Sites of fractures in explanted NeuFlex metacarpophalangeal silicone prostheses

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Abstract

Single-piece silicone implants dominate metacarpophalangeal (MP) joint arthroplasty. The NeuFlex implant was introduced to improve on the clinical performance of other silicone implants by having a pre-flexed hinge. By visually examining a cohort of 30 explanted NeuFlex MP joint prostheses we sought to identify failure modes of these implants. Seven were not fractured, 11 had fractured across the hinge, nine had fractured at the junction of the distal stem and the hinge, and three showed fractures at both the hinge and at the junction of the distal stem and the hinge. This data may prove helpful with identifying how the performance of single-piece silicone implant designs can be improved.

Level IV

INTRODUCTION

Single-piece silicone implants dominate finger arthroplasty of the metacarpophalangeal (MP) joint. The Swanson (Wright Medical, Memphis, USA) implant is the market leader (Norwegian_Arthroplasty_Register, 2016). Known 'problems' include fracture (Kimani et al., 2009), primarily at the junction of the distal stem and hinge (Joyce and Unsworth, 2002). This position of fracture is also seen with the Avanta/Sutter (Sutter Corporation/Avanta, San Diego, USA) single-piece silicone finger implant (Joyce et al., 2003). It is thought to be particularly related to the dominance of subluxing forces in the rheumatoid MP joint (Drayton et al., 2016; Joyce, 2009). In 1998 the pre-flexed NeuFlex implant was introduced. The three designs, Swanson, Sutter and NeuFlex, are shown in Fig 1.

It is recognised that fracture of silicone MP implants is common. Trail et al. reported that two-thirds of 1336 Swanson implants had fractured at 17 years follow-up (Trail et al., 2004). Goldfarb and Stern reported that 67% of their Swanson implants and 52% of their Sutter implants had fractured at 14 years follow-up (Goldfarb and Stern, 2003). A fractured implant does not necessarily mean a clinical failure but recurrent symptoms are more likely with fractured implants (Trail et al., 2004).

Clinically, it has been reported that the NeuFlex MP joint has produced an increased range of motion compared to use of the Swanson implant (Delaney et al., 2005). This finding was also reported by Escott et al, although their patients implanted with a Swanson implant had better self-reported function and aesthetics (Escott et al., 2010). While Namdari and Weiss reported 1/29 fractures in their cohort of NeuFlex implants (Namdari and Weiss, 2009), similar fracture rates between the NeuFlex and Swanson designs have been reported (Kimani et al., 2009). When NeuFlex and Sutter implants were compared in the MP joint, two out of 78 NeuFlex and five out of 78 Sutter implants broke (Pettersson et al., 2006).

The aim of this study was to assess the failure of explanted NeuFlex implants and compare the results with established patterns for other one-piece silicone implants.

METHODS AND MATERIALS

NeuFlex MP joint explants were gathered as part of an ongoing retrieval programme. Following removal the implants were cleaned with a brief immersion in Chlorhexidine for 30 mins and then washed in tap water. The explants were photographed using a digital camera. The position of fracture, if any, was noted. We recorded patient demographics including the patient age, gender, underlying diagnosis, site of surgery and time in situ. The implants were part of a consecutive series of explants for which patient demographic data were available.

Based on the explant results (q.v.), we compared the thickness of the central hinge section of NeuFlex and Sutter/Avanta implants as a thinner section would probably fail quicker, as crack growth resistance is probably key to the longevity of these single-piece, silicone prostheses (ASTM-F1781-15, 2015; Hutchinson et al., 1997). Size 20 and size 40 implants of the NeuFlex and Sutter/Avanta were measured using a Vernier calliper (Mitutoyo, Huddersfield, UK).

RESULTS

Thirty NeuFlex MP joint explants were available for study. The position of the complete implant fracture, if any, is shown in table 1, alongside patient and other information. All revision procedures were undertaken for clinical problems i.e. symptomatic joint replacement failure requiring revision surgery after failure of non-operative treatment.

