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Five-year randomized controlled clinical study comparing cemented and screw-retained zirconia-based implant-supported single crowns

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Abstract

Objectives: To compare screw-retained and cemented all-ceramic implant-supported single crowns regarding biological and technical outcomes over a 5-year observation period.

Materials and methods: In 44 patients, 44 two-piece dental implants were placed in single-tooth gaps in the esthetic zone. Patients randomly received a screw-retained (SR) or cemented (CR) all-ceramic single crown and were then re-examined annually up to 5 years. Outcome measures included: clinical, biological, technical, and radiographic parameters. Data were statistically analyzed with Wilcoxon–Mann–Whitney, Wilcoxon, and Fisher's exact tests.

Results: During the observation period, three patients (6.8%) were loss to follow-up. Eight restorations (18.2%, CI (8.2%, 32.7%)) were lost due to technical (6 patients, 13.6% (CI (5.2%, 27.4%)), 2 CR and 4 SR group, intergroup $p = .673$; implants still present) or biological complications (2 patients, 4.5% (CI (0.6%, 16.5%)), only CR group, intergroup $p = .201$, both implants lost). This resulted in a survival rate of 81.2% (CI (65.9%, 90.1%)) on the restorative level (18 SR; 15 CR, 3 lost to follow-up). At the 5-year follow-up, the median marginal bone levels were located slightly apical relative to the implant shoulder with 0.4 mm (0.5; 0.3) (SR) and 0.4 mm (0.8; 0.3) (CR) (intergroup $p = .582$). Cemented restorations demonstrated a significantly higher biological complication rate (36.8%, SR: 0.0%; intergroup $p = .0022$), as well as a significantly higher overall complication rate (68.4%, SR: 22.7%, intergroup $p = .0049$). All other outcomes did not differ significantly between the two groups ($p > .05$).

Conclusions: All-ceramic single-tooth restorations on two-piece dental implants resulted in a relatively low survival rate. Cemented restorations were associated with a higher biological and overall complication rate than screw-retained restorations.

Riccardo D. Kraus and Catharina Espuelas contributed equally to the study.

KEYWORDS
biologic complications, cemented, ceramic abutments, implant abutments, screw-retained, single crowns, technical complications, zirconia

1 | INTRODUCTION

The use of dental implants as a replacement of missing teeth in partially edentulous patients has become a well-documented treatment option, in particular for single-tooth gaps (Jung et al., 2012; Pjetursson et al., 2012; Pjetursson, Valente, et al., 2018; Rabel et al., 2018). Various materials for implant-supported single crowns were proposed. Metal abutments in combination with metal-ceramic crowns are considered the gold standard, demonstrating excellent survival rates (Bidra & Rungruanganunt, 2013; Jung et al., 2012; Pjetursson et al., 2012; Pjetursson, Zarauz, et al., 2018; Sailer, Philipp, et al., 2009). In order to overcome esthetic limitations in the anterior regions of the jaws, ceramic abutments were introduced. They show particular esthetic advantages, in cases with thin facial mucosa (Sailer, Philipp, et al., 2009). One-piece zirconia abutments can be used, particularly in cases with high esthetic demands, characterized by thin tissues, where a metal abutment could shimmer through the mucosal tissue, and even the widely used all-ceramic CAD/CAM restorations on titanium bases may encounter some esthetic limitations. Previous data suggested similar survival rates of zirconia, compared with metal abutments (Sailer, Philipp, et al., 2009). However, the majority of the studies included abutments on implants with external connections, whereas the documentation on one-piece internally connected zirconia abutments, in particular on two-piece implants, remained scarce.

The choice of the retention mode, cemented and screw-retained, respectively, has been largely debated in the past years. Clinical studies and systematic reviews tried to answer the question whether or not the use of a specific retention mode results in more favorable outcomes over time, suggesting a tendency for a higher rate of biological complications for cemented all-ceramic implant-supported crowns and more technical complications for screw-retained all-ceramic restorations (Pjetursson, Zarauz, et al., 2018; Sailer et al., 2012). Nevertheless, there is still a lack of long-term data showing clear advantages of one retention mode over the other, in particular with respect to one-piece ceramic abutments on two-piece dental implants.

Therefore, the aim of the present 5-year randomized controlled clinical study was to compare screw-retained and cemented all-ceramic implant-supported single crowns regarding biological and technical outcomes over a 5-year observation period.

2 | MATERIALS AND METHODS

2.1 | Study design and subjects

The present study was designed as a parallel, single-center randomized controlled clinical trial. It was registered in the German Clinical Trials Register (DRKS; Nr. DRKS00006221) and adhered to the CONSORT guidelines (Appendix S1). Procedures and materials applied in the study were all approved by the local ethical committee (Kantonale Ethik-Kommission Zürich; KEK-ZH-Nr.2010–0041) and in accordance with the Declaration of Helsinki. All patients provided an informed consent prior to the enrollment.

