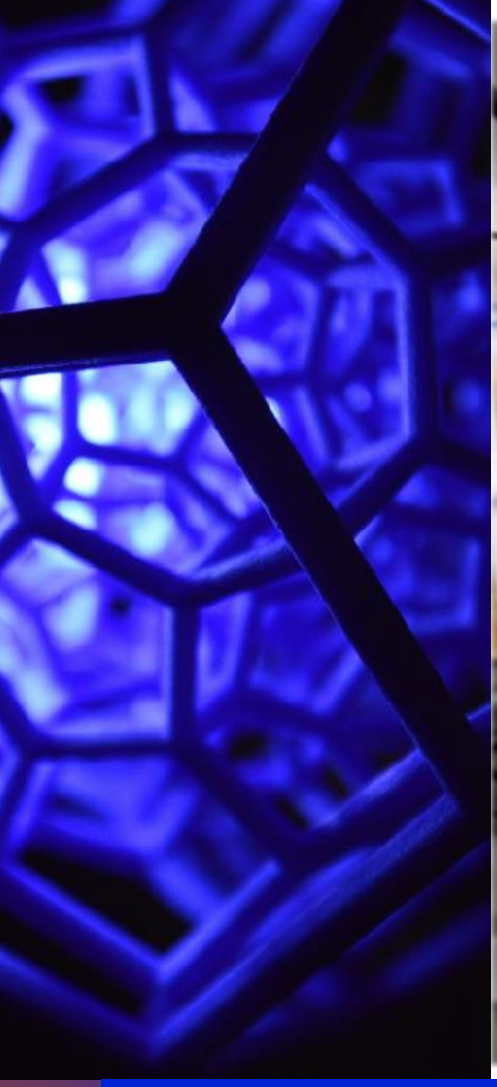


Evan Guilfoyle

EXTREMITY WEAR TESTING

TOTAL ANKLE AND SHOULDER REPLACEMENT TSTING

LUCIDEON
providing material solutions

INTRODUCTION

Wear simulation for implantable knee, hip and intervertebral spinal disc prostheses have all been well documented and standardised tests methods have been created to assess the performance of these medical device implants. Despite the fundamental developments in wear testing for hip, knee, and spine implants there has been little focus on extremity wear testing for other medical implants. Current knowledge of wear performance in Total Ankle Replacements (TAR) and Total Shoulder Replacements (TSR) is limited which has resulted in the need for more detailed examination of the performance of these implants both under in-vivo conditions and in the laboratory.

Even though Total Ankle and Shoulder Replacement surgeries are much less common than other implant surgeries, the need to develop and validate standardised wear test methods is just as important, if not more important, than just focusing on improving current anatomical wear testing.

WHY TEST IMPLANTS?

To understand the performance of implants, mechanical tests must be carried out to assess the various types of fatigue and wear mechanisms occurring throughout implant life; characterisation of any resulting wear particles in the body is also important.

Since there are no standardised wear test methods for ankle and shoulder prostheses, high quality mechanical testing can be extremely useful to implant manufacturers. Mechanical testing of implants can offer numerous advantages: [1] the risk of clinical complications can be reduced by detecting problems during preclinical testing, [2] the performance of different designs can be compared, and [3] the effect of individual factors can be analysed and tested.[1]

ANKLE IMPLANTS

The ankle joint is composed of three articulating couples: the tibiotalar, fibulotalar, and tibiofibular, which allow a large range of motions to be obtained. The primary motion which occurs in the ankle is plantar flexion and dorsi flexion, which is quite easily replicated, but when the range of motion of the ankle and subtalar joints is analysed as a whole, the biomechanics of the ankle joint become more complex and difficult to simulate whilst conducting wear testing.

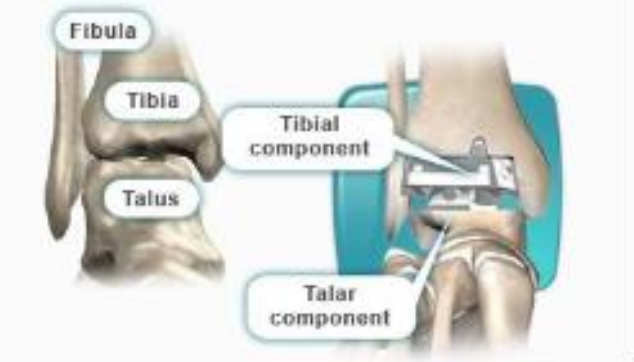


Figure 1.- Ankle implant.[2]

