
A controlled clinical study of the effects of the Ni-Ti Memoria® Leaf Spring Activated Expander

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Objective: To evaluate the dental effects of the Ni-Ti Memoria® Leaf Spring Activated Expander (MLSAE) in adolescent orthodontic patients presenting with maxillary transverse constriction.

Methods: This retrospective controlled clinical study included 22 patients consecutively treated with the Ni-Ti MLSAE (mean age = 12.72 ± 3.07 ; range = 6–16 yrs). The sample was compared with 22 untreated controls from the University of Michigan Growth Study. Controls were matched by gender, CVM stage and inter-first molar width. Digital dental casts were obtained at pretreatment, one week, monthly and post-expansion time-points. Maxillary dental arch measurements of inter-canine, inter-premolar, inter-first molar, arch depth, arch perimeter and molar angulation were evaluated using 3Shape's OrthoAnalyzer software. Data were analysed using paired sample and modified Student's *t*-tests.

Results: Total mean expansion duration was 4.2 ± 1.23 months. Significant increases were observed between baseline and final inter-canine, inter-first and second premolars, inter-first molar, and arch perimeter measurements within the treatment group. No significant differences were found within the controls. Between group analyses showed statistically significant differences between the treatment and control groups for all variables except for arch depth and molar angulation. Average changes for inter-canine, inter-first premolar, inter-second premolar, inter-first molar, and arch perimeter were 1.04, 5.65, 5.80, 4.70 and 2.15 mm, respectively.

Conclusions: The Ni-Ti MLSAE is capable of obtaining adequate expansion in patients, 6–16 years of age, without causing significant dental tipping. It should be considered a slow expansion device that allows for calibrated expansion at a rate of 1–1.5 mm per month when following the suggested protocol.

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Introduction

Maxillary transverse deficiency (MTD) often manifests as a dentoalveolar crossbite with the maxillary teeth positioned lingual to the mandibular teeth in centric occlusion.¹ A posterior crossbite is found in 7.7% of patients in the deciduous or mixed dentition; its incidence increases into adulthood.^{2,3} The cause of MTD is multifactorial and involves congenital, developmental, traumatic and iatrogenic factors.^{4,5} Crossbites do not self-correct, therefore treatment to increase the width of the maxillary dental arch is

advised.⁶ If left untreated, muscle and TMJ strain may lead to skeletal facial asymmetries possibly requiring surgical correction in adulthood.⁷

It is known that traditional rapid maxillary expanders (RME) introduce heavy intermittent forces to the dentoskeletal complex. Isaacson et al.⁸ reported that a single activation of an expansion screw produced approximately 3–10 pounds of force. Slow maxillary expansion appliances typically deliver lower continuous forces of around two pounds.⁹

Several nickel-titanium expanders have been introduced that provide low levels of continuous force application.¹⁰⁻¹² More recently, the Ni-Ti Memoria Leaf Spring Activated Expander (Ni-Ti MLSAE; American Tooth Industries, CA, USA) was presented as a new expansion device by Gianolio et al.¹³ Lanteri et al. reported their experience utilising a 6 mm expander option for two mixed dentition cases,¹⁴ while Manzella et al. reported the effects of a 10 mm expander option in two permanent dentition cases.¹⁵

Following a review of the literature, there were no controlled clinical studies available to assess the efficacy of this new appliance. Therefore the objectives of the present study were to:

- (1) Evaluate whether clinically significant inter-canine, inter-premolar and inter-first molar expansion can be obtained with this device.
- (2) Make clinically supported claims as to whether this product can be used interchangeably with RMEs in clinical practice.

Methods

This was a controlled clinical study. Records of patients at the University of Buffalo School of Dental Medicine treated with the Ni-Ti MLSAE were retrieved and analysed. Pre- and post- expansion, as well as time-point impressions were assessed in order to better evaluate the new device. This study was approved by the University at Buffalo Institutional Review Board (IRB number: 00000718).

A power analysis was conducted to determine the sample size required. A power of 0.80, significance level of 0.05, and sigma of 3.6 was used from previous studies.¹⁶ This analysis resulted in a required sample size of 20 treated subjects and 20 matched controls.

