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Qualitative and quantitative SEM margin analysis of Ormocer restorations in molars and premolars – 4 year long observation

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Die Promovendin ist Zahnärztin.

Meinen Eltern

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1. Introduction

1.1. History of dental fillings

Having a look at the development of dental fillings, we have to admit that amalgam has played an important and actually main role in it [1,2,3,4,5,6]. For over 200 years dentists estimated its advantages: good material properties, strength, relatively easy clinical handling and low cost. On the other hand, amalgam had clear disadvantages like lack of adhesive properties to tooth substance and its non-aesthetic character. In search of the above-mentioned aesthetic, Thomas Fletcher introduced a new aesthetic restorative material - silicate cement [7,8,9] in 1873. Unfortunately, it did not become popular until early 1900th, when significant improvements were introduced. Compared with amalgams, silicate cements won on popularity due to their aesthetic properties as well as the releasing of fluoride, which was said to prevent secondary caries. Poor mechanical properties, however, limited the usage of silicates to small Class III and Class V cavities and, moreover, the cement was quite soluble in the oral cavity. This meant that the search for the perfect restorative material, which could be used in all cavities, was not finished. Disappointment with silicate materials has led to completely different developments of dental restoratives. The era of resin based materials, which have been consequently improved, began a modern way to achieve optimal restorations with a maximal saving of hard tooth tissue [10, 11, 12, 13,14].

1.2. Resin-based materials and their development

First resin-based materials were introduced into the field of conservative dentistry at the end of the 1940s. Strongly marked drawbacks like polymerization shrinkage up to 20 - 25%, poor color stability, low stiffness and lack of adhesion to tooth structure forced further investigations into suitable restorative material. Knock and Glenn [15] tried in 1951 to reduce the polymerization shrinkage by including inorganic filler particles in the resin. Unfortunately, this material still showed a high wear and discoloration rate due to the absence of a coupling agent between the filler particles and the resin matrix. The breakthrough was made in 1956, when Bowen developed the monomer bisphenol

A-glycidyl methacrylate (BisGMA) by attaching methylmethacrylate groups to the exposy monomer[16,17,18]. Together with Buonocore's report concerning the usage of orthophosphoric acid to improve the adhesion of resin to the enamel surface in 1955 [19], real progress in the field of conservative dentistry was made. Resin composites based on BisGMA were introduced in 1962 and three years later they were patented as a combination of BisGMA resin and silane-treated quartz particles. This combination is actually the basis of most resin composites on the market today [20].

Early, chemical cured composites consisted of base and catalyst paste, which were supposed to be mixed; unfortunately, this led to proportional and mixing problems, as well as lack of color stability [21]. Later, light cured composites were introduced [22]. At first, light energy required to carry out polymerization process was gained from ultraviolet light source (365 nm). Its shallow polymerization and mainly iatrogenic side-effects led, however, to its replacement by visible light sources (427-491 nm), which are currently in use. Moreover, visible light in the blue region of the spectrum induces a greater depth of polymerization [23]. It has to be mentioned, however, that short wavelength light (visible light with wavelengths less than 500 nm) may contribute to the premature aging of the retina and senile macular degeneration [24]. Near ultraviolet and blue light may cause the formation of cataract as well [25]. It was also proved that this pathological process has more of a photochemical than thermal or structural effect [26].

1.3. Classification and characteristics of current composites

Dental composites consist of three main chemically different components:

- organic matrix (or so called organic phase),
- inorganic matrix,
- filler or disperse phase.

Additionally, it also contains an organosilane or coupling agent to bond the filler to the organic resin. This agent is a molecule with silane groups at one end (ion bond to SiO_2) and methacrylate groups at the other (covalent bond with the resin) [27,31].

The organic matrix is made up of a system of mono-, di- or tri-functional monomers; a free radical polymerization initiation system. The monomer system can be viewed as the backbone of the composite resin system; Bis-GMA is the most commonly used monomer in nowadays produced composites and usually constitutes around 20% (v/v) of standard composite resin compositions [28].

The disperse phase consists of inorganic fillers, which influence and determine physical and mechanical properties of the composites. An essential aim is to incorporate as high percentage as possible with the organic phase. This way one can reduce thermal expansion, curing shrinkage, provide radio-opacity and improve handling as well as aesthetic results [12,29,30,31,32]. Fillers belong chemically to silicon dioxides, boron silicates or lithium aluminum silicates. Size of the particles is not of less importance; the lower the size of the particles is, the better the finish of the restoration, moreover less curing shrinkage or cusp wall deflection is observed. In order to improve optical performance of the filling, nano-particles are combined with larger-sized particles with an average diameter within visible light wavelengths (about 1 μm), as the nano-particles do not reflect light.

One of the most detailed classifications of composites was assembled by Willems et al [33] and it is based on number of parameters such as Young's module, the percentage (by volume) of inorganic filler, the size of the main particles, surface roughness and compressive stress (see Table 1.1).

Composite type	Filler
Densified composites - Midway-filled Ultrafine Fine - Compact-filled > 60% by volume Ultrafine Fine	 < 60% by volume Particles < 3µm Particles > 3µm > 60% by volume Particles < 3µm Particles > 3µm
Microfine composites - Homogeneous - Heterogeneous	Average particle size = 0.04µm
Miscellaneous composites	Blends of densified and microfine composites
Traditional composites	Equivalent to what macrofilled composites are in other classifications
Fiber-reinforced composites	Industrial-use composites

Table 1.1 Classification of composites (Willems, 1993) [33]

1.4. Consequences of adhesive technology

The term adhesion means in general the fixing of two bodies in mechanical or chemical way. In the dental area, adhesion is responsible for the durable connection between composite and tooth tissue. The different chemical and physical structures of dentine and enamel result in different ways they react with composites.

Enamel etching with phosphoric acid results in the development of a typical rough surface with micro pores. A connection with composite is based on penetration of an adhesive into the above-mentioned pores. Dentine has a higher content of organic substances (about 30%) than enamel has and also a different structure (tubules). Dentine tubules contain hydrophilic liquid and disable optimal connection with hydrophobic

composite material. Moreover, the preparation of dentine is strictly connected with the emergence of a smear layer (consisting of collagen, rests of hydroxyapatite, dentine liquid) that blocks dentine tubules. The above-mentioned layer can be treated in two different ways. If it stays at the cavity surface, it needs special preparation with a primer, which acts through hydrophile monomers in acid solution. As a result, a hybrid layer, which alone represents micro mechanical connection between dentine and composite, is achieved [34]. On the other hand smear layer can be eliminated by etching (so called *total etch method*). This leads to the opening of dentine tubules and demineralization of inter tubule dentine, which releases a free layer of collagen fibers [35]. The above-mentioned procedure allows primer monomer to diffuse into tubules and build up a diffusion zone, a so-called hybrid layer. As a consequence, diffused hydrophobe monomers from the primer enable further chemical connection between composite and dentine.

The subtle connection between hard tissues of the tooth and composite materials has its own consequences in durability of fillings and possible cases of failures. The aim is to achieve not only aesthetic success of filling therapy but also a consistent barrier between filling and tooth. Apart from polymerization shrinkage binding, the main reasons for failure are the development of micro-leakage and a margin gap, both of which lead to secondary caries [36].

1.5. Ormocer technology – future of restorative materials?

The acronym 'ormocer' is the abbreviation for '*or*ganically *mo*dified *cer*amics'; in the literature also described as 'ormosils' ('*or*ganically *mo*dified *sil*icates') [37]. This new group of materials for restorative dentistry was developed by the Fraunhofer Institute for Silicate Research (Würzburg, Germany) in collaboration with the dental industry. As a result of this cooperation in 1998, Degussa (Hanau, Germany) introduced a new dental restorative material - *Definite*. Subsequently, other companies started the production of ormocers as well. Admira by Voco (Cuxhaven, Germany) is one of them.

It has to be mentioned, that the usage of ormocers is not restricted to dentistry only. They have been successfully used in micro-technical- and electronic areas, furthermore,

in the refinement of plastic (to achieve scratch resistant coatings) or anticorrosion coating [38, 39, 40, 41, 42, 43, 44, 45].

Ormocers consist (chemically) of both organic and inorganic networks. They are therefore in their classification placed as materials between organic and inorganic polymers. Each of the three main chemical components is responsible and influences certain properties of the material (Fig. 1.1). Organic polymers influence cross-linking capacity, polarity, hardness and optical behavior; the inorganic parts (glasses and ceramic) are responsible for thermal expansion and thermal-chemical stability. Finally, polysiloxanes affect elasticity with interfacial properties. The organically polymerizing molecular segment has (meth-)acrylate groups, which form an additional highly cross-linked network matrix after induction of a radical-based polymerization. The result is the formation of an inorganic-organic co-polymer [46].

Ormocers are claimed to be mechanically stable, chemically resistant, aesthetic and biocompatible. The low allergo-toxical potential is based on its chemical structure, namely, covalent binding through Si-O-Si of organic and inorganic part. Necessity of adhesive system usage, however, affects biocompatibility in a negative way, as well as an addition of softening molecules to assure easiness of handling. Moreover, further advantages of Ormocers have been already suggested, these are low shrinkage, high abrasion resistance and protection against caries [47].

There are many factors, e.g., moisture-free cavity, strict following of producer instructions, etc., that influence a successful and sustained filling therapy. Contemporary research in the area of dental filling materials focuses mainly on reduction of polymerization shrinkage, which is one of the main reasons for micro-leakage and secondary decay arising. This thesis investigates the properties of Admira, which belongs to the Ormocers group, during a four-year observation time.

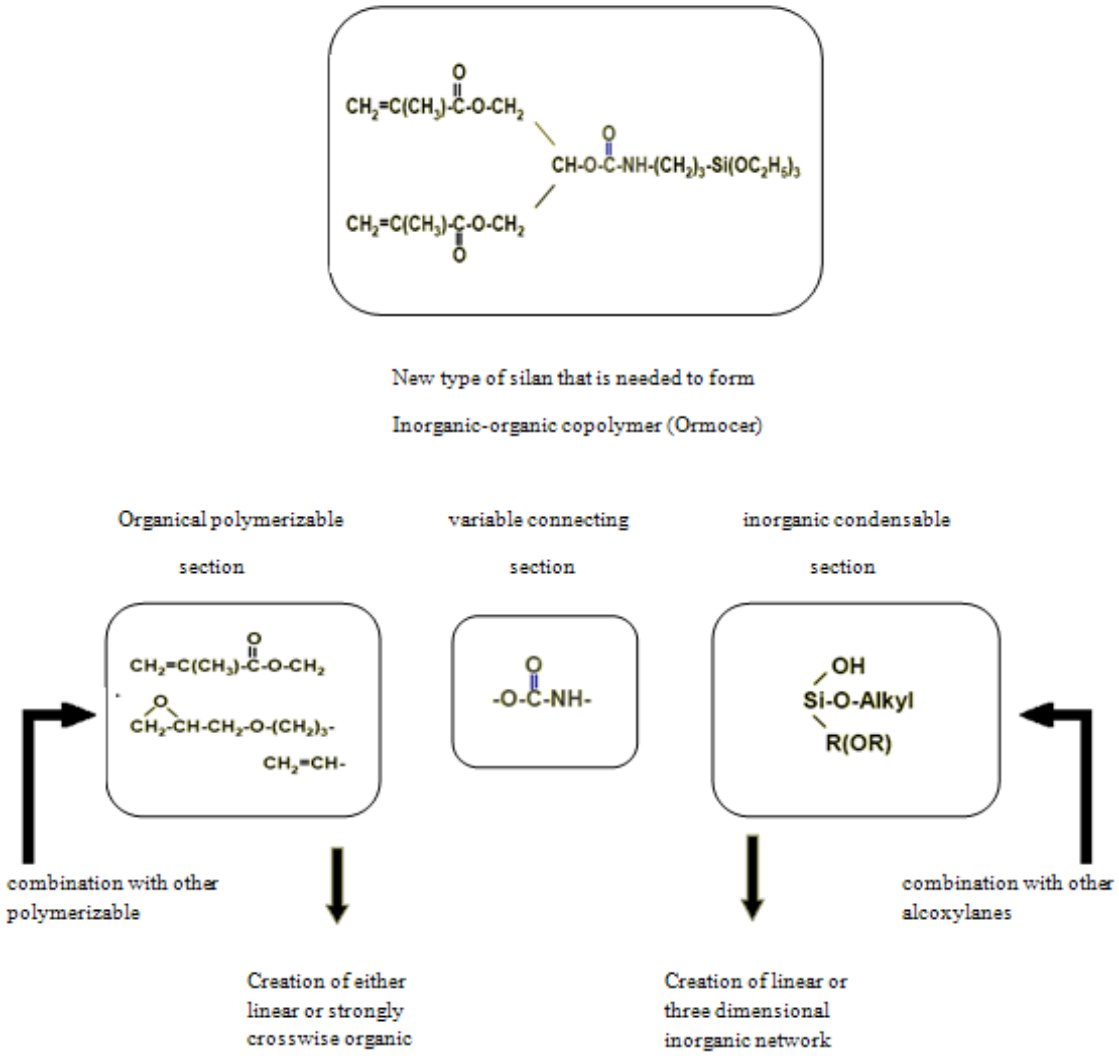

Fig. 1.1 Ormocer's chemical structure [48]

2. Materials and methods

2.1. Admira® restorations of Class I and Class II

Thirty-four patients were invited to participate in the study, that began in June 2000 and was sponsored by Voco® Germany. They were paid 25€ for each of the control appointments. The decision of making a restoration was based on clinical and radiological examination of above mentioned patients and took place in Würzburg University Clinic for Restorative Dentistry. Patients had to sign an agreement after reading informative paper (see Appendix A). Middle and big insufficient restorations in closed teeth row were exchanged (mainly amalgam restorations with secondary caries). The average age of patients oscillated at 34 years, with twenty-five females and nine males. Ninety-five ormocer occlusal or occlusal-approximal restorations were made in molar and premolar teeth. Eight dentists, with suitable prior experience, were trained in the used restorative technique. Later on controls were made by the same practitioners as well.

The course of the clinical part was equalized and the protocol was as follows. Dental loupes with 2x magnification were taken for all procedures. The approximate part of the cavity was prepared with diamond burs in ISO size 008/010 in the red turbine (KaVo, Biberach, Germany), Sonicsys Micro-Instruments (KaVo, Biberach, Germany) and Sonicflex-Airscaler 2000N (KaVo Biberach, Germany). The excavation of decay followed with a conventional rose bur. Cavity margins in occlusal area were finished with fine diamond burs, without beveling. The decision to use the above-mentioned instruments was based on operator's experience to estimate a clinical situation. Form and extension of cavity (resulting in the restoration size) was documented in the patient's card (see Appendix B). This way prepared cavities could be classified into three groups:

- **Grade 1** with a maximal size of ½ intercuspidal distance of the tooth,
- **Grade 2** with a maximal 2/3 intercuspidal distance,
- **Grade 3** with a size bigger than above mentioned.

Moreover, the operator had to evaluate an approximate preparation margin (enamel area or enamel-dentin area). Restorations were made under the protection of a rubber dam.

The physiological approximate contacts were achieved with a convex part matrix (Sectional Matrix Retainer System by 3M™ ESPE™, Seefeld, Germany) and Hawe Adapt® Sectional Matrix (KerrHawe, Bioggio, Switzerland). Wooden wedges and tense rings were used when required. A filling procedure was started with cavity etching (total etch/total bonding technique), with phosphoric acid gel 35% (Vococid by Voco, Cuxhaven, German) from enamel and shortly afterwards dentine, all together 30s. Conditioning followed with a dentine adhesive Admira® Bond (Voco, Cuxhaven, Germany). In deep cavities indirect pulp cupping was implemented; calcium hydroxide was punctually applied at the cavity bottom (Life by KerrHawe, Bioggio, Switzerland) and covered with light cured glassionomer cement (Vitrebond by 3M™ ESPE™, Seefeld, Germany). The first material layer consisted of flow composite (Admira® flow) in "lining technique" that was light cured for 40s (polymerization lamp Aastralis 5 by Ivoclar, Ellwangen, Germany). Polymerization lamps were regularly controlled (with Curing Radiometer by Demetron, Danbury, USA) and had to deliver a minimum efficiency of 600mW/cm^2 by the emission. The Admira® restorative material was placed in the cavity in maximal portions of that resulted in no more than 2mm thickness layers. Each of the layers was light cured for 40s. Finishing and polishing procedures were carried out with fine diamond burs, Proxoshape-files, interdental polishing stripes (3M™ ESPE™ by Seefeld, Germany) and silicone polishers with occlusal polishing brushes (KerrHawe, Bioggio, Switzerland).

In order to compare and estimate the primary situation with further development of the restoration, the following procedures were accomplished: clinical examination, sensibility test with snow spray, and x-rays depending on the situation. Furthermore photographic documentation in 1.8x magnification was made of the: priory situation, cavity before filling and finished restoration. Restorations were later examined by the operator him/her-self or research worker of University Clinic based on modified criterions of US Public Health Service (USPHS), the so-called Ryge-Criterions (Ryge&Snyder 1973, Ryge&Stanford 1977, Ryge 1980). Examinations were carried out with the use of dental loupes with 2x magnification, a dental mirror and a dental probe (X3A probe, Hu-Fiedy, Leimen, Germany), whereas the following criteria were taken into account: color adaptation, marginal discoloration, marginal integrity, surface

structure, anatomical form and fractures. Approximate contact physiology was examined with waxed dental floss (Johnson&Johnson, Nordested, Germany).

Furthermore, to enable SEM analysis during each of those control appointments, a silicone impression of the restoration was taken. To achieve impressions without air blazes, silicone was applied with an application syringe and the first layer was lightly blown with an air spray.

Two in-vivo studies concerning Admira have been completed, presenting separately results after 12 and 48 months. Both above mentioned studies were published [49, 50] and presented as posters as well (see Appendix C)

2.2. Scanning electron microscopy

To allow for the evaluation of interfacial adaptation, the above-mentioned negative impressions were replicated in epoxy resin (EpoxyDie) to obtain positive casts. Since both silicone impression material and epoxy resin have perfect copying properties, they were especially suitable for the above-mentioned procedure [51, 52, 53, 54, 55 and 56]. After being restored in a temperature of 25 degrees Celsius for 24 hours to achieve correct hardness, the casts were prepared for SEM analysis. This included trimming to an optimal shape that could be attached to metal stubs with the graphite adhesive (Leit-C® from Göcke Conductiver Carbon Cement) and coated with gold by the standard evaporation technique (coating device K550 Emitech) - 10mA for circa 2 minutes, which resulted on an average gold layer of 20 nm (Fig. 2.1 and 2.2).

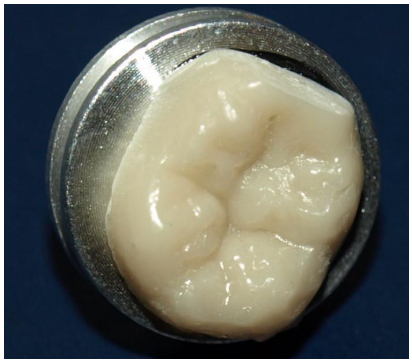

Fig. 2.1 Cast attached on metal stub

Fig. 2.2 Cast after coating with gold

For practical reasons casts were coded with two numbers and a letter.

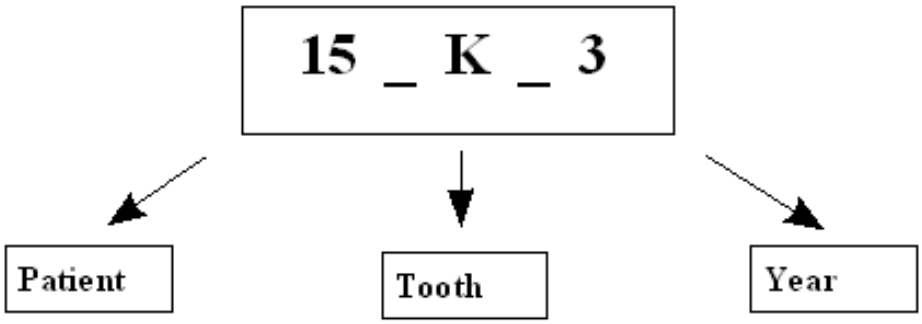

Fig. 2.3 Example of cast code

The letter in the cast code corresponds with the tooth that was treated and filled. Teeth schema from cast codes (see Fig 2.3) were as follows:

A	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**	**J**
18	17	16	15	14	24	25	26	27	28
T	**S**	**R**	**Q**	**P**	**O**	**N**	**M**	**L**	**K**
48	47	46	45	44	34	35	36	37	38

Table 2.1 Cast coding formula

2.3. Quantitative analysis of margins in SEM

Only an occlusal part of prepared casts was evaluated. All interfaces were analyzed with SEM at x200 and completed, when necessary, with other magnifications (Carl Zeiss NTS GmbH, Oberkochen). The quality of interfaces and degree of interfacial breakdowns were compared to standard microphotographs. In order to register existing data, RaEM software was used (®Peter Müller 2006, Würzburg; version number 3.1.1), which enabled exact measurement and judgment of the margins. After the percentage

measurement of each art of margin sections, a statistic analysis was carried out. Quantitative data was obtained by measuring the length of each evaluation and by the score expressed as a percentage of total length of the examined interface.

