

## Evaluation of Conical Self-tapping One-piece Implants for Immediate Loading of Maxillary Overdentures

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**Abstract:** Studies of maxillary overdentures supported by conventional implants often show a high implant failure rate. It was believed that maxillary implants should be splinted to retain a removable maxillary overdenture in order to maintain osseointegration. **Materials and Methods:** The present study evaluated the clinical performance of new generation of OsteoCare's Midi self-tapping self-drilling one-piece (ball type) implants for the support of maxillary overdentures. Seventy five implants were placed in the anterior maxillary region of 14 patients. A transmucosal flapless procedure was used to place four to six implants for each patient and followed by immediate delivery of an overdenture. The patients were evaluated at 6-month intervals for a follow-up period of 18 months. The clinical criteria to be checked were survival rate, Periotest values, radiographic crestal bone level and patient satisfaction. The **results** showed that 73 implants had successfully osseointegrated as indicated by the clinical and radiographic examinations. Implant survival rate of 97.3% was attested. The accumulated mean marginal bone loss was 0.88mm at the end of the follow-up period. Patients showed a very high degree of satisfaction of the treatment outcome due to the highly improved retention with partial palatal coverage using horse shoe designed maxillary over-dentures. 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 utilized with appropriate patient selection. In **conclusion**, the use of the Osteocare's Midi one-piece (ball type) implants is a valid unique simple treatment modality to support maxillary overdentures.

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### 1- Introduction

Implants supported overdentures appear to be highly successful in the edentulous mandible, Burns et al (1995); Feine et al (2002); Chiapasco and Gatti (2003); Zahran (2008). In contrast, treatment outcome with maxillary overdentures seems to be less predictable in comparison to other prosthetic indications with conventional implants. To this date, maxillary overdentures have not been adequately addressed in the literature. Over viewing of the few available maxillary over denture case presentations and studies, reveals a low implant survival rate, Jemt and Lekholm (1992); Jemt (1993); Mericske et al (2002).

With the conventional implant designs and the traditional surgical techniques, maxillary implants appear to cause more problems than mandibular implants supporting overdentures in patients with poor bone quality and severely resorbed maxillae, Misch et al (2004).

In some cases, the retention of the upper dentures is difficult while some patients suffer from the big size of the maxillary denture with full palatal coverage that restricts their tongue movements. The placement of implants to support a maxillary overdenture allows for optimal results which include retention, function, phonetics and patient satisfaction, Cleave (2000).

The traditional original Brånemark's 2-stage protocol initially calls for the submerging of the implants, which remain load-free for a healing period of 3-6 months to ensure successful osseointegration, Branemark et al (1977); Adell et al (1981). The actual need for healing periods of such duration has been greatly questioned because they were determined on 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). 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 of the macro- and the micro-design of the dental implants, including improved implant shape, thread patterns and surface treatments that have demonstrably fostered greater primary stability and faster osseointegration, Stanford (2002); Jones and Cochran (2006); Sakoh et al (2006). These modern implants were designed for the immediate loading procedures and were applied to rehabilitate the edentulous mandible with high predictability. In parallel with the recent technical advances of the implant designs, the better understanding of biology had led to shifting towards the minimally invasive or the a traumatic flapless surgical procedures, Al-Ansari and Morris (1998); Hahn (2000); Kan et al (2000); Becker et al (2005); Zahran and Gauld (2007); Zahran (2008). Appropriate patient selection, single-stage surgery, immediate loading, and flapless site preparation are dependable treatment approaches that offer favorable 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's protocol in its appropriate conditions, 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 prosthesis delivery, all without compromising the success rate of the procedure, Fortin et al.; (2006).

The use of the Midi one-piece (ball type) implants is a unique simple treatment modality which have been specially designed to support overdentures. They are considered an alternative to the conventional implantation regimen and are ideal for immediate loading in varying bone qualities as well as thin atrophic ridges. They allow minimally invasive trans-mucosal flapless placement and limit the requirement for hard tissue grafting procedures. The conical macro-design of the Midi implants, the special buttress thread pattern and the undersized drilling using one drill result in compression or condensation of the bone with the increase of the initial stability of the implants, Zahran and Gauld (2007); Zahran (2008); Zahran (2008 a).

The aim of the present study was to evaluate the clinical performance of the new generation of self-tapping Midi one-piece (ball type) implants for supporting of maxillary overdentures.

## 2-Materials and Methods

### 2.1. Materials:

#### 2.1.1. Subjects:

A total of 14 patients, including 8 males and 6 females, were consecutively included in this study. The average age at the time of implant placement was 60.42 years (range 52-72 years). Six patients were completely edentulous. The other patients had partially edentulous mandibles. All patients were completely edentulous in the maxilla except one patient who has 2 second molars. All the implants were placed well spaced, in the anterior part of the maxilla between the left and right second premolars area to avoid the maxillary sinus.

