**TITLE: Thermiva in Genital Hiatus Treatment (TIGHT) Trial**

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I have read and agree to follow the NHMRC National Statement on the Ethical Conduct in Research Involving Humans.

Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**Executive Summary –**

The symptom of vaginal laxity or looseness is a common problem effecting anywhere from 24% to 50% of parous women(1,2). It is frequently underreported(1,2). Till recently, the only treatment options for this condition have included physiotherapy or surgery. Both are known to have inconclusive results. Additionally, surgical treatment remains largely diverse in technique with no strong literature suggesting it is effective. Also, risks associated with surgery often don’t make it an amiable choice for younger women who are more likely to be affected by this symptom and potentially considering future pregnancy. Recently, monopolar radiofrequency devices have shown some promising impact on the symptom of vaginal laxity(3-6). More importantly, they are a low risk option in comparison to surgery.

Therefore, we propose to perform a single blinded, randomized sham controlled trial at the Townsville Hospital. The trial will compare treatment with The Thermiva to sham treatment. The study will take place over a period of 24 months. Patients in the treatment and sham group will undergo the same study protocol. There will be an enrolment visit followed by three treatments at one month apart. Follow-up will be at the third treatment and at six and twelve months’ post treatment. According to our sample size calculation we need to recruit 154 patients (77 in the treatment and 77 in the sham group).

We will be using the Thermiva monopolar radiofrequency device which is TGA approved and currently being used in Australia for the management of symptoms of vaginal laxity. We will be using the same Thermiva probe for the sham treatments however, will be operating it at sub therapeutic temperatures (at or below 30 degrees Celsius). The temperature suggested to optimal treatment is 47 degrees Celsius. For the Sham will be use 20 degrees Celsius. We will be obtaining HREC approval from The Townsville Hospital prior to commencement of the study.

Timeline for Study –

**Evaluation –**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | Enrolment | 1st Treatment (Rx) | 2nd Rx | 3rd Rx & 3-month follow-up | 6-month follow-up  | 12-month follow-up |
| History Questionnaire | **X** |  |  |  |  |  |
| POP-Q exam (includes GH & Oxford Score) | **X** |  |  |  |  |  |
| GH & oxford score only |  |  |  | **X** | **X** | **X** |
| Vaginal laxity questionnaire | **X** |  |  | **X** | **X** | **X** |
| Vaginal laxity bother score | **X** |  |  | **X** | **X** | **X** |
| Vaginal flatus score | **X** |  |  | **X** | **X** | **X** |
| Female sexual function index | **X** |  |  | **X** | **X** | **X** |

**Track Record –**

I have been involved in two research projects which have been published in peer review journals:

**Risk factors for obstetric anal sphincter injury and postpartum anal and urinary incontinence: a case-control trial** Madeline Burrell, **Sapna Dilgir**, Vicki Patton, Katrina Parkin, Emmanuel Karantanis.

International Urogynecology Journal 07/2014:26(3): 383-9

**Defecatory Dysfunction of the Pelvic Floor** Ajay Rane & **Sapna Dilgir**. Current Obstetrics and Gynecology Reports. 09/2017: 6(3): 237-242

I am currently the principal investigator in a pilot study on ThermiVA being conducted at the Female Pelvic Health Unit at the Mater Hospital in Pimlico. Additionally, I am responsible for supervising medical students undertaking research projects for their honours projects. Lastly, I will be conducting this study under the supervision of my AGES supervisors.

**Introduction –**

Vaginal laxity or the sensation of vaginal looseness affects anywhere from 24 to 50% of post-partum women(2,4). It commonly affects younger women and can results is sexual dysfunction, emotional distress and even marital stress. Still, it is often underreported to gynaecologists. Current treatment options include physiotherapy and surgery. The results from physiotherapy are largely inconclusive. Surgical management options include perineoplasty, perineorraphy or even vaginoplasty. There is a great deal of variation as to how these operations are performed and no conclusive data on their outcome effects. Additionally, surgical options are associated with risks including dyspareunia.

