



Shoulder Repair Roundtable

Ronald Glousman, M.D., Vivek Agrawal, M.D., Timothy E. Kremchek, M.D.
Biomet Sports Medicine

Recently, three surgeons were asked about current issues in shoulder repair and their views on the JuggerKnot™ Soft Anchor, an innovative new anchor from Biomet Sports Medicine. Ronald Glousman, M.D. of the Kerlan-Jobe Orthopaedic Clinic in Los Angeles, California, specializes in sports medicine, shoulder, elbow and knee procedures. Vivek Agrawal, M.D. is director of The Shoulder Center in Zionsville, Indiana, which specializes in providing advanced care for shoulder problems. Timothy E. Kremchek, M.D. of Beacon Orthopaedics & Sports Medicine in Cincinnati, Ohio serves as the Cincinnati Reds Medical Director and Chief Orthopaedic Physician.

Q. What are some of the issues with suture anchors in labral repair?

Ronald Glousman, M.D.: The issues that anchors pose to surgeons are the following: obviously the space that they occupy, and the geometry that they occupy at the time of surgery. A bigger size limits the number of anchors you can put in a given space via the glenoid rim or the footprint of the humerus, so there's a space issue. Obviously, the smaller the anchor, the more anchors that can be safely put in without doing one of two things: either colliding with each other where you would need fixation or perhaps fracturing the bone by having too many within a small area of geometry, or protruding out of the bone if you have them too close to the edge. So all of those things can be alleviated by having a smaller drill hole and a smaller anchor.

Vivek Agrawal, M.D.: There are two major concerns in this area. Placing anchors at angles that cross each other or in close proximity may weaken the fixation of the anchor or damage the anchor itself compromising its strength in bone or its strength in holding suture; the other concern is with converging tunnels of sufficient size, the potential for propagation of a fracture is increased.

Timothy Kremchek, M.D.: One of the things you also worry about with anchors is too many of them getting close together, running into each other, breaking and becoming ineffective. I think when you are talking about screws for the glenoid labrum, you only have so much space and you don't want to burn any bridges, certainly with your suture anchor placement.

Q. What are some of the concerns about suture anchor materials?

Vivek Agrawal, M.D.: While there is a move towards more bone-friendly, resorbable materials incorporating calcium, the potential concern still remains regarding the resorption process and duration as a potential source of weakness. Although more often cited with knotless anchors, the potential for osteolysis/tunnel expansion has been pointed out with resorbable materials. This has partly been responsible for the increase in utilization of apparently biologically-quiet radiolucent permanent materials such as PEEK, which still may leave the potential for fracture propagation and foreign body reaction. Metal anchors have two major drawbacks: imaging limitations (MRI and CT scans with scatter/interference and, for some surgeons, visibility on plain radiographs is a negative) and, as these materials are much harder than cartilage and bone, they may initiate significant chondrolysis/abrasion if prominent.

Ronald Glousman, M.D.: When we talk about material types, the issue with metal is that it's permanent, it is there forever. One worry is that there might be some migration of the device. Usually that happens when they were perhaps not put in correctly or carefully, but nonetheless one worries that there might be damage due to the migration of an anchor. Metal stays around forever and if it happens to migrate, where it becomes proud, it could impinge on the articular surface of the joint and cause other damage.

Frankly the same goes for PLA, because PLA, much as we had hoped it would disappear within a year or so, we're really not finding that. It seems to stay around forever. So PLA can act like and very much create the same problems that metal can. The only disadvantage in comparison, if you suspect a problem with metal, you can naturally take an x-ray and see the progression of it. With PLA, it becomes more difficult. The other problem with PLA is the potential

to induce the formation of a cyst or widening, if you will, of the cavity that it is in. And some problems with osteolysis.

Third, in terms of materials, when we get to the biocomposites, of course, they can migrate and have the same issues as far as damage and impingement. Theoretically, the biocomposites can induce bone formation within the hole and over time have that hole taken back over by bone, and that is obviously a wonderful advantage if that occurs. The jury is still out whether or not that is going to occur predictably in a human being rather than laboratory setting.

