Cementation in adhesive dentistry: the weakest link

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CHAPTER 7

Clinical success and survival of indirect resin composite crowns: results of a three-year prospective study

Abstract

Objectives: The aim of this study was to test the new resin composite “NECO” as a material for indirect restorations clinically.

Methods: Forty-five patients were selected, of which 12 men and 33 women, with a mean age of 53. A total of 91 post-canine indirect resin composite NECO (Heraeus Kulzer, GmbH) restorations were placed, of which 86 full crowns and 5 onlays. Restorations were cemented with either resin cement (2bond2) or resin modified glass ionomer cement (Fuji Plus). The restorations were evaluated 1-2 weeks (baseline), 6 months, 1, 2, and 3 years after placement. At these recalls, success and survival data of the abutment teeth were documented. Survival was defined as the restoration being in situ, and success as the restoration in situ without complications.

Results: After 3 years in service, the restorations showed success and survival rates of 84.8 and 91.6%, respectively. Cementation with Fuji Plus showed a trend (P = 0.054) towards higher success (93.1%) and survival (100%) rates compared to cementation with 2bond2 cement which showed success and survival rates of 81.4 and 87.9% respectively. Restorations on vital teeth resulted in success and survival rates of 86.8 and 95.3% respectively, while restorations on endodontically treated teeth showed success and survival rates of 82.6 and 87.5%. This difference was not statistically significant (P = 0.296).

Significance: Three-year success and survival rates of NECO restorations were 84.8 and 91.6%, respectively. The design of the preparation and restoration should take the material properties into account in order to enhance the clinical performance.
Clinical success and survival of indirect resin composite crowns

Introduction

Ceramics with a framework of zirconium oxide have become the standard for esthetic indirect restorative materials. These full-ceramic systems have high fracture strength and high survival rates clinically. The short- and medium-term results are promising, although further clinical studies and preferably RCT’s are needed to obtain long-term clinical results [1].

There are, however, other possibilities for esthetic tooth-colored indirect restorations. Resin composites have been widely used for decades as tooth-colored direct restorative materials. These restorations are clinically well accepted, and clinical studies show satisfactory results [2], even for more extensive restorations [3]. Numerous clinical studies concerning resin composites as indirect restorative materials for inlays and onlays have been carried out, and show promising results [2, 4]. Concerning full crowns, several clinical studies have been performed. Artglass crowns cemented with 2bond2 cement and solid bond showed a three-year survival of 96.0% [5]. The most common mode of failure was (partial) fracture of the crowns. The five year survival for the same type of crowns dropped to 88.5% [6].

Composites crowns have a number of advantages over zirconium oxide based ceramic crowns. With ceramics, a deep chamfer preparation with a depth of 1-1.5 mm is recommended [7], compared to a 0.5 mm chamfer for composite restorations [8]. This less invasive tooth preparation leaves more natural tooth tissue intact, which will mostly result in a greater ferrule height and residual wall thickness. This is likely to be beneficial to the success of the restoration [9]. Composites do not inflict the high levels of abrasion on antagonizing teeth [10] that ceramics are known to do [11, 12]. Chipping is a major problem with ceramic restorations [1], and repairs are usually carried out with resin composite materials. Composite materials fit well into a “dynamic restoration concept”, in which repairs and alterations to the restoration are easily carried out. The restoration can be repaired with the same material as from which it is made, in case of for instance chipping, or repairing an endodontic access opening. Furthermore, adhesive resin cements are chemically compatible with composite crowns. In contrast, bonding of zirconium oxide frameworks to adhesive resin cements is still a problem [13, 14], and damaging zirconium restorations with an endodontic opening leads to a significant loss of strength [15].
Indirect resin composite restorations may therefore be a viable alternative to ceramic restorations. A new resin composite, NECO (Heraeus Kulzer, GmbH, Hanau, Germany), was developed for the manufacturing of all types of indirect dental restorations as an alternative to other indirect restorative materials. The material is designed as an improved version of Artglass, a resin composite material previously introduced in the dental market for the same indication [5].

In this study, two different cements are used. The first one, 2bond2 (Heraeus Kulzer, GmbH, Hanau, Germany) is a dual-cured adhesive resin cement. This cement has been clinically tested for the cementation of resin-based restorations with satisfactory results [5]. The other cement is a resin-modified glass-ionomer cement, Fuji Plus (GC Corporation, Tokyo, Japan), which has not been tested clinically for the cementation of resin-based crown restorations. Clinical results regarding ceramic inlays however, are promising [17], and in vitro results regarding fracture resistance of fiber-reinforced composite crowns show similar results compared to a resin cement [18]. The use of a resin-modified glass-ionomer cement is less technique-sensitive compared to the use of a multiple-step adhesive cementation system, and might therefore be more appealing to the clinician.

