Development of OSH Risk Assessment in IIUM Orthopaedics Research Laboratory According to ISO/IEC 17025:2017 Accreditation.

Mohd Zulfadzli Ibrahim, Mohd Armi Abu Samah, Ahmad Hafiz Zulkifly, Nurul Hafiza Mohd Jan

ABSTRACT---Orthopaedics Research Laboratory accommodate with biocompatibility testing to meet the requirements of ISO/IEC 17025 for medical device. Towards the implementation of the guideline, laboratory safety is the main issue encountered to reduce the risk of hazardous among the laboratory personal This study aimed to ensure the good practices in safety, health and environment are implemented in ORL according to ISO/IEC 17025: 2017 standard guidelines. The hazard identification at ORL starts from the receiving of laboratory animal, New Zealand White Rabbit (NZWR), animal surgery, radiology assessment and euthanasia. There are many dangers found in all these procedures. In this study, only four safety hazards, two health hazards and one environmental hazard was taken and discussed therein by taking risk assessment rating in ORL. Next, the risk control for each danger was identified and recorded. Only four risk controls were highlighted for each hazard encountered by each procedure. The amounts that the average risk level in the procedures studied in ORL are 2.46 which is in tolerate level. However, since the value is close to 3.0, the level of risk is relatively low and is approaching to moderate. The various risk levels for this study are 2.0. The difference between the highest (operating procedures) and the lowest (euthanasia) which showed the difference of non-essential data. There was no significant difference between the hazards found in ORL with all the procedures studied in one-way ANOVA analysis (F:(3,20) = 0.649, p = 0.592, η2p = 0.09). However, risk assessment may change from time to time depending on the hazard detection and it is strongly recommended that some of the stated control measures be taken to reduce future risk levels that could harm to individuals, organizations and countries.

Keywords—Orthopedic Research Laboratory, HIRARC, Risk Assessment, ISO/IEC 17025

I. INTRODUCTION

Orthopedic department through Orthopedic Research Laboratory (ORL) was establish in 2000 [1] is very optimistic to conduct research related to biomaterial and basic sciences studies related to bone. The main research activities carried out in this laboratory are research related to animals in vivo (processes performed or taking place in a living organism) and ex vivo (takes place outside an organism) such as an organ or a tissue coming from in vivo. All research in ORL uses New Zealand White Rabbit (NZWR) only as the research subject [2]. In addition, ORL has carried out an ex vivo sample analysis and processing service by conducting radiological assessment, undecalcified tissue processing, confocal and inverted microscope analysis, micro-CT

Imaging, bone staining and macroscopic analysis. ORL also operates bone-related surgery services such as implantation

Surgery on tibia, spine, femur, femoral condyles and many more. Meanwhile, ORL also conducts clinical research on new products marketed at Malaysia and internationally. This laboratory is accommodated with biocompatibility testing to meet the requirements that accordance to ISO/IEC 17025 for medical device.

ISO / IEC 17025 is the general requirement for testing and calibration efficiency in laboratories. It is a benchmark as international references for testing and calibration of the laboratory to indicate their ability towards delivering reliable results. Furthermore, this guideline enables laboratories to demonstrate that they operate competently and generate valid results, thereby promoting confidence in their work both nationally and around the world. Besides, it also helps to facilitate cooperation between laboratories and other bodies by generating wider acceptance of results between countries. The outcome from test reports and certificates through this guideline can be accepted from one country to another without the need for further testing, which, in turn, improves international trade. This standard is useful for any organization that performs testing, sampling or calibration for the achievement of the reliable results. It includes with all types of laboratories, either they be owned and operated by government, industry or, in fact, any other organization. The standard is also applicable to all universities, research centres, governments, regulators, inspection bodies, product certification organizations and other conformity assessment bodies towards performing testing, sampling or calibration [3].

Due to the risky workplaces that constitute in the laboratory, the ORL, IIUM management need to assure safe working conditions among the laboratory personal through

Revised Manuscript Received on May15, 2019.

