Cover page:

The FAST- Study: The Follow-up After Shorter Tapes Study Effectiveness and Safety of Shorter Trans-obturator Tapes: A Prospective Observational Study From the Norwegian Female Incontinence Registry

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Study protocol

The FAST- study: The Follow-up After Shorter Tapes study

Part 2 and 3 of the PhD project for Kjersti Rimstad MD

Effectiveness and safety of shorter trans-obturator tapes: A prospective observational study from the Norwegian Female Incontinence Registry

Study participants and roles:

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Collaborators

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- Jon Michael Gran, biostatistician at the Center for Biostatistics and Epidemiology at Oslo University Hospital will be credited under Acknowledgement

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List of abbreviations

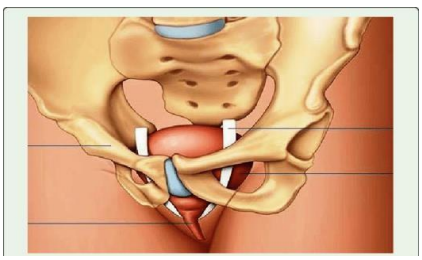
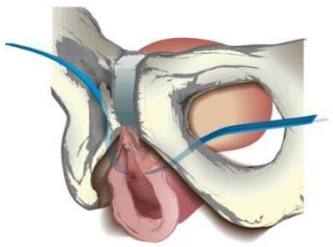
SUI	Stress Urinary Incontinence
MUS	Mid-urethral Sling
MUI	Mixed Urinary Incontinence
NFIR	Norwegian Female Incontinence Registry
TVT-O	Inside-out tension-free tape obturator
MUCP	Maximum urethral closure pressure
OUS	Oslo University Hospital
AHUS	Akershus University Hospital
REK	Regional Committee for Medical and Health Research Ethics in the Southeast Norway
TVT	tension free vaginal tape
SIMS	Single incision mini-slings
TVT-A	TVT-O Abbrevo
TPUS	trans-perineal ultrasound
PFIQ-7	Pelvic Floor Impact Questionnaire
QoL	quality of life
2D UL	Two-dimensional Ultrasound
3D UL	Three-dimensional Ultrasound

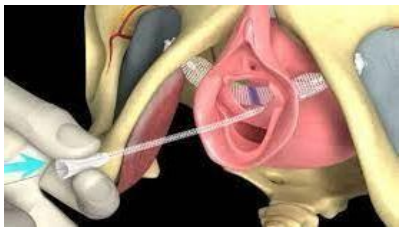
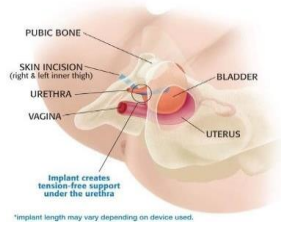
Background:

Stress urinary incontinence can significantly diminish the quality of life for many women, limiting their physical activity and impairing sexual function (1). This condition, defined as urinary leakage when coughing, sneezing, or exerting physical effort, has a prevalence of 12-46 % among the general female population (2, 3). For the past two decades, mid-urethral sling (MUS) procedures have been the dominant surgical treatment for SUI and stress-dominant mixed urinary incontinence (MUI). The traditional MUS procedures involve placing a polypropylene mesh under the urethra either in front of the bladder, passing through the pelvis to the lower abdomen (tension-free vaginal tape (TVT))(4)), or to the side of the pelvis in the groin area (tension-free vaginal tape obturator inside-out (TVT-O)) (5) (Fig. I). These traditional techniques have well-documented, long-lasting results (6, 7), and have improved the quality of life for many women with SUI (8, 9). MUS procedures have good subjective and objective results for both SUI and stress-dominant MUI and are generally considered safe with low rates of complications (2).
However, in recent years there has been increasing awareness of long-term complications associated with synthetic materials used in these slings, such as chronic pain, dyspareunia, and voiding dysfunction (10). Although these complications are rare, affected women may experience a lifetime of severely reduced quality of life, even if the synthetic material is entirely removed (11). As a result, the health regulatory bodies, hospital administrators, individual surgeons and patients have started to seek out alternative surgical methods.

