
Ich bedanke mich bei den unten aufgeführten Kolleginnen und Kollegen für ihre wertvolle Mitarbeit, die sie in den vergangenen zwei Jahren geleistet haben.

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Immediate loading of two unsplinted mandibular implants in edentulous patients with an implant-retained overdenture: an observational study over two years

Key words: immediate loading, implant overdenture, implant survival, unsplinted implants, patient satisfaction

Summary  Objectives: Immediate loading of two unsplinted mandibular implants by means of an overdenture may be a viable and cost-effective treatment option to improve the patient’s oral health-related quality of life. We therefore conducted a prospective observational study to estimate implant survival and patient satisfaction after an immediate loading protocol in edentulous patients.

Materials and methods: Twenty edentulous patients who received two interforaminal implants (Straumann Standard implant, length 12 mm) were included in our study. Immediately after implant placement, ball attachments with a diameter of 2.25 mm were placed on the implants and the respective matrices were directly incorporated in the existing complete denture. Clinical recalls were scheduled 1 week, 1, 3, 6 months, and 1 and 2 years after implant placement. The following clinical parameters were assessed: gingival bleeding index (GBI), visual plaque index (VPI), and soft tissue overgrowth. In addition, we also assessed radiological bone level change (RBLC) using panoramic radiographs, and patient satisfaction using a visual analogue scale at baseline, after 6 months and 2 years.

Results: No implant failures occurred during the 2-year observation period, resulting in a survival rate of 100%. The mean RBLC was 0.67 mm (95% Confidence Interval [95% CI]: 0.47–0.86 mm) two years after surgery. The GBI and VPI after two years were 24 (95% CI: 9–38)% and 36 (95% CI: 19–53)% respectively. Soft tissue overgrowth was 1.6 mm (95% CI: 1.1–2.1) on average after two years. In a multivariate regression model, patients with a GBI ≥ 50% on average showed an increased RBLC (~0.6 mm, p = 0.007). High patient ratings were recorded for overall satisfaction. Overall patient satisfaction measured on a scale between one and ten was 5.2 (95% CI: 2.1–8.5) before implant placement and 9.5 (95% CI: 9.1–10) after 2 years.

Conclusion: Immediate loading of two unsplinted interforaminal implants in overdenture patients using ball attachments is a clinically viable treatment option that leads to a high survival rate and oral health-related quality of life.
Introduction

Implant-retained overdentures are an established treatment option to improve oral health-related quality of life in edentulous patients (Attard et al. 2005, Börrigter et al. 1995). In the edentulous mandible, the use of two implants to anchor an overdenture is considered as an easy, economic and reliable treatment (Feine et al. 2002). Implant survival rates reaching 86–100% have been reported for an observation period of ≥10 years in function (Attard & Zarb 2004, Meier et al. 2004, Naert et al. 2004, van Steenberghe et al. 2001). The prognosis of implants seems to be independent of the prosthetic attachment system once the implants are osseointegrated (Cehrelli et al. 2010). Primary stability and the prevention of implant movements may be important to allow osseointegration and implant survival (Szümker-Moncler et al. 1998). Therefore, a healing period of 3 months was empirically recommended for the mandible (Stephan et al. 2007).

Reduced healing times are beneficial to the patient. Although not evidenced-based, a rigid connection for splinted superstructure was stated to be favorable or even necessary for early or immediately loaded implants to share the load between the implants (Lozada et al. 2004, Romeo et al. 2002). Immediate loading of four splinted interforaminal implants was first reported in 1977 (Ledermann 1977) and survival rates ranging from 88% to 100% have since then been reported (Babbsch et al. 1986, Chiapasco & Gatti 2003, Chiapasco et al. 1997, Gatti & Chiapasco 2002). Similarly, survival rates of 98% or more have been reported for two to three immediately loaded splinted implants (Attard et al. 2005, Stephan et al. 2007, Stricker et al. 2004).

