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The design and development of a finger joint simulator

Thomas J Joyce

School of Mechanical and Systems Engineering

Newcastle University

Claremont Road

Newcastle upon Tyne

NE1 7RU

England

UK

E-mail: Thomas.joyce@ncl.ac.uk

Telephone: +44 191 208 6214

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Abstract

Artificial finger joints lack the long-term clinical success seen with hip and knee prostheses. In part this can be explained by the challenges of rheumatoid arthritis, a progressive disease which attacks surrounding tissues as well as the joint itself. Therefore the natural finger joints' biomechanics are adversely affected and consequently this imbalance due to subluxing forces further challenges any prosthesis. Many different designs of finger prosthesis have been offered over a period of greater than 50 years. Most of these designs have failed and it is likely that many of these failures could have been identified had the prostheses been appropriately tested prior to implantation into patients. While finger joint simulators have been designed, arguably only those from a single centre have been able to reproduce clinical-type failures of the finger prostheses tested in them. This paper describes the design and development of a finger simulator at Durham University, UK. It explains and justifies the engineering decisions made and thus the evolution of the finger simulator. In vitro results and their linkage to clinical type failures are outlined to help to show the effectiveness of the simulator. Failures of finger implants in vivo continue to occur and the need for appropriate in vitro testing of finger prostheses remains strong.

Introduction

The development of successful artificial finger joints (prostheses) presents a number of challenges to bioengineers, surgeons and materials scientists. A key issue is the main disease which leads to the replacement of natural finger joints. This is rheumatoid arthritis, a progressive and debilitating disease for which there is no cure. Rheumatoid arthritis is the second most common form of arthritis in the UK and the most widespread inflammatory joint disorder with a prevalence of approximately 1%[1]. The finger joints are commonly affected by rheumatoid arthritis and multiple finger joints are afflicted. A range of non-surgical treatments are available, and many of these have shown improved results in recent years[2, 3]. However, where less or ineffective, the final option is replacement of the diseased finger joint with a prosthesis[4]. Rheumatoid arthritis attacks surrounding tissues as well as the joint itself, meaning that the natural joint's biomechanics are adversely affected[5, 6]. An important concern is that once the ligaments surrounding the natural metacarpophalangeal (MCP) joint are stretched by the swelling caused by rheumatoid arthritis, subluxing forces dominate resulting in characteristic deformities[7]. Such subluxing forces provide a great challenge to any prosthesis implanted into a MCP joint.

The MCP joint of the hand is crucial to the effective use of the fingers and this is the finger joint that is most commonly replaced. Data from the 2010 Norwegian

arthroplasty register shows that, between 1994 and 2010 in that country, there were 2,615 primary MCP joint replacements compared with 64 primary proximal interphalangeal (PIP) joint replacements[8]. In other words, for every PIP joint replacement there were 40 MCP joint replacements. At the MCP joint level, 2,472 operations were assigned to rheumatoid arthritis while only 68 were set against osteoarthritis. At the PIP joint level, the numbers were equally balanced between the two diseases at 27 each.

The dominance of rheumatoid arthritis over osteoarthritis is in stark contrast to the situation with hip and knee joint replacement. Another noteworthy difference is the distinct difference in implant designs available. While hip and knee prostheses recreate the two articulating surfaces of acetabular and femur, and femur and tibia respectively, the majority of finger prostheses are single-piece silicone spacer designs[9]. The market leader is the Swanson single-piece silicone implant, a design which has been available for over 40 years[10-14]. Other single-piece silicone designs include the NeuFlex[13, 15] and the Sutter/Avanta[12, 16, 17]. The dominance of these three designs is shown from the 2010 Norwegian arthroplasty register which states that, of 2,615 MCP implants, 1,820 (70%) were Swanson (Silastic HP 100), 555 (21%) were Avanta, and 198 (8%) were NeuFlex[8]. Based on this data, 99% of MCP prostheses were single-piece silicone designs[8]. The overriding failure mode of single-piece silicone

designs fitted in the MCP joint is fracture at the junction of the distal stem and the hinge which, from a cohort of explants, has been shown to be due to damage from bone leading to a fatigue fracture[18].

Two-piece designs of finger implant have been used and continue to be used, albeit in relatively small numbers. Conceptually they may allow finger biomechanics to be restored and from a theoretical point of view, under the relatively low loads typically seen across the finger joints and in like material combinations, could allow mixed and fluid film lubrication regimes[19]. Current two-piece designs use bearing surfaces made from pyrocarbon[20-23] or employ the recognisable bearing combination of metal rubbing against polyethylene[24-26]. While in many of these cases the clinical results could be described as mixed, other finger implants have shown high failure rates[27-32]. Such multiple examples of failures of contemporary finger prostheses indicate that there remains a serious need for appropriate in vitro testing.

