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Comparative In Vitro Wear Testing of PEEK and UHMWPE Capped Metacarpophalangeal Prostheses

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Abstract

Six metacarpophalangeal prostheses were each wear tested to five million cycles. Each prosthesis consisted of a metacarpal component with an approximately hemispherical shell on a titanium body, articulating against a titanium phalangeal component. Four prostheses had a shell made from ultra high molecular weight polyethylene (UHMWPE) and two had a shell made from poly ether ether ketone (PEEK). The tests were undertaken using a finger wear simulator. Despite pre-soaking and the use of control components, lubricant uptake by the metacarpal components was significant. Gravimetrically, the UHMWPE test components showed a greater weight gain than the UHMWPE control components. Therefore there was no apparent wear of any of the UHMWPE test metacarpal components. The original concentric machining marks of the UHMWPE components could still be seen after five million cycles of testing. For the metacarpal components with PEEK shells, gravimetric wear could be measured. Gravimetrically, all of the titanium phalangeal components showed little or no wear. Light scratches in the direction of sliding appeared on the articulating faces of all metacarpal and phalangeal test components, indicating slight abrasive wear.

Keywords: metacarpophalangeal, wear, UHMWPE, soaking, titanium, finger simulator.

1. INTRODUCTION

Rheumatoid arthritis, osteoarthritis and traumatic arthritis are all diseases which can lead to the need to replace finger joints. Since the first finger prostheses were implanted at the end of the nineteen fifties, surgeons and bioengineers have worked towards making improved finger prostheses [1]. However, replacement of diseased finger joints currently lacks the success associated with knee and hip prostheses. The most commonly implanted artificial finger joint remains the Swanson single-piece prosthesis [2] [3] which acts as a flexible silicone spacer. While pain relief and improved cosmetic appearance of the fingers are achieved with this prosthesis [4] [5] with time ulnar drift can re-occur. Further, Swanson prostheses can fracture, the maximum reported rate being 82% after five years [6] while a recent paper reported 67% fracture rate after an average of fourteen years follow-up [7]. In an attempt to improve the success of finger prostheses, a number of designs which are intended to mimic the natural joint more closely have been proposed [8] [9] [10]. These are therefore two-piece joints, with one component articulating against the other, and are intended to be implanted before damage to the soft tissues of the finger joints becomes too severe. In addition to these designs, a two-piece metacarpophalangeal (MCP) prosthesis, manufactured from titanium, has also been proposed by Zimmer Europe. The metacarpal component has an approximately hemispherical shell covering its articulating face. Two shell materials have been proposed, ultra-high molecular weight polyethylene (UHMWPE) and poly ether ether ketone (PEEK). The phalangeal component, which has a matching concave hemispherical polished surface, is manufactured entirely from titanium. The aim of this paper is to describe the wear testing of this design of prosthesis and to disclose the results obtained.

2. METHOD AND MATERIALS

Six prostheses were wear tested and each prosthesis consisted of a metacarpal and a phalangeal component (figure 1). Four prostheses had an UHMWPE hemispherical shell and two had a PEEK shell. For each component the nominal spherical radius of the articulating surface was 5mm. The titanium material was designation Protasul 100 [11].

Each prosthesis was tested using a finger wear simulator and each test ran to five million cycles, taking ten weeks. Prostheses were tested in three pairs. In addition to the six test prostheses, six additional metacarpal components were employed to serve as control components in the three pairs of tests. The first pair of prostheses were tested 'as received' while the metacarpal components of the second pair of prostheses were statically loaded and pre-soaked in the test lubricant for 28 days at 37°C prior to wear testing using the finger simulators. The test schedule is given in table 1.

Figure 2 shows an overview of a finger simulator employed for this test. The simulator flexed a test prosthesis cyclically over a 90º range of motion to mimic the light loading seen during flexion-extension, then applied a heavy static load to imitate 'pinch' grip [12]. Motion was uni-planar as flexion-extension is the predominant action of the finger. The light loading simulated those situations where loads were small (10-15N) but the finger was moving quickly [13]. In contrast, situations such as turning a key or holding a handle show minimal motion but large joint forces. These situations were therefore mimicked by the 'pinch' grip action of the simulator, which occurred once after every 3000 cycles of flexion-extension, where a static load of 100N was applied. One hundred Newtons was calculated to be the maximum arthritic pinch grip force [14] [15]. One cycle of flexion-extension consisted of the movement of the phalangeal test component from 0° flexion to 90° flexion and back to 0° flexion. Using these test conditions, the finger simulator had previously produced failure of a Swanson prosthesis in a time and a manner comparable with clinical experience [12] and of two Sutter single-piece silicone prostheses [16]. Therefore it was felt that the finger simulator offered a relevant test for any prosthesis evaluated within it.

The finger simulator employed artificial tendons to apply the loads and motion across the test prosthesis. Within the test chamber of the simulator the metacarpal component was held stationary in a holder which represented the metacarpal bone, while the phalangeal component oscillated against it under the loading and motion imposed by these artificial tendons (figure 3). This loading and motion was supplied via two 10mm bore pneumatic cylinders. The heavier static ‘pinch’ load was provided by an additional 32mm bore pneumatic cylinder. The wear of each component was determined by a gravimetric method after every half million cycles of testing. In all cases, statically loaded control metacarpal components were employed to take account of any lubricant uptake by the test metacarpal components during the five million cycle tests. The lubricant ‘recipe’ employed in all the tests has been employed in previous wear tests [17] [18] and is thought to compare well with natural synovial fluid [19]. Essentially it consisted of one-third bovine serum and two-thirds Ringer solution. The protein content of the lubricant was determined to be 17g/l.

