iJRASET
International Journal For Research in
Applied Science and Engineering Technology

INTERNATIONAL JOURNAL FOR RESEARCH

IN APPLIED SCIENCE & ENGINEERING TECHNOLOGY

Volume: 9 **Issue:** VIII **Month of publication:** August 2021

DOI: https://doi.org/10.22214/ijraset.2021.37531

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International Journal for Research in Applied Science & Engineering Technology (IJRASET)
ISSN: 2321-9653; IC Value: 45.98; SJ Impact Factor: 7.429
Volume 9 Issue VIII Aug 2021- Available at www.ijraset.com

Design and Evaluation of a Hip Joint Implant Wear Simulator

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Abstract: Every year a high number of total hip arthroplasty is reported worldwide and an increase in this number is expected. Several factors may cause hip wear, such as osteoarthritis, obesity, traffic accidents and sport practicing. Wear is a concern when considering hip prostheses, since a prosthesis presents finite life that in many cases is shorter than patient life, and leads to substitution. Also, research is constant and new developments have to be tested, which leads to the necessity of testing devices that reproduce real conditions of hip joint implant functioning. This work describes a low-cost device, according to the ISO 12242. The equipment was built, a set of three commercially available prostheses was tested and the results show wear values coherent with those found in literature. It was found a value of wear rate of (13.30 ± 3,81) mg/10^6 cycles; wear factor found was (0.41 ± 0,09) x 10^{-6} mm^3/Nm. After testing, the device was evaluated and no component presented significant wear.
Keywords: Hip joint simulator; Prostheses; Wear; Arthroplasty; Test machine.

I. INTRODUCTION

Total hip arthroplasty (THA) became usual. Every year, more than 300000 cases are reported in the United States and, a considerable increase in the number of this procedure is expected in the near future. It is recommended in various situations, mostly due to traffic accidents, overweight and natural wear for elderly people. People may present excessive hip wear at different ages and, osteoarthritis is one of the most widespread causes of this degradation process. The purpose of a total hip replacement is to re-establish normal life, providing a joint that functions as normally as possible, resists to dislocation, preserves as much bone as possible and lasts as long as possible [1,2].

The number of THA procedures in Brazil is considerably high as well, and the main causes are obesity related problems and traffic accidents. According to SUS (Brazilian Unified Health System), 317 THA procedures were carried out in the city of São Paulo from August 2011 to September 2012 [3]. Amaral et al. [4] reported a high number of THA caused by accidents related to sport practicing. Since sport practicing mainly involve young people and a prosthesis usually lasts 10-15 years, such patients will need to take the surgery a few more times throughout their lifetime. However, once a new surgery is required, either to replace or to repair a previous THA, both reconstruction process and recovery become more difficult, despite the effort of the surgeon to mitigate surgery impact. Thus, much attention has been focused on dimensions, design and failure analysis of prostheses [5-8]. In addition, literature shows a number of studies on composite materials to be used in the acetabulum and special alloys to be used in the spherical head of the femoral stem, always aiming enhanced durability [3, 9-12]. According to Madl et al. [13], although metal-on-metal (MoM) hip implants were mostly abandoned in the middle 1970s, metal-on-polyethylene (MoP) implants present long-term survival problems, due to degradation of the polyethylene cup after years of wear. Therefore, both MoM and MoP implants may present wear debris related problems that also must be studied. Like in many other fields, computational models have been applied to investigate not only wear but also vibration and noise of hip joint implants, using the finite element method [14-17]. However, accurate results demand real condition tests, and hip joint implant simulators have been widely used for investigating new profiles and materials.

Viceconti et al. [18] presented a discussion on designing hip joint simulators. They reported preliminary indications on the design choices, regarding spatial configuration of loading and motion actuators, in order to improve the simulator ability to reproduce a specific load cycle. A number of authors suggested simulator models, such as Cheng et al. [19], who proposed a parallel test platform, using electric cylinders for providing 3-axis movement and a hydraulic cylinder to load the stem. Oliveira et al. [20] proposed a rigid system, where a biaxial platform performs the angular movements in the X and Y axes, while a cantilever provides movement in the Z axis and load control. Servo motor drivers provide movement in all three axes. In the simulator constructed by Saikko [21], an electronically controlled pneumatic cylinder applies the load and a universal joint makes the cup self-centring on the head.