Historically a number of finger simulators have been developed and these have been reviewed elsewhere[33, 34]. None of the simulators reviewed in those papers, aside from those at the University of Durham, UK, have been shown to be capable of reproducing clinical type failures of single-piece silicone finger implants. This is thought to be because those other simulators had not reproduced the loading conditions seen in rheumatoid MCP joints, namely the

subluxing forces, as well as a combination of light dynamic loading with a heavier static ‘pinch’ load. Has this situation changed since those earlier papers?

One paper has described a finger simulator capable of applying a maximum range of motion of 105°, at a test frequency between 0.2 and 2Hz, under a constant load of between 20 and 500N, while a lubricant heated to 37°C could be used[35]. Unfortunately no tests of finger implants were reported so it is difficult to fully assess this finger simulator[35].

Endolab advertise that they can test artificial finger joints using a spinal simulator[36]. The following brief description is given “EndoLab® uses a modified spinal wear simulator for testing of finger joint implants. The motion is reduced to one axis applying a constant axial force. A typical wear test is performed up to 5 million cycles using three to six implants at 1 Hz test frequency”[36]. Testing of a carbon fibre reinforced poly ether ether ketone (CFR-PEEK) PIP implant has been reported in an abstract, with the testing undertaken at Endolab[37]. From that abstract the following details are given. The test was conducted at 37°C over 5 million cycles in 25% bovine serum (refreshed every 0.5 million cycles). A load of 63N was applied at a frequency of 1Hz with a flexion/extension angle of ±40°. Wear rate was determined by mass loss from each component. Wear rates of 0.09mg/million cycles and 0.07mg/million

cycles for the proximal and distal components were measured[37]. While these appear to be positive results, again the question needs to be asked if the 'finger' (spinal?) simulator has been shown to reproduce clinical type failures of artificial finger joints which have been implanted into patients. There is no evidence that this validation has been achieved.

A finger simulator has also been described by Gibson et al in a book chapter outlining the development of a PIP joint prosthesis[38]. The authors describe a three-station finger simulator. A metal-on-metal design of PIP joint prosthesis was tested. Flexion-extension over a 0° to 90° range of motion at a speed of 3Hz was supplied by an electric motor, during which a load of 10-15N was applied. A pneumatic cylinder also applied a load of 110N at a cycle speed of 1Hz, and the ratio of light to heavy loading was set at 50:1 based on that applied in the Durham finger simulator. A load cell was fitted between the pneumatic cylinder and the test artificial joint. The simulator was controlled by a programmable logic controller while the position of the test prosthesis during flexion-extension was monitored by a digital encoder. A lubricant of dilute bovine serum was used which was warmed through a quartz lighting system to 37°C. Testing ran to 5 million cycles of flexion-extension with gravimetric changes measured every 500,000 cycles. At the end of testing a volumetric wear of 3.19 mm^3 and 2.41 mm^3 per million cycles, for the proximal and distal

components respectively, was measured. In other words a total wear rate of 5.60 mm^3 per million cycles. This is a disconcertingly high wear rate. From a cohort of metal-on-metal hip resurfacings which had been explanted after wear related failures, it was seen that all were associated with wear rates above $3mm^3$/year[39]. Given that a hip joint of radius 20mm will have a capsule volume of 23 times that of a finger of radius 7mm[40], so a finger joint could possibly 'cope' with 1/23 the wear of a hip, then a maximum wear from a metal-on-metal finger prosthesis of $0.13mm^3$/year can be estimated. Before testing, surface roughness values of the articulating surfaces of the PIP prosthesis were less than 0.03µm Ra. During and at the end of testing they increased rapidly to between 0.7 and 1.0µm Ra. Such high values of surface roughness correspond with the high wear volumes measured in the finger simulator. They are very much greater than the surface roughness values measured from explanted metal-on-metal hips where the average maximum roughness from 11 components was 0.135µm Ra[41]. While these results would appear to preclude a metal-on-metal PIP artificial joint, no testing of a clinically available finger implant was reported and therefore it is very difficult to know if the finger simulator is capable of reproducing clinically relevant results. A summary of these three finger simulators, compared with the Durham simulator (Joyce and Unsworth) is given in table 1.

