



**Naples, 21\_22 November 2008**

## **Abstracts**

**Friday, November 21, 2008**

**09.15–10.30: Key Note Lectures**

**Anthony Kalloo**, Baltimore, USA: The Impact of NOTES on therapeutic gastrointestinal endoscopy

**Michael Stark**, Berlin, Germany: Transdouglass surgery: from theory to implementation

**Graf Popken**, Berlin, Germany: Keyhole surgeons – pioneers – visionaries – fantasists

**Luca Cucurachi**, Lecce, Italy: Changes in medicine: Bioethical implications in the new perspectives of surgery

## The impact of NOTES on therapeutic gastrointestinal endoscopy

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Since the first publication of transgastric peritoneoscopy in 2004<sup>1</sup> the concept of natural orifice transluminal surgery (NOTES) has enthralled gastroenterologists and surgeons alike. Furthermore, the prospect of incision-free abdominal surgery has captivated the interest of the public at large. As laboratory feasibility studies are published and anecdotal clinical experiences are reported some have questioned how natural orifice surgery will fit into the practice of gastroenterology. For a select few gastroenterologists, NOTES will revolutionize their practice; for most, NOTES will simply enhance the capabilities of standard endoscopy.

**AN ENDOSCOPIC RENAISSANCE:** The 1970s and 1980s are commonly cited as the golden era of GI endoscopy<sup>2</sup>. Much of today's interventional endoscopy and endoscopic ultrasound was developed during this era. Contemporarily, natural orifice surgery has sparked renewed interest in endoscopy research, quite possibly engendering the modern equivalent of the golden age.

Whereas innovations in endoscopy have stalled over the last decade, medical centers across the United States are now devoting substantial resources to basic science research and technical innovation in endoscopy. For example, a novel endoscope permitting triangulation of instruments and the ability to retract tissue is under development<sup>3</sup>. Such an endoscope might seem specific for transgastric surgery, but it could have broader applications in standard gastrointestinal endoscopy and endolumenal procedures. Retraction and triangulation would permit precise manipulation of tissue, facilitating endoscopic resections. At prima facie value NOTES research may seem field-specific, but there may be broader applications of the innovations.

**IMPACT OF DEVELOPING NOTES-TARGETED DEVICES:** Some of the momentum in NOTES stems from the public's enchantment with "no-scar" surgery. This, in turn, has piqued the interest of some of the endoscopy-associated manufacturing firms. The specter of a popular new field, with its requirement for specialized instrumentation, is obviously appealing to industry. That interest should be considered a boon for gastrointestinal endoscopy.

The need for improved instrumentation is one of the current obstacles in NOTES. Creating a stable operating platform, improving optics, and developing a device for full-thickness closure of a viscerotomy are some of the current industrial pursuits. Again, the applications for these developments are not confined to the field of natural orifice surgery. For example, a reliable full-thickness suturing device might be used to close an unintentional colonic or esophageal perforation.

A stable operating platform and flexible suturing device could open a new vista in endoscopy: full-thickness endoscopic resections. Otherwise unresectable colon polyps and carcinomas-in-situ could be treated with endolumenal resection and serosa-to-serosa closure of the colotomy. The same might be true of early stage esophageal and gastric cancers. This enhances the capability of the standard gastrointestinal endoscopy practiced by most endoscopists.

**A NEW ORGANIZATION:** To guide the progression toward clinical NOTES a new organization was established. Members of SAGES and the ASGE joined to form NOSCAR, the Natural Orifice Surgery Consortium for Assessment and Research. NOSCAR has published its recommendations for laboratory and clinical NOTES research in the "White Paper"<sup>4</sup>. This calls for rigorous investigation into the infectious and immunologic consequences of NOTES. Methods for reliably closing the viscerotomy and monitoring intraabdominal pressure have been recommended. Importantly, NOSCAR suggests that all clinical NOTES be conducted under the aegis of an IRB-approved trial and entered into a centralized database for tracking.

**EMERGENCE OF ENDOSCOPIC SURGERY:** If NOTES should prove to be safe and beneficial, the question arises as to who will actually perform NOTES. Will it be surgeons, gastroenterologists, or both? Most likely it will be a subset from both groups, working in teams, who emerge as the future's endoscopic surgeons. Much like a small proportion of gastroenterologists and surgeons specialize in advanced interventional endoscopy, the same could be said of endoscopic surgery.

Training endoscopic surgeons will require restructuring endoscopic education<sup>5</sup>. To gain proficiency in NOTES, an endoscopic surgeon will need to be a skillful flexible endoscopist. Beyond that, an intimate familiarity with abdominal anatomy, both normal anatomy and the aberrations, is imperative. Mastery of dissection, retraction, and hemostasis is necessary to safely operate within the abdomen. Finally, all endoscopic surgeons should be able to manage the complications that might accompany the operations.

Training such an endoscopic surgeon is complicated. Some general surgeons lack the skills in flexible endoscopy for endoscopic surgery, and gastroenterologists might lack familiarity with abdominal anatomy and surgical principles. Therefore new fellowship training programs may arise.

By necessity, a year of endoscopic surgery training would need to vary for gastroenterologists and surgeons. Most surgical endoscopists would need to gain comfort with endoscopic ultrasound. GI endoscopists might learn the skills of laparoscopy and conventional abdominal surgery, in addition to natural orifice surgery. For both, a substantial amount of time would be spent in the animal and simulation laboratories before proceeding with clinical NOTES.

**EXPANDING THE BREADTH OF ENDOSCOPY:** The initial clinical applications of NOTES will probably consist of unconventional abdominal operations. This will require surgical endoscopists to broaden their knowledge and scope of their practice. For example, appendectomies and cholecystectomies can be safely and efficiently performed laparoscopically using current instrumentation. However, intensive care unit cases may be better suited for NOTES. The portable equipment for NOTES obviates the inherent risks of transporting an ICU patient to the operating room. The potential for operating within the abdomen under deep sedation, rather than general anesthesia, also comports with NOTES in the ICU.

A potential application for ICU-based NOTES is diaphragm pacing<sup>6</sup>. Diaphragm pacing might reduce ventilator dependence in select critically ill patients. Transporting this group of patients to the operating room poses some risk and requires significant resources. If these patients could be treated in their ICU beds using portable equipment under conscious sedation, safety and efficiency would be improved.

As an alternative to laparotomy or CT scan in suspected small bowel infarction, the abdomen could be explored via transgastric peritoneoscopy. Confirmation of massive small bowel necrosis would preclude an operation and its attendant resource requirements. Findings of limited small bowel necrosis would serve to select the patient population that would benefit from laparotomy and bowel resection. In this instance, NOTES could serve as a screening tool to select patients best suited for laparotomy.

The potential portability of NOTES raises interesting possibilities. One scenario could involve surgically managing acute abdominal trauma at the site of injury such as at the scene of motor vehicle accidents or military field. This may provide rapid life saving intervention when timely organ repair is critical.

**PREPARING FOR THE FUTURE:** Clinical natural orifice surgery may not manifest for many years, but gastroenterologists and surgeons with an interest in the field should begin preparation now. The first step is to join forces with other interested colleagues. As dictated by NOSCART, team makeup should consist of both surgeons and gastroenterologists. The success of the team will depend on the free flow of technical knowledge and philosophies.

After formation of a team, laboratory research is a necessity. The laboratory is where the techniques of NOTES should be refined and the physiologic implications should be investigated. Because of the high standards necessary for introducing a novel clinical technique, NOTES will not thrive without accumulating rigorous scientific laboratory data.

CONCLUSIONS: On the surface, it may seem as though NOTES could inexorably alter the field of gastroenterology. After all, natural orifice surgery serves as the vehicle to use the flexible endoscope beyond the confines of the gastrointestinal lumen. NOTES and endoscopic surgery will likely be practiced by a small percentage of gastroenterologists, at least at the outset similar to the evolution of Endoscopic Ultrasound among gastroenterologists. It is conceivable that eventually every tertiary level Endoscopy Unit will have one or two NOTES-trained physicians again much like the evolution of the ERCP or EUS subspecialist

There may be “downstream” benefit to gastroenterologists by the development of NOTES devices. Improved instrumentation may enhance polypectomy capabilities or even permit full-thickness resections. Optics may improve and methods for scope stabilization may become available. Furthermore endolumenal techniques for management of perforations or fistulae may arise.

The real impact of NOTES will be philosophical. Collaboration and communication will prevail over turf battles and secrecy. A small proportion of gastroenterologists and surgeons might practice natural orifice surgery, but the spirit of cooperation that contributed to its development should be palpable across the fields. It is expected that as this field develops other specialties such as Urology, Obstetrics and Gynecology and Cardiothoracic surgery may find the natural orifice to be a kinder and gentler point of entry. One benefit of the team approach is to stimulate creativity. Creative energy should multiply when the team convenes. NOTES was created by pushing the envelope and challenging dogma. Sound science both in the laboratory and with clinical trials will be critical for its success.

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## Transdouglass surgery: From theory to implementation

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Most surgical procedures of today already have endoscopic alternatives. It was shown in many comparative studies that patients having endoscopic procedures have decreased morbidity and a shorter hospital stay and need less postoperative analgesics compared with patients undergoing laparotomies. Nevertheless, laparoscopic procedures have not proved to be completely safe as they are performed using general anaesthesia with intra-abdominal pressure up to 15 mm Hg and with insertion of different trocars.

Besides today's huge experimental work on transgastric surgery, the New European Surgical Academy (NESA) promotes the use of the Douglas pouch as an entry for different abdominal operations in women, as we believe that it might become the next step towards a change which will contribute to safety and excellence.

Appendicectomies following vaginal hysterectomy have been performed for many years, and the pouch of Douglas has also been used as an entry for infertility work-up and for the removal of the gallbladder following endoscopic cholecystectomy. The New European Surgical Academy (NESA) is preparing the prerequisites to use the pouch of Douglas as a routine entry for abdominal operations in women. The expected advantages of this approach are the following:

1. The introduction of the instruments is done under vision, and the intra-abdominal pressure needed should be low enough to enable the performance of various procedures under epidural anaesthesia.
2. The instruments are introduced parallel rather than perpendicular to the major blood vessels, thus minimizing the risk of injury.
3. The diameter of the pouch of Douglas enables the introduction of wide multi-channel devices, so that no extra transabdominal entry is necessary.
4. The vagina can be easily cleaned. The risk of intraperitoneal infection is minimized.
5. The vaginal wall repairs without visible scars.
6. The ergonomics of the operation are improved.
7. For these procedures only one entry port is needed.
8. No risk of herniation or eventration.

A *multidisciplinary* surgical team of scientists, surgeons, gynaecologists, urologists and anaesthesiologists are joining forces in designing transdouglass procedures like cholecystectomies, appendicectomies, hysterectomies and nephrectomies. A U- or S-shape multi-channel instrument respecting the pelvic anatomy and enabling to perform operations in the upper and lower abdomen has been designed and will be introduced, apart from the planned procedures, simulations and the first results.

## **Keyhole surgeons – pioneers – visionaries – fantasts**

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Endoscopic, laparoscopic and robotic surgery such as the surgery through natural body openings has a long history and goes on the 10th century back. Substantially these were essentially influenced through the development of endoscopes beginning of the 20th century. These innovations always were linked to surgeons, ready to go new ways to pursue a visionary thought. In the story of the surgery, it gave always discrepancy between that what was possible for the established old surgeon, and that what others nevertheless already would have been able to do. There was always surgeons – extraordinary appearance – that with the reached satisfied were not and shake at the boundary stakes of the old surgery. These developments were possible only through the personal use of this pioneer and the development contingent through it by technical requisites. Through it that these new diagnostic and therapeutic methods often ways followed, that were not established or well known in the medicine, these protagonists were often blamed as fantasts.

At the examples of the diagnostic and therapeutic endoscopy of the urinary tract, the establishment of the ablative and reconstructive surgery in benign and malignant diseases, this development can be represented.

A further challenge of the next years represents herewith the surgery through natural orifice, the so-called "Natural Orifice Surgery" (NOS). Next to the establishment of this completely new surgery over until there practice access ways, operation strategies and the development of new instruments never is an interdisciplinary experience exchange not only between the surgical disciplines, but rather especially with the endoscopic active internist necessarily. The new ways of the surgery of the next generation will be followed can only by this synergistic effects and out of fantasts visionary thinking pioneers become.

## Changes in medicine: Bioethical implications in the new perspectives of surgery

Cucuracchi L

High Institute of Religious Sciences, Theological Faculty of Puglia, Lecce, Italy

The contents of the presentation are:

- 1) Haptic Vision in Surgery: Sensation and standardization in surgical methods between robotic and fingertip models;
- 2) New Paradigms in Surgery: Bioethical and philosophical issues.

*I would like to suggest a comparison between the “haptic fingertips surgery” approach and the “haptic robotic surgery”. In this context I think we have a co-existence of two different paradigms in the same scientific pattern. I will consider the point of view of history of medicine and its categories of development and changing, by referring particularly to Th. Kuhn and his conception of science and its paradigms, in order to analyse the difference and the relationships between the two methods of “fingertip” and of “robotic” surgery.*

*I'll try to apply Kuhn's theory of science to the surgery changes, by comparing the differences and the specificity of the two haptic approaches, but not to divide but to integrate them.*

*Finally, I want to tackle some bioethical implications which come from the new procedures in haptic surgery, particularly in the fingertip approach.*

The *haptics*, the sense of touch, involves many areas of research in medicine and surgery: haptic systems involve teleoperation, virtual environments and robotic manipulation. The main research activities are: devices that are thin and steerable from outside to improve medical procedures (chemotherapy, radiotherapy to biopsy, tumor ablation, microsurgery); tools to improve motion and activities of impaired humans and to help to master their complex manual skills (particularly in case of naturally and congenital upper-limb amputees and deficiencies, haptic tools could interact with the control of next-generation prostheses); specific biomechanical models, robotic devices and novel control strategies could be applied in many neurological disorders for rehabilitation therapy and optimizing compensation, learning and movement control.

The most interesting field of application of haptic devices is the robot-assisted minimally invasive surgery where it is important to find models of integration between the medicine and the engineering research, in order to manage and utilize haptic information during minimally invasive procedures (through the modelling of forces and deformations of surgical instruments contact and the distance simulation of operative area). This implies an interaction among medicine, technology, physics and engineering.

I will consider T. Kuhn and his differentiation between a “normal period” of science and a “revolutionary period” of science. The revolutionary phase of science is not only a period of changes or exceptional progress in science but it “qualitatively” differs from normal science. Normal science is not only a cumulative model of knowledge, but it is intended as a “puzzle-solving”; this means that the puzzle and its methods of solution have a high degree of familiarity with the puzzle-solvers. Revolutionary science, however, is not cumulative, but it involves a revision of existing scientific beliefs or practice. In the revolutionary period of science some “normal” achievements of the preceding period are preserved.

The comparison between different theories involves complex issues which need to be conducted by determining some criteria such as: incommensurability, the role of the nature of “perception” and “standardization” in case of haptic surgery, the width of the transition from normal to new approach and the properties of new scientific practice and theory.

My contribution consists in a “philosophical” and ethical analysis of methods and goals in minimally invasive surgery, both in its robotic version and in its fingertip method, but also in a bioethical consideration about new conception of physicians-patient relationship.

