A Prospective Clinical Assessment of BioHorizons Tissue-Level Implants

This investigation was designed to evaluate crestal bone stability and soft tissue maintenance to Laser-Lok tapered tissue-level implants. Twelve patients presenting with an edentulous site adequate for the placement of two implants were recruited from four dental offices (2 to 4 patients per office). Each patient received two Laser-Lok tissue-level implants placed with a 3-mm interimplant distance according to a surgical stent. The implants were placed so that the Laser-Lok zone sat at the junction between hard and soft tissues. A total of 24 implants were placed, and all achieved satisfactory crestal bone stability and soft tissue maintenance 1 year after receiving the final prosthetic restoration. Int J Periodontics Restorative Dent 2023;43:105–111. doi: 10.11607/prd.6065

A number of preclinical and human studies have examined the effect of the implant design, surface treatment, surface topography, surface charge, and other variables on bone healing and bone apposition. These studies reported that micro-rough titanium surfaces have a significantly greater percentage of bone-to-implant contact (BIC) compared to machined or polished titanium surfaces. For example, in vitro studies have shown that titanium surface roughness influences a number of events in the process of osteoblast differentiation, including spreading and proliferation; the production of alkaline phosphatase, collagen, proteoglycans and osteocalcin; and the synthesis of cytokines and growth factors.

Despite these improvements in implant surface characteristics, the prevailing contemporary evidence suggests a “die-back effect,” or crestal bone loss, when a two-piece implant is placed. There is evidence of an inflammatory infiltrate (inflammatory connective tissue) associated with the implant-abutment junction that drives the connective tissue element apically, resulting in bone loss. Preclinical trials using an animal model confirmed a 3-mm soft tissue dimension and a 1-mm crestal bone loss to accommodate for the biologic width connective tissue. In a preclinical canine study,
Abrahamsson et al demonstrated that repeated removal and reconnection of a healing abutment compromised the protective connective tissue barrier and resulted in a more apically positioned connective tissue zone.\textsuperscript{15} A subsequent preclinical study also revealed that the abutment portion of the implant influenced the location and the quality of the attachment between the peri-implant mucosa and the implants.\textsuperscript{16}

It was previously demonstrated that the roughened surface of an osseointegrated titanium implant can be mechanically altered to achieve physiological attachment of the supracrestal connective tissue to the implant, emulating the attachment apparatus of a tooth.\textsuperscript{17} The proof-of-principle human histology investigation demonstrated supracrestal connective tissue attachment to the BioHorizons Laser-Lok microchannels.

Previous data indicated that an interimplant distance < 3 mm would decrease the crestal bone level, but the results of a recent investigation suggested that a more optimistic clinical result can be anticipated for implants and abutments with a laser-microchannel surface.\textsuperscript{18,19} This multicenter clinical trial\textsuperscript{19} of platform-switched laser-microchannelled implants supported findings from a previous preclinical trial.\textsuperscript{17}

The objective of this prospective clinical study was to provide a short-term observation of the maintenance of both hard and soft tissues around Laser-Lok tapered tissue-level implants (Fig 1).

**Materials and Methods**

This was a multicenter, prospective, clinical and radiographic study to assess the clinical efficacy of tissue-level implants. These implants (Tapered Tissue Level, BioHorizons) range in diameters from 3.0 to 5.8 mm. All of them have a 1.8-mm transmucosal collar and a 2-mm Laser-Lok zone with precisely defined microchannels (8- to 12-µm width and 6- to 12-µm depth) created by laser ablation. The 1.8-mm transmucosal collar consisted of a machine-polished surface coronally and a Laser-Lok surface apically (Fig 1).

Four clinical centers participated in the present study. Each center recruited 2 to 4 patients requiring two adjacent implants (4 to 8 implants per center, for a total of 24 implants) that were placed with 3-mm interimplant spacing. In total, 12 patients were enrolled and signed an informed consent form based on the 1975 Declaration of Helsinki, as revised in 2013. The inclusion criteria were as follows: (1) between 20 and 70 years of age, with a two-tooth edentulous area (no immediate implant placement) requiring implant treatment options for rehabilitation; (2) willingness to sign an informed consent, participate, and return for follow-up visits; (3) lack of significant medical history and no current consumption of medications that might complicate results (American Society of Anesthesiologists [ASA] class I or II); (4) no smoking habit; and (5) no current pregnancy.

**Surgical Implant Placement and Restoration**

Presurgical periapical radiographs, CBCT scans, and appropriate clinical photos were taken (Fig 2a). Surgical stents with 3-mm interimplant spacing were fabricated for all participants (Fig 2b). A total of two implants per patient were inserted, and implant osteotomies were performed with torque reduction rotary instruments using sterile saline solution. Two implants of the same manufacturer (BioHorizons)
were placed next to each other with an insertion device and a hand ratchet, according to the manufacturer's guideline, while maintaining a 3-mm interimplant spacing (Fig 2c). The implants were placed so that the bone/soft tissue junction was within the Laser-Lok transition zone (Fig 2d). Tissue-level healing abutments (BioHorizons) were inserted, and the flaps were adapted for tension-free wound closure. Periapical radiographs were taken immediately after implant placement. Patients were given amoxicillin (500 mg, tid for 7 days) and ibuprofen (400 mg, tid for 7 days) and were instructed to rinse twice daily with 0.12% chlorhexidine gluconate for 1 week. Patients were followed up monthly until receiving the final restoration 3 months after implant placement, then periodontal maintenance was performed every 3 months.

