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Biomechanical Performance between Single and Double Lag Screw Intra Trochanteric Nail Used to Stabilize Femoral Neck Fracture: A Finite Element Study

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ABSTRACT: The main objective of the present study was to perform a comparative study of biomechanical performance between single and double lag screws when used to stabilize femoral neck fractures. Loading used in this study was a one-legged stance including the influence of muscle forces which reflects the reality of physiological loading conditions. During the early stage of fracture, the high von Mises stress concentration regions were the lag screw and nail contact surface, the tip of the lag screw, the distal screw, and the nail contact surface. High bone stress regions are around the nail insertion hole, distal screw hole, and proximal femoral head, and the magnitude of stress around the nail insertion hole is highest. The nail insertion hole exhibits a high level of stress which ranged from 111.51 to 123.30 MPa. However, the stress on the distal screw presents a lower value which is approximately 9.18-16.60 MPa. Intramedullary fixation is an effective choice to treat the proximal femoral fracture. Intramedullary fixation achieves success in treating intertrochanteric fractures for many patients except a few.

I. INTRODUCTION

Hip fracture or femoral fracture is commonly found in elderly patients, especially, in a group that has an osteoporosis problem. Since a deterioration of bone quality reduces its strength, a low-energy trauma can potentially break a bone. Nowadays, the rising aging population worldwide cause an increased incidence of hip fractures rapidly. This trend was very concerning to orthopedic surgeons because there are many complications related to this fracture. Thus, its motivated researchers in finding the proper implant to manage a fracture.

The available research papers indicated that the internal fixation treatment has a high efficiency in treating a hip fracture (1). This method can be specifically classified into two groups including extramedullary fixators e.g., dynamic hip screw, and intramedullary fixators e.g., trochanteric gamma nail. Previous clinical studies reveal that extramedullary fixators have good clinical outcomes for stable fracture; however, they involve soft tissue invasive (2) and may counter clinical complications such as screw cut out (3), etc. On the other hand, Intramedullary fixators have been proven to be more effective, especially in their biomechanical performance, including a reduction of bending moment stress, and better load sharing (4). In addition, intramedullary fixator also presents good biological advantages such as less blood loss and shorter operation time(5).

Currently, Trochanteric Gamma Nail (TGN) is widely used as an intramedullary fixator for fracture in proximal region. This implant is available with a single and double lag screw design (6). Although a single lag screw intramedullary nail has been widely used to treat unstable femoral fracture, there are some clinical complications related to this type of implant includes screw cut out, implant failure, femoral shaft fracture etc., (7). A double lag screw was designed to minimize these complications. Several researches used double lag screw to treat their cohort patients which resulted good clinical outcomes (8, 9). Comparing with single lag screw, a double lag screw provides less complication rate and lower incidence of screw cut out. However, there still have some research that found no differences in clinical outcomes between both types of the implant (7). To support the clinical works and better understand implant-related complications, a biomechanical study employing Finite Element (FE) analysis has been constructed. Wu et al. (10) performed a comparative study of the single lag screw (PFNA II) and double lag screw (A2FN) for subtrochanteric fractures.

Hsu et al. (11) compared dynamic hip screw, gamma nail, and double lag screw nail in three types of fracture. Helwig et al. (12) used finite element analysis to study the mechanical behavior of four different implants (three single lag screw and one double lag screw) in trochanteric fracture. Brown et al. (13) investigated the biomechanical performance of a double-lag screw system under bending and torsion loading. Nevertheless, few investigations directly compare the biomechanical performance of single and double-lag screws in the treatment of femoral neck fractures. This study aimed to compare the biomechanical behavior including stress on the implant and stability of fracture between the single lag screw and double lag screw trochanteric gamma nail.

OBJECTIVES

To perform a comparative study of biomechanical performance between single and double lag screw TGN, when used to stabilize the femoral fracture in Indian patients, and determine the suitable implant for each fracture.

SCOPE OF WORK

Each case of fracture was classified by OA/OTA classification method.
Four cases were performed in this study.
Case 1: Single lag screw TGN and femoral neck fracture.
Case 2: Single lag screw TGN and femoral neck fracture without lesser trochanter.
Case 3: Double lag screw TGN and femoral neck fracture.
Case 4: Double lag screw TGN and femoral neck fracture without lesser trochanter.
This study used finite element software to acquire the biomechanical perform.

FEMORAL BONE

Femoral bone, commonly called “femur”, is classified as a lower-extremity bone. It is the longest and strongest bone in human body. Femur is located around thigh, connected to pelvis and tibia. Its main function is to support the weight from upper body and provide a mobility in daily life.

FEMORAL NECK

Femoral neck is the most common location that for a hip fracture. It is often due to osteoporosis. Femoral neck has a concave shape and connect to femoral head and femoral shaft. There is one morphological parameter that related to the femoral neck called neck shaft angle (NSA) angle, also known as caput column diaphyseal (CCD) angle. It is an angle between the longitudinal axis of femoral shaft and femoral neck axis. Commonly, normal person has 120º-135º neck shaft angle.

