Prospective 10-Year Cohort Study Based on a Randomized, Controlled Trial (RCT) on Implant-Supported Full-Arch Maxillary Prostheses. Part II: Prosthetic Outcomes and Maintenance

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ABSTRACT

Background: Long-term follow-up studies (i.e., over 5 years), focusing on prosthetic outcomes and maintenance of implant-supported reconstructions in the edentulous maxilla, are scarce in the literature.

Purpose: The purpose of this study was to evaluate and report 10-year data on outcomes and maintenance of screw-retained implant-supported full-arch casted titanium-resin prostheses in the edentulous maxilla.

Materials and Methods: In the randomized control trial cohort of 24 patients, the outcome and maintenance of 23 bridges were registered.

Results: One patient dropped out of the study prior to the 10-year control. Of the 23 remaining patients, 21 still had their original frameworks; one framework fractured after 8 years and one was remade after 7 years to create better support for the acrylic. The remaining 23 prostheses showed criteria of success, survival, and failure in 9, 82, and 9%, respectively. Tightening of two assembly screws was necessary in one patient. No detrimental effects were seen because of long cantilever extensions or opposing dentition. A total of 4.7 resin-related complications per prosthesis were observed; tooth fracture was the most common prosthetic complication. There was an indication of greater prevention in the number of resin-related complications with the use of lingual gold onlay compared with a resilient mouth guard, 0.71 and 1.67, respectively per bridge. The bridges were removed and reinserted 0.83 times per patient. No abutment or abutment screw fractures were registered.

Conclusion: Fracture or wear of the reconstruction materials were considered predictable risks when using resin-based suprastructure materials. Status of opposing dentition and length of cantilevers did not confer additional risk. The use of a lingual gold onlay indicated prevention of resin-related complications. Future research should focus on the suprastructure materials to predict better overall treatment results of implant-supported full-arch bridges in the edentulous maxilla.

KEY WORDS: casted titanium, dental materials, edentulous maxilla, implant-supported, laser-welded, long-term follow-up, prospective cohort study, prosthodontic complications, screw-retained full-arch prosthesis

INTRODUCTION

Over the last few decades, osseointegrated implants have been extensively used in the replacement of missing teeth and surrounding tissues, based on an impressive amount of data concerning implants and the surrounding bone and mucosa. The original concept recommended healing periods of 3 and 6 months in the mandible and maxilla, respectively, before loading the implants.[1–3] To reduce the treatment time, early and immediate loading protocols have increasingly been used. Literature reviews indicate that early loading is a

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

DOI 10.1111/j.1708-8208.2011.00383.x

safe procedure in the anterior mandible.[4] Good short-term treatment results in the maxilla using immediate or early protocols have been demonstrated.[5–7] In the current study, previous 1-, 3-, and 5-year results have supported the use of an early loading protocol for prosthetic treatment of the totally edentulous maxilla.[8–10]

In a literature review of clinical trials on fixed implant rehabilitations in the edentulous maxilla, the authors found that prosthodontic information was limited compared with the evidence focusing on implants.[11] Various risk factors can threaten oral implant treatment success and four risk categories can be identified: 1) complications during surgery; 2) loss or impending loss of implant; 3) fracture or wear of suprastructure parts; and 4) patient dissatisfaction with outcomes.[12] For patients, prosthodontists, and third-party providers (e.g., insurance company), modifications, repairs, or remakes of the initially expensive implant-supported reconstructions can lead to monetary, emotional, and social costs, if information concerning these costs is not explained prior to treatment.

Criteria for successful *implant* treatment (e.g., success, survival, failure) have been used for over 20 years.[13–15] However, *prosthetic* success in the literature has been described using terms such as "success of prosthetic treatment," "continuous prosthesis stability," "prosthesis success," and "success of prosthetic treatment."[16–18] In all cases, there was a stark difference between the authors' success claims and the outcomes according to the six-field protocol proposed by Walton.[19] In recent years, a three-field prosthodontic protocol has been used based on the terms "success," "survival," and "failure."[20] However, no long-term controlled, prospective studies of maxillary full-arch bridges have presented data on prosthetic risk factors, type, and number of measures taken in conjunction with technical and mechanical complications using those terms.

