Evaluation of a Novel 3D Printed Space Maintainer Versus the Conventional Stainless-Steel Band and Loop: A Finite Element Analysis and in-Vivo Study

A Thesis Protocol
Submitted to the Faculty of Dentistry, Suez Canal University
for partial fulfillment of the requirements of the Doctorate Degree of
Dental Science in Pediatric Dentistry
Research code: HR1

Submitted By:

Omar Assem Hanafi Hussein Hodhod

B.D.s, Ainshams University (2011),

M.D.Sc. of Pediatric Dentistry, Ainshams University (2021),

Assistant lecturer in Pediatric Dentistry Department, British University in Egypt.

Supervisors:

Title	Name	Job Title	University	Signature
Dr.	**Mohammed Sherif Mohammed Salah El Din Hassan Farag**	Professor of Pediatric Dentistry, Preventive Dentistry, and Dental Public Health.	Suez Canal University	
Dr.	**Shaimaa Mohammed Mahfouz Omer**	Associate Professor of Pediatric Dentistry, Preventive Dentistry, and Dental Public Health.	Suez Canal University	
Dr.	**Yousra Samir Mohammed Helmy**	Lecturer of Pediatric Dentistry, Preventive Dentistry, and Dental Public Health.	Suez Canal University	
Dr.	**Islam Tarek Abbas Hassan**	Professor of Orthodontics	The British University in Egypt	

Faculty of Dentistry
Suez Canal University
Approval Date 16 May 2023

Faculty of Dentistry

"Thesis Research Protocol"

Student Name:	Omar Assem Hanafi Hussein Hodhod	**Student ID:**	29002070101736

Submission Date:	3/2/2023

Degree:	☐**M.D.Sc.**	☒ **D.D.Sc.**	☐ **Ph.D.**

Department:	Pediatric Dentistry, Preventive Dentistry, and Dental Public Health.
Thesis Title in English:	Evaluation of a Novel 3D printed Space Maintainer Versus the Conventional Stainless-Steel Band and Loop: A Finite Element Analysis and in-Vivo Study.

1. Abstract

Introduction: Space maintenance is recommended in most cases after primary molar loss to avoid or decrease malocclusions in the future; the current gold standard for single deciduous molar loss is the metal Band and loop. Among their disadvantages are bad aesthetics, gingival impingement, and rotation or tilting of abutment teeth; to improve on these faults and decrease lab time and impression discomfort, an optical impression will be taken, and a novel 3D printed space maintainer with a novel design will be tested.

Aim: This study evaluates the simulated and clinical performance of a new 3D-printed material versus the metal band and loop.

Methodology: The study will consist of two stages.

The first stage will be a finite element analysis using two different 3D printing resins to discover which 3D printing resin has superior properties and validate the novel design for a single tooth space maintainer.

The second stage will be a split-mouth Randomized Controlled trial using a 3D Printed Resin space maintainer versus the conventional Band & Loop. The study will be held on 26 newly extracted primary molar single tooth areas in 13 patients over twelve months.

This study will measure clinical success/failure, space loss, rotations, gingival and plaque index, and patient pain and satisfaction.

2. Introduction and Background

The primary dentition significantly influences the child's growth, occlusal relationships, and dentofacial structures **(Bhujel *et al.*, 2016)**. Early deciduous tooth loss brought on by caries, trauma, ectopic eruption, and other factors can result in undesired primary or permanent tooth movements where arch length is reduced **(Shalan and Abo Bakr, 2018).** Deficient arch length may result in crowding, rotations, ectopic eruption, crossbite, excessive overjet, excessive overbite, and unfavorable molar relationships. In addition, this arch-length deficiency may cause malocclusions or worsen existing malocclusion **(Özüdoğru and Tosun, 2021)**.

The most efficient technique to stop future malocclusion due to tooth loss is to install a space maintainer that is efficient, long-lasting, and affordable **(Watt *et al.*, 2018)**. The optimal space maintainer depends on the child's stage of dental development, dental arch, associated missing teeth, occlusion, patient's age, and capacity to comply with and tolerate an appliance **(Ramakrishnan *et al.*, 2019)**.

The classic stainless-steel band & Loop space maintainer is the most common fixed space maintainer for single tooth loss**(Watt *et al.*, 2018)**. The BL space maintainer is affordable, requires little chair time, and is easily adaptable to changing dentition **(Khanna *et al.*, 2015)**.

However, because of the laboratory work, manufacturing metal BL consumes time. Other drawbacks include wedging into gingival tissues, cement deterioration, inadequate aesthetic quality, and inability to stop the rotation and tilting of abutment teeth **(Dhanotra and Bhatia, 2021)**.

