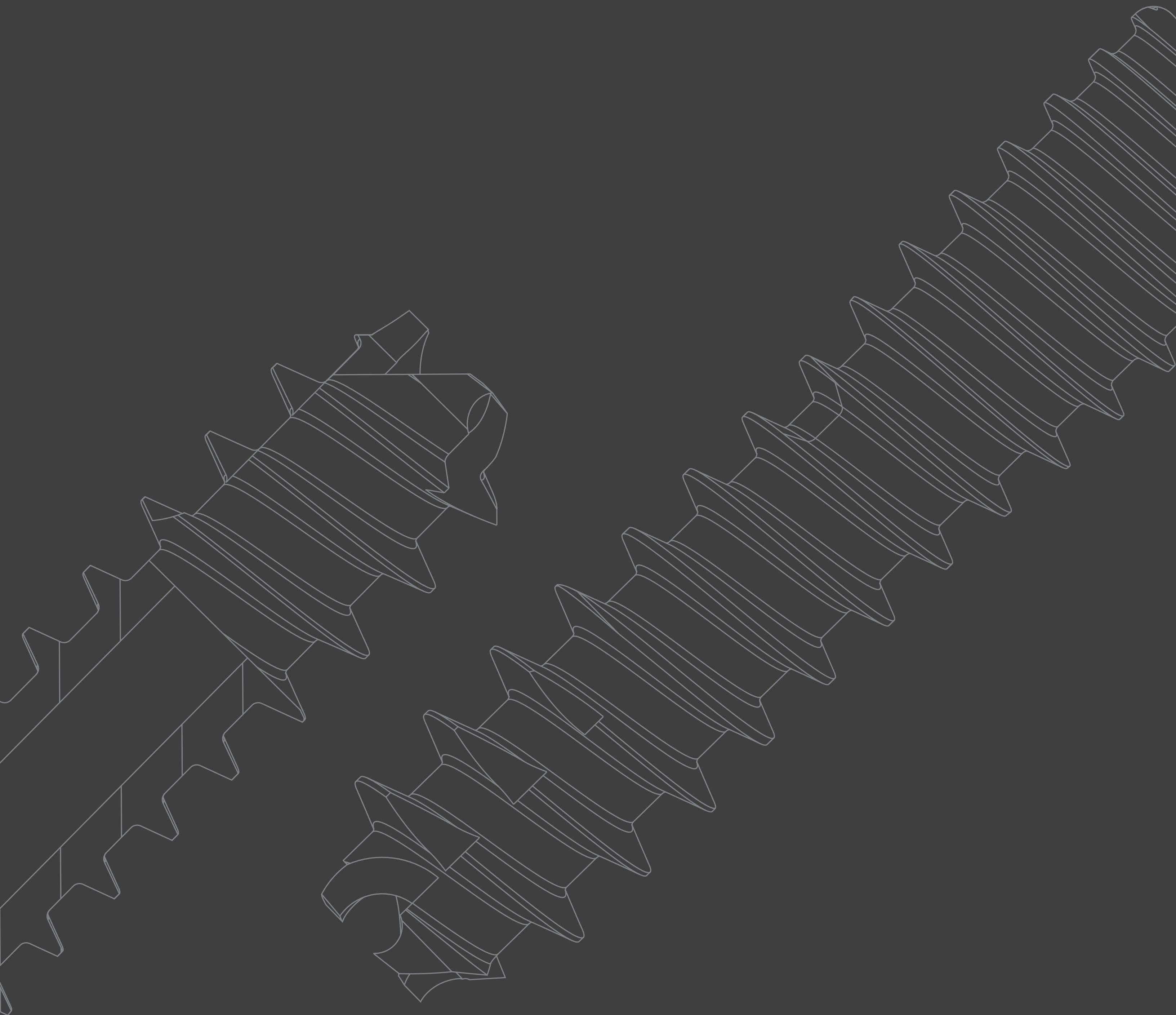
ACUMED®

THE ACUTRAK® FAMILY



A Heritage of Healing

Acutrak® Technology

for Headless Compression Screws

Introduction to Acutrak® Technology for Headless Compression Screws

Acumed® is a global leader of innovative orthopaedic and medical solutions.

