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ORIGINAL ARTICLE

The randomized shortened dental arch study: tooth loss over five years

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Abstract
Objectives The study was designed to provide clinical outcome data for two treatments of the shortened dental arch (SDA).
Material and Methods In a multicenter randomized controlled clinical trial, patients with complete molar loss in one jaw were provided with either a partial removable dental prosthesis (PRDP) retained with precision attachments or treated according to the SDA concept preserving or restoring a premolar occlusion. No implants were placed. The primary outcome was tooth loss.
Results Of 152 treated patients, 132 patients reached the 5-year examination. Over 5 years, 38 patients experienced tooth loss. For the primary outcome tooth loss, the Kaplan–Meier survival rates at 5 years were 0.74 (95 % CI 0.64, 0.84) in the PRDP group and 0.74 (95 % CI 0.63, 0.85) in the SDA group. For tooth loss in the study jaw, the survival rates at 5 years were 0.88 (95 % CI 0.80, 0.95) in the PRDP group and 0.84 (95 % CI 0.74, 0.93) in the SDA group. The differences were not significant. No Cox regression models of appropriate fit explaining tooth loss on the patient level could be found.

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Conclusions The overall treatment goals of a sustainable oral rehabilitation and the avoidance of further tooth loss over longer periods were not reliably achievable. The influence of the type of prosthetic treatment on tooth loss might have been overestimated.
Clinical Relevance Regarding our results, the patient's view will gain even more importance in the clinical decision between removable and fixed restorations in SDAs.

Keywords Tooth loss · Shortened dental arch · Partial removable dental prosthesis · Premolar occlusion

Introduction

There is only sparse evidence concerning the management of the shortened dental arch (SDA) and prosthetic treatments related to this condition. In many cases, implants are considered favorable. For a considerable number of patients, however, the access to this treatment is strongly limited by financial constraints. The remaining options are narrowed to the insertion of a partial removable dental prosthesis (PRDP) or the preservation/restoration of a functional premolar occlusion in SDAs with fixed dental prostheses (FDPs) as described by Käyser in 1981 [1].

Even if the insertion of a PRDP is still the most common treatment aiming at improving patient satisfaction and masticatory performance, it is known to have a high incidence of adverse effects and complications. Increased plaque accumulation, high caries rates, and periodontal breakdown [2–9] may increase the risk of further tooth loss. The SDA concept has been discussed controversially regarding detrimental effects of the non-replacement of molars [10–13]. When teeth have to be replaced in order to restore a premolar occlusion, FDPs have to be inserted. Complications related to FDPs encompass endodontic problems, tooth fracture, gingivitis, and secondary caries [14, 15]. In clinical trials dealing with FDPs, the benefit has been rated high by patients and professionals. The overall success rates of 90 % for FDPs after 10 years of service are considerably high [16, 17]. Naturally, further tooth loss also has to be expected with FDPs as shown by Scurria et al. [17], who reported the loss of 5 % of the abutment teeth after 10 years. Biological failures such as localized periodontal inflammations are mainly attributed to poor marginal adaptation, margin defects of individual restorations, position of crown margins [18–20], developing carious lesions [21], and age [22–24]. Knoernschild and Campbell [18] criticized that in view of the diversity in the applied study designs, specific reasons for the development of periodontal inflammation, a major potential side effect of prosthetic treatment, are difficult to discern. Prospective randomized studies that validate the long-term performance of different treatments regarding biological failures are barely available [25, 26].

The randomized shortened dental arch study was designed to provide relevant clinical outcome data for

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treatments with and without molar replacement [27–29]. Implant treatment should be excluded. The null hypothesis was that treatments with and without molar replacement do not lead to differences in further tooth loss. This paper reports the 5 year results.

Materials and methods

Trial design

The trial design has been published in detail [27]. The study is a multicenter randomized controlled clinical trial with two parallel groups and an allocation ratio of 1. Fourteen dental schools/hospitals participated [27–29]. The trial has been approved by a research ethics board (TU Dresden, EK 260399) and registered at controlled-trials.com under ISRCTN68590603 (pilot trial) and ISRCTN97265367 (main trial).

