

Manufacture and Instrumentation of Bio-Mechanical Shoulder Testing Rig for Medical Applications

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ABSTRACT

Manufacture of medical simulations and devices is complex as parameters are often complex and ill-understood. Until recently the accurate measurement of contact loads acting in the Glenohumeral joint have been difficult to calculate and define. Now, contact forces and moments are measured in-vivo using telemeterized Shoulder implants. This method limits testing opportunities so a dynamic Shoulder testing apparatus has been developed to examine Glenohumeral joint motion and forces. This in-vitro study describes a novel testing arrangement and evaluates the accuracy of forces generated in the Glenohumeral joint using an instrumented prosthetic implant. Forces were applied to cables to simulate loading of the supraspinatus, subscapularis, infraspinatus/teres minor, long head biceps and anterior, middle, and posterior deltoid muscles. The test rig described reproduces the 6DOF of the Glenohumeral joint and accurately recreates the contact forces measured in-vivo. This design will allow many more tests to be simulated including comparison of fixation methods and high impact injuries. As a result of the study it will be possible to make recommendations regarding the biomechanical fixation techniques of the proximal Humerus for varying complexities of fracture, differing bone properties and populations in an attempt to find the optimal treatment to suit each individual patient. It also provides a valuable demonstration of new design and validation techniques used when developing medical simulations and devices.

1. INTRODUCTION

The Glenohumeral joint poses one of the biggest challenges to an orthopaedic surgeon when compared to any other joint within the human body. Due to its complicated anatomy and large range-of-motion (ROM), understanding the dynamic in-vivo kinematics of the shoulder joint is a challenging problem in the field of biomechanics [1].

A key problem in accurately designing ex-vivo (outside of the human body) simulations of the Glenohumeral joint has been defining in-vivo muscle forces. To simulate shoulder activity, in-vitro knowledge of the distribution of forces in the muscles crossing the shoulder is needed [2]. Unlike some other muscles, it is not possible to measure directly in-vivo rotator cuff muscle forces. Therefore, biomechanical models are needed to estimate muscle forces from external loadings on the body [3].

Previous ex-vivo testing has fallen into two categories in-vitro and in-silico. Within each category there have been numerous approaches and techniques employed. In-vitro (mechanical) studies have mainly focused on joint motion and muscular recruitment and not investigated forces generated in the Humeral head [4-6]. These are performed using cadaver specimens which allow direct comparison to the in-vivo in terms of physiological characteristics however display vastly heterogeneous bone quality and strengths [7-8] meaning there is little or no benefit in muscular loading patterns, joint ROM and external loadings. In-silico (computational) studies have been performed in both 2 and 3 dimensions. The main challenge in in-silico studies is the highly nonlinear, isotropic and currently ill-understood biomechanical behaviour of biological materials [9].

To expand on presently developed testing mediums and address the inherent challenges of in-vivo joint force measurement this study aims to develop and validate a functional testing medium to explore forces in the proximal Humeral head.

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This paper defines a novel test rig which simulates the 6DoF motion found in the Glenohumeral joint and uses an instrumented implant to accurately measure the forces generated. The use of in-vitro testing is a huge advantage compared to in-vivo as it allows destructive testing and experimentation to be carried out with implants, fixation methods and fractures.

Accurate simulations of the forces in the Glenohumeral joint are essential for investigation of normal and pathologic shoulder function. It forms the basis for evaluating fracture treatment, joint replacement design and fixation.

2. MATERIALS AND METHODS

To successfully design any functional testing medium a set of design parameters must be established. These are based on an understanding of the anatomy of the joint and functional requirements. This study aims to;

- Apply loading representative of the in-vivo physiological characteristics of the Glenohumeral joints.
- Simulate physiological movement patterns to imitate Activities of Daily Living (ADL's) during cyclical loading patterns
- Produce a large range of motion in 3 distinct axes to replicate the in vivo mechanics of the Glenohumeral joint
- Maintain articular congruency throughout the ROM.
- Simulate the torsional loading / deforming forces applied to the proximal Humerus due to the dynamic muscular stabilisation of the shoulder girdle along the line of action of each of the muscles.
- Replicate the 3 axes of translation found at the Glenohumeral joint to reproduce the articular geometry of the Glenohumeral joint.