Currently, there has been a rise in use of radiofrequency and laser devices for the management of vulvovaginal disorders including vaginal laxity(7). Radiofrequency, devices have been shown to result in the phenomena of collagenesis, neurogenesis, elasticity and increased vascularity secondary to the heating effect(3,6,8). These treatment options are being offered at rather high out of pocket costs to patients. Though, the majority of the current literature consists of small sample sized non-randomized controlled trials (RCT’s) single arm trials(3,6,9). Nevertheless, they have demonstrated some effect in vaginal laxity. Only recently, a reasonable sized RCT(the Viveve one study) using a monopolar radiofrequency device for management of vaginal laxity was published and has shown promising results(1). Therefore, we feel it is important to conduct further RCT’s to consolidate this data.

**Objectives –**

**Hypothesis:**

The monopolar radiofrequency device Thermiva is an effective treatment option of vaginal laxity in comparison to placebo

**Primary outcome:**

To establish that the Thermiva is an effective treatment for vaginal laxity via the vaginal laxity questionnaire (VLQ) (appendix 1)

**Secondary outcome:**

To establish if the Thermiva results in an improvement in vaginal laxity bother score VLBS) (appendix 2) & the vaginal flatus score (VFS) (appendix 3). Also, to establish if it results in an improvement in sexual function as measured by the female sexual function index (FSFI) (appendix 4). Additionally, to measure whether a reduction in the genital hiatus and improvement of the oxford score are achieved with the Thermiva treatment. To establish if there is a difference between treatment related adverse events in the treatment and sham group.

**Sample Size –**

Sample size calculations are based on the Viveve one study which assessed vaginal laxity by the vaginal laxity questionnaire and found a 22 % difference between treatment and sham groups. Our recruitment will be 1:1 and we will need 77 participants in the treatment group and 77 in the sham group to be able to reject the null hypothesis that vaginal laxity of the experimental and control groups are equal with probability (power) 0.9. The type I error probability associated with this test of null hypothesis is 0.04.

(Sample size reference: Results from OpenEpi, Version 3, open source calculator – SSCohort: Fleiss with continuity correction).

**Study Duration –**

The study will take place over a period of 24 months. We will aim to recruit patients for a 12-month period. Treatment will take place monthly over a period of 3 consecutive months. The patients will be offered participation in the study if they complain of vaginal laxity or other associated symptoms (vaginal flatus or sexual concerns related to vaginal laxity). They will have had the opportunity to review the patient information and consent form and discuss it with family, friends and their local doctor. Treatment may commence at the enrolment visit or be organised for a later date. The 2nd and 3rd treatments will take place at monthly intervals from the first treatment. Thereafter, follow-up questionnaires will be filled out at the 3rd treatment and 6 months and 12 months post-their 1st treatment.

**Participant Selection Criteria –**

The study will be advertised in The Townsville Hospital, The Mater Hospital Pimlico and to local referring GP’s. Patients presenting with symptoms of vaginal laxity will be offered participation in the trial. Women can volunteer to be in the trial even if they are not patients at the Mater or Townsville Hospital. The patients will undergo a full history and clinical examination should they choose to participate in the trial. The latter will include an abdominal & pelvic exam, a POP-Q assessment, an Oxford Score and HPV DNA testing if they are due for one.

Inclusion Criteria –

* Women who complain of vaginal laxity (or looseness)
* Women $\geq $ age of 18
* Patients able to and willing to give consent
* History of at least one vaginal delivery

Exclusion Criteria –

* Any contraindication to radiofrequency including (women with cardiac devices, pregnancy, active sexually transmitted disease or urinary tract infections)
* Women with a $\geq $Stage II prolapse
* Women with body dysmorphic disorder
* Women with a history of a recto-vaginal fistula
* Non-English speaking background
* Patients unable to follow-up for a period of 12 months’ post-treatment
* Abnormal HPV DNA test and subsequent abnormal liquid based cytology
* Abnormal uterine bleeding
* Patients undergoing physiotherapy or surgical treatment for the management of their vaginal laxity

**Study design –**

The Thermi Tight study will be a single blinded randomized placebo controlled trial. It will be conducted at the Townsville Hospital. The enrolled subjects will be randomised (1:1) to treatment or a sham group. The study personnel initiating the study will not be blinded. However, the physical examination at the follow-up visits will be conducted by a study doctor who will be blinded. This will help prevent bias. The analysis will be intention to treat.

