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Clinical Applicability, Safety and Effect of Resin Infiltration for Proximal Caries

Inaugural – Dissertation zur Erlangen des akademischen Grades
Doktor der Zahnmedizin (Dr. med. dent.)
der Universitätsmedizin
der Ernst-Moritz-Arndt-Universität Greifswald
2012

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**Ort, Raum: Hörsaal der neuen Zahnklinik in der W.-Rathenau-
Str. 42a. In Greifswald**

Tag der Disputation: 11. April 2013

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Chapter 1: Literature review

1.1 Dental caries

1.1.1 Understanding the dental caries disease

Dental caries can be described by a series of stages or signs which start by a loss of mineral and end with large cavitation or destruction in the structure of the tooth (Fejerskov and Thylstrup, 1994). Consequentially, dentists should deal with caries as a chronic disease and try to control it.

Many dentists consider caries only as decay in the teeth (Steinberg, 2007). From this perspective, they treat the caries with restorations. Actually, they do not treat the caries, but they fill the cavitations which are considered as a sign of the caries disease. In reference to this concept, understanding the terminology of this disease comes first before attempting to make the treatment plan.

Up to now, there are many descriptions and definitions of dental caries. Therefore, it is not surprising when literature review points out that the dentists are using an identical terminology, but they explain and treat the caries process in many different ways (Fejerskov, 1997).

1.1.2 History and etiology of dental caries

For the last 1000 years, the average of dental caries has increased clearly in the western world after the industry evolution in these countries. After World War II, the consumption of sugar increased clearly in both worlds west and east (König, 2004). In the year 1940, researchers confirmed that people who eat or drink a high quantity of sugar tend to have many active caries lesions (Collins et al., 1940). Basically, a high consumption of carbohydrates can be metabolized by oral micro flora to acids which increase the likelihood of developing the caries (Marsh and Nyvad, 2003). However, a series studies in 1950s demonstrated that caries does not occur in germ-free rodents despite the huge consumption of sugar.

In 1940, T. Dean proved the importance of fluorides in the prevention of caries by reducing the cavitations in children's teeth when it was added to the water. As a result, the fluoride, micro flora, nurturing and time were considered to be the essential factors for the caries process and certainly understanding these factors facilitated the choosing of the preventive strategies (Fejerskov and Kidd, 2003).

In addition to the main factors, there are individual ones like socio-economic factors or health behavior which can play an important role and have an effect on the caries process. Eventually, the management of the dental caries is not easy, because it is a complex and multifactorial disease and each one of these factors (environment, behavior, genetic ...) affects the caries progression and interacts with the other factors (Fejerskov, 2004).

Without doubt, the anatomical form of the tooth is a crucial factor too, especially for the incidence and treatment of proximal caries, as the proximal area facilitates the plaque accumulation. Mejàre et al. (2001) found that the rate of caries in the mesial surface of the first permanent molar increases 15 times if the adjacent, second primary molar has a carious distal surface. Therefore, the plaque accumulation in the proximal site is a risky factor not only for the affected tooth, but also for the adjacent teeth.

1.1.3 Epidemiology of dental caries

The goal of epidemiological research is to assess the prevalence, incidence as well as the risk factors of dental and medical diseases. Therefore, researchers need valid indices to turn clinical information into numbers to ensure optimal statistical analysis (Pitts et al., 2004). An example of these indices is the DMFT/S index which expresses caries prevalence numerically. It is obtained by calculating the number of decayed (D), missing (M) and filled (F) teeth and surfaces. With this index, the amount or prevalence of dental caries can be described in individuals (WHO publication Oral Health Surveys, 1997).

Past 1960, a decrease of the caries prevalence has been seen in schoolchildren and adolescents in the most industrialized country (Marthaler, 2004). It was especially early and pronounced in Switzerland (Menghini et al., 2003). König

(1999) stated that the use of fluoride is the most important cause for the caries decline in Western countries during the two last decades. Maybe this reduction can be ascribed to the change in understanding of the caries process, too (Pitts et al., 2004). The detection of proximal caries in epidemiological studies is often complicated. Still, epidemiological data could monitor the caries progression in mesial surfaces of young children, adolescents and young adults (Mejàre and Mjör, 2003). A cohort study in 6-12 and 12-22 years olds found that the rate of the progression of caries in the inner half of the enamel is faster than in the outer half of the dentin, especially in the younger group (Mejàre and Stenlund, 2000). Moreover, progression of proximal caries in adults is slower in enamel than in dentin (Mejàre and Mjör, 2003; Mejåre and Stenlund, 2000).

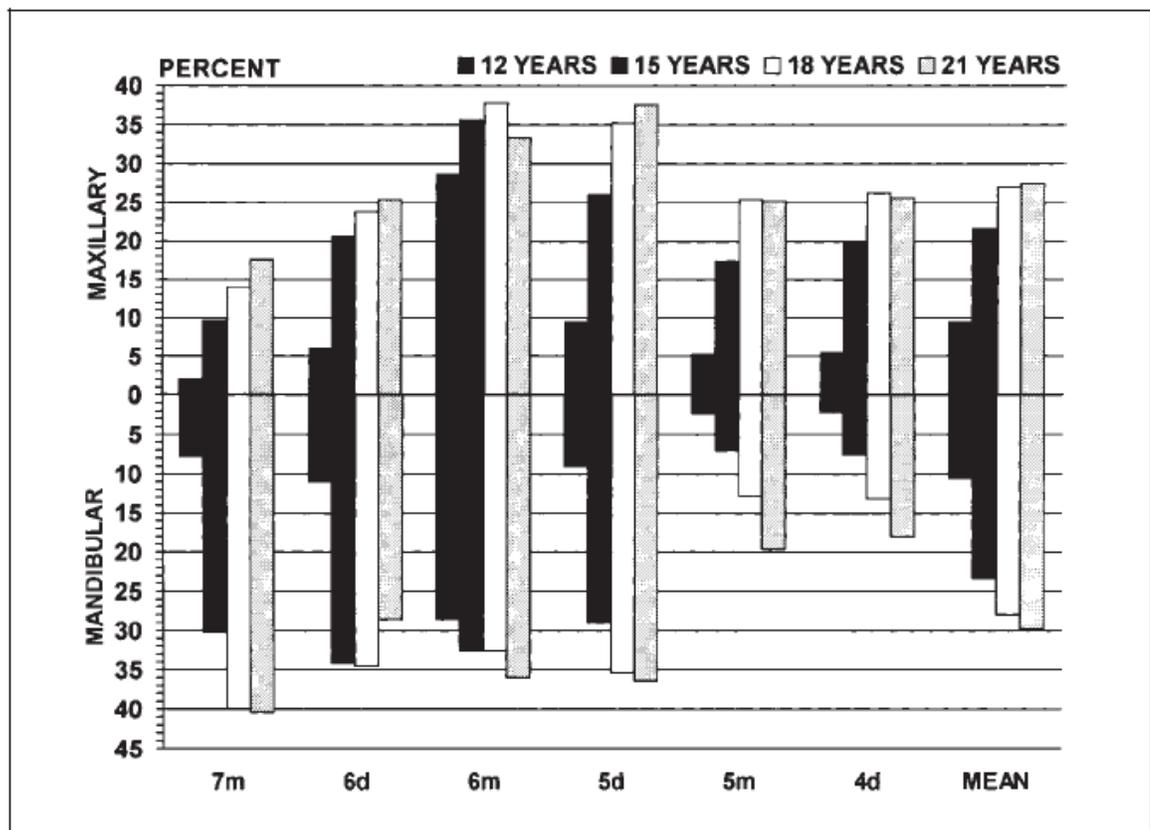


Fig 1.1 – Prevalence of proximal enamel caries (scores 1+2) related to 7m to 4d at 12, 15, 18 and 21 years of age. Right and left side surfaces are combined in percent of the total number of each proximal surface (Mejàre et al., 1998)

The age range from 6-12 years is considered as crucial for the beginning of caries progression in the first permanent molar, particularly for the mesial surface due to the fact that it is partly related to the progression of the adjacent distal surface of the primary second molar (Mejàre and Stenlund, 2000; Mejàre et al., 2001). Regarding proximal caries, the permanent molars have the highest caries risk and are classified as the most caries-susceptible proximal surface (Dummer et al., 1998; Lith et al., 1995; Mejàre et al., 1998) (Fig 1.1).

Generally, the rate of proximal caries rises clearly between adolescents and young adults (Dummer et al., 1998; Chesnutt et al., 1996; Mejàre and Mjör, 2003; Poorterman et al., 2000; Marthaler et al., 1996); occlusal dominates the childhood age (Chesnutt et al., 1996).

1.1.4 Clinical manifestation of dental caries

Dental caries is a chronic disease which can be seen in many stages either as initial loss of mineral, decay or even as a total destruction in the tooth and these stages are described as signs of a process which has been called dental caries. After a microbial colonization, proximal caries begins as loss in the mineral at the ultrastructural level and this stage of caries development is called the proximal white-spot lesion. The typical shape of this stage is characterized as an interdental facet area surrounded by opaque area and the lesion extends in the cervical direction (Fejerskov et al., 2003).

Macroscopically, no changes can be noted after 1 week, the first enamel changes can be seen clinically after 14 days as whitish spot after air-drying. After 3 or 4 weeks from the accumulation of plaque, clinical changes can be discovered without air-drying (Fejerskov et al., 2003) which finally progress to cavitation.

1.1.5 Biological manifestation of dental caries

The dental biofilm exists naturally in the human mouth whether the mouth has carious lesions or not. Thus, *S. mutans* and *Lactobacillus* cannot be accused of being basically behind the caries development rather they are indicators which

describe the conditions in the mouth's environment (Fejerskov, 1997). The health phase persists as long as the mineral exchange system between tooth and biofilm is balanced. In other words, the demineralization should equal the remineralization and caries presents when any disturbance of this equilibrium happens. Thus, caries disease can be defined as dynamic process amid the tooth and the biofilm which covers it (Fejerskov, 1997; Steinberg, 2007).

In this concept, fillings cannot be considered the first solution for caries and caries which appears under the restorations should not be called secondary caries. It rather reflects the continued progression of the untreated caries disease. Therefore, Fejerskov (1997) presumed that the management of caries disease is obtainable but its prevention cannot be achieved.

Therefore, the balance between pathologic factors and protective factors can cause the dental caries or reverse it (Featherstone, 2000).

1.1.6 Histological manifestation

1.1.6.1 Enamel caries

Enamel consists of two components: The inorganic portion includes the rods which are made of individual crystals. The crystals are separated by minute inter-crystalline spaces which comprise the organic portion. Consequentially, the experts consider the enamel as a solid micro-porous composed of tightly packed crystals. The inorganic structure is a main part in the enamel, with 95% mineral and 5% water (Fejerskov et al., 1984; Cate et al., 2003).

The histological examination of the initial enamel lesion shows an increase in the enamel porosity and loss of mineral until a depth of 20-100 μm from the outer surface (Fejerskov, 2003).

After 14 days from the cariogenic challenge, the enamel changes can be seen after air-drying as whitish and opaque changes (Fejerskov, 2003). Histologically, the porosity in the subsurface layer is more prominent after 2 weeks. Also from time to time, single or groups of larger defects, the so called focal holes, can be observed. The dissolution causes the removal of the perikymata overlapping after 3 weeks of a cariogenic attack. By comparing with perikymata overlapping,

there is an extensive dissolution of Tomes's process pits, too. At this level of examination, dissolution in the individual crystals can be seen.

After 4 weeks of lesion formation, the signs of dissolution will be extensive with missing larger parts of the outer microsurface. The dissolution of individual crystals can be identified by more enlargements in the intercrystalline spaces. In this stage, an extensive loss of mineral is happening continuously beneath the outer surface (Holmen et al., 1987, 1985a, b). These changes in the enamel impose clinically as "white spot" lesion.

The polarized light microscopy technique can measure the size of intercrystalline spaces or the pore volume and four recognizable areas have been described within the enamel lesion:

1. Surface zone (pore volume of about 1%).
2. Body of the lesion (pore volume can be more than 25%).
3. Dark zone (pore volume between 2-4%) is located below the body of lesion.
4. Translucent zone (pore volume of about 1%) is located at the interior of the lesion, but it is not always apparent.

The first and second zones can be seen by using water as imbibition media, but the other two zones will be only visible using quinoline (Silverstone, 1973).

1.1.6.2 Dentin caries

Dentin consists also of two parts as enamel. It is comprised of 80% mineral and 20% organic part. The crystallites (mineral phase) have a much smaller size than enamel crystallites, but the similar structure of the enamel crystals, whereas the organic portion consists of collagen (Cate et al., 2003).

In case of a cariogenic attack, the pulpo-dentinal organ reacts with dentin sclerosis, dead tracts or reparative dentin. The tubular sclerosis occurs through deposition of the mineral within the dentin tubules and this process is the most common defense reaction of the pulpo-dentinal complex. This reaction is

mutually related to age, sex, type and the surface of the tooth which has the lesion (Stanely et al., 1983).

Various studies have confirmed that the reaction of the pulpo-dentinal organ begins before the lesion accesses the dentino-enamel junction. Moreover, the results of the early stages of decalcification can be seen in dentin before their visibility in enamel (Cate et al., 2003).

1.1.7 Progression and histology of the proximal caries

The proximal lesion has a special, triangle shape. The cone-shaped proximal caries can be considered as the result of different penetration stages which parallel the direction of enamel rod (Bjørndal et al., 1995)

The peripheral lesion parts show less advanced lesion stages and the highest degree of tissue porosity is located in the line between the deepest point of lesion and the surface. However, the dentin lesion occurs if the progression of caries crosses the enamel-dentin junction.

Histologically, the level of infection in dentin is related to the presence of a cavity in the proximal area (Ratledge et al., 2001). Still, the proximal lesions with cavitations are likely to be less advanced than the cavitated occlusal lesions (Kidd et al., 2003a).

However, the diagnosis, the prevention as well as the treatment of proximal caries are still a challenge in clinical dentistry in spite of the caries decline in many countries over the last 30 years (Marthaler et al., 1996; WHO, 2003).

1.2 Proximal caries diagnosis

Caries diagnosis is an intellectual course which integrates the information about this disease obtained clinically or by other diagnostic aids. One of the most important reasons of diagnosis is forming the basis of treatment decision (Kidd et al., 2003b). Perhaps, the huge difference between dentists is their way to diagnose and make the treatment decision for the small proximal lesions (Vidnes-Kopperud et al., 2011). Actually, making the correct treatment decision is dependent on understanding the diagnostic test parameters. Therefore, non-

cavitated lesions may become restored and the huge hidden dentinal lesions may be left without treatment due to the incorrect diagnosis (Verdonschot, 1999). As non-cavitated caries diagnoses are excluded from the recording system, several studies confirmed that at least half of the total lesion cannot be recorded. These studies stated also that the reliability of the recording system does not decrease in case of including the non-cavitated lesion (Pitts and Fyffe, 1988; Nyvad et al., 1999).

