Case Series

Clinical and Histologic Evaluation of a Granular Bovine Bone Biomaterial Used as an Adjunct to GTR With a Bioresorbable Bovine Pericardium Collagen Membrane in the Treatment of Intrabony Defects

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Background: The aim of the present study is to evaluate the clinical and histologic healing of deep intrabony defects treated with guided tissue regeneration (GTR) with a collagen membrane from bovine pericardium and implantation of granular bovine bone biomaterial.

Methods: Thirty patients with one deep, combined 1- and 2-wall intrabony defect exhibiting a probing depth ≥6 mm and an associated intrabony defect ≥3 mm were treated with GTR with a bioresorbable collagen membrane from bovine pericardium and adjunct implantation of a granular bovine bone biomaterial. The clinical results were evaluated 1 and 3 years after surgery. In addition, five teeth fulfilling the inclusion criteria but scheduled for extraction because of advanced periodontitis or restorative considerations were treated similarly and then extracted along with a portion of their surrounding periodontal tissues for histologic evaluation 6 months after surgery.

Results: Healing was uneventful in all patients. Significant clinical improvements were observed at 1 and 3 years postoperatively (P<0.01; probing depth averaged 4.4 ± 1.6 and 4.7 ± 1.4 mm and clinical attachment level gain was 3.9 ± 1.4 and 3.5 ± 1.3 mm, respectively). The histologic evaluation revealed formation of new cellular cementum and new periodontal ligament in four of the five cases. In general, the xenograft particles seemed to be mostly embedded in connective tissue without any evidence of new bone formation.

Conclusion: GTR treatment of intrabony defects with the collagen membrane from bovine pericardium and adjunct implantation of the new bovine bone biomaterial may result in significant clinical improvements that can be maintained over a period of 3 years, and regeneration of cementum and periodontal ligament, but without bone formation. J Periodontol 2011;82:462-470.

KEY WORDS
Grafting, bone; guided tissue regeneration; histology; periodontitis; regeneration.

A large number of regenerative periodontal treatment approaches have been proposed throughout the years. Guided tissue regeneration (GTR) is a proven treatment protocol that can result in the restoration of the periodontal attachment (i.e., wound healing after periodontal therapy is characterized by the formation of new cementum with functionally oriented inserting collagen fibers on the previously exposed and instrumented portion of the root, paralleled with new alveolar bone formation, and a periodontal ligament with physiologic width and composition1). GTR involves the surgical introduction into the wound of a physical barrier (a membrane), which is
intended to isolate the root surface from the gingival connective tissue and epithelium after flap reposition- ing and simultaneously to create a secluded space to be repopulated by periodontal ligament cells. Improved periodontal treatment outcomes (i.e., larger probing depth [PD] reductions and clinical attachment level [CAL] gains) have usually been observed after GTR treatment in intrabony and furcation defects, compared to what is obtained after conventional periodontal surgery (i.e., open flap debridement). In addition, it has been shown that the improved clinical conditions are maintained over a long period of time.6-11

A critical parameter for periodontal regeneration is unobstructed space provision, which facilitates forma- tion and maturation of a periodontal regenerate.12 To prevent collapse of the membrane onto the root surface or into the defect during wound healing and thereby avoiding the reduction or elimination of the space available for regeneration, GTR is often combined with bone grafts or bone biomaterials. These are implanted into the defect (i.e., under the membrane) to support the barrier material so that it preserves its original position at placement (for review see Stavropoulos13). Moreover, the bone graft or bio- material might also possess osteoconductive or osteoinductive qualities enhancing bone healing.

