Design of Locking Mechanism on Acetabular

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Abstact*: The most important thing when implanting medical devices inside the human body is that the devices have to be standardized, in both hygienic and manufacture. There are two parts in acetabular cup, a Shell and a Liner. A Shell is embedded into patient's Acetabulum and a Liner is used to be a movement guide. These two parts are assembled with some locking mechanisms and act as an Acetabulum. Acetabular cup's manufacturers use the strength testing standard to test their products and compare the results with other brands to satisfy consumer confidence. This study aims to design and test the strength of the redesigned locking mechanism in acetabular Cup by following the international standard ASTM F1820, the testing standard for locking mechanism between Shell and Liner in acetabular cup. This study uses the finite element method to calculate the locking strength. The press fit and snap lock mechanism was obtained in the redesigning process then manufacture it with the Computer numerical control machine (CNC machine). A shell is make form stainless steel as its main material while a liner uses Ultra-High Molecular Weight Polyethylene (UHMWPE). The stimulation-testing result from finite element method in ANSYS program shows that the designed locking mechanism can stand more than 1154.3 N. When the acetabular cup is manufactured and test, the reaction force on load cell shows that the designed acetabular cup can stand more than 2410.67 N before break but the locking mechanism has not damage. Thus,it seems that the redesigned acetabular cup locking mechanism is stronger than the lowest acetabular cup in the market (more than 440 N).

Keywords : Hip prosthesis, acetabular cup, locking mechanism, snap lock

I. INTRODUCTION

Nowadays, advance technology creates many new innovations including the way to find new medical cures that better than ever before. One of the innovations in medical profession is creating prosthesis for the losses, both inside and outside the body. One of the symptoms that often happen to Thai people for a long time is Osteoarthritis. More than 7 million people have suffered from this symptom [1, 2]. This symptom is most found in elders that have severe Osteoarthritis of hip joint, and elders that have Osteoporosis or fracture of femoral neck. Some cases can be found in young people which caused from Osteonecrosis of hip which led to Avascular necrosis of femoral head. The medical treatment can be done by removing the hip joint's damaged parts and replace with hip joint prosthesis. In Thailand, the hip replacement operation requires such a high cost because the hip prosthesis must be imported from foreign countries, and not to mention the price for material and medical services; which can be more than 150,000 baht per hip. Only wealthy patients who have ability to pay can receive the treatment due to its high cost. These problems led to this research question to design and manufacture an acetabular cup that up to the standard and has a lower cost of manufacturing.

Total hip prosthesis is a type of hip prosthesis that solves the problem of pain within the patient's hip joint, which consisted of 3 main parts; stem femoral head and acetabular. Hip prosthesis that are sold in the market are designed for the appropriation for patients and easy for specialized doctors to operate. For example, shape of stem, hole for bone screw on acetabular shell shape of acetabular that uncommon for patients[3, 4].

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Acetabular cup is made up of 2 parts, a shell and a liner. A shell is made of metal which is placed into the acetabulum. A liner is the interior part which made of various materials. The most popular material that being used is ultra-high molecular weight polyethylene (UHMWPE). The shell's inside contains a locking mechanism which designed to lock a liner. The locking mechanism has to strong enough to hold a shell and a liner together because the detachment of these 2 parts is dangerous to patients. There are 2 popular types of locking mechanism, a self-locking mechanism and an assisted-locking mechanism. A self-locking mechanism can be done by designing the shape of shell and liner to attach to each other. The press fit technique with taper is obtained in recent years (sometimes, there is a snap lock to help in locking mechanism)[5].

From Kyun Lee, M.D. and Chul Kim, M.D.'s study, Effect of Inner Taper Angle of Acetabular Metal Shell on the Malseating and Dissociation Force of Ceramic Liner, the result suggested that the taper's angle at 10 degree is harder to detach liner from shell than at 18 degree but also has a higher chance to get mealseat from the samples of taper's angle at 10, 12 and 18 degree[6].

Strength of acetabular cup's locking mechanism can be tested by international standard ASTM F1820. The result from Zimmer Biomet's tests, which can be seen that the test result is at 100-720 lbf or roughly 440-3100 N. The most resistance lock models are Trilogy and Ringloc which use snap ring while other models use snap lock and press fit. It can be seen that the design and production of acetabular cup has a significant effect on domestic patients who are incapable to pay[7].

This study aims to design the locking mechanism between shell and liner using the press fit and snap lock techniques to be a guide for acetabular cup's producers in Thailand. By using the international standard test, ASTM F1820, the study's acetabular cup will has an equivalent or better attachment than acetabular cup in the market.

