ZeroExpander® effectiveness assessment in PEEK or PA12 in a group of paediatric patients with transverse maxillary deficiency

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Abstract

Aim The aim of this article is to compare the performance of ZeroExpander® realised using PEEK or PA12 for the expansion of the maxilla in paediatric patients, exploring a new concept for approaching maxillary expansion with a metal-free fixed automatic appliance, based on pre-programmed set-up and anchored on deciduous teeth.

Matherial and Methods It is a retrospective comparative study with a sample of 40 children in early or mixed deciduous dentition and transversal maxillary deficit, 20 treated with ZeroExpander® in PEEK and 20 treated with ZeroExpander® in PA12 with a mean age of 7.3 years old. The intraoral scans at T0 and at the end of the expansion were all performed by the same operator to obtain digital models on which were performed measurements by two other different operators. A descriptive analysis was conducted using frequencies and percentages for nominal variables and means and standard deviations for continuous variables.

Results A comparison between the two treatments highlighted a different response for variable C, with higher expansion values for PEEK. However, variables D, E and 6° did not show statistical significance. The performed anchoring does not show significant differences in achieving the total set up, whether there is anchoring on the C or not, itself as proof of an expansion similar to what is seen in an orthopaedic expansion. The statistical analysis showed that PEEK and PA12 leads to overlapping results in terms of palatal expansion. The cementation of PEEK devices was more complex, due to their minor flexibility and this led clinicians to prefer ZeroExpander® in PA12 afterwards, because of its greater ease of bonding due to the surface microroughness.

Conclusion In cases of allergy or hypersensitivity to metals or to specific chronic or acute pathological conditions, which may require periodic magnetic resonance imaging (MRI), it may not be possible to use traditional and metal fixed expansion devices. Moreover the concept of autonomous driving in paediatric orthodontics is not only possible, but it is and will be more real and very useful in the future. The "ortho-paediatric dentistry concept" will increase the range of benefits for children and their families which, in addition to care and thanks to technology, demand well-being, safety, comfort and quality of life beyond clinics.

KEYWORDS Automatic Palatal Expansion, Metal-Free Orthodontics, Selfdriving Orthodontics, Intraoral Scan, PEEK, PA12, Cad-Cat, Technopolymers, Quality of Life, ZeroExpander, Paediatric Orthodontics.

Introduction

Starting from the basic assumption of a comfortable and efficient treatment approach, today it is possible to follow a fully digital workflow for diagnosis and therapy [Beretta at al., 2021]. The average compliance [Lanteri et al., 2016] of the young patient and the use of "self" orthodontic devices [Beretta et al., 2019], led researchers to explore the new possibilities offered by the new polymeric materials and the new concept of "self-driving orthodontics" was developed by the authors. Maxillary deficit [Lo Giudice et al., 2020] associated with unilateral or bilateral crossbite or lack of space for the eruption of the lateral incisors and canines is one of the most frequently diagnosed malocclusions [Lanteri et al., 2016]. Maxillary expansion is a common orthodontic treatment to correct transversal upper-arch deficiency [Grippaudo et al., 2020]. The two clinical procedures for the correction of transverse maxillary deficit, that is rapid maxillary expansion (RME) and slow maxillary expansion (SME), have shown to have orthopaedic effects in growing patients [Bucci et al., 2016; Lo Giudice et al., 2017]. Different studies have found that SME allows greater physiologic modification of the maxillary bone and surrounding complex, preventing the accumulation of large residual loads with a more stable bone remodelling [Gianolio et al., 2014].

Compliance, effectiveness, and comfort for the young patient are crucial, as well as no need for further activation either in the dental office or at home. As such, the Leaf Self Expander [Beretta et al., 2019] does not rely at all on patient cooperation. Since the device employs light and continuous forces, it causes no pain even in the initial stages of expansion.