Participants

Any patient over 35 years of age who requested prosthetic treatment and exhibited a dental status meeting the inclusion criteria was considered for participation. All molars had to be missing in one jaw (study jaw) with at least the canine and one premolar present on each side. Further inclusion criteria were health according to ASA classification group one or two [30] and the rejection of implant treatment. Exclusion criteria were psychological disorders, craniomandibular disorders, malocclusion (Angle class II or III), and drug abuse. The data collection was exclusively carried out in dental school/hospital settings.

Interventions

In most cases, an appropriate pretreatment had to precede prosthetic treatment. Periodontal conditions were considered sound in case of probing pocket depths ≤4 mm and bleeding on probing rates ≤25 %. All restorations were made according to a standardized protocol. There were two treatment arms. In the PRDP group, molars and, if required, second premolars were replaced by a PRDP retained by precision attachments (Mini SG, Cendres+ Métaux SA, Biel/Bienne, Switzerland). The attachments were connected to a splinted crown or a fixed dental prosthesis retainer crown on the posterior-most tooth. In the SDA group, no prosthetic extension of the dental arch was conducted if the posterior-most tooth was the second premolar. If the posterior-most tooth was the first premolar, a cantilever FDP for replacement of the second premolar was incorporated. In both treatments, missing anterior teeth were replaced by FDPs. The opposing jaw had to be sufficiently restored up to the first molar in the PRDP group or the second premolar in the SDA group. New restorations were placed if necessary. The treatments were administered by trained dentists (faculty of dental schools). In a number of treatments, dental students were involved under the supervision of the trained dentists.

Outcomes

Tooth loss All losses were recorded. Tooth loss after prosthetic treatment, regardless of jaw and location, was defined as primary outcome. Secondary outcomes were tooth loss in the study jaw and loss of posterior-most teeth in the study jaw.

The following further secondary outcomes were assessed. The respective results will be reported in a separate paper. In this current analysis, we focused only on their influence as potential covariates on tooth loss.

Decayed-missing-filled teeth index Suspicious lesions were examined visually and with a dental explorer (DA406R, Aesculap AG, Tuttlingen, Germany).

Plaque index The plaque index (PlI) was assessed according to Silness and Loe [31] at four sites per tooth.

Vertical clinical attachment loss, probing pocket depth, and bleeding on probing These measurements were conducted with a graduated periodontal probe (PCP-12, Hu-Friedy, Manufacturing C., Chicago, IL, USA) to the nearest millimeter at six sites per tooth. The vertical clinical attachment loss (CAL-V) was measured from the cemento to enamel junction or crown margin.

The outcomes were assessed at screening before enrollment, after treatment (baseline), at 6 months, and annually thereafter. The follow-up examinations were continued in all patients regardless of changes in the dental status and the occurrence of the primary outcome event. All clinical examinations were conducted by trained and calibrated randomly assigned external examiners. In most cases the treatment coordinator was also present on site. Due to the multitude of involved dental hospitals, the calibration of all participating dentists and investigators was essential. An initial calibration meeting was held at the principal investigator's clinic (first author). Independent experts in the fields of periodontology, cariology, and craniomandibular disorders conducted the training and calibration. Recalibration meetings were held annually [27].

Sample, analyses, randomization

The calculation of the required sample size was based on an expected tooth loss rate of 20 % for RDP and 5 % for SDA after 5 years. Applying a two-sided primary significance test (alpha=5 %), 70 patients per group are required to provide

