

# Implant supported overdentures in Sjögren's disease patients: a multicentre prospective cohort study

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## Abstract Objective

To prospectively investigate patient-reported outcomes and clinical performance of implant supported overdentures in edentulous Sjögren's disease (SjD) patients compared to subjects without SjD.

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## Methods

51 implants were placed in 12 patients with SjD and 50 implants in 12 non-SjD patients to support overdentures. Clinical performance, marginal bone-level changes, patient satisfaction and oral health related quality of life (OHRQoL) were assessed at 1 (T1), 6 (T6), 12 (T12) and 18 (T18) months after placement of the overdenture. Patient satisfaction, ability to chew and OHRQoL were assessed with validated questionnaires. Marginal bone-level changes were measured on standardised dental radiographs. Clinical parameters included implant and overdenture survival, plaque, bleeding and gingival indices, and probing depth.

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## Results

OHRQoL in patients with SjD improved significantly after placement of implant supported overdentures at all measuring moments compared to baseline ( $p < 0.05$ ). Nevertheless, ability to chew tough and hard food was significantly better for non-SjD patients at all timepoints after placement of an implant supported overdenture ( $p < 0.05$ ). Implant survival at T18 was 100% in the patients with SjD and 98% in the non-SS group. Mean marginal bone loss at T18 did not differ between patients with SjD and non-SS patients,  $1.12 \pm 0.74$  mm and  $1.43 \pm 1.66$  mm, respectively ( $p = 0.58$ ). Clinical performance was good with no differences between the groups for all outcome measures ( $p > 0.05$ ).

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## Conclusion

Implant-supported overdentures have a positive effect on OHRQoL and dental implants can be successfully applied in edentulous patients with SjD with nearly similar outcomes as in non-SjD subjects.

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## Key words

dental implants, Sjögren's disease, denture, prostheses, quality of life

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## Introduction

Sjögren's disease (SjD) is a chronic inflammatory and lymphoproliferative disease with autoimmune features, characterised by progressive lymphocytic infiltration of the exocrine glands, notably the lacrimal and salivary glands (1, 2). Saliva performs many important functions including antimicrobial activity, mechanical cleansing, regulation of pH, removal of food debris from the oral cavity, lubrication of the oral cavity, control of mineralisation and demineralisation of teeth and maintaining the integrity of the oral mucosa (3-5). A lack of saliva subsequently increases caries risk, which results in progressive degradation of the dentition and, in the end, a need to replace (3) missing teeth. This could be done by a conventional denture, but in dry mouth patients this therapy is not always successful (6, 7). On the contrary, there is no increased risk for periodontal disease in Sjögren's patients (8).

Saliva plays an important role in the functioning of full and partial dentures. The continuous flow of saliva into the oral cavity and the presence of a saliva film between the denture base and the oral mucosa ensures that the oral mucosa remains moist and is not easily damaged (9, 10). Furthermore, saliva contributes to good retention of the denture. If there is a qualitative or quantitative problem with saliva, loss of retention, pain and ulceration may occur while wearing the denture (9, 11). In addition, dry mouth is associated with the occurrence of the sensation of burning mouth, which makes wearing conventional dentures difficult (12). Thus, in SjD patients wearing a conventional full denture might be troublesome.

For SjD patients, an implant supported overdenture could be a better treatment option. Dental implant treatment is a clinically validated and practice proven therapy to support overdentures (13, 14). To date, no prospective clinical trials have been published in which the success of implant supported overdentures in SjD patients was investigated prospectively and compared to subjects without SjD. Only retrospective studies and case series reported on the use of dental implants in edentulous

patients with SjD, often with favourable outcomes comparable to healthy subjects (15-19), but occasionally with less favourable outcomes such as an above average loss of implants (20, 21). Therefore, this study aims to prospectively investigate patient-reported outcome measures and the clinical performance of implant supported overdentures in edentulous SjD patients compared to subjects without SjD. We hypothesise that there is no difference in study outcomes between edentulous patients with or without SjD.

## Material and methods

### Study design

This clinical study was designed as a prospective multicentre clinical trial with a non-inferiority design and an 18-month follow-up. The study was conducted at the Amsterdam University Medical Centre (AUMC), University Medical Centre Utrecht, University Medical Centre Groningen and dental practice Bocht Oosterdiep Veendam. All centres are located in the Netherlands.

Written consent was obtained from all patients prior to treatment. This study followed the principle of the Declaration of Helsinki. The AUMC Research Ethics Board (no. NL2014.541) approved the study. The study protocol is registered at the US National Institutes of Health (NCT02661243). The reporting of this study followed the STROBE guidelines (22).

### Participants

The study population consisted of edentulous patients in the upper and/or lower jaw with and without SjD referred for implant treatment to support overdentures. The patients were considered for inclusion if they fulfilled the following criteria:

- Between 18 and 80 years of age;
- Edentulous in the upper and/or lower jaw;
- The patient was capable of understanding and giving an informed consent;
- Sufficient bone volume to insert dental implants. In case of dehiscence or fenestrations, it was allowed to cover these by autogenous bone. Furthermore, it was allowed to expand the

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volume of bone by buccal plating or a sinus floor elevation in the same procedure as when the implants were placed.

