Medical management of HSDD in Women
Belgian Menopause Society 2010

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The definition of Hypoactive Sexual Desire Disorder

**HSDDD** is the persistent or recurrent deficiency and/or absence of sexual thoughts & fantasies and/or desire for, or receptivity to, sexual activity which causes distress or interpersonal difficulty\(^1,2\)

Classification of Sexual Dysfunctions
APA DSM - IV

- Sexual Desire Disorders
  - Hypoactive Sexual Desire Disorder (HSDD)
  - Sexual Aversion Disorder

- Sexual Arousal Disorders
  - Female Sexual Arousal Disorder
  - Male Erectile Disorder

- Orgasmic Disorders
  - Male/Female Orgasmic Disorder
  - Premature Ejaculation

- Pain Disorders
  - Dyspareunia
  - Vaginismus
Classification of Sexual Dysfunctions
APA DSM – V - In development for 2013

• Working group - “HSDD is highly problematic”

  • Lori Brotto (Psychologist) – “HSDD may be a normal reaction to a problematic context and should not be pathologized”

• Group Aims to....
  • Raise the threshold for diagnosis
  • Min. 6 months symptoms before diagnosis made
  • Merge Sexual Desire Disorder with Sexual Arousal Disorder into “Sexual Arousability disorder”
Potential causes of Hypoactive Sexual Desire Disorder


Major Biological Causes

- Hormones
  - Low androgens (e.g. oophorectomy)
  - Hypothyroidism
- Psychiatric disorders
- Chronic Disease
- Medications
  - SSRI
  - Aromatase inhibitors
  - Anti-hypertensive
  - Chemotherapy

Psychological Causes

- Relationship issues
- Intrapersonal issues

Sociocultural Causes

- Poverty/Low income
- Working conditions
- Sexual norms

Adapted from www.fsdeducation.eu; Educational Slide Sets, Module 2: Classification of Female Sexuality
Role of Endogenous Testosterone
Testosterone: Naturally produced by women

- Healthy young women produce approximately 100 – 400 mcg/day - 3/4 times more testosterone than oestrogen
- About half is derived from the ovaries and half from the adrenal glands
- Decline in testosterone contributes to decline in sexual desire, arousal and orgasm
- Decline in testosterone levels also affects:
  - General well-being
  - Energy
  - Mood
  - Bone physiology
  - Muscle mass
  - Hot flushes

Burger HG. *Fertil Steril* 2002;77, No 4, Suppl 4:S3-S5
Mazer NA. *Int J Fertil* 2002;47(2):77-86
Free testosterone levels decline with age.

Davison SL et al. (2005) *Journal of Clinical Endocrinology & Metabolism*; 90 (7): 3847-3853

n= 595 women

49% reduction from 18-24yrs to 65-75yrs
Impact of Surgical Menopause on Sexual Function
Testosterone levels drop by approximately 50% after oophorectomy.

Premature Ovarian Failure
Incidence of HSDD after surgical menopause

• Spanish Cohort 1083 women < 45yrs BPFSF
  – HSDD in 65.9%
  – Non users of HRT ratio 2:1
    – Castello Branco Climacteric Dec 2009

• Italian Cohort 568 women
  – HSDD in 78.7%
  – Risk increased when <5yrs since menopause
  – Only 36.8% were aware of role of testosterone
    – Nappi et al Climacteric Dec 2009
Premature ovarian failure (POF) has been estimated to affect about 1% of women younger than 40 years, 0.1% under 30 and 0.01% of women under the age of 20. However, as the cure rates of cancers in childhood and young women continue to improve, it is likely that the incidence of prematurely menopausal women will rise rapidly\(^1\). The recent adverse media reports on hormone replacement therapy (HRT) could not have come at a worse time. We live in an era when the naturally menopausal population is growing, but of even greater concern is the impact

clinics that manage women with POF. The data will undoubtedly demonstrate extreme variations in management and deficiencies will emerge. Armed with this information, departments of health can then be petitioned to provide appropriate funding for the setting up of multidisciplinary units for the management of the particular psychological and physical needs of women with POF. Of even more concern are the young women who are not attending recognized clinics and are essentially ‘lost to follow up’. The reality is that we will never know the true scale of the
Premature Ovarian Failure
Prevalence of FSD