Study inclusion/exclusion criteria

Males and females, 6–16 years of age with fully erupted maxillary first molars and requiring maxillary expansion for different reasons were included in the study. Reasons for expansion included unilateral or bilateral posterior cross-bite (two or more teeth) with or without a functional mandibular shift, dental and/or skeletal maxillary transverse deficiency, and/or crowding. Patients who had premolar extractions prior to expansion therapy and those with craniofacial syndromes/abnormalities were excluded from the

study to prevent changes in arch dimension due to mesial migration of teeth into extraction sites.

Treatment group

Data was collected from a pool of 23 consecutively treated orthodontic patients (nine male, 14 female) who underwent expansion therapy using the MLSAE from 2015–2016. Of the 23 treated patients evaluated, eight male and 14 female patients were included in the study. One patient was lost as the expansion appliance was changed to a Hyrax expander in order to obtain expansion more quickly. The sample consisted of 17 Caucasians, three African Americans, one Thai, and one Caucasian/African American. The CVM stages ranged from 1 to 5.¹⁷

Treatment protocol

The patients underwent a standardised protocol of expansion using the Ni-Ti MLSAE. Each appliance design was standardised to have mesial extension arms soldered to maxillary first molar bands (Figure 1). The same 10 mm 800 g screw version was used for every subject. A single laboratory technician fabricated each appliance.

Upon delivery, all appliances were evaluated to ensure proper design and pre-activation by one author (KM). Once cemented, the ligatures holding the compressed Ni-Ti leafs were cut. Each patient was seen approximately one week after insertion to ensure that there were no issues with the appliance. Each patient was then seen one month post-delivery and then at monthly intervals when the treating doctor



Figure 1. Standardized Ni-Ti MLSAE appliance design including mesial extension arms

performed 10 activations until adequate expansion was obtained. (Table I).

Maxillary impressions were taken at each time-point. Many patients completed expansion prior to or after T6, therefore final post-expansion impression (TF) and records were collected at those time-points. Each maxillary alginate impression was mailed, within 24 hours, to OrthoCAD to be digitised.

Control group

A randomly selected historical control group was obtained from the University of Michigan Elementary and Secondary School Growth Study (N = 22). Each control subject was matched to the treated sample by gender, inter-first molar width and CVM¹⁷ at the initial (T0) time-points. The control group consisted of eight male and 14 female Caucasian subjects having CVM stages ranging from 1 to 5. Inter-first molar measurements were taken manually in order to match each control to an appropriate treatment subject using a digital calliper accurate to the nearest 0.01 mm.

Study procedures

Prior to analysis, the control and treatment group digital models were oriented to the occlusal plane determined by placing reference points on the mesiolingual cusp tips of the maxillary first molars and the middle of the incisal edge of the most erupted central incisor. 3Shape's OrthoAnalyzer software's (3Shape, Copenhagen, Denmark) digital caliper was used to measure to the nearest 0.01 mm the inter-canine (cusp tip), inter-first premolar (lingual cusp tip), inter-second premolar (lingual cusp tip) and inter-first molar (mesiolingual cusp tip) widths. The highest point on each cusp tip in the lateral and frontal dimensions was used to determine each point location for width measurements. Arch depth, arch perimeter and molar angulations were measured according to the protocol presented in a previous study.¹⁸

Pilot study

A pilot study was conducted prior to data collection in order to evaluate the accuracy and reliability of transferring physical impressions into the OrthoAnalyzer software program following OrthoCad digitisation. Five maxillary casts were impressed with Kromopan alginate material (LASCOD, IL, USA)

and sent to OrthoCad for digitisation. Files were extracted from OrthoCad and uploaded into 3Shape's OrthoAnalyzer software. Arch width, arch perimeter and molar angulation measurements were made using OrthoAnalyzer software in a randomised manner and then compared with measurements made manually using a digital caliper (accurate to the nearest 0.01 mm) and protractor.

Statistical analysis

Data were analysed using paired sample and modified Student's *t*-tests. Ten digital models were selected at random for intra-examiner reliability testing. Each measurement was redone one week following initial measurements in order to evaluate differences. Intra-class Correlation Coefficients were used to evaluate the agreement between replicate measurements.

Results

Pilot study

There were no statistically significant differences between measurements taken manually or digitally using the OrthoAnalyzer software. The Intra-class

Table I. Time-point activation protocol. *TF Time-point where adequate expansion was obtained and the appliance was stabilised.