SjD-patients only:

- Diagnosed with Sjögren's disease according to the 2002 AECG guidelines (23). Patients were excluded from participation in this study if they met one of the following criteria:
- Medical and general contraindications for the surgical procedures defined as an American Society of Anaesthesiologists score  $\geq 3$  (24);
- Presence of an active periodontal disease as expressed by probing pockets depths  $>4$  mm with bleeding upon probing (in case a patient was edentulous in only one jaw);
- History of radiotherapy to the head and neck region or the use of intravenous bisphosphonates/use of oral bisphosphonates for more than 3 years or other medication, to date known for inhibiting bone remodeling;
- Smoking within 6 weeks before implant placement/bone augmentation.

Non-SjD patients only:

- Xerostomia as measured by the EULAR (European League Against Rheumatism) Sjögren's Syndrome Patient Reported Index (ESSPRI) score Dryness Domain Score (score  $<3$ ) (25).

Retrospectively, all patients with SjD fulfilled the 2016 American Congress of Rheumatology (ACR)/EULAR criteria as well (26).

**Intervention**

All patients received Biohorizons laserlok tapered internal implants (Biohorizons, Birmingham, Alabama, USA) to support an overdenture in the upper and/or lower jaw. Patients received 4 or 6 implants in the upper jaw and/or 2 or 4 implants in the lower jaw (interforaminal region).

*- Surgical procedure*

According to a standard procedure as supplied by the manufacturer of the implant system used, the implants were inserted in the desired position. If nec-

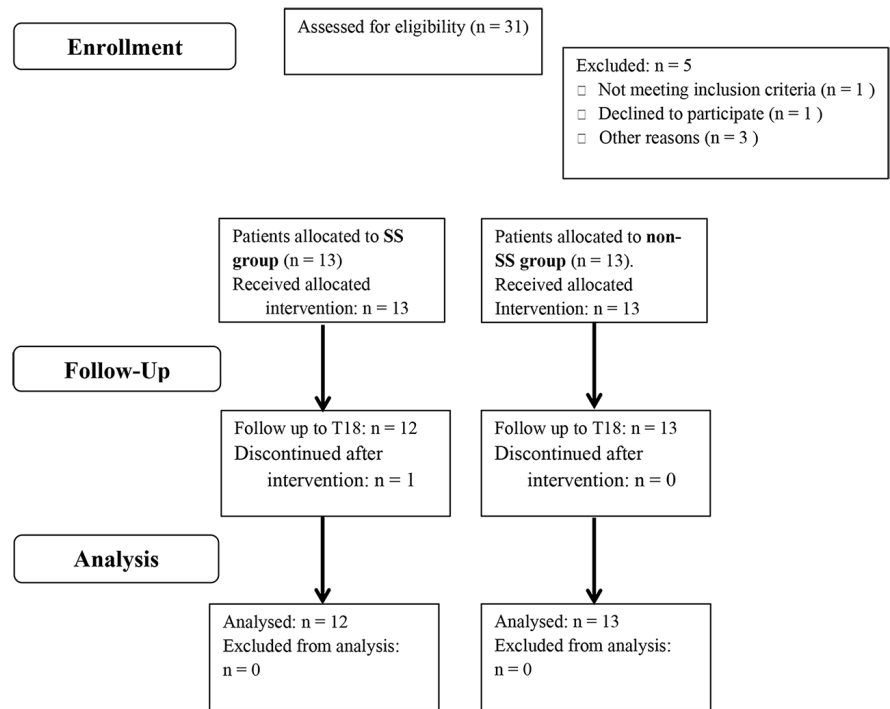


Fig. 1.

Table I. Characteristics of the study population.

Patient variables	Sjögren's disease group	Non-Sjögren disease group
n. (patients)	12	13
Mean age (SD; min-max)	66.3 (11.6; 48-80)	62.8 (9.6; 50-79)
Female gender, n (%)	11 (91.7%)	10 (71.4%)
n. Smokers (6 weeks prior to treatment)	0	0
Mean disease duration (years) <sup>1</sup>	10.5	n/a
Primary SjD, n (%) <sup>2</sup>	7 (58.3%)	n/a
SjD associated with another auto-immune disease, n (%) <sup>2</sup>	5 (41.7%)	n/a
Autoantibodies to anti-SSA or anti-SSB(%)	9 (75%)	n/a
Positive salivary gland biopsy (%)	10 (83.3%)	n/a
Objective ocular involvement (Schirmer test) (%)	7 (58.3%)	n/a
Xerostomia: mean ESSPRI (SD: min-max) (dryness domain)	6.9 (2.51)	2.0 (0.56)
n. (implants)	51	40
n. implants upper:lower jaw	27:24	18:22

<sup>1</sup>Disease duration is years since diagnosis. <sup>2</sup>Classified according the 2002 American European Consensus Group Criteria (AECG). All patients classified as SjD associated with another auto-immune disease had rheumatoid arthritis (RA) (one of these patients was diagnosed with RA and fibromyalgia). <sup>3</sup>Defined as the total EULAR (European League Against Rheumatism) Sjögren's Syndrome Patient Reported Index (ESSPRI) score divided by 3.

essary, small bone augmentation and sinus elevation procedures with intra-oral harvested bone were performed during the implant placement operation. Cover screws were placed and hand-tightened on the implants. The buccal margin of the wound including the soft tissue were repositioned exactly over the cover screw without tension on the wound (2-stage procedure) or adjusted to fit around the healing abut-

ment (1-stage procedure). The patient was not allowed to wear a denture for 2 weeks after the implant placement procedure. After this period the overdenture was adjusted to the new situation. After 3 months of healing and osseointegration, the implants were uncovered and the maxillofacial surgeon placed a healing abutment. In case of additional augmentation, this period could be extended to 6–9 months.

