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Comparison of rapid maxillary expansion and pre-fabricated myofunctional appliance for the management of mouth breathers with Class II malocclusion

X. ZHANG, J.-M. HE, W.-Y. ZHENG

Department of Stomatology, The Second Affiliated Hospital of Jiaxing University, Jiaxing, Zhejiang Province, P.R. China

Abstract. – **OBJECTIVE:** Pre-fabricated myofunctional appliances and rapid maxillary expansion (RME) has been used for the treatment of mouth-breathers with Class-II malocclusion. This study aimed to compare the treatment effects of hyrax and pre-fabricated myofunctional appliance (T4K) for the management of mouth breathers with Class II Malocclusion in mixed dentition stage.

PATIENTS AND METHODS: Case records of mouth breathers with Class II Division 1 malocclusion patients treated at our institute with T4K or hyrax appliance between June 2015 to May 2019 were retrieved. The Pancherz analysis was used to compare the treatment effects.

RESULTS: Data of 28 patients (14 in each group) were compared. Significant advancement of maxilla was seen in both groups while mandibular length improved only with the T4K appliance. SNA and SNB changes were significantly greater in the T4K group. Molar relationship improved in both groups. Molar correction was obtained by 55.6% skeletal change and 44.4% dental change with RME. In the T4K group the corresponding values were 48.1% and 51.9% respectively.

CONCLUSIONS: Our results suggest that both pre-fabricated myofunctional appliance and RME are suitable for the treatment of mouth breathers with Class II malocclusion in the mixed dentition period. Sagittal correction of maxilla and mandible may be somewhat better with the T4K appliance. Although the dental compensation may be slightly more with the T4K appliance and it may inhibit the skeletal remodeling.

Key Words:
Pancherz, Functional appliance, Mixed dentition, Maxillary expansion.

Abbreviations

RME: rapid maxillary expansion; UARS: upper airway resistance syndrome; OSA: Obstructive Sleep Apnea; Cvs: cervical vertebrae maturation stage.

Introduction

Due to several associated comorbidities, mouth-breathing as a condition has been a concern for health-care professionals worldwide[1,2]. Temporary physiological mouth breathing is seen in individuals during strenuous exercise, anxiety, tension, etc. On the other hand, pathological mouth breathing is usually caused by upper airway obstruction on account of several mechanical factors like tonsillar hyperplasia, turbinate hypertrophy, rhinitis, tumors, infectious or inflammatory diseases[2]. The symptoms include snoring, disturbed sleep, with severe cases characterized by sleep-disordered breathing. The spectrum of sleep-disordered breathing encompasses upper airway resistance syndrome (UARS) and Obstructive Sleep Apnea (OSA)[2]. In 2020 survey, Lyra et al[3] reported that the prevalence of sleep-disordered breathing among children with malocclusion is about 33.3%. Similar studies[4,5] by different researchers amongst varied study populations have estimated the prevalence of sleep-disordered breathing to be 1.2% to 10.9%.

The effects of mouth-breathing on craniofacial development are well-known. The habit is known to cause several functional transformations like changes in tongue position and imbalance of the perioral musculature which in turn affect facial development[6]. Features common to mouth-breathers include constricted maxillary dental arch with a narrow and high-arched palate, proclined upper anteriors, steep mandibular plane angle, receding chin and incompetent lips[6,7]. These facial features not only lead to cosmetic concerns, but also have a significant impact on the patient's psychology and quality of life[7]. Early management by means

Corresponding Author: Weiying Zheng, MD; e-mail: zhengwy8986@163.com

of correction of the habit can be particularly important to restore normal facial and dental development.

Trainer for Kids [T4K®, Myofunctional Research Co (T4K), Australia] is a pre-fabricated myofunctional appliance invented by Dr. Farrell Chris from the University of Sydney, Australia. The device is a removable pre-orthodontic trainer which acts by repositioning the mandible and correcting musculature dysfunction. The components of the device include unique tooth channels, labial bows, a lip bumper, and a tongue tag which help in muscle repositioning and stimulating horizontal growth. It is claimed that malocclusions and habits can be effectively treated by the device in early mixed dentition patients[8]. However, the strength of evidence in support of the device is weak. Rapid Maxillary Expansion (RME) is another procedure which reshapes the soft and hard tissues of the maxillofacial region, improves the airway and ventilation and can be used for management of mouth breathing[9]. The technique causes orthopedic expansion of the maxilla by separating the mid-palatal suture, thereby, correcting the constricted maxillary arch and lowering the palatal vault. As the palate also corresponds to the nasal floor, concomitant changes in the nose like lateralization of the turbinates and increase in nasal volume can result in improvement of nasal breathing[10,11]. While transverse changes are known to occur with RME, there is little research on the sagittal changes caused by RME. In this study, we compared the two appliances, T4K and RME, for the treatment of the mouth breathing in Class II malocclusion patients. We aimed to provide a clinical and theoretical basis to guide appliance selection for early management of the mouth breathing patients.

