

# Long-Term Retrospective Clinical and Radiographic Follow-up Evaluation of 108 OsteoCare™ Mini and Midi Ball-Type Implants Subjected to Immediate Loading of Mandibular Overdentures

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## Abstract

**Background:** Dental implants have provided major changes in the treatment planning of completely edentulous patients with atrophic ridges. Objectives: the present study retrospectively evaluated OsteoCare™ Mini and Midi one-piece ball-type dental implants for immediate loading of mandibular overdentures with an emphasis on long-term survival, implant stability, peri-implant soft and hard tissue conditions, and patient satisfaction.

**Methods:** One hundred and eight one-piece ball-type implants were placed in the mandibular interforaminal area of 31 patients (15 females and 16 males) with an age range at the start of the treatment of 28 to 80 years with a mean of 61 years. All implants were placed flaplessly followed by immediate delivery of overdentures. Clinical criteria evaluated were survival rate, probing depth, Periotest M values and patient satisfaction. In addition to

radiographic and crestal bone level recordings

**Results:** Follow-up averaged 5.4 years (range between 5-11 years) and the cumulative survival rate (CSR) was 100%. The mean marginal bone loss at the end of the follow-up period was  $0.42 \pm 0.14$  mm while the mean pocket depth was  $1.79 \pm 0.09$  mm. The mean Periotest M value (PTM) at the end of the follow-up period was -0.9. Review of the patients' satisfaction questionnaires showed a very high scale of satisfaction from the treatment outcomes.

**Conclusion:** OsteoCare™ Mini and Midi one-piece ball-type implants have demonstrated excellent long-term survival, marginal bone response, and soft tissue conditions with immediately loaded mandibular overdentures. They have proved to be a viable and predictable treatment option for completely edentulous mandibles.

**KEY WORDS:** Mini dental implants, immediate loading, overdenture, prosthetics

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## INTRODUCTION

The edentulous state presents a major impairment of oral function in addition to aesthetic and psychological challenges.<sup>1-3</sup> In general, edentulous patients are treated with complete dentures which require adaptation and a complex learning process when considered on somatic and psychological basis.<sup>4</sup> Overtime, patients whom were originally adaptive to complete dentures become maladaptive due to residual ridge resorption which is significantly greater in the mandible than in the maxilla, physiological intra-oral changes and the development of altered muscular patterns.<sup>5,6</sup> Historically, overdentures supported by roots have been a traditional element of prosthodontics treatment planning<sup>2</sup> and were significantly popular as an alternative to complete dentures.<sup>7</sup> Subsequently, implant-supported overdentures became the standard of treatment for edentulous patients after the overwhelming success of osseointegration.<sup>8-10</sup>

Although, there is no general agreement on the number of implants to be used to support a mandibular overdenture, many clinicians currently use between 2 to 6 implants. A consensus was reached in 2002 at McGill University that effectively established the two-implant supported overdenture as the first preference of treatment for the edentulous mandible.<sup>11</sup> Furthermore, in 2009, the New York Consensus Statement concluded that a large body of evidence supports the proposal of a two-implant-supported mandibular overdenture as the minimum presented to edentulous patients.<sup>12</sup>

The implant-retained overdenture, therefore, presents as a treatment option that improves the quality of life and the oral health of the edentulous patient.<sup>13</sup> It also offers several advantages such as higher stability and retention, improved

function and aesthetics, and the reduction of the residual resorption of the alveolar process when compared to conventional complete dentures.<sup>14,15</sup> Although removable dentures do not possess the elegance and finesse of fixed restorations, they are simpler in construction, can require fewer implants and are subsequently lower in cost.<sup>16</sup> Initially the recommended time as proposed by Branemark between the placement and functional loading of oral implants in the mandible has been three months,<sup>17</sup> however with the turn of the millennia, more studies have verified increased bone-to-implant contact occurring at a faster rate, this earlier healing time supports the concept of immediate loading with mandibular overdentures than was previously recommended.<sup>10,18-20</sup>

Immediate loading with mandibular overdentures has been proposed as an alternative to delayed loading as a mean to reduce treatment time and patient discomfort. Immediate loading is not new and was initially suggested with the introduction of dental implants, with a wide range of clinical survival rates<sup>10,21,22</sup> which were demonstrated in some studies for more than 20 years.<sup>23</sup> The most important guidelines for immediate loading protocol include having sufficient bone height to place implants of moderate length and good bone quality, favourable occlusion and enough inter-maxillary arch space.<sup>10,24</sup>

