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Original Research

Active Motion Laboratory Test Apparatus for Evaluation of Total Elbow Prostheses

Taylor Combs, BME, [*] Brody Nelson, BME, [*] Maciej Jakucki, BSE, [*] Johannes Schneppendahl, MD, PhD, [†] Devon Moody, Associate Degree, [‡] Robert A. Kaufmann, MD [§]

[*] Element Materials Technology, Fairfield, OH
[†] Department of Orthopaedics and Trauma Surgery, Evangelisches Krankenhaus Mülheim, Mülheim, Germany
[‡] Bolttech Mannings Inc, North Versailles, PA
[§] Department of Orthopaedic Surgery, University of Pittsburgh Medical Center, Pittsburgh, PA

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Purpose: The goal of this study was to develop a dynamic elbow testing apparatus that reproduces active joint motion at different shoulder positions to quantify the capabilities of total elbow arthroplasty designs.
Methods: We designed a testing apparatus to create active cyclic elbow joint motion in human cadaveric and sawbones composite upper extremities. Two pneumatic actuators recreated humerus-originating muscles while rubber bands simulated forearm muscle action. Arthroplasty durability was quantified through laxity assessment at predetermined cyclic loading intervals.
Results: Humeral forces were recorded in three specimens to generate active elbow motion at different degrees of shoulder abduction. The laxity in varus and valgus was measured as deflection between two fixed markers.
Conclusions: In vitro simulation of elbow biomechanics through active cyclic elbow motion at different degrees of shoulder abduction may characterize in vivo performance of total elbow arthroplasty.
Clinical relevance: Quantifying total elbow arthroplasty stability after cyclic loading in different shoulder positions may assist preclinical evaluation of arthroplasty designs.

Joint simulators have been developed to mimic kinematics and loading in the laboratory to evaluate the biomechanical characteristics of surgical techniques and implants. These experimental setups can be broadly separated into those that use passive motion and those that use active motion. Passive motion investigations are most common whereby major muscles are simulated while the elbow is held in static positions or while an investigator introduces externally applied forces. One such study manually flexed the elbow while the biceps and brachialis were actuated with a 2-kg weight and the triceps with 4 kg. Varus and valgus forces were created by the weight of the adducted and abducted arm and a weight affixed to the ulna, whereas displacement data were collected with an electromagnetic tracking device.[1–3] A similar passive motion model loaded the biceps and brachialis with 10 N, and the triceps with 20 N.[4] Most of the total elbow arthroplasty passive motion tests did not reproduce forearm muscles, which have been shown to stabilize the elbow and decrease joint laxity.[5,6] Just one passive motion experimental setup that tested elbow arthroplasty did incorporate loads that originated from forearm muscles while applying varus and valgus forces to the elbow.[7]

Active motion through pneumatic loading of the biceps, brachialis, brachioradialis, triceps, and pronator teres tendons with forces between 15 and 58 N improved kinematic repeatability.[8,9] This same experimental setup was used to characterize elbow biomechanics in the varus, valgus, and horizontal positions.[10]

Until now, active motion studies have not been used to assess the biomechanics of total elbow arthroplasty. During everyday use,

Declaration of interests: Dr Kaufmann owns Arrch Orthopedics, which has developed this novel method of uncemented elbow arthroplasty. No benefits in any form have been received or will be received by the other authors related directly to this article.

Corresponding author: Robert A. Kaufmann, MD, Department of Orthopaedic Surgery, University of Pittsburgh Medical Center, Kaufmann Medical Building, 3471 Fifth Avenue, Suite 1010, Pittsburgh, PA 15213.
E-mail address: kaufra@upmc.edu (R.A. Kaufmann).