The participants will be randomised based on the ransom list generated using online portal <https://www.randomizer.org/> , into active or sham group. The list of randomisations will only be available to chief investigator.

**Study Description –**

The study will be a single blind placebo controlled randomized control trial. Patients will be allocated to treatment sessions using the Thermiva monopolar radiofrequency device or a sham device. Both groups will have the exactly the same pre-treatment and follow-up protocols. At the initial visit, all patients will undergo a history questionnaire (appendix 5). They will undergo a focused abdominal pelvic examination including speculum, bimanual examination, POP-Q assessment and assessment of their pelvic floor muscle strength using the Modified Oxford Score (appendix 6). If they meet the inclusion criteria they will be offered enrolment in the study. Once informed consent has been taken they will be randomized to treatment or placebo group.

Pre-commencement of treatment, at treatment 3 and at the 6 & 12-month follow-up visits the participants will fill out questionnaire to assess vaginal laxity and sexual function (VLQ, VLBS, VFS, FSFI). These are Likert score based questionnaires. They will be required to complete a female sexual function index (FSFI).

Thermiva is a TGA approved device being utilised for the management of various vulvovaginal disorders including vaginal laxity. The Thermiva is a monopolar radiofrequency device which consists of a small generator, a probe and a grounding pad. The active aspect of the probe is only thumbprint sized and constant movement of the probe allows for tissue cooling to occur. Although, the optimal temperature is 47 degrees Celsius, feedback from the patient determines the maximum temperature achieved. Automated feedback from the machine prevents the clinician from reaching an unsafe temperature range. The device can be moved faster to reduce temperature and more slowly to increase it.

Treatment for the trial will include internal (vaginal canal) and external (labial) treatment. Internal treatment will target each quadrant of the vagina for 2 minutes and bilateral labia for 2 minutes each. The ThermiVA group and placebo group will undergo the same treatment regimens. The only difference being in the placebo group sub therapeutic temperature of maximum 30 degrees Celsius will be maintained. Generally, patients receive a new probe at each visit. However, in our pilot study we have used one probe per patient. The probe is cleaned after each treatment (it does not need sterilisation) and given to the patient to bring back at subsequent treatments.

Patients will be given a post-treatment instruction sheet and will have access to study personnel via phone or e-mail. For urgent matters patients will be asked to attend the emergency department at The Townsville hospital (or nearer hospital if they reside in a surrounding town). Follow-up will be as described above unless the patient requires a medical review at an earlier state.

At the conclusion of the trial the participants will be made of which group they were allocated to. If they continue to suffer from symptoms of vaginal laxity they will undergo repeat assessment and treatment options will be discussed again. If Thermiva proves to be an effective treatment we will be offer the sham group treatment at a reduced cost.

**Risks of the trial –**

We are in the midst of conducting a single-arm pilot study of 30 women undergoing the Thermiva treatment for several different symptoms. Apart from lower abdominal cramps and discomfort and an episode of probe malfunction we have not had any other adverse events occur. However, the risks of the ThermiVa include:

* Lower abdominal cramps and discomfort
* Burning of skin
* Scarring of skin
* Treatment failure

The Thermiva has an automated feedback which allows constant monitoring of the temperature thereby allowing the practioner to remain in the therapeutic range. In addition to this the patient is asked to provide feedback about the temperature which further reduces the risk of overheating tissues. The active electrode is a thumbprint sized device at the tip of the electrode which is moved over the treatment area. This allows tissues that are not in contact with the active electrode to cool and thereby preventing overheating. Lower abdominal cramps and discomfort are managed with nurofen and buscopan.

