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Clinical Evaluation of a New Bonded Space Maintainer

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Early loss of deciduous molars often causes issues that affect the permanent dentition, beginning with drifting of the first permanent molars and eventually leading to ectopic eruptions, reduced arch length, excessive overbite, dental malpositions, and arch asymmetry.[1-4] When extraction of a deciduous molar is necessary, such problems can be prevented by using an effective space maintainer.[5] Cemented maintainers are plaque retentive, however, and need to be removed every year for cleaning and cement replacement.[6,7] Removable space maintainers make oral hygiene easier, but their clinical success depends on patient cooperation, and the appliances can easily be damaged or lost.[7-9] Bonded space maintainers have shown several advantages over cemented and removable versions: they require no impression taking or laboratory work, their effects are completely reversible, and patients do not need to schedule frequent checkup visits or cooperate with appliance wear.[9-11]

The present study was designed to evaluate clinical results achieved with the direct-bonded EZ Space Maintainer.* This device is constructed from two 1mm stainless steel wire arms, tube segments with an internal diameter of 1.2mm, and two bonding bases that are affixed to the buccal surfaces of the teeth adjacent to the extraction space (Fig. 1). The 6-8mm tube segments are soldered to the posterior arm to accommodate the anterior arm. The appliance is adjusted according to the mesiodistal dimension of the extraction space, then stabilized by squeezing one of the tubes with a plier.

Materials and Methods

The study was approved by the Ethical Committee of the Çukurova University Medical School. Inclusion criteria were as follows:

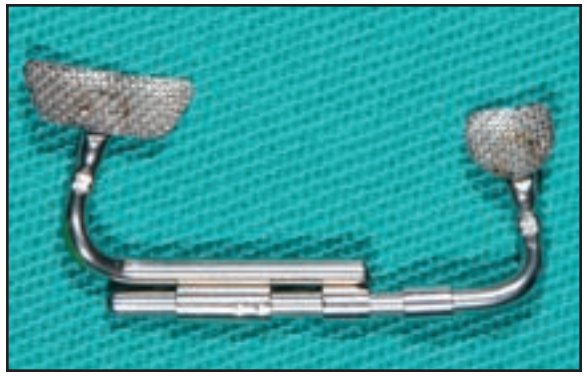

Fig. 1 EZ Space Maintainer.

- Extraction of deciduous teeth no more than two weeks previously.
- Absence of periodontal disease or any other pathology.
- Absence of abnormal dental conditions such as crossbite, open bite, or deep bite.
- Absence of carious lesions on the buccal surfaces of the abutment teeth.
- Good oral hygiene.
- Ability to attend follow-up appointments as required.

Twenty-seven children (16 male and 11 female) between 6 and 12 years of age (mean 8.7) were included in the study. Three of the children had congenitally missing second premolars and were followed until their orthodontic or prosthodontic treatment began. Written and verbal informed consent was obtained from both parents and children, who also received instructions in oral hygiene.

A total of 41 EZ Space Maintainers were bonded—12 maxillary and 29 mandibular, 26 in male patients and 15 in female patients. The appli-

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TABLE 1
STUDY SAMPLE

Group	No. Patients	Total Appliances	Maxillary	Mandibular	Male	Female	Age
A	9	13	5	8	5	4	7.3 ± 0.7
B	11	12	2	10	7	4	8.7 ± 0.7
C	8	10	3	7	5	3	8.9 ± 1.2
D	4	6	2	4	3	1	11.3 ± 2.0
Total	32*	41**	12	29	20	12	8.7 ± 1.6

*Five patients were included in two groups.
**14 patients wore two appliances each.

ances were divided into four groups (Table 1):

Group A: The extracted tooth was a first deciduous molar, and the space maintainer was bonded between the deciduous canine and second deciduous molar.
Group B: The extracted tooth was a second deciduous molar, and the space maintainer was bonded between the first deciduous molar and first permanent molar.
Group C: The extracted teeth were first and second deciduous molars, and the space maintainer was bonded between the deciduous canine and first permanent molar.
Group D: The extracted tooth was a second deciduous molar, and the space maintainer was bonded between the first premolar and first permanent molar.