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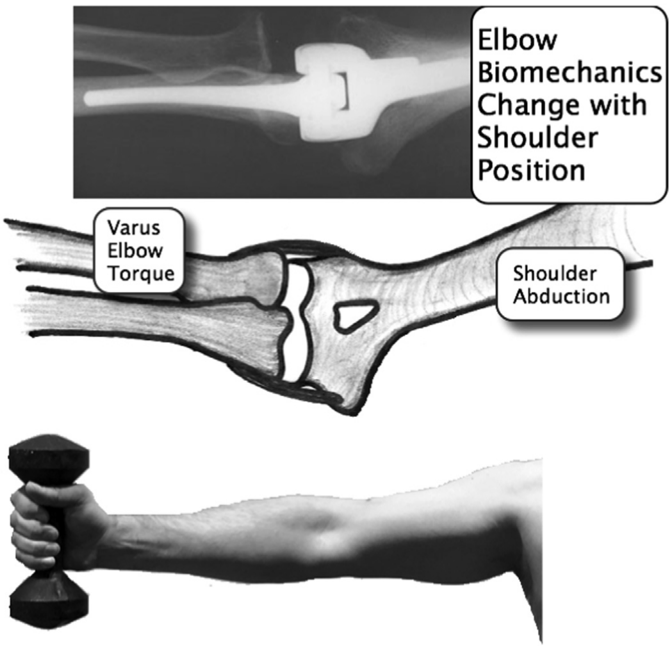

Figure 1. Shoulder abduction is commonly required to perform daily activities and leads to varus loading at the elbow.

the arm is frequently abducted, which creates varus forces that influence elbow biomechanics and may impact elbow arthroplasty function (Fig. 1). Furthermore, varus and valgus forces create polyethylene edge loading that has been identified in explanted semiconstrained total elbow replacement bearings and should be recreated when evaluating elbow arthroplasty.[11]

It has been estimated that approximately 900 flexion/extension cycles occur per day with some object in the hand, but lavatory activities might bring the total number to 1,400. This equates to 500,000 cycles per year for nominal activities of daily living, presumably with some weight in hand. For activities of daily living involving a significant weight in hand (44.5 kg), an average of approximately 20 cycles per day or 7,300 cycles per year was reported.[12,13]

To the author's knowledge, no experimental system has been developed, which is capable of generating active flexion and extension in the dependent, 45° abducted, 90° abducted (varus), 135° abducted, and 90° adducted (valgus) positions. Furthermore, no total elbow arthroplasty (TEA) experimental setup has employed simulated active muscle loading to quantify the durability of total elbow arthroplasty. The objective of this study was, therefore, to develop an elbow motion and loading system that is capable of generating repeatable active elbow flexion and extension in different shoulder positions. Elbow replacement designs may benefit from an experimental setup that creates active motion while reproducing forearm-originating muscles at multiple shoulder positions and better represents in vivo—loading conditions than a passive motion test.

Materials and Methods

A total elbow arthroplasty was implanted into sawbones or cadaver arms using the standard surgical technique. Sutures were attached to the triceps, brachialis, and biceps tendons. The origin of the flexor pronator mass and the extensor mechanism were visualized, and metal hooks were inserted into the lateral and medial epicondyle of the humerus, respectively. The rubber band displacement that created 15 N was identified with a tensiometer. A Steinmann pin was placed at this distance from the hooks so that the rubber bands applied 15 N of tension to power both the flexor pronator mass and the forearm extensor mechanism. The forearm was pinned in neutral rotation. A 1-pound weight was attached to the distal radius with plastic zip ties (Fig. 2).

The specimens were attached to the loading system with a specialized clamp designed to rigidly hold the humerus without constraining elbow motion (Fig. 3). This clamp allowed shoulder abduction and adduction positioning in 15° iterations. The triceps tendon and the brachialis and biceps tendons received Krakow suturing methods with fiber wire sutures. Double acting 0.62″ diameter rear pivot mounting pneumatic cylinders (BIMBA Ltd.) created full active elbow flexion (2″ stroke) and extension (3.5″ stroke) and mimic the lines of action for the biceps and brachialis anteriorly and the triceps posteriorly (Fig. 3). Because the excursion was limited by the length of the cylinder, the force exerted on the tendon stopped at the motion end points, which prevented tendon damage. For each direction of motion, the agonist was active, whereas the antagonist demonstrated minimal activity.[14]