Early loading of unsplit implants in patients with an implant-retained overdenture also led to favorable results in the short term (Payne et al. 2002, Payne et al. 2003, Roynesdal et al. 2001). Procedures such as progressive loading (Payne et al. 2001) or the use of impression material inside the matrix housing (Örmianer et al. 2006) were suggested to prevent full loading of implants immediately after surgery. Recently, successful results were reported for unsplit implants that were immediately loaded after surgery (Liddeelow & Henry 2010, Marzola et al. 2007, Türkylıma 2006). On the other hand, research findings reported a rather low survival rate of only 81.8% after 12 months for unsplit implants that were immediately loaded after surgery (Kronström et al. 2010). Long-term results for unsplit immediately loaded implants retaining an overdenture are not yet available. Since there is a paucity of data on immediately loaded unsplit implants in overdenture patients, we conducted a prospective study to estimate implant survival.

Materials and Methods

Patients with an edentulous mandible who consulted the Clinic for Reconstructive Dentistry and Temporomandibular Disorders (University of Basel, Switzerland) for implant overdenture treatment between December 2005 and July 2007 were asked to participate in the study. A 50% discount on treatment costs was offered to all patients. Approval for the study was obtained from the local Ethics Committee and all patients provided informed consent.

We included patients with (1) an edentulous mandible and sufficient bone volume for the placement of two implants with a length of 12 mm and a diameter of 4.1 mm, (2) healed extraction sites (6 weeks or longer), and (3) satisfying dentures with respect to occlusion, aesthetics, vertical dimension in occlusion, denture base extension and fit. The exclusion criteria included: (1) heavy smokers (>20 cigarettes per day), (2) need of bone augmentation, (3) a history of radiotherapy in the interforaminal region, (4) systemic diseases precluding implant surgery, and (5) an insertion torque less than 25 Ncm using a hand wrench during implant surgery. Implants with an insertion torque less than 25 Ncm were loaded conventionally after a healing period of 6 weeks (Cochran et al. 2002, Ottone et al. 2005).

We used a panoramic radiograph and a replica of the lower denture with titanium pins (Diagnostic pin; Unor, Schlieren, Switzerland) in the canine regions as a radiographic template for planning purposes. The radiographic template was thereafter transformed to a surgical template by reducing the lingual flange. We measured bone height on the panoramic radiograph and bone width during implant surgery with a caliper (Dental Implant Caliper; Ace Surgical Supply, Brockton, MA, USA). A minimal width of 5.5 mm was required for implant placement.

Prior to implant surgery, all patients rinsed with a 0.2% chlorhexidine digluconate solution (Plakout liquid; Kerr Hawe, Bioggio, Switzerland) for 1 minute. No prophylactic antibiotic regimen was used. Local anaesthesia was administered by local infiltration of Articain (Ultracain D-S forte; Sanofi Aventis, Meyrin, Switzerland) buccally and lingually. After a midcrestal incision a minimal mucoperiosteal flap was raised buccally. If the canine position was not considered as suitable because of bony defects, the most appropriate adjacent position was selected. If the width of the alveolar ridge was inadequate and/or if the intermaxillary space for the prosthetic components was minimal, a vertical ridge reduction was performed. The osteotomy was prepared using three consecutive twist drills with diameters of 2.2 mm, 2.8 mm, and 3.5 mm (Institut Straumann AG, Basel, Switzerland). No screw tap was used. Two implants (Straumann Standard SLA; Institut Straumann AG, Basel, Switzerland) with a diameter of 4.1 mm and a length of 12 mm were inserted per patient. The planned insertion torque using a hand wrench was between 25 and 40 Ncm (Goiato et al. 2009). Bone quality according to Lekholm and Zarb as well as the insertion torque was recorded for each implant site (Lekholm & Zarb 1985). Ball attachments with a diameter of 2.25 mm were placed on the respective implants using a torque of 25 to 35 Ncm and closed the flap with interrupted sutures (Seralon; Serag Wiessner, Naila, Germany).

Matrices (Dalbo-Plus; Cendres & Métaux, Biel, Switzerland) were incorporated into the denture with a fast polymerizing autopolymerizing resin (SuperT; AMCO Intl, Conshohocken, Pennsylvania, USA). Patients were instructed to not remove their dentures during the first week except for oral hygiene. Instructions included a daily 0.2% chlorhexidine digluconate mouth rinse (Plakout liquid; Kerr Hawe, Bioggio, Switzerland) for one week and cleaning of the attachments with a soft toothbrush and toothpaste. In addition, patients were instructed to place 0.2% chlorhexidine digluconate gel (Plakout gel; Kerr Hawe, Bioggio, Switzerland) inside the matrix once per day. We prescribed pain medication (Mephadolor 500 Neo; Mepha, Aesch, Switzerland) during the first three days after surgery. No food restrictions were given. All surgical and prosthetic procedures were performed by the same clinician.