Overall, 44 patients (22 women and 22 men) were consecutively recruited at the Clinic of Reconstructive Dentistry, University of Zurich, between November 2011 and February 2014. A detailed description on material and methods was given earlier (Thoma et al., 2016). Two-piece dental implant (OsseoSpeed, Astra Tech Implant System Dentsply Sirona Implants, Mölndal, Sweden) was placed in a single-tooth gap in the esthetic zone. Implant sites included incisor, canine, and premolar positions, in both the upper and lower jaws. At screening, the following inclusion criteria were applied: successful osseointegration, no signs of bruxism, good oral hygiene, no systemic disease, smokers, and non-smokers. Patients were randomly assigned to a screw-retained (SR) or cemented (CR) restoration, according to a computer-generated randomization list. Allocations were concealed using sealed envelopes and eventually disclosed the day of the final impression.

All patients received one-piece customized CAD/CAM zirconia abutments (Atlantis, Dentsply Sirona Implants, Mölndal, Sweden). All abutments were designed by the same dental technician, following manufacturer's guidelines and fabricated in a centralized milling center. The zirconia abutments for the SR group were directly veneered (Creation ZI-F, Creation Willi Geller International GmbH), and the resulting one-piece restorations were fixed with a torque of 20 Ncm onto the implants. The screw holes were sealed using a composite material.

In the CR group, zirconia abutment shoulders were checked for dimension and position. If necessary, the height was adjusted to position it circumferentially 1 mm submucosally. Abutments were then screwed applying a torque of 20 Ncm. A retraction cord (Ultrapak, Ultradent Products GmbH) was placed, and the veneered lithium disilicate crowns (e.max, e.max Ceram, Ivoclar Vivadent) were cemented intraorally with a resin cement (Panavia 21, Kuraray Medical, Kuraray Europe GmbH). Any cement excess was carefully removed, and the presence of further remnants was checked radiographically.

All patients were enrolled in a supportive care program, including annual check-ups by their referring clinicians, as well as professional dental hygiene appointments at the University clinic (1 to 3, according to their individual needs).

2.2 | Follow-up examinations and outcome measures

Included patients were recalled for a baseline examination (BL; 1–3 weeks after crown insertion, Figures 1a and 2a), at 6-month follow-up (FU-6 M), at 1 year (FU-1Y), at 3 years (FU-3Y) as well

as at 5 years (FU-5Y, Figures 1b and 2b). For standardization purposes, all follow-up examinations were executed by a calibrated prosthodontist.

2.2.1 | Biological parameters

Periodontal parameters including probing depth (PD; Ramfjord, 1959), bleeding on probing (BOP) (Ainamo & Bay, 1975), plaque control record (PCR) (O'Leary et al., 1972), and mucosal/gingival recession (REC) were assessed with a periodontal probe at six sites around each implant and control tooth. The width of keratinized mucosa (KM) at implant/control tooth sites was measured at the mid-buccal aspect with the same instrument.

The thickness of the buccal mucosa was measured using an endodontic file at 1 mm below the mucosal (implant site)/gingival (control tooth) margin to the nearest 0.5 mm.

2.2.2 | Radiographic examination

Standardized digital x-rays (Digora Optime, Soredex) were taken at the implant sites applying a paralleling technique with Rinn holders at the day of implant placement (IP), at baseline and all follow-up examinations up to 5 years. An open-source software (Image J; National Institute of Health) was used to measure the marginal bone level (MBL). The pitch distance between two implant threads was used for calibration. Therefore, the distance between the implant shoulder and the bone crest was quantified at the mesial and distal aspect of the implants to the nearest of 0.1 mm (MBL). The operator repeated the measurements 2 weeks after the first assessment. An intra-rater agreement was calculated. Eventually, MBL changes were quantified from baseline to 5 years.

Peri-implant diseases were defined as follows:

- Peri-implant mucositis: clinical signs of inflammation (BOP at >50% of the sites per implant) without crestal bone loss exceeding 2 mm.
- Peri-implantitis: Peri-implant mucositis combined with crestal bone loss exceeding 2 mm.

2.2.3 | Profilometric measurements

At all follow-ups, conventional impressions with an a-silicone material (President, Contène/Whaledent) were obtained and subsequently casts of dental stone class IV were poured. The casts were then scanned with a desktop 3D scanner (Imetric 3D SA) generating stereolithographic files (standard tessellation language, STL). Generated data were imported into an image analysis software (Swissmeda Software, Swissmeda AG). STL files from BL and FU-5Y of each patient were superimposed using a semiautomatic algorithm, followed by manually adjusting according to reference structures. These reference structures mainly consisted in teeth,

