Implant and Prosthodontic Related Clinical Outcomes

Chapter 5

Five years results of fixed implant-supported rehabilitations with distal cantilevers for the edentulous mandible

GALLUCCI G. O.
DOUGTIE C.B.
HWANG J.W.
FIORELLINI J.P.
WEBER H.P.

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German O. Gallucci
Camden B. Doughtie
Jae Woong Hwang
Joseph P. Fiorellini
Hans-Peter Weber

Authors’ affiliations:
German O. Gallucci, Jae Woong Hwang, Hans-Peter Weber, Department of Restorative Dentistry and Biomaterials Science, Harvard School of Dental Medicine, Harvard University, Cambridge, MA, USA
Camden B. Doughtie, DMD Candidate, Harvard School of Dental Medicine, Harvard University, Cambridge, MA, USA
Joseph P. Fiorellini, Department of Periodontics, School of Dental Medicine, University of Pennsylvania, Philadelphia, PA, USA

Correspondence to:
German O. Gallucci
Department of Restorative Dentistry and Biomaterials Sciences
Harvard School of Dental Medicine
Harvard University
188, Longwood Avenue
02115 Boston, MA, USA.
Tel.: +16174325764
Fax: +16174320901
e-mail: german_gallucci@hsdm.harvard.edu

Key words: dental implants, edentulous jaws, hybrid prostheses, success criteria

Abstract

Objectives: The purpose of this study was to evaluate the survival rate, success rate and primary complications associated with mandibular fixed implant-supported rehabilitations with distal cantilevers over 5 years of function.

Material and methods: In this prospective multi-center trial, 45 fully edentulous patients were treated with implant-supported mandibular hybrid prostheses with distal extension cantilevers. Data were collected at numerous time points, including but not limited to: implant placement, abutment placement, final prosthesis delivery, 3 months and 5 years post-loading. Biological, implant and prosthetic parameters defining survival and success were evaluated for each implant including: sulcus bleeding index (SBI) at four sites per implant, width of facial and lingual keratinized gingiva (mm), peri-implant mucosal level (mid-facial from the top of the implant collar, measured in mm), modified plaque index (MPI) at four sites per implant, mobility and peri-implant radiolucency. Survival was defined as implants or prostheses that did not need to be replaced. Success rate was defined as meeting well-established criteria that were chosen to indicate healthy peri-implant mucosa osseointegration, prostheses success and complications.

Results: A total of 237 implants in 45 completely edentulous patients were included in the study. In each patient, four to six implants were placed to support hybrid prostheses with distal cantilevers. Cantilevers ranged in length from 6 to 21 mm, with an average length of 15.6 mm. The ages of the patients ranged from 34 to 78 with a mean age of 59.5 years. The survival rate of implants was 100% (237/237) and for prostheses 95.5% (43/45). The overall treatment success rate was calculated as 86.7% (39/45). Of the six patients that have not met the criteria for success, two patients required replacement of the entire prosthesis and four patients presented >four complications events.

Conclusion: Fixed implant-supported rehabilitation with distal cantilever resulted in a reliable treatment modality over the 5-year observation period. Although biological parameters of MPI, SBI, keratinized tissue and peri-implant mucosal levels showed statistically significant differences over time, the mean values for each patient remained within the normal limits of oral health. Complications were categorized as biological or technical. The majority of complications were technical complications (54/79) and of these most involved fracture of the acrylic teeth and base (20/54). While the survival rate was 100% for implants and 95.5% for prostheses, the application of strict criteria for treatment success resulted in an overall treatment success rate of 86.7%.

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Implant supported prostheses have led to drastic improvements in edentulous patients’ standard of living and quality of life compared with treatment with conventional dentures (Allen & McMillan 2003; Heydecke et al. 2003). Implant supported cantilever prostheses, also known as hybrids, have been largely described in the dental literature (Jent & Lindén 1992; Jent et al. 1996; Lindquist et al. 1996; Yoshida et al. 1996). The term hybrid describes a combination of prosthetic designs defined as ‘the rigid anchorage of a removable denture using splinting implants’ (Besimo et al. 1991) and different materials such as ceramic–metal or resin–metal implant-supported prostheses (LoCascio & Salinas 1997). Increased stability, retention and the cost-effectiveness of placing fewer implants represent the main advantages of cantilevered prostheses.

