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## Adolescent idiopathic scoliosis: spinal fusion and beyond

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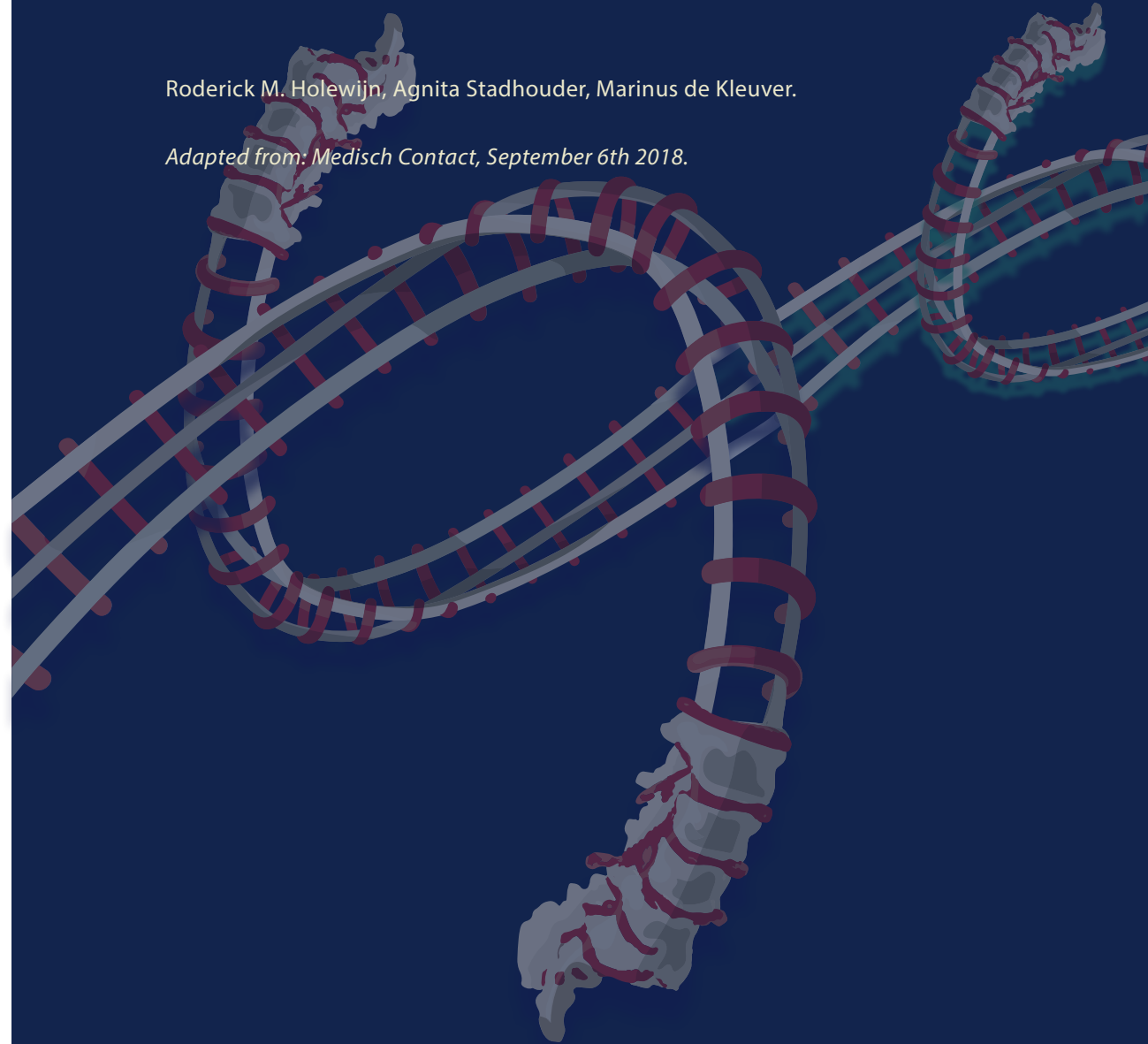
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## Chapter 7

# Introducing a new medical technique? Safety first

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*Adapted from: Medisch Contact, September 6th 2018.*



## Introduction

Over the last decades many new medical interventions have been developed to improve the quality of healthcare. However, all innovations are associated with risks. The problems concerning heart valve prostheses [1,2], leaking PIP breast implants [3], metal-on-metal hip prostheses [4,5] and, more recently, the problematic introduction of the cryoballoon catheter for the treatment of atrial fibrillation are a good illustration [6]. While the new treatment method with the cryoballoon catheter was still experimental, it had already replaced the regular treatment method of radiofrequency ablation. NRC Handelsblad concluded that patients were unknowingly participants in a medical-scientific study [6]. There were parliamentary questions to the then minister Schippers and an investigation by the Inspectorate for Healthcare and Youth (Inspectie voor de Gezondheidszorg en Jeugd). Following this, a newspaper was published with the subtitle “The Inspectorate imposes measures [...] after the non-careful introduction of a new treatment for cardiac arrhythmias” [7].

