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Changes in Oral Health Related Quality of Life of Adolescents with Class III Malocclusion Treated using Facemask or Active Skeletonized Sutural Distractor Appliance: A Randomised Clinical Trial

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ABSTRACT

Introduction: The skeletal and/or dental discrepancies associated with malocclusion may limit a person's physical, social, and psychological functioning, with a considerable impact on social acceptance and interactions, and overall well-being.

Aim: This randomized clinical trial assessed changes in oral health-related quality of life (OHRQOL) of adolescent with Class III malocclusion treated with the conventional facemask (FM) and the Active Skeletonized Sutural Distractor (ASSD) appliance.

Methods: A total of 68 late adolescents with Class III malocclusion were randomized into two treatment groups: the FM group (34 patients) and the ASSD group (34 patients). The OHRQOL of the patients was assessed using the Malay version of 14-item Oral Health Impact Profile (S-OHIP (M)). In each group, the OHRQOL was assessed twice, before treatment (T1) and 1 month after the respective active treatment phase (T2).

Results: Of 68 adolescents, 8 from the ASSD group and 6 from the FM group dropped out, leaving a total of 54 participants, 26 in the ASSD group and 28 in the FM group. No significant difference was found in total mean S-OHIP (M) score between T1 and T2 in both the FM group and the ASSD group. Similarly, no significant difference was found in total mean S-OHIP (M) score between the FM group and ASSD group after treatment.

Conclusion: No changes in OHRQOL were observed following Class III malocclusion treatment using FM and ASSD. In addition, the ASSD appliance did not seem to compromise the OHRQOL compared to the conventional FM.

Key words: *Class III malocclusion, Quality of life, Growing patient*

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INTRODUCTION

Malocclusion is a prevalent public health problem worldwide [1]. The skeletal and/or dental discrepancies associated with malocclusion may limit a person's physical, social, and psychological functioning, with a considerable impact on social acceptance and interactions, and overall well-being [2,3]. The more severe the malocclusion, the higher the impact on the oral health related quality of life (OHRQOL) [4]. Individuals with more severe malocclusion, greater aesthetic impairment, and worse OHRQOL were more likely to seek orthodontic treatment than their respective counterparts [5].

Class III malocclusion represents a growth-related dentofacial deformity as a result of a retrognathic maxilla, prognathic mandible, or combination of both along with vertical and transverse malformations [6]. Associated with a concave profile and vertical functional pattern, Class III malocclusion is considered to be one of the most challenging orthodontic problems to treat [7]. Management of Class III malocclusion is governed by two factors: the age of the patient and the severity of the cases. Non-growing patients with severe Class III malocclusion often require a combination of surgical treatment and orthodontic camouflage treatment [8]. In patients who are still growing, the use of orthopaedic treatment such as functional appliance and facemask (FM) that aim to improve or correct the skeletal discrepancy by modifying the growth of the maxilla can reduce the need for surgical treatment prior to orthodontic treatment [9].

There is a moderate quality evidence to indicate that timely treatment with FM results in short-term improvement of both skeletal and dental discrepancies in Class III malocclusion [10,11]. However, due to its unfavourable size and appearance, patients' adherence to the prescribed wear time which may range from 14 hours per day to full-time wear, may be compromised [12]. To overcome this limitation, an intraoral distractor device known as the Active Skeletonized Sutural Distractor (ASSD) appliance was introduced which can also result in faster protraction of the maxilla [13].

Utilizing the concept of suture distraction osteogenesis, the active component of the ASSD uses a mini expansion screw to expand the palate according to the modified alternate rapid maxillary expansion and contraction (Alt-RAMEC) protocol and intraoral Class III elastics to apply a continuous heavy distraction force 500gm/side to the maxilla while taking hybrid anchorage from both teeth and bone [14]. In general, the ASSD combines sutural distraction, skeletal rigid anchorage devices, contraction, and alternate rapid maxillary expansion.