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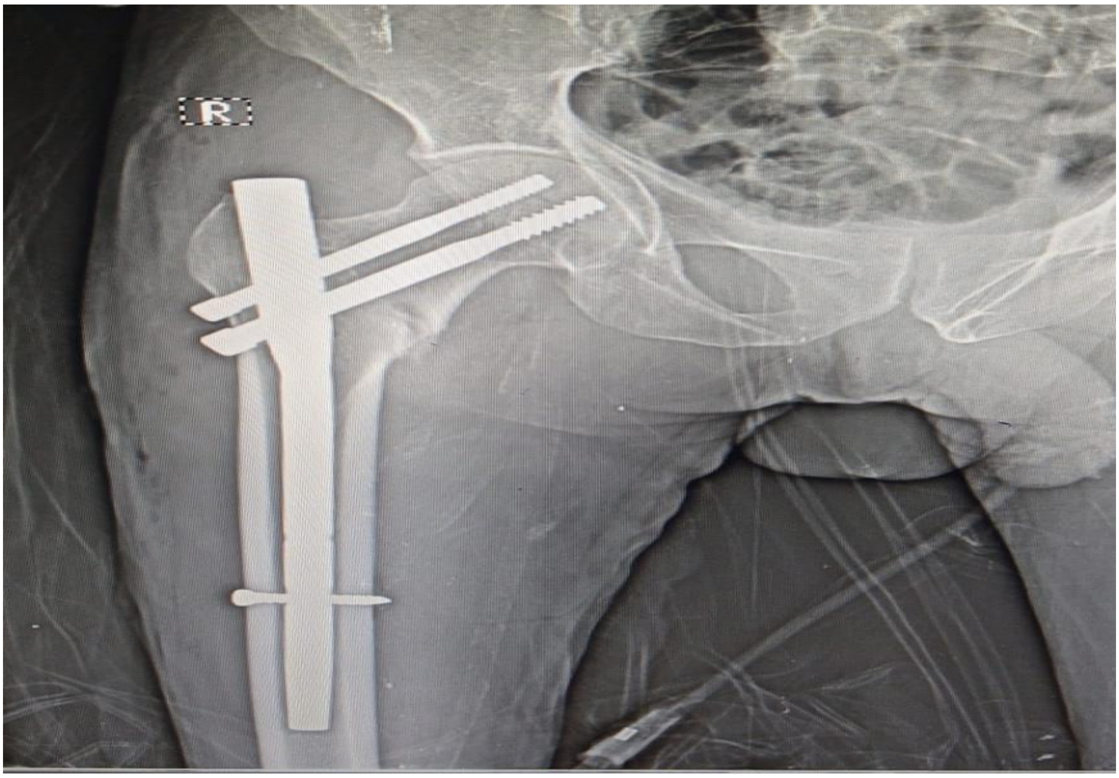
Fig. 1: Neck Shaft Angle of Femoral neck Shown in CT-image Source

FRACTURE CLASSIFICATION

Fracture patterns can be subdivided into many classes. Therefore, there are many classification methods, but the famous one is AO/OTA Fracture Classification by Orthopedic Trauma Association,2 007. This fracture classification is displayed in 4 digits of number and letter combination. As shown below (14).

XX-XX

The first digit represents the type of bone e.g., number 3 represents femoral bone or number 4 represents tibia.

The second digit shows the fracture location e.g., number 1 represents the proximal region, number 2 represents the shaft region and number 3 represents the distal region.

The third digit shows a fracture pattern, usually shown in English letters A, B, and C

The fourth digit shows a sub-fracture pattern.

For example, the fracture pattern 31-A2 means A simple spiral fracture occurs at the femoral shaft region.

PROXIMAL FEMORAL FRACTURE

According to OA/OTA classification method, proximal femoral fractures are classified into code number 31 with three regions include: 31A refers to the intertrochanteric region, 31B refers to femoral neck fracture and 31C refers to femoral head fracture.

Femoral neck fracture

Femoral neck fractures are grouped as intracapsular fractures. It is the most common location for elderly adults who have poor bone density. The severity of a femoral neck fracture is the possibility to tear the blood vessels and cutting off the blood supply to the femoral head. If the blood supply to the femoral head is cut, the bone tissue will die leading to the collapse of the bone.

FRACTURE FIXATION DEVICES

The bone remodeling process can be done without the implant, but the alignment may be not perfect or sometimes has a deformity, especially if the micro-strain is not suitable to induce the bone remodeling process. The orthopedic surgeon must use an implant to align the bone and support the weight during the initial state of the remodelling process.

The basic goal of fracture fixation is to stabilize the fractured bone, to enable fast healing of the injured bone, and to return early mobility and full function of the injured extremity. For lower extremity fractures, stability for weight bearing is the main goal.

The implant used in the market can be separate into 2 groups including external fixator and internal fixator.

EXTERNAL FIXATION

External fixation is one of the surgical treatment methods that used a frame and bar to provide mechanical stability to fracture bone, where A set of fixators is placed outside the body. The external fixator also has a pin and connector to fix all the components together. Materials that used to produce frames and bar are usually be a stainless-steel, titanium (medical grade), aluminum or carbon-fibre. but only stainless steel and titanium can be use in pin.

Fig. 2: External Fixator (Ring Type)

According to figure X, the main disadvantage of an external fixator is the bending moment because the pin that is used to fix the bone acts like a lever arm in a cantilever beam. In addition, the maximum stress usually occurs at the pin. There are two types of the external fixator.

