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3

4 Abstract

5 Objectives:

6 Transverse discrepancy is a common problem in young patients. Many devices are employed to 7 expand the palatal dimension, with different characteristics and biomechanical aspects. The 8 Leaf Expander, a newborn appliance containing nickel-titanium springs, free from activation by 9 parents. We compared Leaf Expander's dental effects to conventional Hyrax's ones, in growing 10 patients.

11 Methods:

All patients who met the eligibility criteria were included between the period from January 2017 to December 2019. The patients had transverse inter-arch discrepancy of at least 5 mm and were treated with Hyrax expander (HEX) or Leaf expander (LEX). All patients had complete follow-up of expansion by remote monitoring. An algorithm established distances between the teeth. It was also used to measure the change in tooth axis.

17 Results:

In the maxilla LEX caused more tipping on the canines and premolars but significantly less on the molars compared to the HEX: -0.154° vs. 3.05° (p < 0.001). In the mandible, LEX caused a greater increase in arch widths and tipping (p < 0.02) in the molars and second premolars, but not in the other teeth. No correlation was demonstrated between mandibular dental movements and increased maxillary arch widths. Alternatively, for the two devices, expansion and tipping were correlated within each dental arch (r > 0.4).

24 Conclusions:

The LEX produced on average more tooth movements than the HEX, except the maxillary first molars. Several correlations exist between the movements within each arch for the two devices, most often between tipping and expansion.

28 Key-words:

29 Functional; digital models; palatal expansion techniques; hyrax; leaf expander.

30 Introduction

31 Maxillary transverse discrepancy affects 8 to 18% of orthodontic patients. It results in a 32 unilateral or even bilateral crossbite leading to a kinetic deviation of the mandible causing 33 masticatory, aesthetic, skeletal and dental disorders¹. Expansion of the maxillary arch with a 34 fixed appliance is a well-known and established practice in clinical orthodontics, but current 35 findings in "evidence-based dentistry" have not yet identified an ideal clinical expansion 36 protocol. Thus, the choice of appliance type based solely on its ability to resolve maxillary 37 constriction problems is no longer relevant. The orthodontist should, based on timing, choose a "patient-oriented" appliance that can minimize the various possible side effects, such as 38 appliance breakage, functional impairments, periodontal tissue injury and, of course, pain². 39

40 Alongside the conventional rapid palatal expander known as HEX, the LEX has been proposed as a measure to overcome parents' cooperation. In addition, it ensures a much less painful 41 treatment^{3,4}. This is an expansion screw using moderate continuous forces generated by Ni-Ti 42 leaves acting as springs ⁵. The literature on this device is rich. The kinetics of action of the LEX 43 44 are different: the expansion lasts several months. During this slow expansion, the mineralization of the intermaxillary suture is faster and even begins concomitantly with the expansion, making 45 it more consistent with histo-physiology ^{6,7}. The vascular development would promote a rapid 46 neo-ossification⁸. 47

Although Hyrax and Leaf expanders seek orthopedic action, they are bonded to the first molars
with two bands. As tooth-borne devices, they intrinsically cause unwanted tooth movements.
Furthermore, the relationships between arches are at the origin of the transmission of

unwanted effects from the maxillary teeth to those of the mandible ⁹. These tooth movements 51 52 can alter the gums and roots of the mandible, but can also generate space. To our knowledge, 53 only one randomized clinical trial has compared these two appliances on the dental level. However, it did not study the dental effects on the mandible ¹⁰. It is interesting to discuss the 54 mandibular effects since mandibular expansion combined with maxillary rapid expansion could 55 56 lead to significantly more favorable results than a HEX protocol alone ¹¹. Additionally, studies 57 comparing HEX and LEX concerning mandibular dental effects have not been reported in the 58 literature vet.

In this context, the primary objectives of this retrospective cohort study were: to compare the dental effects on the maxilla and on the mandible of these two types of expanders. The secondary objective was to test the existing correlations between the different dental parameters for each of these types of treatment in pre-teens patients.

