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Opinion

Pelvic Floor Reconstruction – Quo Vadis ? Should the Actual Development in the Anglo-American Countries Change our Strategy?

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Introduction

February 12, 2019: The FDA convened an advisory committee meeting to share the available evidence and seek expert opinion on how to evaluate the risks and benefits of these devices. The committee was asked to provide scientific and clinical input on assessing the effectiveness, safety, and benefit-risk of mesh placed transvaginally in the anterior vaginal compartment, as well as identifying the appropriate patient population and physician training needed for these devices. As there was no sufficient reply of the manufacturers on April 16, 2019, the FDA ordered all manufacturers of surgical mesh intended for transvaginal repair of anterior compartment prolapse (cystocele) to stop selling and distributing their products immediately. The FDA has determined that the manufacturers, Boston Scientific and Coloplast, have not demonstrated reasonable assurance of safety and effectiveness for these devices, which is the premarket standard that now applies to them since the agency reclassified them into class III (high risk) in 2016 (FDA 2019) [1].

This was definitively not a scientifically based decision, but, had a more or less paramedical history in other English speaking countries:

- December 2017 de facto ban on vaginal mesh use for pelvic organ prolapse NICE conclusion / joint RCOG/BSUG statements UK , since June 2018 they were officially „banned“ !
- 4.January 2018 ban on vaginal mesh for prolapse and single incision(mini) slings for SUI in Australia
- Ban the surgical mesh for any pelvic operations - New Zealand Medicines and Medical Device Safety Authority (Medsafe), de facto in Ireland as well. These decisions on the british isles were provoked by actions of the public in their local parliaments and BBC, that with three prime time transmissions in the TV produced a public motion resulting in a complete refusal of all alloplastic materials by the patients. Even though in the medical community there is no doubt at all about midurethral slings politics and thus the public mixes up everything (Figure1).

Figure 1: From JAMA: showing a midurethral sling and talking about meshes for prolapse !.

- in the Netherlands since 4 years there is a contract with the government that only certified , specialized centers with regular audits are allowed to use meshes – their use went down to < 1% (Figures 2-4) [2].

