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Thermal male contraception: A study of users' motivation, experience, and satisfaction

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Abstract

Purpose: The aim of this study is to evaluate the motivations, experience, and acceptability of thermal male contraception (TMC) in male partners of couples requesting the use of TMC as the only couple contraceptive.

Materials and methods: To the 72 men of couples seeking male contraception and using TMC between 2011 and 2019, we suggested an anonymous online survey (93 questions) exploring population characteristics, contraceptive histories, motivations for choosing TMC, patient experience at the successive phases of use, relations with partner and environment, and satisfaction with this method.

Results: Sixty-seven men agreed to participate (93% response rate); 63 responses were complete and were analyzed (94% participation rate). The main motivations for choosing TMC were “not using hormones” ($n = 59/63$, 94%) and using a method regarded as “natural” ($n = 49/63$, 78%). Most of the men surveyed (68%) adopted the method in less than 2 weeks. During the contraception use phase ($n = 59$ men), they described significantly improved sexual satisfaction, compared to that experienced with their previous contraceptive methods, and they reported high confidence (100% rather/totally confident partner) and support (88% rather/totally supporting partner) from their partner. Most men ($n = 35/59$, 59%) also reported improved self-esteem. The main negative point was discomfort, reported by 24% of the men. The overall satisfaction score of using this method was $3.78 \pm 0.46/4$, and 100% of the men reported that they would recommend the method to other men.

Discussion and conclusion: Men using TMC successfully assumed the responsibility for and performed a daily task to provide couple contraception. This positive evaluation, together with the already published contraceptive efficacy and reversibility of TMC, should encourage the development of this method.

KEYWORDS

contraceptive devices, couple, male thermal contraception, men acceptance of health care, men satisfaction, sexual satisfaction

1 | INTRODUCTION

Unintended pregnancies account for 50% of pregnancies worldwide, despite the numerous contraceptive methods available to women. The only contraceptive methods currently available to men are vasectomy, condoms, and withdrawal, which are used by 2%, 21%, and 5% of couples, respectively.¹

The development of male contraceptive methods has been ongoing with different approaches. Among them, hormonal treatments with testosterone alone or associated with progestin-induced spermatogenesis inhibition (azoospermia or oligozoospermia) with a valuable contraceptive efficacy in thousands of male partners of couples.²⁻¹¹ Moreover, the collected data on semen analyses have led to a strict definition of the sperm contraceptive threshold¹²: The suppression of sperm counts to below 1 million/ml results in fertility rates commensurate with female oral contraceptive pills.¹²

Another way to achieve this sperm contraceptive threshold is based on the thermal dependence of spermatogenesis, that is, thermal male contraception (TMC).^{13,14} In most mammals, optimal spermatogenesis temperature is obtained by thermoregulatory systems; in humans, thermal regulation achieves a testicular temperature 2 to 5°C lower than body temperature.¹⁵ Increased testicular temperature induces apoptosis in the most heat-vulnerable germ cells (pachytene and diplotene spermatocytes, spermatids) and impacts sperm production, in line with relative hyperthermia and exposure time.¹⁶

TMC is based on the induction of a +2°C increase in testicular temperature for 15 to 24 h daily¹⁷⁻¹⁹ using a contraceptive underwear (CU) that maintains the two testes near the external orifice of the inguinal canal.¹⁵ With such a CU, the inhibiting effects on spermatogenesis, as well as the recovery of sperm parameters after stopping CU have been reported.¹⁷⁻¹⁹ The contraceptive efficacy of a +2°C increase in testicular temperature was studied in three different studies using three types of device for 15 to 24 h daily: A total of 51 couples used TMC as their only contraceptive method over a total of 536 cycles and no pregnancy occurred.^{17,20,21}

Since the 2010s, couples or male partner of couples have consulted the andrologists of the Department of Reproductive Medicine requesting a male contraceptive method different from condoms or withdrawal as the only couple contraception. Some chose vasectomy, others wanted reversible contraception. As is the case within the practice of male infertility, and in other areas of medicine, treatments may be prescribed without perfect proof of their effectiveness having been rigorously demonstrated by trials. This is the case for several treatments used in male infertility (e.g., anti-estrogens, antioxidants, anti-inflammatories) whose indication is based on publications reporting efficacy but with a low level of evidence.

The management of these contraceptive requests was made as a clinical application of a method published in the literature. There has never been a process of recruiting volunteer couples. Of course, as

required in this type of care, all contraindications, risks, and follow-up modalities were provided to applicants prior to the implementation of treatment.

The modes of implementation and monitoring of TMC are as follows: Before the first appointment for male contraception, a written document¹⁴ is sent by e-mail for information. After a discussion about the chosen method, a medical interrogation and a clinical andrological examination look for contraindications: history of mal descended testicle, torsion of the spermatic cord, orchitis, inguinal hernia repair, chronic scrotal or inguinal skin diseases (eczema, recurrent mycoses), presence of a clinical varicocele as well as a scrotal or inguinal skin condition in progress and a testis absence or atrophy without known causes. Then the man learns how to set up the CU model adapted to his morphology (Annexure Figures 1 and 2). A semen analysis is prescribed; as recommended, only men with normal semen parameters are accepted.¹² They receive a free CU, manufactured according to the patent previously registered by the Paul Sabatier University and the Toulouse University Hospital, France.

