Cemented versus screw-retained zirconia-based single-implant restorations: 5-year results of a randomized controlled clinical trial

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Abstract

Objectives: To compare cemented and screw-retained one-piece zirconia-based restorations in terms of clinical, radiographic, and technical outcomes 5 years after insertion.

Materials and methods: Thirty-four patients with single-tooth implants were randomly restored with either a cemented lithium disilicate crown on a one-piece customized zirconia abutment (CEM, 17 patients) or a screw-retained crown based on a directly veneered one-piece customized zirconia abutment (SCREW, 16 patients). All patients were recalled for a baseline examination (7–10 days after crown insertion) and then annually up to 5 years. The following outcomes were assessed: marginal bone level (changes), technical, and clinical (bleeding on probing, plaque control record, probing depth, and keratinized tissue) parameters. The Mann–Whitney U-test was used to assess differences between the two groups.

Results: At 5 years, 26 patients (13 in each group) were re-examined. The survival rates on the implant and restorative levels were 100% and 82.4% (equally for both groups), respectively. At 5 years, the median marginal bone level was located at −0.15 mm (IQR: −0.89 mm; 0.27 mm) (CEM) and −0.26 mm (IQR: −0.38 mm; 0.01 mm) (SCREW) below the implant shoulder (intergroup p = .9598). The median changes between baseline and the 5-year follow-up amounted to −0.23 mm (CEM; intragroup p = .0002) and −0.15 mm (SCREW; intragroup p = .1465) (intergroup p = .1690). The overall technical complication rate at 5 years was 15.4% (CEM) and 15.4% (SCREW) (intergroup p = 1.00). Clinical parameters remained stable over time (baseline to 5 years).

Conclusions: At 5 years, screw-retained and cemented restorations rendered largely the same clinical, technical, and radiographic outcomes. Technical complications were frequent in both groups.

Keywords: cemented, crowns, dental abutments, screw-retained, single-tooth dental implants
Dental implants for the rehabilitation of single-tooth gaps are a valuable therapeutic option resulting in high long-term survival and success rates (Donati et al., 2016; Jemt, 2016; Jung et al., 2012; Zembic et al., 2015). Titanium abutments restored with porcelain fused to metal crowns are considered to be the gold standard (Andersson, 1995; Linkevicius & Vaitelis, 2015; Zembic et al., 2014), but leading to a more pronounced discoloration of the mucosa, predominantly in cases with a thin phenotype. In order to improve esthetics, zirconia-based restorations were introduced (Dede et al., 2016; Lops et al., 2013). Zirconia exhibits a high biocompatibility and is reported to lead to less plaque accumulation (Nakamura et al., 2010). Based on systematic reviews, zirconia abutments were found to result in superior clinical parameters (e.g., bleeding on probing) compared with titanium abutments (Sanz-Martin et al., 2018). In contrast, the clinical fracture rate was reported to be higher compared with metal abutments (Nilsson et al., 2017; Sailer et al., 2018).

Apart from the choice of the material, the clinician needs to decide on the type of retention (screw-retained or cemented). Both types of restorations rendered favorable clinical outcomes, but differed in the extent and the type of complication observed (Milen et al., 2015; Sailer et al., 2012; Wittneben et al., 2014). Most importantly, the probability of excess cement around cemented restorations may lead to inflammation of the peri-implant mucosa and subsequently to marginal bone loss (Jepsen et al., 2015; Staubli et al., 2017). A preclinical study, however, reported no difference in the inflammatory infiltrate around cemented crowns in comparison with screw-retained crowns (Assenza et al., 2006). Applying a strict clinical cementation protocol including the placement of retraction cords and searching for excess cement after cementation by using visual, tactile, and radiographic methods, the incidence of excess cement may possibly be reduced.

Cemented all-ceramic restorations on customized zirconia abutments are documented up to 11 years and demonstrated stable marginal bone levels in clinical studies (Zembic et al., 2015), but a high rate of technical complications. This included complications such as minor chipping, occlusal roughness, and loss of retention due to a framework fracture. Screw-retained restorations exhibit more technical complications, but less serious biological complications (Sailer et al., 2012). Moreover, it allows for a simpler clinical procedure and an easier maintenance during the follow-up, since the restorations are retrievable (Jemt, 2009). To date, no RCT compared cemented and screw-retained zirconia-based restorations in terms of radiographic, biological, and technical complications on the mid-term.

