

Review

Male Contraceptives: Why Haven't They Taken Off Yet? A Comprehensive Review

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Abstract: The development of male contraceptive methods has been an area of increasing interest over the past few decades, driven by the need for equitable reproductive responsibility between genders. Despite the prevalence of female contraceptive methods, options for men remain limited to condoms, vasectomy, and withdrawal. This comprehensive review analyzes current and emerging male contraceptive methods, including hormonal, non-hormonal, and physical approaches. We critically examine the efficacy, safety, reversibility, and social implications of these methods, providing an in-depth analysis of preclinical and clinical studies. The review highlights significant barriers to adoption, including societal attitudes, healthcare provider knowledge gaps, and regulatory challenges. Masculinity is defined within cultural contexts that influence contraceptive acceptance. Financial analysis reveals substantial economic benefits of male contraceptive implementation. Future directions emphasize the need for enhanced clinical trials, healthcare provider education, and addressing social barriers to promote gender equity in family planning.

Keywords: Male Contraception; Hormonal Methods; Non-Hormonal Methods; Reproductive Health; Gender Roles in Contraception.

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1. Introduction

Contraception is a critical component of reproductive health, yet the burden of preventing unintended pregnancies has predominantly fallen on women. With growing awareness and advocacy for gender equality, there is an increasing demand for effective and reversible contraceptive options for men [1]. Current male contraceptive methods remain limited to three primary options: condoms, vasectomy, and withdrawal (coitus interruptus). Condoms are the most widely used male contraceptive method, offering the dual benefits of contraception and protection against sexually transmitted infections (STIs). While highly effective when used correctly (Pearl Index: 2-3%), condoms have a typical-use failure rate of 13% due to inconsistent or incorrect use [2]. Despite their accessibility and non-invasiveness, condoms are often criticized for reducing sexual pleasure and spontaneity.

Vasectomy is a highly effective, permanent contraceptive method involving the surgical occlusion of the vases deferens to prevent sperm from entering the ejaculate. With a failure rate of less than 1%, vasectomy is one of the most reliable male contraceptive methods available. However, its permanence is a significant drawback for men who may later desire to father children. Although vasectomy reversal is possible, it is not always successful, and the procedure is more complex and expensive than the initial surgery [3].

Withdrawal, or coitus interruptus, involves the removal of the penis from the vagina before ejaculation to prevent sperm from entering the female reproductive tract. This method has a high failure rate of approximately 20%, largely due to the presence of

sperm in pre-ejaculate and the difficulty of timing withdrawal correctly. While withdrawal is free and does not require medical intervention, its unreliability makes it a less desirable option for contraception. Over the past few decades, various novel male contraceptive methods, including hormonal, non-hormonal, and physical approaches, have been developed, offering significant benefits and reversibility. However, despite decades of research and promising results from clinical trials, these methods have not achieved widespread adoption. This review explores the current state of male contraception, examining why these innovations have not translated into market success and identifying the barriers that continue to impede progress in this critical area of reproductive health (Table 1).

Tabela 1. Summary of Key Studies on Male Contraceptive Methods.

Reference	Method	Study Type	Sample Size	Main Findings
[4]	Hormonal (WHO Trial)	Multicenter RCT	320 men	95% achieved azoospermia/oligospermia
[5]	Testosterone + Nestorone	Phase II Trial	99 men	Effective suppression in 89%
[6]	Retinoic Acid Antagonist	Preclinical (mice)	40 mice	100% infertility achieved
[7]	EPPIN Inhibitors	Preclinical (primates)	12 primates	Infertility in 6-8 weeks
[8]	Adjudin	Systematic Review	Multiple studies	Disrupts spermatogenesis
[9]	Ultrasound	Review/Animal studies	Various	Temporary infertility
[10]	Acceptability Study	Systematic Review	32 studies	34-82% male willingness
[11]	Healthcare Provider Knowledge	Cross-sectional	427 professionals	10% knew hormonal methods

Reference	Efficacy	Reversibility	Limitations	Relevance
[4]	-	-	-	-
[5]	High	Variable (3-12 months)	Daily gel application required	High - novel delivery method
[6]	Very High	Complete in 8-12 weeks	No human trials	Moderate - preclinical only
[7]	High	Complete in few months	Small sample, short follow-up	Moderate - primate model
[8]	High	Variable	Potential testicular toxicity	Moderate - safety concerns
[9]	Moderate	Generally reversible	Tissue damage risk	Low - limited human data
[10]	-	-	-	-
[11]	-	-	-	-

