Immediate Loading of Two Implants Supporting a Ball Attachment-Retained Mandibular Overdenture: A Prospective Clinical Study

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ABSTRACT

Background: A prospective clinical study was conducted to evaluate clinically and radiographically the performance of two implants immediately loaded supporting a ball attachment-retained mandibular overdenture.

Materials and Methods: Seventeen completely edentulous patients were included in the study. Each patient received two implants inserted after a minimal flap reflection and no vestibular extension in order to reduce the postoperative swelling and facilitate immediate prosthesis connection. After implant placement, a mandibular complete denture was connected to the implants using ball attachments of appropriate height according to the depth of the peri-implant tissue. Patients were asked not to remove the denture for 1 week. No limitations to chewing function were given. At implant placement, the maximum value of insertion torque was recorded. Patients were examined at 1, 2, 4, 12, and 52 weeks postsurgery. At postoperative visit, occlusion was checked and the need for any prosthesis maintenance was recorded. The radiographic bone level (RBL) change was measured on periapical radiographs at baseline and 12 months after loading.

Results: After 12 months of loading, no implant failure was reported and the survival rate was 100%. Average RBL change was 0.7 mm ± 0.5 mm. Of the 17 cases, two had major prosthetic complications and five patients required minor extra maintenance appointments.

Conclusions: The immediate loading of two implants by means of ball attachment-retained mandibular complete denture may be a predictable treatment option. This clinical approach offers increased stability and comfort, while keeping a high implant success rate.

KEY WORDS: dental implant, freestanding attachments, immediate loading, overdenture, retentive ball anchors

INTRODUCTION

The progressive bone resorption of the edentulous ridge is the main concern when rehabilitation of the edentulous mandible using a complete denture is considered.[1] Complete dentures are not sufficient for reestablishing the oral function either in relation to chewing efficiency[2] or bite force.[3] In cases of extreme bone resorption, with an appropriate impression technique, adequate prosthesis stability may be achieved, but rarely sufficient retention.[4] Ledger,[5] in 1856, suggested to utilize natural teeth to stabilize removable prostheses and a century later, Miller[6] introduced the concept of tooth-retained overdenture. Currently, implant-retained overdentures (IODs) represent a valuable treatment alternative for completely edentulous patients. Usually, when making IODs, the matrices of the bar or the freestanding attachments are connected 3 to 6 months postimplant placement,[7] when the process of osseointegration is considered clinically completed. During this critical healing phase, patients are asked not to wear the removable prostheses for at least 2 to 4 weeks after the surgery.[8] Then, a series of time-consuming

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appointments for soft relining are necessary to maintain the complete denture stable and clean without jeopardizing the implants' healing.[9] For a long time, the immediate loading of dental implants has been considered detrimental for osseointegration,[10] but the *dogma* of the 3- to 6-month healing without loading was based on empirical data.[11] Clinical research on different implant systems has shown that the healing period can be safely shortened without jeopardizing osseointegration and implant success rate.[12–14] It has also been demonstrated that interforaminal dental implants can predictably be loaded immediately after placement with full-arch fixed restorations.[15–17] Data on partially edentulous patients, treated with immediately loaded implants supporting either a single tooth or fixed partial dentures, seem to be also encouraging.[18–21] Moreover, clinical studies demonstrated that immediate loading of two to four implants splinted with a gold bar and retaining a tissue-supported mandibular overdenture is a valuable treatment option.[22–24] Several clinical reports demonstrated early loading (at 1–3 weeks after implant placement) to be successful when two implants and freestanding attachments were used.[25,26] However, few and inconclusive data are available on immediate loading of two unsplinted implants retaining a mandibular denture with a freestanding type of connection.[27]

The present study aimed to evaluate clinically and radiographically dental implants with titanium oxide surface (MK III® TiUnite, Nobel Biocare AB, Göteborg, Sweden) immediately loaded by means of a complete denture retained by two ball attachments.

MATERIALS AND METHODS

The research protocol was approved by the Institutional Review Board of the School of Dentistry of the University of Bologna, and the patients were selected among the patient population of the Department of Prosthodontics.

Patient Selection

All patients scheduled for IOD were asked to participate. A preoperative prosthetic evaluation of the existing prostheses was made to establish their quality and the eventual need for a new set of complete dentures before the implant placement. After signing the informed consent, the patients were consecutively included in the study, provided that they fulfilled the following inclusion criteria: (1) complete mandibular edentulous arch; (2) sufficient amount of bone volume for placement of implants with a minimum length of 8.5 mm; (3) healed bone sites, at least 4 months postextraction; (4) no need for bone augmentation; and (5) sufficient implant primary stability: insertion torque (IT) $\geq$ 20 Ncm.

