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Wear testing of a DJOA finger prosthesis in vitro

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Abstract Although the market for replacement of diseased metacarpophalangeal (MCP) joints is dominated by single-piece silicone prostheses, several two-piece designs have been implanted. One such is the Digital Joint Operative Arthroplasty (DJOA) which consists of a part-spherical stainless steel metacarpal component which articulates within a matching concave phalangeal component made of ultra high molecular weight polyethylene (UHMWPE). A DJOA MCP prosthesis was tested using a clinically-validated finger simulator while a second DJOA prosthesis acted as a statically-loaded soak-control. Testing ran to 7.1 million cycles of flexion–extension. It was found that the UHMWPE components, both test and control, gained in weight by a similar amount. Therefore apparently there was no wear of the test components. However, the initial and final surface finish values of the test stainless steel metacarpal head were relatively high. Calculations based on this roughness data, plus recent dynamically-loaded soak data, may explain the apparent lack of wear.

1 Introduction

Rheumatoid arthritis is a common inflammatory disease which can have a dramatic and negative influence on the lives of sufferers, including increased mortality [1–4]. The disease attacks multiple joints of the human body and the finger joints are commonly afflicted. The most important joints of the hand are the metacarpophalangeal (MCP) joints but unfortunately these are also those most often attacked by rheumatoid arthritis. In the worst cases, once drugs and other therapies have been tried and found ineffective, replacement of the diseased finger joint with a prosthesis is the final option.

In such instances, single-piece silicone designs such as the Swanson prosthesis are those most commonly implanted [5, 6]. Advantages of such designs include: ease of implantation and, if necessary, removal; improved cosmetic appearance of the fingers; and providing a more functional arc of motion for the MCP joints. However, despite these benefits such prostheses do have certain failings. For example they are known to fracture, they tend to give little increase in range of motion, and there are concerns over silicone synovitis due to wear debris [6].

For these reasons, several two-piece designs have been proposed which aim to more closely match the biomechanics of the natural MCP joint [6]. One of these designs is the Digital Joint Operative Arthroplasty (DJOA) (Landos, Chaumont, France) which consists of a stainless steel metacarpal component which articulates with a matching ultra high molecular weight polyethylene (UHMWPE) phalangeal component (Fig. 1).

Clinical results of the DJOA prosthesis have been mixed [7–9]. Condamine et al. reported positive results for the DJOA implant they designed and implanted [7]. However, these authors reported on both MCP and proximal interphalangeal (PIP) joints, in which the same design of DJOA prosthesis was implanted. The results of 36 cases were reported, of which 20 were inserted in MCP joints, of which 17 were rheumatoid joints. Pain relief was said to be achieved alongside an increased range of motion. Condamine et al. later reported on 27 DJOA prostheses implanted exclusively in cases of osteoarthritis, between 1985 and 1994 [8]. Of these 27, eight involved the MCP

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Fig. 1 The DJOA metacarpophalangeal prosthesis. The stainless steel metacarpal component is shown on the *left*, and the UHMWPE phalangeal component is shown on the *right*

joint; the remainder were implanted in PIP joints. Good results were said to be obtained in terms of pain relief. The average range of movement of the MCP joints was reported to have increased from 35–50°.

In 1999 Rittmeister et al. discussed 69 MCP implant arthroplasties performed in 30 patients with rheumatoid arthritis [9]. The follow-up period averaged 5 years. Nineteen of these implants were the DJOA and 50 were flexible silicone Swanson implants. Using their own grading system, the authors stated that the outcome following MCP joint replacement with the DJOA was never evaluated as 'good'; in 11 joints the result was 'fair', and in 8 joints, 'poor'. In comparison, MCP arthroplasty with Swanson implants gave the results: 'good' in 40 joints; 'fair' in 10 joints; while none were said to be 'poor'. The authors further commented that the DJOA prosthesis did not provide stability in arthritic MCP joints. In all joints replaced with a DJOA prosthesis, dislocation of the articulating surfaces and signs of loosening were present. The authors therefore concluded that the Swanson implants provided superior results when used in the MCP joints of the rheumatoid hand.

Although clinical results of the DJOA prosthesis have been offered [7–9], no in vitro testing of the implant has been reported in the scientific literature. Therefore the aim of the work described in this paper was to undertake the first such laboratory testing using a clinically-validated simulator which had previously been used to test a variety of designs of MCP prosthesis.