Because of the favourable outcomes and low costs associated with two-implant mandibular overdentures, they are recommended as the standard of care for edentulous patients when compared to other forms of implant treatment,<sup>11,12</sup> although the application can be limited for some cases. Such limitations may be attributed to the patient's fear of surgery and psychological issues,<sup>25</sup> the cost could be high for some

individuals,<sup>26</sup> and systemic disease can pose restrictions on operative procedures and the duration of the treatment especially in the elderly.<sup>27</sup> Additionally, local area morphology may limit the use of standard sized implants without the use of additional augmentation procedures which again will incur higher costs, greater discomfort and higher risks of postoperative morbidity.<sup>28</sup>

The use of Mini and Midi one-piece ball-type implants presents an efficient and economical alternative to standard implants because their smaller diameter and tapered design allows insertion in narrow ridges without the need for adjunctive grafting procedures.<sup>10,29</sup> Similarly, the insertion protocols are also faster and simpler requiring a single drill and flapless protocols<sup>10,30</sup> which are more relevant to the elderly.<sup>31</sup> Furthermore, these narrow diameter implants have demonstrated similar survival rates when used for mandibular overdentures as standard implants.<sup>32</sup>

## MATERIALS AND METHODS

The clinical outcome of OsteoCare™ Mini and Midi one-piece ball-type implants supporting overdentures was retrospectively examined. One hundred and eight (108) implants were placed at the first author's private dental practice from the year 2004 to 2010. The study protocol was approved by the Ethical Committee at the Faculty of Oral and Dental Medicine, Cairo University.

A total of 31 consecutive patients comprising 16 males and 15 females, were included in the study. The patients' age ranged from 28 to 80 years displaying an average of 61 years. All patients were completely edentulous in the mandible, and all implants were inserted in the interforaminal region in the mandible for immediate prosthetic restoration.

### Inclusion Criteria

At least 18 years of age to place an implant, systemically healthy, having sufficient bone height to accommodate an implant of 13 mm in length and ridge width of at least 4 mm, demonstrating the ability to sustain oral hygiene and showing willingness and ability to attend follow up to provide a signed informed consent.

### Exclusion Criteria

Patients with lack of skeletal maturity ridges that required significant augmentation for implant site development, ridge width less than 4 mm or ridge height that could not accommodate 13 mm implant, uncontrolled diseases or conditions that could impede bone healing or soft tissue health, mental, emotional or lifestyle factors that could adversely impact treatment or follow up were excluded from the current contemplate.

### Patient Population

All patients had at least 4 mm 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, who had ridge width of 4 mm to 4.5 mm, received Mini implants of 2.8 mm diameter, while others who had a ridge width more than 4.5 mm received Midi implants with a diameter of 3.3 mm or 3.8 mm. The patients were carefully 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 2 to 5 Mini or Midi implants in the mandibular interforaminal area. The selection of the number of the implants to be positioned was dependent

on the clinical assessment of the individual patient. Clinical considerations included the ridge width and shape, the opposing jaw (being partially or completely edentulous) and the allocation of the occlusal forces.

There were two patients suffering from aggressive periodontitis, eleven patients were smokers, two patients developed lung cancer and were subjected to chemotherapy after placement of the implants by 2 and 4 years. Five patients started bisphosphonate therapy three years after implant placement.

### Pre-Surgical Evaluation

Pre-surgical radiographic assessment was carried out with panoramic radiographs, periapical radiographs and cone beam computed tomography (CBCT) whenever indicated. The ridge width was evaluated through the diagnostic casts, ridge-mapping or directly using calipers. Prior to surgery, final impressions of the arches were taken and working model casts were made. The models were mounted on an articulator after bite registration on occlusal rims for establishing the centric relation. Try-in was made and the fit was confirmed with the patients.

### Implants

One hundred and eight (108) OsteoCare™ Mini and Midi one-piece ball-type implants (OsteoCare™ Implant System, London, United Kingdom) (53 Mini, 55 Midi) were used in the current contemplate. Mini implants are of 2.8 mm diameter, while Midi implants have diameters larger than 3 mm. 53 Mini implants with diameter 2.8 mm, 28 Midi implants with diameter 3.3 mm, and 27 Midi implants with diameter 3.8 mm and lengths 13 or 16 mm

were placed. The implants comprised a grit-blasted and acid-etched surface combined with high load buttress, self-tapping threads that permit maximum bone to implant contact. This design resulted in achieving high initial stability even in poor quality bone. The conical macro-design of the Mini and Midi implants offered the advantage of allowing compression and expansion of the bone during insertion. The amount of bone expansion required can be guided with variant tapers, created using incremental implant diameter.

