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A prospective study evaluating a protocol for 6 weeks' loading of SLA implants in the posterior maxilla

One-year results

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Abstract: Experimental and clinical studies have shown that modification of implant surfaces can result in increased bone-to-implant contact at earlier times thus reducing the healing period between surgery and prosthesis. Sandblasted and acid-etched (SLA) implants are in this category and have successfully undergone early loading in patients with good bone quality and quantity. Nevertheless, premature loading of SLA implants was not routinely possible in predominantly trabecular bone, such as the posterior maxilla, as it is often characterized by a deficiency in initial bone to implant contact. The purpose of this prospective clinical investigation is to evaluate the efficacy of a modified surgical protocol followed by loading SLA implants at 6 weeks in the posterior maxilla. Drilling was limited to the minimum, and most of the site preparation was produced with osteotomes. Screw tapping was never performed and primary stability was always achieved. Abutment connection was carried out at 15 Ncm 43 (± 1) days after surgery and provisional restoration was fabricated. Further abutment tightening at 35 Ncm was performed after an additional 6 weeks. Of the 36 SLA implants placed in 19 patients, one was lost before final restoration. Clinical and radiographic measures were taken at baseline and 1 year postoperatively. The preliminary results suggest that, by means of the surgical and restorative technique presented, SLA implants are suitable for loading at 6 weeks in the posterior maxilla. More years of observation will verify whether osseointegration can be equally maintained over a long period.

Rough surface implants lead to enhanced osseointegration compared to smoother surfaces (Buser et al. 1991; Lazzara et al. 1999; Trisi et al. 1999; Klokkevold et al. 2001). Recently, clinical studies have demonstrated that implants with optimized rough surfaces can be loaded at earlier times, thus reducing the period between surgery and restoration (Lazzara et al. 1998; Cochran et al. 2002; Roccuzzo et al. 2001; Testori et al. 2002). Sandblasted and acid-etched (SLA) implants are in this category, and their early loading in patients with good bone quality and quantity has been proven successful (Cochran et al. 2002).

However, the use of an early loading protocol in the posterior maxilla is questioned, as this region has always been considered particularly challenging for long-term successful implant placement because of the deficiency in bone quality and/or quantity (Jaffin & Berman 1991; Bass & Triplett 1991; Friberg et al. 1991; Bahat 1993; Bahat 2000). In a multicenter trial, Cochran et al. (2002) demonstrated that, under defined conditions, solid screw implants with a SLA

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surface can be restored after approximately 6 weeks of healing with a high predictability of success defined by abutment placement at 35 Ncm without countertorque and with subsequent implant success rates of greater than 99% at 2 years post restoration. However, patients with less bone quality (type IV) had restorations beginning after 12 weeks post-implant placement. In a controlled comparative study, Roccuzzo et al. (2001) tested 68 SLA implants in areas other than the second and third maxillary molar. Of the 26 implants in the maxilla, 3 were 'spinning', at abutment connection 6 weeks post surgery using the recommended abutment tightening torque of 35 Ncm. A second tightening was successfully performed after an additional 6 weeks of unloaded healing. Thus, no implant was lost at the 12-month follow-up.

As a result of these studies, early loading of SLA implants has not been suggested in poor quality, highly trabecular bone typically found in the posterior maxilla, especially after a standard surgical protocol, which involves the removal of bone with a graded series of drills of increasing sizes.

In a recent publication Norton & Gamble (2001) suggested to avoid placement of implants in bone of poorest quality since failure is more likely.

According to Szmukler-Moncler et al. (2000) two factors should be taken into account when setting up clinical trials with healing periods inferior to 3 months: 1) the recipient site bone quality and 2) the implant surface. Moreover, he proposed that shorter healing periods should be rather applied to bone type I and II since, under the commonly used placement protocol, implant prognosis is significantly affected by bone quality. At present, however, interest for early and immediate loading is growing and reduction of time between surgery and prosthesis in low-density bone would be beneficial both for patient and dentist, if the risk of failure can be reduced. Thus, careful investigation of this application is necessary.

The aim of this prospective study is to present a modified protocol that allows loading of nonsubmerged SLA implants in the posterior maxilla 6 weeks after surgery and to monitor the periimplant conditions over time. Clinical and radiographic results at 12 months after prosthetic reconstruction are presented.

