P^2 Porous Titanium Implants Improve Early Tendon Healing in a Rat Supraspinatus Repair Model

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INTRODUCTION

Rotator cuff tears are common musculoskeletal injuries which often require surgical repair. Unfortunately, repairs often fail[1] and improved repair strength is essential. In an effort to increase repair strength, various materials and biologics have been incorporated into rotator cuff repairs.[2,3] P^2 Porous titanium (DJO Surgical, Austin TX) has been shown to promote osseointegration[4,5] and subdermal integration.[6] However, the ability of P^2 Porous titanium to aid in a supraspinatus tendon-to-bone repair through tissue ingrowth has not been evaluated. Therefore, the purpose of this study was to investigate P^2 porous titanium implants used to augment supraspinatus tendon-to-bone repair in an established rat supraspinatus repair model.[2] We hypothesized that supraspinatus tendon-to-bone repairs with the addition of P^2 implants would allow for ingrowth and increased repair strength when compared to shoulders receiving standard supraspinatus repair alone.

METHODS:

Experimental design: Thirty-two adult male Sprague-Dawley rats (400-450g) were used in this study (IACUC approved). All rats received bilateral supraspinatus detachment and repair, in which one limb was randomly assigned P^2 titanium implant with the contralateral limb receiving the standard repair. The implant procedure consisted of creating a ~3 mm deep, 3 mm wide recess in the greater tuberosity using a high speed burr. The 3 mm diameter hemispherical implant was tamped into the recess and the supraspinatus was repaired over the implant.[2] Three animals were sacrificed immediately following surgical procedure (time zero) for histological analysis to confirm implant placement and for comparison to ingrowth at later time points. Remaining animals were allowed normal cage activity following surgery and were sacrificed after 2 weeks (n = 6), 4 weeks (n = 9) and 12 weeks (n = 14). Limbs from a subset of animals (n = 4 each at 4 and 12 weeks) were dissected immediately at sacrifice and fixed for histological analysis. The remaining shoulders were frozen for subsequent mechanical testing.

Tendon mechanical testing: Supraspinatus tendon-to-bone complexes (with or without implant) were dissected from the shoulder and cleaned of excessive soft tissue. Stain lines were then placed on the tendon for optical strain measurement. Cross sectional area was measured using a custom laser device. Tendon-to-bone complexes were then subjected to a mechanical testing protocol consisting of a preload to 0.08 N, ten cycles of preconditioning (0.1-0.5N at 1% strain/s), a stress relaxation to 5% strain (5%/s) followed by a 600s hold, and finally a ramp to failure at 0.3%/s. Stress was calculated as force divided by cross sectional area and 2D Langrangian strain was determined optically using custom tracking software.

Histology/SEM: Specimens for histology and SEM were embedded in PMMA for tissue-implant interface analysis. Specimens were first viewed in the SEM under BSE to detect incorporation between P^2 implant and bone. The specimens were then stained with Sanderson's Rapid Bone Stain and viewed under transmitted and polarized light for tissue ingrowth into the P^2 implant.

Statistical analysis: Comparisons were made using Student's t-tests with significance set a $p \leq 0.05$.

RESULTS

Tendon mechanical testing: No differences in cross sectional area were detected at any time point (Figure 1A). Percent relaxation was significantly increased in the P^2 implant group at 2 weeks, but there was no difference at 4 and 12 weeks (Figure 1B). Maximum load was significantly increased in the P^2 implant group at 2 weeks, but not at 4 weeks (Figure 1C - note that maximum load was not reported at 12 weeks due to failure at the grip at this time point). Elastic modulus was significantly increased in the P^2 implant group at 4 weeks, but not at 2 or 12 weeks (Figure 1D). No differences were detected in stiffness at any time point (data not shown).