Time-point	Length of time	# of activations
T1	Cementation	None
T2	1 Week	None
T3	1 Month	10 Activations
T4	2 Month	10 Activations
T5	3 Month	10 Activations
T6	4 Month	10 Activations
TF*	F Month	None

Table II. Pilot study's agreement between manual and digital cast measurements. *Statistically significant ($p < 0.01$).

	Intraclass correlation coefficient	<i>p</i> -value
Inter canine	0.99	<0.001 *
Inter-first premolar	0.99	<0.001 *
Inter-second premolar	1	<0.001 *
Inter-first molar	0.99	<0.001 *
Arch depth	0.99	<0.001 *
Arch perimeter	1	<0.001 *
Molar angulation	0.99	<0.001 *

Correlation Coefficients for all measurements were ≥ 0.994 , yielding p -values of < 0.001 (Table II).

Intra-examiner reliability

Intra-class Correlation Coefficients indicated agreement (> 0.994) between intra-observer replicate dental measurements. Corresponding p -values were all < 0.001 (Table III).

Sample demographics

The mean ages for the control and treatment groups were 11.37 and 12.72 years, respectively (Table IV). In each group five, six, two, eight and one patient(s) were in CVM stages 1, 2, 3, 4 and 5, respectively. The mean initial inter-first molar measurement for the control group and treatment group was 39.16 ± 3.13 and 38.25 ± 3.75 mm, respectively ($p = 0.387$). The mean observation period of the control group was 11.55 ± 1.77 months. The average time from appliance insertion (one week prior to T2) to appliance stabilisation was 4.2 ± 1.23 months. Results from the control sample were adjusted to the treatment time of the treatment group.

Dental changes

Figures 2 and 3 illustrate the changes in all arch dimension measurements over the course of expansion for the treatment and control groups. Tables V and VI describe the changes for each arch dimensions measurement for both the treatment and control groups. There were no statistically significant differences for any measures in the control group. In the treatment group, statistically significant increases were observed in inter-canine, inter-first premolar, inter-second premolar, inter-first molar and arch perimeter. Between groups, statistically significant increases were observed in inter-first premolar, inter-second premolar, inter-first molar and arch perimeter.

Most importantly, a mean change of 4.90 ± 1.62 mm was observed between the initial and final time-points for the treatment group inter-first molar widths ($p < 0.001$, Table VI). During treatment, statistically significant changes compared with initial measurements were observed at each time-point ($p < 0.001$, Table V). Upon evaluation between time-point visits, statistically significant changes ($p < 0.001$) were observed between all time-points except T6-T7

Table III. Intra-examiner reliability Intra-class Correlation Coefficients.
*Statistically significant ($p < 0.01$).

	Intraclass correlation coefficient	p -value
Intercanine	0.99	< 0.001 *
Inter-first premolar	0.99	< 0.001 *
Inter-second premolar	1	< 0.001 *
Inter-first molar	0.99	< 0.001 *
Arch depth	0.99	< 0.001 *
Arch perimeter	0.99	< 0.001 *
Molar angulation	0.99	< 0.001 *

Table IV. Characteristics of Treatment and Control groups.

	Sex	N	Mean age (yrs)	Std. deviation
Control	Female	14	11.43	2.87
	Male	8	11.25	2.97
	Total	22	11.37	2.84
Treatment	Female	14	12.62	3.17
	Male	8	12.88	3.09
	Total	22	12.72	3.07

($p = 0.077$). The mean change over each appointment interval ranged from 0.84–1.63 mm and the largest change was observed between T3 and T4 (mean change = 1.63 mm).

A significant difference was observed between baseline and final arch perimeter measurements for the treatment group ($p < 0.001$). The mean change was 2.47 ± 1.43 mm (Table VI). During treatment, statistically significant changes compared with initial measurements were observed at all time-points except for T2 ($p = 0.167$) and T7 ($p = 0.030$, Table V).

Discussion

Statistically significant differences were found for inter-first premolar, inter-second premolar and inter-first molar locations for most sequential time-points and for most time-points when compared with initial measurements. Those that failed to reach statistical significance were likely due to the reduced sample sizes found during later time-points. From the manufacturer's benchmark studies,¹⁹ the reported force level of the expansion screw, 800 grams, was only



Figure 2. Arch width changes.