Patients and Methods

Patients

This study was approved by the Ethics Committee of the Second Hospital of Jiaxing (Approval No. jxey-2017024). Informed written consent was obtained from the guardians of all patients for the treatment. The methods of the study were in compliance with the principles and requirements of the Declaration of Helsinki.

For the purpose of this study, case records of Class II Division 1 malocclusion patients treated at our institute with T4K or hyrax appliance between June 2015 to May 2019 were retrieved. The following patients were included: (1) patients in early mixed dentition period; (2) SNA (≤85°), ANB (≥5°); (3) upper anterior protrusion ≥5mm; (4) cervical vertebrae maturation stage (Cvs) 2 and 3; (5) patients with no history of trauma and previous orthodontic treatment. Patients with high mandibular plane angle; (2) nasal cavity obstructive disease; (3) temporomandibular joint disorders; 4) congenital malformations; 5) major systemic diseases and 6) bruxism were excluded.

Treatment Protocol

All patients prescribed with a T4K appliance were required to wear it at least 14 hours per day (overnight use and at least two hours during the day). Patients were instructed to keep the tongue positioned on the tongue tag, swallow the saliva, keep the lips together and breathe through the nose. A tape was recommended to be used at night to keep the lips together. Patients were instructed to visit the clinic every 3 months for regular check-up. In T4K phase 1, the soft appliance was worn for about six months, as per the specific clinical conditions of the patients. Patients then entered the T4K phase II when the Harker appliance was utilized. The observation period was one year. Throughout the entire treatment process, “tongue-flicking” and “swallowing” training was delivered to the patients, and the training effects were recorded.

Hyrax appliance (German Forestadent Company) was utilized in the RME group. The appliance was anchored by glass ionomer (GC II) cement. Widening of the maxilla was achieved by expanding 0.5mm a day for 2-3 weeks. Upon the completion of the expansion, glass ionomer cement was used to seal the screw holes and the appliance was kept *in-situ* for about 3-6 months to stabilize the dental arch, and at the same time continue the myofunctional training. After removal of the rapid expander, phase II of the treatment consisting of orthodontic correction was initiated. All patients in the study were treated by one clinician.

Lateral Cephalometry

Lateral cephalometric radiographs were taken before and after completion of treatment for all patients by the same clinician in the radiology department of the author’s hospital. The radiographs were calibrated with respective magnifications. Dolphin Imaging v11.8 software was used to perform fixed-point analysis and measurement on the lateral cephalometric radiographs according to the Pancherz analysis method. Cephalometric measurements were performed by two researchers. Two measurements were conducted on each lateral cephalometric radiograph, and the average value was used for the analysis.

The cephalometric landmarks used were: Sella = S, Nasion = N, Pogonion = Pg, Menton (most inferior point of mandibular symphysis) = Me, Gonion = Go, Condylion (the most posterior superior point of the condyle) = Co, Point A (most concave point of anterior maxilla), Point B (Most concave point on mandibular symphysis), incision superius = is, incision inferius=ii, molar superior - tip of the mesial buccal cusp of the maxillary first molar = ms, molar inferior - tip of the mesial buccal cusp of the mandibular first molar = mi (**Supplementary Figure 1**).

Reference planes used were: OL (the line connecting the incisal superius point of the most convex maxillary central incisor and tip of the mesial buccal cusp of the maxillary first molar), OLP (a straight line perpendicular to OL through point S), SN (anterior skull base plane) , MP (mandibular plane, the line tangent to the lower edge of the mandible through the Me point), SN-MP (mandibular plane inclination).

