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Treatment effects of the Forsus Fatigue Resistant Device in growing patients with Class II Malocclusion

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Abstract

Background: Fixed functional appliances used in the treatment of Class II malocclusion have the advantage of requiring minimal patient compliance, and they can be used simultaneously with fixed orthodontic appliances. The purpose of this retrospective study was to evaluate the treatment effects of the Forsus Fatigue Resistant Device (FFRD) in growing patients with Class II malocclusion.
Methods: A total of 50 pre-treatment (T1) and post-treatment (T2) Lateral Cephalometric Radiographs (LCRs) of 25 patients treated with Forsus fatigue resistant device (mean age =12 ± 0.54years) for the correction of skeletal class II malocclusion were compared with the 25 untreated class II control patients (mean age 12 ± 0.38 years) who did not undergo any treatment during this period. The skeletal, dental, and soft tissue changes were evaluated using cephalometric measurements, and the treatment changes were analyzed by paired t-test.
Results: The LCRs findings showed that the FFRD produced more dentoalveolar changes with less skeletal changes. The dentoalveolar changes in the FFRD group include significant reduction of overjet & overbite ($p<0.001$), retroclination of maxillary incisors ($p<0.001$), proclination and intrusion of the mandibular incisors ($p<0.001$) and mesialization of mandibular first molars ($p<0.001$). A significant improvement in the skeletal, dentoalveolar and soft tissue structures of the face was achieved in the FFRD group compared with the control group.
Conclusion: The FFRD is effective in the treatment of Class II malocclusion. The Class II correction was achieved by a combination of skeletal and dentoalveolar effects, and wherein dentoalveolar changes were more predominant compared to the skeletal changes.

Keywords: Forsus fatigue resistant device, Fixed functional appliance, Class II malocclusion, Cephalometrics, Dentoalveolar effects

1. Introduction

In orthodontic practice Class II malocclusions constitute one-third of all orthodontic problems (1). Research has shown that Class II malocclusion with mandibular retrognathism causes unesthetic facial profile, risk of traumatic injury to the proclined upper anterior teeth, convex profile in children may develop a negative body image and psychological disturbances, which could manifest as poor performance in school, and other functional aberrations of craniofacial region in growing children (2). The goal of present-day orthodontics is to attain optimal facial esthetics in addition to a normal dental occlusion which is achievable only if the underlying jaw bases are in harmony with each other (3).

Fixed functional appliances have been in use for Class II correction and have the advantage of requiring minimal patient compliance and, they can be used simultaneously with orthodontic brackets. Therefore, several varieties of fixed functional appliances such as Herbst, introduced by Emil Herbst in 1905. However, Pancherz (4) reintroduced it in the late 1970s. The disadvantages of this appliance were the rigidity of the mechanism, extensive chairside time, and the requirement of complex laboratory techniques. In 1987, James Jasper developed Jasper Jumper (JJ), the disadvantage of the appliance was the risk of breakage. In subsequent years, many new fixed functional appliances were introduced, such as the Mandibular Protraction Appliance (MPA), Churro Jumper, and the Forsus Fatigue Resistant Device (FFRD) for the correction of Class II malocclusion.

The FFRD (5) (Forsus; 3M Unitek, Monrovia, California, USA) is one of the commonly used hybrid fixed functional appliance with a semirigid telescoping system that allows flexibility in the advancement of the mandible as compared to the Herbst appliance, which advances the mandible more rigidly. The FFRD is relatively well accepted by patients and produces more consistent force, the level of which can be adjusted by choosing the pushrod in five different sizes to satisfy the various clinical situation (6).

Several randomized clinical trials suggested that the FFRD is effective in the treatment of Class II malocclusion with mandibular retrognathism (7,12,14,20,22). Systematic reviews evaluated the skeletal and dentoalveolar effects of the FFRD in the treatment of Class II malocclusion with a matched untreated control group.The FFRD showed retroclination of the maxillary incisors, mesialisation of the lower first molars as well as reduction of overjet and overbite (8).

Therefore, the purpose of this retrospective clinical study was to evaluate the treatment effects of the Forsus Fatigue Resistant Device in growing patients with Class II malocclusion.