2. Emerging Male Contraceptive Methods

2.1 Hormonal Contraception

Hormonal male contraception works by administering exogenous hormones, typically a combination of testosterone and progestins, to suppress spermatogenesis through inhibition of the hypothalamic-pituitary-gonadal (HPG) axis. The goal is to reduce sperm production to azoospermic (no sperm) or oligospermic (very low sperm) levels while maintaining secondary sexual characteristics through testosterone supplementation [12].

A comprehensive analysis of clinical trials reveals both the promise and limitations of hormonal approaches. The World Health Organization (WHO) conducted one of the largest multinational studies, demonstrating that combination testosterone and progestin therapy resulted in azoospermia or severe oligospermia in over 95% of participants, with pregnancy prevention rates of 1-2%, comparable to female hormonal contraceptives [4]. However, critical examination of these studies reveals several limitations that must be acknowledged.

First, the WHO study was terminated early due to safety concerns, particularly related to mood disturbances and depression. A detailed analysis published in the Journal

of Clinical Endocrinology & Metabolism revealed that 20% of participants reported mood disturbances, 10% experienced acne, and changes in sexual function occurred in a subset of men [5]. These side effects, while generally reversible after discontinuation, raise important questions about long-term safety and acceptability.

Second, the reversibility data, while promising, shows significant individual variability. Studies demonstrate that sperm production typically resumes within 3-6 months after stopping treatment, with most men returning to normal sperm levels within a year. However, recovery can vary considerably among individuals, and some men may experience prolonged recovery periods or incomplete restoration of fertility [13]. This variability represents a critical limitation that requires further investigation before widespread clinical implementation. Third, the need for regular injections or daily applications of transdermal gels may impact compliance and acceptability. Current formulations require either monthly injections or daily application of hormone gels, which may be less convenient than female contraceptive options like long-acting reversible contraceptives [14].

The preclinical evidence supporting hormonal contraception is robust, but the translation to human studies has revealed complexities that were not fully anticipated. Animal studies consistently showed effective spermatogenesis suppression with fewer side effects, highlighting the importance of species differences in hormonal responses and the need for more sophisticated preclinical models.

2.2 Non-Hormonal Contraception

Non-hormonal methods focus on targeting specific aspects of sperm production, maturation, or function without altering systemic hormone levels. These approaches offer the theoretical advantage of avoiding hormonal side effects while achieving contraceptive efficacy [15]. Retinoic acid receptor antagonists represent one of the most promising non-hormonal approaches. Retinoic acid is essential for spermatogenesis, and its inhibition can disrupt sperm production. A landmark study by Chung et al. [6] demonstrated that oral administration of a retinoic acid receptor antagonist in mice resulted in 100% infertility after several weeks of treatment, with complete fertility restoration within 8-12 weeks after discontinuation. However, critical analysis of this approach reveals significant limitations in translating these findings into human applications.

The primary limitation is the lack of human clinical trials. While preclinical studies in rodents and non-human primates have shown promising results, the safety and efficacy in humans remain unknown. Retinoic acid plays important roles beyond spermatogenesis, including immune function and cellular differentiation, raising concerns about potential off-target effects that may not be apparent in animal studies. Additionally, the pharmacokinetics and metabolism of retinoic acid receptor antagonists may differ significantly between species, necessitating extensive human safety studies.

Sperm motility inhibitors, particularly those targeting EPPIN (epididymal protease inhibitor), represent another non-hormonal approach. O'Rand et al. [7] conducted studies in non-human primates showing that EPPIN inhibitors rendered males infertile within 6-8 weeks, with fertility restoration within a few months after stopping treatment. The study reported excellent safety profiles with minimal side effects and no disruption to hormonal systems. However, critical evaluation reveals important limitations. The primate studies, while encouraging, involved small sample sizes and short follow-up periods. Long-term safety data are lacking, and the potential for developing neutralizing antibodies against EPPIN inhibitors has not been thoroughly investigated. Additionally, the effectiveness of EPPIN inhibitors may vary among individuals based on genetic variations in EPPIN expression and structure.

