Surgeons debate approaches for the safe, stepwise introduction of TJR implants

European orthopaedic surgeons have recently revisited the pros and cons of a gradual and controlled introduction of orthopaedic devices to the market in the wake of the adverse symptoms some patients have had related to metal-on-metal hip joint implants. They wonder how the situation — and the recall of these prostheses — could have been avoided. As a result, the worldwide orthopaedic community is faced with years of adhering to specific follow-up recommendations, such as blood tests and imaging, for their patients with painful metal-on-metal hip implants.

It has been a decade of failed innovation, according to **Henrik Malchau, MD, PhD,** whose 1995 PhD thesis addressed the importance of introducing hip implant technology in a stepwise fashion. When metal-on-metal (MoM) hip replacement implants first gained popularity, orthopaedic surgeons and implant companies did not foresee or have sufficient data to show the devices would eventually produce and release tiny metal particles into the surrounding joint space, and cause irritation, pain and damage to the bone and tissue surrounding the implant and to the joint itself.


Henrik Malchau

Metal-on-metal articulations were shown in preclinical trials to be a safe concept, he said, but in reality they simply did not work. If a stepwise process of implant introduction had been in place during the time these MoM implants were being designed, Malchau contends the damage that MoM technology has done during the past 10 years would have been minimized.

"But if the stepwise principle, or phased innovation, had been used, where you have a restricted release, it would have been much better," Malchau told Orthopaedics Today Europe. "If you had

1,000 patients, for example, and then released the implants to 1,000 patients in the countries who have a well-functioning registry, monitored them for 3 years, then I guess we could have foreseen the problems that have shown up after 7 [years] to 10 years."

Limiting entrance to the market

By limiting the implants to just 1,000 patients at first, and monitoring the patients and data from the implants, this widespread problem with MoM implants could have been curtailed after a few years of research, Malchau said.

"This should be the model for introducing new orthopaedic joint implants to the market," he said.

By limiting an initial release to just 1,000 patients and monitoring the results, widespread implant failures would not occur, according to Malchau.

> **"We need early on to collect and monitor online the safety data for that implant, to make sure its performance is at least as good as existing implants."**
>
> **— HENRIK MALCHAU, MD, PHD**

"The take-home message for surgeons in the industry, and of course, ultimately for the patients would be that with each new implant release, we need early on to collect and monitor online the safety data for that implant, to make sure its performance is at least as good as existing implants. The tools we can use here are clinical tools, such as RSA, patient-reported outcome scores combined with registry data analysis," he said.

"I have given this message several times in the past 15 [years] to 20 years. The metal-on-metal issues and the recalls are forcing us to improve the methods by which new technology is introduced into

the marketplace. Ultimately the goal is, of course, to make it safer for our patients," he said.


Søren Overgaard

Worldwide problem

Søren Overgaard, MD, DmSc, told Orthopaedics Today Europe he supports test trials and limited releases of total joint replacement (TJR) implants that are similar to how new drugs are approved by the FDA and other regulatory bodies. If a stepwise introduction had been originally used for the MoM implants, then the problematic devices would not have been implanted into more than 1 million patients worldwide, he said.

Few small, randomized trials were used for the MoM implants, he said, which led to the overuse of the products before surgeons or implant companies knew of both their short-term and long-term postoperative difficulties.

New implants would take longer to end up on the market, according to Overgaard, but in the end the products would be safer for patients and this would result in more units sold by the companies that design and manufacture safe implants.

"The companies actually want to market new implants, because they want to have a market share, but they also want to have safe implants. So, safety is a very big issue today, which was not been focused on much in the past, but will be in the future," he said. "Of course, the companies will have to do clinical studies, but this would save some time. It might be 4 [years] or 5 years or so, but in the long run I guess that they will get that money back through increased sales with a safer product."

More data means safer products

Surgeons should also demand more clinical data for new implants, which would ensure safer devices make it to market, Over-

gaard said, noting more often than not the end-users, the surgeons, have insufficient information and data to evaluate or predict how an implant will perform in a patient. They should call for more data on a particular prosthesis before implanting it during surgery, he said.

