Compression Force and Pullout Strength Comparison of Bioabsorbable Implants for Osteochondral Lesion Fixation

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Abstract

We conducted a study to characterize compression forces and pullout strengths of 4 commercially available bioabsorbable nails and screws in a synthetic bone model.

A piezoelectric sensor was used to measure peak compression forces, and a material testing machine was used to measure maximum pullout strengths.

The strongest compression force was found for SmartScrew (12.7 N), then SmartNail (12.3 N), LactoNail (8.5 N), and ReUnite Screw (5.1 N). Mean compression force was significantly (*P*<.05) different between LactoNail and SmartScrew, ReUnite Screw and SmartNail, and ReUnite Screw and SmartScrew. The greatest pullout strength was found for SmartScrew (530 N), then ReUnite Screw (414 N), SmartNail (336 N), and LactoNail (189 N). These values were all statistically significantly (*P*<.05) different from each other.

In this model, SmartScrew had the overall strongest compression force and greatest pullout strength.

Fixation of unstable osteochondral (OCD) lesions traditionally has been done with metal implants, including Kirschner wires, Herbert screws, and AO (Arbeitsgemeinschaft für Osteosynthesefragen) cannulated screws. Recently, self-reinforced polyglycolic acid (SR-PGA) and polylactic acid (SR-PLLA) bioabsorbable fixation devices for OCD lesions have become popular.[1,2] Current implants include rods, screws, and nails. The advantage of using a bioabsorbable fixation device is that it eliminates the need for an additional operation to remove metal hardware. Despite their obvious advantage, bioabsorbable implants have had mixed results: high rates of success with bioabsorbable rods in 2 retrospective case studies[3,4] and complications with bioabsorbable screws (including loosening and breaking of screw heads) in 2 case reports.[5,6]

We conducted a study to evaluate some of the bioabsorbable implants used for fixation of OCD lesions. Our goal was to characterize mechanical compression forces and pullout strengths of 4 types of bioabsorbable nails and screws in a synthetic bone block modeled to simulate an OCD lesion.

Materials and Methods

Biomechanical testing was performed on 2 bioabsorbable nails, SmartNail (PLLA, 2.4 mm × 25 mm; Conmed Linvatec, Largo, Florida) and LactoNail (PGA/PLLA, 2.6 mm × 26 mm; Arthrotek Biomet, Warsaw, Indiana), and on 2 bioabsorbable screws, SmartScrew (PLLA, 2.7 mm × 24 mm; Conmed Linvatec) and ReUnite Screw (PGA/PLLA, 2.5 mm × 25 mm; Arthrotek Biomet). The synthetic bone block used was composed of a foam polyurethane cancellous region with a pore size of 0.5 mm to 1.5 mm (part 3002-1; Pacific Research, Vashon Island, Washington). The experiment was divided into 2 parts: one to measure compression forces and the other to measure pullout strengths.

In part 1, compression forces were measured. A circular aluminum jig 2 cm in diameter was machined

Figure 1. Experimental setup.

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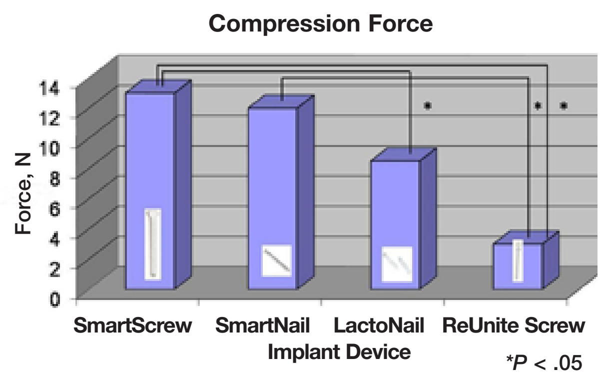

Figure 2. Compressive force generated by each implant type.

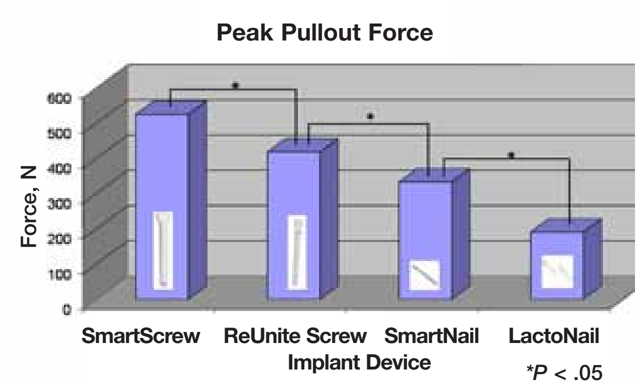

Figure 3. Peak pullout force of each implant device.

specifically for this study. The jig featured 3 holes in a triangular formation matching that of 3 holes (2 mm) drilled into the bone block. Manufacturer-recommended instrumentation was used to insert 3 implants through the jig holes and into the bone block. Drill holes were tapped accordingly for the screws only. A piezoelectric force sensor (FlexiForce; Tekscan, Boston, Massachusetts) was inserted under the jig, between the jig and the bone block. The load was distributed evenly across the sensing area using a 1-mm "puck" machined into the undersurface of the jig, and peak compression forces were recorded. Figure 1 shows the experimental setup.