Spermatogenesis disruptors like adjudging and gamendazole interfere with the interaction between Sertoli cells and developing sperm. Preclinical studies have shown these compounds can cause the release of immature sperm that cannot fertilize eggs. However, concerns about potential testicular toxicity and long-term effects on spermatogenesis have limited their clinical development. The validation of these methods in

humans requires extensive safety studies to address concerns about potential permanent damage to the seminiferous epithelium. The gap between promising preclinical results and human validation represents a critical challenge in non-hormonal contraceptive development. The complexity of human spermatogenesis, individual genetic variations, and the need for long-term safety data necessitate carefully designed clinical trials with adequate sample sizes and extended follow-up periods.

2.3 Physical Methods

Physical methods of male contraception, including heat-based and ultrasound approaches, offer non-pharmacological alternatives by temporarily disrupting spermatogenesis [9]. These methods capitalize on the temperature sensitivity of sperm production, which requires temperatures 2-3°C below core body temperature. Heat-based methods have shown efficacy in reducing sperm counts to oligospermic levels. Studies have demonstrated that sustained scrotal heating through various means (tight-fitting undergarments, heated water baths, or external heating devices) can significantly reduce sperm production. However, critical analysis reveals substantial limitations that have prevented clinical adoption.

The primary concerns include discomfort, practicality, and potential for long-term testicular damage. Prolonged heat exposure carries risks of tissue damage, and the reversibility of effects after extended use remains questionable. Studies examining heat-based contraception have generally involved short exposure periods, and the long-term safety of repeated or prolonged use has not been established. Additionally, individual variations in heat tolerance and sperm sensitivity create challenges in standardizing effective protocols. Ultrasound-based contraception involves applying high-frequency sound waves to temporarily disrupt spermatogenesis. Animal studies have shown that controlled ultrasound treatments can induce temporary infertility with sperm counts dropping to near azoospermia. However, human applications remain largely theoretical due to safety concerns and technical challenges.

The critical limitation of ultrasound methods is the potential for tissue damage. While studies suggest reversibility, the risk of permanent damage to testicular tissue has not been adequately ruled out. The depth of ultrasound penetration, energy levels required for efficacy, and individual anatomical variations create challenges in developing safe and standardized protocols. Both physical methods face significant hurdles in clinical validation. The need for specialized equipment, trained operators, and careful monitoring limits their practical application. More importantly, the long-term safety profiles of these interventions require extensive investigation before they can be considered viable contraceptive options.

3. Financial Analysis of Male Contraceptive Market Potential

The introduction of effective male contraceptives represents a significant economic opportunity with substantial financial benefits across multiple sectors. A comprehensive economic analysis reveals the potential for considerable cost savings and revenue generation.

3.1 Healthcare Cost Reduction

Unintended pregnancies impose substantial economic burdens on healthcare systems globally. In the United States alone, the average cost of an unintended pregnancy, including prenatal care, delivery, and newborn care, exceeds \$12,000 per case. With approximately 2.8 million unintended pregnancies occurring annually in the US, the direct medical costs approach \$35 billion yearly [16]. Economic modeling suggests that even a modest 15-20% reduction in unintended pregnancies through male contraceptive adoption could generate healthcare savings of \$5.3-7.0 billion annually in the US market alone.

When extrapolated globally, particularly in developing countries where unintended pregnancy rates are higher, the potential savings could exceed \$50 billion annually.

3.2 Market Revenue Potential

The global contraceptive market is valued at approximately \$27 billion, with female contraceptives comprising 85% of current sales. Market analysis indicates that male contraceptives could capture 25-35% of the total contraceptive market, representing potential annual revenues of \$6.8-9.5 billion. This estimate is based on acceptability studies showing high male willingness to use novel contraceptives (34-82%) and female trust in male-controlled methods (43-94%) [10]. Pharmaceutical companies investing in male contraceptive development could expect significant returns on investment. Conservative estimates suggest that successful male contraceptive products could generate revenues comparable to blockbuster drugs, with peak annual sales potentially reaching \$2-4 billion for first-to-market products.

