

# Abdominal hernias and adhesions

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## **Valorisation**



## Valorisation

With an increased age of our population an improved treatment for chronic diseases such as adhesions and incisional hernia is mandatory. Subsequently, healthcare costs rise with the increased life expectancy. Therefore, not only functionality of newly developed devices and interventions, but also related costs are nowadays important aims in medical research. Furthermore, quality of life and patient related outcome measurements are crucial to consider when new treatment options are introduced. In the current chapter, the social and economic impact of the research conducted in this thesis, is discussed.

## Relevance

Hernias can be congenital, develop spontaneously or are acquired. Congenital and spontaneously developed hernias are the so-called primary abdominal wall hernias, while acquired hernias develop after abdominal surgery.

Acquired hernias include incisional hernia, parastomal hernia and hernia after stoma reversal. Incidences up to 20%, 30-50% and 30% respectively are reported and the risk to develop them increases with higher BMI. Surgical repair of these hernias is required in 27-44%.

In the Netherlands, it is postulated that 8500 incisional hernia repairs take place yearly. With increasing numbers of intra-abdominal procedures, the number of hernia repair is probably also increasing. Although surgical hernia repair is seen as a low-risk procedure, complications such as hernia recurrence, chronic abdominal pain, mesh infection and adhesion formation in combination with the frequency of the procedure can have a significant impact on health care costs and morbidity.

Postoperative adhesions are frequent complications of intra-abdominal surgery and are related to chronic abdominal pain, bowel obstruction and female infertility. Since this leads to a readmission rate of 35% within 10 years after the index-operation, this will affect the health care system and quality of life of the operated patients significantly.

Furthermore, intra-abdominal placed meshes for hernia repair trigger adhesions to form between meshes and viscera, which may lead to severe complications such as fistula formation between intestines and the mesh. Therefore, prevention of such complications is important for both patients and society.

## Target groups

Results of the studies in this thesis could be of interest to a wide audience. First of all, medical professionals, in particular surgeons, gynecologists and urologists should acknowledge and recognize adhesion-related complications and inform patients preoperatively about the risks of adhesion formation after abdominal surgery. Furthermore, these professionals form the corner stone in prevention of adhesions and

incisional hernias, by using anti-adhesive barriers, prophylactic meshes or closing the abdominal wall according to the small steps small bites technique. Besides, gastroenterologists and general practitioners should be aware of the possible complications of adhesions, since these specialists may also treat patients with chronic abdominal pain, small bowel obstruction or infertility.

Next, patients should take their responsibility in obtaining information about surgical interventions and possible risks. Patients' associations can play an important role in providing this information and can act as a negotiator with medical professionals, policy makers and health insurance companies in order to change current practice.

Furthermore, health insurance companies are an important target group. It might be that the costs of anti-adhesive barriers and prophylactic meshes are a limiting factor in the widespread use, although these products have proven their cost-effectiveness. Health care companies can provide funding or plan together with hospitals and medical professionals to increase the use of these products.

Lastly, companies and researchers that are involved in the development of meshes can profit from the information described in this thesis. Since it is shown that the rat is a good animal model in hernia research, it should be considered to use rats in future mesh research to minimize the use of animals for research goals. Furthermore, an additional decrease in animal research can be reached using the META scoring system described in this thesis, as it makes it easier to compare studies.

## **Activities and products**

Despite activities from the Dutch Adhesion Group and several research groups in the past, the in 2016 repeated adhesion awareness survey showed that the burden of adhesions is still an underestimated problem. To draw attention to this problem, new studies with recent numbers on adhesion-related readmission rates, new adhesion scores and cost-effectiveness studies have been performed. In combination with the Bologna guidelines for the diagnosis and treatment of adhesive small bowel obstruction, this will hopefully lead to an increased awareness and subsequently change of daily practice.

Regarding the newly developed elastic thermoplastic polyurethane (TPU) mesh, results presented in this thesis are promising. The elasticity of this mesh should imitate the function of the abdominal wall and therefore should lead to less complaints. To further explore possible applications of this mesh, studies that investigate the utilization of this elastic mesh as inlay mesh in large abdominal wall defects and the performance of these meshes when used as a parastomal mesh have been performed in pigs. These studies have also shown promising results and thus, additional studies in humans should be designed to conduct randomized clinical trials using this mesh.

## Innovation

Several innovative developments have been addressed in this thesis. The first important innovation covers the development of tools to improve hernia research. Secondly, prophylactic measures to prevent hernias are an important topic of this thesis.

Regarding the performance of hernia research, especially in animals, hardly no guidelines exist. Since there are general concerns about the quality, reproducibility and translatability of animal research, guidelines such as the PREPARE and ARRIVE guidelines have been developed to improve animal research. Nevertheless, in the field of hernia research, it has been shown that many different animal models have been used, subsequently decreasing the reproducibility of these studies. Furthermore, several adhesion scoring systems are available. To improve hernia research, we decided to approach these problems. We showed that rats are a good animal model in hernia research, with comparable outcomes as in humans. Next, we were able to unite a group of experts in the field to develop a new mesh tissue adhesion score. Both subjects can help to improve hernia research by increasing reproducibility and translatability.

In the last years, research with the topic of hernia prevention has been increased. For example, it has been shown that abdominal wall closure with the small steps and small bites technique leads to a decrease in hernia formation. However, it remains unclear if a slow-absorbable or non-absorbable suture should be used. Therefore, we investigated the inflammatory response on both types of sutures, as well as on fast-absorbable sutures. Based on macrophage response, a slow-absorbable suture seems favorable in abdominal wall closure.

Next, prevention of hernia formation using prophylactic meshes has been widely explored. Unfortunately, data on prophylactic mesh placement to prevent incisional hernia after stoma reversal are limited. We decided to perform a systematic review and meta-analysis to give a clear overview. This study showed the effectiveness of a prophylactic mesh, although no information about cost-effectiveness and quality of life exists.

## Schedule and implementation

The research described in this thesis provides the opportunity for interesting follow-up studies.

Regarding the META scoring system, it is important that this scoring system will be validated on the short term, since currently, no validated adhesion score exists. This can be an explanation of the quantity of used adhesion scores. For the validation of the META scoring system, limited additional experimental testing is required. During this process, it might be necessary to add small adjustments to the score in order to clarify the score. As soon as the META scoring system is validated, it should be used as standard mesh tissue adhesion score in both experimental and clinical research. With

the gathered information, the META scoring system could in the future be modified to use as scoring system for post-operative adhesions in general.

Another important finding is that histological outcomes in rats and humans in a hernia model are comparable. Therefore, the rat should be the animal model used in future hernia research. Both abovementioned findings can lead to increased reproducibility and translatability and thus to a decrease in required animal research. Therefore, guidelines in the field of hernia and adhesion research are necessary. These guidelines should include factors as preferred animal type, adhesion models and scoring systems. It seems logical to develop these guidelines in cooperation with the National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs), the organization that is also involved in the development of the ARRIVE guidelines. The European and American Hernia Societies can also play a role in developing and spreading the guidelines.

Furthermore, it is shown that prophylactic mesh placement after stoma reversal is promising. However, sample sizes in these studies are relatively small and the quality of life and cost effectiveness are not described yet. To examine this, several study groups are including patients in randomized clinical trials. Outcomes of these studies will be published in the upcoming years. Due to the high number of treated patients with stoma reversal and the high risk on hernia development, even small improvements can have a significant impact on societal health care.

Lastly, clinical trials to investigate the effectiveness of the newly developed elastic TPU mesh in human should be designed to measure the effectiveness and quality of life in patients who receive this mesh.