T.C.
YEDITEPE UNIVERSITY
INSTITUTE OF HEALTH SCIENCES
DEPARTMENT OF PEDIATRIC DENTISTRY

EVALUATION OF FULL CORONAL ESTHETIC RESTORATIONS IN PRIMARY INCISORS: CLINICAL SUCCESS, PARENTAL SATISFACTION, *IN VITRO* FRACTURE RESISTANCE AND BACTERIAL ADHESION

DOCTOR OF PHILOSOPHY THESIS

DENTIST
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Chair of the Jury:	Assoc. Prof. Dr. Senem SELVİ KUVVETLİ Yeditepe University, Faculty of Dentistry	
Supervisor:	Assoc. Prof. Dr. Senem SELVİ KUVVETLİ Yeditepe University, Faculty of Dentistry	
Co- Supervisor:	Prof. Dr. Nüket SANDALLI Kemerburgaz University, Faculty of Dentistry	
Member/Examiner:	Assoc. Prof. Dr. Didem ÖZDEMİR ÖZENEN Yeditepe University, Faculty of Dentistry	
Member/Examiner:	Prof. Dr. Mübin SOYMAN Yeditepe University, Faculty of Dentistry	
Member/Examiner:	Prof. Dr. Figen SEYMEN İstanbul University, Faculty of Dentistry	
Member/Examiner:	Prof. Dr. Güven KÜLEKÇİ İstanbul University, Faculty of Dentistry	

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This thesis has been deemed by the jury in accordance with the relevant articles of Yeditepe University Graduate Education and Examinations Regulation and has been approved by Administrative Board of Institute with decision dated 31.05.2016... and numbered 2016/12-17

Prof. Dr. Bayram YILMAZ

Director of Institute of Health Sciences

DECLARATION

I hereby declare that this thesis is my own work and that, to the best of my knowledge and belief, it contains no material previously published or written by another person nor material which has been accepted for the award of any other degree except where due acknowledgment has been made in the text.

Date

10.05.2016

Signature

Name Surname

Hanin F. FELLAGH

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ABBREVIATIONS

AAPD	American Academy of Pediatric Dentistry
ASA PS	American Society of Anesthesiologists Physical Status
BIS-GMA	Bisphenol A glycidylmethacrylate
BHI	Brain Heart Infusion
BPA	Bisphenol A
C	Control Subgroup
CFU	Colony forming unit
°C	Centigrade Degree
C. albicans	*Candida albicans*
CT	Computer Tomography
DMFTS	Decay Missing Filling Teeth in permanent teeth
DMFTS	Decay Missing Filling Teeth Surfaces in permanent teeth
dmft	decay missing filling teeth in primary teeth
dmfts	decay missing filling teeth surface in primary teeth
EAPD	European Academy of Paediatric Dentistry
ECC	Early Childhood Caries
E. faecalis	*Enterococcus faecalis*
FCR	Full Coronal Restoration
GA	General Anaesthesia
GICs	Glass Ionomer Cements

HAP	Hydroxyapatite
HF	Hanin FELLAGH
HEMA	Hydroxylethyl methacrylate
KKZ	Kinder Krowns® Zirconia
MD	Mesio distal
MF	McFarland
ml	mililitre
mm	millimeter
MS	Mutans streptococci
MPa	Megapascal
N	Newton
NSZ	NUSMILE® Zirconia
OHI-S	Oral Hygiene Indexes Simplified
OD	Optic Density
PMC	Preformed crowns
PVSSC	Preveneered stainless steel crown
RMGıc	Resin Modified Glass ionomer cement
RCSc	Resin Composite Strip Crowns
RCS	Randomized Clinical Study
Rc	Resin composite
SD	Standard deviation
S-ECC	Severe Early Childhood Caries

SEM	Scanning Electronic Microscope
SES	Socioeconomic Status
SSK	Senem SELVI KUVVETLI
SSC	Stainless Steel Crown
S. mutans	*Streptococcus mutans*
S. sobrinus	*Streptococcus sobrinus*
S. salivarius	*Streptococcus salivarius*
S. sanguis	*Streptococcus sanguis*
S. mitis	*Streptococcus mitis*
S. gordonii	*Streptococcus gordonii*
S. aureus	*Staphylococcus aureus*
S. wiggsiae	*Scardovia wiggsiae*
SFE	Surface Free Energy
S-PRG	Surface Reaction Type Pre Reacted Glass Ionomer
P. intermedia	*Prevotella intermedia*
P. gingivalis	*Porphyromonas gingivalis*
PH	Potential Hydrogen
OD	Optical Density
Tc	Thermocycling subgroup
Ti	Titanium
TEGDMA	Triethylene Glycoldimethacrylate

USPHS	United State Public Health Service
ZR	Zirconia
Zr	Zirconium
Y_2O_3	Yttria Zirconia
YSZ	Yttria stabilized zirconia

SUMMARY

FELLAGH, HF. 2016. Evaluation of Full Coronal Esthetic Restorations in Primary Incisors: Clinical Success, Parental Satisfaction, *In vitro* Fracture Resistance and Bacterial Adhesion. Yeditepe University Institute of Health Sciences Department of Pediatric Dentistry, Pediatric Dentistry Doctorate Programe, Doctor of Philosophy Thesis, Istanbul.

The restoration of severely decayed primary incisors is often a clinical challenge, requirements for an acceptable restoration including; esthetics, durability and biocompatible has been demanded. The aim of this study was to evaluate the clinical performance and the parental satisfaction of three different full coronal esthetic restorations (two zirconia prefabricated crowns and strip crowns), *in vitro;* evaluation of the fracture resistance of prefabricated crown used in the clinical part, and finally assessment of the initial bacterial adhesion on composite resin and zirconia material surfaces. One hundred and sixty five teeth in 42 children were included. Children were randomly assigned to one of three treatment groups, restorations were placed and evaluated at 3, 6 and 9 months interval. A questionnaire was administered to the parents to evaluate their parental satisfaction. The mean force required to fracture the crowns was determined in MPA, then the fractured specimens were assessed with scanning electronic microscope. Asssessment of the initial bacterial adhesion on composite resin and zirconia material surfaces utilizing hydroxyapatite disc as a tooth enamel surrogate was evaluated with both optical density and colony forming unit methods. Overall clinical success and parental satisfaction was comparable between the restorations. There was no significant difference in the force required to fracture the crowns among the prefabricated crowns. The bacterial adherence to the hydroxyapatite discs shows the highest adherence followed by composite and zirconia discs. Concluding that prefabricated zirconia crowns are likely to be successful and may be indicated as an excellent choice for the treatment of carious primary incisors.

Key words: Primary incisors, prefabricated primary zirconia crowns, parental satisfaction, fracture resistance, bacterial adhesion.

ÖZET

FELLAGH, HF. 2016. Süt Kesici Dişlerinde Tam Koronal Estetik Restorasyonların Klinik Başarısı ve Ebeveyn Memnuniyetinin Değerlendirilmesi, *İn vitro* Olarak Kırılma Dayanımı ve Bakteri Adezyonunun İncelenmesi. Yeditepe Üniversitesi Sağlık Bilimleri Enstitüsü, Çocuk Diş Hekimliği Anabilim Dalı, Çocuk Diş Hekimliği Doktora Programı, Doktora Tezi, İstanbul.

Amaç: Yaygın çürük lezyonu bulunan süt kesici dişlerinin restorasyonu genellikle klinik olarak zorlayıcıdır. Bu dişlerde kabul edilebilir bir restorasyonun estetik, kalıcılık ve biyouyumlu olması gereklidir. Bu çalışmanın amacı, süt kesici dişlerine uygulanan üç farklı tam koronal estetik restorasyonun (iki zirkonya prefabrike kuron ve kompozit strip kuron) klinik başarısı, ebeveyn memnuniyeti açısından değerlendirilmesi; *in vitro* olarak da klinik çalışmada kullanılan iki faklı zirkonya kuronun kırılma dayanımının incelenmesi ve zirkonya, kompozit rezin materyallerinin bakteri adezyonu özelliklerinin hidroksiapatit ile karşılaştırmalı olarak incelenmesidir. Gereç ve Yöntem: 42 çocuğun çürük lezyonu bulunan 165 üst süt kesici dişi çalışmaya dahil edildi. Çocuklar rastgele olacak şekilde üç gruba ayrıldı. Yapılan restorasyonlar 3,6 ve 6 aylık kontrollerde renk uyumu, kuron konturu, restorasyon kaybı varlığı ve dişeti sağlığı açısından değerlendirildi. Ebeveyn memnuniyeti anketler aracılığı ile değerlendirildi. Zirkonya kuronların kırılma dayanımı Universal Instron cihazı kullanılarak ölçüldü, kırılmış örnekler taramalı eketron mikroskobu ile incelendi.

Bakteri adezyonu diş minesini taklit eden hidroksiapatit disklerle karşılaştırmalı olarak kompozit rezin ve zirkonya disk örnekleri üzerinde *S.mutans* biyofilm oluşumu optik yoğunluk (OD) ve canlı bakteri sayısı (CFU/ml) ölçülerek değerlendirildi. Bulgular: Restorasyonların klinik başarı düzeyleri ve ebeveyn memnuniyeti birbirine yakın olarak belirlendi. Prefabrike zirkonya kuronların kırılma dayanımları arasında istatistiksel olarak anlamlı bir fark görülmedi. Sonuçlar: Klinik başarı, ebeveyn memnuniyeti, in vitro kırılma dayanımı ve bakteri adezyonu açısından prefabrike tam estetik kuronların çürük süt kesici dişlerin restorasyonunda uygun bir seçenek olduğu düşünülmektedir

Anahtar kelimeler: Süt kesici, prefabrik primer zirkonya kuron, ebeveyn memnuniyeti, kırılma direnci, bakteriyel adezyonunun.

1. INTRODUCTION AND AIM OF THE STUDY

The oral cavity is the entrance to the body and reflects general health and wellbeing (1). Studies have demonstrated an association between oral infections and conditions such as: diabetes, cardiovascular disease, stroke, and adverse pregnancy outcomes (2, 3). Reviews of caries risk prediction models conclude that past caries experience is the best predictor of new caries experience. Additionally good oral health throughout infancy and early childhood contributes to better health in adulthood (4).

Early Childhood Caries (ECC) is an acute, rapidly developing dental disease that can occur at any age after the eruption of the teeth (5). The decay is generally first seen on the maxillary primary incisors, and the four maxillary anterior teeth are usually involved, furthermore the most frequent presentation of early childhood caries (ECC) includes severely decayed primary anterior teeth (6).

Maxillary primary anterior teeth dominate the physical appearance, and their structural loss affects not only esthetics but also leads to compromised mastication, and difficulty in social and psychological adjustment of the child (7).

The restoration of severely decayed primary anterior teeth is often a clinical challenge. Requirements for an acceptable restoration including; natural color, durability, biocompatible, easy and rapid placement has been demanded (8).

Great effort has been made attempting to find an esthetic solution for primary anterior teeth. In the last few years, various types of esthetic crowns for primary teeth appeared in the dental market.

More recently for pediatric dentistry prefabricated primary zirconia esthetic crowns were introduced for pediatric dentistry. Zirconia is a crystalline dioxide of zirconium (ZrO_2), having the following advantages: similar to tooth color, opaque, low thermal conductivity, low corrosion potential, good radiographic contrast, good biologic compatibility, lack of cytotoxicity, less inflammatory infiltrate, less micro vessel density and only slight bacterial adhesion (9).

While the mechanical properties are similar to those of the stainless steel crown (SSC), zirconia is capable of inhibiting crack growth and preventing catastrophic failure and can withstand functional loads in both anterior and posterior region (10).

The vast majority of studies on preformed primary anterior crowns that are available in to the english dental literature are retrospective studies, case reports, or descriptive articles that outline the clinical placement technique of the different crowns (11, 12). The literature on how primary crowns perform in oral environments with differing levels of oral hygiene is also sparse. Few clinical studies reported the oral hygiene of their study participants but no assessment was made to correlate the success of a crown with oral hygiene (13, 14).

The aim of this study was to evaluate;

- The clinical performance of three different full coronal esthetic restorations, the restorations were resin composite strip crowns and two different types of newly introduced prefabricated zirconia crowns for the treatment of the severe form early childhood caries S-ECC affected primary anterior incisor over a period of 9 months in terms of restoration contour, color, failure, gingival response and parental satisfaction.
- *In vitro*, evaluation of the fracture resistance of maxillary primary incisor zirconia crowns from two different manufacturers, NuSmile® (NSZ), and Kinder Krowns® (KKZ) and compare it with the thickness of the zirconia crowns, and assessment of the fractured specimens with scanning electronic microscope.
- *In vitro*, asssessment of the initial bacterial adhesion on composite resin and zirconia material surfaces utilizing standard hydroxyapatite disc as a control.

2. REVIEW OF LITERATURE

2. 1. Early Childhood Caries

1.1.1. Definition

In 1862, an american physician, Abraham Jacobi (Jacobi 1862) was the first to describe the clinical appearance of early childhood caries, which he observed in one of his own patients (15). Whereas, in 1932 Beltrami described this form of caries, as “Les dentes noires des tout petits” (black teeth in small children) (16), then in 1962 Fass was credited with first using the term nursing bottle mouth to describe this caries pattern as early carious involvement of the maxillary incisors followed by the maxillary and mandibular first primary molars and the mandibular cuspids with very mild or no involvement of the lower mandibular incisor. (17).

Then the term “early childhood caries” was suggested at a 1994 workshop sponsored by the Centers for Disease Control and Prevention in an attempt to focus attention on the multiple factors (i.e. socioeconomic, behavioral, and psychosocial) that contribute to caries at such early ages (18, 19).

American Academy of Pediatric Dentistry (AAPD) have defined the early childhood caries (ECC) as the presence of 1 or more decayed (noncavitated or cavitated lesions), missing (due to caries), or filled tooth surfaces in any primary tooth in a child 71 months of age or younger. In children younger than 3 years of age, any sign of smooth-surface caries is indicative of severe early childhood caries (S-ECC).

From ages 3 through 5, 1 or more cavitated, missing (due to caries), or filled smooth surfaces in maxillary primary anterior teeth or a decayed, missing, or filled score of ≥4 (age 3), ≥5 (age 4), or ≥6 (age 5) surfaces constitutes S-ECC (20).

ECC is an acute, rapidly developing dental disease occurring initially in the cervical third of the maxillary primary incisors, destroying the crown completely. Early onset and rampant clinical progression makes ECC a serious public health problem in both developing and industrialized countries (21, 22). It can begin early in life, progresses rapidly in those who are at high risk, and often goes untreated (22), resulting in pain, impairment of function and esthetic, deleterious influence on the child's growth rate, body weight, and ability to thrive, and psychological disturbances of the child thus reducing quality of life (23). The late consequences may continue long after its initial treatment as malnutrition, low self esteem, decay and malocclusion in permanent dentition (24).

ECC is a complex disease, which involves maxillary primary incisors within a month after eruption and spreads rapidly to involve the other primary teeth. Because of the aggressive nature of ECC, areas of demineralization and hypoplasia can rapidly develop cavitation. If untreated, the disease process can rapidly involve the dental pulp, leading to dental infection and possibly life threatening fascial space involvement. Such infections may result in a medical emergency requiring hospitalization, antibiotics and extraction of the offending tooth (25).

2.1.2. Epidemiology

Early childhood caries affects 1-12% of the pediatric population in developed countries, and up to 70% in underdeveloped countries. In developed countries the prevalence is reported to vary between 1 percent and 12 percent. However, in developing countries and within disadvantaged populations in developed countries, the prevalence has been reported to be as high as 70 percent in the preschool population (26).

Studies have found that the frequency of ECC is greater among children in families with a larger number of siblings (27) and those whose mothers are younger (28). Moreover, factors related to the family, such as parents' education level and monthly household income, are related to a greater dental caries prevalence rate (29, 30).

According to the literature, young parent age, a low level of education and insufficient knowledge regarding oral health may lead to a greater prevalence of ECC among children (31). Children from families with a lower income may also have a greater dental caries experience (32).

A survey was conducted between 1988-1991 for over 58 million US children and adolescents 1 to 17 years of age. For infants aged 12-23 months, 0.8% were scored positive for early childhood caries. Over 60% (62.1%) of the children aged 2-9 years were caries-free in their primary dentition. Over half (54.7%) of the children 5-17 years were caries-free in their permanent dentition. The occurrence of caries in the permanent dentition was clustered as: A quarter of the children and adolescents ages 5 to 17 with at least one permanent tooth accounted for about 80% of the caries experienced in permanent teeth (33).

Peressini et al. (2004), conducted a survey in Ontario (Canada) for identifying the prevalence of dental caries in children 7 or 13 years of age concluded that a total of 87 children (59% 5 years old, 54% females) were examined. The mean caries score (decayed, extracted and filled teeth) (dmft+ DMFT) for 7 year old children was 6.2; the mean (DMFT) score for 13 year old children was 4.1. Overall, 95% of children had 1 or more past or active carious lesion (34).

Rosenblatt et al. (2004), concluded in their study that the prevalence of early childhood caries in 12-36 month old children from poor backgrounds in Recife is in accordance with the rate found in other Brazilian cities, which is extremely high compared with that of the world population as a whole. Early childhood caries was not clearly related to the type of feeding in this sample. The prevalence of early childhood caries increased with age and the number of sugary snacks between meals and a cariogenic diet were strongly related to early childhood caries (35).

Hamdan et al. (2002), conducted a survey in Jordan (Amman) including preschool children aged 1 to 5 years selected randomly from nurseries and kindergartens. Overall, 52% of children were caries free. Caries level was significantly related to feeding practices, snacking habits, oral health practices and pattern of dental visiting as well as to socioeconomic background, parents, education level and awareness. The dental caries level was slightly higher than that of children in industrialised countries but lower than that of children in the neighbouring countries. However, the early caries development was seen in children from the lower socio economic classes (36).

Kuvvetli et al. (2008), conducted a study to assess the prevalence of noncavitated and cavitated caries lesions in a group of five year old Turkish children. They concluded that the prevalence of active shallow and deep cavitated caries lesions (21.67% and 16% respectively) were higher than active and inactive noncavitated caries lesions (14.67% and 15.67% respectively) (37).

2.1.3. Etiology

Early childhood caries has a multi factorial etiology and is the result of a time specific interaction of microorganisms with sugars on a tooth surface (38). In addition to the causal factors, the influence of social and behavioural risk factors, which often result from a generally unhealthy lifestyle have been implicated (39, 40).

According to the guideline of European Academy of Paediatric Dentistry (EAPD) on the prevention of ECC, the disease represents a public health problem with biological, social, and behavioural determinants (41).

It was suggested that of the biological determinants, the three key causal factors for dental caries were microorganisms, substrate, and host (42). However, subsequently a fourth time was added by König in 1971 (43).

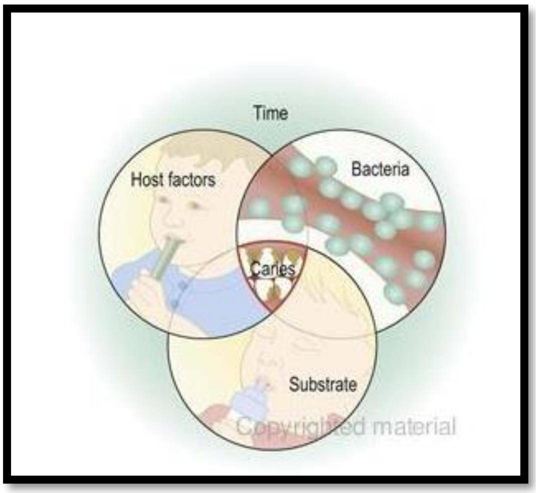

Figure 1.The multifactorial nature of the caries involves the host, substrate, bacteria and time (44**)**

Mutans streptococci (MS) and in particular *Streptococcus mutans (S. Mutans)* and *Streptococcus sobrinus* (*S. Sobrinus)* have been implicated as the most important bacteria for caries initiation and its progression (45). Besides the ability to produce acids from sugars, especially lactic acid, which demineralise tooth enamel, they also produce extracellular polysaccharides that allow for further plaque growth. *S. mutans* can also form intracellular polysaccharides, which allow them to maintain the acid production during periods of low substrate supply (46).

After transmission of cariogenic bacteria and a frequent supply of substrate (sucrose) to the plaque, usually given as a sugary drink (juices and sweetened milk from a feeding bottle) or in older children, in snacks in the form of solid cariogenic foods such as sweets, chocolates, cakes, biscuits, the development of early childhood caries occurs. In addition, during bottle feeding with sugar containing drinks, the upper incisors bathe in these sugar-containing drinks, the saliva from minor salivary glands in the area of these teeth has only limited remineralising properties, whereas the lower incisors remain largely protected by the tongue during bottle feeding (47).

However, many social and behavioural determinants are risk factors for early childhood caries. As with many other chronic non communicable diseases, low socio-economic status, being member of immigrant families, inadequate health literacy and low educational attainment in parents, in particular in mothers, are all risk factors for a number of diseases including early childhood caries. Social and behavioural factors have been described in association with early childhood caries in numerous publications (39, 40).

2.1.3.1. Microbiological Risk Factors

S.mutans and *S.sobrinus* are the main cariogenic microorganisms (48, 49). These acid producing pathogens that cause damage by dissolving tooth structures in the presence of fermentable carbohydrates such as sucrose, fructose, and glucose (50, 51).

Most of the investigations have shown that in children with ECC, *S. mutans* has regularly exceeded 30% of the cultivable plaque flora (52). These bacterial masses are often associated with carious lesions, white spot lesions, and sound tooth surfaces near the lesions.

Conversely, *S. mutans* typically constitutes less than 0.1% of the plaque flora in children with negligible to no caries activity (53).

It is well known that initial acquisition of MS by infants occurs during a well delineated age range that is being designated as the window of infectivity (54).Vertical transmission, also known as mother to child transmission, is the transmission of an infection or other disease from caregiver to child (55).

Scardovia wiggsiae (*S. wiggsiae)* (HOT 195) is a newly named species (56) that had been considered as candidate of a newly recognized caries pathogen which is involved in S-ECC (57). It had previously reported to be associated with advanced dentinal caries in young children using 16S rRNA gene probe analysis and in early, white spot lesions (52), and from occlusal carious lesions of children (58).

Tanner et al. (2011) reported a significant association between *S. wiggsiae* and severe early childhood caries, including those children in whom the primary pathogen of dental caries, *S. mutans*, was not detected. In their study *Scardovia, Parascardovia* species were preferentially isolated on acid agar suggesting a degree of acid tolerance, moreover in the blood agar, *S. wiggsiae* was one of the major species associated with S- ECC in the absence of *S. mutans.* Concluding that *S. mutans* and *S. wiggsiae* showed the highest associations with severe ECC children (57).

2.1.3.2. Feeding Practices

Inappropriate use of baby bottle has a central role in the etiology and severity of ECC. The rationale is the prolonged bedtime use of bottles with sweet content, especially lactose. Most of the studies have shown significant correlation between ECC and bottle feeding and sleeping with a bottle (59, 60).

Breastfeeding provides the perfect nutrition for an infant, and there are a number of health benefits such as; including a reduced risk of gastrointestinal and respiratory infections (61). However, frequent and prolonged contact of primary teeth with human milk has been shown to result in acidiogenic conditions and softening of enamel. Increasing the time per day that fermentable carbohydrates are available is the most significant factor in shifting the remineralization equilibrium toward demineralization (62), morever the insufficient protection caused by reduced nocturnal salivary flow have been considered as another factor to shift the remineralization, demineralization equilibrium toward demineralization (63).

2.1.3.3. Sugars

Fermentable carbohydrates are one of the majör factor in the development of caries. The small size of sugar molecules allows salivary amylase to split the molecules into components that can be easily metabolized by plaque bacteria (64).

This process leads to bacteria producing acidic end products with subsequent demineralization of teeth (65) and increased risk for caries on susceptible teeth. Some authors found a positive relationship between sugar intake and the incidence of dental caries where fluoridation was minimal and dental hygiene was poor (66, 67).

The length of time of exposure of the teeth to sugar is the principal factor in the etiology of dental caries; it is known that acids produced by bacteria after sugar intake persist for 20–40 min. ***Luke et al.(1999),*** studied the clearance of glucose, fructose, sucrose, maltose, and sorbitol rinses, as well as chocolate bars, white bread and bananas, from the oral cavity. Concluding that sucrose is removed the quickest, while sorbitol and food residues stay in the mouth longer. Retentiveness of the food and the presence of protective factors in foods (calcium, phosphates and fluoride) are considered as other factors that contribute to demineralization (68). However, consumption of milk based formulas for infant feeding, even without sucrose in their formulation, were proved to be cariogenic (69).

2.1.3.4. Socioeconomic Factors

Association between ECC and the socioeconomic status (SES) has been well documented. Studies suggested that ECC is more commonly found in children who live in poverty or in poor economic conditions (70), who belong to ethnic and racial minorities, who are born to single mothers (71), whose parents have low educational level, especially those of illiterate mothers (72). In these populations, due to the prenatal and perinatal malnutrition or undernourishment, these children have an increased risk for enamel hypoplasia and exposure to fluoride is probably insufficient (73), and there is a greater preference for sugary foods (74).

2.1.4. Clinical presentation

ECC is initially recognized as a dull, demineralized enamel that quickly advances to obvious decay along the gingival margin (75). The decay is generally first seen on the maxillary primary incisors, in which the four maxillary anterior teeth are usually involved (76).

Carious lesions may be found on either the labial or lingual surfaces of the teeth and, in some cases, on both. The decayed hard tissue is clinically evident as a yellow or brown cavitated area (77).

Furthermore, the expression S-ECC is adopted in the presence of at least one of the following criteria:

• Any sign of caries on a smooth surface in children younger than 3 years.

• Any smooth surface of an antero-posterior deciduous tooth that is decayed, missing (due to caries), or filled in children between 3 and 5 years old.

• The dmft index equal to or greater than 4 at the age of 3 years, 5 at the age of 4 years, and 6 at the age of 5 years (78). However the presentation and the clinical value to recognizing specific patterns of lesions, patterns, which consistute subset of ECC, are clinically associated with differences in lesion location, speed of progression, consequence of manifestation, timing of signs and symptoms, consequence on quality of life, and impact on the integrity of developing dentition may be valuable for purposes of making clinical decisions about disease management, dental repair, and prognosticating future disease (79).

The teeth are affected in the order they erupt (80). The explanation for this pattern of caries distribution is based on the pooling of milk or sweetened liquid from the nursing bottle around the maxillary incisors and other teeth, while the mandibular incisors are physically protected by the tongue (81).

Clinically, ECC presents as one of the following:

2.1.4.1. Type I (mild to moderate) ECC

The existence of isolated carious lesions involving molars and/or incisors. The cause is usually a combination of cariogenic semi solid or solid food and lack of oral hygiene. The number of affected teeth usually increases as the cariogenic challenge persists. This type of ECC is usually found in children who are 2 to 5 years old (82).

Figure 2. Mild Early Childhood Caries.

2.1.4.2. Type II (moderate to severe) ECC

Labiolingual carious lesions affecting maxillary primary incisors, with or without molar caries depending on the age of the child and stage of the disease, and unaffected mandibular incisors. The cause is associated with inappropriate use of a feeding bottle, breast feeding or a combination of both, with or without poor oral hygiene. Poor oral hygiene most probably compounds the cariogenic challenge. This type of ECC could be found soon after the first teeth erupt. Unless controlled, it may proceed to become type III ECC (82).

Figure 3. Moderate Early Childhood Caries.

2.1.4.3. Type III (severe) ECC

Carious lesions affecting almost all teeth including lower incisors. This condition is found between the age of 3 to 5 years. The condition is rampant and generally involves tooth surface/s that are unaffected by caries e.g. mandibular incisors (82).

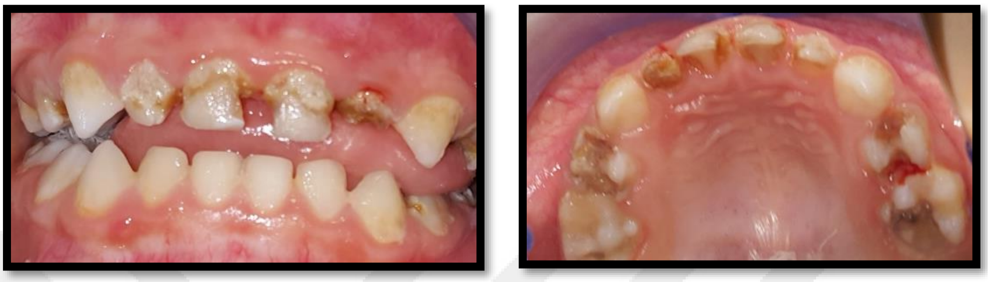

Figure 4, 5. Severe Early Childhood Caries

2.1.5. CONSEQUENCES OF ECC

Consequences of early childhood caries ECC is not self limiting. If treatment for ECC is delayed, the child's condition worsens and becomes more difficult to treat, increasing the cost of treatment. The most common immediate consequence of untreated dental caries is dental pain, which affects children's regular activities, such as eating, talking, sleeping, and playing. Children who had caries in the primary dentition early in life are at greater risk of developing additional carious lesions in their primary and permanent dentition (83).

Severe ECC can lead to the loss of the child’s anterior teeth at an early age. The child may suffer further developmental set backs involving speech articulation, as these years are critical for speech development. Children with ECC can also experience delays in physical development, especially in height and weight. The pain caused by ECC may lead to a decrease in appetite, ultimately resulting in malnutrition (84).

In fact, early extraction or loss of teeth often results in children suffering from psychological trauma from dental procedures required to restore their teeth. Taunting by siblings, peers, and even extended family members may lead to poor self esteem (82).

2.1.6. Prevention

ECC is a preventable disease. The physical, psychological, and economic consequences of ECC can be avoided through the education of prospective and new parents on good oral hygiene and dietary practices, using agents such as fluoride and non-cariogenic sweeteners (85). Prevention of ECC should begin in the pre and perinatal period. Attitudes and awareness of pregnant women may be deficient and unfavourable toward preventive dental practices (86).

Prevention should begin in the pre and perinatal period. It is critical to provide dental care to pregnant women and women of childbearing age, both for their own health and to delay the initial transmission (87, 88).

The safest way is prevention of this complex pathology. EAPD (2008) has recommended general strategies for ECC prevention:

- Oral health assessments with counseling at regularly scheduled visits during the first year of life are an important strategy to prevent ECC.
- Children's teeth should be brushed daily with a smear of fluoride toothpaste as soon as they erupt.
- Professional applications of fluoride varnish are recommended at least twice yearly in groups or individuals at risk.
- Parents of infants and toddlers should be encouraged to reduce behaviours that promote the early transmission of MS (41).

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Based on these recommendations, preventive measures can be classified in:

1. Primary prevention: prenatal and postnatal care.
2. Secondary prevention: parents' and dental professionals' role.

2.1.6.1. Primary Prevention

It should begin during prenatal period and it consists of pregnant woman’s needs’ fulfillment with necessary and healthy products;

- Proper quality of food for the newborn during the enamel maturation phase.
- Fluoridation of newly erupted teeth.
- Antimicrobial therapy with chlorhexidine (89).

2.1.6.2. Secondary Prevention

Mothers’ education on recognizing the first signs of ECC using “lift-the-lip” technique. The aim of this measure is early detection of the so called “white spot”.
Parents should be encouraged to avoid bad feeding habits of their children and give effort for proper feeding:

1. Breast feeding of the baby
2. The use of cup instead of the bottle as early as possible
3. Not sleeping with bottle in mouth
4. Avoid the use of fabricated juices or soda
5. The use of natural, a little sweetened, juice or tea, or just water
6. Reduce the liquid in the bottle, gradually by night.
7. Reduce sweets as much as possible.
8. No sweets between meals.
9. Daily tooth brushing, at least twice a day, obligatory before going to bed.
10. Necessary consultations with the dentist as soon as the first tooth develop in the oral cavity (89).

Bruerd et al. (1989), planned the baby bottle tooth decay project encouraging, tailoring the education materials and strategies to fit each community. Numerous educational materials were used including training manuals, counseling booklets, tippee cups, posters, and bumper stickers. Results documented statistically significant decreases in the prevalence (from 57,2% to 43,4%) of baby bottle tooth decay (90).

Kohler et al. (1982), have reduced high salivary counts of *S. mutans* in mothers by a program consisting of: (1) dietary counseling; (2) professional tooth cleaning with a fluoridated prophylaxis paste, oral hygiene instruction, and topical fluoride application; (3) at-home use of a 0.05% sodium fluoride mouthrinse; and (4) excavation and restoration of large carious lesion (91).

Kohler et al. (1983), showed that a reduction of *S. mutans* in mothers delayed or prevented the establishment of *S. mutans* in their infants during the observation period (92).

The AAPD encourages professional and at-home preventive measures including age-appropriate feeding practices that do not contribute to a child's caries risk, these include:

1. Reducing the mother's/primary caregiver's/sibling (s) *MS* levels (ideally during the prenatal period) to decrease transmission of cariogenic bacteria.

2. Minimizing saliva sharing activities (eg, sharing utensils) between an infant or toddler and his family/cohorts.

3. Implementing oral hygiene measures no later than the time of eruption of the first primary tooth:

a) If an infant falls asleep while feeding, the teeth should be cleaned before placing the child in bed.
b) Toothbrushing of all dentate children should be performed twice daily with a fluoridated toothpaste and a soft, age appropriate sized toothbrush. Parents should use a 'smear' of toothpaste to brush the teeth of a child less than 2 years of age. For the 2-5 year old, parents should dispense a 'pea-size' amount of toothpaste and perform or assist with their child's toothbrushing.
c) Flossing should be initiated when adjacent tooth surfaces can not be cleansed by a toothbrush.

4. Establishing a dental home within 6 months of eruption of the first tooth and no later than 12 months of age to conduct a caries risk assessment and provide parental education including anticipatory guidance for prevention of oral diseases.

5. Avoiding caries promoting feeding behaviors. In particular:

a) Infants should not be put to sleep with a bottle containing fermentable carbohydrates.
b) A libitum breastfeeding should be avoided after the first primary tooth begins to erupt and other dietary carbohydrates are introduced.
c) Parents should be couraged to have infants drink from a cup as they approach their first birthday. Infants should be weaned from the bottle at 12 to 14 months of age.
d) Between meal snacks and prolonged exposures to foods and juice or other beverages containing fermentable carbohydrates should be avoided (93).

2.1.7. Treatment

Treatment of ECC can be accomplished through different types of intervention, depending on the progression of the disease, the child's age, as well as the social, behavioral and medical history of the child (94).

Examining a child early, conducting a risk assessment can provide baseline data necessary to counsel the parent on the prevention of dental decay. Children at low risk may not need any restorative therapy. Children at moderate risk may require restoration of progressing and cavitated lesions, while white spot and enamel proximal lesions should be treated by preventive techniques and monitored for progression. Children at high risk, however, may require earlier restorative intervention of enamel proximal lesions, as well as intervention of progressing and cavitated lesions to minimize continual caries development (95).

However the management of ECC is affected by the extent of the carious lesions and the compliance of the child and parent and can be assessed by the following process (96):

2.1.7.1. Control of the Carious Process

An individualized caries risk assessment is the first important step in the management of ECC. It aims to modify the risk factors, parents should be asked to wean off the child from using a bottle while in bed. In case of considerable emotional dependence on the bottle, parent can be suggested the use of plain water. In addition, parents are instructed to brush child's teeth last thing at night with fluoridated toothpaste (97). In addition, application of chair side topical fluoride varnish (2.2% F) should be carrried out twice yearly in children aged 3-6 years (98).

2.1.7.2. Stabilization of Carious Lesions

The second stage of management would involve stabilization of lesions. If the carious lesion is arrested, it should be monitored to ascertain that it remains in non progressive stage until exfoliation (99).

For non cavitated proximal enamel lesions, a resin infiltration system used in conjunction with fluoride can be used to control caries progression on primary molar teeth (100).

Teeth that require temporization are excavated with spoon excavators and glass ionomer cement is used to seal the teeth. Temporization by sealing of the carious cavity after caries removal reduces the load of bacterial colonization in tooth (101).

Those children at risk for ECC should have care provided by a practitioner who has the training, experience and expertise to manage both the child and the disease process, perform treatment safely, effectively and efficiently. The pediatric dentist often must employ advanced behavior guidance techniques, protective stabilization and/or sedation or general anesthesia (102).

2.1.7.3. Treatment under General Anaesthesia

If the child is unable to be compliant during dental treatment or if the child requires extensive treatment, then the use of general anaesthesia (GA) may be considered. Outcome of treatments related to quality of the restorations performed under GA are reported to be better than sedation for all parameters examined (103). Evidence suggests that comprehensive treatment appears to reduce the bacterial load within the oral cavity and full mouth rehabilitation under general anaesthesia produced a statistically significant decrease in *MS* levels for at least three months (104).

2.1.7.4. Restorative Treatment

Restorative treatment of ECC is based on removal of caries and the treatment approach taken should take into consideration the child's risk factors and age (105). In addition, the choice of restorative material used can be influenced by site and extent of decay, child's ability to cooperate and longevity of the restoration (106). The most commonly used materials used in restoring primary teeth are described in the Table 1.

There are no significant differences in the materials for outcomes as there are not enough clinical trials to support any particular material (108). However, studies on longevities of restorations tend to favour SSC restoration over the resin based materials (109). In young children with high risk of caries, there is good evidence that stainless steel crowns function better than multisurface intraoral restorations (110).

SSC are prefabricated crown forms which can be adapted to individual primary molars and cemented in place to provide a definitive restoration (111).

They have been indicated for the restoration of primary and permanent teeth with caries, cervical decalcification, and/or developmental defects (e.g. hypoplasia, hypocalcification), when failure of other available restorative materials is likely (e.g. interproximal caries extending beyond line angles, patients with bruxism), following pulpotomy or pulpectomy for restoring a primary tooth that is to be used as an abutment for a space maintainer or for the intermediate restoration of fractured teeth is needed (112).

Table1. Advantages and disadvantages of restorative materials used in pediatric dentistry (10)

	Advantages	**Disadvantages**
Amalgam	Simple Quick Cheap Technique insensitive Durable	Not adhesive Requires mechanical retention in cavity Environmental and occupational hazards Public concerns
Composite	Adhesive Esthetic Reasonable wear properties Command set	Technique sensitive Rubber dam required Expensive
Glass Ionomer Cement (GICs)	Adhesive Esthetic Fluoride leaching	Brittle Susceptible to erosion and wear
Resin modified glass ionomer (RMGIC)	Adhesive Esthetic Command set Simple to handle Fluoride release	Water absorption Significant wear
High viscosity glass Ionomer	Adhesive Esthetic Simple to handle Fluoride release High compressive strength and wear resistance	Water absorption Colour not as good a match as composite resins, compomers and other GICs Poorer mechanical properties than compomer and composites
Poly acid modified composite resin	Adhesive Esthetic Command set Simple to handle Radiopaque	Technique sensitive Less fluoride release than GICs
Stainless steel crown SSC	Durable Protect and support remaining tooth structure	Extensive tooth preparation Patient co-operation required Unesthetic

2.2. Full Coronal Restorations (FCR)

Esthetic treatment of severely decayed anterior primary teeth is one of the greatest challenges to pediatric dentists. In the last half century the emphasis on treatment of extensively decayed primary teeth shifted from extraction to restoration. Early restorations consisted of placement of full coverage restorations on severely decayed teeth, thus restoring the function and esthetic (113).

2.2.1. Historical developments in pediatric crowns

In 1947 preformed crowns (PMC) were introduced by Rocky Mountain Company, then in 1950 Stainless steel crown SSC was described by Engel and popularized by William Humphrey in pediatric dentistry (114).

Between 1950-1968 various modifications in preformed crowns were occurred, however several biological restorations were advocated by Chosak and Eildeman in the 1964 (115).

In 1970 polycarbonate crowns were introduced (116), then in 1971 Mink and Hill advised SSC crown restorations for deep sub gingival caries, solder joints for interdental spacing and SSC modification for deep sub gingival caries, undersized crowns and interdental spacing (117).

In 1977 Mc Evoy advised modification of SSC technique for SSC with arch length or space loss (118), between 1980 and 1990 various preveneered stainless steel crowns PVSSC were introduced (119,120), while strip crowns were introduced in 1979 by Webber and colleagues (121), 1981 Nash advocated modification of SSC for adjacent crowns placement (122).

In 1983, Hartman advised veneered SSC technique for esthetic anterior crown restoration (123). In the1987 Cheng crowns were introduced by Peter Cheng, followed by the Kinder Krown® crowns in 1989 (124).

Between 1990 and 1995 Hall technique was introduced by Dr Norna Hall for SSC adaptation on carious tooth without tooth preparation (125). In 1993 Randy advised band adaptation on SSC crown as space maintainer rather than crown and loop (126), in the 1997 Pedo natural crowns were introduced to the dental market.

In 1997 Zirlock incisalock technology was introduced for better retention of preveneered crowns. In the 2002, ***Kupietzky et al. (2002)***, advised split technique and rubber dam isolation technique for restoration of multiple primary anterior teeth restoration (127).

In the recent years zirconia crowns were introduced as esthetic restoration for primary teeth (128, 129).

2.2.2. Ideal requirements for full coronal restoratiom

An ideal FCR should have the following requirements:

- Is esthetically acceptable.
- Have natural color.
- Lasts until exfoliation of primary teeth.
- Is biocompatible and non irritant to the gingiva.
- Can be easily and rapidly placed.
- Is cost effective.
- Esthetic covering would not chip off.
- Can maintain tooth integrity.
- Can retain masticatory function.
- Would not abrade opposing teeth.
- Can protect and preserve tooth structure.
- Can reestablish adequate function.
- Can restore esthetics (130, 131).

2.2.3. Indications for full coronal restorations

Full coronal restoration of carious primary incisors is indicated in the following situation:

1. Caries is present on multiple surfaces.
2. The incisal edge is involved.
3. There is extensive cervical decalcification.
4. Pulpal therapy is indicated.
5. Caries may be minor, but oral hygiene is very poor.
6. The child’s behavior makes moisture control very difficult (131, 132).

2.2.4.Types for full coverage restoration

The crowns available for restoring primary incisors can be classified into two categories:

1) Those that are preformed and held onto the tooth by a luting cement
2) Those that are bonded to the tooth (133).

The types of FCR restoration available to restore anterior primary teeth are mentioned in Table 2.

The types of FCR for anterior primary teeth currently available are:

- Stainless Steel and Open Faced Stainless Steel Crowns
- Pre veneered steel crowns
- Acrylic Resin Crowns
- Polycarbonate crowns
- Laboratory Enhanced Composite Resin Crowns
- Pedo Jacket Crowns
- Resin composite strip crowns (RCSc)
- Zirconia crowns

Crowns of many types are available for maxillary primary incisors and canines. However, the only crown forms currently manufactured that are made specifically for mandibular incisors are zirconia crowns. In some instances, a maxillary lateral strip crown form or a maxillary lateral preveneered crown can be used to restore mandibular incisors; however, this unfortunately often results in a bulky looking restored incisor (11).

Table 2. Full coronal restorations of primary anterior teeth (132)

Esthetic Crowns Available	Manufactures	Anterior	Posterior	Bonded or Cemented	Multiple Shades
Preveneered **Zirconia**	NuSmile® Pediatric Crowns 1-800-346-5133 Houston, Texas	Yes Yes	Yes Yes	Cemented Cemented	2 shades 2 shades
Preveneered **Zirconia**	Cheng Crowns 1-800-288-6784 Exton, Pa.	Yes Yes	Yes Yes	Cemented Cemented	1 shades 2 shades
Preveneered **Zirconia**	Kinder Krowns® Mayclin Dental Studios 1-800-522-7883 St. Louis Park, Minn.	Yes Yes	Yes Yes	Cemented Cemented	2 shades 2 shades
Zirconia	EZ Pedo Crowns 888-539-7336 Loomis, Calif.	Yes	Yes	Cemented	1 shades
Flex preveneered **Life Like Crowns: Lab-enhanced composite resin crown form** **Pedo Jackets: copolyester crown form** **Plastic crown form**	Space Maintainers Laboratories 1-800-423-3270 Chatsworth, Calif.	Yes Yes Yes Yes	Yes Yes Yes No	Cemented Bonded Bonded Bonded	1 shades 1 shades 1 shades Clear
Plastic crown form	3M/ESPE Minneapolis, Minn. 1-800-634-2249	Yes	No	Bonded	Clear

2.2.4.1. Stainless steel and open faced stainless steel crowns

Stainless steel crowns were introduced to pediatric dentistry by the Rocky Mountain Company in 1947 and slightly modified made popular by W. P. Humphrey in 1950 (114). Until then the treatment for grossly decayed primary teeth was extractions. Stainless steel is composed of iron, carbon, chromium, nickel, manganese and other metals. The term stainless steel is used when the chromium contents exceeds 11% (usually a range of 12 to 30%). The chromium oxidizes forms a protective film of chromium oxide which protects against corrosion (12).

In severely decayed primary teeth with minimal enamel remaining for bonding, subgingival caries, and uncontrolled moisture and hemorrhage, stainless steel crowns are the restorations of choice (134). Over the years, many clinical studies including the longitudinal studies have demonstrated the superiority of stainless steel crowns in restoring primary molars with multisurface involvement (135, 136).

However, there are no published studies that have been reported on the use of stainless steel crowns for primary anterior teeth. Despite this lack of data, stainless steel crowns appear to be the most durable and technique friendly restorations to place on decayed primary anterior teeth (113).

The main drawback of these preformed metallic crowns is their unesthetic appearance, for this reason, they are most often used in the restoration of anterior teeth that are less visible, such as the primary canines and mandibular incisors (113).

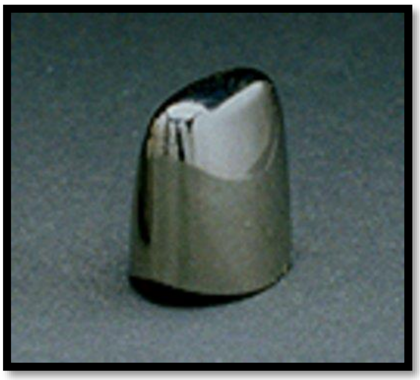


Figure 6. Prefabricate stainless stell crown 3M™ UNITEK™ (12)

One way to improve the poor esthetic appearance of anterior stainless steel crowns is to cut a window on the labial aspect of the crown and place a composite resin material. Such modified crowns are referred to as open faced stainless steel crowns. The drawbacks of this procedure are the increase in chair time due to the placement of a custom-made labial fenestration, and also the metallic appearance of the crown cannot be entirely masked. Open faced stainless steel crowns combine strength, durability and improved esthetics, however they are time consuming to place as the composite facing cannot be placed until the stainless steel crown cement sets and finally the color of the metal margins surrounding the composite adds a grayish tinge to the tooth that is accentuated next to the white enamel of an adjoining or opposing primary tooth (137).

Figure 7. Window on the labial aspect of the prefabricated stainless stell crown 3M™unitek™ (12)

There is also no published data on these open faced stainless steel crowns for the restoration of decayed primary incisors, and thus, there is no evidence to demonstrate their longevity.

2.2.4.1.1. Advantages and disadvantages of stainless steel and open faced stainless steel crowns

The advantages and disadvantages of stainless steel and open faced stainless steel crowns are summarized in the Table 3.

Table 3. The advantages and disadvantages of stainless steel and open faced stainless steel crowns (12)

Type of crown	Advantages	Disadvantages
Stainless Steel Crowns	• They are very durable, wear well and are retentive. • The time for placement is fast compared to other techniques. • They may be used when gingival hemorrhage or moisture is present or when the patient exhibits less than ideal cooperation. • They are fairly inexpensive.	• Esthetics are extremely poor.
Open Faced Crowns	• The esthetics are fair. (The metal shows through the composite facing) • They are very durable, wear well and retentive. • The materials are fairly inexpensive.	• The time for placement is long as it involves a two-step process (crown cementation / composite facing placement • Placement of the composite facing may be compromised when gingival hemorrhage or moisture is present or when the patient exhibits less than ideal cooperation.

2.2.4.2. Preveneered stainless steel crowns

Preveneered stainless steel crowns (PVSS) resolve some of the problems associated with stainless steel crowns, open faced stainless steel crowns, and resin composite strip crowns.

They were introduced in the mid 1990's. They are esthetic, placement and cementation are not significantly affected by hemorrhage and saliva and can be placed in a single appointment. They combines the strength and durability of stainless steel crowns with the esthetics of resin composite strip crowns. These stainless steel crowns are covered on the buccal or facial surface with a tooth colored coating of polyester epoxy hybrid composition (12).

In a retrospective study, ***Roberts et al. (2001),*** evaluated the clinical success and parental satisfaction of a type of pre veneered stainless steel crowns (Whiter Biter Inc.). Over a period of 32 months (mean 20 months), 32% of the crowns (12 out of 38 crowns in 12 children) exhibited partial or complete loss of the resin facing. Despite the high failure rate, parents demonstrated an excellent acceptance of the crowns (138).

The main advantge in these crowns is that are pre fabricated with a resin facing material. Unlike open faced stainless steel crowns or resin composite strip crowns, they can be used when saliva and hemorrhage cannot be adequately controlled, as well as in cases where carious lesions extend subgingivally. The other advantage that these crowns have over open-faced stainless steel crowns is that no additional chair time is necessary for the incorporation of the resin facing (113).

Figure 8. Pre-veneered stainless steel crowns NuSmile® Signature Anterior (128)

2.2.4.2.1. Advantages and disadvantages of preveneered stainless steel crowns

The advantages and disadvantages of preveneered stainless steel crowns are summarized in the Table 4.

Table 4. The advantages and disadvantages of preveneered stainless steel crowns (12)

Advantages	Disadvantages
They are esthetically pleasing.	They are 3 times more expensive than stainless steel, strip and polycarbonate crowns.
They require relatively short operating time.	The technique does not allow for major recontouring and reshaping of the crown.
They have the durability of a steel crown.	The tooth is adjusted to fit the crown, rather than adjusting the crown to fit the tooth.
They are less moisture sensitive during placement than resin composite strip crowns.	As crimping is limited to lingual surfaces there is not a close adaptation of crown to tooth.
	There are reports of the veneer facing fracturing, however it can be easily repaired using the open faced stainless steel crown technique.

A clinical disadvantage is that, they are relatively inflexible as the resin facing is brittle and tends to fracture when subjected to heavy forces or crimping. Because only the lingual portion of the crown can be adjusted (crimped), significant removal of tooth structure must be performed to fit the tooth to the crown rather than the crown to the tooth. Furthermore, there is limited shade choice (11).

2.2.4.3. Acrylic resin crowns

Another treatment approach that has been attempted to meet both the functional and esthetic requirements of primary anterior crowns is the acrylic resin crown. This technique involves the use of a preformed celluloid crown form which is filled with a tooth-colored, self-curing acrylic resin that is seated onto a prepared primary incisor. Once the acrylic resin is cured, the celluloid crown form is removed, the excess acrylic resin is trimmed from the margins of the remaining crown, and a zinc phosphate or acrylic cement is used to cement the acrylic resin crown onto the prepared tooth (139).

The clinical success of these acrylic resin crowns remains anecdotal as there are no published studies that report on the longevity of these crowns. The differences between acrylic crowns and open-faced or pre-veneered stainless steel crowns is that they are more similar to a natural primary tooth and do not have a metallic display. However, the downside of these crowns is that they are porous and tend to discolor quite easily (140).

In 1979, Doyle introduced a technique to help increase the retention of acrylic crowns, which he referred to as acrylic jackets. The author described acid etching the prepared primary tooth and using a composite resin to fill the acrylic jacket, which is then seated onto the tooth, the composite resin is allowed to set, and the margins are finished with a bur. Nonetheless, the advent of many other full coverage crowns for primary incisors have allowed practitioners to draw away from the use of acrylic resin crowns (141).

2.2.4.4. Polycarbonate crowns

Polycarbonate crowns were popular in the 1970’s, they constitute of heat-molded acrylic resin shells that are adapted to teeth with self cured acrylic, prefabricated crowns that are thinner than acrylic resin crown (140).

