J Periodontal Implant Sci. 2022 Dec;52(6):e39
https://doi.org/10.5051/jpis.2105840292
pISSN 2093-2278·eISSN 2093-2286

JPIS
Journal of Periodontal & Implant Science

Research Article
Implant Science

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Quality of life, patient preferences, and implant survival and success of tapered implant-retained mandibular overdentures as a function of the attachment system

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OPEN ACCESS

Received: Nov 12, 2021
Revised: Jan 24, 2022
Accepted: Mar 14, 2022
Published online: Nov 8, 2022

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Funding
The study was supported by Institut Straumann AG, Basel, Switzerland.

ABSTRACT

Purpose: A novel attachment system for implant-retained overdentures (IRODs) with novel material combinations for improved mechanical resilience and prosthodontic success (Novaloc) has been recently introduced as an alternative to an existing system (Locator). This study investigated whether differences between the Novaloc and Locator attachment systems translate into differences in implant survival, implant success, and patient-centered outcomes when applied in a real-world in-practice comparative setting in patients restored with mandibular IRODs supported by 2 interforaminal implants (2-IRODs).
Methods: This prospective, intra-subject crossover comparison compared 20 patients who received 2 intra-foraminal bone level tapered implants restored with full acrylic overdentures using either the Locator or Novaloc attachment system. After 6 months of function, the attachment in the corresponding dentures was switched, and the definitive attachment system type was delivered based on the patient's preference after 12 months. For the definitive attachment system, implant survival was evaluated after 24 months. The primary outcomes of this study were oral health-related quality of life and patient preferences related to prosthetic and implant survival. Secondary outcomes included implant survival rate and success, prosthetic survival, perceived general health, and patient satisfaction.
Results: Patient-centered outcomes and patient preferences between attachment systems were comparable, with relatively high overall patient satisfaction levels for both attachment systems. No difference in the prosthetic survival rate between study groups was detected. The implant survival rate over the follow-up period after 24 months in both groups was 100%.
Conclusions: The results of this in-practice comparison indicate that both attachment systems represent comparable candidates for the prosthodontic retention of 2-IRODs. Both systems showed high rates of patient satisfaction and implant survival. The influence of material combinations of the retentive system on treatment outcomes between the tested systems remains inconclusive and requires further investigations.

Keywords: Dental implant; Mandible; Dentures; Survival; Quality of life

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Author Contributions

Conceptualization: Ilze Indriksone, Susy Linder; Formal analysis: Ilze Indriksone, Pauls Vitols; Investigation: Ilze Indriksone, Pauls Vitols, Viktors Avkstols, Linards Grieznis, Kaspars Stamers; Methodology: Ilze Indriksone, Susy Linder; Project administration: Pauls Vitols, Susy Linder; Writing - original draft: Ilze Indriksone, Susy Linder; Writing - review & editing: Ilze Indriksone, Pauls Vitols, Viktors Avkstols, Linards Grieznis, Kaspars Stamers, Susy Linder, Michel Dard.

Conflict of Interest

The authors disclose that Straumann AG Basel specifically covered the costs for the implants and prosthetic parts that were used as part of the study. Prof. M. Dard and Dr. Susy Linder are employees of Institut Straumann AG, Basel, Switzerland. No author of this manuscript has any conflict of interest concerning this study.

INTRODUCTION

Tooth loss and its rehabilitation represent one of today's major issues in health care. Non-rehabilitated edentulism is associated with several health problems, including nutritional shortcomings [1], obesity [2], cardiovascular disease [3], and higher mortality in elderly individuals [4]. Despite limitations such as ridge resorption and limited patient adaptation, conventional complete dentures (CCDs) still represent the most common treatment for edentulism [5,6]. Implant-retained complete overdentures (IRODs) are a valuable alternative to CCDs that potentially improve oral function, oral health-related quality of life (OHRQoL), and patient satisfaction compared to CCDs, with an adequate long-term clinical prognosis [7-10].

Supported by the positive patient-centered outcomes, IRODs retained by 2 interforaminal implants (2-IRODs) have been described as the first-choice standard of care for treating mandibular edentulism [10-12]. Recent advances in tapered implant designs have further expanded the capability to achieve sufficient primary stability even in situations of compromised bone quality, which might further help expand the target patient population of 2-IRODs [13].

