DePuy Synthes
COMPANIES OF Johnson & Johnson

VARIABLE ANGLE LOCKING CALCANEAL PLATING SYSTEM

VALUE ANALYSIS BRIEF

VALUE SUMMARY

- Calcaneal fractures are the most common fracture of the hindfoot, demanding individualized treatment.
- The Variable Angle Locking Calcaneal Plating System incorporates multiple options that can be used for both open reduction and internal fixation (ORIF) and minimally invasive plating osteosynthesis (MIPO) procedures, thereby enhancing surgeon flexibility.
- The plates and screws, optimized for strength, durability, and anatomic fit, address different fracture types while still providing standardization for efficient hospital purchasing.
- The instrumentation was designed to aid the surgeon with fracture reduction, which may improve the efficiency of the surgical procedure and reduce time in the operating room.

INTRODUCTION

This value brief presents information on the potential clinical, patient, and economic benefits of using the *DePuy Synthes Trauma* Variable Angle Locking Calcaneal Plating System to treat a wide variety of calcaneal fracture types. This plating system consists of the 2.7 mm Variable Angle Locking Calcaneal Plate for ORIF procedures as well as a 2.7 mm Variable Angle Locking Anterolateral Calcaneal Plate for use MIPO surgical approach in combination with independent screws. The referenced data were obtained through a MEDLINE search for clinical and economic studies published from 2004–2014 and resulted in a total of 79 papers. Papers were selected for use in this value brief based on a rigor of clinical data. Recently completed biomechanical studies were also included to support the design features underlying the value propositions for the system.

BACKGROUND

Burden of Illness and Unmet Need

Incidence and Prevalence

Calcaneal fractures are the most common fractures of the hindfoot.[1] An epidemiologic study from the UK found that the annual incidence of calcaneal fracture was 11.5 per 100,000, and that the fractures occurred 2.4 times more frequently in males than females.[1] A US study estimated that the incidence of calcaneal fractures was 0.5 per 100,000 workers per year.[2] Calcaneal fractures are most commonly caused by falls from a height of >10 feet or motor vehicle collisions where there is a high-energy axial load applied to the heel which drives the talus downward onto the calcaneus.[3]

Clinical Burden

Calcaneal fractures have devastating consequences for many patients.[1] Because most calcaneus fractures cause disruption of the anatomy, the goal of treatment is to restore the normal anatomy of the heel, often through surgery. A recent study showed that patient satisfaction and quality of life were greater with surgery, including ORIF and MIPO, compared with nonoperative management.[4] Surgery is, however, associated with a higher risk of complications. Wound healing problems occur in 16% to 25% of patients after ORIF, and have been reported to be as high as 43%.[5–7] Furthermore, despite the best efforts of the doctor and patient, normal foot and ankle motion is rarely regained after a severe fracture. Sometimes, another major surgery is required. If the bone has healed in a deformed position, or if the subtalar joint becomes arthritic, then fusion of the talus and calcaneus may be required. The numerous possible clinical presentations typically demand individualized treatment on a case-by-case basis.[8]

Economic Burden
A retrospective review of US patients who sustained calcaneal fractures in industrial accidents showed that patients who underwent ORIF had an average time loss from work of 35 weeks, and the average total cost of injury was $31,004.[2] For patients who later underwent a hindfoot arthrodesis, the average time off work was 69 weeks and the average total cost of injury was $65,384.[2]

Calcaneal fractures occur mainly in patients (60%) who are still in their wage-earning years (ie, 30 to 50 years old).[4] As a result, these fractures may place considerable economic burden on the individuals and their communities.[9] The interval to return to work with calcaneal fractures is typically 5 to 10 months[6] and up to 50% of patients will not be able to resume work within 1 year.[10] Calcaneal fractures can remain symptomatic for up to 2 years,[6,11,12] often affecting productivity even upon return to work.

