



Frequently Asked Questions

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Frequently Asked Questions

What is FCL® Technology?

The vital differentiating benefit of a Far Cortical Locking (FCL) screw is controlled motion created by a reduced screw shaft diameter that "floats" in the hole drilled on the near cortex. There is a small gap between the screw shaft and the drilled hole in the near cortex, which allows the screw to flex. The result is near-symmetrical axial motion of both cortices at the fracture site (Video 1).

FCL is a unique screw technology that enables rigid locking constructs to become 80% more flexible*, while maintaining the overall strength of the construct. Precise and reproducible motion at the fracture site is beneficial for healing and has been shown to accelerate and strengthen callus formation.¹

In a study of 31 patients, FCL constructs were shown to accelerate and strengthen callus formation. At week 9, the FCL group had a 36% greater callus volume (p = 0.03) and a 44% higher bone mineral content (p = 0.013) than the locked plating group. Callus in the locked plating specimens was asymmetric, having 49% less bone mineral content in the medial callus than in the lateral callus (p = 0.003).

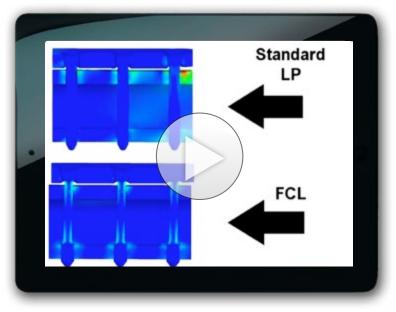
Making a locking construct more flexible without reducing the strength of the construct may seem counterintuitive, but it is possible because FCL screws share the transmission of load throughout the construct across all screws. Where as with traditional locking constructs, load is focused toward the screw furthest from the fracture site and dissipates to very little load to the screw closest to the fracture.

Video 2 shows the difference in loading between a locked construct and flexible construct. The red/orange areas indicate increased strain.

Video 1 (click on image to play video)



Video 2 (click on image to play video)



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^{*}Animal studies and bench testing are not indicative of human clinical performance.

Frequently Asked Questions

What is the difference between FCL and MotionLoc screws?*

The MotionLoc screw design is based on FCL technology. To optimize the MotionLoc screws, the FCL screw design was modified to accommodate the NCB® and ZPLP plating systems and reverse cutting threads were added to the screw shaft. These reverse cutting threads, pictured below, aid in removal of the screw (Figure A). MotionLoc screws provide this advanced design feature to ensure easier removal.

Why are MotionLoc screws important?

The added strength of locking constructs gave surgeons confidence when treating patients with poor quality bone. Today, in the U.S. market almost 80% of plate and screw procedures utilize locking technology.³ The trade-off that comes with this technology shift is excessive construct rigidity which can block biologic healing. Plating constructs that are too stiff inhibit healing. With MotionLoc screws, surgeons can get all of the benefits of locking technology, without the compromise of undesired rigidity.

Figure A (click on image to animate)





Frequently Asked Questions

What journal articles discuss the impact of construct rigidity on healing?*

The patient must be instructed about all postoperative restrictions, particularly those related to occupational and sports activities, and about the possibility that the implant or its components may wear out, fail or need to be replaced. The implant is not as strong, reliable, or durable as natural, healthy bone, and will fail under normal weight bearing or load bearing in the absence of complete bone healing.

Hak DJ, Toker S, Yi C, et al.

The influence of fracture fixation biomechanics on fracture healing.

Orthopedics 2010;33-10:752-5.

This review paper discusses why locked plating is not mechanically designed to promote healing through secondary callus formation. When the fracture gap is too great or the amount of interfragmentary motion is too little, adequate callus formation cannot occur. Increasing the working length of the plate and decreasing the number of screws may reduce locked plate stiffness and increase interfragmentary motion, but only at the far cortex.

Goodship AE, Kenwright J.