2.1 Test procedure

Prior to the start of a test, the prosthetic components were cleaned and weighed to the nearest 0.1mg using a Mettler AE200 balance. The test components were then carefully inserted into their holders in the simulator. The rest of the test chamber of the simulator was reassembled, then filled with 0.2µm filtered lubricant. The control metacarpal component was positioned and statically loaded to 12.5N, the same value as the average dynamic load across the test prosthesis. The heater was switched on and the lubricant allowed to reach a temperature of 37°C. The simulator was then started and the speed adjusted to one cycle per second. At half a million cycle intervals, the test was stopped, the prosthetic components were removed, disinfected in a Neutracon solution, cleaned in an ultrasonic cleaner, washed in acetone, allowed to dry in a laminar air flow cabinet for one hour and weighed using the AE200 balance. Wear of a test metacarpal component was defined as the weight loss with respect to the initial weight, to which was added any increase in weight measured from the control metacarpal component. Therefore weight increase of a control component due to lubricant uptake was assumed to be identical to that of a test component. For the phalangeal component, which was purely titanium, lubricant absorption was assumed to be nil. The wear factor k was determined from the following equation:

$$k = \frac{V}{LD} \qquad (1)$$

but volume = mass (m)/density (ρ) .’.

$$k = \frac{m}{\rho LD} \qquad (2)$$

The density of UHMWPE was taken to be 930kg/m^3, while that of PEEK was taken as 1,320kg/m^3. Prior to the commencement of testing the second pair of prostheses, the four UHMWPE metacarpal components, two test and two control, were statically loaded under 12.5N and immersed in the dilute bovine serum lubricant at 37°C for 28 days. During this 28 day period these metacarpal components were occasionally removed, then cleaned and weighed to the same weighing protocol as used during the simulator testing. This monitoring permitted an indication of the lubricant uptake to be seen. This whole procedure was repeated for the four PEEK metacarpal components, prior to the commencement of testing the third pair of prostheses. At the end of each five million cycles of testing, the prosthetic components were allowed to dry in air. Later, all metacarpal components were placed in an oven at 50°C for 18 days and their weight monitored during, and at the end of, this time.

3 RESULTS

In all tests lubricant uptake by the metacarpal components was significant. The UHMWPE metacarpal test components showed a greater weight gain than the UHWMPE control components (table 2, figures 4 and 5). Therefore there was no apparent wear of any of the four UHMWPE test metacarpal components. When the weights of the UHMWPE metacarpal components at the beginning and at the end of the unsoaked test, after having been allowed to dry out thoroughly, were compared then it was seen that the test components were still heavier than at the start of the test (mean 18 x 10^{-4}g) while the control components had a mean decrease in weight of 2 x 10^{-4}g (table 2). For the soaked UHMWPE components, the metacarpal test components again showed a greater weight gain than the control components, though the mean difference was less at 7 x 10^{-4}g (table 2). During both the soaked and the unsoaked tests, over the five million cycles test duration, a wide variation in the weights of control and test components was seen (figures 4 and 5).

For the PEEK metacarpal components an overall weight loss for the test components was measured (table 2 and figure 6), being an average of 11 x 10^{-4}g after five million cycles and 17 x 10^{-4}g after drying in the oven. Given the latter figure, a mean wear factor of 1.3 x $10^{-6}mm^3/Nm$ can be calculated, or a wear rate of 0.26mm^3 per million cycles.

For the titanium phalangeal components, all tests gave similar results in that the test components showed little or no wear (table 3). Specifically, three component was unchanged in weight, while the remaining three components had each lost 1 x 10^{-4}g, which was the same value as the error of the Mettler AE200 balance. There was no evidence of a transfer film on the articulating face of any of the phalangeal components.

Visually, the original concentric machining marks on the UHMWPE shells could still be seen after five million cycles of testing. This fact further indicated that wear was low. Light scratches in the direction of sliding appeared on the articulating faces of all test components, metacarpal and phalangeal, during the test indicating the importance of abrasive wear. Such scratches were first seen at the one million cycles weighing points. For the PEEK metacarpal components, the original concentric machining marks were removed and a much more polished visual appearance than the equivalent UHMWPE test components was achieved.

As has been noted, lubricant uptake by the metacarpal components was significant. Table 2 shows that the mean increase in weight of the four UHMWPE metacarpal components over their 28 day soak period prior to the start of the second pair of tests was of 93 x 10^{-4} g. This weight increase occurred at a steady rate over the 28 days and saturation did not take place. For the PEEK components the equivalent mean increase in weight after 28 days of soaking was 17 x 10^{-4} g.

4 DISCUSSION

No gravimetric wear of the UHMWPE test components was measured. Such a situation is not unknown in the testing of prostheses [20]. While clearly the finger wear simulator was able to produce wear of the PEEK components in this test, and of other finger prostheses in previous tests [18] the wear of the UHMWPE-titanium combination was so low that the influence of weight increase by the control component became critical. Despite pre-soaking the metacarpal components for 28 days, and employing statically loaded control components throughout, in the case of the UHMWPE samples the test components increased in weight by a greater amount than the test components.

