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ORIGINAL RESEARCH

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Oral health outcomes in children with tuberous sclerosis complex: a matched case–control study evaluating antiseizure medication and mTOR inhibitor exposure

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Abstract

Background: Tuberous sclerosis complex (TSC) is a rare genetic disorder with neurological and systemic involvement. The relationship of TSC and the anti-seizure medications (ASM) and mammalian target of rapamycin (mTOR) inhibitors used in its treatment with oral and dental health is not fully understood. This study compared oral and dental health parameters in children with TSC and healthy controls and investigated the association between pharmacological treatment exposure and these parameters. **Methods**: A case-control study was conducted between January and November 2025 at the Istanbul University Faculty of Medicine Pediatric Neurology Clinic on 19 children aged 3–18 years with TSC and 19 age and sex matched healthy controls. Gingival index, gingival overgrowth index, fibroma, enamel pits, decayed/filled/missing teeth (dmft/DMFT) scores, toothbrushing frequency, dental visit frequency, and Wong-Baker pain scores were evaluated. In the TSC group, disease duration, comorbid conditions, and duration of ASM and mTOR inhibitor use were also recorded. Matched between-group comparisons were performed using paired statistical tests, and associations were assessed using Spearman correlation analysis. **Results**: Gingival index, gingival overgrowth, and enamel pits were significantly higher in the TSC group than in controls ($p < 0.05$). No significant differences were found between in toothbrushing frequency, dental visits, or fibroma group. Within the TSC group, longer ASM exposure was positively correlated with gingival index and gingival overgrowth, whereas mTOR inhibitor exposure showed a moderate positive correlation with gingival overgrowth but no significant correlation with gingival index. **Conclusions**: Compared with age and sex matched controls, children with TSC showed higher gingival index scores (2.0 *vs.* 1.0), greater gingival overgrowth (1.0 *vs.* 0.0), and a higher prevalence of enamel pits (57.9% *vs.* 15.8%). Longer ASM exposure was strongly correlated with gingival index ($\rho = 0.735$) and gingival overgrowth ($\rho = 0.801$), whereas mTOR inhibitor exposure was moderately correlated only with gingival overgrowth ($\rho = 0.488$).

Keywords

Tuberous sclerosis complex; Pediatric dentistry; Gingival overgrowth; Anti-seizure medication; mTOR inhibitors

1. Introduction

Tuberous sclerosis complex (TSC) is an inherited neurocutaneous syndrome caused by inactivating mutations in the tumor suppressor genes *TSC1* and *TSC2*. It is characterized by hamartomatous lesions in multiple organ systems such as the brain, skin, heart, and kidneys. The disease is most commonly associated with epilepsy, developmental delay, and facial angiofibromas, but it can also present with a variety of oral manifestations [1]. Oral findings such as multiple enamel pits, intraoral fibromas, and gingival enlargement have been reported frequently in patients with TSC [2, 3]. According to the 2021 International Tuberous Sclerosis Complex diagnostic criteria, two oral findings are included among the minor diagnostic features: dental enamel pits (≥3) and intraoral fibromas (≥2) [4].

While good oral hygiene and plaque control are among the main determinants of gingival health, certain systemic diseases and medications may adversely affect this balance [5]. This issue may be particularly relevant in children with TSC, in whom anti-seizure medications (ASM) and mammalian target of rapamycin (mTOR) inhibitors are often used for prolonged periods as part of disease management [1]. Recent literature on drug-induced gingival overgrowth has

highlighted the contribution of altered fibroblast function, extracellular matrix accumulation, and inflammatory signaling to medication-related gingival changes [6]. In addition, mTOR inhibitors are known to be associated with oral adverse effects, particularly stomatitis and oral mucosal injury, which may further influence oral health in susceptible patients [7].

Most published studies consist of case reports or small patient series, and comparative studies involving healthy controls are limited. In addition, important parameters such as oral hygiene habits and subjective oral pain experience have rarely been addressed in the literature [3]. This study aimed to evaluate dental and gingival health in children diagnosed with TSC, to investigate the relationship of these findings with disease duration and medication exposure, and to help address gaps in the literature through the inclusion of a healthy control group.