MohdZulfadzli Ibrahim, Senior Medical Laboratory Technologist and MSc. Candidate, Department of Orthopedics, Traumatology and Rehabilitation, Kulliyyah of Medicine, IIUM Kuantan, Campus. Malaysia

MohdArmi Abu Samah, Senior Lecturer, Kulliyyah of Sciences, IIUM Kuantan CampusMalaysia(marmi@iium.edu.my)

Ahmad Hafiz Zulkifly, Arthroplasty surgeon and ORL Director, Department of Orthopedics, Traumatology and Rehabilitation, Kulliyyah of Medicine, IIUM Kuantan, Campus.Malaysia

NurulHafizaMohd Jan, PhD Candidate, Department of Orthopedics, Traumatology and Rehabilitation, Kulliyyah of Medicine, IIUM Kuantan, Campus.Malaysia

systematic and regular hazard identification and risk assessment. Safety procedures and regulations need to be followed by the management as well as the laboratory personals in all levels. Many business enterprises have proven that good safety management in which leads to increased good productivity [4]. By having a good safety management program with proper plan, it is not only provided minor injuries, but also helps to reduce in terms of cost, time consuming, stressful and inconvenient. Due to this reason for reduction of all occupational diseases, injuries/fatalities, corrective and preventive measure should be done and implemented to control the possibility for any accidents to occur [4]. Thus, this paper highlights report on hazard identification, risk assessment and risk control applied in the Orthopaedic Research Laboratory of IIUM in Malaysia. It includes the methodological steps to identify hazard, assess the risk level of the hazards and apply or suggest the possible control measures and corrective actions to reduce or eliminate the risk.

Currently, towards to reach the achievement, Hazard Identification, Risk Assessment and Risk Control (HIRARC) have become as s fundamental tool to the practice of planning, management and the operation of risk management [4]-[6]. A

Hazard identification and risk assessment are processes used to discover and analyse any existing and potential hazards in a workplace, and the methods used to control, reduce and eliminate the hazards identified. The organizations that have carried out with risk assessment at the work place have noted various of changes in their working practice. Those who have already carried out the risk assessment in their work, have reported positive changes in their working practice. Besides, they had also recognized the substandard act and working condition as they develop and take necessary corrective action. Legislation requires that this process should be systematic and be recorded so that the outputs are reliable, and the evaluation is fully complete. The risk assessment process should be continuous performed and should not be regarded as a one-off exercise [4]-[6].

II. METHODOLOGY

As for methodology, the procedure is started from the acceptance of the rabbit until euthanize. This process also relates to safety, health and environmental factors in Orthopaedic Research Laboratory (ORL) in line accordance to ISO / IEC 17025: 2017 standard guidelines. The overview of methods tocomplete this study of HIRARC is as shown in Fig. 1.

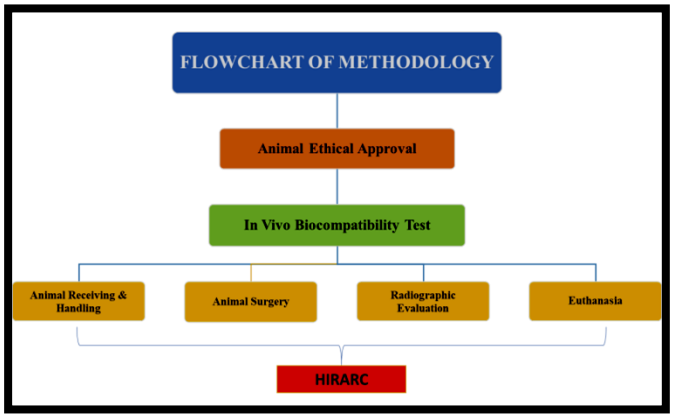

Fig. 1 above illustrate the study's methodology employed

Hazard Identification

The scopes of the observation are focus on the hazards that might occur during the activities being conducted and any other potential hazards that might exist in the laboratories. At ORL there are several ways to identify hazards in the workplace, namely facilities provided, equipment used, procedures and services. This includes routine and non-routine activities performed at this lab daily. Once this laboratory is accredited by ISO / IEC 17025, all procedures and manuals must comply with the guidelines set out in accordance with the section in its standard.

In order to identify type of hazards exist in the ORL, observations have been made by the team members. With the cooperation of laboratories' manager or technicians who are familiar with the equipment's, materials or substances, all the hazards are clearly to be identified. The scopes of the observation focus on the hazards that might occur during the activities being conducted and any other potential hazards that might exist in the laboratory during conducting research activities.

Risk Assessment

The list of risks in the hazard identification of the activities performed at the ORL has been identified and recorded. This classification is based on severity (Table 1) and frequency or likelihood (Table 2). The method used by Advanced Orthopaedic Research Labs is classification through the semi-quantitative method seen in the Risk Ranking Matrix (Table 4). Each decision obtained will determine the type of risk control that should be in accordance with the risk control hierarchy that has been provided. In general, the fundamental definition of risk assessment applied and used by ORL is depicted in the following manner:

Risk magnitude = Severity X probability of likelihood

Fig. 2 above shown the risk assessement formula that impelemented for hazard identification in ORL activities.

