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Cross-sectional survey of testicular lift contraceptive devices: safety, acceptability, efficacy.

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GUIDARELLI Manon

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Examiners of the thesis :

Pr Moustapha DRAME (President)

Prof. Mathieu

NACHER Dr. Daniel

MURILLO Dr. Alan

CHARISSOU

Dr Célia BASURKO (Thesis director)

The President of the University of the West Indies: Michel GEOFFROY
Dean of the UFR Santé des Antilles : Suzy DUFLO
Vice-Dean of the Antilles Health Department: Christophe DELIGNY

University Professors - Hospital Practitioners	
Antoine ADENIS Antoine.adenis@ch-cayenne.fr	**Epidemiology, health economics and prevention** CH de CAYENNE Tel: 0594 39 50 50
Véronique BACCINI veronique.baccini@chu-guadeloupe.fr	**Haematology** CHU of Guadeloupe Tel: 05 90 89 10 10
Pascal BLANCHET pascal.blanchet@chu-guadeloupe.fr	**Urological Surgery** CHU of Guadeloupe Tel: 05 90 89 13 95
Sébastien BREUREC sbreurec@gmail.com	**Bacteriology & Venereology** CHU de Guadeloupe Tel: 05 90 89 12 80
Laurent BRUREAU laurent.brureau@chu-guadeloupe.fr	**Urology** CHU de Guadeloupe Tel: 05 90 89 10 10
André CABIE andre.cabie@chu-martinique.fr	**Infectious Diseases** CHU de Martinique Tel: 05 96 55 23 01
Philippe CABRE philippe.cabre@chu-martinique.fr	**Neurology** CHU de Martinique Tel: 05 96 55 22 61
Raymond CESAIRE raymond.cesaire@chu-martinique.fr	**Bacteriology-Virology-Hygiene option virology** CHU de Guadeloupe Tel: 05 96 89 10 10
Nadège CORDEL nadege.cordel@chu-guadeloupe.fr	**Dermatology & Venereology** CHU de Guadeloupe Tel: 05 90 89 10 10
Pierre COUPPIE pierre.couppie@ch-cayenne.fr	**Dermatology** CH de CAYENNE Tel : 05 94 39 53 39

University Professors - Hospital Practitioners	
CHERET Antoine antoine.cheret@chu-guadeloupe.fr	**Therapeutics-Pain Medicine** CHU de Guadeloupe Tel: 05 90 89 10 10
Michel DE BANDT michel.debandt@chu-martinique.fr	**Rheumatology** CHU of Martinique Tel: 05 96 55 20 00
Bertrand De TOFFOL Bertrand.detoffol@ch-cayenne.fr	**Neurology** CH de CAYENNE Tel: 0594 39 50 50
Magalie DEMAR - PIERRE magalie.demar@ch-cayenne.fr	**Parasitology and Infectiology** CH de CAYENNE Tel: 05 94 39 53 09
Christophe DELIGNY christophe.deligny@chu-martinique.fr	**Internal Medicine** CHU of Martinique Tel: 05 96 55 22 55
Félix DJOSSOU felix.djossou@ch-cayenne.fr	**Infectious and tropical diseases** CH de CAYENNE Tel: 05 94 39 50 50
Moustapha DRAMÉ moustapha.drame@chu-martinique.fr	**Epidemiology, Health Economics** CHU de Martinique Tel: 05 96 55 20 00
Suzy DUFLO suzy.duflo@chu-guadeloupe.fr	**ENT - Cervico-Facial Surgery** CHU de Guadeloupe Tel: 05 90 93 46 16
Narcisse ELENGA Narcisse.elenga@ch-cayenne.fr	**Paediatrics** CH de CAYENNE Tel : 05 94 39 77 37
Loïc EPELBOIN loic.epelboin@ch-cayenne.fr	**Infectious diseases** CH de CAYENNE Tel: 05 94 93 50 00
Karim FARID karim.farid@chu-martinique.fr	**Nuclear Medicine** CHU of Martinique Tel: 05 96 55 21 67
Jocelyn INAMO jocelyn.inamo@chu-martinique.fr	**Cardiology** CHU de Martinique Tel: 05 96 55 23 72 - Fax: 05 96 75 84 38

Hatem KALLEL hatem.kallel@ch-cayenne.fr	**Intensive care medicine** CH de CAYENNE Tel: 0594 39 50 50
University Professors - Hospital Practitioners	
Annie LANNUZEL annie.lannuzel@chu-guadeloupe.fr	**Neurology** CHU de Guadeloupe Tel: 05 90 89 14 13
Harold MERLE harold.merle@chu-martinique.fr	**Ophthalmology** CHU of Martinique Tel: 05 96 55 20 00
Mathieu NACHER mathieu.nacher@ch-cayenne.fr	**Epidemiology, Health Economics and Prevention** CH de CAYENNE Tel: 05 94 93 50 24
Rémi NEVIERE Remi.Neviere@chu-martinique.fr	**Physiology** CHU de Martinique Tel: 05 96 55 20 00
Olivier PARANT nicolas.venissac@chu-martinique.fr	**Gynaecology-Obstetrics** CHU of Guadeloupe Tel: 05 90 89 10 10
Stéphanie PUGET stephanie.puget@aphp.fr	**Neurosurgery** CHU of Martinique Tel: 05 96 55 20 00
Chantal RAHERISON-SEMJEN marie-laure.mistrih@chu-guadeloupe.fr	**Pneumology, Addictology** CHU de Guadeloupe Tel: 05 90 89 10 10
Dabor RESIERE dabor.resiere@chu-martinique.fr	**Pain therapy/medicine** CHU de Martinique Tel: 05 96 55 20 00
Pierre-Marie ROGER pierre-marie.roger@chu-guadeloupe.fr	**Infectious and tropical diseases** CHU de Guadeloupe Tel: 05 90 89 10 10
François ROQUES chirurgie.cardiaque@chu-martinique.fr	**Thoracic and Cardiovascular Surgery** CHU de Martinique Tel: 05 96 55 22 71
Jean ROUDIE jean.roudie@chu-martinique.fr	**Digestive Surgery** CHU de Martinique Tel: 05 96 55 21 01 - Tel: 05 96 55 22 71
Maturin TABUE TEGUO maturin.tabueteguo@chu-guadeloupe.fr	**Internal Medicine: Geriatrics and Biology of Ageing** CHU de Guadeloupe Tel: 05 90 89 10 10

André-Pierre UZEL andre-pierre.uzel@chu-guadeloupe.fr	**Orthopaedic Surgery and Traumatology** CHU de Guadeloupe Tel: 05 90 89 14 66
University Professors - Hospital Practitioners	
Magaly ZAPPA magaly.zappa@ch-cayenne.fr	**Radiology and medical imaging** CH de CAYENNE Tel: 05 94 93 50 00

Associate University Professors - Hospital Practitioners	
Stéphane AMADEO stephane.amadeo@chu-martinique.fr	**Psychiatry** CHU of Martinique Tel: 05 96 55 20 00
Jacqueline DELOUMEAUX-TYNDAL jacqueline.deloumeaux@chu-guadeloupe.fr	**Epidemiology, health economics and prevention** CHU de Guadeloupe Tel: 05 90 89 10 10
Papa Ngalgou GUEYE papa.GUEYE@chu-martinique.fr	**Emergency Medicine** CHU of Martinique Tel: 05 96 55 20 00
Hossein MEHDAOUI hossein.mehdaoui@chu-martinique.fr	**Intensive care medicine** CHU de Martinique Tel: 05 96 55 20 00
Stéphane PLAWECKI splawecki@icloud.com	**Orthopaedic Surgery** CHU of Martinique Tel: 05 96 55 20 00
Patrick PORTECOP patrick.portecop@chu-guadeloupe.fr	**Emergency medicine** CHU of Guadeloupe Tel: 05 90 89 10 10
Marc PUJO Marc.pujo@ch-cayenne.fr	**Emergency Medicine** CH de CAYENNE Tel : 05 94 93 50 00

Senior Lecturer - Hospital Practitioner	
Cindy BERAL cindy.beral@chu-guadeloupe.fr	**Ophthalmology** CHU of Guadeloupe Tel: 0590 89 10 10
Romain BLAIZOT **Blaizot.romain@ch-cayenne.fr**	**Dermatology-Venereology** CH de CAYENNE Tel: 05 94 93 50 00

Moana GELU-SIMEON moana.simeon@chu-guadeloupe.fr	**Gastroenterology and hepatology** CHU de Guadeloupe Tel: 05 90 89 10 10
Clarisse JOACHIM-CONTARET clarisse.joachim@chu-martinique.fr	**Epidemiology, health economics and prevention** University Hospital of Martinique Tel: 05 96 55 20 00
Senior Lecturer - Hospital Practitioner	
Marie-Laure LALANNE-MISTRIH marie-laure.mistrih@chu-guadeloupe.fr	**Nutrition** CHU de Guadeloupe Tel: 05 90 89 13 00
Amélie ROLLE amelie.rolle@chu-guadeloupe.fr	**Anesthesia and Intensive Care Unit** CHU de Guadeloupe Tel: 05 90 89 10 10
Emmanuelle SYLVESTRE Emmanuelle.sylvestre@chu-martinique.fr	**Biostatistics, Medical Informatics and Technology** CHU de Martinique Tel : 05 96 55 20 00
Fritz-Line VELAYOUDOM épse CEPHISE fritz-line.valayoudom@chu-guadeloupe.fr	**Endocrinology** CHU de Guadeloupe Tel: 05 90 89 13 03

Senior Lecturer	
Yoann GARNIER **Yoann.garnier@inserm.fr**	**Molecular and Cellular Biology** INSERM

Associate University Lecturer - Hospital Practitioners	
Maïder FIRPION-COPPRY maider.coppry@chu-guadeloupe.fr	**Hospital Hygiene** CHU of Guadeloupe Tel: 05 90 89 10 10

University Professor of General Medicine	
Jeannie HELENE-PELAGE jeannie.pelage@wanadoo.fr	**General Medicine** CHU of Guadeloupe / Private practice Tel: 05 90 84 44 40

Associate Professor of General Medicine

Franciane GANE-TROPLENT franciane.troplent@orange.fr	**General medicine** Private practice Tel: 05 90 20 39 37

Senior Lecturer in General Medicine	
Philippe CARRERE philippe.carrere@gmail.com	**General medicine** Private practice

Associate Professor of General Medicine	
KANGAMBEGA-CHATEAU-DEGAT Walé drwcdk@gmail.com	**General medicine** Private practice
Franck MASSE mspducos@gmail.com	**General medicine** Private practice

Professor Emeritus	
Eustase JANKY	**Gynaecology-Obstetrics** eustase.janky@univ-antilles.fr

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SUMMARY

Objectives:

Principal: to estimate the safety of at least six months' use of
Testicular uptake contraception (TRC).

Secondary: to describe the socio-demographic and medical profile, the different CRT devices used, the real-life acceptability of the CRT devices, the effectiveness of the CRT devices used, to propose new research leads and protocol, and recommendations for use, based on the results.

Materials and Methods :

A descriptive, cross-sectional, international survey, conducted from 14 December 2021 to 4 March 2022 by means of an anonymous online questionnaire among participants who have used testicular contraception for at least 6 months.

Results :

1050 people responded, 970 responses were analysed. Several CRT devices were used for an average of 14.1 months [+/- 8.7], the Andro-switch device was the majority (96.0%). Most participants did not use the CRT devices as recommended: 44.8% between 15 and 17 hours per day, 68.6% initial spermograms and 74.0% initial medical consultation. Adverse events were frequent, cutaneous and mild. Unexpected adverse effects on urinary function were described. The ASEX sexual dysfunction score before CRT and at the time of the study was unchanged. Satisfaction with sexual quality of life according to the MSHQ was significantly increased for participants and their sexual partners after CRT. Satisfaction was very high (86.5%), and the feeling of constraint low (less than 10% except for sports activities 20%). The main obstacles identified were the need to regularly reposition the testicles, and the accessibility of medical support and spermograms. The contraceptive threshold had been reached by 92.6% who had performed a spermogram to check effectiveness. Six unplanned pregnancies occurred during the inhibition phase (before the contraceptive threshold was reached or within the first three months of use). The estimated Pearl Index after one year of the contraceptive phase (contraceptive threshold reached), and discontinuation of additional contraception, during 3727 exposure cycles, was 0.0%.

Conclusion:

CRT devices appear to be acceptable from a health perspective in terms of adverse effects and effects on sexuality. However, they are not used as recommended. Further studies are needed, as well as training of health professionals in the monitoring of this contraception, and improving access to spermograms.

Key words: male thermal contraception; testicular lift contraception; adverse effects; acceptability; efficacy

INTRODUCTION

Sexuality is a fundamental human need and, depending on sexual practices, the ability to control one's fertility is a major issue in terms of public health and human rights. The right to contraception is therefore recognised as one of the UN's sustainable development goals [1].
However, the current contraceptive context is one of growing public distrust of the available hormonal contraceptive methods: according to the WHO, worldwide, two thirds of sexually active women would like to reduce or stop using contraception because of an adverse effect [2]. In France, the use of hormonal contraception, which is still in the majority, has nevertheless continued to decrease since the crisis of the 3rd and 4th generation pills [3].

At the same time, the reversible contraceptive offer remains very limited for males, consisting of the external condom and the withdrawal method, whose Pearl indices are too high and too little studied (respectively 15/100 and 22/100 use in the first year) [4, 5].

However, several so-called "male" contraceptive methods have been in development for more than thirty years, without being effectively marketed: hormonal, iono-mechanical (e.g. RISUG, VASAGEL), and thermal methods [6].
Obstacles to the development of these contraceptives have been identified; these are economic, political and social [7]. It has been noted that little financial investment is allocated to the development of these methods, which are considered unprofitable by the pharmaceutical industry [8]. Public health policies have invested little in the field of "male" contraception in France in recent years [9, 8]. From a social point of view, since the 1960s, contraception has been seen as a female responsibility; men are excluded from the health system in this respect, considered as not requiring contraception and potentially irresponsible [7]. There also seems to be a confusion of representation between fertility, sexuality and virility, where impaired fertility would be perceived as a decrease in virility, and would imply an endangerment of sexuality [10].

These social representations are in contradiction with several studies, which have proven the acceptability of contraception taken over by men, especially in the post-partum period [11], as well as the existence of a demand from individuals and couples to use new male contraceptive methods if they were available [12].

In this socio-political context, thermal contraception methods have the advantage of being low cost and not requiring surgical or pharmaceutical treatment, making them accessible to the population independently of the health system. They are based on the inhibition of spermatogenesis by raising testicular temperature to reach the contraceptive threshold of less than one million sperm per millilitre [13]. Two main methods have been described: a large temperature rise (generated by an external heat source) or a moderate temperature rise (generated by body heat) [6].

Moderate temperature elevation can be achieved by raising the testicles near the external inguinal opening. The testicles are then held in place by a contraceptive undergarment developed and studied by Dr Mieusset at the Toulouse University Hospital since the 1990s [14, 15, 16, 17]. The protocol for use consists of wearing the device for fifteen hours a day and includes regular verification of the contraceptive threshold by a spermogram [18]. This testicular lift device has been shown to be effective and reversible over a 4-year period in a small number of participants [14]. Recently, the acceptability of this device has been proven among 63 users [19].

In recent years, other devices that allow the testicles to be lifted into the inguinal groin have emerged, either spontaneously or via activist groups for the development of this method of contraception such as ARDECOM (Association for Research and Development of Male Contraception) [20]. Currently, the most widely used are the silicone device Andro- switch® [21] and self-made cloth devices such as the jock-strap. Tutorials are available on the internet for making your own device (Appendix 1). To date, no interventional studies have been carried out on these new devices, whose protocols for use are in all respects similar to that developed by Dr Mieusset.

In contrast to the health system in terms of health authorisation [22] and training of health professionals, a fraction of the single or couple population uses testicular uptake contraceptive devices (TUCs) in ways that are not well known and for which little scientific data exists on a large scale, particularly on adverse effects. A 2019 survey of the Andro-switch device after a minimum of three months of use [23] found 27% did not perform a spermogram to verify the effectiveness of the device. In this study, 88% of users reported use for less than six months, and of those who discontinued use, 83% did so within the first six months of use. Health professionals and associations (CPF, ARDECOM, GARCON, THOMA BOULOU, SLOWCONTRACEPTION) emphasise the lack of data and the lack of training of health professionals on the subject, and advocate for larger clinical studies on the subject. [11, 24].

In this context, and in anticipation of future clinical studies, we propose an inventory of the current practice of contraception by testicular ascent, whatever the device used, as no study of this type exists on the subject. We have constructed an international descriptive survey in French, in collaboration with activists and health professionals in need of scientific data.
The main objective of this study is therefore to describe the current use of testicular lift contraceptive devices in terms of safety. It will also describe the acceptability, and document the contraceptive efficacy. Reversibility will not be studied.

In this study, for the sake of clarity, we will use the masculine form of agreement
The term "neutral" is used to refer to both male and female users of CRT and their sexual partner(s).

THERMAL CONTRACEPTION

I. History of scientific research

The relationship between an increase in body temperature and the disruption of fertility has been presumed since antiquity: in Hippocrates' "Aphorisms" there are references to a dysfunction in the flow of "pneuma" caused by too much body heat, leading to a lack of "semen" [25].

From 1920 onwards, the role of the scrotum in the thermal regulation of the testicles and the physiology of spermatogenesis was demonstrated in animals and then in humans. Several risk factors for alteration of this thermal regulation system were identified, which could explain infertility due to oligospermia: varicocele, high obesity, fever, cryptorchidism, hot baths, sauna, tight clothing, occupational exposure to high heat, etc. [26, 27, 28, 29]. [26, 27, 28, 29]

The first studies looking at increasing intra-scrotal temperature as a contraceptive method were carried out from the 1940s onwards, using hot baths. Dr. Voegli initiated a contraceptive protocol in India during a period of famine between 1930 and 1950 by daily exposure of 45 minutes to a hot bath of 46.7°C for 25 days, and observed reversible infertility from 4 to 7 months. A similar protocol was applied in a study by Dr Tokuyama in 1960 in Japan, by daily exposure of 30 minutes to a bath between 43°C and 47°C for 25 days, with maintenance baths every 3 weeks. The results (unpublished) are reported in a few articles [6, 30].

In 1965, Robinson and Rock in the United States showed that a reversible decrease in sperm concentration was observed by thermally insulating the scrotum, by wearing a "jock-strap" type undergarment used at the time for athletes, to which an insulating polyester/waxed cloth envelope was added [26]. Later in 1992, Shafik developed a polyester scrotal insulation undergarment in dogs and then in humans (n=14), and found reversible azoospermia in all participants [31].

From the 1980s onwards, the elevation of testicular and epididymal (rather than scrotal) temperature is studied as a contraceptive method, inducing "artificial cryptorchidism". Several techniques were studied.

Firstly, the effect of artificial cryptorchidism on spermatogenesis was studied in animals. A first technique of testicular "suspension" by surgical fixation of the testicles at the level of the superficial inguinal pouch, developed by A. Shafik in Egypt, leads to a drastic decrease in the number of spermatozoa in the sperm in dogs. In 1991, A. Shafik obtained similar results in humans (n=15) by suspending the testicles in the inguinal position (by suture) [32].

At the same time, another technique for artificial cryptorchidism was studied: the testicular "lift" technique developed by Dr Mieusset in France, obtained by wearing a support undergarment to position and maintain the testicles near the external orifice of the inguinal canal (without fixation) [14]. As this second technique was considered more acceptable (as it is less invasive than surgery), Dr Mieusset will develop a contraceptive device allowing correct maintenance of the testicles in the inguinal position and inhibition of spermatogenesis in men after 3 months of use, and will open a dedicated specialised contraceptive consultation until December 2021 within the framework of a TAU.

II. Effect of increased temperature on spermatogenesis

Moderate elevation of testicular temperature leads to a reversible disturbance of spermatogenesis. There is a reduction in the number of sperm produced, a decrease in their mobility and an alteration in their morphology.
This is due to apoptosis of the germ cells (spermatocytes and spermatids), without spermatogonial (stem cell) damage. [33].
Alterations in genetic material have also been reported in 2012 and 2019 [34, 33].

III. Different approaches to thermal contraception

From a contraceptive point of view, there are three different methods of achieving a rise in testicular temperature.

A first method is the provision of a relatively high exogenous heat source (between 41°C and 46°C), which causes the thermal regulation capabilities of the scrotum to be exceeded. The heat source can come from exposure to hot baths or saunas [35, 36], or be obtained by wearing heat-generating underwear such as the Spermapause device developed by a French engineer (O.Nago) in 2015.
The contraceptive protocol usually consists of a daily exposure of between 30 minutes and three hours depending on the method used [6]. This method does not require a change in testicular positioning.
No clinical studies have been conducted to date on the Spermapause device, and no recent studies have been conducted on the Spermapause device.
To our knowledge, no studies have been carried out on the effectiveness of hot baths and saunas.

A second method is the relocation and retention of the testes within the inguinal groin, which results in the "shunting" of the scrotal thermal regulation system, and thus a moderate increase in testicular temperature by body heat. This positioning results in an average rise in testicular temperature of 1.8°C. Several efficacy studies have been conducted in small numbers [17].

A third method is thermal insulation of the scrotum, preventing the scrotal regulatory system from venting heat to the outside, using insulating underwear (e.g. polyester). This technique is not widely used and has been little studied since the 1990s [26, 31].

IV. The contraceptive threshold

As contraception that inhibits spermatogenesis (hormonal, thermal, chemical) does not always result in azoospermia (absence of sperm visualised on the spermogram), the question arose of defining the sperm concentration that induces effective contraception.

Studies on the efficacy of hormonal contraception in men by injection of testosterone on sperm concentration were conducted by the WHO from the

1990 and established an acceptable contraceptive threshold below which contraception was considered effective (updated in 2006) [37, 38].

This contraceptive threshold is accepted for any contraceptive method in connection with a decrease in sperm concentration in the ejaculate.

The contraceptive threshold is set at less than one million sperm per millilitre.

V. Testicular uptake contraception (TRC) protocol [18].

The recommendations for use are based on research protocols conducted by Dr Mieusset. It is recommended that the CRT device be worn for a minimum of fifteen hours a day, every day, during the waking period.

Contraception is considered effective if the contraceptive threshold of less than one million sperm per millilitre is achieved on two consecutive spermograms 3 weeks apart. Monitoring of the contraceptive threshold is recommended after 3 months.

Several phases can be described [39]:

- Inhibition phase: between the start of use and reaching the contraceptive threshold
- Contraceptive phase: from the moment the contraceptive threshold is reached (and it can be used as the sole contraceptive device).
- Restoration phase: between stopping use and restoring settings sperm.

Certain medical precautions have been established when using a CRT.
We have differentiated several categories of precaution according to the assumed medical purpose.

1) Personal precautions

Initial medical consultation and follow-up

An initial medical consultation is recommended to screen for contraindications and STIs, the issuing a prescription to perform a spermogram before starting contraception.
Regular medical follow-up is recommended to monitor the occurrence of adverse events and the effectiveness of the method.

Contraindications:

Certain contraindications have been established. These concern anatomical pathologies or malformations that may have an impact on the health of the user when using a CRT. Certain pathologies contraindicate CRT because they may intrinsically have an impact on fertility (cryptorchidism, testicular ectopy).

The contraindications are as follows:

- History of current or past (treated) testicular descent disorders: cryptorchidism and/or testicular ectopy
- Treated or untreated inguinal hernias (relative contraindication for the net)
- Testicular cancer
- Varicoceles grade 3
- Obesity (BMI > 30)
- Significant perineal dermatological lesions (eczema, psoriasis, dermatophytes...)
- Surgically fixed testicular torsion

2) Contraceptive precautions

As CRT requires a delay of between 2 and 4 months before being effective on fertility, it is recommended that additional contraception be used until the contraceptive threshold is reached, verified by spermogram.

It is recommended that a control sperm count be performed regularly (ideally every 3 months) to ensure that sperm concentrations do not rise above the contraceptive threshold.

In case of omission, although there is no established protocol, it is recommended to use additional contraception for three months, and to check that the concentration remains below the contraceptive threshold by a spermogram.

3) Reproductive precautions

An abnormal initial spermogram is a precautionary contraindication in terms of
The reversibility of CRT in the case of an abnormal initial sperm count is not known.

Standards of a spermogram [40] :

- Sperm concentration > 15 million / ml
- Progressive sperm motility (so-called "a+b motility") > 32
- Normal form sperm > 4%.

In view of the lack of knowledge regarding the evolution of a pregnancy following CRT, and the evidence of alteration of genetic material in the event of an increase in testicular temperature [34], it is currently recommended to wait until the spermogram parameters have returned to normal before planning a pregnancy.

If a pregnancy occurs during the use of CRT, close monitoring of
pregnancy should be considered.

VI. The different devices for testicular uptake contraception (TRC).

1) Dr Mieusset's contraceptive device [18].

The device was developed from commercial underwear, modified to allow the penis and scrotal skin to pass through an opening, and reinforced with fabric strips. A ring of fabric was added to the base of the penis to provide better support. Dr Mieusset collected the necessary measurements during the first contraceptive consultation, the device was then made by seamstresses and given to the patient. This consultation therefore required a trip to the Toulouse University Hospital.

2) Self-made devices

The contraceptive jockstrap [41].

The jockstrap was invented in the 1980s based on Dr Mieusset's model of contraceptive underwear. The device is slimmed down, instead of being fashioned from a full undergarment, it is constructed with elastic bands around the waist and hips to hold a ring of fabric around the penis. As with previous contraceptive devices, the skin of the scrotum and the penis are passed through the ring to press the testicles against the body.

The Breton collective "Thoma Boulou" reappropriated the jockstrap around 2010, and increased its diffusion in France. In 2018, E. Taverne, via the Toulouse association "GARCON", will improve and standardise the jockstrap manufacturing protocol (Appendix I).
Currently it is possible to make a jockstrap via tutorials on the internet, or participatory workshops in several cities in France.

Other Do It Yourself (DIY) contraceptive devices

Other tutorials suggest how to make your own fabric devices for testicular enhancement, including from recycled bras.

3) Silicone rings

The Andro-switch silicone device [21]

Invented by Maxime Labrit in 2018, this standardised device is made of platinum-based silicone (used to manufacture medical prostheses in particular). It is a ring, about 1.5cm wide, with several diameter sizes available depending on the user's measurements. The inside is lined with protuberances that improve its adherence to the skin.
It is slipped onto the penis, the user then passes the skin of the scrotum through the ring, while leaving the testicles in their high position, near the inguinal pouches.

