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Frequency of prosthetic complications related to implant-borne prosthesis in a sleep disorder unit --Manuscript Draft--

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Corresponding Author:	Eduardo Anitua, Ph.D, M.D., D.D.S Eduardo Anitua Foundation Vitoria, Álava SPAIN
Corresponding Author Secondary Information:	
Corresponding Author's Institution:	Eduardo Anitua Foundation
Corresponding Author's Secondary Institution:	
First Author:	Eduardo Anitua, Ph.D, M.D., D.D.S
First Author Secondary Information:	
Order of Authors:	Eduardo Anitua, Ph.D, M.D., D.D.S Juan Saracho, DDS Gabriela Zamora Almeida, PhD Joquin Duran-Cantolla, MD, PhD Mohammad Alkhraisat, DDS, BSc, PhD, EU PhD
Order of Authors Secondary Information:	
Abstract:	Sleep bruxism and higher clench index have been associated with obstructive sleep apnea (OSA). However, there is no study that reports on the prosthetic complications in patients with OSA. Patients' records, who had performed a sleep study to diagnose OSA, were examined for the occurrence of prosthetic complications in implant-borne reconstructions. The primary outcome was the frequency of prosthetic complications. The secondary outcomes were anthropometric data, the type of the complication, type of the prosthesis, type of retention, number of supporting implants, number of prosthetic units, and the presence of obstructive sleep apnea. Of the 172 patients, 67 had an implant-supported prosthesis and all were included in the study. They had 61 ± 10 years and 36 were females. Thirty complications in 22 prostheses were identified in 16 patients. The complications were porcelain fracture (14 events), screw/implant fracture (8 events), screw loosening (3 events) and decementation (5 events). The follow-up time was 117 ± 90 months after the placement of the prosthesis. The average time for complications to occur was 73 ± 65 months after the placement of the prosthesis. According to the apnea-hypopnea index, 49 patients had OSA. Thirteen of the 16 patients having a prosthetic complication had also OSA. The highest AHI and thus the severity of OSA was identified for patients with a fracture complication related to an implant, a screw or a porcelain. The frequency of prosthetic complications has been higher in patients with obstructive sleep apnea.
Response to Reviewers:	Reviewer #1: It is a nicely structured study well documented, comprehensive and with good critical discussion of recent literature. Authors: We acknowledge the reviewer for his/her positive comments and opinion

related to the submitted manuscript.

Reviewer#2: Positive declarative statements were used by the reviewer to rate the submitted manuscript. The reviewer rated each statement using a scale from 1-4:

Authors: We thank the reviewer for his/her comments and we will improve the manuscript by answering and taking in consideration the report on the article.

A report on article aaid-joi-D-16-00100
Frequency of prosthetic complications related to implant-borne prosthesis in a sleep disorder unit

Title: Ok

Abstract: needs some linguistic corrections : e.g: *They had 61 ± 10 years and 36 were females*.

It should be : the mean age was 61 ± 10 years and 36 were females.

The highest AHI and thus the severity of OSA. The abbreviation AHI should be explained

Ok

Authors: All the suggested corrections have been done.

The introduction: some linguistic corrections:

An drastic outcome would be implant loosening/fracture. Should be : a drastic outcome

Authors: The sentence has been corrected accordingly.

The second paragraph of introduction: lines 30 and up should reflect the differentiation between Bruxism and Sleep Bruxism(Bruxonomia) it somewhat perplexing specially the statement regarding diagnosis of bruxism with polysomnography. This test is mainly for diagnosis of sleep bruxism.

Authors: The paragraph was modified to "However, the gold standard in the diagnosis of sleep bruxism is polysomnography. This type of study is not accessible to all patients, and is expensive and time-consuming. There is also a risk of assuming the absence of sleep bruxism if an episode does not occur during the performance of the test"

The results: are lacking the data regarding statistical testing and p. values

Authors: The p value and the statistical tests are detailed in Table 1. Modification to the statistical analysis section in the materials and methods has been done "Qualitative variables were expressed in number of events and were compared with χ^2 test and Fisher's exact test for 2×2 and 2×3 contingency tables, respectively."

