Resorbable Fillers Reduce Stress Risers From Empty Screw Holes

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Background: Empty screw holes after hardware removal are stress risers that weaken bone and can lead to refracture in an active individual. We sought to reduce these stress risers. We hypothesize that resorbable screws used as hole fillers would (1) provide immediate strength and (2) maintain this strength during resorption.

Methods: Randomized, prospective controlled animal laboratory study with 75 live New Zealand white rabbits' paired femurs. Single mid-diaphyseal holes were filled with a metal or resorbable screw; contralateral femurs were paired empty hole controls. Main outcome measurements included histologic analysis, torsion to failure, peak torque, energy to failure, and stiffness at baseline, 1 week, and 13 weeks postimplantation.

Results: At time baseline, resorbable fillers produced an immediate 30% increase in the peak torque ($p = 0.01$) and 73% increase in peak energy ($p = 0.006$). Metal screws produced a 17% increase in peak torque ($p = 0.038$), and a 58% increase in the amount of energy to failure ($p = 0.009$). At 1 week, although the resorbable ($p = 0.01$) but not the metal ($p = 0.82$) screws increased the peak torque, both metal ($p = 0.003$) and resorbable ($p = 0.050$) screws increased the peak energy compared with contralateral empty controls. At 13 weeks, metal and resorbable screw-filled bones were as strong as the healed contralateral femurs. Partial screw resorption and new bone formation without lysis was demonstrated histologically. Resorbable screw hole fillers immediately increase the strength of bones without weakening during early resorption.

Conclusions: Placing resorbable fillers in bone defects after hardware removal could reduce the likelihood of refracture.

Key Words: Stress riser, Filler, Resorbable, Screw hole, Refracture.

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Although plates and screws are generally left in place after a fracture has healed, retained hardware has been associated with complications, especially in active athletic individuals. Hardware removal, however, involves surgical risks and produces stress risers, which may lead to refracture. Often these patients require mechanical protection after hardware removal.

Currently, implanted hardware is left in place until it causes a specific problem, but asymptomatic hardware has been associated with severe consequences, particularly in high demand patients. In a 10-year review of National Football League players, there was a 17% refracture rate in football players with well-healed fractures and asymptomatic plates. In this series, the average time to internal fixation was 1.5 days after injury, and all fractures were internally fixed using standard plating techniques without intraoperative complications. The average time to player reactivation was 18 weeks after surgery, but even with these cautious methods, 17% of the players sustained refracture after reactivation.[1] A similar survey of Rugby players in England from 1990 to 1997 revealed a considerable complication rate in players with retained hardware. After fracture fixation, the players resumed their preinjury level of participation within 1 month to 12 months. In this series, 13% of these athletes suffered complications in relation to the retained implant.[2] A refracture or other inactivating complication in an athlete or laborer causes a considerable professional, socioeconomic, and psychological loss.[3]

Routine removal of asymptomatic plates as a method of avoiding these complications may be a more risky policy than leaving them in, however. Besides exposing the patient to the surgical risk, even successfully removed hardware causes localized microtrauma to the bone and leaves behind empty screw holes, which act as stress risers. The combination of the removal process and the residual empty holes weaken bone and place the patient at risk for refracture. To prevent refracture after plate removal, the athlete or high demand patient today must endure a prolonged period of mechanical protection before his or her full reactivation. The duration of this protected period is of some debate, but recommendations range from several weeks[4–7] to a full year.[8] The cost of this inactivation to an active individual is substantial.

Despite risks involved with hardware removal, it is performed routinely,[9] and for decades, the stress concentration resulting from bone defects after hardware removal has presented a challenge to the orthopedic community. Rates of refracture after hardware removal range from 7% to 26% depending on hardware type and location, with higher rates seen in the forearm after the removal of larger plates, partic-

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ularly from young and athletic patients.[2,6,10–13] The weakening effect of plates and screws is a combination of localized osteopenia from plate-induced ischemia,[14] microtrauma at the screw-bone interface, and stress risers from empty screw holes. Although extreme osteopenia will weaken bone,[15] studies indicate that until bone is demineralized by 75%, there is no significant weakening in torsion.[16] Even an uncomplicated screw removal process is thought to cause microtrauma in the surrounding bone as the screw is loosened, but unless a large amount of bone is removed, this represents a minor percentage of the overall weakening effect. With respect to screw holes, however, it has been shown that a bicortical hole representing only 20% the diameter of the cortex resulted in up to 50% reduction in torsional peak load to failure.[17,18] This corresponds to a 3.5-mm screw hole in a 1.7-cm radius, ulna, or fibula. Thus, it is clear that the residual screw holes are a major weakening feature of a bone after hardware removal.

