Shining a New Light on The Contraceptive Patch

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Brooke Faught, DNP, WHNP-BC, NCMP FAANP, IF

Director, Women's Institute for Sexual Health (WISH)
Adjunct Faculty, Vanderbilt University School of Nursing
Nashville, TN

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Learning Objectives

- Identify information that will overcome the most common misperceptions that clinicians may hold regarding contraceptive patches and other non-LARC methods
- Explain the advantages and drawbacks of contraceptive patches and other hormonal non-LARC methods
- Identify counseling strategies for engaging patients in a shared decision-making discussion regarding sexual health and contraception

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Content Outline

- The evolution of the contraceptive patch and other combined hormonal, non-LARC methods
- The creeping Pearl Index and real-world contraceptive usage
- Advantages and drawbacks of contraceptive patches and other combined hormonal, non-LARC methods
- Counseling strategies for engaging patients in a shared decision-making discussion regarding sexual health and contraception

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Contraception
Evolution of Choices

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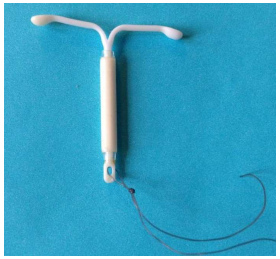

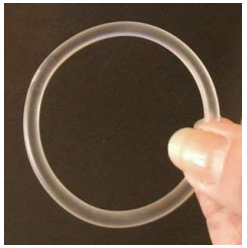






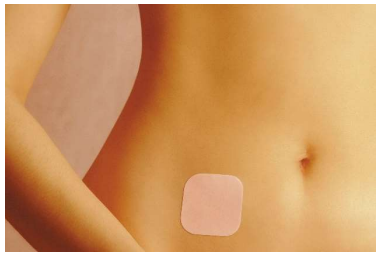


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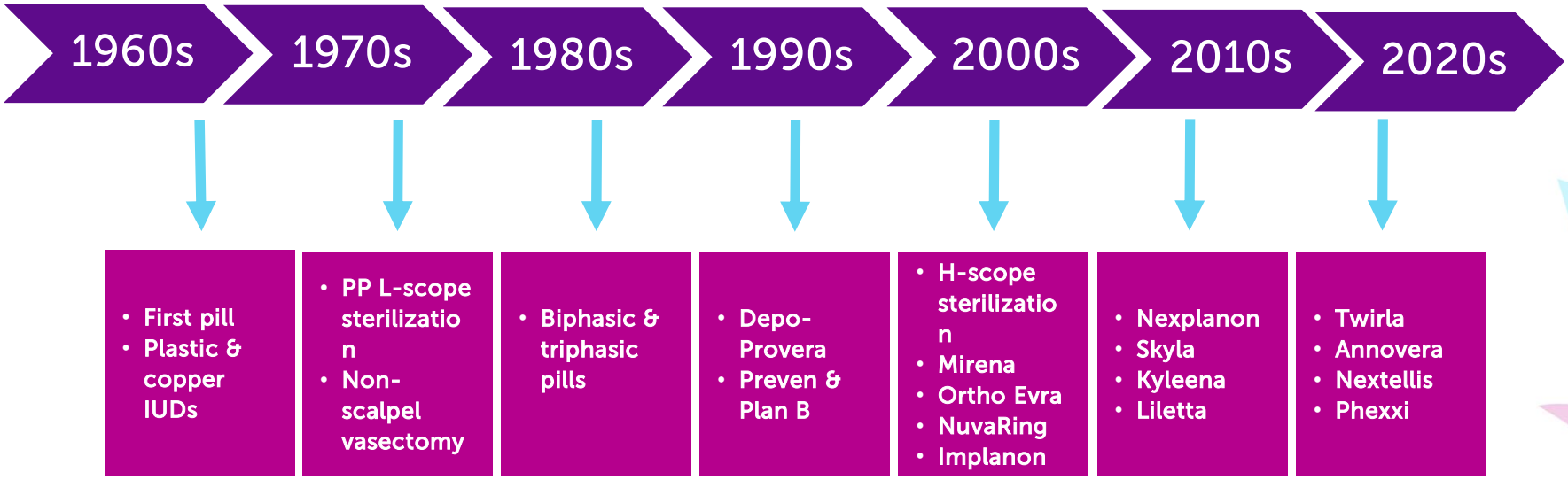
Evolution of Modern Contraception