It is generally accepted that the wear of artificial hip prostheses can be correlated with their longevity in the body [10]. Essentially UHMWPE wear debris provokes a negative cascade of responses within the body which leads to osteolysis (bone death), loosening of the implant, pain for the patient and eventually a revision operation [11]. The importance of wear has also been seen for artificial knee [12], shoulder [13], ankle [14], wrist [15], spinal [16], jaw [17] and finger [18] joints. Therefore, it has recently been stated that "most replacement joints fail as a complication of the basic wear and debris generation process" [19]. Two recent designs of artificial finger joint which have shown poor clinical results due to high in vivo wear include the WEKO [20] and the LPM [21] prostheses. Consequently, as a general guideline, if the wear can be minimised, then implant longevity should be maximised. For this reason the weight change, and thus the wear, of the DJOA components was measured during testing.

2 Materials and methods

The DJOA prosthesis was tested in a finger simulator which had previously been shown to cause fracture of Swanson [22] and Sutter [23] single-piece silicone prostheses in a time and a manner comparable with surgical experience. This correlation between clinical and laboratory results meant that the simulator gave clinically-validated results. The simulator had also been used to test two-piece designs of finger prosthesis [24, 25] therefore the machine provided a unique yet proven test bed.

The finger simulator (Fig. 2) has been described in detail elsewhere [22] but essentially this test machine flexed a test prosthesis cyclically over a 90° range of

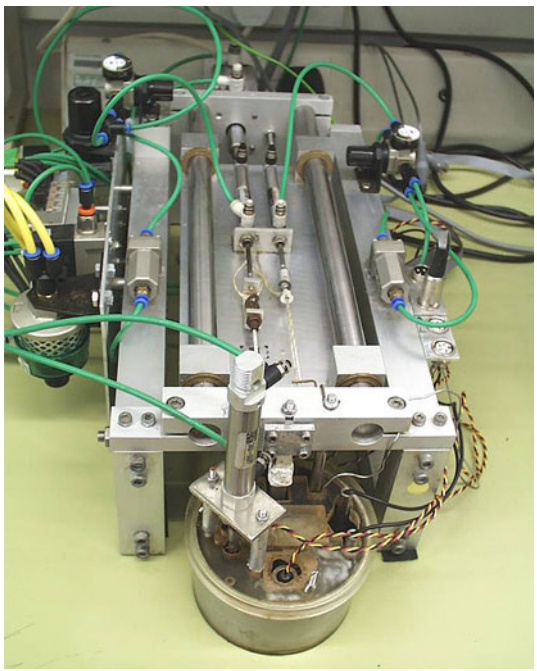

Fig. 2 Overview of the finger simulator. The test chamber is at the *bottom* of the picture. The various pneumatic components which provide loading and motion of the test finger prosthesis are shown *above*

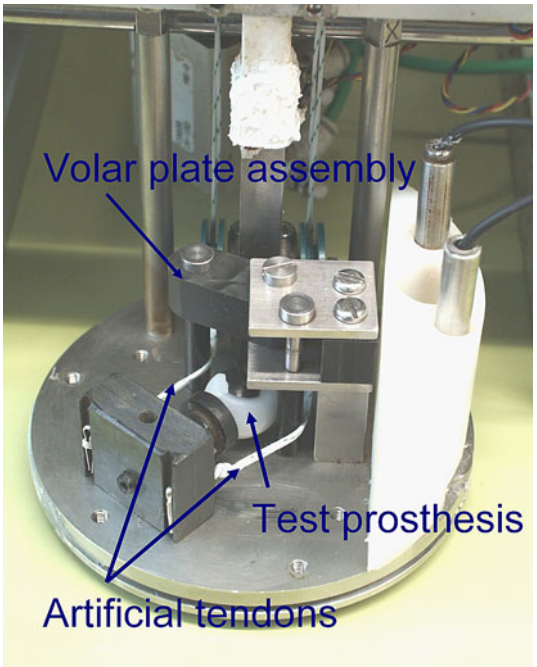

Fig. 3 The test chamber of the finger simulator with the volar plate assembly and artificial tendons indicated. Note that the prosthesis shown is not a DJOA prosthesis

motion to mimic the light loading seen during flexion–extension; then applied a heavy static load to imitate 'pinch' grip. Motion was uni-planar as flexion–extension is the predominant action of the finger although the simulator allowed passive abduction–adduction. The light loading (10–15 N) simulated those situations where loads were small but the finger was moving quickly [26]. 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 3,000 flexion–extension cycles, where a static load of 100 N was applied. One hundred Newtons was calculated to be the maximum arthritic pinch grip force [27, 28]. The simulator ran at a speed of 1.5 Hz during flexion–extension. Loading and motion were supplied by a number of pneumatic components. Two 10 mm diameter cylinders provided flexion and extension respectively, while a single 32 mm bore pneumatic cylinder provided the heavier static 'pinch' load.

