Clinical Evaluation of Laser Microtexturing for Soft Tissue and Bone Attachment to Dental Implants

Gabriele E. Pecora, DDS, MD,* Rolando Ceccarelli, DDS,† Marco Bonelli, DDS,‡ Harold Alexander, PhD,§ and John L. Ricci, PhD‖

Introduction: *A tapered dental implant (Laser-Lok [LL] surface treatment) with a 2 mm wide collar, that has been laser micromachined in the lower 1.5 mm to preferentially accomplish bone and connective tissue attachment while inhibiting epithelial downgrowth, was evaluated in a prospective, controlled, multicenter clinical trial.*

Materials: *Data are reported at measurement periods from 1 to 37 months postoperative for 20 pairs of implants in 15 patients. The implants are placed adjacent to machined collar control implants of the same design. Measurement values are reported for bleeding index, plaque index, probing depth, and crestal bone loss.*

Results: *No statistical differences are measured for either bleeding or plaque index. At all measurement periods there are significant differences in the probing depths and the crestal bone loss differences are significant after 7 months ($P < 0.001$). At 37 months the mean probing depth is 2.30 mm and the mean crestal bone loss is 0.59 mm for LL versus 3.60 and 1.94 mm, respectively, for control implant. Also, comparing results in the mandible versus those in the maxilla demonstrates a bigger difference (control implant − LL) in the mean in crestal bone loss and probing depth in the maxilla. However, this result was not statistically significant.*

Discussion: *The consistent difference in probing depth between LL and control implant demonstrates the formation of a stable soft-tissue seal above the crestal bone. LL limited the crestal bone loss to the 0.59 mm range as opposed to the 1.94 mm crestal bone loss reported for control implant. The LL implant was found to be comparable with the control implant in safety endpoints plaque index and sulcular bleeding index. There is a nonstatistically significant suggestion that the LL crestal bone retention superiority is greater in the maxilla than the mandible. (Implant Dent 2009;18:57–66)*

Key Words: alveolar bone loss/ etiology, dental prosthesis design, crestal bone, implant surface

Titanium alloy dental implants have been designed, fabricated, and tested with microgeometries (surface characteristics in the micron range) to control bone and soft-tissue integration. These surfaces have highly oriented, consistent microstructures that are applied using computer-controlled laser ablation techniques using a pulsed, computer-controlled Excimer laser system and large-area masking. Animal experiments[1] indicate that this technology enhances bone and soft-tissue integration and controls the local microstructural geometry of attached bone.

Colonies of cells grown on the laser machined surfaces show preferential colonization parallel to the grooves. The microgrooved surfaces cause elongated colony growth, which is accelerated in the *x* direction (parallel to the surface microgeometry) and inhibited in the *y* direction (perpendicular to the surface microgeometry). On an individual cell level, the cells are observed to attach and orient along the surface grooves. This causes the cells to be "channeled" in the *x* direction, as compared with control cultures, where the outgrowing cells move randomly on flat surfaces. Cells are observed to attach and orient within the grooves and on flat tops of the grooves. This results in enhanced *x* axis growth and almost no *y* axis growth by cells on these surfaces; the cells are spindle shaped and well oriented.

Implant chamber model studies[2] show that canine bone grows into channels lined with the laser micromachined surfaces faster and more extensively than in channels lined with blast textured surfaces. New bone is observed to attach directly to the laser micromachined surfaces and the trabecular bone adjacent to these surfaces is strongly oriented parallel to the microgrooves. This orientational effect of the laser micromachined surfaces on attached bone is confirmed in an intramedullary rod sample where orientation of attached bone trabeculae follows microgroove orientation

*Private Practice, Rome, Italy.
†Private Practice, Lucca, Italy
‡Private Practice, Imperia, Italy.
§President, Orthogen, LLC, Springfield, NJ.
‖Associate Professor, Department of Biomaterials and Biomimetics, New York University College of Dentistry, New York, NY.

ISSN 1056-6163/09/01801-057
Implant Dentistry
Volume 18 • Number 1

DOI: 10.1097/ID.0b013e31818c5a6d

whether it is circumferential or longitudinal. Bone attachment to the laser micromachined surfaces is strong enough to measure in tension and tensile-tested specimens often show bone left behind in the microgrooves. Bone surfaces exposed after implant removal always show extensive bone attachment and growth into the microgrooves, with trabecular attachments spreading parallel to the microgrooves and blending together to form continuous bands.

Electron microscopic results[1,2] suggest that these surfaces cause orientation of attached cells, which produces oriented extracellular matrix and oriented bone microstructure. This is not observed on textured or polished surfaces. Textured surfaces show moderate direct bone attachment, which is not directional, and polished surfaces show little direct bone attachment and mostly fibrous encapsulation.

Crestal bone loss around endosteal implants is a common phenomenon. Ricci *et al*[3] reported 2.17 ± 1.6 mm of crestal bone loss at 5 years postoperative and Zechner *et al*[4] reported 2.4 ± 0.23 mm of loss at 3 to 7 years. Even as early as 1 year postoperative, Abboud *et al*[5] reported up to 1.21 mm of crestal bone loss and Bryant and Zarb[6] reported 1.4 mm loss. Taylor *et al*[7] and De Leonardis *et al*,[8] using an implant with a similar screw thread and screw surface as the implant used in this experimental study found 1.23 mm and <1 mm of bone loss, respectively.

The clinical question addressed by the study described here is as follows: Will the laser microtexturing surface treatment of the implant collar reduce crestal bone loss and establish a stable soft-tissue seal with no increase in inflammation measures such as bleeding and plaque index?