**Friday, November 21, 2008**

**10.45–13.00: Scientific session: Natural Orifice Surgery (NOS)**

**Tahar Benhidjeb**, Berlin, Germany: Transoral videoassisted thyroidectomy (TOVAT)

**Mark van Berge Henegouwen**, Amsterdam, Netherlands: In vivo studies on NOTES peritoneoscopy

**Andreas Blana**, Regensburg, Germany: NOTES in urology – future or fiction?

**Tom Schneider**, Rotterdam, Netherlands: The anatomy of the fornix vaginalis posterior/cul de sac and surrounding structures – preparation for the transvaginal operation

**Francesco Corcione**, Naples, Italy: Transgastric and transvaginal cholecystectomy

**Gian Carlo Di Renzo, Sandro Gerli**, Perugia, **Riccardo Rolli**, Asiago, Italy: Culdotomy "revised": a promising approach in the era of minimally invasive gynaecological surgery towards the use of the natural orifice.

**Anthony Kalloo**, Baltimore, USA: NOTES: The Future

## **TransOral Video-Assisted Thyroidectomy (TOVAT)**

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**OBJECTIVE:** Aim of this project is the introduction of a technique of thyroid resection that is minimally invasive, safe and cosmetically optimal (scarless) for the patient. The technique that fulfils these criteria is the transoral access because the distance between the retrolingual space and the thyroid gland is short, thus avoiding extensive dissection. Furthermore, the mouth mucosa repairs without leaving any scars.

**METHODS:** In 3 cadavers, safety and reproducibility to reach and resect the thyroid gland was assessed according to a predefined road map. At the end of the procedure the cadavers were autopsied in order to evaluate all defined anatomical key structures regarding possible injuries. The TOVAT itself was performed on 2 further human cadavers using one 5 mm and two 3 mm trocars which were introduced through the mouth floor subplatysmally. A working space was created by insufflating CO<sub>2</sub> at a pressure of 4–6 mmHg.

**RESULTS:** Description of landmarks of surgical steps and dissection of defined anatomic structures could be achieved. One-side subtotal resection could be successfully performed without any skin incision in 60 minutes.

**CONCLUSIONS:** The minimally invasive aspect and the scarless character of TOVAT form the rationale for the preclinical investigation of this method in human cadavers. We could succeed in defining objective parameters, which describe the procedure in detail and also allow an evaluation of the surgery performed. The feasibility of TOVAT could be demonstrated. The next step will be its application in living pigs before it will be applied in humans.

## In vivo studies on NOTES peritoneoscopy

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The presence of peritoneal metastases is a frequent cause of unresectability for GI malignancies such as pancreatic cancer and primary or secondary hepatic malignancies. Preoperative detection is difficult and laparoscopy is frequently required to exclude metastatic disease prior to resection.

NOTES (Natural Orifice Transluminal Endoscopic Surgery) may facilitate performing a peritoneoscopy (transgastric, transvaginal or transcolonic). This may be an alternative to laparoscopy, which could be performed at the time of a staging endosonography. NOTES peritoneoscopy has been studied in numerous studies since the first report by Kalloo et al. in 2004 and has been performed in a small number of humans.

We created a model of peritoneal metastases to evaluate transgastric and transcolonic peritoneoscopy. In a number of consecutive studies we compared these approaches to each other and standardized laparoscopy in a live animal model.

The protocol was performed in the live anesthetized porcine model. 2.5 mm color-coded beads were stapled via a laparoscopic procedure to the peritoneum and organs to simulate metastases. 3 to 7 beads were placed in each of 12 animals (total 64 beads). Locations included: abdominal peritoneum, diaphragm, surface of liver and miscellaneous sites: hepatoduodenal ligament, visceral peritoneum, omentum, anterior stomach and pelvis. 3-port laparoscopy was performed by one of 2 surgeons blinded as to the location and number of beads. Transgastric peritoneoscopy (TGP) was then performed with a 2 channel therapeutic upper endoscope using either standard accessories (forceps, cap) or with a specially designed toolkit (by blinded endoscopist). A 30 min time limit per examination was used. A non-inferiority design was used to calculate the sample size. In a second experiment transcolonic peritoneoscopy (TCP) was evaluated.

Laparoscopy found 61 beads (yield = 95 %), TGP 61 % with standard accessories and 63 % with the toolkit (both  $p < 0.0002$  vs. LAP). TGP was superior for detecting beads on the abdominal and diaphragmatic peritoneum than for the other sites. TCP yielded a success rate of 74 % for the standard procedure (non-inferior to laparoscopy).

**CONCLUSIONS:** NOTES peritoneoscopy might be one of the future procedures in the NOTES field. We successfully created a model for peritoneal metastases and established the benchmark for laparoscopic detection. In this first prospective, blinded, comparative trial TGP was inferior to laparoscopy for the detection of simulated metastases. The transcolonic procedure, however, was not inferior to laparoscopy. This model will be useful for future device development, which should focus on improved access to the region of the liver and enhanced endoscope optics and performance.

## **NOTES in urology – Future or fiction?**

Blana A

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Urologists have always been involved in the development of new surgical techniques. Endoscopic procedures are now routinely used with transurethral and percutaneous approaches. Laparoscopy also has become a standard of care in kidney and prostate surgery. This has led to a dramatic reduction in the invasiveness of most urologic procedures. However, extraction of the surgical specimen through the abdominal wall is still associated with morbidity and scarring.

Natural orifice transluminal endoscopic surgery (NOTES) is an emerging technology that combines principles of laparoscopy and endoscopy. In the field of urology there is an increasing number of reports on NOTES in the laboratory setting as well as first reports on NOTES in selected patients.

A review of the literature was performed to give an updated summary of the current status of NOTES in urology.

## **The anatomy of the fornix vaginalis posterior/cul de sac and surrounding structures – preparation for the transvaginal operation.**

Schneider TAJ

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In a small study we showed that in embalmed cadavers the mean diameter of the fornix vaginalis posterior was less than 3 cm, the size of a big olive.

When asked, the gynaecologist in the Erasmus University Hospital Rotterdam with the longest laparoscopic experience estimates that the biggest myoma he managed to remove through Douglas had a size of 10 x 10 cm, the size of a big apple

David Nichols (1983) compared the differences in the interrelationships between the organs of the living woman and those of an embalmed cadaver with the differences in grapes and raisins.

Is this the only explanation of the difference or does too big cause damage in the passage?

Is there a parallel to the damage done to the endopelvic fascia by the passage of a child during vaginal delivery?

The inconsistency in fruit sizes will be discussed.

## **Transgastric and transvaginal cholecystectomy**

Francesco Corcione, Diego Cuccurullo

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In this study we report our personal experience and the international revue about transluminal cholecystectomy. Until today the already experimented accesses are the transvaginal and the transgastric one, the latest performed with the help of new technological suture systems.

We think that the few cases treated, and the problems due to the complications and the sequels of that approaches don't allow us any enthusiasms; even though we suppose that with the technological evolution there will be a further development and diffusion of the procedures, and maybe an improvement of the outcomes, with possible codification of the indications.

# **Culdotomy "revised": A promising approach in the era of minimally invasive gynaecological surgery towards the use of the Natural Orifice.**

## **Re-evaluated culdotomy techniques with other instrumentations.**

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**OBJECTIVE:** The purpose of surgery for both surgeons and their patients is to obtain the best possible anatomic/functional result along with a satisfactory aesthetical outcome. Surgery has had a turbulent development over the last ten years, which have been more than often criticized.

**STUDY DESIGN:** In this prospective we have re-evaluated culdotomy techniques, in our gynaecological practice, with the intention to widen its indications within the benign pathology of the uterus and adnexae. Also in virtue of its integration with other instrumentations, such as the flexible optics fibre with cold light and the ultrasonography with intra-abdominal probes, that reduces the limits and the disadvantages of the old techniques like limited visibility and brightness in the operating area.

**RESULTS:** From February 2000 to July 2008 we selected 174 patients between the age of 20 and 79 years old (average 37.48 yrs.), 55 null-pares (31.61 %) and 119 pluripares (68.39 %), of which 89 (51.15 %) have had at least a previous abdomino-pelvic surgical intervention. For 64 of them (36.78 %) the preoperative diagnosis was of ovarian benign pathology (liquid cyst or mucinose (36), endometriosis (23), dermoids (5)), for 73 (41.95 %) the diagnosis was in the nature of annessial benign pathology (paratubal cyst (16), EP (3), Fallopian tube bilateral sterilization (53), tube-ovarian abscess (1)), and for 37 (21.27 %) the diagnosis was of uterine benign pathology (fibromyomas). The duration of hospitalization has been on average for 24 hrs (range from 12 to 72 hours) of which 145 (83.33 %) in DH and 29 (16.67 %) in ordinary hospitalization.

**CONCLUSION:** The culdotomy has resulted as a method endowed with numerous advantages, for the operators, thanks to the great technical simplicity, the rapidity of execution, the use of traditional tools even using the techniques control with endoscopy, the minimal invasivity and less operation risk, and regarding the patients' psychological, aesthetical and social advantages, less risks, shorter hospitalization, brief convalescence, and a quick return to ones normal life.

### **EXTENDED ABSTRACT:**

**INTRODUCTION:** In the last few years, many surgical schools have reconsidered Culdotomy techniques as the best approach to gynaecological benign pathologies. This originates from the use of laparoscopy which has taught the gynaecologist to be less aggressive and more perseverant.

Laparoscopy has not only resolved the aesthetic dilemma, but it has also reduced the damage to the surgical site, the duration of hospitalization, post operative recovery time, and mostly the compressive sanitary expenses.

In light of these considerations, many gynaecologist-surgeons have wanted to go further, simply because they are also laparoscopists, therefore they are sensitive to the advantages this technique offers. They have reconsidered a method that was used in the 1960s only for diagnostic purpose. Practically, it was the same route that Semm went through, from diagnostic laparoscopy to operative laparoscopy.

The modern scientific criteria, presently valid to our day, suggest a periodic revision of methods and surgical techniques, to consent a thought-out objective of their effectiveness and mostly the legitimation of their existence.

For this technique, the main individual factor depends on the ability of the surgeon and, in particular, the orientation of his surgical training (e. g. in gynaecology that offers the alternative between laparotomy and vaginal) occupies an important role in decision making.

It is more interesting when, as in case of colpotomy, the technique presents distinctive limitations either in a restricted sense or in a specific assignment that it proposes to technician.

Also, recent publications on culdotomy refer to the traditional method that, thanks to the modern diagnostic technologies, allows a more contemplated surgical approach.

The abdominal and/or transvaginal ultrasonography, the CT, the MRI, the diagnostic Hysteroscopy, Colposcopy, the tumor markers and the beta-hCG evaluations and many others, permit the surgeon to operate with extreme precision. This also permits the surgeon to perform a culdotomy, where the vision of the operating field is scarce, with good results.

Thanks to the diagnostic techniques, the indications of culdoscopy have been reduced while the therapeutic interventions have increased.

We, being laparoscopists, have decided to reconsider the culdotomy technique, adjoining it with new endoscopic tools that permit us to perform the intervention as if it were an endoscopy.

In this prospective we have re-evaluated culdotomy techniques, in our gynaecological practice, with the intention to widen its indications within the benign pathology uterus-annexial. Also in virtue of its integration with other instrumentations, such as the flexible optics fibre with cold light and the ultrasonography with intra-abdominal probes, that reduces the limits and the disadvantages of the old techniques.

In fact, it's from the association between endoscopy, the intra-operative ultrasonography and the culdotomy technique that we are convinced to obtain an identical result and in some cases more advantageous than laparoscopy.

**DEFINITION:** The posterior colpoceliotomy is the most direct access to the female genital reproductive organs. It's also the simplest and the easiest system. Colpoceliotomy requires a certain manual ability, other than a discreet physical force (surgical gymnastics); however it offers, as compensation, some advantages that cannot be ignored as a surgical option in the subject of gynaecological benign pathology.<sup>1</sup>

Culdotomy is better recognized by various names. Other designations have been:

- posterior colpoperitoneotomy
- posterior colpoceliotomy
- posterior vaginoperitoneotomy
- posterior vaginoceliotomy

The standard term defining precisely what is done is "culdotomy"<sup>2</sup>, that is, the incision of the posterior vaginal fornix through which the abdominal cavity is directly accessed.

**TECHNIQUE:** The patient undergoes local anaesthesia and is positioned on the operating bed in the gynaecological position, in Trendelenburg, with an inclination of about 15°.

Once the vagina widens apart, a transversal central line incision is made in the mucosal vaginal wall, between the two uterus-sacral ligaments, approximately 2 to 3 cm under the posterior labia of the cervix. The sub-mucous and the areolar tissue are opened through dissection with scissors to identify the peritoneum. Finally, the leaflet peritoneum is opened widening the incision on both sides.<sup>3</sup> The opening of the abdominal cavity takes about 60 seconds.

To this it is added, and here is our intuition, the pre- and/or post-operative endoscopic vision of the pathology to treat and of the operating field through the flexible endoscopic

fibres, through the creation of a virtual abdominal cavity in gasless but without incisions or trocars on the wall abdominal.

The abdominal wall was lifted in the first procedures by the applied obstetric vacuum on the abdomen; then we use there fixed arms to the operating bed and hooked them in a way that there is absolutely no trauma to the abdomen.

At the end of the procedure the peritoneal cavity is closed with a continuous suture and finally the vagina, also in a continuous suture, with a rapid absorption thread.

Some authors make their incision 3–4 cm under the posterior labia of the cervical os<sup>4</sup>. In these cases, the traction of the uterine neck towards the pubic, through the pliers with two teeth placed on the posterior labia of the uterine neck, a rectal cone that constitutes a danger to avoid.

Some authors make a longitudinal incision on the vagina starting from the zone of reflection of the vagina on the uterine neck; at the end of the intervention they close the peritoneal with "tobacco's purse" like sutures and the vagina with non continuous sutures.<sup>1</sup> In the last few years, many surgeons no longer perform the closure of the peritoneal and, therefore, they limit only the closure of the vagina.

Other authors use epinephrine solutions with a concentration of 1:200.000 to infiltrate the vagina as to avoid bleeding without having hypertensive episodes.

In cases whereby it is necessary to turn the uterus upside-down, a blunt hook can be used or intrauterine probe hysterometre.

In the nulliparity patients with scarce "aditus to antrum" a perineotomy can be practised medially or laterally.<sup>2</sup>

Sometimes, the incision of the anterior fornix, after the ungluing of the bladder, the opening of the peritoneal Retzius has been successful.<sup>5</sup>

Some authors perform, contextually to the culdotomy, a hysteroscopy and/or biopsy in selected cases (suspect of EP, Endometrial cancer, sactosalpinge, etc.).<sup>6</sup>

The duration of the procedure, calculated from the beginning of the vaginal incision at the end of the suture, is in average of 15–20 minutes.<sup>7</sup>

In the female sterilization, the duration of the operation, is at times, just 10 minutes, depending if clips or bipolar electrodes are used.<sup>1</sup>

**PATIENTS' SELECTION:** The preliminary diagnosis is very important and careful evaluation of each caso.<sup>8</sup>

The patients must previously be selected on the basis of clinical-anamnestic and ultrasonographic criterion with the purpose to exclude the presence of possible contraindications and to verify the volume and the position of the masses.<sup>7</sup>

This is the clinical phase that permits us, today, to overcome the obstacles that our colleagues in the 1960s had with this technique. This is also the main reason why this method was abandoned.

Today the new diagnostic technologies like the abdominal and/or transvaginal ultrasonography, the C. T., M. R. I., diagnostic Hysteroscopy, tumor markers and the beta-hCG evaluation and many others, have permitted surgeons to know in detail the location, the extension and the nature of the pathology.

Therefore, from these considerations we assume that our procedure with the culdotomy technique is equal, by vision, to that of laparoscopy.