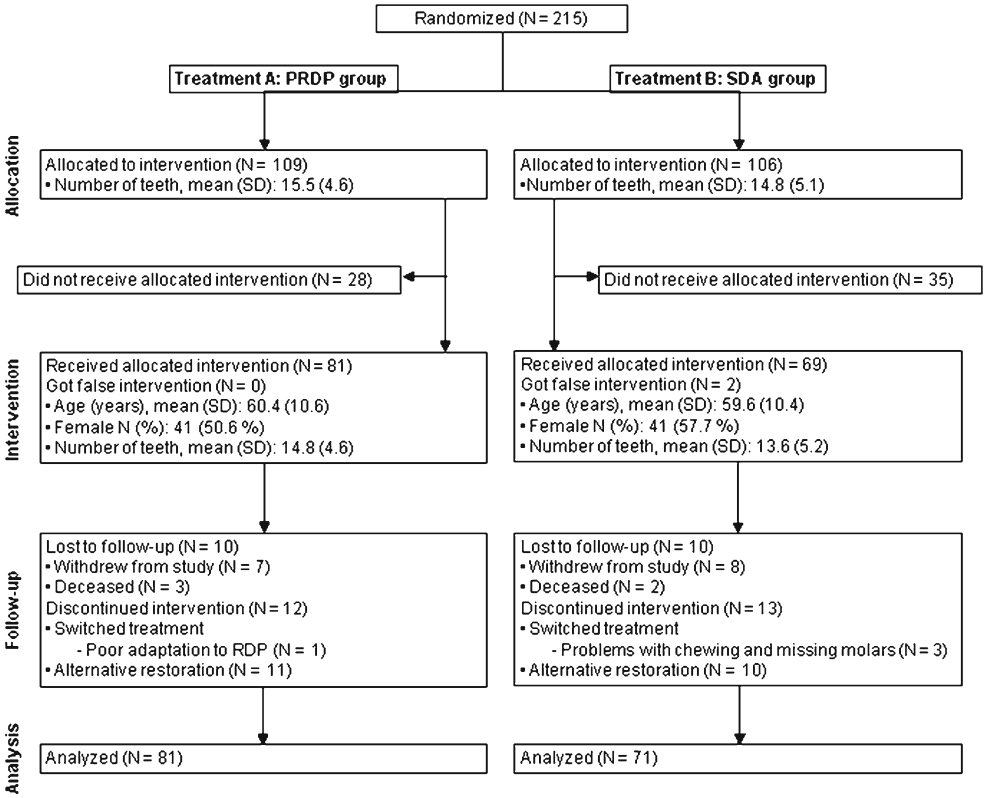

Fig. 1 Participant flow

75 % power of detecting treatment differences of the estimated magnitude [27]. Two interim analyses were scheduled after 1.5 and 3 years. Although the 5-year analysis was planned to be final, the study team agreed in view of the low dropout rate to extend the observation period to 8 years.

Once a patient had given informed consent, randomization between two treatments was conducted by randomization tables with randomly permuted blocks of six, stratified for center and age (over/under 50 years of age). The allocation concealment was warranted because randomization was conducted centrally (Department of Medical Informatics and Biomathematics, University of Münster). The obvious and visible discrepancy between the treatments allowed no blinding.

Statistical methods

The statistical analyses were performed on the intention-to-treat principle using PASW Statistics 18 (version 18.0.0, SPSS Inc., Chicago, IL, USA). For the evaluation of the survival probabilities, patient-related Kaplan–Meier survival analyses were performed. The survival distributions of the two treatment groups were compared with the Logrank test. Results were accepted as significant at p equal or less than 0.05, 95 % confidence intervals (95 % CI) are given. The influence of potential covariates on tooth loss was analyzed through the Cox regression method. Variables tested included age, gender, level of education, smoking, alcohol use, diabetes, study jaw, treatment, decayed-missing-filled teeth index, number of teeth, PlI, CAL-V, probing pocket depth, and bleeding on probing. The results were expressed as hazard ratios with 95 % CIs. Within a stepwise analysis, all variables with $p \leq 0.05$ in univariate analyses were planned to enter the multivariable model building process and be excluded at $p > 0.1$.

Results

Two hundred fifteen patients were enrolled between January 2001 and February 2004 of whom 109 were allocated to the PRDP group and 106 to the SDA group (Fig. 1). One

Table 1 Baseline characteristics

	Age (years)	Gender (female) (%)	Level of education low/intermediate/high (%)	Current smoking (%)	Alcohol use (%)	Diabetes (%)
PRDP group	59.3 (11.2)	49 (45)	4(4.9)/67(82.7)/10(12.3)	15 (18.7)	11 (13.5)	6 (7.4)
SDA group	59.6 (10.3)	58 (54.7)	5(7.1)/57(81.4)/8(11.4)	22 (30.9)	8 (11.2)	7 (9.8)

Means (SD) or numbers (%)

Table 2 Posterior-most teeth per quadrant in the study jaw at baseline

	Maxilla		Mandible	
	First premolar	Second premolar	First premolar	Second premolar
PRDP group	15	15	52	76
SDA group	8	8[a]	61	65[b]

[a] Including one case with all premolars and anterior teeth present

[b] Including five cases with all premolars and anterior teeth present

hundred fifty patients received the allocated treatment from January 2002 to March 2005. Two patients of the SDA group received the wrong treatment. The intention-to-treat-population was regarded to be those who received any of the two study treatments (n=152). Seventy-one and 61 resp. patients reached the 5-year follow-up examination.

