

Using Resorbable Screws for Fixation of Cortical Onlay Bone Grafts: An In Vivo Study in Rabbits

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Purpose: The purpose of this study is to test bioresorbable screws as an alternative to titanium screw graft fixation. When cortical onlay grafts are used, it is necessary to rigidly immobilize them with titanium screws into the recipient site. The screws must be removed before placing implants into this site. Bioresorbable screws may be an alternative to titanium fixation, eliminating the additional morbidity associated with this.

Materials and Methods: Fifteen New Zealand White rabbits were divided into 3 groups. Bilateral tibial onlay bone grafts were placed in the mandible and secured using titanium fixation, bioresorbable fixation, or no fixation. After 6 weeks, all grafted sites were harvested. Hematoxylin-eosin and Giemsa staining were performed to evaluate inflammation, graft integration, and thickness.

Results: The treatment groups showed evidence of consolidation under light microscopy. Smooth integration of the graft borders with the recipient bone was identified. No integration was seen in the control group. The average thickness of the grafted sites was: 1) bioresorbable, 2.28 mm; 2) titanium, 1.87 mm; and 3) control, 1.06 mm. The differences were statistically significant ($P = .0004$) between the titanium group and the control group, as well as between the bioresorbable and the control group ($P = .01$). There was no statistically significant difference between the 2 treatment groups ($P = .19$).

Conclusion: The overall thickness of the treatment specimens was greater than that of the control group. The bioresorbable group showed graft integration equal to that of the titanium group, making it an adequate alternative for graft fixation.

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The placement of dental implants into grafted bone was first discussed by Brånemark et al.¹ Many authors have since published successful results using endosseous implants placed in grafted bone.²⁻⁵ By restoring the natural form of the atrophic edentulous ridge, the surgeon is better able to place implants in a more esthetic and functional position.⁶ In addition, the surgeon can place

a greater number of implants with increased surface area, height, and width.⁷ Augmented alveolar bone also allows the surgeon to place implants in an area producing favorable stress distribution and interarch relationships.^{8,9}

Alveolar ridge augmentation procedures have taken on many forms. Currently, the gold standard for the

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reconstruction of the atrophic alveolar ridge is autogenous bone.¹⁰ Corticocancellous bone grafts are ideal for reconstructing the deficient residual alveolus. They are strong, allowing the surgeon to custom fit them into host alveolar defects. The corticocancellous block will provide not only transplanted viable osteoblasts and growth factors but also structural rigidity.¹¹ This technique provides the surgeon with a predictable and successful increase in bony volume and height.¹² Tolman¹³ found that the autogenous block graft provided predictable increases in bony volume when used in both mandibular and maxillary alveolar ridge augmentation procedures. According to Triplett et al,⁷ implants placed in particulate marrow, cortical, and corticocancellous block grafts have all been shown to have success rates ranging from 85% to 98%.

Once a decision on graft type has been made, it is important that the graft be rigidly fixated to the underlying recipient bed. A study by Phillips and Rahn¹⁴ showed increased graft survival rates in rigidly fixated onlay bone grafts when compared with grafts that were not rigidly fixated. The authors postulated that movement between the graft and recipient bed led to increased bone resorption and resulted in loss of graft volume.

La Trenta et al,¹⁵ using a dog model, also showed an increased survival rate of bone grafts rigidly fixated when compared with those not immobilized. They found that the nonfixed grafts predominately healed with a fibrous union. They postulated that these effects were caused by: 1) immobilization leading to a more rapid revascularization; 2) compression allowing a larger contact surface area between the graft and recipient bed, an ideal situation for “creeping” substitution to propagate resulting in a small resorptive phase and an earlier onset of the appositional phase of the bone healing cascade; and 3) earlier graft consolidation allowing for early appositional phase and osteogenic cell ingrowth.

Titanium plates and screws provide an excellent mechanism for restoring bony form and rigid stability. In addition, these devices have been used for fixation of bone grafts; however, certain limitations with the use of titanium plates and screws have been encountered. Once bony healing has occurred, the titanium plate is no longer needed. The titanium plate may provide protection from normal physiologic stresses.¹⁶ As a result, alveolar bone loss, termed *stress shielding*, can occur. It has also been shown that placement of these devices in the pediatric patient can lead to growth restriction and intracranial migration.¹⁷ In addition, metallic fixation has been shown to produce radiographic artifact. Corrosion, allergic reaction, loosening, and cold sensitivity have all been listed as other potential problems with me-

