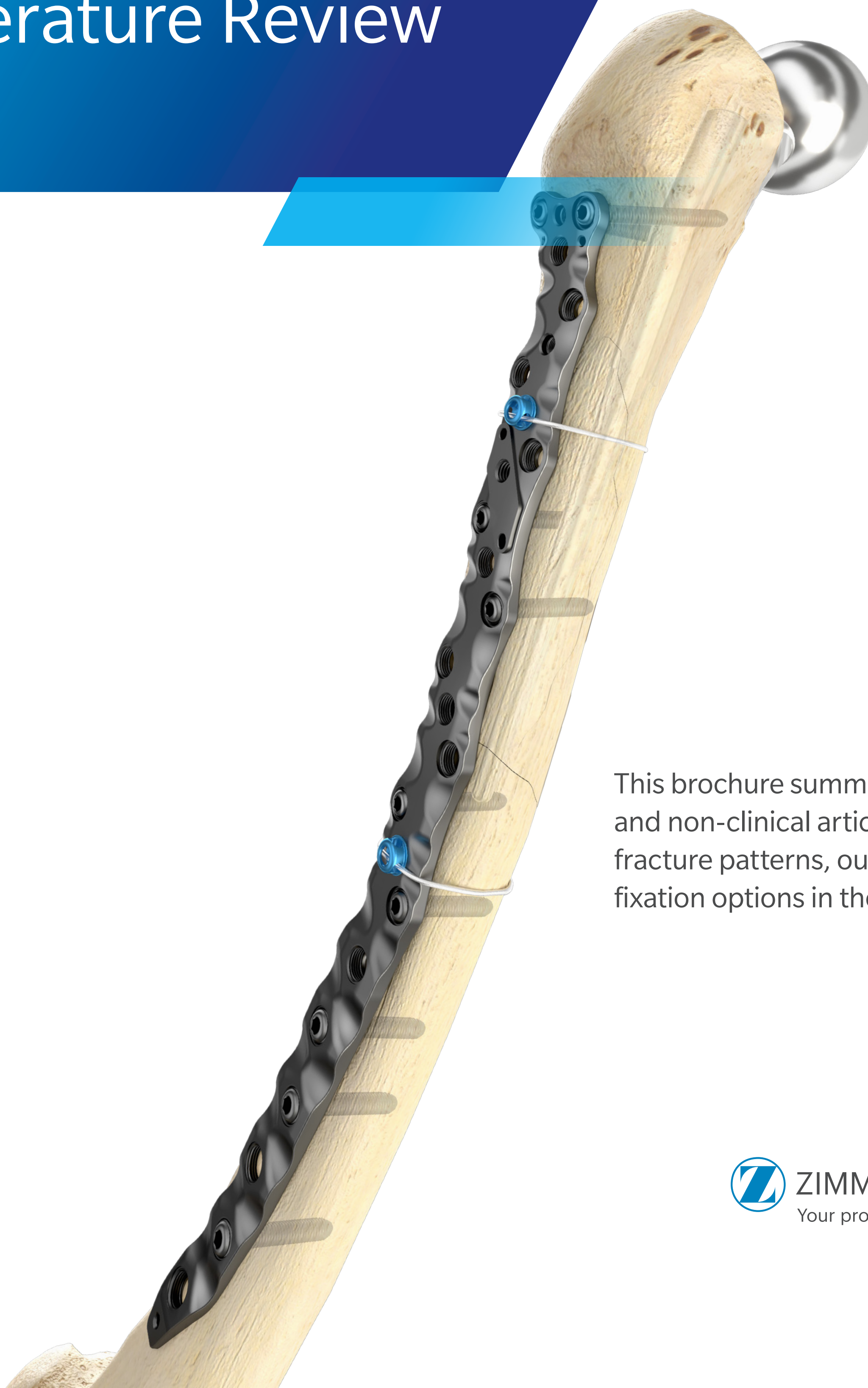
Literature Review



This brochure summarizes clinical and non-clinical articles related to fracture patterns, outcomes, and fixation options in the femur.