Many different attachment systems for mandibular 2-IRODs have been developed [14]. A self-aligning stud attachment system (Locator) with vertical and hinge resilience has been proposed for conditions with reduced inter-arch distances or limited vertical mandibular heights [15,16]. Especially in situations with low vestibular height, considerable transversal forces may act on this type of attachment system [17]. These forces may lead to increased mechanical wear and prosthodontic complications, such as the loss of retention, retention inserts, or mechanical fracture of the denture base, which have been clinically documented in these systems [18-20]. Recently, a retentive system with a novel material combination has been presented (Novaloc). This system comprises a matrix of polyetheretherketone and an abutment coated with amorphous diamond-like carbon. Passia et al. [21] showed in a bench study that this material combination may improve the mechanical resilience of the attachment system against mechanical wear, loss of retention, and potential prosthodontic complications. In addition to the above-mentioned differences in material combinations, the Novaloc system offers straight and angled abutment options and, therefore, may compensate for off-axis forces resulting from angulated implant placement more adequately. To date, no data have been presented on how and whether these differences in material and design translate into different clinical and patient-centered outcomes. This clinical investigation aimed to assess whether the newly introduced retentive system might display possible advantages regarding functional or patient-centered outcomes in implant survival and success compared to the Locator system as the benchmark in a real-world in-practice setting.

MATERIALS AND METHODS

Study design

This study was designed as an open, prospective, non-randomized intra-subject crossover clinical investigation (**Figure 1**). Study settings and training resembled routine clinical in-practice operations to reflect real-world conditions. The in-clinic methodologies and assessments used within this investigation, with the exception of patient-reported outcomes, followed routine in-practice visual and observational assessments and were quantified whenever necessary using predefined rating scales. The study scheme is outlined in **Figure 1**. Novaloc® (Institut Straumann AG-Basel, Basel, Switzerland) (test group) and Locator® (Zest

https://doi.org/10.5051/jpis.2105840292

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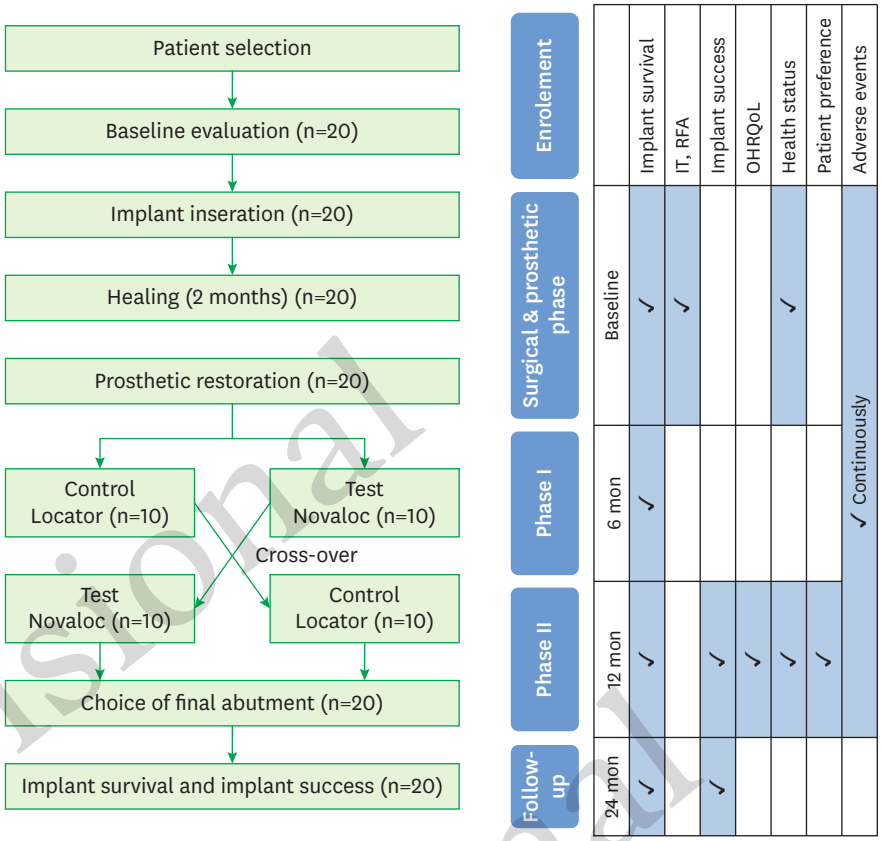