UNILATERAL EXTERNAL FIXATOR

A unilateral external fixator is consisting of a single-axis round bar, a collection of pins, and a connector as shown in figure X. Generally, a unilateral external fixator is used to place on one side of the long bone. Many types of research reveal that a unilateral external fixator causes small damage to soft tissue compared to other types of fixators. A unilateral external fixator is varied in biomechanical properties due to the variability in the construct of the external fixator.

RING EXTERNA FIXATOR

A ring external fixator is consisting of a ring structure and a pin that is used to fix the bone with the implant structure. When the load from the body is applied to the bone, all pin installed around the structure will provide some micro-movement to the bone, resulting in bone contraction that stimulates the bone removed

INTERNAL FIXATION

Internal fixation is a surgical technique that put the implant inside the patient's body to stabilize the fracture. There are two types of internal fixators: extramedullary fixators and intramedullary fixators.

EXTRAMEDULLARY FIXATOR

Extramedullary fixators usually use the plate and screw to stabilize the fracture. An example of this implant is a dynamics hip screw (DHS). DHS is commonly used for hip fractures. There are three components of DHS, including a lag screw, a side plate, and a cortical screw to fix the plate. The orthopedic surgeon will attach the side plate at the lateral side of the proximal femur, then they will insert a lag screw through the femoral head. A plate will provide mechanical stability. Two plates usually use: dynamic compression plate and locking compression plate.

INTRAMEDULLARY FIXATOR

Intramedullary fixation device has a

hollow cylindrical nail appearance. The diameter is around 8-12 millimeters. The function of the nail is to stabilize the fracture. The load will transfer from one piece of bone to another via the nail. There are two types of intramedullary nail: the Kirscher Nail and the Interlocking nail.

Kirscher Nail has a long cylindrical shape with a slot cross-sectional. To use a kirscher nail, orthopedic surgeons will purchase the nail through the femoral canal. Thus, the stability of the nail is depending to friction between implant and bone surface. Higher contact area, more stability, thus in some patient that has a small canal diameter. Orthopaedic surgeon has to bore the canal to larger diameter and use larger implant to receive a high contact area. This type of fracture is suitable for femoral shaft fracture.

The locking nail has a screw locking hole that makes stability to implant and fractures the load transfer via lag screw have two types purchase from the proximal type called antegrade nail, and purchase from the distal side call retrograde nail. Sometime at specific location have a nail e.g., nail that stabilized at the proximal head of femur called trochanteric nail. This implant is resisted to torsion because of close circular cross sectional are increase moment of inertia represent the high resistant to torsion.

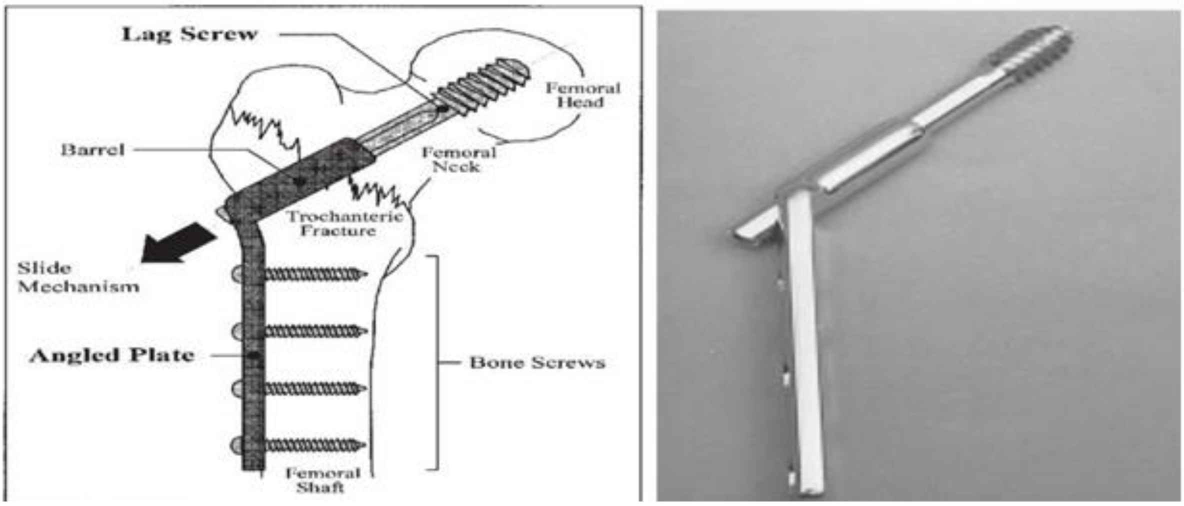

Fig. 3: (a) CT-image of DHS, (b) Sliding Compression Hip Screw

(b) Kaddour Bouazza-Marouf et al., (2000), "Robotic-assisted internal fixation of hip fractures: A fluoroscopy-based intraoperative registration technique".