Vertical lines were drawn to OLP through Pg, A, Co, ms, mi, ii and is. These lines were marked as Pg/OLP (sagittal mandibular position), A/OLP (sagittal maxilla position) , Co/OLP (the vertical distance from Co point to OLP), ms/OLP (maxillary first permanent molar position), mi/OLP (mandibular first permanent molar position), ii/OLP (inferior central incisor position) , is/OLP (position of the upper central incisor incisal edge), is/OLP-ii/OLP (overlap of the maxillary central incisors over the mandibular central incisors), ii/OLP-Pg/OLP (the position of incision inferius relative to the mandible), is/ OLP-A/OLP (the position of the incision superius relative to the maxilla), ms/OLP-mi/OLP (molar relationship), mi/OLP-Pg/OLP (the position of the mandibular first permanent molar relative to the mandible), ms/OLP-A/OLP (the position of the maxillary first permanent molar relative to the maxilla), L1-MP (mandibular central incisor angle), U1-SN (maxillary central incisor angle), U1-L1 (angle of maxillary central incisor and mandibular central incisor).

The following formulas were used for assessing changes in molar relationship and incisal overlap:

Molar relationship improvement: = skeletal change + dental change = (sagittal mandibular skeletal position change before and after treatment-sagittal maxillary skeletal position change before and after treatment) + (first permanent mandibular molar position change relative to mandible before and after treatment - first permanent maxillary molar position change relative to maxilla before and after treatment).

Reduction of overlap: = skeletal change + dental change = (sagittal changes in maxilla before and after treatment-sagittal changes in mandible before and after treatment) + (upper central incisor position relative to maxilla - changes of mandibular first permanent molar position relative to the mandible before and after treatment).

We further assessed the dental and skeletal effect on improvement of molar relationship using the following formulas:

$$\text{Dental effect: } = \frac{\textit{Amount of Dental Changes}}{\textit{Amount of Skeletal Changes} + \textit{Amount of Dental Changes}} \times 100\%$$

$$\text{Skeletal effect: } = \frac{\textit{Amount of Skeletal Changes}}{\textit{Amount of Skeletal Changes} + \textit{Amount of Dental Changes}} \times 100\%$$

Statistical Analysis

SPSS 22.0 (IBM Armonk, NY, USA) software was utilized for data processing. Paired *t*-test was used to analyze whether there were differences in skeletal and occlusal changes before and after treatment with the two appliances. Independent *t*-test was used to analyze whether there were differences in changes before and after treatment between the two groups. The difference is considered statistically significant with $p<0.05$.

Results

A total of 28 cases (15 males and 13 females) with full medical records were identified from the database. 14 patients each were treated with T4K appliance or hyrax appliance. The mean age of patients in the T4K group was 9.2 years, while the mean age of patients in the RME group was 10 years. The age of the total sample ranged from 8.5 to 11.5 years.

Skeletal Changes

Table I presents the cephalometric data for the RME and T4K groups before and after treatment. The position of the maxilla moved forward

Table I. Changes of the maxilla and mandible in the sagittal plane before and after treatment and its calculation analysis.