PERMITTING CONDITION: Every surgical technique has a specific field of application. Then, as years go by and according to the surgical training, the various methods have sustained an evolution of different procedures needed to be completed or as well as through the evolution of new instruments.

Therefore culdotomy should not replace laparotomy or laparoscopy, but it has to be integrated with them and with time will find its place.

There are conditions that permit a culdotomy following pelvic situations:

- Douglas cavity free during palpation and instrumental examination;
- Discreet uterine mobility;
- Absence of malignant uterus-annexial pathology;
- Absence of pelvic infections.

EXAMINATIONS AND PRE-OPERATING PREPARATION: First of all, it is opportune, even if not fundamental, an intestinal preparation, as in laparoscopy, a diet without fiber, for five days. This is, mainly, for the relaxation of the small bowel, a very important factor in endoscopic vision.

Besides the routine examinations and the anaesthesiological consultation, some gynaecologists carry out, between the pre-operative examinations, a Pap test and a vaginal swab.

Besides, many recommend an adequate preparation of the vagina before intervention with a local cream antibiotic and with Povidone-iodine lavenders for at least 7–10 days.<sup>2</sup> We do not perform any vaginal preparation and we have never had post-intervention infections.

INDICATIONS: The indications are dependent upon a precise preoperative diagnosis, on the judgment and experience of the surgeon.<sup>9</sup> There is no need to set any absolute limits to this method, just as there's no limit set for laparoscopy.

In the spirit of the authors that underlined its practicality, and generally, colpotomy have the tendency to reduce the operating risk in particular and well selected subjects.

The therapeutic indications are:<sup>8, 10</sup>

- Drainage and emptying of abscesses and hematomas Douglas sac,
- Lysis of peritubal adhesions,
- Bilateral tubal ligation,
- Tube ectopic pregnancy (when it is not interstitial),
- Salpingectomy,
- Suturing bleeding ovaries, and para-ovarian non-malignant cysts (if they are not malignant),
- Wedge resection of Ovaries
- Enucleation of Ovarian drilling in the syndrome of Stein-Leventhal,
- Ovariectomy,
- Annessiectomy,

- Complementary castration to Breast Carcinoma,
- Repair of uterine perforation,
- Myomectomy (sottosierous or intramural myomas, single or multiple),
- Subtotal Hysterectomies,
- Doyle operation (Para-cervical denervation for rebellious dysmenohrrea).

Some authors have performed appendectomy through culdotomy and even the removal of Meckel diverticula.<sup>11</sup>

**CONTRAINDICATIONS:** The contraindications, in comparison to those found in international literature since the 1960s, has been reduced drastically, either because of the evolution of antibiotic therapy, disinfectant substances, the anaesthesiological drugs or because the diagnostic technology and the surgical instrumentation has advanced.

Among the absolute contraindications there are:<sup>3,4, 9, 12</sup>

- Douglas's obliteration
- Haemoperitoneum with acute or incipient shock
- Chronic severe PID.
- Abortion or septic shock
- Pelvic malignant tumors, excluding endometrial cancer.

Among the relative contraindications are:

- advanced pregnancy (over the 20° week for the risk of abortion)
- inflammation and adhesions
- genital malformations
- uncertain diagnosis.

Normally in virgin patients, it is possible to proceed vaginally.

Even if a precedent gynaecological laparotomy does not represent on its own an absolute contraindication, it is recommended to perform a Douglasscopy in case of precedent hysterectomy: anatomical conditions are so modified that there would be high risk of intestinal damage.<sup>12</sup> Intrauterine pregnancy, before the 20° week, does not constitute a contraindication to this surgical procedure. In fact, in literature seven patients are quoted, treated with colpotomy during pregnancy, that gave birth vaginally at term, without complication attributable to the technique.<sup>11</sup>

**Advantages:** Numerous are the advantages in comparison to all the techniques at our disposition today, including the laparoscopy and precisely<sup>3, 6, 7, 8, 10, 12, 13.</sup>

1. Loco-regional anaesthesia or light narcosis (it is possible to apply loco-regional anaesthesia reducing the potential anaesthesiological risks attributable to the general anaesthesia, especially for elderly or immunodeficiency patient, to the duration of the intervention and the marked Trendelenburg position)
2. Fewer planes to dissect (neither fibro-muscular support structures nor vascular structures are not injured) and repair (reconstructive plain less indigenus and numerous), therefore more rapid operating time

3. Pneumoperitonea is not needed (therefore no phrenic pain under diaphragmatic and to the right shoulder, typical of the laparoscopy)
4. Pulmonary complications are rare, light and better manageable. Respiration and the thoracic contractions are better and without pain unlike the laparotomy.
5. There is no risk of damaging an eventually bowel adherent to the anterior abdominal wall (the use of the "meeting of the fingers" test will permit in presence of adhesions in the Douglas sac to avoid an accidental damage to the adherent organs)
6. Less postoperative distress, that is lesser pain (for the absence of proprioceptive nervous terminations in the zone of entry into abdominal cavity)
7. Less postoperative morbidity in reference to intestinal obstructions, ileums paralytic and pelviperitonitis
8. Less mortality due to less risk of thrombosis and embolisms (operatory and post-operation shock is almost absent)
9. Shorter hospitalization time (the patient resumes walking immediately the first day and recovers quickly)
10. Less patient discomfort shorter amount of time in order to resume everyday activities
11. Absence of external scars (the incision is not visible and involves only two thin layers of tissue, the posterior vaginal wall and the peritonea of Douglas) and, therefore, no aesthetical damage (this has an enormous psychological influence)
12. It does not need expensive or delicate special tools in the traditional version, neither of a particular training of the operators
13. Less risk of peritonitis because, if infection occurs, its manifestation is on the low abdomen where greater resistance exists
14. The "local" intervention causes less anxiety to the patients (the patients consent to undergo intervention via vaginal because they consider it less dangerous)
15. In obese patients, the vaginal route offers a less extensive procedure and the cut heals better
16. There are no problems of post laparotomy or laparoscopy hernia.

CRITICISMS: The criticisms to the technique are all recorded through a "historical" bibliography.<sup>5, 9, 12</sup>

They are:

- Reduced view and, therefore, inadequate exposure,
- Failures up to 4 %,
- Operator's effort due of the difficulty of the technique (for some it would a "surgical gymnastics")
- Potential sepsis due to the "dirty" route of approach

These difficulties no longer exist; perhaps they are problems for those who still perform it in the traditional way.

The panoramic, with our updating technique, is identical to the technique of laparoscopy. The failures are inferior to the laparoscopy technique and, according to our statistics, they are only about 2 %. The physical force of the operator is mainly due to the scarce vision and the individualization of the intramural myomas. This also has been overcome by the use of fibre optics and thanks to the intra-abdominal ultrasonography.

Finally, the potential sepsis, typical of the 1960s, is not as probable thanks to antibiotic therapy and the surgical disinfectants. But how many vaginal hysterectomies do get infected?

**CAUSES OF CONVERSION FROM CULDOTOMY TO LAPAROTOMY:** Today, I confirm it once more, the diagnostic method at our disposition gives us the possibility to perform a surgical intervention of a well catalogued pathology. Therefore, the complications during some operations are very rare if:<sup>5</sup>

- The patient is in good health
- The diagnostic technologies at our disposition are adopted
- The flexible optics fibres are used
- Critical appraisal evaluation during the operation if the procedure is executable through posterior colpotomy
- One can decide, during the culdoscopy, to let go, by closing the Douglas and proceeding with other surgical methods.

As it happens in laparoscopy, and perhaps also the colpotomy followed by laparotomy is not to be considered a failure but a limit to the technique.<sup>9</sup>

Besides in culdotomy the possibilities of operating method alternatives are two:

- Laparoscopy
- Laparotomy

And the vaginal scar, contrarily of those laparoscopies, is neither seen nor felt!

**OUR CASUISTRY:** From February 2000 to July 2008 we selected 174 patients between the age of 20 to 79 years old (average 37.48 yrs.), 55 null-pares (31.61 %) and 119 pluripares (68.39 %), of which 89 (51.15 %) had had at least a previous abdomino-pelvic surgical intervention and precisely:

- Appendicectomy,
- Caesarean section,
- Salpingectomy for ectopic pregnancy,
- Myomectomy,
- Ovarian cyst enucleation,
- Colectomy (Gall bladder asportation),
- Removal of Urethral stones.

For 64 of them (36.78 %) the preoperative diagnosis was of Ovarian benign pathology (liquid cyst or mucinose (36), endometriosis (23), dermoids (5)), for 73 (41.95 %) the diagnosis was in the of nature annexal benign pathology (paratubal cyst (16), EP (3),

Fallopian tube bilateral sterilization (53), tube-ovarian abscess (1)) and for 37 (21.67 %) the diagnosis was of uterine benign pathology (fibromyomas).

The average dimensions of the enucleated masses were of 5.57 cm (range 2.6–10.1 cm) for the leiomyomas and 4.75 cm (range 2.4–14 cm) for the annexial cysts. Antibiotic prophylaxis with cephalosporin of III generation was administrated, via i. v., to all the patients, half an hour before the intervention.

The patients had the culdotomy principal intervention, associated in 11 cases (6.32 %), from the beginning of our culdotomy experience, to video-laparoscopy diagnostic post-intervention to reassure a good outcome. Only 4 cases (2.30 %) required a conversion in laparotomy or laparoscopy and specifically:

**in laparotomy:**

- A tubal interstitial pregnancy,
- A fundus myoma of volume 14 x 13 cm, not well seen with ultrasonography investigation,

**in laparoscopy:**

- Douglas sac endometriosis
- Endometriosis hidden in the left ovarian fossa due to the sigma adherence.

Excluding the 4 cases of conversion, the average duration of intervention had been, in the cases of culdotomy alone, 47 minutes (ranging 15–90 min) and in the cases of culdotomy with endoscope of 62 minutes. In the last procedures, after having overcome the "learning curved", the operating time is reduced to 30 minutes.

The average blood lost (BL) has been of 0.77 g/dL of Hb, with an exception of two (2) cases (1.15 %), a multiple myomectomy with 3 myomas of 10.1, 9.3 and 2.6 cm and an interstitial ectopic pregnancy (EP) with haemoperitonea due to previous intervention and laparotomy conversion, in which the Hb was 4.3 g/dL. In these 2 cases there was the need for haemo-transfusions.

A total 56.32 % of the operated patients were under general anaesthesia. The others, 43.68 %, had analgesia with epidural technique. The general anaesthesia was in the cases of the very first group of patients, while today the subaracnoidea anaesthesia has become a routinely method.

The duration of the hospitalization has been the average of 24 hrs (range from 12 to 72 hours) of which 150 (86.21 %) in DH and 24 (13.79 %) in ordinary hospitalizations.

The complications includes 10 cases (5.74 %): 4 cases (2.30 %) of fever ( $T^{\circ} < 37.5$ ), 1 case (0.57 %) of pelvic pain post intervention, 1 case (0.57 %) of pyometra, 1 case (0.57 %) of post-operation haematomas, 1 case (0.57 %) of bleeding uterine corner, 1 case (0.57 %) of Vicryl allergy, 1 case (0.57 %) of pre-existing chemical pelvic-peritonitis (due to intra-abdominal rupture of a mucinous cyst adenoma, resolved in 5 days with antibiotic therapy i. v.).

In some cases, in the enucleation of ovarian cyst execution, which has been associated with a bilateral tube sterilization. In the 7 operations we performed two procedures, precisely:

- A myomectomy (6 cm) + conization with thermal loop in 60 minutes,
- Two myomectomies (3.8 cm) + ovarian cyst enucleation (4.6 cm) in 45 minutes,
- A myomectomy (7 cm) + para-ovarian cyst (3 cm) in 60 minutes,

- A bilateral tube sterilization + resectoscopy for polypectomy in 30 minutes,
- Two bilateral tube sterilizations + resectoscopy for sub-mucous myomectomy in 55 minutes.

The post-operative outcome without major complications and the short period of hospitalization, after the vaginal procedure, are the characteristics of our method.<sup>5</sup>

Age, vaginal conditions and pregnancy do not represent contraindications because the intervention can be performed rapidly, with simple techniques, when, with the modern methods of narcosis, the pelvic wall muscular is well relaxed. Healing of the wound happens in a short period of time.

As confirmed, it is not necessary to perform, perineotomy in the null-pare as it was done in past. Almost one-third (31.61 %) of our patients operated in culdotomy are null-pare and, despite this, as also Vladov E. confirmed,<sup>8</sup> we have never had to perform Schuckart incision.

We have also abdicated without complications, to drain the Douglas sac, as indicated by Schrank and Schwalm. We can only confirm the observations of Schrank and Wachsmuth, of very few complaints of pain after the procedure. Also the vaginal scar was, after a while from the operation, almost non palpable.<sup>5</sup>

Some patients that subsequently had a laparoscopy investigation for other pathology none were found to have adhesions in the pouch of Douglas.<sup>14</sup>

We have not recorded any complications at the follow-up visit after 30 days.

DISCUSSION: The evolution of surgical techniques has permitted surgeons to carry out enormous progress in the treatment of the gynaecological pathologies, both in terms of appropriateness and of "professional virtuosity".

In the meantime, inspired by the idea of a less invasive surgery, they have experimented with new methods, complementary or alternatives to laparoscopy (e. g.: mini-laparotomy, micro-laparoscopy, the vaginal hydro-laparoscopy operation and the classical vaginal surgery), each with peculiar advantages in their different indications.

Today, the absolute tranquillity that prophylaxis, antibiotic therapy and sterilization offers in surgery, to the difference in time of the pioneers of this technique, has widened more than to circumscribe the limits of procedures with colpotomy method.<sup>3</sup>

Laparoscopy and culdotomy are complementary procedures, both of great value and, therefore, should not be considered as competitive.<sup>9</sup>

Generally, we can say today, that in possession of a secure surgical technique and modern instrumentations, local and psychological conditions of the patient suggest the culdotomy technique a valid alternative, in selected cases, from the surgical and socio-economic point of view, both to laparotomy and to laparoscopy.<sup>3,7</sup>

All the most recent publications on culdotomy written by gynaecologists that have rediscovered the "old technique" and have used it as method. In this case the consents have been more or less positive mainly for poor vision and surgery time.

We do not have this problem, having adjoined the technique with the optics flexible fibre. The duration of surgeries is long because the training, as for the laparoscopy, initially involves an extension of the procedure.<sup>15</sup>

For its undoubted advantages Bognomi A. et coll., believe in the rediscovery of vaginal surgery, today less used by the young gynaecologists for the lack of a valid vaginalists training school.<sup>7</sup>

According to Bleier W. most of the intra-abdominal gynaecological operations can be performed vaginally.<sup>16</sup>

Whoever uses this method should however use a flexible endoscope with cold light that determines optimal conditions in a small basin, without provoking heat to the tissues.<sup>12</sup>

The culdotomy has resulted to be a method endowed with numerous advantages, for the operators, thanks to the great technical simplicity, the rapidity of execution, the use of traditional tools also in the versions with endoscopy control, the minimal invasivity and the less operation risk, and for the patients' psychological, aesthetical and social advantages, lesser risks, lesser hospitalization, brief convalescence, and a quick return to usual activities.

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## NOTES: The Future

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**"Fear not for the future, Weep not for the past"**

*Percy Bysshe Shelley, 1792–1822*

The concept of Natural Orifice Translumenal Endoscopic Surgery (NOTES) has grown in acceptance since 2000 at the time of its introduction. NOSCART has outlined the major obstacles to ensure a safe transition to clinical practice providing a framework to tackle some of the hurdles and foster its growth (1). As a result, many investigators (Gastroenterologists and Surgeons) have developed innovative solutions to some of the problems facing this burgeoning field. Developments in techniques of peritoneal access, closure, surgical techniques and equipment modification have already been published and intensive research is ongoing. Current and future endoscopists will reap the benefit of this research since many techniques and devices that are developed for NOTES will enhance our ability to perform luminal intervention including polypectomy, endoluminal hemostasis and submucosal resection.

