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**Become a ‘Black Box Thinker’**

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 Becoming a reflective thinker is part of the healthcare professional’s role, but the main asset behind this idea is that reflection improves when working within a team. The idea of failure or making errors, especially within healthcare has been misinterpreted as a weakness or worse still feared because grounds for discipline existed. I say existed as this element has been reflected upon in some, but not all areas of our healthcare industry. If it is a problem from the past that would be reassuring but sadly change takes many years and an altered mind-set.

 Reporting of incidents that arise is therefore not a new concept and the process continues to mature within healthcare, although now better integrated into the surgical environment. Reflective Podiatric Practice strikes at the heart of my regular articles. However, for the most part, the pathway for podiatry is gentle and might even appear infallible compared to medicine.  My gratitude goes to Trevor Prior and Suzy Speirs who recommended Matthew Syed’s book to me. As I started writing I stumbled on the disastrous Moje press fit implant which I made into a clinician portal article in February. As one of my newsfeed readers this article contains a little more substance and of course the references that I left off.

# **Introduction**

 *‘Only by redefining failure will we unleash progress, creativity and resilience,’* says journalist and successful former table tennis player Matthew Syed who wrote his book on Black Box Thinking in 2015.

 The opening of Matthew’s book is powerful and hammers home the value placed on teams working with respectful equality, unafraid to offer an opinion, [Syed](https://en.wikipedia.org/wiki/Matthew_Syed).

The premise behind the title is simple and the examples used have been based on quality interviews, steeped in stories of aircraft accidents as well as health care mishaps. Syed does not confine himself to these subjects alone.  Do the links with aircraft incidents have a value to podiatry and her patients?

# **Creating formal reflection**

 Journals deal in factual and well-structured frameworks. However, the human element may not be apparent. There is no room for emotion, pathos and hyperbole. Our scientific narrative is crafted with brevity in mind and every word must be evidenced or referenced. This leaves out down to earth descriptions so that any experience we might gain from an error is not obvious or that awareness of error might be delayed.

 Clinicians often find formal or academic articles less appealing. This is not because they cannot read complex constructs, but because busy lives mean any commitment to reading is more time-consuming. The corollary to this is emphasised by the true power of formal publications, exemplified by the case of the Moje press fit foot great toe implant that was initially heralded as a great breakthrough. So with this is mind let me start with Syed’s book and aviation.

# **Aviation and health – the connect**

 The Black Box Thinker concept comes from incident data within aviation. Aircraft have a so-called Black Box, which happens to be orange, and even when disasters are fatal, events are recorded until the aircraft ceases to be a conveyance for travelling. Learning from the data stored in this so-called black box continues to be valuable after the event. However, the real value of the data can only come from sharing information openly without attributing blame. Beyond aviation, Syed points out, *it is not about creating a literal black box but a willingness to investigate the lessons and exploit their value*.

 Where ‘accidental’ meets ‘criminal intent’ the direction inevitably changes, but for most accidents and incidents in hospitals, these arise more from a reluctance to change historical or entrenched attitudes. And so the term **cognitive dissonance** emerges from the bastions of reluctance to admit fault.

 Sometimes the act of trying to make a decision under pressure is regarded as an error of judgement. One case has been immortalised by the film industry, a film called ‘Sully’, in which the captain is played by Tom Hanks. When (the true story of) Captain Sullenberger ditched his plane in the Hudson River saving the lives of everyone his tale was not over.

 The film concentrates on the aftermath and tells the harrowing story of how he faced criticism for making a decision that did not agree with his aviation board’s judgement based on simulated replay. The simulation showed he should have made corrections to the flight and brought the plane back saving both the plane as well as the passengers following an encounter with a flight of birds impacting his engines. The simulation (according to the film) excluded the human element which the aviation board failed to factor in.

 Time is a critical element often not available under pressure. The critical element focused on the time required to make a decision that under pressure affected the outcome. This is a ‘human’ aspect not accounted for by the simulation. The omission in formal publications often fail to look at this element and so this necessitates thinking outside the metaphorical box.

 Captain Sullenberger used real-time reflection working with his cockpit crew demonstrating how training, experience and teamwork played an important part in decision making. When we, or in the case of Syed, applied this thinking to medicine, we can see how similarities exist.

## **The case of Emily Bromiley**

 Healthcare is no different from the Sully incident, especially when minutes, if not seconds matter. Failing to achieve an adequate airway arose when a young mother presented for routine surgery under general anaesthetic. Irreversible brain damage occurred.

 Fixated by time pressure where the lead doctors focused on a limited management protocol, they failed to reverse events.  Seconds ticked away until there were no seconds left to secure cerebral re-oxygenation. Emily died two days later when vital opportunities at the index event were passed after an attending nurse suggested re-establishing her airway using a tracheostomy kit. The nurse failed to press her suggestion home as she felt that it was not her place to argue with those of higher status. Death followed leaving two young children and a husband were left behind.