Before placement of the space maintainer, a prophylaxis was performed with brush, pumice, and water. The buccal enamel surfaces of both deciduous and permanent teeth were etched with 35% phosphoric acid gel for 60 seconds, then rinsed for 20 seconds. Cheek and tongue retractors, cotton rolls, and saliva ejectors were used for moisture control. The EZ Space Maintainers were all bonded by a single operator according to the manufacturer's instructions, using Transbond XT** primer and adhesive. Each appliance was positioned about 2mm away from the gingival tissue to allow proper gingival hygiene (Fig. 2). Excess adhesive was removed with finishing burs and polishing discs. The mean placement time was 15.5 minutes per appliance.

Plaque index scores were recorded one week after bonding, using the Silness and Loe Plaque Index (PI)[12] and the Loe and Silness Gingival Index (GI)[13] for the abutment teeth and the Vermillion Simplified Oral Hygiene Index (SOHI)[14] for the four other posterior and two other anterior teeth. One month after bonding and every three months during the 600-day study period, the patient returned for a clinical evaluation that included plaque and oral-hygiene index scores. Each examination was conducted by two operators, with a periodontal probe used to check oral hygiene. Radiographic evaluation was performed at six-month intervals.

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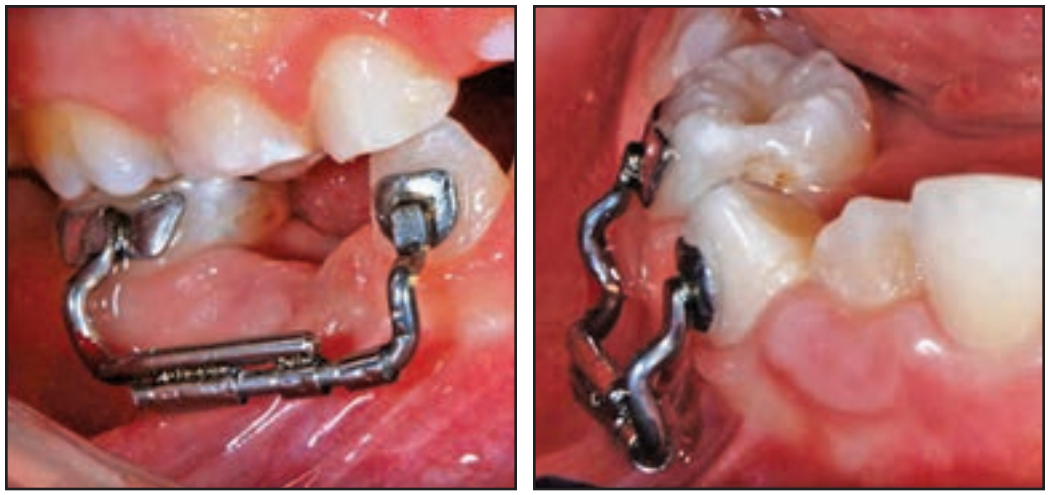

Fig. 2 EZ Space Maintainer bonded 2mm away from gingival tissue (reprinted by permission of Dr. Enis Güray).

The space maintainer was removed when the successor tooth had erupted or one of the abutment teeth had luxated. Study casts were made before treatment and after removal or failure of the space maintainer, and linear measurements of each extraction space were made by two operators according to the method of Swaine and Wright,[9] using a precision caliper.

The space maintainer was considered to have failed if one or both of the bondable bases had dislodged, the appliance had broken, the extraction space had closed to any extent, or periodontal damage had occurred. Patients were divided into two age groups (6-8 and 9-12) to assess the effect of patient age on the failure rate; the effects of the patient's sex and dental arch (maxillary or mandibular) were also evaluated.

Statistical analysis was performed with SPSS version 18.0.*** Cohen's kappa coefficient was used to assess interobserver agreement. Comparisons among groups were made by means of paired t-tests, Student's t-tests, or one-way analysis of variance; time-dependent differences were compared using repeated-measures analysis. Kaplan-Meier survival curves of appliance failures were compared with the log-rank test, and the Kruskal-Wallis test was employed for assessment of plaque and oral-hygiene index scores over time.

Results

Only one appliance remained in use at the end of the study; this last appliance was debonded on its 1,043rd day of wear. The first failure occurred on the 157th day. Six of the 41 space maintainers (14.6%) failed during the study, four in Group A and two in Group C. Two of these failures were observed at the six-month appointment, the other four at the 12-month appointment. There was no statistically significant association between the group and the number of failed appliances ($p = .11$, Table 2).