Current common clinical protocol for GTR includes the placement of a bioresorbable membrane and an “out of the shelf” bone graft or biomaterial. The exist- ing membranes are mostly made of collagen of xeno- genic origin, whereas a large variety of allogenic, xenogenic, and alloplastic bone grafts and biomate- rials are commercially available. In perspective, in two systematic reviews, no added clinical benefit has been observed from the combined use of GTR and a bone graft or biomaterial compared to what was obtained after only GTR in intrabony defects. Nevertheless, large differences exist among the various production methods of proprietary technologies, resulting in products (membranes, bone grafts, or biomaterials) with potentially different physicochemical properties or biologic behavior; this, in turn, necessitates the regular evaluation of new commercially available products.

One proprietary technology** for tissue graft cleaning and preservation has been commercially available for >3 decades and accounts for >1 million implantations of various tissue grafts without any single documented case of disease transmission. The process involves a series of chemical treatments of the graft tissue, which theoretically eliminates the possibility of disease transmission but does not compromise the biologic or mechanical properties of the end product, which thus closely resembles natural bone.15 Recently, a collagen membrane for periodontal indications from bovine pericardium†† and a particulate xenogenic graft from cancellous bovine bone,‡‡ both produced with the previously referred- to process, became available on the market. The aim of the present study is to evaluate clinically and histologically the healing of deep intrabony defects after GTR treatment with the bovine pericardial collagen membrane (TD) and the particulate bovine bone graft (TG).

MATERIALS AND METHODS

Study Population

Thirty white patients (19 males and 11 females; age range 49 to 62 years; average age: 57.8 years) with advanced chronic periodontitis (i.e., chronic periodontitis was classified as generalized when >30% of sites were affected by a clinical attachment loss ≥5 mm) were included in this private practice— (one center in Italy and two centers in Germany) and uni- versity clinic— (Denmark and Hungary) based study (enrollment dates, November 2004 to May 2005). En- rollment in the study was based on the following criteria: 1) no systemic diseases or conditions that could influence the outcome of therapy or contraindicate surgery; 2) ≥1 tooth harboring a combined 1- and 2-wall intrabony defect, with PD ≥6 mm and radiographic intrabony component depth (IC) ≥3 mm, 2 months after completed basic periodontal therapy (i.e., full-mouth scaling and root planing under local anesthesia [baseline]) (Figs. 1A and 1B); 3) no peri- odontal surgery on the test teeth within 6 months of enrollment; and 4) good level of oral hygiene as indicated by absence of plaque on the site and full-mouth plaque scores ≤20% on at least two consecutive appoint- ments. In addition to PD, gingival recession (REC) and CAL equal to PD plus REC were registered and calculated. In cases where position of the cemento-enamel junction was not clearly distinguish- able, a restoration margin was used as a fixed point for the registrations. In each center, all clinical procedures (i.e., clinical registrations, surgeries, controls) were performed by one single dentist (AS, GC, or DC) that had extensive experience with GTR procedures.

In five patients, an additional tooth scheduled for extraction (i.e., deemed irrational or hopeless to treat, or having a root scheduled for resection because of advanced periodontal destruction or further prosthetic considerations) was included in the study with the intention to histologically eval- uate the outcome of healing. This latter part of the study (i.e., tooth extraction for histologic analysis) was solely university-based and approval was pre- viously granted by the ethical committee of the

** Tutoplast Process, Tutogen Medical, Neunkirchen, Germany (now RTI Biologics, Alachua, FL).
†† Tutodent Chips, Tutogen Medical.
‡‡ Tutodent, Tutogen Medical.
Semmelweis University of Medicine, Budapest, Hungary. All enrolled patients signed an informed consent form after thorough oral and written information about the procedures and treatment plan. All clinical registrations were made by the same dentist performing the surgery (PW), who had extensive experience with GTR and biopsy harvesting procedures.