The actual weight increase could be ascribed to the dilute bovine serum lubricant because when the metacarpal components were first weighed after cleaning in acetone alone, and before immersion into the bovine serum lubricant, no weight increase was seen. It would be expected that the UHMWPE would both absorb and adsorb components of the lubricant [21]. Additionally, it is felt likely that some of the lubricant became trapped between the hemispherical shell and the titanium body. With this interface necessitating a tight fit between the shell and the body it is reasonable to assume that any lubricant penetrating the interface would be difficult to remove.

An explanation for the greater increase in weight by the UHMWPE test components compared with the UHMWPE control components is difficult to find, especially as both components were loaded. Work with cross-linked polyethylene finger prostheses soaked in the same dilute bovine serum lubricant at 37ºC indicated that unloaded prostheses adsorbed more proteins from the lubricant than loaded prostheses [18]. Furthermore, their weight gain was greater therefore it is likely that they also absorbed more lubricant. Now, to physically load a component invariably necessitates the use of holders which in turn are likely to cover much of the surface of the prosthesis. Therefore one side effect of loading is that the surface area of the control prosthesis readily accessible to the lubricant is reduced. In the finger simulator, where motion is applied to the test prosthesis, areas of the articulating surface of the metacarpal component will be covered and then uncovered as the phalangeal component is oscillated through its arc of motion. As such, a greater surface area of the test metacarpal component may be open to adsorption of proteins from the dilute bovine serum lubricant, than will be the case with the statically loaded metacarpal components. Similarly the opportunity for increased absorption of lubricant may be available. Perhaps this reason may in part explain why the test metacarpal components gained more weight than the control metacarpal components.

The wide fluctuations in weight of the metacarpal components, both test and control, during the five million cycles of testing are difficult to explain. The weighing protocol was rigorously followed. In addition, measurements of humidity and temperature were made when the weights of components were measured, but there appeared to be no correlation between these atmospheric measurements and the fluctuations in weights. Despite the use of metacarpal components which had been loaded and soaked in the lubricant at 37°C for four weeks prior to testing commencing, subsequent weight measurements still showed a fluctuation over the five million cycles of testing.

Despite the challenges with the wear testing of the UHMWPE components, the test rigs and test procedure were able to generate wear of the PEEK components. Sadly there is relatively little comparative data in the literature regarding the wear of PEEK against hard counterfaces in the presence of a bovine serum lubricant. Two papers by Wang et al showed that in the case of acetabular cup materials for total hip replacement, PEEK wore at 6 to 8 times the rate of UHMWPE [22] [23]. In that PEEK wore more than UHMWPE, the results reported here would agree with those of Wang et al.

Of the other two-piece finger prostheses recently reported in the literature, one employs a pyrolytic carbon couple [10] while the others use a metal against UHMWPE articulation [8] [9]. However, wear testing these implants within a machine designed to simulate the finger joint is not reported. While medical device designers can offer evidence from other biomedical applications, such as heart valves or hip prostheses, to suggest that their choice of biomaterials will provide low wear, it could also be argued that the entire device should be appropriately tested, especially in an application as important as the human body. Although international standards for the testing of hip and knee prostheses already exist, this is not the case with finger prostheses [24]. Nevertheless, testing artificial joints prior to implantation is clearly necessary from an ethical point of view and the use of machines which can reproduce clinical type fractures is advocated [25].

5 CONCLUSION

In all six tests, lubricant uptake by the metacarpal components was significant. All four test UHMWPE metacarpal components ended the test heavier than the equivalent control components. All phalangeal components were the same weight as they started the test, or within the error of the balance used to weigh them. Therefore no wear of the UHMWPE finger prostheses was indicated. Despite pre-soaking the metacarpal components for 28 days prior to simulator testing, statically loading the control components, employing a standardised weighing protocol and allowing all components a significant amount of time to dry out, both in air and in a warm oven, this result of heavier test components than control components remained consistent. For the PEEK finger prostheses, after drying out, gravimetric wear of the metacarpal components was measured. For their matching titanium phalangeal components no change in weight was measured.

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REFERENCES

[1] R. L. Linscheid, Implant arthroplasty of the hand: retrospective and prospective considerations, *Journal of Hand Surgery (American Volume)* **25A** (2000), 796-816.

[2] A. B. Swanson, Flexible implant arthroplasty for arthritic finger joints, *Journal of Bone and Joint Surgery (American Volume)* **54A** (1972), 435-456.

[3] A. B. Swanson, G. de Groot Swanson and H. Ishikawa, Use of grommets for flexible resection arthroplasty of the metacarpophalangeal joint, *Clinical Orthopaedics and Related Research* **342** (1997), 22-33.

[4] N. Massey-Westropp, M. Massey-Westropp, W. Rankin and J. Krishnan, Metacarpophalangeal arthroplasty from the patient's perspective, *Journal of Hand Therapy* **16** (2003), 315-319.

[5] Y. G. Wilson, P. J. Sykes and N. S. Niranjan, Long-term follow up of Swanson's silastic arthroplasty of the metacarpophalangeal joints in rheumatoid arthritis, *Journal of Hand Surgery (British and European Volume)* **18B** (1993), 81-91.

[6] A. G. Kay, J. V. Ljeffs and J. T. Scott, Experience with silastic prostheses in the rheumatoid hand: a five year follow up., *Annals of the Rheumatic Diseases* **37** (1978), 255-258.