It may often occur in patients, due to allergy or hypersensitivity to metal or specific diseases (such as epilepsy, autism or vascular problems), to require periodical MRI of the head district, or in emergency situations (particularly difficult to manage) to require the removal of the device [Beau et al., 2015, Ozawa et al., 2018], due to the magnetism generated by metals. The introduction of new materials, such as technopolymers, in digital orthodontics [Ierardo et al., 2017,

Beretta et al., 2021] is offering new possibilities to clinicians. Polyether-ether-ketone (PEEK) and polyamide 12 (PA12) have ideal chemical-physical features that allow their use in orthodontics. Due to their biocompatibility, low plaque affinity and dimensional stability, they can be employed in the fabrication of orthodontic devices.

ZeroExpander® is a fixed metal-free automatic maxillary expansion device designed with a complete digital CAD-CAT (computer-aided design-computer-aided technofacturing) workflow using metal-free technopolymers (PEEK or PA12), completely individualized and tailor-made. PEEK is a semicrystalline linear polycyclic aromatic polymer that was developed in 1978 and later marketed for industrial purposes [Ma and Tang, 2014, Skirbutis et al., 2017].

By the late 1990s, PEEK had become prominent as a high-performance thermoplastic polymer used in orthopaedic surgery. PEEK is a radiolucent material with thermal stability up to 335.8 °C. Its mechanical properties do not change during sterilisation, and it has a flexural modulus of 140–170 Mpa. Young's elastic modulus is 3–4 GP, close to that of human bone, enamel and dentin. PEEK is hypoallergenic, nontoxic and biocompatible. PA12 is a biocompatible linear semi-crystalline/crystalline thermoplastic 3D-printed composite. Having a thermal stability up to 185 °C, it can be sterilised before use and is one of the most promising materials for use in orthodontics due to its greater flexural strength and modulus than unfilled PA and other PA composites [Rahim et al., 2016; Scherer et al., 2020; Campobasso et al., 2023; Paglia et al., 2022a]. The design of the ZeroExpander® device starts from an intraoral scan and entails an initial virtual set-up of the STL files for the expansion of the upper arch, obtained following the conventional criteria for calculating the expansion requirements in case of palatal transverse deficiency. For the expansion in paediatric patients, the first and second deciduous molars and the deciduous canines are generally used. Today, the average preprogrammed expansion for the ZeroExpander® is 6 mm (considering a 6 mm screw of the Leaf Expander and the Self Expander as the reference point, being the most used in paediatric patients). The device is designed on the virtually expanded upper arch (using 3Shape Dental Designer software; 3Shape, Denmark), defining the anchor teeth according to the needs of treatment (generally, hemi bands on the second deciduous molars and bonded pads on the first molars and/or canines). After the project is generated, the relative STL file is used for the milling process (for PEEK) (Fig. 1 a-b) and 3D printing (for PA12). The dimension of the expansion bar is calibrated to obtain an expansion force of about 450 g (as for the most common screws used for the Leaf and Self Expander) and it has an average diameter of 1.8 mm for PEEK and 3 mm for PA12.

