Sling surgery for stress urinary incontinence; the perfect solution?

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General introduction

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Urinary incontinence (UI) is a common condition that affects millions of people worldwide. Although UI is not a fatal condition, it is associated with severe negative effects on various aspects of life and is therefore considered a major burden by most of its sufferers (1-4). Stress urinary incontinence (SUI) is the most observed type of UI and is defined as the loss of urine following a rise in abdominal pressure such as laughing, sneezing and coughing (1). In women, SUI arises from damage to the muscles, nerves, and connective tissue of the pelvic floor due to causes such as childbirth, surgery, radiation and ageing. In men SUI is mostly observed after prostate surgery which, due to an increase in surgical procedures performed, is encountered more frequently in common day urological practice (5-7). Studies in the Western world currently estimate that up to 60% of the female population between 15-64 years suffer from SUI, with a rapid increase in prevalence at ages 70 through 80 (8;9). In males UI has an estimated prevalence that varies from 11% (60 to 64 years of age), to 31% in those aged 65 years or over. The biggest difference between UI in male and female sufferers, is that in males urge urinary incontinence (UUI) accounts for 40% to 80% of the UI, whereas SUI represents the largest part in females (10).

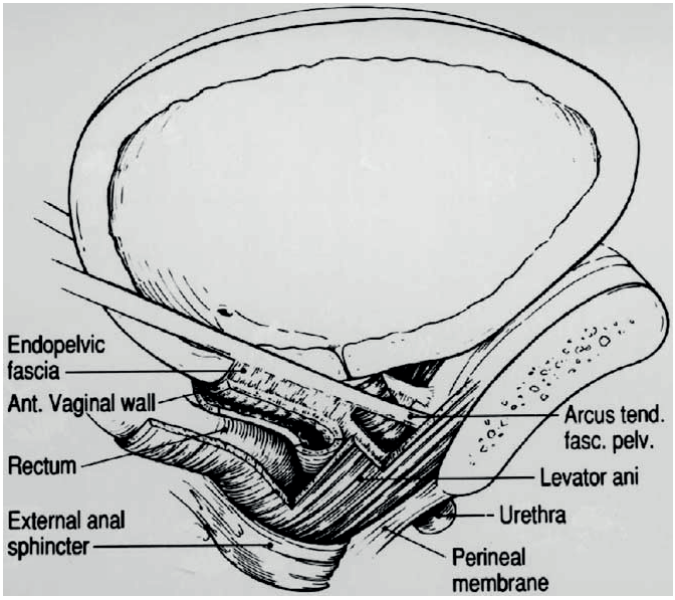
The pathophysiology of SUI in women

Although the concept of maintaining urinary continence (keeping urethral closing pressure higher than bladder pressure) is pretty straight forward, the theories on the pathophysiology of SUI in women have evolved considerably over the past centuries. In 1912, Kelly was the first to publish a clinical description of what we now call SUI (11). In his paper Kelly described an open vesical neck seen with the urethrascope which he subsequently corrected with a surgical procedure that plicated the vesical neck. The 'Kelly plication' became the first routine clinical procedure for the treatment of SUI. During the following decades more and more theories on SUI were presented that focused mainly on anatomical defects, blaming the lack of support of the anterior vaginal wall and subsequent urethral and bladder prolapse (12-16). This one-dimensional vision gradually changed from the 1930's, when theories gradually included the dysfunction of the urethra as possible cofactor in the search for the cause for involuntary leakage of urine (12;15;17). Nowadays these theories have evolved into various complex pathophysiological concepts based on both functional and anatomical mechanisms, that focus on two principal systems; the loss of supportive tissue surrounding the urethra and vesical neck, and dysfunction of the sphincteric system (14;15;18;19).

The following sections will briefly describe these two mechanisms as they are crucial for understanding the basic working mechanisms of the surgical interventions on which this thesis is based.

Loss of urethral support

The urethral support system provides a supportive layer on which the urethra and vesical neck rest and consists of all the structures that surround the urethra. The major components of this system are the anterior vaginal wall, the endopelvic fascia, the arcus tendineus fasciae pelvis and the levator ani muscle.



