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Impact of shortened dental arch on oral health-related quality of life over a period of 10 years — A randomized controlled trial

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ABSTRACT

Objectives: To compare oral health-related quality of life (OHRQoL) in patients with either molar replacement by partial removable dental prostheses (PRDP) or with restored shortened dental arches (SDA) over a period of 10 years.
Methods: In this multi-center RCT, a consecutive sample of 215 patients with bilateral molar loss in at least one jaw was initially recruited in 14 prosthodontic departments. Of those patients, 150 could be randomly allocated to the treatment groups (SDA: n = 71; PRDP: n = 79), received the allocated treatment, and were available for follow-up assessments. OHRQoL was assessed using the 49-item version of the Oral Health Impact Profile (OHIP) before treatment (baseline) and at follow-ups after treatment (4–8 weeks and 6, 12, 24, 36, 48, 60, 96, and 120 months). To investigate the course of OHRQoL over time, we longitudinally modelled treatment and time effects using mixed-effects models.
Results: OHRQoL substantially improved from baseline to first follow-up in both groups indicated by a mean decrease in OHIP scores of 20.0 points (95%-CI: 12.5–27.5). When compared to the SDA group, OHRQoL in the PRDP group was not significantly different (−0.6 OHIP points; 95%-CI: −7.1 to 5.9) during the study period when assuming a constant time effect. OHRQoL remained stable over the 10 years with a statistically insignificant time effect (p = 0.848).
Conclusions: For patients requesting prosthodontic treatment for their lost molars, treatments with SDA or PRDP improve clinically relevantly OHRQoL and maintain it over a period of 10 years with no option being superior to the other.
Clinical significance: Since there was no significant difference between the two treatment options over the observation period of 10 years, and since results have stayed stable over time, patients can be informed that both treatment concepts are equivalent concerning OHRQoL.

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1. Introduction

Tooth loss still is a highly prevalent condition, affecting most people in middle and higher ages. Even though many prevention strategies have been established and implemented during the past decades, loss of teeth is still a major oral health problem with high public and individual health impact [1]. A condition of special interest is the loss of molars. Once all molars are lost on one side of a jaw, the resulting condition is called shortened dental arch (SDA) according to the definition by Käyser [2]. Several treatment options for SDA are available including no treatment. That is, keeping or restoring a dentition limited to a SDA are treatment options increasingly recognized by the dental community [3–6].

However, whether molars actually need to be replaced or not is still under debate. One major concern regarding when not replacing missing molars is or was a potentially increased loading on the temporomandibular joint (TMJ), which has been hypothesized to lead to pain and internal derangements (ID) of the TMJ [7–10]. Since no evidence from long-term prospective studies has supported this assumption, the prevention of TMJ pain and ID is no longer an indication for molar replacement in patients with SDA [11–13]. But missing molars – the loss of occlusal units – have also been associated with impaired oral health-related quality of life (OHRQoL) [14,15]. Furthermore, replacing missing molars in patients with SDA has improved OHRQoL [16]. However, most studies were only observational, limiting validity of the findings. On the other hand, other population-based studies could not establish a negative impact of SDA on OHRQoL [13,17,18]. But it can be argued that only those who do not have problems with their SDA would keep it and all individuals perceiving a significant negative OHRQoL impact would have demanded and received treatment to replace missing teeth [19,20]. Accordingly, evidence of cross-sectional studies is only of limited use to answer the question whether SDA causes impaired OHRQoL and therefore needs to be restored.

However, studies of the highest scientific evidence level are rare. Recent reviews have identified only two RCTs comparing SDA and tooth replacement by removable dental prostheses (RDP) [21,22]. An RCT with 132 Irish patients indicated patients in both groups perceived a significant improvement in OHRQoL at 6 and 12 months following treatment without a statistically significant between-group difference [23]. Interestingly, this study has also emphasized preservation or restoration of a SDA using resin-bonded bridgework is more efficient and cost-effective in terms of achieving minimal important differences (MID) in OHRQoL scores than full rehabilitation with RDP. A German multicenter, university-based RCT with 152 patients (Randomized Study of the Shortened Dental Arch, RaSDA) compared the same treatment options as the Irish RCT but with an observation period of five years [24]. At no follow-up during this trial, molar replacement with RDP has been superior to the SDA concept in terms of OHRQoL [25,26]. However, the long-term stability of the treatment effect and whether equivalence of both treatment options remains stable for more than five years has not been reported so far. In contrast to the Irish and the German RCTs, a recent RCT from South Africa, not included in the above mentioned reviews [21,22], with 50 patients indicated that a posteriorly reduced dental arch was associated with higher satisfaction and OHRQoL than a complete dental arch restored with RDP [27]. But follow-up period was short with only 12 months preventing from any conclusions regarding long-term effects.