The experimental setup mimicked the shoulder's capability to abduct and adduct the arm. Although the experimental setup was able to position arms in neutral (arm is at the patient's side) and then in 45°, 90°, and 135° of adduction or abduction for a total of 7 possible "shoulder" positions, only 5 shoulder positions were tested with the arm in neutral (arm is at the patient's side) and then in 45°, 90°, and 135° of abduction and 90° of adduction (Fig. 3). Intermediate adduction positions of 45° and 135° were not tested due to the unlikelihood of clinically encountering this position.

The flexion and extension of the system, including timing and magnitudes of the applied loads, were controlled with a combination of custom-written DASYlab and Enfield Technologies' Servo Pneumatic Proportional Control System Software (Trumbull). In DASYlab (National Instruments), a sinusoidal voltage signal was generated, and its main parameters (frequency, amplitude, and offset from 0 Volts) were generated. This oscillating voltage signal was then passed to the Servo Pneumatic Proportional Control System, where it was modified before passing to the elbow to generate motion (Fig. 4). The nature of modification was determined by the test operator, who actively monitored the elbow behavior at the beginning of testing to make adjustments to the control system settings. These settings included proportional and derivative gain, force damping, and an offset. As the elbow was positioned at different abduction or adduction angles, these parameters changed to ensure smooth, consistent flexion and extension performance reminiscent of real-life movement. This voltage signal, once modified and passed to the control system, dictated the flow of air from the air supply to the pneumatic cylinders. Air was supplied to the elbow via two hoses coming from the control system. Each supply hose was split so that when air entered the extension valve of the triceps, it simultaneously actuated the contraction valve of the biceps/brachialis, and vice versa.

As the elbow flexed and extended, feedback from the pneumatic cylinders was passed through the control system, where the test operator monitored the feedback signal and compared it with the command signal to ensure that the system was performing as expected. This information, along with the current cycle count and any other parameters of interest, was collected by the custom DASYlab program to create a database of the test.

The cycle count for this experiment was based on the healing environment that would be protected for 12 weeks. We assumed 329 arm cycles per day for 76 days and a weight restriction of one pound during that time, on which it is assumed that bone ingrowth has occurred, and ligaments have healed enough to allow for unprotected motion. We, therefore, cycled the elbow 5,000 times at each shoulder position for a total of 25,000 cycles.