The aim of this three-year study was to determine clinical success and survival rates of NECO used as an indirect restorative material for the manufacturing of posterior full and partial single-unit indirect restorations, without any fiber-reinforced or metal substructure or framework. Furthermore, the cementation with two different cements, 2bond2 and Fuji Plus, was evaluated.

**Materials and methods**

After obtaining approval of the Dutch medical ethical committee, 45 patients of the department clinic of the Department of Dental Materials Science of the Academic Center for Dentistry in Amsterdam (ACTA) were selected. Possible candidates, that met the inclusion and exclusion criteria as summarized in Table 7.1, were asked to cooperate in this study. Restorations were made in the case of a large direct restoration which was an indication for an indirect restoration. After obtaining an informed consent from the patients, the abutment teeth were prepared by one dentist. Each patient received a maximum of three restorations. The restorations were to be placed
Clinical success and survival of indirect resin composite crowns

with either a resin composite based cement (2bond2, Heraeus Kulzer GmbH) or a resin modified glass ionomer cement (Fuji Plus, GC Corporation, Tokyo, Japan).

Table 7.1 Inclusion and exclusion criteria for patients to participate in the NECO study.

<table>
<thead>
<tr>
<th>Inclusion criteria:</th>
</tr>
</thead>
<tbody>
<tr>
<td>The patient is able and willing to maintain the patient-dentist relation during the entire study period</td>
</tr>
<tr>
<td>The patient is older than 18 years</td>
</tr>
<tr>
<td>The patient is willing to undergo the two X-ray evaluations at baseline and after 36 months</td>
</tr>
<tr>
<td>The patient has signed the informed consent form</td>
</tr>
<tr>
<td>The patient objectively needs a full or partial crown restoration</td>
</tr>
<tr>
<td>A minimum of 50% of core dentin should be remaining after preparation of the abutment tooth</td>
</tr>
<tr>
<td>Non-vital tooth can be incorporated in the study under the condition that a core build-up can be made to which an adhesive bond of the restoration is possible.</td>
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<table>
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<tr>
<th>Exclusion criteria:</th>
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<tbody>
<tr>
<td>A known history of resin allergy</td>
</tr>
<tr>
<td>Pregnancy at the beginning of the study</td>
</tr>
<tr>
<td>Use of drugs that may interfere with the oral environment</td>
</tr>
<tr>
<td>Systemic diseases or malignancies at the beginning of the study</td>
</tr>
<tr>
<td>Sufficient drying or the specified application technique is not possible</td>
</tr>
<tr>
<td>Minimal layer thickness of restoration cannot be achieved</td>
</tr>
<tr>
<td>Abnormal stresses are foreseeable in the region of the occlusal surface of the molars, premolars and canines, as a result of—for example—bruxism or other parafunctional activities</td>
</tr>
</tbody>
</table>

The shade of the teeth was determined under daylight conditions using a Vita Lumin Vacuum shade guide. In the case that an abutment tooth contained old non-adhesively placed restorations, the restorations were replaced with a resin composite restoration (Filtek Z250, 3M ESPE, Seefeld, Germany), bonded with a three-step adhesive system (Scotchbond MP, 3M ESPE, Seefeld, Germany). Care was taken that the abutment teeth were completely caries-free and adequately restored according to the treatment protocols as were in force at ACTA to receive the indirect restoration. The teeth were prepared according to the preparation criteria as summarized in Table 7.2. Full-arch impressions were taken using a polyvinylsiloxane impression material.
(Flexitime light-body, heavy body, and putty, Heraeus Kulzer GmbH, Hanau, Germany). The impressions of the opposing jaw were taken with an alginate impression material. Bite registrations were carried out using Memosil (Heraeus Kulzer GmbH, Hanau, Germany). Temporary crown restorations (PreVISION CB, Heraeus Kulzer GmbH, Hanau, Germany) made according to the crown duplication technique were placed with an non-eugenol temporary cement (PreVISION CEM, Heraeus Kulzer GmbH, Hanau, Germany). Anesthesia was applied when applicable.

Table 7.2 Preparation criteria for NECO restorations.

