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ARTICLE

Evaluation of a re-engineered device for penile vibratory stimulation in men with spinal cord injury

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Abstract

Study design Cohort study

Objectives The purpose of this study was to evaluate the performance of a re-engineered device (Ferticare 2.0), which is replacing the previous standard (Ferticare 1.0) for penile vibratory stimulation in men with spinal cord injury. Most men with spinal cord injury are anejaculatory, requiring medical assistance to obtain their semen. Penile vibratory stimulation is generally recognized as the standard of care for semen retrieval in these anejaculatory men.

Setting Major Research University in Miami, Florida, USA.

Methods The Ferticare 2.0 device was applied to 15 men with spinal cord injury in a three-step protocol simulating normal use. Step 1: one device (2.5 mm amplitude, 100 Hz) was applied to the glans penis for 2 min. Step 2: If no ejaculation occurred, the amplitude was increased to 4.0 mm (100 Hz) and the device similarly applied. Step 3: If no ejaculation occurred, two devices, each 2.5 mm and 100 Hz were applied to the dorsum and frenulum of the glans penis. Participants at risk for autonomic dysreflexia were pretreated with sublingual nifedipine (20 mg), 15 min prior to stimulation. Blood pressure and other symptoms of autonomic dysreflexia were monitored. Participants answered a questionnaire about their experience with the device.

Results Thirteen of 15 participants ejaculated with the device. No adverse events occurred. All participants commented they would recommend the device to other men with spinal cord injury.

Conclusions A re-engineered device, the Ferticare 2.0, is safe and effective for inducing ejaculation in men with spinal cord injury.

Introduction

To achieve biologic fatherhood, men with spinal cord injury (SCI) and the clinicians treating them are faced with the following (current) scenario: 1. In general, sperm production is in the normal range although sperm motility is impaired [1]. 2. Approximately 90% of men with SCI cannot ejaculate via sexual activity [2]. 3. Following a simple and proven protocol, with the application of penile vibratory stimulation (PVS) of an appropriate amplitude and frequency, an ejaculate can be obtained in up to 85% of these men with neurogenic anejaculation [3]. The majority of the ejaculates obtained will have >5 million total motile sperm; about half of all ejaculation trials will have >10 million total motile sperm [4]. 4. These ejaculated sperm can be used in an assisted reproductive technology protocol such as intrauterine insemination and achieve results similar to those seen using sperm from non-SCI men with male factor infertility.

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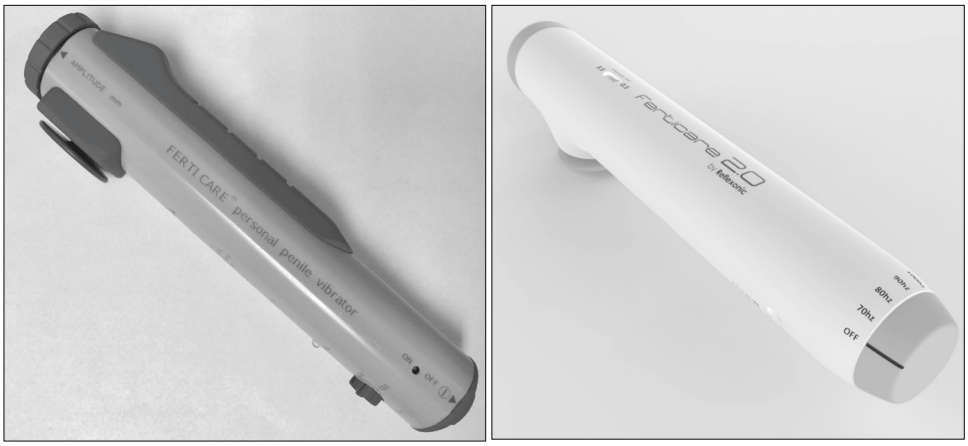


Fig. 1 Penile Vibratory Stimulation (PVS) devices. The Ferticare 1.0 device is shown on the left. This device was commercially available from 1995–2017. The Ferticare 2.0 device is shown on the right.

In fact, there are many published reports showing that, with appropriate guidance, patients can be taught to collect sperm at home, and achieve pregnancy via at-home intravaginal insemination [5–7]. 5. Surgical sperm retrieval (SSR) of testicular or epididymal sperm yields adequate numbers of sperm for IVF/ICSI, but SSR essentially eliminates any of the other options mentioned above [8–10].