Table 1. DISTRIBUTION OF ANIMALS INTO STUDY GROUPS

Group Number	Graft Site	Fixation Type
1	Right mandible	LactoSorb screw
	Left mandible	Titanium screw
2	Right mandible	Control surgery
	Left mandible	LactoSorb screw
3	Right mandible	Titanium screw
	Left mandible	Control surgery

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tallic plates and screws. Finally, in areas where the overlying skin is thin, metallic implants can become palpable and somewhat bothersome to the patient.^{18,19} As a result, bioabsorbable implant devices have been studied in an effort to determine their potential adaptation for use in craniofacial surgery.²⁰⁻²²

Currently there are no studies investigating a resorbable fixation system for autogenous onlay bone grafting. The objectives of this study were to investigate poly-L-lactic acid with poly-L-glycolic acid (PLLA-PLGA) fixation screws as an alternative method for the fixation of autogenous onlay bone grafts in the oral and maxillofacial surgery patient using the rabbit model. This should not only provide adequate stability to allow for consolidation of onlay bone grafts, but also eliminate the need for surgical removal of the fixation appliance. We hypothesize that bone graft fixated in this manner will show bone graft healing with adequate graft stability, decreased inflammatory response, and an overall increase in the recipient site bone volume.

Materials and Methods

Fifteen specific pathogen-free New Zealand White rabbits were delivered to The Ohio State University Veterinarian Laboratory (Columbus, OH). Each animal was fed a high-fiber and water diet. Each animal was weighed on arrival and at a daily interval throughout the study. The veterinarian on staff examined the animals on a weekly basis for evidence of adequate feeding, activity, and signs and symptoms of distress. The study subjects were divided randomly into 3 groups of 5 animals as illustrated in Table 1. This allowed the study of 30 graft sites. Each graft was fixated to its corresponding mandibular side with a resorbable screw (LactoSorb; Walter Lorenz Surgical Inc, Jacksonville, FL), titanium screw, or no fixation (control). The animals were then allowed to heal for 6 weeks.

The surgical procedures were performed under general anesthesia using xylazine 7 mg/kg, acepromazine 1

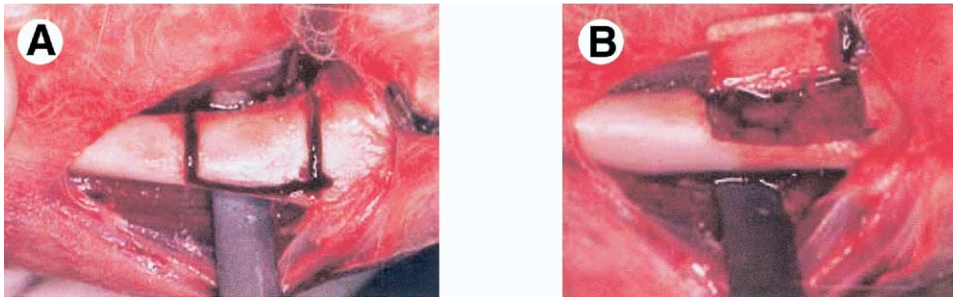


FIGURE 1. A, Bony window on tibial bone using reciprocating saw. B, Tibial cortical block after outfracture.

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mg/kg, and ketamine 40 mg/kg, all administered intramuscularly. All animal subjects received preoperative antibiotics consisting of chloramphenicol 50 mg/kg, also given intramuscularly. In addition, 2% lidocaine with 1:100,000 diluted epinephrine solution was administered via local infiltration for anesthesia and hemostasis. Abnormal behavior, decreased movement, and signs of distress were monitored postoperatively. Buprenorphine 0.01 mg/kg was administered by the attending veterinarian for animals showing postoperative pain and distress.

Once anesthetized, the mandibular body bilaterally and the medial portion of both proximal tibiae were shaved. Using a sterile technique, the hind legs of the New Zealand White rabbits were prepped with a povidone-iodine solution. Approximately 2.5 mL of 2% lidocaine with 1:100,000 epinephrine was injected into the subcutaneous tissues at each proximal tibia. Next, the tibial bone was exposed bilaterally via a medial approach. A skin incision 2 cm in length was made with a #15 scalpel blade. The subcutaneous tissues were incised in a layered fashion exposing the underlying flexor digitorum longus muscle. The muscle was then retracted, exposing the fascia and underlying periosteum. A #15 scalpel was then used to incise the fascia and periosteum. Once the periosteum was dissected free from the proximal portion of the tibial bone, 2 elevators were used to provide retraction of the soft tissues. Using a surgical saw and copious irrigation, a 6 mm × 8 mm × 1 mm monocortical block of bone was removed from the ventral surface (Fig 1). The thickness of each graft was measured with a caliper and found to be consistent with a range of 0.8 to 1.0 mm. The entire dorsal surface of the tibial bone remained intact after graft harvesting.