Caries diagnosis is a complete process including three steps: firstly, the detection of the caries lesion, then the assessment of caries severity and finally the estimation of caries activity (Ekstrand et al., 2001). The diagnosis of caries can be performed at any stage compared to the following levels:

- D1 (enamel lesion, no cavity)
- D2 (enamel lesion, cavity)
- D3 (dentin lesion, cavity)
- D4 (dentin lesion, cavity to the pulp)

Actually, diagnosis of caries at the D1 level is very important for non-operative management of caries (Kidd et al., 2003b).

1.2.1 Clinical diagnosis

The traditional, first step of the clinical diagnosis is the oral examination and visual inspection of the teeth. Caries can be diagnosed as cavitation, enamel breakdown or as a discoloration in the enamel and the dentin. On the other hand, caries may appear as a hardly visible discoloration which comes into view after air-drying. Still, the clinical examination is not sufficient for caries detection due to the fact that visual inspection failed to diagnose 85% of the cavitated proximal caries (Ratledge et al., 2001). Therefore, dentists need many tools and indicators for the caries diagnosis and the assessment of lesions progression.

1.2.1.1 Estimation of caries activity

The term “caries activity” plays a principal role in caries diagnosis and consequently in making the treatment decision.

Clinically, plaque accumulation and gingival status come in the first place as indicators for active, carious lesions. Previously, the dentists assumed that plaque is the main indicator of caries progression. However, the analyses displayed that there was not always a meaningful difference in plaque score comparing caries progression with no caries progression. Quite the contrary, there was a strong association between caries progression and bleeding of the gingiva. Therefore, gingival papilla bleeding in the proximal area can be an important indicator for caries activity (Ekstrand et al., 1998). Moreover, Ratledge et al. (2001) stated that lesions with cavitation have a higher score than non-cavitated lesions using the site-specific gingival index. Generally, the active lesions can be described as chalky lesions with opaque appearance located adjacent to the gingiva which shows localized gingivitis and a considerable amount of plaque (Thylstrup et al., 1994). However, the dentist needs clinical criteria which help to classify each tooth surface and make a judgment for the treatment as shown in table 1.1.

Furthermore, radiography plays an important role in the assessment of proximal lesions progression through the radiographic subtraction which is able to assess and detect the early changes of tooth demineralization. The radiographic subtraction facilitates the imaging of progression or regression, in other words the imaging of mineral losing or gaining. Moreover, the contrast in digital radiography can be visually enhanced to show the changes in lesions obviously (Ellwood et al., 1997; Wenzel et al., 1993).

Table 1.1 – Criteria used for clinical diagnosis (Machiulskiene et al., 1998)

Score	Criteria
0	Sound
1	Active, surface intact
2	Active, surface discontinuity
3	Active, with cavity
4	Inactive, surface intact
5	Inactive, surface discontinuity
6	Inactive, surface intact
7	Filled
8	Filled, with active lesion
9	Filled, with inactive lesion
10	Extracted due to caries

1.2.1.2 Non-invasive diagnostic methods

There are many new aids and tools which improve the caries diagnosis besides the traditional visual inspection with sharp eyes and air-drying. They exploit the physical properties of the affected teeth (Pine et al., 1996).

Tooth separation: As 30% of cavitated lesions in dentin did not show any progression (Hintze et al., 1999), tooth separation is a very useful technique to detect the existence or the absence of cavities in proximal caries. Teeth separation can be performed using an orthodontic elastic band as separator for few days (Kidd et al., 2003b). Moreover, this method can play an essential role in the diagnosis of small lesion in contacting proximal surfaces (Hintze et al., 1999; Pitts & Rimmer, 1992).

Lighting: Using this technique, the lesion can be detected as shadow in the dark mouth after using a lamp to illuminate the enamel (Kidd et al., 2003b). The light scattering method is one of the useful techniques for detection of the mineral loss (Pine et al., 1996).

Fiber-optic transillumination (FOTI) can be used as an optical monitor and it is an effective method for monitoring the deep carious lesions. Actually, the use of FOTI localizes dentin defects, but its sensitivity is lower than bitewing radiographs regarding the dentinal proximal caries (Kidd et al., 2003b; Verdonschot et al., 1999; Pitts, 1997).

Electrical resistance measurements (ERM) are considered as a functional aid for the occlusal caries detection through monitoring the reduction in the enamel minerals (Verdonschot et al., 1999; Pitts, 1997).

Quantitative laser fluorescence (QLF) is a useful method to diagnose the reduction in the mineral as decreasing in the enamel fluorescence. As a result, the carious lesions appear darker than the sound enamel. Equipment for this method needs endoscope and camera. The excitation in this method is executed by the argon-ion laser (Pine et al., 1996). QLF is a specific way for the caries diagnosis in the buccal and lingual surfaces (Verdonschot et al., 1999; Pitts, 1997).

In conclusion, these methods seem suitable techniques which have been suggested for assessing the caries progression and they may also help to detect the small changes in lesions (Verdonschot et al., 1999).

1.2.2 Radiographic diagnosis

As detection of initial proximal caries by clinical inspection is not always possible (Mejàre and Mjör, 2003), the examiner needs other techniques as bitewing radiography which can be integrated with the clinical examination in order to diagnose the proximal lesions. Out of 73 proximal lesions, sixty-nine cases were detected by radiographic methods, nine cases by the visual/tactile method, four cases by FOTI and only two cases assessed by the laser fluorescence (Bader et al., 2002). Kidd and Pitts (1990) reported that the use of bitewing doubles the number of lesions which have been detected by clinical examination. Therefore, many studies have proved that the prevalence of the proximal caries is underestimated if the clinical data are not combined with radiographs (Poortermann et al., 2000). Stephen et al. (1987) stated that FOTI cannot be

more suitable than bitewing radiography in the diagnosis of proximal caries. Machiulskiene et al. (1999) stressed that there is a correlation between the efficiency of bitewing radiography and the refinement of the clinical caries diagnostic criteria.

As the value of bitewing radiographs for the detecting the depth of the proximal lesion is indisputable (Pitts, 2004; Kidd et al., 2003b; Poortermann et al., 2000; Howat et al., 1980), the radiographic examination contributes significantly to the detection of dentin lesions (Machiulskiene et al., 1999). Furthermore, the bitewing radiography is considered as non-invasive method which does not harm the demineralized tissues (Kidd et al., 2003b). The frequently used criteria for the radiographic assessment of proximal caries depth are given in table 1.2.

Table 1.2 – Criteria for assessing proximal caries lesions (Mejäre et al., 1999)

Score	Criteria
R0	No radiolucency
R1	Radiolucency confined to the outer half of the enamel
R2 (R2-3)	Radiolucency in the inner half of the enamel including lesions extending up to but not beyond the enamel-dentin junction (Radiolucency in the dentin; broken enamel-dentin junction but without obvious spread in the dentin)
R3	Radiolucency with obvious spread in the outer half of the dentin (<half way through to the pulp)
R4	Radiolucency with obvious spread in the inner half of the dentin (>half way through to the pulp)

The major problem in the radiography examination is the overlapping of proximal surfaces. In this case, the distinction between the sound surfaces and surfaces with initial caries is not always possible. The other disadvantage of the radiographic inspection of proximal lesions is the overestimation of proximal lesion depth in the case of presence of superficial caries or demineralization on the lingual or buccal surfaces too which can be imaged as carious lesion which

extends into the dentin (Kidd et al., 2003b; Wenzel et al., 1993; Pitts, 1983). Furthermore, there is unwillingness in some people regarding radiographs due to the fact that radiation should be reduced as much as possible (Kidd et al., 2003b).

Besides bitewing (conventional film radiography), there are other methods:

Xeroradiography: This method was developed on the basis, that it was twice as sensitive as conventional radiographic film (D-speed). It was used in vitro for the detection of proximal caries. The use of Xeroradiography is not widespread and it was overtaken by fast developing digital system (Pine et al., 1996).

Indirect digital imaging: Equipment for this method needs a personal computer and digitization. The information which comes from the radiographic image decomposes into bits and bytes during the process of digitization.

Direct digital imaging: The major advantage of this method is to eliminate the time between exposure and displaying the picture compared with the indirect imaging. Moreover, this method facilitates the contrast, density manipulation and transmission of the image. Furthermore, the automated analysis of digital radiography provides a sensitive observation which permits the detection of small lesions (Wenzel et al., 1993). The software tools permit the measurement of digital images and saving them, still the dose reduction is the main advantage of digital imaging (Pine et al., 1996).

However, this system has some disadvantages such as the space for the unit and the expensive price of software tools and the sensors.

1.2.3 Caries prediction (caries risk assessment)

Bratthall (2004) explained the term of caries risk: "Caries risk is the probability that an individual will develop carious lesions, reaching a given stage of the disease in progression during a specified period of time, conditional that the exposure status for risk factors remains stable during the period in question". Thus, the assessment of caries risk means the judgment on the possibility of initiating new carious lesions or progression of others during a specified period.

General diseases, caries experience, dietary habits, oral hygiene, salivary analyses, social factors, malocclusion, disability and use of fluoride are parameters which aid to assess the caries risk. Furthermore, Hausen (2003) revealed that the previous caries experience can summarize the effects of other factors. Therefore, it is considered as the most important predictor for the caries risk assessments (Hänsel Petersson et al., 2002; Hausen, 2003).

Table 1.3 – Weighting factors for caries risk assigned by the University of Florida. Decision-support system in 1997 and 2000 (Benn et al., 1997)

Risk factors	Weight assigned in	
	1997	2000
Dentinal caries	6	6
Enamel caries	4	4
Restoration in last 12 months	3	2
Five or more missing or filled teeth	2	2
Poor oral hygiene	2	2
Cariogenic diet	2	2
Inadequate fluoride exposure	2	2
Reduced salvia flow	2	2
Poor patient compliance	2	2
Poor restoration margin/plaque trap	1	0
Exposed molar root surfaces	1	1
High initial <i>S. mutans</i> (>10 ⁶ cfu/ml)	0	1
High <i>S. mutans</i> post-treatment (>10 ⁵ cfu/ml)	0	1

Bratthall (1996) developed a computer program (Cariogram) which used 10 parameters to predict in term of low, medium and high risk and it suggests preventive strategies too. Cariogram has been evaluated by Hänsel Petersson et al. (2002) who confirmed that it predicted more precisely than any single factor. Another method to predict the caries risk numerically was suggested by Benn et al. (1997) who summarized 13 variables considered in the oral health support system developed at the University of Florida (Table 1.3).

Eventually, the examiner should study the interaction between caries risk factors and, then, he plan a suitable strategy to manage caries.

1.3 Treatment of dental caries

1.3.1 Treatment planning

Huge variation among dentists in clinical treatment planning can be observed (Mileman et al., 1992; Kay et al., 1995), considering the fact that the dentists' judgment of treatment decisions is influenced by their dental school training (Anusavice, 2003). Anyway, many factors must be taken into account before making the treatment decision. The majority of these factors are conditional on patients; the compliance of patients, classification of the patients' caries risk level (low, moderate or high), financial statement and the patient satisfaction with the selected treatment. Still, there are factors which also relate to the dentist and affect making the treatment plan clearly, e.g. dental school training in addition to other ones such as caries activity and other clinical problems (Anusavice, 2003). Before making the treatment plan, the following treatment options should be considered:

- No treatment.
- Non-invasive treatment (secondary prevention).
- Micro- and minimal invasive treatments.
- Operative treatment.

Anusavice (2003) summarized the elements of decision making in eight steps:

- Identifying the principal caries management problem during determining the patient's compliance and the diagnosis of initial caries and cavitation.
- Recording all relevant medical data which result from a dental history.
- Selecting the correct treatment from all potential treatment options.

- Assessment of the outcomes probabilities of the most beneficial treatment options and estimation of the likely adverse effect associated with each option.
- Assigning the values for treatment outcomes by the dentist after discussing treatment outcomes with the patient.
- Calculation of expected values for each beneficial treatment option. The computation should be performed if there are several positive and negative outcomes that also need to be considered.
- Estimation of treatment outcomes relative to preoperative prediction.
- Analyzing treatment outcomes and modifying the treatment choices.

1.3.2 Non-invasive treatment

Clinical management of caries starts with preventive and non-invasive treatment. The principle of the non-invasive treatment is modifying the imbalance between de- and remineralization to the benefit of the last. The accomplishment of this treatment can be achieved through the prevention process. In other words, the term “preventive and non-invasive treatment” is used to surround all measures of prevention in order to control caries disease (Kidd and Fejerskov, 2003).

Many factors as oral hygiene, nutrition, fluoride and antimicrobial agents have a role to play in the prevention process.

1.3.2.1 Dietary control

In conjunction with other preventive measures, dietary control contributes in the multifaceted strategy for caries prevention. In a wide range of human epidemiological and experimental studies, overwhelming evidence of strong association between the frequent consumption of fermentable carbohydrate and the prevalence of dental caries was found (Moynihan et al., 2003). Naturally, the relationship between caries prevalence and the nutrition should not be evaluated only considering the consumption of fermentable carbohydrate, but also with regard to the several factors involving the different intake of patterns, unsuitable intake and use of fluoride and non-cariogenic sweeteners. Karlsbeek and Verrips

(1994) confirmed that the DMFS scores of children who consumed sweet snacks between meals were significantly higher than mean DMFS scores of children with lower reported sweet snack consumption. Hence, many researchers emphasize that the frequency of intake is more important than the amount of sugar intake. Often the number of unsuitable intake with a high degree of adhesiveness tends to increase with the daily number of meals. Therefore, it is of great importance to reduce the number of intakes and to select the food products with a short pH drop (Moynihan et al., 2003), e.g. peanuts, milk products and cheese are indicated as anticariogenic foods (Moynihan et al., 2003; Jenkins and Hargreaves, 1989). Reducing the consumption of sweet products to a minimum is helpful, but this may be very difficult to achieve. The use of non-sugar sweeteners such as sorbitol and xylitol in chewing-gum, sweets, confectionary and drinks offers a caries-protective alternative (Moynihan et al., 2003).

The use of fluoride is the most important factor influencing the DMFT index. The relationship among the frequency of carbohydrate, use of fluoride toothpaste and enamel demineralization has been studied in situ by Duggal et al. (2001). This study demonstrated the importance of fluoride-containing toothpaste in enamel re-/demineralization by varying the frequency of carbohydrate challenge. Despite of the dramatic effect of fluoride on caries, it cannot eliminate caries. Substantially, the use of fluoride does not remove all causes of caries such as sweet snack consumption.