Material and methods

Patient selection

In all, 19 nonsmoking patients (7 male and 12 female, ages ranging from 35 to 65) were selected from those seeking implant rehabilitation, between January and October 1999. The patients agreed to participate in this study and gave their informed consent, in accordance with the Helsinki Declaration on human experimentation. All patients presented with one or two edentulous areas in the posterior maxilla corresponding to the position to the second and/or third molar, to be replaced with single or multiple unit fixed partial denture.

All patients were healthy, with no systemic contraindications to implant placement. The areas to be treated had a good occlusal relationship, and were free from infections or severe bone resorption. Following selection, all patients were instructed in oral hygiene until they reached a clinically acceptable level. Full-mouth plaque score (FMPS) and full-mouth bleeding score (FMBS) were recorded as the percentage of surfaces, four per each tooth, which revealed the presence of plaque (O'Leary et al. 1972) and of bleeding on probing (Ainamo & Bay 1975). At the end of the initial therapy, before entering the surgical procedures, all patients had controlled their periodontal conditions (FMPS $<20\%$, FMBS $<20\%$).

Radiographic evaluations were performed to assess the dimensions of the alveolar process. A minimum of 9 mm in corono-apical height and 6 mm in buccal-lingual width was necessary in order to be included in this study. Patients that required ridge expansion osteotomy and/or sinus floor elevation were excluded from the present protocol.

Surgical procedure

The same operator, with more than 10 years of implant experience (M.R.), performed all surgical procedures. After onset of local anesthesia, a midcrestal incision was made from the distal aspect of the last tooth in the maxilla to the tuberosity. Oblique releasing incisions were made and full-thickness flaps were elevated to expose the bone. The flaps were elevated on the palatal and buccal aspect of the alveolar ridge and sutures were used for retraction. Initial drilling was limited to a 2.0-mm-round bur at 680 r.p.m. to facilitate the use of osteotomes in the sites. The osteotomy sites were prepared using Summers' osteotomes (3i-Implant Innovations Inc., Palm Beach Gardens, FL, USA) according to Summers (1994). Further drilling was performed only when too much resistance to the osteotome was found. Screwtaps were not used. Solid screw nonsubmerged SLA implants were placed according to the manufacturer's instructions (Institut Straumann AG, Waldenburg, Switzerland). All implants were manually inserted in a self-tapping fashion, and primary stability was always achieved. In two cases the 4.1-mm diameter implants presented minimal stability and were immediately removed and replaced with 4.8-mm diameter implants. All implants were placed with the border of the SLA surface approximating the alveolar bone crest, leaving the machined neck portion in the transmucosal area. Healing screws were placed on top of the implants and the flaps were sutured. If necessary, a minor excision of soft tissue was performed in order to allow a close adaptation of the wound margins to the implant shoulder without submerging it. In seven patients one implant was placed following the described technique. Eight patients received two implants each, three patients received three and one patient received four implants using the same placement and loading protocol. The number, position and type of implants in each patient was determined after a thorough diagnosis of the anticipated needs for the planned prosthesis and the presence of anatomic limitations (Taylor et al. 2000). The distribution according to size and location of the total 36 implants is summarized in Table 1.

Post-surgical care

Immediately after surgery, the patients applied ice packs onto the treated area and it was recommended that they be kept in place for at least 4 h. Patients were advised to discontinue toothbrushing and to avoid trauma in the site of surgery for the first 3 weeks. They were also instructed to use 0.2% chlorhexidine digluconate (Corsodyl®, GlaxoSmithkline, S.p.A., Verona, Italy) rinse for 1 min three times a day for the same period of time. Patients were seen at 1, 2, 4 and 6 weeks to monitor their healing. If necessary, a professional

Table 1. **Distribution of the 36 tested implants, according to type and site (*1 lost before final restoration)**

	Surface area[§]	2nd molar	3rd molar	Total
4.1 mm Ø				17
10 mm	133.74 mm^2	9*	3	12
12 mm	163.25 mm^2	5	–	5
4.8 mm Ø				19
8 mm	127.05 mm^2	1	8	9
10 mm	162.30 mm^2	8	2	10

[§]Source: Institut Straumann AG, Waldenburg, Switzerland; *Data on file.*

supragingival prophylaxis was performed. Sutures were removed after 2 weeks.