Other silicone devices

In some regions of France, user groups and associations are making their own silicone rings.

VII. Terminology used in the study

As the terminology for these new contraceptive methods is still being developed, names such as "thermal contraception" or "thermal (male) contraception" will be found in the scientific literature and in media articles. As seen above, these terms do not distinguish between testicular heating using body heat and heating using an exogenous heat source (underwear with heat generator, hot baths, sauna). Some articles use the term "contraception by moderate elevation of testicular temperature"; however, this does not distinguish the method of scrotal isolation from that induced by artificial cryptorchidism.
In this study, we used the terminology "testicular uptake contraception" (TUC)
to avoid confusion.

MATERIAL AND METHOD

I. Type of study

This is a cross-sectional descriptive study conducted by means of an online survey.

II. Conduct of the study

The survey was offered in the form of a self-administered questionnaire on the WEPI (Web questionnaires for epidemiologists and healthprofessionals) website from 14 December 2021 to 4 March 2022. The questionnaire was anonymous and in French. A page was dedicated to this study on the CIC Antilles-Guyana website. It contained a description of the study, the study's information leaflet, a searchable version of the questionnaire and a link to the online questionnaire.
The data collected was stored online on secure European servers, then exported in XLS format and stored on the Cayenne Hospital's computer server.

The decision to conduct a dematerialised survey was motivated by the likely geographical dispersion of the targeted subjects, both nationally and internationally, especially as the dissemination of information about this contraceptive method appeared to be mainly via the internet and activist networks (respectively 51% and 32% concerning Dr Mieusset's contraceptive device between 2011 and 2019 [39], 43% and 21% concerning the Andro-switch device in 2020) [23].
The questionnaire was in French, as the majority of current users of a TRM probably reside in France or Belgium according to the information collected from the different user groups.

III. Inclusion criteria

The inclusion criteria were the use of testicular lift contraception for at least six months, regardless of the testicular lift device used. Participants had to be of legal age, give their consent, and understand the French language.

People using the Spermapause® device were not included in the study. Indeed, as previously mentioned, this device does not follow the same protocol of use, and in particular does not require testicular lifting.
In order to reduce bias, participants reporting chemotherapy or hormone therapy that may reduce fertility were not included, as these treatments are likely to have significant adverse effects on sperm concentration and sexual quality of life.

IV. Exclusion criteria

We excluded from the analysis those participants whose duration of use was less than six months, based on the start dates of use (and end dates of use if applicable).

V. Construction of the questionnaire

The construction of the questionnaire required several initial interviews with people using this contraception, activists, and health professionals involved in the subject.
In particular, several interviews were conducted with Dr Joubert, who wrote his thesis on the acceptability of Dr Mieusset's contraceptive device [39], with Rouanet C., midwife and author of a survey on the acceptability of the Andro-switch device [23], and with Labrit M.,

designer of the Ando-switch device, and Balaud C and Taverne E., involved in the associations ARDECOM, GARCON and THOMA BOULOU, for the jock-strap device.

The questionnaire was reviewed several times by health professionals from different specialities and regions in various environments (France, French Guyana, Belgium).

A working group was set up to ensure that the questionnaire matched the users' expectations. This group consisted of the study leader, a public health doctor and three non-medical users or former users of testicular contraception. These three people were active in activism on the subject, and were active in the user community.
A test sample of 9 users, three of whom were neither activists nor health professionals, was conducted before final validation of the questionnaire.

The questionnaire finally contained 117 questions, grouped into nine themes: socio-economic determinants, medical profile, contraceptive device(s) used, methods of use, adverse effects, sexuality, spermograms, satisfaction, reasons for stopping.
The estimated time to complete the questionnaire was 30 minutes.

VI. Objectives

The three priority themes of the review of the use of contraception by testicular ascent among French-speaking users are those that are essential for any contraception [42]: safety, acceptability, efficacy. Reversibility was not studied in this study.

Main objective

To estimate the safety of at least six months' use of testicular rebreathing contraceptive devices (TRDs)

Secondary objectives

1) Describe the socio-demographic and medical profile of the study population.

2) Describe the different CRT devices used in the study population.

3) To estimate the real-life acceptability of CRT devices in the study population.

4) To describe the effectiveness of the CRT devices used in the study population.

5) Propose new research avenues and protocols, and recommendations for use, based on the results.

VII. Judging criterion

Primary endpoint

Health safety was assessed by three criteria:

- Documentation and proportion of adverse events that have occurred.
- The proportion of compliance with the recommendations for the use of contraception by testicular ascent (according to the protocol established by Dr Mieusset).
- The evolution of the sexual dysfunction score (based on the standardised ASEX questionnaire) and the evolution of the sexual quality of life (based on four items of the standardised MSHQ questionnaire) before the use of CRT and at the time of the study.
  The standardised ASEX questionnaire (included in the questionnaire, see Appendix x) assesses psychological and organic sexual functions. Sexual dysfunction is recognised either by an overall score greater than or equal to 19, or by one item with a score greater than 4, or by three items with a score greater than or equal to 4.
  The standardised MSHQ questionnaire explores male sexuality as a whole. We selected 4 items exploring satisfaction with one's sexuality, and in particular with the relationship with sexual partner(s).

Secondary endpoints

1) Collection of socio-demographic and medical variables of the study population: age, place of residence, sex, gender, level of education, occupation, marital status, paternity, medical and contraceptive history.

2) Collection of the different CRT devices used in the study, and their duration of use.

3) Acceptability was described by 3 criteria:

- Proportion of satisfaction with CRT devices: overall satisfaction, comparison with satisfaction with previous contraception, comparison according to devices used.
- Documentation of barriers: during daily use and proportion of constraints felt according to activities.
- Documentation of interactions with sexual partners: ways of approaching the subject and obstacles encountered.
- Documentation of accessibility: proportion of access to information about CRT, to support from a health professional, to medical follow-up and to the performance and understanding of spermogram results.
- Proportion of dropouts, and collection of reasons for dropouts.

4) Effectiveness was documented by 4 criteria:

- Proportion reaching the contraceptive threshold
- Proportion of rise in concentration above the contraceptive threshold
- Collection of reasons for not reaching the contraceptive threshold
- Proportion of unintended pregnancy and estimation o f a Pearl Index at the contraceptive phase

We looked for an association between reaching the contraceptive threshold and the number of hours of daily device use.

5) Collection of suggestions for improvement of the use protocol.

VIII. Survey dissemination and recruitment

Another objective of the above-mentioned working group was to orchestrate the widest possible dissemination of the study. This collaboration resulted in the creation of a dissemination poster, the identification of partners to be approached at national and international level and of the different communication channels to be used, as well as the coordinated planning of the different follow-up actions.

Recruitment was organised with the collaboration of activist groups (ARDECOM, GARCON, THOMA BOULOU, Slowcontraception) as well as with networks of health professionals potentially involved in the medical monitoring of this contraception (Family Planning Centre, CEGGID, general practitioners, urologists).

Various dissemination channels were used, such as social networks (Facebook, Instagram, Discord, etc.), speaking engagements at congresses (Family Planning Centre), publications in newsletters or mailing lists via THOREME, the ARS of Guyana, the National Institute for Prevention and Health Education, the College of Public Health Interns, etc.

IX. Expected number of subjects

The number of people using testicular contraception in December 2022, in France or in other countries, was unknown. An estimate of about 3000 users in France seemed likely (as previously discussed).
An online survey from October 2020 on the use of the Andro-switch device had collected just over 200 responses in three months.
In our study, it was estimated that at least 200 entries would be collected over a three-month period.

X. Statistical analysis

The descriptive and exploratory analysis of the data was carried out using STATA 16 software.
Categorical variables were described by numbers and percentages of the total sample or subgroups. Continuous variables were described by the mean and standard deviation (normal distribution) or by the median and interquartile range (IQR). Bivariate analyses were performed using the Chi2 test in the case of independent data (or Fischer exact test). In situations of non-independence (e.g. comparison of MSHQ items on sexual quality of life before RTC and at the time of the survey), proportions were compared using the MacNemar test.

The open questions were analysed by thematic grouping. Anonymous quotes from the open questions are sometimes transcribed in the manuscript and illustrate the quantitative results.
The percentage of missing DM values (response modality "do not wish to answer") was less than 1% for almost all questions. They were not included in the analyses.
However, for questions with a higher percentage of missing values (between 1 and 5%), i.e. those on spermogram, MSHQ, degree and occupation, the DMs were represented, and in the statistical analysis of the sexual quality of life of the MSHQ, the DMs were imputed as "dissatisfied" or "not - extremely satisfied".

XI. Ethical Statement

This study falls within the scope of Research not Involving the Human Person and is covered by the
The study was conducted in accordance with the "Reference Methodology" (MR-004) for which CHC signed a compliance undertaking on 21/12/2021. A privacy impact assessment has been carried out and a summary of the study has been published on the Health-Data-Hub website. The legal basis for the data processing is the public interest mission.

The authors declare no conflict of interest.

It seems important to emphasise that those who agreed to participate in this survey had been using a TRM for at least 6 months on their own. There was no promotion of these contraceptive devices. Furthermore, the 3-month inclusion period did not allow for the initiation of a CRT for the sole purpose of participating in this survey.

RESULTS

I. Flow chart

The flow chart for the study is shown in Figure 1.

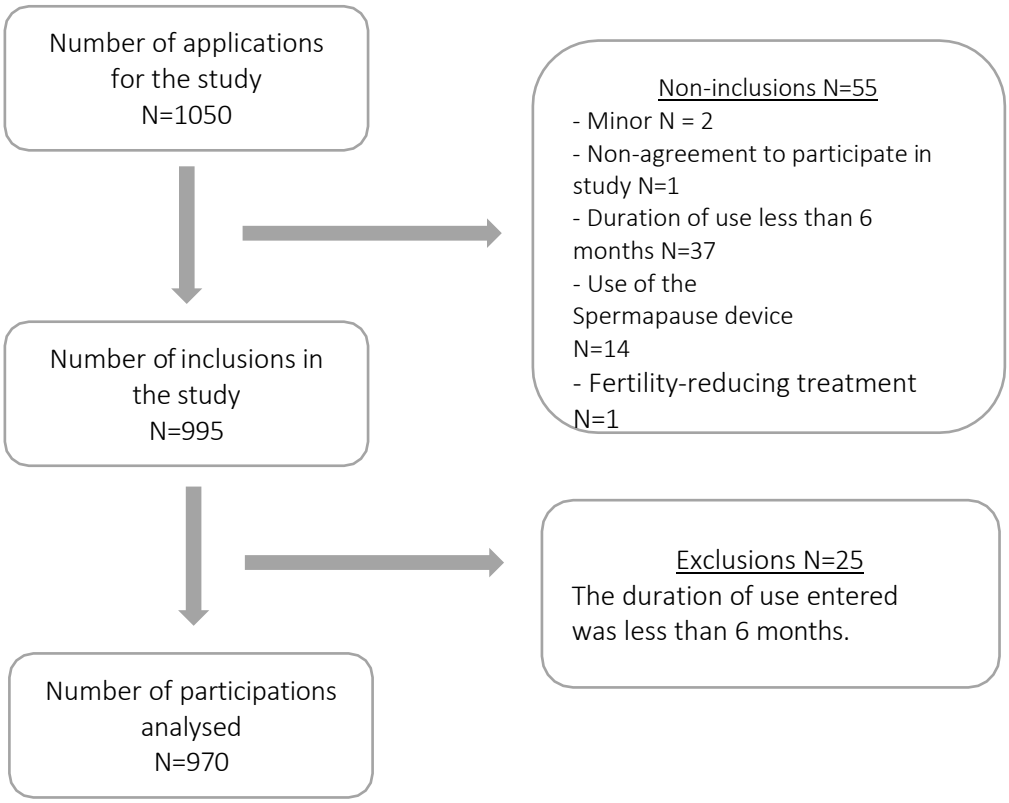

Figure 2. Flow chart of the TESTIS-21 study.

II. Characteristics of the study population

1. Socio-demographic profiles of the study population

The description of the population is presented in Table 1. The study population was under 40 years of age (96.3%) and male. Most participants lived in France (Appendix II), were in a sexually exclusive couple relationship and had no children.

Table 2 shows a level of education equal to or higher than BAC+3 (66.2%). The three most represented professions were managers and higher intellectual professions; craftsmen, shopkeepers and business owners; and students according to the international classification of professions [43].

Table 1. Socio-demographic characteristics of the population. TESTIS_2021.

Variables	Number (%) N = 970
Average age (years)	29.6 [+ /- 6.1] STD
18-25 years	236 (24,3%)
26-35 years	606 (62,5%)
36-100 years	128 (13,2%)
Type	
Male	922 (95,1%)
Non-binary / genderfluid /other	27 (2,8%)
Female	5 (0,5%)
Missing data	16 (1,6%)
Country	
France	833 (85,9%)
Belgium	82 (8,5%)
Switzerland	34 (3,5%)
Other European countries	13 (1,3%)
Other countries	8 (0,8%)
Marital status at the beginning of use	
Single	78 (8%)
In a sexually exclusive couple (two people)	741 (76,4%)
In a sexually free couple	121 (12,5%)
In an emotional relationship with more than two people	23 (2,4%)
Missing data	7 (0,7%)
Change in marital status since start of use	
Yes	203 (20,9%)
No	760 (78,4%)
Missing data	7 (0,7%)
Number of children	
No children	808 (83,3%)
1 child	54 (5,6%)
2 or more children	75 (7,7%)
Missing data	33 (3,4%)
Wish to have another child	
Yes	321 (33,1%)
No	315 (32,5%)
Don't know	324 (33,4%)

Table 2. Characteristic of the population (level of education and occupation). TESTIS_2021

Variables	Number (%) N = 970
Degree levels	
5 years of higher education or more	415 (42,8%)
Bac + 3 or Bac + 4 or equivalent	227 (23,4%)
General, technological or vocational baccalaureate, higher vocational or technical diploma	135 (13,9%)
Bac + 2 or equivalent	105 (10,8%)
CEP, Brevet, None, Other	38 (3,9%)
CAP, BEP, Brevet de compagnon	34 (3,5%)
Do not wish to answer	16 (1,7%)
Professions	
Intellectual and scientific profession	263 (27,1%)
Other	168 (17,3%)
Student	115 (11,9%)
Skilled Industrial and Craft Trades	89 (9,2%)
Intermediate occupation	79 (8,1%)
Director, executive and manager	47 (4,8%)
Administrative type employee	38 (3,9%)
Personnel in direct services to individuals, traders and salespersons	37 (3,8%)
Unemployed	34 (3,6%)
Farmer and skilled worker in agriculture, forestry and fisheries	30 (3,1%)
Looking for a job	29 (3%)
Elementary occupation	8 (0,8%)
Military occupation	5 (0,5%)
Plant and Machine Operator and Assembly Worker	3 (0,3%)
Do not wish to answer	25 (2,6%)

Note: For occupations, the International Standard Classification of Occupations (ISCO-08) was used.

2. Medical profile of the study population

Medical history

14.5% of participants had at least one clinical contraindication (Table 3) to the use of this contraception by testicular ascent (n=141).

61 participants were on regular medication, 24 of which could interfere with spermatogenesis [44]: corticosteroids (n=7), drugs targeting the central nervous system (n=15), other (n=2).

Table 3. Proportion of medical history among CRT users. TESTIS_2021.

Background	Number (%) N = 970
At the level of the penis	
Genital mycoses	88 (9,1%)
Dermatological conditions chronic (eczema, atopy, psoriasis)	51 (5,3%)
Significant curvature of the penis	9 (0,9%)
At the urinary level	
Urinary, kidney or prostate infection	122 (12,6%)
Disorders of the micturition phase	85 (8,8%)
Bladder leakage	18 (1,9%)
Urethral Stenosis	2 (0,2%)
In the prostate	
Hypertrophy of the prostate	6 (0,6%)
Operation	0 (0%)
Radiotherapy	0 (0%)
In the testicles	
Operation	19 (2%)
Swelling of the testicles or testicular veins	18 (1,9%)
Cryptorchidism	13 (1,3%)
Malformation	4 (0,4%)
Tumour	0 (0%)
Miscellaneous background	
Inguinal hernia	38 (3,9%)
Dyslipidemia	13 (1,3%)
Obesity	12 (1,2%)
Diabetes	2 (0,2%)

Hypertension	1 (0,1%)
History of use	
Tobacco	274 (28,2%)
Calming agents	206 (21,2%)
Alcohol	200 (20,6%)
Excitants	88 (9,1%)
Occupational exposure to heat or radiation without protective measures	24 (2,5%)
Medical treatment that can interfere with spermatogenesis	24 (2,5%)

Contraceptive history: methods used and satisfaction.

In the year before the CRT, contraception had been used often ("always" or "most of the time" 83.2%).

The most commonly used contraceptive method(s) were: the external condom, 'female' hormonal methods, the withdrawal method and the copper IUD. More than three quarters of the participants had used 'male' contraception (Table 4).

Regardless of the contraceptive method, sexual partners were more dissatisfied overall with these previous contraceptives than the participants themselves (64.9% dissatisfaction versus 51.7% respectively). This dissatisfaction was higher when the previous contraceptive methods were "female" (Table 4).

Participants reported their sexual partners' experience of significant adverse events due to previous contraception in 68.3% (634/928) of cases; 20.1% (195/928) of unplanned pregnancies, and 25.2% (234/928) voluntary termination of pregnancy.

Concerning vasectomy, 43.3% of the participants had already considered it (404/932).

Table 4. Satisfaction of participants and their sexual partners (as reported by participants) with the contraceptive method(s) used in the year prior to the TRM TESTIS_2021

Contraceptive method	Number of participants (n = 882) Number (%)	of dissatisfaction among participants	of dissatisfaction among sexual partners
External (male) condom	645 (73,1%)	336/645 (52,1%)	349/579 (60,3%)
At least one female hormonal method	445 (50,5%)	233/445 (52,4%)	295/418 (70,6%)
Withdrawal method	246 (27,9%)	158/246 (64,2%)	154/224 (68,8%)
Copper IUD	243 (27,6%)	118/243 (48,6%)	153/216 (70,8%)
Symptothermia	42 (4,8%)	23/42 (54,8%)	24/38 (63,2%)
Internal (female) condom	29 (3,3%)	17/29 (58,6%)	19/28 (67,9%)
Cervical cap, diaphragm and spermicides	14 (1,6%)	6/14 (42,8%)	11/13 (84,6%)
Male hormonal method	1 (0,1%)	1/1 (100%)	0/1 (0%)
At least one male method	673 (76,3%)	353/673 (52,5%)	367/605 (60,7%)
At least one female method	619 (70,2%)	320/619 (51,7%)	403/574 (70,2%)
Missing data	15 (1,7%)	-	-

Note: The grouping of female hormonal methods includes: the estrogen-progestin pill, the hormonal IUD, the vaginal ring, the implant and the quarterly injection. The grouping of female methods includes: female hormonal methods, copper IUD, symptothermia, internal condom, cervical cap and diaphragm. The grouping of "male" methods includes: the external condom and the withdrawal method.

III. The RTA schemes

1. The different types of devices

In our study, different devices allowing testicular lift were used (Figure 2). The Andro-switch device was used by almost all the sample (96.0%).

Participants used a single device (N=924), two devices (N=41), or three devices (N=5) alternately. When the Andro-switch device was used, it was most often used as the only contraceptive device (96.1%, N=895/931), while Dr Mieusset's underwear and other cloth devices were half used alternately with the Andro-switch device, respectively (48.0%, N=12/25) and (44.6%, N=25/56). Only 39 participants were not using the Andro-switch device at the time of the study.

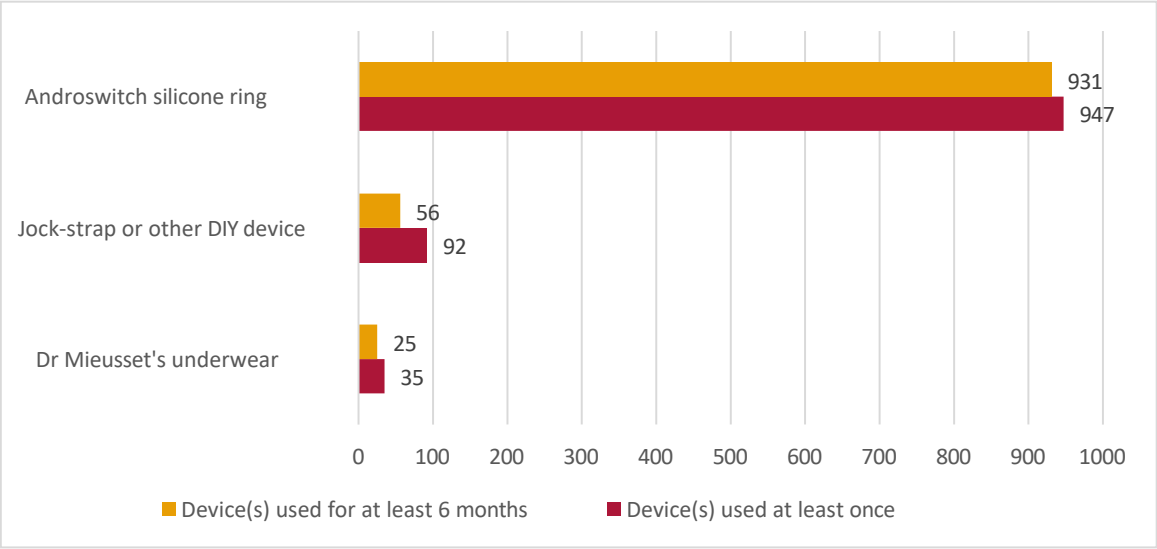

Figure 2: Number of testicular lift contraceptive devices used at least 6 months and used at least once by participants. N=970. TESTIS_2021.

Only 8 participants used devices other than those listed in our questionnaire. These reported using a self-made cloth ring (N=2), a silicone "penis ring or cockring" from another manufacturer (N=4), a self-made silicone ring (N=1) and a mixed device consisting of a jockstrap with an integrated Andro-switch ring (N=1).

2. Duration of use

Table 5 summarises the duration of use according to the devices used. 4 people did not give their stop date, and some were using several devices at the same time, hence the difference in numbers with Figure 2.
At the time of the study, 860 participants were still using a CRT (88.7%). Ten participants had been using a TRM for more than 4 years.

Table 5. Total duration of use and effective duration of use (after contraceptive threshold is reached) according to the RTA devices. TESTIS_2021.

	N	Total duration of use Average [STD] in months	N	Efficient use of time Mean [95% CI] in months
All devices combined	966	14,1 [+/-8,7]	698	11,2 [+/-9,3]
Users of the Andro-switch device alone	891	13,4 [+/-6,6] Min: 6 Max:70	639	10,3 [+/-6,6] Min: 1 Max: 68
Users of Dr Mieusset's contraceptive device	25	22,7 [+/-14,5] Min: 7 Max: 63	22	18,9 [+/-14,7] Min: 2 Max: 53
Users of the jock strap or DIY device	50	23,7 [+/-21,7] Min: 6 Max:118	38	22,2 [+/-24,1] Min: 3 Max: 115

Figure 3: Number of CRT devices by date of commencement of use (N=987)
TESTIS_2021

987 devices started to be used between January 2018 and September 2021.
Andro-switch users had mostly started CRT after December 2019 (95.2% 852/895), as shown in Figure 3.
Prior to 2018, only four users of Dr Mieusset's contraceptive underwear had started CRT, nine for jock-strap or DIY devices, and six for the Andro-switch.

IV. Health security

We assessed safety of use along three axes: compliance with Dr Mieusset's protocol, adverse events, and changes in sexual function and quality of life before use and at the time of the study.

1. How to use in practice

We documented how the CRT devices were used: at the very beginning of use, and then on a daily routine basis.

Beginning of use: modality and time of habituation

Participants were getting used to the CRT :

- Either progressively by wearing less than fifteen hours a day (N=450, 46.4%),
- That is, immediately fifteen hours a day, every day (N=444, 45.9%).

The reported time to get used to wearing the device was less than 15 days for 88.7% of participants (Figure 4).

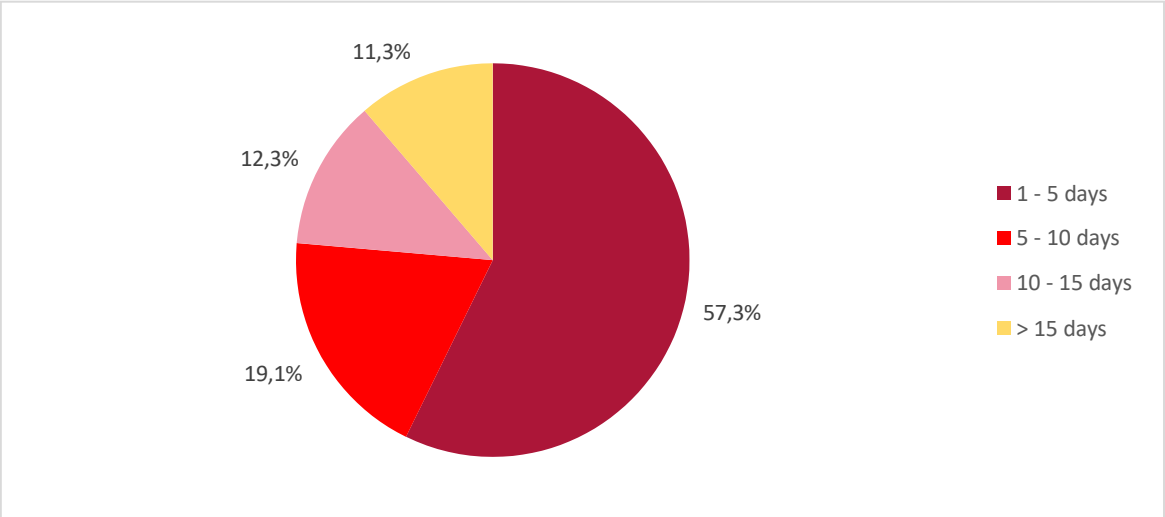

Figure 4. Proportion of participants by time to get used to wearing a testicular lift contraceptive at least 15 hours a day. N=957 *(10 participants reported never having achieved 15 hours daily wear).* TESTIS_2021.

Usual wearing time of contraceptive devices

The usual wearing time differed significantly among users (Figure 5). Three categories were distinguished:

- Less than 15 hours per day (N=315, 32.5%)
- Between 15 and 17 hours per day (N=435, 44.8%)
- More than 17 hours per day (N=220, 22.7%)

For the same individual, the daily wearing time varied little from one day to the next (N=827, 86%).