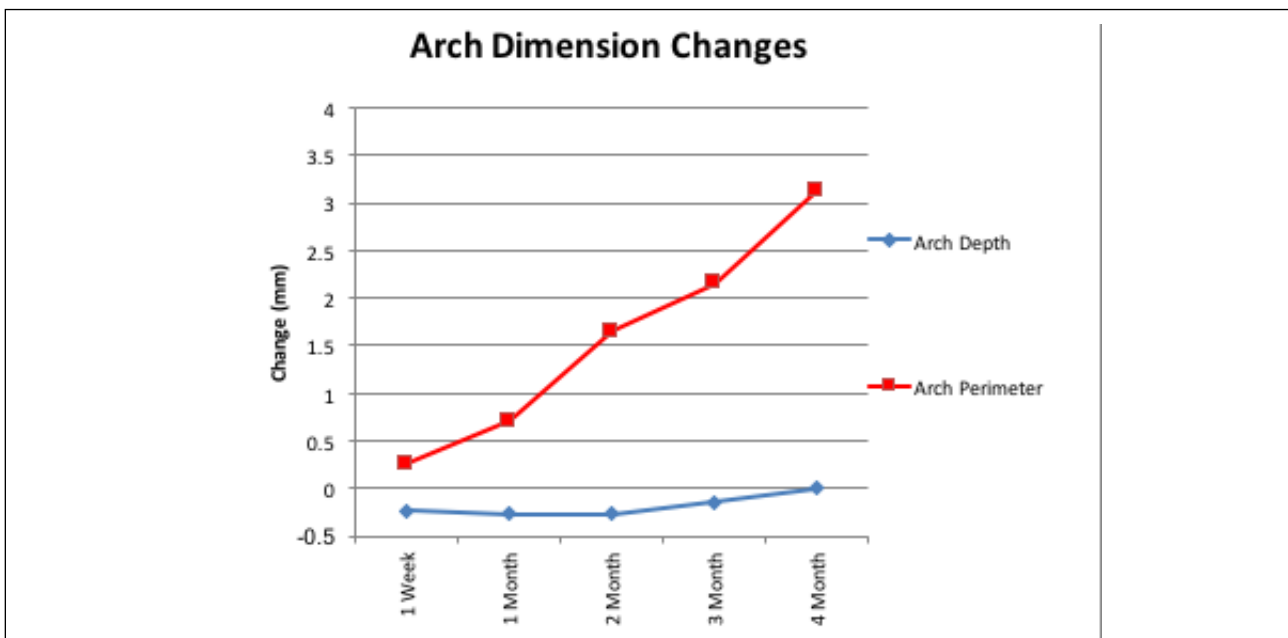


Figure 3. Arch depth and arch perimeter changes.

fully expressed when the leaf springs were compressed 5 mm. The present study confirmed these findings by performing an in-vitro pilot study using a Dillion Quantrol 500N/110lbf universal testing machine to determine the amount of expansive force generated by this appliance. The results found were similar to those reported by the manufacturer. When the leaf springs were compressed 1 mm, they expressed roughly half of the reported force level. This likely explains why nearly half of the expansion observed during the first

month occurred during the first week of treatment for the inter-first premolar and inter-second premolar locations. For the inter-first molar location, more than two-thirds of the expansion observed during the first month occurred during the first week of treatment. No super-elastic characteristics were observed upon deflection, as the nickel titanium leaves remain in an austenitic state at both intraoral and extra-oral temperatures.²⁰ The absence of a phase transition prevents a continuous force application as the leaves

Table V. Time-point changes for the Treatment group. *Statistically significant ($p < 0.01$). All measurements are in mm except molar angulation (degrees).

	Intercanine	Inter-first premolar	Inter-second premolar	Inter-first molar	Arch depth	Arch perimeter	Molar angulation
T2 - T1	0.33	0.91*	0.84*	1.39*	-0.23*	0.26	-0.12
T3 - T1	0.33	1.99*	1.69*	2.08*	-0.27*	0.71*	2.01
T4 - T1	0.95*	4.04*	3.91*	3.49*	-0.27	1.65*	2.81
T5 - T1	1.3	4.97*	5.15*	4.51*	-0.15	2.15*	3.49
T6 - T1	1.75	6.8*	7.36*	5.97*	0	3.12*	5.57
T7 - T1	2.95	8.46	9.61	6.59*	3.79	3	4.58

Table VI. Mean total changes and mean difference observed for the Treatment and Control groups. *Statistically significant ($p < 0.01$). All measurements are in mm except molar angulation (degrees).