[7] C. A. Goldfarb and P. J. Stern, Metacarpophalangeal joint arthroplasty in rheumatoid arthritis, *Journal of Bone and Joint Surgery (American Edition)* **85A** (2003), 1869-1878.

[8] D. Harris and J. J. Dias, Five-year results of a new total replacement prosthesis for the finger metacarpo-phalangeal joints, *Journal of Hand Surgery* **28B** (2003), 432-438.

[9] M. Rittmeister, M. Porsch, M. Starker and F. Kerschbaumer, Metacarpophalangeal joint arthroplasty in rheumatoid arthritis: results of Swanson implants and digital joint operative arthroplasty, *Arch Orthop Trauma Surg* **119** (1999), 190-194.

[10] S. D. Cook, R. D. Beckenbaugh, J. Redondo, L. S. Popich, J. J. Klawitter and R. L. Linscheid, Long-term follow-up of Pyrolytic carbon metacarpophalangeal implants, *Journal of Bone and Joint Surgery (American Edition)* **81A** (1999), 635-648.

[11] M. F. Semlitsch, H. Weber, R. M. Streicher and R. Schön, Joint replacement components made of hot-forged and surface-treated Ti-6Al-7Nb alloy, *Biomaterials* **13** (1992), 781-788.

[12] T. J. Joyce and A. Unsworth, The design of a finger wear simulator and preliminary results, *Journal of Engineering in Medicine* **214** (2000), 519-526.

[13] K. Tamai, J. Ryu, K. N. An, R. L. Linscheid, W. P. Cooney and Y. S. Chao, Three-dimensional geometric analysis of the metacarpophalangeal joint, *Journal of Hand Surgery* **13A** (1988), 521-529.

[14] B. Weightman and A. A. Amis, Finger joint force predictions related to design of joint replacements, *Journal of Biomedical Engineering* **4** (1982), 197-205.

[15] A. R. Jones, A. Unsworth and I. Haslock, A microcomputer controlled hand assessment system used for clinical measurement, *Engineering in Medicine* **14** (1985), 191-198.

[16] T. J. Joyce, R. H. Milner and A. Unsworth, A comparison of ex vivo and in vitro Sutter metacarpophalangeal prostheses, *Journal of Hand Surgery (British and European Volume)* **28B** (2003), 86-91.

[17] C. Rieker, R. Konrad and R. Schön, In vitro comparison of the two hard-hard articulations for total hip replacements, *Engineering in Medicine* **215** (2001), 153-160.

[18] T. J. Joyce and A. Unsworth, The wear of artificial finger joints using different lubricants in a new finger wear simulator, *Wear* **250** (2001), 199-205.

[19] R. M. Streicher, M. Semlitsch, R. Schön, H. Weber and C. Rieker, Metal-on-metal articulation for artificial hip joints: laboratory study and clinical results, *Engineering in Medicine* **210** (1996), 223-232.

[20] O. Muratoglu, C. Bragdon, D. O'Connor, M. Jasty and W. Harris, A novel method of cross-linking ultra-high-molecular-weight polyethylene to improve wear, reduce oxidation, and retain mechanical properties--Recipient of the 1999 HAP Paul Award, *Journal of Arthroplasty* **16** (2001), 149-160.

[21] L. Costa, P. Bracco, E. Brach del Prever, M. P. Luda and L. Trossarelli, Analysis of products diffused into UHMWPE prosthetic components in vivo, *Biomaterials* **22** (2001), 307-315.

[22] A. Wang, R. Lin, V. K. Polineni, A. Essner, C. Stark and J. H. Dumbleton, Carbon fiber reinforced polyether ether ketone composite as a bearing surface for total hip replacement, *Tribology International* **31** (1998), 661-667.

[23] A. Wang, R. Lin, C. Stark and J. H. Dumbleton, Suitability and limitations of carbon fiber reinforced PEEK composites as bearing surfaces for total joint replacements, *Wear* **225-229** (1999), 724-727.

[24] T. J. Joyce and A. Unsworth, A test procedure for artificial finger joints, *Engineering in Medicine* **216** (2002), 105-110.

[25] T. J. Joyce, Personal View. Snapping the fingers, *Journal of Hand Surgery* **26B** (2003), 566-567.

TABLES

Table 1 Summary of test schedule

Test Pair	Metacarpal shell material	Pre-soaking
1	UHMWPE	No
2	UHMWPE	Yes
3	PEEK	Yes

Table 2 Summary of mean weight changes for metacarpal components (x10^{-4}g).

	UHMWPE unsoaked		UHMWPE soaked		PEEK soaked	
Test Point	Test	Control	Test	Control	Test	Control
Unsoaked	0	0	0	0	0	0
At end of soak	N/A	N/A	+89	+97	+16	+17
After 5 million cycles	+32	+11	+75	+53	+17	+28
Dried in air	+22	+1	+46	+35	-6	+13
Dried in oven	+18	-2	+39	+32	-14	+3

Table 3 Weight changes of the six phalangeal test components ($x10^{-4}$g).

	v UHMWPE unsoaked		v UHMWPE soaked		v PEEK soaked	
Test Point	1	2	3	4	5	6
Start	0	0	0	0	0	0
After 5 million cycles	-2	-1	0	-1	0	0
Dry	-1	0	-1	-1	0	0

FIGURE CAPTIONS

Figure 1 Test prosthesis – phalangeal (left) and metacarpal (right) components.

Figure 2 Overview of finger simulator, test chamber in foreground.