1.3.2.2 Oral hygiene

In reference to the positive association among oral hygiene and lower caries rate (Ekstrand et al., 2000; Axelsson et al., 1991), plaque control is considered as one of the basis of caries preventive programs in current times. A strong, positive correlation between the frequency of tooth brushing and the caries decline was observed in many studies (Kuusela et al., 1997; Chesters et al., 1992). Moreover, the effectiveness of tooth brushing is related to the toothpaste, time and the quality of tooth-brushing too. Creeth et al. (2009) found that brushing for 180 seconds removed 55% more plaque than brushing for 30 seconds. Actually,

tooth brushing with fluoride toothpaste has proved high effectiveness as caries preventive measure (Twetman, 2009; Nyvad, 2003; Marthaler, 1990). Still, the use of toothpaste only for 60 seconds cannot increase the removal of plaque.

Several studies have demonstrated that all electric toothbrushes are equal to the manual technique regarding the effectiveness that no relevant differences in the plaque removal and gingivitis controlling ability were clinically observed (McCracken et al., 2004; Aass and Gjermo, 2000; Heintze et al., 1996). However, the patients undergoing orthodontic treatment with fixed appliances and poor oral hygiene may prefer the electric toothbrushes because plaque removal can be achieved easier and faster (Heintze et al., 1996). Frequently, the bacteria remain in surfaces and areas which are difficult to reach, such as proximal surface. Therefore, flossing is significant, even after excellent tooth brushing. Koch et al. (1994) confirmed that flossing after tooth brushing showed more efficient proximal plaque removal in comparison to tooth brushing alone. Furthermore, proximal caries reduction can be improved apparently through professional flossing with NaF or SnF₂ (Gisselsson et al., 1999) or with a 1% CHX gel (Gisselsson et al., 2005).

Finally, daily plaque removal in term of toothbrushing and flossing can be considered as treatment of the active lesions which remain at the invisible stage of caries progression.

1.3.2.3 Chemoprophylaxis of dental caries (antimicrobial agents)

Occasionally, the mechanical control of plaque is difficult to achieve and, therefore, chemoprophylactic agents may offer an adjunct. The antimicrobial agents limit the plaque accumulation through one or more of the following principles (Scheie, 1994):

- Hindering of bacterial colonization.
- Hindering of bacterial growth and metabolism.
- Disruption of mature plaque.
- Modification of plaque biochemistry and ecology.

Chlorhexidine is one of the most effective agents (Scheie, 2003) and it is used as standard to measure the potency of other ones. Chlorhexidine is effective against gram-negative and, especially, against gram-positive microorganisms and it has proven high anticaries activity (Marsh, 1993). Chlorhexidine can be delivered to the oral cavity by various ways such as rinses, dentifrices, chewing-gums, gels and varnishes. However, varnishes appear to be the most effective delivery system (Marsh, 1993). Concerning proximal surfaces, Guiselsson et al. (2005, 1994, 1988) studied the effect of professional flossing with chlorhexidine gel on proximal caries and concluded that this method may be considered as an interesting caries-preventing approach for proximal caries. Schiött (1973) revealed that the plaque and salivary bacterial flora are each reduced by 80-95% by a single mouthrinse with 0.2% chlorhexidine. Therefore, the routine use of antimicrobial agents can destroy the ecological balance within the oral cavity and cause an overgrowth of the resistant bacterial strains which may appear. Hence, such agents should be used restrictively and only if the conventional prophylactic methods are likely to be ineffective.

1.3.2.4 Clinical use of fluoride

Fluoride has proven high efficacy in controlling the caries development and reducing the lesion progression. Actually, three theories have dominated the role of fluoride in the caries remineralization of the dental hard tissues: fluoride disturbs colonization of bacteria, it tends to prevent enamel from dissolving and it reduces the solubility of the apatite through increasing the enamel resistance (Larsen and Bruun, 1994). Fluoride can be considered as therapeutic agent due to the fact that an elevated level of it in the oral environment will interfere with remineralization processes (Fejerskov, 2004; Ellwood and Fejerskov, 2003). There are two ways of using fluoride in caries prevention, either systemic (water, salt, milk and tablets) or topical (dentifrices, tablets, rinses, gels and varnishes). Without doubt, the widespread use of fluoride-containing toothpaste is thought to be the major factor in the worldwide decrease of dental caries. Walsh et al. (2010) found strong evidence that 1000 ppm and above fluoride toothpastes

were more effective than a placebo in preventing caries. As a part of an individually designed oral health program, mouthrinses with fluoride solutions are frequently used. However, the result showed that the control of caries using the mouth rinsing program was very difficult even in the high caries active risk groups (Disney et al., 1989). Gels and varnishes are the most common professional fluoride-delivery methods. Concerning proximal surfaces, fluoride gels (5000-12300 ppm F) in a thixotropic gel vehicle claim to have the ability to flow under pressure and penetrate between the teeth (Ellwood and Fejerskov, 2003). Fluoride varnishes can provide site-specific fluoride delivery, e.g. proximal surfaces. By means of a meta-analysis on the fluoride varnish Duraphat[®], Helfenstein and Steiner (1994) reported a 38% reduction in dental caries. Furthermore, fluoride may be delivered to the oral cavity by the silicate restorative materials and glass-ionomer cements, which contain large amounts of fluoride (about 15-20%). Studies have shown that, even 1 year after application of glass-ionomer restorations in primary teeth, the fluoride concentration in unstimulated saliva was about six times higher than normal (Hatibović-Kofman and Koch, 1991). However, fluoride is considered as therapeutic agent which can reduce the rate of demineralization and enhance the remineralization. Therefore, it offers an effective measure which retards or even arrests the caries progression.

1.3.3 Operative treatment

The clinical management of dental caries consists of treating the cavitations with restorations as a step of this process and not as a synonym of the caries treatment. There are many goals of placing a restoration such as function, pulp prevention and the esthetic reasons (Elderton and Mjör, 1988), but the main goal of operative procedures is facilitating plaque control as a part of the treatment strategy (Kidd and van Amerongen, 2003). Where a cavitated carious lesion is present on proximal surface, the process of remineralization will fail because the patient cannot clean the affected surface sufficiently. Dental flossing can skim the

surface, but not access the cavity (Kidd and van Amerongen, 2003) and, then, the operative treatment is generally recommended.

1.3.4 Minimal operative treatment

Laser, tunnel restoration, ART (atraumatic restorative treatment), air abrasion and fissure sealant are examples for the minimal invasive treatment. Application of fluoride, enhancing the oral hygiene and proper diet (non-operative management of caries lesions) are often successful in hampering the further progression of initial lesions. However, with the increasing lesion extension which is accompanied by an increased risk of surface breakdown, non-operative caries treatment alone is not more sufficient to arrest the caries process effectively (Kidd and Fejerskov, 2003). Adhesive dentistry is a dynamic approach with new trends evolving to preserve a maximum amount of tooth tissue. Furthermore, the minimally invasive intervention is appreciated by patients due to the fact that these methods cause no pain. As a result, minimal invasive treatments offer new safe and effective measures in dental health care.

1.3.4.1 Pit and fissure sealants

Sealing of pits and fissures prevents the accumulation of microbial biomasses and the development of caries in occlusal surfaces. Consequently, it offers an efficient technique for occlusal caries prevention. The practical application of sealants is technically easy and includes four steps: (I) Cleaning of the teeth which will be sealed (II) Etching the surface (III) Rinsing with water spray and airdrying of the etched area and being careful in order not to contaminate the surface, because sealing materials are sensitive to the contamination with saliva (Simonsen, 2002) (IV) Application of the sealing materials and light-curing. Concerning the retention of sealants, Horowitz et al. (1977) reported a 42% complete retention of occlusal sealants after 5 years of follow-up. After 20 years of follow-up, Wendt et al. (2001) referred to 65% complete sealant retention. Furthermore, a relative reduction in caries risk (69%) was reported after 4 years of sealants application (Bravo et al., 1997). Moreover, carious lesions appeared

46% less on sealed versus unsealed teeth after 4 years of sealing the occlusal surfaces (Ismail et al., 1989). In another study and after 17 months of follow-up, no progression on radiographs under the sealants was mentioned (Mertz-Fairhurst et al., 1986). Due to the effectiveness of sealants, sealing of the initial occlusal lesions is recommended (Ekstrand et al., 2001) and the indication seems even to shift from preventive sealants to therapeutic ones (Splieth et al., 2010).

1.3.4.2 Proximal sealing

Many studies confirmed that proximal caries progresses relatively slowly in permanent teeth and needs about 4–6 years to expand into dentine (Mejàre et al., 1998 & 1999). Moreover, Gray and Shellis (2002) suggested that the sealing approach of initial carious lesions could be adopted on proximal surfaces as enhanced preventive approach. However, the idea of establishing a resin barrier between the dental biofilm and initial proximal lesions has also been examined recently. Actually, several clinical studies applied sealant in the proximal area and they used either regular sealant resin (Abuchaim et al., 2010; Martignon et al., 2010, 2006; Gomez, 2005; Tanaka et al., 2000) or polyurethane tape (Alkilzy et al., 2009). The proximal sealing has been performed under the following guidelines: (I) Creating space in the proximal area by placing an elastic orthodontic band resulting in two appointments within a few days (II) Etching the surface of test tooth (III) Application of the bonding agent (adaptation of the adhesive patch on the proximal surface of test tooth, if the polyurethane tape technique is used) (IV) Light curing. Most clinical studies on proximal sealing used bonding agents or conventional sealant materials without the elastic polyurethane foil (Abuchaim et al., 2010; Martignon et al., 2010, 2006; Gomez, 2005; Tanaka et al., 2000), but the new adhesive patch approach seems to be more effective than two layers of enamel bonding in a vitro analysis (Schmidlin et al., 2005). Moreover, Alkilzy et al. (2009) mentioned that the elastic polyurethane foil facilitated the removal of excess cervical bonding prior to light curing. Furthermore, the problem of the thin sealant layers and oxygen inhibition has

been solved by using the new adhesive patch. Incomplete isolation from moisture could be the main reason of early loss such as fissure sealant, therefore, using the rubber dam in this technique-sensitive procedure is recommended.

After 18 months, sealing of the proximal lesions (test lesions) was more effective than flossing (control lesions) as 22% of the test lesions had progressed compared to 47% of the control lesions (Martignon et al., 2006). In another clinical study which assesses the efficacy of sealing non-cavitated, proximal lesions on primary molar teeth (test) in comparison to flossing instructions (control), the progression status data from the radiographically assessment showed that 27% of the test lesions and 51% of the control lesions progressed during the first year. Corresponding numbers after 2.5 years were 46 and 71%, resp. (Martignon et al., 2010). As a result, the proximal sealing was superior to the flossing instructions after 1 and 2.5 years follow-up (Martignon et al., 2006, 2010). Several studies confirmed the therapeutic effect of proximal sealing (Abuchaim et al., 2010; Alkilzy et al., 2009; Gomez, 2005), but they did not report statistically, significant differences in comparison to the flossing and fluoride application. In a clinical study which evaluated the clinical safety of proximal sealants, a good retention, marginal adaptation and colour were reported after 2 years (Alkilzy et al., 2009).

Thus, it is reasonable to conclude that sealing the initial proximal lesions in the permanent and primary dentition is a feasible technique in preventive and minimally invasive dentistry and it frequently shows a higher efficiency as the plaque control using flossing and fluoride.

1.3.5 Micro-operative treatment

Actually, large areas of sound enamel in proximal surfaces have to be removed by filling and even by minimal operative technique such as tunnel restoration or laser, since these techniques require access to the affected parts through destruction of large areas of the sound enamel. Therefore, a new direction appeared in treatment planning recently. This new orientation of micro-operative treatment can be defined as a philosophy of professional care considering the

first occurrence and early stage of the caries. The micro-invasive methods such resin infiltration of proximal caries offer a successful treatment, which hampers the progression of initial lesions or at least postpones the operative intervention for many years.

1.3.5.1 Resin infiltration of proximal lesions

A few studies showed that a penetration of the caries lesion could be achieved at least partially with some commercially available adhesives and fissure sealants (Meyer-Lueckel et al., 2006; Gray and Shellis, 2002; Davila et al., 1975). Moreover, the resin infiltration can reduce the lesion progression in the cariogenic environment (Paris and Meyer-Lueckel, 2010; Paris et al., 2006; Davila et al., 1975). Porosities of enamel caries act as diffusion pathways for acids and dissolved minerals. The infiltration of these lesions with resin might occlude these pathways and consequently arrest or even hamper the caries progression (Meyer-Lueckel and Paris, 2008b; Paris et al., 2007a,b,c).

The infiltration process aims to occlude as many as possible the lesion pores with low-viscosity resins in order to create the diffusion barrier inside the lesion without the need to separate the teeth. In contrast to this, proximal sealing which produces a diffusion barrier on the tooth surface requires placing an elastic orthodontic band for spacing as two appointment procedure. Paris and Meyer-Lueckel (2010) confirmed that caries infiltration hampers lesion progression efficiently without a covering resin coat. On the other hand, the resin coat on top of the lesion surface does not seem to be essential to stop lesion progression *in vitro* if the lesion body is homogeneously infiltrated by resin (Paris et al., 2006). Moreover, leaving excessive material (resin coat) could provide retention sites for the plaque. The low viscous sealants showed deeper penetration after etching the enamel (Irinoda et al., 2000). Moreover, Paris et al. (2007c) confirmed that resin penetration into caries lesions cannot be achieved without etching the surface layer of the lesions, because the surface layer forms a barrier which hampers the infiltration of the lesion body. Due to this concept, the idea of infiltration is improving the penetration of resin into a subsurface lesion by

removing the surface zone of the lesion using a strong acid. Etching with 15% hydrochloric acid for 120 s has been showed a nearly complete removal of the surface layer compared to 37% phosphoric acid gel (Paris et al., 2010a; Meyer-Lueckel et al., 2007). These studies emphasized that no cavitation has been observed, even with the complete removal of the surface layer after etching with 15% HCl (Paris et al., 2010a; Meyer-Lueckel et al., 2007).

In contrast to artificial lesions, adhesives penetrated only superficially into natural lesions even after etching with 15% HCl (Paris et al., 2007c). Therefore, the experimental resins were improved to find an optimal infiltrants with regard to rapid capillary penetration (Paris et al., 2007b). A deeper penetration in natural lesions was achieved by using this improved experimental resin (infiltrants) after etching with 15% HCl compared with commercial adhesives (Meyer-Lueckel and Paris, 2010; Paris et al., 2009; Meyer-Lueckel and Paris, 2008a).