We are dedicated to developing products, service methods and approaches that improve patient care.

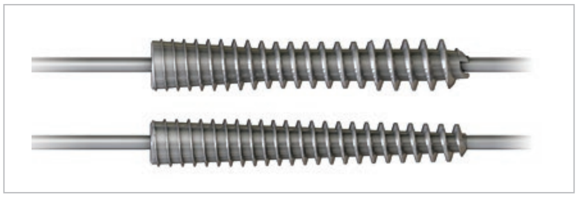


Figure 1: Acutrak® & Acutrak 2® Screws

Acumed® developed the Acutrak® screw technology to provide a headless compression-holding solution to fix fractures using the first fully threaded bone screw with a continuously variable thread pitch along the entire length of the screw.

This white paper will discuss:

- the design rationale behind Acutrak® technology
- the differences between the first and second generation implementations of this technology (Acutrak® and Acutrak 2® respectively)
- examples of indications where each generation has application advantages

This white paper concludes with a comprehensive bibliography of published articles relating to Acutrak® technology biomechanics and clinical results.

Contents

Design Rationale

1. Minimal soft tissue irritation through Headless Fixation
2. Enhanced fracture fixation through a Fully Threaded Construct
3. Enhance window of compression through a Continuously Variable Screw Pitch
4. Versatility using a Cancellous-Based Thread Design

Incorporating the benefits and features above, Acumed® created a new category of bone screw fixation that goes beyond headed and differential pitch screw options by offering surgeons enhanced biomechanical performance in multiple clinical applications.

Fundamental Design Features: (See in Figure 2)

Acutrak® design features include a unique, patented thread pitch that varies continuously from tip to tail. This ensures each screw rotation engages threads into new bone along the screw's entire length. As each successive individual thread advances faster than the trailing thread counterpart, the conical shape becomes seated into bone. This radial expansion of the screw threads, combined with their axial advancement, creates the ability to reduce & compress bone fragments without a traditional screw head.