**Table II.** Results (mean/SD) of the outcome variables bone loss, probing depth, gingival index and chewing ability at 1, 6, 12 and 18 months after overdenture placement.

	Sjögren's disease, 51 implants in 12 patients					non-Sjögren's disease, 40 implants in 13 patients				
	T0	T1	T6	T12	T18	T0	T1	T6	T12	T18
Radiographic bone loss (mm)	n/a	0.98 (0.71)	1.00 (0.69)	1.07 (0.69)	1.12 (0.74)	n/a	0.91 (1.01)	1.17 (1.35)	1.20 (1.31)	1.43 (1.66)
Probing depth (mm)	n/a	2.64 (0.55)	2.67 (0.64)	2.69 (0.65)	2.96 (0.70)	n/a	2.73 (0.85)	2.57 (0.68)	2.88 (0.65)	2.84 (0.69)
Gingival index	n/a	0.36 (0.65)	0.31 (0.67)	0.34 (0.70)	0.36 (0.68)	n/a	0.41 (0.63)	0.52 (0.79)	0.30 (0.59)	0.35 (0.66)
Chewing ability:										
soft food	1.85 (0.54)	1.19 (0.39)*	1.25 (0.35)*	1.18 (0.35)*	1.17 (0.33)*	1.53 (0.62)	1.19 (0.50)*	1.07 (0.19)*	1.02 (0.09)*	1.00 (0.00)*
tough food	2.49 (0.46)	1.86 (0.48)*	1.89 (0.56)*	1.82 (0.50)*	1.83 (0.52)*	2.31 (1.17)	1.40 (0.66)*	1.33 (0.51)*	1.24 (0.38)*	1.26 (0.48)*
hard food	2.76 (0.43)	2.28 (0.72)	2.28 (0.68)	2.27 (0.49)	2.14 (0.66)*	3.31 (1.65)	1.64 (0.78)*	1.64 (0.67)*	1.48 (0.55)*	1.46 (0.60)*

Radiographic bone loss is the average of 2 measurements on the distal and mesial side of the implant expressed in mm. Probing depth is the average of 6 measurements on the distobuccal, buccal, mesiobuccal, distolingual/palatal, lingual/palatal and mesiolingual/palatal sides expressed in mm. Chewing ability is the patients' opinion about the ability to chew nine different kinds of food on a three-point rating scale (0 = good, 1 = moderate, 2 = bad). The items were grouped into three scales: soft food, tough food and hard food. Within group significant differences ( $p < 0.05$ ) compared to baseline (T0) are marked with an asterisk; Corresponding  $p$ -values are reported in the results section.

### - Prosthetic procedure

Custom acrylic resin impression trays (Lightplast; Dreve Dentamid GmbH, Unna, Germany) were fabricated with openings for screw-retained impression copings. The final complete arch impression was made with polyether material (ImpregumF; 3M ESPE, St. Paul, Minn, USA). A composite resin record base (Lightplast base plates; Dreve Dentamid GmbH, Unna, Germany) with a wax occlusion rim was used to determine the occlusal vertical dimension and to record the maxillomandibular relationship. This was followed by a gothic arch tracing to determine central relation. Acrylic resin artificial teeth (Ivoclar Vivadent AG, Schaan, Liechtenstein) were selected and arranged on the record base for a trial arrangement. A predefined occlusion concept was not followed. In case of antagonistic posterior natural teeth, the artificial teeth were occluding without disturbing interferences with lateral of protrusive excursions. The superstructure consisted of a milled titanium bar, screw-retained to the implants, and an overdenture with built-in cobalt chromium reinforcement structure and retentive clips attached to it (27). The patient was instructed in hygiene procedures associated with the overdentures and the bars and scheduled for routine maintenance recalls.

### Outcome measures

Before implant placement (T0) and 1 (T1), 6 (T6), 12 (T12) and 18 (T18) month(s) after definitive overdenture placement, patients were seen for data collection.

### - Chewing ability

All patients completed a "Chewing ability" questionnaire. In this questionnaire patients gave their opinion about the ability to chew nine different kinds of food on a three-point rating scale (0=good, 1=moderate, 2=bad). The nine items were grouped into three sub-groups of three items each, representing the ability to chew soft food, tough food and hard food (28).

### - Oral health related quality of life

OHRQoL was defined as "the absence of negative impacts of oral conditions on social life and a positive sense of dentofacial self-confidence" (29). To quantify the OHRQoL all patients completed the Dutch version of the Oral Health Impact Profile-14 at all time-points. The OHIP-14 comprises 14 items that measure seven domains of impact, each based on two questions: functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability and social handicap. Respondents were instructed to indicate their experience for each item on a five-point Likert scale ranging from 0 to 4 (0=never; 1=hardly ever; 2=occasionally; 3=fairly often; 4=very often). This results in a score for each question ranging from 0 to 4, and a summated score ranging from 0 to 56, where low scores indicate high OHRQoL. The benchmark to assess whether a change in OHRQoL is clinically relevant, known as the Minimally Important Difference (MID), was set at 5 OHIP-14 units (30). Accordingly, a change of 5

units of the summated OHIP-14 score was assumed to be clinically relevant.

