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POST MARKET CLINICAL FOLLOW-UP STUDIES (PMCF)

Clinical evaluation for DALLOP® NM urological tape used for surgical treatment of urine incontinence in women – long-term studies.

REPORT ON CLINICAL TRIAL – LONG-TERM EFFECTS

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1. Objectives of the research

The objective of the clinical research is to evaluate the efficacy and safety of the application of the Dallop® NM urological tape in surgical treatment of urinary incontinence in women with the use of a TOT method (with trans-obturator access) after about 3 years from the procedure.

The research assesses also the risk of complications that might appear after tapes implantation and their further impact on the quality of patient's life.

The report on clinical trials regards Dallop® NM urological tapes manufactured by Tricomed S.A. and marketed after gaining the CE safety mark and a registration certificate.

The study group included patients who were operated on in the period from 13.09.2010 to 08.03.2013 in the Matopat Specialist Hospital in Toruń [Poland] in the gynaecology ward. They had the Dallop® NM urological tape implanted with the TOT method.

2. Product characteristics

The Dallop® NM urological tape (Fig. 1) is manufactured by means of a knitting technique of monofilament polypropylene yarn. On both endings, the tape is equipped in loop handles which make it possible for its safe fixation on the tip of a needle applicator.

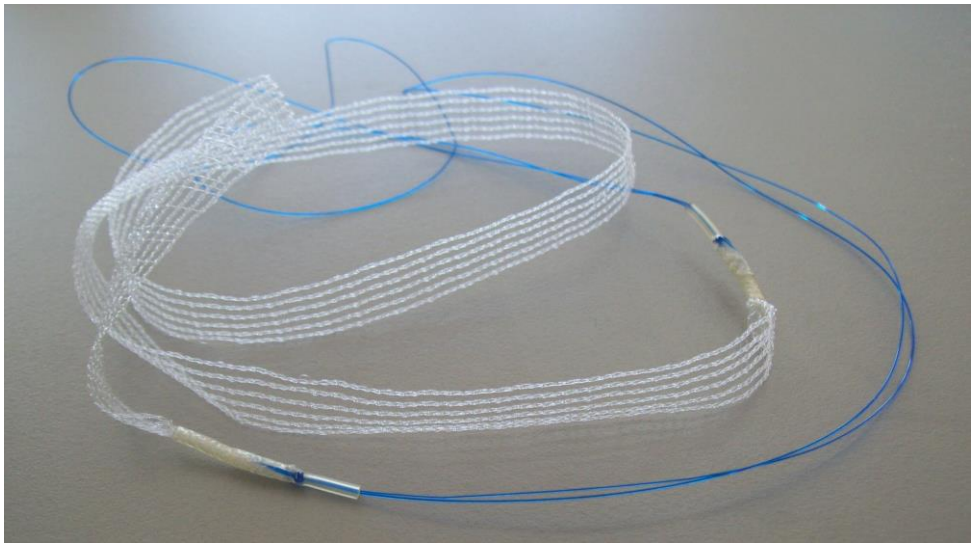

Fig. 1. Dallop® NM urological tape

The device is designed in such a way to meet the requirements for implants used for surgical treatment of incontinence in women by TVT and TOT methods. In these methods an urological tape is introduced by means of needle applicators below the urethra. Creating a support under the urethra,

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the tape brings it back to its natural position which results in patient's recovery. The efficacy of the above-mentioned methods described on the base of literature is of 92%.

Dallop® NM is a class II b medical device according to the Annex IX, rule 8 of the Directive 93/42/EEC.

The Dallop® NM tapes are packed in a double paper-film packaging system (Fig. 2).