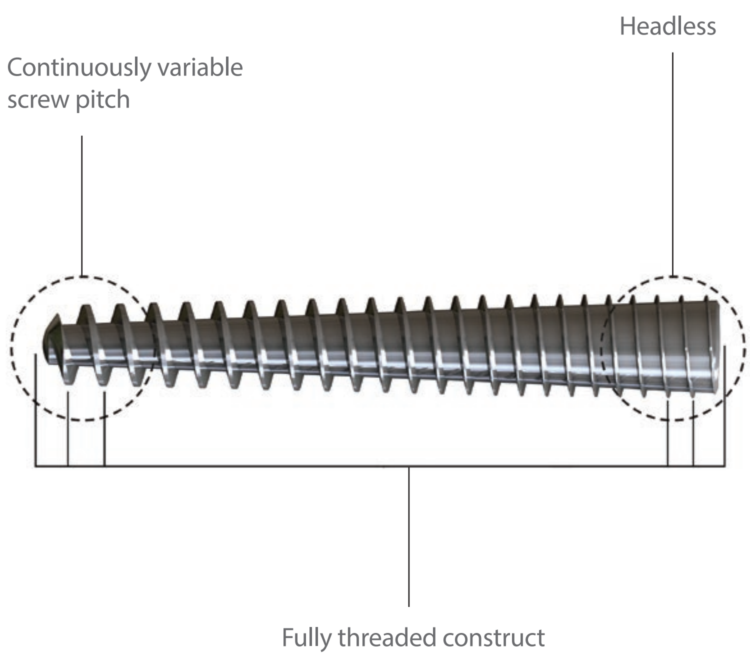


Figure 2: The three fundamental characteristics of Acutrak® technology

Crossing the Fracture Site

Conventional wisdom is that threads cannot cross the fracture site and create compression. Acutrak® technology changed conventional orthopaedic wisdom by creating and maintaining compression as the screw threads travel across the fracture site. The Acutrak® screw's continuously variable screw pitch overcame the inherent limitations of the constant pitch and differential pitch found in more traditional bone screws; these traditional approaches and technologies cannot create compression at the fracture site because the screw threads advance at the same rate within their threaded regions. Compression using these devices had to be created prior to screw installation (pre-compression) or through sacrificing thread purchase somewhere along the length of the bone screw. Acutrak® screw technology eliminates this compromise by utilizing continuously variable screw pitch. By allowing each thread along the entire length of the screw to aid in the reduction and compression, the thread location relative to the fracture site no longer became a limitation.

Figure 3: Acutrak® Technology passes threads across a fracture site & creates compression

Acutrak® Technology's Larger "Window of Compression"

All bone screw technologies have a "window of compression" that determines the number of screw rotations needed to reach a maximum compressive force (beyond which further rotations decrease this value). Traditional bone screws have a narrow window of compression. This narrow window characterizes a fixation construct that becomes very sensitive to loss of compression due to over-rotation and the stripping of thread purchase. Acutrak® technology has a wide window of compression, which is less sensitive to stripping the bone and more flexible in its placement for reaching a maximum amount of compression.

Figure 4 below illustrates the window of compression for Acutrak® technology, traditional bone screws (AO) and differential pitch screws (Herbert)

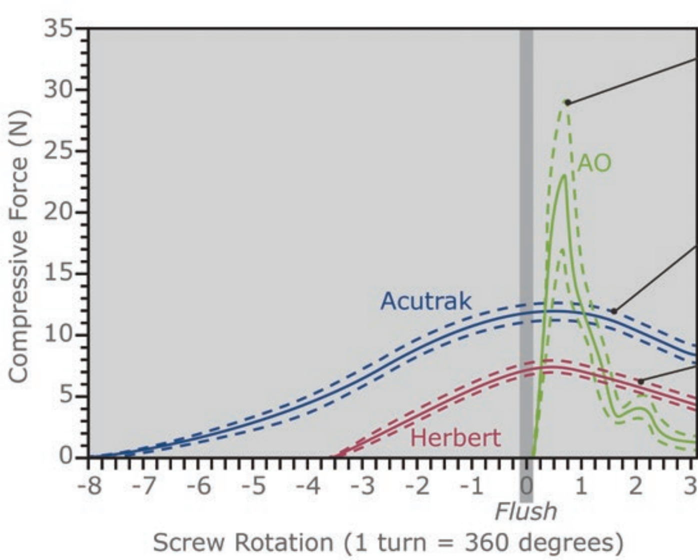


Figure 5: Headed bone screw has the lowest window to reach maximum

Figure 6: Acutrak® screw has the highest window to accomplish maximum compression

Figure 7: Differential pitch falls under both headed and Acutrak® screws in performance

Figure 4: Graph showing the window of screw rotations during which each screw delivers maximum compressive force.

The Acutrak® Screw has the largest window of compression due to the additive property of each variable thread pitch providing compression as a result of being fully threaded.

Introduction to Acutrak® Technology for Headless Compression Screws

Enhanced Fracture Fixation Biomechanics

Pullout strength, resistance to cyclic and torsional loading are the key measureable elements of bone screw fixation performance. Acumed® compared the performance of Acutrak® technology in each of these elements versus traditional (AO) and differential (Herbert) bone screws. A summary of the results is shown in the figures below:

1. Greater Pullout Strength

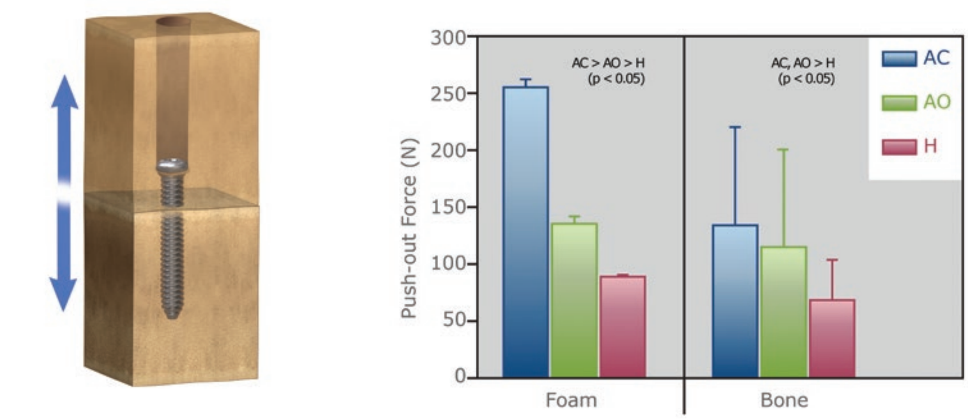


Figure 8: Acutrak® screws have the highest push-out force when compared to AO & Herbert Bone Screws (AC)

2. Greater Resistance to Cyclic Loading

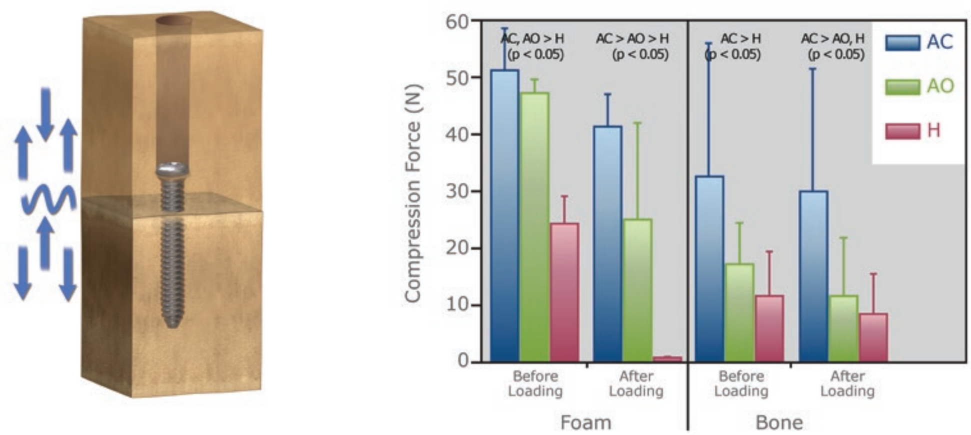


Figure 9: Acutrak® screws have the highest amount of retained compression after cyclic loading when compared to AO & Herbert Bone Screws (AC)

3. Greater Resistance to Torsional Loading

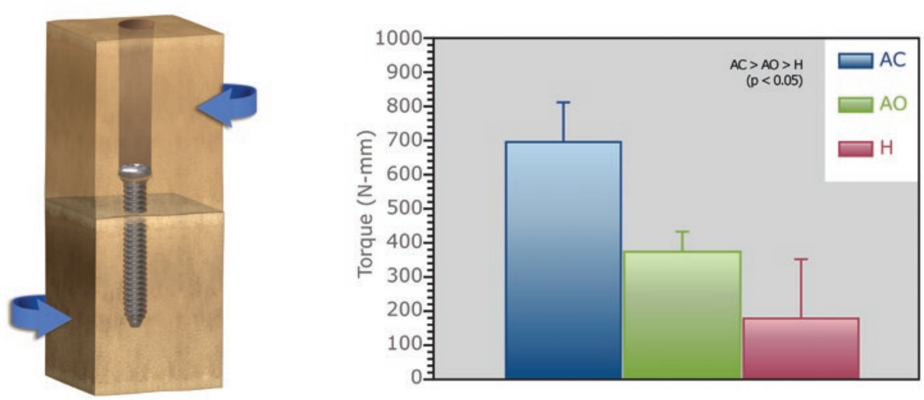


Figure 10: Acutrak® Screws have the highest resistance to torsional loading when compared to AO & Herbert Bone Screws (AC)

Acutrak 2® Screws (Second Generation Acutrak® Technology)

The original Acutrak® screw families have a long history of success and are used in a wide variety of orthopaedic indications ranging from the tip of the finger to the tip of the toes. In 2005, Acumed® released a second generation of Acutrak® technology in the form of the Acutrak 2® screw families. This second generation of Acutrak® technology was based on the experience gained from the first generation of Acutrak® screw families.