To date, no intervention has successfully reduced stress risers immediately after hardware removal[19–21] and maintained initial strength during a healing period.[22] Previous efforts to augment bone strength by accelerating screw hole filling have not been successful. In 1970, Brooks et al.[17] attempted to increase the rate of new bone formation in screw holes by over drilling screw holes after screw removal. They hoped to accelerate the healing process and stimulate bone formation by causing localized bleeding and removing the fibrous tissue that forms in the screw-bone interface. In their study, woven bone filled both drilled and undrilled holes at equal rates, and they were unable to demonstrate increased mechanical strength in the bones with redrilled screw holes. Attempts at bone grafting screw holes in living dogs met with similar disappointment.[20,21] Although bone grafting possibly increased bone quantity in screw holes, there was no evidence that additional bone lead to an increase in whole bone strength.

Calcium phosphate cement injected into unicortical defects in rabbit femurs provided immediate strength to rabbit femurs in vivo, but the intramedullary expansion of the cement seemed to hamper healing and new bone formation, presumably caused by disruption of the intramedullary blood supply, which caused the filled bone to remain weaker than an intact bone, even 3 months after injection.[22]

Our goal in this study was to develop a method that would strengthen bones immediately after hardware removal without weakening the bone during the healing process. Because refractures usually occur shortly after hardware removal,[10,12] any method of reducing stress risers and strengthening bone must satisfy two objectives: (1) provide immediate strength at the time of implantation, and (2) preserve strength during bone replacement. We chose both a permanent metal screw, which would provide immediate strength, as our standard control versus a resorbable screw, which has the theoretic benefits of resorption over time. Also, our resorbable screw would act as a filler, but not theoretically have the detrimental effects of calcium phosphate cement, which may cause expansion and intramedullary blood supply disruption. To our knowledge, although different composition of screws exists, no clinical differences exist between resorbable screws despite resorption time differences. The hypothesis of this study is that the filling of empty bicortical diaphyseal bone holes with screw fillers would improve immediate and long-term effects on bone strength.

MATERIALS AND METHODS

The effect of screw hole filling was tested using paired femurs from 75 rabbits. For each pair, one was filled with either a metal or resorbable bone screw, and the other left empty. The predictable size and growth patterns of the New Zealand white rabbit make it a suitable animal for our model, and it has been commonly used in prior studies.[17,23] Six-month-old rabbits were chosen for their active bone physiology and the appropriate size of their femurs relative to the size of the implants used.[22]

After approval from our Animal Welfare Committee, 75 female New Zealand white rabbits were assigned to three groups to determine the time of bone harvest at time 0, 1 week, and 13 weeks. Time 0 rabbits (n = 15) were killed at the time of screw placement. The remaining rabbits were placed under general anesthesia for surgery and killed at 1 week (n = 30) and 13 weeks (n = 30) postimplantation.

At screw placement, the rabbits were further randomized to receive either a standard 2-mm AO stainless steel screw (Synthes, Paoli, PA), “metal”, or a 2-mm resorbable screw (82% polylactic acid and 18% polyglycolic acid [PGA], Biomet, Inc., Warsaw, IN), “resorbable”. Thread pitch and insertion methods were identical. The metal group was used for comparison with the current familiar clinical scenario of bones filled with metal screws; currently, holes are left empty after removal of metal screws. A single midshaft bicortical hole was drilled in the anteroposterior direction through right and left femurs. The holes were 2 mm in diameter, which was approximately 20% of the overall midshaft diameter. Before screw insertion, the holes were tapped using the specified manufacturer-supplied tap. The screws were inserted through both cortices. The empty holes in the contralateral control bones were also tapped to match the holes in the filled bones.

The rabbits were individually caged and permitted unrestricted motion and weightbearing throughout the postoperative period. They were monitored regularly for signs of infection, fracture, or irregular behaviors, which could indicate other pathophysiologic problems.

Upon harvesting, the femurs were carefully cleaned of the muscle and fascia, and the proximal and distal epiphyses were removed. To prepare the specimens for potting, 1.0-mm crossed k-wires were placed 5 mm from the proximal and distal physes, and the bone ends were potted with polymethylmethacrylate in square aluminum (2.54 cm) tube stock. During potting, care was taken to preserve a constant 45-mm gauge length of free bone between the potting surfaces. When not being potted or tested, the bones were wrapped in salinesoaked gauze, sealed in double slide-lock bags, and frozen at −20°C.

