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Assessing the impact of two treatment methods for primary molars on

gingival health and oral health related quality of life of patients

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Abstract

The present study aimed to investigate the effect of both Stainless-steel crowns and band and loop space maintainers on the gingival health around the primary molars and to evaluate the Oral Health Related Quality Of Life of both treatment modalities on the patients. This study included two equal groups of patients, the first Group (Stainless-steel crowns) and the second Group (space maintainers). Assessment of Gingival Health of the teeth was done in both groups using the Gingival index described by Loe and Silness, while the assessment of oral health related quality of life for the patients was done using the scale of oral health outcomes (SOHO-5). There was no significant difference between both groups regarding different demographic and baseline characteristics (p>0.05). Regarding the Gingival health, at baseline, the Stainless-steel crown group had significantly higher GI value than the Space maintainer group (p=0.004), and there was a significant reduction in GI starting from 6 months to the end of the follow-up interval (p<0.001), while for Space maintainer group, the value increased after baseline (p<0.001). As for the patient satisfaction, at baseline, the Stainless steel crown group had significantly higher values (p<0.05). After 18 months, there was no significant difference between both groups (p=0.081). It was concluded that the gingiva around the band of the band & loop space maintainer showed high gingivitis than that around the stainless-steel crowns. OHrQoL measures were poor on the site of space maintainers.

Keywords: Stainless-steel crowns, primary molars, gingivitis, space maintainers, quality of life.

Full length article *Corresponding Author, e-mail: Heba.Elsayed@fue.edu.eg

1. Introduction

Dental caries remains the most prevalent disease in humans, and is the most common chronic disease in children worldwide1. The prevalence of dental caries increases in many countries, including Egypt. About 70% of Egyptian children have some untreated caries experience as reported by a nationwide survey funded by the World Health Organization (WHO)[2]. The impacts of dental caries may include school absences, reduced self- esteem, impaired speech development, sleeping difficulties, and inadequate diet which in turn affect the Oral Health Related Quality of Life. Therefore, preservation of primary teeth with multiple approaches is one of the major concerns for pediatric dentists [3]. Primary teeth are a valuable asset of a child, and they play a vital role in mastication, phonetics, and esthetics, and they also serve as a space maintainer. Extraction of teeth before the indicated time of exfoliation can lead to space loss for the eruption of their permanent successor and underdevelopment of the basal bone leading to crowding in permanent

dentition4. By preserving primary teeth, these problems can be avoided. Extraction of primary teeth is a relatively common part of pediatric dental practice, often included as part of treatment predicated by caries, trauma, and orthodontic considerations [4]. The premature loss of primary teeth due to caries, trauma, ectopic eruption and many other causes can lead to undesirable tooth movements of primary and/or permanent teeth including loss of arch length11. Arch length deficiency may produce or increase the severity of malocclusions with crowding, rotations, ectopic eruption, crossbite, excessive overjet, excessive overbite, and unfavorable molar relationships [5]. The most effective way of preventing future malocclusion from tooth loss is to place an effective, durable, and economical space maintainer (SM) [6]. The conventional stainless steel band and loop (B&L) space maintainer is the most commonly used appliance among fixed space maintainers for single tooth loss [6].

2. Materials and methods

2.1 Ethical approval and protocol registration

This study's protocol and the informed consent forms contained in were written following the guidelines outlined by the Research Ethics Committee and Institutional Review Board, Faculty of Dentistry, Ain Shams University (FDASU-REC). Approval number: FDASU-Rec ID 072042.

2.2 Study design and settings

The study was conducted at the outpatient clinic of the department of Pediatric Dentistry and Dental Public Health, Faculty of Dentistry, Ain Shams University. Verbal as well as a written consent were obtained from the caregivers of the participants after explaining the objectives of the study and assuring complete confidentiality of data. All caregivers and participants were informed that they have the right to withdraw from the study at any time. Moreover, participants 6 years and older were requested to sign an assent form after an age- appropriate explanation of the trial procedures and their objectives. All consent and assent forms were translated into Arabic. This took place from September 2021 to August 2023 by the same operator.