The objectives of the CU testing phase are: (1) to progressively learn to wear the CU in the different activities of daily life until wearing the CU at least 15 h/day; (2) to make sure that the permanent position of the testicles when wearing the CU is the expected one; (3) to check the absence of any unpleasant or painful sensation (penile, scrotal, testicular); and (4) to finally prepare four additional free CU copies.

The spermatogenesis inhibiting phase is the time required to reduce sperm production to the contraceptive threshold (less than 1 M/ml sperm) as established.¹² Around the third month of daily CU wear for 15 h/day, a semen analysis is performed: If the threshold is not reached, a second or third semen analysis (at 1-month intervals) is performed; if the contraceptive threshold is reached, TMC can be used as the only form of the couple's contraception.

During the phase of CU-use as the only couple contraception (the phase of contraceptive use), the man is requested to perform a semen analysis every 3 months to check that the sperm count remains below the contraceptive threshold. The prescribing physician follows up by e-mail during the successive phases, with the possibility of physical or phone consultation, on request.

Usual male contraceptive methods (withdrawal and condoms) are directly related to the sexual act and are not used outside of it. In contrast, methods inducing spermatogenesis inhibition (hormonal, thermal) are based on daily or repeated actions outside the act of sexual intercourse; these methods are thus rather similar to female contraceptive pills. As no commercially available male hormonal or thermal contraceptive exists, little information regarding the acceptability of these approaches for men has been reported. Publications mainly concern male hormonal contraceptives²²⁻²⁵; only one publication analysed the hypothetical acceptability of TMC.²⁶

The purpose of the current study was to evaluate the experience, acceptability, and satisfaction of TMC in men using TMC as a unique couple contraceptive.

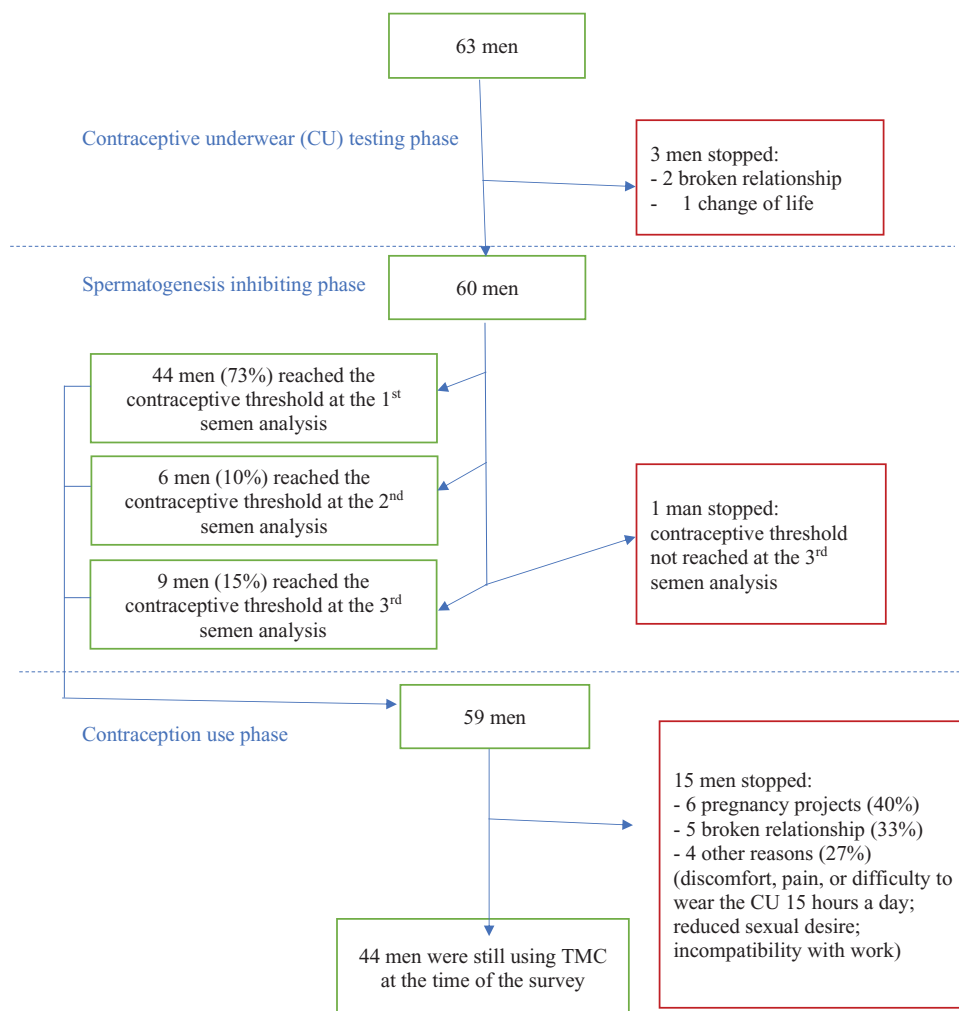


FIGURE 1 Pathway of TMC users. TMC, thermal male contraception; Q, number of the question (Supplement). Source: Supplement Q41.b, Q50, Q51, Q64