Given this above mentioned scenario, the authors of this paper, all of whom are international leaders in the field of management of infertility in men with SCI, have for years considered a trial of PVS as the first step in management of this condition. The mainstay device for PVS, and for many years the only FDA approved device, has been the Ferticare device, which was specifically designed for use in men with SCI [11]. In the last few years, the device was granted approval for over the counter sale in the USA. In 2017 the Ferticare device (Multicept, Denmark) became unavailable from its original manufacturer. A void in the ability to obtain the device existed until the latter part of 2019 when a new, re-engineered version, the "Ferticare 2.0" (Reflexonic, Leesburg, VA) became available. Those of us at the University of Miami had access to a prototype, which had all the mechanical improvements, but was yet not housed in the final exterior casing. We were comfortable with it and found it seemed to work as well as the "old Ferticare," but wanted to test the actual production models in a typical busy clinic situation i.e., 7–8 patients a day, multiple uses without recharging, frequent cleaning, etc. We invited many of our colleagues to attend this structured but informal testing of the Ferticare 2.0 device in a group of men with SCI.

Materials and methods

Evaluators

A panel of experts was assembled, including practitioners from the University of Miami, the University of Michigan, the University of British Columbia (Vancouver, Canada), the University of Copenhagen, The Karolinska Institute in Stockholm, Sweden and the National Rehabilitation Hospital (Washington, DC). Collectively, these practitioners have performed more than 10,000 PVS procedures in 3500 men with SCI, and have more than 150 cumulative years of experience in managing infertility in men with SCI. The practitioners gathered at the University of Miami to directly assess the performance of the Ferticare 2.0 device in a group of volunteer men with SCI.

Device

The device being evaluated was the Ferticare 2.0® manufactured by Reflexonic (Leesburg, VA). Compared with the original Ferticare device (termed Ferticare 1.0), the Ferticare 2.0 had the following changes (Fig. 1). Internally, the Ferticare 2.0 incorporated chip technology to drive a more powerful motor fueled by lithium ion batteries replacing the nickel cadmium batteries in Ferticare 1.0. According to the manufacturer, these lithium ion batteries can last for 3–5 years and lasts for up to 30 min of continuous use. In addition, the amplitude generator was re-designed, although the principle of vibration remained the same as the Ferticare 1.0. The movement and torque mechanism were re-engineered to deliver more durable and powerful vibrations and not stop with resistance. Externally, indicators for amplitude and frequency were re-designed for ease of use. The vibrating disc (removable for cleaning) had been re-designed to reduce the likelihood of breaking off at the point of insertion into the device.

Participants

Participants were 15 men with SCI who were participants in the Male Fertility Research Program of the Miami Project to Cure Paralysis located at the University of Miami Miller

School of Medicine in Miami, Florida. The study was approved by the University of Miami IRB and all participants signed an informed consent form. Participants' neurological level and completeness of injury was determined by the International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI) [12, 13]. The level of injury for all participants included in this study was T10 or rostral based on our previously reported success rate with PVS [3].

Prior to their participation in this study, all participants had tried PVS using other devices, including one or more of the following: the Ferticare 1.0 (Multicept, Denmark) and/or the Viberect X3 (Reflexonic, Leesburg, VA).

Participants for this study were selected to comprise a range of neurological levels of injury, including those with cervical, high thoracic, and low thoracic levels. Presence or absence of bulbocavernosus and hip flexor reflexes for all participants were reported. (Table 1). These reflexes were shown to be good predictors of ejaculation with PVS in men with SCI [14].

Participants were also selected to include some who had, and some who *had not* previously ejaculated with a different device. All participants were asked to abstain from ejaculation for at least 1 week prior to participation in the study.

Protocol

All participants had their bladder emptied prior to performing PVS. Per our Male Fertility Research Program Protocol, participants whose level of injury was T6 or rostral were pretreated with 20 mg sublingual nifedipine to manage possible autonomic dysreflexia [15]. Blood pressure was monitored every minute throughout the PVS procedure.