2. Methods

Sample Description and Ethics Statement

The present research was approved by the Institutional Ethics Committee (IEC No. RIDS - 250/Vol-1/2014). Two groups of 25 subjects in each were considered for this retrospective study. Records of the patients who had been treated with the FFRD (Figure 1.) were compared with the records of children who were not interested / refused the treatment with retrognathic mandible.

Figure 1. Forsus Fatigue Resistance Device

Inclusion and exclusion criteria

All the records were obtained from 4 different private dental offices (from 2014 to 2020) based on the following inclusion criteria: (1) Class II malocclusion with retrognathic mandible (ANB 5° or greater)

(2) Permanent dentition with minimal or no crowding in the mandibular arch (3) Maxillary incisor proclination with overjet of 6 to10 mm (4) Circumpubertal phase of skeletal development (cervical vertebral maturation index (CVMI) stage 2 to 4; evaluated by using lateral cephalometric radiographs) (5) No medical history or any systemic disease. The exclusion criteria: (1) Class II malocclusion patients in the postpubertal period, (2) History of previous orthodontic treatment, and (3) Temporomandibular Disorders (TMDs). The sample size was estimated using G* Power software (Universitat Dusseldorf, Germany) with a test power of 80%.

The FFRD Group: consisted of 25 patients (12 boys and 13 girls) with age between 12 to 13 years and a mean age of 12 ± 0.54 years at the time of initial lateral cephalometric radiograph taken. Control group: 25 children who were not interested / refused the treatment (10 boys and 15 girls), but followed up was done until the end of the study, and records were selected based on the similarity of ages with the FFRD group. The average age of this sample group was 12 ± 0.38 years.

The treatment protocol followed was similar in all the four dental offices, fixed orthodontic appliance followed by FFRD. The FFRD was selected and fixed according to the manufacturer's instruction into a headgear tube and 0.022 × 0.028 inches slot preadjusted edgewise MBT brackets were used. The wire sequence was 0.016 Nitinol, 0.019x0.025 Nitinol and 0.019x0.025 stainless steel in all the dental office. Class II elastics were not used by any one of the orthodontists.

Lateral Cephalometric Radiographs assessment

The pre-treatment (T1) and post-treatment (T2, post appliance removal / equivalent time frame (2 years in controls) records of 25 patients treated with the Forsus appliance and control group (25 patients) were evaluated before and after Forsus appliance therapy. All the pre-treatment and post-treatment Lateral Cephalometric Radiographs (LCRs) of all the patients were taken with the same cephalostat machine (Proline Cephalostat, Planmeca, Finland) and were traced on 0.003" acetate paper, using a 0.03" lead pencil by a single investigator. The cephalometric reference planes and angular measurements (Table 1) were used as defined by Alexander Jacobson (9) and Thomas Rakosi (10).

The following Cephalometric landmarks and reference planes were used (Figure 2 and Figure 3.)

Table 1. The cephalometric reference planes and angles

Cephalometric Parameters	Definition
SNA (°)	Angle between Sella, Nasion and point A
SNB (°)	Angle between Sella, Nasion and point B
ANB (°)	Angle between point A, nasion and point B
Max length (mm)	Linear distance between Condylion and Point A
Mand length (mm)	Linear distance between Condylion and Gnathion
WITS (mm)	Linear distance between Point A and Point B projected on occlusal plane.
BETA (°)	Angle between A-B line and the perpendicular drawn on line Centre of the condyle and Point B.
AFH (mm)	Linear distance between Nasion and Menton
PFH (mm)	Linear distance between Sella and Gonion
Facial Convexity (°)	Angle between nasion, Point A and Pogonion
IMPA (°)	Angle between mandibular plane and long axis of lower incisors
Overjet (mm)	Horizontal linear distance between maxillary incisor edges to mandibular incisors.
Overbite (mm)	Vertical linear distance between the maxillary incisor edge and mandibular incisor edge
Interincisal angle (°)	Angle between the long axes of maxillary and mandibular incisors
Soft tissue convexity (°)	Angle between soft tissue nasion, subnasale(sn) and pogonion
E line (mm)	Linear distance between most anterior point on lip to a line joining soft tissue pogonion and most anterior point on nose
H-angle (°)	Angle between H line (tangent from pogonion- upper lip) and line nasion-pogonion