2.4. Measurement procedure

The SEM was connected with the PC through a Video output with a frame-grabber card, which allowed for the taken pictures to be transported directly to the PC and processed. Pictures of the whole occlusal margin of the filling were taken and the measurement procedure followed. The computer-supported analysis was carried out based on five scores of margin morphology (Table 2.2).

Perfect margin	Continuous transition between tooth and filling material
Margin gap	Tissue and filling are clearly divided from each other with a gap or so-called “hair-split”
Artifact	Transition area between tooth tissue and filling is impossible to assess due to technical procedures for establishing replica casts (such as air bubbles or lack of homogeneity) or while taking impression of filled teeth (unremoved plaque or tartar from the tooth surface); those margin regions are described in SEM analysis as impossible to estimate
Surplus	Originates usually from overlooking the excess of filling material while polishing, which leads to shifting of the tooth-filling margin
Deficiency margin	Originates either while placing the filling or follows from abrasion; however, there is no margin gap present

Table 2.2 Five scores of margin morphology

The evaluation of criterions “artifact”, “surplus” and “deficiency margin” can originate from mistakes made while taking impressions, working out replica casts or incorrect finishing of a filling itself. In this study, “artifact” segments were not discussed at all; “surplus” and “deficiency margin” were judged at the end, percentage incidence of the above-mentioned margin arts was not very significant.

The following SEM pictures (see Fig. 2.4, 2.5, 2.6, 2.7 and 2.8) show each of the above-mentioned margin sections.

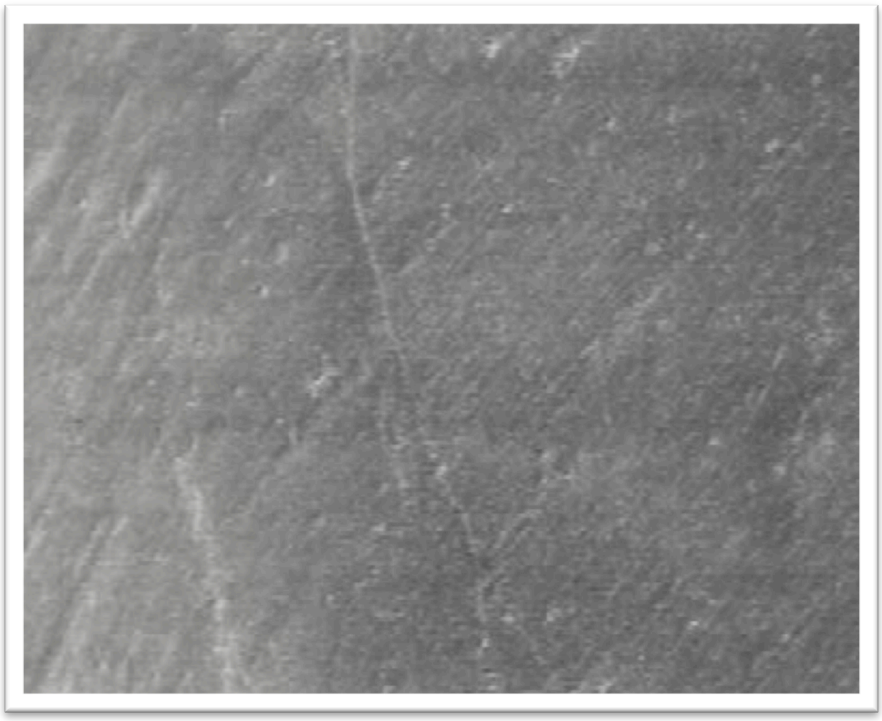

Fig. 2.4 Perfect margin (original magnification x200)

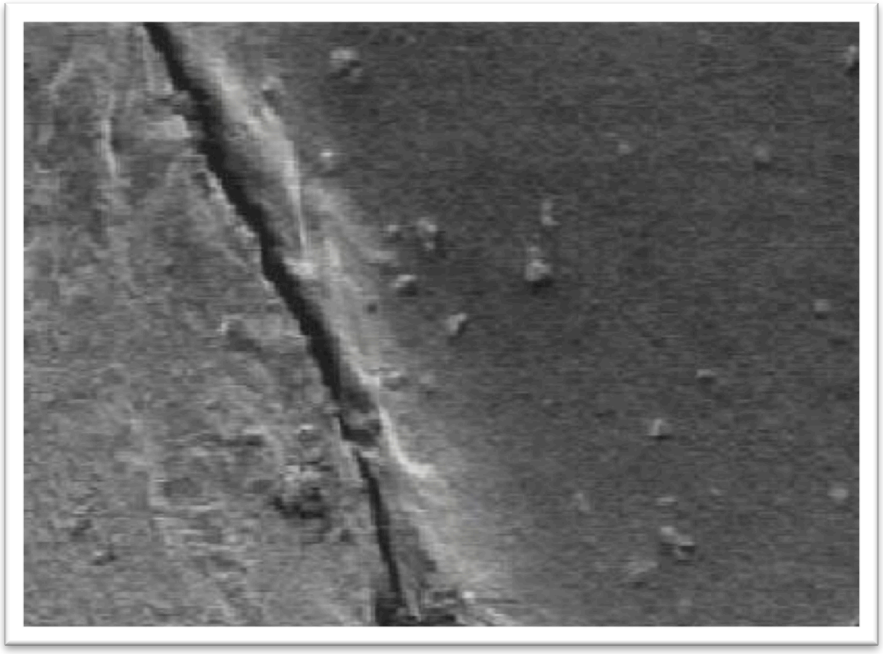

Fig. 2.5 Margin gap (original magnification x200)

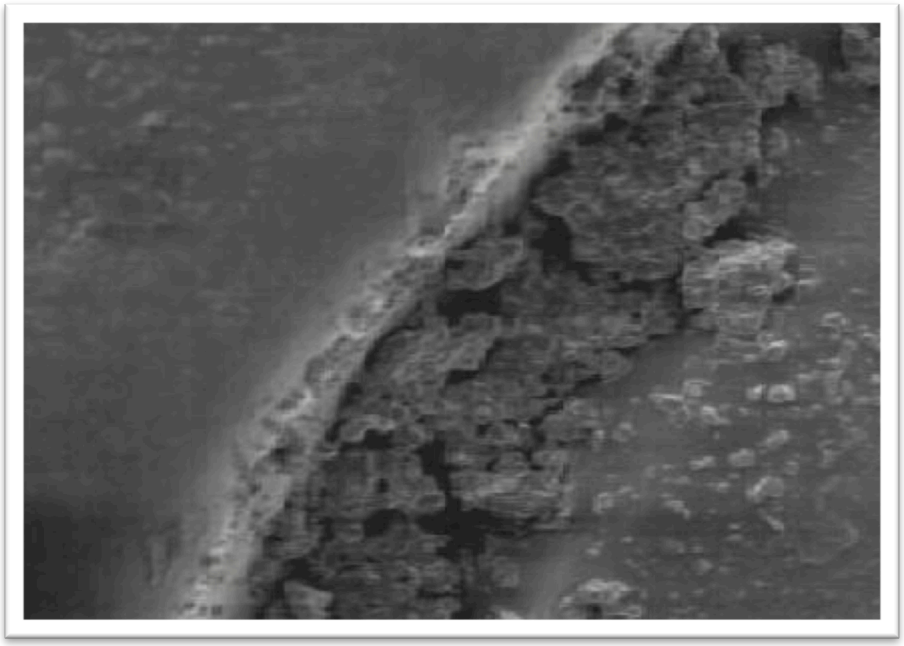

Fig. 2.6 Artifact (original magnification x200)

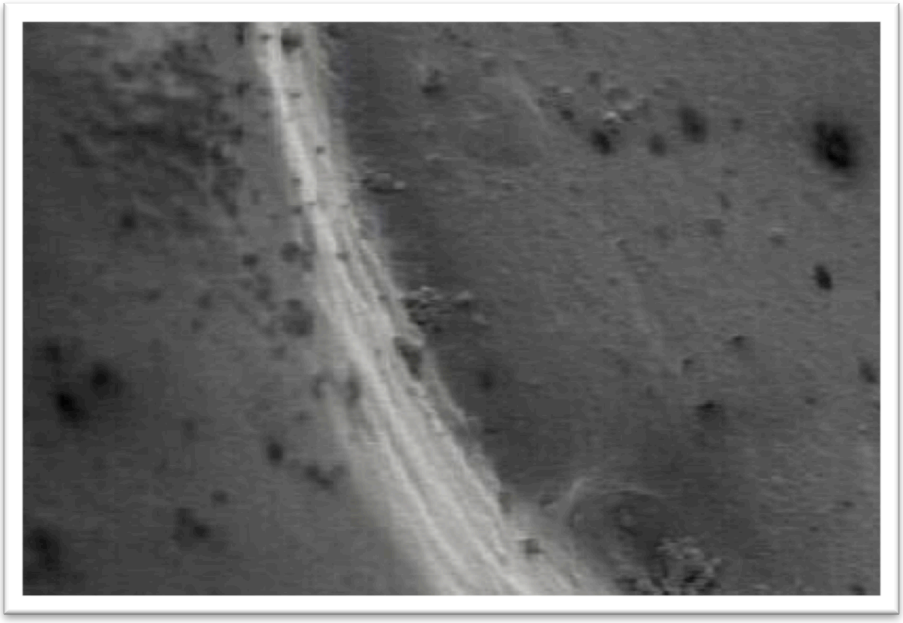

Fig. 2.7 Surplus (original magnification x200)

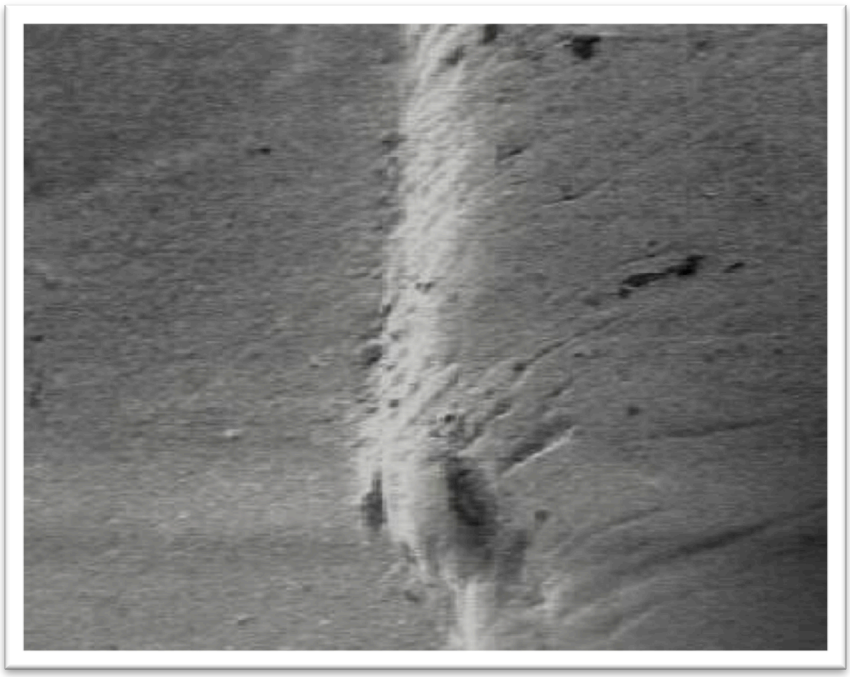

Fig. 2.8 Margins deficiency (original magnification x200)

The aim of this study was to evaluate the quality of fillings made with Admira® (Ormocer group) within four years of clinical examination, mainly focused on the density of the filling's margin.

3. Results

This chapter presents the results of statistical analysis of 43 valid samples with Admira (Ormocers group) during a four-year-long clinical observation. It was unfortunately not possible to examine all 95 primary made filling due to several reasons but mainly because of lack of patients' presence at the follow up appointment. Microsoft Office Excel 2007 was used for generation of diagrams based on input from RaEM software (®Peter Müller 2006, Würzburg; version number 3.1.1). Each diagram (see Fig. 3.1 – 3.43) shows the percentage of *Perfect*, *Margin gap*, *Margin deficiency* and *Surplus* observed, accordingly, after six months (Control 1), in second (Control 2), third (Control 3) and fourth year (Control 4) in the given samples (32G, 13D, 32F, etc.).

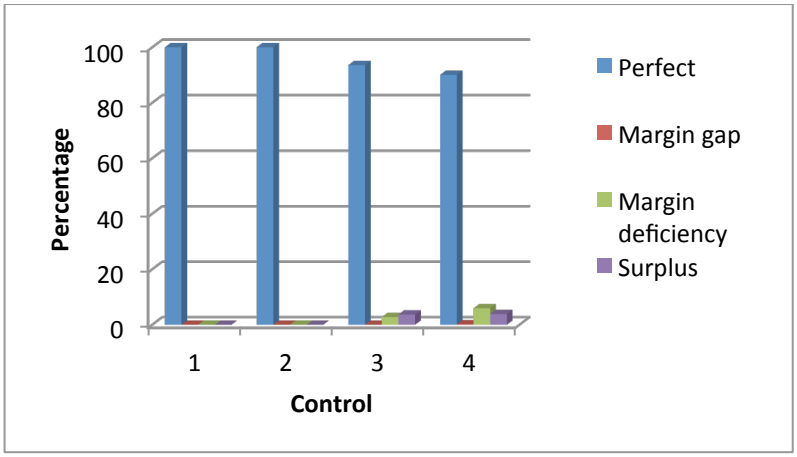

Fig. 3.1 Diagram for sample 32G with Admira during 4-year clinical observation time

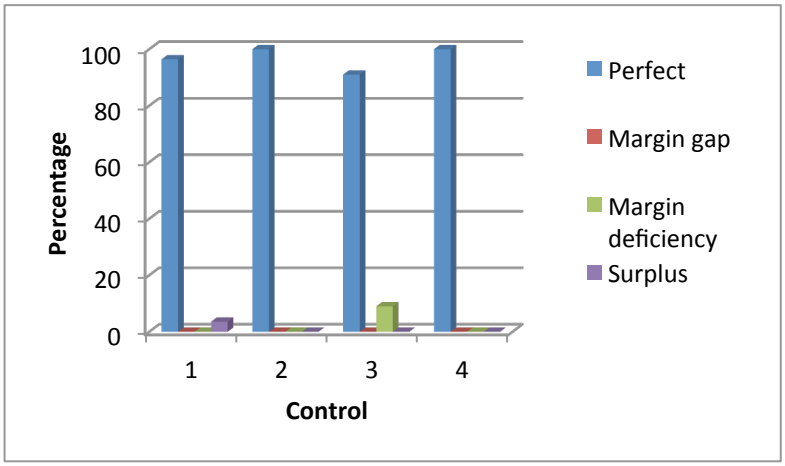

Fig. 3.2 Diagram for sample 13D with Admira during 4-year clinical observation time

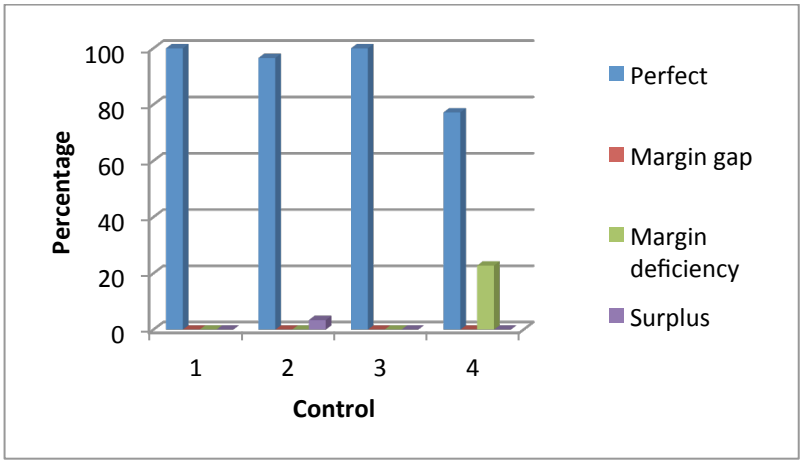

Fig. 3.3 Diagram for sample 32F with Admira during 4-year clinical observation time

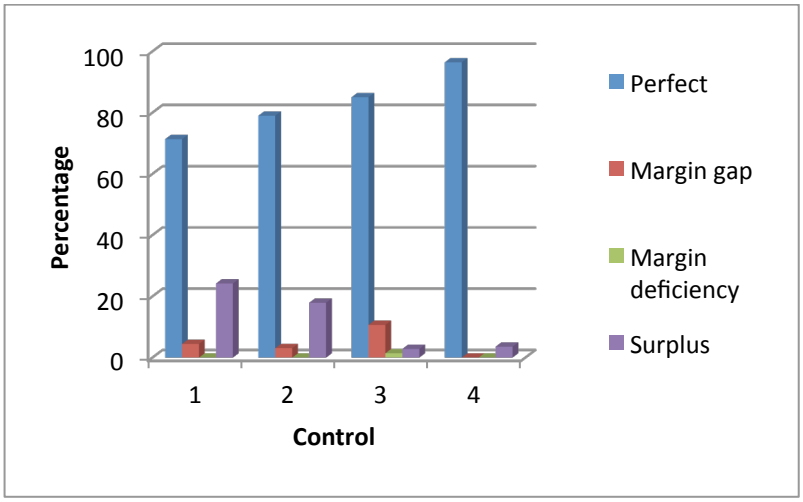

Fig. 3.4 Diagram for sample 22G with Admira during 4-year clinical observation time

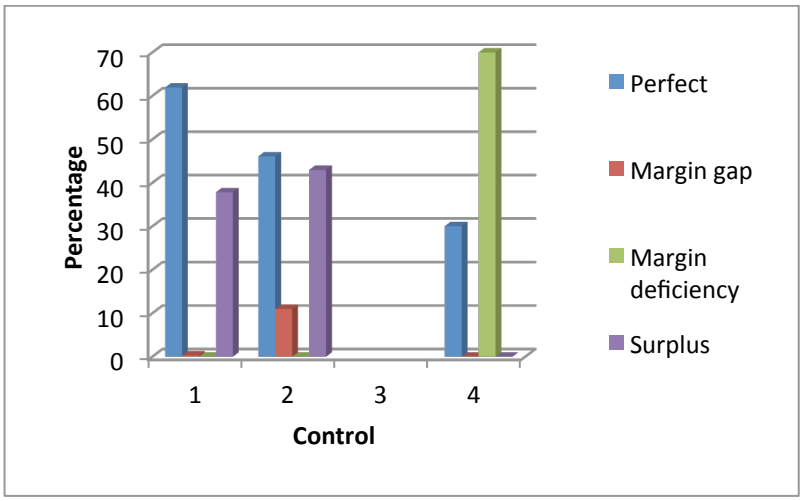

Fig. 3.5 Diagram for sample 2D with Admira during 4-year clinical observation time

