CHAPTER 50

SOFT TISSUE ANCHORS: An Update

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The ever-expanding market of internal fixation devices continues to develop. Not to be left behind, the soft tissue anchor market is keeping pace with the growing industry, and has introduced many new products to an already competitive market. Orthopedic and podiatric applications continue to expand and utilization is increasing even in the face of managed care in many areas of the country.

In a discussion of improvements in internal fixation devices, consideration of several parameters must be evaluated. What are the benefits of this new device? Is it user-friendly in the operating room? Will it save operating room time? How does the overall stability compare to previous techniques?

In the author's experience, soft tissue anchoring systems are a time-efficient alternative to traditional techniques of tissue reattachment. They afford a user-friendly option which provides stability equal to or greater than suture, staple, or screw techniques. In order to use them more efficiently, the surgeon must be acquainted with the characteristics of each system.

NEW DEVICES UPDATE

The newer devices entering the market will be discussed in an effort to update and educate our profession to the advances in this area.

Ogden

Ogden was introduced to the market in 1994. The design is a manually driven "screw" type anchoring system. There is a flat platform below the tip of the anchor which functions to hold a knot placed into the suture (Figs. 1A, 1B). The remaining strands of the suture are pulled through the anchor, and exit the base of the anchor. Needles are then threaded onto the suture strands for re-attachment.

There are currently 5 anchor sizes, ranging from 2.5 mm to 7.4 mm (Fig. 2). The drill bits for these sizes range from 2.1 mm to 4.5 mm. Most podiatric applications require the 2.5 mm and 3.5 mm anchors. Although the three largest sizes may

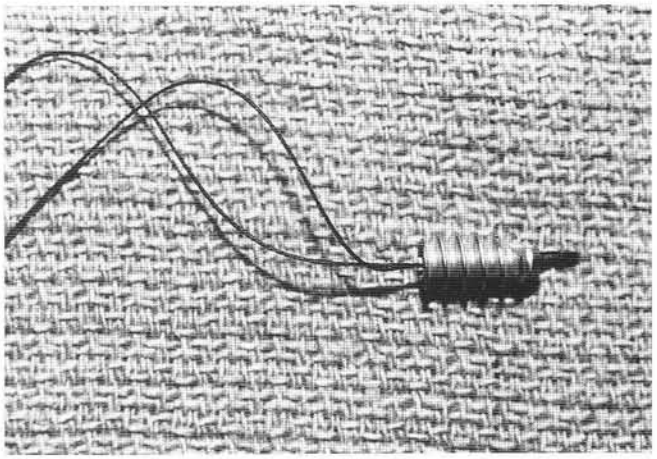

Figure 1A. An Ogden anchor with a knotted suture being pulled from the tip to the base. The knot will seat onto a platform with a central hole just underneath the tip of the anchor, thereby preventing the suture from slipping.

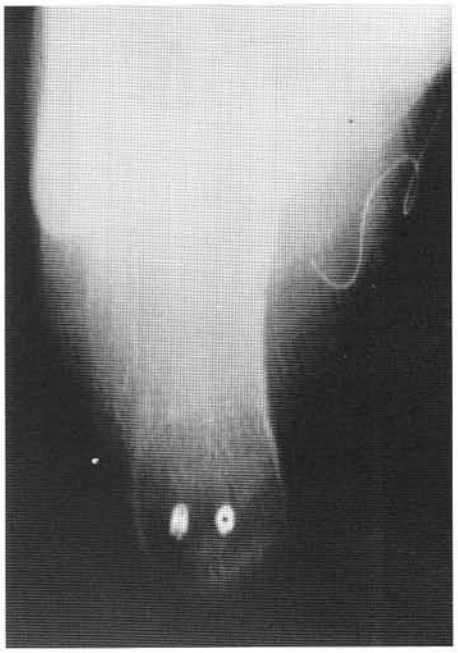

Figure 1B. Radiograph of two Ogden anchors in the posterior calcaneus after re-attachment of the Achilles tendon.

