Immediate rehabilitation of the edentulous jaws with full fixed prostheses supported by four implants: interim results of a single cohort prospective study

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Abstract
Objectives: The purpose of this study was to prospectively evaluate the clinical and radiographic outcomes of immediately loaded full-arch fixed prostheses supported by a combination of axially and non-axially positioned implants in a large cohort of patients with completely edentulous jaws, up to 5 years of function.

Materials and methods: One hundred and seventy-three edentulous patients (80 males and 93 females) were enrolled according to specific selection criteria. Each patient received a full-arch fixed prosthesis supported by two distal tilted implants and two anterior axially placed implants. The provisional functional acrylic prosthesis was delivered the same day as surgery in all cases. All cases were enrolled 4–6 months later. The patients were scheduled for follow-up at 6 and 12 months of function, and annually up to 5 years. At each follow-up plaque and bleeding score was assessed and radiographic evaluation of marginal bone level was performed.

Results: The overall follow-up range was 4–59 months. A total of 154 immediately loaded prostheses (61 in the maxilla and 93 in the mandible) were in function for at least 1 year and were considered for the analysis. Four axially placed implants failed in the maxilla and one tilted implant in the mandible, all within 6 months of loading. No further implant failure occurred to date. Implant survival at 1 year was 98.36% and 99.73% for the maxilla and the mandible, respectively. Marginal bone loss at 1 year averaged 0.9 ± 0.7 mm in the maxilla (204 implants) and 1.2 ± 0.9 mm in the mandible (292 implants). No difference was found in marginal bone loss between axial and tilted implants. Plaque and bleeding scores progressively improved from 6 to 12 months. Fracture of the acrylic prosthesis occurred in 14% of total cases.

Conclusions: The present preliminary results from a relatively large sample size suggest that the present technique can be considered a viable treatment option for the immediate rehabilitation of both mandible and maxilla.

In the recent years, the immediate loading procedure for the rehabilitation of edentulous jaws using osseointegrated implants has gained popularity among clinicians. This was due to both the excellent success rates for several types of immediately loaded prosthetic reconstructions, and the technical advantages and simplification introduced by such procedure as widely reported in previous reviews [Attard & Zarb 2005; Ioannidou & Doufexi 2005; Del Fabbro et al. 2006; Nkenke & Fenner 2006; Avila et al. 2007; Esposito et al. 2007; Jokstad & Carr 2007; Semnerby & Gottlow 2008].

However, the rehabilitation of edentulous jaws is often complicated by poor bone...
quality, especially in the posterior region, and reduced bone volume due to long-term edentulism. Bone grafting procedures to increase the bone volume available for implant placement may be a viable treatment option but they often imply demanding surgical procedures and can be associated to complications, morbidity and high costs. Therefore their acceptance by patients is often poor.

In order to overcome such limitations, different therapeutic alternatives have been proposed, such as long distal cantilever [Shackleton et al. 1994], short implants [Goené et al. 2005; Renouard & Nisand 2005; Maló et al. 2007] or implants placed in specific anatomical areas like, for the maxilla, the pterygoid region, the tuber or the zygoma [Bahat 1992; Khayat & Nader 1994; Venturelli 1996; Balshi et al. 1999; Bränemark et al. 2004; Galán Gil et al. 2007; Aparicio et al. 2008; Maló et al. 2008]. Any of these procedures requires considerable surgical expertise and has its own advantages, limits, surgical risks and complications involving biological and financial costs.

In the last years, several clinical studies have reported that tilting of the implants may represent another feasible treatment option [Krekmanov 2000; Krekmanov et al. 2000; Aparicio et al. 2001; Fortin et al. 2002; Maló et al. 2003, 2005; Calandriello & Tomatis 2005; Capelli et al. 2007; Agliardi et al. 2008, 2009]. Such technique is related to several surgical and prosthetic advantages, like the possibility of placing long implants with improvement of bone anchorage, the reduction of the need for bone grafting, the avoidance of long cantilevers and the possibility of increasing the distance between anterior and posterior abutments, with improvement of the load distribution.