Baseline demographic and clinical characteristics are given in Table 1. The study jaws are characterized in Table 2.

Thirty-eight patients experienced tooth loss between baseline and 5-year examination (Table 3). Among the

Table 3 Tooth losses between baseline and 5 year examination details

PRDP group				SDA group			
Study jaw		Opposing jaw		Study jaw		Opposing jaw	
Tooth	Reason for extraction	Tooth	Reason for extraction	Tooth	Reason for extraction	Tooth	Reason for extraction
24[a, b, c]	Endodontic	17	Periodontal	33[a, b]	Caries	17[a]	Periodontal
23[a, b]	Fracture	17	Caries	34[a, b, c]	Periodontal	15	Endodontic
31	Periodontal	16[a]	Endodontic	34[a, b, c]	Endodontic	14[a]	Endodontic
32[a, b]	Periodontal	14[a]	Fracture	35[a, b, c]	Fracture	13[a]	Endodontic
34[a, b]	Caries	13[a]	Caries	35[a, b, c]	Periodontal	12[a]	Endodontic
35[c]	Caries	12[a]	Periodontal	43[a, b]	Endodontic	11	Caries
35[c]	Fracture	12	Periodontal	44[c]	Endodontic	11[a]	Caries
41	Periodontal	11	Periodontal	44[c]	Caries	21[a]	Periodontal
42	Periodontal	11	Fracture	44[a, b, c]	Endodontic	21	Caries
43	Fracture	21[a]	Periodontal	44[a, b, c]	Fracture	22	Periodontal
44	Endodontic	21[a]	Caries	45[b, c]	Endodontic	23	Periodontal
44	Endodontic	22[a]	Periodontal	45[a, b, c]	Fracture	24	Fracture
45[a, b, c]	Endodontic	23	Fracture			25[a]	Fracture
45[a, b, c]	Caries	23	Fracture			26	Endodontic
45[a, b, c]	Caries	23	Endodontic			36	Caries
45[a, b, c]	Endodontic	24[a]	Fracture			47[a]	Not available
45[a, b, c]	Fracture	24[a]	Fracture				
45[a, b, c]	Fracture	27[a]	Periodontal				
		27[a]	Caries				
		36[a]	Periodontal				
		35	Caries				
		34	Periodontal				
		34	Caries				
		33	Periodontal				
		32	Periodontal				
		43	Caries				
		44	Caries				
		47	Caries				

[a] Primary outcome

[b] First tooth loss in study jaw

[c] Posterior-most tooth in the study jaw

causes for losses related to the primary outcome, which occurred in 22 patients in the PRDP group and 17 patients in the SDA group, were caries, endodontic reasons, fractures, and periodontal reasons, with almost equal frequency. Endodontic reasons (n=7) and fractures (n=6) prevailed with regards to the first losses in the study jaw.

Among the losses of the posterior-most teeth in the study jaw, endodontic reasons (n=7) and fractures (n=6) were also the most frequent causes. Of a total of 30 losses over 5 years in the study jaw, 19 affected the posterior-most teeth. In nine cases in the PRDP group and six in the SDA group, tooth loss lead to a renewal of the prosthetic treatment outside the original concept.

For the primary outcome (first) tooth loss, the Kaplan–Meier survival rates at 5 years (1,826 days) were 0.74 (95 % CI 0.64, 0.84) in the PRDP group and 0.74 (95 % CI, 0.63, 0.85) in the SDA group (Fig. 2). The survival functions did not differ significantly. After 5 years (1,826 days), the survival rates become increasingly uncertain because of the strongly decreasing number of individuals under risk.

For tooth loss in the study jaw, the Kaplan–Meier survival rates at 5 years (1,826 days) were 0.88 (95 % CI, 0.80, 0.95) in the PRDP group and 0.84 (95 % CI, 0.74, 0.93) in the SDA group (Fig. 3).

