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Implementing new surgical instruments in minimally invasive surgery

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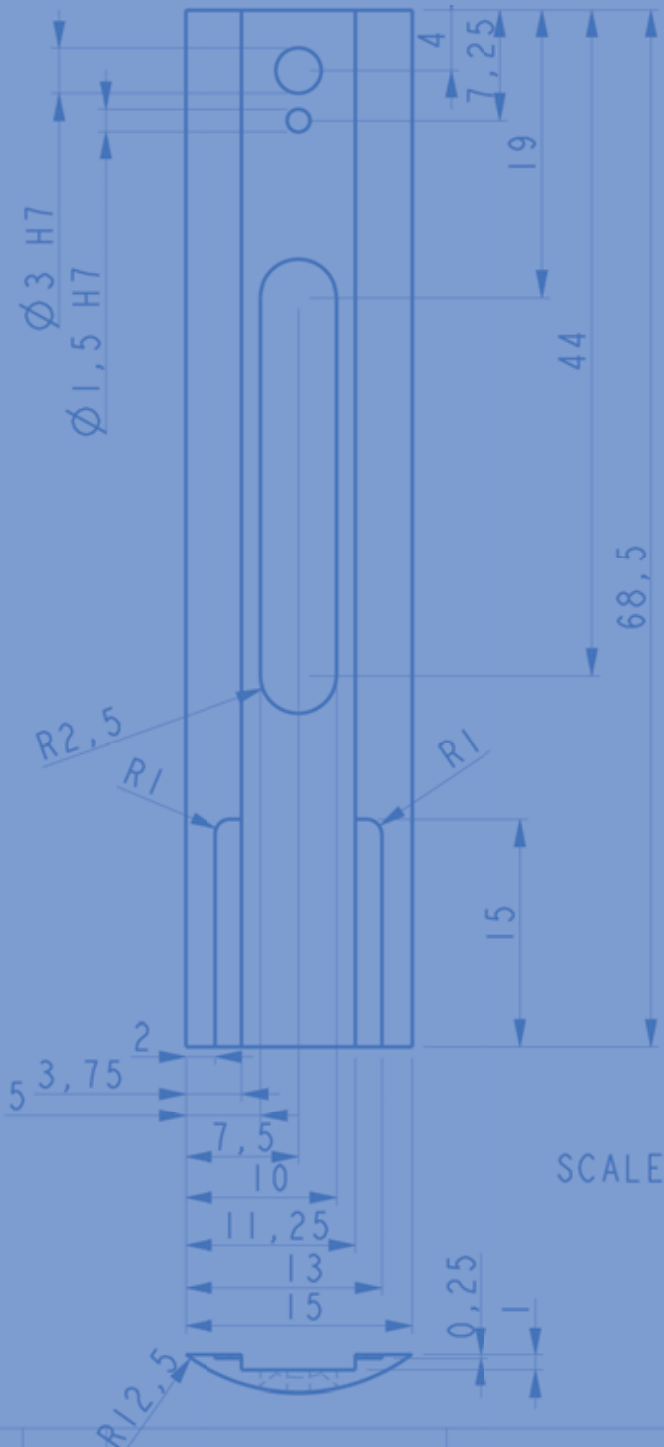
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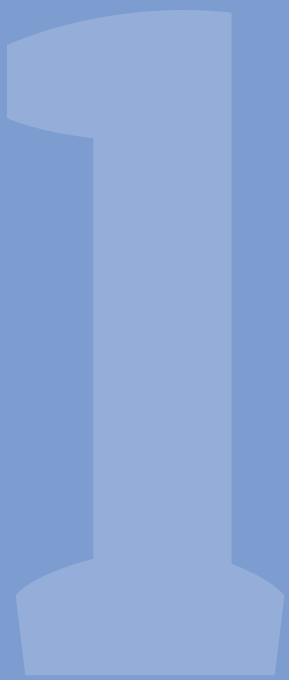
General Introduction