Figure 3 Schematic diagram of key components within test chamber of finger simulator

Figure 4 Weight changes over test duration, unsoaked UHMWPE metacarpal components.

Figure 5 Weight changes over test duration, soaked UHMWPE metacarpal components.

Figure 6 Weight changes over test duration, soaked PEEK metacarpal components.

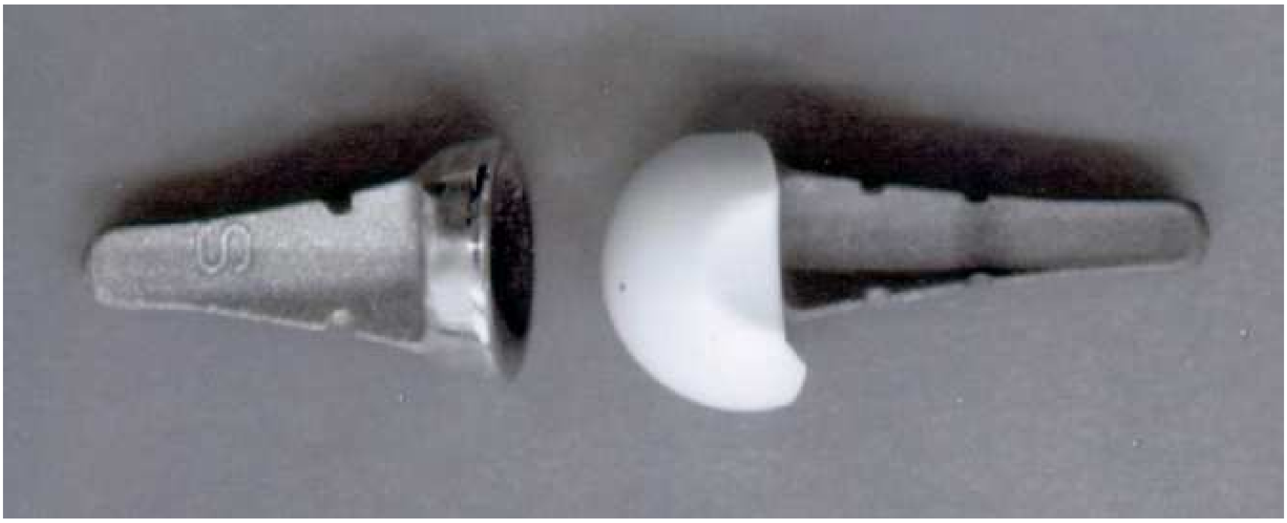

Figure 1 Test prosthesis – phalangeal (left) and metacarpal (right) components.