Were you able to wear the CU 15 hours a day without forgetting?	Good wearing rigor (n=16 ; 27%)	Perfect wearing rigor (n=43 ; 73%)		
Did you ever wear the CU more than 15 hours a day without forgetting?	Sometimes (n=13 ; 22%)	Often (n=30 ; 51%)		Everyday (n=15 ; 25%)
Did you ever wear the CU at night?	Never (n=13 ; 22%)	Sometimes (n=22 ; 37%)	Often (n=11 ; 19%)	Every night (n=13 ; 22%)
Did you remember to ask the prescription for the semen analysis?	Yes (n=39 ; 66%)			No (n=20 ; 34%)

FIGURE 2 Self-assessment of the adherence to CU wearing and the monitoring of semen analyses. $n = 59$ men. CU, contraceptive underwear; Q, number of the question (Supplement). (a) never ($n = 1$; 2%). Source: Supplement Q59–62

2 | MATERIALS AND METHODS

2.1 | Ethics statement

The survey protocol was approved by the institutional review board (IRB) of Aix Marseille University (IRB No. 2020-09-10-005), France. Written informed consent was obtained from each participant.

2.2 | Survey population, consent, and questionnaire responses

In a population of men seeking TMC as the couple's only contraceptive method since June 2011 in Toulouse University Hospital, the survey population was selected as follows: An initial e-mail was sent to each of the 72 men who had started the CU testing phase between June 2011

and September 2019, including an information leaflet about the online survey. Inclusion criteria were men who agreed to answer the survey: They received a message containing a participant number. Participants completed the online questionnaire anonymously using their participant numbers. Exclusion criteria were men who did not respond to the e-mail, refused to participate, or did not complete the questionnaire entirely.

The 93-question questionnaire is composed of three parts (completely available in the [Supplement](#)):

- (A) “You” (seven questions) describes the survey population;
- (B) “Contraception and you,” with three sections: (I) “before TMC” (12 questions), description of men’s contraceptive history from the contraceptive method used before TMC (“N-1” method) to the two previous methods (“N-2” and “N-3”); (II) “when changing contraceptive method to start TMC ” (six questions), exploring the reasons for this change; (III) “at the time of choosing TMC” (three questions), exploring the determinants of the choice of TMC among the other methods;
- (C) “The experience” (65 questions) comprising eight chapters: (I) “accessibility”; (II) “CU testing phase and first semen analysis”; (III) “spermatogenesis inhibiting phase”; (IV) “contraception use phase”; (V) “you stopped TMC”; (VI) “you and your partner while using the TMC”; (VII) “you and your entourage”; and (VIII) “satisfaction and discontent.”

These were primarily multiple-choice questions (Q). Some questions used an increasing satisfaction scale from 1 to 4 (Q13, 16, 19, 32–34, 36, 37, 42, 45, 48, 49, 52, 59–61, 62.b, 69, 74, 75.b, 79, 89, 91, 93.b); one question (Q82) was open-ended. For question 82, the open-ended responses were written in free text and then analyzed according to the themes presented in each response.

This ad hoc questionnaire was designed on purpose. Before diffusion to participants, the questionnaire was tested to validate clarity and duration.

2.3 | Statistical analyses

The questionnaire was generated using “Google Forms” software; responses were saved automatically in the same software program and extracted via an Excel spreadsheet in Microsoft Office 2019 (Microsoft Corporation). Only complete questionnaires were analyzed.

The results of the questions concerning the quality of sexual life were compared over time (from the contraceptive method used before TMC [“N-1” method] to the two previous methods [“N-2” and “N-3”]) among men who had reached the phase of CU use as the only form of the couple’s contraception (contraception use phase): “N-3” stage versus “contraception use phase,” “N-3” stage versus “CU testing phase,” and “CU testing phase” versus “contraception use phase.” These comparisons were made for each satisfaction parameter (mean of 59 values) and for all five parameters (mean of 295 values) by a paired samples Wilcoxon signed-rank test.

TABLE 1 Description of the included population (n = 63)

Variable	Category	N (%)
Age (years)	Mean +/- SD	32.9 +/- 6.1
	Median [min-max]	31 [21–52]
Education level	Stop before HSD	2 (3%)
	HSD to HSD + 2 years	10 (16%)
	Bachelor’s degree	21 (33%)
	Master’s degree or more	30 (48%)
Occupation (ISCO-08) ^a	1	3 (5%)
	2	24 (38%)
	3	6 (10%)
	4	1 (2%)
	5	1 (2%)
	6	5 (8%)
	7	12 (19%)
	8	0 (0%)
	9	1 (2%)
	0	0 (0%)
	In search of employment	7 (11%)
Other	3 (3%)	
Practice of a religion	Yes	2 (3%)
	No	60 (95%)
	No answer	1 (2%)
Still in a relationship with the same partner as at the time of choosing TMC	Yes	48 (76%)
	No	15 (24%)
Children	Yes	14 (22%)
	No	49 (78%)
Parental project	Yes	20 (32%)
	No	24 (38%)
	Do not know	19 (30%)

Note: Values are presented as numbers (%) except for age (mean; SD). Abbreviations: HSD, high school diploma;; Q, number of the question (Supplement); TMC, thermal male contraception.