Timothy Kremchek, M.D.: If you use metal, you always worry about metal particles being left in the joint and certainly what metal particles can do throughout the entire body. You always look at resorption of bone with the material.

Q. *Studies have shown that double row rotator cuff repairs show better tendon to bone contact. Is this also true in labral repairs?*

Vivek Agrawal, M.D.: One of the goals in a labrum repair is to restore the bumper cushion effect by replacing the labrum at the margin of the articular cartilage. The labrum won't heal to the articular cartilage, so ideally enough points of fixation are achieved to provide uniform compression of the tissue and avoid shear during the critical healing period. Having the ability to provide multiple small points of fixation close together may offer the benefit of a greater number of bony welds, as well as spreading the load of fixation across a greater number of fixation points.

Ronald Glousman, M.D.: There is no question that the more fixation, the more contact pressure you're going to have. What we don't know is the clinical relevance of that. Certainly at times in the laboratory, if you have more fixation points, you have more contact of the tissue to that area of bone. The more fixation points, the stronger the repair is—that's just basic biomechanics. The tradeoffs are more anchors in terms of space issues, the time, the cost of implants. The clinical studies so far are controversial in the literature. Clinical studies are not proving that double row necessarily yielded better results clinically than single row, but there's no question the fixation strength is greater.

Timothy Kremchek, M.D.: I think when you are going to repair the labrum, multiple points of fixation may be a better footprint for the labral repair—very similar to the surface area repair that you get in the double row rotator cuff, which is what I do.

Q. *Recent journal articles show an increasing concern of glenoid fractures and bone loss. What concerns does this present for a shoulder reconstructive surgery and current suture anchor technologies?*

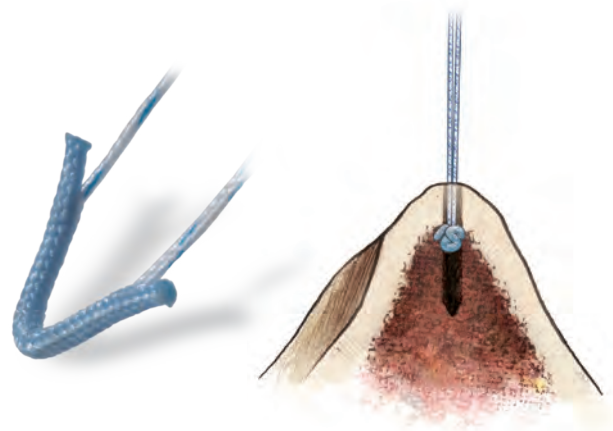
Vivek Agrawal, M.D.: We discussed this with the question regarding resorbable implants, however, the size of the bone

voids created with anchor placement, the configuration of these tunnels as well as the material placed in these tunnels, along with the quality of the overall fixation to address the pathology, all may play a role in the potential for ongoing bone loss/glenoid fracture. For instance, inadequate fixation for instability, leaving the shoulder unstable, can potentially place undue stress on the points of fixation creating micromotion, resorption and potential bone loss, etc. On the other hand, multiple large anchors with multiple bone tunnels may create the potential for fracture propagation with the appropriately directed injury.

Ronald Glousman, M.D.: As we try to add fixation, and add fixation points with multiple anchors—especially in a smaller area of bone such as the glenoid, and especially given the forces put on the rim of the glenoid, each drill hole creates a stress riser within the glenoid. The larger the drill hole and the more drill holes that occur, the greater number of stress risers that occur. Stress is placed on that glenoid rim, which is where we want to put our anchors; the greater the chance of developing a later fracture. It could occur just with overuse, in a heavyweight lifter or someone who just has repetitive stress applied to a shoulder. It could happen with a throwing athlete.

