Tissue Response to Transcutaneous Laser Microtextured Implants

CL Ware, JL Simon, JL Ricci
University of Medicine & Dentistry of New Jersey, New Jersey Dental School, C-813, Newark, NJ, 07103, and
Department of Biomedical Engineering, Rutgers University, Piscataway, NJ, (973) 972-5068, riccijl@umdnj.edu

Introduction: This report describes the use of laser-microtextured transcutaneous implants in a rabbit calvarial model to enhance soft tissue integration. Dental and orthopaedic implants are routinely microtextured to enhance tissue integration. Computer-controlled laser microtexturing techniques that produce microgrooved surfaces with defined 8-12 μm features on controlled regions of implant surfaces have been developed based on results from cell culture experiments and in vivo models [1]. These textures have been replicated onto the collars of dental implants to provide specific areas for both osteointegration and the formation of a stable soft tissue-implant interface. The objective of this study is to evaluate these implants in a transcutaneous rabbit calvarial model to determine whether controlled laser microtexturing can be used to create a stable interface with connective tissue and epithelium.

Methods: Laser microtextures were produced on the 4mm diameter collars of modified dental implants designed for rabbit studies (Figure 1). The implants were 4.5mm in length and the threaded portion was 3.75mm in diameter. Implants were produced and supplied by Orthogen Corporation (Springfield, NJ) and BioLok International (Deerfield Beach, FL). The implant surfaces were modified by ablation of defined areas, using an Excimer laser and large-area masking techniques. Controlled laser ablation allows accurate fabrication of defined surface microstructure with resolution in the micron scale range. Laser machined surfaces contained 8μm and 12μm microgrooved systems oriented circumferentially on the collars. The collars of the control implants were "as machined", and were characterized by small machining marks on their surfaces. All implants were cleaned and passivated in nitric acid prior to sterilization.

Four transcutaneous implants were surgically implanted bilaterally in the parietal bones in each rabbit using single-stage procedures. The surgical protocol was similar to dental implant placement. An incision was made over the sagittal suture, and the skin and soft tissues were reflected laterally. Implants were placed using pilot drills and fluted spade drills to produce 3.4mm sites for the 3.75mm diameter implants. The implants were placed with the threaded portion in bone, and the laser-microtextured collar penetrating the subcutaneous soft tissue and epithelium. Each rabbit received two implants on either side of the midline (1 control and 3 experimental implants per subject). The skin was then sutured over the implants. Punch openings were made to expose the tops of the platforms of the implants, and the cover screws were used to fasten down small plastic washers coated with triple antibiotic ointment. The plastic washers were used to prevent the skin from closing over the implant during the swelling that occurred during early healing. They were removed after two weeks. Twelve rabbits were used in the study. Rabbits were sacrificed at 2, 4, and 8 weeks, and the implants and surrounding tissues were processed for histology. Hard and soft tissue response to the implants was examined histologically.

Results and Discussion: No complications or infections were encountered during the course of the experiment. The 2- and 4-week histology displayed immature soft tissue formation around all implants, and little epithelial interaction with the implant surfaces was noted as the epithelium had not regenerated at the implant surface by 2 weeks, and no clear relationship between epithelium and implant was seen at 4 weeks. 8-week samples showed more mature soft tissue and epithelial tissue. In these samples the epithelium had fully regenerated and the soft tissue showed more mature and organized collagen. In the control samples the epithelium consistently grew down the interface between implant and soft tissue and formed a deep sulcus along the implant collar. This sulcus extended to the bone surface and there was little or no direct soft tissue interaction or integration with the control surfaces. The 8-week laser machined implants produced a different pattern of tissue interaction. The epithelium also produced a sulcus at the upper collars of these implants. However, in most cases the sulcus did not extend down as far as the bone surface, but ended at a 300-700μm wide band of tissue, which was attached to the base of the microtextured collar. Even though the laser-microtexturing extended to the top of the collar, this soft tissue attachment formed only at the lower portion of the implant collar, where a stable "corner" of soft tissue attached to both the implant collar and the bone surface. This arrangement of sulcus, epithelial attachment, and soft tissue attachment was similar to the "biologic width" structural arrangement that has been described around teeth [2] and in some cases around implants [3].