However, although they were more esthetic than stainless steel crowns the polycarbonate material was brittle and did not resist strong abrasive forces, exhibiting frequent fracture and dislodgement. With the advent of resin composite strip crowns they lost their popularity (113).

In the 1990’s new manufacturing techniques made them thinner and more flexible resulting in stronger restoration and resurgence in their use. Several authors have described the use of polycarbonate crowns, as another type of preformed full coverage crown for primary incisors with extensive decay (133, 141, 142). Although there are no published studies that have evaluated their clinical success, there are a few descriptive reports in the literature that outline the placement technique for these crowns, also describe the indications and contraindications for polycarbonate crowns (140).

The indication for such a crown includes the restoration of primary incisors or cuspids with extensive decay (140). Conversely, the use of polycarbonate crowns are cautioned in cases where there is insufficient remaining tooth structure for retention, and also in cases of bruxism and deep overbites, as these crowns have a lower resistance to heavy forces. Crowding of the dentition also precludes the restoration of carious primary anterior teeth, as there must be enough space to accommodate the crowns (141).

The placement technique of polycarbonate crowns include; a preformed crown of adequate size is selected to fit the prepared incisor and the crown form is cemented onto the tooth with an acrylic resin. Alternately, a composite resin material can be used to fill the crown form, which is also seated onto the tooth and held in place until the composite resin has set. Finishing of the margins and polishing of the crown are the final steps in the placement of polycarbonate crowns. Among the problems with polycarbonate crowns is their tendency to fracture or dislodge from the prepared tooth (140).

Myers et al. (1975), proposed a modified technique to help overcome the problem of crown fracture and loss. Firstly, the author suggested adding cervical undercuts on the interproximal surfaces in addition to the labial. Secondly, the author advised against, forcing the crown into a prepared tooth, to prevent stretching forces which may cause eventual splitting of the crown form. Lastly, it was recommended to prepare an escape hole be on the lingual surface of the polycarbonate crown during cementation to allow for the dissipation of stress forces upon seating of the crown (143).

Although these methods have been suggested to help increase crown retention, due to the lack of clinical studies in the literature, it is not possible to precisely determine the long term retentiveness of polycarbonate crowns (144).

Figure 9: Polycarbonate crown by 3M ESPE, USA (3M ESPE, 2014)(145)

Polycarbonate crowns have been shown to lack adequate retention, either by the crown being lost from the prepared primary tooth or from the intermediate cementing agent. Although the various laboratory studies from the 1970s showed some potential in improving crown retention, the popularity of polycarbonate crowns has since declined and they are no longer used (143, 144).

2.2.4.4.1. Advantages and disadvantages of polycarbonate crowns

The advantages and disadvantages of polycarbonate crowns sare summarized below in Table 5.

Table 5. The advantages and disadvantages of polycarbonate crowns (12)

Advantages	Disadvantages
They are very esthetic, with greater durability than resin composite strip crowns and pre-veneered crowns.	They are not recommended in patients that are heavy bruxers.
They are not as technique sensitive as resin composite strip crowns as the fabricated crown is cemented with self adhesive resin cement rather than bonding.	Greater tooth reduction is required
They take about the same amount of time to place as stainless steel crowns, resin composite strip crowns and preveneered crowns and less than open faced stainless steel crowns.	.

2.2.4.5. Pedo jacket crowns

An alternate crown form for grossly decayed or traumatized primary incisors that is commercially available is the Pedo Jacket. The “jacket” consists of a copolyester material in the natural primary tooth color shade A2. The crown is flexible and its length can be adjusted and trimmed with scissors. In contrast with all of the crowns discussed above, it is important to note that this is the only flexible or soft crown option available (139).

This property allows for the Pedo Jacket crown to accommodate the great variability in tooth size and shape and to facilitate adaptation to the teeth, especially in a pre-cooperative child. The tooth preparation is similar to that of strip crowns but often requires less tooth reduction. It includes caries removal and preparation of the tooth to conform to the inner surface of the crown leaving undercuts or parallel surfaces. The crown is then fitted onto the tooth and trimmed with scissors to adjust the length as necessary. The copolyester crown shell must be primed with a plastic primer material provided by the manufacturer (12).

The exact chemical composition of the Pedo Jacket crown or crown primer has not been made available by the manufacturer. The prepared tooth is then conditioned with acid etch and a bonding agent is recommended. The crown is then filled with composite resin or a resin-modified glass ionomer if moisture and hemorrhage control cannot be achieved. Once the crown is seated on the tooth, it is polymerized and the crown form is left on the tooth (146).

Figure 10: Pedo Jacket crowns by Space Maintainers Laboratory, USA (146)

Like all other restorations, Pedo Jacket crowns have their disadvantages. They tend to exhibit wear in areas of heavy occlusion and the crown margin can discolor over time. A common type of failure is the stripping of the Pedo Jacket crown from the filling material. Often the remaining composite resin or resin modified glass ionomer remains intact on the primary tooth. With the copolyester shell completely lost, the remaining restorative material appears as a strip crown, which can be left on the tooth without requiring additional treatment intervention (12).

2.2.4.5.1. Advantages and disadvantages of pedo jacket crowns

The advantages and disadvantages of pedo jacket crowns are summarized in the Table 6.

Table 6. The advantages and disadvantages of pedo jacket crowns (12)

Advantages	Disadvantages
Good esthetics	Can tear margins with rotary instruments
Flexible and easy to adapt	Can wear
Clinically efficient as the crowns do not have to be stripped off at the end of the procedure	Crown can separate from cement
Can act as temporary restorations when used with RMGI	Difficult to place in crowded dentitions
If the crown debonds, the residual RMGI cement appears as a strip crown	Crowns can not be heat sterilize

2.2.4.6. Laboratory enhanced composite resin crowns

Laboratory enhanced composite resin crowns entail a two appointment procedure which involves caries removal and preparation of the affected tooth, followed by an impression with a polyvinyl siloxane material and temporization of the tooth on the first visit. Cementation of the final laboratory fabricated composite resin crown with a resin cement is then performed at the second visit. The second dental visit involves the cementation and finishing of the composite resin crowns (139).

Motisuki et al. (2005), describe a similar technique for the fabrication of indirect composite resin crowns with the addition of a fibreglass post to improve retention of the restoration. The technique also involves two dental appointments for an impression and then insertion of the crowns. The authors claim that the two appointments minimize the time spent in the chair by a potentially uncooperative patient during each appointment, which in turn decreases operative complexities such as moisture contamination (147).

In summary, the few case reports on laboratory enhanced composite resin crowns suggest that there may be several advantages to their use such as more complete resin polymerization, better wear resistance and decreased clinical chair time (148,149).

Nevertheless, it is difficult to extrapolate the relationship of patient behavior at the time of crown placement and the clinical success of the restorations from such case reports. Overall, there is insufficient evidence in the literature to be able to recommend these types of restorations over other more conventional preformed anterior crowns for primary teeth.

2.2.4.7. Resin composite strip crowns (RCSc)

The most popular type of preformed esthetic crowns for primary incisors is the resin composite strip crown. This type of crown was first introduced in **(1979)** by ***Webber et al.*** (121).

Resin composite strip crowns are composite filled celluloid crowns forms. They have become a popular method of restoring primary anterior teeth because they provide superior esthetics as compared to other forms of anterior tooth coverage. Composite strip crowns rely on dentin and enamel adhesion for retention.

The indications for strip crowns include extensive decay of the primary anterior teeth, fractured or malformed teeth, teeth that exhibit discoloration and as coverage for teeth that have received pulp therapy. Conversely, strip crowns are contraindicated in cases where primary teeth are severely decayed that they present with insufficient tooth structure for retention and bonding, deep overbites, and in children with periodontal disease (150).

Figure 11: Strip crowns for anterior teeth by 3M ESPE, USA (151)

Therefore the lack of tooth structure, the presence of moisture or hemorrhage contributes to compromised retention. They are less resistant to wear and fracture more readily than other anterior full coverage restorations (151).

Tate et al. (2002), found that resin composite strip crowns had a failure rate of 51%, compared to an 8% failure rate of stainless steel crowns (152).

With a cooperative patient, the time required for placement is comparable to that of a stainless steel crown or polycarbonate crown (12). Resin composite strip crowns are now widely accepted because of their better esthetics as they resemble more closely the natural appearance of teeth (11). There are numerous case reports and articles in the literature that describe the technique for placement of these crowns (12,150).

The technique involves the reduction of all surfaces of a primary anterior tooth and caries removal, selection of an adequately sized celluloid crown form, trimming of the crown form, acid etching and conditioning of the prepared tooth, filling of the crown form with a composite resin material, and seating of the filled crown onto the tooth. The composite resin is then polymerized, the celluloid crown form is peeled off or “stripped” with a hand scaler, and the remaining composite resin is finished at the margins and polished using a bur (12).

Even in the face of their superior esthetics, resin composite strip crowns present several disadvantages. They require a more delicate placement; proper moisture and hemorrhage control, appropriate patient selection, tooth preparation and application of adhesive and composite which can all lead to the failure of this type of restoration (121,150).

Therefore, a less technique sensitive yet still full coronal restoration is desirable. The placement of direct composite resin for the restoration of carious or fractured maxillary primary incisors presents multiple challenges to the clinician and there are numerous limitations to the material and technique. For instance, lack of patient cooperation and difficulty in obtaining adequate isolation of the teeth leading to hemorrhage and salivary contamination of the working field greatly compromises successful of placement and longevity of resin composite strip crowns (149).

Secondly, incomplete polymerization of the direct composite resin material may occur due to the presence of ambient oxygen. Placement of the composite resin material in small increments can help improve polymerization by increasing the depth of cure but it also increases chair time and possibility of contamination, thus leading to increase risk of failure of the resin restoration (148).

Kupietzky et al. (2003), reported on the clinical and radiographic success of 112 resin composite strip crowns (3M ESPE) in 40 children. It was determined that the crowns had an 88% retention rate with a mean follow-up time of 18 months. Although none of the crowns were completely lost, partial loss of the resin occurred in 12% of the teeth (153).

The same retrospective study sample was used 1 year later to assess parental satisfaction with the esthetic appearance of the resin composite strip crowns, 78% of parents reported to be “very satisfied” with crowns, with durability being significantly related to their overall satisfaction with the crowns (154).

In 2005, the same authors published another retrospective study with clinical and radiographic data on resin composite strip crowns after 3 years of follow-up. The study sample consisted of 145 resin composite strip crowns in 52 children and the results showed a 78% retention rate for a period of over 36 months (155).

Ram et al. (2006), found similar results for crown retention in a 2006 retrospective study. After a 2 year follow-up, 80% of the resin composite strip crowns were successful at the final examination (156).

2.2.4.7.1. Advantages and disadvantages of Resin Composite Strip Crowns (RCSc)

The advantages and disadvantages of RCSc are summarized in the Table 7.

Table 7. Advantages and disadvantages of RCSc (12)

Advantages	Disadvantages
It provides superior esthetics.	It is extremely technique sensitive.
The cost of materials are reasonable.	It is not as durable or retentive as stainless steel/open faced crowns, preveneered crown or polycarbonate crown.
The time for placement is reasonable.	Is not recommended on patients with a bruxism habit or a deep bite.
	Adequate moisture control might be difficult in an uncooperative patient.

2.2.4.8. Prefabricated primary anterior zirconia crowns

Recent addition to the spectrum of choices for preformed primary anterior crowns is the zirconia crown, metal free crowns are made from monolithic zirconia, made like ceramic steel, mimic anatomical contours of natural primary teeth to achieve a natural clinical outcome (12, 129).

The indications for such crowns do not differ from the previously mentioned preformed primary crowns and the placement technique resembles that of pre-veneered stainless steel crowns. Incisal, facial, lingual and interproximal reductions between 0.5 and 0.75 millimeter (facial-lingual surfaces) to 2 millimeter (incisal) are required to passively fit an adequately sized zirconia crown. A major difference from the other types of crowns is that the length of the zirconia crown cannot be adjusted with scissors but instead a rotary bur with water spray must be used. Occlusal and interproximal reductions are also contraindicated due to possible weakening and thinning of the ceramic (12).

2.2.4.8.1. Advantages and Disadvantages of Zirconia Crowns

The advantages and disadvantages of newly introduced zirconia crowns are listed in the Table 8.

Table 8. Advantages and disadvantages of zirconia crowns (12)

Advantages	Disadvantages
Superior esthetic and strength	No crimping
Full coverage protection	Saliva and hemorrhage must be controlled
Biocompatible	Cost
Autoclavable	Difficult to place in crowded dentitions
Good alternative to patient sensitive to nickel	
One visit	

2.2.4.8.2. Parental satisfaction of Zirconia Crowns

Walia et al. (2014), conducted a randomized clinical trial to compare the clinical outcomes of three full coronal restorations, resin composite strip crowns (Pedoform strip crowns forms 3M® St. Paul MN), preveneered stainless steel crowns (NuSmile® Pediatric Crowns, Houston, TX) and prefabricated primary zirconia crowns (Zirkiz® crowns, Hass, South Korea), restorations were evaluated regarding mean of failure, tooth wear of opposing teeth and gingival health. It was concluded that the retention rate was highest for zirconia crowns (100%) followed by pre-veneered SSCs (95%). Resin composite strip crowns were reported to be the least retentive (78%). Zirconia crowns showed low grade abrasion in four opposing teeth (157).

After one year the same authors reported in a successor study that the parental overall satisfaction was highest for zirconia primary crowns followed by resin composite strip crowns and lowest satisfaction was reported for preveneered SSCs (158).

Karaca et al. (2013), reported that at 18 months follow-up, zirconia crowns demonstrate good retention, have superior esthetics and natural appearance with short chair time (159).

Del Pozo et al. (2014), reported that zirconia crowns crowns Zirconia NuSmile® represent a new approach and another alternative to restore the natural appearance of a child‘s’ teeth compromised by caries and/or trauma, supposing that even the teeth may be stressed by a luxation injury after placement, this did not damage the appearance nor the stability of the crowns (160).

Despite their increasing popularity, the clinical performance of these crowns has yet to be reported in the literature. There are a few clinical studies, and until the results of sufficiently large prospective clinical studies with long term follow-ups, the evidence on the clinical success and longevity of the zirconia crowns remains insubstantia

2.2.5. Comparison of full coverage restoration techniques for primary incisors

Full coverage techniques for restoration of primary teeth are summarized in Table 9.

Table 9. Comparison of full coverage techniques for primary incisors (113)

Technique	Esthetics	Durability	Time For Placement	Selection Criteria
Resin composite strip crown	Very good initiallly may discolor over time	Retention dependent on the amount of the tooth structure present	Time required for optimum isolation	When esthetics are a great concern Adequate tooth structure remaining for etching and bonding Gingival hemorrhage is controllable
Prefabricated veenered stainless steel crown	Very good	Good however facing may occasionally chip or fracture	Comparable to strip crown	Esthetic are a concern Hemorrhage difficult to control
Stainless Steel crown	Very poor	Very good	Fasten crown to place	Severely decayed teeth esthetics of no concerns Unable to control gingival hemorrhage
Open face stainless steel crown	Good however some metals show	Good like steel crown are very retentive however facing may be dislodged	May take longest because of two step procedures Crown placement Composite placement	Severely decayed teeth

2.3. Zirconia

2.3.1. Definition and History of Zirconia

Zircon or zirconium silicate, $ZrSiO_4$ (67.2% of ZrO_2 and 32.8% of SiO_2) the mineral was discovered by Martin Henrich Klaproth, a German chemist, who analysed a zircon from Ceylon (Sri Lanka) in 1789 (161).

The impure metal (metallic zirconium) was first isolated by Jöns Jakob Berzelius, a Swedish chemist, in 1824 by heating a mixture of potassium and potassium zirconium fluoride in a small iron tube (162). However, it was impossible to obtain pure zirconium at that time until the beginning of the 19th century. The pure zirconium oxide was first prepared in 1914 by Herzfield. He invented the process of crystallising zirconium oxychloride octahydrate from a concentrated solution of hydrochloric acid to remove large amounts of silica and the oxychloride octahydrate then crystallised out upon cooling (163).

Zirconium is represented by the chemical symbol (Zr) and has the atomic number 40. It is one of the transition metals (elements whose atom has an incompleted subshell) of the Dmitrii Ivanovich Mendeleev's periodic chart (164). Zirconium exits in two forms: the crystalline form, a soft, grayish-white, lustrous metal; and the amorphous form, a bluish-black powder. From ancient times, zirconium has been known as zircon, which probably originated from the Persian word *zargun* wich mean golden in colour (165).

ZrO_2 is a polymorphic material and occurs in three forms: monoclinic, tetragonal and cubic. The monoclinic phase is stable at room temperatures up to 1170 ℃, the tetragonal at temperatures of 1170-2370 ℃ and the cubic at over 2370 ℃ (166).
However, noticeable changes in volume are associated with these transformations: during the monoclinic to tetragonal transformation a 5% decrease in volume occurs when zirconium oxide is heated; conversely, a 3%- 4% increase in volume is observed during the cooling process (167).

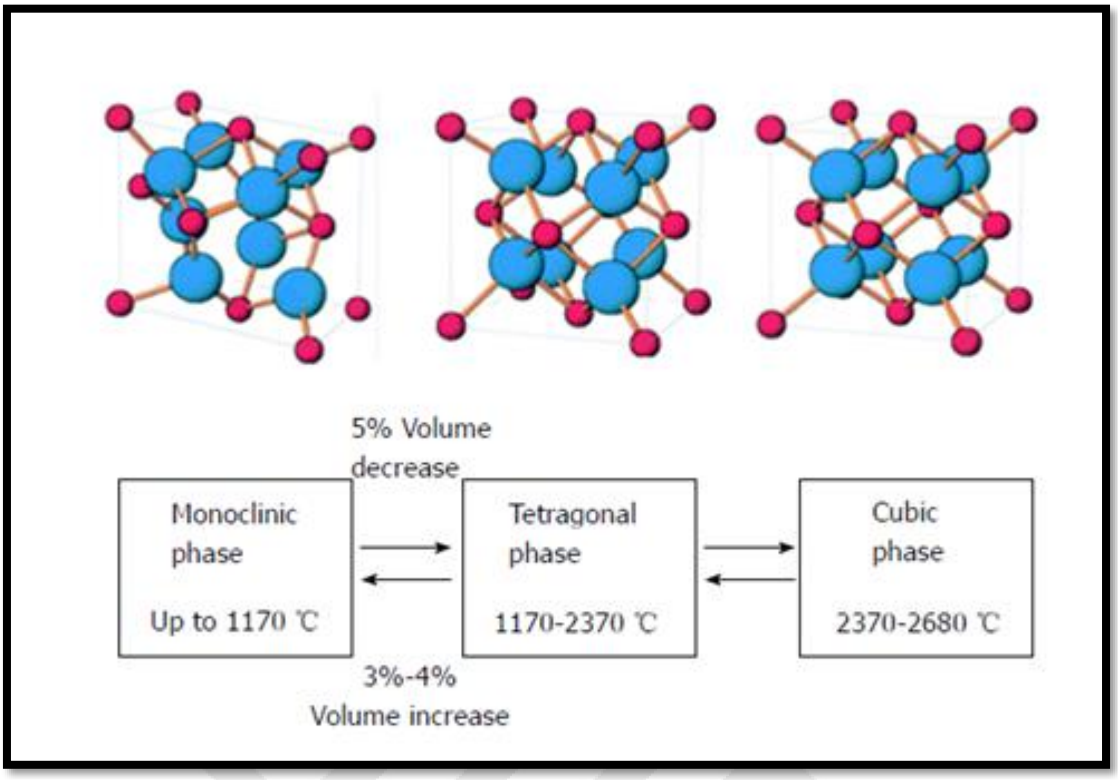


Figure 12. Temperature related phase transformation of zirconia (168)

Yttria stabilized zirconia (YSZ) is a ceramic in which the crystal structure of zirconium dioxide is made stable at room temperature by an addition of yttrium oxide. These oxides are commonly called "zirconia" (ZrO_2) and "yttria" (Y_2O_3), hence the name.

Zirconia ceramic was extended into dentistry in the early 1990s as endodontic posts and more recently as implant abutments and hard framework cores for crowns and fixed partial dentures, having a unique characteristic called transformation toughening, gives it higher strength and toughness compared with other ceramics (169).

2.3.2. Characteristics of zirconia based ceramic

Zirconia ceramics have superior properties compared to other ceramics mainly biocompatibility. However, the properties of zirconia ceramic may be reduced when it contacts thermal and humid environments (170).

2.3.2.1. Biocompatibility

Biocompatibility has been defined as the ability of a material to perform with an appropriate host response in a specific application. The biocompatibility of zirconia has been extensively evaluated (171).

In vitro and *in vivo* studies have confirmed the high biocompatibility of Y-TZP with the use of very pure zirconia powders that have been purged of their radioactive content (172,173). No local (cellular) or systemic adverse reactions to the material were reported (173).

Cell cultures prepared with fibroblasts, blood cells and osteoblast cells were used in *in vitro* tests which were performed on ceramic materials in different physical forms such as powders and dense ceramics (174).

Josset et al. (1999), investigated human osteoblasts in culture with zirconia and alumina discs and they found that cells showed good adhesion and spreading properties (175).

In terms of periodontal health, none of the studies reported any difference or noted any changes in the biological health of the soft and hard tissues around the zirconia-based restorations. Although some data quantified and explored differences in the biocompatibility of zirconia, no instances of gingival inflammation or periodontitis could be shown (175,176). These findings have led to the suggestion that zirconium oxide may be a suitable material for manufacturing implant abutments with a low bacterial colonization potential (177).

2.3.2.2. High strength and toughness

Because ceramics are weak in tension; this aspect should be tested. However, the direct tensile test is difficult to perform. This is due to the difficulty in preparing specimens to have the required geometry and it is also difficult to hold the brittle specimens without pre-stressing and fracturing them. The flexure test is an alternative test to investigate the stress at fracture of brittle materials, which is known as flexural strength. Fracture toughness identifies the resistance of the brittle materials to the catastrophic propagation of flaws under an applied stress (178).

Yttria partially stabilised tetragonal zirconia polycrystal ceramics exhibit flexural strength ranging from 800-1300 Mpa (171) with a toughness of approximately 5-10 MPa.m1/2 depending on processing methods, composition and microstructures (178).

2.3.2.3. Fatigue resistance

2.3.2.3.1. Fatigue failure

Fatigue is the mode of failure, where by a structure eventually fails after being repeatedly subjected to loads that are so small that one application does not cause failure (170). All ceramic materials are susceptible to fatigue mechanisms that can considerably reduce their strength over time. The reduction of mechanical strength due to fatigue is caused by the propagation of natural cracks initially present in the component's microstructure (179).

The influence of moisture contamination has also previously been identified to affect the fracture strength of ceramic-based dental ceramics, resulting in a 20% decrease in the mean fracture strength. The maximum stress, which was recommended to apply during cycling tests due to higher mechanical strength of zirconia was 500 Mpa (179).

Curtis et al. (2006), highlighted that the biaxial flexural strength of Y-TZP ceramic was not detrimentally influenced by water immersion during simulated masticatory forces of 500, 700 and 800 N at 2000 cycles (180).

Sundh et al. (2005), mentioned that loading of 100,000 cycles (force of 50 N) did not affect the strength of YTZP framework (181).

2.3.2.3.2. Fracture resistance after fatigue

All ceramic crown and bridge restorations are subjected on a daily basis to masticatory loading which places the restoration under repeated loading throughout its service life. Repetitive stresses during the chewing cycle may lead to fatigue of the material and eventually fractures when they are exposed to the oral environment (182).

Curtis et al. (2006), conducted a study showing that when using high forces of 500, 700 and 800 N at low numbers of cycles (2,000 cycles) and low force of 80 N at 10,000 and 100,000 cycles, there were no significant differences in the mean biaxial flexural strength between unloaded and zirconia discs that had undergone cyclic loading in both dry and wet conditions. However, Weibull modulus was lower in zirconia discs when loaded for 100,000 cycles due to accumulation of microcrack damage (180).

2.3.2.3.2.1. Effect of the underlying cements on fracture resistance

Even if monolithic zirconia crowns seem to have sufficient fracture resistance, the importance of the cement cannot be underestimated. It has been demonstrated that the supporting materials, such as abutment materials and cement, will influence the fracture resistance of all ceramic crowns (183,184). That is, if the abutment material shows increased elastic properties and/or low compressive strength, the fracture resistance of all-ceramic crowns becomes lower. As for type of cement used, it is suggested that the compressive strength is of importance since it will support the reconstruction (184).

Bindl et al. (2006), demonstrated that the fracture resistance of monolithic all ceramic crowns made of feldspar ceramic, leucite glass ceramic and lithium disilicate glass ceramic increased by using a polymer resin based cement with a compressive strength of 320 Mpa compared to zinc phosphate cement (121 MPa) (185).

Scherrer et al. (1994), suggested that the crown cement interface plays an important role in the fracture resistance of all ceramic crowns, the weaker the bond the lower the fracture resistance becomes (186).

Papia et al. (2014), suggested that is difficult to treat zirconia for an optimal micromechanical adhesion to polymer resin based cement because of the structure of this oxide ceramic (187).

Even though adhesion between zirconia and polymer resin based cement is not well established, the high compressive strength of the polymer resin based cement may be of importance to give the crown-cement tooth complex the ability to withstand masticatory forces. There is little information about the influence of compressive strength of the cement on the fracture resistance of monolithic zirconia crowns.

2.3.2.4. Thermal and environmental ageing

The major issue concerning zirconia ceramics is their sensitivity to low temperature degradation. Ageing occurs by a slow surface transformation from metastable tetragonal phase to a more stable monoclinic phase in a humid environment such as humid air, water vapour and aqueous fluids at a relatively low-temperature ranging from 65-500ºC (188).

The tetragonal to monoclinic transformation can be of benefit due to the compressive layer on the surface of the ceramic, which improves its properties. However, further ageing can result in the reduction of material properties. The transformation of one grain is accompanied by a volume increase causing stresses on the neighbouring grains and microcracking (189).

This offers a path for the water to penetrate and exacerbate the process of surface degradation and the transformation process. The growth of the transformation zone results in severe microcracking and grain pull out and finally surface roughening which leads to strength degradation (190). Several factors influence the ageing rate such as ageing temperature, grain size and stabilising agent. If the temperature rises up to 200-300ºC, the transformation proceeds most rapidly (191).

A widely used ageing technique is thermocycling. The ISO TR 11450 standard (1994) indicates that a thermo-cycling regimen comprised of 500 cycles in water between 5 and 55°C is an appropriate artificial aging test. ***Gale et al. (1999),*** stated in a literature review that 10,000 cycles corresponds approximately to 1 year of *in vivo* functioning, rendering 500 cycles, as proposed by the ISO standard, as being very minimal in mimicking long term bonding effectiveness (246).

The artificial ageing effect induced by thermo-cycling can occur in two ways:
(1) Hot water may accelerate hydrolysis of interface components, and subsequent uptake of water and extraction of breakdown products or poorly polymerized resin oligomers (179).
(2) Due to the higher thermal contraction/expansion coefficient of the restorative material (as compared with that of tooth tissue), repetitive contraction and expansion stresses are generated at the tooth biomaterial interface. These stresses may lead to cracks that propagate along bonded interfaces, and, once a gap is created, changing gap dimensions can cause in- and outflow of oral fluids, a process known as 'percolation' (188).

Chen and Lu et al. (1999), found the highest amount of monoclinic presented at the ageing temperature of 250ºC, which led to the lowest flexural strength 340 MPa compared with the as-received specimen (600 MPa) (182).

Chevalier et al. (2006), studied ageing of zirconia in distilled water at different temperatures from 70-100ºC and he concluded that the amount of monoclinic phase increased with ageing time and temperature (189).

Vult et al. (2006), conducted a study to evaluate the fracture strength of two oxide ceramic crown systems after cyclic pre-loading and thermocycling, they concluded that crowns made with zirconia cores have significantly higher fracture strengths after pre-loading than alumina cores (192).

Kramer et al. (2012), conducted a study to evaluate the effect of thermo-mechanical loading on marginal quality and wear of different crown types for primary molars, they concluded that adhesively bonded crowns showed significantly better marginal integrity to dentine/cementum compared to GIC luted crowns (193).

Baker et al. (1996), tested the shear bond strength of 4 brands of resin veneered crown after soaking the them 90 days prior to thermocycling, they found that crowns soaked in water exhibited the least amount of shear bond strength, concluding that water sorption may have influenced the bond strength of certain resin veneers.

Janice et al. (2014), found statistically significant differences among the forces required to fracture zirconia crowns by three different manufacturers. The increase in force was correlated with crown thickness. The forces required to fracture the preveneered stainless steel crowns were greater than the forces required to fracture all manufacturers' zirconia crowns (195).

2.4. Bacterial Adhesion and Biofilm Formation on Restorative Materials

The oral cavity is an open growth system (196), various organisms are present in the oral cavity, and they are considered to be responsible for tooth decay and infections of the oral cavity (197).

Biofilm formation occurs on all soft and hard surfaces. Microbial colonization on such surfaces is always preceded by the formation of a pellicle. Usually, the survival of the organisms is easy when they adhere to rough surfaces in the mouth (196,198). The roughness of intra oral surfaces has a major impact on the initial adherence and the retention of microorganisms, and if the roughness were sub gingival, the retention of the microorganisms would be more (196).

The physicochemical surface properties of a pellicle are largely dependent on the physical and chemical nature of the underlying surface. Thus, the surface structure and composition of the underlying surface will have influence on the initial bacterial adhesion (199).

The surfaces of composite resins get roughened due to biofilm formation leading to their degradation (200). The colonizing bacteria over composites, usually, invade the interface between the restoration and the tooth, leading to secondary caries and pulpal pathology (201).

Dental plaque is a complex biofilm that accumulates on the hard tissues (teeth) in the oral cavity. Although over 500 bacterial species comprise plaque, colonization follows a regimented pattern with adhesion of initial colonizers to the enamel salivary pellicle followed by secondary colonization through interbacterial adhesion. A variety of adhesins and molecular interactions underlie these adhesive interactions and contribute to plaque development and ultimately to diseases such as caries and periodontal disease (202).

In the formation of a biofilm to a non-shedding surface the following stages have been described:

Stage 1: Conditioning layer formation: The first stage in the development of biofilm is the adsorption of organic and inorganic molecules to the solid surface. This conditioning layer, the pellicle, consists of numerous components including glycoproteins, proline-rich proteins, phosphoproteins, histidine-rich proteins, enzymes, and other molecules that can function as receptors for bacteria.

Stage 2: Transport of bacteria to the substrate surface: The initial transport of microbes to the substrate may occur through Brownian motion, liquid flow, or active bacterial movement (chemotactic activity) and may be influenced by many factors including pH, temperature, flow rate of the fluid, surface energy of the substrate, bacterial growth stage, surface hydrophobocity, etc.

Stage 3: Bacterial adhesion: The next step in biofilm formation is the adhesion of microbial cells to the conditioning layer.

Phase 1: Initial non specific microbial substrate adhesion: The bacterial surface structures form bridges between the bacteria and the conditioning layer. Initially, these bridges may not be strong, however with time the bacteria-substrate bonds gains strength.

Phase 2: Specific microbial substrate adhesion: In this phase polysaccharide adhesins or ligands on the bacterial cell surface bind to receptors on the substrates.

Stage 4: Bacterial colonization and biofilm maturation: In this stage, the monolayer of microbes attracts secondary colonizers forming microcolony. The firmly attached microorganisms start growing, newly formed cells remain attached, and biofilms can develop (203-205).

Among the properties required for materials used in dental restorations are those related to the surface, for example, roughness, free surface energy, surface tension, wettability, hydrophobicity, hydrophilicity, electrostatic interactions, and microhardness are of clinical importance since they may affect plaque accumulation and staining. The higher the surface free energy, the higher will be the adhesion of microorganisms, and alternatively, the more hydrophobic the surface, the less microorganism adherence is expected (198).

2.4.1. Bacterial adhesion and biofilm formation on resin composite restorations

It has been reported that the biofilm formation on resin composite surfaces leads to their degradation. Degradation compromise the resin dentin interface and reduce the longevity of the restoration (206).

Some studies report that resin composite may increase the glucosyltransferase activity of bacteria, while it has been reported that BisGMA degradation products (Bis and GMA) slightly inhibit *S. mutans* growth (207, 208).

Aydin et al. (2010), demonstrated that zinc oxide nanoparticles blended into resin composites display antimicrobial activity and reduce growth of bacterial biofilms (209), while chlorhexidine gluconate has been incorporated into some dental materials in order to enhance the antibacterial activity (210, 211).

Gregson et al. (2012), investigated the impact of bacterial cells on the mechanical and surface properties of dental resin materials, they stated that;

1. Exposure of bacteria results in chemical degradation of dental resin.
2. Exposure to TEGDMA or degradation products derived from TEGDMA (TEG and MA) can influence the number of the bacteria.
3. Exposure to bacteria results in a reduction of the mechanical and surface properties of a dental resin (212).

Fucio et al. (2008), investigated the effects of a 30-day *S. mutans* biofilm on resin composite (Filtek Supreme, 3M, St. Paul, MN, USA) surface roughness, hardness and morphology. The authors found no statistically significant differences in surface roughness and hardness after 30 days of incubation (213).

Poggio et al. (2009), investigated and compared the adherence of different restorative materials to *S. mutans* strain (CCUG35176) in order to ascertain possible differences. The materials tested ranged across different classes including: flowable composites (Gradia Direct LoFlo; Filtek Supreme XT Flowable), anterior composites (Gradia Direct Anterior), universal composites (Filtek Supreme XT), packable composites (Filtek Silorane; Filtek P60), glass-ionomers (Fuji IX Gp Extra; Equia) and a control reference material (Thermanox plastic coverlips). Packable silorane-based composite was found to be less adhesive than posterior packable composite P60, flowable composites and glass ionomers. The author conclude that the difference in bacterial adhesion was related to the particular surface chemistry of the material itself as well as by different electrostatic forces between bacteria and restorative surfaces (214).

Hotta et al. (2014), conducted *in vitro,* an elemental analysis of the ions absorbed into the salivary coat covering the surfaces of S-PRG resin blocks and assessed the adherence of *Streptococcus sanguinis* and *S. mutans* to these saliva-coated S-PRG resin blocks. the saliva-coated S-PRG resin showed significantly greater amounts of absorbed Al_3+, Sr_2+, Na+, F− and SiO_3 2− than the saliva coated unfilled resin.

It was of particular significance that the salivary coating of the S-PRG resin reduced the adherence of *S. mutans* to this resin. However, in the case of *S. sanguinis,* no significant difference in adherence could be recognized between saliva-coated S-PRG resin and saliva-coated unfilled resin (215).

Ono et al. (2007), evaluated the surface properties of three different resin composite materials which may influence *S. mutans* biofilm formation using an artificial mouth system. The material material was divided into two groups: (1) surface was ground with 800-grit silicon paper (SiC#800); or (2) surface was polished with up to 1- microm diamond paste (DP1 microm), no significant differences between the two polishing conditions. Concluding that, polishing did not render all resin composites equally resistant to biofilm formation (216).

2.4.2. Bacterial adhesion and biofilm formation on dental zirconia restorations

The incidence of gingivitis has been reported to be higher around poorly fitting crowns than around the crowns considered to be well adapted. Gingivitis adjacent to restorative materials is likely to be the result of bacterial plaque rather than direct mechanical irritation from the material (196).

Hahn et al. (1993), found that inlays of two types of ceramic surfaces collected less plaque with reduced viability over a three day period of no oral hygiene than did the natural tooth surface (217).

Auschill et al. (2007), showed that biofilms on ceramic biomaterials formed *in vivo* during 5 days were relatively thin (1 - 6 µm), but highly viable (from 34% to 86%). They suggested that thick biofilms are less viable than thin ones, due to a hampered supply of nutrients to a thick biofilm (218).

The effect of surface glazing and polishing of ceramics on early dental biofilm formation was evaluated and it was found that glazed surfaces tended to accumulate more biofilm compared to polished surfaces (219).

Bremer et al. (2011), mentioned that biofilm formation on various types of dental ceramics differed significantly; exhibiting that zirconia has lower plaque accumulation (220).

Kawai et al. (2000), concluded that more plaque was adhered over glazed surfaces of ceramics when compared with their polished surfaces. This means that a glazed surface would not be clinically acceptable from a biologic point of view. Glazing can produce an undulating and rough surface that, usually has irregularities, inducing more adhesion of bacteria and other substances (221).

Teughels et al. (2006), conducted a Medline search and summarized the data of 24 papers as follows:

- Rougher surfaces of crowns, bridges, implant abutments, and denture bases accumulate and retain more plaque.
- After several days of undisturbed plaque formation, rough surfaces harbor a more mature plaque characterized by an increased proportion of rods, motile organisms, and spirochetes.
- Tooth surfaces with rough surfaces are more frequently surrounded by an inflamed periodontium, characterized by a higher bleeding index, an increased crevicular fluid production, and/or an increased inflammatory infiltrate (222).

Al-Shammery et al. (2007), reported that scanning electronic microscope (SEM)clearly revealed that the initial adherence and colonization on the tooth enamel started where surface irregularities were present. These surface irregularities, included cracks, grooves and abrasion defects. The colonization of bacteria then spreads out from these irregularities to other areas of teeth. Surfaces in the oral cavity such as the dorsum of the tongue roughened by presence of papilla and the desquamating epithelium of the mucosa harbors other surfaces for the adhesion of bacteria (223).

Rashid et al. (2014), also concluded that glazed surfaces are rougher as compared to the polished surfaces, although polished surfaces have been reported to have voids and micro cracks on the subsurface of porcelain (224).

Scarano et al. (2003), reported that the bacterial adhesion, which is an important aspect in order to maintain zirconia restorations with out marginal infiltrations or periodontal alterations, proved to be satisfactorily slight; the degree of coverage by bacteria of 12.1% on zirconia as compared to 19.3% on titanium (Ti) (177). For instance, the same author demonstrated in another study that the percentage of the zirconia disc surface covered with bacteria after exposure to the oral environment for 24 hours significantly lower than that of titanium despite that the both discs had similar surface roughness (225).

Rimondini et al. (2006), confirmed these results with an *in vivo* study, in which Yttria stabilized Zirconia accumulated fewer bacteria than Ti in terms of the total number of bacteria and presence of potential putative pathogens such as rods (226).

Kou et al. (2012), compared different polishing systems for zirconia and concluded that polishing creates surfaces similar to the just sintered ones and smoother than only grinding surfaces (227).

Nakamu et al. (2010), reported that zirconia might accumulate less plaque than titanium (228), however, according to recent *in vitro* and *in vivo* studies that were well designed, there seems to be only small or no difference in bacterial adhesion and colonization between zirconia and titanium (229-232).

There also seems to be only little difference between zirconia and other dental ceramics, such as alumina, porcelain and glass ceramics (230, 232). Although additional benefits may not be expected in terms of plaque accumulation, zirconia can be applied to dental restorations as can other dental ceramic materials (220).

3. MATERIAL AND METHODS

This study consisted of four parts:

1. The randomized clinical study of three full coronal restorations.
2. The parental satisfaction of the three full coronal restorations.
3. *In vitro,* compare the fracture resistance of the two types of prefabricated zirconia crowns that was used in the randomized clinical study.
4. *In vitro,* assessment of bacterial adhesion of two types of restoration used in the randomized clinical study.

The randomized clinical study of three esthetic crowns and the parental satisfaction was conducted at Yeditepe University Faculty of Dentistry, Pediatric Dentistry Clinic and Dental Operating Room, the fracture resistance was evaluated at Yeditepe University Faculty of Dentistry, Hard Tissue Research Laboratory, then the specimens were analyzed by scanning electronic microscope (SEM) at Tubitak Marmara, Research Center. While the bacterial adhesion was evaluated at Istanbul University Faculty of Dentistry, Department of Oral Microbiology, Research Laboratory.

3.1.Clinical Study

The randomized clinical study (RCS) of three esthetic crowns was conducted at Yeditepe University Faculty of Dentistry, Pediatric Dentistry Clinic and Dental Operating room for those patients that require treatments under general anesthesia due to lack of cooperation.

3.1.1. Study Design

This project was approved by the Research and Ethics Committees of University of Yeditepe, conducted in compliance with the ethical principles of the Health Sciences Research Ethics Board (Appendix 1). Prior to enrollment, every child's parent/guardian received and signed an informed consent form (Appendix 2).

This was a 9 months prospective, randomized controlled clinical study, conducted by one pediatric dentists (HF), the study participants had to return for 3, 6 month and 9 month recall examinations.

3.1.2. Sample Size

Based on the primary outcomes of restoration failure, and looking for a clinically significant difference in proportion of restoration failures of 25% between groups (2 tailed alpha=0.05 and power of 0.80), a minimum of 46 crowns were required in each group, totaling of at least 138 teeth.

The subjects were randomly allocated to one of the following groups.

• RCSc Group: Resin composite strip crowns

Celluloid strip crowns Opt 4 Dental™ Gmbh N°1.912 (Dental A^2Z) (Fig 25 A,B)

• NSZ Group: Pre fabricated primary zirconia crowns

NuSmile® ZR Pediatric Anterior Crowns (Houston TX) (Fig.17)

•KKZ Group: Pre-fabricated primary zirconia crowns

Kinder Krowns® less preparation (Mayclin Dental St. Louis Park, MN) (Fig.21)

3.1.3. Subject Selection

Forthy eight children/186 teeth were initially examined, The examination was performed on dental chair using: dental hand mirror (Plus 62452104 Size 4, Made in Germany), dental explorer (Oral teach stainless steel, Made in Pakistan), (Figure13) and radiographs; 42 children/165 teeth were then selected who met the inclusion/exclusion criteria described in Table 10. The children were treated for dental caries of the maxillary primary incisors and restored with one of the full coronal restoration over a period of 4 months.

Subjects selected were 3-5 years of age, with good general health, had the mandibular primary incisors present and showed carious maxillary primary incisors, with minimum of two surfaces involved, out of which one must be palatal caries and with dmft of ≥3 (WHO Index) (233).

Figure 13. Diagnostic set including dental mirror and dental explorer

Primary maxillary incisor diagnosed with dental caries that require pulp therapy were treated, according to the AAPD clinical guideline (234), pulpotomy was performed in a primary tooth with extensive caries but without evidence of radicular pathology when caries removal resulted in a carious or mechanical pulp exposure.

The pulpotomy procedure was performed when caries removal results in pulp exposure in a primary tooth with a normal pulp or reversible pulpitis. The coronal tissue was amputated, and after the remaining radicular tissue was judged to be vital without suppuration, purulence, necrosis, or excessive hemorrhage that cannot be controlled by a damp cotton pellet after several minutes, and there were no radiographic signs of infection or pathologic resorption, the remaining vital radicular pulp tissue surface was treated with a long term clinically successful medicament such as Buckley’s Solution of formocresol.

.

A pulpectomy was indicated in a primary tooth with irreversible pulpitis or necrosis or a tooth treatment planned for pulpotomy in which the radicular pulp exhibits clinical signs of irreversible pulpitis (eg, excessive hemorrhage that is not controlled with a damp cotton pellet applied for several minutes) or pulp necrosis (eg, suppuration, purulence). The roots should exhibit minimal or no resorption.

However, correct diagnosis regarding dental pulp treatment was essential to ensure the investigator that inflammation was limited to the coronal pulp. Radiographic examinations was therefore necessary to confirm the need for pulpotomy or pulpectomy pulp therapy (Figure 14).

Figure 14. (A) Periapical radiograph of a 4 years old boy with carious teeth # 51,61,52,62 rated for pulpectomy.

Figure 14. (B) Periapical radiograph of a 5 years old girl with carious teeth # 51,61,52,62 rated for pulpectomy.

Figure 14. (C) Periapical radiograph of a 5 years old girl with carious teeth # 51,61 rated for pulpectomy while tooth n° 52,62 were rated fot pulpotomy.

Figure 14. (D) Periapical radiograph of a 4 years old boy with carious teeth # 51,61,52,62 rated for pulpectomy.

Figure 14. (E) Periapical radiograph of a 5 years old girl with carious teeth # 51,61,62 rated for pulpectomy while tooth n°52 were rated fot pulpotomy.

Table10. Inclusion and exclusion criteria (235-237).

Inclusion criteria	Exclusion criteria
Healthy Children ASA PS 1.	Children excluded from ASA PS 1.
3-5 years of age.	
Carious maxillary primary incisors, with minimum of two surfaces involved.	Carious maxillary primary incisors, with one surface involved.
Mandibular primary incisors should be present.	Absence of the lower incisors.
dmft of ≥3.	
Maxillary primary incisors with enough root support at least 2/3 root present, without mobility.	Presence of root or periapical resorption, teeth near to exfoliation.
Children with normal overbite between 3–5 mm (or approximately 20–30% of the height of the mandibular incisors).	Children with bruxism or deep bite.
Category 1 or 4 Frankl behavior.	Category 2 or 3 Frankl behavior.

According to Frankl Scale Behavior indicating in Table 11 only category 1 and category 4 were included in the present study treating scale 1 under general anesthesia and scale 4 on dental chair using several behavioral technique management such as voice control, tell-show-do, positive reinforcement, distraction and non verbal communication.

Table 11. Frankl Scale Behavior (237).

Frankl Scale	Rating	Behavior
Category 1	(--) Definitely negative	Child refuses treatment, cries forcefully, fearfully, or displays any agitated, overt evidence of extreme negativism. Combative, thrashing, verbal, unable to be restrained, need to terminate procedure
Category 2	(-) Negative	Reluctant to accept treatment and some evidence of negative attitude (not pronounced). Slightly combative, verbal, slightly agitated, able to be restrained and procedure safely completed
Category 3	(+) Positive	The child accepts treatment but may be cautious. The child is willing to comply with the dentist, but may have some reservations. Quiet, not combative, cooperative, nonverbal
Category 4	(++) Definitely positive	This child has a good rapport with the dentist and is interested in the dental procedures, happy, helpful.

3.1.4. Randomisation

Forty-two children were randomly assigned as per the permutation within each group; however, children could not be randomised on the basis of their dmft status as it was difficult to find permuted blocks with similar number of children having the same dmft and number of teeth to be replaced. The distribution of 55 teeth in each group at baseline is shown in Table 12.

Table 12. The distribution of 55 teeth in each group at baseline.

Type of Restoration	No. of teeth restored per child	No. of children in each group
NuSmile® ZR	55	14
Kinder Krown® ZR	55	14
A 2 Dental (resin composite strip crown)	55	14

3.1.5. Clinical Evaluation Criteria

The clinical data collected included the patient's gender, age, dmft, dmfs, diet analysis, number of the teeth treated, pulp treatment techniques (either pulpotomy or pulpectomy) and date of restoration placement. The oral hygiene of every child was recorded using the Greene and Vermillion's oral hygiene index (OHI) (238, 239). A periapical radiograph of the carious maxillary primary incisors was taken either at the examination appointment or at the beginning of the restorative treatment.

Two calibrated examiners (HF, SSK) (the study investigators) completed all clinical evaluations of the crowns with the chairside assessment, this was clinically evaluated with visual assessment of the restoration, with an evaluation rating system similar to the US Public Health Service "USPHS", Alpha criteria rating system (Ryge, 1980) (241) . The definitions and criteria for the rating system are detailed in Table 13. Digital intraoral photographs were taken of the teeth pre and post treatment. When ratings were not in agreement, the 2 examiners reviewed the images together and reached a consensus rating.

Evaluation of gingival health was carried out using a blunt periodontal probe (Double ended probe Williams 1-2-3-5-7-8-9-10 Goldman Fox Flat) according to the Löe and Silness gingival index (240).

Table 13. Clinical and photographic assessment according to USPHS (241).

Color match
A No noticeable difference from adjacent teeth
B Slight shade mismatch
C Obvious shade mismatch
Crown contour
A Crown appears very cosmetic, nicely contoured, and natural looking
B Crown appears acceptable but could have been contoured better, perhaps longer, shorter, wider, thinner.
C Crown not esthetic; detracts from appearance of the mouth
D Crown not present
Presence of restoration failure
A Crown appears normal; no cracks, chips, or fractures
B Small but noticeable areas of loss of material
C Large loss of crown material
D Complete loss of crown
Gingival health
A No obvious signs of inflammation
B Mild marginal gingivitis tissue slightly reddened and edematous
C Moderate marginal gingivitis tissue obviously reddened and edematous
D Severe gingivitis tissue is very swollen; spontaneous bleeding

3.1.6. Restorative Materials

Three full esthetic crowns restoration were used in the present study, two luting full coronal restoration;

1. NuSmile® ZR Pediatric Anterior Crowns (Houston TX5524 Cornish, Houston, Texas 77007-4304,USA) (Figure 18), which were luted with NuSmile® BioCem Universal BioActive Cement (Figure 19) .
2. Kinder Krowns® less preparation (Mayclin Dental St. 2629 Louisiana Ave. S. St. Louis Park, MN. 55426,USA) (Figure 22), was luted with AquaCem® DENTSPLY© (Figure 23).

and one bonding full coronal restoration:

3. Celluloid strip crowns Opt 4 Dental™ Gmbh N°1.912 (Dental A^2Z) (Figure25 A, B), which were fillled with resin composite (3M ESPE, Filtek Z350 XT) and bonded by adhesive (3M, Single bond Universal 3M-ESPE Dental Products, St. Paul 41258®) (Figure 25 E).

3.1.6.1. NuSmile® zirconia (NSZ) anterior crowns

NuSmile® ZR was first introduced in 1991, metal free crowns are made from monolithic zirconia, made like ceramic steel and mimic anatomical contours of natural primary.

Science based anatomy and cervical contours of preformed crowns was developed by using computer tomography (CT) and digital scans of natural primary teeth.

NuSmile® ZR anterior Crowns that were used in the present study were available in 2 shades and in 7 sizes for each primary tooth, sizes are mentioned in Table 15, 16. With a dimensional increase per size by 5-6% anterior primary incisor (Figure 17).

NuSmile® ZR anterior crowns have the following characteristics:

- Polished instead of glazed to reduce wear on opposing dentition.
- Had a chemical union without any visible mechanical adhesion.
- Autoclavable.

Each crown in the kit has an identical in size and shape, pink in color crown called *Try-In* ® NuSmile Crowns. Supplied by the manufactures to assist in trial fittings and preparation refinement.

Figure 15. Various view of NuSmile®ZR Anterior Crowns (129).

Table 14. Chemical composition of NuSmile® ZR Anterior Crowns (129)

COMPONENT	PERCENTAGES
Zirconium oxide	88-96
Yttrium oxide (Y2O3)	4-6
Hafnium oxide (hfo2)	5
Organic Binder	2-5
Pigment	1-4

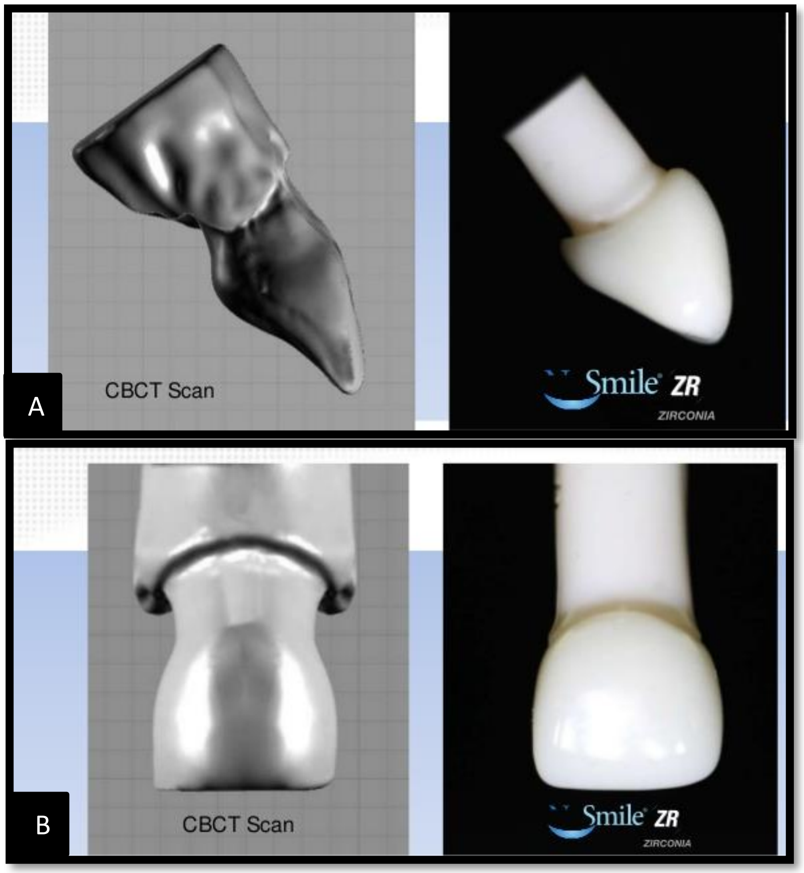


Figure 16. (A,B) Developing of frabricated NuSmile ® ZR crowns by using CT and digital scans of natural primary teeth (129).

