Clinical evaluation of the OsteoCare™ Mini and Midi implants for immediate loading of mandibular overdentures

Professor Amr Zahran BDS MDS PhD evaluates the clinical performance of the implants for the support of mandibular overdentures and discusses the advantages

Abstract

This study evaluated the clinical performance of the new generation of OsteoCare™ Mini and Midi one-piece (ball type) implants for the support of mandibular overdentures. Forty-two (24 Mini and 18 Midi) implants were placed in the interforaminal region of the mandibles of 10 patients. A transmucosal flapless procedure was used to place the implants and followed by immediate delivery of the overdenture. The patients were evaluated at six-month intervals for a follow-up period of 18-24 months. Clinical criteria were survival rate, Periotest values, radiographic crestal bone level and patient satisfaction. Results showed that all the implants had successfully osseointegrated as indicated by the clinical and radiographic examinations. Implant survival rate of 100% was attested. The accumulated mean marginal bone loss was 0.61mm at the end of the follow-up period. Patients showed a very high degree of satisfaction of the treatment outcome. This procedure has many advantages, which include implant placement with minimally invasive transmucosal flapless surgery, decreased postoperative pain and a decreased cost of treatment. Single-stage one-piece implant placement, immediate loading, and transmucosal flapless surgery can result in high success rates when proper techniques are utilised with appropriate patient selection. In conclusion, the use of the Mini and Midi implants is a valid, unique and simple treatment modality to support overdentures.

Introduction

Dental implantology has evolved over the last 30 years to become one of the most predictable forms of treatment currently available to surgeons. Dental implants have offered dramatic changes in the treatment plan of completely edentulous patients with atrophic ridges. In a significant number of cases, the retention of the lower denture is extremely difficult, so the placement of implants to support an overdenture allows for optimal results that include retention, function, phonetics and patient satisfaction. Alternative treatment options, such as vestibuloplasties or augmentation of the alveolar ridges, have proven to be inferior to implant therapy (Burns et al, 1995, Stricker et al, 2004).

The successful prosthetic outcome of implant-supported overdentures has led the academic and clinical community to suggest that the prosthetic rehabilitation with a conventional denture of a patient with a completely edentulous mandible, should no longer be the treatment of choice. The implant-supported overdenture should be the option to consider first (Aalamet et al, 2005, Allen et al, 2003, Balshi and Wolfinger, 1997, Becker et al, 2003, Chiapasco et al, 2001, Chiapasco and Gatti, 2003, Enquist et al, 2004, Feine et al, 2002, Ormianer et al, 2006, Trakas et al, 2006).

The original Brånemark two-stage protocol calls for the submerging of the implants, which remain load-free for a healing period of three to six months to ensure successful osseointegration (Adell et al, 1981, Brånemark et al, 1977). The actual need for healing periods of such duration has been greatly questioned because they were determined on an empirical basis (De Vasconsellos et al, 2006). Many clinicians, however, are unaware that the concept of immediate loading of implants actually began more than 30 years ago (Hahn 2005, Linkow and Miller, 2004). For a long period of time, the success documented for Brånemark's protocol convinced clinicians that this was the only acceptable protocol. On the other hand, earlier results with immediately loaded implants were often unpredictable (Gapski et al, 2003).

Recently, the evolution of the science of dental implantology yielded technological breakthroughs in 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 applied to rehabilitate the edentulous mandible with high predictability.

Figure 1: The Mini/Midi (ball type) implant and the polycarbonate housing

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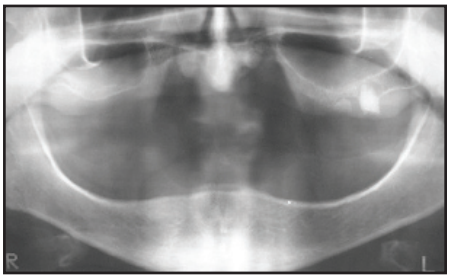