II. DESIGN PARAMETER AND METHOD

A. *Design parameter of locking mechanism*

1) *Conceptual design*

a) Easy to Manufacturing

The concept design of locking mechanism are to design the easiest produced product and more durable than existing product in the market. As the analysis from commercial[5], the chosen design is to include press fit with taper and use snap lock to increase durability instead of snap ring because of the complexity of production,

b) Easy to assembly

Due to difficulty in assembly the liner and shell, injury during the surgery, the designing of locking system is the important thing to do and it would not affect to the patient.

c) Good Locking strength

The locking system should be strong. When testing with the liner by following the standard (ASTM F1820) it would be resist the force more than 440 newton[7]

2) *Define parameters of locking mechanism*

The designing of parameters is defined as mentioned in Figure 2. The concept is the snap lock's shape involves with cutting tool using as mentioned in Figure 3. and groove on shell affects to the shape limitation as mentioned

a) Length of snap on the groove (a_{liner})

The distance that affects to the assembly. Because of the snap wide exceeded. It would be very difficult to put in. But if you could put on, it would be stronger with the pressing by following the standard test. The optimum phase is based on the limitation of the cutting tool and manufacturing.

b) Length of groove on shell (a_{shell})

This parameter is fixed parameter to control length of snap on the groove (a_{liner}) not over than 1 mm.

c) Slope of press fit taper (θ)

This parameter is the degree of taper that could suffer with the pressure are 10 degrees.[6]

d) The location of snap lock and taper form the base (h)

We concluded that in order to reduce stress and according to contact area theory, the location of snap lock should be placed on the taper. Plus, although snap lock should be placed near the base of the acetabular cup, production process needs to hold snap lock before mobilize. The snap lock is located a little higher in this design.

e) Degree of slope at snap lock (β)

The degree affect to the assembly. The high degree makes it easier to insert. On the other hand, if the degree is too small, it may break down of snap. As explanations above, the summarized were concluded in TABLE I.

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Figure 1. Shows the cross section of acetabular cup liner (in white) and shell (in blue) are locked by its shape of call locking mechanism.

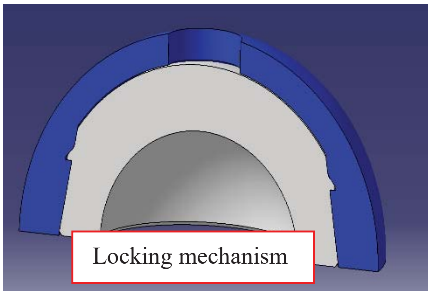

Figure 2. Shows position of design parameter on locking mechanism and the values for design show in TABLE I.

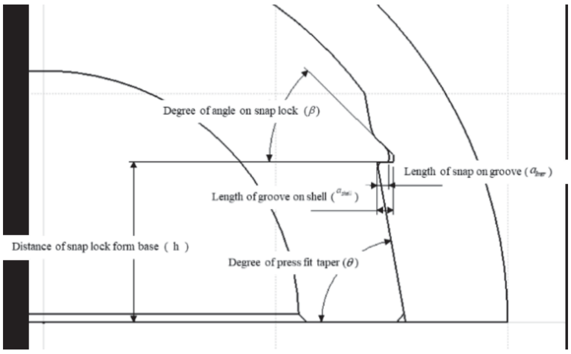

Figure 2. Define of parameter on locking mechanism.

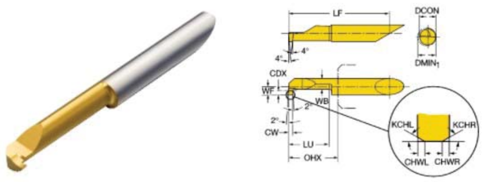

Figure 3. Sanvik CoroTurn XS

TABLE I
Parameter of locking mechanism.

a_{liner}	Length of snap on groove	0.5 mm.
a_{shell}	Length of groove on shell	1 mm.
h	Distance of snap lock form base	7 mm.
θ	Degree of press fit taper	10 degree
β	Degree of angle on snap lock	45 degree

B. ASTM F1820 Standard Test Method for Determining the Forces for Disassembly of Modular Acetabular Devices[8]

This standard test method is being used to measure the axial locking strength of the acetabular liner for modular acetabular devices. Figure 3 show the schematic of liner disassembly.