When introducing a new medical intervention, in addition to the patient-related risks, there is also a risk of reputational damage and therefore potential financial consequences for the institution. Medical innovations are needed to continue the upward trend in healthcare quality. But a fair balance between the innovation and safety must be maintained. With the use of an example from our hospital we will illustrate how a new medical intervention can be implemented in daily practice in the Dutch healthcare system.

### Available tools

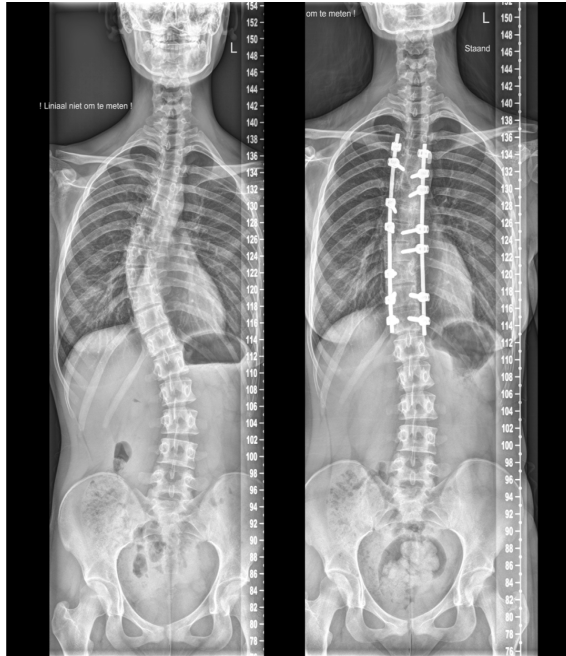
While for new medications a solid footing is available in the form of legislation and guidelines, this has only been under development for medical interventions in recent years. The Federation of Medical Specialists (Federatie Medisch Specialisten) has developed the guidelines ‘Responsibility for medical specialists in the maintenance and management of medical equipment’ (Verantwoordelijkheid medisch specialisten bij onderhoud en beheer van medische apparatuur, 2012) and ‘Responsibility for medical specialists in the purchase and commissioning of medical equipment’ (Verantwoordelijkheid medisch specialisten bij de aanschaf en ingebruikname van medische apparatuur, 2013). In 2014, the guideline ‘New Interventions in Clinical Practice’ (Nieuwe Interventies in de Klinische Praktijk, NIKP) followed [8]. The latter describes how a new intervention (NI) can be introduced, in a prudent and safe manner.

In a step-by-step plan, the NIKP guideline describes the aspects that must be evaluated prior to the introduction of an NI: the innovation class (experimental or locally new with experience elsewhere), the effectiveness, risks (patient related safety, but also risks for the organization and the impact on the budget), training of healthcare professionals and the last monitoring and evaluation of the results. An important part of the roadmap is the prospective risk analysis (PRA). During the PRA, a multidisciplinary team determines the risks of an intervention at an early stage and draws up measures to eliminate or reduce them. The guideline explicitly aims to guide the introduction process without creating unnecessary barriers.

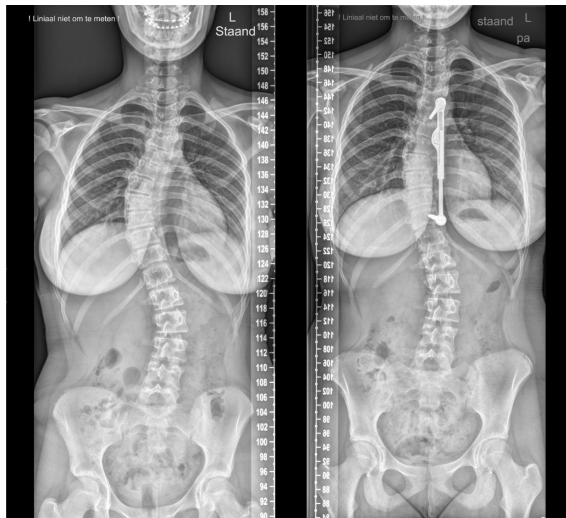
### Practical example

Adolescent idiopathic scoliosis (AIS) is a deformity of the spine. The current standard surgical treatment is based on a correction of the spinal deformity and a spinal arthrodesis, in which the spine is permanently fixed with a rigid construction of metal rods and screws (see figure 1). The operation takes several hours and leaves the patient a large scar. After the operation, patients need four to seven days in the hospital to. However, surgical techniques have lately been developed that correct the scoliosis without the need for arthrodesis. One of these techniques is an extendable rod that is connected to the spinal column with two screws (see figure 2). Postoperatively, the implant can be extended by performing physical exercises, thus correcting the scoliosis step by step. This surgical technique is regarded as less invasive and the flexibility of the spine is maintained because the screw-rod interface is polyaxial. To evaluate the potential introduction of this new implant, the guideline NIKP was followed. What follows is a brief description of this process.

