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SILVER DIAMINE FLUORIDE AND GLASS IONOMER SEALANT USE IN PREVENTING OCCLUSAL SURFACE CARIES FOR SPECIAL NEEDS CHILDREN

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ABBREVIATIONS AND SYMBOLS

ADD: Attention Deficit Disorder

ADHD: Attention Deficit Hyperactivity Disorder

ARCPOH: Australian Research Centre for Population Oral Health

BSPD: British Society of Pediatric Dentistry

CDC: Centers for Disease Control and Prevention

DMFS: Decayed Missed Filled Surface Index

EAPD: European Association of Pediatric Dentistry

GIS (GC Fuji TRIAGE): Glass Ionomer Sealant GC Fuji TRIAGE.

HAP: Hydroxyapatite crystals

OHI-S: Simplified Oral Hygiene Index

SDF: Silver Diamine Fluoride

SHCN: Special Health Care Needs

SIGN: Scottish Intercollegiate Guidelines Network

SPSS: Statistical Package for Social Studies

WHO: World Health Organization.

<: Smaller than

>: Greater than

FA: Fluorapatite

AgF: Silver fluoride

Sd: Standard deviation

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1. ÖZET

Özel Gereksinimli Çocuklarda Oklüzal Yüzey Çürüklerinin Önlenmesinde Gümüş Diamin Fluorid ve Cam İonomer Sealent Uygulaması

Öğrencinin Adı: Rehab Tahseen Alhayo

Danışmanı: Prof.Dr. İlknur Tanboğa

Anabilim Dalı: Pedodonti Anabilim Dalı

Amaç: Bu çalışmanın amacı, özel gereksinimli çocukların yeni süren daimi posterior dişlerinde, oklüzal yüzey çürüklerinin önlenmesinde gümüş diamin fluoridin klinik etkinliğini değerlendirmek ve bir yıllık takip süresince cam iyonomer fissür örtücü ile karşılaştırmaktır.

Materyal ve Metod: Bu klinik çalışma, İstanbul, Marmara Üniversitesi Pedodonti Anabilim Dalı' nda yaşları 6-14 arasında olan özel gereksinimli yirmi üç çocukta yapıldı. Katılımcılar ayna, künt sond ve DIAGNOdent pen kullanarak muayene edildi. DIAGNOdent değerleri 0-20 arasında olan ve en az iki çürüksüz daimi posterior dişe sahip çocuklar araştırmaya dahil edildi. SDF (%38) ağızda sol taraftaki dişlere uygulanırken, cam iyonomer fissür örtücü (Fuji TRIAGE) sağ tarafa uygulandı. Cam iyionomer fissür örtücülerin retansiyonları, OHI-S ve çürük oluşumu 3-6-12 ay sonra değerlendirildi. **Bulgular**: 12 ay sonunda toplam 20 çocuk ve 102 diş değerlendirildi. OHI-S sonuçlarının başlangıç ve 12 Ay değerleri arasında istatistiksel olarak anlamlı bir fark bulundu (p = 0,0001). Simonsen'in kriterlerine göre, cam iyonomer fissür örtücü retansiyon oranları %56,36 A (kayıp yok), %27,27 B (parsiyel kayıp) ve %16,36 C (tam kayıp) olarak bulundu. 12 Ayda çürük oranı, SDF için %2,2, cam iyonomer fissür örtücü içim %1,8 olarak belirlendi. 12 aylık takipten sonucunda malzemeler arasında istatistiksel olarak anlamlı bir fark yoktu (p> 0,05). **Sonuç:** 12 aylık takip sonucunda her iki materyal de, yeni süren daimi posterior dişlerin başlangıç oklüzal çürüklerinin kontrol edilmesinde eşit derecede etkili bulunmuştur.

Anahtar Kelimeler: Gümüş diamin fluorid, cam iyonomer fissür örtücü, özel gereksinimli çocuklar.

2. SUMMARY

Silver Diamine Fluoride and Glass Ionomer Sealant Use in Preventing Occlusal Surface Caries for Special Needs Children

Rehab Tahseen Al-Hayo, Supervisor: Prof.Dr. İlknur Tanboğa, Department of Pediatric Dentistry

Aim: The aim of this study was to evaluate the clinical efficacy of silver diamine fluoride in preventing occlusal surface caries in the permanent posterior teeth for special needs children and comparing it with glass ionomer sealant for one-year follow-up.

Material and methods: A split-mouth design clinical study was conducted to twenty-three children with special needs at Istanbul, Marmara University, Department of Pediatric Dentistry. The ages were between 6 and 14 years. At least each child had two permanent posterior teeth with DIAGNOdent results between 0-20 were included. Application of (SDF) (38%) on the left side of the mouth and GIS (Fuji TRIAGE) on the other side of the mouth. The retention of GIS, OHI-S, and occurrence of caries was evaluated after 3-6-12 months. **Results:** A total of twenty children with 102 teeth were evaluated after 12 months. There was a statistically significant difference between the mean of baseline and followed up of OHI-S results ($p = 0{,}0001$). The retention rates for GIS were 56,36% A (complete retention), 27,27% B (partial loss), and 16,36% C (total loss) according to Simonsen' s Criteria. A few numbers of caries on both sides were found after 12-month, 2,2% at the SDF side and 1,8% at the GIS side, and there was no statistically significant difference between the materials after one year of follow up ($p > 0{,}05$). **Conclusion:** As a result of our study, both materials are equally efficient in controlling initial occlusal caries in newly erupting permanent posterior teeth after 12 months follow-up.

Keywords: Silver diamine fluoride, glass ionomer sealant, special needs children.

3. INTRODUCTION AND AIM

Special needs children, also known as children with special health care needs. These individuals may have been born with a syndrome, profound cognitive impairment, terminal disease, or critical psychiatric issues. In addition to that, included children who have private demands that involving; delays in learning, delays in development, allergies from food, or panic attacks.

According to the National Survey for children with special health care needs, Chartbook 2009-2010, in 2013, approximately one out of seven children under the age of 18 years (11,2) million children were categorized as having Special Health Care Needs (SHCNs). About those children, three-fourth of them (76,0%) were used or need prescription medication. The next most common result is used or need for additional medical and mental health, or services in education (42,1% of CSHCN), followed by need for or use of services for emotional, behavioral, or developmental problems (31,8 %), activities limitation (23,5%), and the using of specific therapies (21,5%). Almost four out of ten (38,5%) use or need more medical care, mental health, or educational services than children without SHCN, allergies (food allergy was not included) (48,6%), asthma (35,3%), and attention deficit disorder (ADD)/attention deficit hyperactivity disorder (ADHD) (30,2%) are the most common conditions.

In Turkey, there are an estimated 9 million children aged 0–18 years who have special care needs and have disabilities. This is equivalent to one disabled member per 7–8 households (Aytaç, 2000). Due to their unique care requirements, the daily care of children with disabilities is distinct from that of children with ordinary abilities who are generally able to handle their specific oral health. The oral health status of those individuals may be affected by the age, the severity of impairment, and living situations. Special needs group may have significant restrictions on of their oral hygiene review because of the potential motor form them, sensory and mental limitations, and are therefore suffer from inadequate oral health conditions. This group of individuals may not even know or suppose responsibility to collaborate with preventive oral health procedures. Those who are very young, severely disabled, and living in institutions are dependent on parents, relatives, or caregivers for general care, oral hygiene included. Many health caregivers lack the essential knowledge or values to recognize the importance of oral hygiene and do not train proper oral hygiene by themselves or select a suitable diet. They may be more prone to tooth decay if they are staying at home, remunerated with cariogenic snacks, and other unhealthy eating habits.

CSHCN might be at high risk for oral disease like; they have more deficient in their oral hygiene and periodontal conditions, more teeth with caries and less remaining teeth due to delays in self-care skills or self-acquiring, education, and understanding needed to promote oral health (Mouradian et al., 2001; Reid et al., 2003).

From a dental point of view, early investigations for intervention and prevention among special needs children strongly suggested by the considerable dental academies. Additionally, based on recent and most dependable evidence, by the American Association of Dental Consultants takes the position that remineralization techniques can stop or reverse the decay process in its initial stages. The organization emphasizes that nonsurgical methods are not only cost-effective but have the advantage of preserving tooth structure.

Besides, A study published by the Journal of the American Dental Association concludes that as long as incipient caries is non-cavitated-meaning free of bacteria. Topical fluoride treatments and sealant applications are the best methods of remineralization.

Fluoride is one of the most important chemical components used for the prevention of dental caries. Indeed, it can effectively promote remineralization, inhibit demineralization and also prevent acid formation by bacteria by inhibits the production of polysaccharides essential for the development and sustainment of bacterial plaque, and the consumption of glycoprotein that found in saliva.

Therefore, the dentist needs to concentrate on the preventive approach. To be able to help those individuals, by preventing their newly erupting teeth from caries, and by using simple and pain-free materials to remove the fear that patients feel when going to see the dentist. There are two fluoride source materials used in preventing tooth caries, which are SDF and GIS.

This study was aimed to compare these two materials, SDF and GIS in terms of their clinical efficacy in preventing occlusal surface caries in newly erupted posterior permanent teeth in specialized health care need children.

4. GENERAL INFORMATION

4.1. Children with special needs

4.1.1. Defining children with special needs

In order to help those individuals, it is very important to understand the definition and nature of special needs children!

Children with special health care needs (CSHCN) are those who have or are at increased risk for a behavioral, chronic physical, developmental, or emotional status and who also need health and associated services of a type or amount beyond that needed by children (McPherson et al., 1998).

The definition of special needs includes a broad term that can indicate a wide range of disabilities and diagnoses. Special needs children may have been born with a syndrome, profound behavioral disorder, psychiatric disorders, or terminal disease. Other children may have special needs that include striving with learning delays, developmental delays, food allergies, panic attacks, or other health conditions that are expected to last at least one year. Children who present with any of these conditions are referred to as CSHCN and have an increased risk to the development of caries (Saghal et al., 2002). That could be due to the high amounts of sugar content in medication prescribed for these patients, their regular consumption of cariogenic foods and drinks as well as a poor salivary flow and buffering capacity.

In the world, more than 1 billion individuals live with special care needs (some disability). That is about fifteen percent of the world's population or nearly one of every seven spirits. The numbers come from a collective work by the World Health Organization and the World Bank. The current time anyone decided to figure out the prevalence of disabilities did back in the 1970s when WHO figured it was about ten percent. A study suggests that the 15 percent estimate will grow as the human population ages (Kassebaum et al., 2017). Approximately 200 million of them experience significant disabilities to function. Many systemic diseases, disabling conditions, and medical treatments may decrease the caries resistance of the patient.
Like the 1970s numbers, the figures today are an approximation at best. Many countries did not carefully collect numbers, and disability definitions differ from one

region to another. The World Bank/WHO communities sought out tabulations of individuals who are having problems with seeing, hearing, remembering, walking, taking care of themselves, or communicating. Depression, followed by hearing and visual difficulties, is the most prevalent disability among individuals under 60 in the world.

In Turkey, about nine million children aged from zero to eighteen years who have disabilities and have special needs, this amounts to one member with a disability per seven to eight households (Aytaç, 2000).

4.1.2. Types of special needs children

There are four significant types of special needs children:

1. Developmental: Down Syndrome (DS), Autism Spectrum disorder (ASD), Dyslexia, Processing disorders.
2. Physical: Muscular dystrophy, multiple sclerosis, chronic asthma, epilepsy.
3. Sensory: Blind, impaired visually, deaf, impaired hearing.
4. Behavioral and/or emotional: Attention deficit hyperactivity disorder (ADHD), bipolar disorder, oppositional defiant disorder (ODD).

Figure 1: Types of special needs children (Margaret, 2017).

4.1.3. Oral health conditions and treatment needs of children with special needs:

The literature records that the oral health conditions of individuals with special health needs has been affected by different sociodemographic factors, including living circumstances and the severity of impairment. WHO defines oral health as a case of being free from chronic facial pain, oral and throat cancer, oral infection and pains, periodontal (gum) disease, tooth decay, tooth loss, and other diseases and disorders that limit individuals ability in biting, chewing, smiling, speaking, and Psychological well-being.

Multidisciplinary health care teams with suitable oral professionals included in those teams should consider the filed of oral health problems, including dental, oral motor, nutrition/feeding, and speech matters. Insurance cover for interdisciplinary team support needs to be addressed (Mouradian et al., 2001).

In these people with special needs the needs of oral health competed with indeed severe chronic health situations, and the results of unmet oral health care needs, including infections and adverse behavior of the oral tissues, and exacerbation of concurrent medical conditions (Schechter, 2000; Edelstein, 2002). Dental care of CSHCN is often neglected (Saunders and Roberts, 1997) cause this group of children could not complain if in pain, so the situation may go unnoticed until the acute stage reached. A preoccupation with the principal medical condition usually results in the delay of another side of the child’s overall health (Saunders and Roberts, 1997). The general health of children who have medical problems is placed under further risk when they suffer from dental disease (Saunders and Roberts, 1997). The dental disease itself or supplying the treatment for dental disease can have severe implications for CSHCN and their caregivers (Parry and Khan, 2000). These kids may also do not collaborate at the dental chair with the dentists. In this situation, another types of behavior management techniques may be used by a doctor present to provide adequate care.

When individuals among special health care demands obtain access to dental treatment services, a significant number get dental treatment under general anesthesia. While a large number of people with disabilities may be treated at a clinic or a dental office, around 20% of persons with disabilities have received general anesthesia (GA) for dental treatment (Leyman et al., 1999). In some tertiary health centers, which are the only place to refer individuals with moderate-to-severe disabilities, up to 60% of the patients have required GA for treatment (Sigal et al., 1988). Dental illness can sometimes negatively affect the success of medical treatment as in the case of children with certain cardiac and hematological conditions (Parry and Khan, 2000). Their dental care is of vital importance because of the risk to their health, or even to life (Parry and Khan, 2000).

Most medications needed by the children who have Special Health Care Needs (CSHCN) can cause some undesirable side effects, such as xerostomia, gingival enlargement, and intrinsic and extrinsic tooth discoloration. The incidence of caries has also been shown to increase by those medications that contain sweeteners. Generally, it is agreed that the group of the pediatric population with special needs holds higher rates of periodontitis, gingivitis, and poor oral hygiene (Boraz, 1989; Mitsea et al., 2001; Ciamponi and Guare Rde, 2003).

In the context of services, policies, research, and training, children and parents with special health care needs participate many of the similar overall matters and needs, and variations between health situations increase other significant policy problems. The comprehensive interdisciplinary team care including oral health concerns, primary care "medical homes" for health services coordination and family needs are essential to all the SCHCN's requirements, and standard monitoring of oral health by a "dental home" or another relevant oral health source (Mouradian et al., 2001).

Disease prevention or health promotion studies are very restricted in the meaning of species groups, and it may not be suitable to extrapolate from the general population. Statements from this huge, varied population among individuals with different social situations are hard to aggregate. Despite these difficulties, the state and national data collection is required. The majority of developmental disability literature reports on clinical experience and articles. There was an excess of work to be accomplished in this area (Mouradian et al., 2001). It is important to highlight in that point that even if their oral status does not demand special treatment, they should receive preventive care as part of complete care for not being at risk of having any oral disease which can compound their situation in many ways (Mouradian et al., 2001).

In addition to that, some studies report that CSHCN were less likely to attend regular dental appointments than their healthy peers (Desai et al., 2001). Only a small portion of these children was taken for regular dental check-ups and preventive interventions. When they were attended for dental treatment, the extraction of their caries teeth was more probable than the restorative treatment (Bradley and Mcalister, 2004).