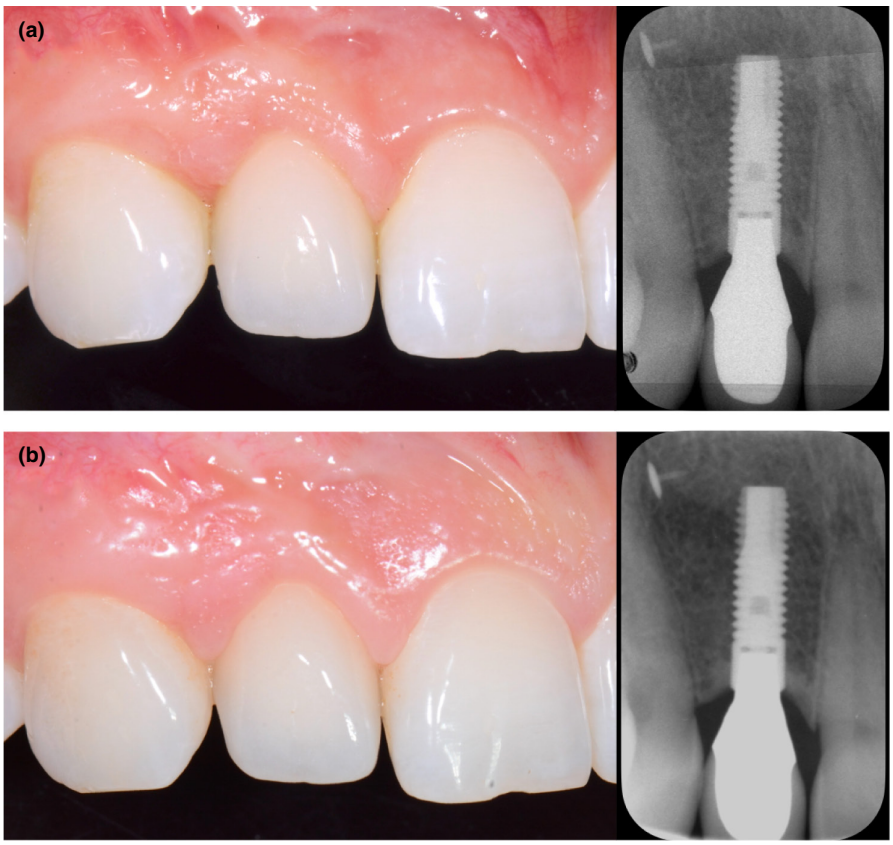

FIGURE 1 All-ceramic implant-borne screw-retained restoration at baseline (a) and at 5-year follow-up (b). Site 12

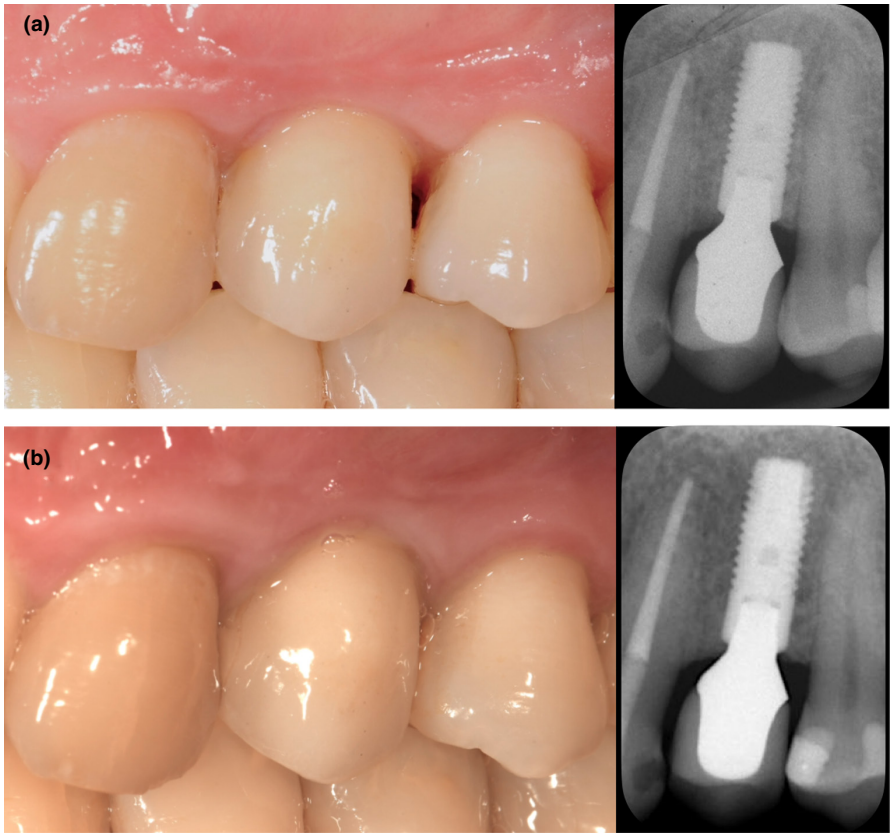

FIGURE 2 All-ceramic implant-borne cemented restoration at baseline (a) and at 5-year follow-up (b). Site 24

