

The Metacarpal Locked Intramedullary Nail: Comparative Biomechanical Evaluation of New Implant Design for Metacarpal Fractures

Chinnakart Boonyasirikool MD*,
Sakkarin Tanakeatsakul MD**, Sunyarn Niempoog MD*

* Department of Orthopedics, Faculty of Medicine, Thammasat University, Pathumthani, Thailand

** Department of Orthopedics, Buddhachinnaraj Hospital, Phitsanulok, Thailand

Background: The optimal fixation of metacarpal fracture should provide sufficient stability to permit early function for all types of fracture. However, it must preserve surrounding soft tissue during application and not require secondary removal due to its prominence. The prototype of metacarpal locked intramedullary nail (MCLN) was designed by our institute aiming to achieve those all features.

Objective: To biomechanically test our newly designed, locked metacarpal nail and compare with common current available fixation methods.

Material and Method: Thirty chicken humeri were divided into 3 groups ($n = 10$ per group) according to fixation techniques: MCLN, 1.5 mm miniplate (Synthes), and Kirschner wire. After complete fixation, all specimens were osteotomized at mid-shaft creating transverse fractures. Five specimens from each group were tested by load of failure under axial compression, and another five under bending force.

Results: In axial compression model, the loads to failure in MCLN group was greatest (460 ± 17 N), which was significant higher than the Kirschner wire group. The MCLN group also showed the highest load to failure in bending test (341 ± 10 N). This value reaches statistical significance when compared with plate and Kirschner wire groups.

Conclusion: The MCLN construct provided higher stability than miniplate and Kirschner wire fixation both in axial and bending mode. Together with the minimally invasive and soft tissue-friendly design concept, this study suggests that MCLN is promising fixation option for metacarpal fracture.

Keywords: Metacarpal, Metacarpal fracture, Locked intramedullary nail, Minimal invasive fixation

J Med Assoc Thai 2015; 94 (Suppl. 3): S91-S95

Full text. e-Journal: <http://www.jmatonline.com>

Metacarpal fracture is a common fracture treated by hand surgeons and general orthopedic surgeons. The incidence is up to 3.7 per 1,000 per year in men with less frequency in women⁽¹⁾. Although some of them are simple and the treatment seems to be straightforward with conventional splinting. The unstable patterns of metacarpal fractures including long oblique, comminuted, segmental and multiple fractures need more stable fixation by surgical means.

Simple, but less stable fixations methods, such as Kirschner wire and wiring need additional external splinting which unavoidably causes the stiffness of fingers and wrist. On the other hand, plate fixation is

stable enough to allow immediate motion, but at the expense of soft tissue adhesion from wider exposure. Many intramedullary fixation methods have been created aiming for minimizing the scar and offering ample stability for all types of fracture without further immobilization after operation⁽⁷⁻¹⁰⁾. Moreover, the ideal intramedullary nail design should not need to be removed due to prominence of the implant. Nevertheless, none of design in market fulfills all these purposes.

This metacarpal locked intramedullary nail (MCLN) is the prototype that have been developed by our institute. The concept of a pre-angled, antegrade tibial nail is adopted to allow closed insertion without violating the articular surface. The locking mechanism by screws is similar to the typical locked nails for larger, long bones. The goals are to provide solely enough stability for all metacarpal fracture patterns without external support for immediate motion, minimal soft

Correspondence to:

Boonyasirikool C, Department of Orthopedics Surgery, Faculty of Medicine, Thammasat University, 99 Moo 18, Khlong Nueng, Khlongluang, Pathumthani 12120, Thailand.
Phone: +66-81-8662825, Fax: +66-2-9269793
E-mail: chinnakartb@gmail.com

tissue dissection during application, and without necessity of secondary removal. In this study, we introduce the prototype implant and the results of the biomechanical testing, comparing our new locked intramedullary nail with the cross Kirschner wire and 1.5 mm miniplate (Synthes) fixation.

Material and Method

Implant design

The MCLN is a pilot implant made of stainless steel (Fig. 1). The design is based on our previous metacarpal geometric study⁽²⁾. The prototype design used in this study has a diameter of 3 mm and a length of 45 mm. The MCLN is pre-angled 10 degree with an apex at 10 mm from distal end. It provides four distal locking holes and three proximal locking holes. The holes deviate 10 degree from each other to ease the locking step. At proximal end, three locking options are also in varying orientation. All locking screws are 1.5 mm standard cortical screws (Fig. 1).

