Comparing Results between New Aiming Device and Freehand Technique for Distal Locking of Intramedullary Implants

Supachoke Wattanakitkrileart MD*,
Boonsin Tangtrakulwanich MD, PhD*, Varah Yuenyongviwat MD*

** Department of Orthopaedic Surgery and Physical Medicine, Faculty of Medicine, Prince of Songkla University, Hat Yai, Songkhla, Thailand*

Objective: *To test the results of a new simple aiming device compared to the freehand method for distal locking screw insertion in the intramedullary (IM) nailing procedure in terms of accuracy, radiation exposure, and operative time.*
Material and Method: *Distal screw locking procedure on 40 synthetic femoral bones with inserted intramedullary nail was done by four senior orthopedic residents using both the freehand and device-assisted techniques. Accuracy, fluoroscopic time, and operative time were recorded for the analysis.*
Results: *The new aiming device minimized fluoroscopic time with statistical significance (p-value <0.001). No operating time difference between the two techniques (p-value = 0.67). Screw misdirection was found in two incidences in the freehand technique but not found in the device-assisted technique.*
Conclusion: *The new simple aiming device can decrease fluoroscopic time and show good precision of distal locking procedure.*

Keywords: *Distal locking screw, Intramedullary nail, Technique*

J Med Assoc Thai 2016; 99 (11): 1180-4
Full text. e-Journal: *http://www.jmatonline.com*

Distal locking screw insertion is one of the problematic parts of the intramedullary (IM) nailing procedure[1]. Because of torsion after the nail passes through the isthmus of the long bone, the extension guide from the proximal nailing attachment cannot provide accurate guiding of screw insertion into the distal holes[2].

The freehand technique is generally used for screw fixation[3,4]. To accurately insert the locking screw into the distal hole with the freehand technique, a "perfect circle" image of the hole should be achieved from the fluoroscope. The drill bit tip must be placed in the middle of the circle and parallel to the X-ray beam before drilling. Every step requires fine adjustment under fluoroscopy that results in a high level of radiation exposure to the operative staff and is time consuming[5-8].

A number of techniques and devices have been developed to solve these problems. With various outcomes, none was assigned as a standardized method for screw insertion[9-12]. To solve the problem, a new simple aiming device was developed to assist in the procedure. The goal of the study was to compare the results of the distal locking screw insertion using the freehand technique and using the device-assisted technique in terms of accuracy, fluoroscopic time, and operative time of the screw insertion.

Description of the new device and technique

The concept of the device was based on the common design of an X-ray image intensifier. The surface of an image intensifier is flat and perpendicular to the X-rays which are released from the X-ray source.

The device was made from radiolucent polyvinyl chloride (PVC) pipe (Fig. 1). It consists of two parts: a body part and a sliding part. One end of the body part has a 90-degree foot-like extension to place on the flat surface of the image intensifier. At the opposite end, a three-way joint can be slided forward and backward to adjust the position while drilling. At the three-way joint, there is a short extension which is perpendicular to the long arm of the body part. The short extension has a half-circle curved holder that provides stable attachment of a power drill (Fig. 2).

Correspondence to:
Yuenyongviwat V, Department of Orthopaedic Surgery and Physical Medicine, Faculty of Medicine, Prince of Songkla University, Hat Yai, Songkhla 90110, Thailand.
Phone: +66-74-451601
E-mail: varahortho@gmail.com

Assembly of the device was meticulously prepared by the Engineering Department of our hospital and can be sterilized by ethylene oxide.

Its function is to support the power drill parallel to the X-ray beam and stabilize the power drill while drilling the bone. After a surgeon puts the drill tip at the middle of the 'perfect circle' by the freehand technique, an assistant helps applying the device by placing the long end on the image intensifier and gently moves the device to the position where the surgeon can firmly place the power drill under the drill holder of the short arm (Fig. 3). This will align the axis of the drill to be parallel to the X-rays without the need of fluoroscopic checking. The curved holder of the short extension helps in holding the power drill in place to prevent misdirection of the screw insertion.

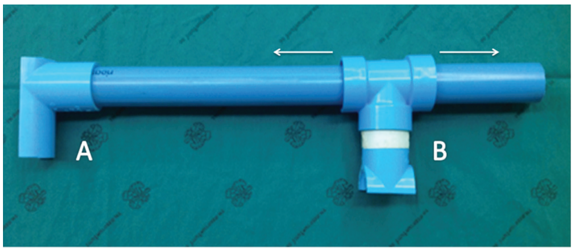

Fig. 1 The aiming device made from PVC pipe (A: body part, B: sliding part). The sliding part can move forward and backward.