Single incision mini-slings (SIMS) such as Ajust (Fig. I), which contain much less synthetic mesh than traditional slings, were introduced worldwide in 2006 (12). Later, in 2010, the intermediate sling TVT-O Abbrevo (TVT-A), was introduced hoping to improve the clinical performance of shorter slings (Fig. I) (13). However, there is still a significant knowledge gap regarding short- and long-term results of these new and shorter slings, particularly in terms of complications such as chronic pelvic pain. While some studies have shown promising short-term results for SIMS and intermediate slings, these studies are often small and hampered by selection bias and high rates of lost follow-up (14-22).

FIG.I: The photos depict the traditional slings (TVT and TVT-O), SIMS Ajust and TVT-A.

TVT (23)  TVT-O (24) 

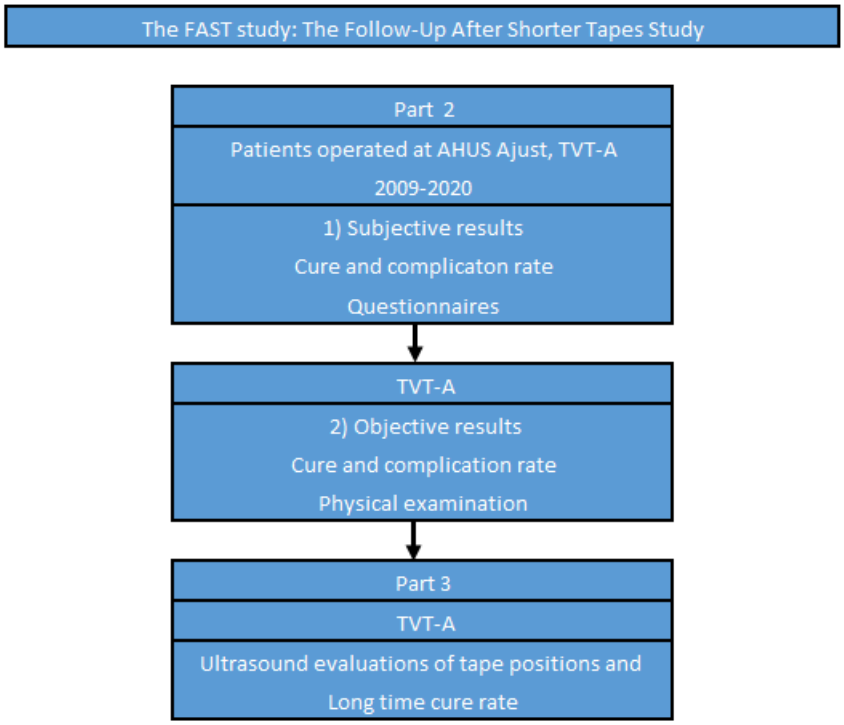
SIMS Ajust (25)  TVT-A (26) 

Given that shorter slings could represent a middle ground between the risk of severe complications and a diminished quality of life (QOL) due to untreated stress urinary incontinence, data on the long-term effects and safety of the newer shorter slings are urgently needed. Retrieving such knowledge would enable the updating of surgical guidelines and provide patients considering surgical options with evidence-based recommendations.

In Norway more than 90% of all female incontinence operations are carried out in public hospitals, and since 2017 the coverage of reporting female incontinence operations has been more than 98 % from public hospitals to the mandatory Norwegian Female Registry (NFIR) (27). This Registry, established in 1998 by The Norwegian Urogynecology Group, is now a compulsory, nationwide quality registry based at Oslo University Hospital (27, 28). Reliable data are collected before surgery, at the time of surgery and at follow-up consultations 6-12-months and 3 years after the surgery. The 6-12 months data has good coverage and will be used in the first part of this PhD project (Part I: REK 22/397503). However, the 3-years reporting has low coverage and are mostly subjective questionnaire-based data. According to the yearly public report from the NFIR, hospitals using the SIMS Ajust and TVT-A slings seem to have fewer short-term complications than hospitals using the traditional slings (either retropubic or transobturator sling) (29). However, there is still a disagreement about whether the SIMS Ajust and TVT-A, due to their shorter length, are as effective as the traditional slings. Since its introduction, the TVT-A has mainly been classified as a TVT-O sling in the NFIR, and any potential differences in results and complications from regular TVT-O slings have therefore not been evaluated. Furthermore, there are to date only a few published studies evaluating the effectiveness and complication rates of the SIMS Ajust and TVT-A (14-22, 30-33). Therefore, it would be of great benefit to surgeons and patients if better scientific data on the short- and long-term effectiveness and complication rates of these slings could be evaluated.