Patients were recalled after 1, 3 and 6 months, and 1 and 2 years after surgery. The following parameters were assessed at recall visits: i) Visual Plaque Index (VPI) according to Ainamo and Bay (Ainamo & Bay 1975); ii) Gingiva Bleeding Index (GBI) according to Ainamo and Bay (Ainamo & Bay 1975) (Fig. 1);
iii) pain on moderate digit pressure on the buccal and oral mucosa; and iv) soft tissue overgrowth above the implant shoulder. Panoramic radiographs were taken at 1 week (baseline), 6 months and 2 years after surgery. The panoramic radiographs were digitally scanned for further evaluation. Knowing the implant length, the distance between the implant shoulder and the crestal bone (Fig. 2) was calculated mesially and distally (ImageJ; open source software) and averaged per implant. The radiological bone level change (RBLC) was calculated as the difference between the measurements at baseline and after 2 years. Patient satisfaction was assessed before implant placement and 6 months and 2 years after implant surgery using a visual analogue scale ranging between 0 (worst state, defined as very unsatisfied with prosthesis) and 10 (best state, defined as very satisfied with prosthesis). The respective Visual Analogue Scale (VAS) question was formulated as “How satisfied are you with your prosthesis in the lower jaw”.

The primary outcome was defined as implant loss. The secondary outcome was defined as RBLC. Data were first descriptively analysed using box-plots and the 95% confidence intervals of the parameters of interest were calculated. Between-group differences of continuous variables were compared using the t-test. In a multivariate linear regression model we assessed the association of potential predictive variables with RBLC. The variables VPI and GBI were dichotomised for further analysis (> = 50% versus < 50%) due to the non-normal distribution of these parameters.

Results

A total of 20 patients (11 males and 9 females) with a mean age of 67.6 years (range: 42 to 86 years) were included in our study. Prior to implant treatment, dentures were renewed in 12 patients and relined in 6 patients. Nine patients already presented with an edentulous mandibular jaw whereas remaining teeth had to be extracted in 11 patients before implant treatment. With respect to the opposite dentition, 16 patients had a complete denture, 3 patients a root overdenture and one patient a partial removable denture.

Between December 2005 and July 2007 all patients received two implants in the mandible that were immediately loaded with an implant-retained overdenture using ball attachments. Insertion torques of 25–30 Ncm, 31–35 Ncm and 36–40 Ncm were recorded in 7 implants, 20 implants and 13 implants, respectively. All implant sites had a bone quality I (3 sites) or II (37 sites).

The average observation period was 27.4 months (range: 24–38 months). One patient died before the two-year recall visit. Three patients were not available for the 2-year recall visit but appeared at the 3-year recall visit. Three-year data of these 3 patients were used for the statistical analysis by using the principle of backward carrying for imputing missing data. Thus, there was one dropout after 2 years.

All implants were in place and functional after 2 years, yielding an implant survival rate of 100%. The mean RBLC 6 months after implant placement was 0.39 mm (95% Confidence Interval [95% CI]: 0.28–0.50 mm) (Fig. 3). The mean RBLC after 2 years was 0.67 mm (95% CI: 0.47–0.86 mm) (Fig. 3); the decrease was statistically significant (p = 0.015). Seven implants showed a RBLC of ≥ 1.2 mm after > 2 years. During the observation period, the average GBI decreased from 44% to 24% and the VPI increased from 31% and 36% (Tab. I). Soft tissue overgrowth of 1.6 mm was recorded 2 years after surgery (Tab. I).