TABLE 1 Probing depth (PD) at screw-retained resp. cemented restorations, as well as at contralateral control teeth, at BL, FU-3Y, and FU-5Y

	PD (mm)						
	Screw-retained restorations (SR)			Cemented restorations (CR)			
	BL	FU–3Y	FU–5Y	BL	FU–3Y	FU–5Y	*p*-value
Mean ± SD	2.7 ± 0.5	3.2 ± 0.7	3.5 ± 0.6	3.0 ± 0.5	3.3 ± 0.6	3.5 ± 0.8	
Median	3.0	3.0	3.5	3.0	3.0	3.5	.821
Q1;Q3	2.5;3.0	2.5;3.5	3.0;4.0	3.0;3.0	3.0;4.0	3.0;4.0	
p-value	<.001*						.309**
	Control tooth (SR)			Control tooth (CR)			
	BL	FU–3Y	FU–5Y	BL	FU–3Y	FU–5Y	*p*-value
Mean ± SD	2.6 ± 0.5	2.4 ± 0.6	2.4 ± 0.5	2.6 ± 0.5	2.5 ± 0.5	2.5 ± 0.6	
Median	3.0	2.0	2.5	3.0	2.8	2.5	.775
Q1;Q3	2.0;3.0	2.0;3.0	2.0;2.5	2.0;3.0	2.0;3.0	2.0;3.0	
p-value	.309*						.542**

Note: *p*-values between the groups (intergroup) for FU-5Y (Wilcoxon).

**p*-values time factor (mixed model).

***p*-value intergroup (mixed model).

which had not been treated during the observation period. This procedure was double-checked and confirmed by a second experienced examiner. A region of interest (ROI) was defined for the STL files in all patients. For that purpose, the coronal border of the ROI was selected to run parallel to the mucosal margin of the implant site with a clearance of approximately 1 mm. Mesio-distally, the ROI was centered and symmetrically narrower than the width of the single-tooth restoration. The software then calculated the mean distance (MD) between the baseline surface and the FU-5Y surface within the ROI.

2.2.4 | Technical parameters

Technical aspects were assessed according to modified USPHS (United States Public Health Service) criteria at 6 months, 1 year, 3 years, and 5 years (Cvar & Ryge, 2005). In short, all restorations were examined for fracture of the framework or the veneering ceramic, occlusal roughness, loss of retention, and over-/undercontouring. All parameters were assigned to either alfa (A) in case of no problem, bravo (B) in case of minor extent of the complication, charlie (C) if the complication was major, and delta (D) in case the restoration had to be replaced because of the complication.

2.2.5 | Soft tissue examinations

The Modified Papilla Index (according to Jemt, scores from 0 to 4) was used to evaluate the mesial and distal papillae of the implant sites (Jemt, 1999).

In order to evaluate possible gingival recession or gain at the implant sites, the superimposed STL files of BL and FU-5Y were analyzed with the same image analysis software (Swissmeda Software, Swissmeda AG). Therefore, the vertical distance between the midfacial mucosal margin of the respective BL and FU-5Y STL files was quantified by the software (in mm).

2.3 | Statistical analysis

Out of all acquired data, mean values, SDs, min, max, and quartiles were calculated and eventually analyzed descriptively. For survival and complication rates, the 95% confidence interval was calculated. The multiple testing was controlled by the Bonferroni correction. Hence, a result was significant if a *p*-value was smaller than .025.

Tests applied for the group comparisons of numeric variables consisted in the Wilcoxon–Mann–Whitney test for independent data and the Wilcoxon test for paired data to analyze the FU-5Y data. The time effect was analyzed conducted with mixed model with all available data, with time and group including their interaction. The survival time was analyzed by Kaplan–Meier survival analysis.

The Fisher's exact test was applied for analyses of frequencies.

3 | RESULTS

Overall, 44 final restorations were inserted (20 CR, 24 SR). An overview on the location of the implant sites is shown in Table S1. Out of the initially included subjects, three patients (6.8%) were not available for the 5-year follow-up. Two of them, both with screw-retained restorations, could not be contacted despite several attempts. The third patient, with a cemented restoration, died 21 months after the baseline examination. Furthermore, eight restorations were lost due to technical (6 patients, 13.6%, CI (5.2%, 27.4%), 2 CR and 4 SR group, intergroup $p = .673$; implants still present) or biological complications (2 patients, 4.5%, CI (0.6%, 16.5%), only CR group, intergroup $p = .201$; both implants lost). All six patients, who lost their original restoration because of technical complications, were provided with new ones and regularly examined. This resulted in 33 subjects (original restorations) and 6 patients (new restorations) attending the 5-year follow-up. For the evaluation of the FU-5Y results, only measurements assessed from the originally inserted restorations (33 patients) were included. The mean age at FU-5Y was 52.8 (±17.1) years.