Figure 2a: The preoperative panoramic radiograph of patient no. 1

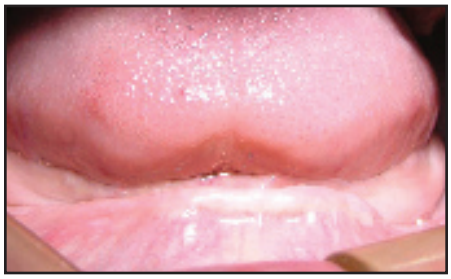

Figure 2b:The clinical picture of fully edentulous atrophic mandible

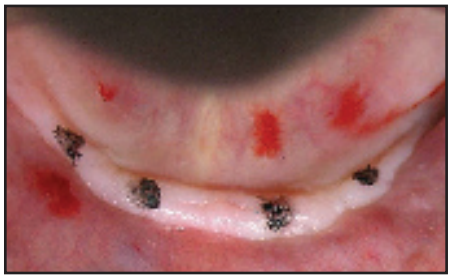

Figure 2c: Tissue marking

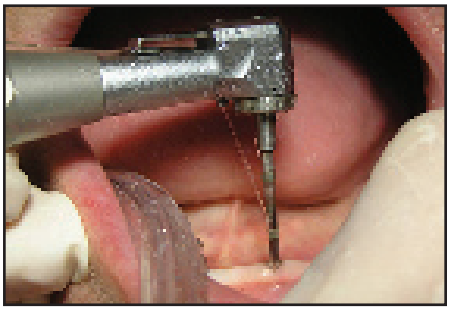

Figure 2d: Transmucosal site preparation using the profile pilot drill

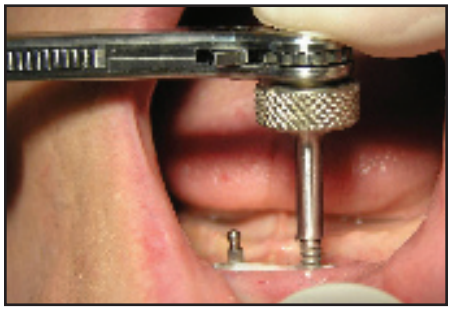

Figure 2e: Implant placement using the ratchet wrench

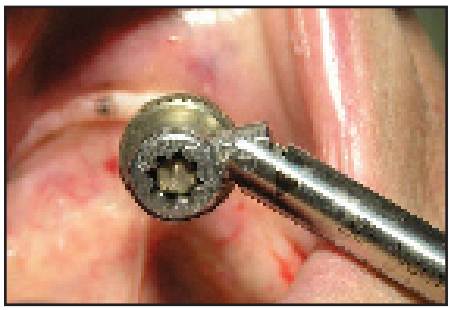

Figure 2f: Checking of the primary stability by using the torque wrench

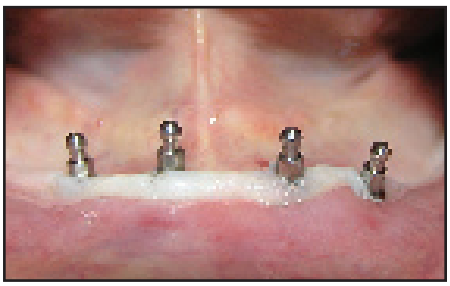

Figure 2g: Immediate postoperative photograph of the placed four Mini implants

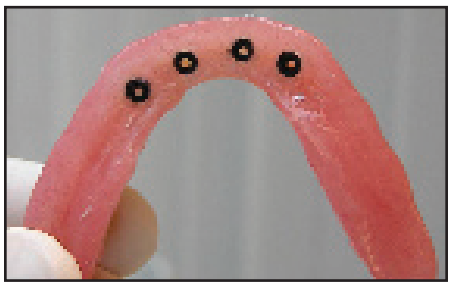

Figure 2h: The finished overdenture with the housings

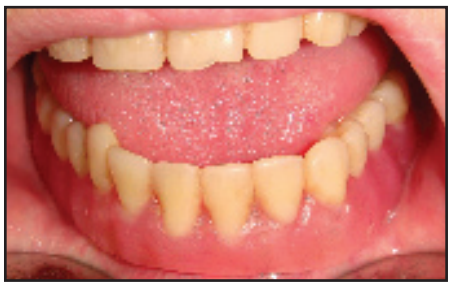

Figure 2i: Immediate delivery of the overdenture

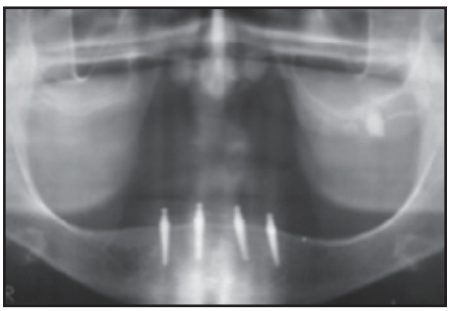

Figure 2j: The immediate postoperative panoramic radiograph

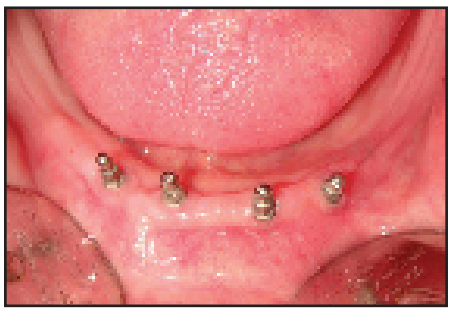

Figure 2k: Clinical aspect at 24 months

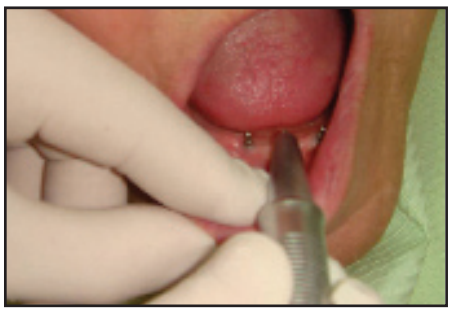

Figure 2l: Testing of the implants' stability using the Periotest

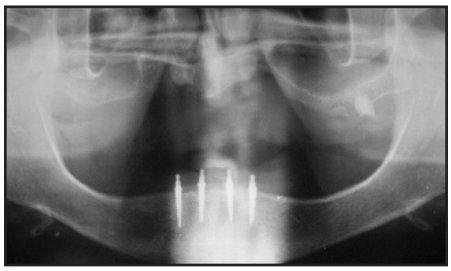

Figure 2m: Panoramic radiograph at 24 months

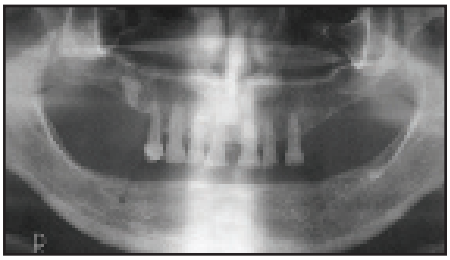

Figure 3a: The preoperative panoramic radiograph of patient no. 2

