# Soft Tissue Augmentation in Connection to Dental Implant Treatment Using a Synthetic, Porous Material – A Case Series with a 6-Month Follow-Up

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## ABSTRACT

*Background:* Bony defects/concavities in the aesthetic zone of maxillae may interfere with the results of prosthetic procedures by producing shading superior to the crown. Such regions can be augmented either by bone or soft tissue autografts, allografts, or xenografts. Tissue shrinkage is thus anticipated, and a method to objectively measure the tissue change is valuable.

*Purpose:* The aim of this study was to evaluate the use of a synthetic, porous material made of polyurethaneurea for buccal soft tissue augmentation in connection with implant placement in the maxillary front region. Further, to measure over time the change in buccal contour using a computerized technique.

*Materials and Methods:* Ten patients received 12 Artelon<sup>®</sup> cylinders ( $5 \times 10$  mm) in connection to implant placement. Preoperative and postoperative (at 3 and 6 months) study casts were obtained for computer measurements, using the preoperative reference model as a base. The volume created between the surfaces of the reference model and each of the two following superimposed models was measured in cubic millimeter. Differences in volume from pretreatment to 3 and 6 months, respectively, were compared.

*Results:* The clinical observation during follow-up showed normal healing. The increase in mean buccal tissue volume was 50 mm<sup>3</sup> (SD 18) after 3 months and 43 mm<sup>3</sup> (SD 21) after 6 months, measured over a 6 mm × 8 mm area in the maxillary front region, in comparison to before insertion of the cylinder. The reduction from 3 to 6 months was not statistically significant (p = .17).

*Conclusion:* A synthetic, porous material for soft tissue augmentation was tested in connection to implant placement in the aesthetic zone of maxillae. The buccal contour was followed-up for 6 months using a computer volumetric technique on preoperative and postoperative study casts. Measured tissue volume showed an obvious increase during the study period. The material was biologically well received.

KEY WORDS: aesthetics, augmentation, soft tissue graft, volumetric measurement

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## **INTRODUCTION**

A reduced or poor bucco-palatal tissue volume is in general caused by a lack of supporting alveolar bone, which upon occasion will interfere with the placement of oral implants. Such a condition may appear in all jaw regions, and to overcome the problem, both buccal and vertical bone augmentation techniques have been described using various bone materials, such as autogenous bone,<sup>1–3</sup> demineralized freeze-dried bone,<sup>4–6</sup> and bovine hydroxy-apatite.<sup>7,8</sup> Guided tissue regeneration techniques using various non-bioabsorbable and

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bioabsorbable barrier membranes have, as well, been used with the effort to increase the alveolar bone volume.<sup>9–11</sup>

Not infrequently, the underlying alveolar bone may have sufficient volume for a proper placement of implants in the aesthetic zone and yet be less favorable because of a buccal bone concavity present or a reduced vertical bone dimension. The aesthetic outcome may then be jeopardized and a need to eliminate the shade from the buccal concavity, a need to level out the gingival/ peri-implant margin, or a need to create more attached/ keratinized mucosa may be at hand. Under such circumstances, the use of connective tissue grafts and free gingival grafts in combination with various flap techniques have been the treatment of choice for decades.<sup>12–16</sup> However, such procedures require donor sites, which at times may lead to postoperative complications, for example, flap necrosis with risk of bone exposition, swelling, bleeding, and pain. To eliminate these problems, some investigators have tried to use other soft tissue augmentation materials such as Acellular Dermal Matrix.<sup>17–20</sup> At the moment, there is insufficient clinical evidence to support that the techniques to correct or augment soft tissues or to increase the width of attached/ keratinized mucosa are beneficial to patients.<sup>21</sup>

For more than a decade, a degradable polyurethaneurea, Artelon<sup>®</sup>, has been successfully used in orthopedic surgery.<sup>22–24</sup> A product has also been developed for soft tissue augmentation in the oral cavity. The purpose of the present investigation was thus to evaluate the use of a synthetic, porous material for buccal soft tissue augmentation in connection with oral implant treatment in the aesthetic zone of maxillas. Further, to measure over time the change in buccal contour using a computerized technique.