The influence of induced micromovement upon the healing of experimental tibial fractures.

J Bone Joint Surg Br. 1985;67:650-655.

This animal study showed that a significant improvement in healing was associated with the application of controlled micromovement at the fracture site compared to rigid external fixation.

Lujan TJ, Henderson CE, Madey SM, et al.

Locked plating of distal femur fractures leads to inconsistent and asymmetric callus formation.

J Orthop Trauma. 2010;24:156-162.

Locked plating constructs may be too stiff to reliably promote secondary bone healing. Stabilization of distal femur fractures with periarticular locking plates can cause inconsistent and asymmetric formation of periosteal callus as measured through a computer algorithm removing bias from the measurement.

Caja V, Kim W, Larsson S, et al.

Comparison of the mechanical performance of three types of external fixators: linear, circular and hybrid.

Clin Biomech (Bristol, Avon). 1995;10:401-406.

This biomechanical study shows that circular wire fixators are characterized by a low general stiffness when compared to linear fixators and clinically remain the gold standard for secondary healing because linear frames can still cause stress shielding. With greater stiffness reduction comes improved secondary healing.

Claes LE, Heigele CA, Neidlinger-Wilke C, et al.

Effects of mechanical factors on the fracture healing process.

Clin Orthop Relat Res. 1998;355: S132–S147.

In this animal and finite modeling study, it is hypothesized that gap size and the amount of strain and hydrostatic pressure along the calcified surface in the fracture gap are the fundamental mechanical factors involved in bone healing. Stiffness reduction of a locked construct allows the fracture gap to see strain, which is essential for healing. With traditional locked constructs, stress shielding prevents the fracture from strain all-together.

^{*}These studies do not involve MotionLoc Technology

Frequently Asked Questions

How much motion does a MotionLoc construct allow?

The stainless steel and titanium screws are slightly different. To achieve secondary callus formation, published literature indicates that the fracture site must achieve between 0.2–1.0 mm of interfragmentary motion. ⁴⁶ MotionLoc screws fall in the middle of that range with 0.3–0.5 mm of motion. The stiffness reduction achieved is directly dependent on the screw diameter, length, material and the quantity of screws used. The longer the MotionLoc screw, the longer the working length and the greater the stiffness reduction.*

What is the average stiffness reduction with these screws?

On average, the titanium MotionLoc screws provide 64% stiffness reduction across all plates and sizes, and the stainless steel MotionLoc screws provide 58%¹³ average stiffness reduction across all plates and sizes. As with total motion, this isn't an entirely simple answer to this question. The stiffness of the MotionLoc screws is dependent on the diameter, length, material and quantity of screws used. The averages above are a good indicator of standard constructs and lengths.



^{*}Animal studies and bench testing are not indicative of human clinical performance.

Frequently Asked Questions

What is bi-phasic stiffness?

To simplify things, think of MotionLoc as an over-drilled hole with the screw shaft perfectly centered in the middle.

The black areas indicate the extra space the screw shafts have to move as they flex. As load is applied, the screws flex until they "bottom out" on the bone of the overdrilled hole (Figure B).

This early flexing period is called the initial stiffness. Once the screw has engaged the bone in the near cortex the secondary stiffness starts.

The loading profile pictured below shows the slope of the line indicating the stiffness (or displacement on the x-axis) for a given load (y-axis) for a standard ocking Plate (LP) and FCL construct (Figure C). The steeper the line, the stiffer the material. During the initial stiffness phase, over the first 0.6mm of motion, the FCL line is fairly flat, indicating low stiffness. Once the screw contacts the bone at the near cortex, the secondary stiffness profile begins and the stiffness is similar to a standard locked construct. These two stiffness profiles together make up bi-phasic stiffness.