The Acutrak 2® design objectives were:

1. Simplify the surgical technique:
    a. Reduce the sensitivity to drill depth as related to screw length
    b. Incorporate self-drilling & self-cutting features
2. Increase the strength of the screw and hex driver interface
3. Increase the stiffness of the guide wires
4. Reduce the radial stress transmitted to the bone without reducing compression or fixation

While retaining the wide "window of compression" and fracture fixation advantages of the original Acutrak® screw design, the Acutrak 2® also minimizes drill depth sensitivity and simplifies the surgical technique.

Simplified Surgical Technique

Drill depth sensitivity quantifies how the Acutrak® technology taper locks into a prepared bone profile. The Acutrak® bone screw taper locks along the entire screw length while the Acutrak 2® screw taper locks along the trailing 1/3 of the screw length. Depth sensitivity emerges when insertion torque rises rapidly upon the taper lock of the screw & prepared bone profile.

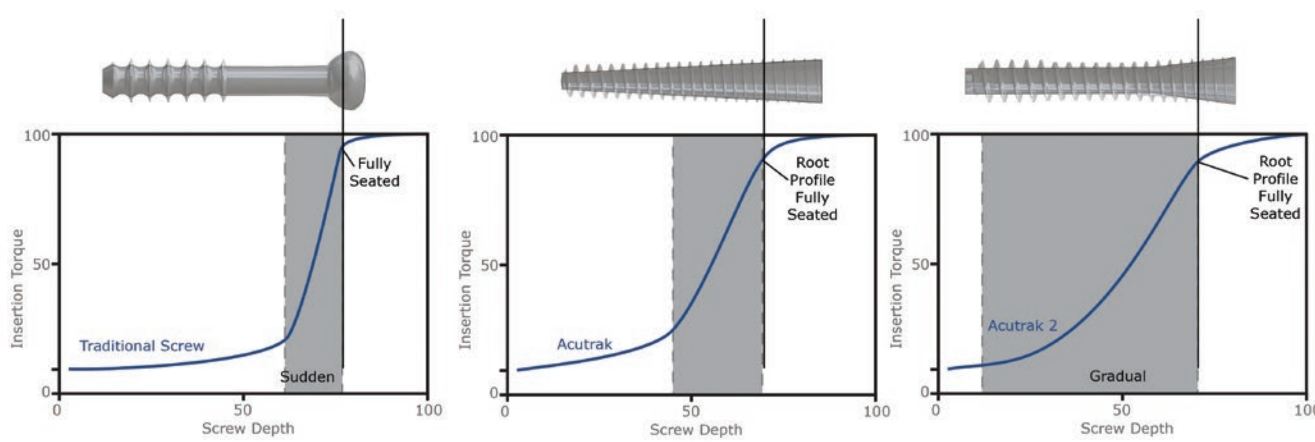


Figure 11: Graphs comparing rise in insertion torque at taper lock between Acutrak® & Acutrak 2® Screws

Simplified Surgical Technique (Continued)

Figure 12: Fully tapered Acutrak® screw root profile

Figure 13: Partially tapered Acutrak 2® screw root profile

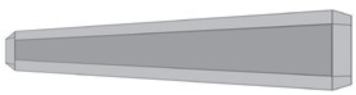


Figure 14: Fully tapered Acutrak® screw profile

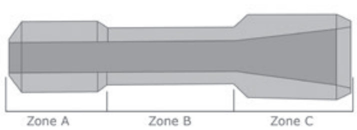


Figure 15: Diameter zones for Acutrak 2® screw

The "Rules of Acutrak®" were created to manage a rapid increase in insertion torque as an effect of depth sensitivity in the original Acutrak® screws. To obtain an optimal outcome, a precise relationship between drill depth & screw length must be maintained. For example, a measured depth of 55mm, drilled to 55mm, required a screw of length of 50mm to be inserted. This Acutrak® screw rule ensured a smaller taper (downsized length) fit into the prepared bone profile and taper locked when the Acutrak® screw was buried beneath the bone surface. However, the mismatch was counterintuitive and created confusion for surgeons accustomed to the traditional technique of measuring, drilling and inserting to the depth of the matching screw length.