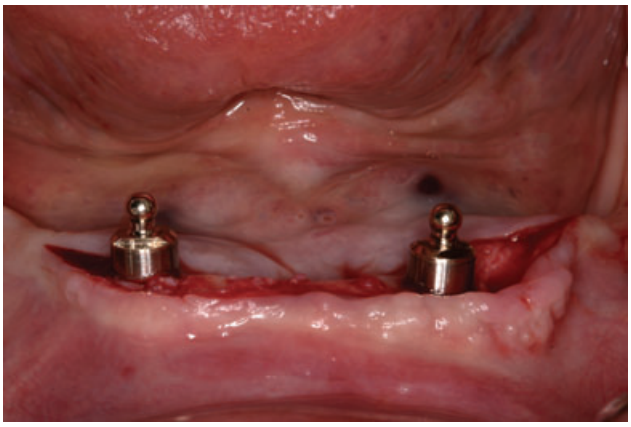

Figure 1 Implants inserted with minimal flap extension and no buccal elevation to reduce the postoperative swelling.

Patients were excluded from the study if (1) the treatment could affect the patient's health condition because of the presence of severe systemic diseases (ASA status 3 and above), active infections, or neoplastic lesions in the area of concern and (2) patient cooperation appeared questionable.

Surgical Treatment

The implants, two MK III TiUnite, were inserted under local anesthesia (mepivacaine 2%, Ogna Farmaceutici, Milan, Italy) following the use of prophylactic antibiotic medications consisting of 2 g of amoxicillin (Pharmacia Italia, Milan, Italy) 1 hour before the surgical procedure. After crestal incision, a full-thickness flap was raised and elevated only in the lingual side to reduce postsurgical edema in the vestibule and to allow surgical access to the lingual aspect of the mandible (Figure 1). The implant osteotomy site was prepared using the 3-mm twist drill as final drill. If a thick cortical bony crest was present, a 3.15-mm drill was utilized. The implant position was decided with a radiographic/surgical guide based on the duplicate of the complete denture and CT scan evaluation. Implants were inserted without screw tapping and the peak of IT was measured during the seating of the most coronal four to five implant threads by means of the Osseocare® surgical unit (Nobel Biocare AB), and recorded as 20,30,40,50 Ncm IT category. Whenever the torque needed for the insertion exceeded 50 Ncm, (the

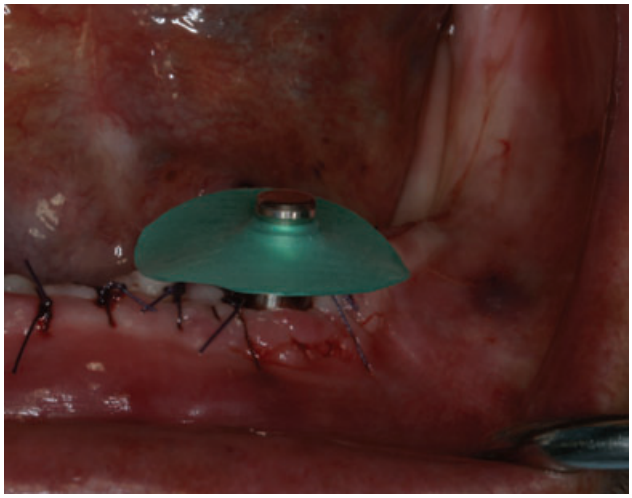

Figure 2 When the sutures are completed, the matrices are placed on the ball attachments and isolated with a portion of a sterile rubber dam before intraoral pickup.

maximum torque allowed by the Osseocare surgical unit), the manual wrench (Nobel Biocare AB) was utilized and the IT was reported as >50 Ncm. Following implant insertion, a ball attachment was connected to the fixture with 32 Ncm torque using the Osseocare® machine. The flap was sutured with a 5-0 suture (Polysorb™, USS-DG, Norwalk, CT, USA). All the surgical procedures were performed by the same operator (G.P.S).