Lateral view of the components of the urethral support from the article of DeLancey et al. (14)

One of the easiest ways to explain the working mechanism of this supportive system is by describing the 'Hammock Hypothesis', which was proposed in 1994 by DeLancey (18). In this paper he describes the supportive layer (composed of the endopelvic fascia and the anterior vaginal wall) on which the urethra lies as a 'hammock' which gains it structural stability through its lateral attachment to the arcus tendineus fasciae pelvis and levator ani musculature. During an increase in abdominal pressure (e.g. when sneezing or coughing) and the concomitant increase in intravesical pressure, two things happen concurrently that help maintain continence. First the contraction of the levator muscles will tighten the hammock-like supportive layer and elevate the urethra and bladder neck. Simultaneously, the pressure from above compresses the urethra against this hammock, closing its lumen and preventing leakage.

Damage to one or more of the major components of the urethral support system (for instance neuromuscular damage during childbirth), can result in SUI. One of the simplest analogies for this mechanism is to compare the urethra to a garden hose which is being compressed by stepping on it. If the hose would be lying on a noncompliant

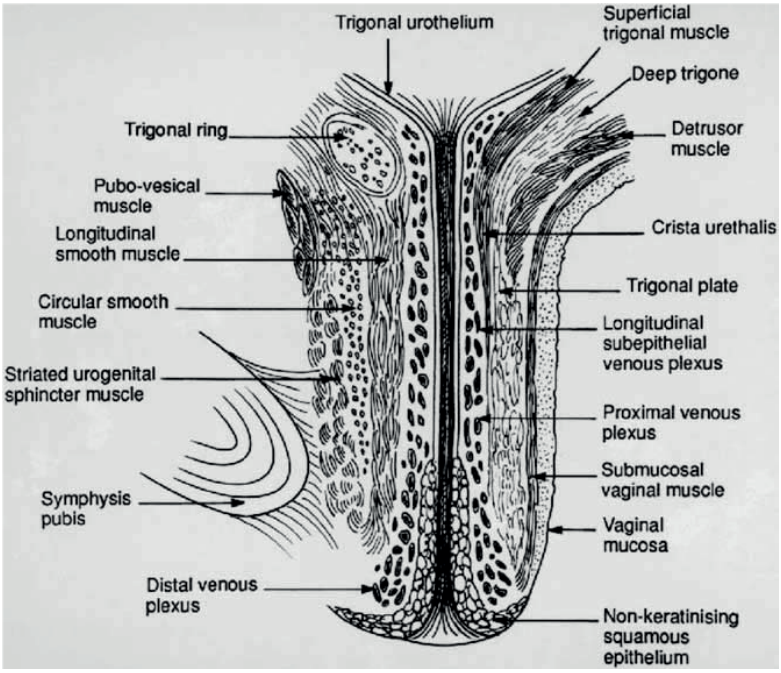
surface (an undamaged urethral support system in this instance), stepping on it would result in closing of the lumen and cessation of the water flow. If the surface would be compliant however (a damaged urethral support system), the hose and surface would simply move downward together when stepping on it, thus resulting in the leakage of water (or urine).

The sphincteric closure system

The second system that is strongly associated with SUI and crucial in understanding the pathophysiology, is the sphincteric closure system or urethral function (14;20;21) . As mentioned earlier, SUI is characterized by the involuntary loss of urine when bladder pressure exceeds the maximum urethral pressure. Urethral pressure is achieved by the sphincteric closure system and should exceed bladder pressure, both at rest and during stress, for urinary continence to occur. The physiologic measure of urethral competence is known as the maximum urethral closing pressure (MUCP). The MUCP is achieved by the collaboration of three main structural components: the striated periurethral muscles (rhabdosphincter), the urethral circular smooth muscles, and the vascular plexus within the submucosa (22).

As the urethra emerges from the bladder wall it is surrounded by a U-shaped loop of striated sphincter muscle. When activated, this loop of muscle will close the lumen of the urethra by constriction. The urethral circular smooth muscle layer can be found in multiple layers of the urethra. The exact role of these layers of smooth muscle still remains to be elucidated, but its circular configuration suggest that it also helps in constricting the urethral lumen when contracted. The vascular submucosal plexus is believed to keep the urethra watertight by forming a vascular cushion and is surrounded by both the striated and circular smooth muscles.