Various epidemiological researches have attempted to determine the treatment needs of patients with special care and assess differences in need with comparison to the general population to reinforce the further interest of the dental community (Feldman et al., 1997; Nunn, 2000).

Several organizations have made suggestions for the use of fluoride, as British Society of Pediatric Dentistry (Rayner et al., 2003), the Centers for Disease Control and Prevention (CDC) in the USA (CDC, 2001), Scottish Intercollegiate Guidelines. Network (SIGN, 2000, 2005), European Association of Pediatric Dentistry (EAPD) (Marks and Martens, 1998), World Health Organization (WHO, 1994), and the Australian Research Centre for Population Oral Health (ARCPOH, 2006). Those are based on the literature review and the opinions of experts.

Also, there was a national study conducted in America about general dentists care of children whose data offered a unique opportunity to gauge the profession's care of children who also have special health care needs (Casamassimo et al., 2004). The results of that study were on the effect of education support to the positive effect of education on the possibility of caring for these patients and the conclusion that-dentists who had not been presented to hands-on and lecture were less likely to care for them. It is also supporting to note that dentists who had been educated in providing this special care observed fewer barriers to providing care to special needs patients which of course reinforces the previous author's claim for more knowledge and training needed. The findings, also, from the same national survey indicate that lower than one in ten general practitioners often observe children with cerebral palsy, mental retardation or medically compromised confirming that dental care is one of the common significant unmet health care needs of this population (Casamassimo et al., 2004; Siegal, 1985).

It is also demonstrated that often the dental needs of these special care patients are reduced by both their carers and the dental profession, and there is need of a system that will ensure that these people will be targeted as a group in particular need of preventive care, access for dental care, for care under general anesthesia when needed, and not been neglected as dental patients (Hennequin et al., 2000).

In that essence, individuals with special needs have periodontal disease, poor oral hygiene, fewer remaining teeth, and more untreated caries. In dental terms, the major dental academies highly recommend for the early intervention and prevention examinations for children with special needs.

4.2. Dental caries

Dental caries, also known as tooth decay, is an extremely common and multifactorial disease involving cariogenic and non-cariogenic bacteria, salivary components (enzymes, proteins, phosphate, calcium, fluoride) and nutritional sources of fermentable carbohydrates (glucose, sucrose) (Selwitz et al., 2007; Hicks et al., 2003). Although its incidence has dropped in most developed countries, the disease remains a significant issue for public health (Selwitz et al., 2007). It is an added burden on CSHCN who have an increased risk of developing caries due to the high sugar content in their medications, regular consumption of cariogenic foods and poor salivary flow.

The natural cleansing mechanisms through the lips, tongue, and cheeks during chewing and swallowing are missing during the stage of the tooth eruption (Carvalho, 2014). The occlusal surfaces of erupting teeth are especially affected by the reduced ability of cleaning (Carvalho et al., 2016) that leads to the accumulation of bacteria and food residues in pits and fissures and the production of a biofilm, demineralization, and caries.

The most susceptible teeth to caries attack are molars and premolars. The elevated susceptibility to caries of these teeth is immediately relevant to the morphology of their occlusal surface, which avoids both of saliva and toothbrush from chemically cleaning. Therefore, the pit and fissures are the most susceptible regions for carious lesions and require special prevention.

The caries risk factors include biological, physical, environmental, behavioral, or lifestyle variables such as elevated cariogenic bacteria, insufficient salivary flow, inadequate exposure to fluoride, poor oral hygiene, lack and inadequate methods of feeding infants.

The early appearance of the caries process is a tiny spot of demineralized (soft) enamel at the tooth surface, frequently concealed from view in the fissures and pits of teeth or in between the teeth. The decay extends under the softer, sensitive part of the tooth beneath the enamel (dentine). The damaged enamel will then collapse, and the tooth will be gradually destroyed. Caries may also attack the roots of the teeth if the gum recession is exposed.

Tooth decay is a progressive mechanism in the hard tissues of the tooth, owing to the disruption in the balance of the demineralization-remineralization processes, the acid pH level triggered by the bacterial deposition (plaque) on the teeth surface. This chronic mechanism begins on the plaque-covered teeth surface and develops into the deeper layers. The initial caries formation stage is reversible, but irreversible destruction is created in time. If the predominance of chemical processes that trigger demineralization leads to caries formation, the original lesion (white spot lesion) is created first. The lesion is limited in this phase to the superficial enamel layers, the disease is reversible, and may even be remineralized from the saliva. When the pH-level of the oral cavity and plaque decreases, calcium and phosphate ions are leached out of the enamel, resulting in demineralization.

The mechanism for the formation of dental caries is basically clear. The plaque on the tooth surface is a bacterial layer that produces acids by metabolism (Loesche, 1986; Loesche et al., 1972), such acids can destroy the calcium and phosphate minerals of the enamel or dentin in the tooth. To be accurate, when metabolizing of fermentable carbohydrates occurs, specific bacteria inside the plaque are acidic; that is, they generate acids, in a method known as demineralization.

Demineralization is a reversible process; its dynamics are determined primarily by the present pH concentrations in the enamel environment. If the pH level falls below a critical level (5,5), demineralization; the process is turned over above this critical level, remineralization can be seen. The white spot lesions will discolor without interference, the enamel prisms collapse in the center, and the lesion advances into the deeper layers of the teeth. The mechanism is irreversible from this stage on, filling treatment is stated. According to these, the formation of caries requires four significant factors (Figure 2):

1. Host (tooth surface): It may be more or less prone to caries depending on the characteristics of the tooth. The less acid-resistant it is, the higher the chances of decomposition of the tooth. This can be affected by age, low consumption of fluoride, or recession of the gum. Also determining the strength of the tooth is the flow of saliva and the buffering ability. With multiple and exaggerated grooves, demineralization is also probable to evolve in teeth.

2. Substrate (food): If the food is retained in the mouth for too long due to an absence of dental hygiene, it helps to increase the risk of caries. Like sugars, sticky foods and saccharose products make things worse, while tooth-cleaning foods such as apple assistance avoid cavities. The diet and proper oral hygiene are therefore essential for keeping the teeth away from caries.

3. Bacteria: The count of bacteria relies on the structure of the plaque, oral hygiene, and fluoride use. Chances of developing tooth decay increase significantly when microbial loads are greater, and plaque is not removed by brushing, to eliminate bacteria current in plaque and strengthen the tooth surface, brushing and flossing are a must, as well as using fluorid. The two most frequently bacteria which cause of dental cavities are Lactobacillus and Streptococcus mutans.

4. Time: Because of the slowness of the demineralization process, a significant amount of time is needed to develop tooth decay. Time is an advantageous characteristic because it allows the topic to respond to a microflora change or the early phases of caries.

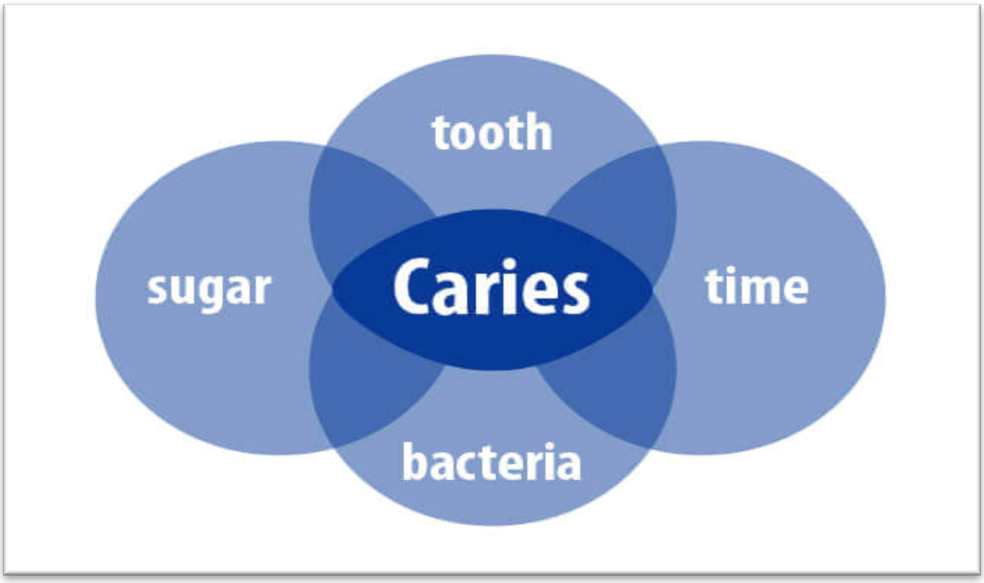


Figure 2: Factors required in the formation of caries (https://www.karex.com/en-de/dental-care/what-is-caries).

The method of dental caries creation begins when the structure of enamel is disrupted after the dental biofilm has been produced (Hannig et al., 2004) (Figure 3), and when the pH of the biofilm fluid decreases rapidly from a pH of (7,0) to a pH of less than (5,0) along with the interface between the enamel surface and biofilm. The critical pH about (5,5) at which the enamel is dissolved.

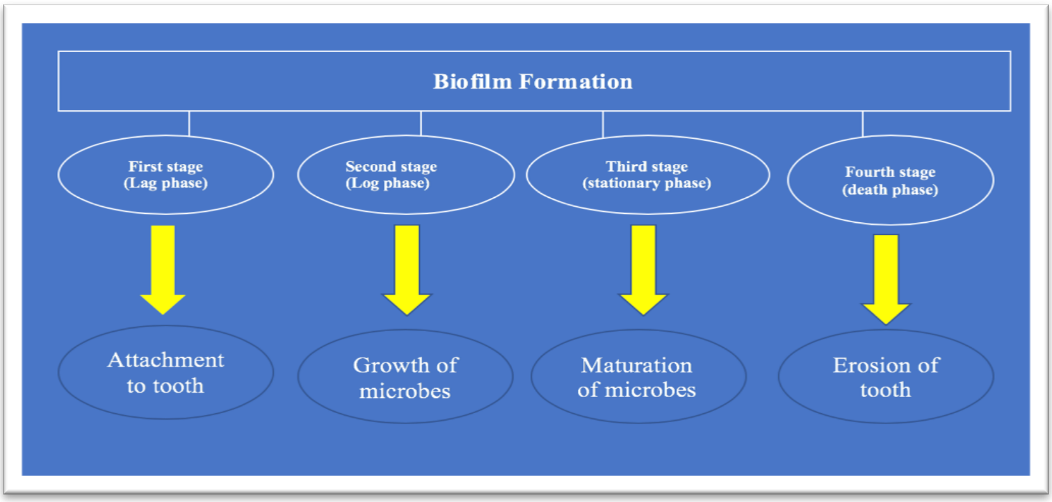


Figure 3: Stages of dental biofilm formation.

After the challenge of the cariogenic acid, the remaining pH of the dental plaque is reestablished, and a factor in the remineralization of the enamel affected is no longer the driving strength of the hydrogen ion concentration (Featherstone et al., 2004). Also, high levels of calcium and phosphate in biofilms, saliva or artificial calcifiers adversely affect the remineralization of enamel (Hannig et al., 2004; Hicks and Flaitz, 2007; Westerman et al., 2006). High calcium and phosphate concentrations lead to fast precipitation on the enamel surface of calcium-phosphate mineral phases, this intervention includes holes that would enable passage to demineralized subsurface enamel, additional restricting the remineralization of the underlying demineralized lesion in sub-surface of enamel due to the solubility limitations of calcium and phosphate minerals in the solvent stage of the biofilm at impartial pH. Raising the levels of phosphate and calcium in the biofilm creates mineral phase deposition resembles to that noticed with the accumulation of tartar.

In summary, the pathological agents, including acidic bacteria (Lactobacilli and Mutans Streptococci), dysfunction of saliva, and nutritional carbohydrates, are associated with the development of caries. Factors of protection including calcium, protein, and phosphate, saliva fluoride, salivary flow, and antibacterial elements or agents may balance, reverse, or prevent dental caries. Figure 4 demonstrates the dynamic process of caries. If appropriate steps are instituted, the balance can be inclined to the remineralization process, and can avoid tooth caries which is clinically detectable.

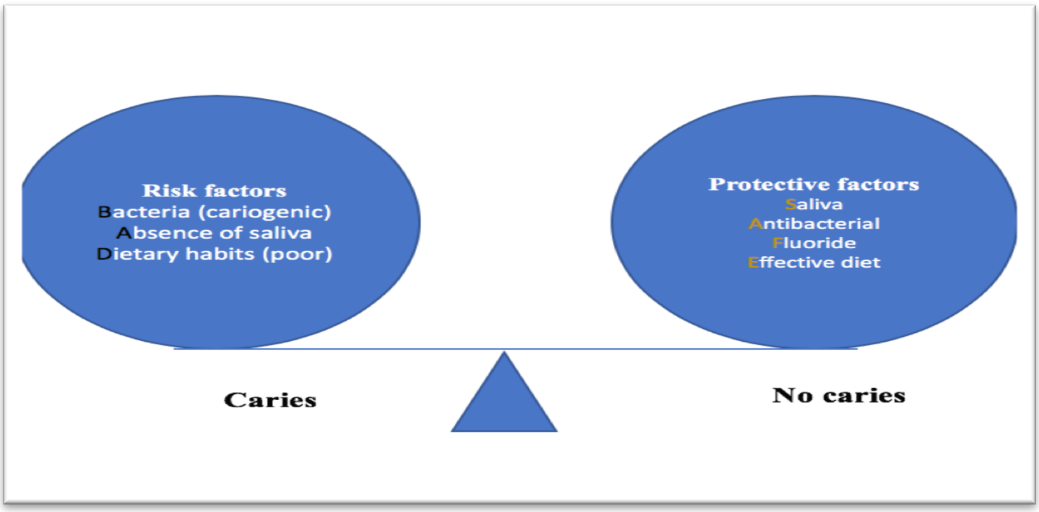


Figure 4: The balance between risk and protective factors in the caries process.

4.3. Fluoride

The most important constituent used in caries prevention is fluoride, which exists naturally in soil, food, and water. It is also presented synthetically for use in drinking water, mouthwash, toothpaste, and various chemical products, e.g., glass ionomer restorations, silver diamine fluoride, and others. Fluoride can inhibit metabolism and bacterial growth in the dental plaque (Płuciennik et al., 2013).

Fluoride is received in two forms: systemic and topical. Systemic fluoride is absorbed inside the body and becomes merged to forming teeth structure. Systemic fluorides can also supply topical protection for teeth because the saliva contains fluoride, which is continuous washes the teeth. Systemic fluorides involve water fluoridation or dietary fluoride supplements in the form of tablets or drops. Topical fluoride works to strengthen teeth already present in the mouth and at the same time making them more resistance to decay. Topical fluorides include kinds of toothpaste, mouth rinse, and professionally applied fluoride therapies.

The effectiveness of topical fluoride in the prevention of dental caries depends on;

a) The concentration used for the fluoride,

b) The period and frequency of application, and to a certain extent,

c) The specific compound of fluoride that used.

According to the Centers for Disease Control and Prevention (CDC), the medium number of decay or missing teeth in 12-year-old children in the United States decreased by 68 percent of the late 1960s through the early 1990s. This was the result of providing fluoridated water to and increasing in communities and adding fluoride in toothpaste and other dental products

The fluoride presents a substantial part in primary and secondary caries prevention “Primary Prevention- trying to prevent the individual from getting a disease. Secondary prevention- trying to detect a disease early and prevent it from getting worse and remineralization of enamel lesions (Garcia and Hicks, 2008). In order to limit demineralization, the appearance of fluoride in biofilm is essential in the occurrence of a little amount of fluoride (0,03 to 0,08 parts per million) (Hannig et al., 2004; Westerman et al., 2006; Hicks and Flaitz, 2007). The fluoride works as a catalyst and raises the ratio of Hydroxyapatite (HAP) and fluoridated HAP production.