Prosthetic Treatment

The complete denture was modified by creating in the intaglio the housing for the matrix of the attachment. The appropriate space without interferences was checked with a pressure-indicating silicone media (Fit Checker®, GC, Tokyo, Japan). Once the appropriate passive relief of the denture was completed, the attachment was picked up intraorally with cold-curing acrylic resin. To avoid contact of the resin with the sutures and the surgical wound, a circular portion of a sterile rubber dam sheet was adapted on the gold cap attachment once placed on the ball-shaped abutment during the pickup procedure (Figure 2). Occlusion was then checked and eventually adjusted as well as the adaptation on the residual ridges, and the patient was dismissed. As postsurgical instructions, the patients were asked not to brush the operated areas and to rinse instead with 0.12% chlorhexidine solution (Dentosan®, Pfizer Italia Srl, Rome, Italy) twice a day for 1 minute for 14 days. Pain control was provided with 400-mg ibuprofen (Brufen®, Boots Healthcare Spa, Milan, Italy) as needed. No limitations to chewing function were given. Sutures were removed after 2 weeks. The patients were instructed not to remove the prosthesis for 1 week.

Follow-Up Visits

Patients were recalled at 1, 2, 4, 12, and 52 weeks after surgery. At the postoperative visit, occlusion was checked as well as the stability and retention of the prostheses and the need for any prosthetic maintenance. The number and nature of any unplanned visit was also recorded. Periapical radiographs were taken at baseline and the 12th-month visit by a paralleling technique using a Rinn® (Dentsply RINN, Elgin, IL, USA) film holder. The radiographs were taken in a way that the platform and the threads were clearly visible both mesially and distally (Figure 3).

Radiographic Bone Level (RBL) Change

RBL change was measured on the periapical radiographs. A calibrated examiner made the bone height measurements. An image analysis software (Digora for

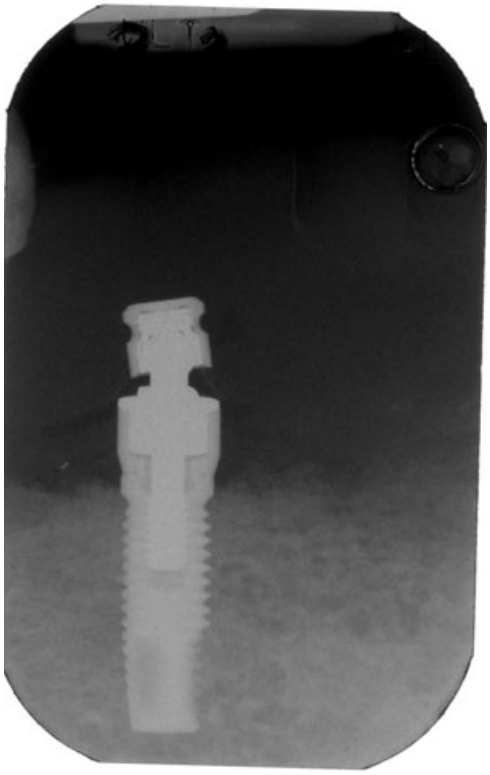

Figure 3 A periapical radiograph of an implant immediately after placement and prosthetic connection. The implant threads are clearly seen both mesially and distally.

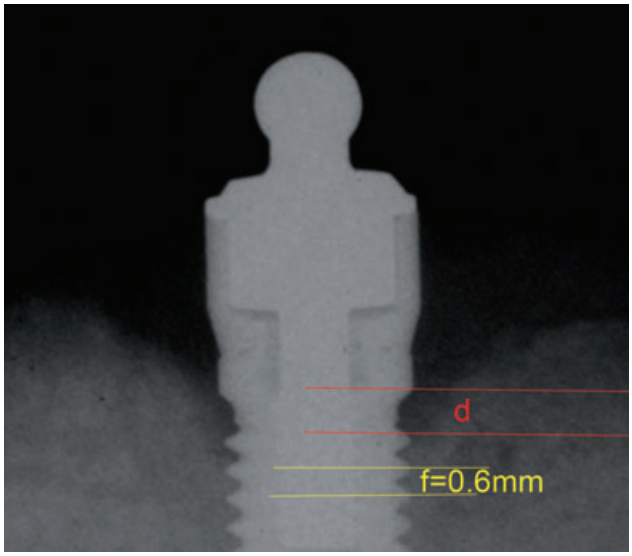

Figure 4 Using an image analysis software, the radiographic bone level change is measured. The software is calibrated using the known distance between the implant threads (f = 0.6 mm) as the reference to determine the bone-loss level ("d").

Windows 2.5, Soredex, Tuusula, Finland) was used to measure the distance between the lower border of the implant shoulder and the most apical level of the bone deemed to be in contact with the implant surface (Figure 4). The bone level at surgery was defined as baseline. Mesial and distal bone height measurements were averaged for each implant. The RBL change was calculated as the difference between the readings at 1 year and the baseline value.