• HSDD was reported in 64% in our POF cohort (> 50% iatrogenic)
  • Singer Hunter Pitkin Panay
    – Climacteric (submitted) 2010

• Probability of HSDD
  – Inversely correlated with age
  – Particularly complex in adolescents
“The menopausal woman”
Differentiating oestradiol deficiency from testosterone deficiency in menopausal women

Oestradiol Deficient
Hot flushes/sweats
Sleep disturbance
Mood changes
Vaginal dryness

Testosterone Deficient
Diminished sense of well-being
Decreased energy
Increased depression
Reduced sexual desire, receptivity and arousal
? Headaches

Impaired sexual function

Low sexual desire is a key symptom of menopause

Frequency of climacteric symptoms

n = 603 menopausal women aged 49-59 years (MRS-Rating)

Adapted from Schultz-Zehden (2003) Der Gynakologie
Treatment of HSDD
"Not tonight. Didn't you get my email?"
Some patients report persistent tiredness, lack of energy, reduced libido or sexual function despite apparently adequate doses of oestrogen replacement. This may be more common in oophorectomized women, and consideration should be given to additional treatment with testosterone.

(Management, Section 2. Hormone replacement therapy)

British Menopause Society Council Consensus Statement

Management of premature menopause

British Menopause Society Council Consensus Statement

Summary

The British Menopause Society Council aims to aid health professionals to inform and advise women about the menopause. There has been some confusion amongst women and health professionals since publication of the Women’s Health Initiative and Million Women studies about the management of premature ovarian failure (POF). Both studies were undertaken in women aged 50 and over and cannot be extrapolated to their younger counterparts who would normally be producing their endogenous oestrogen. Oestrogen-based replacement therapy is the mainstay of treatment for women with POF and is recommended at least until the average age of natural menopause (52 years in the UK). This view is endorsed by regulatory bodies such as the Committee on Safety of Medicines in the UK. No evidence shows that oestrogen replacement increases the risk of breast cancer to a level greater than that found in normally menstruating women.
Androgenic Options

- Implants – only licensed option until recently
- Oral – ? Liver effects
- Livial (tibolone)
- DHEA – weakly androgenic
- Injections – sustanon
- Gel – useful but not licensed
- Transdermal patches

- *Is testosterone Pink Viagra!*?
Postmenopausal Woman - Libido

Studd 1977 (BJOG)
Uncontrolled study of 76 patients with psychosexual problems

• E50mg - effective for dyspareunia and improved libido in 80% patients

• Additional T100mg significantly improved libido in 12 out of 15 patients who had not responded to estradiol alone
Questionnaire of sexual and general health response in women receiving estradiol and testosterone implants

Hawkins A & Studd J 2004
What was the importance of loss of libido to you?

• **Sexual component**
  “made relationship difficult as not interested in sex”
  “libido almost zero” “inability to orgasm and feel satisfied” “no desire, dead meat”

• **Non sexual component**
  “I felt my age”
  “lost self confidence – poor communication”
  “felt less capable”
  “others noticed that I had lost the “it” factor”
  “no creative drive”
  “I hated myself”
In what way has the treatment improved your sexual response?

• “can have easy orgasms and feel satisfied”

• “now feel like sex is part of my life again”

• “orgasms on train journey”

• “returned to normal”

• “like in my 20s with a bigger appetite – it’s wonderful”

• “initiate sex, more orgasms”
Effect on sexuality: Tibolone versus continuous combined HRT

Tibolone (N=111) vs. E\textsubscript{2}/NETA (N=114) - Maturitas 1997

- Frequency
- Fantasies
- Enjoyment
- Arousal
- Orgasm
- Desire
- Problems
- Satisfaction
- Total score

McCoy sex scale

E\textsubscript{2}/NETA, 17\textbeta-estradiol (2 mg/day)/norethisterone acetate (1 mg/day)