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Summary of "Less Invasive Polyaxial Locking Plate Fixation in Periprosthetic and Peri-implant Fractures of the Femur—A Prospective Study of 41 Patients"

Steffen Ruchholtz, Bilal El-Zayat, Dimitri Kreslo, Benjamin Bucking, Ulrike Lewan, Antonio Kruger, Ralph Zettl

Published in 2012

Introduction:

A variety of approaches for fracture stabilization around a THA and TKA exist. In this paper the authors present the results of their experience using a polyaxial, anatomical locking plating system with a standardized less invasive technique in the treatment of periprosthetic fractures (PPFs) and peri-implant (femoral nail) femur fractures.

Methods:

Over the period February 2008 to February 2011, 41 patients with 41 PPFs or peri-implant femoral fractures at one institution (University Hospital of Giessen and Marburg in Marburg, Germany) underwent surgery and the results were prospectively documented. All early and late complication were documented. Two operative techniques are defined and utilized in these procedures: (1) 'mini-open approach' (used in OTA type 32 or 33-A1 fractures) and the 'minimally invasive approach' (used for all other fracture types). This approach involved the use of closed reduction. If the surgeon was not able to adequately reduce these fractures using the minimally invasive approach, then the mini-open approach was utilized. The 41 cases comprised of 17 periprosthetic hip, 10 periprosthetic knee, 3 interprosthetic, and 11 peri-implant fractures. All fractures were treated with the NCB (Non-Contact Bridging) system, Zimmer Inc. The NCB system is a titanium polyaxial locking plating system that uses screws with a 30 degree polyaxial cone. Intrameduallry implants can be 'by-passed' by non-locking screws before these screws are locked into place by a locking cap. From September 2010 onwards all surgeries were performed using the NCB Periprosthetic system, which consists of plates that are modified versions of the original NCB plates (used in the procedures in this case series that occurred prior to September 2010). These NCB Periprosthetic plates have the same locking mechanism but are broader in the metaphyseal region. The average age of the 41 patients was 79.8 years and the cohort consisted of 33 women and 8 men. In 31 cases the NCB Distal Femur plate (original distal femur plating system) was applied, with the NCB Periprosthetic plate being applied in the other 10 cases. The American Association of Anaesthesiologists classification mean score of 2.8 reflected that most of these patients presented with a high pre-operative risk of surgical complications.

Results:

- The mortality rate after 12 months was high (22%, n=9), however none of these deaths was implant-related. The patients who died had a higher mean age (87 years vs. 78 years).
- During the follow-up period of 12 months there were 3 (7%) minor surgical complications (did not require surgical treatment) and 5 (12%) major complication (required surgical treatment).
- In the case of the 5 major complications, revision surgeries were performed.
- The rate of implant failure was very low at 5% and in these 2 cases of plate breakage, the implant failure occurred after 6 months and in both instances, there was a non-union.
- Four of the 5 revisions occurred in the mini-open group
- The study's authors found that while the mini-open approach showed favorable results with A1 fractures, major complications occurred in some instances when used with OTA 32-A2 and 33-A3 "fractures".

Conclusion:

Patients with PPFs typically present with poor pre-existing health conditions and an elevated surgical risk profile. Therefore less invasive surgical techniques are promising options. If possible, direct manipulation of the fracture zone, as in the 'minimally invasive' technique, should be avoided. Only selected two-part spiral fractures (OTA type A1) with a long contact area allow for direct reduction and cerclage fixation in order to achieve optimal axis and rotation. There is an elevated risk of local complications when the 'mini-open' technique is applied to other fracture types. The NCB system with its 30 degree polyaxial locking mechanism allows an average of 5 locked bi-cortical screws around the intramedullary implant. This system offers the surgeon the ability to use every screw as a lag screw through the plate where deemed appropriate. In the 41 cases included in this study, no failure of fixation was observed.

