Bio-Identical Hormone Replacement Therapy

A Medical Approach to Hormonal Balance Utilizing SottoPelle® Precision Prescriptive Dosing Methodology

Hormone Replacement Therapy is not a new or experimental treatment for hormonal imbalance. The science and practice of hormone replacement therapy (HRT) has been around since the 1930's. SottoPelle® has been successfully treating patients with Bio-Identical Hormone Therapy (BHRT) for decades. As the pioneer and leader in the science based methodology of BHRT, SottoPelle created and established the standards that are now considered baselines for BHRT. Our proprietary patent pending dosing method relies on the proven results of thousands of patients and scientific data from some of the leading medical professionals in the world.

Hormone replacement therapy can be successfully used to treat men or women suffering from various health concerns such as all phases of menopause, andropause, and varied medical conditions that can impact hormonal balance. The success of bio-identical hormone replacement therapy (BHRT) relies on several key factors:

- the training and expertise of the treating physician,
- the dosing methodology utilized,
- the follow up and maintenance protocols followed for continuity of care,
- and the quality of the pellets.

The changing perspective and understanding of BHRT has recently been explored and further expanded in current studies. These findings show that more and more physicians are prescribing BHRT.

According to a recent survey conducted by The North American Menopause Society and presented at the American Society for Reproductive Medicine 2015 Annual Meeting, 60 percent of clinicians are prescribing bioidentical (compounded) hormones for the treatment of menopause. The results don't come as surprising news considering that patient demand for bioidentical hormone replacement therapy (BHRT) has reached a whopping 41 percent, despite its controversial status with many national medical organizations. A number of national organizations still push practitioners to use FDA-approved conventional hormone therapies, but more than 47 percent of clinicians say they disagree with these guidelines. This includes 36 percent of OB/GYNs and 58 percent of family practitioners surveyed. The physicians who prescribe bioidentical hormone therapy cite safety and efficacy as the primary reasons for their decision. ¹

The prescribing paradigm is shifting to BHRT by clinicians which is supported by recent data and the increased patient demand for the "natural" and safer alternative of HRT.

A recent Harris survey administered to 801 women aged 45 to 60 years estimated that 1 to 2.5 million US women aged 40 years and older are using compounded bioidentical hormones

¹ http://bioidenticalhormoneexperts.com/new-stats-reveal-more-physicians-prescribe-bioidentical-hormones-over-conventional-hrt/

annually. Among them, 1 in 5 women responded that the treatment was "personalized," and that their own physicians recommended the treatment. A second survey, the Rose survey of 2044 women aged 40 years and older suggested that bioidentical hormone use accounts for 28%-68% of hormone replacement prescriptions from physicians and that up to 2.5 million US women may be currently using them. In the survey, 1 in 4 women stated that their physicians had recommended bioidentical hormones. A survey of physicians found that almost half of respondents disagreed with recommendations of the North American Menopause Society. One third of those who disagreed were obstetricians, and 58% were family physicians. The most important factors cited for prescribing the products were efficacy and tolerability. ²

These statistics don't surprise us. After several decades of experience, working and training many of the practitioners currently administering BHRT, our collective patient data reflects a 98% success and satisfaction rate. Patients not only try BHRT, but the majority continue treatment beyond the first year. Patient satisfaction, retention, and continuity of care can be attributed to abatement of presenting symptoms and increase in quality of life. The key in this high degree of success is directly related to:

- the level of expertise of the medical practitioners administering the BHRT;
- implementation of appropriate dosing;
- maintenance and follow up;
- patient awareness and education;
- quality of BHRT pellets.

More information is now readily available to patients on alternative therapies and/or holistic approaches. This information and the quest for relief to the often debilitating symptoms some patients can experience, drives the demand for BHRT as a safe effective therapeutic option. Many of these patients are not candidates for synthetic variants of HRT as they are contraindicated due to other preexisting medical conditions or medications. For example, BHRT is not synthesized via the liver, so for patients with liver concerns, synthetic forms of HRT may be precluded as an option to treat hormonal imbalance and symptoms that impact quality of life. However, pellets can be a safe and effective therapeutic option.