2.3 Sample size calculation

The sample size was analyzed using PS Power and Sample Size Program 3.1 based on VAS scores of postoperative pain in children undergoing primary molar extraction (Elbay et al. 2016). A minimally clinically important difference of ± 0.18 between the two study groups was determined for the pain assessment using VAS. The power of t-test was calculated to be 80%, using a two-tailed significance level of 5%. The calculated sample size will be 21 primary molars per group for a total of 42. The sample size was increased by 10% to 23 primary molars per group (46 in total) to compensate for drop-outs.

2.4 Eligibility criteria

Participants included were of age from four to seven years. They were assigned into two groups. First group (Stainless-steel crown) having at least one restorable maxillary or mandibular primary molar indicated for treatment and the teeth should have had enough coronal structure for full coverage with a stainless-steel crown. The second group (Space maintainer) having at least one nonrestorable maxillary or mandibular primary molar indicated for extraction and the need for space maintainer must be required. In cases where the second primary molars were included, the first permanent molars should be erupted.History of chief complain, clinical condition of the tooth, history of swelling, presence of a fistula and a periapical radiographic x-ray supported the diagnosis. Exclusion criteria included medically compromised patients, children suffering from any physical or mental disability that will complicate the treatment: Special Health Care needs (SHCN) and children who are extremely uncooperative and difficult to manage. Cases that did not require ring space maintenaners were excluded.

2.5 Clinical procedures

The same operator completed the treatment of all cases.

In the first group (Stainless-steel crown); treatment was achieved in one visit, where pre-operative periapical *Morgan et al.*, 2023

radiograph of the carious tooth was taken as a baseline using a size Zero phosphor plate (ACTEON, USA) which was mounted in a phosphor plate holder (KERR, USA) with radiographic setting of 70kV, 4mA, 0.32 seconds using XGENUS Xray machine (ACTEON, USA)7, and scanned using Vista Scan Image Plate Scanner (DURR Dental, Germany) using paralleling technique8. Assessment of oral health related quality of life for the patient as a baseline using the scale of oral health outcomes (SOHO-5) [9]. The questionnaire consisted of an initial section on toothache experience and current perceptions, followed by questions assessing oral impacts on the usual daily activities of the child. Children were asked seven simple questions whether they had experienced any difficulties with: eating, drinking, speaking, playing, smiling (because teeth hurt), smiling (because of the way teeth look), and sleeping. The questions were worded simply (e.g. Has it ever been hard for you to eat because of your teeth?) and the answer consisted of 3 options (no; a little; a lot).

Also, Assessment of Gingival Health of the t tooth was done as a base line using Gingival index described by Loe and Silness 10. The gingiva around the tooth was examined on the mesial, distal, buccal, and lingual areas using a probe. Each of these four gingival areas was scored according to the criteria described. The scores for each tooth were added and divided by 4 to give the (GI) for the tooth. Topical anesthetic and local infiltration anesthesia were administered and the tooth was isolated with rubber dam, Caries was then completely removed using a #4 sterile round diamond bur (Mani, Japan) mounted in a high-speed handpiece (NSK PANA AIR PA-SU B2). After rubber dam removal, reduction of occlusal and proximal surfaces was done using a blue coded diamond wheel and fine needle stones respectively. The proper size of SSC was selected and cemented at the same visit using Medicem glass ionomer cement after fit and occlusion were checked. Excess cement was removed by threading a dental floss under mesial and distal contact areas. Patients were reminded of oral hygiene instructions as a standard of care after dental procedures.