* \( p < 0.05 \) between groups

Nathorst-Böörs et al., Maturitas 1997
## Transdermal Testosterone preparations

<table>
<thead>
<tr>
<th>Preparation</th>
<th>Formulation</th>
<th>Application</th>
<th>Application Time</th>
<th>Instructions</th>
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<tr>
<td><strong>TESTO GEL</strong></td>
<td>50mg/5 ml sachet</td>
<td>Rub to abdomen, thigh</td>
<td>0.5 - 1ml/day</td>
<td>Allow 5 minutes to dry, No shower for 6 hours</td>
</tr>
<tr>
<td></td>
<td>5-10 mg/day</td>
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<tr>
<td><strong>TESTIM</strong></td>
<td>50mg/5 ml tube</td>
<td>Rub to abdomen, thigh</td>
<td>0.5 - 1ml/day</td>
<td>Allow 5 minutes to dry, No shower for 6 hours</td>
</tr>
<tr>
<td></td>
<td>5-10mg/day</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>INTRINSIA</strong></td>
<td>Transparent patches</td>
<td>Easy to use</td>
<td>Twice weekly</td>
<td>Licensed in Europe</td>
</tr>
<tr>
<td></td>
<td>Deliver 300 ug/24hour</td>
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</tbody>
</table>
Now, the love patch

A ‘Viagra’ to restore ladies’ joie de vivre

WOMEN could be wearing stick-on patches to boost their sex drive within months, say researchers.

The patches release the male sex hormone testosterone to help women overcome a loss of desire. Some experts claim it will be the female version of Viagra.

The latest research showing it can enhance libido and increase the amount of sexual activity enjoyed by women.

Many women are familiar with.

"Now, the love patch"

COMING off the Pill can boost women’s sex drive, according to researchers.

Taking the hormonal contraceptive causes a loss in sexual desire in one in six women, scientists claimed yesterday.

Four weeks after abandoning the Pill, women who had complained of a loss of eroticism found their appetite for sex returned.

They had increased in arousal and orgasm, according to a report at the American Society for Reproductive Medicine conference in Philadelphia.

Not taking the Pill led to Alonso levels of the sex hormone testosterone and a fall in a hormone that can suppress desire.

Experts also believe that the use of sexual appetite experienced by some women on the Pill may be triggered by the elimination of ovulation — nature’s way of telling women to have sex.

Researcher Dr Susan Serafin, of the University of California, Los Angeles, said: ‘Discontinuing hormonal contraception should be considered a first-line treatment for women complaining of sexual dysfunction.’

Around 15 per cent of women taking the Pill, incontinence or using a hormonal patch have symptoms of sexual dysfunction such as sexual distress, low libido and vaginal dryness, she said.

In a pilot study, 29 women aged around 34 stepped taking the Pill after six months. Their sex life improved significantly, with increases in sexual appetite and orgasms, and a cut in sexual distress.

A larger study involving 200 women is now under way.

Dr Marian Damswood, president of ASRM, said: ‘This study presents evidence for an effect..."
Two Intrinsa studies in > 1000 surgically menopausal women

Safety and efficacy of a 300 mcg/day testosterone transdermal patch (TTP) in surgically menopausal (SM) women with hypoactive sexual desire disorder (HSDD) on concomitant oestrogen

- 1,095 women in 2 Phase III Trials (INTIMATE SM 1 and INTIMATE SM 2)
- 24-weeks of treatment
- Women aged 20 – 70 years with bilateral oophorectomy & hysterectomy
- Women receiving concomitant oestrogen

**HSDD key parameters:**
desire, distress, sexual activity

**Primary Endpoint:**
- Change in frequency of total satisfying sexual activity from the Sexual Activity Log (SAL©)

**Secondary Endpoints Included:**
- Change in the Seven (7) Domains from the Profile of Female Sexual Function (PFSF©)
  - Desire
  - Arousal
  - Orgasm
  - Pleasure
  - Concerns
  - Responsiveness
  - Self-Image
- Change in distress with the Personal Distress Scale (PDS©)
- AEs and clinical labs

Buster J. et al., *Obstetrics & Gynecology* 2005;105;944-52


**Effect of Intrinsa v Placebo on Major Outcome Measures**

### Total Satisfying Activity

- **4-wk Mean Change From Baseline**
  - Week: 0, 4, 8, 12, 16, 20, 24
  - Graph shows a significant increase in mean change from baseline by Week 12.