Figure 1. Design of the clinical investigation used to compare the test and control groups. N denotes the number of patients. Checkmarks (√) indicate the time points at which the corresponding parameters were assessed. IT: insertion torque measurements, RFA: resonance frequency analysis, OHRQoL: oral health-related quality of life.

Dental Solutions, Carlsbad, CA, USA) (control group) retentive abutment systems were compared with regards to routine clinical outcomes, implant survival, and implant success. Furthermore, patient satisfaction and preferences and oral health quality of life-related parameters were evaluated.

Based on previously reported similar study setups, a sample size of 20 subjects was considered sufficient to identify potential differences in patient preferences or OHRQoL parameters [16,22].

Ethical approval and informed consent

The investigation was carried out according to the Declaration of Helsinki (2008, ISO 14155:2011) and the ICH-GCP at the University of Riga. Ethics approval was obtained from the local ethics committee (ethics approval No. 14 from 30.06.2016). All study participants signed informed consent. This study adhered to the CONSORT guidelines.

Study population

Twenty subjects (7 women, 13 men) between 43 and 77 years of age at baseline with fully edentulous mandibles and fully or partially restored edentulous maxillae were enrolled. Fourteen non-smokers, 5 light smokers (≤ 10 cigarettes per day), and 1 heavy smoker (> 10 cigarettes per day) were included. All patients displayed a minimum inter-foraminal mandibular bone thickness and height of 6 and 12 mm, respectively. The bone types of the

https://doi.org/10.5051/jpis.2105840292

patients' mandibles were qualitatively derived from the proportion of compact and trabecular bone on panoramic radiographs at baseline as follows: type I: 2 patients, type II: 10 patients, type III: 7 patients, type IV: 0 patients [23]. The bone quality of 1 patient was not recorded during the assessment. Further, the patients' dental and general medical health status and history were assessed at baseline. Only patients with appropriate physical, medical, and mental conditions for surgical treatment were included in the study (American Society of Anesthesiologists class 1 and 2) [24].

Surgical protocol and prosthetic restoration

Two bone level tapered implants (Straumann® Roxolid/SLActive®; Institut Straumann AG-Basel, Ø 3.3 or Ø 4.1 mm, length 10 or 12 mm) were placed per patient in positions 32 and 42 (2 patients) or 33 and 43 (18 patients), respectively, according to the manufacturer's instructions. A 1-stage protocol with unloaded transmucosal healing was followed. Implant diameters and lengths were chosen by the treating clinician. Implants were placed at least 2 months after tooth extraction and without additional bone augmentation [25]. Healing caps with narrow or regular collars (NC or RC; Institut Straumann AG-Basel) were placed until prosthetic restoration. Patients' complete dentures were adapted to accommodate transmucosal unloaded healing.

The implants were restored and loaded 2 months after surgery. New mandibular metal-reinforced complete acrylic resin dentures were prepared using conventional laboratory techniques. Patients were randomly assigned to groups receiving Locator (control group) or Novaloc (test group) retentive systems (phase I) (**Figure 2**). After 6 months, patients were switched between control and test groups for phase II of the study by exchanging the retentive abutments and matrix elements using conventional laboratory methods. Dentures were readapted to the anatomic conditions. Patients' preferences were assessed by allowing the participants to choose the attachment system for final restoration after the completion of phase II, at the 1-year follow-up. The overall implant survival rate and implant success were evaluated at the 2-year follow-up time point. The individual study phases, patient flow, and evaluated parameters are illustrated in **Figure 1**.

Study parameters

Primary implant stability was assessed in terms of insertion torque (manual torque wrench; Institut Straumann AG-Basel) and resonance frequency analysis (Osstell ISQ; Osstell, Göteburg, Sweden) at implant placement. Implant success was assessed in terms of implant mobility, peri-implant radiolucency, clinical signs of infection or suppuration, and any persistent subjective complaints such as pain, foreign body sensation, or dysesthesia [26]. Implant survival was defined as the presence of the implant at the follow-up visit.