3.1 | Biologic outcomes

3.1.1 | Clinical parameters

Clinical parameters such as PCR, BOP, and PD are shown in Tables 1 and 2. Further clinical parameters like width of keratinized mucosa, soft tissue thickness, contour changes, mucosal/gingival level changes, and Modified Papilla Index are presented in Tables S2 to S6. At 5 years, the implant sites revealed a median PD of 3.5 mm (Q1:3.0; Q3:4.0) in the SR and 3.5 mm (3.0; 4.0) in the CR group ($p = .821$). From BL to FU-5Y, the changes in PD were not significantly different between the groups (intergroup comparison $p = .6982$).

TABLE 2 Plaque control record (PCR) and bleeding on probing (BoP) at screw-retained resp. cemented restorations, as well as at contralateral control teeth, at FU-5Y (in %)

	Screw-retained restorations (SR) $n = 18$			Cemented restorations (CR) $n = 15$			
	Mean ± SD	Median	Q1;Q3	Mean ± SD	Median	Q1;Q3	*p*-value
PCR	15 ± 17	17	0;21	19 ± 21	17	0;33	.627
BOP	27 ± 15	33	17;33	43 ± 36	33	17;83	.288
	Control tooth (SR)			Control tooth (CR)			
	Mean ± SD	Median	Q1;Q3	Mean ± SD	Median	Q1;Q3	*p*-value
PCR	21 ± 20	17	0;33	20 ± 18	17	0;33	.939
BOP	17 ± 23	8	0;33	22 ± 23	17	0;33	.413

Note: *p*-values between the groups (intergroup, Wilcoxon).
The factor tooth is significant ($p = .002$) in a mixed model with group and time of all BOP values at FU-5Y, but not for the PCR values ($p = .264$).

The mean plaque control record (PCR) of the implant sites at FU-5Y yielded 15 ± 17% for the SR and 19 ± 21% for the CR group, respectively (intergroup comparison $p = .6265$).

At FU-5Y, implant sites of the CR group showed a higher BOP mean amounting to 43 ± 36%, than the SR group with a mean value of 27 ± 15% (intergroup comparison $p = .2883$).

3.1.2 | Soft tissue thickness and contour changes

From BL to FU-5Y implants, sites revealed a median increase in soft tissue thickness of 1.0 mm (0.5, 1.5) for the SR ($p = .0026$) and of 0.5 mm (0, 1.5) for the CR group ($p = .0889$) (intergroup comparison $p = .3311$).

The profilometric measurements from BL to FU-5Y showed a median decrease of −0.1 mm (−0.4; 0.1) for the SR ($p = .0116$) and −0.1 mm (−0.3; 0.0) for the CR group ($p = .0206$) (intergroup comparison $p = .6381$).

3.1.3 | Biological complications

One implant, supporting a cemented restoration, was lost 9 months after the baseline examination. The reason for the loss remained unknown, given that the implant site revealed no previous signs of peri-implant disease. A second patient (CR) was treated for peri-implant disease, but the therapy remained unsuccessful, and the implant had to be removed between FU-3Y and FU-5Y. After explantation, the restoration revealed cement excess. Over 5 years, only this patient was diagnosed with and subsequently treated for peri-implantitis.

At FU-5Y, 5 implants were diagnosed with peri-implant mucositis (15.2% of all implants); all in group CR (26.3% of the implants/patients in the CR group) (intergroup comparison $p = .0155$).

3.1.4 | Radiographic outcomes

Table 3 displays marginal bone levels (MBL) at the different time points.

The median MBL at baseline amounted to −0.44 mm (−0.70; −0.27) in the SR and −0.52 mm (−0.65; −0.26) in the CR group (intergroup comparison p=0.971). At FU-5Y, the median yielded −0.39 mm (−0.54; −0.28) in the SR and −0.40 mm (−0.79; −0.31) in the CR group (intergroup comparison p=0.582). Hence, median MBL changes of 0.12 mm (−0.15; 0.37) in the SR ($p = .212$) and −0.05 mm (−0.39; 0.17) in the CR group ($p = .463$) were calculated between BL and FU-5Y (intergroup comparison $p = .154$). Only one implant (SR group) showed a loss greater than 1mm over 5 years (1.34 mm).

3.2 | Technical outcomes

All technical outcomes are presented in Table 4.

