Complications with Computer-Aided Designed/Computer-Assisted Manufactured Titanium and Soldered Gold Bars for Mandibular Implant-Overdentures: Short-Term Observations

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ABSTRACT

Background: Implant-overdentures supported by rigid bars provide stability in the edentulous atrophic mandible. However, fractures of solder joints and matrices, and loosening of screws and matrices were observed with soldered gold bars (G-bars). Computer-aided designed/computer-assisted manufactured (CAD/CAM) titanium bars (Ti-bars) may reduce technical complications due to enhanced material quality.

Purpose: To compare prosthetic-technical maintenance service of mandibular implant-overdentures supported by CAD/CAM Ti-bar and soldered G-bar.

Materials and Methods: Edentulous patients were consecutively admitted for implant-prosthodontic treatment with a maxillary complete denture and a mandibular implant-overdenture connected to a rigid G-bar or Ti-bar. Maintenance service and problems with the implant-retention device complex and the prosthesis were recorded during minimally 3–4 years. Annual peri-implant crestal bone level changes (ΔBIC) were radiographically assessed.

Results: Data of 213 edentulous patients (mean age 68 ± 10 years), who had received a total of 477 tapered implants, were available. Ti-bar and G-bar comprised 101 and 112 patients with 231 and 246 implants, respectively. Ti-bar mostly exhibited distal bar extensions (96%) compared to 34% of G-bar ($p < .001$). Fracture rate of bars extensions (4.7% vs 14.8%, $p < .001$) and matrices (1% vs 13%, $p < .001$) was lower for Ti-bar. Matrices activation was required 2.4× less often in Ti-bar. ΔBIC remained stable for both groups.

Conclusions: Implant overdentures supported by soldered gold bars or milled CAD/CAM Ti-bars are a successful treatment modality but require regular maintenance service. These short-term observations support the hypothesis that CAD/CAM Ti-bars reduce technical complications. Fracture location indicated that the titanium thickness around the screw-access hole should be increased.

KEY WORDS: CAD/CAM technology, complications, gold, implant-overdenture, maintenance service, rigid bar, titanium

INTRODUCTION

The mandibular implant-overdenture (IOD) is a popular treatment modality and is based on high evidence. The first studies on placement of interforaminal implants in complete denture wearers go back to the eighties and early nineties.[1–4] The number of implants to be placed and the type of retention that is rigid versus resilient mechanism were controversially discussed. Two single standing implants with ball attachments were sometimes considered a risk and some investigators suggest using four implants with a splinting bar,[5,6] while no differences in clinical findings were reported by

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others.[7] The majority of studies available on mandibular overdentures show that mostly two implants were used. This treatment modality was also considered the standard of care for edentulousness.[8,9] Success rates of > 97% were reported after an observation time of 10 and more years[1,2] independent of the implant system.[1,3,4] Long-term crestal bone resorption at the implant shoulder was minimal and comparable with resorption at teeth.[1] It appears that early and immediate loading may be equally successful[8,10] or minimally more crestal bone loss may be observed.[6] Recently, overdentures supported by only one single implant were also documented clinically.[11,12]

The success of the mandibular implant overdenture treatment was additionally confirmed in studies analyzing its impact on oral health related quality of life, patients' satisfaction and function.[13–18] These studies document successful treatment outcomes and better oral health related quality of life as compared to wearing of complete dentures. Chewing function and chewing forces improved significantly[19–21] if implant overdentures and complete dentures were compared. One study confirmed that the patients' satisfaction was not significantly enhanced if four implants were used with a bar connector as compared to only two implants.[22] With regard to the anchorage system studies, no subjective preference was found between the use of a bar or ball anchors.[18,23–25] If overdentures and full-arch fixed dental prostheses were compared in a cross-over study, the patients did not give distinctly better ratings to the fixed reconstruction.