### - Patients' satisfaction

Patients' satisfaction with their overdenture was scored using the Vervoorn questionnaire before and 1, 6, 12 and 18 months after treatment (31). This is a 54-question questionnaire which focuses on 6 scales: 1. Nine questions concerning functional problems of the lower overdenture; 2. Nine questions concerning functional problems of the upper overdenture; 3. Eight questions concerning functional problems in general; 4. Three items concerning facial aesthetics; 5. Three items concerning neutral space; 6. Twelve items concerning aesthetics of the overdenture. All questions had a 4 scale: 1=no complaints, 2=little complaints, 3 = moderate complaints, 4=severe complaints.

### - Implant survival

Implant survival was defined as the percentage of implants initially placed that was still present and not mobile at follow-up.

### - Radiographic evaluation

Changes in marginal bone level were calculated from standardised digital intra-oral radiographs taken with an individualised aiming device mounted on the titanium bar as previously described (32). Full-screen analysis of the radiographs was performed using the known implant diameter as a reference value for calibration of the radiograph. One trained examiner (FM), unaware of group allocations, evaluated all ra-



diographs. A single observer was chosen to prevent interobserver variability. The vertical distance from the shoulder of the implant to the first bone-to-implant contact was measured at both the distal and mesial site of the implant. For this VisiQuick software (Citodent Imaging B.V, Amsterdam, the Netherlands) was used. Mesial and distal bone changes in this region were averaged and considered as radiographic bone height change. Bone height changes are expressed in mm.

*- Probing pocket depth*

Probing depth was measured at six sites for each implant (mesiobuccal, labial, distobuccal, mesiolingual, lingual, distolingual) using a manual periodontal probe (Williams Colour Coded Probe; HuFriedy, Chicago, IL, USA). The distance between the marginal border of the mucosa and the tip of the periodontal probe was scored as the probing depth. The six scores were averaged resulting in a single score per implant expressed in millimetres.

*- Plaque Index*

The plaque index for each implant was measured on a scale of 0/1/2/3 (0=no plaque; 1=a film of plaque adhering to the free gingival margin and adjacent area of the bar/implant. The plaque may be seen in situ only after application of disclosing solution or by using the probe on the tooth surface; 2=moderate accumulation of soft deposits within the gingival pocket, implant and gingival margin which can be seen with the naked eye; 3 = abundance of soft matter within the gingival pocket and/or on the tooth/implant and gingival margin (33, 34).

*- Bleeding Index*

The BI for each implant was measured on a scale of 0/1/2/3 (0=no bleeding when probe is passed along the gingival margin; 1=isolated bleeding, gingiva looks normal; 2=blood forms a confluent red line on margins; 3=heavy or profuse bleeding) (33, 34).

*- Gingival Index*

The Gingival Index (GI) by Loe & Silness (1963) was measured for each implant. GI scores the marginal tissue on a

**Table III.** Analysis of the differences between the Sjögren's disease group (51 implants in 12 patients) and the non-Sjögren's disease group (40 implants in 13 patients) for all outcome measures after correction for gender and age.

Radiographic bone loss	Coeff	p	95% CI	
			lower	upper
T1	-0.06	0.87	-0.78	0.66
T6	0.18	0.62	-0.54	0.90
T12	0.14	0.71	-0.58	0.86
T18	0.21	0.58	-0.52	0.93
<b>Gingival index</b>				
T1	0.15	0.55	-0.34	0.63
T6	0.31	0.21	-0.17	0.79
T12	0.06	0.79	-0.42	0.55
T18	0.005	0.99	-0.48	0.49
<b>Plaque index</b>				
T1	1.66	0.34	0.58	4.76
T6	0.98	0.97	0.34	2.81
T12	1.18	0.76	0.41	3.44
T18	0.69	0.54	0.21	2.26
<b>Bleeding index</b>				
T1	1.49	0.60	0.33	6.62
T6	1.33	0.71	0.30	6.02
T12	0.95	0.95	0.21	4.36
T18	0.75	0.72	0.15	3.59
<b>Probing pocket depth</b>				
T1	0.009	0.96	-0.42	0.44
T6	-0.18	0.40	-0.61	0.24
T12	0.11	0.62	-0.32	0.53
T18	-0.26	0.23	-0.69	0.17
<b>Chewing ability: soft food</b>				
T0	-0.29	0.05	-0.58	0.003
T1	0.02	0.89	-0.27	0.31
T6	-0.16	0.29	-0.44	0.13
T12	-0.13	0.38	-0.42	0.16
T18	-0.15	0.31	-0.44	0.13
<b>Chewing ability: tough food</b>				
T0	-0.15	0.54	-0.62	0.32
T1	-0.41	0.08	-0.86	0.05
T6	-0.51	0.03*	-0.97	-0.05
T12	-0.55	0.02*	-1.02	-0.08
T18	-0.55	0.02*	-1.02	-0.08
<b>Chewing ability: hard food</b>				
T0	0.57	0.07	-0.06	1.19
T1	-0.61	0.05	-1.22	-0.002
T6	-0.61	0.049*	-1.22	-0.002
T12	-0.80	0.01*	-1.42	-0.17
T18	-0.67	0.04*	-1.29	-0.05
<b>OHIP-14</b>				
T0	-4.02	0.34	-12.20	4.16
T1	-5.10	0.22	-13.15	2.95
T6	-8.25	0.045*	-16.30	-0.19
T12	-7.36	0.073	-15.41	0.70
T18	-7.33	0.078	-15.47	0.81

0 to 3 scale (35). The criteria are: 0=normal gingiva; 1=mild inflammation – slight change in colour and slight oedema, but no bleeding on probing; 2=moderate inflammation – redness, oedema and glazing, bleeding on probing; 3=severe inflammation – marked redness and oedema, ulceration with tendency to spontaneous bleeding. Bleeding is assessed by probing gently along the wall of soft tissue of the gingival sulcus. The

GI of an individual implant was obtained by adding the values of each side of the implant (distobuccal, midbuccal, mesiobuccal, distolingual, midlingual and mesiolingual) and dividing by the number of sides examined.