Major technical complications occurred in 6 out of the 44 initially enrolled patients (4 in the SR and 2 in the CR group). During 5 years

TABLE 3 Marginal bone levels (MBL, in mm) at different time points (BL: baseline, FU-6 M: 6-month follow-up, FU-1Y: 1-year follow-up, FU-3Y: 3-year follow-up, and FU-5Y: 5-year follow-up)

	Marginal bone levels (mm)										
	Screw-retained restorations (SR)					Cemented restorations (CR)					
	BL	FU–6 M	FU–1Y	FU–3Y	FU–5Y	BL	FU–6 M	FU–1Y	FU–3Y	FU–5Y	*p*-value
Mean ± SD	−0.5 ± 0.3	−0.4 ± 0.3	−0.6 ± 0.2	−0.5 ± 0.3	−0.4 ± 0.4	−0.5 ± 0.4	−0.7 ± 0.4	−0.6 ± 0.5	−0.5 ± 0.2	−0.6 ± 0.5	
Median	−0.4	−0.5	−0.5	−0.4	−0.4	−0.5	−0.5	−0.5	−0.4	−0.4	.587
Q1;Q3	−0.7;−0.3	−0.6;−0.2	−0.8;−0.4	−0.5;−0.3	−0.5;−0.3	−0.6;−0.3	−0.8;−0.4	−0.6;−0.4	−0.6;−0.3	−0.8;−0.3	
p-value	.173*										.157**

Note: *p*-values between the groups (intergroup) for FU-5Y (Wilcoxon).
**p*-values time factor (mixed model).; ***p*-value intergroup (mixed model).

TABLE 4 USPHS criteria in percent (and number of restorations) during the 5 years of follow-up, including all crowns (39 patients): 17 cemented restorations (CR) and 22 screw-retained restorations (SR)

		Alfa (A)	Bravo (B)	Charlie (C)	Delta (D)
Fracture of framework	SR	81.8 (18)	-	-	18.2 (4)
	CR	88.2 (15)	-	-	11.8 (2)
Fracture of veneering ceramic	SR	95.5 (21)	4.5 (1)	0.0	0.0
	CR	82.4 (14)	17.6 (3)	0.0	0.0
Occlusal roughness	SR	77.3 (17)	22.7 (5)	0.0	0.0
	CR	29.4 (5)	70.6 (12)	0.0	0.0
Loss of retention	SR	81.8 (18)	Not applicable	0.0	18.2 (4)
	CR	76.5 (13)	0.0 (0)	11.8 (2)	11.8 (2)
Contour of restorations	SR	90.9 (20)	9.1 (2)	0.0	0.0
	CR	94.1 (16)	5.9 (1)	0.0	0.0

(excluding 3 patients lost to follow-up), fractures of the zirconia abutment led to a loss of the restoration in 14.6% of the restorations (18.2% in the SR and 10.5% in the CR group) (intergroup comparison $p = .6681$). For all those patients, new crowns were fabricated and eventually inserted. All new restorations were still in situ at 5 years.

Occlusal roughness was a common finding and was observed in 5 patients in group SR (22.7%) and in 12 patients in group CR (63.2%; intergroup comparison $p = .0124$).

3.3 | Complication and complication-free restorations

The Kaplan–Meier analysis showed, at FU-5Y, an overall survival rate of all-ceramic crowns of 81.2% (CI (65.9%, 90.1%)). The percentage for CR was 79.4% (CI (54.0%, 91.7%)) and for SR 82.6% (CI (60.1%, 93.1%)). The Kaplan–Meier analysis did not show significant differences between the groups ($p = .809$, Figure 3).

Excluding the 3 lost to follow-up patients, and including all technical and biological complications shown in Table 5, the overall rates of complication-free restorations, at FU-5Y, amounted to 77.3% for the SR and 31.6% for the CR group.

Cemented restorations showed a significantly higher complication rate (73.7% of the CR crowns, 36.8% biological, and 36.8% technical) than screw-retained restorations (22.7% of the SR crowns, only technical: 22.7%) (intergroup comparison $p = .0049$).

A detailed presentation of the major complications is shown in Table S7.

4 | DISCUSSION

The present 5-year RCT comparing cemented vs screw-retained zirconia-based single-tooth restorations predominantly demonstrated: (1) a relatively low survival rate of the restorations, (2) a high rate of technical and biological complications, and (3) a higher incidence of complications observed in the CR group.

Over 5 years, the survival rate of the inserted dental implants amounted to 95.5% (SR: 100%, CR: 90.0%), which is in line with survival rates reported in a recent systematic review (95.3% after 5 years) (Rabel et al., 2018). Two major biological complications (one peri-implantitis and one reason unknown) led to the loss of two implants and two restorations, respectively (SR: 0%, CR: 10.0%). On the restorative level, a high incidence of major complications decreased the overall survival rate to 81.2% after 5 years of function (SR: 82.6%; CR: 79.4%). In contrast, the survival rates reported in recent systematic reviews are considerably higher (estimated 5-year survival rate of 93.0%–99.1%; Pjetursson, Valente, et al., 2018; Rabel et al., 2018; Sailer, Philipp, et al., 2009; Zembic et al., 2014). However, those reviews only contain a relatively low number of zirconia abutments, due to a limited number of published clinical studies, in particular, on the long term. The few available studies tend to support the use of zirconia abutments, showing survival rates of 100% after up to 5 years of function (Ekfeldt et al., 2017; Lops et al., 2013; Zembic et al., 2013, 2015).