The patient will be provided details of study personnel whom they should contact should they feel they are suffering from any of the above side effects. If they require immediate medical attention they will be requested to attend the accident and emergency department of the Townsville hospital (or nearer hospital if they live in a surrounding town

If any adverse events (AE) or serious adverse events occur during the study these will be reported to the supervising investigator within a 24-hour period and to the Townsville Hospital HREC representative and Research Governance Officer (RGO) in a 6-monthly report. A final report will be submitted to the HREC and RGO at the completion of the study. AE’s will be classified as adverse events, serious adverse events or suspected unexpected serious adverse reactions. They will be recorded in the Townsville Hospital patient notes and on the excel database. The date the supervising investigator and HREC are made aware will be documented on the database.

The study team will manage the adverse events and seek consultations from another specialist should it be necessary. The patient will be followed-up until her symptoms resolve. Documentation of the management and follow-up of the AE will be written in the patient notes and in short form on the excel database. Whether or not the AE was resolved when the study is completed will be documented with a yes or no on the adverse database. If the study supervisor feels the study should not continue due to any findings the study will be ceased. The patients, HREC and RGO will be made aware of this. If the adverse events are device related the supplier and the TGA will be made aware as soon as possible.

**Evaluation and Record Keeping –**

The history form, exam findings and remaining questionnaires will be stored in the patients file at The Townsville Hospital’s medical records. The data will be stored on an excel spread sheet on a secured computer and a portable storage device for backup which require use of a passcode to enter. Only study personnel will be aware of the passcode. Patient information on this database will be stored using the PIN number.

**Confidentiality –**

Confidential clinical information will be anonymised and identified only by the patient’s unique patient identification number (PIN) and stored in a secure fashion. All clinical documentation will be labelled only with this PIN. Identifiable patient information will be securely stored in patient charts which will be kept with the Townsville Hospital’s medical records. This data will be available for audit in accordance with HREC requirements.

**Statistical Analysis Plan –**

**Sample size & statistical power calculator & Data analysis plan**

Sample size: Group sample sizes of 84 and 84 achieve 80% power to detect a difference of 0.7 between the null hypothesis that both group means are 4.2 and the alternative hypothesis that the mean of group 2 (Sham) is 3.5 with estimated group standard deviations of 1.8 and 1.4 and with a significance level (alpha) of 0.05 using a two-sided two-sample t-test based on the statistical analysis from the Viveve 1 Study(1).

Sample size calculation reference: Results from OpenEpi, Version 3, open source calculator.

Data will be entered into excel sheet which would be available for access only to the supervisors. Data will be stored in a safe and secure location. Data will be analysed using SPSS 23.0. Continuous variables will be tested for normality. Based on the outcome of the test parametric students’ T test or non-parametric Mann-Whitney test will be carried out to determine the significant differences in VLQ, FSFI scores. Categorical data will be analysed using the Chi-squared analysis. Factors contributing to vaginal laxity will be determined using multivariate binary logistic regression. A p value < 0.05 will be considered statistically significant.

**How the data distribution will be assessed?**

Normality of continuous variables will be assessed using Kolmogorov Smirnov test and based on the outcome parametric or non-parametric tests will be run.

**How will missing data be described and sensitivity analysis performed if appropriate?**

* Any missing data will be noted and intention to treat analysis will be carried out
* We will perform a modified intention to treat analysis for women who complete the entire study and follow-up period
* We would ensure that the missing data are necessary for analysis and actually constitute ‘missing data’(10)
* We will make documentation of why data are missing (e.g. side effect related or failure to attend). This will allow us to draw fair conclusions (10)
* A sensitivity analysis will be considered too see if the missing variables effect the output(10)