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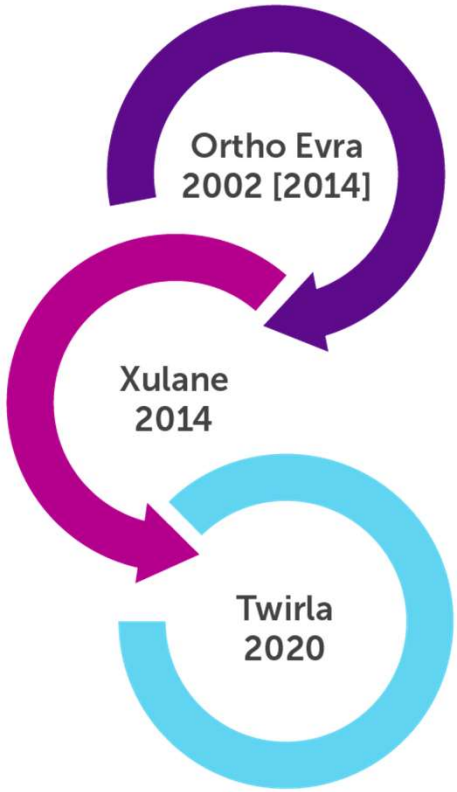
Evolution of Transdermal Hormonal Contraception



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Comparison of Contraceptive Patches

	Ortho Evra (2002)	Xulane (2014)	Twirla (2020)
Estrogen	35 mcg EE	35 mcg EE	30 mcg EE
Progestin	150 mcg norelgestromin	150 mcg norelgestromin	120 mcg LNG
Availability	Discontinued	Generic only	Name brand only
Size	20 cm^2	14 cm^2	28 cm^2
Usage	Weekly x 3wks	Weekly x 3wks	Weekly x 3wks
Contraindication	Discontinued	BMI ≥30 kg/m^2	BMI ≥30 kg/m^2

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Measuring Contraception Efficacy

The Pearl Index

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Pearl Index

DEFINITION

"Number of unintended pregnancies in 100 woman-years of exposure."*

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*Trussell J, Portman D. The creeping Pearl: why has the rate of contraceptive failure increased in clinical trials of combined hormonal contraceptive pills? *Contraception.* 2013;88(5):604-610.

Creeping Pearl Index

- Why is the Pearl Index increasing?
  - More frequent pregnancy testing
  - More sensitive tests
  - Less adherent study populations
  - Increasing BMI