Therefore, aim of the present investigation was to compare OHRQoL over a period of 10 years in patients treated with RDP or with restored SDA.

2. Methods

2.1. Subjects, study design and setting

In this multi-center RCT, a consecutive sample of 215 patients was initially recruited in 14 prosthodontic departments of dental schools in Germany. The recruitment period was January 2001 to February 2004.

For inclusion in the study, patients had to request prosthodontic treatment and have all molars missing in one jaw (study jaw), with at least both canines and one premolar present on each side of the jaw. Furthermore, an age of at least 35 years and good general health status, according to ASA classification [28] group 1 or 2 were required. Patients were excluded in case of demand for implant treatment, Angle class II or III, acute signs or symptoms of temporomandibular disorders (TMD) or grade 2 or higher of the Anamnestic Helkimo Index [29], obvious psychological disorders, and drug abuse.

Allocation to either the shortened dental arch (SDA) group or partial removable dental prosthesis (PRDP) group was performed using computer-generated randomization lists specific for each center. Due to the small number of participants in a single study center, randomization was performed using randomly permuted blocks of six and was stratified for age (threshold: 50 years) to assure similar number of patients in the two treatment groups and to balance patient characteristics. Since treatment characteristics differed substantially, blinding was obviously not possible. A total of 152 patients were randomized and received allocated interventions (Fig. 1). However, two patients in the RDP group were lost after provision of final restoration and no follow-up data are available for them. Accordingly, only 150 patients were included in the final analysis (SDA group: n = 71; PRDP group: n = 79; Fig. 1). The majority of these patients (84.6%) received treatment in the mandible.

Sample size calculation was based on primary outcome of the study, tooth loss [30]. This resulted in a required sample size of 70 patients per group. Results of primary outcome were published elsewhere [31]. In this paper, results of the secondary outcome, OHRQoL, are reported.

This research was conducted in accordance with accepted ethical standards for research practice, undergoing review and approval by the Institutional Review Board at TU Dresden, Germany (EK 260399). The study has been registered at controlled-trials.com under ISRCTN68590603 (pilot study) and ISRCTN97265367 (main study). Written informed consent was obtained from all participants prior to their enrollment.

2.2. Interventions

In the *SDA* group, molars were not replaced. If SDA was complete up to the second premolar, no dental treatment was performed in the posterior region. In cases with missing second premolars, teeth were replaced with conventional cantilever metal-ceramic fixed dental prostheses (FDP).

In the *PRDP* group, molars were replaced. Tooth replacement was carried out by means of PRDPs retained with precision attachments (Mini SG No. 055 675, CMSA, Biel, Switzerland), connected to either splinted metal-ceramic crowns or conventional FDP abutments on the posterior-most teeth on both sides. If the second premolar was missing, it was replaced by PRDPs as well.

Any missing tooth up to the first premolar was replaced by conventional metal-ceramic tooth-supported FDP in both groups. All patients received appropriate initial dental care, including oral hygiene instruction, nonsurgical periodontal treatments, and endodontic treatment, if necessary, to ensure adequate conditions prior to the final prosthodontic treatment phase. In cases with missing teeth in the opposite jaw, teeth were replaced at least up to the second premolar in the SDA group, and up to the first molar in the PRDP group, to ensure adequate occlusion and posterior tooth support. All dental procedures were performed standardized in all participating study centers.

2.3. Assessment of OHRQoL

This paper focused on secondary outcome of the study, OHRQoL, assessed using a German translation of the 49-item Oral Health Impact