This design is applied by these following steps. The nail is inserted from dorsal surface of metacarpal through the junction between articular cartilage and the neck. The entry point is manually created by an awl. The medullary canal is enlarged by curved dilators. With aiming device, the nail is introduced to the metacarpus by manual pushing and a slight rotatory movement. The angulated design makes it curves easily through the medullary canal from the eccentric starting point. The nail is then secured to the bone by distal and proximal screws by free-hand technique under image intensifier guidance.

Biomechanical testing

The biomechanical test was conducted to investigate whether the MCLN provides sufficient stability, comparable to plate fixation, to allow early hand function. Humeri from chickens were used in this investigation to resemble the human metacarpal. Ten humeri were randomly used in each group. Fixation with Kirschner wire was performed in cross fashion by two 1.6 mm wires. Plating is completed at dorsal surface by a 6-hole length miniplate (Synthes) using four 1.5 mm-screws for fixation. In MCLN group, we applied 3 mm diameter nail as per the description above to the specimens and secured them with proximal and distal locking screws. The entry point is at the junction between the humeral head and neck. After fixations, a 1-mm wide osteotomy was made by saw, which contributes to a transverse fracture at the middle of humeral shaft (Fig. 2). Both humeral ends were buried



Fig. 1 Prototype of metacarpal locked intramedullary nail with 3 mm in diameter and 45 mm in length. Locking screws are 1.5 mm in diameter.

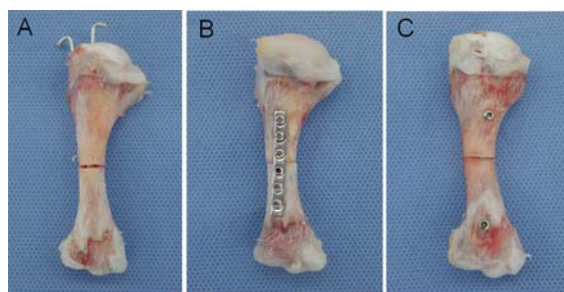


Fig. 2 Demonstrating fixation methods A) 1.6 mm Kirschner wire, B) 1.5 mm miniplate (Synthes), C) metacarpal locked intramedullary nail.

in resin. Biomechanical testing of bone-implant constructs was performed with material testing machine (Bongshin, Korea).

For axial compression test, the force was applied perpendicularly to both ends of resin-embedded specimen. The controlled axial force was loaded constantly at 10 mm/minute velocity until failure was noted⁽³⁾. Average value, for maximum load to failure, was recorded.

In bending testing, the bone constructs were fixed proximally and distally. The 3-point apex dorsal bending model was created by force loaded at palmar of osteotomy level. The controlled bending force was also loaded at the same speed as in axial test. The amount of force that produced the sharp decrease in the load-displacement curve was the ultimate strength, or load to failure.

One-way analysis of variance (ANOVA) test were used to compare the ultimate load to failure between three groups. Statistical significance was set at p -value <0.05 . The Bonferroni method was also performed for multiple comparison across three groups with the significant set at $p < 0.05$. The data analysis

was performed by SPSS software.

Results

All constructs demonstrated an acute change in load-displacement curve, which considered as failure of the construct.

Axial compression test

In axial compression model, the loads to failure in MCLN, miniplate, and Kirschner wire groups were 460 ± 17 , 423 ± 20 , and 152 ± 18 N, respectively. The MCLN group showed the highest load to failure, which was significant higher than the Kirschner wire group. When compared with miniplate fixation, although the load to failure in MCLN group is higher, it did not reach a statistically significant difference.

Bending test

The greatest load to failure belonged to MCLN, which was 341 ± 10 N. In miniplate, and Kirschner wire group, the loads to failure were 193 ± 22 and 170 ± 42 N, respectively. When compared across the fixation methods, MCLN construct provided a significantly higher load to failure than plate and Kirschner wire groups.

Discussion

Metacarpal shaft fracture is relative common fracture treated by hand surgeons. The aims of treatment are to prevent malrotation, excessive angulation and shortening. An improperly treated fracture can cause overlapping at the digital tip, pseudo-

clawing deformity. The stable fractures may be treated by conservative means, while unstable configurations need more rigid, surgical fixations. Commonly used fixation options are Kirschner wire, plate, and intramedullary device.