## SURGICAL PROTOCOL (FLAPLESS TRANSMUCOSAL TECHNIQUE)

### Marking of the Drilling Sites

Using a skin marker, marks were prepared directly onto the patient's dried mucosa covering the alveolar ridge to establish the drilling positions of the implants, as planned from the diagnostic casts and panoramic radiograph.

### Site Preparation

Only one perforation profile drill (1.3 mm diameter) was used for site preparation to give needle point accuracy for position, angle and depth. The use of saline was paramount during making the perforation. As the drill passed through the mucosa (transmucosal), it firstly reached the cortical bone then the cancellous bone. Verification 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 surpass the implant length as the Mini and Midi implants have a strong self-tapping property.



**Figure 1:** Clinical photograph showing 4 Mini ball-type implants placed in 2004.



**Figure 2:** After 11 years postoperative clinical photograph of the same patient from Figure 1 showing the 4 Mini ball-type implants in 2015.

### **Implant Placement**

The implant was removed from its protective pouch and delivered 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.

### **Immediate Loading (Same day of implant placement)**

The initial stability (primary fixation) of the Mini and Midi implants was checked by the torque wrench to validate that initial primary fixation was beyond 30Ncm which was crucial to commencement of loading.

### **Relief of Denture to Accommodate the Housings**

Holes were done in the denture at the pre-

marked positions by means of a laboratory bur. The polycarbonate housings were fixed to the implants and checked to guarantee that they were steadily seated with full passivity. Try-in of the denture was made to check full seating without biting the housings.

### **Pick-up of the Housing (chair-side pickup procedures)**

Once the spaces for the housings had been relieved, they were packed 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. 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.





**Figure 3:** Immediate post-operative panoramic radiograph from Figure 1 after placement of the 4 Mini implants in year 2004.

## FOLLOW-UP

The follow up period extended to the end of year 2015 and ranged from 5 to 11 (Figures 1-4) years with a mean of 5.4 years. Each patient underwent comparative radiographic evaluation using the 6-months postoperative implant placement panoramic radiograph against the previous follow-up radiograph of the follow-up period.

The clinical criteria evaluated at the follow-up intervals were survival rate, pocket depth, Periotest M (Medizintechnik Gulden, Bensheim, Germany) values and radiographic crestal bone level. The following criteria were used to evaluate implant success: (1) Lack of clinically evident mobility, (2) No indication of peri-implant radiolucency on periapical radiographs, (3) Absence of peri-implant infection, (4) No complaint of pain at the location of treatment, (5) Lack of neuropathies or paraesthesia, (6) Crestal bone loss not more than 1.5 mm by the end of first year of functional loading and less



**Figure 4:** After 11 years postoperative panoramic radiograph of the same case from Figure 1 in year 2015.

than 0.2 mm/year in the ensuing years according to the criteria proposed by Albrektsson et al, 1986,<sup>33</sup> (7) Through the follow-up time, panoramic and periapical radiographs were obtained at implant insertion and consequently at the follow-up intervals to assess crestal bone loss.

Periotest M was used to evaluate the implant stability. Periotest M values (PTM) of (-8 to 0) are considered the ideal values that signify successful osseointegration. For appraisal 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 Branemark et al.<sup>29,34</sup>

## RESULTS

The study evaluated 108 mini and midi implants placed in 31 patients that were restored immediately with mandibular overdentures. The patients' age range was between 28 years and 80 years with a mean of 61 years. The sex distribution was 15 females and 16 males. The patients

received between 2 and 5 implants to support the overdentures. Eight patients received 2 implants, two patients received 3 implants, 19 patients received 4 implants, and two patients received 5 implants. The number of implants was decided upon an individual case basis and subject to the available bone in the anterior region of the mandible between the mental foramina. Three implant diameters were used, 2.8 mm (53 implants), 3.3 mm (28 implants), and 3.8 mm (27 implants). The lengths of the implants were 13mm (102 implants) and 16mm (6 implants).