**Monitoring –**

* Timely receipt of clinical trial data will be monitored by the investigating team and avoidance of missing information will be minimised as much as possible
* At the initial visit, month 3, 6 and 12 months, the compliance with study data requirements will be assessed
* Rigorous monitoring will be in place to ensure that each participant returns for their follow-up visit. Those who fail to attend will be contacted by study personnel via phone and e-mail
* Alternate arrangements for follow-up will be made if the participant is willing to continue participation in the study
* Participants who voluntarily withdraw from the study will have to sign a withdrawal of study form. This information will be documented on a study completion form
* After 3 failed attempts of contacting the patient (on 3 different days) the patient will be considered loss to follow-up. This will be documented on the study completion form

**Quality Assurance of Data –**

* Case report forms will be routinely reviewed by Dr Dilgir for completeness and accuracy as well as any evidence that may be indicative of participant risk
* When any discrepancies are noticed, they will be resolved with by Dr Dilgir and the study supervisor Professor Ajay Rane
* When the data are incomplete, every attempt will be made to obtain the data when possible
* Audit of the data throughout the recruitment & follow-up will be performed

**Management of Intercurrent Events –**

* Patients who fail to attend appointments will be contacted
1. Mobile
2. E-mail
* Attempts will be documented in the patient’s note
* If there is a failure to contact the patient after 3 consecutive attempts on 3 different dates the patient will be considered a loss to follow-up
* This will be noted in the patients file, on the case report form and Study Completion Form
* If they are lost to follow-up after attending one of the follow-up visit (3, 6 or 12 month) the information will be analysed to that visit. This will be clearly illustrated in the study

**Budget and Expenditure –**

Cost of probes - $200 AUD/probe – total cost of 30 800 (each patient will be given her own probe to reuse at subsequent treatments)

Covering cost of parking and travel – $ 6000 (based on parking costs of $5/day and need to pay for bus or taxi in special circumstances)

Stationery and computer equipment – $ 500

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***Appendix 1***

***Patient Identification Number:***

***Visit this was this form filled out:***

***Date:***

Appendix 1

**Vaginal Laxity Questionnaire –**

*How would you rate your current level of vaginal laxity or looseness during intercourse?*

Very loose (score =1)

Moderately Loose (score = 2)

Slightly loose (score = 3)

Neither loose nor tight (score = 4)

Slightly tight (score = 5)

Moderately tight (score = 6)

Very tight (score = 7)

Appendix 2

**Vaginal Laxity Bother Score –**

*How much are you bothered by the sensation of vaginal laxity or looseness?*

*Please indicate on a scale of 0 to 10*

Not at all 0 1 2 3 4 5 6 7 8 9 10 11 The worst imaginable

Appendix 3

**Vaginal Flatus Score –**

**How often to you feel wind or an air bubble coming out of your vagina (also known as vaginal flatus)?**

Almost never (score = 1)

A few times (score = 2)

Sometimes (score = 3)

Most times (score = 4)

Almost always (score = 5)