Furthermore, no difference in the marginal bone loss between tilted and axially placed implants, placed in either jaw has been reported, suggesting that tilting of the implants causes no detrimental effect on the osseointegration process [Krekmanov 2000; Aparicio et al. 2001; Capelli et al. 2007; Koutouzis & Wennström 2007; Agliardi et al. 2009]. A high degree of patient satisfaction was also reported as related to this clinical procedure [Capelli et al. 2007; Testori et al. 2008; Agliardi et al. 2009].

The aim of this prospective study was to assess the clinical and radiographic outcome of immediately loaded full-arch fixed prostheses supported by a combination of axially and non-axially placed implants in a large cohort of patients with edentulous jaws, up to 5 years of function. This article reports preliminary data on implants survival and peri-implant bone loss.

Materials and methods

Study protocol

This was an open, single cohort prospective study in which patients with severely resorbed mandible or maxilla were consecutively enrolled and treated.

The investigation was conducted according to the principles embodied in the Helsinki Declaration of 1975 for biomedical research involving human subjects, as revised in 2004. At the preliminary visit all patients were duly informed on the nature of the study and on any possible alternative treatment. Before enrolment a written informed consent was obtained.

Selection criteria

Patients of any race and gender were included in the study if they were at least 18 years old and in good general health condition, physically and psychologically able to undergo conventional implant surgery and restorative procedures (ASA-1, ASA-2). Further inclusion criteria were: presence of atrophic fully edentulous mandible or maxilla, in need for bone augmentation procedures, or presence of teeth with an unfavourable long-term prognosis; rehabilitation with oral implants was the elective treatment; patients manifested their preference for a fixed solution but were reluctant to undergo grafting procedures.

Exclusion criteria were: presence of active infection or inflammation at the sites intended for implantation; presence of systemic diseases (i.e. haematologic disease, uncontrolled diabetes, serious coagulopathies and diseases of the immune system), irradiation to the head or neck region within 12 months before surgery; presence of unresorbed allograft at the implant site; severe bruxism or clenching habits; pregnancy; poor oral hygiene; poor motivation to return for scheduled follow-up visits.

Preliminary radiographic screening was performed using panoramic orthopantomographs and computed tomography (CT) scans. A careful clinical examination of the patients was performed assessing jaw size and relations, bone volume and occlusal relations. Figs 1 and 2 show examples of a panoramic radiograph and a CT scan, respectively, for a patient included in the study.

The included patients were treated in a dental clinic by a single surgeon (E.A.) with considerable clinical expertise in immediate loading procedures.

According to the above criteria from April 2004 to January 2009 a total of 173 patients have been rehabilitated with an immediately loaded implant supported fixed full prosthesis supported by four implants in the mandible or in the maxilla. A total of 692 implants was inserted (404 in the mandible and 288 in the maxilla).

Pharmacological treatment associated with surgical procedure

Antibiotic prophylaxis was prescribed 1 h before surgery, consisting of 2 g of amoxicillin and clavulanic acid (Augmentin®, Roche S.p.A., Milan, Italy).

Starting 3 days before surgery and then daily for 7 days following surgery, chlorhexidine digluconate 0.2% mouthwash (Curasept®, Curaden HealthCare s.r.l., Saronno, Italy) was prescribed. A sedative presurgery medication with 5 mg i.v.

Fig. 1. Pre-operative OPG.
diazepam [Valium®, Roche S.p.A.] was administered.

Implant surgery was performed using local anaesthesia with articaine chlorhydrate 4% and epinephrin 1:100,000 (Alfacaina N, Weimer Pharma, Rastat, Germany).

Corticosteroids (dexamethasone 4 mg, Soldesam®, Laboratorio Farmacologico Milanese S.r.L., Milano, Italy), anti-inflammatory drugs (ketorolac tromethamine 30 mg, Lixidol®, Roche S.p.A.) and anti-acidity drugs (ranitidine, Zantac 50 mg, Glaxo Wellcome S.p.A., Verona, Italy) were given during the surgery.

For mandible, the mental foramina, the length of the mental nerve loop and the shape of the bone were assessed, using an atraumatic instrument, in order to determine the ideal angulation of the posterior implants.

Soon before implants placement all compromised teeth were extracted, when present, and sockets were carefully debrided.

