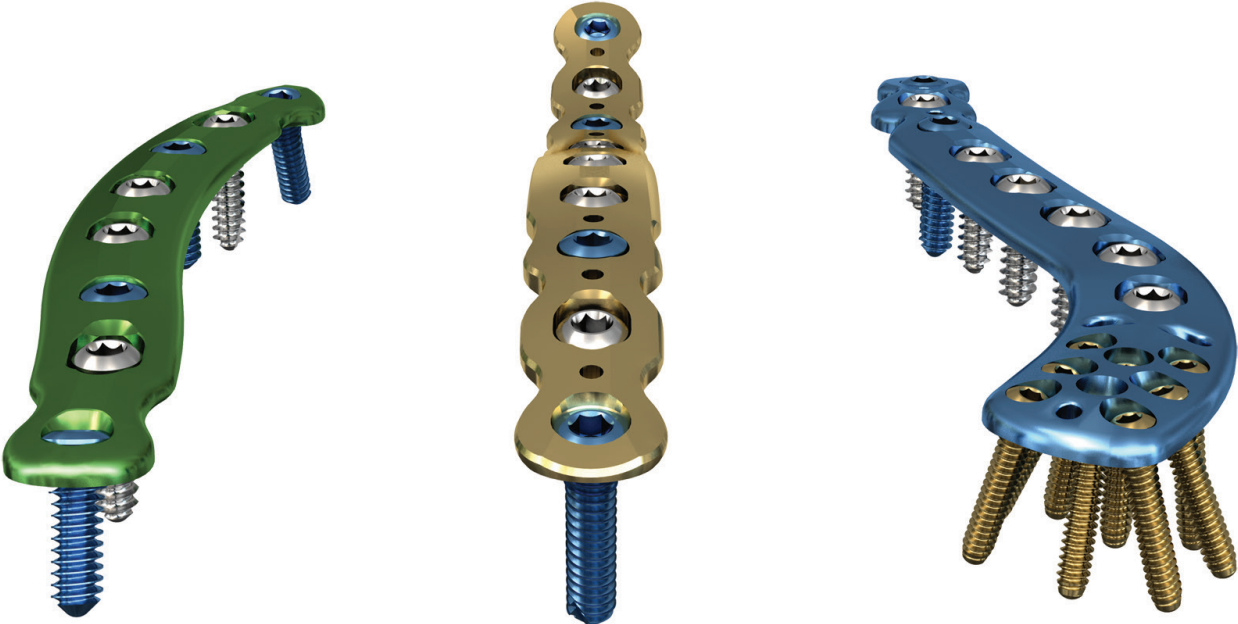


Clavicle Fracture Solutions

Value Analysis Committee - Resource Guide



Clavicle Fractures

Incidence and Patient Demographics

Current clinical literature estimates that approximately 2% to 5% of all fractures in adults and 10% to 15% of all fractures in children involve a fracture of the clavicle.¹ Based upon an analysis of the 2009 Healthcare Cost and Utilization Project data approximately 54,000 patients presented to hospital Emergency Departments with clavicle-related fractures.²

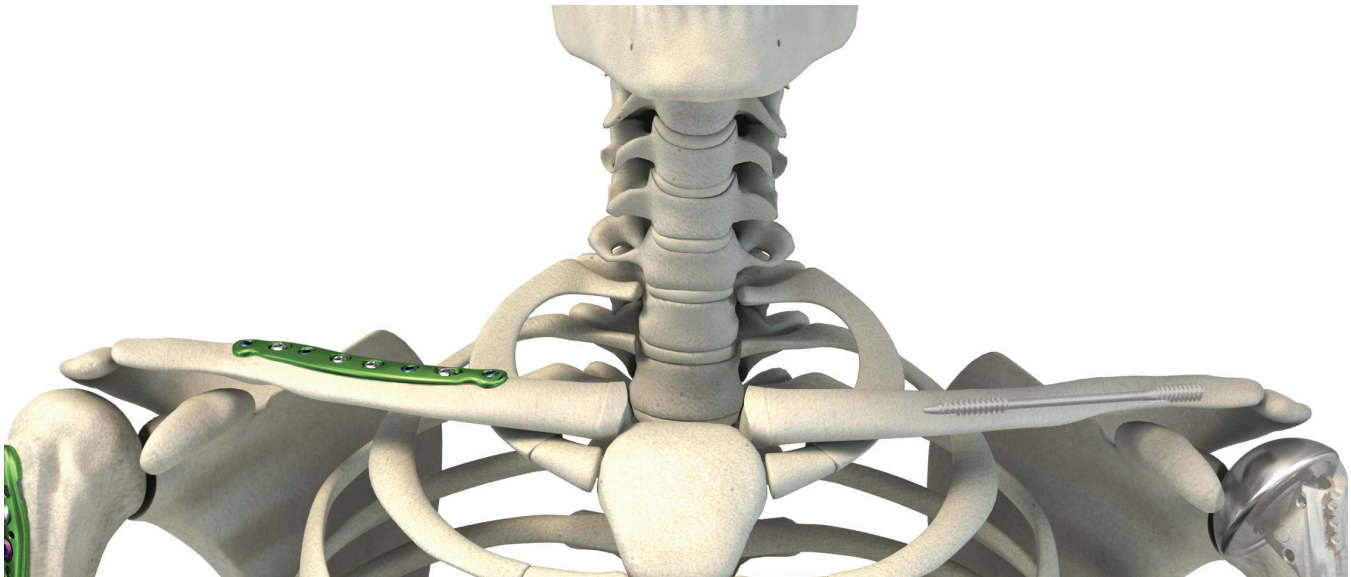
The literature continues with the projected incidence rate of a clavicle fracture in the adolescent and adult population to be between 29 and 64 per 100,000 persons annually. There tends to be a higher incidence rate for younger male patients, aged less than 30 years and elderly patients aged over 70 years to be at higher risk for clavicle fractures.³