2.1. EXPERIMENTAL MODAL

The ex-vivo mechanical test rig is designed in an attempt to model the in-vivo characteristics of the Glenohumeral joint as closely as possible. This design, shown in figure 1, allows for accurate and detailed data collection on multiple tests and movement in 6 Degrees of freedom (6DOF) with function to adjust the position of the Glenoid simulating movement in the Scapulothoracic plane.

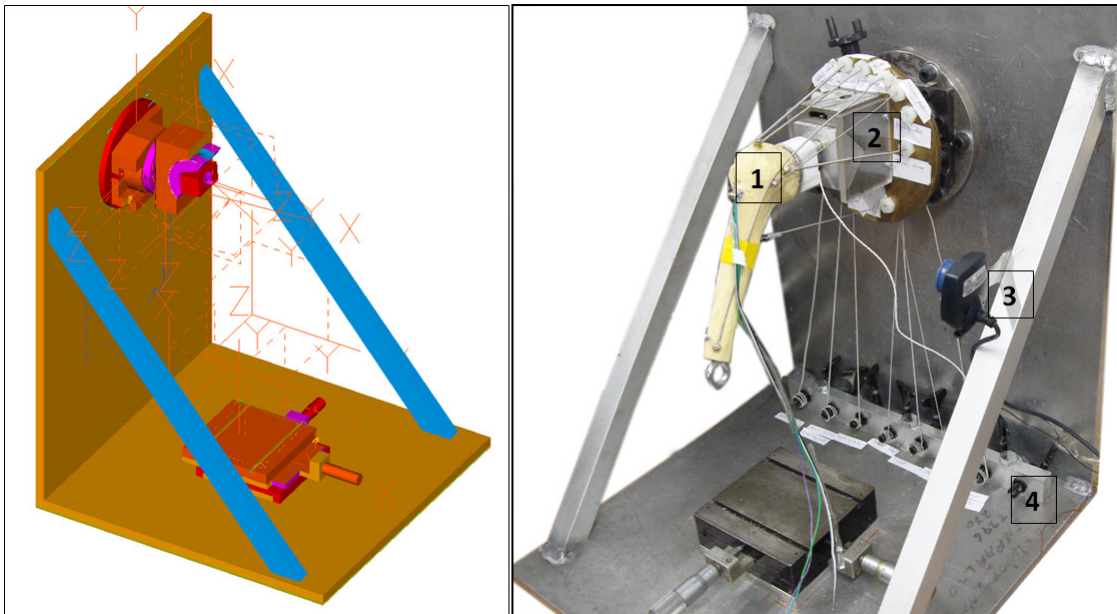


Figure 1. The developed test rig showing muscular attachments and mobile scapula mounting block. Highlighted points: 1 – Glenoid mounting arm comprising of a rotational plate and variable angle plate, 2 – Proximal Humerus with instrumented implant and nylon Glenoid capsule, 3 – Adjustable module mounting plate, 4 – Muscle wire Tensioners.

The proximal Humeral head is located centrally to the Glenoid during all testing, this is considered standard practice during shoulder simulation [10-11]. Artificial musculature is simulated using ductile wire sutured to the musculo-tendinous junctions of the muscles to allow the application of muscle forces. The use of wire to simulate muscular attachments is a well-established procedure [12]. The anatomic location of the footprints was taken from the investigation of Curtis et al. [13]. Muscle forces are applied individually to each muscle wire according to the simulated motion. Muscle recruitment is based on work by Favre et al. [14] who define a validated computational model for recruitment though forces are not measured in favour of simply maintaining central Humeral location.

Composite bones are used in this study which, display both Cancellous and Cortical bone developed from polyurethane and epoxy (custom Synbone) (SYNBONE AG, Malans, Switzerland). The practice of composite bones is described and justified by Dunlap et al. [15]. The use of composite bones simplifies the testing and allows for accurate and destructive testing to be carried out. All bones were based on a 50th percentile 40 year old man with a body mass of 75Kg.