The production of fluoridated HAP generates minerals that maintain acid to a similar range as fluorapatite (FA) (Hicks et al., 2004; Featherstone, 2004). Fluoride which presents at saliva, or exogenous sources, such as fluoride mouth rinses, varnish, gel, and toothpaste is taken up preferentially by biofilms, reduces the influences of an acidogenic challenge and promotes remineralization when the stable pH back to 7,0. However, similar to increased concentrations of calcium and phosphate in biofilm, saliva and synthetic calcifying fluids, extreme levels of fluoride guide to active mineral precipitation on the enamel surface and obturation of the surface enamel pores that interact with the underlying demineralized lesion, this process further ends the remineralization of the subsurface demineralized enamel. There is an optimal level of calcium, phosphate, and fluoride in dental biofilm, saliva and synthetic calcifying fluids that allow for remineralization of the enamel lesion to its sufficient extent.

The first theories related to the fluoride action mechanism were based solely on its pre-eruptive impact. Arnold was the first author in 1957 to mention the posteruptive effect of fluoride in drinking water and the capacity of topical fluoride to decrease caries incidence (Mellberg et al., 1983).

The mechanism by which fluoride rises caries resistance can result from both systemic and topical fluoride applications and can be widely grouped as follows: increased enamel resistance, increased maturation rate, remineralization of incipient caries, interference with microorganisms and enhanced tooth morphology (Mellberg et al., 1983). Fluoride has three principal topical mechanisms of action:

1- Enhancing remineralization, with adsorption of the crystal surface and attracting calcium ions, followed by phosphate ions, leading to the creation of new minerals.
2- Inhibiting demineralization during an acid challenge when fluoride is present on the crystal surfaces.

3- Inhibiting bacterial metabolism when the plaque is acidified and after spreading of fluoride into the bacteria as hydrogen fluoride.

The enamel of the tooth is dissolved whenever sugar is ingested by decreasing the pH in dental plaque due to acid creation. Nevertheless, if fluoride is available in the biofilm fluid, and the pH is not less than the critical pH, hydroxyapatite (HAP) is dissolved and at the same time, fluorapatite is created (Figure 5). Besides, fluorapatite is stored on the enamel surface layer while HAP is dissolved from the subsurface. Fluoride has this indirect impact in reducing enamel demineralization when pH falls is supplemented by its normal affect on remineralization when the pH increases and the redeposition increases of Ca and $PO4^{3-}$ occur in the biofilm-fluid on demineralized enamel (Cury and Tenuta, 2009). The accessibility of calcium and phosphate limits its capacity to encourage remineralization. Hence, this can be the limiting factor (Reynolds et al., 2008). On the smooth surface caries, fluoride may be extremely efficient, but the effects on pit and fissure caries are constrained.

The concentration of fluoride in oral fluids is retained by releasing this ion from bioavailable reservoirs on the teeth, oral mucosa, and dental plaque, most importantly due to its connection with the caries mechanism. Reservoirs of oral fluoride seem to be of two forms:

1-Biological reservoirs, especially fluoride (about dental plaque) retained by calcium-fluoride bonds to bacteria or bacterial fragments;

2- Mineral reservoirs, especially calcium fluoride or 'calcium-fluoride-like' deposits contaminated with phosphate.

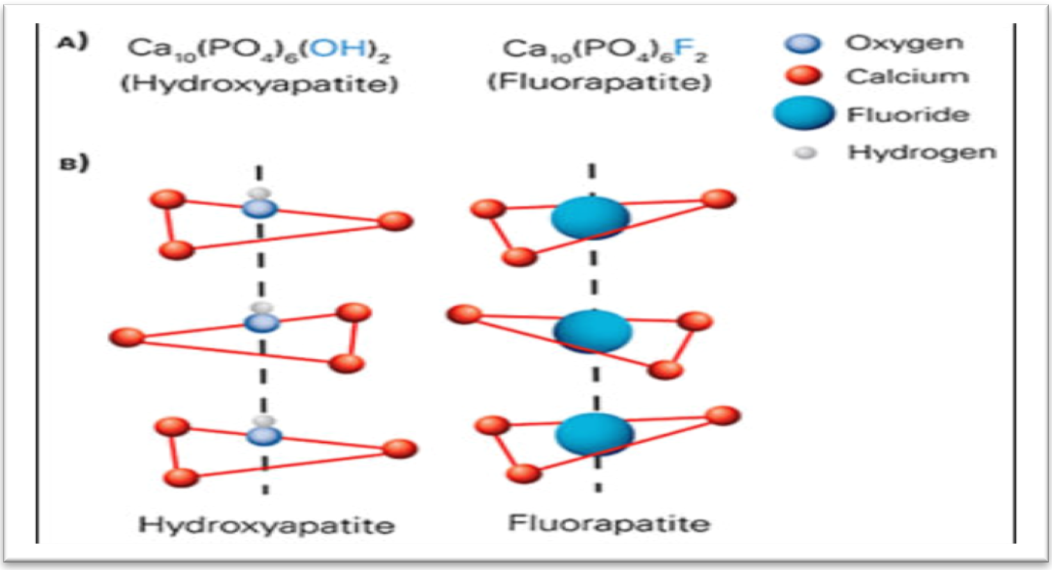


Figure 5: Fluorapatite Formation. (A) Fluoride ions (F–) replace hydroxyl ions (OH–) in hydroxyapatite to form fluorapatite in the tooth enamel. (B) A portion of the apatite crystal lattice is depicted showing the replacement of hydroxide for fluoride. Adapted from (Posner, 1985).

The fact that calcium mediates all these reservoirs means that their formation is restricted by the low calcium concentration in oral fluids. The formation of these fluoride reservoirs after topical fluoride applications can be significantly improved by using novel processes to overcome this restriction. Although these rises are linked with substantial rises in salivary and plaque fluoride and therefore a prospective boost in cariostatic impact, it is uncertain whether such modifications are associated with rises in the quantity of these reservoirs or changes in the types of fluoride deposits created (Buzalaf et al., 2011). Fluoride's capacity to avoid and arrest caries has been widely investigated.

In this research, it was mentioned about two types of fluoride sources:

1- Silver diamine fluoride SDF 38%;
2- Glass ionomer sealant (GC Fuji TRIAGE).

4.3.1. Silver Diamine Fluoride (SDF):

SDF is a simple, low-cost, and a colorless aqueous solution which contains 25 percent silver, 8 percent ammonia, and 5 percent fluoride (Figure 6). The benefit of silver works as an antimicrobial, ammonia works to stabilize the high concentrations in solution and fluorides use to promote remineralization, with a pH of 10. SDF can create an alkaline environment that makes it possible for the covalent bonds of phosphate groups on proteins and thus provides a favorable atmosphere for the development of crystallites, this is a mechanism that attaches the phosphate to the dentine collagen in saliva. After the phosphate in the collagen has been integrated, it contributed to the binding sites for calcium ions, thereby facilitating the apatite nucleation onto the collagen. SDF 38% is existing in an 8 mL bottle (Advantage Arrest Silver Diamine Fluoride 38%, USA) (Figure 7) and indicated for preventing, arresting dental caries and immediate relief of tooth hypersensitivity. Each bottle contained 250 drops, can treat more than 1,250 surfaces; each drop can treat five surfaces.

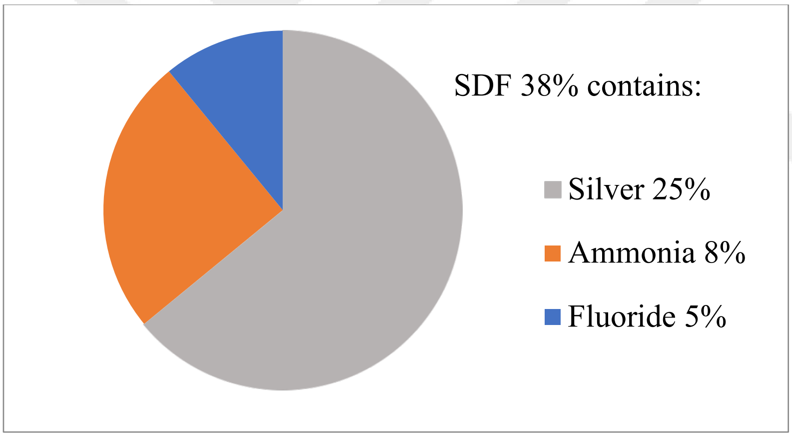


Figure 6: Components of Silver Diamine Fluoride 38% (25% Silver, 5% Fluoride, 8% Ammonia)

Silver Diamine Fluoride has been handled in Japan for over 50 years to arrest caries and decrease tooth hypersensitivity in primary and permanent teeth. During the previous decade, many other countries, including China and Australia, have been utilizing this compound with equivalent success, as marketed in the United States.

SDF is used for caries prevention and arrest as alternative treatments. (Peng et al., 2012). In 2014, SDF was approved by the US Food and Drug Administration as a treatment for dentinal sensitivity. SDF had been used off-label for caries arrest; however, it was recently approved by the American Dental Association. CDT 2017 Dental Procedures code (D1354) as interim caries arresting medicament.

Figure 7: Advantage Arrest Silver Diamine Fluoride 38%, USA.

Clinical studies have demonstrated the effectiveness of SDF in childhood caries prevention and arrest. Semiannual applications of SDF at 38% concentration have been recommended (Sharma and Puranik, 2015). SDF was suggested for difficult lesions and increased incidence of caries patients, including medical or behaviorally complicated individuals, individuals requiring numerous therapy visits and patients without any access to dental care (Horst et al., 2016). When comparing it with topical medicament treatments, such as four-times-per-year applications of fluoride varnish, or chlorhexidine varnish, they have found better caries prevention with annual application of SDF (Llodra et al., 2005; Zhi et al., 2012; Shah et al., 2014; Sharma and Puranik, 2015).

From the laboratory studies, the antibacterial properties of SDF were investigated in eleven studies, and they concluded that SDF was bactericidal to cariogenic bacteria, especially on the Streptococcus mutans. In Addition to that, it inhibited the growth of cariogenic biofilms on teeth (Chu et al., 2012; Mei et al., 2013). SDF possesses a potent inhibitory effect on the activity of matrix metalloproteinases (Mei et al., 2012) and cysteine cathepsins (Mei et al., 2013). The other twenty laboratory research mentioned the remineralization of demineralized enamel or dentine by SDF, and they discovered that mineral loss of demineralized enamel and dentine was decreased after SDF treatment, due to a highly mineralized surface abundant of calcium and phosphate was shaped on arrested carious lesions.

In addition, there were four studies mentioned the effect of SDF on dentine collagen, and they noticed that SDF not only promotes the remineralization of demineralized enamel and dentin and inhibits demineralization but also inhibit degradation of the dentin collagen in caries-affected dentin (Thanatvarakorn et al., 2016; Zhao et al., 2018).

The main downside of SDF is the nonesthetic permanent black discoloration of the arrested lesion (Figure 8). That could be a deterrent for patients who have esthetic concerns, and this can be overcome with the eventual restoration of the tooth. Also, the staining can occur if accidentally applied to other tissues (e.g., gingiva, oral mucosa), but it is temporary and usually resolves several days after exposure. Permanent staining can occur on clothing and countertops. As far as possible, when SDF touches the skin, the material should be absorbed by gauze and should be avoided from the wipe because that can be spread the material further, and a bigger staining spot can occur. Then the region should be carefully washed with water and soap, or using iodine tincture, or 3% peroxide, which helps the staining of skin to disappear.

If there is a history of silver allergy, SDF is contraindicated and should be cautiously used with ulceration or stomatitis. Although, SDF is safe, dentists should exercise caution with an asymptomatic tooth, partially necrotic or, otherwise pulpal involved tooth.

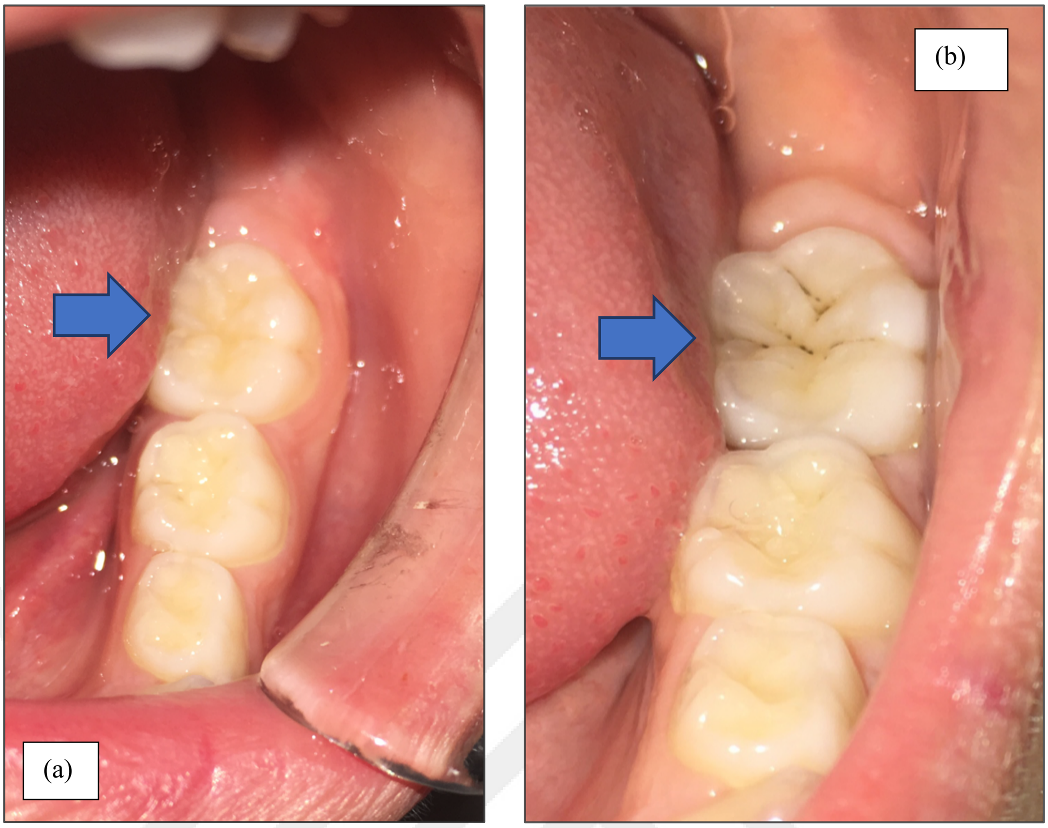


Figure 8: photographs showing the appearance of the lower first permenant molar (a) before and (b) after application of SDF on the occlusal surface, mean of the DIAGNOdent pen readings for this tooth was 18 at baseline and 20 after one year (Marmara University, Istanbul, Turkey, 2017-2018).

4.3.2. Glass Ionomer Sealant GIS:

In the 1960s, dental sealants were applied, mainly in the pits and fissures of the occlusal tooth surfaces, to help prevent dental caries. Sealants work to avoid the development of bacteria that can end up causing tooth decay. Evidences indicate that fissure sealants prevent caries relative to non-sealants are efficient in children and adolescents. Practitioners have been attempting to find conservative ways to treat pit-and-fissure defects for years. In 1955 Buonocore guessed the ability to prevent caries by sealing pits and fissures with a bonded resin material, and he and a co-author published a paper on pit-and-fissure sealants in 1967 (Cueto and Buonocore, 1967). Since then, there have been hundreds of clinical and laboratory studies documenting the effectiveness of pit and fissure sealants.

