

## COMPLICATIONS AND LONG TERM RESULTS OF THE TRANSOBTURATOR TAPE. A RETROSPECTIVE SURVEY ON OBTAPE® EN URATAPE®.

### Hypothesis / aims of study

Stress urinary incontinence (SUI) is a frequently occurring problem. The most common surgical therapy for SUI is the transobturator tape (TOT) procedure. This is thought to be an effective surgical treatment. However, data concerning long term follow-up of specific slings are rare. ObTape® en UraTape® (Mentor-Porgès) are two types of TOT made of a fusion welded, nonwoven, nonknitted polypropylene mesh with small pore size (< 50 µm). The high rate of vaginal extrusion has made the use of these slings obsolete. The objective of this study is to describe the complications associated with these tapes and the subjective cure after five to eight years.

### Study design, materials and methods

Records of all patients who underwent a TOT procedure by ObTape® or UraTape® between January 2002 and December 2005 were assessed retrospectively. Files were searched on the report of reoperations, erosions, vaginal discharge and persisting or recurring incontinence. Furthermore, all patients were approached by telephone and asked for subjective cure of incontinence, complaints of vaginal discharge or erosions and any reoperations in other hospitals.

### Results

From October 2002 until June 2005 43 TOT procedures were performed (7 ObTape®, 36 UraTape®). Follow-up information was available for 36 women, three patients were deceased. In our study seven women, all with UraTape, required a reintervention because of complications. Four patients underwent a reoperation with total or partial removal of the sling or excision of erosive tissue, in one patient an extruded tape was removed at the outpatient clinic. Two patients had developed a fistula in contact with the tape. The mean time from TOT procedure to reintervention was 38 months (range from 3 to 63 months). Recurrence or aggravation of urinary incontinence occurred in 78% of the respondents. Ten of them had undergone an additional anti-incontinence procedure, with most of the time a prior removal of the tape.

### Interpretation of results

We found that reoperations because of erosions or fistula are as high as 19% after five to eight years after incontinence surgery. Moreover, a very high rate (78%) of recurrence or aggravation of incontinence was found, 28% underwent an additional anti-incontinence procedure.

### Concluding message

The high percentage of erosions and forming of fistula in ObTape® en UraTape® is in correspondence with other studies (1,2). Furthermore, the insufficient ingrowth of the tapes leads to poor effectiveness. This illustrates the need for determination of the long term safety and effectiveness of slings before they can be safely introduced on the market.

### References

1. Siegel, A.L.: Vaginal mesh extrusion associated with use of Mentor transobturator sling. Urology. 2005 Nov;66(5):995-9
2. Yamada, B.S.: High rate of vaginal erosions associated with the mentor ObTape. J Urol. 2006 Aug;176(2):651-4.

<b>Specify source of funding or grant</b>	<b>None</b>
<b>Is this a clinical trial?</b>	<b>No</b>
<b>What were the subjects in the study?</b>	<b>HUMAN</b>
<b>Was this study approved by an ethics committee?</b>	<b>No</b>
<b>This study did not require ethics committee approval because</b>	<b>In consultation with the local ethics committee it was not necessary because it concerns a retrospective study</b>
<b>Was the Declaration of Helsinki followed?</b>	<b>Yes</b>
<b>Was informed consent obtained from the patients?</b>	<b>No</b>