Biomechanical Mapping of the Female Pelvic Floor: Position Statement

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According to the American College of Obstetrics and Gynecology (ACOG) and American Urogynecologic Society (AUGS) Practice Bulletin on Pelvic Organ Prolapse (POP), recurrence of POP is possible after any POP surgery with anatomical failure as high as 25% [1] and the rates for the repeat surgery between 6% and 30% [2]. The Lancet's large scale PROSPECT (Prolapse surgery: Pragmatic evaluation and randomized controlled trials) in the UK conclusively demonstrated that over 80% of patients continued suffering from the POP symptoms after the POP surgery and serious adverse effects were found in 10%-14% of patients in the first 2 years following the POP surgical intervention [3]. Should surgeons be performing such pelvic floor surgeries which do little to help and could have catastrophic effects on the quality of life? Is it really possible to successfully restore a biomechanical integrity of the female pelvic floor in prolapse or incontinence surgeries without knowledge of affected pelvic structures and their pliability to be cured or replaced? These questions affect an estimated 50% of women in their life-times with about 300,000 POP surgeries completed each year in the US only [4].

Recently, AUGS came to the understanding that mechanistic characterization of pelvic supportive structures is number one among the five top priority research questions pertaining to pathophysiology and treatments of pelvic organ prolapse (POP) [5]. AUGS found that (a) patient-reported outcomes for POP have not been well studied or defined, and there are currently no patient-reported outcome tools for use in patients with POP; (b) there is a need to understand how expulsive forces are applied and distributed within the female pelvic floor; and (c) there is a need to understand the risks and benefits of POP treatments for specific patient subgroups so treatments can be tailored and individualized to optimize outcomes.

For the past decade, our multidisciplinary team has been developing a new biomechanical approach and tools for assessment of female pelvic floor structures and tissues *in vivo* [6]. The developed technology, Vaginal Tactile Imager (VTI), allows biomechanical mapping of the soft tissue along the entire length of the anterior, posterior, and lateral vaginal walls at rest, with manually applied deflection pressures and with muscle contraction, muscle relaxation, and Valsalva maneuver. VTI allows a large body of measurements to evaluate individual variations in tissue elasticity, support defects, as well as pelvic muscle function. Postulating that 1) the female pelvic floor organs are suspended by ligaments against which muscles contract to open or close the outlets and 2) damaged ligaments weaken the support and may reduce the force of muscle contraction, we developed a new biomechanical paradigm to characterize multiple pelvic floor structures from VTI data [7]. We have completed six clinical trials (feasibility, development and validation) to demonstrate VTI safety and effectiveness [8-20]. The VTI has FDA clearance [21, 22] and a new emerging technology CPT procedure code 0487T for biomechanical mapping, transvaginal, with report [23]. In a common clinical case, a female patient presents with complaints of increasing vaginal pressure, discomfort, backache, and bulging exacerbated by lifting and straining. The physician performs transvaginal biomechanical mapping with the VTI probe to assess her pelvic floor support status, tissue elasticity, and muscle function and uses the information to determine the best course of treatment. Multiple (up to eight) tests are completed to collect comprehensive biomechanical data for characterization of the vaginal and pelvic floor conditions. The recorded images are visualized in real time on a display to provide feedback to an operator and are mapped to produce an examination report, in a form of a computer file and hard-copy record, so that the physician can review and interpret the results, dictate a report, and discuss the results with the patient. The clinical conditions where VTI could be used to optimize and monitor treatment include: POP, stress urinary incontinence, tissue atrophy, and pelvic pain - because their etiology includes changes of pelvic tissue biomechanical properties and functions. The proposed VTI approach may also help further differentiate the types of pelvic floor conditions, their underlying severity, and understand how to individually tailor treatments for each patient in a most effective manner [7].