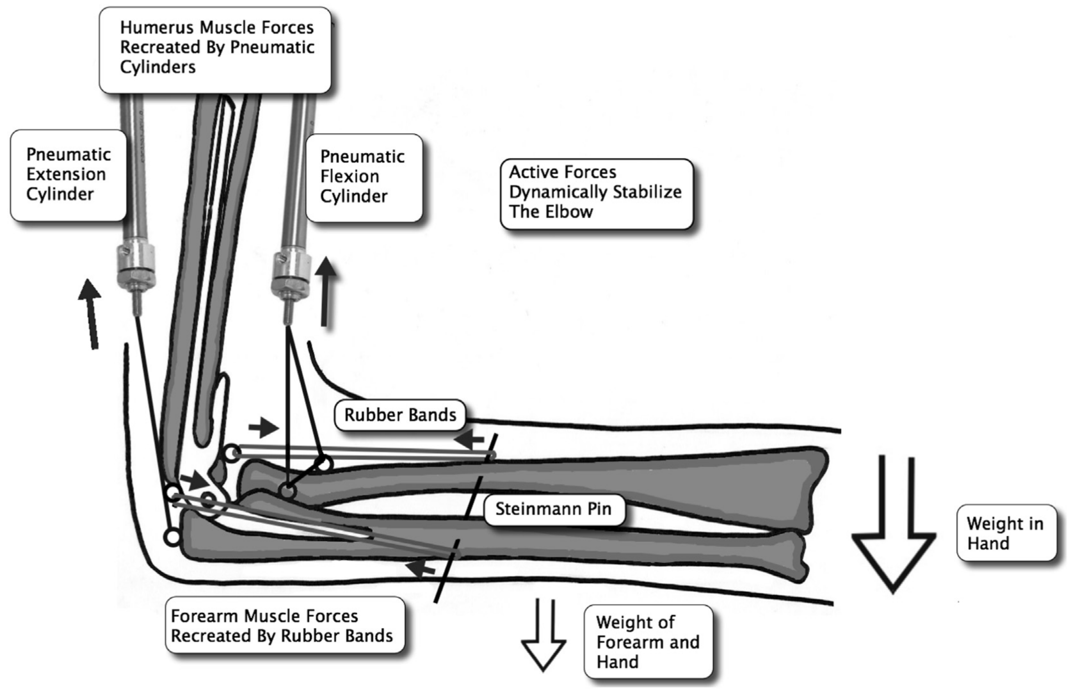

Figure 2. Experimental setup consisting of a humeral clamp that is able to position the humerus into different degrees of shoulder abduction and adduction. The humeral and forearm-originating muscles are reproduced with pneumatic cylinders and rubber bands, respectively.

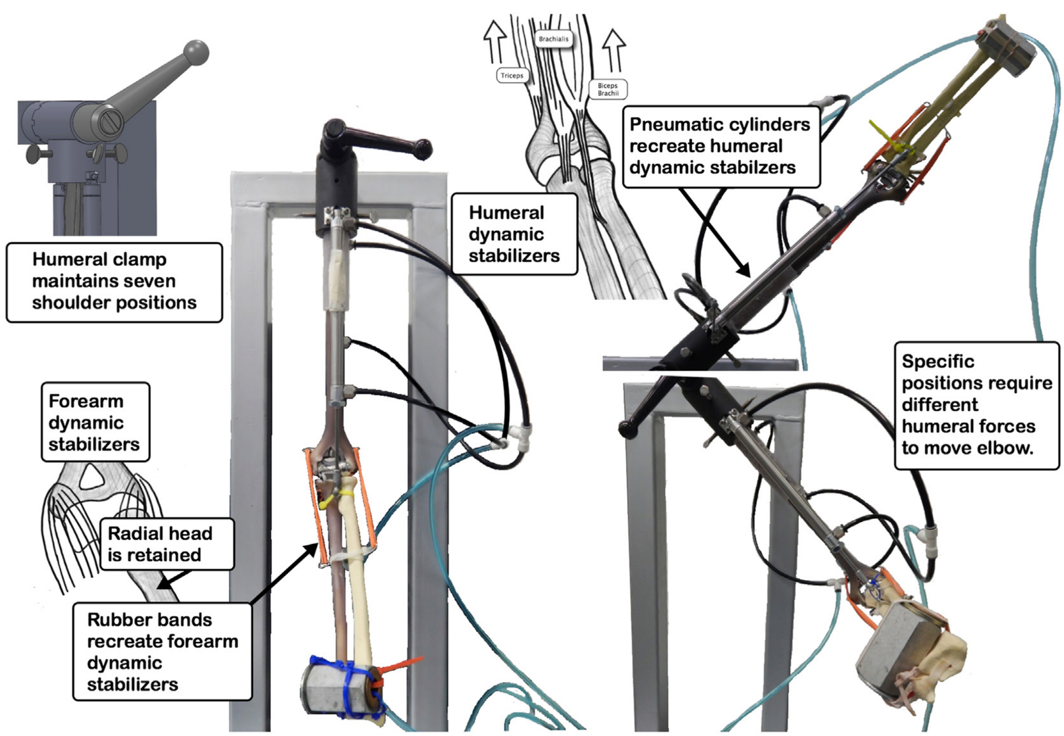

Figure 3. Schematic demonstrating the forces acting on the elbow. The triceps was actuated with a pneumatic cylinder, and the biceps and brachialis are actuated with a pneumatic cylinder.