63 1 Material and Methods

64 1.1 Participants

65 The Ethics Committee of the XXXXX Hospital gave its approval for this retrospective study 66 (Opinion n° 21.67). Data from 89 patients treated consecutively for maxillary expansion, in the 67 orthodontic department of the XXX Hospital between January 2017 and December 2019 were 68 used. All of these patients had been diagnosed with transverse maxillary discrepancy. Inclusion 69 criteria were as follows: (1) beginning treatment between 7 and 13 years old; (2) maxillary 70 constriction with posterior uni or bilateral crossbite; (3) maxillomandibular transverse 71 discrepancy greater than 5 mm in the first molars; (4) radiolucent spaces between the outer 72 edges of the maxilla and the mandibular ramus on frontal radiography; (5) maxillomandibular 73 width differential according to Ricketts and Betts greater than 14 mm; (6) patients treated with 74 either a Hyrax or a Leaf expander of 900g; and (7) patients whose treatment was followed by 75 the Dental Monitoring tool. Exclusion criteria were as follows: (1) cranio-facial abnormalities 76 (clefts, syndrome); (2) patients exhibiting poor oral hygiene; (3) previous or other orthodontic 77 treatment; (4) preexisting gingival recessions; (5) loss of appliance; and (6) missing data such as 78 models or X-ray.

79 1.2 Expanders design and activation rates

All patients were treated with a maxillary expander bonded to the first molar with two bands
(Ketac CEM 3M). Patients were divided into two groups depending on the appliances used:

- HEX cohort: A Hyrax Expander (Dentaurum, Germany), consisting of a 10 mm cylinder
 and two arms in contact with the premolars (or temporary molars) and canines.
- LEX cohort: A Leaf Expander (Leone, Italy) with a 900g nickel-titanium spring.

85 Both expanders used were made by the same technician according to a standard scheme. Briefly, the devices were located directly above the resistance centers of the maxillary molars or 86 87 as close as possible to the mucosa. The arms of the devices were welded to the bands and then 88 applied to the palatal surfaces of the premolars and canines. The activation patterns were as 89 follows: for HEX, two activations per day and for LEX 10 activations per month. Reactivation of the LEX is performed in the office. A quarter turn corresponds to 0.1 mm of activation 5 . The 90 91 starting point for patient follow-up (TO) corresponded to the day of insertion and the start of 92 activations after explanations.

93 1.3 Digital models' analysis

94 Measurements were made using two methods. A first step was conducted on the Trios 4 95 impressions (3Shape). In a second step, the measurements were made from the data of the 96 remote monitoring.

97 All the patients included were followed by the Dental Monitoring application. The follow-up was 98 regular, every 4 days. The activation phase was stopped to obtain contact between the palatal 99 cusps of the first maxillary molars and the vestibular cusps of the first mandibular molars when 100 the patient was biting in Angle Class I. For the LEX group the spring was embedded in composite 101 to stop the activity. At the end of the activation phase, a stabilization phase of 1 month for the 102 LEX and 3 months for the HEX was performed. The passive device was left in place. The final 103 measurements (T1) were made after the stabilization phase.

104 The application made it possible to track changes in tooth position. Specifically, the algorithm 105 was used to establish the distances between the buccal cusps of the teeth. It was also used to measure the change in tooth axis: the difference between the perpendicular to the occlusalplane and the tooth axis at T0 and T1.

108 The calculation of method error was not performed because the data were derived from an 109 algorithm and not from a human examiner.

110 1.4 Outcomes

- 111 The following parameters were examined both for maxillary and mandibular arches:
- Width between teeth, from canines to molars, measured between mesio-buccal cusps;
- Dental tipping, from canines to molars; the values retained were the average of the left
 and right sides. Tipping was the change in tooth axis, i.e., the difference between the
 perpendicular to the occlusal plane and the tooth axis at TO and T1;
- The dental arch perimeter, distance from the distal of the first permanent molar on one
 side to the same surface on the opposite side;
- 118 Duration of treatment of active phase

119 1.5 Statistical analysis

Statistical analysis was performed with RStudio version 1.2.5001 (RStudioTeam) with R 3.6.1 (RCore Team). Qualitative data were analyzed by Pearson's chi2 test. The means were compared by Student's t test, after testing the equality of variances and normality, with Bonferroni adjustment for multiple comparisons (2 = 0.05). Pearson's correlations were used. P values \leq 0.05 were considered significant.

125 With 28 and 24 measurements in the groups, a post hoc power calculation for unpaired two 126 tails t-tests conducted using the statistical tool G*Power (Version 3.1.9.4), indicates a power of 127 82% to detect a large effect size (Cohen's d = 0.80) at a significance level of 0.05.