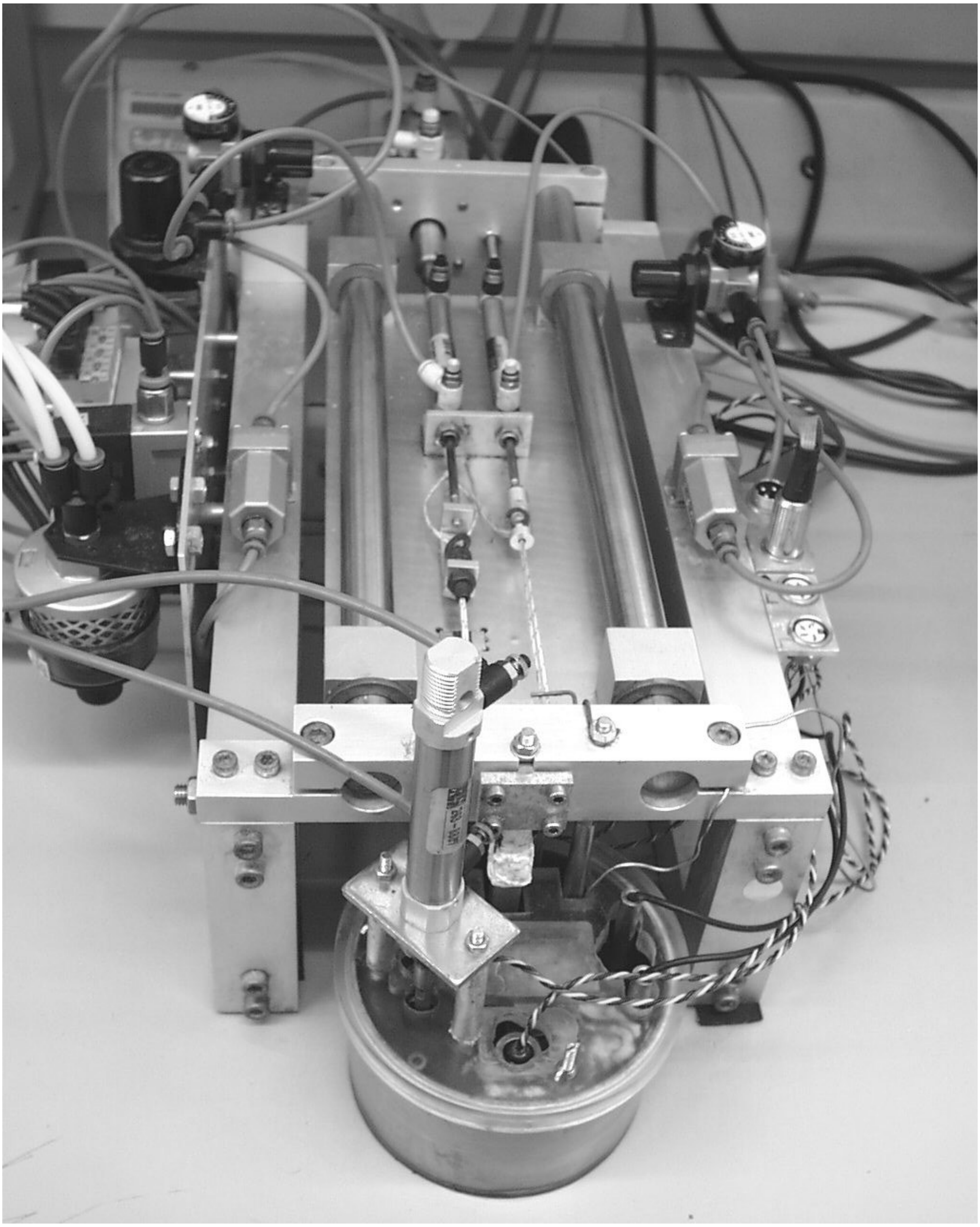

Figure 2 Overview of finger simulator, test chamber in foreground.

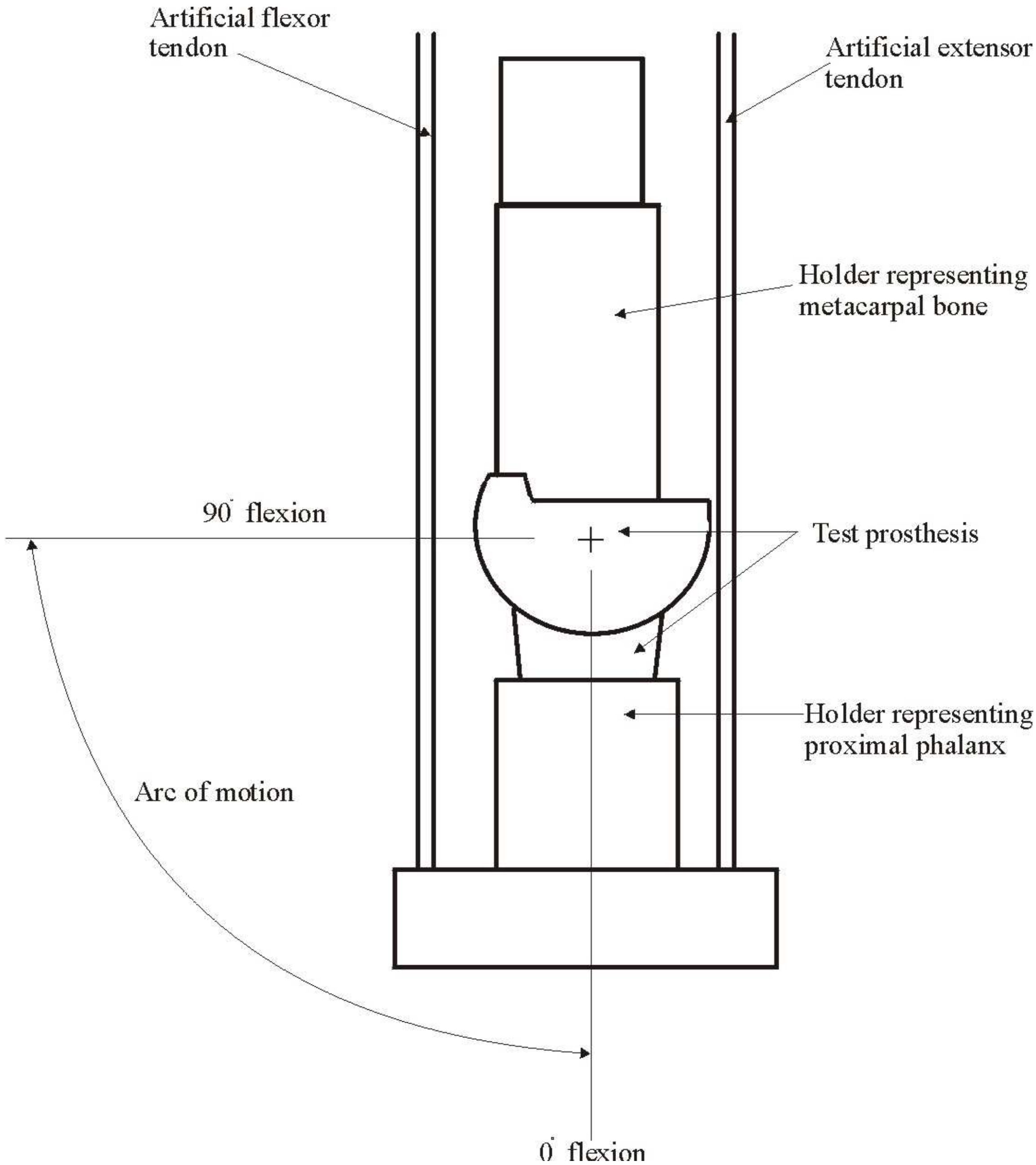

Figure 3 Schematic diagram of key components within test chamber of finger simulator