The following stimulation protocol was administered to each subject. Step 1: One Ferticare 2.0 was applied to the dorsum of the glans penis. The amplitude of the device was 2.5 mm, and the frequency was 100 Hz. If no ejaculation occurred after 2 min of stimulation, PVS was stopped. The integrity of the penile skin was assessed. Step 2: If the subject's penile skin and vital signs were stable, the Ferticare 2.0 was again applied to the dorsum of the glans penis, with the amplitude of the device increased to 4.0 mm and the frequency remaining at 100 Hz for 2 min. If no ejaculation occurred, PVS was stopped. Step 3: If the penile skin and vital signs remained stable, PVS was again administered with two Ferticare 2.0 devices, one placed on the dorsum of the glans penis and one placed on the frenulum of the glans penis for 2 min. Each device was set at 2.5 mm amplitude and 100 Hz frequency. If no ejaculation occurred, the patient was considered a PVS failure for this study.

Table 1 Demographic information.

Subject ID	Age (Years)	Years post-injury	Neurological level of injury	Cause of injury	BCR	HFR
1	51.0	19.2	T10 (AIS A)	Fall	+	+
2	30.0	12.0	T4 (AIS A)	MVA	+	+
3	58.6	20.5	T7 (AIS A)	MVA	+	+
4	30.3	12.9	T9 (AIS A)	MVA	−	−
5	44.4	13.4	C1 (AIS B)	MVA	+	−
6	33.5	12.0	T3 (AIS A)	MVA	+	−
7	35.6	3.1	T3 (AIS A)	GSW	+	+
8	41.4	10.5	C7 (AIS B)	Diving accident	−	+
9	39.6	18.4	C5 (AIS A)	Fall	−	−
10	37.5	20.6	T4 (AIS A)	MVA	+	+
11	44.2	21.4	T10 (AIS A)	GSW	+	−
12	48.0	18.0	T5 (AIS A)	MVA	−	−
13	31.3	12.2	C6 (AIS A)	Diving Accident	+	+
14	46.0	24.8	T3 (AIS A)	MVA	+	−
15	65.3	21.5	T6 (AIS A)	GSW	−	+
Mean ± SD	42 ± 10	16 ± 5.7				

Table 1 shows the age and years post-injury of each subject. Neurological level and completeness of injury was assessed using the International Standards for Neurological Classification of Spinal Cord Injury. C = cervical, T = Thoracic. The cause of injury is presented.

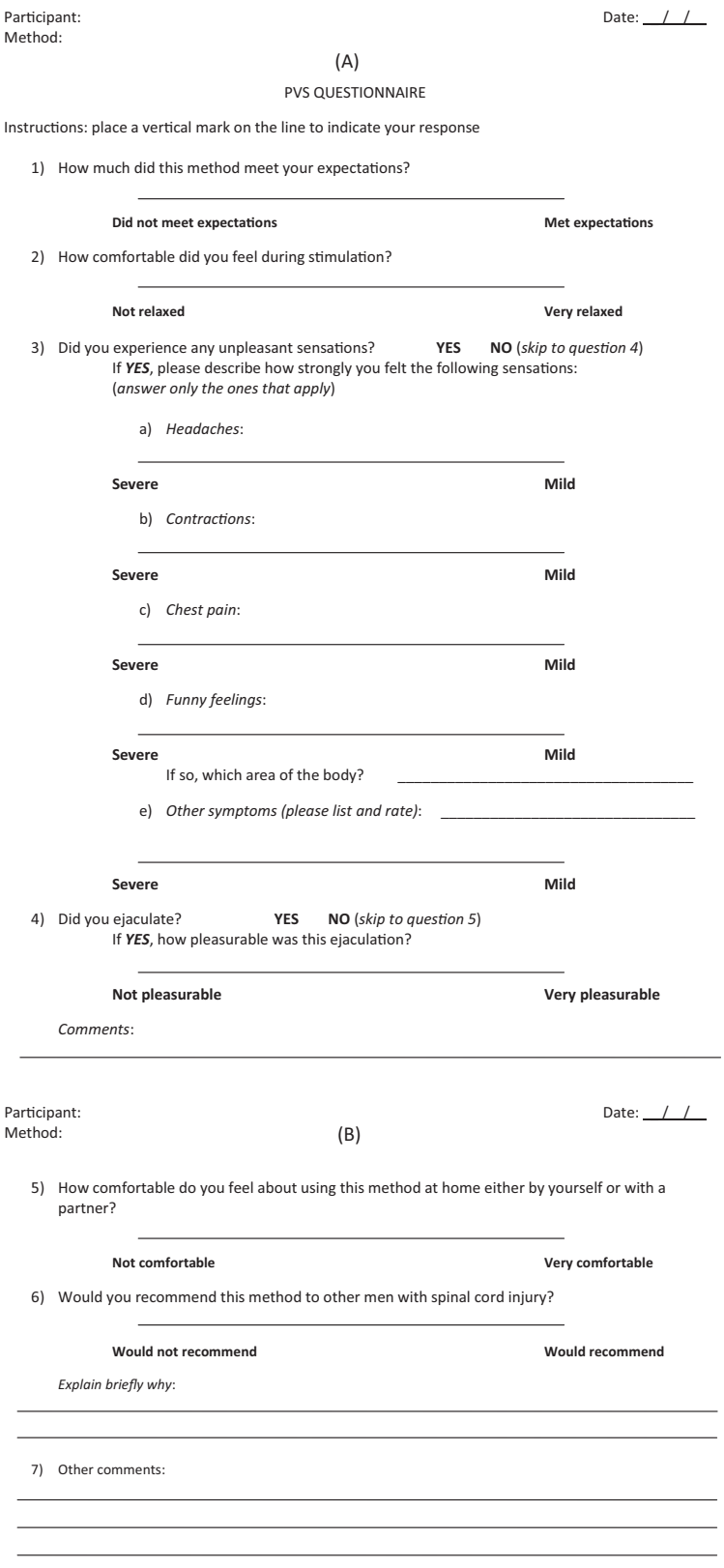
MVA motor vehicle accident, *GSW* gunshot wound, *BCR* bulbocavernosus reflex, *HFR* hip flexor reflex, (+) present, (−) absent.