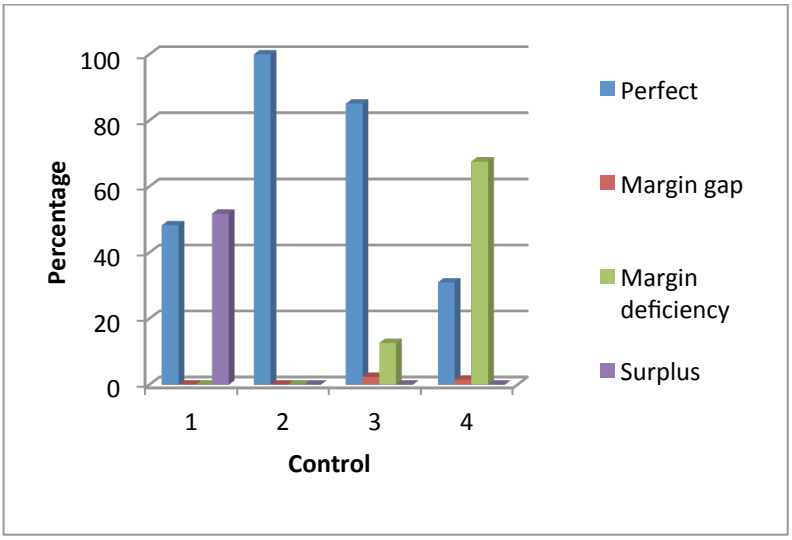

Fig. 3.6 Diagram for sample 3Q with Admira during 4-year clinical observation time

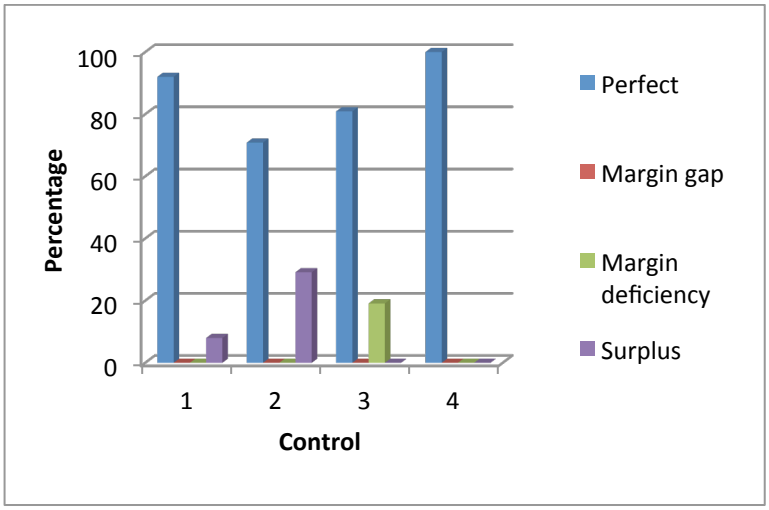

Fig. 3.7 Diagram for sample 24D with Admira during 4-year clinical observation time

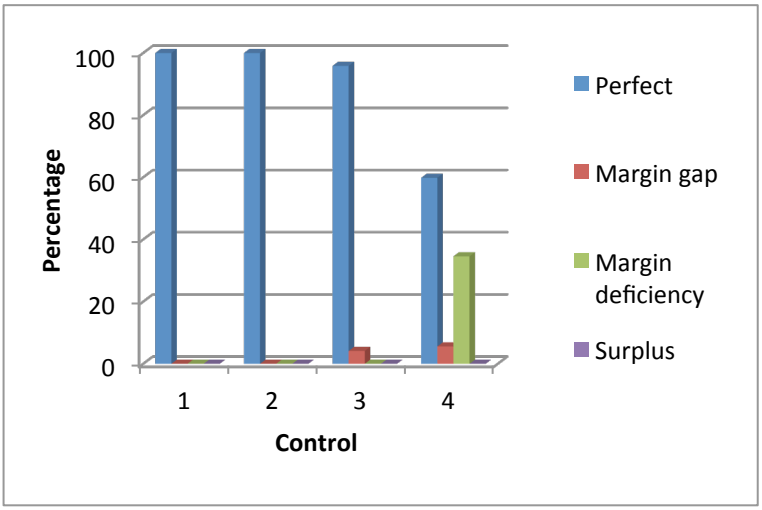

Fig. 3.8 Diagram for sample 29F with Admira during 4-year clinical observation time

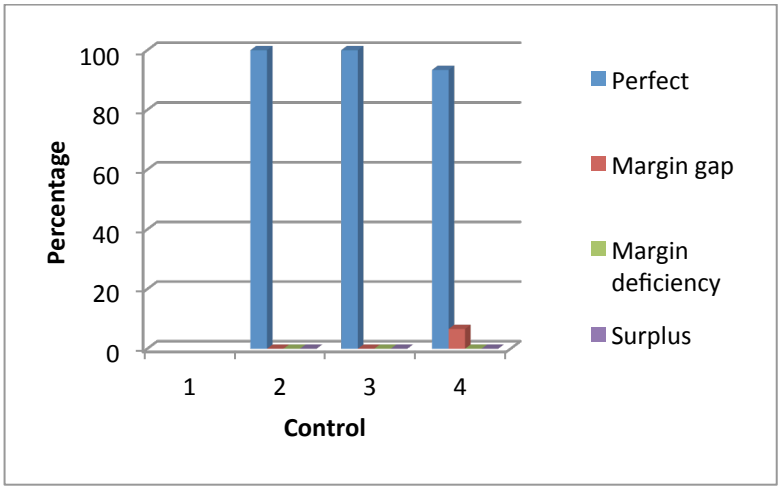

Fig. 3.9 Diagram for sample 8Q with Admira during 4-year clinical observation time

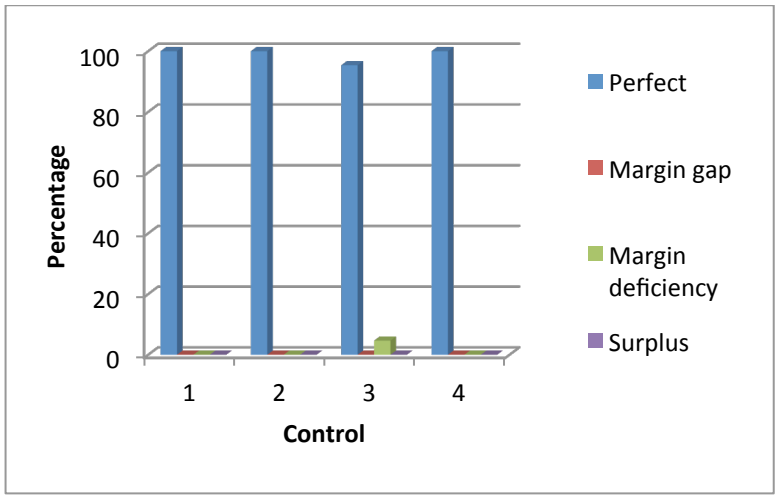

Fig. 3.10 Diagram for sample 32D with Admira during 4-year clinical observation time

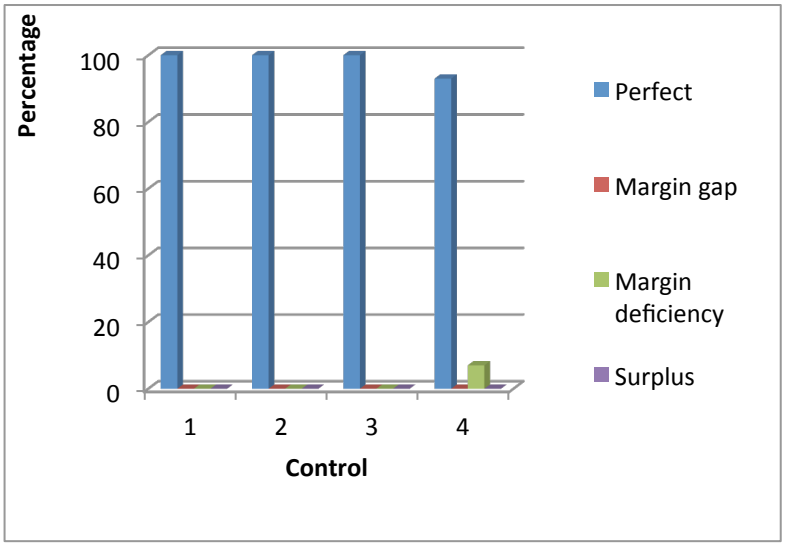

Fig. 3.11 Diagram for sample 27F with Admira during 4-year clinical observation time

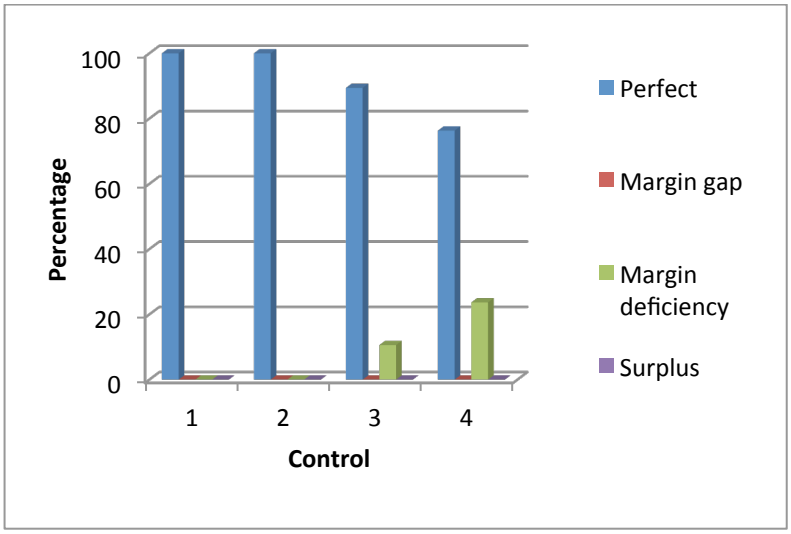

Fig. 3.12 Diagram for sample 29G with Admira during 4-year clinical observation time

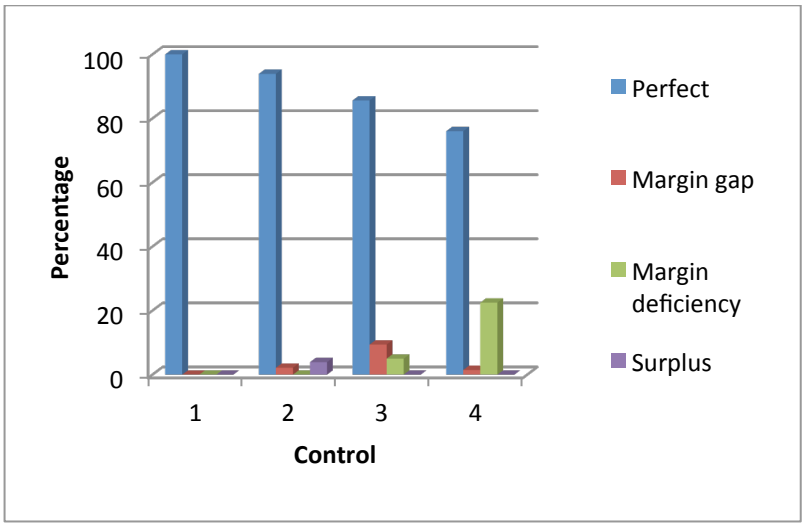

Fig. 3.13 Diagram for sample 21E with Admira during 4-year clinical observation time

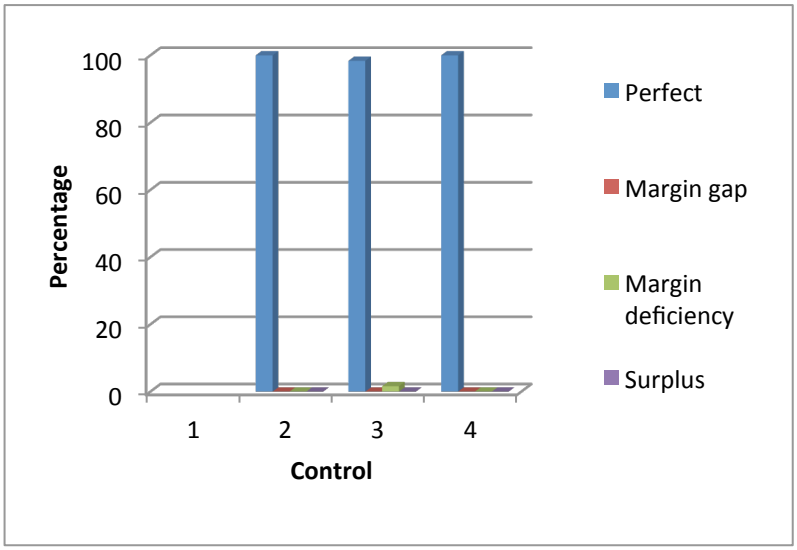

Fig. 3.14 Diagram for sample 29D with Admira during 4-year clinical observation time

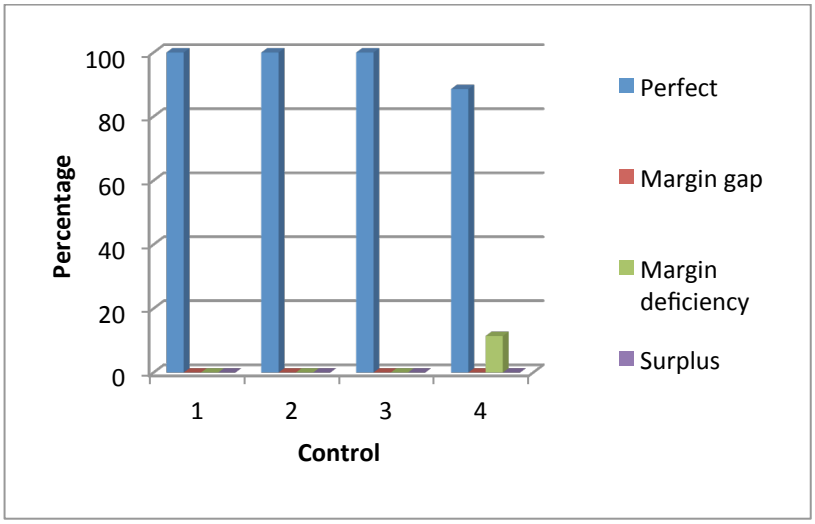

Fig. 3.15 Diagram for sample 29G with Admira during 4-year clinical observation time

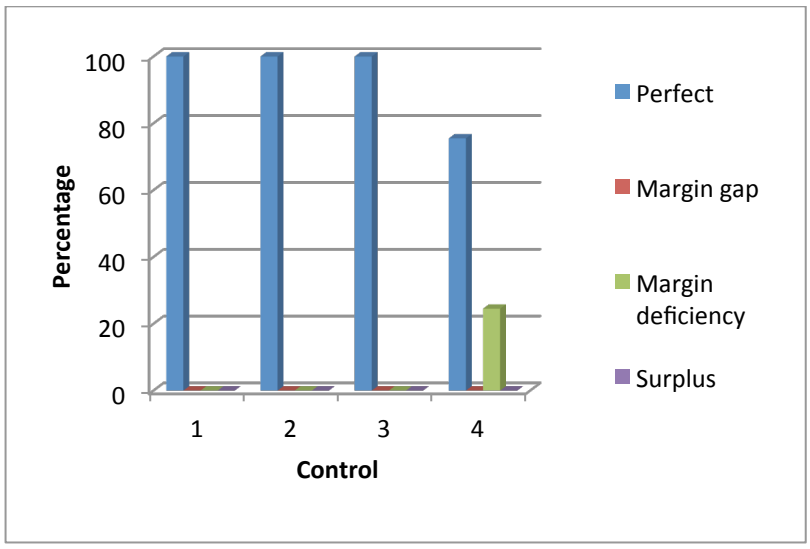

Fig. 3.16 Diagram for sample 10Q with Admira during 4-year clinical observation time

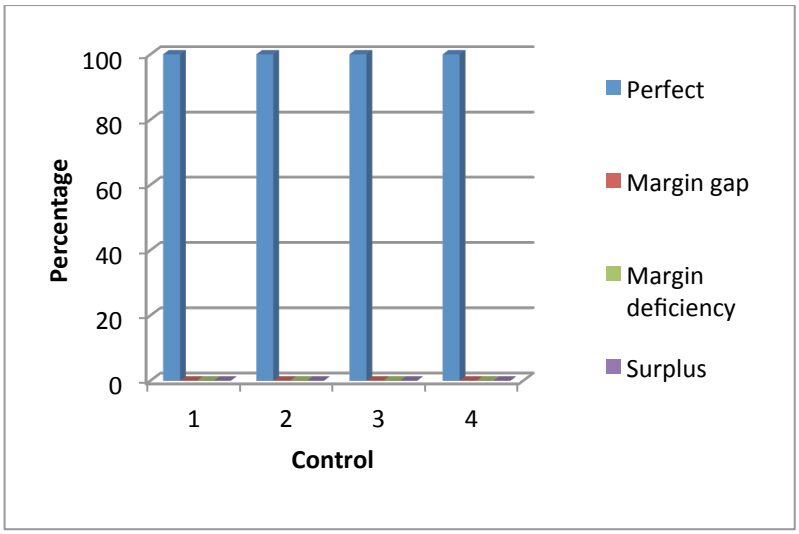

Fig. 3.17 Diagram for sample 8P with Admira during 4-year clinical observation time

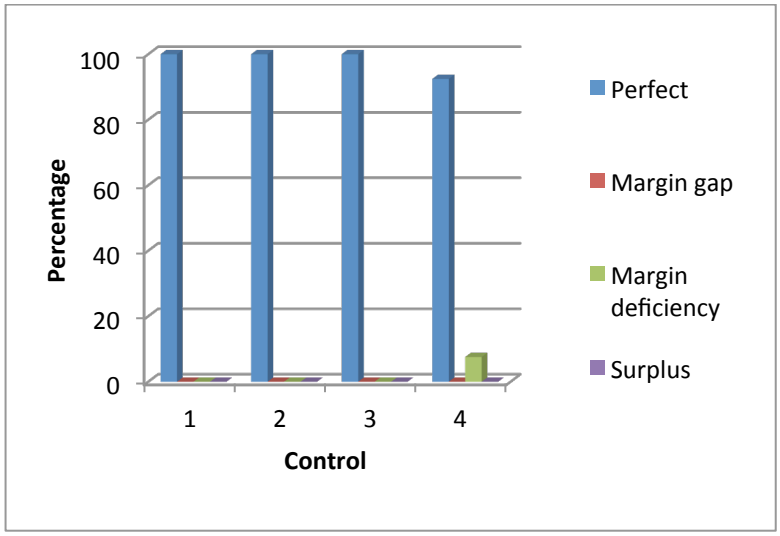

Fig. 3.18 Diagram for sample 6P with Admira during 4-year clinical observation time

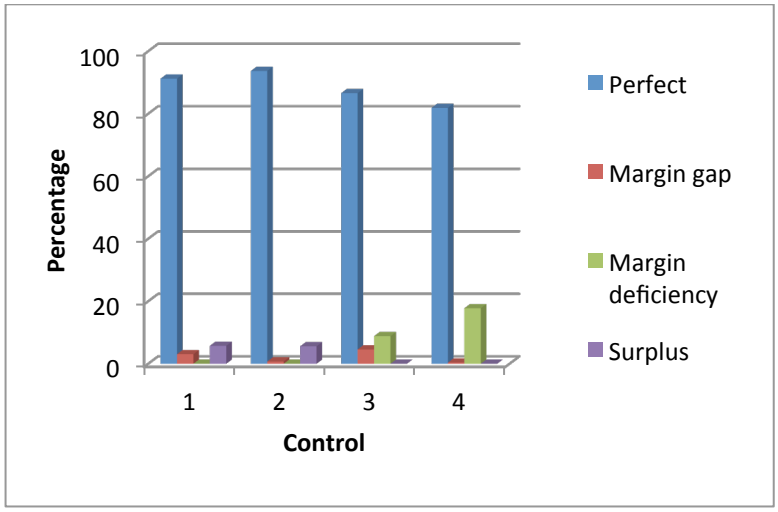

Fig. 3.19 Diagram for sample 12G with Admira during 4-year clinical observation time

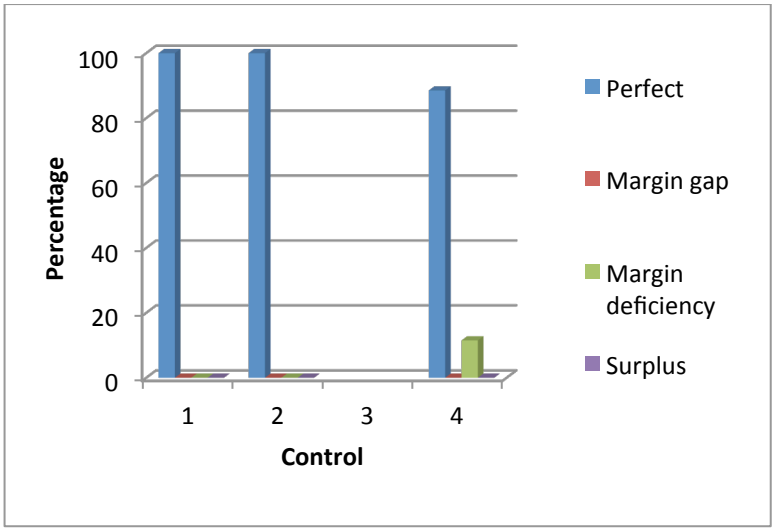

Fig. 3.20 Diagram for sample 14Q with Admira during 4-year clinical observation time