Figure 17. Increase in size of NuSmile® ZR Anterior crowns by 5-6%.

Table 15. Pediatric maxillary central incisor crowns sizing guide mesial-distal dimensions in millimeters (mm) of NuSmile® anterior ZR

SIZE	Max. central
0	6.12
1	6.49
2	6.85
3	7.24
4	7.58
5	7.95
6	8.35

Table 16. Pediatric maxillary lateral incisor crowns sizing guide mesial-distal dimensions in millimeters (mm) NuSmile® anterior ZR.

SIZE	Max. Lateral
0	4.73
1	5.05
2	5.40
3	5.78
4	6.19
5	6.64
6	6.97

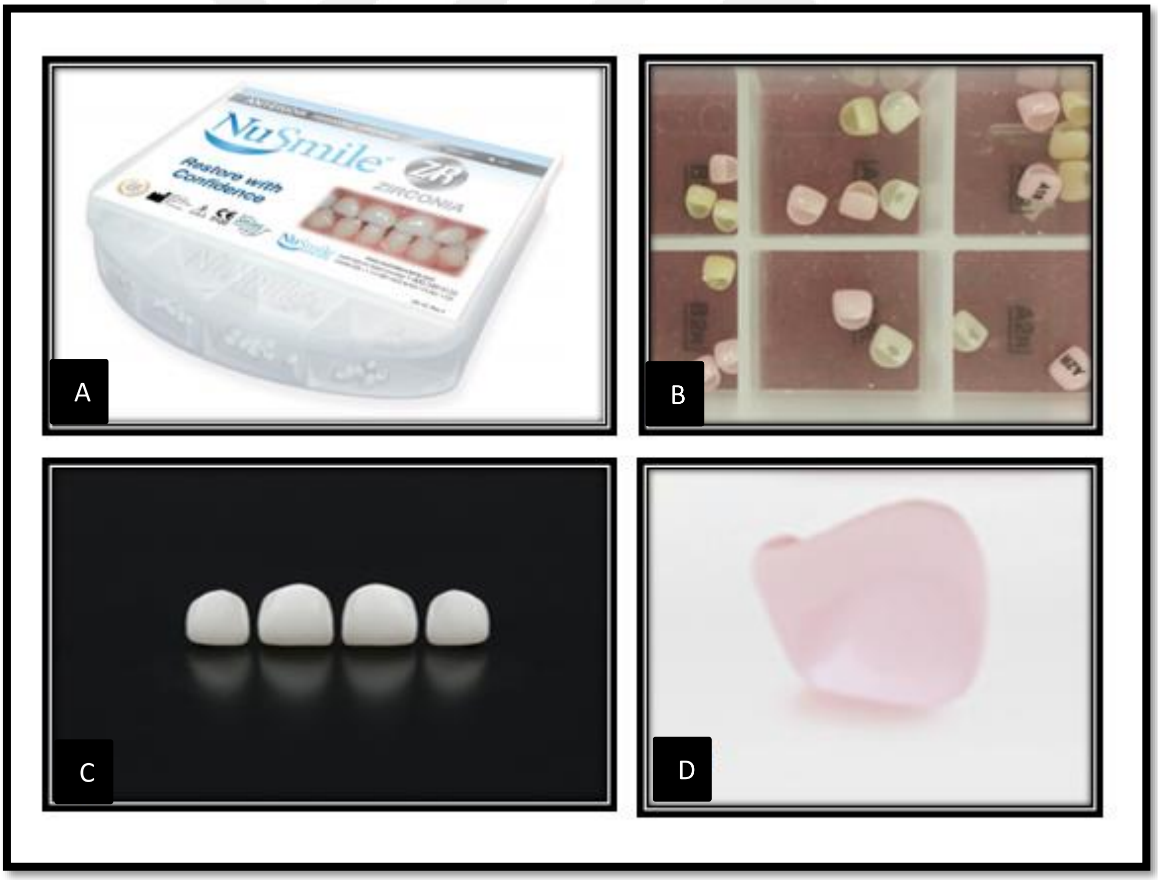


Figure 18. (A, B) NuSmile® ZR Anterior Crowns starter kit, (C) NuSmile® ZR Anterior Crowns for central and lateral incisor, (D) *Try-In* NuSmile® Crowns (129).

3.1.6.1.1. Luting Cement

NuSmile® ZR Pediatric Anterior Crowns (Houston TX) was luted with Universal BioActive Cement BioCem NuSmile® (Figure 19), BioCem is a radiopaque resin modified glass ionomer (RMGI) cement specifically designed for pediatric dentistry.

NuSmile® BioCem's dual cure formula in form of two-paste system housed in an easy to store and use double-barreled syringe. The cement is delivered through an efficient low waste auto-mix tip, it does not require etching or priming of dentin and cures through two self-curing mechanisms, additionally accelerated by light cure. The material contains no HEMA, Bis-phenol A, Bis-GMA or BPA derivatives.

BioCem cement's has bioactive components form hydroxyapatite, a key building block in tooth structure, that integrates with the tooth to protect and strengthen the remaining dentin after restoration (Figure 20).

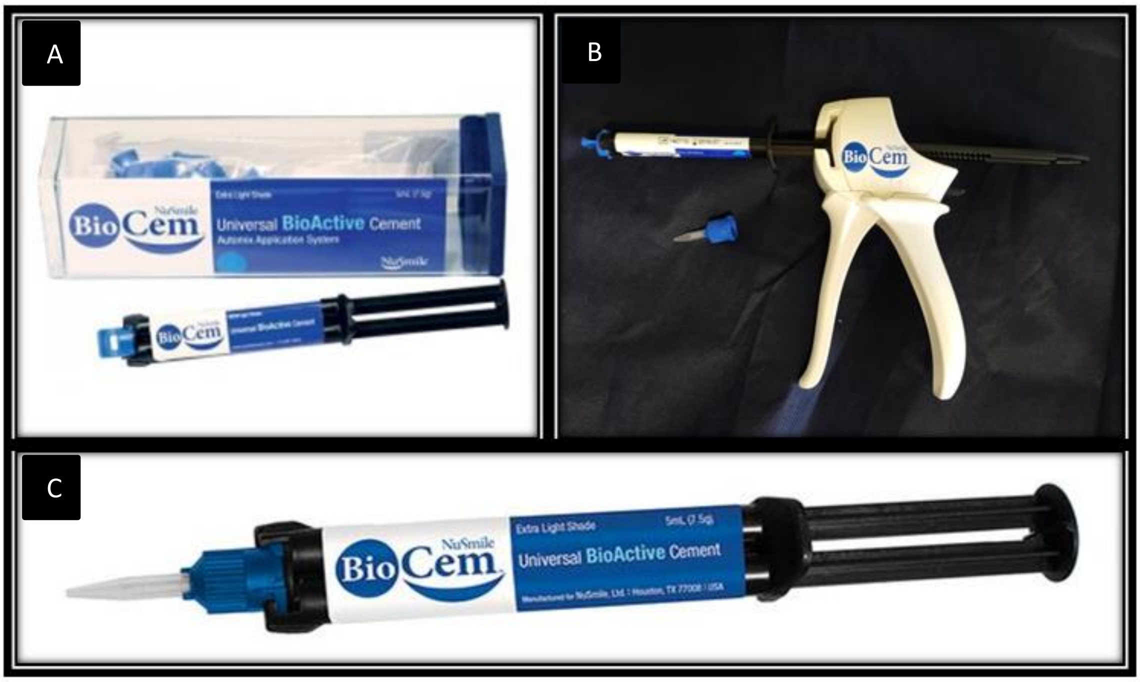


Figure 19. (A, C) Biocem NuSmile®Universal Bioactive Cement (B) Biocem NuSmile® Cement Dispenser (129).

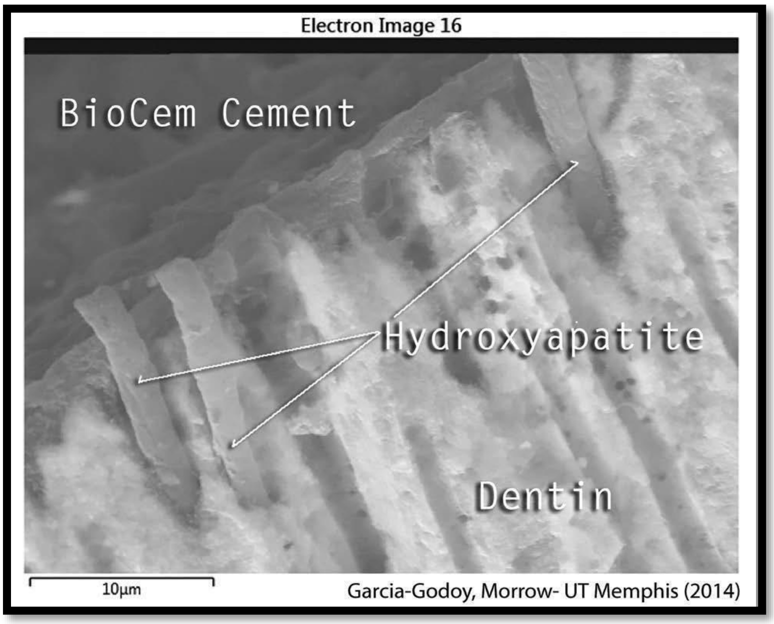


Figure 20. Electron image showing Biocem® forms hydroxyapatite to integrate with and replenish the tooth (129).

Table 17. Physical properties of NuSmile® BioCem (129).

Physical Properties	NuSmile® BioCem
Setting time	<20 seconds
Depth of light cure	4mm
Self-cure working time	90 - 100 seconds
Fluoride release @ 1 day	360ppm
Flexural strength	88.4 mpa / 12,800 psı
Flexural modulus	3.7 gpa
Compressive strength	210 mpa / 30,500 psı
Diametral tensile strength	37 mpa / 5365 psı
Film thickness	11 microns

3.1.6.2. Kinder Krowns® (KKZ)

The original Kinder Krowns® were introduced to the market in 1989. Kinder Krown® zirconia crowns are rated at 1234 MPa (178,976 Psi), made from raw materials of TOSOH Corporation, Japan.

Then the introduction of IncisaLock was in 1997 by adding more mechanical retention by internal grooves, to achieve both mechanical retention and chemical bonding.

Kinder Krowns® ZR anterior crowns less preparation that were used in the present study were available in one shades and 6 sizes for each primary tooth, sizes are mentioned in Table 18, 19. With a dimensional increase per size by 5-6% anterior primary incisor.

KKZ anterior crowns have the following characteristic:

- Had IncisaLock combining between mechanical and chemical bonding
- Autoclavable with outer label
- Polished instead of glazed
- Have a unique universal contour

Figure 21. Various view of Kinder Krowns® anterior crowns

Figure 22. (A, B) Kinder Krown® anterior zirconia (C) Increase in size of kinder krown® ZR anterior crowns by 5-6%

Table 18. Pediatric maxillary central incisor crowns sizing guide mesial-distal dimensions in millimeters (mm) Kinder Krown® anterior ZR.

SIZE	Max. central
1	5.82
2	6.28
3	6.68
4	6.84
5	7.28
6	7.63

Table 19. Pediatric maxillary lateral incisor crowns sizing guide mesial-distal dimensions in millimeters (mm) Kinder Krown® anterior ZR.

SIZE	Max. lateral
1	4.32
2	4.87
3	5.35
4	5.85
5	6.03
6	6.24

3.1.6.2.1. Luting Cement

Kinder Krowns® less preparation was luted with AquaCem® DENTSPLY. AquaCem® is a light-yellow, translucent glass-ionomer luting material consisting of a blend of alumino-silicate glass and polyacrylic acid. According to the manufactures instruction the powder was mixed with distilled water to produce a luting material which adheres to dentine and enamel producing tightly sealed cementations.

Table 20. Aquacem® manufacturer description.

Brand name	**Aquacem®**
Manufactures	DENSPLY DeTrey GmbH
Type of the material	Glass Ionomer Cement
Iso certification	9917:1991 for Polyalkenoate luting Cements
Composition	Calcium-sodium-fluoro phosphoroaluminium-silicate, Polyacrylic acid, Tartaric acid, Yellow Ferric Oxide
Working time	2 min 30 sec.
Settıng time	3 1/ 2 to 5 minutes

Figure 23. AquaCem® DENTSPLY

3.1.6.3. Resin Composite Strip Crowns (RCSc) OPT 4 DENTAL™

Celluloid strip crowns Opt 4 Dental™ Gmbh N°1.912 (Dental A^2Z) (Figure 25 A, B) were fillled with resin composite (Filtek Z350 XT,3M ESPE, St. Paul, MN, USA) shade A 1, 2 and 3 (Figure 25 C), the description is detailed in Table 22.

The tooth surfaces were etched for 15 seconds with a 37% phosphoric acid Jumbo Etch Royal, (Pulpdent Corporation, Watertown, MA, 02471 USA) (Figure 25 D) and then the surfaces were bonded by light cure bonding adhesive (3M, Single bond Universal 3M-ESPE Dental Products, St. Paul 41258®) (Figure 25 E).

The surfaces of the restorations were polished using Sof-Lex (Multi-step) 3M ESPE, St. Paul, MN, USA) (Figure 24), the composition of the polishing system is described in Table 22.

Table 21. Pediatric maxillary incisor crowns sizing guide mesial, distal dimensions in millimeters (mm) OPT 4 DENTAL™ (242).

Crown shape	Number of size	Width range available in mm
Upper central incisor	1-5	6.0-8.1
Upper lateral incisor	1-5	4.3-6.7

Table 22. Description of resin composite used in the present study.

Type of Material	Chemical Composition	Brand Name	Manufacturer
Resin composite	Bis-GMA, UDMA, TEGDMA, and BIS-EMA, silica filler, zirconia filler, and aggregated zirconia/silica Cluster filler(5-20 nm)	Filtek Z350 XT	3M ESPE St. Paul, MN, USA

Table 23. The composition of the polishing systems.

Polishing system	Composition	Particle size	Manufacturer
Sof-Lex (Multi-step)	Aluminum oxide-coated disk	Medium (40 mm) Fine (24 mm) Ultrafine (8 mm)	3M ESPE, St. Paul, MN, USA

Figure 24. Polishing disc Sof-Lex (3M-ESPE, St. Paul, MN, USA)

Figure 25. (A, B) OPT 4 DENTAL™ Deciduous transparent crown kit (C) Resin composite (3M ESPE, Filtek Z350 XT) shade 1, 2 and 3 (D) Phosphoric acid Jumbo Etch Royal, (Pulpdent Corporation, Watertown, MA, 02471 USA) (E) Bonding adhesive (3M, Single bond Universal 3M-ESPE Dental Products, St. Paul 41258®) (F) Starlight pro. LED curing light (Mectron s.p.a. Italy CE 0476).

3.1.7. Placement Procedures

3.1.7.1. Resin Composite Strip Crown Placement Procedures

3.1.7.1.1. Tooth Preparation

The following steps for tooth preparation were carried out

1. Administration of local anesthesia (Ultracaine® DS).
2. Removal of the carious lesion was performed with a small round bur (ACCURATE Tungesten carbide bur N 58), and spoon excavator (SCHWERT 3462-37.1.5mm Stainless GERMANY Tuttlingen).
3. Pulp treatment either by pulpotomy or pulpectomy (Figure 27 B).
4. Reducing the interproximal surfaces by 0.5-1.0 mm was carried out by a tapered diamond bur to produce knife edge cervical margins (Figure 26) while the interproximal walls were parallel. Proximal reduction was performed to allow a crown to slip over the tooth, which in turn snaps fit of the crown.
5. Reducing incisal edge approximately 1-1.5 mm was performed using fine tapered diamond bur.
6. Reducing the facial surface by at least 1.0 mm and lingual by at least 0.5 mm creating a knife edge in the gingival margin and round the line angle.
7. If sufficient tooth structure remains a small cervical undercut was performed with inverted cone (ACCURATE Diamond Bur N 35).

3.1.7.1.2. Crowns Placement

The following steps for crown placement were carried out

1. Selection of the crown form (Figure 27 A).
2. Selection of a primary celluloid crown form with a mesiodistal (MD) incisal width equal to the incisal edge of the tooth or by measuring the MD dimension of the tooth to be restored and matching it with required crown form.
3. Selection of the composite shade using shade guide under natural light.
4. The control of gingival bleeding was carried using retraction cords with hemostatic medicaments (Figure 27 C).

5. Trimming of the selected crown form to remove excess material from the cervical third was performed with crown scissor (Denovo, Baldwin, Calif) (Figure 27 G).
6. Trial checking was performed for fitting of crown form on prepared tooth. The crown form was fit 1mm below gingival margin with comparable height to adjacent teeth, considering the length of the lateral incisor to be shorter than the central incisor by 0.5-1mm (Figure 27 J).
7. Punching a small hole was performed with sharp explorer at palatal surface of trimmed crown form to produce vent to flow of excessive composite material while placement (Figure 27 H).
8. The prepared teeth were etched with acid etching 37% phosphoric acid Jumbo Etch Royal, (Pulpdent Corporation, Watertown, MA, 02471 USA) (Figure 27 B) for 15 seconds, rinsing and drying of the tooth followed by bonding agent application (3M, Single bond Universal 3M-ESPE Dental Products, St. Paul 41258®) (Figure 27 E) and curing for 20 seconds using Starlight Pro LED curing light (Mectron s.p.a., Italy CE 0476) (Figure 27 F) was performed.
9. Filling the crown forms with selected composite (3M ESPE, Filtek Z350 XT) shade material (Figure 27 I) to approximately two-third of length and seat on to the tooth and checking for the correct position excess material flow from the gingival margin and the vent hole remove the excess composite with explorer (Figure 27 K).
10. Light curing of the celluloid crowns to polymerization the composite material from both the labial side and the lingual side was performed using Starlight Pro. LED curing light (Mectron s.p.a., Italy CE 0476) (with wave-length comprised between 440 nm and 480 nm with a peak at 460 nm.
11. After proper curing removing the celluloid crown form was carried out with the explorer from the cervical side (Figure 27 L) or by using a composite finishing bur removal of the celluloid crown form was begun from the palatal side to avoid scratches on the labial side.
12. The occlusion was checked.
13. Minimal finishing with polishing disc Sof-Lex (3M-ESPE, St. Paul, MN, USA) (Figure 27 M) on the facial gingival areas sometimes was required.

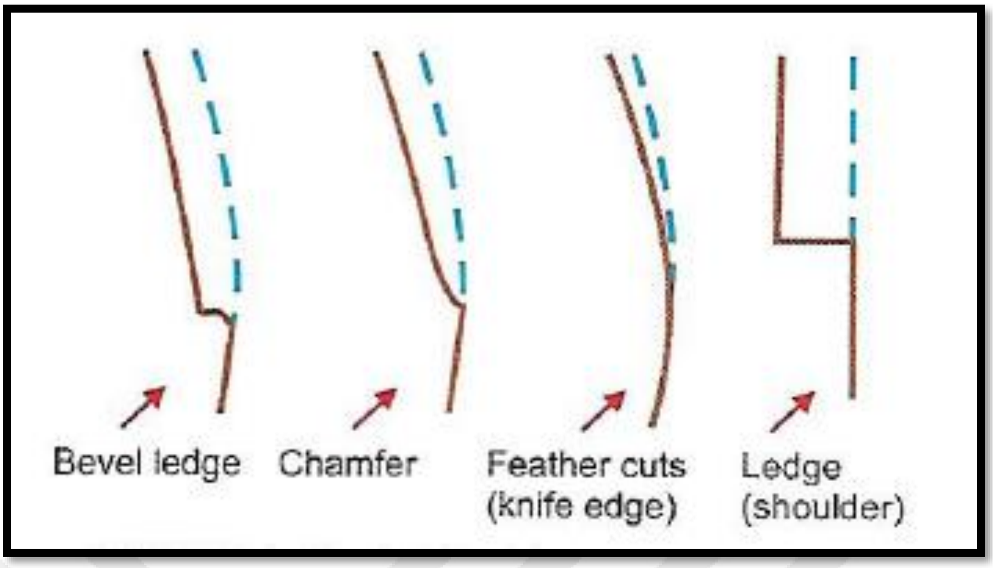


Figure 26. Gingival finish lines, chamfer, feather, knife edge and ledge formation (131).

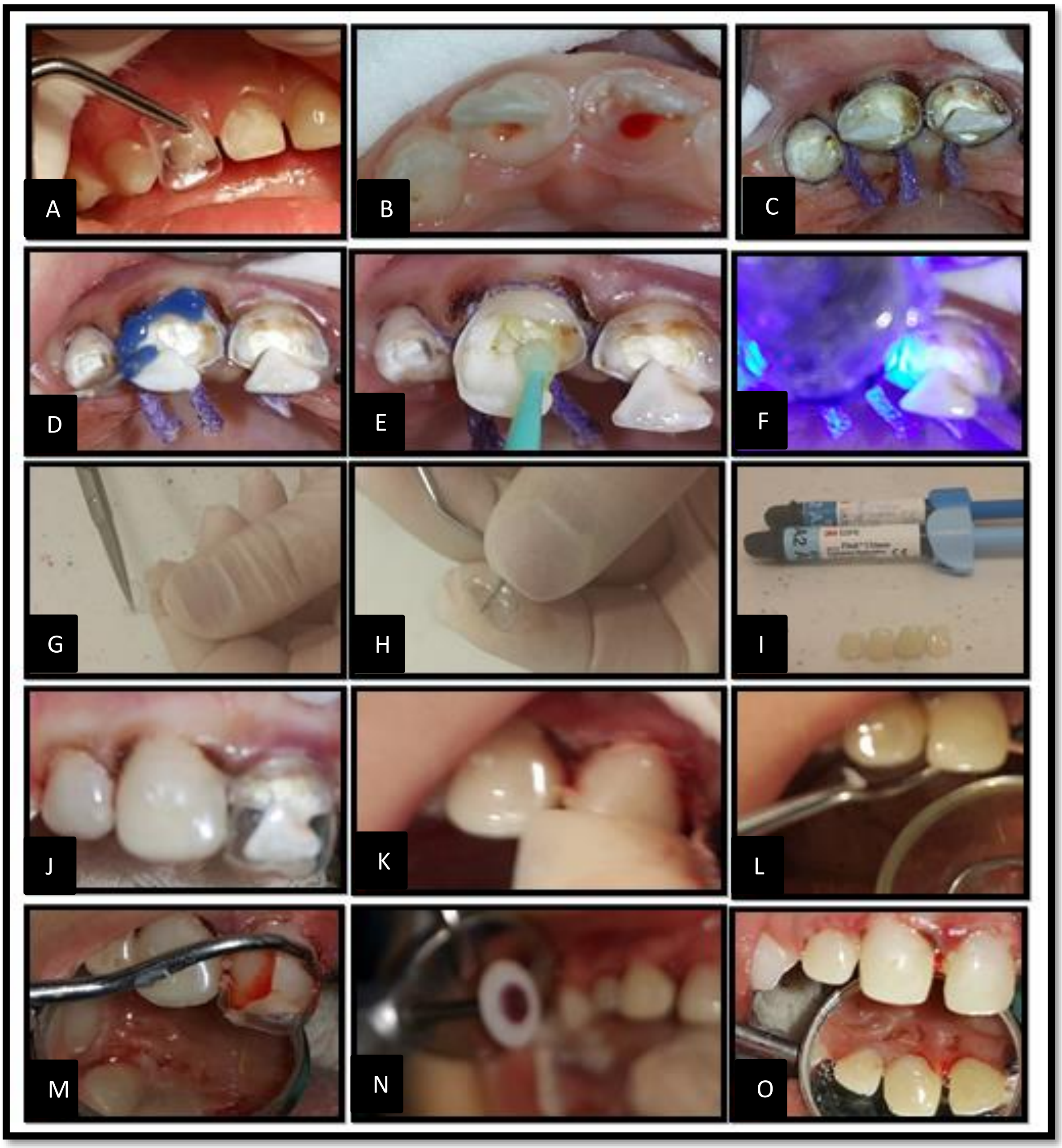


Figure 27. (A) Selection of the crown form (B) Pulp treatment (C) Control of gingival bleeding using retraction cords (D) Acid etching with 37% phosphoric acid (E, F) Bonding agent application and light curing (G) Remove excess crown form with crown scissor (H) Punching a small hole (I) Celluloid crowns filled with (3M ESPE, Filtek Z350 XT) (J) Trial checking for fitting of crown placement (K) Removal of the exceess composite (L, M) Removal of the celluloid crown (N) Polishing disc Sof-Lex (3M-ESPE, St. Paul, MN, USA) post (O) Post operative view.

3.1.7.2. NuSmile® ZR crowns placement procedures

1. Selection of the appropriate crown size, this was determined using NuSmile *Try-In* NuSmile® ZR Crowns (Figure 29 A).
2. Evaluation of the occlusal relationship and the relation of the opposing teeth.
3. Administration of local anesthesia (Ultracaine® DS).
4. Removal of the carious lesion with small round bur (ACCURATE Tungesten bur N 58), and spoon excavator (SCHWERT 3462-37.1.5mm Stainless GERMANY Tuttlingen).
5. Pulp treatment either by pulpotomy or pulpectomy and sealing the cavity with glass ionomer cement (Ketac® 3M ESPE, St. Paul, Minn) (Figure 28 A).
6. Reducing the incisal length (Figure 29 D) by approximately 1.5-2mm, with N° 5855-012 coarse end tapered bur (NuSmile® Bur preparation kit) (Figure 29 B, D).
7. Opening the interproximal contacts, with N° 5855-012 coarse tapered bur (NuSmile® Bur preparation kit) (Figure 29 C).
8. The proximal reduction was adequate to allow the selected crown to fit passively.
9. Reduction of the tooth circumferentially by approximately 20-30%, or 0.5-1.25mm. This reduction was performed gradually and on all planes of the tooth, with N° 134f-014 thin tapered bur (NuSmile® Bur preparation kit) (Figure 29 B) resulting in a preparation which is parallel to slightly converging incisally, follows the natural contours of the existing clinical crown meeting in a thin, tapered incisal edge.
10. The subgingival margin was carefully extended (Figure 29 E) and refined to a feather-edge approximately 1-2mm subgingivally on all surfaces with N° 6852-012 thin tapered bur (NuSmile® Bur preparation kit) (Figure 29 B, D).
11. Line angles and point angles were removed with N° 6852-012 thin tapered bur (NuSmile® Bur preparation kit) (Figure 29 B, D).
12. Try in was performed using *Try-In* NuSmile® ZR Crowns (Figure 29 F).
13. To ensure proper positioning, central crowns were seated first and then the lateral crowns.
14. Final passive fit of the crown was confirmed and cemented with BioCem NuSmile® using the automix dispenser according to the manufactures instructions, (Figure 29 G) and the cement was allowed to self set for 120 seconds by immobilizing the restoration for with gentle pressure then flash cure with Starlight pro. LED curing

light (Mectron s.p.a. Italy CE 0476.) for 1-2 seconds each facial and palatal margins was performed (Figure 29 J).

15. Removing the excess cement using explorer, and clearing the contact and interproximal areas was carried out using with dental floss (Oral B dental floss) (Figure 28 C) (Figure 29 I).
16. Finally curing of both facial and palatal surfaces for 20 seconds was performed.

.

Figure 28. (A) Ketac® 3M ESPE, St. Paul, Minn (B, C) NuSmile® preparation kit bur (D) Dental floss (Oral B dental floss)

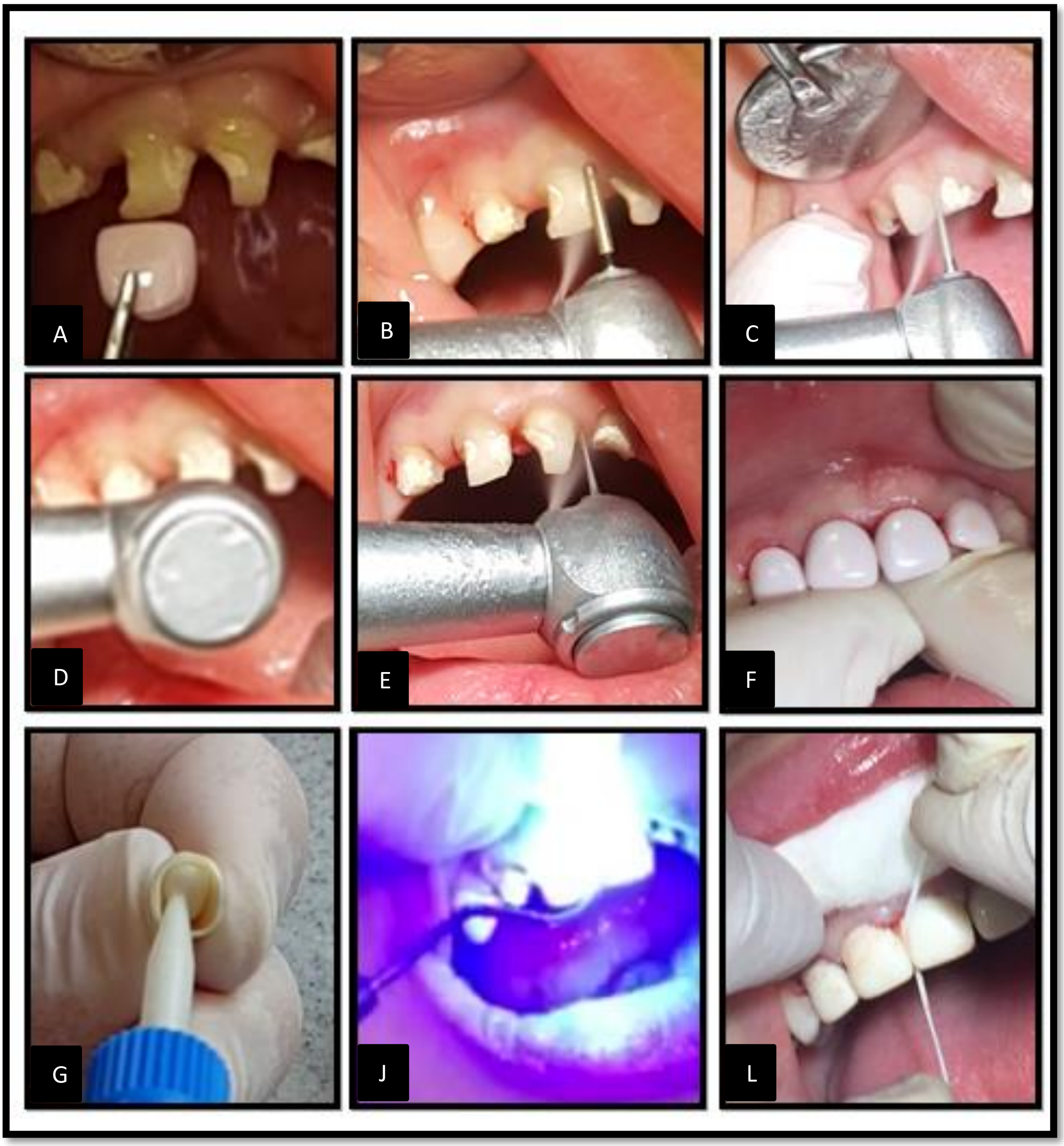


Figure 29. (A) Selection of the crown using *Try-In* NuSmile® ZR (B) Reduction of the tooth circumferentially (C) Opening the interproximal contacts, (D) Reducing the incisal length (E) The subgingival margin was carefully extended and refined to a feather edge (F) Try in was performed using *Try-In* NuSmile® ZR (G) BioCem NuSmile® using the automix dispenser(J) Light curing for 20 seconds (L) Clearing the contact and interproximal dental floss

3.1.7.3. Kinder Krown®Zirconia Crowns Placement Procedures

1. Selection of the appropriate crown size by measuring the MD dimension of the tooth to be restored and matching it with required crown form (Figure 31 A).
2. Evaluation of the occlusal relationship and the relation of the opposing teeth.
3. Administration of local anesthesia (Ultracaine® DS).
4. Removal of the carious lesion was carried out with a small round bur (ACCURATE Tungesten bur N 58), and spoon excavator (SCHWERT 3462-37.1.5mm Stainless GERMANY Tuttlingen).
5. Pulp treatment either by pulpotomy or pulpectomy (Figure 31 B) was carried out; sealing the cavity with $G\imath c_s$ (Ketac® 3M ESPE, St. Paul, and Minn).
6. Reducing the incisal length by approximately 1mm, with coarse wheel diamond bur N° C335-012 Kinder Krown® Preparation Kit Bur.
7. Opening the interproximal contacts by approximately 1mm, with round end tapered diamond bur N° C338-012. Kinder Krown® Preparation Kit Bur (Figure 31 C).
8. The proximal reduction was adequate to allow the selected crown to fit passively.
9. Reducing the facial and the palatal surfaces by approximately 1mm was carried out with round end tapered diamond bur N° C338-012 Kinder Krown® Preparation Kit Bur.
10. Subgingival reduction: the preparation margin was extended and refined to a feather-edge so that no undercuts or subgingival ledges remain approximately 1 mm subgingivally on all surfaces, this was carried out with fine flame shaped diamond bur N° C382-013 (Figure 31 D).
11. For proper positioning of anterior crowns, seating of the central crowns first and then the lateral crowns were done.
12. Final passive fit of the crown was confirmed and cemented with Aquacem®, the cements was mixed according to the manufactures instructions (Figure 31 G) and the cement was allowed to self set for 5 minutes by immobilizing the restoration for with gentle pressure.
13. Removing the excess cement using explorer, clearing the contact and interproximal areas was carried ou using dental floss (Oral B dental floss).

Figure 30. Kinder Krown® Preparation Kit Bur.

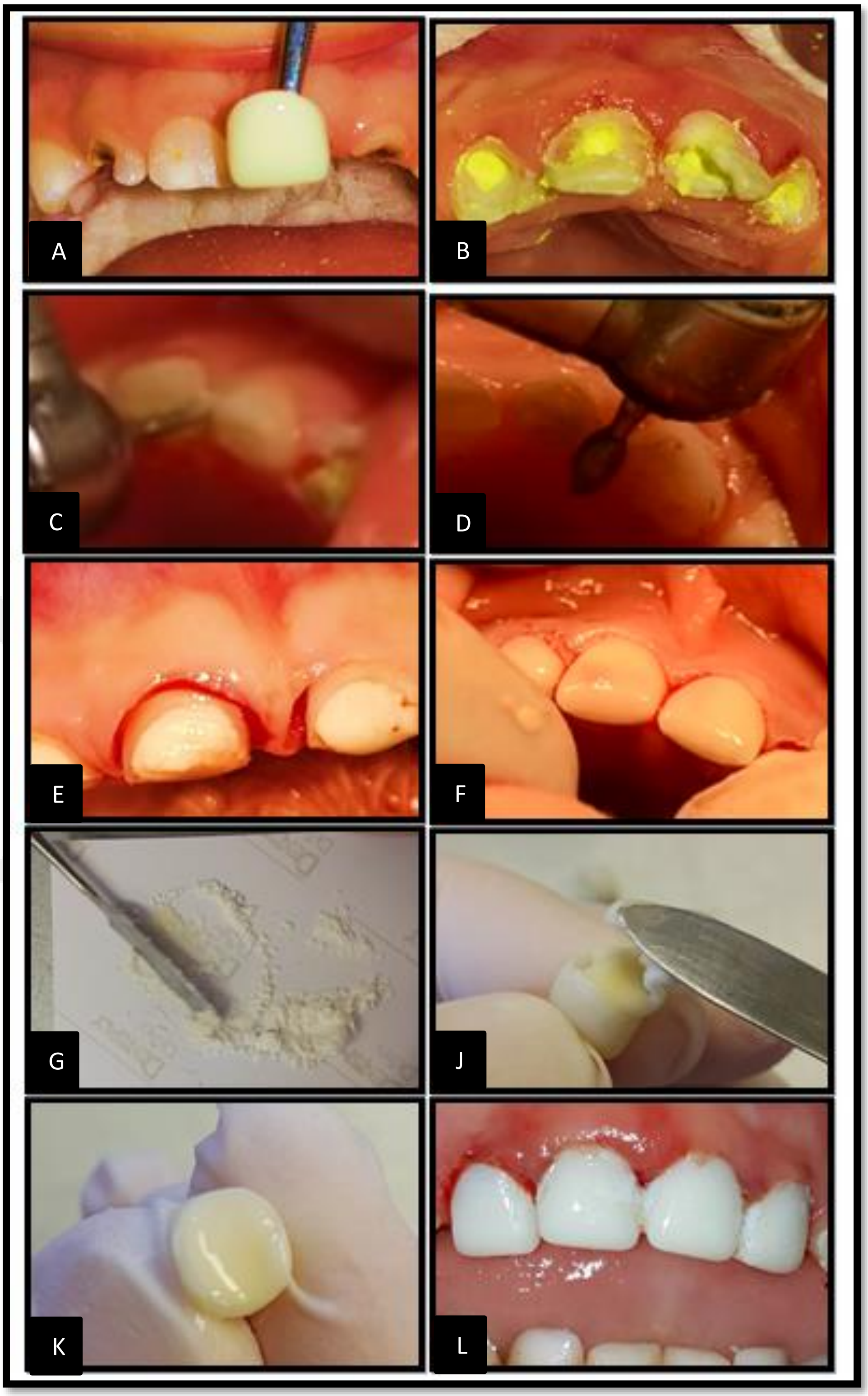


Figure 31. (A) Selection of the crown (B) Pulp treatment (C) Opening the interproximal contacts (D) Reducing the incisal length (E) Post operative after tooth preparation (F) Try in (G) Aquacem® mixing (J, K) Filling the crown with cement (L) clearing the contact and interproximal.

3.2. Parental Satisfaction

A questionnaire using 5 point Likert type scale was administered by the investigator (HF) to a convenience sample of 42 parents at recall of their child at period of 6 months after placement of NSZ, KKZ and RCSc.

The questionnaire (Appendix 3) asked about durability, color, size, shape, esthetic and retention. Each of these criteria were scored using the following scale: 1=very dissatisfied; 2=dissatisfied; 3=neutral satisfied; 4=satisfied; 5=very satisfied (245).

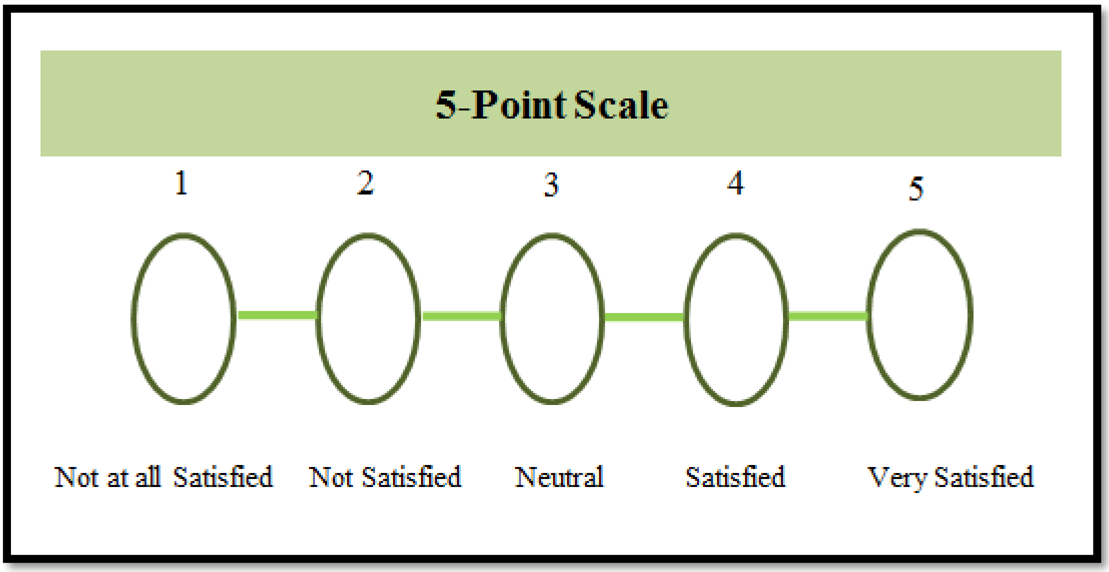


Figure 32. Likert scales, levels of measurement.

3.3. *In vitro* Assessment of Fracture Resistance of Prefabricated Zirconia Crowns

3.3.1.Sample Size

Testing was conducted on esthetic zirconia crowns manufactured by 2 companies (Kinder Krowns® ZR less preparation, St. Louis Park, MN and NuSmile® Primary Crowns, Houston, TX). Twenty specimens of each brand were tested.

The crowns were all primary central incisor; NuSmile® anterior ZR right central, size 5 and Kinder Krown® ZR, central Universal contour, size 5.

The sample size of 20 in each group was based on a preliminary power analysis. Blinding was not possible in the present study due to the distinctive color and appearance of the two brands of crowns.

3.3.2. Sample Measurements

An Iwanson spring measuring caliper (Jensen JP-1 German S.S.28-337-10 CE) (Figure 33), was used to measure the thickness of the crowns, in the middle third of smooth surfaces at five different locations (mesial, distal, facial, palatal, incisal) of all crowns, as shown in (Figure 34).

Figure 33. Iwanson spring measuring caliper.

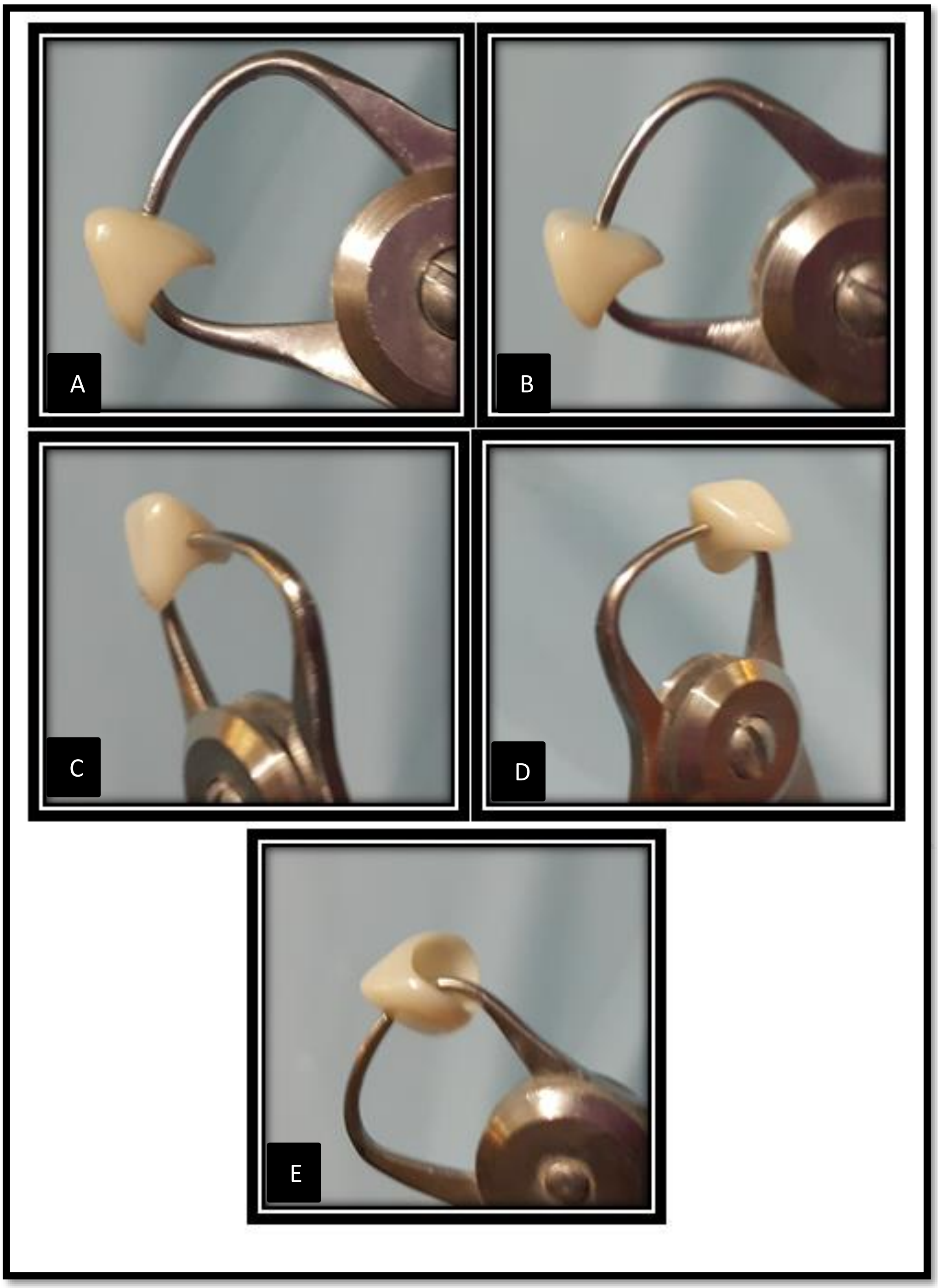


Figure 34. Measurement techniques for crowns: (A) labial (B) palatal (C) mesial (D) distal (E) incisal.

3.3.3. Specimen Preparation

1. A negative replica of each company's crown was fabricated with silicon impression mold (Impregum Penta Soft; 3M ESPE, Seefeld, Germany) (Fig.35 A), impression material using a silicon mold (15mm diameter) to produce an even thickness of impression material then, was allowed to set for 24 hours (Fig.35 B,C).
2. This impression was then used to fabricate an idealized acrylic die (Imicryl 0-80 transparent self cure© konya /TÜRKİYE) (Fig.35 D), for each crown and it's support base surrounded by a tight fitting metal ring (12mm diameter)(Fig.35 E).
3. Each was putted on the dental vibrator (Vibrax Renfert USA) to remove additional air bubbles on the surface and then allowed to set for 24 hours (Fig.35 F).
4. The crowns and dies were tried on to ensure a passive fit. Any visible undercuts in the dies were removed with a acrylic finishing bur (Fig.35 H, I).

1. The esthetic ZRcrowns were cemented onto the dies (Fig.36 A) according to each manufacturer's instructions:

- NuSmile® ZR anterior were cemnted using BioCem NuSmile® and light cured (Fig.35 H,J).
- Kinder Krown® ZR were cemented using AquaCem® DENTSPLY

2. The die crown units were immersed and stored in individual plastic containers (Fig.36 b), filled with 5 ml of distilled water at 37 °C then stored in an incubator (Memmert GmbH + Co. KG) (Fig.36 C) at 37 °C for 24 hours (Fig.36 D).
3. The test specimens (n = 10) of each company's crown were submitted to one of the experimental conditions:

1. Control (C) subgroup: specimens were tested immediately.
2. Thermocycling (Tc) subgroup: thermal cycles were made in a thermocycling machine (Dentester, Salubris Technica, Istanbul, Turkey) (Fig.37). The ISO TR 11 450 standard indicates that a thermocycling regimen comprising 2400 cycles in water between 5 and 55 °C is an appropriate artificial aging method (ISO, 1994) (246) with a 10 second dwell time. A small basket that could hold 20 crowns on their dies was used to cycle the crowns between the two baths.

Figure 35. (A) Impregum Penta Soft; 3M ESPE, Seefeld, Germany (B,C) Negative replica of NuSmile® taken in the silicon mold (D) Imicryl 0-80 transparent self cure© Konya / TÜRKİYE) (E) Pouring the acrylic die into the supporting metal (F) Specimens on dental vibrator (Vibrax Renfert USA) (G) Die specimen (H, I) Removal of undercut wıth an acrylıc bur (K, J) Light cure the NuSmile® (L) Cemented specimen

Figure 36. (A) Specimens (B) The Specimens were placed in distilled water (C) Incubator (Memmert Gmbh + Co. KG) (D) Specimen were placed in the incubator

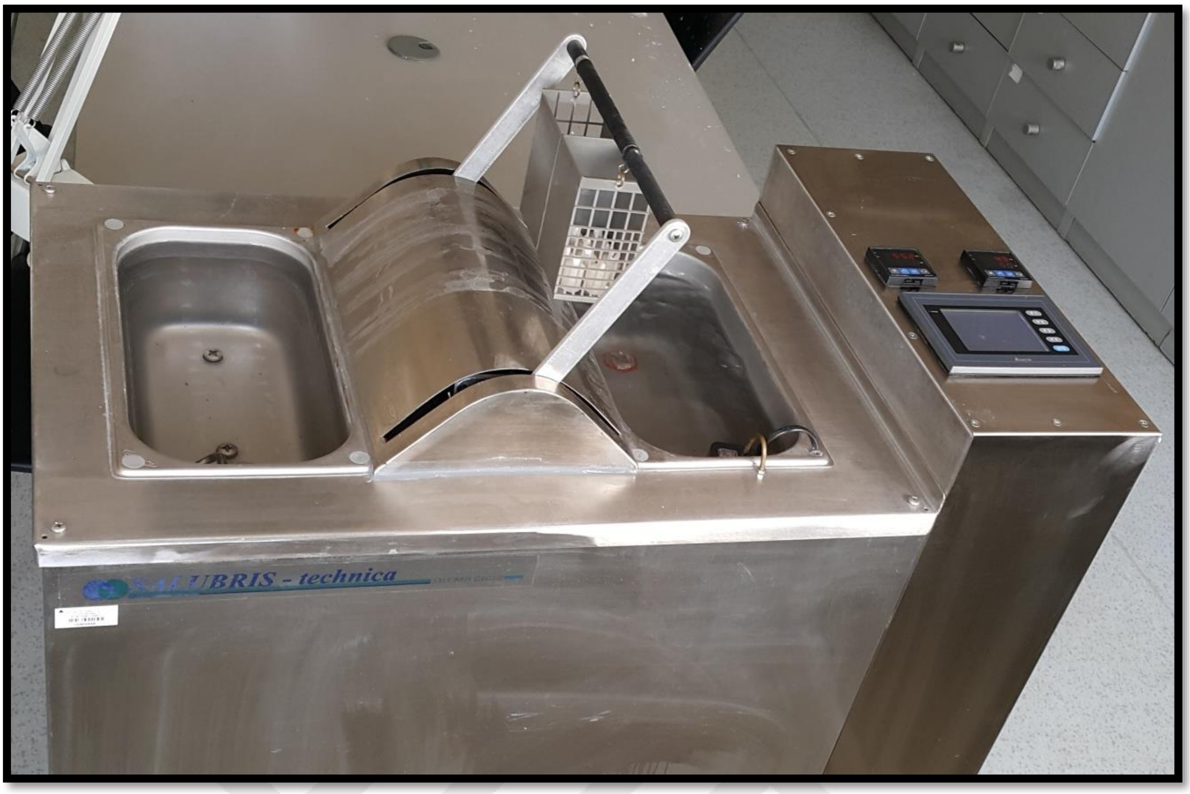


Figure 37. Thermocycling Machine (Dentester, Salubris Technica, Istanbul, Turkey)

3.3.4. Testing the Fracture Resistance

1. The fracture load of the crown was measured in a universal testing machine (Instron 3345; 3345J7324 Instron Corp, USA) (Figure 38).
2. The specimens were attached at 45 degrees to the long axis of the crown, on the lingual side, the specimens were mounted to provide a 135°, and hemispherical reinforced stainless steel and a loading stylus (3.0 mm diameter) were used (Figure 39).
3. A load was applied to the lingual surface 2 mm from the incisal edge.
4. To prevent load dispersion and sliding of the loading stylus on the ceramic surface, a plastic sheet 1-mm thick layer of polyethylene vacuum forming shell (Copyplast; Scheu Dental Technology gmbh, Iserlohn, Germany) (Figure 39) was placed between the zirconia crown and the loading stylus.
5. The crosshead speed was set at 1.0 mm/min according to ISO 10477 (247).
6. The specimens were loaded until fracture occurred and the load was recorded.
7. The compressive load (N) required to cause fracture was recorded for each specimen.