In the present study, abutment fracture was the main reason for the loss of restorations in both groups (SR: 18.2%, CR: 10.5%). Fracture as a catastrophic failure has been reported in the literature. However, long-time follow-up studies reported significantly lower fracture rates (Ekfeldt et al., 2017; Lops et al., 2013; Zembic et al., 2013, 2015) and a systematic review calculated a cumulative 5-year abutment fracture rate of 1.8% for ceramic abutments (Pjetursson, Zarauz, et al., 2018). It has to be emphasized that, in a large number of studies on zirconia abutments, the restorations were supported by implants with external connections, reporting no or very few fractures (Ekfeldt et al., 2017; Kim et al., 2013; Zembic et al., 2013, 2015). In contrast, the one-piece zirconia abutments in the present study were inserted on implants with internal connection. The speculation that the higher fracture rate could be associated with the connection design is supported by a series of in vitro (Sailer et al., 2009; Truninger et al., 2012) and clinical studies (Ferrari et al., 2016), as well as by a systematic review (Gou et al., 2019). In contrast, a recent systematic review did not disclose any statistically significant difference in the fracture rate of ceramic abutments with either

internal or external connection design (5-year complications' summary estimate: 1.9% for internal and 2.0% for external connection) (Pjetursson, Zarauz, et al., 2018). If the available data on the connection designs seem to be contradictory, another possible explanation for the high fracture rate in the present study could be the implant site. Indeed, four of the six fractured abutments were located in premolar area (3 maxillary and 1 mandibular premolars). However, the majority (75%) of the all-ceramic abutments investigated were located in the premolar area and a correlation between abutment fracture and implant site cannot be proven. Nevertheless, this speculation is in line with a randomized clinical trial including the same abutment type as in the current study, reporting a high incidence of fractures predominantly in posterior sites (4 out of 5 fractures; Ferrari et al., 2016). In contrast, another 5-year follow-up study reported survival rates of 100% even in posterior regions (premolar/molars; Lops et al., 2013).

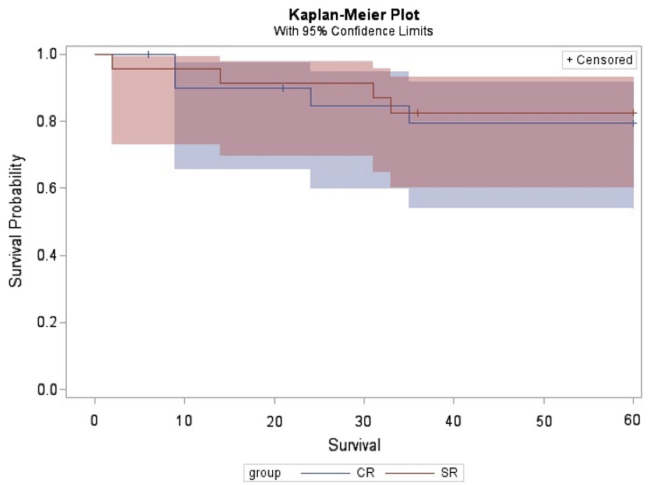

FIGURE 3 Kaplan–Meier plot with 95% confidence limits

Besides the implant-abutment connection type and implant site, variations in wall thickness may have an influence on the survival of zirconia abutments. A series of in vivo (Fabbri et al., 2017; Ferrari et al., 2016; Roe et al., 2011) and in vitro (Sailer et al., 2018; Truninger et al., 2012) studies exhibited the primary fracture location in one-piece internal connection zirconia abutments to be located at the neck of the implant or below the implant shoulder (Fabbri et al., 2017; Ferrari et al., 2016; Roe et al., 2011; Sailer et al., 2018; Truninger et al., 2012). The critical wall thickness of the zirconia abutment still remains unclear. It has been suggested that the dimension should be above 0.5 mm (Amorfini et al., 2018) or at least 0.7 mm (Wilson, 2009). Precise information on both fabrication and handling on zirconia abutments has to be provided in future clinical studies in order to draw conclusions regarding their influence on the clinical success of the abutments.

In the present study, minor technical complications mainly consisted in minor chipping (9.8% of all restorations; SR: 4.5%, CR: 15.8%) and screw loosening (4.9% of all restorations; SR: 0%, CR: 10.5%). Those results are in line with a recent systematic review, which evaluated technical complication rates after 5 years. Chipping was observed for 9.0% (CI (5.4%, 14.8%)) and screw loosening for 3.6% (CI (1.6%, 8.4%)) of all cases included (Rabel et al., 2018).