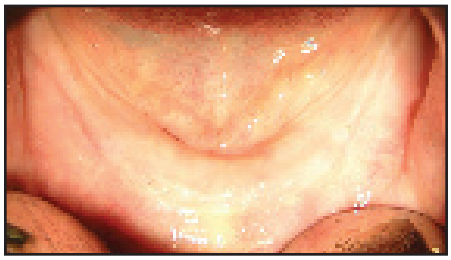

Figure 3b: The clinical picture of the atrophic ridge

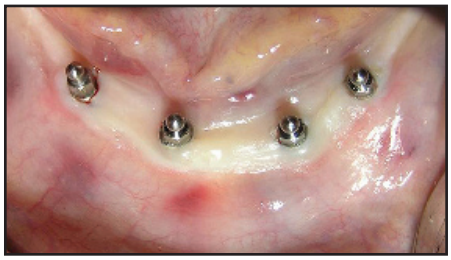

Figure 3c: Immediate postoperative photograph of the placed four Midi implants

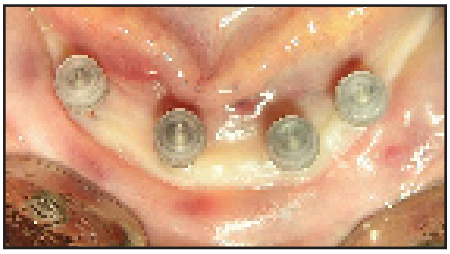

Figure 3d: Placement of the polycarbonate housings on the implants

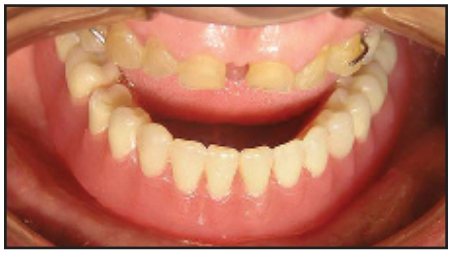

Figure 3e: Immediate delivery of the overdenture

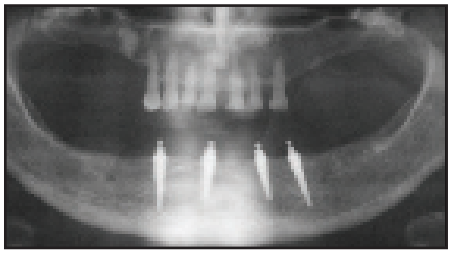

Figure 3f: Immediate postoperative panoramic radiograph

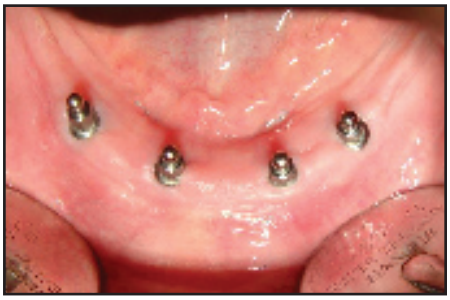

Figure 3g: Clinical aspect at 24 months

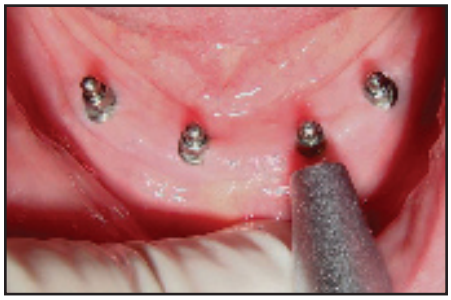

Figure 3h: Testing of the implants' stability using the Periotest

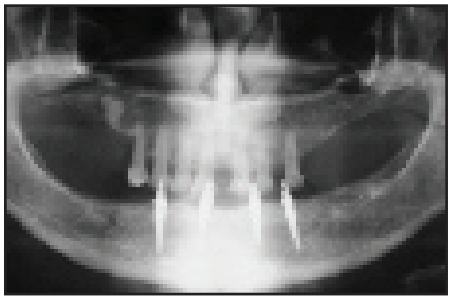

Figure 3i: Panoramic radiograph at 24 months

In parallel with recent technical advances in implant designs, a better understanding of biology had led to shifting towards minimally invasive or the atraumatic flapless surgical procedures (Al-Ansari and Morris 1998, Becker et al, 2005, Hahn 2000, Kan et al, 2000). Appropriate patient selection, single-stage surgery, immediate loading, and flapless site preparation are dependable treatment approaches that offer favourable long-term prognosis (Fortin et al, 2006).

Nowadays, many clinical studies validate the immediate loading protocols as a viable therapeutic alternative to the original Brånemark protocol in the appropriate conditions (Glauser et al, 2001a, Misch et al, 2004, Romanos 2004). The ultimate goal of an immediate loading protocol is to reduce the number of surgical interventions and shorten the time frame between surgery and prosthesis delivery, all without compromising the success rate of the procedure (Testori et al 2004).

In some atrophic mandibles, the lack of bone width prevents the placement of conventional implants. Therefore, in these situations, numerous augmentation techniques have been reported to facilitate implant placement. However, these augmentation procedures have some drawbacks and significant side effects. They also require experience and a high degree of surgical skills. In addition, a considerable rate of morbidity had to be dealt with (Stoelinga et al 1986).

The use of the Mini and Midi one-piece (ball type) implants is a unique and simple treatment modality which has been specially designed to support overdentures. They are considered an alternative to the conventional implantation regime and are ideal for immediate loading in varying bone qualities, as well as thin atrophic ridges. They allow for minimally invasive transmucosal flapless placement and limit the requirement for hard tissue grafting procedures.

