Biomechanical and Histologic Comparison of Two Soft Tissue Fixators Made of Bioabsorbable Copolymers

SK Woolf,1 YH An,1 DL Powers,2 M Sonawala,2 R Hawkins,3 WS Pietrzak4

1 MUSC Department of Orthopaedic Surgery, Charleston, SC
2 Clemson University, Clemson, SC
3 Steadman Hawkins Clinic, Vail, CO
4 Biomet, Inc., Warsaw, IN
Introduction

• Reattaching soft tissue to bone is a challenge in orthopaedics
  – e.g. anterior glenoid labrum, knee collateral ligaments

• Soft tissue-bone interface typically requires 6-8 weeks for healing
  • Rodeo et al, 1993

• Screws, staples, suture-anchors, tacks, pins
  – arthroscopic or open

• Metal versus Bioabsorbable?
Introduction
Bioabsorbable polymers

• Bioabsorbable fixation offers advantages
  – Radiopacity
  – No need for removal with a second surgery
  – No retained hardware to cause impingement or discomfort

• Commonly used bioabsorbable polymers
  – Poly-glycolic acid (PGA)
  – Poly-lactic acid (PLA)
  – Poly-dioxanone sulfate (PDS)
  – Poly-hydroxybuterate (PHB)
Introduction
Bioabsorbable Polymers - continued

• High molecular weight poly-hydroxyacids formed by a ring-opening polymerization of cyclic diesters
• Designed to maintain strength during tissue healing and then gradually degrade
• Degrade by hydrolysis of ester bonds and then conversion to CO₂ and H₂O
• Macrophages and inflammatory cells remove debris
Introduction

Previous Work

• Numerous studies have investigated various polymers either \textit{in vitro} or \textit{in vivo}  
  – (Daniels et al. 1994; Migliaresi et al. 1994; Bos et al. 1989; Atkinson et al. 1998)

• Few studies include both \textit{in vivo} and \textit{in vitro} data on any polymer  
Introduction

• Two bioabsorbable soft tissue fixators available are composed of copolymeric bioabsorbable materials:
  – Suretacs
    • polyglyconate (PGA/trimethylene carbonate)
  – Pop Rivets
    • Lactosorb (PGA/PLLA)

• Both systems are “sutureless” tacks that can be used to reattach soft tissues directly to bone
Purpose

The purpose of this work was to perform *in vitro* and *in vivo* biomechanical and histological comparisons of these two bioabsorbable copolymer tack systems.
Materials

- Suretac I
  - polyglyconate
    - glycolic acid/trimethylene carbonate (2:1)
  - Cannulated
  - Impacted into a 3.7 mm predrilled hole
Materials

- Pop Rivet
  - Lactosorb
    - PGA/PLLA (18%/82%)
    - Insertion instrument used to place implant into a 3.5 mm predrilled hole
    - Pin is distracted, ends of fixator flare out until pin snaps
Methods

in vitro study

• Determine uniaxial pullout strength from a synthetic bone substrate as a function of time in a phosphate buffer bath (pH 7.4, 37°C)

• Substrate was a polyurethane synthetic block with 3.0 mm cortical thickness and underlying foam cancellous region
Methods

- Uniaxial pullout testing was performed after insertion and at 2, 4, 6, 8, 12 weeks
- Sintech 1/s
  - 3 cm/minute
- Metal fixture used to transmit uniaxial load.
- Compare mean decrease in failure load over time
  - t-test, p<0.05
Methods

*in vivo* study

- 25 mature goats
  - Bilateral (both fixators used in each animal)
  - Exposed medial collateral ligament (MCL)
  - MCL elevated from distal attachment and reattached with two Suretacs on one leg and two Pop Rivets on the other (11 mm apart)
  - Distal attachment of MCL then severed
  - Routine closure, immediate weight bearing
  - Full compliance with NIH Guide for Care and Use of Laboratory Animals
^ Predrilled holes

Two Suretacs in place
Methods

*in vivo* study

- Implants harvested at 3, 6, 12, 52, 72 weeks
  - 4 goats at each time point (3 at time zero)
    - Histology - 1 specimen
    - Mechanical testing - 3 specimens
    - Controls - 4 unoperated specimens
Methods

*in vivo* study

- Mechanical testing
  - Knees harvested *en bloc* and distal femur/proximal tibia potted in fixtures enabling mating with the mechanical testing system
  - Knees placed in extension and construct engaged at 3 cm/minute parallel to MCL fibers until failure (90% drop from maximum load)
  - Compare mean change in failure load over time
    - t-test, *p*<0.05
Methods

*in vivo* study

- **Histology**
  - Proximal tibiae fixed in 10% neutral buffered formalin
  - Embedded in Technovit (Energy Beam Sciences, Agawam, MA) methyl methacrylate embedding medium
  - Transverse sections polished to ~70 microns
  - Stained with toluidine blue and viewed under light microscope
Results

_in vitro_

- Initial pull-out values of \(~300\) N
- Two failure modes observed
  - extraction
  - fragmentation
    - more common upon degradation
Results

*in vitro*

- At 4 weeks, Pop Rivets retained 53% of initial strength; Suretacs retained <3%
- At 12 weeks, Pop Rivets had 3% of initial strength
  - trend noted ($p=0.083$)
- Suretacs fragmented at 6 and 12 weeks
## Results

