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Schepke, Ulf

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CHAPTER 03

Clinical bonding of Resin Nano Ceramic restorations to zirconia abutments: a case series within a randomized clinical trial

• PART A •

This chapter is an edited version of:

Clinical bonding of Resin Nano Ceramic restorations to zirconia abutments: a case series within a randomized clinical trial

Abstract

New dental materials are introduced and promoted in the field without extensive clinical testing. Using those materials in a clinical setting might result in unacceptable early failure rates. The purpose of this paper was to analyze bonding of a new dental restorative material to either zirconia stock abutments or zirconia customized abutments.

Fifty participants seeking single implant treatment were included in a prospective study. Resin Nano Ceramic (RNC, Lava Ultimate, 3M ESPE, Seefeld, Germany) crowns were digitally manufactured and extraorally bonded to either a stock or a customized zirconia abutment (ZirDesign and ATLANTIS, DENTSPLY Implants, Mölndal, Sweden) by means of a resin composite cement (RelyX Ultimate in combination with Scotchbond Universal, 3M ESPE, Seefeld, Germany), strictly following the manufacturers recommendations. The final restorations were screw-retained to the implants and followed during twelve months. Primary outcome parameter was uncompromised survival of the restoration, secondary outcome parameter was mode of failure.

No implants were lost. The uncompromised survival rate of the RNC crowns bonded to zirconia abutments after one year of clinical service was only 14% (n=7). Catastrophic failure occurred in 3 cases (6%), whereas debonding failure between RNC crowns and zirconia abutments occurred in 80% of the cases (n=40) within the first year of service. No statistical significant difference in uncompromised survival rate could be identified between abutment types ($X^2= 1.495, p =0.209$). Uncompromised survival rate after 1 year was highly significantly different ($X^2= 104.173, p < 0.001$) from a reference standard, which was set at 95 %.

RNC crowns luted to stock and customized zirconia implant abutments with the particular resin composite cement used in this trial have a poor prognosis, regardless of the abutment type used.
Introduction

Implant-supported single crowns (SC) show acceptable performance but mechanical complications. Both, implant components and restorative materials are of clinical concern. Scientists and product developers increasingly take the view that using nature as a role model can improve treatment success. This is at odds with the functional ankylosis of dental implants and the common use of stiff restorative materials implementing different biomechanical properties compared to natural teeth with regard to haptic perception and resiliency of the periodontal ligament (PDL).

Several suggestions have been done to mimic the flexibility of the PDL in an implant system. Van Rossen introduced the term ‘flexible element’ in the nineties of the last century, implying abutments with some kind of micro-motion mechanism or resilient element, thereby generalizing the terminology used by others such as ‘shock absorber’, ‘stress distributor’, ‘intramobile element’, ‘intramobile connector’ and ‘flexible insert’. He concluded that bone around implants with a flexible element reacted differently from bone around rigid implants on a histological level. From finite element studies it was suggested that implants with flexible elements, or indeed implants with a flexible, biocompatible coating induce a more favorable stress distribution compared to rigid implant systems.

Modern technology even allows the production of an implant abutment with an internal resilient component that allows micro-movement rather similar to the biomechanical behavior and resiliency of a natural tooth.

Combining flexible resin, either as a veneering material or in combination with stiff abutment materials is another approach, although its effect on stress distribution around an implant is controversially discussed in the literature: some report on a more favorable stress distribution based on finite element analysis, other don’t anticipate a notable difference. To the knowledge of the authors, clinical verification of a presumed beneficial effect on the bone level has not been published to date.

However, resilient materials might prevent biomechanical complications at the level of the restoration. Magne compared composite with ceramic veneers, both bonded to zirconia abutments. Even though the fracture resistance was comparable, the composite veneers showed more “friendly” failures, i.e. maintaining the restoration–abutment adhesive interface and rendering the abutment itself intact. The idea was likewise to introduce a buffer in the SC-Implant complex that could aid in absorbing chewing forces by mimicking the PDL. Yet another approach was to use a resilient (composite) abutment combined with ceramic and composite veneers.