The first human NOTES appendectomy by Rao and Reddy (2) led the way to other pioneering work in humans. Transvaginal and transgastric cholecystectomies have been performed successfully in Europe, Latin America and the United States (3–8). Thus far these procedures were performed without any complications under an IRB approved protocol and supervision. These results are encouraging and are cause for enthusiasm for the future widespread application of NOTES.

Where do we go from here? What do we envision for NOTES? NOTES is not yet accepted into clinical practice and so is it untimely to predict its future role? However ideas that seemed possible only in Hollywood movie sets are close to becoming a reality. To predict the future, it is also important to look back at the past. The lessons garnered from laparoscopy have both forecasted the need for caution and for some, stimulated great enthusiasm for NOTES. The current popularity of laparoscopic intervention is a result of its less post operative stress, pain, short recovery and less scarring as compared to open surgery. NOTES with its potential for "scarless" surgery will be a strong driving force for its acceptance by the general population that is ever image conscious. The same benefits of laparoscopy over open surgical approach may be surmised when comparing NOTES to laparoscopy. Currently, advanced endoscopic procedures can be performed using deep sedation raising the possibility that, unlike laparoscopic and open surgery, translumenal procedures could be performed without general anesthesia and endotracheal intubation.

We will now attempt to predict the future of NOTES by describing potential applications for certain clinical scenarios and conditions. These concepts are for the most part early in laboratory evaluation.

**NOTES FOR PERITONEAL INTERVENTIONS IN THE INTENSIVE CARE UNIT:** Patients in the intensive care setting have multiorgan dysfunctions that preclude transportation and major surgical interventions. NOTES may avoid the issue of transportation to an operating room allowing for bedside intervention. One example that has been described in the laboratory is diaphragmatic pacing for patients who are difficult to wean from ventilators (9). This has been shown by laparoscopy to benefit select patients. NOTES has already been performed to rescue a displaced PEG tube using the transgastric route in an ICU patient (10). NOTES may be a more practical approach to diagnose ischemic bowel in the ICU patient who have contraindications for a more definitive imaging study such as a CT or MRI (11).

**NOTES FOR PREHOSPITAL MANAGEMENT OF TRAUMA:** Prehospital management of critical patients has resulted in improved outcomes. This is mainly due to the proper resuscitation of patients and appropriating triaging (12). Despite these developments many patients with blunt or other urban related injuries do not make it to the hospital because of improper triaging and stabilizing measures. NOTES can become an integral and critical

step in this setting since all instruments that are required are portable and can be fit into current emergency care vehicles. Imagine a scenario where a patient involved in motor vehicle accident with splenic trauma is given proper triaging and stabilizing hemostasis measures before reaching the hospital where traditional and more definitive surgical approaches can be performed. All these, of course could only be attained if there are more refined tools to enable easy access and closure of the access site with minimal risk of infection and without adding time needed to transport the patient to the hospital.

**NOTES FOR ACUTE MANAGEMENT OF BLUNT TRAUMA:** The use of NOTES as a method of achieving immediate assessment of organ injury and repair is theoretically possible. The minimally invasive nature due to the lack of abdominal incision and a need for a general anesthesia makes NOTES an attractive approach for use in the pre-hospital trauma/disaster setting.

In a preliminary study performed at our laboratory we were able to demonstrate the feasibility of NOTES in the assessment of penetrating abdominal injury. We performed a controlled injury to intraabdominal organs (liver, spleen, kidney and small bowel loops) under laparoscopic guidance using a laparoscopic shears. Transgastric peritoneal access was then attained using a PEG like approach by an operator blinded to the sites of organ injury. The finding of NOTES was compared to laparoscopic findings. The peritoneal cavity was systematically examined including the anterior abdominal wall, the diaphragmatic dome, liver, spleen and both kidneys was possible in all animals. The mean duration from the time of entry to the peritoneum to identification of lesion was 11 minutes. The mean duration of identification of site of injury based on the organ was 12 minutes to the liver, 15 minutes to the spleen, 17 minutes to the small bowel, and 6 minutes to the kidneys. The difference in the mean time in the identification of was significant in that injury to the anterior liver surface was identified more quickly as compared to injury to the small bowel. Based on these results we concluded that NOTES provided rapid and accurate identification of organ injury for penetrating wounds to the abdominal viscera (13).

Our group also assessed the feasibility of achieving hemostasis after organ injury using nonthermal hemostatic mechanisms. In this study three non thermal methods of achieving hemostasis were compared. The first group was randomized to QuikClot (QC; Z-Medica, Wallingford, CT) which is a granular zeolite powder with 1 % residual moisture that, when placed on a bleeding wound, adsorbs water in an exothermic reaction, thereby concentrating platelets, erythrocytes, and clotting factors at the site of application. It has been tried in the battlefield with excellent success rate in achieving hemostasis. Several studies including a swine liver injury model have also shown its effectiveness as a hemostatic agent in life threatening bleeding. The second group was randomized to Oxidized regenerated cellulose is also used adjunctively in surgical procedures to assist in the control of capillary, venous, and small arterial hemorrhage when ligation or other conventional methods of control are impractical or ineffective. The third groups of animals were randomized to SHISH – a novel bioabsorbable hemostatic agent (Cook bioengineering prototype material).

The anterior liver surface was then lacerated using a laparoscopic shear to create a grade three (> 3 cm) liver laceration. Modified endoscopic delivery systems were used for the delivery of the hemostatic agents. The oxidized regenerated cellulose (ORC) was placed effectively covering the site of injury in all animals. Delivery of the QC granules to the site of bleeding was also straightforward. Accurate placement of the granules to the site of injury was achieved in all animals. In the third group of animals SHISH was also able to be applied with resulting hemostasis in all animals. There was no statistically significant difference in the time to achievement of hemostasis between the QC and ORC group (P = 0.33). The conclusion from these studies was that intraperitoneal hemorrhage can be easily and quickly controlled with these novel endoscopic therapies (14).

**NOTES – EVOLVING BEYOND THE TRADITIONAL OPERATING ROOM:** In today's world where building the future operating room is a multibillion dollar industry, NOTES maybe a cost effective solution especially for procedures in the abdominal cavity. Given that the development of accessories and other integral components of NOTES needs to take place, by keeping the focus of sterility to the gastrointestinal tract, instruments and accessories, the need for the sterile operating room environment could be eliminated. The potential cost reduction is staggering since the cost of using an OR is obviated as is

the use of transportation staff, operating room energy and operating costs. The fact that NOTES can also be performed not under general anesthesia but under sedation also will have a great impact in obviating the need for post operative ventilator complications including vent dependency.

**NOTES IN DEVELOPING COUNTRIES:** Surgical care is not considered a priority in many developing countries due to scarcity of health care resources. Despite this many untreated conditions lead to preventable deaths and to chronic conditions that could have been managed effectively. Currently general surgical procedures are cost effective at the district level in most Southeast Asian and sub-Saharan African countries. Majority of the population though reside in the rural areas far from these districts hindered by poor road and transportation infrastructure (15). Due to these hurdles NOTES can play a major role in averting preventable surgical deaths since it does not require general anesthesia, a sterile operating room and may be performed by a highly mobile, portable easily disinfected instruments. Other factors for the poor health care delivery in those countries, such as lack of trained healthcare personnel and economic ability need to be eliminated before this dream can be a reality.

**ROBOTS FOR NOTES:** The concept of deploying a mobile robot via NOTES into the peritoneal cavity may appear very futuristic. This limitation may be solved by using robotics and this technique has been shown to be feasible by Rentschler et al (16). A 12 mm diameter *in vivo* robot was advanced into the gastric cavity using a sterile overtube and was able to traverse within the cavity under endoscopic guidance. The robot with its helical wheel was able to navigate the gastric lumen with no apparent tissue injury. In the peritoneal cavity, the robot successfully navigated and maneuvered several organs including the liver and small bowel. Development of an *in vivo* robot with camera and multipurpose arms capable of performing several tasks in addition to the endoscopic imaging will enable performance of moderately complex surgeries such as cholecystectomies. Furthermore, a robot with visual capabilities will help to overcome the problem of spatial orientation (1).

**NOTES FOR INTRAUTERINE FETAL INTERVENTIONS:** Although transabdominal, laparoscopic fetoscopy has proven to be a useful technique in human fetal surgery for such diseases as twin-twin transfusion syndrome and spinal meningocele, it is still limited by rigid instruments and allowing only anterior access to the uterine cavity. In addition, the performance of intraperitoneal procedure by the traditional percutaneous route can have consequences of wound dehiscence and induction of preterm labor. NOTES can theoretically provide unlimited access to the uterus since the flexible nature and the straight shot direction from the transgastric route provide unparalleled access to the uterine cavity. Moreover, the absence of abdominal wall incision and general anesthesia also provide an added benefit to NOTES. Based on these assumptions our group evaluated the feasibility of NOTES in pregnant sheep. During this acute non survival experiment NOTES allowed visualization of the anterior, posterior and lateral walls of the uterus. In addition all intraperitoneal organs could also be identified and were easily accessible. Using endoscopic ultrasound the fetus, various body parts and placenta could be easily identified. Amniocentesis and intracardiac fetal interventions were technically feasible with the EUS scope in the peritoneal cavity (17).

**NOTES FOR SPINAL PROCEDURES:** Surgical spine procedures most commonly include trans-thoracic and posterolateral percutaneous approaches. Open surgical techniques require separation of musculoskeletal structures and traction of nerve roots to create an opening large enough to accommodate surgical tools. The morbidities associated with these surgical approaches include post-surgical neuralgia resulting from traction injuries to nerve roots, lacerations of the dura mater, scars from skin incisions, muscular atrophy or trauma. Minimal invasive surgical techniques including thoracoscopy and video-assisted thoracic spine surgery (VATS) have reduced the extent of percutaneous incisions and spreading open of the chest wall. Nevertheless, the consequences of a percutaneous access are not totally avoided and complications such as lung atelectasis and retropleural effusions from single lung ventilation are additional morbidities (19).

NOTES provides a closer and direct anterior access to the vertebral column. In laboratory experiments we found that the proximity of the esophagus to the spine allowed immediate access to posterior mediastinum and excellent visualization of the entire thoracic ver-

tebrae and intervertebral spaces via NOTES techniques. This innovative approach to the anterior vertebral column allows the development of novel spinal interventions under direct endoscopic guidance such as vertebroplasty and kyphoplasty for osteoporotic or pathological vertebral bone fractures, discectomies and interbody fusion for herniated discs, and release of the anterior ligament at different levels of vertebral column in patients with severe scoliosis. In addition, the lumbosacral spine could be also approached for anterior endoscopic procedures via trans-gastric access. The advantages of NOTES for spinal interventions are similar to anterior laparoscopic spinal surgery but without the limitations of rigid instrumentation. These benefits include maintenance and ease of restoration of intervertebral disc height, avoidance of removal of bone from the spine which is an integral component of posterior spinal surgery and preservation of normal spinal anatomy since this approach takes advantage of normal tissue planes with no removal of bone tissue. In addition the complications of posterior spinal surgery such as injury and damage of nerves from manipulation and retraction of nerves and hematoma around nerves that may cause scarring and chronic pain can be thwarted (20).

**CONCLUSION:** Maybe it is premature to hypothesize on the future of NOTES when it yet has to reach clinical application. However NOTES offers exciting possibilities that cannot be ignored. It already has blurred the boundaries of specialties such as gastroenterology, surgery, gynecology and urology. It has challenged traditional principles which not only that have stood the test of time but have guided physicians for decades as to the boundaries of safe practice. The future of NOTES will be determined by the skill, imagination and ingenuity of physicians and engineers who dare to challenge conventional philosophy.

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**Friday, November 21, 2008**

**14.00–16.00: Scientific session:**

**Novelties in surgery I: An interdisciplinary session**

**Tahar Benhidjeb**, Berlin, Germany: A new approach for thyroidectomy.  
The Axillo-Bilateral-Breast-Approach (ABBA)

**Marc Possover**, Zurich, Switzerland: The laparoscopic implantation of  
neuroprothesis on pelveo-abdominal nerves for the treatment of  
neurogenic bladder dysfunctions

**Klaus J. Neis**, Saarbruecken, Germany: Combined laparoscopic and  
vaginal surgery of deep infiltrating endometriosis

**George Zografos**, Athens, Greece: Mammary ductoscopy

**Abe Baruchin**, Ashkelon, Israel: Er:YAG laser for sialolithotripsy

## **A new approach for thyroidectomy (the ABBA method)**

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**OBJECTIVE:** Conventional thyroid surgery is established and standardized since more than one hundred years. The technology development of the past two decades in the field of video-assisted surgery has opened up new opportunities, including in thyroid surgery. The technique of minimally invasive video-assisted thyroidectomy (MIVAT) is the method that has so far become most widespread. Limiting factors of this method include the bothersome 20 mm cervical incision and consequently the specimen size to remove. Several publications have recently described an access outside the front neck region. Among them the Axillo-Bilateral-Breast-Approach (ABBA) is a procedure that allows thyroid resection without any scar at the neck, aiming to improve the cosmetic outcome by making the incisions in the axilla and around the areola. We report about our experience with the first 100 patients who underwent this procedure.

**METHODS:** The operation is performed under general anaesthesia. The patient is placed in supine position, with the neck slightly extended, and both arms lifted up in order to extend the axilla. A 5 mm incision is performed along the medial upper margin of both mammary areolas, and an additional incision (10 mm) is made in the right axilla. After blunt dissection of the subcutaneous tissue of the chest, a subplatysmal working space is created using CO<sub>2</sub> at a pressure of 6–8 mmHg. A 5 mm video-endoscope is inserted through the 5 mm trocar on the right mammary areola. Dissection is performed using a 5 mm harmonic scalpel that is being inserted through the 5 mm trocar on the left mammary areola. After dissection of the strap muscles both lobes of the thyroid are fully exposed. First, the isthmus is divided along the central line of the trachea. Following that, dissection continues at the lower pole and proceeds to the posterior/lateral parts and upper pole of the gland. The recurrent laryngeal nerve is being identified and preserved. The resected specimen is retrieved through the axillar trocar. A drainage tube is placed overlying the dissected areas.

**RESULTS:** Between February 2005 and May 2007, 100 female patients with thyroid nodules underwent thyroidectomy using the ABBA technique. The mean age was 46.7 (19–71) years. Mean thyroid volume was 24 (6–130) ml. Subtotal thyroid resection was performed in 94 patients. Mean operative time was 108 minutes. Intraoperative complications occurred in two patients. Conversion was necessary only in one case. Postoperatively, 4 patients showed transient recurrent laryngeal nerve palsy. In two cases the palsy became permanent. Only minimal subcutaneous emphysema and haematoma around the trocar positions were observed. Hospital stay after the operation was 2.6 (1–23) days.

**CONCLUSIONS:** Our experience shows that the ABBA technique is a feasible and safe procedure in selected patients. The primary aim of this method is cosmetic since it does not comply with the use of the term “minimally invasive”, because it is associated with an extensive dissection of the chest and neck region.