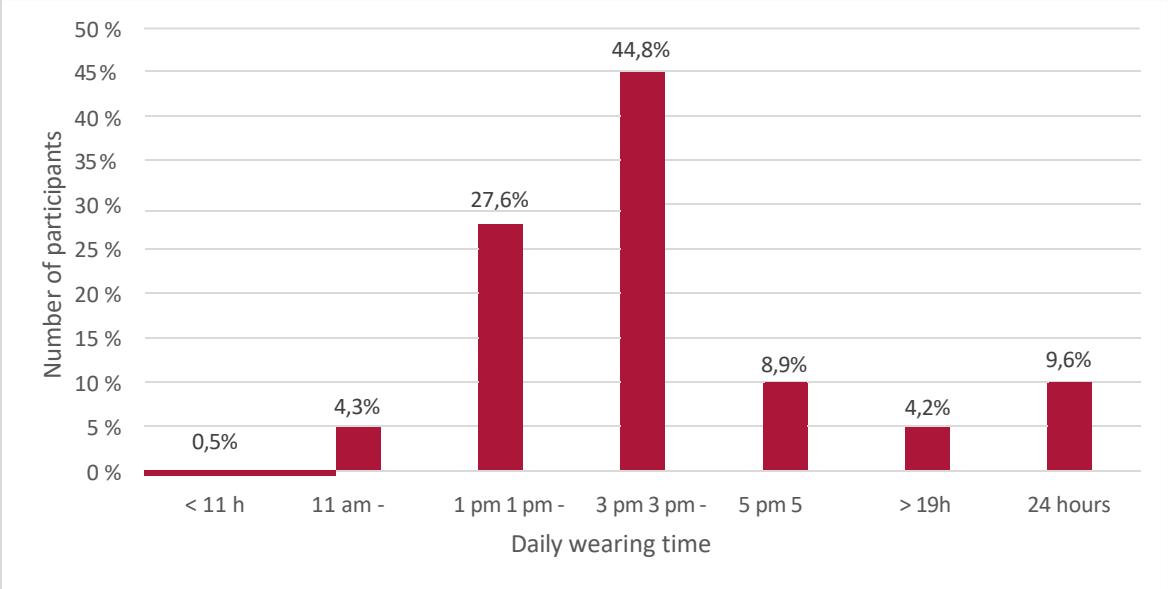

Figure 5. Proportion of participants according to usual daily wearing times of testicular upwelling at the time of the study (in hours per day), N=970. TESTIS_2021.

Reasons for using less than 15 hours

Table 6. Distribution of reasons for less than 15 hours of use per day. TESTIS_2021

	Reason for wearing less than 15 hours N = 315
The threshold is reached with less than 15 hours of wear	174 (55,2%)
The organisation of daily life does not allow it to be worn for longer	166 (52,7%)
Don't think it's necessary	51 (16,2%)
Adverse effects prevent longer wear	29 (9,2%)
Didn't know to wear it longer	8 (2,5%)
Other	21 (6,7%)
Don't know	12 (3,8%)
Do not wish to answer	12 (3,8%)

In addition, the open-ended question on other reasons also mentioned: long nights incompatible with longer wearing time during the day (N=7), discomfort due to longer wearing time (N=1), activities incompatible with longer wearing time (N=2).

Table 7. Distribution of reasons for using more than 17 hours per day. TESTIS_2021

	Reason for wearing more than 17 hours N = 220
A lack of rigour on schedules: compensation by longer wearing time	98 (44,5%)
Forgetting to remove the device	98 (44,5%)
The fear of inefficiency of the method with a lower port	36 (16,4%)
The threshold is not met with less than seventeen hours of wear	23 (10,5%)
Other	65 (29,5%)
Don't know	1 (0,5%)
Do not wish to answer	0 (0%)

Periods of wearing the devices over a day.

The times of day when CRT devices were worn differed among the participants (Figure 6). The vast majority of devices were worn during the day and night (67%), with a preponderance of daytime use.

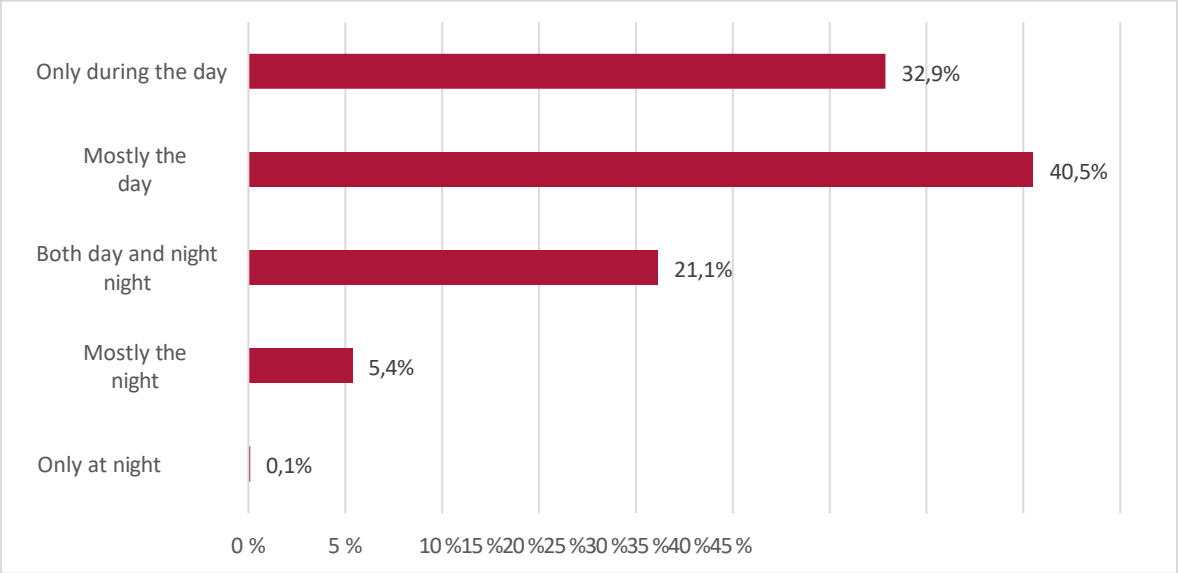

Figure 6. Proportion of participants according to periods of contraceptive device use in a day, N=970. TESTIS_2021.

Forgetfulness: frequency and protective behaviour.

The majority of participants reported no forgetfulness (74.3%, 716/963), 9.2% reported forgetting to wear their device at least once a month (N=89), and 1.1% at least once a week (N=11).

We looked for behaviours that could reduce the risk of unplanned pregnancy in the event of of oblivion.

When they forgot, the majority of participants in stable relationships informed their sexual partners ("Always": 71.6%, 159/222). They used additional contraception systematically and for at least one month in only 26.7% of cases.

2. Performing a spermogram

The vast majority of participants had performed at least one spermogram since the start of CRT (859/925, 92.9%). There were 45 missing data on this part of the questionnaire. Participants had performed several spermograms (N=694, 75.0%), only one spermogram (N=165, 17.8%) or no spermogram (N=66, 7.1%).

An initial spermogram (before starting CRT) was performed by 68.6% (635/925) of the participants; 94.4% of the results were reported to be within the norms.

A control spermogram was performed by 89.4% (827/925) of the participants after a few months. month to check that the contraceptive threshold has been reached.

Spermograms were mostly performed in a city or hospital laboratory (N=686/694). 10 participants reported performing sperm counts on their own. Two techniques were reported: the use of electron microscopes with counting cells (N=7); and the use of Exseed fertility self-tests (N=3).

Participants who performed multiple spermograms (N=694) reported performing their spermograms at different frequencies (Figure 7).

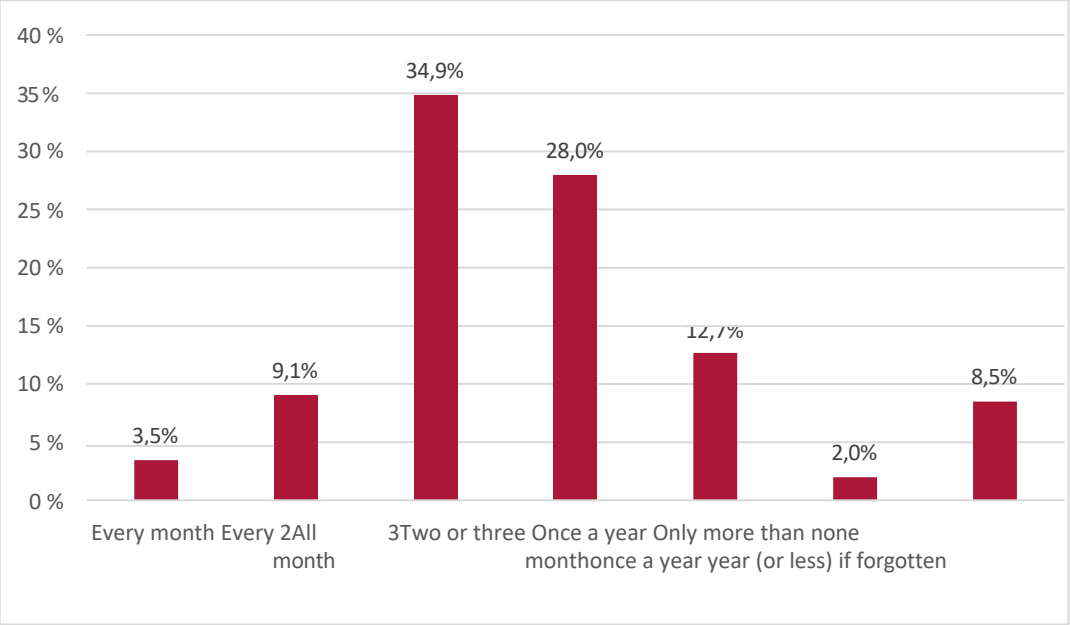

Figure 7. Proportion of participants according to the frequency of performing spermograms at the time of the study, among users with multiple spermograms, N=694, TESTIS_2021

3. Compliance with Dr Mieusset's protocol

The pattern of CRT use according to Dr Mieusset's protocol is listed in Figure 8. Less than 5% used their contraception strictly according to this protocol (43/970). The least complied with were the wearing of the device only when awake and the number of hours of daily wear between 3pm and 5pm.

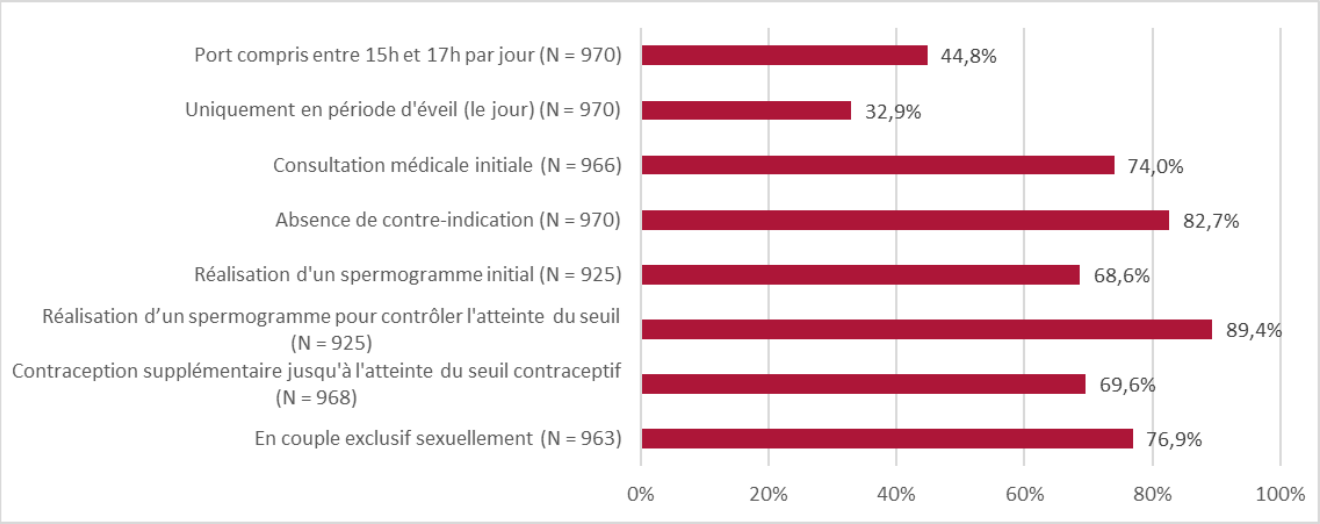

Figure 8. Proportion of adherence to contraceptive device use recommendations by testicular raising according to Dr Mieusset's protocol. TESTIS_2021.

This protocol establishes individual, contraceptive and reproductive health precautions in line with current scientific knowledge.

Regarding personal precautionary measures, at least 8.7% of participants (84/970) used their device between 3 and 5 p.m. daily and only during the day, had consulted a health professional beforehand, and had no medical contraindications (including abnormal spermogram results).

Regarding contraceptive precautionary measures, at least 31.5% of the participants (306/970) wore their devices every day (without forgetting), had used additional contraception until the contraceptive threshold was reached, and performed regular check-ups (at least two or three times a year).

A few comments illustrated the issues between users of an RTA and the health care system.

"I am not always comfortable with the medical profession. I don't have a regular doctor anymore. A few years ago I consulted a doctor who refused to accompany me in the male contraception..."

"I actually went to a doctor who prescribed a visit to the urologist, but I didn't want to be supervised by the medical profession for my contraception.

"An apprehension due to the incompetence of professionals in this field, lack of information to them and lack of acceptance on their part.

"I did not feel the need to do so, I was well advised by groups and individuals close to this approach [...] whom I trusted.

"I spoke to my GP about it and he said he had no say in the matter until it was recognised by French medicine.

4. Undesirable effects

We have classified the adverse events according to their frequency of occurrence in this study [45].

Very common	> 10%
Common	1,1 - 10 %
Uncommon	0,1 - 1%

The first times

We identified adverse events that occurred during the first few uses of a testicular lift device (Table 8). During the first few days of use, discomfort or pain was very common.

Table 8. Proportion of adverse events reported during the first days of use of a Testicular uptake contraception, N=970. TESTIS_2021.

Adverse effects on first use	Number (%) N = 970
None of these effects	184 (19%)
Felt discomfort in a or both testicles	444 (45,8%)
Felt discomfort in the lower abdomen	278 (28,7%)
Experienced pain in a or both testicles	179 (18,5%)
Felt a sense of unease	121 (12,5%)
Feeling pain in the lower abdomen	89 (9,2%)
Has an allergic reaction	26 (2,7%)
Lost consciousness	1 (0,1%)
You don't know	5 (0,5%)
Do not wish to answer	1 (0%)

In response to the open-ended question "What other sensations or side effects did you experience during the first few uses? "were reported: "burning or hot sensation" (N=4), "thrombosis of the penile veins"(N=1), "tearing sensation in the inguinal areas" (N=1), sleep disturbance (N=3), "slight oedema at the base of the penis" (N=1), "formation of a small air pocket under the glans after an erection" (N=1), and "bruising on the penis" (N=1), tightness in the penis (N=1), discomfort when sitting (N=2).

We then identified all adverse events that had occurred since the start of the use of This contraception is grouped by anatomical and functional category (Tables 9 to 14).

At the level of the penis

Table 9. Proportion of adverse events reported in the penis since the start of testicular lift contraception use. TESTIS_2021.

Adverse effects on the penis	Number (%) N = 970
None of these effects	247 (25,5%)
Skin irritation (on friction areas)	515 (53,1%)
Itching (on friction areas)	446 (46%)
Irritation due to pubic hair	313 (32,3%)
Change in the colour of the skin at the base of the penis	142 (14,6%)
Changes in skin texture at the base of the penis	83 (8,6%)
Skin irritation or infection of the penis, which required medical treatment	9 (0,9%)
Unusual swelling of the penis (oedema)	9 (0,9%)
A mycosis of the penis	8 (0,8%)
A decrease in sensitivity in the penis	1 (0,1%)
You don't know	6 (0,6%)
Do not wish to answer	1 (0,1%)

At the level of scholarships

Table 10. Proportion of adverse events reported at the level of grants since the beginning of the the use of testicular lift contraception. TESTIS_2021.

Adverse reactions in the bursa	Numbers (%) N = 970
None of these effects	323 (33,3%)
Skin irritation (on friction areas)	503 (51,9%)
Itching (on friction areas)	437 (45,1%)
Changes in skin texture at the level of grants	36 (3,7%)
Change in skin colour in the bursa	35 (3,6%)
Unusual pain in the bursa	9 (0,9%)
A mycosis in the bursa	6 (0,6%)
Irritation or infection of the skin of the bursa that required medical treatment	3 (0,3%)
Unusual swelling of the bursa	2 (0,2%)
You don't know	1 (0,1%)
Do not wish to answer	0 (0%)

In the testicles

Table 11. Proportion of testicular adverse events reported since the start of the use of testicular lift contraception. TESTIS_2021.

Adverse effects on the testicles	Number (%) N = 970
None of these effects	577 (59,5%)
Decrease in testicular size	306 (31,5%)
Testicular discomfort when using contraception	85 (8,8%)
Testicular pain when using contraception	46 (4,7%)
Persistent discomfort in the testicles even after removing the contraception	15 (1,5%)
Persistent testicular pain even after removing the contraception	10 (1%)
Swelling in the testicles or testicular veins	4 (0,4%)
A hard mass in the testicles	3 (0,3%)
Testicular torsion (requiring emergency surgery)	0 (0%)
You don't know	9 (0,9%)
Do not wish to answer	1 (0,1%)

Erectile function

There was symptomatology relevant to erectile function (Table 12). After analysis of the open-ended questions, changes in erection hardness, duration and speed seemed to occur when an erection occurred with the device in place. Some participants detailed a similar effect to penile ring or cock ring sex toys resulting in increased erection hardness, speed and duration (N=2). One participant described a loss of spontaneity during intercourse due to pain during the onset of an erection.

Free commentary:

"Stronger, longer, faster erections with a harder penis.

Table 12. Proportion of erectile adverse events reported since the start of testicular lift contraception use. TESTIS_2021.

Adverse effects on erectile function	Number (%) N = 970
None of these effects	620 (63,9%)
Painful night-time erections or unpleasant when you wear the contraceptive	227 (23,4%)
Painful daytime erections or unpleasant when you wear the contraceptive	114 (11,8%)
A change in the hardness of your erections	47 (4,8%)
A change in the duration of your erections	38 (3,9%)
A change in how quickly you can get an erection	25 (2,6%)
Painful or unpleasant erections even after removing the contraceptive	2 (0,2%)
Unusual deviation or curvature of the erect penis	3 (0,3%)
One or more erections that lasted more than 4 hours (priapism)	1 (0,1%)
You don't know	11 (1,1%)
Do not wish to answer	0 (0%)

Urinary function

At the urinary level, there was a functional symptomatology involving the micturition phase, notably with a very high frequency of experience of unusual delayed drops (Table 13).

Table 13. Proportion of urinary adverse events reported since initiation of testicular uptake contraception. TESTIS_2021.

Adverse effects in the urinary tract	Number (%) N = 970
None of these effects	695 (71,7%)
Unusual late drops (a few drops of urine flowing away after going to the toilet)	208 (21,4%)
A feeling of not having urinated completely	77 (7,9%)
A feeling of blockage to urinate (having to push)	40 (4,1%)
Longer time to start urinating	35 (3,6%)
Difficulty urinating while standing	13 (1,3%)
Difficulty urinating while sitting	11 (1,1%)
Bladder leakage	9 (0,9%)
A urinary tract, kidney or prostate infection	3 (0,3%)
Blood in the urine	1 (0,1%)
Urinary burning	0 (0%)
You don't know	13 (1,3%)
Do not wish to answer	1 (0%)

Other adverse effects

Other adverse events were reported in free text by some users (Table 14), which does not allow us to estimate their frequency. A significant number of reports of urinary symptoms during the filling phase (N=26) should be noted. Regarding the micturition phase, several participants (N=8) spontaneously reported a disappearance of symptoms when they removed their contraceptive device when urinating.

Table 14. Number of participants reporting other adverse events since initiation of testicular lift contraception. TESTIS_2021.

	Workforce Total N = 970
At the urinary level: filling phase	
Increased frequency of urination	21
Increased bladder sensitivity or urgency	5
At the urinary level: micturition phase	
Delayed initiation, or push urination	3
Renal: renal colic	1
In the testicles or bursa	
Testicle(s) repositioning in the bursa despite the contraceptive device	11
Extension of scholarships (increase in size)	7
Sensitivity in the upper pole of the testicles or spermatic cord	5
In the penis	
Incomplete recapping of the glans when wearing the device	3
Inguinal level	
Dilatation of the inguinal pockets	3
At the level of ejaculation	
Decreased ejaculate volume	2
Nocturnal ejaculations	1
Delayed ejaculation	1
At the positional level	
Discomfort or pain when lying prone	4

A few participants reported in free text that adverse events disappeared after a change in device size (N=8). On the other hand, a decrease in testicular volume resulted in more frequent repositioning of the testicles in the bursa despite wearing the contraceptive, or requiring a device size adjustment (N=3).

Some free comments were selected to clarify these symptoms.

"Sometimes a testicle would slip out from under the ring which was quite uncomfortable. Sometimes the ring would slip off which was uncomfortable to put back on in public.

"I have to be really relaxed to urinate, ideally sitting down to avoid bladder leakage. Sometimes I even take the ring off while I urinate to avoid the problem."

"Urinating with the ring is a little less easy, you have to push a little.

"Complement [on adverse effects] urinary: the effects occur only when the contraceptive is worn and are completely mechanical (the ring presses on the urinary tract).

"Painful testicle descent if contraceptive method not the right size."

"The side effects were largely related to a ring size problem, the change in size has largely solved the problems.

In total, almost all participants reported at least one adverse event (94.8%). Excluding dermatological side effects (irritation, itching, pubic hair, change in texture and colour) and testicular size reduction, 56.6% of participants reported at least one side effect.

Among users who had used CRT for more than 4 years (n=10), one participant reported urinary leakage associated with a feeling of incomplete emptying. This participant was 28 years old, had no contraindications to the method, and reported a history of urinary tract infections. The other participants had no significant adverse effects.

5. Sexuality

Overall sexual impact

Participants felt an overall positive impact on the quality of their sex life among non-cohabiting participants. Participants in a couple relationship rated the impact on their partners' quality of sexual life even more positively (Figure 9).

It should be noted that the participants' quality of sexual life was improved regardless of the previous contraceptive method used. However, this improvement was significantly greater when the previous contraception was a male method (the withdrawal method or the external condom). This difference was not found for the rest of the contraceptives. This result is similar for sexual partners.

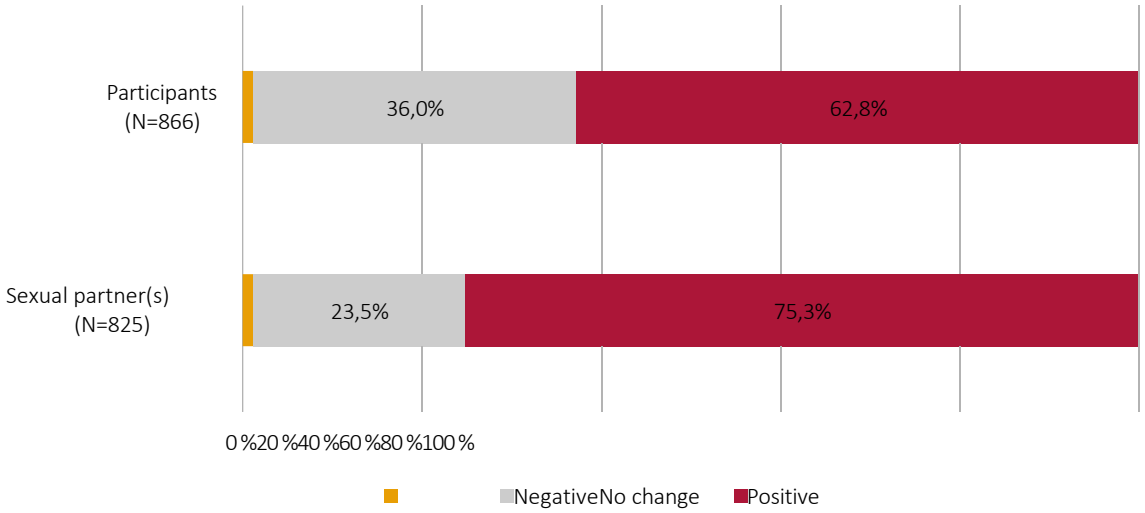

Figure 9. Proportion of changes related to sexual quality of life (felt) among non-celibate participants and their sexual partners (filled in by the participant). TESTIS_2021.

ASEX rating scale

The standardised ASEX questionnaire (included in the questionnaire, see Appendix III) assesses psychological and organic sexual functions. Sexual dysfunction is recognised either by an overall score greater than or equal to 19, or by one item with a score greater than 4, or by three items with a score greater than or equal to 4.

Before the use of testicular lift contraception, according to the ASEX scale, very few sexual dysfunctions were reported (14/944, 1.5%). At the time of the study, an equivalent proportion of sexual dysfunctions were found (12/944, 1.3%). There was no significant difference between the proportion of sexual dysfunctions before use and at the time of the study.

MSHQ assessment scale

The standardised MSHQ questionnaire assesses sexual quality of life. We selected four items of interest out of 25 items (no calculation of the overall score possible).

A significant difference in satisfaction with the quality of sexual life before CRT and at the time of the survey was found. There was a significant improvement in the "extremely satisfied" category for all four items (quality of sex, frequency of sex, tenderness during sex, and talking about sex with sexual partners). (See Figure 10).