Seven explants were not fractured (Fig 2A). Eleven explants had completely fractured at the hinge (Fig 2B). A further nine explants had completely fractured at the junction of the distal stem and hinge (Fig 2C). Three explants had completely fractured at both the hinge and at the distal stem (Fig 2D).

We saw a mix of fractured and intact implants in some patients, for example explants 8-11 came from the hand of one patient. One explant was intact, two had fractured at the distal stem and one had fractured at the hinge. Separate to this we saw an explant (no. 19) with an incomplete fracture.

NeuFlex MP explants ranged in size from 0 to 40. As might be expected, smaller sizes were retrieved from the smaller fingers of hands, while larger implants tended to come from the index and middle fingers. The age at revision ranged from 43 to 81 (median 58) years. The time in situ ranged from 6 to 120 (median 58.5) months. In all but two cases the diagnosis was rheumatoid arthritis. Discolouration of some explants had occurred (Fig 3). The significance of this is unclear but it could represent some change in material properties of the implant.

The size 20 NeuFlex and Sutter/Avanta implants were each measured to have a hinge thickness of 1.9 mm and the size 40 implants were each measured to have a hinge thickness of 2.3 mm.

DISCUSSION

As shown in table 1, 11 NeuFlex explants had fractured across the hinge (Fig 2B); this has not previously been reported in vivo. Fracture at the hinge occurred when three NeuFlex implants were tested in vitro in a finger function simulator (Joyce and Unsworth, 2005). Nine NeuFlex explants had fractured at the junction of the distal stem and hinge (Fig 2C). This is similar to the site of implant fracture seen with Swanson implant fractures (Gellman et al., 1997; Trail et al., 2004) and Sutter/Avanta (Joyce et al., 2003) implant fractures. In vitro tests have shown that Swanson (Joyce and Unsworth, 2000) and Sutter (Joyce et al., 2003) implants fracture at the junction of the distal hinge and stem, in both cases matching clinical experience.

Intriguingly, 10% of the cohort fractured at the hinge and at the junction of the distal stem and hinge (Fig 2D). The authors are not aware of such a failure mode having been reported previously. That it happened in three explants, and that one of the un-fractured NeuFlex explants (no. 19) also showed substantial damage at both the hinge and the junction of the distal stem and hinge indicates that the

failure mode was not an anomaly; of greater note 11 (37%) fractured just at the hinge. Overall 14 (47%) suffered fractures of the implant hinge. Silicone implant hinge fractures have not previously been reported. It is unclear whether this occurs before, after or separate to stem fractures.

The one incomplete fracture (no. 19) showed that fracture began dorsally. This matches with the fracture initiation site of silicone MP joint implants seen previously (Joyce, 2009).

Discolouration of most explants occurred (Fig 3) likely indicating that the silicone material can change when in the body. This may affect the material properties of the implants and could therefore be a useful area for future research.

We appreciate that fractures would likely have occurred sometime before removal of the implants and therefore time in situ does not equate with time to fracture.

Ex vivo analysis of finger implants potentially highlight key areas of failure, thus providing information that could be used to reduce failures by improving future designs. For example, based on the empirical evidence provided in this paper and by other previous publications (Drayton et al., 2016; Joyce, 2009; Joyce et al., 2003), subluxing forces need to be minimised, to reduce the shear stresses on the implant at both the junction of the distal stem and hinge and probably at the hinge. In addition, consideration could be given to increasing the thickness of the hinge to reduce the time taken to fracture, although there may be a concomitant increase in stiffness of the implant.

With improved designs, patients could achieve more with their replaced joints while increased prosthesis longevity should lead to fewer revision operations. The latest Norwegian Arthroplasty Register shows that revision MP joint arthroplasties accounted for 42% of all MP joint replacement operations in 2015 (Norwegian_Arthroplasty_Register, 2016). Therefore revision MP joint arthroplasty is common and opportunities to reduce such operations are substantial.