To simplify the surgical technique and enhance insertion flexibility, the Acutrak 2® screw was broken into zones. The outer diameter has three zones - tip, middle and tail - with the tail zone being identical for each screw length. The root diameter has two zones: a cylindrical section with a tapered tail zone, which is also identical for each screw length. The tail zones are approximately 1/3 of the screw length.

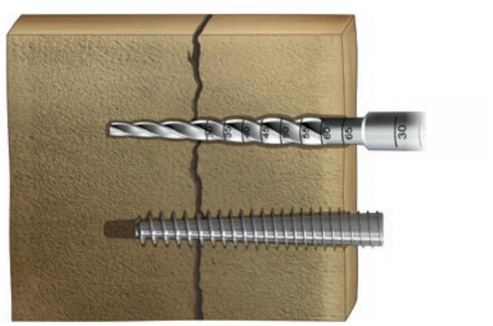


Figure 16: Acutrak® screw, conical drill

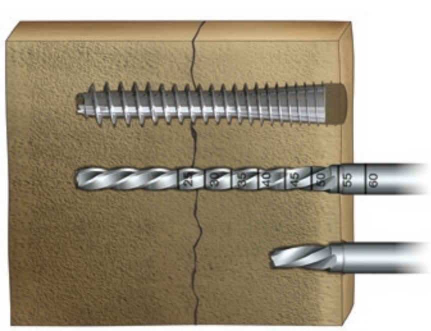


Figure 17: Acutrak 2® screw, taper and conical drill pair

The Acutrak 2® Screw minimizes depth sensitivity by pairing a cylindrical drill with a tapered profile drill, which eliminates the requirement of "downsizing" as described for the Acutrak® screw

Please refer to the Acutrak® and Acutrak 2® surgical procedures for more specific details on appropriate drilling technique.

Self Centering versus Self-Cutting: Increased Initial Distraction of Distal Bone Fragments

Acutrak® screws are self-centering and Acutrak 2® screws are self-cutting.

The fully tapered profile of an Acutrak® screw initially self-centers with the fully prepared bone profile by crossing over the fracture, fusion or osteotomy site.

The tip of an Acutrak 2® screw must cut into the opposing bony fragment and may distract slightly until the self-cutting tip engages. This momentary distraction is then eliminated as the screw is seated and does not impact the final compression.