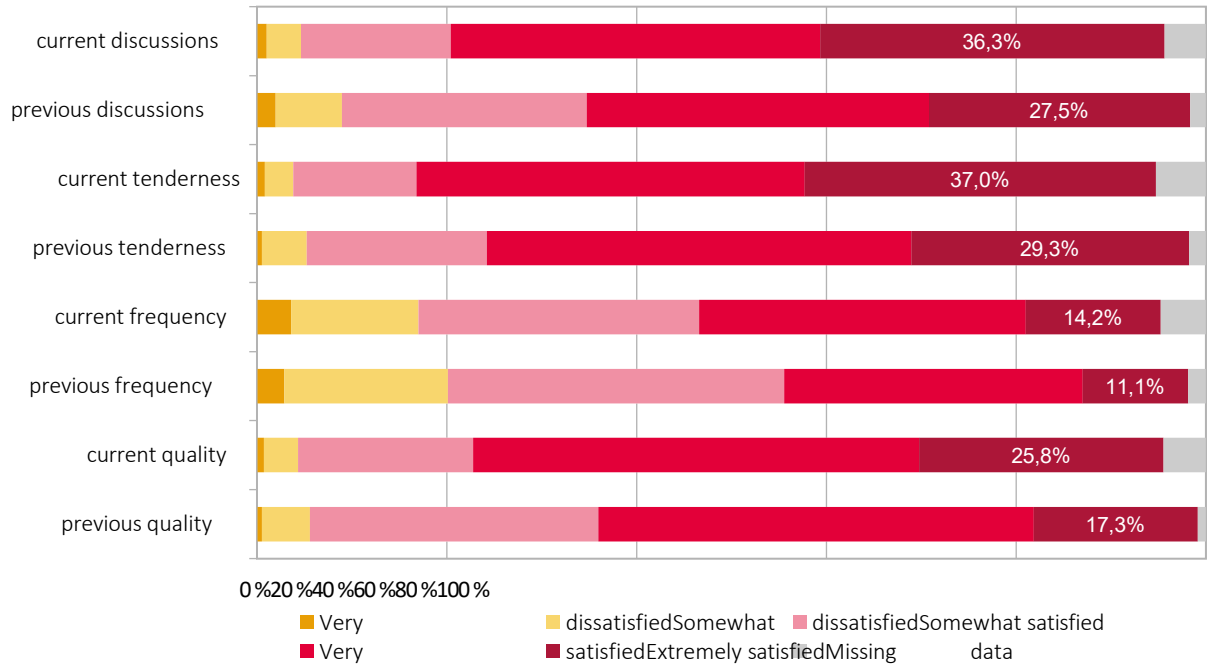

Figure 10. Comparison of satisfaction with sexual quality of life according to the MSHQ questionnaire before CRT and at the time of the study (N=970). TESTIS_2021. Note: 4 items: quality of sex, frequency of sex, tenderness during sex, and talking about sex with sexual partners)

V. Acceptability

1. Satisfaction

General satisfaction

The vast majority (86.5%) of participants were at least "Very satisfied" with the TRM (Table 15).

We looked for an association between satisfaction and the duration of daily wear of the devices, as well as the total duration of use of the devices. No significant difference was found.

In contrast, reaching the threshold was significantly associated with positive satisfaction with the CRT.

Table 15. Proportion of satisfaction as a function of duration of use. TESTIS_2021.

	Duration of use of less than one year (n = 505)	Duration of use of More than one year (n = 454)	Total participants (n=963)
Extremely satisfied	221 (43,8%)	246 (54,2%)	470 (48,8%)
Very satisfied	202 (40%)	160 (35,2%)	363 (37,7%)
Quite satisfied	65 (12,9%)	40 (8,8%)	105 (10,9%)
Somewhat dissatisfied	13 (2,5%)	7 (1,6%)	20 (2,1%)
Very dissatisfied	4 (0,8%)	1 (0,2%)	5 (0,5%)
Never satisfied	0 (0%)	0 (0%)	0 (0%)

Of the 860 participants who were still using a TRC at the time of the study, 97.8% wanted to continue. In addition, 92.3% of participants (893/968) said they had learned more about their anatomy and how their fertility works.

Reasons for dissatisfaction collected in free text included mainly failure to reach the contraceptive threshold (N=12), skin side effects (N=7), perceived constraint (N=5), poor testicular maintenance (N=3). One participant reported not regaining *"fertility"* after one year off CRT. This participant had performed a spermogram prior to starting CRT, which was reported to be within the norm.

Satisfaction with the CRT and previous contraceptives used

Overall satisfaction is significantly higher with CRT than with previous contraception, regardless of the contraceptive method previously used (Figure 11).

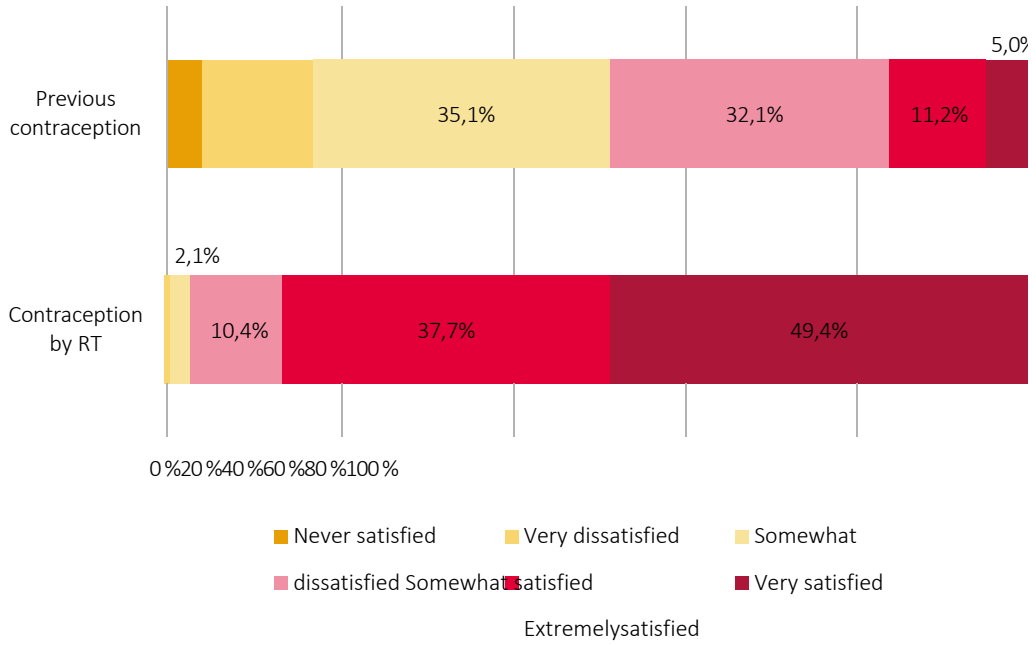

Figure 11. Comparison of satisfaction with previous contraception and CRT, among participants who used one (or more) contraception previously, N=857. TESTIS_2021.

Satisfaction according to the devices used

Fabric devices (Dr Mieusset's underwear, jock-strap or other DIY devices) were described as causing less skin irritation and providing better testicular support (Figure 12). The Andro-switch device was described as more convenient to use, and more comfortable to use at night.

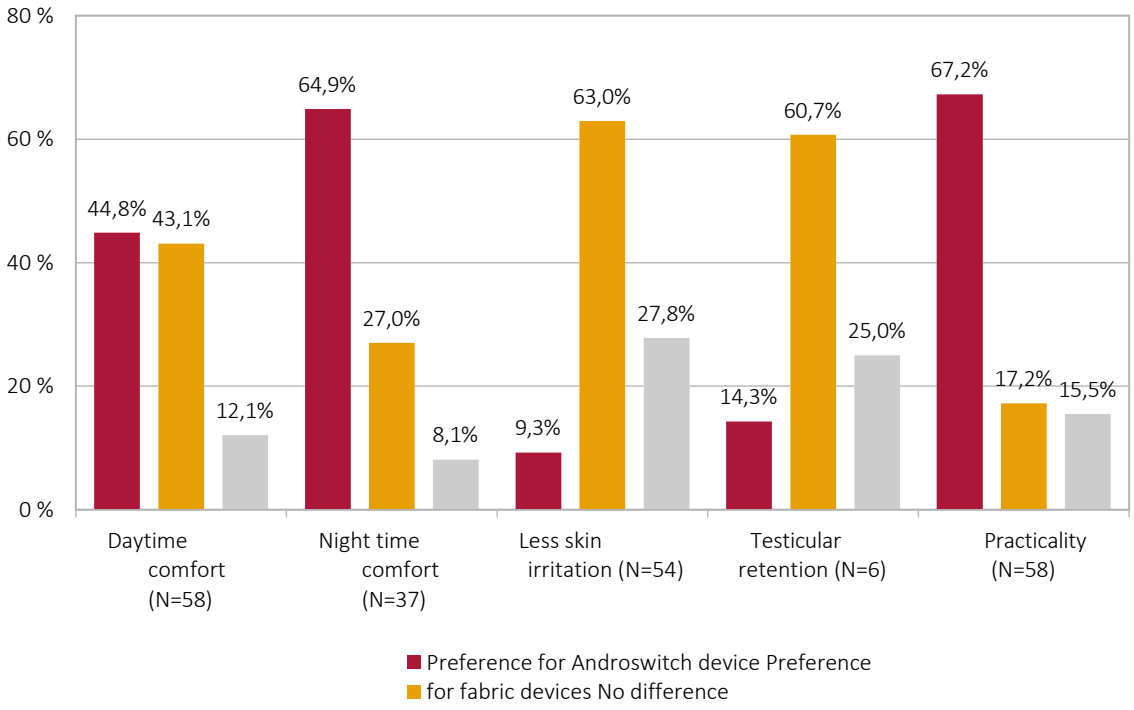

Figure 12. Comparison of participants' feelings according to the RTA devices used.
Note: Fabric devices include the jockstrap, Dr Mieusset's device and other DIY devices. TESTIS_2021.

2. Brakes

Barriers to optimal daily use

We have identified several barriers to optimal daily use of contraceptive devices (Figure 13).

Participants who reported that wearing at least 15 hours per day was a barrier (N=224) frequently wore their device less than 15 hours per day (N=131, 58.5%). Those who reported that regular forgetting was a barrier (N=33) tended to forget once a month or more (57.6%).

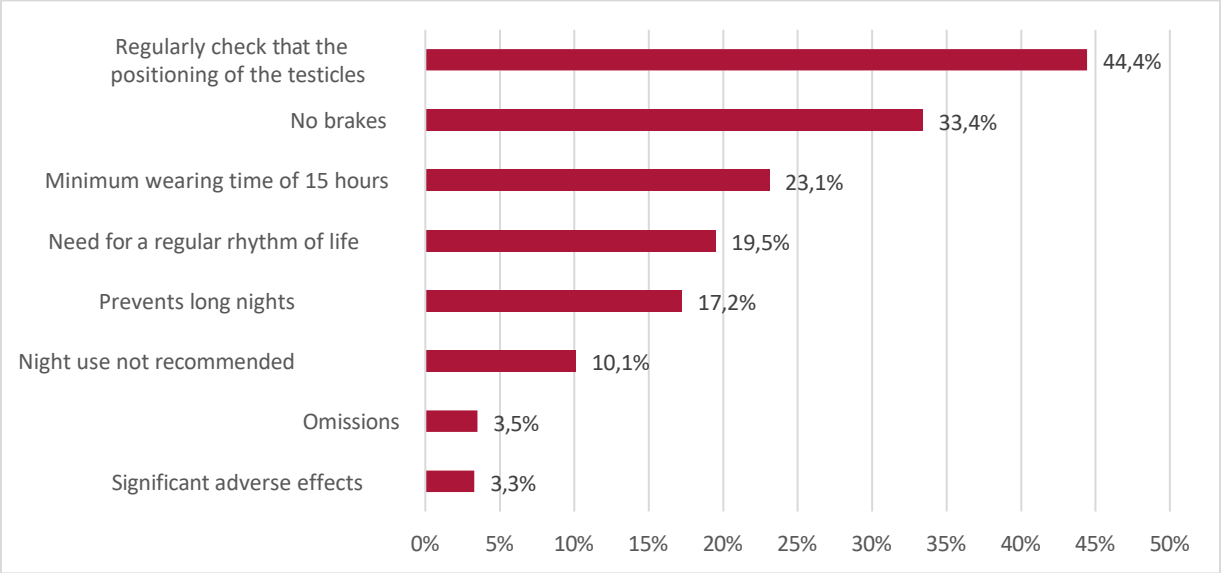

Figure 13. Proportion of barriers to optimal daily use of testicular lift contraception, N=970. TESTIS_2021.

Among the other obstacles declared in free text, there was a lack of access to medical follow-up (N=5), to a regular spermogram (N=10) and the lack of scientific data on the subject (N=3).

"The ring moves quite often (one testicle goes back down) and I don't realise it right away so I have to fall asleep with it on to make sure I have the total hours.

"Few laboratories for spermograms in the countryside, and very long waiting times."

"The margins of error regarding wearing time (e.g. longer night) are unclear.

Constraints

This contraception was described in different activities as "Not at all restrictive" or "Not at all restrictive". This was described as "not very constraining" by more than 75% of the participants (Figure 14).

Professional activities were the least constrained by a CRT; sporting activities, on the other hand, were the most impacted (20.0% declared "Somewhat constraining" or "Very constraining").

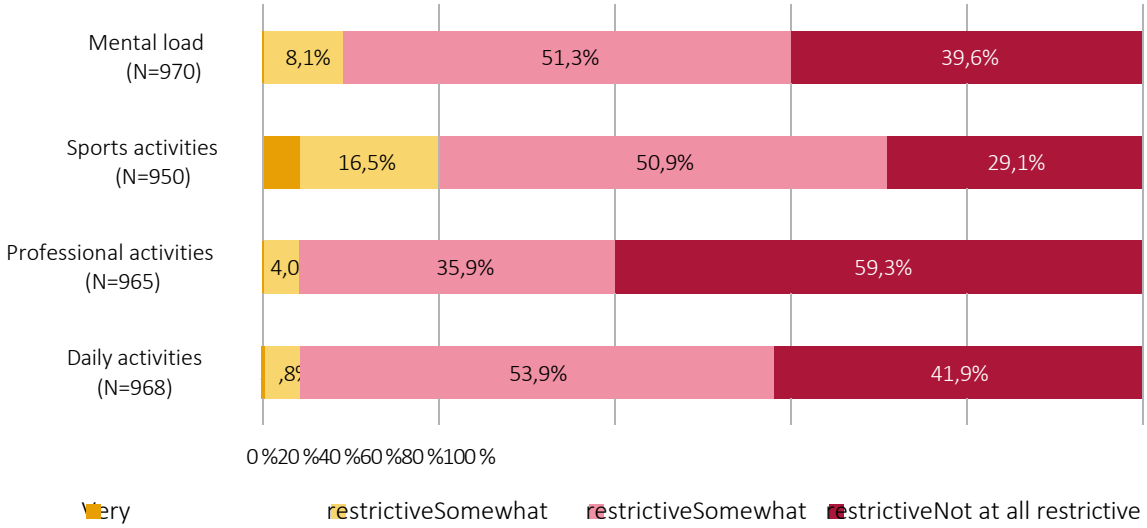

Figure 14. Proportion of constraints according to activities: daily, professional, sports and mental load of using a CRT. TESTIS_2021.

3. Interactions with sexual partners

We have documented the ways in which participants discuss CRT with their partners, among the non-single participants (Table 16).
CRT was more immediately accepted when the participant approached the subject first than when sexual partners approached the subject ($p<0.05$). There was no significant difference when the subject was discovered at the same time.

Table 16. Distribution of the ways in w h i c h participants and their families address the topic of TRM partners, among non-celibate participants (N=873). TESTIS_2021.

	The CRT was accepted immediately N=639	A delay was necessary to accept the CRT N=234
Topic addressed by the participant	309 (48,4%)	75 (32,1%)
Topic discussed by sexual partners	219 (34,3%)	137 (58,5%)
Topic covered / discovered at the same time	111 (17,3%)	22 (9,4%)

There was no significant difference in overall satisfaction depending on whether the topic was discussed by the participant or the sexual partners.
Similarly, there was no significant difference in strain in terms of mental load, or difficulty in wearing the device for fifteen hours a day, depending on whether the subject was discussed by the participant or the sexual partners.

We documented the obstacles encountered with sexual partners since the start of the CRT. Most participants had not encountered any difficulties with their sexual partners (Table 17).

Table 17. Proportion of relationship difficulties experienced with sexual partners since starting CRT, among all participants, N=949. TESTIS_2021.

Response options (multiple choice)	Number (%) Total N = 949
No difficulties	740 (76,3%)
Your partner(s) did not trust the effectiveness of this method (fear of an unplanned pregnancy)	127 (13,1%)
Your partner(s) did not trust your ability to use this contraception correctly	59 (6,1%)
Your partner(s) wanted to keep responsibility for contraception	43 (4,4%)
Your partner(s) did not accept This contraceptive method for aesthetic reasons	6 (0,6%)
Your partner(s) felt that this contraception undermined your 'manhood	6 (0,6%)
This contraceptive caused a decrease in desire in your partner(s)	3 (0,3%)
Other	37 (3,8%)

Among the non-celibate participants who had reached the contraceptive threshold (N=698), a lack of confidence in the effectiveness of the CRT by the partner, or in the ability to use this method of contraception (N=109), led to the maintenance of additional contraception among 23.8% of sexual partners. When the partner wished to retain responsibility for contraception (N=32), this resulted in the maintenance of additional contraception in 65.6% of cases even after the contraceptive threshold was reached.

Other difficulties with partners were specified in free text, including concern from sexual partners about side effects and consequences for fertility (N=15), and concern about fidelity (N=1).

A few comments have been selected to illustrate the relational issues of this contraception.
"Some partners admit that they would not trust (1) the method or (2) the thoroughness of their partner, knowing that if anything goes wrong, it is all on them. These people were, however, sexual partners only.

"My partner was very eager and excited to be free of this burden, which made me a little nervous at first, then she felt a little worried/guilty on her part when she saw the constraints. Total satisfaction from both after 3 months."

"Having to learn to communicate about forgetting, experiences etc. to give my partner confidence in my ability to use my contraception correctly (not really a difficulty but at least one that has been a necessity)

"There was little information available. We went to the doctor together so that she also had all the information about the method.

4. Accessibility

Access to information

89.0% (864/970) of participants reported easy access to information about the use of this contraception.

Accompaniment by a health professional

74.0% (715/966) of the participants had consulted a health professional before starting contraception, and of these, 48.1% had regular medical follow-up for this contraception.

At the time of this initial consultation, 41.0% (291/710) described the health professional as not being supportive of the contraceptive process, and only 16.8% (49/291) had found another health professional to support them.
Initial non-attendance was significantly associated with subsequent non-medical follow-up.

Not initially consulting a health professional was associated with a lower proportion performing at least one spermogram, performing a spermogram before starting, and performing a spermogram to check efficacy ($p<0.05$).

Access to spermograms

7.1% (66/925) of the participants had not performed a spermogram. The reasons given in free text were mainly: difficulty in obtaining an appointment and lack of time to go to the laboratory (N=25); no need to carry out a spermogram (N=10); reluctance to collect in the laboratory (N=7); confidence in the method (N=5).

In addition, 14.5% (136/938) of participants who had performed at least one spermogram stated that they had not performed one (or more) due to a lack of prescription from a health professional.

The delay in obtaining a laboratory appointment was greater than one week for 80.0% of participants (545/681). For 48.4% of participants it was between one week and one month (N=330); and more than one month for 31.6% (N=215).

39.5% of the participants (253/640) wished they could perform a spermogram "more often"; of these, 66.9% performed a spermogram a few times a year or less, or no spermogram at all.

14.2% of participants found laboratory semen collection difficult to perform (97/681); and over 20% of participants found laboratory findings difficult to understand (142/677).

5. Abandonment

Of the participants still using CRT at the time of the study, only 2.2% said they wanted to stop CRT, or did not know if they would continue (19/860).

More than 10% (110/970) of the participants had stopped CRT at the time of the study. On average, they were 30.2 years [+/- 5.0] STD, and had used their contraceptive device(s) for 13.1

months [+/- 8.6] STD: Andro-switch device (N=98), Dr Mieusset device (N=6), other fabric devices (N=14).

In the free text, there were different reasons for having stopped or considering stopping CRT, which we have grouped into four profiles, with their occurrences.

- CRT was no longer appropriate for the contraceptive need: celibacy (N=19), little sexual intercourse (N=8), STI protection needed (N=4), partner maintaining contraception (N=2), partner's menopause (N=2), desire to procreate (N=20), vasectomy (N=7), condom (N=2), symptothermia (N=2), Spermapause device (N=2), tubal ligation (N=2), IUD (N=3).
- CRT was not effective: contraceptive threshold not reached (N=12)
- CRT was not acceptable: adverse effects (N=13), constraints (N=12), fear of long-term effects (N=1), spermogram impossible to perform (N=5), device not accessible (N=4), ANSM decision (N=1).
- Need to verify reversibility on spermogram (N=5).

When CRT was discontinued, less than 70% of participants had used additional contraception (or had not had fertile sex) until the spermogram was normalised (N=73/108).

VI. Efficiency

1. The contraceptive threshold

Proportion reaching the contraceptive threshold

In our study, 79% (766/970) of the study population reported reaching the contraceptive threshold of less than one million sperm per millilitre, or 92.6% (766/827) of participants who performed an efficacy check spermogram.

The average time to reach the contraceptive threshold was 3.3 months [+/- 1.3] STD with a minimum of 1 month and a maximum of 12 months. 9.8% of the participants reported a delay of more than 4 months to reach the contraceptive threshold (68/700) (Figure 15).

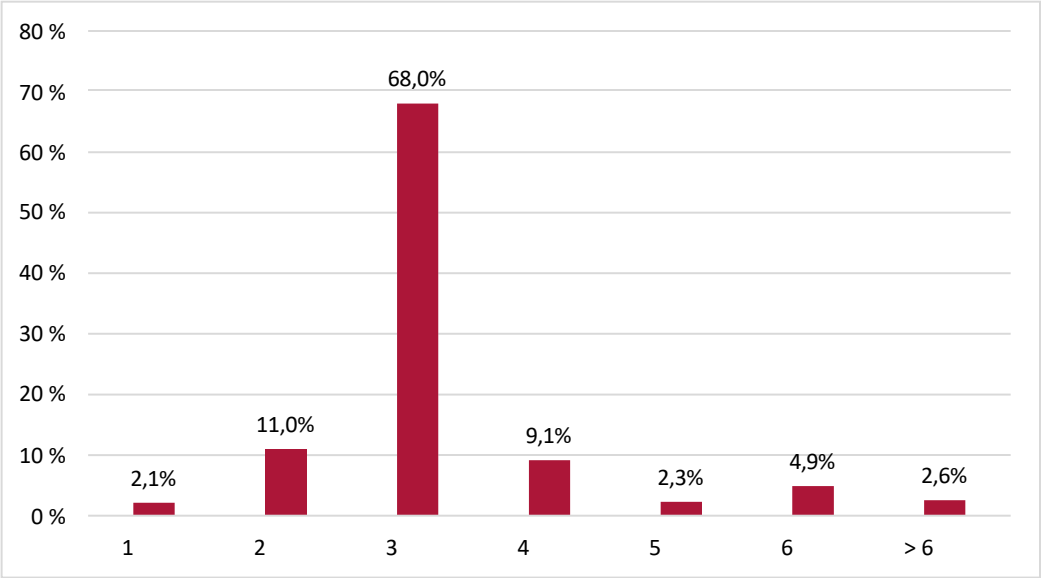

Figure 15. Distribution of time to use a testicular lift device to achieve the contraceptive threshold of less than one million sperm per millilitre, N=700, DM=66 TESTIS_2021

There was no significant difference in the proportion of contraceptive thresholds achieved according to the number of hours of use per day (grouped into three categories) (Figure 16).

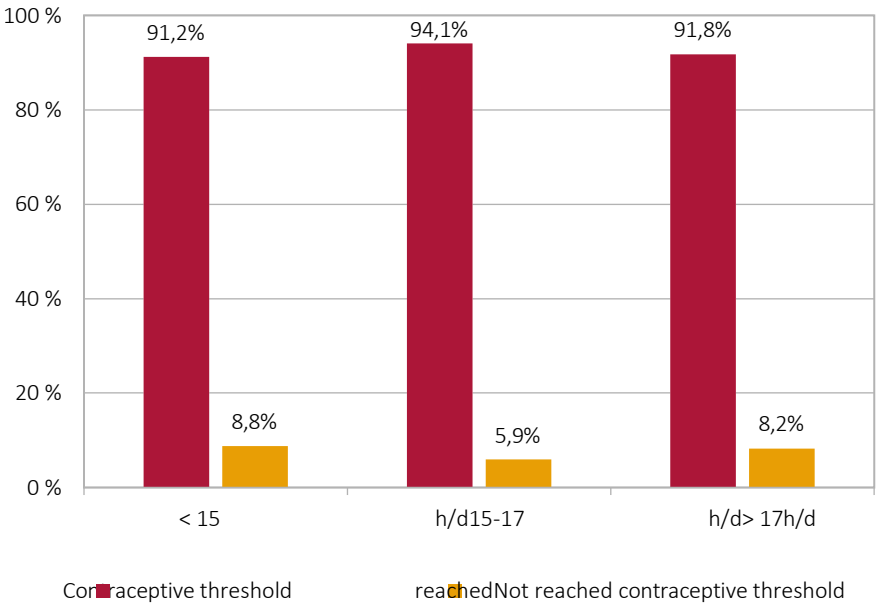

Figure 16. Proportion of contraceptive thresholds reached according to the duration of daily wear of a CRT, N=827. TESTIS_2021.

Proportion of rise in sperm concentration above the contraceptive threshold

Among the participants who performed several spermograms, 36 participants (5.7%) found one or more sperm concentrations that had subsequently risen above the contraceptive threshold. Forgetfulness was low among them (91.7% less than once a month). The daily wearing time was lower than the rest of the sample (50% vs 27.6% wore it between 13 and 15 hours a day).

Reasons for not reaching the contraceptive threshold

7.4% (61/827) of participants had not reached the contraceptive threshold at the time of the study. On average, they had used CRT for 11.9 [+/- 5.6] months STD and 89% performed a spermogram several times a year to check for threshold achievement.

Among the reasons given in free text for not reaching the threshold, there was a lack of compliance with frequent forgetfulness or wearing less than 15 hours a day (N=24) and a failure to maintain the testicles in the inguinal position (N=19). No explanation was given for 13 participants who described strict adherence to the protocol, or even an increase in the number of hours of daily wear or continuous 24-hour wear.

2. Contraceptive effectiveness in practice

In our study, 6 unplanned pregnancies were reported among 964 participants who had used CRT for at least 6 months (0.6%). No pregnancies occurred after the contraceptive threshold was reached.

Factors that may explain an absence of pregnancy in the study

Possible factors (other than the use of CRT) that may explain a lack of pregnancy after reaching the contraceptive threshold have been documented in Table 18 (Table 18).

Table 18. Confounding factors identified that may explain non-pregnancy other than by testicular uptake contraception. TESTIS_2021.