Due to the variety in reported muscle forces, results generated by Favre [14] are used in this study. This data set is selected as the basis for defining muscular loadings for FE simulation because using an algorithm allows for further development and repeatability not possible in an in-vivo study. Eight dynamic muscular attachments are applied to the proximal Humeral head to accurately simulate the in-vivo conditions, these being; Superspinatus, Subscapularis, Long Head Biceps, Infraspinatus and Teres minor, Teres major, Posterior Deltoid, Pectoralis. In the model the Infraspinatus and Teres minor are considered as one combined force, this is a common simplification as the muscles work very closely together [12]. Muscles are loaded specifically for each movement goal.

2.2. INSTRUMENTED HEAD

The design and validation of the ex-vivo instrumented implants used in this study has been described in our previous publications [11, 16]. A resurfacing head is shown to be an improved method of joint force measurement as it maintains more of the natural physical characteristics of the bone [16]. In this study a Bio-met Copeland resurfacing head (Biomet UK Ltd, Bridgend, South Wales, UK) is used and modified allowing the insertion of data collection instrumentation. The heads are instrumented with two semiconductor strain gages (350_, type KSP 1-350-E4, Kyowa, Japan) one at 0° and one at 90° relative to the neck axis measuring the strain in the coronal (Y) and sagittal (X) direction based on the globe system [20]. The strain gauges are mounted in the neck of the implant similarly to the Orthoload [17, 18] implant. The influence of changing body temperature is irrelevant in this study but room temperature is factored in at the start of each test [18]. The transverse (Z) force component is measured using an Omega LCMWD-10KN washer load cell mounted behind the Glenoid. The generated signal from all gauges is amplified using a 24 pin DIL strain gauge amplifier before being data captured. A Nylon Glenoid replacement insert is used for both heads.

2.3. CALIBRATION

The instrumented heads are calibrated using a Lloyd LRX 102175 Universal Materials Testing Machine which applies a series of known loads incrementally in the coronal (Y), sagittal (X) and transverse (Z) planes. The test rig was calibrated each time a new test was performed, this accounts for small changes such as temperature change and gauge wire deformation. This is a similar approach to that described by Westerhoff [18] of the Orthoload implanted prosthetic approach. All testing is defined to start in the “at rest” position (see Table 1).

All tests were based on a 50th percentile 40year old man with a body mass of 75Kg though forces are given in N in this paper they can be converted into %body weight using this data. The test rig is capable of generating forces equal to over 2 times body weight in all axes under these conditions.

2.4. VALIDATION

To validate the developed testing mediums in-vivo data of the functional Glenohumeral joint forces are required. As discussed many techniques have been applied for mechanically measuring the forces generated in the Humeral head.

The current gold standard data is collected by Bergmann and Westerhoff [17-18] as part of the Orthoload Project [19]. To accurately validate against this “gold standard” data a similar implanted strain gauge method is applied.

All tests are based on co-ordinates suggested by the international society of bio-mechanics [20] this makes the tests repeatable and removes the variation in forces caused by different movement patterns noted in the in-vivo instrumented implanted head studies [18].

Table 1. Summary of test conditions showing motion path, applied loads and standardised global positioning data [20].

| <i>Test</i> | <i>Motion Summary (Global positioning co-ordinates [20])</i> |
|---------------------|--|
| At Rest | Arm by the side starting position (3,24,0) |
| 45° Abduction | Arm from “at rest” to position (13,91,20). 14.9N added distally for arm mass. |
| 45° Abduction + 2Kg | Arm from “at rest” to position (13,91,20). 19.62N added distally for arm mass. |
| 75° Abduction | Arm from “at rest” to position (13,137,21). 14.9N added distally for arm mass. |
| Steering 2 Hands | Hands at 10to2 position. 7Nm torsion force in wheel. Humerus flexed to 51° with 7° internal rotation |
| Steering 1 Hand | One hand steering. . 7Nm torsion force in wheel. Humerus flexed to 47° with 7° internal rotation |
| Flexion | Arm raised in front of the body to position (98,148,55). 14.9N added distally for arm mass. |
| Coffee Pot | Functional application of flexion. The arm is flexed from 30° to 60°. The coffee pot has a mass of 14N. |
| 10Kg Weight | Lifting of a moderate burden (10 kg) by the side of the body. The mass is lifted through retro-flexion of the Glenohumeral joint starting from the “at rest” position. |