Timothy Kremchek, M.D.: Certainly, glenoid fracture and bone loss are a concern, especially with resorption around anchors. I think the bigger anchors you use, the greater chance you have for fracture. Certainly with the JuggerKnot Anchor, this is a smaller hole, and these concerns are much less. (See Exhibit 1.)

Exhibit 1: JuggerKnot Soft Anchor (Biomet Sports Medicine)



Q. *The JuggerKnot Soft Anchor was recently introduced at the AAOS meeting. What has been your experience with this anchor?*

Vivek Agrawal, M.D.: Over the past six months, we have utilized several hundred of the JuggerKnot anchors for a variety of shoulder conditions. Instability/labrum repair has been the major indication (1.4mm drill hole with

a suture only anchor has allowed us to place multiple anchors very closely, ~5mm, to create uniform compression of the repaired labrum/bumper cushion circumferentially). (See Exhibit 2.) Articular sided rotator cuff tears allow percutaneous placement of the anchors at the articular margin of the rotator cuff footprint to repair these tears with minimal trauma to surrounding tissue. We have also placed these anchors at the articular margin to function as the medial row sutures for our transosseous equivalent dual row rotator cuff repairs and arthroscopic acellular dermal graft augmentation cases for rotator cuff repair.

We have not had any clinical failures or complications with the device and have been very pleased with our early clinical outcomes.

Exhibit 2: JuggerKnot 1.4mm drill hole.



Ronald Glousman, M.D.: Overall, excellent experience with the JuggerKnot Anchor, from myself and from other surgeons I have spoken to. Excellent fixation of the implant, a low profile knot, ease of use, ease of insertion and adaptability to be able to put in multiple anchors anywhere one may need it in the glenoid.

Timothy Kremchek, M.D.: I have used the JuggerKnot Anchor for the last three months. First of all, it's a nice small hole, it's easy to use, it's reproducible. I don't feel like I'm placing a giant device into a small area, so I am very comfortable putting multiple holes in to increase my surface area and feel more secure about my repair. So far, the outcomes have been excellent. I have been able to do aggressive physical therapy, range of motion, without a significant concern of re-tearing or re-injury.

Q. *The JuggerKnot Soft Anchor is implanted into a 1.4mm hole. Why is the size of the implant hole important for soft tissue repairs?*

Vivek Agrawal, M.D.: It conserves bone, increases the tissue-to-bone interface, allows multiple points of fixation while still reducing the overall amount of bone loss/void from drilling and placing anchors.

Ronald Glousman, M.D.: The smaller the hole, the greater surface area will be in contact with the bone rather than just an implant hole. So in that same surface area, if you have three holes that are each 3mm vs. three holes that are each 1.4mm, there is going to be a greater surface area contact to the tissue that is being repaired with the smaller hole. There is less bone that is being taken away.

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Timothy Kremchek, M.D.: I think the smaller the hole, the more you are able to conserve the bone, the more you are able to place multiple anchors without concern of hitting the other anchors or communicating the bone holes, which would weaken the repair. The multiple points of fixation allow you to have that increased surface area and more control over your repair which essentially will go into your rehabilitative process for range-of-motion and security of your repair.

Q. *The JuggerKnot Soft Anchor is a 100% true suture anchor. What advantages does this present for a shoulder reconstructive surgery and other applications?*