The purpose of this 10-year prospective cohort study was to report all mechanical and technical risks and complications and measures taken in conjunction with maintenance of implant-supported full-arch prostheses in the edentulous maxilla.

MATERIALS AND METHODS

Materials and methods have previously been described in detail in the previous 1-,[8] 3-,[9] and 5-year[10] publications, and in Part 1 of this report; therefore, materials and methods will be outlined here, focusing on the prosthodontic elements and registrations.

Patients and Prostheses

At start, a total of 24 patients (16 females, 8 males; mean age 64 years) with totally edentulous maxilla were enrolled in the study. Opposing dentition for the prostheses during 10-year follow-ups is presented in Table 1.

TABLE 1 Opposing Dentition for the Prostheses

		Number of Patients			
Dentition	Support	At Treatment Planning	At 1 Year Follow-Up	At 5 Years Follow-Up	At 10 Years Follow-Up
Removable prostheses					
Complete denture	Mucosa	1	0	0	0
	Implant		1	1	1
Partial denture	Tooth	6	0	1	1
Conus construction	Tooth	1	0	0	0
Fixed prostheses					
Complete	Tooth	1	1	1	1
	Implant	1	6	5	7
Partial	Tooth	5	8	7	7
	Implant		2	2	2
Single crown	Implant		1	1	1
Natural		8	4	4	3
None (edentulous)		1	1	1	0
Total		24	24	23	23

At the 10-year follow-up, one prosthesis was lost and no data were found.

Fifteen prostheses were registered according to the original randomized, control trial (RCT) protocol with medical records, and radiographic and clinical examinations.

Eight prostheses were lost to the original RCT protocol concerning clinical registrations; three of these prostheses were followed up by radiographic examinations according to the RCT protocol.

The protocol for the study was approved by the regional research ethics committee, Uppsala, Sweden. Informed consent was obtained from all patients.

Surgical Procedures

Each patient received five or six dental implants with a sandblasted, large-grit, acid-etched surface (diameter 4.1 mm, lengths from 8 to 12 mm; Institut Straumann AG, Basel, Switzerland) in the maxilla between the left and right second premolar positions. Detailed information regarding the surgical procedures can be found in the 1-year publication from this study. Eight of the implants were loaded with full-arch prostheses.

Prosthetic Materials

The framework of each prosthesis was fabricated from titanium-casting metal (Tritan™, Dentaurum, Ispringen, Germany), using an acrylic resin (Duralay™, Reliance, Worth, IL, USA) to join sectioned titanium components prior to welding, if needed. The cylinders were made of titanium (Octa, Institut Straumann AG, Basel, Switzerland). The base material for the prostheses was poly(methyl methacrylate) (PMMA; Microdent, Esschem Europe Ltd, Durham, UK). Front teeth and diatorics were fabricated from methacrylate (Biostabil and Bioplus respectively, DENTSPLY de Trey Gmbh, Dreieich, Germany). Occlusal retention screws were made of titanium (SCS, Institut Straumann AG). Gold onlays were made of casting gold alloy (Bio Heragold B, Heraus Kulzer Gmbh, Hanau, Germany). Resilient mouth guards were made of one 3-mm thick plate of ethylenvinylacetat (Erkoflex, Erkodent, Pfalzgrafenweiler, Germany). The filling material for screw-retention holes and small repairs to the teeth and acrylic base was a composite with a matrix of dimethacrylates (Tetric Evo Flow, Ivoclar Vivadent AG, Schaan, Liechtenstein). For loose teeth where only a chair-side treatment was necessary, a light cured acrylic resin (Unident LC, GC Dental Product Corp., Kasugai, Japan) was used.