While the survival of implants and oral hygiene was the primary outcome of many early studies, prosthetic maintenance including economic aspects became the focus of various investigators later on.[26–32] Complications with the implant-retention device complex and the overdenture itself were analyzed, including comparisons of the retention mechanism. One study[27] came to the conclusion that the use of rigid (parallel wall) soldered gold bars (G-bars) had a lower complication rate than resilient retention devices as there are round soldered G-bars clips or single ball anchors. These findings were further confirmed in a clinical study with long-term results up to 24 years.[33] It is assumed that the functional effect of rigid parallel-wall bars is comparable to fixed prostheses and associated with a lower impact of rotational movements.[34,35] This will reduce wear of the material and subsequently technical complications. So far, most studies reported on prefabricated soldered G-bars and studies on mandibular computer-aided design/computer-assisted manufacturing (CAD/CAM) fabricated titanium bars (Ti-bars) are not available. The weakest link of soldered bars is the solder joint. Titanium has not often been used before in the CAD/CAM area, since processing was difficult and not offered by technical laboratories. Thus, the standard remained the soldered G-bar. Today, it is assumed that the CAD/CAM Ti-bars may have technical advantages due to the absence of solder joints, the absence of heat process and the better options for an individualized design.

Thus, the aim of the present study was to evaluate the performance of rigid CAD/CAM fabricated Ti-bars in comparison with rigid soldered G-bars for mandibular implant-overdentures. The primary endpoint was the bar survival with the bar fracture as outcome variable. The secondary endpoint was prosthetic service and complications with retention devices and dentures. Additionally, peri-implant crestal bone level changes were analyzed. The null hypothesis was that there are no differences in the endpoints between Ti-bar and G-bar.

MATERIALS AND METHODS

Patients and Implants

Completely edentulous elderly patients were consecutively admitted for treatment with maxillary dentures and mandibular implant-overdentures. Mostly two implants were placed in interforaminal position. Three implants were placed for patients who exhibited a narrow curved anterior jawbone.

All patients were in fair conditions when the implants were placed. Exclusion criteria were irradiation or chemotherapy, long-term intake of steroids, history of recent heart attack, psychiatric problems, unrealistic expectations of the patients, insufficient jawbone volume to accommodate two implants of minimum 10 mm length. All implants used had a medium rough surface with a 1.5 mm machined neck and root-shape design (ReplaceSelect Tapered; Nobel Biocare, Gothenburg, Sweden). The implant placement followed a standard procedure as prescribed by the manufacturer. The polished neck of the implant was placed not within the osteotomy resulting in a 1–1.5 mm supracrestal position of the implant shoulder.

Simultaneous, local bone augmentation (GBR) was performed in 39% of the patients. A healing phase of

2 months with the implants submerged was maintained. The surgical and prosthodontic treatment was performed by various prosthodontists under supervision of one and the same person. The patients covered the entire costs for the treatment and maintenance service themselves.

Prosthodontic Treatment

The prosthodontic treatment protocol was the same for all patients. The implants were placed in the planned position using surgical splints. During the healing time of 2 months the patients did wear the new provisional or old dentures that were slightly relieved at the inner surface and adapted with soft reliner. Then new dentures were fabricated in both jaws and completed together with the bar devices. The patients had the option to get a standard G-bar or a Ti-bar fabricated by means of the recently introduced CAD/CAM technology. The G-bar was designed with parallel walls, thus provided a rigid retention. Prefabricated gold copings and G-bar segments (Dolder bar attachment macro; Cendres+Métaux SA, Biel/Bienne, Switzerland) were first fitted with a gap of <0.2 mm, connected with resin and then embedded for the solder procedure (SG 750; Cendres+Métaux SA). This bar type has a height of 3 mm and a width of 2.2 mm. Distal extensions were added in cases, if from a prosthetic point of view it appeared that they would significantly improve the support and relieve pressure on the mandibular foramen or if for anatomical reasons the implants were not placed in fully symmetrical position. The rule was that uni- or bilateral distal extensions of G-bars had a maximum length of 5 to 6 mm. They should not extend beyond the first premolar of the denture teeth.