MATERIALS AND METHODS

This study evaluates the Silhouette Dental Implant (Laser-Lok (LL), Bio-Lok International, Deerfield Beach, FL) with laser microtexturing surface treatment of the implant collar (LL) versus a control tapered implant with a standard machined collar (control implant). The control implant used in this study is a tapered implant with a reverse buttress thread design and a 2 mm wide collar. The body of the implant has been roughened by blasting with a resorbable blast media. The Silhouette with laser microtexturing surface treatment has the same body design and screw area surface treatment as the control, but has a laser micromachined collar. This implant, shown in Figure 1, has a 2 mm wide collar that has been laser micromachined in the lower 1.5 mm. The lower, 0.8 mm (bone contacting) region, has been laser grooved with 12 μm wide by 10 μm deep grooves that have been previously shown in preclinical studies to optimize the surface for bone attachment.[1,2] The next 0.7 mm of the collar has been laser grooved with 8 μm wide by 5 μm deep grooves that have been previously shown to optimize the surface for connective tissue attachment. The upper 0.5 mm of the collar, as machined, encourages epithelial tissue colonization.

Baseline Demographic Data

Clinical testing has been performed by the group for implant research in Italy. The 2 implants are compared against each other and with historical controls previously published on the Bio-Lok Micro-Lok implant system.[8,9] Each patient received 2 single tooth implants, with and without laser surface treatment (LL vs control implant). All implants were restored at 4 months postoperative. The study was performed with 5 investigators and a total of 15 patients who received 20 sets of implants. The patients included 6 men and 9 women ranging in age from 42 to 69 years old with a mean age of 55.8 years. Among the 20 implant pairs, 8 were in the mandible and 12 were in the maxilla.

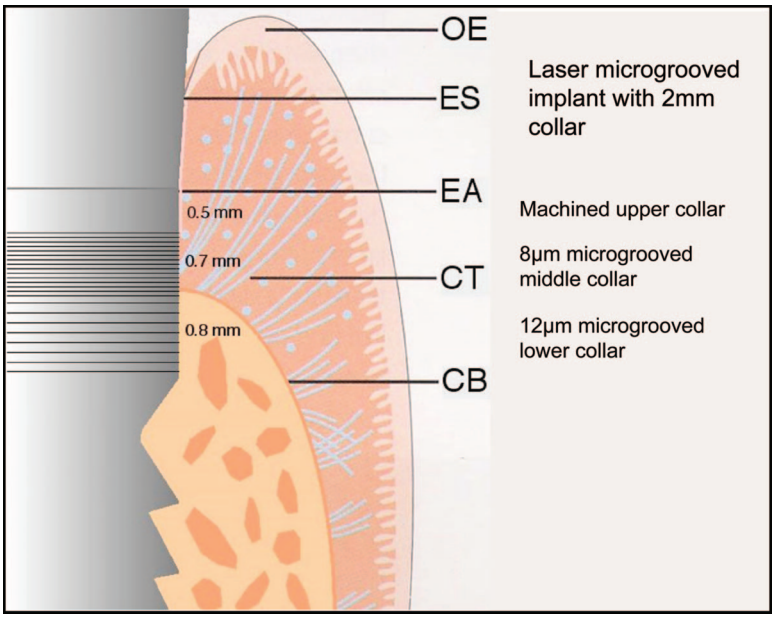

Fig. 1. Positioning of the laser microtexured collar in bone.

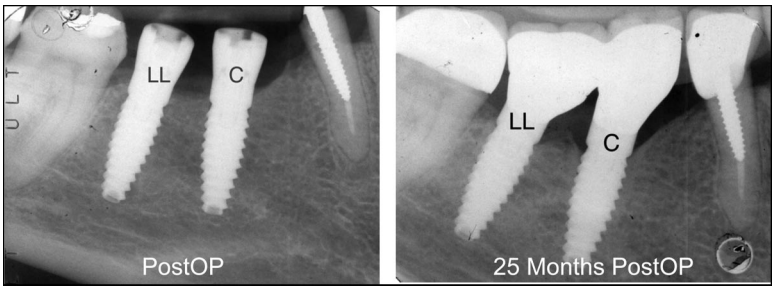

Fig. 2. At implant placement and 25 months postoperative, 44 year, male. Control and Silhouette with Laser-Lok surface treatment (LL).

Each patient signed a consent form indicating the experimental nature of the devices, the purpose of the study, their rights, and their obligations.

Endpoints

A comparison between means was done using *t* tests for all measurements and the resulting *P* values were recorded.

Effectiveness endpoints. The primary effectiveness endpoints are probing depth (the average of 4 measurements taken at the mesial, buccal, distal, and lingual surfaces of the implant) and crestal bone loss (average of the 2 radiographic measurements taken at the mesial and distal locations of the implant).

Safety endpoints. The safety endpoints are plaque index and sulcular bleeding index. Each of these endpoints are measured at the mesial and distal locations of the implant on a 4-point scale, with the categories of 0 (no plaque detected), 1 (plaque was noted only by running a probe across the smooth marginal surface of the implant), 2 (plaque could be seen by the naked eye), and 3 (an abundance of soft matter) for the plaque index and 0 (no bleeding when a periodontal probe was passed along the gingival margin adjacent to the implant), 1 (only isolated bleeding was visible), 2 (blood formed a confluent red line on the margin), and 3 (presence of heavy or profuse bleeding) for the sulcular bleeding index. The scores assigned to the 2 measurements were averaged to create a numeric score.

All measurements were initiated at 1-month postoperative, after soft tissue healing and were done at 2-month intervals up to 37 months.

RESULTS

Patient Accountability

No patient was lost to follow-up. In one patient (patient 1) the site implanted with the LL implant failed to osseointegrate and the implant was removed. All other implants, LL and control implant, have been followed for the full 37 months.

Effectiveness Results

X-rays for a typical case postoperatively and at 25 months are shown in Figure 2 for a 44-year-old male. The crestal bone seems to be retained around the Silhouette with laser surface treatment (LL), whereas there is noticeable bone loss evident around the implant without laser surface treatment (control implant).

The 2 primary effectiveness endpoints are probing depth and crestal bone loss. The differences between the LL and control implants were tested at each study visit by a paired *t* test.