Histology/SEM: The BSE analysis demonstrated bone ingrowth and skeletal attachment of the implant to the host bone which was significantly greater at both time points analyzed, 4 and 12 weeks when

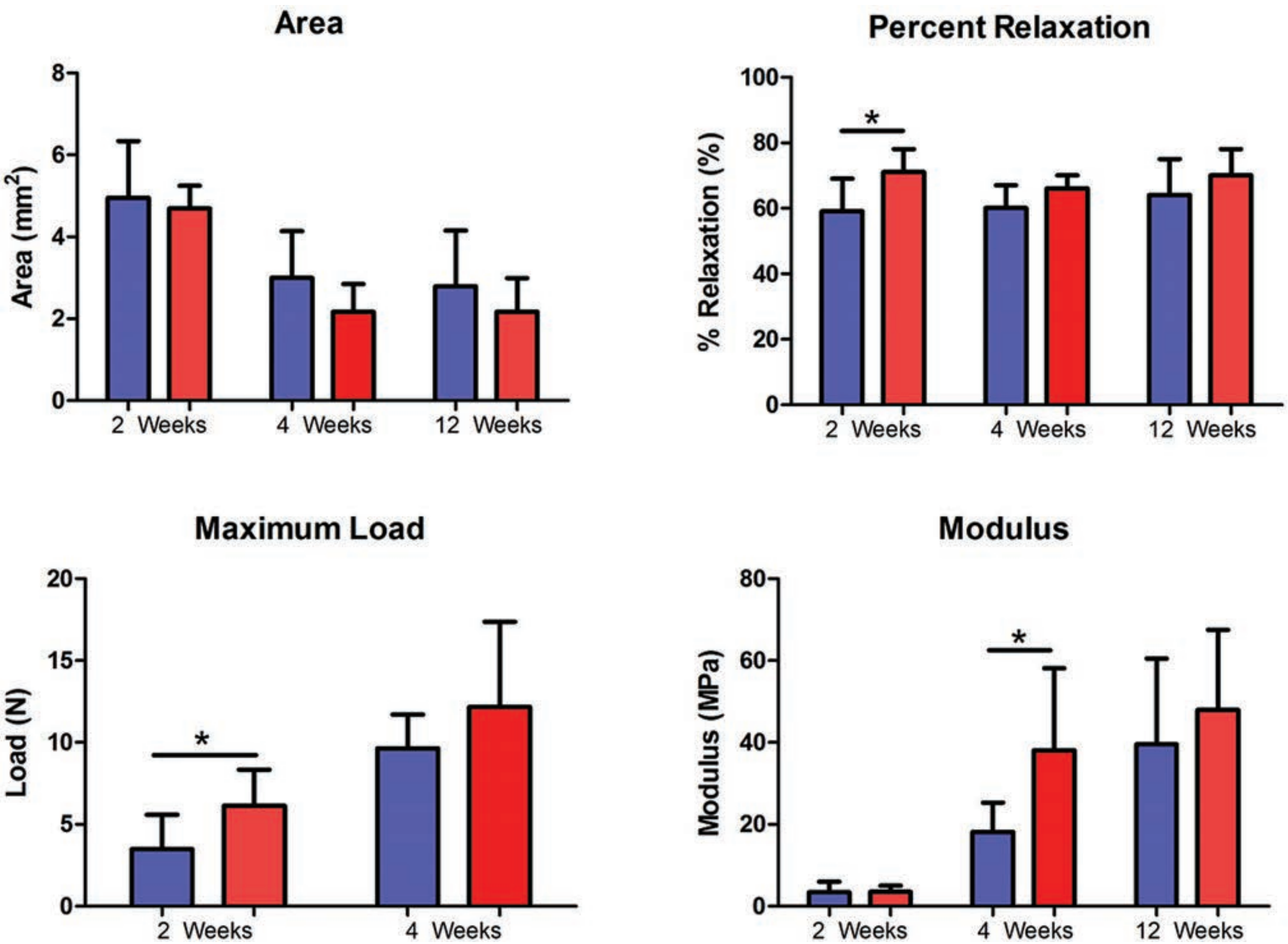

Figure 1. (A-D) (A) No differences in area were noted at any time point. (B) P² implant group had significantly increased percent relaxation at 2 weeks. No differences were noted at 4 and 12 weeks. (C) P² implant group had significantly increased maximum load (76%) at 2 weeks. No differences were noted at 4 weeks; 12 weeks not reported due to failure at the grip at 12 weeks. (D) P² implant group had significantly increased modulus at 4 weeks. No differences were noted at 2 and 12 weeks.

