ORIGINAL ARTICLE



Two short implants versus one short implant with a cantilever: 5-Year results of a randomized clinical trial

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[Correction added on 23 April 2022, after first online publication: CSAL funding statement has been added.1

Abstract

Aim: To test whether or not the use of a short implant with a cantilever results in similar clinical and radiographic outcomes compared to two adjacent short implants with single tooth reconstructions.

Materials and methods: Thirty-six patients with two adjacent missing teeth in the posterior region were randomly assigned to receive either a single 6-mm implant with a cantilever (ONE-C) or two 6-mm implants (TWO). Fixed reconstructions were inserted 3-6 months after implant placement and patients were re-examined up to 5 years (FU-5).

Results: A total of 26 patients were available for re-examination at FU-5. The survival rate amounted to 84.2% in ONE-C and to 80.4% in TWO (inter-group: p = .894). Technical complication rates amounted to 64.2% (ONE-C) and to 54.4% (TWO) (inter-group: p = 1.000). From baseline to FU-5, the median changes of the marginal bone levels were 0.13 mm in ONE-C and 0.05 mm in TWO (inter-group: p = .775). Probing depth, bleeding on probing, and plaque control record values showed no significant differences between the two treatment modalities (p > .05).

Conclusions: Short implants with a cantilever render similar clinical and radiographic outcomes compared to two adjacent short implants at 5 years, however, they tend to fail at earlier time points suggesting an overload of the implants. Considering the modest survival rates, the clinical indication of either treatment option needs to be carefully evaluated. ClinicalTrials.gov (NCT01649531).

KEYWORDS

cantilever, dental implants, implant-supported crowns, overloading, short implants

Clinical Relevance

Scientific rationale for study: The combination of short implants with a cantilever may expand the therapeutic options in implant dentistry and reduce patient morbidity, treatment time, and cost. However, the clinical evidence to support this treatment concept is scarce.

Principal findings: Short implants with cantilever tend to fail at earlier time points, suggesting a potential overload of the implants. However, they do not significantly increase the failure and complication rates compared to two adjacent short implants at 5 years of follow-up.

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Practical implications: Both treatment options resulted in modest survival rates; however, short implants with a cantilever might be prone to earlier failures and earlier technical complications. Any clinical applicability for two-unit gaps in the posterior region of the jaws needs to be carefully evaluated.

1 | INTRODUCTION

The clinical situation with two adjacent missing teeth is often encountered in the posterior area of the jaws. If implant therapy with fixed reconstructions is chosen, two options exist to restore function and aesthetics: two adjacent implants, or a single implant with a cantilever.

The first option is considered the treatment of choice and probably chosen by the majority of clinicians. Single-tooth implants are a well-documented treatment option demonstrating high survival rates at the implant and restorative level after 5 years of function (Jung et al., 2008, 2012; Roccuzzo et al., 2020). Moreover, marginal bone levels (MBLs) for the major implant systems show minimal changes over time according to recent randomized controlled clinical trials (RCTs; Gamper et al., 2017; Ioannidis et al., 2019) and a systematic review (Laurell & Lundgren, 2011).

The second option is the placement of a single implant and the insertion of an implant crown with a cantilever. Apart from being more economical than the placement of two implants, it provides an alternative in case of unfavourable anatomical conditions at the alveolar ridge. These unfavourable anatomical conditions include limited mesio-distal space, pre-existing bone deficiencies, and the proximity of the alveolar nerve or the maxillary sinus. It has been hypothesized that cantilevers may increase occlusal and functional forces on the implant (Quirynen et al., 1992; Rangert et al., 1995; Sertgoz & Guvener, 1996; Stegaroiu et al., 1998; de Souza Batista et al., 2017; Lima et al., 2019). Such forces could theoretically lead to a higher rate of biological complications, expressed by an increased amount of marginal bone loss and a lower implant survival rate. This hypothesis has been investigated in clinical studies for short-span fixed dental prostheses (FDPs) with two implants with a cantilever. The results of these studies, however, failed to demonstrate a higher marginal bone loss in comparison to noncantilever FDPs (Wennstrom et al., 2004; Aglietta et al., 2009; Roccuzzo et al., 2020). Nonetheless, the situation of a single implant with a cantilever may be more challenging from a biomechanical point of view (Halg et al., 2008), resulting in a higher rate of technical complications (Quaranta et al., 2014).

Recently, several studies on single implants with cantilevers have been published (Aglietta et al., 2012; Palmer et al., 2012; Roccuzzo et al., 2020). In these studies, the bone-level changes were similar to those observed at implants without cantilevers. The outcomes are, however, limited to some extent by the study design being most often of retrospective nature (Schmid et al., 2021) or without a control group (Palmer et al., 2012) and with a limited

number of patients. A generalization of the obtained results is therefore questionable.