Overall patient satisfaction before implant treatment was on average 5.2 (95% CI: 2.1–8.5) and increased to 9.7 (95% CI:
Discussion

In our study we have shown that immediate loading of unsplinted implants with overdentures leads to a survival rate of 100% over 2 years. Mean radiological bone loss was 0.66 mm (95% CI: 0.47–0.86 mm). Patients with a GBI of 50% or more had on average 0.59 mm more bone loss than patients with a lower GBI at 24 months. Our study further documents that patient satisfaction increases dramatically after implant treatment and remains stable thereafter.

Our results are in line with other recent studies examining two unsplinted implants that were immediately or early loaded using ball attachments in overdenture patients (Marzola et al. 2007, Payne et al. 2005). On the other hand, our results are in contrast to the study of Kronström et al. that reported a rather high failure rate of 18% after 1 year (Kronström et al. 2010). Our results are further comparable to studies evaluating implants that were immediately loaded with a bar-retained overdenture (Attard et al. 2005, Chiapasco & Gatti 2003) and may suggest that splinting is not an important factor in determining implant survival.

Although all implants placed in our study survived over 2 years, radiological bone loss was observed in most patients. A RBLC of less than 1.2 mm, however, is within the expected range during the first 2 years after implant placement (Albrektsson et al. 1986). A higher RBLC was observed in 7 implants in our study. The implants in our study consisted of a threaded, parallel-sided, roughened body and a polished conical neck that usually remains supracrestal. To achieve an insertion torque greater than 25 Ncm, the conical neck was placed below the mucosa. Hence, soft tissue overgrowth may not necessarily represent an inflammatory response but rather a consequence of the submucosal shoulder position. Offering different abutment heights would solve this problem. Finally, our study shows a substantial improvement of the patient's oral-health related quality of life following implant treatment that is in agreement with other reports (Attard et al. 2006, Boerrigter et al. 1995).

The present study has several limitations. First, we did not include a control group; however, implant survival rate using a delayed loading protocol is well documented in the literature (Cehreli et al. 2010). Furthermore, the use of a control group would have led to a smaller number of patients per group and hence a lower precision of the survival estimate. Second, the observation period in the present study was limited to 2 years. A longer observation period would be beneficial to confirm implant survival estimates over 5 to 10 years. Third, radiological bone level change measurements were based on panoramic radiographs. The head position during imaging may additionally influence radiographic measurements. However, current evidence suggests that there is some tolerance of various head positions with respect to angular and linear measurements on panoramic radiographs (Stramotas et al. 2002).

In conclusion, immediate loading of two unsplinted interforaminal implants in overdenture patients using a ball attachment may be a clinically viable treatment option that leads to a high survival rate and quality of life.

### Tab.I Mean values (95% Confidence Interval) of GBI (gingival bleeding index), VPI (visual plaque index) and soft tissue overgrowth during the first 2 years after implant placement

<table>
<thead>
<tr>
<th>Variable</th>
<th>1 month</th>
<th>6 months</th>
<th>2 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>GBI (50% and more)</td>
<td>44 (34–53)%</td>
<td>25 (17–29)%</td>
<td>24 (9–38)%</td>
</tr>
<tr>
<td>VPI (&gt; = 50% versus &lt;50%)</td>
<td>32 (21–43)%</td>
<td>31 (19–42)%</td>
<td>36 (19–53)%</td>
</tr>
<tr>
<td>Soft tissue overgrowth</td>
<td>2.2 (1.6–2.6) mm</td>
<td>1.7 (1.2–2.2) mm</td>
<td>1.6 (1.1–2.1) mm</td>
</tr>
</tbody>
</table>

### Tab.II Multivariate regression model of factors associated with radiological bone level change (RBLC) after 2 years

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean difference in RBLC (in mm)</th>
<th>Standard error</th>
<th>t-value</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female versus male</td>
<td>0.3355</td>
<td>0.1971</td>
<td>1.7020</td>
<td>n.s.</td>
</tr>
<tr>
<td>Age (per one-year increase)</td>
<td>0.0107</td>
<td>0.0086</td>
<td>1.2491</td>
<td>n.s.</td>
</tr>
<tr>
<td>Non-smoker versus smoker</td>
<td>0.1656</td>
<td>0.1607</td>
<td>1.0307</td>
<td>n.s.</td>
</tr>
<tr>
<td>VPI (&gt; = 50% versus &lt;50%)</td>
<td>–0.0452</td>
<td>0.1854</td>
<td>–0.2436</td>
<td>n.s.</td>
</tr>
<tr>
<td>GBI (&gt; = 50% versus &lt;50%)</td>
<td>–0.5948</td>
<td>0.2039</td>
<td>–2.9168</td>
<td>0.0074</td>
</tr>
<tr>
<td>Soft tissue overgrowth (per mm)</td>
<td>0.0338</td>
<td>0.0786</td>
<td>0.4301</td>
<td>n.s.</td>
</tr>
</tbody>
</table>

n.s. = no statistically significant difference.