3.3 Societal Economic Benefits

Beyond direct healthcare savings, male contraceptives offer broader societal economic benefits. Improved family planning leads to 1) Increased workforce participation: Reduced unintended pregnancies enable both partners to maintain career trajectories, increasing household income and tax revenues. 2) Educational investment: Planned pregnancies allow families to invest more resources in education for existing children, contributing to long-term economic growth. 3) Reduced public assistance costs: Government spending on welfare, food assistance, and housing subsidies decreases when families can better plan and prepare for children. Economic modeling suggests that every dollar invested in male contraceptive development and distribution could yield \$3-6 in societal economic benefits, like returns observed with female contraceptive programs.

3.4 Cost-Effectiveness Analysis

Comparative cost-effectiveness analysis indicates that male contraceptives could offer favorable economic profiles. Assuming a price point similar to female hormonal contraceptives (\$50-100 per month), male contraceptives would be cost-competitive with existing options while providing additional benefits of shared contraceptive responsibility. Long-term economic analysis suggests that male contraceptives with high efficacy and acceptability could become dominant market options, particularly among couples seeking to share reproductive responsibility equally.

4. Societal Barriers and Prejudices

4.1 Traditional Gender Roles and Masculinity

Traditional gender roles have historically assigned reproductive responsibility primarily to women, creating significant cultural barriers to male contraceptive adoption. The concept of masculinity, as defined within various cultural contexts, often encompasses notions of virility, fertility, and sexual dominance that may conflict with contraceptive use [17]. In Western cultures, masculinity is frequently associated with sexual spontaneity, physical strength, and reproductive potency. These cultural constructs can create resistance to male contraceptive methods, particularly those perceived as interfering with "natural" male functions. For example, hormonal contraceptives that temporarily suppress testosterone or sperm production may be viewed as threatening to masculine identity, despite their reversible nature.

Cross-cultural analysis reveals significant variations in masculinity concepts and their impact on contraceptive acceptance. In some African and Asian cultures, male fertility is closely tied to social status and family honor, creating additional barriers to contraceptive adoption. Conversely, certain Scandinavian societies with strong gender equality values show higher acceptance of shared contraceptive responsibility.

4.2 Healthcare Provider Attitudes and Knowledge Gaps

Healthcare providers play a crucial role in contraceptive counseling and prescription, yet significant knowledge gaps exist regarding male contraceptive options. A comprehensive study by Tcherdukian et al. [11] revealed alarming deficiencies in healthcare provider knowledge and training. The study found that while 98% of healthcare providers knew about condoms and 89% about withdrawal, only 10% were familiar with hormonal male contraception and 24% with thermal methods. More concerning, 55% of providers never or infrequently discussed male contraceptive options during contraceptive counseling sessions with couples.

Only 14% of healthcare providers had received formal training on male contraception, despite 96% expressing desire for additional education. This knowledge gap directly impacts patient care and limits the adoption of emerging male contraceptive methods. The lack of healthcare provider education represents a critical barrier that requires systematic intervention through medical school curriculum updates to include comprehensive male contraceptive education, continuing medical education programs focused on emerging male contraceptive technologies, clinical practice guidelines that emphasize shared contraceptive responsibility, and provider confidence-building through hands-on training and case studies.

4.3 Educational and Awareness Campaigns

The success of male contraceptive adoption requires comprehensive educational campaigns targeting multiple audiences. Current public awareness of male contraceptive options beyond condoms and vasectomy remains extremely low. Educational interventions must address: 1) Public education about emerging male contraceptive methods, their safety, and efficacy; 2) Myth-busting campaigns to address misconceptions about masculinity and contraception; 3) Healthcare provider education to ensure informed counseling and prescription practices; and 4) Couple-focused education emphasizing shared reproductive responsibility. Evidence from successful public health campaigns, such as those promoting female contraceptive acceptance in the 1960s-70s, suggests that sustained, multi-channel educational efforts can effectively shift cultural attitudes and increase adoption rates.

4.4 Trust and Reliability Concerns

A significant barrier to male contraceptive adoption is the concern about reliability and trust. Some women express skepticism about depending on male partners for contraceptive responsibility, stemming from: historical experiences where reproductive decisions were made without full partner involvement; concerns about consistent use and adherence to contraceptive regimens; fear of unintended pregnancies due to male partner's contraceptive failure; and perceived differences in investment in preventing pregnancy between partners. However, systematic reviews of acceptability studies contradict these concerns, showing that 43-94% of women express willingness to trust male contraceptive methods [10]. This discrepancy between perceived and actual female attitudes suggests that trust concerns may be more related to lack of information and cultural stereotypes than actual partner reliability.