[Insert Table 1]

In summary, various designs of finger simulator have been offered since the 1970s. These have been reviewed and it has been argued that an effective simulator (i.e. one that can reproduce clinical type failures) has to apply not only flexion-extension motion, but also a heavier static 'pinch' load, while reproducing the altered finger biomechanics seen in rheumatoid finger joints[33, 34]. This novel set of requirement represents a major design challenge but one solution will now be described in detail.

Method

The finger simulator which is the basis of this paper was designed at the University of Durham, UK. It is a dual cycle machine in that it applies relatively light loading to a test finger prosthesis during flexion-extension motion, followed by a period of a heavier static 'pinch' load. All loading is applied via artificial 'tendons' and the operation of the volar plate and ligamentous support around the MCP joint is reproduced mechanically.

The Durham finger simulator has been fully described elsewhere[33] but will be described here with an emphasis on design aspects which will help interested readers to design better joint simulators. At the heart of the simulator was a test bath where the test prosthesis was held and subject to loading and motion (figure 1). Design of the simulator began here, with consideration of the finger implants which could be tested. The dimensions of the various finger prostheses then available were determined and thus the test bath began to be sized. The test prosthesis was held in two polymeric holders which represented the bones of the metacarpal and proximal phalanx respectively. Nylon was chosen as it was relatively inexpensive, easy to machine and lightweight but with sufficient strength. In addition it has previously been used as an orthopaedic bone substitute, with a yield stress similar to cortical bone ranging from approximately 50–100 MPa, and hence was selected to be an appropriate

“bone substitute” material for the holders[42]. The end of the metacarpal ‘bone’ which did not hold the finger prosthesis was stepped down in diameter and fitted in and against a hole at the bottom of a square-section cantilever (figure 1). At the top of the cantilever, away from any test lubricant, were positioned two full strain gauge bridges. These allowed the load across the test prosthesis to be measured in two directions, at 90° to each other. Strain gauges were chosen for a combination of reasons, namely relatively low cost and high accuracy. Above the strain gauges, the cantilever was also stepped down to a square section stem which fitted inside a milled groove in the simulator framework. This combination of square section stem and matching milled groove prevented rotation of the cantilever.

[Insert Figure 1]

The phalangeal ‘bone’ which held the distal part of the test MCP prosthesis was, like the metacarpal ‘bone’, stepped down in diameter and located within a drilled hole in a polymeric block termed the ‘phalangeal clamp’ (figure 1). The phalangeal clamp also included two flat-bottomed holes. Inside each of these were placed a cylindrically shaped magnet. Each magnet formed one part of a Hall Effect sensor which in turn served to limit the motion of the test component to a pre-determined arc. The second part of these Hall Effect sensors sat in a curved polymeric arc piece above the flexion-extension arc traversed by the

phalangeal clamp. As with other parts of the simulator the ‘phalangeal clamp’ offered a simple yet effective design.

The operation of the volar plate was mimicked via a simple, four-component pivoted arm (figure 1). These four components were a stainless steel threaded pin, a polymeric distance piece, a plain stainless steel pin and a polymeric sleeve which fitted over the plain pin. To mimic the lack of the volar plate, as often occurs with silicone interpositional arthroplasty, the plain stainless steel pin and polymeric sleeve could simply be detached. As with other components, the polymeric and stainless steel materials were chosen on the basis of their corrosion resistance and relatively low cost. Simplicity of design was emphasized throughout the simulator by focussing on the essentials of what the design needed to achieve. The artificial flexor and extensor tendons were provided by fishing line. Braided dacron of 130lb (578N) breaking strain was found to be the best material amongst several that were tried. Testing took place on a 316 stainless steel baseplate (figure 1). Holes were drilled in the baseplate and resistors fitted. These then acted as heating elements for the test lubricant. The heating circuit also employed a type K thermocouple to monitor the lubricant temperature. The baseplate was connected to the framework of the simulator by two stainless steel rods (figure 1), threaded at

each end beneath shoulders. Employing these rods ensured that the baseplate, and thus the centre of rotation of the test joint was fixed.

The baseplate was circular in shape and sat within a bespoke stainless steel container with a bespoke, clear perspex lid. Perspex was chosen as it allowed the operation of the test components to be viewed, particularly when a transparent lubricant such as distilled water or Ringer solution was used. Resistors, which acted as heaters for the lubricant, were mounted in the baseplate.

Motion and loading of the test MCP implant was provided by an electro-pneumatic circuit. Figure 2 shows an overview of the simulator including some of the pneumatic components. Pneumatics were chosen as they offered a relatively inexpensive yet controllable method of applying appropriate loading and motion. Two 10mm diameter double-acting pneumatic cylinders (figure 2) provided the light (10-15N) loading seen during flexion-extension. Each cylinder also had a dedicated pressure gauge and control valve so the air pressure, and thus the load across the test implant, could be controlled and varied.