Mechanical testing of the paired bones was accomplished by applying a torque in external rotation using a servohydraulic torsional testing machine (Model 8521s, Instron Corporation, Canton, MA). The bones were torqued at a constant rate of 10 degrees per second, and torque-rotation data were recorded at 200 Hz with a digital data acquisition system. Torque versus rotation data were reduced to determine the peak torque, total energy to failure, and stiffness of the specimen. The peak torque was defined to be the maximum value of the torque-rotation curve to the point of failure. The total energy was determined by integrating the torque-rotation curve to the point of failure. The stiffness was determined by measuring the slope of the linear portion of the torque-rotation curve after exclusion of the toe region using custom-designed LabView software (National Instruments, Austin, TX). The paired data were analyzed by Student *t* test with Instat software (Graphpad Software, Inc., San Diego, CA) on a personal computer. The values on the filled side were expressed as a percentage increase over the paired empty bone, which facilitated comparison between young rabbits' bones at small forces and older rabbits' bones at larger forces.

At the conclusion of testing, the fracture pattern of each bone was also assessed. Notation was made of the fracture type (spiral, transverse, or comminuted), as well as the angle of the fracture relative to the long axis of the bone (measured with a miniature goniometer). In addition, we noted whether the fracture passed through none, one, or both of the two cortical defects created by a single bicortical screw hole and these data were analyzed using χ^2 in Instat software (Graphpad Software, Inc.).

Eight randomly selected rabbits from 1 week (n = 2) and 13 weeks (n = 6) were harvested in an identical manner, and their femora were set aside for histologic analysis. These bones were decalcified in a modified Richman-Gellfand Hill solution (10% HCl, 12.5% formic acid, and 3% floroglucinol) for 12 days, embedded in paraffin, and histologic slides were stained in hematoxylin and eosin and Safranin O. These slides were used for qualitative analysis of the bone replacement process. A power analysis was performed to assure statistical validity.

RESULTS

Of the 75 rabbits entered into the study, there were 11 unexpected exclusions, resulting in 64 rabbits available for data collection (mechanical testing or histology) at time 0 (n = 12), 1 week (n = 24), and 13 weeks (n = 20) postimplantation. The exculsions were because two rabbits that were killed early (one because of self-mutilation and the other because of a spine fracture resulting in paralysis). An additional nine rabbits were excluded because they fractured their femurs before data collection: eight in vivo and one during specimen preparation (time 0 group). In each case, it was the empty femur, not its paired filled femur that fractured. The distribution of those unexpected fractures was one in the metal 1-week group, one in the metal 13-week group, one in the resorbable 0 week group, four in the resorbable 1-week group, and two in the resorbable 13-week group. It is unclear when the fractures in the 13-week group occurred, as they were partially healed at harvest. After these 11 rabbits were eliminated, 64 rabbits remained for data collection. Of these, eight rabbits were randomly selected for histologic analysis: two were from the resorbable 1-week group, three were from the resorbable 13-week group, and three were from the metal 13-week group, resulting in a total of 56 rabbits available for mechanical testing.

Mechanical Properties Testing

At time 0, filling the empty hole with resorbable fillers immediately produced a mean increase of 23% in the torque to failure ($p = 0.01$) and a 73% increase in the amount of energy to failure ($p = 0.006$). The metal fillers also increased the peak torque and energy to failure, but less than the resorbable fillers did. A metal filler immediately produced a mean 17% increase in maximum torque to failure over its paired empty hole bone ($p = 0.038$), and a 58% increase in the amount of energy to failure ($p = 0.009$). At time 0, there was no difference in stiffness of the empty bones and bones filled with either metal or resorbable fillers (Fig. 1).