Measurement items	RME group			T4K group		
	T1	T2	*p*	T1	T2	*p*
Jaw bone measurements (mm)						
A/OLP	70.14 ± 2.47	71.67 ± 2.67	0.003*	70.53 ± 2.86	72.93 ± 3.14	0.018*
Pg/OLP	69.58 ± 4.55	71.71 ± 3.03	0.039*	69.61 ± 4.25	73.03 ± 3.98	0.006*
Co/OLP	-5.51 ± 2.49	-6.01 ± 2.85	0.512	-4.03 ± 1.65	-5.03 ± 2.13	0.045*
Go/Me	54.63 ± 4.40	55.63 ± 3.27	0.124	50.87 ± 1.68	54.37 ± 2.23	0.006*
Alveolar measurements (mm)						
is/OLP	79.57 ± 2.84	80.29 ± 2.76	0.174	79.49 ± 3.35	82.57 ± 3.53	0.022*
ii/OLP	71.44 ± 3.10	73.29 ± 2.48	0.02*	72.39 ± 3.90	75.73 ± 3.11	0.024*
ms/OLP	48.47 ± 2.99	49.4 ± 2.38	0.127	48.33 ± 3.53	50.71 ± 3.46	0.021*
mi/OLP	47.88 ± 3.64	50.45 ± 3.12	0.006*	46.47 ± 3.57	50.96 ± 2.66	0.003*
Incisor angle (°)						
U1-SN	110.88 ± 10.52	109.09 ± 10.27	0.157	108.07 ± 5.83	112.42 ± 8.05	0.15
L1-MP	98.38 ± 8.98	98.73 ± 9.67	0.797	105.52 ± 3.77	105.27 ± 3.90	0.932
U1-L1	115.10 ± 13.63	116.65 ± 12.07	0.485	113.48 ± 7.19	110.85 ± 10.65	0.486
Jaw rotation (°)						
SN/MP	35.64 ± 8.19	36.53 ± 8.16	0.86	32.94 ± 3.41	31.46 ± 4.04	0.126
The position and relationship of the maxilla and mandible (°)						
SNA	81.12 ± 2.68	81.17 ± 2.92	0.906	82.99 ± 2.29	84.38 ± 3.08	0.022*
SNB	74.47 ± 3.28	74.86 ± 2.86	0.39	75.48 ± 2.07	77.96 ± 2.58	0.003*
ANB	6.65 ± 1.98	6.31 ± 2.11	0.337	7.51 ± 1.18	6.44 ± 1.71	0.055
Measurement items (mm)						
Overjet	8.13 ± 2.42	7.21 ± 2.36	0.186	6.01 ± 4.42	6.83 ± 2.53	0.594
Molar relation	0.59 ± 1.66	-0.85 ± 1.84	0.018*	1.89 ± 1.91	-0.21 ± 2.22	0.01*
is/OLP-A/OLP	9.44 ± 2.42	8.82 ± 2.16	0.093	7.86 ± 3.10	9.63 ± 2.18	0.163
ms/OLP-A/OLP	-21.68 ± 1.68	-22.07 ± 1.76	0.515	-22.20 ± 0.80	-22.20 ± 0.57	1
ii/OLP-Pg/OLP	1.87 ± 2.81	1.58 ± 2.47	0.632	2.76 ± 3.53	2.70 ± 2.76	0.94
mi/OLP-Pg/OLP	-21.71 ± 2.17	-21.26 ± 2.47	0.32	-23.17 ± 2.98	-22.09 ± 2.71	0.058

T1: Before treatment T2: After treatment.*Statistical significant difference.

in the sagittal direction for both groups with a significant increase in A/OLP. The mandibular length (Pg/OLP, Co/OLP, Go/Me) were significantly increased in the T4K group. On the other hand, only Pg/OLP increased significantly in the RME group. There was statistically significant difference in the SNA and SNB angle in the T4K group but not in the RME group.

Occlusal Changes

Significant anterior movement of the lower central incisor position relative to OLP (ii/OLP) and improvement in the molar relationships were seen in both groups. There was statistically significant advancement of the maxillary first permanent molar (ms/OLP) in the T4K group but not in the RME group. However, significant advancement of the mandibular first permanent molar (mi/OLP) was seen in both groups. In the RME group, the percentage of molar relationship improvement from dental effect was 44.4% (0.64 mm) and from skeletal effect was 55.6% (0.8 mm). In the T4K group, the corresponding figures with dental effect were 51.9% (1.09 mm) while the skeletal improvements accounted for 48.1% (1.01 mm).

Inter-Group Comparison

Comparison of difference in changes between the two groups is presented in Table II. Minimal changes in SNA were noted in the RME group while the SNA in the T4K group increased by 1.39±1.11°. The SNA changes (ΔSNA) are statistically significant between the two groups. The changes in point A (A/OLP) for the RME group were smaller as compared to T4K group but not statistically significant. After treatment, the SNB increased by 0.39±1.5° the RME group, and by 2.48±1.27° in the T4K group. SNB changes (ΔSNB) were statistically different between the two groups. Changes in SN/MP were lower in the RME group as compared to the T4K group

Table II. Comparison of changes before and after treatment in the rapid expansion group and MRC group ($\bar{x} \pm s$, n = 28).