As seen in Figure 3, the LL treatment yielded consistently lower probing depth at each visit with significance for all time periods ($P < 0.001$). As seen in Figure 4, LL was numerically superior to control implant in crestal bone loss at each month after month 1, and achieved nominal statistical significance at month 7 ($P = 0.003$), and each month thereafter ($P < 0.001$). This difference is seen to increase numerically at each successive visit.

All 20 implant pairs were included in analyses up to 7 months, and only 19 pairs at months 9 through 37. This is because the LL implant in patient 1 failed at 7 months and the implant was removed. To conduct an intent to treat analysis, which uses all implants, a difference between treatments of zero (consistent with the null hypothesis of no effect due to the LL surface treatment) was imputed for all missing data for Patient 1 for both probing depth and crestal bone loss, and the aforementioned analyses were repeated. The resulting differences at each of the visits in which a value was imputed (months 9–37) remained significant ($P < 0.001$).

A subgroup analysis was performed on the 20 pairs of implants to compare implants in the mandible with those in the maxilla. Mean differences between treatments were computed for probing depth and crestal bone loss. LL was numerically superior to the control implant at each month for implants in the mandible and implants in the maxilla, for both probing depth and crestal bone loss. However, there is no statistical significance to these data. Therefore, the data only suggest a possible greater effect of LL surface treatment on implants in the maxilla than in the mandible.

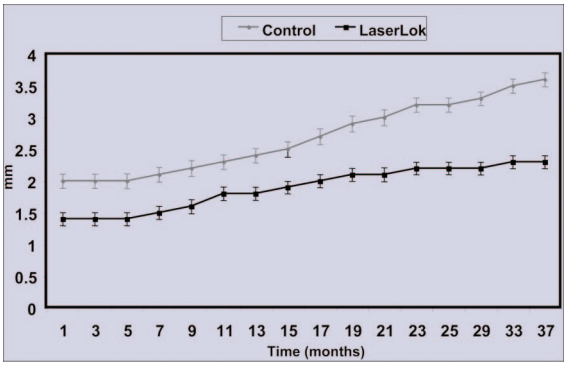

Fig. 3. Probing depth, LL versus control for 37-month follow-up. Error bars = standard error: $P < 0.005$ for all time periods.

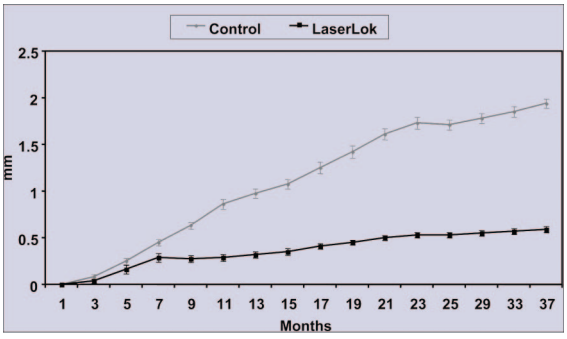

Fig. 4. Crestal bone loss, LL versus control for 37-month follow-up. Error bars = standard error: $P < 0.005$ after month 5.

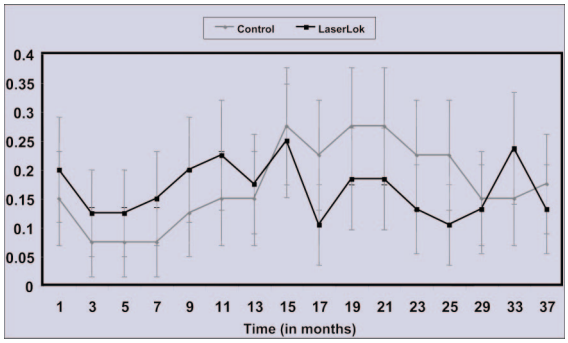

Fig. 5. Plaque index, LL versus control followed for 37 months. Error bars = standard error: not significantly different for all time periods.

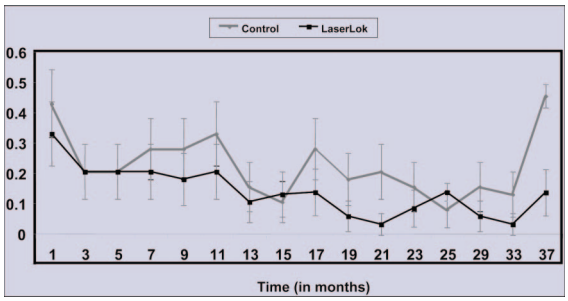

Fig. 6. Sulcular bleeding index, LL versus control followed for 37 months. Error bars = standard error: not significantly different for all time periods except months 21 and 37 where LL is superior.

Justification for Pooling Investigators

Five surgeons implanted between 2 and 7 pairs of implants each. To assess the poolability of the data from these 5 surgeons, the month 37 data for each of the effectiveness endpoints was analyzed by surgeon. The means for each surgeon and treatment were computed, along with the differences between treatments. The LL treatment was consistently superior to the Silhouette for each endpoint and surgeon. This consistency of treatment effect among the 5 surgeons indicates that the data are poolable.

Safety Results

The safety endpoints were plaque index and sulcular bleeding index. All individual values for each of these indices were either a 0 or a 1, hence, the resulting averages of the mesial and distal determinations were either a 0, 0.5 (one value was 0 and the other was 1), or 1. The resulting data at each visit are shown in Figures 5 and 6, respectively. A one-sided 95% upper confidence bound on the differences in the means was computed. No statistically significant differences in the 2 data sets were found except for sulcular bleeding at 21 and 37 months where LL was superior. Generally, however, there seems to be no clinically significant safety endpoint differences between LL and control implant.