#### MATERIALS AND METHODS

#### Patients

The current study comprised 10 patients referred for rehabilitation in the aesthetic zone of the maxilla. The treatment was executed at the Brånemark Clinic, Göteborg, Sweden, between September 2007 and June 2008. The patients' mean age at the time of surgery was 27 years (range 17–67 years) and the gender distribution revealed a preponderance of males (8 out of 10). Exclusion criteria for participation were defined and are presented in Table 1.

#### TABLE 1 Exclusion Criteria for Participation in the Study

- Ongoing infection
- Serious illness
- Uncontrolled diabetes
- · Malignancy within the last 10 years
- · Radiation within the treatment area
- Ongoing medication inappropriate for the study, such as immunosuppressive treatment, fenantoin, or calcium antagonists
- Pregnancy
- Smoking

Pre-surgical evaluation displayed the need for oral implant treatment in 9 of the 10 patients in combination with soft tissue augmentation. One patient already had the implant in function in right canine position, although demanding improved soft tissue aesthetics. Two patients had, approximately 6 months prior to the current treatment, received bone grafts in the region of interest. Ten Brånemark System® implants (Nobel Biocare AB, Göteborg, Sweden) were inserted in the nine patients, that is, one patient received two implants. A total of 12 Artelon® Cosmetic cylinders were placed in the 10 patients and thus, two patients received two cylinders each.

All patients completed an informed consent form and the study had the approval of the local ethics committee in Göteborg (096-07).

## Augmentation Material

The Artelon<sup>®</sup> material (Artimplant AB, Västra Frölunda, Sweden) is a polycaprolactone-based polyurethaneurea as described by Gisselfält and colleagues.<sup>25</sup> The material degrades by hydrolysis over several years.<sup>25</sup> The complete hydrolysis takes approximately 6 years at 37°C, as shown by in vitro studies. The degradation results in a resorbable and a non-resorbable fraction. The resorbable fraction is eliminated from the body through the Krebs cycle (citric acid cycle), primarily as carbon dioxide and in urine. The non-resorbable fraction is incorporated in the surrounding host tissue without eliciting any inflammatory or foreign body response.

Artelon<sup>®</sup> Cosmetic has the shape of a cylinder with the diameter of 5 mm and height of 10 mm (Figure 1), and has a weight of ~25 mg. The porosity of the

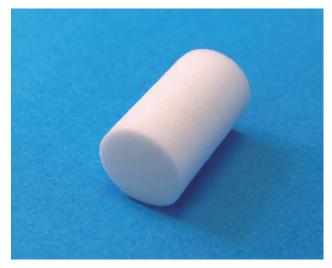


Figure 1 The cylindrical Artelon® Cosmetic.

cylindrical scaffold was created by a solvent casting/ particle leaching process.<sup>26</sup> The pore-to-volume-ratio in the scaffold is ~90%, and the open pore structure has a mean pore size of 100  $\mu$ m. The open pore structure and the high porosity make the implant a good scaffold for immediate tissue ingrowth.<sup>27</sup>

#### **Clinical Procedures**

Before the surgical procedure, clinical photographs and impressions for study casts were obtained. Data of various soft tissue characteristics such as keratinized tissue height, tissue color, and tissue surface structure were collected and registered on case report forms. During the study period, patients were asked to give their subjective opinion on a visual analog scale (VAS) regarding treatment discomfort and postoperative problems, rating best possible as 0 and worst imaginable as 10.

Surgery was performed under local anesthesia and a prophylactic antibiotic (2 g amoxicillin or 600 mg clindamycin) was given 1 hour preoperatively. A tensionfree flap was raised and implant placement was executed according to standard procedures. Seven of the implants were inserted in central incisor positions, and three were placed in lateral incisor positions.

The cylindrical scaffold was cut to the desired shape with a scalpel, soaked for at least 5 minutes in a sterile saline solution and was thereafter inserted on the buccal bone bed (Figure 2). Precautions were taken to minimize bacterial contamination. The flap was carefully repositioned and sutured to ensure complete coverage of the entire cylinder (Figure 2). Clinical photographs were obtained for documentation. An antibiotic regime was prescribed for the coming 10 days (1.5 g amoxicillin or 450 mg clindamycin per day). Duration of the surgical procedure was registered on the case report form.