All patients received four intraforaminal implants [Bränemark System™ MKIV or NobelSpeedy™ Groovy™, Nobel Biocare AB, Göteborg, Sweden]. At first the two distal tilted fixtures were placed. The drill was inserted crestally in correspondence with the alveolar nerve foramen and tilted by about 30° relative to the occlusal plane. Thereafter, the two mesial fixtures were inserted at the level of the lateral incisors.

Bone density was assessed by the clinician during the early phase of drilling and scored according to the Lekholm and Zarb classification [Lekholm & Zarb 1985]. The implant site was usually under prepared by avoiding countersinking, so as to maximize implant stability.

A torque controller (Osseocare™, Nobel Biocare AB) with a torque limit of 50 N cm was used during implant placement. A manual wrench was also used in case of incomplete seating of the fixture.

Multi-unit abutments (MUA™, Nobel Biocare AB) were connected to the implants. On the distal fixtures abutments with an inclination of 30° relative to the fixture axis were placed (n = 202), to allow for an optimal prosthetic screw access, while standard abutments were placed over the mesial fixtures (n = 202). A torque controller (Osseocare™, Nobel Biocare AB) with a torque limit of 50 N cm was used to tighten abutment screws at 25 N cm.

Surgical procedure for the maxilla

A crestal incision was performed starting from the pterygomaxillary region and a mucoperiosteal buccal flap was raised exposing the vestibular bony wall so as to identify the anterior wall of the maxillary sinus.

The most distal implants were firstly placed, engaging the anterior wall of the maxillary sinus. They were inserted with an angulation of about 30–45° relative to the occlusal plane. In order to control if the implant site was entirely bordered by bone and to assess the proper axis of the drill, a direction pin was positioned into the implant site before fixture insertion and a radiograph taken. In case of risk of perforation of the sinus membrane, the drilling axis was corrected. The two axial implants were then inserted in the lateral incisors position. All the implant sites were under-prepared avoiding countersinking so as engage as much cortical bone as possible.

Multi-unit abutments (MUA™, Nobel Biocare AB) were connected to the implants. On the distal fixtures, abutments with an inclination of 30° relative to the fixture axis were placed (n = 144), while standard (n = 127) or 17° (n = 20) abutments were placed over the mesial fixtures (n = 202). The same torque controller used for mandible was used to tighten abutment screws at 25 N cm.

Delivery of the provisional prosthesis

After positioning the coping, the soft tissues were sutured with a 5-0 resorbable suture [monocryl or vicryl], Johnson & Johnson Intl., St Stevens, Woluwe, Belgium and an impression was taken by means of a silicon putty [Elite Implant Impression Material, Zhermack S.p.A., Badia Polesine, Italy] directly on the coping. Healing caps were then positioned over the multi-unit abutments.
No later than 3 h of surgery an acrylic provisional prosthesis with 10 teeth was delivered. Again a torque controller was used to tight prosthetic screws at 15 N cm. Centric and lateral contacts were limited to the intercanine zone. An orthopantomograph was made to check implant position and the coupling between prosthetic components (Fig. 3).

**Post-surgical phase**

After surgery patients were instructed to avoid brushing and any trauma to the surgical site. Cold food was suggested for the first day and a soft diet for the first week. Pain killers (sodium naproxene, Synflex Forte®, Recordati, Milano, Italy) were prescribed in case of pain.

After 4–6 months of function, in the absence of pain and inflammation, the patients underwent the final prosthetic protocol. The final prosthesis was fabricated using the CAD-CAM Procera® System (Nobel Biocare, Stockholm, Sweden) (Fig. 4).

**Variables assessed**

The following outcome measures were evaluated in this study:

[a] **Implant survival**: Implant functional and stable (the stability of individual implants was tested using two opposing instruments’ pressure after unscrewing the prosthesis), no peri-implant radiolucency on radiographs, no suppuration or pain at the implant site, no signs of peri-implantitis, no neuropathies or persistent paraesthesia.

[b] **Marginal bone level**: All radiographs were scanned at 600 dpi with a scanner and the marginal bone level (the most coronal bone-to-implant contact) was assessed on mesial and distal aspects using an image analysis software. The implant neck was the reference for each measurement. Mesial and distal values were averaged so as to have a single value for each implant.