Discussion section:

Needs some revision to insert reference number : e.g: Engel et al. have evaluated the effect of occlusal wear (as sign of oral parafunction) on vertical bone loss around dental.

Authors: A reference number has been added.

The authors acknowledge the limitations of their study. which is nice.

Authors: We thank the reviewer for this comment.

References are nicely written

Authors: We thank the reviewer for this comment.

This study tries to cast light on an interesting area, however if it was associated by some examinations regarding occlusal errors and or high spots it would have been much more important

Authors: We thank the reviewer for this comment however, due to the limitation of the retrospective design of the study, it is not possible to have this information. However, the results of the this study encourages the performance of a prospective study and the parameter of occlusal errors and high spots will be selected as one of the variables to evaluate.

**Frequency of prosthetic complications related to implant-borne prosthesis in a
sleep disorder unit**

Eduardo Anitua MD, DDS, PhD^{1,2,3}, Juan Saracho DDS¹, Gabriela Zamora Almeida
PhD^{4,5}, Joaquin Duran-Cantolla MD, PhD^{4,5}, Mohammad Hamdan Alkhraisat DDS, MSc,
PhD^{2,3}

¹ Private practice in oral implantology, Vitoria, Spain.

² Eduardo Anitua Foundation, Vitoria, Spain.

³BTI Biotechnology Institute, Vitoria, Spain

⁴Bioaraba Research Institute. OSI Araba University Hospital. Vitoria. Spain.

⁵Interdisciplinary Sleep Unit. OSI Araba University Hospital. Vitoria. Spain.

Short title: Prosthetic complications and OSA

Correspondence address: Dr. Eduardo Anitua, Eduardo Anitua Foundation; C/ Jose
Maria Cagigal 19, 01007 Vitoria, Spain; Phone: +34 945160653, e-mail:
eduardoanitua@eduardoanitua.com

Conflict of interest statement

EA is the Scientific Director of BTI Biotechnology Institute (Vitoria, Spain). He is the
head of the Foundation Eduardo Anitua, Vitoria, Spain. JS, GZA and JDC has no conflict
of interests. MHA is scientist at BTI Biotechnology Institute (Vitoria, Spain).

Abstract

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Sleep bruxism and higher clench index have been associated with obstructive sleep apnea (OSA). However, there is no study that reports on the prosthetic complications in patients with OSA. Patients' records, who had performed a sleep study to diagnose OSA, were examined for the occurrence of prosthetic complications in implant-borne reconstructions. The primary outcome was the frequency of prosthetic complications. The secondary outcomes were anthropometric data, the type of the complication, type of the prosthesis, type of retention, number of supporting implants, number of prosthetic units, and the presence of obstructive sleep apnea. Of the 172 patients, 67 had an implant-supported prosthesis and all were included in the study. The mean age was 61 ± 10 years and 36 were females. Thirty complications in 22 prostheses were identified in 16 patients. The complications were porcelain fracture (14 events), screw/implant fracture (8 events), screw loosening (3 events) and decementation (5 events). The follow-up time was 117 ± 90 months after the placement of the prosthesis. The average time for complications to occur was 73 ± 65 months after the placement of the prosthesis. According to the apnea-hypopnea index, 49 patients had OSA. Thirteen of the 16 patients having a prosthetic complication had also OSA. The highest apnea-hypopnea index (AHI) and thus the severity of OSA was identified for patients with a fracture complication related to an implant, a screw or a porcelain. The frequency of prosthetic complications has been higher in patients with obstructive sleep apnea.

Keywords: Dental implants; fixed dental prostheses; technical complications; obstructive sleep apnea; apnea- hypopnea index.