Due to these drawbacks and the growing popularity of cosmetic dentistry, innovative materials, and designs for space maintainers were developed, which include fiber-reinforced composite, directly bonded, and prefabricated space maintainers. **(Mittal *et al.*, 2018)**.

The most popular form of additive manufacturing 3D Printing finds new uses in dentistry daily; it can generate a tangible item of almost any shape based on a digital 3D model **(Methani *et al.*, 2020)**. This technology uses a variety of machines and biocompatible materials **(Vasamsetty *et al.*, 2019)**.

The introduction of Digital additive (3D Printing) and subtractive manufacturing (CAD/CAM) in dentistry has raised the bar for finding a replacement for the shortcomings of the metal band and loop space maintainers today. In addition, different novel materials and uses are being discovered as digital manufacturing is more accessible to dentists **(Rekow, 2020)**.

Numerous dental institutions and laboratories now have different 3D printing technology systems available. Due to its technological

benefits in precision, speed, and quality, it is becoming an alternative to famous traditional treatment options **(Methani *et al.*, 2020)**.

The ability to create accurate custom appliances without needing impression taking or laboratory work is a benefit of adopting 3D scanning and Printing to create space maintainers. In addition to saving cost and time, printing the appliance as a mono-block reduces the likelihood of breakage, which lowers the risk of appliance failure **(Muta *et al.*, 2020)**.

Numerous 3D printing techniques are used in the dental field, such as stereolithography (SLA), digital light projection (DLP), polyjet or multijet, inkjet printing, fused deposition modeling (FDM), and powder bed fusion. The differentiating factor between these techniques is the materials used and how the layers are deposited to generate the 3D object **(Oberoi *et al.*, 2018)**.

Many materials are available for 3D Printing, such as polymers, metals, ceramics, and composites .Polymers represent the most common 3D printing material used by dental 3D printers out of all the alternatives .These polymers come in various shapes, including filament, powder, and resin **(Javaid and Haleem, 2019)**.

Band and loop space maintainer made via 3D Printing has the advantages of reducing human error, lengthy laboratory procedures, and chair side time.

However, there needs to be more clinical proof that these new, novel SMs are more effective than their traditional counterparts ***(Khanna et al.*, 2021)**.

Since the 3D-Printed resin materials used for orthodontic splints, Crowns, and bridges were tested in numerous studies before**(Prpic *et al.*, 2019; Shin *et al.*, 2020; Wang *et al.*, 2019)**, while no study up till now clinically evaluates a resin 3D-printed space maintainer, so this study aims to evaluate the simulated and clinical performance of a resin 3D-printed space maintainer versus the conventional band and loop space maintainer.

3. Research Question:

How does the novel resin 3D printed space maintainer perform in Finite element analysis and its clinical success compared to the conventional Band & Loop space maintainer?

4. Research Hypothesis, Aim, Objectives & Expected Outcomes

a. Hypothesis

Null Hypothesis:

There is no significant difference in Finite element analysis or clinically between the resin 3D printed space maintainer and the conventional Band and Loop.

Alternative Hypothesis:

The resin 3D printed space maintainer shows a significant difference in Finite element analysis and clinical success than the conventional Band and Loop.

b. Aim

This study aims to evaluate the simulated and clinical performance of a resin 3D-printed space maintainer versus the conventional band and loop space maintainer.

c. Objectives

This study aims to evaluate the simulated and clinical performance of a resin 3D-printed space maintainer versus the conventional band and loop space maintainer though these two stages :

1. **Finite Element Analysis (simulated performance)**

The final choice of design and materials for the clinical tests will be chosen after finding the most success in the following tests:

i. Maximum stress before plastic deformation.
ii. Fracture resistance.
iii. Stress distribution.
iv. Mechanical behavior and cyclic fatigue resistance.
v. Moment or rotation of the device

2. **An *In Vivo* Analysis**

Clinical comparison using the optimal design and material for resin 3D printed Space maintainer decided by the Finite Element Analysis vs. conventional Band and loop with one year of follow-up.

Evaluated bypass or Fail:

i. Cement loss / Debonding.
ii. Fracture of the space maintainer.
iii. Caries of abutment teeth.

Measured outcomes:

iv. Gingival index of abutment teeth.
v. Plaque index of abutment teeth.
vi. Space Change measured by software.

vii. Rotation of abutment teeth measured by software.

viii. Wong-Baker Faces Scale to check: Patient pain experience, patient satisfaction, and mastication experience.

d. Expected Outcomes

For the simulated test:

Finite element analysis will show that the novel design and 3D printing resin which are suitable for use as a single tooth space maintainer.

