

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Device feasibility, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Adenoid and tonsil diseases in children

Interventions
Participants and Sample Size:
Sixty-four (64) patients meeting the inclusion criteria will be enrolled. Eligible patients will be children with Brodsky grade 3–4 tonsillar hypertrophy and an adenoid-to-nasopharyngeal ratio greater than 0.67 as defined by Fujioka et al.
The sample size of 64 was determined using G*Power software. The calculation was based on mean and standard deviation values for the Pediatric Voice Handicap Index (pVHI), fundamental frequency (F0), Jitter, Shimmer, Noise-to-Harmonic Ratio (NHR), and a visual analog scale (VAS) for dysphonia severity, as reported in a previous study by Lee et al. involving 51 patients. Cohen's d was calculated from these values. The most conservative value was for F0 (d=0.44). Considering that repeated measures would be analyzed using ANOVA (both within and between groups), the effect size *f* was calculated from F0 as 0.22, representing a small-to-medium effect. With this effect size, and using the following parameters—α: 0.1 (with Bonferroni correction), power (1-β): 0.8, 2 groups, 3 repeated measurements, and an inter-measurement correlation of 0.5—the total sample size was calculated as 52 patients. Accounting for a potential 20% dropout rate, the required sample size increased to 63. To ensure equal group allocation, the final total sample size was set at 64 patients.

Intervention and Randomization:
Enrolled patients will be randomly allocated into two groups of 32 patients each (16 male, 16 female per group). One group will undergo tonsillectomy using the bipolar dissection technique, while the other will undergo tonsillectomy using the cold dissection technique. All 64 patients in both groups will also undergo curettage adenoidectomy. All patients will be hospitalized for one day postoperatively for observation and monitoring.

Outcome Measures and Follow-up:
As part of the routine clinical follow-up for adenotonsillectomy patients at our institution, the following voice-related parameters will be assessed at three timepoints: preoperatively, at 1 week postoperatively, and at 1 month postoperatively:
Objective Acoustic Analysis: Fundamental Frequency (F0, Hz), Jitter (%), Shimmer (%), and Noise-to-Harmonic Ratio (NHR).

Subjective Assessment:
Dysphonia severity evaluated using a 100-mm Visual Analog Scale (VAS) anchored on a 10-point numeric scale.
Pediatric Voice Handicap Index (pVHI), Turkish version.

Voice Assessment Protocol:
For objective voice analysis, recordings will be made in a sound-isolated room (ambient noise <40 dB). The PRAAT acoustic analysis software (version 6.4.23) will be used. Recording will be

performed inside an acoustic booth using a microphone at a fixed mouth-to-microphone distance (15 cm). Patients will be asked to sit outside the booth for approximately 10 minutes prior to recording to relax. After a deep breath, they will be instructed to sustain the vowel /a/ for 5 seconds, three times. The best quality sample among the three recordings will be used for analysis.
For subjective assessment, parents will be asked to mark their child's perceived dysphonia severity on the VAS line, from left (normal) to right (severe). Parents will also complete the Turkish pVHI questionnaire at each follow-up visit.

Assessment Timeline and Outcome Measures: Voice parameters will be assessed at three time points:
Preoperatively (Baseline):
Objective Acoustic Measures: Fundamental Frequency (F0), Jitter, Shimmer, and Noise-to-Harmonic Ratio (NHR).
Subjective Measures: Dysphonia Severity Visual Analog Scale (VAS) and the Pediatric Voice Handicap Index (pVHI).
Postoperative Week 1:
Objective Acoustic Measures: F0, Jitter, Shimmer, and NHR.
Subjective Measures: Dysphonia Severity VAS and the pVHI.
Postoperative Month 1:
Objective Acoustic Measures: F0, Jitter, Shimmer, and NHR.
Subjective Measures: Dysphonia Severity VAS and the pVHI.
All acoustic analyses will be performed using PRAAT software on standardized voice recordings. The VAS and the Turkish version of the pVHI will be completed by the parents or guardians.

Statistical Analysis:
Objective and subjective outcome data will be statistically evaluated. Repeated-measures ANOVA will be used to analyze changes over time within and between the two surgical intervention groups.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Fundamental frequency measured using objective acoustic analysis at preoperatively (baseline), postoperative week 1 and postoperative month 1

Key secondary outcome(s)

Completion date
01/01/2027

Eligibility

Key inclusion criteria
1. Pediatric population (aged 5-12 years/pre-puberty) should be able to easily perform acoustic analysis tests.
2. Surgical treatment should be recommended due to chronic adenoiditis and tonsillitis, obstructive sleep disorders due to adenotonsillar hypertrophy.
3. Otoscopic examination before surgical treatment should be normal.
4. Patients with stage 3-4 tonsillar hypertrophy according to Brodsky; adenoids with an

adenoidonasopharyngeal ratio greater than 0.67 as defined by Fujioka et al.
5. Adenoidectomy and tonsillectomy should be performed together.

Healthy volunteers allowed
No

Age group
Child

Lower age limit
5 Years

Upper age limit
12 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Presence of craniofacial malformation
2. Presence of developmental disability
3. Presence of significant preoperative voice disorder and vocal cord pathology
4. Presence of a systemic disease or medication the patient is taking regularly
5. Presence of a proven allergy
6. Presence of any hearing impairment

Date of first enrolment
22/12/2025

Date of final enrolment
15/12/2026

Locations

Countries of recruitment
Türkiye

Sponsor information

Organisation
Muğla Sıtkı Koçman Training and Research Hospital

Funder(s)

Funder type

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available