## **The Laparoscopic Implantation of Neuroprothesis on pelveo-abdominal nerves for the treatment of neurogenic bladder dysfunctions**

Possover M

Department of Surgical Gynaecology & Neuro-Pelveology, Hirslanden Clinic, Zurich, Switzerland

We report the feasibility of the laparoscopic approach to all the pelvic somatic and autonomous nerves: Due to the magnification effect and the possibility of a bloodfree dissection even in the deepness of the pelvis, laparoscopic surgery in the retroperitoneum is becoming one of the most useful and important instruments for learning the pelvic retroperitoneal anatomy. Using the laparoscopic transperitoneal approach, exposure of all pelvic nerves involved in bladder functions, as well for storage as for micturition became feasible in routine conditions. The LANN technique offers intraoperatively confirmation of the integrity of the motoric nerves involved in all these functions. Based on these new technique and knowledge of pelvic neuroanatomy, we have developped the Laparoscopic Implantation Of Neuroelectrodes – LION procedure – to the pelvic nerves for the treatment of neurogenic bladder dysfunctions. We will report about our experience with the LION procedure to the pelvic nerves to control bladder overactivity associated with different etiologies, such as in interstitial cystitis, in multiple sclerosis or in spina bifida patients. Furthermore we will report about our results with this technique in patients with complete paralyzie after spinal cord injury or in spina bifida for recovery storage and voiding functions but also the sexuality. At last we will report about our technique of LION procedure to the superior hypogastric plexus to treat bladder atonia secondary to pelvic surgery.

## **Combined laparoscopic and vaginal surgery of deep infiltrating endometriosis**

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Saarbrücken, Germany

The deep infiltrating endometriosis in the recto-vaginal septum makes high demands on the skills of the laparoscopic surgeon. On the search for a simplification of surgical techniques we tried to solve the problem by combining the two minimal invasive methods, laparoscopy and vaginal surgery analogue to the LAVH.

In cases of deep infiltrating endometriosis, at first, the tumour is laparoscopically mobilised and if necessary also the rectum. Then, the tumour is distanced from the ureters and the intra-abdominal endometriosis will be remediated completely. The second part of the operation is done vaginally: The endometriosis is cut out in the vagina and the preparation then looks for reaching the laparoscopic preparation level. Thereafter, the endometriosis is removed from the rectum. In this step of operation it is advantageous that the preparation should be done by using the tactile ability of the surgeon's fingers. Due to the individual situation, also an anterior rectum resection or a stapler resection can be carried out vaginally.

The surgery is safe, with very few complications and relapse. In today's view, one can surely perform the described operation in NOS too.

## **Mammary ductoscopy**

Zografos G

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Mammary ductoscopy is a safe technique used for the direct visualization of the ductal system of the breast through nipple orifice cannulation and exploration.

Over the last years Mammary ductoscopy has proved to be a useful diagnostic adjunct especially in patients with pathological nipple discharge as it allows direct visualization of the mammary ducts using sub-millimeter fiber optic microendoscopes inserted through the ductal opening onto the nipple surface.

Mammary ductoscopy offers the advantage of accurate localization of the pathology, ductal lavage under direct visualization and intraoperative guidance especially for lesions deep within the ductal system. Microendoscopes (rigid or flexible that use excellent fiber optics and measure between 0.9 and 1.2 mm in external diameter) allow to magnify breast tissue up to 60 times the normal size and pinpoint small lesions and can be gradually moved into peripheral sites.

Since 85 % or more of breast cancer originate in the epithelial lining of mammary ducts from morphologically identifiable precursor lesions, mammary ductoscopy can potentially detect breast cancer several years before detection by mammography. Despite the lack of reliable evidence, supporting the role of ductal lavage, it is currently being used in several centers to guide risk-reducing strategies in high risk women.

However, further research and evaluation on mammary ductoscopy's potential use is required as: a) the direct observation of intraductal lesions is limited by two ductoscope parameters, length and an outside diameter and b) there are inadequate data regarding the correlation between lavage cytology findings and the pathologic diagnosis of tissue biopsies.

The overall objective of the presentation will be not only to review existing bibliography but also to discuss future prospects as it is becoming more and more evident that the combination of mammary ductoscopy (ductal lavage) with molecular diagnostic markers can enhance ability to direct and limit subsequent surgery.

**KEY WORDS:** Breast Cancer, Mammary ductoscopy, ductal lavage, intraductal lesions, Molecular markers

## Er:YAG laser for sialolithotripsy

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Endoscopic applications of Erbium:YAG lasers are still very limited due to lack of appropriate fiber delivery capabilities. Recent advances with this laser for lithotripsy of urethral stones prompted us to develop an Er:YAG fiber delivery system for endoscopic lithotripsy of salivary calculi. We report on the development of this system and its clinical use on 17 patients with sialolithiasis using a commercial dental Er:YAG laser (Lumenis Opusdent 20). Metal hollow waveguides optimized for Er:YAG laser transmission were end sealed with a polished sapphire rod of 0.63 mm diameter and designed to adapt to the Opusdent laser and to a Storz sialoendoscope. The system was tested ex vivo for durability and clinical compatibility at input energies up to 700 mJ, 10–20 Hz. Following Helsinki approval the system was clinically tested on 17 patients. Lithotripsy threshold was around 80 mJ/pulse (26 J/cm<sup>2</sup>) while efficient fragmentation, with microscopic fragments, was observed at an output energy range of 150–300 mJ/pulse. At 10 Hz, fragmentation rates of about 1.8 mm (3)/second were achieved enabling lithotripsy of a 6 mm stone in about 2 minutes. Front surface damage to the sapphire rod occurred but did not contribute to significant loss in fragmentation efficiency. Of the 21 stones treated, 5 were fully fragmented, 7 were prepared for extraction by mini forceps, and 9 were released from surrounding soft tissues for subsequent removal. Fifteen of the 18 treated glands returned to normal function.

**CONCLUSIONS:** The described Er:YAG endoscopic delivery system is a clinically viable and cost-effective device for a range of hard and soft tissue wet field applications accessible through rigid or semi-rigid endoscopes. Further improvements in the waveguide may allow access also through fully flexible endoscopes.

**Friday, November 21, 2008**

**16.30–18.30: Scientific session:**

**Novelties in surgery II: An interdisciplinary session**

**Dov Maor**, Haifa, Israel: MR guided focused ultrasound – A totally non-invasive technology for tumor ablation

**Sergio Casciaro**, Lecce, Italy: Novel mini-invasive therapeutical systems

**Alfredo Damiani**, L. Melgrati, Milan, Italy: Laparoscopic myomectomy for very large myomas: the isobaric approach

**Abe Baruchin**, Ashkelon, Israel: Laser osteotomy in orbital blowout fractures surgery

**Dan Amroch**, Italy: Laparoscopic cholecystectomy using the harmonic scalpel in the 21st century. Last frontier?

**Mariano Iaccarino**, Naples, Italy: The modification of surgical techniques

## **MR guided focused ultrasound – A totally non-invasive technique for tumor ablation**

Maor D

Clinical Marketing, InSightec Ltd., Tirat Carmel, Israel

Focused ultrasound surgery generates localized high temperatures in the focal volume that induce within seconds cell destruction while outside that volume no damage is created. Absorption of ultrasound energy in tissue is very variable and therefore on-line control is required. This is enabled by MRI operating in a special temperature mapping sequence. Since no biological change is caused outside the ablated volume, there is no limitation on repeat treatments if necessary. This novel technology has been designated MR guided Focused Ultrasound Surgery (MRgFUS).

Main clinical applications addressed so far:

**UTERINE FIBROIDS:** The treatment of symptomatic uterine fibroids has FDA PMA approval and CE marking. In the treatment, a large part of the fibroid is ablated, without affecting nearby structures. Significant reduction in bleeding and mass symptoms has been achieved in 85–90 % of patients. Durability up to 3 years has been demonstrated. Although the original studies were performed on women who had finished their family planning, by now information on 41 pregnancies and 17 live births has accumulated. No significant treatment related complications were registered in any of the pregnancies or deliveries.

**PAIN PALLIATION OF BONE METASTASES:** A preliminary study of 35 patients with osteolytic and osteoblastic bone metastases has found complete or significant improvement in pain in 75 % of patients. Newer ongoing studies show that with patient selection and system improvements the percentage is considerably higher. The procedure has received CE-marking.

**BREAST CANCER:** 190 patients have been treated, most with ensuing surgery and pathological analysis. Latest results show complete coverage of the tumor and 95–100 % destruction of tumor cells – thus the potential to replace lumpectomy. An FDA approved study will start soon to confirm the above results in a 220 patient cohort.

**LIVER:** Treatment of liver tumors is complicated by motion with respiration and access problems to a large fraction due to ribs. An ongoing feasibility study uses general anesthesia (not required for other applications) in synch with a respirator enabling short apnea periods during which the energy is delivered. It targets lesions accessible under the ribs. Preliminary results show good ablation for HCC and metastatic tumors.

**PROSTATE CANCER:** A 1000-element two-dimensional trans-rectal applicator with 1 mm accuracy has been developed and animal studies are ongoing. In combination with the MR control it will enable effective treatment with extremely low side effects that are common to all current treatment methods.

**CONCLUSIONS:** Accumulated experience has proven the potential of MRgFUS to treat different conditions considerably reducing patient morbidity and ensuring very good outcomes. Clinical studies in many applications are ongoing and development of additional applications is underway.

## **Novel mini-invasive therapeutical systems**

Casciaro S

National Council of Research, Institute of Clinical Physiology (CNR-IFC), Lecce, Italy

Minimally invasive Therapies are an important clinical trend that represent a challenge in the development of new technological embedded systems necessary for the diffusion and use of minimally invasive surgery approaches and interventions. ARISER is a multi-institutional and multidisciplinary European Consortium (<http://www.ariser.info>) created to facilitate and support the development of minimally invasive technologies and platforms considering all involved disciplines (advanced imaging, haptic interfaces, robotics, etc.). In this talk, some main results obtained in ARISER will be presented. Besides, the new available perspectives related to the use of novel emerging nanosystems for clinical diagnosis and therapies will be described. The National Council of Research, Institute of Clinical Physiology (CNR-IFC) of Lecce (<http://www.ifc.cnr.it/lecce>) is indeed involved in both research activities also thanks to industrial research projects in collaboration with other important national and international research institutes which all collaborate to the main research objective of reaching a strong reduction of the current surgical invasiveness.

## Laparoscopic myomectomy for very large myomas: the isobaric approach

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Laparoscopic myomectomy using pneumoperitoneum for large myomas, is limited by several factors, such as the increased operative time, the risk of perioperative bleeding, and the risk of conversion to laparotomy. With the introduction of isobaric laparoscopy using a subcutaneous abdominal wall lifting device (Laparotenser), the myomectomy can be performed through laparoscopy using conventional surgical instruments, introduced into the abdominal cavity through two small incisions.

This surgical procedure is safe and reliable, with reduced operative times, without restrictions of the myoma's number, size and location (*the only limiting factor is the lack of space for the surgical movements*), with anatomic and functional results similar to those of laparotomic surgery and with a reduced learning curve.

The Isobaric laparoscopic myomectomy offers several advantages compared to laparoscopy with pneumoperitoneum, such as elimination of the adverse effects and potential risks associated with CO<sub>2</sub> insufflation, use of conventional instruments that facilitate several steps of the procedure, reduction of the operative times and costs. Therefore, it can represent an excellent option for the minimally invasive removal of very large myomas, as an alternative to more aggressive surgery.

## **Novel applications of Er:YAG laser endoscopic fiber delivery system in maxillofacial surgery.**

### **Laser osteotomy in orbital blowout fractures surgery**

Nahlieli O, Baruchin AM  
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ORBITAL BLOWOUT FRACTURES (OBFs): An orbital blow-out fracture consists of a fracture of the bones of the eye "socket". This may involve the orbital floor, walls, or roof. Most cases, however, involve the orbital floor with subsequent prolapse of the orbital contents. An orbital blow-out fracture is almost always secondary to a blunt blow from a relatively large object, such as a fist, elbow, baseball bat, etc., usually greater in diameter than the orbital rim. Most patients will present with pain, tenderness around the eye, swelling, diplopia in some fields of gaze. Pain with attempted eye movement is also common. If untreated, these injuries may cause enophthalmos, persistent hypoesthesia of the infraorbital nerve, or even blindness. Treatment of OBFs has been discussed in numerous papers and symposiums throughout the years, so each surgeon will eventually prefer the method with which he or she is most familiar. Among the approaches to treating OBFs are external or transcutaneous approaches, including subciliary, transconjunctival, midtarsal, and transantral approaches, including transnasal and transmaxillary, which are usually endoscopically assisted. These methods can be used simultaneously, all with the relative advantages and disadvantages that each entails. One of the most challenging issues in treating OBFs is the difficulty of visualizing the posterior border of the defect, thus hindering reduction. To overcome this problem, the transantral, or "Caldwell-Luc", approach is often used. This approach helps the surgeon visualize the entire extent of the defect and also provides direct visualization of the prolapsed orbital content to the maxillary sinus. Some authors have described transantral techniques for the treatment of OBF, with or without the use of endoscopes. Some have reported combined approaches that facilitated their ability to evaluate bony defects. In recent years, the use of endoscopes in head and neck surgery has increased significantly, especially in sinus surgery (i. e., functional endoscopic sinus surgery), salivary stone removal, thyroid surgery, facial plastic surgery, and facial trauma reconstruction. The need for a minimally invasive technique for the correction of OBFs has been noted in the various approaches described in the literature over the years; however, none of these approaches uses the orbital floor as a scaffold for the correction of the fracture. We decided to harness this evolving technology for the reduction of OBF through a transantral approach without additional skin incision, using the orbital antral bony floor as the real scaffold for anatomic reduction when possible and using titanium mesh as an internal fixation for support.

The Er:YAG endoscopic delivery system described is a clinically viable and cost-effective device for a range of hard and soft tissue wet field applications accessible through rigid or semi-rigid endoscopes. An osteotomy of 2.0–1.5 cm is performed, with extreme care taken to avoid damaging the tooth roots, and with care taken to perform the posterior vertical osteotomy line in the buttress area. We used a Lumenis Opusdent 20 Erbium laser which delivers up to 1 J/pulse, 20 Hz at a wavelength of 2.94 microns. Pulse durations are 250–300 mseconds. The laser beam is delivered to a detachable dental handpiece through a metal hollow waveguide with a 1 mm inner diameter. With the dental handpiece attached the beam may be delivered through short, straight or tapered metal hollow waveguides. Osteotomy threshold was around 80 mJ/pulse (26 J/cm<sup>2</sup>) while efficient cut, was observed at an output energy range of 150–300 mJ/pulse. As of July 2007, 10 patients were treated with this new technique. Comparisons of the Er:YAG osteotomy with conventional techniques are discussed. Preliminary clinical observations for the 10 patients treated with the technique are provided and demonstrated by means of short video clips.

## **Laparoscopic cholecystectomy using the harmonic scalpel in the 21st century – Last frontier?**

Dan Amroch D, Fanti G, Chiara GB

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**BACKGROUND:** With the advancement of technology, its safety, effectiveness and efficiency, a 5 mm Harmonic scalpel was used to operate and remove gallbladders in patients with cholelithiasis without using clips.

**METHODS:** In our department in 2007 104 patient were operated upon with this technique, 64 of whom on elective basis; the other had various forms of acute cholecystitis. The harmonic scalpel was used as the only instrument for the sealing and division of the cystic artery and the cystic duct, as well as for the dissection of the gall bladder from the liver's bed. 3 patients with cystic duct of over 5 mm in diameter received an additional ligature with vycril endoloop.

**RESULTS:** No patient developed postoperative hemorrhage or bile leakage.

**CONCLUSION:** The 5 mm harmonic scalpel proved to be a reliable device for sealing and dividing the cystic artery and the cystic duct, and might be a good alternative for standard closure with clips or ligature closure. This is a cost saving procedure that is using a single disposable device.