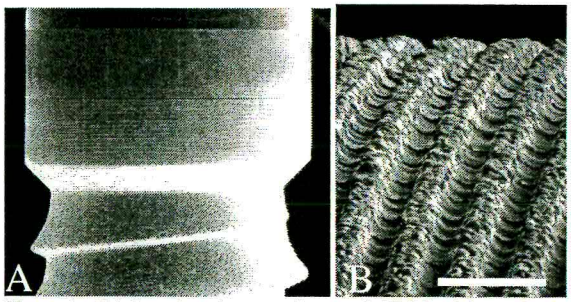

Figure 1. (A) Scanning electron micrograph (SEM) of the surface of a laser microtextured implant. The microtexturing is in two bands on the two millimeter-wide collar. (B) Higher magnification SEM of the laser microtextured surface showing 12 μm grooves and ridges (bar = 40μm).

Conclusions: This preliminary study suggests that laser microtextured surfaces can be applied to transcutaneous implants and used to improve soft tissue integration. Results suggested that the soft tissues at the skin interface are capable of producing an arrangement similar to the "biologic width" arrangement seen around teeth. These laser-machined microtextures are hypothesized to work by increasing surface area for tissue attachment, while controlling the microstructure and organization of attached cells and tissues. They can be used to form a functionally stable interface with soft tissues, establishing an effective transcutaneous barrier. While longer-term studies are needed, the results suggest that performance of transcutaneous prosthetic fixation may be enhanced through the use of regional organized microtexturing.

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3. Berglundth and Lindhe, J Clin Periodontol 23:971-973, 1996.

Tissue Response to Transcutaneous Laser Microtextured Implants

Courtney L. Ware[1], Josh L. Simon[2], and John L. Ricci[3]

[1]Rutgers University Graduate School of Biomedical Engineering and Prosthetics, Piscataway, NJ
[2]Rutgers University Department of Biomedical Engineering, Piscataway, NJ
[3]UMDNJ - New Jersey Dental School, Newark, NJ

ɔduction and Objectives

Dental and orthopaedic implants are routinely microtextured to enhance tissue integration. Microtexturing is usually produced using abrasive blasting or a combination of abrasive blasting and acid etching. We have developed computer-controlled laser microtexturing techniques that produce surfaces with defined microstructures. These surfaces can be applied to specific areas of implant surfaces in organized patterns. Microgrooved surfaces with 8 and 12 µm features (groove size, ridge size, and groove depth) have been developed based on results from cell culture experiments and in vivo models [1]. These textures have been produced on the collars of dental implants to enhance both osseointegration and the formation of a stable soft tissue-implant interface. These implants are being used in clinical studies and are showing better tissue integration, and less crestal bone loss, than implants with untextured collars. The objective of this study is to evaluate these modified implants in a transcutaneous rabbit calvarial model in an effort to determine whether controlled laser microtexturing can be used to create a stable series of interfaces with connective tissue and epithelium.

Experimental Methods

Laser microtextures were produced on the 2mm high by 4mm diameter collars of modified dental implants designed for rabbit studies (Figure 1). The implants were 4.5mm in length and the threaded portion was 3.75mm in diameter. The implants were produced and supplied by Orthogen Corporation (Springfield, NJ) and BioLok International (Deerfield Beach, FL). The implant surfaces were modified by ablation of defined areas, using an Excimer laser and large-area masking techniques. Controlled laser ablation allows accurate fabrication of defined surface microstructure with resolution in the micron scale range. Laser machined collar surfaces were fabricated with 8µm and 12µm microgrooved systems, in 1mm circumferential bands, with the 8µm surfaces in the upper position in one half of the implants, and the 12µm surfaces in the upper position in the other half.. The collars of the control implants were "as machined", and were characterized by small (<4µm) machining marks on their surfaces. All implants were cleaned and passivated in nitric acid prior to sterilization.

Four transcutaneous implants were surgically implanted bilaterally in the parietal bones in each rabbit using single-stage procedures. The surgical protocol was similar to single-stage dental implant placement. An incision was made over the sagittal suture of the rabbbit skull, and the skin and soft tissues were reflected laterally. Implants were placed using pilot drills and fluted spade drills to produce 3.4mm sites for the 3.75mm thread diameter implants (Figure 2). A 4mm countersink drill was used to seat the implant collars. The implants were placed with the threaded portion in bone, and the laser-microtextured collar penetrating the subcutaneous soft tissue and epithelium, with the base in the bone. Each rabbit received two implants on either side of the midline (1 control and 3 experimental implants per subject). The skin was then sutured over the implants. Punch openings were made to expose the tops of the platforms of the implants, and the cover screws were used to fasten down small plastic washers coated with triple antibiotic ointment. The plastic washers were used to prevent the skin from closing over the implant during the swelling that occurred during early healing (Figure 3). They were removed after two weeks. Twelve rabbits were used in the study. Rabbits were sacrificed at 2, 4, and 8 weeks (four rabbits at each time period), and the implants and surrounding tissues were processed for histology. Hard and soft tissue response to the implants was examined histologically using undecalcified, plastic-embedded preparations

A series of measurements were taken on each histological slide (Figure 4). These included sulcus depth, width of epidermal attachment, collar to distal epidermis, and bone to collar distance.