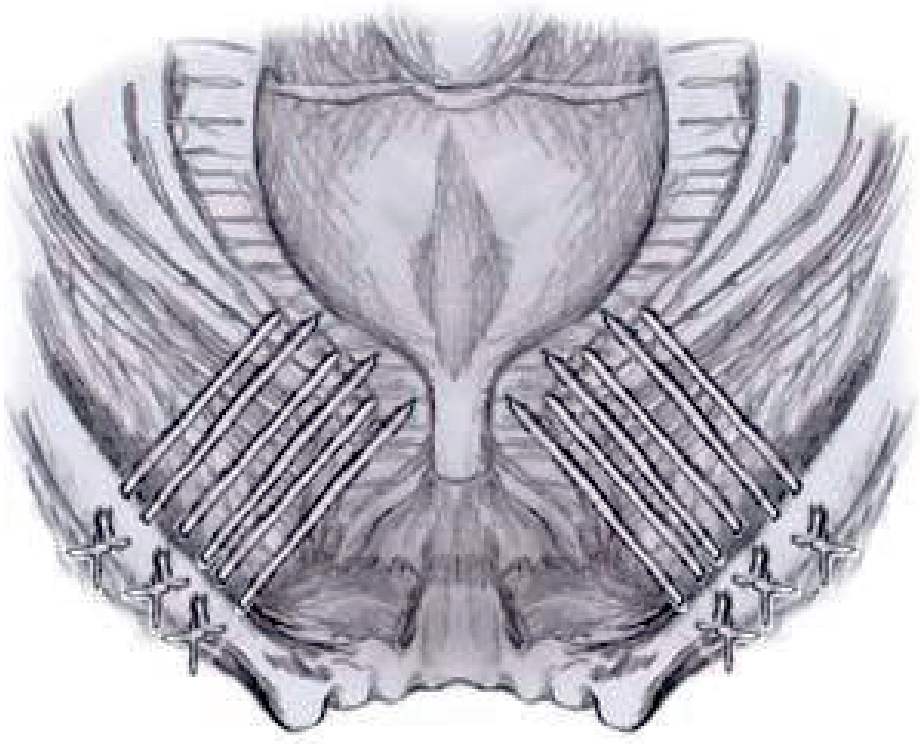
When one (or more) of these three components is damaged, the ability of the sphincteric closure system to adequately react to a sudden increase in abdominal pressure will subsequently be reduced, and could potentially lead to the loss of urine. In incontinent women, the loss of circular smooth muscles and striated muscles are believed to result from both nerve damage (eg. during vaginal childbirth) and age-related deterioration due to hypoestrogenism (24-28). The vascular submucosal plexus is known to weaken in postmenopausal women as well, probably as a result of hormonal changes (25;29-31).



Midsagittal section showing the anatomy of the urethra from an article by Strobehn et al. (23)

A brief history of surgery for SUI in women

Since Kelly introduced his revolutionary technique in 1912, a lot has changed in the surgical treatment of SUI. The most important advancements after the Kelly plication came in 1949 and 1961, when F. Marshall, A. A. Marchetti and K. E. Krantz, and J. C. Burch introduced their methods of an anterior urethropexy and colposuspenion (32;33). The Marshall-Marchetti-Krantz (MMK) and Burch procedures use an open retropubic approach to place non-absorbable stitches in order to suspend and stabilize the urethra. This suspension and stabilization then allows normal pressure transmission during periods of increased intra-abdominal pressure, thus restoring continence. Both the MMK and the Burch procedures reach cure rates of about 80% after an extended period of time. The Burch soon became the 'gold standard' procedure against which other operative managements of SUI were compared (34-36).



