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Implant-supported mandibular removable partial dentures; patient-based outcome measures in relation to implant position

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Keywords: Randomized controlled crossover clinical trial Removable partial denture Patient outcomes Quality of life ABSTRACT

Objectives: To assess the benefits of implant support to Removable Partial Dentures (RPD) in patients with a bilateral free-ending situation in the mandible and to determine the most favorable implant position: the premolar (PM) or the molar (M) region.

Methods: Thirty subjects with a bilateral unbounded posterior saddle received 2 PM and 2 M implants. A new RPD was placed. Implant support was provided 3 months later. Two PM implants supported the RPD. After 3 months the 2 M implants were used or vice versa. Outcome measures included oral health related quality of life (OHIP-NL49), general health status (SF-36), contentment assessed on a Visual Analogue Scale (VAS) and the number of hours that the RPD was worn. Data were collected prior to treatment, 3 months after having functioned with a new RPD and after 3 and 6 months with implant support. Finally, patients expressed their preferred implant position.

Results: The general health status (SF-36) was not influenced. OHIP-NL49 values and mean wearing-time were statistical significantly more favorable for ISRPD's, regardless of the implant position. Per day, the ISRPD's were worn 2–3 h more than the unsupported new RPD. Patients' expectations were met as the VAS-scores of anticipated and realized contentment did not reach a statistical significant level (p > 0.05). VAS scores for ISRPD's with M implant support were higher than for PM implant support. Finally, 56.7% of subjects preferred the M implant support, 13.3% expressed no preference and 30% opted for PM implant support.

Conclusions: Mandibular implant support favorably influences oral health related patient-based outcome measures in patients with a bilateral free-ending situation. The majority of patients prefer the implant support to be in the molar region.

Clinical significance: Patients with a bilateral free-ending situation in the mandible opposed by a maxillary denture benefit from implant support to their mandibular removable partial denture. Most patients prefer this support to be in the molar region.

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1. Introduction

According to the concept of the shortened dental arch, patients with reduced numbers of posterior teeth generally have ample

http://dx.doi.org/10.1016/j.jdent.2016.10.008 0300-5712/© 2016 Elsevier Ltd. All rights reserved. adaptive capacity to function adequately as long as 3–5 occlusal units remain, even though their masticatory performance is impaired [1,2]. Nevertheless, recent prospective studies suggest an improvement in patients' Oral Health Related Quality of Life (OHRQoL) after replacing posterior teeth with a fixed implantsupported restoration [3,4] or with a Removable Partial Denture (RPD). RPD problems are frequently recurrent and the positive effect on OHRQoL is more pronounced in case of an arch that is interrupted in the anterior [5–8]. The former findings are particularly interesting, since they relate to a common condition in clinical practice: the mandibular Kennedy class I or II situation







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opposed by a full maxillary denture. Under these conditions, conventional RPD's may be troublesome and unpredictable as patients frequently complain from a lack of stability and retention, discontinue wearing them or insist on replacement by a new one [9–11], particularly so in cases with unbounded posterior saddles [12,13]. Occlusal forces move the saddles into a tissue-ward direction because distal support is lacking, compromising the anterior abutment teeth as well through potentially destructive rotational forces. Long term use of an RPD is associated with poor adaptation of retainers, occlusal disharmony, pain, periodontal problems and ongoing resorption [14–16].

Several studies in a systematic review showed that providing a removable partial denture with implant support improves patient satisfaction in case of bilateral distal-extension partial edentulism, although they stress the need for long-term randomized controlled trials [17]. Providing implant support may help improve stability, retention and chewing ability, patient comfort in general, and even nutrient intake [15,16,18-22]. A Kennedy class I or II situation is basically transformed into a class III situation, with a more favorable transmission of forces from the mucosa toward the implant(s) and tooth abutment(s). The use of unaesthetic clasps can often be avoided with implant support [17]. However, the evidence for implant supported RPD's (ISRPD's) is obtained from a rather heterogeneous group of studies. Populations studied often include patients with a variety of intraoral conditions and prostheses with different retention concepts. Furthermore, evidence is often based on case reports or studies of a retrospective nature with few subjects or finite element methods. Consequently, better controlled and randomized clinical trials to validate the outcomes of ISRPD's are needed [17.23]. The position for the implant that offers the optimal support is also not elucidated in the literature.