A further relevant factor when planning dental implants is the implant length. In the posterior area, the vertical bone height is often limited by the maxillary sinus or the inferior alveolar nerve. This often results in the use of shorter implants. Several review articles have concluded that the survival rates of short implants with rough surfaces are similar to those of longer implants (Kotsovilis et al., 2009; Pommer et al., 2011; Telleman et al., 2011; Thoma et al., 2015). Consequently, a combination of shorter dental implants with cantilevers might further expand treatment options and reduce patient morbidity, treatment time, and costs.

The aim of the present study was, therefore, to test whether the use of short implants with a cantilever results in similar clinical, radiographic, and technical outcomes to two adjacent short implants with single-tooth reconstructions after 5 years of loading.

2 | MATERIALS AND METHODS

This article is reported according to CONSORT guidelines for reporting parallel group randomized trials (Moher et al., 2010).

2.1 | Study design

The present study was designed as a prospective RCT with two parallel study groups with a duration of 10 years and conducted at the Clinic of Reconstructive Dentistry, Center of Dental Medicine, University of Zurich, Switzerland. The local ethical committee approved the clinical study protocol (KEK-ZH-Nr 2012-0097), which was registered at ClinicalTrials.gov (NCT01649531). This study also followed the principles of Good Clinical Practice.

2.2 | Study population

Thirty-six patients in need of dental implant therapy with FDPs were consecutively enrolled in the study after having signed the informed consent. The enrolled patients had to fulfil the following inclusion criteria:

Healthy individuals according to the System of the American Society of Anesthesiology (Abouleish et al., 2015) and aged 18 years or older;

- No general medical condition representing a contraindication to implant therapy (Bornstein et al., 2009);
- Two adjacent missing teeth in the maxilla or mandible from the first premolar to the second molar;
- At least one tooth present adjacent to the edentulous space;
- At least 8 mm of vertical bone height in the mandible, allowing for the placement of a 6-mm implant (2 mm safety distance to inferior alveolar nerve) or 6 mm of vertical bone height in the maxilla (from the alveolar crest to the sinus floor);
- No periodontal disease (periodontal probing depth [PD] <4 mm);
- At least 6 mm of vertical bone height in the maxilla;
- Good oral hygiene (full-mouth plaque index <25%) (O'Leary et al., 1972);
- Adequate control of inflammation (full-mouth bleeding on probing [BOP] <25%) (Ainamo & Bay, 1975).

Patients not meeting the inclusion criteria were not considered for the study. In addition, the presence of any one of the following exclusion criteria led to exclusion of the participant:

- Smoking more than 15 cigarettes a day;
- Active periodontal disease:
- Pregnancy or breastfeeding at the date of inclusion.

2.3 | Randomization

All patients were randomly allocated using a computer-generated randomization list to receive either one short implant (ONE-C) or two short implants (TWO). All implants were 6 mm in length and had a diameter of 4.1 mm (Straumann Standard Plus, SLActive; Straumann AG, Basel, Switzerland). Allocation was concealed from the surgeon until after flap elevation by using sealed envelopes.

2.4 | Surgical procedure

The surgical procedures were performed according to standard protocols and based on the manufacturers' recommendations. After raising a full-thickness flap, the implant site was prepared. In group ONE-C, one implant was placed in the position with the more favourable bone conditions (vertical bone height; horizontal bone width), ideally at the distal site to allow for a mesial cantilever. In group TWO, two implants were placed. In case of a bone deficiency after implant placement, guided bone regeneration was carried out. In brief, following implant insertion, the type of defect (dehiscence or fenestration) was grafted with demineralized bovine bone mineral (Bio-Oss; Geistlich AG, Wolhusen, Switzerland) and covered with a bioresorbable collagen membrane (Bio-Gide; Geistlich AG, Wolhusen, Switzerland). After periosteal releasing incisions, the flap was repositioned and adapted with sutures. No restrictions were made regarding the healing protocol (submerged vs. transmucosal healing).

2.5 | Prosthetic procedure

The prosthetic procedures were made according to the guidelines of the respective implant system. Group ONE-C was restored with single crowns with a cantilever, whereas group TWO was restored with non-splinted single crowns. A conventional loading protocol (3–6 months) was applied, and screw-retained porcelain-fused-to metal reconstructions were subsequently inserted following a group function occlusion. A baseline examination was carried out 1–3 weeks following insertion of the final prosthesis. Follow-up examinations were performed at 6 months, 1 year, 3 years, and 5 years after the baseline examination. For every patient, an individually designed maintenance program with regular dental hygiene sessions (ranging from 3 to 12 months) was performed during the entire study period.

2.6 | Outcome measures

For the record of the outcome measures, four different time points were defined:

- BL: 1-3 weeks after loading of the implant (baseline);
- FU-6m: 6 months after loading;
- FU-1: 1 year after loading;
- FU-3: 3 years after loading;
- FU-5: 5 years after loading.

