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Design of Femoral Head in Total Hip for Vietnamese Patients

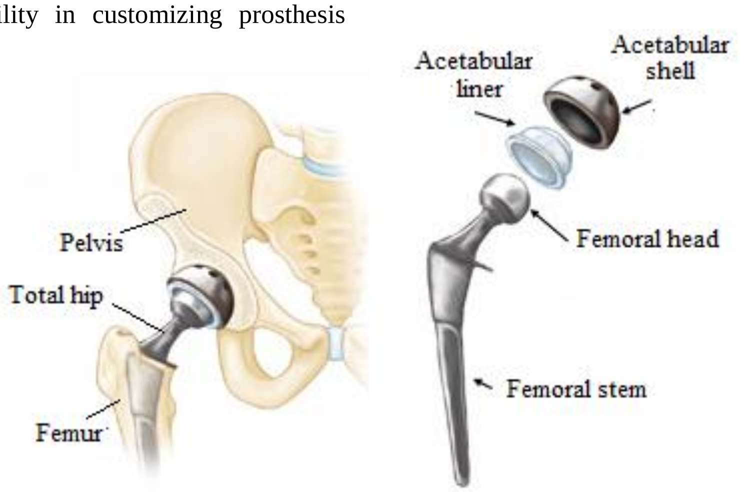
PHAM NGOC TUAN[1], NGUYEN VAN TUONG[2], PHAN PHUONG TRINH[3]
[1]Faculty of Mechanical Engineering, HCMC University of Technology, Ho Chi Minh City, Vietnam
[2]Faculty of Mechanical Engineering, Nha Trang University, Nha Trang, Vietnam
[3]Saigon Center for Development of Industrial Technology and Machinery, Ho Chi Minh City, Vietnam
Email: pntuan.vn@hcmut.edu.vn, tuongnv@ntu.edu.vn, trinh.phan@cenintec.com

Abstract: This paper presents the design procedure of femoral head in total hip for Vietnamese patients according to ISO 7206-1, ASTM F1636-95, and ASTM F2033-12. By referring, comparing and analyzing some commercialized total hips, the femoral head was designed to be suitable for Vietnamese patients. The design process includes comparing, analyzing to define the structure of the femoral head, determining basic dimensions of the femoral head from collected Vietnamese hip joints, modelling three dimensional model of the femoral head. A femoral head was also manufactured and tested for determination of resistance to static load of the femoral head according to ISO 7206-10.

Keywords: *Femoral Head, Total Hip, ISO 7206-1, ISO 7206-10, ASTM F1636-95, AFTM F 2033-12*

1. Introduction:

Total hip replacement is a surgical procedure that is used to surgically remove the diseased ball and socket of the normal hip joint and replacing them with an artificial ball and stem inserted into the femur bone and an artificial cup socket, as shown in Fig.1a. Modern total hips are modular. This modularity enhances the flexibility in customizing prosthesis sizing and fit. A total hip prosthesis consists of a femoral stem, a femoral head, an acetabular liner and an acetabular shell as shown in Fig. 1b. The femoral head, the liner and the shell act an acetabulum to retrieve the movement range of the hip.



a) in position b) unassembled

Figure 1: Total hip [1].

At present, in Vietnam, all total hips are imported from western countries. These total hips are quite expensive, compared with the average income of Vietnamese patients. Besides, most of these hips are designed and manufactured entirely to suit the geometrical considerations of the Western population [2] and they do not accurately match with most Asian patients [3]. Using a prosthesis that does not match with the anthropometry of the patient can cause complications such as aseptic loosening, improper load distribution, and discomfort [4]. Hence, designing of total hips for Vietnamese patients is a need at the moment. This paper presents the design of femoral head for Vietnamese patients, based on ISO 7206-1, ASTM F1636-95, and ASTM F2033, referenced some femoral heads which are common in Vietnam and sizes of hips of Vietnamese people.

2. Materials and methods

2.1 Principles of the design

Up to now, numerous successful designs of total hips have been commercialized and they were also standardized by the ISO and ASTM. However, there is no design of total hips for Vietnamese patients. In this study the femoral head of cementless modular total hips was designed based on the following: the structures of femoral heads standardized by the ISO and ASTM, the structures and sizes of femoral heads of some manufacturers which are common in Vietnam, some published studies on design of hip prostheses and anthropometric hip joint data of Vietnamese patients.