Complete soft tissue healing was generally monotonous in all patients within the first two weeks after implant placement. The patients reported minimal postoperative swelling or pain experiences with no incidence of hematoma and minimal need for medications and analgesics. Most patients returned to their normal lives the day subsequent surgery.

All the patients were followed-up for a minimum of 5 years with a mean of 5.4 years; two patients were followed-up for six years, one for eight years, and one for 11 years. Two patients (each had two implants) developed lung cancer after 3 years of implant placement and they were subjected to chemotherapy. Five patients started bisphosphonate therapy after three years from implant placement. Eleven patients were smokers.

Fifteen O-rings housings were replaced due to damage or loss. Two patients presented with a broken denture one after 5 years and the other after 11 years and new dentures were remade.

The patients whom started chemotherapy were instructed to decrease the use of their dentures to the absolute minimum during the period of the treatment and for a period of 4 weeks following the end of the chemotherapy.

One of the two patients also was under bisphosphonate treatment with the chemotherapy.

The baseline data for the evaluation was set at the readings obtained after six months of implant placement, with comparative evaluation of the parameters being performed at the end of the entire follow-up period. The mean marginal bone loss at the end of the follow-up was  $0.42 \pm 0.14$  mm for all the 108 implants. Paired-t test was used to conduct the statistical analysis between the baseline and the follow-up which concluded insignificance: with a p value: 1.22 (significance at  $< 0.001$ ) and at a confidence interval of 95%. The mean Periotest M values (PTM) at the end of the follow-up period was -0.9. Paired-t test was used to do the statistical analysis between the baseline data and the follow-up which concluded insignificance with a p value: 1.87 (significance at  $< 0.001$ ) and a confidence interval of 95%. The mean pocket depth at the end of the five year follow-up was  $1.79 \text{ mm} \pm 0.09$  for all the 108 implants. Paired-t test was used to perform the statistical analysis between the baseline and the follow-up which concluded insignificance with a p value: 1.73 (significance at  $< 0.001$ ) at a confidence interval of 95%. The total survival rate of the implants was 100%. Review of the patients' satisfaction questionnaires showed subjective answers that demonstrated a very high degree of satisfaction from the treatment outcome.

## DISCUSSION

The survival and success rates attained in the present study are consistent with the results of Griffiths et al.<sup>35</sup> whom presented success rates over 97.4% and concluded that, "the use of mini-dental implants are a highly successful treatment option" and that the implants are "relatively afford-

able and overall patient satisfaction is excellent". Nearly the same results were reported by Zahran et al.<sup>36</sup> with a survival rate of 97.3% attested after 18 months follow-up period. Furthermore, a retrospective study on 510 narrow diameter implants over a period of 88 months by Degidi et al.<sup>37</sup> have shown survival rates of 99.4%. The high success rate in this study may be attributed to the fact that the location of the implants was in the anterior mandible which presents good bone density, therefore providing an ideal bed to attain excellent initial stability for the implants. It is considered that the macro geometric design of the implants played a main role in achieving this primary stability, as was reported by several authors<sup>38,39</sup> that the conical implant design in conjunction with an undersized drill form leads to initial higher stability than conventional implants, this was evident by the Periotest M values obtained. In addition, the survival rates of the mini and midi implants are comparable to that of immediate-loaded conventional-diameter implants supporting mandibular overdentures.<sup>40,41</sup>

Regarding the Periotest M values attained; the results are similar to other studies on mini and small diameter implants<sup>42,43</sup> but are higher than those reported with standard-diameter implants in the anterior mandible.<sup>43,44</sup> These results may be attributable to the fact that mini-implants possess a higher flexural modulus than standard-diameter implants.<sup>43</sup>

It should be noted that the decreased implant diameter does not affect osseointegration as was demonstrated by Block et al.<sup>45</sup> who examined the effect of implant diameter on the required pull out force after 15 weeks for osseointegration, and concluded that no correlation was found to the diameter but only with its length. Fur-

thermore, in a clinical study by Renouard and Nisand<sup>46</sup> it was concluded that short implants were often accompanied by failure but long narrow implants demonstrate good prognosis.