2.7 | Implant and reconstruction survival

Implant and reconstruction survival rates were calculated at the patient level for the time point FU-5 (5 years). Implant survival was defined as the implant being in place and stable, as assessed by hand-testing. Reconstruction survival was defined as the reconstruction being in situ.

2.8 | Biological and technical complications

The incidence of biological and technical complications was assessed at the different time points. As a biological complication, peri-implant mucositis and peri-implantitis were assessed according to the consensus report of the 2017 World Workshop on the Classification of Periodontal and Peri-Implant Diseases and Conditions.

Peri-implant mucositis case definition (Renvert et al., 2018):

- Presence of profuse (line or drop) bleeding and/or suppuration on probing;
- An increase in PDs compared to baseline;
- Absence of bone loss beyond crestal bone-level changes resulting from the initial remodelling.

Peri-implantitis case definition (Berglundh et al., 2018; Renvert et al., 2018):

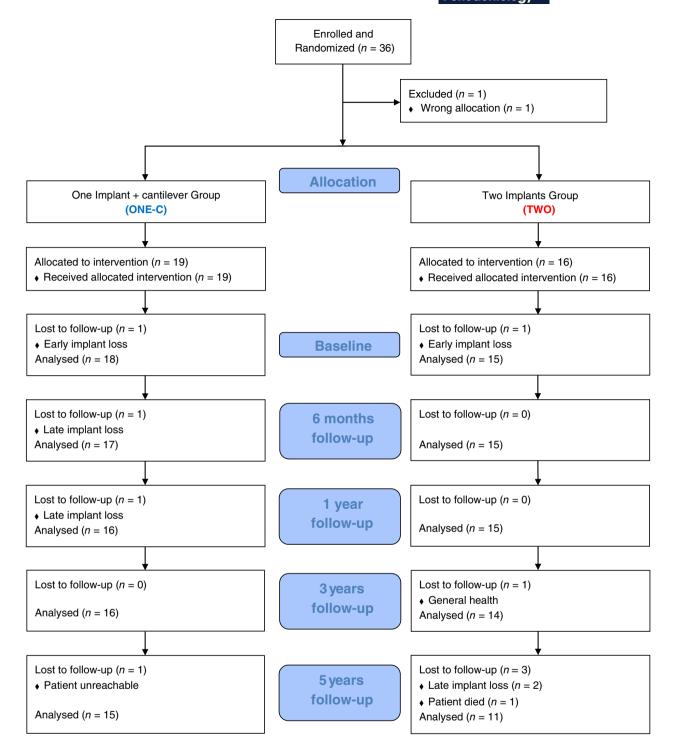


FIGURE 1 Flow diagram

- Presence of bleeding and/or suppuration on gentle probing;
- Increased PD compared to previous examinations;
- Presence of bone loss beyond crestal bone-level changes (≥2 mm) from baseline;
- PDs of ≥6 mm.

The recorded technical complications were as follows: implant fracture, abutment fracture, fracture of the veneering ceramic (chipping), loosening of the abutment screw, and fracture of the abutment screw. If necessary, appropriate treatment was carried out until the complication was resolved.

2.9 | Radiographic assessment

Periapical radiographs were taken immediately at baseline after loading (BL) and at 6 months (FU-6m), 1 year (FU-1), 3 years (FU-3), and 5 years (FU-5). Standardized intra-oral radiographs were obtained

using a paralleling technique with Rinn holders. X-rays were then imported to an open-source software (ImageJ 1.43; National Institute of Health, Bethesda, USA). MBLs were assessed at a magnification of $10-15\times$. The pitch distance between two implant threads was used to calibrate and determine the exact magnification of the individual images. MBL was examined at both the mesial and distal aspect of each implant by measuring the distance between the flat top of the implant shoulder and the bone crest. The mean of mesial and distal MBL was then calculated. The changes in MBL from BL to FU-6m, FU-1, FU-3, and FU-5 were also calculated.

2.10 | Clinical parameters

At the follow-up examinations, the following variables were assessed at six sites per implant (mesio-buccal, buccal, disto-buccal, disto-lingual, lingual, and mesio-lingual) and averaged:

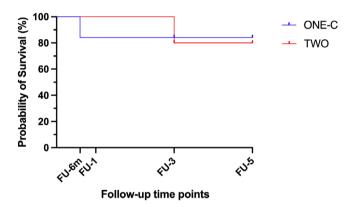


FIGURE 2 Kaplan–Meier estimates of survival in both treatment groups. No significant differences were noticed between the groups. FU-6m, 6 months follow-up; FU-1, 1-year follow-up; FU-3, 3 years follow-up; FU-5, 5 years follow-up

- PD (in mm):
- BOP (%) (Ainamo & Bay, 1975);
- Plaque control record (PCR, %) (O'Leary et al., 1972).