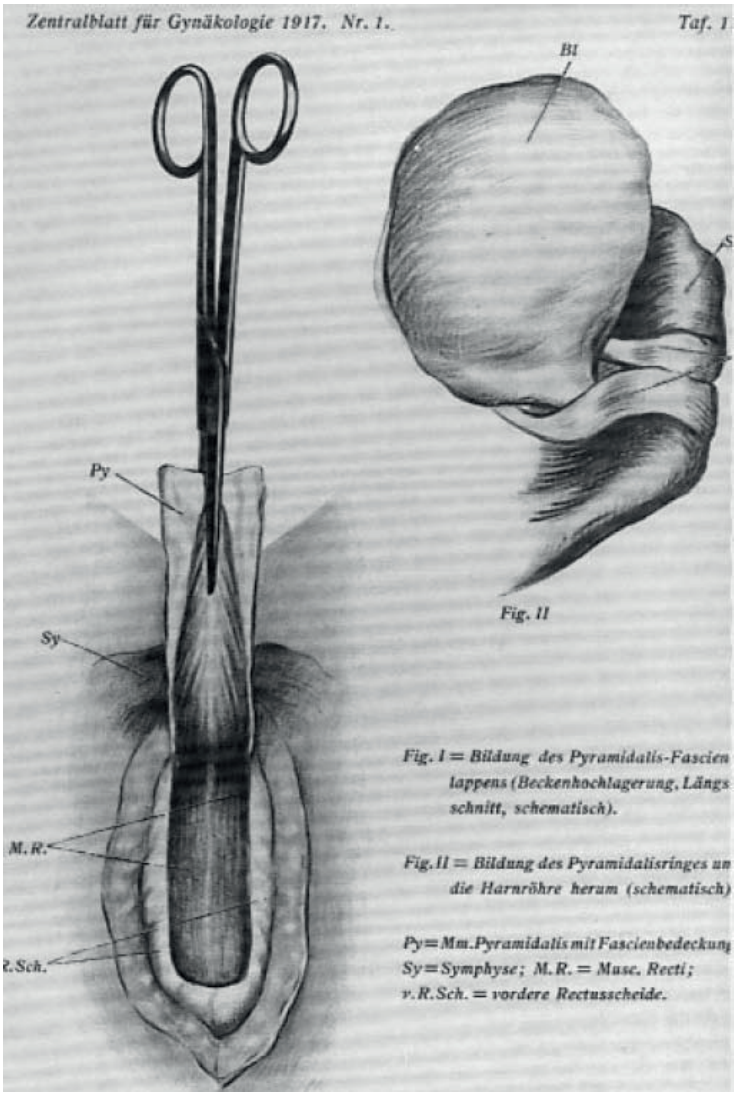
Burch colposuspension (source: emedecine.medscape.com)

Another technique that has to be mentioned in this brief history on the surgical treatment of SUI is the needle suspension. The first needle suspension was introduced in 1959 by A.J. Pereyra as a minimally invasive improvement on the MMK procedure and did not require an open abdominal retropubic dissection (in contrast to the MMK and Burch) (34). The Pereyra needle suspension uses a long needle to thread sutures from the vagina to the anterior abdominal fascia through either a vaginal or trans-abdominal approach. The sutures are placed in the para-urethral tissue on either side of the bladder neck, thereby stabilizing and supporting it. In the following years, the initial procedure was altered and modified several times by others such as Raz, Stamey and Gittes (37-39). For decades the needle suspension was considered one of the treatments of choice for SUI but has nowadays largely fallen out of favor due to its poor long-term results (40).

Sling surgery for SUI

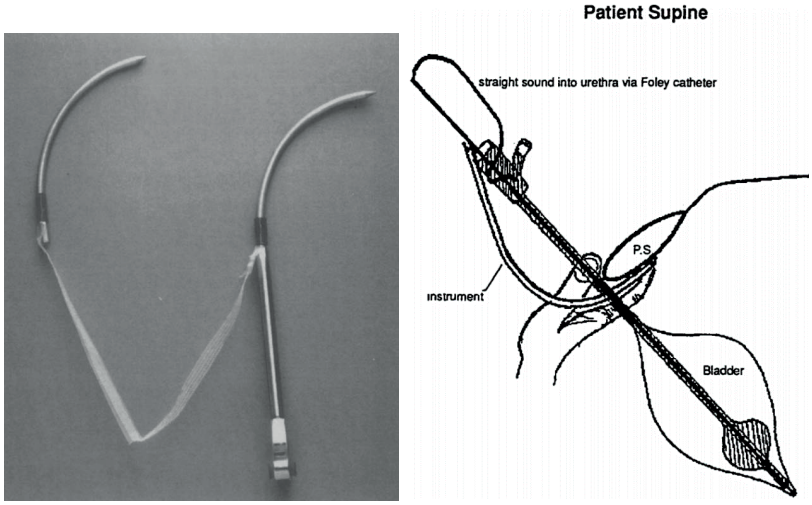
Based on the concept of SUI being caused by the loss of supportive tissue around the urethra (see the section on the pathophysiology of SUI in women), physicians at-

tempted to correct these anatomical abnormalities with the use of pubovaginal slings as early as the 1900's (41-43).