Prosthetic reconstruction

Abutment connection was carried out at 15 Ncm 43 (± 1) days post surgery, by the same operator (M.R.). Solid abutments for cemented restorations were selected according to the amount of intermaxillary space and provisional restorations were immediately fabricated (Fig. 1). Six weeks later, the abutments were tightened to 35 Ncm in order to proceed with the final restorations. Impressions were made with impression caps and positioning cylinders to transfer the oral position of the implant to the master model. A variety of porcelain-fused-to-gold crowns and bridges were fabricated and cemented, none of them with distal cantilevers. Of the 36 implants, 11 (31%) were placed for single-tooth restorations, 20 (55%) supported short-span bridges, and 5 (14%) were splinted to natural teeth to support longer reconstructions.

Clinical assessments

One calibrated examiner collected data at baseline, i.e. at abutment connection, and 12 months postop. Probing depth (PD) according to Fiorellini & Weber (1994) was evaluated at the mesial, distal, buccal and palatal aspects of each implant by means of a periodontal probe (XP23/UNC 15, Hu-Friedy, Chicago, IL, USA), and rounded off to the nearest millimeter (Fig. 1). At the same time and sites, the presence of dental plaque (Pl) and of bleeding on probing (BOP) were recorded (Lang et al. 2000). Standardized periapical radiographs were taken at baseline (Fig. 2), i.e. immediately after surgery, and 1 year post surgery, according to the technique previously described (Roccuzzo et al. 2001) (Fig. 3).

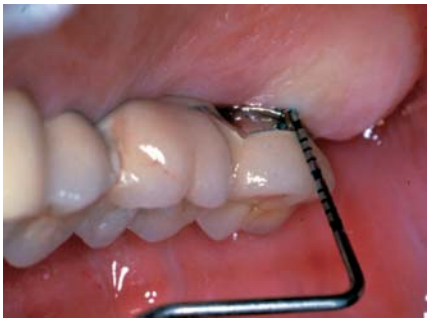

Fig. 1. Porcelain-to gold fused fixed partial denture. Probing at the palatal site of the early loaded tested implant (1-year follow-up).

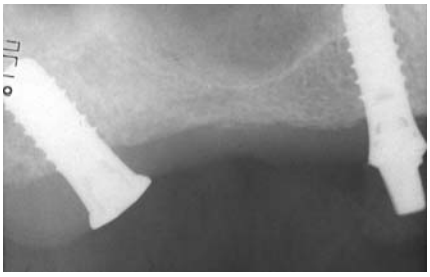

Fig. 2. Periapical radiograph at baseline, ie immediately after positioning of the distal implant. Note the pneumatization of the sinus distally to implant in 1.5 with abutment and provisional resin crown.

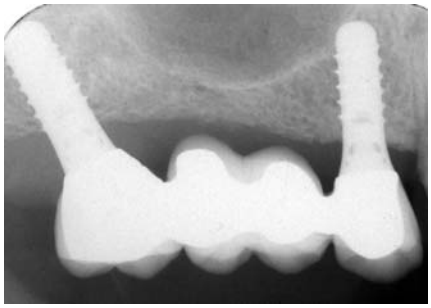

Fig. 3. Periapical radiograph at 1-year follow-up in the posterior right maxilla (only distal implant was early loaded and considered for the study).

Statistical analysis

The statistical analysis was performed using the Wilcoxon signed rank test and the paired-sample *t*-test to assess the significance of the differences between the clinical (PD) and the radiographic (BL) data. The quality differences for Pl and BOP were tested using the Chi-square test. A *P*-value <0.05 was considered to be statistically significant (Colton 1974).

Results

In all patients, healing proceeded without complications and with minimal postoperative discomfort. No patient dropouts were registered during the first year of observation.

Of the 36 cases, one 10 – 4.1-mm in diameter implant rotated slightly, during abutment connection 42 days after surgery; the patient reported slight pain and connection was not completed. The implant was removed a few days later because of evident lack of osseointegration and infection.

The clinical data of the remaining 35 implants, both at baseline and 12-month measurements, are listed in Table 2. There were no significant differences in mean PD (3.5 ± 1.3 mm vs. 3.7 ± 1.2 mm) around the implants when comparing the two measurements.

Plaque was found on 24 (= 17%) of the 140 examined surfaces at baseline and on 33 (= 24%) at the 1-year follow-up, with again no differences between the two times. Thirty-six (= 26%) sites presented bleeding on probing at abutment connection and 42 (= 30%) 12 months after loading. The mean interproximal bone loss (BL) was measured at 0.55 ± 0.49 mm after 1 year of loading.

