Clinical evaluation

Clinical evaluation of OsteoCare™ Midi one-piece implants for immediate loading

Amr Zahran, Professor of Periodontology at Cairo University evaluates the clinical performance of these implants for immediate loading of single or multiple tooth restorations in partially edentulous patients

Introduction

The high long-term success of dental implants has been well-documented over the past three decades, using the conventional Brånemark two-stage protocol which allows a load-free healing period of three to six months (Adell et al 1981, Albrektsson et al 1986, Brånemark et al 1977). The actual need for healing periods of such duration having been greatly questioned because they were determined on an empirical basis (De Vasconsellos et al 2006). For a long period of time, the success documented for Brånemark’s protocol convinced clinicians that this was the only acceptable protocol.

However, immediate loading of dental implants is increasingly gaining popularity as an attractive advantage for both patients and clinicians alike. Today, quick delivery of implant-supported restorations can be considered as the standard of care in case of missing teeth. Many clinicians, however, are unaware that the concept of immediate loading using titanium one-piece implants is actually not new and began in the early 1960s (Tramonte 1965). Also immediate loading was the initial protocol suggested with dental implants and these implants yielded a wide range of clinical survival. A direct bone interface, on occasion, could be developed and maintained for more than 20 years (Linkow and Miller 2004).


Throughout the past few years, the immediate loading protocol has been expanded to include single tooth implants. Many clinical case presentations have described immediate loading of single implants using provisional acrylic resin crowns (De Vasconsellos et al 2006, Dhanrajani and Al-Rafee 2005, Lorenzoni et al 2003, Misch et al 2004, Randow et al 1999, Tsiridis 2005, Wang et al 2006).

Some clinical reports evaluated the success of immediately loaded dental implants which were placed in fresh extraction sites versus healed bony sites and demonstrated controversial results (Chen et al 2004, Lorenzoni et al 2003, Schwartz-Arad and Chaushu 1997). Moreover, it has been suggested that immediate placement may preserve alveolar bone height and width, and allow for optimal soft tissue aesthetics (Gapski et al 2003).

Animal studies have shown conflicting results, some reported that immediate loading of dental implants jeopardises osseointegration, while others have not observed differences in bone-to-implant contact or peri-implant bone density with newly designed screw implants compared with unloaded control (Romano et al 2001, Sagara et al 1993).

There are many advantages of the immediate loading protocol, which include reduction in the number of surgical interventions and in the overall treatment time. Furthermore, there is substantial evidence that immediate loading of implants can be carried out without jeopardising the survival rates, providing high initial stability of the implant and controlled loads (Barzilay 1993, Misch et al 2004a, Misch et al 2004b, Randow et al 1999, Romanos 2004, Zahran 2007).

Recently, the evolution of the science of dental implantology yielded technological breakthroughs of the macro and micro-design of dental implants, including improved implant shape, thread patterns and surface treatments which have demonstrably fostered greater primary stability and faster osseointegration (Jones and Cochran 2006, O’Sullivan et al 2000, Sakoh et al 2006, Stanford 2002). These modern implants were designed for the immediate loading procedures and were applied to rehabilitate the partially edentulous patients with high predictability. In parallel with the recent technical advances of the implant designs, the better understanding of biology had led towards the minimally invasive or the atraumatic flapless surgical procedures (Al-Ansari and Morris 1998, Becker et al 2005, Fortin et al 2006, Hahn 2000, Kan et al 2000, Zahran 2007, Zahran and Gauld 2007). With appropriate patient selection, single-stage surgery, immediate loading and flapless site preparation are dependable treatment approaches which offer favourable long-term prognosis (Fortin et al 2006).

The one-piece implant design eliminates the manipulation of the soft tissue portion after initial healing period, therefore the need for placing healing collars or aesthetic abutments is avoided. The immediate construction and placement of provisional restorations after...
implant insertion, allow for better soft tissue adhesion and seal to form a healthy collar. The restorative process with the one-piece implant resembles that of a natural tooth. The easily prepared abutment part enables an individualised borderline of the preparation to exactly follow the contour of the gingival margin, without violating the soft tissue seal, potentially leading to better preserved interproximal bone and papillae (Hahn 2005).