During the 5 years of follow-up, the biological complication rate was 17.1%, which is to be considered higher than data reported in the literature (5.3% over 5 years [Pjetursson, Valente, et al., 2018]). Out of those, the majority consisted in minor complications (peri-implant mucositis). Whereas the SR group displayed no biological complications, in the CR group two major (loss of implant, 10.5%) and 5 minor (peri-implant mucositis, 26.3%) biological complications were observed during 5 years of function. This difference between the groups was significant ($p = .0022$), while PCR values were similar ($p = .6265$). A recent systematic review reported a total biological complication rate of 6.6% over 5 years. The rate of soft tissue complications was 2.3%. The rate of substantial marginal bone loss for cemented single

TABLE 5 Total complications in number of restorations (and in percent) during the 5 years of follow-up

Complications	Total amount ($n = 41$)	Screw-retained restorations ($n = 22$)	Cemented restorations ($n = 19$)	p-value
Technical complications				
Abutment fracture	6	4	2	.6681
Screw loosening	2	0	2	.2085
Minor chipping	4	1	3	.3210
Biological complications				
Implant loss	2	0	2	.2085
Peri-implant mucositis	5	0	5	.0155
Total technical complications	12 (29.3%)	5 (22.7%)	7 (36.8%)	.4926
Total biological complications	7 (17.1%)	0 (0.0%)	7 (36.8%)	.0022
Total complications	19	5	14	.0017
Total restorations with complications	18 (43.9%)	5 (22.7%)	13 (68.4%)	.0049

Note: Patient 38 (CR) had 2 complications (screw-loosening/peri-implant mucositis).
p values (chi-squares).

crowns was significantly ($p < .001$) higher (1.9%) than the comparable complication rates for screw-retained restorations (0%; Pjetursson, Zarauz, et al., 2018). Another systematic review reported on the prevalence of peri-implant disease varying between 0% and 64% for screw-retained and between 13% and 75% around cemented restorations (Staubli et al., 2017). Those large ranges reflect the inconsistent results of a series of clinical studies, claiming on the one hand, there was no clinical or radiographic difference between the two retention types (Jemt, 2009) and no association between the type of retention and peri-implant disease (Kotsakis et al., 2016), and on the other hand, reporting a great difference of the prevalence of peri-implant disease between screw-retained (1.08%) and cemented restorations (75%) (Linkevicius et al., 2013). A possible explanation for higher incidence around cemented restorations could be attributed to cement excess. In the literature, excess luting cement has been associated with clinical signs of peri-implant mucositis (Linkevicius, Puisys, et al., 2013; Pesce et al., 2015; Renvert & Polyzois, 2015; Wilson, 2009). It has been suggested to place the restoration margins at or above the peri-implant mucosal margin, ensuring proper cement removal (Linkevicius, Puisys, et al., 2013). In esthetically relevant sites, restoration margins should not exceed a 1-mm submucosal level, since the increase in cement remnants was statistically higher between 1 and 2 mm submucosally (Linkevicius, Vindasiute, et al., 2013). In the present study, the abutment shoulders (in the CR group) were checked for dimension, position and if necessary, adjusted to be circumferentially located 1mm submucosally. Furthermore, after cementation, a careful removal of excess cement and a radiographic remnant control were performed. Despite all previously described precautions, one implant revealed signs of peri-implant disease and had to be removed eventually. Cement remnants were detected at the submucosal part of the restoration. A study showed that even after cement removal by experienced clinicians, remnants could still be detected at the abutments (Agar et al., 1997).

Considered as a limitation of the present study may be the number of enrolled patients (44) and the drop-out rate of 6.8% after 5 years. Furthermore, restored implants were mainly located in the posterior premolar site (33) compared with the anterior area (11), which could be considered as a confounding factor when it comes to technical outcome measures. Moreover, technical outcomes could have potentially been confounded by the design of the two retention types. While the veneering ceramic was directly applied on the zirconia abutment in the SR group, in the CR group lithium disilicate was used as crown-framework material. However, despite those differences, there was no statistical significance in technical outcomes, like fracture of the veneering ceramic, between the two groups.

5 | CONCLUSIONS

All-ceramic single-tooth restorations on two-piece dental implants resulted in a relatively low survival rate. Cemented restorations were associated with a higher biological and overall complication rate than screw-retained restorations.

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CONFLICT OF INTEREST

The authors report no conflict of interest.

AUTHOR CONTRIBUTIONS

Riccardo D. Kraus: Data curation (equal); Formal analysis (equal); Validation (equal); Visualization (equal); Writing – original draft (equal); Writing – review & editing (equal). **Catharina Espuelas:** Data curation (equal); Formal analysis (equal); Validation (equal); Visualization (equal); Writing – original draft (equal); Writing – review & editing (equal). **Christoph H. F. Hämmerle:** Conceptualization (supporting); Methodology (supporting); Validation (supporting). **Ronald E. Jung:** Conceptualization (supporting); Methodology (supporting); Validation (supporting). **Irena Sailer:** Conceptualization (supporting); Methodology (supporting); Validation (supporting). **Daniel S. Thoma:** Conceptualization (lead); Data curation (supporting); Formal analysis (supporting); Methodology (supporting); Validation (equal); Writing – review & editing (equal).

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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