2.2 Material selection of femoral head

The femoral head moves within the acetabular liner. Both components become a bearing pair to restore the range of motion of the hip. The choice of materials for the femoral head and acetabular liner can be classified into two major groups: hard-on-hard and hard-on-soft. The former uses either metal or ceramic for both components, whereas, in the later group the femoral head is made of metal or ceramic and the liner is made of polymer. Materials of the femoral head must be highly resistant to deformation, wear and corrosion. Femoral heads can be made of CoCr alloys, titanium alloys or ceramic [5, 6]. CoCr alloys and titanium alloys have high hardness. Ceramic femoral heads have low friction than that of alloy femoral heads, and the corrosion of the liners can be reduced. However, ceramic femoral heads are more brittle and their fracture toughness is low compared to metals [5, 6]. In this study, the femoral head material is Ti-6Al-4V while the liner is made of ultra high molecular weight polyethylene (UHMWPE). Some properties of Ti-6Al-4V are presented in Tab. 1.

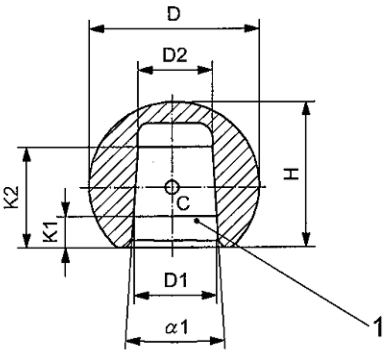
Table 1: Some properties of Ti-6Al-4V [5]

Endurance	414 MPa
Ultimate strength	965 MPa
Yield strength	880 MPa
Elastic modulus	110 GPa
Fracture toughness	44-66 $MPa.m^{1/2}$

2.3 Determination of shape and size of the femoral head

In the past few decades there has been a trend toward modularity using designs that include metal-on-metal conical taper connections. Modularity offers several benefits, including the pairing of mismatched sizes and materials by the surgeon to best accommodate the specific physiological and anatomical needs of a patient without exorbitant manufacturing cost [5]. The femoral head of a modular total hip is quite simple. It is often a truncated spherical ball with a borehole. The spherical surface is the bearing surface of the hip. The femoral head and the femoral stem of a modular total hip are connected by a Morse taper junction – the taper neck of the stem and the borehole of the head.

Although the shape modular femoral heads is simple but the designs of modular femoral heads are varied by manufacturers mainly in dimensions and the geometry of the borehole. Two borehole shapes namely the flat bottom and keyhole are currently used in the manufacturing industry for hip joint prostheses [7]. The length, surface roughness and angle of the taper of the borehole vary with the manufacturer [8]. The ISO 7206-1 standard [9] gives designation of dimensions of modular femoral heads as illustrated in Fig. 2. This study chose the type of femoral head which is described in ISO 7206-1. Besides, some specifications of boreholes in the ASTM F1636-95 [10] and bearing surfaces in ASTM F2033−12 [11] were also used.



C – Nominal center of the head; D – Diameter of head; D1 – Female cone diameter at K1; D2 – Female cone diameter at K2; H – Head length K1 – Measurement distance 1, female cone K2 – Measurement distance 2, female cone; α1 – Female angle; 1- Female cone
Figure 2: Designation of dimensions of modular heads [9].

The diameter of a femoral head depends on the sizes of acetabular components. To define these sizes, the geometrical parameters of femurs and pelves have to be determined. In this research, the left and right hip joints of 65 Vietnamese patients in the age range of 20 to 35 were evaluated. The hip joints were scanned by a scanner. After scanning, the CT images of each femur and pelvis, saved in DICOM format, were imported to Mimics environment (Materialise, Belgium) in order to generate a 3D (three-dimensional) model of the femur and the pelvis. In Mimics, the 3D model of the femur and the pelvis were developed. These 3D models were then exported to STL (Stereolithography) format. The STL files of the 3D femur and pelvis models can be processed in CATIA V5 (Dassault Systemes, France) to determine their geometrical parameters. From the measured data, some basic dimensions of the hip prosthesis for Vietnamese patients were defined as follows:

- The outside diameter of the acetabular shell: 48 mm.
- The inside diameter of the acetabular liner: 28 mm.
- The femoral head diameter: 28 mm.