The cortical bone block was then stored in sterile saline. Next, a 1.5 mm titanium plate was cut to the appropriate length, adapted, and fixed across the bony gap to allow for postoperative stability (Fig 2). The area was then irrigated with sterile saline and the overlying subcutaneous tissues and skin were closed using a 2-0 polyglactin 910 (Vicryl; Ethicon, Somerville, NJ) resorbable suture, taking care to bury the knots.

Next, the mandibular body and angle were prepared bilaterally in a sterile fashion using a povidone-iodine solution. Approximately 1.0 mL of 2% lidocaine with 1:100,000 epinephrine was injected into the subcutaneous tissues bilaterally. A skin incision was made using a #15 scalpel blade below the inferior border of the mandible extending anteriorly 1.5 cm. The subcutaneous tissues, masseteric sling, and the periosteum were then sharply incised. The lateral cortex and angle of the mandible were exposed with sharp dissection. Next, the cortical bone grafts were fixated to the mandibular angle using either a 1.5 mm LactoSorb screw (7 mm in length) or a 1.5 mm titanium screw (7 mm in length) (Fig 3). As a control, we place the bone graft into the dissected area over the mandibular angle without fixation according to the group assignment. Once the bone grafts were placed and the area was irrigated with sterile saline, the periosteum and masseteric sling are re-apposed with a 3-0 polyglactin 910 suture. Finally, the remaining skin and soft tissues were closed in layers using a 3-0 polyglactin 910 suture. The animals were then allowed to recover. Once fully recovered, the animals were returned to the university laboratory animal resource housing area.

FIGURE 2. A, A 1.5 mm titanium plate fixated to span the tibial residual bony defect. B, Healed defect showing the bone growth over the titanium plate after 6 weeks.

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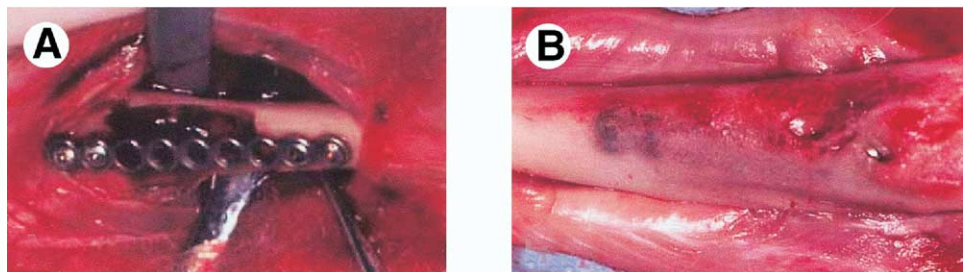
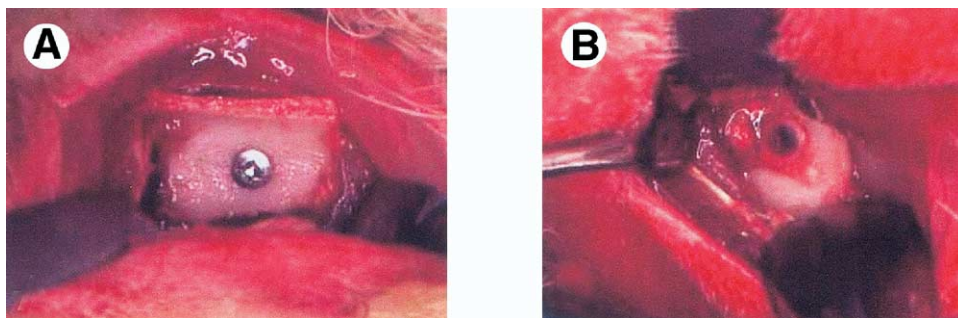


FIGURE 3. A, A cortical onlay block graft fixated with a 1.5 mm diameter titanium screw. B, Cortical onlay block graft fixated with a 1.5 mm diameter bioresorbable screw.