Discussion

The aim of the present study was to verify whether SLA implants could be successfully loaded after 6 weeks in the posterior maxilla, using a bone condensing implant site preparation technique, and to monitor the periimplant conditions over time. The technique described allows for shorter post-treatment healing times using non-submerged implants. Implant placement in the posterior maxilla is often complicated

Table 2. **Clinical parameters around the 35 loaded implants at baseline and 1 year after placement**

	Baseline	12-month follow-up	Statistical difference
PI	17%	24%	N.S.
BOP	26%	30%	N.S.
PD	3.5 (1.3) mm	3.7 (1.2) mm	N.S.

PI, Presence of dental plaque. BOP, Presence of bleeding on probing. PD, Mean probing depth (Standard Deviation). N.S., Not significant.

by a deficiency in bone quality. By using the osteotomes, it was possible to compact bone and to improve the probability of initial implant stability. However, no scientific data are currently available regarding the influence of bone condensing on bone biology. Further histomorphometric studies are necessary to fully understand bone healing in compacted sites before any firm conclusion can be reached.

Due to the surgical technique employed, it was not possible to precisely assess the percentage of sites with less bone density (class IV according to the classification of Lekholm & Zarb 1985). However, the possibility of a reliable clinical evaluation to differentiate among the various types of bone in practice has recently been questioned (Trisi & Rao 1999). Moreover, in a recent publication Sullivan et al. (1997) suggested the use of implants with a chemically enhanced surface in areas of poor quality bone, both type III and IV.

The success rate for implant placement in the posterior maxilla has been reported to be lower when compared to that in other areas of the mouth (Bass & Triplett 1991; Friberg et al. 1991; Jaffin & Berman 1991; Bahat et al. 1993, 2000). Nonetheless, it must be noted that all published results were based on implants placed according to standard drilling protocols. Recently, Nocini et al. (2000) presented a case of implant placement in the maxillary tuberosity with modified osteotomes. However, in this case report, the waiting time between surgery and loading was not specified.

In the study reported here, all implants were manually placed and self-tapped. By avoiding the use of drills, and using a bone condensing technique with osteotomes, it was possible to achieve sufficient implant stability, which was considered necessary for early loading. Nonetheless, it is not possible to conclude whether the bone condensing preparation or the reduced abutment torquing at 6 weeks (or both) leads to the positive outcome.

If primary stability was not achieved with a 4.1-mm diameter implant, it was immediately removed and replaced with a 4.8-mm diameter version. It must be noted, however, that this happened only in two cases at the beginning of our experience with this technique. Fortunately, both implants were carefully removed, avoiding contamination, placed in adjacent surgical areas and successfully loaded according to standard protocol.

Osteotomes also allow expansion of the ridge and elevation of the sinus floor. Recently, an osteotome sinus floor elevation with simultaneous nonsubmerged implant placement was described by Ioannidou & Dean (2000) with a technique that presented several similarities to that described in this paper. However, the case selection in the present study excluded situations where these additional procedures of sinus floor elevation and/or ridge expansion were necessary.

Much effort was made to reduce the inclination of the implants as much as possible. However, in eight cases the implant was placed with an angulation of more than 20° with respect to the occlusal plane, as a consequence of the straight shape of the osteotome. Even though this does appear to have a detrimental effect on the long-term stability (Venturelli 1996) it would be desirable, from a prosthetic point of view, to place all implants in a parallel fashion. In six cases, it was possible to place the implants by means of osteotomes in the 2nd molar area but not more posteriorly, where the implants were placed according to a standard drilling protocol and loading was possible after 3–4 months. A modification of the configuration of the osteotomes with a curvature would be beneficial in order to improve the access in the most posterior areas, especially in patients with a limited capability to open the mouth.

Even though it has been demonstrated that bone-to-implant interfacial strength is influenced by surface area, in all previous studies, implants have been loaded according to similar protocols regardless of length and width (Bahat 1993; Buser et al. 1997; Buser et al. 2000). It is interesting to note that the present investigation was limited to implants that presented a surface area greater than 125 mm^2 (Table 1). Unlike other studies where a higher failure rate was found for short implants in the posterior region of the maxilla (Bahat 2000; Jaffin & Berman 1991), all 8-mm implants showed clinical success in this preliminary evaluation. Further studies are necessary to establish more precise loading protocols according to the type of implants employed.

