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Datum
25.06.2019

THE REVIEW

of the Thesis Board member on the thesis of

Kubin Nikita Dmitrievich

on the topic:

**“Personalized approach to the treatment of patients with stress urinary
incontinence and pelvic organ prolapse”**

submitted for the degree of Doctor of Medical Sciences with specialization
14.01.23 in Urology.

Kubin Nikita Dmitrievich submitted a thesis of 160 pages with the additional
English version.

In a comprehensive way Kubin Nikita Dmitrievich introduces in over 29 pages
the key questions, which were underlined with the most current literature.
In addition to the anatomical situation, he presents the published results of
the different surgical techniques for the short and long-term outcomes.
Beside the evolution of the surgical techniques and their outcome, which are
closely related to the mesh material and amount/size, Kubin Nikita
Dmitrievich raises the awareness its complications. Of particular note, the

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United States Food & Drug Administration (FDA) recently challenged the re-evaluation of the use of synthetic meshes to surgically treat Pelvic Organ Prolapse (POP) and even Stress Urinary Incontinence (SUI). The newest result is that all US-based companies removed their POP products from the market.

Despite the evolution of this treatment, which was influenced through public view and the involvement of the FDA, there is still an enormous demand to provide women with affordable and effective treatment options to treat POP and SUI. This underlines the need to further develop surgeries or implants to minimize the possible side effects/complications and to increase the long term improvement and even "healing".

The purpose of this study was to improve the efficiency and safety of the treatment of patients with POP and SUI by introducing new methods of surgical correction, enhancing clinical protocols for patient management and evaluating their cost and cost effectiveness.

After a detailed study of the currently published literature and theoretical discussion of the recently developed surgical techniques using a new line of endoprotheses, the development, registration and production of which, was carried out jointly with the company Linteks LLC (St. Petersburg). This impressive study involved 1246 patients, who were treated for either POP or SUI at the Department of Urology of Saint Petersburg State University Clinic of Advanced Medical Technologies n.a. Nikolay I. Pirogov. Further the study was performed by internal university clinical support from February 2015 to October 2017. The presented results are based on the analysis of the results of surgical treatment of 673 women with pelvic organ prolapse (POP; subdivided in into three subgroups: 474 women had anterior-apical (group A), 116 - posterior-apical (group B) defects of the pelvic floor, 83 patients suffered from post-hysterectomy vaginal vault prolapse) and 573 patients with stress urinary incontinence (SUI).

This extensive evaluation was performed at the preoperative, early and postoperative stages (1 month, 6 months and 1 year) by both internationally accepted general and specialized examinations (anamnesis, filling in specific questionnaires (PFDI-20, PSIQ-12, ICIQ-SF), vaginal examination with an assessment of the degree of POP in the POP-Q system, stress test, both standing and lying, uroflowmetry with determination of residual urine). The

synthetic sling for the SUI treatment was developed using the patent (RU No. FRS 2008/02207) and (RU No. FRS 2009/04493) as an adjustable synthetic sling. The POP surgical procedures were further enhanced using comprehensive anatomical studies and current published data, which resulted in the patent (RU2661042) that introduced a bilateral sacrospinous fixation allowing reliable apical support.

With minimal mean surgical time to reconstruct the POP of 27 minutes (15-84), the objective effectiveness was 88,9% vs. subjective: 96.9% (group A) and satisfaction of 98.2% (group B) was reached. This statistic is outstandingly high for a POP treatment with minimal comorbidities. For group C, a surgical time of mean 30 (27-34) min with an anatomical efficiency of 88% and subjective satisfaction of 96.3% after 12 months is outstanding. With regard to the SUI sling implantation, the median duration of the operation was 12 (10-14) min. With the need for modifying the sling tension (increased in 154 (26.8%); weakening in 96 (16.7%) cases) they demonstrated a) the need of an adjustable sling and b) were able to reach the objective 95.1% and subjective - 96.7% of efficiency (adjustability became possible by the invention related to the patent). The developed algorithms made it possible to unify work processes for patients with POP and SUI to demonstrate increased efficiency and safety, which makes these techniques and the patent materials applicable for other patients.

As a result of the submitted thesis, Kubin Nikita Dmitrievich published **17 articles** (3 in English and 15 in Russian). Twenty **abstracts and posters** were accepted and presented at national and international meetings.

Related English publications:

1. Shkarupa D, **Kubin N**, Shapovalova E, Zaytseva A, Pisarev A, Staroseltseva O. The novel technique of posthysterectomy vaginal vault prolapse repair: Apical sling and "neocervix" formation. *Eur J Obstet Gynecol Reprod Biol.* **2017** Jul
2. Shkarupa D, **Kubin N**, Staroseltseva O, Shapovalova E. Adjustable transobturator sling for the treatment of primary stress urinary incontinence. *Int Urogynecol J.* **2018** Sep;29(9):1341-1347
3. Shkarupa D, **Kubin N**, Pisarev A, Zaytseva A, Shapovalova E. The hybrid technique of pelvic organ prolapse treatment: apical sling and subfascial colporrhaphy. *Int Urogynecol J.* **2017** Sep;28(9):1407-1413

Presentations at important international annual society meetings:

1. International Society of Pelviperineology (**ISPP**) Congress (Istanbul, Turkey, **2015**; Tel-Aviv, Israel, **2016**)
2. European Association of Urology (**EAU**) Congress (London, UK, **2017**; Copenhagen, DK, **2018**), second prize in nomination **Best video** "Adjustable miduretral tape for surgical treatment of SUI: Two-years follow-up"
3. American Urological Association's (**AUA**) Annual Meeting (Boston, USA, **2017**; San-Francisco, USA, **2018**)
4. Annual Meeting of the International Continence Society (**ICS**) (Florence, Italy, **2017**)
5. Annual Meeting of the International Urogynecological Association (**IUGA**) (Austria, Vienna, **2018**).

In addition to the academic activity at national and international meetings, Kubin Nikita Dmitrievich was involved in the **3 patents** filed by the group.

The thesis of Kubin Nikita Dmitrievich on the topic: "Personalized approach to the treatment of patients with stress urinary incontinence and pelvic organ prolapse" meets the main requirements stated by the Order № 6821/1 dated September 01, 2016 "About the conferring of degrees in Saint-Petersburg State University". The doctoral candidate Kubin Nikita Dmitrievich is recognized to confer the degree of Doctor of Medical Sciences with specialization 14.01.23 in Urology. Article 11 of the mentioned Order is not violated by the defender of thesis.

Thesis Board member

June15, 2019


Professor Karl-Dietrich Sievert, MD, PhD