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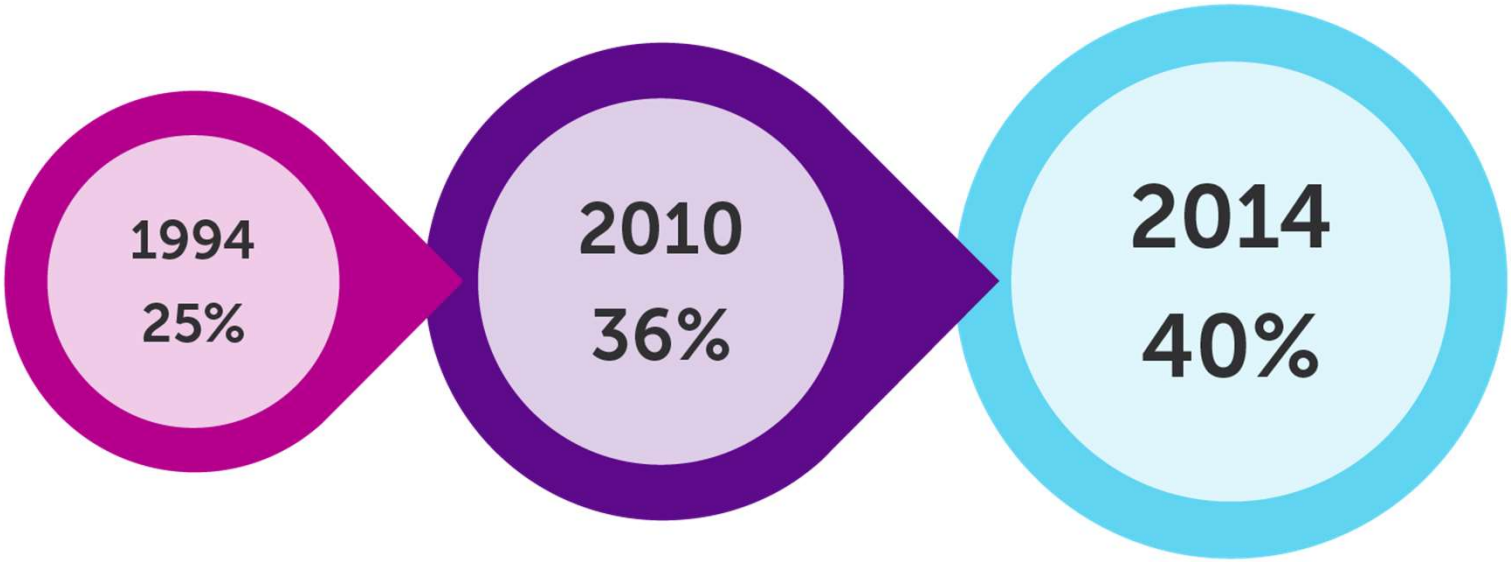
Trussell J, Portman D. The creeping Pearl: why has the rate of contraceptive failure increased in clinical trials of combined hormonal contraceptive pills? *Contraception.* 2013;88(5):604-610.

Creeping BMI: US Women Over the Age of 25 Classified as Obese



"So this is a radical difference over the years, and this is a very strong potential for that creeping Pearl Index and reduced contraceptive efficacy when we're talking about hormonal contraceptive agents."

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Fryar CO, Caroll MD, Ogden CL. *Prevalence of Overweight, Obesity, and Severe Obesity Among Adults Aged 20 and Over: United States 1960-1962 Through 2015-2016.* Centers for Disease Control and Prevention, National Center for Health Studies; 2018.

FDA Draft Guidance (2019)

Establishing Effectiveness and Safety for Hormonal Drug Products Intended to Prevent Pregnancy: Guidance for Industry

- Most recent patch clinical trial implemented the following criteria per the FDA guidance:
  - No enrollment restrictions on weight or BMI
  - Included women >35 years old to assess safety
  - Anticipated regular sexual activity (at least once per month)
  - Completed eDiary and captured backup contraception and sexual activity
  - Regular pregnancy testing at home and in the clinic

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US Food and Drug Administration. *Guidance for Industry: Establishing Effectiveness and Safety of Hormonal Drug Products Intended to Prevent Pregnancy*. US Food and Drug Administration, US Department of Health and Human Services; 2019. Nelson AL, Kaunitz AM, Kroll R, et al. Efficacy, safety and tolerability of a levonorgestrel/ethinyl estradiol transdermal delivery system: phase 3 clinical trial results. *Contraception*. 2021;103(3):137-143. Data on file, Clinical Study Report 023; Agile Therapeutics.

Pros/Cons of CHCs

Non-LARC Options

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Advantages of OCPs

- Ease of dosing, discreet
- Many available options on the market
  - Variety of estrogens and progestins
- Cost – many available generics
- Long-term safety and efficacy data
- Newest COC contains new form of estrogen (estetrol)
- Newest POP with more serologic stability and fewer side effects

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Disadvantages of OCPs

- Daily dosing
- Fluctuating serologic hormone levels
  - Breast tenderness, nausea, migraines/headaches
- COCs
  - Impact on SHBG (reduction in free/bioavailable testosterone)
- POPs
  - Increased potential for BTB compared to COCs
  - Decreased efficacy compared to COCs