*- Complications*

Complications were defined by a fracture of the implant, retention bar, fixture screw or overdenture.

**Table IV.** Mean OHIP-14 scores and standard deviations for each question and the summated scores at each timepoint (T0, T1, T6, T12, T18). For the within and between group analysis a correction for age and gender was applied.

	T0 SjD	T0 non-SjD	<i>p</i>	T1 SjD	T1 non-SjD	<i>p</i>	T6 SjD	T6 non-SjD	<i>p</i>	T12 SjD	T12 non-SjD	<i>p</i>	T18 SjD	T18 non-SjD	<i>p</i>
<b>Functional limitations</b>															
1. Trouble pronouncing words	2.92 (1.00)	2.71 (0.99)	0.39	2.42 (0.79)	1.71* (0.99)	<b>0.02</b>	2.58 (1.08)	1.43* (0.76)	<b>&lt;0.001</b>	1.91* (0.70)	1.13* (0.48)	<b>0.02</b>	2.00 (1.04)*	1.09* (0.30)	<b>0.006</b>
				<i>p</i> <0.001	<i>p</i> <0.001		<i>p</i> <0.001	<i>p</i> <0.001		<i>p</i> =0.001	<i>p</i> <0.001		<i>p</i> <0.001	<i>p</i> <0.001	
2. Sense of taste worsened	3.25 (1.60)	2.64 (1.22)	0.17	1.92* (1.08)	1.79* (1.42)	0.74	2.08* (1.38)	1.57* (1.09)	0.25	1.73* (0.79)	1.38* (1.12)	0.21	1.92* (1.00)	1.18* (0.40)	0.29
				<i>p</i> <0.00	<i>p</i> =0.003		<i>p</i> <0.001	<i>p</i> <0.001		<i>p</i> <0.001	<i>p</i> <0.001		<i>p</i> <0.001	<i>p</i> <0.001	
<b>Physical pain</b>															
3. Pain in mouth	3.67 (1.50)	2.57 (1.16)	<b>0.008</b>	2.42* (1.16)	1.86* (1.23)	0.17	2.17* (1.19)	1.50* (0.85)	0.11	1.82* (0.87)	1.38* (0.77)	0.19	2.08* (1.00)	1.18* (0.40)	0.09
				<i>p</i> <0.001	<i>p</i> =0.029		<i>p</i> <0.001	<i>p</i> =0.001		<i>p</i> <0.001	<i>p</i> <0.001		<i>p</i> <0.001	<i>p</i> <0.001	
4. Discomfort eating food	3.92 (1.08)	3.50 (1.29)	0.33	2.83* (1.03)	1.86* (1.23)	<b>0.02</b>	2.67* (0.98)	1.86* (1.10)	0.06	2.64* (1.03)	1.54* (0.88)	<b>0.005</b>	2.58* (1.16)	1.55* (0.82)	<b>0.049</b>
				<i>p</i> =0.001	<i>p</i> <0.001		<i>p</i> <0.001	<i>p</i> <0.001		<i>p</i> <0.001	<i>p</i> <0.001		<i>p</i> <0.001	<i>p</i> <0.001	
<b>Psychological discomfort</b>															
5. Feeling self-conscious	3.17 (1.53)	2.71 (1.54)	0.22	1.67* (1.07)	1.64* (1.08)	0.82	1.92* (1.31)	1.36* (0.84)	0.14	1.36* (0.50)	1.31* (0.85)	0.52	1.58* (1.00)	1.27* (0.65)	0.83
				<i>p</i> <0.001	<i>p</i> <0.001		<i>p</i> <0.001	<i>p</i> <0.001		<i>p</i> <0.001	<i>p</i> <0.001		<i>p</i> <0.001	<i>p</i> <0.001	
6. Felt tense	2.83 (1.80)	2.43 (1.34)	0.24	1.83* (1.11)	1.50* (0.76)	0.32	1.92 (1.24)	1.29* (0.61)	0.08	1.45* (0.52)	1.15* (0.55)	0.23	1.75* (1.22)	1.09* (0.30)	0.22
				<i>p</i> =0.004	<i>p</i> =0.004			<i>p</i> <0.001		<i>p</i> <0.001	<i>p</i> <0.001		<i>p</i> =0.002	<i>p</i> =0.001	
<b>Physical disability</b>															
7. Unsatisfactory diet	3.17 (1.40)	3.00 (1.24)	0.66	2.08* (1.08)	1.71* (1.14)	0.33	2.17* (1.03)	1.29* (0.61)	<b>0.02</b>	1.64* (0.67)	1.23* (0.60)	0.19	1.92* (1.08)	1.09* (0.30)	0.11