Experimental method

1. Assemble liner and shell then put them into experimental device. (see in figure 4)
2. An axial load should be to the liner through a center hole in the shell at a rate of 5.1 cm/min.
3. Record the maximum disassembly force.
4. Do the experiment until one of these events occur
   - 4.1 There is significant drop in compression force
   - 4.2 There is a damage on experimental device

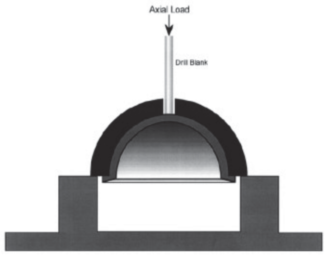

Figure 4. Schematic of Liner Disassembly

C. Primary test with Finite element method

The finite element analysis is done by using ANSYS program for primary testing before manufacturing and experiment. The acetabular cup's locking mechanism is modeling by CATIA program. All shape function that use to solve in this program is equation form element type "SOLID187 3-D 10-Node Tetrahedral Structural Solid"

1) The ANSYS's settings.

a) Type of contact

Frictional type contact will be chosen. It's the contact surfaces which when friction is included, shear forces can develop between the two bodies.

Figure 5. shows contact area that apply frictional type contact. Blue and red area are area on shell and liner respectively. The coefficient of friction is set at 0.15

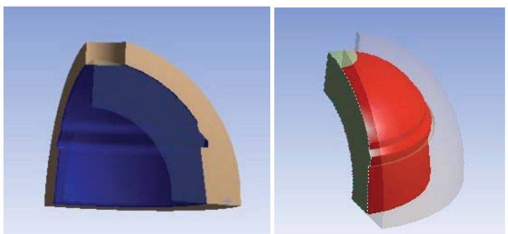

Figure 5. Chosen area on shell and liner

No separation contact: Once the contact is detected, then the target and contact surface are tied up for the rest of the analysis. The slide is allowed, but the nodes in contact are bonded to the target surface in normal direction.

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Figure 6. shows chosen target of contact area at liner and rod. Blue and red area are area on liner and rod respectively.

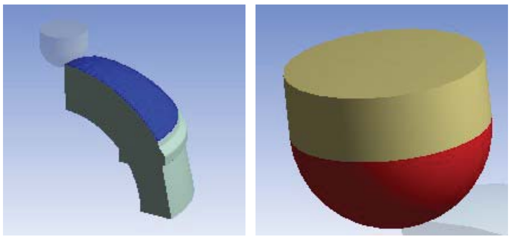

Figure 6. Chosen area on liner and rod

b) Type of support

Frictionless supports will be chosen. It will place a normal constraint on an entire surface. Translational displacement is allowed in all directions except into and out of the supported plane. Frictionless support is applied on bottom side of shell. Figure 7 show the position of support applied on the base of shell and the side of rod that apply frictionless support.

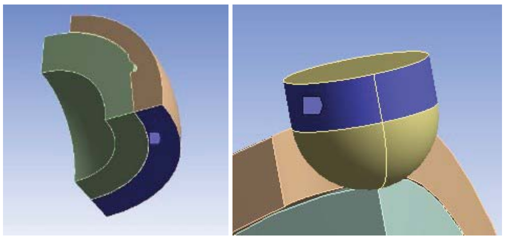

Figure 7. Chosen area frictionless supports on shell and rod

c) The element meshing

Applied function Proximity and curvature to arrange the elements. Figure 8. shows model's element using proximity and curvature meshing. There are 255,506 nodes and 133,830 elements.

Use function refinement to the area on liner as Figure 9. to show more detailed solution.

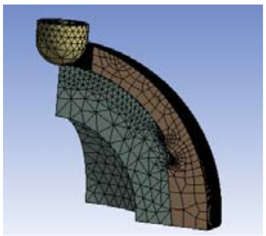

Figure 8. Model's element using proximity and curvature meshing

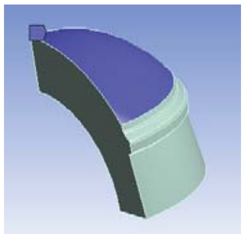

Figure 9. Chosen refinement area on liner

d) Symmetry function

Symmetry function is being used to reduce calculation time. Figure 10 show the chosen areas that will be used in symmetry function.