Introduction

1 The reliability and high success rate of implant-borne prosthetic reconstructions have
2 made this option a standard of care in oral rehabilitation¹. The implant survival rate of
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4 implant-supported fixed partial denture is reported to be 92-97%². However, implants
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6 fail and prosthetic complications occur. It has been reported that 40% of the implant
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8 failures occur during the period of osseointegration (early failures) and 60% occurred
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10 after loading (late failures)^{3,4}. Excessive overloading would challenge biomechanically
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12 the prosthetic construction and the implant fixture. On the long-term it would precipitate
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14 a fracture of an abutment, tooth and/or prosthodontic material⁵. Excessive mechanical
15
16 stress would also increase the risk of screw loosening/fracture, abutment fracture,
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18 chipping of the ceramic and the fracture of the prosthesis^{6,7}. A drastic outcome would be
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20 implant loosening/fracture.
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27 Bragger et al have found a significant correlation between bruxism and technical
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29 prosthetic complications but not with implant failure⁸. The diagnosis of bruxism is
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31 frequently performed on the basis of questionnaires or information provided by the
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33 patient, bed partner and/or relatives. The presence of clinical signs of occlusal wear
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35 patterns on natural teeth or restorative materials is frequently used to diagnose bruxism⁹,
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1 patients with OSA, the activation of masseter muscles after respiratory events could be
2 an unspecific motor activity that depends on the duration of sleep arousal rather than a
3 response to respiratory events ¹⁶.
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8 However, there is no study that report on the prosthetic complications in patients with
9 OSA. The purpose of the study was to analyze the frequency of prosthetic complications
10 in implant-borne prostheses at a sleep disorder unit. The investigators hypothesize that
11 there is no association between the frequency of prosthetic complications of implant-
12 supported prostheses and OSA. The specific aims of the study were: 1) estimate the
13 frequency of prosthetic complications, 2) identify the type of the prosthetic complication
14 and the type of the prosthesis, 3) calculate the average number of implant supporting the
15 prosthesis, 4) calculate the average number of prosthetic units, 5) estimate the frequency
16 of obstructive sleep apnea according to the presence/absence of prosthetic complication.
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34 **Materials and methods**

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37 This article was written following the STROBE (Strengthening the Reporting of
38 Observational studies in Epidemiology) guidelines. This retrospective clinical study was
39 conducted at a private centre. The study was performed in accordance with the
40 Declaration of Helsinki.
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47 Patients records were reviewed to select those who were seen in the Sleep Disorders Unit
48 at the dental centre. Patients from both sexes were eligible to participate in this study and
49 were selected according to the following inclusion criteria:
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- 54 – Have a sleep study performed. It is important to mention that this study was
55 previously prescribed by a sleep specialist to diagnose obstructive sleep apnea.
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- Have implant-borne prosthesis

All patients who did not fulfill the inclusion criteria were excluded. There were no specific exclusion criteria.

To achieve a blinded evaluation, a prosthodontist was responsible for reviewing the patients records and had no chance to see the results of sleep analysis. Patients records (including photographs and radiographs) were reviewed to identify the occurrence of a prosthetic complication as fracture of abutment tooth, connector fracture, screw loosening/fracture, abutment fracture, chipping of the ceramic and the fracture of the prosthesis and implant loosening/fracture. Once identified a complication, the type of the prosthesis and the retention system, location, number of dental units and number of supporting implants were recorded.

Sleep study

A simplified respiratory polygraphy (BTI APNiA; BTI Biotechnology Institute, Vitoria, Spain) was employed to perform the sleep study at the patient's own home. The device recorded the intra-nasal pressure via a nasal cannula and was attached to a belt that surrounded the patient's chest. Cutaneous pulsioximetry with a finger probe was used to measure oxygen saturation (Nonin, Amsterdam, The Netherlands). The recordings were visualized in the BTI APNiA software and were analyzed automatically according to the criteria of the Spanish Respiratory Association ¹⁷. The minimum time of recording was 6 hours and the minimum time of sleep was 180 minutes. The following definition of the respiratory variables were used:

- Apnea: a drop in the respiratory signal of more than 90% during a minimum of 10 seconds.