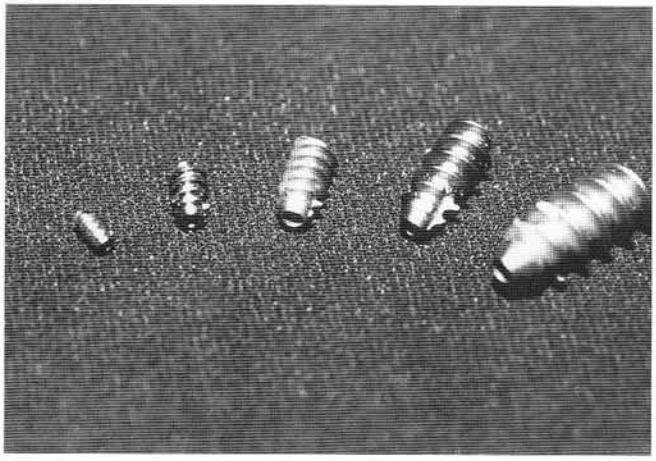

Figure 2. The five sizes of the Ogden anchor.

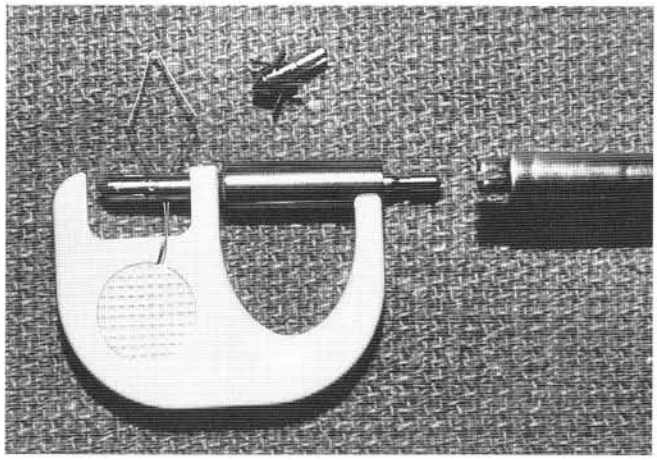

Figure 3. The UltraFix anchor (deployed) with the cartridge (non-deployed) and the tip of the inserter.

theoretically be used in the calcaneus, the other sizes are probably sufficient.

One unique property of the anchor involves the ability to thread more than one suture through the eyelet for augmentation of the attachment technique. This is dependent on both the size of the anchor, and the suture selected. The number of sutures however, must be decided upon prior to threading the first suture through the anchor. Once one suture is locked in place on the anchor platform, no other suture strands can be placed in the same anchor. In the 2.5 mm and 3.5 mm anchors, multiple sutures are available if one chooses 2-0 and 3-0 sutures for reattachment, respectively. The author would not recommended 3-0 suture for reattachment of soft tissue proximal to Lisfranc's joint.

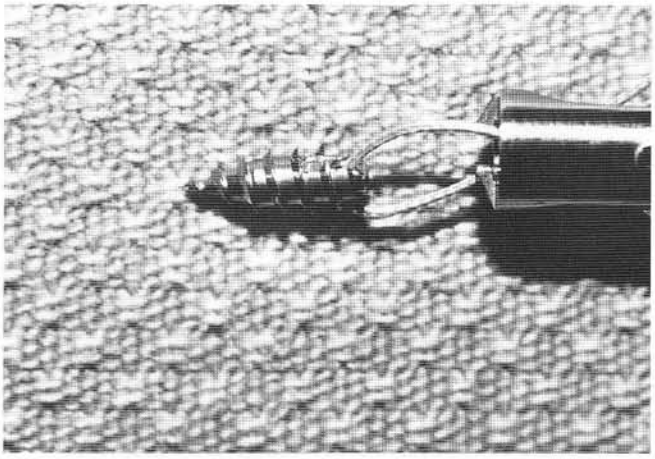

Figure 4. Example of the Wright Medical "Anchorlok" device. Note the countersink which is built into the tip of the inserter to help smooth the edges of bone.