^aInternational Standard Classification of Occupations 2008 (ISCO-08). 1: Managers; 2: Professionals; 3: Technicians and associate professionals; 4: Clerical support workers; 5: Services and sales workers; 6: Skilled agricultural, forestry and fishery workers; 7: Craft and related trades workers; 8: Plant and machine operators and assemblers; 9: Elementary occupations; 0: Armed forces occupation.

Source: Supplement Q1–Q7.

Pearson’s χ^2 test was used to compare the data in Table 3. A difference was considered significant when $p < 0.05$.

3 | RESULTS

3.1 | Demographics and contraceptive history

The flowchart of the survey is presented in Figure 1. The response rate was 93% (67/72): Five men never respond to the first e-mail, neither to the three recall e-mails. The participation rate was 94% (63/67): Three men refused to participate (broken relationship; refuse to use the questionnaire online; no explanation given), and one did not complete the questionnaire online.

Table 1 reports the description of the population. The majority (81%) of the men had a bachelor’s degree or more, and the main occupational

TABLE 2 Contraceptive history of the 63 men before the use of thermal male contraception (TMC)

Contraceptive methods	N-3 ^a		N-2		N-1	
	Use	Main reasons for termination	Use	Main reasons for termination	Use	Main reasons for termination
Male methods	27 (43%)		25 (40%)		24 (38%)	
-Male condom	20 (32%)	Decreased sexual pleasure	22 (35%)	Decreased sexual pleasures	10 (16%)*	Decreased sexual pleasure
-Withdrawal	5 (8%)	Fear or experience of unwanted pregnancy	2 (3%)	Fear of unwanted pregnancy	10 (16%)	Fear of unwanted pregnancy
-Male condom and withdrawal	2 (3%)	Not applicable	1 (2%)	Not applicable	4 (6%)	Not applicable
Female methods ^b	23 (37%)		33 (52%)		36 (57%)*	
-Female pill	19 (30%)	Desire to reduce hormone intake	13 (21%)	Desire to reduce hormone intake	15 (24%)	Desire to reduce hormone intake
-IUD (with or without hormones)	4 (6%)	Desire to reduce hormone intake, too painful application and/or removal	13 (21%)	Too painful application and/or removal	16 (25%)**	Desire to reduce hormone intake, side effects on health and sexuality
-Male and female methods	2 (3%)		3 (5%)		2 (3%)	
-No contraception	11 (17%)		2 (3%)		1 (2%)	

Note: Values are presented as number (%).

^aN-1: contraceptive method men were using immediately before the use of TMC; N-2: contraceptive method used immediately before the N-1 method; N-3: contraceptive method used immediately before the N-2 method.

^bFemale pill, intrauterine device (IUD), subcutaneous implant, thermal curve, female condom, or cervical cap.

* N-3 versus N-1: $p < 0.05$; ** N-3 versus N-1: $p < 0.001$.

Source: Supplement Q10, Q11, Q14, Q15, Q17, Q18; Q, number of the question (Supplement)

activities were professionals (38%) or craft and related trade workers (19%).

Table 2 presents the last three contraceptive methods used prior to TMC. The proportion of men using a male method of contraception was stable over time (38% to 43%), except for male condom use, which decreased significantly with time. The proportion of men using a female method increased significantly over time, particularly with the use of the intrauterine device (IUD). The reasons for discontinuing these methods were comparable regardless of the time of use.

3.2 | Motivations, criteria, and modalities for choosing TMC

Among the men whose couple's contraception method immediately before TMC (N-1) was a female method ($n = 36/63$, 57%), the main reasons for switching to a male contraceptive method were the wish to share the role of providing contraception in a couple ($n = 31/36$, 86%), the willingness to take responsibility for contraception ($n = 21$, 58%), and the absence of expected harmful effects on desire and pleasure in the couple ($n = 19$, 53%; Supplement Question (SQ) 20.b). Among the men whose couple's contraception method immediately before TMC (N-1) was a male method (condom or withdrawal, $n = 20/63$, 32%) (SQ10), the main reasons for stopping were decreased sexual pleasure ($n = 9/20$, 45%) and fear of unwanted pregnancy ($n = 9/20$, 45%; SQ11).

Changing the couple's contraceptive regimen from a female form or a traditional male method to a new method was introduced slightly more often by the man ($n = 29/63$, 46%) than by the woman ($n = 23$, 37%).

When choosing TMC, 65% of the men did not consider other methods (SQ26). The main reasons for choosing TMC were the non-use of hormones ($n = 59$; 94%) and the perception of TMC as a "natural" method ($n = 49$; 78%; SQ27).

The evolution of fears and perceptions at the different phases of TMC are presented in Table 3. At the time of choosing TMC, the majority (70%) of men had specific fears about the method, which decreased significantly at the spermatogenesis inhibiting phase ($p < 0.01$).

3.3 | Experience at different stages

The ease of adoption of the CU was evaluated at 2.89 ($+/- 0.67$; SQ37) on a scale of 1 (*very difficult*) to 4 (*very easy*); 68% of the men adopted the CU in less than 2 weeks (SQ38). During this CU testing phase, 43% of the men did not experience any difficulties (SQ41). Difficulties related to the CU are described in Table 4: they were easily resolved ($n = 20/36$, 56%) and/or may have required modifications to the CU ($n = 19/36$, 53%; SQ41).

