Fit-and-Fill Analysis of Trochanteric Gamma Nail for the Thai Proximal Femur: A Virtual Simulation Study

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The present study present a three-dimensional virtual simulation method to evaluate the fit-and-fill effect of the insertion of a trochanteric gamma nail (TGN) in 98 Thai dadaveric proximal femora. The circular best fit of the 2-dimensional cross-section of the femoral canal and the nail at 4 levels [d100, d120, d140 and d160] which were located at 100, 120, 140 and 160 mm distal to the tip of the greater trochanter were calculated. The evaluation of each level included; 1) the diameters of the medullary canal, 2) the percentage of area filled by the nail in the unreamed medullary canal, 3) the minimal reamer diameter that required enlargement of the canal to accommodate TGN insertion, 4) the minimal inner cortical reaming thickness that needed to be removed, 5) the percentage of cortical bone area that needed to be removed prior to nail insertion and 6) the deviation of the nail center from the center of the medullary canal. The results showed that at 4 studied locations the diameter of unreamed medullary canal averaged 10.3 to 11.8 mm. The nail cross-section that could fill the medullary canal averaged 86.9-95.1%. The minimal reaming diameter for the medullary canal to accommodate the TGN insertion averaged 11.3 to 12.3 mm. The inner cortical thickness that should be removed averaged 0.6 to 0.8 mm. The cortical bone that needed to be removed averaged 13.6 to 19.3% of the total cortical area. The deviation of the nail center from the canal center averaged 0.3 to 0.8 mm. The present study showed some mismatching of the TGN to that of the Thai proximal femur. Appropriate reaming to prepare the medullary canal should be considered prior to TGN insertion to prevent technical problem. Future re-design of the implant may be considered for Thai patients.

Keywords : *Fracture, Trochanter, Intramedullary nail*

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A standard gamma nail (SGN) has been widely used to stabilize the trochanteric fractures and most reported papers are from European countries[1-6]. However, when the SGN was used in a small sized Asian population it found a higher incidence of complications such as thigh pain, bursting of the trochanter and cracking of the femoral shaft[7,8]. Those complications were related to the mismatch of the SGN to the proximal femur of Asian patients[7,8]. Because the SGN is very stiff, over-reaming of the medullary canal for 2-mm larger than the diameter of the nail to be inserted has been recommended[9]. However, aggressive over reaming to accommodate the large SGN in a small sized proximal femur in an Asian population will thin the bone and may compromise the bone strength[1-8]. To optimize the proper configuration of the nail the modified gamma nail (gamma AP)[10] and later the trochanteric gamma nail (TGN) were developed. The TGN has a smaller diameter (11mm at the distal part and 17 mm at the proximal part) with 4 degree valgus bending of the proximal part and with a shorter nail length of 180 mm[11]. The TGN has been launched into the market and has become

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one of the alternative fixation devices for the unstable type of trochanteric fractures. To provide more information and keep surgeons alert to the potential problem with the nail configuration, the authors, therefore conducted the fit-and-fill analysis to evaluate the geometric mismatch of a TGN to the geometry of the proximal femoral canal. The study was performed by the virtual simulation method using computerized tomography images combined with three-dimensional reverse engineering techniques for the evaluation.

Material and Method

Data of 98 Thai cadaveric femora were retrieved from the authors' previous study of Thai cadaveric femora database[8]. The donor ages ranged from 22 to 83 years (average, 48.5) at the time of death. The authors' former database for the geometry of Thai proximal femora was collected by using the CT scan with a Philips spiral CT scanner (Tomoscan AV). In the proximal region of the femur, CT scan acquisition was performed with 3 mm slice thickness and reconstruction was done with 1 mm interpolated slice thickness. For the femoral shaft, CT scan acquisition was performed with 10 mm slice thickness and reconstruction was done with 5 mm interpolated slice thickness. The optimized contours of the outer and inner cortices were developed from CT images by using 2 different thresholding values technique in the medical image processing software (Mimics, Materialise NV, Belgium). A lower thresholding value was applied to the outer cortical surface while a higher thresholding value was applied to the inner cortical surface. The resulting optimized inner and outer contours were then exported into the IGES format[8].