[Insert Figure 2]

Applying the heavier, static ‘pinch’ load to the test finger prosthesis was more involved and required three additional double-acting pneumatic cylinders. The first cylinder was mounted above the test bath and acted as a ‘thumb’ against which the ‘pinch’ load would be applied (figure 2). A stainless steel rod was connected to this cylinder and, when the pneumatic cylinder was activated, this rod passed through a hole in the curved polymeric arc piece and into a hole in the baseplate. Sequentially, through the control programme, the ‘phalangeal clamp’ would be pulled against this rod. A second double-acting pneumatic cylinder served to transfer loading between the flexor ‘tendon’ and an aluminium ‘slider plate’ upon which the flexor and extensor cylinders were mounted (figure 2). In turn this ‘slider’ plate was attached via a universal coupling (to account for any misalignment) to a large (32mm diameter) double-acting pneumatic cylinder which applied the necessary ‘pinch’ loading (of up to 392N). 392N was calculated to be the maximum loading seen in a typical non-diseased MCP joint[33]. In the finger simulator, ‘pinch’ load was applied through the flexor apparatus with the extensors relaxed, as occurs in the body[43]. This arrangement required a dedicated pneumatic valve which dumped air from the extensor cylinder. By this mechanism a compressive force with large subluxing force was applied to the test prosthesis. To do so necessitated a complex set-

up of valves and additional pneumatic cylinders, but this was required to apply clinically relevant loading conditions.

To design out any potential problems of the ‘tendons’ stretching, leading to gradual load reduction across the test prosthesis, a solution was achieved by the use of pneumatics and also choosing pneumatic cylinders with a sufficiently long stroke length. Essentially, when the tendons stretched, the rod of the cylinder was simply pushed back by the distance the tendon stretched.

Pneumatic components were purchased from SMC Pneumatics. Part of the reason for choosing this supplier was that the components were of a small size compared with other suppliers. As well as having a superior aesthetic appearance, smaller pneumatic valves had internal components with a lower inertia. These valves were also of such a small size that they could be mounted on the side of the simulator (figure 2). The closer the valve to its slave pneumatic cylinder, the shorter the air-line required and the quicker the circuit response time. Therefore the combination of low inertia valves plus shorter air lines permitted an increase in the speed of the simulator during flexion–extension to above 3Hz, should such a high speed be required. The simulator framework was of aluminium in stock sizes which was anodised after manufacture to give a consistent and professional appearance.

Control of the simulator was achieved through a dedicated computer programme written in QuickC. This controlled the pneumatic valves in a predetermined sequence so that the following load cycle was repeatedly completed: 3,000 cycles of flexion-extension (from 0° flexion to 90° flexion and back to 0° flexion); followed by 45 seconds of a 'pinch' load. During all of this time values of loading across the test MCP prosthesis were output to the screen of a computer. The two full strain gauge bridges were connected to a dedicated analogue to digital (AD) converter and strain gauge amplifier card fitted within the computer.

In summary, the design of the single-station finger simulator allowed for a number of parameters to be varied including loading, motion, load cycle, size of implant, test lubricant, and other joints of the fingers as well as the MCP joint. A major emphasis had been on low cost solutions as limited funding was available for the simulator. An additional basic aim had been reliability as the finger simulator was needed to dependably run for millions of cycles. All of these design criteria were achieved.

Test conditions employed in the finger simulator included an overall load cycle of 3,000 cycles of flexion-extension (10-15N loading) followed by 45 seconds of static 'pinch' load (106N). 106N was calculated to be the maximum arthritic pinch load[33]. These test conditions have been fully described elsewhere[34].

With any simulator, a link to clinical results must be made to validate the machine. In the case of the finger simulator, testing was first undertaken on a size 2 Swanson finger prosthesis. It fractured across the junction of the hinge and the distal stem at just under one million cycles[33]. Fracture at the junction of the hinge and the distal stem is the common mode of failure in Swanson prostheses implanted into rheumatoid MCP joints[11].

The simulator was developed during the author's PhD[44]. Two subsequent post-doctoral projects were funded and this allowed an additional six finger simulators to be manufactured to permit further in vitro testing[15, 16, 24, 45]. At this point, power supplies were 'tidied up' in that a dedicated rather than portable power supply was assembled alongside other electronic components into a bespoke control unit. This also included an electronic temperature display and a series of lights to indicate working of the various pneumatic valves. Overall this helped to give a more permanent and professional appearance.