				<i>p</i> <0.001	<i>p</i> <0.001		<i>p</i> =0.002	<i>p</i> <0.001		<i>p</i> <0.001	<i>p</i> <0.001		<i>p</i> <0.001	<i>p</i> <0.001	
8. Interrupted meals	3.42 (0.79)	2.79 (1.25)	0.10	2.08* (1.38)	1.57* (1.16)	0.18	2.33* (1.23)	1.36* (0.50)	<b>0.01</b>	1.91* (0.94)	1.23* (0.60)	<b>0.04</b>	1.67* (0.78)	1.27* (0.65)	0.53
				<i>p</i> <0.001	<i>p</i> <0.001		<i>p</i> =0.002	<i>p</i> <0.001		<i>p</i> <0.001	<i>p</i> <0.001		<i>p</i> <0.001	<i>p</i> <0.001	
<b>Psychological disability</b>															
9. Difficulty relaxing	2.50 (1.45)	2.57 (1.24)	0.94	1.67* (0.78)	1.43* (0.76)	0.40	1.75* (1.14)	1.21* (0.43)	0.08	1.27* (0.47)	1.15* (0.55)	0.38	1.42* (0.67)	1.00* (0.00)	0.41
				<i>p</i> =0.005	<i>p</i> <0.001		<i>p</i> =0.012	<i>p</i> <0.001		<i>p</i> <0.001	<i>p</i> <0.001		<i>p</i> <0.001	<i>p</i> <0.001	
10. Embarrassment	2.92 (1.38)	2.93 (1.59)	0.94	2.17* (1.19)	1.57* (0.94)	0.14	2.25 (1.14)	1.50* (1.16)	0.06	1.55* (0.69)	1.23* (0.83)	0.33	1.83* (1.03)	1.18* (0.40)	0.41
				<i>p</i> =0.031	<i>p</i> <0.001			<i>p</i> <0.001		<i>p</i> <0.001	<i>p</i> <0.001		<i>p</i> =0.002	<i>p</i> <0.001	
<b>Social disability</b>															
11. Irritability with other people	2.67 (1.15)	2.43 (1.16)	0.33	1.50* (0.80)	1.43* (0.65)	0.68	1.58* (0.90)	1.07* (0.27)	0.06	1.55* (0.69)	1.23* (0.60)	0.11	1.67* (1.07)	1.00* (0.00)	0.10
				<i>p</i> <0.001	<i>p</i> <0.001		<i>p</i> <0.001	<i>p</i> <0.001		<i>p</i> <0.001	<i>p</i> <0.001		<i>p</i> <0.001	<i>p</i> <0.001	
12. Difficulties doing usual jobs	2.42 (1.31)	2.14 (1.41)	0.36	1.50* (0.67)	1.57 (0.94)	0.90	1.36* (0.67)	1.21* (0.43)	0.65	1.27* (0.47)	1.15* (0.55)	0.45	1.58* (1.00)	1.00* (0.00)	0.21
				<i>p</i> <0.001			<i>p</i> <0.001	<i>p</i> =0.002		<i>p</i> <0.001	<i>p</i> <0.001		<i>p</i> <0.001	<i>p</i> =0.002	
<b>Handicap</b>															
13. Life less satisfying	2.67 (1.23)	2.50 (1.51)	0.56	1.83* (1.27)	1.43* (0.94)	0.24	1.58* (0.90)	1.36* (0.74)	0.46	1.18* (0.40)	1.31* (1.11)	0.77	1.75* (0.97)	1.00* (0.00)	0.34
				<i>p</i> =0.006	<i>p</i> <0.001		<i>p</i> <0.001	<i>p</i> <0.001		<i>p</i> <0.001	<i>p</i> <0.001		<i>p</i> =0.003	<i>p</i> <0.001	
14. Ability to function	1.75 (0.87)	1.57 (1.02)	0.40	1.25* (0.62)	1.21 (0.43)	0.79	1.25* (0.62)	1.21 (0.58)	0.79	1.18* (0.40)	1.08* (0.28)	0.46	1.42 (0.90)	1.00* (0.00)	0.20
				<i>p</i> =0.03			<i>p</i> =0.03			<i>p</i> =0.02	<i>p</i> =0.019			<i>p</i> =0.04	
<b>Summated OHIP-14</b>	41.3 (8.40)	36.5 (8.76)	0.34	27.2* (5.53)	22.3* (5.35)	0.22	27.6* (5.60)	19.2* (4.61)	<b>0.045</b>	22.5* (4.15)	17.5* (3.91)	0.07	25.2* (5.12)	15.9* (2.93)	0.08
				<i>p</i> <0.001	<i>p</i> <0.001		<i>p</i> <0.001	<i>p</i> <0.001		<i>p</i> <0.001	<i>p</i> <0.001		<i>p</i> <0.001	<i>p</i> <0.001	