The survival rates for hybrid prostheses were proposed as ranging from 88.5% to 100% in a 5–15-year follow-up (Zarb & Schmitt 1990; Friberg et al. 1991; Henry et al. 1995; Ortorp et al. 1999). The success rate for hybrid mandibular implant rehabilitations has been mainly calculated in terms of fixture parameters (Albrektsson & Zarb 1993; Ortorp et al. 1999; Fischer & Stenberg 2006), however, limited information is available regarding the effect of implant and peri-implant soft tissue health, prosthodontic and patient satisfaction parameters on the calculation of an overall treatment success rate. Although hybrid prosthesis have been used in the treatment of edentulism for more than two decades, much concern still exists regarding the number of complications associated with this type of rehabilitation (Friberg et al. 1991; Jent & Lindén 1992; Jent et al. 1996; Ortorp et al. 1999; Engfors et al. 2004).

The purpose of this investigation was to evaluate cantilever hybrid prostheses as a treatment option in mandibular edentulism over a 5-year observation period. The specific aim was to clearly define the survival and success rates based on well-established parameters including implant health, peri-implant soft-tissue health, prosthodontic qualities and complications and patient satisfaction.

Materials and methods

Data used for this study were collected as part of a multicenter trial to assess the safety and efficacy of the ITI dental implant system from the following five centers: University of Connecticut, UCONN Health Center – USA, University of Texas – Health Science Center, USA, Baylor, USA, Harvard School of Dental Medicine, USA and Birmingham, UK.

Inclusion criteria

From this multicenter study, related data to edentulous patient either in the maxilla or mandible that completed the 5-year follow-up were selected. At allocation, all patients demonstrated adequate oral hygiene, and had an absence of any local inflammation. Adequate bone height was present for the placement of dental implants. In addition, neither residual roots nor mucosal diseases were present. For the purpose of this study, data related to patients receiving hybrid prostheses and completing the full-length of the study was assessed.

Exclusion criteria

Patients were excluded if they met any of the following criteria: moderate to heavy smoking (more than 10 cigarettes/day) or chewing tobacco, alcoholism or drug use, severe bruxism or clenching habits, untreated periodontitis, high risk for subacute bacterial endocarditis, poor general health, pregnant at the time of evaluation, patients at risk with surgical procedures, history of radiation to head and neck, previous graft at intended surgical sites, lack of motivation or compliance, physical handicaps that would interfere with good oral hygiene and use of an investigational drug within 30 days before intended implant placement.

Patients were explained all potential adverse effects and complications of treatment and were invited to sign informed consent forms. The study was approved by the Institutional Review Board of the Harvard Medical School. Treatment planning for all patients included mandibular fixed implant-supported rehabilitations with distal cantilevers.

Pre-surgical assessment and treatment planning

Alginite impressions and radiographs were taken for diagnostic purposes and treatment planning. Soft issue was examined for pathology with particular care at sites of intended implant placement. Oral hygiene instructions were reviewed. Pre-surgical documentation of opposing dentition, adequate inter-occlusal space and bone quality was recorded. Occlusion was recorded as normal or abnormal.

Abnormal occlusion was recorded when a patient’s inter-arch relationship in the pre-excising dentures presented an overjet of more than 4 mm, an open bite, a deep bite, edge-to-edge occlusion or a crossbite (Gesch et al. 2006).

Implant placement

Patients received prophylactic antibiotic regime before surgery (amoxicillin 500 mg) and rinsed with 0.12% chlorhexidine gluconate for 1 min for local disinfection. The peri-oral skin was washed with a skin disinfectant. Rough surface one-part implants were placed under local anesthesia and aseptic conditions with a contra-angle hand piece with drilling speeds limited to a maximum of 800 rpm and provisions of cooling with sterile saline. Healing caps were placed and flaps sutured leaving the implants (Straumann AG, Basel, Switzerland) in a transmucosal position. All implants were placed in an upright position and no insertion torque measurement was carried out at this time. After implant placement, old dentures were relieved completely from direct implant contact and adjusted with soft reliner (GC America Inc., Leuven, Belgium). All patients were instructed on post-operative home care. Data recorded at this time included: implant catalog and lot number, bone quality, achievement of primary stability and complications or difficulties encountered. Necessary follow-up appointments were scheduled.