Virtual Insertion

Using the 3-D reverse engineering technique, the virtual insertion or superposition of a TGN into three-dimensional reconstructed proximal femur derived from CT medical images was performed using CAD software (Surfacer, Imageware division, EDS Inc.).The details of each for the virtual insertion of the TGN into the proximal femur are summarized as follows:

o The contours of the inner and outer cortices of the proximal femur were imported into the reverse engineering CAD software and displayed as point clouds (Fig. 1).

o The following parameters: *proximal shaft axis, femoral head center* and *femoral head diameter* of the proximal femur were evaluated[8].

o The virtual insertion of the TGN; nail, lag screw and distal locking screw into the intramedullary canal by aligning the distal axis of the nail with the *proximal shaft axis.* The TGN was then rotated and translated along the *proximal shaft axis* until the *lag screw axis* passes through the *femoral head center*. The tip of the lag screw was positioned 10-mm away from the boundary of the femoral head.

Fit-and-Fill Evaluation

The TGN employed in the study had a 17-mm proximal diameter, 11-mm distal diameter, 180-mm length, 130-degree neck-shaft angle and 4-degree valgus angle, with only one transverse distal locking screw hole. The lag screw had a 12-mm diameter and distal locking screw has 6.2-mm diameter. The important parameters to be used for fit-and-fill evaluation of the TGN to the Thai proximal femur and the details of each step were as follows:

- The first step was to find out the ideal nail entry point that was located centrally at the tip of the greater trochanter. It was used as a reference point (d0, C) in the study (Fig. 2). The highest CT slice in the greater trochanteric area was used to optimize the

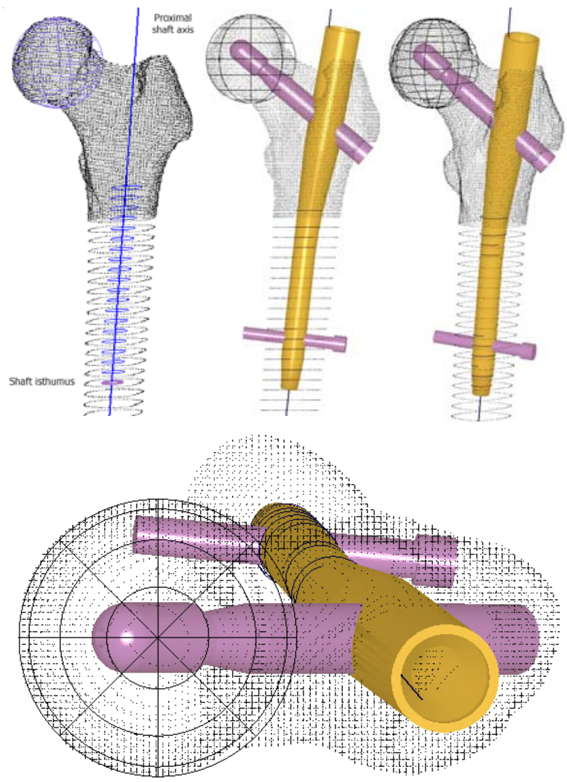


Fig. 1 The insertion of a TGN into the 3D proximal femur derived from CT images

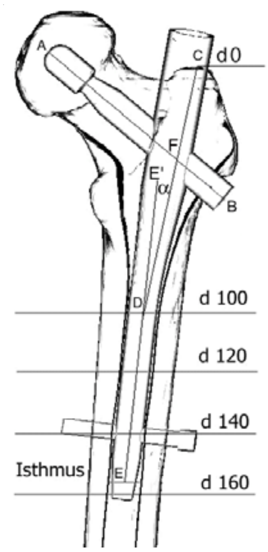
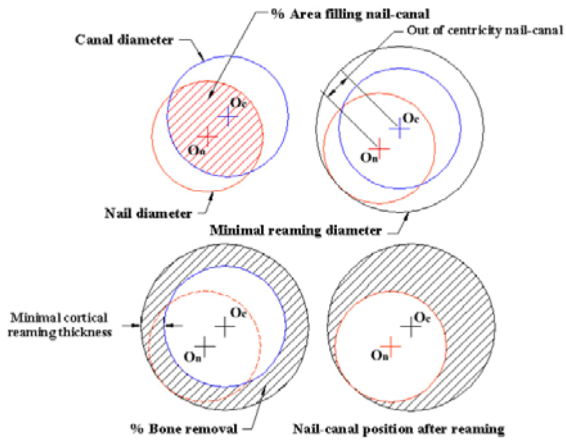


Fig. 2 The diagram of fit-and-fill study of the TGN in the proximal femur



O$_c$: Center of canal diameter; **O**$_n$: Center of nail diameter

Fig. 3 The calculated parameters for the evaluation of the fit-and-fill analysis

circular or either the elliptical fit to the extracted contour. From this circle or ellipse, the tip of the greater trochanter can be derived as its center.