There are limitations on this research. There is no denominator to show the rate of implant failure. The details of the original operations are unknown; there may have been factors leading to implant failure. There is no correlation with the biomechanics of the failed joints.

This study provides new data on the failure of NeuFlex implants raising questions about their design and its possible link to mechanical failure.

CONFLICT OF INTERESTS

None declared

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REFERENCES

ASTM-F1781-15. Standard specification for elastomeric flexible hinge finger total joint implants. West Conshohocken, ASTM, 2015.

Delaney R, Trail IA, Nuttall D. A comparative study of outcome between the neuflex and swanson metacarpophalangeal joint replacements. J Hand Surg Br. 2005, 30: 3-7.

Drayton P, Morgan BW, Davies MC, Giddins GEB, Miles AW. A biomechanical study of the effects of simulated ulnar deviation on silicone finger joint implant failure. J Hand Surg Eur. 2016, 41: 944-7.

Escott BG, Ronald K, Judd MGP, Bogoch ER. Neuflex and swanson metacarpophalangeal implants for rheumatoid arthritis: Prospective randomized, controlled clinical trial. J Hand Surg. 2010, 35: 44-51.

Gellman H, Stetson W, Brumfield RH, Costigan W, Kuschner SH. Silastic metacarpophalangeal joint arthroplasty in patients with rheumatoid arthritis. Clin Orthop Rel Res. 1997, 342: 16-21.

Goldfarb CA, Stern PJ. Metacarpophalangeal joint arthroplasty in rheumatoid arthritis. J Bone Jt Surg. 2003, 85A: 1869-78.

Hutchinson DT, Savory KM, Bachus KN. Crack-growth properties of various elastomers with potential application in small joint prostheses. J Biomed Mat Res. 1997, 34: 94-9.

Joyce TJ. Currently available metacarpophalangeal prostheses: Their designs and prospective considerations. Expert Rev Med Devs. 2004, 1: 193-204.

Joyce TJ. Analysis of the mechanism of fracture of silicone metacarpophalangeal prostheses. J Hand Surg Eur. 2009, 34: 18-24.

Joyce TJ, Milner RH, Unsworth A. A comparison of ex vivo and in vitro sutter metacarpophalangeal prostheses. J Hand Surg Br. 2003, 28B: 86-91.

Joyce TJ, Unsworth A. The design of a finger wear simulator and preliminary results. J Engng Med. 2000, 214: 519-26.

Joyce TJ, Unsworth A. A literature review of 'failures' of the swanson finger prosthesis in the metacarpophalangeal joint. Hand Surg. 2002, 7: 139-46.

Joyce TJ, Unsworth A. Neuflex metacarpophalangeal prostheses tested in vitro. J Engng Med. 2005, 219: 105-10.

Kimani BM, Trail IA, Hearnden A, Delaney R, Nuttall D. Survivorship of the neuflex silicone implant in mcp joint replacement. J Hand Surg Eur. 2009, 34: 25-8.

Namdari S, Weiss A-PC. Anatomically neutral silicone small joint arthroplasty for osteoarthritis. J Hand Surg. 2009, 34: 292-300.

Norwegian_Arthroplasty_Register. Nasjonalt register for leddproteser. 2016. http://nrlweb.ihelse.net/eng/Rapporter/Report2016_english.pdf (25 September 2017).

Pettersson K, Wagnsjö P, Hulin E. Neuflex compared with sutter prostheses: A blind, prospective, randomised comparison of silastic metacarpophalangeal joint prostheses. Scand J Plas Reconstr Surg Hand Surg. 2006, 40: 284-90.

Trail I, Martin J, Nuttall D, Stanley J. Seventeen-year survivorship analysis of silastic metacarpophalangeal joint replacement. J Bone Joint Surg Br. 2004, 86-B: 1002-6.