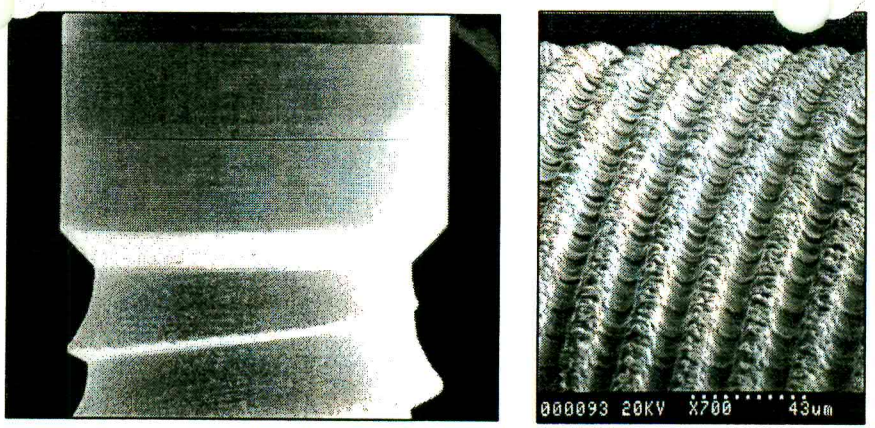

Figure 1. (A) Scanning electron micrograph (SEM) of the surface of a laser micromachined implant used in the transcutaneous study. The laser microtexturing is in two bands on the two millimeter-wide collar. (B) Higher magnification SEM of the laser microtextured surface showing the 12 µm grooves and ridges (bar = 43µm).

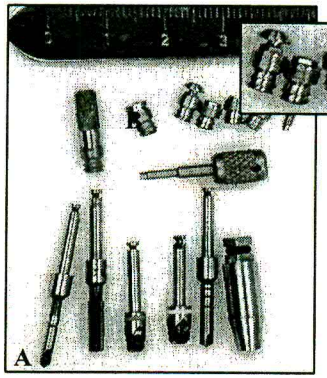

Figure 2. (A) Instrumentation used in the transcutaneous implant study. (B) Control implants (first and fourth from left) and laser microtextured implants (second and third from left) used in transcutaneous study.

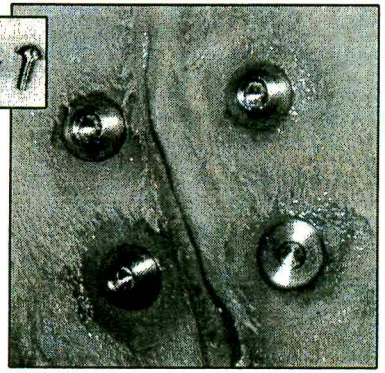

Figure 3. Post-operative surgical photograph of four transcutaneous implants in place in the rabbit parietal bones.

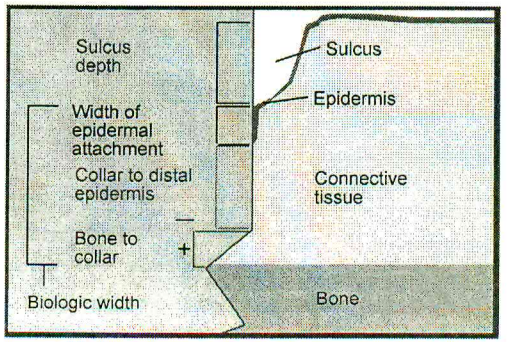

Figure 4. Schematic diagram of measurements taken on histological specimens. Measurements of sulcus depth, width of epidermal attachment, collar to distal epidermis, and bone to collar distance are shown. The bone to collar measurement can be either positive or negative depending on whether the bone height is above (-) or below (+) the lower edge of the collar.