For the clinical tests:

One-year clinical follow-up will show that the novel design of the resin 3D printed resin has a success rate comparable to or better than the conventional band and loop space maintainer concluding if it is suitable for use as a single tooth space maintainer.

5. Research Design and Methods

I. Materials

Materials used in this study are in table 1.

Table (1):tradename , composition and Manufacturers

Trade name	Material composition	Manufacturer
Ortho-rigid C&B MFH	Monomer based on acrylic esters 3D printing material	Vertex-Dental B.V., Netherlands
G-CEM™ Capsule Self-Adhesive Luting Cement in Capsules	Resin Cement	G.C. Corporation, Tokyo, Japan
Cavex Cream Alginate	Alginate material	Cavex, Holland.
Molar bands	Ready-made molar Bands	American Orthodontics. Washington Avenue, USA
Loop	A 0.9 mm (0.036 inches) stainless steel wire	
Rapidshaper 3D printer	Resin 3D printer	Vertex-Dental B.V., Netherlands
TRIOS®3, 3Shape intraoral scanner	Intraoral scanner	3shape, Copenhagen, Denmark
Pedo jaw model 6-year-old dentition	Soft Gingiva Jaw Model	NISSIN DENTAL PRODUCTS INC. *Kyoto 601-8469 JAPAN*

II. Methods

II.1. Study setting

This study will be composed of 2 different stages:

Stage I: an *in vitro* 3D finite element analysis study.

A Finite element analysis simulating the mechanical stresses of a child's functioning oral cavity will be tested to find the most optimal design that will accommodate stresses and strains that will be distributed on the material. In addition, two types of 3D printing resins will be compared to the conventional stainless-steel stage at the Faculty of engineering labs, British University in Egypt **(Ozkalayci and Yetmez, 2018; Sabeti *et al*., 2020)**.

Evaluate and find the optimal design suitable for a resin space maintainer, then test Two different resin materials' properties vs. the conventional Band and loop using the finite element method simulating the forces in the oral cavity.

Stage II: an *in vivo* study

A randomized controlled trial split-mouth design will be conducted in the Pediatric Dentistry Department Outpatient Clinic, Faculty of Dentistry, Suez Canal University. Each child will have an indication for a single-tooth space maintenance to maintain space until the eruption of the successor or shedding of abutment teeth. The calculated sample size will be mentioned later.

II.2.Sample selection:

Children will be considered eligible according to the following inclusion and exclusion criteria:

II.2.a.Inclusion Criteria: (Kamki *et al*., 2021; Khalaf *et al.*, 2022)

(1) Apparently healthy children.
(2) Children of both genders aged 6-9 years old.
(3) Guardians agree to join the study and sign the informed consent.
(4) Recent premature loss of primary first molars or having primary first molars indicated for extraction on both sides.
(5) Sound buccal and lingual surfaces of abutment teeth (primary second molar and primary canine).
(6) Good oral hygiene.
(7) Absence of radiographic periapical pathology related to the abutment teeth.
(8) Absence of abnormal occlusal conditions such as posterior crossbite, deep bite, and scissor bite.
(9) All the indications for a band and loop space maintainer are met.

II.2.b.Exclusion criteria: (Kamki *et al*., 2021; Khalaf *et al.,* 2022)

(1) The patient is not able to attend regular follow-up visits.
(2) Allergic condition to any of the used materials.

II.3.Sample Grouping:

1. **Finite element analysis groups:**

- **Group A:** 3D printing Resin I: Orthodontic Rigid Resin.
- **Group B:** 3D Printing Resin II: Crown and bridge resin.
- **Group C:** Stainless steel Band & Loop space maintainer

2. The *in-vivo* groups:

The randomized controlled trial Randomization will occur by a coin flip which will be done for each patient to decide which side of the mouth is allocated to which group of the following:

- Group I: Resin 3D printed space maintainer (Material and design decided by the Finite Element Analysis).
- Group II: Band and loop space maintainer.

II.4.Study Procedures:

a) Finite Element Analysis(Ozkalayci and Yetmez, 2018; Sabeti *et al., 2020)*

- A Nissin pediatric training model will have its lower primary second molars removed.
- An impression will be acquired with the intra-oral scanner.
- A stainless-steel band and loop will be constructed and scanned.
- A space maintainer will be designed with resin 3D printing in mind with the 3Shape appliance designer software.
- Mouth and space maintainer model data will be exported to the FEA lab, Faculty of Engineering, British University in Egypt.
- Discretization and meshing of the models will be done.
- Boundary conditions will be applied.
- Material properties like Young's modulus of elasticity and poisons ratio will be added.
- Forces of occlusion will be added to the magnitude.

b) Clinical Procedures

All participant's guardians will have the procedures explained to them, then they need to read and sign/stamp the informed consent (appendix1), and the participants will have a brief explanation and will check the informed Assent.