### Sexual Desire

- **Mean Change From Baseline**
  - Week: 0, 4, 8, 12, 24
  - Graph shows a significant increase in mean change from baseline by Week 12.

### Distress

- **Mean Change From Baseline**
  - Week: 0, 4, 8, 12, 24
  - Graph shows a significant decrease in mean change from baseline by Week 12.

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§Analysis combined Intimate SM1 & SM2

- Placebo*
- Transdermal testosterone patch*

*All women received concomitant estrogen therapy

* p < 0.05

Kingsberg S et al. *Poster presentation at the Annual Meeting of the American Obstetrics and Gynecology Society*, May 2005
Effect of Intrinsa on domains of Profile of Female Sexual Function (PFSF)

Mean Change from Baseline

Arousal  Orgasm  Pleasure  Decreased Concerns  Responsiveness  Self-Image

Placebo*  Transdermal testosterone patch*

*All women received concomitant estrogen therapy

Effect of Estrogen Type on Total Satisfying Sexual Activity at Week 24†
(SM1&2 Weeks 0-24 Double-blind)

†Combined SM Phase IIb, III Studies

*p<0.05
“What makes you think the hormone replacement therapy is having side effects, Mrs Brown?”
# Safety focus: Androgenic AEs

<table>
<thead>
<tr>
<th>Androgenic AE (%)</th>
<th>Placebo (N = 545)</th>
<th>TTP (N = 549)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acne</td>
<td>5.1</td>
<td>6.7</td>
</tr>
<tr>
<td>Alopecia</td>
<td>2.9</td>
<td>4.2</td>
</tr>
<tr>
<td>Unwanted Hair Growth</td>
<td>5.9</td>
<td>7.3</td>
</tr>
<tr>
<td>Voice Deepening</td>
<td>2.2</td>
<td>2.7</td>
</tr>
<tr>
<td>Withdrawal due to Androgenic AE</td>
<td>0.6</td>
<td>1.6</td>
</tr>
</tbody>
</table>

Buster J. et al., *Obstetrics & Gynecology* 2005;105;944-52
P&GP Data on file - ES02-2005
Free Testosterone levels following 24 weeks of treatment

Buster J. et al., *Obstetrics & Gynecology* 2005;105;944-52

Whiskers describe the 10th and 90th percentiles; dots represent the median values.
Dashed lines denote reference ranges in premenopausal women (0.9 – 7.3 pg/mL).

*All women received concomitant estrogen therapy.
Conclusions from the testosterone patch phase III SM studies

In surgically menopausal women with Hypoactive Sexual Desire Disorder (HSDD) on concomitant oestrogen:

- The 300 mcg/day testosterone patch
  - significantly improved desire and personal distress at 24 weeks
  - significantly increased satisfying sexual activity at 24 weeks
  - was generally well tolerated
Over 36 months in surgically menopausal women with hypoactive sexual desire disorder (HSDD), the 300 mcg/day testosterone transdermal patch:

- Was well tolerated and
- No clinically relevant safety concerns were detected

† receiving concomitant oestrogen

* The absence of a parallel placebo treated control group limits our ability to draw definitive conclusions from these data

Nachtigall et al., NAMS, 2006
No Significant effect on:

- Blood Pressure
- Triglycerides
- Total Cholesterol
- Alkaline Phosphatase, Alanine Aminotransferase, Aspartate Aminotransferase or Total Bilirubin

Over 3 years, patients experienced a small weight gain of 1.7 kg (p<0.05)

Nachtigall et al., NAMS, 2006
Testosterone Patch for the treatment of Hypoactive Sexual Desire Disorder (HSDD) in naturally menopausal women: results from the INTIMATE NM1 study

Jan L. Shifren, MD,1 Susan R. Davis, MD,2 Michele Moreau, MD,3 Arthur Waldman, MD,4 Celine Bouchard, MD,5 Leonard DeRogatis, PhD,6 Christine Derzko, MD,7 Patricia Bearonson, MD,8 Norman Kakos, MD,9 Sheila O’Neill, MD,10 Stephen Levine, MD,11 Kathryn Wexelman, PhD,12 Akshay Buch, PhD,12 Cynthia Rodenberg, PhD,12 and Robin Kroli, MD13

ABSTRACT

Objective: To evaluate the efficacy and safety of a testosterone patch for the treatment of women with hypoactive sexual desire disorder after natural menopause.