Prosthodontic treatment

Three to 5 months after implant placement, patients returned for abutment and temporary prosthesis placement. If necessary, a minor gingivectomy was performed. Four to 6 months after implant placement, patients received final prostheses consisting of a metal framework with acrylic [n = 41] or ceramic [n = 4] veneering. All of the prostheses were screw-retained. The lengths of the left and right distal cantilevers were recorded from the distal aspect of the most distal abutment to the most distal part of the prosthesis.
Follow-up and parameters defining success

Patients were recalled yearly and, if needed oral prophylaxis was performed. For the purpose of this investigation, related data were collected at the following time points: at baseline at final prosthetic delivery, 3 months and 5 years post-loading. Objective data recorded included parameters such as modified plaque index (MPI), sulcus bleeding index (SBI), keratinized mucosa levels, peri-implant mucosal levels and presence or absence of implant mobility. Complications were recorded at any time during the 5-year duration of the study and were categorized as biological/technical and new/recurrent. Data were recorded for each complication regarding the severity (mild, moderate or severe) and the outcome (resolved or ongoing). Subjective parameters were recorded through patient questionnaires in which they rated satisfaction with appearance, ability to chew, ability to taste and general satisfaction as excellent, good, fair or poor.

The implant and prosthodontic survival rate was calculated based on the number of individual failures by means of an implant removal or prosthesis replacement.

The criteria for defining treatment success were accounted per individual patient and defined by the presence of all of the following parameters:

1. Implants were stable and without signs of ongoing infection, discomfort or radiolucency (Buser et al. 1997, 2002).
2. Implants and surrounding tissues presented temporary discomfort, infection or radiolucency that became completely asymptomatic.
3. Patients had a mean MPI and SBI value of 1 or less throughout each time point.
4. Maintenance of at least 1.5 mm of keratinized mucosa (buccal and lingual).
5. Recession of <0.5 mm for the peri-implant soft tissue.
6. Patients with four or less complications of mild or moderate severity that were terminated.
7. Patients who rated their overall treatment satisfaction as good or excellent.

Data analysis

Descriptive statistics summarize objective and subjective values. Statistical analysis was conducted using t-test and $\chi^2$ to evaluate changes in the biological parameters at final prosthetic delivery, 3 months and 5 years post-loading. Statistical significance was set at a P-value $<0.05$.

Results

A total of 45 patients were enrolled in the clinical study, which was composed of 26 females [average age 60.2 years] and 19 males [average age 58.8 years]. At the pre-surgical evaluation 42 participants presented with normal occlusion. One patient had limited inter-occlusal space, and all opposing dentitions were maxillary complete dentures (Table 1).

At the time of surgery all 237 implants were placed using a non-submerged technique and were left undisturbed for at least a 3-month healing period. The number of implants per patient, implant type and length and the bone quality are presented in Table 2.

After the healing period, each patient received screw-retained hybrid-type prosthesis with distal cantilevers. The mean length of the right extension was of 15.7 mm (ranging from 6 to 21 mm) and 15.6 mm (ranging from 7 to 21 mm) for the left cantilever. Most of the patients [$n = 41/45$] received an acrylic base and prosthetic teeth mounted onto a metallic framework. The four remaining patients received metal/ceramic restorations [Table 3].

MPI, SBI, width of the keratinized gingiva and peri-implant mucosa levels were recorded at the delivery of the hybrid prosthesis, 3-month follow-up and 5-year follow-up. Mean values at each time point and statistically significant differences in mean values over time are presented in Tables 4 and 5. Although some of the periodontal parameters show statistically significant differences over time, the mean values of all subjects individually and as a whole remained within the normal limits of oral health and were in accordance with the definition for treatment success. [Tables 4 and 5].

