

A NEW TYPE OF NEEDLE FOR SAFE, PRECISE, AND EASY PUNCTURE IN TRANSOBTURATOR TAPE PROCEDURE FOR STRESS INCONTINENCE

Hypothesis / aims of study

In the outside-in transobturator tape (TOT) procedure for stress incontinence, a puncture needle is blindly advanced into the vagina; this involves a risk of injury to the adjacent organs and the puncture line is not constant. We report the clinical use of a new type of needle for the TOT procedure. This needle facilitated the safe, precise, and easy puncture for the insertion of the mesh tape.

Study design, materials and methods

1. Structure of the new needle

Fig. 1 shows the schematic diagram of the needle. The needle comprises a puncture part, handle, and target part. The needles are available in pairs, one for the left side and the other for the right side. The puncture part and the handle are fixed, while the target part rotates along the axle line around the handle. When the puncture part is advanced into the body, it moves with the handle around the axle line and accurately reaches the target part. Upon reaching the target part, the puncture part stops because the axle has a stopper (Fig. 2).

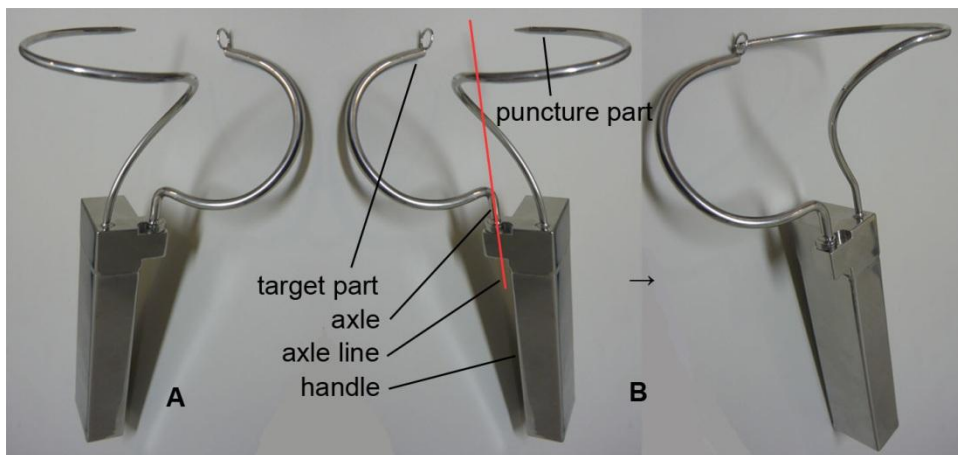


Figure 1 The schematic diagram of the needle

A: for the right side B: for the left side before and after advancing the puncture part

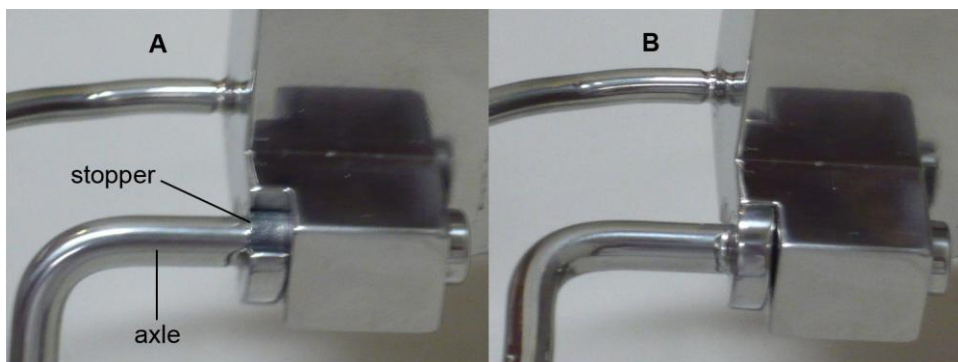


Figure 2 The stopper of the axle A: In the start of the puncture B: In reaching the target part

2. How to create a puncture

The TOT procedure is performed in the usual manner until the stage where a puncture needs to be created. The target part is placed in an ideal position. Without fixing the target position, the tip of the puncture part is pushed at a distance of about 3–4 cm in a straight line in the direction of the patient's head. When the target part is placed in the ideal position again, the tip of the puncture part automatically turns toward the target part (Fig. 3A). When the handle is advanced around the axle without moving the target part, the puncture part moves around the axle line and accurately reaches the target part (Fig. 3B). Because the tip of the puncture part stops at the target part, the puncture part along with the target part can be removed out of the vagina (Fig. 3C).

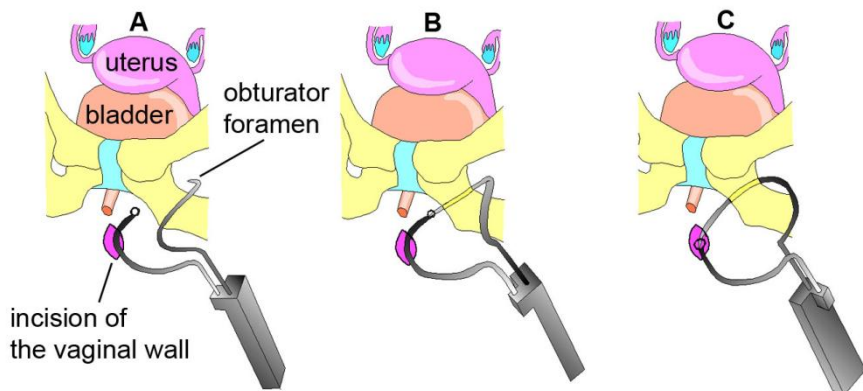


Figure 3 How to create a puncture

Results

When this new needle is used for performing the TOT procedure, the puncture part of the needle easily reaches the target part without being interrupted by any bone or causing any injury to the adjacent organs.

Interpretation of results

This needle has the following merits.

1. The start and the end of a puncture line are decided automatically; hence, even an unskilled technical operator can create an ideal, safe, precise, and easy puncture.
2. An operator does not need to blindly move the tip of needle within the body to determine an appropriate location in vaginal dissection; hence, there is little injury to the adjacent organs.
3. After the tip of the puncture part reaches the target part, it keeps advancing within the target ring; hence, there is little risk of injury to the surrounding organs.

Concluding message

When the TOT procedure is performed using this needle, a stable puncture line is achieved. This not only reduces the injury to the adjacent organs but also allows creation of an effective puncture line for repairing stress incontinence. Creation of a puncture using this needle does not require technical skill, and the procedure is simple; hence, it is easier to teach this procedure to beginners.

<i>Specify source of funding or grant</i>	none
<i>Is this a clinical trial?</i>	Yes
<i>Is this study registered in a public clinical trials registry?</i>	No
<i>Is this a Randomised Controlled Trial (RCT)?</i>	No
<i>What were the subjects in the study?</i>	HUMAN
<i>Was this study approved by an ethics committee?</i>	Yes
<i>Specify Name of Ethics Committee</i>	medical ethics committee, Faculty of Medicine, University of Miyazaki
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	Yes