Total ankle replacements have been carried out since the 1970s with designs being continuously modified to improve wear rates and reduce revision surgeries. There are two types of ankle prosthetics that can be used depending on the type of implant needed. The majority of ankle replacements have a mobile bearing located between the talar and tibial components which allows the ankle joint to move during motion. The other type is known as a fixed bearing ankle replacement which consists of two components. The type of prosthetic chosen whether it be mobile or fixed, depends on the client's symptoms. The primary goal of all implants is to reduce pain with the secondary goals to improve motion, strength and increase biomechanical function.

To improve and develop standardised testing of TAR, there needs to be more in-vivo testing carried out to analyse both the relative range of motion and forces acting on in-vivo ankle prosthetics and the long-term effects associated with these implants.

CURRENT ANKLE TEST CONDITIONS

Current wear tests carried out on ankle prosthesis follow the same set up format as standardised hip and knee wear tests. Due to the lack of research

and testing into ankle prosthetics, there is limited knowledge of the kinematics and loading conditions.

Therefore, most TAR wear tests to date refer to using B. Reggianis[3] profiles or slightly modifying his kinematics profiles depending on the wear testing being carried out.

Figure 2 below shows an example of an input profile used to analyse a new TAR mobile bearing. Kinematic inputs were derived from an extensive review based on the literature available to CJ Bell & Fisher at the time.

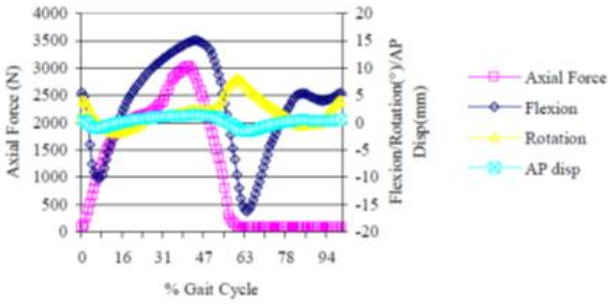


Figure 2.- CJ Bell & Fisher – Simulator kinematic input profiles derived from the literature. [3]

Below shows a table the other test parameters used in the literature which all follow similar paths to that of the above profile. The following parameters are applied to the majority of current tests

- Plantar–Dorsi flexion angle (PD)
- Internal–External rotation (IE)
- Antero–Posterior translation (AP)

Test	Axial Load (N)	PD Range (Deg)	IE Range (Deg)	AP Range (mm)
Reggiani	1600	30	10.3	
Bell & Fisher	3100	30	10	3
S. Affatato	2600	58	7.6	5.2

Loading to the TAR is applied perpendicular to the tibial component to follow anatomical conditions. The loading range can vary depending on the TAR implant and can be scaled for various tests.

During the stance phase the Axial Load increases along the gait cycle and can be seen in the profile produced by CJ Bell above. Minimum load is applied during the swing phase to mimic real life conditions.

ANKLE IMPLANT WEAR TESTS IN KNEE SIMULATORS

All wear tests conducted for TAR implants follow the same test conditions as ISO 14242 and ISO 14243 Wear of Hip and Knee Joint Prosthesis. Current wear tests are conducted for 3-5 Million cycles at frequencies ranging between 1-1.5 Hz. After every 500,000 cycles the bovine serum is replaced, and gravimetric weighing of the components is performed. The used serum is then frozen for particle isolation and for characterisation of the wear debris at a later stage.

The applied kinematics for the various tests is carried out in displacement control for the following degrees of freedom: Plantar–Dorsi flexion angle, Antero–Posterior translation, and Internal–External rotation, to ensure excessive motions did not occur, which may result in dislocation of the ankle joint.

Figure 3.- The three-components of the ankle prosthesis, in the neutral position, i.e. aligned in all three anatomical planes: (A) tibial, (B) meniscal, (C) talar component. [2]

In order to carry out ankle wear tests in knee simulators, fixture holders need to be designed and manufactured to position the ankle prosthetic with a consistent neutral anatomical position which can be seen in Figure 3 above. When designing these fixtures, care needs to be taken in order to achieve the desired set up positions and to ensure that the centres of curvature of the two circular arcs are positioned correctly in order to achieve accurate wear result.