The aim of the study was to evaluate the clinical performance of the new generation of OsteoCare™ Mini and Midi one-piece (ball type) implants for the supporting of mandibular overdentures.

Materials and methods

Patients

A total of 10 patients, including four males and six females, were consecutively included in this study between September 2004 and March 2005. The average age at the time of implant placement was 66 years (range 50-76 years). There was one patient who was completely edentulous. Nine patients had 2-11 teeth in the maxilla, with removable partial dentures or fixed bridges. All patients were completely edentulous in the mandible, and all implants were inserted in the interforaminal region of the mandible for immediate prosthetic restoration.

All patients had at least 3mm of ridge width for the placement of implants. The ridge width of each patient is evaluated by ridge-mapping or

by using callipers. The patients, who had ridge width less than 4mm, received Mini implants of 2.8mm diameter, while others who had ridge width more than 4mm received Midi implants with diameter of 3.3mm or 3.8mm. 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.

The treatment plan for the patients in this study included placement of 3, 4, 5 or 6 Mini or Midi implants in the mandibular interforaminal area. The choice of the number of the implants to be placed depended on the clinical assessment of the patients. Clinical evaluation included the ridge width and shape, the opposite jaw (being partially or completely edentulous) and the occlusal forces.

No patients were excluded from treatment because of documented risk factors such as smoking, controlled Diabetes Mellitus or poor bone quality. This study included four controlled diabetic patients and two smokers; therefore it provided more realistic clinical information from a 'real-world' environment.

Pre-surgical evaluation

Pre-surgical radiographic evaluation was carried out with panoramic radiographs, periapical radiographs and dental computed tomography (CT) scans whenever indicated (Figures 2a and 3a).

The ridge width was evaluated through the diagnostic casts, ridge-mapping or directly in the patient's mouth using callipers (Figures 2b and 3b).

Before surgery, final impressions of the arches were made, and working models cast. The models were mounted in an articulator, after bite registration on occlusal rims for establishing the centric relation. Try-ins were made and confirmed by the patients.

Implants

The 42 implants used in the study were OsteoCare™ Mini and Midi one-piece (ball type) implants (Figure 1). Mini implants are smaller in diameter than 3mm while Midi implants have diameters larger than 3mm. Both Mini and Midi implants have a range of diameters (2.80, 3.30, 3.80 and 4.30mm) and lengths (10, 13, and 16mm). The implants have a grit-blasted and acid-etched surface, with a high load 'buttress' thread that allows maximum bone-to-implant contact. This will result in achieving high initial stability even in poor quality bone. The conical macro-design of the Mini and 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 varying tapers, produced using incremental implant diameters. The 42 implants used in the present study included 24 Mini and 18 Midi (ball type) one-piece implants.

Surgical protocol (Flapless transmucosal technique):

Marking of the drilling sites:

Using a skin marker, marks were made directly onto the patient's dried mucosa covering the alveolar ridge to determine the drilling positions of the implants, as planned from the diagnostic casts and panoramic radiograph (Figure 2c).

Site preparation

Only one perforation profile drill (1.3mm diameter) was used for site preparation to give needlepoint accuracy for position, angle and depth. The use of saline was paramount when making the perforation. As the drill passed through the mucosa (transmucosal), it firstly reached the cortical bone 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 Mini and Midi implants have a strong self-tapping property (Figure 2d).

Implant placement

The implant was removed from its protective pouch and offered to the site, then manually placed after the transmucosal site preparation. It was rotated clockwise for approximately three revolutions or until the plastic carrier could no longer rotate the implant. Then the hex driver with the ratchet wrench was used to complete the seating of the implants (Figures 2e, 2g and 3c).

Immediate loading (Same day of implant placement)

The initial stability (primary fixation) of the Mini and Midi implants was carefully checked by the torque wrench to confirm that initial primary fixation was exceeding 30N/cm which was crucial to start loading (Figure 2f).