Figure 38. Instron 3345 (3345J7324 Instron Corp, USA).

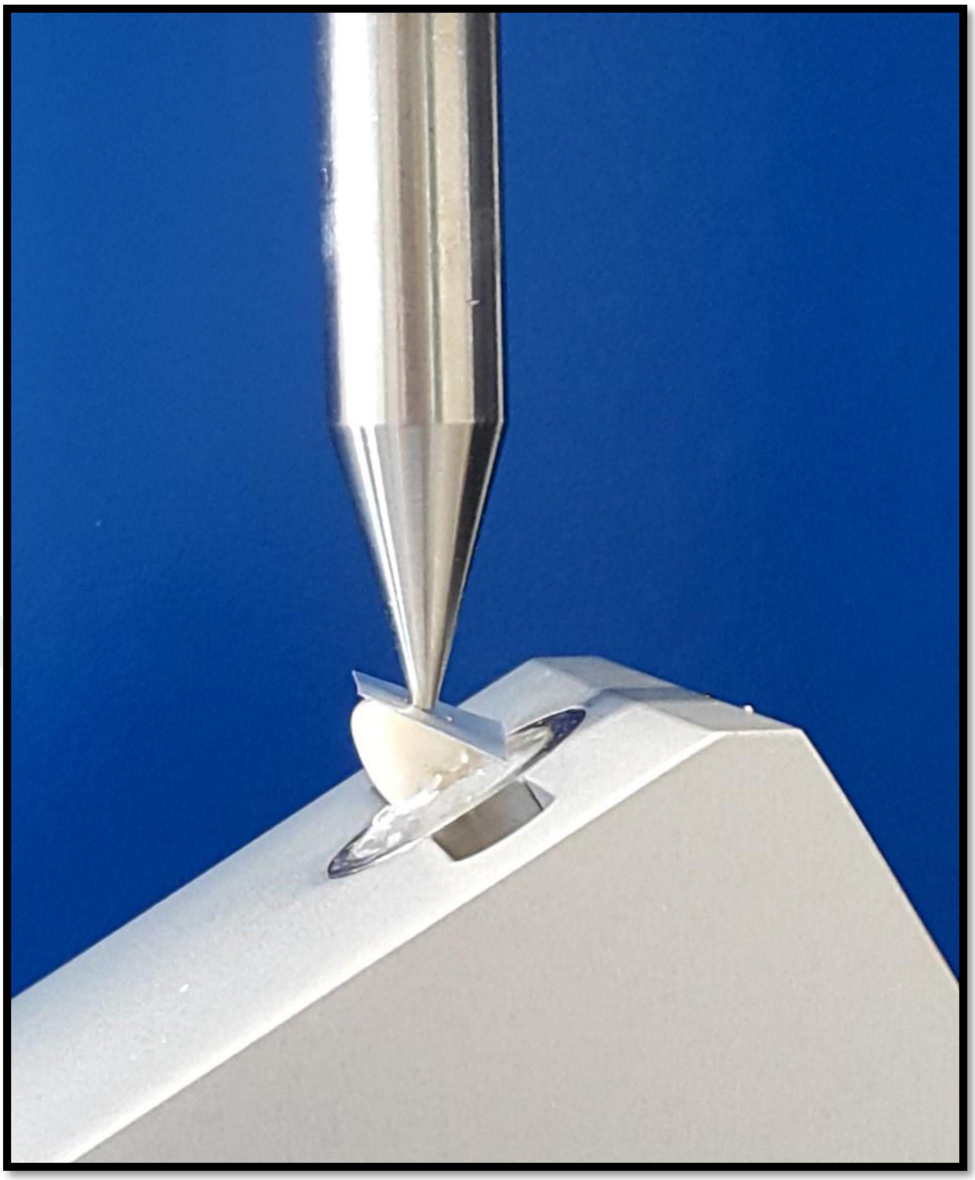


Figure 39. The specimens were attached at 45 degrees to the long axis of the crown.

3.3.5. Assessment of the fractured specimen with scanning electronic microscope

The fracture pattern and surface details of the interface were examined using scanning electronic microscope (SEM) (FE-SEM, JSM-6700F, Jeol, Tokyo, Japan) in the hard tisuue laboratory in Tubitak Marmara, Research Center.

Imaging of specimens was also undertaken at a magnification of 250X, 550X, 1000X.

Figure 40. Hard Tissue Research Laboratory Tubitak Marmara, Research Center.

Figure 41. Scanning Electronic Microscope**.**

3.4. *In vitro* Assessment of Bacterial Adherence of Zirconia and Composite Surfaces

3.4.1. Sample Size

Two different restorative materials were used in the present study. The materials included resin composites and zirconia while hydroxyapatite disk (HAP) served as control group. A total of 38 specimens, 9 mm in diameter and 1.25mm thick were used, 13 zirconia disc were prefabricated by NuSmile® company (Z) (Houston TX5524 Cornish, Houston, Texas 77007-4304,USA), 12 specimen of hydroxyapatite discs (3D Biotek, LLC 1, ILENE Court, Building 8, Unit 12, Hillsborough, NJ 08844, USA), 13 resin composite specimens (CS), which were prepared in the Yeditepe University Faculty of Dentistry, Hard Tissue Research Laboratory.

Table 24. Composition and description of material used.

Type of material	Chemical composition	Manufacturer
Zirconia	Zirconium oxide, yttrium oxide, halfium oxide, organic binder, pigment.	NuSmile® company
Composite Resin	Bis-GMA, UDMA, TEGDMA, and bis-EMA, silica filler, zirconia filler, and aggregated zirconia/silica Cluster filler	3M ESPE

3.3.6. Preparation of the specimens

A perspex mould with twenty circular top and buttom openings of 9 mm diameter and 1.2 mm thickness (Figure 42) was used for the preparation of resin composite disc specimens. The mould was placed on a clean glass slab and the test materials were packed into the mould, covered with a mylar strip and pressed flat with a microscopic glass slide 1 mm thick to extrude excess material and to produce a smooth, flat surface and photo polymerized according to manufacturer's instruction using light cured with a light intensity of 460 mW/cm^2 with halogen curing unit (Optilux 501, Kerr, CA, USA) according to the manufacturer's instructions, and finally removed from the mould. A total of 13 composite disc were fabricated and then polished using Sof-lex.

The polishing procedure consisted of repetitive strokes of ten seconds per step, to prevent heat buildup and formation of grooves. A conscious effort was made to standardize the strokes, downward force, and the number of strokes for each polishing procedure.

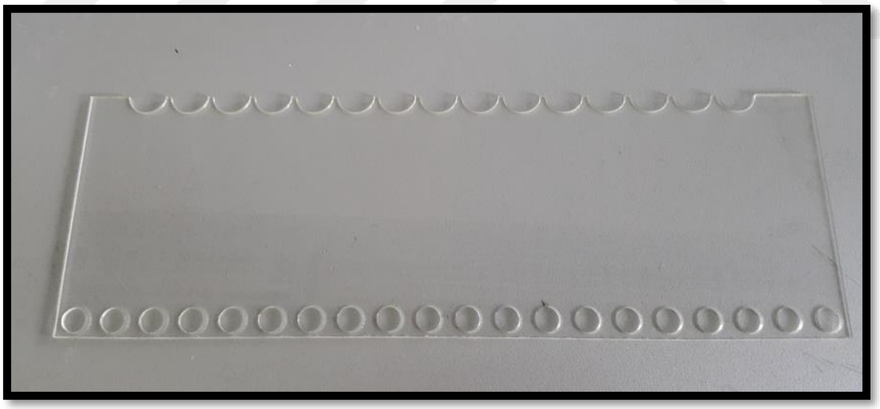


Figure 42. Perspex mould

Figure 43. Placement of composite in the perspex mould

Figure 44. Optilux 501, Kerr, CA, USA

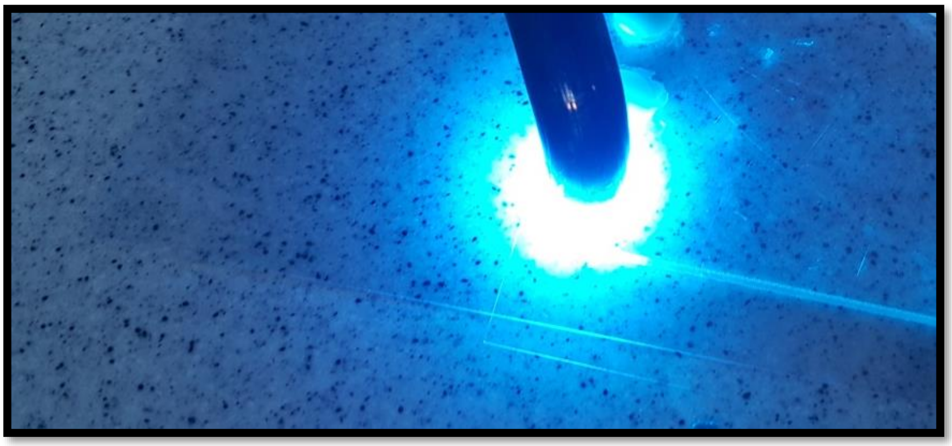


Figure 45. Light curing of the specimen

Figure 46. Measuring the specimen with electronic digital caliper

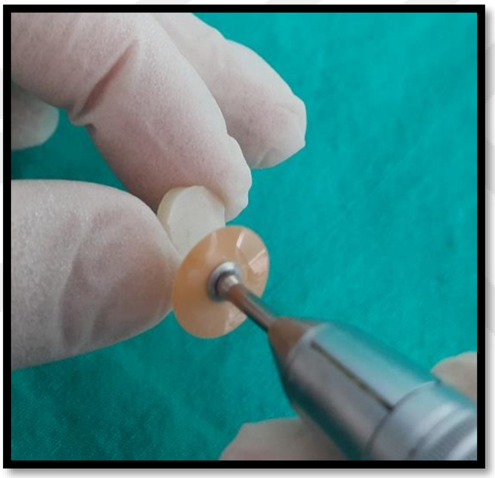


Figure 46. Polishing the specimen with Sof-lex (3M ESPE).

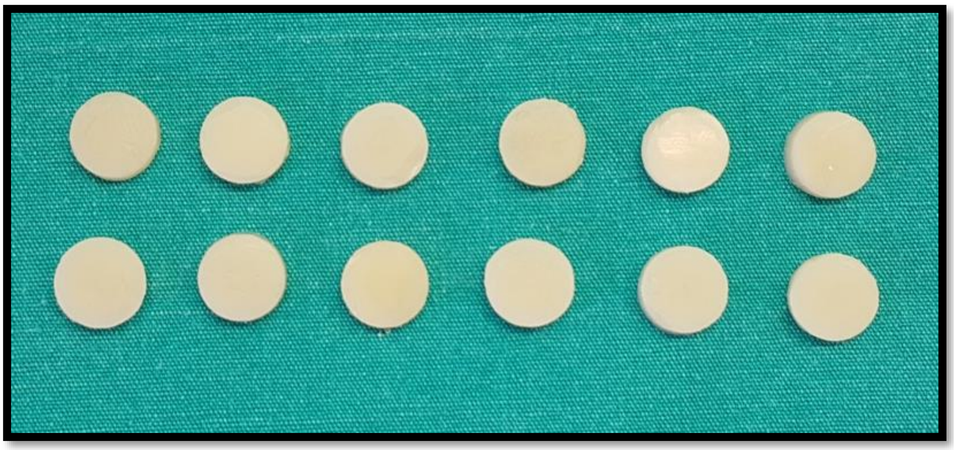


Figure 47. Resin composite disc specimens.

3.4.3. Sterilization of the specimens

The company (3D Biotek, LLC 1, ILENE Court, Building 8, Unit 12, Hillsborough, NJ 08844, USA), provide th HAP disc packed separately and sterilized with gamma radiation (Figure 48).

Figure 48. Hydroxyapatite disc

In the other two groups, thirteen sample discs for each group were washed with distilled water in an ultrasonic cleaner, every specimen was packed separately and then sterilized with hydrogen gas plasma sterilization (STERRAD® 100S**)** at 50°C for 50 minutes (Figure 49, 50), prior to the biofilm formation experiment.

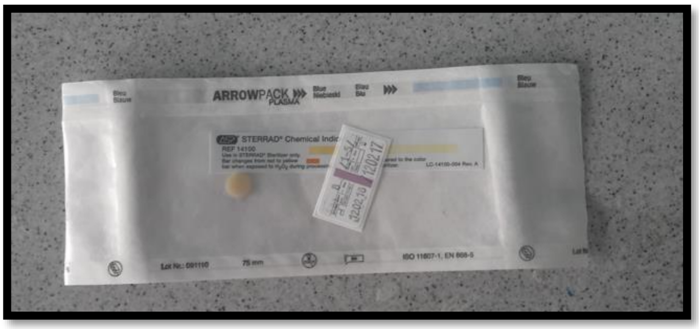


Figure 49. Sterilized composite disc in plasma sterilization pack.

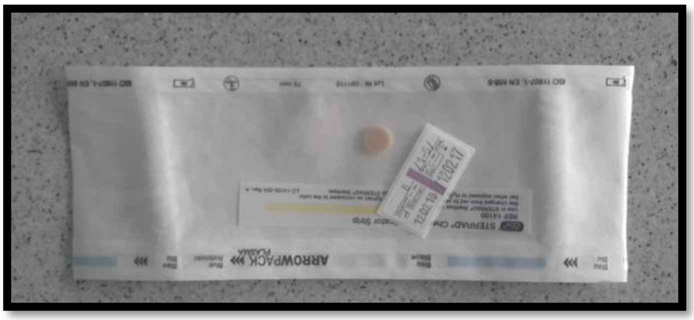


Figure 50. Sterilized zirconia disc in plasma sterilization pack.

3.4.4. Bacterial Strain and Growth Conditions:

Streptococcus mutans ATCC-25175 was used for biofilm assay. A preculture was prepared by inoculating a single colony of the bacteria into 10 ml of brain heart infusion medium (BHI), followed by an overnight incubation at 37°C under anaerobic conditions. The bacterial suspensions were prepared by diluting the preculture in a 1:20 ratio in BHI and incubating for an additional 2.5 h. The turbidity of the suspension was adjusted to the McFarland 0.5 turbidity standard (final concentration of 1.5 x 10^8 CFU/ml).

Figure 51. Preparation of bacterial suspensions from the *S.mutans* ATCC 25175 culture.

3.4.5. Saliva Processing:

Unstimulated whole saliva was obtained for 1 h per day for several days from a healthy volunteer into ice-chilled cups. At all times, saliva samples were then pooled, clarified by centrifugation (15,000 g for 15 min at 4ºC), sterilized by 0.22 lm filtration, and stored in aliquots at -20ºC. Undiluted saliva was used in all the experiments.

Figure 52. Sterilized saliva.

3.4.6. Biofilm Formation and Harvesting:

The discs were placed into 24 well polystyrene cell culture plates (CELLSTAR®) and incubated with 500 µl of saliva prepared for 1 h at 37°C. The discs were washed with 10 mM PBS pH 7 then, were covered with 1.6 ml of BHI broth supplemented with 5% saccharose added and was inoculated with 200 µl of bacterial suspension. The plates were incubated at 37°C for 24 hours.

After incubation which was carried out at 37˚C in a CO_2 chamber, the discs were gently dip washed three times in physiological saline to remove the loose bacteria. The discs were transferred into a sterile 15ml polistyrene tubes containing 1 ml of physiological saline and were then vortexed to allow mechanical disruption, for 60 seconds to harvest the adherent bacteria. The number of cells in suspension was counted in a spectrophotometer (TECAN, Spectra Image) for the optical density test, while the suspension was then ten fold serially diluted in sterile physiological saline and plated onto a BHI agar. The plates were incubated anaerobically for 48 h at 37°C, and the numbers of colony-forming units (CFUs) (CFU/mL) were then determined.

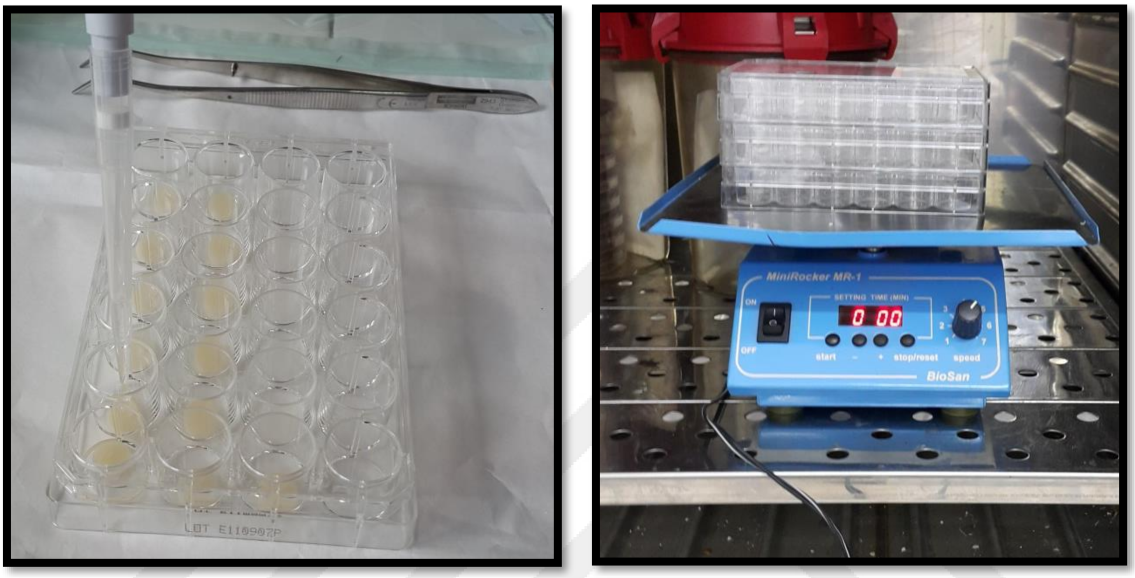


Figure 53. The discs were placed into 24 well polystyrene cell culture plates and incubated with 500 µl of saliva prepared for 1 h at 37°C.

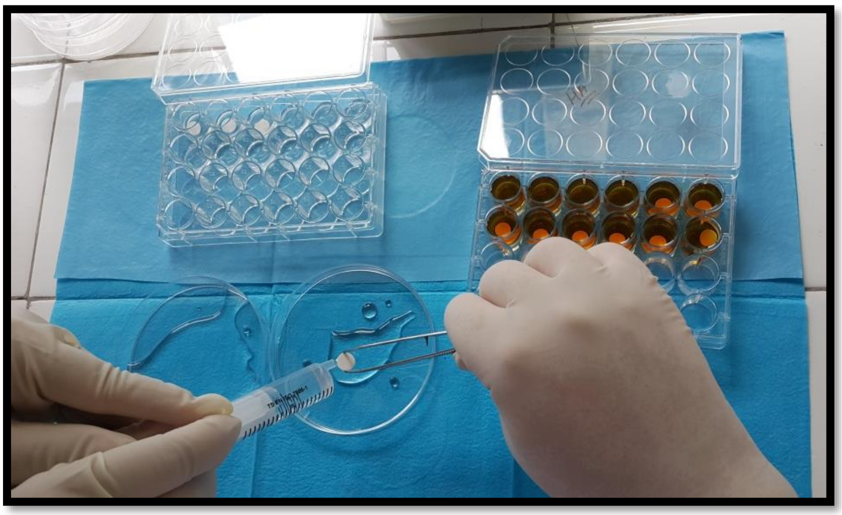


Figure 54. The discs were washed with 10 mM PBS pH 7 then, were covered with 1.6 ml of BHI broth supplemented with 5% saccharose.

Figure 55. The plates were incubated at 37°C for 24 hours.

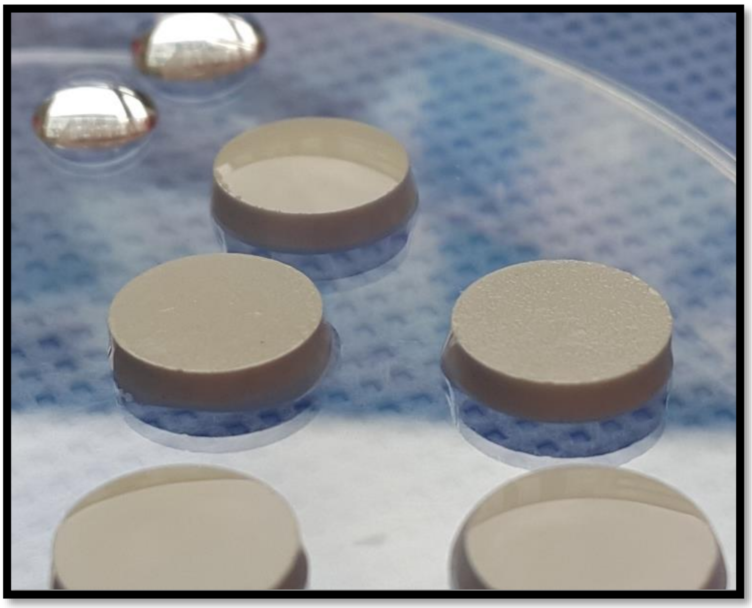


Figure 56. Hydroxyapatite specimens after 24 hours of inoculation with bacterial suspension.

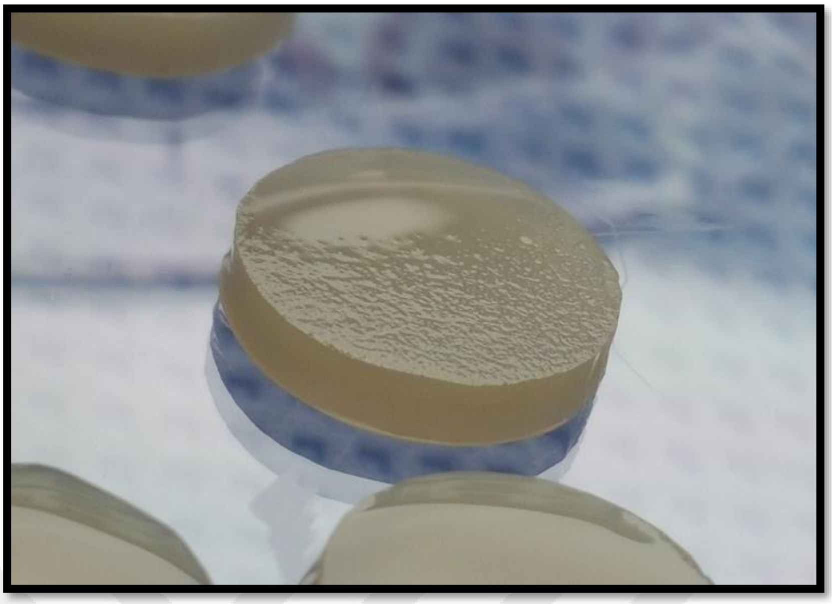


Figure 57. Resin composite specimens after 24 hours of inoculation with bacterial suspension.

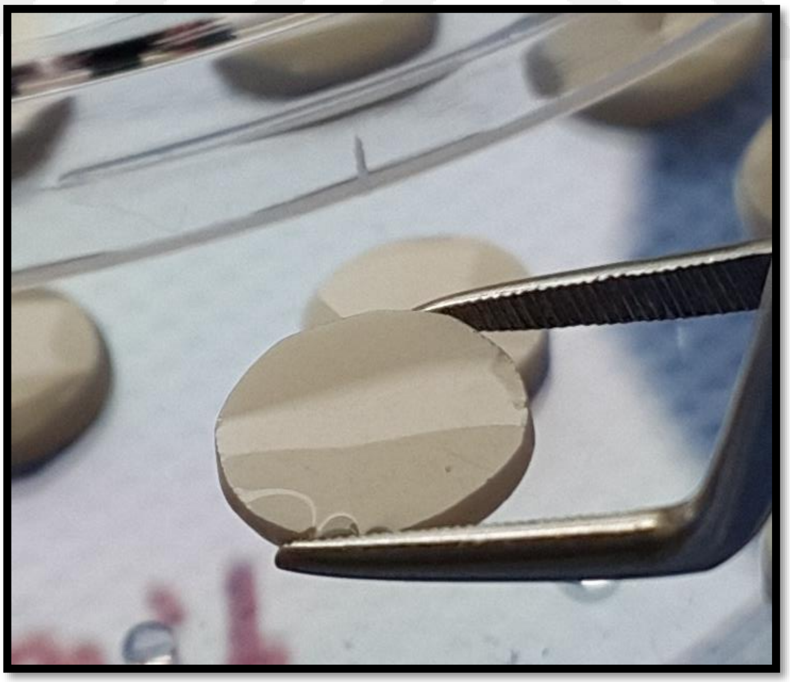


Figure 58. Zirconia specimens after 24 hours of inoculation with bacterial suspension.

Figure 59. The discs were transferred into a sterile 15ml polistyrene tubes containing 1 ml of physiological saline.

Figure 60. The discs were vortexed for 60 seconds.

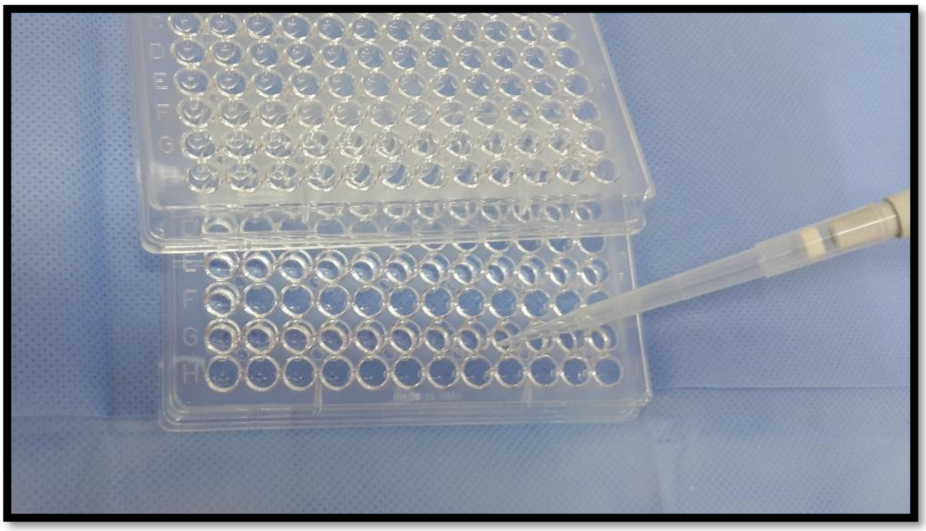


Figure 61. The suspension in the microtiter plates.

Figure 62. The microtiter plates placed in the Spectrophotometer.

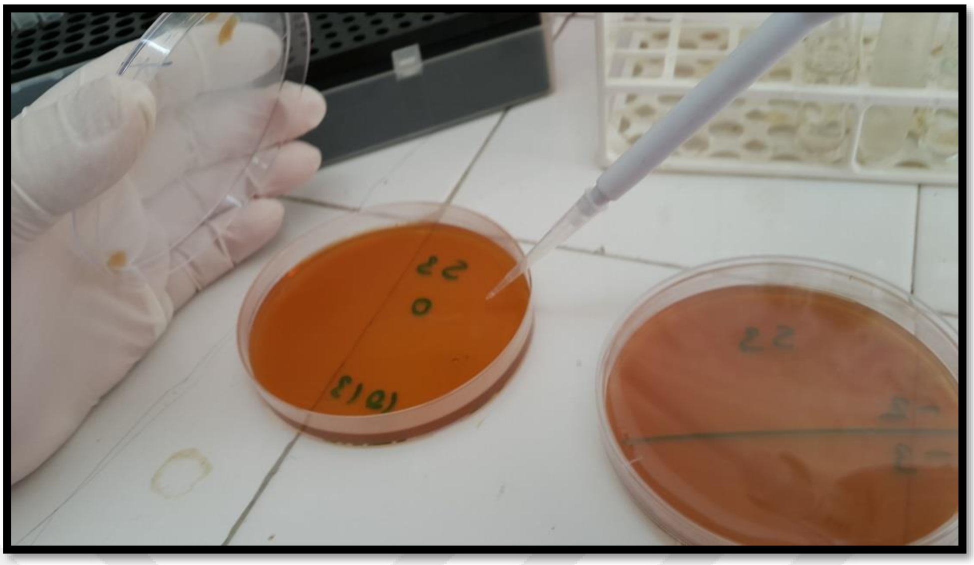


Figure 63. The suspensions were ten-fold serially diluted in sterile physiological saline and plated onto a BHI agar.

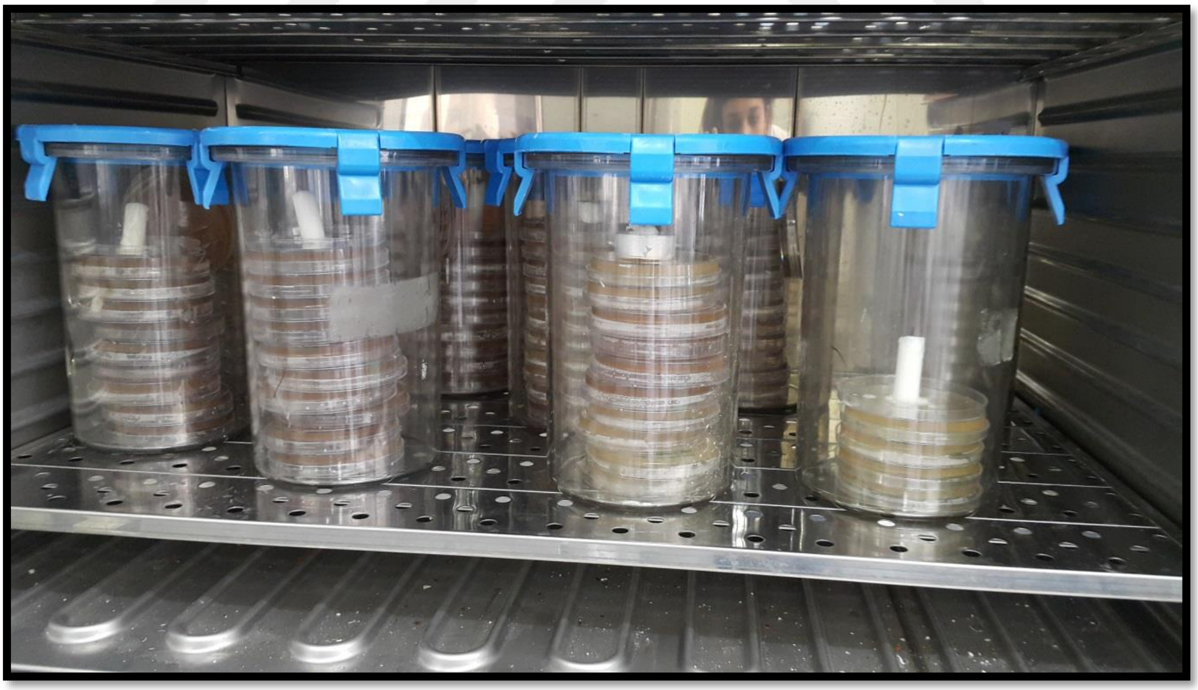


Figure 64. The plates were incubated anaerobically for 48 h at 37°C.

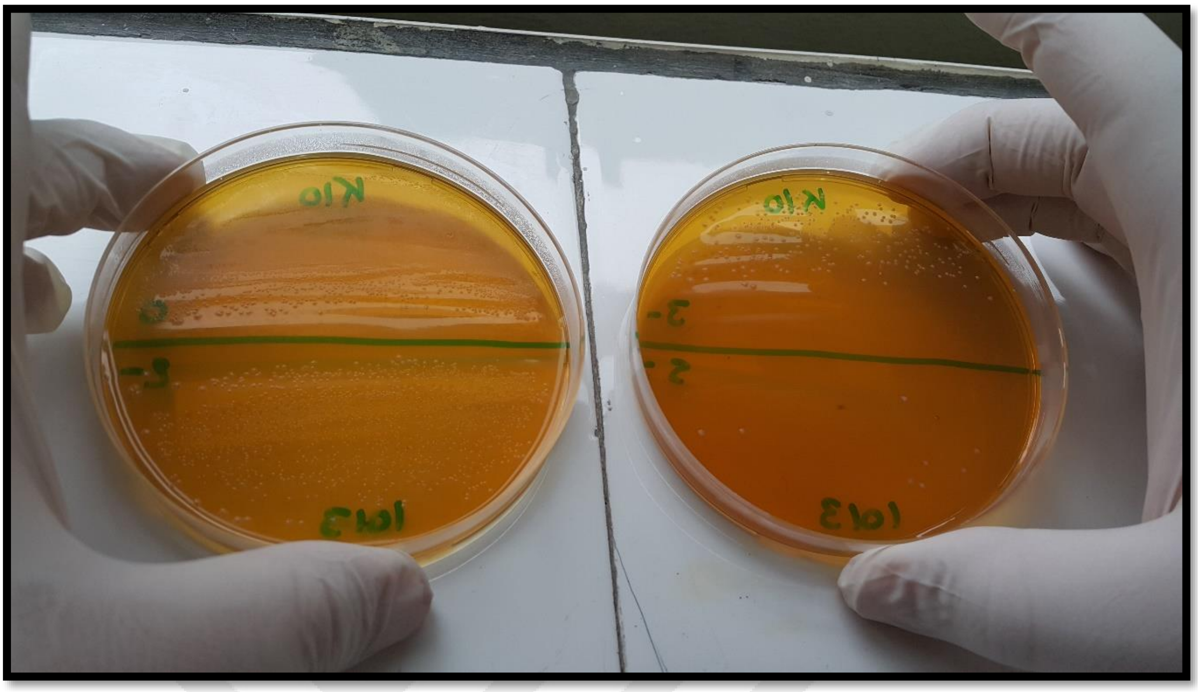


Figure 65. The composite group plates after incubation at 37°C for 24 hours

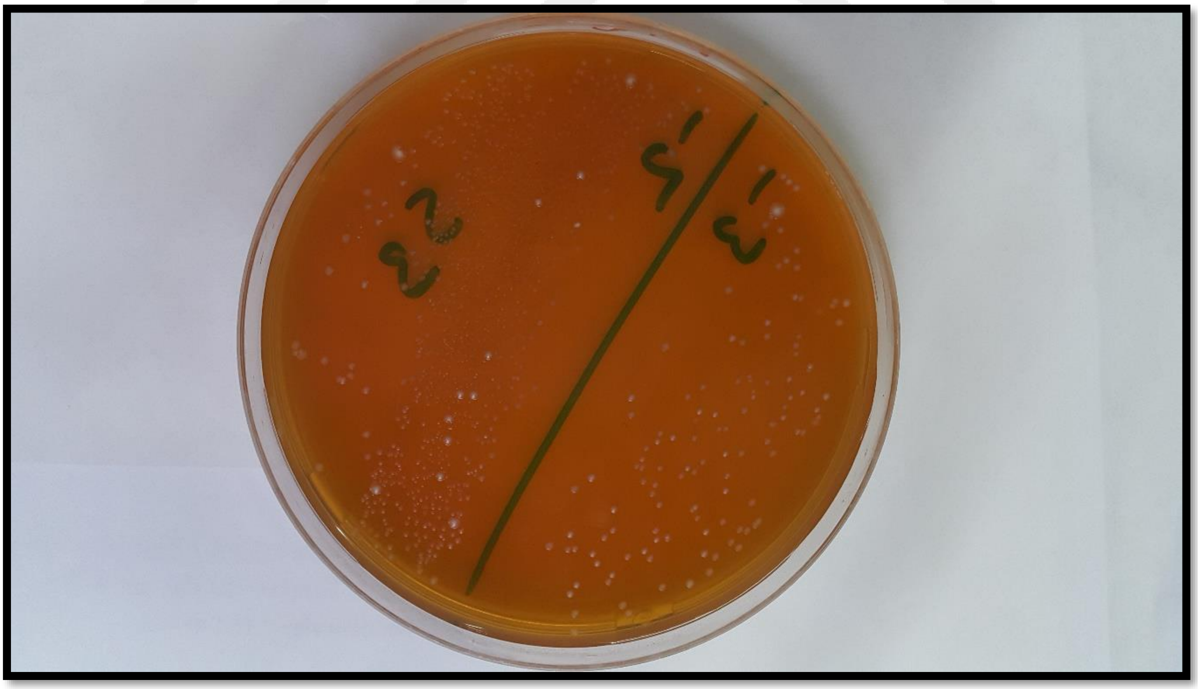


Figure 66. The zirconia group plate after incubation at 37°C for 24 hours

Figure 67. The hydroxyapatite plate after incubation at 37°C for 24 hours

4.Statistical Analysis

Statistical calculations were performed with (Number Cruncher Statistical System) 2007 Statistical Software (Utah, USA) program for Windows. Besides standard descriptive statistical calculations (mean and standard deviation), one way ANOVA was used in the comparison of groups, post Hoc Tukey multiple comparison test was utilized in the comparison of subgroups, paired t test was used in the comparison of two groups, paired t-test was employed in the assessment of pre and post treatment values, and Chi square test and Mc Nemar’s test were performed during the evaluation qualitative data, Pearson's correlation test was used to determine the relationships between the variables.

Statistical significance level was recorded at $P<0,05$.

5. RESULTS

5.1. Randomization Clinical Study

Forty two children who met the inclusion criteria and provided consent to participate were enrolled in this randomized clinical trial (27 males, 15 females). Among the 42 participating children, 165 maxillary primary anterior teeth were treated and restored with one of the three full coronal restoration as follow:

- 27 central incisors, 28 lateral incisors for NSZ.
- 25 central incisors, 26 lateral incisors for KKZ.
- 28 central incisors, 29 lateral incisors for RCSc.

Of the 42 children, 3 children were lost to follow-up. The reasons included inability to contact families of participants due to moved, altered or lost telephone services, or because the families were not interested in continuing in the study.

Thirty nine children with 154 treated teeth (25 males, 14 females) remained in the study. The children were seen as close to the 3, 6 and 9 month intervals as possible, however, the time interval was longer in some cases due to the varying compliance of the study participants with their recall visits.

The mean age of the children was calculated 3.60 ± 0.78, (3.33 to 4.95) at the time of crown placement.

Twenty three children were allocated to category 1 (definitely negative) Frankl scale and in relation to this, they were treated under general anesthesia. Whereas 19 children were defined as category 4 (positive) and were treated under local anesthesia.

The distribution of the study sample according to gender, frankl score, treatment method and mean dmft, dmfs scores is presented in (Table 25).

Table 25 described the summary statistics of the study sample, however the following statistically findings can be summarized as follow

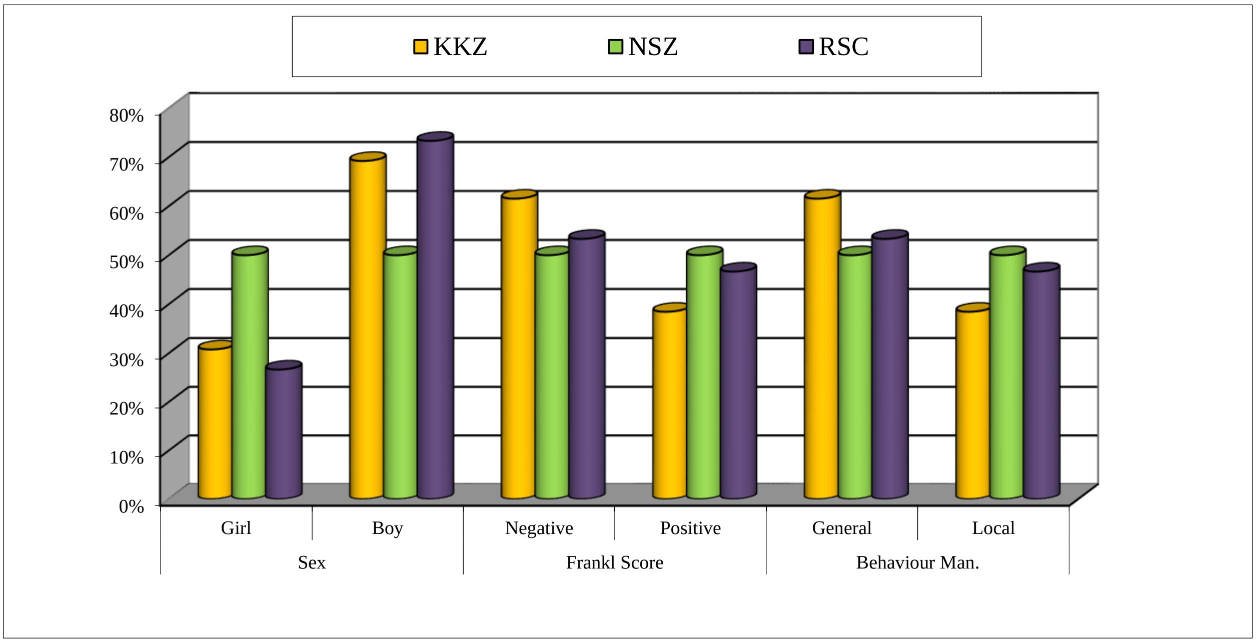
- No statistically significant difference was found between the zirconia and resin composite strip crown groups in terms of mean age and gender distribution ($p>0.05$).
- Frankl score distribution between the three groups showed no statistically significant difference ($p=0.826$).

- No statistically significant difference was seen between the three groups in terms of treatment method distribution (p=0.826).
- Mean dmft, dmfs scores showed no statistically significant difference between the three groups (p=0.437), (p=0.824) respectively (Graphic 1).

Table 25. The distribution of the study sample

		KKZ n:13		NSZ n:14		RCSc n:15		p
Age		3.54±0.81		3.88±0.82		3.4±0.7		0.260
Sex	**Girl**	4	30.77%	7	50.00%	4	26.67%	0.383
	Boy	9	69.23%	7	50.00%	11	73.33%	
Frankl Score	**Negative**	8	61.54%	7	50.00%	8	53.33%	0.826
	Positive	5	38.46%	7	50.00%	7	46.67%	
Treatment method	**General**	8	61.54%	7	50.00%	8	53.33%	0.826
	Local	5	38.46%	7	50.00%	7	46.67%	
dmft		12.92±1.75		11.71±2.92		12.4±2.41		0.437
dmfs		26±4.4		25.5±6.41		26.67±4.05		0.824

***One-Way ANOVA test, Chi Square test.**



Graphic 1. Distribution of the study sample

The mean and the standard deviationof PI and GI before and after treatment are presented in Table 26.

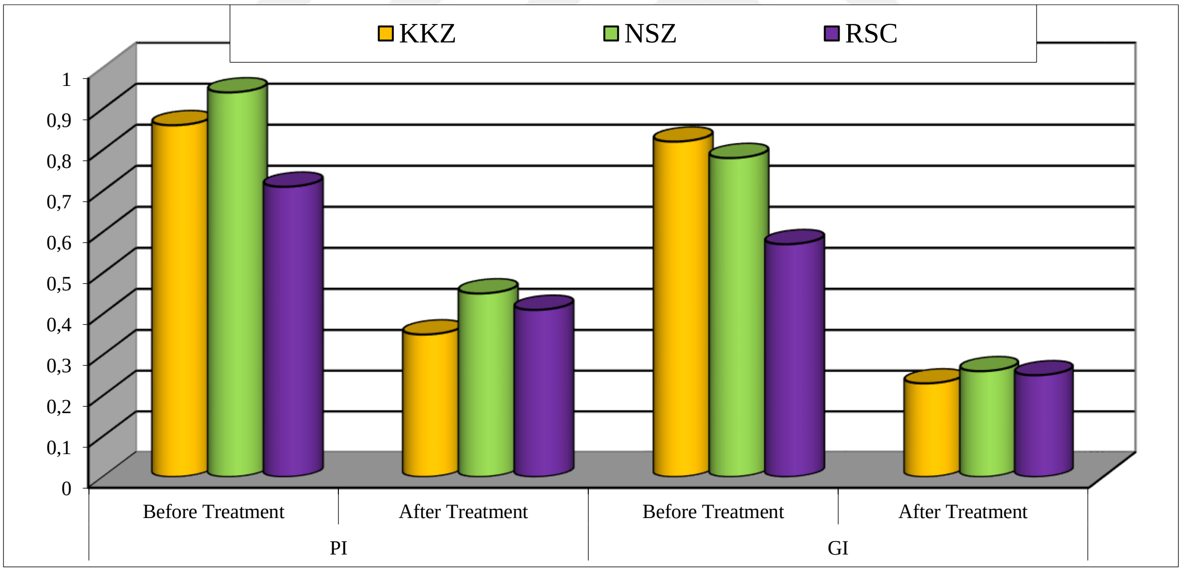
- The mean PI before and after treatment showed no statistical difference beetween the three groups (p=0.194).
- The mean PI value in the KKZ group after treatment showed a significantly lower value than before treatment **(p=0.0001)**.
- The mean PI value in the NSZ group after treatment showed a significantly lower value than before treatment **(p=0.0001)**.
- The mean PI value in the RCSc group after treatment showed a significantly lower value than before treatment **(p=0.0001)**.
- The mean GI value of the before and after treatment showed no statistical difference beetween the three groups (p=0.165).
- The mean GI value in the KKZ group after treatment showed a significantly lower value than before treatment **(p=0.0001)**.
- The mean GI value in the NSZ group after treatment showed a significantly lower value than before treatment **(p=0.0001)**.
- The mean GI value in the RCSc group after treatment showed a significantly lower value than before treatment (p=0.018).

Among the 42 participating children, 168 teeth, 3 teeth were extracted, 165 teeth had received pulp therapy. Sixty teeth were treated with pulpotomy and 105 were treated with pulpectomy. There were no statistically differences between the three groups regarding the mean of types of pulp treatment for the primary right maxillary central incisor 51 (p=0.797), primary right maxillary lateral incisor 52 (p=0.834), primary left maxillary central incisor 61 (p=0.622), primary left maxillary lateral incisor 62 (p=0.737) (Table 27), (Graphic 3).

Table 26. The mean and SD of PI and GI scores before and after treatment according to the study groups.

		KKZ n:13	NSZ n:14	RCSc n:15	P*
PI	**Before Treatment**	0.86±0.3	0.94±0.44	0.71±0.26	0.194
	After Treatment	0.35±0.13	0.45±0.19	0.41±0.13	0.264
	p+	**0.0001**	**0.0001**	**0.0001**	
GI	**Before Treatment**	0.82±0.22	0.78±0.43	0.57±0.43	0.165
	After Treatment	0.23±0.06	0.26±0.1	0.25±0.1	0.686
	P+	**0.0001**	**0.0001**	**0.018**	

***One-Way ANOVA test, +paired t test.**

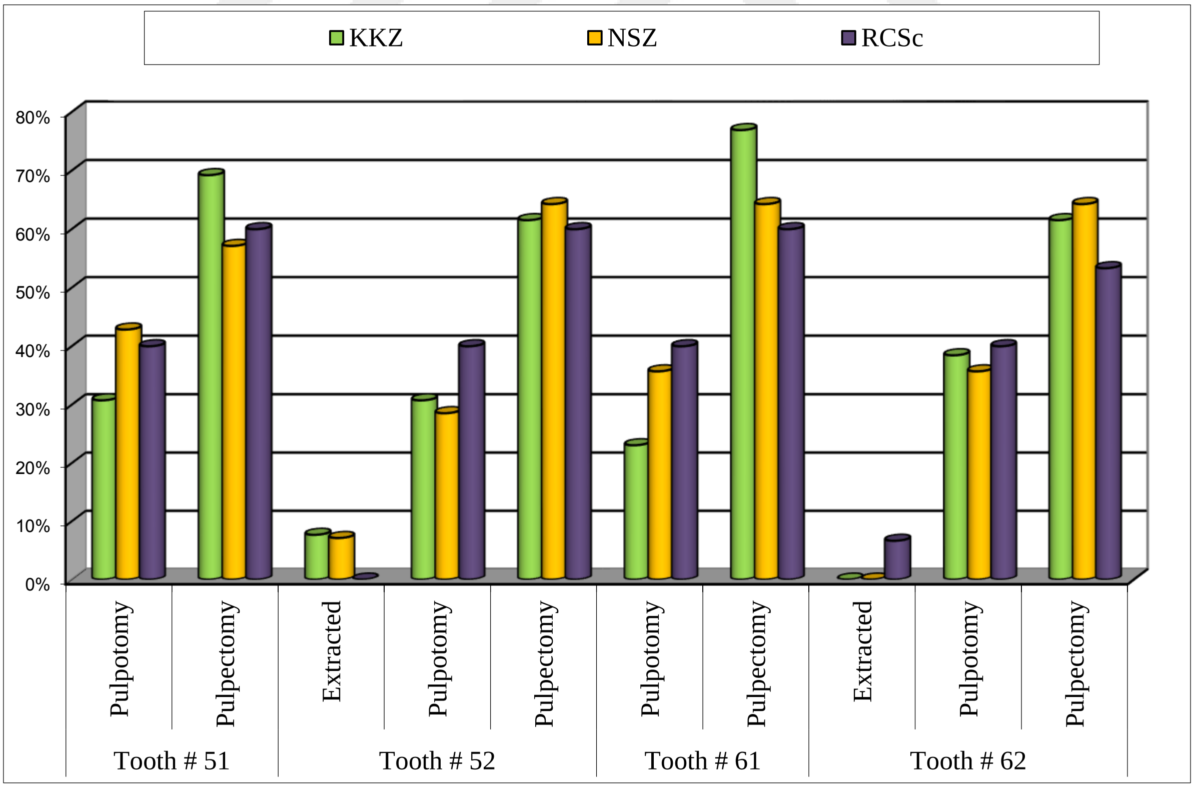


Graphic 2. The distribution of PI and GI scores before and after treatment according to the study groups.

Table 27. The distribution of treatments according to tooth number and study groups

Number of tooth	Pulp therapy	KKZ n:13		NSZ n:14		RCSc n:15		p
# 51	**Pulpotomy**	4	30.77%	6	42.86%	6	40.00%	0.797
	Pulpectomy	9	69.23%	8	57.14%	9	60.00%	
# 52	**Extracted**	1	7.69%	1	7.14%	0	0.00%	0.834
	Pulpotomy	4	30.77%	4	28.57%	6	40.00%	
	Pulpectomy	8	61.54%	9	64.29%	9	60.00%	
# 61	**Pulpotomy**	3	23.08%	5	35.71%	6	40.00%	0.622
	Pulpectomy	10	76.92%	9	64.29%	9	60.00%	
# 62	**Extracted**	0	0.00%	0	0.00%	1	6.67%	0.737
	Pulpotomy	5	38.46%	5	35.71%	6	40.00%	
	Pulpectomy	8	61.54%	9	64.29%	8	53.33%	

***Chi Square test.**



Graphic 3. The distribution of the type of treatments

5.1.1. Color match evaluation

The distribution of color match scores (USPHS) recorded for the maxillary primary right central incisor (#51) in the three follow-up periods and the comparison between the study groups according to x^2 test and Mc Nemar's test are presented in Table 28.