- The second step was to optimize the circular fit to the 2D cross-section of the medullary canal and the nail at the level of d100, d120, d140 and d160 mm respected to the tip of the greater trochanter (d0, C). The measurement of each circular cross-section was done and evaluated the difference between the diameter of the medullary canal and the nail at the same level.
- The third step was to calculate the percentage of area of the nail cross-section that will fill into the medullary canal as intersection cross-sectional area between the nail and medullary canal (Fig.3) The measurement of the diversion of the central axes (out of centricity) between the nail and medullary canal of each cross-section was also performed.
- The fourth step was to calculate the minimal reaming diameter and the minimal inner cortical removal thickness (inner cortical thickness that needed to be removed to accommodate TGN insertion) as shown in Fig 3. Furthermore, the percentages of cortical bone removal at the level of d100, d120, d140 and d160 can be calculated as percentage of the subtraction area between the minimal reaming diameter and medullary canal diameter as in the following equations.

(1) Minimal reaming diameter = 2 x ($\text{Radius}_{\text{canal}}$ + $\text{Distance}_{\text{out of centricity}}$)

(2) Minimal inner cortical reaming thickness = (Minimal reaming dia - Medullary canal dia)/2

(3) % Bone removal = %[($\text{Area}_{\text{minimal reaming}}$ - $\text{Area}_{\text{canal}}$)/$\text{Area}_{\text{canal}}$]

- The fifth step was to measure the *valgus angle* (C-D-E', a), [13] which is the angle between the line from the tip of the greater trochanter (same as the entry point) to the circular center at level d100 and the proximal shaft axis.
- The final step was to measure the distance between the entry point level (d0) and the shaft isthmus level ($d_{\text{shaft isthmus}}$).

Results

From the study (Table 1), the medullary canal in the Thai proximal femur of the studied levels averaged 10.3-mm to 11.8-mm, ranging from the distal level (d160) to the proximal level (d100). The calculated results showed that 86.9-95.1% cross-sectional area of the nail could be contained inside the unreamed medullary canal. Virtually, the minimal reamer diameter needed to enlarge the medullary canal to accommodate the TGN insertion at the studied levels averaged 11.3 to 12.3 mm, ranging from the distal level (d160) to the proximal level (d100). The inner cortical thickness that needed to be removed before the TGN could be inserted averaged 0.6 to 0.8 mm. The cortical bony area of the studied levels that needed removal to accommodate the TGN averaged 13.6 to 19.3% of the cortical bony portion. The deviation of the nail center from the canal center averaged 0.3 to 0.8 mm.

Table 2 shows that in the Thai proximal femur the valgus angle averaged 4.1-degrees which is very similar to that of the TGN (4 degrees of valgus angle). The average distance from the level of entry point to the distal end of the nail level was 163-mm

Table 1. The results of the morphometric measurements for each parameter

Parameter	Level			
	d100	d120	d140	d160
Diameter of medullary canal (mm)				
Mean (SD)	11.8(2.4)	10.9(2.1)	10.6(1.8)	10.3(1.8)
95% confidence interval	11.4-12.3	10.5-11.3	10.2-10.9	9.9-10.7
Area of nail filling in canal (%)				
Mean (SD)	91.9(14.3)	95.1(11.4)	94.7(10.9)	86.9(17.7)
95% confidence interval	89.1-94.7	92.8-97.3	92.5-96.9	83.1-90.8
Minimal reaming diameter (mm)				
Mean (SD)	12.3(1.1)	11.7(0.7)	11.8(0.9)	11.3(1.9)
95% confidence interval	12.1-12.5	11.5-11.8	11.7-12.0	10.9-11.7
Minimal reamed cortical thickness (mm)				
Mean (SD)	0.6(0.8)	0.7(0.8)	0.8(0.9)	0.8(1.1)
95% confidence interval	0.5-0.8	0.5-0.8	0.7-1.0	0.6-1.0
Cortical area of bony removal (%)				
Mean (SD)	13.6(19.4)	15.4(20.7)	19.3(24.5)	18.8(28.3)
95% confidence interval	9.7-17.4	11.3-19.5	14.5-24.1	12.6-30.0
Out of centricity nail-canal (mm)				
Mean (SD)	0.6(0.5)	0.3(0.4)	0.4(0.5)	0.8(0.9)
95% confidence interval	0.5-0.7	0.2-0.4	0.3-0.5	0.7-1.0

SD = standard deviation

Table 2. The data of the valgus angle and the distance from the entry point to shaft isthmus

N= 98	Valgus angle (degree)	Entry point-shaft isthmus (mm)
Mean (SD)	4.1 (1.9)	163.3 (19.5)
95% confidence interval	3.8-4.5	159.5-167.2

while the TGN was 180-mm in total length. This means that there will be a proximal part with an average of 17 mm in length that will protrude out of the tip of the greater trochanter.