 As an educationalist, I warmed to Syed’s succinct observation that students no longer study failed scientific theories but look at successful outcomes as part of their learning process. Few (podiatry) colleagues talk about failure and those that do often fail to embrace the positive side. The journey to reach success is predicated by the values of failure. Science is littered with examples and tales from Galen of Pergamon to Galileo Galilei and James Dyson to David Beckham, all beautifully told by Syed and are all valid examples reflection on mistakes. If we review our failures repeatedly we can be stronger and eventually get it right. Perhaps this should justify the reason that history should remain on any educational curriculum.

## **Hospital accidents**

 Reflection comes from identifying success and applying the principles to one’s own field. This happened to Dr Gary Kaplan who used the motor industry as an example of learning transfer. He observed that in a Japanese production plant any problem arising on the shop floor of a car factory could be interrupted without recourse to the so-called hierarchical framework. The lowest person in the chain could make a decision and not be considered penalised.

### **Learning from failure**

 Kaplan saw the method used to make decisions on the shop floor of the Japanese factory as a transferable process in creating the concept of **Patient Safety Alerts**. The reduction in accidents and deaths in the Virginia Mason hospital was recorded at a staggering 74% improvement. The introduction of the WHO checks emerged both from black box thinking and from safety alerts, the latter came from the motor car industry. Clinicians should constantly reflect on their processes, even if they bear no relationship to the prime industry they work in. In the UK this is turned into the well-known concept of **health & safety** protocols.

Innovation comes from the success of learning about failure. Syed quote’s Eleanor Roosevelt’s, ‘*Learn from the mistakes of others. You can’t live long enough to make them yourself.*‘ Until you embrace or if you prefer, recognise your own errors, it is unlikely that you will change. While the case history I am describing next is ‘surgical’ it as an example of a process that could equally fit in with any new device or product that might fail. While it is not a ***Thalidomide*** moment, it shares many of the hallmarks.

### **The podiatrist’s clinical case history**

# **The Moje Implant**

 In 1994 a new toe implant was developed by German orthopaedic surgeon, Dieter Werner and ceramic engineer Hans Jürgen Moje. After the first generation implant failed the original screw fixation element was replaced with a press-fit design. Many foot surgeons, as well as hand surgeons, started to use the new properties of ceramic material that was intended to replace the metal and silicone alternatives. The relevance to the surgical community would ideally improve patient recovery as well as deliver long lasting relief from first toe pain. The material was considered to be strong and despite the development of a second generation implant and early warnings, the prosthetic shiny white porcelain-like material was promoted.

 Brewster et al (2010) reviewed his earlier comments based from 2001 and 2006 on clinical cases. In 2010 he concluded

*‘Based on these [*32 joint replacements*] results, we concluded that first MTPJ total joint replacement with the Moje device remains promising, but still has room for improvement before the results match those obtained with larger joint (knee, hip) arthroplasty.’*

 This was a dispassionate piece of reporting that taken in isolation meant little. The clinical numbers were low and revision of 2 implants occurred between 41-63 months. Taken as an acceptable feature of any foot surgery, this might not appear bad. I put thirteen second-generation devices in between 1999-2002 and took 4 out. Some colleagues used less, some more. It took one poor case to make me stop. Fortunately, one colleague drew his concerns to the podiatric surgical community at a conference. Being small in number we managed this in-house. My last revision surgery was 10 years after my first. One patient, quite rightly, was compensated. However, the two surgical foot professions (orthopaedic and podiatric) were not only slow to respond but failed to produce an alert in 2001. These alerts would be the type of safety alerts that emanated from Kaplan’s work but would be issued from within healthcare and from the National Institute for Health Care Excellence (NICE). They were not sign-posted.  We saw patients with faulty breast implants recalled, but the foot and any scrutiny for the Moje was sadly omitted. *Why was there a delay?* Well, it is reasonable to assume sufficient reports of success clouded those cases which were unsatisfactory, success, in other words, came before failure. Additionally, there is no threshold set before an alert is published. This might be based on smaller complainant numbers or what might appear of great value to the media.

Success came before recognition of failure

 In 2004 Malviya et al extolled the joint’s virtue, not because the authors intended to deceive, but the process of longitudinal study could not be invoked so early on. Success, in this case, came before recognition of failure. This is the conclusion reproduced from Malviya’s paper:

*‘…The implant has been tolerated well by all the patients. It seems to be an improvement over the previous design and is a good and relatively simple procedure with gratifying results. While the Moje Pressfit Ceramic implant may not be a final answer, our review does show that it is a reasonable and acceptable option when replacement of the first metatarsophalangeal joint is being considered. A long-term follow-up with a larger series of patients is obviously desirable before arriving at a final conclusion.’*

 The implant was not a simple procedure but it provided an impression of ease because of the press fit design. Incorrect alignment would go on to have irredeemable results.

### **Early warnings ignored**

 Nearly eight years on and a hint of concern appeared in published form. We must bear in mind that the Pharmacy industry has a reporting mechanism at the back of every BNF.