Measurement items	Correction change in RME group (ΔT)	Correction change in T4K group (ΔT)	*p*
Jaw bone measurement (mm)			
A/OLP	1.53 ± 1.42	2.40 ± 1.81	0.196
Pg/OLP	2.33 ± 3.19	3.41 ± 2.04	0.239
Co/OLP	-0.5 ± 2.57	-1.00 ± 0.97	0.535
Go/Me	1.00 ± 2.09	3.50 ± 2.07	0.006*
Alveolar measurement (mm)			
is/OLP	0.72 ± 1.71	3.09 ± 2.46	0.01*
ii/OLP	1.85 ± 2.38	3.34 ± 2.72	0.155
ms/OLP	0.93 ± 1.97	2.39 ± 1.89	0.071
mi/OLP	2.57 ± 2.66	4.49 ± 2.35	0.067
Incisor angle (°)			
U1-SN	-1.80 ± 4.12	4.35 ± 6.45	0.009
L1-MP	-0.36 ± 4.70	-0.25 ± 6.85	0.8
U1-L1	1.55 ± 7.46	-2.63 ± 8.68	0.21
Jaw rotation (°)			
SN/MP	-0.11 ± 2.20	-1.47 ± 2.03	0.121
The position and relationship of the maxilla and mandible (°)			
SNA	0.05 ± 1.39	1.39 ± 1.11	0.013*
SNB	0.39 ± 1.50	2.48 ± 1.27	0.001*
ANB	-0.34 ± 1.17	-1.06 ± 1.10	0.123
Measurement items (mm)			
Overjet	-0.92 ± 2.28	0.81 ± 3.54	0.161
Molar relation	-1.44 ± 1.82	-2.10 ± 1.39	0.314
is/OLP-A/OLP	-0.62 ± 1.17	1.77 ± 2.73	0.01*
ms/OLP-A/OLP	-0.38 ± 1.99	0.00 ± 0.30	0.519
ii/OLP-Pg/OLP	-0.29 ± 2.06	-0.06 ± 1.78	0.762
mi/OLP-Pg/OLP	0.45 ± 1.52	1.09 ± 1.14	0.248

ΔT: Change in measurement before and after treatment (T2-T1). *Statistical significant difference.

but the difference did not reach statistical significance. Go-Me was significantly increased in the T4K group as compared to RME group. The maxillary central incisor position in the RME group increased by 0.72 mm relative to the OLP (is/OLP), and that of the T4K group increased by 3.09 mm relative to the OLP (is/OLP) ($p<0.05$).

Discussion

It is widely recognized that the class II malocclusion is a result of the combined effect of genetic and environmental factors[12,13]. Kawala et al[14] in a study of serology and morphology of 164 twin-pairs have found that the influence of environmental factors is crucial in the occurrence of malocclusions and early interventions are needed to intercept and disrupt the influence of adverse environmental factors. Early management is usually in the form of myofunctional appliances that can significantly reduce the time and correction required with phase 2 orthodontic treatment[15]. While several treatment modalities and appliances exist to manage mouth breathers with Class II malocclusion, we compared RME by means of hyrax and the T4K appliance to better elucidate the difference in the two modalities.

In recent years several comparative studies[16,17] on Class II malocclusion have used the Pancherz analysis for evaluation of treatment differences. The analysis is known to comprehensively demonstrate the potential problematic areas of Class II malocclusion. As the occlusal plane does not change much before and after treatment, the reference system established in the analysis is relatively stable and the overlap before and after treatment is better. In addition, this analysis method relies mainly on linear data measurements. It has been shown that, linear changes are more effective than angular measurements to assess dental and skeletal changes[18,19]. In this context, the Pancherz analysis was used to assess the treatment changes in our study.

The baseline maxilla position in all the cases of this study was normal, with the SNA values within the normal range of distribution. Patients with mouth breathing often have narrow maxilla and mandibular retrusion. Narrow maxilla restricts the normal growth and development of the mandible, limits its forward and lateral growth, and directly affects the shape, posture and size of the mandible. This restriction can be improved by maxillary expansion that will help mandibular growth[20]. In our study, the mean increase of Pg/OLP was more than that of A/OLP, indicating greater growth of the mandible in the sagittal direction. Studies have suggested that after maxillary expansion there is an increase in volumes of the nasal floor, the nasopharynx, and the velopharyngeal which improve the nasal ventilatory function and in turn also promote mandibular development[10,11]. Reyes et al[21] have reported that the peak of maxillary sagittal development occurs in the Cvs-2/Cvs-3 stage, and the mandible has significant growth in the sagittal direction during the entire growth and development period (Cvs1-Cvs6). As a result, active intervention to patients with sagittal growth imbalance during the peak of growth and development can promote the improvement of skeletal and facial shape and reduce the difficulty of phase 2 orthodontics correction.

In the RME group, the mean maxillary advancement was 1.53 mm which was statistically significant as compared to baseline values. Similar results have been obtained by Haas et al[9] and Davis et al[22]. It is postulated that the advancement of the maxillary with RME is related to the opening of the palatal sutures. Others suggest that the opening of both sphenoidal and ethmoidal bones may contribute to maxillary advancement[23]. Baratieri et al[24] have reported that after RME and correction, the maxilla is displaced in a forward and downward direction. However, Weissheimer et al[25] believe that the downward displacement of the maxilla may be due to the delayed measurement performed three months after the end of the palatal expansion and the vertical change is the outcome of growth.