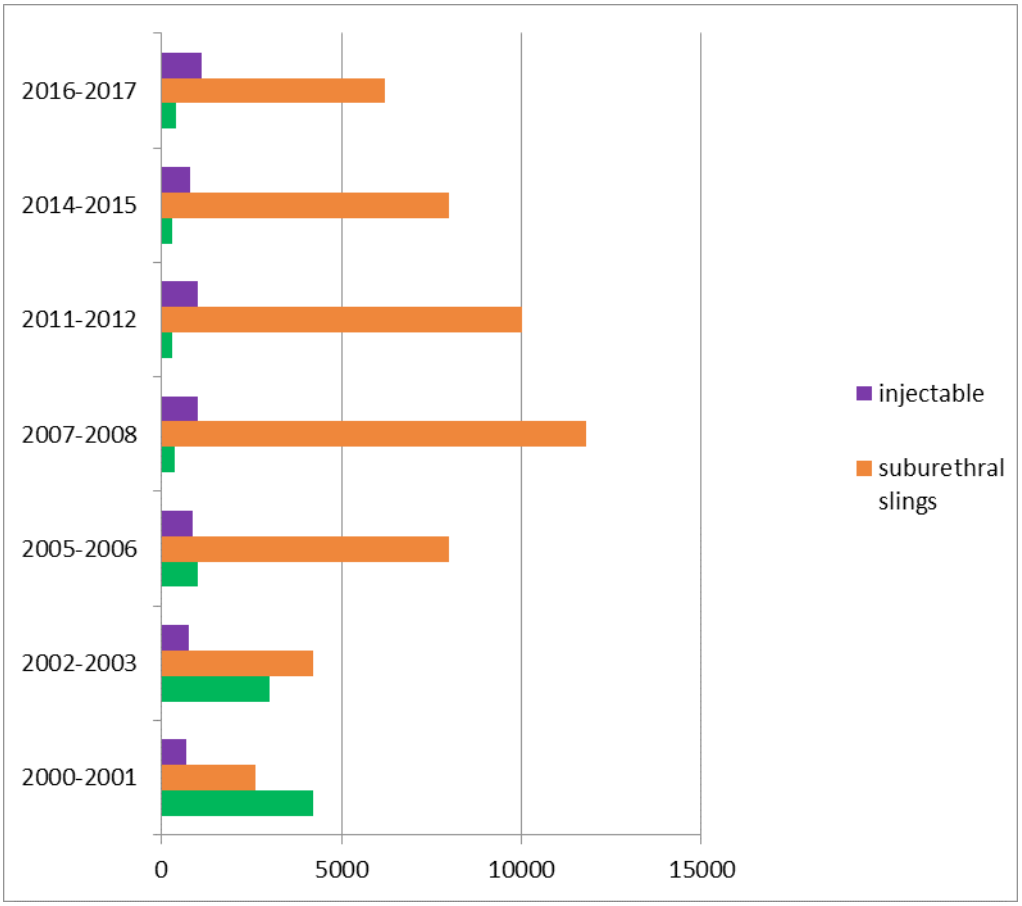
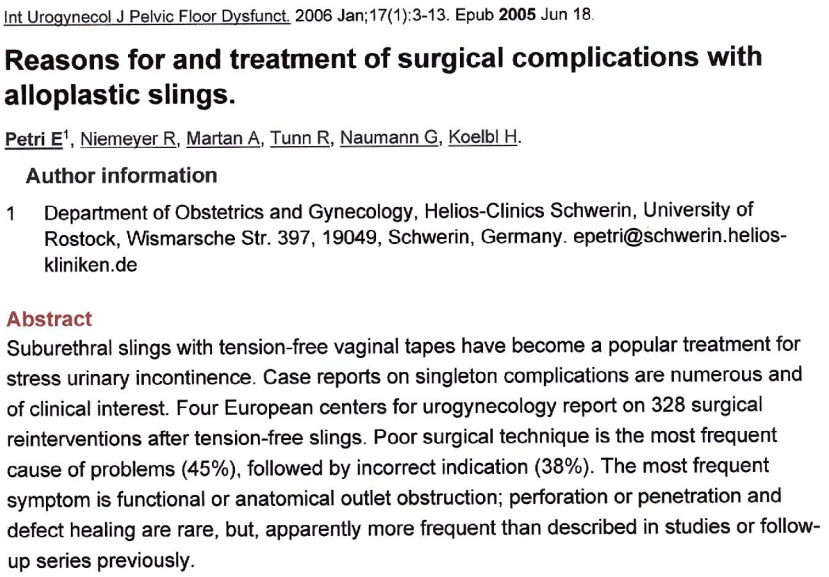


Figure 2: Development of anti-incontinence surgery in England . conventional procedures have gradually disappeared, suburethral slings decreasing dramatically, revival of intraurethral injections [3].

History of alloplastic materials
we already had Mersilene, Marlex, Nylon, GoreTex,…
1995 Indroduction of TVT by Ulmsten and Petros
1998 FDA „approval“
2001 TOT Delorme 2003 TVT-O De Leval
2002 IVS Petros/Farnsworth
2004 TVM Debodinance
2005,2006 Petri et al. – complications
2008 FDA notification: „serious complications…“
2011 FDA update on the safety and effectiveness…
since 2011 many products have dissappeared from the market
April 2019 FDA „taking all meshes from the market !“

2014,2015,2016 Moalli, Chai, Klosterhalfen et al.: basic research in animal experiments looking at tissure reaction and scar tissue formation !

Figure 3: History of alloplastic materials being introduced very quickly with small patient series – basic research started nearly 20 years later.



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Reasons for and treatment of surgical complications with alloplastic slings.

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Abstract

Suburethral slings with tension-free vaginal tapes have become a popular treatment for stress urinary incontinence. Case reports on singleton complications are numerous and of clinical interest. Four European centers for urogynecology report on 328 surgical reinterventions after tension-free slings. Poor surgical technique is the most frequent cause of problems (45%), followed by incorrect indication (38%). The most frequent symptom is functional or anatomical outlet obstruction; perforation or penetration and defect healing are rare, but, apparently more frequent than described in studies or follow-up series previously.

Figure 4: At a time when single case reports on complications and their management still were published in important journals we reported on 328 surgical reinterventions and earned a shit-storm by the producers and fanatic followers of these products.

What was The Reason for The Widespread Acceptance of Alloplastic Materials ?