Addressing trust concerns requires (1) transparent communication about contraceptive efficacy and proper use, (2) shared decision-making frameworks for contraceptive choice, (3) couple-based counseling that addresses concerns from both partners, (4) real-world evidence demonstrating male contraceptive reliability and user satisfaction.

4.5 Regulatory and Approval Challenges

Regulatory pathways for male contraceptives present unique challenges compared to female contraceptives. Current regulatory frameworks were primarily designed for female contraceptive evaluation, creating potential mismatches in risk-benefit assessment for male methods. Key regulatory challenges include: 1. Lack of established efficacy

endpoints specifically designed for male contraceptives; 2. Uncertainty about acceptable safety profiles for healthy male users; 3. Limited guidance on reversibility assessment and long-term follow-up requirements; 4. Challenges in designing appropriate clinical trial protocols for male contraceptive evaluation. The regulatory environment requires adaptation to accommodate male contraceptive development while maintaining appropriate safety standards. This includes developing male-specific clinical trial guidance, establishing clear efficacy thresholds, and creating streamlined approval pathways for promising methods.

5. Conclusion and Future Directions

Male contraceptives represent a critical yet underutilized component of comprehensive reproductive healthcare. Despite decades of research and promising clinical results, the translation from laboratory to clinical practice has been limited by a complex interplay of scientific, social, and regulatory barriers. The scientific evidence demonstrates that effective, reversible male contraceptive methods are achievable. Hormonal approaches have shown high efficacy in clinical trials, with pregnancy prevention rates comparable to female contraceptives. Non-hormonal methods offer the promise of effective contraception without systemic hormonal effects, though most remain in preclinical development stages. Physical methods provide non-pharmacological alternatives but require further safety validation.

Critical analysis reveals that current research limitations include inadequate long-term safety data, limited understanding of individual variability in response, and insufficient validation of preclinical findings in human populations. Future research priorities must include: 1. Long-term safety studies with extended follow-up periods to assess reversibility and potential delayed effects; 2. Genetic and pharmacogenomic studies to understand individual variations in contraceptive response; 3. Head-to-head comparisons of different male contraceptive approaches to identify optimal methods; 4. Development of standardized efficacy and safety endpoints for regulatory evaluation; and 5. Investigation of combination approaches that may enhance efficacy while minimizing side effects.

The societal barriers to male contraceptive adoption require systematic intervention through multiple channels. Healthcare provider education emerges as a critical intervention point, given the substantial knowledge gaps identified in current practice. Medical education reform, continuing education programs, and clinical practice guideline development are essential for improving provider confidence and patient counseling quality.

Public education campaigns must address cultural misconceptions about masculinity and contraception while promoting accurate information about emerging methods. These campaigns should target both men and women, emphasizing shared reproductive responsibility and dispelling myths about male contraceptive reliability. The economic analysis reveals substantial potential benefits from male contraceptive adoption, including significant healthcare cost savings, market revenue opportunities, and broader societal economic gains. These economic incentives should motivate increased investment in research, development, and implementation programs. Regulatory frameworks require updating to accommodate male contraceptive development while maintaining appropriate safety standards. This includes developing male-specific clinical trial guidance, establishing clear efficacy thresholds, and creating efficient approval pathways.

Future success in male contraceptive implementation will require coordinated efforts across multiple domains: continued scientific research to address current limitations, systematic healthcare provider education to improve knowledge and counseling practices, comprehensive public education to address cultural barriers, and regulatory framework development to facilitate appropriate evaluation and approval processes. The potential impact of successful male contraceptive implementation extends beyond individual reproductive choices to broader societal benefits including gender equity in re-

productive responsibility, reduced unintended pregnancies, improved family planning outcomes, and substantial economic benefits. Achieving these benefits requires sustained commitment from researchers, healthcare providers, policymakers, and society.

With continued research investment, systematic barrier removal, and cultural shifts toward shared reproductive responsibility, male contraceptives could become integral components of comprehensive reproductive healthcare, contributing significantly to global reproductive health goals and gender equity objectives.

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