<table>
<thead>
<tr>
<th>Preparation criteria</th>
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<tbody>
<tr>
<td>Occlusal reduction of 1.5 mm at minimum</td>
</tr>
<tr>
<td>Uniform removal of hard tooth tissue; at occlusal and incisal sites it should follow the original tooth shape</td>
</tr>
<tr>
<td>A supragingival position of the crown margin should be intended.</td>
</tr>
<tr>
<td>The preparation shoulder should be rounded and approximately 0.5 mm wide (chamfer type).</td>
</tr>
<tr>
<td>Avoid sharp edges, beveled margins or undercuts.</td>
</tr>
<tr>
<td>The preparation angle is preferably 7-10°.</td>
</tr>
<tr>
<td>For partial crowns the dentin-composite edge should not be in the antagonist contact area.</td>
</tr>
<tr>
<td>The surface of the core should be smooth.</td>
</tr>
</tbody>
</table>

The restorations were manufactured by the ACTA dental laboratory. For the fabrication of the master model a super hard stone gypsum (type 4) was used, in a neutral light-grey color. For easier removal of the crown from the master model, the die walls and occlusal surface were covered with a thin layer (0.05-0.10 mm) of neutral colored wax, ending approximately 1 mm from the preparation margin. The preparation margin was marked, and the stone areas not covered by wax were covered with insulating gel (Heraeus Kulzer GmbH, Hanau, Germany). The crown was built up with different layers with a maximum thickness of 2 mm, and, if applicable, different colors of NECO composite. NECO is a light curing nanohybrid composite. The monomer matrix includes a mixture of polyether and urethane based (meth-)acrylate monomers, and a new TCD (tricyclodecane) monomer. The composite material does not contain Bis-GMA monomer making it toxicologically advantageous, as no
Bisphenol-A can be released [16]. The filler particles are a mixture of various particle size fractions of a commonly used, radiopaque dental glass. The composite material contains non-agglomerated nano-particles, cross-linking and reinforcing the polymer network. The composition and properties [19, 20] of the used materials are summarized in Table 7.3. After applying each layer, the restoration was light-cured for 90 s (Heraflash, Hereaus Kulzer GmbH, Hanau, Germany). To simplify the adaptation of the composite, small amounts of C&B liquid (Hereaus Kulzer GmbH, Hanau, Germany) were applied to wet the dental instrument. This was also used to restore the inhibition layer in case it was damaged. Individual color characterization of the crowns was carried out using Cre-active colours (Hereaus Kulzer GmbH, Hanau, Germany). These stains are not wear-resistant and had to be covered with a final layer of NECO. After applying this last layer, a final polymerization of 180 s was carried out. Finishing and polishing was done using metal carbide burs at low speed and low pressure, silicone polishers, Kevlar brushes and diamond paste (Amalgant HK-A). High gloss was achieved by polishing with a rotating wool instrument “wollschwabbel”. After cleaning, the inside of the restoration was roughened with 50 μm Al₂O₃ at a pressure of 2000 hPa. For each crown the minimal wall thickness was measured by the dental technician on four locations: cervical, equatorial, fissures, and cusps, before insertion. These data, together with used composite material and color, were documented.

After try-in and occlusal adjustment if necessary, the restorations were repolished at the adjusted areas. Prior to cementation, the inner surfaces of the restorations were pretreated with C&B liquid. The abutment tooth was prepared for cementation, preferably with rubber dam, otherwise with cotton rolls. In the case of cementation with 2bond2 cement, the preparation was pretreated with 37% phosphoric acid for 15 s and the restoration was cemented in place under finger pressure with 2bond2 cement in combination with Gluma Comfort bond and desensitizer (Hereaus Kulzer GmbH, Hanau, Germany) according to manufacturers’ instructions. Excess cement was removed with explorers or scalers. Where necessary, finishing carbide burs were used to finish the margins of the restorations. In case of cementation with Fuji Plus cement, the preparations were pretreated with Fuji Plus conditioner (GC Corporation, Tokyo, Japan) and the restorations were cemented with Fuji Plus, all according to manufacturers’ instructions. All restorations were prepared and placed by one dentist.
One to two weeks after placement of the restoration, the first recall (baseline) visit was made. Recalls were carried out by three dentists. Further recalls were carried out after 6 months, 1, 2 and 3 years after placement of the restorations. Documentation at recalls included recording of occlusal contacts and possible complications. Most complications occurred in between recall data, and patients were seen to document the complications. Complications were analyzed, photographed if possible, and specified concerning failure reason, i.e. material breakdown, material weakness, indication limits, and failure behavior (i.e. chipping, total or partial breakage or hints on the breakage initiation point and risk) or other reasons like for instance total discoloration or loss of marginal integrity. The clinical success and survival of the crowns was recorded. Clinical success was defined as the restorations being present without any complications. A surviving restoration was defined as a restoration present in the mouth, with or without any kind of complication.