By reference to femoral heads of Zimmer Biomet (Warsaw, Indiana, USA) and Naton (Beijing, China) which are most common in Vietnam, some dimensions of the head can be defined as follows:

- Head length, H = 24.5 mm.
- Depth of cone hole: 16.2 mm.
- Distance from the nominal center of the head to the flat surface of the head: 10.5 mm.

- Angle of entry chamfer: 30^0.
According to ASTM F1636-95:
- Female cone diameter at K1: D1 = 11.2 mm.
- Measurement distance 1 of female cone: K1 = 8.7 mm.
- Female cone: $\alpha1 = 5^051'$.
According to ASTM F2033−12, the spherical bearing surface of a femoral component shall have R_a (arithmetic average roughness) value not greater than 0.05 µm, this surface shall have a departure from roundness of not greater than 10 µm. In addition, the spherical bearing surface shall have a diameter equal to the nominal diameter with a tolerance of +0.0, -0.2 mm. This study used these values for the design of the femoral head for Vietnamese patients.

2.4 Determination of resistance to static load of modular femoral head

In modular total hip, the head and the neck are of sufficient strength to withstand the static axial load likely to be exerted on the prosthesis during use [12]. The strength of this connection depends on the design of the taper, the force that is used to impact the taper, and the condition of the taper surfaces [13]. The strength of this connection can be evaluated by measuring the head pull-off force according to ISO 7206-10.
In this study, the femoral head was assembled with a femoral stem made of Ti-6Al-4V. The neck of the stem has a conical taper of $5^043'30''$. The stem and the head were assembled with a force of 2 kN, at a loading rate of 0.5 kN/s. The implant components were mounted in a special fixture designed according to ISO 7206-10 then disassembled with a materials testing machine (Series 300DX-F2-G1, Instron, Norwood, MA, USA) to detect the tensile force as an indicator for the taper strength. The tension test was performed at a stroke rate of 0.008 mm/s.

3. Results and discussion

The shape and sizes of the femoral head is illustrated in Fig.3. The 3D model of the femoral head, created in Creo Parametric 3.0 (PTC, Needham, Massachusetts, USA), is presented in Fig. 4.

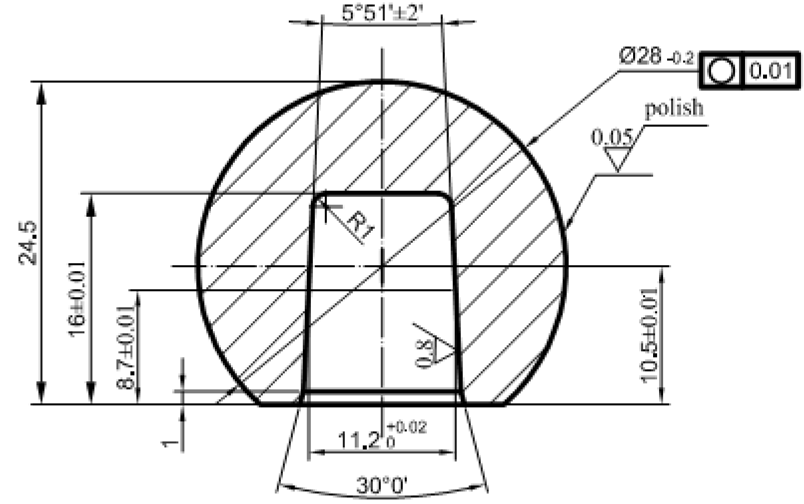


Figure 3: Shape and sizes of the femoral head

Figure 4: 3D model of the femoral head

Common diameters of femoral heads are 22 mm, 26 mm, 28 mm, 32 mm and 36 mm. According to some studies, a lager femoral head diameter can reduce the risk of dislocation induced by impingement, and increasing the femoral head diameter can decrease contact stresses and corrosion of the head [14, 15, 16]. With the diameter of 28 mm, the designed femoral head can be big enough and suitable for Vietnamese patients.
It can be seen that the shape of the designed femoral head is simple. Hence, it is easy to be machined. For trial purpose, some femoral heads were manufactured at the National Key Laboratory of Digital Control and System Engineering (Vietnam National University - Ho Chi Minh City). The machined result shows that the femoral head can be machined to meet its requirements by domestic technologies. Figure 5 presents a femoral head assembled in a total hip prosthesis of this research.