Historically, many clavicle fractures have been treated utilizing non-surgical techniques. The most common method has been applying the use of a sling or figure-8 brace to immobilize the shoulder and allow the patient to heal. Recent studies have begun to show that certain types of clavicle fractures either fail to heal properly or, possibly not at all resulting in nonunion, shoulder dysfunction or residual pain after use of non-surgical management techniques. Studies now show that certain clavicle fractures require surgical intervention in order to heal properly.⁴

Classification of Clavicle Fractures

There are several different types of clavicle fractures. Certain fracture patterns can be medically managed without surgical intervention while others require some type of fixation in order to heal properly. The primary classification system in use today for clavicle fractures is anatomically divided into medial (type I), middle (type II), and lateral (type III) thirds. Each of the three types is then subdivided based on the degree of fracture fragment displacement. Fracture displacement of less than 100% falls into subgroup A, whereas fractures displaced by greater than 100% are subgroup B.

The number of displaced midshaft clavicle fractures treated surgically is increasing.⁵ Depending on the degree of displacement and the direction of displacement, surgeons may use either plate fixation devices, such as the Locking Clavicle Plating System, or intramedullary pin fixation devices, such as Dual-Trak, to stabilize and repair the clavicle fracture.



Acumed® is the first and only orthopaedic implant provider to offer a comprehensive pre-contoured plating system, an indication specific intramedullary clavicle device (The Dual-Trak Intramedullary Clavicle Screw), as well as an AC/CC tendon repair device (Acu-Sinch). Our goal is to provide surgeons with products that improve patient outcomes, provide for ease of use by the surgeons, and decrease time in the operating theater.

Acumed® Recognized with the AME Manufacturing Excellence Award

Acumed® received the 2011 AME Manufacturing Excellence Award, an honor which recognizes North American manufacturing sites that have demonstrated operational excellence through continuous improvement, best practices, creativity, and innovation.

The Association for Manufacturing Excellence is North America's premier organization for the exchange of knowledge in Organizational Excellence through the implementation of techniques such as Lean Tools, Leadership, Lean Product Development, Lean Supply Chain and Lean Accounting.

The AME Manufacturing Excellence Award recognizes North American manufacturing plants that have demonstrated excellence in manufacturing and business. The primary focus of the award is to acknowledge continuous improvement, best practices, creativity, and innovation. This award supports AME's vision, mission and values of inspiring commitment to enterprise excellence through shared learning and access to best practices.

Acumed® Dedication to Product Development and Innovation

With ten years of product development within the clavicle fixation and over 100,000 successful cases, Acumed is the technology leader in options for operative treatment of displaced clavicle fractures. Acumed® dedicates significant resources to the development of implants that improve patient outcomes and advances the field of orthopedic surgery. As a partner, Acumed® provides a pipeline of leading-edge products.

Acumed® Maintains Ethical Behaviors with Respect to Compliance Standards and Laws

Industry Compliance

As a logo member of the Advanced Medical Technology Associate (AdvaMed), Acumed® endorses the AdvaMed Code of Ethics. Adherence to this Code ensures our ethical interaction with healthcare professionals. Acumed® requires anti-corruption training for employees who interact with healthcare professionals or government officials (foreign or domestic). In addition, US sales representatives and international distribution partners must complete anti-corruption training programs.