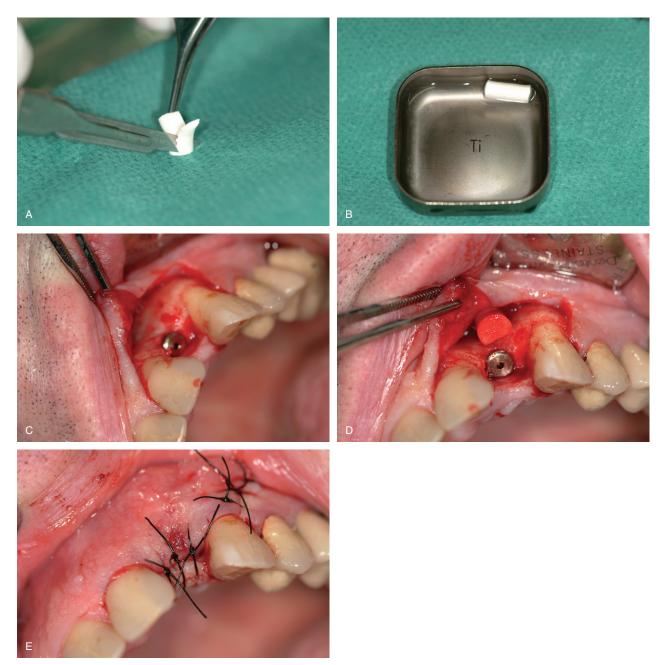
Patients were asked to return to the clinic after 1 week (suture removal and clinical registrations), after 1 month (clinical registrations), and also after 3 and 6 months (clinical photographs, impression for study cast, and clinical registrations). During the latter visit, abutments were connected onto the implants. Thus, the time between implant placement and abutment connection was extended, so that volumetric analyses could be made of the soft tissue volume without interference of the prosthetic procedure.

#### **Computer Measurements**

Impressions for study casts of the upper jaws were made prior to the surgical procedure, and after 3 and 6 months, respectively. Care was taken to reproduce the entire buccal vestibulum of the anterior part of the jaw. These study casts were used to measure changes of buccal mucosa volume, as accounted for in earlier publications.<sup>2,28,29</sup> In brief, the casts were placed in an optical three-dimensional scanner (Atos®, GOM International AG, Switzerland). The scanner measured the surfaces of the models by projecting different light fringe patterns onto the object, which were recorded by two video cameras. The pixels from the images of the two cameras were then calculated to three-dimensional coordinates with a calculated three-dimensional accuracy of 150 to 200 µ for this setup.<sup>2</sup>

The digitalized three-dimensional images of the different casts were arranged in the same coordinate system in the computer by using anatomical landmarks in the palate for correct orientation. The pretreatment study cast was used as the reference for the following two casts when comparing buccal contour of the jaw in the region of the inserted Artelon® cylinder.<sup>2,28,29</sup> A horizontal reference line was placed in the computer through the estimated gingival/crown margin of the adjacent teeth in the reference model (Figure 3).<sup>2</sup> Parallel lines were placed in an apical direction with an interline distance of 2 mm. Corresponding vertical lines were then placed, thereby creating sections of 2 mm × 2 mm areas at various levels of the crest (Figure 3).

Via the computer, the lines were then orientated in the same positions for the two follow-up models using the reference model as a base. The volume created



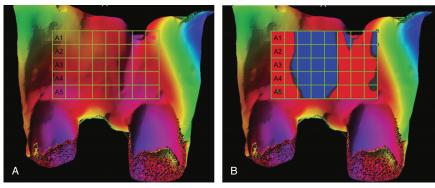
**Figure 2** *A*, The cylinder is cut to the desired shape. *B*, Before insertion the cylinder is soaked for at least 5 minutes in sterile saline solution. *C*, The dental implant has been inserted in position 22. *D*, The cylinder has been positioned in the buccal bony defect. *E*, The flap has been carefully repositioned and sutured to ensure complete coverage of the entire cylinder.

between the surfaces of the reference model and each of the two following superimposed models were measured in cubic millimeter, given as "increase" or "decrease" of volume in relation to the contour of the reference model. Compartments placed in close association to the Artelon® cylinder were measured (Figure 3).