## **The modification of surgical techniques. Clinical evaluation of efficacy and morbidity of posterior IVS with "STRATASIS TF" (COOK).**

Iaccarino M, Luise C, Varvarigos E

Unit of Obstetrics & Gynaecology, Clinica Mediterranea, Naples, Italy

SETTINGS: Unit of Obstetrics & Gynaecology, Clinica Mediterranea, Naples, Italy

AIM: As "Stratasis TF" implants become incorporated into the native tissue, the aim is to allow quicker tissue remodelling following surgery for vaginal vault prolapse reducing long term fibrosis and improving sexual, bowel and bladder functions.

MATERIALS AND METHODS: "Stratasis TF" single use device made of porcine material. The IVS tunneller device is thinner than conventional devices, easy to insert and with good handling. Using aseptic techniques the device is rehydrated in a sterile saline solution for 10 minutes and the sling placed in the same way as for the synthetic mesh tape devices.

INCLUSION CRITERIA: vaginal vault prolapse of grade 2 or more  
symptomatic prolapse

EXCLUSION CRITERIA: known sensitivity to porcine material products  
rectal inflammatory disease (e.g. Crohn)

RESULTS: Between January 2006 and December 2006 12 patients of age between 42 and 76 were treated under regional anaesthesia. In the presence of rectocele and/or enterocele as well as vault prolapse, these were repaired and reinforced by the IVS procedure. No intraoperative complications occurred.

Tissue remodelling was already seen at 6 weeks follow-up and all the patients treated showed restoration of the support of all anatomical compartments. Alleviation of symptoms and improvement of sexual, bowel and bladder functions at 3 and 6 months follow-ups.

There were no allergic reactions or infections and patient satisfaction through a quality of life questionnaire was close to 100 %. We have not observed yet any case of fibrosis but larger numbers and longer follow-ups are required.

**Saturday, 22 November 2008**

**Aula Magna**

**09.00–11.00: Scientific session: Quality control and safety**

**Umberto Rossi**, Milan, Italy: The contribution of clinical medicine to transfusion safety

**George Peltecu**, Bucharest, Romania: Safe Surgery Saves Lives: a WHO international project

**Anja Aldenhoff**, Hamburg, Germany: Securing hospital future through corporate culture

**Umberto Rossi**, Milan, Italy: Blood-sparing medicine and surgery: the ESTM experience

## **The contribution of clinical medicine to transfusion safety**

Rossi U

European School of Transfusion Medicine (ESTM), Milan, Italy

Clinical transfusion practice was largely driven in Europe by feelings of apprehension and fear, surprisingly coexisting with often unjustified prescription and astonishing abuse of blood transfusion: while, unfortunately, basic knowledge of Transfusion Medicine (TM) still receives little attention in the medical curriculum of most European Universities.

Several aspects of TM have been discussed in Europe in the last few years.

Agreement was reached on basic requirements, essential to build an acceptable safety of blood donation and transfusion: clear definition of medical specialisation in TM; sufficient number of dedicated TM specialists; presence of TM competence in general doctors and other specialists, nurses and technicians; well functioning organisation of voluntary donation; feeling of belonging to a national and European medical community; proper cultural approach to blood safety and risk management; widespread application of "quality" principles, in the frame of quality management.

It became clear that nearly all medical and transfusion problems of Europe need to be addressed not only by national measures, but also by a common "transversal", regional approach.

Within this frame, ESTM activities have been oriented towards full appreciation of the critical relevance of the contribution of clinical medicine to transfusion safety.

Council of Europe's 2002 and 2004 Recommendations showed the essential role of hospital's clinicians and nurses in assuring a safe and effective performance of patients' transfusion.

Clinical medicine, in order to provide patients with the safest possible blood, has much more to give than to receive, to do than to wait, to care for than to expect from. A cultural and behavioural change is ahead of European clinical medicine concerning safe blood: no more addressing patients' families to provide "replacement" donors, but convincing them to become themselves voluntary, non-remunerated, anonymous donors; no more assuming clinical indications to transfusion as correct, but checking them against scientific and medical evidence; no more running away, but spending time; no more delegating, but personally caring; no more abstaining, but getting involved; no more exclusively receiving, but also becoming properly co-responsible of the safety of blood given to their patients.

***Blood is too important in our life to be left only to others!***

## Safe Surgery Saves Lives. A WHO international project

Peltecu G

Department of Obstetrics and Gynecology, Filantropia Clinical Hospital, Bucharest, Romania

The 52<sup>nd</sup> World Health Assembly (WHA) adopted in 2002 a resolution urging member countries to strengthen health care safety and monitoring system.

In 2004 the 57<sup>th</sup> WHA approved the creation of an International alliance to improve patient safety as a global initiative.

In October 2004 was launched the World Alliance for Patient Safety. The aim of the national agencies, policy-makers and patient groups was to reduce the adverse health and social consequences of unsafe health care.

A core element of the Alliance was the Global Patient Safety Challenge (GPSC), which brought together the expertise of leading specialists in specific fields.

The first GPSC plan, between 2005 and 2006, was health care associated infection. The second problem chosen by the WHO for the second GPSC, for 2007 and 2008, was improving the safety of surgical care.

Surgical complications have become a major cause of death and disability worldwide (estimated volume of major surgery in 2004: 184–276 million operations; assuming a perioperative adverse event rate of 3 % and a mortality rate of 0.5 % globally, with the result that 7 millions patients were harmed and 1 million died following surgery).

There are four underlying problems in surgical safety:

1. it is not recognized as a significant public health problem;
2. few information about significant complications;
3. safety interventions seem not to be reliably employed in any country (e. g. antibiotic prophylaxis);
4. the increasing complexity of the surgical procedures (i. e. many critical steps, each with opportunities for failure or injury).

Operating teams are one of the most important resources of the health care, but in the same time the most critical for surgical quality and safety.

Preventing/remedy to the possible risk factors for patient safety is the aim of the *Safe Surgery Saves Lives* program.

SAFE SURGERY SAVES LIVES CHALLENGE: The aim of this program was to provide knowledge and support to reduce avoidable deaths and complications in surgery.

Four areas of expertise were designated:

- 1) safe anesthesia;
- 2) infection prophylaxis;
- 3) safe surgical team;
- 4) measurement of the surgical services.

*Anesthesia* is a cornerstone in the care of the surgical patient. In individual incidents, a list of contributing factors could be enumerated: inadequate experience, inadequate

familiarity with equipment, poor communication among team members, haste, fatigue, inattention, poor equipment design.

Huge progresses were made in the field of anesthesia safety (mortality dropped more than 95 %, that is 1 in 200,000 cases).

*Use of a checklist to reduce complications.* Advantages: recall memory; make the minimum steps in a complex process; establish a higher standard of a baseline performance.

The checklist divides the operation into three phases, each corresponding to a specific time period in the normal flow of a surgical procedure: the period prior to induction (the "sign in"); the period after the induction and prior to surgical incision (the "time out"); the period after the wound suture (the "sign out"). In each phase, the checklist coordinator must confirm that the team successfully completed it.

In the "sign in" phase, the following items must be completed: consent obtain; site marked/not applicable; pulse oximeter on patient and functioning; patient confirmed identity, site and procedure; anesthesia safety check completed (allergy, difficult airway).

In the "time out" phase, the following items must be completed: surgeons, nurse and anesthesia professionals verbally confirm patient, site, procedure and position; antibiotic prophylaxis given in the last 60 min; essential imaging displayed; anticipated critical events, by surgeon, anesthetist and nursing team.

In the "sign out" phase the following items must be completed: 1) surgeon review with the entire team: what procedure was done; important intra-operative events; management plan; 2) anesthesia professional review with the entire team: important intra-operative events; recovery plan; 3) nurses review with the entire team: instruments and sponge count; specimen labeling; important intra-operative events and recovery plan.

## **Securing hospital future through corporate culture**

Aldenhoff A, Hillebrand JS  
Tristan Consulting, Hamburg, Germany

**OBJECTIVE OF INVESTIGATION:** Financial success of hospitals is related to corporate culture up to 31 percent – via the engagement of the employees.

There are many challenges hospitals and the people working there have to face these days: more patients, less employees, shorter periods of hospital stay, advanced treatment standards and more requirements and expectations from the patients.

On the other hand, corporate communication often lacks to fulfill the needs of employees as transparency, involvement and appreciation.

**METHODS USED:** We present an innovative way to establish a valuable corporate culture using transfer models from a different social context. Creating a work of art, may it be a play, a chorus or a dancing competition, establishes another emotional level in a working context. In this environment people are confronted with hidden conflicts and subconscious behavior and are enabled to find creative ways to solve their problems.

**RESULTS:** Using a transfer model establishes a new level of communication in the working environment. Via this pathway, relevant working themes can be enclosed, communication will be improved, conflicts are solved more easily and the intensity of cooperation will be strengthened.

**CONCLUSIONS:** One should be encouraged to go unusual ways to establish a positive forthcoming corporate culture. Ongoing communication successes cannot be established only via cognition. Emotion and experience are key success factors.

## **Blood-sparing medicine and surgery: the ESTM experience**

Rossi U

European School of Transfusion Medicine (ESTM), Milan, Italy

The increasing interest of the medical world in transfusion safety is expressed by higher attention to education in blood-sparing medicine and surgery.

Out of 19 ESTM residential courses in the last 7 years, 9 were focused on optimal use of blood.

Efficient efforts to obtain a safest possible blood donation are unfortunately often spoiled by unjudicious criteria of blood prescription and administration.

Specific ESTM courses in Ukraine (2002), Serbia (2003), Latvia (2004), Albania (2005), Czech Republic (2006), Italy and Spain (2007), and Macedonia (2008) clearly evidenced some ethically unacceptable aspects of clinical transfusion practice, such as under-transfusion due to justified fear of unsafe blood, or uncritical transfusion of blood components due to incorrect clinical criteria.

Widespread ignorance of basic principles of clinical transfusion practice in Europe is often explained by a low basic knowledge of Transfusion Medicine (TM), still receiving little attention in the medical undergraduate curriculum of most European Universities.

General agreement in the medical profession was reached, however, on the paramount importance for a good practice of TM of the 4 classical "pillars" of blood safety: promotion and maintenance of voluntary non-remunerated blood donation; donor testing and prevention of blood-transmissible diseases; rational clinical use of blood components; general organisational measures (including a quality assurance system defined by official guidelines or regulations), concerning also integration of TM into national policies of Public Health and clinical medicine.

In many European countries, moreover, medical communities have become increasingly aware that, although basic economical resources are needed for constructing any Transfusion Service, what makes blood transfusion safe and effective is rather political maturity, moral solidarity, cultural development and medical competency: all factors dependent much more on human dedication than on financial prosperity.

Responsible voluntary donors, essential blood testing, rational clinical use of blood components: these fundamental bases of transfusion safety can only be the result of a continuous "education to quality" of the public at large, of school children, University students, general practitioners, medical doctors, transfusion specialists, nurses and technicians, and public officers.

**Saturday, 22 November 2008**

**Room A**

**10.00–11.00: Workshop: Toward Multisensual Surgical Tools:  
Surgery in the Era of Robotics**

**Michael Stark, Berlin, Germany: Back to the fingertips**

## Back to the fingertips

Stark M

The New European Surgical Academy (NESA), Berlin, Germany

Since the end of the 20<sup>th</sup> century, endoscopic surgery has eliminated the surgeon's ability to palpate, feel and diagnose the operative findings. Direct vision has been replaced by looking at a monitor, and the role of haptic sensation has been considerably diminished.

In many musical instruments, the players use their fingertips to make strings vibrate, manipulate keyboards, or cover the holes of wind instruments. Painters use their fingers to hold the brushes, and sophisticated Eastern cultures use their fingertips to hold the eating sticks. Since the beginning of modern surgery, the fingertips were used to hold the instruments, palpate tissues and distinguish between the physiological and pathological findings.

Today, most surgical procedures have endoscopic alternatives. However, the only two surgical procedures for which there are no endoscopic alternatives, the vaginal hysterectomy and the caesarean section, have been analyzed in randomized prospective studies. It was shown that in these operations, where the fingers are used to stretch the abdominal structures, the peritoneum and the uterus as well as to remove the uterus through the vagina, the results were lower febrile morbidity and a reduced need for pain killers.

The NESA's working group on Natural Orifice Surgery (NOS) believes that the use of the natural openings of the human body, and mainly the use of the Douglas pouch in women as an entry, will replace many of the traditional endoscopic procedures, for aesthetical and safety reasons. The introduction of the instruments is parallel rather than perpendicular to the main blood vessels, which prevents haemorrhages, and the required intra-abdominal pressure is lower; therefore most of these procedures can be performed using peridural anaesthesia.

The ergonomic challenge is how to develop novel sophisticated surgical methods and instruments and at the same time revive the traditional usage of the human senses during surgical procedures. For this reason a team of engineers and surgeons are planning a set of new instruments which, despite of their simplicity, will combine sophisticated procedures, haptic sensation, and safety.

It seems that despite of the major technical development in all surgical fields, human touch and immediate tactile evaluation seem to be irreplaceable.

**Saturday, 22 November 2008**

**Aula Magna**

**11.30–13.00: Scientific session: The future of surgery**

**Liselotte Mettler**, Kiel, Germany: The progress in robotic surgery

**Emilio Ruiz Morales**, Ispra, Italy: ALF-X opens a new era for tele-robotics surgery

**Bruno van Herendael**, Antwerpen, Belgium: Laparoscopic approach in female pelvic oncology

**Vladimir Akinfiyev**, Ashkelon, Israel: The HDH device for suture-less vascular anastomosis: the novel surgical technique

## The Progress in robotic surgery

Mettler L

Department of Obstetrics and Gynaecology, University Hospitals Schleswig-Holstein, Campus Kiel, Germany

The growing popularity of laparoscopic surgery focused new attention on the need for both improved laparoscopic camera control and instrument range in terms of motion and dexterity.

The first robotic camera assistant used in endoscopic surgery was AESOP® (Computer Motion, Goleta, CA). This hand, foot or voice-controlled arm allows the surgeon to perform complex laparoscopic surgery faster than with an assistant holding the camera. The next surgical robot was a voice-controlled robot ZEUS® (Computer Motion, Goleta, CA), that consists of AESOP to hold the camera and two additional AESOP-like units which have been modified, to hold the surgical instruments. The modern robot generation named da Vinci® Surgical System, is based on the technologies of Computer Motion and developed by Intuitive Surgical® (Mountain View, CA). It was approved by the US Food and Drug Administration (FDA) in May 2005 for clinical use in gynecology, and was first used in reproductive gynecology for tubal surgery. There are four main components to the da Vinci® Surgical System:

1. Surgeon console: the surgeon sits viewing a magnified three-dimensional image of the surgical field
2. Patient side-cart: this system consists of three instrument arms and one endoscope arm.
3. Detachable instruments (endowrist® instruments and intuitive® masters): these detachable instruments allow the robotic arms to maneuver in ways that simulate fine human movements. There are seven degrees of freedom, which offer considerable choice of rotation in full circles. The surgeon is able to control the amount of force applied, which varies from a fraction of a gram to several kilos. Tremor and scale movements are filtered out. The movements of the surgeon's hand can be translated into smaller ones by the robotic device
4. Three dimensional vision system: the camera unit or endoscope arm provides enhanced three-dimensional images with the result that the surgeon knows the exact position of all instruments in relation to the anatomical structures.