Prosthetic Procedures

Maxillary Full-Arch Bridge Procedures. Stone casts of the mandibular and maxillary arches were mounted in an articulator and a wax-up of the prosthesis, including teeth and casting cylinders, was completed. The vertical dimension, occlusion, esthetics, phonetics, and fit of the wax-up were checked intraorally. Once the wax-up was verified, a rigid titanium framework was cast, which was attached to the abutments by occlusal screws. Fit was assessed both clinically and radiologically; if inadequate, the framework was sectioned and the components individually attached to the abutments by occlusal screws and joined using acrylic resin. After laser welding, another try-in was performed. Once an acceptable fit had been achieved, the prosthesis base was fabricated from heat-cured PMMA, in which the teeth were secured. All bridges were screw-retained. Examples of the screw-retained, full-arch prostheses can be seen in Figure 1.

Additional Procedures and Measures. In order to protect the acrylic teeth and prosthesis base material from wear and fatigue damage, a gold onlay or resilient mouth guard was made. If severe damage was anticipated, a gold onlay was produced lingually from teeth 14–24 of the full-arch bridge (Figure 2); otherwise, a resilient mouth guard was made for the mandible. No prosthesis was provided with a gold onlay or resilient mouth guard before insertion of the bridge.

Prosthodontic Complication and Risk Criteria

Success: The prosthesis remained unchanged and did not require any intervention during the entire observation period.

Survival: The prosthesis remaining in situ at the follow-up examination irrespective of its condition.

Failure: Any condition leading to replacement with a new prosthesis.

Mechanical failure: Failure of a prefabricated component.

Technical failure: Failure of a laboratory-fabricated prosthesis or its materials.

Mechanical risk: Risk of a complication or failure of a prefabricated component caused by mechanical forces.