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After 6 weeks of healing, the rabbits were euthanized using a lethal dose of ketamine 40 mg/kg intramuscularly and 200 mg of methohexital sodium administered intramuscularly. The grafts were inspected clinically for evidence of bony consolidation, soft tissue interposition, and graft mobility. In addition, the overlying soft tissue was evaluated for any evidence of reactive tissue. Next, a surgical reciprocating saw was used to remove the bone graft sites from the rabbit mandible with a 1 cm margin of bone to prevent graft damage (Fig 4). The titanium screws were then removed from the corresponding specimens. The excised bony segments were immediately placed into properly labeled watertight jars with 10% neutral formalin. The specimens were sent to the Ohio State University Department of Oral Pathology Laboratory for preparation and light microscopic evaluation. Surgical specimens from both mock treatment and graft sites were fixed overnight in 10% buffered formalin and decalcified in a solution of 50% formic acid and 20% Na citrate for 48 hours. A block section roughly 4 mm in anterior-posterior thickness was made of each separate mandible segment. In graft sites, the anterior margin approximated the medial edge of the screw or screw hole. In sites where no graft could be identified (ie, mock treatment), an attempt was made to section the specimen in a mirror-image fashion to that of the contralateral jaw specimen. The specimens were then routinely processed, sectioned at 4 μm, and histologic sections were stained with both hematoxylin-eosin (H&E) and May-Grunwald-Giemsa.

Specimens were examined in a blinded fashion by 1 examiner under routine light microscopy and evaluated for: 1) the presence of inflammation; 2) graft

integration; and 3) mandibular graft site thickness. Inflammation was assessed on a 0 to 4 scale, with 0 representing none; 1, mild; 2, mild to moderate; 3, moderate to heavy; and 4, heavy. Graft integration was assessed by inspection of the cortical margin of the recipient site for presence of intervening fibrous connective tissue. The tissue adjacent to the screw hole was similarly examined for fibrous versus osseous material. Mandibular thickness was measured by ocular micrometer at the greatest medial-lateral thickness of the specimen adjacent to the screw hole in graft recipients or the most anatomically similar position of the contralateral specimen from the same animal.

Each tibial graft was measured before placement in its donor site, and the thickness was found to be fairly consistent in a range of 0.8 mm to 1.0 mm. In an effort to decrease surgical trauma to the animals, we elected not to measure the mandibular thickness of each recipient site. This would require a much larger incision and risk damage to the facial artery that was in close proximity to our surgical site. We measured the thickness of 5 rabbit cadaveric mandibular angles at various locations. The average thickness was found to be 1.0 mm with a range of 0.75 mm to 1.35 mm.

Data were analyzed using JMP 3.16 (SAS Institute, Inc, Cary, NC). A paired *t* test was used to analyze the differences in thickness between each of the treatment modes.

Results

All 15 animals tolerated the general anesthesia and surgical procedures. Four animals showed hind leg



FIGURE 4. A, LactoSorb specimen 6 weeks post graft. B, Titanium screw specimen 6 weeks post graft. C, Control group 6 weeks post graft.

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Table 2. THICKNESS OF POST-GRAFT SPECIMENS

Group Number	Specimen Width (mm)
1a	2.0 T
1b	1.2 C
2a	0.8 C
2b	2.1 R
3a	1.9 R
3b	1.2 C
5a	2.0 R
5b	0.8 C
6a	2.0 T
6b	0.8 C
7a	1.9 T
7b	1.0 C
8a	0.7 C
8b	2.0 R
9a	2.0
9b	4.1 R
13a	2.1 R
13b	2.0 T
14a	1.5 R
14b	1.6 T
15a	1.9 R
15b	1.7 T

NOTE. No information is listed for animals 4, 10, 11, and 12 because they had to be euthanized early due to tibial bone fracture.

Abbreviations: T, titanium screw site; R, resorbable screw site; C, control.

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avoidance within 1 week and were examined clinically and radiographically. These animals were found to have sustained tibial bone fractures adjacent to the graft donor sites and were subsequently euthanized. The remaining 11 animals went on to heal without complication (Table 2).

Gross examination revealed that the treatment groups (LactoSorb and titanium) all showed graft consolidation with obvious osseous thickening in the recipient area. There was no evidence of graft mobility or fibrous tissue interposition. Both screw heads were found to be flush with the lateral surface of the graft, indicating a lack of resorption in this area. In addition, the surrounding tissues appeared healthy without signs of foreign body reaction or inflammation. The control groups, on gross examination, did not show evidence of graft consolidation. The majority of specimens lacked any

cortical thickening and an outline of graft borders was very difficult to distinguish. There was no evidence of residual bone graft in the surrounding soft tissue.

As mentioned previously, all samples were evaluated in a blinded fashion for the amount of inflammation present using a scale of 0 to 4. Only 3 samples received a score of 2, which was the heaviest inflammatory response encountered. Each group (titanium, LactoSorb, and control) was represented in this category. Only 1 sample showed no inflammatory response at all. The remaining samples all received a score of 1 and thus had a slight chronic inflammatory response associated with the grafting procedure. No evidence of a severe inflammatory reaction was identified in any of our specimens.