The CAD/CAM Ti-bar had the identical dimensions as the G-bar for the same female retainers were used. Ti-bar fabrication comprised digitizing of the implant platform with specific implant scan bodies (NobelProcera™ Position Locator Model; Nobel Biocare, Gothenburg, Sweden) and of the bar wax-up (NobelProcera™ Forte Scanner; Nobel Biocare) for the final designing by one experienced technician in a private laboratory. After CAD with the NobelProcera™ Software (Nobel Biocare), information of each bar was individually transmitted to the production center, where a CNC-milling machine (NobelProcera™ Innovation Center; Stockholm, Sweden) performed CAM from a homogenous block of titanium (Ti6Al4V). For both bar types, the retainers were extended along the entire bar segment with the housing directly in the acrylic denture base. The bars were screw-retained directly at the implant shoulder without the interposition of an abutment. For fixation of the bars at the implant-shoulder the same type of screw was used. The patients had the choice to select the standard G-bar or the Ti-bar that was based on CAD/CAM technology. The production procedure of the Ti-bar and G-bar is shown by the Figure 1A,B,C,D and Figure 2A,B,C,D.

Follow Up and Data Collection

When the treatment was completed, all patients were scheduled for regular recall appointments twice a year. The dental hygienist was responsible to organize and perform the recall appointments under supervision of the dentist. During the recall session, hygiene and peri-implant tissues were examined and fit of dentures checked. The implants and dentures were cleaned and motivation for adequate home care was reinforced. Minor prosthetic service was simultaneously performed by the dentist like tightening of bar screws and female retainers or removal of sore spots. If complications with implants and retention devices and/or major need for prosthetic maintenance were identified that also required collaboration with the laboratory technician, the patients were scheduled for an additional appointment with the dentist.

Digital orthopantomographic radiographs (OPT) were obtained before and after completion of the treatment and thereafter each year during the individual follow-up period to a maximum of 4 years. The Dimaxis Pro software (version 4.3.2; Planmeca, Finland) program was applied to analyze the radiographs and calculate changes of crestal bone. The vertical distance from the implant shoulder to the first bone implant contact (BIC) was measured at mesial and distal implant sites. The OPT that was taken when the new dentures were delivered and the implants subjected to load served as a baseline reference. Mean values per implant were calculated and expressed as ΔBIC.

Prosthetic Complications

Data from prosthetic complications comprising maintenance service, technical problems and repairs were reported. These complications were detected by the dentist or reported by the patients at the recall visits or at unscheduled appointments. All these prosthetic