Regardless of specific details, a simulator must meet parameters imposed by the ISO 14242 standard [22-24]. For instance: a) orbital, biaxial or triaxial stem movement on the acetabulum; b) dynamic load in accordance with the profile given in the first part of the standard; c) prosthesis immersed in amniotic fluid (of any kind); d) loading synchronized with kinetics and stable enough to carry out the necessary number of uninterrupted cycles. In order to meet the standard requirements, constructing a simulator demands complex mechanisms and precise actuators. Thus, this kind of equipment tends to present prohibitive cost. In fact, Affatato et al. [25] presents a review of the cost of commercially available equipment up to 2007, which confirms the high price.

Therefore, based on the above considerations, the purpose of this work is to present the design of a test bench for simulating the functioning of a hip joint implant. The efforts were mostly directed to design a low-cost device that attends the ISO 14242 standard.

II. TEST BENCH

Figure 1 shows the proposed test bench and main design details: a) drive system; b) load actuator; c) kinematic actuator; d) fluid tank. The simulator tests one sample at time. The cup/head reverse configuration allows both easily prosthesis positioning in the tank and fluid temperature control. The temperature control system that maintains the fluid in which the prosthesis is submerged, according to the norm, at 37 ± 2 °C. The system was developed through the Arduino microcontroller, which provided the temperature values measured by the sensor in a display and also were recorded on a memory card for data analysis. The same data was used to make a proportional control through the activation of the controller, which receives the signal and applies to the load, through the realization of two different codes. In addition to the project reaching its goal, it also presented cost below the commercial temperature control systems.

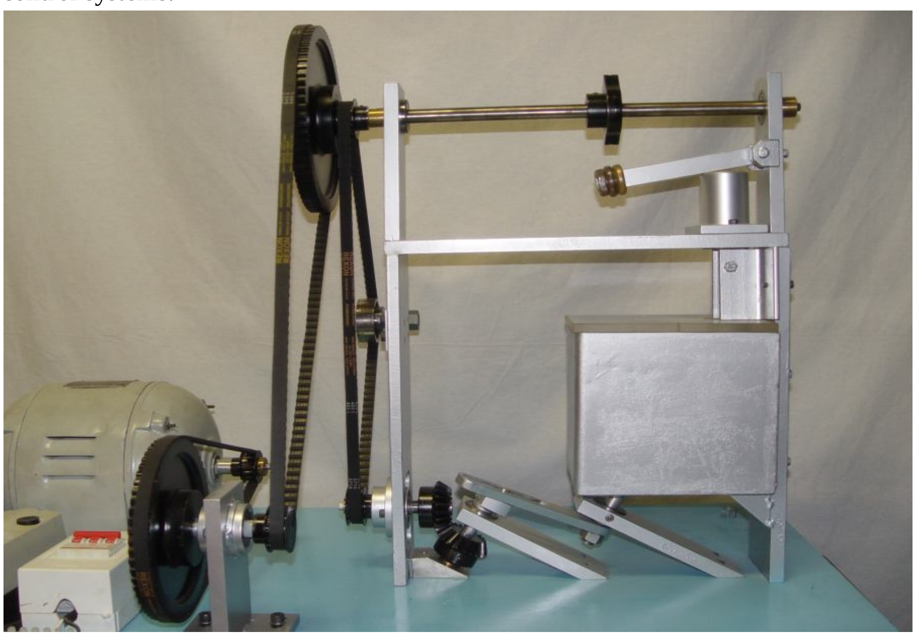

Fig. 1 The hip joint simulator.

III.DRIVE SYSTEM

A 2 HP three-phase motor, running at 1800 rpm, drives the system. A set of pulleys and toothed belts couples it to the main axis, which turns at (1 ± 0.1) Hz.

