

UNIVERSITY TWENTE AND GELRE HOSPITAL APELDOORN

# FUNCTIONAL OUTCOME OF VAGINAL MESH FOR PELVIC ORGAN PROLAPSE IN GELRE HOSPITAL APELDOORN

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Masterthesis Health Science

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## Abstract

### Objective

Evaluation of the performances of Gelre Hospital Apeldoorn on Prolift™ treatment for prolapse. With these results a benchmark between providers of this treatment will be possible.

### Background

Transvaginal mesh in pelvic prolapse surgery has been introduced in 2005 (1). In recent years, it became clear that mesh can increase the success rate but also can cause serious complications, leading to FDA warnings to protect over courageous patients and doctors (1-3).

### Materials and methods

A prospective cohort research was done. It used descriptive statistics to describe patient characteristics, complications and symptoms. Analyzes were done to see whether there were relations between preoperative data with follow-up at six weeks and eleven months or later postoperative follow-up outcomes in women treated with transvaginal mesh (Prolift™) between 2006 and 2010. The importance of all different kind of symptoms were valued by the use of the Analytic Hierarchy Program. Data was collected by the use of Pelvic Organ Prolapse Quantification measurements, IUGA/ICS complication qualification, Urogenital Distress Inventory, Defecation Distress Inventory and several separate questions. Besides general patient characteristics several performance indicators were measured like: complications, reoperations, anatomical outcomes, symptoms and quality of life.

### Results

Of the 107 selected women eventually 105 women received a mesh implant. Women could receive three different types of mesh implants: 21% (N = 22) received an anterior implant; 29% (N = 30) a posterior implant and 51% (N = 53) a total implant. The anatomical success rate of this research group was 72% (N = 58). 38% (N = 32) of the women had some kind of complication, of whom 8,3% (N = 7) presented with erosion. The Analytic Hierarchy Program showed that bowel problems are the most preferred group of symptoms to be solved. Individually, visible or tangible genital prolapse and fecal incontinence are the most preferred symptoms to be solved by treatment. Genital prolapse symptoms decreased significantly after surgery and 74% (N = 66) of these problems were solved. None of the women suffered from aggravated or de novo genital prolapse problems. Fecal incontinence problems decreased, but not significantly, after surgery. 35% (N = 10) of these problems were solved; 12% (N = 10) got aggravated and 8,6% (N = 7) of the women suffered from de novo fecal incontinence problems. 90% (N = 84) of all women in this research improved on their quality of life experience in some extend.

### Conclusion

In some areas the outcomes of this treatment in Gelre hospital Apeldoorn are comparable to other known numbers. These are areas like erosion and de novo incontinence. On de novo dyspareunia the hospital scores extremely well with no cases found in this study. There are also areas that could be improved. These are anatomical success; resolution of visible or a tangible prolapse and fecal incontinence symptoms. Despite these improvement points, nearly all women feel improved after mesh treatment for prolapse.

## Foreword

In front of you lies my masterthesis that will be the end of my masterprogram Health science at the University Twente.

It has been a long and interesting road from the start of the research up till this point where the report is finished.

From this place I would like to take the opportunity to thank some people. Without them this research and report would not have been possible. First of all, I would like to thank my supervisors at Twente university, Marjan Hummel and Jeanette van Manen. You have guided my in the right direction en gave me a lot of good advice and feedback. Second, I would like to thank the people at Gelre hospital Apeldoorn, for collecting data, answering all of my questions and feedback on the process and outcomes. Third, I would like to thank Patty Geerdink, Wendy Veldhuis, Jolien Hessels and Evelien van der Maas for reviewing my report. And at last, I would like to thank all women that were involved in this research.

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## 1. Introduction

Pelvic Organ Prolapse (POP) has a major influence on the quality of life in women with this condition. The chance of being operated for prolapse before the age of 80 is around 10% (4). In prolapse surgery with native tissue, the recurrence rate is 17-29% (5). The use of mesh should reduce this risk (6). The anatomical success rate is reported higher than with the use of native tissue. The success rate for mesh use is about 87% (3). On the other hand, this treatment is associated with a higher complication rate (7) such as mesh erosion which occurs in 7-20% of the cases (3;8). These things are only a few of the performance indicators that could be used in the description of the performances of a certain hospital on this treatment. Symptoms that occur with POP can be divided into three major groups: urinary problems, bowel problems and sexual problems (9). A major problem with POP treatment is new symptoms that occur after treatment, called de novo. De novo incontinence symptoms occur in 14% of the cases (10) and de novo dyspareunia in 9,1% of the cases (11). The visible or tangible genital prolapse should decrease significantly after the treatment (12) and should even be solved in 91,6 to 100% of the cases (13). These are only a few of the possible outcomes and symptoms involved in prolapse treatment. Since there is such a long list of symptoms and outcomes, it is expected that these are not preferred in the same extent by patients. Some symptoms will be more preferred than others to be solved by treatment.

Followed in time on the publications above, the American Food and Drug Administration (FDA) published in July 2011 an update on the safety and effectiveness of the use of surgical mesh implants in the treatment of prolapse. This article contained a warning for all medical specialists and patients concerning the use of these materials. They stated that there were several concerns about the safety and effectiveness of these implants (1). Several Dutch media, like the national paper “de Volkskrant” and a research journalistic documentary program “Zembla”, recently paid attention to this subject in a negative way (14). There are many different factors that influence the success of mesh surgery (1;14). Therefore it is important for hospitals to have insight in their own performances on several performance indicators for this particular treatment. Benchmarking is a good practical way of doing this.

Benchmarking is known as a way to find out how others do something better than you and how you can improve on their techniques (15). In other words; it is a way of comparing procedures and outcomes between, in this case, hospitals that provide mesh implants as treatment for POP. Benchmarking is designed as a tool in strategic management in order to determine the best practice (15). A result of a benchmark should be the improvement of the competitive advantage of a company, or in this case a hospital (16). Since a prolapse can occur in combination with many different kinds of symptoms and problems it can be expected that these symptoms do not contribute to quality of life in the same extent. Some symptoms will be more preferred by patients to be solved than others. The AHP (Analytic Hierarchy Process) method can be used to provide insight in the most preferred symptoms to be solved by treatment for patients. The AHP comes to a set of numbers that reveals the relative importance or priority of these symptoms (17). The outcome of the AHP analysis will provide symptoms on which benchmarking should focus on.

## 2. Theoretical framework

### 2.1 Prolapse

A network of muscles, ligaments and skin holds various organs inside the female body in place. Due to several factors, these structures, which are called the pelvic floor, can become weak over time, which can result in a vaginal prolapse (18;19). A Pelvic Organ Prolapse (POP) is a bulge of pelvic organs and the vaginal segments that are associated with it, into or through the vagina (20). This can be the uterus, bladder, rectum, and the bowel which descent from their original and normal position towards or through the hymen (21;22). Even though a prolapse is not a life threatening condition, it can affect the health of woman with a prolapse in other manners. Women suffering from prolapse often report limitations in their functioning on physical, social and emotional levels (23).

### 2.2 POP-Q

For the diagnosis of prolapse and the description of the position of pelvic organs the POP-Q method (Pelvic Organ Prolapse Quantification) was developed by the International Continence Society (ICS)(9). Nine defined points and their distance to the hymen qualify the prolapse. The hymen is chosen as a reference point for the POP-Q because it is easily to detect and is cannot change its position. The prolapse is classified in five different stages. Stage zero means that there is no kind of prolapse present. In stage one the most distal point of the prolapse is more than one centimeter above the level of the hymen. Stage two means that the most distal point of the prolapse is between -1 and +1 cm to the plane of the hymen. Stage three occurs when the most distal point is more than 1cm below the hymen, but no further than the total length of the vagina minus 2 cm. Stage four is the most prolapsed stage. This is classified when the vagina is totally prolapsed. The quantification value for this stage is more than the total length of the vagina minus 2 cm (9).

### 2.3 Types of prolapses

#### 2.3.1 Anterior compartment

In the anterior compartment the bladder and urethra are supported. Defects in this support are called an anterior defect or a cystocele. The definition of a cystocele is a herniation of the bladder through the anterior wall of the vagina (24;24;25).

#### 2.3.2 Apical compartment

The apical compartment supports mainly the uterus or the upper vagina in case of a hysterectomy. A downward protrusion of the cervix and uterus is called a uterine prolapse. When the uterus protrudes so far outside the vagina that the entire vagina turns inside out, there is a total prolapse. In case of a hysterectomy and an eversion of the entire vagina it is called a total vagina vault prolapse (24).

#### 2.3.3 Posterior compartment

In the posterior compartment the rectum and the small bowel are supported. A weakness or defect in this support is called a rectocele or enterocele. A rectocele is the prolapse of the rectum into the vagina through the posterior vaginal wall (24;25). In case of an enterocele the small bowel protrudes into the vagina. This type of pelvic support disorders is the only true herniation (24).

Combinations of several types of prolapses are not rare. Different types occur in combination with other types like recto-enterocele (18).

## 2.4 Incidence

About 40% of the women of 45 years or older have an anatomical prolapse. The chance of needing surgical treatment for the repair of the prolapse is about 11-20% (4;10). Part of the difference between the incidence and surgery rate can be explained by the fact that for many women the prolapse does not cause symptoms (26). Each year around 13.000 prolapse surgeries are performed in the Netherlands (27). Since both the incidence and the prevalence of prolapse increase with age and the increasing age of the western population, it is expected that the incidence of prolapse will increase further over time (28).

## 2.5 Symptoms

The severity of the prolapse often does not correlate with the severity of the symptoms experienced by the patient (26). This means that patients with severe prolapse do not necessarily need to be suffering from prolapse symptoms (25).

Prolapses can cause many different types of symptoms, which do not necessarily occur all in one case or at the same time. The symptoms that occur can be distinguished into four groups: typical prolapse symptoms, urinary symptoms, bowel symptoms and sexual symptoms (9).

### 2.5.1 Typical prolapse symptoms

A typical symptom that could occur is a heavy feeling or pressure in the vagina. Also vaginal pain or lower back pain could occur. And besides that there is the sensation or awareness or observation of tissue coming out of the vagina (9;25).

### 2.5.2 Urinary symptoms

Most common forms of urinary incontinence are stress, urge and mixed incontinence (9;29). Stress incontinence is the leakage of urine when the intra-abdominal pressure exceeds the closure pressure of the bladder in absence of detrusor activity. This can happen while coughing, lifting, jumping and other pressure increasing activities (29;30). The leakage occurs when the intravesical pressure rises beyond the pressure that the urethral closure mechanism can handle (20). Urge incontinence is defined as loss of urine in combination with a strong urge to urinate, which comes up unexpected and rapidly, and cannot be suppressed (29). Mixed incontinence is a combination of aforementioned types of incontinence (29).

Another urinary symptom is increased daytime frequency of voiding. In case of a prolapse the frequency can rise till many times. The feeling of an incomplete emptying and recurrent cystitis are also common symptoms of cystocele (9;29).

### 2.5.3 Bowel symptoms

Just like the urinary symptoms, bowel symptoms can occur in different types. The main problem of posterior prolapse is difficulty to defecate and discomfort when having defecation. Sometimes women need digital manipulation to be able to defecate or complain of incomplete defecation. Other symptoms that can occur are fecal incontinence and urgency. The incontinence can be of liquid stool, solid stool or flatus (9).

### 2.5.4 Sexual symptoms

One must realise that not every woman with a prolapse is sexually active. This is not always because of the prolapse, but is often due to other factors such as disease of the husband or lack of sexual

desire. It is important to find out whether women stopped having intercourse due to discomfort or urinary leakage that is caused by the prolapse or due to other factors. Sexual symptoms could also present itself in a decrease of the frequency of sexual activity. Sexual symptoms that could occur are: dyspareunia (pain during sexual intercourse), feelings of shame towards the partner about the prolapse itself or other discomforts that come along with the prolapse, like incontinence (9).

## **2.6 Causes**

The weakening and tearing of the muscles, ligaments and connective tissue in the pelvic floor is the main cause of a prolapse. There are several causes for this pathologic process. One of the causes is the long-term increase of abdominal pressure due to chronic coughing, constipation and obesity. Also pregnancy and vaginal delivery can permanently weaken and tear the tissue in the pelvic floor(20;27). A vaginal delivery can increase the chance of pelvic organ prolapse by 4-11 times (31). Familial predisposition can increase the chance of a vaginal prolapse (27). The aging of women and the loss of estrogen can also cause prolapses. This is one of the main reasons that vaginal prolapse occurs mainly at elderly women (32). A previous hysterectomy increases the risk of prolapse by 5 to 6 times (24;33).