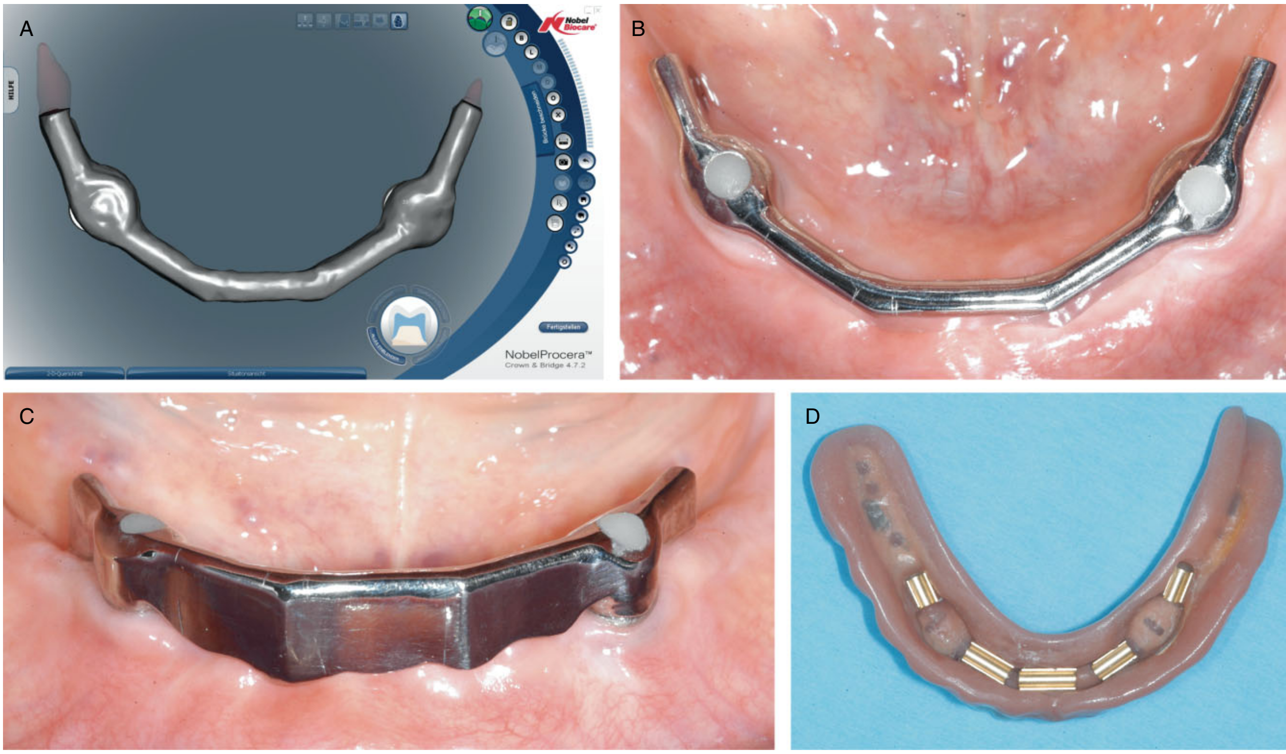

Figure 1 (A) Computer-assisted designing of the future CAD/CAM titanium bar. (B) Occlusal view of a CAD/CAM titanium bar in situ that was milled from a single block of homogenous titanium and where the access holes were covered with acrylic composite material. (C) Frontal view of a CAD/CAM titanium bar (U-shape with parallel walls) with an individualized vertical height. (D) Internal view of a bar supported implant-overdenture with the prefabricated female retainers.

complications were considered to be an objective treatment need and had to be carried out for maintaining proper function. Comparable to previous studies,[33,36,37] the following three categories were investigated: 1) anchorage system (fracture of bars or bar extensions, tightening of bar screws, fractures of bar screws, activation of female retainers, change of loose, broken and lost matrices), 2) denture repair (fracture of denture base or teeth, new dentures or redesign of denture), and 3) denture adaptation (sore spots, relining, occlusal adjustment and re-arrangement of teeth, new teeth because of wear).

This survey was part of a quality control assessment of the dental consultation and was approved by the institutional ethical committee. The patients gave their informed consent to use their data including the photographs and the radiographs.

Statistical Analysis

The data were subjected to statistical analysis using SPSS 20. Descriptive statistics were used for patients' demographics, calculation of the type and total number of events for prosthetic complications. Censored data on bar fractures were described by the Kaplan–Meier curve. The results report the data of 3 to 4 years of observation, since the number of patients with a longer observation period was still small. The Null-hypothesis was that there is no difference between survival of both types of bars. The significance level was set to 0.05.

RESULTS

Altogether, the data of 213 edentulous patients with 477 tapered implants supporting bar-overdentures were available for the present study. The average age of the patients was 68.0 ± 9.9 years at the time of implant treatment. The percentage distribution was 56% female and 44% male patients. Five implants failed during the healing period, but new ones were placed and the treatment plan was maintained. All loaded implants remained stable during the observation period.

The group with the Ti-bars comprised 101 patients with 231 implants, while G-bars comprised 112 patients with 246 implants (Table 1). The maximum

