‘Locking the stable door’
Dr Thomas J Joyce, 2008

In 1999, describing the history of metacarpophalangeal prostheses, Robert Beckenbaugh spoke of a pathway ‘*littered with many cleverly designed and manufactured implants that have failed*’ [1]. In the 21st century we can add to this list of failures the WEKO and LPM finger prostheses. For the WEKO implant, one paper reported that the entire cohort of 28 prostheses had been removed after less than a mere two years *in vivo* [2]. For the LPM proximal interphalangeal prosthesis, I have been told that over 50% of those implanted in the UK have failed. Although work is said to be ongoing to understand why these LPM failures occurred, for the patients and hand surgeons concerned, is it case of locking the stable door after the horse has bolted?

Clinical results from the WEKO study revealed large amounts of black staining of tissue caused by titanium wear debris [2]. This did not surprise me; the hard cobalt chrome material of the stem of the hinge section pistoning against the far softer titanium of the prosthesis stems would rapidly produce such debris. For the LPM prosthesis, I suspect that the very hard, golden-coloured Titanium Niobium coating failed at its attachment to the substrate. Resulting in a very hard, golden-coloured grinding paste within the patients’ proximal interphalangeal joints. While I could be wrong, and I hope an analysis of failed LPM implants will be published, such interface failures have been reported in the scientific literature for the coated heads of artificial hip joints which were fitted in the 1990s [3]. The history of coatings applied to joint replacements has generally not been a happy one therefore the news of LPM failures came with a sense of déjà vu.

What do the LPM and the WEKO finger prostheses have in common with the rest of the ‘*cleverly designed … implants that have failed*’? One shared factor is that they have not been appropriately tested prior to implantation. Otherwise they would have expired in the laboratory rather than failing, unbecomingly, in patients. Given this situation is it unsurprising that some hand surgeons and many rheumatologists do not believe in the effectiveness of metacarpophalangeal joint arthroplasty [4]?

Hand surgeons ought to be aware of failures of finger prostheses. Concern voiced at the Autumn 2005 BSSH meeting over the LPM implant resulted in an audit being initiated [5]. Furthermore, at a BSSH meeting in 2006 the best poster prize was awarded to a paper entitled ‘Failure of the Mathys Finger Joint Replacement System’. Like the WEKO, these implants have all failed *in vivo*. Why do we allow this appalling situation not only to occur, but to repeat itself? Where were the peer-reviewed papers entitled ‘pre-clinical testing of (insert prosthesis name) to ten million cycles of flexion-extension’?

One of the perverse pleasures of attending BSSH meetings is to peruse the trade stands to see the latest ideas in finger prostheses in all their myriad shapes, sizes, concepts and materials. When I ask how these devices are tested *in vitro* I am assured that comprehensive assessment has been undertaken. But I have rarely seen results of independent testing appear in the peer-reviewed literature. Instead I read clinical reports of finger prosthesis failures while other prostheses seem to slip away quietly, never to be heard of again.

Outside of BSSH meetings, a look at manufacturers' websites shows a remarkable range of finger prostheses. Such implants include: the stainless steel Digitale II®; the metal-on-metal Andigo® prosthesis; the Moje ceramic-on-ceramic finger implant; and the remarkable BioSpring® with its two titanium intramedullary screws and two springs to allow motion at the joint. Perhaps one of these devices is the implant we have been waiting for, the one that will dethrone the Swanson prosthesis? How would we know if that were the case? Well a cohort could be implanted into a large group of patients by a number of independent surgeons at different centres and the clinical results followed for many years.

Alternatively, they could be tested in the laboratory using a test device which had, say, caused a Swanson prosthesis to fracture at the junction of the distal stem and the hinge, as many tend to do *in vivo*. Why is this such a radical idea to many people concerned with finger joint replacement? With a reliable test device running at 1Hz, then a 1 million cycle test, as a rule of thumb equivalent to a year *in vivo*, could be achieved in a fortnight. The equivalent of ten years *in vivo* tested in five months. With more than one test device then multiple tests could be undertaken in parallel. Imagine the invaluable testing that could be done, and without the involvement of a single patient.

I would contend that the lack of appropriate *in vitro* testing has meant that finger joint arthroplasty has not developed as rapidly as it might have done. The Swanson prosthesis has been available since the late 1960s and, with minor modifications since then, has become the market leader. Contrast this with recent advances in knee joint replacement – the introduction of low wearing cross-linked polyethylene, 'mobile bearing' knees, and uni-condylar devices – all have been tested and verified *in vitro* using knee simulators and the data published in peer-reviewed journals.

The lack of extensive *in vitro* testing of finger prostheses compared with hip and knee prostheses would explain why Ronald Linscheid began his review of implant arthroplasty of the hand with the observation '*there is some frustration among hand surgeons in not being able to match the success of our colleagues who perform large total joint arthroplasties*' [6].

Producing a suitable test device for finger implants is not straightforward. Back in 1972 Alfred Swanson reported testing his design of finger prosthesis to 400 million cycles of flexion-extension and noted no problems with the tested prosthesis [7]. This result implied that the Swanson prosthesis would be suitable for any patient who might live to the ripe old age of 400, Methuselah for example. Yet such longevity has not been seen *in vivo*. For instance a clinical study gave an account of a patient whose four Swanson implants in one hand had all fractured one year after implantation [8]. Colleagues at Wrightington reported that two-thirds of the 'gold standard' Swanson prostheses that they implanted into diseased metacarpophalangeal joints had fractured after seventeen years [9]. Therefore, simply flexing and extending a prosthesis over and over again *in vitro* as Dr Swanson did could be insufficient.

Yet by combining flexion-extension with static 'pinch' loading and employing artificial tendons to apply appropriate forces and motion to a test implant, at Durham University there is a design of rig which has been used to test Swanson, Sutter and

NeuFlex silicone prostheses. In each case clinical-type fractures of the implants have been reproduced and all of these results have been reported in the peer-reviewed scientific literature. Moreover, there is not just one of these test rigs, but seven.

What is the implication of the lack of appropriate pre-clinical testing of finger prostheses for hand surgery? We will continue to see new designs of finger implants fail. Some will be reported, I suspect many more will not. If current and future designs of finger prostheses were appropriately tested *in vitro* then those shown to be the best available could be implanted with a degree of confidence. This confidence could ripple outwards to our colleagues in rheumatology who help to propose patients for hand surgery and, perhaps most important of all, to the patients themselves.

I have a vision in which all new designs of finger prosthesis are tested *in vitro* and the results then shared in the scientific literature. We would all learn from this. Designs which initially gave disappointing results could be strengthened where needed and improved. Again, this positive experience could be shared with those of us concerned with improving finger prostheses. With such an encouraging foundation colleagues in rheumatology may begin to be persuaded that arthroplasty can work. Patients will be convinced too. While the *in vivo* test will always be the truest test, *in vitro* testing has a critical part to play to ensure that the implants which reach the patients are the best available.

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