OHIP-14: Oral Health Impact Profile-14.

Within group significant differences (*p*<0.05) compared to baseline (T0) are marked with an asterisk and the corresponding *p*-values are placed in the same cell.

The *p*-values for the between group differences at each timepoint are provided in a separate column. Significant *p*-values are in bold (*p*<0.05).

**Table V.** Mean Vervooorn questionnaire scores (standard deviations) for each question for both the Sjögren's disease (12 patients) and non-Sjögren's disease (13 patients) groups for each timepoint (before implant placement (T0), 1 month (T1), 6 months (T6), 12 months (T12) and 18 months (T18) after denture insertion).

	T0 SjD	T0 non-SjD	<i>p</i>	T1 SjD	T1 non-SjD	<i>p</i>	T6 SjD	T6 non-SjD	<i>p</i>	T12 SjD	T12 non-SjD	<i>p</i>	T18 SjD	T18 non-SjD	<i>p</i>
1. Aesthetics	1.35 (0.50)	1.25 (0.18)	0.24	1.03* (0.06) <i>p</i> <0.001	1.14 (0.22)	0.23	1.07* (0.19) <i>p</i> =0.001	1.07* (0.10) <i>p</i> =0.023	0.95	1.01* (0.02) <i>p</i> <0.001	1.15 (0.22)	0.11	1.08* (0.29) <i>p</i> =0.002	1.12 (0.21)	0.63
2. Complaints in general	2.04 (0.86)	1.79 (0.40)	0.06	1.45* (0.31) <i>p</i> <0.001	1.44* (0.40) <i>p</i> =0.002	0.71	1.57* (0.56) <i>p</i> <0.001	1.29* (0.32) <i>p</i> <0.001	0.06	1.29* (0.25) <i>p</i> <0.001	1.15* (0.23) <i>p</i> <0.001	0.21	1.62* (0.59) <i>p</i> <0.001	1.17* (0.28) <i>p</i> <0.001	<b>0.004</b>
3. Complaints upper denture	2.22 (1.25)	1.72 (0.50)	<b>0.002</b>	1.26* (0.21) <i>p</i> <0.001	1.31* (0.38) <i>p</i> =0.001	0.71	1.22* (0.35) <i>p</i> <0.001	1.25* (0.35) <i>p</i> <0.001	0.63	1.16* (0.22) <i>p</i> <0.001	1.21* (0.24) <i>p</i> <0.001	0.79	1.22* (0.33) <i>p</i> <0.001	1.17* (0.18) <i>p</i> <0.001	0.40
4. Complaints lower denture	1.80 (0.86)	2.42 (0.80)	<b>0.003</b>	1.39* (0.61) <i>p</i> =0.02	1.20* (0.35) <i>p</i> <0.001	0.28	1.44* (0.63) <i>p</i> =0.04	1.19* (0.24) <i>p</i> <0.001	0.15	1.31* (0.29) <i>p</i> =0.008	1.09* (0.10) <i>p</i> <0.001	0.31	1.25* (0.32) <i>p</i> =0.003	1.13* (0.14) <i>p</i> <0.001	0.53
5. Neutral space	1.17 (0.32)	1.31 (0.44)	0.57	1.31 (0.41)	1.33 (0.36)	0.97	1.61* (0.74) <i>p</i> =0.002	1.26 (0.34)	<b>0.02</b>	1.18 (0.50)	1.26 (0.36)	0.98	1.25 (0.35)	1.18 (0.32)	0.55
6. Physiognomy	1.70 (1.00)	1.97 (0.80)	0.53	1.14* (0.27) <i>p</i> =0.001	1.18* (0.29) <i>p</i> <0.001	1.00	1.36* (0.62) <i>p</i> =0.04	1.13* (0.32) <i>p</i> <0.001	0.23	1.09* (0.30) <i>p</i> =0.001	1.33* (0.53) <i>p</i> <0.001	0.45	1.28* (0.37) <i>p</i> =0.01	1.38* (0.69) <i>p</i> =0.002	0.75

Within group significant differences (*p*<0.05) compared to baseline (T0) are marked with an asterisk and the corresponding *p*-values are placed in the same cell.

The *p*-values for the between group differences at each timepoint are provided in a separate column. Significant *p*-values are in bold (*p*<0.05).

*- Feeling of oral dryness*

All SjD-patients were asked to complete the EULAR (European League Against Rheumatism) Sjögren's Syndrome Patient Reported Index (ESSPRI) questionnaire (25) at T0. Only the dryness domain was reported to compare groups.

*Statistical analysis*

It was assumed that clinical and patient-reported outcome of implants supporting an implant supported overdenture in SjD patients was not inferior compared to non-SjD patients (non-inferiority hypothesis) A convenience sample was used. Difference between the groups in the outcome variables over time were analysed with linear mixed model analysis (for the normally distributed continuous outcome variables) or with logistic generalised estimating equations (GEE) analysis (for the dichotomous outcomes). Mixed model analysis and GEE analysis are used to take into account the dependency of the observations within the patient over time. The models included time (a categorical variable represented by dummy variables), group and the interaction between time and

group. The analysis was adjusted for age and gender and was performed by a statistician (JWRT) unaware of group allocation. Data were analysed with STATA (StataCorp, College Station, TX, USA). A *p*-value of 0.05 or lower was considered statistically significant.

**Results**

At the start of the study, we included 26 patients in which 91 implants were placed. Twenty-five patients completed the study between May 2015 and September 2020 of which 12 patients in the SjD group and 13 in the non-SjD group (Fig. 1). One patient in the non-SjD group lost interest in the study and was lost to follow-up at T18. Only data from implants with a complete follow-up period were used in a per-protocol analysis. In the SjD group 51 (27 upper jaw and 24 lower jaw) and in the non-SjD group 40 (18 upper jaw and 22 lower jaw) implants were placed. Characteristics of the study population are presented in Table I and medication use in the Supplementary Table S1. The mean age of the SjD patients (66.3 years; SD: 11.6) was significantly not different compared to the age of the

non-SjD patients (62.8 years; SD: 9.6) (Table I).