Prosthetic survival rates were evaluated based on device-related adverse events. The product-limit survival of individual abutment systems was defined as the prosthesis and abutment remaining *in situ* without adverse events throughout the corresponding study phases (6 months). Adverse events were classified as any event that required a prosthodontic intervention, including any failure of the prosthesis to function nominally reported by the patient or as diagnosed by the treating clinician during recall visits. The cumulative prosthetic survival rate was defined as 100% minus the proportion of study participants who reported adverse events. The cumulative survival rate was reported individually for both study phases and over both study periods. The hazard rate was defined as the probability of failure of a test-to-failure of a control device considering the effect of the placement order, patient sex, and smoking status.

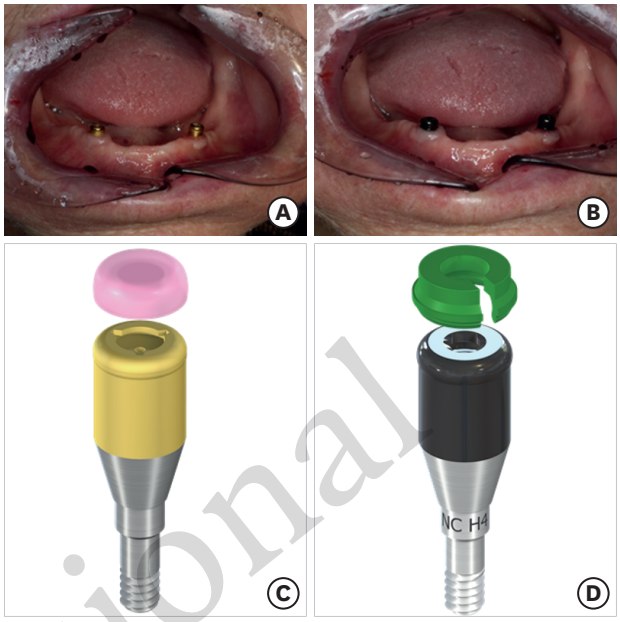

Figure 2. Intraoral view and schematic representation of implant overdenture attachment systems in the (A, C) control group (Locator®) and (B, D) test group (Novaloc®).

Patient satisfaction was quantified by verbal questioning by the clinician, prompting the patient to rate his or her satisfaction on a scale from 1 to 20. Patient-reported OHRQoL-related parameters were assessed using the Oral Health Impact Profile-14 (OHIP-14) questionnaire [27]. The results were quantified using a grade of 0 for "never," 1 for "hardly ever," 2 for "occasionally," 3 for "fairly often," and 4 for "very often." The OHIP-14 dimensions (psychological impact, pain/discomfort, functional limitation) and summary scores were evaluated separately [28].

The patients' self-reported health status was assessed using the European Quality of Life 5 Dimensions (EQ-5D) questionnaire [28,29]. The European Quality of Life 5 Dimensions 3 Level Version (EQ-5D-3L)-related parameters included evaluations of mobility, self-care, usual activities, pain/discomfort, and anxiety depression using a 3-level graded questionnaire comprising the states "no problems," "some problems," and "extreme problems." Patients were further asked to rate their actual health status on a visual analog scale (VAS) scale graded from 0 to 100 for the worst and best imaginable health states. The EQ-5D-related parameters were grouped and reported as the EQ-5D-3L sum scores and indices, respectively. Patient preference was evaluated as the patient's choice for the individual restoration to be used after the study.

Statistical analysis

Categorical parameters were summarized using counts and proportions. Continuous parameters were summarized using means, standard deviations, and ranges of extreme values. The reported differences in prosthetic function and survival, patient satisfaction, and quality of life-related parameters between the test and control groups were examined using the non-parametric Wilcoxon signed rank test for paired samples. Possible associations between these values in both groups were also examined using mixed linear regression models adjusted by the effects of factors such as time point, sex, and smoking status as fixed effects and for the effect of the patient as a random effect. Prosthetic function and

https://doi.org/10.5051/jpis.2105840292

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the cumulative survival rate were evaluated using the Kaplan–Meier method. The risk of mechanical complications was calculated using proportional hazard regression models and reported as the hazard ratio.