Application of sealants in pits and fissures is still one of the most commonly accepted techniques under the present cavity prevention programs, because of the favorable situations in which 80 percent of dental caries develop in the pits and fissures of the tooth, and because fluoride is not able to act in this location (Flório et al., 2001; Feigal, 2002; Subramaniam et al., 2008). Effectiveness may, however, be correlated to caries incidence level of the population. The application of high viscosity GIC as sealants has newly developed due to their increasing retention rate concerning conventional GIC and to their fluoride releasing capacity (Beiruti et al., 2006). The authors of a Cochrane database systemic review concluded that sealants placed on the occlusal surfaces of permanent molars in children and adolescents lessen caries up to 48 months when compared with no sealant (Ahovuo et al., 2013).

Cement Glass-Ionomer (GIC), created in 1972 by Wilson and Kent. This material is continually improved and has become widely known because of the adhesion and ability to release fluoride as a restorative material. Laboratory studies have mentioned that glass ionomer cement can serves as a rechargeable reservoir, providing a continuous low level of fluoride due to uptake from fluoridated solutions, mouthwashe and toothpaste (Yip et al., 1999).

Glass Ionomer Sealants (Fuji TRIAGE) (Figure 9) have developed from glass ionomer cement, which can adhere immediately to tooth substance (Figure 10). Glass ionomer materials release fluoride over time and have the benefit of being less sensitive to moisture contamination than resin-based materials (Poggio, 2016). GIS should be applied to pit and fissure surfaces that are sound or that have demineralization that appears confined to the enamel. The efficiency of the sealing procedures depends on the correct application technique. Following an operative protocol will assure the longer-lasting retention of the sealant on the occlusal surface and subsequently increases the protection against caries. To improve penetration and adherence of the material, a gloved finger with a thin layer of petroleum jelly (vaseline) used to push glass ionomer sealant into pits and fissures. After 60 seconds of pressure, the excess material removes and the material cover with a surface protector.

Figure 9: Glass Ionomer (GC Fuji TRIAGE) CAPSULE.

An in-vitro study discovered that GC Fuji TRIAGE could release 213 mg/mm2 of fluoride in the first day after setting which was twice the amount released by a resin-modified glass ionomer (Bayrak et al., 2010). Also, there was another study proposed that fissures sealed with glass ionomer are more resistant to demineralization than free fissures, even after macroscopic sealant loss, this may be the result of the mixed effect of fluoride released by glass ionomer and residual material at the bottom of the fissures (Seppä and Forss, 1999). The advantages of the high concentration of fluoride ion released from GIS may assist in the arresting of active caries and preventing new dental caries development, which is easy to handle, and the etching with acid is not necessary, elevated filler content, optional controls, radiopaque, and biocompatible (Antonson et al., 2006). So, it will likely benefit individuals with special health care needs, patients diagnosed with salivary dysfunction, medically compromised patients, the deprived, and individuals with severe early childhood caries. It can also be useful to treat lesions that are otherwise difficult or untreatable by conventional techniques (Horst et al., 2016). The advantages of dental sealants for pits and fissures are dependant on retention and integrity over time. Despite, the retention of GIS is not permanent, the local discharge of fluoride from the sealant material could enhance this physical impact (Lobo et al., 2005).

Disadvantages of this material: Tacky, sticks to instruments and relatively low diametral tensile strength.

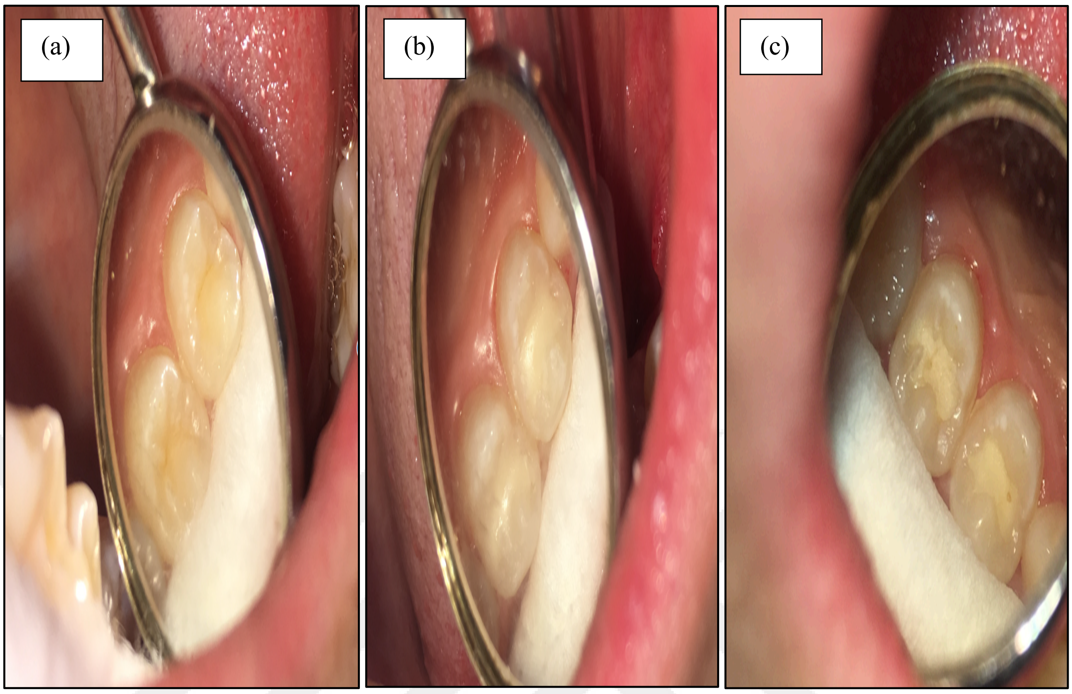


Figure 10: Three photoraphs showing upper right premolars teeth (a) before, (b) after application of GC Fuji TRIAGE and (c) the retention of material after one-year follow-up, (Marmara University, Istanbul, Turkey, 2017-2018).

5. MATERIALS AND METHODS OF RESEARCH

5.1. Materials

5.1.1. Patient selection inclusion and exclusion criteria:

The Ethics Committee of Marmara University in Istanbul, Turkey approved with number 2017-109 this project. Written informed consent in Turkish was signed by the parents of all individuals who participated in the research before starting any examination.

The study included children with special health care needs who presented to our dental clinic for a comprehensive dental examination, at the Department of Pediatric Dentistry of Marmara University in Istanbul, Turkey. It was carried out between 2017 and 2019. The criteria for selection included minimum 20 children with special health care needs of both gender, and age from 6-14 years. All patients included in the study take prescription medications every day, and at least each child has two erupted permanent premolars and or /molars one tooth on the right side and another tooth on the left side of the mouth with DIAGNOdent results from 0-20 (Table 1). The only sound occlusal surface of molars and premolars teeth were considered in the study.

The candidates were excluded if they were non-cooperative children, they were using any type of tooth desensitizer, had received a fluoride varnish treatment within the last month, they have painful sores areas on gums (i.e., Ulcerative gingivitis) or anywhere in the mouth (i.e., Stomatitis). Also, those who were not taking prescription medications every day, individuals with known sensitivity to silver or other heavy-metal ions, and DIAGNOdent results 21-99 (Table1) were excluded.

Table 1: Manufacturer's cut-off points for DIAGNOdent pen used in this study

Fluoroscence values	Clinical criteria
0-5	No demineralization
6-14	Outer enamel demineralization
15-20	Inner enamel demineralization
21-99	Dentine demineralization

5.2. Method

This study was approved by the Ethics Committee of the Faculty of Dentistry, the University of Marmara, Department of Pedodontics and was carried out between 2017 and 2019. The parents of all children provided signed informed consent before the clinical interventions. All children with special needs and their parents received general information about oral hygiene and dietary habits regarding the prevention and control of dental caries.

5.2.1. Sampling

From 1500 screened participants 23 children with 115 teeth met the inclusion criteria, this split-mouth design study conducted to (14 males and 9 females), aged 6 to 14 years old. 7 of them with asthma, 3 with gastrointestinal disorder (GI), 2 with renal disorders, 3 with epilepsy,1 with joint disease, 3 with cardiac disorders, 2 with a psychiatric disorder, and 2 with haematological disorders.

5.2.2 Oral health and caries experience assessment

All participants were examined while sitting in a dental chair with the use of a dental mirror, and a blunt dental probe. Also, a mouth prop with conscious athetotic patients, as the jaws may suddenly clench. Epilepsy falls and sudden uncontrolled movements also render them prone to dental injury.

The examinations were performed on the individual's teeth, including the use of oral hygiene index (OHI-S) and DMFS-dmfs scores. Specifically, for dental and oral assessment the subject's teeth examined visually and tactilely under artificial illumination, according to WHO (World Health Organization) procedures (WHO, 1997); caries prevalence assessed using the Decayed, Missing and Filled (DMFS) index is used to describe DMFS for permanent tooth, the components are:

D component: Used to describe (Decayed teeth) which include:

- Carious tooth.
- Filled tooth with recurrent decay.
- Only the root is left.
- Defect filling with caries.
- Temporary filling.
- Filled tooth surface with another surface decayed.

M component: Used to describe (Missing teeth due to caries) other cases should be excluded these are:

- Tooth that extracted for reasons other than caries should be excluded,
- Unerupted teeth.
- Congenitally missing.
- Avulsion of teeth due to trauma or accident.

F component: Used to describe (Filled teeth due to caries). Teeth were considered filled without decay when one or more permanent restorations were present and there was no secondary (recurrent) caries or other area of the tooth with primary caries. A tooth with a crown placed because of previous decay was-recorded in this category. Caries status was assessed visually and with the aid of DIAGNOdent pen.

Obtaining oral hygiene of the patient with the Simplified Oral Hygiene Index (OHI-S) by Greene and Vermillion (Greene and Vermillion,1964) was done. (OHI-S) composed of two components:

1- Simplified Debris Index.
2- Simplified Calculus Index.

This index measures the extension of debris and calculus. The six surfaces were examined (**Figure 11**) for the OHI-S are selected from four posteriors (16, 26, 46, 36) and two anterior teeth (11,31) and one surface for each tooth lingual surface for lower posterior teeth and the buccal for the others. Partially erupted, crowned and fractured teeth should be excluded and substitution by the second (17) or third molar. The examination was done by using a mouth mirror and explorer. World Dental Federation (**Figure 12**) for tooth numbering system was used.

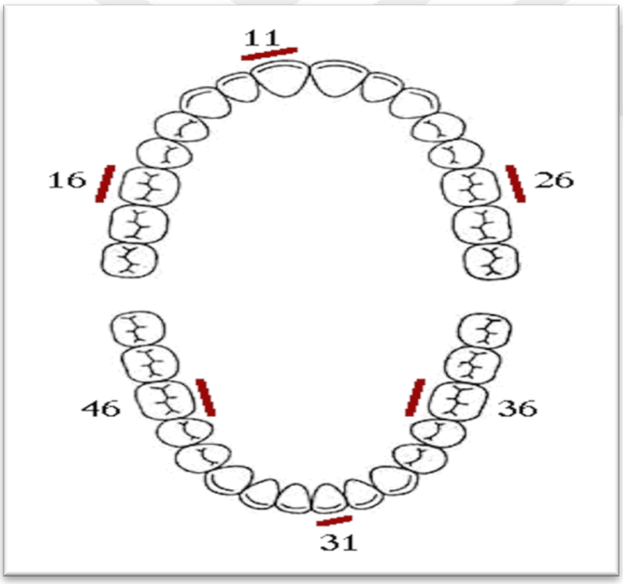


Figure 11: Surface selection for OHI-s

Selected surfaces are examined and scored for the extent of debris and calculus (**Table 2**). The amount of debris was scored as 0 to 3 for each tooth surface depending on the extent to which soft debris or stain covered a tooth surface (**Figure 13**).

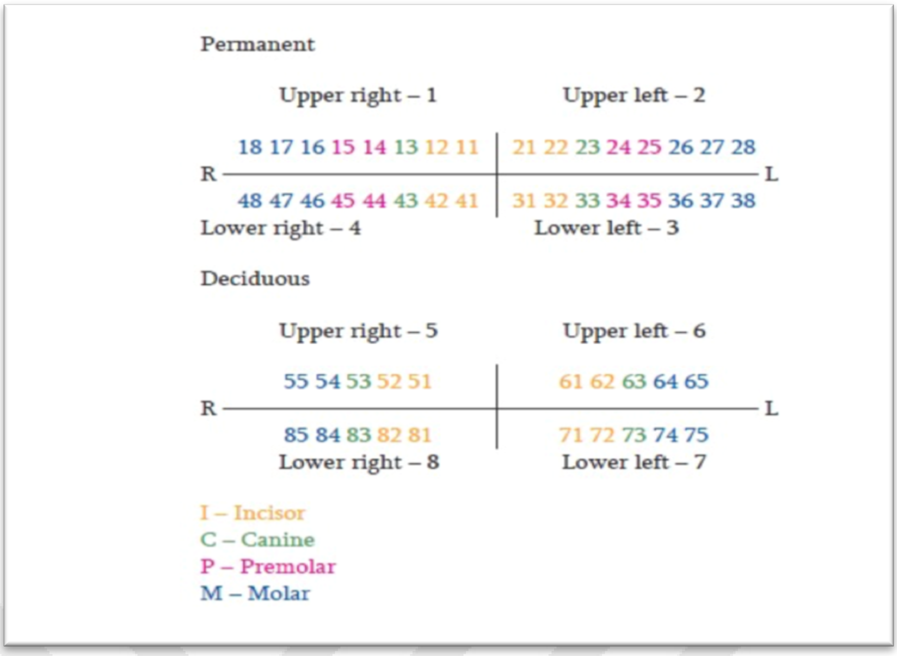


Figure 12: FDI world dental federation notation.

Figure 13: Debris accumulation scores for our study group.

Table 2: Criteria for classifying debris.

Scores	Criteria
0	For no debris or stain present;
1	Soft debris covering not more than one-third of the tooth surface, or presence of extrinsic stains without other debris regardless of surface area covered;
2	Soft debris covering more than one-third, but not more than two thirds, of the exposed tooth surface;
3	Soft debris covering more than two-thirds of the exposed tooth surface.

The amount of calculus is also scored in the same way depending on the degree of supragingival or subgingival calculus covering the tooth (**Table 3**).

Table 3: Criteria for classifying calculus.

Scores	Criteria
0	No calculus present;
1	Supragingival calculus covering not more than a third of the exposed tooth surface;
2	Supragingival calculus covering more than one-third but not more than two-thirds of the exposed tooth surface or the presence of individual flecks of subgingival calculus around the cervical portion of the tooth or both;
3	Supragingival calculus covering more than two-third of the exposed tooth surface or a continuos heavy band of subgingival calculus around the cervical portion of the tooth or both.

After the scores for debris and calculus are recorded, the index values are calculated. For each individual, the debris scores are totaled and divided by the number of surfaces scored. At least two of the six possible surfaces must have been examined for an individual score to be calculated. After scoring for a group of individuals is obtained by computing the average of the individual scores. The average individual or group score is known as the Simplified Debris Index (DI-S). The same method is used to obtain the calculus scores or the Simplified Calculus Index (CI-S). The average individual or group debris and calculus scores are combined to obtain the Simplified Oral Hygiene Index (J. G. Greene & Vermillion, 1964). The CI-S and DI-S values may range from 0-3, the OHI-S values from 0-6. The oral hygiene of each child was classified as 'good' when the OHI-S score was 0–0,9, 'fair' when it was 1,0–1,9 and 'poor' when it was 2,0 up to 6.