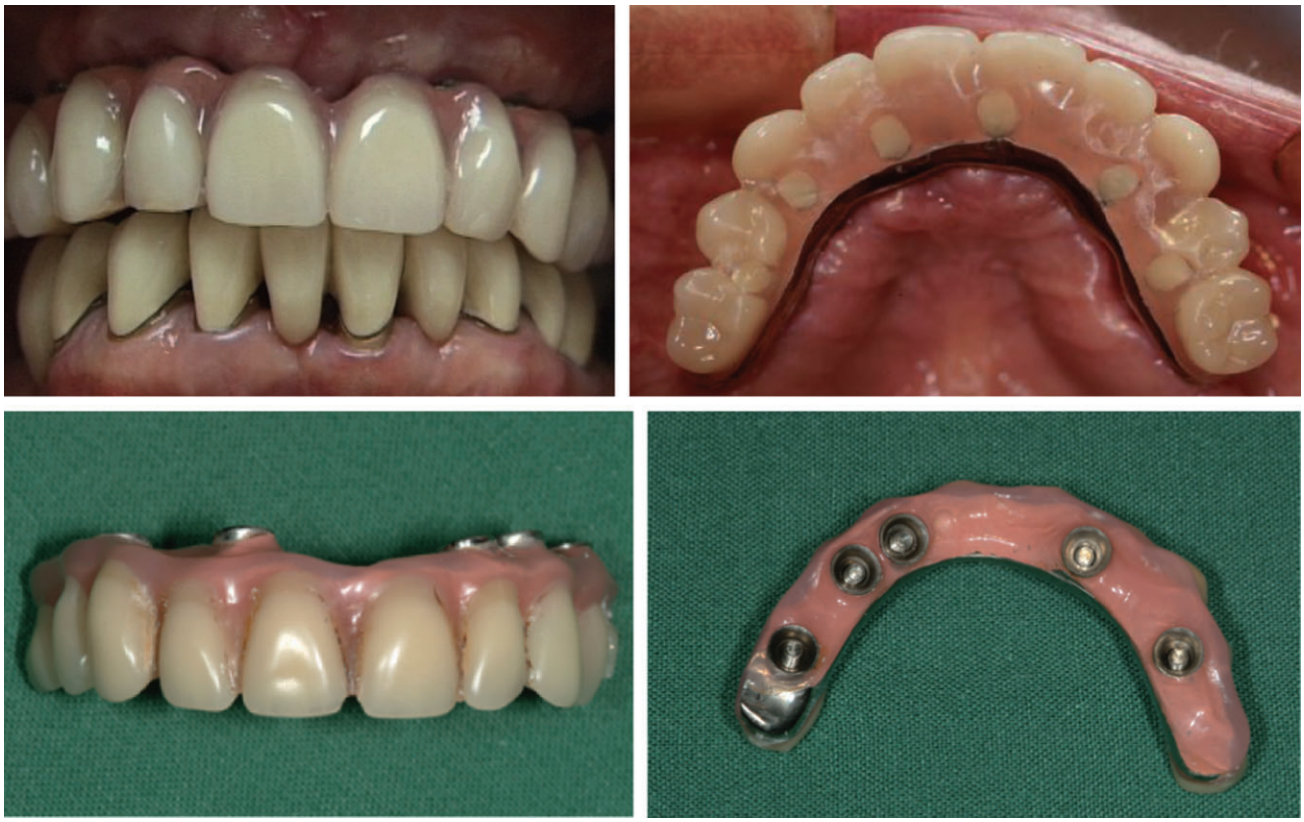

Figure 1 Clinical pictures of implant-supported, screw-retained full-arch prosthesis in the edentulous maxilla.

Technical risk: Risk of a complication or failure of the laboratory-fabricated prosthesis or its materials.

Clinical Examination

The patients were recalled for clinical and radiographic examinations after 1, 3, 5, and 10 years of loading. The clinical examinations were performed because of prosthodontic criteria, and maintenance work made if necessary. At the 3-, 5-, and 10-year follow-up, the prostheses were removed. In addition, all dental records were scrutinized and the number of and reasons for dental visits during the 10-year period were recorded. If any adverse event occurred between scheduled clinical examinations, then patients attended their regular dentist.

Data Analysis

Data are presented with descriptive statistics.

RESULTS

Previous publications have reported the 1-, 3-, and 5-year data from this study, and implant and bone level data have been reported in Part 1 of this analysis.[8–10] A total of 142 implants were placed, 139 of which were loaded with screw-retained full-arch bridges and followed for 10 years. One patient dropped out of the study prior to the 10-year follow-up evaluation. After 10 years, medical records could be obtained for the remaining 23 patients (132 implants). Additional radiographic information was obtained from 18 patients (102 implants) and clinical examinations were performed for 15 patients (84 implants).

Clinical Findings and Complications

Based on the prosthodontic criteria, two (9%) full-arch maxillary prostheses showed success and 19 (82%) survived. Two (9%) prostheses were failures and needed to be remade. Reasons for failure were framework fracture and problem with the framework design in retaining the resin material. Therefore, of the 23 prostheses remaining in the study, one (4%) framework fracture occurred.

Prostheses were removed a total of 19 times, 0.83 times per patient, over the 10-year study period. The most common complications were technical, the majority of which were resin related (Table 2); these included re-cementing of teeth, installation of new teeth, filling of