RESULTS

Enrollment, surgery, and prosthetic restoration

All 20 patients successfully completed implant surgery and prosthetic restoration. No adverse events were encountered during the surgical phase. Descriptive parameters related to the implant placement and provisional restoration of the implants are summarized in **Table 1**. The mean implant insertion torque and resonance frequency analysis values were 37.75±5.91 N·cm and 70.6±11.3 arbitrary resonance frequency units (a.u.), with ranges from 15 to 50 N·cm and 30 to 83 a.u., respectively.

Clinical parameters and implant survival rates

None of the implants showed clinical signs of implant mobility, peri-implant radiolucency, infection, or suppuration at the 24-month follow-up time point. Further, no subjective implant-related complaints were received. The implant success and survival after 12 and 24 months was 100% in both groups.

Prosthodontic survival

The cumulative survival rates of prosthetic restorations without any adverse events were analyzed individually and as a sum over both treatment phases. **Table 2** reports the survival rate

Table 1. Descriptive statistics of patient demographics, clinical parameters, and used materials between patient subcohorts first assigned to the test group (group 1) or to the control group (group 2)

Characteristics	Parameter	Group 1 (test first, control second)	Group 2 (control first, test second)
Patient demographics			
Age (yr)	Average ± SD (range)	64 ± 8.1 (44–76)	65.8 ± 5.7 (56–77)
Sex	Females/Males	10/0	6/4
Smoking status	Smokers/Non-smokers	3/7	3/7
Bone quality	I/II/III/IV	1/5/4/0	1/5/3/0
Implant-related parameters			
Insertion torque (N·cm)	Average ± SD (range)	38.25 ± 7.46 (15–50)	37.25 ± 3.7 (30–45)
Osstell ISQ (a.u.)	Average ± SD (range)	70.25 ± 11.66 (30–83)	70.95 ± 10.37 (35–81)
Implant type	BLT, NC, SLActive	12	14
	BLT, RC, SLActive	8	6
Implant diameter	3.3 mm	12	14
	4.1 mm	8	6
Implant length	10 mm	4	6
	12 mm	16	14
Healing abutment			
Type	Ø4.8 × 3.5 mm	12	14
Type	Ø5 × 4 mm	8	6
Abutment type			
Novaloc, height	3 mm/4 mm/5 mm	2/13/5	0/16/4
Locator height	3 mm/4 mm/5 mm	2/13/5	0/16/4
Novaloc angulation	(0°)	20	20
Locator angulation	(0°)	20	20
Novaloc retentive force mominal[a] (g)		1,650	1,650
Locator retentive force nominal (g)		1,360	1,360

SD: standard deviation, a.u.: arbitrary units, BLT: bone level tapered, NC: narrow collar, RC: regular collar.
[a]Values as indicated by the corresponding manufacturers; the same type of retentive matrix was used for all patients.

https://doi.org/10.5051/jpis.2105840292

Table 2. Cumulative prosthetic survival rates and proportional hazard rate/risk ratio for the incidence of a prosthetic complication of the test abutment compared to the control abutment summarized over both study phases and for individual study phases taking into account only first-occurring mechanical complications in individual restorations

Group	Cumulative survival rate	Hazard rate
	No. (%)[a]	Risk ratio (*P*-value)
Overall over both study phases		
Control	11 (55.0)	Reference
Test	14 (70.0)	0.610 (0.360)
Study phase I		
Control	5 (50.0)	1.961 (0.364)
Test	7 (70.0)	0.756 (0.738)
Study phase II		
Control	6 (60.0)	0.913 (0.909)
Test	7 (70.0)	Reference

[a]Total number of prosthetic restorations without prosthetic complications over the follow-up period of the individual study phases (6 months).

of prosthetic restorations without failure for the individual and summarized over both study phases. The summary cumulative survival rates for the test and control prosthetic components over both study phases were 70.0% and 55.0%, respectively. The difference between survival rates was not statistically significant (*P*=0.324). The cumulative survival rates were equally comparable for the individual study phases, without a statistically significant difference.