DISCUSSION

The Silhouette design implant combines proven design concepts[7,9] (reverse buttress thread and high surface area microtextures) with a novel tapered design.[10] The Silhouette implant with LL surface treatment combines these Silhouette features with organized microtextures in critical areas. The Osseo-Lok high surface area microtexture on the threaded portion of the implant has been shown in preclinical animal testing to enhance bone apposition to the implant.[11] The LL surfaces have been shown to inhibit fibrous encapsulation, enhancing bony attachment in bony areas, enhance the formation of a soft-tissue seal in soft-tissue areas and control local tissue microarchitecture.[11] This combination of organized cells and organized extracellular matrix results in unique tissue formation at the interface resulting in true "endosseous incorporation."[1,2]

The bleeding index for both implants after the initial healing period ranges from 0.45 to 0.03 with no statistical difference between pairs except at 2 time points where LL is superior. The historical data from an earlier study of Bio-Lok implants presents a range from 0.00 to 0.50 with a mean of 0.25.[8,9] The plaque index goes as high as 0.27 for the control implants and 0.25 for the LL implants with no statistical difference between pairs. The historical data had a mean plaque index of 0.27, close to the highest mean at any time period for either the LL or the control implants. These data indicate that there is no increase in these inflammation measures (bleeding and plaque indices) as compared with either prospective controls or historical data.

The consistent difference in probing depth between the implant pairs with and without the Laser microtexture surface treatment implies that a soft-tissue seal above the bone has been established in the LL implanted sites. This was demonstrated histologically in a previous canine implant study.[11] Accounting for the crestal bone loss with both implants, an ~1.0 to 0.7 mm probing difference is maintained throughout the study. This is approximately the height of the 8 μm texturing (0.7 mm) on the LL implant.

The crestal bone loss data are the most dramatic result of this study. The LL bone loss is limited to 0.59 mm whereas the control data demonstrates up to 1.94 mm of bone loss. The data reported for other implant systems is in the range from 1.0 to 2.5 mm.[3,6,12] The LL surfaced implant is superior in this important measure to consecutive controls and literature reports on other implant systems.

CONCLUSIONS

The combined results of this study with preclinical animal studies[1,2,11] and analyses[13] have demonstrated that it is not necessary to accept up to 2.5 mm of crestal bone loss around dental implants

as has been proposed in the literature.[3,6,12] At 3 years postoperative the Silhouette implant with LL surface treatment enables the reduction of crestal bone loss to 0.59 mm. It is hypothesized that this has been accomplished by reducing the stress in the crestal bone through a combination of implant design and surface modification[13] and effecting soft-tissue attachment above the bone.[11] These benefits, accomplishing true "endosseous incorporation," were demonstrated without any degradation in plaque index and sulcular bleeding index as compared with controls.

Disclosure

John L. Ricci and Harold Alexander were consultants to BioLok in the development of the implant studied. Gabriele E. Pecora, Rolando Ceccarelli, and Marco Bonelli claim to have no financial interest in any entity that is commercially related to the products mentioned in this article.

REFERENCES

1. Ricci JL, Charvet J, Frenkel SR, et al. Bone response to laser microtextured surfaces. In: Davies JE, ed. *Bone Engineering*. Toronto, ON: EM2 Inc; 2000. Chapter 25.

2. Frenkel SR, Simon J, Alexander H, et al. Osseointegration on metallic implant surfaces: Effects of microgeometry and growth factor treatment. *J Biomed Mater Res*. 2002;63:706-713.

3. Ricci G, Aimetti M, Stablum W, et al. Crestal bone resorption 5 years after implant loading: Clinical and radiologic results with a 2-stage implant system. *Int J Oral Maxillofac Implants*. 2004;19:597-602.

4. Zechner W, Trinkl N, Watzak G, et al. Radiologic follow-up of peri-implant bone loss around machine-surfaced and rough-surfaced interforaminal implants in the mandible functionally loaded for 3 to 7 years. *Int J Oral Maxillofac Implants*. 2004; 19:216-221.

5. Abboud M, Koeck B, Stark H, et al. Immediate loading of single-tooth implants in the posterior region. *Int J Oral Maxillofac Implants*. 2005;20:61-68.

6. Bryant SR, Zarb GA. Crestal bone loss proximal to oral implants in older and younger adults. *J Prosthet Dent*. 2003;89: 589-597.

7. Taylor RC, McGlumphy EA, Tatakis DN, et al. Radiographic and clinical evaluation of single-tooth Bio-Lok implants: A 5-year study. *Int J Oral Maxillofac Implants*. 2004;19:849-854.

8. De Leonardis D, Garg AK, Pecora GE. Osseointegration of rough acid-etched titanium implants: 5-year follow-up of 100 minimatic implants. *Int J Oral Maxillofac Implants*. 1999;14:384-391.

9. De Leonardis D, Garg AK, Pecora GE, et al. Osseointegration of rough acid-etched implants: One-year follow-up of placement of 100 minimatic implants. *Int J Oral Maxillofac Implants*. 1997;12:65-73.

10. Shapoff CA. Clinical advantages of tapered root form dental implants. *Compend Contin Educ Dent*. 2002;23:42–44, 46, 48 passim.

11. Weiner S, Simon J, Ehrenberg DS, et al. The effects of laser microtextured collars upon crestal bone levels of dental implants. *Implant Dent*. 2008;17:217–228.

12. Heydenrijk K, Raghoebar GM, Meijer HJ, et al. Clinical and radiologic evaluation of 2-stage IMZ implants placed in a single-stage procedure: 2-year results of a prospective comparative study. *Int J Oral Maxillofac Implants*. 2003;18:424–432.

13. Alexander H, Ricci JL, Hrico GL. Mechanical basis for bone retention around dental implants. *J Biomed Mater Res B.* 2009;88B:306–311.