Three failures occurred in the maxillary arch (25.0% of the appliances placed) and three in the mandibular arch (10.3%), but this difference was not statistically significant ($p = .22$). Although the failure rate was higher in male patients (19.2%) than in females (6.7%), the difference again was not statistically significant ($p = .27$). Since all six failures occurred in the 6-8 age group (27.3%), patient age was a statistically significant risk factor ($p = .01$, Table 3).

Appliance failures were caused by periodontal problems (one case) and bonding problems (five cases). Every bonding failure occurred at the enamel-resin interface, with all composite remain-

***IBM Corporation, Armonk, NY; www.ibm.com.

TABLE 2
FAILURES BY GROUP

	Group A		Group B		Group C		Group D		Overall		
	Appliances	Failures	Appliances	Failures	Appliances	Failures	Appliances	Failures	Appliances	Failures	Failure Pct.
Maxillary Arch	5	2	2	0	3	1	2	0	12	3	25.0%
Mandibular Arch	8	2	10	0	7	1	4	0	29	3	10.3%
Total	13	4	12	0	10	2	6	0	41	6	14.6%

ing on the mesh base. Two of these appliances failed after facial trauma, and one while the patient was chewing a sticky food. No etiological factors were identified for the other two bond failures.

The mean survival time for the EZ Space Maintainer was 220 days; the median survival time was 212 days. There were no statistically significant differences in survival time among groups ($p = .30$, Fig. 3, Table 4) or by dental arch ($p = .30$) or patient sex ($p = .23$). A significant difference in survival time was found between the 6-8 and 9-12 age groups (Fig. 4).

Plaque accumulation was noted in the bonded areas, but no caries were observed around the bonding bases. The mean PI score of each group increased sharply at the one-week follow-up exam, but then declined gradually over time (Fig. 5). Group B showed higher levels of plaque retention than in the other groups, but the differences were not statistically significant ($p > .05$). The mean GI score remained below 2 (moderate inflammation) throughout the study (Fig. 6), despite the slightly elevated mean PI. Mean SOHI scores of 0-1.2 (adequate) indicated that the patients maintained proper oral hygiene during the study period (Fig. 7). Interobserver agreement was calculated as .86.

There was no statistically significant difference among groups in mean extraction-space measurements before treatment and after space maintenance ($p > .05$). Three patients exhibited space closure of at least .5mm; in all three cases, the appliance bonds had failed. Interobserver agreement in space measurement was .77. The successor teeth erupted easily in all cases, with no interference from the appliances (Fig. 8).

TABLE 3
FAILURES BY PATIENT AGE*

Age	Appliances	Failures	Failure Pct.
6-8	22	6	27.3%
9-12	19	0	0.0%
Total	41	6	14.6%

*$p = .01$ (chi-square test).

Discussion

Several studies have found promising results from the use of direct-bonded space maintainers made of round wires, stainless steel strips, or light-cured composites over six to 12 months of use.[7,9-11,15] Although survival time was not measured in these reports, the failure rate of the EZ Space Maintainer after six months was quite low (4.8%) com-

TABLE 4
MEAN SURVIVAL TIMES, FAILURES, AND SUCCESS RATES BY GROUP

	Survival Time	Failures	Success Rate
Group A	466 days	4	69.2%
Group B	264 days	0	100.0%
Group C	242 days	2	80.0%
Group D	251 days	0	100.0%
Overall	220 days	6	86.4%

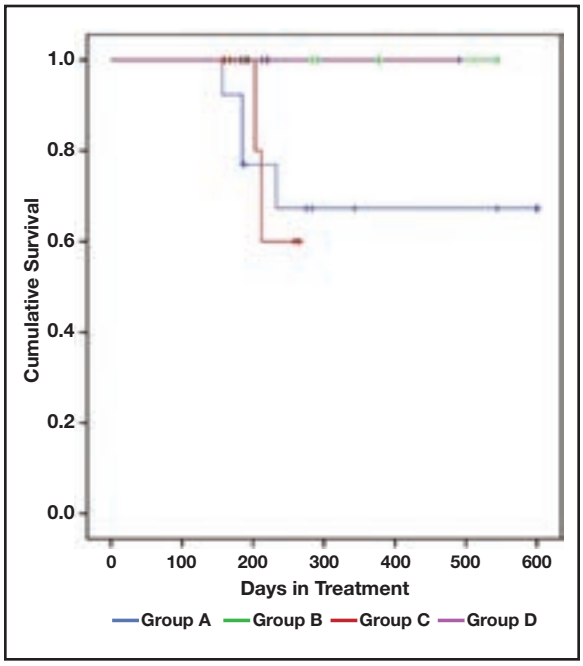

Fig. 3 Kaplan-Meier survival curves for each group.