	Treatment Group Tf-T1±Std. Dev.	<i>p</i> -value	Control Group Tf-T1±Std. Dev.	<i>p</i> -value	TG-CG Mean Difference ±Std. Error	<i>p</i> -value
Intercanine	1.31±1.35	.004*	0.27±0.71	0.196	1.04±0.42	0.024
Inter-first premolar	5.71±2.28	<0.001*	0.06±0.35	0.603	5.65±0.58	<0.001*
Inter-second premolar	5.81±2.63	<0.001*	0.01±0.24	0.878	5.8±0.66	<0.001*
Inter-first molar	4.90±1.62	<0.001*	0.2±0.50	0.074	4.7±0.37	<0.001*
Arch depth	0.49±3.97	0.567	-0.03±0.74	0.867	0.52±0.86	0.553
Arch perimeter	2.47±1.43	<0.001*	0.32±1.04	0.167	2.15±0.38	<0.001*
Molar angulation	3.15±7.63	0.066	-0.34±5.49	0.781	3.49±2.02	0.092

decompress. It is possible that decreasing the time-point interval to two weeks could maintain expansion forces closer to the reported 800 grams in between activation visits. Even if the expansion cycle increased, the rate and the force level would still be considered slow rather than rapid maxillary expansion and this device should not be considered interchangeable with a traditional RME.^{9,21,22}

When the full treatment group and control group mean changes were compared between initial and final time-points, significant differences were observed for the inter-canine, inter-first premolar, inter-second premolar, inter-first molar and arch perimeter measurements. The mean difference in inter-first molar width for the treatment group was found to be 4.70 mm. The mean difference in arch perimeter was 2.15 mm. Although not statistically significant, an increase in molar angulation of 3.49° was observed over the course of expansion after considering changes due to normal growth. This suggests that the first molars have a tendency to tip buccally during expansion. Similar findings were reported by

Manzella et al. in 2018 when evaluating two growing patients with permanent dentitions treated with the Ni-Ti MLSAE.¹⁵ These findings were also similar to those of Wong et al.,²³ who reported 4.3 mm of inter-first molar expansion, 4° of buccal crown tipping, and 3.27 mm of arch perimeter increase using a Haas-type, Hyrax and quad-helix appliances in mixed dentition patients. Inter-first molar expansion by the Ni-Ti MLSAE appears similar to changes observed following quad-helix appliance used in the mixed dentition. Bell et al., Erdinç et al., Boysen et al. and Sandikçioğlu et al. reported similar findings utilising quad-helix expanders.²⁴⁻²⁷ McNamara et al. and Handelman et al. also reported similar arch dimension changes using RMEs compared with those observed in the present study.^{18,28} McNamara et al. reported an increase in maxillary molar angulation of 4.8°, while Handelman et al. reported only a minor increase of 0.6°. Compared with the present findings, McNamara et al. reported much larger increases in maxillary arch perimeter. It was found that maxillary expansion resulted in a mean increase in arch perimeter of 6.3 mm.