**Surgical Procedures**

Teeth exhibiting mobility >1 degree were splinted before surgery to the neighboring teeth either with synthetic resin reinforced with a glass-fiber tape or by means of a provisional, fixed partial denture if indicated by the final restorative and treatment plan. After intracrevicular incisions, mucoperiosteal flaps were raised buccally and orally (Fig. 1C). In general, vertical releasing incisions were avoided, unless deemed necessary to obtain sufficient access to the defect or to achieve better closure of the wound. All granulation tissue was removed from the defects, and the roots were thoroughly scaled and planed using hand and ultrasonic instruments. In the five teeth scheduled for extraction, a horizontal notch was prepared on the root surface using a 1-mm diameter diamond bur at the most apical extent of calculus or instrumentation (if no calculus was visible) to serve as a landmark during histologic measurements. For reasons of orientation during the histotechnical procedures and standardization of the histologic evaluation, a vertical notch indicating the deepest site of the intrabony component was also prepared on the crown of the tooth at a distance coronal to the anticipated post-surgery position of the gingival margin using a flame-shaped diamond bur. After completed debridement, the defects were filled with the granular bovine bone biomaterial (0.25 to 1 mm granule diameter),§§ with only light condensation of the material and without prior root surface conditioning (Fig. 1D). Then, a collagen membrane from bovine pericardiumiii was trimmed, adapted, and placed without suturing to completely cover the defect extending ≥3 mm beyond its margins (Fig. 1E). Finally, the mucoperiosteal flaps were repositioned coronally to completely cover the membrane and were fixed with vertical or horizontal mattress sutures (Fig. 1F).

**Infection Control**

All patients received systemic antibiotics for 1 week (1 g amoxicillin per day), starting 1 hour before surgery. The sutures were removed at 10 to 14 days after surgery and the patients were instructed to abstain from brushing the teeth in the operated area and to rinse with 0.2% chlorhexidine digluconate twice daily for the first postoperative month. Recall appointments were performed once per week for the first 4 weeks, then once per month for the following 3 months, and at 6 and 12 months postoperative; professional tooth cleaning consisting of supragingival scaling or polishing was the only treatment provided at the recall visits. No subgingival instrumentation was performed in the operated areas throughout the study period. After the 12-month control, the patients were referred back to their private dentist for maintenance.

§§ Tutodent Chips, Tutogen Medical.

iii Tutodent, Tutogen Medical.
The patients were again invited for a control 3 years after surgery.

**Data Collection and Handling**

All baseline clinical registrations were repeated 1 year after surgery. In each center, a single experienced investigator (AS, GC, or DC) made all clinical registrations at all time-points, on six sites per tooth with the same type of manual periodontal probe. On each experimental tooth, the site with the deepest PD at baseline was chosen as the site of interest for clinical or histometric evaluation of the treatment outcome. In case of more than one site with the same PD, the one presenting the deepest IC was chosen as the site of interest. Statistical evaluation of differences between baseline and 12-month data was performed with a statistical software package.

**Surgical Biopsies**

After recording of all relevant clinical parameters at 6 months post-surgery, mucoperiosteal flaps were raised and the five teeth scheduled for extraction or root resection were carefully removed together with a portion of the area immediately adjoining the marginal periodontal tissues at the site of interest. Attempts were made for the biopsy to contain part of the bone wall of the original intrabony defect. Utmost care was exercised to avoid damaging neighboring teeth and vital anatomic structures. Postbiopsy wounds and remaining roots were managed to restore tissue contours, including soft and hard tissue augmentation procedures, and to support fixed prosthetic rehabilitation as indicated according to individualized treatment plans.

**Histologic Procedures**

The biopsies were fixed in 10% buffered formalin, decalcified in EDTA, dehydrated in graded ethanol series, and prepared for embedding in paraffin. Immediately before embedding, the roots and teeth were split in two along their long axis exactly at the site of interest (i.e., each biopsy provided two specimen blocks; Fig. 2). Thus, histologic sections representing the deepest aspect of the defect (before treatment) could readily be obtained without the need for exhausting sectioning. Twenty sections from each of the two blocks per specimen were obtained with the microtome set at 8 μm and subsequently stained with hematoxylin and eosin.