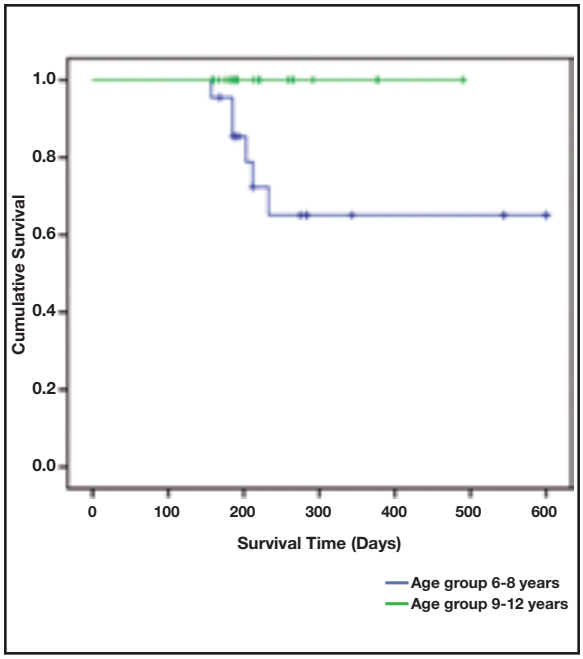

Fig. 4 Kaplan-Meier survival curves for 6-8 and 9-12 age groups.

pared to that of direct-bonded maintainers in earlier investigations by Swaine and Wright (30%),[9] Artun and Marstrander (19%),[7] and Santos and colleagues (8.3%),[15] and similar to the results found by Simsek and colleagues (3.1%)[16]—perhaps reflecting improvements in adhesives over the years covered by these studies. The EZ Space Maintainer's failure rate after 12 months (14.6%) was higher than that observed by Simonsen (2.8%).[10]

Other authors have measured survival times for space maintainers ranging from five to 27 months,[9,15,17-20] compared to our mean survival time of 220 days (about seven months). Neither the patient's sex nor the dental arch seemed to have any significant relationship to longevity, corroborating results published by Qudeimat and Fayle[18] and Rajab.[20] The significant effect of patient age in our study should not be surprising, since children 6-8 years of age have to wear the appliance longer than children 9-12 years of age before the eruption of permanent teeth. Failures in patients under 8 might also be attributed to the difficulty of moisture control in this age group.

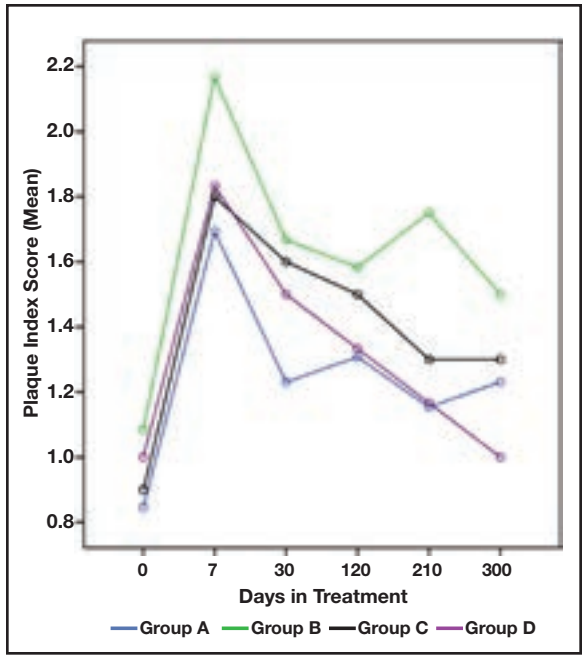

Fig. 5 Kruskal-Wallis analysis of mean Plaque Index scores for each group.