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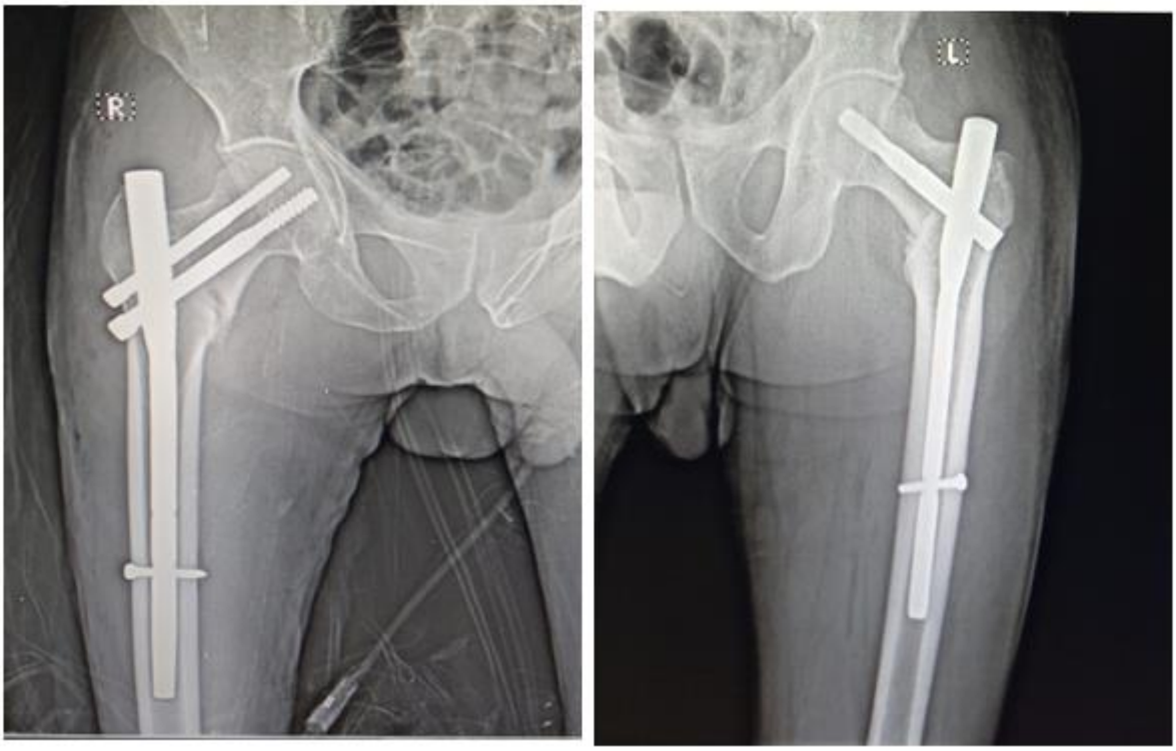

Fig. 4 : AP view of a trochanteric fracture treated with a Gamma nail.

FINITE ELEMENT ANALYSIS

Finite element analysis (FEA), or sometimes known as finite element method (FEM), is a numerical technique used to acquire the approximate solution of engineering problems. Most engineering problems have complicated geometry and boundary conditions, which makes it difficult to solve an exact solution. Thus, a numerical method such as Finite Element Method, Finite Difference Method and Finite Volume Method were introduced to provide approximate solutions to complicated engineering problems. Finite Element Method is the most powerful. FEM can be adapted to problems of great complexity and unusual geometry using grid or mesh, it is an extremely powerful tool for solving problems in heat transfer, fluid mechanics, electrostatics, and structural and mechanical systems. Furthermore, the availability of fast and inexpensive computers allows engineers and architects to solve daily engineering problems in a straightforward manner using Finite Element Method.

APPLICATION

Nowadays, Finite element method is commonly used in a wide variety of engineering field such as biomechanical, automotive, aircraft etc. Many of industries used finite element method as a tool to develop their products.

The important of FEM is its applications to any irregular geometry with various boundary conditions. Many engineering problems can be expressed by “governing equations” and “boundary conditions”. Benefits of FEM include increased accuracy, enhanced design, a faster and less expensive design process, higher quality products, increased revenue and reduced chance of field failure. But the successful application of FEM depends on the formulations, appropriate parameters and proper interpretation of the results. We now view certain applications ofFEM.

This powerful design tool has significantly improved both the standard of engineering designs and the methodology of the design process in many industrial applications. The introduction of FEM has substantially decreased the time to take products from concept to the production line. It is primarily through improved initial prototype designs using FEM that testing and development have been accelerated. In summary, benefits of FEM include increased accuracy, enhanced design and better insight into critical design parameters, virtual prototyping, fewer hardware prototypes, a faster and less expensive design cycle, increased productivity, and increasedrevenue.

For biomechanical study, the geometry of human bone is very complex. The shape of bone is irregular and varies with the position, age, gender, and race. FEM plays an important role for solution of the large and complex problems related to the human anatomy which has irregular geometry. FEM can model for biomechanical problems and treatments like implantation or analysis of deformation of various parts of human body. The 3-Dimensional FE models can be effectively used to address the medical problems, internal injuries and diseases related to knee, joints and bones.