5.2.3. Clinical Procedure

The teeth surfaces were cleaned thoroughly by using a dry bristle brush in a slow handpiece (**Figure 14**), isolated with cotton rolls, and dried with air syringe. Surfaces of test sites were examined using DIAGNOdent pen (**Figure 15**) according to manufacturer's instructions.

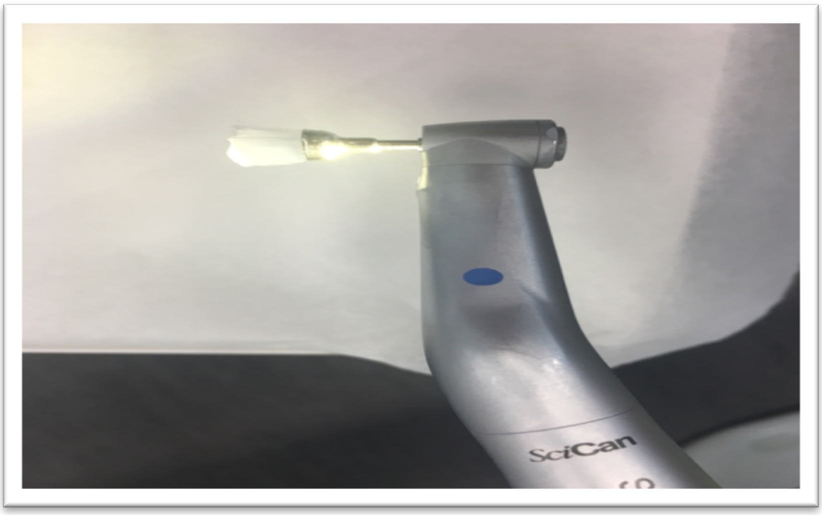


Figure 14: A bristle dental brush in a slow handpiece.

Figure 15: DIAGNOdent pen by kavo, Germany.

Probe ‘2’ (Figure 16) was used under cotton roll isolation and after air drying with an air syringe. Probe ‘2’ was placed perpendicular to the test site and rotated along the fissure to completely scan the area. Baseline reading for each tooth was taken by placing the probe on the sound tooth surface. Only occlusal surfaces of molars and premolars teeth were considered in the study. Three measurements were performed for each tooth, and the mean of them was taken. Then scoring was given according to the cutoff limits given by the manufacturer (Table 1).

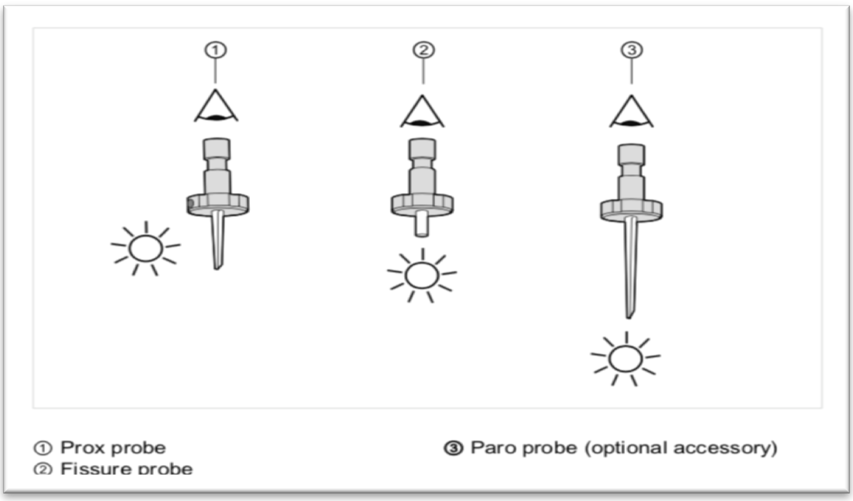


Figure 16: KaVo. DIAGNOdent pen probes

Before starting the procedure, the whole mucosal surface of the oral cavity was covered with petroleum jelly (**Figure 17**), to protect it from mild burning sensation due to SDF, and isolation of the teeth was done with the help of cotton rolls and high-volume suction.

Figure 17: Petroleum Jelly (Vaseline).

Each child selected for the study was received the preventive materials in the form of split-mouth design. Application of the materials was randomly divided into two sides of the mouth by using the coin toss methods, on the left side of the mouth, the application of SDF 38% was done in the following steps: one drop of SDF was pressed out into a dappen dish. A thin coat of SDF was applied by a micro brush (Figure 18). SDF was allowed to dry and cotton rolls removed after 2 minutes.

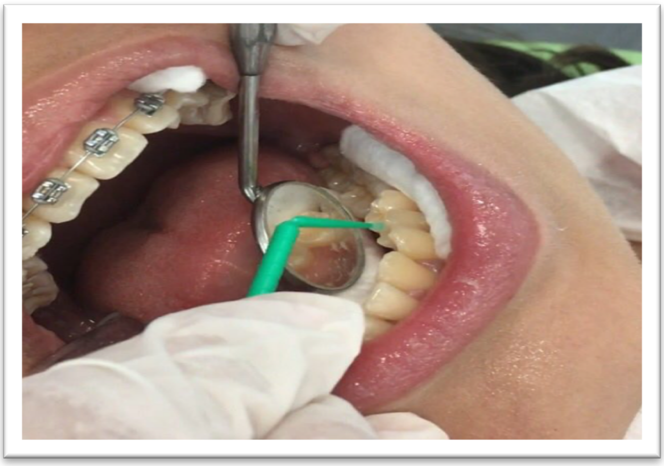


Figure 18: Application of SDF by using a micro brush.

On the contralateral side of the mouth, the sealant (GC Fuji TRIAGE Capsule) was mixed according to the manufacturer's instructions and applied by one operator following the "press finger technique," described in the ART-WHO manual. This technique is used to enhance adherence and penetration of the material, by a gloved finger with petroleum jelly was used to push the material into pits and fissures. After one minute of pressure, the excess was removed, and the material was covered with a surface protector. Teeth were also examined to assess sealant retention at 3-month, 6-month, and 12-month after the sealants had been placed. The sealant retention rate was checked with the Simonsen's criteria. Which is as follows: A score of (C) was given for complete retention, (P) was given for partial retention and (M) was given for missing- no trace for sealant is detectable (Simonsen, 1991).

Patients were instructed not to rinse the mouth and to avoid eating for one hour. Follow up examination was repeated every three months for 12 months. Applications of SDF repeated every six months (two times per year). At baseline and follow-up examinations, the examination with the DIAGNOdent pen (kavo) was done.

5.2.4. Methods of statistical analysis:

Data were recorded in an Excel table using patient names, identification numbers, DIAGNOdent readings, DMFS score, OHI-S score and the retention scores for GIs. All of the analyses were conducted using SPSS (Statistics Package for Social Science, version 22.0 for Windows; SPSS Inc., Chicago, IL, USA).

The measures of mean, standard deviation (SD), median, frequency, percent, 95% Confidence Interval for Mean were used for descriptive statistics. Two-way repeated-measures ANOVA, Paired sample T-test, independent sample T-test, Mann Whitney U test, and Chi-square test were used to determine significant differences in data ($p<0,05$). The dependent variable was whether the tooth was prevented from caries or not at the 3-6-12 month examinations by DIAGNOdent readings, DMFS score, OHI-S score. The independent variables included the child’s disorder type, age, gender, and tooth type.

6. RESULTS

Table 4: The mean age of participants

	Mean	Sd	Median	95% Confidence Interval for Mean	
				Lower	Upper
Age	10,54	2,1	11,46	9,34	11,73

The mean age of 23 participants was 10,45.

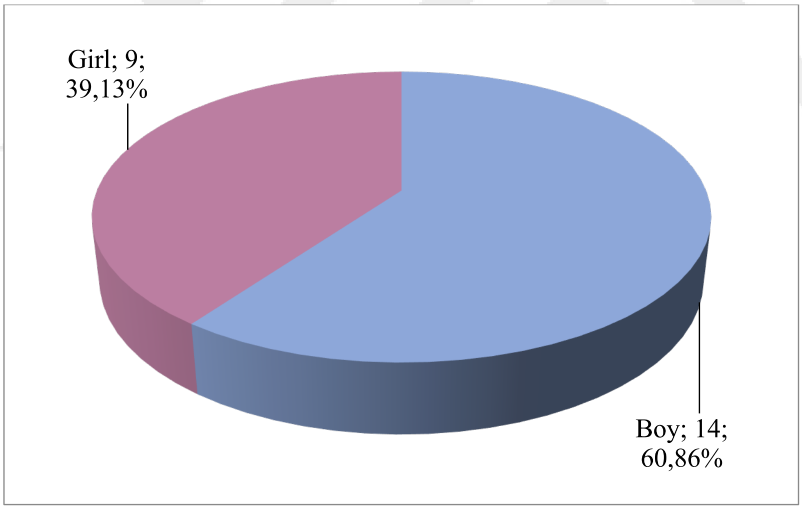


Figure 19: Prevalence of participants, by gender

Gender frequency of 23 participants was 14 males (%60,86) and 9 females (%39,13).

Table 5: Prevalence of disorders types among the participants.

TYPE	No. of patients	Percentage
GI disorders	3	13,04
Asthma	7 n=1 excluded n=6 included	30,43
Blood disorders (including anemia)	2 n=1 excluded n=1 included	8,69
Cardiac disorders	3	13,04
Epilepsy	3	13,04
Joint problems	1	4,34
Renal disorders	2	8,69
Psychatric disorder	2 n=1 excluded n=1 included	8,69
Total	23	100%

The Type and frequency of disorder for the participants: GI disorders frequency was 3 (%13,04), asthma frequency was 7 (%30,43), Blood disorders frequency was 2 (%8,69), cardiac disorders frequency was 3 (%13,04), epilepsy frequency was 3 (%13,04), joint disease frequency was 1 (%4,34), Renal disorders frequency was 2 (%8,69) and psychiatric disorder frequency was 2 (%8,69).

** Because three-children did not arrive for the follow-up examinations, all the statistical and clinical results were conducted for twenty children.

Table 6: Distribution of the studied materials according to tooth numbering system, number (n) and percentage (%) of teeth included in the study.

	SDF		GIS		TOTAL	
Tooth numbering	N	Column N %	N	Column N %	Count	Column N %
14	-	-	13	23,6%	13	12,7
15	-	-	11	20,0%	11	10,8
16	-	-	4	7,3%	4	3,9
17	-	-	1	1,8%	1	1,0
24	12	25,5%	-	-	12	11,8
25	7	14,9%	-	-	7	6,9
26	4	8,5%	-	-	4	3,9
27	1	2,1%	-	-	1	1,0
34	11	23,4%	-	-	11	10,8
35	9	19,1%	-	-	9	8,8
36	3	6,4%	-	-	3	2,9
44	-		13	23,6%	13	12,7
45	-		10	18,2%	10	9,8
46	-		3	5,5%	3	2,9

The frequeccy of tooth number 14 (according to FDI world dental federation notation)(chart1) was 13 teeth (%12,75), tooth number 15 was 11 (%10,78), tooth number 16 frequency is 4 (%3,92), tooth number 17 frequency is 1 (%0,98), Tooth number 24 frequency is 12 (%11,76), tooth number 25 frequency was 7 (%6,86),tooth number 26 was 4 (%3,92), tooth number 27 was 1 (%0,98), tooth number 34 was 11 (%10,78), tooth number 35 was 9 (%8,82), tooth number 36 was 3 (%2,94), tooth number 44 was 13 (%12,75), tooth number 45 was 10 (%9,8) and tooth number 46 was 3 (%2,94).

Table 7: Evaluation of retention rates for GIs according to Simonsen' s Criteria of the studied teeth over time.

Time	C=(completely Retained)	P=(Partialy retained)	M: Missing
Baseline	100 %	0 %	0 %
After 3months	88,23 %	9,8 %	5,88 %
After-6 months	74,54 %	16,36 %	9,09 %
After one year	56,36 %	27,27 %	16,36 %

Retention rates for GIs according to Simonsen' s Criteria for one-year follow-up were:

a. 100% (C) at baseline;
b. 88,23% (C), 9,8% (P), and 5,88% (M) after 3 months of materials applications.
c. 74,54% (C), 16,36% (P), and 9,09% (M) after 6 months;
d. 56,36% (C), 27,27% (P), and 16,36% (M) after one year.

Table 8: Descriptive and inferential analysis of sealant's retention according to Simonsen's criteria:

Groups	N	Simonsen's retention index						Comparison	P-value*	Sig.
		3 months		6 months		12 months				
		Mean	SD	Mean	SD	Mean	SD			
Upper teeth	29	1.250	±0.585	1.483	±0.738	1.552	±0.736	Upper vs lower teeth (3 months)	0.635	NS
								Upper vs lower teeth (6 months)	0.104	NS
Lower teeth	26	1.160	±0.473	1.192	±0.492	1.654	±0.797	Upper vs lower teeth (12 months)	0.651	NS

* Mann Whitney U test

In term of the presence of caries for the teeth with GIS;

a. None of the teeth, even if they had lost the sealant's retention showed caries during clinical examination at 3 months follow-up,
b. 3 of 5 teeth, they had lost retention completely showed caries at 6 months follow-up,
c. One of 9 teeth, they had lost retention completely showed caries at 12 months follow-up.

Table 9: Mean of DIAGNOdent pen readings for SDF and GIS and number (n) of teeth for each side at baseline and follow-up examinations.

	Mean	Sd	Median	95% Confidence Interval for Mean	
				Lower	Upper
D Baseline					
SDF (n=47)	11,55	4,41	11,33	10,21	12,89
GIS (n=55)	10,10	4,33	10,33	8,91	11,30
D 3 Months					
SDF (n=45)	10,30	5,00	9,83	8,78	11,82
GIS (n=53)	9,45	3,56	10,00	8,46	10,43
D 6 Months					
SDF (n=47)	15,23	5,11	15,17	13,67	16,78
GIS (n=55)	12,98	4,96	13,00	11,62	14,35
D 12 months					
SDF (n=47)	10,45	4,20	9,00	9,17	11,72
GIS (n=55)	10,21	4,33	9,33	9,01	11,40

When evaluated in terms of D Baseline (DIAGNOdent readings at the baseline), the mean SDF of the participants was 11,55±4,41 and the mean GIS of the participants was 10,1±4,33.

When evaluated in terms of D 3 Months (DIAGNOdent readings at 3-month follow-up), the mean SDF of the participants was 10,3±5 and the mean GIS of the participants was 9,45±3,56.

When evaluated in terms of D 6 Months (DIAGNOdent readings at 6-month follow-up), the mean SDF of the participants was 15,23±5,11 and the mean GIS of the participants was 12,98±4,96.

When evaluated in terms of D 12 months (DIAGNOdent readings at 12-month follow-up), the mean SDF of the participants was 10,45±4,2 and the mean GIS of the participants was 10,21±4,33.