The finger simulator employed artificial 'tendons' to apply the loads and motion across the test MCP prosthesis. The simulator also included a pulley arrangement, named the 'volar plate assembly', which reproduced the action of the collateral and metacarpoglenoidal ligaments. These ligaments are often irreversibly stretched by rheumatoid arthritis, in turn leading to an increased shearing force across the natural MCP joint. Therefore, with the volar plate assembly removed, the finger simulator was able to mimic such shearing loads. Equally, with the pulley assembly left in place, 'normal' and osteoarthritic loading could be reproduced. For testing the DJOA prosthesis the volar plate assembly was employed as soft tissue balancing is crucial to these two-piece implants when used in rheumatoid cases. Otherwise such two-piece implants tend only to be used in cases of osteoarthritis when the soft tissues are generally in better condition. Figure 3 shows a view of the test chamber of the finger simulator with the volar plate assembly and artificial tendons indicated.

Prior to testing in the finger simulator, two DJOA MCP prostheses were subject to a static load of 12.5 N while submerged in the test lubricant at 37°C. This soaking lasted for 57 days and during this time the weight change of the components was regularly measured, using the same weighing protocol as would later be employed during testing. Components were pre-soaked to minimise fluid-sorption during the wear tests and it has been stated that the error due to fluid-sorption can be reduced through pre-soaking [29]. The test lubricant consisted of one-third bovine serum and two-thirds Ringer solution. Such a lubricant is said to be a closer approximation to human synovial fluid than dilute bovine serum alone [30]. After soaking, one prosthesis was tested while the second served as a statically-loaded control (again under 12.5 N load) to account for any further weight changes due to lubricant uptake.

A consistent cleaning and weighing protocol was employed throughout. The wear of each component was determined by a gravimetric method at regular intervals during testing. All components were weighed to the nearest 0.1 mg on a Mettler AE200 balance. Wear of a test 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 the weight increase of a control component due to lubricant absorption was assumed to be identical to that of a test component.

From the weight change, the wear factor k (mm^3/Nm) could be determined from the equation

$$k = \frac{V}{LD}$$

Here, V is the volume of material lost (mm^3), L is the average dynamic load (N) and D is the sliding distance (m).

At the beginning and end of the test, surface roughness values of the stainless steel metacarpal components were measured using a ZYGO NewView non-contacting profilometer. Roughness average (Ra) was measured at nineteen equispaced points along the central line of flexion–extension.

Modelling the ball and socket implant as an equivalent ball-on-plane model and employing elastohydrodynamic

theory [31] allowed the minimum effective film thickness (h_{min}) to be calculated from:

$$\frac{h_{\min}}{R_x} = 2.80\left(\frac{\eta u}{E^* R_x}\right)^{0.65}\left(\frac{w}{E^* R_x^2}\right)^{-0.21}$$

Where R_x is the equivalent radius (m), η is the viscosity of the lubricant (Pa s), u is the entraining velocity (m/s), E* is the equivalent elastic modulus (Pa), and w is the load (N). In turn, given that R_a is the surface roughness and assigning subscript 1 to the metacarpal 'ball' and subscript 2 to the phalangeal 'socket' of the DJOA prosthesis, then the lambda ratios were calculated from:

$$\lambda = \frac{h_{\min}}{\left[(R_{a1})^2 + (R_{a2})^2\right]^{1/2}}$$

This allowed the lubrication regime to be identified, as $\lambda < 1$ indicates boundary lubrication, $\lambda > 3$ designates fluid film lubrication, and between these values mixed lubrication is indicated [32].

Appropriate values to permit the calculation of lubrication regimes were taken from the literature and included for UHMWPE a density of 930 kg/m^3, Young's modulus of 1GPa [33], Poisson's ratio of 0.4 [34]. For stainless steel a Poisson's ratio of 0.3 and a Young's modulus of 193 GPa were taken [35]. The viscosity of the lubricant was measured on a Ferranti–Shirley cone-on-plate viscometer at a shear rate of 3000 s^{-1} and at room temperature.