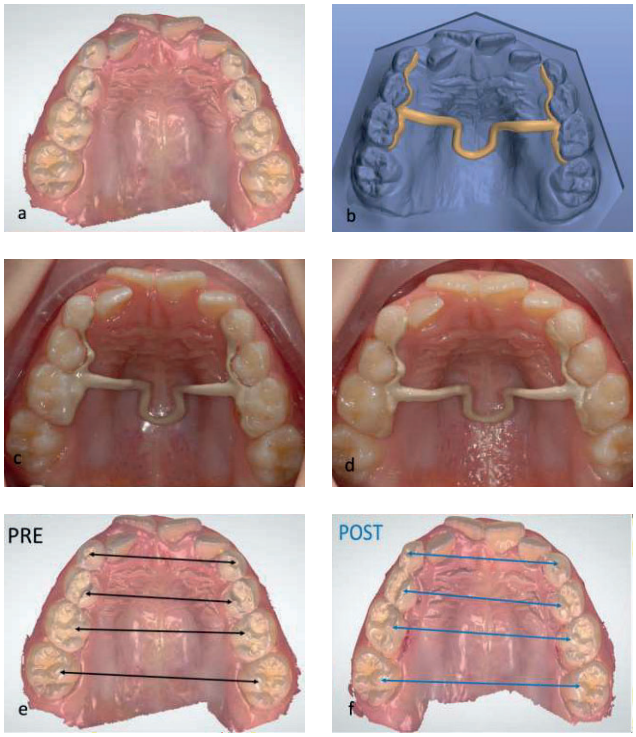

FIG. 1 A: female of 7 years old, with transverse maxillary deficiency and crowding B-C: virtual Set-Up, digital design of ZE, ZE in peek bonded with anchorage on second, first deciduous molars and canines D: images of the clinical expansion obtained E-F: comparison between pre and post expansion intraoral scans, on which the measurements for this study were carried out.

The central loop that contributes to the flexibility and resilience is custom designed on the basis of the palate of the patient, the type of expansion required, and other features that can be added to the appliance. The clinical procedure entails etching and adhesive cementation, using preferably a self/light curing bioactive cement (Activa Bioactive Cement, Pulpdent, USA; Transbond Plus, 3M, USA), especially for PA12, or other materials (Transbond LR, 3M, USA; Relyx, 3M, USA), better performing with PEEK (Fig.1 C-D). The intraoral positioning on the anchoring teeth surface requires the transversal contraction of the device to fit the upper arch (acting on both sides simultaneously or one by one, depending on the clinical situation and the level of cooperation of the patient). The ZeroExpander®, due to its shape memory, progressively expands like a compressed open coil spring (like a sort of preactivated Quad-Helix), until it reaches the original dimension at the end of a virtually planned expansion, in a very controlled and comfortable way for the young patient, on average in 4 months. Afterwards, it is normally kept in place for another 6 to 8 months to maintain the obtained expansion (Fig. 1 E-F; Fig. 2 A-B-C).

The aim of this article is to compare the performance of ZeroExpander® realised using these new materials for the expansion of the maxilla in paediatric patients.

FIG. 2 A: start of treatment; B: images of the clinical expansion obtained; C: end of paediatric orthodontic treatment after 15 months from the beginning, where, after the expansion, utility arches were used to achieve early alignment.

	PEEK			PA12			p-value
	T0	T1	Mean difference T2 – T1 p-value	T0	T1	Mean difference T2 – T1 p-value	Comparison among groups
C	28.77±2.83	33.02±2.94	(4.08±1.26) - 0.0001*	27.64± 2.84	30.64±2.91	(2.99±1.80) - 0.0001*	0.0197°
D	29.39±2.44	34.20±2.63	(4.81±1.32) - 0.0002*	28.25 ±2.28	32.46 ±3.02	(4.18±1.51) - 0.0001*	0.1913
E	33.66±2.46	38.17±2.33	(4.51±2.25) - 0.0001*	31.98±2.63	36.21±2.68	(4.22±1.09) - 0.001*	0.4017
6°	38.68±1.94	40.99±2.22	(2.32±1.20) - 0.0003*	37.01±2.93	39.15±2.64	(2.14±1.22) - 0.0006*	0.857

* using Two-Way Repeated Measures ANOVA
°p<0.05-time treatment interaction; significance indicates that the two treatments over time exhibit a different response; values expressed as Mean ±SD.

TABLE 1 Distribution of mean values by treatment and time.

Materials and methods

2.1. Retrospective comparative study

The sample was selected from the patients' pool of Matteo Beretta, attending his private clinic in Varese. All patients signed a written informed consent. The research protocol complies with the Declaration of Helsinki of 1975, revised in 2000.