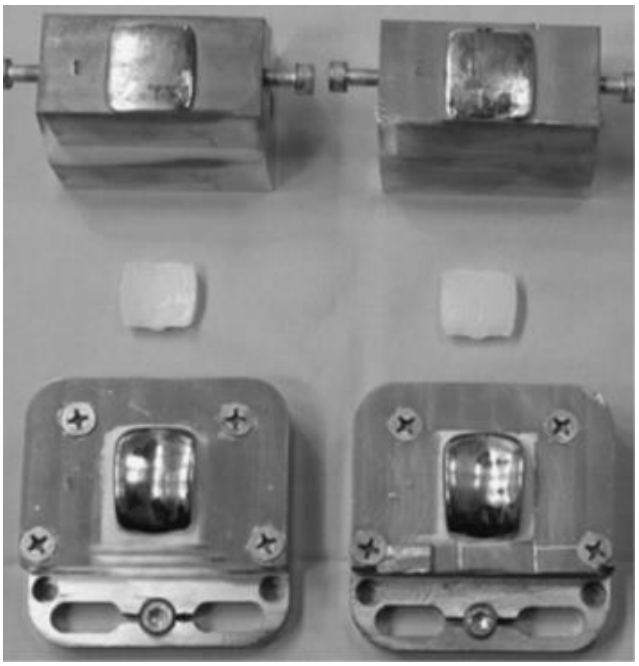


Figure 4.- Fixture set up for ankle wear testing performed using a four-station Shore Western USA knee joint simulatortibial (above), talar (below) and meniscal bearing (in between). [2]

The design set up in Figure 4 is one of the many ways in which a knee simulator can be set up to carry out ankle wear testing. The two metal components were fixed both top and bottom with bone-cement in the desired anatomical position.

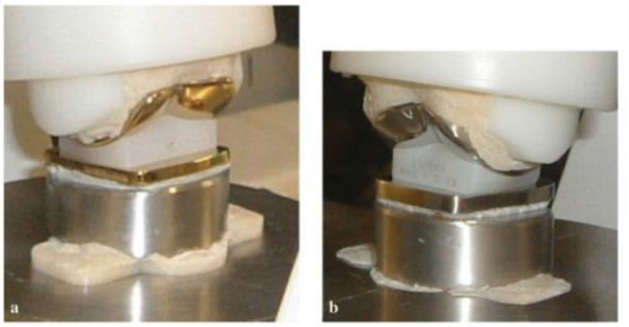
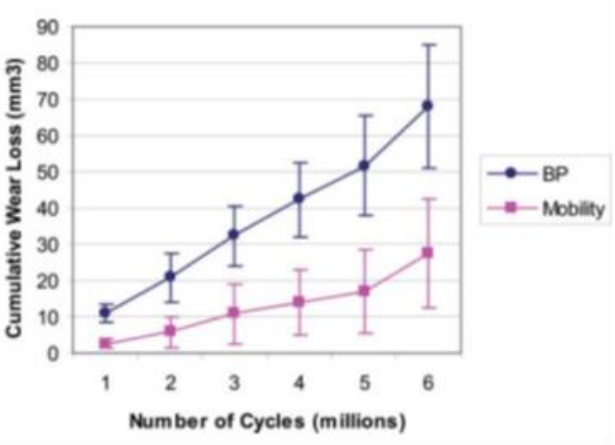


Figure 5.- Inverted ankle wear testing of two mobile bearing ankle designs.

A six station ProSim knee simulator, which can be seen above, has been modified to allow for ankle joint wear testing. This test method was carried out to compare the wear associated with a new mobile bearing design to a previous design. This set up varies from the previous one as the components are being tested in an inverted position. Both tibial plates were set up as recommended clinically. The kinematic inputs and outputs were monitored daily during the test and adjusted to ensure all stations were behaving in a similar manner.



Graph 1.- Mean wear rates + error bars comparing BP and mobility components after 6 million cycles.5

As can be seen in Graph 1 above, the wear rate for the mobility components was lower than that for the BP ankles; however, only three samples of each were tested. To achieve more significant results more replicates are required.

The two current wear test set ups using knee wear simulators confirmed their ability to accurately reproduce load-motion cycles throughout both of their desired testing periods. Despite the large and complex motion imposed on the tibial and talar components, it was observed that a knee simulator can be adapted to run wear tests on ankle prosthesis.