When simulating walking of different people, one should consider different cycle frequencies. Youth tend to walk faster than elderly people and even the same person walks slower or faster depending on the situation. Saikko [21] worked with an average frequency of 1.06 Hz. González-mora et al. [26] worked with 1.23 Hz. Hua and Zhang [27] simulated a few conditions and varied cycle frequency from 0.2 Hz to 5 Hz. Oliveira et al. [20] conducted their experiments under 0.6, 1.0 and 2.0 Hz.

Another set of toothed belt and equal-diameter pulleys transmits rotation from the main axis to the bottom axis, which drives the mechanism of the acetabulum. This set received a tensioner and oblong slots at the bottom for adjusting belt stress. By means of a digital tachometer, the device was periodically inspected. The tachometer-measuring tip was positioned at the centering hole of the upper axis and a piece of reflective tape was stuck to the bottom axis. Measured values varied from 1.073 Hz to 1.085 Hz, which is within the range specified by the standard.

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IV. DYNAMIC LOAD MECHANISM

The dynamic load mechanism consists of a rotating cam, coupled to the main axis, which presses a follower positioned at the extremity of a cantilever. As the follower moves down it brings the cantilever, which presses an element positioned at the top of a helical spring; the compressed spring loads the femoral stem. Based on the spring constant of the selected spring, the necessary deflection was determined to achieve the required force. As required by ISO 14242, the angular displacement between load application axis (femoral stem axis) and acetabulum axis is 60° (Fig 2).

An ALPHA Instruments SV200 S-type load cell was positioned between the helical spring and the stem for load control. The loading profile was achieved by means of a Spider8 signal acquisition system and Catman software. One easily sees that the maximum load applied is little higher than 1 kN, instead of 3 kN, as determined by the standard (Fig 3). The load profile, on the other hand, is in accordance with that required by the standard. At this point, it should be emphasized that several authors did not respect standard load determination. Correia et al. [28] varied load values from 1.3 kN to 4.0 kN and controlled it by means of piezo resistive sensors. Sagbas et al. [29] varied load values from 0.2 kN to 1.5 kN in order to analyze temperature evolution during movement. Essner et al. [30] used 2.45 kN. Trommer et al. [31], who studied the tribological behavior of an UHMWPE/metal prosthesis, followed the standard determination.

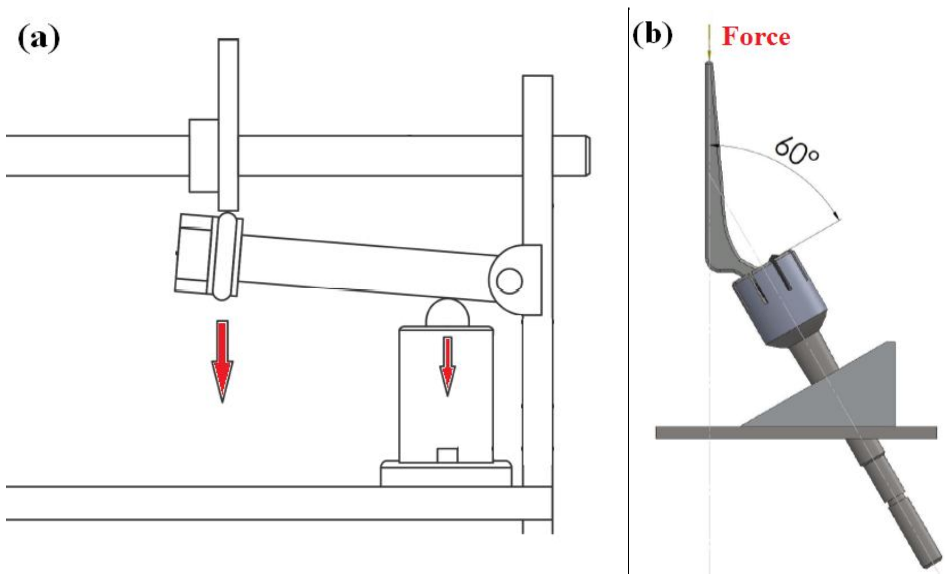


Fig. 2 Dynamic load system: (a) force provided by cam-shaft system; (b) force applied onto the stem, inclined 60º with respect to acetabular cup.