2.2 Selected sample

The sample was constituted by 40 children, 20 treated with ZeroExpander® in PEEK (8 females, 12 males) and 20 treated with ZeroExpander® in PA12 (12 females and 8 males).
The mean age of the sample was 7.3 years.

Inclusion Criteria

- early or mixed deciduous dentition;
- transversal maxillary deficit;
- no previous orthopaedic or orthodontic treatment.

Exclusion criteria

- dysmorphias;
- absence of E.

2.3 Intervention

Each patient underwent maxillary expansion therapy with ZeroExpander®, 20 were treated with a milled PEEK device, and 20 with a PA12 molded device. The T0 scans were performed using a 3Shape scanner (3Shape, Copenhagen, Denmark) and the image exported in Standard Triangulation Language file (STL) format. The device was designed on the virtually expanded arch using the 3Shape Dental Designer software (3Shape, Copenhagen, Denmark), and subsequently the related STL file was used to mill ZeroExpander® if it was produced in PEEK, or to print it, if it was produced in PA12. The appliances were bonded to anchorage deciduous teeth using a self/photo bioactive cement (Activa Bioactive Cement, Pulpdent, USA; Transbond Plus, 3M, USA), especially for PA12, or other better performing materials with PEEK (Transbond LR, 3M, USA; Relyx, 3M, USA).

2.4 Comparison

Primary outcome

The primary outcome considered is the quantitative comparison of the transverse diameters of the upper arch between the two study groups. The intraoral scans at T0 and at the end of the treatment were all performed by the same operator MB, with a 3Shape scanner (3Shape, Copenhagen, Denmark). Expansion data were observed at the end of treatment on digital models using Ortho Viewer software (3Shape, Copenhagen, Denmark).

The distance in mm was calculated by measuring the distance between the maxillary contralateral elements, specifically:

- distance between the cusps of the deciduous canines (C);
- distance between the lingual cusp of the first deciduous molars (D);
- distance between the mesial palatal cusps of the deciduous second molars (E);
- distance between the mesial palatal cusps of the first permanent molars (6).

The measurements were performed by SC and MP and from these, the average values were obtained using Excel (Microsoft Corporation, Redmond, WA, USA).

Secondary outcomes

The data analyses the relationship between:

- Male and female patients;
- Anchorage used;
- Set-up.

2.5 Statistical Analysis

A descriptive analysis of the investigated variables was conducted using frequencies and percentages for nominal variables and means and standard deviations for continuous variables. Differences in age and gender between children undergoing PEEK and PA12 treatments were assessed through the χ^2 test and Mann-Whitney test. A Two-Way Repeated Measures ANOVA test was performed to evaluate the statistical significance of differences in means of measurements between the two treatments, at the two observation times. The tests used are two-tailed and applied at a significance level of 5%. Data were processed using the statistical software (StataCorp. 2023., Stata Statistical Software BE: Release 18. College Station, TX: StataCorp LLC).

Results

Primary outcome

The statistical analysis revealed that PEEK treatment led to a statistically significant variation in variables C (p=0.0001), D (p=0.0002), E (p=0.0001), and 6° (p=0.0003). Following the PA12 treatment, significant variations were observed in variables C (p=0.0001), D (p=0.0001), E (p=0.0001), and 6° (p=0.0006). A comparison between the two treatments over time highlighted a different response for variable C, with higher expansion values in the PEEK group (4.08 vs 2.99,

	Total N = 40	PEEK n (%) 20 (50.00)	PA12 n (%) 20 (50.00)	p value
Sex, n (%)[a]				
Male	20 (50.00)	12 (60.00)	8 (40.00)	0.206
Female	20 (50.00)	8 (40.00)	12 (60.00)	
Age, years, mean ± SD[b]	7.41 ± 1.14	7.40 ± 0.96	7.43 ± 1.33	0.898

[a]χ^2 test.
[b]Mann-Whitney test.
p > 0.05, no statistically significant difference between groups.
p < 0.05, statistically significant difference between groups.
Values expressed as absolute frequency, percentage, and Mean ±SD.