SHOULDER IMPLANTS

The shoulder consists of a ball-and-socket joint which has a large range of motion associated with it. It allows the arms to be raised, twisted, moved forward and backward and from side to side. This large range of motion, along with the flexibility associated with the various shoulder ligaments, can be hard to accurately replicate in the design of shoulder implants.

There are two types of shoulder implants which are currently available: the conventional shoulder implant, consisting of a metal ball and stem which is inserted into the humerus with a polyethylene cup located in the socket of the shoulder blade; and a reverse total shoulder replacement joint. As the name suggests the positions of the implant in this type are reversed. A new metal hemisphere is used to replace the socket of the shoulder blade and a metal and high-strength plastic socket is used to replace the head of the humerus. These two different implant set ups can be seen below in Figure 6.

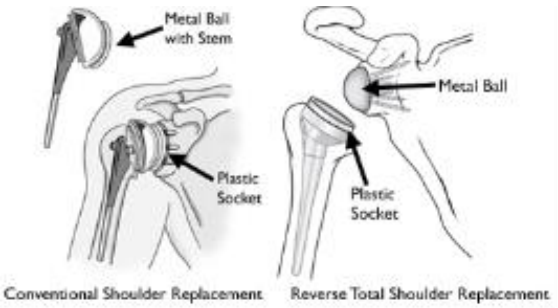


Figure 6.- (left) A conventional total shoulder implant which mimics the normal anatomy of the shoulder and (right) a reverse total shoulder replacement. [4]

The type of prosthetic chosen depends on the shoulder pain felt by the client. The primary goal of both types of shoulder implants is to reduce pain with the secondary goals to improve motion, strength and increase shoulder function. Shoulder arthritis is among the most prevalent causes of shoulder pain and loss of function and when non-surgical treatment is no longer effective joint replacement surgery is usually indicated; this however can have both pros and cons. [7]

CURRENT SHOULDER PROBLEMS

Currently, there is no evidence to indicate which type of shoulder prosthetic design is more effective. The primary reason for total shoulder failure is loosening of the glenoid component which has been reported in one third of all complications occurring with the joints. [6]

Factors which cause glenoid loosening include problems in achieving the desired component orientation during surgery, failure of the bone cement, and off-centre loading caused by eccentric forces acting on the component and humeral head. Other reports suggest that loosening of shoulder prosthetics can also be caused by osteolysis of the bone due to wear particles produced by the implant. [1]

FACTORS TO CONSIDER WHEN TESTING SHOULDER IMPLANTS

There are many factors which influence the wear of total joint replacements but the main factors that need to be addressed in more detail in order to create standardised wear test methods include [1] the loading profile to be carried out during a mechanical dynamic test, [2] the motion involved to replicate real life wear conditions [3] the initial set up positions and [4] the geometries of the prostheses design.

There has been limited research carried out on the effects of dynamic wear testing on shoulder implants. In order to fully understand the wear biomechanics of shoulder joints more in-vivo testing needs to be carried out to analyse the relative range of motion and forces acting on in-vivo shoulder implants. By understanding the

mechanical properties and in-vivo conditions that cause shoulder prosthetic devices to fail, design changes can be made to improve wear and reduce failure rates.

CURRENT SHOULDER IMPLANT WEAR TESTS IN HIP SIMULATORS

Current tests carried out for shoulder prosthetics follow similar chamber test conditions as used in the Wear of Hip and Knee Joint Prosthesis. The components are tested in bovine calf serum with the test fluid and chamber in accordance with either ISO 14242 or 14243. The used test serum is then collected and frozen to analyse the wear particles – gravimetric weighing of the component is taken at various stages.

One of the main factors contributing to this lack of test data is that there is no commercially available test apparatus that simulate in-vivo wear conditions for shoulder implants. Shoulder implant testing is currently being carried out in modified hip simulators. Custom fixtures for current simulators are being designed and manufactured by testing laboratories in order to carry out wear testing of both conventional and reverse shoulder implants.

TOTAL SHOULDER REPLACEMENT TESTING

The following image shows the set-up of an AMTI 6-station control joint simulator which has been used to test conventional shoulder prosthetics.