3. RESULTS

Repetability in the instrumented head was tested using 300N directly applied 30 times along the X, Y and Z planes. Loadings were generated using a Lloyd LRX 102175 Universal Materials Testing Machine. Mean results and standard deviations are shown below in Table 2.

Table 2. Mean force results and standard deviation of repetability test for 300N applied directly in the X, Y and Z planes. C = Copeland Resurfacing Head. Z = Zimmer Stem implant.

| Head | <i>X</i> | | <i>Y</i> | | <i>Z</i> | |
|---------------------|----------|---------|----------|---------|----------|---------|
| | C | Z | C | Z | C | Z |
| Mean Ave (N) | 302.21 | -301.44 | 300.17 | 304.1 | -299.68 | 302.37 |
| Std Dev | 0.36076 | 0.4225 | 0.361652 | 0.49436 | 0.341306 | 0.32111 |

Results are presented in measured forces in the coronal (x), sagittal (y) and transverse (z) planes. Previous results are compared with the measured data using the mechanical and simulation mediums. A visual comparison is made in Figure 2 between the data collected in this study using the instrumented Copeland resurfacing head and that collected by Bergmann [17] regarding Abduction to 45° with and without a 2Kg mass.

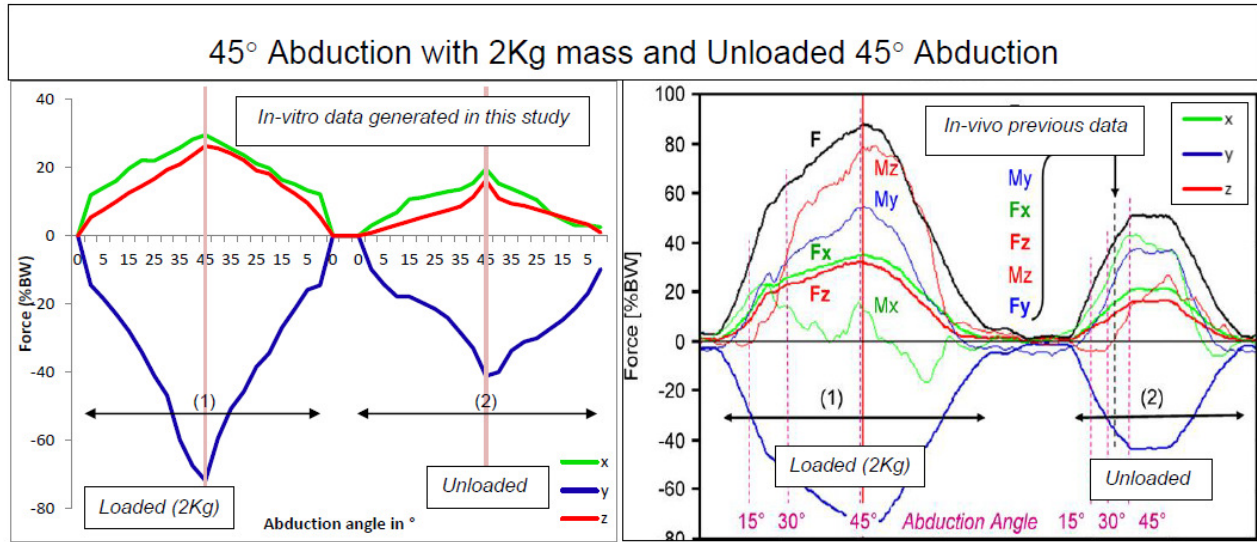


Figure 2. Comparison of the mechanical test rig results from the present study using the resurfacing head with previous data [17]. Similarity in forces and loading patterns can be seen between the data collected in this study and that previously collected in-vivo by Bergmann (Fx, Fy, Fz on right hand graph). The moment results on the Bergmann graph are currently ignored in this study. Data at points (1) show forces recorded during 45° Abduction with 2Kg held in the hand and points (2) show the same unloaded distally.