Laxity was determined at 90° of abduction and 90° of adduction before testing and after each 5,000-cycle test with a digital angle indicator with an accuracy of 0.2° and repeatability of 0.1° (Dixey) to recreate maximum varus and valgus loads (Fig. 5). The reading was zeroed when the angle indicator was placed on the humerus. It was then moved to a marked location at the distal end of the forearm to record the measurement. A consistent reference point was chosen on the forearm of each specimen, which ensured

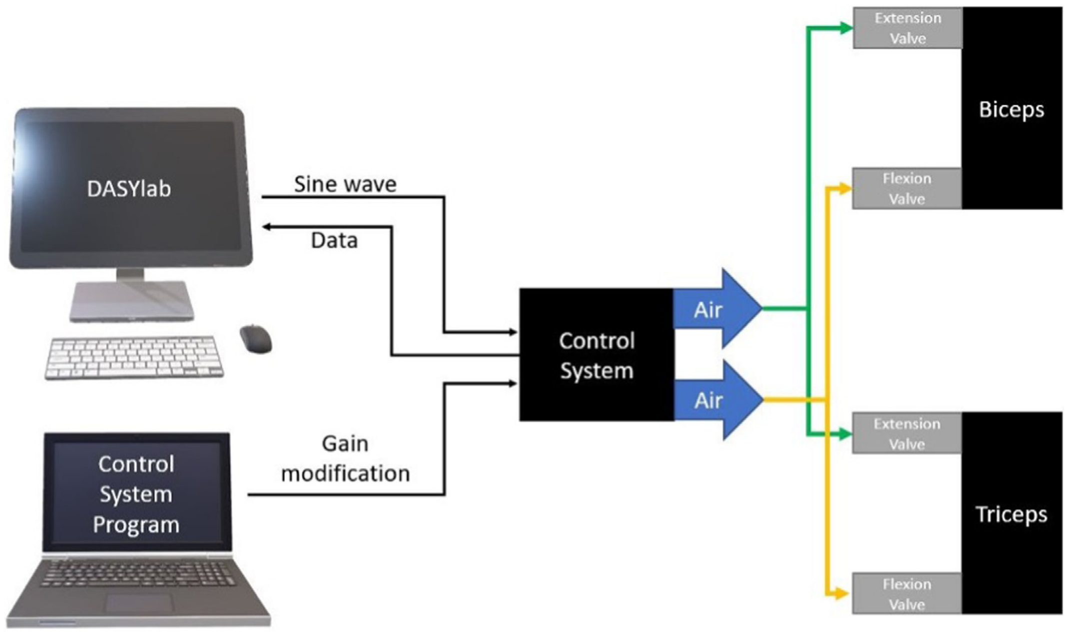

Figure 4. Schematic illustration of the pneumatic control system that modulates active flexion and extension of the elbow at different shoulder positions.