There was a general increase in strength of filled and empty femurs in all groups as the rabbits grew (Table 1). At 1 week, the femurs that had their holes filled with resorbable fillers showed a greater peak torque than their empty pairs did (2.88 Nm ± 0.55 Nm vs. 2.48 Nm ± 0.5 Nm, $p = 0.01$), with no significant difference at 13 weeks (6.63 Nm ± 0.84 Nm vs. 6.51 Nm ± 0.8 Nm, $p = 0.41$). Likewise, the energy absorption to failure also trended higher for the resorbable-filled bones than for their empty pairs (12.95 Nm ± 5.23 Nm vs. 11.53 Nm ± 3.57 Nm · deg $p = 0.0501$) at 1 week, with no significantly difference at 13 weeks (43.68 Nm ± 7.07 Nm vs. 46.12 Nm ± 8.38 Nm · deg, $p = 0.08$). In contrast to the resorbable group, the metal-filled bones demonstrated no difference when compared with their empty pairs in torsional load at 1 week (3.54 Nm ± 0.92 Nm vs. 3.47 Nm ± 0.86 Nm, $p = 0.82$). They did, however, demonstrate a higher energy to failure (18.42 Nm ± 8.31 Nm vs. 11.49 Nm ± 2.79 Nm · deg, $p = 0.03$) at 1 week, and no difference in peak torque (6.82 Nm ± 0.75 Nm vs. 6.4 Nm ± 1.75 Nm, $p = 0.23$) or energy (41.8 Nm ± 16.79 Nm vs. 44.55 Nm ± 6.39 Nm · deg, $p = 0.64$) at 13 weeks. There was no change in the stiffness of metal or resorbable-filled bones throughout the experiment.

Bone and Fracture Characteristics

Upon gross inspection of the specimens at 1 week and 13 weeks, the empty drill hole in the control femoral shafts became progressively smaller over time as new bone formed. Thirteen weeks postoperatively, the hole was only occasionally visible as a tiny dimple in the empty hole specimens. The

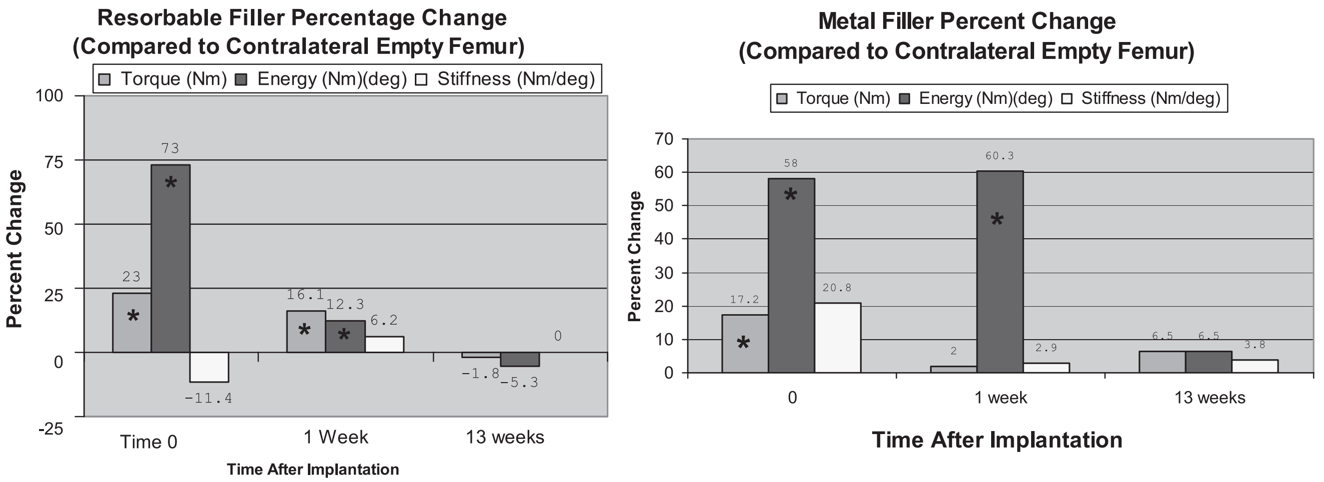

Fig. 1. *Graphs depicting percentage change of torque (Nm), energy (Nm · deg), and stiffness (Nm/deg) for metal- and resorbable-filled femurs compared with their paired empty hole femurs at time 0, 1 week, and 13 weeks.* *$p \leq 0.05$.