**Table (1): Overview of clinical data of patients and number of implants included in the study.**

Patient	Age	Sex	Number of implants	Opposing arch	Comments
1	63		6	Implant supported overdenture	
2	58		6	Partially edentulous	
3	72		6	Implant supported overdenture	
4	52		4	Partially edentulous	
5	54		4	Implant supported overdenture	
6	60		4	Implant supported overdenture	
7	57		6	Implant supported overdenture	1 failed implant
8	62		6	Implant supported overdenture	
9	58		5	Partially edentulous	
10	64		6	Partially edentulous	
11	62		6	Implant supported overdenture	
12	66		6	Partially edentulous	
13	58		4	Implant supported overdenture	1 failed implant
14	60		6	Implant supported overdenture	

All patients had at least 5mm of ridge width for the placement of implants. The ridge width of each patient is evaluated by ridge mapping or by using bone callipers. The patients received Midi implants with diameters of 3.3mm, 3.8mm and 4.3mm 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. Clinical evaluation included the ridge

width and shape, the opposite jaw (being partially or completely edentulous with an overdenture) and the occlusal forces. The selected patients were systemically healthy and not heavy smokers.

### 2.1.2. Implants

The treatment plan for the patients in this study included placement of 4-6 Midi implants in the anterior maxillary area and the premolar region of the alveolus bilaterally. Eight patients received six implants, one patient received five implants and five patients received four implants. The implants were placed in healed bony sites with bone types (D1 to D3). The 75 implants used in the study were OsteoCare's Midi one-piece (ball type) implants (OsteoCare™ Implant System, London, United Kingdom). Midi implants have range of diameters (3.30, 3.80 and 4.30mm) and lengths (10, 13, and 16 mm). The implants have blasted and acid etched surface, and a high load "buttress" thread that has the advantage of allowing maximum bone-to-implant contact. This results in achieving high initial stability in even poor quality bone. The conical macro-design of the Midi implants has the advantage of allowing for the compression and expansion of the site.

**Table (2): Implant number, diameter (mm) and length (mm).**

Size of implants	Number	Failed Implants
3.3x 13 mm	4	1
3.8x 13 mm	65	1
4.3x13mm	6	0
Total	75	2

## 2.2. Methods:

### 2.2.1. Pre-surgery evaluation:

Pre-surgical radiographic evaluation was carried out with panoramic radiographs, periapical radiographs and cone beam volumetric tomography (CBVT) whenever indicated.

The ridge width was evaluated through the diagnostic casts, ridge mapping or directly in the patients' mouth using callipers.

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

### 2.2.2. Surgical Protocol and implant placement (using Flapless trans-mucosal technique):

#### 2.2.2.1. 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 the panoramic radiograph.

#### 2.2.2.2. Site preparation:

The implant surgical procedures were performed under local anesthesia and without sedation. 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. When the drill passed through the mucosa (trans-mucosal), it reached firstly the cortical bone then the cancellous bone. Confirmation of reaching the cancellous bone was achieved via the physical feel; the drilling was harder through the tough cortical plate and became far easier when engaging the softer cancellous bone. Preparation of the osteotomy was shorter than the implant length as Midi implants have a strong self-tapping self-drilling property.

#### 2.2.2.3. Implant Placement:

The implant was removed from its protective pouch and offered to the site. The implant was manually placed after the trans-mucosal site preparation and was rotated clockwise for approximately three revolutions or until the plastic carrier could no longer rotate the implant manually. Then the over-hex driver with the ratchet wrench was used to complete the seating of the implants.

#### 2.2.2.4. Immediate Loading (Same day of implant placement):

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

#### 2.2.2.5. 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 were checked to make sure that they were securely seated with full passivity. Try in of the denture was made to check full seating without binding on the housings.

#### 2.2.2.6. 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. 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.

**2.2.3. Post-operative care:**

After the implants placement and delivery of the overdenture, the patients were instructed to consume easily chewable food for 2 months. No preoperative or postoperative antibiotics were prescribed. Analgesics were used when needed.

**2.2.4 Post operative follow-ups and evaluation**

The patients were evaluated at 6-month intervals for 18 months. The clinical criteria to be checked were survival rate, 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 1.5 mm by the end of first year of functional loading and less than 0.2 mm/year in the ensuing years (according to the criteria proposed by Albrektsson et al.; (1986) up to the 18 months of the follow-up period.

Panoramic and periapical radiographs were obtained at implant insertion and subsequently at 6-month intervals up to 18 months postoperatively to evaluate crestal bone loss. The linear measurement obtained by means of conventional radiographs and indirect digital images evaluated by the Digora software for Windows, version 1.5 (Soredex, Helsinki - Finland), Kawauchi et al (2004).



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



Figure 1b: The clinical picture of the fully edentulous atrophic maxilla of patient no.1



Figure 1c: Immediate postoperative photograph of the placed four Midi implants

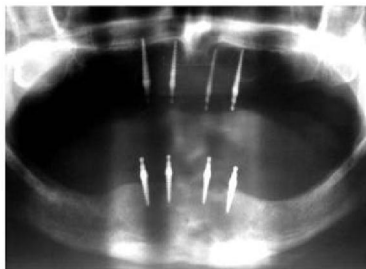


Figure 1d: The immediate postoperative panoramic radiograph



Figure 1e: Clinical aspect at 6 months

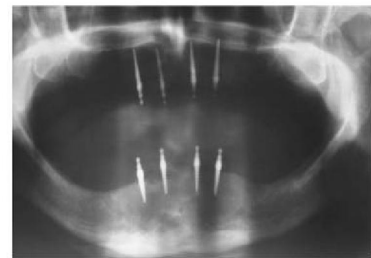


Figure 1f: Panoramic radiograph at 18 months



Figure 1g: Clinical aspect at 18 months



Figure 1h: Placement of the polycarbonate housings on the implants



Figure 1i: The finished overdenture with the housings



The Periotest M (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.