Pelvic surgeons have been told for decades how little success they had with native tissue repair. This is caused by thousands of papers and presentations with small personal series with personal modifications and a lack of objective parameters of the surgical results and, most important, of patient satisfaction. There never was a generally accepted standard and the biggest problem has definitively been the many combinations of repairs of different compartments together with or without total or subtotal hysterectomies.

Industry promoting their new products convinced many colleagues about the superiority of their kits. Working up the literature with strong parameters we can state

- that the success rates of traditional procedures in good studies were **not** inferior
- a lack of anatomical skills and surgical expertise may be the main reason for bad results
- there is an increasing recurrency rate in long-term follow-up with the new techniques
- many , so far unknown complications with the new procedures
- medico-legal problems
- patients sometimes know more than we believe

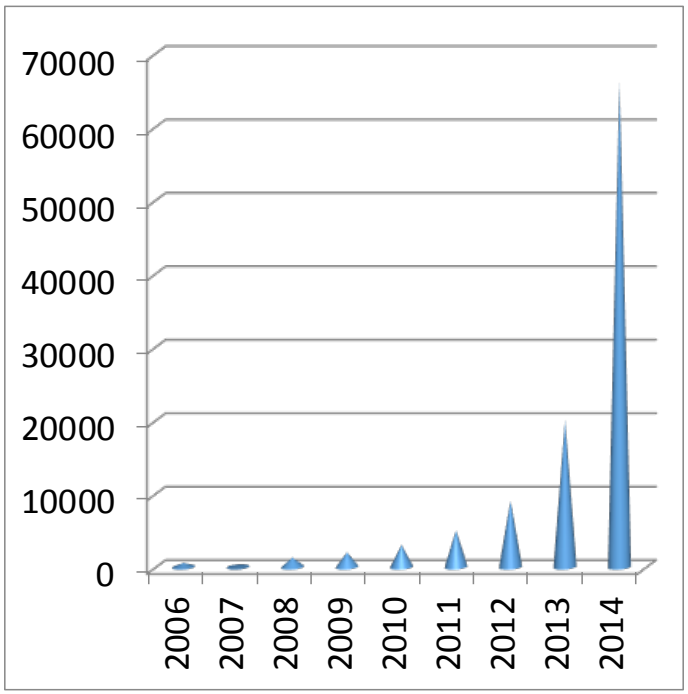
From the very beginning of the development of polypropylene slings and meshes the number of patients in the studies was very small, sometimes products came out of the research units of major companies with the remark "not to be used in humans". In a „clinical practice bulletin" of the American College of Obstetricians and Gynecologists in February 2007 it was stated: „the procedure should be considered experimental and patients should consent to surgery with that understanding" (http://commomhealth.wbur.org/2011). 7 months later the word "experimental" had disappeared, because of possible refusal of responsibility of health care providers and , most important, insurance companies. Lewis Wall talked about the "power of commercial interests reorganizing pelvic floor surgery…" (2010) [4].

The number of medico-legal cases going to court in the USA passing the 100 000 actions filed in 2014 starting with compensations around 2 Mill $, in February 2013 Linda Gross received 11,11 Mill, actually Martha Salazar was awarded 73 Mill $, the amount reduced to 34,6 Mill.$ by change of law in Texas (nevertheless highest compensation known so far).

Using http://meshmedicaldevicenewsdesk.com you can get all information about the actual new verdicts, number of legal cases about different products and companies, the amount of money in open verdicts.

In other countries, especially in central Europe , the medical community argues with their „good experience" and study data (e.g. in France and Germany), continuing the widespread use of

alloplastic meshes, even developing new products without reliable study data.



- In the European Union a new law is decided, starting 26. March 2020 as EUDAMED (european centralized documentation) changing national regulations in prospective rules for the 28 members of EU.
- The EUDAMED will provide data on medical devices and products from that day on.
- This will improve supervision at least for medical products class III ("high risk") [5].

Whether the wish for national or even international registries will be acomplished will depend on the attractivity of participation. Recent registries were successfully established without participation of industry e.g in Austria (Tamussino et al. 2007) or Finland [6,7], others have been cancelled with doubts about their effectivity, leaving the recommendation for randomized multi-center-studies [8].