Table 1 **Torque (Nm), Energy (Nm · deg), and Stiffness (Nm/deg) for Metal and Resorbable-Filled Bones Compared With Their Paired Empty Hole Bones at Time 0, 1 wk, and 13 wk**

	Torque			Energy			Stiffness		
	Nm	Change (%)	*p*	Nm · Deg	Change (%)	*p*	Nm/Deg	Change (%)	*p*
Resorbable									
Time 0									
Empty, n = 6	1.44 ± 0.18	22.9	0.011	3.38 ± 0.81	73.4	0.006	0.35 ± 0.05	–11.4	0.053
Filled, n = 6	1.77 ± 0.33			5.86 ± 1.71			0.31 ± 0.06		
1 wk									
Empty, n = 8	2.48 ± 0.59	16.1	0.01	11.53 ± 3.57	12.3	0.050	0.32 ± 0.073	6.2	0.31
Filled, n = 8	2.88 ± 0.55			12.95 ± 5.23			0.34 ± 0.073		
13 wk									
Empty, n = 10	6.63 ± 0.84	–1.8	0.41	46.12 ± 8.38	–5.3	0.085	0.5 ± 0.071	0	0.62
Filled, n = 10	6.51 ± 0.66			43.68 ± 7.07			0.5 ± 0.06		
Metal									
Time 0									
Empty, n = 6	1.68 ± 0.47	17.2	0.038	5.66 ± 2.18	58	0.009	0.24 ± 0.07	20.8	0.3
Filled, n = 6	1.97 ± 0.38			8.97 ± 2.72			0.29 ± 0.05		
1 wk									
Empty, n = 16	3.47 ± 0.86	2	0.823	11.49 ± 2.79	60.3	0.003	0.34 ± 0.035	2.9	0.67
Filled, n = 16	3.54 ± 0.92			18.42 ± 8.31			0.35 ± 0.055		
13 wk									
Empty, n = 10	6.4 ± 1.75	6.5	0.23	41.8 ± 16.79	6.5	0.642	0.52 ± 0.07	3.8	0.74
Filled, n = 10	6.82 ± 0.75			44.55 ± 6.39			0.54 ± 0.092		

heads of resorbable screws were partially dissolved at 13 weeks, and several were covered with bone. In contrast, all the metal screw heads and tips were plainly visible.

Histologically, the empty screw holes filled in with normal appearing woven bone, with partial reconstitution of the cortex at 13 weeks. Predictably, the bone surrounding the metal-filled holes showed very little histologic change, with a distinct outline of the screw threads visible at 13 weeks. In contrast, the resorbable screws demonstrated the early phases of implant degradation and resorption, with gradual new bone formation and partial cortex reconstitution at 13 weeks (Fig. 2). There was no evidence of bone lysis or inflammatory reaction during this resorption process.

The fractures in specimens from the early groups (time 0 and 1 week) occurred in a spiral pattern at a 45-degree angle (±2 degrees) to the long axis of the bone. A single bicortical hole creates two cortical defects; if a hole was filled with a resorbable screw, the fracture was more likely to miss one of the two defects than it was in the group with metal-filled holes (Fig. 3). In the early groups (time 0 and 1 week), the fractures of only 3 of 14 resorbable-filled bones passed through both cortical defects, whereas the fractures in 9 of 14 of their contralateral empty pairs passed through both cortical defects. This difference in the resorbable group was statistically significant by χ^2 (χ^2 = 0.02). For the metal groups, fractures passed through both cortical defects in 7 of 22 filled

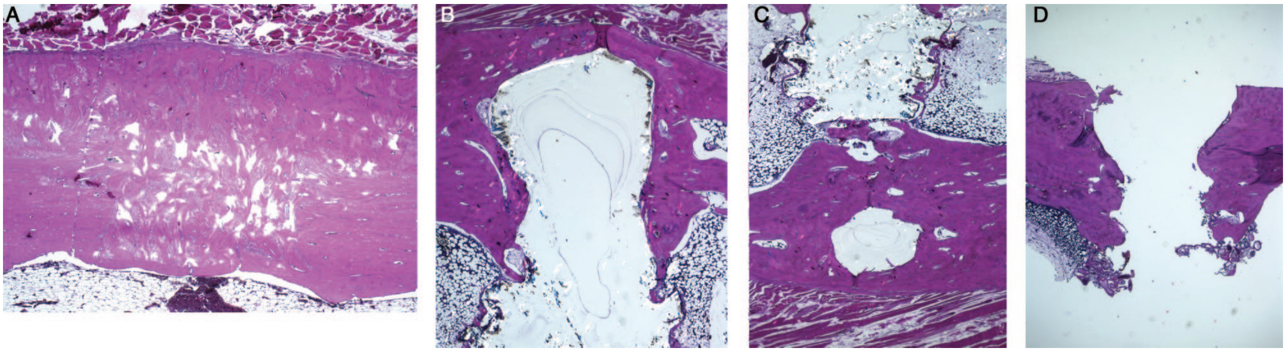

Fig. 2. *Histology: hematoxylin and eosin stain. Empty holes, resorbable-filled holes, and metal-filled holes at 13 weeks.* (A) *Unfilled controls filled in with woven bone at 13 weeks. Resorbable-filled bone at 13 weeks, demonstrating partial resorption, early new bone formation, and no lysis or inflammatory cells at the screw head* (B) *or tip* (C). (D) *Metal-filled bone at 13 weeks, demonstrating no new bone formation at the screw-bone interface, and a full-sized cortical defect.*