Summary of “Clinical outcome of Interprosthetic Femoral Fractures Treated with Polyaxial Locking Plates”

M.F. Hoffmann MD, S. Lotzien MD, T.A. Schildhauer MD, PhD

The authors declared that they did not have any conflict of interest related to this topic. The authors also declared that they did not receive grants or outside funding in support of their research or preparation of the manuscript.
Published in 2015

Introduction:

Few studies have focused on the difficulty of achieving adequate fixation in the case of interprosthetic fractures. The aim of the treatment of these fractures is to restore femur length, axis and rotation, to achieve stable fixation, and to achieve quick mobilization; all while allowing for the proper function of the surrounding prostheses and the avoidance of the need for further surgery. Over the years, a range of treatment options have been utilized for the treatment of these fractures. Initial results from plating of these fractures were poor, mainly due to rigid fixation, which disrupted periosteal blood supply and led to soft tissue damage. The use of the NCB Plate, Zimmer, might prove advantageous. This study evaluates the fixation of interprosthetic fermoral fractures with the use of the NCB plate. Particular emphasis is placed on surgical technique, complications, and clinical outcome.

Methods:

This study is a restrospective cohort study of patients who underwent surgery to address periprosthetic femur fractures over the period 2005 – 2012 in one Level I Trauma Center. All procedures were performed by fellowship-trained orthopedic trauma surgeons. Inclusion criteria were: interprosthetic femur fracture with well-fixed total hip and knee components and internal fixation, while the exclusion criteria were: extramedullary fixation with implants other than NCB or the utilization of an intramedullary implant, additional bone grafting or bone morphogenetic protein (BMP), follow-up less than 6 months, metastatic disease, and insufficient medical or radiographic data. One hundred and forty three patients underwent surgery to address 144 periprosthetic fractures during this period. Of these cases, 32 fractures were identified as being interprosthetic fractures, and of these 32, 5 were excluded due to: double plating (1 patient) and loss to follow-up (4 patients). The NCB Plate was applied (sub-muscularly if possible) through a lateral approach without polyethylene exchange.

Results:

The 2 male and 25 female patients had a mean age of 80.2 years. A total of 24 of the 27 fractures (88.9%) healed after the procedure. 3 out of the 27 patients experience a non-union, with one experiencing hardware failure. All 3 of non-unions were classified as an AO/OTA Type B fracture.

Conclusion:

Although interprosthetic fractures remain challenging to treat due to limited bone stock, poor bone quality and blood supply in many instances, the NCB locked plating provides surgeons with a reliable option for these types of fractures that may provide satisfactory results. Because AO/OTA Type B fracture showed a significantly higher non-union rate, it is important for surgeons to select the appropriate fracture type when choosing this option.

Summary of "Use of Locking Plates for Fixation of the Greater Trochanter in Patients with Hip Replacement"

Allison K. Tetreault, BA, Brian J. McGrory, MD, MS

Published in 2016

Introduction:

Fixation of the greater trochanter with total hip arthroplasty (THA) patients is a challenge. There are several possible complications with greater trochanter fixation. This study reports the first completed case series of locking plates being used in a greater trochanter fixation application. The purpose of this study was to analyze the use of locking plates in the treatment of greater trochanter fixation with the central research question being the successful use of these plates in this specific application and secondary measures being post-operative hip function; the presence of post-operative pain or limp; complications; and hardware removal.

Methods:

This retrospective study analyzed all patients within one institution who required trochanteric fixation between November 2004 and July 2014 and who had a minimum follow up of 10 months. Based on these criteria, 32 patients (10 males and 22 females) were included in the study. These 32 cases consisted of 8 primary THAs, 19 revision THAs and 5 conversions. Patients with fractures (11 of the 32) fell in 2 categories: 1. trochanteric periprosthetic fracture with prior THA and 2. trochanteric periprosthetic during THA. Osteotomy patients represented 6 of the 32 and did not included patients with extended trochanteric osteotomies. The remaining 15 patients were non-union patients. Two modes of fixation were used: 1. NCB Trochanter Plate affixed to a short NCB Periprosthetic Femur Plate, Zimmer [10 cases], and 2. a tibial plate (Zimmer, Indiana) in conjunction with cable augmentation [22 cases]. Earlier in the case series, the tibial plate and cable construct was used. At the time of the publication of the study, the institution used the NCB Trochanter Plate exclusively for this application. Maximum fixation using the 3.5mm screws were utilized proximally in the NCB Trochanter Plate for the trochanter fragment, while a minimum of 3 distal screws were used in the proximal femur plate. Primary post-operative assessment was used as the evidence for osseous consolidation/union. Hip function was rated using the modified Harris Hip Score.