**Histologic and Histometric Evaluation**

On the section with the best technical quality, one experienced examiner (AS) assessed the following parameters (all in millimeters) by means of a computer-assisted toolbox, while viewing the biopsies on an LCD flat screen with live streaming of images captured by a digital camera adapted to the light microscope: 1) cementum regeneration height, distance between apical extension of the root planing and the coronal extension of a continuous layer of new cementum or cementum-like deposit on the planed root; 2) periodontal ligament regeneration height, distance between apical extension of the root planing and the coronal extension of a functionally oriented periodontal ligament on the planed root; 3) bone regeneration height, distance between the apical extension of root planing and the coronal extension of regenerated alveolar bone along the planed root; 4) root resorption, combined linear heights of distinct resorption lacunae on the planed root; and 5) ankylosis, combined linear heights of ankylosic union between the regenerated alveolar bone and the planed root. Histologic signs of inflammation or foreign body reaction adjoining the bone graft substitute particles were evaluated with a six-step scale: 1) non-present, 2) minimal, 3) slight, 4) moderate, 5) marked, and 6) severe.

**RESULTS**

**Clinical Findings**

Healing after surgery occurred without major complications, and only minor adverse events including mild postoperative swelling and pain were observed. In 34% of all cases, and in one of the five biopsied teeth (#2119), suture line dehiscence and minor exposures of the membranes at the interproximal spaces were observed during the two first postoperative controls. The exposed membranes usually disappeared within 2 weeks, disclosing new interproximal tissues. From the 30 operated patients, two did not present at the 1-year control and one had the treated tooth removed by his own dentist because of “increased mobility.” In the remaining 27 patients, treatment resulted in significant clinical improvements as indicated by the PD reduction, residual PD, and CAL gain observed (Fig. 1, G and H), averaging 4.8 ± 1.8, 4.4 ± 1.6, and 3.9 ± 1.4 mm, respectively (Table 1). No site presented worsening of periodontal conditions after treatment, whereas 60% of the sites showed a CAL gain of ≥4 mm and a residual PD of ≤4 mm (Table 2).

Twenty-five patients (92.6%) attended the 3-year control. Only one of the patients had lost the treated tooth, approximately 2 years postoperatively, apparently because of continuous periodontal problems. This specific patient had exhibited a poor response to treatment, with the tooth presenting an 8-mm PD at the 1-year control. In general, the clinical improvements observed 1 year after therapy were preserved after surgery.
for two additional years for most of the cases; depending on whether the threshold to characterize sites losing attachment was set to 1 or 2 mm, 61% or 83% of the sites, respectively, did not experience CAL loss from the 1- to the 3-year control. PD reduction, residual PD, and CAL gain 3 years after treatment averaged 4.4–1.7, 4.7–1.4, and 3.5–1.3 mm, respectively (Tables 1 and 2). Nevertheless, the small, most likely clinically insignificant, CAL loss was statistically significant (P<0.01).

**Histologic Findings**

Evaluation of the biopsies revealed formation of new cellular cementum coronally (range: 0.1 to 2.13 mm) to the apical extent of root instrumentation and a periodontal ligament–like connective tissue in four of five cases (Fig. 3 and Table 3). A functional orientation of the collagen fibers was, however, rarely observed. Coronally to the new cementum, a long junctional epithelium could be observed on the previously involved root surface in two cases, whereas in another two cases a narrow zone of connective tissue adhesion was observed between new cementum and epithelium. In general, a large number of graft particles with empty osteocytic lacunae were observed inside the defect space. The xenograft particles seemed to be mostly embedded in connective tissue without any evidence of having enhanced new bone formation. A mostly amorphous, mineralized, occasionally cellular tissue was sometimes observed in direct contact with the bone graft particles. No obvious signs of foreign body reaction or ongoing resorption of the particles was observed, and only a mild inflammatory reaction was observed in two of the cases. Ankylosis or root resorption was never observed. In the last evaluated case, only epithelium was found in contact with the instrumented root surface.