2.11 | Sample size

The sample size calculation was based on the anticipated differences in the primary outcome (radiographic marginal bone loss) between the two treatment arms. The power calculation was performed with a two-sample t-test using data from previous studies (Albrektsson et al., 1986; Palmer et al., 1997). Assuming a difference of 0.5 mm between both treatment arms in the primary outcome along with a common standard deviation of 0.46 mm, the two-tailed effect size for a t-test amounted to 1.086. Considering a type-I error rate of 5%, a power of 80%, and a drop-out rate 15%, 18 participants per group were needed to detect a difference of 0.5 mm in the primary outcome between the groups.

2.12 | Statistical analysis

The metric variables with mean, standard deviations, median, quartiles, minimum, and maximum were described. Categorical variables were summarized by counts and proportions of the categories. The comparisons of the group medians of the metric variables were performed with nonparametric methods (Wilcoxon–Mann–Whitney test) because of the small sample sizes and nonnormality of the data. Changes over time were analysed nonparametrically with the Wilcoxon signed-rank test for each group. Differences in survival rates between the groups were assessed by the Kaplan–Meier estimator in combination with the log-rank test. The proportions of the categorical parameters were compared with the Chisquare test. The level of significance was set at 5%.

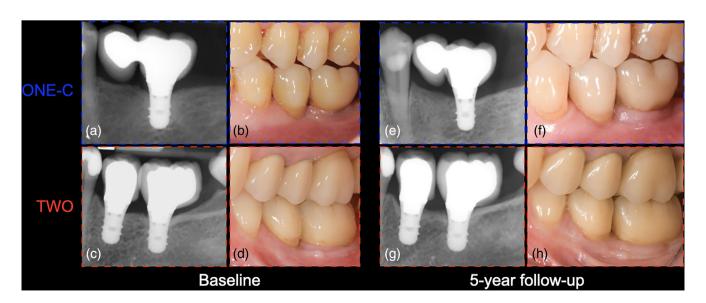


FIGURE 3 Representative cases of each treatment modality. Periapical radiographs (a,c) and clinical situation (b,d) at baseline (crown delivery). Periapical radiographs (e,g) and clinical situation (f,g) at 5 years follow-up

TABLE 1 Clinical outcomes for ONE-C and TWO at the time of loading or baseline (BL), 6 months (FU-6m), 1 year (FU-1), 3 years (FU-3), and 5 years (FU-5) of follow-up, including the changes between different time points