Soon thereafter, a global manufacturer of restorative materials (3M ESPE, Seefeld, Germany) launched a new Computer Aided Design/Manufacturing (CAD/CAM) restorative material, emphatically based on Magnes first findings (source: 3M, LavaUltimate CAD/CAM Restorative, Technical Product Profile, 2011). The combination of a high flexural strength (ca. 200 MPa) and a low flexural modulus (ca. 12 GPa) should make the material most suitable for implant-supported SC restorations (source: 3M, Lava Ultimate Implant Crown Restorative, 2012). Enhanced optical properties combinable with the ability to make use of the esthetically more advanced cut back technique and various
favorable mechanical properties made the material an all-round high-quality and economical CAD/CAM restorative material (source: 3M, Lava Ultimate, Restorative, 2013). This highly filled polymer was classified by the manufacturer as Nano Resin Ceramic (NRC), stressing the aim of combining positive, mainly esthetic ceramic attributes with biomimetical properties of a resin composite (i.e. mechanical, shock absorbing properties of dentin and the PDL). As this classification has not yet reached scientific nomenclature, there is no other material called NRC so far. Instead, the term “CAD/CAM polymer” has won recognition since it was used by Edelhoff in 2012, which nowadays covers a variety of related materials.

The first scientific article about NRC emerged in 2012, around the same time that the material was officially launched in Europe during the International Dental Show in Cologne in spring 2012. This in vitro case report shows technical aspects of cutting back the monolithic crown and enhance esthetics with luting translucent resin composite.

It took another 2 years before the results of the first in vitro studies on RNC were published with promising results regarding fracture strength, even with considerable less material thickness than required by the manufacturer (i.e. 1.5 mm). More recently, the benefits of silica-sandblasting CAD/CAM polymers were discussed. Generally, the in vitro tests revealed sufficient bond strength, even though there were statistical differences within different CAD/CAM polymers. This was later confirmed by a third in vitro study. Also wear, optical properties and reparability were assessed in vitro and the results appeared to be favorable. However, no clinical studies with this new material were published to date.

The aim of the study is to evaluate early in vivo performance of NRC crowns bonded to either stock or customized zirconia implant abutments when used as single implant restorations.

Materials and Methods

This is a cases series of RNC restorations within a randomized clinical trial comparing two zirconia abutment types: stock or customized. Consecutive subjects, during a 13 month inclusion period (January 2013 to February 2014), missing one tooth in the premolar region of the mandible or maxilla, that were assessed to have a bone height ≥ 10 mm beneath the maxillary sinus and ≥ 10 mm above the mandibular nerve and a bone width of at least 6 mm were considered eligible to participate in this study when complying with the other inclusion and exclusion criteria (Table 1). The screening procedure included a clinical and radiographic examination. One subject was excluded because he or she did not fulfill the inclusion criteria, and one choose not to participate (figure 1). Exclusion criteria are listed in Table 1. Permission from the medical ethics committee of the university medical center Groningen, the Netherlands was granted (METc number 2012.388, ABR number NL 42288.042.12) and informed consent was obtained from each participant.
<table>
<thead>
<tr>
<th>Inclusion criteria:</th>
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<tr>
<td>Missing first or second premolar in the maxilla or mandible</td>
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<tr>
<td>Wish to replace the missing premolar with an implant</td>
</tr>
<tr>
<td>Willing to sign for informed consent</td>
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<tr>
<td>Bone height ≥ 10 mm beneath the maxillary sinus and ≥ 10 mm above the mandibular nerve and a bone width of at least 6 mm</td>
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<th>Exclusion criteria:</th>
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<tr>
<td>Missing teeth mesial or distal from implantation site</td>
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<tr>
<td>Orthodontic treatment at the time of impression-taking</td>
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<td>Severe bruxism</td>
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<tr>
<td>Acute periodontitis</td>
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<tr>
<td>History of implant loss</td>
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<tr>
<td>Documented extreme gagging reflex</td>
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<tr>
<td>Poor medical condition (ASA score 3 or higher)</td>
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<td>Previous therapeutic radiation of the head-neck region</td>
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<td>Chronic pain in orofacial system</td>
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<td>Younger than 18 years at time of inclusion</td>
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<td>Reduced mental capacity</td>
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Implant surgery was performed using the standard protocol for ASTRA TECH Implant system (DENTSPLY Implants, Mölndal, Sweden) to a final drill diameter. One hour pre-operative antibiotic prophylaxis (3 g amoxicillin or, if allergic to penicillin, 600 mg clindamycin) was given. Postoperative treatment included a chlorhexidine rinse twice daily started one day before the operation and ending 10 days later. No further anti-microbial therapies were used. The surgical procedure was performed under local anesthesia. A crestal incision was made and the implant (OsseoSpeed TX 3.5x, either 9, 11, or 13 mm in length; DENTSPLY Implants, Mölndal, Sweden) was placed. Maximum torque used during implant installation was set according to ASTRA TECH Implants System’s surgical manual and primary implant stability was estimated manually. A healing abutment was placed and the wound was closed with slowly resorbable sutures (Vyncyl & Johnson Health Care, Piscataway, USA). Restorative treatment commenced 3 months later. An analog impression with a polyether material (Impregum; 3M ESPE, Seefeld, Germany) in an open, semi-individual impression tray
was made, always by the same operator (U.S.). A screw-retained SC was provided consisting of a digitally designed and milled RNC crown (Lava Ultimate, 3M ESPE, Seefeld Germany), bonded to either a stock (ZirDesign, DENTSPLY Implants, Mölndal, Sweden, n=25) or a customized (ATLANTIS, DENTSPLY Implants, Mölndal, Sweden, n=25) zirconia abutment, strictly following the manufacturers recommendations (Table 2).