2. Materials and methods

2.1 Study design and participants

This cross-sectional and matched case control study was conducted at the Istanbul University Faculty of Medicine, Department of Pediatrics, Division of Pediatric Neurology between January 2025 and November 2025. Ethical approval was obtained from the Istanbul University Faculty of Medicine Ethics Committee (12.09.2024-2858322), and written informed consent forms were signed by the parents of all participating children. The inclusion criteria for the TSC group were: (1) age between 3 and 18 years, (2) a diagnosis of TSC according to the 2021 International TSC diagnostic criteria, and (3) attendance at the pediatric neurology clinic during the study period. Patients were excluded if parental consent was not obtained or if clinical oral examination could not be completed. A total of 19 patients met the eligibility criteria and were included in the study [4]. Each patient with TSC was individually matched with one healthy control of the same age and sex. The inclusion criteria for the control group were: (1) age between 3 and 18 years, (2) attendance at the pediatric dentistry clinic for routine dental examination, and (3) absence of a history of chronic systemic disease, neurological disorder, genetic syndrome, or regular medication use. Children were excluded from the control group if parental consent was not obtained or if the clinical oral examination could not be completed.

2.2 Data collection and clinical assessments

Demographic and medical information of all participants, together with oral health-related habits, was collected from parents using a standardized study form. Recorded variables included age, sex, age at diagnosis (for the TSC group), presence of comorbid epilepsy and/or neurodevelopmental disorders, anti-seizure medications (ASM) and mTOR inhibitors used (if any), duration of medication use (years), toothbrushing frequency, and frequency of dental visits. Complaints of oral pain or discomfort were assessed using the Wong-Baker Faces Pain Rating Scale, which ranges from 0 (“no pain”) to 10 (“very severe pain”) and is particularly useful in younger children and in those with limited verbal communication [8].

All participants underwent a whole-mouth clinical intraoral examination performed by a single pediatric dentist under adequate lighting conditions using a standard dental mirror and probe. The following parameters were assessed and recorded systematically for each participant: dmft/DMFT scores, gingival index, gingival overgrowth index, presence of intraoral fibromatous lesions ($\geq$2), and presence of dental enamel pits ($\geq$3) [9–11]. Caries experience in the primary and permanent dentitions was recorded using the dmft/DMFT index [9]. Gingival health was assessed clinically using the Löe-Silness Gingival Index, based on visual signs of gingival inflammation and bleeding tendency on gentle probing [11]. Gingival enlargement was assessed clinically using the Gingival Overgrowth Index according to the extent of hyperplastic tissue relative to the clinical crown [10]. Intraoral fibromatous lesions and enamel pits were recorded according to the thresholds used for TSC-related oral findings in the literature [3]. In participants who were able to cooperate, intraoral photographs were also obtained to document the clinical findings.

2.3 Statistical analysis

Statistical analyses of the data were performed using R software (version 4.0.2). Descriptive statistics were calculated for all variables; continuous variables were summarized as mean $\pm$ standard deviation or median (interquartile range), and categorical variables were summarized as number and percentage. Given the rarity of tuberous sclerosis complex, the study included all eligible patients followed at our institution during the study period who agreed to participate. As a result, no formal a priori sample size calculation was performed, and the sample size reflects the available patient population. In line with the study design cases and controls were matched in terms of age and sex; therefore, statistical tests that could be used between-group comparisons were performed. Paired *t*-tests were applied for continuous data when the distribution of differences between the two groups was approximately normal; when the distribution was not normal or the data were ordinal, the Wilcoxon signed-rank test (the paired equivalent of the Mann-Whitney U test) was used for non-parametric comparison. The McNemar test was preferred for paired categorical data (for variables with more than two categories, the Chi-square test or Fisher exact test was used when appropriate). Effect sizes were reported along with corresponding results to describe the magnitude of between-group differences, including, Cohen’s *d* for paired *t*-tests, rank-biserial correlation (*r*) for the Wilcoxon test, and paired odds ratio (OR) for the McNemar test.

Within the TSC patient group, additional analyses were performed for specific sub variables. The Spearman rank correlation coefficient was used particularly to evaluate the relationship between cumulative drug exposure (the sum of the duration of use of ASM and/or mTOR inhibitor therapies, in years) and gingival clinical outcomes. This non-parametric correlation analysis was selected due to the ordinal nature of the gingival index data and the limited sample size. Spearman correlation coefficients (ρ) and their corresponding *p*-values were reported. The establishment of multivariable models for potential confounding variables was also investigated to be

used in the study; however, adequate convergence could not be achieved in such models due to the small sample size and the quasi-complete separation in some variables. Therefore, in accordance with the sample size, multivariable modeling was not applied, and the final analyses were based on univariable matched tests considered reliable for rare diseases and the correlation analysis described above. All tests were applied as two-tailed, and $p < 0.05$ was considered statistically significant.