Figure B (click on image to animate)

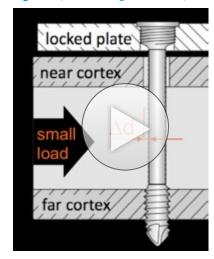
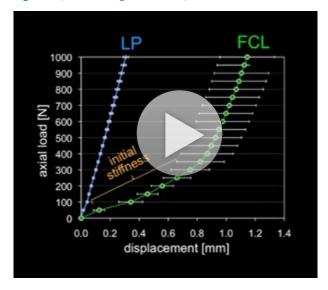


Figure C (click on image to animate)





Frequently Asked Questions

How does MotionLoc compare to a non-locked construct?

One of the workarounds that surgeons use to attempt to reduce the stiffness of constructs is to use only non-locking screws in the diaphyseal/shaft of a plate. The theory goes that in patients with good bone quality that do not require locking screws, it may be sufficient to just use non-locking screws while avoiding overly stiff constructs with locking screws. There is some published evidence that calls these assumptions into question.

- 1.) Non-locked constructs are **at least as stiff as** locked constructs, as shown in a bench top testing study by Fitzpatrick et al.⁷ The AO Foundation originally designed standard compression plates to target primary bone healing by providing **absolute** stability.
- 2.) Evidence of the danger of overly stiff non-locking plates can be found in a book entitled, Current Concepts of Internal Fixation of Fractures, published in 1980. It is a compilation of 60 research articles from the late 1970s and includes some of the most well-known names of the day like Drs. Perren, Bagby, & Schatzker. Amazingly, 19 of the 60 articles study the negative impact of non-locking plate stiffness or possible workarounds to avoid the negative effects of this stiffness.



Frequently Asked Questions

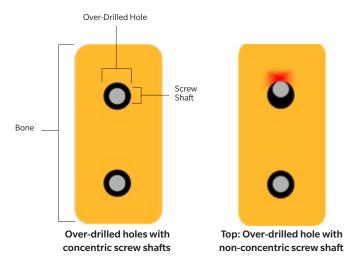
Will over-drilling the near cortex using standard locking screws give the same performance as MotionLoc screws?

The technique of over-drilling with standard locking screws has been proposed in a recent mechanical study.⁸ Although this technique does decrease construct stiffness, there are some disadvantages relative to MotionLoc technology;

Technique Limitations. Over-drilling in the near cortex requires several steps. First, the plate is applied and a standard drill is used to drill through both the near and far cortices for screw placement. Then the plate is removed to over-drill the near cortex with a drill bit approximately 1mm greater in diameter. Finally, the plate is reapplied and the screws placed through the drilled holes. The additional steps add complexity to the case and potentially time in the OR as well. This deviation from standard techniques is accentuated when the plating is performed percutaneously, as is often the case with bridge plating techniques that call for decreased stiffness of the construct.

Questionable Motion. The amount of stiffness reduction with an over-drilled construct is less than that provided with MotionLoc technology. An animal study of an over-drilled construct has been shown to be approximately twice as stiff as an equivalent MotionLoc construct. MotionLoc screws rely on the screw shaft diameter to achieve the desired flexibility (**Figure D**).

Figure D





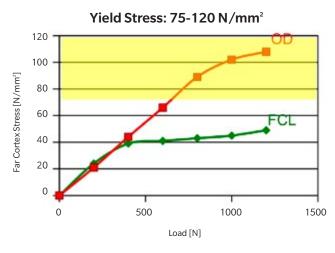
Frequently Asked Questions

Cont.

Far Cortex Load Transfer. There is also concern that using the over-drilling technique with a standard locking screw puts too much load on the far cortex. Compared to an FCL MotionLoc construct, the greater stiffness of the standard locking screws in an over-drilled construct can induce over twice the stress in the far cortex which can lead to resorption and screw loosening **(Figure E)**.