The deeper penetration and caries-inhibiting properties of infiltrants could be observed with increasing the penetration coefficient and accordingly deeper penetration can be shown (Meyer-Lueckel and Paris, 2010). A solvent-free material containing of triethylene glycol dimethacrylate (TEGDMA) as the main constituent showed the best penetration abilities (Meyer-Lueckel and Paris, 2008a; Paris et al., 2007b) and it seemed to be preferable for infiltration of natural caries lesions (Meyer-Lueckel and Paris, 2010). Additionally, the penetration depth depends on penetration time (Paris et al., 2007b). Meyer-Lueckel and Paris (2008b) revealed that a good negative correlation between the progression of lesion depth which has been measured by the confocal laser scanning microscope and the square root of the product of penetration coefficient and application time could be found. The occasional progression of deeply infiltrated lesions might be attributed to incompletely infiltrated regions within the resin layer and cleft-like inhomogeneities, caused by polymerization shrinkage during light curing (Paris et al., 2007b, 2006). Therefore, Robinson et al. (2001) pointed that a repeated application of resin can reduce this leakage and reduce the further lesion progression. Furthermore, infiltration of the porous lesion structures might strengthen the attacked tooth mechanically and prevent

cavitation in the permanent and primary dentition (Paris et al., 2007c). Certainly, using rubber dam will diminish the possibility of contamination of the lesion pores, which might hamper resin penetration. In a clinical study, Paris et al. (2010b) assessed the effectiveness of infiltration of proximal lesions in inhibition of caries progression. The study design was a split-mouth placebo-controlled randomized clinical trial and it included proximal lesions with radiolucencies involving the inner half of enamel up to the outer third of dentin. After 18 months, 2/27 lesions (7%) in the test group and 10/27 lesions (37%) in the control group showed progression. With digital subtraction radiography, significantly reduced caries progression could be found in the test group compared with the control group. As a result, caries infiltration was efficacious in reducing the lesion progression in comparison to preventive, non-invasive treatment. Moreover, no unwanted effects such as surface breakdown, loss of vitality or gingival alterations were observed in the two groups. In another clinical study, the efficacy of resin-infiltrated lesions covered with fluoride varnish was assessed versus fluoride varnish only in proximal lesions on deciduous primary molars of 5 to 8 year olds (Ekstrand et al., 2010). The resin infiltration in conjunction with fluoride varnish treatment of proximal lesions on deciduous molars was superior to fluoride varnish treatment only in reducing caries progression as 31% of the test lesions and 67% of the control lesions had progressed clinically as well as 23% and 62% had progressed radiographically after 1 year. In a 3-year randomized clinical trial, Martignon et al. (2012) compared the therapeutic effects of infiltrating vs. sealing proximal caries lesions and placebo treatment on young adults. The study showed that infiltration is more effective than placebo treatment for reducing the caries progression of proximal lesions, but there was no significant difference between infiltration and proximal sealing.

In particular for proximal surfaces, large areas of sound enamel have to be removed even with minimally invasive techniques. Therefore, caries infiltration can be considered as new successful technique for arresting the caries progression of initial proximal lesions.

Chapter 2: The aim of the study

Caries infiltration is a new approach which aims to occlude lesion pores with low-viscosity resins in order to create diffusion barriers and, hence, arrest caries progression. This procedure does not need prior temporary tooth separation and, therefore, it requires only one visit. Thus, the aims of this practice-based study were (1) to evaluate the clinical applicability of the new resin infiltration technique in children and adult patients, (2) to estimate its clinical safety and (3) to assess the therapeutic effect of resin infiltration of proximal caries in reducing the lesion progression.

Chapter 3: Material and Methods

3.1 Sample

After the approval by the Ethics Committee of University of Greifswald, 50 patients (29 male; 21 female; age range 5–35 years; mean age 17.9 years \pm 6.8) were included in the study. The inclusion criterion for the children, adolescents and young adults who were enrolled in the study was the presence of a proximal lesion in enamel or outer dentine on deciduous or permanent teeth assessed by radiographs (E1, E2 or D1 without cavitation, Fig 3.1a/b, 3.4) according to the following classification (Paris et al., 2010b):

- E1: radiolucency in the outer half of the enamel
- E2: radiolucency in the inner half of the enamel including lesions extending up to but not beyond the enamel-dentin junction
- D1: radiolucency with obvious spread in the outer third of dentin
- D2: radiolucency with obvious spread in the middle third of dentin
- D3: radiolucency with obvious spread in the inner third of dentin

The exclusion criteria were: pregnancy, retardation, allergies (especially to resin materials) and the presence of cavitation on the tested proximal surfaces. All patients who participated in this investigation had to give their informed constant and, then, they were admitted to the baseline examination by the investigators (MB.A) and (M.A). Moreover, all patients have gotten documents which explain substantially the resin infiltration process and the preconditions for joining in the study.

3.2 Lesion selection

3.2.1 Clinical assessment

The baseline examination consisted of the medical history (general diseases, retardation, medication and allergies especially resin) and the dental status. This

included the decayed, missing, filled teeth and surfaces (DMFT/S; dmft/s) and thermal vitality testing of the tooth assigned for infiltration and the adjacent teeth using cold spray (Pluradent[®], Offenbach, Germany) which were assessed in the baseline. Furthermore, the clinical status, plaque accumulation as well as the gingival status of the test teeth was recorded descriptively before the performance of the treatment. Clinical status was scored as 0: healthy, 1: stain/initial lesion, 2: carious defect. Plaque accumulation was scored as 1: no visible plaque, 2: little, 3: moderate, 4: excessive after the use of a plaque detector (Mira-2-Tone, Hager & Werken, Duisburg, Germany). Gingival status was scored as 1: healthy, 2: bleeding after probing with a WHO probe, 3: swelling, 4: strongly reacted.

3.2.1 Radiographic examination

The bitewing radiographs were taken with digital x-ray (Sirona, 60 kV 7 mA; using the software_ SIDEXIS[®] Sirona, Bensheim, Germany) after individualizing the holder with silicon impressions (Optosil[®] P plus, Hanau, Germany) to standardize the radiographs at the follow-ups (Fig 3.2a/b). After the clinical and radiographic examination, if all selection criteria were fulfilled, the patient was enrolled in the study.



Fig 3.1a/b – Initial proximal lesion on mesial surface of tooth 36 without cavitation scored E2 radiographically



Fig 3.2a/b – X-ray holder with individualized silicon impressions

3.3 Resin infiltration

Infiltrations with Icon[®] (Proximal Mini Kit, DMG, Hamburg, Germany) can be performed by any licensed dentist after purchasing the product from a dental supplier. Following the flow chart, applying an infiltration should be feasible for any dentist familiar with adhesive techniques. The treatment in the present study was performed by ten dentists at University of Greifswald. Without previous practical training before the study, the dentists applied the resin infiltration after reading the instruction manual from the producer and monitoring the flow chart on the box (Icon[®] Proximal Mini Kit, DMG, Hamburg, Germany) (Fig 3.3a/b) which explains the practical steps of this treatment. This is equivalent to the first use of a regular dentist in private practice.

The infiltration of proximal caries was performed according to the following guidelines:

- Proximal surface of the effected and adjacent tooth cleaned with dental floss.
- Rubber dam (Ivory[®] Heraeus Kulzer, Hanau, Germany) was placed including neighboring teeth.
- Special dental wedge (Icon[®] Proximal Mini Kit, DMG, Hamburg, Germany) was inserted in the proximal region for better access to the proximal area (Fig 3.5).

- Proximal surface of test tooth etched with 15% hydrochloric acid for 120 s (Icon[®] Proximal Mini Kit, DMG, Hamburg, Germany) (Fig 3.6).
- The test surface rinsed with water and dried for 30 s (Fig 3.7).
- The surface was dehydrated by evaporation of superficially applied 95% ethanol (Icon[®] Proximal Mini Kit, DMG, Hamburg, Germany) and air-drying for 30 s (Fig 3.8).
- Infiltrant resin (Icon[®] Proximal Mini Kit, DMG, Hamburg, Germany) was applied on the lesion for 180 s (Fig 3.9).
- Excess material was removed with dental floss.
- Infiltrant resin was light-cured (Mini L.E.D, Sirona, Bensheim, Germany) from three sides for 40 s according to the manufacturer's instructions (Fig 3.10).
- Infiltrant resin was applied again for 60 s and light-cured.
- The contour of proximal surface was finished and polished with finishing discs and polishing strips (Soft-Lex, 3M ESPE, MN, USA) (Fig 3.11).



Fig 3.3a/b – Icon[®] Proximal Kit (DMG); materials and flow chart explaining the practical steps performed by the dentists in the study and to other users



Fig 3.4 – Baseline bitewings radiograph showing two initial lesions



Fig 3.5 – Separation using special dental wedge to gain sufficient proximal space



Fig 3.6 – Etching using special proximal applicator which is permeable only for one side

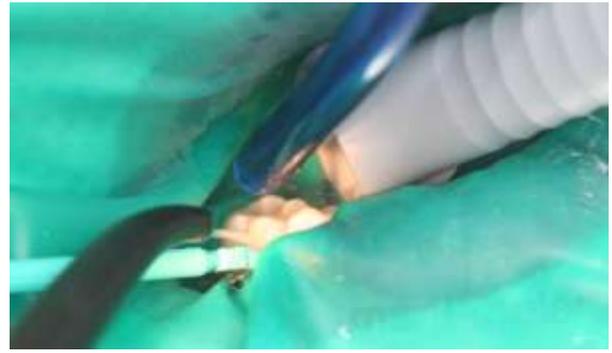


Fig 3.7 – Rinsing with water and drying the test surface



Fig 3.8 – Dehydrating by superficially evaporation of alcohol at the test surface



Fig 3.9 – Resin infiltration using special proximal applicator which is permeable only for test surface



Fig 3.10 – Light-curing the resin material from all sides



Fig 3.11 – Finishing and polishing the contour of infiltrated surface

3.4 Evaluation of the clinical applicability

The applicability of the new technique was estimated by using two questionnaires filled out by the dentist and the patient after the procedure.

The dentist's questionnaire evaluated:

- The time of procedure including rubber dam application and infiltration.
- The difficulty of rubber dam application and the proximal place after separation.
- The problems during the infiltration process and the need to finishing.
- The comparison between caries infiltration and composite filling; complexity and duration.

The patient's questionnaire evaluated the medical history, individual oral hygiene such as tooth brushing, flossing, using of fluoride toothpaste and frequency of visiting the dentist and the patient satisfaction with the rubber dam and the new treatment in aspects of comfort, duration, taste and smell. The patients were asked about the interest, complexity and desire for repeating this new treatment without drilling again for other lesions.

3.5 Assessment of the clinical safety and quality

The clinical safety and quality of resin infiltration was assessed by two trained examiners who had to perform the screening and the estimation at baseline. Patients were clinically examined after one week, six and twelve months. At every recall appointment, the changes of the medical or dental status were assessed. The clinical status, plaque accumulation and gingivitis were recorded according to the used criteria at baseline. In order to assess the quality of the resin infiltration, the discoloration and marginal adaptation tests were performed. The discoloration of the infiltrated surfaces was scored as 1: no discoloration, 2: partial discoloration at the margins, 3: discoloration of the whole surface. The marginal adaptation was recorded according the following scores: 1: smooth transition (no margins could be detected), and 2: sharp-edged margins (detection with a probe is possible). At 6 and 12 months recalls, thermal vitality testing of the infiltrated and adjacent teeth was repeated and the risk level of the individuals was recorded again.

3.6 Radiographic assessment

The follow-up radiographs were taken at the one year recall. The clinical effect of resin infiltration on the caries progression (regression, progression or stable lesion) was assessed through evaluation of radiographs. The baseline and follow-up bitewing radiographs were collected and evaluated by visual-paired examination.

A team of two clinical investigators (MB.T and M.A) was chosen for testing the reliability of reading the radiographs. Both examiners were trained in many calibration sessions for the pair-wise visual reading. The radiographs were coded and randomly organized. The examiners read the radiographs pair-wise and evaluated the bitewing radiographs with the same criteria at the baseline examination. In the case of a discrepancy, they discussed on the basis of the evaluation criteria to find the unanimous vote. After 6 weeks, the conventional

pair-wise visual of radiographs was repeated to assess the intra-examiner reproducibility.

3.7 Statistical analysis

All data were entered into Microsoft Office Excel 2007 and transferred into SPSS software (SPSS16.0 for windows, SPSS Inc., Chicago, IL, USA) for further statistical analysis. The distribution of the lesions according to the tooth type, radiographic score and surface were calculated. Descriptive statistics were used to characterize the time of the procedure and the other data from the questionnaire. In addition to calculating the mean application time, it was examined whether the treatment time decreased with each repetition of the procedure by assessing the association between the number of the treatment (first, second, etc.) and its duration (Spearman-test). The proportions of baseline and recalls data were compared by Wilcoxon Signed Ranks test (2 groups) and Friedman test (more than 2 groups). In all tests, p values below 0.05 were defined as statically significant. Moreover, kappa statistics (Landis and Koch, 1977) was used to assess the inter- and intra-examiner reproducibility.

Chapter 4: Results

4.1 Baseline data

4.1.1 Distribution of sample in the recall analysis

In 3 patients (6%), it was not possible to gain sufficient proximal space for the infiltration. These patients were included in the analysis of clinical applicability and excluded from the follow-up. Thus, the follow-up sample comprised of 47 children, adolescents and young adults (21 female) with an age range of 5–35 years (mean age 17.6 ± 6.9). The reasons for the drop-out and study flow are outlined in Fig 4.1.