Each side will be treated with a different group. Both impressions will be carried out at the same visit and the delivery of both groups will be done at the consecutive visit.

- **Stainless steel Band and Loop side:**

(a) A stainless-steel band appropriate for the abutment tooth distal to the space will be selected.

(b) The Band will be seated on the tooth, contoured to adapt closely to the abutment teeth.

(c) A complete arch impression using alginate impression material.

(d) A metal loop fabricated in the lab is soldering to the Band.

(e) Before cementation, the position of the loop will be checked, and abutment teeth will be cleaned with a polishing paste.

(f) Isolation will be acquired using cotton rolls and low-volume suction.

(g) G-Cem self-etching cement will be used to cement the Space maintainer.

- **Construction of 3D printed space maintainer:**

(a) Proper isolation using a cheek retractor and suction apparatus will be needed.

(b) The lower arch will be scanned using a distance ranging from 0-5mm to obtain an optical impression.

(c) The. stl File of the model will be imported to the 3Shape Appliance Designer Program

(d) The. stl File will also be imported to the 3Shape Ortho analyzer for space analysis and comparison.

(e) The Space Maintainer will be designed.

(f) The Space maintainer will be printed on the Rapidshape resin 3D printer.

(g) The device will be washed and cleaned from excess resin.

(h) Isolation using cotton rolls and low-volume suction will be done in the patient's mouth.

(i) G-Cem self-etching cement will be used to cement the device.

II.5.Methods of Evaluation

The patients will be recalled at 3, 6, 9, and 12 months to be evaluated for:

a) Success and failure rate(Deshpande *et al*., 2018)

1. Cement loss / Debonding.

   Any cement or debonding loss will be considered a failure if the space maintainer becomes loose.

2. Fracture of the SM.

   If the SM is broken, fractures will be regarded as a failure.

3. Caries of abutment teeth.

   Any caries of the abutment teeth will be regarded as a failure.

b) The plaque index(Table 2) and the Gingival index (Table 3) of the abutment teeth as by Sillness and Loe(Özüdoğru and Tosun, 2021).

Plaque index (PI) (Table 2) and Gingival index (GI)(Table 3), as described by Sillness and Loe, will be used to monitor the gingival health and plaque accumulation at three scoring sites for each patient:

(**A)** Banded or anchor abutment tooth (distal tooth).

(M) Mesial abutment tooth.

(C) Control molar tooth in the opposing arch.

A periodontal probe will be used before the placement of space maintainers and in follow-up visits. Each tooth will be examined around each tooth from the mesial, distal, buccal, and lingual areas. After scoring according to the table, it will be divided by 4 to give the score for the tooth.

Table (2) Evaluation of the plaque deposits according to the (PI) described by Silness and Loe (1964):

Score	Criteria for the plaque Index
0	No plaque
1	A film of plaque adhering to the free gingival margin and adjacent area of the tooth. The plaque may be seen in situ only after the disclosing agent or using the probe on the tooth surface.
2	Moderate accumulation of plaque in the gingival sulcus.
3	An abundance of soft matter within the gingival pocket and/or on the tooth and gingival margin.

Table (3) Evaluation of the gingival health according to the (GI) described by (Loe and Silness, 1963):

Score	Criteria for the Gingival Index
0	No inflammation.
1	Mild inflammation: slight redness, slight edema, no bleeding on probing.

2	Moderate inflammation: redness, edema, glazing, bleeding on probing.
3	Severe inflammation: marked redness and edema, ulceration, and a tendency of spontaneous bleeding.

c) Measurements of Space difference before and after follow-up, measurements of any rotations:

The ability of the space maintainer to maintain the space during the follow-up period will be evaluated by the linear and spatial relationships between the two abutment teeth.

These measurements will be done on initial digital impressions and the follow-up impressions using the 3Shape Orth Analyzer software. The spatial measurements will demonstrate whether there was any rotating movement of teeth and any space loss.

- ***Space Change:***

After the follow-up period, another scan will be made of the arch, and the 3Shape ortho-analyzer software will measure the space difference between the abutment teeth.

- ***Rotations:***

The arch scans will be overlayed to calculate any angular changes during the space maintenance phase.

d) Pain rating and Patient Satisfaction

The patients will receive a pain rating survey during insertion and each visit.