## **2.7 Treatment**

There are three types of treatment for prolapse. These are: pelvic floor physiotherapy, pessaries and surgery (34).

### **2.7.1 Pelvic floor muscle training**

There are several studies that show that pelvic floor muscle training is an effective way of treating stress and mixed urinary incontinence. Therefore it is recommended that muscle training is the first-line treatment for women with these kinds of symptoms. According to Bø (35) there are three types of pelvic floor muscle training: training of pre-contraction of the pelvic floor muscles before and during a stress increasing event (like coughing, laughing or jumping); training to strengthen the muscles and building up more volume of these muscles, and abdominal muscle training which indirectly should strengthen the pelvic floor muscle. Although physiotherapy can treat incontinence and will help in strengthening the pelvic floor, it will not make a symptomatic prolapse disappear. The goals of pelvic muscle training are prevention of worsening of the prolapse, decreasing the symptoms, strengthening of the muscles and delaying or even avoiding surgical treatment (24).

### **2.7.2 Pessaries**

Pessaries are removable devices that are placed in the vagina to support the pelvic organs. Pessaries do not solve the prolapse problem, but they can treat the symptoms very well. They also could slow down the progress of the development of a worse prolapse. Pessaries are only of use when there is still enough support to keep the pessary in place. Pessaries are first choice when the risks of surgery are high, in case the woman is pregnant or wants to be in the future, or when there is no certainty in the causal relation between a small prolapse and the occurring symptoms (18).

### **2.7.3 Surgery**

The aim of prolapse surgery is to relief symptoms by restoring the vaginal anatomy (24). Nowadays there are three types of surgery for the treatment of prolapse. Restorative procedures have been the standard treatment for prolapse for years. The endogenous tissue of the patient is plicated and ligaments are shortened or used as fixation. Compensatory procedures use permanent graft materials to replace deficient support. Finally, obliterative procedure close the vagina partially (24).

In case of compensatory procedures, the surgical mesh that is mainly used is made of non-absorbable synthetic polypropylene (1). Since 1960 polypropylene is used in the treatment of stress incontinence (36). The aim of the use of surgical mesh in pelvic repair surgery is to provide additional support which will reduce the risk of recurrence. This is especially of importance for women who have a recurrent prolapse (21). About 29% of the women who underwent surgical treatment for their prolapse, need to undergo a re-operation at some point in their further life (4;5). Re-operation rates of traditional prolapse surgery methods run up to unsatisfying rates of more than 40% (19). The rates for treatment with the use of surgical mesh seem to be lower (19;37). Also, the anatomical outcomes for the mesh are better and even up to 87% (3).

## **2.8 Surgical complications of mesh**

### **2.8.1 ICS/ IUGA complication registration**

The International Continence Society developed a standardized tool to describe complications due to the insertion of prostheses (which the surgical meshes are one of). This tool describes the type of complication that has occurred, divided into seven different types of complications. Besides the category of the complication the tool also provides the opportunity to classify the amount of pain that occurs, the time on which the complication is diagnosed and the location of the deviation (7). Appendix A shows an overview of the complication classification tool.

### **2.8.2 Erosion**

Erosion of mesh is one of the main complications in the use of surgical mesh for the treatment of prolapse. Mesh erosion occurs when the implant exposes into the vagina, bladder or even the bowel so that it is no longer covered with tissue (27;38). Symptoms of erosion are discharge and vaginal bleeding. Feiner et al. (3) report a 7% rate for the presence of erosion in patients who were treated with the Prolift™ mesh kit. Deffieux et al. (8) report a erosion rate up to 20% after placement of a vaginal mesh implant. Risk factors for erosion are higher age of the patient, smoking, diabetes, concomitant hysterectomy and the experience of the surgeon (11;22).

### **2.8.3 De novo symptoms**

Symptoms that did not occur before the prolapse treatment but do occur in the follow-up period are called de novo.

#### ***Prolapse***

Research shows that treatment of prolapse with mesh could cause the development of a POP in another compartment of the vagina. This means, for example, that when an anterior prolapse was treated with mesh, the posterior wall shows a prolapse after some time, or the already existing prolapse is getting worse. This could be caused by the fact that the vaginal wall that is supported by the mesh does not support the other vaginal wall as much anymore, which causes this compartment to prolapse (5;39).

#### ***Incontinence***

Another problem is de novo stress incontinence after prolapse surgery. Often the cause of the incontinence is an already existing weak support of the urethra, which is compensated by the prolapse. Once the anatomy is restored, the formerly 'masked' incontinence now becomes symptomatic (10). The occurrence rate of de novo stress incontinence is 14%. De novo incontinence is not necessarily a complication that occurs after a mesh treatment. This type of

complications occurs after all types of prolapse surgery. In most cases it includes a “hidden” incontinence which shows after the repair of prolapse (10). That’s why can be stated that de novo incontinence does not have to be a complication of the treatment. On the other hand research showed that this problem occurs more often after mesh treatment than after surgery with native tissue (40).

### **Dyspareunia**

De novo dyspareunia is mentioned in many studies as an unwanted outcome of mesh surgery for prolapse. Studies show de novo dyspareunia after mesh surgery ranging from 7,7 – 16,7% (8;41-43). A systematic review of Abed (11) reports 71 different studies that report dyspareunia. The overall incidence in these studies is 9,1%.

#### **2.8.4 Other complications**

The retraction of the tissue surrounding the mesh implant is a complication that could occur. On the average the mesh shrinks around 25% till 30%. Therefore some surgeons use larger implants to prevent problems with retraction (44). The shrinkage of the mesh can result in pelvic pain or dyspareunia (45;46). Vaginal narrowing and shortening are symptoms than can occur postoperatively and may cause sexual difficulties like dyspareunia (47).

## **2.9 Treatment outcomes**

### **2.9.1 Anatomical outcome**

The American National Institute of Health (NIH) differentiates between an optimal anatomic outcome and a satisfactory anatomical outcome. In case of an optimal outcome the POP-Q stage needs to be zero and for a satisfactory outcome the POP-Q stage needs to be one. POP-Q stage zero inquires a perfect anatomic support, and stage one requires a support higher than 1 cm proximal to the hymen (48). Carey et al. (49) report a successful surgery in case of the absence of POP-Q stage 2 or more. Stanford et al. (50) say an anatomic success full outcome is a POP-Q stage equal to or smaller than one. A 87% success rate is described (3).

### **2.9.2 Subjective outcomes**

Over the years, it becomes clearer that not necessarily the anatomical outcome of a prolapse treatment determines the satisfaction of the patient with the treatment. There are even women who do not experience improvement, or even experience worsening of the situation, although the anatomy may be improved. Especially de novo symptoms cause dissatisfaction with the treatment. About 25% of the treated women report de novo symptoms like incontinence and difficult defecation (28). Women who still need to undergo POP surgery mainly hope for an improvement in urinary symptoms, followed by improvement in bowel symptoms and after that improvement in sexual symptoms. Most feared are de novo symptoms of any kind followed by recurrence of the prolapse, surgical complications and sexual symptoms (51).

### **2.9.3 Success definition**

The success rate of a treatment strongly depends on the used definition of success. The American NIH advises to use a combined definition for success of the prolapse treatment. They say that the definition should include the absence of bulge symptoms, an anatomic outcome using the hymen as threshold and the absence of re-treatment (48).

### 3. Research question

#### 3.1 Goal of the research

The main objective of the study is to describe the performance of Gelre hospital Apeldoorn on pelvic organ prolapse treatment using polypropylene mesh (Prolift™) in the period of 2006-2010. Not only the anatomical outcome but also quality of life will be considered. This will be done because of the great impact a prolapse can have on the experienced quality of life. Besides that there is a wide range in the extent women experience symptoms and problems due to their prolapse. It is even possible that women do not experience any kind of symptom or problem at all (23;26). Complications, reoperations and symptoms will be included in this research to provide a complete overview of the outcomes of the treatment. In this research there will be no comparison between different types of treatment for POP, but only a description of the performance of Gelre hospital Apeldoorn on this particular treatment. In this research the performance of Gelre Hospital Apeldoorn on the Prolift™ treatment for prolapse will be analyzed based on several performance indicators. Not only will this research provide a transparent overview of the outcomes of this treatment it will also provide a way in which Gelre hospital Apeldoorn can be compared to other providers of this treatment. A third way in which the outcomes of this research can be used is as feedback on the own performance of Gelre hospital Apeldoorn on this treatment.

#### 3.2 Research question

To be able to structure the proposed research the following two research questions are phrased:

How does Gelre hospital Apeldoorn perform on the performance indicators: anatomical success, complications, symptoms and quality of life for women with prolapse treated with Prolift™ in the period of 2006-2010?

What are the patient preferences on symptoms to be solved by the Prolift™ treatment in women with a prolapse treated in Gelre Hospital Apeldoorn in the period April 2012-July 2012?

##### 3.2.1 Sub-questions

In order to answer the main research question several sub-questions are addressed:

1. What are the overall characteristics of the women treated for prolapse with the use of polypropylene mesh in Gelre Hospital Apeldoorn in the period of 2006-2010?
2. How does Gelre hospital Apeldoorn perform on anatomical success of the prolapse itself?
3. How does Gelre hospital Apeldoorn perform on complications and reoperations after Prolift™ treatment?
4. Which symptoms were solved, improved, did not change, got aggravated or were new on women treated in Gelre hospital Apeldoorn between 2006 and 2010?
5. What are the patient preferences according to solving groups of symptoms and individual symptoms with the Prolift™ treatment?
6. In which way changed the quality of life of women treated in Gelre hospital Apeldoorn in the period between 2006 and 2010?

## 4. Materials and methods

### 4.1 Research design

The research had a quantitative design in which anatomical results of the treatment, symptoms, complications and quality of life are measured. The research contains a retrospective cohort.

### 4.2 Research population

A total of 107 women were eligible for transvaginal mesh surgery for pelvic organ prolapse and were intended to be treated with a Prolift™ mesh in the period of March 2006 till September 2010 in Gelre Hospital Apeldoorn. Two of these women eventually did not receive a mesh implant due to complications. The other 105 women were included and represent the research population.

For the AHP analysis another research population was formed. This included all women treated surgically for a prolapse between the period of April 2012 and July 2012. Ten of these women agreed to fill out the questionnaire.

### 4.3 Data collection

Data was collected before surgery, during surgery, six weeks post surgery and at a follow-up. In 2011 all women received an invitation to come back at the gynecologists office for a follow-up. This period is widespread. Women treated in 2006 will have a much longer follow-up period than women treated in 2010. Before surgery and at follow-up women were asked to complete validated questionnaires. A new group of women were asked to fill out a second questionnaire for the AHP analysis. Figure 1 provides an overview of the different moments in time on which data was (possibly) collected. The time period between T1 and T2 is for every women approximately six weeks. All other periods between measurements could vary for every individual woman. Moment T3 did not occur for every woman involved in this research. Women who did not needed to undergo a reoperation, transferred from T2 immediately to T4.