bones and 9 of 22 of their paired empty bones, which was not statistically different by χ^2 ($\chi^2 = 0.33$). At 13 weeks, both metal and resorbable-filled bones, as well as their healed empty pairs, produced a comminuted pattern, with no single discernable fracture line (Fig. 3).

DISCUSSION

The weakening effect of stress risers after hardware removal continues to challenge the orthopedic community. In this study, we sought to reduce the stress riser effect of an empty screw hole by filling it with a resorbable filler. Our mechanical data demonstrate an immediate strength increase without weakening during implant resorption.

Refracture is primarily a concern in young high-demand patients, but in the Medicare population alone, roughly 500,000 patients per year sustain fractures requiring the care of an orthopedic surgeon. Rates of surgical treatment of these fractures involving hardware implantation vary geographically and with fracture type but are as high as 77.1% in the ankle and 65.2% in the forearm.[23] A reported associated hardware removal rate of 23% in the ankle, for example,[9] means that problems associated with removal of orthopedic hardware are of concern for all practicing orthopedic surgeons worldwide. Rates of surgical treatment and subsequent hardware removal are likely to be even higher in a high-demand patient population.

The current gold standard for orthopedic hardware removal is to leave screw holes empty after hardware removal. Therefore, the comparison between an empty hole and its paired resorbable-filled bone is of key importance. Reminger et al.[24] showed that a bicortical screw was stronger than an empty bicortical hole; however, both were weaker than intact bone. Our data demonstrate an immediate strengthening effect of filling screw holes with resorbable screws, with no evidence of lysis or weakening as they are replaced by bone. Resorbable-filled bones were immediately able to withstand a higher load and absorb more energy before fracture than are their matched empty femurs at both time 0 and 1 week. There was no significant weakening effect during implant resorption and bone replacement. At 13 weeks, the ultimate torsional load, energy absorption to failure, and torsional stiffness of the metal and resorbable screw-filled bones were as strong as the healed bones, which had been left to fill in naturally. These values were comparable to those of intact femurs.[23]

It is noted that of the unexpected fractures of empty (control) femurs, a significantly higher number of the resorbable empty femurs than the metal femurs fractured unexpectedly. This is likely caused by the fact that the different screw systems required the use of slightly different taps, and we conclude that the resorbable tap system was more damaging than the metal screw tap was. This means that the protective effect of the resorbable screw fillers was demonstrated in the face of a weaker bone construct than the metal screws were. It suggests that the resorbable screw fillers have an ability to strengthen bones, which have been weakened from the microtrauma associated with screw removal.

Of additional interest is the fact that the increase in peak load of the resorbable-filled bones is greater than the peak load increase in the metal-filled bones at time 0 and 1 week. Although metal screws demonstrated a higher increase in energy to failure than the resorbable screws did at 1 week, the greater increase in peak load for the resorbable group is intriguing. The metal-filled bones represent the condition of a bone before screw removal and their controls were likely tapped by a less damaging instrument, which explains why they demonstrated a higher energy to failure at 1 week. In a clinical setting, these findings suggest that changing a metal screw with a resorbable screw may result in a construct that can withstand higher torsional loads.

Our findings support our hypothesis that filling an empty screw hole with a resorbable screw can immediately reduce its stress riser effect. Clinical studies indicate that refracture usually occurs shortly after plate removal,[10,12] and animal studies demonstrate early screw hole filling and increased