***Patient Identification Number:***

***Visit this was this form filled out:***

***Date:***

Appendix 4

Female Sexual Function Index –

|  |  |
| --- | --- |
| 1. Over the past 4 weeks, how often did you feel sexual desire or interest?
 | 5 = almost always4 = most times (more than half the time)3 = sometimes (about half the time)2 = a few times (less than half the time)1 = almost never or ever |
| 1. Over the past 4 weeks, how would you rate your level (degree) of sexual desire or interest?
 | 5 = very high4 = high3 = moderate2 = low1 = very low or none at all |
| 1. Over the past 4 weeks, how often did you feel sexually aroused (“turned on”) during sexual activity or intercourse?
 | 0 = no sexual activity5 = almost always or always4 = most times (more than half the time)3 = sometimes (about half the time)2 = a few times (less than half the time)1 = almost never or never |
| 1. Over the past 4 weeks, how would you rate your level of sexual arousal (“turn on”) during sexual activity or intercourse?
 | 0 = no sexual activity5 = very high4 = high3 = moderate2 = low1 = very low or none at all |
| 1. Over the past 4 weeks, how confident were you about becoming sexually aroused during sexual activity?
 | 0 = no sexual activity5 = very high confidence 4 = high confidence 3 = moderate confidence 2 = low confidence 1 = very low or no confidence  |
| 1. Over the past 4 weeks, how often have you been satisfied with your arousal (excitement) during sexual activity or intercourse?
 | 0 = no sexual activity5 = almost always or always 4 = most times (more than half the time)3 = sometimes (about half the time)2 = a few times (less than half the time)1 = almost never or never  |
| 1. Over the past 4 weeks, how often did you become lubricated (“wet”) during sexual activity or intercourse?
 | 0 = no sexual activity5 = almost always or always4 = most times (more than half the time)3 = sometimes (about half the time)2 = a few times (less than half the time)1 = almost never or never  |
| 1. Over the past 4 weeks, how difficult was it to become lubricated (“wet”) during sexual activity or intercourse?
 | 0 = no sexual activity1 = extremely difficult or impossible2 = very difficult3 = difficult4 = slightly difficult5 = not difficult  |
| 1. Over the past 4 weeks, how often did you maintain your lubrication (“wetness”) until completion of sexual activity or intercourse?
 | 0 = no sexual activity5 = almost always or always4 = most times (more than half the time)3 = sometimes (about half the time)2 = a few times (less than half the time)1 = almost never or never  |
| 1. Over the past 4 weeks, how difficult was it to maintain lubrication (“wetness”) until completion of sexual activity or intercourse?
 | 0 = no sexual activity 1 = extremely difficult or impossible3 = difficult4 = slightly difficult 5 = not difficult |
| 1. Over the past 4 weeks, when you had sexual stimulation or intercourse, how often did you reach orgasm (climax)?
 | 0 = no sexual activity5 = almost always or always4 = most times (more than half the time)3 = sometimes (about half the time)2 = a few times (less than half the time)1 = almost never or never |
| 1. Over the past for weeks, when you had sexual stimulation or intercourse, how difficult was it for you to reach orgasm (climax)?
 | 0 = no sexual activity 1 = extremely difficult or impossible2 = very difficult 3 = difficult 4 = slightly difficult5 = not difficult  |
| 1. Over the past 4 weeks, how satisfied ere you with your ability to reach orgasm (climax) during sexual activity or intercourse?
 | 0 = no sexual activity 5 = very satisfied4 = moderately satisfied3 = about equally satisfied & dissatisfied 2 = moderately dissatisfied1 = very dissatisfied  |
| 1. Over the past 4 weeks, how satisfied have you been with the amount of emotional closeness during sexual activity between you and your partner?
 | 0 = no sexual activity5 = very satisfied 4 = moderately satisfied3 = about equally satisfied & dissatisfied2 = moderately dissatisfied 1 = very dissatisfied  |
| 1. Over the past 4 weeks, how satisfied have you been with your sexual relationship with your partner?
 | 5 = very satisfied 4 = moderately satisfied 3 = about equally satisfied and dissatisfied2 = moderately dissatisfied1 = very dissatisfied  |
| 1. Over the past 4 weeks, how satisfied have you been with your overall sexual life?
 | 5 = very satisfied4 = moderately satisfied3 = about equally satisfied & dissatisfied2 = moderately dissatisfied1 = very dissatisfied  |
| 1. Over the past 4 weeks how often did you experience discomfort or pain during vaginal penetration?
 | 0 = did not attempt intercourse1 = almost always 2 = most times (more than half the time)3 = sometimes (about half the time)4 = a few times (less than half the time)5 – almost never or never |
| 1. Over the past 4 weeks, how often did you experience discomfort or pain following vaginal penetration?
 | 0 = did not attempt intercourse1 = almost always or always2 = most times (more than half the time)3 = sometimes (about half the time)4 = a few times (less than half the time)5 = almost never or never  |
| 1. Over the past 4 weeks, how would you rate your level (degree) of discomfort or pain during or following vaginal penetration?
 | 0 = did not attempt intercourse1 = very high2 = high3 = moderate4 = low5 = very low or none at all |