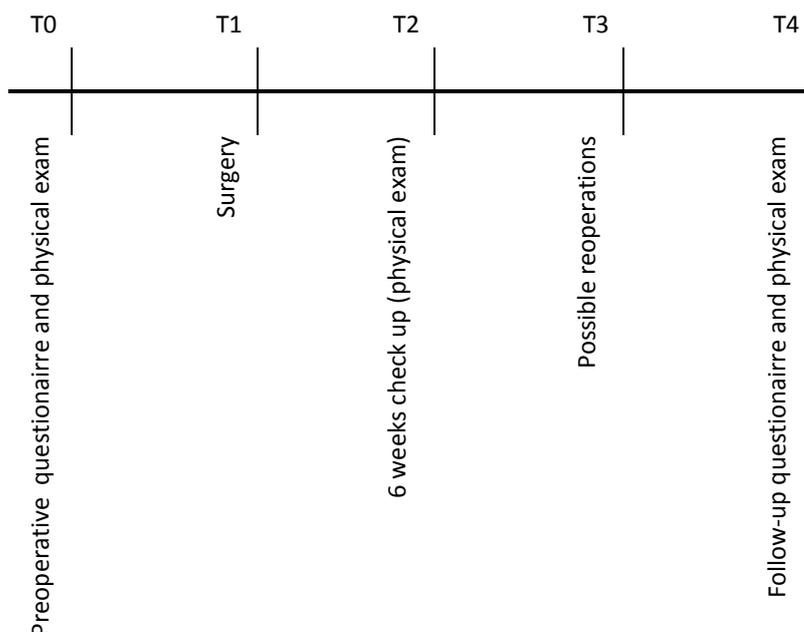


Figure 1: Data collection timeline

### 4.3.1 Hospital charts

During the operation general data was collected in order to answer the first sub question. The duration of the surgery was registered in minutes. Blood loss during the surgery was registered in ml. Body Mass Index (BMI) was registered in  $\text{kg}/\text{m}^2$ .

### 4.3.2 Questionnaire

For the measurement of quality of life (sub question 6) and symptoms (sub question 4) that could occur with POP a questionnaire was completed. The questionnaire needed to be filled out preoperative and at follow-up. It combined two different types of preexistent questionnaires and some additional questions. This preexistent questionnaires used are the Urinary Distress Inventory (UDI) and the Defecation Distress Inventory (DDI).

The Urinary Distress Inventory (UDI) consists of twelve questions and measures urinary symptoms and the amount of bother they cause(23). For the analysis both parts of the question are combined and transformed into a numerical score on a scale from 2-5: 2 = symptom is not present or symptom is present but does not cause bother; 3 = symptom is present and cause slight bother; 4 = symptom is present and causes moderately bother; 5 = symptom is present and causes great bother. The UDI consist of five domains. These are: overactive bladder, obstructed micturation, incontinence, pain and genital prolapse. Per domain, all questions involved, these scores are transformed into a score on a scale from 0-100. Appendix C contains a formula on how to transform the individual question scores into a combined score per domain. A high score on a certain domain indicates more bother.

The Defecation Distress Inventory (DDI) measures defecatory symptoms and the amount of bother they cause (23). For the analysis of both parts of a question the same scale is used as in the UDI questions. The DDI also consists of five domains. These are: constipation, obstructed defecation, pain, fecal incontinence and flatus incontinence. Per individual question a score between two and five points can be achieved. Appendix B shows how these scores can be transformed into a score on a scale from 0-100 per domain. As the DDI score per domain gets higher, the more severe the bother is.

The general quality of life is measured by two separate questions about the health state in the past week and the perception of quality of life in the past week on a scale from one to six. The scores on both questions are transformed into a score on a scale from 0-10, by summing up both scores and deducting two. A high score indicates a good experienced quality of life.

The sexual questions involved; indication of sexual activity, satisfaction and incontinence, narrowing and pain symptoms during sexual intercourse. All questions contain two parts. Together they score on a scale of 2-5. 2 = not sexual active or sexual active but not satisfied; 3 = sexual active and slightly satisfied; 4 = sexual active and moderately satisfied and 5 = sexual active and satisfied. For the questions about symptoms and the bother they cause, there is also a scale from 2-5. 2 = symptom is not present or symptom is present but does not cause bother; 3 = symptom is present and cause slight bother; 4 = symptom is present and causes moderately bother; 5 = symptom is present and causes great bother. All scores on the individual questions are transformed into a scale from 0-100. A high score on the satisfaction scale corresponds with a high satisfaction. A high score on the symptom domains indicates a high bother of these symptoms. A copy of the questionnaire used for this research can be found in appendix C.

### **4.3.3 Physical examination**

Besides the questionnaires, women underwent a physical examination before surgery, six weeks after surgery and at follow-up to measure the anatomical outcome of the treatment and to determine occurred complications. This physical examination was done in order to answer sub question 2 and 3. These physical examinations consist of a check up for complications, registered with the IUGA/ICS complication registration form, and a POP-Q measurement.

### **4.3.4 Analytic Hierarchy Program (AHP)**

For answering sub question 5 the AHP analysis will be used. Since a prolapse can cause many different kinds of symptoms and problems it can be expected that these symptoms do not contribute to the quality of life in the same extent. Some symptoms will be more preferred by patients to be solved than others. The AHP (Analytic Hierarchy Process) method can be used to provide insight in the prioritizing of symptoms by patients. AHP is a multicriteria decision-making process, which supports researchers in different types of decisions. The AHP provides a set of numbers that reveal the relative importance or priority of different factors that are involved in a decision that needs to be taken (17). The AHP consists of three major compartments: a decision goal, decision criteria and decision options. The AHP analysis starts with the determination of all the involved criteria and decision alternatives. They will be compared pair wise for every possible combination. This comparison will lead to a prioritized list of factors involved in the decision. The AHP analysis should enable the researcher to combine objective and subjective measures, which together produce a certain outcome (17;52). In this case the AHP will provide a prioritized list of all symptoms involved in prolapses. The most preferred symptoms that will come out of this analysis need to be the focus symptoms in benchmarking between hospitals which provide this treatment. To obtain data about patient preferences in the symptoms that they would like to be solved the most, patients who underwent a prolapse surgery in the period April 2012 till July 2012 were asked to complete a questionnaire. The outcome of the questionnaire should provide a ranking of the possible symptoms occurring in prolapses. The questionnaire can be found in appendix D.

### **4.3.5 Performance indicators**

In this research there are several indicators that provide information about the performances of Gelre hospital Apeldoorn on the Prolift™ treatment. These indicators are: anatomical outcomes; complications; reoperations; urinary problems; bowel problems; sexual problems and quality of life. Each reoperation is a result of a complication, but not every complication will lead to a reoperation.

## **4.4 Data analysis**

### **4.4.1 General data**

The statistical program Statistical Package for the Social Science (SPSS) version 16 was used for the display and analysis of general data in this research. Averages, ranges and percentages were collected with the use of this statistical program.

### **4.4.2 Calculation of solved and aggravated symptoms**

This research analyses the solved symptoms or problems. When a woman experienced a domain symptom which bothers her preoperative and no longer at follow-up, the domain symptom is considered solved. This can either be that the domain symptom is completely disappeared, or that the domain symptom is still present but no longer causes bother. When a domain score (on a scale from 0-100) is smaller preoperative than at follow-up, the domain is considered aggravated.

### 4.4.3 Analysis

Descriptive statistics were used for an overview of all variables involved. All variables were tested for normality with Kolmogorov-Smirnov and Shapiro-Wilk test. In case of normal variables student-t test would be used for the determination of possible significant changes in these variables. In case of not normal variables Wilcoxon signed rank test was used for the determination of possible significant changes in these variables. Since the data contains dependent groups, there was chosen for pair wise testing. Wilcoxon signed rank test was used for the POP-Q values, possible significant changes in UDI, DDI and sexual domains, between the preoperative data and follow-up. This research contained many tests. To correct for multiple testing the significance level needed to be adjusted. For the determination of the significance level Bonferroni method was used. All tests surrounding the anatomical outcome and symptoms were combined. Also all tests surrounding the quality of life measurements were combined. The Chi-square test was used for the determination of possible significant differences in mesh types according to de novo symptoms.

### 4.4.4 AHP and correlations

For the analysis of the questionnaires about patient preferences Expert Choice version 11 was used. The most preferred symptoms were used as a base for the hypotheses to describe the correlations between the subjective improvement of someone's quality of life and prolapse symptoms. Pearson correlation coefficient was used. The bivariate correlation test was done with SPSS version 16.

## 4.5 Sub questions and data

Figure 1 showed the several moments in time on which data was collected. Table 1 provides an overview of which data from which moment in time was used to produce results that will lead to an answer on the sub questions.

Table 1: Used data for sub questions

<u>Sub question</u>	<u>Data used</u>	<u>Time</u>	<u>Sub question</u>	<u>Data used</u>	<u>Time</u>
1	Questionnaires	T0; T4	4	Questionnaires	T0; T4
	Physical exams	T0; T2; T3 and T4		Physical exams	T0; T2; T3 and T4
	Hospital charts	T1 and T3		Hospital charts	T1 and T3
2	Questionnaires	T0; T4	5	AHP	
	Physical exams	T0; T2; T3 and T4			
	Hospital charts	T1 and T3			
3	Physical exams	T2; T3 and T4	6	Questionnaires	T0; T4
	Hospital charts	T3		Physical exams	T0; T2; T3 and T4
				Hospital charts	T1 and T3

## 5. Results

### 5.1 Research population

One hundred and seven women were intended to be treated with a Prolift™ mesh. For two women was decided not to treat them with the use of mesh during the surgery. They were excluded and the other one hundred and five women made the total population for this research. Of these women the preoperative physical data was available. Ninety-seven of them (92%) filled out the questionnaire preoperative. The six week follow-up POP-Q scores were available of 103 women (98%). At the long-term follow-up 81 women (77%) were physically examined and a total of 91 women (87%) filled out the questionnaire. Eighty women (76%) did both, eleven women (11%) only filled out the questionnaire and 1 woman (1,0%) only underwent the physical exam. A total of 13 women (12%) was lost to follow-up time because of refusal, moving to another city or cognitive disorder.

The mean age of the women was 66 years (range 39-88 years). The median Body Mass Index (BMI) at time of surgery was 26 (range 18-62 kg/m<sup>2</sup>). The median follow-up time was 35 months (range 11-64 months). More than half of the women received a total implant, 21% had an anterior and 29% had a posterior mesh. Patient characteristics can be found in table 2.

For the AHP analysis a total of ten women agreed to fill out the questionnaire. Eight of these were usable in order to analyze the preferences of these women.

**Table 2: General characteristics of the research population**

	N	%	Mean	Std	Range		
<b>Age</b>			66	10,6	39-88		
< 45 years	7	7,4%					
45-60 years	22	23%					
60-75 years	47	50%					
> 75 years	17	20%					
			<b>Minimum</b>	<b>Q1</b>	<b>Median</b>	<b>Q3</b>	<b>Maximum</b>
<b>BMI (kg/m<sup>2</sup>)</b>			18	24	26	28	62
Underweight (≤ 18,5)	1	1,0%					
Normal weight (18,5 - 25)	33	31%					
Overweight (25 - 30)	56	53%					
Obesity (> 30)	15	14%					
<b>Follow-up</b>			11	23	35	47,5	64
≤ 1 year	5	4,8%					
1-2 years	22	21%					
2-3 years	28	27%					
3-4 years	27	26%					
4-5 years	17	16%					
> 5 years	6	5,7%					
<b>Mesh implant</b>							
<i>Anterior</i>	22	21%					
<i>Posterior</i>	30	29%					
<i>Total</i>	53	51%					

### 5.1.1 Additional information

Table 3 provides some additional patient information. These include the mean operation time in minutes and the blood loss in milliliters. Concomitant interventions were additional interventions done during the surgery besides the implantation of the surgical mesh. The table shows that 15 women underwent a prolapse surgery for the first time. All other women underwent at least one prolapse surgery before.

**Table 3: additional information**

	<b>N</b>	<b>%</b>	<b>Minimum</b>	<b>Q1</b>	<b>Median</b>	<b>Q3</b>	<b>Maximum</b>
<b>Operation time (min)</b>			45	60	80	90	120
<b>Blood loss (ml)</b>			0	50	100	200	1900
<b>Concomitant interventions</b>	25	24%					
<b>OR complications</b>	4	3,8%					
<b>Previous hysterectomy</b>	66	65%					
<b>Primary prolapse surgery</b>	15	15%					

## 5.2 Anatomical outcome

Since all three types of Prolift™ meshes that can be implanted (anterior, posterior and total are included in the research) the anatomical outcome section is divided into the same categories.

