Editorial

The innovation trap

Without innovation, we would still be performing resection arthroplasties for end-stage osteoarthritis instead of well-functioning joint replacements. But the road towards successful joint replacement has been paved with failures, and innovation has sometimes resulted in disasters.

Recommendations on how to introduce new implants have been ignored much too often (Bauer 1992, Malchau et al. 2011, Kärrholm 2012). The introduction of novel concepts must be accompanied by a sound evaluation of safety and efficacy—safety in the sense that a novel device or technique does not present any danger to the patient, and efficacy in the sense that an innovation must actually result in a clinically relevant improvement compared to the previous state of the art. And it is here that the orthopedic community tends to fail: exhilarated by tantalizing new toys, we want to go home and try them out for ourselves. We are sometimes further motivated by the wish to accommodate patient demands that have sometimes been raised by clever merchandising, and we end up broadly introducing new technologies or devices before proper evaluation.

This issue of *Acta Orthopaedica* contains 3 sad case series that describe failed arthroplasty devices. The common denominators are that well-established implants with proven efficacy and safety were modified in order to keep the innovation pipeline running; they were introduced onto the market in large numbers without following the course of stepwise introduction, and they all failed. Morlock et al. (2016) describe how a well-known uncemented titanium stem was fitted with a titanium sleeve (i.e. adapter) in order to accommodate a large metal head, with the effect that tapers broke. The patients reported by Reito et al. (2016) had all received cemented stems of a world-reknowned brand combined with large, high-offset heads, with another series of broken tapers as the result. And finally, Fokter et al. (2016) describe 6 more fractured modular femoral necks, some of them in an uncemented stem that is widely used in North America.

There is another common denominator to the 3 case series: all modifications described above were performed in order to maximize head size and/or offset—with the purpose of reducing the risk of dislocation or in order to restore anatomical lever arms. But it is certainly remarkable that the failures described are not entirely novel or unique. Taper corrosion after the use of large-diameter heads together with a titanium sleeve—as encountered in the patients described by Morlock et al.—has also been described in titanium stems of other brands (Langton et al. 2012). The underlying mechanism is severe crevice corrosion at the interface between titanium tapers and sleeves (Witt et al. 2014). Modular neck fractures occurring in the hip reconstruction system described by Fokter et al. have been repeatedly reported internationally from 2010 onwards (Atwood et al. 2010, Wilson et al. 2010, Wright et al. 2010, Skendzel et al. 2011), obviously without causing either the manufacturers or orthopedic surgeons to reconsider the concept. Finally, large heads that caused stainless steel taper fractures as reported by Reito et al. also appear to have the potential to increase strains on a different type of titanium taper design. This strain resulted in elevated levels of metal ions in the serum of patients who had received 36-mm heads (Craig et al. 2014), which was highly indicative of taper corrosion.

The history of joint replacement is a success story, but it is also full of small modifications with unfortunate consequences, and such stories are by no means unique to the manufacturers behind the failed implants described in the 3 case series presented in this issue, as many other examples show (Rokkum et al. 1995, Furnes et al. 1997, Espehaug et al. 2009, Dangles and Altstetter 2010, Davies et al. 2013, McGrory et al. 2015). An early warning about undersized tapers and additional junctions was issued as early as 1991: "[…] unnecessary junctions should be avoided in order to minimize corrosion. This is a well-known principle in marine engineering […]" (Mathiesen et al. 1991). Even after further cautionary advice (Panagiotidou et al. 2013), taper dimensions have been shrunk by most manufacturers regarding both length and width, and additional modularity in the form of sleeves has been introduced to accommodate large heads made of metal or ceramics.

Manufacturers and regulatory bodies have a legal responsibility to ensure that only safe devices are approved for clinical use. However, as orthopedic surgeons we must ask ourselves whether the added potential advantage of a novel concept is worth taking the associated additional risk for, and we must make sure that only sound innovations make it into patients' bodies. Although the level-of-evidence pyramid has come to regard anecdotal case reports as almost worthless, the odd case series on failures can be important when it comes to alerting the orthopedic community to innovations that are of questionable value, such as the historic Boneloc cement (Suominen 1995). And at *Acta Orthopaedica*, we will continue to publish all kinds of scientific evidence that empower us to make informed decisions, for the benefit of our patients.

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