TABLE 2 Distribution by gender and age among children in the PEEK and PA12 groups.

	PEEK n (%)			PA12 n (%)		
Anchorage	Achieved Set-Up n (%)	Not achieved Set-Up n (%)	p-value	Achieved Set-Up n (%)	Non achieved Set-Up n (%)	p-value
			0.479			1.00
No	2 (18.18)	0 (0.00)		13 (86.67)	4 (80.00)	
Yes	9 (81.82)	9 (100.00)		2 (13.33)	1 (20.00)	
Total	11 (55.00)	9 (45.00)		15 (75.00)	5 (25.00)	

Using Fisher's Exact test
'No' indicates anchoring that does not include the C values, 'Yes' indicates anchoring that includes the C values.

TABLE 3 Distribution of values achieved in all predetermined Set-Up and anchoring for each treatment.

		PEEK n (%)		PA12 n (%)		p value
SET-UP	N	FAILURE n (%)	SUCCESS n (%)	FAILURE n (%)	SUCCESS n (%)	
4 mm	10	4 (66.67)	2 (33.33)	2 (50.00)	2 (50.00)	0.598
5 mm	20	5 (50.00)	5 (50.00)	9 (90.00)	1 (10.00)	0.051
6 mm	7	0 (0.00)	2 (100.00)	3 (60.00)	2 (40.00)	0.429
8 mm	3	2 (100.00)	-	1 (100.00)	-	-
Total	40	11 (55.00)	9 (45.00)	15 (75.00)	5 (25.00)	

Using χ^2 test or Fisher's Exact test

TABLE 4 Percentage distribution of successes and failures in achieving predetermined Set-Up values by treatment.

p=0.0197). However, variables D (p=0.191), E (p=0.414), and 6° (p<0.865) did not show statistical significance (Table 1).

Secondary outcome

The two groups are homogeneous in terms of age and gender; in the comparison between the two groups, no statistically significant differences emerged for age and gender (Table 2).

The performed anchoring does not show significant differences in achieving the total set-up, whether there is anchoring on the C or not (Table 3).

The percentage distribution of successes and failures in achieving predetermined set-up values by treatment does not show significant differences (Table 4).

Discussion

In cases of allergy or hypersensitivity to metals or to specific chronic or acute pathological conditions such as epilepsy, autism, or vascular problems, which may require periodic magnetic resonance imaging (MRI) or emergency of cranial district, it may not be possible to use traditional and metal fixed expansion devices ("special needs" patients).

In the wake of scientific and clinical research on the slow expansion achievable with Leaf or Self Expander device, the primary objective of this study was to evaluate the expansion effectiveness of a slow and metal-free expansion device, called ZeroExpander®, milled in PEEK or printed in PA12.

The statistical analysis revealed that PEEK treatment led to a statistically significant variation in variables C, D, E and 6°.

Following the PA12 treatment, significant variations were observed in variables C, D, E and 6°. A comparison between the two treatments over time highlighted a different response for variable C, with higher expansion values in the PEEK group. However, variables D, E and 6° did not show statistical significance.

This means that the deciduous intercanine maxillary diameter showed a change equal to the excursion of the E

set-up, which in itself is evidence of an expansion similar to what is sometimes seen in an orthopaedic expansion.

The statistical analysis showed that PEEK and PA12 leads to overlapping results in terms of palatal expansion.

During the bonding procedure, it is necessary that the device is contracted so that it can adhere precisely to the teeth of the upper arch. From a clinical point of view, the cementation of PEEK devices was more complex to avoid detachments, due to his minor flexibility [Paglia et al., 2022]. This first limitation led clinicians to prefer afterwards ZeroExpander® in PA12, because of its greater ease of bonding due to the surface microroughness (Fig. 3 a-f; Fig. 4 a-c).