Table 2
Manufacturers’ recommendations were strictly followed in the dental laboratory. Additional details applied in this study are highlighted in italic letter type.

<table>
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<th>Recommendations</th>
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<tr>
<td>*Bonding procedure - Scotchbond Universal, Adhesive and RelyX Ultimate</td>
</tr>
<tr>
<td>Resin Cement Adhesive, Instructions for Use, both 2013 by 3M. A GC Labolight LV-III device was used for 5 minutes to additionally light-cure the cement.</td>
</tr>
<tr>
<td>*Pretreatment of Lava Ultimate Restoration and extraoral polishing procedure - Clinical Preparation and Handling Guidelines for Dentists and Dental Labs Lava Ultimate, 2013 by 3M</td>
</tr>
<tr>
<td>*Pretreatment abutment - Cement-retained restorations, Clinical and laboratory procedures, 2013 by Dentsply- The surface of the zirconia abutment was sandblasted with Rocatec Soft 30 μm at two bars from a distance of 2-10 mm until the surface appears matte, as roughening the surface is recommended by the manufacturer of the abutment to obtain mechanical retention. Subsequently, the abutments were cleaned with air pressure from possible Rocatec remnants.</td>
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The crowns were individually designed and milled to the full contour. The sprue, which was located lingually or buccally was cut back with coarse rubber wheels or medium-to-fine burrs. Finishing of the sprue area was performed with medium rubber wheels or cups. The dimensions of the crown were designed in accordance with normal anatomy, appropriate for the mesio-distal dimension of the diastema and the interocclusal distance.

The abutment type was randomly allocated (www.sealedenvelope.com). The customized abutments were designed in accordance to the full crown preparation recommendations from the manufacturer (i.e. ≥1.5mm occlusal and circumferential and ≥1.0mm close to the margin), ensuring adequate conical walls for retention of the restoration. The dimensions of the stock abutment determined the thickness of the crown in this group. They were reduced in height in case of inadequate interocclusal clearance to ensure a minimum occlusal thickness of 1.5mm. All implant supported SC’s were made by the same laboratory and the manufacturing procedures were standardized beforehand.

Three weeks after impression making the implant supported SC was placed and screwed to the implant, using a torque wrench (20 Ncm). The abutment fixation screw was protected with sterile Teflon tape and the screw access hole was filled with a glass ionomer restorative material (Fuji II, GC...
European, Leuven, Belgium). Static and dynamic occlusions were checked meticulously. Planned follow-up appointments were at one week and at 12 months after delivery of the restoration. Unplanned appointments occurred at the participants’ initiative in case of perceived complication or complaints and at the earliest convenience. Debonded or broken implant-supported SC’s were sent to the laboratory and repaired or renewed within two weeks. In case of debonding, a reparation protocol was administered: The inner surface of the RNC-crowns was carefully sandblasted with 2 bar (Rocatec soft, 3M ESPE, Seefeld, Germany) to remove the cement, then the original bonding procedure was repeated. Primary outcome parameter was ‘uncompromised survival,’ defined as undisturbed and uncompromised function, also on the scheduled clinical examination at 1 year after crown placement. Uncompromised survival of the restoration at 12 months was compared between the 2 abutment types (i.e. stock and customized) and presented by means of a survival analysis (figure 2).