3. Results

A total of 19 children diagnosed with TSC and 19 age- and sex-matched controls were included in the analysis. The descriptive characteristics of the study population are presented in Table 1, and the clinical characteristics and systemic involvement of patients with TSC are summarized in Table 2.

Compared with controls, children with TSC had significantly higher gingival index and gingival overgrowth scores. Gingival Index scores were higher in the TSC group (median 2.0 (interquartile range (IQR) 1.5–3.0)) than in the control group (median 1.0 (IQR 0.5–1.0)), with a large effect size (Wilcoxon signed-rank test, $p < 0.05$; rank-biserial $r = 0.85$). The prevalence of enamel surface pitting (≥3) was significantly higher in the TSC group than in the control group (57.9% *vs.* 15.8%; McNemar test, $p < 0.05$; matched OR = 9) (Fig. 1A,B). Intraoral fibromas (≥2) were observed only in the TSC group (26.3%), whereas none were detected in the control group; however, this difference did not reach statistical significance ($p = 0.074$) (Fig. 1C,D) Gingival overgrowth scores were also significantly higher in patients with TSC than in controls (median 1.0 (IQR 0.0–2.0) *vs.* 0.0 (IQR 0.0–0.0)), again with a large effect size ($p < 0.05$; rank-biserial $r = 0.91$) (Table 3; Fig. 1E,F). No significant between-group differences

TABLE 1. Sociodemographic, clinical, and oral health characteristics of patients with TSC and the matched control group.

Variables	Control (n = 19)	TSC patients (n = 19)
Age (yr)	12.00 (6.50–16.50)	12.00 (6.50–16.50)
Sex (female/male)	10 (female)/9 (male)	10 (female)/9 (male)
Time since diagnosis (yr)	0.00 ± 0.00	8.37 ± 4.03
Anti-seizure medicine use (yes)	0 (0.0%)	12 (63.2%)
Epilepsy (yes)	0 (0.0%)	12 (63.2%)
mTOR inhibitor use (yes)	0 (0.0%)	8 (42.1%)
Neurodevelopmental disorders (yes)	0 (0.0%)	15 (78.9%)
Frequency of dental visits	1.00 (1.00–1.00)	1.00 (1.00–1.00)
Tooth brushing frequency	2.00 (2.00–3.00)	2.00 (1.50–3.00)
dmft/DMFT	6.26 ± 3.28	7.00 ± 4.28
Presence of enamel pits (≥3) (yes)	3 (15.8%)	11 (57.9%)
Intraoral fibroma (≥2) (yes)	0 (0.0%)	5 (26.3%)
Gingival index (GI)	1.00 (0.50–1.00)	2.00 (1.50–3.00)
Gingival overgrowth index (GOI)	0.00 (0.00–0.00)	1.00 (0.00–2.00)
Wong-Baker Faces Pain Rating Scale	1.00 (0.00–2.00)	1.00 (0.00–2.00)

Values are presented as mean ± standard deviation, median (interquartile range), or n (%). Groups were matched for age and sex. TSC: Tuberous Sclerosis Complex; dmft/DMFT: decayed/filled/missing teeth; mTOR: Mammalian target of rapamycin.

TABLE 2. Clinical characteristics and systemic involvement of patients with Tuberous Sclerosis Complex.

Variables	n (%)
Brain involvement	17 (89.5%)
Ocular involvement	2 (10.5%)
Epilepsy	12 (63.2%)
Intellectual disability/developmental delay	8 (42.1%)
Autism spectrum disorder	2 (10.5%)
Renal involvement	5 (26.3%)
Cutaneous involvement	15 (78.9%)
Cardiac involvement	7 (36.8%)

TABLE 3. Pairwise comparisons between patients with TSC and the matched control group.