For the tooth loss in the posterior-most teeth of the study jaw (first or second premolar), the Kaplan–Meier survival rates at 5 years (1,826 days) were 0.90 (95 % CI 0.83, 0.97) in the PRDP group and 0.85 (95 % CI 0.76;,0.94) in the SDA group (Fig. 4).

Additionally, we examined the influence of baseline characteristics and values as potential covariates on tooth loss. The univariate analyses in the statistical model building process showed no significant influences. This applied to all three dependent variables which were tested analogous to the survival analyses. Therefore, no Cox regression models of appropriate fit could be found.

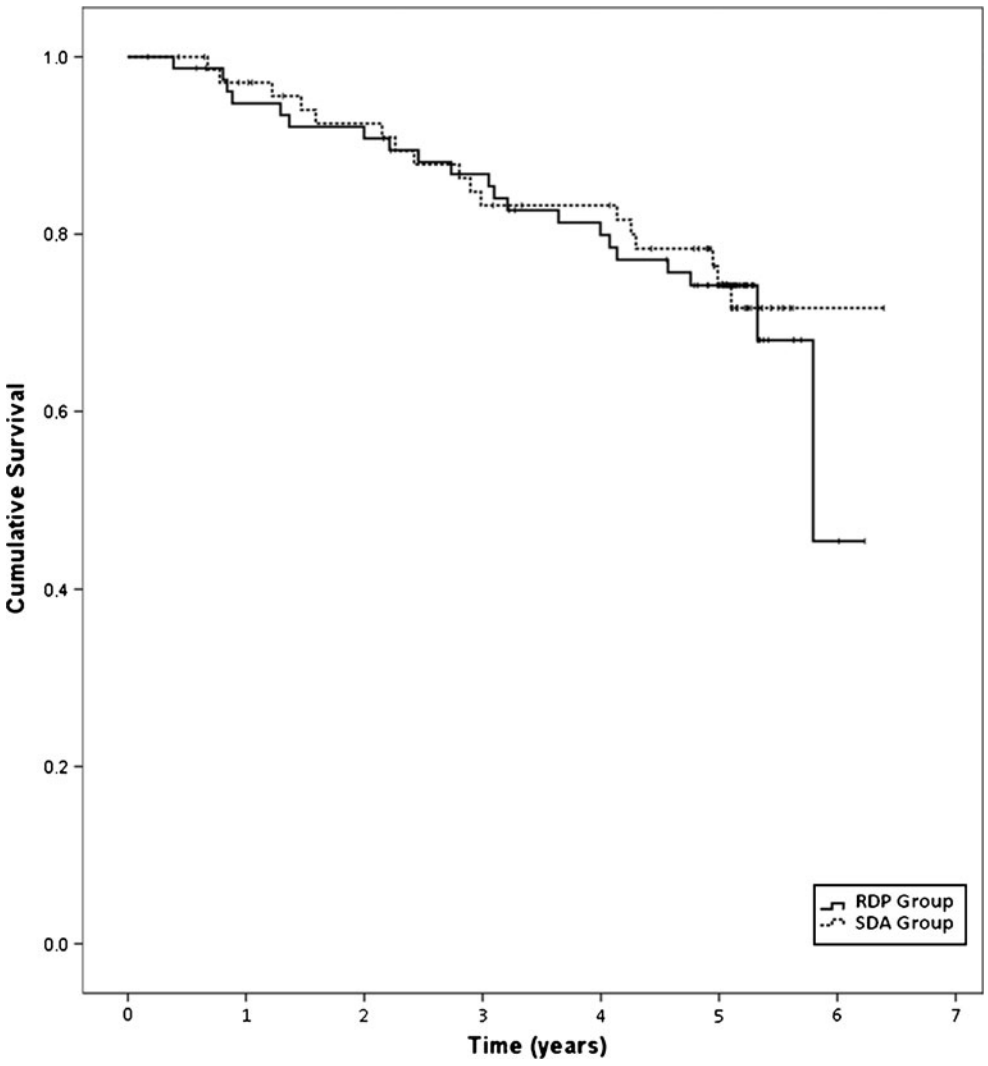

Fig. 2 Primary outcome measure. Tooth loss regardless of jaw. Kaplan–Meier survival functions. No significant difference (p=0.90)