Figure 2
Undisturbed survival according to Kaplan-Meier of 50 RNC crowns luted to zirconia stock (green) and customized (blue) abutments. Failures were recorded a) at the participants’ initiative in case of perceived complications or complaints or b) when participants were examined at T12 and the crown appeared to be debonded from the zirconia abutment. The sudden drop in survival rate at T12 occurred can be attributed to the restorations that were found debonded during the scheduled clinical evaluation after 1 year, without the participant having noticed it. All 50 participants were examined at T12, which was set at 365 days (mean 364 days, SD 21 days).
For the statistical analysis the benchmark for clinical success in the first year was defined at 95%, based on a systematic review from Jung et al.² The null hypothesis was that the one year survival of RNC crowns, bonded to zirconia abutment restorations would be equal to a one year survival that was considered clinically acceptable (i.e. 95%), which was tested with a chi-square test. Also the mode of failure (catastrophic vs. repairable) and the frequency of failures within one individual were recorded. Some of the repaired implant supported SC’s failed again, so a combination of different failure modes was possible (figure 3).

Figure 3
Failure mode, frequency and clinical success after 12 months of clinical service. Failure occurred when the participant attended the clinic because of perceived problems or at the scheduled visit after 12 months.

The null hypothesis was that all modes of failure happened equally distributed among both groups of abutment types (i.e. stock and customized). This hypothesis was tested by using Pearsons’ chi-square test. Additionally, the location of the residual cement was identified with the aid of a microscope (OPMI Pico, Carl Zeiss, Oberkochen, Germany). Statistical significance level was set at \( p=0.05 \) for all tests. A standard statistical program was used for all computations (IBM Corp. SPSS Statistics for Windows, Version 22.0. Armonk, USA).
Results

A total of 50 participants (34% males and 66% females, mean age 47.7 years, SD=12.8 years) were included and analyzed (figure 1). Fifteen maxillary first, 26 maxillary second, 2 mandibular first, and 7 mandibular second premolars were replaced by an implant-retained SC. All participants completed the one-year evaluation period. Implant survival was 100% at the 12 month evaluation.

The uncompromised survival at 12 months for the stock and custom abutment groups were 8% (n=2) versus 20% (n=5) respectively. None of the zirconia abutments failed.

The chi-square test verified statistically a significant difference of the survival compared with 95% one-year survival ($X^2= 104.173, p < 0.001$).

The survival of the restorations in both groups is presented in figure 2. Three SC’s showed initial catastrophic failure (in all three cases the RNC crown broke vertically into pieces and the margin of the screw access hole was affected) and 7 SC’s (14%) showed uncompromised survival after one year of clinical service. From the initial 40 debonding failures (80%), 22 were noticed by the participant (44%) and repaired as soon as possible. One repaired implant supported SC showed catastrophic failure. The participant reported that the RNC-crown had debonded while chewing and was destroyed accidentally. The aetiology of the initial 3 catastrophic failures remains unclear.

In 100% of the observed debonding events (n=50), the residual cement was predominantly located in the RNC crown and not on the abutment (figure 4). Pearson’s chi-square test could not confirm any statistically significant differences in uncompromised survival between the abutment types ($X^2= 1.495, p=0.209$).

Figure 4
Stock (left) and customized (right) implant supported single crowns after debonding. Note that typically, the cement remnants are found in the crown, not at the zirconia abutment interface.
Discussion