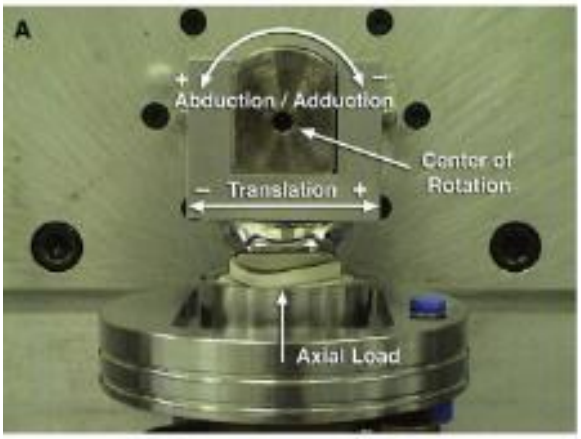


Figure 7A.- Shoulder wear testing setup in neutral position on joint simulator. [7]

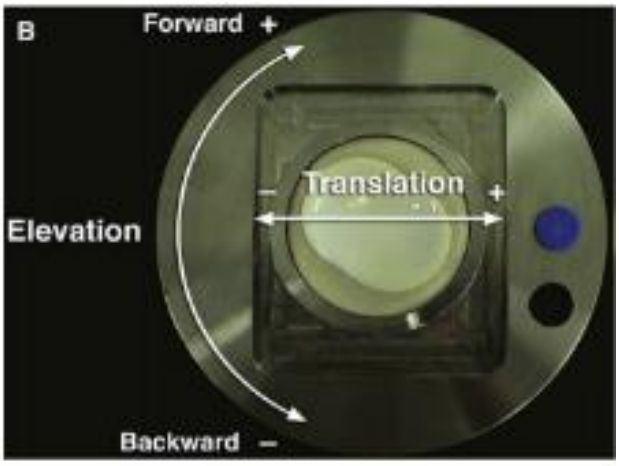


Figure 7B.- Top view of glenoid component mounted on associated fixture. [9]

The glenoid component is cemented to the base of the simulator which acts as the back of the glenoid socket while the humeral component is fixed to the central axis as shown. This set up has been designed to position the glenoid component with the desired starting position as shown in Figures 7A & 7B.

A constant axial load of 750N is maintained throughout the abduction-adduction, elevation, and translation kinematic motions cycle. The input profile can be seen below. This is designed to simulate rolling, sliding, and cross shear at the glenoid-humerus interface, to mimic daily shoulder movement.

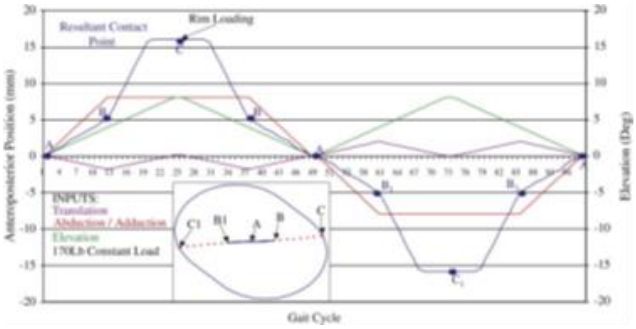


Figure 8.- Joint simulator kinematics input. The gate cycle motions include translation (+-2mm) elevation (+8°), and abduction/adduction (+-8°).[9]

The main aim of this study was to compare the wear rates between cross-linked and conventional UHMWPE prosthetic glenoids. As the graph shows below the cross-linked glenoid performed better, showing a total of 7mg/Mc compared to 46.7mg/Mc for the conventional UHMWPE.

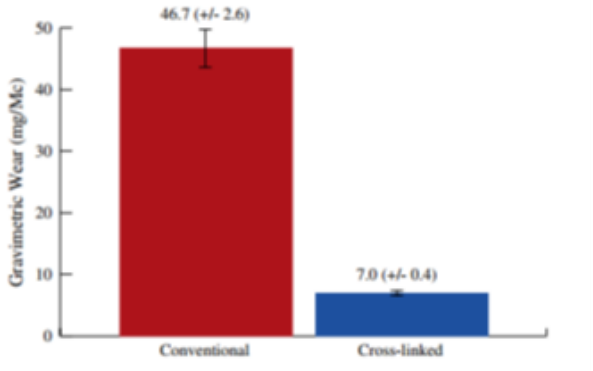


Figure 9.- Bar graph showing wear rates calculated for both conventional and crosslinked test groups. [9]

Even though the kinematic motions carried out during this test highly underestimate the complex motions associated with TSR implants, the results are still valuable and prove that hip simulators can be used to carry out valuable wear testing on shoulder implants.