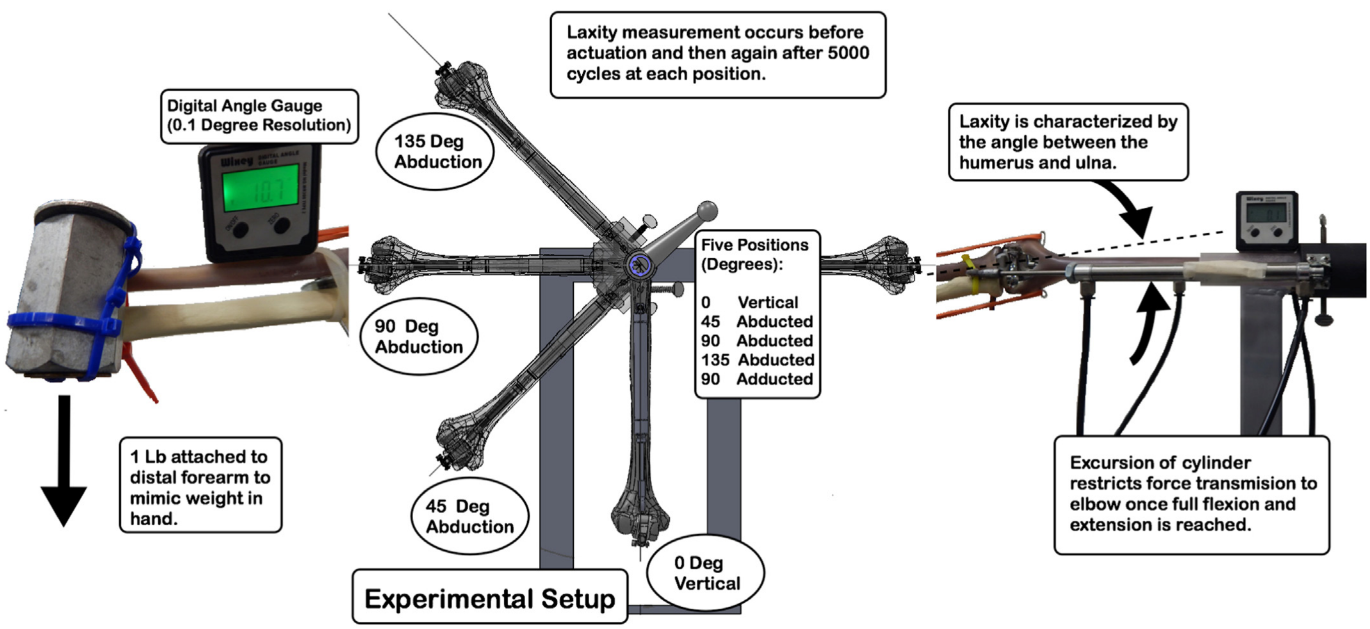

Figure 5. Varus laxity is measured at 90° of abduction, and valgus laxity is measured at 90° of adduction before instituting cyclic loading and then again after each 5,000-cycle interval for a total of 6 measurements.

repeatable angle indicator placement. Varus valgus laxity data were measured 6 times over the course of the 25,000-cycle test to determine laxity progression. When recording laxity measurements, the initial deviation (laxity before cyclic testing) was added to any change in laxity that was recorded in 5,000-cycle iterations.

Data were collected at the following times:

1. Before cyclic testing.
2. After 5,000 cycles with the arm at the side (5,000 cumulative cycles).
3. After 5,000 cycles with the arm at 45° of abduction (10,000 cumulative cycles).
4. After 5,000 cycles with the arm at 90° of abduction (15,000 cumulative cycles).
5. After 5,000 cycles with the arm at 135° of abduction (20,000 cumulative cycles).
6. After 5,000 cycles with the arm at 90° of adduction (25,000 cumulative cycles).

Results

We used three cadaver specimens to determine the force range that was required to actuate the arm. Each tested arm required

Table
Biceps and Triceps Force Required for Active Elbow Motion at Different Degrees of Shoulder Abduction*

Position	Specimen A		Specimen B		Specimen C	
	Biceps Force (N)	Triceps Force (N)	Biceps Force (N)	Triceps Force (N)	Biceps Force (N)	Triceps Force (N)
0° Abduction	18.7	0	20.3	0	17.5	0
45° Abduction	13.8	0	14.1	0	13.4	0
90° Abduction	4.0	4.2	3.8	4.0	4.2	3.7
135° Abduction	0	6.2	0	6.5	0	6.1
90° Adduction	6.7	6.5	6.4	6.2	6.3	6.6

* The greatest force is required to achieve flexion with the arm in the dependent position.