Open Reduction and Internal Fixation (ORIF) & Minimally Invasive Plating Osteosynthesis (MIPO)
Compared to open procedures, closed reduction with percutaneous fixation has a lower risk of wound complications, a shorter operative time, and more rapid healing because of the reduced handling of soft tissue.[3] This approach is, therefore, typically used in patients with significant comorbidities, soft tissue compromise or impaired healing, or specific types of fractures such as true tongue-type fractures.[3] It is considered a good option for extra-articular fractures.[8] Due to potential difficulties in reducing severely displaced fractures, the MIPO procedure is currently recommended for less severe fracture patterns.[3,8]

The Future of Calcaneal Fracture Care
Experts continue to work to improve the outcomes of calcaneal fracture injuries. New developments for treating calcaneal fractures, including the development of better plates and screws, are evolving. Such technologies look to optimize the recovery of patients with calcaneal fractures and may result in better patient-centered outcomes (eg, patient satisfaction and quality of life). The use of smaller incisions and better reduction techniques, etc, could possibly decrease surgical time, anesthesia, and risk of infection.

2.7 MM VARIABLE ANGLE LOCKING CALCANEAL PLATING SYSTEM*

One System for 2 Leading Surgical Techniques

The capability for using the same technology for both types of surgeries enhances surgeon flexibility and customization to patient needs. There are 2 plates in the Variable Angle (VA) Locking Calcaneal Plate System, 1 for ORIF and the other for MIPO used in combination with independent screws to address the 2 leading surgical techniques.

ORIF: 2.7 mm VA Locking Calcaneal Plates are designed to treat complex fractures with multiple fixation points targeting key areas of hard cortical bone in the calcaneus (Figure 1).

Figure 1. Plates available in Small, Medium, and Large, Left and Right. Plates with tabs also available in Medium and Large.

MIPO: 2.7 mm VA Locking Anterolateral Calcaneal plates in combination with independent screws are designed for a minimally invasive approach to calcaneal fractures to help preserve soft tissue on the lateral calcaneal wall (Figure 2).

Figure 2. Plates available in Short and Long, Left and Right.

*For a complete list of indications for use, warnings, and precautions, please see the package insert or surgical technique.

Provides Multiple Fixation Options Targeting Key Areas of the Calcaneus

- The 2.7 mm VA Locking Calcaneal plates have been designed for the 2 surgical approaches (MIPO and lateral extensile) and provide multiple fixation options to match the patient's anatomy and specific fracture pattern

ORIF: 2.7 mm VA Locking Calcaneal Plates, for Lateral Extensile approach

- Designed to treat a broad array of complex fractures with multiple fixation points targeting key areas of hard cortical bone (Figure 3)
  - VA Locking screws are targeted to buttress posterior and middle facet and converge in hard bone of the sustentaculum
  - Tuberosity screws are angled inferiorly and posteriorly to target hard cortical bone around the perimeter of the tuberosity

Figure 3. Calcaneal bone with lateral extensile plate showing multiple options for screw placement

- A strut down the center of the plate provides additional support for lateral wall comminution (Figure 4)

Figure 4. Lateral extensile plate allows for placement of screws around the perimeter of the calcaneus in hard cortical bone

MIPO: 2.7 mm VA Locking Anterolateral Calcaneal Plates

- VA Locking screws are targeted to buttress the posterior and middle facet and converge in the hard bone of the sustentaculum (Figure 5)
  - Short and long plates available, providing options for fracture fixation

Figure 5. MIPO anterolateral plates provide multiple fixation options. Final construct to be used with independent fixation

Designed to Minimize Additional Trauma to Soft Tissue and Fracture Fragments

ORIF: 2.7 mm VA Locking Calcaneal Plates (Figure 6)

- Precontoured, low-profile plates are designed to reduce likelihood of soft tissue irritation along lateral calcaneal wall
- Precontoured plates may save time in the operating room (OR)
- Plate profile and screw holes are located above the incision line to reduce the likelihood of the implant causing stress on the incision area

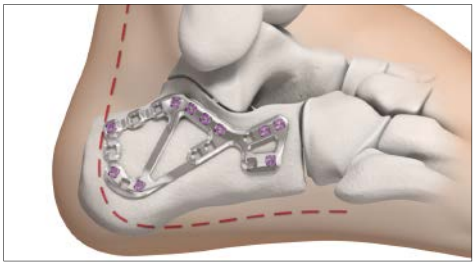

Figure 6. Lateral extensile plate tracing perimeter of bone with supportive center strut