	Participants who reached the contraceptive threshold. N= 766 Number (%)
Maintenance of parallel contraception by the partner(s) after reaching the contraceptive threshold	99 (12,9%)
Low frequency of sexual intercourse in the past year (once a year) months or less)	87 (11,4%)
Abnormal results of the first spermogram	28 (3,7%)
Taking treatment that may reduce fertility	24 (2,5%)
Occupational exposure to heat / radiation / pesticides	17 (2,2%)

In our study, 36.6% (355/970) of the participants had: had regular sexual intercourse in the previous year (several intercourses per month), were not using any other contraceptive method in parallel, had first spermogram results within the norms and did not report any occupational exposure or regular medical treatment that could reduce fertility. No unplanned pregnancies were reported after the contraceptive threshold was reached.

Unplanned pregnancies

Six participants reported the occurrence of an unplanned pregnancy (0.6%). On average, participants had used CRT for 13 months [+/- 4.6] STD.

Of these participants, three reported not having reached the contraceptive threshold at the time of the study (i.e. in the inhibition phase), after 8 months, 12 months and 15 months of using a CRT.

One participant reported reaching the contraceptive threshold after three months, and one non planned during the first three years of use (during the inhibition phase).

Two participants reported that they had not verified that the contraceptive threshold had been reached by a spermogram, and that an unplanned pregnancy had occurred during the first three months of use (during the inhibition phase).

Two participants used their contraception for less than 15 hours per day; the reasons given in free text were: lack of knowledge of the protocol for using at least 15 hours per day, and difficulties in maintaining the testicles in the inguinal groin due to the devices.

Two participants needed more than three months to become accustomed to using their contraception daily. Five participants were still using an RTC device at the time of the study (one participant had stopped).

Four participants did not routinely use additional contraception during the inhibition phase.

Estimation of a Pearl Index

The Pearl Index is used to estimate the effectiveness of contraception. It represents the number of pregnancies per 100 couples during one year, depending on the contraceptive method used. It can be calculated using the following formula:

(Number of unplanned pregnancies / Number of cumulative female exposure cycles) x 1200

The exposure times are summarised in Table 19. One cycle of female exposure was considered equivalent to one month of CRT use. The "effective" exposure time is the cumulative number of months since the contraceptive threshold was reached, in the absence of additional contraceptive use.

Table 19. Duration of exposure (in number of female cycles) to testicular lift contraception (in months). TESTIS_2021.

	Total duration of exposure to CRT (months) N=966	Effective exposure time (months) N=568	Effective exposure time 1 year N=183
Sum (in months)	13634	6386	3727
Number of pregnancies	6	0	0
Pearl Index	0,53	0	0

Note: Total duration = number of months of exposure over the entire duration of CRT use; Effective duration = number of months of exposure since reaching the contraceptive threshold and in the absence of additional contraception; Effective duration of use 1 year: number of months of exposure since at least one year of reaching the contraceptive threshold and in the absence of additional contraception

No pregnancies occurred among 183 participants who used one or more CRT devices at least one year after reaching the contraceptive threshold, i.e. after at least one year of use in the contraceptive phase.

DISCUSSION

I. Summary of the main results

Prior to using CRT, participants were using contraception regularly (83.2%), half were dissatisfied (51.7%), and their sexual partners were dissatisfied (64.9%). A history of significant adverse events due to their previous contraception was found in sexual partners in 68.3% of cases.

The CRT devices used were the Andro-switch device (96.0%), Dr Mieusset's device (2.6%), and/or self-made cloth devices (jock-strap and other DIY) (5.8%). Most participants became accustomed to using CRT within 15 days (88.7%). The CRT devices had been used for an average of 14.1 months [+/- 8.7]. Most participants had started CRT after December 2019 (95.2%).

Less than 5% of participants used the devices strictly as recommended.
RT devices were worn: less than fifteen hours per day (32.5%), between fifteen and seventeen hours per day (44.8%) or more than seventeen hours per day (22.7%). The devices were worn mainly during the waking period.
Before starting CRT, 74.0% of participants consulted a health professional; 68.6% performed an initial spermogram. A spermogram was performed to verify that the contraceptive threshold was reached in 89.4% of cases.

Very common adverse events were skin (about 50% penile and scrotal skin irritation or itching), discomfort in the testicles (45.8%) or lower abdomen (28.7%) during the first few uses, reduction in testicular size (31.5%), painful or unpleasant erections while wearing the CRT (nighttime 23.4%, daytime 11.8%), and the experience of unusual delayed drops after urination (21.4%). Several participants spontaneously reported an increase in frequency of urination.
Participants felt that CRT had a positive impact on their sexuality in 63.3% of cases, or no impact in 35.6% of cases. The ASEX sexual dysfunction score was unchanged before CRT and at the time of the study, and there was a significant improvement in sexual quality of life on 4 MSHQ items. Participants felt that CRT had a positive impact on their sexuality with their sexual partner(s) (75.5%) or no impact (23.3%).

Satisfaction with the CRT was very high (86.5% "extremely" or "very satisfied"). The overall feeling of constraint was low (above 75% "not at all constraining" or "not very constraining"), and mainly concerned sports activities (20% "quite constraining" or "very constraining").
This is a "very restrictive" approach.) At the time of the study, 88.7% of participants were still using a CRT, and
Of these, 97.8% wanted to continue.
Fabric devices (jock-strap, Dr Mieusset's contraceptive underwear and other DIY devices) were reported to hold the testicles in place better and cause less skin irritation. The Andro-switch device was reported to be more comfortable at night and easier to use.

The main barriers identified were the need to regularly check the correct positioning of the testicles (44.4%) and the minimum required wearing time of 15 hours per day (23.1%). Most participants did not encounter any difficulties with their sexual partners regarding the CRT (76.3%). The difficulties identified were mainly related to the sexual partners' lack of confidence in the effectiveness of this contraceptive method (13.1%).

Delays in performing a spermogram were greater than one week (80.0%), and 41.0% of participants described not being accompanied by the health professional during the consultation; 48.1% had regular medical follow-up.

The contraceptive threshold was reached by 92.6% of participants who performed an efficacy check spermogram, on average after 3.3 months [+/- 1.93] of use. No significant difference in contraceptive threshold achievement was found according to daily wear time. Six unplanned pregnancies were reported. These pregnancies all occurred during the inhibition phase: either within the first three months of CRT use, or before the contraceptive threshold was reached. The estimated Pearl Index for participants who used a CRT at least one year after reaching the contraceptive threshold and stopped using additional contraception was 0.0% for 3727 exposure cycles.

II. Limitations and biases of the study

The very high number of participants is one of the strong points of this study. This number reflects the involvement of the various activist groups and health professionals in the dissemination of this survey, as well as the investment of users in their contraception. It also reflects the growing use of this method of contraception in Europe.
Another strength and originality of this survey is that it includes all unrestricted testicular lift devices (jock-strap, Andro-switch, self-made devices, Dr Mieusset's device), that it is international, and that it accurately documents the adverse events that occurred and the impact on sexuality.

However, there are some biases in this study.

First of all, there is a classification bias, as the participants answered independently, and some questions, particularly of a medical nature, could have been misinterpreted or misunderstood. A working group on the questionnaire was set up with non-health professionals in order to minimise this bias. Some questions concerning sexual partners (concerning previous satisfaction with contraception or the impact on the quality of sexual life) were filled in by the participants, so there is a classification bias.

There is a recall bias, as some questions explored events that took place before testicular contraception, or at the start of use, which is more than 6 months ago, or even several years for some users.

Regarding recruitment, the questionnaire had to be fully completed in order to be validated, which may have discouraged some participants, although it is not possible to quantify the number of participants who dropped out during completion. However, given the number of respondents, we can assume that the time taken to complete the questionnaire was acceptable.
Furthermore, regarding the devices themselves, almost all participants used the Andro-switch device, which probably constitutes a recruitment bias. Admittedly, as this device is more easily accessible due to greater media visibility and the possibility of ordering online, it is used more. However, according to Joubert's study from 2011 to 2019, Dr Mieusset's contraceptive consultation had an active file of at least 72 users [39]. In addition, activist workshops for the self-confection of jockstraps and other devices have been held for several years. We would therefore have expected a greater recruitment of users of Dr Mieusset's device, or of self-made cloth devices in our study. This can be explained by the communication around this study, which was mainly done through social networks and activist groups, and did not reach users not involved in social networks.

Finally, participants were required to have used a CRT device for at least 6 months, suggesting that many users who were dissatisfied before this time and had stopped did not respond to this survey. Similarly, if a pregnancy occurred before 6 months, it can be assumed that this resulted in discontinuation of contraception and non-participation in this study.

Study population

The participants in this study were mostly young, of high socio-professional category, in a couple relationship, had no children and had little medical history. Most of them lived in France or in Europe.
This population is not representative of the general population; however, it is similar to those of other recent studies on CRT in which more than 80% of the participants are under 35 years of age, have a high level of education (Joubert: 80% higher than Bac+3), are in a couple (Rouanet: 73%), and have no children (Joubert: 78%; Rouanet: 79%; Lalieux: 95%) [19, 23, 46].

With regard to vasectomy, the proportion o f individuals who had considered this contraception was more
The number of people who have been exposed to this type of violence is much higher than in Dr Joubert's study (11%).

III. Analysis of the results

1. CRT health security

Adverse effects:

Almost all participants reported adverse effects. It should be noted that this study did not characterise whether the adverse effects were temporary or permanent. These adverse effects could be grouped into two categories in terms of health impact.

On the one hand, in our study, frequent and mild side effects were skin irritation (53.1% on the penis and 51.9% on the scrotum), discomfort (8.8%) and testicular pain (4.7%). The proportion of discomfort was 45.8% for first-time users, and 18.5% for testicular pain.
These side effects, although very frequent, were rarely a hindrance. Moreover, they could be assumed to have no functional impact and seemed to be acceptable in view of the high level of satisfaction and low sense of constraint.
Although studies in the 1990s reported no change in sexuality and very few adverse effects [14], recent studies have described similar adverse effects. From 2011 to 2019, a study in France by Dr Joubert [39] of 63 subjects described 59% skin irritation, 35% pain, and 56% discomfort during the first trials of Dr Mieusset's contraceptive underwear. The frequency of these manifestations declined with the duration of wear: 23% pain and 33% discomfort during the first months of use (inhibition phase), then 7% pain and 24% discomfort after the contraceptive threshold was reached (contraceptive phase).
In 2021, a study by Dr LALIEUX in Belgium on 22 individuals using the Andro- switch device [46] found 54.5% of skin irritation or itching, and 31.8% of pain or discomfort (testicular or penile). These adverse effects could be a reason for discontinuation (9%).

Our study found similar proportions of skin irritation and testicular pain, and a lower frequency of discomfort (apart from initial use). In addition, our study found the same proportions of testicular volume reduction (30%) as a 1994 study of 9 individuals [14].

On the other hand, some adverse effects required particular attention as they could have a significant health impact. In particular, CRT raises questions in the medical community concerning the risk of testicular torsion, testicular tumours, venous thrombosis and urethral stenosis, the symptoms of which we looked for in our study,

At the urinary level, the impact on the micturition phase has not been described in the literature to date. From a physiological point of view, it can be assumed that wearing a contraceptive device creates an overpressure downstream of the bladder outlet, leading to discomfort during the flow of urine with a symptomatology found in our study evoking an obstructive mechanism (need to push to urinate, lengthening of the time to urinate, sensation of incomplete micturition, frequent and pressing micturition urge, delayed drops).

Our study found less than 1% of severity criteria (infectious signs or urinary incontinence), and no reports of acute retention of urine were made. Moreover, the disappearance of urinary symptoms when the device was removed (reported by some participants) is a reassuring element, and in disfavour of a diagnosis of urethral stenosis, of similar symptomatology. It seems important to study these phenomena in order to confirm a causal link and to understand the mechanism and the long-term effects on bladder activity. As a precautionary measure, it would seem justified to recommend the systematic removal of the contraceptive device at the time of urination.

In terms of allergic risk, 2.7% of allergy declarations were made during the first few days of use, without any further details. This represents a limitation of our study: are these allergies true allergies, or another skin condition? It should be noted that none of the participants declared that they had stopped using the device because of an allergy to it.

One participant reported in free text the occurrence of *"penile vein thrombosis"* without specifying superficiality or depth. Superficial venous thrombosis of the penis is a poorly understood phenomenon, the diagnosis of which is clinical and is expressed by superficial pain involving the venous pathway, which may occur during sexual intercourse [47]. In our study, there was a high frequency of discomfort or pain during daytime or nocturnal erections, however, only 0.2% of participants reported persistent pain after removal of the device, and 0.9% reported the need for medical treatment of the penis (however, superficial venous thrombosis can involute spontaneously in a few weeks). Regarding deep venous thrombosis of the penis, which is a therapeutic emergency [48], our study found 0.9% of oedema of the penis, 0.1% of decreased sensitivity of the penis, and 0.1% of priapism. No participant reported the need for emergency medical treatment.

The very low frequency of occurrence of specific clinical signs provides reassurance regarding the occurrence of venous thrombosis. However, it seems necessary to study these phenomena for future clinical studies, especially as the use of cock-ring devices seems to be a risk factor [48].

At the erectile level, we found a high frequency of discomfort and pain during daytime and nighttime erections while wearing the device. Participants also described changes in erectile function in terms of duration (4.8%), stiffness (3.9%), or rapidity (2.6%). A limitation of our questionnaire was that we did not collect information on the content of the erectile changes (increase or decrease in ability elicited), and whether these occurred while wearing the device and/or when not wearing it.

Several free text responses described a positive 'cock-ring' effect increasing erectile capacity, while others reported that the devices could impact on the spontaneity of their sexual encounters by causing pain during erection.

On this subject, the study by Dr LALIEUX [46] on the Andro-switch device found 18.1% discomfort during erection and/or sexual intercourse, which resolved spontaneously when the device was removed. Dr Joubert's study [19] on Dr Mieusset's contraceptive undergarment found 5% negative feelings about erections and 92% no change in erections, without specifying whether or not the undergarment had been used.

We can therefore provide two interesting pieces of information: some participants kept their contraceptive devices on during sex, and there seems to be an impact on erectile function for some users (less than 5%). This impact can be positive or negative depending on the participants. In view of the high level of satisfaction with the quality of sexual life at the time of the study, the absence of change in the ASEX score assessing sexual dysfunctions before and after contraception (particularly on the question of erectile dysfunction), and the absence of discontinuation as a result of erectile dysfunction, our study seems to provide reassuring elements concerning the preservation of erectile function, particularly in the event of withdrawal of the device during sexual relations. However, it seems interesting to question the systematic and long-term use of these devices during sexual acts.

Sexuality

Sexual function according to the ASEX scale was not altered before and after at least six months of CRT use (desire, pleasure, erection, orgasms). The quality of sexual life in relation to sexual partners according to the MSHQ questionnaire was improved (quality and frequency of intercourse, communication and tenderness around sexuality). The overall quality of sexual life was felt to have improved by the participants, and this also applied to their sexual partners, who were reported to be even more satisfied.

These data suggest that the perceived improvement in sexual quality of life is likely to be due to relational and qualitative aspects around sexuality, rather than to an improvement in organic sexual function per se. In addition, the higher perceived improvement in sexual partners may be due to a ranking bias. However, this could also be explained by the cessation of previous contraception affecting the sexuality of sexual partners.

Our results are in agreement with Joubert's study [19] which shows an overall improvement in sexuality with the use of a CRT, particularly in terms of desire, pleasure and frequency of sexual intercourse, compared with the contraceptives previously used. One hypothesis could be that the participant's ownership of contraception promotes communication about sexuality within the couple or with sexual partners. However, studies of vasectomy, which have shown no negative effect on sexual function or satisfaction, have not found any significant improvement in sexuality [49, 50].

One may therefore wonder whether the specific use of a CRT, through the daily involvement it requires and thus the paradigm shift in contraceptive load, and through the improved knowledge of the users' body and fertility, would lead to changes in sexuality that would be perceived as beneficial by the protagonists and their sexual partners? Further studies, involving sexual partners, are needed to investigate these findings further.

Compliance with the recommended protocol

Dr Mieusset's protocol was very poorly adhered to in practice, with a high proportion of participants using the devices for less than fifteen hours a day. However, the wearing times proposed in our questionnaire were broken down into two-hour slots: "between 1pm and 3pm" and "between 3pm and 5pm", etc. It is therefore possible that a number of participants used their devices for more than one day. Therefore, it is possible that a number of participants using their devices between 14 and 16 hours a day reported (incorrectly) an average use of less than 15 hours.
Furthermore, it is important to note that the two main reasons for using less than 15 hours per day were either that the contraceptive threshold was still reached or that the daily organisation prevented longer wear. The occurrence of adverse effects was less frequently involved (10%).
On the contrary, the two main reasons for using the method for more than 17 hours a day were: either a desire to compensate for a lack of rigour in the wearing schedule, or forgetting to remove the device after 15 hours of wear. Fear of the ineffectiveness of the method itself was less frequently cited (16%). In his study, Dr Joubert found a similar proportion of participants wearing their device for more than 15 hours a day for fear of an unplanned pregnancy (20%).

31.4% did not perform a spermogram before starting their CRT. Our study does not explore the reasons for this. It can be assumed that some participants who had already had children did not feel the need to check their sperm concentration. It is also possible that access to a medical prescription or laboratory was not possible. It is also possible that some participants did not want to perform the spermogram. In Dr Joubert's study, 10% of the participants who did not perform the initial spermogram did so for fear of discovering infertility.

2. Acceptability of the CRT

After six months of use, this contraception was considered very satisfactory and not very restrictive, and almost all users wanted to continue using it. However, in order to participate in this study, participants had to have used a CRT for at least six months; however, a recent study showed that dropouts occurred within the first six months of use [23]. This constitutes a major bias in the assessment of satisfaction in our study, suggesting that the feeling of satisfaction may be overestimated, just as the feeling of constraint is underestimated.

The time to get used to the contraceptive devices was shorter in our study than in Dr Joubert's (less than 15 days for 88.7% vs 68%) [39], perhaps due to the greater ease of use of the Andro-switch devices, which are used in the majority of cases.

Among the obstacles, the need to regularly check the correct positioning of the testicles was identified, in higher proportions than in Dr Lalieux's study [46] on the Andro-switch (44.4% vs 36.6%), but lower than that of Dr Joubert [39] on the contraceptive pants, which found 54% of spontaneous descent of the testicles. However, in our study, participants comparing different devices reported better support with cloth devices. It is possible that some innovations in the manufacture and sizing of jock-strap and DIY devices have occurred since then, explaining the better fit.
Although 82.8% said it was easy to wear the device for 15 hours a day, a large proportion of participants wore it for less than 15 hours, and identified this minimum duration as a barrier to contraceptive use (23.1%), particularly because it forces them to maintain a regular lifestyle and prevents them from sleeping too long. These percentages are higher than those in Dr. B. B.'s study.

Lalieux [46] who found 9% difficulty in respecting the carrying schedule. In the different activities, the main constraint concerned sports activities and was similar to the study by Dr Lalieux [46] (19.6% vs 18%).
The lack of access to spermograms in our study is described in Dr Joubert's study (19% too long delay, 13% lack of proximity). Similarly, Joubert describes a lack of medical support (47%).

It is interesting to note that when the subject of CRT was broached by sexual partners, a delay was necessary before the use of this method was accepted by the protagonists. The fact that, conversely, sexual partners accepted more immediately leads to two hypotheses. Firstly, it is possible to imagine that non-acceptance by sexual partners leads to non-use of CRT, which is not visible in this study. Conversely, it is possible that sexual partners are more motivated by a change in contraception within the couple, and therefore more inclined to accept immediately. It should be noted that the discussion of this contraceptive topic by sexual partners did not seem to have an impact on the participants' feelings of satisfaction and constraint.

A small proportion of sexual partners lacked confidence in the participants. This is in contradiction with the socially promoted representation of male irresponsibility [7]. Similarly, the low proportion of barriers identified with sexual partners is likely to be underestimated, as it may result in non-use of CRT.

Few participants who discontinued CRT responded to this survey. The reasons for discontinuation were mainly related to the acceptability of CRT (side effects, accessibility, constraints) or to a change in contraceptive need. The reasons for discontinuation are similar in Dr Joubert's study (30% related to celibacy or a desire to procreate; 19% related to side effects) [39]. It should also be noted that some patients stopped in order to check that their sperm concentration had returned to normal, reflecting fears identified in Dr Joubert's study (7% fear of the lack of experience with this method) [39].

3. Effectiveness of the TRM

At the time of the study, of those participants who had verified that they had reached the contraceptive threshold, 92.6% had done so. After 3 months, 81.1% had reached the threshold, and 97.4% after 6 months. The average time to reach the contraceptive threshold was 3.3 months. 6 pregnancies occurred before reaching the contraceptive threshold or before 3 months of use. No pregnancies occurred after one year of reaching the contraceptive threshold and stopping other contraceptive methods, i.e. after 3727 cycles of female exposure (Pearl index of 0.0%).

In 1994, Mieusset and Bujan [14] conducted a study using Dr Mieusset's contraceptive undergarment consisting of a cloth ring, with 6 couples over a period of 4-46 months. Participants reached the contraceptive threshold after an average of 3.5 months (86.4% of participants, one participant discontinued the study), and no pregnancies occurred in 117 female exposure cycles after the threshold was reached (Pearl Index 0.0%).

From 2011 to 2019, Joubert reports no pregnancies among 59 subjects who used the contraceptive undergarment and reached the contraceptive threshold [39]. In 2021, Lalieux [46] reported that 64% of participants reached the contraceptive threshold after an average of 3.75 months in 22 individuals using the Andro-switch device. No pregnancies occurred over 40 cycles after the threshold was reached (Pearl index 0.0%).

In comparison, the contraceptive threshold was reached more frequently in our study, and faster on average. This duration is also probably overestimated by the recommendations to perform a control spermogram after 3 months of use; a verification of the achievement of the contraceptive threshold before 3 months was in fact only rarely performed by the participants.
The number of exposure cycles is much higher than in previous studies and provides a strong argument for the efficacy of this method, once the contraceptive threshold is verified.

However, as this study was non-interventional and cross-sectional, it does not allow conclusions to be drawn about contraceptive efficacy. In particular, some pregnancies may have occurred within the first 6 months of use and may have led to discontinuation of CRT. In addition, it is possible that some participants were not informed of the occurrence of a pregnancy. Finally, the achievement of the contraceptive threshold was only declarative, with no control of the biological sperm parameters.

In addition, 7.3% had not reached the threshold (after regular spermogram checks) after an average period of use of almost one year. While some explanations were given by participants regarding poor compliance with the protocol, or difficulties with the device, 13 participants reported not reaching the contraceptive threshold despite correct use, or even an increase in the number of daily hours.

In addition, 5.7% of participants described a subsequent rise in concentrations above the threshold, without repeated oversights being involved. It can therefore be assumed that some individuals are unresponsive, either immediately or secondarily, to a moderate increase in testicular temperature, either through physiological compensation or anatomical variability. The term "thermoresistance" seems to be emerging in this respect [46].

IV. Perspectives and public health strategy

1. Recommendations from the study

The data from our study encourage us to propose some recommendations for good practice, and perspectives for future clinical studies.

As a personal precautionary measure, it would seem justified to recommend the systematic removal of the contraceptive device when urinating. It would also seem worthwhile to question the systematic use of the device during sexual intercourse (if any).
While the majority of participants in this study used devices that can be described as
While some participants were using "standard" devices (Andro-switch, jock-strap, Dr. Mieusset's underwear), a few participants were making other DIY devices, or misappropriating "cock-ring" type objects to contracept themselves. It seems important to have the capacity to provide suitable and regulated devices to people wishing to use testicular contraception.

As a reproductive precautionary measure, it seems necessary to strongly encourage an initial spermogram and waiting for the parameters to return to normal after stopping CRT. It seems essential to formally warn users of the potential teratogenic risk for up to 6 months after stopping CRT and to explain what to do if a pregnancy occurs. This course of action should be equivalent to those defined for pregnancies exposed to teratogenic drugs currently on the market, such as isotretinoin or valproate [51].
In addition, consideration should be given to the psychological and medical management of individuals who discover abnormal results during the initial spermogram. The current data on reversibility having been studied for a maximum duration of 4 years and on a small number of individuals, a reflection on the CECOS indications could be opened.

In view of the diversity of daily wearing times in real practice - a shorter time does not seem to prevent the contraceptive threshold from being reached, and a longer time does not show any significant difference in terms of adverse effects or satisfaction - new protocols of use could be studied, allowing a progressive adjustment of wearing time according to individual variability. Furthermore, as the majority of users use their contraceptive device at least partially at night, new protocols could validate the effectiveness of night-time CRT use.

As the main obstacle identified is the need for regular repositioning of the testicles, it would be relevant to include in future studies the alternating use of different devices according to activities and needs, as each seems to have its own advantages; in particular, the good maintenance of the testicles for cloth devices (although the number of users who used two devices was low in our study). In addition, the decrease in testicular volume appears to result in more frequent repositioning of the testes in the lower position. A change of device size after a few months, or the use of adjustable devices seems to be an option for some users.

Another obstacle identified was the difficulty of respecting regular wearing times and the difficulty of calculating a "catch-up" time in the event of irregularity. It would be interesting to study the effectiveness of an average wearing time over 48 hours, for example, which could allow users to adjust their hours more flexibly from one day to the next. The implementation of a time calendar type tool could also facilitate user compliance by making it easier to track wearing times.

If the device is forgotten for more than one day, it seems to be a priority to carry out clinical studies to observe the subsequent impact on spermatogenesis and to establish a standardised course of action.

Finally, in order to promote accessibility and reduce the risk of unplanned pregnancy during the inhibition phase, after a forgetfulness, or after a period of irregular schedules, it seems essential to improve access to a spermogram within an acceptable timeframe. Immunological self-tests are currently available in pharmacies to check the effectiveness of vasectomy (threshold of 250,000 spermatozoa/mL) [52]. The development of similar self-tests to regularly monitor the maintenance of a sperm concentration of less than one million per millilitre would greatly facilitate access to this contraception; this request was made by 64% of the participants in Dr Joubert's study [39]. Concerning the achievement of the contraceptive threshold, our study suggests that more than 10% would probably reach the threshold before 3 months. In this sense, recommending a spermogram after 2 months could be of interest.

2. Public health strategy

In terms of accessibility, the current context of the health ban on the Andro-switch device and the cessation of specialised consultations at the Toulouse University Hospital leaves couples or individuals wishing to undergo CRT with little choice but to self-fabricate, as no standardised and medically validated manufacturing protocol is currently available.
It seems important to anticipate a decrease in the use of - or even a lack of confidence in - the healthcare system in this area, especially as some healthcare professionals, faced with the absence of recommendations and the lack of scientific data on the subject, could find themselves in difficulty and fear that they will be held liable if they agree to monitor these patients.
However, our study shows that less than 5% of participants complied with the recommendations use of the devices.