The aim of this study was, therefore, to compare cemented and screw-retained zirconia-based restorations in terms of clinical, radiographic, and technical outcomes up to 5 years after insertion. Changes of the marginal bone levels from crown insertion to 5 years were considered as primary outcome.

The clinical and laboratory procedures were described in detail in a previous publication (Thoma et al., 2018). In brief, after impression taking (digitally or conventionally) the zirconia abutments (Straumann CARES system) were designed and fabricated. For group...
CEM (cemented crowns), it was essential to have the correct position of the abutment margin in relation to the peri-implant mucosa. The crown margin was placed 0.5 mm submucosally and confirmed during a clinical try-in. Lithium disilicate crowns (IPS e.max press, Ivoclar Vivadent, Schaan, Liechtenstein) were then fabricated. All abutment screws were tightened to 35 Ncm. The abutments were designed and then directly veneered using veneering ceramics. The restorations were inserted with a torque of 35 Ncm. A Teflon tape and composite (Tetric, Ivoclar Vivadent) were used to close the screw access holes of the crowns.

2.3 | Maintenance and follow-up

All patients were recalled for a baseline examination (7–10 days after crown insertion) and at 6 months, 1 year, 3 years, and 5 years of loading. At all time-points, the following outcomes were assessed:

2.4 | Marginal bone level

Standardized single-tooth radiographs were taken and marginal bone levels calculated at 10x to 15x magnification using an open-source software (ImageJ, National Institute of Health). The distance between the implant shoulder and the bone crest was assessed at the mesial and distal aspect of each implant (MBL). The known distance between the implant threads (0.8 mm) was used for the calibration of the images. Mesial and distal values were averaged for further calculations. Changes over time were determined as the difference between MBL at 5 years and MBL at baseline (5 years−BL); positive values represent MBL gains, and negative values represent MBL losses.

2.5 | Technical outcome measures

Technical aspects were evaluated using modified USPHS (United States Public Health Service) criteria (Cvar & Ryge, 2005). In brief, the abutments and restorations were examined for catastrophic fracture, fracture of the veneering ceramic, abutment screw fracture, abutment screw loosening, occlusal wear, marginal adaption, and loss of retention. All parameters were rated alpha (A) in case of no complication, bravo (B) in case of minor extent of the complication, charlie (C) if the complication was major, or delta (D) if the abutment and/or restoration had to be removed due to the complication.

2.6 | Clinical and esthetic parameters

Biological parameters included the plaque control record (PCR) (O’Leary et al., 1972) bleeding on probing (BOP) and probing depth (PD) values. These parameters were assessed at six sites of the implants and the adjacent mesial and distal teeth by means of a periodontal probe (PCB 12; Hu-Friedy). The width of keratinized tissue (KT) was assessed at the buccal midfacial aspect of the implant and neighboring teeth. The thickness of buccal mucosa was measured 1 mm apically of the mucosal margin using an endodontic file. The clinical crown height was measured by means of a periodontal probe from the buccal midfacial mucosa margin to the middle of the incisal edge of the implant crown. Furthermore, the gingival recession (REC) as well as the height of the papilla was evaluated (Jemt, 1997).

2.7 | Statistical analysis

A power analysis was carried out in order to determine the sample size with a two-sample t-test using data from previous studies (Albrektsson et al., 1986; Palmer et al., 2000). A sample size of 15 in each group was supposed to have a power of 80% to detect a difference in means of −0.5 mm (the difference between the control group [2.3 mm] and the test group [2.8 mm]), assuming that the common standard deviation is 0.46 mm using a two-group t-test with a 0.05 two-sided significance level. Assuming a drop-out rate of 10%, the target sample size in each group was increased to 17.

Descriptive statistics (mean, SD, median, and quartiles) were calculated for all metric parameters. Differences between the CEM and SCREW group with respect to the primary endpoint (marginal bone) were tested with the Mann–Whitney U-test at baseline and at 5 years with exact p-value calculations because of the small sample sizes. The changes within each group between baseline and 5 years were tested with the Wilcoxon signed-rank test with exact p-value calculations. The significance level α was set to 5%. All statistical analyses and plots were computed with the statistical software SAS 9.4 (SAS Institute Inc.). For categorical parameters, frequencies were derived and the comparison of the two groups is based on the chi-square test with exact p-value derivations.

3 | RESULTS

Twenty-six patients with 26 implants (mean age 55.9 ± 16.0 years, with a range of 28.4 to 85.4 years) were re-examined at the 5-year follow-up (Figures 1 and 2).