A sagittal plane was also created, placed through the central part of the edentulous area, presenting the tissue contour of the reference model in relation to the different follow-up casts.<sup>29</sup> The maximal increase of the buccal contour was measured for each of the two follow-up casts, compared with the contour of the reference model, made before the surgical intervention (Figure 4).

## Statistical Analyses

The differences between the volume change from pretreatment to 3 and 6 months, respectively, were



**Figure 3** *A*, Reference model with oriented "squared pattern," including compartments from A1 to A5 with an area of each  $2 \text{ mm} \times 2 \text{ mm}$ . *B*, Reference model with 6-month follow-up cast superimposed. Increased volume indicated with blue color in the "squared pattern."

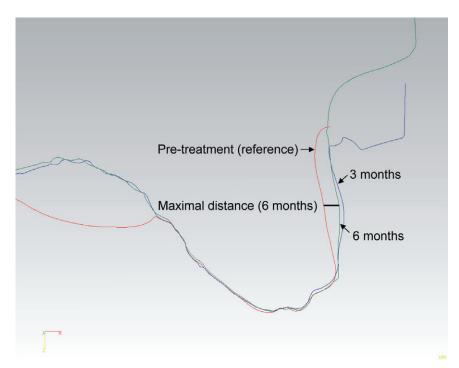
compared with the Wilcoxon signed rank test and given with 95% confidence intervals (CIs). Significance tests were two-tailed and conducted at the 5% significance level.

## RESULTS

# **Clinical Observations**

All operations were performed without complications. At the 6-month follow-up visit, all implants were found stable and consequently equipped with abutments. There were no signs of inflammation, infection, or dehiscences. Soft tissue characteristics at 6 months, such as the keratinized tissue height, showed a mean value of 4.1 mm (SD 2.3), which was very similar to the pretreatment value of 4.3 mm (SD 3.0). Further, the mucosa in the region of interest was assessed to be similar in color as compared with the pretreatment situation, and the tissue surface showed a tendency toward a more stippled character.

Patients' subjective evaluation of treatment discomfort and postoperative problems (VAS) revealed at 1 week postoperatively a mean value of 1.6 (SD 1.6) and



**Figure 4** Sagittal plane illustrating the buccal contour before treatment (red line) and after 3 (blue line) and 6 months (green line). The maximal distance between the contours was measured.

TABLE 2 Total Buccal Tissue Volume in an Area with Mesial-Distal Width of 6 mm and Coronal-Apical Height of 8 mm

	Pretreatme	nt to 3 Months	Pretreatme	nt to 6 Months	Difference 3 to 6 Months		
	Tissue Volume mm <sup>3</sup>	Distance between Sagittal Planes mm	Tissue Volume mm <sup>3</sup>	Distance between Sagittal Planes mm	Tissue Volume mm <sup>3</sup>	Distance between Sagittal Planes mm	
Case 1	74.8	2.3	51.5	1.8	-23.3	-0.5	
Case 2	33.7	1.3	24.7	1.0	-9.0	-0.3	
Case 3	64.5	1.8	53.0	1.5	-11.5	-0.3	
Case 4	37.3	1.2	3.9	0.5	-33.4	-0.7	
Case 5*					14.8	1.1	
Case 6	55.3	1.8	52.8	1.6	-2.5	-0.2	
Case 7	25.0	1.0	43.2	1.5	18.2	0.5	
Case 8	43.0	1.5	50.9	1.7	7.9	0.2	
Case 9	44.0	1.4	32.5	1.2	-11.5	-0.1	
Case 10	76.2	3.0	82.0	2.9	5.8	-0.1	
Mean (SD)	49.8 (18.1)	1.7 (0.6)	42.7 (21.1)	1.5 (0.7)	-3.44 (16.60)	-0.05 (0.53)	

See shaded area in Figure 5, and also the distance between the contours in the sagittal planes (see Figure 4). The difference between the models at 3 and 6 months was calculated.

\*In one patient the model at pretreatment could not be analyzed, but the 3- and 6-month models were analyzed and compared.

2.6 (SD 2.2), respectively, while the corresponding figures at 6 months (end of study period) were 0.8 (SD 0.6) and 0.7 (SD 0.7).

The total time consumed for the surgical procedure with placement of the titanium implant and the cylinder was registered for each patient, showing a mean of 31 minutes (range 20–45). Artelon<sup>®</sup> Cosmetic was easily handled when cut to the desired shape, which did not add many minutes to the implant operation.