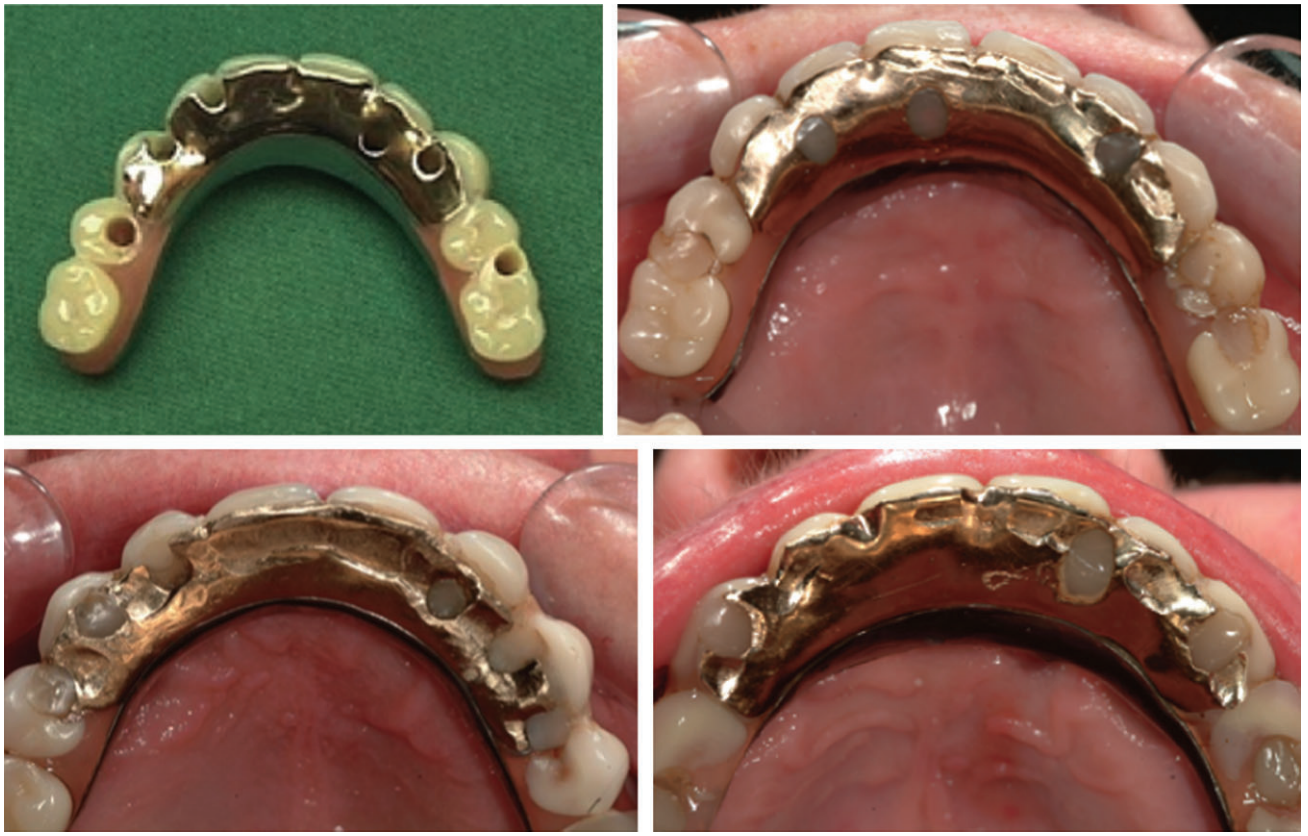

Figure 2 Clinical pictures of implant-supported, screw-retained full-arch maxillary prostheses provided with a gold onlay.

tooth fracture, and filling of retention hole. The previously mentioned framework fracture and framework design problem were the only nonresin-related technical complications. The only mechanical complication was the loosening of the assembly screw, which occurred twice in one patient. No fractures of the assembly screws or abutments were noted over the 10-year observation period. Fewer technical complications were observed after installation of a gold onlay (eight complications in seven prostheses) compared with a resilient mouth

TABLE 2 Type and Number of Measures Taken in Conjunction with Technical and Mechanical Complications

Type of Treatment	1 Year *n* = 24	3 Years *n* = 24	5 Years *n* = 23	10 Years *n* = 23	Total *n* = 23	Per Prosthesis
Bridge on and off	9	6	2	8	25	0.8
Gold onlay	4	3			7	0.3
Resilient mouth guard	4	2	3		9	0.4
Number of recemented teeth	13	5	9	26	53	2.3
Installation of a new tooth	6	1	9	3	19	0.8
Filling of tooth fracture	3	3	6	8	20	0.9
Filling of retention hole	1	1	6	8	16	0.7
Filling of prosthesis base	1	1	1		3	0.1
Assembly screw tightening		2			2	0.09
Flap operation	1	1	1	2	4	0.17
Failure and Remaking of bridge				2	2*	0.09

*In one patient, the framework fractured after 8 years. In one patient, a new design of the framework was needed after 7 years to give a better support for the acrylic. After failure of the prostheses, no registrations were noted for these two patients.