The individual domain scores and full scale (overall) score of the FSFI can be derived from the computational formula outlined in the table below. For individual domain scores, add the scores of the individual items that comprise the domain and multiply the sum by the domain factor (see below). Add the six domain scores to obtain the full-scale score. It should be noted that within the individual domains, a domain score of zero indicates that the subject reported having no sexual activity during the past month. Subject scores can be entered in the right-hand column.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Domain | Questions | Score Range | Factor | Minimum Score | Maximum Score | Score |
| Desire  | 1, 2 | 1-5 | 0.6 | 1.2 | 6 |  |
| Arousal  | 3, 4, 5, 6 | 0-5 | 0.3 | 0 | 6 |  |
| Lubrication | 7, 8, 9, 10 | 0-5 | 0.3 | 0 | 6 |  |
| Orgasm | 11, 12, 13 | 0-5 | 0.4 | 0 | 6 |  |
| Satisfaction | 14, 15, 16 | 0 (or 1) - 5 | 0.4 | 0.8 | 6 |  |
| Pain | 17, 18, 19 | 0-5 | 0.4 | 0 | 6 |  |
| Full scale range score |  |  |  | 2 | 36 |  |

***Patient Identification Number:***

***Visit this was this form filled out:***

***Date:***

Appendix 5

**Patient Demographic Details, Comorbidities, Obstetric, Gynaecological, Medical & Surgical History**

**Background -**

Age (obtained from date of birth)

Relationship status:

Married

Single

De facto

Divorced

Widowed

**History -**

**Please answer yes or know to the follow. If yes, please state the name of the conditions.**

**For the below questions**

**Yes = score of 1**

**No = score of 0**

**Details are requested so the medical professional can confirm history and category and ensure the condition or previous surgery will not be affected by study or affect the study.**

Do you suffer from any **cardiac** (heart) conditions?

Yes or No

If Yes, please state the name of your condition (s):

Do you suffer from **high blood pressure**?

Yes or No

If Yes, please state the name of your conditions (s):

Do you suffer from any **pulmonary (lung)** conditions?

Yes or No

If Yes, please state the name of your conditions (s):

Do you suffer from any **renal** (**kidney)** problems?

Yes or No

If Yes, please state the name of your conditions (s):

Do you suffer from any **liver** problems?

Yes or No

If Yes, please state the name of your condition (s):

Do you suffer from any conditions of involving your **gastrointestinal tract (bowel)**?

Yes or No

If Yes, please state the name of your condition (s)

Do you suffer from any **neurological** conditions?

Yes or No

If Yes, please state the name of your condition (s):

Do you suffer from any **hematologic (blood)** conditions?

Yes or No

If Yes, please state the name of your condition (s):

Do you suffer from any **dermatologic (skin)** condition?

Yes or No

If Yes, please state the name of your condition (s):

Do you suffer from any **gynaecological** conditions?

Yes or No

If Yes, please state the name of your condition (s):

Have you ever had a **sexually transmitted disease** in the past?

Yes or No

If Yes, please name the disease:

Was it treated Yes or No

Have you had any **surgery** in this past?

Yes or No

If Yes, please state the name of all your operations?

Did this include a hysterectomy – Yes or No

Did this include vaginal surgery – Yes or No

Please provide details of the vaginal surgery:

Do you suffer from any **psychiatric** conditions?

Yes or No

If Yes, please state the name of your condition (s):

Have you ever been a victim of **domestic violence**?

Yes or No

Have you ever been a **victim of sexual abuse**?

Yes or No

**It is important to be aware of a history of abuse or violence due to the nature of the study.**

Obstetric Screening:

How many pregnancies have you had?

How many full-term deliveries have you had?

How many pre-term deliveries have you had?

Haw many caesarean section shave you had?

How many vacuum deliveries have you had?

How many forceps deliveries have you had?