Wong–Baker Faces Scale Fig (1) will be given to the patients on the first and the last visit to check patient satisfaction will be carried out **(Ahmad *et al.*, 2018)**.

The patient will be asked to rate the following:

1. **Pain Experience**
2. **Ease of mastication on each side.**
3. **General satisfaction**

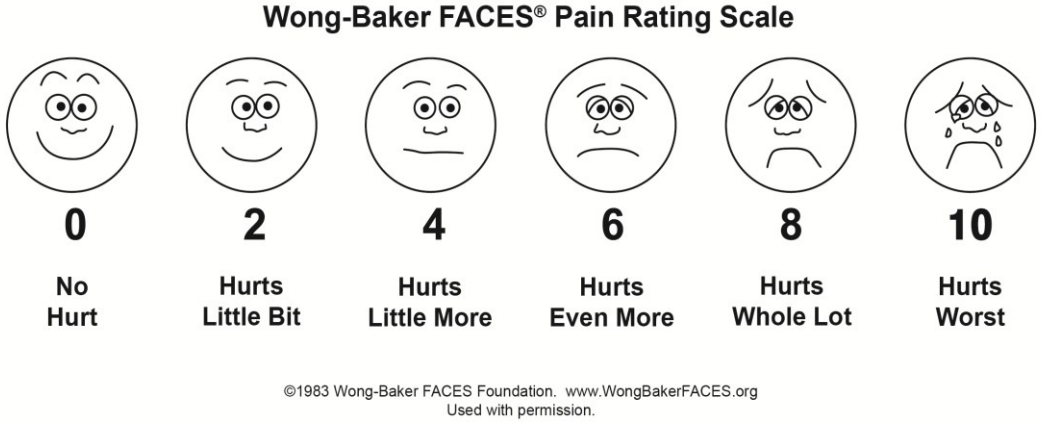

Figure 1 Wong-Baker FACES pain scale

6. Statistical Plan

6.1.Sample size calculation:

The sample size was calculated using the G*power 3.1.9.2 Software based on success rate data of conventional band-and-loop space maintainers from a previous study**(Tunc *et al.*, 2012)**, reporting a 12-month success rate of 90% compared to 20% of fiber-reinforced composite space maintainers. The power of the z-test was calculated to be 95%, using a two-tailed significance level of 5%. The calculated

sample size will be 10 primary second molars per group for a total of 20. The sample size will be increased by 30% to 13 primary molars per group (26 in total) to compensate for dropouts.

6.2.Statistical Analysis

All the data will be calculated, tabulated, and analyzed using a suitable statistical test. In addition, a normality test (Kolmogorov-Smirnov) will be done to check the normal distribution of the samples.

Statistical analysis will be performed using the computer program SPSS software for windows version 26.0 (Statistical Package for Social Science, Armonk, NY: IBM Corp) at significant levels 0.05 (P- Value ≤0.5).

i. Descriptive data:

Descriptive statistics will be calculated as Mean ± Standard deviation (SD), range (Max-Min).

ii. ANOVA - test or Kruskal-Wallis test (*According to the types of data*)

Two ways ANOVA (Analysis of variance) or ANOV with repeated measures will be used to compare the groups and period interval under study. Post hoc tests will be performed to evaluate any statistical significance among the groups. P value < 0.05 is considered to be statistically significant.

iii. T-test or Mann-Whitney test (*According to the types of data*)

Independent Student's T-test or Mann-Whitney will be performed for the pairwise comparison in the three groups at P value < 0.05.

7. Ethics consideration

For Clinical Studies (*In - vivo Studies*)

The present research will be conducted after the approval of the Research Ethics Committee (REC) of the Faculty of Dentistry, Suez Canal University. It will be conducted on *13 children* in need of a bilateral single space maintainers. The researcher will undertake ethical considerations regarding patient well-being and confidentiality and informed written consent will be signed by the subjects' guardian before commencing the study explaining all clinical examinations, procedures, and follow-ups. (Appendix 1)

8. Time Plan

- **Starting time:** after faculty approval of the protocol.
- **Ending time:** after 24 months

Activity/Month	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**	**21**	**22**	**23**	**24**
Finite element analysis	☒	☒	☒	☒	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Patient selection and material collection	☐	☐	☐	☐	☒	☒	☒	☒	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Follow-up	☐	☐	☐	☐	☐	☐	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒	☐	☐	☐	☐
Statistics	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☒	☐	☐	☐
Thesis writing	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☒	☒	☒	☐
Collection of thesis	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☒

9. Research the Estimated Budget in Egyptian pounds and United States dollars

Supplementary						Publications	**Total**
histopathology	drugs/ Lab chemicals	Lab-investigations	Software	Material	Others (mention)		
		Finite element analysis 1500 USD	University license	2500 USD	Metal Band and loop lab work: 7500	2000 USD	6000 USD + 7500EGP