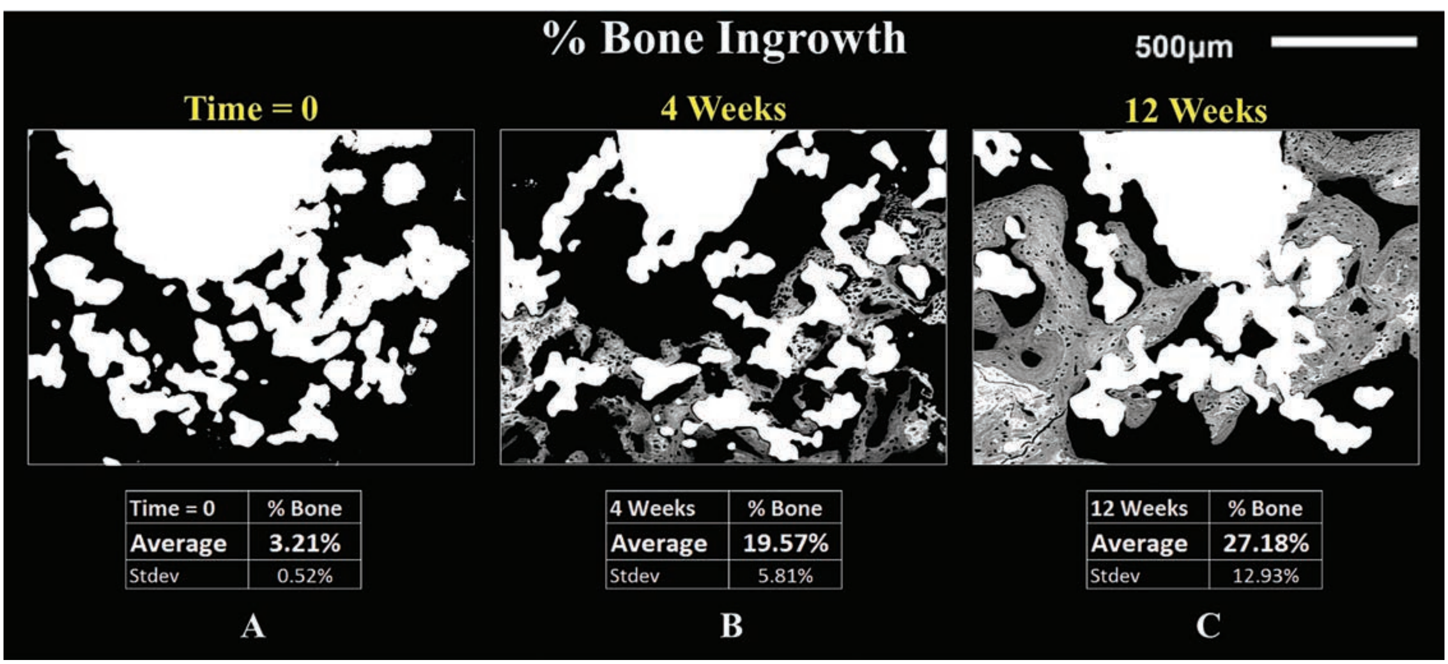

Figure 2. (A-C) Scanning Electron Microscope BSE images showing % bone attachment to the P² at all time points. White = implant, Black = pore space and Grey = bone. (A) Time = 0 specimens showed 3.21 ± 0.52%, (B) 4 Week specimens showed 19.57 ± 5.81% and the (C) 12 Week specimens showed 27.18 ± 12.93% of bone present within the porous coating (in growth was significantly greater at 4 and 12 weeks when compared to 0 weeks).