Discussion

With the progress of computer technology, the simulation analysis can be done to evaluate the conformity of the complex geometrical structures without destroying the specimens. To our knowledge only one study has reported the use of the simulation method to evaluate the conformity of the proximal femoral nail (PFN) and the standard gamma nail (SGN) to the proximal femoral canal[14]. However, no previous reports have studied the 3D geometric mismatch of the recent nail design or trochanteric gamma nail (TGN) for the proximal femur.

The present study presented a three-dimensional virtual simulation method to analyze the fit-and-fill of the TGN within the proximal femoral canal. The results will indirectly reflect the geometric mismatch of the TGN in the Thai proximal femur. The verification of mismatching of the TGN can be confirmed by the reported values of the calculated percentage of area of the nail cross-section that can be contained within the unreamed femoral canal. This value averaged 86-95% of the nail cross-section area. This means that the unreamed medullary canal of the proximal femur cannot accommodate the total cross-section of the nail in all studied levels. The diversion of the nail axis from the medullary axis (out of centricity between nail and canal centers) averaged 0.3-0.8 mm in the studied levels. This means that the nail axis is not well conformed to that of the axis of the medullary canal. However, this small amount of diversion can be easily compensated if the nail is smaller than the medullary canal with more room for adjusting the nail position.

The present study performed the fit-and fill analysis at the subtrochanter and proximal femoral shaft only. This is because this region has a smaller canal and thicker cortex which will have less accommodation for the mismatching problem. The area of trochanteric portion was not included for the evaluation. This is due to the fact that the trochanteric region was relatively large and can accommodate the mismatching problem well. There was also no definite medullary canal that could be outlined from the reverse engineering for the evaluation.

From Table 1, the average value of the medullary canal diameter of the Thai proximal femur was smaller than the diameter of the distal nail (11 mm) especially in the isthmus and mid-shaft region. Thus, it is necessary to ream the medullary canal to accommodate the TGN insertion. Theoretically, the minimal reaming diameter and minimal inner cortical reaming thickness can be calculated as shown in Table 1. However, due to the fact that the geometry of the nail is straight while the medullary canal of the femur has an ante-curvature, some degree of over-reaming may be necessary. The choice of minimal reaming diameter to accommodate the nail insertion should be referred to the calculated minimal reaming diameter at level d100 (12.3mm). The chosen reamer would be at least 12.5 mm in diameter for the proximal femoral shaft. Over reaming for 2-mm larger than the nail diameter (13-mm reaming for TGN 11-mm) as recommended by the surgical technique may be acceptable and close to that of the present analysis. Reaming the subtrochanteric portion of less than 12.5 mm for the TGN insertion should be avoided. This will face difficulty of nail insertion and may create cracking of the bone.

On the contrary, too much over-reaming of more than 13-mm at the subtrochanteric portion may result in thinning the bone and weakening the bone strength[8]. Pratt el al[15] showed that a 37% decrease in the torsional strength of the adult femur occurred after reaming of the medullary canal to 12 mm; after reaming to 15 mm, strength decreased by 63%. They noted a significant decrease in strength (65%) when the isthmus was reamed to 48% of the diaphyseal diameter. Reaming also is believed to increase operative time, blood loss, fracture comminution and ramping effect.

Should this trochanteric gamma nail be re-designed for Thai patients, is a common question from most Thai orthopaedic surgeons. This is because they have experienced some problems in the TGN insertion during surgery and the protruded portion of the proximal part out of the bone that may cause irritation during ambulation. If the proximal femoral nail needs to be re-design for Thai patients by taking into account the morphometric data of Thai proximal femora[12], the proximal part should be shortened for at least 10 mm to reduce the protruded portion. The proper size of the distal nail should be reduced to 10-mm diameter. Reaming the canal by 12-mm (2-mm over-reaming) will accommodate to the nail insertion well without too much thinning of the cortex. However, to reduce the size of the nail may reduce its mechanical strength. This postulation for a smaller diameter trochanteric nail (10-mm diameter) for Thai patients needs to be confirmed further with the biomechanical analysis both *in vitro* and *in vivo* testing.