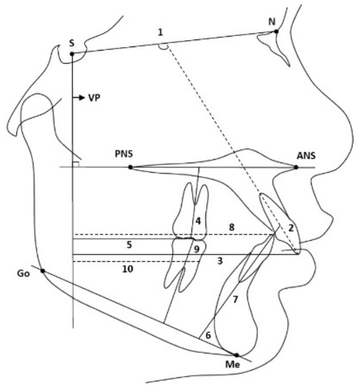

Figure 2. Skeletal and Dental Parameters

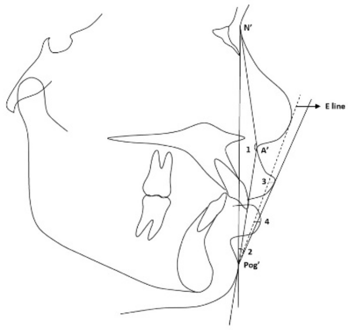

Figure 3. Soft tissue Parameters

Palatal plane: A line joined by ANS and PNS was used as a Horizontal Plane (HP) for the maxillary teeth. Mandibular plane: The plane formed by joining Gonion (Go) and Menton (Me). (HP for mandibular teeth) and Vertical plane (VP): The reference plane constructed through sella turcica perpendicular to the palatal plane.

The horizontal movement of the maxillary teeth was measured from VP, whereas vertical changes were measured relative to the palatal plane. Similarly, the mandibular plane and vertical plane were used to determine the mandibular teeth movement.

Method error evaluation

The sample size was calculated based on previous research (28). Sample size determination was performed using G. power 3.1 software. A total of 200 samples (40 in each group) were required for power of 80% at the 0.05 level of statistical significance.

Statistical analysis

The Statistical tests were performed using SPSS software version 20 (SPSS Inc., IBM Corporation, New York, USA). The skeletal, dentoalveolar, and soft tissue changes between pre (T1) and post-treatment (T2) were calculated using a paired t-test. The Wilcoxon signed-rank test was used when data were not normally distributed, and the Man-Whitney U test was used to compare the treatment changes between the two groups (Table 3). A P value ≤ 0.05 was considered to be statistically significant.

3. Results

The descriptive statistics and pre and post-treatment comparison between the FFRD and control groups are summarized in Table 2. In comparison, the percentage changes between the two groups are presented in Table 3, and Figure 4.

Table 2. Summary of Descriptive statistics between FFRD and Control groups (T1 & T2)