Implant Success and Failure Criteria

The success criteria for the implants were (1) no radiolucency around the implant, (2) no mobility, and (3) no suppuration, pain, or ongoing pathologic process. Implants that did not fulfill the success criteria were considered as failed.

Statistical Analysis

The data relative to the patient population and the implants were analyzed with descriptive statistics and presented as means with standard deviation, percentage, and distribution among the sample.

RESULTS

Implant-Related Outcomes

Seventeen patients (11 females and 6 males) were included in the present clinical trial, with a mean age of 65.82 years (range 36–91). Thirty-four implants were placed supporting 17 complete dentures immediately loaded after implant placement. Every patient received two dental implants within the mandibular foramina approximately in the canine position.

All patients participated until the end of the study; no clinical dropout occurred. Patients healed with minor discomfort; no swelling or surgical complications were reported. All the implants placed fulfilled the study requirements. Overall, the survival rate (SR) after 1 year of function was 100%. IT distribution is reported on Table 1. RBL change distribution is reported on Table 2, and implant length and diameter distribution are reported in Table 3. The average RBL change after 1 year of function was 0.7 mm ± 0.5 mm (range 0–1.90).

Prosthetic Outcomes

Clinical complications and need for extra maintenance were recorded on 7 of the 17 patients, as reported in Table 4. Major complications occurred only in two cases (patients 3 and 11). In these two patients the dentures fractured twice; therefore, they were repaired the second time with a complete laboratory reline by adding also a metal framework inside the prostheses to increase fracture resistance, and the gold cap attachments were repositioned. In patient 3, the fracture of the prosthesis was probably caused by screw loosening of the ball attachments. Patient 11, before the fracture of the complete denture, had an intraoral reline by simply adding cold-curing acrylic resin in the portion of the prosthesis between the implants. Patients 1 and 12 had the original gold cap attachments matrices substituted with new ones because of early wear. Patient 7 had the gold cap attachments repositioned 2 months from surgery. Patients 13 and 17 had an intraoral reline by simply

TABLE 1 Peak of Insertion Torque (IT) Distribution at Implant Placement

Peak of IT (Ncm)	20	30	40	50	>50
Number of implants	3 (9%)	8 (24%)	9 (26%)	4 (12%)	10 (29%)

TABLE 2 Radiographic Bone Level (RBL) Change Distribution at 12 Months

ΔRBL (mm)	<0.5	0.5–1	>1–1.5	>1.5–2	>2
Number of implants	13 (38%)	14 (41%)	3 (9%)	4 (12%)	0

adding cold-curing acrylic resin in the portion of the prosthesis between the implants to increase stability.

DISCUSSION

The 100% SR of dental implants observed in the present study is comparable to previous reports relative to ball-retained overdentures.[22–24,28–30] The only study that evaluated immediate loading of dental implants supporting ball attachment IOD showed a SR of 96.5%.[27] However, in this last report, the housing for the attachments in the mandibular dentures were filled with impression material and the retaining mechanism was not connected immediately to the ball attachments to reduce potentially negative forces on the implants. Conversely, in the present investigation, the prosthesis was delivered immediately after surgery, with a fully functional connection of the attachment mechanism of the ball attachment.

RBL change after 1 year of function was within the value reported in the literature and was consistent with a previous report on implant-supporting bar-retained overdenture loaded immediately.[31] The high CSR and the limited peri-implant bone remodeling observed in the present investigation may be a result of several factors, which include implant primary stability, prosthetic design, and control of the occlusal forces.

Implant primary stability at the time of surgical placement is one of the most important clinical parameters to avoid excessive micromovement when immediate loading is attempted.[9] Implant stability depends on bone quality and implant design.[32] The bone quality at the implant site, in the present study, was quantified by the peak of IT[33]; 41% of the implants placed were inserted with an IT $\geq$ 50 Ncm, and 67% of the implants had an IT above 40 Ncm. Moreover, the screw-shaped implant design used in this investigation seems to allow the most favorable mechanical retention,[34] reducing interfacial shear stress in favor of compressive forces to the peri-implant bone.[35]

TABLE 3 Implant Size Distribution

Implant length (mm)	8.5	10	11.5	13	15
Number of implants (diameter = 3.75 mm)	2	0	0	2	0
Number of implants (diameter = 4 mm)	0	8	16	5	1