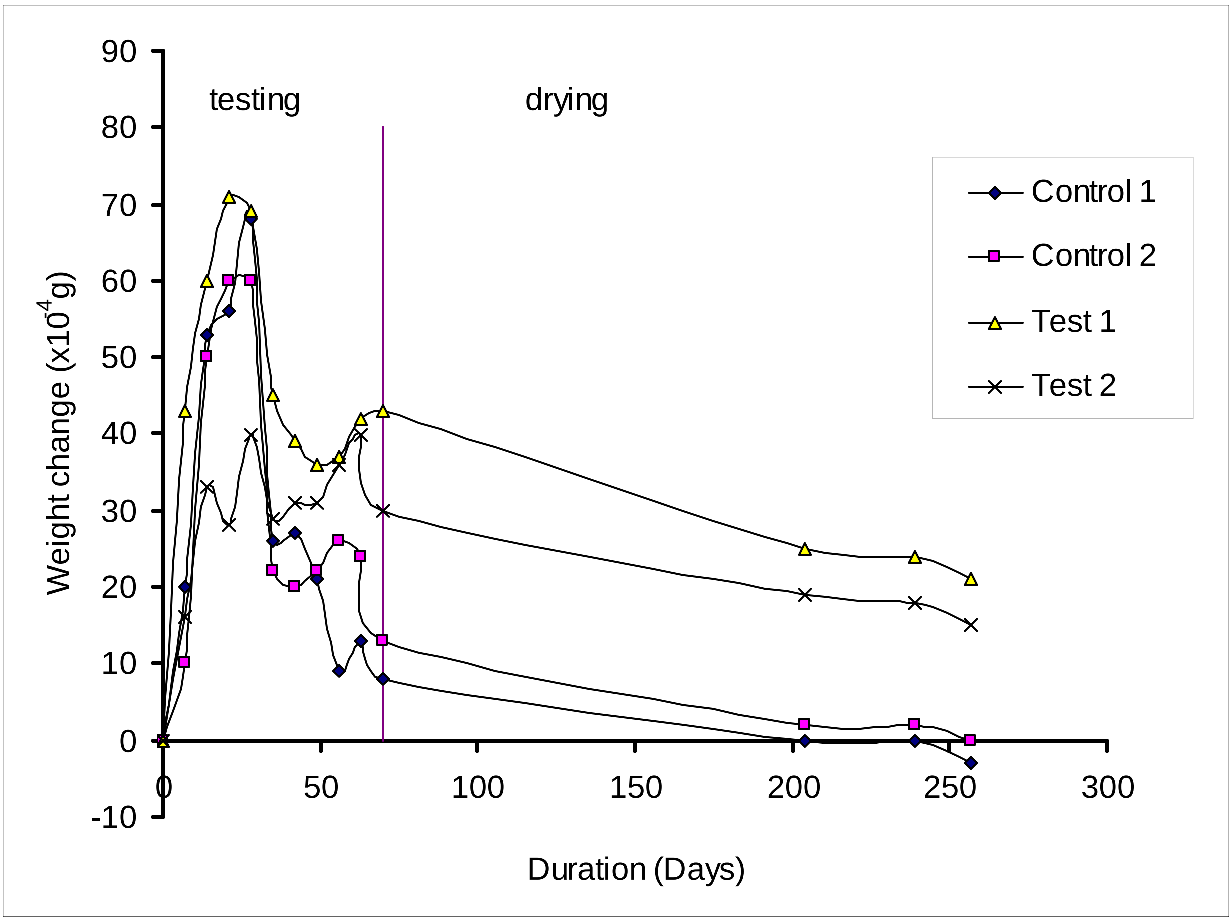

Figure 4 Weight changes over test duration, unsoaked UHMWPE metacarpal components.