Introduction

Innovations regarding surgical techniques and instruments (henceforth called technology) play a major role in enhancing the efficacy and safety of surgical procedures. Technological developments in the past have enabled a minimally invasive approach to surgical procedures that were previously performed via laparotomy. For instance, the laparoscopic approach is currently the scientific standard in appendectomy, cholecystectomy and hemicolectomy. In gynecology, hysterectomy is increasingly performed via minimally invasive surgery (MIS) and studies have demonstrated that 25% up to 37% of all hysterectomies are currently performed via MIS.[1,2] The importance of the developments leading to MIS was recently acknowledged anew by confirming the advantages of MIS over laparotomy regarding surgical outcomes and patient benefits. [3]

However, since the efficacy and safety of a new technology has usually not been established on a large scale before introduction in the field, innovations may consequently go hand in hand with an impairment of patient safety. Short and long term adverse events have been described after the introduction of new surgical techniques in daily practice. An example of a short term adverse event was the rise in major complications such as major hemorrhage and ureteric injury during the early introduction of laparoscopic hysterectomy (LH).[4] However, these complications could be attributed to learning curve issues. Combined with improvements made in technologies such as electrosurgery, major complications in LH declined and this technique is now considered superior to laparotomy. [5]

And on the other end of the spectrum, adverse events caused by new technology may be only observed long after its introduction in clinical practice. In 2014, 21 years after its introduction in US market, the electromechanical (or *power*) morcellator was discredited. The power morcellator is a surgical device that allows the removal of an enlarged uterus or fibroid via laparoscopic trocars by shredding the tissue into fragments which are small enough to fit through these trocars. However, when reports were published regarding the accidental morcellation of preoperatively undiagnosed uterine sarcoma resulting in a possible upstaging of the malignancy, the U.S. Food and Drug Administration (FDA) decided to discourage the further use of this device. [6]

In this light, the *industry driven approach* to innovations (i.e. coming from medical devices manufacturing companies) and the *clinically driven approach* (based on analyses of problems encountered in daily surgical practice) should be considered. Unequivocally the introduction of the power morcellator has played a role in the successful implementation of the laparoscopic approach to hysterectomy and myomectomy. By manufacturing

more powerful devices, even very large uteri and myoma were eligible for removal via laparoscopy. Yet, an analysis with respect to clinical indications and possible risks of the device was not performed, although early warnings regarding the occurrence of malignant tissue spill were issued in scientific literature.[7-12] The vast majority of all publications regarding power morcellators discussed industry driven specifications such as morcellation speed.[13]

To minimize the chance of unforeseen adverse events, efforts have been made in the past century to regulate the introduction of new technologies. In a research setting human subjects are protected by several medical ethical legal entities, in particular by the 1947 Nuremberg Code, the 1964 Declaration of Helsinki and the 1978 Belmont Report.[14-16] In contrast, in daily surgical practice adaptations and innovations aiming to provide the best care for the individual patient are considered "standard" care. Unfortunately, the distinction between daily surgical practice and research is not always clear. The Belmont report defines daily practice as "*interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success"* and research as "*an activity designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge"*.[16] However it is also stated that "*the fact that a procedure is 'experimental', in the sense of new, untested or different, does not automatically place it in the category of research"*.[16] As a result a grey area exists between daily practice and research, meaning that surgeons may circumvent research regulations by declaring that the innovation is aimed to improve the health of the individual patient. [17,18] Laparoscopic cholecystectomy was introduced in such a fashion. In gynecology, ample experience existed with laparoscopy. In fact, the first laparoscopic appendectomy was performed by a gynecologist.[19] Since the laparoscopic approach to appendectomy was successful and appeared safe, together with the introduction of videoscopy, it was suggested that this approach to cholecystectomy must also be safe. The first laparoscopic cholecystectomy performed in The Netherlands was supervised by a gynecologist since the surgeon was unexperienced with MIS.[20] The laparoscopic route quickly became the new standard in surgery, although comparative trials were lacking. Finally, when larger case series were published it became apparent that complications were significantly higher during laparoscopy due to bile duct lesions.[18,21] Another example is robotic surgery, which quickly became an accepted alternative to routine laparoscopy and open surgery after it was initially introduced in a research setting.[17] In the U.S. alone the number of procedures performed robotically increased by more than 500%, even though convincing evidence preferring robotic surgery over laparoscopy does not exist and learning curve issues as well as patient safety have been questioned.[17]