For the evaluation of the patient satisfaction, questionnaires were filled by the patients at the 6 months follow-up visit. The questions were based on the questionnaire proposed by Brånemark et al (1999).

### 3. Results:

**3.1.** Complete soft tissue healing was generally uneventful in all patients within the first 2 weeks



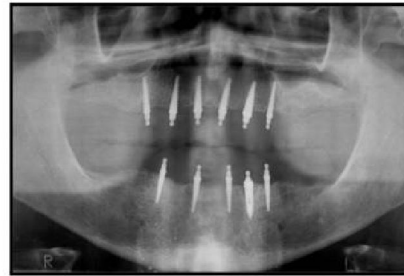
**Figure 2a: Immediate postoperative photograph of the placed six Midi implants of patient no. 2**



**Figure 2b: Placement of the polycarbonate housings on the implants**



**Figure 2c: The finished overdenture with the housings**



**Figure 2d: Panoramic radiograph at 18 months**



**Figure 2e: Immediate delivery of the overdenture**

**3.3.** During the 18 months postoperative follow-up period, all patients showed no postoperative inconveniences. Seventy three Midi implants were successfully osseointegrated as revealed by clinical and radiographic examinations. Implant survival rate of 97.3% was attested.

**3.4.** The mean marginal bone loss was 0.72mm at 12 months, while it was 0.88mm at 18 months. The mean values of linear radiographic measurements were recorded using digital programs.

**3.5.** The Periotest values (PT) during the 18 months follow-up period never exceeded a maximum of (PT= 0) and the minimum value was (PT= -5) for all the successfully osseointegrated implants.

**3.6.** Reviewing of the patient satisfaction questionnaires showed subjective answers that demonstrated a very high degree of satisfaction of the treatment outcome. All patients have verbally indicated their comfort with the horse shoe denture design due to their partial palatal coverage. It

provides them with more room for their tongue and exposes more palatal tissues and improves the feeling of the texture of their food.

#### **4. 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 maxillary jaws are restored with an implant supported overdenture. They are at the highest risk of occlusal overload for immediate loading protocols when conventional implants are used to support a maxillary overdenture, Jemt and Lekholm (1992); Jemt (1993); Mericske et al (2002).

The high failure rate of the maxillary overdentures supported by conventional implants is related to the inadequate bone volume and the low bone density of the completely edentulous maxilla. Generally, the bone is less dense in the anterior maxilla than the anterior mandible. The maxilla presents very thin porous cortical labial bone and the trabecular bone is usually very fine, Cleave (2000); Misch et al (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 the micro designs, surface textures, and dimensions of the implant. Occlusal factors involve the quality and quantity of force and prosthetic design, Gapski (2003).

The 97.3% successful results of the present study illustrated that the new generation of OsteoCare's Midi dental implants present the opportunity to provide patients with 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 maxillary overdentures.

The OsteoCare's Midi one-piece dental implants have a number of unique points that set them apart from their conventional counterparts. There is no similarity between the OsteoCare Midi implants that were placed in this study and the other commercially available conventional implants.

All the 75 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 Midi implants have been used to increase initial stability as well as to improve the bone quality, Zahran and Gauld (2007); Zahran

(2008); Zahran (a) 2008).

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, O'Sullivan et al (2000); Sakon et al (2006). Also experimental and clinical studies proved that the implant surface roughness and the thread design are major factors in achieving success with immediate loading Stanford (2002).

The trans-mucosal flapless procedure for placement of the 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 admits a maintained better blood supply to the marginal bone, thus reducing the likelihood of bone resorption, Al-Ansari and Morris (1998); 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, Becker et al (2005).

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 procedures, 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 esthetics of the overdenture O-ring prosthesis. Clinical comparisons of ball and bar designs for mandibular over-dentures revealed a significantly higher number of complications and/or repairs for the bar group, Trakas et al (2006).

Implant retained over-dentures could be considered the treatment of choice for most patients of advanced age who are already denture wearers, Romanos (2004). They have an increased probability of having medical problems such as diabetes mellitus or using anticoagulant therapy, so they need a simple a traumatic surgical protocol as offered by the use of the Mini and Midi implants. 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. Another important advantage is the possibility of removal of the palatal part of the maxillary overdenture that results in having smaller horse shoe designed denture that gives bigger space for the patient's tongue. This will result in improvement of phonetics, taste sensation as well as patient's self confidence.

### Conclusion

The use of four to six Midi one-piece (ball type) implants in the maxilla is a feasible treatment option to support maxillary 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 for atrophic ridges. They are 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.

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