Less stable methods of fixation are wiring and Kirschner wire fixation. Both techniques need additional immobilization due to the insufficient stability construct. Wiring also needs wide exposure with stripping of enveloping periosteum that may preclude fracture-healing process. While Kirschner wire fixation is a popular method due to ease of percutaneous insertion, soft tissue friendly and availability, however, it can, however, result in insufficient rigidity to perform early daily activity. One of the concerned complications is pin tract infection, which was reported up to 15%⁽⁴⁾.

Plate fixation provides sufficient stability to allow immediate postoperative motion. Several complications, which may lead to unfavorable results, have been reported. One-third of patients experience complications including difficult bone healing, stiffness and implant breakage⁽⁶⁾. Besides, an inevitably soft tissue violation during wide exposure, an implant measuring several millimeters thickness is enough to produce disturbing skin and tissue irritation in many patients as high as 31%⁽⁵⁾.

The Intramedullary nail theoretically seems to be the fixation of choice for metacarpal fracture. Located inside metacarpal medullary canal, nail provides load-sharing property and do not hinder surrounding structures. Nevertheless, without locking mechanism, intramedullary fixations do not give rotational stability. Therefore, they require external splinting especially in long oblique and bicortical comminution^(7,8). Immediate rehabilitation is still impeded in these situations. Recently invented locked metacarpal nails as in the series from Orbay et al⁽⁹⁾, provides for a locking mechanism at the proximal end and is prominent, but routine secondary nail removal is needed. Another locked intramedullary fixation design (Smith and Nephew Richards Inc., Memphis, TN) was reported to be a stable technique for severe comminuted fracture, secondary to gunshot injury⁽¹⁰⁾. However, the application of a rod is performed by open technique in this design. So additional wound and scarring were unavoidable.

Ideal metacarpal nail should be able to be applied by closed technique without prominence of the implant. Secondary removal must be unnecessary. The stability of the bone-implant construct should be

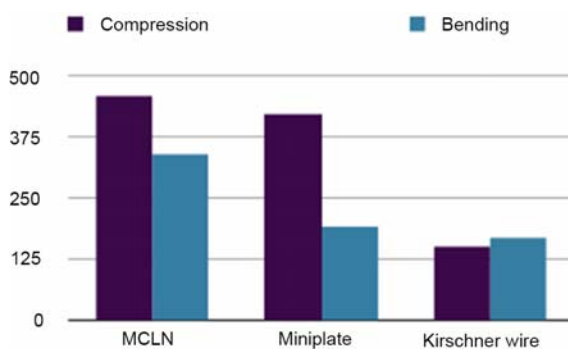


Fig. 3 Histogram showing average load to failure in each group in axial compression and bending models. In compression model, the load to failure of ILM was significant higher than Kirschner wire group only ($p < 0.05$). While in bending test, the MCLN group had significantly higher load to failure than miniplate and Kirschner wire ($p < 0.05$).

strong enough to allow prompt rehabilitation for early hand function. Our MCLN prototype was designed based on these needs. The ability to withstand the load of MCLN were tested in this study. The result showed a comparable axial construct stability of MCLN and plate groups, with slightly higher stability in MCLN group. The loads to failure in MCLN and plate groups were significantly higher than cross Kirschner wire fixation. In the bending model, MCLN still demonstrated significantly greater load to failure than plate and cross Kirschner wire group. According to study, the force across metacarpal bone during handgrip is about 200 N^(11,12). The results suggest that our MCLN fixation provides sufficient stability to allow immediate gentle motion without added external support similar to conventional plate fixation. Moreover, with less soft tissue injury during and after application, the MCLN is an interesting implant for unstable metacarpal fractures to be used in clinical setting.

There are several limitations to this biomechanical study. The chicken humeri are not fully comparable to human metacarpal bones and their mechanical properties are different. However, if the MCLN construct can tolerate higher load than the conventional plate, which is used in clinical practice in the same bones, we assume that the results from this study are able to imply in clinical use. Additionally, the test was performed on an isolated bone, in a clinical setting. Adjacent metacarpal and integrity of intermetacarpal ligaments, which might be concomitant, injured or intact, will affect the stability of the construct. The assumption that closed insertion technique will lessen the scar and joint stiffness is currently based on conceptual ideas, clinical investigation has to be further conducted.