**DISCUSSION**

The present study shows that GTR treatment of deep periodontal intrabony defects with TD and adjunct implantation of TG resulted in significant PD reduction and CAL gain 1 year after surgery. In addition, these improvements in clinical parameters were stable for 2 additional years. Such results come as no surprise considering the plethora of previous publications on GTR treatment of periodontal intrabony defects, with or without adjunct use of bone grafts or substitutes, where significant clinical improvements have been reported (for review see Murphy and Gunsolley4). For example, GTR with a bioresorbable porcine collagen type I and III membrane and adjunct implantation of deproteinized bovine bone particles (DBB),‡‡‡ a product similar in terms of origin and configuration to the one used in the present study, has resulted in PDs and CAL gains at 1 year postoperative of comparable magnitude with those observed in the present group of patients.17-20

However, despite the relatively large clinical improvements, a limited amount of cementum regeneration and no bone formation, and thus no periodontal regeneration, was observed in the present group of biopsies. In contrast, reports from histologic evaluations of human cases after GTR plus DBB21-25 have shown that the observed clinical improvements were indeed in part characterized by periodontal regeneration. For example, Sculean et al.25 observed cementum and bone regeneration in seven of eight evaluated human biopsies, averaging 2.6 and 2.3 mm, respectively. Although no direct comparisons can be made, the substantial differences between the histologic observations after GTR plus TG in the present study and those after GTR plus DBB may be attributed to differences in the production method of TG and DBB that result in products with variable physicochemical properties despite the common source material. Indeed, in a thorough

‡‡‡ Bio-Oss, Geistlich Pharma, Wolhusen, Switzerland.
physicochemical characterization of various bovine bone–derived biomaterials,\(^{15}\) including TG and DBB, significant differences regarding their composition were disclosed, the most profound being the presence of 26 wt% organic material (i.e., organic bone matrix and soft tissues) in TG compared to 0 wt% in DBB. Such observations stress the need for constant evaluation of new products in relevant preclinical and clinical models despite apparent, or commercial claims about, similarities with previously available materials.

Previous studies in animals have indicated that implantation of slowly resorbing or non-resorbing bone biomaterials in conjunction with periodontal regenerative procedures, including GTR, may delay wound maturation or obstruct periodontal wound healing and regeneration.\(^{26,27}\) In the present study, no new bone formation was observed in any of the samples. Graft particles embedded in connective tissue and without any appreciable sign of ongoing resorption persisted inside the defect space in all samples. In a small-size clinical trial, where TG blocks versus autogeneous bone were compared in the treatment of unstable fractures of the thoracolumbar junction, a large failure rate in terms of lack of osseointegration of the xenograft material (as evaluated clinically and on computerized tomography scans) was observed compared to patients grafted with autogeneous bone.\(^{28}\) However, in an experimental study in a pig-calvaria defect model, an almost complete consolidation of TG-implanted defects with no difference in terms of bone fill compared to defects grafted with autogeneous bone was observed.\(^{29}\) Another study reported good bone regeneration and complete graft remodeling 6 months after TG implantation in rabbit femoral defects.\(^{30}\) Similarly, good bone integration of TG was presented in a human histologic case series report on hip arthroplasties biopsied 1 year postoperatively.\(^{31}\) Such substantial differences in terms of TG integration in bone among the latter studies, the previously mentioned one,\(^{28}\) and the current study might be caused by differences in the recipient bed environment. In both studies showing good osseous integration of TG,\(^{29,31}\) the recipient bed was only bone. In contrast, the recipient bed in the previously mentioned study\(^{28}\) (spine) and the present study (periodontium) involves a variety of tissues contributing to the wound healing process. These observations seem to indicate that TG is an osteocompatible material but may have limited osteoconductive potential.