Medico-legal considerations sometimes seem to intervene in the management of patients wishing to use these contraceptive methods. Some health professionals may have refused to accompany these patients for fear of being held responsible in the event of a health problem. We can recall here that ethics and medical duty justify accompanying patients in their request for care, whatever their morals, whether their practices are recommended or not [53]. A parallel can be drawn with the monitoring of patients in the context of the use of illicit substances, which in no way engages the responsibility of the accompanying doctor, but which would engage his or her responsibility in the event of refusal of care, without referral to a competent health professional. A protective withdrawal of health professionals on this subject would be reminiscent of the social struggles of the 1960s that were necessary to make the oestroprogestogen pill accessible, and a few years later, for the right to abortion.

In view of the probable increase in the number of individuals and couples wishing to use a CRT, and the relative autonomy of use of these devices in relation to the health system, it seems essential to put in place a health monitoring and risk reduction strategy rather than a ban on the practice, in order to encourage the maintenance of the link between users and health care systems. A public health policy encouraging the funding of clinical studies on CRT, the production of good practice guidelines, and the training of health professionals, to the extent that scientific data are available, seems to be a priority, as is reintegrating individuals with testicles into the sexual and reproductive health care system [7].

The existence of a dynamic activism around this subject - with the Slow Contraception and ARDECOM associations in particular - and communities of users helping each other on social networks, are all support, relays and expertise already in place to accompany the training of health professionals and the development of future research projects.

CONCLUSION

Testicular uptake contraception (TRC), as used in our study, appears to be a medically, sexually, and socially acceptable method among relatively young and high socioeconomic participants.

In terms of safety, most participants did not use their CRT devices strictly as recommended. Documented adverse events appear to be mostly mild; particular attention should be paid to urinary function. The use of CRT seems to have a positive impact on the quality of sexual life of users and their sexual partners.

In terms of acceptability, CRT is not very restrictive in daily activities and users are very satisfied. In the vast majority of cases, no difficulties with sexual partners were reported. The main obstacles identified are the need to check regularly that the testicles are correctly positioned, and the time constraints. The CRT does not seem to be sufficiently accessible for medical follow-up and regular spermograms.

More than 90% of participants who performed a spermogram efficacy check reached the contraceptive threshold. A small number of unplanned pregnancies were reported (0.6%), occurring before the contraceptive threshold was reached or before 3 months of use.

Clinical studies are needed to assess the effectiveness and safety of the different devices currently used by the population, and to propose a standardised course of action in case of omission.

Opening

In addition to the contraceptive aspect, the CRT addresses the broader issue of equality between men and women through contraceptive burden sharing and autonomy in controlling one's own fertility.

While CRT favours this approach for individuals with testicles, symptothermal methods are another under-researched body-centred contraceptive approach for female bodies [54, 55].

These different approaches address a chapter little explored by contemporary medicine: that of individual learning and experience of the functioning of one's own body, in this case for contraceptive purposes.

A third approach would be to promote a principle that is fundamentally known and yet absent from the Western coital sexual imagination: that of the need for contraception only in the case of fertile sexual practices.

This public health study should be seen as a plea for research and development of the testicular uptake contraceptive method, and more generally, of other shared contraceptive practices, including the promotion of plural sexualities that are uncorrelated with systematic fertilising sexual practices [56, 57].

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APPENDIX I: JOCK-STRAP TUTORIAL

GAR CON

ÉTAPE 1
PRÉPARATION DE L'ANNEAU

C'EST LA PARTIE LA PLUS IMPORTANTE SUR LAQUELLE IL FAUT VRAIMENT S'APPLIQUER.

1. PRÉPARATION DU CORDON

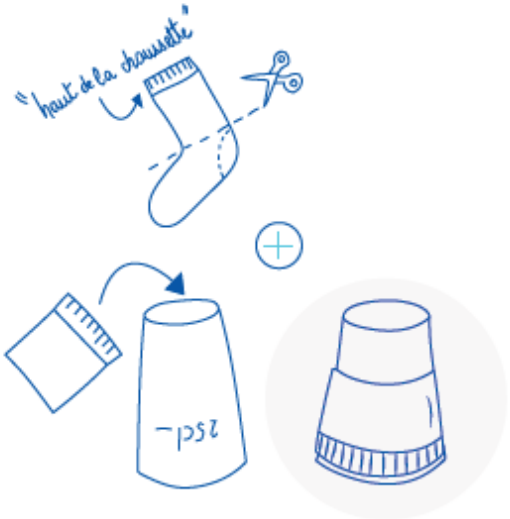
- Coupez 50 cm de cordon (à plus ou moins 2 cm).
- Faites fondre chaque extrémité avec un briquet pour former une boule de plastique fondu.
- Soufflez dessus quelques secondes
- Plongez-la dans l'eau pour qu'elle conserve cette forme.
- Faites ensuite un nœud à chaque extrémité.

Vous obtenez ainsi des extrémités qui ne s'effilochent pas, qui ne risquent pas de piquer, gratter, ni de rentrer à l'intérieur de l'anneau, ce serait compliqué à faire ressortir.

2. DÉCOUPE DE LA CHAUSSETTE

- Coupez juste au-dessus du talon pour garder un maximum de la partie cylindrique qui constitue la partie haute de la chaussette.
- Enfilez-la sur l'écocup en respectant le sens indiqué sur le schéma.

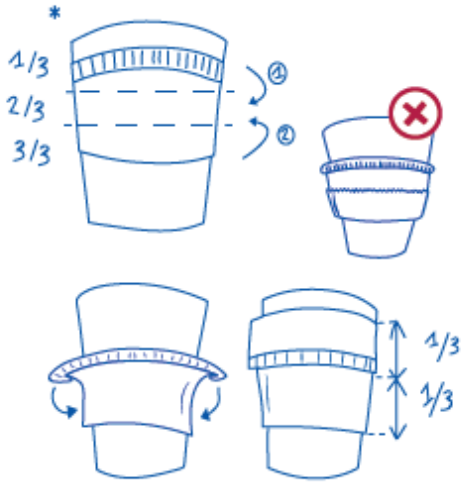
L'écocup permet d'une part de garder le tissu étiré pendant la couture. Il garde ainsi son extensibilité. D'autre part, cela facilite le placement de vos doigts pour maintenir l'ouvrage et pour passer l'aiguille là où elle doit.



3. PLIAGE DE LA CHAUSSETTE

- On commence par la rabattre sur elle-même selon ses trois tiers*, dans un ordre à respecter.

- On plie d'abord le tiers qui correspond au haut de la chaussette : il est moins doux, donc on le rabat à l'intérieur de l'anneau pour qu'à la fin il ne soit pas en contact avec la peau.



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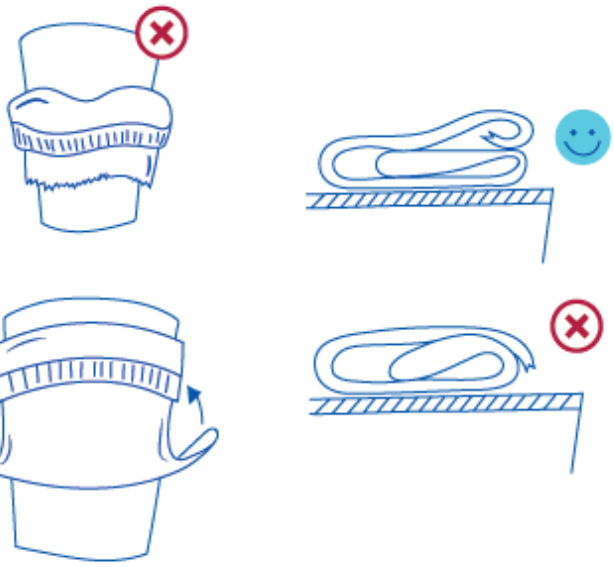
3. PLIAGE DE LA CHAUSSETTE / SUITE

• Prenez le temps de former chaque pli bien droit.
Vous obtiendrez ainsi un anneau plus confortable.

• Quand vous repliez le dernier tiers, laisser la partie découpée s'enrouler vers l'intérieur.
Vous éviterez ainsi que le tissu s'effiloche à l'usage.

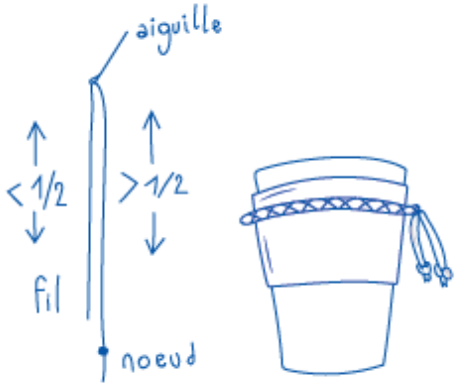


4. COUTURE DE L'ANNEAU

• Choisissez pour votre premier anneau un fil dont la couleur contraste avec celle de la chaussette : vous verrez plus facilement ce que vous faites.
• Prenez une bonne longueur de fil pour coudre en une seule fois tout le tour de l'anneau. Vous aurez besoin d'au moins 70 à 80 cm, à condition de ne pas doubler le fil. Si vous ne connaissez pas cette technique, comprenez qu'on fera coulisser l'aiguille le long du fil, presque au milieu, au fur et à mesure que l'ouvrage avance.
Le nœud d'arrêt doit être suffisamment gros, car il a tendance à passer à travers le tissu de la chaussette qui est très extensible.

• Placez le cordon autour de la chaussette.
Vous pouvez éventuellement faire un nœud pour le maintenir en place, sans serrer trop fort.

• Pliez encore en deux la chaussette sur elle-même, bord à bord, très soigneusement pour éviter qu'ensuite des points durs qui pourraient être inconfortables ne se forment.
Le cordon est ainsi pris en sandwich. Les bords que vous allez coudre doivent être au bord de l'écocup pour pouvoir faire ressortir l'aiguille facilement à chaque point.



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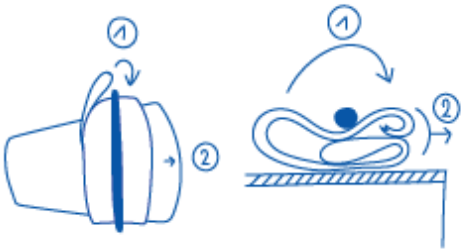
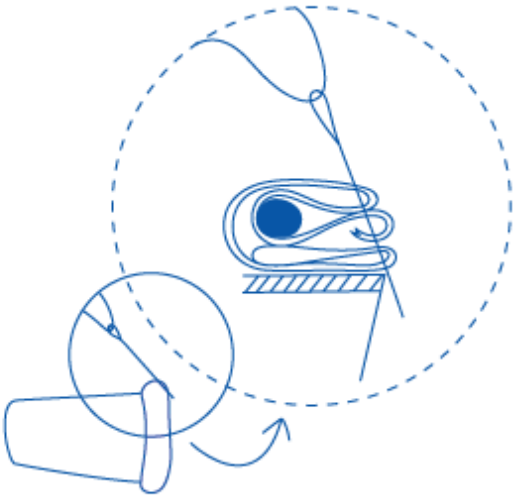
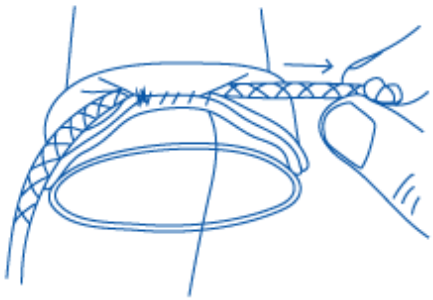


4. COUTURE DE L'ANNEAU / SUITE

• Quand tout est en place, commencez à coudre en faisant attention à ne pas piquer le cordon pour qu'il puisse coulisser dans l'anneau.
• Cousez d'abord 3 ou 4 points au même endroit pour que le point de départ soit résistant à l'usure.
• Cousez tout le tour de l'anneau, sans tirer fort sur le fil : vous risqueriez de former un point dur sur l'anneau qui pourrait le rendre inconfortable.
Les points ne doivent pas être trop rapprochés pour pouvoir coudre tout le tour de l'anneau avec le même fil. Vous pouvez les espacer d'environ 5`mm les uns des autres.

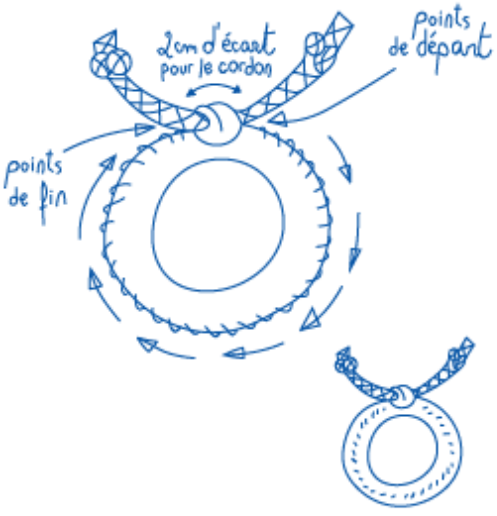




Même en faisant attention, il arrive assez facilement qu'on pique le cordon. Pour ne pas vous rendre compte trop tard que le cordon est bloqué, faites-le coulisser d'un ou deux centimètres dans l'anneau tous les 3 ou 4 points pour vérifier. Si besoin, défaites les derniers points un par un. Pour cela, retirez l'aiguille du fil et glissez sa pointe sous le fil. Tirez-le alors le fil du dernier point pour le défaire entièrement puis recommencer avec le point suivant autant que nécessaire.

Quand vous arrivez à 1 ou 2 cm du point de départ, faites 3 ou 4 points au même endroit pour former le point de fin. *Faites particulièrement attention à ne pas piquer le cordon à cette étape.*

• Retirez l'anneau de l'écocup.
• Tirez sur les deux extrémités du cordon pour resserrer l'anneau au maximum, puis étirez l'anneau pour lui redonner sa forme normale.
• Répétez cette opération trois ou quatre fois pour former l'anneau et le rendre très confortable.
• Roulez l'anneau sur lui même pour que la couture se place sur une face plutôt que l'autre. Placée vers l'avant du jockstrap, elle n'entrera pas en contact avec la peau et sera complètement imperceptible.



ÉTAPE 2
PRÉPARATION DU BAUDRIER

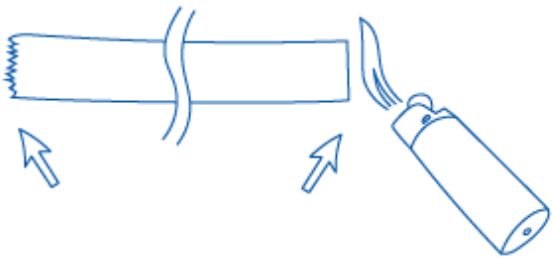
1. PRÉPARATION DE LA CEINTURE

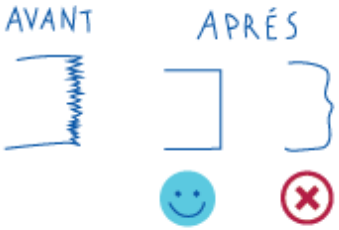
• Mesurez votre tour de taille à l'endroit où passe la ceinture de votre sous-vêtement habituel.

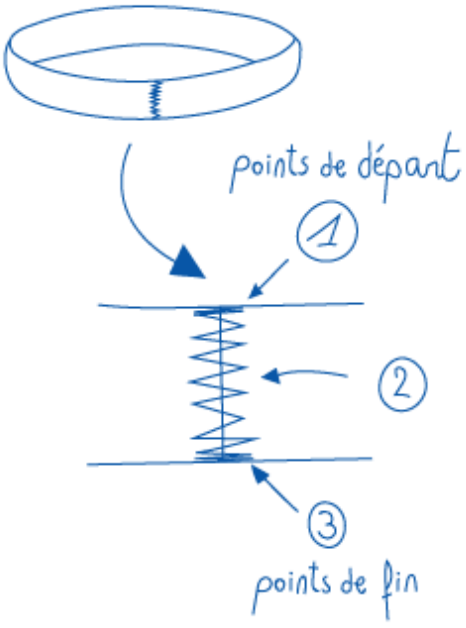
• Coupez un morceau de bande élastique environ 20 cm plus courts que cette mesure. La découpe doit être bien droite, et bien perpendiculaire à la bande.

• Faites fondre légèrement les extrémités pour éviter l'effilochement. Les coins de la bande ont tendance à fondre plus rapidement, alors passez le briquet très rapidement. Le bord doit rester bien droit.

Nous présentons ici la méthode utilisant une machine à coudre, mais il est tout à fait possible de la réaliser à la main.
Nous donnons ici à titre indicatif les réglages que nous utilisons pour la machine dont nous disposons (silvercrest SNM 33 C1).







2. COUTURE DE LA CEINTURE

• Assemblez les deux extrémités et cousez à l'aide d'un point zigzag.

Tension AUTO (4/8)
1/ Longueur des points : 0
Largeur des points : 3 points de largeur 5mm
puis 2 points de largeur 2mm

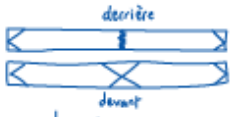
2 / Longueur des points : 1 mm
Largeur des points : 5 mm

3/ Longueur des points : 0
Largeur des points : 3 points de largeur 5mm
puis 2 points de largeur 2mm

2. COUTURE DE LA CEINTURE / SUITE

• On place quelques repères à la craie sur la ceinture :
- Pliez la ceinture en deux, la couture étant l'une des deux extrémités.
- Tracez un V à l'autre extrémité sur chaque face.

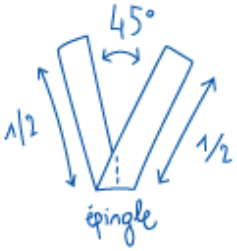
• Une fois la ceinture dépliée, les deux V forment un X qui repère l'avant du jockstrap. La couture doit se trouver à l'arrière, au niveau d'une vertèbre pour être tout à fait imperceptible.

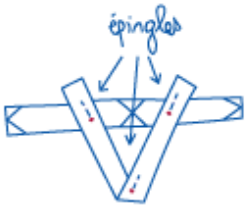


• Superposez la couture et le X et posez à plat l'ensemble pour marquer de la même manière les côtés gauche et droit de la ceinture par deux autres croix.

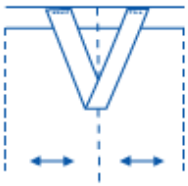
3. PRÉPARATION DU V

• Pour votre premier jockstrap, découpez 40 cm de bande élastique. Pliez-la en 2 moitiés que vous écartez ensuite pour former un V d'un angle d'environ 45 °. Maintenez-le ainsi à l'aide d'épingles.





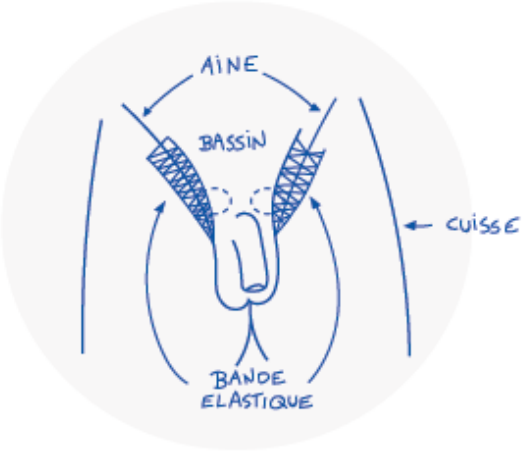
• Épinglez-le sur la ceinture en respectant la symétrie* de l'ensemble puis enfilez-le.



Vous devez maintenant procéder aux ajustements pour le faire correspondre à votre anatomie :

* *vous pouvez vous aider d'une feuille sur laquelle sont tracées des lignes parallèles équidistantes.*

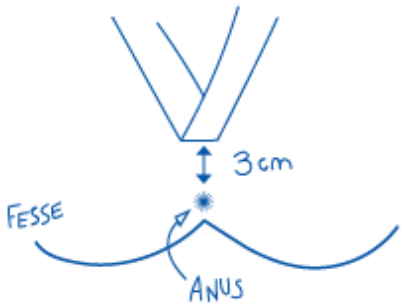
• Modifiez **l'angle du V** et la longueur de ses branches autant de fois que nécessaire en replaçant les épingles. Vous pouvez placer des marques à la craie pour prendre vos repères entre les différents essais.
• *Dans la partie basse du V,* les branches doivent passer dans le pli de l'aine en débordant de chaque côté sur la cuisse et sur le bassin. On évite ainsi que le bord de l'élastique irrite le pli de l'aine.
• *Dans la partie haute du V,* les branches ne doivent pas être trop écartées. Elles devront recouvrir partiellement les testicules remontés dans le canal inguinal pour les maintenir au plus près de la chaleur corporelle.

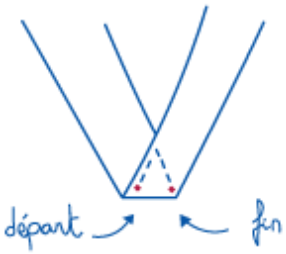


3. PRÉPARATION DU V / SUITE

• Pour déterminer **la longueur des branches du V**, tirez légèrement la pointe du V vers l'anus comme le feront les bretelles. La pointe du V doit arriver à environ 3 cm de l'anus. L'avant de la ceinture doit se déformer un peu.

• Quand tout semble correct, vérifiez une dernière fois la symétrie avant de coudre et marquez bien les emplacements à la craie.
• Coupez le surplus de bandes élastiques aux extrémités du V et les faire fondre très légèrement.





Astuce : Pour changer de direction, laissez l'aiguille en position basse, relevez le pied presseur, faites pivoter l'ouvrage, baissez le pied presseur, et continuez à coudre.

4. COUTURE DU V

• Cousez d'abord la pointe du V :
double point droit (le point droit simple peut suffire pensez alors à faire quelques points arrière au début et à la fin).
- Longueur du point 2mm
- largeur du point 0mm
- Tension AUTO

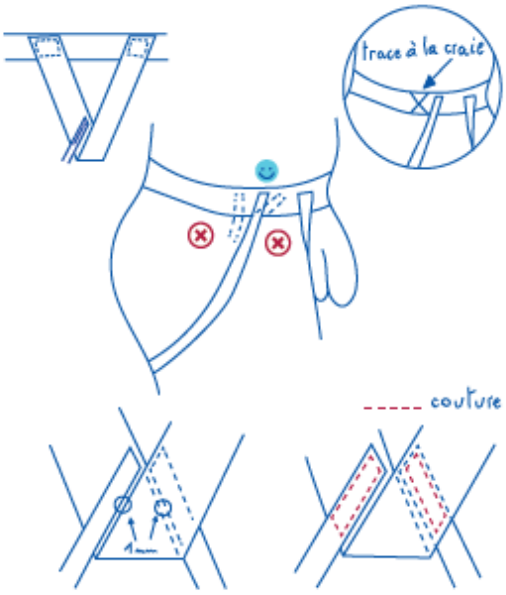
• Repositionnez les épingles si nécessaire pour faciliter le travail à la machine.
• Cousez les extrémités du V, toujours au double point droit 2mm. Elles peuvent être à l'intérieur ou à l'extérieur de la ceinture. Le choix est purement esthétique et ne change rien en termes de confort.

5. PRÉPARATION DES BRETELLES

• Épinglez une extrémité de la bretelle à la pointe du V pour la maintenir facilement pendant la prise de mesure.

Les bretelles passent dans le pli de la fesse puis remontent sur le long des hanches pour venir très légèrement à l'avant du bassin. Elles vont se détendre un peu à l'usure alors prenez suffisamment de marge : retirez environ 4 cm à la longueur qu'elles ont sans être tendues.

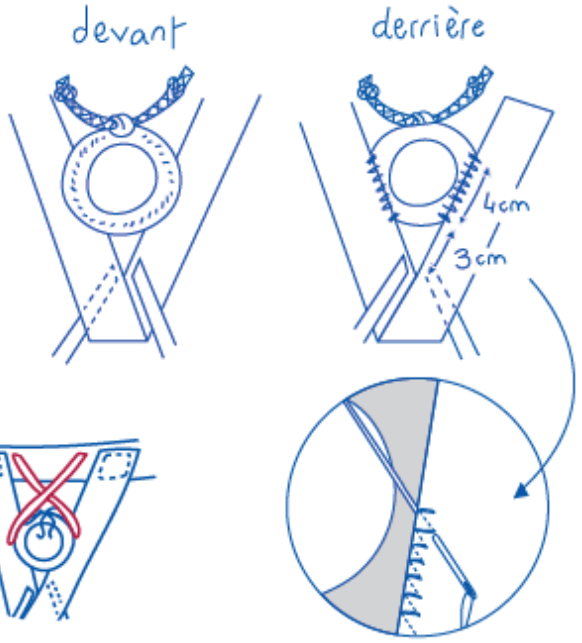
Chaque bretelle est cousue de part et d'autre de la pointe du V.
• Faites fondre très légèrement les extrémités de chaque bretelle.
• Laissez 1 mm entre la bretelle et la bande élastique pour faciliter le pli qui doit se faire à cet endroit.
• Vérifiez que les bretelles s'enrouleront correctement autour de la fesse!
• Cousez, toujours au double point droit de 2 mm de long.



ÉTAPE 3

ASSEMBLAGE DU BAUDRIER DE L'ANNEAU

• Cousez l'anneau à la main par l'arrière.
Faites plusieurs points au même endroit à chaque extrémité : ce sont des zones de tensions importantes.
Veillez à placer la couture de l'anneau vers le devant du jockstrap pour plus de confort.
Faites attention à ne pas piquer dans le cordon : l'aiguille reste assez en surface de l'anneau.
Les points doivent être un peu larges et le fil à peine tendu.



Le jockstrap est a priori terminé. Si le maintien des testicules n'est pas assez bon (c'est très rare, mais ça peut arriver), vous pouvez ajouter deux bouts de bretelles supplémentaires.