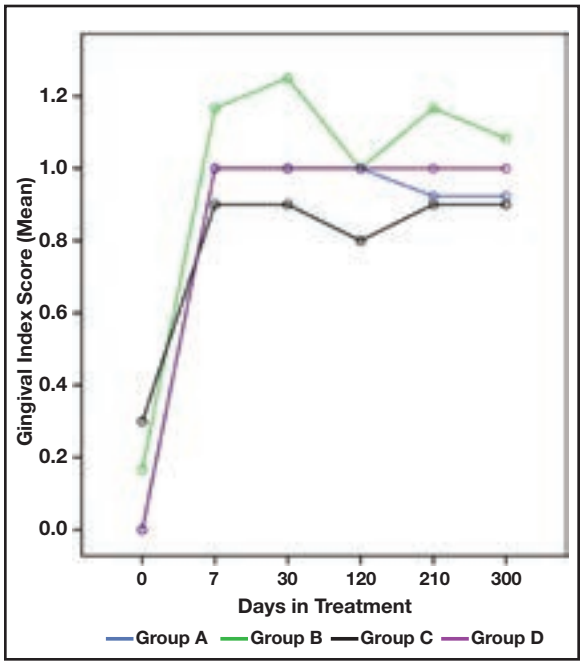

Fig. 6 Kruskal-Wallis analysis of mean Gingival Index scores for each group.

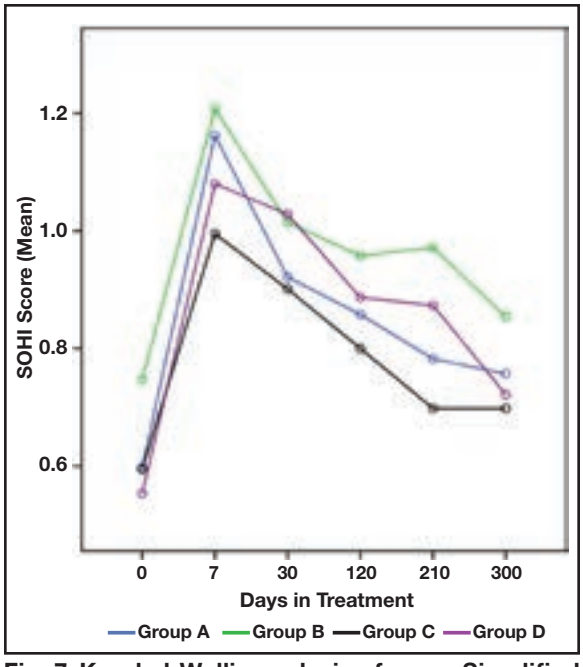

Fig. 7 Kruskal-Wallis analysis of mean Simplified Oral Hygiene Index scores for each group.

Space maintainers made from straight wire segments with loops or grooves for bonding are less tolerant of occlusal forces than the EZ Space Maintainer, which was designed to minimize the occlusal force load regardless of appliance length. In addition, the mesh pads of the EZ Space Maintainer facilitate bonding to the abutment teeth—a critical factor for longevity. All five adhesive failures in our sample occurred between the enamel and the adhesive resin, indicating that the mesh bonding bases were able to withstand the occlusal forces.

There is some controversy regarding optimal etching times for deciduous teeth, whose prismless zones have a negative effect on bond strength. Some authors recommend grinding the outer enamel layer to remove prismless enamel, while others suggest increasing the etching time to improve adhesion.[21-23] In our study, where the abutment teeth were etched for 60 seconds without grinding, four of the five adhesive failures occurred in the group (A) with deciduous abutment teeth.

Fig. 8 Eruption of successor tooth in extraction space (reprinted by permission of Dr. Enis Güray).

Both fixed and removable space maintainers have been associated with increased plaque accumulation and inadequate oral hygiene.[7,14,24] Although Boyd and Baumrind,[25] Gwinnett and Ceen,[26] and Weitman and Eames[27] all reported plaque accumulation around direct-bonded brackets, bands, and composites, no previous authors have evaluated the effects of direct-bonded space maintainers on periodontal conditions. We observed an increase in PI scores immediately after placement of the EZ Space Maintainer—especially around the abutment teeth—but relatively low GI scores, with only one appliance failure due to periodontal conditions. The first week after appliance bonding seemed to be the most important time for patient adaptation and oral-hygiene education, though our patients generally exhibited acceptable oral hygiene throughout the study.

The method of space analysis devised by Swaine and Wright[9] may not have been entirely appropriate for our study, since cusp abrasion of the deciduous teeth made it difficult to measure the post-maintenance casts. Any luxation of the deciduous teeth mesial to the extraction sites was caused by physiological root resorption, rather than a deficiency of the space maintainer. A simpler and more accurate model analysis would be useful for future studies.

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