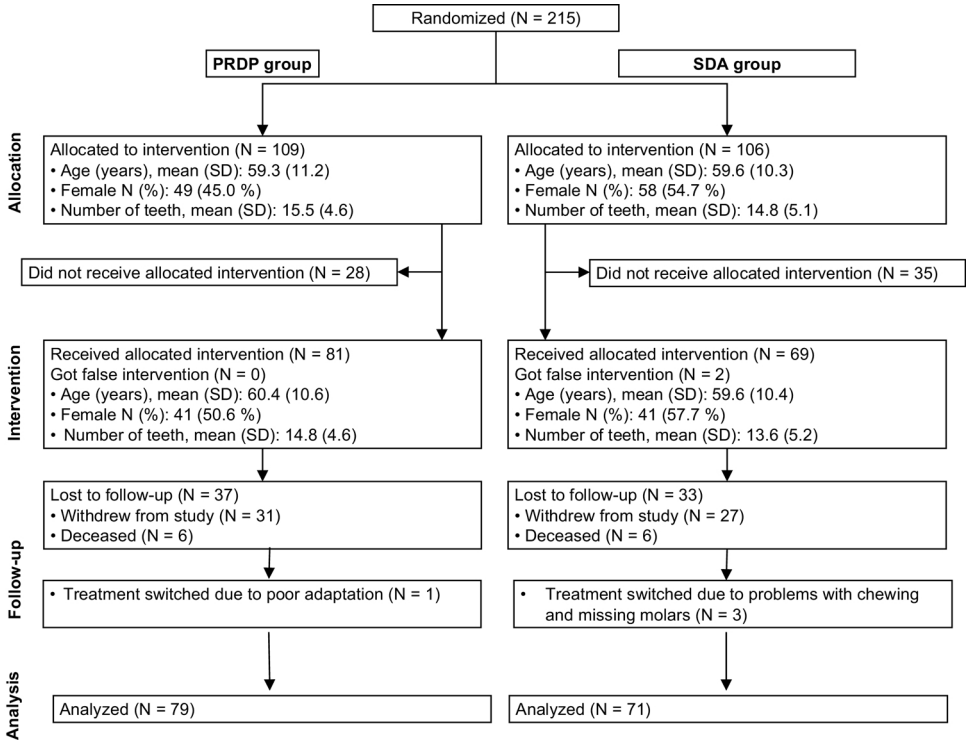

Fig. 1. CONSORT Flowchart.

Profile [26,32]. Each OHIP item asks a patient to rate how often a specific impact on OHRQoL has been experienced, with possible responses on a five-point ordinal rating scale ("never" = 0, "hardly ever" = 1, "occasionally" = 2, "fairly often" = 3, "very often" = 4). OHRQoL was operationalized as the simple sum of all 49 OHIP items with potential summary scores ranging from 0 to 196 points. Higher scores indicated more problems, and hence lower OHRQoL.

Patients completed OHIP as a self-administered questionnaire before prosthodontic treatment (baseline) and at follow-ups after treatment (4–8 weeks, 6 months, 12 months, 24 months, 36 months, 48 months, 60 months, 96 months, and 120 months).

Cronbach's alpha [33] as a measure of internal consistency was at baseline 0.97 and average inter-item correlation of all 49 OHIP items was 0.42. Accordingly, reliability of OHIP was considered satisfactory [34,35], what is in line with a previous study on OHIP dimensionality [36].

2.4. Data analyses

2.4.1. Baseline analyses

Patients' demographic and socio-economic characteristics and oral and general health perceptions at baseline are presented using measures for central tendency (means) and variability (standard deviation; SD) for continuous measures, and frequencies and proportions for ordinal and categorical measures. Patient histories of both groups (SDA and PRDP) were compared to test for statistically significant differences using two-sample *t*-test for continuous data (age), Wilcoxon rank-sum test for ordinal data (level of education, oral and general health perceptions) and chi-squared test for categorical data (gender, marital status, professional activities).

2.4.2. Analyses of treatment and time effect on OHRQoL

Which treatment (SDA or PRPD) worked better for patients with a SDA over a time period of 10 years was the primary target of the analysis. Consequently, the difference in OHIP-49 points between PRPD and SDA was the primary effect measure of the study. The effect was called "treatment effect." A positive number would indicate patients with PRPD had worse OHRQoL than patients with SDA.

How the two treatments affected patients over the 10-year time period, *i.e.*, how long the initial treatment influence lasted, was the secondary target of the analysis. The difference in OHIP-49 points between follow-ups represented this effect. The effect was called "time effect." A positive number would indicate that patients with OHRQoL improved over time.

Both treatment and time effect were visually assessed in graphs presenting mean OHRQoL levels for both treatments over time. In addition, when informative, effects were also assessed in terms of clinical relevance and statistical significance. OHIP-49's Minimal Important Difference (MID) of six points was used as a benchmark to determine what was relevant for patients [37].

All analyses were conducted following the intention-to-treat (ITT) approach: all patients who received the study treatment were analyzed based on the allocated treatment regardless of their per-protocol status.

The analysis had four steps with increasingly more stringent assumptions for treatment and time effect:

Raw treatment and time effects: To assess treatment effect for SDA and PRDP patients, OHIP mean scores were computed for each follow-up. Nine differences between the two treatments, *i.e.* nine treatment effects, were derived with accompanying confidence intervals. P-values were computed using two-sample *t*-tests, and standardized effects sizes (Cohen's *d*) were determined. Effect size (ES) represents degree of difference and is defined as difference between means divided by pooled standard deviations of measures. Guidelines suggest ES of 0.2 is considered small, 0.5 medium, and 0.8 large [38]. Based on review, an ES of 0.5 is clinically relevant [39]. Time effect was visually assessed in plots of OHRQoL means over time.

Modelled treatment effects, *i.e.*, repeated outcome measurement and patients' baseline characteristics were taken into account: Outcome measurement was repeated at ten follow-ups and a mixed-effects model with patients as random effect and an unstructured covariance matrix addressed this. Fixed model effects included age (four age quartiles as indicator variables), gender, and baseline OHRQoL. Treatment effects

Table 1
Socio-demographic characteristics and perceived health of study participants at baseline, and stratified for treatment group.