*in vitro*

<table>
<thead>
<tr>
<th>Time (Weeks)</th>
<th>Suretac® (n=4)</th>
<th>PopRivet® (n=5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>304.7  25.8</td>
<td>300.2  18.2</td>
</tr>
<tr>
<td>2</td>
<td>148.1  45.4</td>
<td>147.7  34.3</td>
</tr>
<tr>
<td>4</td>
<td>8.5   6.7</td>
<td>158.4  52.9*</td>
</tr>
<tr>
<td>6</td>
<td>NA+</td>
<td>85.9  8.9</td>
</tr>
<tr>
<td>8</td>
<td>0.89  1.33</td>
<td>62.3  48.9*</td>
</tr>
<tr>
<td>12</td>
<td>NA+</td>
<td>10.7  4.0</td>
</tr>
</tbody>
</table>
Results

in vitro

Uniaxial Pullout Failure Load (N)

Suretac®

PopRivet®

Time (weeks)
Results

in vivo

• No complications
• All wounds healed normally, no infections
• Minimal lameness observed with rapid return to normal function (within 1 week)
• No evidence of joint instability
• Clinical examinations all normal
Results

in vivo

• Biomechanical testing
  – All ligaments failed at insertion sites
  – By 6 weeks, repairs with either fixator failed at greater than 550 N compared with controls at 411 N
  – By 52-72 weeks, failure loads at 800-1000 N
• No significant differences in failure loads for either fixator (p=0.326)
## Results

*in vivo*

<table>
<thead>
<tr>
<th>Time (Weeks)</th>
<th>Mean Failure Load (N) S.D.</th>
<th>Failure Site</th>
<th>Mean Failure Load (N) S.D.</th>
<th>Failure Site</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>106.3 20.5</td>
<td>0 femora, 3 tibiae</td>
<td>107.6 16.0</td>
<td>0 femora, 3 tibiae</td>
</tr>
<tr>
<td>3</td>
<td>536.9 18.7</td>
<td>2 femora, 1 tibia</td>
<td>346.1 166.8</td>
<td>2 femora, 1 tibia</td>
</tr>
<tr>
<td>6</td>
<td>576.9 225.1</td>
<td>2 femora, 1 tibia*</td>
<td>554.7 131.7</td>
<td>2 femora, 1 tibia</td>
</tr>
<tr>
<td>12</td>
<td>626.0 85.9</td>
<td>1 femur, 1 tibia, 1 NA</td>
<td>663.2 126.3</td>
<td>2 femora, 1 tibia</td>
</tr>
<tr>
<td>52</td>
<td>818.9 78.3</td>
<td>0 femora, 3 tibiae</td>
<td>919.4 48.9</td>
<td>0 femora, 3 tibiae</td>
</tr>
<tr>
<td>72</td>
<td>1023.0 149.9</td>
<td>1 femur, 2 tibiae</td>
<td>872.3 163.2</td>
<td>1 femur, 2 tibiae</td>
</tr>
<tr>
<td>Unoperated Controls</td>
<td>411.0 37.8</td>
<td>2 femora, 2 tibiae</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Device’s head popped off.

N = Newtons, S.D. = Standard Deviation.
Results (in vivo)

- **Suretac**
- **PopRivet**
Results

in vivo

• Histology
  – Both fixators intact at three weeks
  – Periosteal and endosteal woven bone formation
    • normal healing around implants
  – Fibrous encapsulation of fixator heads
  – Minimal evidence of inflammation
  – No histological evidence of material from either fixator by 52 weeks
  – All MCLs had healed and new bone replaced implants
Results

*in vivo*

Suretac

Pop Rivet

52 weeks
Discussion

• *In vitro* and *in vivo* comparison of two soft tissue fixators made of different bioabsorbable copolymers
  – PGA/PLLA copolymer retained pull-out strength longer *in vitro* than the PGA/trimethylene carbonate copolymer
  – *In vitro* strength retention of the PGA/PLLA device still somewhat less at eight weeks than previously published (Suganuma and Alexander, 1993; Pietrzak et al., 1997)
Discussion

- PGA/trimethylene carbonate and PGA/PLLA devices appear to be equivalent in vivo despite differences in their in vitro degradation profiles
  - Internal controls - both devices were used in each animal
  - Immediate cyclic loading since animals were allowed to bear weight after surgery
Discussion

• Both devices appear to provide adequate fixation to allow complete healing
  – Initial failures at tibial side
    • 25% of strength noted in control animals
  – As soft tissues healed, failure occurred equally between tibial and femoral insertion sites as early as three weeks
  – Surpassed native shear strength by six weeks
Discussion

Histology

• Progressive degradation from time zero to 12 weeks
  – No evidence of necrosis or avascularity of soft tissue under the heads of the devices
  – No evidence of sterile abscesses or significant inflammatory response
  – No histologic evidence of residual implant material at 52 weeks
Conclusion

• Both devices provided adequate fixation of the goat MCL to allow immediate, unrestricted weight bearing without jeopardizing soft tissue healing

• Reasonable alternatives to non-degradable implants for soft tissue-bone fixation
Thank You!