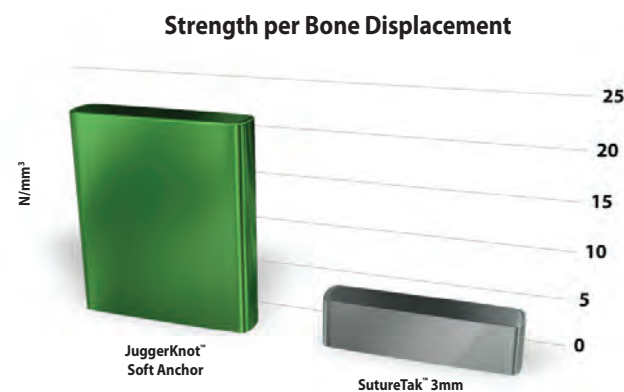
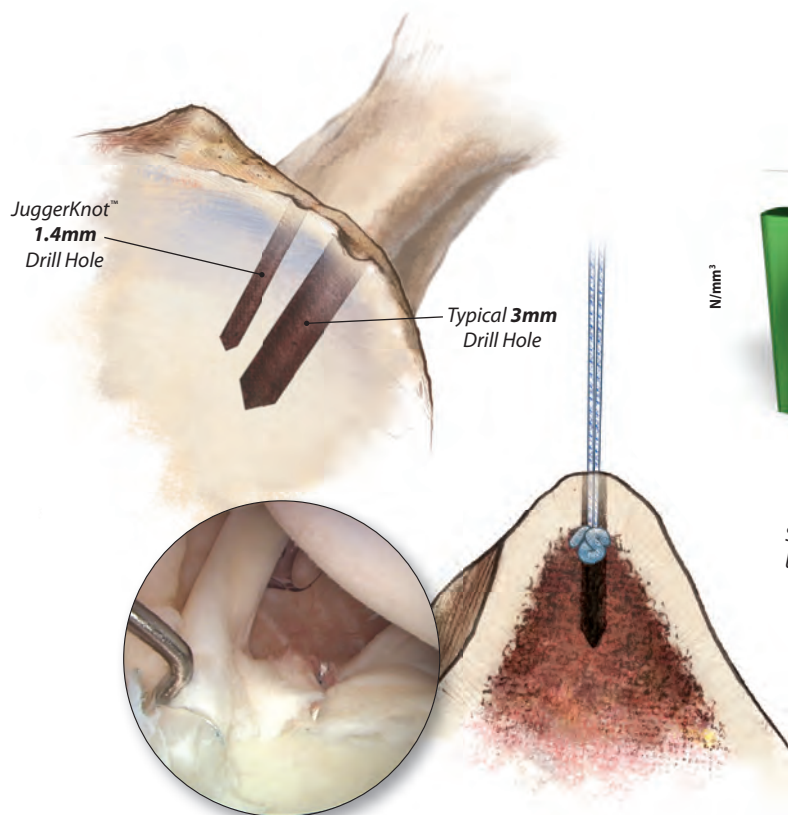
Ronald Glousman, M.D.: In my experience, the suture wedge that's formed by the JuggerKnot implant presents lower risk to the joint were it to migrate or for some reason fall out of place. Suture fixation dates back to the early days of surgery, long before implants were ever developed. It's rare to see complications arise from the use of suture.

Vivek Agrawal, M.D.: Suture has a long clinical history—it eliminates the use of rigid materials. These are significant advantages, along with the hollow suture functioning as a wick/conduit for marrow/pluripotential cells to access the site of repair, potentially providing a biologic benefit in healing. The small size of the bone defect created should also reduce the expected time of bone healing/incorporation.

Timothy Kremchek, M.D.: It does eliminate the rigid materials inside of the shoulder, which I think is important to decrease your post-op complications, which we all see as experienced shoulder surgeons. I think suture has a long history. I am very confident about its incorporation into the bone. Intraoperatively, I have noticed I am very secure with the pullout strength and the techniques that I use to make sure that the suture anchor fixation is strong enough.

It's small. It's strong. And it's all suture.

The 1.4mm JuggerKnot™ Soft Anchor represents the next generation of suture anchor technology. It's suture-based and the first of its kind.