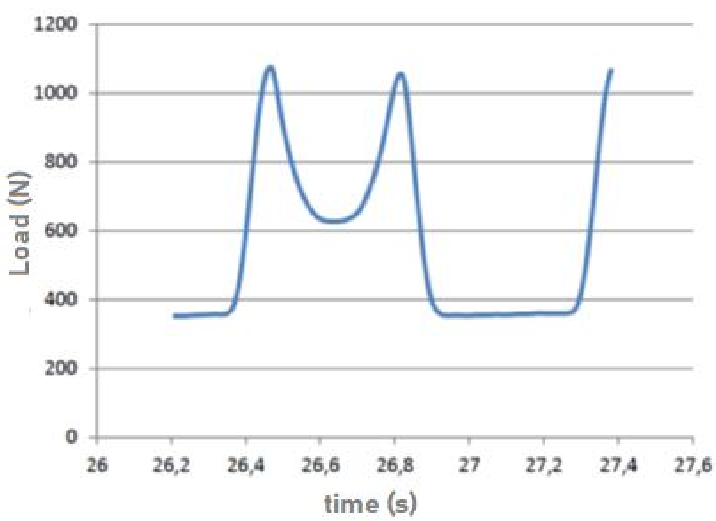


Fig. 3 Load profile obtained with the load system shown in Fig. 2.

V. ACETABULUM MOVEMENT SYSTEM AND AMNIOTIC FLUID TANK

According to ISO 14242-3 standard, when one walks the hip joint performs 3 angular movement variations: abduction/adduction at an angle of ± 23°; extension/flexion at an angle of ± 23°; and internal/external rotation at ± 2°. Thus, the acetabulum movement system is classified into 3 types: (i) orbital, when only one of the three angular movement variations is observed; (ii) biaxial, when two of them are observed and (iii) triaxial, when all of them are observed. Cao and Mishler [32] present a comparison of wear values resultant from each type of acetabulum movement. Other authors reported results obtained with biaxial movement devices [26, 27, 33]. Saikko and Shen [34] compared biaxial and triaxial devices and concluded that statistically, wear rates do not differ significantly.

The test bench presented in this work comprises an orbital movement system (Fig. 4), comparable to that presented by Oliveira et al. [20]. In this test bench, the movement between acetabulum and the sphere at the top of the stem promotes extension/flexion movement. A toothed belt connects the acetabulum mechanism to the upper axis, through a Scotch yoke mechanism and both move at the same rotation. The toothed belt ensures synchronization between load and extension/flexion movement. Although there is evidence of peculiar wear behavior in multiaxial condition, especially when applied to UHMWPE acetabulum materials [34], the proposed device simulates extension/flexion movement, since this is the prevailing movement during a normal person walking. Therefore, being the main cause for wear of prostheses.

A tweezers like device positions the acetabulum. The load is applied on the axis of the stem and the acetabulum is positioned at an angle of 60° relative to the axis of the stem [24]. Saikko et al. [35] studied the effect of cup placement on wear and concluded that at an angle of 60° the tribological behavior was excellent, but when this value is exceeded, the contact area is asymmetric and leads to prosthesis lubrication failure, thus, significantly increasing the wear rate. Mccarthy et al. [36] reported the importance of placing the acetabular cup at specific angles, to properly simulate the squatting position in which the individual lifts up an object. Different angles represent unsafe regions for the test. The 1.5 liter amniotic fluid tank presents an electrical heating system, which in conjunction with a thermocouple, provides temperature control during test. Tests must be conducted at a temperature similar to that of the human body, i.e. (37 ± 2) °C [24].