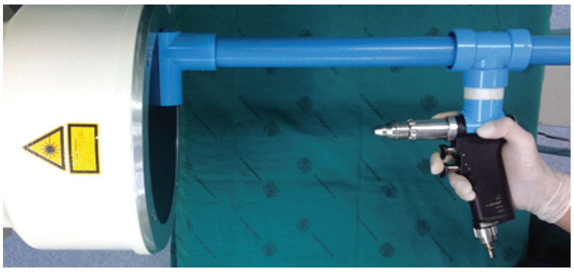

Fig. 2 The 90-degree foot-like extension of the body part was laid on the surface of the image intensifier. A power drill was placed at the half-circle curved holder of the sliding part which places the drill parallel to the X-rays beam.

Fig. 3 An assistant holds the device. The 90-degree foot-like extension of body part must be rested against the image intensifier and the drill holder at the sliding part must be placed snuggly on the power drill body.

Material and Method

The present study was approved by the Institutional Review Board, Faculty of Medicine, Songklanagarind Hospital, Prince of Songkla University.

To compare the results of the new aiming device, an experimental study using synthetic femoral bones was performed. The authors simulated the femoral IM nail operation with the patient in the supine position on a fracture table. In this setting, an 11 mm IM nail (Universal Femoral Nail®; Synthes™, West Chester, Pennsylvania, USA) was inserted into a synthetic femoral bone with a canal diameter of 12 mm (Foam cortical shell #1130-37; Sawbones®; Vashon Island, Washington, USA) and was fixed to the operative table by a synthetic bone holder. Forty synthetic femoral bones were used in the present study and each of them was covered with sponges and plastic bags as soft tissue coverage. The authors used the same image intensifier and power drill (Compact™ Air Drive II; Synthes™, West Chester, Pennsylvania, USA) throughout the study.

Four senior orthopedic residents from the Songklanagarind hospital were included in the present study and instructed to operate the screw insertion with the freehand and device-assisted techniques under the same fluoroscopic setting. Each surgeon performed the distal locking insertion 10 times that included five times with the conventional freehand technique and other five times with the device-assisted technique. The two techniques were performed alternatively under the supervision of the attending orthopedic surgeon.

Each synthetic femoral bone was used for one distal locking screw procedure and only the static distal hole was used for the test. Totally, the number of tests was 20 times for each technique.

In the present study, the accuracy of the screw insertion was calculated from the number of successful procedures which was verified by direct visual inspection of the distal locking screw inserted into the distal hole of the IM nail. If the screw was located outside of the distal hole of the IM nail, the error would be counted as "misdirected or unsuccessful" screw insertion.

Recording of the fluoroscopic time and operative times for distal locking insertion started immediately after the surgeon placed the drill tip in the middle of the 'perfect circle' and continued until the two cortices of the synthetic femoral bones were completely drilled. The fluoroscopic time and operative times were recorded in seconds from the fluoroscopic machine monitor.

Statistical analysis

Chi-square test was used for comparison of accuracy. The Wilcoxon rank sum test with continuity correction was used for comparison of radiation time and operative time.

A *p*-value <0.05 was used for statistical significant. The analyses were performed with R version 3.1.0 software (R Foundation).

Results

Twenty distal locking screws were inserted with freehand technique and another 20 distal locking screws were inserted using the device-assisted technique. All of the distal locking procedures with the device were successful except two of the distal locking procedures with the freehand technique were inserted out of the distal hole (*p*-value = 0.146). The new aiming device significantly minimized the fluoroscopic time compared with the free hand technique (*p*-value <0.005). There was no statistical difference in operative time between the two techniques (*p*-value = 0.67) (Table 1).

Discussion

The radiation exposure to surgeons is usually related to the duration of fluoroscopic time. As recommended by the International Commission on Radiological Protection, the annual dose limit of radiation exposure to the extremities is 500 mSv. Müller et al found that the average radiation exposure to the dominant hand of surgeons during the IM nail procedure was 1.27 mSv to the primary surgeon and 1.19 mSv to the first assistant[6]. Although there is no strong evidence of radiation hazard from intra-operative fluoroscopy to operative personnel, every attempt should be made to reduce the radiation exposure to the staff and patients.