128 2 Results

129 2.1 Inclusion of patients

130 89 patients were selected. In the HEX group, 11 had missing data, mainly in the follow-up with131 Dental Monitoring and 5 were lost. For the LEX group, 14 patients were excluded for lack of data

and 5 for discontinuation of follow-up, mainly due to the loss of the device. This leaves a sample
of two groups of 26 and 28 patients with a sex ratio of 1:1 and a mean age of 10.2 years (Figure
1).

135 2.2 Comparability of groups

The first step was to check the initial comparability of the groups. It was validated in terms ofage, sex, arch widths and perimeters (Table 1).

138 2.3 Duration of the active phase of treatment and whole expansion

Patients in the HEX group had a significantly shorter active phase (15.8 \pm 3.4 days versus 134.4 \pm 22.1 days) (p < .0001). The expansion rates were 0.35 mm/day for HEX and 0.27 mm/week for LEX. The total duration of wearing the device (T0 to T1) was close in the two groups, of the order of 4 months.

143 2.4 Effects on maxillary teeth

The arch perimeter has increased from 96.5 \pm 5.63 to 100.3 \pm 6.65mm in the HEX group and from 95.9 \pm 4.57 to 99.9 \pm 5.08mm for LEX. Within each group, this increase was significant (p < 0.0001). However, no difference was found between groups (p > 0.9).

147 If we focus on the arch widths, the variations ranged from 3.98 ± 1.80 to 5.57 ± 1.27 mm for HEX 148 and from 4.54 ± 2.31 to 6.65 ± 2.26 mm for LEX. However, there was no significant difference 149 between groups except at the level of the first premolars (p = 0.4). Here, the increase for LEX 150 was 6.65 ± 2.26 mm while it was only 5.30 ± 2.03 mm for HEX.

The tipping values appeared disparate between groups. For HEX, they fluctuated from 3.05 ± 1.98 to 5.55 ± 2.65° while for LEX, the interval went from -0.154 ± 1.52 to 12.5 ± 3.31°. When analyzed more closely, the premolars were the most exposed teeth in the HEX group. Alternatively, the canines and first molars suffered a weak tipping. For LEX, the canines and second premolars had a similar buccal tipping of about 9°. The first premolar had a strong tipping reaching 12°. Conversely and interestingly, the molars did not undergo any movement, except for a slight straightening of the axis. Nevertheless, except for the second premolar, the

tipping was statistically different between groups (p < 0.001). The LEX caused few 2nd order
movements on the molars but much more on the other teeth (Table 2).

160 2.5 Effects on mandibular teeth

The arch perimeter increased from 90.49 ± 5.28 to 90.86 ± 5.47 mm in the HEX group and from 89.29 \pm 3.97 to 89.62 \pm 4.31mm for LEX. This increase in the order of 0.3mm is not statistically significant.

164 If we now consider the arch widths for the HEX group, all of them increased similarly from 0.364 165 to 0.493mm. In contrast, for the LEX cohort, the widths increased more in the posterior part of 166 the arch than in the front. The canine to canine width progressed by 0.530 ± 0.843 mm, while 167 that at the level of the molars grew by 1.54 ± 0.822 mm. A comparison of the two groups 168 revealed significant differences in the modification of arch widths between the first molars and 169 the second premolars but not for the first premolars and canines.

The tipping values for the HEX group have always remained below the 2.0° threshold. The highest value was found for the second premolar ($1.96 \pm 2.25^{\circ}$). For the LEX group, the tipping degrees ranged from $3.76 \pm 2.76^{\circ}$ to $1.10 \pm 1.87^{\circ}$. Note that, for both groups, the most important movement was found for the second premolar and then for the first molar. If we compare the two groups, the tipping was more important for the LEX and this significantly for the molars (Table 3).

176 2.6 Data correlation for each device

177 For HEX, few parameters appeared to be correlated. The analysis demonstrated a strong 178 correlation between the increase in inter-dental distances and tipping. In the maxilla, the 179 Pearson correlation coefficient was greater than 0.45 and increased in the anterior part of the 180 arch. In the mandible, it fluctuated between 0.58 and 0.72. At both arches, the strongest 181 correlations between tipping and expansion were found for canines and molars. We can also 182 see that the expansion and tipping of the premolars was positively correlated with the 183 expansion of the molar level (r > 0.4). Other values were highlighted: the variation in the 184 perimeter of the maxillary arch was positively correlated with both that of the mandibular arch 185 (r = 0.51) and with the increase in the width between maxillary teeth (r > 0.41) (Figure 2).