The aim of this study was to assess the perceived benefits of implant supported Removable Partial Dentures (ISRPD) in patients with a bilateral free-ending situation in the mandible who perceive functional problems with their RPD, yet would like to continue wearing one and to determine the most favorable implant position: the premolar (PM) region or molar (M) region.

2. Materials and methods

2.1. Study set-up and patient population

The study was set up as a within-subject comparison randomized clinical trial for which permission from the medical ethical committee of the University Medical Center of Groningen was granted (METc 2011.194). Thirty subjects with a full upper denture and complaints regarding their bilateral free-ending mandibular RPD were included. They all had conventional RPD's made in the past and either still wore them or had discontinued wearing them. The following inclusion criteria applied:

- \geq 18 years of age;
- the saddle area reaches until the first mandibular premolar or cuspid, both left and right;
- the bone volume distal from the most posterior abutment teeth is sufficient to place the implants. In the premolar region, implants with a length of 8 mm and a diameter of 3.3 mm and in the molar region with a length of 6 mm and diameter of 4.1 mm were inserted. A cone beam CT (CBCT) was used to measure the bone volume [24];
- the patient is capable of understanding and giving informed consent.

Potential subjects with medical and general contraindications for the surgical procedures, with a history of local radiotherapy to the head and neck region, who experienced implant loss in the past, who are incapable of performing basal oral hygiene measures, with decreased masticatory function due to physical disability or with active, uncontrolled periodontal pathology of the remaining dentition were excluded from participation.

2.2. Surgical and prosthetic procedures

All subjects gave informed consent and received 2 implants on either side of the mandible (Straumann RN, Straumann, Switzerland) that were provided with cover screws and submerged. Two implants were placed in the premolar region (PM implant support) and two were placed in the molar region (M implant support). A surgical guide was used to achieve the right position and inclination. After 3 months, all implants were exposed in a second-stage surgery and low healing abutments were inserted.

A new RPD was made according to standard prosthetic procedures. The design involved a lingual plate and a clasp on either side. The housing of the Locator[®] abutment (Zest Anchors, Inc., Escondido, California, USA) was already incorporated in the RPD, but not the Teflon matrix so it provided neither retention nor support to the RPD. Three months later and following a randomization scheme, either the PM or M implants were provided with a Locator[®] abutment. The remaining implants were left unloaded for future investigation. After 3 months, the other pair of implants was loaded. Fig. 1 shows an example of a typical clinical case. A clear timeline is displayed in Fig. 2.

2.3. Patient-based outcome measures

Five patient-based outcome measures were assessed: oral health related quality of life, patient reported general health status, general contentment, daily wearing-time of the RPD and patients' preference for the PM or M implant position. The clinician who collected the data (CJ) was involved during the inclusion of the subjects and the organisation of the trial, but provided neither surgical, nor prosthodontic care.

Oral Health Related Quality of Life (OHRQoL) was considered the primary outcome measure and assessed using the Dutch translated and validated version of the Oral Health Impact Profile questionnaire (OHIP-NL49) [25–27]. It consists of 49 questions arranged in seven conceptually formulated domains: functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability and handicap. For each item, subjects were asked how frequently they had experienced the impact of that item in the last month. Responses are given on a Likert-scale (0-never, 1-hardly ever, 2-occasionally, 3-fairly often, 4-very often). OHIP-NL49 sum scores per domain and an overall score characterize the OHRQoL impairment in which higher scores indicate greater OHRQoL impairment.

Patient-reported perceived general health status was determined using the Dutch translated and validated version of the Short Form Health Survey (SF-36). It measures to what degree patients feel disabled during their daily activities [28]. It is comprised of 36 questions divided into 8 scaled scores which are transformed into a range from 0 to 100: vitality, physical functioning, bodily pain, general health perceptions, physical role functioning, emotional role functioning, social role functioning and mental health. One additional question addresses changes in health condition. The lower the score, the more disability.

In addition, patients were asked to express their general contentment with their oral function during the different stages of treatment on a Visual Analogue Scale (VAS) ranging from 0 (very discontent, major concerns) to 100 (very content, no concerns at all). At the start of treatment they were also asked to express their

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