

Natural Orifice Surgery: Transdouglass Surgery—a New Concept

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ABSTRACT

Background: During the 20th century, laparoscopic procedures replaced most traditional abdominal operations and achieved high-quality standards. It seemed that the optimal surgical method had been achieved; however, a new concept, which might possibly become even safer and simpler is now being developed, the concept of Natural Orifice Surgery (NOS). The existing natural openings of the body started to be used for introduction of surgical instruments for diagnostic purposes and surgical procedures, avoiding penetrating the abdominal wall. Parallel to the American Natural Orifice Surgery Consortium for Assessment and Research (NOSCAR) group, is the New European Surgical Academy (NESA) established in Berlin on June 23, 2006. It is the first European-based NOS working group with participation of scientists and surgeons from different disciplines and countries. After the published experimental achievements had been presented and discussed, the working group decided to concentrate mainly on the transvaginal/transdouglass access in women.

Database: A new surgical instrument, the Transdouglass Endoscopic Device (TED) has been designed. This is a flexible multichannel instrument enabling single-entry surgical, urological, and gynecological operations. TED respects the anatomy of the pelvis. To get to the upper abdomen, an S-shaped device was designed, bending first to the front, and then backwards. For the lower abdomen, the U-shaped mode of the instrument was designed. The wide diameter of the device (35 mm) and its multichannel design enables simultaneous use of different instruments, therefore avoiding hybrid procedures. Various surgical and gynecological procedures have been successfully

simulated, and the manufacturing of the device is in progress. Preclinical studies will start soon.

Conclusions: Transvaginal/transdouglass surgery is expected to be a valid alternative to traditional endoscopic procedures in women. It seems that NOS will create a spectrum of innovative and high-quality procedures performed by an interdisciplinary team and will improve patient safety.

Key Words: Natural Orifice Surgery (NOS), Transvaginal-transdouglass approach.

INTRODUCTION

Today, many abdominal operations are being done endoscopically. Laparoscopic operations are expected to have the same outcome as laparotomies, but with fewer intra- or postoperative complications. In comparison with patients undergoing laparotomy, patients having endoscopic surgery need less postoperative analgesics and have decreased morbidity and shorter hospital stay.¹ Is it, despite the high standards achieved, still possible to make abdominal surgery simpler and safer? A new surgical concept, Natural Orifice Surgery, seems to be the next step in the evolution of minimally invasive surgery.

The Natural Orifice Surgery (NOS) Concept

The NOS idea is not new. For many years, gastroenterologists have used natural openings for various procedures, such as gastroscopy, duodenoscopy, rectoscopy, and colonoscopy. Transsphenoidal surgery for pituitary adenomas has already been in use for over 4 decades.² Furthermore, for the last few years, surgeons have performed the transanal endoscopic microsurgery procedure routinely,³ and since the end of the 19th century, gynecologists have used the vaginal route for hysterectomies in benign cases and in malignancies. Appendicectomies following vaginal hysterectomies have already been performed,^{4,5} and the pouch of Douglas has also been used to remove a gallbladder at the end of an endoscopic cholecystectomy⁶ and as an entry point for some gynecological procedures, such as the removal of fibroids.^{7,8} Recently, perito-

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neoscopy, appendectomy, liver biopsy, splenectomy, and partial hysterectomy have been done experimentally transgastrically with endoscopes.^{9,10} Claimed advantages of NOS include less invasiveness, elimination of abdominal incision, reduction in postoperative abdominal wall pain, wound infection, hernia formation, and adhesions.¹¹

The Transvaginal-Transdouglass Approach

Parallel to the American Natural Orifice Surgery Consortium for Assessment and Research (NOSCAR) group is the New European Surgical Academy (NESA) established in Berlin on June 23, 2006, the first European-based NOS working group.^{12,13}

While the Natural Orifice Transluminal Endoscopic Surgery (NOTES) working group includes transgastric peritoneal access, NESA is exploring the transdouglass route. The difference between the terms “NOS” and “NOTES” is not accidental. “T” in NOTES stands for transluminal. NOS includes NOTES because it refers to all surgical procedures performed through all body openings.¹⁴

Members of the NOS working group are scientists, surgeons, gynecologists, anesthesiologists, urologists, physiologists, and pharmacologists from Germany, The Netherlands, England, Denmark, Austria, Italy, France, Switzerland, Israel, the United States, and Canada as well as representatives from the industry (**Table 1**). During meetings, the concept of Natural Orifice Surgery and published experimental achievements have been presented and discussed, and the pharmacological and physiological challenges concerning the transgastric approach have been considered. Three main problems concerning transgastric access have been identified:

1. The risk of bacteriological contamination when instruments are introduced into the peritoneal cavity after passing through contaminated areas.
2. The optimal way of the gastric wall repair has to be defined.
3. The existing multichannel endoscopes have to be improved.