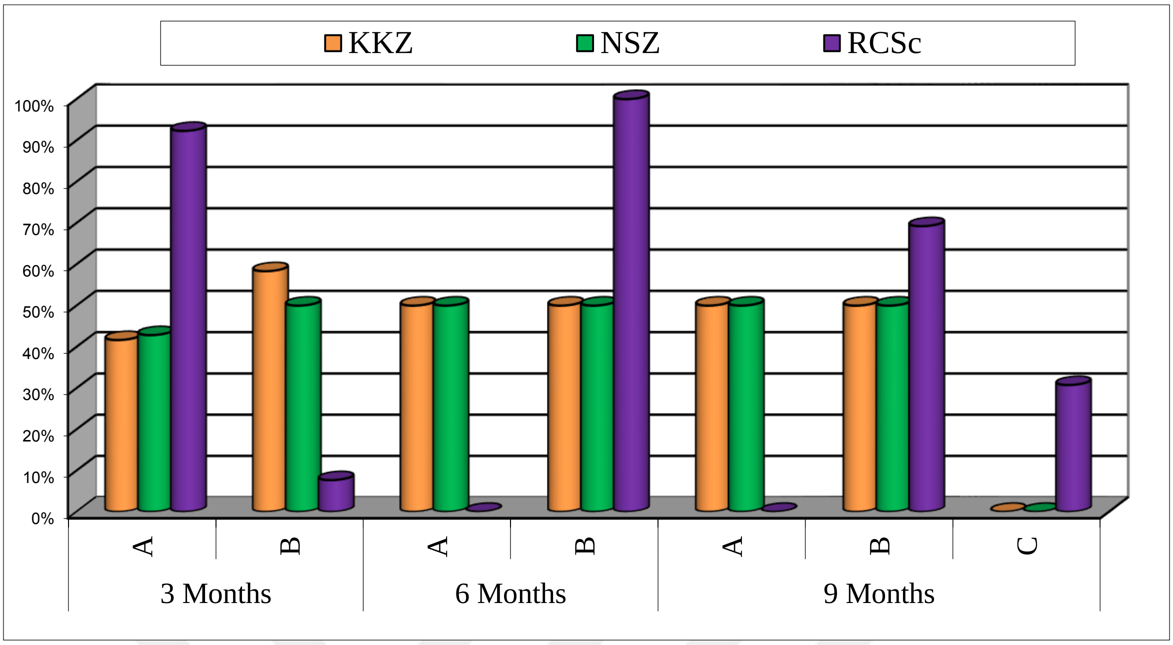
In the first visit (3 months), a statistically significant difference was observed between the study groups (p=0.035). Significantly less number of B scores were recorded in RCSc group compared to KKZ and NSZ groups in the first follow-up (3 months). However, in the second visit (6 months), slight shade mismatch was found to be higher in the RCSc group than the other groups and the difference was statistically significant (p =0.008). In the third visit (9 months), a statistically significant difference was observed between the number of color match scores in the study groups (p =0.005). Obvious shade mismatch was found to be statistically higher in the RCSc group than the other groups. Color match scores recorded for the tooth #51 during the 3, 6 and 9 month follow-up periods did not show any statistically significant changes in NSZ (p=0.357) and KKZ (p=0.368) groups, whereas the changes in RCSc group scores were found statistically significant **(p=0.0001)**, (Graphic 4).

Table 28. Comparison of color match scores (USPHS) between the groups recorded for the tooth #51 in the follow-up periods.

Follow-up period	Color match score USPHS	KKZ n:12		NSZ n:14		RCSc n:13		p*
3 Months	A	5	41.67%	6	42.86%	12	92.31%	0.035
	B	7	58.33%	8	57.14%	1	7.69%	
6 Months	A	6	50.00%	7	50.00%	0	0.00%	0.008
	B	6	50.00%	7	50.00%	13	100.00%	
9 Months	A	6	50.00%	7	50.00%	0	0.00%	0.005
	B	6	50.00%	7	50.00%	9	69.23%	
	C	0	0.00%	0	0.00%	4	30.77%	
	p+	0.368		0.357		**0.0001**		

*** Chi Square test +Mc Nemar's Test.**

A: Alpha. B: Beta, C: Charlie.



Graphic 4. Distribution of color match scores in the follow-up periods.

The comparison of color match scores recorded for #51 in RCSc group in the three follow-up periods according to Mc Nemar's Test is presented in Table 29. The difference between the number of color match scores recorded in 3 and 9 months was found significant **(p= 0.041)**. Also the difference between the number of color match scores in 6 and 9 months was statistically significant **(p= 0.046).**

Table 29. Comparison of color match scores for RCSc group in the follow-up periods

Follow-up periods	P*
3 Months / 6 Months	0.157
3 Months / 9 Months	**0.041**
6 Months / 9 Months	**0.046**

*** Mc Nemar's Test.**

The distribution of color match scores (USPHS) recorded for the maxillary primary left central incisor (#61) in the three follow-up periods and the comparison between the study groups according to x^2 test and Mc Nemar's test are presented in Table 30.

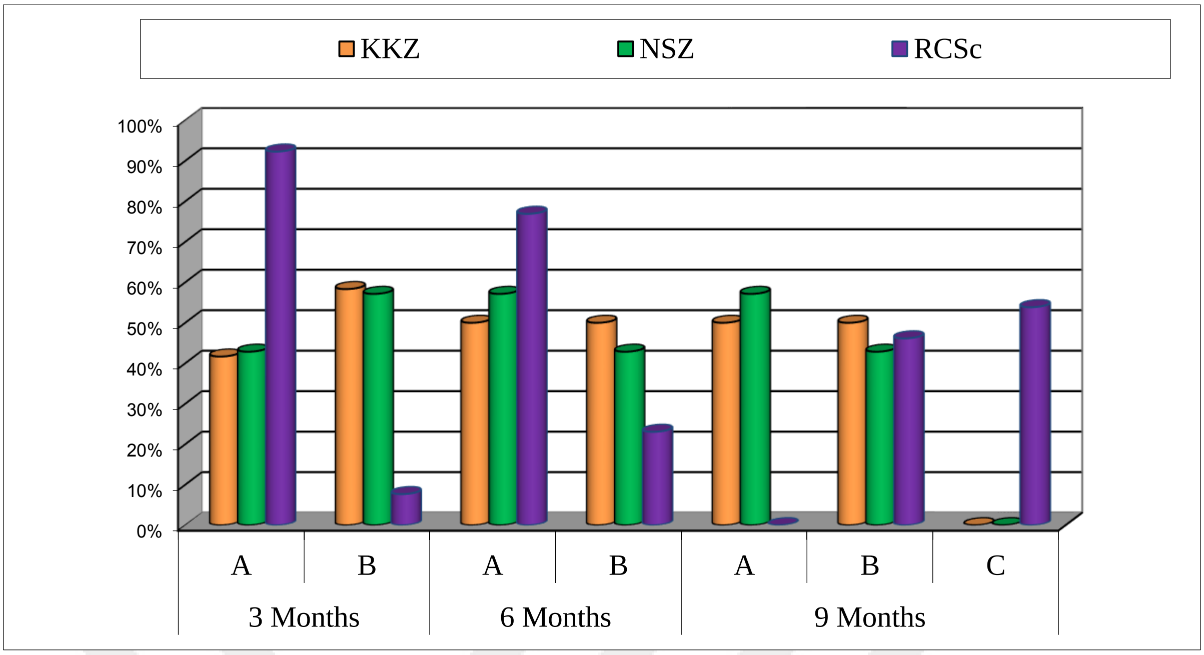
In the first visit (3 months), a statistically significant difference was observed between the study groups (p=0.011). Significantly less number of B scores were recorded in RCSc group compared to KKZ and NSZ groups in the first visit (3 months). However, in the second visit (6 months), there were no statistically significant difference between KKZ and NSZ groups (p=0.352). In the third visit (9 months), a statistically significant difference was observed between the number of color match scores in the study groups (p =0.0001). Obvious shade mismatch was found to be statistically higher in the RCSc group than the other groups. Color match scores recorded for the tooth #61 during the 3, 6 and 9 month follow-up periods did not show statistically significant changes in NSZ (p=0.135) and KKZ (p=0.365) groups, whereas the changes in RCSc group scores were found statistically significant **(p=0.0001),** (Graphic 5).

Table 30. Comparison of color match scores (USPHS) between the groups recorded for the tooth #61 in the follow-up periods

Follow-up period	**Color match score USPHS**	**KKZ n:12**		**NSZn:14**		**RCSc n:13**		**P***
3 Months	**A**	5	41.67%	6	42.86%	12	92.31%	**0.011**
	B	7	58.33%	8	57.14%	1	7.69%	
6 Months	**A**	6	50.00%	8	57.14%	10	76.92%	0.352
	B	6	50.00%	6	42.86%	3	23.08%	
9 Months	**A**	6	50.00%	8	57.14%	0	0.00%	**0.0001**
	B	6	50.00%	6	42.86%	6	46.15%	
	C	0	0.00%	0	0.00%	7	53.85%	
	P+	0.365		0.135		**0.0001**		

*** Chi Square test +Mc Nemar's Test.**

A: Alpha, B: Beta, C: Charlie.



Graphic 5. Distribution of color match scores in the follow-up periods.

The comparison of color match scores recorded for # 61 in RCSc group in the three follow-up periods is presented in Table 31**.** The difference between the number of color match scores recorded in 3 and 9 months was found significant **(p= 0.002)**. Also the difference between the number of color match scores in 6 and 9 months was statistically significant **(p= 0.002).**

Table 31. Comparison of color match scores for RCSc group in the follow-up periods

Follow-up periods	**P***
3 Months / 6 Months	0.157
3 Months / 9 Months	**0.002**
6 Months / 9 Months	**0.002**

*** Mc Nemar's Test.**

The distribution of color match scores (USPHS) recorded for the maxillary primary right lateral incisor (#52) in the three follow-up periods and the comparison between the study groups according to x^2 test and Mc Nemar's test are presented in Table 32.

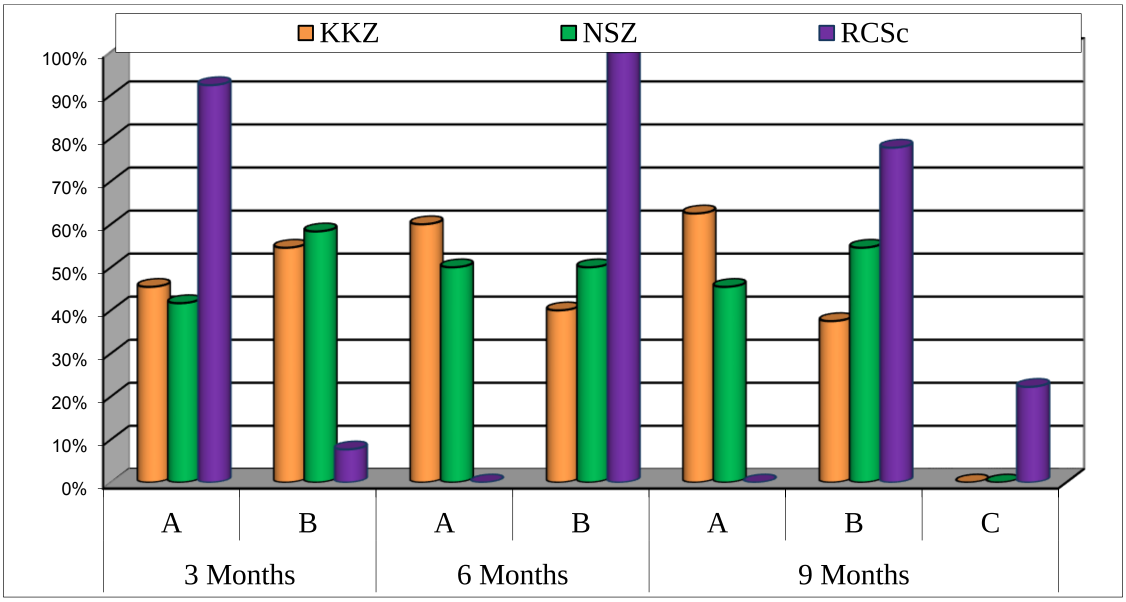
In the first visit (3 months), a statistically significant difference was observed between the study groups (p=0.015). Significantly less number of B scores were recorded in RCSc group compared to KKZ and NSZ groups in the first visit (3 months). However, in the second visit (6 months), slight shade mismatch was found to be statistically higher in the RCSc group than the other groups and the difference was statistically significant (p =0.02). In the third visit (9 months), a statistically significant difference was observed between the number of color match scores in the study groups (p =0.032). Obvious shade mismatch was found to be statistically higher in the RCSc group than the other groups. Color match scores recorded for the tooth #52 during the 3, 6 and 9 month follow-up periods did not show statistically significant changes in NSZ (p=0.717) and KKZ (p=0.368) groups, whereas the changes in RCSc group scores were found statistically significant **(p=0.001)**, (Graphic 6).

Table 32. Comparison of color match scores (USPHS) between the groups recorded for the tooth # 52 in the follow-up periods

Follow-up period	Color match score USPHS	KKZ n 11		NSZ n 13		RCSc n13		p*
3 Months	A	5	45.45%	5	41.67%	12	92.31%	0.015
	B	6	54.55%	8	58.33%	1	7.69%	
6 Months	A	6	60.00%	6	50.00%	0	0.00%	0.02
	B	4	40.00%	6	50.00%	13	100.00%	
9 Months	A	5	62.50%	5	45.45%	0	0.00%	0.032
	B	3	37.50%	6	54.55%	7	77.78%	
	C	0	0.00%	0	0.00%	2	22.22%	
	p+	0,368		0.717		**0.001**		

***Chi Square test +Mc Nemar's Test.**

A: Alpha, B: Beta, C: Charlie.



Graphic 6. Distribution of color match scores in the follow-up periods.

The comparison of color match scores recorded for # 52 in RCSc group in the three follow-up periods is presented in Table 33. The difference between the number of color match scores recorded in 3 and 6 months was found significant **(p= 0.001)**. Also the difference between the number of color match scores in 3 and 9 months was statistically significant **(p= 0.008).**

Table 33. The comparison of color match scores for RCSc group in the follow-up periods

Follow-up periods	P*
3 Months / 6 Months	**0.001**
3 Months / 9 Months	**0.008**
6 Months / 9 Months	0.157

***Mc Nemar's Test.**

The distribution of color match scores (USPHS) for the maxillary primary left lateral incisor (# 62), in the three follow-up periods and the comparison between the study groups according to x^2 test and Mc Nemar's test are presented in Table 34.

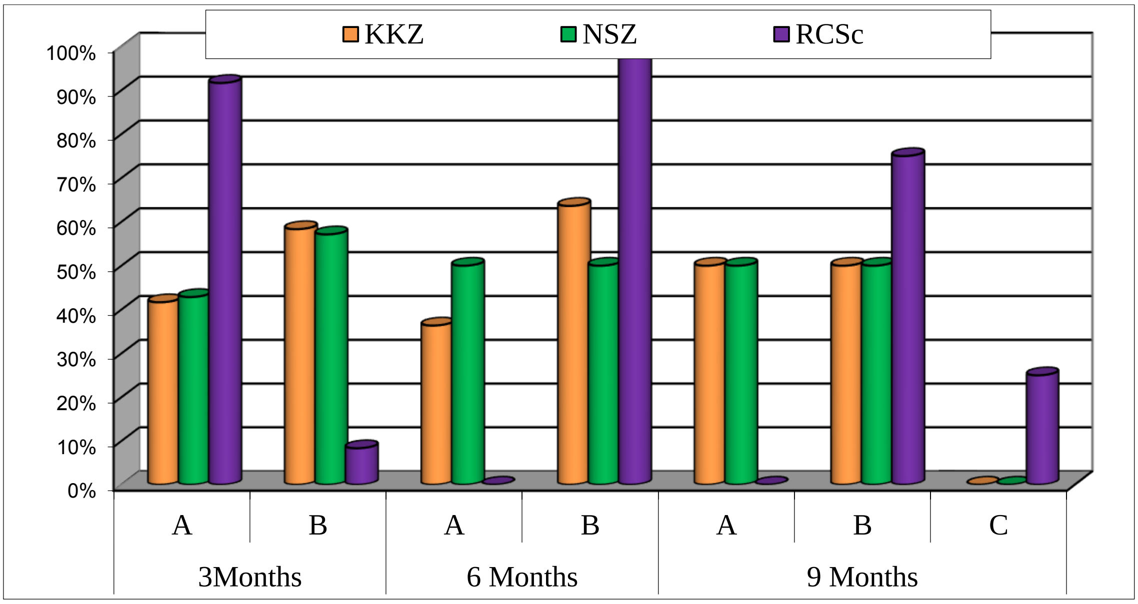
In the first visit (3 months), a statistically significant difference was observed between the study groups (p=0.016). Significantly less number of B scores were recorded in RCSc group compared to KKZ and NSZ groups in the first visit (3 months). However, in the second visit (6 months), slight shade mismatch was found to be statistically higher in the RCSc group than the other groups and the difference was statistically significant (p =0.023). In the third visit (9 months), a statistically significant difference was observed between the number of color match scores groups (p =0.01). Obvious shade mismatch was found to be statistically higher in the RCSc group than the other groups. Color match scores recorded for the tooth #52 during the 3, 6 and 9 month follow-up periods did not show statistically significant changes in NSZ (p=0.717) and KKZ (p=0.367) groups, whereas the changes in RCSc group scores were found statistically significant **(p=0.0001)**, (Graphic 7).

Table 34. Comparison of color match scores (USPHS) between the groups recorded for the tooth # 62 in the follow-up periods

Follow-up period	Color match score USPHS	KKZ n 12		NSZ n 14		RCSc n 12		P*
3 Months	A	5	41.67%	6	42.86%	11	91.67%	0.016
	B	7	58.33%	8	57.14%	1	8.33%	
6 Months	A	4	36.36%	7	50.00%	0	0.00%	0.023
	B	8	63.64%	7	50.00%	12	100.00%	
9 Months	A	6	50.00%	7	50.00%	0	0.00%	0.01
	B	6	50.00%	7	50.00%	9	75.00%	
	C	0	0.00%	0	0.00%	3	25.00%	
	P+	0.367		0.717		**0.0001**		

Chi Square test +Mc Nemar's Test.

A: Alpha. B: Beta, C: Charlie.



Graphic 7. Distribution of color match scores in the follow-up periods

The comparison of color match scores recorded for # 62 in RCSc group in the three follow-up periods is presented in Table 35.

The comparison of color match scores recorded for # 62 in RCSc group in the three follow-up periods is presented in Table 35. The difference between the number of color match scores recorded in 3 and 6 months was found significant **(p= 0.002)**. Also the difference between the number of color match scores in 3 and 9 months were statistically significant **(p= 0.002).**

Table 35. The comparison of color match scores for RCSc group in the follow-up periods

Follow-up period	P*
3 Months / 6 Months	**0.002**
3 Months / 9 Months	**0.002**
6 Months / 9 Months	0.083

***Mc Nemar's Test.**

Figure 68. A 4 years old patient treated under local anesthesia,(A) before treatment (B) after treatment (C) after 3 months follow-up (D) after 6 months follow-up (E) after 9 months follow-up showing moderate to severe discoloration of the restoration.

5.1.2. Crown contour

The distribution of crown contour scores (USPHS) recorded for the maxillary primary right central incisor (#51) in the three follow-up periods and the comparison between the study groups according to x^2 test and Mc Nemar's test are presented in Table 36.

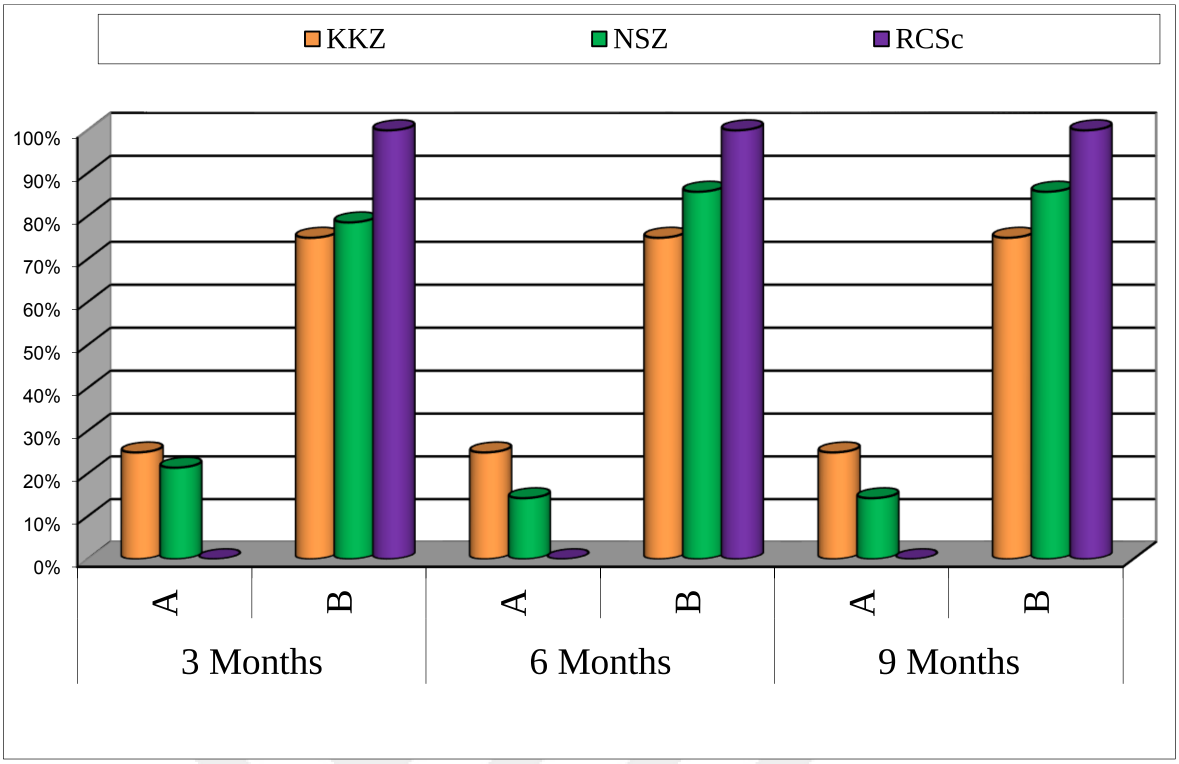
In the first visit (3 months), no statistically significant difference was observed between the study groups (p=0,165). Also, in the second visit (6 months) and in the third visit (9 months) no statistically significant difference was observed between the study groups (p=0.171), (Graphic 8).

Table 36. Comparison of crown contour scores (USPHS) between the groups recorded for the tooth # 51 in the follow-up periods

Follow-up period	Crown contour score USPHS	KKZ n:12		NSZ n:14		RCSc n:13		p*
3 Months	A	3	25.00%	3	21.43%	0	0.00%	0.165
	B	9	75.00%	11	78.57%	13	100.00%	
6 Months	A	3	25.00%	2	14.29%	0	0.00%	0.171
	B	9	75.00%	12	85.71%	13	100.00%	
9 Months	A	3	25.00%	2	14.29%	0	0.00%	0.171
	B	9	75.00%	12	85.71%	13	100.00%	
	p+	-		0.368		-		

Chi Square test +Mc Nemar's.

A: Alpha, B: Beta, C: Charlie.



Graphic 8. Distribution of crown contour scores in the follow-up periods

The distribution of crown contour scores (USPHS) recorded for the maxillary primary left central incisor (# 61) in the three follow-up periods and the comparison between the study groups according to x^2 test and Mc Nemar's test are presented in Table 37.

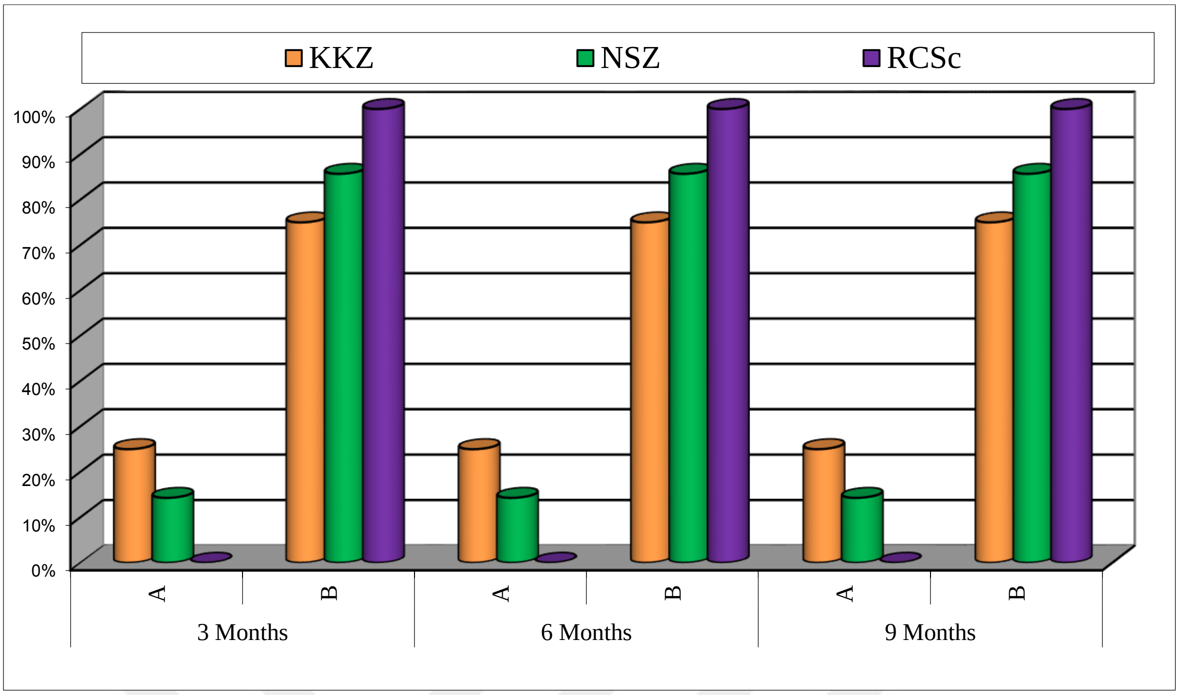
In the first visit (3 months), no statistically significant difference was observed between the study groups (p=0.171). Also, in the second visit (6 months) and in the third visit (9 months) no statistically significant difference was observed between the study groups (p=0.171), (Graphic 9).

Table 37. Comparison of crown contour scores (USPHS) between the groups recorded for the tooth # 61 in the follow-up periods

Follow-up period	Crown contour score USPHS	KKZ n:12		NSZn:14		RCSc n:13		p*
3 Months	A	3	25.00%	2	14.29%	0	0.00%	0.171
	B	9	75.00%	12	85.71%	13	100.00%	
6 Months	A	3	25.00%	2	14.29%	0	0.00%	0.171
	B	9	75.00%	12	85.71%	13	100.00%	
9 Months	A	3	25.00%	2	14.29%	0	0.00%	0.171
	B	9	75.00%	12	85.71%	13	100.00%	
	p+	-		-		-		

***Chi Square test +Mc Nemar's Test.**

A: Alpha, B: Beta, C: Charlie.



Graphic 9. Distribution of crown contour scores in the follow-up periods

The distribution of crown contour scores (USPHS) recorded for the tooth # 52 in the three follow-up periods and the comparison between the study groups according to x^2 test and Mc Nemar's test are presented in Table 38.

In the first visit (3 months), for the maxillary primary right lateral incisor (# 52), no statistically significant difference was observed between the study groups (p=0.213). Also, in the second visit (6 months) and in the third visit (9 months) no statistically significant difference was observed between the study groups (p=0.068) and (p=0.532) respectively.

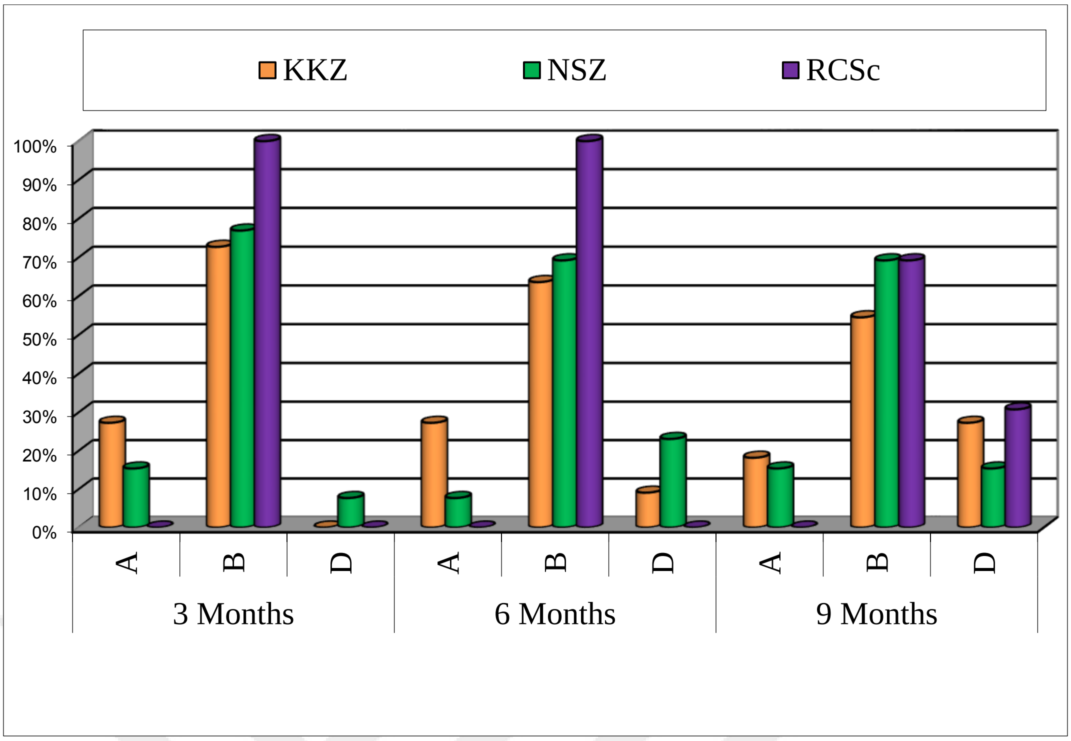
Crown contour scores recorded for the tooth # 52 during 3, 6 and 9 month follow-up periods did not show statistically significant changes in the KKZ (p=0.097) and NSZ (p=0.368) whereas the change in RCSc group scores were found statistically significant. Morever, more number of D scores were recorded in RCSc group compared to KKZ and NSZ groups in the third follow-up (9 months), (Graphic 10).

Table 38. Comparison of crown contour scores (USPHS) between the groups recorded for the tooth # 52 in the follow-up periods

Follow-up period	**Crown contour score USPHS**	**KKZ n:11**		**NSZn:13**		**RCSc n:13**		**P***
3 Months	**A**	3	27.27%	2	15.38%	0	0.00%	0.213
	B	8	72.73%	10	76.92%	13	100.00%	
	C	0	0.00%	1	7.69%	0	0.00%	
6 Months	**A**	3	27.27%	1	7.69%	0	0.00%	0.068
	B	7	63.64%	9	69.23%	13	100.00%	
	D	1	9.09%	3	23.08%	0	0.00%	
9 Months	**A**	2	18.18%	2	15.38%	0	0.00%	0.532
	B	6	54.55%	9	69.23%	9	69.23%	
	D	3	27.27%	2	15.38%	4	30.77%	
	p+	0.097		0.368		**0.018**		

***Chi Square test +Mc Nemar's Test.**

A: Alpha, B: Beta, C: Charlie.



Graphic 10. Distribution of crown contour scores in the follow-up periods

The comparison of crown contour scores recorded for # 52 in RCSc group in the three follow-up periods is presented in Table 39. The difference between the number of crown contour scores recorded in 3 and 6 months was not found significant **(p= 0.998)**. However the difference between the number of crown contour scores in 3 and 9 months and between 6 and 9 months were statistically significant **(p= 0.046)** and **(p=0.046)** respectively.

Table 39. The comparison of crown contour scores for RCSc group in the follow-up periods

Follow-up period	P*
3 Months / 6 Months	0.998
3 Months / 9 Months	**0.046**
6 Months / 9 Months	**0.046**

***Mc Nemar's Test.**

The distribution of crown contour scores (USPHS) recorded for the tooth # 62 in the three follow-up periods and the comparison between the study groups according to x^2 test and Mc Nemar's test are presented in Table 40.

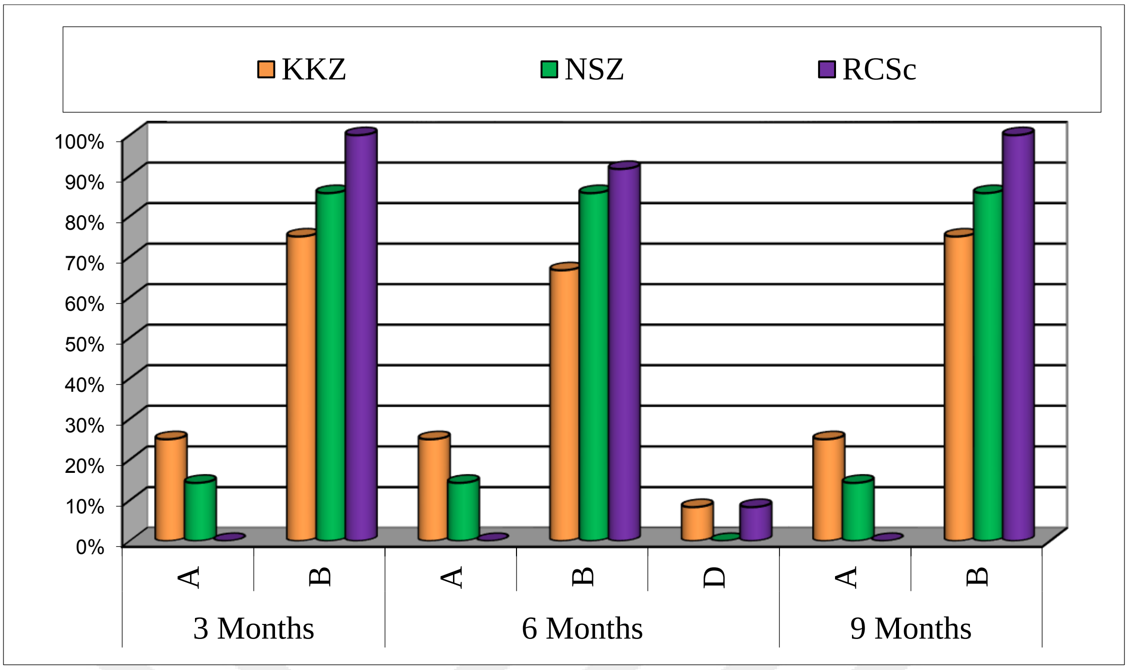
In the first visit (3 months), for the maxillary primary left lateral incisor (# 62), no statistically significant difference was observed between the study groups (p=0.191). Also, in the second visit (6 months) and in the third visit (9 months) no statistically significant difference was observed between the study groups (p=0.337) and (p=0.191) respectively, (Graphic 11).

Table 40. Comparison of crown contour scores (USPHS) between the groups recorded for the tooth # 62 in the follow-up periods

Follow-up period	Crown contour score USPHS	KKZ n:13		NSZ n:14		RCSc n:12		P*
3 Months	A	3	25.00%	2	14.29%	0	0.00%	0.191
	B	9	75.00%	12	85.71%	12	100.00%	
6 Months	A	3	25.00%	2	14.29%	0	0.00%	0.337
	B	8	66.67%	12	85.71%	11	91.67%	
	D	1	8.33%	0	0.00%	1	8.33%	
9 Months	A	3	25.00%	2	14.29%	0	0.00%	0.191
	B	9	75.00%	12	85.71%	12	100.00%	
	P+	0.368		-		0.365		

***Chi Square test +Mc Nemar's Test.**

A: Alpha, B: Beta, C: Charlie.



Graphic 11. Distribution of crown contour scores in the follow-up periods

5.1.3. Presence of restoration failure

The distribution of presence of restoration failure scores (USPHS) recorded for the tooth # 51 in the three follow-up periods and the comparison between the study groups according to x^2 test and Mc Nemar's test are presented in Table 41.

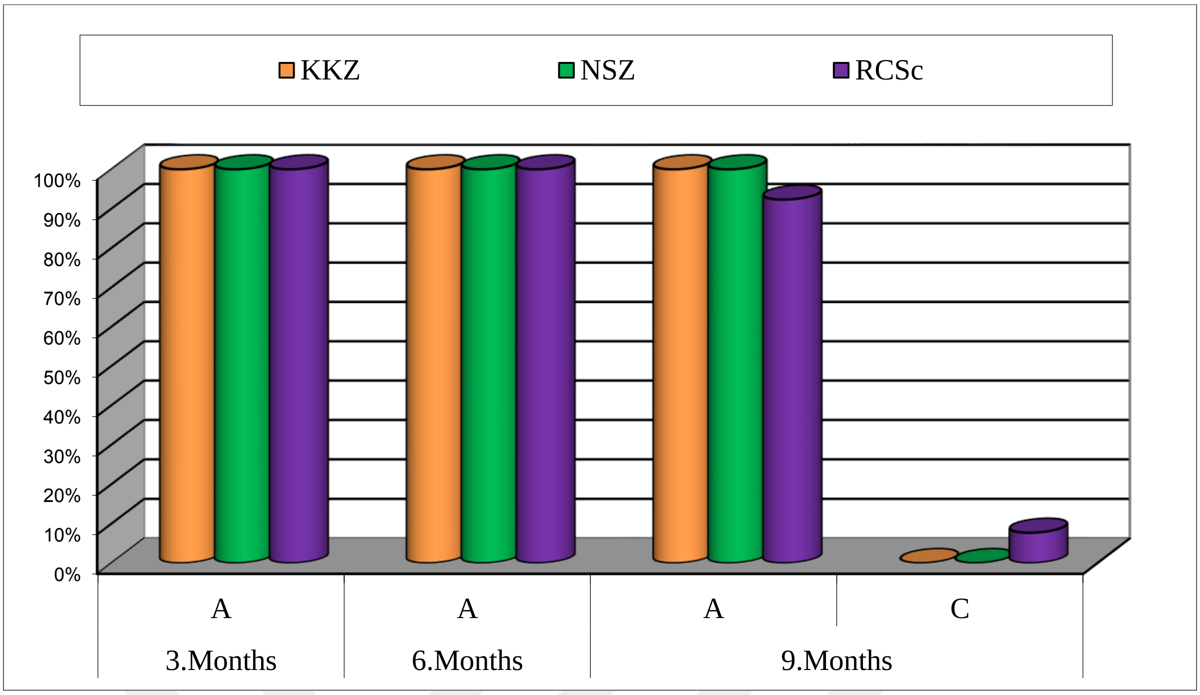
In the first and second visit (3 months and 6 months respectively), for the maxillary primary right central incisor (# 51), no statistically significant difference was observed between the study groups. Also, in the third visit (9 months) no statistically significant difference was observed between the study groups (p=0.358), (Graphic 12).

Table 41. Comparison of presence of restoration failure scores (USPHS) between the groups recorded for the tooth # 51in the follow-up periods

Follow-up period	Presence of restoration failure score USPHS	KKZ n:12		NSZ n:14		RCSc n:13		P*
3 Months	A	12	100.00%	14	100.00%	13	100.00%	
6 Months	A	12	100.00%	14	100.00%	13	100.00%	
9 Months	A	12	100.00%	14	100.00%	12	92.31%	0.358
	C	0	0.00%	0	0.00%	1	7.69%	
	P+	-		-		0.368		

***Chi Square test +Mc Nemar's Test.**

A: Alpha, B: Beta, C: Charlie.



Graphic 12. Distribution of presence of restoration failure scores in the follow-up periods

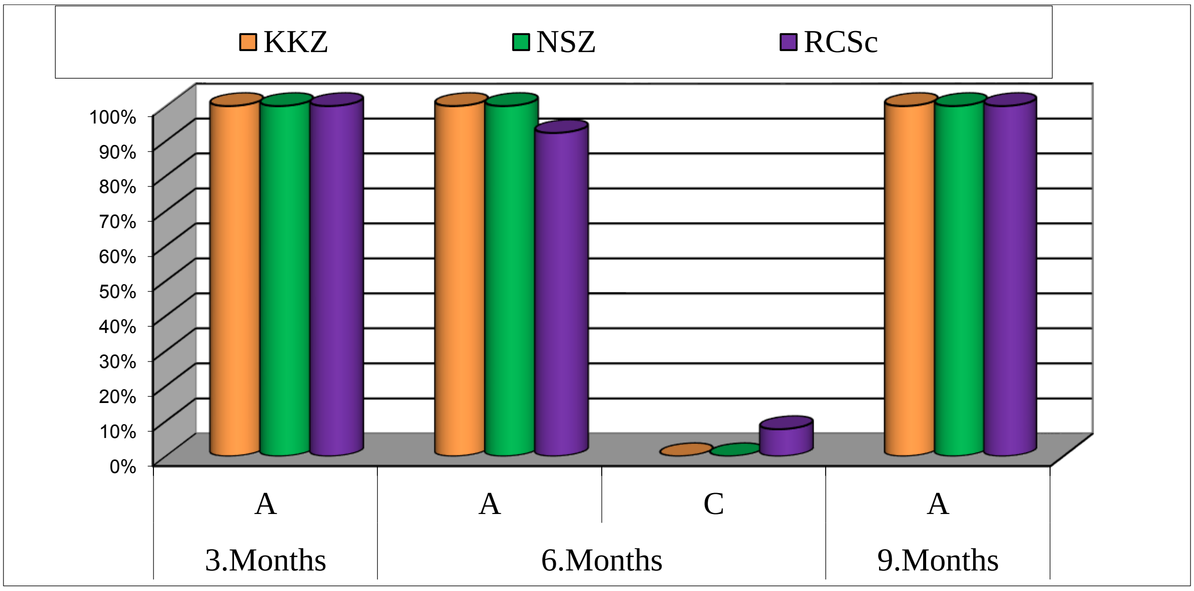
The distribution of presence of restoration failure scores (USPHS) recorded for the maxillary primary left central incisor (# 61) in the three follow-up periods and the comparison between the study groups according to x^2 test and Mc Nemar's test are presented in Table 42. Only one restoration failure was observed in the second visit (6 months) in the RCSc group and the difference between the study groups was not significant (0.358), (Graphic 13).

Table 42. Comparison of presence of restoration failure scores (USPHS) between the groups recorded for the tooth # 61in the follow-up periods

Follow-up period	Presence of restoration failure score USPHS	KKZ n:12		NSZ n:14		RCSc n:13		P*
3 Months	**A**	12	100.00%	14	100.00%	13	100.00%	
6 Months	**A**	12	100.00%	14	100.00%	12	92.31%	0.358
	C	0	0.00%	0	0.00%	1	7.69%	
9 Months	**A**	12	100.00%	14	100.00%	13	100.00%	
	p+	-		-		0.368		

***Chi Square test +Mc Nemar's Test.**

A: Alpha, B: Beta, C: Charlie.



Graphic 13. Distribution of presence of restoration failure scores in the follow-up periods

The distribution of presence of restoration failure scores (USPHS) recorded for the maxillary primary right lateral incisor (# 52) in the three follow-up periods and the comparison between the study groups according to x^2 test and Mc Nemar's test are presented in Table 43.

In the first visit (3 months), no statistically significant difference was observed between the study groups (p=0.387). Also, in the second visit (6 months) and in the third visit (9 months) no statistically significant difference was observed between the study groups (p=0.257) and (p=0.556) respectively.

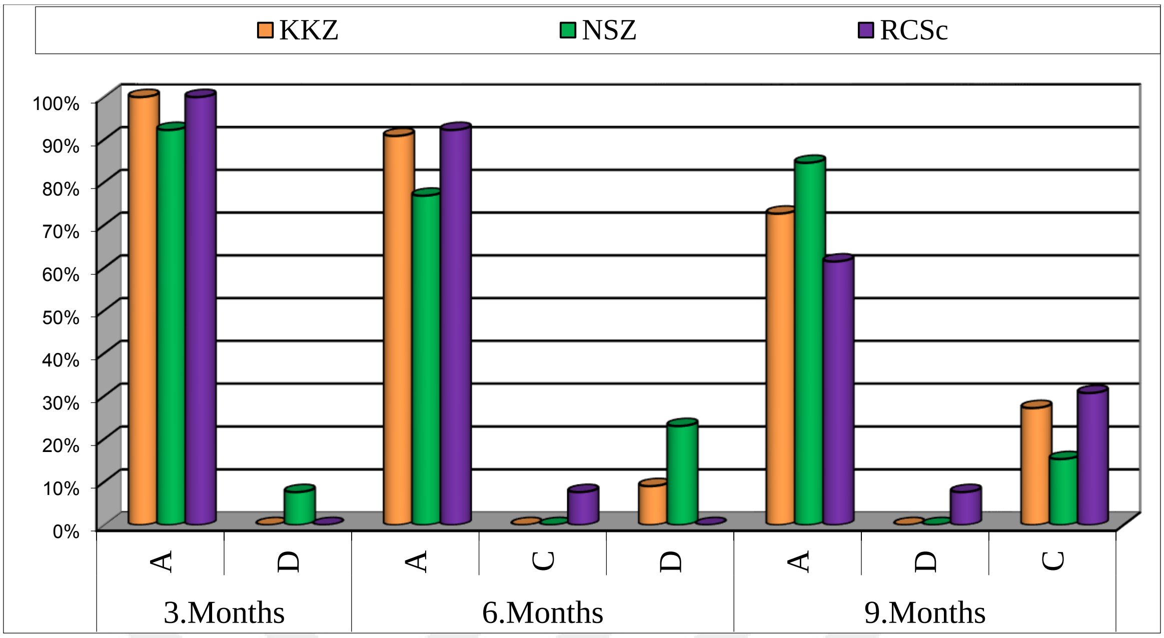
Presence of restoration failure scores recorded for the tooth # 52 during 3, 6 and 9 month follow-up periods did not show statistically significant changes in the KKZ (p=0.097) and NSZ (p=0.368), whereas the change in RCSc group scores was found statistically significant **(p=0.03).** Morever, more number of D scores were recorded in RCSc group compared to KKZ and NSZ groups in the third visit (9 months), (Graphic 14).

Table 43. Comparison of presence of restoration failure scores (USPHS) between the groups recorded for the tooth # 52 in the follow-up periods

Follow-up period	**Presence of restoration failure score USPHS**	**KKZ n 11**		**NSZ n 13**		**RCSc n 13**		**P***
3 Months	**A**	11	100.00%	12	92.31%	13	100.00%	
	D	0	0.00%	1	7.69%	0	0.00%	0.387
6 Months	**A**	10	90.91%	10	76.92%	12	92.31%	
	C	0	0.00%	0	0.00%	1	7.69%	
	D	1	9.09%	3	23.08%	0	0.00%	0.257
9 Months	**A**	8	72.73%	11	84.62%	8	61.54%	
	C	0	0.00%	0	0.00%	1	7.69%	
	D	3	27.27%	2	15.38%	4	30.77%	0.556
	p+	0.097		0.368		**0.03**		

***Chi Square testi +Mc Nemar's Test.**

A: Alpha, B: Beta, C: Charlie.



Graphic 14. Distribution of presence of restoration failure scores in the follow-up periods

The comparison of presence of restoration failure scores recorded for # 52 in RCSc group in the three follow-up periods is presented in Table 44. The difference between the number of restoration failure scores recorded in 3 and 9 months was found significant **(p= 0.034)**. Also the difference between the number of presence of restoration failure scores in 6 and 9 months was statistically significant **(p= 0.042).**

Table 44. The comparison of restoration failure scores for RCSc group in the follow-up periods

Follow-up period	P*
3 Months / 6 Months	0.317
3 Months / 9 Months	**0.034**
6 Months / 9 Months	**0.042**

+Mc Nemar's Test.

The distribution of presence of restoration failure scores (USPHS) recorded for the tooth # 62 in the three follow-up periods and the comparison between the study groups according to x^2 test and Mc Nemar's test are presented in Table 45.

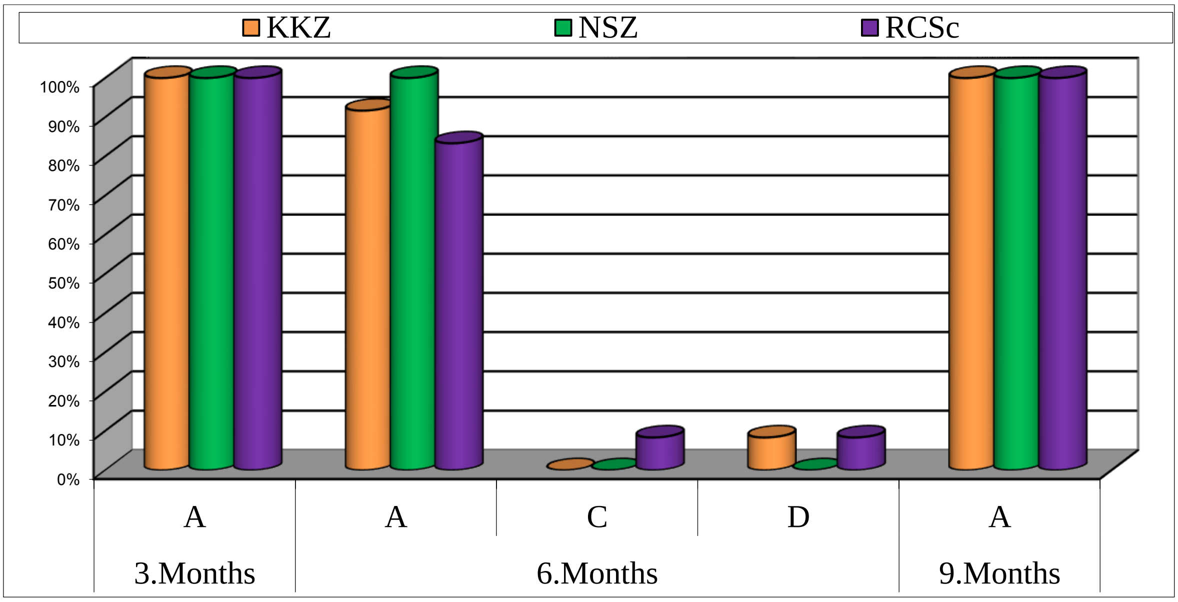
In the first visit (3 months), for the maxillary primary left lateral incisor (#62), no statistically significant difference was observed between the study groups. Also, in the second visit (6 months) (p=0.474), and in the third visit (9 months) no statistically significant difference was observed between the study groups, (Graphic 15).

Table 45. Comparison of presence of restoration failure scores (USPHS) between the groups recorded for the tooth # 62 in the follow-up periods

Follow-up period	Presence of restoration failure score USPHS	KKZ n:12		NSZn:14		RCSc n:12		P*
3 Months	A	12	100.00%	14	100.00%	12	100.00%	
6 Months	A	11	91.67%	14	100.00%	10	83.33%	0.474
	C	0	0.00%	0	0.00%	1	8.33%	
	D	1	8.33%	0	0.00%	1	8.33%	
9 Months	A	12	100.00%	14	100.00%	12	100.00%	
	p+	0.368		-		0.135		

***Chi Square testi +Mc Nemar's Test.**

A: Alpha, B: Beta, C: Charlie.



Graphic 15. Distribution of presence of restoration failure scores in the follow-up periods

Figure 69. RCSc restoration of the left central incisor presented in the third follow-up, rated with B (Presence of restoration failure) in patient of 5 years old.

Figure 70. NSZ restoration of the right central incisor presented in the second follow-up, rated with D (complete loss of restoration) in patient of 5 years old.

5.1.4. Gingival Health Evaluation

The distribution of gingival health evaluation scores (USPHS) recorded for the maxillary primary right central incisor (#51) in the three follow-up periods and the comparison between the study groups according to x^2 test and Mc Nemar's test are presented in Table 46.

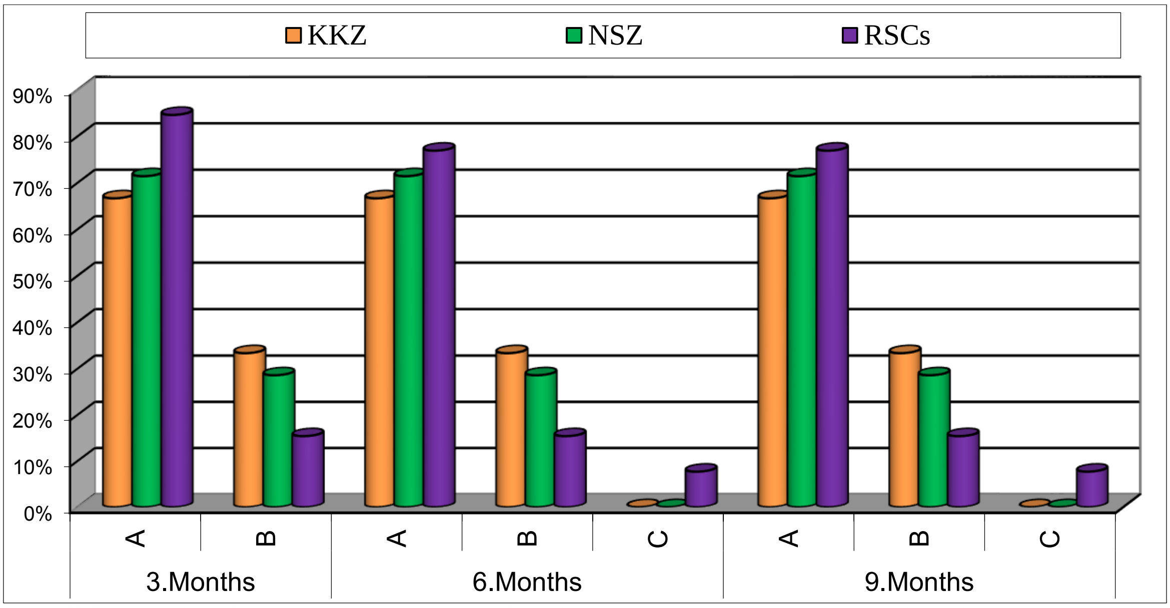
In the first visit (3 months), no statistically significant difference was observed between the study groups (p=0,562). Also, in the second visit (6 months) and in the third visit (9 months) no statistically significant difference was observed between the study groups, (Graphic 16).