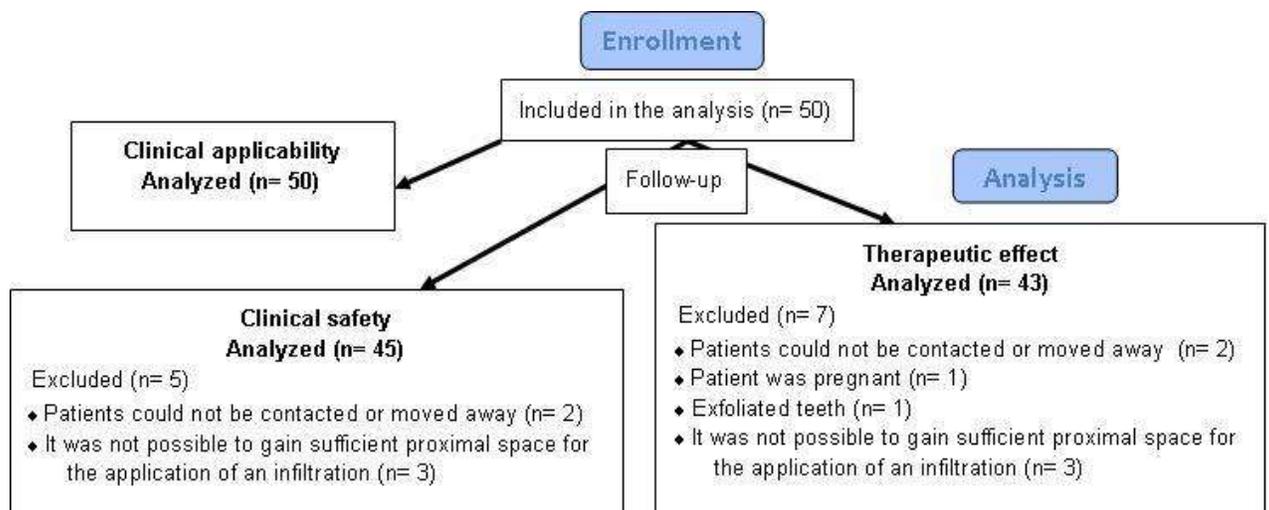


Fig 4.1 – The study flow diagram

4.1.2 Distribution of infiltrated teeth

After excluding 3 teeth from the treatment due to separation problems, the number of infiltrated surfaces was 47 (Table 4.1). The sample consisted of molars, premolars, front teeth and primary molars and 61.7% of the tested surfaces were distal.

Table 4.1 – Distribution of the infiltrated lesions according to tooth type and surface

Teeth	Infiltrated teeth				Infiltrated surfaces	
	Permanent Molar	Permanent Premolar	Permanent Front tooth	Primary Molar	Mesial	Distal
Number (47)	21	19	2	5	18	29
Proportion (%)	44.7	40.4	4.3	10.6	38.3	61.7

4.1.3 Medical history

The evaluation of the patients' questionnaires showed a short medical history (Table 4.2) which is normal regarding the age range of the sample.

Table 4.2 – Medical history findings of the study population (number)

General diseases	Asthma (1), Hashimoto's thyroiditis (1), Crohn's disease (1), Diabetes mellitus (1)
Allergy	Penicillin (1), Pollen (3), Nuts (1), Plasters (1), Cough medicine (1)
Medication	Thyroxine (1)

4.1.4 Dental status

The study sample presented with a low DMFT/S (dmft/s) average like the respective age group in Germany and other industrialized countries (Table 4.3). The standard deviation showed a considerable amount of variation which mirrors the age range in the sample. The vitality test of the teeth which were designated for the infiltration showed a positive response in all cases. Moreover, the adjacent teeth were also vital except for one tooth which had been endodontically treated. Furthermore, the baseline examination of the infiltrated surfaces showed a considerable amount of plaque (63.8%), but little gingival bleeding (36.2%).

Table 4.3 – Distribution of DMFT/S (dmft/s) indices in study sample at baseline

	Minimum	Maximum	Mean	SD
DMFS	0	40	6.21	8.22
DMFT	0	17	3.83	4.36
dmfs	0	14	3.82	4.24
dmft	0	9	2.27	2.69

4.1.5 Patients' home dental care

The study sample showed a very good level of home dental care according to the questionnaires. The majority of the patients (n = 37, 78.7%) brushed their teeth more than one time per day and all patients do use dentifrices with fluoride. Moreover, 21 patients (44.7%) are using dental floss more than two times at week. Besides, the vast majority of them (n = 45, 95.7%) reported semiannual check-up visits at the dentist.

4.2 Clinical applicability and patient satisfaction

The duration of the infiltration had a mean of 24.3 min (\pm 7.4) including the time of the rubber dam application (7.7 min \pm 4) leaving 16.6 min for actual infiltration (\pm 5.8) (Fig 4.2).

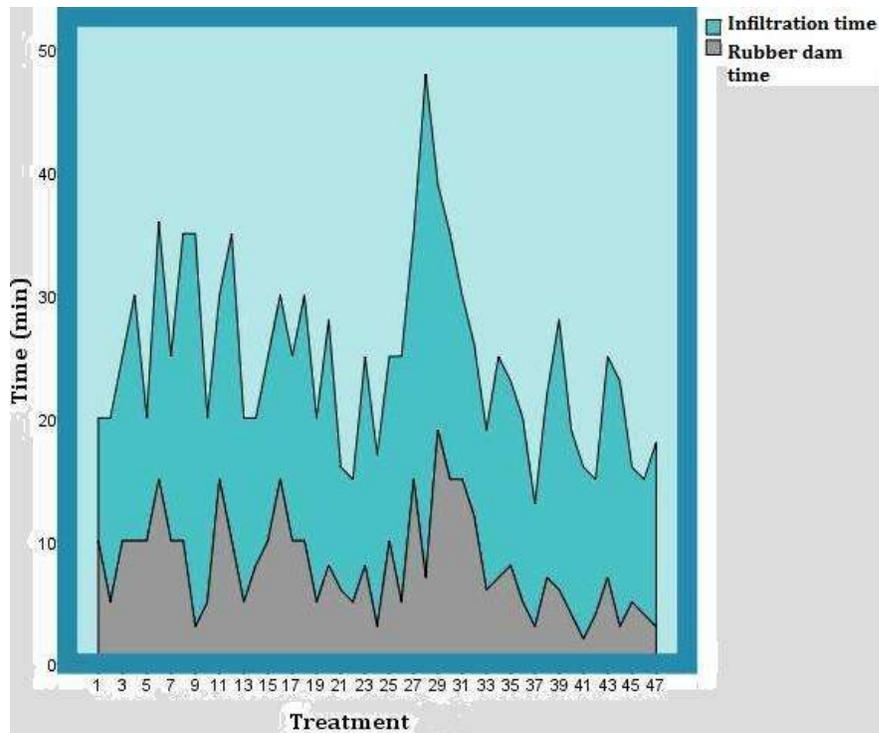


Fig 4.2 – Time of the treatment including caries infiltration and application of rubber dam

In 3 patients (6%), it was not possible to gain sufficient proximal space for the infiltration. In the majority of the cases (85.1%), the dentists found that the infiltration needed relatively little time and most of them (80.8%) stated that the new treatment was easy to perform. In four patients (8.5%), difficulties with the separation of the teeth prolonged the infiltration time (36 min ± 2). In ten cases (21.3%), the dentists reported that the place in the proximal region was quite narrow in spite of using the special dental wedge. Sometimes it was difficult to perform the infiltration treatment, when the clamp of the rubber dam had to be placed on the infiltrated tooth.

In seven patients (14.9%), the dentists mentioned that the time of the infiltration (29.1 min ± 7.5) including rubber dam application (10.7 min ± 4.5) was quite long, because the procedure had to be performed on the most distal tooth with the rubber dam on the tooth which had to be infiltrated. Furthermore, a strong, inverse, statistically significant association between the number of the treatment and the according treatment time was found ($r = -0.545$, $P < 0.001$, Spearman-

test) which indicate to a clear learning curve with a reduction of treatment time for subsequent treatments (Fig 4.3).

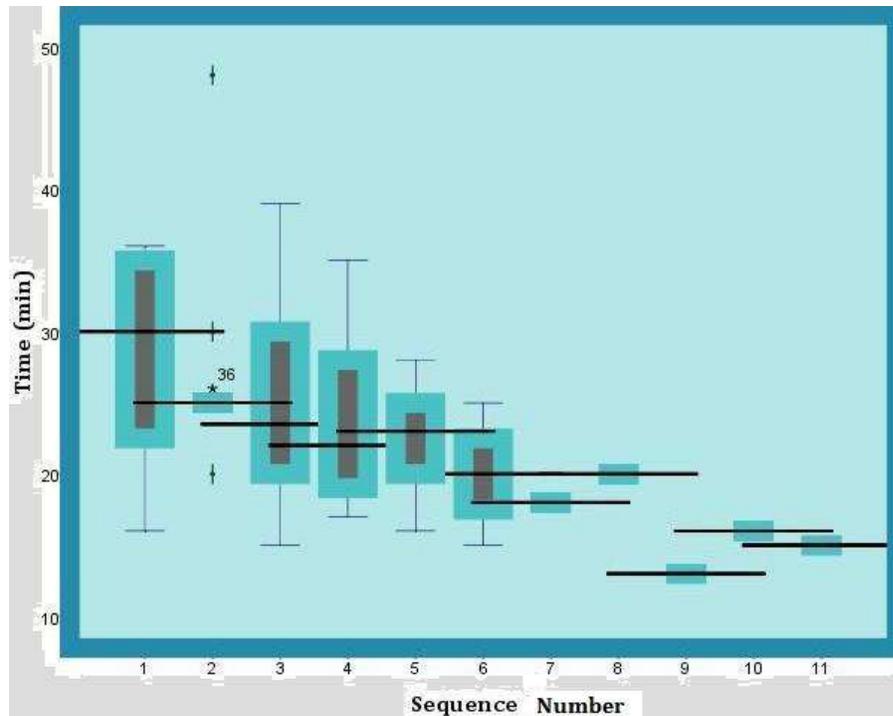


Fig 4.3 – The dentists' learning curve during the study time

In most cases, the dentists reported that the infiltration was comparable to the application of a composite filling (40.4%) or even easier (55.3%, Table 4.4).

The results showed good patient satisfaction with the duration of the procedure (93.6%). In addition, the infiltration treatment was not complicated for most of them (93.6%).

The majority of the patient showed a very high acceptance with the new procedure including the application of the rubber dam (Table 4.5). Only a small group of the patients ($n = 4$, 8.5%) found that the caries infiltration was strenuously, but they were still satisfied with the application time. In two of these cases, the dentists also stated that rubber dam application and gaining proximal space was very difficult. Some patients ($n = 10$, 20%) complained about the taste of the new material, but only one patient mentioned that there was an unpleasant smell.

In addition, the vast majority of the patients (n = 44, 93.6%) would opt for an infiltration again, 37 patients (78.8%) would even be willing to pay for it privately.

Table 4.4 – Dentists' perception of caries infiltration in comparison to proximal composite filling

Caries infiltration is	much easier	easier	comparable composite	more difficult	much more difficult
Number	11	15	19	2	0
Proportion	23.4%	31.9%	40.4%	4.3%	0%

Table 4.5 – Patients' satisfaction with rubber dam application and the caries infiltration

Comfort	Comfortable Number (%)	Ok Number (%)	Strenuous Number (%)
Rubber dam	11 (23.4)	31 (66)	5 (10.6)
Caries infiltration	12 (25.5)	31 (66)	4 (8.5)

4.3 Clinical safety and quality

In the follow-up appointments, no changes in the medical status, local or systemic effect due to the infiltration treatment could be reported. Furthermore, no changes in the vitality of the infiltrated teeth or in the vital, adjacent teeth were found during the course of the study.

The mean DMF-S of the sample was 7.4 ± 8.9 , and the DMF-T corresponded to 4.9 ± 4.5 at one-year recall which showed a marginal increase in the patients' caries experience after 12 months (Fig 4.4).

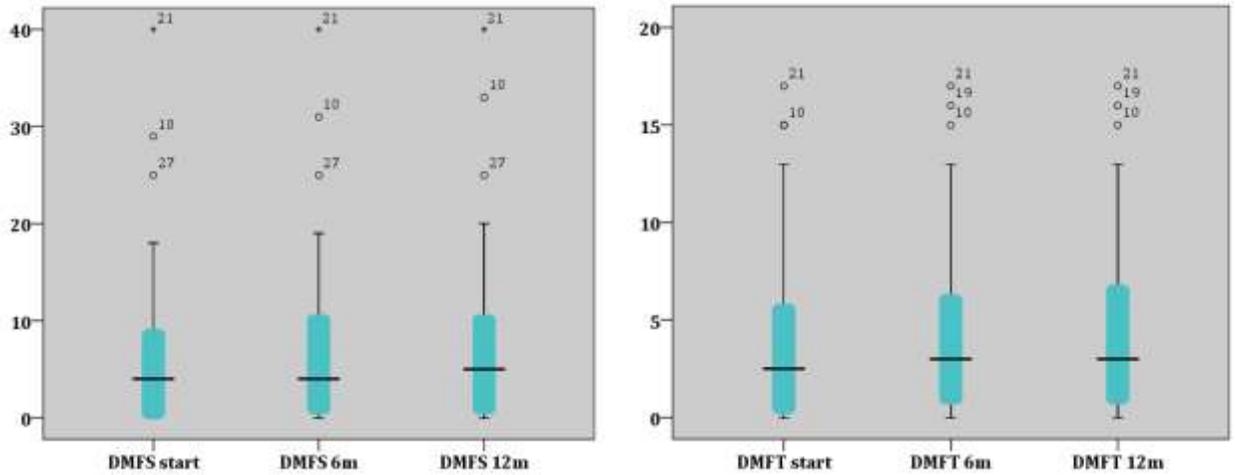


Fig 4.4 – Caries prevalence of study sample; DMFS (left) and DMFT at baseline (start), 6- and 12-month follow-up

The infiltrated surfaces showed almost consistent scores of plaque accumulation which did not differ significantly between the recall appointments (Fig 4.5, Table 4.6).

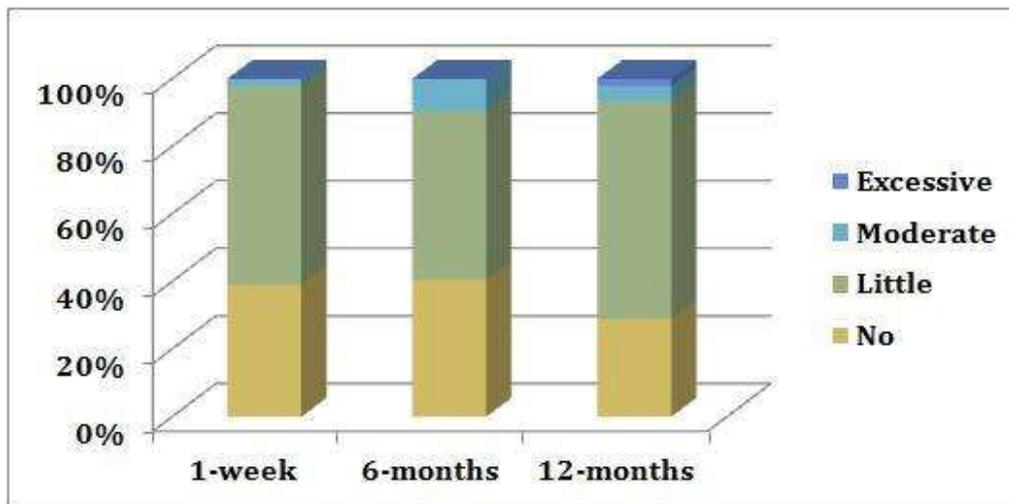


Fig 4.5 – Distribution of plaque accumulation at recall appointments

Despite of the slight increase of gingival bleeding, no statistically significant difference was observed for the recalls (Table 4.6). Furthermore, no swelling or

strong reaction in adjacent gingiva was recorded after the assessment of gingival status (Fig 4.6, Table 4.6).