Chewing ability increased significantly after placement of the implant supported overdentures in the non-SjD group compared to baseline for soft, tough and hard food. In the SjD group significant improvement in chewing ability compared to baseline was found for soft food and tough food but not for hard food. Patients without SjD were able to chew tough and hard food significantly better at 6, 12 and 18 months after placement of the overdenture compared to patients with SjD (Table II and III). OHRQoL was significantly improved in the SjD group and the non-SjS compared to baseline at all timepoints (Table IV). The changes in the summated OHIP-14 score after placement of the implant supported overdentures changed in both groups more than 5 OHIP units compared to baseline indicating a clinically relevant improvement up to 18 months. At baseline the summated OHIP-14 score was higher in the SjD group (M=41.3) compared to the non-SjD group (M=36.5). Although this difference was not significant (*p*=0.34) it did surpass the MID of 5 OHIP units. Af-

ter placement of the implant supported overdentures the mean summated OHIP-14 score was only significantly lower at T6 in the non-SjD group (M=19.2) compared to the SjD group (M=27.2;  $p=0.045$ ). We also analysed the OHIP-14 for every item separately (Table IV). It was found that in both groups most items improved significantly compared to baseline. Furthermore, it was found that in the SjD group the items 'Trouble pronouncing words', 'Discomfort eating food' and 'Interrupted meals' were significantly higher at most time points compared to the non-SjD group. Interestingly, SjD patients experienced significantly more pain in their mouths before placement of the implant supported overdenture compared to the non-SjD patients ( $p=0.008$ ). This difference disappeared after insertion of the implant supported overdenture.

Patients' satisfaction increased significantly after placement of the implant supported overdentures in the non-SjD group compared to baseline for all items except for aesthetics (Table V). In the SjD group, significant improvement in satisfaction compared to baseline was found for items 'Aesthetics', 'complaints related to the lower denture' and 'Complaints related to the upper denture'.

Before placement of the implant supported overdentures the SjD group (M=2.22) had significant more complaints related to the upper denture compared to the non-SjD group (M=1.72;  $p=0.002$ ). Interestingly, non-SjD patients had significantly more complaints about the lower denture compared to the SjD group (M=2.42 and 1.80, respectively;  $p=0.003$ ).

Implant survival was 100% in the SjD group and 98% in the non-SjD group. One implant was lost in the non-SjD group due to mobility and pain at T18. At all timepoints, marginal bone loss was higher in the non-SjD group compared to the SjD group, but the Mixed Models analysis revealed no significant differences in mean marginal bone loss between both groups at all timepoints (Table II). For pocket depth, GI, PI and BI no significant differences were found at all time points (Tables II and III, and Suppl. Table S2).

## Discussion

No implants were lost in the SjD group and 1 implant was lost in the non-SjD group. This result is comparable to the findings of two systemic reviews of implant supported overdentures in non-SjD patients (36, 37). Our results are also in line with the results from a retrospective study investigating the implant survival and performance in patients with SjD (16).

We found higher, but not significant different BI scores in the non-SjD group at all timepoints. It could be speculated that this could have a long-term effect which was not yet measurable in our study as long-standing inflammation of the gingiva could result in an increase of loss of bone. This difference could possibly be explained by that SjD patients may be more aware of the importance of good oral hygiene and therefore make more effort to clean the implants. Cross-sectional studies have shown that dentate patients with SjD have a high caries experience despite good oral hygiene (38). Boutsi *et al.* found that SjD patients were characterised by having lower salivary flow rates, better oral hygiene habits, slightly higher gingival scores, but similar plaque scores, compared to the non-SjD patients (39). In addition, non-SjD patients participating in our study may have lost their dentition prematurely because of poor oral hygiene and poor oral hygiene may persist after placing implants despite oral hygiene instructions.

It should be noted that in our previous study, investigating implant supported crowns in dentate patients, the opposite was found. Those SjD patients seemed to have more signs of peri-implant soft tissue inflammation despite comparable pocket-probing depths compared to non-SjD patients. In that study, we speculated that these signs of inflammation could be related to the reduced salivary secretion in patients with SjD as well as the subsequent diminished self-clearance of the oral cavity (16). That in the edentulous patients the opposite was found could be explained by the ease with which the titanium bar can be cleaned compared to a fixed crown on an implant. This is also described in a study by Heydecke *et al.*

in which cleaning a bar is described as easier than cleaning a fixed bridge on implants (40).

After placement of implant supported overdentures, the patients without SjD experienced significant improvements after 6 months compared to patients with SjD for their ability to chew tough and hard food. Moreover, patients with SjD did experience improvement compared to baseline in the ability to chew soft and tough food but not for hard food. Therefore, it could be concluded that implant supported overdentures improve the ability to chew for SjD patients, but that a larger improvement is found in non-SjD patients. This might be explained by the effect of the severe oral dryness the SjD patients are experiencing. Their problems with eating are not only related to the ability to use a denture but also to the ability to lubricate the mouth and swallow the food.

A limitation of this study is that we were not able to find a gender-matched non-SjD group. In the SjD group no males could be included. We decided to include female and male patients in the non-SjD group because it was difficult to find patients without SjD that were willing to participate in our study. Therefore, we adjusted our analysis for gender. This was especially important for the analysis of the Oral Health Related QoL measured using the OHIP-14 questionnaire because in previous research it was found that OHIP-14 scores of males were lower compared to females (41).

## Conclusion

From this study it can be concluded that replacing conventional dentures by implant supported overdentures improves the OHR-QoL of SjD-patients. Furthermore, dental implants to support overdentures in patients with SjD show a clinical performance comparable to implants in patients without SjD up to 18 months.

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