TABLE 3 Further Occurrence of Mechanical and Technical Complications in Full-Arch Prostheses after Installation of a Lingual Gold Onlay Region 14 . . . 24 (Figure 2)

Patient Number in RCT Study	Registered at 5 Years Control	Registered at 10 Years Control
07		
08	X	X
13		X
16		X
20		
22		
24		X

Gold onlay ($n = 7$). Complication = X.

guard (15 complications in 9 prostheses; Tables 3 and 4). Distal cantilever lengths, and corresponding success and survival information for each respective prostheses, are shown in Table 5. The lengths of cantilevers and the dentition of opposing jaw have not affected upon the prosthodontic treatment results.

Risk Analysis

Based on the results of the present study there is a technical risk in using resin material to make the implant-supported full-arch prostheses. This use can lead to a need for maintenance work of five to six times per bridge during a 10-year period (see Table 6). To use a casted titanium framework as presented in the current

TABLE 4 Further Occurrence of Mechanical and Technical Complications in the Full-Arch Prostheses after Delivery of a Resilient Mouth Guard

Patient Number in RCT Study	Registered at 5 Years Control	Registered at 10 Years Control
01/	X	X
05/	X	
08/	X	X
10/	X	X
13/	X	X
14/	X	X
15/	X	X
18/	X	X
20/		

Resilient mouth guard in the lower jaw ($n = 9$). Complication = X (see Table 2); RCT = randomized, controlled trial.

TABLE 5 Distribution and Length of Prostheses Distal Cantilevers per Patient and Occurrence of Prosthetic Outcomes (Success, Survival, Failure)

Patient Number in the RCT Study Cohort	Left (mm)	Right (mm)	
01	9	6	Svl
02	10	6	Svl
03	6	5	Svl
04	8	8	Svl
05	7	9	Svl
06	5	9	Svl
07	13	12	Svl
08	10	14	F
09	7	8	Drop out
10	12	16	Svl
11	15	16	Svl
12	9	11	Svl
13	5	5	Svl
14	5	10	Svl
15	7	10	Svl
16	13	12	Svl
17	5	10	S
18	11	8	F
19	2	12	S
20	6	5	Svl
21	8	10	Svl
22	7	8	Svl
23	7	8	Svl
24	8	3	Svl

Based on registrations on all 24 patients after loading with full-arch maxillary prostheses (see Figure 1).
RCT = randomized, controlled trial; S = success; F = failure; Svl = survival.

TABLE 6 Risk Factor Analysis Based on 10 Years of Function

Type of Risk	Incidence
Technical	
Resin related	5–6 times/prosthesis
Metal related (fracture of cast titanium framework)	4 prostheses/100
Operator related (design)	4 prostheses/100
Mechanical	
Fracture of prefabricated components	0
Loose assembly screw	9 screws/100 prostheses

study can lead to fractures in 4 out of 100 frameworks. Design problems will follow the same pattern. No mechanical fracture risk will occur using the prefabricated components. The only eventual mechanical risk is the loose assembly screws.

DISCUSSION

Patients in the present study have been presented in RCTs of early and delayed loading.[8–10] Small test and control groups, and no important prosthetic differences between the groups comparing 5-year results,[10] implicated to pool the groups in the 10-year evaluation.

The clinical results of this prospective cohort study reported in Part I demonstrated no loss of implants supporting maxillary full-arch prostheses between the 5- and 10-year evaluations. The prosthetic complications during this period were frequent. The majority of complications were related to the acrylic part of the prosthesis. These findings indicate that more focus on prosthetic part of implant-supported treatment is needed.

Because the introduction of implants and implant-supported constructions, evidence-based research has focused more strongly on the implants themselves than on the prosthetic elements. However, good knowledge about *implant* treatment risk factors and complications has been obtained. The four-field criteria[13–15] to assess the results of *implant* treatment has been widely accepted among researchers and helped to obtain this knowledge. In contrast, previously well-accepted criteria for outcomes relating to the suprastructure have not been extensively used in recent years. In 1998, a six-field protocol suggesting criteria for prosthodontic outcomes was published.[19] Although extensive, these criteria have seldom been used in clinical studies reporting treatment results of implant-supported constructions. The three-field prosthetic criteria of success, survival, and failure used in the current study, have been adopted in earlier studies.[20,21] The value of using well-defined and generally accepted prosthetic criteria to obtain evidence-based knowledge cannot be underestimated.