"The surgeons want to have saving plans, they do not want to be the test patients for the companies, which they have been for the MoM cases around the world. Because the surgeons do not have the knowledge to evaluate whether this is a good or bad implant, the average surgeon is not educated to evaluate that," he said.

Surgeons should ask for a clinical evaluation and register results before they start using a new implant, according Overgaard.

"That is a very important point. If they can't get any clinical data and register results from non-designer surgeons then they have to wait for clinical data," he said.

A detriment to innovation?

Not all surgeons favor the virtues of a stepwise introduction for TJR products. **Johan Bellemans, MD, PhD,** of Belgium, said phased innovation or stepwise introduction of orthopaedic devices will extend the years it takes for a prosthesis to go on the market, which will stem innovation and creation among surgeons, as well as those who design new and better products. However, a stepwise introduction for new products is not a "bad idea," according to Bellemans. If it delays by years the availability of products that may help patients, it is not worth implementing and putting into practice, he said.


Johan Bellemans

"There is a growing trend in Europe where decision makers, and also surgeons, tend to believe this is the right way to go. It is for sure a safe way to go, but it is counterproductive to innovation. It means almost a decade would pass before a new design is made available to the public," Bellemans told Orthopaedics Today Europe.

If a stepwise introduction had been in effect in Europe since the conception of hip and knee implants, for example, surgeons would not have today many of the successful hip and knee implants used throughout the continent. Furthermore, the introduction of many of these implants would have been completely halted if they had to go through a stepwise introduction process, he said.

"For example, if you look 20 years ago to the introduction of modern knee prostheses, these introductions would never be possible with the stepwise introduction system being suggested today," Bellemans said. "These introductions have been necessitated with

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relatively high failures in the beginning. They picked up fast, led to subtle refinements from their catastrophic beginning to being successful — and still successful for what we use today. Think about the initial experiences of pioneers in hip and knee arthroplasty."

Bellemans proposed a revised stepwise introduction program that requires greater clinical data collection and improved registries worldwide. He also said it is the responsibility of the surgeon to speak up and report implant failures and defects when they notice them during procedures and follow-up examinations.

"In the U.K., people are speaking now about new products having to pass a track record of 10 years before they go to the market. That is counterproductive to putting innovative products on the market," he said. "Today there is also no obligation whatsoever for surgeons to report something whenever they are faced with a failure related to an implant. As a matter of fact, most failures are only picked up on by independent surgeon groups that see adverse events, rather

than registries, which are slow and relatively ineffective in detecting underperformance of implants."

Balance innovation and safety

Rob Nelissen, MD, PhD, said a stepwise introduction would actually increase innovation among the designers of orthopaedic implants. If an implant does not receive good feedback 2 years in and has poor clinical results, he said, the designers of the implants would have to show "real innovation" to improve the product and thus not only improve quality but also safety for patients.


Rob Nelissen

"When you have a stepwise introduction, you will expose a small patient group to a potentially innovative product, but if early problems occur with the implant, problems are not only exposed to this small (informed consent) patient group, but these results will also induce real innovation among the designers," Nelissen told Orthopaedics Today Europe. "Innovation nowadays is more market-based and not innovation-based when it comes to these implants."

Nelissen said a stepwise introduction of a TJR implant in three phases to determine the safety, performance and implant-bone stability (ie., RSA, 3-D implant migration) would result in "improvement in innovation and prevent disaster to patients."

Ultimately the responsibility for the safety of patients undergoing TJR procedures belongs in the hands and "evidence-based" minds of the surgeons. If surgeons do not report an implant or product is failing at a certain level, then the faulty products are still used in more patients, when they should not. Thus, national implant registries should be mandatory for patient safety, he said.

"The doctors are responsible. They need to have some knowledge of the research and they should not believe all the industry informa-

tion coming out about new implants. There has to be some open discussion and transparency," Nelissen said. "In the end, the surgeon is responsible. You cannot only blame the government or the industry. It is us, in conjunction with them, but we are the lead for our patients." – *by Robert Linnehan* OtE

Reference:
Bellemans J. Presentation #IL16-9002. Presented at: European Society of Sports Traumatology, Knee Surgery and Arthroscopy Congress; May 14-17, 2014; Amsterdam.