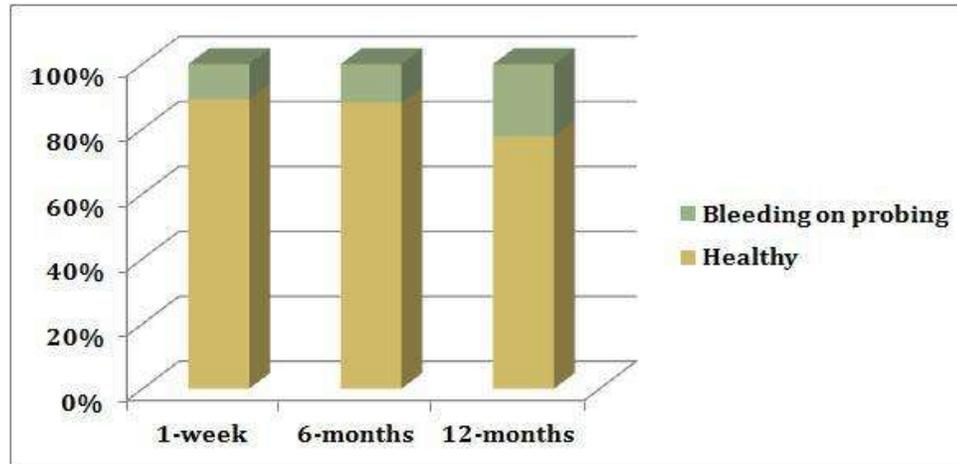


Fig 4.6 – Changes of the gingival status during the study time

Table 4.6 – Plaque accumulation and gingival status according to the used criteria at 1-week, 6- and 12-months recalls

Criteria	Code	1-week N = 46	6-months N = 42	12-months N = 45	P value (changes between recalls)	
					1 week and 12 months	1 week, 6 and 12 months
Plaque accumulation	1	18 (39.1%)	17 (40.5%)	13 (28.9%)	0.115	0.230
	2	27 (58.7%)	21 (50%)	29 (64.5%)		
	3	1 (2.2%)	4 (9.5%)	2 (4.4%)		
	4	0 (0%)	0 (0%)	1 (2.2%)		
Gingiva status	1	41 (89.1%)	37 (88.1%)	35 (77.8%)	0.096	0.082
	2	5 (10.9%)	5 (11.9%)	10 (22.2%)		
	3	0 (0%)	0 (0%)	0 (0%)		
	4	0 (0%)	0 (0%)	0 (0%)		

Considering the clinical status, a statistically significant decrease in the discoloration of the tested surfaces was observed through the treatment recorded after one week ($P = 0.005$, Wilcoxon Signed Ranks Test) possibly associated with infiltrating the pores of the lesion. In contrast to the improvement through the treatment at the one week recall, the infiltrated surfaces showed a statistically significant increase in the discoloration within the following year ($P = 0.014$, Wilcoxon Signed Ranks Test, Fig 4.7, Table 4.7). The clinical status of the lesion did not change significantly during the study time ($P = 0.366$, Wilcoxon Signed Ranks Test) and no carious defects were recorded at the final assessment.

In the vast majority of cases ($n = 44/46$, 95.7%), the marginal adaptation showed smooth transition and no sharp edged margins (Table 4.7). Furthermore, stable results without changes were reported after repeating the marginal adaptation test at 1 week, 6 and 12 months recalls (Fig 4.8).

Table 4.7 – Marginal adaptation and discoloration tests according to the used criteria at 1-week, 6- and 12-months recalls

Criteria	Code	1-week <i>N = 46</i>	6-months <i>N = 42</i>	12-months <i>N = 45</i>	P value <i>(changes between recalls)</i>	
					<i>1 week and 12 months</i>	<i>1 week, 6 and 12 months</i>
Marginal adaptation	1	44 (95.7%)	40 (95.2%)	43 (95.6%)	1.000	1.000
	2	2 (4.3%)	2 (4.8%)	2 (4.4%)		
Discoloration	1	41 (89.1%)	34 (81%)	35 (77.8%)	0.014	0.009
	2	5 (10.9%)	7 (16.7%)	9 (20%)		
	3	0 (0%)	1 (2.3%)	1 (2.2%)		

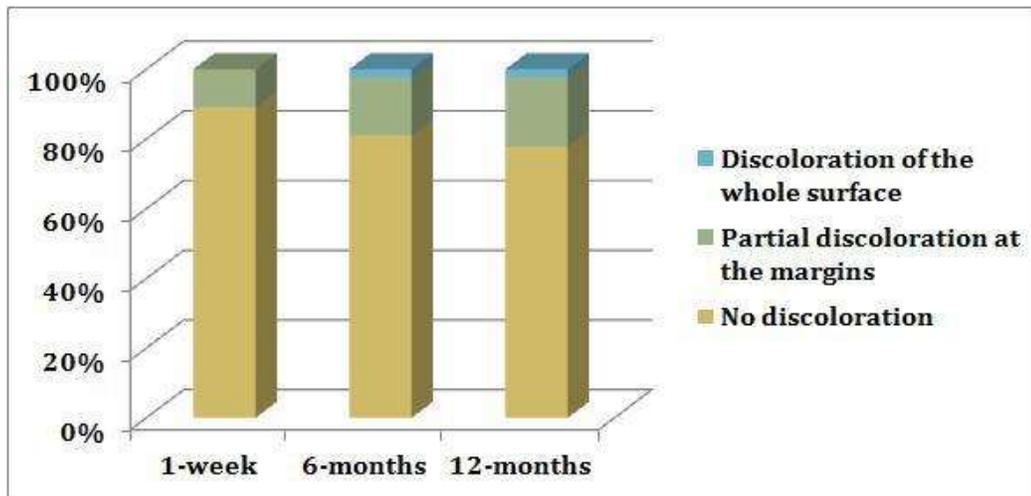


Fig 4.7 – Distribution of plaque accumulation at recall appointments

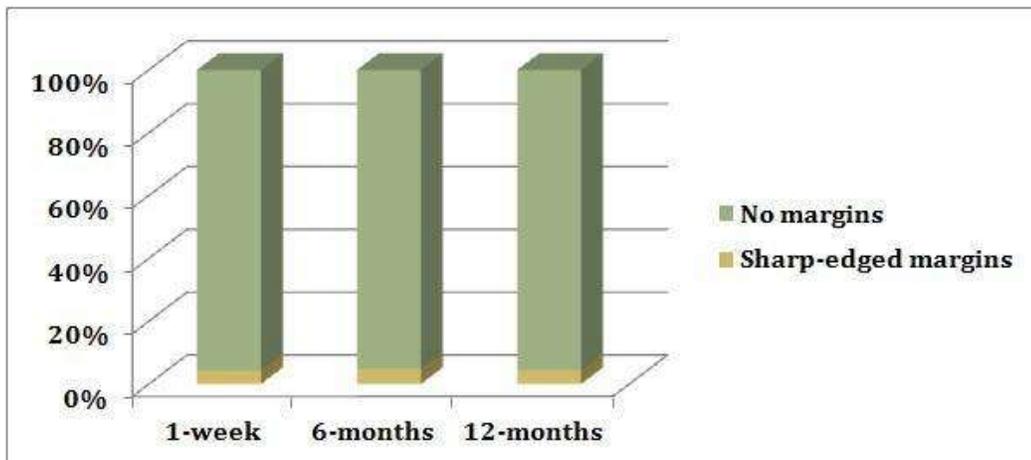


Fig 4.8 – Marginal status during the study time

4.4 Clinical effect

Pair-wise comparison of the radiographs has been performed after 1 year. For pair-wise comparison, the inter-rater reliability showed substantial agreement and the intra-examiner reproducibility was almost perfect (0.739 and 0.835 kappa values). The radiographic evaluation of reading the bitewing radiographs showed no progression in 41/43 lesions (95.3%) (Fig 4.9, 4.10). Moreover, the progression status data revealed that only 2 lesions (5.3%) had progressed from

E2 to D1. Moreover, one lesion (D1) showed a progression within the same score.

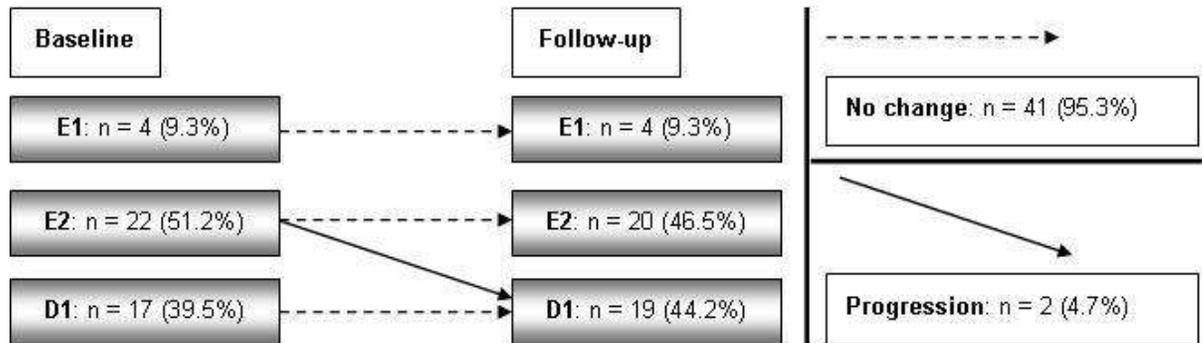


Fig 4.9 – Distribution and behavior of lesions radiographically during the study time

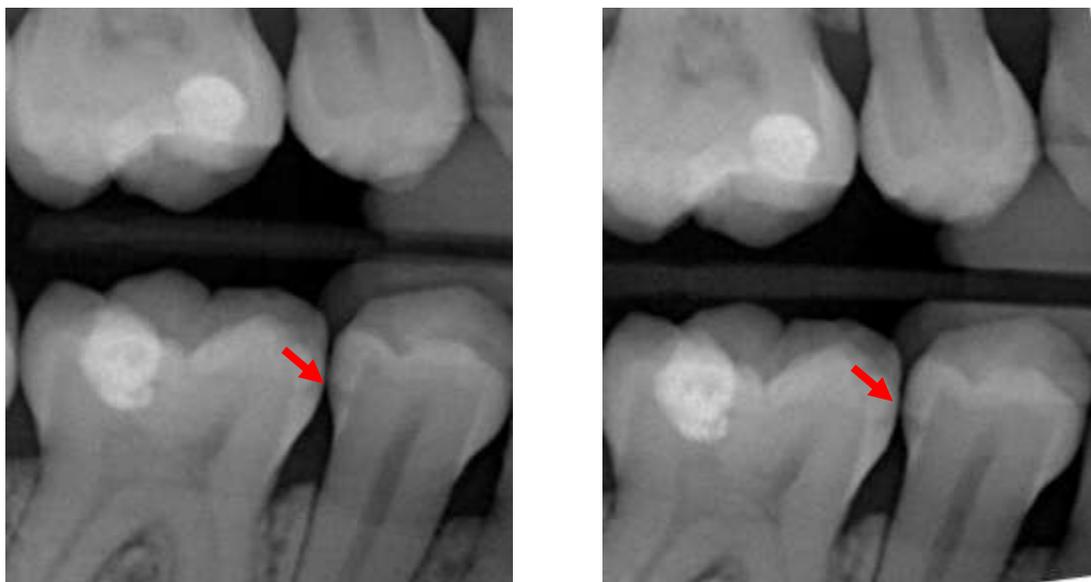


Fig 4.10 – Stabilization of infiltrated lesion (45 d) in a high caries risk patient

Chapter 5: Discussion

The dealing with proximal caries, especially lesions which do not reach the middle third of dentine, reveals a huge variation in the treatment philosophy between the dentists (Vidnes-Kopperud et al., 2011; Gordan et al., 2009). Both non-invasive and restorative treatments have their drawbacks. Caries infiltration offers a new procedure which can be as an efficacious technique to arrest or reduce the progression of non-cavitated proximal lesions. Furthermore, resin infiltration may provide a simple, fearless alternative for treating the initial proximal lesions. Therefore, its clinical applicability, safety and effect are of special interest, which was assessed in the present study.

The present investigation was conducted on children, adolescents and young adults due to the high prevalence of initial proximal caries in these age groups (Maragakis et al., 2007; Mejàre et al., 2004; Marthaler et al., 1996). The individuals in this study represented equivalent caries levels compared to respective age group in Germany and other industrialized countries (Mejàre et al., 2004; Holst and Schuller, 2000). Caries incidence of the sample throughout the study was similar to other studies assessing the clinical effect of proximal sealing or infiltrating lesions in young adults in Germany with respect to the age range in this study which included children and adolescents in addition to the young adults (Alkilzy et al., 2009; Paris et al., 2010b).

An important factor for the introduction of new techniques is its sensitivity to operator-related factors. In contrast to the enormous literature on the performance of different restorative materials, studies on the performance of the dentist, applicability and the dentist's or patient's perception of the treatment are rare. Bouillaguet et al. (2002) detected that if dentists have routine experience with a particular material, they can achieve better results than others who had no previous experience. Therefore, this clinical study employed ten dentists to perform the resin infiltrations without explicit previous training which is equivalent to the situation of any dentist in private practice. This allows assessing the

clinical applicability of this new treatment for dentists who start to use the infiltration technique.

Applicability or, at least, the perception of applicability by the dentists often decides about the use of dental techniques. Several investigations have shown that stainless steel crowns were offered rarely as a treatment option for carious primary molars by the dentists (Blinkhorn and Zadeh-Kabir, 2003; Threlfall et al., 2005) despite of their extremely high success rates in primary molar teeth (Fayle, 1999). Dentists believed that stainless steel crowns needed a lot of time and a complex preparation including local anaesthesia. They also feared that children find it difficult to tolerate the procedure (Threlfall et al., 2005). In children, the perception of treatment procedures is also directly linked to their compliance and cooperation. The data on the patient satisfaction with the infiltration procedure and the time of the treatment including rubber dam application showed a very high acceptance in the present study. The patients also confirmed that the new treatment was not complicated for them to tolerate. The dentists stated that the effort for a caries infiltration was comparative to a proximal composite filling but that it was easier to perform. Thus, patients and dentists had a positive impression of the resin infiltration.