Table 46. Comparison of presence of restoration failure scores (USPHS) between the groups recorded for the tooth # 51 in the follow-up periods

Follow-up period	Gingival health score USPHS	KKZ n:12		NSZ n:14		RCSc n:13		P*
3 Months	A	8	66.67%	10	71.43%	11	84.62%	0.562
	B	4	33.33%	4	28.57%	2	15.38%	
6 Months	A	9	75 %	10	71.43%	10	76.92%	0.566
	B	3	25%	4	28.57%	2	15.38%	
	C	0	0.00%	0	0.00%	1	7.69%	
9 Months	A	10	83.33%	12	85.71%	10	76.92%	0.566
	B	2	16.67%	2	14.28%	2	15.38%	
	C	0	0.00%	0	0.00%	1	7.69%	
	p+	-		-		0.607		

***Chi Square test +Mc Nemar's.**

A: Alpha, B: Beta, C: Charlie



Graphic16. Distribution of gingival health evaluation scores in the follow-up periods

The distribution of gingival health evaluation scores (USPHS) recorded for the tooth # 61 in the three follow-up periods and the comparison between the study groups according to x^2 test and Mc Nemar's test are presented in Table 47.

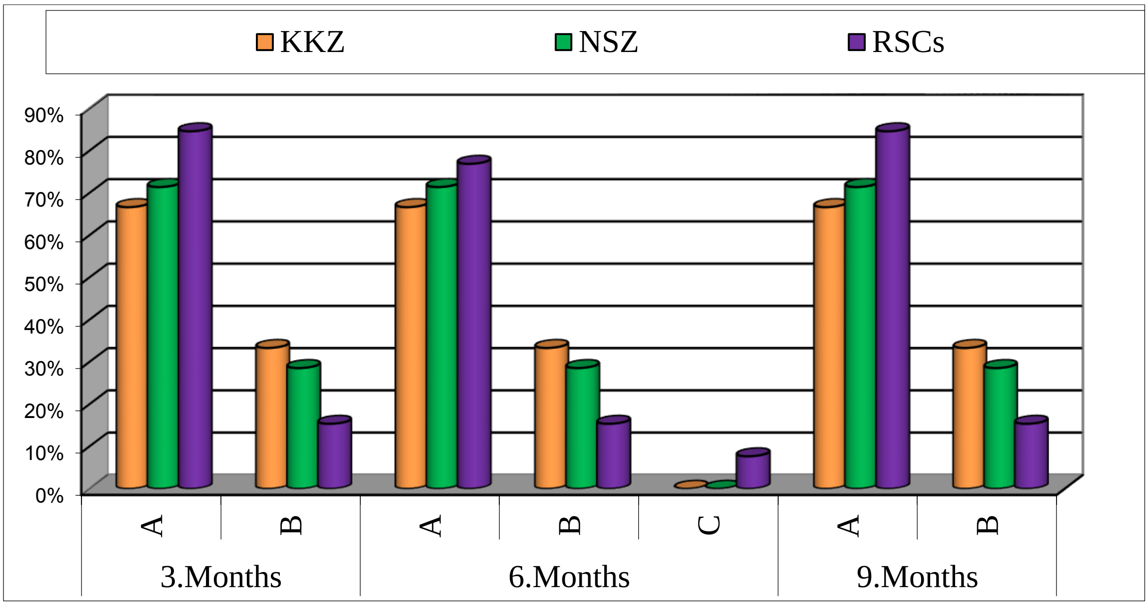
In the first visit (3 months), for the maxillary primary left central incisor (# 61), no statistically significant difference was observed between the study groups (p=0,562). Also, in the second visit (6 months) and in the third visit (9 months) no statistically significant difference was observed between the study groups. Morever no statistically significant difference was observed between the study groups (p=0.368), (Graphic 17).

Table 47. Comparison of presence of restoration failure scores (USPHS) between the groups recorded for the tooth # 61 in the follow-up periods

Follow-up period	Gingival health score USPHS	KKZ n:12		NSZ n:14		RCSc n:13		P*
3 Months	A	8	66.67%	10	71.43%	11	84.62%	0.562
	B	4	33.33%	4	28.57%	2	15.38%	
6 Months	A	9	75%	10	71.43%	10	76.92%	0.566
	B	3	25%	4	28.57%	2	15.38%	
	C	0	0.00%	0	0.00%	1	7.69%	
9 Months	A	10	83.33%	12	85.71%	11	84.62%	0.562
	B	2	16.67%	2	14.28%	2	15.38%	
	p+	-		-		0.368		

***Chi Square test +Mc Nemar's.**

A: Alpha, B: Beta, C: Charlie.



Graphic17. Distribution of gingival health evaluation scores in the follow-up periods

The distribution of gingival health evaluation scores (USPHS) recorded for the maxillary primary right lateral incisor (#52) in the three follow-up periods and the comparison between the study groups according to x^2 test and Mc Nemar's test are presented in Table 48.

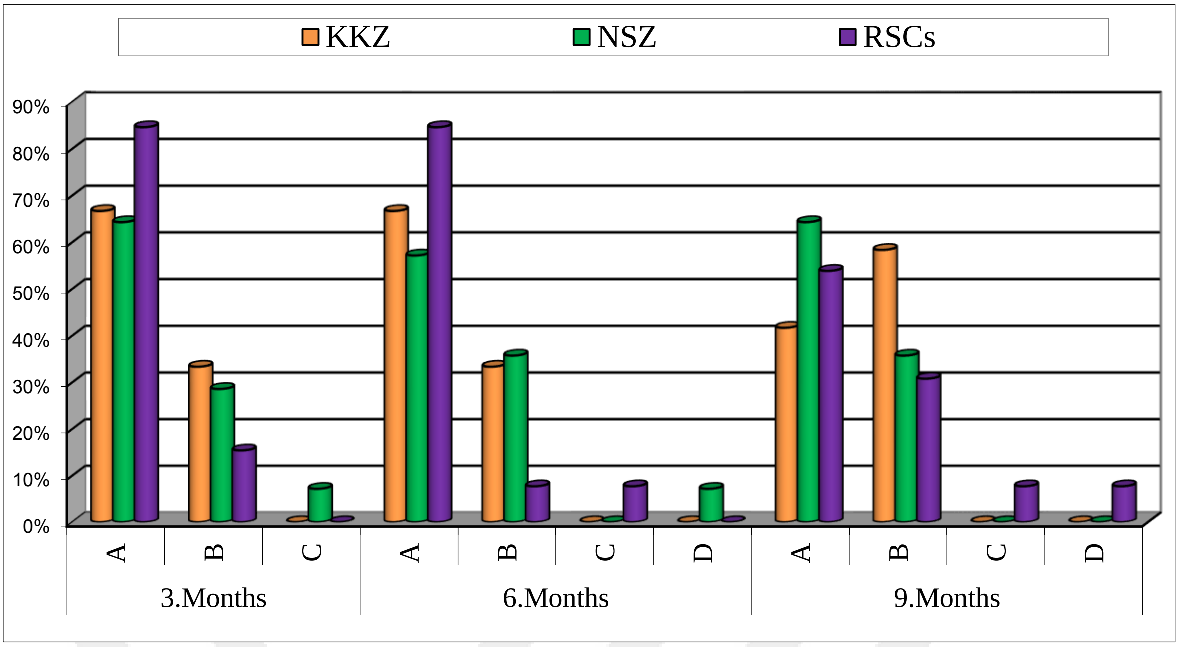
In the first follow-up (3 months), no statistically significant difference was observed between the study groups (p=0,542). Also, in the second follow-up (6 months) and in the third follow-up (9 months) no statistically significant difference was observed between the study groups. (p=0,321), (p=0,432) respectively, (Graphic 18).

Table 48. Comparison of presence of restoration failure scores (USPHS) between the groups recorded for the tooth # 52 in the follow-up periods

Follow-up period	Gingival health score USPHS	KKZ n:12		NSZn:14		RCSc n:13		P*
3 Months	A	8	66.67%	9	64.29%	11	84.62%	0.542
	B	4	33.33%	4	28.57%	2	15.38%	
	C	0	0.00%	1	7.14%	0	0.00%	
6 Months	A	9	75%	9	69.23%	11	84.62%	0.321
	B	3	25%	3	23.07%	1	7.69%	
	C	0	0.00%	0	0.00%	1	7.69%	
	D	0	0.00%	1	7.69%	0	0.00%	
9 Months	A	8	66.66%	10	71.42%	7	53.85%	0.432
	B	4	33.34%	4	28.57%	4	30.77%	
	C	0	0.00%	0	0.00%	1	7.69%	
	D	0	0.00%	0	0.00%	1	7.69%	
	p+	0.055		0.779		0.074		

***Chi Square test +Mc Nemar's Test.**

A: Alpha, B: Beta, C: Charlie.



Graphic18. Distribution of gingival health evaluation scores in the follow-up periods

The distribution of gingival health evaluation scores (USPHS) recorded for the maxillary primary left lateral incisor (# 62) in the three follow-up periods and the comparison between the study groups according to x^2 test and Mc Nemar’s test are presented in Table 49.

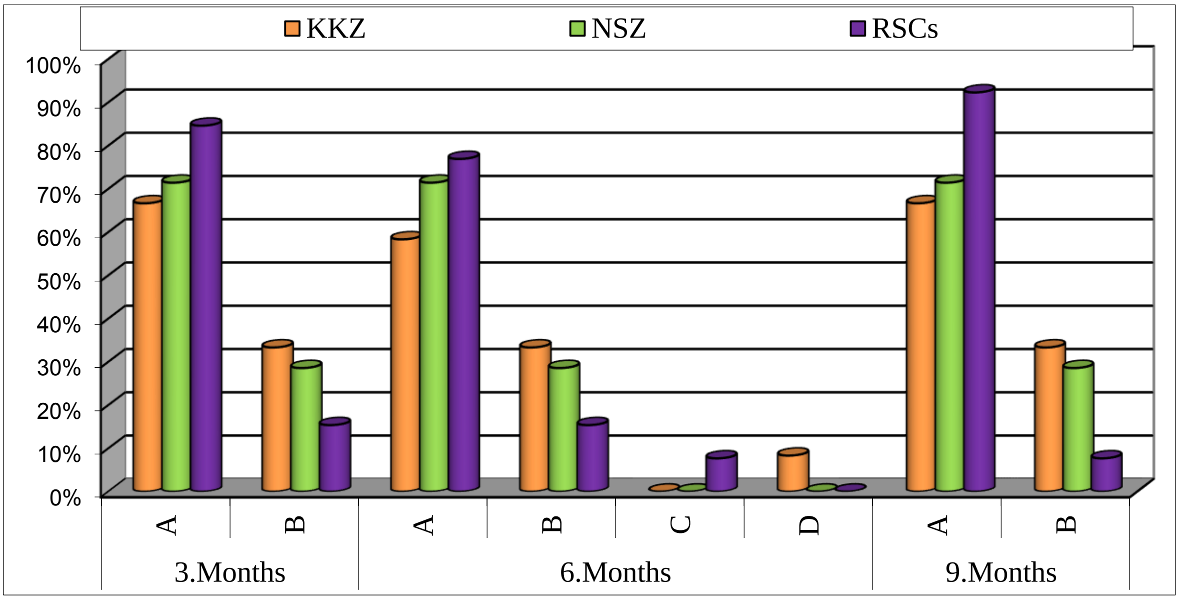
In the first visit (3 months), no statistically significant difference was observed between the study groups (p=0,562). Also, in the second visit (6 months) and in the third visit (9 months) no statistically significant difference was observed between the study groups. (p=0,489), (p=0,262) respectively, (Graphic 19).

Table 49. Comparison of presence of restoration failure scores (USPHS) between the groups recorded for the tooth # 62 in the follow-up periods

Follow-up period	Gingival health score USPHS	KKZ n:12		NSZ n:14		RCSc n:13		P*
	A	8	66.67%	10	71.43%	11	84.62%	
3 Months	B	4	33.33%	4	28.57%	2	15.38%	0.562
	A	9	75%	10	71.43%	10	76.92%	
	B	2	15.38%	4	28.57%	2	15.38%	
	C	0	0.00%	0	0.00%	1	7.69%	
6 Months	D	1	8.33%	0	0.00%	0	0.00%	0.489
	A	7	66.67%	10	71.42%	12	92.31%	
9 Months	B	5	33.33%	4	28.57%	1	7.69%	0.262
	p+	0.368		-		0.156		

***Chi Square test +Mc Nemar’s Test.**

A: Alpha, B: Beta, C: Charlie.



Graphic19. Distribution of gingival health evaluation scores in the follow-up periods

Figure 71. A 3 year old girl treated under GA, after pulp therapy the four maxillary incisors were restored with NSZ. (A, B) Preoperative view (C, D) Immediate post operative view (E, F) 3 Months follow-up (G, H) 6 Months follow-up (I, J) 9 Months follow-up.

Figure 72. A 4 years old boy treated under local anesthesia, after pulp therapy the four maxillary incisors were restored with NSZ. (A, B) Preoperative view (C, D) Immediately post operative view (E, F) 3 Months follow-up (G, H) 6 Months follow-up (I, J) 9 Months follow-up.

Figure 73. A 5 years old girl treated under local anesthesia, after pulp therapy the four maxillary incisors were restored with NSZ. (A, B) Preoperative view (C, D) Immediately post operative view (E, F) 3 Months follow-up (G, H) 6 Months follow-up (I, J) 9 Months follow-up.

Figure 74. A 5 years old boy treated under LA, after pulp therapy the four maxillary incisors were restored with KKZ. (A, B) Preoperative view (C, D) Immediately post operative view (E, F) 3 Months follow-up (G, H) 6 Months follow-up (I, J) 9 Months follow-up.

Figure 75. A 3 years old boy treated under GA, after pulp therapy the four maxillary incisors were restored with KKZ. (A, B) Preoperative view (C, D) Immediately post operative view (E, F) 3 Months follow-up (G, H) 6 Months follow-up (I, J) 9 Months follow-up.

Figure 76. A 4 years old boy treated under GA, after pulp therapy the four maxillary incisors were restored with KKZ. (A, B) Preoperative view (C, D) Post operative view after 1 week (E, F) 3 Months follow-up (G, H) 6 Months follow-up (I, J) 9 Months follow-up.

Figure 77. A 4 years old girl treated under GA, after pulp therapy the four maxillary incisors were restored with RCSc. (A, B) Preoperative view (C, D) Immediately post operative view (E, F) 3 Months follow-up (G, H) 6 Months follow-up (I, J) 9 Months follow-up.

Figure 78. A 5 years old boy treated under local anesthesia, after pulp therapy the four maxillary incisors were restored with RCSc. (A, B) Preoperative view (C, D) Immediately post operative view (E, F) 3 Months follow-up (G, H) 6 Months follow-up (I, J) 9 Months follow-up.

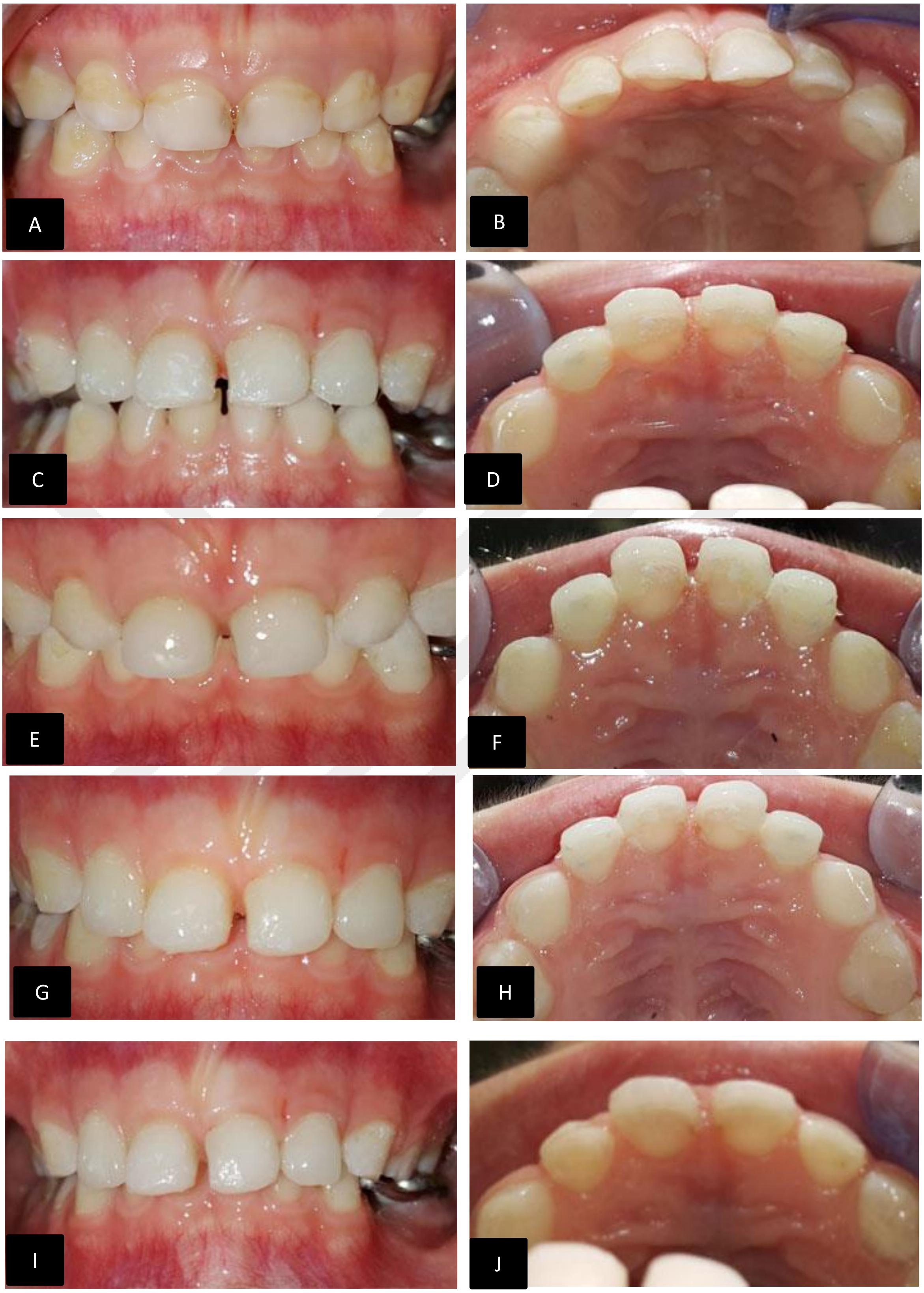


Figure 79. A 4 years old boy treated under local anesthesia, after pulp therapy the four maxillary incisors were restored with RCSc. (A, B) Preoperative view (C, D) Immediately post operative view (E, F) 3 Months follow-up (G, H) 6 Months follow-up (I, J) 9 Months follow-up.

5.2. Parental Satisfaction

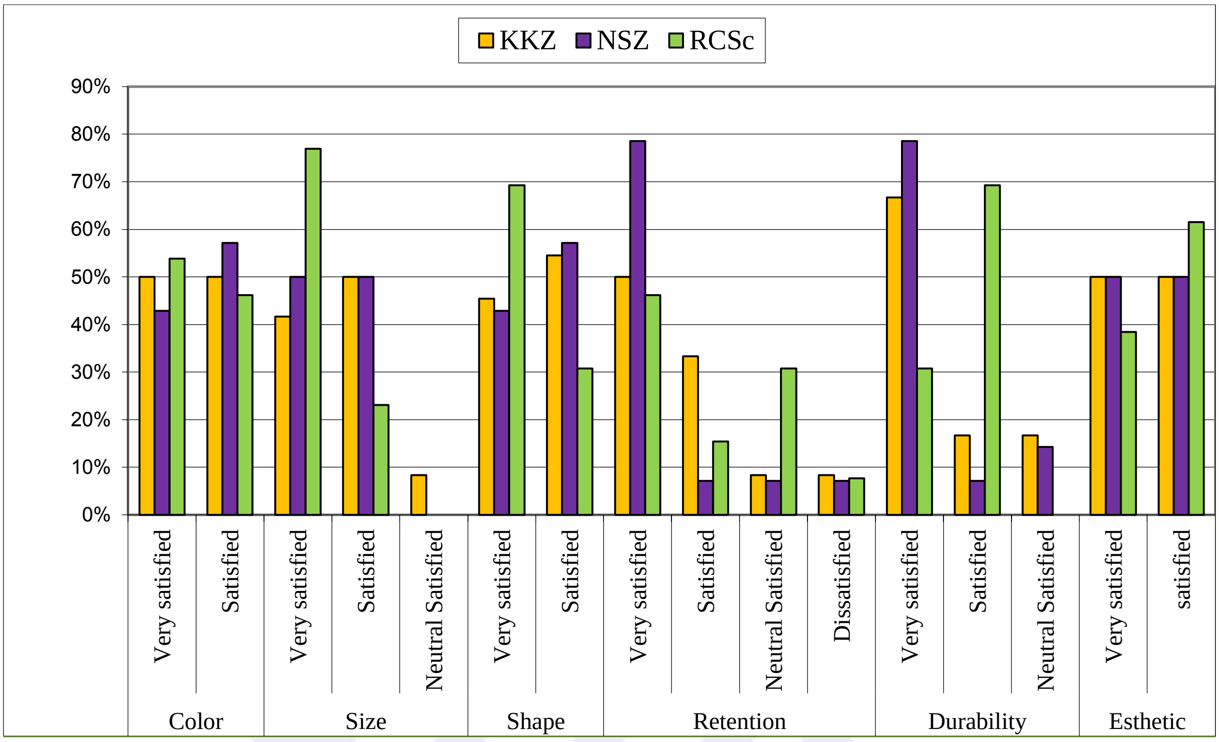
The distribution and comparison of parental satisfaction scores in the three study groups are presented in Table 50.

Parental satisfaction regarding the color, size, shape, retention and esthetic of the restoration showed no statistically significant difference between the three groups (p=0.936), (p=0.256) (p=0.333), (p=0.321) and (p=0.331) respectively. Whereas, parental satisfaction regarding the restoration durability showed statistically significant difference between the three groups. Significantly less number of very satisfied were recorded in the RCSc group compared to the KKZ and NSZ groups **(p=0.006)**, (Graphic 20).

Table 50. The distribution of parental satisfaction scores in the three study groups

Satisfaction criteria	**Level of satisfaction Likert scale**	**KKZ n:12**		**NSZ n:14**		**RCSc n:13**		**P***
Color	**Very satisfied**	6	50.00%	6	42.86%	7	53.85%	0.936
	Satisfied	6	50.00%	8	57.14%	6	46.15%	
Size	**Very satisfied**	5	41.67%	7	50.00%	10	76.92%	0.256
	Satisfied	6	50.00%	7	50.00%	3	23.08%	
	Neutral satisfied	1	8.33%	0	0.00%	0	0.00%	
Shape	**Very satisfied**	5	45.45%	6	42.86%	9	69.23%	0.333
	Satisfied	6	54.55%	8	57.14%	4	30.77%	
Retention	**Very satisfied**	6	50.00%	11	78.57%	6	46.15%	0.321
	Satisfied	4	33.33%	1	7.14%	2	15.38%	
	Neutral satisfied	1	8.33%	1	7.14%	4	30.77%	
	Dissatisfied	1	8.33%	1	7.14%	1	7.69%	
Durability	**Very satisfied**	8	66.67%	11	78.57%	4	30.77%	**0.006**
	Satisfied	2	16.67%	1	7.14%	9	69.23%	
	Neutral satisfied	2	16.67%	2	14.29%	0	0.00%	
Esthetic	**Very satisfied**	6	50%	7	50%	4	38.46%	0.821
	Satisfied	6	50%	7	50%	9	61.53%	

***Chi Square test.**



Graphic 20. The distribution of parental satisfaction scores in the three study groups

5.3. *In vitro* Assessment of Fracture Resistance of Prefabricated Zirconia Crowns

In Table 51 the minimum, maximum, mean and SD values of the forces required for fracture of zirconia crowns in MPA are presented. The comparison of mean and SD of the forces in Control (C) and Thermocycling (Tc) subgroups according to Unpaired t test is presented in Table 52.

- The force required to fracture the crown did not differ significantly between the C subgroups of KKZ and NSZ groups (p=0.522).
- The force required to fracture the crown did not differ significantly between the Tc subgroups of KKZ and NSZ groups (p=0.146).
- The median value of force (MPA) required to fracture the crown was found to be lower in Tc subgroups in both KKZ and NSZ groups and the difference was statistically significant **(p=0.0001)** , (Graphic 21).

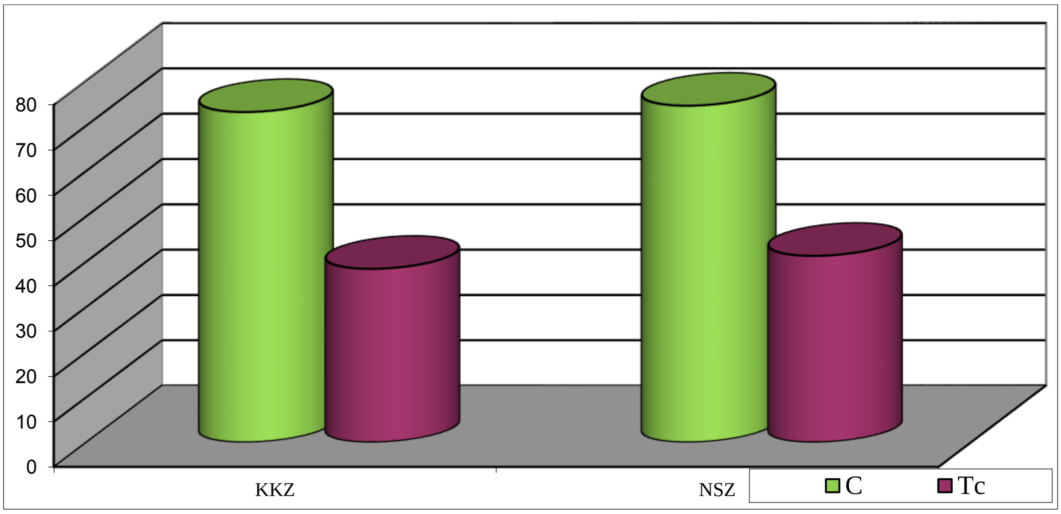
Table 51. The mean and SD of the forces required to fracture of the zirconia crowns in MPA

		N	Minimum	Maximum	Mean	Std. Deviation
KKZ	**C**	10	64.40	79.27	72.9841	4.54580
	Tc	10	31.82	46.14	38.3864	5.56867
NSZ	**C**	10	65.14	81.65	74.3866	5.04036
	Tc	10	38.11	46.00	41.2448	2.11405

Table 52. The comparison of mean and SD values of the forces in control (C) and thermocycling (Tc) subgroups of KKZ and NSZ groups

MPa	KKZ	NSZ	P*
C	72.98±4.54	74.38±5.04	0.522
Tc	38.39±5.57	41.25±2.11	0.146
P*	**0.0001**	**0.0001**	

***Unpaired t test.**



Graphic 21. The force required to fracture crowns between the C and Tc subgroups

In Table 53. The minimum, maximum, median and SD values for the thickness of the crowns in five locations (mesial, distal, incisal, palatal and labial) are presented.

The thickness values (mm) were measured significantly higher in three locations (mesial, distal and incisal) for NSZ group compared to that KKZ group (p=0.0001). However, the thickness values measured in palatal and labial aspects of NSZgroup were significantly lower than KKZ group (p=0.0001).

Table 53. Measurement of crown thickness (Median±, Min. Max, Standart deviation)

Location	Type of the crown	Median±SD	Min. (mm)	Max. (mm)	P*
Mesial	**KKZ**	0.7219±0.0007	0.721	0.723	**0.0001**
	NSZ	0.8657±0.0012	0.864	0.867	
Distal	**KKZ**	0.7232±0.0008	0.722	0.724	**0.0001**
	NSZ	0.876±0.0008	0.875	0.877	
Incisal	**KKZ**	0.8223±0.0012	0.821	0.824	**0.0001**
	NSZ	1.148±0.0079	1.14	1.16	
Palatal	**KKZ**	0.957±0.0008	0.956	0.958	**0.0001**
	NSZ	0.686±0.0008	0.685	0.687	
Labial	**KKZ**	0.7546±0.0012	0.753	0.756	**0.0001**
	NSZ	0.7429±0.0009	0.742	0.744	

***Chi Square test. P<0,05**

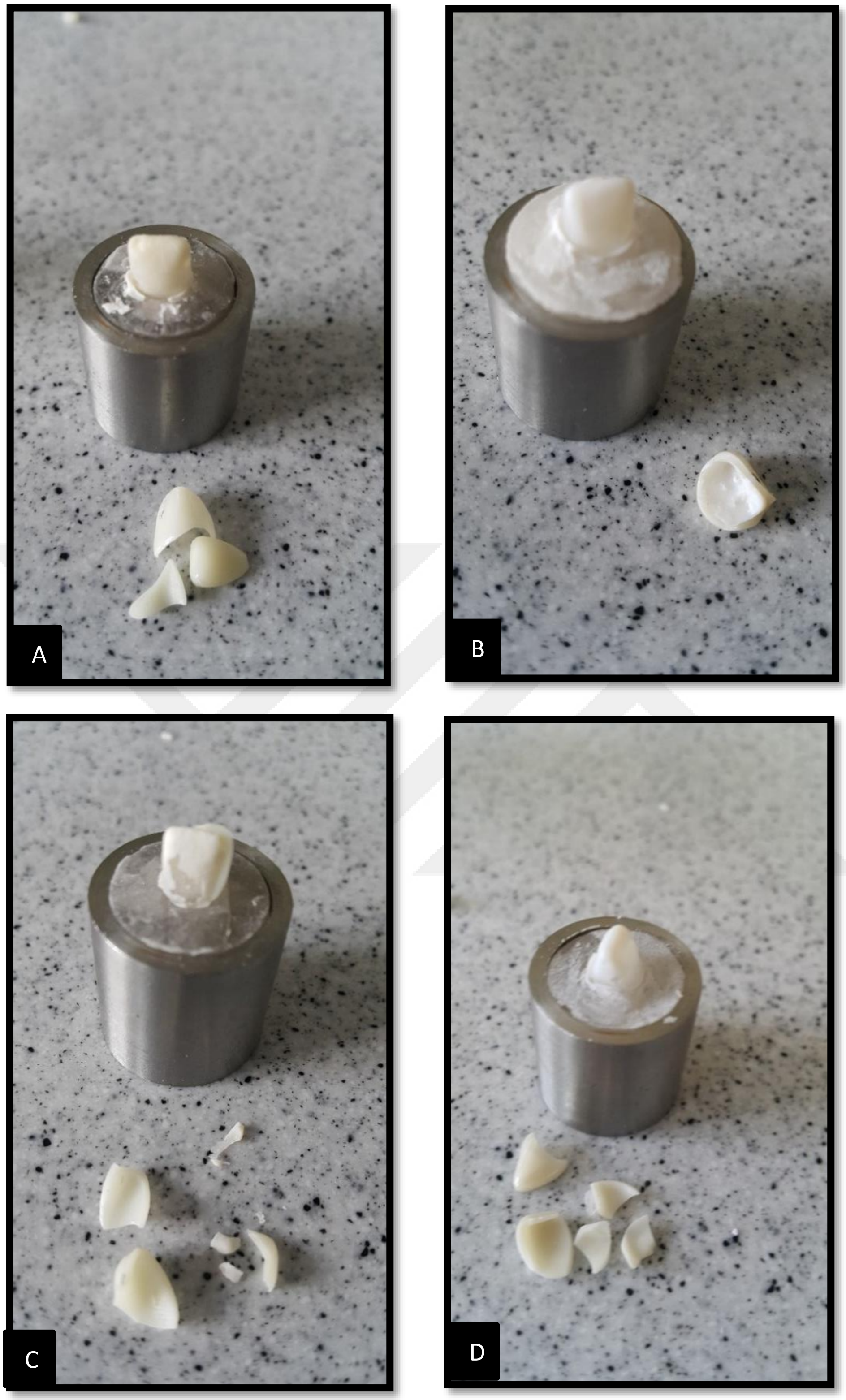


Figure 80. (A) A fractured specimen from the C subgroup of KKZ group (B) A fractured specimen from the C subgroup of NSZ group (C) A fractured specimen from the Tc subgroup of KKZ group (D) A fractured specimen from the Tc subgroup of NSZ group.

SEM analysis:

In the present study, thermocycling loading neither induced the phase transformation but affected the crown strength. No signs of phase transformation was detected with SEM analysis after thermocycling loading. However, it is still possible that thermocycling loading may have induced the phase transformation at localized areas around micro cracks since the observations were limited to one cross section per crown.

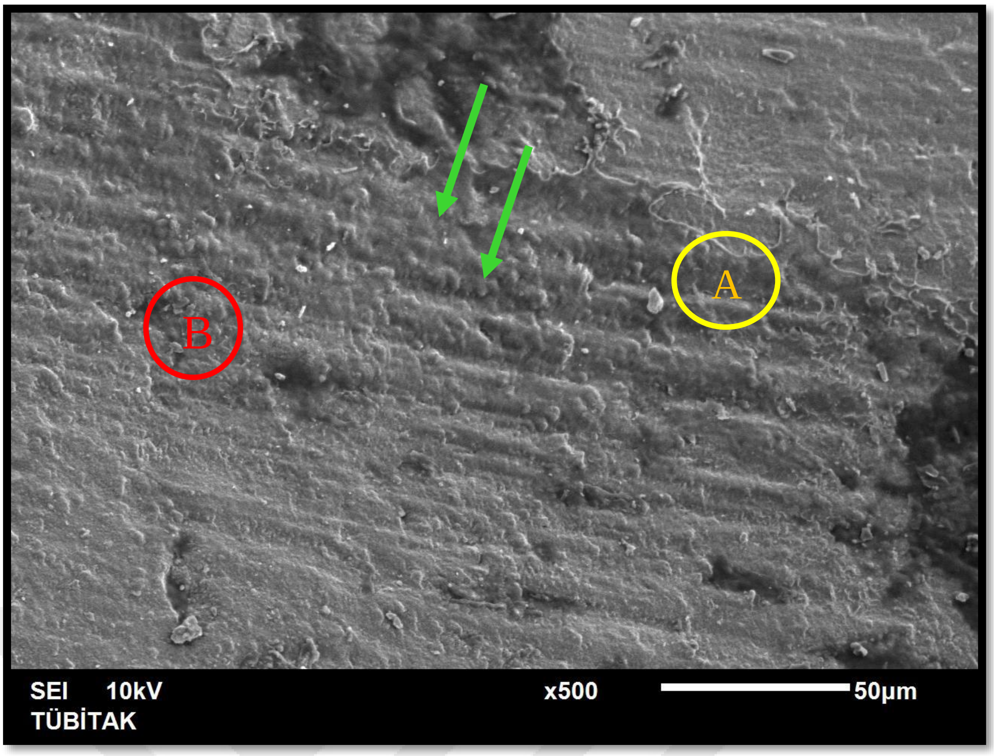


Figure 81. Fractured specimen from the C subgroup of KKZ group (A) Internal mechanical grooves (B)Aquacem® luting cement at a magnification of X500.

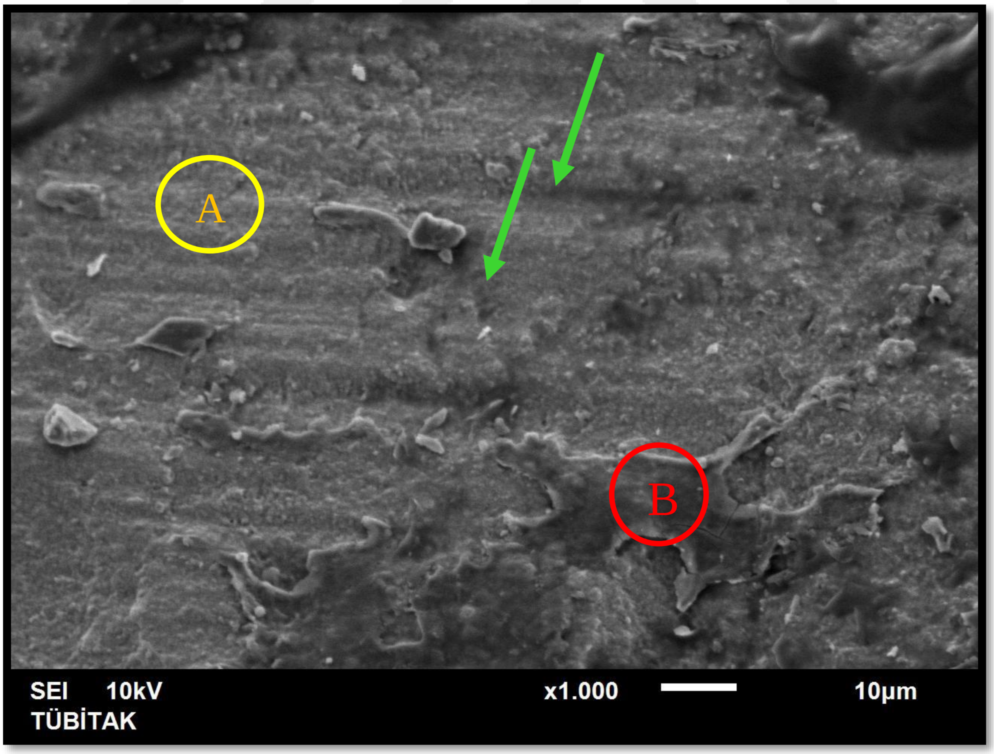


Figure 82. Fractured specimen from the C subgroup of KKZ group (A) Internal mechanical grooves (B) Aquacem® luting cement at a magnification of X1000.

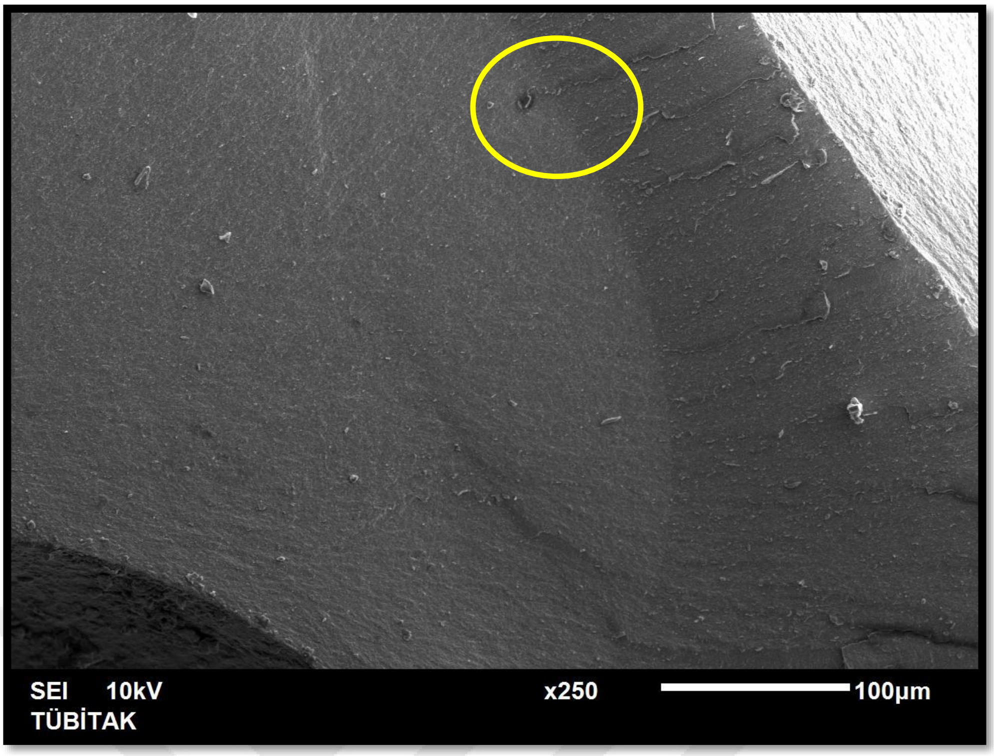


Figure 83. Scanning electron microscopic view of a fractured specimen from the C subgroup of KKZ group of X250.

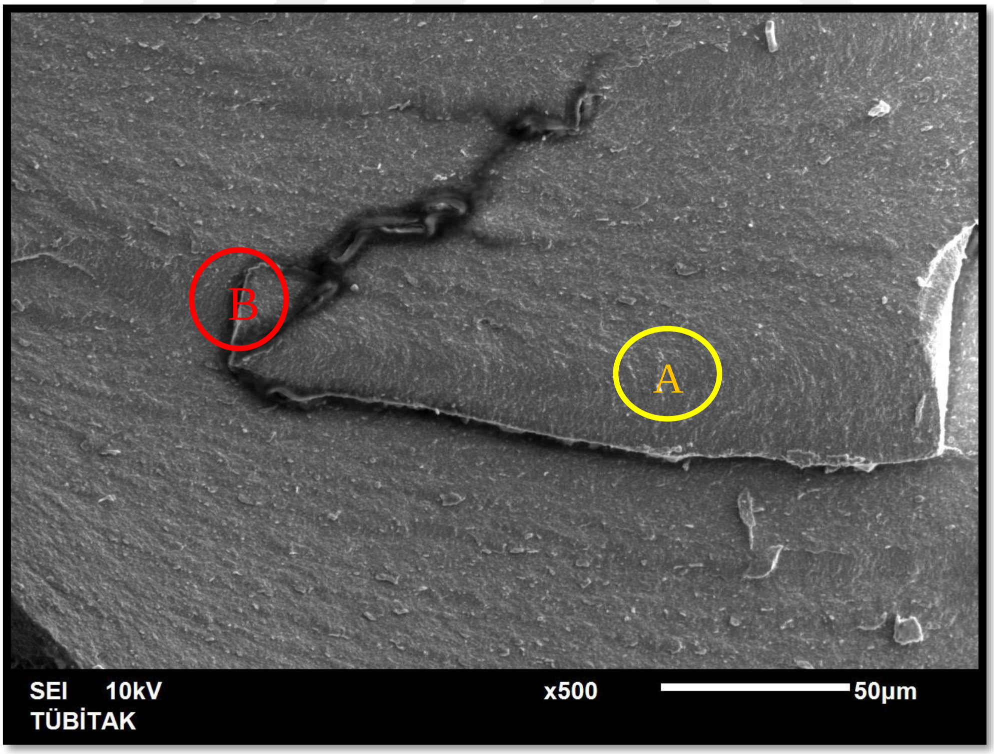


Figure 84. Further magnification of the circled area in **Figure 83**, shows crazing (internal cracks of vestibular surface), (A) showed the propagation crack (B) fracture line.

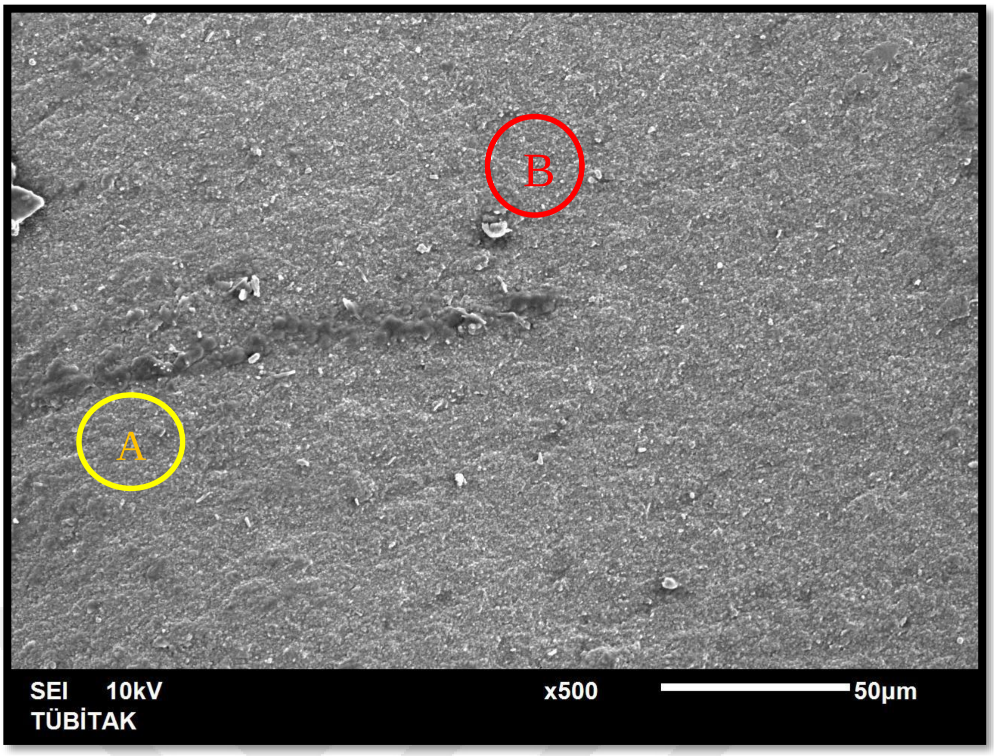


Figure 85. Fractured specimen from the C subgroup of NSZ group (A) Shows crazing (internal cracks of internal surface) (B) Biocem NuSmile®Universal cement at a magnification of X500.

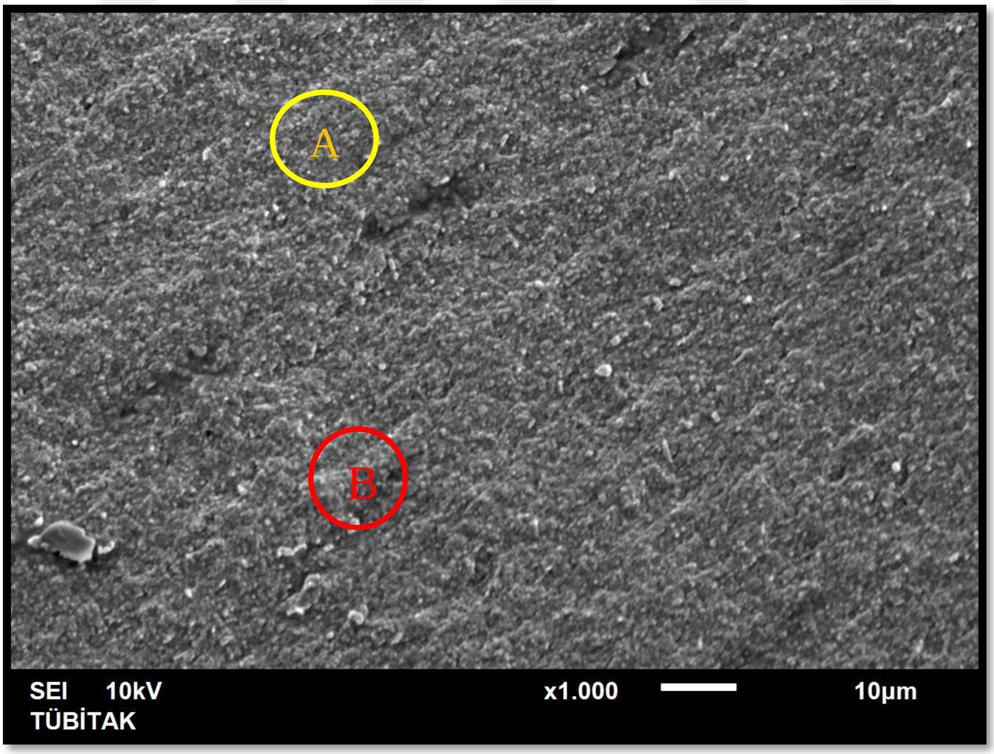


Figure 86. Further magnification of the **Figure 85,** shows (A) crack (B) pitted area.

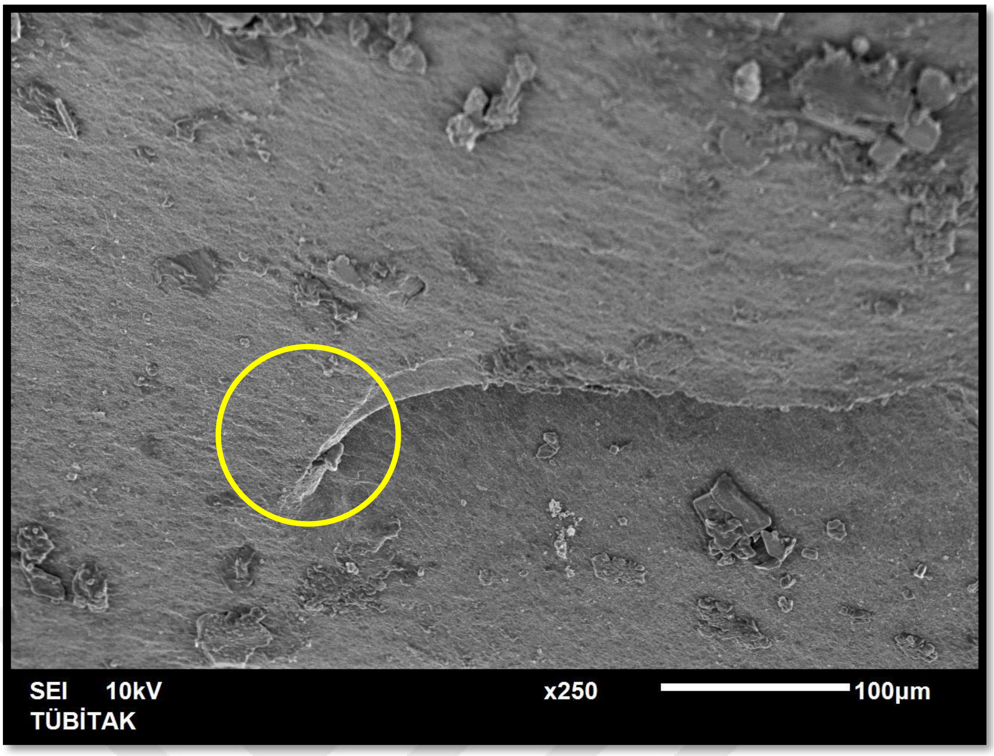


Figure 87. Scanning electron microscopic view of fractured specimen from the C subgroup of NSZ group at a magnification of X250.