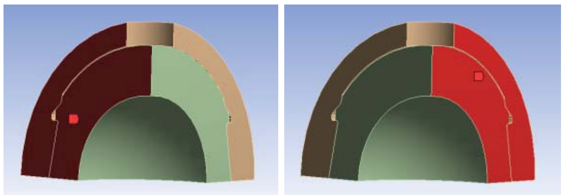

Figure 10. Area target choose for Symmetry function

e) Displacement input

To make model meets ASTM F1820 standard, the Displacement rate will be set at -5.1 cm/min in Z axis then apply at yellow area. Show in Figure 11.

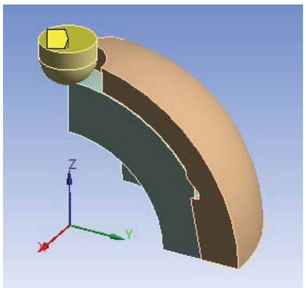

Figure 11. Chosen area displacement input.

D. Result and Discussion of Finite element method

Finite element result stated that reaction force in frictionless support has a value of 1154.3 N at 2.334 mm. Figure 12 shows liner's deform distance which can be seen that snap lock did not loosen from groove on shell

Calculated force show on frictionless support at the base of the shell it action as applied force to the top of the liner and in the snap lock, the maximum deformation occurs at the contact surface between the rod and the upper liner, where the snap lock does not move. Maximum stress occurs at the pressure position on the liner (Show in figure 13), so the finite element method calculation crash at the contact surface between the liner and the rod element on liner begins to break down at the 2.334 mm.

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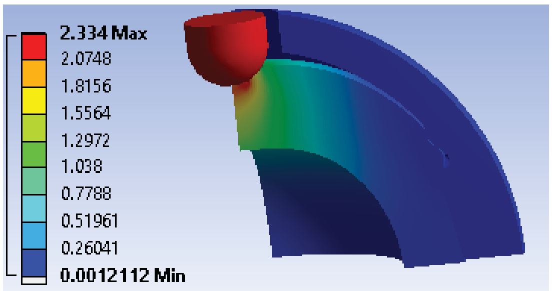

Figure 12. Total deformation of model

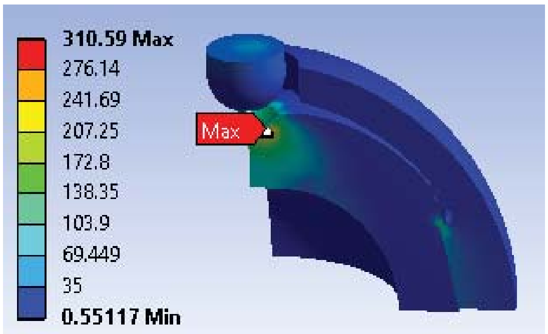

Figure 13. Position of maximum equivalent stress of model

III. PERIMENT

A. Experimental equipment

1) Testing machine INSTRON E10000 [9]

The ElectroPulsTM E10000 Linear-Torsion is a state-of-the-art, all-electric test instrument designed for dynamic and static testing on a wide range of materials and components. Specifications of INSTRON E10000 show at TABLE II.

TABLE II
Specifications of machine INSTRON E10000

Linear Dynamic Capacity	±10 kN (±2250 lbf)
Linear Static Capacity	±7 kN (±157 0 lbf)
Torsional Capacity	±100 Nm (±800 in-lb)
Stroke	60 mm (2.36 in)
Rotation	±135° as standard, ±16 revolutions
Load and Torque Weighing Accuracy	±0.5 % of indicated load or torque, or ±0.005 % of load cell capacity, whichever is greater
Daylight Opening	877 mm (34.5 in) maximum with actuator at mid stroke)
Configuration	Twin-column with actuator in upper crosshead
Lift and Locks	Electrically powered lifts with manual lever clamps
Load Cell	±10 kN ±100 Nm DynacellTM mounted to base
Electrical Supply	208 VAC to 240 VAC 32A single phase 50/60 Hz

2) Testing system base

Testing system base is the platform that use to lock acetabular cup in place by using bolt M8 6 unit onto Load Cell as can be seen in Figure 14.

Figure 14. Testing base

3) Pressing rod

Pressing bar diameter 6 mm. made of stainless steel. On the top side make flat plate to install on the gripper as can be seen in Figure 15.

Figure 15. Pressing bar

4) Acetabular cup

The shell's design that will be used in the experiment will be adjusted from the design in Figure 16 to the design in Figure 17 as a result of an easier manufacturing. This experiment will follow the standard test ASTM F1820. Figure 18 and 19 show manufacturing process and test specimen of liner and shell

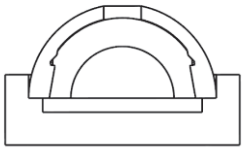

Figure 16. Cross-sectional view of acetabular cup and a testing base before redesigning.