The corresponding calculated risk of failure of a test compared to the control abutment was 0.610 (*P*=0.360) over both study phases. When considering the placement order and using the test abutment as a reference, risk ratios of 1.961, 0.913, and 0.756 were calculated for the control abutments in phases I and II and the test abutments in phase I, respectively. The risk ratios for prosthetic failure between the test and control attachment systems after both or individual study phases did not show a statistically significant difference.

OHRQoL-related parameters, general health, and patient satisfaction and preference

The results related to OHRQoL, general health, and patient satisfaction and preferences are summarized in **Table 3**.

The self-reported subjective overall health status of the test and control groups assessed by the EQ-5D method were statistically comparable. Furthermore, no statistically significant differences between the groups with regard to the impact of treatment on EQ-5D sub-categories or the self-rated VAS score for subjective actual overall health status could be detected. The summary parameters for overall health in the test and control groups were also comparable.

The OHRQoL-related parameters assessed by the OHIP-14 questionnaires for the dimensions of psychological impact, pain/discomfort, and functional limitations indicated a trend towards slightly higher values and lower QoL in the test group than in the control group. This trend is consistent with the OHIP-14 summary scores of 6.95±5.18 for the test group and 6.0±6.06 for the control groups. However, the differences in individual dimensions and the OHIP summary score were small and statistically insignificant, indicating an overall equivalent subjective OHRQoL status for both treatment groups.

Patient satisfaction was relatively high, comparable for both groups over both treatment phases, and did not show any statistically significant difference (test: 16.85±4.36 vs. control:

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Table 3. Comparison of quality of life-related parameters as assessed by the OHIP-14, patient satisfaction, and patient preferences for the test and control group and attachment system, respectively

	Phase	Test		Control	
		Adjusted mean (95% CI)	*P*-value	Adjusted mean (95% CI)	*P*-value
General Health Score (VAS scale 0 to 100)	I	76.76 (65.7–0.98)	0.983	77.18 (66.13–88.24)	0.991
	II	77.96 (67.1–0.97)	0.971	75.68 (64.44–86.93)	Ref.
EQ-5D-3L sum score (scale 0 to 1)	I	0.89 (0.79–0.98)	0.981	0.91 (0.82–1.00)	0.997
	II	0.93 (0.84–0.89)	0.890	0.90 (0.80–0.99)	Ref.
EQ-5D-3L index (scale of 0 to 1)	I	0.89 (0.79–0.98)	0.981	0.91 (0.82–1.00)	0.997
	II	0.93 (0.84–0.89)	0.890	0.90 (0.80–0.99)	Ref.
OHIP-14 3D: psychosocial impact (scale 0 to 32)	I	0.38 (0.12–0.73)	0.731	0.34 (0.09–0.59)	0.975
	II	0.37 (0.11–0.93)	0.927	0.29 (0.03–0.55)	Ref.
OHIP-14 3D: pain discomfort (scale 0 to 16)	I	1.11 (0.57–0.74)	0.743	1.05 (0.53–1.57)	0.942
	II	1.10 (0.58–0.88)	0.878	0.90 (0.37–1.43)	Ref.
OHIP-14 3D: functional limitation (scale 0 to 8)	I	0.55 (0.12–0.96)	0.955	0.26 (–0.16–0.68)	0.691
	II	0.46 (0.04–1.00)	0.997	0.45 (0.07–0.93)	Ref.
OHIP-14 summary score (0 to 56)	I	7.63 (3.46–0.62)	0.620	6.97 (2.88–11.07)	0.986
	II	7.57 (3.48–0.92)	0.918	6.33 (2.16–10.51)	Ref.
Patient satisfaction (scale 1 to 20)	I	17.17 (14.31–0.99)	0.991	16.17 (13.35–18.99)	0.791
	II	17.07 (14.25–0.99)	0.986	17.57 (14.71–20.43)	Ref.
Patient preference – number of patients deciding for a specific retention system at specific time point		No.	%	No.	%
Yes	I	1	5	1	5
	II	9	45	9	45
No	I	9	45	9	45
	II	1	5	1	5