Results:

Trochanteric union was achieved in 29 of the 32 cases (90.6%). Nineteen of the 22 tibial plate cases healed (fixation rate = 86.4%). All 10 NCB Trochanter Plate cases achieved union (100%). Trochanteric pain (6 of the 32 or 18.8%) was the most common complication. All 6 patients were from the tibial plate group. Other complications included: 1. Five patients having hardware removal; and 2. One patient with cable breakage. All complications were among the patients in the tibial plate with cable augmentation group.

Conclusions:

Locking plate technology is a successful method to address trochanter fixation in THA patients. The NCB Trochanter plate that is specifically designed for this application shows promising results.

Summary of "Locking Cap Designs Improve Fatigue Properties of Polyaxial Screws in Upper Extremity Applications"

Surena Namdari, MD, MS, Samir Mehta, MD, Ann Tierney, MS, Michael W. Hast, PhD
Published in 2017

Introduction:

Locking screw technology has increased the options that surgeons have in their armamentarium to treat fractures in a variety of anatomical locations. Polyaxial screws are usually secured through one of two mechanisms: (1) through the use of a locking cap that threads directly into the plate and through friction with the head of a non-locking screw, secures the screw in a fixed position (LC); and (2) through engaging the threads in the head of a locking screw with the threads of the plate (referred to in this study as cross threaded or CT design). There have been studies that have suggested that polyaxial locking implants offer no significant advantages in terms of clinical results versus fixed-angle implants. Other studies has suggested that plate and screw constructs that feature increased screw angulation are subject to performance deficiencies. This study seeks to examine the fatigue properties of polyaxial locking screw designs by classifying these implants into two groups (locking cap [LC] implants and CT implants) and compares them in the use of small fragment implants used in upper extremity fracture application at screw insertion angles of 0, 10 and 15 degrees. The study hypothesizes that LC implants would have superior fatigue properties compared to CT implants and that increased angulation in LC implants would have no impact but that increased angulation in CT implants would have a negative impact.

Methods:

Seventy-two screws were tested in 4 upper extremity implant designs using screw angles of 0, 10, and 15 degrees from center. There were 2 LC implants (LC1 – 3.5mm Proximal Humerus Implant; Miami Design Solutions; and LC2 – 4.0mm Non-Contract Bridging Proximal Humerus: Zimmer Biomet); and 2 CT implants (CT1 – 3.5mm Peri-Loc Variable-Angle Locked Plate System; Smith & Nephew; and CT2 – 3.5mm VariAx Locking System, Stryker). The order of testing was randomized. Shear force was applied using a stepwise increasing load protocol, which consisted of 11 steps. The first step imparted cyclic shear force of between 10 and 100N on the screw for 5000 cycles at a rate of 2 Hz. Each subsequent step of 5000 cycles increased the maximum force by 50 N, which increased the moment applied to the screw-plate interface by 0.2Nm. The process was repeated until failure or for a maximum of 55,000 cycles.

Results:

The results of testing showed that screw angle did not have an impact on the fatigue life of the LC implants, but that increased screw angle significantly decreased the fatigue life of the CT implants. None of the specimens in the CT group completed the 55,000 cycle fatigue test, however 32 of the 35 LC specimens completed the protocol.

Conclusion:

The use of LC constructs in the operating room requires additional time however, it provides significantly stronger screw fixation especially at oblique angles*. The authors suggest that the reason for the fatigue characteristics of LC constructs not being affected by increased angulation could be due to the spherical geometry of the screw heads and caps, which seems to result in a similar torque resistance regardless of the orientation of the screw.