Results

Human Implant Studies

BioLok implants have been reported to have a 99% success rate at 1 year and 98% success rate at 5 years. They lose, on average, 0.78mm of crestal bone at one year and 0.82mm of bone by 5 years [4,5]. No LaserLok™ implant failures have been reported. LaserLok™ implants showed no differences in probing depth, plaque index or other parameters when compared with the standard implants (Table1). However, the LaserLok™ implants were observed to retain more crestal bone height than the standard implants. Differences in crestal bone height were noted radiographically as early as 4 months in both multi-stage procedures (Figure 5) and in bone grafted sites (Figure 6). Data from the first 26 patients indicated that LaserLok™ implants lost 0.56mm of bone at one year, a 28% reduction in bone loss (Table 2). In a small series of 6 patients that were treated using single-stage procedures, only 0.20mm of crestal bone loss was observed at 1 year. This is a 78% reduction in bone loss, but represents only a small number of patients.

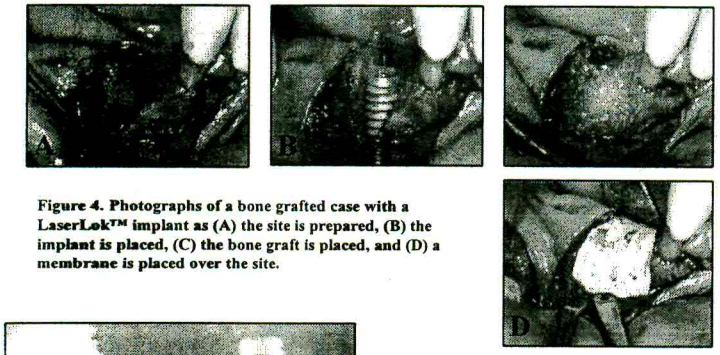

Figure 4. Photographs of a bone grafted case with a LaserLok™ implant as (A) the site is prepared, (B) the implant is placed, (C) the bone graft is placed, and (D) a membrane is placed over the site.

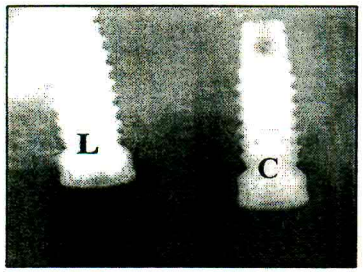

Figure 5. Radiograph of a 45-year old male patient with a LaserLok™ implant (L) and a control implant (C), after 4 months. Little crestal bone loss is evident around the LaserLok™ implant.

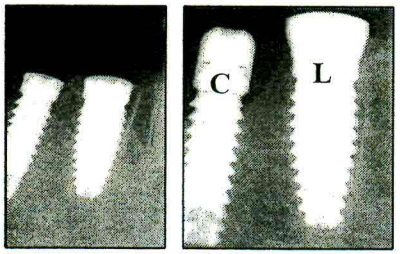

Figure 6. Radiographs of a clinical case where bone graft was placed around the implants, (A) at the time of surgery, and (B) after 4 months. No crestal bone loss is evident around the LaserLok™ (L) implant, while bone loss is observed around the control implant (C).

Table 1. Clinical Results

Parameter	Published 1-yr results [4]	LaserLok™ Results
PI (plaque index, 0-3)	0.27±0.51	0.28±0.50
SBI (sulcular bleeding index, 0-3)	0.25±0.54	0.24±0.53
PD (probing depth, mm)	2.68±0.79	2.56±0.79
DSM (dist abut shoulder to mucosal margin)	-0.17±0.98	-0.31±0.78
AL (attachment level, PD + DSM)	2.51±0.90	2.25±0.90
WKM (width of keratinized mucosa)	3.27±2.14	2.89±2.12

Table 2. Clinical Results — Crestal Bone Loss (DIB)

Parameter	Published 1-yr results [4]	LaserLok™ Results
DIB (distance from implant shoulderto bone)	0.78±0.30*	0.56±0.65
Additional breakdown		
DIB (thin soft tissue, early exposure, N = 4)		0.98
DIB (thin soft tissue, non-submerged, N = 6)		0.20
DIB (submerged, N = 16)		0.60
* 5-year bone loss is 0.82±0.83 [5]		

Conclusions

Animal studies and early clinical results suggest that laser microtextured surfaces with specific structure sizes and orientations can be applied to dental implants and used to improve bone and soft tissue integration. Human clinical results indicate that the LaserLok™ implants retain more crestal bone than non-laser treated implants and show no increase in plaque formation. While it is too early to determine significance of this data, the results are promising and evaluation continues. These laser machined microtextures work by increasing surface area for tissue attachment, and controlling the microstructure and organization of attached cells and tissues. They form mechanically stable interfaces with bone and soft tissue, and early results suggest that they can be used to establish an effective transcutaneous interface in the intraoral environment.

References

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