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Disclosures: Bellemans receives financial compensation and/or intellectual property rights in the last calendar year from Biomet, Stryker, Corin, Smith & Nephew and Zimmer; he has received institutional support in the last year from Sanofi Aventis, Smith & Nephew, DePuy Johnson & Johnson, Zimmer, Pfizer, Medtronic, Biomet and Technische Orthopedie Belgie. Malchau receives royalties from MAKO; he is an unpaid consultant to Biomet; he has stock or stock options in RSA Biomedical; he receives research support from Biomet, DePuy, Zimmer and MAKO; he is a board member for RSA Biomedical. Nelissen is on a fixed salary from Leiden University Medical Center (LUMC); he receives institution grants from Dutch Arthritis Association, STW, ZonMW, Anna-NOREF, Zimmer, Biomet, Stryker, Smith & Nephew, Implant Cast and Springer; RSACore LUMC is within the Department of Orthopaedics; he is the vice president of the Dutch Orthopaedic Association and the Board Dutch Arthroplasty Register; he is the president of ERASS (European rheumatism & arthritis surgical society) and the Anna-NOREF Foundation. Overgaard receives grants from Biomet DK and Biomet, DePuy, Protesekompaniet and Zimmer; he is a principal investigator for Eli Lilly.

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Is it possible for the stepwise introduction of orthopaedic implants to both improve patient safety and foster innovation in implant development?

POINT

Patient safety of concern

Stepwise introduction of orthopaedic implants is about protecting patients against potentially inferior implants. This is not an imaginary risk. We have had several disasters in the past, such as Boneloc bone cement, the Capital hip prosthesis, the Inter-Op hip acetabular shell, and others, but also more recently with metal-on-metal resurfacing and large head hip prostheses.

Edward R. Valstar

The negative impact of these disasters is immense. Patients suffer. Orthopaedic surgeons and health insurers are losing their trust and confidence in innovation in orthopaedic implants. Costs are running into billions of euros, and some implant manufacturers have not survived the financial impact these disasters have caused.

Not only the orthopaedic community, but also implant manufacturers, will benefit from stepwise introduction of orthopaedic implants. It will be the only way to regain trust, and the confidence that innovation will truly benefit patients.

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In the near future, innovation will not be possible without scientific proof of the effectiveness of these new implants. Stepwise introduction will deliver that scientific proof. And, in case the results of a new implant would be negative, just a small number of patients will have been exposed. This will reduce patient suffering, but also save money for the manufacturers, money that can be invested in beneficial innovations.

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Disclosure: *Valstar has no relevant financial disclosures.*

COUNTER

Innovation, safety can co-exist

I will respond to this question with another question: Is it possible to introduce orthopaedic implants without considering the complete safety of the patient? The answer is, of course not, both from a legal and ethical standpoint. As orthopaedic surgeons, our job is to improve patient outcomes, and patient safety and security are essential aspects of any durable therapeutic measure we employ. Therefore, patient safety and implant development must have the same purpose and endpoint and this may mean that a longer, more demanding process is necessary for the introduction of new implants and materials. But this is the only way to foster innovation and accumulate the best possible clinical results. More time and investigations may be necessary for the process, but this approach can ultimately lead to better outcomes for patients, as well as true and durable innovation.

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Today, we are no longer in a pioneering era in orthopaedic surgery and a stepwise introduction is therefore mandatory because it directly affects the care and well-being of our patients. This approach is not in opposition to innovation. In fact, it can improve the safety of the treatments we offer and encourage effective, ongoing innovation. Before the availability of registry data, independent clinical trials, patient-related outcome measures, more sophisticated radiological evaluation, such as RSA, proved to be essential tools for arthroplasty surgery.


Luigi Zagra

If anything, bureaucracy by authorities, undue commercial pressure by the orthopaedic companies and superficiality by surgeons are the major factors against true innovation, not a reasonable and careful stepwise introduction of implants.

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Disclosure: *Zagra has no relevant financial disclosures.*