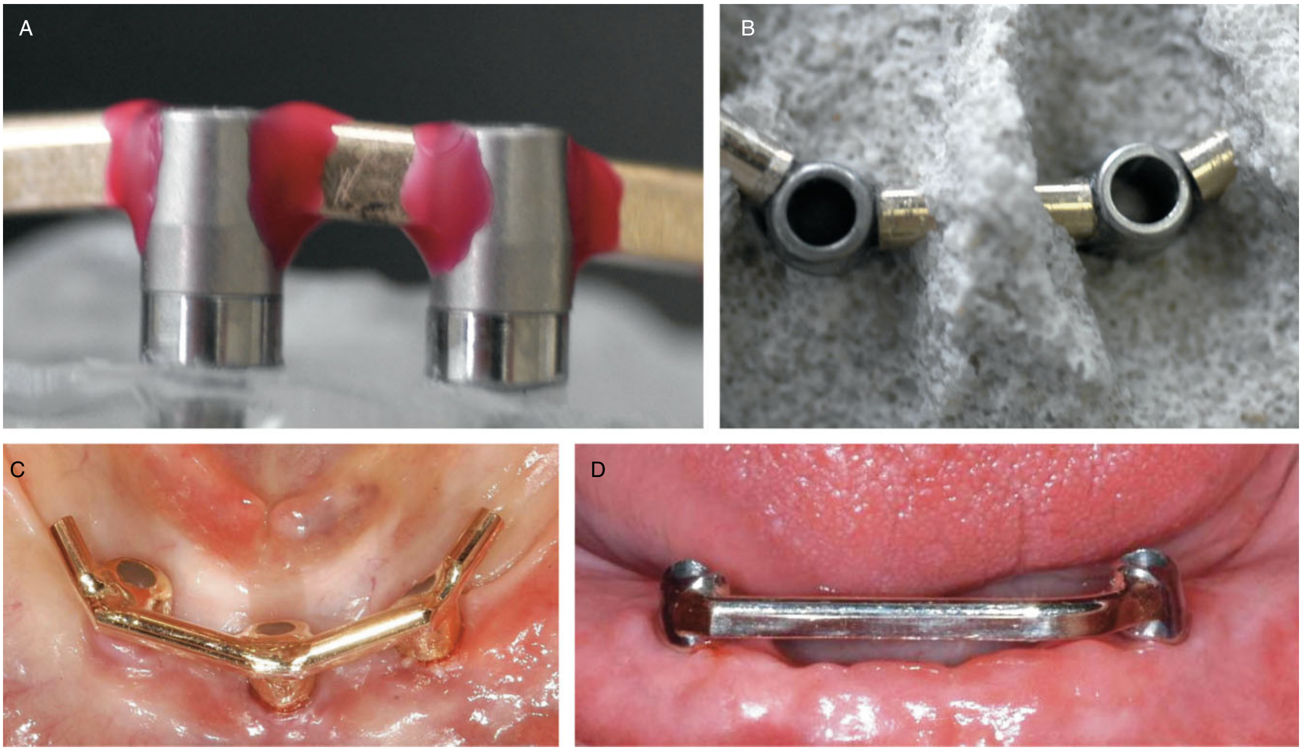

Figure 2 Close up of the solder joints that connect the prefabricated gold abutments and bar segments (A) before and (B) after fixation for solder procedure. Occlusal (C) and frontal (D) view of gold bars (U-shape with parallel walls) with and typically without distal extensions.

observation time was 5.8 and 6.6 years for Ti-bars and G-bars, respectively. Both groups matched each other with regard to the number of patients and implants, age, gender and observation time. Altogether, Ti-bars exhibited distal bar extensions in 96% of the patients versus 34% of the patients with G-bars (Table 2). Bilateral extensions were identified with a higher frequency with Ti-bars than with G-bars (94% vs 21%, $p < .001$).

Fractures of the bar were all located at the extensions (Figure 3A, B). In Ti-bars nine fractures out of totally 192 extensions occurred resulting in a fracture rate of 4.7%. This was significantly different ($p < .001$) to the G-bars with a fracture rate of 14.8% (9 of 61). The fractures in both groups occurred 8 months up to 4 years after delivery of the dentures without a typical temporal pattern for either group (Figure 4). The Null-hypothesis had to be rejected; the survival rate of the Ti-bars was significantly higher.

Complications with the implant-retention device complex and the dentures were frequent. The first event within a short observation time – a few days or weeks after denture delivery – was development of sore spots in 130 patients and matched both groups. The complication rate per patient with fractured matrices was significant ($p < .001$) between Ti-bar (1 of 101, 1%) and G-bar (15 of 112, 13%). Activation of matrices was required 2.4× less often in Ti-bar. No difference was observed for denture repair (fracture of base or teeth) and need for relining. Table 3 gives an overview of the prosthetic complications recorded. The crestal bone remained stable around the implants of both groups with minimal changes of BIC. No significant difference between both groups was observed at any time point (Figure 5).