Implant surfaces with a roughness ranging between 0.9 and 1.5 μm seem to enhance cell differentiation and bone deposition during the early healing phase.[36,37] The implants used in this investigation have a surface modified by titanium oxide (TiO_2) deposition through a process of anodic oxidation. This method results in a TiO_2 layer and a porous structure with a roughness ranging from 0.8 to 1.2 μm from the coronal part to the apex, respectively.[38] Animal experiments and histology of clinically retrieved implants with a TiO_2 surface have demonstrated a rapid establishment of a firm direct bone-implant contact.[39,40] It seems that bone integration can occur through so-called contact osteogenesis,[41] implying bone formation directly to the implant surface. Histological evidence in animal studies[42] showed that, immediately after placement, the implant is supported by mechanical interlocking with the bony wall of the osteotomy site. During the early phase of healing, the bone in contact with the implant surface goes to necrosis and remodeling; simultaneously, newly formed bone emerge from the host bone toward the implant. Between the second and fourth week of healing, the balance between the newly formed bone and the parent bone is critical to provide support to the implant against dislocating forces. The use of an implant surface that enhances bone deposition, ensuring implant secondary stability (osseointegration) in a short period of time, may be significant for the clinical success of immediate loading. Hence, it may be speculated that the implant surface used in this investigation may partly explain the clinical outcome.

To reduce the detrimental forces over the implants when immediate loading of IOD is planned, the prosthetic treatment should be carefully designed. In the present report, the need for a precise adaptation and equilibration of the prostheses before the surgical

TABLE 4 Prosthetic Complications That Occurred during Treatment

	Type of prosthetic maintenance							
Patient	Screw loosening of ball attachments	Fractured denture teeth	Fractured prostheses*	Fractured opposing denture	Intraoral reline†	Laboratory reline	Detachment of matrix	Repositioning‡ and/or replacement§ of matrix
1	0	0	0	0	0	0	0	1‡
2	0	0	0	0	0	0	0	0
3	2	0	2	0	0	1	0	1‡
4	0	0	0	0	0	0	0	0
5	0	0	0	0	0	0	0	0
6	0	0	0	0	0	0	0	0
7	0	0	0	0	0	0	0	1§
8	0	0	0	0	0	0	0	0
9	0	0	0	0	0	0	0	0
10	0	0	0	0	0	0	0	0
11	0	1	2	0	1	1	0	1‡
12	0	0	0	0	0	0	0	1§
13	0	0	0	0	1	0	0	0
14	0	0	0	0	0	0	0	0
15	0	0	0	0	0	0	0	0
16	0	0	0	0	0	0	0	0
17	0	0	0	0	1	0	0	0
Total	2	1	4	0	3	2	0	5

*Two prostheses fractured twice and were repaired with a laboratory reline and the addition of a metal framework inside the prostheses.
†Acrylic resin was added in the portion of the prostheses between the ball attachments.
‡,§Matrices were replaced and/or substituted in pairs.

procedure is emphasized. A stable and retentive prostheses may allow proper healing of the immediately loaded implants by reducing excessive micromotion.

Attard and colleagues[43] evaluated bar clip-retained prostheses and questioned whether the immediate loading of IOD is a cost-effective clinical procedure. They reported more prosthetic complications and need for maintenance when an immediate loading approach was used compared with the conventional approach; the prosthetic shortcomings included clip dislodgement, tooth fractures, and the need for acrylic resin addition/reline. The data on freestanding attachments reported in the present study disagree with those findings. In our sample, minimal prosthetic interventions were necessary as only four prostheses were modified either by a laboratory or clinical reline. The other complications reported were minor, easy to solve, and not attributable to the immediate loading protocol. The low frequency of major complications could be a result of two factors. First, the minimal flap design with no buccal elevation, used during the implant placement, significantly reduced postoperative swelling. This allowed to maintain intact the intaglio of the prostheses, with the exception of the area correspondent to the implants where the gold cap attachments were picked up. Hence, the need for a complete relining was minimized. Second, the use of ball attachments allowed for negligible modification of the prostheses compared with a bulky bar-clip design that needs more space to be adapted in the prostheses and consequently weakens the complete denture. Thus, the risk of prostheses fracture was reduced.

CONCLUSION

In conclusion, within the limit of the present trial, the immediate loading of two mandibular implants with a fully functional ball attachment-retained mandibular complete denture seems to be a suitable alternative treatment option, provided that primary stability of the fixtures is achieved and occlusal forces are well distributed with careful occlusal equilibration and functional adaptation of the prostheses. Nevertheless, further investigations on a wider patient population are certainly needed to confirm this finding.

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