Transparency in Business Practices

Acumed® is committed to transparency in its business practices. In 2012 the company began preparing to track and report spending in accordance with Physician Payment Sunshine Act. Acumed® utilizes a robust due diligence process to ensure that our distribution partners share our values with respect to anti-corruption and compliance. Potential distributors go through due diligence analysis and a robust on-boarding training and education in order to become an Acumed® partner.

Commitment to Sustainable Business Practices

Acumed® has formed a cross-functional group dedicated to preserving the environment and educating Acumed® on the benefits of being "green". The Green Team's purpose statement is:

WE EMPOWER ACUMED® AND THE GLOBAL COMMUNITY THROUGH EDUCATION, ENCOURAGEMENT, AND EXECUTION OF SUSTAINABLE BUSINESS PRACTICES. BY DOING THIS, WE ENGAGE OUR SPHERE OF INFLUENCE TO DELIVER INNOVATIVE PRODUCTS THAT RESPECT THE COMMUNITY'S NATURAL SYSTEMS, SUPPORT ETHICAL EQUITY AND DRIVE CUSTOMER LOYALTY.

The Green Team is currently driving an awareness campaign called "The More You Know" and distributes information to Acumed® employees about various environmental issues. An example of this is our 5S auction program to reuse items that would otherwise be discarded.

Clavicle Fracture Treatment Options

Surgical Versus Non-Surgical Intervention

Recent studies have shown that immediate surgical intervention for certain displaced clavicle fractures may result in better patient outcomes, reduced shoulder dysfunction and the avoidance of residual long-term pain. Particularly, fractures of the middle clavicle (Type II) with displacement of the fracture and shortening of the clavicle greater than 1.5 to 2 cm have reduced incidences of malunion and nonunion.⁵

“Operative fixation of a displaced fracture of the clavicular shaft results in improved functional outcome and a lower rate of malunion and nonunion compared with nonoperative treatment at one year of follow-up.”⁶

A meta-analysis performed by Zlowodzki M, et al showed that the rate of nonunion for middle clavicle fractures was 15.1% for fractures treated non-surgically, as compared to 2.2% for the fractures that were treated surgically with plate fixation.⁷

While this meta-analysis focused on clavicle fracture repairs with plate fixation, there are several options among the open reduction with internal fixation (ORIF) surgical approach. Today, surgeons have choices of ORIF fixation that include the use of intramedullary pin fixation, generic non-contoured plating devices, and the predominant use of precontoured plating devices specifically designed to address the unique anatomy of the clavicle.

Surgical Intervention with Plate Fixation

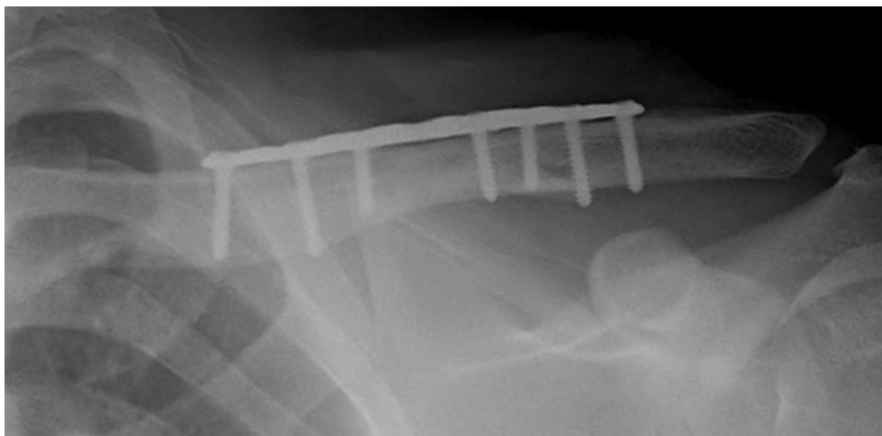
Dynamic Compression Plates

Historically, a variety of non-anatomic plating systems have been used to repair clavicle fractures. Among the earliest utilized, dynamic compression plates are non-anatomic and require bending the plate prior to use in order to attempt to accommodate a patient’s clavicle anatomy, a time consuming activity in the operating theater. Additionally, bending a compression plate may weaken the strength of the plate and because dynamic compression plates are non-clavicle specific, the plates may not fit a patient’s unique clavicle anatomy properly. A poorly fitting plate can cause soft tissue irritation and possibly skin erosion at the site of implant.