REVERSE TSR TESTING

The same process is carried out for the testing of Reverse Shoulder Prosthetics. Again, custom fixtures were used to adapt this 12-station hip simulator to carry out wear testing. These fixtures seen below were designed to simulate both glenohumeral abduction and flexion. The test was carried out for a total of 5 million cycles with fixtures switched from abduction-adduction to flexion-extension every 250,000 cycles.

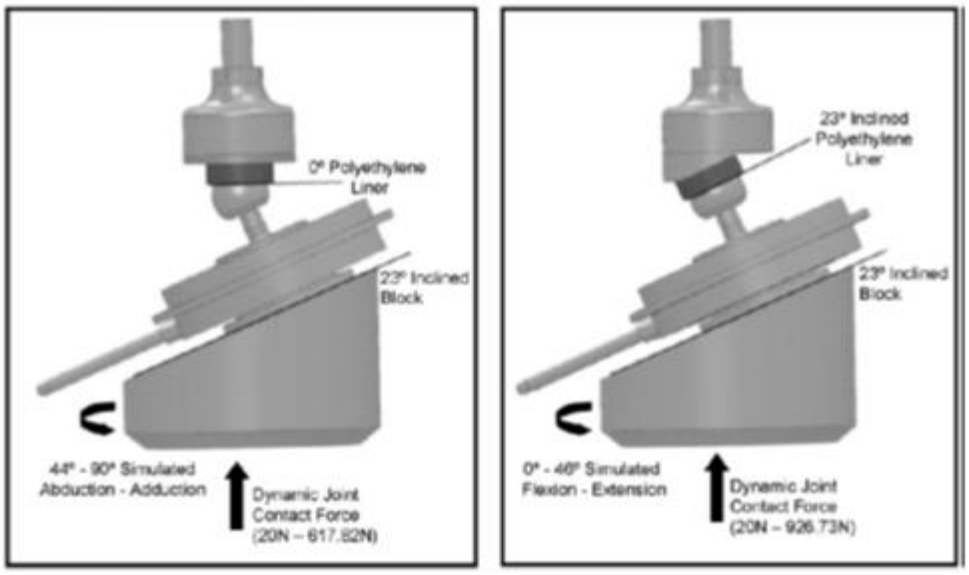


Figure 10.- Customised fixtures for rTSR abduction-adduction (left) and flexionextension (right). Angles are measured from the neutral testing machine base. [10]

The two fixtures were designed in order to analyse the wear due to abduction as well as flexion. The first fixture design simulates glenohumeral abduction from 44° to 90° with the second design simulating glenohumeral flexion ranging between 0° and 46°. The loading profiles used during the simulation were taken from in-vivo tests carried out by Bergmann et al to find the glenohumeral contact forces present with rTSR throughout everyday life activities. A sinusoidal load ranging between 20N and 618N (90% body weight) was used for the abduction fixture while a 20N to 927N load (135% body weight) was used for the flexion test, which was in good agreement with the current contact forces available in the literature.[10]

The aim of this study was to develop a testing method to evaluate the effect of wear rates on two different glenosphere designs, humeral cups articulating with and without holes, and to interpret the relationship between the loading profiles and simulated range of motion.

The results exhibit similar wear rates and total volume loss between the two designs tested in this study. Similar particle characteristics from both designs were also seen.

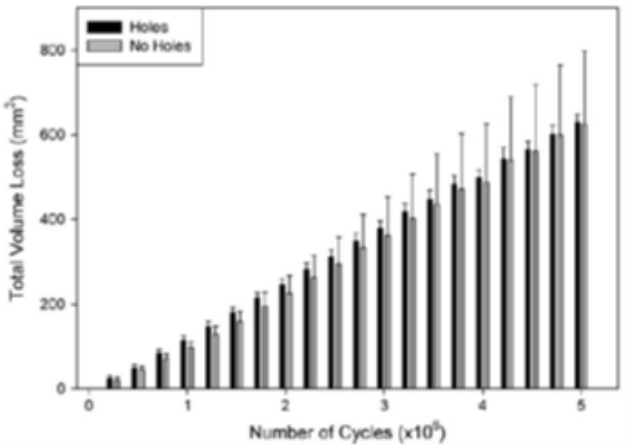


Figure 11.- Average total volumetric loss between glenospheres with holes and glenospheres without holes.[10]

The following load-motion profile for wear testing of reverse shoulder implants was performed by two IMA 3 Station Type E hip joint simulators to analyse the effect of swapping the materials associated with rTSR implants i.e UHMWPE Inlay and CoCr Glenosphere - to the reversed pairing- UHMWPE Glenosphere and CoCr Inlay. Again, like the previous hip simulators, custom fixtures were designed in order to align the rTSR in the correct anatomical position.