## Measurements of Buccal Contour

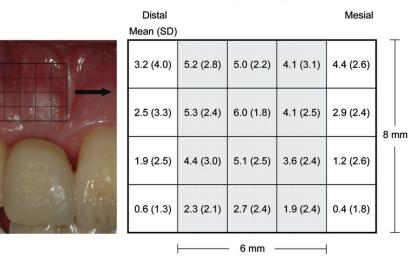
Buccal volumes after 3 and 6 months of healing in relation to the initial buccal contour at the defect sites (before surgery) are given in Table 2 for all individual patients. Data is also presented for the separate compartments, given as mean values after 3 and 6 months, respectively (Figure 5). The baseline impression of patient #5, obtained immediately prior to conducting surgery, resulted in a non-readable study cast. This patient was, thus, excluded from baseline registrations, albeit the study casts from 3 and 6 months postoperatively were analyzed and compared. The increase in mean buccal volume was 50 mm<sup>3</sup> (SD 18) after 3 months, and 43 mm<sup>3</sup> (SD 21) after 6 months, measured over a 6 mm × 8 mm area in the maxillary front region, in comparison to before insertion of the cylinder. The buccal contour showed, on an average, a reduced volume from 3 to 6 months (Table 2), but not reaching a significant level (p = .17, 95% CI -3.9-18.0).

Measured maximal distances between the buccal contours of the presurgical and the 3- and 6-month follow-up models (Figure 4) was on average 1.7 mm (SD 0.62) and 1.5 mm (SD 0.66), respectively (Table 2). Only small changes in this distance was observed for the individual patients from 3- to 6-month measurements, not reaching significant levels (p = .17, 95% CI -0.1-0.5).

#### DISCUSSION

The presence of a bony defect/concavity may have a devastating shading effect on tooth- or implantsupported prosthetic constructions in the aesthetic zone of maxillae. To eliminate or minimize its impact, various augmentation materials may be used. However, the apprehension of the aesthetical appearance is most subjective and a need to evaluate the stability of the procedure over time using volumetric measurements is at hand. The computerized measurement technique of buccal contour changes on preoperative and postoperative study casts, as previously described in relation to jaw bone augmentation,<sup>2,29</sup> was found useful also in relation to the current soft tissue augmentation. А

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Buccal tissue volume at 3 months compared to pre-treatment

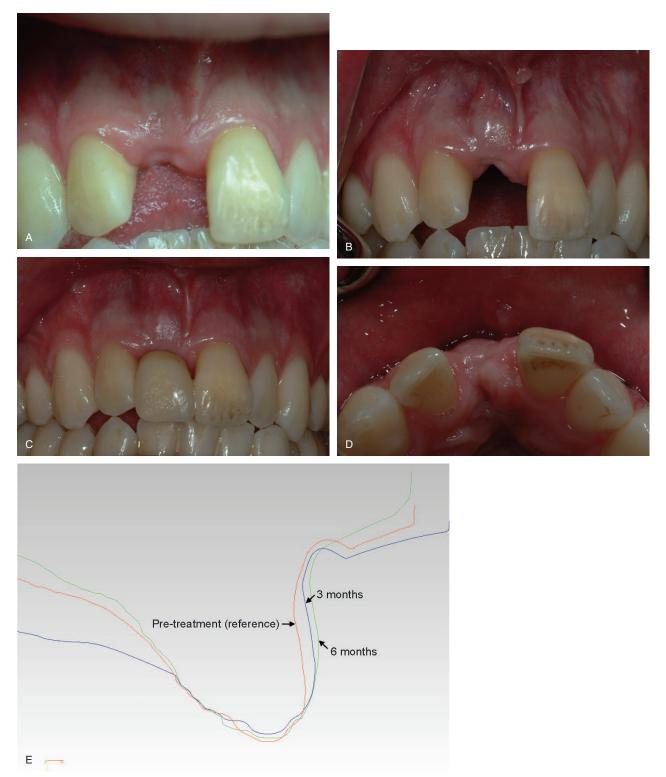
Buccal tissue volume at 6 months compared to pre-treatment