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- Hypopnea: A drop in the respiratory signal between 30% and 90%, accompanied by a drop in oxygen saturation $\geq 3\%$ and/or arousal.

Statistical analysis

Quantitative data were described by the calculation of the mean and standard deviation. Continuous variables were expressed by mean \pm typical deviation and were compared with Mann-Whitney Test. Qualitative variables were expressed in number of events and were compared with χ^2 test and Fisher's exact test for 2×2 and 2×3 contingency tables, respectively. The frequency of qualitative variables was also calculated. Statistical analysis was performed using SPSS 15.0. Statistical significance was set at p value < 0.05 .

Results

One hundred and seventy two patients had been seen in the sleep disorder units. Sixty seven patients had an implant-supported prosthesis and all were included in the analysis. The patients demographics indicated an average age of 61 ± 10 years (range: 33 to 84 years) and 36 patients were females.

Prosthetic outcomes

A total of 30 complications in 22 prostheses occurred in 16 patients. These complications were porcelain fracture (14 events), screw/implant fracture (8 events), screw loosening (3 events) and decementation (5 events). Most of the complications occurred in the posterior sectors (all screw loosening events, 6 of screw/implant fractures, 10 of porcelain fractures and 2 of decementation events). The follow-up time was 117 ± 90 months (range: 10 to 279 months) after the placement of the prosthesis. The average time for complications to

1 occur was 73 ± 65 months (range: 5 to 272 months) after the placement of the prosthesis.

2 The implant/screw fracture occurred at an average time ≥ 112 months. Meanwhile, the
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4 decementation or screw loosening occurred after an average time ≥ 44 months.
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8 A total of 82 implants were inserted to support 74 prostheses. Twenty seven prostheses
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10 were single crowns, 45 were partial fixed prostheses and 2 were complete fixed
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12 prostheses (Table 1). These prostheses were divided in two groups according to the
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14 occurrence of a complication. Twenty two prostheses in 16 patients formed the
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16 experimental group and 52 in 49 patients formed the control group (Table 1).
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21 The frequency of the type of the prosthesis according to the presence/absence of
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23 complications are shown in Table 1. There was no statistically significant differences
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25 between groups in the frequency of partial and complete fixed prostheses but the
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27 experimental group had significantly more single crowns. The number of implants placed
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29 to support a prosthesis showed no statistically significant differences between the control
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31 and the experimental groups. However, the prosthesis had a significantly more units in
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33 the experimental group. There was no significant differences in the type of fixation
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35 between groups (Table 1).
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41 Table 2 shows the frequency of prosthetic complications according to the type of the
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43 prosthesis. Most of these complications were related to a fixed partial prosthesis. This
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45 prosthetic type was also the most frequent in this study. Moreover, 15 of the prosthetic
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47 complications were related to a cemented prostheses in comparison to 7 that were related
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49 to screwed prostheses (Table 2).
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54 Sleep study

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57 The sleep analysis indicated the presence of obstructive sleep apnea in 49 patients of the
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59 69 included in the analysis (Table 3). The cross tabulation of OSA and the presence of a
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prosthetic complications indicated the co-existence of these two factors in 13 patients (Table 3). Thus, 81% of the patients having a prosthetic complication had also OSA. The AHI was then averaged according to the type of the prosthetic complication (Table 4). The highest AHI and thus the severity of OSA was identified for patients with a fracture complication related to an implant, a screw or a porcelain.

Discussion

Prosthetic complications have been more frequent in patients having an apnea-hypopnea index ≥ 5 . Even more, patients with a fracture complication related to an implant, an abutment screw or a porcelain had the highest AHI. For that, the null hypothesis could not be accepted.