The new Midi one-piece (post type) implants offer a unique simple treatment modality, and have been specially designed for immediate loading of fixed restorations. They are considered an alternative to the conventional implant placement regimen and are ideal for immediate loading in varying bone qualities and quantities. They allow minimally invasive
transmucosal flapless placement and limit the requirement for hard tissue grafting procedures (Zahran and Gauld 2007). The aim of the present study was to evaluate the clinical performance of the new OsteoCare™ Midi one-piece (post type) implants for immediate loading of single or multiple tooth restorations in partially edentulous patients with healed bony sites or in immediate post-extraction situations.

**Materials and methods**

**Patients**

Forty-eight patients (25 females and 23 males) with a mean age of 46 years (range 20–72 years) were consecutively included in this study between September 2004 and December 2005 (Table 1).

All the selected patients were considered ideal for immediate loading, as the two-stage conventional implant protocol may dissuade them from seeking any implant treatment at all. They would not accept the conventional implant protocol because of the nature of their occupations or for psychological reasons. The patients were required to be in good general health, and had no condition that might jeopardise the outcome of the treatment. Five patients had controlled diabetes mellitus and seven patients were smokers. The previous dental conditions of these patients included 24 with moderate to advanced chronic periodontitis. All patients had at least 3.5mm of ridge width for the placement of implants of at least diameter of 3.3mm and length of 13mm. The patients were thoroughly informed of the immediate loading protocol and of all the risks associated with this type of procedure. They all gave their full informed consent.

**Pre-surgical evaluation (Figures 1a, 1b, 2a and 2b)**

Pre-surgical radiographic evaluation was carried out with panoramic radiographs, periapical radiographs and dental computed tomography (CT) scans where indicated. The ridge width was evaluated through the diagnostic casts, ridge-mapping or directly in the patient’s mouth using callipers.

**Implants**

The 84 implants used in the study were OstecoCare™ Midi one-piece (post type) implants. Midi implants are machined from titanium alloy that incorporates both the implant body and an integral fixed abutment in a single component. Available in three diameters (3.3, 3.8, and 4.3mm) and lengths 10, 13, and 16mm. They are grit-blasted and acid-etched, with a high load ‘Buttress’ thread that allows maximum bone-to-implant contact, resulting in high stability even in poor quality bone. Midi implants are intended for the long-term restoration of missing teeth and their titanium alloy (6AL-4V ELI) construction provides maximum strength which allows placement in areas with deficient bone quantity and quality, as well as limited tooth-to-tooth spacing. The conical macro-design of the Midi implants has the advantage of allowing for the compression and expansion of the site. The amount of the bone expansion can be finely controlled with
Clinical evaluation

varying tapers produced using incremental implant diameters (Zahran 2007, Zahran and Gauld 2007).

Of the 84 immediately loaded one-piece midi implants, 27 (32.1%) were placed in fresh extraction sockets and 57 (67.8%) placed in healed bony sites. Forty-seven implants (55.9%) were placed in the maxilla and 37 implants (44.0%) were placed in the mandible. The number of Midi implants placed in the anterior area was 47 (55.9%), premolar area 30 (35.7%) and posterior molar area 7 (8.3%) (Tables 1, 2 and 3).

Surgical procedure

All implant surgeries were performed under local anaesthesia. For immediate post-extraction implant placement (27 implants), no flaps were designed before or after careful at- traumatic tooth extraction. Presence of intact buccal plate of bone was considered crucial for immediate post-extraction implant placement procedure. An osteotomy probe through the extraction socket assessed the integrity of the buccal plate. For late implant placement in healed bony sites (57 implants), the flapless transmucosal approach was used.

Site Preparation

Only one perforation profile drill (1.3mm di- ameter) was used for site preparation to give needlepoint accuracy for position, angle and depth and the use of saline was paramount when making the perforation. As the drill passed through the mucosa (transmucosal), it reached firstly the cortical bone and then the cancellous bone.

Confirmation of reaching the cancellous bone was achieved via the physical feel, as drilling was harder through the tough cortical plate and became far easier when engaging the softer cancellous bone. Preparation of the osteotomy did not exceed the implant length as the Midi implant has a strong self-tapping property (Zahran 2007). In cases of immediate post-extraction implantation, drilling was extended 2-5mm beyond the apex of the extraction socket.