Have you had a 3rd degree or 4th degree tear previously?

Yes No Not sure I do not know what a 3rd degree or 4th degree tear is

When was your last baby born in months?

What was the weight of your biggest baby in grams?

Are you planning on having more children? Yes No

Are you on any of the following categories of medications?

Blood thinners

Antidepressants or anti-anxiety?

Regular analgesics (pain-relief)?

Contraception

Do you have any drug allergies? Yes or No

If Yes, please state:

Do you smoke?

Yes or No

If Yes, how long have you been smoking for and how many packs a day do you smoke?

Do you drink alcohol?

How many standard drinks do you drink over a period of 7 days?

Do you use illicit drugs?

Yes or No

If yes, please state the name of the drugs you use:

If yes, please state how many days of the week you use drugs:

***Patient Identification Number:***

***Visit this was this form filled out:***

***Date:***

Appendix 6

***Examination at Enrolment –***

Height

Weight

BMI to be calculated

< 18.5 = underweight

18.5 – 24.9 = health weight range

25 – 29.9 = overweight

> 30 = obese

Abdominal pelvic exam –

POP-Q assessment –

|  |  |  |
| --- | --- | --- |
| Aa | Ba | C |
| gh | pb | TVL  |
| Ap | Bp | D |

* Six points are measured at the vagina with respect to the hymen
* Points above the hymen are negative numbers; points below the hymen are positive numbers
* All measurements except tvl are measured at maximum valsalva
* All values are rounded to nearest 0.5 cm

|  |  |  |
| --- | --- | --- |
| Point | Description | Range of Values  |
| Aa  | Anterior vaginal wall 3 cm proximal to hyen | * 3 cm to + 3 cm
 |
| Ba  | Most distal position of the remaining anterior vaginal wall | * 3 cm to + tvl
 |
| C | Most distal edge of the cervix or vaginal cuff scar |  |
| D | Posterior fornix (N/A if post-hysterectomy) |  |
| Ap | Posterior vaginal wall 3 cm proximal to the hymen | * 3 cm to + 3 cm
 |
| Bp  | Most distal position of the remaining upper posterior vaginal wall | * 3 cm to + tvl
 |

* Genital Hiatus (gh) – measured from middle of external urethral meatus to posterior midline hymen
* Perineal body (pb) – measured from posterior margin of gh to middle anal opening
* Total vaginal length (tvl) – depth of vagina when point D or C is reduced to normal position

POP-Q Staging Criteria –

|  |  |
| --- | --- |
| Stage 0 | Aa, Ap, Ba, Bp = -3 amd C pr D ≤ - (tvl – 2) cm  |
| Stage I | Stage 0 criteria not met and leading edge < - 1 cm |
| Stage II | Leading edge ≥ -1 cm but ≤ + 1 cm  |
| Stage III | Most distal edge is > + 1 but < + (tvl – 2) cm  |
| Stage IV  | Leading edge ≥ + (tvl – 2) cm  |

Modified Oxford Grading –

* Score is obtained by digital palpation of pelvic floor muscles
* One finger is placed on the posterior vaginal wall approximately 2 cm deep into the vaginal. The patient is asked to try and ‘squeeze’ the finger’ in order to assess the strength of their pelvic floor musculature

|  |  |
| --- | --- |
| 0 | No contraction |
| 1 | Flicker |
| 2 | Weak |
| 3 | Moderate (with lift) |
| 4 | Good (with lift) |
| 5 | Strong (with lift)  |

***Patient Identification Number:***

***Visit this was this form filled out:***

***Date:***

Appendix 7

***Examination at 3, 6 and 12 months to take place by a blinded examiner –***

Genital Hiatus Measurement value in cm (rounded to nearest 0.5 cm)

Modified Oxford Score

|  |  |
| --- | --- |
| 0 | No contraction |
| 1 | Flicker |
| 2 | Weak |
| 3 | Moderate (with lift) |
| 4 | Good (with lift) |
| 5 | Strong (with lift)  |