Advantages of Vaginal Rings

- Avoidance of daily dosing
- Self-management
- Newest ring contains progestin derived from progesterone
- Newest ring lasts 1 full year

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Disadvantages of Vaginal Rings

- Requires vaginal insertion/removal
- Non-discreet – partner awareness of contraception with internal penetration
- May increase potential for vaginal discharge/infection/ irritation

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Advantages of Transdermal Contraception

- Weekly change versus daily dosing
  - Good choice for women with difficulty remembering daily pill
- Self-management versus reliance upon office procedure
- Continuous absorption: avoidance of peaks/troughs of serum hormonal levels
  - Reduced incidence/severity of SEs: breast tenderness, nausea, headache

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Advantages of Transdermal Contraception (cont.)

- Most recent patch with lower estrogen exposure
  - 30 mcg EE (vs 35 mcg EE)
  - The steady-state concentration for LNG/EE patch was 14% lower than 35 mcg EE OCP
- Most recent patch with safety, efficacy, tolerability data in inclusive/diverse population
  - Consistent with FDA draft guidance for hormonal contraceptive studies

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Disadvantages of Transdermal Contraception

- Potential for localized skin irritation
- Not ideal for women with frequent water exposure
- Cost of name-brand products
- Reduced efficacy and increased risk of VTEs with increasing BMI
  - Patch contraindicated in BMI ≥30 kg/m^2
    - Reduced efficacy in BMI ≥25 to <30 kg/m^2
  - Unlike the patch, there is limited data on the vaginal ring in obese women

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Disadvantages of Transdermal Contraception (cont.)

- Does not protect against STIs
- External visibility
  - All patches only come in one flesh tone

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Patient Counseling
Transdermal Contraception

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Questions for Patients

- Contraceptive goals
  - Contraception
  - STI prevention
  - Menstrual regulation
- Partner(s) – past and future
- Future family planning
- Experience with contraception

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Questions for Patients (cont.)

- Comfort with application, insertion, swallowing, procedures, etc.
- Cost (immediate/long term)
- Hormonal/nonhormonal
- Personal preferences:
  - Lifestyle (travel, etc.)
  - Conservationist
  - Likely compliance

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FDA Class Label Warning for CHCs

- Combined hormonal contraceptives = CHCs
- CHCs = OCPs, vaginal rings, contraceptive patches
- Class label warning:
  - "Cigarette smoking increases the risk of serious cardiovascular events from combined hormonal contraceptive use. This risk increases with age, particularly in women over 35 years of age, and with the number of cigarettes smoked. For this reason, **CHCs are contraindicated in women who are over 35 years of age and smoke. CHCs should not be used in women with a high risk of arterial or venous thrombotic disease, including women with a BMI ≥30 kg/m^2**; have headaches with focal neurological symptoms, migraine with aura, women over 35 years of age with any migraine headache; liver tumors, acute viral hepatitis, or severe (decompensated) cirrhosis, or liver disease; undiagnosed abnormal uterine bleeding; pregnancy; current or history of breast cancer or other estrogen- or progestin-sensitive cancer; hypersensitivity to any components of TWIRLA; and use of hepatitis C drug combinations containing ombitasvir/paritaprevir/ritonavir with or without dasabuvir."

Proper Patient Identification: Patch

- Women of reproductive potential desiring contraception
- If smoker, <35 years old
- BMI <30 kg/m^2
  - Ideal <25 kg/m^2
- No cardiovascular or VTE risk factors
- Capable of applying and managing patch changes
- No frequent or prolonged water exposure

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Talking Points

- Proper patch placement
  - Location: abdomen, arm, buttock
    - Best adhesion: abdomen
    - Best absorption: buttock
  - Clean, dry skin

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Talking Points (con't.)

- Check adherence after water exposure
  - Newest patch had 95% patch adherence in 1-year trial
  - If full detachment, old patch should be replaced with new patch
- Change weekly, patch-free week on 4th week
  - Continuous usage considered off-label

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Final Thoughts

- Varied available contraceptive options meet the needs of modern women
- Recent studies more representative of diverse women

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