All complications that occurred within the 5-year duration of the study were recorded and analyzed. Table 6 lists the number of complications in each category that occurred and is divided into biological and technical complications. Biological

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### Table 1. Pre-surgical Assessment

<table>
<thead>
<tr>
<th>Gender</th>
<th>Occlusion</th>
<th>Inter-occlusal space</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>Male</td>
<td>Normal</td>
</tr>
<tr>
<td>26</td>
<td>19</td>
<td>42</td>
</tr>
<tr>
<td>45</td>
<td>45</td>
<td></td>
</tr>
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</table>

### Table 2. Implant related data

<table>
<thead>
<tr>
<th>Number of implants placed per patient</th>
<th>Type of implant</th>
<th>Implant length</th>
<th>Bone quality (type)</th>
<th>Implant Survival Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Four</td>
<td>Five</td>
<td>Six</td>
<td>Hollow</td>
<td>Solid</td>
</tr>
<tr>
<td>6</td>
<td>26</td>
<td>13</td>
<td>7</td>
<td></td>
</tr>
<tr>
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<td>237</td>
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<td>237</td>
<td>237</td>
<td>237</td>
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</tbody>
</table>

### Table 3. Prosthodontic descriptive data

<table>
<thead>
<tr>
<th>Occlusal material</th>
<th>Retention method</th>
<th>Mean length of cantilevers</th>
<th>Prosthesis survival rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Porcelain</td>
<td>Acrylic</td>
<td>Cement</td>
<td>Screw</td>
</tr>
<tr>
<td>4</td>
<td>41</td>
<td>0</td>
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</tbody>
</table>
Table 4. Periodontal Measurements, Sulcus Bleeding Index & Modified Plaque Index

| Biological | Systemic | Change in medical condition | 1 |
| Local | Reversible numbness of mental nerve | 4 |
| TMJ pain | 1 |
| Inflammation around an implant | 3 |
| Inflammation under prosthesis | 2 |
| Bone loss around an implant | 3 |
| Ulcer(s) | 1 |
| Hypertrophy or hyperplasia of tissue | 3 |
| Cheek biting | 1 |
| Swelling of soft tissue | 1 |
| Soft tissue healing | 1 |
| Hard tissue healing | 2 |
| Implant components | 2 |

N = 25

Table 5. Periodontal Measurements, Width of Keratinized Mucosa & Peri-Implant Mucosal (PIM) Level

| Table 6. Complications and Treatment Related Adverse Events |
| Biological | Systemic | Change in medical condition | 1 |
| Local | Reversible numbness of mental nerve | 4 |
| TMJ pain | 1 |
| Inflammation around an implant | 3 |
| Inflammation under prosthesis | 2 |
| Bone loss around an implant | 3 |
| Ulcer(s) | 1 |
| Hypertrophy or hyperplasia of tissue | 3 |
| Cheek biting | 1 |
| Swelling of soft tissue | 1 |
| Soft tissue healing | 1 |
| Hard tissue healing | 2 |
| Implant components | 2 |

N = 25

Table 7. Distribution of Complications among Patients

| Biological | Systemic | Local | Surgical | Technical | Implant | Prosthesis |
| Distribution of complication(s) |

The treatment success rate was calculated by evaluating each individual patient against a set of well-defined criteria. Patients were considered successful only if all of the stipulations were met. Thirty-nine patients (86.7%) were determined to have had successful treatment at the completion of the 5-year study. Six patients (13.3%) did not attain the minimum parameters in order to be considered successful. Of the six, one patient had a severe complication resulting in the replacement of the entire hybrid prosthesis. The remaining five patients experienced >4 complications.

complications accounted for 31.6% (n = 25/79) of the total number of complications. Within the biological, one event was categorized as systemic, 19 events were recorded as localized and five events were related to surgery. Technical complications (68.4% or n = 54/79) were more frequently encountered during the 5-year follow-up. Implant related technical complications were observed on eight occasions vs. 46 for prosthodontic related adverse events (Tables 6 and 7). No implants were lost during the 5-year observation period, resulting in a 100% implant survival rate (Table 2). The survival rate for prostheses was 95.5% (n = 43/45) as shown in Table 3. Two hybrid prostheses had to be replaced due to fracture of the framework. Of the two, one failed at 5 months after delivery due to technical problems with the framework fabrication and the other was replaced at 3.3 years after delivery.
each. Specifically, two patients had six complications (12 total: three biological, nine technical), two patients had seven complications (14 total: five biological, nine technical) and one patient had eight prosthetic complications (8 total: eight technical) that resulted in replacement of the hybrid prosthesis. No statistical correlation could be established relating the number of implants, peri-implant soft tissue health or prosthetic design to the number of complications experienced. For the subjective evaluations all patients rated ability to chew, ability to taste, appearance and general satisfaction as good or excellent.