186 For LEX, many more variables seemed correlated. However, only a couple of those had a 187 biological rationale. Expansion and tipping were also correlated. In the mandible, the correlation 188 was forceful (r > 0.73). The lowest coefficient was found for the molars. In the maxilla, the 189 coefficients varied from 0.4 for the molars to 0.86 for the first premolars. It is interesting to note 190 that the variations in the dimensions of both arches are not correlated. However, the increase in 191 the perimeter of the maxillary arch is strongly linked to the expansion between the maxillary 192 teeth (r > 0.58). The tipping of the mandibular molars was also correlated with the parameters 193 qualifying the mandibular premolars (r > 0.54) (Figure 3).

194 One particular element must also be highlighted. In no case were the movements of the 195 mandibular teeth correlated with the increase in arch width at the level of the maxillary molars.

196 3 Discussion

197 The maxillary expansion is the most common orthopedic procedure to correct transverse discrepancy and posterior crossbite ¹². Many studies have analyzed the effects of slow and rapid 198 expansion with variable devices: Haas, Hyrax, guad'helix or removable device ^{13,14}. Rapid 199 200 expansion using a Hyrax expander is the most prescribed technique currently ¹⁵. However, 201 Martina shows that using this device with a slow or fast activation rate makes no difference in terms of expansion⁹. In our study, the LEX was used to do the slow expansion. We have chosen 202 203 to study it because according to the literature, it offers many advantages: continuous and low intensity forces (900gr), freedom of patient cooperation and it is more comfortable for pediatric 204 patients ^{4,5,16}. Its effectiveness in opening the mid-palate suture has already been demonstrated 205 by CBCT ^{17,18}. Like any tooth-borne device, it potentially causes undesirable effects. The 206 207 consequences of these movements are numerous, such as the weakening of the alveolar bone 208 ¹⁹. To date, few studies has compared the dental effects of these two devices in the maxilla, let 209 alone the mandible. The outcome of this retrospective study was therefore to describe more 210 precisely the arch modifications resulting from rapid expansion by HEX or slow by LEX in pre-211 teens patients.

212 In our study, measurements were made using two methods. The first method was through 213 digital impressions; the 3Shape TRIOS[®] system has an accuracy of $42.9 \pm 20.4 \mu m^{20}$. The second

214 method was the Dental Monitoring (DM) algorithm. A 2019 study compares the measurements 215 given by the algorithm to those on plaster models during expansion. The data are recorded at 216 both the inter-canine and molar distances. The comparable results attest to the reliability of this method ²¹. Additionally, a recent study concluded that 3-Dimensional models generated by DM 217 were sufficiently accurate enough for clinical application²². Beyond these studies, few papers 218 219 have focused on the precision of DM, but two other publications assure that the system allows 220 the optimization of aligner treatments. Without the necessary precision, especially in the posterior areas, this type of optimization would be counterproductive ^{23,24}. These are the 221 reasons why we decided to use this innovative data collection solution. 222

223 Regarding the maxillary dental effects, the two devices had comparable effectiveness. These 224 results are comparable to those obtained by a randomized controlled trial which showed no 225 difference between HEX and LEX at the dental level, except on the inter-canine distance parameter ¹⁰. A study using HEX showed comparable changes in inter-tooth distances and arch 226 perimeter, except for canines, in a sample of equivalent average age ²⁵. However, it was higher 227 than those found by Alves et al ²⁶. A CBCT study, performed on older patients, found values of 228 this order ²⁷. The expansion rates were different between the groups but comparable to those 229 found by Akkaya for slow and rapid maxillary expansion ²⁸. The tipping was more important with 230 231 the LEX for teeth with a punctiform support of the appliance. The free tipping imposed by the 232 front arms of the devices and the longer application time explained that. Alternatively, the tipping was not significant on the molars in the LEX group. The tipping of the first molars with 233 HEX is close to that found in the Lagravère meta-analysis: 3.10°²⁹. The tipping observed with 234 LEX was less than that observed in the literature for slow expansion. Wong noted an average 235 buccal tipping of 4° 1 . The powerful forces, reaching 10 kg, applied by the HEX can explain that 30 . 236 237 They may exceed the stiffness threshold of the appliance or produce a weakening of the buccal 238 bone. In this regard, the results of the literature obtained from CT scans show that changes in alveolar heights around the first molars were insignificant during LEX expansion ¹⁹. This is 239 240 interesting because the correction of the dental compensation of the transverse discrepancy will be done by palatal tipping of the molars. It will be even simpler and less risky at the root 241

level that the buccal tipping will be limited ²⁴. However, LEX has more undesirable effects on
other teeth, in particular tipping.