Table 10: Evaluation of the DIAGNOdent pen values in terms of time difference for each material

		Greenhouse-Geisser; F	P
A two-way repeated measures ANOVA	Time	32,706	*0,001
	Time * Material	1,616	0,192
Material	Time	T-test	P
SDF	D Baseline- D 3 Months	1,728	,091
	D Baseline- D 6 Months	-5,303	*,0001
	D Baseline- D 12 months	,971	,337
	D 3 Months- D 6 Months	-7,742	*,0001
	D 3 Months- D 12 months	-,219	,828
	D 6 Months- D 12 months	8,601	*,0001
GIS	D Baseline- D 3 Months	1,092	,280
	D Baseline- D 6 Months	-3,887	*,0001
	D Baseline- D 12 months	-,336	,738
	D 3 Months- D 6 Months	-5,880	*,0001
	D 3 Months- D 12 months	-1,307	,197
	D 6 Months- D 12 months	5,312	*,0001

When evaluated in terms of Time, difference was found as statistically significant (Greenhouse-Geisser; p=0,001).

When evaluated in terms of Time, difference between materials was not found as statistically significant (Greenhouse-Geisser; p=0,19). In other words, change in time would be the same when SDF or GIS material was used.

When time change was evaluated at SDF and GIS groups with Paired Sample T-Test, higher value of 6^{th} month than other months at both SDF and GIS groups was found as statistically significant ($p<0,05$).

When material difference was investigated according to Time with Independent Sample T-Test, difference between materials at 6^{th} month was found as statistically significant (t=2,26; p=;0,026; $p<0,05$). It was not found as statistically significant for other months (**Baseline** t=1,57; p=0,12;**3 Months** t=0,86; p=0,39; 12 **Months** t=0,41; p=0,69; $p<0,05$).

Table 11: Distribution of caries detection by DIAGNOdent pen at follow-up examinations: Number (N) and percentage (%) of sound and carious teeth

	SDF		GIS	
	N	%	N	%
Gr D Baseline				
No caries (<20)	47	100,0%	55	100,0%
Gr D 3 Months				
No caries (<20)	44	97,8%	53	100,0%
Caries	1	2,2%	0	0,0%
Gr D 6 Months				
No caries (<20)	42	89,4%	52	94,5%
Caries	5	10,6%	3	5,5%
Gr D 12 months				
No caries (<20)	46	97,8%	54	98,2%
Caries	1	2,2%	1	1,8%

Difference between the groups in terms of caries was not found as statistically significant ($p>0,05$).

Table 12: Mean DMFS of the study population at baseline and follow-up examinations.

	Mean	Sd	Median	95% Confidence Interval for Mean	
				Lower	Upper
DMFS BASELIE	6,75	5,62	4,50	4,12	9,38
DMFS 6M	7,70	5,56	7,50	5,10	10,30
DMFS 12M	8,20	5,63	7,50	5,57	10,83

When evaluated in terms of The mean DMFS BASELIE of the participants was 6,75±5,62. When evaluated in terms of The mean DMFS 6M of the participants was 7,7±5,56. When evaluated in terms of the mean DMFS 12M of the participants was 8,2±5,63.

Table 13: Difference of the DMFS between the times of follow-up.

	Chi-Square	P
Time- General	20,600	0,0001
	T	P
DMFS BASELIE- DMFS 6M	-3,329	,004
DMFS BASELIE- DMFS 12M	-4,650	,000
DMFS 6M- DMFS 12M	-2,236	,038

Difference in time was found as statistically significant in terms of DMFS (p=0,0001). Differences between 2 times was found as statistically significant (p<0,05).

Table 14: Mean and Standard Deviations of time variables with OHI-s as a dependent variable

	Mean	Sd	Median	95% Confidence Interval for Mean	
				Lower	Upper
OHI-S Baseline	1,45	0,59	1,24	1,18	1,73
OHI-S 3 months	1,13	0,56	1,00	0,87	1,39
OHI-S 6M	1,49	0,60	1,66	1,21	1,77
OHI-S 12M	1,43	0,84	1,22	1,03	1,82

When evaluated in terms of The mean OHI-S Baseline of the participants was 1,45±0,59. When evaluated in terms of The mean OHI-S 3 months of the participants was 1,13±0,56. When evaluated in terms of Mean The mean 1,131 of the participants was 0,56±1. When evaluated in terms of the mean OHI-S 6M of the participants was 1,49±0,6. When evaluated in terms of the mean OHI-S 12M of the participants was 1,43±0,84.

When performing the Chi-square statistical analysis; Difference in time was found as statistically significant in terms of OHI-s (p=0,0001). When differences between 2 times was investigated, the difference of 3rd month with other months was found as statistically significant (p<0,05).

OHI-S of the participants: At baseline from 20 participants there was 17 (9 of 12 male, 8 of 8 female) of them were with fair and 3 (3 of 12 m, 0 f) of them poor oral hygiene, after 3 months of follow-up from 19 participants 3 (1 of 11 m, 2 of 8 f) of them were with good, 14(8 of 11 m, 6 of 8 f) with fair and 2 (2 of 11m) with poor oral hygiene, after 6 months of follow-up; from 20 paticipants 3 (2 of 12 m, 1 of 8 f) of them were with good, 13 (5 of 12 m, 7 of 8 f) with fair and 5 (5of 12) with poor oral hygiene, After 12 months of follow-up; from 20 participants 3 (1of 12 m, 2 of 8f) of them were with good, 14 (8 of 12 m, 6 of 8f) with fair and 3 (3 of 12 m) with poor oral hygiene.

Table 15: Difference of the OHI-S for one-year follow-up.

	Chi-Square	P
Time- General	9,288	,026
	T-test	P
OHI-S Baseline- OHI-S 3 months	3,005	,007
OHI-S Baseline- OHI-S 6M	-,268	,791
OHI-S Baseline- OHI-S 12M	,180	,859
OHI-S 3 months- OHI-S 6M	-2,636	,016
OHI-S 3 months- OHI-S 12M	-2,516	,021
OHI-S 6M- OHI-S 12M	,512	,615

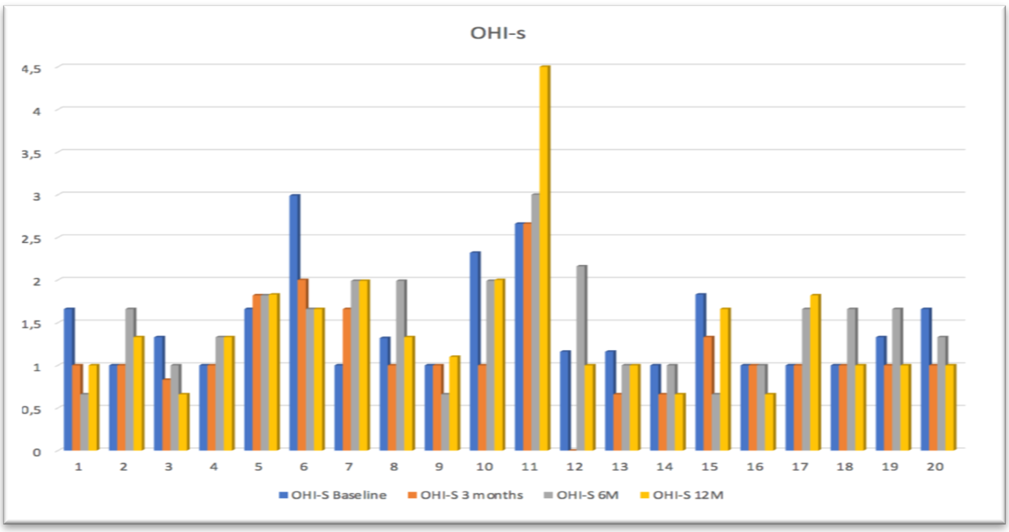
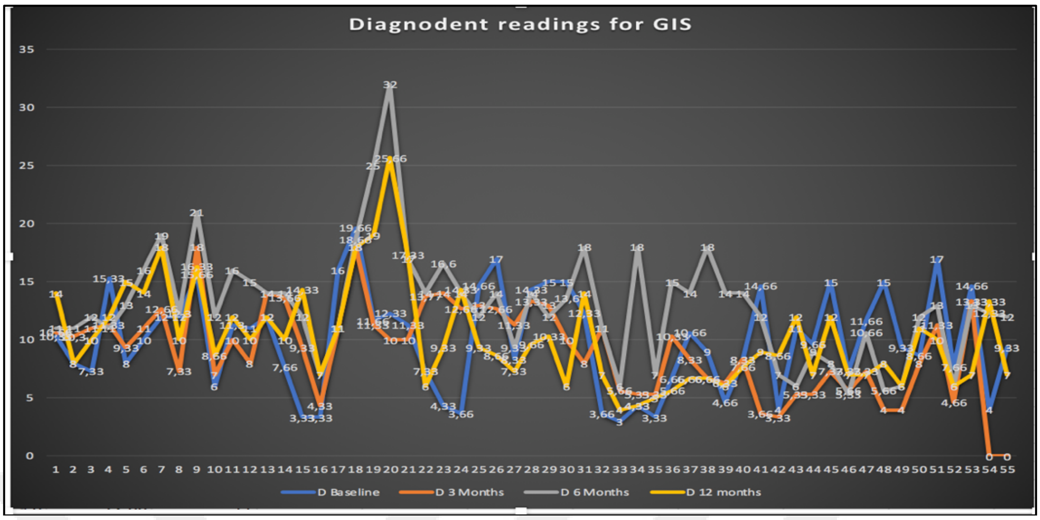


Figure 20: Oral hygiene status of the participants; (at baseline and follow-up examinations.

Caries status of the participants: There was no caries in both side after 3-months of materials application, at 6-month follow-up caries has occurred with the children who have a reason that impedes oral hygiene which led the plaque and calculus to cover all the occlusal surface (Figure 21), and at 12-month follow-up there was a decrease in the DIAGNOdent readings for the same teeth which appeared caries at 6-month follow-up. This decrease was observed for the patient who was following oral hygiene instruction.

Figure 21: Photograph showing the posterior teeth of the patient, who did not follow the oral hygiene instruction, and did not use his left side of the mouth during eatting for more than 2-month.

Alternative Graphs



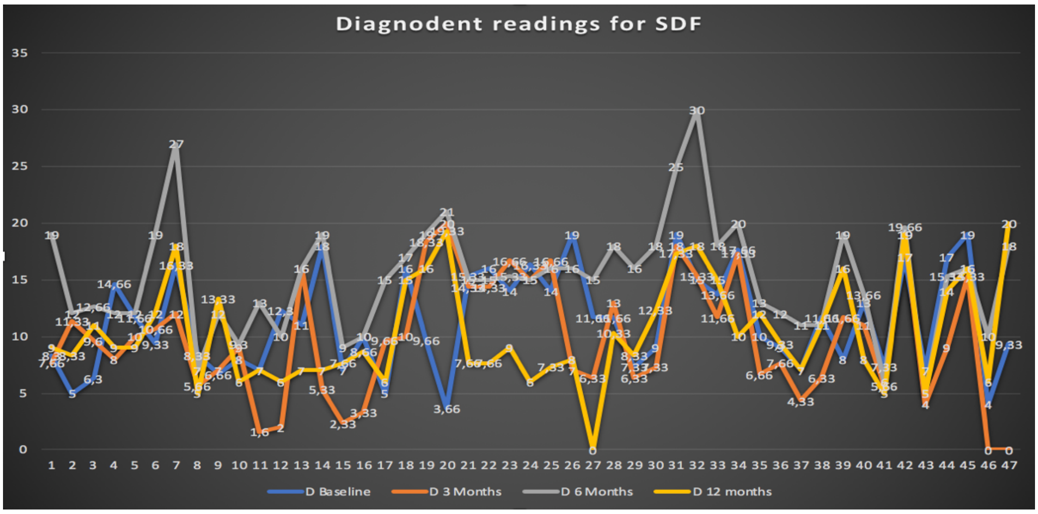
Graph 1: DIAGNOdent pen readings for the teeth with GIS for one-year follow-up.

D Baseline = DIAGNOdent readings at baseline for teeth at right side of the mouth with GIS

D 3 months= DIAGNOdent readings at 3 months follow-up for teeth at right side of the mouth with GIS

D 6 months= DIAGNOdent readings at 6 months follow-up for teeth at right side of the mouth with GIS

D12 months= DIAGNOdent readings at 12 months follow-up for teeth at right side of the mouth with GIS



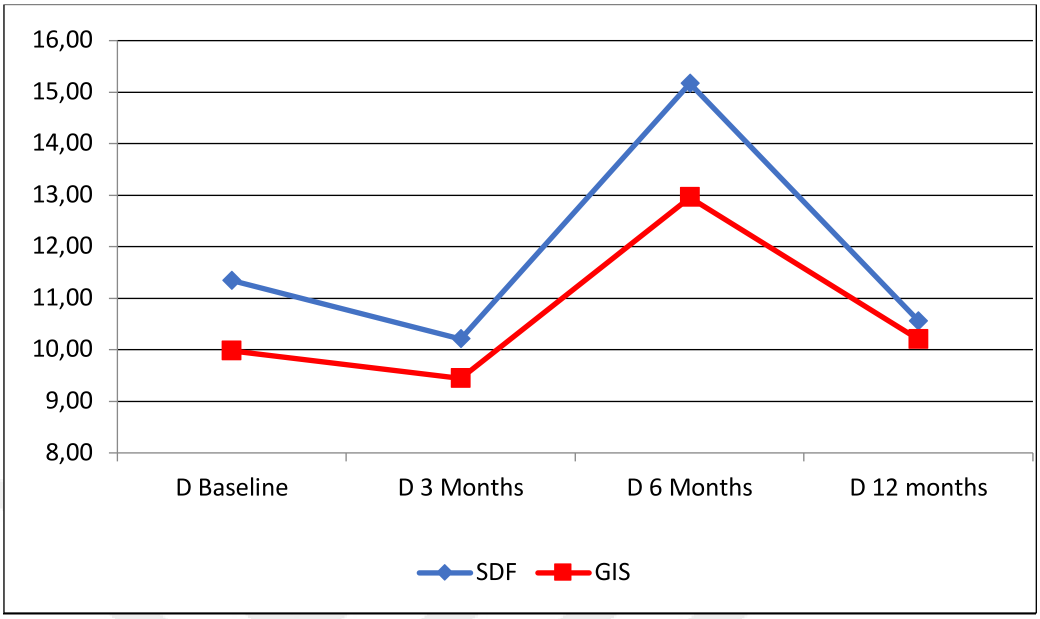
Graph 2: DIAGNOdent pen readings for the teeth with SDF for one-year follow-up.

D Baseline = DIAGNOdent readings at baseline for teeth at left side of the mouth with SDF

D 3 months= DIAGNOdent readings at 3 months follow-up for teeth at left side of the mouth with SDF

D 6 months= DIAGNOdent readings at 6 months follow-up for teeth at left side of the mouth with SDF

D12 months= DIAGNOdent readings at 12 months follow-up for teeth at left side of the mouth with SDF



Graph 3: Showing DIAGNOdent pen readings for the teeth with SDF and with GIS for four times a year; the blue color for SDF and the red color for GIS.

7. DISCUSSION

The aim of this study was to use the simplest, inexpensive, pain-free materials to remove the fear that patients experience when visiting the dentist. According to the major dental academies, and the most effective material to prevent dental caries is SDF which is usually recommended for those individuals with SHCN (Shah et al, 2014; Sharma et al, 2015) in preventing occlusal surface caries. Thus, the current study aimed to test the efficacy of SDF and compare it with (GC Fuji TRIAGE) after one year of follow-up.

In the developed countries, many studies have found that dental care is the most common unsatisfactory health care needs for individuals with special needs (Tesini, 1981; Martens et al., 2000; Nicopoulos et al., 2007). If the importance of oral health was not observed, the children would not be taken for regular dental exams (Nagahama et al., 2002). Lack of the cooperation of the family with dental care for their children may also contribute in the reduction of the knowledge about long-term health risks that potentially could impede a child that does not receive urgent-care needs (Roman, 2007).