10. References

Ahmad, A., Parekh, S., and Ashley, P., (**2018**). 'Methods of space maintenance for premature loss of a primary molar: a review'. *European Archives of Paediatric Dentistry* Vol19, pp311–320.. https://doi.org/10.1007/s40368-018-0357-5

Bhujel, N., Duggal, M., Saini, P., and Day, P., (**2016**). 'The effect of premature extraction of primary teeth on the subsequent need for orthodontic treatment'. *European Archives of Paediatric Dentistry* Vol17, pp423–434.. https://doi.org/10.1007/s40368-016-0247-7

Deshpande, S., Bendgude, V., and Kokkali, V., (**2018**). 'Survival of Bonded Space Maintainers: A Systematic Review'. *International Journal of Clinical Pediatric Dentistry* Vol11, pp440–445.. https://doi.org/10.5005/jp-journals-10005-1554

Dhanotra, K., and Bhatia, R., (**2021**). 'Digitainers—digital space maintainers: A review'. *International Journal of Clinical Pediatric Dentistry* Vol14, ppS66–S72.. https://doi.org/10.5005/jp-journals-10005-2040

Javaid, M., and Haleem, A., (**2019**). 'Current status and applications of additive manufacturing in dentistry: A literature-based review'. *Journal of Oral Biology and Craniofacial Research* Vol9, pp179–185. https://doi.org/10.1016/j.jobcr.2019.04.004

Kamki, H., Kalaskar, R., Balasubramanian, S., Badhe, H., and Kalaskar, A., (**2021**). 'Clinical effectiveness of fiber-reinforced composite spacmaintainer and band and loop space maintainer in a pediatric patient: A systematic review and meta-analysis'. *International Journal of Clinical Pediatric Dentistry* Vol14, ppS79–S90.. https://doi.org/10.5005/jp-journals-10005-2044

Khalaf, K., Mustafa, A., Wazzan, M., Omar, M., Estaitia, M., and El-Kishawi, M., (**2022**). 'Clinical effectiveness of space maintainers and space regainers in the mixed dentition: A systematic review'. *Saudi Dental Journal* Vol34, pp75–86.. https://doi.org/10.1016/j.sdentj.2021.09.025

Khanna, P., Mittal, S., and Sunda, S., (**2015**). '"Keep My Space"- A Review Article'. *International Journal of Oral Health Dentistry* Vol1, pp11–15.

Khanna, S., Rao, Di., Panwar, S., Pawar, B., and Ameen, S., (**2021**). '3D Printed Band and Loop Space Maintainer: A Digital Game Changer in Preventive Orthodontics'. *Journal of Clinical Pediatric Dentistry* Vol45, pp147–151.. https://doi.org/10.17796/1053-4625-45.3.1

Methani, M., Cesar, P., de Paula Miranda, R., Morimoto, S., Özcan, M., and Revilla-León, M., (**2020**). 'Additive Manufacturing in Dentistry: Current Technologies, Clinical Applications, and Limitations'. *Current Oral Health Reports* Vol7, pp327–334.. https://doi.org/10.1007/s40496-020-00288-w

Mittal, S., Sharma, A., Sharma, A., Gupta, K., Gaur, A., and Pathania, V., (**2018**.) 'Banded versus Single-sided bonded space maintainers: A Comparative Study'. *Indian Journal of Dental Sciences* Vol10, pp29.. https://doi.org/10.4103/IJDS.IJDS_76_17

Muta, S., Ikeda, M., Nikaido, T., Sayed, M., Sadr, A., Suzuki, T., and Tagami, J., (**2020**). 'Chairside fabrication of provisional crowns on FDM 3D-printed PVA model'. *Journal of Prosthodontic Research* Vol64, pp401–407.. https://doi.org/10.1016/j.jpor.2019.11.004

Oberoi, G., Nitsch, S., Edelmayer, M., Janjic, K., Müller, A.S., and Agis, H., (**2018**). '3D printing-Encompassing the facets of dentistry'. *Frontiers in Bioengineering and Biotechnology* Vol6, pp1–13.. https://doi.org/10.3389/fbioe.2018.00172

Ozkalayci, N., and Yetmez, M., (**2018**). 'New Design for an Adjustable Cise Space Maintainer'. *BioMed Research International* Vol2018.. https://doi.org/10.1155/2018/5434609