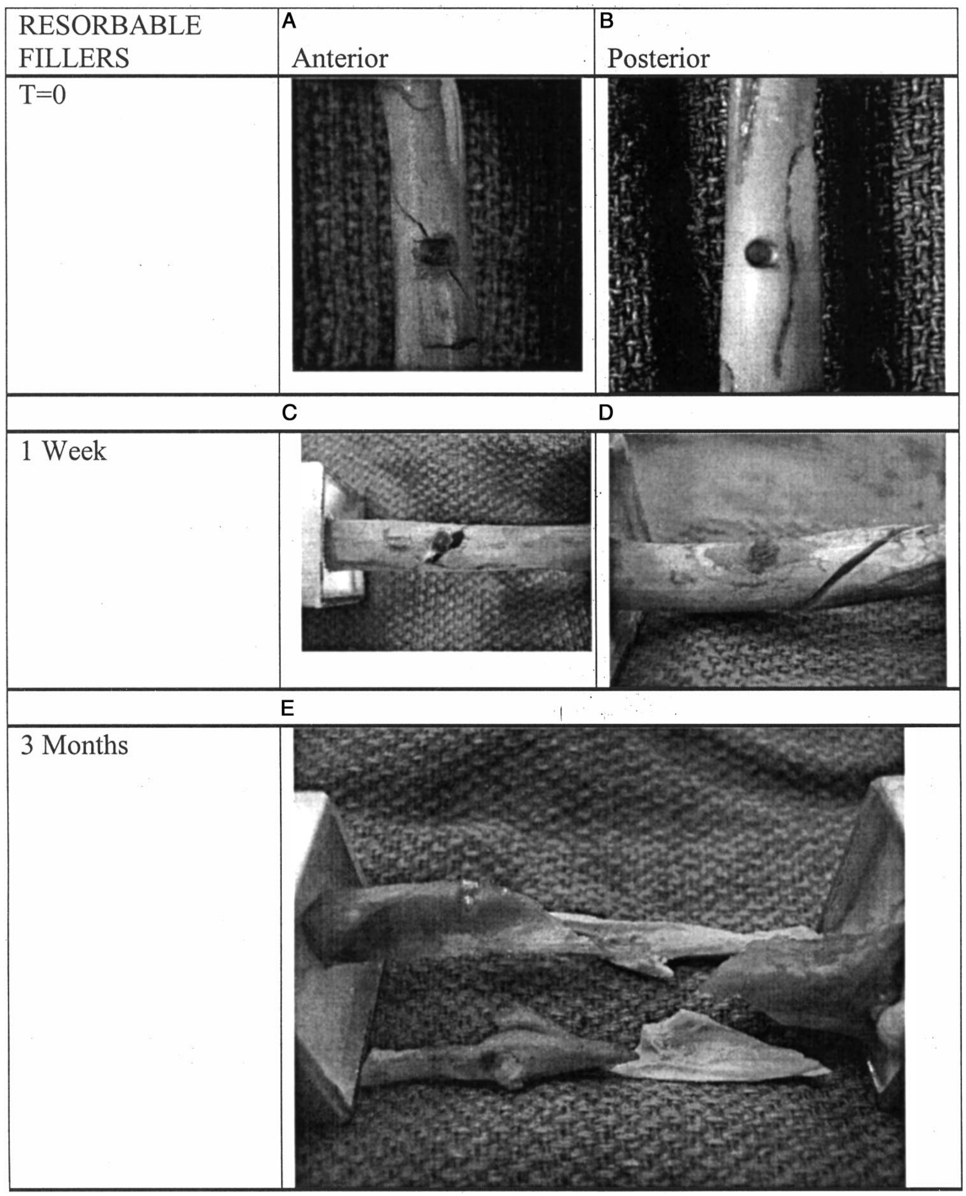

Fig. 3. *Fracture lines were more likely to miss holes filled with resorbable fillers. At 3 months, the fracture pattern is a higher energy, comminuted pattern. At time 0, the fracture line included the anterior cortical defect (*A*), but not the posterior cortical defect (*B*). At 1 week, the fracture line included the anterior cortical defect (*C*) but not the posterior defect (*D*). At 13 weeks, all bones demonstrated a highly comminuted pattern (*E*).*

strength just 4 weeks after screw removal.[19] Therefore, we propose that an immediate increase in maximum load to failure and energy absorbing capacity could raise the threshold for refracture in active patients during this early risky period after hardware removal. The fact that these fillers had no weakening effect during the early phases of resorption and new bone formation is particularly encouraging, because of the concerns of bone lysis or loosening during polymer resorption.