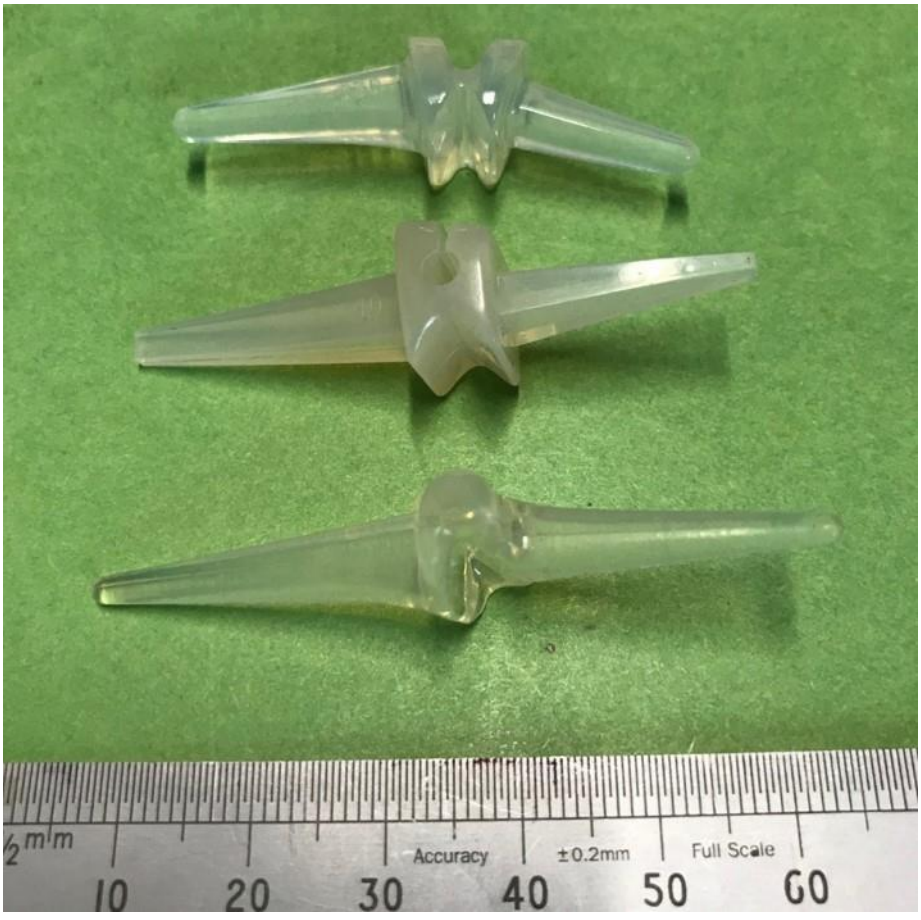
Weiss A-PC, Moore DC, Infantolino C, Crisco JJ, Akelman E, McGovern RD. Metacarpophalangeal joint mechanics after 3 different silicone arthroplasties. J Hand Surg. 2004, 29: 796-803.

Figure legends

Figure 1 – different designs of silicone single-piece finger implants. Top NeuFlex, middle Sutter/Avanta, bottom Swanson. In all cases the distal stem is to the right.

Figure 2 A (top left) – An un-fractured NeuFlex explant (explant 15); B (top right) – A NeuFlex explant (explant 28) showing fracture at the hinge; C (bottom left) – A NeuFlex explant (explant 24) showing fracture at the junction of the distal stem and hinge; D (bottom right) – A NeuFlex explant (explant 13) showing fracture at both the hinge and at the junction of the hinge and the distal stem

Figure 3 – Two NeuFlex explants (explant 18 above and explant 13 below) showing discolouration. Note that discolouration of explant 13 has occurred to the entire material and not just the outer surfaces.



