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Implant supported dental rehabilitation following segmental mandibular reconstruction- quality of life outcomes of a prospective randomized trial

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ABSTRACT

Purpose: The primary objective of this study was to assess the difference in quality of life (QoL) in patients with dental rehabilitation using two or four implant-supported overdentures following segmental mandibulectomy defect reconstruction with fibula free flap.

Material and methods: This prospective, parallel designed, randomized clinical study was conducted with a 1:1 ratio. At baseline, all participants already had fibula flap reconstruction for segmental defects of the mandible and rehabilitation with conventional (non-implant supported) removable partial dentures. The participants were then randomized into two groups. Group I received implant supported overdentures on two implants, and Group II received four implants. QoL outcomes were evaluated using standardized questionnaires (EORTC_QLQ c30, H&N35, OHIP, DSI). Outcomes of treatment were evaluated at 6 months (T1) and 1 year (T2) following rehabilitation.

Results: A total of 52 patients were randomized into two treatment groups (26 each). After accounting for the loss to lack of follow-up, 22 patients in Group I and 24 patients in Group II were evaluated for QoL at the end of the study. There was a significant improvement in QoL with implant-assisted dental rehabilitation. However there were no significant differences in QoL between the two-implant and four-implant groups.

Conclusion: Implant-supported removable overdentures improve QoL outcomes in patients with reconstructed mandibles. This study showed no significant difference in QoL outcomes in patients with two- or four-implant supported removable prostheses.

1. Introduction

In patients who undergo segmental resection of the mandible (e.g., for benign or malignant tumors, osteomyelitis, or severe trauma), the fibula free flap is a reconstructive option of choice (Hidalgo and Pusic, 2002). The final goal of treatment of patients with pathologic conditions that require reconstruction of the mandible is optimal functional and esthetic rehabilitation (Holzle et al., 2007; Anne-Gaelle et al., 2011). Despite significant improvements in reconstructive surgery, dental and masticatory rehabilitation results remains suboptimal (Urken et al., 1991; Vaughan et al., 1992). Recent emphasis on quality of life (QoL) has focused attention on improvement of functional outcomes along with esthetic results in patients requiring reconstructive surgery of the jaws (Kreeft et al., 2009; Albornoz et al., 2013; Hutcheson and Lewin, 2013).

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QoL studies have demonstrated that patients consider chewing, swallowing, and speech to be of importance after reconstructive surgery. Patients' perceptions of difficulty in eating, prolonged meal times, messy eating, as well as the need for special preparations of food are associated with depression and decreased social interaction (List et al., 1990; Rogers et al., 1999; Rogers et al., 2002; Shaw et al., 2005). Dental and oral rehabilitation play major roles in the feeling of "well-being" and oral health-related quality of life (OHRQoL) (Smolka et al., 2008; Anne-Gaelle et al., 2011; Dholam et al., 2011; Bodard et al., 2015).

Successful oral rehabilitation of patients with a reconstructed mandible is challenging. Conventional methods of prosthetic rehabilitation rely solely on remaining teeth and tissue for support, retention, and stability (Weischer et al., 1996). This method often produces limited functional benefits (Buchbinder et al., 1991; McGhee et al., 1997; Mericske-Stern et al., 1999; Garrett et al., 2006). Insufficient bone height, decreased vestibular space, and suboptimal condition of the soft tissue overlying the bone graft creates an unfavorable environment for the tissue-borne prosthesis. In addition, irradiated oral mucosa is frequently unable to tolerate the pressure and friction created by the acrylic base of the denture. The xerostomia often encountered after radiation reduces the patient's ability to wear removable dentures (Buchbinder et al., 1991; McGhee et al., 1997; Mericske-Stern et al., 1999). Therefore, for many patients, an implant-supported prosthesis offers more effective rehabilitation, including improvement of function as well as esthetics (Schmelzeisen et al., 1996; Esser and Wagner, 1997; Schliephake et al., 1999; Grötz KA et al., 2000; Shaw et al., 2005).