Variables	Statistical test	*p*-value	Effect size
Anti-seizure medicine use (yes)	McNemar	0.002*	Matched OR not estimable ($b = 12$, $c = 0$)
Epilepsy (yes)	McNemar	0.002*	Matched OR not estimable ($b = 12$, $c = 0$)
mTOR inhibitor use (yes)	McNemar	0.013*	Matched OR not estimable ($b = 8$, $c = 0$)
Neurodevelopmental disorders (yes)	McNemar	<0.001*	Matched OR not estimable ($b = 15$, $c = 0$)
Frequency of dental visits	Wilcoxon signed-rank	1.000	Rank-biserial $r = 0$
Toothbrushing frequency	Wilcoxon signed-rank	0.402	Rank-biserial $r = -0.29$
dmft/DMFT	Paired *t*-test	0.473	Cohen's $d = 0.17$
Presence of enamel pits (yes)	McNemar	0.027*	Matched OR = 9 ($b = 9$, $c = 1$)
Intraoral fibroma (yes)	McNemar	0.074	Matched OR not estimable ($b = 5$, $c = 0$)
Gingival index (GI)	Wilcoxon signed-rank	0.001*	Rank-biserial $r = 0.85$
Gingival overgrowth index (GOI)	Wilcoxon signed-rank	0.003*	Rank-biserial $r = 0.91$
Wong-Baker Faces Pain Rating Scale	Wilcoxon signed-rank	0.338	Rank-biserial $r = -0.32$

*Matched tests were used according to the type of variable. *$p < 0.05$ indicates statistical significance.*
dmft/DMFT: decayed/filled/missing teeth; OR: odds ratio; mTOR: Mammalian target of rapamycin.