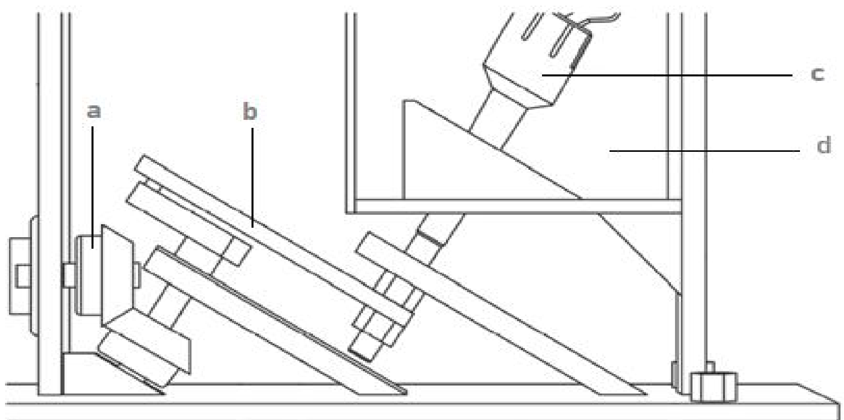


Fig. 4 Schematic representation of the acetabulum movement system: (a) gear assembly receives movement from the toothed belt; (b) scotch yoke mechanism; (c) acetabular setting device; (d) fluid tank.

VI. TESTING PROCEDURES

Three sets of hip joint prostheses were purchased and tested in order to evaluate the performance of the Simulator. They consisted of a titanium stem and a cobalt femoral head of 28 mm in diameter. The titanium acetabulum was internally coated with polyethylene of density 0.93 mg/mm^3.

According to the ISO 14242-2 standard, each polyethylene acetabulum was immersed in deionized water and put into an ultrasonic cleaner. After that it was dried in a vacuum chamber and blown with inert gas. The procedure was repeated 5 times. At this point the component was weighed.

For starting the test, the sample was placed in the simulator and the tank was filled with amniotic fluid. One million cycles were run under the frequency of (1.0 ± 0.1) Hz, which took a 12-day period for the complete test. Frequency was controlled 6 times a day using a digital tachometer. During this period, the whole assembly was regularly observed for ensuring that the entire test was run under proper conditions. At the end, the components were removed and the cleaning procedure was repeated.

The wear performance of the prostheses was evaluated based on wear and wear rate. The wear factor was calculated using Equation [1], where (Vd) is the volume of worn material, (L) is the normal load applied on the acetabulum and (n) is the number of cycles [37].

VII. POST-TEST EVALUATION

The initial average mass of the acetabulum specimens was (16.124 ± 0,003) g and after testing the average mass was (16.111 ± 0.002) g. Thus, the worn value (wear rate) was (13.30 ± 3,81) mg/10^6 cycles, which leads to worn volume (Vd) of 14.301 mm3. According to Saikko et al. [38], a stem with its head measuring 28 mm in diameter, under an applied load of 1.0 kN and submitted to 1 million cycles results in a value of 34.4 Nm to be used in Equation [1]. The resulting wear factor (K) for the tested prosthesis is then (0.41 ± 0,09) x 10^{-6} mm^3/Nm.

Also, after conducting the tests, the device was disassembled and component stability was completely checked. As expected, components that work in contact, such as cam/follower and follower/shaft show some wear, which was considered negligible and suggests that a considerable number of tests can be run before any maintenance is required.

VIII. CONCLUSION

A device for simulating hip joint implant functioning was constructed and tested. It is presented as a reasonable alternative when compared to other devices, due to its simplicity and low number of components. In spite of its low cost and simple operation, it attends the ISO 14242 standard and showed itself as a robust and reliable equipment. A set of three commercially available prostheses was tested and results were coherent with those found in literature.

REFERENCES

[1] Kurtz, S. M., Ong, K. L., Lau, E. (2014), "Impact of the economic downturn on total joint replacement demand in the United States: updated projections to 2021", J. Bone Joint Surg. Am., 96 (8) pp. 624-631.

[2] Affatato, S., Ruggiero, A., Merola, M. (2015), "Advanced biomaterials in hip joint arthroplasty. A review on polymer and ceramics composites as alternative bearings", Compos. Part B Eng., 83, pp. 276–283.

[3] DATASUS, http://www2.datasus.gov.br acessed February 20, 2013.

[4] Amaral, M., Maru, M. M., Rodrigues, S. P., Gouvêa, C. P., Trommer, R. M., Oliveira, F. J., Achete, C.A, Silva, R. F. (2015), "Extremely low wear rates in hip joint bearings coated with nanocrystalline diamond", Tribol. Int., 89, pp. 72–77.