### Anterior mesh

Preoperative and six weeks after surgery the POP-Q examination of all 22 women were available. At follow-up there were 16 women available for the physical examination. Table 4 shows the numerical outcomes of the POP-Q examination for all the women with an anterior implant. Table 5 shows the numerical outcomes of POP-Q examination only for women who did not get lost to follow-up. Both table 4 and 5 shows that Ba (the most descended point on the anterior site) decreases significantly after surgery. Ba decreased significantly comparing the preoperative measurement and the six weeks measurement (respectively Wilcoxon = -4,147 and -3,559;  $p < 0,001$ ). There is a decreased value between the six weeks and follow-up measurement, but not significant. The total decrease of Ba over time is significant (Wilcoxon = -3,550 ;  $p < 0,001$ ). Bp (the most distal point on the posterior site) improves over time, but not significantly. Point C (the most distal edge of the cervix or vaginal cuff) improves significantly over time. The decrease of C in value from preoperative to six weeks post surgery (respectively Wilcoxon = -3,854 and -3,219;  $p < 0,001$  and  $p = 0,001$ ) is significant.

Table 4: POP-Q overview for anterior mesh

	<u>Preoperative</u> (N=22)		<u>6 weeks</u> (N=22)		<u>Follow-up</u> (N=16)	
	Mean	Std	Mean	Std	Mean	Std
<b><u>Anterior</u></b>						
Aa	1,7	0,9	-1,7	0,6	-1,9	0,5
Ba <sup>*,**</sup>	2,4	2,0	-1,7	0,6	-1,9	0,5
<b><u>Apical</u></b>						
C <sup>*</sup>	-3,8	3,7	-6,8	1,2	-6,0	1,2
D	-2,7	5,2	-7,1	1,5	-6,2	1,3
<b><u>Posterior</u></b>						
Ap	-1,2	1,2	-1,2	0,6	-1,5	1,0
Bp	-0,9	2,5	-1,2	0,6	-1,5	1,0
GH	4,2	1,0	3,8	0,7	3,6	1,0
PB	3,1	0,4	3,1	0,5	3,4	0,7
TVL	8,5	1,2	8,6	1,1	8,3	0,8

\*Significant difference between preoperative and 6 weeks after surgery; Wilcoxon signed rank test; significance level = 0,00185

\*\* Significant difference between preoperative and follow-up; Wilcoxon signed rank test; significance level = 0,00185

Table 5: POP-Q overview anterior mesh without women lost to follow-up

	<u>Preoperative</u> (N=16)		<u>6 weeks</u> (N=16)		<u>Follow-up</u> (N=16)	
	Mean	Std	Mean	Std	Mean	Std
Ba <sup>*,**</sup>	1,75	0,931	-1,75	0,447	-1,87	0,5
C <sup>*</sup>	-4,5	1,751	-6,38	0,885	-6	1,155
Bp	-1,38	0,806	-1,13	0,619	-1,5	0,966

\*Significant difference between preoperative and 6 weeks after surgery; Wilcoxon signed rank test; significance level = 0,00185

\*\*Significant difference between preoperative and follow-up; Wilcoxon signed rank test; significance level = 0,00185

The categorization of the POP-Q measurement into the five different stages, described by Bump (9), is displayed in table 6. The table shows that all women who had an anterior mesh implanted had a preoperative prolapse stage two or higher. At six weeks postoperative and at follow-up all prolapses were stage two or less.

**Table 6: POP-Q stages for anterior mesh**

	<u>Preoperative</u> (N = 22)		<u>6 weeks</u> (N= 22)		<u>Follow-up</u> (N = 16)	
	N	%	N	%	N	%
<b>Anterior</b>						
Stage 0	0	0%	1	4,5%	1	6,4%
Stage 1	0	0%	13	59%	12	75%
Stage 2	7	32%	8	36%	3	19%
Stage 3	14	64%	0	0%	0	0%
Stage 4	1	4,5%	0	0%	0	0%
<b>Apical</b>						
Stage 0	19	86%	22	100%	16	100%
Stage 1	0	0%	0	0%	0	0%
Stage 2	2	9,1%	0	0%	0	0%
Stage 3	0	0%	0	0%	0	0%
Stage 4	1	4,5%	0	0%	0	0%
<b>Posterior</b>						
Stage 0	1	4,5%	0	0%	1	6,2%
Stage 1	11	50%	7	32%	9	56%
Stage 2	9	41%	15	68%	6	38%
Stage 3	0	0%	0	0%	0	0%
Stage 4	1	4,5%	0	0%	0	0%

### Posterior mesh

Preoperative and six weeks after surgery the POP-Q examination of all 30 women with a posterior mesh were available. At follow-up there were 26 women available for the physical examination. Table 7 shows the numerical overview of the POP-Q for the posterior mesh group. Table 8 shows the numerical overview without the women who got lost to follow-up. The data shows that Bp decreases significantly at six weeks after surgery (respectively Wilcoxon = -4,817 and -4,484;  $p < 0,001$ ) and at follow-up (Wilcoxon = -4,489;  $p < 0,001$ ). The prolapse of Ba is worsening over time, but it is not a significant increase. The total decrease of C between preoperative measurement and follow-up is significant for the entire group of women who received a posterior mesh (Wilcoxon = -3,319;  $p = 0,001$ ). In the group of women without those who got lost to follow-up C decreases significantly between preoperative and six weeks after surgery (Wilcoxon = -3,956;  $p < 0,001$ ).

Table 7: POP-Q overview for posterior mesh

	<u>Preoperative</u> (N = 30)		<u>6 weeks</u> (N = 30)		<u>Follow-up</u> (N = 26)	
	Mean	Std	Mean	Std	Mean	Std
<b>Anterior</b>						
Aa	-1,4	0,9	-1,3	0,9	-0,9	1,3
Ba	-1,4	0,9	-1,2	1,1	-0,9	1,5
<b>Apical</b>						
C <sup>*,***</sup>	-3,5	2,7	-6,2	2,1	-5,6	1,8
D	-3,4	3,8	-6,3	1,9	-6,6	1,5
<b>Posterior</b>						
Ap	1,9	1,2	-1,9	0,7	-2,2	0,7
Bp <sup>**,***</sup>	2,4	1,4	-1,9	0,7	-2,2	0,6
GH	4,2	1,0	3,9	0,9	3,9	0,9
PB	2,9	0,7	3,1	0,5	3,5	0,8
TVL	8,4	1,9	8,3	1,3	7,9	1,1

\* Significant difference between preoperative and 6 weeks after surgery; Wilcoxon signed rank test; significance level = 0,00185

\*\*Significant difference between 6 weeks after surgery and follow-up; Wilcoxon signed rank test; significance level = 0,00185

\*\*\*Significant difference between preoperative and follow-up; Wilcoxon signed rank test; significance level = 0,00185

Table 8: POP-Q overview for posterior mesh without women lost to follow-up

	<u>Preoperative</u> (N=26)		<u>6 weeks</u> (N=26)		<u>Follow-up</u> (N=26)	
	Mean	Std	Mean	Std	Mean	Std
Ba	-1,35	0,892	-1,23	1,107	-0,85	1,461
C <sup>*</sup>	-3,42	2,873	-6,12	2,233	-5,62	1,768
Bp <sup>**,***</sup>	2,42	1,447	-1,92	0,744	-2,19	0,634

\*Significant difference between preoperative and 6 weeks after surgery; Wilcoxon signed rank test; significance level = 0,00185

\*\*Significant difference between preoperative and follow-up; Wilcoxon signed rank test; significance level = 0,00185

When the numerical data is characterized into the different stages of prolapse it shows that all women had a posterior prolapse of stage two or higher (table 9). Six weeks after surgery and at follow-up the prolapses at the posterior site decreased to stage two or less.

**Table 9: POP-Q stages for posterior mesh**

	<u>Preoperative</u> (N = 30)		<u>6 weeks</u> (N = 30)		<u>Follow-up</u> (N = 26)	
	N	%	N	%	N	%
<b>Anterior</b>						
Stage 0	0	0%	0	0%	1	3,8%
Stage 1	15	50%	15	50%	10	39%
Stage 2	14	47%	14	47%	14	54%
Stage 3	1	3,3%	1	3,3%	1	3,8%
Stage 4	0	0%	0	0%	0	0%
<b>Apical</b>						
Stage 0	21	70%	28	93%	24	92%
Stage 1	7	23%	0	0%	1	3,8%
Stage 2	1	3,3%	2	6,7%	1	3,8%
Stage 3	0	0%	0	0%	0	0%
Stage 4	1	3,3%	0	0%	0	0%
<b>Posterior</b>						
Stage 0	0	0%	5	17%	8	31%
Stage 1	0	0%	21	70%	15	58%
Stage 2	5	17%	4	13%	3	12%
Stage 3	25	83%	0	0%	0	0%
Stage 4	0	0%	0	0%	0	0%

### **Total mesh**

Preoperative, POP-Q data of all 53 women were available, six weeks after surgery data of 51 women were available and at follow-up data of 39 women. Table 10 provides an overview of the POP-Q and the changes after surgery with a total transvaginal mesh. Table 11 displays an overview of the women without those who got lost to follow-up. Ba decreases significantly between preoperative and 6 weeks after surgery and to follow-up. C decreases significantly between all moments in time. Bp decreases significantly between preoperative and six weeks after surgery and to follow-up. Ba and Bp did not change significantly between six weeks after surgery and follow-up. Table 12 displays the Wilcoxon test values and p-values.

Table 10: POP-Q overview for total mesh

	<u>Preoperative</u> (N = 53)		<u>6 weeks</u> (N = 51)		<u>Follow-up</u> (N = 39)	
	Mean	Std	Mean	Std	Mean	Std
<b>Anterior</b>						
Aa	1,4	1,6	-1,6	0,7	-1,7	0,6
Ba <sup>*,***</sup>	2,1	2,1	-1,5	0,7	-1,7	0,6
<b>Apical</b>						
C <sup>*,**,***</sup>	-1,7	3,7	-6,6	1,4	-5,2	3,0
D	-0,2	3,9	-6,1	1,0	-5,7	2,7
<b>Posterior</b>						
Ap	0,4	1,5	-1,8	0,5	-2,1	0,3
Bp <sup>*,***</sup>	0,6	1,9	-1,8	0,5	-2,1	0,3
GH	5,0	1,1	3,9	0,9	3,9	1,1
PB	3,1	0,5	3,0	0,3	3,4	0,7
TVL	8,9	1,1	8,2	1,1	8,3	1,2

\*Significant difference between preoperative and 6 weeks after surgery; Wilcoxon signed rank test; significance level = 0,00185

\*\*Significant difference between 6 weeks after surgery and follow-up; Wilcoxon signed rank test; significance level = 0,00185

\*\*\*Significant difference between preoperative and follow-up; Wilcoxon signed rank test; significance level = 0,00185

Table 11: POP-Q overview for total mesh without women lost to follow-up

	<u>Preoperative</u> (N=39)		<u>6 weeks</u> (N=39)		<u>Follow-up</u> (N=39)	
	Mean	Std	Mean	Std	Mean	Std
Ba <sup>*,***</sup>	1,97	2,096	-1,46	0,757	-1,67	0,621
C <sup>*,**,***</sup>	-2,15	3,829	-6,61	1,498	-5,18	2,964
Bp <sup>*,***</sup>	0,67	2,043	-1,84	0,437	-2,05	0,32

\*Significant difference between preoperative and 6 weeks after surgery; Wilcoxon signed rank test; significance level = 0,00185

\*\*Significant difference between 6 weeks after surgery and follow-up; Wilcoxon signed rank test; significance level = 0,00185

\*\*\*Significant difference between preoperative and follow-up; Wilcoxon signed rank test; significance level = 0,00185

**Table 12: Wilcoxon signed rank test outcomes for total mesh**

	<u>All women with total mesh</u>		<u>Without women lost to follow-up</u>	
	<u>Wilcoxon</u>	<u>p</u>	<u>Wilcoxon</u>	<u>p</u>
<b>Ba</b>				
<i>preoperative - 6 weeks</i>	-5,926	< 0,001	-5,095	< 0,001
<i>6 weeks- follow-up</i>	-1,489	0,137	-1,489	0,137
<i>preoperative - follow-up</i>	-5,13	< 0,001	-5,13	< 0,001
<b>C</b>				
<i>preoperative - 6 weeks</i>	-6,152	< 0,001	-5,293	< 0,001
<i>6 weeks- follow-up</i>	-3,852	< 0,001	-3,852	< 0,001
<i>preoperative - follow-up</i>	-4,119	< 0,001	-4,119	< 0,001
<b>Bp</b>				
<i>preoperative - 6 weeks</i>	-5,675	< 0,001	-4,894	< 0,001
<i>6 weeks- follow-up</i>	-2,138	0,033	-2,138	0,033
<i>preoperative - follow-up</i>	-5,276	< 0,001	-5,276	< 0,001

Categorization of the data into the prolapse stages is shown in table 13. This table demonstrates that women who received a total Prolift™ had a anterior and posterior prolapse of stage one to three and a apical prolapse of stage zero to four. At the six weeks after surgery examination all prolapses in all compartments were of stage two or smaller. At follow-up the anterior and posterior prolapses were of stage two or less and the number of women without a prolapse (stage zero) increased in both compartments. At follow-up there were four recurrent prolapse stage two-four of the apical compartment instead of none at six weeks postoperative.