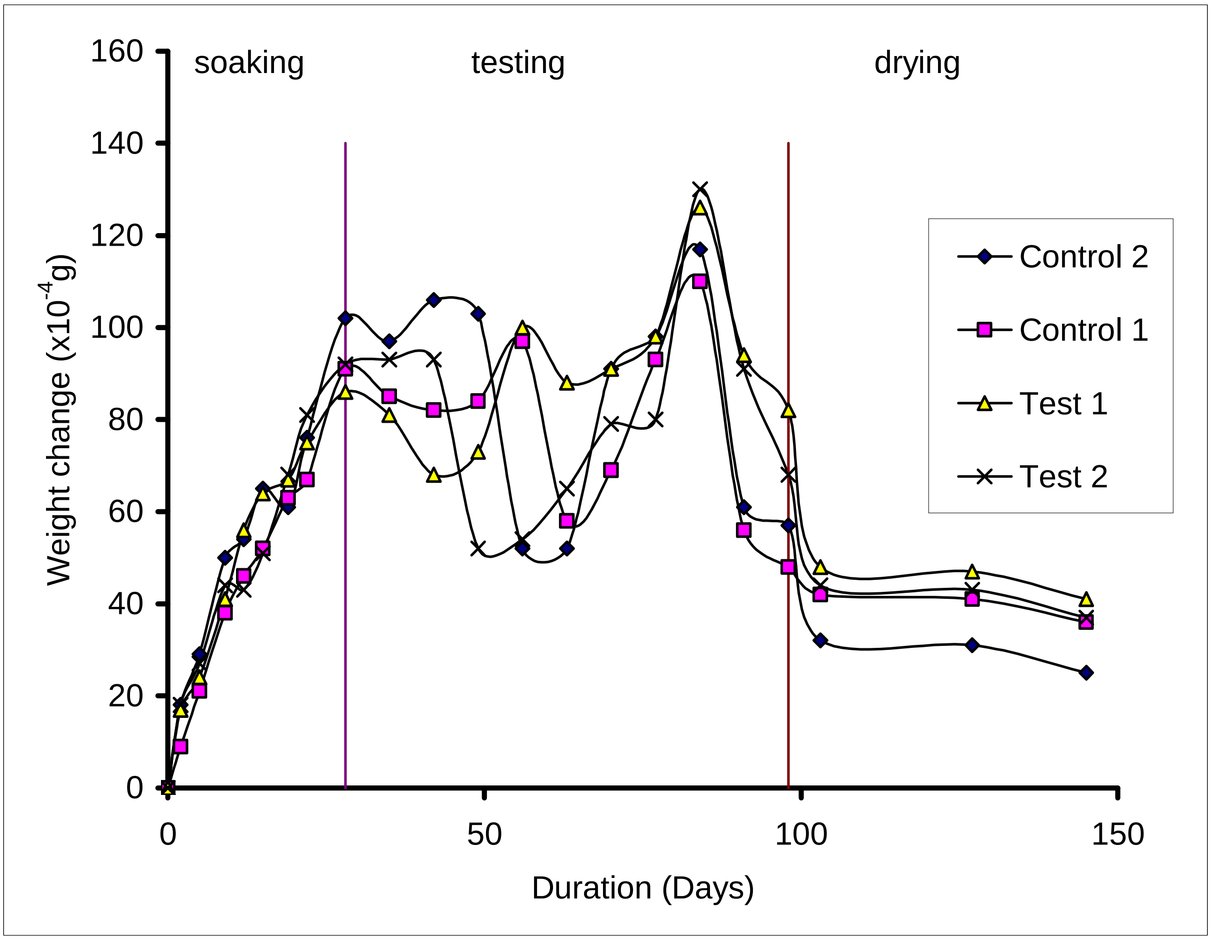

Figure 5 Weight changes over test duration, soaked UHMWPE metacarpal components.

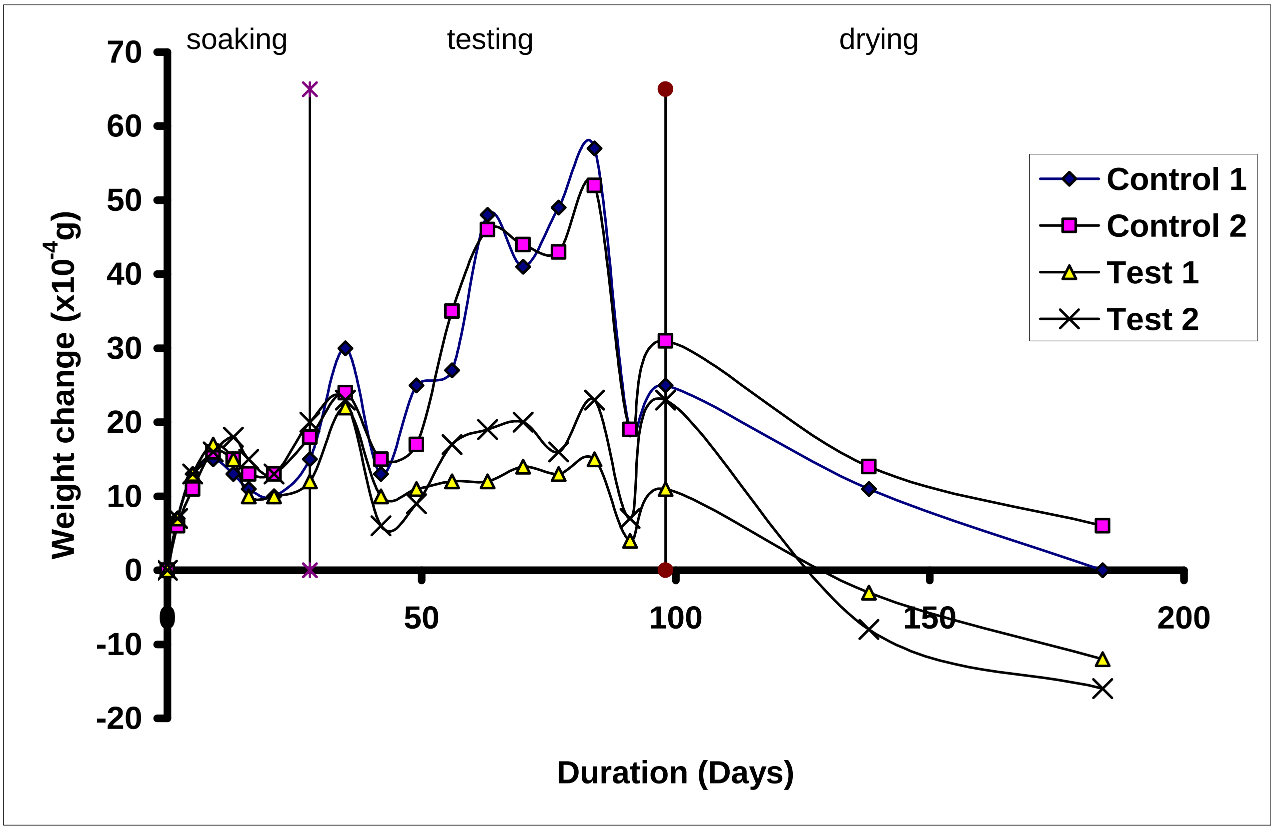

Figure 6 Weight changes over test duration, soaked PEEK metacarpal components.