	All	Treatment group		
	(n = 150) *Mean (SD) or n (%)*	SDA (n = 71)	PRDP (n = 79)	Significance *P-value*
Socio-demographic characteristics				
Gender				0.473
Male	68 (45.3)	30 (42.3)	38 (48.1)	
Female	82 (54.7)	41 (57.7)	41 (51.9)	
Age				
Years	59.8 (10.6)	59.3 (10.5)	60.3 (10.6)	0.583
Marital status[a]				0.013
Married or long-term relationship	113 (79.0)	45 (69.2)	68 (87.2)	
Single, widowed, or divorced	30 (21.0)	20 (30.8)	10 (12.8)	
Level of education[b]				0.438
Up to 8 y of school	26 (17.8)	13 (19.1)	13 (16.7)	
10 – 12 y of school	10 (6.8)	3 (4.4)	7 (9.0)	
Apprenticeship	61 (41.8)	26 (38.2)	35 (44.9)	
College, higher education, university	49 (33.6)	26 (38.2)	23 (29.5)	
Professional activities[c]				0.562
Job or business	66 (45.2)	29 (42.6)	37 (47.4)	
Unemployed or retired	80 (54.8)	39 (57.4)	41 (52.6)	
Perceived health				
General health[d]				0.425
Excellent	1 (0.7)	1 (1.5)	0 (0.0)	
Very good	18 (12.4)	5 (7.5)	13 (16.7)	
Good	82 (56.6)	40 (59.7)	42 (53.8)	
Fair	36 (24.8)	17 (25.4)	19 (24.4)	
Poor	8 (5.5)	4 (6.0)	4 (5.1)	
Oral health[e]				0.601
Excellent	1 (0.7)	0 (0.0)	1 (1.3)	
Very good	4 (2.8)	3 (4.5)	1 (1.3)	
Good	48 (33.3)	21 (31.8)	27 (34.6)	
Fair	62 (43.1)	26 (39.4)	36 (46.2)	
Poor	29 (20.1)	16 (24.2)	13 (16.7)	

[a] n = 7 patients with missing values for marital status (n = 6 for SDA and n = 1 for PRDP).
[b] n = 4 patients with missing values for level of education (n = 3 for SDA and n = 1 for PRDP).
[c] n = 4 patients with missing values for professional activities (n = 3 for SDA and n = 1 for PRDP).
[d] n = 5 patients with missing values for perceived general health (n = 4 for SDA and n = 1 for PRDP).
[e] n = 6 patients with missing values for perceived oral health (n = 5 for SDA and n = 1 for PRDP).

were modelled as treatment-time interaction and nine treatment effects resulted. Again, time effect was visually assessed.

Modelled treatment effects assuming a constant treatment effect: Because the nine treatment effects at follow-ups did not vary substantially, a constant treatment effect over time was analyzed next. A single treatment effect resulted. As previously, time effect was visually assessed.

Modelled treatment effects assuming a constant treatment effect and a constant time effect: Because OHRQoL over time did not vary substantially, a linear time effect, *i.e.*, per time unit OHRQoL increases or decreases by a constant OHIP-49 score. In the previous three steps, eight different time effects (OHRQoL differences 1–6, 6–16, … 96–120 months) for each of the two treatments existed. While these time effects were visually assessed in steps 1–3, step 4 assumed one constant time effect per time unit. A likelihood ratio test compared this simple model with a linear time effect against a more flexible model with a quadratic time effect, allowing a curved (quadratic) OHRQoL course over time.

Table 2
Course of OHRQoL over study period for all patients and stratified for treatment group.

Assessment	All		Treatment group			
			SDA		PRDP	
	N	*Mean (SD)*	*N*	*Mean (SD)*	*N*	*Mean (SD)*
Pre-treatment	145	48.7 (37.1)	67	51.9 (39.8)	78	46.0 (34.7)
4-8 wks	146	28.7 (27.3)	69	27.4 (27.7)	77	29.9 (27.0)
6 mos	137	24.7 (27.8)	65	26.0 (30.7)	72	23.4 (25.1)
12 mos	139	24.1 (27.8)	66	25.4 (31.1)	73	22.8 (24.5)
2 yrs	136	25.6 (29.3)	61	27.2 (32.9)	75	24.3 (26.2)
3 yrs	132	25.1 (27.4)	61	25.6 (29.1)	71	24.7 (26.1)
4 yrs	125	27.2 (29.5)	58	30.8 (33.3)	67	24.0 (25.6)
5 yrs	130	27.5 (29.6)	60	29.9 (31.5)	70	25.6 (28.0)
8 yrs	93	24.6 (24.7)	41	24.0 (24.1)	52	25.2 (25.4)
10 yrs	81	23.8 (22.3)	37	22.7 (23.1)	44	24.7 (21.9)

2.4.3. Missing data

The number of patients with completed OHIP questionnaires ranged from 148 (98.7%) at 4–8 week follow-up, to 81 (54.0%) at the 10-year follow-up. On average, OHIP information for participating patients was available for 8.5 occasions, and 61 patients (40.7%) providing information for all ten occasions.