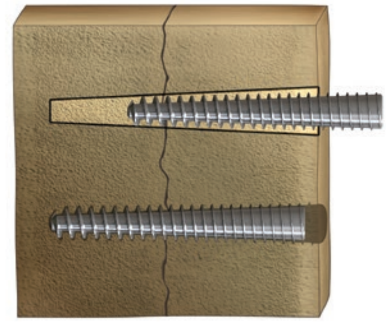


Figure 18: Acutrak® screw, self-centering

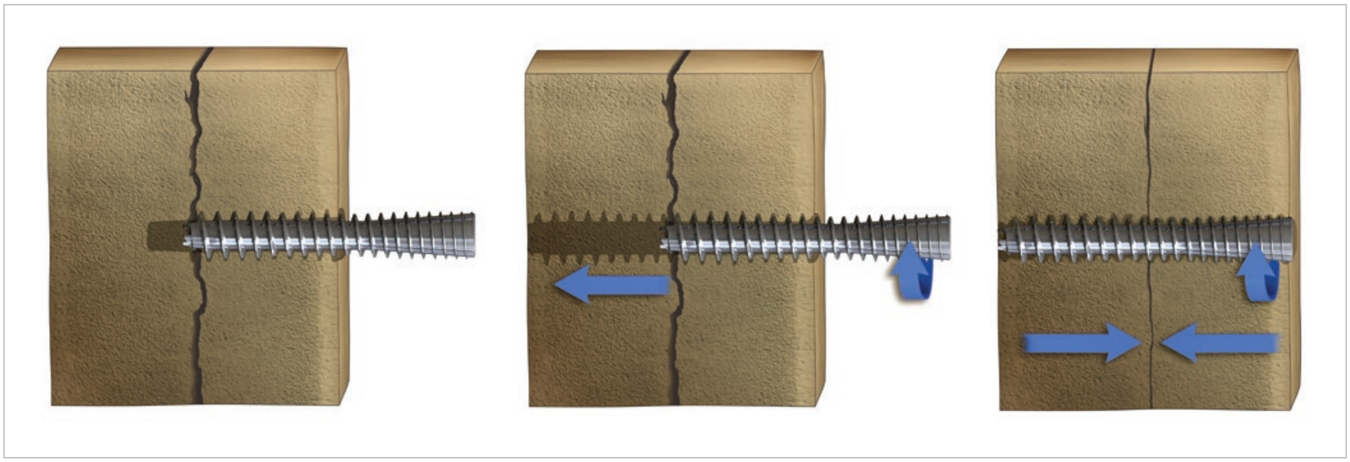


Figure 19: Acutrak 2® screw, distraction and final compression

Performance differences between Acutrak® and Acutrak 2® screws

Both the Acutrak® and Acutrak 2® bone screw families have been characterized for compression and pullout strength.

Acutrak® and Acutrak 2® products provide equivalent levels of compression.

The Acutrak 2® screws have higher levels of pullout strength as shown to the right.

- The increase in pullout strength is largely due to the similarity of Acutrak 2® tip & tail diameters