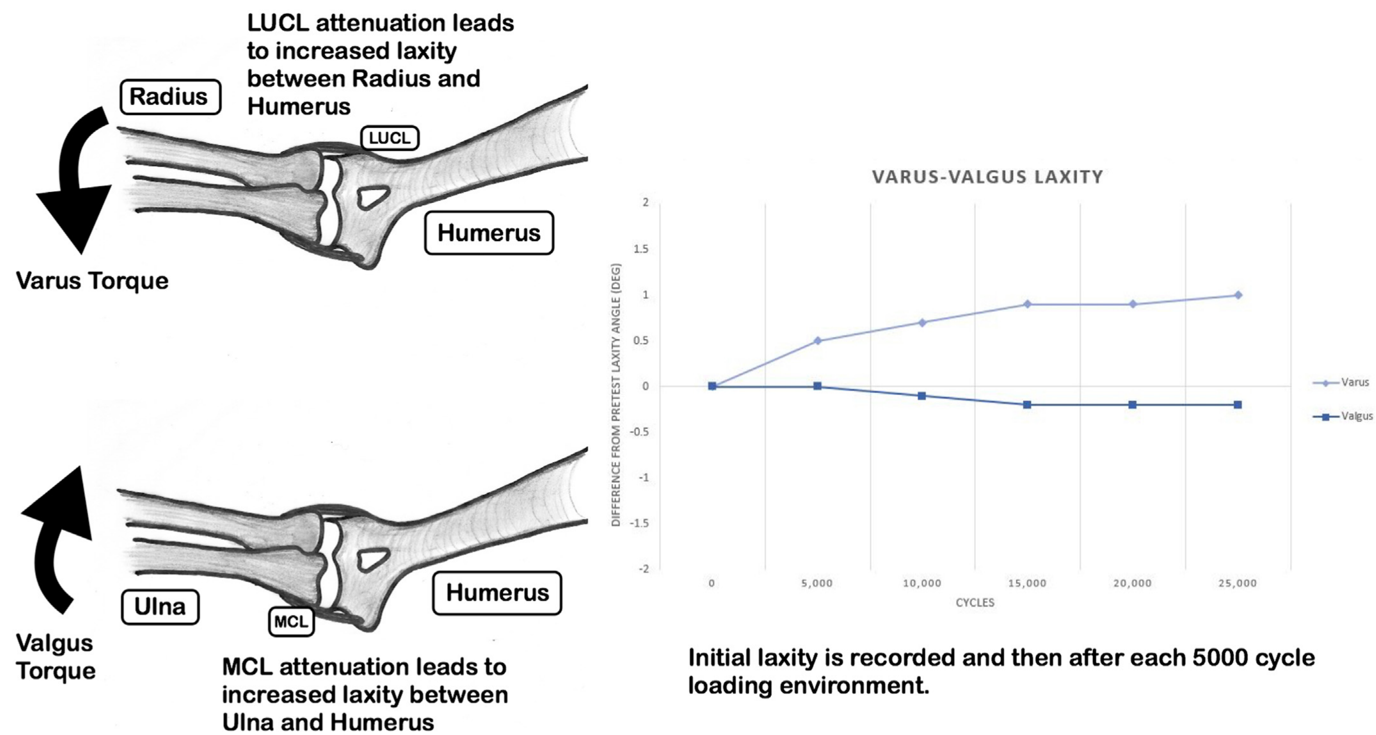

Figure 6. Varus and valgus laxities are recorded before testing and after each 5,000-cycle loading interval. LUCL, lateral ulnar collateral ligament; MCL, medial collateral ligament.

different forces to create active elbow motion with a range between 3.8 and 20.3 N depending on shoulder position (Table).

Varus and valgus laxities were recorded in these specimens as a change from the beginning laxity. Each specimen was characterized by 6 single-point laxity measurements that were obtained at each 5,000-cycle interval (Fig. 6). A sign convention was adopted, which considered varus torque to be positive laxity and valgus torque to be negative laxity.