Under light microscopic examination, a smooth integration of the graft with the cortical boundary of the recipient site was virtually complete in all instances. A mixture of woven and lamellar bone was identified in the grafted sites together with evidence of active osteoblastic remodeling activity. In contrast, the control specimens consisted primarily of mature lamellar bone (Fig 5). Giemsa staining provided a vivid demonstration of immature woven bone as seen in our treatment models. Interestingly, a thin (20 to 40 μm) fibrous connective tissue layer could be seen adjacent to the screw holes. In some areas, the formation of new bone was seen on the lingual surfaces of the mandible where the screws had penetrated the bone.

Using the ocular micrometer, the mandibular thickness of each specimen was measured. The LactoSorb-treated group was found to have a mean recipient graft site thickness of 2.28 mm, with a range of 1.5 mm to 4.1 mm. The titanium group's average graft site thickness was slightly smaller at 1.87 mm, with a range of 1.6 mm to 2.0 mm (Table 2). Finally, the control group had a mean graft site thickness of 1.06 mm (range, 0.7 mm to 2.0 mm). There was a statistical difference between the titanium group and the control group as well as the LactoSorb group and the control group ($P = .0004$; $P = .013$, respectively). In contrast, there was no statistical difference seen between the titanium group and the LactoSorb group ($P = .19$).

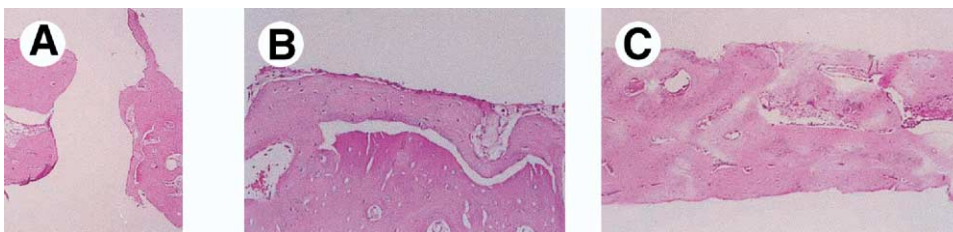


FIGURE 5. A, Magnification ($\times 4$) of the H&E-stained treatment group. B, Magnification ($\times 20$) of the H&E-stained treatment group. C, Magnification ($\times 10$) of the H&E-stained control group.

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Discussion

Currently, cortical onlay bone grafts are stabilized using titanium screws of varying lengths. The titanium fixation screws require secondary removal from the bone graft before placement of the dental implants. Certain problems can arise from the need to remove these screws. The patient not only incurs increased morbidity from the initial surgery, but additional pain and morbidity is experienced when the fixation screws are removed. A large incision with additional extensive soft tissue stripping is required for removal of the titanium fixation screws. At times, the screw can become osseointegrated into the graft. Removal of an osseointegrated titanium screw can cause damage to the underlying grafted bone. In addition, as the bone graft heals and bone resorption occurs, the head of the titanium screw can protrude causing discomfort, soft tissue dehiscence, infection, and potentially graft failure.

Bioabsorbable fixation devices offer many advantages over their metallic counterparts. The elasticity of these devices is close to that of bone, thus enhancing the stress protection.²³ As the bone is healing, the bioabsorbable plates will gradually degrade, allowing physiologic stresses to be transferred back to the healing bone. As a result, stress shielding is avoided. Bioabsorbable fixation devices do not need to be removed and obviate the need for additional surgery. In addition, these plates do not interfere with skeletal growth, making them useful in pediatric craniofacial surgery. As technology has improved, more bioabsorbable medical implants have been developed.

The low inflammatory response associated with all 3 study groups indicated that the biologic response to the procedure was favorable for graft consolidation. Historically, the bioresorbable polymers were associated with host tissue reaction and had led to some difficulty using these materials. The modern bioabsorbable materials such as LactoSorb are designed to avoid these reactions and thus have shown great success in head and neck surgery. The absence of a severe inflammatory reaction in our treatment groups is consistent with previous studies using this material as an osseous fixation device.²⁴⁻²⁷ This absence of a severe inflammatory response is what makes possible the placement of implants in the healed grafted site, drilling through the remains of the resorbable screw if necessary, with no risk of compromising implant survival. We have already performed this procedure a number of times in our clinic patients with very favorable results.

The present study showed that bioresorbable screws provide for excellent initial graft stability at the graft placement phase. At the graft retrieval stage, it was noted that grafts had consolidated to the un-

derlying mandible without evidence of inflammatory reaction, bone mobility, or loss of graft volume comparable to grafts fixated with titanium screws. On gross examination, it was apparent that bone resorption had not taken place in either of our treatment groups.

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