9.1–10) after 6 months and remained stable at 9.5 (95% CI: 9.1–10) after 24 months following implant surgery.

The multivariate linear regression model showed that a higher GBI (50% and more) was associated with a statistically significantly higher RBLC, i.e. bone loss (p = 0.0074, Tab. II). Other potential predictors were not statistically significantly associated with RBLC in our multivariate regression model (Tab. II).
Acknowledgements

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Résumé

La qualité de vie de patients édentés peut être augmentée de façon substantielle par la mise sous contrainte immédiate d’implants non reliés rigide, pour la stabilisation d’une prothèse totale dans le maxillaire inférieur. Dans la présente étude d’observation prospective, sur une durée d’observation de 2 ans, le taux de survie d’implants sous contrainte immédiate a été évalué chez des patients qui étaient déjà pourvus d’une prothèse totale dans le maxillaire inférieur. De plus, le degré de satisfaction des patients et la perte osseuse péri-implantaire marginale ont été mesurés.

Les patients remplaçant les critères ci-après ont été inclus dans l’étude: (1) patients avec maxillaire inférieur édenté, ayant suffisamment de volume osseux pour l’insertion de 2 implants interforaminaux d’une longueur de 12 mm et d’un diamètre de 4,1 mm; (2) des alvéoles d’extraction guéries, i.e. l’extraction alvéolaire remontant à plus de 6 semaines; (3) patients chez lesquels la prothèse totale dans le maxillaire inférieur a été considérée comme satisfaisante par rapport à l’occlusion, l’esthétique, la dimension verticale et la base de la prothèse. Les critères d’exclusion comprenaient (1) les gros fumeurs (> 20 cigarettes par jour), (2) les patients chez lesquels une augmentation osseuse était nécessaire (3) après une radiothérapie dans la région interforaminaire, (4) des maladies systémiques rendant une insertion impossible et (5) un couple de torsion inférieur de 2,25 mm et les matrices directement polymérisées dans la prothèse ont été mesurees.

Les implants étaient mis sous contrainte de façon conventionnelle après 6 mois. Immédiatement après l’intervention chirurgicale, les implants ont été munis d’une rétention à boule (diamètre: 2,25 mm) et les matrices directement polymérisées dans la prothèse totale déja en place. Les examens postopératoires ont eu lieu après une semaine, 1, 3 et 6 mois, ainsi qu’après 1 et 2 ans. En outre, les pertes osseuses péri-implantaires marginales (RBLC) ont été mesurées après 6 mois et 2 ans.

Vingt patients, qui tous étaient pourvus, dans le maxillaire inférieur, de deux implants interforaminaux (implants Straumann Standard, longueur: 12 mm), ont été inclus dans l’étude. Les couples de torsion se situaient entre 25 et 30 Ncm pour 7 implants, entre 31 et 35 Ncm pour 20 implants, et entre 36 et 40 Ncm pour 13 implants. La qualité osseuse, selon Lekholm et Zarb, était de classe I pour 3 localisations d’implant, et de classe II pour 37 localisations d’implant. Le temps d’observation moyen était de 27,4 mois (intervalle: 24–38 mois). Un patient est décédé avant le recall planifié de 2 ans.