Similar proportional increase can be seen between the collected data and in-vivo data.

(%BW= Percentage body weight based on 75Kg man).

Comparison is made between the previous in-vivo data [17-18], and the mechanical test rig in table 3.

Table 3. - Comparison of the FE model forces with results from the resurfacing head and previously published data [17-18]. (Sagittal=Sag, Coronal=Cor, Transverse=Trans, Conformity=Confo).

| Test | Max Force Components (N) – in-vivo prosthesis | | | Max Force Components (N) Mechanical – Resurfacing | | |
|------------------|---|--------|--------|---|---------|--------|
| | Sag | Cor | Trans | Sag | Cor | Trans |
| 45° Abduction | 206.01 | -431.6 | 156.96 | 195.59 | -411.59 | 161.45 |
| 45° Abd + 2Kg | 343.35 | -725.9 | 313.92 | 294.73 | -717.73 | 262.92 |
| 75° Abduction | 333.54 | -725.9 | 245.25 | 296.07 | -692.94 | 269.81 |
| Steering 2 Hands | 137.34 | -372.7 | 117.72 | 103.40 | -334.81 | 129.69 |
| Steering 1 Hand | 343.35 | -645.8 | 529.74 | 266.04 | -464.75 | 209.25 |
| Flexion | 304.11 | -657.2 | 225.6 | 233.90 | -565.67 | 203.03 |
| Coffee Pot | 372.78 | -876.6 | 304.11 | 293.56 | -676.52 | 281.84 |
| 10Kg Weight | 242.37 | -641.5 | 376.39 | 222.00 | -583.39 | 321.03 |

Results are compared in Table 4 as 3D vector components. Percentage error is average error to the previous in-vivo results.

Table 4. 3D vector comparison between the test mediums showing percentage error between tests [17].

| <i>Test</i> | <i>In-vivo</i> | <i>In-vitro</i> | <i>%Error</i> |
|------------------|----------------|-----------------|---------------|
| 45° Abduction | 503.34 | 483.45 | -3.95 |
| 45° Abd + 2Kg | 862.18 | 819.22 | -4.98 |
| 75° Abduction | 835.65 | 800.38 | -4.22 |
| Steering 2 Hands | 414.27 | 373.64 | -9.80 |
| Steering 1 Hand | 903.08 | 574.94 | -36.33 |
| Flexion | 758.47 | 644.91 | -14.97 |
| Coffee Pot | 999.93 | 789.48 | -21.04 |
| 10Kg Weight | 782.26 | 701.92 | -10.27 |

4. DISCUSSION

This paper describes the manufacture of a new combined testing medium for the assessment of Glenohumeral joint forces. Medical simulations and devices prove a complex challenge, the parameters for which are complex and ill-understood. Ex-vivo data is generated and validated against current gold-standard in-vivo data.

The developed testing rig meets all the design requirements re-creating the in-vivo loading conditions and geometry of the Glenohumeral joint. There are 3 novel aspects to the testing method in this setup; the use of synthetic bone, standardised motions and Scapulothoracic movement. Synthetic bones are used for validation of the test rig in this project ensuring repeatability of the tests. The use of synthetic bones also allows for destructive testing of the proximal Humerus and Glenoid and tests to be carried out on pre fractured models. This will be invaluable when collecting data relating to fixation techniques and injury causes. Standardised motions are used in this study suggested by the international society of bio-mechanics [20] making tests repeatable and removing variation in forces caused by different movement patterns noted in the in-vivo instrumented implanted head studies [18]. The ability to simulate Scapulothoracic movements in all directions greatly improves on previous designs which fix the Scapula ignoring the effects of the Scapulothoracic plane [2].