In the second group (Space maintainer); treatment was achieved in two visits. In the first visit, pre-operative periapical radiograph of the carious tooth was taken as a baseline using a size Zero phosphor plate (ACTEON, USA) which was mounted in a phosphor plate holder (KERR, USA). Assessment of oral health related quality of life for the patient as a baseline using the scale of oral health outcomes (SOHO-5)9. Assessment of Gingival Health of the abutment tooth was done as a base line using Gingival index described by Loe and Silness [10]. Alginate impression was taken for the side of the extracted to be molar for construction of band and loop space maintainer. The impression was then cast using dental stone within 30 minutes of impression taking then sent to the lab. Fabrication of the metal loop in the lab and soldering it to the band. All band and loop SMs were constructed by the same dental technician. In the second visit, topical anesthesia was administered followed by buccal infiltration of local anesthetic solution containing 4% Articaine 1:100.000 epinephrine (INIBSA Dental S.L.U, Spain). Extraction was done using the appropriate molar forceps, a sterile gauze was applied on the extraction site and post- operative instructions were given to the patients. Prior to cementation of band and loop SM, position of the loop was checked for its correct position, then isolation precautions

were taken using cotton rolls and low volume suction. Cementation of the band & loop space maintainer was achieved using Medicem glass ionomer cement.

2.6 Data collection and management Participants' data was recorded in an examination sheet and stored as hard copy files. Patients' information was regarded as confidential and was not revealed at all times. This was ensured by assigning codes to participants' teeth undergoing intervention. Data collected for each participant included: baseline age; gender; tooth treated; treatment done for the tooth; treatment date and clinical evaluation of the treated tooth at follow up appointments.

2.7 Patient Withdrawal

Several attempts were made to call participants on the phone for clinical follow up appointments at 6, 12 and 18 months. Patients who were no longer willing to continue in the study had the right to quit at any time and their dental treatment needs were addressed at the department's outpatient clinic.

2.8 Follow up

All patients were recalled after 6-, 12- and 18-months intervals. In each follow up visit, the health of the gingiva at the margins of the band and loop space maintainer and the stainless-steel crown was re-evaluated using the Gingival Index (GI) by Loe and Silness, 1963. Assessment of oral health related quality of life for the patient was done using the scale of oral health outcomes (SOHO-5) 10 as previously described.

2.9 Statistical analysis

Categorical and ordinal data were presented as frequency and percentage values. Categorical data were analyzed using chi-square test. Numerical data were presented as mean and standard deviation values. They were analyzed for normality using Shapiro-Wilk test. Parametric data (age) was analyzed using independent t-test. The significance level was set at p<0.05 within all tests. Statistical analysis was performed with R statistical analysis software version 4.3.2 for Windows.

3. Results

A total of 42 participants met the inclusion criteria and were enrolled in the study. There were 11 males and 10 females in the stainless-steel crown group and 14 males and 7 females in the extraction and space maintainer group. The mean age of the cases in the stainless-steel crown group was (5.43 ± 1.20) years and in the extraction group was (5.97 ± 1.04) years. The majority of treated teeth in both groups were lower first primary molars. There was no significant difference between both groups regarding different demographic and baseline characteristics (p>0.05). (Table 1)

3.1 Gingival health status

At baseline, stainless-steel crown group had significantly higher GI value than the space maintainer group (p=0.004), with mean GI (1.52 ± 0.27) compared to mean GI

(1.27±0.22) of the space maintainer group. There was a significant reduction in GI starting from 6 months to the end of the follow-up interval (p<0.001). Whereas, gingival health around the band of the space maintainer deteriorated throughout the follow up interval periods, the value increased after baseline with mean GI (1.27±0.22) to (1.58±0.33) after 6 months. The highest value was after 18 months (1.49±0.19), thus, giving a significant difference (p<0.001) (Table 2).

3.2 Quality of life related oral health/ patient satisfaction

At baseline, the stainless-steel group had significantly higher score value (less satisfaction) than the space maintainer group (p=0.049). While after 6 and 12 other intervals, the space maintainer group had significantly higher values (p<0.05). After 18 months, there was no significant difference between both groups (p=0.081).

For the stainless-steel group, there was a significant reduction in measured score starting from 6 months to the end of the follow-up interval (p<0.001). While for the space maintainer group, the value decreased after baseline (p<0.001) (Table 3).