Reprint requests and correspondence to:
J. L. Ricci, PhD
New York University College of Dentistry
345 East 24th Street, Room 813B
New York, NY 10010
Phone: 212-998-9623
Fax: 212-995-4244
Cell: 732-778-8296
E-mail: john.ricci@nyu.edu

ID Abstract Translations

GERMAN / DEUTSCH

AUTOR(EN): G. E. Pecora, DDS, MD, R. Ceccarelli, DDS, M Bonelli, DDS, H. Alexander, PhD, J. L. Ricci, PhD. *Korrespondenz an: J. L. Ricci, PhD, zahnmedizinische Fakultät der Universität New York, 345 East 24th Street, Room 813B, New York, NY 10010. Telefon: 212-998-9623, Fax: 212-995-4244, Mobil: 732-778-8296. eMail: john.ricci@nyu.edu*

Klinische Beurteilung von Laser-Mikrostrukturierungsbehandlungen an Weichgewebe und Knochenbefestigungen für Zahnimplantate

ZUSAMMENFASSUNG: Einleitung: Ein spitz zulaufendes Zahnimplantat (LL) mit einer Kragenweite von 2 mm, das mittels Laser in den unteren 1.5 mm mikrobearbeitet wurde, um darüber eine Verbesserung der Knochen- und Bindegewebsanhaftung zu erzielen, während gleichzeitig Epitheltiefenwachstum verhindert werden soll, wurde in einer klinischen, kontrollierten, Multizenter-Prospektivstudie bewertet. ***Materialien und Methoden:*** Es werden Angaben zu Messzeitpunkten von 1 bis zu 37 Monaten nach erfolgtem operativem Eingriff für 20 Paare von Implantaten bei insgesamt 15 Patienten festgehalten. Die Implantate werden direkt neben Kontrollimplantaten mit maschinell bearbeitetem Kragen (C) des gleichen Designs eingesetzt. Es werden die nachfolgenden Messwerte festgehalten: Blutungsindex, Plaque-Index, Sondierungstiefe und Knochengewebsverlust in der Kammgegend. ***Ergebnisse:*** Es ergeben sich keinerlei statistische Unterschiede für sowohl den Blutungs- als auch den Plaque-Index. Zu allen Messzeitpunkten gab es maßgebliche Unterschiede in der Sondierungstiefe. Außerdem sind die Unterschiede hinsichtlich des Knochengewebsverlusts in der Kammgegend nach 7 Monaten bedeutend ($P < 0.001$). Nach 37 Monaten lag die durchschnittliche Sondierungstiefe bei 2.30 mm und der durchschnittliche Knochengewebsverlust im Kammknochen betrug 0.59 mm für LL gegenüber 3.60 mm bzw. 1.94 mm für C. Vergleicht man außerdem die Ergebnisse im Unterkiefer mit denen im

Oberkiefer, so weisen sich größere Unterschiede (C minus LL) im durchschnittlichen Knochengewebsverlust in der Kammgegend und in der Sondierungstiefe im Oberkiefer auf. Allerdings waren diese Ergebnisse im Hinblick auf die statistischen Ermittlungen nicht signifikant. ***Diskussion und Schlussfolgerungen:*** Die beständige Differenz in Bezug auf die Sondierungstiefe zwischen LL und C weist auf die Bildung einer stabilen Weichgewebsversiegelung über dem Kammknochen hin. LL begrenzte den Knochengewebsverlust im Kammbereich auf den 0.59 mm-Bereich im Gegensatz zum für C berichteten Knochengewebsverlust an Kammknochen von 1.94 mm. Das LL-Implantat war in Bezug auf den Sicherheitsendpunkt-Plaque-Index und den Rinnen-Blutungs-Index mit dem C-Implantat vergleichbar. Es besteht die nicht statistisch bedeutsame Vermutung, dass die Verhaltungsüberlegenheit des LL-Kammknochens im Oberkiefer größer ist als im Unterkiefer.

SCHLÜSSELWÖRTER: alveolarknochenverlust/ätiologie, design der zahnprothese, kammknochen, implantatoberfläche

SPANISH / ESPAÑOL

AUTOR(ES): G. E. Pecora, DDS, MD, R. Ceccarelli, DDS, M. Bonelli, DDS, H. Alexander, PhD, J. L. Ricci, PhD. *Correspondencia a: JL Ricci, PhD, New York University College of Dentistry, 345 East 24th Street, Room 813B, New York, NY 10010. Teléfono: 212-998-9623, Fax: 212-995-4244, Celular: 732-778-8296. Correo electrónico: john.ricci@nyu.edu*

Evaluación clínica de la microtexturización con láser de la fusión de tejido suave y hueso a implantes dentales

ABSTRACTO: Propósito: Se evaluó un implante dental cónico (LL) con un cuello de 2 mm de ancho, que había sido micromaquinado con láser en los 1.5 mm más bajos para lograr la fusión del tejido conectivo preferencialmente mientras que se impedía el crecimiento epitelial hacia abajo en una prueba clínica controlada, prospectiva, realizada en varios centros. ***Materiales y métodos:*** Se informaron los datos a períodos de medición desde el 1 al 37 meses luego de la operación en 20 pares de implantes en 15 pacientes. Los implantes se colocan adyacentes a los implantes de control con cuello maquinado (C) del mismo diseño. Los valores de la medición se informaron del: índice de sangrado, índice de placa, profundidad del sondaje y pérdida del hueso crestal. ***Resultados:*** No se midieron diferencias estadísticas para el índice de sangrado o de placa. En todos los períodos de medición hubo diferencias significativas en las profundidades del sondaje y las diferencias de pérdidas del hueso crestal fueron significativas después de los 7 meses ($P < 0.001$). A los 37 meses, la mediana de la profundidad del sondaje es de 2.30 mm y la mediana de la pérdida crestal del hueso es 0.59 mm en LL contra un 3.60 y 1.94 mm, respectivamente, en C. Además, la comparación de los resultados en la mandíbula versus el maxilar demuestra una mayor diferencia (C menos LL) en la mediana de la pérdida de hueso crestal y la profundidad del sondaje en el maxilar. Sin embargo, este resultado no fue estadísticamente significativo. ***Discusión y Conclusiones:*** La diferencia consistente en la profundidad del sondaje entre LL y C demuestra la formación de un sello de tejido suave estable encima del hueso crestal. LL limitó la pérdida del hueso crestal alrededor de los 0.59 mm comparado con la pérdida de hueso crestal de 1,94 mm de C. Se encontró que el implante de LL es comparable al implante de C en el índice de placa de los puntos extremos y el índice de sangrado del sulcus. Existió una sugerencia no estadísticamente significativa que la superioridad de la retención del hueso crestal LL es mayor en el maxilar que en la mandíbula.