[c] **Plaque index and bleeding index**: Every implant was inspected on four sites. The sites in which plaque or bleeding could be detected were recorded as positive or negative, as described previously (Francetti et al. 2008).

[d] **Prosthesis success (i.e. prosthesis functional and stable)**: A prosthesis was considered failed if the function was compromised for any reason.

All biological complications such as peri-implantitis, periimplant mucositis, bleeding on probing, suppuration, fistulas, abscesses numbness of the lower lip or chin, as well as mechanical or prosthetic complications, like fracture of the implant or of any prosthetic component, were recorded.

**Follow-up**

During the first month after surgery the patients were seen once a week for control visits, in which tissue healing and prosthetic function were evaluated. Further visits were scheduled at 6 and 12 months and yearly thereafter up to 5 years.

During the first year plaque index and bleeding index were assessed every 6 months. Orthopantomographs and, when possible, periapical radiographs were taken at any scheduled control visit to assess the marginal bone loss and the overall bone level throughout the study. Fig. 5 shows OPT follow-up.

At the 1-year control visit stability of the implants and prosthesis as well as proper occlusion were also checked.

**Data analysis**

Cumulative implant survival rate was assessed using the Kaplan–Meier statistics.
Results

A total of 692 implants (92 Branemark System MKIV and 600 Nobel Speedy Groovy, all with TiUnite surface) were placed in 173 patients [80 males and 93 females, mean age at surgery 57.3 ± 8.5 (SD) years, range 42–74 years]. Forty-eight of the included patients (27.8%) were smokers. Seventy-two maxillary and 101 mandibular prostheses were delivered. All prostheses were supported by four implants. All implants could be seated with an insertion torque of at least 30 N cm. All provisional prostheses could be delivered the same day of surgery as planned.

Implant distribution according to implant type and implant length is detailed in Tables 1 and 2, respectively. The outcome analysis is based on those 154 patients (89% of total patients treated) that had their prosthesis in function for at least 1 year at the time of the present clinical report.

Ninety-three prostheses (372 implants) were immediately loaded in the mandible. The follow-up range was 12–53 months (mean value 26.9 ± 12.5 m). Patients had different types of opposing dentition: removable prostheses (50 cases), natural teeth (15 cases), natural teeth and fixed prostheses on teeth (three cases), implant-supported bridges (nine cases), natural teeth and two implant-supported bridges (four cases).

Sixty-one prostheses (244 implants) were immediately loaded in the maxilla. The follow-up range was 12–59 months (mean value 31.3 ± 14 m). The opposing dentitions were implant-supported fixed prostheses (25 cases), removable prostheses (22 cases), natural teeth (nine cases) and fixed prostheses on teeth (five cases).

No complications occurred during the surgical phase. None of the patients reported any post-surgical biological complication.

Four axially placed implants in the maxilla [in four female patients] and one tilted implant in the mandible [in one male patient] failed within 6 months of function, due to mobility. In all cases implant failure did not compromise prosthesis function. All implants could be successfully replaced. No late failures have been recorded to date. No relation was found between implant failure and the opposing dentition.

The overall cumulative implant survival after 1 year was 99.19% [98.36% and 99.73% for implants placed in the maxilla and mandible, respectively, as shown in the two life table analyses of Tables 3 and 4 that include only cases with more than 1-year follow-up].

The only prosthetic complication in this study was the fracture of the acrylic prosthesis that occurred in 24 cases [15.6%], of which 14 in the mandible [15%] and 10 in the maxilla [16.4%].

The average marginal bone loss after 1 year from implant placement was 0.9 ± 0.7 mm in the maxilla (204 implants in 51 patients) and 1.2 ± 0.9 mm in the mandible (292 implants in 73 patients). Such difference was not statistically significant. No significant differences in bone loss were found between axially placed and tilted implants.

A progressive decrease in plaque and bleeding scores was observed in the first year.

Plaque index averaged 29.1% at 6 months (from 153 patients) and 20.7% at 12 months (from 124 patients); bleeding on probing averaged 7.4% at 6 months and 2.6% at 12 months. The improvement at 12 months was statistically significant for both indexes.