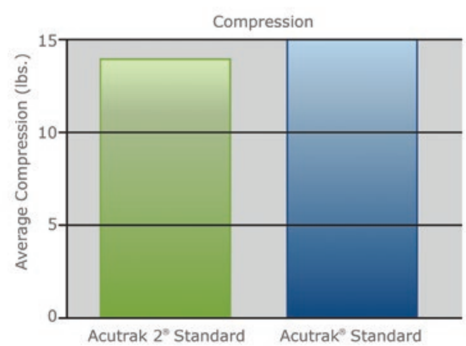


Figure 20: Acutrak® screw compression levels

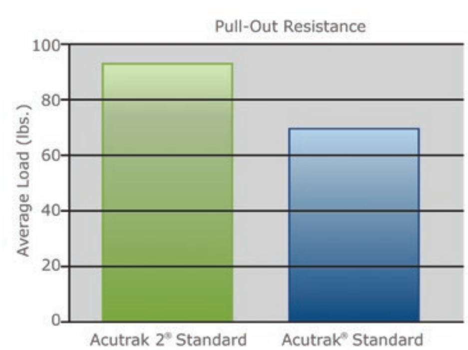


Figure 21: Acutrak® screw pullout strength

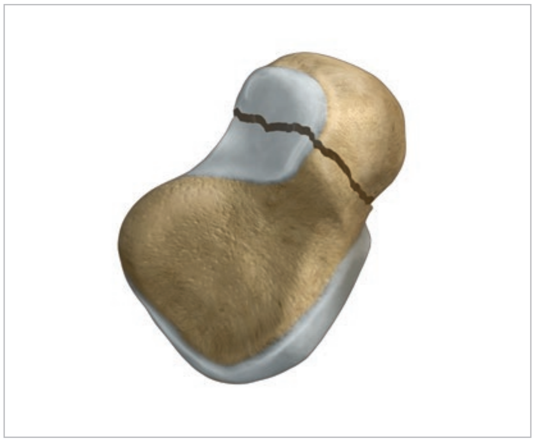


Figure 22: Illustration of a Proximal Pole Fracture in a Scaphoid

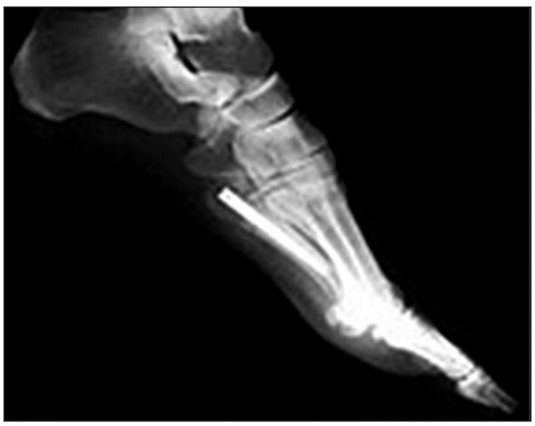


Figure 23: 5th Metatarsal Fracture with Acutrak®

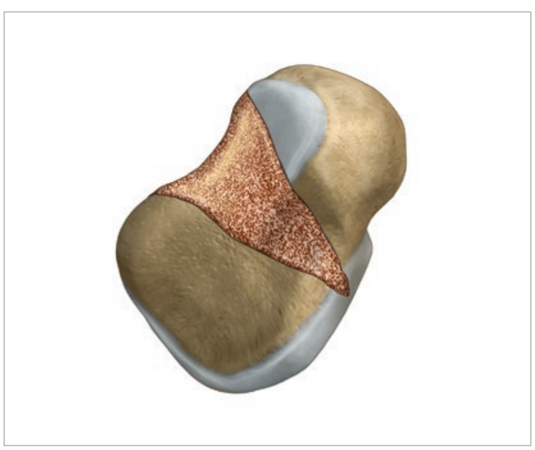


Figure 24: Illustration of bone graft for non-union of the scaphoid & a lateral column opening wedge osteotomy

Selecting Acutrak® vs Acutrak 2® bone screws

Acumed believes that both the Acutrak® and Acutrak 2® families of bone screws work well in a broad range of indications. However, surgeons may want to select one versus the other based on the unique aspects of a particular case.

Factors to consider when selecting Acutrak® vs Acutrak 2® are:

1. If significantly less than 50% of the distal bone fragment is present and initial distraction is a concern, Acutrak® may be a better choice. An example is proximal pole fractures of the scaphoid.

2. If fracture fixation requires the use of a screw in the intramedullary canal of a bone, and the anatomy has a conical shape, Acutrak® may be a better choice. Proximal 5th metatarsal fractures are a prime example of this.

3. If fracture fixation requires attempting to join more than two bone fragments with a single screw, Acutrak® screws may be a better choice due to the self-centering feature. Bone grafting for indications such as non-unions of the scaphoid or lateral column opening wedge osteotomies are examples of indications where this situation may exist.

In all other situations, the Acutrak 2® bone screws may provide a more "user friendly" surgical technique because of:

1. Reduced sensitivity to drill profile alignment with screw profile

2. Larger guide wire diameter, resulting in less sensitivity to bone density during guide wire insertion

3. Larger hex drivers, which increase the amount of torque at the driver & screw interface, making screw insertion easier

4. Micro screw option for small fractures, fusions or osteotomies when cannulation is desired & limited bone stock is available

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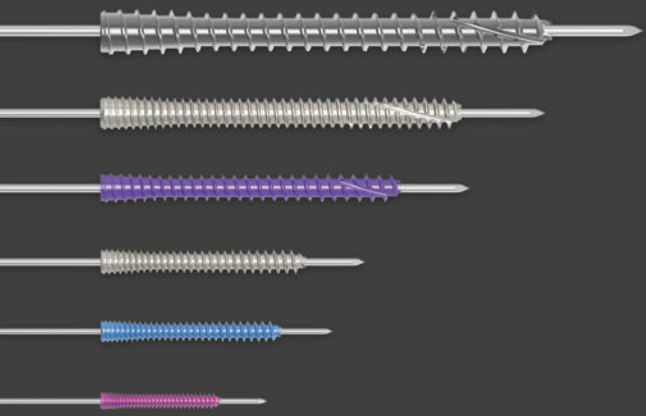

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Effective: 3/2013