The patient lies in a horizontal position with both arms tucked alongside his or her body. Four trocars are placed next to the optic trocar. The surgeon sits at the console and the first surgical assistant is seated, in most cases, on the patient's left side. This assistant controls the left accessory ports into which the instruments that are used for vessel sealing, retraction, suction, irrigation and suturing are inserted. The middle robotic arm is attached to the optical trocar, with two lateral working arms to the right and one to the left. The robotic arms are connected at the beginning of the procedure and disengaged from the trocars at the end of the operation. The incisions are stitched and the incision lines are re-approximated.

A three-dimensional vision allows the surgeon to perform ultraprecise manipulations with intraabdominal articulated instruments while providing the necessary degrees of freedom. The da Vinci® Surgical System is large, expensive and has a steep learning curve. It is, however, well on the way to being fully integrated into existing healthcare systems for all specialties.

In gynaecologic minimal invasive surgery the da Vinci plays the number one role particularly in oncologic surgery. However, other robotic instruments and surgical systems are already produced in many countries. A literature survey on robotic-assisted gynecological oncology clearly supports the use of the da Vinci surgical system in laparoscopic oncological surgery. Robotic precision in tumor excision, easier intracorporal suturing and favorable ergonomics for the surgeon make the da Vinci robot particularly suitable for per-

forming complex laparoscopic microinvasive surgical operations in gynecological oncology.

**SUMMARY:** Robotic surgery combines the advantages of open surgery and endoscopic surgery. In our opinion, robotic surgery may lead to better results than conventional laparoscopic surgery, particularly in the field of gynecological oncology. However, this opinion has yet to be confirmed by randomized studies.

## **ALF-X opens a new era for tele-robotics surgery**

Ruiz Morales E

EC-JRC Institute for the Protection and Security of the Citizen, Ispra, Italy

ALF-X, standing for “Advanced Laparoscopy through Force refleCTion”, is a breakthrough in tele-robotics surgery thanks to a vast range of unprecedented features covering tactile sensing capabilities, versatility, safety and ease of use for laparoscopic surgical procedures.

Tactile sensation is the capability of feeling exerted forces on patient tissues by robotics surgical instruments. Since the early days of tele-robotics surgery in the late 90s, tactile sensation has been the most desired and requested feature but, for the first time, ALF-X successfully provides it in a cost-effective way. In fact, ALF-X's remote tactile sensing opens new horizons in the use of tele-robotics surgical systems by improving safety and efficiency of surgical interventions. For instance, better surgeon perception than in manual procedures, avoidance of suture knots breaking, and reduction of incisions damages are characteristics that increase surgeons' confidence, improve the quality and reduce the duration of the intervention.

The ALF-X versatility for any type of laparoscopic intervention is given by the quick insertion and replacement of surgical instruments independently from the patient's positioning on the operation table, and by the capability to simultaneously use up to five ALF-X robotics arms remotely operated by one or two surgeons. ALF-X is also easily retractable to allow the surgeon access to the patient and specifically designed to minimize its workload for the assistant and its overhead on the intervention time.

In practice, ALF-X does not alter the surgical procedures and is currently aimed at experienced surgeons in laparoscopy offering them an intuitive command interface that can be located outside the operation room.

The ALF-X tele-robotics surgical system is the result of a fruitful R & D collaboration between the Italian pharmaceutical company SOFAR spa and the Institute for the Protection and Security of the Citizen of the EC-Joint Research Centre (JRC-IPSC).

## Laparoscopic approach in female pelvic oncology

Van Herendael BJ

ZNA Stuivenberg, Antwerp, Belgium

Università degli Studi dell' Insubria, Varese, Italy

**INTRODUCTION:** When approaching an oncological problem one has to have in mind the famous line of Harry Reich: "Laparoscopy is a way of access not a technique". What most laparoscopists forget is that in the approach of oncological situations one has to think and more so act as an oncologist.

**MATERIAL AND METHODS:** Laparoscopy has the advantage of small entry ports – psychological advantage especially in carcinoma patients –, proven diminished stress enhanced biological parameters (statistical and evidence based), above all a much better sight at the operative field because of the enlargement of up to 40 times and a quicker recovery in the post operative stage allowing for an earlier start of chemotherapy (statistical and evidence based). Laparoscopy has one huge disadvantage **TIE: The Inexperienced Endoscopist**. Surgeons forgot Harry Reich's line and thought that they could get away with everything having the excuse of laparoscopy (abdominal wall metastases are the consequence of not protecting the abdominal wall and too high an intra-abdominal pressure during the surgery). Another is the theatre occupancy time that statistically exceeds the laparotomy.

**DISCUSSION:** When I started to do total laparoscopic hysterectomies and pelvic lymph node dissection in 1991 there was a tremendous resistance from the oncological surgeons. This year the first phase III randomized clinical trial comparing Laparoscopic (Robotic and hand free) versus the classical Laparotomic approach in A I BI cervical cancer did start (1). The main reason the authors state is that it is impossible to start a trial if the technique, laparoscopy, is too young quote "As with all surgical trials, timing of the trial is crucial. If the trial is conducted early, the new technique may still undergo too many modifications to allow application of a standardized procedure" end of quote. They are right of course and although I do admire their efforts the outcome now a days is predictable. The laparoscopic, and for the ones that have the money – laparoscopic robotic – approach is better than the abdominal. At the end of the day it is the scar that matters. In my personal series of 72 radical surgeries with lymph node dissection the main age of the patients is 64.6. The patients have all been walking on the first day post operative. The main hospital stay has been 2.4 days. This means losing money in theatre winning money in the postoperative period mainly less medication (pain killers and antibiotics) and less nursing.

The main objection of the classical surgeons was less lymph node collection we now have statistical prove that this is not so, even sentinel nodes are detected 100 % and slightly a larger number at laparoscopy (2).

**CONCLUSION:** There is no doubt in my mind that diligent application of laparoscopy is to the benefit of our patients, does save money and yields exactly the same results as the classical approach. It is therefore in my opinion a mistake to continue to treat some forms of cancer with classical surgery.

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2. Diaz-Feijoo B., Gil-Moreino A., Perez-Benavente M., Morchon S., Martinez-Palones J.M., Xercavins J. "Sentinel Lymph Node Identification and Radical Hysterectomy with Lymphadenectomy in Early Stage Cervical Cancer: Laparoscopy versus Laparotomy". Jmig: 2008: (15-5);531-537

## **The HDH device for suture-less vascular anastomosis: the novel surgical technique**

Yoffe B<sup>1</sup>, Bass A<sup>2</sup>, Kobzantsev Z<sup>2</sup>, Akinfiyev V<sup>3</sup>, Kavounovski I<sup>3</sup>

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2 Vascular Surgery Department, Asaf Harofeh Medical Center, Israel

3 HDH Medical, Haifa, Israel

The vascular surgery community is in a long search for an easier and more reliable anastomosis technique.

The nowadays practice is suturing of vascular graft by the surgeon to the intended vessel. It can be technically complicated, time consuming and requires a prolonged cross clamping.

The HDH anastomotic device (B. Y.-Fix) is used to connect any standard vascular graft to the blood vessel of a patient. Sutureless and leak proof anastomosis is performed in less than ten minutes, even for major vessels, which shortens the cross-clamping time by an order of magnitude, and reduces the operative and post operative complications, providing unrestricted blood flow.

The clinical indications of the device include repair of aortic aneurysms and occlusions, vascular trauma and peripheral occlusions to be performed more rapidly with the same quality of anastomosis like the manual one.

Full tool kits for open and laparoscopic delivery and insertion of B. Y.-Fix device was developed and tested.

The B. Y.-Fix is biocompatible polymer cone with the several rows of short flexible barbs on the external surface for anchoring. Their design permits only forward longitudinal movement and when pulled back slightly, the barbs penetrate the internal layers of the vessel wall, providing quick and leak proof secure fixation.

The experimental animal study and the multi-central human clinical trial in patients enrolled proved the feasibility and safety of the technique. There were no significant operative and postoperative complications observed during 3–6 months of follow up (no leakages/migrations), which was confirmed by the imaging studies and physical examinations.

The laparoscopic application was investigated in animal studies. The use of the device for this application will shorten significantly the learning curve of training for Lap vascular procedures and fasten its adoption rate.

**CONCLUSION:** The suture-less B. Y.-Fix's performance in vitro and in vivo proved that this technique is very promising for vascular anastomosis, and its use is faster and simpler than the vascular anastomosis techniques commonly in use.

**Saturday, 22 November 2008**

**Room A**

**11.30–13.00: Scientific session: Meet the expert**

**Andreas Blana**, Regensburg, Germany: Long-term results with transrectal HIFU in patients with localized prostate cancer

**Georgi Grasczew**, Berlin, Germany: Real-time e-learning and distributed medical intelligence in the digital medicine

**Klaus J. Neis**, Saarbruecken, Germany: Management of entry complications in laparoscopy

**Renato Seracchioli**, Bologna, Italy: Standards for ureteral management in cases of deep infiltrating endometriosis (DIE)

## **Long-term results with transrectal HIFU in patients with localized prostate cancer**

Blana A

Department of Urology, University of Regensburg, St. Josef Hospital, Regensburg, Germany

**OBJECTIVE:** High intensity focussed ultrasound (HIFU) has been used for more than 10 years to treat patients with prostate cancer. This is a report on the first study evaluating long-term efficacy of HIFU therapy for patients with localized prostate cancer.

**MATERIAL AND METHODS:** Patients with T1–T2 NxM0 prostate cancer, a PSA < 15 ng/ml and a Gleason score (GS) ≤ 7, treated with prototypes or first generation Ablatherm™ HIFU devices between October 1997 and August 2001 were included in this multicenter analysis. Biochemical failure was defined as PSA nadir + 2 ng/ml. Treatment failure was defined as biochemical failure or positive biopsy or salvage therapy requirement.

**RESULTS:** 140 patients with a mean (SD) age 69.1 (6.6) years were included.

Mean (SD) follow-up was 6.4 (1.1) years. Control prostate biopsies (3 months after HIFU) were negative in 86.4 % of patients. Median PSA nadir was 0.16 ng/ml (range: 0.0–9.1 ng/ml) achieved at a mean (SD) of 4.9 (5.2) months. A PSA nadir ≤ 0.5 ng/ml was recorded in 68.4 % of patients. The actuarial biochemical failure-free survival rates (SR) at 5 and 7 years were 77 % and 69 %, respectively. The actuarial salvage treatment-free SR at 5 and 8 years were 87 % and 79 %, respectively. The actuarial disease-free SR at 5 and 7 years were 66 % and 59 %, respectively.

**CONCLUSIONS:** This study demonstrates the effective long-term cancer control achieved using HIFU in patients with low or intermediate risk localized prostate cancer.

## **Real-time e-learning and distributed medical intelligence in the digital medicine**

Graschew G, Roelofs TA, Rakowsky S, Schlag PM

Surgical Research Unit OP 2000, Max-Delbrueck-Center and Charité – University Medicine Berlin, Germany

Due to the distributed medical intelligence in telemedical networks e. g. a general practitioner or a hospital for basic care can request online assistance from the next university hospital in case of unexpected findings. The possibility to be supported by external experts, the improvement of the precision of a surgical intervention by computer-assisted surgery and the online documentation and evaluation of patient data contribute to a continuous improvement of patient care. Virtual Hospitals (VH) with international partners aim to support the interconnection and interoperability of the various technological platforms and medical services of the organisations participating in the telemedical network, by integrating them into a consistent set of services. Thus, the development of VH and digital medicine helps to bridge the digital divide between different regions of the world and enables equal access to high-level medical care.

Global networks like in the VH and the use of computers for educational purposes stimulate and support the development of virtual universities for e-learning. Especially real-time interactive applications like realized in the EMISPHER Virtual Medical University can play an important role in tailored and personalised services. The objective of real-time education and training in medicine is live transmission directly from the operating theatre. By implementing interactive connections to the “point of action” and remote control of cameras to be viewed on the local monitors, live interaction with and participation in the remote event becomes possible. Rather than putting emphasis only on the required technologies as means for e-learning, it will be necessary to focus also on the users and their needs and take this as primary driver for developments towards ubiquitous learning in the VH.

## **Management of entry complications in laparoscopy**

Neis KJ

European Training Center for Gynecologic Endoscopy and Gynecologic Surgery (ETC),  
Saarbrücken, Germany

The complication rate in case of gynaecologic endoscopic procedures is between 0.5 % and 3 %. Here applies that the complication rate decreases with growing experience also for extended surgeries. Astonishingly, the rate of entry complications lies at about 30 % of the complication rate in all collectives, whether performed by experienced or inexperienced surgeons.

By use of detailed analysis of the individual facts of each single patient (status after Pfannenstiel cut or longitudinal cut, adiposity, size of the findings to be operated) it is possible to adapt the access to these special conditions. The possible approaches will be demonstrated.

Conformingly, the open laparoscopy did not bring any improvement of the complication rate.

## Standards for ureteral management in cases of deep infiltrating endometriosis (DIE)

Seracchioli R

Minimally Invasive Gynecological Surgery Unit, S. Orsola Hospital, University of Bologna, Bologna

**STUDY OBJECTIVE:** The purpose of the present study was to discuss our clinical and surgical experience with 30 cases of ureteral endometriosis.

**DESIGN:** Retrospective analysis (Canadian Task-force Classification II-3)

**SETTING:** Tertiary care university hospital.

**PATIENTS:** Records were assessed for all patients who underwent laparoscopic surgery for deep infiltrating endometriosis in the Minimally Invasive Gynecological Surgery Unit, S. Orsola-Malpighi Hospital, Bologna University, from June 2002 through June 2006. Thirty patients who were laparoscopically diagnosed and histologically confirmed to have ureteral involvement by endometriosis.

**INTERVENTIONS:** Laparoscopic retro-peritoneal examination and management of ureteral endometriosis.

**MEASUREMENTS AND MAIN RESULT:** Variables assessed were; **pre-operative findings** (patients' characteristics, clinical presentation, pre-operative workup), **operative details** (type and site of ureteral involvement, associated endometriotic lesions, type of intervention, intra-operative complications) and **post-operative follow up** (short and long-term outcomes).

We recorded 30 patients with a median age of 33.33 years and a median body mass index of 21.96. Symptoms reported were: No urinary symptoms in 20/30 patients (66.7 %), specific urinary symptoms in 10/30 (33.3 %); dysuria (30 %), renal angle pain (10 %), hematuria (3.3 %) and 33.3 % of patients presented with hydro-uretero-nephrosis. Ureteral endometriosis was presumptively diagnosed before surgery in 40 % of patients. Ureteric involvement was on the left side in 46.7 %. On the right side in 26.7 % and bilateral in 26.7 %. It was extrinsic in 86.7 % and intrinsic in 13.3 %. It was associated with endometriosis of homolateral uterosacral ligament in 30/30 (100 %), the bladder in 50 % of cases, recto-vaginal septum in 80 %, ovaries in 53.3 % and bowel in 36.7 %. Laparoscopic intervention was: ureterolysis only in 73.3 %, segmental ureteral resection and termino-terminal anastomosis in 16.7 %, segmental ureterectomy and uretero-cystoneostomy in 10 %. Early post-operative complications included: fever > 38° requiring antibiotics for seven days in 7 patients, one patient had transient urinary retention requiring catheterization that resolved without further treatment. During a mean follow up period of 14.6 months, endometriosis recurred in 3 patients with no evidence ureteral re-involvement.

**CONCLUSION:** Ureteral involvement is a silent, serious complication which has to be suspected in all cases of deep infiltrating endometriosis. Retroperitoneal laparoscopic isolation and inspection of both ureters helps to diagnose silent ureteral involvement. Conservative laparoscopic procedures provide a safe, feasible modality for management of ureteral endometriosis.