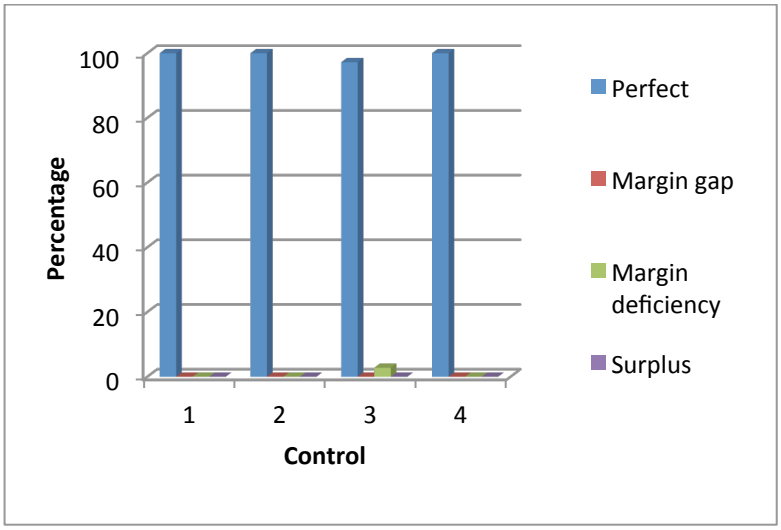

Fig. 3.21 Diagram for sample 29C with Admira during 4-year clinical observation time

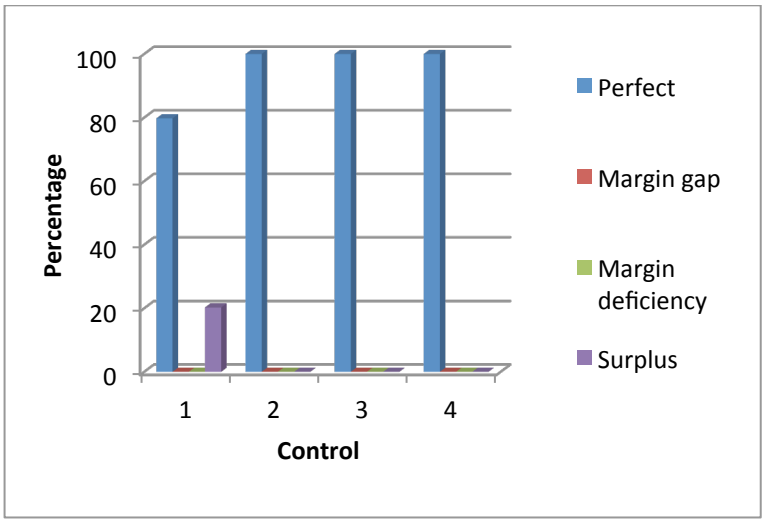

Fig. 3.22 Diagram for sample 20F with Admira during 4-year clinical observation time

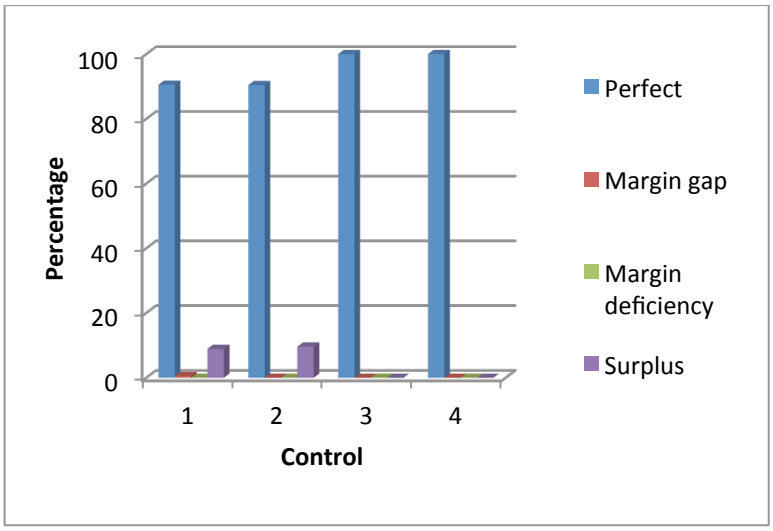

Fig. 3.23 Diagram for sample 2M with Admira during 4-year clinical observation time

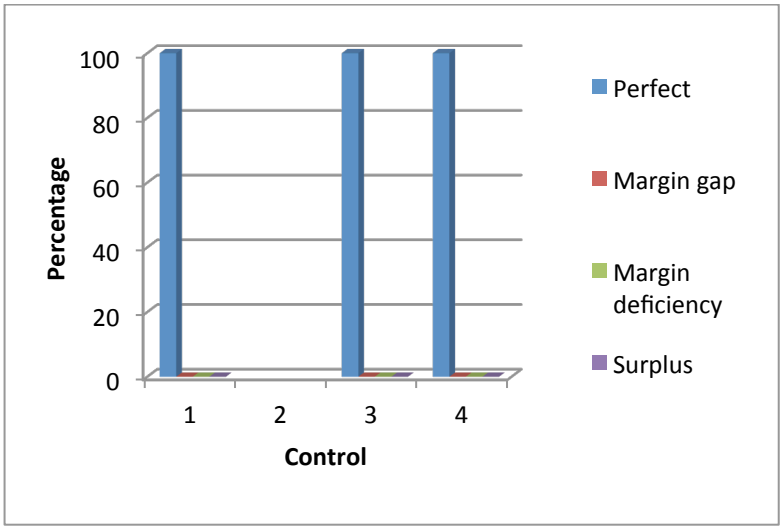

Fig. 3.24 Diagram for sample 3B with Admira during 4-year clinical observation time

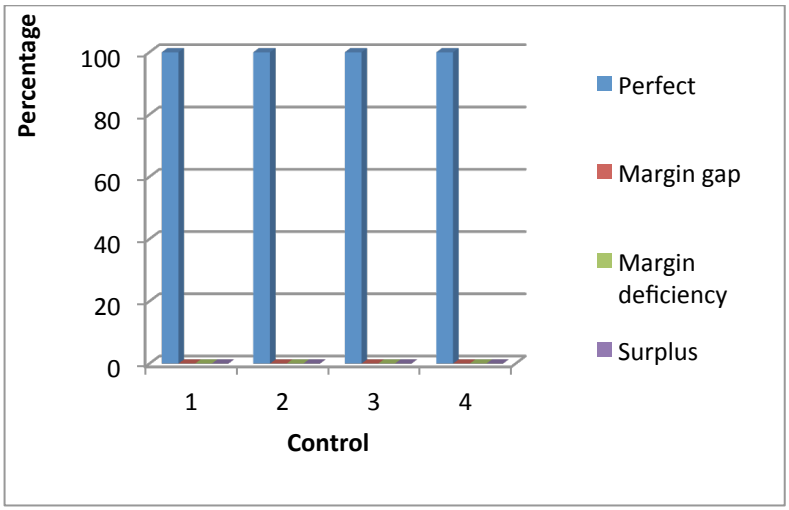

Fig. 3.25 Diagram for sample 3L with Admira during 4-year clinical observation time

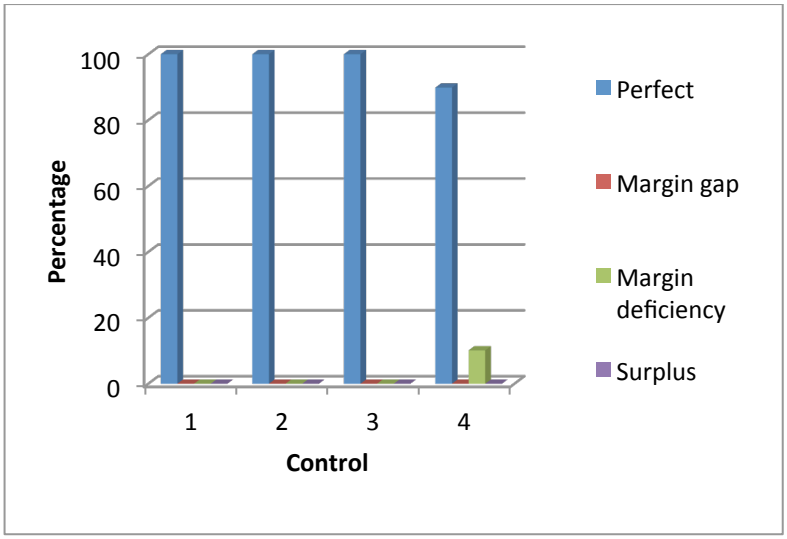

Fig. 3.26 Diagram for sample 3S with Admira during 4-year clinical observation time

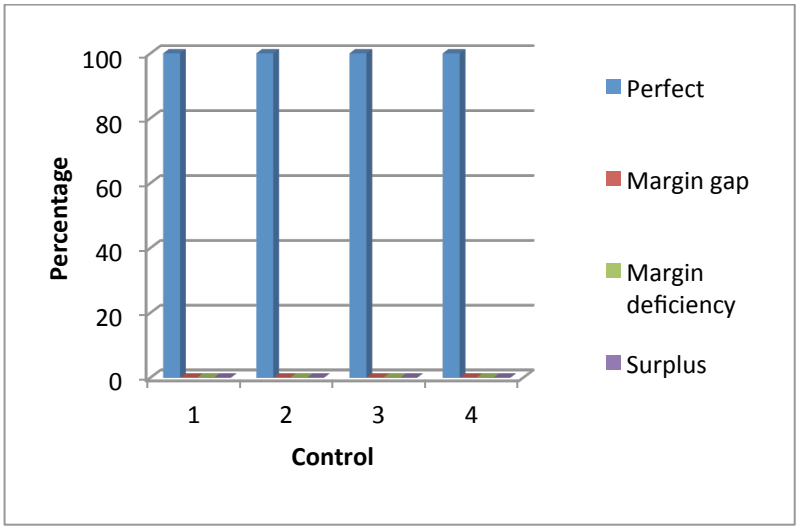

Fig. 3.27 Diagram for sample 8M with Admira during 4-year clinical observation time

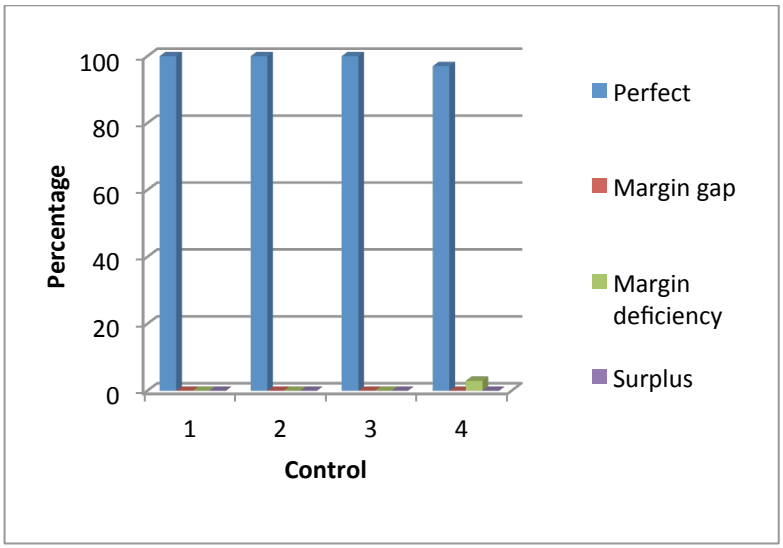

Fig. 3.28 Diagram for sample 8R with Admira during 4-year clinical observation time

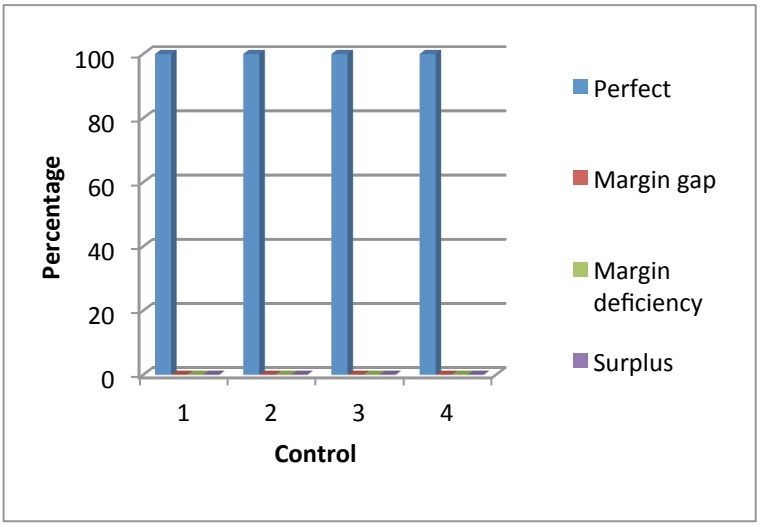

Fig. 3.29 Diagram for sample 8S with Admira during 4-year clinical observation time

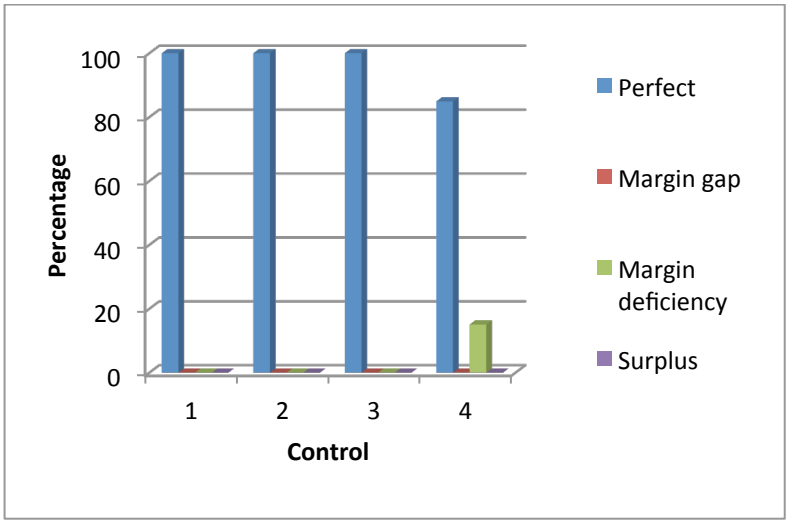

Fig. 3.30 Diagram for sample 9C with Admira during 4-year clinical observation time

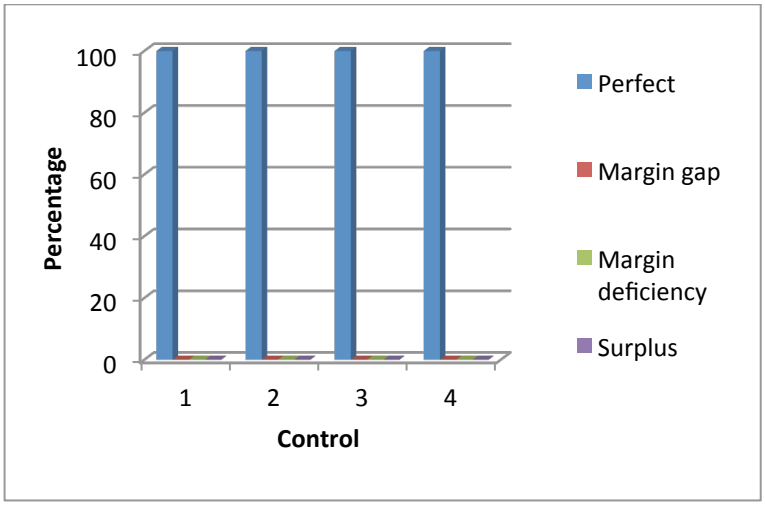

Fig. 3.31 Diagram for sample 9L with Admira during 4-year clinical observation time

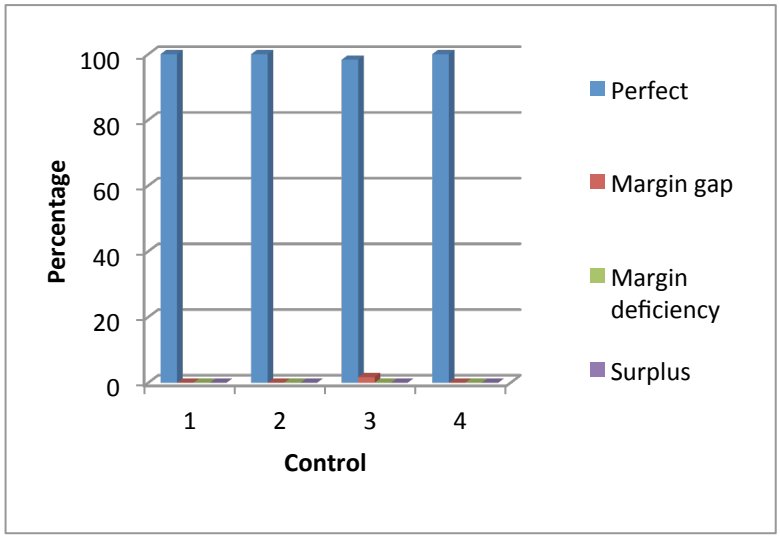

Fig. 3.32 Diagram for sample 12L with Admira during 4-year clinical observation time

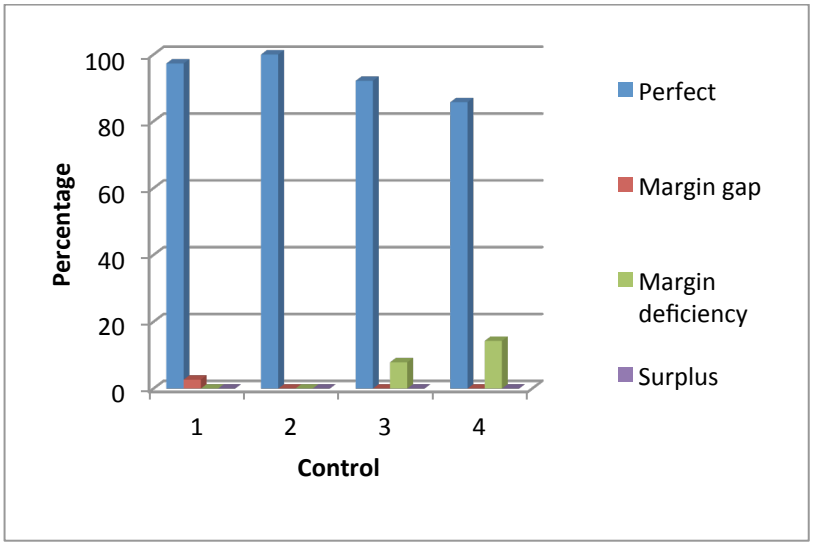

Fig. 3.33 Diagram for sample 12M with Admira during 4-year clinical observation time

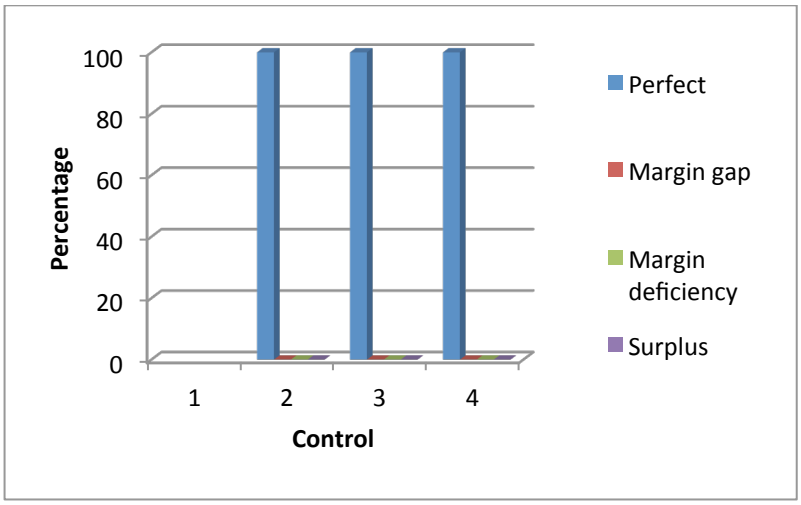

Fig. 3.34 Diagram for sample 13L with Admira during 4-year clinical observation time