In discussing determinants of correct clinical reporting, Albrektsson & Zarb suggested that the ultimate determinants of an overall success dental implant treatment are the time-dependent prosthodontic outcomes.[14] Despite this, information on suprastructure outcomes in the literature is still scarce. In a systematic literature review investigating biological and *technical complications* in prospective clinical studies, the authors found that technical complications were considered in only 60–80% of studies, a figure considered to be probably underestimated.[22] The main complications after 10 years were technical and were related to the resin (acrylic) material, mainly comprising resin veneer fractures and severe wear in the later follow-up stages. This is in accordance with results from studies on prosthesis in the maxilla[23] and mandible.[24] The risk factors causing the resin-related complications have been extensively discussed in the 5-year report;[10] briefly, mechanical factors such as occlusal load, force direction, and shape of the restorative material play a major role. In the same article, potential improvements in resin shear bond strength and durability were also presented.

Durable dental materials and good impression techniques are needed to achieve good long-term overall implant treatment results and diminish the costs of maintenance. A photogrammetric impression technique to make good fit of prosthesis is presented.[25] From a practical point of view, the choice of occlusal material has no bearing on force generation to the implants.[26] Thus, solid materials such as metal, composite and ceramic ought to be used as occlusal surface materials, though ceramic may be preferred from an esthetic point of view. All-composite resin single-tooth restorations have demonstrated inferior success rates compared with all-ceramic restorations.[27] Significantly more porcelain fractures were obtained on implant-supported versus tooth-supported fixed partial dentures.[28] One explanation may be that patients lacking information from periodontal receptors show an impaired fine motor control of the mandible,[29] which may result in higher biting forces. Early all-ceramic fixed dental prostheses (FDPs), which arrived in the mid-1960s, showed poor performance; metal/ceramic combinations were preferred. Nowadays, the zirconium-based all-ceramic construction is suggested to be the system of choice for the future;[30] a systematic literature review indicated lower survival for all-ceramic FDPs compared with metal-ceramic FDPs.[31] In a 5-year follow-up of implant-supported two- to five-unit bridges comparing the clinical performance of two different all-ceramic systems (Denzir [DZ] and In-Ceram Zirconia [InZ]), 9 of 13 restorations in the DZ group and 2 of 12 restorations in the InZ group showed superficial cohesive (chip-off) fractures. The amount of veneering porcelain fractures was unacceptable with DZ exhibited,

indicating that it could not be recommended for two- to five-unit implant-supported FDPs.[32] Evidence for zirconium as a material for odontological applications has been presented in a thesis in which one of the clinical implications states that veneering seems unnecessary for hot isostatic pressed yttria-stabilized tetragonal zirconia polycrystal (Y-TZP), that is crowns and fixed partial dentures can be left un-veneered in the mouth.[33] Data concerning the possibility to use this material in full-arch bridges are rare, but the research dealing with all-ceramic and improved dental materials has begun to show promising results. A universal primer improved bonding to zirconia ceramic whereas the cleaning method had little or no effect.[34]

In the current study, 4% of the *frameworks* fractured and 9% were remade after 10 years. Corresponding fracture rates from a 10-year follow-up study of two types of frameworks for full-arch mandibular prostheses with laser-welded prefabricated titanium parts were 50% (Ti-1) and 14% (Ti-2), while 14% (Ti-1) and 9% (Ti-2) were remade.[35] The percentage of remade prostheses in the Ti-2 group after 10 years corresponds with the results obtained in the present study, which used casted, sectioned, and laser-welded frameworks. The precision of framework fit to implants supporting fixed complete prostheses made using commercially pure titanium or cobalt-chromium alloy castings and a computer numerical controlled (CNC)-milled titanium implant bridge has been studied in vitro. No frameworks presented a perfect, completely passive fit to the master; a passive fit is not perfect, but applying external pressure can produce a perfect fit with a negligible effect on the prosthesis. However, the CNC-milled frameworks had significantly fewer vertical distortions than the casted groups.[36] Results from a recent study of 23 maxillary CNC-milled titanium frameworks over 10 years showed one framework fracture, in line with results from the current study. The overall conclusion was that a CNC-milled framework is a viable alternative to gold-alloy castings to restore patients with implant-supported prostheses in the edentulous jaw.[37] In a 15-year comparative follow-up study of early laser-welded titanium frameworks supported by implants in the edentulous mandible, gold alloy frameworks tended to be superior when compared with welded titanium frameworks. Fracture of titanium frameworks were observed in 15.5% of the patients, and resin and veneer fractures were the most common complications.[38] The results indicate more resin-related complications for the patients in the present study. This can be explained by unfavorable shear forces, which are more frequent on constructions in maxilla than mandible.