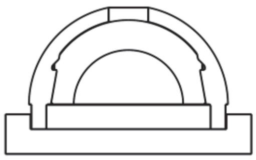

Figure 17. Cross-sectional view of acetabular cup and a testing base after redesigning

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Figure 18. Manufacturing process and Test specimen of liner

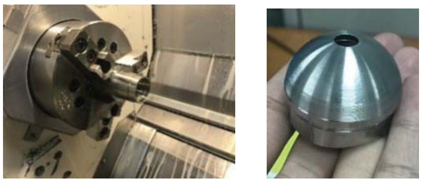

Figure 19. Manufacturing process and Test specimen of shell

Figure 20. shows the Assembled experimental device on INSTRON before the experiment. It consists of griper, pressing rod, acetabular cup, testing base, and load cell respectively

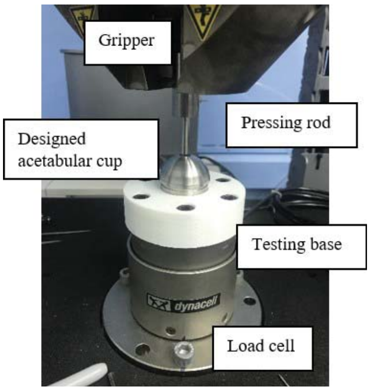

Figure 20. Assembled experimental device on testing machine before experiment.

B. Result and Discussion of Experiment

Result from testing machine can be seen in Figure 21. The X-axis shows pressing rod's position. While the Y-axis shows the force that being press onto the liner. At the beginning, the pressing rod did not contact with liner, and thus, force was equal to 0 N when the pressing rod contacted with liner at position -4.63 mm, force increase. At position -5.928 mm the maximum force is 2410.67 N, the liner was torn apart then the measured force reduced. Figure 22. shows the torn liner.

The result from the simulation and experiment is consistent. The result from finite element shows that at axial load of 1154.3 N, the liner deform 2.334 mm. while result from the experiment shows that at the measured force of 1390.6 N, the liner deform 2.33467 mm.

Limitation of finite element program could not be able to calculate until the element is torn apart which is the representation of raw material. Thus, the calculation was finished before the event which pressing rod drive through the liner.

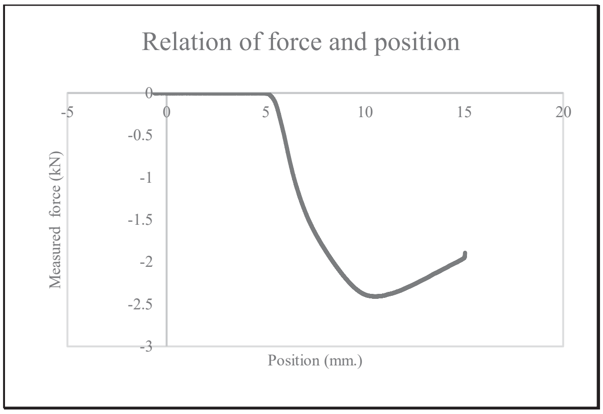

Figure 21. Result of Experiment

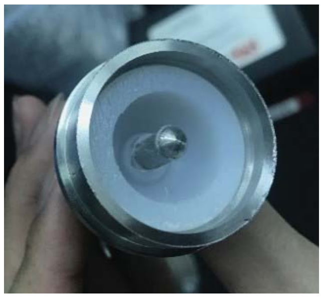

Figure 22. The break of liner after Experiment

IV. CONCLUSION

Design locking mechanism by using fixed parameter in the system of press fit and snap lock is defined by testing finite element method shows that the locking system could be stand with the force as 1154.3 Newton before the break of the liner and the locking system does not damaged. When producing and testing again with experiment, at nearly position before beak of liner in simulation test the measured force is nearly calculation force (1390.6 Newton in experiment) and liner was torn apart without locking mechanism damaged at 2410.67 Newton. It could be confirmed and demonstrated that the designed locking system is not less strong than the minimum (approximately 440 Newton) in the standard market by testing with ASTM standard F1820.

FUTURE WORK

As the experiment mentioned before, to use the finite element method for calculating the initial test is the acceptable. In the future, it would be adapt the design by changing parameter and initial calculation by using finite element for finding optimal value before producing and testing to ensure the calculation result. To be continue the production of hip prosthesis in Thailand.

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