TABLE 1 Number of Implants Per Patient for Ti-Bar and G-Bar IODs

Implants Per Patient	Ti-Bar IOD Implants / Patients	G-Bar IOD Implants / Patients	Total Implants / Patients
2	148 / 74	180 / 90	328 / 164
3	75 / 25	66 / 22	141 / 47
4	8 / 2	0 / 0	8 / 2
Total	231 / 101	246 / 112	477 / 213

G-bar = gold bar; IOD = implant-overdenture; Ti-bar = titanium bar.

TABLE 2 Number of Bars, Distal Extensions, and Number of Bar Fractures

	Ti-Bar 101 Patients	G-Bar 112 Patients	p (χ^2)	Total
No distal extension	4 (4%)	74 (66%)	<0.001	78 (37%)
Unilateral distal extension	2 (2%)	15 (13%)	<0.001	17 (8%)
Bilateral distal extensions	95 (94%)	23 (21%)	<0.001	118 (55%)
Total extensions	192	61	<0.001	253
Extensions / patient	1.9	0.6	<0.001	1.2
Total fractures	9	9	ns	18
Fracture rate	4.7%	14.8%	0.008	7.1%

G-bar = gold bar; ns = not statistically significant; Ti-bar = titanium bar.

DISCUSSION

The importance of regular maintenance to maintain implants and prostheses in good conditions is important. It is influenced by the patients' behavior regarding their recall attendance.[18,38,39] A study documented well compliant patients during a long observation period up to 24 years.[33] The problem of providing adequate long-term aftercare and of maintaining contacts to caregivers is an increasingly important aspect in a society of high mobility and otherwise with a larger segment of the older population. Data collections on maintenance, complications and failures therefore often cover only short time periods.

The present data collection cannot be considered to be a prospective study in a strict sense. The patients did not start their treatment at the same time point. The patient cohorts were not randomized, but matched each other well. All patients were completely edentulous and followed the same treatment protocol with the same type of implants and denture design. The original treatment plan was maintained for all patients and maintenance provided. In contrast to the long-term clinical experience with G-bars as previously reported,[18,27,33] the new technology adopted for the fabrication of Ti-bars might reflect a learning curve. This could influence the treatment outcome of the present study but is difficult to measure. The present study focused on technical complications and the primary endpoint of the present study was the bar failure that is fracture. Distal extensions enhance prosthesis stability, particularly if the bar is short. However, they may act as a cantilever and may lead to high loading impact and fracture. One study reported on fractures of bar-extensions and the authors concluded that bar fractures occurred as a consequence of distal extensions. Therefore, they recommended not to use this bar design.[40] Distal extensions that often exceeded 6 mm of length were frequently identified in the present study since it was assumed, that the risk of

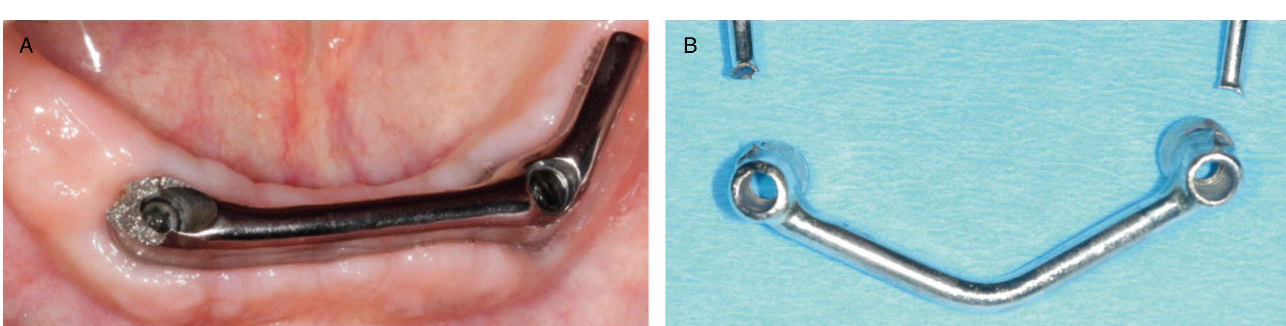

Figure 3 (A) CAD/CAM titanium bar with complete fracture of the right distal extension. The fracture started in the occlusal aspect of the lingual and buccal walls leading toward the distal cervical part of the screw-access whole. (B) Soldered gold bar with bilateral complete fractures of the distal extensions. The fracture was typically located distal of the gold abutment at the solder joints.