The NOS Working Group decided to focus on the use of the transdouglass approach in women because (**Table 2**):

1. In transdouglass operations, there is little risk for bacterial contamination compared with the transgastric pathway. Unlike the mouth cavity, oesophagus, and stomach, the vagina can be cleaned and disinfected more easily, thus minimizing the risk of intraperitoneal infection.

Table 1.

Members of the Natural Orifice Surgery (NOS) Working Group

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Table 2.
Comparison of Different Minimally Invasive Accesses

	Transvaginal-transdouglass	Transoral-transgastric	Laparoscopic
Traditional	>100 yrs	No	-
Veress-Needle	No	No	Yes
Access Under Vision	Direct, manual	Indirect, endoscopic	No
Closure Under Vision	Direct, manual	Indirect, still unsolved	Yes
Contamination Risk	Minimal	Yes	No
Ergonomy	Ideal	Good	Bad
No. of Instruments	1	1	3≤
Wound Pain (skin)	No	No	Yes
Ventral Hernia Risk	No	No	Yes
Cosmetic	No scars	No scars	Scars

2. The opening and closure of the vaginal wall is safe and is done under vision.
3. The vaginal wall repairs itself without leaving any visible scars and without causing long-term dysfunction.
4. The introduction of the instruments will be done under vision and parallel to the major blood vessels, thus minimizing the risk of them being injured.
5. Because the traditional 15mm Hg CO₂ pressure is not needed for the introduction of the device, we expect that the working pressure will not exceed 8mm Hg or 9mm Hg. This will enable procedures to be performed with epidural anesthesia.
6. The transdouglass approach improves operation ergonomics. The surgeon can sit comfortably during the procedure.
7. There is no risk for postoperative herniation or eventration.
8. The pouch of Douglas enables the introduction of wide multichannel devices, so that no extra entry and no additional trocars are necessary.

The Transdouglass Endoscopic Device (TED)

An unavoidable step in the development of the transdouglass approach is the establishment of a multidisciplinary team. Surgeons, gynecologists, and urologists have to learn from one another and work as a team.

Another challenge is the development of adapted surgical instruments. Currently used conventional or modified endoscopes are inadequate to perform such complex surgeries. The main aim of our group is the development of a device that will enable the performance of the complete surgical procedure by using a single entry, the transvaginal one, thus avoiding hybrid procedures.¹⁵ That means no need for any additional abdominal wall incision or puncture (one entry, one device!). Furthermore, the transdouglass endoscopic instrumentation must take into account the pelvic anatomy. The Os sacrum and the promontorium require instruments that follow the pelvic anatomy. Such an instrument, the Transdouglass Endoscopic Device (TED) is actually being developed. Its diameter is 35 mm, and it consists of working channels in sizes from 3 mm to 5 mm in diameter, integrated with insufflation and a control system.

To insert the TED, just a pincer and scissors are necessary to perform the posterior colpotomy. For this purpose, the instruments—pincer and scissors—together with the arms on which they are controllably and movably mounted are hidden in the head of the device. There are no sharp edges or any other obstacles allowed at the outer shell of the head that could lead to any injury (**Figure 1**). After the TED has been inserted into the body, the arms with the pincer and scissors will be deployed (**Figure 2**). For a surgeon to perform surgical procedures, these instruments need to be moveable. Besides pivoting, they will be partly rotatable and move forwards and backwards. This will



Figure 1. The Transdouglass Endoscopic Device (TED) in closed state.



Figure 2. The Transdouglass Endoscopic Device (TED) with 2 instruments driven out.

enable tissue manipulation with traction and countertraction in all planes. Besides the 2 instruments, there will be housed in the head a camera, a light, and the instrument for flushing and sucking. Light and camera both will remain operative when the instruments are hidden in the head. Thus, light and camera are already usable during the insertion of the TED into the body. There is also a central channel that runs through the complete surgical device. This central channel corresponds to the “working channel” of endoscopy.

What makes the TED special, in comparison with other known endoscopy or video-endoscopy devices, are the fold-out arms in the small narrow head of this new surgery device. These fold-out arms allow movements in nearly every direction and at the same time a hand-like approach from opposing sides to a surgery exist, until now only an idea or concept. The development of TED is in its final stage.

CONCLUSIONS

Transvaginal/transdouglass surgery seems to be a valid alternative to traditional endoscopic procedures in women. We strongly believe that TED will create a spectrum of innovative and high-quality operations performed

by an interdisciplinary team and will improve patient safety.

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