Indeed, PEEK is best performed for non-active devices such as space maintainers, Nance buttons or small paediatric dental prostheses [Beretta et al., 2022a].

In most cases, the diagnosis and the therapeutic approach at the right time allow to prevent the onset, the accentuation of a defect or even correct the malocclusion early [d'Apuzzo et al., 2023; Quinzi et al., 2023].

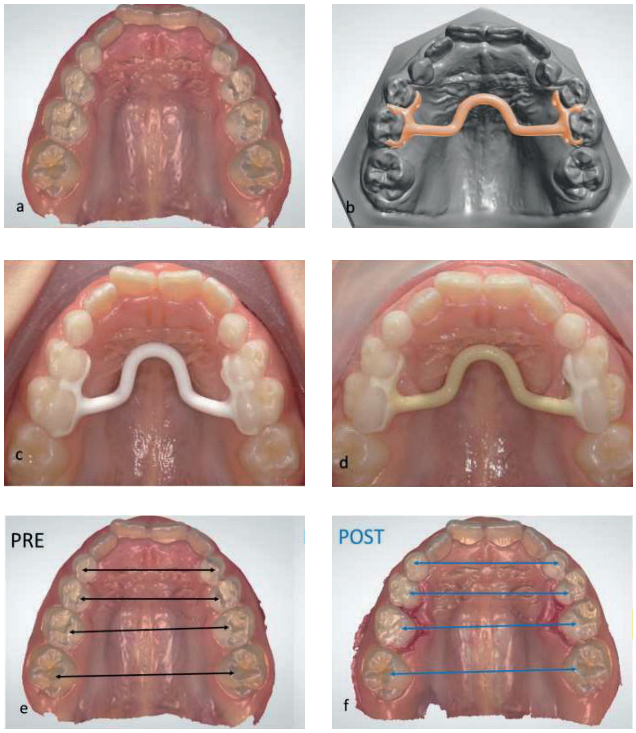

FIG. 1 A: Female of 6.9 years old, with transverse maxillary deficiency; B-C: virtual set-Up, digital design of ZE, ZE in PA12 bonded with anchorage on second and first deciduous molars, D: images of the clinical expansion obtained; D, E, F: comparison between pre and post expansion intraoral scans, on which the measurements for this study were carried out.

The principles are those of child orthopaedics, from the Greek *orthos paidos*, or "straight child" [Paglia and Beretta, 2021]. Transverse maxillary deficit is associated with functional and aesthetic problems. Its correction is easily achievable using rapid maxillary expansion (RME) or slow maxillary expansion (SME) devices [Lanteri et al., 2018].

The literature indicates that rapid and slow expansion leads to comparable clinical outcomes [Agostino et al., 2014; Bucci et al., 2016; Mummolo et al., 2014; Patil et al., 2023].

However, slow expansion has the advantage of being more gentle and more comfortable for the patient who experiences minor pain [Lagravère et al., 2005; Rutili et al., 2022] and it is possible to achieve it without collaboration from the family [Lanteri et al., 2018; Beretta et al., 2019].

Unlike studies conducted by CBCT [Rosa et al., 2016] or by measurements on plaster models [Cozzani et al., 2003], this study performs measurements on intraoral scans. This method was already used for studies conducted by Beretta et al. [2019]. Intraoral scans offer the advantage of not having to subject the young patient to radiographic investigation techniques, as in the case of CBCT, and of eliminating possible inaccuracies and defects due to the use of traditional impression materials before and the creation of the plaster model after, two steps that could lead to dimensional variations also due to the characteristics of the material itself.

This technology applied to paediatric dentistry, allows us to detect a fully accurate impressions of the dental arches, in a few seconds and with absolute comfort for our little patients. Starting from intraoral scan, it is possible to design and create a device that, if properly "trained", can work for the patient and for us in a condition of controlled autonomy.