Precontoured Clavicle Plates

A precontoured clavicle plate is a plating system that is anatomically precontoured which assists in restoring the original structure of the patient’s anatomy with little or no bending of the plate by the surgeon at the time of surgery. Avoiding the need to bend a precontoured clavicle plate saves valuable Operating Room time during the operative procedure. The Acumed® comprehensive system of plates replicate the anatomical contours of the clavicle and act as templates when reconstructing a malunion, nonunion or a highly comminuted fracture to maximize support and accurately reduce the fracture.

“A contoured plate designed for the clavicle has been used to decrease the time required for intraoperative contouring and to decrease soft-tissue irritation.”⁸



Clavicle Fracture Treatment Options

Plate Construction

Another important consideration when choosing a plating system is the material from which the plate is constructed. The elasticity of the plate material can impact the strength of the healing fracture. In order for the clavicle to heal properly the bone must be under constant load, thereby strengthening the newly formed bone during the healing process. Therefore, the plate must have enough elasticity to create stress on the healing clavicle while maintaining enough support and stabilization during the healing process.

Each unique material bears with it a different measures of elasticity. While surgical steel has traditionally been used in the past due to its high strength, it has since been surpassed by titanium as the preferred option. Titanium offers both a strength and elasticity closer to that of natural bone and is more often used for clavicle plates due to its optimal elasticity and biocompatibility. Acumed® has designed the Clavicle Plate System utilizing alloyed Titanium. Due to the grade of Titanium alloy utilized in the Acumed® Clavicle Plate System, narrow profile plates have been developed, further lessening soft-tissue disruption and providing the best match to patient anatomy. The Acumed® Clavicle Plates also offer the unique feature of a low-contact undersurface to help better preserve periosteum* growth and support of the healing clavicle.

Acumed® Clavicle Plates generate improved healing capacity resulting from several key features:

- Machined from a premium grade titanium alloy, the plates perform with a modulus of elasticity that closely replicates bone and reduces the propensity for stress shielding
- A limited contact design eases compression of the periosteum to improve blood supply to the healing zone
- Tapered plate ends lessen the possibility of bone refracture above or below the plate due to excess stress concentration

Anatomic Complexity

Recent studies have shown that a patient's clavicle is anatomically asymmetrical and differs by gender.^{9,10} These differences make it advantageous to have a variety of different plate options available to the surgeon that allows for a better fit for the particular patient as well as the ability to treat a greater variety of fracture patterns. Aided by extensive cadaveric research and clinical experience, the Acumed® Plate System, is a comprehensive collection of precontoured, approach-specific plates designed to replicate the anatomic contour of the clavicle. Comprised of 31 plates across three distinct surgical designs: - Superior Midshaft, Superior Distal, and Anterior - Acumed® provides a complete clavicle plating solution with multiple options for different fracture patterns.



**Periosteum is a membrane that lines the outer surface of all bones, except at the joints of long bones. The periosteum contains cells that are essential to the healing process. The periosteum has nociceptive nerve endings, making it very sensitive to manipulation and it provides nourishment by providing the blood supply.*

Clavicle Fracture Treatment Options

The Acumed® Advantage

Precontoured anatomic plate design assists in restoring the original structure of the patient's anatomy with little or no bending, which saves valuable operating time. The Acumed® comprehensive system of plates replicate the anatomic contours of the clavicle and can act as a template when reconstructing a malunion, nonunion or a highly comminuted fracture to maximize support and accurately reduce the fracture.

The implant is machined from a premium-grade titanium alloy, the plates perform with a modulus of elasticity that closely replicates bone and reduces the propensity for stress shielding;

The limited contact design of the implant is intended to ease compression of the periosteum to improve blood supply to the healing zone;

The tapered plate ends lessen the possibility of bone refracture above and or below the plate resulting from excess stress concentrations and is intended to reduce soft tissue irritation.

The Unique Design of the Acumed® Clavicle Plating System

The Acumed® Clavicle Plating System is designed for improved patient outcomes:

- Low-profile and smooth surface is designed to reduce soft tissue irritation
- Limited contact undersurface to support healing of periosteum
- Beveled in the anterior/posterior plane designed to reduce soft tissue irritation
- Compression slots and locking holes provide for screw fixation without compromising the integrity of the plate
- The Acumed® distal plates are designed to be placed far distally to address the most lateral of fracture patterns and capture best bone quality

Surgical Intervention with Intramedullary Screw Fixation

It is generally accepted that surgical intervention for displaced middle third clavicle fractures may result in better patient outcomes for a variety of fracture patterns. Today, the two most common surgical treatment intervention options for displaced middle third clavicle fractures are plate fixation and intramedullary screw fixation. Surgeons have found additional value in the use of the minimally invasive intramedullary fixation for certain clavicle fracture patterns for the following reasons:

- Smaller incisions decrease the risk of infection and result in less scarring
- Reduced periosteal stripping can reduce damage to the bone's vascular supply
- Elimination of painful prominent hardware and potential long-term hardware complications due to the necessity of removing the hardware

In a recent study, surgeons determined that for acute, simple or wedge-type fractures intramedullary screw fixation can be just as effective as plating, thus providing the patient with multiple surgical treatment alternatives.

