



## Editorial

## Changes in surgical gynecology - Sense and nonsense

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The changes in operative gynecology in the past decades have been dramatic in terms of shifting strategies. For example there has been a shift not only from ultraradical techniques such as exenterations, which were first proposed by Brunschwig in 1948<sup>1</sup> and used in gynecologic oncology by Felix Rutledge in 1974,<sup>2</sup> to minimally invasive techniques such as endoscopic or robotic surgery, but also the level of training in terms of anatomical and surgical skills, which are significantly influenced by medico-legal aspects (i.e., legal regulations). Thus there has been a significant reduction of personal expertise and a changing attitude towards life goals. Moreover, with the European Working Time Directive leading to a reduction in working hours and expansion of the number of trainees, surgical training in areas such as operative experience, patient management, communication, and teaching skills has been getting worse.<sup>3</sup>

The economic pressure on clinics and physicians and conflicts of interest of a financial, personal, academic, and institutional nature initially had stimulating effect, but are now regionally paralyzing further constructive development. Due to complete transparency of information, there is often more paramedical influence from politics and the media, not least due to patient's interest. Together with the increasing digitalization of everyday life and the demands for a higher quality of life, interest in surgical activity and the psycho-physically stressful acquisition of surgical expertise are dwindling.

The changes in surgical gynecology will be represented by gynecological oncology, pelvic floor dysfunctional disease and hysterectomy as follows.

### 1. Gynecological oncology

The era of ultraradical surgery for all tumors, regardless of stage, which was characterized by high patient morbidity and mortality, was

followed by the use of a stage-adapted, combined surgical and radio-chemotherapeutic strategy, which resulted in a significant reduction of secondary complications for patients. In breast carcinoma treatment, the change from the mutilating Rotter-Halsted operation to breast-conserving surgery incorporating plastic-cosmetic reconstructive techniques to the abandonment of axillary lymphonodectomy has been clear.

For malignant ovarian tumors, the current treatment guidelines describe a surgical balancing act and the high demands on the treating physician. On the one hand, patients with “early” ovarian cancer (FIGO stages I to IIA) should receive comprehensive staging, since the detection of further tumor manifestations may result in upstaging and thus, in addition to the need for complete tumor resection, changes in subsequent systemic therapy. Ultimately, definitive treatment can only be provided by a gynecologic oncologist but not by gynecologists in some medical center. On the other hand, the goal of primary surgery for advanced ovarian cancer is macroscopically complete resection. Systemic retroperitoneal lymphadenectomy was widely used as a surgical treatment for advanced ovarian cancer until the famous LION trial<sup>4</sup> changed the trend. Because this randomized trial proved that there was no survival benefit for systematic retroperitoneal lymphonodectomy of macroscopically inconspicuous lymph nodes in patients with peritoneal metastatic ovarian cancer and complete intra-abdominal resection, more advanced ovarian cancer patients have benefited from the new strategy of no lymphadenectomy since the randomized trial was published. To achieve this strategy, a great deal of surgical experience is needed, and it is probably not sufficient for a gynecologist and a surgeon to operate; the surgeon be a specialist in the field of gynecological oncology or special oncologic visceral surgery.

The “second-look surgery” in ovarian malignancies that used to be popular in many hospitals, which is performed after primary surgery and

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postoperative chemotherapy in the absence of evidence of residual tumors during noninvasive procedures, has not been shown in any study to improve prognosis for resections as a result of second-look surgery.<sup>5,6</sup> Even if the detection or fail tumors during second-look surgery allows eventual conclusions about prognosis, this has no therapeutic consequence; therefore, there is no indication for second-look surgery.<sup>7</sup>

In all oncological surgeries, a balance should be maintained between reasonable radicality and the possible complications. For example, in patients with deep infiltrating endometriosis, the surgeon must choose between conservative surgery and colorectal resection. Despite the high technical standards of surgery, complications are possible. Even the shift to laparoscopic techniques has not led to a decrease in complication rates, e.g., for bowel resections. Ultra-deep anastomoses are a particular risk.