Statistical analysis was carried out using PASW statistics 18 (SPSS Inc.). Kaplan Meier curves were calculated for success and survival. The differences between the Kaplan Meier curves were statistically analyzed using the Log Rank test. The influence of the variables cement (2bond2 or Fuji Plus) and endodontic status (endodontically treated or vital teeth) on success and survival were statistically analyzed using the Cox Regression model. The significance level \( \alpha \) was set at 0.05.
Table 7.3  Chemical composition and properties of used materials. All data from manufacturer, unless otherwise stated.

<table>
<thead>
<tr>
<th>Product</th>
<th>Manufacturer</th>
<th>Composition</th>
<th>E-modulus</th>
<th>Fracture strength</th>
</tr>
</thead>
</table>
| NECO          | Hereaus Kulzer GmbH, Hanau, Germany | Filler particles: Silanized Ba-Al-B-F silicate glass (particle size 400-8000nm), silanized non-agglomerated SiO₂-nanoparticles  
Monomers: Tricyclodecane (TCD)-urethane diacylate, urethane dimethacrylate, polyether dimethacrylate, > 3% triethyleneglycoldimethacrylate (TEGDMA)  
Others: Rheological modifiers (hyperbranched polyurethane), photoinitiators (camphorquinone-based), stabilizers, color pigments | 14-16 GPa   | Flexural strength |
|               |                               |                                                                                                                                                                                                             |              | 160-170 MPa/129.3 MPa [19] |
| Fuji Plus cement | GC Corporation, Tokyo, Japan.  | Powder: alumino-silicate glass particles  
Liquid: HEMA 37%, polyacrylic acid 22%, proprietary resins 10%, tartaric acid 6%, distilled water 25%.  
| Fuji Plus conditioner | GC Corporation, Tokyo, Japan.  | Citric acid 10%, ferric chloride 2%, distilled water 88%.  | Flexural strength |
| 2bond2 cement | Hereaus Kulzer GmbH, Hanau, Germany | UDMA, 1,12-  
Dodecandidimethacrylate, multifunctional methacrylates, Ba-Al-B-Si glass (700 and 2000nm), highly dispersed silicon dioxide (10-40 nm), strontium fluoride (< 1000 nm)  
Filler load base: 69.5 wt.%, catalyst: 63.2 wt.% | Flexural strength |
| Gluma comfort bond & desensitizer | Hereaus Kulzer GmbH, Hanau, Germany | Methacrylate, 4-META, polyacrylic acid, ethanol, photoinitiators, glutaraldehyde.                                                                                                                        |              |                   |
Results

The study group consisted of 45 patients, of which 9 men, who received 18 restorations, and 33 women, who received 73 restorations. The age range was 29-70, with a mean age of 53 at the start of the study. A total of 91 post-canine restorations were made. The restorations consisted of 5 partial crowns and 86 full crowns. The 5 partial crowns, of which 4 were placed on molar abutment teeth and 3 were placed on endodontically treated abutment teeth, were all cemented with 2bond2. Of the total 91 restorations, the first 64 were cemented with 2bond2 cement, and the last 27 were cemented with Fuji Plus cement. Of the 91 restorations, 61 were placed on molar abutment teeth (2bond2 n = 45; Fuji Plus n = 16), and 30 were placed on premolars, (2bond2 n = 19; Fuji Plus n = 11). Of the abutment teeth, 48 were vital at the start of the study (2bond2 n = 32; Fuji Plus n = 16), and 43 had previously received an endodontic treatment (2bond2 n = 32; Fuji Plus n = 11). The mean occlusal thickness of the crowns was 0.98 (0.36) mm at the fissures and 2.30 (1.08) mm at the cusps. The mean cervical thickness was 0.87 (0.37) mm. The cervical thickness was quite high compared to the preparation criteria. The occlusal thickness in the fissures was low, due to the elaborate fissure patterns created by the dental technicians.

The recall rate, calculated on the basis of surviving restorations, was 97.8% at the baseline evaluation, and 95.6, 97.8, 97.8, and 87.9% at the 6 month, one, two, and three year recalls, respectively.