Discussion

This experimental setup was developed to perform in vivo testing of novel total elbow arthroplasty designs that are uncemented and without mechanical linkage and that require a ligament reconstruction to ensure stability. These designs may be particularly vulnerable in the first 3 months after implantation as osseointegration of the implant and ligament healing occur. Our goal was to mimic the forces in the first 3 months where lifting restrictions would be required and varus and valgus forces are limited through a hinged brace. We chose active elbow motion to quantify arthroplasty function, which has demonstrated improved kinematic repeatability when compared with passive motion experimental setups.[10,15,16]

By alternating tension between the triceps and biceps—brachialis tendons, we recreated dynamic stability that in vivo ensures that no tensile (distraction) loads are transmitted across the elbow, regardless of the force applied at the hand.[5,10,12,14,17] The force range that accomplished the active range of motion was between 3.8 and 20.3 N, which is less than the 15 and 58 N that was required to achieve active motion by pneumatically loading the biceps, brachialis, brachioradialis, triceps, and pronator teres tendons in cadavers.[8,9] Forces were likely decreased because of lower arm weight, variations in elbow morphology, and lower friction of the implant.[8,9]

We used a prime mover load-controlled method of actuation and actuated both the biceps and brachialis tendon insertion sites with either one ensuring good kinematic performance.[8,15,16] This experimental setup also reproduced the flexor pronator mass and the common extensor muscles, which have been shown to resist valgus and varus forces, respectively.[6,12,14,18–20]

Given the propensity for arthroplasty failure because of varus- and valgus-induced edge loading, we chose five shoulder positions to accurately characterize TEA.[11] Our simulated active motion loading algorithm created 25,000 loading cycles at different shoulder positions and characterized TEA performance by measuring laxity at 5,000 cycle increments. The cycle count was chosen to represent the anticipated loading in the first 3 months after implantation.

We measured laxity as the degree of angular deviation between the humerus and ulna and quantified the degree to which the implant was able to resist varus and valgus loads. We believed that laxity assessment would evaluate the mechanical interaction of the mating articular surfaces and the soft tissue stabilizers. We postulated that laxity would increase as the ability to resist varus and valgus forces diminished. Implant loosening of the humeral and ulnar stems and stretching of the collateral ligaments represent possible reasons for increased laxity.

Sources of error

Different loads were needed to achieve motion

A limitation of this study lies in the loading of the humeral muscle groups that gradually increased until desired motion was achieved. A series of humeral force iterations was necessary to achieve the target motion. This iterative method has been performed in another active motion experimental setup and resulted in smooth output motions, despite the absence of true motion control.[9]

Forearm-generated muscles

We used 15 N force as an approximation of the forearm-generated force but realize that greater forces have been used in other biomechanical studies.[6,8] We also applied the same force to both medial and lateral sides of the forearm, although different forces likely occur as EMG activity to resist a valgus force may not be as large as is seen to resist a varus force.[14] Our equal force actuation, therefore, does not mimic the ability of these muscles to decrease either varus or valgus torque as a function of shoulder position. Their influence may be substantial, however, because the humeral muscle forces decrease as the arm becomes more abducted and gravity is eliminated. At 90° of abduction or adduction, the humeral forces that are required to flex and extend the elbow are small when compared with the dependent position (Table). Maintaining a constant forearm force represents a source of error.

Not enough weight in hand

We imparted forces that were able to flex and extend the elbow but only lifted a 1-lb weight in the hand. Greater applied loads would have increased the loads seen by the implant. Another similar study did not apply any load to the hand.[7] We believe that 1 lb in hand generated a loading environment that allowed for measurement of construct loosening and laxity while not compromising tendon integrity, given that preliminary cadaveric trials with a weight in hand of greater than 1 lb led to cadaver damage after only a few hundred cycles, primarily at the interface to the biceps, brachialis, and triceps tendons. No cadaveric compromise was identified at 1 lb of weight in hand.

Laxity measurement

Although consistent reference points were used for the placement of the digital angle measurement device, there remains potential for human error during this process.

A novel laboratory method was developed to evaluate the durability of different total elbow prostheses and may be considered for the preclinical characterization of total elbow replacements. We recreated the dynamic forces that cyclically act on the elbow while also positioning the arm into different shoulder abduction and adduction positions. Construct integrity was assessed through laxity measurement before and at different stages after cyclic loading had occurred. This system has been successfully employed to quantify the laxity of a novel uncemented arthroplasty that was stabilized with a ligament reconstruction.[21]

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