Discussion

The finger simulator described in this paper has reliably been used for over 170 million test cycles of flexion-extension for testing two-piece and single-piece MCP implants (more tests have been done but for contractual reasons not all

have been reported). For single-piece silicone implants these total approximately 61 million cycles of flexion-extension for Swanson, Sutter and NeuFlex prostheses[15, 16, 33]. For two-piece implants these include approximately 82 million cycles of flexion-extension testing of the 'Durham', Digital Joint Operative Arthroplasty (DJOA), and Zimmer Elogenics implants [24, 45-48].

Crucially, where comparable clinical data was available, all failure modes seen in the finger simulator have matched those reported in vivo. For the Swanson[33] and the Sutter[16] MCP implants these include fracture at the junction of the distal stem and the hinge. For the NeuFlex this failure mode is fracture across the hinge[15]. For the two-piece DJOA implant it was found that the prosthesis dislocated unless the volar plate assembly was fitted in the finger simulator[45]. This matched the clinical experience where the DJOA performed adequately in osteoarthritic joints, but poorly in rheumatoid joints[49].

The finger simulator also allowed tribological tests of two-piece MCP prostheses[24, 46-48] and permitted investigations of different tribological phenomena to be undertaken. Crucially, the finger simulators have done this with great reliability. The only component that was changed regularly was the artificial 'tendons'. However this was expected as these were subject to varying loads in a corrosive environment and had to travel around two pulley wheels and a pivot point. Changing the tendons was very straightforward. The end of

the tendon within the test bath was held by a stainless steel split pin while the end at the flexion-extension pneumatic cylinders was simply tied in a knot.

Recent failures in finger implants[27-32, 50] show that there is still an insistent need for appropriate in vitro testing of finger prostheses. This need was highlighted over 10 years ago[51]. The finger simulator described in this paper has the capacity to undertake such testing. In the last two years the simulators have begun to be used again. Testing of pyrocarbon PIP joint prostheses to 5 million cycles of flexion-extension has been undertaken[52]. Crucially, these in vitro results can be compared against ex vivo pyrocarbon prostheses[23]. Most recently, testing of a commercially available metal-on-polyethylene finger prosthesis to 5 million cycles has also been completed[42].

In the author's opinion the two engineering inputs which can help to take forward finger joint replacement at this point in time are appropriate in vitro testing of finger prostheses and analysis of finger prostheses removed from the hands of patients.

Conclusion

The finger simulator design described in this paper has been used for over 15 years to test multiple designs of artificial finger joints. In all those cases where

such data is available, clinical type failures have been reproduced. Details of the finger simulator design have been shared to help industry and academia to design better simulators. Finger prostheses, finger biomechanics and therefore finger simulators offer quite distinct challenges compared with hip and knee prostheses. As with other joints of the body which are less commonly replaced, such as the wrist, the elbow and the ankle, these differences need to be appreciated. Once appreciated, it is likely that simulators offering clinically relevant testing can be designed. There remains a need for improved artificial finger joints and finger simulators capable of providing clinically relevant tests will likely be part of the route by which such improved finger implants will be obtained.

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Figure titles

Figure 1. Test chamber of the simulator. The external lubricant container, arc piece and Hall Effect switches have been removed for clarity. The white metacarpal component of a two-piece finger prosthesis can be seen in the centre of the image. Either side of the prosthesis are the artificial tendons. Above the prosthesis is the volar plate assembly. The stainless steel pins with their black polymeric sleeves can be seen. Behind the test prosthesis are two stainless steel columns (one marked 'X') which connect the circular stainless steel baseplate to the framework of the simulator. To the right of the image there are two stainless steel 'funnels' which guide wires to the heating elements in the baseplate. The white polymeric piece to the right of the image is a spacer which serves to reduce the volume of lubricant required in the test chamber. In the centre of the image is the square-section cantilever which holds the metacarpal component. On it, covered by a protective white sealant, are the strain gauges which facilitate load measurement. In the left foreground the 'phalangeal clamp' can be seen with the ends of the 'tendons' held by stainless steel split pins.

Figure 2. Overview of the finger simulator. In the foreground is the test chamber (figure 1) enclosed by a stainless steel lubricant container which is topped with a clear Perspex cover. On the top left hand side of the cover is the ‘thumb’ pneumatic cylinder with its two green airlines. Behind the stainless steel container the anodised aluminium framework of the simulator can be seen. Within the framework is an aluminium slider on which are mounted the two small (10mm diameter) pneumatic cylinders which applied the flexion and extension motions respectively. On the left hand side of the image are the pneumatic valves and other pneumatic circuitry.

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