Most individuals with special health care needs, oral health needs are struggling also with difficult chronic health situations. The effects of unsatisfactory oral health care needs include oral tissue infection, adverse behavior, and aggravation of accompanying medical conditions (Edelstein, 2002; Schechter, 2000). Most of this group of individuals cannot express or complain when feeling with discomfort or pain, so the situation may go unnoticed until the acute phase is reached.

It was decided that it would be advantageous to conduct a study in dental caries prevention programs by using oral health prevention strategies that possess the potential to lessen the burden of disease among people with special needs. Thereby lessen the need for dental surgical procedures; one of these strategies can be achieved by; preventing tooth caries by using fluoride and or sealants. This is compatible with the usual recommendation that children at high risk for caries should get more frequency of topical fluoride applications (Azarpazhooh and Main, 2008). The use of simple caries arrest treatment in public health services will be of great significance in controling of the prevalent dental caries problem in many child populations (Petersen, 2003), especially in children with special health care needs who are at high risk for dental caries.

There was difficulty in the present study to obtain the required sample according to inclusion and exclusion criteria. Out of 1500 patient, who have attended our dental clinic for a comprehensive dental examination, at the Department of Pediatric Dentistry of Marmara University, Turkey. Only 20 children were included. The sample comprises 60% males and 40% females, mean age (11,08±2,55, and range 6-14). The selection of the participants in this study was carried out between July 2017- January 2018. The inclusion criteria for the study were: children with special health care needs, six to fourteen years old, who had at least two newly erupted permanent posterior teeth with a sound occlusal surface “Sound” include clinically and all stages of enamel caries up to but not including visible dentinal caries lesions according to procedures described by WHO and DIAGNOdent pen reading was less than 20 (Lussi et al., 2001), and children who use oral medication every day which may cause a dry mouth as a side-effect and considered that as a common factor for the participants. Exclusion criteria were: children who have fifteen years or older, five years or smaller, if they used any type of tooth desensitizer, had received a fluoride varnish treatment within the last month, individuals with known allergy to silver or other heavy metal ions, their families did not agree and children who did not meet the inclusion criterion.

The present study is probably the first to investigate the effectiveness of the annual paint-on of Glass Ionomer Sealant GC Fuji TRIAGE and comparing it with the effectiveness of the biannual application of SDF 38% to prevent dentine caries in newly erupting posterior permanent teeth for children with special health care needs. It was a split-mouth design study. The oral data were measured, including the use of oral hygiene index (OHI-S). For dental and oral assessment, the subject’s teeth examined visually and tactilely under artificial illumination, according to the World Health Organization (WHO) procedures (WHO, 1997); caries prevalence assessed using the Decayed, Missing and Filled (DMFS) index for permanent dentition. Histological validation was not possible in this study. So, the diagnosis of the occlusal surface of the posterior teeth was conducted by using the DIAGNOdent pen.

This device was used by America et al., 2016, in which the authors used a similar method but with some differences in materials. In their study a split-plot design was performed on twenty-two children to compare the effectiveness of two materials to enhance dental remineralization by using a laser cavity detection pen. Other studies conducted by (Shi et al., 2000, 2001; Pinelli et al., 2002; Staudt et al., 2004; Mendes et al., 2005) their results suggested that the DIAGNOdent had produced an excellent outcome of research interest in the early detection of carious lesions on occlusal and smooth surfaces. In addition to that, several studies show that the sensitivity and specificity of DIAGNOdent in laboratory investigations were almost the same as radiography (Kuhnisch et al., 2008).

Application of SDF solution on the left side of the mouth every six months corresponds with the commonly recommended repetition of recall visits for high-risk patients (Beirne et al., 2007; Evans et al., 2008) and an annual application of GIS on the other side (Zhi et al., 2012).

The current study reported that no statistically significant difference was found between the biannual application of SDF 38% and an annual application of GIS fuji triage after one year of follow up ($p > 0{,}05$) Further, both materials were effective treatment to arrest initial caries and prevent dental caries from occurring. In contrast, another study results reported by (Zhi et al., 2012) found that 38% SDF was significantly higher (53,0 %) for arresting caries rate when applied semiannually as compared with 38% SDF (37,0 %) or GI (28,6 %) annual application ($p < 0{,}05$) after one year follow-up.

The frequency of SDF application may be annual or repeated applications every 3, 6, or 12 months. One research mentioned that increasing the frequency of application improved the caries arrest rate (Zhi et al., 2012). In addition, caries arrested rate for the initial dental caries of semi-annual application of SDF after 12 months follow-up was similar to that conducted in a previous study on chines children (Qing Hui Zhi et al., 2012) the authors found when the recurrence of SDF application was every six months, the proportion of initial dental caries had become arrested increased, this is in consistency with the general suggestion that children at high risk require more frequent topical applications for fluoride (Azarpazhooh and Main, 2008; Journal of the American Dental Association 2006; 137:1151–9).

Furthermore, it was necessary to investigate the efficacy of sealant's retention to the appearance of dental caries in this study. Most studies found that the effectiveness of sealant as a caries preventive agent is dependents upon its complete retention. Several authors recorded that the caries increment is low when there is full retention of the sealant (Jensen et at., 1985; Sol et al., 2000; Poulsen et al., 2001; Ninawe et al., 2012). In the present study, at 3-month evaluation period for the teeth examined found the complete retention of the glass ionomer sealant was (88,23%), at 6-month evaluations was (74,54%) and at 12-month was (56,36%). These teeth did not show any evidence of caries activity, that was compatible with previous studies (Jensen OE et at., 1985; Sol et al., 2000; Poulsen et al., 2001; Ninawe et al., 2012). The same result was found in the teeth that have lost the retention of GIS partially, and this part of our study was similar to that found in a previous study conducted by Wendt and Koch. They mentioned that, if a certain part of the sealant is lost the retention in the fissures, there is still enough material in the deep area to prevent caries (Wendt and Koch, 1988). This could be due to the inherent properties of GIS like fluoride release and adherence to dental compositions, complete retention or partial loss is not considered to be a problem, as a little portion of material remaining in the fissures results in cariostatic effect (Pardi et al., 2003; Herle et al., 2004).

In addition to that, in this study was found; in the teeth that lost retention of the GIS completely, at 6-month follow-up three out of five teeth were affected with caries, and at one-year follow-up, one tooth out of nine teeth was with caries. This reduction in caries appearance may be related to the appearance of GIS material at the opposite side of the occlusal surface of the tooth, due to glass ionomer which acts as a reservoir from which additional fluoride is released gradually into the oral cavity to prevent enamel demineralization and enhance remineralization (Loveren, 1999). Another possible explanation that the patient who was committed to oral hygiene instruction. The effect of GIS on the adjacent tooth in this study was similar to that found in an earlier study on 6-7 years old schoolchildren. The result of the latter study demonstrated protective effect of GIS against dental caries, and there was evidence that (high-viscosity GIC or RB sealant containing fluoride materials) afforded additional protection for the tooth nearest to the sealed tooth (Cagetti et al., 2014). Also, there was a study mentioned that the application of fluoride-releasing dental materials was proposed to provide an additional advantage in caries prevention on adjacent teeth surfaces (Donly et al., 1999). That was concurring with a previous study conducted by (Alsaffar et al., 2011).

The retention of dental sealant by the teeth was also studied comparing mandibular teeth with maxillary teeth. Some studies reported higher retention of sealants in maxillary teeth compared with mandibular teeth (Burt et al., 1975; Whitehurst and Soni, 1976; Urvashi and Maridula, 2017). Another research found no difference in sealant retention in mandibular and maxillary teeth (McCune et al., 1979). In the present study, the results were analyzed by the Mann Whitney U test, found no statistical difference in sealant retention in the mandibular and maxillary teeth ($p> 0,05$).

A comparison of OHI-S scores by gender of the participants in this study was also investigated. The literature review suggested that males had inadequate oral hygiene and periodontal status compared to their female counterparts (Kumar et al., 2009). Females seem to be more mature, and health concerned compared to males (Ferrazzano et al., 2008). Their plaque control record was good, and that contrasted to males (Ramseier et al., 2007). The results of this study noted that the OHI-S scores for males were poorer than the female's counterparts. In 1998, Denloye observed a similar trend among mentally disabled children of Nigeria, where higher OHI-S scores were recorded among males than females. The oral hygiene status of the participants in the present study just at a 3-month follow-up examination was better than at baseline, and the difference was statistically significant, and after 6-12-month of follow-up, the result was not a statistically significant difference.

In this study, the mean of DMFS index was found as statistically significant ($p<0,05$) between the examinations at baseline and after a one-year follow-up. Although the DMFS for children had deteriorated, both materials were successful in preventing dental caries on the teeth to which the material was applied.

Application of a flowable GIS offers an alternative therapy if the application of the SDF solution is not permitted because of its taste or blacking effect of the arrested lesion which could be a deterrent for patients with esthetic issues (Qing Hui Zhi et al., 2012). In particular, the lighter color of the arrested caries lesion gives it an interesting method to apply glass ionomer rather than an SDF solution. In this study, the parental satisfaction with their child's dental appearance, was the same result between the two materials, because the parents were not so worried about the color of the teeth, while the presence of dental caries for their child was a more significant problem. That was similar to another study conducted by (Crystal et al., 2016).

Finally, the findings of the present study should be confirmed by further studies with more robust designs for corroborating the comprehensive use of GIS and SDF in public oral healthcare services, especially for those individuals with special needs. Moreover, further studies are needed with a longer follow-up period and with a multidisciplinary collaboration between the laboratories and pediatric dentists to obtain the effect of both materials in the prevention of dental caries in children with special health care needs with more definite results.

8. CONCLUSION

- This split-mouth study enrolled 20 subjects, all of them with special health care needs (12 males and 8 females), aged 6 to 14 years old. 6 of them with asthma, 3 with GI disorder, 2 with renal disorders, 3 with epilepsy,1 with joint disease, 3 with cardiac disorders, 1 with a psychiatric disorder, and one with Haematological disorders.

- At three months follow-up, there was no caries on both sides of the patient's mouth.

- At six months follow-up, three teeth were occurred with caries at the GIS side, among the teeth that lost the retention of GIS completely, and five teeth at SDF side had developed caries for the patients who have limitations that impede oral hygiene.

- At twelve months of follow-up, there was only one tooth with caries at the GIS side, that one was among the teeth that lost the retention of GIS completely, and one tooth at the SDF side had developed caries for the patients who have limitations that impede oral hygiene.

- Clinically, this study reported that the biannual application of silver diamine fluoride and an annual application of Fuji Triage are effective treatment to arrest initial caries and prevent dental caries from occurring at the occlusal surface of newly erupted permanent posterior teeth.

- Statistically, the efficacy of the biannual application of silver diamine fluoride solution and the annual application of Fuji Triage to prevent dental caries in permanent posterior teeth did not differ significantly.

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10. ENCLOSURES

Enclosure 1. Hasta Takip Formu

Adı **Soyadı:**
Tarih:

Telefon:

Cinsiyet: Kız ☐ **Erkek** ☐

Doğum Tarihi:

Type/s of disabilities:

	DIAGNOdent values for GIS ( ) / SDF ( )		GI sealant retention	Caries GIS / SDF	
baseline					
3-m					
6-m					
12-m					

Simonsen' s Criteria:

C: **Complete (**Complete retention)

P: **Partial (**Partial Loss)

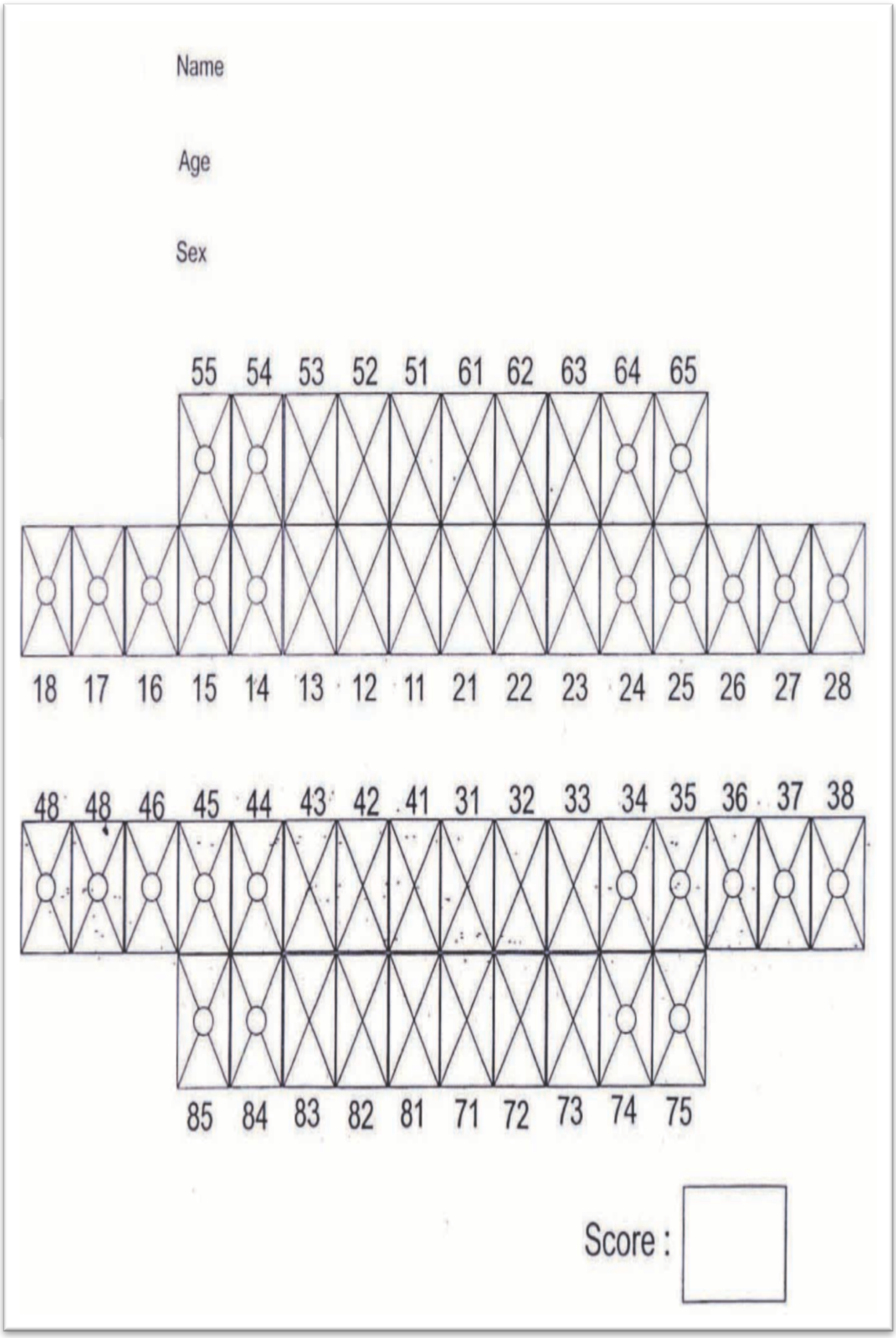
M: **Missing** (Total Loss)

Caries

0: No caries.