One of the first pubovaginal slings; the retropubic pyramidalis muscle–fascia sling according to Walter Stoeckel (1917) (43)

Throughout the years numerous different techniques and slings, both autologous and synthetic, have been used in an attempt to effectively cure SUI with a wide variation in success rates. This all changed in 1995, when Papa Petros and Ulf Ulmsten described the use of a revolutionary, new, minimally invasive intravaginal sling plasty as a method of restoring the posterior pubourethral ligament. This procedure, which was henceforth known as the IVS, was performed on 50 patients and reached a cure rate of 78% (44). It would, however, be the paper by the same Ulmsten in 1996 that truly rocked the foundation of the treatment for SUI (45). In this paper he presented the results of the modified version of the IVS: the TVT. This modified sling, fully named the Tension-free Vaginal Tape®, is a polypropylene tape that is transvaginally placed in a mid-urethral position using two needles through the cavum Retzii. The TVT creates an artificial tension free hammock-like suspension underneath the urethra, providing the support needed to restore continence during an increase in abdominal pressure. The initial study on the TVT included 75 women with (genuine) stress urinary incontinence and presented a postoperative cure rate of 84% after a follow up of two years. What made the TVT so revolutionary was the fact that it combined impressive cure rates with a minimally invasive surgical technique that could be performed under local anesthesia, little per- and postoperative complications and a huge decrease in operative time. The TVT rapidly gained worldwide popularity due to this unique combination and it soon became (and still is) the gold standard in the surgical treatment of SUI.



Original photo of the TVT and its technique used in the article by Ulmsten in 1996 (45)

Introduction of new slings for the treatment of SUI in women

Following the successful introduction of the TVT, with its relatively simple but hugely effective technique, it did not take long for medical companies (and physicians) to realize the enormous potential of synthetic slings for the use in incontinence surgery in women. Since 1995 there have been dozens of newly marketed synthetic slings and techniques, all claiming to achieve equal, if not better, results in comparison to the original TVT. Nonetheless, peer-reviewed scientific literature, mostly performed after the commercial introduction, identified serious safety and effectiveness concerns on many of these 'revolutionary' new slings and techniques (46-48). Currently, when a new drug is introduced, the (obligatory) research conducted may take up to 12 years and include well over a 100.000 pages of research protocols, presented evidence and test results. It is only after this extensive evaluation that a new pharmaceutical product receives its Food and Drug Administration (FDA) clearance or Conformité Européenne (CE) mark and can be launched for commercial use.

In contrast to the introduction of a new pharmaceutical, a new medical product such as a sling, is cleared for sale in the USA after making assertions to the FDA of "substantial equivalence" under section 510 (k) of the Food, Drug and Cosmetic Act. According to the FDA, substantial equivalence is established with regard to intended use, design, energy used or delivered, materials, chemical composition, manufacturing process, performance, safety, effectiveness, labelling, biocompatibility, standards and other characteristics, as applicable. In short this act states that any new device should be at least as safe and effective as comparable devices already marketed, without the need of any (published) premarket research. In the European Union a CE mark notification is obtained by approval from an independent notified body and a declaration of conformity. When seeking approval by an independent notified body this is usually done by site audits and an assessment of technical documentation. A declaration of conformity is a statement by the manufacturer that the product meets the requirements of the European directive. As in the USA, this procedure does not require any additional research on either the safety or efficacy of the sling. If the device is permitted, the company receives a clearance to market by the FDA or, in Europe, the CE mark. As most devices are relatively comparable with an established sling such as the TVT, permission is generally granted without major obstacles.

SUI and UI curing surgery in men

Two of the most frequently performed surgical procedures in urology are the radical prostatectomy (RP) and the transurethral resection of the prostate (TURP). Two of the major complications following these surgical procedures are stress urinary incontinence (SUI) and sexual dysfunction (SD) (5;6;49;50).

SUI following a prostatectomy may be caused by either sphincter dysfunction or bladder dysfunction. SUI following a TURP is usually caused by damage to the proximal part of the (rhabdo) sphincter distal to the seminal colliculus (7). The post-RP SUI rates show a wide range throughout literature, but incontinence rates as high as 87% have been reported in the past (51). Despite an evolution in surgical techniques for RP following the introduction of the (robot-assisted) laparoscopic prostatectomy over the past years, recently reported postoperative SUI rates are still between 5% and 48% (52). Incontinence following a TURP is usually estimated around 5% and has a significant impact on the quality of life of its sufferers (4). Initial therapy following SUI after either a RP or TURP consists of lifestyle interventions, scheduled voiding and pelvic floor muscle training. After initial treatment has failed, invasive therapy is often the next option. The current gold standard in the invasive treatment for SUI after prostate surgery is the implantation of an artificial urinary sphincter (AUS). The first, externally worn, urethral cuff was introduced in 1947 by Foley and its subsequent modifications by Kaufman in 1973 eventually led to the first fully internal AUS (53;54). Since then, the AUS has proven itself to be an effective method of curing all types and degrees (mild to severe) of UI in males (including SUI) and success rates vary between 59% and 91.4% in current literature (55-57). The AUS has a serious downside however; surgical revision due to malfunction, erosion or pain is often required and explantation rates can be as high as 36% within 5 years (57-59).