Considering that social and psychological effects are often the key motives for seeking orthodontic treatment [5], assessment of OHRQOL has become an important measure of orthodontic treatment outcome. However, there is only low to moderate quality of evidence to support the benefits of orthodontic treatment on OHRQOL [15,16]. Evidence on OHRQOL improvement following orthognathic surgery for Class III correction was also inconclusive [17,18]. This study assessed changes in OHRQOL of adolescents with Class III malocclusion treated with FM and ASSD.

METHODS

Study design and study population

This was a parallel, randomized control trial conducted according to the guidelines of the Declaration of Helsinki with adherence to the consolidated standards of reporting trials (CONSORT) statement. The source population was middle adolescents with Angle Class III malocclusion or skeletal Class III malocclusion with maxillary retrognathic with or without mandibular protrusion, selected from secondary schools in XXX. Adolescents with other types of Class III malocclusion, have other craniofacial anomalies, or have any contraindications to placement of mini screws such as history of bisphosphonate therapy, hypersensitivity, titanium allergies, metabolic bone disorders, bone pathologies, poor bone healing, cardiovascular disease, psychosomatic disease, undergoing radiation therapy, unsuitable for surgical procedures, decreased bone quality/quantity or localized active infection were excluded.

The sample size was calculated using the PS Power and Sample Size Calculation Software for comparing means from an equal ratio of control and experimental subjects at a power of 80% and significance level of 0.05. The standard deviation of the mean OHRQOL score among patients with Class III malocclusion was estimated at 9.91 [19]. A detectable difference of 7.5 was set, giving a sample size of 28 subjects per group. Anticipation of 20% drop out rate was taken into consideration, and a sample size of 34 subjects per group was decided for this study. The study protocol was reviewed and approved by the Universiti YY Human Research and Ethics Committee (UYY/JEPeM/15120548).

Block randomization (www.randomization.com) was used to assign 68 eligible adolescents into two groups: the FM group (n=34), and the ASSD group (n=34). Blinding of either patient or clinician was not possible. However, we did not anticipate any bias since assessment of OHRQOL was done using anonymous self-administered questionnaire.

Research tools and data collection

Detailed explanation about the purpose of the study and data collection procedures was given to the parents or guardians of the adolescents who met the inclusion and exclusion criteria. Written informed consent were obtained from the parents or guardians who agreed to enter their child in this study, and those who agreed to participate were given appointments to come to the Orthodontic Specialist Clinic, Hospital Universiti YY for further investigations and respective treatment. All clinical procedures were performed by the first author.

ASSD appliance

The ASSD appliance comprise of the following components: 1) Active component using an expansion screw (OrthoCare, UK), 2) Skeletal component using a mini-screw system (Absoanchor, Korea), 3) Sutural distractor component using intra-oral elastics (3M, USA), and 4) Intraoral upper and lower metal framework (OrthoCare, UK) (Figure 1).

First, bands were fitted on all first permanent molars before alginate impressions were taken for the fabrication of study models and for constructing the ASSD. On the upper study model, two palatal arms made

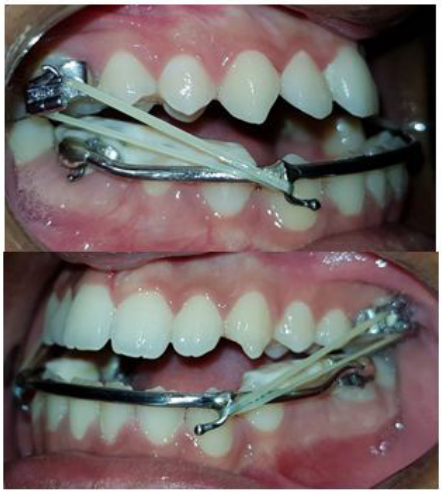

Figure 1: Application of Class III intraoral elastics to the buccal hooks of the upper and lower appliance of ASSD.

from a 2mm stainless steel wire were soldered to the expansion mini screw, as well as two 1.2mm stainless steel wire teardrop loops. The teardrop loops are used for insertion of two anterior mini implants at the level of first premolar. On the lower study model, a buccal arch made of 2 mm stainless steel wire was soldered to the lower molar bands on both sides. Two buccal stainless-steel hooks are soldered to the buccal arch at the level of the lower canines bilaterally for the attachment of the Class III intraoral elastics.

