PROTOCOL
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Transvaginal treatment of anterior and apical genital prolapses using an Ultra lightweight mesh: Restorelle® Direct FixTM.

A retrospective study on feasibility and morbidity.

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Study coordinator: Dr Philippe Ferry

Groupe Hospitalier de la Rochelle Ré Aunis
Service de gynécologie
Rue du Dr Schweizer
17019 La Rochelle
Philippe.ferry@ch-larochelle.fr

Content

1 Background

Pelvic organ prolapse (POP) is a functional disease that has a significant impact on quality of life (1). The prevalence of pelvic organ prolapse stage 2 or higher, according to the Pelvic Organ Prolapse Quantification system (POP-Q), ranges from 37 to 50% (2,3). Treatment methods can be conservative or surgical. Conservative treatments are for patients with moderate prolapse, while treatment of symptomatic prolapse remains essentially surgical (4). Surgical techniques can be performed by abdominal or vaginal approach depending on medical history and physical exam. Laparoscopic sacrocolpopexy is often the method of choice and is successful in 80% to 100% of cases (5–8). However, this technique is not always appropriate, especially for patients who have a high anaesthesia risk and/or a multi-operated abdomen. In these cases, a vaginal approach offers an interesting surgical alternative.

Transvaginal mesh was developed to maintain the advantage of a vaginal procedure, while reducing the risk of recurrent prolapse compared with native tissue repair. Four percent of women require repeated surgery due to prolapse recurrence after surgery without mesh, and from 1% to 7% after surgery with mesh.

The US Food and Drug Administration (FDA) published two safety alerts (in 2008, then in 2011)(9) concerning the risks of transvaginal placement of surgical mesh to treat pelvic organ prolapse and urinary incontinence. However, most studies have evaluated mesh types that are no longer available on the market. They have been replaced by new lighter mesh which lack evidence of safety (10).

Restorelle® Direct FixTM is a single incision mesh indicated for transvaginal anterior and posterior surgical repair as reinforcement of pelvic floor defects. It is an Ultra lightweight (19 g/m2) pre-cut macroporous mesh with four lateral arms. It allows an anterior sacrospinous ligament (SSL) approach, using a disposable device (Digitex®) (**Erreur ! Source du renvoi introuvable.**) intended to deliver a suture to the operative site without direct visualization. The proximal arms of the mesh are sutured to the SSL and the distal arms of the mesh are sutured in the arcus tendinous fascia pelvis with the same device.

2 Participants

All adult women who had vaginal repair of pelvic organ prolapse (recurrent or not) planned with anterior Restorelle® Direct FixTM mesh (with or without posterior mesh) were eligible. Patients are excluded if they did not attend their follow up visit within 30 days of surgery.

3 Study design and settings

This is a retrospective multicenter study in gynaecology.

Data collection from patients taken care between January 2013 and December 2016, in 10 secondary and tertiary French care centers.

4 Data

Preoperative assessment consists of

- a detailed medical history,
- a urogynecological examination,
- and prolapse quantification by the simplified Pelvic Organ Prolapse Quantification (POP-Q) system (measurement of total vaginal length at rest and points Ba, C/D, and Bp at maximum Valsalva) (11,12).

Anaesthesia type and concomitant surgery are reported.

Perioperative complications are graded using the Clavien-Dindo classification (13) and their management and outcome are described.

Perioperative, early (< 30 days post-operative) and late (> 30 days post-surgery) postoperative symptoms and complications are recorded.

5 Information for data collection

All information required by the protocol must be recorded on the case report forms and an explanation must be provided for each missing data. The data must be collected as it is obtained and transcribed in these case report forms clearly and legibly.

6 Statistical analysis

The primary outcome measure is the perioperative morbidity (up to 30 days after surgery). It comprised the number of patients with bladder wound, ureteral wound, rectum wound, abnormal bleeding requiring blood transfusion, urinary retention, urinary tract infection, hematoma, ureteral complication, second surgery, or fail of procedure.

The secondary outcome is the number of patients with late complications (up to 3 years after surgery). It includes self-catheterization, recurrent urinary tract infections, de novo urinary stress incontinence, chronic pain, vaginal mesh exposure, prolapse recurrence, de novo dyspareunia, secondary surgery, vaginal granuloma, anatomic (Ba point ≤ −1) and functional failure.

A descriptive analysis of the data will be reported. Median, range, numbers, percentages and confidence intervals were used to describe quantitative and qualitative variables, respectively. Association between demographic and clinical factors (age, body mass index, history of hysterectomy, of POP and stress urinary incontinence surgery, cystocele ≥ 3, concomitant hysterectomy and concomitant sub uretral sling) and perioperative complications will be studied. Bivariate ORs and 95 % confidence intervals will be estimated. Outcomes after surgery with Restorelle® anterior alone or with sling will be compared using a chi-square or a Fisher test.

An alpha level of 0.05 will be used.

7 Number of subjects

The largest users of Restorelle Direct Fix have been selected from all the centers specialized in the management of genital prolapse in France. This series will collect data from the first French installers. This is to obtain a representative sample of at least 100 patients, in accordance with AFNOR NF S94-801 standard (4).

8 Ethical and legal aspects

Data access

Acceptance of participation in the protocol implies that the investigators will make available the individual documents and data strictly necessary for monitoring, quality control and audit to those who have access to these documents in accordance with the laws and regulations in force.

Source data

Source data are all information in original documents or in authenticated copies of these documents relating to clinical examinations, observations or other research activities necessary for the evaluation of the research. The documents in which the source data are stored are called the source documents.

Data confidentiality

In accordance with current legislation, those with direct access to the source data will take all necessary precautions to ensure the confidentiality of information about experimental data, and participating patients and, in particular, their identity and the results obtained. These persons, in the same way as the investigators themselves, are subject to professional secrecy.

During and after the research, the data collected from the patients and forwarded to the sponsor by the investigators (or other specialists) will be made anonymous. They must in no case show clearly the names of the concerned persons or their address.

The sponsor will ensure that each participating patient to the research has given his consent for access to his individual data.

Ethical conduct of the study

The sponsor and the investigators ensure that this research is carried out in accordance with the current applicable Law on research involving human subject and is in agreement with good clinical practice (ICH version 4 of November 9th 2016 and Decision of November 24th 2006) and the Helsinki Declaration (which can be found in its full version at http://www.wma.net).

The data recorded are subject to a computerized treatment in compliance with the law n°78-17 of January 6th 1978 relating to data processing, files and freedoms as amended by Law 2004-801 of August 6th 2004.

9 References

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