In this study, we found a small increase in SN-MP in some patients, although the results were not statistically significant. The potential reason could be that in some patients undergoing RME there is downward rotation of the maxilla with buccal molar tipping followed by sagging of the palate tip. This may cause slight downward rotation of the mandible. Through a computed tomographic study, Baratieri et al[24] have also observed downward displacement of the maxillary bones and the buccal inclination of the molars, followed by changes in the mandible after maxillary expansion in class II malocclusion patients. While the sagittal change is said to be temporary with gradual improvement in a year, there are uncertainties with regard to such improvements[24,25].

In this study, the mean treatment time of the appliance in the T4K group was 7.5 months. For the RME group, due to influence of deciduous teeth replacement during the mixed dentition period, the mean treatment time was less at about 6.5 months. Due to the difference in treatment times between the two groups, there may be a certain bias when comparing the T4K group and the RME group. It was observed that in the T4K group, maxillary and mandible growth in the sagittal direction were better than that of the RME group. This is in contrast to the results of Myrlund et al[26] who have reported that the preformed myofunctional appliance mainly corrects the incisor overbite and canine relationship in Class II patients with limited effect on mandibular shape and ANB angle. It is also important to note that compared to the hyrax appliance, the TK4 appliance is highly dependent on patient compliance. Treatment with the T4K appliance was terminated in a total of 9 patients during the study period owing to the children's non-cooperation. Therefore, from the perspective of patient compliance, the RME group has more advantage than the T4K group. Further, studies have also shown that after having received the prolonged pre-formed myofunctional appliances treatment, most patients still need phase 2 fixed orthodontics once the mixed dentition phase is over[27].

The improvement of the molar relationship by RME is still controversial. Lione et al[28] analyzed the molar relationships of patients in mixed dentition stage with class II malocclusion undergoing rapid maxillary expansion and found no improvement of sagittal molar relationship. On the other hand, McNamara et al[29] have reported significant improvement in the molar relationship by 1.5 mm after RME. In this study, the molar relationship of the RME group was improved by 1.41mm, consistent with the results of McNamara et al[29]. According to Pancherz analysis, the dental effect accounted for 44.4% and the skeletal effect accounted for 55.6% of the improvements. In the T4K group, the improvement of the molar relationship from dental effect was more than that of skeletal effect. Therefore, it is evident that RME can better achieve the purpose of correction through skeletal effects rather than through dental compensation.

Our study has some limitations. First, dental compensatory changes including the changes in the inclination angle of the upper and lower anterior teeth and position of the lips are not assessed in the Pancherz analysis. Second, this is a retrospective study with its inherent bias to generate strong conclusions. Third, the sample size of our study was limited and hence the results may not be generalized without further larger comparative studies.

However, our study does present some novel findings. The high prevalence of mouth breathing habit has received increased attention from patients, as well as clinicians in recent years with widespread use of prefabricated myofunctional appliances. The use of such appliances without scientific evidence on its efficacy can hamper the growth and development of such patients. In this context, our study presents a comparative analysis of two appliances exploring the treatment efficacy and therefore provides a guide to practitioners.

Conclusions

In summary, our results suggest that both pre-fabricated myofunctional appliance and RME are suitable for the treatment of mouth breathers with Class II malocclusion in the mixed dentition period. Sagittal correction of maxilla and mandible may be somewhat better with the T4K appliance. However, the T4K appliance may lead to greater dental compensation with inhibition of the skeletal remodeling, therefore extra caution may be needed with this appliance. Further studies with larger sample size are needed to corroborate the current results.

Conflict of Interest

The Authors declare that they have no conflict of interests.

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Availability of Data and Materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Ethical Approval

This study was approved by the Ethics Committee of the Second Hospital of Jiaxing (Approval no. jxey-2017024).

Patients Consent

Informed written consent was obtained from the guardians of all patients for the treatment. The methods of the study were in compliance with the principles and requirements of the Declaration of Helsinki.

Authors' Contribution

XZ conceived and designed the study. JH and WZ collected the data and performed the analysis. XZ was involved in the writing of the manuscript. WZ edited the manuscript. All authors have read and approved the final manuscript.

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