Metal-on-metal hip arthroplasty

Chapter X

Valorisation

Persistence can change failure into extraordinary achievement

(Marv Levy)

This paragraph describes how the knowledge acquired in the reserach for this thesis can be made available for economic and social utilization.

The litature concerning results of metal-on-metal (MoM) hip arthroplasty, both large head metal-on-metal (LHMoM) total hip arthroplasty (THA) and hip resurfacing arthroplasty (HRA), showed how expectations turn out to be different. A discrepancy between the expected advantages and the long-term patient related outcomes in clinical practice is observed. The theoretical advantages were presented as the new 'big thing' in hip arthroplasty. Money-driven strategies with patient-attraction magnets ('sportship') were only beneficial for investors and developers of HRA. Unfortunately, the sales talk and news spread faster than the acquisiton of postoperative results, the disadvantages of HRA only became clear after hundreds of thousands of patients had already been operated. The influence of industries, e.g. by direct mailing to patients to make a connection to the 'consumers', and of health care insurance companies should not be underestimated. In 2012, the NetherlandsOrthopaedicAssociation (NOV) advised against the use of any MoM hip arthroplasty [1]. Hereafter, the use of hip arthroplasties with a MoM articulation decreased. The Dutch Arthroplasty Register (LROI) data showed that MoM was used in 5.2% of THA cases in 2010, 1.51% in 2012 and 0.02% to 0.12% between2014 and 2019 [2]. Interestingly and in contrast to the advice of the NOV, health care insurances provided patients with opportunities to travel abroad for HRA procedures. The financial incentive seemed more important than protecting and informing patients.

Orthopaedic surgeons are obligated to inform patients about both conservative and operative therapies according to the Hippocratic Oath [3]. A decision for treatment is ideally based on a shared-decision process. For surgeons, it is easier to perform a hip arthroplasty than to convince and support patients to lose weight and increase their physical activity. Currently, there is too little attention for preventive medicine. Prevention of overweight, smoking and inactivity is not stimulated enough and should start as early as possible, preferably in primary school. In the current situation, opting for a surgical intervention is easier for both the patient and the surgeon. In the training of orthopaedic residents, this temptation should be addressed with more urgency. Communication skills and recognizing the right indication for surgery are equally important as surgical skills. As residents have numerous 'general tasks' and their training is divided into stages (e.g. hip, knee, spine, trauma), it can be difficult to follow a patient over time. However, it is highly important for a resident to follow a patient during the postoperative phase after indicating the patients for surgery, so that postoperative results can be used as feedback. Of course, this

also applies to conservative treatment. In addition, conducting scientific research leads to developing a critical view and, among other things, improves planning and organizational skills.

The introduction of new orthopaedic implants should be phased and evidence-based, none of which was the case in the introduction of MoM hip arthroplasty. A decent pre-market setting to detect early failure modes would have shown the increased risk of femoral neck fractures. Also, with careful thinking in combination with in-vitro testing, wear of the articulating surfaces and release of metal ions could have been predicted. New designs of HRA are developed and implanted in the context of clinical research, e.g. HRA with a cobalt-chromium femoral component and cementless acetabular cups with a cross-linked ultra-high molecular weight polyethyelene (XLPE)-acetabular liner and with a ceramic-on-ceramic (CoC) bearing [4, 5].

A phased and evidence-based introduction should not only consider subjective outcomes, such as clinically administered tools and patient-reported outcome measures (PROMs); as the present research has demonstrated, it is highly valuable to include objective measures, such as wearable activity monitors, to obtain objective data on physical activity in daily living. The new designs of HRA described above should be subject to meticulous clinical research. Physical activity should be measured objectively both pre- and postoperatively in these patients and should be compared with physical activity measurements of patients who received conventional stemmed THA. In this way, the theoretical advantages of HRA could be evaluated on objective grounds. Before new materials and techniques are investigated, there must first be a clear understanding of the problem of the existing technique that needs to be solved.

Physical activity monitoring, with the use of wearable monitors, could be used in a wide spectrum, both in clinical settings and in research. This thesis showed that PROMs hardly capture the intensity levels and behavioral differences that can be objectively measured by monitoring physical activities of daily living. PROMs are increasingly used to assess pain and physical function and to serve as indicators of outcome quality in national joint registries, but the true functional recovery after joint arthroplasty can be better determined with objective outcome assessment, such as wearable activity monitoring. There is ample evidence of the importance of physical inactivity as a major risk factor for a number of adverse health outcomes. Wearable activity monitors may be used in cardiovascular, neurodegenerative and orthopaedic patient populations. Also, the geriatric patient population might

benefit from activity monitoring as a wearable fall detection system in daily living. Often, falls and related injuries mark the onset of deterioration of health [6].

The long-term follow-up of patients after hip arthroplasty is questionable. In prostheses with known excellent long-term clinical results, especially those validated by joint registry studies, follow-up could be modified. Routine follow-up of asymptomatic patients after hip arthroplasty may be highly costly and perhaps unnecessary. Other, less intensive review methods might be more appropriate, such as objective physical activity monitoring with wearables. With the recent improvements of the capabilities of smartphones and smartwatches, these appliances could be useful in the follow-up of patients after total joint arthroplasty. Applications can support and guide patients and can deliver data and patient reported feedback to facilitate improved care, outcomes and satisfaction. Physical activity tracking is available, but it is not yet as complete as the wearable activity monitoring used in the present thesis. However, a smartphone is a more accesible platform with 93% of the Dutch population owning a smarthphone. Various patient-proof applications are already widely available. Apps were developed to inform the patients about their pre-, peri- and postoperative phase and to obtain information regarding their activites. The use of smartphone applications is highly interesting for patient monitoring at a distance and for putting the patient in control of their own rehabilitation, for instance after a hip arthroplasty. Issues may arise about data ownership, since this information may offer a source of profit both for industries and health insurances. Current laws lack specific regulation. Another option might be the use of smart hip implants, which have been available since 1966 and have been used to measure pressure, forces, strain, displacement, temperature and physical paramaters from inside the body. However, smart implants have only been used in research and have not yet become a part of daily clinical practice. With the rapid advance of technology, it seems that the widespread implementation of smart implants is near and will potentially affect clinical care and enable personalized medicine [7]. It is, however, questionable if that makes sense for smart implants in or with THA; they are probably mainly usefull in clinical research.

After MoM hip arthroplasty, patients should be routinely monitored. Those with a painful hip will find their way to the outpatient clinic. In all other cases, monitoring should focus on the general symptoms of chronically raised metal ion concentrations as described in this thesis. At this moment, it is still unclear what the effects of chronically elevated metal ion concentrations are (unexpected failures at the post-market phase). Ideally, these effects should be investigated with a validated questionnaire, followed by referral to a specialist (ophthalmologist, ENT

doctor, neurologist, cardiologist, internal physician, toxicologist), determination of blood metal ion concentrations and, if necessary, explantation or revision of the MoM hip. Orthopaedic surgeons all around the world decided to implant this type of hip arthroplasty without knowing the potential side effects. It is our responsibility, in cooperation with the implant industry, to support these patients where possible.

This thesis underscores the importance of training medical specialists in independent thinking, of doing the appropriate research before introducing new techniques and materials, and of carefully examining the clinical processes and not taking for granted what is suggested by others.

References

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