Compared with the findings reported by Lanteri et al.¹⁴ using the Ni-Ti MLSAE, similar amounts of expansion were obtained in the premolar and molar regions. Compared with the Arndt expander (Ortho Organizers, CA, USA), the Ni-Ti MLSAE showed less buccal molar tipping and slightly less increase in inter-first molar width. Ciambotti et al. reported an average increase of 11.69° in molar angulation and 6.26 mm in inter-molar width using the Arndt expander over the course of approximately five months.²⁹ Karaman et al. observed 8.68 mm of inter-premolar and 8.50 mm of inter-molar expansion using the Arndt expander in 13.9-year-old patients.³⁰ However, significant relapse was noted upon review. As the Arndt expander does not have a rigid steel framework like the Ni-Ti MLSAE, more molar buccal tipping would be expected. Compared with the NiTi-MLSAE, the Nitanium Palatal Expander 2 (NPE2) also showed larger increases in buccal molar tipping. Ferrario et al. reported a mean increase in molar angulation of 17.3° in the mixed dentition following NPE2 use.³¹ The NPE2 was found to increase inter-canine and inter-molar widths by 0.04–6.4 mm and 0.3–4.9 mm, respectively. The Memory Palatal Split Screw (MPSS) has been shown to increase anterior arch width 6.88 ± 2.47 mm and posterior arch width 7.88 ± 2.07 mm over the course of two weeks.¹² It was also reported that each of the ten patients evaluated showed disrupted mid-palatal sutures on occlusal radiographs within one week of the start of expansion. This expander is designed to accomplish rapid palatal expansion as it is activated six times a day and produces a constant force of 1,224–1,428 grams. Halicioğlu et al. reported a similar inter-molar width increase of 6.83–8.94 mm.³² The MPSS resulted in an increase in 8–9° of both the left and right maxillary molars, buccal tipping much larger than what was observed with the NiTi-MLSAE in the present study.³²

There were several limitations associated with the present study. A larger sample size would have allowed for an analysis with greater power at the later time-points. An evaluation of expansion effects in relation to CVM stage was attempted but could not be performed due to the small sample size. Another limitation was the difficulty in using more traditional points to make inter-arch measurements. Typical expansion studies use the junction of the gingival margin to the lingual groove of the maxillary first molars as the landmarks to measure inter-first molar width. As the molar

bands covered these points throughout treatment, those locations were not available for measurement. Therefore, the compromise to use the mesio-lingual cusp tips as measurement points was accepted, knowing that an increase in arch width as a result of buccal crown tipping was possible.

Research implications

Pre-expansion and post-expansion occlusal radiographs or cone beam CTs may be beneficial in appreciating the skeletal effects of this appliance at different age groups. Evaluating the efficacy of the different appliance force levels and length versions would help to determine which versions are indicated at different skeletal maturity levels. Although the present study was standardised, a well-controlled prospective trial with a larger sample size would be beneficial. Running a parallel study with a quad-helix and/or a Hyrax expander would allow for a more accurate comparison of effects. More research is required to evaluate the relapse potential in order to determine whether a significant consolidation period is required following appliance stabilisation.

Clinical implications

The reported appliance design is recommended when using the Ni-Ti MLSAE appliance. The larger screw option with the most force (10 mm, 800 gram version) is suggested for more skeletally mature patients. If orthopaedic changes are desired, slow expanders should not be utilised in skeletally mature patients due to mid-palatal suture complexity. Since the mean increase in inter-first molar width was 4.90 ± 1.62 mm and the average length of active expansion was 4.2 ± 1.23 months, 1–1.5 millimeters per month of expansion may be expected when following this protocol. Since more than half of the expansion occurs within the first week after appliance cementation, clinicians may consider activating the appliance bi-weekly rather than monthly in order to shorten the active expansion phase. More research is required in order to evaluate this change in protocol. The appliance should theoretically be capable of delivering heavy-intermittent forces that are similar to those produced by traditional RMEs if the expansion screw is activated when the leaves are fully compressed. More investigation is needed to determine if clinicians may consider activating the expander five turns upon

insertion to begin the expansion process. When following this standardised protocol, the appliance functions as a slow expander similar to a quad-helix appliance; however, the design of the Ni-Ti MLSAE allows for calibrated activation that may make it more reliable. No central diastema formation was noted in any subject. If significant arch perimeter gain is required, a traditional RME may be preferred. Since slow expanders deliver lighter forces over longer time periods, Ni-Ti MLSAE may be better tolerated in patients exhibiting behavioural, compliance, or dental anxiety concerns. Therefore, clinicians should use their clinical judgment when deciding between different expansion approaches. Appliance cost, time constraints, required arch-perimeter gain and patient characteristics should be considered prior to deciding which appliance is best indicated.

Conclusions

1. The Ni-Ti MLSAE is capable of obtaining adequate expansion in patients 6–16 years of age without causing significant buccal molar tipping when compared to untreated controls.
2. This device should be considered a slow expansion device that allows for calibrated expansion at a rate of 1–1.5 mm per month when following this protocol.
3. More research is required to evaluate the skeletal effects of this appliance in different age groups.

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