Cephalometric Variable	FFRD T1 % Mean± SD	FFRD T2 % Mean± SD	FFRD T2 vs T1 Significance (P)	Control T1 % Mean± SD	Control T2 % Mean± SD	Control T2 vs T1 Significance (P)
SNB (°)	74.10±2.54	74.84±2.47	0.110 NS	73.10±2.40	73.44±2.47	0.110 NS
ANB (°)	4.80±1.98	3.45±2.10	0.003 **	5.50±2.0	5.10±2.00	0.14 NS
MAX length	90.61±4.42	90.71±4.82	1.01 NS	86.70±3.60	87.40±4.49	0.148 NS
MAND length	110.20±4.08	111.90±4.02	0.010 *	108.10±5.01	108.90±5.01	0.158 NS
WITS (mm)	4.46±2.02	2.34±2.14	<0.001	4.40±1.19	4.17±1.15	0.12 NS
BETA (°)	21.14±3.45	23.78±3.53	<0.001	20.19±1.56	20.59±1.59	0.15 NS
AFH (mm)	112.42±4.51	120.08±2.62	<0.001	108.83±5.01	109.10±5.01	0.169 NS
PFH (mm)	73.46±3.08	78.30±3.08	<0.001	71.05±4.04	71.26±4.09	0.055 NS
Facial Convexity (°)	9.52±2.43	7.56±1.25	0.002**	8.76±4.01	8.78±4.09	0.071 NS
U1-SN (°)	111.56±2.44	103.26±7.01	<0.001	108.82±8.56	109.00±8.46	0.601 NS
U1-HP (mm)	23.86±3.56	27.52±2.39	<0.001	26.42±2.75	27.04±3.05	0.002 *
U1-VP (mm)	78.10±3.39	74.50±3.39	<0.001	73.77±5.24	73.98±5.42	0.820 NS
U6-HP (mm)	20.34±1.65	19.02±2.23	0.052NS	20.41±2.02	20.64±2.10	0.115 NS
U6-VP (mm)	42.34±5.18	40.42±4.89	0.06 NS	39.02±3.50	39.07±3.55	0.058 NS
L1-NB (°)	5.06±1.77	6.72±1.78	<0.001	6.39±1.79	6.47±2.10	0.560 NS
IMPA (°)	97.14±4.05	102.62±1.71	<0.001	98.36±4.51	99.02±4.50	0.054 *
L1-HP (mm)	41.52±2.05	40.10±2.29	0.012**	38.66±4.20	38.74±4.19	0.556 NS
L1-VP (mm)	69.14±5.29	72.14±4.28	<0.001	68.36±4.38	68.82±4.37	0.410 NS
L6-HP (mm)	30.14±1.82	33.08±2.53	<0.001	30.22±2.78	30.76±2.82	<0.001
L6-VP (mm)	40.06±4.24	44.24±5.05	<0.001	50.80±4.35	51.12±4.31	<0.001
Overjet (mm)	9.34±2.33	4.22±0.95	<0.001	9.06±1.40	8.80±1.31	<0.001
Overbite (mm)	5.26±1.52	3.42±0.79	<0.001	5.54±0.92	5.28±1.00	0.004 **
Interincisal angle (°)	116.08±4.71	119.28±3.85	<0.001	110.84±6.12	110.78±6.34	0.329 NS
Soft tissue convexity (°)	154.62±3.47	155.72±2.68	0.012**	156.48±4.26	155.04±4.42	0.56 NS
H angle (°)	25.62±3.87	22.54±2.62	<0.001	22±5.17	19.70±2.54	0.085 NS
UL-E line (mm)	0.88±1.10	-1.02±0.88	<0.001	2.76±1.48	2.01±1.58	0.08 NS
LL-E line (mm)	2.70±1.70	2.08±2.27	<0.001	4.50±2.52	4.50±2.71	1.00 NS

Note: SD: Standard Deviation, NS: Non Significant, HP: Horizontal Plane, VP: Vertical Plane, AFH: Anterior Facial Height, PFH: Posterior Facial height, U1-HP: Upper 1 to Horizontal plane, IMPA: Incisal Mandibular Plane Angle, U1-VP: Upper 1 to Vertical plane, U6-VP: Upper 6 to Vertical plane, U6-HP: Upper 6 to Horizontal plane, L1-HP: Lower 1 to Horizontal plane, L1-VP: Lower 1 to Vertical plane, L6-HP: Lower 6 to Horizontal Plane, L6-VP: Lower 6 to Vertical plane, U1-SN: Upper 1 to SN plane. p > 0.05 = NS, * p < 0 .05 = Significant, ** p < 0 .01 = Highly Significant, *** p< 0 .001 = Very highly significant.

Table 3. Percentage changes between FFRD and Control groups

Cephalometric Variable	FFRD % Change Mean± SD	Control % Change Mean± SD	FFRD vs Control Significance (P)
SNA (°)	0.62±1.95	0.56±1.00	<0.001
SNB (°)	0.81±5.86	0.61±1.06	0.226
ANB (°)	28.65±43.79	6.31±20.54	<0.001
Max length (mm)	0.65±4.26	0.57±3.46	0.188
Mand length (mm)	2.24±3.39	0.37±0.79	<0.001
WITS (mm)	45.06±43.69	7.80±20.54	<0.001
BETA (°)	13.11±7.86	3.40±2.86	<0.001
AFH (mm)	6.94±3.34	0.34±0.94	<0.001
PFH (mm)	7.52±5.43	0.51±1.02	<0.001
Facial Convexity (°)	15.27±26.69	0.49±10.53	<0.001
U1-SN (°)	8.34±5.83	-0.09±0.84	<0.001
U1-HP (mm)	17.33±12.02	2.83±2.86	<0.001
U1-VP (mm)	5.44±1.85	0.01±1.00	<0.001
U6-HP (mm)	-1.65±6.65	1.10±3.16	0.010**
U6-VP (mm)	-3.45±5.34	-0.04±1.73	<0.001