Most of the 39 departments offering female incontinence surgeries in Norway use traditional MUS. However, one of the largest hospitals, Akershus University hospital (AHUS), has been using shorter slings as their preferred MUS since 2009, initially SIMS Ajust and later TVT-A. At AHUS, we therefore have a unique opportunity to study the long-term results and complication rates of shorter slings by inviting women back for a long-term follow-up after undergoing sling surgery at AHUS. In addition to quality of life, complications, and patient satisfaction, this follow-up provides the possibility of investigating sling position using 2D dynamic and 3D transperineal ultrasound (TPUS) (34-37). This innovative technique that dynamically investigates the pelvic floor and sling placement is not widely used in Norway, but is available at AHUS, which also has expertise in advanced ultrasound within the research group. How the positioning of intermediate slings under the urethra may affect long-term success rates and adverse events is largely unknown. Studies on traditional slings suggest that placement more proximal or distal to the mid-part of the urethra is associated with poorer outcomes (34-36).
Whether this is coincidental or represents an actual association between sling position and long-term success and complication rates is not established for intermediate slings. To go even further, we will evaluate if there is an “optimal sling placement zone”, particularly for shorter slings. This information is currently lacking and makes it difficult for gynaecologists evaluating patients in need of repeat surgery, due to either treatment failure or long-term complications. Understanding the biomechanical effects visualized by ultrasound of the increasingly popular shorter slings would be pioneering work and enable researchers and doctors to further develop the treatment techniques for female incontinence.

Research questions and hypotheses, theoretical approach and methodology



PhD-project, Part 2

Our over-all aim is to evaluate long-term subjective and objective outcomes of shorter slings.
Study design: Prospective observational study

1) Long-term subjective outcomes

Study population: Women treated with SIMS Ajust (n = 744) at Akershus University Hospital between 2009 and 2016 and Intermediate sling TVT-A (n= 318) at Akershus University Hospital between 2016 and 2020.
Follow-up: Potential study participants for both groups will be identified in the local quality database for female incontinence surgery (local NFIR) at AHU S and invited to a long-term follow-up (4-14 years) with questionnaires. The following questionnaires will be sent electronically to the patients together with study invitation and consent form: The validated NFIR questionnaire, the validated Pelvic Floor Impact Questionnaire (PFIQ-7) (38, 39) as well as additional questions regarding pain (40).

a. *Primary outcomes:* Long-term subjective cure rate.

- Long-term subjective cure is estimated by calculating a stress urinary incontinence index score (SUIS) from 4 clusters of questions measuring degree of symptom bother in the validated NFIR questionnaire, from 0 (no symptoms) to 12 (high symptom load) where a score < 3 is defined as subjective cure (41).

b. *Secondary outcomes:* Long-term treatment satisfaction scores, quality of life score and complication rates.

- Differences in improvement of quality-of-life using a Quality-of-life index score (QoLIS) generated from 4 questions in the NFIR questionnaire measuring QoL impact. This index ranges from 0 (excellent quality of life) to 16 (poor quality of life) (41). In addition, the Pelvic Floor Impact Questionnaire (PFIQ-7) (38, 39) will be used to further evaluate the Quality-of-life impact.

- Differences in treatment satisfaction rates are defined as the percentage of women answering "very satisfied with treatment" given the options "very satisfied", "moderately satisfied", "neither satisfied nor dissatisfied", "moderately dissatisfied" or "very dissatisfied" in the NFIR questionnaire.
- Differences in total complication rates (all types included), re-operation rates, vaginal tape exposure, persistent and de novo urgency incontinence and prolonged pain.
    - Persistent and de novo urgency incontinence is calculated from the NFIR questionnaire using 4 clusters of questions that generate an urgency urinary incontinence score (UUIS) quantifying the degree of urgency symptom bother from 0 (no symptoms) to 8 (high symptom load) (41). De novo urgency incontinence will be defined as having had a UUIS of ≥ 4 at the long term follow up in women who had no urgency incontinence symptoms before surgery (preoperative urgency urinary incontinence score = 0).
    - Differences in prolonged pain defined as postoperative pain more than 3 months after surgery in the NFIR questionnaire or having had treatment for pain caused by the surgery, e.g removal of the sling or part of the sling. Patients having persistent ongoing pain will further be asked to answer a newly developed non-validated NFIR pain questionnaire (40).