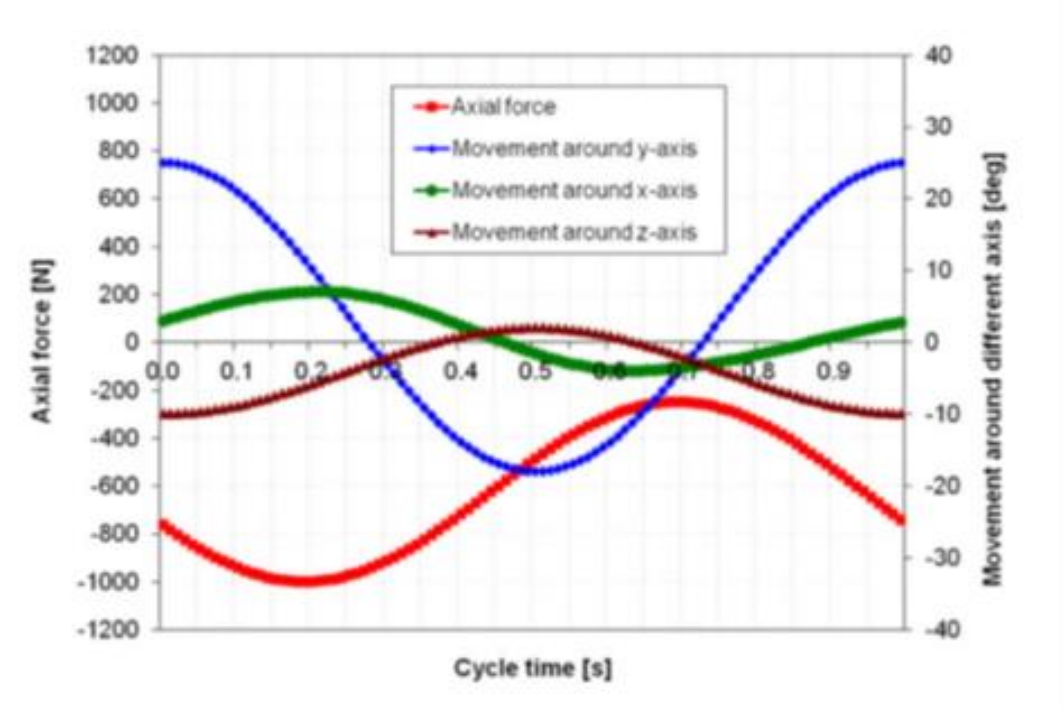


Figure 12.- Synchronisation of the load and motion curves at the simulator adapted for shoulder conditions. [11]

CONCLUSION

In recent years Total Ankle and Shoulder Replacement surgeries have become more and more common but there has been little focus on the effects of implant wear and the performance associated with these implants. Standardised test methods for TAR and TSR implants need to be published in order to regulate the performance of these implants. To do this more in-vivo testing needs to be carried out to assess the true load-motion profiles to be carried out during mechanical test.

Currently, ankle and shoulder prosthetics are being tested using modified knee and hip simulators. Despite the lack of designated TAR and TSR wear simulators, there has been some valuable data retrieved from the current testing of these extremity implants which can be seen in the above studies.

The kinematic load–motion profiles presently carried out during extremity testing may underestimate the complex motions associated with in-vivo prosthetics, but the results obtained are still valuable and prove that both hip and knee simulators can be modified to carry out wear testing.

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ABOUT LUCIDEON

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Evan is a Mechanical Engineer with a first-class honour Bachelor Degree in Mechanical and Materials Engineering. Evan has extensive experience in the construction industry and is currently exploring the use of Digital Image Correlation as a new means of measurement testing within the Construction and Healthcare departments.

Evan has been working in Lucideon's Healthcare department on the development of anatomical wear testing as well as wear particle isolation and characterisation.

All details correct at time of initial publication.