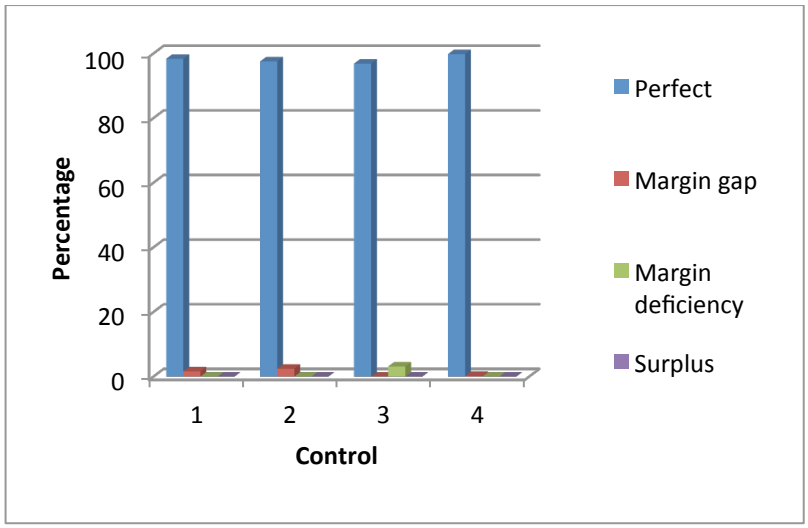

Fig. 3.35 Diagram for sample 13S with Admira during 4-year clinical observation time

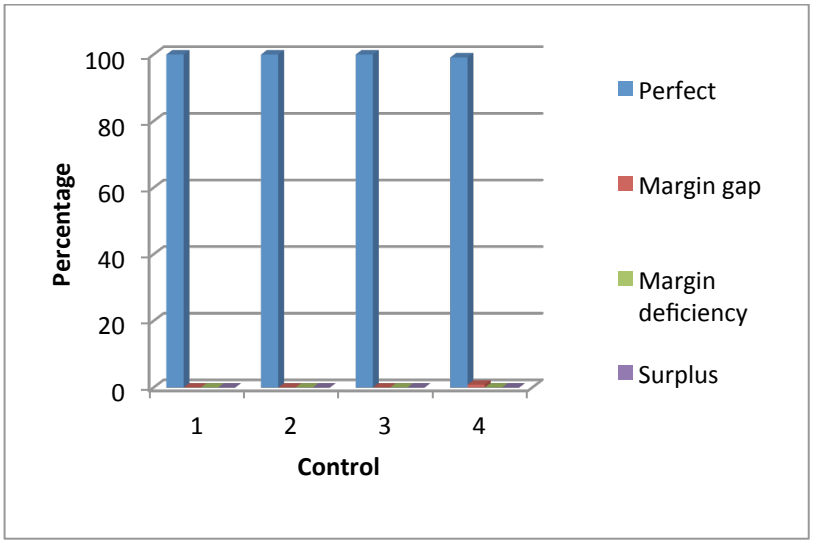

Fig. 3.36 Diagram for sample 14R with Admira during 4-year clinical observation time

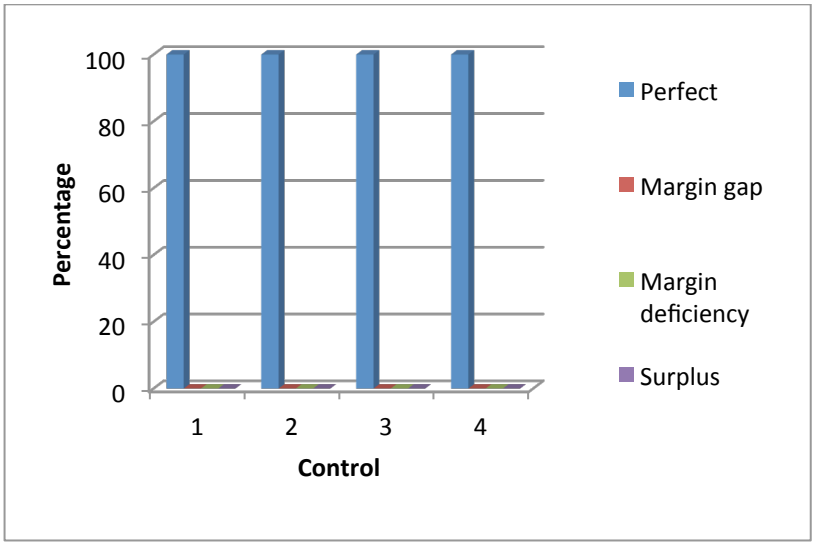

Fig. 3.37 Diagram for sample 14S with Admira during 4-year clinical observation time

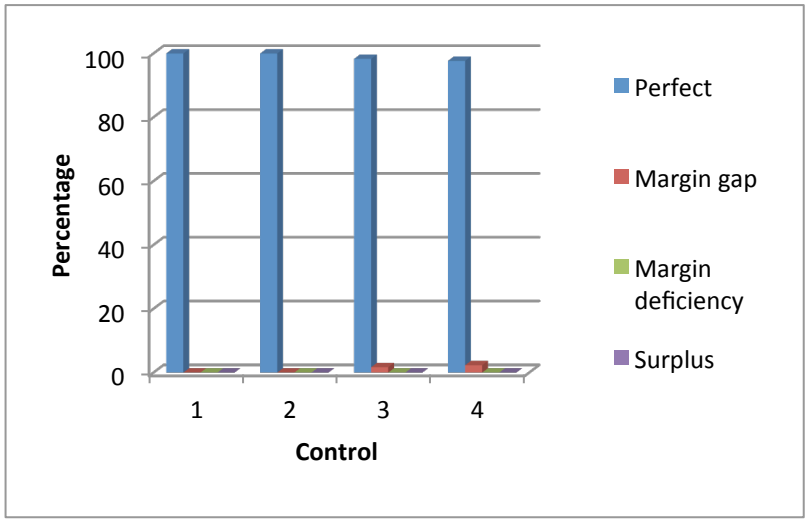

Fig. 3.38 Diagram for sample 18M with Admira during 4-year clinical observation time

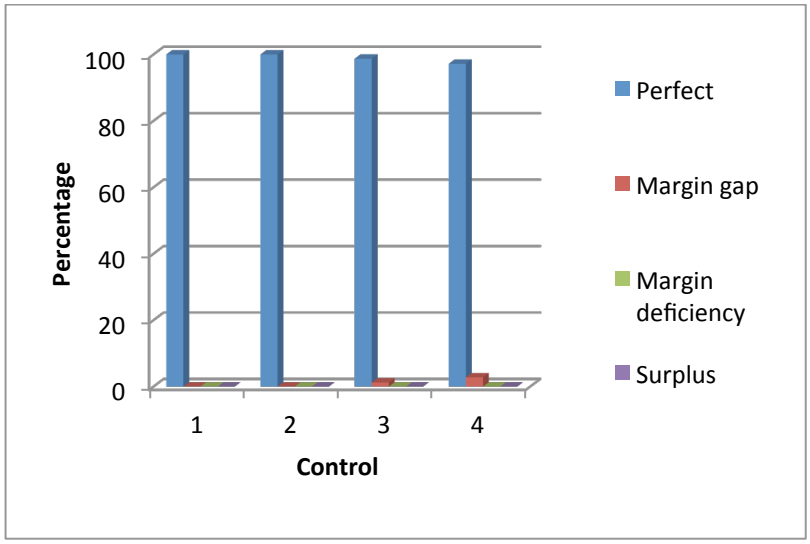

Fig. 3.39 Diagram for sample 19B with Admira during 4-year clinical observation time

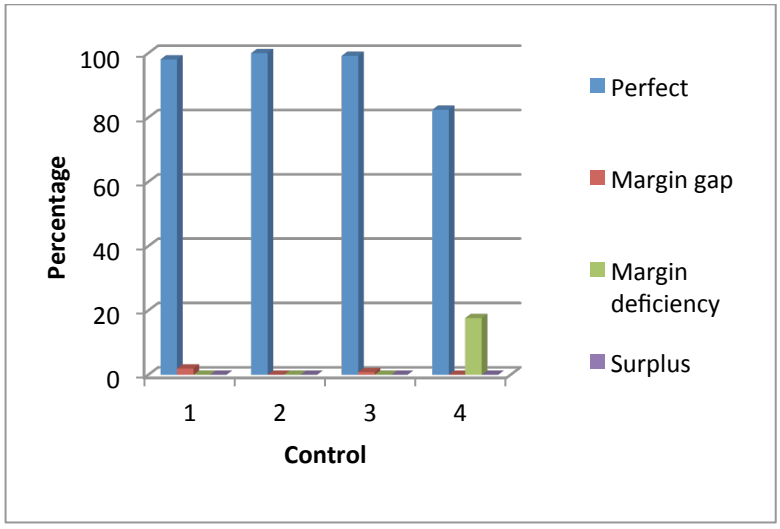

Fig. 3.40 Diagram for sample 21I with Admira during 4-year clinical observation time

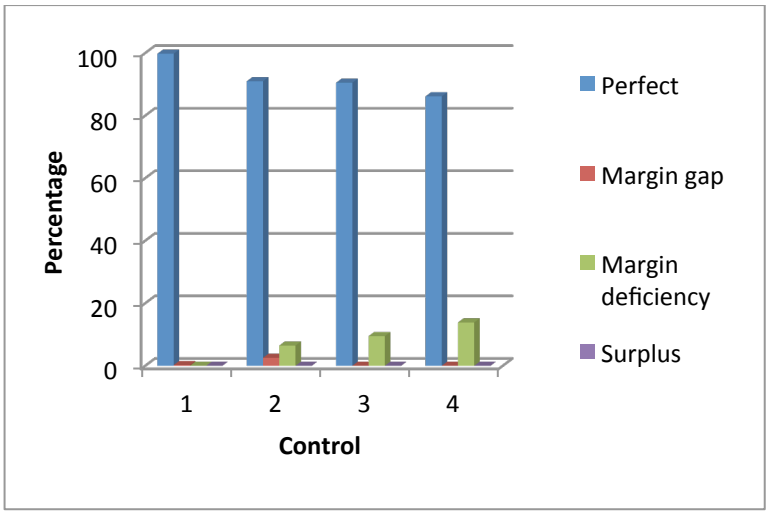

Fig. 3.41 Diagram for sample 22L with Admira during 4-year clinical observation time

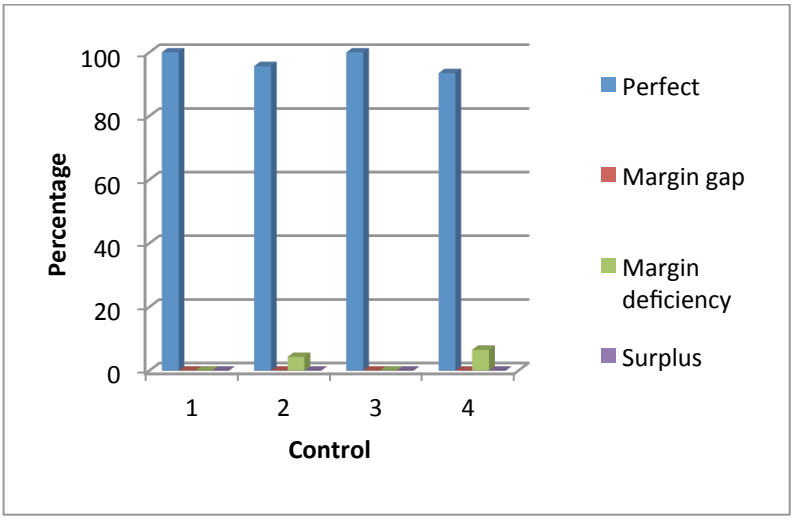

Fig. 3.42 Diagram for sample 24C with Admira during 4-year clinical observation time

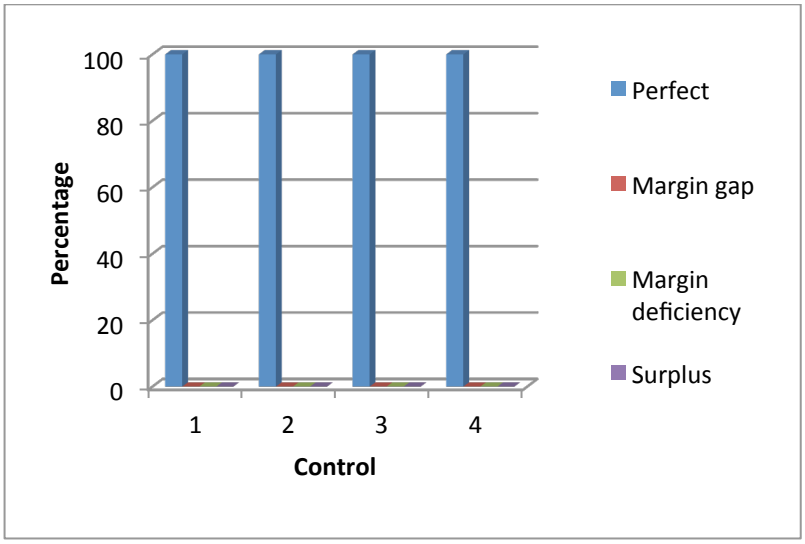

Fig. 3.43 Diagram for sample 24M with Admira during 4-year clinical observation time

3.1. Aggregated results – Control 1

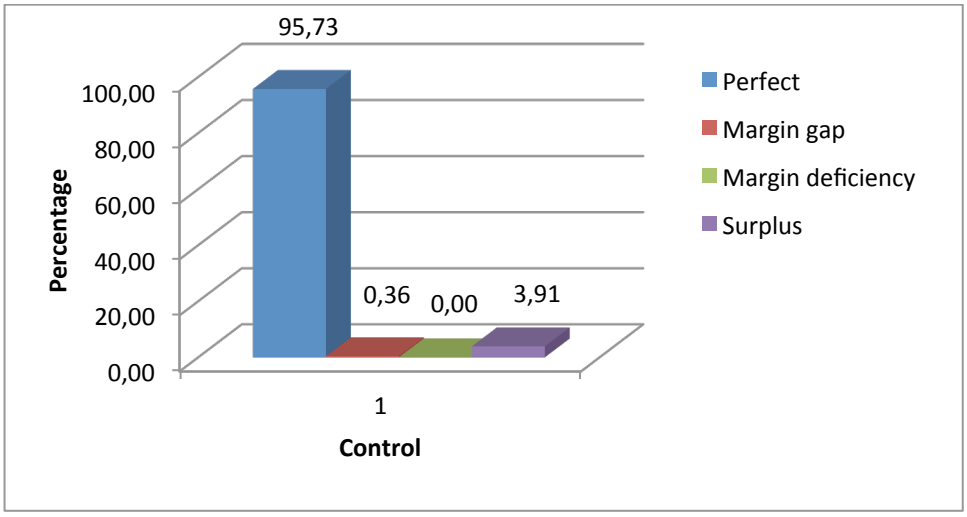

Fig. 3.44 Aggregated (average) with Admira (Ormocers group) after 6 months of clinical observation

After six months of clinical observation one can see that the great majority of fillings have perfect margin adaptation, achieving more than 95%. There is only slight margin gap, which remains under 0.5%. Surplus resulted most likely in the overlooking of material while polishing and finishing of the restoration. One has to indicate however that less than 4% of the whole margin quality is not perfect and this percentage is very low. Moreover this small percentage is rather connected with human failure while making a filling than with material properties itself.

3.2. Aggregated results – Control 2

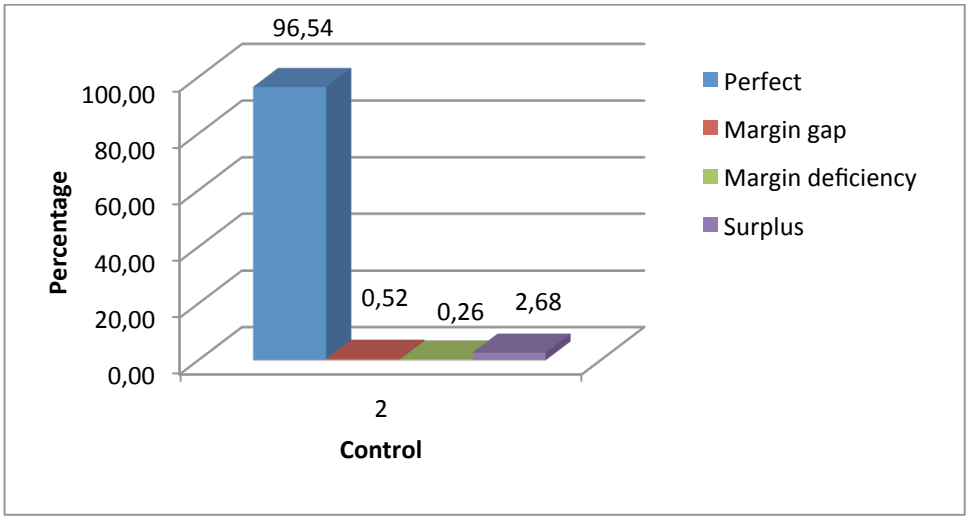

Fig. 3.45 Aggregated (average) with Admira (Ormocers group) after 1 year of clinical observation

Results after first year show some slight differences compared with above discussed cases after the first six months. One can observe that gap formation increased to more than 0.5%. There are changes according to other parameters as well. Surplus reduced to 2.68% and margin deficiency parameter increased up to 0.26%. This connection results from the occlusal stress that takes place while chewing. Surplus reduced and margin deficiency increased, which means that the wear rate of the filling has grown. The slight difference between the percentage of perfect margin after the first six months and first year of observation appears as to be an experimental error made during the measurement procedure.

3.3. Aggregated results – Control 3

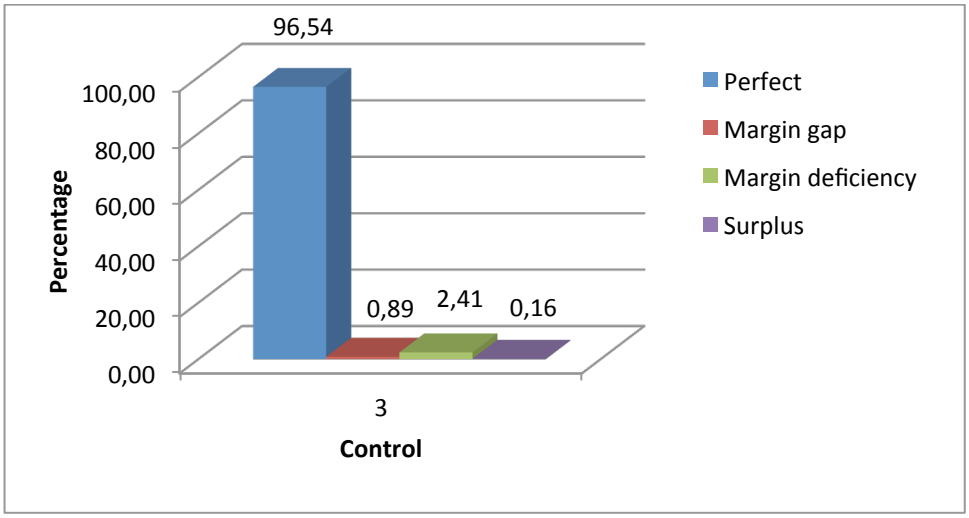

Fig. 3.46 Aggregated (average) with Admira (Ormocers group) after 2 years of clinical observation

The second year of the observation in this study shows no significant changes in the area of perfect margin parameter. On the other hand however clear changes had developed regarding three other parameters. Gap formation increased by circa 0.4% and one additional year of loading influenced wear rate and as a consequence margin deficiency level. Just like after the first year, surplus was seen to diminish continuously.