Between the baseline visit and the 5-year follow-up, eight patients were considered as drop-out (23.5%) for the following reasons: diseased (three patients, two CEM and one SCREW), non-compliance (three patients, CEM), or moved away (one patient, SCREW). One patient (CEM) was excluded after the baseline visit because the abutment had been modified with veneering ceramic in the subgingival part due to a misunderstanding with the technician. The 26 implants in the patients attending the 5-year follow-up replaced:
(i) CEM: 5 incisors, 2 canines, and 6 premolars; two implants were in the mandible and 11 in the maxilla.
(ii) SCREW: 4 incisors, 1 canine, and 8 premolars; eleven implants were in the maxilla and 2 in the mandible.

3.1 Marginal bone levels and changes

All data are presented in Table 1. The median marginal bone levels (MBLs) at baseline were 0.05 mm (Q1 = −0.66; Q3 = 0.33) in group CEM and 0.03 mm (Q1 = −0.21; Q3 = 0.49) in group SCREW (intergroup comparison p = .5271). At the 5-year follow-up, the median MBL was located at −0.15 mm (Q1 = −0.89; Q3 = 0.27) (CEM) and −0.26 mm (Q1 = −0.38; Q3 = −0.01) (SCREW) below the implant shoulder (intergroup comparison p = .9598). The changes between baseline and the 5-year follow-up amounted to −0.23 mm (Q1 = −0.55; Q3 = −0.07, p = .0002) for CEM and −0.15 mm (Q1 = −0.51; Q3 = −0.10, p = .1465) for SCREW (intergroup comparison p = 0.1690) (Table 1).

3.2 Clinical parameters

BOP, PCR, PD, or KT values were stable over time (baseline to 5 years) in groups CEM and SCREW as well as at control teeth (Table 2).

3.3 Technical outcomes

Over 5 years including all 34 patients examined at baseline, the following technical complications occurred: two abutment fractures (SCREW), five minor chipping (four CEM, one SCREW), and one major chipping (CEM). The latter happened in a patient that had two minor chippings prior to the major chipping. The restoration was subsequently replaced. The overall technical complication rate for the 26 patients being re-examined at 5 years was 15.4% (CEM) and 15.4% (SCREW) (intergroup p = 1.00).

In group CEM, one restoration had a visible cementation gap on the X-ray at baseline as well as at 5 years.

All technical outcome measures are reported in Table 3. All esthetic parameters including mucosal thickness, papilla index (Jemt, 1997), and crown height are reported in Table 4.

4 DISCUSSION

The present RCT demonstrated similar clinical and technical outcomes for cemented (CEM) and screw-retained zirconia restorations. Implants restored with cemented restorations exhibited slightly higher changes in marginal bone levels than implants with screw-retained restorations. Technical complications occurred frequently in both groups.

Zirconia-based restorations on dental implants were evaluated in numerous clinical studies, predominantly in the esthetic zone.
Clinical data are supportive for this type of material with the longest follow-up being 11 years (Ekfeldt et al., 2017; Passos et al., 2016; Zembic et al., 2015). The majority of data on zirconia restorations is derived from studies applying two-piece implants with a matching implant-abutment junction. Based on a systematic review with estimated 5-year data comparing zirconia and metal-based restorations, survival rates on the restorative level were similar (Jung et al., 2012). In the past, implant systems were further developed. Moreover, the clinical community appears to favor two-piece implants with a horizontal offset (nonmatching implant-abutment junction) (Cochran et al., 2009, 2013; Monje & Pommer, 2015). It is important to bear in mind that systematic reviews hardly ever distinguish between different implant systems and designs. The reported estimated survival rates can therefore not be generalized. Based on laboratory studies, the type of connection between the implant and the abutment significantly influences fracture strength and bending moments (Sailer et al., 2009, 2018). Considering that the implant design has an influence at least on technical outcomes in vitro and only limited data exist for a minority of implant systems with a horizontal offset (Eisner et al., 2018; Laass et al., 2018; Schnider et al., 2018), it is of importance to study the two commonly used modes of fabrication with further implant systems and a longer-term follow-up. Based on the