4. Discussion

Primary teeth should be preserved until their normal exfoliation time so as to maintain arch length and function in order to provide proper guidance for the eruption of permanent teeth, enhance esthetics and mastication, prevent aberrant tongue habits, aid in speech and prevent the psychological effects associated with tooth loss[11]. In most cases and due to several socioeconomic reasons, children arrive too late at the dentist's office, therefore caries is already frequently associated with pulpitis which when irreversible may even lead to premature extraction [12]. Also, the American Academy of Pediatric Dentistry stated that caries and resulting pulpal pathology was the most common reason for extraction of primary teeth and that despite the dramatic improvement in pediatric oral health over the last decades, recent evidence suggests that dental disease remains a continued source of tooth loss in a percentage of all pediatric populations [4]. It was reported that the lack of treatment of a deciduous tooth pulpal necrosis can cause damage to the succedaneous tooth and produce negative impacts on the child's oral health- related quality of life (e.g., pain, missed school days and difficulty in chewing) [13]. Therefore, teeth presenting these conditions should be extracted or subjected to root canal treatment as reported by Carrotte, P. in his study[14]. Children aged four to seven years old were recruited to the study, as a four-year child is expected to show cooperation in the dental practice [15,16]. The study was conducted on 21 healthy subjects (21 teeth). No significant difference was found in gender distribution or age. Tooth type and arch designation parameters, namely maxillary or mandibular molar or first or second primary molar, also showed no significant differences as stated in literature [17]. Clinical and radiographic criteria of the included primary molars were adopted based on the indications criteria for extraction suggested by the American Academy of Pediatric Dentistry (AAPD). Preoperative radiographs, using the standardized paralleling technique, were still valuable in detecting teeth with evidence of periradicular radiolucency [18].

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Parameter		Stainless-steel crown	Space maintainer	p-value
Gender [n (%)]	Male	11 (52.38%)	14 (66.67%)	0.346ns
	Female	10 (47.62%)	7 (33.33%)	
Age (Mean±SD) (years)		5.43±1.20	5.97±1.04	0.127ns
Treated primary tooth [n (%)]	First molar	14 (66.67%)	11 (52.38%)	0.346ns
	Second molar	7 (33.33%)	10 (47.62%)	
Treated arch [n (%)]	Lower	16 (76.19%)	13 (61.90%)	0.317ns
	Upper	5 (23.81%)	8 (38.10%)	

Table 1: Intergroup comparisons and summary statistics for demographic data.

*; significant (p<0.05) ns; non-significant (p>0.05)

Table 2: Inter, intragroup comparisons, mean and standard deviation (SD) for GI.

Time	GI	n-vəlue	
	Stainless-steel crown	Space maintainer	p-value
Baseline	1.52 ± 0.27^{A}	1.27±0.22 ^B	0.004*
6 months	1.00±0.26 ^B	1.58±0.33 ^A	<0.001*
12 months	1.04 ± 0.27^{B}	1.56±0.25 ^A	<0.001*
18 months	1.05±0.33 ^B	1.49±0.19 ^A	<0.001*
p-value	<0.001*	<0.001*	

NA: Not Applicable, Values with different superscript letters within the same <u>vertical column</u> are significantly different *; significant (p<0.05) ns; non-significant (p>0.05).

Table 3: Inter, intragroup comparisons, mean and standard deviation (SD) for satisfaction score.

Time	Satisfaction score (Mean±Sl	n-vəluq	
	Stainless-steel crown	Space maintainer	p-value
Baseline	8.86 ± 1.85^{A}	7.76±1.55 ^A	0.049*
6 months	0.29 ± 0.46^{B}	0.76 ± 0.70^{B}	0.020*
12 months	0.14±0.36 ^B	0.76±0.94 ^B	0.013*
18 months	0.19±0.40 ^B	0.52 ± 0.68^{B}	0.081ns
p-value	<0.001*	<0.001*	

Values with different superscript letters within the same vertical column are significantly different *; significant (p<0.05) ns; non-significant (p>0.05).