All complications occurred with full crowns. During the three-year observation period, a total of 20 complications occurred, of which 13 were repairable (Table 7.4). Repaired restorations were followed as normal. Repairable complications were debonding (n = 6), repairable core fracture (n = 2), and need for endodontic (re)treatment (n = 5). Other complications however, were not repairable and the restorations did not survive.
Table 7.4  All complications occurred during the three-year follow-up, specified concerning complication type, cement type, endodontic status and days in service until complication.

<table>
<thead>
<tr>
<th>Type of complication</th>
<th>Restoration nr.</th>
<th>Survival</th>
<th>Tooth number</th>
<th>Cement type</th>
<th>Endodontic status</th>
<th>Days until complication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Debonding</td>
<td>1</td>
<td>yes</td>
<td>16</td>
<td>2bond2</td>
<td>endod. treated</td>
<td>290</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>yes</td>
<td>37</td>
<td>2bond2</td>
<td>vital</td>
<td>768</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>yes</td>
<td>16</td>
<td>2bond2</td>
<td>endod. treated</td>
<td>355</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>yes</td>
<td>37</td>
<td>2bond2</td>
<td>vital</td>
<td>573</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>no</td>
<td>37</td>
<td>2bond2</td>
<td>vital</td>
<td>672</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>yes</td>
<td>46</td>
<td>2bond2</td>
<td>vital</td>
<td>357</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>yes</td>
<td>45</td>
<td>2bond2</td>
<td>vital</td>
<td>42</td>
</tr>
<tr>
<td>Core fracture</td>
<td>1</td>
<td>no</td>
<td>16</td>
<td>2bond2</td>
<td>endod. treated</td>
<td>867</td>
</tr>
<tr>
<td></td>
<td>7</td>
<td>no</td>
<td>37</td>
<td>2bond2</td>
<td>endod. treated</td>
<td>376</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>yes</td>
<td>24</td>
<td>2bond2</td>
<td>endod. treated</td>
<td>462</td>
</tr>
<tr>
<td></td>
<td>9</td>
<td>no</td>
<td>26</td>
<td>2bond2</td>
<td>endod. treated</td>
<td>267</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>no</td>
<td>45</td>
<td>2bond2</td>
<td>endod. treated</td>
<td>577</td>
</tr>
<tr>
<td></td>
<td>10</td>
<td>yes</td>
<td>35</td>
<td>Fuji Plus</td>
<td>endod. treated</td>
<td>180</td>
</tr>
<tr>
<td>Endodontic treatment needed</td>
<td>11</td>
<td>yes</td>
<td>45</td>
<td>2bond2</td>
<td>endod. treated</td>
<td>63</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>yes</td>
<td>45</td>
<td>2bond2</td>
<td>vital</td>
<td>402</td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>yes</td>
<td>26</td>
<td>2bond2</td>
<td>vital</td>
<td>70</td>
</tr>
<tr>
<td></td>
<td>13</td>
<td>yes</td>
<td>26</td>
<td>2bond2</td>
<td>vital</td>
<td>1007</td>
</tr>
<tr>
<td></td>
<td>14</td>
<td>yes</td>
<td>27</td>
<td>Fuji Plus</td>
<td>vital</td>
<td>874</td>
</tr>
<tr>
<td>Root fracture</td>
<td>11</td>
<td>no</td>
<td>45</td>
<td>2bond2</td>
<td>endod. treated</td>
<td>833</td>
</tr>
<tr>
<td>Crown fracture</td>
<td>15</td>
<td>no</td>
<td>37</td>
<td>2bond2</td>
<td>endod. treated</td>
<td>348</td>
</tr>
</tbody>
</table>
These complications consisted of root fracture \( (n = 1) \), crown fracture \( (n = 1) \), debonding with no possibility for recementation \( (n = 1) \) and irreparable core fracture \( (n = 4) \), which in three cases resulted in extraction of the tooth.

Debonding only occurred with restorations cemented with 2bond2. In one of the five cases needing endodontic treatment, the endodontic status of the tooth was unsure before the restorative procedure was started. In another case, endodontic retreatment was needed because an earlier endodontic treatment just before the study proved not to eliminate the periapical pathology. Five out of seven cases of debonding occurred with vital teeth, while all cases of core fracture occurred with endodontically treated teeth.