2) Long-term objective outcomes

Study population: The 318 women having been treated with the currently most used shorter sling (TVT-A) at Akershus University Hospital between 2016 and 2020 will be invited to a physical follow-up were they will undergo a clinical examination including assessment of objective cure, sling erosions and development of pelvic organ prolapse using the POP-Q system (42).
Exposure: Having had TVT-A sling operation at AHUS.

a. *Primary outcomes:* Long-term objective cure rates.

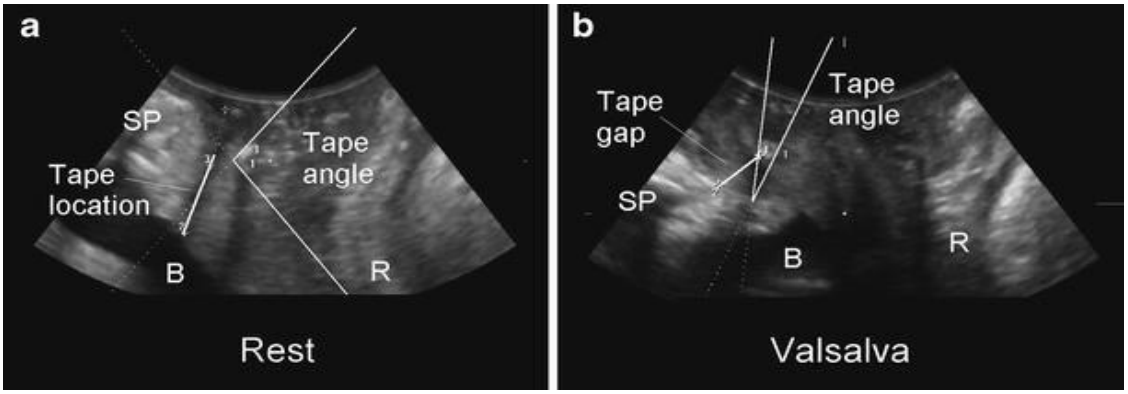
- Objective cure will be defined as having no leakage (0 g) at a cough-jump pad weighing stress test (43).

b. *Secondary outcomes:* The same as defined under 1) Long-term subjective outcomes.

- In addition, we will evaluate differences in the rate of mesh exposures and the development of pelvic organ prolapse (POP) using the POP-Q evaluation system (42).
- The severity of tape exposure will be evaluated using the ICS and IUGA prosthesis and graft complication classification system (44). In addition, we will evaluate the intervention for surgical complications using the Clavien-Dindo Classification (45, 46).

PhD-project, Part 3

We will study the positioning of the shorter sling TVT-A under the urethra using dynamic 2D and 3D ultrasound. We will evaluate if there is an "optimal sling placement zone" for shorter slings.



(35)

Our aim is to study the association between sling position, tension and anchoring under the urethra, and subjective and objective cure rate, and long-term complication rates, especially chronic pelvic pain.

Our null hypothesis is that there are no associations between sling position, tension or anchoring of the tape and subjective and objective outcomes including complications such as chronic pain development.
Study design: Prospective observational study
Study population: 318 women having had surgery with the intermediate sling TVT-A at AHUS between 2016 and 2020.
Follow-up: Women who consent to study participation and attend the physical follow-up will undergo a clinical examination that includes a transperineal ultrasound (TPUS) examination in the dorsal lithotomy position using a 3,5-6 MHz curved array abdominal probe (47). The TPUS volumes and images will be obtained with an empty bladder at rest and under full Valsalva (48).
Exposure: Position, tension (shape) and anchoring of the sling, and measuring sling position in relation to well-defined anatomical markers.

a. *Primary outcomes:* Any association between sling position, tension or anchoring and subjective and objective cure rate, complication rates and especially the development of chronic pelvic pain. For the definitions of cure rates, *see under part 2*.
b. *Secondary outcomes:* Any association between sling position, tension or anchoring and long-term complications, especially chronic pelvic pain, *see part 2*.

Statistics, power and sample size:

PhD-project, Part 2

This is a follow-up study of all women having been operated at AHUS with SIMS Ajust or TVT-A in the study period. Few studies with long-term outcomes after shorter slings have been published. The first part of the long-term follow-up will therefore be a prospective follow-up study with no group comparisons. For this part, power calculations are not feasible as all women having had SIMS Ajust or TVT-A in the study period consenting to study participation will be analysed for subjective outcomes, whereas all women in the TVT-A group consenting to study participation will be analysed for objective outcomes.