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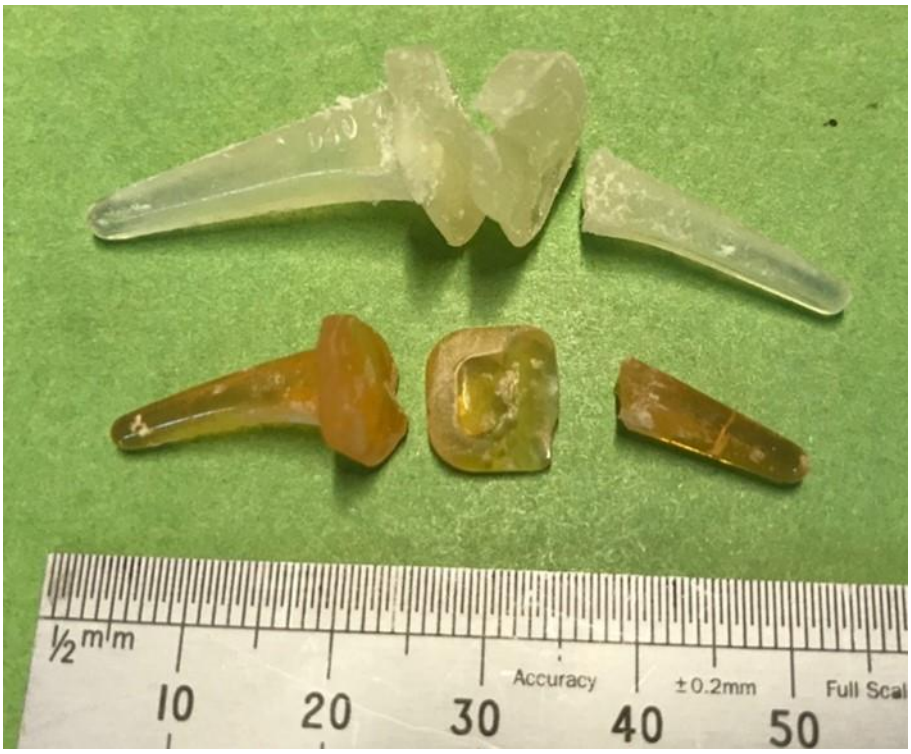

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Explant	Finger	Explant Size	Patient age at revision	Time in situ (months)	Diagnosis	Position of fracture
1	Index	30	43	36	RA	Hinge and distal stem
2	Little	10	43	36	RA	Hinge
3	Middle	30	43	36	RA	Hinge
4	Index	40	58	63	RA	Distal stem
5	Middle	40	58	63	RA	Distal stem
6	Ring	30	58	63	RA	Distal stem
7	Little	20	58	63	RA	Distal stem
8	Index	30	78	54	RA	Distal stem
9	Middle	40	78	54	RA	Distal stem
10	Ring	20	78	54	RA	No fracture
11	Little	10	78	54	RA	Hinge
12	Ring	20	57	78	RA	Hinge and distal stem
13	Little	10	57	78	RA	Hinge and distal stem
14	Index	30	58	63	RA	No fracture
15	Ring	20	58	63	RA	No fracture
16	Little	20	58	63	RA	No fracture
17	Middle	40	58	63	RA	Hinge
18	Middle	40	84	18	OA	Distal stem
19	Index	40	84	18	OA	No fracture
20	Little	10	73	24	RA	No fracture
21	---	40	70	120	RA	Hinge

22	Little	10	62	18	RA	Hinge
23	Index	40	81	31	RA	Distal stem
24	Middle	40	81	31	RA	Distal stem
25	Little	20	81	31	RA	No fracture
26	Index	30	56	84	RA	Hinge
27	Middle	30	56	84	RA	Hinge
28	Ring	20	56	84	RA	Hinge
29	Little	0	56	84	RA	Hinge
30	Index	30	49	6	RA	Hinge

202 **Table 1 – table of data regarding NeuFlex MP joint explants. RA = rheumatoid arthritis; OA =**

203 **osteoarthritis.**

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