Table 1: Marginal bone levels at baseline and at 5-year follow-up

|                     | Cemented          | Screw-retained      | p-value |
|---------------------|-------------------|---------------------|---------|
| **Baseline**        |                   |                     |         |
| N                   | 17                | 16                  |         |
| Mean ± SD           | −0.06 mm ± 0.63   | 0.16 mm ± 0.53      | 0.5271  |
| Median (Q1;Q3)      | 0.05 mm (−0.66; 0.33) | 0.03 mm (−0.21; 0.49) |         |
| **5 year follow-up**|                   |                     |         |
| N                   | 13                | 13                  |         |
| Mean ± SD           | −0.39 mm ± 0.82   | −0.2 mm ± 0.28      | 0.9598  |
| Median (Q1;Q3)      | −0.15 mm (−0.89; 0.27) | −0.26 mm (−0.38; −0.01) |         |
| **change**          |                   |                     |         |
| N                   | 13                | 13                  |         |
| Mean ± SD           | −0.34 mm ± 0.31   | −0.20 mm ± 0.41     | 0.1690  |
| Median (Q1;Q3)      | −0.23 mm (−0.55; −0.07) | −0.15 mm (−0.51; −0.11) |         |

Abbreviations: SD, Standard deviation; Q1, quartile 1; Q3, quartile 3.
### TABLE 2 Clinical parameters at baseline and at the 5-year follow-up

| Variable                | Cemented | Screw-retained |
|-------------------------|----------|----------------|
|                         | Mean ± SD | Median (Q1; Q3) | Mean ± SD | Median (Q1; Q3) |
| Baseline BOP (%)        | 32.4 ± 26.7 | 33.3 (0.0; 58.3) | 16.7 ± 14.9 | 16.7 (0.0; 33.3) |
| Baseline PCR (%)        | 9.8 ± 20.5 | 0.0 (0.0; 8.3) | 5.2 ± 10.0 | 0.0 (0.0; 12.5) |
| Baseline PD (mm)        | 2.9 ± 0.51 | 2.8 (2.5; 3.3) | 3.0 ± 0.58 | 2.9 (2.7; 3.2) |
| Baseline KT (mm)        | 3.0 ± 1.4 | 3.0 (2.0; 4.0) | 3.9 ± 0.9 | 4.0 (3.0; 5.0) |
| 5 year follow-up BOP (%) | 37.2 ± 32.0 | 33.3 (16.7; 66.6) | 33.3 ± 28.4 | 33.3 (4.2; 50) |
| 5 year follow-up PCR (%) | 12.8 ± 15.4 | 0.0 (0.0; 33.3) | 6.9 ± 11.1 | 0.0 (0.0; 16.7) |
| 5 year follow-up PD (mm) | 3.2 ± 0.6 | 3.3 (2.8; 3.6) | 3.2 ± 0.5 | 3.1 (2.7; 3.5) |
| 5 year follow-up KT (mm) | 3.0 ± 1.3 | 3.0 (2.3; 3.8) | 3.5 ± 1.2 | 3.8 (2.3; 4.5) |

Abbreviations: BOP, Bleeding on probing; PCR, plaque control record; PD, probing depth; KT, keratinized tissue; implant, implant site; tooth, contralateral tooth.

### TABLE 3 Technical outcome measures (USPHS) at baseline and at the 5-year follow-up

|          | Cemented | Screw-retained |
|----------|----------|----------------|
|          | A  B  C  |                | A  B  C  D  |
| Baseline |          |                |          |
| Patient’s satisfaction | 17 0 0 0 | 16 0 0 0 |
| Marginal adaptation | 16 1 0 0 |  |
| Veneering fracture | 15 2 0 0 | 16 0 0 0 |
| Abutment fracture | 17 0 0 0 | 16 0 0 |
| Anatomical form | 17 0 0 0 | 16 0 0 0 |
| Proximal contact mesial | 12 4 1 | 11 3 2 |
| Proximal contact distal | 10 5 1 | 11 2 3 |
| Occlusion | 13 0 4 | 14 0 2 |
| Occlusal wear | 17 0 0 | 16 0 0 |
| Color | 17 0 0 0 | 16 0 0 0 |
| X-ray: cementation gap visible | 16 1 0 0 |  |
| After 5 year follow-up |          |                |          |
| Patient’s satisfaction | 13 0 0 0 | 13 0 0 0 |
| Marginal adaptation | 10 3 0 0 |  |
| Veneering fracture | 11 2 0 0 | 12 1 0 0 |
| Abutment fracture | 13 0 0 0 | 12 1 0 |
| Anatomical form | 13 0 0 0 | 12 1 0 0 |
| Proximal contact mesial | 6 3 4 | 3 3 7 |
| Proximal contact distal | 8 4 0 | 7 3 3 |
| Occlusion | 11 0 2 | 8 0 5 |
| Occlusal wear | 8 5 0 | 11 2 0 |
| Color | 12 1 0 0 | 13 0 0 |
| X-ray: cementation gap visible | 13 0 0 0 |  |