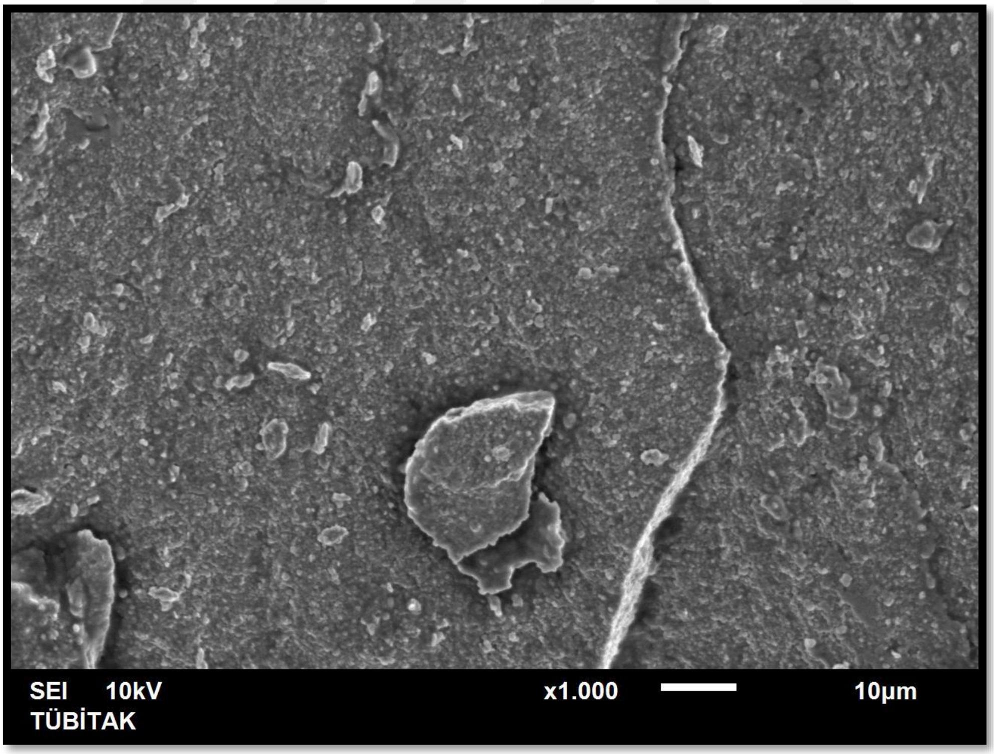


Figure 88. Further magnification of the Fig.88 shows the line of the crack at a magnification of X1000.

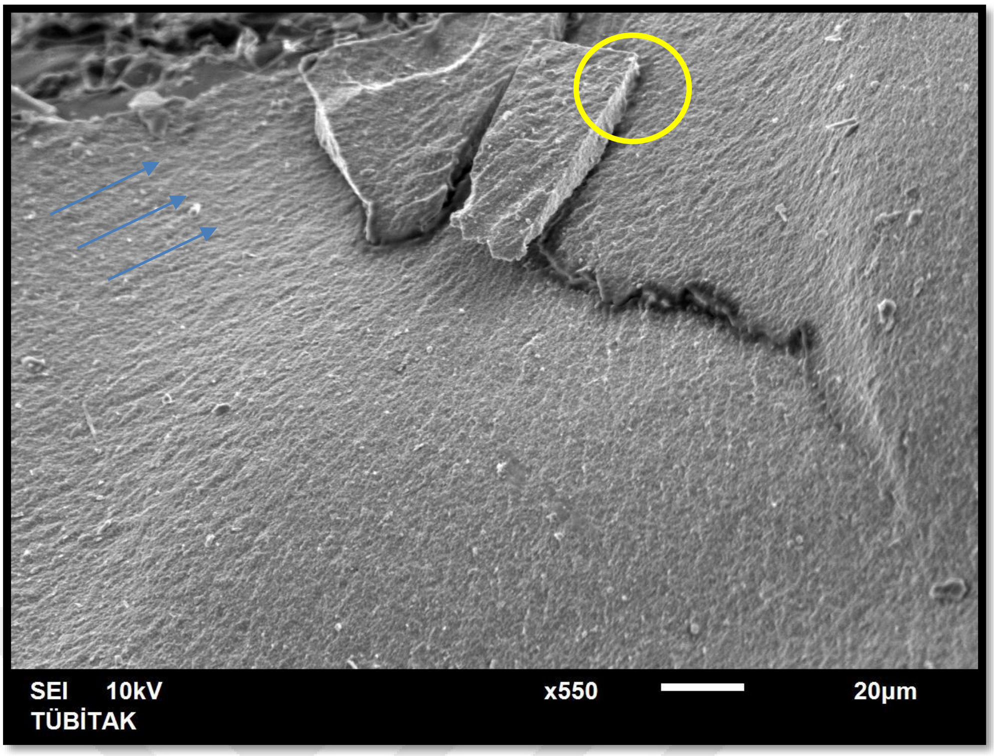


Figure 89. Scanning electron microscopic view of fractured specimen from the Tc subgroup of KKZ group at a magnification of X550.

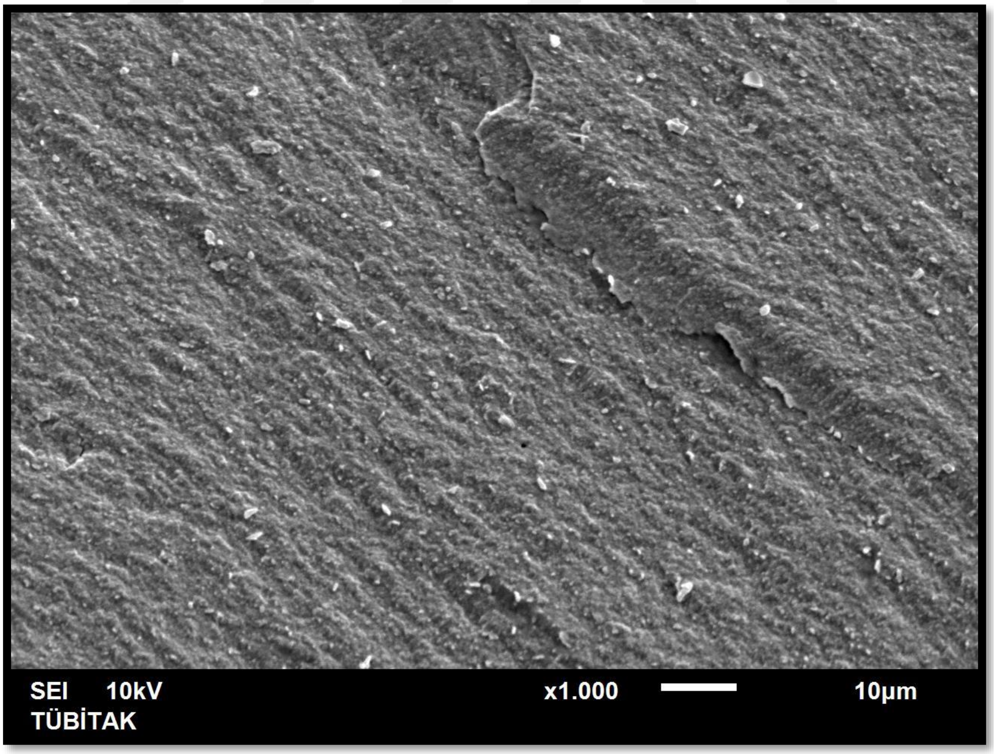


Figure 90. Further magnification of the circled area in the figure above. Shows (a) misbreaking sheet resulting from inappropiate separation at a magnification of X1000.

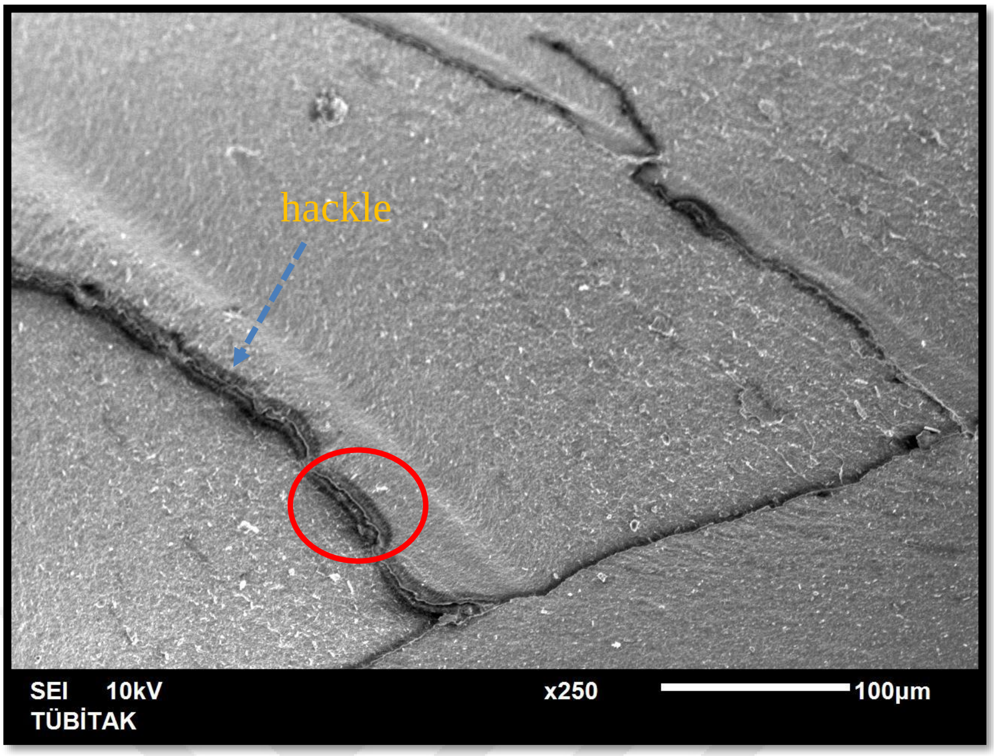


Figure 91. Scanning electron microscopic view of fractured specimen from the Tc subgroup of KKZ group at a magnification of X250**.**

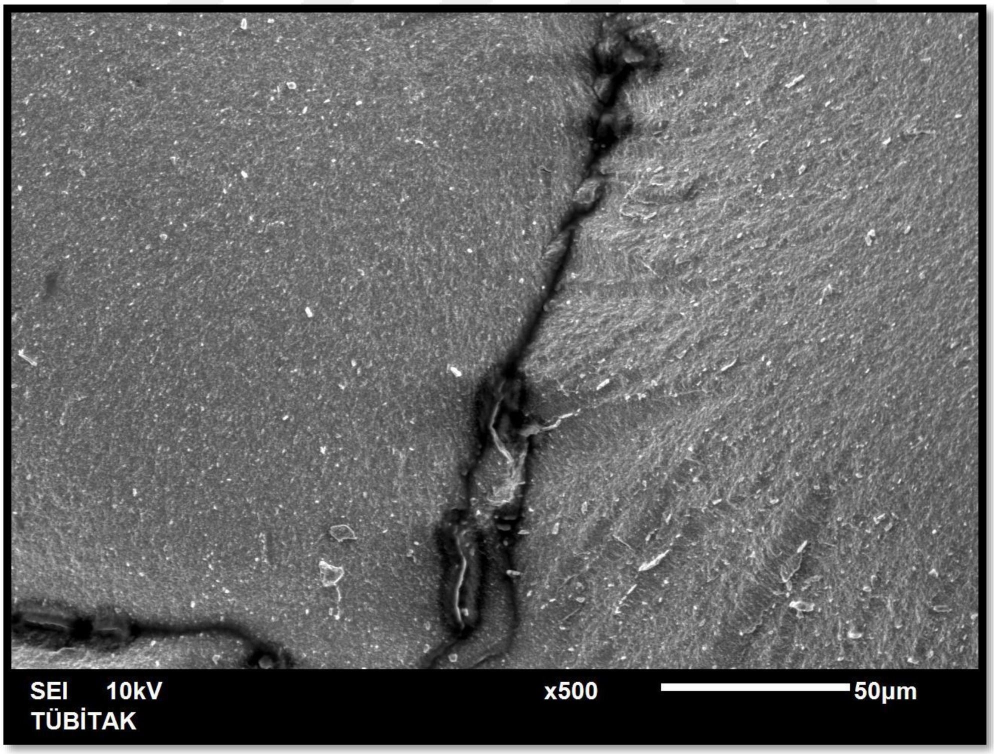


Figure 92. Further magnification of the circled area at a magnification of X550.

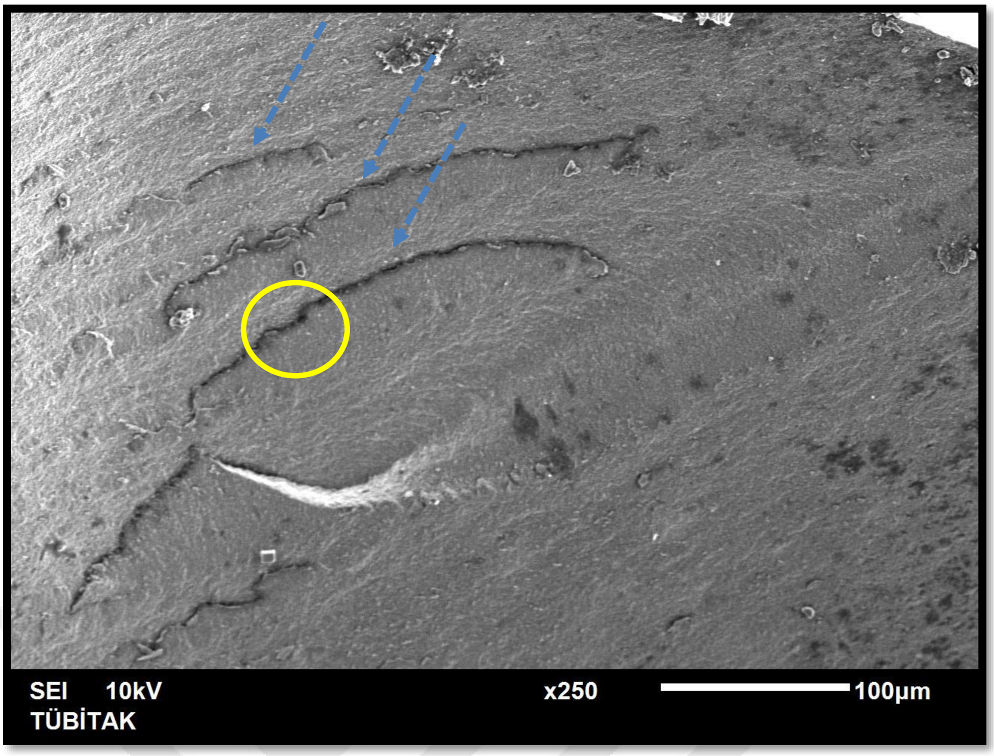


Figure 93. Scanning electron microscopic view of a fractured specimen from the Tc subgroup of NSZ group, showing secondary wallner line created by a crack propagation at a magnification of X250.

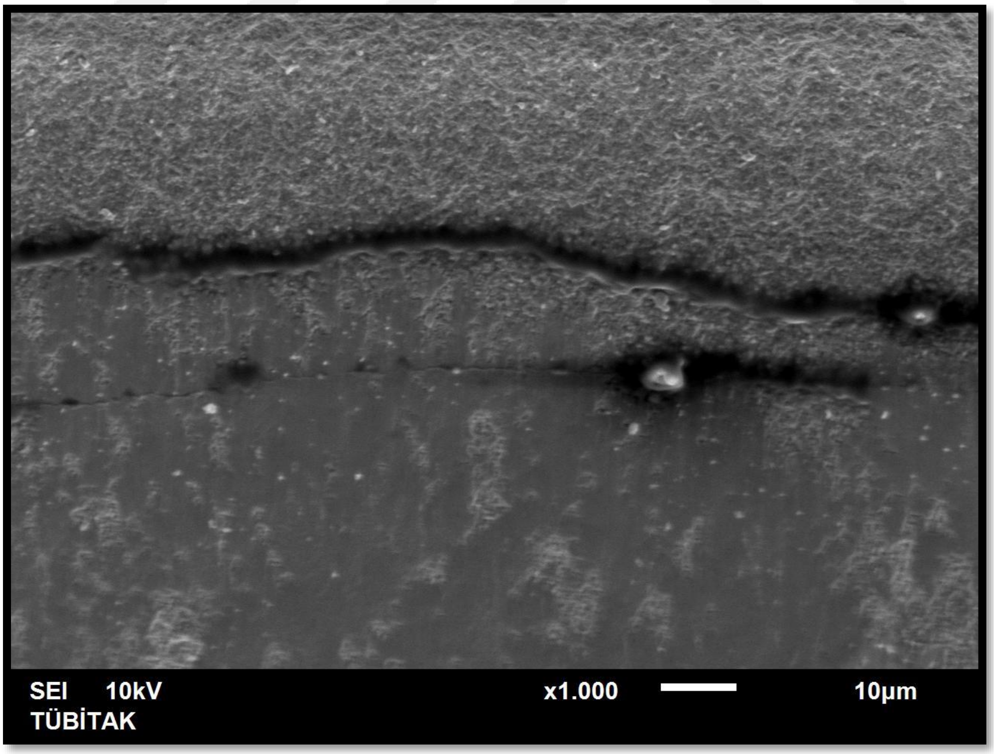


Figure 94. Further magnification of the circled area at a magnification of X1000 showing widespread roughened surface wear.

5.4. *In vitro* Assessment of Bacterial Adhesion to Zirconia and Resin Surfaces

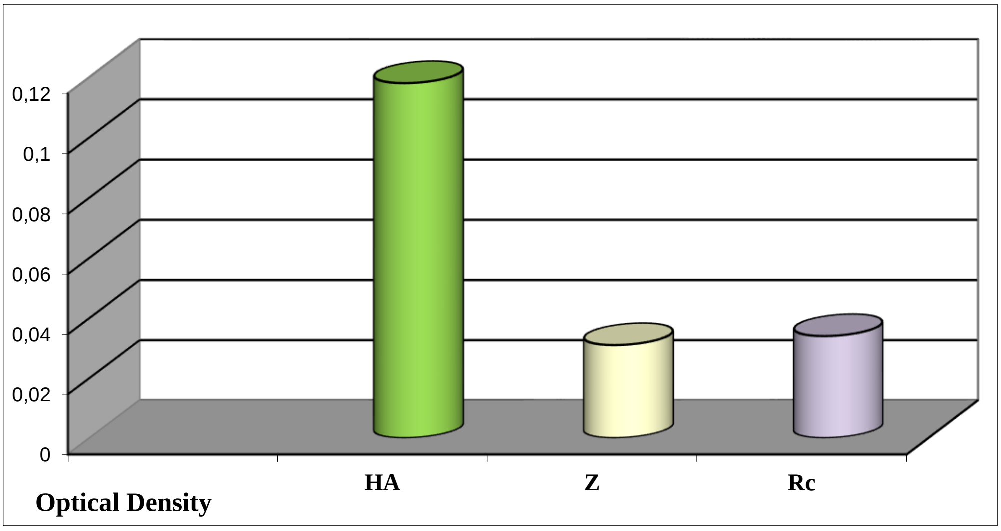
The comparison of mean and the standard deviation of optical density (OP) values that were read in hydroxyapatite (HAP), zirconia (Z) and resin composite (Rc) groups are presented in the Table 54.

HAP study group exhibited significantly higher bacterial adhesion values than (Rc) and (Z) study groups, while the the zirconia group exhibited lower bacterial adhesion values than the resin composite group. The median OD values for bacterial adhesion showed statistically significant difference between the zirconia, hydroxyapatite and resin composite groups **(p=0.0001)**, (Graphic 22).

Table 54. The comparison of the mean and the SD of OD values between the HAP, Z and Rc groups

Groups	N	Optical Density *S.mutans*
HAP	12	0.118±0.041
Z	12	0.031±0.005
Rc	12	0.034±0.005
P*		**0.0001**

***Chi Square test.**



Graphic 22. The distribution of OD readings in the study and control groups

The multiple comparison of OD values between the HAP, Z and Rc groups according Tukey's multiple comparison test is presented in Table 55.

The difference between the HAP and Z groups values and the difference between the HAP and Rc groups values were found statistically significant (p=0.0001). Whereas no statistically significant difference was found between the Z and the Rc groups values (p=0.982).

Table 55. The multiple comparison of OD values between the HAP, Z and Rc groups

Groups	P*
HAP/ Z	**0.0001**
HAP / Rc	**0.0001**
Z / Rc	0.982

* Tukey's multiple comparison test.

Bacterial growth values (CFU) for *S. mutans* and the comparison between the hydroxyapatite group (HAP), zirconia (Z) and resin composite (Rc) groups are presented in Table 56

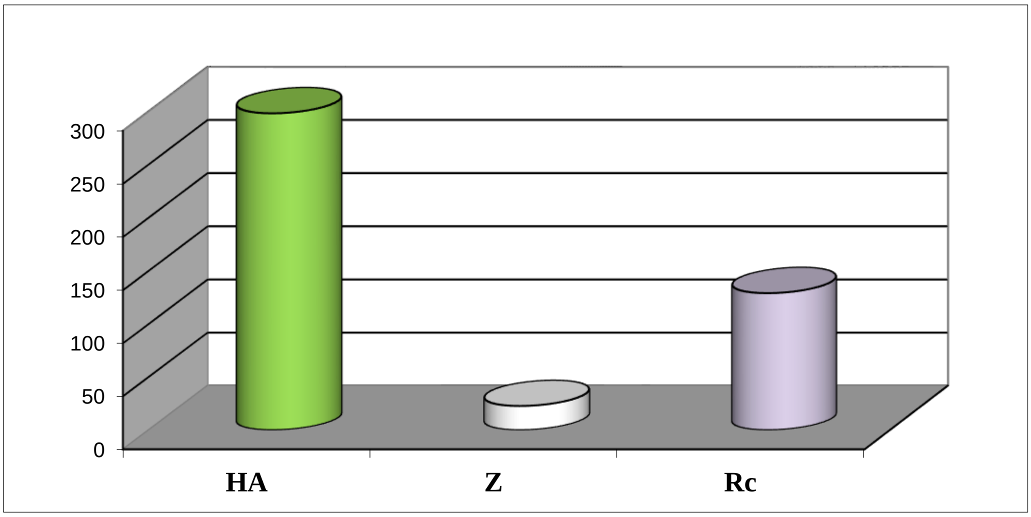
HAP group exhibited significantly higher amount of *S. mutans* **(p=0.0001)**, than resin composite and zirconia groups, morever the resin composite group exhibited higher bacterial adhesion values than the zirconia group **(p=0.0001).**

The difference between the CFU/ ml of zirconia, hydroxyapatite and resin composite groups were found statistically significant **(p=0.0001)**, (Graphic 23).

Table 56. Amount of bacterial growth *S. mutans* (CFU/ml × 10^5) and the comparison between the control and study groups

Groups	N	***S.mutans*** **(CFU/ml × 10^5)** **Mean ± SD**
HAP	12	298.33±92.03
Z	13	22.77±11.11
Rc	13	129.23±83.91
P*		**0.0001**

***Chi Square test.**



Graphic 23. The median value of bacterial growth (*S. mutans)* in HAP, Z and Rc groups using CFU method.

The multiple comparison of CFU/ ml between the HAP, Z and Rc groups according to Tukey's multiple comparison test are presented in Table 57.

The difference between the HAP and Z group values and difference between HAP and Rc group values were found statistically significant (p=0.0001). Morever a statistically significant difference was found between Z and Rc group values (p=0.002).

Table 57. The multiple comparison of amount of bacterial growth (CFU/ ml) between the HAP, Z and Rc groups

Groups	P*
HAP / Z	**0.0001**
HAP / Rc	**0.0001**
Z /Rc	**0.002**

* Tukey's multiple comparison test.

6. DISCUSSION

6.1. Randomized Clinical Study

The development of ECC occurs due to loading of the plaque with sugars, this mostly occurs at bedtime (night) with the absence of tooth brushing, caries can progress rapidly. In addition, during bottle feeding with sugar containing drinks, the upper incisors bathe in these sugar containing drinks, the saliva from minor salivary glands in the area of these teeth has only limited remineralising properties, whereas the lower incisors remain largely protected by the tongue during bottle feeding (248).

The clinical appearance of severe early childhood caries follows a definite pattern. There is early carious involvement of the maxillary incisors followed by the maxillary and mandibular first primary molars and the mandibular cuspids (79).

Esthetic treatment of severely decayed anterior primary teeth is one of the greatest challenges to pediatric dentists. In the last half century the emphasis on treatment of extensively decayed primary teeth shifted from extraction to restoration (11). Despite the continuing prevalence of dental caries in maxillary primary anterior teeth in children, the esthetic management of these teeth remains problematic (249).

There is little scientific support for any of the clinical techniques that clinicians have utilized for many years to restore primary anterior teeth, and most of the evidence is regarded as expert opinion. While a lack of strong clinical data does not preclude the use of these techniques, it points out the strong need for well designed, prospective clinical studies to validate the use of these techniques (148).

The aim of this clinical research was to evaluate and compare three esthetic full coronal restorations on maxillary primary central and lateral incisors over a period of 9 months, and to give an usefull clinical data.

Esthetic restoration of primary anterior teeth can be especially challenging due to: the small size of the teeth; close proximity of the pulp to the tooth surface; relatively thin enamel; lack of surface area for bonding; and issues related to child behavior (11).

Patient behavior is an important factor in deciding which treatment modality is best suited for a child and their parents.

Eidelman et al. (2000), conducted a retrospective study to compare the quality of the restorations and the presence of secondary caries in children treated for ECC under general anesthesia or sedation. They reported that a successful marginal adaptation and anatomic form of resin composite strip crowns were more frequent in teeth restored under GA (90% and 86%, respectively) than under sedation (63% and 65%, respectively). The outcome of treatments related to quality of the restorations for performed under GA was found to be better for all parameters examined (103).

Maclean et al. (2007), also conducted a restrospective study to asses the clinical outcomes of NuSmile® anterior pre-veneered stainless steel crowns (Orthodontic Technologies, Houston, TX 77210 USA). The majority of patients (42 children) were treated under general anesthesia while the remainders were treated either with non pharmacological behavior management techniques (1 patient), nitrous oxide (2 patients) or oral sedation (1 patient). It was concluded that, patients treated with non pharmacological methods or mild sedation, were considered to have a positive behavior, which was significantly related to the overall appearance of the preveneered crowns, resulting of an overall 91% of crowns that retained good to excellent clinical appearance (13).

Ram et al. (2006), evaluated the longevity of resin composite strip crowns placed under oral sedation in a retrospective study and they have concluded that behavior had no influence on the clinical and radiographic findings of the crowns (156).

In the present study the mean age was 3.60 months, in these young children, their negative behaviors can influence the clinician’s ability to place the restorations under ideal circumstances. To have a valid, a useful clinical study, the behaviour of the children should be similar when all the restorations are placed, therefore to ensure the same quality of dental treatment only score 1 and 4 Frankl behaviour were selected, with no statistically significant differences in frankl score and behaviour management among the KKZ, NSZ and RCSc groups (P=0.826) and (P=0.826) respectively.

Additionally, because incisors will generally not become carious, except in children with a high caries risk, restorations placed in children may perform differently than a similar restoration in a low caries risk child, in the present study all the subject were in high caries risk group, (children with severe ECC), with no statistically significant difference in dmft, dmfs between the three groups (12.92±1.75, 11.71±2.92, 12.4±2.41) (26±4.4, 25.5±6.41, 26.67±4.05) for KKZ, NSZ and RCSc respectively.

After dental treatments, the OHI-S scores revealed that most participating children had good oral hygiene levels. The mean PI and GI scores in the KKZ, NSZ and RCSc groups after treatment showed a significantly lower values than before treatment **(p=0.0001)**. This was related to the oral hygiene instructions which was given to the patients' parents after the treatment. Additionally, the sensitivity caused by the tooth brush may be decreased after dental treatments leading to an adequate toothbrushing performed by the parents.

This was a similar finding reported in the study conducted by ***Jankauskiene et al. (2014).*** The aim of the study was to determine if educating parents after their child's treatment under general anesthesia would improve oral health outcomes. They concluded that there was an improvement in oral hygiene, as measured by OHI, and an increase in brushing frequency for all children who received oral hygiene instructions (250).

Similarly, ***Cunnion et al. (2010)*** suggested that after dental interventions, giving an oral hygiene instruction to children with ECC had a significant positive impact on their overall oral health (251).

In the present study inclusion and exclusion criteria were similar to those clinical trials of other types of preformed anterior crowns for primary teeth were used (13, 14, 11, 113). In the present study, one of the inclusion criteria was, carious maxillary primary incisors, with minimum of two surfaces involved, these teeth usually have short and narrow crowns, the pulp chamber is relatively large with thin enamel, dentin and when two surface are involved, in the most of the cases caries removal results in pulp exposure, then pulp therapy is indicated.

It is difficult and definitely important to make a correct diagnosis and treatment plan according to the status of the pulp (252), the correct therapy of the primary teeth requires a good knowledge of the healing and immune defense potential of the pulp (253). The width of enamel prisms is 4-7 mm in primary teeth, and 6-10 mm in permanent teeth (254), the mineral content in the inorganic part of primary enamel (86%) is less than that of permanent enamel (92%) (255), thinner and less mineralized enamel, and increased interprismatic pore volume are causes of faster progress of caries in primary teeth (252, 255).

In addition, it was also reported that almost all of the enamel caries lesions, that were detected radiographically, progressed to dentin in a short period of time (256).

Research has shown that even small carious limited to enamel might cause pulp inflammation, due to the diameter of the dentinal tubules which happen to be largest near the pulp and this increases the permeability (256, 257). Therefore, the caries progress in dentin is faster in primary teeth than permanent teeth (258).

It has been reperted that the pulpodentinal system reaction is proportional to the intensity and duration of the offending agents related to caries, trauma, medicaments, or restorative materials. A correct diagnosis of pulp conditions in primary teeth is important for treatment planning (259, 260).

In t the present study, 60 teeth (35.7%) were treated by pulpotomy, 105 teeth (62.5%) were treated by pulpectomy and 3 teeth (1.78%) were extracted. This was in contrast with other study were conservative treatment were prefered than pulp therapy (127,153,155).

Pulpotomy was performed when caries removal was limited to the coronal tissue, without evidence of radicular pathology (20), teeth in which caries has not reached the inner layer of dentin because once dentin is invaded by microorganisms very early during lesion formation, many microorganisms could be left within the dentin, resulting in further lesion progression or pulpal reaction (258-260). However, it has been reported that as soon as the demineralized enamel is in contact with the enamo-dentinal junction, demineralization of the dentin is initiated. Pain is another indicator, however pain in very young children can not be very reliable (257).

The level of skills required for the placement of a restoration is another important consideration in treating a young child with ECC. Zirconia crowns were generally found to be easy to use in the dentitions that were spaced or well aligned, in dentitions with minimal spacing or crowding they were reported to be difficult to use. However, crowded dentitions with significant amounts of tooth overlap would be difficult to restore regardless of the modality (11, 148).

6.1.1. Color Match Evaluation

In the present study, the RCSc group (92.1% or 47 teeth), (80.3% or 41 teeth) had no or mild discoloration (affecting 2 surfaces or less) which did not require intervention and were considered esthetically acceptable after 3 and 6 months respectively. While in the third follow-up 34% or 16 teeth (11 were central incisor and 5 were lateral incisors), displayed severe discoloration (affecting more than 2 surfaces of the crown). However just 47 teeth from 51 teeth were evaluated in third follow-up due to loss of the restoration.

Kupietzky et al. (2003), concluded in a clinical trial that 74% of resin composite strip crowns (83 teeth) showed a good color match relative to adjacent teeth over a mean period of 18 months (153). In 2005, the same author conducted another study, concluding that 88% of resin composite strip crowns (127 teeth) also did not show noticeable difference in color match over a period of 3 years (155).

In the above mentioned study only 11 teeth had pulpal treatment, according to the author the esthetic components of color were found to have fewer ideal ratings 74% than retention 88%, the author mentioned that if teeth treated pulpally were eliminated from the ratings, the color match ratings will improve significantly. The author suggested that the discoloration of teeth that undergone pulpal treatment could be minimized by using an opaquing agent on the facial aspect of the preparation, prior to strip crown placement or using a glass ionomer in the coronal one third of the pulp canal to prevent coronal discoloration by the endodontic paste in the canal (153, 154, 155).

Ram et al. (2006), conducted a retrospective study in 200 children in which 179 (90%) were cooperative during treatment, while 21 (10%) were uncooperative, the total number of decayed surfaces present at baseline: 12% of the incisors had three or more carious surfaces, 66% had two affected surfaces, and 22% had only one carious surface, endodontic treatment was carried out only after disclosure of periapical lesions on radiographs, only teeth without signs of pulp involvement. The colour and texture of the resin composite strip crown restorations remained either good or acceptable, with no pitting or discoloration that compromised the esthetic results in 96% of the central incisors and 98% of the lateral incisors. The authors concluded that at 24 months follow-up, the colour was still acceptable for vital teeth, even when the restorations were chipped or caries was present in the gingival margin (156).

In the present study 66% of resin composite strip crowns (83 teeth) showed a good color match relative to adjacent teeth over a mean period of 9 months, the value was relatively less than the previous studies, however this can be related to many factors, one attributed factor was the pulp therapy. The endodontic paste used in the present study was an iodoform paste (Metapex, META BIOMED, CE 0015), which has a yellow color, however trying to overcome this, glass ionomer cement were placed in the coronal one third portion. Another factor which may be considered is the translucent nature of the resin composite, allowing the discolored tooth color to show through the restoration.

There are many reasons of resin composite discoloration, can be attributed to, in the oral cavity, because of superficial degradation or a slight penetration and adsorption of staining agents at the superficial layer of the resin composite, discoloration of the surface or subsurface of the resin restorations can result (261). Moreover, externally induced discoloration can be related to surface roughness, surface integrity, and the polishing technique (262).

In the present study Sof-lex (3M-ESPE, St. Paul, MN, USA) was preferred as the polishing system which consists of aluminum oxide discs. Studies reported that using aluminum oxide discs lead to obtain the smoothest surfaces. The smoother the surface the less plaque accumulation occurs, plaque accumulation lead to superficial staining, secondary caries and change in color (224).

Venna et al. (2016), conducted a study in order to investigate the effects of finishing and polishing procedures on four novel resin composites, four composites classified according to their filler size, were selected: Filtek™ Z350 XT Nanofill (3M™ ESPE™), Esthet-X HD/Hybrid (Dentsply Caulk), Te Econom/Microfill (Ivoclar Vivadent ®), Tetric EvoCeram ® /Nanohybrid (Ivoclar Vivadent ®). Composite resin specimens were made in Plexiglass molds and polished with Soflex (3M ESPE), Enhance + Pogo (Dentsply Caulk). The authors concluded that among the polishing systems, Soflex showed the smoothest surface and was significantly different from Pogo (263).

Berber et al. (2013), investigated the color stability of resin composite restorations using different finishing systems and drinks. Mylar strip (Mylar, DuPont, Wilmington, Del. USA), Sof-Lex (3ESPE St. Paul, MN, USA), Enhance (Dentsply-DeTrey GmbHD Konstanz, Germany), Hiluster (KerrHawe, Bioggio, Switzerland), Opti Disc (KerrHawe, Bioggio, Switzerland) were 5 finishing system groups. The samples in the groups were immersed in different drinks such as water, coffee, coffee with sugar, tea, tea with sugar, diet coke, coke, light sour cherry juice or sour cherry juice. The results of this study showed that Mylar strip group demonstrated signicantly highest color change; Enhance groups demonstrated signicantly lowest color change, whereas no statistically significant differences among the other polishing system including sof-lex were observed (264).

Color changes in composite resins occur from intrinsic and extrinsic factors. Intrinsic factors involve the discoloration of the resin material itself, such as the alteration of the resin matrix and of the interface of the matrix and the fillers (265). Extrinsic factors for discoloration include staining by adsorption or absorption of colorants as a result of contamination from exogenous source, the degree of discoloration from exogenous source varies accpording to oral hygiene and the eating drinking habits of the patient (262, 264).

Several studies have been conducted to determine the effect of staining solutions on the surface characteristics of esthetic restorations (262, 264, 266,)

The resin composite strip crowns are require a very sensitive technique, during the procedures contamination with blood can alter the shade or the color of the material, to overcome this, use of retraction cords with or without medicaments is reccommended (11, 127).

In the present study, retraction cords were used to ensure moisture, saliva and hemorrhage control and provide proper etching and bonding of enamel and dentin. There is evidence from a meta analysis showing that adequate etching and bonding of enamel and dentin significantly decreases marginal staining and detectable margins in resin composite restorations (267).

The KKZ group showed mild discoloration which did not require intervention and were considered esthetically acceptable after 3 months (57.4% or 27 teeth) and 6 months (53.1% or 25 teeth) respectively. While in the third visit almost half of the teeth displayed (52.2% or 23 teeth) no discoloration and were considered esthetically acceptable. However just 44 teeth from 47 teeth were evaluated in third visit due to loss of the restoration.

The NSZ group showed mild discoloration which did not require intervention and were considered esthetically acceptable after 3 months (57.4% or 31 teeth) and 6 months(50% or 27 teeth) respectively. In the third visit 27 teeth (50.9%) displayed no discoloration and were considered esthetically acceptable. However just 53 teeth from 55 teeth were evaluated in third visit due to loss of the restoration.

In the first and second visits RCSc group showed statistically signficant lower values in slight shade mismatch than the other groups. In contrast, in the third visit no obvious shade mismatch was recorded in both KKZ and NSZ groups, while obvious shade mismatch scores were significantly higher in the RCSc group.

This can be attributed to the difference of zirconia than the resin composite in mean of color, so when placing zirconia restoration beside a resin composite restoration (placing zirconia in the maxillary incisor and resin composite in the canine) can lead to a slight shade mismatch, in addition resin composite restoration (Filtek™ Z350 XT) exhibits three shades, NSZ® have two shades, while KKZ® have only one shade.

In third visit moderate to obvious discoloration can occur in resin composite restoration due to its staining properties, in contrast to zirconia, that has mechanical properties very similar to those of metals, yet it has a color similar to that of teeth (9,165). A material which provide adequate translucency, preventing showing through, estimating a color stable property (171).

The advantages of color stability of zirconia overcome the disadvantages of preveneered stainless steel crowns. ***Roberts et al. (2001),*** showed that 24% (7 out of 29 teeth) restored with resin faced stainless steel crowns had color mismatch with adjacent teeth after a mean period of 20 months (138).

Shah et al. (2004), conducted a study on Kinder Krowns® PVSSC, they found that 20% of crowns had minor color changes compared to the original crowns (249). In contrast to the results of the study by ***Maclean et al. (2007),*** in which 3 teeth out of 226 restored with NuSmile® PVSSC crowns (1%) were reported to exhibite color change after at least 6 months (13).

In the english dental literature there is a lack of strong clinical data, obtained with well designed, prospective studies, regarding the newly introduced zirconia crowns. Only few case reports, and just one prospective clinical study that has only a six month follow-up period were published. In that study authors evaluated just restoration failure, abrasion in the opposing dentition, gingival health of the restored teeth limited the frame of discussion regarding the color assessment (157).

6.1.2. Crown Contour Assessment

The placement of resin composite strip crown is a very sensitive technique and descriptions of the placement of the restoration are well defined in various case reports (121, 150, 153, 154, 267). Since the procedure is very technique sensitive, any lapses in patient selection, moisture and hemorrhage control, tooth preparation, adhesive application and resin composite placement can lead to failure (154). The difficulty in application is reflected in a study that only 21% of general dentists surveyed perform resin composite strip crowns compared to 73% of pediatric dentists (150, 153).

Dentin of the primary teeth is less mineralized, despite the presence of a gradient of mineralization, the prismless layer of primary teeth does not respond well to acid etching (254). ***Corniff and Hamby (1976)*** recommended that a diamond bur should be used to remove the enamel’s prismless layer before acid etching. In order to increase surface area, mechanical locks or slots were placed to prevent dislodgement of restorations. These dovetails were recommeded to be placed on the labial as well as the lingual surfaces (268).

In the present study, if there was sufficient tooth structure remaining, a small cervical undercut with inverted cone were placed, to gain more retention of the resin restoration as it act as mechanical lock.

During the procedures, it is suggested to fill and cure each crown individually with unfilled crown forms in place on their respective teeth to ensure proper spacing between restorations (153). Special care should be taken to carefully to remove a collar of cured bonding agent (prior to filled crown placement), which will interfere with proper seating of the crown form if it is left in place (154).

In the present study a probe was used to peel off the strip crown, resulting in minimal damage to the cured restoration and consequently preserving any polishing, lustering the labial crown surface, the crown was pierced with a sharp explorer at the palatal side to create a core vent for the escape of any air bubbles entrapped in the crown, avoiding overfilling the crown with resin since excessive material escape from that vent since over filling the crown with resin composite material, resulting in the tearing of the mesial and distal seams of the crown, leading to loss of the retention.

In the present study crown contour margins demonstrated that 98% of the RCSc crown contour appear acceptable in the second visit. Although we used several methods to gain retention, in the third visit 90.1% of the restorations in RCSc group crown contour appeared acceptable, while 7.84% were lost. This can be related to the fact that resin composite strip crowns relies on dentin and enamel adhesion for retention and if a lot of tooth structure is loss, the longevity of the crown is jeopardized. In RSCc group, all the teeeth that exhibited crown loss were lateral incisors, due to the miniature morphology of this teeth, after removal of the caries a markedly amount of tooth structure were lost.

The crowns in both KKZ and NSZ groups are manufactured with pure zirconia. These monolithic crowns have no facial upper structure, as they are made up of solid zirconia leading to no chance of facial veneer fracture. The flexural strength of zirconia oxide materials has been reported to be in the range of 900 to 1.100 MPa. This is approximately twice as strong as alumina oxide ceramics currently in the market and 5 times greater than standard glass ceramics (269). Another important property is their fracture toughness making them perdurable and a highly strong restoration (270).

These crowns showed durablity to cracks and fracture in the present study, instead some of the crowns were completely lost. No teeth were found to exhibit alteration in the crown contour form. Besides being highly acceptable, due to their slightly bulky appearance most of the restorations in both groups the crown contour was judged as score B.

In the NSZ group, in 81.8% of the restorations clinical crown contour was judged as being either acceptable in the second visit and in the third visit, while 3.63% were lost.

In the KKZ group, in 70.2% of the restorations clinical crown contour was judged as being either acceptable in the second visit, while in the third visit 6.32% were lost.

In both KKZ and NSZ groups, clinical crown contour were rated worse than RCSc, this may be related that zirconia crowns are slight bulky in their appearance. However retention rate of RCSc were less successful than zirconia crowns group, which is a result that was similar to that of ***Walia et al. (2014).***

Walia et al. (2014), conducted a randomized clinical study to compare the clinical outcomes of three types of full coronal restorations (resin composite strip crowns, pre-veneered stainless steel crowns [SSCs] and pre-fabricated primary zirconia crowns) in a total 129 maxillary primary incisors consisting of 66 central and 63 lateral incisors of 39 children. They concluded that the retention rate was highest for zirconia crowns (100%) followed by pre-veneered SSCs (95%) and strip crowns were the least retentive (78%) (156).

Kupietzky et al. (2003), reported on the clinical and radiographic success of 112 resin composite strip crowns in 40 children. Other than loss of resin material, less than ideal crown contour and crown discoloration, mainly in pulp treated teeth were reported as the main drawbacks of the crowns (153).

6.1.3. Presence of Restoration Failure Assessment

Retention of a restoration is related to many factors one of which is the remaining tooth structure. The lesser the tooth structure exists, the less retention of a restoration will be achieved (150, 271). Along with this factor, bonding and/or cementation quality represent another important factor. In the present study the restorations in RCSc group were bonded to the tooth surface with adhesion procedures, while in KKZ and NSZ groups the crowns were cemented to the tooth surface. Cementation is an important and critic factor related to the retention of the restoration (272).

Cementation of zirconia crowns is accepted as an important issue. Zirconia cannot be etched and bonded because of lack of silicone of the glass ceramic. Sandblasting has been reported to introduce micro cracks into the zirconia and is not recommended. Acid etching either with phosphoric acid or hydrofluoric acid will not alter the intaglio surface of the restorations and therefore have no effect on the overall retention of the restorations (159). Conventional or self adhesive resin cements have been recommended as luting agents for zirconia crowns. Another important point to consider is that zirconia crowns not contaminated with blood or saliva have better adhesion to cement (129). To overcome this problem NuSmile® came up with using a *Try-In* NuSmile® pink crown for precement trial fittings, so that the crown to be placed remains untouched until final cementation.

NSZ exhibits only chemical bonding, while KKZ exhibits IncisaLock, combining between mechanical and chemical bonding. Both of them were cemented glass ionomer based luting material to minimize the risk of recurrent caries.

KKZ were cemented with Aquacem® which is biomimetic material that creates an alkaline environment (high pH) to resist acid and bacteria, has thermal properties similar to dental tissues, is biocompatible and does not require optimal conditions for a good seal. No etching or priming is required and its viscoelastic consistency helps the crown to slip easily in its place. In addition, it is easy to remove the excess during the “rubbery phase”.

NSZ were cemented with Biocem® which has bioactive components of hydroxyapatite that can integrate with the tooth and also exhibits antimicrobial properties. According to the manufacturer instructions, it is advised to cure just for two seconds, allowing the removal of the excess cement during rubbery phase and then to cure for 20 seconds labially and 20 seconds palatally.

The first objective of the present study was to prospectively evaluate the clinical performance of three types of esthetic restorations in primary incisors. Our 9 month results showed that the retention of KKZ, NSZ was high (93.6%), (96.3%) respectively, whereas for RCSc group an overall of 88.2% retention rate was registered during the 9 months study period.

A few of the children in the study were found to have both successful and failed crowns in the same individual. Although the exact explanation cannot be determined based on the study results, some reasons for children having both intact and failed crowns include trauma, biting of a toy and excessive intake of sticky food likes gums and candies.

These results can be compared to only two other prospective studies available in the dental literature, which pertain to the retention of resin composite resin crowns. The first study found a retention rate of 100% after 12 months, and out of 92 teeth, only 4 teeth had recurrent decay (273). The second prospective study showed partial or complete retention in 81.2% of 96 resin composite strip crowns at 18 months (274).

The majority of other studies in the literature are retrospective, with reports of resin composite strip crown success ranging from 49% to 100% with follow-up periods from 6 to 36 months (103, 109, 153, 155, 156, 275).

Kupietzky et al. (2003), reported on the clinical and radiographic success of 112 resin composite strip crowns in 40 children. It was determined that the crowns had an 88% retention rate with a mean follow-up time of 18 months. Although none of the crowns were completely lost, partial loss of the resin occurred in 12% of the teeth. Other than loss of resin material, less than ideal crown contour and crown discoloration, mainly in pulp treated teeth, were reported as the main drawbacks of the composite resin strip crowns (153). The same retrospective study sample was used 1 year later to assess parental satisfaction with the esthetic appearance of the resin composite strip crowns (154).

In 2005, the same authors published another retrospective study with clinical and radiographic data on resin composite strip crowns after 3 years of follow-up. The study sample consisted of 145 resin composite strip crowns in 52 children and the results showed a 78% retention rate for a period of over 36 months (155). Similar to the previous study, the crowns that were considered “lost” only exhibited partial loss of the resin composite material. The authors concluded that resin composite strip crowns are an excellent treatment choice when adequate tooth structure remains after caries removal (153).

Ram et al. (2006), found similar results for crown retention in a retrospective study, after a 2 year follow-up, 80% of the resin composite strip crowns were successful at the final examination (156).

Eidelman et al. (2000), compared the durability of restorations placed in children under sedation to those placed under a general anesthetic. In a sample of 34 children followed between 6 and 24 months, successful marginal adaptation and anatomic form were found in 90% and 86%, respectively. In comparison, out of 31 children who were treated with sedation, marginal adaptation and anatomic form were considered successful in 63% and 65%, respectively. This difference between successful treatment under general anesthesia and conscious sedation was statistically significant. The results of this study suggested that resin composite strip crowns placed under general anesthesia may exhibit superior longevity (103).

Al Eheideb et al. (2003), evaluated the integrity and longevity of restorative and pulpal procedures performed on primary teeth under general anesthesia. Fifty-four children, who received comprehensive dental treatment under general anesthesia, postoperative examination period ranged from 6 to 27 months. Children were examined and the quality of the restorations were recorded and evaluated. Results showed that restoration of posterior teeth with stainless steel crowns were more successful (95.5%) when compared to amalgam or resin composite restorations (50%). In the anterior teeth, resin composite strip crowns had a success rate similar to that of Class III, IV and V composite resin materials (276).

Judd et al. (1990), in a prospective clinical study with a 1 year follow-up, reported a 100% retention rate of the resin composite strip crown in a sample of 92 teeth (274).

Grosso et al. (1987), and a case report by ***Mendes et al. (2004),*** also described the use of a resin composite short post in the pulpal chamber of an anterior tooth that had received a pulpectomy (277, 278).

Tate et al. (2002), reported the failure rates of restorative procedures for children undergoing dental rehabilitation under general anesthesia, by review of 504 dental records of children receiving comprehensive dental treatment under general anesthesia, (48%) of the records were evaluated. Stainless steel crowns had significantly lower failure rates than amalgams. The highest failure rates were seen in composite resin restorations and resin composite strip crowns. It was emphasized that while SSCs are the most reliable restorations, composite resin restorations are the least durable. Failure of restorations appears to be related to follow-up length (152).

Su et al. (1992), evaluated the comprehensive dental treatments for children under general anesthesia. 57 children with mean age of 3 years 2 months were treated, followed up with a minimal of 1 year. The most frequent treatment procedures were the extraction of teeth, resin composite restoration and Ni-Cr crown restoration. The Ni-Cr crown (1.7% failure rate) was more successful than the amalgam and resin composite restorations (9.7% failure rate). Pedo strip crown had the highest failure rate (22%) for anterior teeth restorations. The researchers found a 78% success rate for 50 teeth that had received resin composite strip crowns, with fracture of the resin composite being the main type of failure (280).

O'Sullivan et al. (1991), reviewed 80 children who were treated under general anesthesia, in which only 16 teeth received resin composite strip crowns in with a follow-up period of 2 years, the authors reported a 100% success rate (279).

However, zirconia crowns exhibit some disadvantages: inability to crimp the crowns for tight marginal seal, need to prepare the tooth to fit the crown rather than adjusting the crown to fit the preparation, cost per crown and need for good hemorrhage control to get good cementation, need for sufficient remaining tooth structure onto which the crown can be luted. In spite of these concerns, the natural appearance of these crowns, coupled with the high strength for fracture resistance and biocompatibility, will likely result in becoming a popular restorative option in both the anterior and posterior regions of the primary dentition.

To date, there is virtually no information in the dental literature regarding clinical performance of these primary crowns. One prospective clinical study that has only a six-month follow-up period and just two case reports have been published.

Walia et al*.*(2014), published a short term prospective study, reporting that none of the zirconia crowns had been lost or fractured after six months; whereas 22 % of the resin composite strip crowns had either fractured or been lost completely and 5 % of the preveneered crowns had lost a portion of the veneer (157).

Karaca et al. (2013), suggested that zirconia crowns promise superior esthetics and natural appearance with short chair time (159). While ***Del pozzo et al. (2014),*** described the crowns as a new approach and another alternative to restore the natural appearance of a child's primary teeth that are compromised by caries or trauma (160).

6.1.4. Gingival Health Assessment

It is desirable that all dental restorative materials feature low susceptibility to adhere oral microorganisms since plaque formation on dental restorations may lead to secondary caries and periodontal inflammation (218). The adsorption of saliva constituents to tooth and restorative surface is considered as the first step in oral biofilm formation that is followed by the adhesion of facultative anaerobic pioneer bacteria has been discovered in early plaque, too, and has furthermore been found to be one of the major causative agents for dental caries. Compared with other dental materials, such as composite resins or methacrylate systems, low adhesion of oral bacteria to ceramic surfaces was shown in numerous *in vitro and in vivo* studies (213, 226, 227).

When a crown is placed on a tooth in a healthy periodontal environment, the maintenance of good periodontal health depends on marginal integrity of the crown, the crown's contour and the patient's oral hygiene. The results of studies that have examined the relationship between full coverage restorations and the maintenance of a healthy periodontium and healthy gingiva are somewhat discouraging (196, 198).

Moreover, controversy exists on the occurrence of soft tissue reactions when an SSC is used to restore a primary tooth (281). It has been suggested that the presence of a full veneer crown with subgingival margins on a permanent tooth encourages or promotes gingival inflammation. Although their study did not include data on control teeth, ***Goto et al. (2000),*** reported that the degree of gingivitis was strongly associated with poor-fitting SSCs (282).

In the present study we evaluated the gingival health around three types of restorations, in the first visit, the gingival health was optimal and no obvious sign of inflammation were observed in 65.95%, 69.09%, 86.27% of the teeth in the KKZ, NSZ and RCSc groups respectively, while in the second visit, the percentage of teeth showing mild signs of marginal gingivitis were recorded as 23.41%, 29.1% and 21% for the KKZ, NSZ and RCSc groups respectively. In the third visit after 9 months, the gingiva considered to be healthy in 78.72 %, 80%, 76.43% of the teeth in the KKZ, NSZ and RCSc groups respectively in the study sample.