Tab. 1: The definition of severity

Index	Probability	Description
4.0	Known to be a common or repeating occurrence (in ORL)	▪ Very likely ▪ Could happen frequently. Exposures are excessive
3.0	Known to occur or has happened in the past (in University)	▪ Likely ▪ Could happen occasionally. Exposures are not adequately control.
2.0	Unlikely but could happen (in ORL)	▪ Could happen but only rarely. Exposures are controlled and likely remain so.
1.0	Practically Impossible (in ORL)	▪ Highly unlikely ▪ Could happen but probably never well. ▪ Exposures are negligible.

Index	Severity	Description
4.0	Fatality or permanent disability	▪ Fatality or permanent disability ▪ Death / Property Damage
3.0	Serious illness or injury	▪ Serious illness or injury ▪ Absent from work more than 3 days ▪ Normally irreversible. Permanent partial disability. Property damage.
2.0	Moderate illness or injury	▪ Moderate illness or injury- Absent from work less than 3 days ▪ Normally reversible and affect work performance. Property damage.
1.0	No impact, minor illness or injury	▪ Not affecting work performance. ▪ First aid case and No Property Damage ▪ No impact, minor illness or injury ▪ No lost time injury

Tab. 2: The definition of likelihood

Tab. 3: The ORL Risk Ranking Matrix

		PROBABILITY			
		1.0	**2.0**	**3.0**	**4.0**
SEVERITY	**1.0**	**1.0 T**	**2.0 T**	**3.0 M**	**4.0 M**
	2.0	**2 .0 T**	**4.0 M**	**6.0 M**	**8.0 S**
	3.0	**3.0 M**	**6.0 M**	**9.0 S**	**12.0 S**
	4.0	**4.0 M**	**8.0 S**	**12.0 S**	**16.0 I**

Legend: T - Trivial or tolerable with range level 1-2, M – Moderate with range level 3-6, S – Substantial with range level 8-12, I - Intolerable with level 16.

Risk Control

As for risk control, the description of different categories of controls with regards to the above risk level in ORL as shown in the Table 4 below. This assessment had been practiced by ORL towards providing a clear example on how each safety health and environment hazard are evaluated based on the station's activities. For risk categorized under intolerable, a risk reduction measure such as the Occupational Safety and Health Program must be established within effective time period to ensure the risk are within control.

Statistical Analysis

The data collected was analyzed using the IBM SPSS version 25 for window software (IBM Corp. and SPSS Inc., Chicago, USA) which is easier to analyses and manipulate for accurate risk assessments obtained at ORL. For the purposes of statistical hypothesis testing, One Way ANNOVA test was done to determine the accuracy of the data and the test by utilizing significant level α:0.05 (P> 0.05). The hypothesis is performed on the significance of the hazard found in ORL with the risk assessment.

Tab. 3: The ORL risk-based control plan

Risk Level	Action and Timescale
Trivial or Tolerable	No action or additional controls shall be required.
Moderate	Work continues, and effort should be made to reduce the risk, but the costs of prevention should be carefully measured and limited. Monitoring is required to ensure that the controls shall be maintained.
Substantial	Work continues with extra supervision. Risk reduction measures/OSH Management programs to be implemented within the effective time.
Intolerable	Work shall not be started or continued until the risk has been reduced. If it is not possible to the reduce risk work must remain prohibited.

III. RESULTS AND DISCUSSIONS

Figures and Tables

The risk levels are documented based on the type of hazard and classification of each parameter studied as shown in Table 5. Overall, this risk assessment is necessary to assess the risks in the ORL where there are many hazards that can occur there. The highest hazard occurring in animal

Published By:
Blue Eyes Intelligence Engineering
& Sciences Publication

houses indicates that safety hazards have monopolized the first place with a risk rank of 4.0 while the biological hazard was in second place position. Meanwhile, ergonomic hazards record the highest risk ranking of 6.0 in all assessments in ORL in surgical procedures while electrical hazard and safety with risk ranking of 3.0 is the first-place evaluation in the radiographic procedure. The overall risk level for each classification is obtained by taking on average all the hazards involved in the ORL laboratory

Tab. 5 below show the overall risk level for each classification in the ORL laboratory procedure

Table 6 below is summarizing of the hazards occurring when each procedure is carried out. Three of the four procedures were exposed to the types of safety hazards, biological and ergonomic. The average risk assessment level under the scope of safety, biology and ergonomics is 4 out of 16 considered moderate to be highlighted and resolved soon but the situation is still in acceptable condition. Here is a summary that will be described in table 6.