In the search for a less invasive but equally effective technique, the development of synthetic slings for the use in male incontinence surgery has expanded enormously these past years. Parallel to the slings in female SUI, male slings are currently being introduced in a wide variety of shapes, sizes, materials and techniques. In contrast to novel slings in women however, male patients undergoing these new surgical techniques are for the greater part included in cohort studies focusing on the functioning and safety of these devices. Some of these techniques have indeed shown promising results in preliminary studies, but solid (Grade I and II) evidence is still lacking and the AUS remains the gold standard up to the present day (57).

Incontinence surgery and SD

In female patients, one logically hopes that incontinence curing surgery improves the sexual function by eliminating the disabling effects of the loss of urine. If one conducted a literature search on this subject however, you would find that this theory has in fact not been confirmed in current literature (57-67).

One logical explanation for this phenomenon would be the neurovascular damage or anatomical changes caused by the surgery or implant itself (68;69). However, despite millions of female slings having been implanted worldwide, only a limited number of

studies actually address the neurological and vascular risks and provide detailed information on the anatomical relationship between slings and the pelvic nerves.
Although the link between UI and SD in women is a fairly straightforward one, this is a much more complex issue in male patients. As mentioned earlier, two of the most frequently encountered functional complications following prostate surgery are erectile dysfunction and SUI (6;49;50). If a patient suffers from SUI after prostate surgery and finds himself in the need of invasive therapy (e.g. AUS or male sling), it is a complicated task to establish the actual effects (improvement or worsening) of the incontinence surgery on sexual functioning. Nevertheless, a male sling could just as easily cause neurovascular damage and thereby (further) impair sexual function.

Outline of this thesis

The aim of this thesis is to evaluate the efficacy and safety of slings in urological and uro-gynecological (male and female) practice. This thesis consists of eleven chapters and is comprised of clinical data, anatomical studies and reviews on available literature on both male and female slings. The main question of this thesis is whether slings, old and new, for either male and female, can live up to the expectations of both patients and physicians by being both safe and effective in curing urinary incontinence. Secondly, the question is raised whether sling surgery is anatomically safe with regard to those nervous systems which are essential for the sexual function or may actually be responsible for iatrogenic neurological damage during placement.
To solve this issue, it must first be assessed how a new sling is actually introduced on the commercial market and which evidence is used and presented in the process by its inventors and manufacturers. In order to achieve this objective, the pre-market research performed on new mid-urethral slings for curing stress urinary incontinence in women was evaluated and the results are presented in **chapter two**.
The MiniArc® is one of the more recently introduced 'mono incision minislings', that aims to treat SUI with a less invasive, but equally effective sling technique in comparison to the original TVT. **Chapter three** describes the clinical results of the MiniArc sling in a cohort of women after one year.
This thesis continues in **chapter four** with a study that describes the efficacy and safety of mid-urethral slings in a non-selected population of women in the specialized pelvic floor center of a Dutch teaching hospital.
Up to present there is no consensus on the correct treatment of late complications (erosion and/or displacement) following sling surgery in women. **Chapter five** describes the results of a surgical procedure that uses a collagen sling implant following partial

removal of a synthetic sling due to erosion and/or displacement in a tertiary referral center.

As mentioned earlier, one of the most common complications after a TURP is SUI. Little is currently known on the efficacy of sling surgery in this specific group of patients. **Chapter six** describes the effects of the Virtue® male sling for treating incontinence following a TURP. Moreover an overview of the available literature on sling surgery following incontinence in TURP patients is presented.

Neuro-anatomical studies on incontinence curing slings are relatively rare and are seldom found in current literature. In order to extend this knowledge we conducted two studies on the course of these slings in the male and female pelvis. In **chapter seven** and **eight** the possible side effects of sling surgery in both sexes (Tension Free Vaginal Tape®, Tension free Vaginal Tape-Obturator® and AdVance® male sling) are evaluated from a neuro-anatomical point of view. These chapters focus on the actual course of these slings in both the male and female pelvis and describe them in relation to the pelvic nerves that are vital for the sexual function.

Chapter nine provides an English summary (abstracts) and in **chapter ten** the main findings and implications of this thesis on future practice and research are discussed. In **chapter eleven** the Dutch summary of the thesis is provided.

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