Sur une durée d’observation de 2 ans, il n’y a pas eu de perte d’implants, ce qui signifie que le taux de survie était de 100%. La perte osseuse péri-implantaire moyenne se situait à 0,67 mm (intervalle de confiance de 95%: 0,47–0,86). L’index de saignement gingival (GBI) et l’index de plaque visuel (VPI) étaient respectivement de 24% (IC 95%: 9–38%) et de 36% (CI 95%: 19–53%). Dans un modèle de régression multivariante, les patients avec GBI de plus de 50% présentaient une perte osseuse péri-implantaire plus élevée (RBLC = 0,6 mm, p=0,007). La moyenne concernant la satisfaction des patients, mesurée sur une échelle allant de 1 (pas satisfait du tout) à 10 (très satisfait) était, avant l’implantation, de 5,2 (intervalle de confiance de 95%: 2,1–8,5) et après 6 mois comme après 2 ans de 9,5 (intervalle de confiance de 95%: 9,1–10).

La mise sous contrainte immédiate d’implants non fixés rigide, dans un maxillaire inférieur édenté pour la stabilisation de prothèses totales a présenté, dans cette étude, un degré de succès de 100%. Le degré de satisfaction des patients s’est accru de manière substantielle, et la perte osseuse marginale moyenne, avec –0,67 mm, n’a pas augmenté après 2 ans.

Zusammenfassung


Patienten, die die folgenden Kriterien erfüllten, wurden in die Studie eingeschlossen: (1) im Unterkiefer zahnlose Patienten mit genügend Knochenvolumen für die Insertion von zwei interforaminalen Implantaten mit einer Länge von 12 mm und einem Durchmesser von 4,1 mm, (2) abgeheilte Extraktionsalveolen, d.h. eine eventuelle Extraktion lag mindestens sechs Wochen zurück, und (3) Patienten, bei denen die Totalprothese im Unterkiefer in Bezug auf Okklusion, Ästhetik, vertikale Dimension und Prothesenbasis als befriedigend eingestuft wurde. Ausschlusskriterien beinhalteten (1) starke Raucher (> 20 Zigaretten pro Tag), (2) Patienten, bei denen eine Knochenaugmentation notwendig war, (3) erfolgte Strahlentherapie in der interforaminalen Region, (4) systemische Erkrankungen, welche die Implantatinsertion verunmöglichen, und (5) ein Insertions torque von weniger als 25 Ncm. Falls dieser Wert nicht erreicht wurde, wurden die Implantate konventionell nach sechs Wochen belastet. Unmittelbar nach dem operativen Eingriff wurden die Implantate mit einem Kugelanker (Durchmesser von 2,25 mm) versorgt und die Matrizen direkt in die bestehende Totalprothese einpolymerisiert. Nachuntersuchungen fanden jeweils nach einer Woche, nach ein, drei und sechs Monaten sowie nach ein und zwei Jahren statt. Zusätzlich wurde radiologisch der periimplantäre marginale Knochenverlust (RBLC) nach sechs Monaten und zwei Jahren gemessen.


Über die Beobachtungszeit von zwei Jahren traten keine Implantatverluste auf, somit lag die Überlebensrate bei 100%. Der marginale periimplantäre Knochenverlust nach zwei Jahren lag bei 0,67 mm (95%-Vertrauensintervall: 0,47–0,86 mm). Der gängige Blutungsindex (GBI) und der visuelle Plaqueindex (VPI) nach zwei Jahren lagen bei 24% (95%-CI: 9–38%) bzw. 36% (95%-CI: 19–53%). In einem multivariaten Regressionsmodell wiesen Patienten mit einem GBI von 50%+ einen höheren periimplantären marginalen Knochenverlust auf.

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References

(Received – 0.6 mm, p = 0.007). Die mittlere Patientenzufriedenheit, gemessen auf einer Skala von 1 (überhaupt nicht zufrieden) bis 10 (sehr zufrieden), lag vor der Implantation bei 5.2 (95%-Vertrauensintervall: 2.1–8.5) und nach sechs Monaten wie auch nach zwei Jahren bei 9.5 (95%-Vertrauensintervall: 9.1–10).

Die Sofortbelastung von unverblockten Implantaten im zahnlosen Unterkiefer zur Stabilisierung von Totalprothesen wies in der vorliegenden Studie nach zwei Jahren eine hohe Erfolgsrate von 100% auf. Die Patientenzufriedenheit nahm substanziell zu, und der mittlere marginale Knochenverlust war mit –0.67 mm nach zwei Jahren nicht erhöht.