Many techniques and devices reported reduced fluoroscopic time in the distal locking procedure. Finelli et al reported the freehand technique with a dip-stick technique to reduce radiation exposure time by using the standard intramedullary nail guide wire[13]. Stathopoulos et al reported successful results for the distal locking procedure by an electromagnetic computer-assisted guidance system[14]. However, all of these techniques are not widely used. This might be due to the limitation of special instruments or a learning curve was required to perform these techniques.

The new aiming device for distal locking of the IM nail is a fluoroscopic-based targeting device. It can be used with general fluoroscopic machines with a flat surface of the image intensifier. While most of the fluoroscopic-based techniques for distal locking screw insertion require eye-hand coordination of the surgeon and fine adjustment for perfect alignment, this device helps a surgeon to quickly place the power drill parallel to the X-ray beam without the need of fluoroscopy. The use of this aiming device is easy to learn and the results are reproducible. The device is resterilizable and inexpensive. From this study, the aiming device proved to significantly reduce radiation exposure. The two distal locking procedures were misdirected in the group performing the freehand technique because the surgeon was unable to hold the power drill steady while drilling the synthetic bones. The curved holder of the short arm helps to stabilize the power drill which results in better accuracy of the distal locking than in the freehand technique. However, there was no statistical significance. The operative times were not significantly different between the two techniques due to the time needed to ensure precise contact of the device to the image intensifier and to the power drill. There are limitations in the use of the device. It can be used only in the step of setting the power drill parallel to the X-ray beam and not in the whole procedure which includes distal locking screw insertion. Also, the device requires an assistant to help apply the device.

Table 1. Accuracy, median (range) fluoroscopic time, and median (range) operative times

n = 20 for each group	Freehand	New device	*p*-value
Accuracy (%)	90	100	0.146[1]
Fluoroscopic time (seconds)	8 (6-20)	3.1 (1-6)	<0.001[2]
Operative time (seconds)	27 (16-78)	21.5 (8-57)	0.160[2]

[1] Chi-square test, [2] Wilcoxon rank test

Conclusion

In the present experimental study, the new aiming device proved to reduce radiation exposure and have good accuracy in distal locking of an IM nail procedure. It can be considered as an optional technique for the distal locking procedure. Further clinical studies should be done to confirm the results.

What is already known on this topic?

Many devices and techniques were developed to solve the problem of distal locking of an IM nail. They range from freehand techniques to electromagnetic devices but none of them have become a standard technique for distal locking.

What this study adds?

This study showed that the new simple aiming device might be an alternative for the distal locking of an IM nail procedure which is cost effective and reliable.

Acknowledgements

The authors would like to thank the Faculty of Medicine, Prince of Songkla University for funding, and Glenn Shingledecker for English proof reading of this report.

Potential conflicts of interest

None.

References

1. Winquist RA. Locked Femoral Nailing. J Am Acad Orthop Surg 1993; 1: 95-105.
2. Krettek C, Mannss J, Miclau T, Schandelmaier P, Linnemann I, Tscherne H. Deformation of femoral nails with intramedullary insertion. J Orthop Res 1998; 16: 572-5.
3. Pennig D, Brug E, Kronholz HL. A new distal aiming device for locking nail fixation. Orthopedics 1988; 11: 1725-7.
4. Mehlman CT, DiPasquale TG. Radiation exposure to the orthopaedic surgical team during fluoroscopy: "how far away is far enough?". J Orthop Trauma 1997; 11: 392-8.
5. Levin PE, Schoen RW Jr, Browner BD. Radiation exposure to the surgeon during closed interlocking intramedullary nailing. J Bone Joint Surg Am 1987; 69: 761-6.
6. Müller LP, Suffner J, Wenda K, Mohr W, Rommens PM. Radiation exposure to the hands and the thyroid of the surgeon during intramedullary nailing. Injury 1998; 29: 461-8.
7. Kelley SS, Bonar S, Hussamy OD, Morrison JA. A simple technique for insertion of distal screws into interlocking nails. J Orthop Trauma 1995; 9: 227-30.
8. Knudsen CJ, Grobler GP, Close RE. Inserting the distal screws in a locked femoral nail. J Bone Joint Surg Br 1991; 73: 660-1.
9. Whatling GM, Nokes LD. Literature review of current techniques for the insertion of distal screws into intramedullary locking nails. Injury 2006; 37: 109-19.
10. Tyropoulos S, Garnavos C. A new distal targeting device for closed interlocking nailing. Injury 2001; 32: 732-5.
11. Krettek C, Mannss J, Konemann B, Miclau T, Schandelmaier P, Tscherne H. The deformation of small diameter solid tibial nails with unreamed intramedullary insertion. J Biomech 1997; 30: 391-4.
12. Suhm N, Jacob AL, Nolte LP, Regazzoni P, Messmer P. Surgical navigation based on fluoroscopy--clinical application for computer-assisted distal locking of intramedullary implants. Comput Aided Surg 2000; 5: 391-400.
13. Finelli CA, Ziran BH, Torini AP, Fernandes HJ, Dos Reis FB. Interlocking screws placed with freehand technique and uni-planar image intensification: the "dip-stick" technique. Injury 2014; 45 Suppl 5: S21-S25.
14. Stathopoulos I, Karampinas P, Evangelopoulos DS, Lampropoulou-Adamidou K, Vlamis J. Radiation-free distal locking of intramedullary nails: evaluation of a new electromagnetic computer-assisted guidance system. Injury 2013; 44: 872-5.