Insertion of the ASSD into the patient's mouth was done by cementing the appliance to the teeth using glass ionomer cement (3M, USA). Following cementation, the mini implant was inserted at the distal end of the two teardrop loops and passively fit over it. The expansion screw was activated to achieve 1mm expansion. The mini implant was inserted according to the manufacturer instructions using the Cope placement protocol. The two mini implants were inserted about 3mm away from the mid-palatal suture. In the anterior palate bilaterally (1.8mm width and 10mm length) at the level of the second premolars and about 8mm posterior to the incisive foramen, at a position that coincides with the plane of maximum resistance of the maxilla and near to the maxillary centre of resistance.

Twenty-four hours after insertion of the ASSD, the patients were instructed to perform the alternate rapid maxillary expansion and contraction according to a schedule given, starting from 4 turns per day of opening and closing the expansion screw based on the specific schedule which correspond to 1mm of activation, until 28 turns per month which correspond to 7mm until the end of the active treatment phase. The opening and closing of the expansion screw (4 turns opening and 4 turns closing) was done until the patient achieve 2mm positive overjet for maximum 6 months duration.

Two weeks after starting the treatment, the patients were instructed to wear intra-oral elastics that were attached to the upper and lower part of the appliance (3M, USA) for exerting protraction forces of about 500gm on each side. The patients were examined monthly to monitor the correction of the Class III malocclusion for 6 months. After patient's malocclusion was corrected (achieve 2mm positive overjet), the patients were asked to continue wearing the Class III elastic at night only for 3 months of retention period. Fixed appliances were fitted after 3 months retention and oral hygiene of the patients was closely monitored throughout the treatment.

Facemask

First, upper molars bands were fitted before an alginate impression of the upper jaw was taken and poured into stone for fabrication of the working model. An upper appliance consisting of mid-palatal mini-expansion screw with two palatal arms extended to the buccal hooks at the area of upper canines was fabricated (Figure 2). The appliance was cemented in the mouth using glass ionomer cement (3M, USA), and the expansion screw was opened by 1mm by the clinician. After 24 hours, the patients were asked to perform rapid maxillary expansion (RME) of 4 turns per day for opening the expansion screw which correspond to 1mm of activation per day for 6 days aiming to luxate the maxilla, regardless of whether they exhibit posterior cross-bite. The patients were asked to wear the FM and elastics exerting about 500gm force per side for 14 hours daily at day 7 until 6 months of the duration.

The patients were examined monthly to monitor the correction of the Class III malocclusion for maximum 6 months. The activation was stopped when patient achieved 2mm positive overjet. Once the malocclusion is corrected, the patients were asked to continue wearing the Class III elastic at night only for 6 months. After 6 months of retention period, fixed appliances were fitted. Oral hygiene of the patients was closely monitored throughout the treatment.

Oral Health Impact Profile (OHIP) questionnaire

The short Malay version of the Oral Health Impact Profile (OHIP) questionnaire, known as the S-OHIP(M), was used to measure individual perceptions of oral impacts on life experiences [20]. Seven domains of impact were assessed: functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability, and handicap. The S-OHIP(M) has 14 items with 2 items for each of the seven domains.

A five-point Likert scale with ordinal codes that range from '0' for 'never', '1' for 'hardly ever', '2' for 'occasionally', '3' for 'fairly often', and '4' for 'very often' was used to

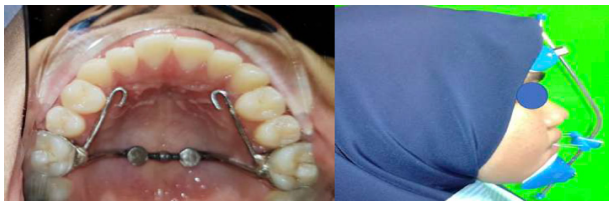

Figure 2: Intra-oral appliance & Facemask with elastic traction to the hooks at canine area.