ANNEX II: GEOGRAPHICAL DISTRIBUTION

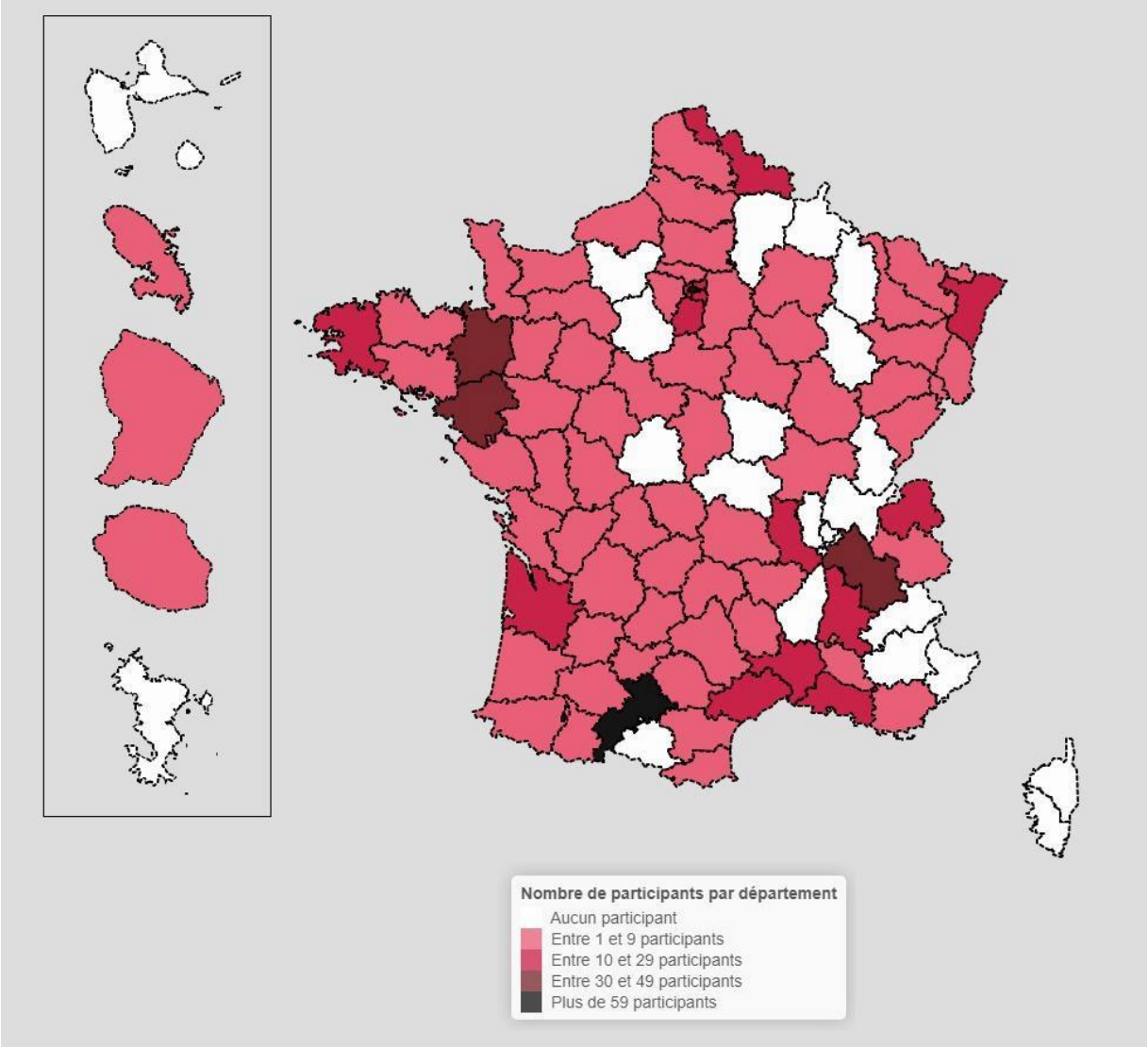


Figure 17. Number of participants having used a CRT for at least 6 months in France and by department. TESTIS_2021.

ANNEX III: STUDY QUESTION

TESTIS_2021 Cross-sectional survey of testicular lift contraceptive devices: safety, acceptability, efficacy.

Number	Questions and answers	Number of responses	Missing data
Q.0_1	Are you of legal age (according to your country's regulations)?	-	-
	[1] Yes	-	-
	[0] No	-	-
Q.0_2	Do you agree to participate in this study?	-	-
	[1] Yes	-	-
	[0] No	-	-
Q.0_3	Have you used testicular lift contraception for at least 6 months?	-	-
	[1] Yes	-	-
	[0] No	-	-
Q.0_4	Do you use the Spermapause pants (pants with an integrated heating system)?	-	-
	[1] Yes	-	-
	[0] No	-	-
Q.0_5	Are you undergoing chemotherapy or other treatment? Hormonal drugs that can reduce your fertility?	-	-
	[1] Yes	-	-
	[0] No	-	-
	[2] You don't know	-	-
	[3] You are not taking any treatment	-	-
	INCLUSION IN THE STUDY		
Q.1 MCQS	Tick all the testicular contraceptives you use have already used :	N=970	
	[0] Dr Mieusset's contraceptive underwear (Toulouse underwear)	35	
	[1] Andro-switch silicone ring	947	
	[2] The contraceptive Jockstrap	45	
	[3] A pair of DIY briefs or pants (that you have made yourself)	47	
	[4] Other (please specify in the next question)	15	
Q.1_0 *(text free)*	You have ticked 'other', can you describe?	N=15	
Q.2 QRU	Are you currently still using testicular lift contraception?	N=970	
	[1] Yes	860	
	[0] No (You have stopped)	110	
Q.3 MCQS	What contraceptive method(s) do you use? CURRENTLY?	N=860	
	[0] Dr Mieusset's contraceptive underwear (Toulouse underwear)	19	
	[1] Andro-switch silicone ring	833	
	[2] The contraceptive Jockstrap	24	
	[3] A pair of DIY briefs or pants (that you have made yourself)	15	
	[4] Other (please specify in the next question)	9	
Q.3_0 *(free text)*	You have ticked 'other', can you describe?	N=9	

Q.3_1 MCQ	What contraceptive methods have you used for AT LEAST 6 MONTHS?	N=110	
	[0] Dr Mieusset's contraceptive underwear (Toulouse underwear)	6	
	[1] Andro-switch silicone ring	98	
	[2] The contraceptive Jockstrap	5	
	[3] A pair of DIY briefs or pants (that you have made yourself)	12	
	[4] Other (please specify in the next question)	0	
Q.3_2 *(free text)*	You have ticked 'other', can you describe?	0	
Q.4 *(text free)*	In which country do you live?	N=970	
Q.5 *(free text)*	In which town do you live (postcode if France)	N=941	DM=29
Q.6 *(free text)*	How old are you?	N=970 29,6 [+/- 6,1]	
Q.7 QRU	What was the last degree you obtained?	N=970	
	[0] No degree	2	
	[1] Certificate of Education: Primary (CEP)	2	
	[2] Brevet des collèges, BEPC (Brevet d'études du premier cycle)	8	
	[3] CAP (Certificat d'aptitude professionnelle), BEP (Brevet d'enseignement professionnel), Brevet de compagnon	34	
	[4] General, technological or professional Baccalaureate, Brevet higher education, vocational or technical	135	
	[5] Bac + 2 or equivalent: BTS, DUT, DEUG	105	
	[6] Bac +3 (Licence) or Bac +4 or equivalent: Licence, professional licence, Master's degree	227	
	[7] Bac +5 or more: Master, DESS, PhD	415	
	[9] Other degree.	26	
	[10] Does not wish to answer	16	
Q.8 QRU	What is your profession? (For details of this international nomenclature : https://www.ilo.org/public/french/bureau/stat/isco/docs/resol08.pdf)	N=970	
	[1] Director, executive and manager	47	
	[2] Intellectual and scientific profession	263	
	[3] Intermediate occupations	79	
	[4] Administrative type employee	38	
	[5] Direct service personnel, tradesperson and seller	37	
	[6] Farmer and skilled agricultural, forestry and fishery worker	30	
	[7] Skilled Industrial and Craft Trades	89	
	[8] Plant and Machine Operator and Construction Worker assembly	3	
	[9] Elementary occupation	8	
	[10] Military	5	
	[11] Student	0	
	[12] Looking for work	29	
	[13] Homemaker	0	
	[14] Unemployed	34	
	[15] Other.	168	
	[16] Does not wish to answer	25	
Q.9 QRU	What is your gender?	N=970	

	[0] Male	922	
	[1] Female	5	
	[2] Non-binary	22	
	[3] Genderfluid	4	
	[4] Other	1	
	[9] You don't know	5	
	[10] Does not wish to answer	11	
Q.10 QRU	What was your marital status the first time you started testicular contraception?	N=970	
	[0] Single	78	
	[1] In a (sexually) exclusive couple relationship	741	
	[2] In a free (sexual) couple relationship	121	
	[3] In a multi-partner relationship (more than two people)	23	
	[4] Other.	2	
	[9] You don't know	1	
	[10] Does not wish to answer	4	
Q.11 QRU	Has your marital situation changed since the beginning of the the use of testicular contraception?	N=970	
	[1] Yes	203	
	[0] No	760	
	[10] Does not wish to answer	7	
Q.12 QRU	What is your current marital status?	N=203	
	[0] Single	80	
	[1] In a (sexually) exclusive couple relationship	68	
	[2] In a free (sexual) couple relationship	34	
	[3] In a multi-partner relationship (more than two people)	17	
	[4] Other.	3	
	[9] You don't know	1	
	[10] Does not wish to answer	0	
Q.13 *(free text)*	How many children do you have?	N=937	DM = 33
Q.14 QRU	Would you like to have (more) children?	N=970	
	[1] Yes	321	
	[0] No	315	
	[9] You don't know	324	
	[10] Does not wish to answer	10	
Q.15 QRU	In the year before starting contraception with testicular reflux, were you using any other contraception (or your partner)?	N=970	
	[0] Always	616	
	[1] Most of the time	189	
	[2] Sometimes	44	
	[3] Rarely	31	
	[4] Never	87	
	[9] You don't know	1	
	[10] Does not wish to answer	2	
Q.16 MCQS	What contraceptive(s) did you (or your partner) use? Tick ALL the ways.	N=882	
	[0] Male condom (external)	645	
	[1] Female condom (internal)	29	
	[2] Withdrawal method	246	
	[3] Female hormonal pill	358	
	[4] Copper IUD	243	
	[5] Hormonal IUD	94	
	[6] Subcutaneous implant (in the arm)	50	

	[7] Symptothermia (temperature monitoring, observation of mucus, cervix)	42	
	[8] Hormonal male contraception	1	
	[9] Spermicidal creams	9	
	[10] Cervical cap (diaphragm)	8	
	[11] Hormonal vaginal ring	30	
	[12] Quarterly hormonal injection	0	
	[13] Others.	13	
	[14] You don't know	1	
	[15] Does not wish to answer	1	
Q.17 QRU	How satisfied were you with this contraception?	N=882	
	[0] Extremely satisfied	43	
	[1] Very satisfied	96	
	[2] Quite satisfied	278	
	[3] Somewhat dissatisfied	303	
	[4] Very dissatisfied	112	
	[5] Never satisfied	31	
	[9] You don't know	11	
	[10] Does not wish to answer	8	
Q.18 QRU	How satisfied was your partner(s) with this contraception	N=807	
	[0] Extremely satisfied	33	
	[1] Very satisfied	63	
	[2] Quite satisfied	176	
	[3] Somewhat dissatisfied	242	
	[4] Very dissatisfied	213	
	[5] Never satisfied	48	
Q.19 MCQS	Do any of your partners already have :	N=970	
	[0] Had significant contraceptive side effects	634	
	[1] Had an unwanted pregnancy	195	
	[2] Performs an abortion	234	
	[3] None of his proposals	235	
	[9] You don't know	38	
	[10] Does not wish to answer	4	
Q.20 QRU	Have you ever considered having a vasectomy?	N=970	
	[1] Yes	404	
	[0] No	528	
	[9] You don't know	37	
	[10] Does not wish to answer	1	
Q.21 QRU	How was your sexual drive? sexual)	N=970	
	[0] Extremely strong	69	
	[1] Very strong	321	
	[2] Quite strong	491	
	[3] Quite low	71	
	[4] Very low	3	
	[5] Absent	0	
	[9] You don't know	10	
	[10] Does not wish to answer	0	
Q.22 QRU	How easily were you sexually aroused?	N=970	
	[0] Extremely easy	138	
	[1] Very easily	478	
	[2] Quite easily	331	
	[3] With some difficulty	17	
	[4] Very difficult	0	

	[5] Never	0	
	[9] You don't know	1	
	[10] Does not wish to answer	5	
Q.23 QRU	Could you easily get and keep an erection?	N=970	
	[0] Extremely easy	253	
	[1] Very easily	480	
	[2] Quite easily	211	
	[3] With some difficulty	20	
	[4] Very difficult	1	
	[5] Never	0	
	[9] You don't know	1	
	[10] Does not wish to answer	4	
Q.24 QRU	How easy was it to have an orgasm?	N=970	
	[0] Extremely easy	145	
	[1] Very easily	469	
	[2] Quite easily	299	
	[3] With some difficulty	41	
	[4] Very difficult	6	
	[5] Never	0	
	[9] You don't know	5	
	[10] Does not wish to answer	5	
Q.25 QRU	Were your orgasms satisfying?	N=970	
	[0] Extremely satisfactory	165	
	[1] Very satisfactory	485	
	[2] Quite satisfactory	283	
	[3] Quite unsatisfactory	28	
	[4] Very unsatisfactory	4	
	[5] Never	0	
	[9] You don't know	2	
	[10] Does not wish to answer	3	
Q.26 QRU	Were you satisfied with the pleasure you experienced in your sexual activities?	N=970	
	[0] Extremely satisfied	209	
	[1] Very satisfied	496	
	[2] Quite satisfied	230	
	[3] Somewhat dissatisfied	27	
	[4] Very dissatisfied	5	
	[5] Never	0	
	[9] You don't know	0	
	[10] Does not wish to answer	3	
Q.27 QRU	In general, were you satisfied with the quality of your sexual relations?	N=970	
	[0] Extremely satisfied	168	
	[1] Very satisfied	445	
	[2] Quite satisfied	295	
	[3] Somewhat dissatisfied	49	
	[4] Very dissatisfied	5	
	[5] Never	0	
	[9] You don't know	3	
	[10] Does not wish to answer	5	
Q.28 QRU	Were you satisfied with the frequency of your sexual relations?	N=970	
	[0] Extremely satisfied	108	
	[1] Very satisfied	305	
	[2] Quite satisfied	344	
	[3] Somewhat dissatisfied	167	

	[4] Very dissatisfied	28	
	[5] Never	0	
	[9] You don't know	8	
	[10] Does not wish to answer	10	
Q.29 QRU	Were you satisfied with the signs of tenderness you and your partner(s) expressed during sex?	N=970	
	[0] Extremely satisfied	284	
	[1] Very satisfied	434	
	[2] Quite satisfied	184	
	[3] Somewhat dissatisfied	46	
	[4] Very dissatisfied	5	
	[5] Never	0	
	[9] You don't know	5	
	[10] Does not wish to answer	12	
Q.30 QRU	Were you satisfied with the way you and your partner(s) talk about sexuality?	N=970	
	[0] Extremely satisfied	267	
	[1] Very satisfied	350	
	[2] Quite satisfied	250	
	[3] Somewhat dissatisfied	68	
	[4] Very dissatisfied	19	
	[5] Never	1	
	[9] You don't know	6	
	[10] Does not wish to answer	9	
Q.31 MCQS	At the level of the VERGE (of the penis) :	N=970	
	[0] No, none of these diseases.	805	
	[1] A significant curvature of the penis	9	
	[2] A narrowing or stenosis of the urine duct (urethra)	2	
	[3] One or more genital mycoses	88	
	[4] A "skin disease" on the penis (eczema, psoriasis, allergy, or other)	51	
	[9] You don't know	27	
	[10] Does not wish to answer	3	
Q.32 MCQS	At the URINARY level, have you ever had :	N=970	
	[0] No, none of these diseases.	751	
	[1] Bladder weakness	18	
	[2] A urinary tract, kidney or prostate infection	122	
	[3] Difficulty in urinating (feeling blocked, feeling incomplete emptying)	85	
	[9] You don't know	22	
	[10] Does not wish to answer	2	
Q.33 MCQS	In terms of the PROSTATE, have you ever had :	N=970	
	[0] No, none of these diseases.	947	
	[1] An increase in the size of the prostate	6	
	[2] A prostate operation	0	
	[3] Radiotherapy treatment of the prostate	0	
	[9] You don't know	20	
	[10] Does not wish to answer	1	
Q.34 MCQS	In terms of TESTICS, have you ever had :	N=970	
	[0] No, none of these diseases.	912	
	[1] An operation on one or both testicles	19	
	[2] One or two testicles that had not descended to the birth	13	
	[3] A malformation in the testicles	4	

	[4] Abnormal swelling of the testicles or testicular veins	18	
	[5] A tumour of the testicles	0	
	[9] You don't know	10	
	[10] Does not wish to answer	1	
Q.35 QRU	Have you ever had an inguinal hernia? groin area, which appears when coughing or wearing a heavy load, and which may be awkward or painful)	N=970	
	[0] No	906	
	[1] Yes	38	
	[9] You don't know	26	
	[10] Does not wish to answer	0	
Q.36 MCQS	Do you CURRENTLY have one or more of the following diseases following:	N=970	
	[0] None of these diseases	939	
	[1] Obesity	12	
	[2] Hypertension	1	
	[3] Diabetes	2	
	[4] Too much cholesterol or triglycerides	13	
	[5] You don't know	10	
	[6] Does not wish to answer	1	
Q.37 MCQS	Do you CURRENTLY consume:	N=970	
	[0] None of these consumptions	531	
	[1] Tobacco	274	
	[2] Calming substances (cannabis, morphine, calming drugs, etc.)	206	
	[3] Exciting substances (cocaine, other drugs, etc.) are also used. stimulants, stimulant drugs, etc.)	88	
	[4] Alcohol almost every day	200	
	[9] You don't know	3	
	[10] Does not wish to answer	4	
Q.38 *(free text)*	If you are undergoing REGULAR treatment, please specify (REGULAR medication, or radiotherapy, chemotherapy, hormones, etc.).	N=61	
Q.39 QRU	In your work, are you exposed to high heat, radiation or pesticides WITHOUT PROTECTION?	N=970	
	[1] Yes	942	
	[0] No	24	
	[9] You don't know	4	
Q.40 *(free text)*	Can you explain the two or three main reasons that led you to use testicular contraception? some words)	N=960	DM=10
Q.41 QRU	Did you consult a health professional before starting this contraception? urologist, andrologist, gynaecologist, midwife)	N=970	
	[1] Yes	715	
	[0] No	251	
	[10] Does not wish to answer	4	
Q.41_0 *(free text)*	If not, why not? Give the main reason.	N=235	DM=16
Q.42 QRU	Did this professional accompany you in your approach?	N=715	
	[0] Perfectly accompanied	188	
	[1] Rather accompanied	231	
	[2] Rather unaccompanied	153	
	[3] Not at all accompanied	138	

	[10] Does not wish to answer	5	
Q.42_0 QRU	Have you found another health professional to accompany you in your journey?	N=296	
	[1] Yes	50	
	[0] No	243	
	[10] Does not wish to answer	3	
Q.43 MCQS	During this consultation (or these consultations), did you have :	N=715	
	[0] A sexually transmitted infection check-up	156	
	[1] A genital examination	180	
	[2] A palpation of the testicles	234	
	[3] A blood pressure test	212	
	[4] None of these tests	489	
	[9] You don't know	37	
	[10] Does not wish to answer	51	
Q.44 QRU	Were you able to benefit from or do you benefit from medical follow-up for this contraception?	N=715	
	[1] Yes	344	
	[0] No	364	
	[10] Does not wish to answer	7	
Q.45 *(free text)*	When did you first start using this contraception?	N=970	
Q.46 QRU	Did you easily find the information you needed to What is the best way to use this contraception?	N=970	
	[0] Yes very easily	456	
	[1] Yes, quite easily	408	
	[2] No, rather hardly	92	
	[3] No, with great difficulty	14	
	[9] You don't know	0	
	[10] Does not wish to answer	0	
Q.47 QRU	How did you start using it (to get used to it)? to the rhythm)?	N=970	
	[0] Immediately every day and 15 hours a day	444	
	[1] 15 hours a day, but not every day	31	
	[2] Every day, but only a few hours a day	450	
	[3] A few hours a day, not every day	43	
	[9] You don't know	1	
	[10] Does not wish to answer	1	
Q.48 QRU	How long did it take you to get to the point of using it? fifteen hours a day, every day?	N=970	
	[0] Between 1 and 5 days	548	
	[1] Between 5 and 10 days	183	
	[2] Between 10 and 15 days	118	
	[3] Between 2 and 3 weeks	44	
	[4] Between 3 weeks and 1 month	29	
	[5] Between 1 and 2 months	13	
	[6] Between 2 and 3 months	7	
	[7] Between 3 and 6 months	11	
	[8] More than 6 months	4	
	[9] You never got there	10	
	[10] You don't know	1	
	[11] Does not wish to answer	2	
Q.48_0 *(free text)*	You say that it took you 1 month (or more) to get to use it. Can you explain the difficulties you encountered? (in a few words)	N=45	

Q.49 QRU	Did you use an additional method of contraception for the first three months (or until you reached the threshold)? contraceptive)?	N=970	
	[0] Always	674	
	[1] Most of the time	121	
	[2] Sometimes	28	
	[3] Rarely	15	
	[4] Never	62	
	[5] You did not need (no sexual intercourse having need for contraception)	68	
	[9] You don't know	1	
	[10] Does not wish to answer	1	
Q.49_0 *(free text)*	Can you explain why you did not use an additional method of contraception (or not all the time)? time)?	N=96	DM=9
Q.50 QRU	How many hours a day do you use your contraception (approx.)? If you stopped, how many hours on average did you use it?	N=970	
	[0] Less than 9 hours per day	1	
	[1] Between 9 and 11 hours per day	4	
	[2] Between 11 and 13 hours per day	42	
	[3] Between 13 and 15 hours per day	268	
	[4] Between 15 and 17 hours per day	435	
	[5] Between 17 and 19 hours per day	86	
	[6] More than 19 hours per day	41	
	[7] 24 hours a day (almost all the time)	93	
	[9] You don't know	0	
	[10] Does not wish to answer	0	
Q.51 QRU	Does the number of hours of use vary much from day to day?	N=970	
	[1] Yes	130	
	[0] No	827	
	[9] You don't know	13	
	[10] Does not wish to answer	0	
Q.51_0 MCQ	If you use it less than 15 hours a day, is it because :	N=315	
	[0] You still reach the contraceptive threshold of less than of one million sperm per mL with this duration of use	174	
	[1] You can't wear it any longer because of the effects unwanted	29	
	[2] The organisation of your daily life does not allow you to to wear it longer	166	
	[3] You don't think it's necessary	51	
	[4] You didn't know that you had to wear it at least fifteen times a week. hours per day	8	
	[5] Other (please specify in the next question)	21	
	[9] You don't know	12	
	[10] Does not wish to answer	12	
Q.51_1 *(free text)*	Why do you use it less than 15 hours a day?	N=21	
Q.51_2 MCQ	If you use it more than 17 hours a day, is it because :	N=220	

	[0] You do not reach the contraceptive threshold of less than one million if you wear it for less time	23	
	[1] You are concerned that the method is not effective enough otherwise	36	
	[2] You think it is better to wear it longer because you find it difficult to keep to strict schedules	98	
	[3] You often forget to take it off	98	
	[4] Other (please specify in the next question)	65	
	[9] You don't know	1	
	[10] Does not wish to answer	0	
Q.51_3 *(free text)*	Why do you use it more than seventeen hours a day?	N=65	
Q.52 QRU	During which period(s) of the day do you use your contraception?	N=970	
	[0] Daytime only	319	
	[1] Mostly during the day	393	
	[2] Mostly at night	52	
	[3] Only at night	1	
	[4] As much by day as by night	205	
	[10] Does not wish to answer	0	
Q.53 QRU	In general, do you think it is HARD to respect the 15-hour wearing time?	N=970	
	[0] Yes, very difficult	12	
	[1] Yes, rather difficult	151	
	[2] No, rather easy	490	
	[3] No, very easy	313	
	[9] You don't know	4	
	[10] Does not wish to answer	0	
Q.54 QRU	How often do you forget to use your contraception, or not being able to use it, for at least a day?	N=970	
	[0] Never	716	
	[1] Several times a week	0	
	[2] Once a week	11	
	[3] Several times a month	12	
	[4] Once a month	66	
	[5] Several times a year	62	
	[6] Once a year	97	
	[9] You don't know	6	
	[10] Does not wish to answer	0	
Q.55 QRU	Did you use additional contraception for at least one month after you forgot?	N=254	
	[0] Always	58	
	[1] Most of the time	18	
	[2] Sometimes	8	
	[3] Rarely	19	
	[4] Never	114	
	[5] You have never been in a situation that requires it	36	
	[9] You don't know	1	
	[10] Does not wish to answer	0	
Q.56 QRU	After an oversight, do you inform your partner(s)?	N=238	
	[0] Always	159	
	[1] Most of the time	27	
	[2] Sometimes	15	
	[3] Rarely	9	

	[4] Never	12	
	[5] You have never been in a situation that requires it	14	
	[9] You don't know	0	
	[10] Does not wish to answer	2	
Q.57 QRU	Apart from forgetting, do you use your contraception every day?	N=254	
	[1] Yes	250	
	[0] No	4	
	[9] You don't know	0	
	[10] Does not wish to answer	0	
Q.57_0 *(free text)*	Why don't you use it every day?	N=3	DM=1
Q.58 *(free text)*	The current protocol for use recommends wearing this testicular contraceptive every day, 15 hours and during the day. Based on your experience, would you have any changes to make to the protocol? propose?	N=738	DM=232
Q.59 QRU	How are your sexual urges? sexual)	N=970	
	[0] Extremely strong	103	
	[1] Very strong	358	
	[2] Quite strong	412	
	[3] Quite low	85	
	[4] Very low	6	
	[5] Absent	0	
	[9] You don't know	2	
	[10] Does not wish to answer	4	
Q.60 QRU	How easily are you sexually aroused?	N=970	
	[0] Extremely easy	174	
	[1] Very easily	521	
	[2] Quite easily	245	
	[3] With some difficulty	22	
	[4] Very difficult	3	
	[5] Never	1	
	[9] You don't know	0	
	[10] Does not wish to answer	4	
Q.61 QRU	Can you easily get and keep an erection?	N=970	
	[0] Extremely easy	261	
	[1] Very easily	502	
	[2] Quite easily	189	
	[3] With some difficulty	11	
	[4] Very difficult	1	
	[5] Never	1	
	[9] You don't know	4	
	[10] Does not wish to answer	1	
Q.62 QRU	How easy is it to have an orgasm?	N=970	
	[0] Extremely easy	166	
	[1] Very easily	535	
	[2] Quite easily	228	
	[3] With some difficulty	30	
	[4] Very difficult	4	
	[5] Never	1	
	[9] You don't know	2	
	[10] Does not wish to answer	4	
Q.63 QRU	Are your orgasms satisfying?	N=970	