PROCEDURE

PRE-PROCESSING

Pre-processing phase used to prepare a computational model. All input data are all defined in this stage to perform an equation of the system, this process can be subdivided into 5 steps:

COMPUTATIONAL DOMAIN

Computational domain refers to an analysis model in terms of geometrical and boundary condition. Reverse engineering method play an important role in this step. Reverse engineering has become a famous method to perform a 3D model of an interested physical object. The reverse-engineering process involves measuring an object and then reconstructing it as a 3D model. The physical object can be measured using 3D scanning technologies like CMMs, laser scanners or CT (computed tomography) scanner. The measured data alone, usually represented as a point cloud, lacks topological information, and is therefore often processed and modelled into a more usable format such as a triangular-faced mesh, a set of NURBS surfaces, or a CAD model. In biomechanical study, bone is commonly acquired the geometry by computed tomography scanner (CT scan) or magnetic resonance imaging (MRI).

MESH GENERATION

Meshing is a process that divide computational domain into small element, each element is connected by node. Element has a geometric shape with three types, includeone-dimensionelement,two-dimensionelementandthree-dimensionelement.

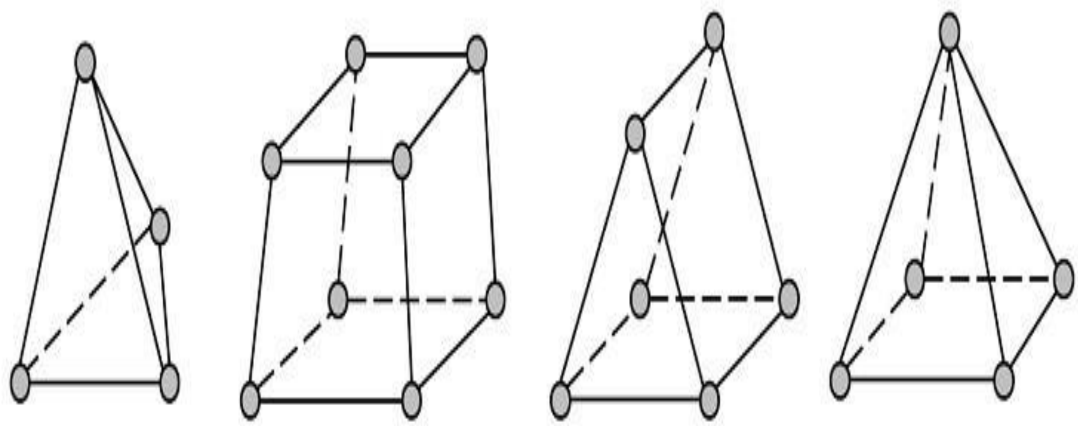

Fig : 5 : Example of three-dimensional Element MATERIAL PROPERTIES

To perform an analysis in finite element software, material properties have to be defined, commonly uses Elastic modulus and Poisson's ratio. In biomechanical study, many of research simplify the problems by define the material of bone as an isotropic.

CONTACT & LOADING CONDITION

If the computational has more than one part, it is necessary to define the contact condition. There are two types of contact condition: no relative displacement and relative displacement, depend on the physical of a computational model. Furthermore, If the contact condition is set to be a relative displacement, a coefficient of fraction is required.

II. LITERATURE REVIEW

Finite element analysis is widely accepted as one of the techniques to study about biomechanical performance of bone and implant. Many of published papers generally reported a stress-strain distribution, displacement, and strain energy density of bone and implant.

IMPLANT

Trochanteric Gamma Nail(TGN)

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TOOL
3D Sense laserscanner

METHOD
DATA ACQUISITION
Femur

Before a three-dimension model of a femur could be performed, a two-dimensional data of bone is necessarily required. Since in this study focus on a single leg stance condition, we use only one leg data from Thai woman patient with her permission to use her data for the study. A left femur was scanned with a 64-slice spiral computed tomography (CT) scanner. The scan was performed with 0.625 mm slice thickness in all regions. All CT images were saved in DICOM (Digital Imaging and Communications in Medicine) file format, then they were imported to in-house development medical image processing software to create a three-dimensional model.


Fig. 6: AP view of femoral bone in Mimics software

TGN

TGN set were acquired the geometry by 3D laser scanner (Sense, 3D System, UK). The parameters of nail showed in Figure 1. After the scan was done. The data was imported to CAD software to perform a virtual insertion of femur and implant. The insertion model is a computational model in this study.

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Fig. 7: Sample photo of TGN used in the study.

III. RESULTS

MESH CONVERGENCE

Figure X and Table X show the convergence test results. The number of elements over 84,467 shows less different in maximum von Mises stress level. Inall convergence cases, the result show that the maximum von Mises stress exhibited on contact between lag screw and TGN, conform to the hypothesis. Therefore, the number of elements over 84,467 was used in this study, as shown in FigureX.