Figure 5: A total hip prosthesis of the research

In this study, the taper neck of the stem offered a surface finish Ra of 1.72 µm, whereas the surface finish Ra of the borehole is 0.64 µm. Figure 6 shows the result of the tensile test for determination of resistance to static load of the femoral head according to ISO 7206-10. The maximum pull-out force was 4304.1 N without the occurrence of failure. This result indicated that the pull-out force was more than two times higher the assembly force. Rehmer et al. [17] assessed the influence of assembly forces (2 kN, 3 kN, 4 kN) on the taper junction strength of various material combinations. The test result was that the mean pull-off forces relative to the assembly forces were 44% for CoCr taper with CoCr head, 58% for Ti taper with CoCr head and 64% Ti taper with ceramic head. It can be seen that the maximum pull-out force of this study is extremely high compared to the pull-off force in [17]. This is because there are some differences in the head and stem materials, the Morse tapers and their mismatch. However, it is too early to conclude that this junction (and then this design) is perfect.

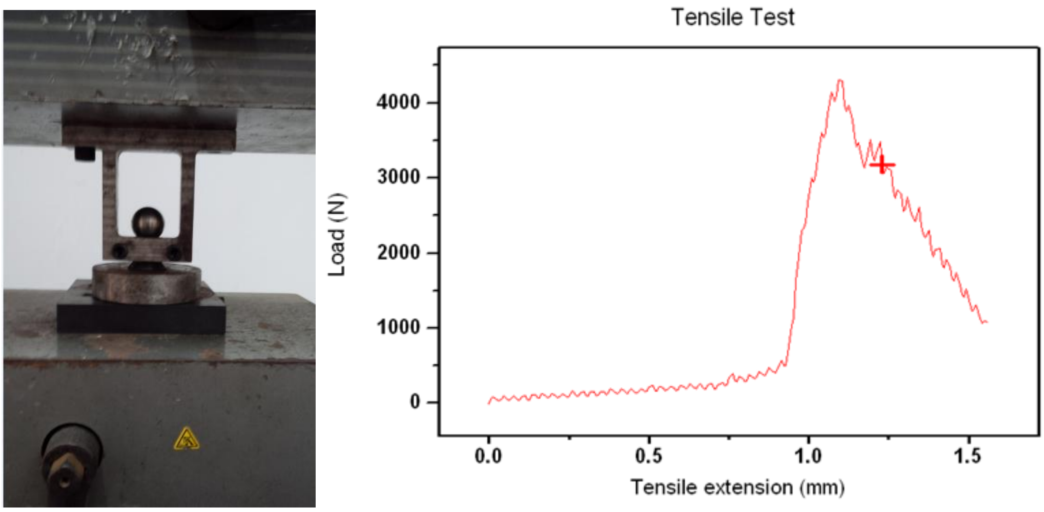


Figure 6: Tensile test for determination of resistance to static load of the femoral head

4. Conclusion

The femoral head of modular total hip prosthesis for Vietnamese patients was designed in this study. This head is made of Ti-6Al-4V. The shape of the head was designed according to ISO 7206-1. The head diameter was in a relationship with the sizes of the acetabular components and they were defined from the geometrical parameters of Vietnamese hip joints which were measured by using reverse engineering. Other dimensions and the engineering requirements of the head were chosen based on ASTM F1636-95, and ASTM F2033, referenced some femoral heads which are common in Vietnam. The result of the test for determining of resistance to static load of modular femoral head shows that the taper junction strength can be very high. However, some more tests have to be performed to get a reliable result. Studying the influence of the taper angle, straightness and circularity of the head bore and cone to the taper junction strength, and calculating the strength of the femoral head under the condition of weight of Vietnamese people are some future work that needs to be carried out to get a better design.

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