3.4. Aggregated results – Control 4

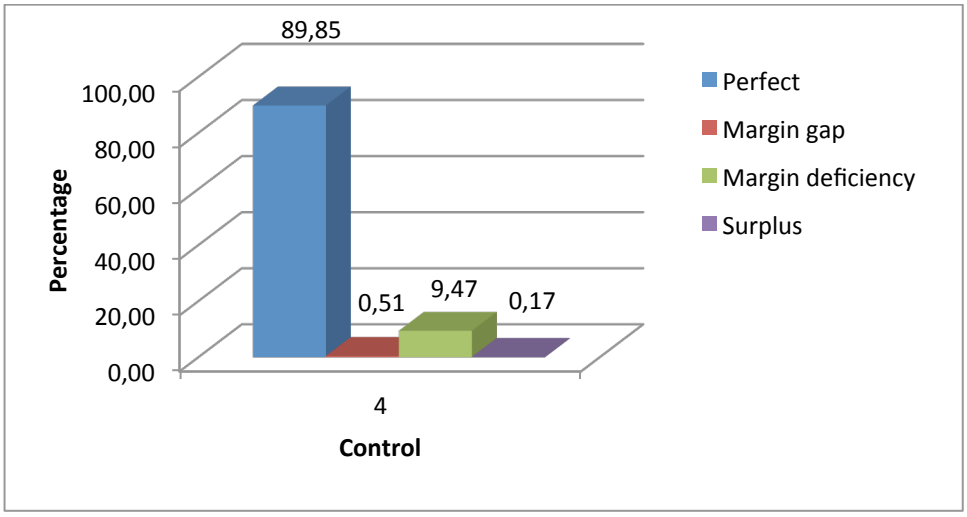

Fig. 3.47 Aggregated (average) with Admira (Ormocers group) after 4 years of clinical observation

The fourth year of this study brought some significant and interesting changes. There was quite a high difference in perfect margin percentage, which reduced to ~ 90% and an almost 6% increase of margin deficiency indicating again some wear induced by loading. Surprisingly, margin gap percentage diminished by circa 0.4% as well. This could suggest that the gap did not form through the whole filling depth and due to the increased wear rate, the fillings adaptation in lower layers showed good quality.

3.5. Detailed data analysis

Using only average values for data analysis is not enough in most cases for detailed investigation, because a distribution of experimental collected data is also of high importance. For large volumes of data, a statistical analysis can be very helpful to identify key characteristics of the given distribution, such as mean and average square deviation for Gaussian (normal) distribution, but in this case, with a relatively small number of samples, such statistical analysis is usually not very helpful [57]. In this case, it is much better to perform a detailed data analysis to find experimental collected data boundaries (MIN and MAX) and distribution for attributes of interest, such as, margin gap and margin deficiency [58].

First, presented below are the values for minimum, average and maximum (see Table 3.1) observed for margin deficiency in the samples presented in Chapter 3.

	Control 1	**Control 2**	**Control 3**	**Control 4**
MIN	~ 0% (e.g., Sample 14S)	~0% (e.g., Sample 21I)	~0% (e.g., Sample 19B)	~0% (e.g., Sample 18M)
AVERAGE	~ 0%	0.26%	2.41%	9.47%
MAX	~0% (e.g., Sample 14S)	6.45% (Sample 22L)	19.10% (Sample 24D)	69.98% (Sample 2D)
Δ = MAX - AVERAGE	**~0%**	**6.21%**	**16.69%**	**60.51%**

Table 3.1 Minimum, average and maximum of margin deficiency observed in studied samples

As one can see from Table 3.1, some significant difference Δ between the maximal margin deficiency and the average one was observed in years 1, 2 and 4, which has to be further studied in the following data classification analysis.

Second, we present values of minimum, average and maximum (see Table 3.2) observed for margin gaps in samples presented in Chapter 3.

	Control 1	**Control 2**	**Control 3**	**Control 4**
MIN	~ 0 % (e.g., Sample 14S)	~ 0 % (e.g., Sample 14S)	~ 0 % (e.g., Sample 14S)	~ 0 % (e.g., Sample 14S)
AVERAGE	0.36 %	0.52 %	0.89%	0.51%
MAX	4.45 % (Sample 22G)	10.98 % (Sample 2D)	10.68% (Sample 22G)	6.62% (Sample 8Q)
Δ = MAX - AVERAGE	**4.09 %**	**10.46%**	**9.79%**	**6.11%**

Table 3.2 Minimum, average and maximum of margin gap observed in studied samples

As one can see from Table 3.2, some significant difference Δ between the minimum of margin gap and the average one was observed after 6 months as well as in years 2, 3 and 4, which has to be also further studied in the following data classification analysis.

Third, to visualize a distribution of observed values of margin deficiency and margin gap, a detailed data analysis was performed for experimental observed values in samples with the atomic values ("Good", "Acceptable" and "Bad") for "Margin deficiency" and ("Good", "Small gap", "Clear gap" and "Bad") for "Margin gap" attributes observed in samples:

- "Margin deficiency"
    - 0% ≤ Value (in percent) ≤ 3 % → "Good"

- 3 % < Value (in percent) ≤ 15 % → "Acceptable"
- 15% < Value (in percent) → "Bad"

- "Margin gap"
  - Value (in percent) = 0 % → "Good"
  - 0 % < Value (in percent) ≤ 3 % → "Small gap"
  - 3% < Value (in percent) ≤ 6 % → "Clear gap"
  - 6 % < Value (in percent) → "Bad"

We can now arrange all samples year by year with margin deficiency attribute, as it is presented in Tables 3.3, 3.4, 3.5 and 3.6.

"Margin deficiency" during Control 1		
Good	**Acceptable**	**Bad**
32G, 13D, 32F, 24D, 29F, 32D, 27F, 29G, 21E, 29G, 10Q, 8P, 6P, 12G, 14Q, 2M, 3B, 3L, 3S, 8M, 8R, 8S, 9C, 9L, 12L, 12M, 13S, 14R, 14S, 18M, 19B, 21I, 22L, 24C, 24M, 29C, 20F, 22G, 2D, 3Q **Total: 40 (100%)**	**Total: 0 (0%)**	**Total: 0 (0%)**

Table 3.3 Arrangement of samples with margin deficiency during Control 1

”Margin deficiency” during Control 2		
Good	**Acceptable**	**Bad**
32G, 13D, 32F, 3Q, 29F, 8Q, 32D, 27F, 29G, 21E, 29D, 29G, 10Q, 8P, 6P, 12G, 14Q, 20F, 2M, 3L, 3S, 8M, 8R, 8S, 9C, 9L, 12L, 12M, 13L, 13S, 14R, 14S, 18M, 19B, 21I, 24M, 29C, 22G, 2D, 24D **Total: 40 (95%)**	22L, 24C **Total: 2 (5%)**	**Total: 0 (0%)**

Table 3.4 Arrangement of samples with margin deficiency during Control 2

”Margin deficiency” during Control 3		
Good	**Acceptable**	**Bad**
32G, 32F, 29F, 8Q, 27F, 29D, 29G, 10Q, 8P, 6P, 20F, 2M, 3B, 3L, 3S, 8M, 8R, 8S, 9C, 9L, 12L, 13L, 14R, 14S, 18M, 19B, 21I, 24C, 24M, 29C, 22G **Total: 31 (75.5 %)**	13D, 32D, 12M, 13S, 22L, 21E, 12G, 29G, 3Q **Total: 9 (22%)**	24D **Total: 1 (2.5%)**

Table 3.5 Arrangement of samples with margin deficiency during Control 3

”Margin deficiency” during Control 4		
Good	**Acceptable**	**Bad**
13D, 22G, 24D, 8Q, 32D, 29D, 8P, 20F, 2M, 3B, 3L, 8M, 8R, 8S, 9L, 12L, 13L, 13S, 14R, 14S, 18M, 19B, 24M, 29C **Total: 24 (56%)**	32G, 27F, 6P, 24C, 29G, 14Q, 3S, 12M, 22L **Total: 9 (21%)**	32F, 29G, 21E, 10Q, 12G, 9C, 21I, 2D, 3Q, 29F **Total: 10 (23%)**

Table 3.6 Arrangement of samples with margin deficiency during Control 4

We can now arrange all samples year by year with margin gap attribute, as it is presented in Tables 3.7, 3.8, 3.9 and 3.10.

”Margin gap” during Control 1			
Good	**Small gap**	**Clear gap**	**Bad**
32G, 13D, 32F, 3Q, 24D, 29F, 32D, 27F, 29G, 21E, 29G, 10Q, 8P, 6P, 14Q, 20F, 3B, 3L, 3S, 8M, 8R, 8S, 9C, 9L, 12L, 14S, 14R, 18M, 19B, 24C, 24M, 29C	2D, 2M, 12M, 13S, 21I, 22L	22G, 12G	
Total: 32 (80%)	**Total: 6 (15%)**	**Total: 2 (5%)**	**Total: 0 (0%)**

Table 3.7 Arrangement of samples with margin gap during Control 1

”Margin gap” during Control 2			
Good	**Small gap**	**Clear gap**	**Bad**
32G, 13D, 32F, 3Q, 24D, 29F, 8Q, 32D, 27F, 29G, 29D, 29G, 10Q, 8P, 6P, 14Q, 20F, 2M, 3L, 3S, 8M, 8R, 8S, 9C, 9L, 12L, 12M, 13L, 14S, 14R, 18M, 19B, 21I, 24C, 24M, 29C	21E, 12G, 13S, 22L	22G	2D
Total: 36 (85.5)	**Total: 4 (9.5%)**	**Total: 1 (2.5%)**	**Total: 1 (2.5%)**

Table 3.8 Arrangement of samples with margin gap during Control 2

”Margin gap” during Control 3			
Good	**Small gap**	**Clear gap**	**Bad**
32G, 13D, 32F, 24D, 8Q, 32D, 27F, 29G, 29D, 29G, 10Q, 8P, 6P, 20F, 2M, 3B, 3L, 3S, 8M, 8R, 8S, 9C, 9L, 12M, 13L, 13S, 14S, 14R, 24C, 22L, 24M, 29C	3Q, 12L, 18M, 19B, 21I	29F, 12G	22G, 21E
Total: 32 (78%)	**Total: 5 (12%)**	**Total: 2 (5%)**	**Total: 2(5%)**

Table 3.9 Arrangement of samples with margin gap during Control 3

”Margin gap” during Control 4			
Good	**Small gap**	**Clear gap**	**Bad**
13D, 32F, 22G, 2D, 24D, 32D, 27F, 29G, 29D, 29G, 10Q, 8P, 6P, 14Q, 20F, 2M, 3B, 3L, 3S, 8M, 8R, 8S, 9C, 9L, 12L, 12M, 13L, 14S, 21I, 24C, 22L, 24M, 29C	32G, 3Q, 21E, 12G, 13S, 14R, 18M, 19B	29F	8Q
Total: 33 (76.5%)	**Total: 8 (18.5%)**	**Total: 1 (2.5%)**	**Total: 1 (2.5%)**

Table 3.10 Arrangement of samples with margin gap during Control 4

One of the conclusions after this detailed data analysis is that despite the fact that the average values of margin deficiency and margin gap for samples used in experiments were very good, in some cases, such as in samples 24D and 2D, a margin deficiency of more than 20% and respectively 60% was observed in years 2 and 4 respectively (see Table 3.1). The same correlation exists for the margin gap parameter in analyzed samples (see Table 3.2) after 6 months and in years 1, 2, and 4, where for some samples the percentage of margin gap, e.g., more than 20%, was significantly higher than the average. This may require further investigation for future work, e.g., under which circumstances those fillings were made, by whom and for which patients. The distribution of samples in Tables 3.3 – 3.10 confirms, however, that the number of such samples with bad margin deficiency percentage and bad margin gap percentage was relatively minor.

3.6. Statistical test

Analyze-it Statistics Software (www.analyze-it.com) and Microsoft Office Excel 2007 were used for the statistical test. The statistical test of sample margin data from SEM at Controls 1, 2, 3 and 4 was performed in Analyze-it Statistics Software using Mann-Whitney U test (test for differences in mean and variance) with a significance level of 5 percent (two-tailed). Two sample groups (randomly selected) were statistically analyzed:

- Group 1 (n_1 = 20 samples): 32G, 2M, 3B, 3L, 2D, 8M, 8R, 8S, 8Q, 9L, 27F, 12M, 21E, 13S, 29G, 14S, 8P, 19B, 21I and 22L
- Group 2 (n_2 = 20 samples): 20F, 13D, 32F, 22G, 3S, 3Q, 24D, 29F, 9C, 32D, 12L, 29G, 13L, 29D, 14R, 10Q, 18M, 6P, 12G and 14Q

Means for Perfect part in Groups 1 and 2 were:

- at Control 1: Group 1 = 97.29 % and Group 2 = 93.95 %;
- at Control 2: Group 1 = 95.94 % and Group 2 = 97.00 %;
- at Control 3: Group 1 = 95.13 % and Group 2 = 95.21 %;
- at Control 4: Group 1 = 90.96 % and Group 2 = 87.53 %.

The distributions in two groups differed insignificantly ($U_{obtained} > U_{critical}$) according to critical values for the Mann-Whitney U test ($U_{critical}$ = 127 for $n_1 = n_2 = 20$; significance level < 0.05 two-tailed) [33]:

- at Control 1: Mann–Whitney $U_{obtained}$ = 190;
- at Control 2: Mann–Whitney $U_{obtained}$ = 175;
- at Control 3: Mann–Whitney $U_{obtained}$ = 164;
- at Control 4: Mann–Whitney $U_{obtained}$ = 173.

4. Discussion

4.1. Problem statement

Resin composite materials have their stable place in dental usage since the 1970s. In the beginning they were materials of choice as substitution for silicate cement. As a result their main application was more or less restricted to class III, IV and V cavities. In the 1990s the application of composite fillings extended to posterior areas as well. The above-mentioned changes were also strictly connected with a growing demand for aesthetic restoration among patients and also with the fear of mercury in dental amalgam. There was however only minor amount of quicksilver detected in the human body [59] and so far no significant correlation was found and proved between quicksilver exposure and damages to health [60, 61]. Years of discussions nevertheless have led to significant enhancement of uncertainty among patients. We have to admit that the way to reduce cytotoxity of composite materials was also long. But this biocompatibility is of a paramount importance and any adverse reactions due to the leaching of components from these dental materials into the oral cavity environment is of clinical concern. That is why cytotoxity testing is nowadays an integral component of the biological evaluation of dental restorative materials and is an essential part of standard screening procedures [62]. Within years composite fillings gained in importance and were recognized for their positive aspects due to reduced wear of restoration (that had been achieved with reduced filler size) [63, 64] and improvement of handling of bonding systems.

There still remains however one important unsolved problem with composite therapy: polymerization shrinkage. Generally shrinkage can be described and understood as a densification or loss of volume [65]. In contrast to polymerization of resins in the air, within cavity this type of contraction does not occur freely [66]. The shrinkage forces internally generated in the material are partially transmitted to the tooth restoration adhesive interface, compromising the marginal integrity. As a result the restoration becomes more susceptible to microleakage and postoperative sensitivity [67]. Studies showed that polymerization shrinkage leads to enhancement of the gap between filling and tooth tissue that later on influences the possibility of micro-leakage and secondary

caries evaluation [68]. Marginal and interfacial integrity is nevertheless crucially important for the durability of a restoration. Investigations have shown that factors affecting resin based composite depth of curing are: curing source intensity and light exposure duration, filler size and content, interactions filler-matrix as well as shade and translucency of material. It has been also proven that the shrinkage stress of composite material can be eliminated by applying the material in layers which should be light cured separately [69, 70, 71, 72]. Further advantages of the layer technique are better color adjustment and avoidance of lacunas' inclusions [73]. Since the resin matrix is responsible for polymerization process, the usage of ormocer as the matrix in composites is considered as an alternative method in obtaining low shrinkage resins with improved clinical performance.

The aim of this four-year-long study was to investigate the quality of occlusal fillings made with Admira® ormocer material.

4.2. Discussion of materials and methods

In this in-vivo study originally 34 patients took part. Occlusal and occlusal –proximal fillings were made with Admira®. Fillings were supposed to be controlled regularly during four years in regular intervals of 6 months, 12 months, 2 years and 4 years.

The first problem that has to be taken into account is that not all of the patients attended the control appointments regularly. This led to large number of drop outs that reduced the amount of investigated casts to forty three. It has been proved however in many studies that even such a small number of casts in that kind of studies can deliver reliable results [74, 75, 76, 77].

In order to achieve casts for further evaluation in SEM, silicone impressions were taken. Later, resin epoxid casts were poured out. Due to the great forming properties of both materials it is possible to achieve a very exact surface of later evaluated casts [78, 79]. It is however very important to apply the mass carefully avoiding air blazes that can be

easily closed inside. Moreover it is of great importance to avoid any moisture on the restoration surface while taking the impression with the above-mentioned material. These disadvantages have consequences in establishing resin casts. Inaccuracies in impressions lead to arising of artifacts on investigated surface and are the second main reason for drop outs in this study (replicas could not be evaluated). The criteria of artifact, surplus and margin deficiency are definitely result of mistakes while developing resin casts or while elaborating and polishing them. That is why this work is not further investigating the aspect of artifact criteria, since it follows from the obvious failure.

Fillings were controlled at regular intervals. Based on resin casts (achieved from silicone impressions made while each control appointment) the whole occlusal margin of the filling was investigated with a scanning electron microscope (SEM). The quantitative analysis of the fillings margin in combination with replica casts technique has proved to be a reliable method of evaluating adhesive tooth restorations, there was unfortunately a high possibility of failure as well. This replica technique is especially useful after the chewing load, because the evaluation takes place out of the patients mouth and does not lead to the destruction of the filling itself (which is the case while using coloring penetration method, bacterial or electromechanical tests) and, moreover, there is no possibility to imitate the conditions of oral cavity in any existing in vitro studies [80]. On the other hand, however, it is not possible to evaluate the depth of existing gaps in restorations margins, which can be easily accomplished with the usage of a dye penetration test [81].

4.3. Discussion of results

Admira® with its specially developed adhesive delivered good results by and large. After four years of clinical observation more than 90 percent of the restoratives margins showed perfect adaptation. These results confirm other studies with this material, which was in most cases compared with either hybrid or nano-fill composites [82, 83, 84, 85, 86]. It can be concluded that there is no significant difference in failure between ormocers and hybrid composites. Studies that investigated Admira® separately and in

comparison with other ormocer materials proved that Admira® exhibited the lowest overall micro-leakage [87, 88, 89, 90]. It is very important to emphasize that this study shows long-term results from four years, in comparison to other studies, where only up to 3-year long clinical or in vitro deliverables were presented.

Good results of this study are most likely also correlating with low polymerization shrinkage, which the producer claims circulates about 1.97 Vol%. Besides it is worth reminding, that this study was carried out with Admira®Bond, which was not always the case in other studies. Admira®Bond is Primer-Adhesive based on aceton and should be applied in one layer. Aceton itself has an interesting property to eliminate water due to its volatility and this way ability to change the surface tension of water. This phenomenon has own consequences in applying, namely avoiding of drying of the dentine [91]. It has been also proven that with this so-called Wet-Bonding-Technique one can achieve up to 30% better adhesion to dentine [92]. This way Admira automatically places itself in a much better position than many other commercial composites.

There is still a very important drawback remaining in this study. It is namely proved that the adhesion of composite material shows clear differences in dentine and enamel. Enamel displays much better properties to bind with composites than dentine [93, 94, 95, 96]. This in vivo study is based upon the occlusal part of restorative margins and, therefore, there is no possibility to compare the properties of the material in other tooth tissue areas than enamel. It is important however to emphasize, that other studies have already been investigating characteristics of Admira® in II class cavities (even ones that were not surrounded completely with enamel) with very good results [82].

5. Summary

The most important aim of restorative therapy in dentistry is to achieve a restoration that remains dense from bacteria and this way from tooth pulp irritations as well. The decision which material the practitioner should chose still causes dilemmas. First of all the restoration should show perfect adaptation to the tooth tissue and still remain easy to handle and model for example approximate contacts. Patients almost always expect to get tooth colored restorations and, on the other hand, they do not want to abandon the dense of the filling.

The aim of this study was to evaluate the Admira filling material and its future in the area of restorative dentistry. Admira with the specially developed adhesive on the whole delivered good results. After four years of clinical observation more than 90 percent of the restoratives margins showed perfect adaptation.