During the spermatogenesis inhibiting phase ($n = 60$), the main fear of the men ($n = 33$, 55%) was that they would not be able to provide contraception for the couple on a daily basis. The main positive point

TABLE 3 Evolution of concerns, negative and positive aspects in the successive phases of TMC

	When choosing TMC (n = 63; Q28)	Spermatogenesis inhibiting phase (n = 60; Q43, Q46, Q47)	Phase of contraception use (n = 59; Q57, Q58)
Concerns			
None	9 (14%)	16 (28%)	
Lack of efficiency	11 (17%)	11 (18%)	
Specific to the method ^a	44 (70%)	21 (35%)**	
Not being able to ensure the couple's contraception on a daily basis	36 (57%)	33 (55%)	
Questioning of virility	5 (8%)	1 (2%)	
Impact on sexuality	9 (14%)	5 (8%)	
Becoming sterile	8 (13%)	2 (3%)	
Testicular cancer	4 (6%)	2 (3%)	
Mockery	3 (5%)	2 (3%)	
Other	1 (2%)	0	
Negative aspects			
None		15 (25%)	28 (47%)*
Related to the method and/or the CU		31 (52%)	23 (39%)
Difficulty to wear the CU 15h/D		8 (13%)	1 (2%)
Related to sexuality		2 (3%)	1 (2%)
Difficulties in performing semen analysis		5 (8%)	3 (5%)
Being mocked		5 (8%)	1 (2%)
Other		1 (2%)	5 (8%)
Positive aspects			
None		0	3 (5%)
Satisfaction of having appropriated the method and/or the CU		48 (80%)	47 (80%)
Satisfaction and/or relief at being able to wear CU 15h/D		36 (60%)	34 (58%)
No deleterious effect on sexuality		36 (60%)	29 (49%)
Positive change in sexuality		11 (18%)	18 (31%)
No difficulty in performing the first or following semen analyses		30 (50%)	23 (39%)
Not being mocked		15 (25%)	0
Other		12 (20%)	2 (3%)
-Of which reinforcement of the self-esteem		7 (12%)	1 (2%)

Note: Values are presented as number (%).

Abbreviations: 15h/D: 15 h a day; CU, contraceptive underwear; Q, number of the question (Supplement).

^aConcerns of discomfort (n = 40; 63% and n = 15; 25%), of pain (n = 12; 19% and n = 8; 13%), of lack of hindsight with a new method (n = 8; 13% and n = 4; 7%), of a method too difficult to access (n = 1; 2% and n = 0); of a method taking too long to set up (n = 5; 8% and n = 3; 5%).

^bThe CU was uncomfortable (n = 20; 33% and n = 14; 24%), painful (n = 14; 23% and n = 4; 7%), other (n = 6; 10% and n = 8; 14%), I had trouble putting on and/or taking off CU (n = 1; 2% and n = 0 respectively).

**p < 0.01; *p < 0.05.

(n = 48, 80%) was the satisfaction of having adopted the method and/or CU (Table 3).

During the contraception use phase (n = 59), adherence to CU wearing and the monitoring of semen analyses was high (Figure 2). Most of the men had never been afraid of facing contraceptive

failure (n = 38/59; 64%). For the remainder, this fear may have led them to wear the CU more than 15 h per day (n = 12, 20%) or at night (n = 8; 14%; SQ77). Finally, the quarterly frequency of follow-up semen analysis was acceptable to most (n = 48, 81%) men (SQ63).

TABLE 4 Difficulties encountered with contraceptive underwear during the testing phase

Did you experience any difficulties with the contraceptive underwear?	
(Several answers possible, $n = 63$)	
Initial underwear poorly adapted	59 (94%)
Of which:	
-Discomfort when wearing CU	35 (56%)
-Pain when wearing CU	22 (35%)
-Skin irritation	37 (59%)
-The testicles descended spontaneously	34 (54%)
Erections did not give way and/or were painful ^a	9 (14%)
Difficulties during installation and/or removal of CU	4 (6%)
No difficulties	3 (5%)
Hypersudation	3 (5%)
Other	3 (5%)

Note: Values are presented as number (%);

Abbreviations: CU, contraceptive underwear; Q, number of the question (Appendix).

^aRelated to night-time wearing of CU (not suitable for this type of CU).

Source: Supplement Q39.

At the different phases of TMC, fears and negative and positive aspects evolved (Table 3). The transition from the choice of TMC to the spermatogenesis inhibiting phase resulted in a significant decrease in fears about the method (70% vs. 35%, $p < 0.01$), and there was a downward trend in all but two concerns: that of not being able to ensure the couple's contraception on a daily basis (57% vs. 55%, respectively) and concerns about a lack of efficiency (17% vs. 18%, respectively).

The transition from the spermatogenesis inhibiting phase to the contraception use phase of TMC resulted in a significant increase in satisfaction: The proportion of men expressing no negative aspect increased from 25% to 47% ($p < 0.05$). The most frequently expressed negative aspect of the contraception use phase was discomfort ($n = 14$, 24%, SQ58).