measure the frequency of impact experienced. The severity of impact is the sum of all ordinal response codes. The severity of impact may range from 0 to 56 and the mean severity score is the mean S-OHIP(M) score. In addition, the mean score for each domain that may range from 0 to 8 was determined. Higher scores indicate a poorer OHRQOL. The S-OHIP(M) was self-administered, and the participants in both ASSD and FM groups completed the questionnaire twice, before the start of treatment (T1) and at the end of active treatment phase (T2) when patient achieved positive overjet 2mm.

Statistical analysis

The IBM SPSS statistics version 20.0 (IBM Corp., Armonk, NY) was used for data entry and analysis. Descriptive statistics: mean and standard deviation (SD) for continuous variables, and frequency and percentage (%) for categorical variables were determined. Paired t test

Table 1: Demographic characteristic.

Variable	Frequency (%)	
	FM group (n=28)	ASSD group (n=26)
Age (years)	15 (1.0)*	15 (1.4)*
Sex		
Male	4 (14.3)	11 (42.3)
Female	24 (85.7)	15 (57.7)
Ethnic group		
Malay	3 (10.7)	11 (42.3)
Chinese	25 (89.3)	15 (57.7)
Main presentation		
Maxillary retrusion	9 (32.1)	7 (25.0)
Mandibular protrusion	13 (46.5)	10 (35.7)
Both	6 (21.4)	11 (42.3)
Family history of class III malocclusion		
Yes	18 (64.3)	10 (38.5)
No	10 (35.7)	16 (61.5)
FM=Facemask		
ASSD=Active Skeletonized Sutural Distractor		
*Mean (standard deviation)		

Table 2: Comparison of pre-treatment (T1) and post-treatment (T2) mean S-OHIP(M) severity score in the FM group (n=28).

S-OHIP(M) domains and items	Mean (SD)		Mean difference (95% CI)	t-statistics (df)	P value
	T1	T2			
Functional limitation					
Difficulty chewing any foods	1.0 (1.12)	1.1 (1.05)	0.1 (-0.4, 0.5)	0.27 (27)	0.394
Problems caused bad breath	0.8 (0.91)	0.5 (0.91)	-0.3 (-0.7, 0.2)	-0.87 (27)	0.456
Physical Pain					
Discomfort eating any food	1.3 (1.42)	1.4 (1.17)	0.1 (-0.5, 0.6)	0.76 (27)	0.783
Ulcers in mouth	1.4 (1.16)	1.2 (1.12)	-0.2 (-0.6, 0.2)	-0.28 (27)	0.214
Psychological Discomfort					
Discomfort due to food getting stuck	2.2 (1.10)	2.0 (1.11)	-0.2 (-0.7, 0.3)	-3.32 (27)	0.102
Felt shy	2.0 (1.59)	1.4 (1.22)	-0.6 (-0.7, 0.6)	-1.69 (27)	0.774
Physical disability					
Avoided eating certain foods	0.6 (0.99)	1.3 (1.12)	0.7 (-0.3, 1.0)	0.29 (27)	0.485
Avoided smiling	1.7 (1.39)	1.3 (1.18)	-0.4 (-0.9, 0.8)	-0.71 (27)	0.537
Psychological Disability					
Sleep been disturbed	0.8 (1.30)	0.7 (0.95)	-0.1 (-0.6, 0.4)	-0.63 (27)	0.573
Concentration been disturbed	1.0 (1.12)	0.8 (1.06)	-0.2 (-0.7, 0.3)	-0.57 (27)	0.136
Social disability					
Avoided going out	0.4 (0.68)	0.5 (0.84)	0.1 (-0.2, 0.3)	1.54 (27)	0.177
Problems in carrying out daily activities	0.4 (0.74)	0.3 (0.56)	-0.1 (-0.3, 0.2)	-1.39 (27)	0.342
Handicap					
Had to spend a lot of money	0.1 (0.45)	0.4 (0.68)	0.3 (-0.1, 0.5)	0.97 (27)	0.394
Felt less confident	1.4 (1.42)	1.3 (1.21)	-0.1 (-1.0, 0.2)	-0.27 (27)	0.456
Total S-OHIP(M)	15.6 (8.86)	14.4 (8.66)	-1.2 (-4.0, 1.4)	-0.87 (27)	0.783
FM=Facemask					
ASSD=Active Skeletonized Sutural Distractor					
SD=Standard deviation					
CI=Confidence Interval					
df=Degree of Freedom					