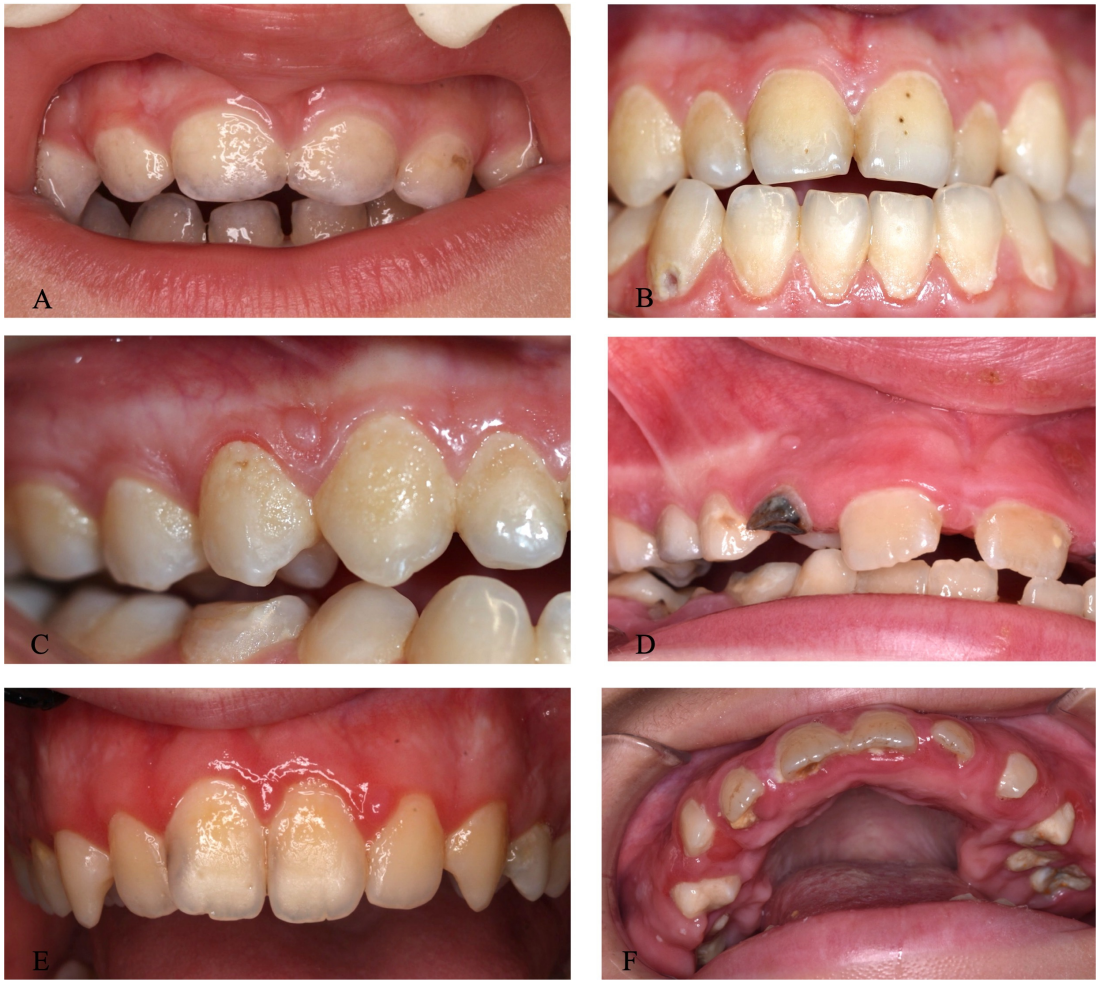

FIGURE 1. Oral lesions in children with Tuberous sclerosis complex. (A) enamel defects on the labial surfaces of the primary maxillary incisors; (B) discolored pits on the labial enamel surface of maxillary central incisors; (C) fibrous proliferation in the papilla between the right maxillary canine and first premolar; (D) fibrous proliferation in the gingiva above the right maxillary primary lateral incisor; (E) generalized gingivitis and enamel pitting on the labial surface of the right maxillary central incisor; (F) severe generalized gingival hyperplasia.

were found in dmft/DMFT scores ($p = 0.473$; Cohen's $d = 0.17$) or pain perception assessed using the Wong-Baker Faces Pain Rating Scale ($p = 0.338$; rank-biserial $r = -0.32$). Oral hygiene habits, including toothbrushing frequency and frequency of dental visits, were also similar between patients with TSC and controls (toothbrushing frequency: $p = 0.402$, rank-biserial $r = -0.29$; dental visit frequency: $p = 1.000$, rank-biserial $r = 0$). Epilepsy, neurodevelopmental disorders, ASM use, and mTOR inhibitor use were significantly more prevalent in the TSC group (all $p < 0.05$).

In the TSC group, the ASMs used were vigabatrin (n = 3), valproate (n = 6), levetiracetam (n = 3), carbamazepine (n = 4), topiramate (n = 3), clobazam (n = 5), lamotrigine (n = 1), and lacosamide (n = 1), administered either as monotherapy or in combination.

Within the TSC group, cumulative duration of ASM exposure was strongly positively correlated with both Gingival Index scores (Spearman's $\rho = 0.735$, $p < 0.001$) and gingival overgrowth scores ($\rho = 0.801$, $p < 0.001$). In contrast, cumulative mTOR inhibitor exposure was not significantly correlated with Gingival Index scores ($\rho = 0.278$, $p = 0.250$) but showed a moderate positive correlation with gingival overgrowth ($\rho = 0.488$, $p = 0.034$) (Table 4).

Scatter plots illustrating the relationships between cumulative ASM and mTOR inhibitor use (years) and gingival overgrowth scores in the TSC group are presented in Fig. 2. Each point represents a single patient, and the solid lines indicate linear trends for visualization purposes only.

4. Discussion

This matched case–control study provides new evidence on oral health outcomes in children with tuberous sclerosis complex (TSC), with particular attention to cumulative pharmacological exposure. By combining matched between-group comparisons with within-group correlation analyses, our findings suggest that gingival pathology in children with TSC may be more closely associated with long-term medication exposure than with oral hygiene habits alone.

In the matched analysis, children with TSC exhibited significantly poorer gingival health than controls, as reflected by higher Gingival Index scores and greater gingival overgrowth. Previous studies have suggested that poorer gingival health in individuals with TSC may be partly explained by reduced attention to routine oral care in the context of intensive medical follow-up and complex systemic needs [12, 13]. In the present study, however, toothbrushing frequency and dental visit patterns were similar in the TSC and control groups. This finding suggests that behavioral or access-related factors alone are unlikely to fully explain the observed differences in gingival status and supports the possible contribution of disease and treatment-related factors.

One of the most notable findings of this study was the strong positive correlation between cumulative ASM exposure and both gingival inflammation and gingival overgrowth within the TSC group. Previous studies have reported an association between antiepileptic therapy and gingival enlargement in pediatric populations [10, 14], and our findings are in line with this literature. In addition, our results extend the current evidence by showing that, in children with TSC, longer cumulative ASM exposure was associated with worse gingival outcomes. Given the chronic nature of antiseizure treatment in many patients with TSC, this finding is clinically relevant and may help explain why gingival pathology was prominent despite oral hygiene habits comparable to those of the control group.