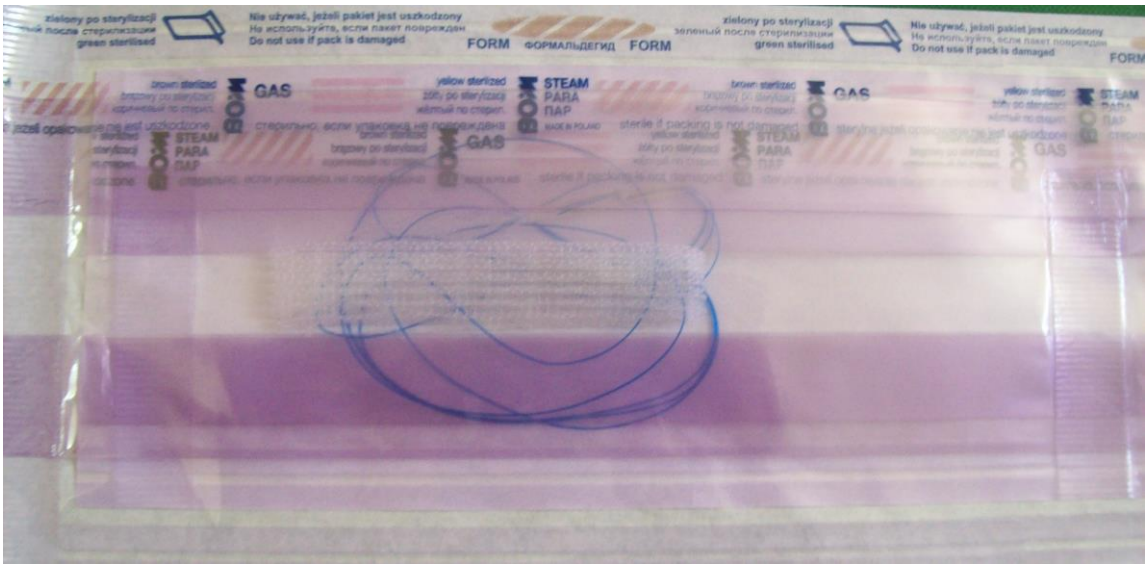

Fig. 2. Packaging system of Dallop® NM tapes

The tested device is offered in a sterile version. The tapes are sterilised in a validated process by means of ethylene oxide. Before they are released for sales, their sterility and any residue of ethylene oxide is evaluated to eliminate hazards related to the presence of toxic derivatives of the sterilising agent.

3. Material and methods

20 female patients with diagnosed with stress urinary incontinence or a mixed type of this disorder with a predominantly stress component took part in the assessment. Each patient had one Dallop® NM tape implanted with the TOT method; the surgical procedures were performed in the period 13.09.2010 – 08.03.2011. With 17 of them phone contact was possible.

During the phone call the patients were offered a consultation and gynaecological examination in the gynaecological outpatient clinic of the Matopat Hospital in Toruń [Poland] to evaluate their health condition by the doctors that had qualified them and performed the surgical procedure of tape implantation three years earlier.

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During the phone call all the patients declared the improvement of their health condition after the operation, no complications related to the procedure and no relapse of stress urinary incontinence.

Four patients definitely refused to take part in the examination, explaining in good health condition. Two patients did not show up for the appointment on an agreed date.

The eleven patients who showed up for the appointment will be taken into account for further evaluation.

Those patients had their intraoperative data and control check-up data after 6 months from the surgery analysed again. A medical interview was conducted, paying special attention to any additional risk factors of urinary incontinence and life quality after the operation. A complete gynaecological examination with ultrasonography of the reproductive system and a cough stress test was performed.

4. Scope of the report

The report is completed with data from the pre- and postoperative period individually for each patient, and data an examination conducted three years after the operation collected in form of questionnaires with giving the number of months from the procedure. The time from the operation to the control examination was 35-38 months, on average 36 months.

5. Research results

The age of the study group was 46 – 77, on average 56 years. BMI was 21 – 33, on average 27. Eight of the patients were operated for stress urinary incontinence, and three had a mixed form. Natural births 0 – 3, on average 1.5.

Two patients in the preoperative period performed heavy physical work, and after three years four performed heavy physical work. From the pre-operative data one patient smoked cigarettes, and during the control examination two reported smoking. Two patients had earlier the uterus surgically removed, two had the uterine appendages removed, one suffered from diabetes, one suffered from chronic progressive inflammatory rheumatism. After 3 year from the operation additionally one patient was diagnosed with bronchial asthma. Compared with the preoperative period in four patients (36.3% of the whole group) within three years after surgery there appeared additional risk factors for stress urinary incontinence.

Length of hospital stay after the surgery - two days (in one case one day). Time to return to full life activity the patient determined in the range of 2 - 4 weeks, an average of 2.6 weeks.

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Pain associated with the history of the surgery in VAS (visual analogue scale in the range of 0-10), all the patients reported the value of "0" - no pain.

Perceptible discomfort associated with the history of the surgery (0-5) (0 - pain, need to remove the tape, 1 - huge discomfort, 2 - extreme discomfort; 3 - medium discomfort; 4 - slight discomfort; 5 - no discomfort) in all patients was estimated at 5 = no discomfort.

None of the patients reported any discomfort associated with stress urinary incontinence. All the patients declared that the quality of life improved after the surgery.

During the gynaecological examination no gynaecological complications and deviations from normal condition associated with the implantation the tape in none of the patients were observed. The cough stress test result in all the patients was negative.

One of the operated patients (9.1% of the study group) in the period of more than six months after the surgery reported mild urinary urgency and she received anticholinergics. There is no possible to conclude whether the symptoms were associated with the surgery (appeared in a distant time from the surgery).

The patient, like the others, indicated that the quality of life improved after surgery.

6. Summary

In the study group in the remote period (three years) after the implantation of the Dallop® NM tape all the patients reported improved quality of life:

- The efficacy of the operation was 100%, according to the data from the medical history and results of the physical examinations, despite the fact that in the group in 36.3% of the respondents there appeared additional risk factors for stress urinary incontinence;

- None of the patients had serious complications requiring surgical intervention (erosion of the tape etc.);

- In one case (9.1%) after 6 months from the tape implantation mild urinary urgency appeared, treated with good effect with anticholinergics, in ten patients 90.9% there were no health problems that could have anything to do with the operation.

7. Conclusions

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Based on the results of the three-year follow-up studies of the group of eleven women, the Dallop® NM urology tape can be considered as an effective, convenient for doctors and patients, and safe method of treatment of stress urinary incontinence in women.

In the study group all patients achieved good results of the surgical treatment and there were no serious complications associated with the history of the surgeries and the tape implanted.

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