was used to compare the mean difference in S-OHIP(M) score between T1 and T2 in each group. Additionally, independent t test was used to compare the differences in mean S-OHIP(M) score between the groups at T2. The level of significant was determined at P<0.05.

RESULTS

Of 68 participants, 8 adolescents from the ASSD group and 6 adolescents from the FM group dropped out from the study. The demographic characteristics of the remaining 54 adolescents who completed their respective treatment are shown in Table 1. Most adolescents in both groups were female and belonged to the Chinese ethic group. Mandibular jaw protrusion was the main complaint to seek treatment for both groups.

Table 2 shows the difference in mean S-OHIP(M) severity scores between T1 and T2 among adolescents in the FM group. No statistically significant difference was found in total mean S-OHIP(M) severity score, as well as in individual item scores between T1 and T2.

The difference in mean S-OHIP(M) severity scores between T1 and T2 among adolescents in the ASSD group are shown in Table 3. No statistically significant difference was found in total mean S-OHIP(M) severity score. However, a significantly higher mean S-OHIP(M) severity score was detected after treatment with ASSD appliance in item "avoided eating certain foods" under the physical disability and item "problems in carrying out daily activities" under the social disability domain. No statistically significant difference in mean S-OHIP(M) severity score was found in other items.

Table 4 shows the difference in mean S-OHIP(M) severity scores between FM and ASSD groups after the respective treatment. No statistically significant difference was found in total mean S-OHIP(M) severity score, as well as in individual item scores between the FM group and ASSD group after treatment.

DISCUSSION

The main aim of an orthodontic treatment is to correct skeletal and/or dental discrepancies although it is not the physical impairment that often prompt patients to seek treatment but the psychological and social impact of the malocclusion. Hence, in addition to improvements in clinical parameters that are of concern mainly to clinicians, assessment of changes in OHRQOL has become another important treatment outcome indicator to evaluate patients' expectations and satisfaction with treatment. In managing growing adolescent with class III malocclusion, use of an orthopaedic appliance may be indicated to correct skeletal discrepancies in addition to correction of dental discrepancies using orthodontic appliances. This parallel, randomised control trial assessed the changes in OHRQOL of growing adolescents

Table 3: Comparison of pre-treatment (T1) and post-treatment (T2) mean S-OHIP(M) severity score in the ASSD group (n=26).

