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# Innovation or regulation – differing needs in different areas

The history of orthopaedic surgery is one of innovators – a star-studded cast stretching from Thomas with his splint through to Charnley with his hip and beyond. Like all histories, the history of orthopaedics is written by the victors. Think of the Judet family, and the acetabular views and decortication technique come to mind, not the poor-outcome acrylic hips. However the truth is that for every Charnley Low Friction Arthroplasty, there were many more 'Delbet Rubber Femurs', 'Hey-Groves Ivory Hips' and 'Ring Metal on Metal' hips. Innovation in the time of our forefathers was embraced and the truth is that it was acceptable to experiment on patients.

This is of course no longer true. Established technologies such as hip replacement are now 'designed' with iterative changes hoping for ever improved results. It is easy to see why with every passing year and improving results 'tinkering' is discouraged. I would argue that for the majority of hip replacement candidates the problem is solved. A well-performed modern hip replacement will last longer than most patients. This success, combined with the increase in regulation, surgeon level results and benchmarking has moved orthopaedic technologies from one of 'shift' where big changes in treatments, prosthesis and techniques – with an almost continual 'reinvention' with each cycle – to one of drift where carefully calculated changes are introduced one a time.

A good thing? Certainly a less risky option and one that should be embraced in established technologies.

The difficulty is this approach stifles change.

In this edition of *360*, Fred Robinson ably describes the current 'state of the art' in ankle replacements. A far from proven or established technology, and one in which it would be reasonable to say some further work is needed. Small design-based iterative improvements are (by necessity) the changes likely to occur over the foreseeable future. Are we as a profession stifling innovation and thereby compromising individual patient care? It was not so long ago that the 'reverse' shoulder was designed an innovation one can't help but wonder if it would be possible to introduce into today's climate.

The problems with designing change don't just extend to arthroplasty and implant design. As regulation surrounding other novel and innovative treatments emerges, I wonder how easy it will be to have wholesale about-turns in standards of care and improvements in knowledge. A recent example where things have changed markedly for the better is trauma resuscitation fluid management; a topic easily traced through articles in the *BJJ* over the past few years.

It stands to reason that resuscitation is a 'good thing'. Advanced Trauma Life Support teaches us that 'filling' the patient improves outcomes. For many years (as can be seen from the selection of articles published in *BJJ*) we have refined the process of 'filling'. Early articles focussed initially on simple stabilisation with little regard for fluid management,[1] as crystalloid and colloid became commonplace we refined our resuscitation strategies and sought to explain the beneficial effects.[2] Then something happened in the early 2010s; *BJJ* started reporting use of major haemorrhage protocols in the armed forces.[3] We now know that fluid resuscitation (rather than blood) is associated with poorer outcomes in trauma[4,5] and blood resuscitation has become the widely-accepted practice. Three decades of slow 'drift' to optimise practice and without the 'shift' enforced by combat injuries, we would never have reached today's understanding of trauma resuscitation. There is a risk that over-regulation will stifle innovation, even in treatments we feel are 'established'.

Carefully designed changes to established treatments are a key to refining those treatments and clearly should be regulated and evaluated to make sure they aren't just gimmicks. Introduction of novel technologies carries with it considerable risk of harm, be that a new medicine, technique or implant. This is where there stands to be the biggest gains and also the biggest risks for patients and innovators. The regulatory system needs to be fit to monitor and ensure safety without compromising innovation. In the post ASR hip days, this is becoming increasingly difficult to do.

## REFERENCES

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