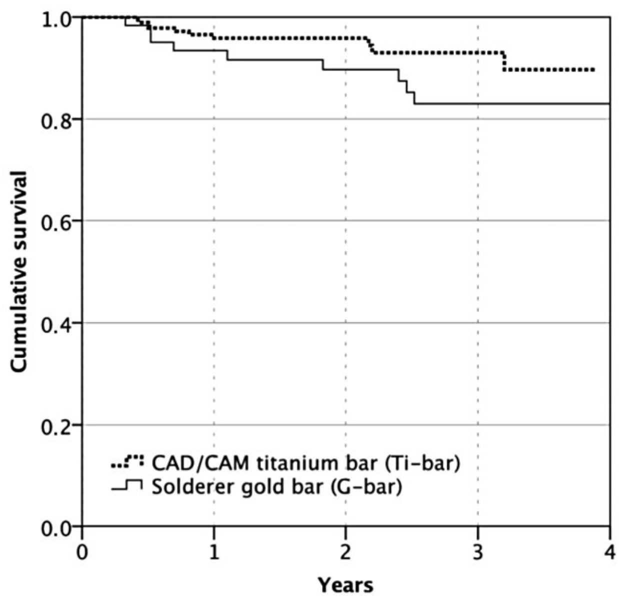

Figure 4 Bar fracture related survival function of Ti-bar and G-bar.

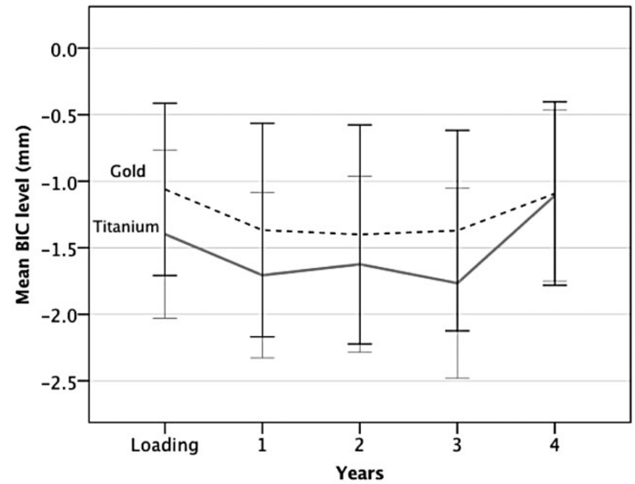

Figure 5 Peri-implant crestal bone level changes for Ti-bar and G-bar.

fracture would be reduced if bars are milled from one Titanium block and are not soldered. The present results show that the CAD/CAM technology with Ti-bars did not eliminate fractures, but the number of fractures was significantly lower with Ti-bars than with G-bars. The fractures of Ti-bars mostly occurred at the access hole for the bar screw, while the G-bars mostly exhibited fractures at the solder joints. As a conclusion from these observations, minor changes of the Ti-bar design have to be considered. It appears that the material thickness

TABLE 3 Maintenance Service Categories and Number of Interventions Performed during the 3- to 4-Year Observation Period

Complication	Ti-Bar IOD (*n* = 101) Number of Events	G-Bar IOD (*n* = 112) Number of Events	Total (*n* = 213) Number of Events
1) Anchorage system (total)	57	136	193
– Tightening of occlusal screws	0	1	1
– Fractured occlusal screw	2	1	3
– Activation of matrices	42	110	152
– Fractured matrices	1	15	16
– Fractured bar extensions	9	9	18
2) Repair of prosthesis (total)	11	11	22
– Fracture of acrylic denture base	3	4	7
– Fracture of teeth	7	7	14
– New denture or redesign	1	0	1
3) Adaptation of prostheses (total)	208	279	487
– Sore spots	135	193	328
– Relining	23	19	42
– Occlusal correction, remounting	50	51	101
– Rearrangement of teeth	0	4	4
– Excessive tooth wear	0	3	3
– Hyperplasia	3	7	10
– Discoloration of acrylic material	0	2	2
Total events	276	426	702

G–bar = gold bar; IOD = implant–overdenture; Ti–bar = titanium bar.

around the access hole was insufficient and should be increased.