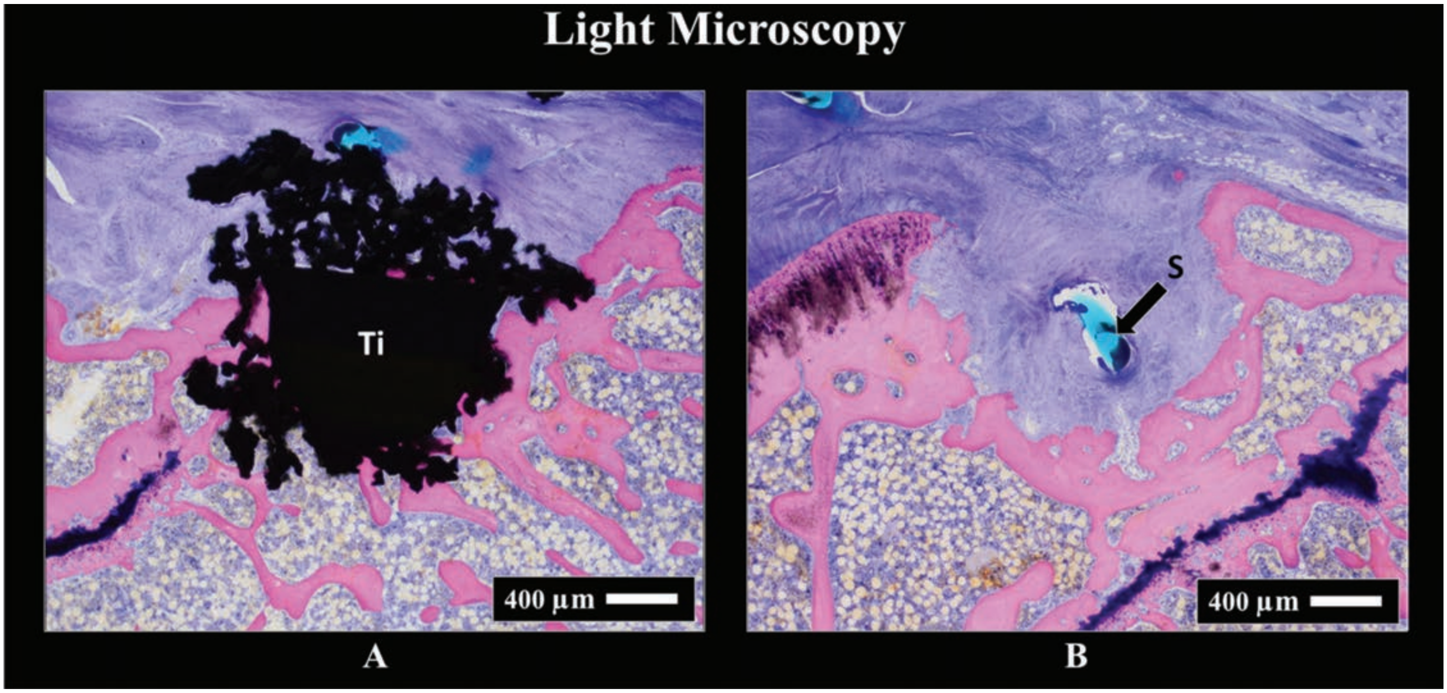

Figure 3. (A-B) Light Microcopy ground PMMA sections stained with Sandersons's Rapid Bone Stain (SRBS). Black = implant, Blue = Tissue and Pink = bone. (A) 12 Week P^2 specimen showing bone and tissue attachment to the P^2 (Ti) coating. (B) 12 Week control specimen showing the (S) suture.

compared to time zero (Figure 2). The histological analysis showed soft tissue integration with both the implant and bone (Figure 3).

DISCUSSION

Results indicate superior mechanical properties in the P^2 implant group compared to standard supraspinatus repair at 2 and 4 weeks, and tissue ingrowth at all time points. Importantly, at 2 weeks, the P^2 implant group had a 76% increase in maximum load compared to standard repair. As supraspinatus tendon re-tears are extremely common early[1] and occur at the tendon to bone interface, this finding supports the reduction of re-tear risk with the P^2 implant. Although no differences were detected in maximum load at 4 weeks, the increase at 2 weeks denotes that P^2 implants improved early tendon-to-bone healing (through so-called "Velcro effect" and early tissue ingrowth). Additionally, at 4 weeks, the P^2 implant group had significantly increased elastic modulus, further supporting increased mechanical properties due to the P^2 implant. Clinically, improved early healing might allow a faster rehabilitation and associated recovery, with the ability to resume daily activities sooner. This study demonstrates that the P^2 implant improves tendon-to-bone healing up to 4 weeks (with no detrimental effects at longer time points), suggesting that the P^2 porous titanium may be of benefit for use in clinical rotator cuff repairs.

SIGNIFICANCE

This data supports the use of porous titanium implants to improve tendon-to-bone healing based on a rat supraspinatus repair model.

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