244 In the second part, we focused our work on the effects on the mandibular arch. A spontaneous response following rapid maxillary expansion has been described in the past ^{31,32}. For both 245 groups, our results are comparable to the literature that reports an increase in the mandibular 246 inter-molar distance ³². Here, the LEX allows for straightening of the posterior tooth axes that is 247 positively correlated with an increase in arch widths, which are greater than those observed for 248 249 the HEX. In fact, the lingual tipping initially present is reduced. However, these variations do not 250 result in a saving of space since the perimeter of the mandibular arch did not change 251 significantly during the expansion in a group. In fact, the literature describes a decrease in mandibular arch length during adolescence ³³. More precisely, a decrease of up to 1mm has 252 been demonstrated during the transition from deciduous to permanent dentition ³⁴. We can 253 assume here that the dental movements imposed by the maxillary expansion erase this 254 255 reduction of the arch perimeter.

The dento-alveolar effects were most significant on the molars and second premolars. This can be explained by the strong occlusal relationship between the molars and by the weak anchorage of the mandibular second premolars. The total durations of treatment were similar, but those of the active phases differed. The stresses applied to the mandibular teeth progressed slowly for LEX, which resulted in greater mandibular movements. This spontaneous correction concludes that the longer duration of the active phase in the maxilla allows the correction of mandibular teeth without the use of lower braces.

263 Nevertheless, this study had several limitations. First, one of the main weaknesses of retrospective studies is that they generate a large number of missing data. Here 35 patients had 264 265 to be excluded because of missing data. Second, these data must be weighed against the fact 266 that temporary and permanent teeth were pooled. Indeed, we did not conduct a subgroup 267 analysis according to the stage of dentition. Replacement of temporary molars most often 268 results in a change in tooth axis that is not qualified here. Third, although the data from remote 269 monitoring using the Dental Monitoring algorithm is reliable, this type of protocol remains 270 marginal, which makes the data acquired questionable, but allows us to validate the good

compliance in the HEX group. Prospective protocols will have to be proposed, probably withstratification on the stage of dentition, to decide on the dental effects of these appliances.

273 4 Conclusions

- 274 The objectives of this retrospective cohort study were to compare the dento-alveolar effects of
- 275 HEX and LEX on both arches in growing patients. Four conclusions can be drawn:
- LEX did not produce significant tipping on the maxillary molars, but much more on the
 other teeth.
- In no case were the movements of the mandibular teeth correlated with expansion
 between the maxillary molars.
- The space saving in the mandible following maxillary expansion was negligible in both
 groups.
- There was a strong correlation between tipping and expansion at the mandible in the
 LEX group.

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- 374

375 6 Captions

- Figure 1: Flowchart of the patients included in this study, following CONSORT statement.
- 377 Figure 2: Correlogram of the various parameters related to the expansion by HEX. The
- 378 coefficients presented are those of Pearson for a statistical significance at risk of 5%.
- 379 Figure 3: Correlogram of the various parameters related to the expansion by LEX. The
- 380 coefficients presented are those of Pearson for a statistical significance at risk of 5%.

- Table 1: Descriptive elements of groups at T0. The initial comparability was validated using
 Student's T tests and by Pearson's Chi2 at the 5% significance level.
- 383 Table 2: Evolution of measurements of maxillary arch perimeters, arch widths and tipping of
- teeth during treatment. The comparisons of the two groups were tested using Student's T tests
- 385 at the 5% significance level and the Bonferroni correction for multiple testing (q-values).
- 386 Table 3: Evolution of measurements of mandibular arch perimeters, arch widths and tipping of
- teeth during treatment. The comparisons of the two groups were tested using Student's T tests
- 388 at the 5% significance level and the Bonferroni correction for multiple testing (q-values).