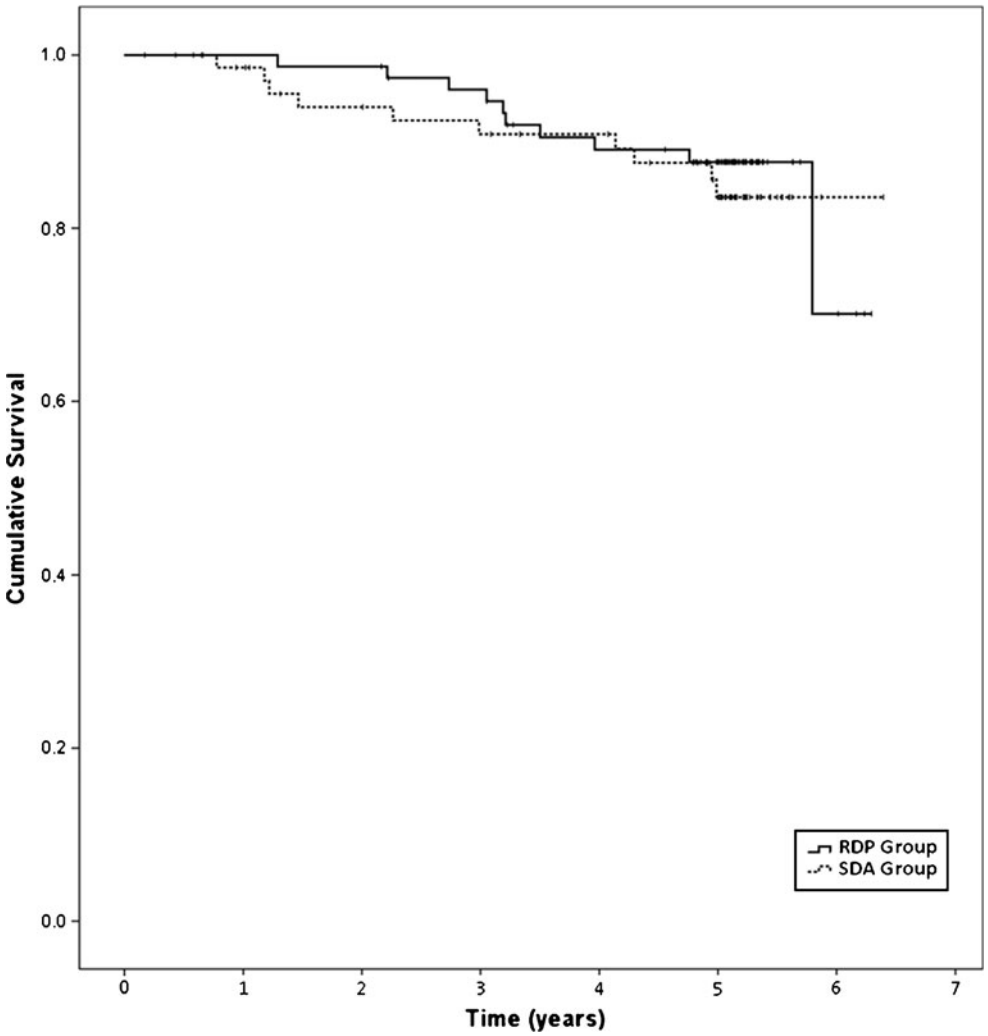

Fig. 3 Tooth loss in the study jaw. Kaplan–Meier survival functions. No significant difference (p=0.54)

Discussion and conclusions

Overall and in view of the randomized trial design, the data quality and validity can be considered high. The dropout rate over 5 years was relatively low. Presumably, this can be partially attributed to the financial compensation the patients received for all appointments which increased over time. There might be some controversy about the chosen primary outcome. Tooth loss after complex dental treatment, however, has a high clinical impact and is associated with failure from the patient's point of view [8, 26]. Basically, it is a reliable and widely accepted clinical endpoint. It can be assumed further that a complex treatment like ours in one jaw could also affect the life expectancy of teeth in the opposing jaw (loading, changes in microbiological environment). On the other hand, the outcome tooth loss is certainly rough. Small differences between the groups might not be measurable over short-term and middle-term observation periods. In this respect, surrogate outcome measures like clinical attachment loss could be more effective [32–34].