SD Avidan														
Modes SD		ONE-C						ОМТ						
2.67 + 0.79 2.45 2.45 2.45 2.45 2.45 2.45 2.45 2.44 2.41 2.71 3.24 2.00 to 3.00 0.00 </th <th></th> <th>Mean ± SD (mm)</th> <th>Q1</th> <th>Median (mm)</th> <th>93</th> <th>Range (mm) min. to max.</th> <th>Paired p-value</th> <th>Mean ± SD (mm)</th> <th>Q1</th> <th>Median (mm)</th> <th>69</th> <th>Range (mm) min. to max.</th> <th>Paired p-value</th> <th>p-Value</th>		Mean ± SD (mm)	Q1	Median (mm)	93	Range (mm) min. to max.	Paired p-value	Mean ± SD (mm)	Q1	Median (mm)	69	Range (mm) min. to max.	Paired p-value	p-Value
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277-2674 217 267 312 150a 433 NA 288-646 241 271 338 2160 633 NA 297-16024 217 217 326 312 150a 433 NA 288-6464 283 228 2100 6375 NA 329-1604 217 324 325 2170 600 NA 300-1038 287 312 2500 6375 NA 329-1614 217 325 327 2130 447 NA 300-103 287 326 250 6375 NA 1 -01211 -013 -016 1 -2170 200 57 -007 502 -064 0.04 0.04 100 0.04 100 0.04<		2.87 ± 0.79	2.45	2.75	3.33	1.50 to 5.17	NA	2.90 ± 0.36	2.62	3.04	3.14	2.00 to 3.41	۸	.739
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CODE-1117		3.09 ± 0.91	2.67	က	3.67	1.33 to 4.67	Ϋ́	3.00 ± 0.38	2.67	က	3.25	2.50 to 3.75	Ϋ́	.73
	n-BL	-0.12 ± 1.17	-1.33	-0.16	1	-2.17 to 2.00	.57	-0.07 ± 0.62	-0.64	0.04	0.49	-1.00 to 0.83	.791	998.
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0.05 ± 0.14 0.00 0.17 0.05 0.0 0.14 0.25 ± 0.15 0.13 0.13 0.03 0.04 0.05 0.04 0.05 0.04 0.0		0.11 ± 0.13	0.00	0.08	0.17	0 to 0.33	NA	0.20 ± 0.22	0.00	0.12	0.35	0 to 0.66	۸	.227
0.09 ± 0.20 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.01 0.00 0.00 0.01 0.00		0.15 ± 0.14	0.00	0.17	0.17	0 to 0.50	Ν	0.25 ± 0.15	0.12	0.33	0.33	0 to 0.50	Ϋ́	.054
0.07 ± 0.25 0.00 0.08 -0.17 to 1.00 .312 0.18 ± 0.29 0.00 0.08 0.41 -0.08 to 0.75 .033 0.09 ± 0.16 0.00 0.08 0.17 -0.17 to 0.33 .056 0.19 ± 0.22 0.00 0.08 0.29 0 to 0.66 .003 0.13 ± 0.15 0.00 0.17 0.10 to 0.50 .007* 0.23 ± 0.16 0.12 0.29 0.08 to 0.50 .001*	m-BL	0.09 ± 0.20	0.00	0.00	0.08	0 to 0.67	.125	0.14 ± 0.27	0.00	0.04	0.16	-0.08 to 1.00	.013*	.573
$0.09 \pm 0.16 \qquad 0.00 \qquad 0.08 \qquad 0.17 \qquad -0.17 \pm 0.03 \qquad 0.05 \qquad 0.19 \pm 0.22 \qquad 0.00 \qquad 0.08 \qquad 0.29 \qquad 0.00 + 0.00 \qquad 0.00 \qquad$	-81	0.07 ± 0.25	0.00	0.00	0.08	-0.17 to 1.00	.312	0.18 ± 0.29	0.00	0.08	0.41	-0.08 to 0.75	.033*	.335
0.13 ± 0.15 0.00 0.17 0.17 0.10 0.50 0.07* 0.23 ± 0.16 0.12 0.25 0.33 -0.08 to 0.50 0.01*	-8L	0.09 ± 0.16	0.00	0.08	0.17	-0.17 to 0.33	.056	0.19 ± 0.22	0.00	0.08	0.29	0 to 0.66	.003*	.315
	-BL	0.13 ± 0.15	0.00	0.17	0.17	0 to 0.50	*200.	0.23 ± 0.16	0.12	0.25	0.33	-0.08 to 0.50	*100.	.061

Note: Patient-level analysis with means, standard deviations (SD), medians, interquartile ranges (IQR), and range from minimum to maximum for both groups (ONE-C and TWO). p-Values for the patient-level analysis were calculated with the nonparametric paired Wilcoxon test to assess the influence of time. Bold values reached the level of significance. Abbreviations: BOP, mean bleeding on probing; NA, not applicable; PCR, mean plaque control record; PD, mean probing depth.

*Statistically significant difference.

Radiographic data of marginal bone levels (MBLs) at the time of loading or baseline (BL), 6 months (FU-6m), 1 year (FU-1), 3 years (FU-3), and 5 years (FU-5) of follow-up, including the changes between different time points TABLE 2

	2	ONE-C						2	OWL						
MBL		Mean ± SD (mm)	Q1	Median (mm)	63	Range (mm) min. to max.	Paired p-value		Mean ± SD (mm)	Q1	Median (mm)	83	Range (mm) min. to max.	Paired <i>p</i> -value	p-Value
BL	18	1.28 ± 0.77	1.14	1.26	1.94	-0.44 to 2.17	¥ Y	15	1.71 ± 0.58	1.36	1.79	2.22	0.41 to 2.44	NA	.089
FU-6m	17	1.46 ± 0.74	0.92	1.38	1.98	0.26 to 2.74	₹ Z	15	1.90 ± 0.67	1.27	1.85	2.46	0.96 to 3.26	ΑN	.139
FU-1	16	1.32 ± 0.79	0.83	1.3	1.89	0.09 to 2.83	Ϋ́	15	1.90 ± 0.74	1.38	1.69	2.22	0.72 to 3.73	ΝΑ	.076
FU-3	16	1.62 ± 0.88	1.06	1.78	1.94	-0.12 to 3.78	₹ Z	14	2.10 ± 0.67	1.60	1.95	2.64	1.26 to 3.48	ΑΝ	.112
FU-5	15	1.53 ± 0.73	1.09	1.36	2.1	0.15 to 2.78	₹ X	11	1.78 ± 0.77	1.30	1.70	2.21	0.61 to 3.57	ΝΑ	.443
FU-6m- BL		0.17 ± 0.67	-0.27	0.22	99:0	-1.07 to 1.61	.258		0.15 ± 0.48	-0.17	0.2	0.52	-0.7 to 1.01	.274	.837
FU-1-BL		0.03 ± 0.48	-0.31	-0.06	0.57	-0.92 to 0.72	.85		0.2 ± 0.52	-0.14	90:0	0.59	-0.54 to 1.29	.274	.371
FU-3-BL		0.32 ± 0.59	-0.11	0.08	0.74	-0.29 to 1.61	960.		0.46 ± 0.48	0.11	0.28	0.92	-0.46 to 1.15	900.	.377
FU-5-BL		0.29 ± 0.63	-0.18	0.13	0.56	-0.44 to 1.52	.187		0.17 ± 0.59	-0.1	0.05	0.45	-0.85 to 1.32	.375	.775