MIPO: 2.7 mm VA Locking Anterolateral Calcaneal Plates (Figure 7)

- Soft tissue is preserved on the lateral wall of the calcaneus due to the small incision recommended with the new calcaneal plate
- Small lateral oblique incision provides direct visualization of the subtalar joint to aid in the reduction of the articular surface

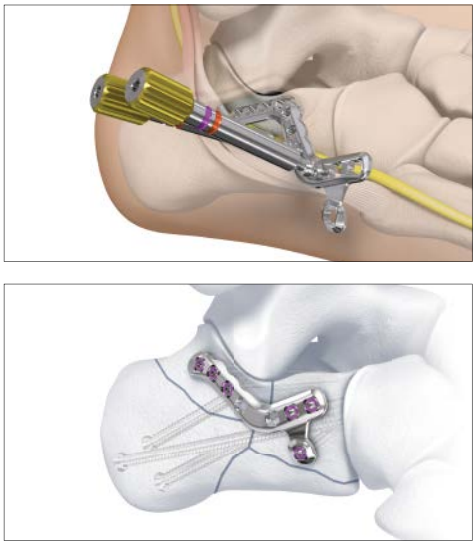

Figure 7. Minimally invasive plate inserted through small incision. Final construct shown with Independent Fixation through the tuberosity

Evidence-Based Design: Plates Optimized for Anatomic Fit

- The new calcaneal plate design was based on a thorough analysis of calcaneal bones (n=30) at the University of Tennessee Bone Bank
  - The Tennessee Bone Bank study was conducted to ensure the plate size, profile, and contour would fit the majority of the population and to confirm screw trajectory locations
  - The study (n=30) included a wide range of specimens with varying height, ethnicity, age, and gender to account for different anatomies and patient types
    - Critical measurements included:
      - Overall dimensions of the calcaneus including length, width, and height to confirm plate sizing
      - Distance between the plate and the bone to confirm plate contour
      - Screw trajectory locations, making sure they avoided articular surfaces
      - The results of this analysis show the design of the VA Locking Calcaneal plates optimize fit in at least 97.7% of the patient population

Uncompromised Strength and Durability

- To help prevent plate failure or loss of fracture fixation, plates used to treat calcaneal fractures must provide adequate fatigue strength and sufficient durability[13]
  - Fatigue is the weakening of a material caused by repeatedly applied loads
- The VA Locking Calcaneal Plate is smaller and thinner than the 3.5 *DePuy Synthes Trauma* LCP Calcaneal Plate construct without compromising strength (MT14-248)

Figure 8 shows the fatigue strength of the VA Locking Titanium (Ti) and VA Locking Stainless Steel (SS) Plates are greater than the fatigue strength of the Locking Calcaneal Plate and the Stryker Calcaneal Mesh Plate based on a finite element study (MT14-248).

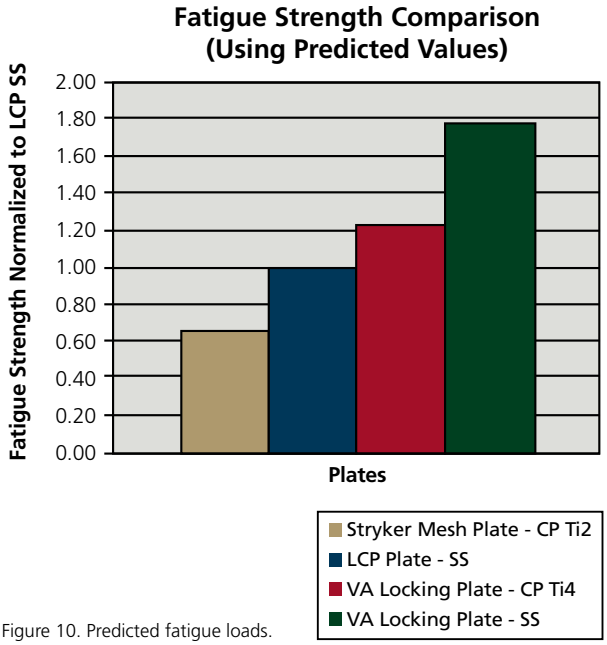

Figure 10. Predicted fatigue loads.