Evaluation of retrograde ejaculation

No attempt was made to control for factors, such as medications, that may affect the semen quality of the participants in this study. For this reason, complete semen analysis data is not presented. It is often important, however, to note if retrograde ejaculation occurred, because sperm obtained from the retrograde fraction may be useful or sometimes necessary in assisted conception procedures. All participants were catheterized after completion of the three protocol steps if necessary, regardless of the outcome, and assessed for the possibility of retrograde ejaculation. Retrograde ejaculation was defined as 10% or more of the combined total sperm count being represented by the retrograde fraction.

Questionnaire

At the conclusion of the PVS protocol, responders were asked to rate their experience with the device on a questionnaire with scaled responses. The measured distance from zero of a vertical mark on a 10 cm line indicated a rating between 0 and 10 (Fig. 2a, b).



Participant: Date: __/__/__
Method:

(A)

PVS QUESTIONNAIRE

Instructions: place a vertical mark on the line to indicate your response

1) How much did this method meet your expectations?

Did not meet expectations **Met expectations**

2) How comfortable did you feel during stimulation?

Not relaxed **Very relaxed**

3) Did you experience any unpleasant sensations? **YES** **NO** (*skip to question 4*)
If ***YES***, please describe how strongly you felt the following sensations:
(*answer only the ones that apply*)

a) *Headaches*:

Severe **Mild**

b) *Contractions*:

Severe **Mild**

c) *Chest pain*:

Severe **Mild**

d) *Funny feelings*:

Severe **Mild**

If so, which area of the body? _____

e) *Other symptoms (please list and rate)*: _____

Severe **Mild**

4) Did you ejaculate? **YES** **NO** (*skip to question 5*)
If ***YES***, how pleasurable was this ejaculation?

Not pleasurable **Very pleasurable**

Comments:

Participant: Date: __/__/__
Method:

(B)

5) How comfortable do you feel about using this method at home either by yourself or with a partner?

Not comfortable **Very comfortable**

6) Would you recommend this method to other men with spinal cord injury?

Would not recommend **Would recommend**

Explain briefly why:

7) Other comments:

Fig. 2 Penile Vibratory Stimulation (PVS) Questionnaire. The questionnaire shown in Fig. 2a, b was administered to participants following administration of PVS with the Ferticare 2.0 device.

Results

Responses to PVS

The PVS procedure was well-tolerated by all 15 participants. Blood pressure and other symptoms of autonomic dysreflexia were well-managed by the protocol described in the methods. No PVS procedure was aborted due to symptoms of autonomic dysreflexia or other adverse events. There were no occurrences of penile skin bleeding or edema from the PVS procedures performed in this study.

Table 1 shows demographic information for the participants included in this study. Each subject that had previously responded to PVS with another device also responded to PVS with the Ferticare 2.0, the response of each individual participant is also reported. (Table 2). The two participants that were failures to PVS with other devices were also failures to PVS with the Ferticare 2.0 (participants 4 and 11). All three steps of the protocol were completed in the two PVS failures in this study.