At the spermatogenesis inhibiting phase, the main positive aspects were the satisfaction of having adopted the method and/or the CU ($n = 48$, 80%), satisfaction with being able to wear the CU 15 h a day ($n = 36$, 60%), and the absence of any deleterious effects on sexuality ($n = 36$, 60%). These positive points were not significantly altered in the contraception use phase (SQ57).

For the 59 men involved in the contraception-use phase, their partner's confidence and support for TMC were perceived as high; links of trust and male image were perceived as mostly strengthened (Figure 3). Most of the men reported having better self-esteem ($n = 35$; 59%; SQ80) and feeling an improvement in their partner's image (53%, SQ73). The man's overall sexual satisfaction increased significantly between stage N-3 and the phase of contraceptive use (Figure 4).

Finally, among the 59 men involved in the contraception-use phase, the overall satisfaction level with TMC was rated at 3.78 (+/- 0.46; scale of 1 "not at all satisfied" to 4 "very satisfied"; SQ79). All the men responded that they would recommend this method to other men

(SQ81), mainly because of sharing the contraceptive burden (49%), the simplicity of the method (47%), and its perception as "natural" (not chemical; 46%; Table 5).

4 | DISCUSSION

The current TMC user population differs from the general population. TMC users had a high level of education: 81% had a bachelor's degree or higher versus 21% in the French working population.²⁷ They were often overqualified for the trade they exercised: Occupations corresponding to a level of education above the high school degree (International Standard Classification of Occupation 1, 2, and 3)²⁸ represented only 53% of the men (Table 1).

4.1 | Before choosing TMC, the men already had a higher rate of use of male contraception than men in the general population

Prior to the use of TMC, the men in the survey showed a greater use of male contraceptive methods than men in the general French population: 38% versus less than 20% (especially withdrawal, 16% vs. less than 5%) at the expense of the contraceptive pill (24% vs. 33%).²⁹ This overuse of male contraceptive methods, however, was comparable to that of a population of new fathers for whom "contraception before pregnancy was primarily ensured by the female partner via contraceptive pills (51%) and by the male partner via condoms (30.4%) and withdrawal (13.4%)."²⁶ Moreover, in a study of Italian men testing a male contraceptive hormonal regimen, 29% were using condoms before the study started.²²

4.2 | Motivations for choosing TMC

The main reasons for choosing the thermal method of contraception were the non-use of hormones (94%) and its perception as a "natural" method (78%). These reasons are consistent with the benefits of TMC as perceived by potential users: "natural (52%), no adverse effect (38%), non-hormonal (36%), reversible (36%)."²⁶

We can distinguish two types of situations at the time of choosing TMC. On the one hand, 36 men (57%) were "using" female methods; the reasons for discontinuing were the desire to reduce hormonal intake and the side effects impacting health and sexuality. The desire to share the burden of contraception in the couple and the willingness to take responsibility for it are well-represented in these men (86% and 53%, respectively). On the other hand, 24 men (38%) used the usual methods of male contraception (condom and/or withdrawal), which affected sexual intercourse. The reasons for stopping were the decrease in sexual pleasure and the fear of pregnancy (38% each). In these two types of situations, the mental load of the man is either absent (female methods) or of limited duration (during sexual intercourse [withdrawal, condom]).

Assessment of the partner's confidence regarding:

Your ability to put on correctly the CU	Quite confident (n=5 ; 8%)	Completely confident (n=54 ; 92%)
Your ability to wear the CU every day	Quite confident (n=6 ; 10%)	Completely confident (n=53 ; 90%)
Your ability to wear the CU 15 hours a day	Quite confident (n=12 ; 20%)	Completely confident (n=47 ; 80%)

Assessment of the relationship within the couple

During the use of TMC, was your partner supportive towards you?	a	b	Quite supportive (n=17 ; 29%)	Completely supportive (n=35 ; 59%)	
Did the relationship of trust within the couple change?	No, no change (n=27 ; 46%)			Yes, they were rather strengthened (n= 32 ; 54%)	
During the use of TMC, did your partner change her opinion of you?	c			No (n=27 ; 46%)	Yes, she had a better image of me (n= 31 ; 53%)

FIGURE 3 Quality of the relationship within the couple during the use of TMC as the only form of the couple's contraception (contraception use phase). $n = 59$ men. CU, contraceptive underwear; Q, number of the question (Supplement). (a) Not supportive at all ($n = 2$; 3%). (b) Not very supportive ($n = 5$; 8%). (c) Yes, she had a poorer image of me ($n = 1$; 2%). Source: Supplement Q68, Q69, Q73, Q74