**Figure 7.1** Kaplan Meier curve of success and survival of NECO restorations. (—) Survival curve. (---) Success curve. (+) Censored case.
In some cases, a repairable complication occurred prior to an irreparable one. In one case, debonding occurred before irreparable core fracture. In another case, endodontic retreatment was followed by root fracture. One crown debonded twice, after the second time the decision was made not to recement it, but to replace the restoration. One restoration debonded, was recemented, later needed endodontic treatment and after that experienced irreparable core fracture. Because after the debonding the restoration was no longer successful, but remained surviving until the irreparable core fracture, the endodontic treatment could not be incorporated in the
Kaplan Meier statistics, as was the tooth still stated as endodontically untreated, because that was the status at the start of the study.

The overall success and survival curves are depicted in Figure 7.1. The success rate of NECO restorations was 84.8% and the survival rate was 91.6% after three years. The annual failure rate based on the survival rate of the NECO restorations after three years is therefore 2.8%.

Figure 7.3 Kaplan Meier curve of success and survival of restorations placed on vital teeth and restorations placed on endodontically treated teeth. (—) Survival curve vital teeth. (---) Success curve vital teeth. (—) Survival curve endodontically treated teeth. (---) Success curve endodontically treated teeth. (+/-) Censored case.
With the use of Fuji Plus cement, all complications were repairable, which lead to a success rate of 93.1% and a survival rate of 100% after three years. This was much higher than the success and survival rates of 81.4 and 87.9% respectively for restorations cemented with 2bond2 cement (Figure 7.2).

The success and survival rates after three years for restorations on vital teeth were 86.8% and 95.3% respectively, compared to a success rate of 82.6% and a survival rate of 87.5% for restorations on endodontically treated teeth (Figure 7.3). This makes the success rates similar, but the survival rates higher for vital teeth, indicating that not so much the number but the severity of the complications was different. The differences between the curves were not statistically significant however. The Log Rank (Mantel-Cox) test had a p-value of 0.080 for cement and a p-value of 0.293 for endodontic status, while the Cox proportional hazards model showed a p-value of 0.054 for cement and of 0.296 for endodontic status after three years.

Discussion

The success rate of NECO restorations was 84.8% and the survival rate was 91.6% after three years, with an annual failure rate based on survival of 2.8% This is within range of previously reported failure rates for composite inlays and onlays [2], although this is not directly comparable to full coverage crown restorations as in the majority of this study. The comparison to other research is not straightforward, since success and survival criteria may be defined differently, and the experimental set-up may differ between studies. Success and survival percentages also vary considerably between studies, even for the same materials. The study of Ohlmann et al. showed a success rate of 92.1%, for fiber-reinforced composite crowns, 87.5% for non-fiber-reinforced composite crowns, and 92.3% for metal-ceramic crowns after one year. Delamination of veneering composite and endodontic complications were the most common complications [21]. These results are poor in comparison with this study. Rammelsberg et al. found a survival rate of 96% in three years, in which partial and total fractures of the restorations were the most common mode of failure [5]. These results are favorable compared to our study.
Comparing studies concerning other indirect materials is even more difficult. For instance, Burke et al. [22] reported a five-year success rate of 80% for all-metal crowns, 68% for porcelain crowns, and 76% for metal-ceramic crowns placed within the General Dental Services in England and Wales. Vanoorbeek et al. compared CAD/CAM-generated restorations, and found inferior esthetics and wear resistance of composite crowns compared to ceramic crowns. The success and survival rates after three years were 87.9 and 55.6% for composite crowns and 97.2 and 81.2% for all-ceramic crowns respectively [23]. In meta-analysis, the estimated 5-year survival rate was 93.3% for all-ceramic (non-zirconia based) crowns and 95.6% for metal-ceramic crowns [24]. In a review by Della Bona et al., survival rates of 82-100% have been reported for single-unit all-ceramic crowns [25]. These outcomes seem favorable compared to NECO restorations. Differences between studies can be explained by differences in material characteristics, but differences in experimental set-up, duration of the study, and study population are very important factors, which makes these studies hard to compare.

A meta-analysis showed a mean annual failure rate for direct composite restorations of 2.2% (range 0-9%) [2]. Compared to this mean annual failure rate, the NECO restorations do not perform well. For one- [26], and two-surface restorations [2, 27, 28], direct composites show excellent results, even long-term. However, a NECO restoration is not made in case of a class I or class II restoration, on which most clinical studies are based. It is therefore more relevant to compare the NECO restorations with large composite restorations. Opdam et al. showed a favorable survival rate even for large direct composite restorations, which is very much competitive to the survival rates of NECO [3]. In this light, the indication of NECO restorations is questionable. However, the annual failure rate for larger restoration, with more surfaces involved, is higher than that for small restorations [2], and lies above the 2.8% annual failure rate for NECO restorations as reported in this study [27, 28]. In this respect NECO performs better than large direct composite restorations.