**Table 13: POP-Q stages for total mesh**

	<u>Preoperative</u> (N = 53)		<u>6 weeks</u> (N = 51)		<u>Follow-up</u> (N = 39)	
	N	%	N	%	N	%
<b>Anterior</b>						
Stage 0	0	0%	0	0%	3	7,7%
Stage 1	5	9,4%	33	65%	22	56%
Stage 2	11	21%	18	35%	14	36%
Stage 3	37	70%	0	0%	0	0%
Stage 4	0	0%	0	0%	0	0%
<b>Apical</b>						
Stage 0	31	59%	50	98%	33	85%
Stage 1	2	3,8%	1	2,0%	2	5,1%
Stage 2	10	19%	0	0%	2	5,1%
Stage 3	9	17%	0	0%	1	2,6%
Stage 4	1	1,9%	0	0%	1	2,6%
<b>Posterior</b>						
Stage 0	0	0%	1	2,0%	3	7,7%
Stage 1	6	11%	38	75%	35	90%
Stage 2	29	55%	12	24%	1	2,6%
Stage 3	18	34%	0	0%	0	0%
Stage 4	0	0%	0	0%	0	0%

### 5.2.1 Anatomical success

Anatomical success of the implantation of mesh is defined as the absence of a prolapse of stage two or higher in the treated compartment at follow-up. Table 14 shows the success rates per implant type. It shows that the anterior and posterior mesh type have a success rate of 81% and 89%. The total mesh showed anatomical success in 56%. In total, 58 mesh surgeries (72%) were considered anatomical successful at follow-up.

**Table 14: Anatomical success per mesh type at follow-up**

	<u>N</u>	<u>%</u>
Anterior mesh (N = 16)	13	81%
Posterior mesh (N = 26)	23	89%
Total mesh ( N = 39)	22	56%
Total (N = 81)	58	72%

## 5.3 Complications

The complications that occurred are described following the IUGA/ICS complication classification. Fifty-two women (62%) did not suffer any complications at any time of the follow-up period. Twenty-eight of these women received a total mesh, 15 a posterior mesh and nine an anterior mesh. The unique IUGA/ICS complication classification codes of the women who did have a complication are summarized in table 15. For the corresponding complications presented by the different codes, see appendix A. Some of these codes appeared several times, in total 37 complications occurred in 32

women (38%). Eleven complications occurred in the group of women who received an anterior mesh, divided over eight women (N anterior mesh = 22; 36%). Fourteen complications occurred in 13 women (N posterior mesh = 30; 43%) with a posterior mesh and eleven complications occurred in eleven women with a total mesh implant (N total mesh = 53; 21%). Most women had a 1B complication, which corresponds with unusual discomfort, pain, dyspareunia or bleeding. Ten of the category one complications occurred in the group of women who received a totalis implant. Nine of them received a posterior implant, and five received an anterior implant. Seven women (8,3%) had some kind of erosion during follow up (category 2 or 3). Three of these erosions appeared in women who received an anterior implant. In both women with a posterior mesh and with total mesh two cases of erosion occurred. Three women underwent a reoperation to correct an occurred complication: one woman was treated for pain complaints and two for the correction of erosion. There were three women with multiple complications. Two of them had two types of complications (a category one and seven; and a category three and four). The other woman presented with four different types of complications in the follow-up time. She had two category six complications, one category seven and one category two complication. She received an anterior mesh.

**Table 15: Occurred complications according to the IUGA/ICS classification of complications**

1	2	3	4	6	7
1AaT4S1 (2x)	2AaT4S1	3AaT3S1	4AxT1S1	6BeT3S4	7A T2S2
1AaT4S3 (3x)	2B T4S1	3B T4S2		6BeT4S1	7AeT1S3
1BbT3S1	2BeT4S1	3BaT4S1			7AeT2S4
1BbT4S1 (6x)	2BxT3S1				
1BbT4S2 (3x)					
1BbT4S3 (4x)					
1BcT3S2					
1BcT3S3					
1BcT4S3					
1BdT4S3					
1BeT4S2					

## 5.4 Reoperations

A total of 21 reoperations were performed on 19 different women (18%). Eight of these women received a total transvaginal mesh. Six women received a posterior mesh and five women an anterior mesh. Eleven women needed an additional surgery to correct stress urinary incontinence (Tension free Vaginal Tape). Six new prolapse surgeries were performed, of which four were done with the insertion of a new mesh implant in another compartment. One woman with an anterior mesh developed a posterior prolapse for which she was treated with a Prolift™ posterior. One woman with an anterior mesh developed a new anterior prolapse and was treated with a Prolift™ anterior. Two women with a posterior mesh developed an anterior prolapse for which they were treated with a Prolift™ anterior. One woman underwent a hysterectomy. As mentioned earlier three women underwent a surgery to correct a complication due to the earlier implanted mesh. One patient had to undergo reoperation because of pain complaints, and in two patients mesh erosion was corrected operatively.

## 5.5 Urinary problems

Table 16 provides an overview of the mean values of the UDI for each domain. The table shows that after surgery all five domains reduce in value. The absolute difference between the preoperative UDI scores and follow-up score is the largest for genital prolapse and smallest for urinary incontinence. All domains, except urinary incontinence, improve significantly.

**Table 16: Overview of UDI domains preoperative and at follow-up**

	Preoperative			Follow-up			Wilcoxon	p
	Number	Mean	Std	Number	Mean	Std		
Overactive bladder*	97	27,9	25,8	90	21,3	24,7	-3,797	<0,001
Urinary incontinence	97	24,6	27,3	91	22,9	22,5	-0,681	0,496
Obstructive micturation*	97	26,8	29,8	90	15,0	20,0	-3,479	0,001
Pain*	97	38,0	32,1	90	15,0	22,9	-5,985	<0,001
Genital prolapse*	97	59,5	30,5	89	3,9	12,3	-7,471	<0,001

\*Significant difference between preoperative UDI and follow-up; Wilcoxon signed rank test; significance level = 0,005

Since the variables are not normal divided the median should be the value that needs to be displayed in order to summarize the data. But this resulted in a distorted way of displaying these data. Therefore, the mean is given in table 16 and in table 17 the numbers and percentages of the values zero and larger than zero are given for a complete overview of the data concerning urinary problems.

**Table 17: Scores 0 and larger than 0 for UDI domains**

	Preoperative				Follow-up			
	0		> 0		0		> 0	
	Number	%	Number	%	Number	%	Number	%
Overactive bladder	26	27%	71	73%	34	38%	56	62%
Urinary incontinence	37	38%	60	62%	31	34%	60	66%
Obstructed micturation	41	42%	56	58%	49	54%	41	46%
Pain	22	23%	75	77%	55	61%	35	39%
Genital prolapse	8	8,2%	89	92%	78	88%	11	12%

### 5.5.1 Resolved urinary problems

Table 18 shows that mostly symptoms of the genital prolapse domain problems were resolved, followed by symptoms of the pain domain. The other domains are summarized in the table.

**Table 18: Resolved symptoms of the UDI domain**

	N preoperative	N resolved	%
Overactive bladder	71	18	25%
Urinary incontinence	60	11	18%
Obstructive micturation	56	22	39%
Urinary pain	75	35	47%
Genital prolapse	89	66	74%

### 5.5.2 Aggravated urinary problems

After surgery, some women experienced worsening of specific symptoms, especially urinary incontinence. Thirty women (35,7%) experienced more bother from their incontinence problems at follow-up than at preoperative measurement. This and the other domains are displayed in table 19.

**Table 19: Aggravated urinary problems**

	<b>N</b>	<b>%</b>
Overactive bladder	18	21%
Urinary incontinence	30	36%
Obstructive micturation	12	14%
Urinary pain	5	6,0%
Genital prolapse	0	0%

### 5.5.3 De novo urinary problems

Six women (7,2%) reported symptoms of de novo overactive bladder symptoms at follow-up. Significantly more women with a posterior mesh (five in total; compared with the other mesh types) had these new symptoms (chi-square 7,732;  $p = 0,021$ ). De novo urinary incontinence appeared in twelve women (14%). Ten women (12%) showed complaints of obstructive micturation that did not occur preoperatively. Two women (2,4%) experienced new complaints of pain. No women showed a genital prolapse that was de novo.

## 5.6 Bowel problems

Table 20 shows the DDI domain scores preoperative and at follow-up. Flatus incontinence scores are the highest and is the most severe problem experienced by these women. Constipation (Wilcoxon = -3,355;  $p = 0,001$ ); obstructed defecation (Wilcoxon = -3,247;  $p = 0,001$ ) and pain (Wilcoxon = -3,065;  $p = 0,002$ ) decreased significantly.

**Table 20: Overview of DDI domains**

	<b>Preoperative</b>				<b>Follow-up</b>			
	<u>Number</u>	<u>Mean</u>	<u>Range</u>	<u>Std</u>	<u>Number</u>	<u>Mean</u>	<u>Range</u>	<u>Std</u>
Constipation*	97	16,5	0-100	24,9	91	7,7	0-67	14,1
Obstructed defecation*	97	17,5	0-100	23,0	88	8,8	0-67	14,9
Pain*	97	14,6	0-100	25,4	91	5,9	0-100	17,1
Fecal incontinence	97	11,9	0-83	21,5	87	7,7	0-83	17,2
Flatus incontinence	97	34	0-100	34,8	91	26,4	0-100	30,1

\*Significant difference between preoperative and follow-up; Wilcoxon signed rank test; significance level = 0,005

Since the variables are not normal divided the median should be the value that needs to be displayed in order to summarize the data. But this resulted in a distorted way of displaying these data. Therefore, the mean is given in table 20 and in table 21 the numbers and percentages of the values zero and larger than zero are given for a complete overview of the data surrounding bowel problems.

**Table 21: Scores 0 and larger than 0 for DDI domains**

	<b>Preoperative</b>				<b>Follow-up</b>			
	<b>0</b>		<b>&gt; 0</b>		<b>0</b>		<b>&gt; 0</b>	
	<b>Number</b>	<b>%</b>	<b>Number</b>	<b>%</b>	<b>Number</b>	<b>%</b>	<b>Number</b>	<b>%</b>
Constipation	57	59%	40	41%	66	73%	25	28%
Obstructed defecation	45	46%	52	54%	54	61%	34	39%
Pain	67	69%	30	31%	77	85%	14	15%
Fecal incontinence	68	70%	29	30%	66	76%	21	24%
Flatus incontinence	40	41%	57	59%	45	50%	46	51%

### 5.6.1 Resolved bowel problems

Besides the improvement in the experience of bowel problems over time there are also women who do not experience any symptoms anymore at the follow-up measurement. Their symptoms have been resolved, or the symptoms do not cause bother anymore. The most resolved symptom is pain. Thirty women (60%) who experienced these symptoms preoperative, did not experience these anymore at follow-up. The other symptoms are displayed in table 22.

**Table 22: resolved symptoms of the DDI domains**

	<b>N preoperative</b>	<b>N resolved</b>	<b>%</b>
Constipation	40	16	40%
Obstructed defecation	52	23	44%
Pain	30	18	60%
Fecal incontinence	29	10	35%
Flatus incontinence	57	12	21%

### 5.6.2 Aggravated bowel problems

Obstructed defecation is the most experienced symptoms that got aggravated comparing preoperative and follow-up. Fifteen women (19%) experienced this aggravation. Pain is the least aggravated problem. These and the other bowel symptoms are listed in table 23.