Cited References

1. The American College of Obstetrics and Gynecology, American Urogynecologic Society. Practice Bulletin: Pelvic Organ Prolapse. *Female Pelvic Med Reconstr Surg* 2017; 23: 353-364.
2. Dällenbach P. To mesh or not to mesh: a review of pelvic organ reconstructive surgery. *Int J Womens Health* 2015; 7: 331-43.
3. Glazener CM, Breeman S, Elders A, Hemming C, Cooper KG, 83 Freeman RM, For the PROSPECT study group (2017) Mesh, graft, or standard repair for women having primary transvaginal anteri or posterior compartment prolapse surgery: two parallel-group, multicentre, randomised, controlled trials (PROSPECT). *Lancet* 2017: 389: 381–392.
4. Smith FJ, Holman CD, Moorin RE, et al. Lifetime risk of undergoing surgery for pelvic organ prolapse. *Obstet Gynecol* 2010; 116: 1096-100.
5. Siddiqui NY, Gregory WT, Handa VL, DeLancey JOL, Richter HE, Moalli P, Barber MD, Pulliam S, Visco AG, Alperin M, Medina C, Fraser MO, Bradley CS. American Urogynecologic Society Prolapse Consensus Conference Summary Report. *Female Pelvic Med Reconstr Surg*. 2018 Jan 5; [Epub ahead of print].
6. Egorov V, van Raalte H, Lucente V, Sarvazyan A. Biomechanical characterization of the pelvic floor using tactile imaging. In: *Biomechanics of the Female Pelvic Floor*, Eds. Hoyte L, Damaser MS, 1st Edition, Elsevier, 2016: 317-348.
7. Lucente V, van Raalte H, Murphy M, Egorov V. Biomechanical paradigm and interpretation of female pelvic floor conditions before a treatment. *International Journal of Women's Health* 2017; 9: 521-550.
8. Kim K, Egorov V, Shobeiri SA. Emerging imaging technologies and techniques. In: *Practical Pelvic Floor Ultrasonography*, Ed. Abbas Shobeiri, 2nd Edition, Springer International Publishing AG, 2017: 327-336.
9. van Raalte H, Egorov V. Laparoscopic tactile imager for urogynecological surgery: First clinical expierence. *Female Pelvic Medicine & Reconstructive Surgery* 2017; 23(5): S122.
10. Van Raalte H. New biomechanical apporach characterizes vaginal conditions. *The Aetshetic Guide 2017*; May-June: 38.
11. van Raalte H, Lucente V, Ephrain S, Murphy M, Bhatia N, Sarvazyan N, Egorov V. Intra- and inter-observer reproducibility of vaginal tactile imaging. *Female Pelvic Medicine & Reconstructive Surgery* 2016; 22(5): S130-131.
12. van Raalte H, Bhatia N, Egorov V. Is it all just smoke and mirrors?: Vaginal laser therapy and its assessment by tactile imaging. *International Urogynecology Journal* 2016; 27 (S1): S120-121.
13. van Raalte H. Egorov V. Tactile imaging markers to characterize female pelvic floor conditions. *Open Journal of Obstetrics and Gynecology* 2015; 5: 505-515.
14. van Raalte H, Egorov V. Characterizing female pelvic floor conditions by tactile imaging. *International Urogynecology Journal* 2015; 26(4): 607-609.
15. van Raalte H, Lucente V, Egorov V. High definition pressure mapping of the pelvic floor muscles during Valsalva manever, voluntary muscle contraction and involuntary relaxation. *Female Pelvic Medicine & Reconstructive Surgery* 2015; 21(5): S149-150.
16. van Raalte H, Egorov V, Lucente V, Murphy M, Saiz C. 3D tactile imaging in early prolapse detection. *Neurourology and Urodynamics* 2013; 32 (6): 704-705.
17. Egorov V, van Raalte H, Lucente V. Quantifying vaginal tissue elasticity under normal and prolapse conditions by tactile imaging. *International Urogynecology Journal* 2012; 23(4): 459-466.

18. Incontinence: Tactile Imaging for Quantifying Vaginal Elasticity in Prolapse. *Nature Reviews Urology* 2012; 9(2): 60.

19. van Raalte H, Lucente V, Egorov V. 3D imaging and quantifying vaginal tissue elasticity under normal and prolapse conditions. *International Urogynecology Journal* 2011; 22(S1): S183-184.

20. Egorov V, van Raalte H, Sarvazyan A. Vaginal Tactile Imaging. *IEEE Transactions on Biomedical Engineering* 2010; 57(7): 1736-1744.

21. FDA – Vaginal Tactile Imager 510(k) Summary Approval Letter (K142355; May 28, 2017). U.S. Food and Drug Administration, Center for Devices and Radiological Health. Available at: <http://www.fda.gov> (accessed on November 28, 2017).

22. FDA – Vaginal Tactile Imager Product Classification Premarket Notification (August 25, 2014). U.S. Food and Drug Administration, Center for Devices and Radiological Health. Available at: <http://www.fda.gov> (accessed on November 28, 2017).

23. New and Emerging Medical Technologies and Procedures. Medical Policy Manual Medicine, Policy No. 149. Effective: January 1, 2018: http://blue.regence.com/trgmedpol/medicine/med149.pdf