[5] Hernandez-Rodriguez, M. A. L., Ortega-Saenz, J. A., Contreras-Hernandez, G. R. (2010), "Failure analysis of a total hip prosthesis implanted in active patient", J. Mech. Behav. Biomed. Mater., 3, pp. 619–622.

[6] Fehring, K.A. and Fehring, T. K. (2015), "Modes of Failure in Metal-on-Metal Total Hip Arthroplasty", Orthop. Clin. North Am., 46, pp. 185–192.

[7] Okazaki, Y. (2014), "Effect of head size on wear properties of metal-on-metal bearings of hip prostheses, and comparison with wear properties of metal-on-polyethylene bearings using hip simulator", J. Mech. Behav. Biomed. Mater., 31, pp. 152–163.

[8] Dowson, D., Hardaker, C., Flett, M., Isaac, G. H. A (2004), "Hip Joint Simulator Study of the Performance of Metal-on-Metal Joints Part II : Design", Journal of Arthoplasty, 9, pp. 124–130.

[9] Affatato, S., Freccero, N., Taddei, P. (2016), "The biomaterials challenge : A comparison of polyethylene wear using a hip joint simulator", J. Mech. Behav. Biomed. Mater., 53, pp. 40–48.

[10] Maru, M. M., Amaral, M., Rodrigues, S. P., Santos, R., Gouvea, C. P., Archanjo, B. S., Trommer, R. M., Oliveira, F. J., Silva, R. F., Achete, C. A. (2015), "The High performance of nanocrystalline CVD diamond coated hip joints in wear simulator test", J. Mech. Behav. Biomed. Mater., 49, pp. 175–185.

[11] Oliveira, A. L. L., Lima, R.G., Cueva, E. G., Queiroz, R. D. (2011), "Comparative analysis of surface wear from total hip prostheses tested on a mechanical simulator according to standards ISO 14242-1 and ISO 14242-3", Wear, 271, pp. 2340–2345.

[12] Dowson, D., Hardaker, C., Flett, M., Isaac, G. H. (2004), "A Hip Joint Simulator Study of the Performance of Metal-on-Metal Joints Part I : The Role of Materials", Journal of Arthroplasty, 19, pp. 118–123.

[13] Madl, A. K., Liong, M., Kovochich, M., Finley, B. L., Paustenbach, D. J., Oberdörster, G. (2015), "Toxicology of wear particles of cobalt-chromium alloy metal-on-metal hip implants Part I : Physicochemical properties in patient and simulator studies", Nanomedicine Nanotechnology, Biol. Med., 11, pp. 1201–1215.

[14] Pakhaliuk, V., Polyakov, A., Kalinin, M., Kramar, V. (2015), "Improving the finite element simulation of wear of total hip prosthesis' spherical joint with the polymeric component", Energy Procedia, 100, pp. 539–548.

[15] Lin, Y., Wu, J. S., Chen, J. (2016), "The study of wear behaviors on abducted hip joint prostheses by an alternate finite element approach", Comput. Methods Programs Biomed., 131, pp. 143–155.

[16] Fialho, J. C., Fernandes, P. R., Ec, L. (2007), "Computational hip joint simulator for wear and heat generation", Tribology International, 40, pp. 2358–2366.