For a properly trained practitioner using quality pellets, BHRT represents a medically sound and effective option for the treatment of hormonal deficits, and to maintain hormonal equilibrium in a manner that supports the patient's lifestyle. The subcutaneous insertion of BHRT pellets has solid empirical data to support the effectiveness of this delivery method. And coupled with "no effort" patient compliance (patients don't have to remember to dose themselves or risk taking an incorrect amount) increases patient success, satisfaction and effectiveness. Additional clinical information on the actual process for implementation of pellets is available upon request with our Physician Support Team.

As physicians you already understand the mechanics and symptomology of menopause and andropause. But do you have a clear understanding between natural and bio identical hormone therapy as a distinguishing factor in choosing the best treatment protocol for your patients? SottoPelle[®] trained physicians understand this distinction and it is a critical factor in their success. In 2015, Harvard Health Publications clearly noted the important distinguishing aspects of the BHRT and benefits.

² http://www.medscape.com/viewarticle/855845

Bioidentical hormone therapy is often called "natural hormone therapy" because bioidentical hormones act in the body just like the hormones we produce. But here again, that tricky word natural muddies the waters. Pregnant mares' urine is natural, but Premarin is not bioidentical, at least not to human estrogen. The same goes for Cenestin, which is made from plants but is not bioidentical. Technically, the body can't distinguish bioidentical hormones from the ones your ovaries produce. On a blood test, your total estradiol reflects the bioidentical estradiol you've taken as well as the estradiol your body makes. On the other hand, Premarin is metabolized into various forms of estrogen that aren't measured by standard laboratory tests. Proponents of bioidentical hormones say that one advantage of bioidentical estrogen over Premarin is that estrogen levels can be monitored more precisely and treatment individualized accordingly. Skeptics counter that it hardly matters, because no one knows exactly what hormone levels to aim for, and symptoms, not levels, should be treated and monitored.³

The key differentiating factors between many BHRT providers and SottoPelle[®] lies in experience and understanding, our quality of the pellets used, proprietary and precise dosing algorithm, and our advanced physician training and extended support. Individualized and precise treatments coupled with consistent attention to symptoms are critical in the patient's success with BHRT. SottoPelle[®] created the first dosing site to be used for BHRT that considers many variables of patient medical status when dosing. Many others try to copy our methodology and science, but don't settle for an imitation when it comes to your patients and practice. We are and have been the worldwide leader in BHRT for a very long time. *There is a reason why celebrities, professional athletes, veterans, and anyone who understands BHRT are our patients – they believe in excellence.*

Our business model and technology has allowed SottoPelle to be implemented and made available worldwide. We created the standards for patient care in BHRT, and are continually developing, innovating, and evolving via physician training and support, patient education, and field research.

SottoPelle[®] realizes that BHRT (or HRT) is not for everyone.

Every practitioner will ultimately choose the best fit for his or her practice and patients. SottoPelle is NOT for every doctor or patient, as we understand health is a very personal choice. This choice should be made by an informed patient who has the guidance of an experienced medical professional. We strive to make that choice easier for our physicians and patients with ongoing education, support, and excellence. Our processes and protocols demand rigorous clinical and eLearning physician training. This promotes patient trust and confidence. It also enables successful and effective patient treatment. We provide hands on and timely support to assure that best practices are being followed on dosing and pellet implementation. Our goal is to educate and fully support physicians so that they can deliver the highest quality of care to their patients, and experience heightened effectiveness with a proven and safe methodology. These high standards benefit both your patients and practice. Our mandatory dosing site ensures that all physicians must monitor their patient's treatment protocol and note any potential issues should they arise. Dr. Gino Tutera realized in 1992 that there areno "one size fits all" or

³ http://www.health.harvard.edu/womens-health/what-are-bioidentical-hormones

"experimentation" when it comes to BHRT – SottoPelle represents decades of precision proven practical experience.

Please remember, only trained and certified medical professionals can provide SottoPelle[®]. Our providers are worldwide and are carefully vetted. They are in good standing with their medical peers and already have successful medical practices. We represent the top medical professionals in your community who are dedicated to providing only the very best medical care to their patients.

If you want to learn more about the science behind SottoPelle[®] and how it can help your patients and practice, please contact us today.

Additional Case Studies to review at your convenience to learn more about BHRT and how it can help your patients:

BHRT:

1. Hotze SF and Ellsworth DP. Point/Counterpoint: The case for bioidentical hormones. J Am Physicians and Surgeons 2008; 13:43-36.