Incidence of Complications

Dyspareunia (de novo or worse than preoperatively) are described in 14-24% (sometimes even not mentioned at all !), vaginal mesh erosions or defect healing in 6-19% (in smokers 3 X higher) and mesh retraction or shrinkage associated with pain and dyspareunia in 3-19% [9]. In a Multi-Center-Study 347 women with sling/mesh complications were treated, 49,9% after sling insertion, 25,6% after meshes and 24,2% after a combination of both. 42,7% had a defect healing, 34,6% pelvic pain and 30% a dyspareunia. At an average 2 revisions were necessary (1–9), 60% needed > 2 revisions [10], which corresponds to our experience [11]. Long-lasting pain in the upper thigh and the groin (especially after TVT-O) [12], defect healing in the vaginal fornices with dyspareunia up to hispareunia with penile lacerations by exposed alloplastic material [13] up to osteomyelitis and osteonekrosis in the area of the pelvic bones (we haven't seen since the times of Marshall-Marchetti-Krantz) and sometimes serious cases of necrotizing fasziitis. Most of the complications are **not** caused by the mesh material oft he kits, but, wrong indication for surgery or false surgical technique of insertion ("see one, do one, modify one") [14,15].

More than 10 years with a widespread use of alloplastic meshes specialized centers now have started to investigate biomechanical changes in the vaginal wall and the epthelium, inflammatory reaction oft he tissues, degeneration of vaginal collagen, increasing elastine-synthesis with consecutive stiffness of the vaginal wall in animal experiments. These changes correlate with the weight of the material and cannot be prevented by „Plasma-coating" or other technical modifications [16-20]. Discussing whether the use of meshes improved patient satisfaction there was an editorial in the New York Times am 22.10.2010 fest: "The bottom line is not only there were more complications, but the mesh didn't prove any better than traditional surgery." [4]. For experienced pelvic surgeons in Europe there might be another expertise and medical strategy, misleading to the statement that the american situation cannot be compared with our standards; the extremely variable distribution of the mesh use in different areas in my country should raise the question about a correct indication, sometimes apparently used in all primary cases.

Even though medico-legal cases are rare in Europe a controlled system of certified specialized centers should be recommended. The European Board and College of Obsterics and Gynaecology (EBCOG) offers a system of certifications with regular audits with quality statements. These ensure patients (looking in the internet more frequently than we think) and are a good promotion for the institution at the same time.

Personal Message

- In pelvic floor prolapse native tissue repair is the method of first choice
- Reconstruction of anatomy is not automatically achievement of good function
- The vaginal approach is the most physiological with lowest complication rates and cost effective
- Midurethral slings in SUI are standard in an international consensus

- Colposuspension still is effective , especially in paravaginal defect
- Intraurethral injections are indicated in high risk patients, otherwise 2.choice
- Vaginal meshes are still in their starting phase and will have a future in competition with sacrocolpopexy
- Cooperation with patients and industry in order to improve results
- New products only in controlled and randomized studies
- Complex procedures and recurrencies in centers with adequate expertise

Lessons to Learn

Even though there is no medial and ethical reason to ban alloplastic meshes in prolapse surgery, complication rates are very low (< 5%) and thousands of women happy with their result of surgery; but, we should always be aware that these are elective procedures. Complications frequently are asymptomatic and not automatiocally need surgical revision. But, if they occur , they might result in life-long symptoms and reduction of quality of life. It is our duty as active physicians to explain to our patients and health care providers and politicians to separate different indications and surgical techniques. The use of synthetic midurethral slings for surgical treatment of SUI in (both male) and female patients has good efficacy and acceptable morbidity (Consensus Statement of the European Urology Association and the European Urogynaecological Association on the Use of Implanted Materials for Treating Pelvic Organ Prolapse and Stress Urinary Incontinence.2017) [21-35]. Synthetic mesh for prolapse repair should be used only in complex cases with recurrent prolapse in the same compartment and restricted to those surgeons with appropriate training who are working in multidisciplinary referral centers. New surgical techniques and approaches including marked modifications should only be allowed within approved multicenter studies, patients have to be included in this decision making process. Apparently we did not learn our lesson looking at all the new sub-modifications of meshes and slings and the wide-spread use of laser in central Europe with first small studies coming up now, more than 5 years after the introduction of various technical equipments with physically very different effects, sometimes not comparable at all.

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