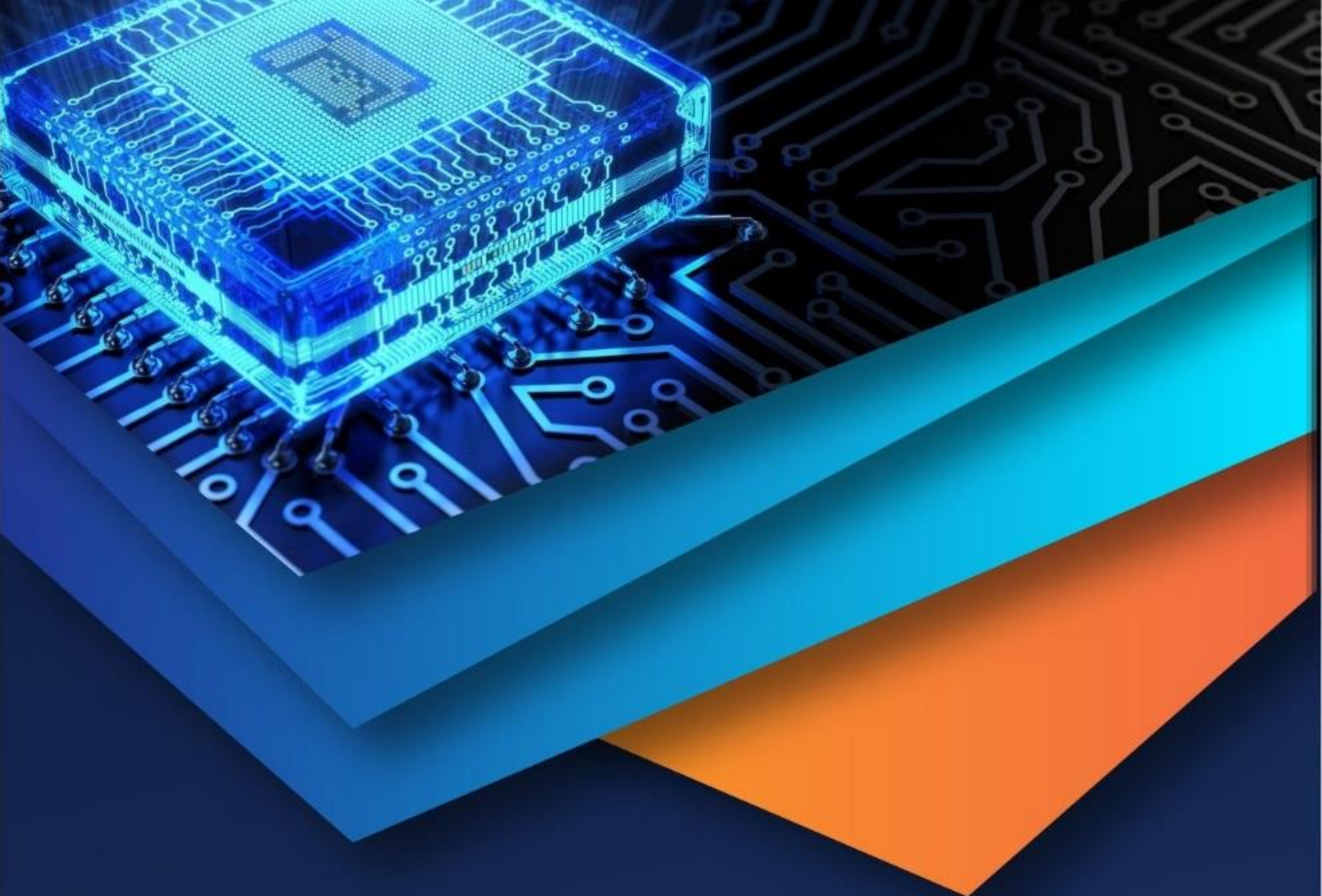
[17] Sariali, E., Stewart, T., Jin, Z., Fisher, J. (2010), "Three-dimensional modeling of in vitro hip kinematics under micro-separation regime for ceramic on ceramic total hip prosthesis: An analysis of vibration and noise", J. Biomech., 43, pp. 326–333.

[18] Viceconti, M., Cavallotti, G., Andrisano, A. O., Toni, A. (1996), "Discussion on the design of a hip joint simulator", Med. Eng. Phys., 18, pp. 234–240.

[19] Cheng, G., Li, Y., Feng, L., Shan, X., Yang, J. (2015), "Configuration bifurcation and self-motion analysis of 3SPS + 1PS bionic parallel test platform for hip joint simulator", Mech. Mach. Theory, 86, pp. 62–72.

[20] Oliveira, A. L. L., Trigo, F. C., Queiroz, R. D., Carvalho, R. T. (2013), "Development of a protocol for the performance evaluation of wear machines used in tests of joint prostheses", Mech. Mach. Theory, 61, pp. 59–67.