In essence, the results are in line with the 3-year analysis [28]. Tooth loss was more frequent than expected. Even in a standardized study setting, the overall treatment goals of a sustainable oral rehabilitation and the avoidance of further tooth loss over longer periods were not reliably achievable. The causes of our rates of patients affected by tooth loss can only be speculated. It should be mentioned that there might exist treatment options, such as implant restorations, which could have been more successful than those we included in this study. The same applies to stricter maintenance concepts. Further, a misjudgment of tooth prognosis and patient-related factors in the planning stage could have played a major role. In a retrospective study, the tooth-specific periodontal prognosis was a significant predictor of tooth loss [7, 35]. Teeth with an initial prognosis other than good were shown to be at an increased risk. Particularly in the opposing jaw where the treatment protocol was not as strict as in the study jaw, compromised teeth might have been preserved for different reasons. Holm-Pedersen et al. [26] concluded that the decision of dentists to extract a tooth is rarely based purely on the

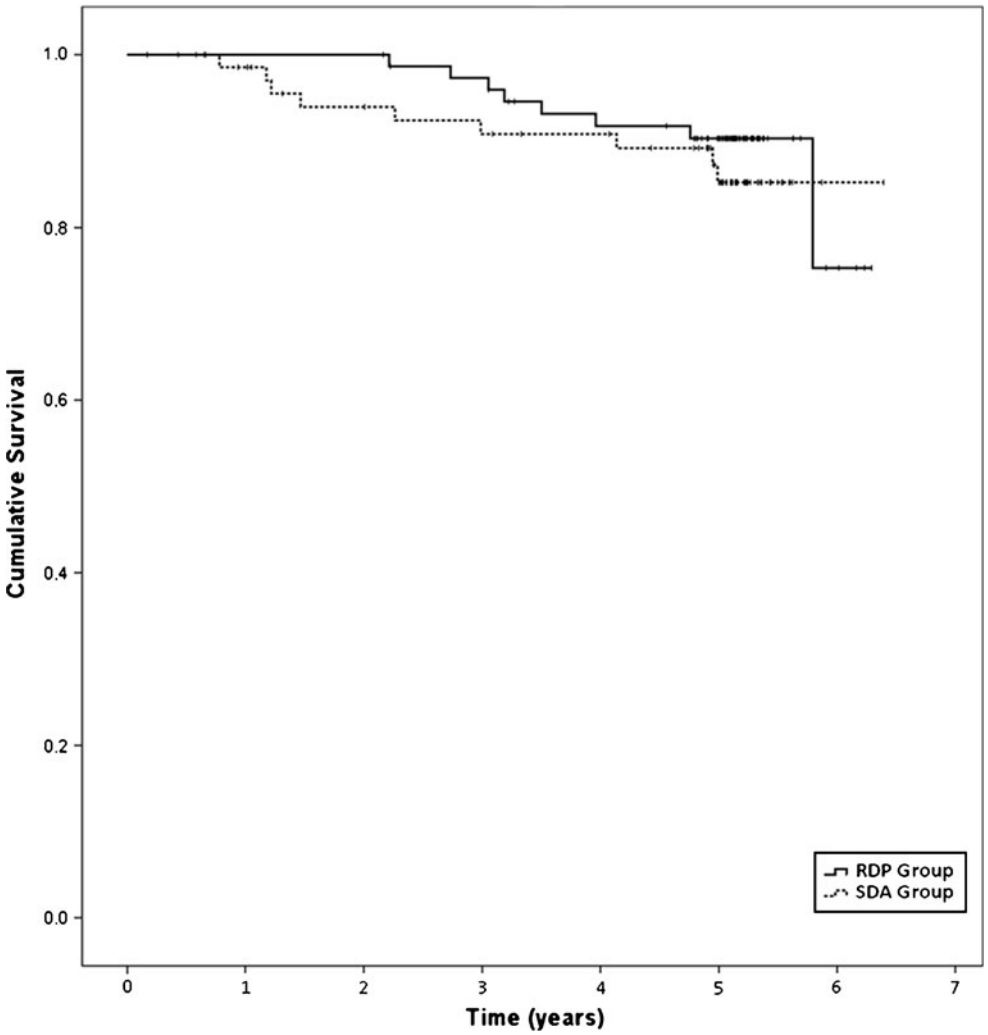

Fig. 4 Loss of posterior-most teeth in the study jaw. Kaplan–Meier survival functions. No significant difference (p=0.38)