## 2. Pelvic floor dysfunctional diseases

The development of the tension-free polypropylene tape (TVT) by Ulmsten and Petros (1995) resulted in an epoch of explosive development of new surgical techniques for pelvic floor reconstruction, including dozens of modifications and modifiers. Despite this period of euphoria, in which all traditional surgical techniques were thrown overboard, a new era of critical realism has now arrived. After many new, unforeseen, and even unknown complications such as tissue erosion and pelvic pain became known, a sense of restraint set in many countries. Concerns often had more of a paramedical basis in that medico-legal disputes with, in part, previously unimaginable compensation sums caused manufacturers to withdraw their products from the market, or politicians believed they had to intervene in a regulatory way by banning products. The lay press had the same, almost hysterical reaction, to silicone breast prostheses, “Robodoc” hip prostheses and power morcellation. For example, the statement by the United States’ Food and Drug Administration (FDA) on the use of power morcellation for the minimally invasive treatment of uterine fibroids (leiomyomas) in 2014 caused substantial controversy in the gynecologic community. The extent to which the press, radio, and television are now changing indications can be seen in England, where after several prime-time BBC broadcasts, tension-free tapes were rejected by patients, although the international professional societies in urology and gynecology have unanimously declared them to be the standard for treating female and male stress incontinence. Although with every surgical approach there is both potential harm and benefit, the benefits of the techniques have been left out of sometimes. The tool is not the problem, but the appropriate use of the tool is the key issue. It is more important to use the tools correctly and in the appropriate patient rather than strictly abandon them. Nevertheless, in the Organization for Economic Co-operation and Development (OECD) countries whether to receive meshes is handled quite differently.

There has been increasing criticism of the approval process in the United States in which new products without any prior review are approved using the “equivalence assessment”; for example, for new medical devices only an FDA 510(k) application has to be submitted as a “premarket notification” indicating the comparability of the product with already approved products. While some countries (France, Germany) refer to doctors’ “good experience” and continue to implant alloplastic tapes and meshes, these products are politically “banned” in England, Scotland, Australia, New Zealand, and in others (the Netherlands) they are only approved under extenuating conditions with regular audits being performed in certified facilities.

Further improvements of the materials have to be awaited with the complexity of individualized management for the pelvic floor dysfunctional disease. Vaginal mesh surgery is still in its infancy, with new products being tested in multicenter trials, such as degradable estradiol-coated mesh. As the conventional polypropylene mesh has recently caused serious complications such as tissue erosion, there are studies focusing on 3D printed hormone-loaded meshes with various geometries.

In vivo tests of the use of electrospinning to prepare mesh implants loaded with 17- $\beta$ -estradiol (E2) for pelvic floor repair have demonstrated that estradiol-releasing mesh can double the number of blood vessels in the tissue surrounding the implant.<sup>8,9</sup> These proof-of-concept studies demonstrate the possibility of preparing patient-specific proangiogenic meshes and show how material choice and mesh geometry can be modified to prepare meshes with safer mechanical properties.<sup>10</sup>

## 3. Hysterectomy

The number of hysterectomies has been declining in Germany for years along with an increase in organ-preserving techniques and conservative treatment options. Under (justified) pressure from patients, the use of techniques leading to hysterectomy-induced urinary incontinence or pelvic pain has given way to an individualized approach and has led to a 28.5% reduction in hysterectomies. This is true for both abdominal and vaginal procedures. The decrease in vaginal hysterectomies has occurred despite the guidelines of all countries specifying that vaginal access be the first preference with its least side effects. In Canada and the US, > 50% of hysterectomies are still abdominal surgeries (in some cases they are just coded differently). There are no reliable arguments for supracervical amputation, which was already practiced by our surgical grandfathers trying to reduce the rate of bleeding from the uterine artery and ureteral injuries but being proved no benefit compared to total hysterectomy in surgical outcomes,<sup>11</sup> and which is used again and again today for various, mainly paramedical, reasons. The fact is that vaginal hysterectomy is the gentlest uterine technique. This is also mentioned in all international guidelines. In Germany, vaginal hysterectomy has decreased by almost 10,000 cases in favor of endoscopic techniques. This trend is incomprehensible because the effort, scarring, and financing are inferior to vaginal method.

## 4. Summary

The general social conditions and increasing economic pressure have completely changed the daily operative routine in gynecology in the following ways:

1. Working hours have changed (due to the European working time law), but there has also been an increase in the number of part-time positions and other working time models with demographic change in our specialty.
2. There has been specialization of facilities and a change in operative competencies.
3. There has been a significant decrease in absolute surgery case numbers due to stricter indications, and conservative treatment strategies have led the trend.
4. The more critical attitudes of patients, have resulted in more second opinions taking place.
5. The lack of qualified instructors poses a real problem in the field of operative gynecology.
6. A lack of junior staff and less interest among residents in surgical activities are also an issue.
7. Massive economic pressure, up to OTA (operation technical assistant), which further restricts the possibility of surgical training, is still going on.

Specialty society and sub-disciplines must develop concrete training plans and new concepts (e.g., phantom courses, computer models, and video demonstrations) and facilitate and promote interdisciplinary exchange with other institutions to make surgical work in gynecology attractive again. Residency training should be further streamlined to include colleagues aiming for surgical work earlier and to make training available for the remaining surgical procedures while respecting the required “specialist standard”.

## Declaration of competing interest

The authors have no conflicts of interest.

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