Within these four years however one can observe interesting changes among the investigated criteria. First six months of loading resulted with very small percentage of margin gap (under 0.5%) and surplus, which remained after overlooking while finishing the filling. After twelve months only slight changes occur within margin gap parameter - it reaches the level of 0.52%. The mostly noticeable modification takes place within surplus. One can observe reduction of its percentage almost by half. Occlusal stress that is performed in the mouth while chewing leads to abrasion of the fillings surface and this way to elimination of previously existing surplus. After loading time of twenty-four months wear rate grew continuously resulting in reducing the surplus to only 0.16% and increasing the margin deficiency rate tenfold. The perfect margin rate stayed on more or less the same level. This is directly connected with the changes of surplus, which while reducing to above-mentioned level contributed to the stability of the first one. Additionally margin gap level enlarged to almost 0.9%, which almost doubles the result of the control after twelve months. The last control after forty-eight months showed clearly that changes that occurred within all parameters had an undeniable pattern. Wear rate of all the examined fillings lead to continuous reduction of surplus and after four years perfect margin as well. Constant grow within margin deficiency parameter shows how the surface of the filling suffered under pressure of chewing process as well as possible parafunctions like bruxism. Interestingly margin gap shows a very significant

and important transformation in the last control. Namely, not as expected it showed a slight reduction of 0.38%. Possible reason to explain this fact is that the filling's adaptation through the whole depth of the cavity may show irregularities. Margin gap within one of the layers does not imply its continuation through the whole filling depth.

It cannot be directly concluded that Admira delivers perfect replacement of amalgam, however it seems to be a promising alternative with encouraging results. One of the critical points still remains the dense of restorations in cement and dentine tissue, which unfortunately, this study was unable to answer.

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Appendix A (Information for patients)

Poliklinik für Zahnerhaltung und Parodontologie
der Julius-Maximilians-Universität Würzburg
Direktor: Prof. Dr. med. dent. Bernd Klaiber

Aufklärung und Einverständniserklärung

Die Poliklinik für Zahnerhaltung und Parodontologie wird bis maximal 4 (vier) ADMIRA-Füllungen für Sie kostenlos anfertigen.

Als Patient erklären Sie sich bereit, an den erforderlichen Nachuntersuchungen nach 6 Monaten sowie nach 1, 2, und 4 Jahren teilzunehmen. Die finanzielle Entschädigung beträgt nach 2 Jahren DM 50,- und nach 4 Jahren DM 100,-, sofern Sie an allen Nachkontrolluntersuchungen teilgenommen haben.

Als Patient sind Sie darüber informiert worden, daß als Voraussetzung für eine erfolgreiche Füllungstherapie Karies durch Bißflügelröntgenaufnahmen des linken und rechten Seitenzahnbereichs ausgeschlossen werden muß (vor der Behandlung und nach Fertigstellung der Füllungen). Sie sind mit der Anfertigung dieser Röntgenaufnahmen einverstanden, falls keine Aufnahmen dieser Bereiche vorliegen, die nicht älter als 6 Monate sind. Bei den Nachkontrolluntersuchungen werden Abformungen des Ober- und des Unterkiefers zur Überprüfung der Füllungen und zur Dokumentation der Situation vorgenommen. Über Voraussetzungen und Ablauf bei der Versorgung mit ADMIRA-Füllungen werden Sie von Ihrem behandelnden Zahnarzt nochmals aufgeklärt.

Sollten Sie sich nicht zur Teilnahme an der Studie entschließen, wird Sie der behandelnde Zahnarzt über alternative Versorgungsmöglichkeiten nach dem aktuellen wissenschaftlichen Stand der zahnmedizinischen Füllungstherapie aufklären.

Als Patient haben Sie auch nach Beginn der Behandlungsphase jederzeit das Recht, aus der Studie auszuscheiden. Dies schließt das Recht auf kostenlose Entfernung der bereits gelegten ADMIRA-Füllungen ein. Ein Anrecht auf eine kostenlose Weiterbehandlung haben Sie jedoch nur dann, wenn objektiv ein studienbedingter Schaden nachgewiesen werden kann.

Treten objektiv nachweisbare gesundheitliche Schäden durch das verwendete Füllungs- bzw. Bondingmaterial ein, so besteht Versicherungsschutz durch die Firma VOCO GmbH, D-27472 Cuxhaven (über: HDI Haftpflichtverband der Deutschen Industrie V.a.G., Postfach 11 15 25, 20415 Hamburg, Probanden-Versicherung Nr. 20-005012-0303-390).

Poliklinik für Zahnerhaltung und Parodontologie

der Julius-Maximilians-Universität Würzburg

Direktor: Prof. Dr. med. dent. Bernd Klaiber

Merkblatt für Patienten zur Versorgung mit ADMIRA / ADMIRA BOND

Das Medizinprodukt ADMIRA ist ein lichthärtendes zahnfarbenes Füllungsmaterial für den Seitenzahnbereich.. Die werkstoffkundlichen Eigenschaften sind mit denen der bekannten Seitenzahnkomposite vergleichbar. Neu ist ein deutlich reduziertes Schrumpfungsverhalten während der Polymerisation, dadurch bedingt eine geringere Neigung zur Randspaltbildung und somit eine bessere Eignung zur Versorgung auch größerer Defekte im Seitenzahnbereich.

Im Rahmen dieser klinischen Studie sollen Erfahrungen mit ADMIRA und dem damit verbundenen Adhäsivsystem ADMIRA BOND für die Sekundärversorgung (Erneuerung defekter Amalgamfüllungen) gesammelt werden. Diese Langzeiterfahrungen werden durch regelmäßige Überprüfung der gelegten Füllungen im Rahmen der Studie ermittelt und dokumentiert.

Als Patient erklären Sie sich bereit, an den erforderlichen Nachuntersuchungen nach 6 Monaten sowie nach 1, 2 und 4 Jahren teilzunehmen. Die finanzielle Entschädigung beträgt nach 2 Jahren DM 50,- , nach 4 Jahren DM 100,- für die Teilnahme an der Nachuntersuchung, sofern Sie an allen Untersuchungen teilgenommen haben.

Als Patient sind Sie weiterhin darüber informiert worden, daß als Voraussetzung für eine erfolgreiche Füllungstherapie Karies durch Bißflügelröntgenaufnahmen des linken und rechten Seitenzahnbereichs ausgeschlossen werden muß (vor der Behandlung und nach Fertigstellung der Füllungen). Mit der Anfertigung dieser Röntgenaufnahmen sind Sie einverstanden, falls nicht bereits entsprechende Aufnahmen dieser Bereiche vorliegen, die nicht älter als 6 Monate sind. Bei den Nachkontrollen werden Abformungen des Ober- und des Unterkiefers zur Überprüfung der Füllungen und zur Dokumentation der Situation vorgenommen. Über Voraussetzungen und Ablauf bei der Versorgung mit ADMIRA-Füllungen werden Sie von ihrem behandelnden Zahnarzt nochmals aufgeklärt. Ihr Einverständnis mit dieser Vorgehensweise erklären Sie bitte durch Ihre Unterschrift auf dem Formblatt ***" Aufklärung und Einverständniserklärung ".***

Patient: .....

Geb.-Datum: .....

Straße: .....

PLZ, Wohnort: .....

Telefon: .....

Behandelnder Zahnarzt: .....

Würzburg, den .....

....

(Unterschrift des Patienten) (Unterschrift des behandelnden Zahnarztes)

Appendix B (Documentation of restoration)

ADMIRA-STUDIE

Patient:..... Zahn:..... Rest.Datum:..... Behandler:.....

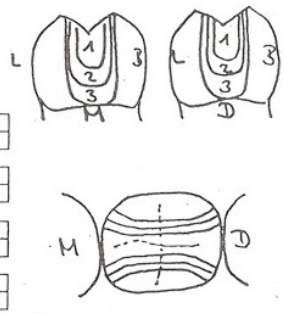
Diagnose

Primärversorgung:
O mesial O distal
Ersatzversorgung von:
O AM, O KOM, O GO-IN
O ADH-IN

DMFT:

	17	16	15	14	13	12	11
	47	46	45	44	43	42	41
	21	22	23	24	25	26	27
	31	32	33	34	35	36	37

Füllungsextension



- mesial:
S. approx: O Nr. 2, O Nr. 3, O Nr. 4, O >Nr. 4
zervikale Position
O Schmelz ≥ 1 mm
O Schmelz ≥ 0,5 mm
O Dentin
Besonderes: .....

- distal:
S.approx : O Nr. 2, O Nr. 3, O Nr. 4, O >Nr. 4
zervikale Position
O Schmelz ≥ 1 mm
O Schmelz ≥ 0,5 mm
O Dentin

Höckerüberdeckung:
O mes. b. O dis. b. O tragend
O mes. l. O dis. l. O tragend
Besonderes: .....

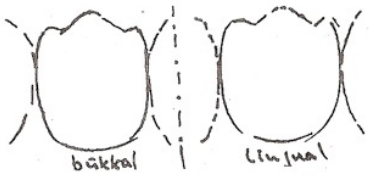
Klinische Beurteilung

Untersuchungsdatum:	Ausgang	6 Mte.	12 Mte.	24 Mte.	48 Mte.
Farbe: Datum:					
A kein Unterschied:	A☐	A☐	A☐	A☐	A☐
B geringer (nur im Spiegel sichtbarer) Unterschied:	B☐	B☐	B☐	B☐	B☐
C starker (ohne Spiegel sichtbarer) Unterschied:	C☐	C☐	C☐	C☐	C☐
Randverfärbung:					
A ohne:	A☐	A☐	A☐	A☐	A☐
B oberflächlich:	B☐	B☐	B☐	B☐	B☐
C in die Tiefe reichend:	C☐	C☐	C☐	C☐	C☐
Randschluß:					
A Rand intakt:	A☐	A☐	A☐	A☐	A☐
B Randspalt tastbar:	B☐	B☐	B☐	B☐	B☐
C Randspalt sichtbar:	C☐	C☐	C☐	C☐	C☐
D Fraktur/Verlust d. Füllung:	D☐	D☐	D☐	D☐	D☐
Oberflächentextur:					
A glatt:	A☐	A☐	A☐	A☐	A☐
B einzelne Rauhigkeiten:	B☐	B☐	B☐	B☐	B☐
C starke Rauhigkeiten	C☐	C☐	C☐	C☐	C☐
Anatomische Form:					
A keine Randstufe sondierbar:	A☐	A☐	A☐	A☐	A☐
B Stufenbildung tastbar:	B☐	B☐	B☐	B☐	B☐
C Stufenbildung sichtbar:	C☐	C☐	C☐	C☐	C☐
D Freiegung von UF/ Dentin:	D☐	D☐	D☐	D☐	D☐
Sensibilität:					
A sensibel u. beschwerdefrei:	A ☐	A ☐	A ☐	A ☐	A ☐
B1 empfindlich auf Kälte:	B1 ☐	B1 ☐	B1 ☐	B1 ☐	B1 ☐
B2 empfindlich auf Belastung:	B2 ☐	B2 ☐	B2 ☐	B2 ☐	B2 ☐
C Zahn desensibel:	C ☐	C ☐	C ☐	C ☐	C ☐
Approximalkontakt:					
A physiologisch (ML 1)	A☐	A☐	A☐	A☐	A☐
B leicht offen (ML 2)	B☐	B☐	B☐	B☐	B☐
C deutlich geöffnet (ML 3)	C☐	C☐	C☐	C☐	C☐
Bissflügel-Röntgen	☐	☐	☐	☐	☐

Untersuchungsdatum:	Ausgang	6 Mte.	12 Mte.	24 Mte.	48 Mte.
Datum:					

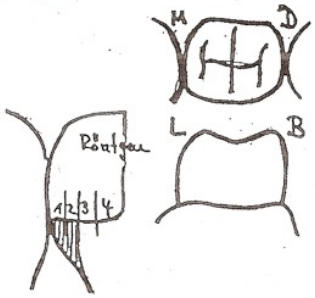
Risse (Diaphanoskopie):

A keine	A ☐	A ☐	A ☐	A ☐	A ☐
B sichtbar	B ☐	B ☐	B ☐	B ☐	B ☐
C1 tastbar	C1 ☐	C1 ☐	C1 ☐	C1 ☐	C1 ☐
C2 Verfärbung	C2 ☐	C2 ☐	C2 ☐	C2 ☐	C2 ☐



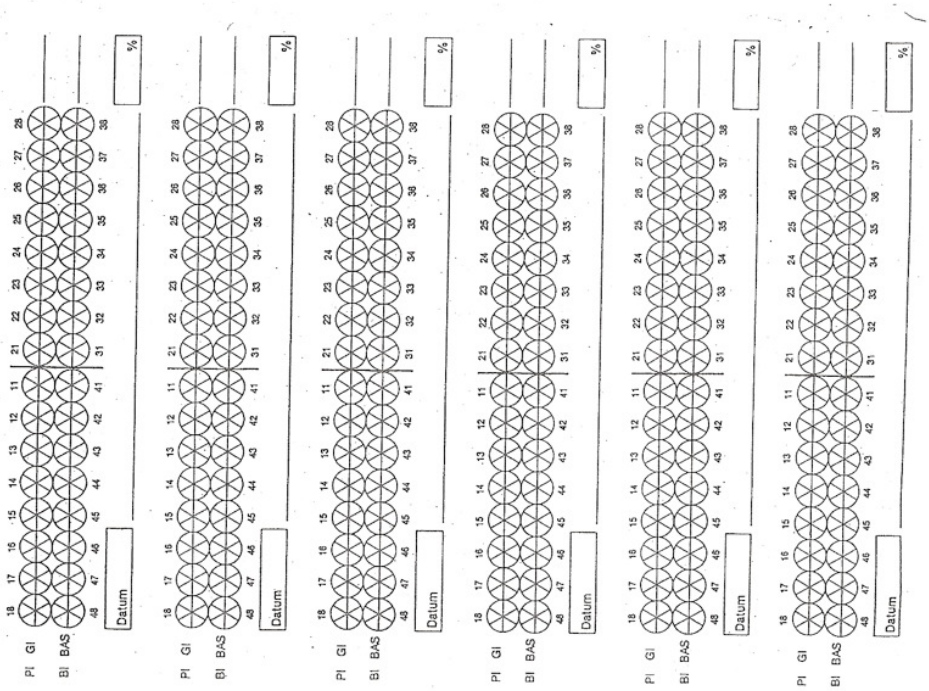
Mißerfolg: **Datum:** .....

O Fraktur der Restauration, wo?.....
O Randkaries, wo? .....
O Sekundärkaries, radiologisch;
Schmelz ...1...../.....2.....
Dentin .....3...../.....4.....



Maßnahme:

O Vollständiges Erneuern gegen .....
O Partielles Erneuern gegen .....
O Lokale Reparatur .....



Appendix C

19(49) In-vivo-Untersuchung von Seitenzahnrestaurationen mit dem Ormocer Admira in Klasse-II-Kavitäten

W. Denner[1], E. Orth[1], B. Klaiber[1] und B. Hugo[2]

[1]Universität Würzburg, Poliklinik für Zahnerhaltung & Parodontologie

[2]Universität Würzburg, Poliklinik für Kieferorthopädie

Einleitung

Die 1998 in die Zahnheilkunde eingeführten Ormocere („organically modified ceramics") weisen im Vergleich zu anderen modernen Feinhybridkompositen bei sonst vergleichbaren physikalischen Materialeigenschaften durch ihre partielle anorganische Matrixstruktur eine deutlich verringerte initiale Monomerfreisetzung[1] auf.

Im Rahmen einer In-vivo-Studie sollten das Langzeitverhalten und die Qualität von Klasse-II-Kompositrestaurationen mit dem auf Ormocer basierenden Füllungsmaterial Admira (Voco) untersucht werden.

Material und Methoden

Bei 34 Patienten wurden 95 mittelgroße bis große direkte Klasse-II-Kompositrestaurationen als Sekundärversorgung insuffizienter Amalgam- und Kompositfüllungen gelegt. Die Applikation erfolgte unter Kofferdam bei Anwendung der „total etch/total bonding"-Technik mit dem Admira Bond Adhäsivsystems. Anschließend wurde die Kavität mit Admira-Flow in Lining-Technik benetzt und schichtweise mit dem hochviskösen Ormocer restauriert. Die klinische Reevaluation erfolgte nach der Restauration und nach einer Tragedauer von 6, 12 und 24 Monaten anhand der modifizierten USPHS-Kriterien, den sog. Ryge-Kriterien[2,3], die klinisch die Ergebnisse der Gesamtrestauration bewerten. Beurteilt wurden Farbanpassung, Randverfärbung, Randschluss, Oberflächentextur, anatomische Form, Sensibilität, Approximalkontakt und Risse im Schmelz. Die Bewertung mit A/B kennzeichnen sehr gut bis gute (A) und klinisch noch akzeptable Ergebnisse (B), wohingegen C/D klinisch inakzeptable Restaurationen mit baldigem (C) bzw. sofortigem (D) Austauschzwang markieren.

Ergebnisse

Nach 6 Monaten konnten 91 und nach 12 Monaten 85 Restaurationen nachuntersucht werden. Elf Restaurationen konnten nicht weiter verfolgt werden. Nach einer Liegedauer von 24 Monaten wurden bisher 58 Admira-Restaurationen reevaluiert. Insgesamt drei Misserfolge (USPHS-Kriterien C oder D) - eine irreversible Pulpitis, eine Füllungsteilfraktur und ein insuffizient gewordener Approximalkontakt - machten eine weitere Behandlung erforderlich. Zwei konnten durch Reparatur behoben werden. Der verbleibende Anteil der untersuchten Restaurationen wurde mit der Bewertung A oder B als klinisch erfolgreich eingestuft.

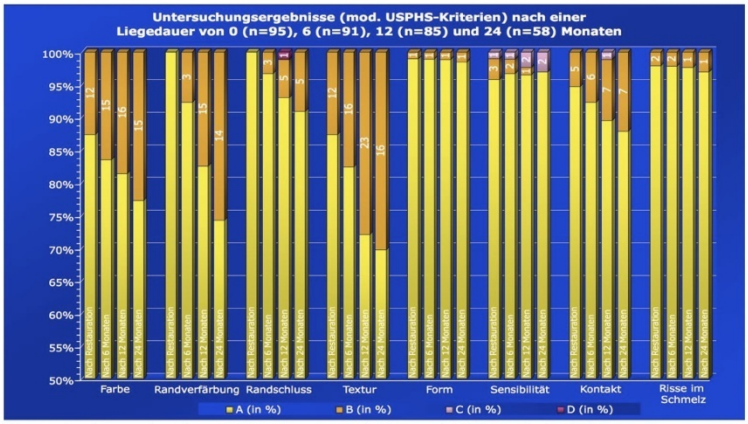


Abb. 1: Resultate der untersuchten Admira Restaurationen zu allen Reevaluationszeitpunkten in Prozent. Absolutwerte für B-, C- und D-Kriterien.

Insgesamt wurde eine geringe Komplikationsrate festgestellt. Die Resultate aller Untersuchungszeitpunkte sind im Balkendiagramm (Abbildung 1) als vergleichende Übersicht dargestellt.

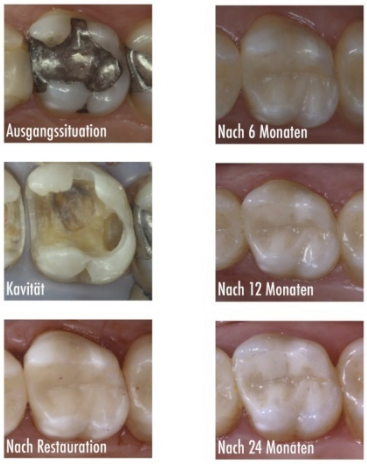


Abb. 2 bis 7: Photodokumentation einer klinisch erfolgreichen Admira Restauration zu allen Untersuchungszeitpunkten

Diskussion

Der hohe Anteil der klinisch erfolgreichen Restaurationen zeigt sich bei allen Reevaluationskriterien. Ein ähnliches Resultat wurde auch für den Einsatz von Admira in Klasse-V-Kavitäten gefunden[4]. Auffällig ist jedoch die Verschiebung von A- zu B-Kriterien im Verlauf der Nachuntersuchungen bei den Bewertungspunkten Oberflächentextur und Randverfärbung. Dieser Trend zeigt sich in deutlich schwächerem Ausmaß auch beim Approximalkontakt und bei der Randschlussqualität. Letzterer zeigt mit 91,4% A- und 8,6% B-Wertungen nach 24 Monaten, dass der Einsatz des Ormocers Admira im Seitenzahnbereich auch bei größeren direkten Restaurationen klinisch gerechtfertigt ist.

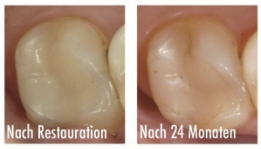


Abb. 8 und 9: Oberflächliche Randverfärbung nach 24 Monaten sind klinisch noch akzeptabel und erhielten eine B-Wertung.