Note: Patient-level analysis with means, standard deviations (SD), medians, interquartile ranges (IQR), and range from minimum to maximum for both groups (ONE-C and TWO). p-Values for the patient-level to assess the influence of time. analysis were calculated with the nonparametric Mann–Whitney U-test and nonparametric paired Wilcoxon test

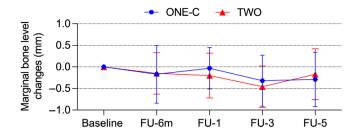


FIGURE 4 Marginal bone level changes over time in both treatment modalities. The data represent the means ± standard deviations. No significant differences were noticed between the groups at any time point. FU-6m, 6 months follow-up; FU-1, 1-year follow-up; FU-3, 3 years follow-up; FU-5, 5 years follow-up

3 | RESULTS

3.1 | Study sample and demographic data

A total of 36 patients were included in the study, and 54 implants were placed (18 in group ONE-C and 36 implants in group TWO). One patient was not treated according to the randomization, and therefore considered as a drop-out (Figure 1). The location and distribution of the implants are shown in Figure S1. At baseline, the mean age of the patients was 67.5 ± 11.6 years, and 69.9% of the patients were females. Two patients (one in group ONE-C and one in group TWO) had early failures (before loading, all implants in the maxilla) and therefore dropped out of the study. In total, 33 patients received implant reconstructions (18 patients in group ONE-C, 15 in group TWO). During the 5-year follow-up, four late implant failures were observed (all in the mandible). In group ONE-C, one implant failed soon after the crown delivery and another failed after 6 months of follow-up, whereas in group TWO, two implants failed after the 3-year time point. From the four failures, two implants (one from group TWO and one from group ONE-C) were in a free-ending situation and two implants (one from group TWO and 1 from group ONE-C) were not in a free-ending situation. During the 5-year follow-up, three additional patients (one in group ONE-C and two in group TWO) were considered dropouts due to lack of response, death, or general health conditions, respectively (Figure 1). At 5 years, 26 out of the 36 patients originally recruited attended the follow-up examination (15 in group ONE-C; 11 in group TWO). At the patient level, the implant survival rate at 5 years amounted to 84.2% (CI: 58-94) in ONE-C and 80.4% (CI: 50-93) in TWO (inter-group comparison: p = .894) (Figure 2).

3.2 | Technical complications

During the 5-year follow-up, a total of 25 technical complications occurred in 16 implants (some implants had more than one technical complication). Out of these complications, 18 occurred in group ONE-C and 7 in group TWO. The majority of complications were screw-loosening (44%) and chipping (44%). The complication rates

amounted to 27% (ONE-C) and 6.6% (TWO) (inter-group comparison: p=.186) at FU-6m, 31.2% (ONE-C) and 13.3% (TWO) (inter-group comparison: p=.519) at FU-1, 31.2% (ONE-C) and 21.4% (TWO) (inter-group comparison: p=.563) at FU-3, and 64.2% (ONE-C) and (TWO) 54.4% (inter-group comparison: p=1.000) at FU-5. The complication rates tended to be higher in ONE-C at all time points but without reaching statistical significance (p > .05).

3.3 | Clinical outcome measures

Two representative cases of each treatment modality are displayed in Figure 3. The results of the clinical outcomes at the patient level are presented in Table 1 for all time points. PD values neither differed statistically significantly between the two groups at any time point (p > .05) nor changed significantly between BL and FU-5 (p > .05). BOP and PCR values showed no significant differences between the groups irrespective of the time point (p > .05). However, BOP and PCR significantly increased in group TWO from BL to every follow-up time point (BL to FU-6m, BL to FU-1, BL to FU-3, and BL to FU-5; p < .05). An increase in BOP and PCR was also observed in group ONE-C, but only from BL to FU-5 (p < .05). Peri-implant mucositis amounted to 29.4% (ONE-C) and 33.3% (TWO) (inter-group comparison: p = .811) at FU-6m, 18.7% (ONE-C) and 46.6% (TWO) (intergroup comparison: p = .09) at FU-1, 43.7% (ONE-C) and 71.4% (TWO) (inter-group comparison: p = .126) at FU-3, and 56.2% (ONE-C) and (TWO) 63.6% (inter-group comparison: p = .701) at FU-5. None of the implants developed peri-implantitis.