In contrast, cumulative mTOR inhibitor exposure was not significantly correlated with Gingival Index scores but showed a moderate positive correlation with gingival overgrowth. This pattern may suggest that gingival inflammation and gingival enlargement are not entirely overlapping processes and may be influenced differently by specific treatment exposures. While mTOR inhibitors are well known to be associated with oral adverse effects, particularly oral mucosal injury and stomatitis [7], their relationship with gingival enlargement remains less clearly defined. The existing literature suggests that the effects of rapamycin on gingival tissues may be context dependent; therefore, the moderate positive correlation observed in our cohort between mTOR inhibitor exposure and gingival overgrowth should be interpreted with caution and warrants further investigation [15].

Children with TSC also showed a significantly higher frequency of enamel pits than healthy controls, whereas intraoral fibromas were observed only in the TSC group, although the between-group difference did not reach statistical significance. These findings are consistent with the established literature describing enamel pits and intraoral fibromas as characteristic oral findings in TSC [3, 4, 12, 16, 17]. Because controlled studies focusing on pediatric populations remain limited, our results add comparative data supporting the diagnostic importance of careful oral examination in children with suspected or confirmed TSC.

Interestingly, dental caries experience (dmft/DMFT) and pain perception assessed with the Wong-Baker Faces Pain Rating Scale did not differ significantly between groups. A similar pattern has been reported previously, suggesting that gingival

TABLE 4. Associations between cumulative drug exposure (years) and gingival health outcomes in the TSC group.

Exposure	Result	Spearman's ρ	p-value
Anti-seizure medicine use (yr)	Gingival Index	0.735	<0.001*
Anti-seizure medicine use (yr)	Gingival overgrowth	0.801	<0.001*
mTOR inhibitor use duration (yr)	Gingival Index	0.278	0.250
mTOR inhibitor use duration (yr)	Gingival overgrowth	0.488	0.034

*Spearman rank correlation was used. *$p < 0.05$ indicates statistical significance. mTOR: Mammalian target of rapamycin.*