The bodies responsible for the admittance of new medical devices are the Conformité Européenne (CE) for Europe and the Food and Drug Administration (FDA) for the United States of America. The CE-marking on a product is a declaration of a manufacturer that the device meets the essential requirements of European health, safety and environmental protection legislation.[22] However it is important to realise that the CE mark does not evaluate or guarantee the clinical safety of a device. The FDA has two objectives: providing the public reasonable assurances of safe and effective de- vices while avoiding overregulation of the industry.[23] A premarket approval process was installed for new devices in which the safety and effectiveness for the devices intended use has to be demonstrated by standard scientific methods.[23] However, the FDA has been criticized for its methods. Firstly, to avoid overregulation an alternative for the premarket approval process was installed, called the 510(k) provision (named after section 510(k) of the Food, Drug and Cosmetic Act). It states that new versions of existing (and deemed safe) devices are exempt from the premarket approval process. In the meantime, the criteria for the 510(k) provision were broadened, which has resulted in an increase of new medical devices on the market that were not extensively tested for their safety and effectiveness. For example, approval of the radiofrequency ablation of liver tumors was granted merely by proving that this technique could actually ablate liver tissue. However, no evidence existed regarding the clinical efficacy of this treatment compared to standard treatment at that time.[21] Moreover, it was shown that the majority of devices that were withdrawn from the market due to safety issues, were FDA approved based on the 510(k) provision.[23] Secondly, the FDA does not regulate the manner in which a device is used in daily clinical practice, meaning that devices may be used off-label without FDA surveillance.[17]

In the Netherlands, the shortcomings of current regulations regarding the introduction of new technology were also acknowledged. In 2014, a cooperation between *de Orde van Medisch Specialisten, het Zorginstituut Nederland,* and *het Kennisinstituut van Medisch Specialisten*, resulted in a guideline called *Leidraad Nieuwe Interventies in de Klinische Praktijk* (NIKP).[24] This guideline aims to structure the introduction of new technology in health care interventions (such as surgery) to better warrant patient safety. Interestingly, emphasis is put on the preclinical stage of the development of new technology, before it is applied in human subjects. In general, 5 stages are considered in surgical innovation, yet only the very first stage *(stage 0)* concerns in-vitro tests. [18] (table 1) In all other stages the new technology is applied in human subjects. The Dutch guideline provides methods that can be applied in this first stage when evidence regarding safety and efficacy does not yet exist.

Table 1: 5 stages of surgical innovation

Stage		Title	Setting
0		Innovation	Pre-human
1		Innovation	In human
2	a	Development	In human
	b	Early dispersion and exploration	In human
3		Assessment	In human
4		Long-term implementation and monitoring	In human

With this in mind this thesis was initiated to explore a range of possible assessment methods, including those suggested by the NIKP, that can be used in stage 0 of surgical innovation. Using LH as a starting point, two medical devices acted as a template for the assessments used in this thesis. To begin, the NIKP guideline was applied to the technical development of a new prototype for a uterine manipulator that is designed to facilitate the manipulation of the uterus and its separation from the vagina during LH. Next, the controversies regarding the use of a power morcellator were addressed. This device is currently a highlight in minimally invasive gynecological research topics. With the new design of the manipulator and the morcellator in mind, several studies were undertaken combining a clinical and technical point of view. The main objective of this thesis is to assess different methods and tools that are available in stage 0 of surgical innovations. It was hypothesized that ideally, major hazards to patient safety can be identified before new technology is introduced in daily surgical practice.

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