**Table 23: Aggravated bowel problems**

	<b>N</b>	<b>%</b>
Constipation	8	9,5%
Obstructed defecation	15	19%
Pain	7	8,3%
Fecal incontinence	10	12%
Flatus incontinence	10	12%

### 5.6.3 De novo bowel problems

Five women (6,0%) presented with constipation symptoms at the follow-up measurement that were not present at the preoperative measurement. Eleven (14%) of the women suffered from new obstructed defecation. Pain was a new symptoms for four (4,8%) women. A total of fourteen women presented with de novo incontinence symptoms. Seven (8,6%) with fecal incontinence and also seven (8,3%) with flatus incontinence.

## 5.7 Sexual problems

Table 24 provides an overview of sexual activity and problems of the women in the research population. Women were considered sexual active if they stated to have sexual intercourse. Women were considered sexual inactive when they did have a partner but no sexual intercourse. The total amount of women with a partner decreases over time. The number of sexual active women decreased. In this group of sexual active women the incontinence problems increased significantly (Chi-square = 16,0;  $p < 0,001$ ) and narrowing problems decreased significantly (Chi-square = 70,4;  $p < 0,001$ ). Besides six sexual active women (14%) with problems due to feeling that the vagina is too narrow, there were two women (5,1%) who complained about that the vagina was not narrow enough at follow-up.

Table 24: Sexual problems

	<u>Preoperative</u>		<u>Follow-up</u>	
	N	%	N	%
Partner	82	85%	73	80 %
Sexual active	56	58%	43	48 %
<i>Incontinence*</i>	3	6,9%	5	9,5 %
<i>Dyspareunia</i>	43	96%	22	47 %
<i>Narrowing*</i>	40	89%	9	19 %
Sexual inactive with partner	25	26%	29	32 %
<i>Incontinence</i>	0	0%	1	3,4 %
<i>Dyspareunia</i>	4	16%	4	14 %
<i>Narrowing</i>	4	16%	3	10 %

\*Significant difference between preoperative and follow-up; Chi-square test;  $p = 0,05$

### 5.7.1 Resolved sexual problems

In several women their sexual symptoms were solved after surgery. They are no longer present or they do not bother the woman anymore. 55% of the women who experienced narrowing problems preoperatively, did no longer at follow-up. These and the percentages of the other sexual symptoms are displayed in table 25.

Table 25: Solved sexual problems

	N preoperative	N resolved	%
Incontinence	5	1	20%
Pain	59	23	39%
Narrowing	56	31	55%

### 5.7.2 Aggravated sexual problems

There were eight women (19%) in whom the pain during intercourse had aggravated after surgery. Most of these women (five) received a posterior implant. Two received a total implant and one received an anterior implant (Chi-square = 6,121;  $p = 0,047$ ). Six women (14,0%) experienced more problems with intercourse because of the feeling of a narrow vagina. And two women (4,7%) had

aggravated incontinence during sexual intercourse. Both of these women received an anterior implant.

### 5.7.3 De novo sexual problems

Of all sexual active women two (4,7%) suffered from de novo incontinence during sexual intercourse. Both of them had an anterior implant. One of the sexual inactive women (3,4%) had de novo problems with narrowing of the vagina at follow-up. This woman received a total implant. No women, sexual active or inactive, reported de novo dyspareunia.

## 5.8 Quality of life

The mean general quality of life preoperatively was 6,99 (N=97; 0-10) and at follow-up increased significantly to 7,36 (N= 91; 0-10) (Wilcoxon -2,470; p = 0,014). Table 26 displays a general overview of all women in the research population and their quality of life at follow-up compared to preoperative.

**Table 26: Quality of life changes at follow-up compared to preoperative**

	<b>N</b>	<b>%</b>
<b>Better</b>	<b>84</b>	<b>90%</b>
<i>Very much better</i>	20	22%
<i>Much better</i>	58	62%
<i>Little bit better</i>	6	6,5%
<b>No change</b>	<b>3</b>	<b>3,2%</b>
<b>Worse</b>	<b>6</b>	<b>6,5%</b>
<i>Little bit worse</i>	2	2,2%
<i>Much worse</i>	3	3,2%
<i>Very much worse</i>	1	1,1%

## 5.9 Patient preferences and correlations

The outcome of the AHP provides a top three symptoms which patients value in a higher matter than others. This outcome forms the base of three hypotheses for the correlation between the presence of these symptoms and the changes in the quality of life of the treated women. Chosen out of urinary problems, bowel problems and sexual problems; bowel problems are the most preferred symptom group to be solved. Table 27 shows the three most preferred individual symptoms to be solved by patients and their correlation to the quality of life patients indicate at follow-up compared to preoperative measurement. All three symptoms correlate in a significant way ( $\alpha = 0,05$ ) with the way the women feel. The Pearson values are of a negative kind, which means that the quality of life improves when the mean values of the symptoms decrease. Solid stool incontinence is the most contributing symptom for the quality of life that is experienced. Liquid stool incontinence is the third most contributing symptom to the quality of life. Genital prolapse is the seventh most contributing (in a group of 13 symptoms) symptom to the quality of life.

Table 27: AHP outcome and correlation of symptoms to quality of life

<u>Symptom</u>	AHP	<u>Correlated to quality of life</u>	
		Pearson	P
Genital prolapse	0,148	-0,211	0,047
Liquid stool incontinence	0,138	-0,41	<0,001
Solid stool incontinence	0,104	-0,502	<0,001
Urge incontinence	0,075	-0,385	<0,001
Incontinence during sexual intercourse	0,075	-0,477	0,001
Pain during defecation	0,073	-0,011	0,921
Flatus incontinence	0,065	-0,252	0,016
Narrowing	0,058	-0,091	0,537
Manual guidance of defecation	0,056	0,047	0,663
Pain during sexual intercourse	0,056	-0,098	0,512
Stress incontinence	0,055	-0,368	<0,001
Voiding pain	0,055	-0,195	0,066
Voiding frequency	0,042	-0,179	0,09

### 5.9.1 Preferred symptoms to be solved and quality of life

The three most preferred symptoms to be solved by patients are displayed in table 28. These are distinguished for the different indicators for quality of life. The table shows that the mean scores for the different groups are higher when the quality of life of the woman is worse.

Table 28: Most preferred symptoms for quality of life changes

	<u>Genital prolaps</u>		<u>Liquid stool incontinence</u>		<u>Solid stool incontinence</u>	
	<u>Mean</u>	<u>Std</u>	<u>Mean</u>	<u>Std</u>	<u>Mean</u>	<u>Std</u>
<b>Better</b>	<b>2,71</b>	<b>10,085</b>	<b>7,53</b>	<b>16,738</b>	<b>2,51</b>	<b>8,798</b>
<i>Very much better</i>	1,74	7,571	6,95	13,822	1,74	7,571
<i>Much better</i>	3,35	11,319	5,5	12,414	2,44	8,724
<i>Little bit better</i>	0		27,67	28,95	5,5	13,472
<b>No change</b>	<b>16,67</b>	<b>16,503</b>	<b>22,33</b>	<b>38,682</b>	<b>33,33</b>	<b>57,735</b>
<b>Worse</b>	<b>14</b>	<b>26,84</b>	<b>39</b>	<b>32,955</b>	<b>40,2</b>	<b>36,697</b>
<i>Little bit worse</i>	33,5	47,376	67	0	67	0
<i>Much worse</i>	5,67	9,815	11	19,053	0	0
<i>Very much worse</i>	0		67		67	

## 6. Discussion

Of all 105 treated women baseline physical and surgical data were available. 97 (92%) of them also filled out the first questionnaire about occurring symptoms and quality of life. Nearly all women (103; 98%) came back for the six-week check-up. At the follow-up moment there were 13 women lost for different reasons, like moving away, dementia or just not wanting to participate anymore. Especially this last group is interesting. A possible reason for not wanting to participate in this research could be the satisfied state in which these women are in. Another reason could be that their health situation concerning their prolapse treatment is so bad that they no longer want to participate in this research. The women who were lost in follow-up without known reason were not asked why they no longer wanted to participate, so their motivation stays unknown. More than three quarters of the original group underwent a new physical examination and more than 85% filled out the questionnaire at follow-up.

The median follow-up time was 35 months. The six weeks check-up period was predefined, but the time between the surgery and the follow-up examination was more flexible. This resulted in women who had a follow-up period between 11 months and 64 months. The long follow-up time provides the possibility for gathering a wide range of data on several moments in time. Therefore the available data was large and widespread. A possible difficulty with the wide range in follow-up time is that it becomes more difficult to compare data between these women. Since there is a possibility that a woman with a large follow-up period developed more complications or other outcome measures than a woman with a much shorter follow-up period. With the widespread follow-up time, and the great differences between individual women, a problem for a good benchmark occurs.

Half of the women received a total mesh implant, slightly more than 20% received an anterior mesh and the others a posterior mesh implant. The anatomical success of the anterior mesh was 81%, the posterior mesh was 89% and the total mesh was 56%. This is a much smaller group than the other mesh types. All these types of meshes combined gives a total anatomical success rate of 72%. This is 15% lower than the anatomical success that is described in literature (87%) (3).

A in literature described major benefit of mesh implant in the treatment of POP is the low recurrence rate. The recurrence rate in this group is 18%. This is more than 10% lower than described in literature, where the recurrence rate is determined at 29% (4;5).

A total of 37 different complications were defined in 32 different women (38%). The most described complication in literature for mesh treatments is erosion. In literature, erosion rates between 7% and 20% are described (3;8). Seven women (8,3%) in this group had some kind of erosion. This is between the range that is described in literature. Three women underwent surgery to correct some kind of complication, one to correct pain complaints and two for treatment of erosion.

A predefined problem with mesh treatment for POP was de occurring of de novo incontinence problems. 14% of the women in this research experienced these symptoms, which corresponds to the percentage mentioned in literature (10).

De novo dyspareunia is mentioned in literature as a major risk in the use of meshes, but none of the women in this research group suffered from de novo dyspareunia. In literature an overall rate for de novo dyspareunia of 9,1% is described (11). However, the reason for women with a partner not to be sexual active is not known. This does not necessarily have its cause in the prolapse problems. The

health situation of the partner, a low need for sexual contact or other factors could be involved in the sexual activity of the women in the research population.

More than 90% of the women in this research group indicate to feel better than before surgery. Nearly one out of five women in this group say that they feel very much better than before. And more than 60% of the group feels much better. 6,5% of the women feel worse in some extent. In 2010, 87% of the Dutch population stated that they were happy with life, which corresponds with the more than 90% in this group that feels better than before (53). The way in which these women feel is just a one-moment registration. It is very difficult to determine whether or not this subjective measure of the quality of life that is used, is corresponding with their situation surrounding the aftermath of their prolapse. The indication the women give for their situation at the present moment compared to their situation before surgery can be influenced by many other factors that do not correlate with their prolapse.

Looking at the three major groups of symptoms that are defined surrounding the prolapses, urinary; bowel and sexual, the women who got the chance to express their preferences selected bowel symptoms as the most preferred symptom group to be solved. Looking at single symptoms the most preferred symptom to be solved was visible or tangible genital prolapse, followed by liquid stool incontinence and solid stool incontinence. The genital prolapse problems decreased significantly after surgery which is also seen by Ignjatovic et al. (12). Of nearly three quarters of the women, their genital prolapse problems were solved at follow-up. This is much lower than the percentage of the resolution of these problems that Gad et al. report. Their research showed a resolution rate of 91,6 till 100% (13). None of the women experienced aggravated problems and also none experienced de novo genital prolapse problems. Treatment did not cause a significant decrease in the bother women experienced for fecal incontinence symptoms after surgery. More than one out of three women with fecal incontinence problems did see her problems be solved at follow-up. In 12% of the women her fecal incontinence problems got aggravated and 8,6% experienced new fecal incontinence problems at follow-up. Most performed researches on the outcomes of mesh treatment focus mainly on urinary problems and their outcomes. This makes it undoable to compare the bowel outcomes of this research in a right manner to other research outcomes. And therefore makes it impossible to place them in good reference.

The top three symptoms that resulted from this analysis were also in the top of most contributing symptoms to the situation women count themselves into comparing their quality of life before and after the treatment. There were not that many women who participated in the AHP analysis, which resulted in a consulting role for the outcome of the analysis, instead of an exclusive outcome for the most influential domains. Because of the small amount of women involved in the AHP analysis, the outcomes should be read and interpreted with care. They could only be used as indicators for the patient preferences. The outcomes of the AHP combined with the correlation tests provide a way in which hospitals can improve their way of comparing their outcome with each other. When major differences occur between hospitals in performances on certain symptoms, the AHP indicates the importance of these differences. The importance increases when patients highly prefer these symptoms. Major differences in performance on symptoms that are preferred less, become less important. The use of the AHP analysis enabled this research to come to focus areas in a large amount of possible important symptoms for patients. These focus areas make it possible to do a

funded benchmarking with a substantiated choice between symptoms to focus on, and to compare between hospitals.