Relief of denture to accommodate the housings

Holes were made in the denture at the pre-marked locations by using a laboratory bur. The polycarbonate housings were placed on the implants and checked to make sure that they were securely seated with full passivity (Figure 3d). Try-in of the denture was made to check full seating without binding on the housings.

Pick-up of the housing (chair-side pick-up procedures)

Once the spaces for the housings had been relieved, they were filled with self-cured acrylic resin and the denture was placed over the housings (Figure 3d). The patient was allowed to bite in centric occlusion. After setting of the self-cured acrylic resin, all the excess was removed and the denture was trimmed and polished (Figures 2i and 3e).

After implant placement and the delivery of the overdenture, the patients were instructed to consume easily chewable food for two months. No preoperative or postoperative antibiotics were prescribed. Analgesics were used when needed.

Follow-up

The patients were evaluated at six-month intervals up to two years (Figures 2k and 3g). Clinical criteria were survival, Periotest values and radiographic crestal bone level.

The following criteria were applied to evaluate implant success:

(1) Absence of clinically detectable mobility when tested with opposing instrument pressure, (2) no evidence of peri-implant radiolucency on periapical radiographs, (3) absence of recurrent or persistent peri-implant infection, (4) no complaint of pain at the site of treatment, (5) no complaint of neuropathies or paraesthesia, (6) crestal bone loss not exceeding 1.5mm by the end of first year of functional loading and less than 0.2mm/year in the ensuing years (according to the criteria proposed by Albrektsson et al, 1986) up to the two years of the follow-up period.

Panoramic and periapical radiographs were obtained at implant insertion and subsequently at six-month intervals up to 24 months postoperatively to evaluate crestal bone loss (Figures 2g, 2m, 3f and 3i). The latter was measured from the radiographs by the same digitised technique of Yoo et al (2006).

The periotest (Medizintechnik Gulden, Bensheim, Germany) was used to evaluate the clinical stability (Figures 2l and 3h). Periotest values (PT) of (-8 to 0) were considered the ideal values that denote successful osseointegration. For the evaluation of patient satisfaction, questionnaires were completed by the patients at the six-month follow-up visit. The questions were based on the questionnaire proposed by Brånemark et al (1999).

Results

Complete soft tissue healing was generally uneventful in all patients within the first two

weeks after implant placement. The patients reported minimal postoperative swelling or pain experiences with no occurrence of hematoma and minimal need for medications and analgesics. Most patients returned to their normal lives the day following surgery. During the 18-24 months postoperative follow-up period, all patients showed no postoperative inconveniences. All the 42 Mini and Midi implants were successfully osseointegrated as revealed by clinical and radiographic examinations. Implant survival rate of 100% was attested. No differences in healing pattern were found between the healthy patients and the controlled diabetic patients or the smokers.

The mean marginal bone loss was 0.42mm (SD= 0.22; n= 42) at six months, 0.09mm (SD= 0.02; n=42) at 12 months, 0.07mm (SD= 0.07; n=42) at 18 months and 0.03mm (SD= 0.06; n=14) at 24 months. The accumulated mean marginal bone loss was 0.61mm.

The Periotest values (PT) during the 24 months follow-up period never exceeded a maximum of (PT= 0) and the minimum value was (PT= -05) for all the 42 immediately loaded implants. Reviewing of the patient satisfaction questionnaires showed subjective answers that demonstrated a very high degree of satisfaction of the treatment outcome.

Discussion

Immediate loading of dental implants is becoming a widespread therapeutic procedure for the rehabilitation of patients with edentulous jaws. In general, patients with completely edentulous mandibles are restored with an implant supported overdenture. They are at the least risk of occlusal overload for immediate loading protocols. Recent reports, suggest two or more implants to support an overdenture (Misch et al, 2004). The ultimate goal of an immediate loading protocol is to reduce the number of surgical interventions and shorten the time frame between surgery and prosthetic delivery (Testori, 2004).

Several factors may influence the results of immediate implant loading. These could be divided into the following categories: surgery, host, implant, and occlusion-related factors. Surgical factors consist of primary implant stability and surgical technique. Host factors comprise the quality and quantity of bone, and wound healing. Implant factors include the macro and micro-designs, surface textures, and dimensions of the implant. Occlusal factors involve the quality and quantity of force and prosthetic design (Gapski, 2003).