The bone loss associated with the study of mini and midi implants is similar to that reported for narrow and standard-diameter implants.<sup>42,43,47</sup> This may be related to the fact that although the reduced implant diameters are subjected to higher load transfer through horizontal forces as compared to conventional diameter implants causing increased marginal bone loss,<sup>48</sup> the utilization of a flapless approach results in minimal disruption to the periosteum, preserves peri- and endosteal blood supply and preserves the bone height around the implant post surgically.<sup>10,49</sup> Another factor that aids in bone change maintenance around mini implants is their design which allows an auto-advance technique that results in increasing the bone density in the immediate surrounding area and thus minimising crestal bone loss due to their osseo-compressive properties.<sup>50</sup> Furthermore, the prosthetic connection and the pick-up technique of the attachment play a major role in bone preservation. Since the pick-up of the attachment is done under bite force, most of the vertical forces are borne by the soft tissue.<sup>51</sup> Finally, the use of resilient O-ring attachments allows for shock absorbing properties and a reduction of the bending movements on the mini-implants.<sup>49,52</sup> The effect of smoking on marginal bone loss was insignificant in this study, which is in accordance to the findings of Sanna et al.<sup>53</sup> whom, when using flapless implant insertion, did not observe any significant change in marginal bone levels between smoking and non-smoking patients after 1-year follow-up.



Chemotherapy has been identified as an absolute but temporary contraindication to implant therapy by Zitzmann et al.,<sup>54</sup> but there was no direct association between implant failure and survival rate and a history of chemotherapy.<sup>55</sup>

Due to the limited available literature on the management of implant patients subjected to chemotherapy, the management of the patients in this study was both preventive and symptomatic. As the more common oral complications with chemotherapy are mucositis, xerostomia and bleeding tendency (which are all reversible if not complicated with infection) are all inter related and in severe conditions, the development of osteonecrosis (ON),<sup>56</sup> management should be preventive. Therefore the patients were instructed to reduce the use of their dentures in an attempt to reduce tissue injury due to mucositis during the treatment period. Usually the oral side effects of chemotherapy subside after a period of two to four weeks<sup>57</sup> after which the patients could use their dentures again, and it is recommended to use sialogogues thereafter to counteract the effects of xerostomia and prevent mucosal ulcerations.<sup>56</sup>

Bisphosphates (BP) are used for the treatment of osteoporosis, some bone diseases as Paget's disease and may also be used in the management of cancer patients in conjunction with chemotherapy.<sup>58</sup> The major complication associated with BP is ON of the jaws, which has been related to the strength and half-life of the BP.<sup>59</sup>

There is much controversy in available literature about the effects of BP and dental implants in relation to the development of ON. Several studies reported no correlation between them as reported in the present study. One retro-

spective study by Fugazzoto et al.<sup>60</sup> reported no cases of ON in 61 patients treated with BP for periods ranging from 1 to 5 years (an average of 3.3 years). Also in a controlled study on ON around dental implants by Jeffcoat,<sup>61</sup> it was reported that there were no statistical significances between osteoporotic patients under BP treatment and the control group.

The American Association of Oral and Maxillofacial Surgeons<sup>62</sup> presented performance guidelines for patients treated with BP. The guidelines divided these patients into two categories: 1) patients under intravenous BP therapy for cancer therapy, present a contraindication to dental implants, 2) patients undergoing oral BP therapy may be divided into three possible subcategories: (a) Treatment for less than 3 years have no clinical risk to dental implants, (b) Treatment for less than 3 years in combination with corticoids, BP must be stopped for at least 3 months and should not be re-administered before complete healing of the bone, (c) Treatment for more than 3 years, dental implants could be placed only if the BP are stopped for at least 3 months and should not be re-administered until complete healing of the bone occurs.

## **CONCLUSION**

The use of Mini and Midi implants for the retention of mandibular overdentures has been proven to be a viable and predictable option for the management of mandibular edentulism. They are of particular importance in clinical situations that would otherwise disregard larger implants as a treatment option. In addition, from a patient's perspective: the high success rate associated with this treatment option in consid-

eration with the advantages gained from implant size, minimal surgical technique, lack of need for further surgical intervention and long-term serviceability provide additional comfort and satisfaction. Based on the long-term results of Mini and Midi implants and the increased life span of patients due to advancements in medical care and life styles, it is recommended that further controlled studies be formulated to evaluate the effects of medical conditions and medications on the use and serviceability of previously placed implants to be able to reach special consensus for such arising conditions. ●

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**Disclosure**

The authors report no conflicts of interest with anything in this article.

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