Degradation of the most commonly used synthetic biodegradable polymers, poly-(L-lactide) and polygycolide (PGA) begins with hydrolysis as the implant absorbs water.[25–27] The resulting fragments are phagocytosed by macrophages and polymorphonuclear leukocytes,[28–30] and lactic acid polymers are reduced and dissimilated via the Krebs Cycle.[31] Regional lactic acid overload could lead to prostaglandin release and osteolysis.[32,33] The likelihood of this problem occurring is determined by polymer type, implant size, and the rate of implant degradation, which is determined by the material's crystallinity. Highly crystalline poly-(L-lactide) implants persist 20 months after implantation and have entered lymphatic systems in sheep.[33,34] More rapid breakdown seen with PGA implants is associated with sterile abscesses and osteolysis.[30,35]

The resorbable fillers used in this study were 82% L-lactic acid and 18% PGA (polylactic acid/PGA) (Biomet, Inc., Warsaw, IN), a ratio that modulates the degradation rate for a predictable resorption and bone ingrowth process.[35] Our histology demonstrates a controlled degradation of the resorbable screw, with simultaneous peripheral new bone formation, with no evidence of inflammation, sterile abscess formation, or bone lysis.

At present, the precise mechanism of the fillers' protective effect is unclear. An interesting feature of the resorbable screws used in this study is that they swell slightly as they absorb water,[35] which may prestress the hole and limit the local stress rising effect by changing the stress concentration around the hole. As metal fillers do not expand, this difference may explain the increased strength advantage of the resorbable screws at some data points over metal fillers. As cortical bone is weaker in tension than compression, the first failure occurs in tension where the forces are maximally oriented at a 45-degree angle to the long axis of the bone. Once a fracture initiates, it propagates along the 45-degree angle spiral path to the opposite cortex. In the resorbable-filled, but not the metal-filled, group, the fracture often missed the defect in one cortex. This may represent a strengthening effect, which redirects that fracture propagation away from the stress riser into intact bone. A second possible mechanism is that the presence of a screw mechanically links the anterior and posterior cortices, which would require that the whole bone fail as a single system, thereby raising the threshold for fracture. The fact that the metal screws do not resorb may increase their ability to link cortices at later time points, and may explain a higher percentage increase in load to failure in the metal group after 1 week. There is no evidence in our data that placing either a metal or resorbable filler increases the stiffness of the specimens.

There are obvious concerns with drawing clinical conclusions from an animal study. Rabbit bone physiology allows bones to heal more rapidly and fill holes more rapidly[36] than human bones do. This fact, although detracting from our ability to draw direct clinical conclusions toward a human condition, means that the empty controls were filling in more rapidly than they would in the human condition. It is, therefore, more difficult to demonstrate a benefit when comparing these rapidly filling empty holes with the screw-filled holes. A second concern is that in our model, small bones were subjected to pure torsional loads; actual injuries occur in larger bones, at higher energy levels with complex loads. Despite this limitation, the carefully controlled nature of the mechanical testing allowed us to isolate the effect of the filled screw holes, revealing an intriguing protective effect of the filled versus empty holes, even at these low magnitude forces. Presumably, these mechanical features would apply to bones of any size. An additional limitation of the study is that although we demonstrate a protective effect of filling a single diaphyseal hole, clinical scenarios usually involve multiple holes, often at varying angles and screw sizes. Additionally, localized trauma from multiple screws or associated plates, disuse osteopenia, and local bone remodeling around an implant, all are clinical factors that contribute to actual refracture in patients. Follow-up studies and further work are necessary to evaluate the effect of filling multiple holes in larger bones.

The overall weakening effect of a removed screw in a clinical setting is a sum of the effect of the residual hole, which acts as a stress riser, and the microtrauma at the screw-bone interface caused by the removal process. Because the study design did not begin with removal of implanted hardware, we are unable to comment on the isolated destructive effect of screw removal. We are, however, able to show that the empty hole's contribution to the weaker state of the bone after hardware removal is mitigated when that hole is filled with a resorbable screw.

In conclusion, any method of reducing stress risers and strengthening bone after hardware removal should satisfy two objectives. The first is to provide an immediate strengthening effect at the time of implantation compared with a hole left empty. The results of this study suggest that immediately after hardware removal, a bone weakened by an empty screw hole could be made stronger if the hole was filled with either a metal or resorbable screw. Filling the hole with a metal screw would defeat the purpose of hardware removal and would not satisfy the second objective, which is for the filler to allow for eventual replacement by bone. The resorbable fillers demonstrated no significant weakening effect during the resorption process, and our histologic analysis demonstrate early resorption and new bone formation without lysis.

If the two mechanisms for the strengthening effect of the filler are by (1) prestressing the hole and (2) linking the cortices, the ideal implant for reducing stress risers would swell slightly to prestress the holes, and maintain its ability to link both cortices of the screw hole as it is incorporated biologically. With further investigation, it may be possible to develop a protocol for mitigating the stress riser effect and raising the threshold for refracture after hardware removal.

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