OHIP information was complete (no missing values) for 55.7% of the questionnaires. On average, each questionnaire contained 1.9 missing responses. For all subjects in the study, 3.8% of OHIP information was missing. In all questionnaires with less than 20 items with missing information, values were imputed using a median imputation (within person and occasion response vectors) for each OHIP item since OHIP is essentially unidimensional [36]. A total of 18 (1.4%) questionnaires had more items with missing information and were excluded from analyses (baseline: N = 2; 4–8 weeks: N = 2; 6 months: N = 5; 12 months: N = 1; 2 years: N = 2; 3 years: N = 2; 4 years: N = 3; 5 years: N = 1).

All analyses were performed using statistical software package STATA (Stata Statistical Software: Release 14.2. StataCorp LP, College Station, TX, USA), with probability of a type I error set at the 0.05 level.

3. Results

3.1. Characteristics of participants

At baseline, slightly more participants were female than male, and mean age was 60 years with no statistically significant differences in gender or age between treatment groups (Table 1). However, the proportion of participants being married or living in a long-term relationship was higher in the PRDP group (87.2%) than in the SDA group (69.2%; $p = 0.013$). No between-group differences were observed for socio-economic status and health perceptions.

3.2. OHRQoL over study period

Pretreatment OHIP summary score mean of all study participants was 48.7 points (Table 2). After treatment at 4–8 week follow-up, OHRQoL substantially improved, indicated by a decrease in OHIP scores to a mean of 28.7 (difference: 20.0; 95% CI: 12.5 to 27.5) points. At the end of the 10-year period, mean OHIP summary score of all patients was 23.8 OHIP points.

Table 3
Treatment effect estimates for all follow-up assessments.

Assessment	Treatment effect estimates						
	Raw treatment effect			Modelled treatment effect		Modelled constant treatment effect	
	Diff (95% CI)	*ES*	*P-value*	*Diff (95% CI)*	*P-value*	*Diff (95% CI)*	*P-value*
4-8 wks	2.4 (−6.5; 11.4)	0.09	0.590	4.5 (−3.4; 12.3)	0.266	−0.6 (−7.1; 5.9)	0.855
6 mos	−2.6 (−12.0; 6.8)	0.09	0.588	−2.1 (−10.1; 5.8)	0.597	−0.6 (−7.1; 5.9)	0.855
12 mos	−2.6 (−11.9; 6.8)	0.09	0.584	−1.1 (−8.9; 6.8)	0.786	−0.6 (−7.1; 5.9)	0.855
2 yrs	−2.9 (−12.9; 7.1)	0.10	0.567	0.2 (−7.6; 8.0)	0.958	−0.6 (−7.1; 5.9)	0.855
3 yrs	−0.9 (−10.5; 8.6)	0.03	0.844	0.9 (−7.0; 8.7)	0.831	−0.6 (−7.1; 5.9)	0.855
4 yrs	−6.8 (−17.2; 3.6)	0.23	0.200	−4.6 (−12.5; 3.4)	0.260	−0.6 (−7.1; 5.9)	0.855
5 yrs	−4.3 (−14.6; 6.1)	0.14	0.414	−2.7 (−10.7; 5.3)	0.508	−0.6 (−7.1; 5.9)	0.855
8 yrs	1.2 (−9.1; 11.5)	0.05	0.819	−1.9 (−11.4; 7.5)	0.689	−0.6 (−7.1; 5.9)	0.855
10 yrs	2.0 (−8.0; 12.0)	0.09	0.688	−0.8 (−11.5; 9.8)	0.878	−0.6 (−7.1; 5.9)	0.855

3.3. Treatment and time effects

3.3.1. Raw treatment and time effects

At follow-ups, treatment effects ranged from −6.8 to 2.4 OHIP points (Table 3). Judged against the threshold for clinical relevance, OHIP's MID, eight treatment effects were not clinically relevant and only one was. Four years after treatment, patients treated with SDA presented with 6.8 OHIP points more than patients treated with PRDP. However, confidence intervals for all treatment effects were wide and effects were not statistically significant. Furthermore, none of ES exceeded the value 0.5 that indicates a medium effect.

