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Implants in free fibula flap supporting dental rehabilitation – Implant and peri-implant related outcomes of a randomized clinical trial

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ABSTRACT

Objectives: The objective of this study was to assess the difference in success rates of implants when using two or four implant-supported-overdentures following segmental mandibular reconstruction with fibula free flap.
Methods and designs: This prospective, parallel designed, randomized clinical study was conducted with 1:1 ratio. At baseline, all participants already had segmental reconstruction of mandible with free fibula flap. The participants were randomized into two groups: Group-I received implant-supported-overdentures on two tissue-level implants and Group-II received implant-supported-overdentures on four tissue-level implants. Success rates of the implants were evaluated at 3 months, 6 months and 12 months following implant loading using marginal bone level changes as well as peri-implant indices (Buser et al., 1990).
Results: 52 patients were randomized into two treatment groups (26 each), out of which 18 patients (36 implants) of Group-I and 17 patients (68 implants) of Group-II were evaluated. One implant in Group-I was lost due to infective complications and one patient in the same group had superior barrel necrosis. There was a statistically significant increase at both time points ($p = 0.03$, $p = 0.04$ at 6 months, 12 months) in the amount of marginal bone loss in Group-I (0.4 mm, 0.5 mm at 6 months, 12 months) as compared to Group-II (0.1 mm, 0.2 mm at 6 months, 12 months). There were no clinically significant changes peri-implant parameters between both groups. Peri-implant soft tissue hyperplasia was seen in both groups, 32% of implants at 3-months, 26% at 6-months and 3% at 12-months follow-up.
Conclusion: The results of this study show that patients with 2-implant-supported-overdentures had higher marginal bone loss as compared to patients with 4-implant-supported-overdentures. There were no clinically significant differences in peri-implant soft tissue factors in patients with 2- or 4-implant-supported-overdentures. Hyperplastic peri-implant tissues are common in the early implant-loading phase and tend to decrease over time under appropriate management.

1. Introduction

In patients who undergo segmental resection of the mandible, the fibula free flap is the reconstructive option of choice (Hidalgo and Pusic, 2002; Kumar et al., 2009; Bak et al., 2010). Following reconstructive surgery, dental and oral rehabilitation plays a major role in the feeling of "well-being" (Smolka et al., 2008; Anne-Gaelle et al., 2011; Dholam et al., 2011; Koch et al., 2015; Kumar et al., 2016a). Successful oral rehabilitation of patients with a reconstructed mandible is challenging, and often requires the support of implants for an effective solution (Schmelzeisen et al., 1996; Esser and Wagner, 1997; Schliephake et al., 1999; Grötz et al., 2000; Shaw et al., 2005). 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).

Previous studies have shown that the quality and quantity of the fibula flap used for reconstruction of the mandible are favourable for the placement of osseointegrated dental implants (Frodel et al., 1993; Kumar et al., 2012, 2016b; Sagheb et al., 2016). However, the

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quality of the overlying soft tissue surrounding the reconstructed mandible is not optimal for dental rehabilitation (Anne-Gaelle et al., 2011; Kumar et al., 2015b). Attached gingiva and fixed mucosa are anatomically peculiar entities that are seen only in relation to the alveolus of the native jaws and are not present in reconstructed jaws.

In reconstructed jaws, the intraoral lining is either the skin paddle of the osteocutaneous fibula flap or the lining mucosa formed by suturing the buccal/labial mucosa to the floor of the mouth. In view of dental rehabilitation both of these are a poor substitute for attached mucosa. The skin paddle is bulky, with layers of muscle, adipose tissue and skin appendages such as hair. This bulky soft tissue is mobile as it is not fixed onto the underlying bone and has been compared to "a multiple layered mattress over the bony bed" (Kumar et al., 2015b). The lining mucosa (in cases where a skin paddle is not used) moves along with the movement of the lips and tongue and is not fixed onto the underlying reconstructed bone. Irrespective of the type of the soft tissue, most patients have a lack of vestibular space. Additionally, when single barrel fibula is used, the height of the reconstructed mandible is much lesser than the native mandible. Due to this, there would be excess of soft tissue thickness in those regions. If corrective measures to improve the soft tissues are not done, it generally leads to poor hygiene around implants, hyperplastic peri-implant tissue, soft tissue infections, and abscesses that start as peri-implant marginal bone loss and may eventually lead to loss of the implant and the dental rehabilitation (Chiapasco et al., 2006; Kumar et al., 2015b). Hence constant assessment and monitoring of peri-implant hard and soft tissue parameters are extremely important in evaluating the performance of implant-supported treatment in reconstructed jaws.

This present paper reports the peri-implant parameters of a randomized clinical study in patients with segmental reconstructions of the mandible that received 2-implant supported removable overdenture as compared to 4-implant supported overdenture. A previous publication of the same RCT study has reported on the "Quality-of-Life (QoL)" outcomes (Kumar et al., 2016a). It showed that there was no difference in QoL outcomes in patients with either 2 or 4 implant-supported overdentures. This paper evaluates the success of implants as well as peri-implant soft tissue parameters.

The hypothesis of the study was that there were no differences in success rates of implants (as defined by Buser et al., 1990), in patients who had two- or four-implant-supported overdentures following segmental mandibular reconstruction with free fibula flap.

2. Materials and methods

2.1. Study objectives

The primary objective of this study was to compare success rates of implants (as defined by Buser et al., 1990) in patients who had two- or four-implant-supported overdentures following segmental mandibular reconstruction with free fibula flap. Secondary ancillary objectives of the study were to investigate the influence of the number of barrels and type of soft tissue corrective techniques on peri-implant soft tissue parameters.

This study describes the clinical features of the same patient group of the study published on QoL (Clinical Trial Registry India (CTRI/2012/07/002764)). The detailed study design, setting of study, study population, recruitment of patients, inclusion criteria, exclusion criteria, interventions, randomization and sample size estimation have been published in detail before (Kumar et al., 2016a). A brief description has been provided here again.

2.2. Study design

This prospective, randomized clinical study was conducted with equal allocation ratio. The participants were randomized into two study groups: one group received implant-supported over-dentures on 2 implants (Group-I) and the other group received implant-supported over-dentures on 4 implants (Group-II), which were placed in the previously reconstructed mandible.

Primary outcome parameter was success rates of implants. This was evaluated considering peri-implant hard marginal bone level changes (at 6 and 12 months post loading) as well as peri-implant soft tissue parameters (peri-implant indices probing depth and type of hyperplastic tissue) at 3, 6 and 12 months post loading.

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 centres 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 (VVK) between May 2012 and August 2013.

2.4. Recruitment of patients

Reconstructed 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 radiographs and computerized tomographic scan 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 (by VVK). The code was sealed in an envelope that was sequentially numbered and was opened only upon inclusion of the patient for the study. Participants were assigned to the respective groups based on the concealed allocation sequence (Fig. 1).

Group I patients had 2 implants and Group II had 4 implants that were inserted into the reconstructed mandible. All the implants used for the study were Soft Tissue Level Implants of the same type with similar diameters and similar lengths (Straumann Standard

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