3.4 | Radiographic results

An overview of the radiographic results reported at the patient level is displayed in Table 2. The relative distances between the implant shoulder and the bone crest ranged from 0.15 to 2.78 (ONE-C) and from 0.61 to 3.57 mm (TWO) at FU-5. Negative values indicate that the implant shoulder is located more apically relative to the bone crest. From BL to FU-5, the medians and the interquartile Q1 and Q3 of the mean MBL were 1.36 mm (Q1: 1.09 mm; Q3: 2.10 mm) for ONE-C and 1.70 mm (Q1: 1.30 mm; Q3: 2.21 mm) for TWO (intergroup comparison: p=.443). The median changes of the MBL amounted to 0.13 mm in group ONE-C (intra-group: p<.05) and 0.05 mm in group TWO (intra-group: p<.05) (inter-group comparison: p=.775) between BL and FU-5 (Figure 4).

4 | DISCUSSION

The present RCT, comparing one short implant with a cantilever to two short implants at 5 years of follow-up, revealed the following: (i) similar survival rates between both treatment modalities; (ii) comparable MBLs and changes over time; and (iii) similar rates of biological and technical complications.

The survival rates were similar between both treatment modalities, amounting to 84.2% in group ONE-C and 80.4% in group TWO. These rates are, nevertheless, relatively low compared to standard length implants with fixed reconstructions (Papaspyridakos et al., 2018). Recent systematic reviews have reported survival rates ranging between 95% and 100% at 5 years of follow-up (Papaspyridakos et al., 2018). The use of short implants (6 mm) in the present study might explain these lower survival rates. A recent RCT used the same implant system and compared 6- to 10-mm implants in the posterior region of the jaws (Naenni et al., 2018). That study revealed a significantly lower survival rate for the 6-mm implant group with a survival rate of 91% versus 100% for the 10-mm group at 5 years of follow-up (Naenni et al., 2018). Interestingly, that study also revealed that the majority of late implant failures occurred after 3 years in function. This is in line with the present results, revealing that most implant failures occurred after 3 years of loading.

All failures were in the mandible, two in group TWO and two in group ONE-C, resulting in the removal of the implants. Implant failures have been attributed to major technical (implant fracture) and/or biological (peri-implantitis) complications (Jung et al., 2008, 2012). However, no major technical or biological complications were observed in the present the study. This supports the notion that the bone surrounding the implants was not able to withstand the occlusal forces, leading to the failure of the implants. Indeed, the late failures in group ONE-C occurred at early time points (within 1 year), whereas in group TWO they occurred after 3 years of loading. It seems plausible that the use of two implants in group TWO may have allowed a better distribution of the occlusal forces, thereby delaying the implant losses as compared to the cantilever group where the implants failed within the first year of loading. Regarding short implants without cantilever, similar outcomes were observed in a recent multi-centre study where 6-10 mm implants were compared (Rossi et al., 2016). That study revealed a survival rate of 86.7% in the 6-mm implant group (Rossi et al., 2016). Moreover, the authors concluded that the lower survival rates in the 6-mm implant group were likely associated with a fracture of the surrounding supporting bone (Rossi et al., 2016). This further supports the hypothesis of a potential overload of the implants failing in the current study and is consistent with the shortterm failures observed in the cantilever group. In contrast, outcomes from a very recent multi-centre study revealed higher survival rates for 6-mm implants than in the present study (Gulje et al., 2020). In that study of 95 patients, 49 received 6-mm implants and the remaining 46 patients received 11-mm implants in the posterior region. At 5 years of follow-up, the survival rate in the 6-mm group was 96% and in the 11-mm group 98.9% (Gulje et al., 2020). This difference with the present results might be due to the different implant system used. Available epidemiological data indicate that the specific implant system used may have an influence on the occurrence of late failures (Derks et al., 2015).

Technical complications included mostly either screw-loosening or chipping. The complication rates tended to be higher in group ONE-C at all time points but without reaching a statistical significance difference. The complication rates ranged between 27% (ONE-C) and 6.6% (TWO) at 6 months, and between 64.2% (ONE-C) and (TWO)

54.4% at 5 years. In addition, some patients experienced technical complications more than once, which is in accordance with previous reports over a 5-year period (Karlsson et al., 2018). To date, there is limited clinical data regarding technical complications with single implants with cantilevers (Storelli et al., 2018). The trend towards more technical complication in group ONE-C, nevertheless, is in line with a recent systematic review indicating that implant-supported cantilevers are more prone to technical complications (Van Nimwegen et al., 2017). Conversely, a more recent systematic review evaluating the complication rate in single implants with a cantilever concluded that there was insufficient data available to determine a technical complication rate (Storelli et al., 2018) with this type of reconstruction. In summary, a relatively high rate of technical complications was observed in the present study irrespective of the treatment modality.