PALABRAS CLAVES: pérdida de hueso alveolar/etiología, diseño de la próstesis dental, hueso crestal, superficie del implante

PORTUGUESE / PORTUGUÊS

AUTOR(ES): G. E. Pecora, Cirurgião-Dentista, Médico, R. Ceccarelli, Cirurgião-Dentista, M. Bonelli, Cirurgião-Dentista, H. Alexander, PhD, J. L. Ricci, PhD. *Correspondência para: J. L. Ricci, PhD, New York University College of Dentistry, 345 East 24th Street, Room 813B, New York, NY 10010, USA. Telefone: 212-998-9623, Fax: 212-995-4244, Celular: 732-778-8296. e-mail: john.ricci@nyu.edu*

Avaliação Clínica de Microtexturização a Laser para Inserção de Tecido Mole e Osso em Implantes Dentários

RESUMO: Introdução: Um implante dentário afunilado (LL) com colarinho de 2 mm de largura, que foi microusinado a laser no 1.5 mm inferior para realizar preferencialmente inserção de osso e tecido conjuntivo enquanto exibia migração epitelial, foi avaliado num ensaio clínico multicentro, controlado e em perspectiva. ***Materiais e Métodos:*** Os dados são relatados em períodos de medição de 1 a 37 meses após a cirurgia para 20 pares de implantes em 15 pacientes. Os implantes são colocados adjacentes a implantes de controle de colarinho usinado (C) com o mesmo projeto. Valores de medição são relatados para: Índice de Sangramento, Índice de Placa, Profundidade de Sondagem e Perda de Crista Óssea. ***Resultados:*** Nenhuma diferença estatística é medida para índice de sangramento ou de placa. Em todos os períodos de medição há diferenças significativas nas profundidades de sondagem e as diferenças de perda de crista óssea são significativas após 7 meses ($P < 0.001$). Em 37 meses a profundidade de sondagem média é 2.30 mm e a perda de crista óssea média é 0,59 mm para LL versus 3.60 mm e 1.94 mm, respectivamente, para C. Além disso, comparar resultados na mandíbula versus aqueles na maxila demonstra uma diferença maior (C menos LL) na perda de crista óssea média e profundidade de sondagem na maxila. Contudo, este resultado não foi estatisticamente significativo. ***Discussão e Conclusões:*** A diferença consistente em profundidade de sondagem entre LL e C demonstra a formação de uma vedação estável

de tecido mole acima da crista óssea. LL limitou a perda de crista óssea ao intervalo de 0,59 mm em oposição à perda de crista óssea de 1,94 mm relatado para C. O implante LL foi considerado comparável ao implante C em índice de placa de parâmetros de segurança e índice de sangramento sulcal. Há uma sugestão estatisticamente não significativa de que a superioridade de retenção da crista óssea de LL é maior na maxila do que na mandíbula.

PALAVRAS-CHAVE: perda de osso/etiologia, projeto de prótese dentária, crista óssea, superfície de implante

RUSSIAN / РУССКИЙ

АВТОРЫ: GE Pecora, доктор стоматологической хирургии, доктор медицины, R Ceccarelli, доктор стоматологической хирургии, M Bonelli, доктор стоматологической хирургии, H Alexander, доктор философии, JL Ricci, доктор философии. *Адрес для корреспонденции: JL Ricci, PhD, New York University College of Dentistry, 345 East 24th Street, Room 813B, New York, NY 10010, USA. Телефон: 212-998-9623, Факс: 212-995-4244, Мобильный телефон: 732-778-8296, Адрес электронной почты: john.ricci@nyu.edu*

Клиническая оценка влияния лазерного микротекстурирования на прикрепление мягких тканей и кости к зубным имплантатам

РЕЗЮМЕ: Введение: В рамках проспективного контролируемого многоцентрового клинического исследования была проведена оценка зубного имплантата конической формы (LL) с шейкой шириной 2 мм, нижние 1,5 мм поверхности которого подверглись микрообработке лазером, чтобы, в первую очередь, обеспечить фиксацию кости и соединительнотканной связки десневого кармана, и в то же время препятствовать образованию эпителиального дефекта. ***Материалы и методы:*** Предоставлены данные за периоды измерений продолжительностью от 1 до 37 месяцев после установки 20 пар имплантатов 15 пациентам. Имплантаты установлены рядом с контрольными имплантатами с полированной шейкой (C) той же конструкции. Значения измерений были предоставлены для следующих величин: индекс кровоточивости, индекс налета, глубина зондирования, потеря костной массы альвеолярного гребня. ***Результаты:*** В отношении индексов кровоточивости и налета статистической разницы обнаружено не было. Во все периоды измерений статистическое значительное расхождение для глубины зондирования и потери костной массы альвеолярного гребня наблюдается после 7 месяцев ($p<0.001$). Через 37 месяцев средняя глубина зондирования составляет 2,30 мм и средняя потеря костной массы альвеолярного гребня – 0,59 мм для имплантата типа LL по сравнению с 3,60 мм и 1,94 мм соответственно для имплантата типа C. Также, если сравнить результаты, полученные для нижней и верхней челюстей, заметна большая разница (C минус LL) в средних значениях потери костной массы альвеолярного гребня и глубины зондирования на верхней челюсти. Однако эти результаты не являются статистически значимыми. ***Обсуждение и выводы:*** Систематически наблюдаемая разница между значениями глубины зондирования для имплантатов типов LL и C подтверждает формирование постоянного барьера из мягкой ткани на альвеолярном гребне. Имплантаты типа LL сокращают потерю костной массы альвеолярного гребня до 0,59 мм, в отличие от потери костной массы альвеолярного гребня 1,94 мм, что получено для имплантатов типа C. Оказалось, что имплантаты типа LL сравнимы с имплантатами типа C в максимальных безопасных значениях индексов налета и кровоточивости. Существует статистически незначимое предположение, что ретенция альвеолярного гребня при установке имплантатов типа LL больше выражена на верхней челюсти, чем на нижней.