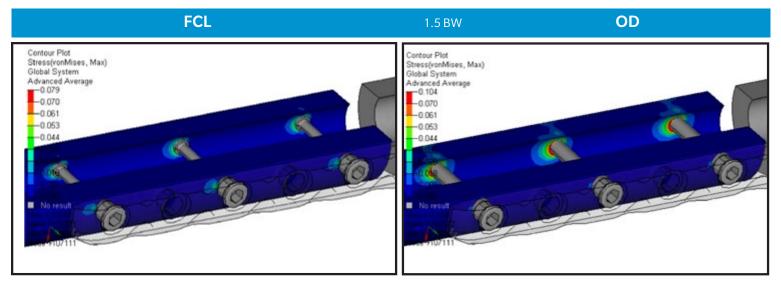
Reproducibility. Finally, if the near cortex hole is not drilled concentrically in all screw holes, point contact loading in the near cortex may result in stress concentrations, which will increase the risk for technique failure. A single non-concentric screw can reduce or prevent elastic flexion of all screws, impeding stiffness reduction and interfragmentary motion. The picture below illustrates the impact of a near cortex hole that has not been drilled concentrically (**Figure F**).

Figure E



Reilly et al., JBJS, 1974







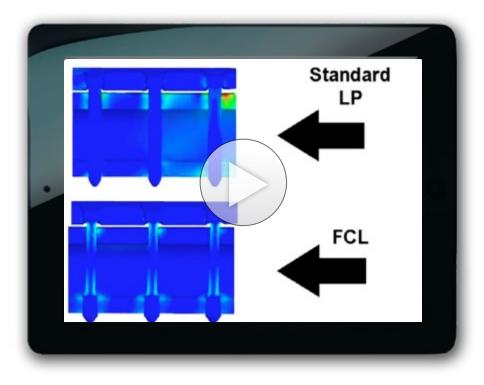
Frequently Asked Questions

Is there a risk of fatigue failure with MotionLoc screws?

In fatigue testing, MotionLoc constructs were more durable than stiffer constructs as they can distribute the load over a wider area and avoid stress risers responsible for fatigue failure. Video 3 shows the difference in loading between a locked construct and flexible construct. The red/orange areas indicate increased stress.*

In the MotionLoc construct, the load is shared across all three or four screws in the shaft. A biomechanical study demonstrated that FCL flexible constructs can be up to **54**% stronger in torsion and up to **21**% stronger in bending, while retaining **83**% of axial strength compared to a standard locked plating construct. The MotionLoc construct is equivalent, or stronger, in strength to a standard locked plating construct.

Video 3 (click on image to play video)



^{*}Improper selection, placement, positioning and fixation of the implant components may result in unusual stress conditions reducing the service life of the implants. The following adverse effects are possible: Fatigue Fracture.

Frequently Asked Questions

Cont.

In a second biomechanical study with cadaveric femurs under dynamic physiologic loading, MotionLoc constructs were as durable and strong as standard locked plating constructs. In that study, MotionLoc constructs did not sustain hardware failure. Instead they failed through the loss of metaphyseal fixation or bone fracture.

Zimmer Biomet fatigue testing demonstrated that in a properly placed construct, the plate will break in fatigue before the MotionLoc screws. The key design feature is the motion envelope at the near cortex, which protects the screw shaft from excessive bending and fatigue.¹¹

Video 4 (click on image to play video)



Frequently Asked Questions

Do MotionLoc screws change the surgical technique?

Using MotionLoc screws does not change the standard locking plate technique. No additional instrumentation is required. The same drill bits are used to insert locking and MotionLoc screws. There are a couple of tips to keep in mind to maximize the MotionLoc effects.

1.) Fix articular segment first.