Values are stratified by treatment phase and are shown as adjusted mean and 95% Cis as derived from mixed linear regression models. The patient factor was introduced in the model as a random effect. The effects of sex and smoking were introduced as fixed effects. *P*-values were adjusted according to the Dunnet-Hsu method for multiple comparisons. Ref. indicates *P*-values for interfactor comparisons. The EQ-5D-3L sum score represents the sum of all 5 items: mobility, self-care, daily activities, pain, and anxiety or depression).
OHIP-14: Oral Health Impact Profile-14, CI: confidence interval, VAS: visual analog scale, EQ-5D-3L: European Quality of Life 5 Dimensions 3 Level Version.

16.6±3.56, *P*=0.837). A subgroup statistical analysis did not indicate any impact of the treatment phase, the patients' sex, or smoking habit on this parameter.

With regards to patient preferences, 18 out of 20 subjects chose to implement permanently the abutment used during phase II. In contrast, 1 patient per group decided to switch back and permanently implement the retentive abutment system used in phase I. No difference in patient preferences between the 2 abutment systems could be identified.

DISCUSSION

This in-practice intrasubject crossover clinical investigation compared Novaloc (test) and Locator (control) attachment systems for the retention of 2-IRODs. Both attachment systems are very similar with regards to their form, shape, and dimension. Compared to Locator, Novaloc attachments comprise a specific material combination and surface coating of the abutment. This combination may render Novaloc mechanically more stable than Locator abutments [21]. Therefore, the central hypothesis of our investigation was whether the differences in material combination might potentially lead to differences in prosthodontic survival, implant survival, and implant success. It was further investigated whether such differences may directly or indirectly affect patients' perceptions (i.e., patient-centered outcomes and patient preferences).

Overall, patient satisfaction was relatively high and comparable in the test and control groups. Patient preferences for 1 specific system at the end of the investigation phases were also

https://doi.org/10.5051/jpis.2105840292

comparable. Neither group displayed any implant loss or major implant-related complications. Therefore, it can be assumed that this aspect did not affect patient-centered outcomes.

The frequency of prosthetic incidence in this study could be considered moderate and might reflect the nature of the clinical investigation. Specifically, this study was carried out under real-world routine in-practice conditions, which implied a lower level of patient training and qualification when compared to more standardized prospective clinical study setups [30]. This aspect might specifically be related to the fact that patients were not explicitly acquainted with the concept of an IROD before providing them with the specific study devices for investigation. Although this study did not reveal any impact of the attachment system on the cumulative prosthetic survival rate, the overall scores for patient satisfaction-related parameters, interestingly, were all relatively high. Furthermore, no significant differences in the types and incidences of failure modes could be identified between the analyzed retentive systems. The failure modes were in line with previous reports and were mainly related to the loss of retentive elements and the dislodgement of the matrix housing from the denture base, causing a perceived loss in retention [20].

In a very similar study setup, Krennmair et al. [19] recently investigated the incidence of required post-insertion maintenance between the Locator attachment system and ball retentive systems and analyzed the results in the context of patient satisfaction. Specifically, the authors also investigated 2-IRODs with a similar crossover design using a follow-up period of 2 × 3 months [19]. In their comparison, the authors reported that all domains of satisfaction significantly improved when comparing the follow-up outcomes to baseline. Interestingly, the authors also reported that although the Locator system resulted in a higher incidence of required postinsertion maintenance, no difference in patient preferences or satisfaction regarding the used retentive system was detected [19].

It is also interesting to consider these aspects with respect to the applied crossover study design. This study design implies that each patient could directly compare the different attachment systems. Based on the comparable patient-reported outcomes and preferences, it might be assumed that patients did not perceive any specific differences between the systems or that potentially perceived differences were not directly relevant for the applied scores [31]. In this context, it is noteworthy that Krennmair et al. [19] reported that patients positively perceived the transition from a conventional to a fixed implant-retained restoration. This positive perception might possibly outweigh and probably compensate for any minor perceived differences between attachment systems. Likewise, it may also have outweighed any potentially negatively perceived restorative complications in our study.