Lobezoo et al. have defined bruxism as a repetitive jaw-muscle activity characterized by clenching or grinding of the teeth and/or by bracing or thrusting of the mandible ¹⁸. Bragger et al have found a significant correlation between bruxism and technical prosthetic complications but not with implant failure. Six out of 10 bruxers experienced technical complications, whereas 13 out of 75 non-bruxers had such a complication (mostly porcelain fractures) ⁸. However, the method of diagnosis of bruxism was not identified. In another study, Kinsel et al found that 34.9% of patients exhibiting signs of bruxism experienced metal ceramic fracture, compared to 18.3% patients without bruxism ¹⁹. This was equivalent to 18.9% and 5.1% of the dental units (implant-supported metal ceramic crowns and implant-supported fixed partial dentures) placed in patients with and without bruxism, respectively.

Parel et al have evaluated immediate function of four implants in the maxilla supporting a complete denture in completely edentulous patients ¹⁰. A total of 40 of 1140 implants

1 had failed in 20 patients, 9 of them were bruxers. Engel et al. have evaluated the effect of
2 occlusal wear (as sign of oral parafunction) on vertical bone loss around dental implants
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5 8. There was no indication that implants in patients with occlusal wear may have an
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7 increased bone loss rate.
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10 Sleep bruxism has been associated with obstructive sleep apnea syndrome (OSA) ¹²⁻¹⁵.
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12 Moreover, a significant correlation between clench index and the apnea-hypopnea index
13 (AHI) has been established ²⁰. These events may increase the risk of mechanical
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15 overloading of the prosthetic rehabilitation. Our findings have indicated that 81% of the
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17 prosthetic complications occurred in patients with OSA. Even more, the most serious
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19 complications (implant and screw fracture) have been associated with the highest apnea-
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21 hypopnea index. In a recent study ²¹, the frequency of obstructive sleep apnea in dental
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23 patients with tooth wear was more than 3 times higher than its prevalence in a previous
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25 study where 2148 patients with a mean age about 50 years have been analyzed ²². A
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27 statistically significant correlation between the severity of tooth wear and the severity of
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29 OSAS has been also found ²¹. Worth mentioning, obstructive sleep apnea has a higher
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31 frequency in aged patients ²². The patients enrolled in this study has a mean age of 61 ±
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33 10 years.
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43 In our study prosthetic complications have been more frequent in a cement-retained
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45 prostheses. In a recent systematic review, no significant differences has been found
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47 between cement- and screw-retained prostheses (single crown, partial denture or complete
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49 denture) for survival or failure rates ²³. The observation of our study could be related to
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51 that fact that 68% of the analyzed reconstructions have been cement-retained.
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56 Porcelain fracture has been the most frequent prosthetic complication in this study.
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58 Pjetursson et al indicated, in a systematic review, that fracture of the veneer material is
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1 the most frequently reported technical complication²⁴. All the porcelain fracture observed
2 in this study has been related to a partial denture. This could be related to the previously
3 reported data where the risk of the fracture of the veneering material is increased by the
4 size of the prosthetic reconstruction²⁴. Herein, the number of prosthetic units has been
5 higher in those patients with a prosthetic complication.
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12 Dental implant fracture is rare but constitutes the most serious complications to face²⁴,
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25. In our study, the rate of implant fracture was 6.2% during a follow-up time of 117 ±
90 months (range: 10 to 279 months). In one study, 4636 implants were followed-up for
15 years and the total fracture rate has been below 5%²⁶. Most of the implant and screw
fractures has occurred in the premolar and molar regions, where mastication and lateral
mandibular movements in association with cusp inclination generate undesirable forces²⁷.
Biomechanical overloading of the prosthetic reconstruction has been identified as the
most common cause of implant fracture.²⁵ Rangert et al have identified implant fracture
to coexist with bruxism and excessive occlusal loads in 56% of the study group.²⁷