Responses to the questionnaire

Questionnaires were administered to the 13 participants who responded to PVS. Their responses are shown in Table 3A. Scores were generally favorable for Question 1 ("How much did this method meet your expectations?"); Question 2 ("How comfortable did you feel during stimulation?"); Question 5 ("How comfortable do you feel about using this method at home, either by yourself or with a partner?"); and Question 6 ("Would you recommend this method to other men with SCI?").

Question 3 asked: "Did you experience any unpleasant sensations?" Eleven of 13 participants answered "no." Participants 6 and 7 answered "yes," and their reported sensations are shown in Table 3B. Question 4 asked: "How pleasurable was this ejaculation?" The mean ± SD rank was 6.6 ± 3.0 on a scale from 0 (not pleasurable) to 10 (very pleasurable). Two participants (1 and 8) entered comments for Question 4 (comments shown in Table 3C). For Question 6, participants were asked to "explain briefly why" they would or would not recommend this method to other men with SCI. Comments to this query are shown in Table 3D. General comments (solicited in Question 7) are shown in Table 3A.

Table 2 Response to Ferticare 2.0.

Participant ID	Responder to previous PVS device?	Responder to Ferticare 2.0?		
		One device set at 2.5 mm?	One device set at 4.0 mm?	Two devices set at 2.5 mm?
1	Yes	No	No	Yes
2	Yes	Yes	NA	NA
3	Yes	No	Yes	NA
4	No	No	No	No
5	Yes	Yes	NA	NA
6	Yes	Yes	NA	NA
7	Yes	Yes	NA	NA
8	Yes	Yes	NA	NA
9	Yes	Yes	NA	NA
10	Yes	Yes	NA	NA
11	No	No	No	No
12	Yes	No	No	Yes
13	Yes	Yes	NA	NA
14	Yes	Yes	NA	NA
15	Yes	Yes	NA	NA

Table 2. Each participant's response to PVS with another device (administered at least 1 week prior to the Ferticare 2.0) and their response with the Ferticare 2.0 at specific setting are indicated.

NA not applicable.

Evaluation of retrograde ejaculation

Two of the 15 participants had antegrade and retrograde ejaculation (participants 6 and 8). The remaining 13 participants had only antegrade and no retrograde ejaculation, including the two PVS failures (participants 4 and 11).

Discussion

SCI affects millions worldwide and there are thousands of new cases each year. The majority of spinal cord injuries occur to young men at the peak of their reproductive health [16]. Following SCI, most men are anejaculatory [2, 17]. To achieve biologic fatherhood, medically assisted semen retrieval is required. The first line of treatment for semen retrieval for anejaculatory men with SCI is PVS [3, 4].

For many years, the "gold standard" device for PVS of men with SCI was the Ferticare 1.0 [18]. It was engineered to deliver the optimal frequency and amplitude required for inducing ejaculation in men with SCI [11]. The Ferticare 1.0 was manufactured from 1995 to 2017. Recently, a re-engineered device (Ferticare 2.0) has become commercially available. Both patients and practitioners have made numerous inquiries to the authors of this paper regarding the performance of this device. This is the first study to report on the performance of the Ferticare 2.0.

A panel was convened to test the Ferticare 2.0. Our goal was to achieve consensus and disseminate information rapidly to the medical and lay communities that are seeking information about the performance of this device. The panel met November 18–19, 2019 at the University of Miami in

Table 3 Participants' responses to post-PVS Questionnaire.

(A) Responses to questionnaire

Participant ID	Q1	Q2	Q3	Q4	Q5	Q6	Q7
1	10	10	No	1 (See Table 3C)	10	10 (See Table Table 3D)	"To help bladder functions"
2	10	10	No	–	10	10 (See Table 3D)	_
3	10	10	No	10	10	9	"Better than previous device"
5	10	10	No	10	10	10	"Good device, precise and does the job"
6	10	7	Yes (See Table 3B)	10	10	10 (See Table 3D)	_
7	10	6	Yes (See Table 3B)	7	10	10 (See Table 3D)	"Get the job done"
8	10	8	No	5 (See Table 3C)	3	10 (See Table 3D)	"A great tool for having a baby"
9	9	10	No	6	10	10 (See Table 3D)	–
10	10	10	No	5	5	10 (See Table 3D)	–
12	5	9	No	5	10	10 (See Table 3D)	–
13	0	10	No	–	10	10 (See Table 3D)	–
14	10	10	No	–	10	10 (See Table 3D)	"The sound is very scary"
15	10	10	No	–	10	10 (See Table 3D)	"It is convenient to use at home"
Mean ± SD	8.8 ± 3.0	9.2 ± 1.4		6.6 ± 3.0	9.1 ± 2.3	9.9 ± 0.28	