In part 2, maximum pullout strengths were measured. The bone block, containing the jig and 3 implants, was fastened to the base of an Instron material testing machine (Instron, Norwood, Massachusetts). The jig was attached to the crosshead of the machine through a metal coupling. After a preload of 5 N was applied to the construct, the jig was pulled from the bone block at a rate of 30 mm per minute until failure.

Failure load and mode were recorded for 18 implants (3 implants × 6 sets) in each part of the experiment, so implants were tested 36 times in each part, or 72 times in the experiment as a whole.

Statistical analysis was performed with a repeated-measures analysis of variance, with significance set at $P<.05$.

Results

The strongest compression force was found for SmartScrew (12.7 N; 95% confidence interval [CI], 10.6-14.9), then SmartNail (12.3 N; 95% CI, 10.2-14.5), LactoNail (8.5 N; 95% CI, 6.3-10.6), and ReUnite Screw (5.1 N; 95% CI, 3.0-7.3). Mean compression force was significantly ($P<.05$) different between LactoNail and SmartScrew, ReUnite Screw and SmartNail, and ReUnite Screw and SmartScrew. Compression forces are depicted in Figure 2.

The most pullout strength was found for SmartScrew (530 N; 95% CI, 490.2-569.8), then ReUnite Screw (414 N; 95% CI, 374.7-454.3), SmartNail (336 N; 95% CI, 296.2-375.8), and LactoNail (189 N; 95% CI, 149.9-229.4). These values were all statistically significantly ($P<.05$) different from each other. Failure mode was at the implant–bone interface in all cases, except in 1 SmartNail and 1 LactoNail, where the heads pulled through the jig before maximum failure load. Pullout strengths are depicted in Figure 3.

Discussion

The operative fixation method for OCD lesions is controversial, and no single procedure is universally accepted. Many devices, including Kirschner wires,[7] Herbert compression screws,[2] and cannulated AO screws[1] have been shown to be effective in achieving fixation. The disadvantage of these implants is their tendency to become prominent over time and the subsequent abrasion of the opposing tibial articular surface. Hence, another procedure is required for implant removal after the OCD lesion has healed and before weight-bearing. For the patient, the second procedure means increased risk and cost.

Recently, SR-PGA and SR-PLLA bioabsorbable fixation devices for OCD lesions have become popular because of the clear advantage in there being no need for removal. Current implants include rods, screws, and nails. Despite their obvious advantage, biodegradable implants have had mixed results. Dervin and colleagues[3] reported good to excellent results in 8 of 9 patients using SR-PLLA bioabsorbable rods (Biofix; Bioscience, Finland) with a mean follow-up of 1.3 years. Tuompo and colleagues[4] reported good to excellent clinical results in 20 of 24 patients using both SR-PGA and SR-PLLA bioabsorbable rods with a mean follow-up of 3.3 years. However, Scioscia and colleagues[5] reported 3 cases of SR-PLLA screw backout and loose body formation with subsequent damage to the articular cartilage, possibly caused by inconsistent degradation of the screws. Friederichs and colleagues[6] reported similar results in 2 cases using the same screws. Fridén and Rydholm[8] described a case of severe aseptic synovitis in the knee after inserting 8 SR-PGA rods. However, Larsen and colleagues[9] reported good clinical results with healing of OCD lesions in 6 of 7 patients using a PGA-PLLA screw for fixation. Leinonen and colleagues,[10] comparing SR-PLLA tacks (of a design nearly identical to that of SmartNail) with SR-PLLA screws in cadaver metatarsal bones, found that the tacks had significantly better pullout strengths.

For OCD lesions, the ideal fixation device is one that is used with relative ease in arthroscopic procedures; that ensures long-term, stable compression of the fragment; that is made of a bioabsorbable material (no second procedure needed); that degrades uniformly over time; and that is inert. In our study, SmartScrew had the overall best compression force and pullout strength. However, its prominent head and the need for torsional stress during insertion are concerns for this application. Torsional stress is a source of strain on the bioabsorbable material, particularly at the head–shaft junction.

The SmartNail design may make this device better suited for fixation of OCD lesions. Its compression force and pullout strength are comparable to those of SmartScrew, and its low-profile head can be easily recessed below the cartilage surface. Furthermore, during insertion, SmartNail is tapped in, so there is no torsional stress applied to the shaft. Another advantage is that drill holes need not be tapped for SmartNail insertion.

Compared with SmartNail, LactoNail had considerably less compression force and pullout strength, perhaps because of its PGA–PLLA mixture, which is less rigid than the SR-PLLA of SmartNail. In addition, LactoNail does not have the barbed SmartNail design.

Of the implants tested in this study, ReUnite Screw had the weakest compression forces, secondary to a hexagonal head designed to shear off with application of torque. This implant, then, is the least desirable for this application.

Conclusion

In a biomechanical comparison, overall best compression force and pullout strength were found for SmartScrew, over SmartNail, LactoNail, and ReUnite Screw.

Authors' Disclosure Statement and Acknowledgments

The authors are employees of the US government. The opinions or assertions contained herein are the private views of the authors and are not to be construed as official or reflecting the views of the US Department of Defense or the US Government. The authors report no actual or potential conflict of interest in relation to this article.

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