Some dozen patients in Europe were already treated with this new, but CE-certified, implant. However, the technique did not belong to the standard surgical treatment of AIS and was thus considered experimental. On the basis of the possible advantages mentioned, the implant was deemed to have a potential added value compared to the conventional surgical technique. After consultation with the departments of procurement and finance, the operating rooms and the department of pediatrics, it was decided to evaluate the new intervention in a small number of patients. For the PRA several professionals were consulted alongside the orthopedic surgeons, including a trauma surgeon, a clinical physicist, a researcher, a quality employee, the supplier, the manufacturer, a procurement employee and the physiotherapists. A total of twelve risks were identified and divided into three categories: pre-operative, intra-operative and postoperative. Some examples of the identified potential risks are; the lack of certain implant sizes, incorrect indication, incorrect



**Figure 1.** Regular surgical technique based on intra-operative correction and arthrodesis (fusion) of the spine.



**Figure 2.** New technique based on an expandable rod and poly-axial screws.

placement of the implant, or poor performance of postoperative physiotherapy exercises. A risk management measure was drawn up for each risk, such as being able to measure in advance the correct implant size, intra-operative participation of an orthopedic surgeon experienced with this new implant, and guidance of the patients by physiotherapists at the hospital. Last but not least, there was a possible risk of material breakage: a worst-case scenario.

To further analyze this latter risk, the implant was tested in vitro in spines of deceased human donors and pigs [9]. The experiment showed that spines with the new implant were more flexible than with the standard surgical method (i.e. arthrodesis/fusion). However, the flexibility was still limited, and as such loading of the implant could occur in vivo. In time, this may result in a risk of material breakage. Still, the implant could withstand greater forces for longer periods than the conventional rods and screws. For this reason, it was decided to introduce more intensive radiological monitoring than after regular surgical treatment. Moreover, it was estimated that in case of material breakage, revision by conventional surgery would always be possible.

As the risks can take various forms, the control measures to minimize the risks also show great variation. Finally, based on the PRA and the biomechanical in vitro evaluation, it was decided to first evaluate the implant in a research context before using it in daily clinical practice. On the basis of a small-scale prospective cohort study, the risks and the effectiveness of the treatment will be evaluated. The research bureau and the medical ethics review committee were consulted and agreed to the study protocol. Lastly, the Association of Scoliosis Patients (Vereniging van Scoliosepatiënten) was consulted about the way subjects were to be informed and guided during treatment.

#### **First on a small-scale**

Because of the medical (patient related) and non-medical risks (e.g. logistics, financial, or reputation), adequate consultation of colleagues with knowledge and expertise from other medical and non-medical departments is a requisite. It goes without saying that it is recommended to evaluate high-risk new interventions with little experience on a small scale at first. In spite of a careful PRA, risks can always be overlooked that only come to light after the introduction of the new intervention. Thus, the clinical results should be monitored prospectively.

The NIKP guideline has not led to unnecessary time and energy wastage in the discussed example. The risks have been identified with all parties involved and a clear introduction plan has been drawn up. This meant that many risks could be limited and the introduction of the new intervention could be managed in the right direction. Based on the results of the clinical study, we will know whether the new treatment method is an effective and safe option for this patient group and whether it actually offers the presumed benefits.

## Future changes

The current legislations for medical devices are severely out-dated and do not offer any obligations regarding effectiveness or safety. Radar's television broadcast, in which supervisors judged positively about the CE-certification of a mandarin string bag for use as a pelvic floor mat, is still fresh in the memory and exemplifies the limitation of the current system based on just CE-certification. The European Union has therefore drawn up new regulations (EU Regulation 2017/745) to ensure that healthcare professionals can rely on the quality of a new medical technology [10]. This regulation will come into effect in May 2020 for medical devices (such as breast implants or hip prostheses) and in-vitro diagnostics (such as blood glucose meters or pregnancy tests) in May 2022. Important improvements are:

- the manufacturer must perform a clinical evaluation for devices with a potentially high risk for patients;
- checks are carried out on the notified bodies (an organisation designated by a EU country) who designate whether new techniques conform to the safety standards;
- there will be an EU-wide database for medical devices.

The study design for the clinical evaluation must be scientifically and ethically evaluated to guarantee the reliability of the clinical data generated. Checks on the inspection authorities should lead to a higher quality of the evaluation process of new medical devices and the removal of conflicts of interest. Both measures must prevent unsafe medical techniques from entering the market. EUDAMED, a EU-wide database, is the basis for the so-called post-market surveillance in which the performance and safety of a medical technology is maintained throughout its life. Both care providers and patients can consult this database. Apart from the fact that we, as healthcare professionals, can better rely on the quality and effectiveness of a new medical device, the developments also demand a commitment from doctors. As of 1 January 2020, it is mandatory to register all implanted implants in the National Implant Registry (Landelijk Implantaten Register, LIR). Patients and caregivers can report side effects in this registry. In case of a safety concern, individual patients can then be identified quickly.

There is increasing pressure from the professional groups, policy makers and patients to justify safety, effectiveness, and costs. The knowledge of the guideline NIKP, the upcoming legislation and the LIR can therefore not be

underestimated: every medical professional in the Dutch healthcare system will eventually come into contact with it.

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