During the 16 follow-up to follow-up changes between month one and month 120 in the two treatment groups (time effects), OHRQoL three times increased and three times decreased (larger than 1 OHIP point), and the change was ten times less than 1 point (Table 4). Only one change reached the level of clinical relevance. From the first follow-up 4–8 weeks after treatment to the second one after six months, patients in the PRDP group indicated a decrease in the OHIP mean score of 7.1 (95% CI: 3.5 to 10.7) points. However, a pattern of more or less OHRQoL over time was not apparent (Fig. 2, Panel A).

3.3.2. Modelled treatment effects

Model-based treatment effects for all follow-up assessments ranged from −4.6 to 4.5 OHIP points (Table 3). Compared to raw differences in step 1, effects were smaller and none reached the threshold of clinical relevance. No effect was statistically significant.

Time effects also decreased in magnitude (Fig. 2, Panel B).

3.3.3. Modelled treatment effects assuming a constant treatment effect

Assuming one constant treatment effect, the difference between PRDP and SDA was −0.6 (95% CI: −7.1 to 5.9) OHIP points (Table 3).

Time effects decreased further (Fig. 2, Panel C; Table 4).

3.3.4. Modelled treatment effects assuming a constant treatment effect and a constant time effect

Treatment effect did not change notably (−0.6, 95% CI: −7.1 to 5.9 OHIP points) when time had a constant effect on OHRQoL (Fig. 2, Panel D). Only the lower confidence interval exceeded MID.

When this model with a linear time effect was compared to a more complex model (with a quadratic shape of time effect), the more complex model appeared not to be statistically superior ($p = 0.896$). Therefore, we adopted the simpler model. Time effect in this model was 0.5 (95% CI: −4.1 to 5.1; $p = 0.848$) OHIP points over the 10-year period with confidence interval not reaching MID (Table 4).

4. Discussion

This RCT indicates SDA and PRDP are equivalent treatment options for patients requesting prosthodontic treatment for their lost molars. Even more important, OHRQoL remained stable over the 10-year study period after treatment effect had been received.

Our confidence in these results is strong because the difference in OHRQoL between the two treatments was very small with 0.6 OHIP points. Only one bound of the 95% confidence interval slightly exceeded with 7.1 points the MID of 6 points. Furthermore, only a change of 0.5 OHIP points was observed over the entire study period with confidence interval excluding MID. However, while treatment had a strong and long-lasting effect for patients around 60-years old who had a SDA dentition, these patients still have a notably impaired OHRQoL compared to the general population [40] even after receiving state of the art treatment.

Findings of our study can be compared to the existing literature with respect to two important aspects: (i) comparison between both performed treatment options SDA and PRDP, and (ii) assessment of duration of both treatment options' effect on the patient. For treatment-

Table 4
Time effect estimates for all follow-up to follow-up comparisons.

Follow-up to follow-up	Time effect estimates					
	Raw time effect		Modelled time effect [a]		Modelled constant time effect [a]	
	SDA *Diff (95% CI)*	PRDP	SDA *Diff (95% CI)*	PRDP	SDA *Diff (95% CI)*	PRDP
4-8 wks to 6 mos	0.4 (−4.6; 5.5)	7.1 (3.5; 10.7)	3.8 (0.7; 7.0)	3.8 (0.7; 7.0)	0.0 (−0.2; 0.2)	0.0 (−0.2; 0.2)
6 mos to 12 mos	1.0 (−3.5; 5.4)	0.6 (−2.9; 4.1)	0.5 (−2.7; 3.7)	0.5 (−2.7; 3.7)	0.0 (−0.2; 0.3)	0.0 (−0.2; 0.3)
12 mos to 2 yrs	−2.1 (−7.4; 3.2)	−1.5 (−4.3; 1.3)	−0.8 (−4.1; 2.4)	−0.8 (−4.1; 2.4)	0.0 (−0.4; 0.5)	0.0 (−0.4; 0.5)
2 yrs to 3 yrs	0.5 (−2.7; 3.7)	0.1 (−3.5; 3.8)	0.4 (−2.8; 3.7)	0.4 (−2.8; 3.7)	0.0 (−0.4; 0.5)	0.0 (−0.4; 0.5)
3 yrs to 4 yrs	−3.9 (−8.7; 0.8)	0.0 (−3.8; 3.7)	−2.8 (−6.2; 0.5)	−2.8 (−6.2; 0.5)	0.0 (−0.4; 0.5)	0.0 (−0.4; 0.5)
4 yrs to 5 yrs	1.5 (−3.8; 6.8)	−0.5 (−4.8; 3.8)	0.4 (−3.0; 3.8)	0.4 (−3.0; 3.8)	0.0 (−0.4; 0.5)	0.0 (−0.4; 0.5)
5 yrs to 8 yrs	0.5 (−7.3; 8.2)	0.3 (−3.6; 4.3)	2.1 (−1.8; 6.0)	2.1 (−1.8; 6.0)	−0.1 (−1.2; 1.5)	−0.1 (−1.2; 1.5)
8 yrs to 10 yrs	1.2 (−6.1; 8.4)	−0.8 (−5.8; 4.2)	−0.1 (−4.4; 4.2)	−0.1 (−4.4; 4.2)	−0.1 (−0.8; 1.0)	−0.1 (−0.8; 1.0)

[a] Modelled constant treatment effect.