The *wear* risk of the teeth used in maxillary bridges has also been studied. For example, an in vitro investigation showed that exposure of the resin material to acidic slurry accelerated the wear.[39] A definite connection between wear resistance and the chemical composition of the dental teeth materials could not be found.[40] The antagonist material is a major consideration in the choice of the artificial teeth to be used in the prosthesis.[41] The results from the current clinical study indicate that the status of the opposing dentition does not confer additional risk of fracture or wear of the reconstruction. The results from an extensive literature review of commonly used restorative materials and their effects on the opposing dentition showed that the extent and rate of wear are influenced by many intraoral factors, including the restorative material. Some clinical implications of this were that the selection of restorative materials must be based on the knowledge of their wear behavior and the individual patient needs, and that the lowest wear rates for restorations and the opposing dentition occur with metal alloys, machined ceramics, and micro-filled and micro-fine hybrid resin composites.[42] Important properties of the dental restorative materials can be improved by nanotechnology; nano- and microcrostructured sol-gel components can produce protective and wear-resistant coatings for teeth and metal alloys.[43] With the recent advances in nanotechnology and nanomaterials, it is postulated that the mechanical properties and polymerization shrinkage, which can still cause problems with currently used dental materials, may be significantly improved.[44]

In the current clinical study, *mechanical* and technical risks were defined according to Salvi and Brägger,[21] that is mechanical risk was a risk of complication/failure of a prefabricated component caused by mechanical forces; while a technical risk was a risk of a complication/failure of the laboratory-fabricated suprastructure or its materials. No abutment, abutment screw, or assembly screw fractured during the 10 years of function. In contrast, such fractures have been reported in other studies.[22,45] The different experiences may be due to the hexagonal connection between the abutment and implant and the use of titanium assembly screws in the present study as opposed to the flat-to-flat connection

between abutment and implant and gold alloy assembly screws used in the study by Johansson & Palmqvist[45] and in most of the studies presented in the literature review by Berglundh et al.[22] Only one mechanical complication (loose assembly screw, twice in one patient) was observed in the current study. This patient showed Angle Class III occlusion with anterior cross-bite but was included in the study because of expected good occlusion; however, signs of heavy bruxism were seen from an early stage in the study. Despite a gold onlay on the maxillary bridge and a removable resilient mouth guard in the mandible, the titanium framework fractured in the midline after 8 years. The probable risk factor was the combination of Angle Class III cross-bite and heavy bruxism; however, the technical risk of problems with the dimensional stability of the titanium framework cannot be excluded.

The incidence of need for taking the *bridge on and off* makes the retrievability an important consideration. Another important consideration in implant dentistry must be to *inform the patient* about the risks of prosthodontic complications and the costs of maintenance.

In the current study, fracture or wear complications of the prosthesis were considered predictable risks when using resin-based suprastructure materials, although no additional risk appeared to be conferred by the status of opposing dentition or length of cantilevers. There was a greater reduction in resin-related complications following the use of an anterior lingual gold onlay compared a resilient mandibular mouth guard. Future research should focus on the suprastructure materials to predict better overall treatment results of implant-supported full-arch bridges in the edentulous maxilla.

CONFLICT OF INTEREST STATEMENT

The authors have no conflicts of interest to declare.

ACKNOWLEDGMENTS

The authors would like to acknowledge Colin McKinnon (Institut Straumann AG, Basel, Switzerland) for assisting in the preparation of the manuscript.

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