Conclusion

To our knowledge, there is no locked intramedullary nail in clinical practice, which can be applied in minimally invasive technique, yet provides sufficient stability to permit immediate rehabilitation and without the need for secondary removal. The ability of the MCLN is to withstand greater load to failure than plate construct in both axial compression and bending model. Moreover, this design can be applied by closed means and the locking mechanism is less prominent, which make our MCLN a promising fixation option for metacarpal fracture.

What is already known on this topic ?

This is prototype of new locked metacarpal

nail designed by our institute. This implant is conceptually designed to achieve all characters of ideal fixation for metacarpal fractures. Thus, there is no prior investigative study needed concerning our newly designed, locked metacarpal nail.

What does this study add ?

The study provides preliminary data of load to failure of our new implant compared across currently used techniques. This data are applicable furthermore, to clinical use of this implant.

Acknowledgement

Special thanks should be given to technicians of the biomechanics laboratory of the National metal and Materials Technology Center, Thailand for their help in a project.

Potential conflicts of interest

None.

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แกนโลหะตามชนิดมีสกรูยึดสำหรับกระดูก metacarpal: การทดสอบเปรียบเทียบความแข็งแรงของแกนโลหะตามชนิดมีสกรูยึดชนิดใหม่

ชินกาจ บุญญสิริกุล, ศักรินทร์ ธนเกียรติสกุล, สัณญาณ เนียมบุก

ภูมิหลัง: วิธีการผ่าตัดยึดตรึงกระดูก metacarpal ที่หักที่โคนนิ้วควรให้ความแข็งแรงเพียงพอที่จะสามารถให้ผู้ป่วยเริ่มการเคลื่อนไหวเพื่อฟื้นฟูสภาพการใช้งานของมือได้ทันทีหลังผ่าตัด ในขณะที่เดียวกันวิธีการผ่าตัดต้องไม่รบกวนเนื้อเยื่อโดยรอบมากนัก รวมทั้งไม่จำเป็นต้องมาผ่าตัดเพื่อเอาโลหะออกภายหลัง ทางสถาบันจึงออกแบบแกนโลหะตามกระดูกชนิดมีสกรูยึดเพื่อให้อบสนองคุณสมบัติดังกล่าว

วัตถุประสงค์: เพื่อทดสอบความแข็งแรงทางชีวกลศาสตร์ของคั่นแบบแกนโลหะตามกระดูกชนิดมีสกรูยึด

วัสดุและวิธีการ: ใช้กระดูก humerus ของไก่จำนวน 30 ชิ้น แบ่งออกเป็น 3 กลุ่ม ตามวิธีการยึดกระดูกได้แก่ แกนโลหะตามกระดูกชนิดมีสกรูยึด แผ่นโลหะตามกระดูก และลวดตามกระดูก (Kirschner wire) หลังจากยึดกระดูกแล้วกระดูกทั้งหมดถูกตัดให้เกิดรอยหักแนวขวาง บริเวณกึ่งกลางกระดูก แต่ละกลุ่มถูกทดสอบด้วยแรงกด และแรงดัดเพื่อหาแรงที่จุดเสียหาย

ผลการศึกษา: ในการทดสอบด้วยแรงกด แรงที่จุดเสียหายของกระดูกที่ยึดด้วยแกนโลหะตามกระดูกชนิดมีสกรูยึด มีค่ามากที่สุด (460 ± 17 นิวตัน) ซึ่งมากกว่ากลุ่มที่ยึดด้วยลวดตามกระดูกอย่างมีนัยสำคัญ และเมื่อทดสอบด้วยแรงดัด กลุ่มที่ยึดด้วยแกนโลหะตามกระดูกชนิดมีสกรูยึดก็ยังมีค่าแรงที่จุดเสียหายมากที่สุด (341 ± 10 นิวตัน) ซึ่งมากกว่ากลุ่มที่ยึดด้วยแผ่นโลหะและลวดตามกระดูกอย่างมีนัยสำคัญ

สรุป: การยึดกระดูก metacarpal ที่หักด้วยแกนโลหะตามกระดูกชนิดมีสกรูยึดมีความแข็งแรงมากกว่า การยึดด้วยแผ่นโลหะและลวดตามกระดูก เมื่อประกอบกับแนวคิดการออกแบบที่ช่วยลดการบาดเจ็บต่อเนื้อเยื่อขณะใส่ แกนโลหะตามกระดูกชนิดมีสกรูจึงน่าจะสามารถเป็นวิธีการยึดตรึงกระดูก metacarpal ที่เหมาะสมได้