	Distal Mean (SD)				Mesial	
#	1.9 (3.2)	3.9 (3.0)	4.7 (2.6)	3.3 (2.8)	3.2 (3.1)	8 mm
an and a second	1.7 (3.0)	4.2 (2.8)	5.2 (2.1)	3.5 (2.3)	2.0 (2.3)	
	1.7 (2.7)	3.8 (3.4)	4.5 (2.4)	3.2 (2.1)	1.1 (2.2)	
	0.7 (1.1)	2.1 (2.3)	2.5 (2.4)	1.8 (2.0)	0.5 (1.6)	
6 mm						

Figure 5 Mean buccal volume increase in each of 2 mm  $\times$  2 mm measurement area from pretreatment to 3 (A) and 6 months (B), respectively.

Independent of augmentation material used, almost all such surgical procedures are afflicted with a postoperative tissue shrinkage over time.<sup>2,16,17,29–32</sup> In the study by Johansson and colleagues,<sup>30</sup> a reduction in augmented bone tissue volume of 45 to 50% was noted 6 months postoperatively, as measured on computed tomography scans. Similar figures (~50%) were demonstrated with the present measurement technique, 12 months postgrafting by Jemt and Lekholm.<sup>2</sup> Contraction of connective tissue grafts and xenogenic collagen matrix reached >60% at 6 months in the effort of increasing the keratinized tissue, as reported by Sanz and colleagues.<sup>32</sup> Shrinkage of the horizontal ridge width of >41%, when using acellular dermal matrix grafts in a case series of localized alveolar defects, was shown after 6 months by Batista and colleagues.<sup>17</sup> Techniques that objectively measure the change in tissue volume are thus most valuable.

The present augmentation material produced an obvious increase in mucosa volume and increased distances between the sagittal planes as measured 3 months after placement, also observed clinically (Figure 6). Even though the following 3-month period demonstrated with individual variations a nonsignificant reduction on measured parameters, the buccal contour showed stability throughout the study period of 6 months. Because of the high porosity and open structure of the material, ingrowth of patients' own tissue to replace the scaffold was at hand. However, one patient (case #4, Table 2) lost most of the gained total tissue volume registered at 3



**Figure 6** *A*, Before treatment, the patient had a buccal concavity in the frontal area (position 11). *B* and *C*, The same area 3 months after insertion of the cylinder and also 6 months after treatment. *D*, View from the crest with the provisional crown removed. *E*, Sagittal plane illustrating the buccal contour before treatment (red line) and after 3 (blue line) and 6 months (green line).

months, when later compared with the 6-month registration. This is more difficult to explain, although postoperative tissue remodeling, pattern of material resorption and tissue shrinkage, differences in anatomy, etc., may result in a variety of response to treatment. The material was well received by the biological tissue, which is also in agreement with previous findings from its use in orthopedic surgery and dermal template.<sup>23,24,26</sup> Because of its soft and yet dense character, it provides a tool to the implant clinician to improve a situation where the bucco-palatal bone dimension is somewhat insufficient, resulting in an implant placement with buccally fenestrating metal threads, and with the subsequent shading effect on the covering mucosa.

Augmentation procedures with allografts,<sup>17–20</sup> with xenografts,<sup>32</sup> as well as with synthetic materials like the present one, always imply a higher risk for bacterial contamination with subsequent infection and loss of the material. For this reason, meticulous care was taken to keep the scaffolds away from the flap edges and sutures. Together with the use of an antibiotic regime for 10 postoperative days, sufficient efforts were made to avoid infections during the study period. The advantage, however, of utilizing these foreign materials, and thus refraining from connective tissue autografts, entails that a donor site can be excluded with less patient morbidity and postoperative discomfort. This positive outcome was also confirmed by the patients' subjective evaluation of the postoperative course (VAS).

The present study, although limited in patient number, showed promising results on soft tissue augmentation and brings about a further need to test Artelon<sup>®</sup> Cosmetic more widely in a multicenter study approach.

## CONCLUSION

A synthetic, porous material was tested in a case series of 10 patients in relation to soft tissue augmentation procedures in the aesthetic zone of maxillae. The buccal contour was followed for 6 months using a computer volumetric technique on preoperative and postoperative study casts. Measured total tissue volume showed an obvious increase during the study period. The material was biologically well received.

## ACKNOWLEDGMENTS

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