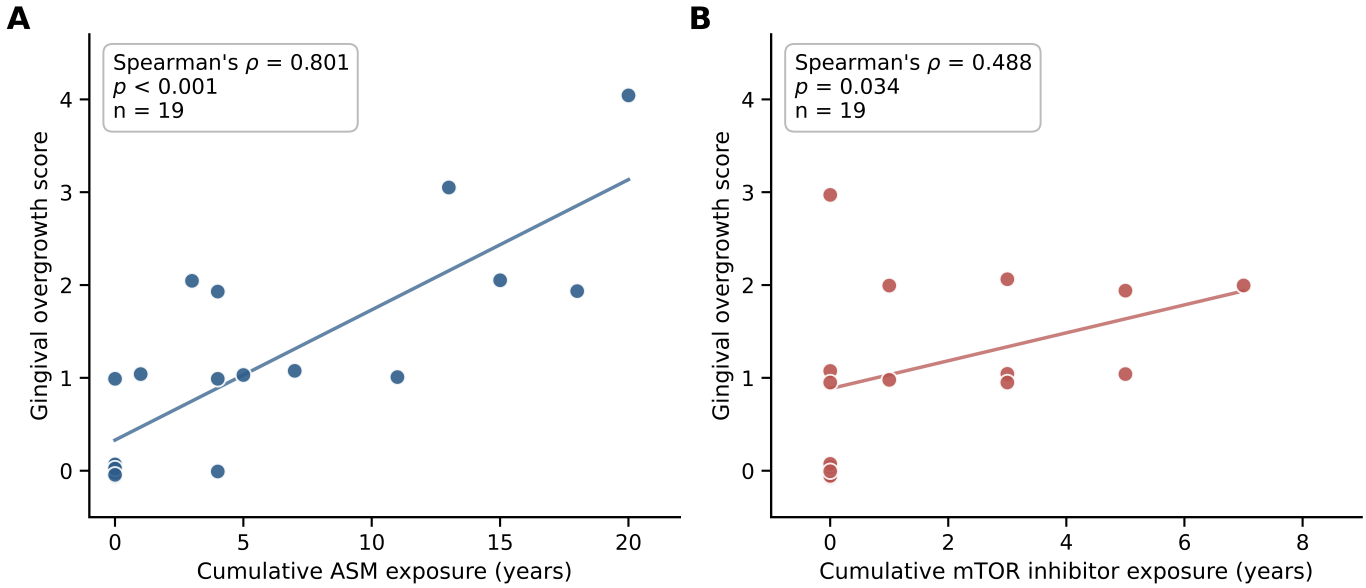

FIGURE 2. Association between cumulative anti-seizure medication (ASM) and mTOR inhibitor exposure and gingival overgrowth in children with tuberous sclerosis complex (n = 19). (A) Scatter plot showing the relationship between cumulative duration of ASM use (years) and gingival overgrowth score (Spearman's $\rho = 0.801$, $p < 0.001$). (B) Scatter plot showing the relationship between cumulative duration of mTOR inhibitor use (years) and gingival overgrowth score (Spearman's $\rho = 0.488$, $p = 0.034$). Each point represents a single patient; small random jitter was applied on the y-axis to reduce overlap of identical ordinal scores. Solid lines indicate linear trends for visualization purposes only. ASM: anti-seizure medication; mTOR: Mammalian target of rapamycin.

pathology may not necessarily parallel overall caries burden or subjective oral discomfort in patients with TSC [12]. From a clinical perspective, this finding highlights the importance of targeted periodontal assessment rather than relying solely on general oral health indicators when evaluating children with TSC. This study has several strengths. The matched design reduced imbalance in age and sex between groups, and the inclusion of a healthy control group allowed more direct interpretation of oral findings in TSC. In addition, oral hygiene habits, dental attendance, and oral pain experience were evaluated alongside clinical findings, thereby addressing parameters that have been infrequently examined in previous studies [3, 5, 12].

Several limitations should also be acknowledged. First, the sample size was necessarily limited, which is understandable in a rare pediatric condition but still restricts generalizability and precluded more complex multivariable modeling. Second, participants with TSC were recruited from a pediatric neurology clinic, which may have resulted in a cohort enriched for neurological involvement, epilepsy, and ASM exposure compared with the broader TSC population. Third, medication exposure was evaluated according to cumulative duration of use rather than dose-adjusted exposure, and this may have obscured differences between specific drug regimens. Finally, because of the cross-sectional design, the findings should be interpreted as associations rather than causal relationships.

Future studies with larger multicenter samples and longitudinal follow-up are needed to clarify the temporal relationship between medication exposure and gingival changes in TSC, to explore the effects of specific ASM and mTOR inhibitor regimens, and to determine whether preventive periodontal strategies can reduce treatment-associated oral morbidity in this population.

Overall, the present findings support the importance of integrating dental and periodontal monitoring into the routine care of children with TSC, particularly in those receiving long-term ASM therapy. Early recognition of gingival changes may facilitate preventive care, timely referral, and closer collaboration between pediatric neurologists and pediatric dentists.

5. Conclusions

In conclusion, children with TSC showed less favorable gingival health than matched healthy controls, and longer cumulative ASM exposure was associated with worse gingival outcomes within the TSC group. These findings support the integration of regular dental and periodontal monitoring into the routine care of children with TSC, particularly for those receiving long-term ASM therapy. Early recognition of gingival inflammation or overgrowth may facilitate timely preventive care and closer clinical follow-up. Because oral health is an important component of overall health and quality of life, it should not be overlooked in children with TSC despite the complexity of their medical care. Close collaboration among pediatric dentists, pediatric neurologists, and parents may help improve the comprehensive management of this patient population. Our findings also provide a basis for future longitudinal studies aimed at clarifying the relationship between treatment exposure and oral health outcomes in children with TSC.

ABBREVIATIONS

TSC, tuberous sclerosis complex; ASM, anti-seizure medicine; DMFT, permanent decayed/filled/missing teeth; dmft, primary decayed/filled/missing teeth; OR, odds ratio; IQR, interquartile range; mTOR, mammalian target of rapamycin.

AVAILABILITY OF DATA AND MATERIALS

The datasets generated and/or analyzed during the current study are not publicly available due to privacy and ethical restrictions involving pediatric clinical data but are available from the corresponding author on reasonable request.

AUTHOR CONTRIBUTIONS

MK, EPY and HMG—designed the research study. BMB and CÖY—performed the research; wrote the manuscript. KG and HMG—provided supervision and advice. MT and BMB—analyzed the data. All authors contributed to editorial changes in the manuscript. All authors read and approved the final manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Ethical approval was obtained from the Istanbul University Faculty of Medicine Ethics Committee (12.09.2024-2858322), and written informed consent forms were signed by the parents of all participating children.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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