- In addition, physical construct testing was done using a test method based on musculoskeletal loads during gait (ie, walking)[14]
  - A comparison of the construct median fatigue strength for the VA Locking Calcaneal Ti Plate versus the Stryker Calcaneal Mesh Plate showed that the VA Locking Calcaneal Ti Plate is significantly stronger in fatigue (MT13-247)
  - A comparison of the construct median fatigue load for the VA Locking Calcaneal Ti Plate versus the LCP Locking plate showed there is no statistically relevant difference between the 2 plates (MT13-016)

In summary, biomechanical testing data show although the VA Locking Calcaneal plate is smaller and thinner than the LCP Locking Plate, strength and durability are not compromised.

DePuy Synthes Trauma Market-leading Variable Angle (VA) Locking Technology

- Variable angle locking screws provide the ability to create a fixed-angle construct while allowing the surgeon the freedom to adapt screw trajectories to varied calcaneal anatomies and fracture patterns
- This platform technology is incorporated in many *DePuy Synthes Trauma* plating systems, and used for various types of trauma surgical procedures

Figure 9. Variable Angle Locking technology allows screws to be angled anywhere within a 30° cone around the central axis of the plate hole (15° off axis in either direction).

- *DePuy Synthes Trauma* VA Locking is achieved without the use of bushings, end caps, additional implants, or multiple technique steps
- VA Locking technology may be used in various types of trauma surgeries and, therefore, may reduce hospital inventory
- 2.7 mm VA Locking screw holes accept multiple screw types:
  - VA Locking screws
  - Metaphyseal screws
  - 2.7 mm Locking screws, inserted at the nominal angle
  - Cortex screws

Innovative Instrumentation to Aid in Fracture Fixation

- Instrumentation designed to facilitate procedural efficiency in the OR
  - Reduction joystick aids in fracture manipulation
  - Provides a larger surface area to reduce the likelihood of cut-out in cancellous bone

Figure 10. Reduction joystick facilitates reduction of tuberosity.

- The following instrument sets offer additional options for calcaneal procedures which are available separately:
  1. Compression/Distraction Device set
     - Offers a precise compression/distraction mechanism of joints and bones for fracture treatment, arthrodesis, and osteotomies
  2. Bone Harvesting Set
     - Enables bone harvesting or bone biopsies
  3. General Foot Instruments
     - Compact set of commonly used instruments for forefoot, midfoot, and hindfoot cases
     - Bone Spreader fits into tight joint spaces, helping with joint prep
     - Small Hohmann Retractors designed specifically for foot surgery

Optimized for Hospital Standardization

- The VA Locking Calcaneal Plating System offers the hospital a single set with 2 surgical options to provide surgeons with a full range of choices to treat a wide variety of fracture types
- Standardization of physician preference items, such as trauma implants, is one method for enhancing the efficiency of a hospital's supply chain and supports improved profitability[15]
- In addition to cost reduction, standardizing implants can improve efficiency and quality of care[16]
- The above statements are consistent with the American Academy of Orthopedic Surgeons Information Statement on Prevention of Medical Errors that states, "Studies have suggested that the use of standard order sets have decreased hospital length of stay and improved the quality of care"[17]
- In addition to the single VA Locking Calcaneal Plating System with 2 surgical options, this system utilizes screws that may be used with multiple types of *DePuy Synthes Trauma* plates. This feature also facilitates hospital standardization
  - VA Locking screws used with this system are part of the *DePuy Synthes Trauma* VA Locking Platform Technology used across various trauma surgeries, and the instrumentation for VA screws is inter-changeable with other plating procedures
  - VA Locking technology enables desired screw positioning and offers a wide array of options to address surgeon preference for treating a full range of fracture types

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WARNING: In the USA, this product has labeling limitations. See package insert for complete information.

CAUTION: USA Law restricts these devices to sale by or on the order of a physician.

Not all products are currently available in all markets.

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DSUS/TRM/1114/0295(1) 3/15 DV

CAN 104873-190104