Literatur

1 Hofmann, N., Renner, J., Hugo, B., Klaiber, B.: Elution of leachable components from resin composites after plasma arc vs standard or soft-start halogen light irradiation. J Dent 30(5-6), 223-32 (2002).
2 Ryge, G., Snyder, M.: Evaluating the clinical quality of restorations. J Am Dent Assoc 87(2), 369-77 (1973).
3 Ryge, G.: Clinical criteria. Int Dent J 30(4), 347-58 (1980).
4 Hennig, A.C., Helbig, E.B., Haufe, E., Richter, G., Klimm, H.W.: [Restoration of Class V cavities with the Ormocer-based filling system Admira]. Schweiz Monatsschr Zahnmed 114(2), 104-14 (2004).

In-vivo-Untersuchung von Seitenzahnrestaurationen mit dem Ormocer® Admira® in Klasse-II-Kavitäten

070

W. Denner[1], E. Orth[2], F. Eichelsbacher[2], B. Klaiber[2]
[1]Praxis Dr. C. Lex & Dr. W. Denner, Kressengartenstrasse 2, 90402 Nürnberg
[2]Universität Würzburg, Poliklinik für Zahnerhaltung & Parodontologie

Einleitung

Die 1998 in die Zahnheilkunde eingeführten Ormocere („organically modified ceramics") weisen im Vergleich zu anderen modernen Feinhybridkompositen bei sonst vergleichbaren physikalischen Materialeigenschaften durch ihre partielle anorganische Matrixstruktur eine deutlich verringerte initiale Monomerfreisetzung[1] auf.

Im Rahmen einer In-vivo-Studie sollten das Langzeitverhalten und die Qualität von Klasse-II-Kompositrestaurationen mit dem auf Ormocer® basierenden Füllungsmaterial Admira®(Voco) untersucht werden.

Material und Methoden

Bei 34 Patienten wurden 95 mittelgroße bis große direkte Klasse-II-Kompositrestaurationen als Sekundärversorgung insuffizienter Amalgam- und Kompositfüllungen gelegt. Die Applikation erfolgte unter Kofferdam bei Anwendung der „total etch/total bonding"-Technik mit dem Admira®Bond Adhäsivsystems. Anschließend wurde die Kavität mit Admira-Flow in Lining-Technik benetzt und schichtweise mit dem hochviskösen Komposit restauriert. Die klinische Reevaluation erfolgte nach der Restauration und nach einer Tragedauer von 6, 12, 24 und 48 Monaten anhand der modifizierten USPHS-Kriterien, den sog. Ryge-Kriterien[2,3], die klinisch die Ergebnisse der Gesamtrestauration bewerten. Beurteilt wurden Farbanpassung, Randverfärbung, Randschluss, Oberflächentextur, anatomische Form, Sensibilität, Approximalkontakt und Risse im Schmelz. Die Bewertung mit A/B kennzeichnen sehr gut bis gute (A) und klinisch noch akzeptable Ergebnisse (B), wohingegen C/D klinisch inakzeptable Restaurationen mit baldigem (C) bzw. sofortigem (D) Austauschzwang markieren.

Ergebnisse

Nach einer Liegedauer von 6 Monaten konnten 91, nach 12 Monaten 85, nach 24 Monaten 82 und nach 48 Monaten 64 Admira-Restaurationen reevaluiert werden. 31 Restaurationen konnten nicht weiter verfolgt werden. Insgesamt vier Misserfolge (USPHS-Kriterien C oder D) - eine irreversible Pulpitis, ein verfärbter Überschuss, eine Füllungsteilfraktur und ein insuffizient gewordener Approximalkontakt - machten eine weitere Behandlung erforderlich, wobei drei durch Reparatur behoben wurden. Der verbleibende Anteil der untersuchten Restaurationen wurde mit der Bewertung A oder B als klinisch erfolgreich eingestuft.

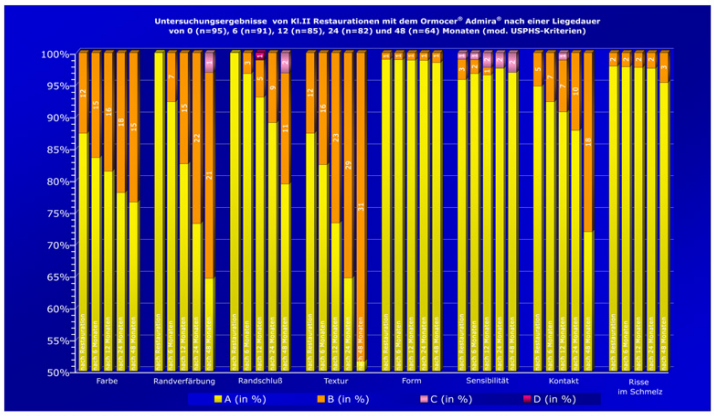


Abb. 1: Resultate der untersuchten Admira® Restauration zu allen Reevaluationszeitpunkten in Prozent- und Absolutwerten

Insgesamt wurde eine geringe Komplikationsrate festgestellt. Die Resultate aller Untersuchungszeitpunkte sind im Balkendiagramm (Abbildung 1) als vergleichende Übersicht dargestellt.

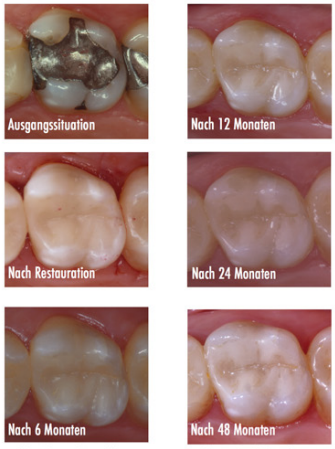


Abb. 2 bis 7: Photodokumentation einer klinisch erfolgreichen Admira® Restauration zu allen Untersuchungszeitpunkten

Diskussion

Der hohe Anteil der klinisch erfolgreichen Restaurationen zeigt sich bei allen Reevaluationskriterien. Ein ähnliches Resultat wurde auch für den Einsatz von Admira® in Klasse-V-Kavitäten gefunden[4]. Auffällig ist jedoch die Verschiebung von A- zu B-Kriterien im Verlauf der Reevaluationen besonders nach 24 und nach 48 Monaten bei den Bewertungspunkten Oberflächentextur, Approximalkontakt, Randverfärbung und Randschlussqualität. Letzterer zeigt jedoch mit 79,4% A- und 17,5% B-Wertungen nach 48 Monaten, dass der Einsatz des Ormocers Admira® im Seitenzahnbereich auch bei größeren direkten Restaurationen klinisch gerechtfertigt ist.

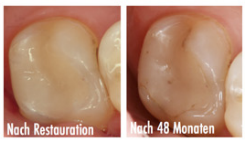


Abb. 8 und 9: Restauration mit oberflächlicher Randverfärbung nach 48 Monaten erhielt eine B-Wertung.

Literatur

1 Hofmann, N., Renner, J., Hugo, B., Klaiber, B.: Elution of leachable components from resin composites after plasma arc vs standard or soft-start halogen light irradiation. J Dent 30(5-6), 223-32 (2002).
2 Ryge, G., Snyder, M.: Evaluating the clinical quality of restorations. J Am Dent Assoc 87(2), 369-77 (1973).
3 Ryge, G.: Clinical criteria. Int Dent J 30(4), 347-58 (1980).
4 Hennig, A.C., Helbig, E.B., Haufe, E., Richter, G., Klimm, H.W.: [Restoration of Class V cavities with the Ormocer-based filling system Admira]. Schweiz Monatsschr Zahnmed 114(2), 104-14 (2004).

Appendix D (Clinical case presentation)

A few pictures of clinical the cases are presented below. Unfortunately, not every restoration was photo-documented during the control appointments and, therefore this is only partial representation of the restorations.

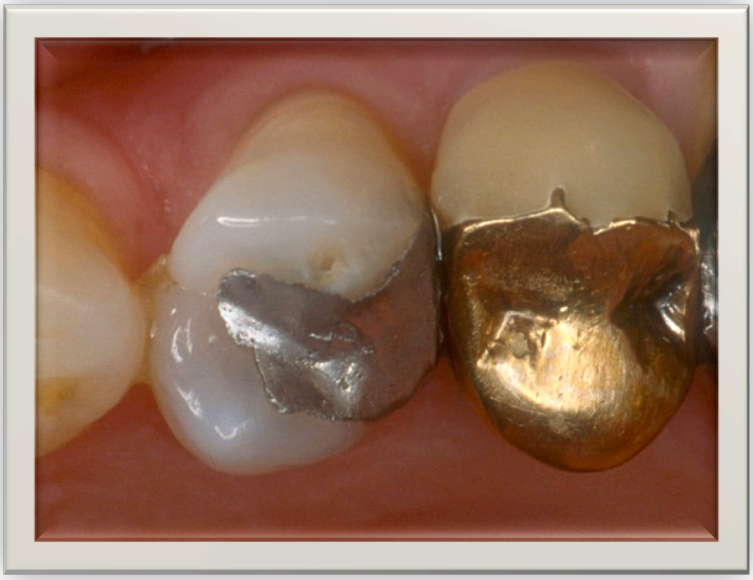


Fig. C.1.1 Sample 21E - Tooth 14 primary situation

Fig.C. 1.2 Sample 21E - Tooth 14 after preparation and rubber dam application

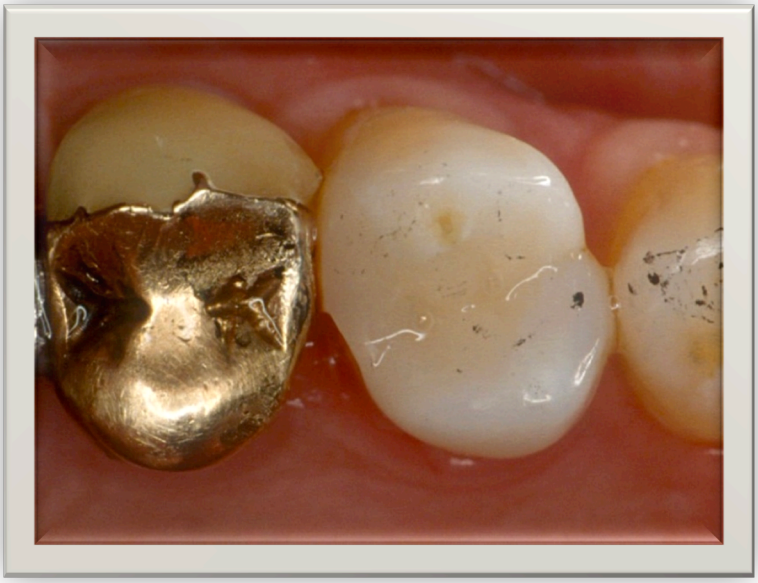


Fig.C.1.3 Sample 21E - Tooth 14 after finishing of the restoration

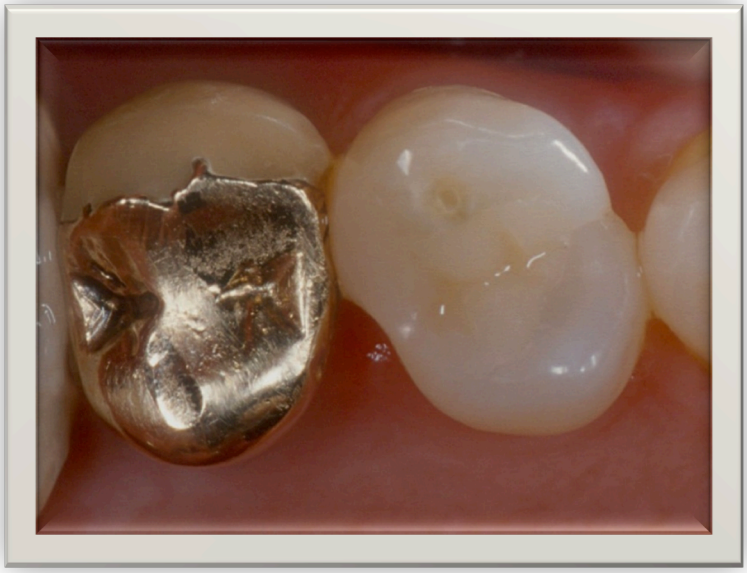


Fig.C.1.4 Sample 21E - Tooth 14 at first control appointment

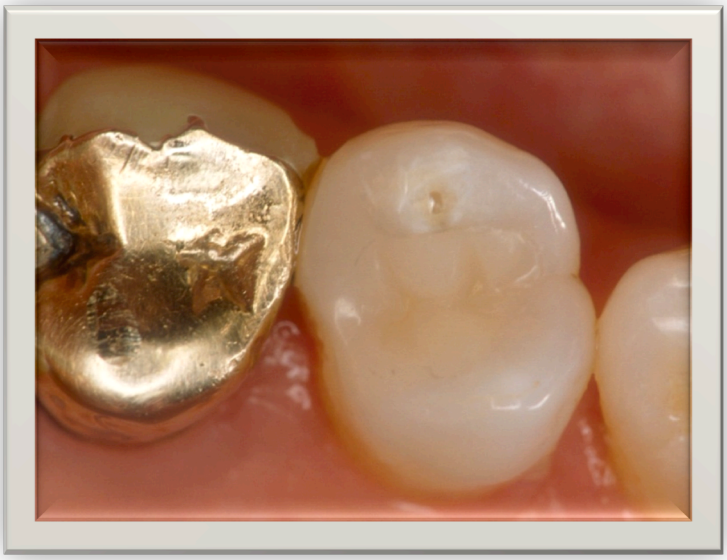


Fig. C.1.5 Sample 21E - Tooth 14 at second control appointment

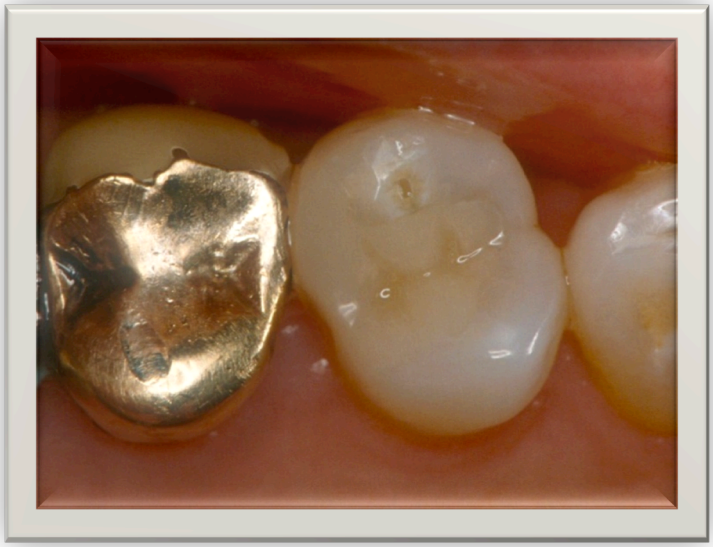


Fig.C.1.6 Sample 21E - Tooth 14 at third control appointment

As already mentioned in chapter Results, this sample did not show perfect quality of margins already at third control. Having a look at restoration during clinical investigation, it does not provide clear information about margin quality.

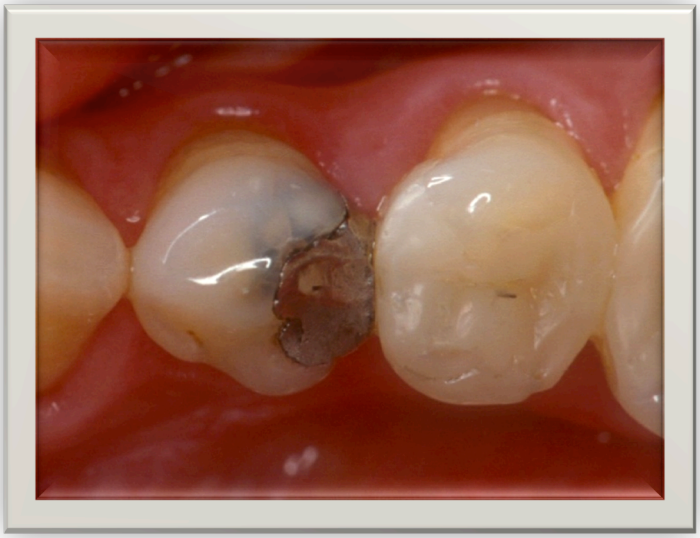


Fig.C.2.1 Primary situation of Sample 8P

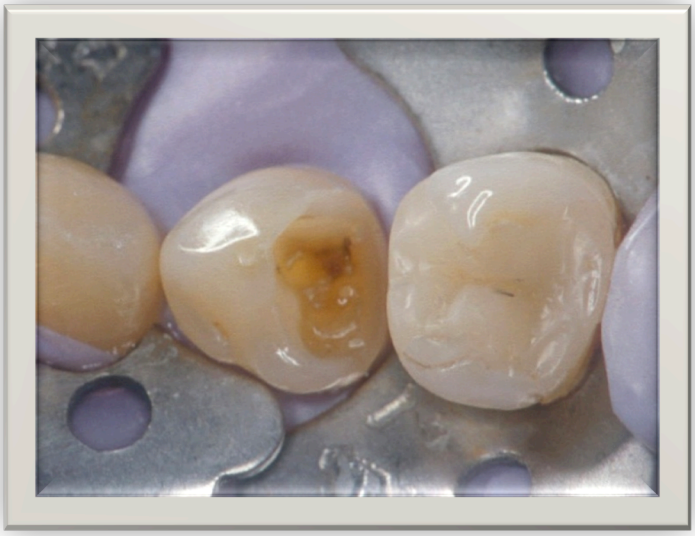


Fig.C.2.2 Preparation after removal of old amalgam restoration in Sample 8P

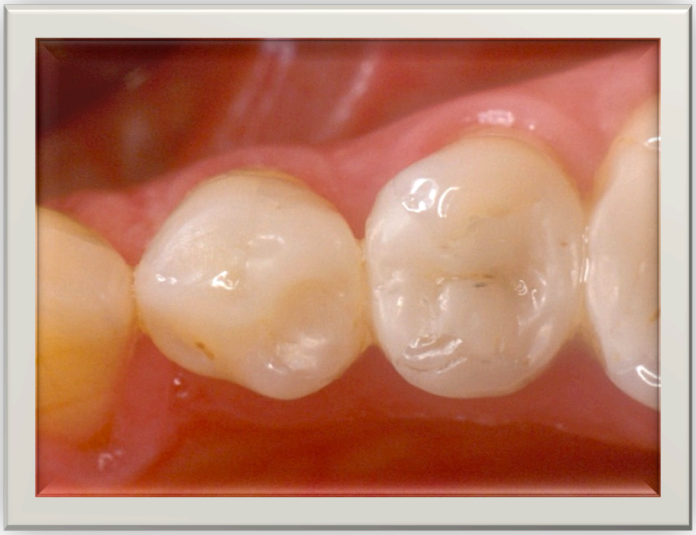


Fig.C.2.3 Sample 8P - Restoration at first control appointment

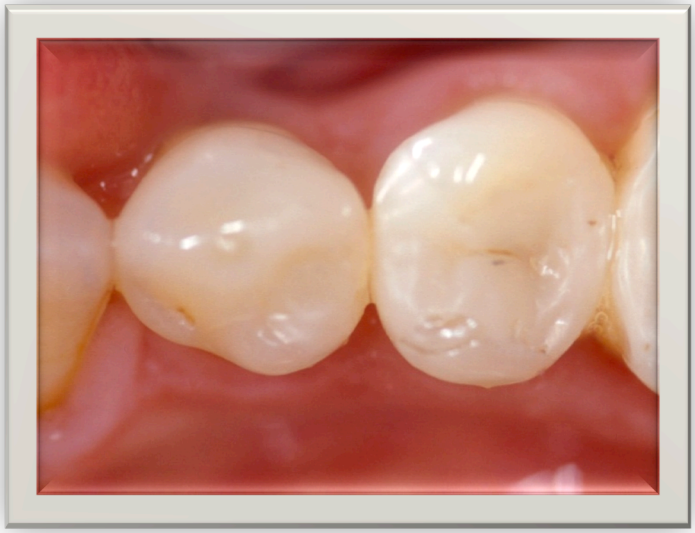


Fig.C.2.4 Sample 8P - Restoration at second control appointment

Sample 8P showed perfect margin quality during the whole process of evaluation. The above-presented photos provide useful information about lack of possible discolorations on the whole margin surface. It has been reported that cavomarginal discolorated restorations tend to fail 8.7 times more frequently than the ones with sound margins [65].

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