Tab. 6 revealed the average of risk assessments data for the entire 4 categories of ORL laboratory procedures.

Procedure Classification	Overall Ranking / Rating
Animal Receiving	2.6 (Trivial)
Operative Procedures	4.0 (Moderate)
Radiographic	2.67 (Trivial)
Euthanasia	2.0 (Trivial)

Risk Assessment Statistical Analysis

Table 7 showed that there were no statistically significant differences among the 6 group of hazards had been identified in ORL means as determined by one-way ANOVA, (F:(3,20) = 0.649, p = 0.592,η^2p = 0.09). The p value indicates that there is no significant difference between the hazards found with the risk that ORL employees would encounter in all the procedures studied. Hence, it shows a strong evidence to state that the mean risk assessment rating on hazard had been identified in ORL are equal and save. However, risk control and control measures need to be done to minimize the risk of accidents at the workplace. Since the calculated test statistic value F = 0.486 and P:0.592 are failing to reject H_0.

Tab. 7: The summary of One-Way ANOVA

	df	Sum of Squares	Mean Square	*F*	*Sig.*
Between Groups		3.458	.153	ɔ49	ɔ92
Within Groups	0	35.500	.775		
Total	3	38.958			

Note: Significant level: 0.05

To achieve the objectives of OSH and guidelines of ISO/ IEC 17025:2017, the writer suggested that HIRARC evaluation tool is implemented as a basic assessment of occupational safety, health and environment in ORL. The activities of HIRARC were consist of Hazard Identification, Risk Assessment and Risk Control Element [7]. Hazard identification meaning is recognizing of things which may cause injury or harm to a person. Risk assessment is looking at the possibility of injury or harm occurring to a person if exposed to a hazard. The introduction of measures which will eliminate or reduce the risk of a person being exposed to a hazard is known as risk control [4]-[6]. At ORL, the HIRARC's activities were carried out comprehensively covering personnel aspects, work skills, procedures, equipment and environment but in this report only examine procedures related to animal receiving, animal surgery procedure, radiology imaging assessment and euthanize or harvesting of animal. Every critical point (in accordance with procedures) has been checked and found that there are only four safety hazards, two health hazards and an environmental hazard have been studied and highlighted in this report.

Overall, in the risk assessment analysis rating score for animal receiving is 2.6 which is trivial or tolerable conditions while reception of NZWR in the animal house. The laboratory personnel will face with a fierce rabbit because that rabbits are still new and not familiar with the ORL surrounding environment or it is undergone stress after a long-time journey in their carriage [8]. This is one of the major factors why safety hazard value is calculated by value 4. In addition, there are also biological hazards when handling NZWRs such as bacterial infection, allergies and exposed to bites. Therefore, value 3.0 is given to biological hazards. However, other hazards such as electrical and environmental hazards can still be tolerated because each has a risk rating of 2.0 because the wiring and electricity supply problems are not always happened, and environmental hazards have been monitored by previous laboratory management. Ergonomic hazard was doesn't give any effect to laboratory personnel because the animal acceptance and examination process doesn't take at a long time. Control measures had been taken and applied in every animal procedure performed at ORL animal house.

As for intra-operative procedure, there had overall rating score been 4.0 which is moderate conditions to all laboratory personnel including those surgeons had been performed their surgery with diligent and carefully. This surgery procedure requires a high commitment and focus. Most procedures in animal surgery involved in static posture and the repetition of the procedure causes an ergonomic problem was occurred. In addition, some surgeons and their assistants have had a cramp due to their long-term bending during procedures resulting in back pain to them. This is one of the main factors why the position of the ergonomic hazard risk rating is calculated by the value of 6.0. The handling of sharp surgical equipment and instruments such as scalpel, suture, oscillating drill, catspaws, mayo scissors, and others can bring safety hazards to the surgeon and his assistant with risk ranking of 4.0. Likewise, with biological hazards, discharges such as urine, faeces, and blood that are infected with various types of bacteria or fungus can infect anyone who touches or inhale it. There is also a problem of dehydration, eye strain and lost concentration following the temperature in the laboratory extremely cold during the surgery. Control measures have been taken and applied in every surgical procedure performed at ORL.