* Laboratory studies are not necessarily indicative of clinical performance

Summary of “Plate Positioning in Periprosthetic or Interprosthetic Femur Fractures with Stable Implants – A Biomechanical Study”

Matthias G. Walcher, MD, Karlmeinrad Giesinger, MD, MSc, Ryan du Sart, MD,Robert E. Day, BEng, MBiomedEng, Markus S. Kuster, MD, PhD, FRACS

Published in 2016

Introduction:

Periprosthetic fractures are occurring at an increasing rate and pose a challenge to orthopedic surgeons and to healthcare systems. Periprosthetic fractures occasionally are interprosthetic fractures, occurring between a hip implant such as in the case of a short intramedullary nail or a total hip arthroplasty; and a knee implant such as in the case of a total knee arthroplasty. In the event of these fractures, a variety of treatment options are detailed in literature. Among them is the use of angular stable plate fixation around a stable implant. However, there is need for further biomechanical testing and analysis to demonstrate whether there is an optimal or safe amount of plate-to-stem overlap or gap in order to reduce the probability of additional fractures.

Methods:

This biomechanical study featured 38 composite femurs, which were reamed to an inner diameter of 23mm to mimic osteopenic bone. A cemented Weber stem was applied to each model along with an NCB Distal Femur plate, which was applied with a distance to the stem which varied from an 8cm gap to an overlap of 6cm, in 2cm increments. A total of 3 NCB Distal Femur plates and 3 Weber stems were used for this biomechanical testing, which necessitated repeated dismounting and re-use due to the number of composite femurs featured in this testing. Each construct was tested in cyclic axial loading (400 N - 1500 N) and then cyclic torsion (0.6 Nm-50 Nm) for an average of over 26 cycles excluding the first three and last cycles. 3D imaging was used to measure peak load strain around the tip of the femur. Then finally, each femur was axially loaded to failure.

Results:

The results were divided into 2 groups – a close group (<4cm overlap or gap) and a far group (>4cm overlap or gap). The results showed that strain increased with decreasing overlap or gap and was significantly higher in the close group for both torsional and axial loading. Failure load was also significantly higher in the close group.

Conclusion:

The study concluded that to minimize stress risers, a minimal gap and/or overlap of at least 6cm is recommended in osteopenic bone.

Summary of "Tangential Bicortical Locked Fixation Improves Stability in Vancouver B1 Periprosthetic Femur Fractures: A Biomechanical Study"

Gregory S. Lewis, PhD, Cyrus T. Caroom, MD, Hwabok Wee, PhD, Darin Jurgensmeier, MD, Shane D. Rothermel, BS, Michelle A. Bramer, MD, and J. Spence Reid, MD

Published in 2015

Introduction:

The increased numbers of joint arthroplasty cases has resulted in an increase in the number of periprosthetic fractures. Vancouver B1 fractures (displaced fractures below a well-fixed stem) is generally treated with plating, however achieving solid screw fixation proximally can be challenging owing to the presence of the hip implant. Several studies have examined the biomechanical strength of different approaches for treatment of periprosthetic femur fractures. This study seeks to compare torsional and axial strength and stiffness of bicortical, unicortical, and cable constructs under quasi-static conditions.

Methods:

Cemented hip stems were placed into 30 composite synthetic femurs. The distal aspect of the femur was osteotomized and plates were fixed proximally with either: (1) cerclage cables only; (2) unicortical locking screws; (3) a composite of locked screws and cables; or tangentially directed bicortical locking screws using either (4) a stainless steel LCP system with a Locking Attachment Plate (Synthes), or (5) a titanium alloy NCB System (Zimmer). A total of 6 specimens were assigned to each of the five constructs. Specimens were tested to failure through either torsional or axial loading. Three specimens from each of the five groups were tested to failure using torsional internal rotational, with the 3 other specimens from each group being subjected to axial loading.

Results:

Bicortical constructs resisted higher maximum forces than the other three constructs in torsional loading ($p<0.05$). Cables constructs exhibited lower maximum force than all other constructs, in both axial and torsional loading. The bicortical titanium construct (NCB PP) was stiffer than the bicortical stainless steel construct in axial loading.