PhD-project, Part 3

For the transperineal ultrasound (TPUS) part of the project, various outcomes will be evaluated based on sub urethral sling position, tension and anchoring. As there is little scientific published data on how sling placement affect subjective and objective outcomes of sling surgeries, a pre-study sample size estimation must in part be made on best clinical guess. Based on the following assumptions:
We estimate that 80 % of the women will have the sling placed in the “optimal position” and 20 % outside the optimal position as shown in a small study published in 2017 by Hegde and co-workers (37). Therefore, the estimated group ratio will be 1:4.
A clinically relevant effect size (group difference) regarding subjective outcomes is not established, but based on our clinical experience, we have set the minimal relevant group difference in success rate to 30 % (85 % subjectively cured in the “optimal position” group vs 55 % in the “non-optimal position group”).
With a significance level (α) of 0,05 and a statistical power (β) of 80%, the estimated sample size to be included for TPUS evaluation is 107 women (37). Even though we invite all 318 TVT-A women to attend the physical long-term follow-up with ultrasound evaluation, realistically we estimate that only 50 % will want to participate. Even with 50 % participation we should, based on our sample size calculation, be able to draw valid conclusions.

Risk evaluation and countermeasures
The main risk to the project is patient inclusion. To get robust and valid scientific data we are depending on women being willing to participate in the project with clinical examinations and ultrasound measurements. Based on previous experience, Norwegian women usually do want to participate in long-term follow-up studies. In the 10-year follow-up study of retropubic TVTs conducted by the main supervisor Svenningsen 89 % consented to study participation, and 60 % to a physical follow-up (6). Even a conservative estimate of 50 % would therefore be enough to draw valid conclusions. However, if less than 50 % agree to study participation, we do have the possibility to extend the study period to include women operated in 2021. According to the work plan for the PhD project (below) these women will then be evaluated in 2024 at the earliest and as such have follow-up of minimum 4 years.

User Participation
The project has two user representatives, Trude Lyng as part of NFIRs national Advisory Unit and Lene Marie Brobakken as user representative at the Women's Clinic, AHUS. They have both participated in the planning of the project and given valuable comments in developing the study protocol. Both have agreed to stay on as part of the project group. We plan on having quarterly meetings with the user representatives throughout the whole project period.

Ethical considerations
The Department Head at AHUS has already approved the study. Furthermore, the study will be sought approved by NFIR Management team, NFIRs professional council, The Data Protection Officer at AHUS as well as the Regional Committee for Medical and Health Research Ethics in the Southeast of Norway (REC South East). Signed consent will be obtained from all study participants.

Study participants will only be examined using established techniques for the evaluation of women after incontinence surgery, the exception being the 3D ultrasound examination. None of them involves any additional risk for the participants.

Questionnaires and consent forms will be sent electronically and stored at the Services for Sensitive Data (TSD), as well as the research server at AHUS. Study participants who report persistent or recurring incontinence as well as any long-term complications related to the slings will be offered a full new clinical evaluation.

Potential impact of the proposed research
The proposed research has the potential to significantly impact the surgical management and treatment of women with urinary incontinence, both nationally and abroad. This study aims to address critical knowledge gaps that, when filled, could improve the quality of life for women with this condition. The study's pioneering approach of establishing an "optimal placement zone" for slings may prove to be an innovative tool in decision-making after failed surgery and in women experiencing severe long-term complications, such as chronic pelvic pain. Providing women with evidence-based data on short- and long-term success rates of shorter slings and the incidence of long-term risks for severe complications, such as chronic pain, is highly sought after in the ongoing controversy surrounding the use of synthetic implants vaginally.

Publication of results
The results from the PhD project will be published as three Papers in internationally peer-reviewed journals. Furthermore, the study´s findings will be presented at the Annual Meeting of The Norwegian Society for Gynecology and Obstetrics, and at the Yearly NFIR meeting, and at international Urogynecology conferences such as the Annual Meeting of the International Continence Society. This is crucial in ensuring

that new knowledge derived from this project reaches surgeons in Norway and abroad who use these methods. The results will be communicated to all women, in cooperation with the user representatives, through the hospital Blogs, related websites and research meetings as well as through podcasts and women's magazines.

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