Although clinical examination and dental history are of paramount importance in the selection of cases for pulp therapy, the physical and medical condition of the child can affect treatment prognosis and should be considered.18 Therefore, for ethical reasons and to eliminate confounders related to a compromised immune response, medically compromised children were excluded from this study. Many oral health related quality of life (OHRQoL) measures have been developed and tested in various populations to assess the impacts of oral conditions on the daily life of people. Such measures have also been developed specifically for child and adolescent populations, in line with the respective general health measures [19,20,21,22]. However, they have predominantly focused on children aged 8 years and older [23,24,25] except for a parental report measure for children aged 6 years and older [26]. While a self-reported set of OHRQoL questions has been used on very young children, [27] those were treated as independent questions, rather than a composite measure, without presenting concrete evidence on psychometric properties. Recently, an OHRQoL measure that included both parental and children reports was developed and validated for preschool and school-aged children, though the child self-report version was only used on children aged 8 years or older [28] Children's perceptions about the impact of oral conditions on their life are based on their experience of oral diseases and are influenced by their immediate fam- ily environments and the wider social context including friends, schools and neighbourhoods [20,29]. Furthermore, their understanding of illness and health is age dependent due to social, language, emotional, and cogni- tive development [20,29] these developmental stages should be carefully considered within the appropriate social contexts when constructing subjective measures for young children. Abstract thinking is not initiated before the age of 6 years and understanding of even basic health concepts may be problematic in younger children [30]. It is even later in childhood that they can evaluate their feelings and thoughts and compare them with those of their peers [31]. All these challenges have led to the lack of appropriate measures or the use of parental reports as proxies for young children's perceptions of OHRQoL. On the other hand, there is evidence that 4-6 year-old children can report reliably on more concrete domains of their own general health and quality of life, including pain and dysfunction, though not on abstract domains such as emotional well-being [32]. Previous studies on children have mostly used composite OHRQoL measures based on parental reports [26,32]. Despite being commonly used as proxies to assess impacts of chronic conditions on younger children, parents do not always accurately perceive their children's quality of life, thereby parental proxy reports bring a different perception but do not substitute for children self-reports [33].

Therefore, in the current study, the scale of oral health outcomes for 5-year-old children (SOHO-5) was used. It consisted of an initial section on toothache experience and current perceptions, followed by questions assessing oral impacts on the usual daily activities of a child of that age. Children were asked whether they had experienced any difficulties with: eating, drinking, speaking, playing, smiling (because teeth hurt), smiling (because of the way teeth look), and sleeping. The questions were worded simply (e.g. Has it ever been hard for you to eat because of your teeth?) and the answer consisted of 3 options (no; a little; a lot) [9]. In a RCT *Morgan et al.*, 2023

study conducted by Abanto et al., [34] to compare the impact of two management options for primary molars with pulp necrosis (pulpectomy or extraction) on children's oral healthrelated quality of life (OHRQoL) in children aged 3-5 years using early childhood oral health impact scale (B-ECOHIS) which was completed by the parent proxy reports at baseline and after 4, 8 and 12 months. They concluded that Pulpectomy resulted in an improved OHRQoL scores after 12 months when compared to tooth extraction and should be considered as the treatment of choice for necrotic primary molars. Furthermore, higher anxiety levels were reported for dental extraction compared to pulpectomy. Although it is well known that the maintenance of these spaces prevents later complications such as crowding, ectopic eruption, impaction of successor teeth and malocclusion [35,36,37] the use of space maintainers has also been shown to result in an increased plaque accumulation, which can lead to dental caries and periodontal disease [38,39]. The presence of bacterial plaque due to poor oral hygiene is the primary cause of gingival inflammation and periodontitis in children as well as adults [38,39]. The retention of plaque and the development of gingivitis are dramatically affected by local factors [37]. Orthodontic bands are reported to influence plaque growth and maturation40, and orthodontic appliances are reported to promote plaque accumulation and cause gingivitis [36,41]. Periodontal studies examining the effects of orthodontic appliances on periodontal health and the presence of oral microorganisms have mainly been conducted with adolescents [37,42]. However, the age profile of the patients using space maintainers tends to be much younger, and the effects of plaque accumulation due to possible poor compliance to oral hygiene instructions among younger patients may be much worse. Despite the importance of this issue, there is only one published study [37] investigating the effects of space maintainers on plaque accumulation and periodontal health. Therefore, in our current study, assessment of the gingival heath of the abutment teeth was conducted using the Gingival index by Loe & sileness because it is considered to be a simple and accurate method in epidemiological and clinical research [43,44].