Although there are numerous reports relating to oral rehabilitation with dental implants after mandibular free flap reconstruction, most of these studies have the drawbacks of being retrospective in nature (Bodard et al., 2015; Hakim et al., 2015; Shaw et al., 2005), having an insufficient sample size (Garrett et al., 2006; Dholam et al., 2011), or being based on varying types of prosthetic rehabilitation (Tang et al., 2008; Raoul et al., 2009). Osseointegrated dental implants have a high level of evidence to support their use in "nonreconstructed patients" (Klein et al., 2009) as well as in an edentulous population in which there are definitive guidelines on the number of implants needed for satisfactory function of implant-supported mandibular overdentures (Wismeijer et al., 1997; Feine et al., 2002; Timmerman et al., 2004). However, there is only limited evidence for the benefit of implant-supported overdentures in patients with reconstructed mandibles (Shaw et al., 2005; Tang et al., 2008).

It has been suggested that implant-supported overdentures in reconstructed jaws can be stabilized with as few as two implants (Raoul et al., 2009; Korfage et al., 2014). However, some studies suggest the need for four implants to achieve maximal implant support for the prosthesis and to relieve the vulnerable underlying soft tissues (Weischer et al., 1996; Schoen et al., 2008). It has also been reported that in a reconstructed mandible it is preferable to place a greater number of implants because if there is a single implant failure, other implants may still be able to adequately support the restoration (Schliephake et al., 1999). Hence, at present, there is a lack of consensus in the literature regarding improvement in QoL with dental implant-supported rehabilitation as well as the minimum number of implants required.

2. Material and methods

2.1. Study objectives

The primary objective of this study was to compare QoL and denture satisfaction outcomes in patients who had two or four implant-supported dental rehabilitation following segmental mandibular reconstruction with free fibula flap.

The secondary objective of this study was to assess the difference in QoL between the baseline value (with conventional, non-implant-supported removable partial dentures) and the final treatment outcome with implant-supported removable partial overdentures in patients who had undergone resection followed by reconstruction of the mandible using free fibula flap.

2.2. Trial design

This prospective, randomized clinical study was conducted with an equal allocation ratio. The participants were randomized into two study groups: one group received implant supported overdentures on two implants (Group I), and the other group received implant supported overdentures on four implants (Group II), which were placed in the previously reconstructed mandible (Fig. 1).

2.3. Setting and study population

The study was conducted in a tertiary care referral hospital (Department of Head and Neck Surgical Oncology, Mazumdar Shaw Cancer Center, Narayana Health City, Bangalore, India) as well as in a teaching hospital (M.R. Ambedkar Dental College & Hospital, Bangalore, India) from May 2012 to November 2014. The study included patients referred from cooperating tertiary care centers and private clinics.[1] All patients who had undergone resection of the mandible followed by reconstruction using free fibula flap were assessed for eligibility for the study. The assessments for eligibility were performed by a single surgeon (V.V.K.) between May 2012 and August 2013.

2.4. Recruitment of patients

Reconstruction patients were informed about the study design as approved by the Registered Institutional Review Board and Ethical Committee of Narayana Hrudayalaya (NH/IRB-CL-2012-021). Written informed consent was obtained from all patients wishing to participate. Primary inclusion and exclusion criteria were reviewed before radiographic examination and are listed in Table 1. As part of standard of care, the patients meeting the inclusion and exclusion criteria underwent panoramic radiography and computed tomography to determine whether the bone height and bony relation of the reconstructed neo-mandible (fibula) met the secondary inclusion criteria (Table 1). If all primary and secondary inclusion criteria were met, the patients were included in the study.

2.5. Interventions and randomization

The selected patients were randomly assigned to one of the two treatment groups by computer-generated block randomization with a block size of four. The code was sealed in an envelope that was sequentially numbered and was opened only upon inclusion of the patient in the study. Participants were assigned to the respective groups based on the concealed allocation sequence (Fig. 1).

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