One recent publication presented the positive results of a multicenter study evaluating loading of 123 maxillary implants with microtextured acid-etched surface 2 ± 0.7 months after surgery (Testori et al. 2002). The healing time varied considerably. In the present study, abutment connection was carried out in all cases exactly 6 weeks after surgery, i.e. 42 ± 1 days.

The question is open if extra time may have resulted in a better bone anchorage and thus avoided the loss of one implant. Also, the possibility of abutment connection at 35 Ncm after 6 weeks for the posterior maxilla is currently undetermined. However, the feasibility of abutment connection at 15 Ncm, for provisional restoration only, is confirmed by these results. The 1-year marginal bone levels were statistically significantly different from the measurements taken in the immediate postop radiographs and were consistent with data from similar previous results (Brägger et al. 1998; Weber et al. 2000; Roccuzzo et al. 2001).

The results of this clinical investigation suggest that successful functional loading of the SLA dental implant is possible at 6 weeks in the posterior maxilla according to the protocol described, in the following conditions:

- nonsmoking patients, with high levels of oral hygiene;
- implants with a surface area greater than 125 mm^2;
- primary implant stability at surgery;
- first abutment connection at 15 Ncm.

This procedure therefore represents an important step forward in the definition of

early and immediate loading protocols. More years of observation are, however, necessary (Weber et al. 1997) to verify whether osseointegration can be maintained equally over a long period of time.

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Résumé

Des études expérimentales et cliniques ont indiqué que la modification des surfaces implantaires pouvait résulter en une augmentation du contact os-implant à des moments précoces réduisant ainsi la période de guérison entre la chirurgie et la mise en charge. Des implants sablés et mordançés (SLA) se retrouvent dans cette catégorie et ont permis une mise en charge précoce chez des patients ayant un os de bonne qualité en quantité suffisante. Cependant une telle mise en charge prématurée des implants SLA n'était pas possible de manière routinière dans de l'os essentiellement trabéculaire, comme dans la partie postérieure du maxillaire qui est souvent caractérisée par une déficience de contact initial os-implant. Le but de cette étude clinique prospective a été d'évaluer l'efficacité d'un protocole chirurgical modifié suivi par l'insertion d'implants SLA mis en charge six semaines plus tard dans la région maxilliare postérieure. Le forage a été limité au maximum et la préparation du site a été essentiellement effectuée par ostéotomie. Le tapotement de la vis n'a jamais été réalisé et la stabilité primaire était toujours accomplie. La connection du pilier a été exécutée à 15 Ncm 43 (±1) jours après la chirurgie et la restauration provisoire a été fabriquée. Un serrage du pilier à 35 Ncm a été effectué après six semaines supplémentaires. Des 36 implants SLA placés chez 19 patients, un a été perdu avant la restauration finale. Des mesures cliniques et radiographiques ont été prises lors de l'examen initial et un an après l'opération. Les premiers résultats ont montré que grâce à la technique chirurgicale et prothétique présentée les implants SLA peuvent avoir une mise en charge six semaines après leur placement dans la partie maxillaire postérieure. Davantage d'années d'observation vérifieront si l'ostéoïntégration peut être aussi bien maintenue sur une période plus étendue.