การศึกษาการเปรียบเทียบผลของอุปกรณ์ช่วยเล็งชนิดใหม่กับการใส่สกรูด้วยวิธีการใช้มือเปล่าแบบมาตรฐาน สำหรับการผ่าตัดใส่สกรูที่ส่วนปลายของอุปกรณ์ยึดตรึงกระดูกภายในโพรงกระดูก

ศุภะโชค วัฒนกิจไกรเลิศ, บุญสิน ตั้งตระกูลวาณิชย์, วราห์ ยืนยงวิวัฒน์

วัตถุประสงค์: *เพื่อทดสอบผลของอุปกรณ์ช่วยเล็งที่ประดิษฐ์ขึ้นใหม่ ที่ช่วยในการผ่าตัดใส่สกรูที่ส่วนปลายของอุปกรณ์ยึดตรึงกระดูกภายในโพรงกระดูก เปรียบเทียบกับวิธีผ่าตัดใส่สกรูด้วยวิธีใช้มือเปล่าแบบมาตรฐาน โดยศึกษาในด้านความแม่นยำในการใส่สกรู ปริมาณรังสีที่ใช้ และระยะเวลาที่ใช้ในการผ่าตัด*

วัสดุและวิธีการ: *ทำการทดสอบโดยใช้กระดูกต้นขาจำลอง จำนวน 40 ชิ้น โดยแต่ละชิ้นใส่อุปกรณ์ยึดตรึงกระดูกภายในโพรงกระดูก และให้แพทย์ประจำบ้านสาขาศัลยศาสตร์ออร์โธปิดิกส์ จำนวน 4 คน ทำการใส่สกรูที่ส่วนปลายของอุปกรณ์ยึดตรึงกระดูกภายในโพรงกระดูก โดยใช้อุปกรณ์ช่วยเล็งชนิดใหม่ และใช้มือเปล่าแบบมาตรฐาน แพทย์แต่ละคนจะทำการผ่าตัดทั้งสองวิธี วิธีละ 5 ครั้ง รวมเป็นวิธีละ 20 ครั้ง บันทึกความแม่นยำในการใส่สกรู ปริมาณรังสีที่ใช้ และระยะเวลาที่ใช้ในการผ่าตัด เพื่อวิเคราะห์เปรียบเทียบผล*

ผลการศึกษา: *พบว่าอุปกรณ์ช่วยเล็งชนิดใหม่ สามารถลดปริมาณรังสีที่ใช้ในการผ่าตัดอย่างมีนัยสำคัญทางสถิติเมื่อเทียบกับวิธีผ่าตัดใส่สกรูด้วยวิธีใช้มือเปล่าแบบมาตรฐาน (p-value <0.001) แต่ไม่พบความแตกต่างกันของเวลาที่ใช้ในการผ่าตัดของทั้งสองวิธี (p-value = 0.67) โดยพบการยิงสกรูผิดตำแหน่งสองครั้งในกลุ่มผ่าตัดด้วยวิธีใช้มือเปล่าตามมาตรฐาน แต่ไม่พบการยิงสกรูผิดตำแหน่งในกลุ่มที่ใช้อุปกรณ์ช่วยเล็งชนิดใหม่*

สรุป: *อุปกรณ์ช่วยเล็งชนิดใหม่ สามารถลดปริมาณรังสีที่ใช้ในการผ่าตัด และมีความแม่นยำในการผ่าตัดใส่สกรูที่ส่วนปลายของอุปกรณ์ยึดตรึงกระดูกภายในโพรงกระดูกเป็นอย่างดี*