Özüdoğru, S., andTosun, G., (**2021**). 'Survival and clinical evaluation of various space maintainers used for early primary tooth loss'. *International Dental Research* Vol11, pp222–227.. https://doi.org/10.5577/intdentres.2021.vol11.suppl1.32

Prpic, V., Slacanin, I., Schauperl, Z., Catic, A., Dulcic, N., and Cimic, S., (**2019**). 'A study of the flexural strength and surface hardness of different materials and technologies for occlusal device fabrication'. *Journal of Prosthetic Dentistry* Vol121, pp955–959.. https://doi.org/10.1016/j.prosdent.2018.09.022

Ramakrishnan, M., Dhanalakshmi, R., and Subramanian, E., (**2019**). 'Survival rate of different fixed posterior space maintainers used in Paediatric Dentistry – A systematic review'. *Saudi Dental Journal* Vol31, pp165–172.. https://doi.org/10.1016/j.sdentj.2019.02.037

Rekow.D., (**2020**). 'Digital dentistry: The new state of the art — Is it disruptive or destructive?'. *Dental Materials* Vol36, pp9–24.. https://doi.org/10.1016/j.dental.2019.08.103

Sabeti, A., Karimizadeh, Z., and Rafatjou, R., (**2020**). 'Maximum equivalent stress induced and the displacement of the developing permanent first molars after the premature loss of primary second molars: A finite element analysis'. *Dental and Medical Problems* Vol57, pp401–409.. https://doi.org/10.17219/DMP/122041

Shalan, H., and Abo Bakr, R., (**2018**). 'Oral Health Status of Preschool Children in Egypt' Vol2, pp67–72.

Shin, W., Kim, .E., Choi, J., Shin, H., Nam, E., Shim, S., and Lee, K., (**2020**). 'Evaluation of the color stability of 3d-printed crown and bridge materials against

various sources of discoloration: An in vitro study'. *Materials* Vol13, pp1–13.. https://doi.org/10.3390/ma13235359

Tunc, E. Sen, Bayrak, S., Tuloglu, N., Egilmez, T., and Isci, D., (**2012**). 'Evaluation of survival of 3 different fixed space maintainers'. *Pediatric Dentistry* Vol34, ppe97-102.

Vasamsetty, P., Pss, T., Kukkala, D., Singamshetty, M., and Gajula, S., (**2019**). '3D printing in dentistry - Exploring the new horizons'. *Materials Today: Proceedings* Vol26, pp838–841.. https://doi.org/10.1016/j.matpr.2020.01.049

Wang, W., Yu, H., Liu, Y., Jiang, X., Gao, B., (**2019**). 'Trueness analysis of zirconia crowns fabricated with 3-dimensional printing'. *Journal of Prosthetic Dentistry* Vol121, pp285–291.. https://doi.org/10.1016/j.prosdent.2018.04.012

Watt, E., Ahmad, A., Adamji, R., Katsimbali, A., Ashley, P., and Noar, J., (**2018**). 'Space maintainers in the primary and mixed dentition – a clinical guide'. *British Dental Journal* Vol225, pp293–298.. https://doi.org/10.1038/sj.bdj.2018.650

11. Appendices

Suez Canal University

Faculty of Dentistry

Research Ethics Committee (REC.)

Investigator Application Form

1-Name of researcher: Omar Assem Hanafi Hodhod

2-Name of Department: Pediatric Dentistry and public health

3-Adress of researcher: 16 Ahmed El Zomor Street, Nasr City, Cairo, Egypt

a- Email:omarhodhod@gmail.com
b- Phone number:01006688484

1- Name (s) of Co-investigator (s):
Dr. Mohammed Sherif
Dr. Shaimaa Mahfouz
Dr. Islam Tarek

5- Grade of protocol:

*M.Sc. ( ) *Ph.D. ( ) *Doctorate degree (D.Sc.) (✓) *Other ( )

*Domestic ( ) *Multi-Centre within Egypt (✓) *International ( )

6- Title of the research: Evaluation of a Novel 3D printed Space maintainer versus the traditional metal Band and Loop: An in-Vivo Study.

7-Type of the research:

*Drug trial ( ) *Surgical technique ( ) *Investigative technique (✓)

*Devise study ( ) *Survey study ( ) *Blood sampling ( )*Review of old records ( )

8-Subjects of research:

*Children (< 18 years): (✓) *Adults (>18 years) ( )

* Vulnerable groups (yes) or (no): The patients' ages range from 6-8years old

.-1-

Suez Canal University

Faculty of Dentistry

Research Ethics Committee (REC.)

9-Request is being made to ***waive***(give-up) informed consent: Yes: ( ) No: (✓)

If yes, please explain why?