	[0] Extremely satisfactory	241	
	[1] Very satisfactory	489	
	[2] Quite satisfactory	205	
	[3] Quite unsatisfactory	28	
	[4] Very unsatisfactory	0	
	[5] Never	1	
	[9] You don't know	3	
	[10] Does not wish to answer	3	
Q.64 QRU	Are you satisfied with the pleasure you get from your sexual activities?	N=970	
	[0] Extremely satisfied	275	
	[1] Very satisfied	497	
	[2] Quite satisfied	164	
	[3] Somewhat dissatisfied	23	
	[4] Very dissatisfied	1	
	[5] Never	1	
	[9] You don't know	2	
	[10] Does not wish to answer	7	
Q.65 QRU	In general, are you satisfied with the quality of your sexual relations?	N=970	
	[0] Extremely satisfied	250	
	[1] Very satisfied	456	
	[2] Quite satisfied	179	
	[3] Somewhat dissatisfied	35	
	[[4] Very dissatisfied	7	
	[5] Never	1	
	[9] You don't know	14	
	[10] Does not wish to answer	28	
Q.66 QRU	Are you satisfied with the frequency of your sexual relations?	N=970	
	[0] Extremely satisfied	138	
	[1] Very satisfied	334	
	[2] Quite satisfied	287	
	[3] Somewhat dissatisfied	130	
	[4] Very dissatisfied	35	
	[5] Never	1	
	[9] You don't know	12	
	[10] Does not wish to answer	33	
Q.67 QRU	Are you satisfied with the signs of affection that you and your (or your What do you think your partner(s) say during sex?	N=970	
	[0] Extremely satisfied	359	
	[1] Very satisfied	397	
	[2] Quite satisfied	126	
	[3] Somewhat dissatisfied	29	
	[4] Very dissatisfied	8	
	[5] Never	1	
	[9] You don't know	16	
	[10] Does not wish to answer	34	
Q.68 QRU	Are you satisfied with the way you and your partner(s) talk about sex?	N=970	
	[0] Extremely satisfied	352	
	[1] Very satisfied	378	
	[2] Quite satisfied	153	
	[3] Somewhat dissatisfied	35	
	[4] Very dissatisfied	10	

	[5] Never	0	
	[9] You don't know	14	
	[10] Does not wish to answer	28	
Q.69 QRU	Over the past year, on average, how often have you had sex?	N=970	
	[0] Less than one per month	54	
	[1] One per month	70	
	[2] Between 2 and 3 per month	193	
	[3] One per week	236	
	[4] More than one per week	385	
	[9] You don't know	14	
	[10] Does not wish to answer	18	
Q.70 MCQS	The first few times you used this contraception, have: (SEVERAL POSSIBLE ANSWERS)	N=970	
	[0] Feels uncomfortable	121	
	[1] Lost consciousness	1	
	[2] Feels discomfort in one or both testicles	448	
	[3] Feels discomfort in the lower abdomen	278	
	[4] Feeling pain in one or both testicles	179	
	[5] Feeling pain in the lower abdomen	89	
	[6] Have an allergic reaction	26	
	[7] Other (you can elaborate in the next question)	220	
	[8] You have not experienced any adverse effects	184	
	[9] You don't know	5	
	[10] Does not wish to answer	1	
Q.70_0 *(free text)*	If other: what sensations or side effects did you experience during the first uses?	N=220	
Q.71 QRU	Did these symptoms continue afterwards?	N=781	
	[1] Yes	128	
	[0] No	647	
	[9] You don't know	4	
	[10] Does not wish to answer	2	
Q.72 MCQS	At the level of the VERGE (penis)?	N=970	
	[0] None of these effects	247	
	[1] Skin irritation (on friction areas)	515	
	[2] Itching (on friction areas)	446	
	[3] Irritation from pubic hair	313	
	[4] Irritation or infection of the skin, which required MEDICAL treatment	9	
	[5] A mycosis of the penis	8	
	[6] Unusual swelling of the penis (oedema)	9	
	[7] decreased sensitivity in the penis	1	
	[9] You don't know	6	
	[10] Does not wish to answer	1	
Q.73 MCQS	At the level of the ERECTION?	N=970	
	[0] None of these effects	620	
	[1] Painful or unpleasant NIGHTtime erections when wearing contraception	227	
	[2] Painful or unpleasant DAYtime erections when wearing contraception	114	
	[3] Painful or unpleasant erections even after the first day. having removed the contraception	2	
	[4] An UNUSUAL deviation or curvature of the erect penis	3	
	[5] A change in the duration of your erections	38	

	[6] A change in the stiffness of your erections	47	
	[7] A change in the speed with which you can have an erection	25	
	[8] One or more erections that lasted more than 4 hours (priapism)	1	
	[9] You don't know	11	
	[10] Does not wish to answer	0	
Q.74 MCQS	In the BOURSES (the skin around the testicles, or scrotum)?	N=970	
	[0] None of these effects	323	
	[1] Skin irritation (on friction areas)	503	
	[2] Itching (on friction areas)	437	
	[3] Irritation or infection of the skin of the bursa, requiring MEDICAL treatment	3	
	[4] A fungus in the bursa	6	
	[5] Unusual swelling of the bursa	2	
	[6] Unusual pain in the bursa	9	
	[9] You don't know	1	
	[10] Does not wish to answer	0	
Q.75 MCQS	At the level of the TESTICLES?	N=970	
	[0] None of these effects	577	
	[1] Testicular discomfort when using contraception	85	
	[2] Testicular pain when using contraception	46	
	[3] Persistent discomfort in the testicles even after removed the contraception	15	
	[4] Persistent testicular pain even after removing contraception	10	
	[5] Swelling in the testicles or testicular veins	4	
	[6] A hard mass in the testicles	3	
	[7] A testicular torsion (requiring surgery in emergency)	0	
	[9] You don't know	9	
	[10] Does not wish to answer	1	
Q.76 MCQS	Have you noticed any URINARY changes?	N=970	
	[0] None of these effects	695	
	[1] A longer time to start urinating	35	
	[2] A feeling of blockage to urinate (having to push)	40	
	[3] A feeling of not having urinated completely	77	
	[4] Difficulty urinating while standing	13	
	[5] Difficulty urinating while sitting	11	
	[6] Unusual late drops (a few drops (e.g., urine runs out some time after going to the toilet)	208	
	[7] Bladder weakness	9	
	[8] Urinary burning	0	
	[9] A urinary tract, kidney or prostate infection	3	
	[10] Blood in the urine	1	
	[11] You don't know	13	
	[12] Does not wish to answer	1	
Q.77 *(free text)*	If you have had ANY OTHER unwanted or unexpected effects, Can you elaborate?	N=139	
Q.78 MCQS	Have you noticed any physical changes?	N=970	
	[0] No change	503	
	[1] Decreasing the size of your testicles	306	

	[2] Change in skin colour at the base of the skin the penis	142	
	[3] Change in skin texture at the base of the penis	83	
	[4] Change in skin colour in the bursa	35	
	[5] Change in skin texture in the bursa	36	
	[6] Weight gain	14	
	[7] Weight loss	4	
	[8] Other (please specify in the next question)	19	
	[9] You don't know	29	
	[10] Does not wish to answer	0	
Q.78_0	What other physical change has occurred?	N=19	
Q.79 *(free text)*	Based on your experience, would you have any advice on skin irritations caused by this contraception?	N= 479	DM=491
Q.80 QRU	Have you ever performed one or more spermograms?	N=970	
	[0] Yes, only one	165	
	[1] Yes, several	694	
	[9] No, none	66	
	[10] Does not wish to answer	45	
Q.80_0 *(free text)*	Why did you not perform a spermogram? some words)	N=59	DM=7
Q.81 QRU	Did you perform a spermogram before starting testicular lift contraception?	N=859	
	[1] Yes	635	
	[0] No	224	
	[10] Does not wish to answer	0	
Q.82 QRU	Were the results of this spermogram normal? (spz > 15 million/mL, progressive motility > 32%, normal morphology > 4%)	N=635	
	[1] Yes	600	
	[0] No	29	
	[9] You don't know	6	
	[10] Does not wish to answer	0	
Q.83 QRU	How do you perform your spermograms? POSSIBLE ANSWERS)	N=	
	[0] In hospital or city laboratory	686	
	[1] Other (please specify in the next question)	19	
	[10] Does not wish to answer	0	
Q.83_0 *(free text)*	If other, can you detail how you carry out your spermograms?	N=19	
Q.84 QRU	Do you find the laboratory spermogram findings easy to understand?	N=686	
	[0] Very simple	229	
	[1] Pretty simple	306	
	[2] Rather difficult	127	
	[3] Very difficult	15	
	[9] You don't know	9	
	[10] Does not wish to answer	0	
Q.85 QRU	How long does it take to get an appointment for a spermogram in the laboratory (approximately)?	N=686	
	[0] Less than a week	136	
	[1] Between 1 week and 1 month	330	
	[2] Between 1 and 2 months	156	
	[3] Between 2 and 3 months	48	
	[4] More than 3 months	10	

	[5] More than 6 months	1	
	[9] You don't know	4	
	[10] Does not wish to answer	1	
Q.86 QRU	Have you reached the contraceptive threshold?	N=859	
	(has your sperm concentration dropped to less than 1 million sperm/mL)		
	[2] You have not had a spermogram to check	30	
	[1] Yes, you have reached the contraceptive threshold	766	
	[0] No, you have not reached the contraceptive threshold	61	
	[10] Does not wish to answer	2	
Q.86_0 *(free text)*	Why do you think you never reached the threshold (In a few words)	N=57	DM=3
Q.87 *(free text)*	In how many MONTHS did you reach the contraceptive threshold? If you don't know, please write the number 99.	N=700 3,3 [+/-1,3]	DM=66
Q.88 QRU	How often do you currently perform a spermogram (approximately)? If you have stopped using contraception, how often do you use it? did you realize?	N=694	
	[0] Several times a month	0	
	[1] Every month	24	
	[2] Every two months	63	
	[3] Every three months	242	
	[4] 2-3 times a year	194	
	[5] 1 time per year (or less)	88	
	[6] Only when you have forgotten to use your contraception	14	
	[7] Never	59	
	[9] You don't know	9	
	[10] Does not wish to answer	1	
Q.89 QRU	Would you like to have a spermogram more often? spermogram more often?)	N=686	
	[1] Yes	253	
	[0] No	387	
	[9] You don't know	45	
	[10] Does not wish to answer	1	
Q.90 QRU	After reaching the contraceptive threshold, have you ever had sperm concentrations rise above 1 million/mL?	N=631	
	[0] Yes, once	31	
	[1] Yes, several times	5	
	[2] No	431	
	[3] You don't know	162	
	[4] Does not wish to answer	2	
Q.91 QRU	Have you ever been unable to have a spermogram because you couldn't get a prescription from a health professional?	N=970	
	[0] Yes, once	82	
	[1] Yes, several times	54	
	[2] No	782	
	[3] You don't know	20	
	[4] Does not wish to answer	32	
Q.92 QRU	Regarding the collection of sperm in the laboratory, is this procedure easy for you?	N=686	
	[0] Very easy	230	

	[1] Pretty easy	354	
	[2] Rather difficult	83	
	[3] Very difficult	14	
	[9] You don't know	4	
	[10] Does not wish to answer	1	
Q.93 QRU	In general, how do you feel about this contraception?	N=970	
	[0] Extremely satisfied	470	
	[1] Very satisfied	363	
	[2] Quite satisfied	105	
	[3] Somewhat dissatisfied	20	
	[4] Very dissatisfied	5	
	[5] Never satisfied	0	
	[9] You don't know	7	
	[10] Does not wish to answer	0	
Q.93_0 *(free text)*	Why do you feel dissatisfied? (in a few words)	N=24	DM=1
Q.94 QRU	Since using this contraception, has there been any unplanned pregnancy?	N=970	
	[0] Yes, BEFORE reaching the contraceptive threshold (or before 3 months of use)	6	
	[1] Yes, AFTER reaching the contraceptive threshold (or after 3 months of use)	0	
	[2] No, no unplanned pregnancy	958	
	[9] You don't know	2	
	[10] Does not wish to answer	4	
Q.95 QRU	Since using this contraceptive, how often has a woman used it? of your partners taken the morning-after pill?	N=970	
	[0] Never	920	
	[1] 1 time	33	
	[2] Between 2 and 5 times	6	
	[3] Between 5 and 10 times	0	
	[4] More than 10 times	0	
	[9] You don't know	6	
	[10] Does not wish to answer	5	
Q.96 QRU	Do you find this contraception restrictive? Regarding your daily activities (sitting, standing, etc.) standing, walking, urinating, sweating, …)	N=970	
	[0] Not at all binding	406	
	[1] Not very binding	522	
	[2] Quite restrictive	37	
	[3] Very restrictive	3	
	[9] You don't know	1	
	[10] Does not wish to answer	1	
Q.97 QRU	Concerning your sports activities (jogging, swimming, hiking, water sports, cycling, horse riding...)	N=970	
	[0] Not at all binding	276	
	[1] Not very binding	484	
	[2] Quite restrictive	157	
	[3] Very restrictive	33	
	[9] You don't know	19	
	[10] Does not wish to answer	1	
Q.98 QRU	Concerning your activities at work :	N=970	
	[0] Not at all binding	572	

	[1] Not very binding	346	
	[2] Quite restrictive	39	
	[3] Very restrictive	8	
	[9] You don't know	3	
	[10] Does not wish to answer	2	
Q.99 QRU	Concerning the "mental burden" of this contraception (having to think about it every day, dealing with forgetting...)	N=970	
	[0] Not at all binding	384	
	[1] Not very binding	498	
	[2] Quite restrictive	79	
	[3] Very restrictive	9	
	[9] You don't know	0	
	[10] Does not wish to answer	0	
Q.100 QRU	You have indicated that you use the Androswitch silicone ring AND a FABRIC underwear (or jockstrap). Is one more comfortable (or practical) on DAY?	N=59	
	[0] Yes the Androswitch ring	26	
	[1] Yes, the fabric underwear (or jockstrap)	25	
	[2] No, both are the same	7	
	[9] You don't know	1	
	[10] Does not wish to answer	0	
Q.101 QRU	Is one more comfortable (or practical) at NIGHT?	N=41	
	[0] Yes the Androswitch ring	24	
	[1] Yes, the fabric underwear (or jockstrap)	10	
	[2] No, both are the same	3	
	[9] You don't know	4	
	[10] Does not wish to answer	0	
Q.102 QRU	Does one cause less skin irritation?	N=59	
	[0] Yes the Androswitch ring	5	
	[1] Yes, the fabric underwear (or jockstrap)	34	
	[2] No, both are the same	15	
	[9] You don't know	5	
	[10] Does not wish to answer	0	
Q.103 QRU	Does one hold the testicles in place better?	N=59	
	[0] Yes the Androswitch ring	8	
	[1] Yes, the fabric underwear (or jockstrap)	34	
	[2] No, both are the same	14	
	[9] You don't know	3	
	[10] Does not wish to answer	0	
Q.104 QRU	Is one easier (or more convenient) to use?	N=59	
	[0] Yes the Androswitch ring	39	
	[1] Yes, the fabric underwear (or jockstrap)	10	
	[2] No, both are the same	9	
	[9] You don't know	1	
	[10] Does not wish to answer	0	
Q.105 QRU	In general, are you confident in your ability to how to use this contraception correctly?	N=970	
	[0] Always	670	
	[1] Most of the time	284	
	[2] Sometimes	12	
	[3] Rarely	2	
	[4] Never	0	
	[9] You don't know	2	
	[10] Does not wish to answer	0	

Q.106 MCQS	Which of the following reasons prevent you from using how best to use your contraception?	N=970	
	[0] None	324	
	[1] Regular forgetfulness	34	
	[2] Not being able to use it at night (according to the recommendations)	98	
	[3] Having to check the correct position of the testicles regularly	431	
	[4] To have to use it at least fifteen hours a day	224	
	[5] Having to wake up in the morning to wear your contraception (prevents long nights)	167	
	[6] The need for a regular rhythm of life	189	
	[7] Adverse effects that are too strong	32	
	[8] Other (please specify in the next question)	49	
	[9] You don't know	5	
	[10] Does not wish to answer	3	
Q.106_0 *(free text)*	What other reasons prevent optimal use for you (in a few words)	N=47	DM=2
Q.107 QRU	Do you intend to continue using this contraception?	N=860	
	[1] Yes	841	
	[0] No	2	
	[9] You don't know	17	
	[10] Does not wish to answer	0	
Q.108 QRU	Do you think that this contraception has helped you to learn more about your anatomy, your body and the How does your fertility work?	N=970	
	[0] Totally agree	566	
	[1] Rather agree	327	
	[2] Somewhat disagree	32	
	[3] Strongly disagree	29	
	[4] You don't know	14	
	[5] Does not wish to answer	2	
Q.109 QRU	In your opinion, has this contraception changed the quality of your sex life?	N=970	
	[0] Yes, very positively	258	
	[1] Yes, in a rather positive way	342	
	[2] Yes, in a rather negative way	9	
	[3] Yes, in a very negative way	1	
	[4] You do not feel any change	336	
	[9] You don't know	21	
	[10] Does not wish to answer	3	
Q.110 QRU	In your opinion, has this contraception changed the quality of sexual life of your partner(s)?	N=919	
	[0] Yes, very positively	316	
	[1] Yes, in a rather positive way	332	
	[2] Yes, in a rather negative way	9	
	[3] Yes, in a very negative way	1	
	[4] You do not feel any change	200	
	[9] You don't know	56	
	[10] Does not wish to answer	5	
Q.111 QRU	How was the subject initially discussed with your partner(s)?	N=885	
	[0] Your partner(s) brought up the subject, and you were from the outset starting	219	

	[1] Your partner(s) brought up the subject, and it took you a while to get to know them. little time to agree	137	
	[2] You brought up the subject, and your partner(s) were from the outset	309	
	[3] You brought up the subject, and it took a little while to your partner(s) to agree	75	
	[4] You discussed this topic at the same time, and you were all on board	111	
	[5] You have all addressed this subject at the same time, and you have all needed time to agree	22	
	[9] You don't know	7	
	[10] Does not wish to answer	5	
Q.112 MCQS	What difficulties have you had with your partners about this contraception? (life partners or sexual partners)	N=970	
	[0] No difficulty	740	
	[1] Your partner did not trust your ability to use this contraception correctly	59	
	[2] Your partner did not trust the effectiveness of this method (fear of an unplanned pregnancy)	127	
	[3] Your partner wanted to keep responsibility for contraception	43	
	[4] Your partner did not accept this contraceptive for aesthetic reasons	6	
	[5] Your partner felt that this contraception undermined your 'manhood	6	
	[6] This contraceptive method led to a decrease in desire at your partner(s)	3	
	[7] Other (please specify in the next question)	37	
	[9] You don't know	13	
	[10] Does not wish to answer	8	
Q.112_0 *(free text)*	What other difficulties have you encountered with your partner(s)?	N=37	
Q.113 QRU	After you have reached the contraceptive threshold, do you your partner (or partners) continued to use a additional contraception in parallel?	N=728	
	[1] Yes	99	
	[0] No	619	
	[9] You don't know	4	
	[10] Does not wish to answer	6	
Q.114 *(free text)*	You stopped this contraception: On what date did you stopped (approximately)	N=106	DM=4
Q.115 QRU	Did you use any other contraception until your sperm count became fertile again, or for at least 6 months?	N=110	
	[1] Yes	52	
	[0] No	35	
	[2] You did not need it (no sexual relations requiring contraception)	21	
	[9] You don't know	0	
	[10] Does not wish to answer	2	
Q.116 *(free text)*	You have stopped, or are thinking of stopping this contraception: Can you explain why? (The three main reasons)	N=104	DM=6

Q.117 *(free text)*	If you would like to share any comments or testimonials about your experience:	N=457	

QCM: Multiple Choice Question QRU:

Single Answer Question

H PPOCR TE SER

"I promise and swear that I will be faithful to the laws of honour and probity when I am admitted to practice medicine.

My first concern will be to restore, preserve or promote health in all its elements, physical and mental, individual and social.

I will respect all persons, their autonomy and their will, without any discrimination according to their condition or beliefs. I will intervene to protect them if they are weakened, vulnerable or threatened in their integrity or dignity. Even under duress, I will not use my knowledge against the laws of humanity.

I will inform patients of the decisions being considered, the reasons for them and their consequences. I will never mislead their trust or use the power of circumstance to force their consciences.

I will give my care to the needy and to anyone who asks me. I will not allow myself to be influenced by the thirst for gain or the search for glory.

Admitted to the intimacy of people, I will keep the secrets that are entrusted to me. Received inside the I will respect the secrets of the home and my conduct will not serve to corrupt morals.

I will do everything to relieve suffering. I will not unduly prolong agonies. I will never deliberately cause death.

I will maintain the independence necessary for the accomplishment of my mission. I will not undertake anything beyond my competence. I will maintain and develop my skills to provide the best possible service.

I will help my colleagues and their families in t i m e s o f adversity. May men and my fellow-workers esteem me if I am faithful to my promises; may I be dishonoured and despised if I fail to do so."

GENEVA DECLARATION

AS A MEMBER OF THE MEDICAL PROFESSION

I MAKE A SOLEMN COMMITMENT to devote my life to the service of humanity;

I WILL consider the health and well-being of my patient as my priority;

I WILL RESPECT the autonomy and dignity of my patient;

I WILL ensure absolute respect for human life;

I WILL NOT allow considerations of age, illness or disability, creed, ethnic origin, gender, nationality, political affiliation, race, sexual orientation, social status or any other factor to come between my duty and my patient;

I WILL RESPECT the secrets entrusted to me, even after the death of my patient;

I WILL PRACTICE my profession with conscience and dignity, in accordance with good medical practice;

I WILL PERPETUATE the honour and noble traditions of the medical profession;

I WILL give my teachers, colleagues and students the respect and recognition they deserve;

I WILL SHARE my medical knowledge for the benefit of the patient and for the advancement of health care;

I WILL look after my own health and well-being and maintain my training to provide impeccable care;

I WILL NOT use my medical knowledge to infringe on human rights and freedoms
even under duress;

I MAKE THESE PROMISES on my honour, solemnly, freely.

Annex 7

UNIVERSITY OF THE WEST INDIES
HYACINTHE BASTARAUD FACULTY OF MEDICINE

REQUEST FOR IMPRIMATUR

THESIS FOR THE DEGREE OF DOCTOR OF MEDICINE (SPECIALITY - SPECIALISED MEDICINE)

Presented by, Madame GUIDARELLI Manon Born
on 20/03/1992 in Aix-en-Provence
Department Bouches du Rhone (13) Country France

And entitled

Cross-sectional survey of testicular lift contraceptive devices: safety, acceptability, efficacy.

Jury proposes

President: Professor DRAME Moustapha
Judges: Professor NACHER Mathieu
Professor MURILLO Daniel
Doctor CHARISSOU Alan

Seen, on	For
The President of These Pr Drame Moustapha. Professor Mousta,ha DRAME c.ordonnateur llu CES **lie** Santt 11ublque **Subdivision** Antilles- Guyane CHU de Martinique - 97261 Fort-de-France Secretariat: +596 596 55 26 96 **Coun1el:moustapha.drame@chu-**	**Le Doyen de l'UFR Santé** UNIVERSITÉ UFR SANTÉ ANTILLES **Pr Suzy DUFLO**

AUTHORIZED TO SUPPORT AND PRINT THE THESIS

Pointe-A-Pitre, on . -g- JAN, 2023

Pr Michel GEOFFROY

SURNAME AND FIRST NAME: GUIDARELLI Manon

THESIS SUBJECT: Cross-sectional survey of testicular lift contraceptive devices: safety, acceptability, effectiveness.

THESIS: MEDICINE

Qualification: General Practice □

Specialised Medicine **x**

YEAR: 2023

IDENTIFICATION NUMBER :

KEYWORDS: male thermal contraception; testicular lift contraception; adverse effects; acceptability; effectiveness

Context
Several contraceptive devices by testicular ascent are used in France and in Europe without any studies having been carried out to prove their safety, their effectiveness and their acceptability.

Objectives
Main objective: to estimate the safety of at least six months' use of testicular rebreathing contraceptive devices (TRDs).

Secondary: to describe the socio-demographic and medical profile, the different CRT devices used, the real-life acceptability of the CRT devices, the effectiveness of the CRT devices used, to propose new research leads and protocol, and recommendations for use, based on the results.

Method
A descriptive, cross-sectional, international survey, conducted from 14 December 2021 to 4 March 2022 by means of an anonymous online questionnaire among participants who have used testicular contraception for at least 6 months.

Results
1050 people responded, 970 responses were analysed. Several CRT devices were used for an average of 14.1 months [+/- 8.7], the Andro-switch device was the majority (96.0%). Most participants did not use the CRT devices as recommended: 44.8% between 15 and 17 hours per day, 68.6% initial spermograms and 74.0% initial medical consultation. Adverse events were frequent, cutaneous and mild. Unexpected adverse effects on urinary function were described. The ASEX sexual dysfunction score before CRT and at the time of the study was unchanged. Satisfaction with sexual quality of life according to the MSHQ was significantly increased for participants and their sexual partners after CRT. Satisfaction was very high (86.5%), and the feeling of constraint low (less than 10% except for sports activities 20%). The main obstacles identified were the need to regularly reposition the testicles, and the accessibility of medical support and spermograms. The contraceptive threshold had been reached by 92.6% who had performed a spermogram to check effectiveness. Six unplanned pregnancies occurred during the inhibition phase (before the contraceptive threshold was reached or within the first three months of use). The estimated Pearl Index after one year of the contraceptive phase (contraceptive threshold reached), and discontinuation of additional contraception, during 3727 exposure cycles, was 0.0%.

Conclusion
CRT devices appear to be acceptable from a health perspective in terms of adverse effects and effects on sexuality. However, they are not being used as recommended. Further studies are needed, as well as training of health professionals in the monitoring of this contraception, and improving access to spermograms.

JURY : **Chairman :** Pr Moustapha

Judges : DRAME Pr Mathieu

NACHER Dr Daniel

MURILLO Dr Alan

CHARISSOU

ADDRESS OF THE APPLICANT :

Flat 103, Building i, AZTECA Residence, 97233 SCHOELCHER