L1-NB (°)	35.45±26.35	8.84±6.89	<0.001
IMPA (°)	6.73±4.16	0.68±0.56	<0.001
L1-HP (mm)	75.88±18.55	0.24±1.48	0.016**
L1-VP (mm)	5.46±2.83	0.72±0.71	<0.001
L6-HP (mm)	8.44±4.84	1.59±1.41	<0.001
L6-VP (mm)	8.54±5.25	0.91±1.05	<0.001
Overjet (mm)	59.86±13.66	5.50±3.48	<0.001
Overbite (mm)	43.55±17.74	7.27±8.64	<0.001
Interincisal angle (°)	-2.84±2.65	-0.12±0.62	<0.001
Soft tissue convexity (°)	-0.67±2.20	0.41±0.30	0.006**
UL-E line (mm)	48.14±237.98	9.31±18.96	0.002**
LL-E line (mm)	40.30±140.25	3.40±31.85	0.054*
H-angle (°)	13.28±9.87	3.62±3.57	<0.001

Note: SD: Standard Deviation, NS: Non Significant, HP: Horizontal Plane, VP: Vertical Plane, AFH: Anterior Facial Height, PFH: Posterior Facial height, U1-HP: Upper 1 to Horizontal plane, IMPA: Incisal Mandibular Plane Angle, U1-VP: Upper 1 to Vertical plane, U6-VP: Upper 6 to Vertical plane, U6-HP: Upper 6 to Horizontal plane, L1-HP: Lower 1 to Horizontal plane, L1-VP: Lower 1 to Vertical plane, L6-HP: Lower 6 to Horizontal Plane, L6-VP: Lower 6 to Vertical plane, U1-SN: Upper 1 to SN plane. p > 0.05 = NS, * p < 0 .05 = Significant, ** p < 0 .01 = Highly Significant, *** p< 0 .001 = Very highly significant

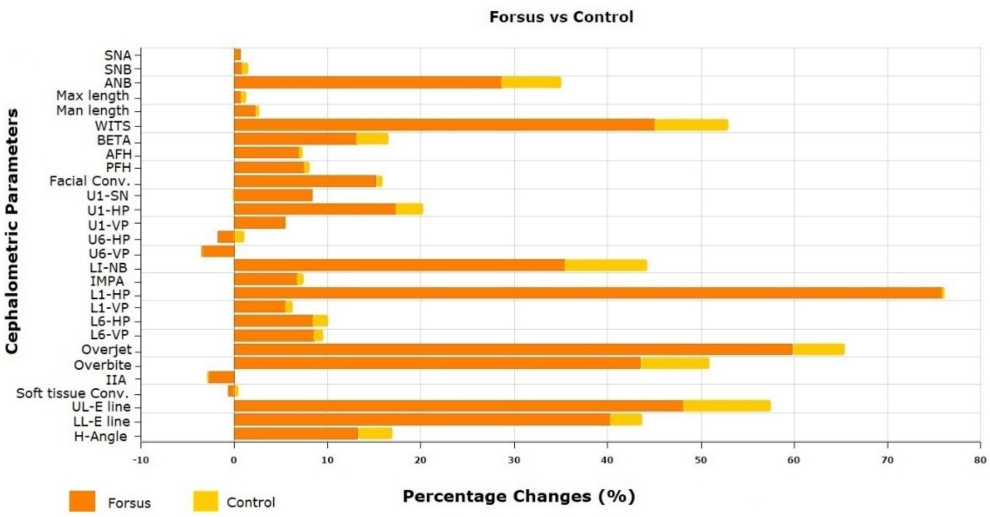

Figure 4. Percentage changes between Forsus and Control groups

Figure 4. Percentage changes between Forsus and Control groups

Lateral Cephalometric Radiographs Findings

A significant improvement in the sagittal skeletal relationship, Class I molar and canine relationship, decrease in overjet and overbite were observed in the patients treated with the FFRD.

At the skeletal level, the FFRD group showed a significant increase in the total mandibular length (Co-Gn = 1.7 mm), Beta angle (2.9°), lower anterior facial height (ANS-Me = 1.5 mm), whereas the ANB angle reduced by (1.5°), Wits reduced by (2.7 mm), and there was only a minor change in the untreated control group.