MBLs changed similarly over time in both groups. From loading to the 5-year follow-up, the median MBL change amounted to 0.13 in ONE-C and 0.05 mm in TWO, without significant differences. This lack of difference indicates that the presence of a cantilever does not lead to higher marginal bone loss, in line with previous clinical data (Wennstrom et al., 2004; Halg et al., 2008; Aglietta et al., 2009; Roccuzzo et al., 2020). The present MBL changes are within the range of the results from two previous clinical studies comparing 6-mm implants with standard-length implants at 5 years of follow-up (Rossi et al., 2016: Thoma et al., 2018). One study reported a median MBL change of 0 mm (Thoma et al., 2018) in the 6-mm group. whereas the second study reported a median change of 0.08 mm in the short implant group (Rossi et al., 2016). The present MBL changes are somewhat smaller than in a previous study using the same length and implant system with a median bone level change of 0.29 mm after 5 years of loading (Naenni et al., 2018). Conversely, a recent RCT using a different implant system revealed a mean change of 0.01 ± 0.45 mm (bone gain) with 6-mm implants after 5 years of loading (Gulje et al., 2020). It should be noted, however, that the latter study included neither the median changes nor interquartile ranges, thereby precluding an accurate comparison with the present findings.

Biological complications, namely peri-implant mucositis, were observed over the course of the present study. At 5 years, the prevalence of peri-implant mucositis amounted to 56.2% in ONE-C and 63.6% in group TWO without significant difference. This can be explained by the significant increase in plague and BOP over time in both groups, despite the provision of regular dental hygiene sessions and annual check-ups. Plaque and BOP scores increased at earlier time points in group TWO. One might speculate that proper hygiene of two adjacent implants requires more effort and time for the patient. Interestingly, peri-implantitis was not observed in the present study. The sudden loss of stability of the implants that failed could not be attributed to peri-implantitis. In those implants, neither deep PD values (PD > 4 mm) nor MBL changes ≥ 2 mm between the recall visits were present during the follow-up. One possible explanation is the case definition of peri-implantitis. Peri-implantitis was defined according to the 2017 World Workshop on the Classification of Periodontal and Peri-Implant Diseases and Conditions (Berglundh et al., 2018; Renvert et al., 2018). A recent study revealed that the

2017 classification has a low sensitivity, meaning that it might be unable to capture the early stages of peri-implantitis (Romandini et al., 2021). Another plausible explanation would be overloading (Quirynen et al., 1992; Isidor, 1996, 1997), indicating a fracture of the supporting bone (Rossi et al., 2016) rather than an infectious disease. Notably, this hypothesis seems to be supported by the present findings, as short-term late failures occurred only in the cantilever group. However, the clinical evidence for overloading is till is scarce and mainly based on pre-clinical models (Lima et al., 2019).

The present study has a number of limitations. The primary outcome and the corresponding sample size calculation were based on marginal bone loss, which may explain the lack of significant differences in the secondary outcomes between both treatment groups. This primary outcome, however, was selected because of the lack of previous RCT assessing short implants with a cantilever. In addition, at 5 years, 26 out of the 36 participants were available for re-examination, limiting the power to detect statistically significant differences. This becomes particularly important for the possible overload observed with short implants and a cantilever within the first year, as the clinical evidence to support the hypothesis of implant overloading is still lacking. Furthermore, there were clinical variables including the location of the implants (maxilla or mandible) and cantilevers (mesial or distal) as well as free-ending situations that may have influenced the present results. Finally, despite the good oral health of the participants at the beginning of the study, their previous clinical records were not available, which could have provided further insights into the modest survival rates observed. Hence, these findings should be interpreted with caution until further studies are performed.

5 | CONCLUSION

At 5 years, both treatments modalities exhibited similar survival rates, technical complications, and radiographic outcomes. However, short implants with a cantilever tended to fail at earlier time points, suggesting an overload of the implants. Consequently, the feasibility and clinical applicability of either of the two options needs to be carefully assessed in daily practice.

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CONFLICT OF INTEREST

All authors declare no conflict of interest.

ETHICS STATEMENT

Ethical approval was obtained from the ethics committee at the Canton of Zurich, Switzerland (KEK-ZH-Nr 2012-0097).

AUTHOR CONTRIBUTIONS

All authors made substantial contributions to this study. Daniel Thoma, Christoph H. F. Hämmerle, and Ronald Jung contributed to the conception and design of the study. Karin Wolleb, Roman Schellenberg, and Franz-Josef Strauss contributed to the clinical phases of the study and collected the data. Jürg Hüsler and Franz Strauss performed the statistical analysis. Franz Strauss, Daniel Thoma, and Christoph H. F. Hämmerle contributed to interpretation of the data and drafted and finalized the manuscript. All authors critically reviewed and approved the final manuscript.

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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