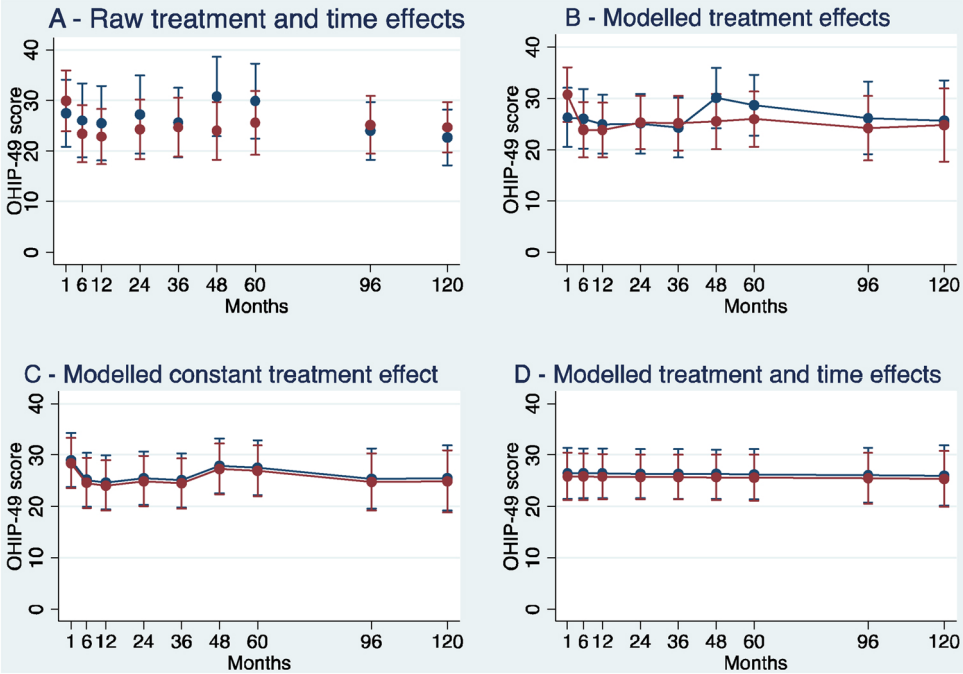

Fig. 2. Stepwise development of final model; Symbols in navy: SDA group, symbols in maroon: PRDP group.

specific changes in OHRQoL, there is no useful benchmark from similar studies because the longest reported evaluation period of other studies was one year [20,23]. Results of these two studies in combination with previous findings of our study [25] were summarized in a recent systematic review [22]. There was no statistically significant difference in OHIP-49 summary scores between SDA and PRDP at 6 or 12 months post-treatment, a result that is in accordance with our findings for the 10-year follow-up. However, a recent RCT reported different findings. In patients with a posteriorly reduced dental arch, satisfaction and OHRQoL were higher than in patients with complete dental arches restored with PRDP [27]. Besides the short follow-up period of only 12 months, the two interventions in this study were somewhat different to those in our study. Instead of using the definition of SDA, they included patients with three to six posterior occluding pairs of teeth also referred to as a posteriorly reduced dental arch. Furthermore, PRDPs were retained with cobalt-chrome clasps while in our study precision attachments were used. These treatment characteristics might explain the different findings in terms of OHRQoL when compared to our study. Regarding long-lasting treatment effects, we are not aware of any prospective study assessing the course of OHRQoL after prosthodontic treatment over a period of ten years. There are only some studies with follow-up periods of up to two years [41–44]. A common finding is that after varying periods of adaption of some weeks to several months treatment effects in terms of OHRQoL improvement were largest. However, in one study OHRQoL slightly decreased after the maximum treatment effect and approached pretreatment status of OHRQoL impairment asymptotically [41]. This was not observed in the current study and might have several reasons. Probably the most important one is the setting of the study. Our study was an RCT with frequent regular recalls, i.e., oral health maintenance was a specific and important part of the study. Accordingly, potential oral health problems and need for treatment were identified early and a tailored intervention prevented more severe problems and subsequent OHRQoL deterioration. In contrast, most of available prospective studies on OHRQoL changes after prosthodontic treatment were rather observational and were conducted in a regular clinical setting without short recall intervals [41,42].