Using the rubber dam in this technique-sensitive procedure is essential in order to diminish the possibility of blood, biofilm as well as moisture contamination, which might hamper the resin penetration (Robinson et al., 1990; Shellis et al., 2002). Lynch et al. (2007) found that the use of rubber dam even during a variety of operative and root canal treatments is rare in Irish general dental practitioners. Thus, a huge number of the dentists and patients have no routine experience with rubber dam. This was also confirmed by a project analyzing the use of rubber dam during the placement of posterior amalgam and composite fillings in Germany. In this sample of 217 patients, 69 posterior composite fillings had been placed, but all patients confirmed that they had never seen or experienced a rubber dam (Badzio and Hahn, 2000). Therefore, the time and the difficulties of the rubber dam application are a relevant problem regarding clinical applicability

of the resin-based restorations or resin infiltration. In this study, placing the rubber dam, especially in recently erupted molars was sometimes difficult and it took almost as long as the subsequent infiltration. The procedure was also more time consuming, when it had to be performed on the most distal tooth where also the rubber dam had to be placed on. In this case, the clamp of the rubber dam interfered often with separation wedge or application of the infiltration material. Thus, an infiltration is more complicated in children.

Very few studies examine how clinical experience influences dental treatment. In a clinical study which had to assess the factors associated with the longevity of resin composite restorations, 24 dentists performed 503 fillings (Kubo et al., 2011). One of them, whose specialty was adhesive dentistry, had to do 433 fillings and obtained the best result regarding the longevity of the restorations. Moreover, the clinical performance of these 433 restorations was less influenced by operator factors compared to those of the other 23 dentists. In the present study, the strong and highly significant association between the number of the treatment by the individual dentist and the corresponding treatment time clearly confirmed a positive learning curve for repeating the procedure regarding its duration. Thus, experience in performing the infiltration has a great effect on its duration. A mean application time of 24 min for dentists without prior experience for their first infiltrations seems a reasonable time frame. Still, in some cases, the proximal spacing created difficulties with the separation of the teeth, which prolonged the time for the procedure and which could not even be compensated by experience. The findings of the present study confirmed that the location of the infiltrated tooth, separation problems as well as routine experience of the dentist are important factors which can influence the duration of the infiltration treatment noticeably.

Taking the massive loss of tooth substance or the risk of an iatrogenic damage of the adjacent teeth in account when a proximal restoration is placed (Qvist et al., 1992; Medeiros and Seddon, 2000), the resin infiltration of initial caries lesions seems to offer a feasible, ultra-conservative approach. In this study, the majority

of the patients would even be willing to pay for the new treatment privately which shows patients' satisfaction not only with the procedure but also with its principle of minimal invasion.

As caries infiltration offers a new technique in dentistry, the estimation of its safety was an important purpose assessed in this study. In the study sample, no adverse effect on general health was recorded in the follow-up appointments. Moreover, the vitality of the infiltrated and adjacent teeth did not change during the study time.

An obvious drop in the quality of composite restoration was recorded in several studies which monitored their survival time (Burke et al., 2005; Brunthaler et al., 2003). Marginal integrity and colour match were always considered as important factors to assess the quality of posterior composites (Bayne and Schmalz, 2005; Cvar and Ryge, 2005). These widely used USPHS criteria were adapted in this study for a micro-invasive treatment. In a randomized, clinical study aimed to evaluate the performance of conservative composite restorations placed with two different matrix systems, Demarco et al. (2011, 2007) reported that 15.5% of 129 fillings showed sharp margins (explorer catch) after one year. In another investigation assessing the clinical safety of proximal sealants using polyurethane patch (Alkilzy et al., 2009), sharp-edged margins were found in 12 out of 42 cases (28.6%) after 12 months. The marginal adaptation of the infiltrated surfaces in this study showed perfect transition and no steps or margins could be detected in 43/45 cases (95.6%) which is superior to composite fillings (Demarco et al. 2011, 2007; Türkün and Aktener, 2001) and proximal patches (Alkilzy et al., 2009). Moreover, stable results of the marginal adaptation were observed during the follow-up recalls. These results seem normal and self-explanatory, taking into consideration the resin infiltration concept of rapid penetration into the lesion porous driven by capillary forces (Meyer-Lueckel et al., 2007; Mueller et al., 2006; Meyer-Lueckel et al., 2006) which means that the resin coat on top of the lesion is not necessary if the porous lesion was homogeneously infiltrated (Paris et al., 2006). Therefore, there is no additional

risk factor for creating sharp margins which can cause greater amounts of plaque and higher degree of gingivitis (Lang et al., 1983). Increased plaque accumulation and gingivitis are others factor affecting the quality of dental restoration, especially of composite fillings (Svanberg et al., 1990). The gingival status and plaque accumulation data of the infiltrated and adjacent surfaces did not differ significantly during the study.

Several in vivo-studies (Hammad et al., 2012; Kim et al., 2011) revealed that the low viscosity resin (infiltrant) can modify the opaque colour of the enamel white spot lesions and restore their translucency and normal colour. This aesthetic property may explain the huge, rapid improvement regarding the discoloration of the infiltrated surfaces one week after the treatment which was reduced in the subsequent 12 months. This increase in the discoloration (11.1%) is still acceptable in comparison to the standard composite filling where 61.2% showed a mismatch of colour and translucency after one year (Demarco et al., 2011, 2007).

Regarding the therapeutic or protective effect of caries infiltration of proximal caries, the data of this study showed a high efficacy of resin infiltration which is similar to the results from Paris et al. (2010) with 93% after 18 months. Moreover, the effect of the resin infiltration on caries progression reported in this study is superior to other studies (Martignon et al., 2012; Ekstrand et al., 2010). This disparity among the studies was ascribed to the varying proportion of dentin lesions by some researchers (Meyer-Lueckel et al., 2012; Martignon et al., 2012). In contrast to these speculations, the two lesions which have been progressed in the present study were located in enamel and there was no further progression in the dentin lesions. Moreover, the length of follow-up duration on the progression remains a questionable explanation after observing the varying results from two studies with a 3-year evaluation of resin infiltration (Meyer-Lueckel et al., 2012; Martignon et al., 2012). Naturally, the different level of caries activity, structured prevention as well as home dental care between the samples and their societies can be considered as important factor explaining the different results among the

various investigations. In this study, the sample showed adequate levels of home dental care including the use of dental floss, at least according to the patients' self-report.

Thus, caries infiltration showed no clinical problems and very good results regarding the clinical quality and safety. Furthermore, the current radiographic data confirm the high efficacy of caries infiltration in hampering the progression of initial proximal lesion extending radiographically in the enamel or the outer third of dentin.

Chapter 6: Summary

Until now proximal caries is still a significant problem in the clinical dentistry in spite of the caries decline recently. As resin infiltration offers a new micro-invasive treatment to arrest the progression of proximal initial carious lesions, this study aimed to evaluate its clinical applicability, safety and effect.

In the study population of 50 children, adolescents and young adults (mean age 17.9 years \pm 6.8), ten dentists at University of Greifswald applied the infiltration material ICON® (DMG, Germany) on non-cavitated proximal lesions in permanent and primary teeth as described in the manual instructions from the producer.

The results showed good patient satisfaction with the procedure. The time for the infiltration (24.3 min \pm 7.4), which included rubber dam application (7.7 min \pm 4), and the effort were perceived as comparable to a composite filling by the dentist or as even easier. In three patients (6%), it was not possible to gain sufficient proximal space for the application of an infiltration. The location of the infiltrated tooth, separation problems as well as the routine of the dentists with the infiltration technique had an effect on the duration of the infiltration. A clear learning curve with a reduction of treatment time for subsequent treatments was observed ($P < 0.001$). Within the follow-up interval of 12 months, vitality of all infiltrated teeth was still positive and no relevant differences in plaque accumulation or gingival status were recorded. In addition, the infiltrated surfaces showed smooth margins and considerable decrease in the discoloration. In the radiographic evaluation after one year, only two lesions (4.7%) have progressed.

Thus, caries infiltration is an applicable method for the treatment of initial non-cavitated proximal lesions without prior temporary tooth separation. Even without special training it can be applied easily by dentist and they experience a clear learning curve within the first 5-10 applications. In addition, the infiltration technique shows a high acceptance by the patients. Furthermore, caries

infiltration lead to very good results regarding safety and preventing the lesion progression of non-cavitated proximal caries lesions located in the enamel or in the outer third of dentin.

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Chapter 8: Appendixes

8.1 Patient's study information

Patienten-/Elternaufklärung

Studie „Infiltration der approximalen Karies "

Abteilung für präventive Zahnmedizin und Kinderzahnheilkunde

Leiter: Prof. Dr. Ch. H. Splieth, Walther-Rathenau-Straße 42, 17489 Greifswald

Ziel der Studie/Studienaufbau

Bei Ihnen/Ihrem Kind wurde beginnende Karies zwischen den Backenzähnen festgestellt. Im Anfangsstadium kann mit Fluoridanwendungen versucht werden, die Karies zum Stehen zu bringen, was eine exzellente häusliche Plaqueentfernung einschließlich Zahnseide nötig macht. Wenn das Dentin mit betroffen ist, ist normalerweise eine Füllung nötig.

Auf den Kauflächen wird die Versiegelung seit 20 Jahren erfolgreich zur Kariesprävention und Therapie von Initiailläsionen eingesetzt. Auch zwischen den Zähnen können jetzt durch Versiegelungen/Infiltration karieshemmende Wirkungen festgestellt werden. Mit einem neuartigen Verfahren ist es möglich, ähnliche Kunststoffe in die Läsion zu infiltrieren.

Dieses neuartige Verfahren wird erstmalig in Deutschland angeboten. An Stelle einer Füllung können Sie und Ihr Kind an der Studie teilnehmen, wenn

- Zähne beginnende Karies haben
- Ihr Kind für 1 Jahre voraussichtlich im Raum Greifswald für Nachuntersuchungen zur Verfügung steht
- keine Allgemeinerkrankungen oder Allergien (z.B. gegen Kunststoffe) bestehen
- keine zahnbezogenen Gründe (Lockerung, Krone, kein Nachbarzahn, etc.) dagegensprechen.

Vorzugsweise werden Milchzähne infiltriert, die aufgrund des Zahnwechsels bald verloren gehen, bzw. bleibende Zähne, die aufgrund einer kieferorthopädischen Behandlung entfernt werden.

Die Kontrolle erfolgt z. T. durch klinische Untersuchungen (½ Jahr und ein Jahr nach der Infiltration) und eine Röntgenaufnahmen nach einem Jahr, um einen Kariesfortschritt auszuschließen. Die Milchzähne werden mit einem farbigen Kunststoffpunkt gekennzeichnet und müssen beim Zahnwechsel in der Klinik abgegeben werden, um im Labor nachuntersucht zu werden.

Risiken/bekannte Nebenwirkungen

- Sehr selten treten allergische Reaktionen auf Kunststoffe auf.
- Trotz Füllungen und Infiltration ist kein absoluter Schutz gegen Karies gegeben, wenn weiterhin eine hohe Kariesaktivität besteht.

Vorteile für Teilnehmer an der Studie

Die Teilnehmer werden vorab gründlich zahnärztlich untersucht erhalten und auch weiterhin regelmäßig auf die Kariesentwicklung hin kontrolliert. Die Infiltration der kariösen Läsion bietet die Chance, eine spätere Füllung zu ersparen.

Meldepflicht

Es ist unbedingt erforderlich, dass Sie den Prüfarzt vor Beginn der Prüfung über bisherige Erkrankungen und eingenommene Medikamente informieren. Geben Sie an, ob und wogegen Sie/Ihr Kind allergisch ist. Ebenso ist es notwendig, dass Sie alle während der Studie auftretenden Gesundheitsbeeinträchtigungen und Störungen des Wohlbefindens dem Prüfarzt mitteilen, auch wenn Sie einen Zusammenhang mit Wirkung des Prüfpräparates für unwahrscheinlich halten. Dies geschieht zum einen zur Ihrer/Ihres Kindes Sicherheit, zum anderen aus versicherungsrechtlichen Gründen.

Versicherungsschutz

Teilnehmer an der Studie sind entsprechend den gesetzlichen Bestimmungen gegen etwaige im Zusammenhang mit der Studie auftretende gesundheitsbedingte Vermögensschäden versichert. Eine Gesundheitsschädigung, die als Folge der klinischen Prüfung eingetreten sein könnte, ist dem Prüfarzt oder dem Leiter der klinischen Studie unverzüglich anzuzeigen.

Datenschutz

Gemäß Arzneimittelgesetz dürfen nur solche Personen an einer klinischen Prüfung teilnehmen, die der Datenaufzeichnung und der Einsichtnahme in personenbezogenen Daten ausdrücklich zustimmen. Während der Prüfung werden Daten (Untersuchungsbefunde, etc.) aufgezeichnet, nach Verschlüsselung gespeichert und zur wissenschaftlichen Auswertung weiterverarbeitet. Zur Überprüfung der ordnungsgemäßen Durchführung der klinischen Studie ist es notwendig, dass entsprechend befugte Mitarbeiter der zuständigen Überwachungsbehörde Einblick in die personenbezogenen Daten Ihres Kindes nehmen. Die Personen unterliegen der Schweigepflicht und müssen Ihre Daten streng vertraulich behandeln. Eine Publikation der Daten geschieht nur in anonymisierter Form. Die gesetzlich geltenden Datenschutzbestimmungen werden hierbei befolgt.

Allgemeines

Die Teilnahme an dieser Studie ist freiwillig. Sie können jederzeit Ihr Einverständnis zur Teilnahme an der Studie widerrufen, ohne dass Ihnen daraus ein Nachteil entsteht oder dies Ihr Verhältnis zum Sie betreuenden Zahnarzt negativ beeinflusst.

Der Prüfarzt hat das Recht, die Teilnahme an der Studie jederzeit zu beenden, falls die Sicherheit Ihres Kindes oder die ordnungsgemäße Durchführung der Prüfung dieses erfordern oder andere Gründe eingetreten sind, die Prüfung vorzeitig abubrechen.

Vor Einschluss in die jetzige Studie darf Ihr Kind/Sie an einer anderen Studie zuletzt vor einem Monat teilgenommen haben. Nach Ende der Studie müssen Sie eine Pause von einem Monat bis zur nächsten Studien einhalten.