**Saturday, 22 November 2008**

**14.00–16.00: Scientific session:  
New and revised technologies and methods**

**Domenico Vitobello**, Abano Terme, Italy: Gynaecologic robotic-assisted laparoscopy – preliminary experience

**George Peltecu**, Bucharest, Romania: New modalities for breast cancer treatment

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## **Gynaecologic robotic-assisted laparoscopy – preliminary experience**

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We report our preliminary experience in a variety of gynaecological procedures where we tried to evaluate the efficiency of da Vinci in different kind of operations

The study is a case series of 60 patients who underwent various gynaecologic pathologies treated by robotic-assisted laparoscopic surgery. All the complications and the technique difficulties have been evaluated. Also the assembly time to prepare the da Vinci robot was measured.

The patients underwent a variety of gynaecologic operations, such as myomectomies, total hysterectomies, ovarian cystectomies, endometriosis, sacral colpopexy, radical hysterectomy (Piver II-Wertheim) with pelvic bilateral lymphadenectomy. The assembly time to switch from laparoscopy to robotic-assisted surgery was 12 minutes (range: 6 to 25). Two myomectomies failed with robotic-assisted laparoscopic surgery for technical problems during the da Vinci® robot's assembly.

Robotic-assisted laparoscopic surgery has advantages in improving the surgical precision doing the sutures following myomectomies, in decreasing fatigue and tension tremor of the surgeon, especially during lymphadenectomy, in providing a three-dimensional visualization of the operative field. It was always possible to perform all kinds of gynaecologic operations using the da Vinci® system.

## **New modalities for breast cancer treatment**

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The surgical treatment of the breast cancer evolved, after about seven decades, from radical mastectomy to limited surgery.

The reduce of the extent of surgery was proven to influence not only the patients' survival, but also to have a great impact on body image and quality of life.

After three decades of limited surgery, performed by standard techniques, some new non-surgical methods are studied. These are based on the principle of destroying the breast cancer cells by heating or freezing. These techniques are called 'in situ' ablation.

All the techniques presented here are experimental and there are not enough data to support their use as a standard treatment.

**RADIOFREQUENCY ABLATION (RFA):** RFA delivers an electrical current to the breast tumor causing a vibration of the tumor tissue and frictional heating. A probe is inserted by surgeon in the center of the tumor. The probe has small prongs that are developed around it (umbrella-like). The probe is connected to a generator and an electric current is delivered rising the temperature up to 95° C for 15 minutes. Then the tumor is removed by classic surgery and examined by pathologist. In almost all cases the tumor is completely destroyed by RFA.

A second phase of this project consists in using radiation therapy after RFA and avoiding surgery.

**LASER THERAPY (LT):** LT uses high temperature to destroy the breast tumor. A fiberoptic cable is placed within the tumor using an ultrasound (US) guidance and it has at its tip a diffusing quartz. Light energy passing through the cable produces the heating of the tumor tissue. The amount of energy necessary to destroy the tumor can be calculated on the base of the tumor size. It has to include a safe margin of 0.5 cm. Then the tumor is removed surgically and examined by the pathologist. In almost all cases tumor is completely destroyed.

**CRYOSURGERY (CS):** Its principle is based on the use of freezing temperature to destroy cancer cells. This method is studied for the treatment of early stage of breast cancer.

The cryoprobe is placed by US guidance through a small incision in the center of the tumor. It has a ball-tip that gets very low temperature. Area of destruction can be visualized by US. At the end of the procedure the probe is removed and the skin closed (steri-strip). In almost all cases the tumor is completely destroyed.

All three techniques presented (RFA, LT, CS) use the placement of a probe within the tumor through a small incision, named "minimally invasive" procedures.

All the techniques presented here are experimental and there are not enough data to support their use as a standard clinical treatment.

## The laparoscopic management of neural pelvic pain

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Chronic pelvic pain is a commonly encountered problem in many medical offices and it is estimated that 12 % of all women around the world suffer from chronic pelvic pain. As one of the first steps in pelvic pain management in women is to find an etiology to be treated, laparoscopy has become the standard for diagnosis and treatment of classical etiologies such as adhesions, endometriosis or inflammatory pelvic disease. However lesions to pelvic nerves can also lead to pelvic pain: Lesions to the somatic pelvic nerves during surgery to the lateral pelvic wall can lead to "somatic pelvic pain", while lesion of sympathetic nerves especially those contained in the inferior hypogastric plexi can induce chronic "visceral pelvic pain". While on one hand gynecologists are not trained either in clinical neurology or in operative techniques of neurosurgical procedures and on the other hand neurosurgeons and neurotraumatologists are not trained in pelvic surgery – especially in laparoscopic pelvic surgery – and are not trained in gynecologic pathologies, the patients with neural pelvic pain following surgery are mostly referred from one specialist to another and a variety of different but ineffective treatments are attempted. This situation must change as laparoscopy offers a reproducible and safe neurosurgical approach to all somatic and autonomous pelvic nerves which have never been reached in this way before by classical open surgery; due to progress in video endoscopy, the development of laparoscopic microsurgical instruments and the introduction of intraoperative electrostimulation of the pelvic nerves, laparoscopy has become an unavoidable method for the etiologic clarification of pelvic neuralgia and treatment as classical neurosurgical procedures such as neurolysis or implantation of electrodes for neuromodulation are now laparoscopically feasible techniques. We will report about the laparoscopic management, diagnostic and therapeutic, of neural pelvic pain but also about neuropathic pain of the lower extremities.

## Diversity of vaginal hysterectomies

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**INTRODUCTION AND DEFINITION:** Today, laparoscopic hysterectomy, be it TLH, LAVH or LASH, represents an alternative to abdominal hysterectomy in every progressive clinic when:

1. vaginal hysterectomy is difficult or contraindicated
2. abdominal pain has to be verified
3. the uterus is large or immobile.

Indications for LAVH are given in multiparous women after several vaginal deliveries with a well descending uterus. The abdomen can be inspected, freed of adhesions and the uterine arteries are well accessible transvaginally. TLH facilitates hysterectomy in all sizes of uteri up to 1 kg. The uterine vessels can be well ligated, coagulated, themofused, etc. within the minor pelvis, even in large uteri. Uterine manipulators support the three dimensional movement of the uterus with demonstration of the vessel channels. Oncologic surgeons add the necessary radical components to the procedure.

The easiest surgical hysterectomy is the laparoscopic subtotal hysterectomy (LASH) which requires a subtle morcellation of the enlarged uterus and preserves the surrounding nerves, vessels and organs. CISH (Classic Intrafascial Subtotal Hysterectomy), which includes coring of the cervix, has a specific stand, excluding postoperative cervical cancer development for the future.

**MEASUREMENTS AND MAIN RESULTS:** Between 1990 and 2007 a fluctuating number of hysterectomies (100–300 annually) were performed in benign cases at the Department of Obstetrics and Gynaecology, University Hospitals Schleswig-Holstein, Campus Kiel. This number reflected the influence of the team leader and his understanding of indications and necessities. Thus, in 17 years a stabilization of all 3 techniques occurred.

Today, the selection of the surgical hysterectomy technique depends largely on accompanying factors, such as adnexal pathology, prolapse, endometriosis and previous surgeries. Within the last two years, 315 hysterectomies were performed in 85 cases via laparotomy (malignancies of cervix, uterus and ovaries), in 125 cases transvaginally and in 102 cases laparoscopically.

**CONCLUSION:** Vaginal surgery has limited indications, TLH and LAVH help to miss unclear pathology and LASH is a part of organ-preserving surgery that we should not forget.

## Posters

**George Alex**, Dual Aspect Dissecting Forceps

**George Alex**, A novel suction syringe

**Nicolas Jitea**, Laparoscopic Treatment in Umbilical Hernia

**Charles Lai**, A Case Series of Total Wrist Arthroplasty in Patients with Non-functional Wrists

## Dual Aspect Dissecting Forceps

Alex G

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**AIM:** To describe a dissecting forceps for use when handling different forms of tissue at the same time is needed. The tips of dissecting forceps are usually either toothed or non toothed. Toothed forceps are used for holding tissues. Non toothed forceps are used to move dressings, holding, tying or removing sutures and similar activities. Toothed forceps are generally of interdigitating type. The standard interdigitating type is of the one-into-two pattern i. e. one tip has a single V shaped projection/tooth interdigitating between the two V shaped projections/teeth on the other tip.

As dissecting forceps are either toothed or non toothed, their uses are quite defined. Non toothed forceps provide less fixation of the tissue compared with toothed forceps. Toothed forceps provide more fixation and cause trauma to the tissue. When one needs to hold different types of tissue at the same time, e. g. holding on the side of a wound where one side is smooth skin and the other is subcutaneous tissue, using a non toothed forceps provides less fixation whilst using a toothed forceps causes more trauma.

**METHOD:** A dual aspect dissecting forceps is described here for use especially while needing to handle different forms of tissue at the same time. It has a V shaped projection (tooth) on one tip/end and an aperture on the other tip/end onto which the V shaped projection/tooth enters on approximating the two limbs of the forceps. When holding on the side of a wound where one side is smooth skin and the other is subcutaneous tissue, the tip with the aperture is kept on the skin side of the tissue to be handled and the tip with the tooth is used on the subcutaneous tissue side of the tissue to be handled.

**RESULTS:** The toothed tip provides adequate fixation when applied on the subcutaneous tissues.

The non toothed tip on the skin side causes hardly any trauma.

**CONCLUSION:** The dual aspect dissecting forceps provides adequate fixation while causing hardly any trauma when needing to handle different forms of tissue at the same time.

## **A novel Suction Syringe**

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**AIM:** To describe an instrument for use in liposuction i. e. in breast lipomodelling. The first part of lipomodelling is liposuction. Here, a 10 cc syringe is connected to a cannula which is introduced into fat rich areas i. e. thigh, buttocks or anterior abdominal wall. The plunger of the syringe is retracted and kept retracted and the cannula moved in different directions. The negative pressure causes suction of fat into the syringe. The fat obtained is centrifuged resulting in 3 layers; blood, centrifuged fat and oil. The oil and blood are removed and centrifuged fat used for lipomodelling. To obtain 100 ml of centrifuged fat, about 200 ml of fat needs to be harvested. To harvest 200 ml of fat, 20 to 30 syringes (each with 8–10 ml) of fat are required. While harvesting fat, having to keep the plunger of the syringe retracted while each of the 20–30 syringes gets filled can be quite strenuous.

**METHOD:** A Suction syringe is described here. This consists of a modified syringe barrel and a modified plunger. The plunger when withdrawn to a certain extent and slightly rotated gets locked in place and remains retracted without manually having to hold it retracted.

The modified syringe barrel has towards its back end two projections which project into the inside of the syringe barrel. The modified plunger on the plastic disc just behind the rubber end of the plunger has two notches opposite each other and just adjacent to opposite fins on the plunger.

After attaching a cannula onto the syringe and introducing the cannula into a fat rich area (harvest site), the plunger is withdrawn. As soon as the two projections on the syringe barrel have passed through the notches on the plunger, the plunger is rotated slightly and found to stay retracted.

**COMPONENTS:** This invention is made up of a modified plunger used inside a modified syringe barrel.

**Modified syringe barrel:** This has two projections on its inner surface near the finger flange, which project into the inside of the syringe barrel.

**Modified Plunger:** On the plastic disc (just behind the rubber end of the plunger) are two notches opposite each other and just adjacent to opposite fins on the plunger.

**RESULTS:** Suction gets constantly applied without the need to manually hold the plunger retracted.

The chance of the cannula coming out of the tissue inadvertently is lessened as the operator is able to hold the front end of the syringe.

**CONCLUSION:** The suction syringe makes liposuction part of lipomodelling a less strenuous and more efficient procedure. The suction syringe can also be used for fine needle aspiration.

## **Laparoscopic Treatment in Umbilical Hernia**

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**INTRODUCTION:** The laparoscopic approach for umbilical hernia is more and more used, but few results are reported.

**THE AIM** is to evaluate the efficacy and safety of using the Prolene mesh placed laparoscopically in umbilical hernia treatment.

**MATERIAL AND METHOD:** Between 2004–2007, 25 patients with umbilical hernia, aged 34 to 77 years, were submitted to intraperitoneal application of a Prolene mesh to cover the umbilical ring. The mesh was sewed by Protack staples or transfascial stitches. Before deflating the patients, the greater omentum was interposed between the mesh and the bowel. It is notice that 9 patients were obese, 8 patients had omental or bowel adhesions to the peritoneal sac and 6 patients had ascites due to liver cirrhosis. The patients were discharged 24 to 48 hours after the operation and followed up for 6 to 12 months.

**RESULTS:** All patients were followed up, without hernia recurrence or complications due to the Prolene mesh in the abdominal cavity. In 3 patients we registered subcutaneous seromas for 1 to 3 weeks (imposing evacuation by puncture) and 5 patients kept a mildly deformed umbilical scar after the cure of large hernias.

**DISCUSSIONS:** In the literature techniques using composite or two-layers meshes are described. Prolene meshes are not accepted by some authors, for the supposed risk of bowel lesions. In our trial there were no such complications.

**CONCLUSION:** Laparoscopic repair using Prolene intraperitoneal mesh in umbilical hernia is a safe, efficient and rapid method, avoiding infections and other complications in obese or cirrhotic patients.

## **A case series of total wrist arthroplasty in patients with dysfunctional wrists**

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**BACKGROUND:** The wrist is essential for augmentation of fine motor control of the hand and fingers. The normal wrist motion involves a complex interaction of multiple articulations from the radius, ulna and carpal bones. Hence, when a disease process disrupts any one of these elements, a painful, deformed and dysfunctional wrist arises. Total wrist arthroplasty is considered an alternative surgical option to wrist fusion for the management of advanced wrist arthritic diseases. Though less commonly performed in comparison to lower-limb arthroplasty, wrist arthroplasty has its role as a salvage procedure to alleviate pain and to preserve function in the wrists.

**METHOD:** A total of four patients were collected from the centre of hand surgery, and medical records of these patients were reviewed. The patients were carefully selected through multiple interviews and medical consultations. The patient's pre- and post-operative functional status via clinical and radiographic assessments was closely followed over an average period of five years to ensure the continuity of progress. A summary table was formulated to provide an objective survey of both quantitative and qualitative improvement of a patient's wrist function.

**SURGICAL TECHNIQUE:** The standard dorsal approach was performed in all four patients. Layers of tissues, including the extensor synovium, were divided to expose the radiocarpal and radioulnar joint. The decision on the types of wrist prosthesis used is based on the patient's soft tissue integrity and underlying bone stock. One patient received an uncemented Mayo Clinic implant and additional Swanson's metacarpophalangeal joint prostheses in fingers. One patient received the Swanson wrist prosthesis with titanium grommets. Two patients underwent cemented biaxial prostheses which involves the resection of the proximal third of carpal row and distal ulna. The dorsal capsule is repaired in all patients to ensure equal tension between the palmar and dorsal soft tissues.

**RESULT:** The four patients underwent total wrist arthroplasty received different types of prostheses. This is an indication of a lack of universal acceptance of wrist anatomy and biomechanics. Regardless, all patients in this study had improved functional outcomes and satisfactory results from the procedures. Pain-relief was the most successful aspect of wrist arthroplasty during post-operative follow-ups. The successful outcome of these patients in the study has proven that total wrist arthroplasty can provide pain relief and an improvement in hand function through appropriate patient selection, careful peri-operatively planning, sound operative technique and well-designed postoperative hand therapy.