The test results show the rigs ability to generate accurate results when compared with the results published by Bergmann [17] during simple motions. Comparison in this paper is not made to previous in-silico studies as these are not as valid as clinical in-vivo data. It is clear that more complex motions have a greater error when compared to the Westerhoff data [18]. There are a number of possible sources of error which could lead to the discrepancy with previously published results. Bergmann et al. [17] and Westerhoff et al. [18] clearly indicate a series of limitations in their study these include; the subject age, damage to the rotator cuff during surgery, irregular joint friction and varying motions. The use of healthy bone models in this study does not directly correlate therefore but is an advantage for future testing. A significant limitation in the previous in-vivo study is that patients were not advised how to perform actions [21] (The variation in movement can be clearly seen in the motion videos [17]). This allows subjects to achieve tasks using multiple different muscular combinations and postures for example the lifting coffee pot test can be performed at any torso angle and with a variable degree of rotation in the Glenohumeral and Scapulothoracic joints. These inevitably generate different and unrepeatably results. Using the test rig, described here, we can generate repeatable tests using motions from the globe system [20]. This standardises the experiments and allows the data to be replicated by other researchers but limited to the assumption of a middle aged male subject.

Each test was run 15 times to ensure repeatability. Standard deviation between peak forces during 45° Abduction is seen to be 0.0004mV, it is important to note however that mV change is naturally very low when using strain gauges. This correlates in Newton's as approximately 8N in the resurfacing head. Repeatability across all testing was very high. This is a significant benefit to in-vitro testing and the use of synthetic bone models.

The data from the first 45° of abduction without an external load shows -3.95% error. This closely matches the values calculated by Poppen et al. [22]. An additional weight of 2kg when lifting the arm increases the force by 66% which is directly comparable to the 51–75% described by Bergmann et al. [17]. During ADL's, the highest joint forces were determined when lifting a coffee pot in front of the body. Lifting 10kg by the side shows -10.27% error compared to the Westerhoff data [18]. This result is further confirmed by the work of Arborelius et al. [23]. Further validation is inhibited by the fact that other previous studies did not use ISB standards making comparison of results difficult [24].

The FE model is also validated against previous data. Given the inherent complexities of FE modelling, the generated results show moderate conformity to the previous values and mechanical testing rig. The obvious main source of error is the applied muscular forces. As discussed, the numerous muscular combinations and variations in muscular forces are significant.

The main functional motions; abduction and flexion, show -14.18% and -20.09% error respectively. As discussed the muscles were loaded according to the work of Favre et al [14], but also confirmed with work by Perry et al. [25] & Wilk et al. [26]. The Shoulder when abducted in this study showed maximum forces of 382.5N. Previous simulation and mathematical studies have shown results between 660N and 370N [22]. Close relationship can be seen between the generated results and work by Poppen et al. [22] and the Dutch model described by van der Helm et al. [27] during abduction. The Dutch model, until recently, has been a gold standard of Shoulder simulation thus further confirming the result of this study. Similar validation can be made between head forces proposed by Favre et al. [14] during flexion. This not only further confirms the result but further confirms the correct application of the muscle forces.

Results for steering with one hand shows conformity to the in-vitro tests, however not to the previous data. A full understanding of this is not currently possible however as the same motion pattern and loading conditions are used further investigation into the natural loading of the steering motion is clearly necessary.

5. CONCLUSIONS

The developed testing medium provides repeatable and reproducible results for forces within the Glenohumeral joint. Collected results are validated against current gold standard in-vivo data. High accuracy is noted in functional movements and similar loading patterns for both functional movements and ADL's. The significant benefits of validated ex-vivo testing are displayed using a novel approach in accurately recreating in-vivo joint mechanics. The testing medium can now be used to further understand joint kinematics, injuries, fracture prorogation and fixation. It will also provide a valuable training aid for a complex joint. Better understanding, testing and training of new techniques, tools and traumas is now possible. This will aid in reducing injury prevalence, severity, healing time and ultimately improving quality of life.

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