Design: A multicenter, randomized, double-blind, placebo-controlled, parallel-group trial was conducted in naturally menopausal women with hypoactive sexual desire disorder receiving a stable dose of estrogen with or without progesterin (N = 509). Women were randomized to receive testosterone 300 µg/day or placebo patches twice weekly for 24 weeks. The primary efficacy measure was change from baseline in frequency of total satisfying sexual activity over a 4-week period (weeks 21–24).

Results: A total of 483 women (88%) were included in the primary analysis population (those with baseline sex hormone binding globulin levels ≤160 nmol/L). The change from baseline in number of total satisfying sexual episodes was significantly greater for testosterone compared with placebo (participants with baseline sex hormone binding globulin levels ≤160 nmol/L, mean change of 2.1 ± 0.28 versus 0.5 ± 0.23 episodes/4 weeks; P < 0.0001; intent-to-treat population, mean change from baseline of 1.9 ± 0.26 versus 0.5 ± 0.21 episodes/4 weeks, P < 0.0001). Testosterone also produced statistically significant improvements compared with placebo in all secondary efficacy measures, including sexual desire and personal distress. The testosterone patch was well tolerated.

Conclusions: Testosterone patch treatment increased the frequency of satisfying sexual activity and sexual desire, decreased personal distress, and was well tolerated in naturally menopausal women with hypoactive sexual desire disorder.

Key Words: Transdermal testosterone – Hypoactive sexual desire – Natural menopause – Postmenopausal women – Libido.
Increased Total Satisfying Sexual Activity at 24 Weeks

<table>
<thead>
<tr>
<th>% Increase From Baseline</th>
<th>19%</th>
<th>73%</th>
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</table>

* Testosterone compared to placebo

* p<0.0001

INTMATE NM 1
Testosterone for Low Libido in Postmenopausal Women Not Taking Estrogen

Susan R. Davis, M.D., Ph.D., Michele Moreau, M.D., Robin Kroll, M.D., Céline Bouchard, M.D., Nick Panay, M.D., Margery Gass, M.D., Glenn D. Braunstein, M.D., Angelica Linden Hirschberg, M.D., Ph.D., Cynthia Rodenberg, Ph.D., Simon Pack, Ph.D., Helga Koch, Ph.D., Alain Moufarege, M.D., John Studd, M.D., for the APHRODITE Study Team

814 women receiving 150 v 300 mcg Intrinsa v placebo

Results: 300mcg v placebo

24 week increase in satisfying sexual episodes
2.1 v 0.7 (p<0.001)

Androgenic symptoms A 30 v P 23%
TESTOSTERONE FOR THE TREATMENT OF HSDD IN NATURALLY MENOPAUSAL WOMEN: THE ADORE STUDY

N Panay F. Al-Azzawi², C. Bouchard³, SR. Davis⁴, J. Eden⁵, I. Lodhi⁶, M. Rees⁷, CA. Rodenberg⁸, J. Rymer⁹, A. Schwenkhagen¹⁰, D. Sturdee¹¹

²Leicester Royal Infirmary, Leicester, UK ³Clinique de recherche en santé des femmes, Quebec, Canada ⁴Monash Medical School, Melbourne, Australia ⁵Royal Hospital for Women, NSW, Australia ⁶Procter & Gamble Pharmaceuticals, Egham, UK ⁷John Radcliffe Hospital, Oxford, UK ⁸Procter & Gamble Pharmaceuticals, Mason, Ohio, USA ⁹Guy’s Hospital, London, UK ¹⁰Gynäkologicum im Schanzentor, Hamburg, Germany ¹¹Solihull Hospital, Solihull, UK

Panay et al EMAS May 2009, Panay et al Climacteric 2010
TESTOSTERONE FOR THE TREATMENT OF HSDD IN NATURALLY MENOPAUSAL WOMEN: THE ADORE STUDY

The ADORE study was designed to evaluate the efficacy and safety of TTP in:

- naturally menopausal women with HSDD
- either on concurrent transdermal or oral “non-CEE” estrogen with or without progestins
- or not on HRT

Panay et al EMAS May 2009, Panay et al Climacteric 2010
Total Satisfying Sexual Episodes at Week 24

**Mean Change from Baseline (± SE)**

**ITT**
- Placebo: n=128, Mean Change = 0.5, p=0.0089
- TTP 300: n=119, Mean Change = 1.5

**Non HRT**
- Placebo: n=93, Mean Change = 0.5
- TTP 300: n=87, Mean Change = 1.5, p=0.0193

*Increased Sexual Activity*

Panay et al EMAS May 2009, Panay et al Climacteric 2010
Sexual Desire and Distress at Week 24

- Increased Desire
- Decreased Distress

Mean Change from Baseline

- Placebo
- TTP

- ITT
- Non-HRT

P-values:
- Placebo vs. TTP:
P<0.0007
P<0.0032

Sample sizes:
- ITT: n=128, n=93
- Non-HRT: n=123, n=91

- Placebo vs. TTP:
p=0.0024
p=0.0137

p=0.0024
p=0.0137
Conclusions

In this large clinical study transdermal testosterone patches

- Increased satisfying sexual events and sexual desire and decreased personal distress
  - in naturally menopausal women with or without concurrent HRT

- Were well tolerated with no serious safety concerns identified during 24 weeks of treatment.
  - Mild androgenic effects were seen (acne, hirsutism), but this didn’t lead to a higher withdrawal rate
## TTP Clinical Trial Program

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<tr>
<th></th>
<th>Menopause</th>
<th>Concomitant HRT</th>
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<td>SM2</td>
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<td>NM1</td>
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<tr>
<td>ADORE</td>
<td>19*</td>
<td>81</td>
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* No oral CEE
TTP Clinical Trial Program
- Satisfying Sexual Episodes

Difference between placebo and TTP in mean change from baseline [events / 4 weeks]

- SM1
- SM2
- NM1
- NM2* (P=0.0162)
- T-only
- ADORE (P<0.01)

* Adjusted & capped data
Conclusions

The consistency of these data across the TTP clinical trial program in 3309 women provides confirmation of:

- Efficacy of treatment of distressing low sexual desire (HSDD) with 300mcg/d transdermal testosterone patches
- No serious safety concerns and good tolerability over up to 52 weeks of treatment
Ongoing Research

• RCT of testosterone patches v placebo on CVD risk markers (vascular compliance / insulin resistance) & HSDD in HRT users
  – Collaboration of Stevenson / Panay / Collins – NHLI / C & W

• Large 5 year US study of testosterone gel (Libigel) on CVD and Breast Cancer risk
  – No androgen preparations licensed by FDA to date
Non hormonal Options
Non hormonal Options

• Flibanserin
  – 5HT (1A) agonist 5HT (2A) antagonist
  – Improvement in sexual functioning in MDD trials
  – 2 RCTs in pre menopausal women with HSDD (abstracts at ESSM Lyon 2009)
  – Only 0.7 extra satisfying sexual episodes per month
  – No difference v placebo for sexual desire
Non hormonal Options

- Flibanserin
  - FDA review
    - Unanimous rejection “due to failure of overall efficacy and “worrying” side effects.”
      - 15% discontinuation due to AEs (dizziness, nausea, fainting, sedation)
    - More data required esp in menopausal women (studies delayed by FDA ruling)
Conclusions

• Hypoactive sexual desire disorder (HSDD) can significantly impact a menopausal woman’s well being and her relationship

• A simple, open approach with patients facilitates a symptom-based diagnosis of HSDD

• Low sexual desire is a key symptom of both surgical & natural menopause

• Testosterone levels decline particularly rapidly after a surgical menopause
Conclusions

• Evidence for benefits of testosterone in oestrogen replete women in both SM and NM women

• Published data also for effect of transdermal testosterone alone in naturally menopausal women

• Transdermal testosterone is licensed in Europe for surgically menopaused women with HSDD using oestrogen.

• Off label use of product should be confined to specialists until licensing in NM / unopposed usage

• Benefits of non hormonal options for HSDD still awaiting confirmation and approval
• Are women still waiting for their drug? Some have found it!