"Intramedullary pin fixation for acute, simple, or wedge-type midshaft clavicle fractures provides a safe and predictable alternative to plate and screw fixation."¹

Traditional Intramedullary fixation devices for the clavicle provided external means of reduction; i.e., fixation which would increase the risk of soft-tissue irritation and necessitates removal in the majority of cases. While hardware removal following fracture healing may reduce long-term hardware complications, the necessity for a second surgical procedure to remove the intramedullary screw provides additional opportunity for infection and intraoperative hardware complications.

Clavicle Fracture Treatment Options

The Acumed® Dual-Trak Clavicle Screw

The Acumed® Dual-Trak Clavicle Screw is designed to address the common complications of previous intramedullary clavicle fixation technologies. Designed to provide excellent fracture stability and restoration of anatomical alignment, this minimally invasive implant offers several advantages which may lead to improved patient outcomes. User-friendly surgical techniques and instrumentation eases the procedure for both the surgeon and the operating room staff and minimizes overall surgery time.

The Dual-Trak Clavicle Screw is a completely intramedullary device that provides and maintains superior compression, eliminates external means of fixation and with it hardware irritation, offering a minimally invasive surgical technique of benefit to both the patient and surgeon. Implanted entirely within the canal of the clavicle, the subosseous Dual-Trak Clavicle Screw preserves the periosteum and surrounding soft tissue and is designed to lessen tissue trauma.

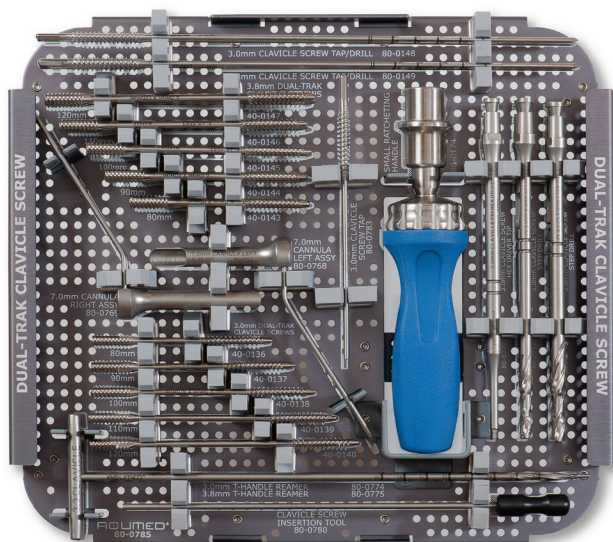
Moreover, minimized hardware prominence reduces soft tissue irritation and can increase patient acceptance. Unlike other intramedullary implants available on the market, the Dual-Trak Clavicle Screw does not require any external means of fixation in order to maintain compression or prevent implant migration. Since the Dual-Trak Clavicle Screw is a fully intramedullary implant it removes the need for hardware removal via a second surgery and with it eliminates the risk of infection and intra or post-operative complications.

The Acumed® Dual-Trak Clavicle Screw Construction

Similar to the Acumed precontoured plates, the elasticity of the intramedullary screw material can impact the strength of the healing fracture. In order for the clavicle to heal properly the bone must be under constant load, thereby strengthening the newly formed bone during the healing process. Therefore, the intramedullary screw must have enough elasticity to create stress on the healing clavicle while maintaining enough support and stabilization during the healing process.

Each unique material bears with it different measures of elasticity. While surgical steel has commonly been used in the past due to its high strength, it has since been surpassed by titanium as the preferred option. Titanium offers both a strength and elasticity closer to that of natural bone and is more often used for intramedullary screws due to its optimal elasticity and biocompatibility.¹³ The Acumed® Dual-Trak Clavicle Screw utilizes an alloyed Titanium for optimal fracture healing.

The Dual-Trak Clavicle Screw System is housed in a well organized, comprehensive tray with all the instruments necessary to implant the screw. The versatility of the system allows it to be used as either a stand-alone system or in conjunction with the Acumed® Clavicle Plate System, to create one complete clavicle solution system for surgeon and hospital convenience.



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