[21] Saikko, V. (2015), "Adverse condition testing with hip simulators", Biotribology, 1-2, pp. 2–10.
[22] ISO 14242-1 (2014), "Implants for surgery – Wear of total hip-joint prostheses – Part 1: Loading and displacement parameters for wear-testing machines and corresponding environmental conditions for test", ISO International Organization for Standardization.
[23] ISO 14242-2 (2016), "Implants for surgery – Wear of total hip-joint prostheses – Part 2: Methods of Measurement", ISO International Organization for Standardization.
[24] ISO 14242-3 (2009), "Implants for surgery—wear of total hip joint prostheses—part 3: loading and displacement parameters for orbital bearing type wear testing machines and corresponding environmental conditions for test", ISO International Organization for Standardization.
[25] Affatato, S., Spinelli, M., Zavalloni, M., Mazzega-fabbro, C., Viceconti, M. (2008), "Tribology and total hip joint replacement : Current concepts in mechanical simulation", Tribology International, 30, pp. 1305–1317.
[26] González-mora, V. A., Hoffmann, M., Stroosnijder, R., Gil, F. J. (2009), "Wear tests in a hip joint simulator of different CoCrMo counterfaces on UHMWPE", Mater. Sci. Eng. C., 29, pp. 153–158.
[27] Hua, Z. K. and Zhang, J. H. (2008), "A New Simulator for Bio-Tribological Study", J. Bionic Eng, 5, pp. 143–147.
[28] Correia, V., Sencadas, V., Martins, M. S., Ribeiro, C., Alpuim, P., Rocha, J. G., Morales, I., Atienza, C., Lanceros-Mendez, S. (2013), "Piezoresistive sensors for force mapping of hip-prostheses", Sensors Actuators, A Phys, 195, pp. 133–138.
[29] Sagbas, B., Durakbasa, M. N., Sagbas, M., Koyun, A. (2014), "Measurement and theoretical determination of frictional temperature rise between sliding surfaces of artificial hip joints", Measurement, 51, pp. 411–419.
[30] Essner, A., Schmidig, G., Wang, A. (2005), "The clinical relevance of hip joint simulator testing: In vitro and in vivo comparisons", Wear, 259, pp. 882–886.
[31] Trommer, R. M., Maru, M. M., Oliveira Filho, W. L., Nykanen, V. P. S., Gouvea, C. P., Archanjo, B. S., Martins Ferreira, E. H., Silva, R. F., Achete, C. A. (2015), "Multi-Scale Evaluation of Wear in UHMWPE-Metal Hip Implants Tested in a hip Joint Simulator", Biotribology, 4, pp. 1–11.
[32] Cao, S. and Mischler, S. (2016), "Assessment of a recent tribocorrosion model for wear of metal-on-metal hip joints : Comparison between model predictions and simulator results", Wear, 362-363, pp. 170–178.
[33] Loving, L., Kinfay, R., Ms, L., Herrera, L., Paul, A., Ms, E., Nevelos, J. E. (2013), "Wear Performance Evaluation of a Contemporary Dual Mobility Hip Bearing Using Multiple Hip Simulator Testing Conditions", J. Arthroplasty, 28, pp. 1041–1046.
[34] Bergstrom, J. S., Rimnac, C. M., Kurtz. S. M. (2003), "Prediction of multiaxial mechanical behavior for conventional and highly crosslinked UHMWPE using a hybrid constitutive model. Biomaterials", 24, pp. 1365–1380.
[35] Saikko, V., Ahlroos, T., Revitzer, H., Ryti, O., Kuosmanen, P. (2013), "The effect of acetabular cup position on wear of a large-diameter metal-on-metal prosthesis studied with a hip joint simulator", Tribology International, 60, pp. 70–76.
[36] Mccarthy, T. F., Alipit, V., Nevelos, J., Elmallah, R. K., Mont, M. A (2016), "Acetabular Cup Anteversion and Inclination in Hip Range of Motion to Impingement", J. Arthroplasty. 31, pp 264–268.
[37] Calonius, O. and Saikko, V. (2003), "Analysis of relative motion between femoral head and acetabular cup and advances in computation of the wear factor for the prosthetic hip joint", Acta Polytechinica, 43, pp 43-54.
[38] Saikko V. et al. (2001), "Wear simulation of total hip prostheses with polyethylene against CoCr, alumina and diamond- like carbon", Biomaterials, pp 1507-1514.



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