

INFORME ESTUDIOS GMI® - FACULTAD DE ODONTOLOGÍA DE LA UNIVERSIDAD
DE VALENCIA

PRONÓSTICO DE 100 IMPLANTES GMI® FRONTIER TRAS UN AÑO DE SEGUIMIENTO DE LA CARGA PROTÉSICA: ESTUDIO DE TEJIDOS BLANDOS Y DUROS PERIIMPLANTARIOS:

60 IMPLANTES GMI® en prácticas clínica odontológica Máster Cirugía Oral de la Universidad de Valencia (*COLOCADOS 65 IMPLANTES*).

40 IMPLANTES GMI® para publicación de estudios (*COLOCADOS 45 IMPLANTES*):

- Estudio 1 a: **Cambios en los parámetros periodontales tras la colocación de implantes unitarios interdentes: estudio clínico prospectivo comparando la incisión intrasulcular y la incisión trapezoidal.** (*Estudio de 16 implantes a 6 meses de seguimiento. Y estudio de 20 implantes a 1 año seguimiento*)
 - o Fue llevado en formato póster al congreso SECIB Madrid el 28 de Noviembre de 2013
 - o Y al congreso SEPA Valladolid el 24 de Mayo de 2014

- Estudio 1 b: **Changes of clinical periodontal parameters after interdental single implant placement: a prospective clinical study comparing intrasulcular incision vs. trapezoidal incision.** (*Estudio de 16 implantes a 12 meses de seguimiento. TODOS COLOCADOS*)
 - o Este estudio se mandó en Septiembre de 2014 a la revista JOMI (International Journal Oral Maxillofacial Implants), en Noviembre nos contestaron que está aceptado con modificaciones de la muestra, teniendo que ampliar a 15 pacientes por grupo de incision (En lugar de 10 y 10). A finales de Abril se enviará de nuevo el artículo con la muestra nueva.
 - o Fue llevado en formato póster al congreso EAO en Roma el 27 de Septiembre de 2014, siendo publicado como artículo resumen en la revista COIR (Clinical Oral Implant Research)

- Estudio 2: **Influence of incision design on interproximal bone loss at interdental single implant placement: intrasulcular vs. trapezoidal. Radiological study.** (*40 implantes a 12 meses de seguimiento. 20 COLOCADOS*)
 - o Empezando con la medición de la pérdida ósea para llevarlo al próximo congreso de SECIB Bilbao en 2015. Este estudio es a más largo plazo debido al seguimiento de los pacientes.

- Estudio 3: **Análisis de las interleuquinas-6, 8, 10, 12 según el tipo de incisión intrasulcular y trapezoidal en 20 implantes unitarios interdentes y su relación con el volumen de fluido crevicular.** (*40 implantes. 20 COLOCADOS*)
 - o Fue llevado en comunicación al congreso SECIB Salamanca el 22 de Noviembre de 2014, recibiendo el PREMIO ACCESIT COMUNICACIÓN ORAL DE INVESTIGACIÓN BÁSICA. Por la comunicación: “*Respuesta inmunológica de los dientes adyacentes a implantes unitarios: estudio clínico prospectivo aleatorizado comparando incision intrasulcular y trapezoidal*” en el XII Congreso de la Sociedad Española de Cirugía Bucal, celebrado en Salamanca.

Changes on periodontal clinical parameters after interdental single implant placement: a randomized clinical trial comparing two incision types

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Background: In dental implant surgery, different designs of incisions are applied to get access to the bone. As the bone level constitutes the base for the supra-crestal soft tissue, bone loss may negatively influence the soft tissue topography and the esthetic outcome of the implant therapy. Experimental studies in animals and humans have demonstrated that the exposure of the alveolar bone by flap elevation induces osteoclastic activity and results in bone resorption. Fickl et al. demonstrated in a histologically study in dogs that the elevation of a partial-thickness flap technique can have a certain potential to be superior over full-thickness flaps concerning preservation of alveolar bone. Gómez-Roman demonstrated that the use of a limited flap design is recommended to minimize interproximal crestal bone loss and possible loss of the papillae. The level of bone support and the soft tissue dimensions around implants are factors suggested to be important for the esthetic outcome of implant therapy.

Aim/Hypothesis: To date, it is unclear if raising a flap with a design of an intrasulcular incision or a trapezoidal incision, is effective to limit changes in clinical periodontal parameters in adjacent teeth to interdental single implants. Thus, the aim of the present clinical trial was to analyze what incision type results is a clinically relevant advantage.

Material and methods: A prospective randomized clinical trial was carried out in the Oral Surgery and Implantology Unit of a University Clinic, between January 2012 and March 2014. The study was approved by the local ethics committee, and was performed following the principles of the Declaration of Helsinki. All patients included required the placement of an interdental single implant (Frontier Ilerimplant®S.L.-GMI S.L., Lleida, España). The incision type was randomized by sealed envelopes into two groups using the SPSS statistical package (SPSS, Chicago, IL, USA): group (a) intrasulcular incision and group (b) trapezoidal incision. The impression for crown restoration was taken from the implant level, three months after implant placement. All the restorations were single screw retained crowns. The present study focused on dimensional alterations of the periodontal soft tissues during two different phases of the treatment with implant-supported single-tooth restorations, the surgical phase and the prosthetic phase. Before implant placement, 1 month after surgery, the day of the abutment connection, 3 and 6 months postloading, the following parameters were measured: probing depth, gingival recession and bleeding index. The day of the abutment connection, 3 and 6 months, the following parameters were measured: scar on periimplant vestibular mucosa and interproximal papilla. Before implant placement, 7 days after implant placement and 1 month after surgery: periodontal crevicular fluid volume was measured.

Results: Eighteen implants were included, nine in the intrasulcular group and nine in the trapezoidal group. Comparing probing depth from pre-surgery and at 6 months in both incision types and in any of the three studied positions, no statistically significant differences were found. The periodontal crevicular fluid volume was statistically significantly higher in the intrasulcular incision, comparing pre-surgery and 7 days after surgery. Six months postloading of presurgery, the recession obtained similar results on teeth adjacent to the implant, comparing both incision types. Significant differences were obtained in the papilla parameter in both groups at six months loading, in the intrasulcular group papilla mesial and distal were statistically significantly (P -value = 0.034 and 0.083 respectively), in the trapezoidal group just the mesial papilla obtained significant differences. Statistical significance were observed in the vestibular scar parameter, observed in pre-surgery and at 6 months of loading.

Conclusion and clinical implications: This study demonstrated that an intrasulcular incision causes only a slight increase in gingival recession, a decrease in the volume of crevicular fluid, a greater increase in papilla fill and no presence of a vestibular scar. This findings are important because increased of periodontal crevicular fluid volume and probing depth, may confer a risk on bone loss and influence the soft tissue topography and the esthetic outcome of the implant therapy.