10- The research is for the good of society: Yes: (✓) No: ( )

11-Study design:

a-Phase type I: ( ) II: ( ) III: ( )

b-Randomization: Yes: (✓) No: ( )

c-Placebo: Yes: ( ) No: ( )

d-Genetic sampling: Yes: ( ) No: (✓)

e-Other: Yes: ( ) No: ( )

12-Facilities for the research are available: Yes: (✓) No: ( )

13- List the risks of the study: loss of the space maintainer, breakage of the space maintainer, caries of the abutment teeth, and gingival inflammation.

14- List the potential benefits, if any, to the subjects: Free treatment, better aesthetics space maintenance, prevention of abutment caries, tilting, and rotation.

15-Are the risks reasonable to the potential benefits to the subjects, if any, or to the knowledge to be gained? Yes: (✓) No: ( )

16-Privacy and confidentiality of subjects are assured. Yes: (✓) No: ( )

17-The subject of the research could quit at any time without penalty or loss of any benefits to which they would otherwise be entitled. Yes: (✓) No: ( )

Signature of the principal investigator Date:

Omar Assem Hanafi Hussien Hodhod 2/3/2023

Suez Canal University
Faculty of Dentistry
Scientific Research Ethics Committee

Informed Consent Form for Medical Research on Volunteer Participants

Participant Name (Patient): ..... Gender:.....

Age: ..... Date of Birth:.....

1. Research Title:

Clinical Evaluation of a Novel 3D-Printed Space Maintainer Compared with Conventional Space Maintainers

2. Scientific Background and Research Objectives:

This study aims to introduce an innovative 3D-printed space maintainer design and compare it with conventional band-and-loop space maintainers through the following parameters:

Clinical performance of the 3D-printed space maintainer versus conventional band-and-loop space maintainers over a specified period.

3. Detailed Research Procedures:

- Research Duration & Location: 24 months at Pediatric Dentistry Outpatient Clinics, Faculty of Dentistry, The British University in Egypt.

- Number of Participants: 13 (patients and healthy volunteers)

Inclusion Criteria: Children must meet all of the following:

- Aged 6-9 years
- Experienced premature loss of primary molars
- Sound adjacent teeth (mesial and distal to edentulous space)

Exclusion Criteria: Children will be excluded if they have:

- Poor oral hygiene
- Systemic diseases or medical conditions that could complicate treatment
- Dental caries on adjacent teeth (mesial and distal to edentulous space)

4. Research Procedures:

- Your child's participation is voluntary
- After examination at the Pediatric Dentistry Clinic to identify non-restorable primary molars and necessary radiographs:

Tel:01006688484 E-mail: omar.hodhod@bue.edu.eg

1. Dental impressions will be taken

2. Two space maintainers will be placed:

- - Conventional metal band-and-loop on one side
- - Novel 3D-printed device on the contralateral side
- Placement will require two visits
- Follow-up appointments at 3, 6, 9, and 12 months

Expected Research Benefits:

- - Advancements in less painful pediatric dental treatments

Direct Participant Benefits:

- - Maintenance of space for permanent tooth eruption

Scientific/Indirect Benefits:

- - Development of improved treatment protocols

5. Potential Risks:

Fracture or debonding of space maintainers
Possible gingival inflammation

6. Compensation for Complications:

Any complications will be fully treated at no additional cost

7. Alternatives to Participation:

Standard conventional treatment will be provided if you decline participation

8. Confidentiality:

Your information will remain strictly confidential and accessible only to the principal investigator. You will receive study results and any health-related findings.

9. Right to Withdraw:

You may withdraw at any time without penalty or explanation

10. Biological Samples:

Any collected samples will not be used for other research

Tel:01006688484 E-mail: omar.hodhod@bue.edu.eg

Suez Canal University
Faculty of Dentistry
Scientific Research Ethics Committee

11. Contact Information:

Principal Investigator: Omar Assem Hanafy Haddad
Phone: 01006688484
Alternate Contact: Dr. Shaimaa Mohamed Mahfouz Omar
Phone: 01222328727
Ethics Committee Chair: ..... Phone:.....

I confirm that I have read, understood, and consent to the research procedures described above.

Participant in Research	Principal Investigator
Name:	Omar Assem Hanafy Hussein Haddad
Signature:	Signature: .....
(Fingerprint):	Date: .....

Note: Volunteers are entitled to a copy of this consent form

Research Classification:

☐ Master's Thesis Research

☑ PhD Thesis Research

☑ Unfunded Research

☐ Funded Research Project
Funding Agency: .....

Approved by Scientific Research Ethics Committee on: .....

This approval is valid until: .....

Committee Chair Committee Seal