1: Caries

DMFS, dmfs index



Enclosure 2. Gönüllü Bilgilendirme Formu

GÖNÜLLÜ BİLGİLENDİRME FORMU

Amaç: Özel gereksinimli çocuklarda gümüş diamin fluorid ve cam iyonomer fissür örtücünün, diş çürüklerinin önlenmesinde etkinliğinin değerlendirilmesi

Araştırmada kullanılacak yöntem:

Araştırmada özel gereksinimi olan çocuğunuzun çürük olmayan azı dişlerine, çürümelerini engellemek amacı ile koruyucu uygulamalar yapılacaktır. Bu amaçla sırasıyla aşağıdaki basamaklar izlenecektir:

1) Çocuğunuzun tedavi öncesi ağız içi durumunun tespiti amacıyla klinik muayenesi yapılacaktır. Muayene bulguları sizinle paylaşılacaktır.
2) Çürük dişlerinin tedavileri için size randevu verilip, tedavisine Marmara Üniversitesi Diş Hekimliği Fakültesi Pedodonti Anabilim Dalı' nda bölümümüzde devam edilecektir.
3) İlk seansta çocuğunuzun durumuna ve tedavi seansının süresine göre bir veya iki adet dişinin koruyucu tedavileri yapılacak ve sağ-sol yarım çenede iki farklı materyal kullanılacaktır.
4) Daha sonraki seanslar 6. ve 12. ayda olup; yeni çürük oluşup oluşmadığı ve koruyucu dolgunun (fissür örtücünün) durumu incelenecektir.
5) Çalışma kapsamındaki tedaviler aynı diş hekimi tarafından yapılacaktır.

Araştırmaya katılmakla meydana gelebilecek yan etkiler ve olumsuzluklar:

Araştırmaya katılmakla hiçbir yan etki ve olumsuzluk söz konusu değildir.

Gizlilik:

Araştırmaya katılan bireylerin isimleri gizli tutulacak ve kendi rızası olmadan açıklanmayacaktır.

Enclosure 3. Gönüllü Onam Formu

GÖNÜLLÜ ONAY FORMU

Yukarıda gönüllüye araştırmadan önce verilmesi gereken bilgileri gösteren metni okudum. Bunlar hakkında bana yazılı ve sözlü açıklamalar yapıldı. Bu koşullarla söz konusu klinik araştırmaya kendi rızamla hiçbir baskı ve zorlama olmaksızın katılmayı kabul ediyorum.

Gönüllünün
Adı-soyadı:
Adresi (varsa telefon no., faks no,...):

İmzası:

Velayet veya vesayet altında bulunanlar için

veli veya vasinin adı-soyadı:
adresi (varsa telefon no., faks no,...):

İmzası:

Açıklamaları yapan araştırmacının adı-soyadı, imzası:

Rıza alma işlemine başından sonuna kadar tanıklık eden kuruluş görevlisinin

adı-soyadı:
görevi:

İmzası:

Katılımcının/Hastanın Beyanı

Sayın Rehab Tahseen Al-hayo tarafından Marmara Üniversitesi Diş Hekimliği Fakültesi Pedodonti Anabilim Dalı' nda tıbbi bir araştırma yapılacağı belirtilerek bu araştırma ile ilgili yukarıdaki bilgiler bana aktarıldı. Bu bilgilerden sonra böyle bir araştırmaya "katılımcı" (denek) olarak davet edildim.

Eğer bu araştırmaya katılırsam hekim ile aramda kalması gereken bana ait bilgilerin gizliliğine bu araştırma sırasında da büyük özen ve saygı ile yaklaşılacağına inanıyorum. Araştırma sonuçlarının eğitim ve bilimsel amaçlarla kullanımı sırasında kişisel bilgilerimin ihtimamla korunacağı konusunda bana yeterli güven verildi.

Projenin yürütülmesi sırasında herhangi bir sebep göstermeden araştırmadan çekilebilirim. Ancak araştırmacıları zor durumda bırakmamak için araştırmadan çekileceğimi önceden bildirmemim uygun olacağının bilincindeyim. Ayrıca tıbbi durumuma herhangi bir zarar verilmemesi amacıyla araştırmacı tarafından araştırmadan çıkartılabileceğimi de biliyorum. Araştırma için yapılacak harcamalarla ilgili herhangi bir parasal sorumluluk altına girmiyorum. Bana da bir ödeme yapılmayacaktır. İster doğrudan, ister dolaylı olsun araştırma uygulamasından kaynaklanan nedenlerle meydana gelebilecek herhangi bir sağlık sorunumun ortaya çıkması halinde, her türlü tıbbi müdahalenin sağlanacağı konusunda gerekli güvence verildi. Bu tıbbi müdahalelerle ilgili olarak da parasal bir yük altına girmeyeceğimi biliyorum.

Araştırma sırasında bir sağlık sorunu ile karşılaştığımda; Rehab Tahseen Al-hayo, Dr. Başak Durmuş, Dr. Figen Eren Giray ve Dr. Işıl Kalyoncu' yu, MÜ. Diş Hekimliği Fakültesi, Pedodonti Anabilim Dalı' nda ve 02164211621/1542 numaralı telefondan arayabileceğimi biliyorum, araştırmaya katılmak zorunda değilim ve katılmayabilirim. Araştırmaya katılmam konusunda zorlayıcı bir davranışla karşılaşmış değilim. Eğer katılmayı reddedersem, bu durumun tıbbi bakımıma ve hekim ile olan ilişkime herhangi bir zarar getirmeyeceğini de biliyorum.

Bana yapılan tüm açıklamaları ayrıntılarıyla anlamış bulunmaktayım. Kendi başıma belli bir düşünme süresi sonunda adı geçen bu araştırma projesinde "katılımcı" olarak yer alma kararını aldım. Bu konuda yapılan daveti büyük bir memnuniyet ve gönüllülük içerisinde kabul ediyorum. İmzalamış bulunduğum bu form kâğıdının bir kopyası bana verilecektir.

Enclosure 4. Ethical Committee Approval

T.C.
MARMARA ÜNİVERSİTESİ
Diş Hekimliği Fakültesi
Klinik Araştırmalar Etik Kurulu
ARAŞTIRMA BAŞVURUSU ONAY BELGESİ

	KLİNİK ARAŞTIRMALAR ETİK KURULU
PROTOKOL ADI VE KODU	SILVER DIAMINE FLOURIDE AND GLASS IONOMER SEALANT USE IN PREVENTING OCCLUSAL SURFACE CARIES FOR SPECIAL NEEDS CHILDREN, Prot:2017-109
ETİK KURULUN ÇALIŞMA ESASI	İlaç ve Biyolojik Ürünlerin Klinik Araştırmaları Hakkında Yönetmelik, İyi Klinik Uygulamaları Kılavuzu
BAŞKANIN UNVANI / ADI / SOYADI:	Prof.Dr.Nimet Gençoğlu

UNVANI/ADI/SOYADI	UZMANLIK ALANI	KURUMU	İMZA
Prof. Dr. Nimet Gençoğlu	Endodonti	Marmara Üniversitesi Diş Hekimliği Fak.	
Prof.Dr.Ali Recai Menteş	Çocuk Diş Hekimliği	Marmara Üniversitesi Diş Hekimliği Fak.	
Prof.Dr.İlknur Tanboğa	Çocuk Diş Hekimliği	Marmara Üniversitesi Diş Hekimliği Fak.	
Prof.Dr.Filiz Onat	Tıbbi Farmakoloji	Marmara Üniversitesi Tıp Fakültesi	
Prof.Dr.Yaşar Özkan	Ağız Diş ve Çene Cerrahisi	Marmara Üniversitesi Diş Hekimliği Fak.	
Prof.Dr. Ahu Acar	Ortodonti	Marmara Üniversitesi Diş Hekimliği Fak.	
Prof.Dr.Zühre Hale Cimilli	Endodonti	Marmara Üniversitesi Diş Hekimliği Fak.	
Prof.Dr. Şebnem Erçalık Yalçınkaya	Ağız Diş ve Çene Radyoloji	Marmara Üniversitesi Diş Hekimliği Fak.	
Doç.Dr. Afife Binnaz Hazar Yoruç	Metalürji ve Malzeme Mühendisliği	İstanbul Yıldız Teknik Üniversitesi	
Doç.Dr. Buket Evren	Protetik Diş Tedavisi	Marmara Üniversitesi Diş Hekimliği Fak.	
Doç.Dr. Tolga Güven	Deontoloji	Marmara Üniversitesi Tıp Fakültesi	
Dr. Zerrin Kurşun	Halk Sağlığı	Çekmeköy Toplum Sağlığı Merkezi	
Avukat Burçak Çopuroğlu	Hukuk	Serbest	
Gürol Pekel	Sivil	Serbest	

Etik Kurul Başkanının
Unvanı/Adı/Soyadı:Prof.Dr.Nimet Gençoğlu
İmza:

Not: Etik kurul başkanı, imzasının yer almadığı her sayfaya imza atmalıdır.

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MARMARA ÜNİVERSİTESİ
Diş Hekimliği Fakültesi
Klinik Araştırmalar Etik Kurulu
ARAŞTIRMA BAŞVURUSU ONAY BELGESİ

BAŞVURU BİLGİLERİ			
	PROTOKOL KODU	2017-109	
	PROTOKOL ADI	SILVER DIAMINE FLOURIDE AND GLASS IONOMER SEALANT USE IN PREVENTING OCCLUSAL SURFACE CARIES FOR SPECIAL NEEDS CHILDREN	
	SORUMLU ARAŞTIRMACI	Dt.İLKNUR TANBOĞA	
	DİĞER ARAŞTIRICILAR	Dt. REHAB TAHSEEN AL-HAYO,Dr.BAŞAK DURMUŞ, Dr.FİGEN EREN GİRAY,Dr.IŞIL ÖZGÜL KALYONCU	
	ARAŞTIRMA MERKEZİ	M.Ü.DİŞ HEKİMLİĞİ FAK:	
	DESTEKLEYİCİ		
	ARAŞTIRMANIN FAZI VE TÜRÜ	FAZ 1	☐
		FAZ 2	☐
		FAZ 3	☐
		FAZ 4	☐
		Gözlemsel ilaç çalışması	☐
		Tıbbi cihaz klinik araştırması	☐
		İn vitro tıbbi tanı cihazları ile yapılan performans değerlendirme çalışmaları	☐
		İlaç dışı klinik araştırma	☒
		Diğer ise belirtiniz	
	ARAŞTIRMAYA KATILAN MERKEZLER	TEK MERKEZ ☐ · ÇOK MERKEZLİ ☒ · ULUSAL ☐	ULUSLARARASI ☐

DEĞERLENDİRİLEN BELGELER	Belge Adı	Tarihi	Versiyon Numarası	Dili		
	ARAŞTIRMA PROTOKOLÜ			Türkçe ☒	İngilizce ☐	Diğer ☐
	BİLGİLENDİRİLMİŞ GÖNÜLLÜ OLUR FORMU			Türkçe ☒	İngilizce ☐	Diğer ☐
	OLGU RAPOR FORMU			Türkçe ☐	İngilizce ☐	Diğer ☐
	ARAŞTIRMA BROŞÜRÜ			Türkçe ☐	İngilizce ☐	Diğer ☐

DEĞERLENDİRİLEN DİĞER BELGELER	Belge Adı		Açıklama
	SİGORTA	☐	
	ARAŞTIRMA BÜTÇESİ	☐	
	BİYOLOJİK MATERYEL TRANSFER FORMU	☐	
	İLAN	☐	
	YILLIK BİLDİRİM	☐	
	SONUÇ RAPORU	☐	
	GÜVENLİLİK BİLDİRİMLERİ	☐	
	DİĞER:	☐	

KARAR BİLGİLERİ		
	Karar No:2017-104	**Tarih: 06.06.2017**
	Yukarıda bilgileri verilen başvuru dosyası ile ilgili belgeler araştırmanın/çalışmanın gerekçe, amaç, yaklaşım ve yöntemleri dikkate alınarak incelenmiş ve uygun bulunmuş olup araştırmanın/çalışmanın başvuru dosyasında belirtilen merkezlerde gerçekleştirilmesinde etik ve bilimsel sakınca bulunmadığına toplantıya katılan etik kurul üye tam sayısının salt çoğunluğu ile karar verilmiştir. İlaç ve Biyolojik Ürünlerin Klinik Araştırmaları Hakkında Yönetmelik kapsamında yer alan araştırmalar/çalışmalar için Türkiye İlaç ve Tıbbi Cihaz Kurumu'ndan izin alınması gerekmektedir.	

Etik Kurul Başkanının
Unvanı/Adı/Soyadı:Prof.Dr.Nimet Gençoğlu
İmza:

Not: Etik kurul başkanı, imzasının yer almadığı her sayfaya imza atmalıdır.

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Enclosure 5. Publication

O:35 Silver diamine fluoride and glass ionomer sealant use in preventing occlusal surface caries for special needs children

Rehab Tahseen Alhayo, Figen Eren Giray, Ilknur Tanboga

Department of Pediatric Dentistry, Faculty of Dentistry, Marmara University, Istanbul, Turkey

Objectives: The first objective is to compare the effectiveness of silver diamine fluoride (SDF) with glass ionomer sealant (GIS) in the prevention of dental caries on occlusal surfaces of the permanent teeth for special needs children; the second objective is to measure the efficacy of both materials to the oral hygiene index (OHI-S). **Material-Methods**: A randomised clinical trial conducted on 23 children (aged 6-14 years) with special needs at Istanbul, Marmara University, Department of Pediatric Dentistry. The participants were examined using a dental mirror, blunt dental probe and DIAGNOdent pen. At least each child had two permanent posterior teeth with DIAGNOdent results 0-20 were included. Application of (SDF) (38%) on one side of the mouth and GIS (GC Fuji TRIAGE) on the other side of the mouth. The retention of GIs and occurrence of caries were evaluated at 3-months. For statistical analysis paired T-Test was used. **Results**: A total of twenty children with 104 teeth were evaluated after 3-months. There was statistically significant difference between the mean of baseline and 3-months follow up of OHI-S results. The retention rates for GIs were 80.4% A (complete retention), 14.3% B (partial loss), and 5.3% C (total loss). There was no caries in both groups after 3 months. And for 6 months follow up the study

is on-going and the result in progress. **Conclusion**: SDF and GIs are effective in preventing occlusal dental caries for special needs children for 3- months.

Key words: *Silver diamine fluoride, glass ionomer sealant, special needs children*

11. CURRICULUM VITAE

Name	Rehab	**Surname**	Alhayo
Place of Birth	Iraq	**Date of Birth**	19.5.1989
Nationality	Iraqi	**Tel**	00905358578092
E-mail	Dr.re34@yahoo.com		

Educational Level

	Name of the Institution where he/she was graduated	**Graduation year**
Masters	MSc in Pediatric and Special Care Dentistry, Marmara University, Istanbul, Turkey.	
Undergraduate	Bachelor of Dental Surgery (B.D.S) from University of Baghdad-Iraq.	**2012**
High school	Al-yarmook, Baghdad-Iraq.	**2007**

Foreign Languages	**Reading comprehension**	**Speaking***	**Writing***
English	Very good	Very good	Very good
Turkish	Good	Very good	Good
Arabic	Mother language	Mother language	Mother language

Computer Knowledge

Program	**Use proficiency**
Microsoft office	Good

*Evaluate as very good, good, moderate, poor.

PRESENTATIONS AND AWARDS:

- Rehab T Alhayo, F Giray, I Tanboga, "Silver diamine fluoride and glass ionomer sealant use in preventing occlusal surface caries for special needs children", oral Presentation, The 24th International Association for Disability and Oral Health Congress, Dubai – UAE, August 2018.

- Rehab T Alhayo, F Giray, I Tanboga, "The most important materials in preventing occlusal surface caries for special needs children", poster presentation, The 7th International Cerebral Palsy and Developmental Disorders Congress, Turkey, 2018.