Ultra-Fix

This anchor was first introduced to the market in 1995. The system comes with a ergonomic inserter and the suture anchor, which comes with its own loading cartridge (Fig. 3). The design is unique in which barbs are deployed in both directions, which is an anti-migration, self-centering design. This anchor also gives the surgeon the ability to evaluate placement prior to actually deploying the anchor. The pre-deployed anchor and inserter can be fully inserted into the drill hole, and removed if placement is not satisfactory. The drill hole is 2.9 mm in diameter and 14.0 mm in depth. Once deployed, there are 8 barbs, 4 in each direction, and this expands to approximately 4.5 mm. The deployed anchor resembles two Mitek Superanchors placed back to back. The design will prevent migration of the anchor in any direction, yet this has never been a real concern with any of the anchors.

Wright Medical

The design of the "Anchorlok" is one of a screw-type device. This is a hand-driven anchor with the sutures and needles attached under a plastic sleeve. The anchor is made of titanium alloy and comes in four sizes 1.9 mm, 2.5 mm, 3.5 mm, and 5.0 mm. This device is very similar to the designs of the Statak and Fasten anchors, with two unique differences. The tip is very sharp to allow for easy penetration through even cortical bone without additional instrumentation (Fig. 4). Also, the base of the inserter is beveled to provide a wider counter-sink to the cortical surface of the bone.

This prevents a potential sharp edge from damaging the suture, while tightening down the soft tissue.

Bionix

Similar to the Absorbable PLLA Screws, Bionix has produced an absorbable anchor. This is currently marketed as the "SmartTack," and the primary indication is for ruptures of the ulnar collateral ligament in the thumb. The design is essentially one of a thumbtack, with a smooth head and shaft. The tack is placed through the soft tissue and then press-fit into a drill hole, eliminating the need for suture or needles. The dimensions are 1.1 mm in diameter and 15 mm in length. This size can be adapted to virtually any area in the foot.

Mitek

Mitek continues to dominate the field of soft tissue anchoring. In 1994, Mitek was purchased by Johnson and Johnson, yet still managed to maintain its own product identity and quality. This company has devoted their entire efforts to anchoring, and several years ago controlled roughly 70% of the market. Because the company has designed many anchors for different applications in the body, only the orthopedic anchors will be discussed. Their G-II products have been the standard with three anchors available: The Mini G-II (1.8 mm), G-II (2.4 mm), and the Superanchor (2.9 mm). In October 1996, a 1.3 mm (mini Mini-GII) will also be on the market. This anchor is designed primarily for the phalanges of the hand, yet can be utilized for the phalanges of the foot, as well.

Mitek has now introduced the "Fasten," a line of "screw" anchors almost identical to the Statak line. This has been possible due to their purchase of the Zimmer Statak products. These are also self-drilling and self-tapping with a sharp tip for easy penetration (Fig. 5). The company feels the screw-type anchor may perform better in cancellous bone, where purchase of the barbed design may be compromised without the cortical support. The sizes available are 2.0 mm (Tacit), 3.0 mm, 4.0 mm, and 5.2 mm. A removal product for the Fasten anchors is also available in this new line. This is the "Fastout" device which will fit into the drill hole and subsequently the base of the anchor. As the anchor is removed, it is drawn into the sleeve of the Fastout device.

New to Mitek's collection is a bio-absorbable anchor, the "Stealth." This is a 2.9 mm anchor, with a body made of Poly-lactic Acid (PLA) and their patented "nitinol" barb (Fig. 6). The PLA boasts strength retention for 6 to 8 weeks prior to weakening through hydrolysis. This should be an adequate time frame for secure tenodesis to occur. The author believes the PLA will retain its strength even longer, based on European studies on strength retention in the PLA screws.

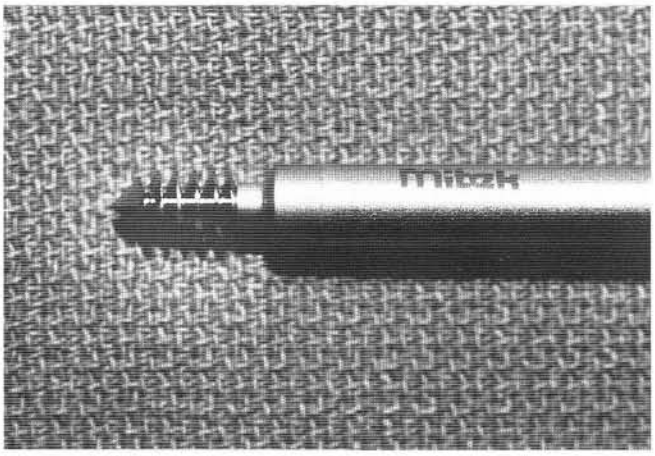

Figure 5. Example of the "Fasten" screw-type anchor on its metal sleeve. The tip is sharp for easier penetration, with deep threads for increased holding power.