The only biological complication encountered was the need for endodontic (re)treatment (5.5%). It should be noted that one of the abutment teeth already had an uncertain endodontic status before the restorative procedure was started. Goodacre et al. report a mean incidence of endodontic treatment need with existing crowns of 3% [29], which is comparable to the percentage in our study.
Figure 7.4  Graphical depiction of the fractured restoration. (Top) Restoration in situ at the 6-month recall. In the central fissure of tooth 37 a pre-crack is visible, which is stained with erythrosine. (Middle) SEM image (magnification 250x) of a duplicate of the restoration in (Top). The crack is clearly visible. (Bottom) Fractured restoration with the fracture originating from the pre-crack in the central fissure. Fracture occurred five months after the six-month recall. The thickness of the restoration at the crack initiation site was only 0.3 mm.
Other complications were of mechanical nature. One restoration fractured. It could be seen in the lab documentation sheet that the minimal occlusal thickness of this restoration was only 0.3 mm, instead of the recommended 1.0 mm. This was most likely the cause of the fracture, since it acted as a point of weakness from which a crack was propagated. This could be seen in the clinical photographs (Figure 7.4). This failure was not caused by material weakness but by a manufacturing fault. For Artglass crowns, more (partial) fractures were found [5]. In contrast, we hardly experienced failures at all that could be attributed to material weakness or breakdown, since all but the one crown that fractured remained intact, even if the core underneath was fractured. The failure modes we did encounter consisted mainly of debondings and core fractures. These failures could be attributed to the modulus of elasticity of composite materials that is very low compared to metals and ceramics, and is related to the ferrule effect.

The principle of the ferrule-effect is based on the encircling of the coronal part of the tooth by a stiff material, for instance a cast metal, resulting in a reinforcing effect [30]. It is considered to be one of the most important factors in indirect restoration success [30, 31]. However, the stiffness of resin composite is much lower than that of ceramics or metal alloys. As a consequence, it is expected that the ‘reinforcing’ effect of a ferrule does not work as well in the case of a composite crown. Furthermore, it is known from stiff materials like metals and ceramics, that when an occlusal or horizontal force is applied, the stresses are partly distributed to the outline of the restoration, where natural tooth tissue can bear these stresses. In contrast, with composite resin crowns the stresses are concentrated in the contact points [32, 33]. Since stresses are not distributed to the outline of the restoration, there seems to be no need to extend composite restorations to the cervical outline. In this study, and many previous studies, a classic crown preparation design was chosen, comparable to the design of a metal crown. The application of this design for resin composite based restorations is questionable. In this study the composite material was processed as being “white gold”, which is a conceptual mistake for a material with such different mechanical properties. For ceramic restorations, in some way “extension for prevention” is executed to create restorations with sufficient thickness and strength. In contrast, for resin composite restorations, the minimally invasive approach must be the leading concept, leaving more sound tooth tissue intact, which in turn will probably lead to higher success and survival rates [9]. Instead of a chamfer preparation, a knife
edge preparation only covering (part of) the walls for retention and esthetic purposes might be a better preparation guideline. This makes the material greatly suitable for minimally invasive partial crowns, inlays and onlays, and this leads to another more or less unique indication area for indirect resin composite/NECO restorations, perhaps bridging the gap between large composite restorations and full-coverage crowns.

The results of this study suggest that the success and survival rates of NECO restorations are dependent on cementation and endodontic status of the tooth. Tooth site (molar or premolar) or restoration type (full or partial crown) did not have any effect on success and survival. The differences are, however, not statistically significant, although the factor “cement” shows a trend towards significance with a p-value of 0.054. With a relatively small study group, and most of the study group consisting of censored cases, it is very difficult to achieve statistically significant results. Even though the more favorable performance of Fuji Plus was not statistically significant, it is interesting to rationalize the differences between the two cements. Conventional glass-ionomer cements are not recommended for the cementation of ceramic inlays due to insufficient retention of the restorations [34]. The fracture resistance of indirect composite crowns is negatively influenced by cementation with a conventional glass-ionomer cement, compared to cementation with an adhesive cement in vitro [35]. Fuji Plus, however, being a resin-modified glass-ionomer cement, cannot be directly compared to conventional glass-ionomer cements. The use of Fuji Plus has so far not been tested for the use of cementing indirect composite restorations clinically. Regarding the cementation of ceramic inlays however, there were no statistically significant differences in survival of restorations cemented with Panavia 21 or Fuji Plus after 5 years of clinical service [17], which is promising, although cementation of ceramic restorations cannot be directly compared to cementation of composite restorations. The fracture strength of ceramic crowns in vitro is negatively influenced when cemented with Fuji Plus compared to an adhesive resin cement, but this effect is not seen with fiber-reinforced composite crowns [18]. Moreover, it has been shown in vitro that thermocycling of composite inlays cemented with Fuji Plus leads to a decrease in marginal gap formation, due to hygroscopic expansion, whereas inlays cemented with Panavia showed an increased marginal gap formation after thermocycling [20]. Fuji Plus has been reported to have a high water sorption compared to resin cements, which explains its rather high hygroscopic expansion [36]. For a resin-modified glass-ionomer cement this is to be expected. However, 2bond2
has a relatively high water solubility compared to other resin cements [37], which could lead to marginal gap formation during clinical function.