The major strength of this study is its long duration of 10 years with several scheduled assessments during this period. This allowed determination and comparison of the duration of OHRQoL treatment effects. Treatment allocation had been based on a computer-based randomization list, limiting a potential bias due to patient characteristics. Furthermore, OHRQoL was assessed using the full 49-item version of OHIP, the internationally most commonly used and methodologically best investigated OHRQoL instrument. This ensured comparability of findings to those from other studies. However, only 55.7% of all OHIP questionnaires were completely answered by the participants and a total of 3.8% of information was missing. This is somewhat higher than in other studies using the OHIP-49. [45] A reason might be that the OHIP contains three items with denture-related problems usually not occurring in subjects without PRDP or complete dentures as in our SDA group. We used a commonly applied method for imputation of missing data considering most recent research on dimensionality of the OHIP [36,46], resulting in only 18 (1.4%) questionnaires that had to be excluded from analyses due to too many items with missing information, what seems to be acceptable. Blinding of patients, treating dentists, or examiners at follow-ups was obviously not possible. Even though the number of study participants decreased during the study period, we do not consider this a major limitation. The number of drop-outs did not substantially differ between groups, and withdrawal was unlikely to be related to a specific treatment option. This assumption is supported by low number of participants switching treatment. Only three participants in the SDA group had problems with chewing and requested a PRDP, and only one participant did not adapt well to the PRDP and switched to a SDA. However, these participants were analyzed following the ITT approach. The majority of the patients received the treatment in the mandible and only a minority in the maxilla. Therefore, findings are more valid for patients requesting prosthodontic treatment for their lost mandibular molars than for patients with lost maxillary molars. Advanced statistical models allowed to include data of all available follow-ups and determine a general treatment effect and, additionally, time effect. Accordingly, statistical power was sufficient to gain precise estimates.

In this study, dental implants were not considered. Lack of significant difference between groups raises the question concerning impact of implants in combination with SDA, especially since implant treatment combines already discussed advantages of SDA and PRDP

while eliminating their disadvantages. With implant-based molar replacement, an increase in OHRQoL of 2.1 OHIP-49 sum score points could be achieved per additional occlusal unit in SDA patients [14]. On the other hand, Fueki and coworkers showed both replacement of missing posterior teeth with either PRDPs or implant retained crowns improved OHRQoL. The mean OHIP-49 summary score decreased significantly after PRDP treatment, and it tended to decrease, though not statistically significant, after IFPD treatment. Restoration of one occlusal unit was associated with a 1.2-point decrease in OHIP-49 summary score [20]. This underlines the treatment concept of implant therapy must be taken into consideration when informing patients about treatment alternatives. However, it should not be seen as the default treatment from an OHRQoL perspective. Since all three treatment options are very different in terms of cost, chewing comfort, ease of cleaning, esthetics, psychological factors and invasiveness, patients often have a strong preference for a treatment. This was highlighted by two aspects of population-based studies: (i) It has been stated already in the introduction section that only patients who are dissatisfied with the SDA concept will ask for alternatives, whereas patients without problems will stay with the SDA concept [19,20]; (ii) Anxiety and fear to undergo a surgical procedure such as an implant insertion affects a substantial number of patients. When edentulous patients (over 65 years of age) who participated in an overdenture trial were offered a free implant overdenture, 36% refused [47]. In our study this strong preference is reflected by the fact that a substantial number of patients withdrew their consent after allocated treatment had been revealed to them [30,31]. This suggests a strong preference by patients for one treatment over another.

This study has important clinical implications. Since there was no significant difference between the two treatment options over the observation period of 10 years, and since results have stayed stable over time, both treatment concepts can be considered as equivalent concerning OHRQoL. Therefore, the patient must be informed in detail about treatment options, including advantages and disadvantages. The aim of this consultation is to bring the patient up to a level of information that enables "shared-decision making" - a joint decision-making process between patient and dentist [48]. In this context, a PRDP treatment approach may combine the advantage of improved chewing function with the disadvantage of the discomfort wearing a removable prosthesis. SDA, on the other hand, combines the advantage of absence of PRDP with disadvantage of a somewhat reduced chewing function. Based on this information an informed consent can be achieved and an informed (and legally binding) consent can be agreed [48].

In conclusion, both SDA and PRDP are treatment options with long-lasting and clinically relevant effects on OHRQoL for a period of 10 years with no option being superior in terms of OHRQoL improvement in patients requesting prosthodontic treatment for their lost molars.

Declaration of interest

None.

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Author Contributions

SW, BM, MW, RPL, and GH developed the conception and the design of the study. BM, MW, MK, RK, FN, HS, OS, BW, WH, TM, PP, JB, DE, EB, FJ, SH, and GH contributed to the acquisition of the data. DRR, MTJ, BM, and MW performed the analysis of the data. DRR, SW, MTJ, BM, MW, and GH interpreted the data. DRR drafted the manuscript with help of SW, MTJ, and GH. All authors critically revised the manuscript, have reviewed the final version of the manuscript, approve it for publication, and agreed to be accountable for all aspects of the work.

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