This argument may also be supported by other studies indicating that even pronounced differences in geometries and general properties between different attachment systems do not necessarily result in different patient-reported outcomes. Specifically, Cune et al. [31] recently compared splinted and unsplinted 2-IROD attachment systems. The authors failed to show differences in patient satisfaction between these systems immediately after restoration or after 10 years in function. Independent of the attachment system, patients' appreciation for implant-retained dentures remained high over time. Similarly, Burns et al. compared 3 retention systems and showed that retention forces quantified by force gauge or criterion-based measurements might not necessarily influence patients' preferences [32]. However, including such a parameter in future study setups would help provide a more complete and comprehensive picture of the overall clinical performance of the attachment system.

Regarding patient preferences and choices, Pisani et al. [33] recently compared hedonic and qualitative patient-centered outcomes between Locator and Ball attachments in a crossover trial. The authors reported a pronounced tendency of patients to keep the retentive system used in the second study phase after the crossover, which is clearly in line with the observations in this study. Furthermore, the research of Pisani et al. [33] also indicated that the decision process and patient preferences for a specific attachment system are multifactorial and not necessarily directly related to the attachment system itself.

This study did not reveal any significant differences in the overall health and OHRQoL status between the 2 groups. To our knowledge, only 1 other clinical study has so far compared OHRQoL related parameters between different retentive systems. Bilhan et al. [16] compared Ball and Locator-retained 2-IRODs and reported significantly improved parameters in the domain for physical disability in the Locator group. However, a subgroup analysis indicated that this difference was related to differences between the individual retentive systems to compensate for missing gingival height. Based on similar argumentation, the lack of any significant difference in QoL-related parameters and perceived general health between Novaloc and Locator might indirectly indicate that both systems were perceived as equivalent regarding their intraoral properties and functionality.

This study further investigated the clinical performance of bone level tapered implants to support 2-IRODs as part of a conventional loading protocol. The observed survival rate of 100% after 24 months confirmed the generally high survival rate of implants bearing mandibular IRODs reported throughout the literature. Specifically, Kern et al. recently reviewed the survival rate of removable mandibular 2-IRODs in an extensive meta-analysis [34]. The authors identified 19 studies, reporting on a total of 1134 implants. From their analysis, the authors derived an average estimated 5-year implant survival rate of 98.4%.

Compared to straight-screw implants, tapered implants represent attractive candidates to achieve increased stability in bone types typically considered difficult for implant therapy. Finite element analysis further indicates a unique force distribution to the surrounding bone during implant seating [13]. These features potentially qualify tapered effect implants for the treatment of edentulous patients with limited bone quality and quantity. Only a few studies have specifically reported the implant survival and success rates of tapered implants in conjunction with IRODs. Salman et al. recently reported an implant survival rate of 100% over 5 years for 2-IRODs retained by Locator attachments using an immediate or a delayed protocol [35]. Despite the lack of a difference in survival rate, the authors interestingly reported lower levels of crestal bone loss in the immediately loaded group. However, these promising results need to be put into context with the significantly lower risk for implant loss of mandibular removable IRODs that has been reported for conventional compared to immediate protocols [34]. Therefore, it would be interesting to investigate the performance of the reported configuration as part of an immediate-type treatment protocol in future research.

The results of this in-practice real-world intra-individual crossover clinical evaluation suggest that Locator and Novaloc attachment systems both represent viable treatment modalities for the retention of mandibular 2-IRODs. The type of retentive system used in this study did not affect implant survival or success after 24 months and resulted in 100% implant survival in both groups. Both attachment systems resulted in high and comparable overall levels of patient satisfaction. It appears likely that the incidence of prosthetic complications did not affect the overall level of patient satisfaction and reported general health and OHRQoL

parameters. The ability of patients to differentiate between both attachment systems remains questionable. Patients' preferences were comparable for both systems, while the relevance of potential differences for the derived patient-reported outcome scores remains unclear.

ACKNOWLEDGMENTS

The author would like to thank Leticia Grize from the University of Basel (Switzerland) for the statistical analysis, Novonexile AG (Switzerland) for writing assistance and editorial support in preparing the manuscript, and Dr. med. Dent. Pedro Gonçalves for assisting in the planning of the study.

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