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1 The effects of simulated ulnar deviation on

2 metacarpophalangeal joint implant failure

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13 Introduction

14 One-piece silicone (silastic) arthroplasties have been used successfully to treat 15 symptomatic finger metacarpo-phalangeal (MP) joint and proximal inter-16 phalangeal (PIP) joint arthritis (Trail et al. 2004). The implants do not however, 17 last as well as the hard bearing arthroplasties of major joints in the upper and 18 lower limbs. This is in spite of the fact that implant testing originally suggested 19 that the Swanson silastic implant could withstand 400 million cycles "without 20 evidence of breakdown" (Swanson 1972) and no fractures were reported in five 21 implants after 10 million cycles (Weightman et al. 1972). It was felt that the 22 earlier failure was due to bone spikes initiating tears in the silicone which then 23 propagated (Swanson 1972). This led to the development of grommets which 24 were initially felt to be beneficial (Rittmeister et al. 1999; Schmidt et al. 1999). 25 Longer term review has however suggested no benefit (Trail et al. 2004). 26 Subsequent testing with a jig with pinch force led to fracture of a Swanson size 2 27 implant in 1 million cycles (Joyce and Unsworth 2000). This is more compatible 28 with clinical experience where there have been reports of earlier failures even 29 within 14 months (Weightman et al. 1972); the largest ever review of silicone 30 MP joint arthroplasties showed that the outcomes were worse in patients who 31 had had successful thumb carpometacarpal and MP joint arthrodeses (Trail et al., 32 2004). This further implies that lateral pinch forces increase the stresses on the 33 implants leading to earlier failures.

34

Most MP joint arthroplasties and some PIP joint arthroplasties drift into ulnar deviation (Blair et al. 1984; Kay et al. 1978; Wilson et al. 1993). This is associated with poorer outcomes, which might be improved by crossed intrinsic transfers (Trail et al. 2004). No implants have been tested specifically in a jig with ulnar deviation to assess the effect of that on silicone finger joint wear and failure.

- The aim of this study was to test whether movement of finger implants in a test rig causes more wear and implant failure in ulnar deviation than in neutral. We
- 42 tested the null hypothesis that there would be no difference.
- 43

44 Methods and Materials

A mechanical test rig was designed and constructed (fig 1) to test 12 size 6
silicone MP joint implants supplied by Osteotec (fig 2). The rig consisted of an
aluminium beam with 12 stations to hold the distal stems of the finger joint
implants driven by a slider crank mechanism to cyclically flex the implants.
Cavities to receive the stems of the finger joints were moulded using bone
cement with a tapered steel former to create shaped recesses into which the

51 stems fitted after the cement had cured. The stems were a close but not tight fit 52 replicating the insertion into the intramedullary bone cavity in vivo. The finger 53 joint implants were tested in groups of four implants in 0[°], 10[°] and 20[°] of 54 deviation simulating ulnar deviation following implantation.

55

56 The rig was cycled at 1.5Hz with an arc of motion from 0^o- 90^o simulating full 57 extension to full flexion. The implants were submerged in a bath of Ringer's 58 solution at 37^oC throughout the experiment. The rig was stopped and the 59 implants were inspected with 3.5 x magnification every 500,000 cycles until a 60 total of 4 million cycles.

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- 62

63 **Results**

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65 No silicone implant failed. All implants remained in situ throughout the 66 experiment. There were minimal changes in any implants up to 1 million cycles. 67 Signs of damage started to emerge after 1 million cycles primarily in the 68 implants in greater deviation. For the purposes of clarity the side of the deviation 69 is described as the ulnar side in simulation of the normal direction of drift 70 following MP joint arthroplasties; the side opposite the deviation is described as 71 the radial side. The observed signs of damage all increased consistently with 72 increasing numbers of cycles. We report the results at 4 million cycles. The 73 findings in the three groups were:

74

In 0° deviation there was symmetrical light wear either side of the necks of the
implant i.e. where the stems of the implants reach the body (Fig 3). There was
evidence of pistoning with signs of wear from impingement on the palmar distal
aspect of the hinge (fig 3).

79

In 10^o deviation there was light fretting to the radial side i.e. the side opposite to
the deviation (fig 4). There were light striations to the palmar-radial and dorsalulnar aspects of the implants (fig 4). There was slight rotation of the body of the
implant into supination and ulnar deviation.

84

85 In 20° deviation there was heavy fretting to the radial side of the neck of the 86 implants. There were deep striations to the palmar-radial and dorsal-ulnar 87 aspects of the implant (fig 5). On inspection these measured over 2mm in each 88 implant whereas the surface changes at 0° and 10° were \leq 1mm. There was even 89 more marked plastic deformation leading to rotation of the body of the implant 90 into supination and ulnar deviation.

91

92 There were appreciable differences in the wear of the implants from the 0°
93 group to the 10° group and even more to the 20° group. Thus the null hypothesis
94 can be rejected.

95

96 Discussion

Silicone arthroplasties are known to fail. It has long been thought to be related to
the extent of deviation of the joint (Oster et al., 1989; Clarke et al. 2001). Trail et
al. (2004) clearly identified that joint replacement failure is more likely in fingers

100 with greater deviation. Silicone fails by fracturing (tearing) of the surface which

then propagates to catastrophic structural failure. Anything that reduces the risk
of initiation and propagation of the tearing of the silicone should reduce the risk
of joint replacement failure. Grommets were used to reduce the risk of tearing
from sharp bone spikes. These do not appear to improve the outcome of these
implants and have been abandoned (Trail et al., 2004).

106

107 More recently hard bearing implants have been developed and used with good 108 results in osteoarthritis (Simpson-White et al. 2013) but are often too unstable in 109 joints destroyed by inflammatory arthritis. There is still a need for soft (silicone) 110 implants. There are a number of different silicone implants with the Swanson 111 type implant the most commonly used (Trail et al. 2004). It is not established 112 what is the best design of silicone implant (Trail et al., 2004).

113

This study has assessed more implants than any other biomechanical test of silicone finger implants. It is also the only study to assess several implants simultaneously in different conditions. We have shown that increasing ulnar deviation causing increasing silicone implant wear as recognised in clinical practice. The effect of the ulnar deviation would be likely to be greater if we also simulated pinch loading (Joyce and Unworth 2000) and simulated sharper bone edges (Swanson 1972).

121

There are weaknesses of this study: we only tested 12 types of one design of implant; the implants were not tested to destruction; the differences in wear were subjective but differed appreciably between the implants in the three groups; the rig simulated "normal" movement but patients rarely achieve a 90° arc of motion and the deviation will not be as rigidly fixed as in this jig; and we did not simulate the sharp bone spikes as we wanted to test ulnar deviation in isolation.

129

Despite the weaknesses of this study we have clearly shown for the first time that increasing "ulnar" deviation of silicone implants on its own leads to increasing wear of the implants. In vivo this will probably combine with sharp bone edges and lateral pinch forces leading to catastrophic failure. In future there need to be more efforts made to reduce the risk of tearing of the implant possibly by changes in the material and by surgical techniques aimed at reducing post-operative ulnar deviation.

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Figures







Fig 1c

Fig 1 b

Fig 1 The rig



- Fig 2 Osteotec size 6 implant prior to testing 257

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Arrows point to clear wear on the volar side of the implant stems

Fig 4 Implants tested with 10^o deviation and analysed after 4 million cycles

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