2. Barlow DH, Abdalla HI, Roberts ADG, et al. Long-term hormone implant therapy – hormonal and clinical effects. Obstet Gynecol 1986; 67:321-325.

3. Andres D Ruiz, Kelly R Daniels, Jamie C Barner, John J Carson and Christopher R Frei, Effectiveness of Compounded Bioidentical Hormone Replacement Therapy: An Observational Cohort Study. BMC Women's Health 201111:27

Andropause:

4. Aminorroaya A. Kelleher S, Conway AJ, et al. Adequacy of androgen replacement influences bone density response to testosterone in androgen-deficient men. Eur J Endocrinol 2005; 152:881-886.

5. Synder PJ, Peachey H, Berlin JA. Effects of testosterone replacement in hypogonadal men. J Clin Endocrinol Metab 2000; 85:2670-2677.

6. Schubert M, Bullman C, Minnemann, et al. Osteoporosis in male hypogonadism: responses to androgen substitution differ among men with primary and secondary hypogonadism. Hormone Res 2003; 60:21-28.

7. Wang C, Swerdloff RS, Iranmanesh A, et al. Transdermal testosterone gel improves sexual function, mood, muscle strength, and body composition parameters in hypogonadal men. J Clin Endocrinol Metab 2000; 85:2839-2853.

8. Isidori Am, Giannetta B, Greco EA, et al. Effects of testosterone on body composition, bone metabolism and serum lipid profile in middle-aged men: a meta- analysis. Clin Endrocrinol 2005; 63:280-293.

9. Ohlsson C, Barrett-Connor E, Shalender, et al. High serum testosterone is associated with reduced risk of cardiovascular events in elderly men. The MrOs (Osteoporotic Fractures in Men) Study in Sweden. J Am Coll Cardiol 2011; 58:1674-1681.

Menopause:

10. Khastgir G, Studd J, Holland N, et al. Anabolic effect of estrogen replacement on bone in postmenopausal women with osteoporosis: histomorphometric evidence in a longitudinal study. J Clin Endocrinol Metab 2001; 88:289-295.

11. Pereda CA, Hannon RA, Naylor KE, et al. The impact of subcutaneous oestradiol implants on biochemical markers of bone turnover and bone mineral density in postmenopausal women. Br J Obstet Gynaecol 2002; 109:812-820.

12. Barbosa IC, Coutinho EM, Oladapo L, et al. An open-label study of subdermal implants of estradiol-only versus subdermal implants of estradiol plus nomegestrol acetate: effects on symptom control, lipid profile and tolerability. Gynecol Endocrinol 2009; 25:269- 275.

13. Holland EFN, Chow JWM, Studd JWW, et al. Histomorphometric changes in the skeleton of postmenopausal women with low bone mineral density treated with percutaneous estradiol implants. Obstet Gynecol 1994; 83:387-391.

14. Fletcher CD, Farish E, Hart DM, et al. Long term hormone implant therapy – effects on lipoproteins and steroid levels in post- menopausal women. Acta Endocrinol 1986; 111:419-423.

15. Khastgir G, Studd JW, Fox SW, et al. A longitudinal study of the effect of subcutaneous estrogen replacement on bone in young women with Turner's syndrome. J Bone Miner Res 2003; 18:925-932.

16. Vedi S, Purdie DW, Ballard P, et al. Bone remodeling and structure in postmenopausal women treated with long-term, high- dose estrogen therapy. Osteoporosis Int 1999; 10:52-58.

17. Davis SR, Walker KZ, Strauss BJG. Effects of estradiol with and without testosterone on body composition and relationship with lipids in postmenopausal women. Menopause 2000; 7:395-401.

18. Farish E, Fletcher CD, Hart DM, et al. The effects of hormone implants on serum lipoproteins and steroid hormones in bilaterally oophorectomised women. Acta Endocrinol 1984; 106:116-120.

19. Worboys S, Kotsopoulos D, Teede H, et al. Subcutaneous testosterone implant therapy improves endothelium-dependent and independent vasodilation in postmenopausal women already receiving oestrogen. Heart Lung Circ 200; 9:A109.

20. Notelovitz M, Johnston M, Smith S, et al. Metabolic and hormonal effects of 25 mg and 50 mg 17 β -estradiol implants insurgically menopausal women. Obstet Gynecol 1987; 70:749-754.