A uniform definition of what is considered normal maintenance and otherwise a complication does not exist. The difference may be the frequency of an event that requires some intervention by the dentist. Problems with the implant-retention device complex of removable dentures are the crucial aspect, resulting in higher complication rate if compared to fixed prostheses. One study reported that maintenance costs for fixed dentures be lower than for implant overdentures.[41] So far, in spite of many clinical results nowadays available, the selection of the retention devices is not based on good scientific evidence and stringent conclusions, neither with regard to crestal bone resorption nor maintenance service could be drawn.[18,23,42–44] Better scores for prosthetic maintenance after a 10-year period with ball anchors as compared to bars or magnets were observed,[42,45] while other investigators reported on less service for bars as compared to single anchors.[46] In fact, controversy exists between the performances of bars or ball anchors if the literature is screened. It has to be taken into account that the bar design differs and clinical findings are related to clip-bars or egg-shaped and rigid bars. One study reported that in the first 3 years after delivery of the mandibular overdentures only 10% of the patients remained without maintenance.[47] Particularly, the first year is sensitive to minor complications.[44] This observation was made also by other authors and also for maxillary overdentures.[25,36,37] The present results show a high initial incidence of complications. These often consisted in minor adaptation of the denture base, that is elimination of sor spots or minor occlusal grinding. Both are a typical measure after delivery of overdentures in the initial days and weeks after denture delivery. In the present study, initial sore spots were comprised when calculating complications, which means that no patient remained without complications during the reported observation time. If these interventions are considered as normal service and are not included, the complication rate becomes distinctly lower in both groups. Both bars were designed directly from the implant shoulder without the interposition of an abutment. For both bar designs, the same type of occlusal screw was useed and tightened with 35 Ncm and re-tightening of the bar screw rarely occurred. In the present study, the stock prefabricaed gold matrices available for the U-shaped Dolder were used also for the Ti-bar. Activation of matrices is not really an objectively measurable criteria for complications, it may be driven by patients who require high stability, while others may hav difficulty to remove a tightly connected overdenture. Fractures of the matrices or loosening from the denture base housing is a problem that needs repair associated with laboratory procedures. It apperas to be more frequent if the bar segment is short.[44] There was a slight tendency to identify more fractures of matrices with G-bars as compared to Ti-bars. One explanation or speculation could be that the individualized Ti-bar enhanced the denture stability and diminished wear of the materal, which is a cause of fractures. All other service provided and events recorded were not different for both groups and are typical for overdentures supported by implants. In accordance to previously mentioned studies, prosthetic maintenance is regularly needed.

A significant incidence of marginal infection around the implants was not found during the still short observation time. A study with an observation time >10 up to 24 years confirmed that crestal bone remains stable over long time periods.[48] The results of the present analysis would not be different if the patients had been used as the statistical unit. Due to a high mouth floor and advanced jaw resorption periapical films could often not be properly placed and OPT had to be used. In a cadaver study, crestal bone measurements of interforaminal implants were compared using different radiographic techniques, including digital OPTs. The authors found that all imaging techniques showed acceptable accuracy for peri-implant bone level measurements, without statistically significant differences.[49] One study investigated the effect of distal extensions on marginal bone alterations around implants. The extensions were up to 12 mm long, while the control group did not exhibit extensions. There was no difference seen between both groups and the length of bar extensions did not have a negative effect on marginal bone loss.[50] Thus, these authors concluded that bar extensions might be recommended as an effective treatment concept. In the present study, no trend was identified toward the bar material and no effect of bar extensions was observed related to the crestal bone level changes.

CONCLUSIONS

Implant overdentures supported by soldered gold or CAD/CAM Ti-bars are a successful treatment modality but require regular maintenance service. CAD/CAM technology allows for the fabrication of one-piece Ti-bars with bilateral extensions resulting in less frequent fractures of bars and extensions as compared to soldered G-bars. These short-term observations demonstrate that CAD/CAM Ti-bars may reduce technical complications. Bar fracture location indicated that the material thickness around the screw access hole of CAD/CAM Ti-bars should be increased.

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