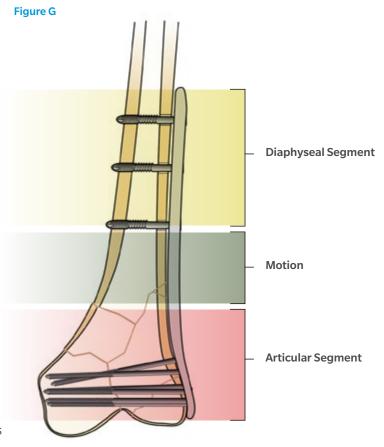
MotionLoc screws are only effective in the shaft. Address the articular segment first with standard plating techniques. Compression/lag screws are still used in the metaphysis, especially for intra-articular fractures, as well as locking or non-locking screws and pins. The surgeon can then move to the shaft of the bone and complete that fixation with the MotionLoc screws. In this way, a complicated fracture with multiple pieces can be simplified into two separate segments: the articular segment and the motion/shaft segment (Figure G).

2.) To maximize movement, do not compress the shaft of the plate to the bone.

It is ideal for the MotionLoc screws if the plate is elevated slightly off the bone in the shaft to reduce the friction between the bone and the plate as the screws are flexing. For the stainless steel screws, this takes care of itself. When no compression/cortical screws have been used through the shaft of the plate, the plate naturally sits off the bone slightly as the threads of the locking screw engage in the plate. For the NCB® Plating System, a spacer can be used and removed once MotionLoc screws have been placed, or more commonly, the MotionLoc screws can be backed off half a turn before placing the locking cap.

3.) Do not mix MotionLoc screws and other screw types on one side of the fracture.

Mixing other screws with the MotionLoc screws in the shaft will impede motion. Whether the additional screw is locking or non-locking, it will prevent motion and take the majority of the load until it breaks and allows the MotionLoc screws to flex within their motion envelope.





Frequently Asked Questions

How do the stainless steel MotionLoc screws differ from the titanium MotionLoc screws?

The function of the titanium and stainless steel MotionLoc screws is identical. The most notable difference is in the head of each of the screws. The titanium screw is designed for the NCB Plating System, which uses a locking cap to lock a polyaxial screw into the plate (Figure H). The stainless steel screw is compatible with the Periarticular Locking Plate System with locking threads in the head (Figure I).

Both screws have a reduced core diameter for motion at the near cortex and reverse cutting threads in the middle of the shaft for removal.

Figure H



Titanium MotionLoc Screw without locking threads on the head of the screw.

Figure I



Stainless steel MotionLoc screw with locking threads on the head of the screw.



Frequently Asked Questions

What are the diameters of the MotionLoc screws?

The stainless steel and titanium screws are slightly different. To achieve secondary callus formation, the fracture site should be allowed between 0.2–1.0mm of interfragmentary motion.³⁻⁵ MotionLoc screws were designed to fall in the middle of that range with 0.3–0.6mm of motion, as is reflected in the different diameters of the drill bits and the screws for the titanium version (Figure J). For the stainless steel MotionLoc screws, the design uses an 'Expanded Core Diameter' section to achieve this motion envelope.

Screw Profiles and Corresponding Drill Sizes 5.0mm Titanium Screw - Drill Bit = 4.3mm 4.0mm Titanium Screw - Drill Bit = 3.3mm 4.5mm Stainless Steel Screw - Drill Bit = 3.7mm 3.5mm Stainless Steel Screw - Drill Bit = 2.7mm

Figure J



Frequently Asked Questions

What happened to the Synthes DLS screw?

The Synthes Dynamic Locking Screw (DLS) was released mid-year 2012. The DLS screw is a screw shaft within an outer sleeve, as pictured to the right (Figure K).

The outer sleeve acts as the MotionLoc over-drilled near cortex hole and the inner screw shaft flexes inside of the motion envelope provided. The outer sleeve is fully threaded, allowing the claim of fixation on both the near and far cortex. The screw does achieve some flexibility though the amount of motion is very constrained by the outer sleeve. Due to dimensional restrictions of the plate hole and drill bit, there is minimal space for the inner screw shaft to flex, limiting micromotion to only 0.1mm. This limited micromotion falls outside the optimum parameters for secondary callus formation (0.2–1.0mm). The end result is a much lower stiffness reduction for the overall construct.