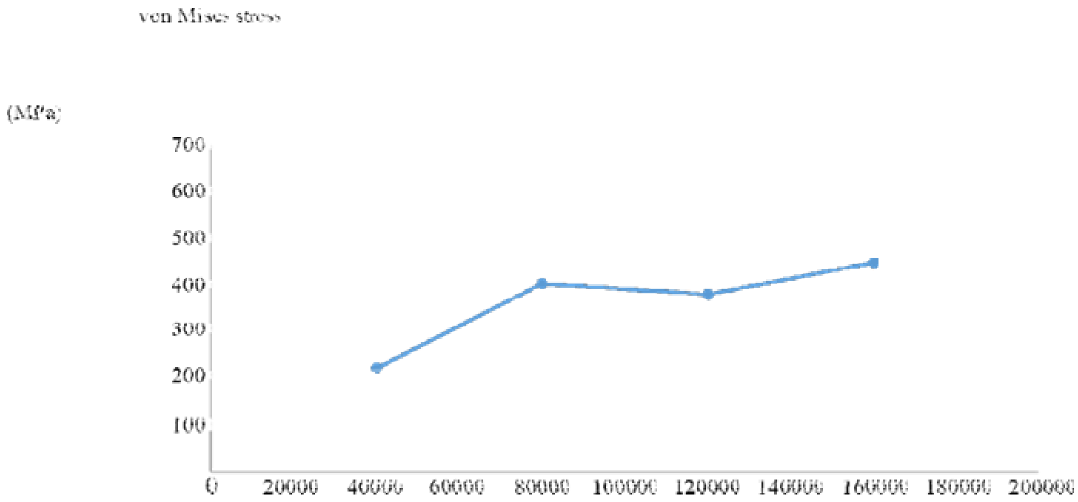

Fig. 8: Convergence test in term of maximum von Mises stress

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Element	Maximum von Mises stress (MPa)
47828	223.2
84467	403.2
136186	380.1
174412	447.4

Table 1: Mesh convergence test result

VON MISES STRESS ON THE IMPLANTS
FRACTURE TYPE I

During the early stage of fracture, the high von Mises stress concentration regions were the lag screw and nail contact surface, tip of lag screw, distal screw and nail contact surface, as shown in Figure 8. According to Table 1, it shows that the TGN with single lag screw presents a stress level close to double lag screw.

FRACTURE TYPE II

According to Table 2, the von Mises stress on the single lag screw TGN for stabilization femoral neck fracture with loss of lesser trochanter were higher than fracture type 1. However, the von Mises stress on a double lag screw TGN trochanter was reduced to lower value.

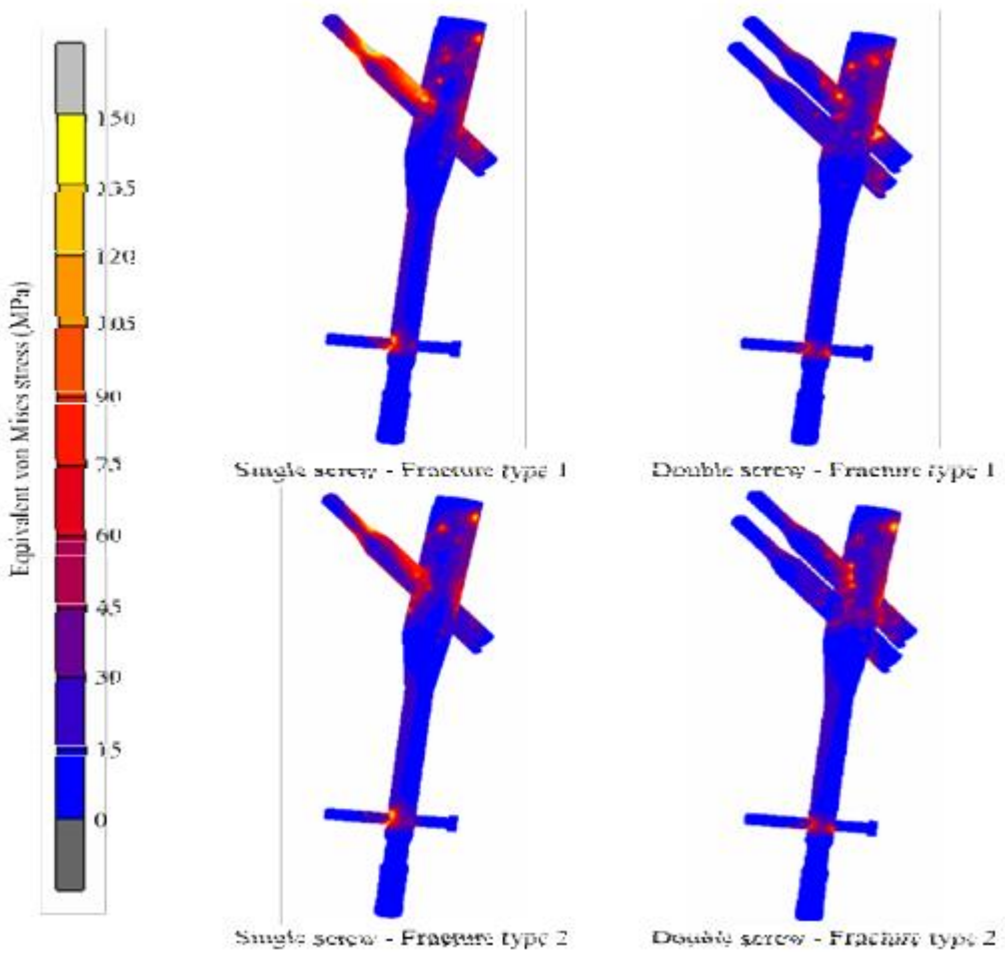

Fig. 9 : Stress distribution on the implant in case of both fracture

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Von Mises stress on the implant (MPa)

Part	Fracturetype1		Fracture type2	
	Single	**Double**	**Single**	**Double**
Lag Screw	403.2	387.5	951.0	133.3
Distal Screw	243.6	255.9	295.3	274.7
NailShaft	382.1	331.0	336.0	265.6

Table 2: Von Mises stress on each part of TGN

FRACTURE STABILIZATION

According to Table 3, the von Mises stress on the single lag screw TGN for stabilization femoral neck fracture with loss of lesser trochanter were higher than fracture type 1. However, the von Mises stress on a double lag screw TGN trochanter was reduced to lower value.