In this context, the concept of "autonomous driving in paediatric orthodontics" [Beretta and Federici Canova, 2017] is fully inserted, which can begin to be represented by a category of devices, such as the ZeroExpander®, really pre-programmed on the basis of a virtual set-up, made with the latest generation of technopolymers [Beretta et al., 2021] and used to carry out their task without the need for collaboration, neither by the child nor his family, except for an adequate maintenance of oral hygiene at home.

Finally, there is a key aspect to take into consideration: the well-being of the little patient [Beretta et al., 2022b]. If technology runs fast, attention to the well-being of the patient must also be a *concidicio sine qua non* to treatment, especially when we are dealing with children.

It is necessary to create a child-friendly environment, in which the whole team is instructed in the right way: the use of appropriate language and clinical procedures always associated with comfort techniques [Beretta and Federici Canova, 2017, Beretta et al., 2021, Libonati et al., 2018] such as relative analgesia [Arcari and Ferro, 2008; Arcari and Moscati, 2018], ozone or intraoral scans [Beretta et al., 2021].

FIG. 2 A: female of 6.9 years old, with transverse maxillary deficiency, left crossbite and mandibular shift; B: images of the clinical expansion obtained; C: end of paediatric orthodontic treatment after 18 months from the beginning, where, after the expansion, a custom made elastomeric removable appliance was used to accomplish the treatment.

FIG. 1 A: Female of 6.9 years old, with transverse maxillary deficiency; B-C: Virtual set-up, digital design of ZE, ZE in PA12 bonded with anchorage on second and first deciduous molars d: images of the clinical expansion obtained; D, E, F: comparison between pre and post expansion intraoral scans, on which the measurements for this study were carried out.

Precautions that must be implemented especially with special needs patients.

These custom-made and child-friendly devices are fully part of this *modus operandi*, called by the authors "Spa-inspired oral care", borrowing from the Latin phrase *Salus per Aquam* (health through water), to describe this approach to the little patient, aimed to make both the children and the families as comfortable as possible [Beretta et al., 2022b].

Therefore, children are at the centre of our attention as individuals, and the focus is more on "how we do it" rather than "what we do", to meet clinical and diagnostic, but also family needs.

This approach, where applicable, leaves room for a review of the management methods of a paediatric-orthodontic therapeutic management. The maxillary expansion or the control of the "arch shape" can be delegated to a device that thinks for itself, also deciding the quality of expansion, as well as the quantity, after a clinical evaluation (Fig 5 a-b).

The next phase can then be carried out, according to the needs of the therapeutic path, with fixed devices of another type or removable, such as transparent paediatric aligners or elastodontic devices, with different collaboration needs, also designed virtually and tailor-made to achieve individual objectives in a pre-programmed way.

Therefore, "teleorthodontics" will be able to monitor remotely the treatment, thanks to the augmented reality based on Artificial Intelligence, which can allow a controlled reduction of clinical visits, a simplification of ergonomics and organisation for families, freeing up time and space on clinician side for more complex or delicate cases, which certainly require and will still require direct clinical control.

Conclusion

In light of scientific and clinical research on the gradual expansion achievable with the Leaf or Self Expander device, this study evaluates the expansion effectiveness of a slow and metal-free expansion device known as ZeroExpander®. The device is technofactured (CAD-CAT) using either milled PEEK or printed PA12.

Modern orthodontics shows increased demand for metal free, customised and fully digital workflow materials. These kind of appliance, metal free, fully digital and customised, represent the right steps towards the current tailor-made orthodontics.

More clinical research is necessary to explore other materials that can be used for this type of orthodontic appliance, even easier to bond or with specific surface characteristics to simplify oral hygiene.

The concept of autonomous driving in paediatric orthodontics is not only possible, but it is and will be more real and particularly useful than ever if correctly applied.

The ortho-paedo thinking and acting, will increase the range of benefits for all parties involved, but especially for children and their families which, in addition to care and thanks to technology, demand well-being, safety, and comfort.

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