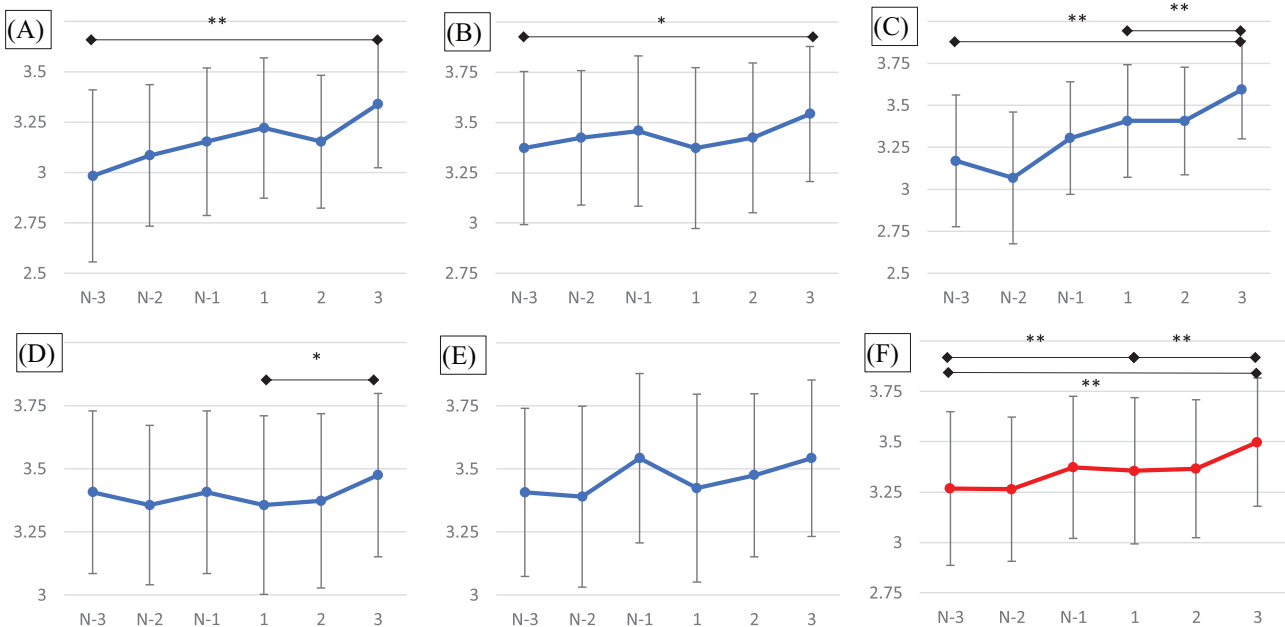


FIGURE 4 Changes in sexual satisfaction scores before TMC and at three different phases of TMC use. $n = 59$ men. TMC, thermal male contraception; Q, number of the question (Supplement). For each figure, each point represents the mean score \pm SD for each period (3 before TMC + 3 during TMC use). Each score was given in whole numbers on a scale from 1 (not at all satisfied) to 4 (completely satisfied). N-1, contraceptive method used immediately before TMC; N-2, contraceptive method used immediately before N-1; N-3, contraceptive method used immediately before N-2. Three different phases of TMC use: 1: contraceptive underwear testing phase; 2: Spermatogenesis inhibiting phase; 3: phase of contraception use. Criteria of sexual satisfaction scores: (A) frequency of sexual intercourse; (B) sexual desire; (C) sexual pleasure; (D) morning erections; (E) erections during sexual intercourse; (F) all criteria (A to E). $**p < 0.01$; $*p < 0.05$. Source: Supplement Q13, Q16, Q19, Q36, Q42, Q52

4.3 | Fears when starting TMC

At the time of choosing TMC, 86% of the men had fears about this method. Some of these fears decreased over time, while others

remained stable. The most frequent fears (70% of men) were about the method itself: discomfort, pain, method that was too difficult to access and/or too long to set up, lack of hindsight into a new method. Some of these fears ("delayed effectiveness"; "uncomfortable"; "time required

TABLE 5 Reasons for recommending this method

Main topics covered in the free text responses (n = 59)	Number of men (%)
Distribution of “contraceptive responsibility” (or burden, load)	29 (49%)
“Simple,” “easy to use,” “practical” method	27 (46%)
“Natural,” “non-hormonal,” “non-chemical” method	26 (44%)
“Efficiency”	25 (42%)
“No side effects” or “fewer side effects than other methods”	14 (24%)
Ecological, non-polluting	13 (22%)
Economic accessibility (“free” or “low cost” method)	13 (22%)
“Comfortable” or “no discomfort,” “little discomfort,” “pleasant”	9 (15%)
“Fertility control,” “paternity,” “contraception by the man himself”	5 (8%)

Note: The open-ended responses were written in free text and then analyzed and grouped by themes spontaneously present in each response. Source: Supplement Q82; Q, number of the question (Supplement).

to wear CU”) have already been reported.²⁶ Learning the time-limited but daily manipulation of the penis and scrotum, as well as the new testicular position, were unknown factors that may explain these fears. Indeed, the frequency of this type of concern was significantly reduced after the testing phase (Table 3).

Other fears related to sexuality (14%), infertility (13%), virility (8%), and testicular cancer (8% as already reported by some (“damage to virility; delayed reversibility”) in new fathers.²⁶ Studies have already shown that men who were asked about the possible use of male hormonal contraception were afraid of side effects and health implications. In 115 men, 71% associated the “male pill” with side effects.³⁰ In a study in which a male contraceptive pill was offered to 54 men, 53% of the respondents were concerned about possible biological side effects and 26% about adverse health effects.³¹ In the present survey, these fears appeared to decrease over time but not significantly; this should be further investigated in future studies on larger numbers.