As the simulator ran at a speed of 1.5 Hz, the test DJOA prosthesis of 3.5 mm radius (r) moving through an arc from 0 to 90° and back to 0°, had an average entraining velocity (u) of 5.5 mm/s calculated using the equation:

$$u = r\omega/2$$

where ω is the angular velocity [36].

3 Results

The viscosity of the dilute bovine serum lubricant was measured to be 0.003 Pa s, a value which matched that reported elsewhere [35]. Using a Mitutoyo Crysta 544 co-ordinate measuring machine the spherical diameters of metacarpal heads and phalangeal sockets were measured so that a radial clearance of 0.2 mm was determined. The roughness of the articulating surface of the UHMWPE phalangeal socket at the beginning of the test was measured to be 1.3 μm Ra, obtained using a Mitutoyo Formtracer 4100. At the end of the test this roughness value was measured to be 0.27 μm Ra.

Over the 57 day soak period, during which weight changes were measured every 3–4 days, the two UHMWPE components increased in weight by 1.1 and 0.9 mg respectively. The soak period lasted 57 days as by this point the weight increase had reached a plateau. Testing of the DJOA metacarpophalangeal prosthesis ran to 7.1 million cycles of flexion–extension. The weight changes of the UHMWPE components, both test and control, over this test duration are shown in Fig. 4. As can be seen both components had gained in weight by a similar amount. Values were 2.2 mg for the test component and 1.9 mg for the control component after 7.1 million cycles of testing. Based on such values, as the test component gained in weight by a greater amount than the control, so apparently no wear occurred and it was therefore not possible to calculate a wear factor. The stainless steel metacarpal components were unchanged in weight during testing and soaking.

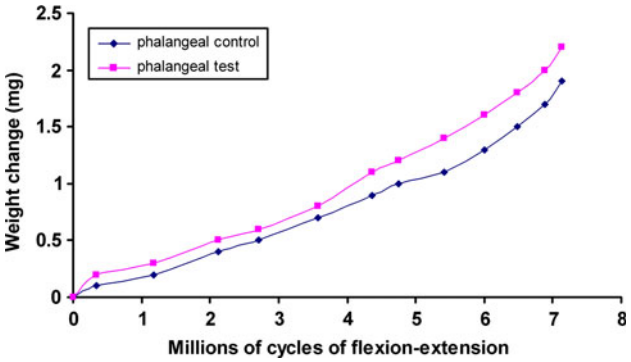

Fig. 4 Weight change of the UHMWPE phalangeal test and control components over 7.1 million cycles

Prior to testing, the roughness of the stainless steel metacarpal head was undertaken, with 19 equispaced readings being taken along the central line of flexion extension. This analysis was repeated at the end of the test. Mean values before and after testing were 0.147 and 0.209 μm Ra respectively. Although metacarpal head roughness did increase somewhat due to testing, Ra values were high throughout the test duration. Figure 5 shows an 'intensity map' image of one part of the head of the test metacarpal component at the end of testing indicating typical scratching of the articulating surface.

Based on such roughness values, lambda ratios of 0.009 and 0.034 were calculated for the DJOA prosthesis at the beginning and end of testing respectively. As both of these values are less than 1, it indicates that the finger prosthesis would have operated in the boundary lubrication regime throughout testing.

4 Discussion

Weight change results suggested no wear of the DJOA prosthesis however the initial and final roughness values of the metacarpal head were relatively high. A number of

Fig. 5 ZYGO Intensity Map image of part of the surface of the metacarpal test component. Note the multi-directional nature of scratching on the surface. Scale 0.244 × 0.183 mm

researchers have described a direct link between counterface roughness and wear of UHMWPE in the presence of a dilute bovine serum lubricant. For example Saikko et al. [37] offered the relationship:

$$k = 5.87\,x\,(R_a)^{0.91}$$

Therefore taking the value of 0.209 μm Ra for the test metacarpal stainless steel component measured at the end of the test, and using the above relationship, an expected value of k would be 1.4×10^{-6}mm^3/Nm.