Zusammenfassung

Experimentelle und klinische Studien haben gezeigt, dass Veränderungen an der Implantatoberflöche zu einem beschleunigten und verbesserten Knochen-Implantatkontakt führen können, und somit auch die Einheilphase von der Implantation bis zur Rekonstruktion verkrzt. Sandgestrahlte und säuregeγtzte (SLA) Implantate gehören zu dieser Kategorie, denn sie haben bei Patienten mit guter Knochenqualität und -quantität auf eine frhe Belastung gut reagiert. In einem vorwiegend trabekulären Knochen war jedoch die frühe Belastung von SLA-Implantaten nicht routinemässig möglich. Dies ist zum Beispiel im hinteren Oberkieferbereich, wo der initiale Knochen-Implantat-Kontakt oft ungenügend ist, der Fall. Das Ziel dieser klinischen Langzeitstudie ist es, die Auswirkungen eines modifizierten chirurgischen Protokolls, gefolgt von einer Belastung dieser SLA-Implantate im hinteren Oberkieferbereich bereits nach 6 Wochen, zu überprüfen. Das Vorbohren wurde auf ein Minimum reduziert, der Hauptteil der Präparation des Implantatbettes erfolgte mit Osteotomen. Da auch nie ein Gewinde geschnitten wurde, erlangte man in jedem Fall eine Primärstabilität. Die Montage der Sekundärteile erfolgte 45 (+1) Tage nach der Chirurgie mit einer Anzugskraft von 15 Ncm, anschliessend wurde ein Provisorium angefertigt. Ein weiteres und festeres Anziehen der Sekundärteile mit 35 Ncm fand nach weiteren 6 Wochen statt. Von den bei 19 Patienten implantierten 36 SLA-Implantaten ging eines vor der definitiven Rekonstruktion verloren. Man führte am Anfang und nach einem Jahr eine klinische und röntgenologische Untersuchung durch. Die ersten Resultate lassen vermuten, dass mit der hier vorgestellten chirurgischen und rekonstruktiven Technik, die SLA-Implantate im hinteren Oberkiefer durchaus nach 6 Wochen belastet werden können. Es braucht aber eine längere Beobachtungszeit, um sicherzustellen, dass diese Osseointegration über eine lange Zeit erhalten werden kann.

Resumen

Estudios experimentales y clínicos han mostrado que la modificación de las superficies de los implantes puede resultar en un incremento del contacto hueso-implante en tiempos mas cortos, por lo tanto, reduciendo el periodo de cicatrización entre cirugía y prótesis. Los implantes pulverizados con arena y gravados con ácido (SLA) están en esta categoría y se han sometido con éxito a carga temprana en pacientes con una buena calidad y cantidad de hueso. Sin embargo, la carga prematura de implantes SLA no fue rutinariamente posible en hueso predominantemente trabecular, tal como el del maxilar posterior, que se caracteriza con frecuencia por una deficiencia en el contacto hueso-implante. El propósito de esta investigación clínica prospectiva es evaluar la eficacia de un protocolo quirúrgico modificado seguido de carga de los implantes a las 6 semanas en el maxilar posterior. El fresado se redujo al mínimo, la mayor parte de la preparación se realizó con osteotomos. No se realizó nunca el tapping del tornillo y siempre se logró la estabilidad primaria. La conexión del pilar se llevó a cabo con una fuerza de 15 Ncm a los 43 (±1) días tras la cirugía y se fabricó una restauración provisional. Se llevó a cabo un ajuste a 35 Ncm después de 6 semanas adicionales. De los 36 implantes SLA colocados en 19 pacientes, uno se perdió antes de la restauración final. Se tomaron mediciones clínicas y radiográficas en el momento inicial y un año postoperatoriamente. Los resultados preliminares sugieren que por medio de la técnica quirúrgica y restaurativa presentada los implantes SLA son adecuados para carga a las 6 semanas en el maxilar posterior. Más años de observación verificaran si la osteointegración puede igualmente ser mantenida a lo largo de un gran periodo.

要旨

実験及び臨床研究は、インプラント表面の修飾によって、骨とインプラントの接触が早期に増加し、手術と補綴物装着の間の治癒期間が短縮されることを示している。サンドブラストと酸エッチングを施した（ＳＬＡ）インプラントは、この分類に属し、骨質、骨量の良好な患者においては成功裏に早期荷重を達成している。しかし上顎臼歯部のように、骨梁が大半を占める骨では、最初の骨とインプラントの接触が不十分な場合が多いため、ＳＬＡインプラントの早期荷重が常に可能なわけではない。本前向き臨床試験では、上顎臼歯部において術式を改良しＳＬＡインプラントを６週間目に荷重することの有効性を評価した。切削は最小限にとどめ、骨床形成の大半はオステオトームで行った。スクリュー・タップは決して行わず、初期固定は常に達成した。アバットメントの連結は１５Ｎｃｍで術後４３（±１）日後に行い、暫間修復物を製作した。さらに６週間後にアバットメントを３５Ｎｃｍで再度締めた。患者１９名に埋入した３６本のＳＬＡインプラントのうち、１本が最終補綴物を装着する前に失われた。臨床検査とレントゲン撮影をベースライン時及び術後１年後に行った。本研究の予備的結果は、同術式及び補綴治療の方法によって、上顎臼歯部においてＳＬＡインプラントは６週間後の荷重に適していることが示唆している。骨性統合が長期間同等に維持されるかどうか、さらに長期間の観察によって証明されるであろう。

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