Benchmarking should result in an indication of the best practice for this treatment. But because of lack of good comparable research results it is not possible yet to conclude something about this matter.

Some last points that needed to be taken into account when the results and conclusions of this research are read is that due to the chosen research design there was only data available of women treated in the same hospital. This is a limitation for the possibilities to generalize the outcomes of the research. And it could be of influence for the women included in the research. It could be possible that certain types of women do not get treatment in this hospital, but somewhere else. Besides that, in literature is described that the outcomes of this treatment can be influenced by the experience of the surgeon. This could not be taken into account in this research. Besides the research design, there is the problem with the small amount of women that participated in the AHP analysis; the wide range on the follow-up period and the lack of comparative literature in order to put the results of this research in perspective.

Even though there are many concerns about this type of treatment for prolapse, this research has shown that not all of them are funded in this group of women. Some objectives score much better and others not so good as it could be. But the most important thing seems to be that more than 90% of the women in this research indicate that their quality of life has improved after surgery.

## 7. Conclusion

Gelre hospital Apeldoorn performed diversified on the different performance indicators. The overall anatomical success rate was not as high as described in literature (71,6% versus 87% (3)). Nearly 40% of the women in this research suffered from some kind of complication, which is a large group. 8,3% suffered from erosion, which is within the literature range (3;8). The hospital performed very well on de novo dyspareunia symptoms. None of the women in this group suffered from this symptom. De novo incontinence problems, another described problem with vaginal mesh implants, scored comparable with literature (10). 14% of the women in this group suffered from this symptom. The average rate for the quality of life improved significantly over time from 6,99 till 7,36. Besides that, 90% of the women indicated that their situation improved after surgery.

Of the three main groups of symptoms patients prefer bowel symptoms to be solved after surgery the most. Looking at individual symptoms, visible or tangible genital prolapse, solid stool incontinence and liquid stool incontinence are the three most preferred symptoms to be solved by treatment. Genital prolapse was solved for 74% of the women. This is not nearly as high as described in literature (91,6-100% (13)). The Prolift™ treatment did not cause a significant decrease in the problems women experience from fecal incontinence.

This research resulted in a wide range of available analysis and overviews of many different factors involved in prolapse. This is one of the strong points of this research. Because of the various moments in time on which data was possibly collected and the wide range of types of data collected, a large diversity existed. Another strong point was the high response rate, not only at the six-week point, but also at follow-up. Due to the design of this research a wide range of follow-up periods existed. This could become a problem in analyzing the data. Because of the large differences between women, outcomes could be different due to time. This also could be a problem in conducting a benchmark between hospitals. Another problem with this research was the small amount of women participating in the AHP analysis. Therefore these outcomes need to be read with care. And at last there were some difficulties with finding good reference material for some objectives in this research. The main focus of many articles at this moment lies on urinary problems after vaginal mesh treatment. Therefore it became difficult to place the outcomes on bowel problems in a good perspective. Nevertheless, this research makes a good starting point for the performance of a benchmark between Dutch hospitals concerning vaginal mesh treatment for POP.

## 8. Further research

For gynecologists, to be able to inform the patients in the best possible way it is important to extend the AHP study into a much larger group of women. A larger research population leads to a more reliable ranking of the symptoms that women most preferably want to be improved by the treatment. These rankings can be compared to the actual outcome of the treatment. These together give a good insight in the similarities and differences between both. This information can be used on forehand of the surgery to prevent false hopes in women who want something to be improved that often does not improve that much.

To improve the possibilities to perform a good benchmark between different hospitals the current research needs to be extended. Several hospitals need to be included in the research design. In the case that exactly the same research is done in different hospitals differences between these can be found. And a good judgment can be made about the performances of these hospitals.

Literature shows an overwhelming amount of information about urinary problems that occur surrounding prolapse. Bowel symptoms and the problems they cause are much less described. This research showed the importance of bowel problems to patients. The amount of research about bowel problems as symptom of prolapse should increase to be able to compare this research to other outcomes.

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**10. Appendix**

## Appendix A : ICS complication classification overview



Joint project of the International Continence Society  
and the International Urogynecological Association

**Prosthesis/Graft Complication Classification Code:**  [+ Native Tissue Calculator](#)

**Category Required**

**Category:**

**1 - Vaginal: no epithelial separation**  
Include prominence (e.g. due to wrinkling or folding), mesh fibre palpation or contraction (shrinkage)

**2 - Vaginal: smaller ≤ 1cm exposure**

**3 - Vaginal: larger >1cm exposure (or any extrusion)**

**4 - Urinary Tract**  
Compromise or perforation. Including prosthesis (graft) perforation, fistula and calculus

**5 - Rectum or Bowel**  
Compromise or perforation. Including prosthesis (graft) perforation and fistula

**6 - Skin and / or musculoskeletal**  
Complications including discharge pain lump or sinus tract formation

**7 - Patient compromise**  
Including hematoma or systemic compromise

**Division:**

---

**Pain:**

**Unspecified**

**a - Asymptomatic or no pain**

**b - Provoked pain only**  
(during vaginal examination)

**c - Pain during sexual intercourse**

**d - Pain during physical activities**

**e - Spontaneous pain**

**Time:**

**T1 - Intraoperative to 48 hours**

**T2 - 48 hours to 2 months**

**T3 - 2 months to 12 months**

**T4 - over 12 months**

**Site:**

**S0 - No site applicable**

**S1 - Vaginal: area of suture line**

**S2 - Vaginal: away from area of suture line**

**S3 - Trochar passage (except intra-abdominal)**

**S4 - Other skin or musculoskeletal site**

**S5 - Intra-abdominal**

Source: <http://www.icsoffice.org/complication>

## Appendix B: Calculated values overview

<b><u>Term</u></b>	<b><u>Based on questions</u></b>
<b>UDI</b>	
Overactive bladder	7; 8 and 18
Incontinence	9 and 10
Obstructed micturation	11 and 12
Pain	13 and 14
Genital prolapse	15 and 16
<b>DDI</b>	
Constipation	19 and 20
Obstructed defecation	21; 22; 28 and 29
Pain	23 and 24
Fecal incontinence	25 and 26
Flatus incontinence	27
<b>Sexual</b>	
Sexual contact	43
Incontinence	45
Pain	46
Narrowing	47

For the calculated value, sum per question part a and b (yes = 1; no = 2; not at all = 1; a little bit = 2; quite = 3 and a lot = 4). Then sum all questions involved. Take the average of this, minus 2 and times 100/3.

### **Example:**

Score = (average question 7, 8 and 18) – 2 \* 100/3



1 Helemaal niet      2 Een beetje      3 Nogal      4 Heel erg

c. Hoe vaak verliest u ongewild urine als u aandrang voelt om te plassen?

- 0. nooit
- 1. dagelijks
- 2. paar keer per week
- 3. 1 keer per week
- 4. 1 keer per maand
- 5. 1 keer per jaar

10. a. Heeft u ongewenst urineverlies bij lichamelijke inspanning, hoesten of niezen?

1 Ja      2 Nee (ga naar 11 en omcirkel bij 10c "nooit")

↓

b. Zo ja, hoeveel last heeft u hier van ?

1 Helemaal niet      2 Een beetje      3 Nogal      4 Heel erg

c. Hoe vaak verliest u ongewild urine bij lichamelijke inspanning, hoesten of niezen?

- 0. nooit
- 1. dagelijks
- 2. paar keer per week
- 3. 1 keer per week
- 4. 1 keer per maand
- 5. 1 keer per jaar

11. a. Heeft u moeite uw blaas leeg te plassen?

1 Ja      2 Nee (ga naar 12.)

↓

b. Zo ja, hoeveel last heeft u hier van ?

1 Helemaal niet      2 Een beetje      3 Nogal      4 Heel erg

12. a. Heeft u wel eens het gevoel dat de blaas na het plassen niet helemaal leeg is?

1 Ja      2 Nee (ga naar 13.)

↓

b. Zo ja, hoeveel last heeft u hier van ?

1 Helemaal niet      2 Een beetje      3 Nogal      4 Heel erg

13. a. Heeft u wel eens een drukkend gevoel onder in de buik?

1 Ja      2 Nee (ga naar 14.)

↓

b. Zo ja, hoeveel last heeft u hier van ?

1 Helemaal niet      2 Een beetje      3 Nogal      4 Heel erg

14. a. Heeft u wel eens pijn onder in de buik of in de schaamstreek?

1 Ja      2 Nee (ga naar 15.)

↓

b. Zo ja, hoeveel last heeft u hier van?

1 Helemaal niet      2 Een beetje      3 Nogal      4 Heel erg

15. a. Heeft u wel eens het gevoel dat er iets uit de vagina stulpt?

1 Ja      2 Nee (ga naar 16.)

↓

Vragenlijstbekkenbodembest. voorbehandeling versie 1.1

- b. Zo ja, hoeveel last heeft u hier van?  
 1 Helemaal niet      2 Een beetje      3 Nogal      4 Heel erg
16. a. Heeft u wel eens gezien dat er iets uit de vagina stulpt?  
 1 Ja      2 Nee (ga naar 17.)  
 ↓  
 b. Zo ja, hoeveel last heeft u hier van?  
 1 Helemaal niet      2 Een beetje      3 Nogal      4 Heel erg
17. Hoe vaak heeft u het afgelopen jaar een blaasontsteking gehad?  
 0              Nooit  
 1              1 keer  
 2              tussen de 2 en 4 keer  
 3              meer dan 4 keer
18. a. Moet u 's nachts meer dan 1 keer plassen?  
 1 Ja      2 Nee (ga naar 19.)  
 ↓  
 b. Zo ja, hoeveel last heeft u hier van?  
 1 Helemaal niet      2 Een beetje      3 Nogal      4 Heel erg

---

*De navolgende verschijnselen zijn beschreven door vrouwen met klachten van de stoelgang. Geef u aan welke verschijnselen u tegenwoordig herkent en hoeveel last u daarvan heeft.*

---

19. a. Heeft u minder dan driemaal per week ontlasting?  
1 Ja      2 Nee (ga naar 20.)  
    ↓  
    b. Zo ja, hoeveel last heeft u hier van?  
        1 Helemaal niet      2 Een beetje      3 Nogal      4 Heel erg
20. a. Moet u om ontlasting te krijgen in meer dan een kwart van de keren persen?  
1 Ja      2 Nee (ga naar 21.)  
    ↓  
    b. Zo ja, hoeveel last heeft u hier van?  
        1 Helemaal niet      2 Een beetje      3 Nogal      4 Heel erg
21. a. Heeft u wel eens aandrang tot ontlasting terwijl er dan op het toilet geen ontlasting komt?  
1 Ja      2 Nee (ga naar 22.)  
    ↓  
    b. Zo ja, hoeveel last heeft u hier van?  
        1 Helemaal niet      2 Een beetje      3 Nogal      4 Heel erg
22. a. Heeft u wel eens het gevoel dat er iets uit de anus hangt of er iets voor zit?  
1 Ja      2 Nee (ga naar 23.)  
    ↓  
    b. Zo ja, hoeveel last heeft u hier van?  
        1 Helemaal niet      2 Een beetje      3 Nogal      4 Heel erg
23. a. Ervaart u pijn tijdens de aandrang tot ontlasting?  
1 Ja      2 Nee (ga naar 24.)  
    ↓  
    b. Zo ja, hoeveel last heeft u hier van?  
        1 Helemaal niet      2 Een beetje      3 Nogal      4 Heel erg
24. a. Ervaart u pijn tijdens of vlak na de ontlasting?  
1 Ja      2 Nee (ga naar 25.)  
    ↓  
    b. Zo ja, hoeveel last heeft u hier van?  
        1 Helemaal niet      2 Een beetje      3 Nogal      4 Heel erg