Conclusion:

The use of bicortical locking screw fixation of the proximal femur likely provides proximal fixation in Vancouver B1 fractures when compared to traditional unicortical screws and cable-only techniques*. Although a limited sample size was used for this study, the study found that the addition of cerclage cables to unicortical screws might not offer much improvement in construct strength when treating these fractures.

* Laboratory studies are not necessarily indicative of clinical performance

Summary of "Fatigue Strength Comparison of the Zimmer NCB Periprosthetic Proximal Femur Plate and the Synthes LCP Curved Broad Plate"

Richard Compton
This was a Zimmer White paper funded by Zimmer.
Published in 2010

Introduction:

Zimmer has developed a series of fracture fixation plates designed for the femur, including one for use with a well-fixed in-situ femoral hip prosthesis. These NCB Periprosthetic Proximal Femur Plates use the same polyaxial locking screw technology as the Zimmer NCB Distal Femoral Plating System. The NCB Femoral Periprosthetic Plate System provides plates for the proximal, shaft, and distal aspects of the femur. The NCB Proximal Femur (NCB Proximal) Plate is designed to contain three regions, and is manufactured from Ti-6Al-4V ELI alloy. The prosthesis overlap zone is wide with a plurality of screw holes to allow flexibility in the surgeon's choice of screw configurations to best fit around an in-situ prosthesis. The transition zone narrows in the distal direction until the more conventional screw hole pattern is established in the distal end of the plate. The transition and prosthesis overlap zones are intended to span the fracture and support the femur during healing. The shaft zone is intended to secure the plate to the femur below both the fracture and the distal tip of the in situ hip prosthesis. To ensure the mechanical performance of the NCB Proximal Plate, a fatigue test was conducted using a locked NCB Proximal plate and NCB screw construct. The results of the fatigue test were compared to test results for the Synthes 4.5mm LCP Curved Broad Plate (LCP Plate), part number 426.622, which is manufactured from commercially pure titanium, Grade 3. This Synthes plate is indicated for use in femoral periprosthetic fractures and is a part of the Synthes LCP Periprosthetic System. Fatigue tests of the LCP plate were conducted using essentially identical methods as those used for the NCB Proximal plate.

Methods:

To provide a relevant comparison between the LCP and NCB Proximal Plates, the test method for the NCB Proximal plate should be as close as possible to that used for the LCP plate. For this reason, the test method rationales and test methods were essentially identical for both plates. Indications for these two plates include fixation of femoral fractures, including periprosthetic fractures, as classified by the Vancouver Classification. The test model was aimed at Vancouver Type B and C fractures. The NCB Proximal and LCP constructs were tested using MTS MiniBionix II servohydraulic fatigue test frames with 2,500 N capacity compression load cells. The polymeric load applicators of the test frame were indexed onto the femoral heads located on the test fixture. The test load was applied sinusoidally with a load ratio of 0.1 (R=0.1) at 6 Hz. During testing constructs were immersed in aqueous 0.9% sodium chloride solution at a temperature of 37° C. Constructs were tested to failure or to 1,000,000 cycles (whichever came first). Peak load levels for the test constructs were selected to develop estimated 1,000,000 cycle fatigue curves for each plate. Following testing, all constructs were disassembled and the plates and screws visually and fluorescent penetrant inspected to detect cracking.

Results:

For the 10 NCB Plates, 6 plates completed 1,000,000 cycles with no fracture, while 4 plates failed (fractured before reaching 1,000,000 cycles). With the LCP plate, 3 plates completed 1,000,000 cycles, with no fracture, while 4 plates failed (fractured before reaching 1,000,000 cycles). The 1,000,000 cycle fatigue strength of the locked NCB Proximal Plate and screw constructs was estimated to be 500 N load and 24.5 N-m bending moment. These values exceed the estimated 1,000,000 fatigue strength of the locked LCP constructs of 240 N load and 11.8 N-m bending moment.

Conclusion:

The NCB Proximal Plate was determined to be approximately twice as strong as the LCP Plate in bending when tested using a clinically relevant test methodology*.

* Laboratory studies are not necessarily indicative of clinical performance

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