Published By:
Blue Eyes Intelligence Engineering
& Sciences Publication

In radiological examination activities, the overall rating score is 2.67 which is trivial or tolerable conditions compared to other procedures because it is a simple process and used

under full digital method. Every report and evaluation of the decisions is also read in fully computerized. Although the hazard is not much, the impact and risk assessment are largely inadequate. Safety and electrical hazards contribute to increased risk analysis with a risk rating of 3.0. This is influenced by the exposure of safety hazards to radiologists and laboratory personnel while electrical safety hazards are hazardous because they involve highly volatile machines and can generate secondary radiation. Biological hazards have relatively harmless risk rating assessments of 2.0 because it involves manual methods of handling such as anaesthesia of NZWR and carry out them into x-ray rooms. In addition, hazardous chemical, environment and ergonomic hazards are also acceptable (trivial) as it does not cause harm to the overall hazard score during radiological procedure.

IV. RECOMMENDATIONS

The overall risk level in ORL procedure related to animals can be classified at a low level. The safe working procedures practiced by all laboratory management staff seem to be effective for the present. Based on the discussion, there are several suggestions on improvements that can be made to maintain or lower the current level of risk. They are:

Enforce or Strict the Safety Procedures in Orthopedic Research Laboratory – Only workers, lecturers, students and visitors who are using complete personal protective equipment are allowed to enter the laboratory [9]. They need to wear them at designated area in ORL laboratory including animal houses. When they want to get out of the place, they need to remove the personal protective equipment, so they do not carry the hazard out of the laboratory or the animal house.

All Equipment Require Continuous Maintenance – Currently, there are no preventive maintenance practices used by most laboratories, including ORL laboratory. The purpose of preventive maintenance is to increase the reliability of equipment and life. Besides, it is also to prevent accidents that occur due to equipment failure. Servicing periodically whether internally or externally improves process accuracy and eliminates errors in metrology traceability calibration results. Good financial planning is needed to ensure that all these preventive maintenances can be done successfully.

Provide Larger and More Adequate Space to the Laboratory and Animal House – The number of requests for research received either from lecturer research grants, in vivo services from external and internal sponsors led to the increase in sample and use of NZWR every year. There is a congestion that occurs when the process is in place and the place where the place will take place will cause discomfort. To date, animal houses can only accommodate 42 rabbits only and animals crowded need to be avoided because it will cause uncomfortable and stress to the animals [10]. For now, the step taken such as research and booking process that is continually practiced is the best way to overcome this problem. Larger space can make a person comfortable and definitely will be performed well with high quality. If there is adequate space, airflow and laboratory temperature and humidity can be maintained and accident can be avoided.

Improve the Instruments and Chemicals Storage – Efficient storage systems not only recommended for future use but also for security purposes. Storage of equipment related to laboratory animals such as J feeders and water bottles should be well kept. This accessory apparatus if it is not well kept, it will be rusted and fast to decay. Moreover, it also can cause accident or incident in animal house. In the laboratory, the chemical storage system should follow the safety guidelines set [11]-[12]. Storage according to its type and chemical reaction is very important so that no incident or explosion occur. Make the SDS of each kimono material as the main reference materials.

Increase Management Commitment Concerns – ORL laboratory personnel, lecturers, students and visitors should show their concerns about safety by improving supervision over their work. They should also be responsible in implementing safety and health programs in these laboratories and animals and their surroundings [7]-[13]. The top management of the university should provide full cooperation in terms of moral and financial support to this laboratory. They also need to visit the ORL to discuss with the laboratory management in relation to the problems arising as this laboratory becomes a sample laboratory and holds a university KPI since 2014.

V. CONCLUSION

In conclusion, it is understood that the risk assessment level at ORL is 2.46 ($p = 0.592$) which entered the fact at low level. However, since the value is really close to 3, the risk level is somewhat lower and approaches a moderate level. The various risk levels for this study are 2, the difference between the highest (operative procedure) and the lowest (euthanasia), indicating that data differences are non-essential. Regards to the outcome retrieved, it is strongly recommended that some of the precautions need to be taken to further reduce the level of risk in the future.