25. a. Verliest u wel eens dunne ontlasting zonder dat u daar controle over heeft?  
 1 Ja      2 Nee (ga naar 26 en omcirkel bij 25 c “nooit”.)  
 ↓
- b. Zo ja, hoeveel last heeft u hier van?  
 1 Helemaal niet      2 Een beetje      3 Nogal      4 Heel erg
- c. Hoe vaak komt het voor?  
 0. nooit  
 1. dagelijks  
 2. paar keer per week  
 3. 1 keer per week  
 4. 1 keer per maand  
 5. 1 keer per jaar
26. a. Verliest u wel eens vaste ontlasting zonder dat u daar controle over heeft?  
 1 Ja      2 Nee (ga naar 27 en omcirkel bij 26 c “nooit”.)  
 ↓
- b. Zo ja, hoeveel last heeft u hier van?  
 1 Helemaal niet      2 Een beetje      3 Nogal      4 Heel erg
- c. Hoe vaak komt het voor?  
 0. nooit  
 1. dagelijks  
 2. paar keer per week  
 3. 1 keer per week  
 4. 1 keer per maand  
 5. 1 keer per jaar
27. a. Verliest u wel eens windjes zonder dat u daar controle over heeft?  
 1 Ja      2 Nee (ga naar 28 en omcirkel bij 27 c “nooit”.)  
 ↓
- b. Zo ja, hoeveel last heeft u hier van?  
 1 Helemaal niet      2 Een beetje      3 Nogal      4 Heel erg
- c. Hoe vaak komt het voor?  
 0. nooit  
 1. dagelijks  
 2. paar keer per week  
 3. 1 keer per week  
 4. 1 keer per maand  
 5. 1 keer per jaar
28. a. Moet u wel eens via de schede mee drukken om ontlasting te krijgen?  
 1 Ja      2 Nee (ga naar 29.)  
 ↓
- b. Zo ja, hoeveel last heeft u hier van?  
 1 Helemaal niet      2 Een beetje      3 Nogal      4 Heel erg

29. a. Moet u de ontlasting wel eens met de vingers via de anus verwijderen?  
1 Ja      2 Nee (ga naar 30.)



- b. Zo ja, hoeveel last heeft u hier van?  
1 Helemaal niet      2 Een beetje      3 Nogal      4 Heel erg

*De volgende vragen gaan over de seksualiteit. Het is de bedoeling dat u bij het beantwoorden denkt aan de situatie van de afgelopen maand. Wilt u het voor u meest passende antwoord omcirkelen.*

---

- g)** Heeft u een partner?

- 1 Ja      2 Nee (Omcirkel bij vraag 43 “nee”, bij vraag 44 “nooit” en beëindig de vragenlijst).

43. Heeft u wel eens seksueel contact met uw partner? (Denk hierbij aan *alle vormen* van seksueel contact en niet alleen aan geslachtsgemeenschap)

- 1 Ja (beantwoord ook vraag b en 44 t/m 47)      2 Nee (omcirkel 44 “nooit” en beëindig de vragenlijst)



- b. Zo ja, hoe tevreden bent u daarover?  
1 Helemaal niet      2 Een beetje      3 Nogal      4 Heel erg

44. Hoe vaak heeft u geslachtsgemeenschap?

- 0      Nooit  
1      minder dan 1 keer per maand  
2      1 tot 2 keer per maand  
3      1 keer per week  
4      meerdere keren per week

45. Verliest u wel eens urine tijdens de geslachtsgemeenschap?

- 1 Ja      2 Nee (ga naar 46)



- b. Zo ja, hoeveel last heeft u hier van?  
1 Helemaal niet      2 Een beetje      3 Nogal      4 Heel erg

46. Ervaart u pijn tijdens de geslachtsgemeenschap?

- 1 Ja      2 Nee (ga naar 47)



- b. Zo ja, hoeveel last heeft u hier van?  
1 Helemaal niet      2 Een beetje      3 Nogal      4 Heel erg

47. Is de vagina zo nauw dat geslachtsgemeenschap daardoor bemoeilijkt is?

- 1 Ja      2 Nee (beëindig de vragenlijst)



- b. Zo ja, hoeveel last heeft u hier van?  
1 Helemaal niet      2 Een beetje      3 Nogal      4 Heel erg

**Heeft u alle vragen ingevuld?**

**Hartelijk dank!**

Vragenlijstbekkenbodempoorbehandeling versie 1.1

## Appendix D: AHP questionnaire

Apeldoorn, maart 2012

Geachte mevrouw,

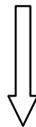
U bent recentelijk geopereerd aan een verzakking van uw vagina, blaas, endeldarm of baarmoeder. Op de polikliniek hebt u met uw gynaecoloog de operatie en de verwachtingen met betrekking tot herstel doorgesproken. Een verzakking kan vele verschillende klachten veroorzaken. Sommige klachten staan voor u mogelijk meer op de voorgrond dan andere klachten. Natuurlijk wilt u het liefst dat al uw klachten verbeteren na een operatie. Soms is dit helaas niet het geval. Wij hebben daarom telkens twee klachten tegenover elkaar gezet. U kunt daarop aangeven welke klacht voor u zwaarder weegt. Indien u één of beide klachten niet ervaart vragen wij u uw inlevingsvermogen aan te spreken en op basis daarvan een keuze te maken.

Milou Scheltes, onderzoeker Universiteit Twente

Dr. G van de Pol, gynaecoloog Gelre Ziekenhuizen

Dr. W.A. Spaans, gynaecoloog Gelre Ziekenhuizen

Hieronder volgt een voorbeeld:



	9	8	7	6	5	4	3	2	1	2	3	4	5	6	7	8	9	
<b>Pijn bij het plassen</b>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<b>Vaak moeten plassen</b>											

Als u het getal één (1) in het midden aanvinkt, dan zijn de klachten “pijn bij het plassen” en “vaak moeten plassen” voor u even belangrijk om verholpen te worden. In het bovenstaande voorbeeld is vijf (5) aangevinkt. In dit voorbeeld is er dus een voorkeur “om pijn bij het plassen” te verhelpen ten opzichte van “vaak moeten plassen” als hiertussen gekozen zou kunnen worden.

Nr.	Betekenis
1	Beide klachten even belangrijk om te verhelpen
3	Iets belangrijker om te verhelpen
5	Veel belangrijker om te verhelpen
7	Heel veel belangrijker om te verhelpen
9	Extreem veel belangrijker om te verhelpen
2,4,6,8	Tussenliggende waardes

## Categorie klachten

Kunt u van de onderstaande groepen klachten aangeven of u deze ervaart.

	Ja	Nee
Klachten met het plassen	<input type="radio"/>	<input type="radio"/>
Klachten met de ontlasting	<input type="radio"/>	<input type="radio"/>
Klachten met vrijen	<input type="radio"/>	<input type="radio"/>

Kunt u nu in de onderstaande keuzemogelijkheden aangeven welke groep klachten u het liefst verbeterd wilt zien na de behandeling? Indien u één of beide klachten niet ervaart vragen wij u uw inlevingsvermogen aan te spreken en op basis daarvan een keuze te maken.

	9	8	7	6	5	4	3	2	1	2	3	4	5	6	7	8	9	
Klachten met plassen	<input type="radio"/>	Klachten met de ontlasting																
Klachten met ontlasting	<input type="radio"/>	Klachten met vrijen																
Klachten met vrijen	<input type="radio"/>	Klachten met het plassen																

## Klachten met het plassen

Kunt u van de onderstaande klachten aangeven of u deze ervaart

	Ja	Nee
Vaak moeten plassen	<input type="radio"/>	<input type="radio"/>
Urineverlies bij inspanning, hoesten, niezen	<input type="radio"/>	<input type="radio"/>
Urineverlies bij aandrang om te plassen	<input type="radio"/>	<input type="radio"/>
Pijn bij het plassen	<input type="radio"/>	<input type="radio"/>
Zichtbaar of voelbaar iets uit de vagina	<input type="radio"/>	<input type="radio"/>

Kunt u in de onderstaande keuzemogelijkheden aangeven welke klacht u het liefst verbeterd wilt zien na de behandeling?

Indien u één of beide klachten niet ervaart vragen wij u uw inlevingsvermogen aan te spreken en op basis daarvan een keuze te maken.

	9	8	7	6	5	4	3	2	1	2	3	4	5	6	7	8	9	
Vaak moeten plassen	<input type="radio"/>	Urineverlies bij inspanning																
Urineverlies bij inspanning	<input type="radio"/>	Urineverlies bij aandrang																
Urineverlies bij aandrang	<input type="radio"/>	Pijn bij het plassen																
Pijn bij het plassen	<input type="radio"/>	Zichtbaar of voelbaar iets uit de vagina																
Vaak moeten plassen	<input type="radio"/>	Urineverlies bij aandrang																
Urineverlies bij	<input type="radio"/>	Pijn bij het plassen																

inspanning																	
Urineverlies bij aandrang	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	Zichtbaar of voelbaar iets uit de vagina
Vaak moeten plassen	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	Pijn bij het plassen
Urineverlies bij inspanning	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	Zichtbaar of voelbaar iets uit de vagina
Vaak moeten plassen	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	Zichtbaar of voelbaar iets uit de vagina

## Klachten met de ontlasting

Kunt u van de volgende klachten aangeven of u deze ervaart

	Ja	Nee
Vergemakkelijken van de ontlasting met de vingers via de schede of anus	<input type="radio"/>	<input type="radio"/>
Pijn bij ontlasting	<input type="radio"/>	<input type="radio"/>
Ongecontroleerd verlies van dunne ontlasting	<input type="radio"/>	<input type="radio"/>
Ongecontroleerd verlies van vaste ontlasting	<input type="radio"/>	<input type="radio"/>
Ongecontroleerd verlies van windjes	<input type="radio"/>	<input type="radio"/>

Kunt u in de onderstaande keuzemogelijkheden aangeven welke klacht u het liefst verbeterd wilt zien na de behandeling.

Indien u één of beide klachten niet ervaart vragen wij u uw inlevingsvermogen aan te spreken en op basis daarvan een keuze te maken.

	9	8	7	6	5	4	3	2	1	2	3	4	5	6	7	8	9	
Vergemakkelijken van ontlasting met vingers via schede of anus	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	Pijn bij ontlasting
Pijn bij ontlasting	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	Ongecontroleerd verlies van dunne ontlasting
Ongecontroleerd verlies van dunne ontlasting	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	Ongecontroleerd verlies van vaste ontlasting
Ongecontroleerd verlies van vaste ontlasting	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	Ongecontroleerd verlies van windjes
Vergemakkelijken van ontlasting met vingers via schede of anus	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	Ongecontroleerd verlies van dunne ontlasting
Pijn bij ontlasting	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	Ongecontroleerd verlies van vaste ontlasting
Ongecontroleerd verlies van dunne ontlasting	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	Ongecontroleerd verlies van windjes
Vergemakkelijken van ontlasting met vingers via schede of anus	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	Ongecontroleerd verlies van vaste ontlasting

Pijn bij ontlasting	<input type="radio"/>	Ongecontroleerd verlies van windjes																
Vergemakkelijken van ontlasting met vingers via schede of anus	<input type="radio"/>	Ongecontroleerd verlies van windjes																

### Klachten met vrijen

Kunt u van de onderstaande klachten aangeven of u deze ervaart

	Ja	Nee
Incontinentie tijdens de geslachtsgemeenschap	<input type="radio"/>	<input type="radio"/>
Pijn tijdens de geslachtsgemeenschap	<input type="radio"/>	<input type="radio"/>
Vernauwing van de vagina	<input type="radio"/>	<input type="radio"/>

Kunt u in de onderstaande keuzemogelijkheden aangeven welke klacht u het liefst verbeterd wil zien na de behandeling.

Indien u één of beide klachten niet ervaart vragen wij u uw inlevingsvermogen aan te spreken en op basis daarvan een keuze te maken.

	9	8	7	6	5	4	3	2	1	2	3	4	5	6	7	8	9	
Incontinentie tijdens gemeenschap	<input type="radio"/>	Vernauwing van de vagina																
Vernauwing van de vagina	<input type="radio"/>	Pijn tijdens gemeenschap																
Pijn tijdens gemeenschap	<input type="radio"/>	Incontinentie tijdens gemeenschap																

Heeft u alle vragen ingevuld? Hartelijk dank voor uw medewerking.