КЛЮЧЕВЫЕ СЛОВА. Потеря костной массы альвеолярного гребня / причины потери костной массы альвеолярного гребня, конструкция зубных протезов, альвеолярный гребень, поверхность имплантата

TURKISH / TÜRKÇE

YAZARLAR: G. E. Pecora, DDS, MD, R. Ceccarelli, DDS, M. Bonelli, DDS, H. Alexander, PhD, J. L. Ricci, PhD. *Yazışma için: JL Ricci, PhD, New York University College of Dentistry, 345 East 24th Street, Room 813B, New York, NY 10010, ABD. Telefon: 212-998-9623, Faks: 212-995-4244, Cep: 732-778-8296. e-posta: john.ricci@nyu.edu*

Dental İmplantlara Yumuşak Doku ve Kemik Bağlanması için Lazerle Yapılan Mikrotekstürün Klinik Değerlendirmesi

ÖZET: **Giriş:** Prospektif, kontrollü, çok merkezli klinik bir çalışmada, alt 1.5 mm'lik kısmında kemik ve bağ dokusunun bağlanmasını sağlamak fakat aşağıya doğru epitel büyümeyi inhibe etmek üzere lazerle mikrotekstür yapılmış, 2 mm genişliğinde kelepçesi olan konik bir dental implant (LL) değerlendirildi. **Gereç ve Yöntem:** 15 hastadaki toplam 20 çift implanttan operasyon sonrasındaki 1. aydan 37. aya kadarki ölçüm süresinde alınan veriler değerlendirildi. İmplantlar, aynı tasarımda, makineden geçmiş kelepçeyi içeren kontrol (K) implantlarının yanına yerleştirildi. Şu kategorilerde ölçüm değerleri alındı: Kanama Endeksi, Plak Endeksi, Prob Derinliği ve Kret Kemik Kaybı. **Bulgular:** Kanama veya plak endeksinde istatistiksel bir farklılık görülmedi. Tüm ölçüm dönemlerinde prob derinliklerinde anlamlı farklılıklar bu-

lundu ve kret kemik kaybı farklılıkları 7. aydan sonra anlamlı idi (P < 0.001). 37. ayda LL için ortalama prob derinliği 2.30 mm ve ortalama kret kemik kaybı 0.59 mm iken K için bunlar sırasıyla 3.60 mm ve 1.94 mm idi. Ayrıca, alt çeneye ait sonuçların maksilladan alınan değerlerle karşılaştırması (K'ye karşı LL) maksillada ortalama kret kemik kaybı ve prob derinliği açısından daha büyük bir farklılık gösterdiyse de, bu fark istatistiksel yönden anlamlı değildi. **Tartışma ve Sonuç:** LL ile K arasında prob derinliğine ilişkin olarak görülen tutarlı farklılık, kret kemiğinin üstünde stabil bir yumuşak doku oluşumuna işaret etmektedir. LL için kret kemik kaybı 0.59 mm düzeyinde kalmış ve buna karşın, K için kret kemik kaybı 1.94 mm olarak kaydedilmiştir. LL implantının, güvenlik son noktaları plak endeksi ve sulkus kanama endeksi açısından K implantına benzer olduğu görüldü. İstatistiksel olarak önemli olmamakla beraber, LL için kret kemiğinin maksillada alt çeneye nazaran daha üstün bir şekilde korunduğu düşünülmektedir.

ANAHTAR KELİMELER: alveoler kemik kaybı/etiyoloji, dental protez tasarımı, kret kemiği, implant yüzeyi

JAPANESE / 日本語

デンタルインプラントへの軟組織と骨付着を目的とするレーザーマイクロテクスチャリング加工臨床評価

共同研究者氏名: GE・ペコラ（GE Pecora） DDS, MD, R・セッカレリ（R Ceccarelli） DDS, M・ボネリ（M Bonelli）DDS, H・アレキサンダー（H Alexander） PhD, JL・リッチ（JL Ricci） PhD

研究概要:

序論: 上皮組織の根尖側移動を抑制しながら、骨と接続組織付着を優先的に達成するために下部1.5mmをレーザーマイクロマシン加工した2mmワイドカラー付先細デンタルインプラント(LL) を、将来性を見込んだ対照マルチセンター臨床テストで評価した。

素材と方法: 15名の患者に埋入したインプラント20対のデータを、術後1ヶ月から37ヶ月の測定期間で記録した。これらのインプラントは、同デザインのマシーンカラーコントロールインプラント(C) に隣接して埋入されたものである。 測定値は次の項目で記録された： Bleeding Index, Plaque Index, Probing Depth そして歯槽頂骨吸収である。

結果: Bleeding IndexあるいはPlaque Indexのどちらにも統計上差異は測定されなかった。測定全期間においてProbing Depthと歯槽骨吸収に著しい差異が見られ、7ヶ月後にはかなりの差異を示している (p<0.001)。37ヶ月目には LLの平均Probing Depthは2.30 mmで平均歯槽骨吸収 が0.59 mm、これに対しCはそれぞれ3.60 mmと1.94 mmを示した。また、下顎骨に対して上顎骨を比較した結果にも、上顎骨の歯槽骨吸収とProbing Depth平均値にかなり著しい差異が明確になっている (Cマイナス LL)。しかし、この結果は統計上重要とみなさない。