*‘There is an unacceptably high incidence of failure of the press-fit Moje implant and we do not recommend its use. Patients who already have this implant in situ should have regular radiographic surveillance.’ Nixon (2008)*

*‘This implant offers less reliable outcomes than the ‘gold standard’ arthrodesis and one would advise caution regarding its use for osteoarthritis of the first MTPJ.’ Barwick et al (2008)*

### **Findings start to emerge**

*‘In spite of the good clinical outcome at the mid-term stage with 91% implant survival, given the widespread loosening and subsidence encountered in our study, the long-term outcome following this procedure is uncertain.’* McGraw et al (2010).

Was Brewster playing his own concerns down as these papers were published in the same year?

‘*Although previous studies have suggested favorable initial outcomes with the MOJE prosthesis, all have focused only on the early results. In our series, the reoperation rate of 26% at up to 8 years is worryingly high, especially given that 16 (52%) showed loosening. Although there appears to be a cohort of patients who have satisfactory outcomes with the MOJE, we would suggest that these results do not support the continued use of this implant.’* Dawson-Bowling (2012)

Another reflective article from Mathias Nagy reported –

*‘The results of second-generation ceramic first MP joint replacement in our series demonstrated poor clinical and radiological results with a high revision rate.’* M.T. Nagy et al (2014), and went on to say,

*‘The results in our series demonstrated poor clinical and radiological results with a high revision rate. The replacement failed to preserve the function of the joint and the range of movement was limited in most cases. … we do not recommend the routine use of this prosthesis and all patients who have this type of prosthesis need regular follow-up consultations at least yearly with weight-bearing radiographs to assess the position of the implant.’*

 There were problems with loosening and less well-reported collapse and cracking, something the representatives assured would not occur. One case could not be repositioned in my list so the toe sat ‘proud’ in a less than desirable position. Three surgeries were required, ending with fusion. It is no wonder why arthrodesis has seen an emergence in podiatric surgery. Revision is bad enough but the speed of recognising the problems from publications started to illustrate the long term effects of this ‘press fit implant’. Nagy’s experience was worse than my own highlighting a caseload reflecting 24 patients. His radiographic pictures make alarming reading.

 Gupta et al (2017) reported, *‘There is a high rate of complications with the Toefit-Plus™ implant resulting in revision surgery. Patients should have the risks associated with arthroplasty clearly explained, including the risk of revision, and the option of arthrodesis should be discussed when planning surgery. Further trials and redesign of implants may help to improve results. The authors would not recommend the Toefit-Plus™ implant due to poor results seen in one third of patients.’*

**My own reflection**

 Reflecting on a 40-year career this was my biggest black box event which made me feel bad for the patients affected. It did not matter to me that I was exonerated for my actions. After all, I had travelled to Germany to learn from Dr Werner together with other podiatric surgeons before I started to use the Moje Press Fit, the screw system had been withdrawn at that time.

 In 2001 I saw the effects of the breast augmentation implant suffer from a similar problem where industrial silicone was used instead of medical grade fillers in France. Later the effect reached the UK.  The real take-home feature of this article is that in medical health care we are given products to use that cannot hope to be tested properly until used in humans. Who in fact is the guinea pig? It is both patient and clinician. This is not the only example but it is one that has a good trail of post-development feedback. First, the publications looked good but it took 8 years before anyone took any notice and even now NICE has no red flag posted and their great toe implant advice dates to November 2005.

 It has been axiomatic that clinical incident reporting has in some cases has been adopted for entirely the wrong reasons. Personal grievances can see the misuse of the system. This then leads to the gravity of one event being diluted by a multitude of minor events, many based around lack of resources. The healthcare system learns slowly, often not joined up, while ‘Health & Safety’ becomes diluted by misrepresentation and sadly peppered by shotgun politics.

 As Syed points out from his many breathtaking interviews, Tony Blair and David Cameron declined to accept that they were wrong about going to war in Iraq, or failing to plan for a vote to leave Europe in the event of the country voting ‘out’. Why? To do so would be an admission of guilt. This provides a good example of cognitive dissonance, which exists in healthcare.

 Leadership is not about knowing everything and acting in immovable ways. Forgiveness and acceptance are better when we admit we were or are wrong and can learn from the event. It may not make up for the mistake but denial punishes both the victim and the administrator.

**Elaine Bromiley should have the final word**

 And finally, the family left without a mother following brain death.

Husband Martin Bromiley, a pilot, responded differently to the premature death of his wife Elaine who died in 2005. He worked hard to share the incident based on the evidence he had finally uncovered. This was reluctantly admitted and many anaesthetists around the world thanked him for recognising that the real problem did not lie with clinician incompetence or negligence but factors that overtook human nature.

 Had they listened to the nurse, who herself felt she could not question her consultants, then Elaine would be alive today. The strength within Bromiley comes from taking responsibility for an event that left his family devastated. By turning it into a vehicle for learning he saved many other lives.

 Even now I wonder whether the Hillsborough disaster in 1989 has achieved all it needed to, but then I wasn’t a victim. I only know that society wants scalps even if those scalps might be unwarranted given the bigger picture. I do know that as a former consultant myself I wish I could have embraced black box thinking earlier in my career, but then reflection is what it is all about.

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