Lack of periodontal regeneration in the present group of biopsies theoretically could also be caused by suboptimal attributes of the bovine pericardium membrane (i.e., non-cross-linked type I collagen) for implantation.

| Table 1. |
| Mean (SD) Clinical Values in Millimeters at Baseline and 1 and 3 Years After Surgery |

<table>
<thead>
<tr>
<th>Clinical Value</th>
<th>N</th>
<th>Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PD Baseline</td>
<td>27</td>
<td>9.2 (± 1.9)</td>
</tr>
<tr>
<td>1 year</td>
<td>27</td>
<td>4.4 (± 1.6)</td>
</tr>
<tr>
<td>3 years</td>
<td>24</td>
<td>4.7 (± 1.4)</td>
</tr>
<tr>
<td>REC Baseline</td>
<td>27</td>
<td>1.7 (± 1.2)</td>
</tr>
<tr>
<td>1 year</td>
<td>27</td>
<td>2.6 (± 1.6)</td>
</tr>
<tr>
<td>3 years</td>
<td>24</td>
<td>2.6 (± 1.7)</td>
</tr>
<tr>
<td>CAL Baseline</td>
<td>27</td>
<td>10.9 (± 2.4)</td>
</tr>
<tr>
<td>Gain 1 year</td>
<td>27</td>
<td>3.9 (± 1.4)</td>
</tr>
<tr>
<td>Gain 3 years</td>
<td>24</td>
<td>3.5 (± 1.3)</td>
</tr>
</tbody>
</table>

| Table 2. |
| Frequency Distribution of PD and CAL Gain in Millimeters at 1 and 3 Years After Surgery |

<table>
<thead>
<tr>
<th>Time Point</th>
<th>CAL Gain</th>
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<tr>
<td>≤0</td>
<td>≤2</td>
</tr>
<tr>
<td>1 year</td>
<td>0</td>
</tr>
<tr>
<td>3 years</td>
<td>0</td>
</tr>
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</table>

<table>
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<tr>
<th>Time Point</th>
<th>PD</th>
</tr>
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<tbody>
<tr>
<td>≤3</td>
<td>4</td>
</tr>
<tr>
<td>1 year</td>
<td>29.6</td>
</tr>
<tr>
<td>3 years</td>
<td>26.2</td>
</tr>
</tbody>
</table>

| Table 3. |
| Histologic Values in Millimeters From the Five Evaluated Teeth |

<table>
<thead>
<tr>
<th>Biopsy No.</th>
<th>New Cementum</th>
<th>New Bone</th>
<th>Graft Particles</th>
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<tbody>
<tr>
<td>2,119</td>
<td>0.1</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>2,123</td>
<td>2.1</td>
<td>—</td>
<td>+</td>
</tr>
<tr>
<td>2,128</td>
<td>—</td>
<td>—</td>
<td>+</td>
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<tr>
<td>2,133</td>
<td>1.0</td>
<td>—</td>
<td>+</td>
</tr>
<tr>
<td>2,135</td>
<td>0.9</td>
<td>—</td>
<td>+</td>
</tr>
</tbody>
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GTR applications (i.e., because of lack of sufficient barrier function). Although the necessary time a GTR barrier should preserve its integrity for optimization of the results is not yet determined, observations from an animal study suggest that substantial amounts (i.e., of clinically significant magnitude) of periodontal regeneration can be achieved even if barrier function is already terminated 2 to 3 weeks post-surgery.32 Studies have revealed that TD shows good tissue integration and vascular penetration and preserves its barrier function for 8 weeks.33,34 In those latter studies, apart from the enzymatic activity of macrophages and polymorphonuclear leukocytes, a mild foreign body reaction was observed in association with TD biodegradation, similar to other collagen membranes. However, this feature might have negatively influenced healing in the current study, most likely only in the vicinity of the membrane and not in the major portion of the intrabony component (i.e., the area evaluated in the biopsies). Another factor that can influence the histologic outcome of GTR, especially in terms of bone regeneration, is membrane exposure. From the biopsies evaluated here, only one was recorded having an exposure during healing; thus, the observed lack of bone regeneration in the present group of biopsies should not be attributed to membrane exposure. In this context, the teeth included in the current analysis were scheduled for extraction because of advanced periodontal disease among other reasons, and it can be speculated that the regenerative potential at such sites might have been extremely limited or even exhausted. Nevertheless, all sites were deemed as having some potential for regeneration because of the 1- or 2-wall (or combination thereof) bone configuration of the intrabony component.