Cementation of indirect composite crowns with 2bond2 cement has been reported to have high clinical success rates [5]. A clinical study concerning indirect composite resin inlays cemented with 2bond2 showed an annual failure rate of 3.2%, which is comparable to this study [38]. A study by Bouillaguet et al. shows a microtensile bond strength of 13.9 MPa to flat root dentin for Fuji Plus [39]. Tensile bond strength to dentin of 2bond2 in combination with Gluma Solid Bond has been reported to be 5 MPa [40], while another study shows a tensile bond strength to dentin of 18 MPa for the same adhesive system [41], which is however much lower than the 43 MPa found for Variolink in the same study. It is, therefore, not clear which cement has higher bond strength to dentin. Nevertheless, Fuji Plus, is able to establish a chemical bond through its glass-ionomer phase, as well as a micro-mechanical bond, compared to 2bond2 which can at best only establish a micro-mechanical bond. Furthermore, the positive effect of cementation with Fuji Plus cement compared to cementation with 2bond2 cement could be due to the relatively low technique sensitivity of the first cement in relation to the frequently occurring subgingival margins. Only a limited amount of restorations could be placed under the protection of rubber dam, and moisture control is likely to have been a weak link in the cementation with 2bond2 cement. The sensitivity for moisture probably is less of a problem for resin-modified glass ionomer cements like Fuji Plus.

The positive effect of restorations on vital teeth may be attributed to the higher amount of residual dentin compared to endodontically treated teeth. Tooth strength is reduced in proportion to coronal tissue loss, due to either caries lesions or restorative procedures, and endodontic access opening significantly weakens the remaining tooth structure [42]. In earlier research a negative effect on success of an endodontically treated abutment tooth has been described [22]. Core fracture, repairable and irreparable, only occurred with endodontically treated teeth. Most debondings occurred with vital teeth. There was one case of debonding on an endodontically treated tooth, but after recementation the core fractured. It seems that the endodontic status of the abutment tooth, in other words the amount of residual dentin, is predictive for the failure mode. Therefore, the success and survival data of endodontically treated vs. vital teeth needs some explanation. Although the amount of complications is approximately the same in both groups, the vital group showed failure modes like
endodontic treatment need and debonding, while the endodontically treated group showed more severe failure modes like root fracture and (irreparable) core fracture. This reflects in the survival curve, which is lower for endodontically treated teeth even though this difference is not statistically significant. It is not only the amount of complications, but also the severity that matters.

Future research regarding preparation design, cementation method, and indication area should preferably be carried out in a double-blind RCT-design. Possible indication areas for NECO could be indirect anterior esthetic veneer restorations, and occlusal onlay restorations for the treatment of patients who suffered from severe dental erosion or dental abrasion and need occlusal rehabilitation. Furthermore, the material could fill the gap between large direct composite restorations and indirect full coverage crowns.

**Conclusion**

The success and survival percentages of NECO restorations in this study are 84.8 and 91.6% respectively. Restorations cemented with Fuji Plus cement showed a tendency to perform better than restorations cemented with 2bond2 cement although this was not statistically different with $\alpha = 0.05$ ($P = 0.054$), and the remaining tooth structure seems to be an important factor. With current knowledge, we cannot recommend this material as used in this design as a viable alternative to direct resin restorations or ceramic restorations. However, it is important to keep in mind that the material properties of NECO are very different from ceramic or metal materials, and therefore special attention should be paid to the best possible design and indication for indirect composite restorations. A better design and indication area may improve the clinical performance of NECO restorations. A good indication for this material might be to fill the gap between large direct composite restorations and full coverage crowns.
References