Discussion

This prospective study aimed at evaluating the clinical and radiographic outcomes of a technique for the immediate rehabilitation of patients with edentulous jaws. The preliminary results indicate that such technique may lead to excellent prognosis, at least in the short term. To our knowledge, this is the largest prospective study on patients treated using a combination of axially placed and tilted implants in either jaw.

The excellent results of the present study are well comparable with previous retrospective [MALÒ et al. 2003, 2005] and prospective single cohort studies (Capelli et al. 2007; Agliardi et al. 2008, 2009; Testori et al. 2008) that adopted similar techniques. Indeed, in some of these prospective reports (Capelli et al. 2007; Agliardi et al. 2008, 2009; Testori et al. 2008), six implants instead of four were used for the immediate maxillary rehabilitation. Furthermore, a different implant system was adopted in two of these studies [Capelli et al. 2007; Testori et al. 2008], with a different type and angulation of the implant–abutment connection for the tilted implants, and also a different technique for the fabrication of the final prosthesis.

The incidence of fracture of the acrylic prostheses in the present study [15.6% of the total cases] was lower as compared with that reported by Malò et al. (2003) [27%], and similar to that previously reported by Francetti et al. (2008) and Agliardi et al. (2008) [11%]. This complication was observed mainly in men with a short face morphotype, usually between 3 and 6 months of function. It could be hypothesized that a possible cause for such trouble was the progressive modification of the diet, from a diet consisting of

| Table 1. Implant distribution according to the implant type |
|-------------------|------|-----|------|
| Maxilla           | Mandible | Total |
| MKIV              | 44    | 48  | 92   |
| Speedy groovy     | 244   | 356 | 600  |
| Total             | 288   | 404 | 692  |

| Table 2. Implant distribution according to the implant length |
|-------------------|---|---|---|---|---|---|
| Number of implants (% maxilla) | 18 (6.25) | 164 (56.94) | 49 (17.01) | 40 (13.88) | 17 (5.91) | 0 |
| Number of implants (% mandible) | 0 | 210 (51.98) | 101 (25) | 53 (13.11) | 28 (6.93) | 12 (2.98) |
| Number of implants (% total) | 18 (2.6) | 374 (54.05) | 150 (21.68) | 93 (13.44) | 45 (6.5) | 12 (1.73) |

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soft food to a one including hard food. Another factor in the genesis of provisional prosthesis fracture could be the progressive wear of the resin due to repeated deglutation and mastication cycles. It was noted that most of the fractures took place next to one of the anterior temporary abutments, which is a weak point of the prosthetic reconstruction. All the fractures had been promptly repaired by the clinician without sending the prostheses back to the laboratory, thereby avoiding further discomfort to the patient. No correlation between these fractures and the type of opposing dentition could be found.

For the rehabilitation of the edentulous mandible and maxilla, especially in those cases of extremely reduced posterior ridges, the ideal approach should endeavour at the following: minimization of the total number of implants to decrease surgical morbidity, reduction of the distal cantilever without compromising the functional support, avoidance of demanding bone grafting procedures and decrease of total treatment time and costs. The latter item may be achieved by adopting an immediate loading protocol. Another predictable and cost-effective solution for the immediate rehabilitation of the fully edentulous mandible can be represented by implant-supported overdentures (Bryant et al. 2007). However, due to their partial mucosal support in the posterior regions, patients with extremely reduced posterior mandible might experience pain due to compression of the retroforaminal zones during mastication.

With the present protocol the level of patient’s satisfaction was very good, post-surgical discomfort was limited and an immediate recovery of mastication and aesthetic function could be provided. In general, the treatment acceptance by patients was extremely favourable.

The progressive reduction of plaque and bleeding scores reflected a good compliance of the patients to the oral hygiene instructions. In this instance, the role of the dental hygienist could be of utmost importance, not only for the professional cleaning but also for its active role in patient’s education and motivation.

### Concluding remarks

The results of the present prospective study show that a combination of axially placed and tilted implant for the immediate rehabilitation of edentulous jaws leads to excellent clinical outcomes. The advantages of the immediate loading procedure, the reduced morbidity, the high patient’s satisfaction and the relatively low costs of this surgical technique should be taken into account when a decision among the alternative therapeutic options has to be made.

### References


