

AUA/SMSNA POSITION STATEMENT ON RESTORATIVE THERAPIES FOR ED

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The SMSNA strongly supports the development of novel erectogenic therapies, given that many men with ED either fail currently available treatments or find them unpalatable. The society, however, recognizes the need for adequately powered, multicenter, randomized, sham/placebo-controlled trials in well-characterized patient populations to ensure that efficacy and safety are demonstrated for any novel ED therapy. The society agrees with the regulatory agency pathway of Phase I, II and III studies to achieve such a goal. Without FDA approval, the use of any novel therapy is considered off-label. The emergence of low intensity shock wave therapy (LiSWT), intracavernous stem cell therapy (SCT), intracavernous platelet rich plasma (PRP) therapy (and other agents such as amniotic fluid) represent a new frontier of investigative restorative therapies for ED treatment. In contrast to existing pharmacologic therapies that treat symptoms, therapies such as LiSWT, SCT, PRP represent potentially restorative modalities based on the concept that they might regenerate erectile tissues.

There exists robust basic science evidence in a variety of animal models (aged, diabetic, cavernous nerve injury) supporting the ability of LiSWT and SCT to improve erectile function. However, to date, there is an absence of robust clinical trial data supporting their efficacy and long-term safety in humans. Furthermore, the precise treatment parameters (energy settings, dosing, frequency of use, and duration of therapy among others) and cell source allowing optimization of these evolving therapies remain as yet, undefined. There exists only a small number of animal studies in a single model (cavernous nerve injury) establishing PRP as a potential erectogenic therapy. At this time, there are no human studies evaluating PRP as an erectogenic therapy.

Although several plausible and scientifically sound mechanisms of action have been proposed to explain how restorative therapies might improve erectile function, rigorous experimental data conclusively validating these mechanisms is currently lacking. This is in part because, unlike conventional pharmacologic therapies which generally have a primary, well-defined target, the mechanism of action of restorative therapies is likely to be complex involving a number of pathways inherent to the regenerative potential of the host. The SMSNA both advocates for and supports the application of high-quality research, both pre-clinical and clinical, aimed at better understanding the mechanisms involved, the magnitude and durability of benefit and the long-term safety of restorative therapies.

Thus, given the current lack of regulatory agency approval for any restorative (regenerative) therapies for the treatment of ED and until such time as approval is granted, SMSNA believes that the use of shock waves or stem cells or platelet rich plasma is experimental and should be conducted under research protocols in compliance with Institutional Review Board approval. Patients considering such therapies should be fully informed and consented regarding the potential benefits and risks. Finally, the SMSNA advocates that patients involved in these clinical trials should not incur more than basic research costs for their participation.