From Table 2, it can be seen that the average distance from the entry point level to the isthmus level (C-E) was less than the total length of the nail (180-mm) that means the nail was inserted passing the smallest cross-section of the medullary canal. This may effect the difficulty or jamming during nail insertion. This may also be due to the bow angle in the medullary canal, which starts at the shaft isthmus level. This problem can be prevented by reducing the size by tapering the distal end of the nail. Another alternative is to choose the shorter length of the nail, which would provide fewer complications during and after surgery.

In conclusion; the present study shows that there is some degree of mismatching of the 3-D geometry of the TGN to that of the Thai proximal femur. Careful attention for adequate reaming and not too much over-reaming of the proximal femoral canal should be considered prior to TGN insertion. This will help prevent bursting and also weakening of the proximal femur. Future re-design of the trochanteric nail to minimize the geometric mismatch may need consideration for Thai patients.

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การศึกษาความพอเหมาะของรูปทรงแกนดาม Trochanteric Gamma กับกระดูกต้นขาส่วนต้นของคนไทย: การศึกษาโดยจำลองเหตุการณ์ด้วยคอมพิวเตอร์

บรรจง มไหสวริยะ, กฤษณ์ไกรพ์ สิทธิเสรีประทีป, Philip Oris, เอกชัย ชัยชนะสิริ, จินตมัย สุวรรณประทีป

การศึกษาด้วยวิธีการจำลองเหตุการณ์การสอดแกนดาม trochanteric gamma nail (TGN) เข้าในโพรงกระดูกต้นขาส่วนต้นโดยใช้ข้อมูล 3 มิติ ของกระดูกคนไทย 98 ชิ้น ด้วยวิธี reverse engineering ทำการวิเคราะห์ข้อมูลภาคตัดขวางของการวางตัวของ TGN ในโพรงกระดูกที่ระดับ 100, 120, 140, 160 มม. ต่ำจากยอดของกระดูก trocanter โดยทำการวัดและวิเคราะห์ค่าต่าง ๆ ได้แก่ 1) ขนาดเส้นผ่านศูนย์กลางของโพรงกระดูก, 2) พื้นที่ภาคตัดขวางของแกนดามที่สามารถบรรจุอยู่ในโพรงกระดูก 3) ขนาดเส้นผ่านศูนย์กลางที่เล็กที่สุดของเครื่องมือคว้านโพรงกระดูกที่ต้องใช้สำหรับคว้านโพรงกระดูกให้ใหญ่พอสำหรับการสอดแกนดาม TGN ได้ 4) ความหนาของเปลือกกระดูกที่ต้องถูกคว้านออก 5) พื้นที่ของเปลือกกระดูกที่ต้องถูกคว้านออก ก่อนที่จะสอดแกนดาม TGN ได้ 6)ระยะเบี่ยงเบนระหว่างแนวแกนของแกนดามTGNและแนวแกนของโพรงกระดูก จากการศึกษาพบค่าเฉลี่ยของขนาดโพรงกระดูกมีค่า 10.3-11.8 มม. พื้นที่ภาคตัดขวางของ TGN ที่สามารถบรรจุในโพรงกระดูกก่อนทำการคว้านมีค่าเฉลี่ยร้อยละ 86.9-95.1 ขนาดของเครื่องมือคว้านโพรงกระดูกเล็กที่สุดที่จำเป็นต้องใช้เฉลี่ย 11.3 - 12.3 มม. ความหนาของเปลือกกระดูกชั้นในที่จะต้องถูกคว้านออกก่อนสามารถสอดแกนดามTGNได้ เฉลี่ย 0.6-0.8 มม และพื้นที่ของเปลือกกระดูกที่จะต้องถูกคว้านเฉลี่ยร้อยละ 13.6-19.3 พบระยะเบี่ยงเบนของแนวแกนดาม TGN จากแนวแกนของโพรงกระดูกเฉลี่ย 0.3-0.8 มม. จากการศึกษานี้ พบว่าแกนดามTGNมีลักษณะใหญ่กว่าโพรงกระดูกส่วนต้นของคนไทย และมีรูปร่างไม่สอดคล้องพอดี จำเป็นต้องคว้านโพรงกระดูกอย่างเหมาะสมจึงจะสามารถใส่แกนดาม TGN ได้โดยไม่เกิดปัญหา การพิจารณาดัดแปลงรูปทรงของแกนดามให้มีขนาดเล็กและสั้นลง อาจช่วยให้เกิดความเหมาะสมยิ่งขึ้นสำหรับคนไทย