Despite pre-soaking and the use of a statically-loaded control component throughout the 7.1 million cycle duration test, weight changes due to lubricant uptake remained important. How can the wear factor of 1.4×10^{-6}mm^3/Nm, which would be expected due to roughness values, be explained when the weight changes actually measured indicated no wear? The most likely explanation lies with data from a recent paper [38]. Here the authors compared statically-loaded UHMWPE control samples with dynamically-loaded control samples, using the same lubricant 'recipe' as used in the DJOA tests reported here. The authors stated that dynamically-loaded UHMWPE soak controls increased in weight by 2.2 times the weight of the statically-loaded controls [38]. Taking this relationship and applying it to the DJOA results meant that while the weight increase of the test UHMWPE component (which was dynamically loaded) remained at 2.2 mg, the control UHMWPE component had a compensated weight increase of 2.2×1.9 or 4.2 mg. On this basis it was possible to calculate a wear factor of 2.2×10^{-6}mm^3/Nm for the test DJOA prosthesis. This value fitted more closely with the expected wear implied by the relatively high roughness of the test metacarpal component. However, the wear factor of 2.2×10^{-6}mm^3/Nm should only be taken as indicative, as the shape of test samples used by Schwenke et al. was different to that of a DJOA finger prosthesis. Nevertheless, the key finding to be taken from the work by Schwenke et al. is that, for the same bovine serum based lubricant as used in the DJOA test, the proportionality of lubricant uptake between dynamically loaded and statically loaded samples.

Given the greater hardness of the stainless steel metacarpal component compared with the UHMWPE phalangeal component, the roughness of the metallic component is the more important, hence it was analysed to a greater extent than the polymeric component. The decrease in roughness of the UHMWPE test component during testing, from 1.3 to 0.27 μm Ra, can be explained by it articulating against the harder stainless steel component, and gradually assuming a roughness similar to that of the metacarpal component. Such a situation is also seen with retrieved total hip prostheses [39, 40]. The reduction in roughness of the test UHMWPE component is another indicator that wear took place. The stainless steel metacarpal head was found to have roughened over the duration of testing. This may have been due to contamination of the lubricant from atmosphere as, due to the use of artificial tendons in the finger simulator, the test chamber was unable to be fully sealed. However, it should be recognised that hip prostheses also tend to roughen in vivo [10, 41]. While the cause may be different, this feature of increased roughness over time was therefore reproduced in the finger simulator.

Given the situation applicable to the DJOA prosthesis, in terms of roughness values of the articulating surfaces, material properties for stainless steel and UHMWPE, and of the size of the implant, calculations showed that the prosthesis operated in the boundary lubrication regime. This result matched that reported for other metal-on-polymer MCP prostheses [42]. The fact that scratching was seen on the articulating surfaces of the test prosthesis would support the theoretical calculation of boundary lubrication.

A limitation to this study is the small sample size. However, only two components were supplied and these were said to be the final stock. Efforts were made to compensate for fluid uptake—by pre-soaking and employing a statically loaded soak control. However the results offered in this paper show that a more sophisticated soak regime, namely the incorporation of dynamically loading the control component, would be needed if similar tests were undertaken in future.

It is interesting to note Rittmeister et al's comment that in rheumatoid joints all of the DJOA prostheses dislocated [9]. This result matched that found in the finger simulator. Here, if the volar plate assembly was not fitted, to simulate the lack of support from stretched collateral ligaments found in rheumatoid MCP joints, the test DJOA prosthesis

dislocated. However, with the volar plate assembly fitted, to simulate undamaged collateral ligaments generally found in normal and osteoarthritic MCP joints, the test DJOA prosthesis did not dislocate. This finding is an important result. It shows that the finger simulator mimicked the clinical situation—without the volar plate assembly (i.e. under 'rheumatoid conditions') the DJOA prosthesis dislocated, the same result as reported from Rittmeister et al's clinical study [9]. It can only be speculated whether implantation of the DJOA prosthesis in rheumatoid patients would ever have taken place, if the manufacturers had undertaken in vitro testing using a finger simulator such as the machine employed in this paper.

5 Conclusion

A DJOA prosthesis was tested to 7.1 million cycles of flexion–extension. Gravimetric measurements suggested that wear was minimal despite pre-soaking in the test lubricant for 57 days and the use of a statically-loaded control during testing in the simulator. However, when these gravimetric measurements were compensated through the use of external data for dynamically-loaded UHMWPE samples in the same lubricant, it was possible to calculate a wear factor of 2.2×10^{-6}mm^3/Nm. This value fitted far more closely with expectations based on roughness data and tribological theory which indicated that the test finger prosthesis should operate in the boundary lubrication regime.

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