A new generation of monolithic, millable, hybrid materials has emerged (for example: VITA Enamic, VITA Zahnfabrik, Bad Säckingen, Germany; Lava Ultimate Restorative, 3M Company, St. Paul, USA; Cerasmart, GC corporation, Tokyo, Japan). They combine the favorable features of resin composite materials and glass ceramics and possess a relatively high flexural strength and modulus of resistance and low flexural modulus. The former may be a particularly interesting feature for implant restorations. Hybrid ceramics have a higher load to fracture than veneered zirconia restorations and because of their lower modulus of elasticity may be an attractive alternative to monolithic ceramics. They maintain the ability to be luted adhesively to tooth material, so non-retentive preparations, saving tooth material, are possible. Little information is available regarding the clinical performance of these hybrid materials yet. This study is the first to report on the performance of one of those materials (RNC crowns) when luted to zirconia implant abutments and serving as screw-retained restorations. Although a screw access hole challenges the integrity of the material, only few cohesive failures were seen during the course of the trial compared to the number of adhesive failures. The difference in survival rate of the restorations luted to customized abutments compared to stock abutments (20% vs. 8%) can be explained by the smaller surface of the stock abutments. Due to the relatively small number of participants a statistically significant difference of failure types or clinical success after one year could not be identified. A power calculation now seems feasible, but a second clinical trial on this topic would neither be ethical nor necessary to show clinical unacceptable survival rates of the presented method for either group of abutments. Suggestions made in the literature to enhance the bond strength to oxide-based ceramics, among which is zirconia have recently been summarized in detail by Özcen & Bernasconi among which are roughening of the surface by means of air-borne particle abrasion to improve micro-mechanical retention, physicochemical activation of the ceramic surface using silica-coated particles, followed by silanization or chemical activation with functional-monomer containing adhesive promotors or resins. In addition to or in combination with the former methods, the use of cements that contain the phosphate ester monomer 10-methacryloyloxydecyldihydrogenphosphate (MDP) has been proposed. Not all methods proved effective. Critical review of studies involving macro- and microtensile tests using the aforementioned methods and / or materials reveal a lack of standardization of the methods used, which makes it difficult to stipulate conclusions and clinical recommendations. Nevertheless, physicochemical conditioning of zirconia and the use of MDP-based resin improves tensile values. Bonding to zirconia with the RelyX Ultimate applied in combination with Scotchbond Universal has recently been critically discussed. It does not contain MDP, but this particular choice of resin cement is not very likely to be the reason for the many early clinical failures that were observed in this study. The stock abutments have naturally a smaller retention surface than the customized ones, which are designed to support the restoration maximally (figure 4). However, both types are designed to offer as much mechanical retention as possible and should ensure a durable bond between the crown and the abutment, even if a conventional cement with less bonding strength would have been used instead.
For this reason we hypothesize that the clinical debonding of the RNC crowns in our study might have to do with the RNC material, rather than with the used cement. As the ankylosic implant/abutment complex shows hardly any resiliency, most of the elastic deformation resulting from chewing forces occurs within the RNC crown and might be transformed into stress concentrations in the adhesive layer. As a consequence, debonding occurs at what is supposed to be the weakest point, the zirconia cement interface, although data in comparing bond strength to zirconia and this particular resin material are lacking. It was presumed that other (for example MDP-containing) cements or procedures to enhance bonding to zirconia would not effectively prevent the type of failures as seen in this trial. Based on this assumption it was decided to apply the same bonding procedure and replace the RNC crowns with lithium disilicate (LS2) specimen (e.max Press, Ivoclar Vivadent, Schaan, Liechtenstein) at the regular T12 appointment. Presently, all 50 participants received a LS2 crown luted to a zirconia abutment, and we have not experienced any debondings to date. Our assumption is that the higher flexural modulus of the LS2 (ca. 95 GPa for LS2 versus 12 GPa for RNC) prevents this from happening. However, this has to be confirmed when one year survival data are available. It is noteworthy that the manufacturer issued a ‘change in indication’ for the RNC material as from June 12th 2015, implying that they no longer consider the material suitable for crown indications because of ‘debonding issues’ (www.3m.com/3M/en_US/Dental/Products/Lava-Ultimate/). This, in combination with the results from the present study, underscore the obligation and responsibility to test materials thoroughly, also clinically prior to clinically use. More fundamental and clinical research is necessary to understand the interrelationship between the used materials in the present study. At present, clinical application of RNC implant supported SC’s in combination with zirconia abutments should not be advised.

**Conclusion**

Resin Nano Ceramic crowns luted to stock and customized zirconia implant abutments with one particular resin composite cement, following the manufacturers’ instructions, have a poor functional prognosis, regardless of the abutment type used.

**Acknowledgments**

This study was made possible through a grant by Dentsply (grant number: D-2011-005) and by the authors’ institutions. Restorative materials were provided by 3M, Ivoclar Vivadent and Dentsply free of charge. The restorations were manufactured by Elysee Dental / Oosterwijk Dental labs, Utrecht, the Netherlands. The funding sources had no involvement in the study design, collection, analysis and interpretation of the data or in the decision to submit the article for publication.
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