**Clinical and Radiographic Evaluations**

All patients were required to return at 6 months and 1 year postrestoration for clinical evaluations and assessment of probing depth, bleeding on probing (BOP), recession, and the keratinized tissue width around implant sites. Periapical radiographs were also updated, taken with the paralleling technique using the Rinn XCP positioner.

**Results**

Twelve patients were enrolled and completed the study. Two implants were placed per patient for a total of 24 implants, of which 10 were placed in the posterior maxilla and 14 were placed in the posterior mandible. All sites healed uneventfully, and all implants achieved clinical osseointegration. Furthermore, crestal bone stability and soft tissue maintenance were achieved. Two cases are presented as examples.
Case 1

The maxillary left second premolar and first molar implants were placed with the Laser-Lok transition zone located right at the junction of the alveolar crest and soft tissue. Periapical radiographs taken at implant placement and 1 year after prosthetic delivery showed excellent crestal bone stability without the signs of die-back typically observed after 1 year of loading (Figs 3a and 3b). At initial prosthetic delivery, 1 mm of recession was observed (Fig 3c) and was completely resolved 1 year later (Fig 3d). This clearly demonstrated the excellent soft tissue maintenance achieved with the Laser-Lok surface.

Case 2

The maxillary right first and second premolar implants were placed with the Laser-Lok transition zone located right at the junction of the alveolar crest and soft tissue (Figs 4a to 4d). In this case, the two implants were placed with a vertical discrepancy due to the slanting of the alveolar ridge. Comparing the soft tissue results obtained at prosthetic delivery (Fig 4e) and 1 year later (Fig 4f) revealed excellent maintenance. Periapical radiographs taken at implant placement (Fig 4d) and 1 year after prosthetic delivery (Fig 4g) showed excellent crestal bone stability without the signs of die-back typically observed after 1 year of loading, despite the difference in vertical positions between the implants.

Discussion

The present study demonstrated that Laser-Lok Tapered Tissue Level implants placed 3 mm apart resulted in good maintenance of both hard and soft tissues 1 year after prosthetic delivery. The implant design has two main features: Macroscopically, this is a tissue-level implant characterized by a 1.8-mm transmucosal collar; microscopically, there is a 2.0-mm Laser-Lok zone consisting of laser-ablated microchannels. The transmucosal collar is comprised with both a coronal machine-polished surface corresponding to the junctional epithelial zone and an apical microchanneled surface corresponding to the connective tissue zone.

The periodontium of natural teeth has perpendicular attachment of dentogingival connective tissue fibers that prevent the apical migration of the epithelium. However, in most implant systems, peri-implant connective tissue is comprised of bundles of collagen fibers that run parallel and circumferentially around the implant surface and...
are thus unable to resist epithelial downgrowth.\textsuperscript{20,21} In contrast, previously published histologic studies in canines and humans showed that the laser-ablated microchannels could guide and stabilize fibroblasts to produce functionally oriented connective tissue fibers that perpendicularly attach to the implant surface.\textsuperscript{17,20}

Marginal bone loss around two-piece implant systems may be caused by the microgaps at the implant-abutment junction, which favor bacterial colonization.\textsuperscript{22,23} Tissue-level implants have the advantage of moving this junction transmucosally, which reduces bone alteration; however, soft tissue esthetics could be compromised, as there is a risk of the metal collar becoming visible.\textsuperscript{24} In the present study, both hard and soft tissue maintenance were optimal at 1 year in all implants. In one case, a 1-mm recession at prosthetic delivery was completely resolved at 1 year. This result could be contributed to both the transmucosal collar design as well as the establishment of

\textbf{Fig 4} Case 2. (a) Initial clinical view of the maxillary right edentulous ridge. (b) Implants were placed according to the surgical stent, with a 3-mm interimplant distance. (c) Transmucosal healing abutments were placed, and the flap was closed. (d) Periapical radiographic view at implant placement. (e) Clinical views at crown delivery and (f) 1 year after prosthetic delivery. (g) Periapical radiographic view 1 year after prosthetic delivery. Note the excellent maintenance of bone level.
functionally oriented connective tissue fibers to the Laser-Lok surface. Furthermore, the laser-ablated microchannels have been shown to reduce or eliminate inflammatory infiltrates.25,26 The tissue-level design and the laser-ablated microchannels may act synergistically to preserve the bone and enhance soft tissue outcomes.

A limitation of this study is that it is a relatively short-term clinical trial with only 12 participants and no control group. Nevertheless, together with previous preclinical and clinical trials, it adds to the mounting evidence to show that a laser-microchanneled surface has the potential to preserve crestal bone and maintain soft tissue integrity.

Conclusions

Within the limitations of the present study, the results clinically confirm and support previous histologic findings from preclinical trials and expand the potential use of the Laser-Lok surface to tissue-level implants. All implants in the study showed preservation of crestal bone and optimal, if not improved, soft tissue maintenance 1 year after prosthetic delivery. The clinical and radiographic evidence provide an optimistic outlook for this system.

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References