Implant placement (Figures 1c and 2c)

The implant was removed from its protective pouch and offered to the site, then manually placed after the transmucosal site preparation or through the extraction socket. It was rotated clockwise for approximately three revolutions or until the plastic carrier could no longer rotate the implant. The hex driver with the ratchet wrench was used to complete the seating of the implant. It was then placed and seated until the first thread was flush with the cortical bone level in cases of late implant placement. In cases with immediate post-extraction implant placement, the implant first thread was placed 1-2mm apical to the crestal bone of the socket.

Attaining primary stability of over 30N/cm was considered crucial with all the placed im- plants in the extraction sockets or healed bony sites to allow for the immediate loading protoco. Primary stability of the implants was evaluated by the torque wrench.

Abutment preparation (Figure 1e)

Diamond or carbide high-speed burs were used to adjust the angulation and height of the abut- ment where necessary. The abutment prepara- tion was carried out under a copious stream of irrigation to prevent overheating.

Impression taking

The prepared abutments were treated as a nor- mal crown and bridge case. Full-arch rubber base impressions were made using the regular impression techniques.

Provisional Restoration (Figures 1f and 2d)

Once the abutment preparation and impression-taking were completed, the provisional acrylic resin restorations were fabricated either in the laboratory or by the dentist at chair-side. It was important to have a smooth contour of the provisional tooth to avoid irritation of the soft tissue. The provisional acrylic resin restora- tions were then temporary cemented to the prepared abutments of the Midi implants. The provisional crowns and bridges were carefully adjusted out of direct occlusal contacts.

The patients were instructed to consume easily chewable food for two months and to avoid direct biting on the provisional restoration. No preoperative or postoperative antibiotics were prescribed and analgesics were used as required.

Final restorations (Figures 1g, 1i and 2f)

After a healing period of six months, the proviso- nal acrylic resin restorations were removed and replaced by definitive ceramometal restora- tions.

Follow-up:

The patients were examined and evaluated preoperatively, six months post-surgery, at fi- nal prosthesis insertion and at twelve months thereafter (Figures 1d, 1j, 1k, 2e, 2g and 2h). The clinical criteria to be checked were survival, Periotest values and radiographic crestal bone level. Panoramic and periapical radiographs were obtained at implant insertion and subse- quently at six months and twelve months post- operatively to evaluate crestal bone loss. The latter was measured from the radiographs by the same digitised technique used by Yoo et al. 2006. The Periotest (Medizintechnik Gulden, Bensheim, Germany) was used to evaluate the clinical stability. Periotest values (PT) of (-8 to 0) were considered the ideal values that denote successful osseointegration.

Results

Complete soft tissue healing was generally une- venful in all patients within the first two weeks after implant placement. The patients reported minimal postoperative swelling or pain experi- ences, no occurrence of haematoma and mini- mal need for medications and analgesics. Most patients returned to their normal lives the day following surgery. During the twelve month postoperative follow-up period, all patients showed no postoperative inconveniences. One Midi implant failed, which was placed in a healed bony site during the first two months. The patient with the failed maxillary anterior implant did not suffer from pain or swelling but he felt slight mobility of the implant. This patient was the youngest (20 years) and he reported gum chewing (non-compliant patient).

The survival rate at six months and twelve months of postoperative follow-up was 98.8% as no more failures were reported. The mean marginal bone loss was 0.47mm (SD= 0.31, n= 56) at six months and 0.05mm (SD= 0.04, n=56) at twelve months for the Midi implants which were placed in healed bony sites.

For the implants placed in fresh extrac- tion sockets, the mean marginal bone loss was 0.64mm (SD= 0.28, n= 27) at six months and 0.03mm (SD= 0.02, n=27) at twelve months. The accumulated mean marginal bone loss was 0.52mm for the late implant placement while it was 0.67mm for the immediate post-extract- tion implants. The amount of marginal bone loss was not statistically significant between the implants placed in fresh extraction sockets or healed bony sites (ANOVA test, P= 0.766).

The Periotest values (PT) at the six months and twelve months follow-up periods never exceeded a maximum of (PT= 0) and the mini- mum value was (PT= -07) for all the immedi- ately loaded implants. The median Periotest value was (PT= -4) at the six months and (PT= -3) at the twelve months follow-up periods without any significant differences. No differ- ences in healing pattern and implant survival rate were found between the healthy patients and the controlled diabetic patients or the smokers.