Abbreviations: A, Alpha; B, Bravo; C, Charlie; D, Delta.
above-mentioned three- and five-year data of a prospective clinical study (Eisner et al., 2018; Laas et al., 2018), all-ceramic restorations based on zirconia abutments tend to result in an increased rate of technical complications. This was further underlined by the present study, using a different implant system, but a similar connection, with an overall rate of 15.4% of technical complications in both groups. Clearly, internally connected zirconia-based restorations were prone for technical complications including abutment fracture, major chippings, and minor chipping. This is slightly higher to the commonly reported chipping rates for single-implant-borne restorations of 4.5% at 5 years based on a systematic review (Jung et al., 2012). Similarly, higher incidences of chippings for all-ceramic zirconia-based restorations with veneering were reported in a retrospective study and predominantly when compared to porcelain fused to metal crowns or monolithic crowns (Schwarz et al., 2012).

The bone loss in the present study is within the regular range for this type of implant, mostly occurring within the first year after loading (Albrektsson et al., 1986; Schnider et al., 2018). Only minor median crestal bone changes relative to the implant shoulder were observed between baseline and the 5-year follow-up. Changes from crown insertion to 5 years were −0.23 mm (CEM) and −0.15 mm observed between baseline and the 5-year follow-up. Changes from median crestal bone changes relative to the implant shoulder were −0.23 mm (CEM) and −0.15 mm (SCREW). Similar results were presented in previous clinical data for two-piece dental implants with a horizontal offset revealing only minor changes over time and bone levels close to the implant shoulder (Nilsson et al., 2017; Schnider et al., 2018; Wittneben et al., 2017). Even though revealing slight differences (not statistically significant) in terms of marginal bone level changes, the radiographic outcomes were similar for both groups.

The outcomes of the present study are to some extent limited by the small sample size, a relatively high drop-out rate (8 out of 34 patients). Moreover, single-tooth implants in the posterior region were not included. Due to higher chewing forces, zirconia abutments for molars might be more prone to fracture although a comparison between titanium and zirconia abutments over 5 years did not find any difference in technical complications between the two materials in the posterior region (Zembic et al., 2013). Furthermore, according to strict inclusion criteria, patients with poor oral hygiene, heavy smokers, or pregnant patients were excluded. For these reasons, the present outcomes cannot be generalized.

5 | CONCLUSION

Limited by a relatively high drop-out rate and strict inclusion criteria excluding molars, screw-retained and cemented single crowns on customized zirconia abutments demonstrated similar clinical, technical, and radiographic outcomes at 5 years. The rate of technical complications, however, was relatively high in both groups.

ACKNOWLEDGMENTS

The authors would like to thank Mrs Gisela Müller for the data management and general support of the study. The study was supported by a grant of the International Team for Implantology (ITI), ITI research grant 780_2011 and by the Clinic of Reconstructive Dentistry, University of Zurich. Open Access funding provided by Universitat Zurich.

CONFLICT OF INTEREST

The authors report no conflict of interest.

AUTHOR CONTRIBUTIONS
Sofia Lamperti: Data curation (equal); Formal analysis (equal); Investigation (equal); Visualization (equal); Writing – original draft (lead). Karin Wölleb: Conceptualization (equal); Data curation (equal); Funding acquisition (equal); Methodology (equal); Project administration (equal); Writing – review & editing (equal). Christoph H.F. Hämmerle: Conceptualization (equal); Funding acquisition (equal); Methodology (equal); Resources (equal); Supervision (equal); Writing – review & editing (equal). Ronald Ernst Jung: Conceptualization (equal); Supervision (equal); Writing – review & editing (equal). Juerg Huesler: Formal analysis (equal); Visualization (equal); Writing – review & editing (equal). Daniel S Thoma: Conceptualization (equal); Formal analysis (equal); Funding...
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How to cite this article: Lamperti, S. T., Wolleb, K., Hämmerle, C. H. F., Jung, R. E., Hüslér, J., & Thoma, D. S. (2022). Cemented versus screw-retained zirconia-based single-implant restorations: 5-year results of a randomized controlled clinical trial. *Clinical Oral Implants Research*, 33, 353–361. https://doi.org/10.1111/clr.13895