This study suffers from the limitation of retrospective design where the dependency on
the availability and accuracy of medical/dental records could not be excluded. It is
difficult to control bias and confounders although the prosthodontist was not aware of the
results of the sleep study. Moreover, a selection bias could not be ruled out as patients
were selected from those who had a sleep study performed. This means that there was a
need for a sleep study from the point of view of a specialist in sleep medicine. However,
the outcomes justify the performance of a research to evaluate the association between
prosthetic complications and OSA and to identify confounders that may influence this
association.

60 **Conclusions**

1 The null hypothesis of no association between the frequency of prosthetic complications
2 and obstructive sleep apnea could not be accepted. There is a need to explore, in future
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4 research, the risk/frequency of prosthetic complications of an implant-retained
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6 constructions in patients with obstructive sleep apnea.
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10 **Abbreviations**

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12 AHI: apnea-hypopnea index

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15 OSA: obstructive sleep apnea
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Table 1. Description of the prostheses inserted in patients with/without prosthetic complications.

		Prosthetic complications		P value
		No	Yes	
Number of implants		2 (range: 1 to 10)	3 (range: 1 to 6)	0.188 ^a
Number of units		2 (range: 1 to 13)	4 (range: 1 to 8)	0.009 ^a
Type of fixation	screwed	17	7	0.878 ^b
	cemented	35	15	
Type of prosthesis	Crown	24	3	0.001 ^c
	Complete prosthesis	1	1	
	Partial prosthesis	27	18	

a: Mann-Whitney test

b: Chi-square test

c: Fisher's exact test

Table 2. Frequency of prosthetic complications according to the type of the prosthesis.

Prosthetic complication	Prosthesis type			Fixation type	
	Crown	Complete prosthesis	Partial prosthesis	screwed	cemented
No complication	24	1	27	17	35
Screw loosening	1	0	2	2	1
Implant fracture	1	0	1	0	2
Porcelain fracture	0	0	10	3	7
Screw fracture	0	1	2	2	1
decementation	1	0	3	0	4
Total	3	1	18	7	15

Table 3. Number of patients having prosthetic complication according to the presence or absence of obstructive sleep apnea (OSA).

	OSA		Total	
	No	Yes		
Prosthetic complication	No	15	36	51
	Yes	3	13	16
Total		18	49	67

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Table 4. The mean apnea-hypopnea index (AHI) according to the type of the
prosthetic complication.

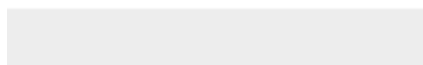
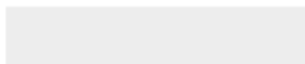
Type of event	AHI	Range
Screw loosening	5.7	5.6 - 7.5
Implant fracture	21.0	14.2 - 28.5
Porcelain fracture	17.3	5.3 - 47
Screw fracture	24.5	4 - 55
Decementation	10.4	0.9 - 25

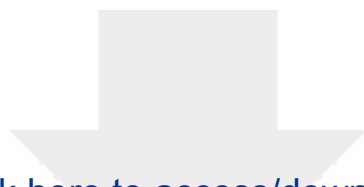


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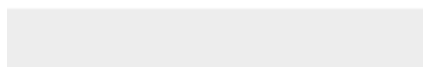
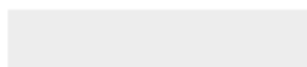


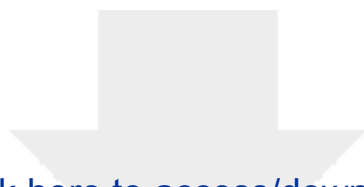


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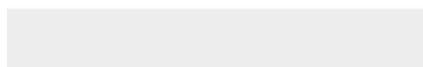
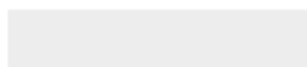




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