Figure 6. The Stealth design of incorporating a PLLA absorbable body with the nitinol barbs. The body of the anchor should maintain its strength for at least 8 to 10 weeks prior to any significant weakening.

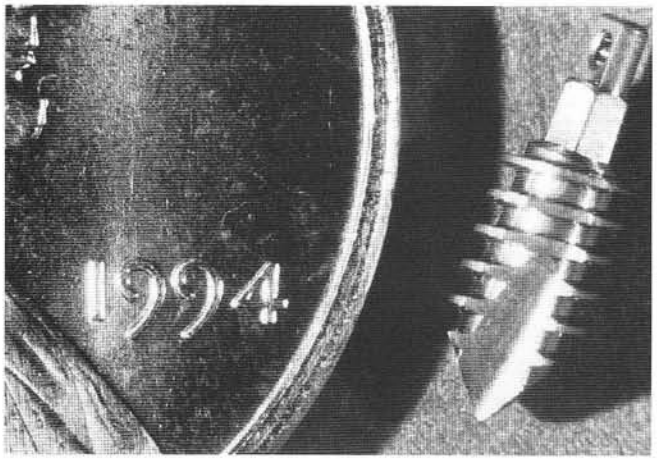

Figure 7. The newer generation Statak anchors. Note the deeper threads and sharper tip as compared to the older design.

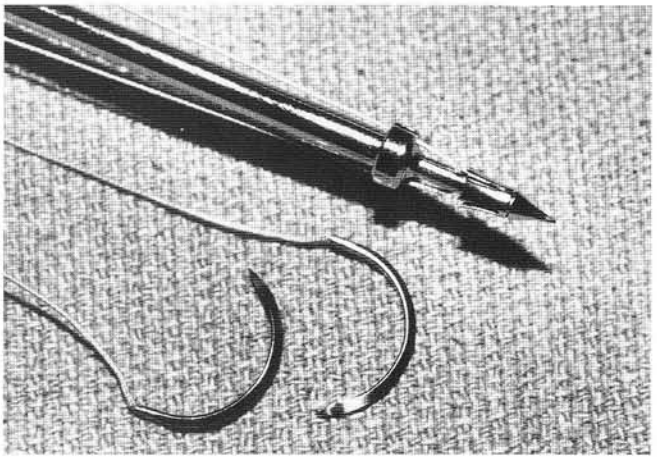

Figure 8A. The Arthrotek "Harpoon" with the suture and needles attached for convenience. This device is made of stainless steel.

Statak

Several years ago, Zimmer modified their design to produce an anchor which possessed a sharper tip and deeper threads (Fig. 7). The anchors are made of titanium and are available in four sizes 2.5 mm, 3.5 mm, 5.0 mm, and 5.2 mm. The one-step drill application is still the same. Now this product line has been purchased by Johnson and Johnson (Mitek) and the future of these products is unknown.

Arthrotek

Arthrotek is a stainless steel anchor known as the "Harpoon" which appears to mimic the Mitek Superanchor design. There are two sizes which are both compatible with podiatric applications 2.1 mm and 3.2 mm. There are four flat barbs connected to a central body with a sharp tip for easy penetration into the bone. The tip can be secured with gentle tapping from a mallet (Figs. 8A, 8B). The barbs are designed to prevent pull-out once they are introduced into the bone, yet do not possess as wide of an open diameter as the Mitek counterpart. The Arthrotek "Harpoon" has the suture and needles attached under a protected plastic sleeve.

Figure 8B. Seating of the Arthrotek "Harpoon" tip.

