Survival and success of MIS C1 implants- a field Study

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Introduction

Dental implants have become a standard therapy for partial and total edentulism. Various implant designs have been studied for enhancement of survival and success as well as ease of tratment.

Research Plan

The aim of the present study is to evaluate the 1-year survival and success of MIS® C1 implants with a length of 10-15mm.

Specific Aims

1. To study 1 year implant survival rate C1 implants
2. To study 1 year implant bone level changes of C1 implants

Materials and Methods:

Patients will be recruited by twelve dentists in locations of their respective dental practices.

Inclusion criteria:

1. Age between 18-75.
2. Patient expresses his wish to restore the missing tooth/teeth with implant therapy.
3. Partial edentulism with available bone height for dental implants ≥ 10mm mm.

Exclusion criteria:

1. Contraindicating medical conditions such as uncontrolled diabetes, untreated malignancies, pregnancy, previous/current bisphosphonate therapy.
2. Untreated periodontal disease, untreated caries, PA pathology in contact with the location of the prspective implant.
3. Major bone augmentation in conjunction with implant placement. Localised bone augmentation in conjunction with implant placement, of up to 3 mm on 1-2 aspects of the implant will be allowed.
4. One stage immediate loading/restoration.

Patient and Location Assignment

12 implants will be allocated to each of the ten dentists, for a total of 120 implants. All the implants needed in the surgical area of the recruited patients will be allowed into the study.

Clinical Measurements

The following data will be collected for each patient/implant:

1. Patient data including birthdate, health, surgery date.
2. Implants' length, diameter
3. Insertion torque
4. Periapical radiographs (at insertion, and twelve months post surgery).
5. Post operative complications and adverse events.
6. Periodontal data around Ramfjord teeth (16, 21, 24, 36, 41, 44)[1]: Plaque index, Gingival Index, Probing depth in six sites and Bleeding on probing in six sites, at baseline and twelve months post surgery.

Study Design

A. A calibration meeting(s) of all participating dentists will precede study commencement, in which the study design, inclusion criteria and surgical techniques will be discussed and unified. All participating periodontists will receive identical implant surgical kits to be used during the implant operative procedures of the study patients as well as 10 MIS® C1 dental implants.

B. Patients attending the dental offices of the dentists will be screened for the study. Those patients that meet the inclusion and exclusion criteria will be offered to participate in the study. Patients will be examined and diagnosed, cause-related therapy including caries treatment and all periodontal treatment given, including oral hygiene instructions, scaling and root-planing and periodontal surgery as necessary. Final eligibility will then be evaluated and patients will be accepted into the study.

Study models, periapical and/or panoramic and/or CT radiographs will be used for evaluation and treatment planning as necessary.

Surgery will be performed whereby patients will be given an antibiotic dose 1 hour prior to surgery, consisting of 875mg Augmentin+ 1.5g amoxicillin or 500mg Augmentin+ 1.5g amoxicillin or 2g amoxicillin, or, in cases of penicillin allergy, 600mg of clindamycin. Implants will be installed and a healing abutment will be connected and flaps sutured; implant type, length and diameter, and periapical radiographs will be recorded.

Patients will be given postoperative instructions, antibiotic and analgesic therapy. Patients will be examined 7-10 days after surgery for suture removal and then after 4 weeks, 3, 6 and 12 months post surgery. Maintenance periodontal treatment will be provided at 1-month post surgery and then every 3 months. At 3-6 months interim implant success evaluated and implants will be restored by their dentists. First year implant evaluation will be performed at 12 months post surgery and study termination evaluation will be performed at 36 months. Patients will pay the cost of treatment excluding the cost of the implant, the implant abutment and the follow up appointments. All necessary data will be recorded in a patient report booklet

Data management and analysis

Data collected will be reported in a patient report booklet, including the various clinical parameters and adverse events, recorded during clinical examinations. Periapical radiographs will be used for radiographic measurement of the distance in mm between implant margin and alveolar bone crest at the distal and mesial aspects of the implant

Following the completion of the study data will be analyzed with the collaboration of the statistical unit at the Rambam Health Care Campus.

1 References:

[1] Ramfjord SP. Indices for prevalence and incidence of periodontal disease. J Periodontol 1959;30:51–9.