REFERENCES

1. BioNexus Partner Programs (BNP), "Shared Assess to Research Facilities and Insfrastructure for the Life Sciences Industry -Orthopaedic Research Laboratory," *Malaysian Biotechnology Corporation*, 2014, 32–33.
2. Orthopedics Research Laboratory (ORL). *'Laboratory Technical Manual (ORTHO-LAB-TM-01)'*. Kuantan: Department of Orthopaedics, Traumatology and Rehabilitation, IIUM, 2014, revision 06(1), 5-6.
3. Standards Malaysia. *'Transition to ISO / IEC 17025:2017 General Requirements for The Competence of Testing and Calibration Laboratories (SAMM Circular 4/2017)'*. Cyberjaya: Department of Standards Malaysia [Online], 2017, 1-7. Available: http://www.jsm.gov.my/documents/10180/1932067/11+

SAMM+Circular+4+2017+Transition+to+ISOIEC+17025+2017%2C%20Issue+1%2C%2026+Dec+2017.pdf/d045a671-e1bb-44bc-949c-44acce7a08f5

4. AsmaliaChe Ahmad, Ida NiantiMohdZin, Muhammad Kamil Othman, Nurul Huda Muhamad, "Hazard Identification, Risk Assessment and Risk Control (HIRARC) Accidents at Power Plant," *MATEC Web of Conferences* [Online] 2016, 66(105), p.1-6. Available: http://doi.org/10.1051/matecconf/20166600105.
5. N.A. Shuaib, M.F. Ghazali, C.D.M. Asyrafand H. Azmi, "Applications of HIRARC at UniMAP Laboratories". *National Symposium on Advancements in Ergonomics and Safety* Malaysia, 2009, p. 167-171.
6. Nam Joon Cho and Yong GuJi, *"Analysis of Safety Management Condition & Accident Type in Domestic and Foreign Laboratory,"*ErgonSoc Korea 2016; 35(2): 97-109.
7. Agwu, M, "*The Effects of Risk Assessment (HIRARC) on Organisational Performance in Selected Construction Companies in Nigeria"*. British Journal of Economics, Management & Trade, 2(3), 212–224. Available: http://doi.org/10.9734/BJEMT/2012/1317.
8. Ehlers, Harvey, A., & Bryant, R., "*Stress-related and adjustment disorders*." New Oxford Textbook of Psychiatry, 2012, 693–728.
9. Koh, D., & Aw, T.-C. "*Surveillance in Occupational Health."* Occupational Environment Medicine 60,2003 705–710.
10. Esch, T., Stefano, G. B., Fricchione, G. L., & Benson, H. "*Stress-related diseases - a potential role for nitric oxide*." Medical Science Monitor: International Medical Journal of Experimental and Clinical Research, 2002, 8(6), RA103-A118.
11. Norliana, S., Abdulamir, A. S., Abu Bakar, F., &Salleh, A. B. "*The health risk of formaldehyde to human beings*." American Journal of Pharmacology and Toxicology [Online], 2009, 4(3), 98–106. Available: http://doi.org/10.3844/ajptsp.2009.98.106.
12. Zhang, L., Tang, X., Rothman, N., Vermeulen, R., Ji, Z., Shen, M., …Lan, Q. "*Occupational exposure to formaldehyde, hematotoxicity, and leukemia-specific chromosome changes in cultured myeloid progenitor cells*." Cancer Epidemiology Biomarkers and Prevention [Online], 2010, 19(1), 80–88.Available: http://doi.org/10.1158/1055-9965.EPI-09-0762.
13. Abdallah, S. S., Hussien, S., &Hisham, N. a. "*The Experience of Islamization of Knowledge at the International Islamic University Malaysia*." New Intellectual Horizons in Education, 2011, 91–111.

AUTHORS PROFILE

Mr. MohdZulfadzli Ibrahim, Senior Medical Laboratory Technologist andMSc. Candidate,Department of Orthopedics, Traumatology and Rehabilitation, Kulliyyah of Medicine, IIUM Kuantan, Campus.

Asst. Prof. Dr. MohdArmi Abu Samah, Senior Lecturer,Kulliyyah of Sciences, IIUM Kuantan Campus
Corresponding Author :marmi@iium.edu.my

Prof. Dr. Ahmad Hafiz Zulkifly, Arthroplasty surgeon and ORL Director, Department of Orthopedics, Traumatology and Rehabilitation, Kulliyyah of Medicine, IIUM Kuantan, Campus.

Mrs. NurulHafizaMohd Jan, PhD Candidate**,** Department of Orthopedics, Traumatology and Rehabilitation, Kulliyyah of Medicine, IIUM Kuantan, Campus.