Strength achieved by suture anchors with respect to the bone disruption.¹

- **1.4mm**—smaller implant allows more tissue-to-bone contact
- **Smaller cannula** is less invasive to surrounding tissue
- **Smaller anchor diameter** allows multiple anchors to be placed
- **69% less bone** removed as compared to a standard 3mm anchor¹
- Reduces likelihood of drilling into other anchors when placing multiple anchors



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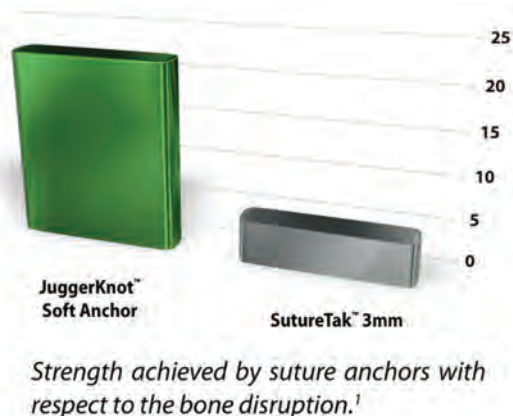
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Q. With the JuggerKnot Soft Anchor being 100% suture, and utilizing such a small hole, do you have any concerns with anchor pull out?

Ronald Glousman, M.D.: I do not. I have had the opportunity to use this anchor in surgery, and after reviewing the data that's been submitted thus far, fixation strength appears to be above what is necessary to hold fixation in the healing process. (See Exhibit 3.)

Exhibit 3: Strength per Bone Displacement.



Vivek Agrawal, M.D.: The strength of fixation of the anchor places the likely site of failure at the suture itself, reducing concerns about bone loss, fracture, etc.

Timothy Kremchek, M.D.: Initially when you put the JuggerKnot in, you do have a concern, “My goodness, is this going to hold?” But the techniques I use for the JuggerKnot Anchor have been the same that I have used for the last 15 years. Of all the devices I have used in the shoulder, I have been able to replicate that same technique with the JuggerKnot and have had no pull out issues. I never leave an operating room after repairing a labrum without doing this, and every time I have used the JuggerKnot Anchor it has not been a problem. No matter if it is a SLAP, or anterior, posterior labrum. (See Exhibit 4.)

Exhibit 4: Intraoperative image of SLAP repair with the JuggerKnot Soft Anchor (Ronald Glousman, M.D.)



Q. How does the JuggerKnot Soft Anchor address concerns of bone loss, glenoid fracture and tendon-to-bone contact?

Vivek Agrawal, M.D.: No biologic resorption process, rather just healing of a small 1.4mm bone tunnel. Transosseous sutures have a long history of healing in orthopaedics.

Timothy Kremchek, M.D.: I think the small holes reduce bone removal. I don't need to do as much as the preparation as I would with the other anchors. It certainly takes up less space. And with less space, I feel comfortable placing one or two more anchors to gain that increased surface area and the security of the repair.

Q. How is the JuggerKnot Soft Anchor advantageous to patients?

Vivek Agrawal, M.D.: By allowing the anchors to be placed in closer proximity, the stress on the repaired tissue is reduced, potentially improving rates of successful bony healing.

Ronald Glousman, M.D.: Reduced potential for complications that are inherent to metal and PLA anchors while providing the same fixation—that's one advantage. Second, the increased ability to provide fixation in geometrical areas of the glenoid that might have been difficult to access with a larger anchor. So in summary, improved fixation and reduced complications.

“The techniques I use for the JuggerKnot Anchor have been the same that I have used for the last 15 years. Of all the devices I have used in the shoulder, I have been able to replicate that same technique with the JuggerKnot and have had no pull out issues.”

Timothy Kremchek, M.D.: From my clinical observation, it's strong. It's easy to insert. It's all suture. So, I don't have any concerns about metal fragmentation which may interfere with the joint itself. And that is a major concern with a metal anchors that surgeons use and that I *used* to use.

References

1. Barber FA, Herbert MA, Beavis RC, Oro FB. “Suture Anchor Materials, Eyelets, and Designs.” *Arthroscopy* 2008;24:859-67.
2. Data on file at Biomet Sports Medicine, Inc. Bench test results are not necessarily indicative of clinical results.

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Interested parties may contact Biomet Sports Medicine at robin.brown@biomet.com for more information.

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