A new assessment tool to measure the efficacy of a testosterone patch for treatment of Hypoactive Sexual Desire Disorder (HSSD) in surgical menopausal women: the brief profile of female sexual function© (B-PFSF©)

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Objective
Quantify the clinical response to testosterone patch treatment and identify what score changes of this new short assessment tool are associated with patients' experience of a meaningful benefit.

Design & Methods
A representative sample of 132 surgically menopausal women with HSDD from two randomized, placebo-controlled trials (INTIMATE SM1+2; N=1094) assessing efficacy and safety of the testosterone patch (300 mcg/day) over 24 weeks was interviewed at study end, prior to unblinding, to determine whether or not a meaningful treatment benefit was experienced. B-PFSF© score values for both baseline and week 24 assessments were compared between the groups that experienced a meaningful benefit or not using a covariance analysis (ANCOVA). ROC analysis was conducted to ascertain what B-PFSF© score changes were associated with experiencing a meaningful treatment benefit and to identify the optimal threshold differentiating between the two groups. The proportion of women on testosterone meeting the threshold criteria were compared to that on placebo in the SM trials.

Results
The score for the earlier published B-PFSF© HSDD screening questionnaire ranges from 0 – 35 with a score of ≥20 corresponding to a non-HSDD state. In this analysis the baseline B-PFSF© scores for patients experiencing a meaningful treatment benefit were similar to those for patients not experiencing a meaningful benefit (mean scores 10.0 and 9.5 respectively) and were consistent with an HSDD state. After 24 weeks of treatment with testosterone or placebo, mean score levels for patients reporting a meaningful treatment benefit were 21.1 [SE 1.0] corresponding to a non-HSDD state, while patients not responding to treatment showed almost no change in mean score value (11.4 [SE 0.8]). ROC analysis showed the B-PFSF© to have excellent discriminatory ability (AUC = 0.84). Sensitivity and specificity analysis suggested a score change of ≥5 to best classify patients as experiencing a meaningful treatment benefit. Application of the B-PFSF© to the intent-to-treat population of the SM 1+2 trials showed significantly greater score changes in patients randomized to testosterone as compared to placebo patients ($p<0.006$), significantly more patients in the testosterone group returned to a non-HSDD state (34% vs. 22%, $p<0.0001$) and had a score change of ≥5 (55% vs. 36%, $p<0.0001$) corresponding to a treatment effect that was meaningful to the patient.

Conclusion
The easy-to-use B-PFSF© questionnaire will enable physicians not only to screen for women that may suffer from HSDD but also to validate HSDD patients' feedback on meaningful treatment response with testosterone.