Discussion

In this prospective multi-center trial, 45 patients were treated with distal extension implant-supported fixed restorations. Patients were evaluated over 5 years of function on biological parameters, complications, subjective patient satisfaction and criteria defining success and survival rates.

Well-defined inclusion and exclusion criteria selected for the study design aimed to ensure sample homogeneity. Furthermore, all included patients had a complete denture as the opposing dentition. While female patients were slightly more numerous than male patients, the average age was similar for both groups.

The health of the peri-implant soft tissue was monitored by recording the MPI and SBI (Mombelli & Lang 1994) at four sites around each individual implant. Also, the width of the keratinized mucosa was assessed as an indicator of peri-implant mucosal health. The mean values for MPI and SBI at each evaluation are presented in Table 4. Statistically significant differences were mainly observed between baseline/3-month follow-up and 5-year follow-up. The overall trend of increased mean MPI and SBI over time could be attributed to the delivery of the hybrid prostheses that likely made oral hygiene more challenging. A similar phenomenon was described by Engfors et al. (2004) when they compared mandibular implant supported prostheses in young and elder populations and found implant maintenance problems mainly in the elder group. It is likely that a combination of factors led to increased inflammation, including decreased manual dexterity with age and the presence of a prosthesis in contrast to patients’ previous state of edentulism. Despite the statistically significant differences in MPI and SBI, each individual’s mean values were <1 throughout the entire study. This can be attributed to patients’ periodic recall appointments. The width of buccal keratinized mucosa showed a statistically significant decrease from baseline to 3-month follow-up but increased by 5-year follow-up. This implies that there was peri-implant soft tissue long-term stability. On the lingual surface, the overall mean width of keratinized mucosa decreased more from baseline to 3 months (2.2–1.6 mm) when compared with changes that occurred on the buccal. Yet, similarly to the buccal tissue, the lingual tissue increased and stabilized by the 5-year follow-up (1.7 mm). Overall, the mean values remained above the 1.5 mm required for treatment to be considered successful. In addition, PIM levels showed no statistically significant changes, indicating stability of the peri-implant mucosal attachment level (Table 5).

In this study, four to six implants were placed in the anterior mandible to support cantilever hybrid prostheses. The average cantilever length was similar for right (15.7 mm) and left sides (15.6 mm) and was designed to reach at least first molar occlusion. The treatment rendered can be explained by the anatomical limitation of the mental foramina, corresponding to the first or second mandibular bicuspid region, which confined the placement of implants to the mandibular anterior. Screw-retained prostheses were fabricated for all patients who received a metal framework veneered with acrylic base and stock prosthetic teeth with the exception of four patients that received ceramic–metal rehabilitations. Complications were recorded by type and reviewed descriptively. Similar number and type of complications related to prosthetic materials have been reported in the literature (Jemt & Linden 1992; Jemt et al. 1996; Ortorp et al. 1999; Engfors et al. 2004; Fischer & Stenberg 2006).

Biological complications included reversible numbness of mental nerve (four events), peri-implant inflammation (three events) and peri-implant mucosal hyperplasia (three events) (Table 6). These complications were all terminated by natural healing or professional intervention. Mild bone loss was recorded around three implants, one in one patient and two in another. Other mild complications related to the surgical intervention included complications with secondary healing of soft tissue (one event), sequestered bone particle (two events) and the implant insertion device breaking at the time of implant placement (two events). Each of them occurred as a single event in individual patients and was professionally resolved.

Technical complications were divided into those related to the implant vs. the prosthesis. Among the implant related complications, screw loosening/fracture was observed in seven events and all were resolved by either retightening or screw replacement (Table 6). Of the prostheses related technical complications, fracture of the acrylic base or acrylic teeth accounted for 20 events and hence was the overall most frequent adverse event. Similar findings were reported in several other publications (Jemt & Linden 1992; Jemt et al. 1996; Lindquist et al. 1996; Ortorp et al. 1999; Engfors et al. 2004). The explanation for such a high frequency of this type of complication was stated as the deformation module of the framework when distal cantilevers are present (Jemt 1995). One interesting finding in our study was that 12 events were recorded for fractures of the opposing complete denture. Therefore, it seems important to check the status of the opposing denture when working with fixed implant rehabilitation in the opposing arch. Suggestions to minimize these frequent complications include fabricating new prostheses for both arches at the same time and using a reinforcement to increase resistance to fracture of the removable denture. Fractures of the metal framework resulted in two prosthodontic failures and were attributed to imperfections at the time casting/soldering. This problem has also been encountered by previous scientific reports suggesting the advantage of using laser-welded or milled titanium frameworks (Jemt et al. 2003; Ortorp & Jemt 2008).