4.4 | Contraceptive mental load

In addition, the proportion of men who expressed the fear of not being able to ensure the couple’s contraception on a daily basis remained stable between the time of choosing TMC (57%) and the spermatogenesis inhibiting phase (55%). The achievement of the contraceptive threshold as verified by the semen analysis at the end of the inhibitory phase appears to have resolved this fear; indeed, 63% (37/59) answered positively to the following question: “I was happy to ensure the couple’s contraception by a male method that is neither withdrawal nor the use of condoms” (SQ57). This answer clearly illustrates one of the aspects of the mental load associated with the man’s daily management of the couple’s contraception in real life. Other aspects are reflected by the proportion of men reporting either their satisfaction with having

assumed the different technical aspects of the method (80%) or having managed to wear the CU for 15 h a day (58%; SQ57). Some men went so far as to wear the CU more than 15 h/day (20%) for fear of an unwanted pregnancy (SQ77).

4.5 | Improvement of sexual satisfaction

Our survey found that the overall sexual satisfaction of TMC users increased significantly between the N-3 method of contraception (long before TMC) and the phase of contraception use of TMC. It seems difficult to compare our results with those of men using male hormonal contraception, which may involve excessive testosterone intake or require compensation for progestin-induced hypotestosteronaemia.³² On the other hand, we can compare our results regarding sexual pleasure with those existing for the main methods used at N-3 (male condom, pill, withdrawal, IUD). In the survey population, the proportion of men using male condoms decreased significantly between the N-3 and N-1 periods, with the main reason being a decrease in sexual pleasure. The role of decreased sexual pleasure in the non-use of male condoms has already been established in the literature.³³ Fewer data exist regarding withdrawal; however, among 300 Iranian women “using” withdrawal, 34% reported a decrease in sexual pleasure, and 42% reported a decrease in sexual pleasure in their partner.³⁴ In a population of 1101 women, female hormonal contraceptive methods have also been associated with decreased sexual pleasure.³⁵ Only the IUD has not been clearly associated with a decrease in sexual pleasure.³⁶

4.6 | Strengths and weaknesses of the study

Our survey has at least two strengths. First, a high participation rate (94%) suggests strong involvement and interest in male contraception in our population. Second, our survey reports for the first time the acceptability, experiences, fears, and satisfaction of a series of men who have used TMC as the only form of a couple’s contraception. With regard to the developing methods of male contraception based on inhibition of spermatogenesis, little information regarding their acceptability by men has been reported. The literature focuses on male hormonal contraceptives.^{22–25} For each of those studies, the initial assessment was based on the suppression of spermatogenesis: They reported that 50% to 66% of men would be willing to use it if it was available. The conditions of those assessments, in which the female partner had to continue using another contraceptive method, were not like the actual “real-life” conditions of our survey, in which TMC was the couple’s only contraception. The assessment of acceptability was therefore made in these studies^{22–25} without taking into account the risk for pregnancy. Nevertheless, these studies have provided information on men’s attitudes toward male contraception.

Our survey has limitations. First, the survey population may seem small (63 men). However, it is not different from that of the aforementioned studies^{22–25} on male hormonal contraception, which included 20, 38, 79, and 57 men, respectively. Second, our survey population

may not be representative of the population of men using male contraception as the unique couple contraceptive method. Indeed, TMC is less accessible and known by the general French population than condom and vasectomy.²⁶ The low accessibility of TMC consultations could have selected men much more interested in male contraception than men in the general population, and our results should be interpreted with this view. Nevertheless, this population is suitable for the study of men's motivations for choosing TMC, which was one of our survey's purposes. Third, our survey lacked a similar questionnaire for the female partners.

4.7 | Perspectives

A wider diffusion of the CU would be possible for Phase III testing, as soon as a public funding supports a multicentric trial in France, and as soon as other European teams are ready to participate. The results of our survey indicate opportunities for future studies of TMC users, in particular, studies of their female partners (especially the impact on their sexual satisfaction); and the real-life contraceptive efficiency of this method over the entire period of use of this historical cohort. Finally, a qualitative study on the social attitudes of men toward the availability of a male hormonal contraceptive suggested that Phase IV studies are necessary to establish long-term side effects³⁷; such a suggestion also seems valid for TMC.

5 | CONCLUSION

This first survey of the experience and acceptability of TMC in men using this method as a couple's only form of contraception showed that the men were mainly motivated to use a non-hormonal method that is regarded as "natural." Then, they rapidly adopted the method (despite frequent initial fears), and during the phase of contraception use, they described significantly improved sexual satisfaction with the method and reported confidence and support from their partner. These men successfully assumed the mental load of a daily action to provide the couple's contraception, and this improved their self-esteem. The main negative point was discomfort, which was reported by 24% of the respondents. The satisfaction score for using this method was high, and 100% of men reported they would recommend the method to other men. This positive evaluation, together with the already published contraceptive efficacy and reversibility of TMC, should encourage the development of this method.

CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

AUTHOR CONTRIBUTIONS

Research conception and design: RM and JP. Questionnaire design: All authors. Participants' solicitation and inclusion: RM. Data acquisition: SJ. Data analysis and interpretation: SJ, RM and JP. Statistical analysis:

SJ. Drafting of the manuscript: SJ, RM and JP. Critical revision of the manuscript, approval of final manuscript: All authors.

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