The 100% success rate of the present study illustrated that the new generation of OsteoCare™ Mini and Midi dental implants present the opportunity to provide a minimally invasive, less costly, less complicated, and less surgically intensive treatment in a high percentage of cases that would be difficult to treat with the current inventory of conventional root-form implants for supporting of mandibular overdentures.

The OsteoCare™ Mini and Midi are one-piece dental implants which have a number of unique points which set them apart from their conventional counterparts. There is no similarity between the OsteoCare™ Mini implants that were placed in this study and the other commercially available temporary mini-implants. This is due to the large range of different diameters, and permutations of implant forms, thread pattern and surface treatment. An additional distinction in this new range of implants is the Midi implant. This range of implants has larger diameters reaching 4.3mm. This paper is considered the first to introduce the Midi implant.

In this study, all the 42 Mini and Midi implants reached high initial stability over 30 N/cm due to their conical design, buttress threads and the roughened surface (grit-blasted and acid-etched). Also, the under dimensioned drilling and the bone condensing property of the Mini and Midi implants have been used to increase initial stability.

It was reported that conical implant design in combination with the use of an undersized form drill could lead to higher initial stability than conventional implants (Jones, 2006, O'Sullivan et al, 2000, Sakoh et al, 2006) . Also experimental and clinical studies proved that the implant surface roughness and the thread design are major factors in realising success with immediate loading (Stanford, 2002).

The transmucosal flapless procedure for placement of the Mini and Midi implants resulted in minimal swelling and pain with no occurrence of hematoma. The patients required minimal postoperative medication. The flapless procedure resulted in a very high increase of the patient acceptance and satisfaction of this treatment modality. It was reported that flapless surgery also maintains a better blood supply to the marginal bone, thus reducing the likelihood of bone resorption (Fortin et al, 2006, Hahn, 2000, Kan et al, 2000).

Although flapless implant placement is considered a blind surgical procedure, there is a learning curve with every surgical procedure, after which it becomes routine. There are many advantages for the patient as well as for the surgeon, since the procedure is less time consuming, bleeding is minimal, implant placement is expedited, and there is no need to place and remove sutures.

The one-piece implant design eliminates the need for placing healing collars and makes it possible to avoid manipulation of the soft tissue portion after initial healing. The implant-abutment junction in a two-piece implant design constitutes a structural weakness that may complicate the procedure (Hahn, 2005).

The polycarbonate housings with rubber O-rings were successfully used for retention of the overdentures. O-rings possess a number of advantages, including ease of use and maintenance and low cost. The patients were pleased with the function and aesthetics of the overdenture O-ring prosthesis. Clinical comparisons of ball and bar designs for mandibular overdentures revealed a significantly higher number of complications and/or repairs for the bar group (Trakas et al, 2006, Yoo et al, 2006).

Implant supported overdentures could be considered the treatment of choice for most patients of advanced age who are already denture wearers. They have an increased probability of having medical problems such as diabetes mellitus or using anticoagulant therapy, so they need a simple atraumatic surgical protocol as offered by the use of the Mini and Midi implants. Although this study covered a limited patient complement, it showed that controlled diabetic patients and smokers had the same successful results without increased risk of surgical complications. Advantages of this procedure include implant placement without any bone augmentation surgery, minimally invasive surgery resulting in virtually no bleeding, decreased pain and a decreased cost of treatment.

Conclusion

The use of the Mini and Midi one-piece (ball type) implants is a valid, unique and simple treatment modality to support overdentures. These implants have a number of distinct features that set them apart from their conventional counterparts. They allow minimally invasive flapless transmucosal placement. Immediate loading is also possible and they are ideal for most types of bone qualities, quantities and thin atrophic ridges. Their unique design is tailored for long-term indications rather than being transitional. They are simple, reliable and cost effective implants that bring secure dentures within the reach of many patients, who are medically or financially compromised. This technique can contribute to a higher degree of implant treatment acceptance due to less discomfort and generally shorter treatment times.

A full list of references are available from: zahranref@dentistry.co.uk