No clear trends were found between number/type of complications and location along the prostheses. The 20 events of acrylic tooth fracture (n=20/79) occurred within nine patients. Six patients...
experienced one single event of this type. In terms of location of fracture along the prosthesis, three were not specified, one was in the middle of the prosthesis and one was located in the left distal cantilever. One patient had two events classified as acrylic fractures. Both occurred near teeth #23 and 24. One patient experienced five acrylic fractures, with each fracture located in a different area of the mandibular prosthesis. Lastly, one patient had seven acrylic fractures, all of which involved tooth #24 in the center of the prosthesis. Of note is that none of the patients that experienced acrylic fractures were classified in the pre-surgical assessment as having abnormal occlusion.

Distal cantilevers ranged in length from 6 mm to 21 mm, with an average length of 15 mm. Twenty out of the 45 patients enrolled in the study had cantilevers of lengths ≥ 18 mm. Of these 20 patients, two were considered to have unsuccessful treatment based on our criteria for success. Both required replacement of the prosthesis. On the other hand, seven of the 20 patients with ‘long’ cantilevers did not experience any complications and four had complications that were classified only as biological and were resolved. Therefore, no clear trends were found between increased length of the distal cantilevers and number or type of complications experienced. In future studies, increasing the sample size of patients with cantilevers > 17 mm may help to reveal clearer trends and correlations.

No correlations were found between patients classified as having abnormal occlusion and number/type of complications. Of the three patients with abnormal occlusion at pre-surgical assessment, one had no complications, one had one complication and one had six complications. In the patient with six events, four involved fracture and/or discomfort with the upper denture.

The need for replacement of implants/prosthesis was used to calculate individual implant and prosthetic survival rates. In accordance with other publications the survival rate for implants was 100% [237/237] and 95.5% [43/45] for the prostheses over a 5-year observation period. Evaluation of success was examined per patient and was based on parameters of implant and peri-implant soft tissue health, frequency of complications, survival of implants and prostheses and lastly subjective data. Several criteria for success have been previously described [Albrektsson & Zarb 1993; Buser et al. 1997, 2002; Roos et al. 1997; Ortrop et al. 1999; Fischer & Stenberg 2006]. However, previous definitions of success mainly involved implant related parameters with scarce criteria regarding prostodontic, MPI, SBI, width of keratinized mucosa, complication frequency per patient and subjective parameters. Using well-defined criteria for treatment success, 39 patients were considered to have had a successful treatment. These patients presented with implants that were stable and without signs of ongoing infection, discomfort or radiolucency, mean MPI and SBI values of 1 or lower maintained throughout the length of the study, maintenance of at least 1.5 mm of keratinized mucosa, peri-implant recession of <0.5 mm, four or fewer biological/technical complications of mild or moderate severity that were terminated and, lastly patient rating of overall treatment satisfaction as good or excellent. For the remaining six patients considered to have an unsuccessful treatment outcome, one patient had a prosthesis replacement due to a fracture of framework and the other five patients suffered more than four complications. These findings raise the question of whether the long-term behavior of the hybrid prosthetic design is compatible with a successful treatment. In this particular study technical complications related to the prosthetic design were observed to exclusively be the determinant of long-term treatment outcome.

Conclusions

- Hybrid-type implant supported fixed rehabilitations for the treatment of mandibular edentulism, over an observation period of 5 years, presented an 86.7% success rate according to well-defined criteria.
- The implant survival rate was 100% and the prosthetic survival rate was 95.5%.
- MPI, SBI, width of keratinized mucosa and peri-implant mucosal levels remained compatible with success criteria and oral health throughout the observation period.
- Technical complications occurred with a higher frequency than biological complications.
- Within the technical complications, prostodontic complications had a markedly higher incidence than implant related complications.

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