The present study shows that TD plus TG treatment results in significant clinical improvements for most of the treated teeth, with 60% of the cases showing CAL gain ≥4 mm and 80% showing PD ≤5 mm. In addition, these clinical improvements were basically maintained for 2 additional years for most cases (61% or 83% depending on whether the threshold to characterize sites losing attachment was set to 1 or 2 mm, respectively). Stability of the improved clinical conditions obtained after GTR, with or without the adjunct use of a bone biomaterial, over a long period of time has been previously reported.6-11,36-38 In this context, most studies previously presented28,29,31 indicate that TG is a barely resorbable material. Indeed, no osteoclasts or multinucleated cells are observed in the proximity of TG in the biopsies in the present study. It is reasonable to anticipate that biomaterial particles will continue to reside inside the defect space for a long period of time. Nevertheless, based on the observations in the current study, it is also reasonable to suggest that the mere presence of TG particles inside the healed periodontal tissues may have no consequence per se on the stability of the improved clinical conditions. Similar conclusions have been previously drawn regarding other non-resorbing or slowly resorbing materials (e.g., DBB).21-25,36-38 An important unknown issue, however, is how sites containing amounts of TG entrapped inside connective tissue would respond in the event of recurrent infection or inflammation.

In the present study, a control group is lacking; undoubtedly, it would have been better if such a control group was included. However, the evaluated biomaterials were new in the market at the time the

**Figure 3.** Photomicrograph representative of healing in the central aspect of the intrabony defect. A) Overview. B and C) High magnifications of aspects of A. A) Red arrowhead indicates the coronal level of continuous new cementum formation. Blue arrowhead indicates the most apical termination of junctional epithelium. Green line indicates the apical level of root instrumentation. B) New cellular cementum (red arrowheads) had formed on the instrumented root surface. Few biomaterial particles (blue asterisks), partly covered with a mineralized, occasionally cellular tissue (green asterisks), but mostly embedded in connective tissue can be observed. C) No functional orientation of the collagen fibers can be appreciated. Blue asterisk = biomaterial particle; green asterisk = a mineralized, occasionally cellular (red arrowhead) tissue that partly covers the biomaterial particle. (H&E; original magnification ×5 [A]; ×25 [B]; and ×50 [C]). NC = new cementum.
study was performed; therefore, it was reasonable to first evaluate their performance at the clinical (i.e., rate of postoperative complications, outcomes in terms of PD reduction and CAL gains, along with the long-term stability of the results) and histologic (i.e., formation of new cementum, new periodontal ligament, and new bone formation, along with the presence or absence of pronounced inflammation or foreign body reaction) levels before performing a randomized controlled clinical trial. No claims can be made regarding the superiority or inferiority of the GTR technique or the biomaterials used herein compared to other non-surgical or surgical techniques or other biomaterials, based solely on the current study design.

CONCLUSION

Based on the results of the present case series, GTR treatment of intrabony defects with the collagen membrane from bovine pericardium and adjunct implantation of a bovine bone biomaterial may result in significant clinical improvements that can be maintained over a period of 3 years and regeneration of cementum and periodontal ligament, but without bone formation.

ACKNOWLEDGMENTS

This study was partially funded by Tutogen Medical, Neunkirchen am Brand, Germany, which manufactures the bovine pericardium collagen membrane and the particulate bovine bone graft used in this case series. The authors report no conflicts of interest related to any products used in this case series.

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Submitted May 31, 2010; accepted for publication August 15, 2010.