S-OHIP(M) domains and items	Mean (SD)		Mean difference (95% CI)	t-statistics (df)	P value
	T1	T2			
Functional limitation					
Difficulty chewing any foods	1.0 (1.08)	1.4 (1.06)	0.4 (-0.3, 0.9)	1.03 (25)	0.311
Problems caused bad breath	0.9 (0.86)	1.1 (0.86)	0.2 (-0.3, 0.7)	0.87 (25)	0.395
Physical Pain					
Discomfort eating any food	1.1 (0.90)	1.4 (0.85)	0.3 (-0.2, 0.6)	0.96 (25)	0.346
Ulcers in mouth	1.1 (1.14)	1.0 (1.04)	-0.1 (-0.6, 0.3)	-0.72 (25)	0.476
Psychological Discomfort					
Discomfort due to food getting stuck	1.5 (1.07)	1.6 (1.14)	0.1 (-0.4, 07)	0.55 (25)	0.589
Felt shy	1.4 (1.33)	1.0 (1.23)	-0.4 (-0.7, 0.6)	-0.12 (25)	0.456
Physical disability					
Avoided eating certain foods	0.5 (0.81)	1.0 (1.11)	0.5 (0.1, 0.9)	2.69 (25)	0.013*
Avoided smiling	1.3 (1.21)	1.0 (1.06)	-0.3 (-0.8, 0.2)	-1.40 (25)	0.175
Psychological Disability					
Sleep been disturbed	0.5 (1.07)	0.7 (0.87)	0.2 (-0.2, 0.6)	1.00 (25)	0.327
Concentration been disturbed	0.8 (0.94)	0.7 (0.83)	-0.1 (-0.5, 0.4)	-0.37 (25)	0.713
Social disability					
Avoided going out	0.4 (0.75)	0.3 (0.55)	-0.1 (-0.3, 0.1)	-0.81 (25)	0.425
Problems in carrying out daily activities	0.1 (3.3)	0.5 (0.76)	0.4 (0.1, 0.6)	2.81 (25)	0.010*
Handicap					
Had to spend a lot of money	0.2 (0.59)	0.3 (0.55)	0.1 (-0.3, 0.4)	0.49 (25)	0.627
Felt less confident	1.1 (1.39)	1.0 (1.15)	-0.1 (-1.0, 0.1)	-2.59 (25)	0.578
Total S-OHIP(M)	13.0 (7.29)	12.2 (7.14)	-0.8 (-3.7, 2.2)	-0.54 (25)	0.597

FM=Facemask

ASSD=Active Skeletonized Sutural Distractor

SD=Standard deviation

CI=confidence interval

df=degree of freedom

*P<0.005

Table 4: Comparison in mean S-OHIP (M) severity score between FM and ASSD groups post-treatment (T2) (n=54).

S-OHIP(M) domains and items	Mean (SD)		Mean difference (95% CI)	t-statistics (df)	P value
	FM	ASSD			
Functional limitation					
Difficulty chewing any foods	1.1 (1.05)	1.4 (1.06)	-0.3 (-1.0, 0.5)	-0.63 (52)	0.529
Problems caused bad breath	0.5 (0.91)	1.1 (0.86)	-0.6 (-1.1, 0.2)	-1.47 (52)	0.147
Physical Pain					
Discomfort eating any food	1.3 (1.17)	1.4 (0.85)	-0.1 (-0.8, 0.6)	-0.36 (52)	0.718
Ulcers in mouth	1.2 (1.12)	1.0 (1.04)	0.2 (-0.6, 0.6)	0.08 (52)	0.934
Psychological Discomfort					
Discomfort due to food getting stuck	2.0 (1.11)	1.6 (1.14)	0.4 (-1.1, 0.6)	0.91 (52)	0.367
Felt shy	1.4 (1.22)	1.0 (1.23)	0.4 (-0.8, 0.6)	0.29 (52)	0.775
Physical disability					
Avoided eating certain foods	1.3 (1.12)	1.0 (1.11)	0.3 (-0.4, 0.7)	0.53 (52)	0.598
Avoided smiling	1.3 (1.18)	1.0 (1.06)	0.3 (-0.7, 0.6)	0.27 (52)	0.792
Psychological Disability					
Sleep been disturbed	0.7 (0.95)	1.0 (0.87)	-0.3 (-0.9, 0.4)	-0.84 (52)	0.407
Concentration been disturbed	0.8 (1.06)	0.7 (0.83)	0.1 (-0.8, 0.6)	0.31 (52)	0.759
Social disability					
Avoided going out	0.5 (0.84)	0.3 (0.55)	0.2 (-0.2, 0.5)	0.99 (52)	0.326
Problems in carrying out daily activities	0.3 (0.56)	0.5 (0.76)	-0.2 (-0.8, 0.66)	-2.37 (52)	0.721
Handicap					
Had to spend a lot of money	0.4 (0.68)	0.3 (0.55)	0.1 (-0.3, 0.6)	0.66 (52)	0.514
Felt less confident	1.3 (1.21)	1.0 (1.15)	0.3 (-0.6, 0.9)	0.51 (52)	0.615
Total S-OHIP(M)	14.4 (8.66)	12.2 (7.14)	-2.2 (-4.4, 3.4)	-1.56 (52)	0.793
FM=Facemask					
ASSD=Active Skeletonized Sutural Distractor					
SD=Standard deviation					
CI=confidence interval					
df=degree of freedom					

with Class III malocclusion treated with ASSD appliance in comparison with the conventional FM therapy prior to correction of dental discrepancies using orthodontic appliances.