The dentoalveolar changes produced by the FFRD were a significant decrease in overjet (-4 mm) and overbite (-1.5 mm), and the molar relationship improved by 4.5 mm. The maxillary incisors were retroclined (U1 to SN = -3°), whereas mandibular incisors showed proclination and intrusion (IMPA = +4.0o) and mesialization of the mandibular molars (L6 to VP = 4.0 mm).

Soft-tissue profiles improved significantly with an increase in the soft-tissue convexity and the significant decrease in the H-angle, retrusion of the upper lip and lower lip to E-line. Overall, at the end of treatment, there were only minor skeletal, dentoalveolar and soft tissue changes were seen in the untreated control group.

4. Discussion

Fixed functional appliances used in the treatment of Class II malocclusion have the advantage of requiring minimal patient compliance, full-time forces and, they can be used simultaneously with fixed orthodontic appliances. This study evaluated the skeletal, dental, and soft-tissue changes produced by the FFRD.

The present study showed no significant restriction of maxilla similar to the previous studies (11-14), but contradicted other studies (15,17,18,19,20). Giuntini V et al., (19) and Eissa O et al., (20) found the significant restriction of maxilla with reduction of SNA (-1.1°) and (-0.51° ± 0.57°) respectively with FFRD. This controversy may be due to variation in the patients' age group, different treatment mechanics, or treatment duration.

The peak in mandibular growth takes place between cervical vertebra maturation (CVM) stages C2 and C4. Treatment of Class II malocclusion with mandibular retrognathism is most effective during this phase as the fixed functional appliances stimulate the growth of the mandible. In this study, the FFRD showed an increase in mandibular length of 1.7mm in accordance with other studies. Heinig and Göz (11), Karacay et al., (18) studies showed a 1.2mm increase of mandibular length with the Forsus spring. Pancherz (15) and Valant and Sinclair (16) reported significant forward growth of the mandible by 2.5mm and 3.3mm, respectively, using the Herbst appliance. Previous studies of the FFRD by Jones G, et al., (12) found a mean increase in mandibular length of 2.6mm, Cacciatore G, et al., (14) (mandibular length +1.6 mm), Giuntini V, et al., (19) (mandibular length +2 mm), Turkkahraman H, et al., (23) (mandibular length +1.5 mm). In contrast, several studies (12,13,20,21,22) reported no significant increase in mandibular length.

The sagittal relationship improved in the FFRD group due to the ANB angle reduced by (1.5°), Wits reduced by (2.7 mm) and increase in Beta angle (2.9o). These findings are in agreement with previous FFRD studies (14,18,19,20). There was an increase in the lower anterior facial height and posterior facial height similar to previous studies (13,14,18,20) but contradictory to other studies (12,13,19) which reported FFRD did not induce any significant change in the vertical skeletal relationships.

In the FFRD group, the maxillary incisors were retroclined (-3.62 mm) significantly, whereas the maxillary first molars were intruded (0.62 mm) and distalised (2 mm). The mandibular molars moved mesially (+5.36 mm) and extruded (2.74 mm) and, this mesialisation of the lower molars helped to correct the Class II molar relation. Contrarily, the mandibular incisors were significantly protruded and intruded with labial tipping (significant increase in lower incisor to NB and IMPA), which may be due to downward and forward forces on the mandibular dentition produced by the FFRD. A significant reduction in the overjet (-5mm) and overbite (-3 mm) and improved the molar relationship. These results suggesting the predominant dentoalveolar changes produced by the FFRD and is in agreement with most of the previous FFRD studies (11-14,19,20,21,21,24,25).

The soft-tissue profiles improved significantly, reflecting the changes in the underlying skeletal and dentoalveolar structures. The soft-tissue convexity improved significantly. There was a decrease in the H-angle, retrusion of the upper lip and lower lip to the E-line. These changes helped to improve convex facial profiles of the Class II malocclusion. These findings were similar to previous studies (13,18,20,23,25). However, to evaluate the soft tissue changes more accurately, long-term prospective randomized clinical trials and Three-dimensional (3D) quantification of the soft tissue changes are required to overcome current limitations (2-dimensional measurements) in our understanding of the soft tissue changes obtained with the use of functional appliances.

Conclusion

The Forsus Fatigue Resistant Device is effective in the treatment of Class II malocclusion. The Class II correction was achieved by a combination of skeletal and dentoalveolar effects, and wherein dentoalveolar changes were more predominant compared to the skeletal changes.

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