Notfalladressen

Zentrum für Zahn-, Mund- und Kieferheilkunde, Kinderabteilung, Walther-Rathenau-Straße 42, 17489 Greifswald (Tel. 03848 867112) oder als Notdienst Mund-, Kiefer-, Gesichtschirurgie, Klinikum Sauerbruchstr. (Tel. 867170)

Einverständniserklärung

Ja, ich bin damit einverstanden, dass ich/mein Kind _____ an der Studie „Infiltration der approximalen Karies“ teilnehme/teilnimmt. Ich wurde über Wesen, Bedeutung und Tragweite der Studie sowie den bestehenden Versicherungsschutz informiert worden. Eine Kopie

dieses Informationsblattes und der Einwilligungserklärung habe ich erhalten. Ich fühle mich über die vorliegende Prüfung ausreichend informiert, kann aber jederzeit weiter Fragen an den Prüfarzt stellen. Alle meine Angaben werde ich nach bestem Wissen machen und erkläre, dass ich mich nach den Anweisungen des Prüfarztes richten werde. Ich weiß, dass ich mein Einverständnis zur Teilnahme an der Studie jederzeit zurückziehen kann und auch dass der Prüfarzt meine Studienteilnahme beenden kann.

Ich bin mit der Aufzeichnung der personenbezogenen Daten meines Kindes und ihrer Weitergabe zur Auswertung und Überprüfung an zuständige Überwachungsbehörden einverstanden.

Es besteht keine bekannte Allergie gegen Kunststoffe.

Es bestehen folgende Allgemeinerkrankungen:

_____.

Es werden keine Medikamente eingenommen.

Ich/mein Kind befinde(t) sich zur Zeit wegen _____ in ärztlicher Behandlung.

Greifswald, den _____

Unterschrift des Patienten/Erziehungsberechtigten

ggf. Unterschrift des Kindes

Der oben genannte Patient wurde von mir gemäß AMG § 40 (1) 2 aufgeklärt.

Greifswald, den _____

8.2 Informed consent for study

Abteilung für Präventive Zahnmedizin und Kinderzahnheilkunde

(Leiter: Prof. Dr. Ch. Splieth)

Zentrum für Zahn-, Mund- und Kieferheilkunde

Ernst-Moritz-Arndt-Universität Greifswald

Prüfstelle: Abt. für Präventive Zahnmedizin und Kinderzahnheilkunde, Rathenastr. 42 a,
17475 Greifswald, Tel. 867136, 8619639, 867101

Prüfarzt: ZA. MB. Altarabulsi, Dr. M. Alkilzy, Prof. Dr. Ch. Splieth.

**„Clinical Applicability and Effect of Resin Infiltration of Proximal Caries in
Children and Adolescences“**

„Infiltration der Approximalkaries bei Kindern und Jugendlichen“

Einwilligungserklärung

Ich erkläre, dass ich/mein Kind.....Geb.Datum:.....an der
oben genannten klinischen Prüfung freiwillig teilzunimmt.

Ich bin in einem persönlichen Gespräch durch den Prüfarzt
_____ ausführlich und verständlich über das Prüfprodukt
und die Vergleichstherapie sowie über Wesen, Bedeutung, Risiken und Tragweite der
klinischen Prüfung aufgeklärt worden. Ich hatte die Gelegenheit in einem
Beratungsgespräch mit dem Prüfarzt über die sonstigen Bedingungen der Durchführung
der klinischen Prüfung zu sprechen. Alle meine Fragen wurden zufrieden stellend
beantwortet. Ich habe darüber hinaus den Text der Patientenaufklärung gelesen und
verstanden. Ich hatte ausreichend Zeit, mich zu entscheiden.

Mir ist bekannt, dass ich jederzeit und ohne Angabe von Gründen meine Einwilligung zur
Teilnahme an der Prüfung zurückziehen kann (mündlich oder schriftlich), ohne dass mir
daraus Nachteile für meine ärztliche Versorgung entstehen.

Es besteht keine bekannte Allergie gegen Kunststoffe.

Es bestehen folgende Allgemeinerkrankungen:

_____.

Es werden keine Medikamente eingenommen.

**Ich/mein Kind befinde(t) sich zurzeit wegen _____ in ärztlicher
Behandlung.**

Möglichkeit zur Dokumentation zusätzlicher Fragen seitens des Patienten oder sonstiger
Aspekte des Aufklärungsgesprächs:

Datenschutz:

Mir ist bekannt, dass bei dieser klinischen Prüfung personenbezogene Daten, insbesondere medizinische Befunde, über mich erhoben, gespeichert und ausgewertet werden sollen. Meine Teilnahme an der klinischen Prüfung setzt folgende freiwillig abgegebene Einwilligungserklärung voraus, d.h. ohne die nachfolgende Einwilligung kann ich nicht an der klinischen Prüfung teilnehmen.

1. Ich erkläre mich damit einverstanden, dass im Rahmen dieser klinischen Prüfung erhobene Daten, insbesondere Angaben über Gesundheit, in Papierform und auf elektronischen Datenträgern in der Abt. für Präventive Zahnmedizin und Kinderzahnheilkunde aufgezeichnet werden. Soweit erforderlich, dürfen die erhobenen Daten pseudonymisiert (verschlüsselt) weitergegeben werden:

a) im Falle unerwünschter Ereignisse: zuständige Bundesoberbehörde

2. Außerdem erkläre ich mich damit einverstanden, dass autorisierte und zur Verschwiegenheit verpflichtete Beauftragte des Auftraggebers sowie die zuständigen inländischen und ausländischen Überwachungsbehörden in meine beim Prüfarzt vorhandenen personenbezogenen Daten, insbesondere meine Gesundheitsdaten, Einsicht nehmen, soweit dies für die Überprüfung der ordnungsgemäßen Durchführung der Studie notwendig ist. Für diese Maßnahme entbinde ich den Prüfarzt von der ärztlichen Schweigepflicht.

3. Ich bin darüber aufgeklärt worden, dass ich jederzeit die Teilnahme an der klinischen Prüfung beenden kann. Im Fall eines solchen Widerrufs meiner Einwilligung, an der Studie teilzunehmen, erkläre ich mich damit einverstanden, dass die bis zu diesem Zeitpunkt gespeicherten Daten ohne Namensnennung weiterhin verwendet werden dürfen, soweit dies erforderlich ist, um

a.) die Eignung des Medizinproduktes für den vorgesehenen Verwendungszweck festzustellen

b.) sicherzustellen, dass meine schutzwürdige Interessen nicht beeinträchtigt werden

c.) der Pflicht zur Vorlage vollständiger Zertifizierungs- oder Zulassungsunterlagen zu genügen.

4. Ich erkläre mich damit einverstanden, dass meine Daten nach Beendigung oder Abbruch der Prüfung mindestens zehn Jahre aufbewahrt werden. Danach werden meine personenbezogenen Daten gelöscht, soweit nicht gesetzliche, satzungsmäßige oder vertragliche Aufbewahrungsfristen entgegenstehen.

5. Ich bin über folgende Regelung informiert: Falls ich meine Einwilligung, an der Studie teilzunehmen, widerrufe, müssen alle Stellen, die meine personenbezogenen Daten, insbesondere Gesundheitsdaten gespeichert haben, unverzüglich prüfen, inwieweit die gespeicherten Daten für die in Nr. 3 a) bis c) genannten Zwecke noch erforderlich sind. Nicht mehr benötigte Daten sind unverzüglich zu löschen.

Ein Exemplar der Patienteninformation und der Einwilligungserklärung habe ich erhalten.
Ein Exemplar der unterschriebenen Einwilligungserklärung verbleibt im Prüfzentrum.

Datum:

Unterschrift des Patienten

Ich habe das Aufklärungsgespräch geführt und die Einwilligung des Patienten eingeholt.

Datum:/.....

Name des Arztes/Ärztin (Druckschrift)/Unterschrift des

aufklärenden Arztes

Possibility to isolate adjacent tooth: easy 1 2 3 4 5 not possible (why):

Difficulties to etching: easy 1 2 3 4 5 not possible (why):

Difficulties to drying: easy 1 2 3 4 5 not possible (why):

Difficulties to infiltrating: easy 1 2 3 4 5 not possible (why):

Need to finishing: yes no

Comparison to filling: easier same more difficult as filling.

Further treatment for dentition:

Occlusal sealant for test teeth! and in addition:

Tooth_____ lesion_____ treatment _____performed by_____

Please make appointment for baseline II to check infiltrated tooth: Date_____!!

8.4 Patient's questionnaire

Patienten-Fragebogen

Infiltration

CodeNr.-----

Allergien----- Allgemeinkrankheiten----- Medikamente----- Geschlecht---

Rechtshänder, Linkshänder.

Zähneputzen: 2mal/Tag 1mal/Tag weniger als 1mal/Tag

Zahnpasta mit Fluorid ja nein

Zahnseide: täglich 2mal/Woche weniger als 1mal/Woche

Zahnarztbesuch: > 2mal/Jahr 2mal/Jahr 1mal/Jahr weniger als 1mal/Jahr

Zufriedenheit mit dem Kofferdam

Komfort gut ok gering

Applikationsdauer ok zu lang

Zufriedenheit mit der neuen Behandlung (nur Infiltration, außer Kofferdamm)

Komfort angenehm in Ordnung anstrengend

Dauer in Ordnung zu lang

Geschmack angenehm neutral schlecht

Geruch angenehm neutral schlecht

Behandlung ohne Bohren

sehr interessant interessant nicht interessant

sehr einfach in Ordnung kompliziert

Würden Sie wieder eine Behandlung ohne Bohrer/Infiltration wünschen? ja

nein

Sind Sie bereit selbst zur Kariesbehandlung ohne Bohrer zu bezahlen? ja nein

8.5 Dentist's questionnaire

Zahnarzt-Fragebogen **Infiltration** Datum ----- Code Nr. -----

Uhrzeit Beginn Kofferdamm: _____

Kofferdamm Applikation

Schwierigkeit: 1 (sehr gering) 2 3 4 5 6 (sehr schwierig)
Dauer 1 (sehr kurz) 2 3 4 5 6 (sehr lange)

Uhrzeit Ende Kofferdamm: _____

Separieren

Schwierigkeit: 1 (sehr gering) 2 3 4 5 6 (sehr schwierig)
Platz: 1 (sehr viel) 2 3 4 5 6 (sehr eng)

Infiltrieren

Schwierigkeit: 1 (sehr leicht) 2 3 4 5 6 (sehr schwierig)
Dauer 1 (sehr kurz) 2 3 4 5 6 (sehr lange)

Finishing

Schwierigkeit: 1 (sehr gering) 2 3 4 5 6 (sehr schwierig)
Dauer 1 (sehr kurz) 2 3 4 5 6 (sehr lange)

Uhrzeit Ende Infiltration komplett: _____

Im Vergleich zu Kompositfüllung 1 (viel leichter) 2 3 (identisch) 4 5 6 (viel schwieriger)

Patient Komplicance 1 (sehr gut) 2 3 4 5 6 (sehr schlecht)

Bemerkungen -----

8.6 Recall sheets (1 week, 6 and 12 months)

Recall after 1 week of application: Date_____ Examiner_____ Code Nr. ...

Clinical quality control of infiltrated tooth 1-2 weeks after placement:

		tooth__ surf.____
Discoloration of the infiltrated surface	1: no discoloration 2: partial discoloration at the margins 3: discoloration of the whole surface	
Marginal adaptation	1: smooth transition (can not be probed) 2: sharp-edged margins (evaluation with a probe possible)	
Gingival status	1: healthy 2: light reddening 3: bleeding on probing 4: swelling 5: strongly reacted	
Plaque accumulation	1: no 2: little 3: moderate 4: excessive	

		tooth___ surf. ___
Discoloration of the infiltrated surface	1: no discoloration 2: partial discoloration at the margins 3: discoloration of the whole surface	
Marginal adaptation	1: smooth transition (can not be probed) 2: sharp-edged margins (evaluation with a probe possible)	
Gingival status	1: healthy 2: light reddening 3: bleeding on probing 4: swelling 5: strongly reacted	
Plaque accumulation	1: no 2: little 3: moderate 4: excessive	

Further treatment for dentition:

Tooth___ lesion___ treatment _____ performed by _____

Tooth___ lesion___ treatment _____ performed by _____

Eidesstattliche Erklärung

Hiermit erkläre ich, dass ich die vorliegende Dissertation selbständig verfasst und keine anderen als die angegebenen Hilfsmittel benutzt habe.

Die Dissertation ist bisher keiner anderen Fakultät vorgelegt worden.

Ich erkläre, dass ich bisher kein Promotionsverfahren erfolglos beendet habe und dass eine Aberkennung eines bereits erworbenen Doktorgrades nicht vorliegt.

Datum

Unterschrift

Lebenslauf

Geburt: 21.06.1985, Zabadani- Syrien

1991-2003: Schulbildung (primary and secondary schools) in Damaskus-Syrien

2003-2008: Studium der Zahnmedizin in Universität Damaskus- Syrien

2008: D.D.S Titel (Doctor Dental Surgeon)

2008-2009: Arbeit in der privaten Praxis

2009- : Wissenschaftlicher Mitarbeiter in der Abteilung für Präventive Zahnmedizin und Kinderzahnheilkunde/Universität Greifswald-Deutschland

2012: Spezialist in Kinderzahnheilkunde/Universität Greifswald-Deutschland

Mitglied in: Syrian Dental Association
Deutsche Gesellschaft für Zahn-, Mund- und Kieferheilkunde
Deutsche Gesellschaft für Kinderzahnheilkunde

The following publication is based on this PHD-thesis:

- Altarabulsi MB, Alkilzy M, Splieth C. Clinical applicability of resin infiltration for proximal caries. Quintessence Int. 2012 [Accepted, in press]

Danksagung

Alles Lob gebührt dem allmächtigen Gott „Allah“, dem Herrn der Welten, und Segen und Frieden dem letzten Propheten Muhammad und allen anderen Gesandten Gottes.

Mein besonderer Dank gilt Herrn Prof. Dr. Christian H. Splieth für die unbegrenzte Unterstützung, hilfreiche Betreuung meiner Arbeit und die vielen wertvollen Hinweise bei der Erstellung dieser Arbeit.

Bei Herrn Prof. Dr. Georg Meyer möchte ich mich für die Unterstützung bedanken.

Bedanken möchte ich mich bei den Schwestern und dem Arbeitsteam der Abteilung Kinderzahnheilkunde für die Unterstützung und die freundliche Atmosphäre.

An dieser Stelle möchte ich mich bei Maren Krause für die ständige Ermutigung bedanken.

Mein großer und herzlicher Dank gilt meinen Eltern, ohne ihre großzügige Unterstützung und enorme Motivation wäre es nicht möglich gewesen, diese Arbeit durchzuführen.