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Evaluation of a FDA and Health Canada Compliant Novel Medical Device for Improving Erectile Function Across Erectile Dysfunction Etiologies

"A clinical study of the Xialla device demonstrated significant benefit to erectile function and sexual enhancement for 14/21 (66%) of patients."

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About Dr. Bella

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Objectives

We sought to evaluate a new FDA and Health Canada compliant medical device consisting of a soft silicone occlusion loop (SSOL) with geodesigned anchoring in a cross-section of men. The SSOL design is novel, offering a unique means of loop fixing compared to traditional penile occlusion bands (POB) or c*ck rings (CR). We identified complimentary force vectors to circular constriction applied by the anchoring mechanism and theorized that this may optimize venous trapping in CVOD ED. Finally, the design of the SSOL is less obtrusive to the man and his partner, and does not impact external genitalia of the partner, which may make acceptance as a sexual function (SF) enhancement device for intimacy easier

Methods and Materials:

SSOLs were obtained in January 2016. Groups using POB/CR, PDE5i use for ED contributed to most likely by CVOD, Peyronie's disease (PyD) less than 45 degrees responsive to PDE-5i or ICI (buckling segment or maximum EHS score 3 with PDE5i.), and men considered to have "normal" erectile function but seeking improved function, were offered SSOLs.

Standard operating procedures in the clinic include IIEF-15, IPSS, and if applicable, PDQ/Pyd questionnaires. In-office teaching of ICI as well as the SSOL is strictly adhered to.

Results

Pts (n=21) evaluated comprised of 7 POB/CR, 5 PDE5i/CVOD, 5 PyD, and 4 "normal" patients with IIEF-15 scores of 25 or greater referred for "optimization of performance". 4/7 POB/CR pts preferred ongoing use of the SSOL, 2/7 did not attain meaningful improvement compared to POB/CR most likely due to body habitus preventing optimal positioning, and 1/7 penile girth was too large for fit.

For the PDE5i group, 4/5 men reported improved SF with concurrent SSOL use, and surprisingly 2/5 reported SSOL-only satisfactory EF (without PDE5i). For 1/5 men, the SSOL could not be positioned properly in office. All 4 PyD pts reported improvement in EF and girth, with PDE5i vs PDE5i plus SSOL measurements supporting an approximate 8 mm circumferential improvement.

The PyD ICI patient was able to penetrate with PDE5i and SSOL. "Normal" patients demonstrated improvement in IIEF-15 scores compared to baseline, with 2/4 using the SSOL regularly, one on occasion, and one not at all as he is between partners. Partner acceptance was uniform, likely due to a combination of SSOL characteristics and the fact that almost all pts previously used ED treatments.

Conclusions

In a select cohort of men post-RP, with extensive in-office testing and failure of ICI and ICI-VS (EHS 1 or 2), the addition of the SSLO converted treatment failures to EHS 3 rigidity sufficient for intercourse for 6 of 11 men. At three month s, 45% continue to utilize ICI and the SSLO.