At baseline, in both groups, the S-OHIP(M) items with the highest severity scores were the item discomfort due to food getting stuck and the item felt shy, both of which belong to the psychological discomfort domain. Psychological discomfort describes unpleasant feelings or emotions that impact the level of functioning by interfering with the activities of daily living. It can result in negative views of the environment, others, and the self, manifested as sadness, anxiety, distraction, and symptoms of mental illness. This finding agrees with previous studies that showed the greatest impact of malocclusion on OHRQOL was seen in psychological domains [2,4].

The next item with the highest severity score in our study was avoided smiling under the physical disability domain. Our participants were in the middle stage of adolescence. It is a period of significant emotional, intellectual, and social development, where teens in this stage are normally extremely concerned with their look. Such concern about the appearance explains the impact experienced by our participants as Class III malocclusion can considerably affect the aesthetic appearance of the smile that has a strong influence on facial attractiveness and personal interpersonal relationships.

While FM has been shown to be effective in correcting Class III malocclusion in the short term, [10,11] no psychosocial benefit was evident [21]. In agreement, findings of this study showed that the OHRQOL of the adolescents did not significantly improve following treatment with FM. This is possibly because OHRQOL is multidimensional construct, and orthopaedic treatment alone is not adequate to confer a clinically significant psychosocial benefit. Additionally, this could be because FM mainly corrected the skeletal problem and there was still a need for patients to undergo orthodontic treatment to correct the remaining dental discrepancies such as crowding, cross bite, and open bite. Our finding contrasts to that reported by Mandall, et al. [22] who showed that there was a reduced impact of malocclusion following active treatment with FM.

Similarly, following treatment with ASSD, no significant change was seen in the overall OHQROL. However, a significant increase in the S-OHIP(M) severity score was seen after the ASSD active treatment phase in the item avoided eating certain foods and the item problems in carrying out daily activities. These findings suggested that the ASSD treatment to correct the class III malocclusion gave negative impact on the physical disability and social disability domains. The ASSD is an intraoral appliance that is known to cause eating difficulty or restriction of eating certain types of food to avoid damaging the appliance [23]. These issues with eating, one of the activities of daily living, may affect the

patients socially due to the time taken to eat, chewing problems, change in taste and embarrassment when food got caught in the appliance while eating [23].

The severity of impacts experienced by the participants after treatment using the ASSD, nevertheless, was not significantly different than the impact experienced by those treated using the conventional FM. The use of ASSD as an alternative to FM has additional benefits of being more aesthetic and comfortable than FM because it is worn intraorally, allowing patients to easily open the mouth. These benefits, however, did not confer a significant improvement in OHRQOL of patients treated using ASSD compared to those treated using FM. This lack of improvement in OHRQOL is possibly attributed to the negative impact of ASSD on the physical disability and social disability of the participants as previously highlighted. Additionally, it is possible that the skeletal outcomes were similar following both treatments such that there were no detectable differences in the psychological outcomes.

CONCLUSION

No changes in OHRQOL were observed following Class III malocclusion treatment using FM and ASSD. In addition, the ASSD appliance did not seem to compromise the OHRQOL compared to the conventional FM.

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ETHICS COMMITTEE APPROVAL

Ethical committee approval was received from the Universiti Sains Malaysia Human Research and Ethics Committee (USM/JEPeM/15120548).

INFORMED CONSENT

Written informed consent was obtained from all participants of this study.

CONFLICT OF INTEREST

The authors have no conflict of interest to declare.

FINANCIAL DISCLOSURE

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