論考と結論： LLとC間の一貫したProbing Depth差異は歯槽骨上にしっかりと密封する軟組織が形成されていることを明らかにしている。Cで記録された1.94 mmの歯槽骨吸収に反して、LLは歯槽骨吸収を0.59 mm範囲内に抑えており、LLインプラントは安全性エンドポイント Plaque Indexと歯肉溝Bleeding IndexにおいてCインプラントと比較に価することが判明している。 また、非統計でLL歯槽骨保持に関しては下顎骨よりも上顎骨でより優勢を示しているという重大な示唆も提示されている。

キーワード: 歯茎骨吸収/病因学, 義歯デザイン, 歯槽骨, インプラント表面

ご質問の宛先： JL Ricci, PhD, New York University College of Dentistry, 345 East 24th Street, Room 813B, New York, NY 10010, US

電話: 212-998-9623 **FAX:** 212-995-4244 **携帯電話:** 732-778-8296 **電子メール:** john.ricci@nyu.edu

CHINESE / 中国語

軟組織與牙科植體骨附連的雷射微組織臨床評估

作者：GE Pecora, DDS, MD；R Ceccarelli, DDS；M Bonelli, DDS；H Alexander, PhD；JL Ricci, PhD

摘要：

簡介：在一項控制的前瞻性多中心臨床試驗中評估一顆頸圈寬 2mm的椎狀牙科植體 (LL) ，在阻止上皮內生的同時也將其下方 1.5mm 經雷射微機電化，以優先完成骨與締結組織連結。

資料與方法：報告包括 15 名患者共 20 對植體在手術後 1 到 37 個月的測量資料。將植體置入在相同設計的機械化齒頸控制植體 (C) 旁。報告測量值包括出血指數、牙菌斑指數、探測深度以及骨脊流失。

結果：測量的出血指數及牙菌斑指數沒有統計差異。探測深度在所有測量期間都出現顯著差異，骨脊流失在 7 個月後有顯著差異 ($p<0.001$)。在 37 個月的平均探測深度是 2.3mm；LL 平均骨脊流失為 0.59 mm，C 則分別為 3.60mm 和 1.94 mm。同時，比較下頷和上頷結果，顯示上頷的平均骨脊流失以及探測深度有較大的差異 (C 減 LL)，不過結果並不顯著。

討論與結論：LL 與 C 在探測深度的一致性差異，顯示骨脊上軟組織密封穩定形成。LL 將骨脊流失限制在 0.59 mm 範圍內，相反的，C 則出現 1.94 mm 的骨脊流失。LL在安全療效指標牙菌斑指數和牙齦溝內出血指數上可與 C 植體比較。LL 的上頷骨脊保持比下頷高，不過沒有統計差異。

關鍵字：齒槽骨流失／病因、牙科贋復設計、骨脊、植體表面

通訊方式：JL Ricci, PhD, New York University College of Dentistry, 345 East 24th Street, Room 813B, New York, NY 10010, USA
電郵信箱：john.ricci@nyu.edu 電話： 212-998-9623 傳真：212-995-4244 手機：732-778-8296

KOREAN / 日本語

치아 임플란트에 대한 연부조직 및 골 부착 면에서 레이저미세구조술의 임상적 평가

저자: GE 페코라 (GE Pecora), 구강외과박사 (DDS), 의학박사 (MD), R. 세사렐리 (R Ceccarelli), 구강외과박사 (DDS), M 보넬리 (M Bonelli), 구강외과박사 (DDS), H 알렉산더 (H Alexander), 이학박사 (PhD), JL 리시 (JL Ricci), 이학박사 (PhD)

요약:

도입: 상피세포 하향성장을 억제하면서 골 및 결합조직 부착을 이루기 위해 레이저 미세기계를 이용해 1.5mm로 점차 가늘게 만든 2mm 너비 관의 치아 임플란트(LL)를 전향적, 대조, 다기관 임상시험에서 평가하였다.

재료 및 방법: 환자 15명의 임플란트 20쌍에 대해 술후 1~37개월 측정기간의 자료를 보고하였다. 임플란트를 동일한 디자인의 기계로 만든 관 대조 임플란트(C) 주위에 장착하였다. 측정 수치는 '출혈지표', '치석지표', '탐침깊이' 및 '골능선 소실'에 대해 보고하였다.

결과: 출혈 또는 치석 지표 면에서 통계학적인 차이는 확인되지 않았다. 모든 측정기간 중 7개월 후에 탐침깊이 및 골능선 소실 면에서 유의적인 차이가 확인되었다($p<0.001$). 37개월째, LL에서 평균 탐침길이는 2.30mm였고 평균 골능선 소실은 0.59mm였으며, C에서는 각각 3.60mm 및 1.94mm였다. 또한, 하악 결과와 상악 결과를 비교한 결과, 상악에서 평균 골능선 소실 및 탐침깊이 면에서 더 큰 차이(C-LL)가 관찰되었다. 그러나, 이러한 결과는 통계학적으로 유의적이지 않았다.

토론 및 결론: LL 및 C 사이의 일관된 탐침깊이 차이를 통해 일정한 연부조직 형성으로 골능선 위가 메워지는 것으로 확인된다. LL은 0.59mm 범위로 골능선 소실을 제한한 반면, C에서의 골능선 소실은 1.94mm였다. LL 임플란트는 안전성 종점인 치석지표 및 열구출혈지표 면에서 C 임플란트와 유사한 것으로 확인되었다. LL 골능선 유지가 하악보다 상악에서 더 우세하다는 사실은 통계학적으로 유의적이지 않다.

키워드: 치조골 소실/원인, 치아 보철물 설계, 골능선, 임플란트 표면

연락정보: JL 리시 (JL Ricci), 이학박사 (PhD), New York University College of Dentistry, 345 East 24th Street, Room 813B, New York, NY 10010, USA
전화: 212-998-9623 팩스: 212-995-4244 휴대폰: 732-778-8296 이메일: john.ricci@nyu.edu