Synthes initiated a voluntary recall of the DLS on June 11, 2013. According to the letter submitted to the FDA, the recall was initiated due to customer complaints of breakages at the distal tip of the screw where the weld between the two pieces failed upon attempted removal, leaving the outer shaft in the bone.

Figure K



| | Optimum Parameters | Synthes DLS | MotionLoc® Screw Technology |
|------------------------------|---|--|---|
| Stiffness Reduction | Not specified; just know some is necessary | 7-16% | 50-80% depending on construct |
| Induced Motion | 0.2-1mm | 0.1mm – fall outside of target IFM range for secondary healing! | 0.4mm, on average |
| Overall Implant Construct | Easy, minimally invasive, affordable | Compatible with stainless steel and titanium; broke upon removal | Titanium and Stainless Steel options; reverse cutting threads to aid in removal |



Frequently Asked Questions

References

- Bottlang M, Lesser M, Koerber J, Doornink J, von Rechenberg B, Augat P, Fitzpatrick DC, Madey SM, Marsh JL. Far cortical locking can improve healing of fractures stabilized with locking plates. J Bone Joint Surg Am 2010;92-7:1652-60.
- Bottlang M, Fitzpatrick D, Sheerin D, Kubiak E, Gellman R, Vanda Zandschulp C, Doornink J, Earley K, Madey S. Dynamic Fixation of Distal Femur Fractures Using Far Cortical Locking Screws: A Prospective Observational Study. J Orthop Trauma 2014;28:181-188.
- 3. 2010 iData Market Research Report.
- 4. Goodship AE, Kenwright J. The influence of induced micromovement upon the healing of experimental tibial sheep fractures. J Bone Joint Surg Br 1985;67-4:650-5.
- 5. Claes LE, Heigele CA, Neidlinger-Wilke C, Kaspar D, Seidl W, Margevicius KJ, Augat P. Effects of mechanical sheep factors on the fracture healing process. Clin Orthop Relat Res 1998-355 Suppl:S132-47.
- Kenwright J, Richardson JB, Cunningham JL, White SH, Goodship AE, Adams MA, Magnussen PA, Newman JH. Axial movement and tibial fractures. A controlled randomised trial of treatment. J Bone Joint Surg Br 1991;73-4:654-9.
- 7. Fitzpatrick DC, Doornink J, Madey SM, Bottlang M. 2009. Relative stability of conventional and locked plating fixation in a model of the osteoporotic femoral diaphysis. Clin Biomech (Bristol, Avon) 24(2):203-9.
- 8. Gardner MJ, Nork SE, Huber P, Krieg JC. Stiffness modulation of locking plate constructs using bench test near cortical slotted holes: a preliminary study. J Orthop Trauma 2009;23-4:281-7.
- 9. Bottlang M, Doornink J, Byrd GD, Fitzpatrick DC, Madey SM. A nonlocking end screw can decrease fracture risk caused by locked plating in the osteoporotic diaphysis. |B|S Am 2009;91-3:620-7.
- 10. Bottlang M, Doornink J, Fitzpatrick DC, Madey SM. Far cortical locking can reduce stiffness of locked plating constructs while retaining construct strength. | Bone |oint Surg Am 2009; 91-8:1985-94.
- 11. Internal Research Reports: ZRR WA 2198 10 Rev. 1, ZRR WA 2219 10.
- 12. Bottlang M, Lesser M, Doornink J, von Rechenberg B, Augat P, Fitzpatrick DC, Madey SM, Marsh JL. Effect of construct stiffness on healing of fractures stabilized with locking plates. J Bone Joint Surg Am 2010; AAOS Award of Excellence, accepted for publication.
- 13. Internal Research Report: ZRR_WA_2674_13.



^{*} Animal studies and bench testing are not indicative of human clinical performance.