Fracture	Equivalent elastic strain(με)	
	Single	Double
Fracture type 1	127.98	71.79
Fracture type 2	94.10	56.64

BONE STRESS

According to Table 4, it represents slight differences in magnitude of stress for both femoral head and femoral shaft regions. High bone stress regions are around nail insertion hole, distal screw hole and proximal femoral head, which the magnitude of stress around nail insertion hole are highest. The nail insertion hole exhibits high level of stress which ranged from 111.51 to 123.30 MPa. However, the stress on the distal screw presents the lower value which approximately 9.18-16.60 MPa.

Von Mises stress on the implant (MPa)

Portion	Fracturetype1		Fracture type2	
	Single	**Double**	**Single**	**Double**
Insertion Hole	118.70	123.30	115.51	113.49
Distal Screw	16.60	9.41	11.73	9.18

Table 4 : Stress occurs in bone

STRAIN ENERY DENSITY ON CANCELLOUS BONE

Table 5 shows strain energy density (SED) on cancellous bone. Figure 10 shows the high concentrate SED regions are around lag screw and nail. Especially in a double lag screw TGN. The region between both lag screw in femoral head present relatively high SED magnitude which is $0.357 J/mm^3$ and $0.280 J/mm^3$ for fracture type 1and 2 respectively. SED absorbed by cancellous bone in fracture type 2 reduce to a lower value in both single and double lag screw, compared with fracturetype1.

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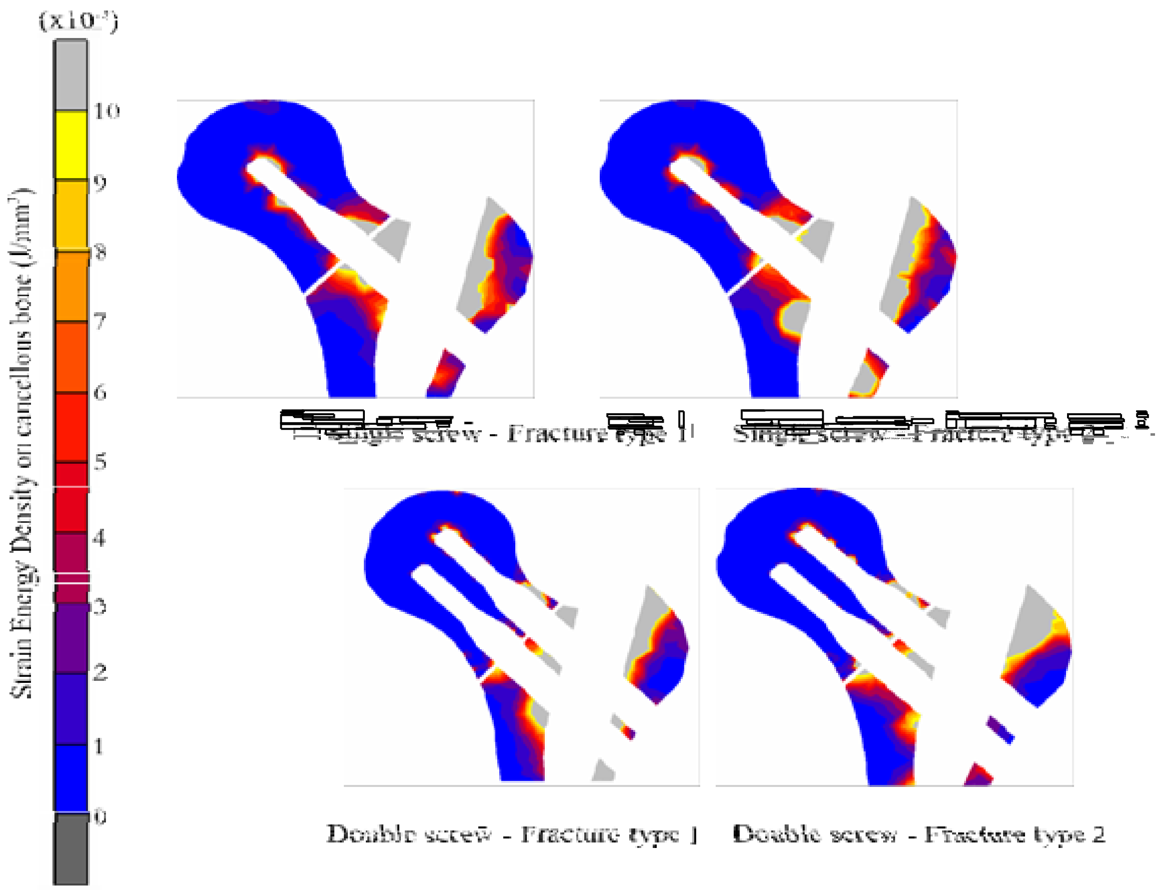

Fig. 10: Strain energy density contour on superior and inferior cancellous bone

SED (J/mm^3)

Portion	Fracturetype1		Fracture type2	
	Single	**Double**	**Single**	**Double**
Superior	0.029	0.139	0.028	0.048
Inferior	0.156	0.357	0.060	0.280

Table 5 : Strain energy density (SED) on cancellous bone.