evaluation of single risks as endodontic or periodontal problems. Among others, the remaining tooth structure, the extent of previous restorations, and the strategic importance within the dentition are considered additionally. A current systematic review on tooth loss under periodontal maintenance is available [36]. With observation periods of at least 5 years, the rate of patients not affected by tooth loss was found to range from 50.0 to 88.5 % for practice-based studies and from 36.0 to 79.4 % for university-based studies. Although these results are not appropriately comparable because of the variation in the observation times and dissimilar samples, they might be considered as lying in the same scale. In a review on tooth loss in Europe, an annual incidence of persons losing one or more teeth varying from 1 to 14 % was found [37]. Although a respective incidence calculation from our data was not intended, the estimated rate might also lie in this range.

The finding of more than 60 % of tooth losses in the study jaw affecting posterior-most teeth shows that these teeth might be at a particular risk in shortened dental arches. By this finding, our approach of analyzing these teeth separately is supported. The following reasons for the relatively high share of losses of posterior-most teeth can be assumed. First of all, posterior-most teeth might already exhibit a significant preexisting damage. Due to the study design, these teeth had to be crowned in most patients. Serving as abutment tooth was reported to be a factor positively related to tooth loss [22, 38]. In addition, the area adjacent to a PRDP might be especially prone to plaque accumulation.

As with the 3-year analysis, the study after 5 years also found no evidence that one treatment is superior to the other in terms of tooth loss [28]. We failed to reject the null hypothesis. The null hypothesis has not been proven, however. Possibly, it might be rejected with a higher number of cases and after a longer period of time. Essentially, the lacking evidence concerning the superiority of one treatment applies only to the treatments that had been actually carried out. The designs of PRDPs in different countries and settings vary considerably. The attachment-retained PRDP is common particularly in Central Europe, whereas it plays no significant role in North America. We assume that, in line with a number of recent papers, tooth loss is associated with an array of causal factors of which the type of prosthetic

treatment might have been overestimated [15, 26, 39]. In a retrospective study, PRDP abutment teeth had about a three-fold higher risk of loss than FDP abutment teeth [7]. In retrospective nonrandomized trials, however, the decision for a certain prosthetic treatment might have been strongly dependent on the prognosis of the prospective abutment teeth. Therefore, a comparison can be biased. Randomized trials are probably the only source of valid data in this respect. In one of the few available randomized trials, no differences of failure rates between treatments with PRDPs and cantilever resin-bonded bridges in SDAs were found over 5 years [25]. Data on tooth loss were not reported.

The rationale for using baseline values in the multivariate analyses was that we wanted to detect predictors for tooth loss which would be helpful in judging the prognosis of a treatment in advance. Unfortunately, no regression models of appropriate fit could be found. A possible reason could be that we focused on tooth loss on the patient and not on the tooth level. We therefore included independent variables on the patient level and tooth-specific variables related to the whole dentition. An analysis on the tooth level might have been more expressive but outside the main scope of this study. Moreover, essential factors may have been left out of consideration in designing the study. A factor considered potentially relevant for tooth loss was the number of missing teeth which indicates the preexisting damage of a dentition [32, 40]. Therefore, we included the number of teeth in the independent variables. In our sample, however, the variation of tooth numbers, at least in the study jaw, was limited by the inclusion criteria. This might have been the reason for not reaching significance. Again, the literature is not very conclusive in terms of predictors of tooth loss. Different from our results, age, smoking, and initial prognosis on tooth level were found to be associated with tooth loss in a systematic review [36].

The results strengthen the understanding of tooth loss being a multifactorial outcome [26, 37] that is difficult to predict. Professional judgment and patient preferences influence the clinical decision between removable and fixed restorations in SDAs. Regarding our results relative to the lacking impact of prosthetic treatment on tooth loss, the patient's view will gain even more importance.

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Conflict of interest The authors declare that they have no conflict of interest.

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