Our results revealed that the gingival health of the abutment teeth deteriorated in the follow up period after placement of the band and loop SM. The mean GI of the abutment teeth at the base line was (1.27 ± 0.22) and increased after 6, 12 and 18 months with GI mean (1.49±0.19) giving a significant difference. In a study conducted by Volkan Arikan et al., [45] to measure gingival index on patients aged 4–10 years requiring either fixed or removable space maintainers, they found that the gingival index scores increased significantly from 0.20 ± 0254 to 0.54 ± 0417 in the regions with fixed space maintainers. Moreover, they also stated that the index scores in their study were obtained from teeth within the same region as the space maintainers, and these were compared with those in regions where no space maintainers were present. Thus, proving the fact that fixed appliances are a source of plaque accumulation retention. Boyd and Baumrind [46] compared the periodontal status of bonded and banded molars before, during and after treatment with fixed orthodontic appliances. Corroborating our results, they reported that, during treatment, both maxillary and mandibular banded molars showed significantly greater gingival inflammation and plaque accumulation. These authors also observed that there was significantly more 309

plaque accumulation and gingival inflammation in adolescents than in adults, thereby emphasizing the effect of age on oral hygiene status. Arikan et al [45] examined changes in the microflora and parameters including plaque index, bleeding index, pocket depth, and the presence of E. faecalis after the use of SM. It was concluded that both fixed and removable SM can cause an increase in plaque accumulation. Children with fixed appliances showed an increase in plaque and bleeding index compared to patients with removable SM, and the authors suggested that special attention should therefore be given to young patients with fixed appliances. Tabatabai et al., [47] conducted a systematic review on the effect of treatment with space maintainers and they concluded that the available evidence showed that, however, the treatment with SM may preserve arch length, it also caused an increase of plaque accumulation and some other periodontal parameters. On the other hand, in the present study, when assessing the gingival health around the SSC, it was found that the GI scores decreased from the baseline throughout the end of the follow up period. We assume that excavating the rough carious lesions which are plaque retentive and covering the teeth with SSC exhibiting smooth surfaces aided in inhibition of plaque accumulation and thus improving the gingival status of teeth. This agrees with the study conducted by Kara and Yilmaz [48] who found that plaque did not accumulate for the first 9 months around the teeth that were restored with an SSC because of the smooth surfaces of the SSC. The smooth surface of an SSC is a frequently cited reason for decreased plaque adherence to surfaces that are adjacent to SSC. They also found that although the mean GI scores of the restored teeth progressively increased with time, the GI scores were never greater than one. This finding indicates that the level of gingivitis in the study children was low for the entire duration of the 18-month study period. This is consistent with our study results where the mean GI at baseline was (1.52 ± 0.27) which decreased at 6, 12 and 18 months with GI mean values (1.00±0.26), (1.04±0.27) and (1.05±0.33) respectively. On the contrary, Salama et al. [49] concluded that individuals with poor oral hygiene showed pronounced tissue degeneration despite the quality of the SSC and that improperly contoured restorations predispose the gingiva to more severe inflammation. Gingivitis is the predominant form of periodontal disease in children and adolescents, and it consists of a nonspecific inflammation of the marginal gingiva. It has been reported that gingivitis often occurs around primary teeth restored with steel crowns due to diverse factors, mainly to improper techniques during all the therapeutic process [50] Alagl [51] however, reported that plaque can accumulate around crowns with well-adapted margins. He also proposed that the gingivitis around teeth that were restored with an SSC is dependent on the presence of bacterial plaque and not dependent on mechanical irritation due to the crown's presence.

5. Conclusions

Within the limitations of the study, it can be concluded that, band and loop space maintainers caused gingivitis at a higher level than the stainless-steel crown, this may be due to the smooth surface of the crowns which resulted in less plaque accumulation. OHrQoL measures showed poor values on the extraction site.

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