IV. DISCUSSION

Intramedullary fixation is an effective choice to treat proximal femoral fracture. From the previous studies(24-26), the implant showed a good post-operative outcome. However, some of these still reported an implant-related complication especially a screw cut out and implant failure. A double lag screw nail has been proposed to solve with these complications. It is believed to improve the stability and reduce the risk of lag screw cut out.

The principal goal of this study was to compare the biomechanical performance between a single and double lag screw TGN when treated with femoral neck fracture. Loading used in this study was one-legged stance including influence of muscles forces which reflects the reality physiological loading conditions.

According to the finding, it can be observed that the stress concentrates highly in lag screws, especially in single lag screw stabilization. This can be explained that the effect of moment due to hip contact loading influences the bending of lag screw. Contact surface between lag screw and TGN is considered to be a pivot point of bending moment. As a result, the Equivalent von Mises stresses w high in these regions. In addition, a double lag screw produces the lower stress level than single lag screw. This can be explained that a double lag screw has the larger area to withstand the hip contact (body weight) than single lag screw. Stress in superior lag screw were higher than inferior lag screw because the load transferred to superior lag screw first before to inferior screw. Load is shared between both screws; therefore, the stress reduces to the lower magnitude. In the same way, the contact between lag screw and TGN acts as a pivot point, the stress then concentrates around that area.

Success of lag screws stabilization in TGN depends also on the quality of bone. The quality of bone determines its ability to resist deformation and absorb stress (27). A deterioration of bone is one of factors that related to bone fragility and loss of bone mass such as osteoporosis can lead to secondary fracture (28). With lower bone density, although the double lag screw is used, it may not be able to withstand the load. This may lead to lag screw penetration through cortical bone layer (29).

Under single leg stance loading condition. It can be noticed that there is a little difference in the maximum von Mises stress between both implant in fracture type 1. According to Table 4, a single lag screw TGN exhibit only 4% higher stress than double lag screw. In addition, the maximum von Mises stress of both implants are not reach beyond the yield of the stainless-steel material, which ranges from 750-960 MPa. This indicated that there is a low risk in implant failure for both implants, so we can use either single or double lag screw TGN in the treatment of a femoral neck fracture. This finding is relevant to a previous work of Hsu et al. They found that there is nosignificant difference between gammanail an ddouble screwnail when used in stable fracture. They proposed that any kind of the implant could be used to treat with the neck fracture or subtrochanteric fracture.

In the fracture type 2, the result revealed that a stress is much higher in a single lag screw TGN. The stress value reach over the yield stress. This behaviour occurs because the loss of lesser trochanter reduced the structural integrity of bone and lose mechanical support(30), so the stress mostly concentrates on the implant. It can be considered that a single lag screw TGN has a very high implant failure rate in this type of fracture. However, the double screw model showed a favourable result. An additional screw increase load sharing. The double screw TGN is highly recommended in the treatment of fracture without lessertrochanter.

According to the result, the distal screw is another region where high stress occurs. A hole on the nail surface causes a stress riser effect, high stress is concentrated near the contact of distal screw and insertion hole. This mechanical behaviour is considered as a risk of distal screw breakage. However, the stress level in these areas is much below the yield stress of material.

Elastic strain is an indicator to evaluate the stability of fracture after implant stabilization. Many previous studies used elastic strain to evaluate so (11, 18, 23). Lower elastic strain presents the better fracture stability. According to Table 5, a double lag screw TGN showed lower elastic strain value which provided a better neck fracture stabilization. The result agreed to those the clinical studies, which proposed that a double lag screw has an increased rotational stability(31, 32).

For mechanical behaviour of bone, according to table 6, femoral head and distal screw hole present a slight difference in magnitude of stress value. With these values, it is considered as sufficient low to be not a risk of fracture in this region. However, the nail insertion hole exhibited much higher stress. The values are just below the yield strength of the bone, which is around 100-170 MPa(33-37) depend on gender, age and size of the bone. There is a risk of a fracture in this region.

In order to analyse the cancellous bone, SED is used for determining the amount of energy that bone absorb. The results showed that a double lag screw TGN has a higher SED value, especially in the inferior region. This can be explained that a double lag screw TGN has to bore greater bone amount than single lag screw TGN for two lag screws insertion. The significant reduction of bone mass causes the bone in.

V. CONCLUSION

The main objective of the present study was to perform a comparative study of biomechanical performance between single and double lag screw, when used to stabilized femoral neck fracture. Loading used in this study was one-legged stance including influence of muscles forces which reflects the reality physiological loading conditions. Intramedullary fixation is an effective choice to treat proximal femoral fracture. Intramedullary fixation achieves success in treating intertrochanteric fractures for many patients exceptfew.

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