PeBA

The PeBA (Permanent Bone Anchor) is the anchor from Orthopedic Biosystems, Ltd. There are currently two designs on the market: the PeBA and PeBA "C." Both anchors are made of titanium and sit slightly recessed on the surface of the bone with an eyelet exposed for threading of the suture. This allows multiple passes of suture through the eyelet, as well as easy access in case any strands of suture may break. The PeBA is a press-fit design into a drill hole and the PeBA "C" is a double-helical screw design for increased holding ability in the cancellous bone.

The PeBA is currently available in two sizes, 2.1 mm and 4.0 mm (Fig. 9). Due to the press-fit design, the drill holes are 1.9 mm and 3.2 mm respectively. The PeBA "C" is available in two sizes, 4.0 mm and 6.5 mm. The double helix screw configuration is a clever design, which provides

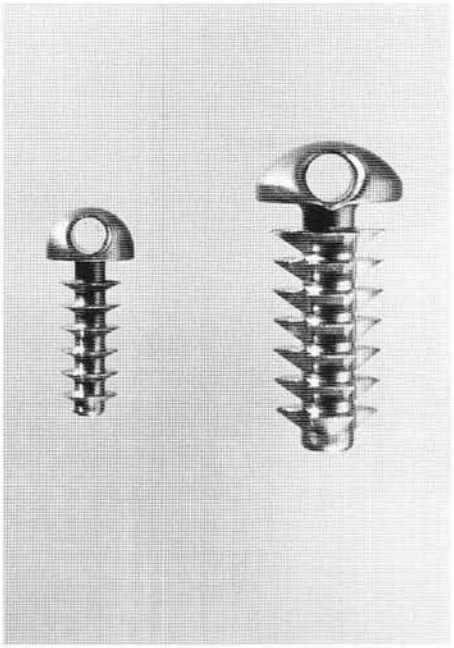

Figure 9. Example of the two sizes of the PeBA anchor device. This is the press-fit design which seats the head of the anchor just on top of the surrounding bone. The eyelet sits above the bone and therefore allows easier passage of several needles and sutures if the surgeon desires.

two separate diameters of screw threads for increased holding power. Both anchors possess a large eyelet on the surface of the bone to accommodate 2 to 3 sutures comfortably, and also allow easier removal if necessary.

DISCUSSION

The newer devices presently on the market seem to emphasize two main factors, the ability to thread two or more sutures on each anchor, and the ease of anchor removal after placement. The first point is probably more practical due to the fact that about half of the devices are packaged individually, without any suture attached. This allows the surgeon to select the desired suture. Depending on the size of the anchor and the eyelet, it is possible to place several strands of suture into the anchor for greater versatility. This can currently be achieved with the Mitek, PeBA, Ogden, and Ultrafix devices.

The removal of the anchor has always been a topic of discussion. Primarily the screw-type devices are much easier to remove than the barbed devices. If removal is necessary, the suture and soft tissues are first cleared away from the drill hole. The inserter or similar instrument can then be placed onto the base of the anchor and used to back the anchors out if necessary. This will work well if no bone has grown over the drill hole. It is necessary to trephine away any osseous overgrowth that has occurred so the inserter can fit into the hole again. With the barbed designs, it is helpful to look at preoperative radiographs prior to the actual removal of the device. This will allow one to appreciate the direction of the barbs, and minimize the potential use of a larger trephine to remove the anchor.

The method of tying the sutures for re-attachment should also be discussed. Usually non-absorbable sutures are utilized for tissue re-attachment. In the area of the posterior calcaneus, the author prefers to place the knot deep to the tendon. This will minimize any irritation of a superficial knot with the posterior heel counter of the shoe, secondary to a thin subcutaneous tissue layer. One method to achieve this is to pass the suture from deep to superficial through the tendon and then pass the suture back deep to the tendon. This can be performed with one or both of the suture ends. The assistant can securely hold the tendon against the bone as the surgeon ties the knot tightly. In other areas of reattachment, where subcutaneous tissue coverage is much thicker (eg. the plantar-medial navicular), the author prefers to attach the soft tissue directly onto the bone with a superficial knot. Any time soft tissues are attached down to bone, it is recommended to roughen up the tendon at the potential point of attachment so there is a greater chance of a successful tenodesis.