In the RCSc group, 86.27% of the restorations exbited no signs of inflammation in the first visit. In the second visit (6 months), 7 teeth (13.72%) had only mild gingival inflammation, whereas 4 (7.84%) exhibited moderate to severe gingival inflammation.

The increased mean gingival health score of teeth restored with composite resin strip crowns can be affected by tooth preparation and cementation (238). ***Waggoner et al. (2006),*** also reported similar results in their studies (148).

It is very well known that it is preferable to keep the restoration margins coronal to the free gingival margin (284). Obviously, subgingival margin placement is often unavoidable for primary teeth. Retention of full coverage crowns for primary teeth comes mainly from subgingival placement (138). In the present study the subgingival margin were placed about 1.5-2 mm subgingivally.

The degree of gingival inflammation is directly related to the location of crown margin ***Newcomb et al. (1974),*** stated that as the margin goes from supra to a sub gingival position, the gingival health deteriorates (285).

Kupietzky et al. (2003), found in their study that the gingival health surrounding the composite resin strip crowns and adjacent teeth demonstrated either no gingival inflammation (43%) or mild marginal gingivitis (56%). Mild gingival inflammation was reported to be about twice as likely around the SSCs as around the adjacent teeth without crowns (153).

In the present study, we found that the PI scores of the teeth that were restored with an RCSc gradually increased along the 9 months follow-up. Our finding which shows plaque accumulation increased 9 months after crown placement could be related to reduced compliance with the oral hygiene instructions that were given to the children. Our results also suggest that the extent to which a crown is adapted and the restorative material itself have influence on the amount of plaque that accumulates on a restored tooth. This suggestion is supported with the results of the *in vitro* bacterial adhesion experiment in the present study.

In the first visit after third months 65.95% of the teeth in the KKZ group exbited no signs of inflammation, whereas in the second visit, only 11 teeth (23.4%) showed mild gingival inflammation and no teeth exhibited moderate to severe gingival inflammation.

In the NSZ group, 69.09% of the teeth exbited no signs of inflammation in the first visit after third months, while in the second visit, 9 teeth (16.36%) had only mild gingival inflammation. Moderate to severe gingival inflammation were not obsrved in any of the teeth.

The findings in the present study were similar to the results of ***Walia et al. (2015),*** who concluded that at the 6 month follow-up, the mean gingival index scores was increased in both strip crown and preevenered crown groups, while in teeth restored with zirconia crowns the mean gingival index scores were significantly reduced **(p=0.01)** (157).

Teeth restored with the KKZ and NSZ crowns also showed mild gingival inflammation at 6 months in the present study. This could be due to plaque retention and remnants of the cement in the sulcus that could irritate the gingiva causing mild gingival inflammation.

Teeth restored with zirconia crowns showed a significant decrease in gingival health scores compared to RCSc group at the third visit. Zirconia as tooth material is highly biocompatible and possesses a polished and smooth surface leading to less plaque accumulation and hence less gingival irritation. Previously published studies on Federal Procurement Data System with zirconia framework in permanent dentition arrived at the same conclusion of low plaque accumulation (172, 173, 287).

6.2. Parental Satisfaction

Carious primary teeth often require full coverage restorations, and the stainless steel crown (SSCs) is accepted as the most reliable restoration. In today's cosmetically conscious society, however, most parents demand more esthetic restorations, often preferring extraction to a metal crown's unattractive appearance (138).

Over the last two decades, a higher esthetic standard is expected by parents that have resulted in an increased request for tooth colored pediatric dental restorations. To fulfill the parental expectations has become one of the most important deciding parameter in selection of dental restoration in children. Esthetics, toxicity, durability and cost are common factors that parents consider before they give their consent for any restoration technique (113).

Full coronal restorations are also being advocated; such as resin composite strip crowns, ready made crowns like preveneered stainless steel crowns (PVSSC) and the recently introduced pre fabricated primary zirconia crowns (148).

Studies document and compare both function and parental acceptance of PVSSCs. In the first clinical retrospective study of preveneered SSCs using Whiter Biter II crowns (Whiter Biter, Inc), which are no longer commercially available (13, 148).

Roberts et al. (2001) found that, while all Whiter Biter crowns remained intact and retentive, one third of the facings showed complete or substantial loss. Despite this failure rate, overall parental acceptance remained surprisingly high, with most stating they would choose the preveneered crowns for their child again. The lowest scores were received for appearance and color, while parents were most satisfied with the shape and size of the resin veneered crowns (287).

A similar study by ***Shah et al. (2004),*** evaluated the failure rate and parental acceptance of PVSSCs Kinder Krowns®. Forty six teeth were evaluated in l2 children. Resin fracture resulting in partial or total loss of the facing was observed in 34% of crowns. Wear was limited to the crown's incisal one third in 15% of teeth. The parents were satisfied considering such factors as appearance, color, shape, size, and durability, the crowns' appearance received the lowest score, while parents were most happy with the crown's size (249).

Champagne et al*. *(2007), releaved in their study that parental satisfaction regarding the color of preveneered stainless steel crowns was 89%, which was the lowest rating related to crown features due to its overly white color (288).

Kupietzky et al. (2003) and ***Waggoner et al. (2006),*** showed poor durability with bonded resin composite strip crowns which was negatively reflected in the parental satisfaction. However, Kupietzky evaluated parental satisfaction in the 2003 and 2005 studies with regards to the resin composite strip crowns and found that parents were least satisfied with the color of the crowns (154, 148). While ***Shah et al. (2004),*** reported that facial fracture of composite material from PVSS crowns affects the durability and it resulted in negative effect on total parental satisfaction (249).

The vast majority of the stuides in the dental literature has evaluated parental satisfaction of either resin composite strip crowns or PVSS crowns individually, but there has been no comparative evaluation regarding parental satisfaction with various esthetic full coronal crowns for maxillary primary incisors (11, 119). In the present study we compared the parental satisfaction obtained with various esthetic full coronal restorations for maxillary primary incisors.

The overall parental satisfaction regarding the color with KKZ, NSZ and RCSc crowns were 53.85%, 42.86% and 50% respectively. The zirconia crowns are available in only two shades light and very light which can sometimes mismatch with the natural tooth color.

Although zirconia primary crowns are available in two shades, they have much superior life like esthetics and are highly matchable to the natural teeth with regard to shape and form. Resin composite strip crowns are easy to match with the adjacent natural teeth due to availability of different shades for resin composites, however discoloration occurs in time which effects the esthetic outcome in composite resins. Significant relationship was also found between durability of strip crowns and the overall dissatisfaction **(p=0.006)** regarding the other groups. However in the present study the overall parental satisfaction regarding the size and shape with KKZ, NSZ and RCSc crowns were 41,67%, 50%, 76.92% and 45.45%, 42.86%, 69.23% respectively.

Similar results were found by ***Kupietzky et al. (2003)*** and ***Waggoner et al. (2006),*** (154) who concluded that the durability or retention of resin composite strip crowns was the single most important factor affecting parental satisfaction. They were willing to compromise with color, shape, and appearance of these crowns, but their overall satisfaction was affected by failure of the restoration, 78% of parents reported to be "very satisfied" with crowns, with durability being significantly related to their overall satisfaction with the crowns(154).

In the present study parental satisfaction regarding esthetic of NSZ, KKZ and RCSc were found similar (p =0.341) and was positive 50%, 50% and 61.53% respectively.

The highest satisfaction scores in the RCSc group were given for shape and size of the crown (69.23%, 76.92%), while the lowest satisfaction scores were for durability (30.77%). While non of the participants reported an overall dissatisfaction with the crowns.

Only when there is a large discrepancy between expected and perceived performance (eg, the crown fell off within a few months of treatment) will dissatisfaction result. It is, therefore, highly recommended to advise and educate parents regarding the various treatment options available for the treatment of their child and help assist them in the decision making process, but not to make the decision for them. When they are educated about the pros and cons of treatment and then make the choice on their own, they are less likely to express dissatisfaction with results since they were the ones choosing the treatment (154).

The highest satisfaction scores for the NSZ and KKZ groups was for the durabilty of the crown (78.57%) and (66.67%), while the lowest satisfaction scores were for shape (42.86%, 45.45%). Nevertheless, non of the participant reported an overall dissatisfaction with the crowns.

Salami et al. (2015), conducted a study to evaluate and compare the parental satisfaction among composite resin strip crowns, preveneered stainless steel crowns and the newly introduced pre-fabricated primary zirconia crowns for restoring maxillary primary incisors. The study showed that parents were satisfied with all three types of tooth colored full-coronal restoration techniques. A significant relationship was found between colour of PVSSC (p=0.003) and durability of resin composite strip crowns (p=0.009) with the overall parental satisfaction levels. Parental overall satisfaction was found to be highest in zirconia primary crowns followed by resin composite strip crowns and lowest satisfaction was reported for PVSSC (158).

This is inferred in higher parental satisfaction with zirconia crowns in terms of its esthetics and durability. From above results, it can be stated that in today's society apart from dental esthetics, parents are highly concerned about the retention of any restoration.

The advantages of PVSSC that overcome the zirconia crowns is the closer adaptation of palatal metal margins which helps in better retention; however, fracture of facial composite veneer affects their overall durability. While in the zirconia crowns there is no chance of facial veneer fracture as they are monolithic made up of solid zirconia and have no facial upper structure. However in the present study the parental satisfaction regarding the restoration retention showed no statistically significant difference between the three groups (p=0.321).

Parents who were very dissatisfied with the durability of RCSc rated their overall acceptance levels for these type of crowns as satisfied. Additionally parental satisfaction regarding esthetics of the restorations showed no statistically significant difference between the three groups (p=0.821). Although not formally recorded for the study participants, the crown discoloration was more of a concern for the clinician and rarely if ever did the parent or the child complain about the color.

When parents state their overall satisfaction, they often include many dimensions of treatment that the clinical evaluation may not include. Parents may cognitively construct their experience with their child's treatment in 3 distinct ways: (1) psychosocial outcomes; (2) clinical outcomes; and (3) the treatment process. Therefore durability and psychosocial benefits outweighed the visible clinical outcome.

Limitations

Some of the limitations in this randomized clinical study should be noted:

1. The small sample sizes and short follow-up periods with one operator, also restrict one's ability to relate the study results to clinical decision-making and practice. Ideally, a longer follow-up period than 12 months is desirable in order to assess the long-term outcome.
2. In the follow-up visits no radiographies were taken and evaluation were just performed on a clinical basis rather than a clinical and radiographic evaluation, periodical clinical, radiographic follow-up until primary tooth exfoliation is mandatory for long term success.
3. Since composite resin materials rely highly on the remaining tooth structure for bonding, the amount of clinical tooth structure after caries removal and crown preparation is critical to their retention rate. Secondly, composite resins are moisture sensitive and lack of child cooperation can compromise its bonding; although a proper isolation technique and rubber dam application was not performed in all the cases. This could have negatively affected the outcome of the crowns and the overall success of the crowns may have been underestimated in the present study.
4. Another limitation is that the results here represent one resin composite material (Filtek™ Z350 XT, 3M-ESPE Dental Products, St. Paul, Minn) and 1 bonding agent (Universal Single Bond, 3M-ESPE Dental Products, St. Paul, Minn). It is possible that results may differ with different materials.
5. The limited ability to crip the crowns in both KKZ and NSZ resulting in a significant tooth reduction.
6. Forty two children were randomly assigned as per the permutation within each group; however children could not be randomised on the basis of their dmft status as it was difficult to find permuted blocks with similar number of children having the same dmft and number of teeth to be replaced.
7. A doctor patient relationship may have existed between the provider and family that might soften criticism of the esthetic result.
8. While overall satisfaction was very high, some parents, when probed by questionnaire, did find room for improvement in elements of the esthetic result, although this was not significant.

6.3. *In vitro* Assessment of Fracture Resistance of Prefabricated Zirconia Crowns

Full coronal restoration represent an attempt to meet parents' desires for an esthetic restoration while addressing dentists's desires for a durable restoration that can withstand the occlusal forces of biting and mastication (154).

Newly introduced full zirconia crown restorations are made of pure zirconia and zirconia based ceramics for dental restorations has risen in popularity due to their superior fracture strength (180, 271, 170) however, they are reported to be very susceptible to fracture when they are exposed to tensile or flexural stresses (270).

Composition, grain size, shape of the zirconia particles, type and amount of the stabilizing oxides, interaction of zirconia with other phases and processing are also factors that have impact on the metastability of the transformation. Compressive stresses developed in the vicinity of a crack tip, arrest crack propagation and lead to high toughness. The application of stress to zirconia has been known to prevent crack propagation and improve strength by means of phase transformation. However, according to ***Kosmac et al**. **(2000),*** the physical properties of zirconia may decline because of an increase in its surface roughness, microcracks on the surface, and particle release caused by adjustment (289).

In children aged 3-5 years old, ***Kamegai et al. (2005),*** observed that the mean bite force was 186.2 N in boys and 203.4 N in girls, whereas ***Maeda et al. (1989),*** found values of 212.16 N in this age range. For ***Rentes et al**. **(2002),*** the mean value was 213.17 N in children from 3 to 5.5 years old with normal occlusion (290-292).

In children, low variability should occur in bite forces, chewing maturation is a learned behavior, thus allowing an improvement in performance. Moreover, chewing in small children depends on the daily performance and on the neuronal and psycho social maturation as well as on the developmental status. Therefore, the muscle efficiency and force generated during mastication could not be considered the primary determinants of masticatory performance (293).

The present study was undertaken to assess the fracture resistance of maxillary primary incisor prefabricated zirconia crowns from two different manufacturers, NuSmile® (NSZ) ZR anterior, and Kinder Krowns® ZR anterior less preparation (KKZ), the same prefabricated zirconia crowns that were used in our clinical study. Our results shows that, the force required to fracture the control (C) subgroup crowns was above the average force generated by a child's biting pressure, 729.8 N and 743.8 N for KKZ and NSZ respectively.

We statistically compared these values with the average bite load generated by 3 to 5 year old patients and related it with the thickness of the zirconia crowns, and it was found that the mean thickness measured in mesial, distal and incisal aspects of the KKZ group was statistically significantly lower than that of NSZ group **(p=0.0001)**, in contrast the mean labial and palatal thickness of the KKZ group was statistically significantly higher than the NSZ group.

These results can be compared with findings reported by ***Townsend et al. (2014),*** who suggested that, the crown exhibiting the highest fracture resistance, was significantly thicker than at least one other zirconia crown in every location, however in the present study the KKZ crowns were found to be relatively thinner than NSZ crowns just in mesial, distal and incisal thickness (195).

Zirconia ceramics have superior properties compared to other ceramics and (170) biocompatibility (177). However, the properties of zirconia ceramic may be reduced when it contact with thermal and humid environments (189). In order to assess strength and toughness, some kind of fatigue and ageing test must be used. To resemble this fatigue and ageing, we exposed the specimens to thermocycling and this procedure significantly decreased the forces (MPA) required to fracture the crown compared to the control group in which no ageing procedures were applied, in both KKZ and NSZ crowns **(p=0.0001)**.

Thermocycling is a way to expose materials to fatigue and to simulate ageing of the retentive system of crowns and other dental restorations. The abrupt change in temperature when specimens are submerged into baths creates stresses in the specimens and especially in the zones between different materials (192).

In the present study, 10 KKZ and 10 NSZ crowns in the Tc subgroups underwent 2400 thermocycles between 5 and 55 °C prior to the pre loading procedure (loading until fracture), two thousand four hundred cycles was the number of thermocycles chosen to approximate two year of clinical service for a zirconia assuming that a maximum of ten extreme thermocycles would occur a day with a short dwell time of five seconds. This was similar to the protocol adopted by ***Waggoner et al. (1995) and Krämer et al. (2012)*** (193,294).

Waggoner et al. (1995), investigated the amount of shear force required to fracture or dislodge the veneered facings of four commercially available veneered primary incisor stainless steel crowns (SSC) and to characterize the veneer failures. The crowns tested were: ChengCrown (SSC), (Peter Cheng Orthodontic Laboratory); Kinder Krowns® (Mayclin Dental Studio, Inc); NuSmile® Primary Crowns (Orthodontic Technologies, Inc); and Whiter Biter Crown® II (WB), (White Bite Inca). Each crown was cemented with zinc polycarboxylate onto a standardized die and then thermocycled at 4°C and 55°C for 2500 1-min cycles. Each die was then placed into a custom holder on the Instron (Model 4204) testing machine, the force was applied at the incisal edge of the veneer at 148 º(the primary inter-incisal angle), with a crosshead speed 1 mm/min until the veneer fractured or was dislodged. They concluded that the Whiter Biter veneered crown was significantly better able to resist a shearing force on the veneer than the other crowns tested. The average force required to break one of these veneers for all four types of crowns tested, ranged from 397 N (Kinder Krowns®) to 687 N (Whiter Biter), which makes it unlikely that a child would crack or break a veneer through normal incisive function. Based on the results of this *in vitro* study, it was suggested that it is probably more likely that the breakage occurs as a result of traumatic forces, not incisive forces (294).

Krämer et al. (2012), evaluated the effect of thermo mechanical loading on marginal quality and wear of different crown types for primary molars, stainless steel crowns (3M ESPE) and NuSmile® crowns (Orthodontic Technologies Inc.) and Protemp crowns (3M ESPE). The crowns were luted with resin composite crowns Filtek Z250 (3M ESPE) and Heliomolar (Ivoclar Vivadent). The specimens were subjected to 2,500 thermal cycles between 5-55°C. After TML, all crowns were intact. The adhesively bonded crowns showed significantly better marginal quality to dentine/cementum compared to GIC luted crowns (p<0.05). They concluded that different crown types showed a good performance concerning the evaluated parameters marginal quality and wear (193).

Thermocycling has been found to have a negative influence on cements in general (295), this could explain why five of 20 crowns exhibited loss of retention during thermocycling in the present study. Three of the crowns were NSZ crowns which were cemented with Biocem, and the other two were KKZ crowns which were cemented with Aquacem. Both cements were unable to withstand the shear and tensile forces to which it was subjected during the thermocycling fatigue test. Another explanation is adhesive failure, due to increased water sorption which might change the strength of the material and/or bond to some degree since they were dislodged intact. However, these five crowns were loaded until fracture without recementation considering lack of evidence that those crowns showing no loss of retention in fact might have lost their retention partially. Supposedly, this measure had no negative effect as there was no statistical difference between crowns with or without signs of losses.

KKZ uses mechanical and chemical means of retention for the union between the esthetic coating and the underlying base. The crowns produced by NSZ had a chemical union without any visible mechanical adhesion, however there was no statistically significant difference between fracture resistance between two material groups in both C and Tc subgroups specimens (p>0.05).

This finding was similar to the results of a study conducted by ***Vulvon et al. (2006),*** which investigated the fracture resistance of zirconia crowns and to compared the results with crowns made of a material with known clinical performance, in away that reflects clinical aspects, 7 of 20 crowns exhibited loss of retention during thermocycling in that study. The cement used for cementation was zinc phosphate, zinc phosphate is a brittle cement, which was unable to withstand the shear and tensile forces (192).

The impression materials and epoxy dies used in the present study mimicked the protocol used by ***Beattie et al. (2010)*** (296) and ***Townsend et al. (2014)*** (195). The aim of these above mentioned studies was to compare fracture resistance of preveneered SSCs and all zirconia crowns. While our study aimed to compare the fracture resistance of two types of zirconia before and after thermocycling.

The fracture resistance of zirconia, as with all ceramics, is dependent on the elastic modulus of the supporting material. The less a supporting material can be elastically or plastically deformed, the greater the fracture resistance. The epoxy die used, in the present study, is estimated to be 77 MPa.

Beattie et al. (2010), conducted a study to evaluate the fracture resistance of 3 types of esthetic SSCs. Esthetic SSCs for first primary mandibular molars were cemented to idealized epoxy dies with glass ionomer cement. The die crown units were fractured on a universal testing machine The force required to fracture, did not differ significantly among the 3 brands of esthetic SSCs: 1730 N ± 50 N, 1826 N ± 62 N and 1671 N ± 68 N, respectively (p = 0.19), well below the maximum bite force of pediatric patients determined in several studies. The authors concluded that esthetic SSCs were proven to be able to resist occlusal forces over short clinical periods (296).

Townsend et al. (2014), assessed the fracture resistance of primary mandibular first molar zirconia crowns from three different manufacturers EZ Pedo, NuSmile® and Kinder Krowns® and related it with the thickness of the zirconia crowns and the measured fracture resistance of preveneered stainless steel crowns. The thickness of 20 zirconia crowns from three manufacturers were measured. The force required to fracture EZ® Pedo crowns was found significantly higher than that for NuSmile® or Kinder Krown® crowns **(P<.001).** Moreover, the force required to fracture preveneered stainless steel crowns was significantly higher than the force required to fracture all three zirconia crowns **(*P*<.001)** (195).

In the above mentioned study a glass ionomer cement was used for cementation and the authors mentioned that the result may be altered if a bioceramic cement, which is used for permanent ceramic crowns was used.

In the force loading step, long axis of the indenter in the Instron Machine was aligned at 45 degrees to the long-axis of the mounted zirconia crown on the lingual side. For mechanical testing, the specimens were mounted to provide a 135° relationship between the long axis of the simulated the interincisal angle maxillary incisor and the mandibular incisor (the indenter) according to the well established cephalometric interincisal relationships. This was done to closely mimic the off axis loading of the central incisor in the mouth (297,298).

In the present study the fabricated crowns were made of purely of zirconia. The fracture strength of veneering porcelain is weaker than that of purely zirconia (167). It has been reported that a disadvantage of preveneered SSCs is the fracture of the veneer over time, yet the zirconia crowns had lower fracture resistance. Studies hypothesize that the bonding of the porcelain veneer is an area of weakness and may sustain high uniaxial forces but is susceptible to shear forces (174). Zirconium crowns are made of one material and do not have a weak bonding area.

Both of the zirconia crowns tested in the present study far exceeded the mean maximum bite force of children in the primary dentition. Additionally a significant difference between the fracture resistance of the two different manufacturers was not found.

The pitting observed in SEM images, could lead to the initiation of microcracks and under further wear and in the presence of moisture, to subsequent, more pronounced destruction of the ceramic.

Maintenance of a smooth ceramic surface during clinical use is the key to avoiding initiation or progression of microcracks and to limiting abrasion of the opposing teeth. ***Fischer et al. (2003),*** observed a continuous decrease in the strength of ceramic veneer with increasing surface roughness (299).

Initiated crack can act as even a bigger stress concentrator, so that the subsequent mechanical loads will enlarge the crack, a process known as crack propagation. Catastrophic failure will occur when crack propagation has extended to a level affecting the structural integrity of the material.

Limitations

1. The elastic modulus of primary dentin is higher than the epoxy die used. Because ceramics have little tolerance to elastic deformation, the force required to fracture the crowns *in vivo* may have been underestimated in the present study.
2. The relationship between the thickness of the individual surfaces and the fracture resistance of the crowns is still uncertain.
3. More accurate comparison between the zirconia crowns and their resistance to fracture under a multiaxial force application is highly desirable.
4. The number of samples tested was small and may have precluded the ability of the study to detect statistical significance.
5. Each individual crown was measured and recorded prior to testing, allowing the correlation between material thickness and fracture resistance to be measured specifically for each crown. Nevertheless, obtaining the uniform thickness of cement is not always possible in the clinical practice.
6. In clinical practice, one may postulate that increased cement space resulting from caries may result in a decreased modulus of elasticity and an increased risk of fracture. Future studies are needed to test this hypothesis.
7. In clinical practice, the crown preparation is rarely a perfect match for the selected preformed crown. In addition, the chemical characteristics and the temperature of the oral environment cannot be strictly controlled.

6.4. *In vitro* Assessment of Bacterial Adherence of Zirconia and Composite Surfaces

In the oral cavity, biofilm formation occurs on all soft and hard surfaces. Microbial colonization on such surfaces is always preceded by the formation of a pellicle. The physicochemical surface properties of a pellicle are largely dependent on the physical and chemical nature of the underlying surface (300). Thus, the surface structure and composition of the underlying surface will have influence on the initial bacterial adhesion. In the present study we compared the biofilm formation on composite resin restorative material (Filtek Z350 XT), zirconia, the material used for fabrication of the zirconia crowns used in the clinical part of this study, and hydroxyapatite (as a tooth enamel surrogate).

Surfaces with a low surface energy usually display lower adherence to biofilms than similar surfaces with higher surface energy. Most dental materials, with the exception of ceramics, have a higher surface energy than enamel and have thus a greater risk of biofilm accumulation (232). This was supported with our results showing the significantly lower bacterial adhesion values in the zirconia group compared to composite resin and HA **(p=0,0001).**

Cheng et al. (2012), developed a nanocomposite containing amorphous calcium phosphate and calcium fluoride nanoparticles, and reported that the novel nanocomposite could reduce biofilm formation (211). In the present study a nanofilled composite were used, the mean OD readings for *S.mutans* in the hydroxyapatite group was found statistically significantly higher than zirconia and composite resin groups **(p=0,0001)**. However there was no statistically significant difference between the composite resin and zirconia groups (p>0,05).

Finishing applied to restorative materials and polishing operations also affect biofilm formation (301-303). Morever the effect of surface glazing and polishing of ceramics on early dental biofilm formation was evaluated, it has been found that glazed surfaces tended to accumulate more biofilm compared to polished surfaces (219). In the present study, the zirconia discs were fully polished instead of glazed while, the polishing procedure of resin composite discs consisted of repetitive strokes of ten seconds per step, to prevent heat build up and formation of grooves.

Kawai et al. (2000), concluded that more plaque was adhered over glazed surfaces of ceramics as compared with their polished surfaces. This means that a glazed surface would not be clinically acceptable from a biologic point of view. Glazing can produce an undulating and rough surface that, usually, has irregularities, inducing more adhesion of bacteria and other substances (304).

Scotti et al*. *(2007), reported that glazed zirconia surfaces tend to accumulate even higher numbers of bacteria than untreated zirconia surfaces. It might be thinkable that exposed zironia frameworks may yield even less plaque than glass ceramic surfaces, as adhesion of streptococci to polished zirconia surfaces was mostly similar as adhesion to the other ceramics (219).

Rashid et al. (2012), also concluded that glazed surfaces are rougher as compared to the polished surfaces. Although polished surfaces have been reported to have voids and micro cracks on the subsurface of porcelain, these superficial defects did not contribute to the average roughness values or the amount of plaque adhesion. Contrary to other reports, polishing with diamond paste is helpful for obtaining a smoother surface that will prevent plaque from accumulating (305).

The samples prepared from restorative materials used to evaluate the adhesion and the bacterial density must be sterile. Some studies before the bacteria adhesion assay, sterilized the samples with ethanol (306, 307). Some studies sterilized the samples in an autoclave at 121˚C (214, 306, 308). In the present study, the samples were sterilized with hydrogen peroxide gas plasma sterilization method. HAP discs were provided by the manufacturer company (3D Biotek, LLC 1, ILENE Court, Building 8, Unit 12, Hillsborough, NJ 08844, USA) packed separately and sterilized with gamma radiation.

Adhesion of bacteria in the oral environment, depends on the relationship between pellicle coated surface with surface molecules of the bacteria (300). Salivary proteins and enzymes in pellicle simulate holding of the bacteria (49). Some studies use an artificial saliva (308) were other studies used collected saliva from human (301, 307, 310, 311).

Shahal et al. (1998), analyzed the effects of pellicles on the adherence of *S. gordonii* and *S.mutans* using unstimulated saliva. They concluded that salivary pellicles were found to play a significant role in the initial adhesion of oral streptococci to dental restorations (312).

Steinberg et al. (2002), investigated biofilm formation on various materials using *S.sobrinus*. Restorative materials absorbed salivary protein into the surface, pointing out the importance of the type and amount of proteins which vary depending on the material surface and reported that these proteins have the effect of bacterial adhesion (313).

Pereira et al. (2011), conducted a study to evaluate *S.mutans* biofilm adhesion on the surface of three resin composites (nanofilled, Filtek Z350, 3M ESPE, Salt Lake City, UT, USA; nanohybrid, Vit-1- escence, Ultradent Products, South Jordan, UT, USA; and microhybrid, Esthet X, Dentsply, Milford, DE, USA) following different finishing and polishing techniques, they incubated half of the samples with human saliva for 1 hour, and all the samples were subjected to *S. mutans* (ATCC 35688) biofilm development. They concluded that, samples incubated in human saliva exhibited a significant increase of *S.mutan*s biofilm growth to nanofilled, nanohybrid and microhybrid composites and demonstrated the powerful ability of salivary components to modulate biofilm adhesion as oral bacteria adhere to receptors of the host origin in saliva pellicle (301).

In the present study bacterial adhesion and thus biofilm formation were generated using human saliva to simulate the oral environment. For this purpose, researcher (HF) as a healthy donor who did not show any active carious lesions or periodontal diseases collected her own saliva.

It was suggested that, early plaque formation was influenced predominantly by the presence of the salivary pellicle rather than by material dependent parameters whereas the composition of all the ceramics appeared to have influenced the percentage of viable cells during the adhesion process (307, 311) **.**

S. mutans is also involved with biofilm formation and accumulation on the tooth surfaces (314). The adherence of bacterial cells on the surface of the materials was variable depending on: (1) type of dental materials, (2) bacterial strains, and (3) the presence or absence of the experimental pellicles. The bacterial adherence on hard surfaces in the oral cavity is mediated by non specific (e.g. electrostatic attractions and hydrophobic interactions) and highly specific (e.g. adhesin receptor interaction) processes (315, 316).

The adhesion of *S. mutans* to the dental material surfaces in many studies, is considered as an indicator of the likelihood of the amount of plaque and caries development (214, 216, 301).

In the present study, for the adherence assays, *S. mutans* was selected because these organisms can bind to the hard surfaces in the oral cavity (e.g. tooth surface) through various specific interactions, such as between bacterial adhesins and receptors in the acquired pellicle, and glucan mediated processes (315).

Castor et al. (2008), conducted a study to determine the pattern of salivary and serum proteins present in pellicles formed on titanium and zirconia ceramic surfaces, and the ability of bacterial cells to adhere to the experimental pellicles. In addition, they compared to those formed on hydroxyapatite surface. For the adherence assays, *S.mutans* and *Actinomyces naeslundii* were selected, resulting that titanium and zirconia surfaces display similar pellicle protein composition and bacterial binding properties; however, significant differences were observed when both materials were compared to hydroxyapatite (317).

Kupietzky et al. (2005) and Jeevarathanet al. (2008), suggested in their studies a minimum of incubation time for the growth of the microorganism was 24 hours. In the present study we used the same protocol, and the plates were incubated for 24 hours at 37˚(318, 319).

Traditional methods of bacteriology in the calculation of biofilm formation (CFU) and staining methods are used (311, 320, 321). In this method the alive bacteria can be calculated (320). As well as high-resolution techniques, such as microscopic techniques are used or spectrophotometer (320,321). As in the present study, other studies in the spectrophotometer by optical density (OD) was determined by measuring the bacterial density (322-324). In this method alive or dead bacteria are detected indiscriminately, optical density (OD) measures the density value, CFU provides more accurate detection of bacterial adhesion and the detection of viable bacteria on the surface. However, both methods (OD and CFU) were used in the present study in order to empower the results.

In the early stages of bacterial growth, after 48 hrs culture with *S. mutans* the HAP showed the highest adherence (298.33±92.03 CFU), followed by composite resin group (129.23±83.91 CFU), while the zirconia group showed the lowest adherence rate (22.77±11.11 CFU) and the differences between the three groups was found statistically significant.

Hahn et al. (1993), found that inlays of two types of ceramic surfaces collected less plaque with reduced viability over a three-day period of no oral hygiene than did the natural tooth surface (217).

Auschill et al. (2007), showed that biofilms on ceramic biomaterials formed *in vivo* during 5 days were relatively thin (1 - 6 µm), but highly viable (from 34% to 86%) (218).

Bremer et al. (2011), mentioned that biofilm formation on various types of dental ceramics differed significantly and found that zirconia exhibited low plaque accumulation (220).

Meier et al. (2008), described a correlation between streptococcal viability and the glass content of the ceramic materials rather than their surface properties (307).

Rimondini et al. (2006), found lower adhesion of *S. mutans, S. sanguinis, Actinomyces viscosus*, *A. naeslundii*, and *Porphyromonas gingivalis* to zirconia than to titanium *in vitro. In vivo,* they reported lower bacterial adherence to zirconia than to titanium implant material (226).

In contrast, ***Rosentritt et al. (2008)***, reported slightly higher adhesion of *S. mutans* to various dental ceramics in comparison with alloy materials, but decisively lower adhesion to the ceramics in comparison to resin composite materials. These findings are in accordance with the findings of our study, and underline the low susceptibility of dental ceramics to adhere oral microorganisms (231).

In addition, ***Meier et al. (2008)***, reported that no significant differences in the adherence of various streptococci to various ceramic materials was observed (307).

Gerspach et al. (2007), conducted a study to compare the adhesion of *S.sanguinis* to saliva coated human enamel and dental materials during a one hour period using an *in vitro* flow chamber system which mimicked the oral cavity. The number of adherent bacterial cells was higher on titanium, gold, and ceramic surfaces and lower on composite as compared to enamel. The percentage of vital adherent *S.sanguinis* was highest on enamel whereas it was significantly lower on the restorative material tested ranging 41.5%to 69.1% (325).

Ghani et al. (2014), investigated the surface roughness of glass ionomer cement and resin composite materials. A total of 112 specimens consisting of Fuji II LC (microfilled GIC), Ketac N100 (nanofilled GIC), Z250 (microfilled composite) and Z350 (nanofilled composite) were used. Filtek Z250 and Filtek Z350 both showed the lowest surface roughness values. This significant difference was assumed to occured due to the relatively smooth surface composite resin has compared to GIC (326).

Finnegan et al. (2010), tested four different types of surfaces to examine their effects on biofilm formation of *C. albicans, S. mutans,* salivary bacteria, and salivary bacteria mixed with *C. albicans,* they concluded that surface features influence the adherence of microorganisms (327). So we determined to investigate the biomass accumulation of the different types of biofilms on each test surface. Interestingly, *S. mutans* cells did not exhibit differential adherence and the total biomass of *S. mutans* biofilms was independent of the type of surface. However, on the HAP surface, the overall biofilm morphology of *S. mutans* appeared to be different and more compact microcolonies were observed compared with the other test surfaces.

Byung Chul Lee (2011), investigated the adhesion of initial colonizer, *S.sanguis*, on resin, titanium and zirconia under the same surface polishing condition. Specimens were prepared from Z-250, Ti and yttria zirconia tetragonal zirconia polycrystal and polished with 1 µm diamond paste. After coating with saliva, each specimen was incubated with *S. sanguis*. The results of the study demonstrated that bound bacteria were more abundant on resin in comparison with titanium and zirconia. It was emphasized that, surface hydrophobicity is another crucial element for influencing the bacterial adhesion. *S. sanguis* is highly hydrophobic microorganism. It was suggested that the difference of bacterial adhesion is derived from the surface hydrophobicity of different materials. Hydrophobicity of a resin surface is lower than that of titanium and zirconia and more bacterial adhesion was observed.

This result was thought to be due to the difference of surface roughness of the materials (328).

Limitations:

- In this *in vitro* study, only one species of bacteria used, for this reason the results are limited in reflecting the oral environment.
- The differences of bacterial binding between the dental materials and HAP might be related to other physical factors that were not determined in the present study, such as surface roughness, distance of the bacteria to the surface, the ionic strength of the surrounding liquid medium, and the surface free energy of the bacterium, which can influence the initial bacterial adhesion.

7. CONCLUSION

1. In the clinical study, composite resin strip crowns performed well to restore primary incisors with large or multisurface caries. They provide an esthetic and durable restoration for carious primary incisors. However, color match of these crowns with adjacent teeth may be significantly reduced over the time.

2. Overall clinical success was very good with NuSmile® zirconia crowns, Kinder Krown® zirconia crowns and resin composite strip crowns which were used in the present study to restore primary incisors with large or multisurface caries, demonstrating an overall of retention rate after 9 months 93.6%, 96.3%, 88.2% respectively.

3. The clinical performance of anterior NuSmile® zirconia crowns and Kinder Krowns® less preparation zirconia crowns was comparable; both provided successful full coverage restoration for a minimum of 9 months. However longer follow-up period than 12 months is desirable in order to assess the long term outcome.

4. This study suggests that newly introduced zirconia crowns are likely to be successful and may be indicated as an excellent choice for the treatment of carious primary incisors with adequate tooth structure after caries removal, especially if esthetic concerns predominate.

5. Full mouth rehabilitation lead to improvement in the oral hygiene of children. The mean Plaque Index and Gingival Index scores in all study groups after treatment showed significantly lower values than before treatment **(p=0,0001)**,

6. Parental satisfaction regarding esthetic of NuSmile® zirconia anterior crowns, Kinder Krowns® less preparation zirconia anterior crowns and composite resin strip crowns was comparable (p =0.341) and was very satisfied in 50%, 50% and 61.53% of parents respectively.

7. The highest satisfaction scores for the composite resin strip crowns group were given for shape and size of the crown (69.23%, 76.92%), while the lowest satisfaction scores were for durability (30.77%). Nevertheless, non of the participants reported an overall dissatisfaction with the crowns.

8. The highest satisfaction scores for the NuSmile® zirconia anterior crowns, Kinder Krowns® less preparation zirconia anterior crowns groups was for the durablity of the crown (78.57%) and (66.67%), while the lowest satisfaction scores were for shape (42.86%, 45.45%). Again, non of the participant reported an overall dissatisfaction with the crowns.

9. In the *in vitro* fracture resistance experiment, NuSmile® zirconia crowns were significantly thicker in three of five locations compared to Kinder Krown® zirconia crowns tested (p=0.0001). NuSmile® zirconia crowns had greater fracture resistance compared to Kinder Krown® zirconia crowns in control subgroup. However the difference was not statistically significant (p=0.522).

10. Both brands of zirconia crowns tested had similar fracture resistance to the application of uniaxial force. Further studies to evaluate their performance under cyclical and multiaxial force loads in order to determine their potential for clinical success are needed.

11. SEM analysis revealed areas of pitting and roughened surface wear, both of which can cause tendency to micro cracks that will lead to catastrophic fractures and influences the formation of bacterial biofilm.

12. All of the zirconia crowns tested in the present study far exceeded the maximum bite force of children in the primary dentition.

13. In the *in vitro* bacterial adhesion experiment, in the early stages of bacterial growth, after 48 hrs culture with *Streptococcus mutans* the hydroxyapatite discs showed the highest adherence, followed by composite resin discs, while the zirconia disc showed the lowest adherence rate with a statistically significant difference (p=0.0001).

14. These findings indicate that it is better for the clinicians, to use zirconia crowns instead of composite resin restorations in patients with high risk of plaque accumulation.

15. The results of this *in vitro* bacterial adhesion study confirmed the impact of various surface characteristics on the initial bacterial adhesion. Composite resin and zirconia materials exhibited statistically significantly lower adhesive properties compared to hydroxyapatite when contaminated with *Streptococcus mutans* after 48 hours (p= 0.0001).

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9. APPENDIX 1

T.C. YEDİTEPE ÜNİVERSİTESİ

Sayı : 37068608-6100-15-1125 12/11/2015
Konu: Klinik Araştırmalar Etik Kurulu Başvurusu hk.

İlgili Makama (Sayın Hanin Fellagh)

Yeditepe Üniversitesi Diş Hekimliği Fakültesi Çocuk Diş Hekimliği Fakültesi Prof.Dr.Nüket Sandallı'nın sorumlu olduğu **"Erken çocukluk dönemi çürüklerinin üç farklı yöntemle restarasyonunun değerlendirilmesi, kırılma direncinin ve in vitro koşullarda bakteri adezyonunun karşılaştırılması** "isimli araştırma projesine ait Klinik Araştırmalar Etik Kurulu (KAEK) Başvuru Dosyası (**1116** Kayıt Numaralı KAEK Başvuru Dosyası), Yeditepe Üniversitesi Klinik Araştırmalar Etik Kurulu'nun **11.11.2015** tarihli toplantısında incelenmiştir.

Kurul tarafından yapılan inceleme sonucu, yukarıdaki isimi belirtilen çalışmanın yapılmasının etik ve bilimsel açıdan uygun olduğuna karar verilmiştir (**KAEK Karar No: 544**).

Bilginizi ve gereğini saygılarımla arz ederim.

Prof. Dr. Turgay ÇELİK
Yeditepe Üniversitesi
Klinik Araştırmalar Etik Kurulu Başkanı

Yeditepe Üniversitesi 26 Ağustos Yerleşimi, İnönü Mahallesi Kayışdağı Caddesi 34755 Ataşehir / İstanbul
T. 0216 578 00 00 www.yeditepe.edu.tr F. 0216 578 02 99

9. APPENDIX 2

YEDİTEPE ÜNİVERSİTESİ HASTANESİ	Klinik Araştırmalar Etik Kurulu Bilgilendirilmiş Gönüllü Olur Formu

Hastanın veya yerine onam verecek **kişinin okuma, anlama, konuşma, dil** sorunu mevcut mu? Evet ☐ Hayır ☒ Cevabınız EVET ise Hasta İlişkileri Sorumlusu ile iletişim kurunuz.	Tercüman gerektiyse; Tercümanın adı ________________ İmza ________________ Tarih ________________

Sayın Hastamız,

- Bu belge bilgilendirilme ve aydınlatılmış onam haklarınızdan yararlanabilmenizi amaçlamaktadır.
- Size gerçekleştirilebilecek klinik araştırmalar amaçlı girişimler konusunda, tüm seçenekler ile bu girişimlerin yarar ve muhtemel zararları konusunda anlayabileceğiniz şekilde **bilgi alma hakkınız ve bir kopyasını isteme hakkınız** vardır.
- Yasal ve tıbbi zorunluluk taşıyan durumlar dışında bilgilendirmeyi reddedebilirsiniz. Yazılı bildirmek koşulu ile bilgi almama veya yerinize güvendiğiniz bir kimsenin bilgilendirilmesini talep etme hakkına sahipsiniz.
- klinik araştırmalara katılım konusunda bilgilendirildikten sonra bunu kabul edebilirsiniz. Ya da karar verebilmek için uygun zaman talep edebilirsiniz.
- Hayatınız veya hayati organlarınız tehlikede olmadığı sürece onamınızı (yazılı talep etme koşulu ile) **dilediğiniz zaman geri alabilir** ya da önceden kabul etmediğiniz herhangi bir tanı/tedavi amaçlı girişimi tekrar talep edebilirsiniz.
- Hastanemizde verilen hizmetleri Hastane **Tanıtım Broşürü**nden edinebilirsiniz. Ayrıca Hastanemiz personeli hakkında http://www.yeditepehastanesi.com.tr/ web sayfamızdan daha detaylı bilgilere ulaşabilirsiniz.
- Burada belirtilenlerden başka sorularınız varsa bunları yanıtlamak görevimizdir.

TANIMLAMA

Araştırmanın Adı / Protokol numarası

ERKEN ÇOCUKLUK DÖNEMİ ÇÜRÜKLERİNİN ÜÇ FARKLI YÖNTEMLE RESTORASYONUNUN DEĞERLENDİRİLMESİ, KIRILMA DİRENCİNİN VE İN VİTRO KOŞULLARDA BAKTERİ ADEZYONUNUN KARŞILAŞTIRILMASI

Araştırma Konusu Okul öncesi dönemindeki çocuklarda görülen diş çürüklerinin tedavisinde kullanılan üç farklı yöntemin klinik başarısının, ebeveyn memnuniyetinin, bakteri tutunma ve kırılmaya direnç özelliklerinin karşılaştırılması

Araştırmaya Katılımcı Sayısı 45

Bu araştırmanın

Amacı

Bu randomize klinik çalışmada (RKÇ) çürüklü üst süt kesici dişlerine uygulanan üç farklı tam koronal restorasyon (kompozit rezin strip kuron, prefabrik primer zirkonya kuron Nusmile^{TM} ve Kinderkrown^{TM}) ile çocuk hastalarda elde edilen klinik sonuçlar ve ebeveyn memnuniyetinin belirlenmesi; *in vitro* koşullarda zirkonya kuronlardan hazırlanan örneklerin yüzeyinde *Streptococcus mutans'*ın adezyon düzeyi ve kuronların kırılma direncinin karşılaştırmalı olarak değerlendirilmesi amaçlanmaktadır.

Süresi 12 AY

İzlenecek Yöntem / Yöntemler

Çalışma grubuna dahil edilen çocukların çürük olan süt kesici ve azı dişlerinin klinik durumuna ve radyografik tanıya göre gerekli görülen pulpa tedavileri diş hekimi ünitinde/genel anestezi altında tamamlandıktan sonra, üç farklı kuron tipinden biri ile restorasyonu yapılacaktır. Restorasyonların bitiminden sonra 1. 6. ve 12. ay kontrolleri yapılacak ve klinik başarı kriterleri açısından değerlendirilecektir. Restorasyonlar ile ilgili ebeveyn memnuniyeti, 6. Ay kontrolünde ebeveynlere verilen bir soru anketi ile değerlendirilecektir. Ayrıca dişeti sağlığı ve ağız hijyen düzeyleri ilgili indeksler yardımı ile ölçülecektir.

Araştırma Sonunda Beklenen Fayda

Erken çocukluk dönemi çürükleri nedeniyle süt dişlerinde meydana gelen doku yıkımına bağlı olarak estetik ve fonksiyonel sorunlar yaşayan çocukların klinik rehabilitasyonunda kullanılan farklı restoratif tekniklerin klinik başarı düzeylerinin anlaşılması; bu konuda çalışmak isteyen çocuk diş hekimlerine objektif ve yol gösterici bilgiler sağlanması.

Alternatif Tedavi Veya Girişimler

Bu restoratif tedavi yöntemlerinin alternatifleri, amalgam, kompozit reçine, cam iyonomer gibi dolgu materyalleri ile restorasyon veya ilgili dişlerin çekiminin ardından gerçekleştirilecek olan sabit veya hareketli yer tutucu uygulamalarıdır.

Araştırma Sırasında Karşılaşılabilecek;

Riskleri	***Rahatsızlıklar***
a) Dişe uygulanan kuronun düşmesi b) Tedavi sonrasında ilgili dişte abse, fistül oluşumu c) Pulpa tedavisi yapılan dişlerin köklerinin zamanından önce rezorbe olması (erimesi)	a) Tedaviler esnasında/sonrasında ağrı veya rahatsızlık. b) Ağzın fazla açılmasını gerektiren durumlarda, ağız köşelerinde gerilmeye bağlı kızarıklık ve çatlama c) Ağız hijyeni uygulamaları yeterince yerine getirilmezse restore edilen dişleri çevreleyen dişeti vb. dokularda iltihaplanma

Risk / rahatsızlık durumlarında yapılması gerekenler

Restorasyonların yenilenmesi, ilgili dişin çekimi, yer tutucu uygulamaları, dişlerin hastanın kendisi ve diş hekimi tarafından temizlenmesi ile dişeti iltihabının giderilmesi.

Aşağıdaki özel durumlara ait katılımcı var mı?

	EVET*	HAYIR
Çocuk	**EVET**	
Mahkum		
Gebe		
Mental yetersizlik		
Sosyoekonomik eğitim olarak yetersiz		

***Ancak çocuklarda, hamilelik, lohusalık ve emzirme dönemlerinde ve kısıtlılık durumunda; gönüllüler yönünden araştırmadan doğrudan fayda sağlanacağı umuluyor ve araştırma gönüllü sağlığı açısından öngörülebilir ciddi bir risk taşımıyor ise, usulüne uygun bir şekilde alınmış bilgilendirilmiş gönüllü olur formu ile birlikte ilgili etik kurulun onayı ve Bakanlık izni alınmak suretiyle araştırmaya izin verilebilir.

ONAM (RIZA)

Bilgilendirilmiş Gönüllü Olur Formundaki tüm açıklamaları okudum. Bana, yukarıda konusu ve amacı belirtilen araştırma ile ilgili yazılı ve sözlü açıklama aşağıda adı belirtilen hekim tarafından yapıldı. Araştırmaya gönüllü olarak katıldığımı, istediğim zaman gerekçeli veya gerekçesiz olarak araştırmadan ayrılabileceğimi ve kendi isteğime bakılmaksızın araştırmacı tarafından araştırma dışı bırakılabileceğimi biliyorum. Bu durumda hastanenin çalışma düzeni ve hastalara verilen bakımda aksaklık olmayacağı konusunda bilgilendirildim. Bu araştırmaya katılırken zorlama, maddi çıkar ve ast üst ilişkisine dayalı herhangi bir baskı olmaksızın bu çalışmaya katıldığımı beyan ederim. Bu bilimsel çalışmanın devamı esnasındaki süreçle ilgili olarak ayrıca eklenen çalışma protokolü ile bilgilendirildim.

Söz konusu araştırmaya, hiçbir baskı ve zorlama olmaksızın kendi rızamla katılmayı kabul ediyorum.

Gönüllünün Adı / Soyadı / İmzası / Tarih

Açıklamaları Yapan Kişinin Adı / Soyadı / İmzası / Tarih

Gerekiyorsa Olur İşlemine Tanık Olan Kişinin Adı / Soyadı / İmzası / Tarih

Gerekiyorsa Yasal Temsilcinin Adı / Soyadı / İmzası / Tarih

24 Saat ulaşılabilir iletişim bilgiler

Bilgilendirilmiş Gönüllü Onam Formu asgari olarak yukarıda belirtilen başlıkları içermelidir.

APPENDIX 3

Yeditepe Üniversitesi Diş Hekimliği Fakültesi

Çocuk Diş Hekimliği Anabilim Dalı

Çocuğunuzun dişlerinin restorasyonu için uygulanan seramik kuronlarla ilgili memnuniyet derecenizi aşağıdaki tabloda 'x' şeklinde işaretleyiniz

	Çok memnunum	Memnunum	Ne memnunum ne memnun değilim	Memnun değilim	Hiç memnun değilim
Renk					
Boyut					
Şekil					
Tutuculuk (Düşüp düşmemesi)					
Dayanıklılık (Kırılıp kırılmaması)					
Estetık					

Çocuğunuzun ağzında bulunan seramik kuronlarla ilgili başka herhangi bir yorumunuz ya da öneriniz var mı? Varsa yazınız.

....
....
....
....

Katılımınız için teşekkürler

10. CURRICULUM VITAE

Name Hanin F.	Surname FELLAGH
Place of birth 23/10/1980	Date of birth tripoli LIBYA
Nationality Libyan	TC Identification Number 99259296326
E-mail hfellagh@yahoo.com	Tel 05393041025

Education degree	Area	Graduated Name of Organization	Graduation year
Doctorate			
Master degree	Pediatric dentistry	Yeditepe university	2013
Bachelors	Dental and Oral surgery	Trablus University	2004
High school		Trablus school	1998

Languages	Foreign exams note
Arabic	
Italian	
English	
Turkish	

Computer Information Program	Using skills
International Computer Driving Lıcence	Very good

Presented international scientific meetings and published in (Proceedings) papers

Oral manifestations of hypophosphatemic rickets: a case report. FDI 101st Congress, 28-31 Aug 2013 Istanbul, Turkey (Poster Presentation, P068).
The regenerative endodontic treatment approach to traumatized immature permanent teeth. CED-IADR 2013 46th Meeting of the Continental European Division of the International Association for Dental Research with the Scandinavian Division (NOF) September 4-7 2013 – Florence, Italy. (Poster Presentation, S0174).

Muayenesinin Çocukların Ağız Sağlığı Üzerine Etkilerinin Değerlendirilmesi. 20. Türk Pedodonti Derneği Bilimsel Kongresi 07-10 Kasım 2013, Kayseri. (Oral presentation, S07).
Yeditepe Üniversitesi Diş Hekimliği Fakültesi Pedodonti Kliniği'nde Son Üç Yılda Görülen Travmatik Diş Yaralanmalarının Değerlendirilmesi. 20. Türk Pedodonti Derneği Bilimsel Kongresi 07-10 Kasım 2013, Kayseri (Oral presentation, S08).
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