(B) Responses to question 3 follow up query

Participant ID	a) Headaches	b) Contractions	c) Chest pain	d) Funny feelings (where)	e) Other symptoms (Please list and rate)
6	–	5	–	9 (Stomach and legs)	–
7	–	5	–	5 (Overall, hard to pinpoint)	–

(C) Comments to question 4

Participant ID	Comment
1	"Did not feel pleasure"
8	"Not the same feeling as ejaculation prior to injury"

(D) Comments to question 6

Participant ID	Comments
1	"This will help other men to avoid having prostate cancer"
2	"It relaxes body"
3	–
5	–
6	"Speed of results and ease of use. The vibrations felt mild but still produced strong contractions to ejaculate. I liked that the vibrations felt concentrated in my private parts area and not noticed in other areas of my body."
7	"Very effective and fast"
8	"For trying to have baby"
9	"Because it works"
10	"It is a good way to prevent UTI. Best way to relieve spasms"
12	–
13	"It easier for men with SCI to ejaculate using this ferticare easy and convenient"
14	"it works faster and hopefully the size should be the same as the other ferticare"
15	"Men with SCI like me will benefit on this method to know their fertility"

Table 3A:

Participants who responded to PVS (all subjects except 4 and 11) were administered the questionnaire shown in Fig 2. Participants were asked to rank their responses to the following questions.

Question 1 (Q1): How much did this method meet your expectations? Rank from 0 (Did not meet expectations) to 10 (Met expectations).

Question 2 (Q2): How comfortable did you feel during stimulation? Rank from 0 (Not relaxed) to 10 (Very relaxed).

Question 3 (Q3): Did you experience any unpleasant sensations? Respond: Yes or No. If yes, a follow up question was presented (see Table 3B and Fig. 2).

Question 4 (Q4): Participants who ejaculated were asked: How pleasurable was this ejaculation? Rank from 0 (Not pleasurable) to 10 (very pleasurable). A comment field was offered.

Question 5 (Q5): How comfortable do you feel about using this method at home either by yourself or with a partner? Rank from 0 (Not comfortable) to 10 (Very comfortable).

Question 6 (Q6): Would you recommend this method to other men with spinal cord injury? Rank from 0 (Would not recommend) to 10 (Would recommend). A comment field was offered.

Question 7 (Q7) was an open comment field at the end of the questionnaire that solicited "Other comments."

"–" indicates no response to the question.

Table 3B:

Subjects 6 and 7 answered "Yes" to Q3: Did you experience any unpleasant sensations?

Table 3B shows their answers to the follow up question: If yes, please describe how strongly you felt the following sensations. Rank from Severe (0) to Mild (10)

(The complete questionnaire is shown in Fig. 2).

"–" indicates no response.

Table 3C:

Question 4 (Q4) asked: How pleasurable was this ejaculation? Rank from 0 (Not pleasurable) to 10 (very pleasurable). Rankings are shown in Table 3A. A comment field was offered for Question 4: Participants 1 and 8 entered comments which are shown. The other subjects did not enter a comment for Question 4. The complete questionnaire is shown in Fig. 2.

Table 3D:

Question 6 (Q6) queried: Would you recommend this method to other men with spinal cord injury? Rank from 0 (Would not recommend) to 10 (Would recommend). Rankings are shown in Table 3A. A comment field was available for subjects to explain briefly why they would or would not recommend the FertiCare 2.0 to other men with spinal cord injury. Table 3D shows the comments. The complete questionnaire is shown in Fig 1. The questionnaire was not administered to non-responders (Subjects 4 and 11).

"–" indicates that no response.

Florida, and included leaders in the management of infertility in men with SCI. A PVS protocol was agreed on and applied to participants with SCI.

The consensus of participants and panel members was that the Ferticare 2.0 device is safe and effective for inducing ejaculation in men with SCI. Thirteen of the 15 participants in this study responded to the Ferticare 2.0. These 13 participants had previously responded to PVS with other devices. Two participants did not respond to the Ferticare 2.0. These two participants (4 and 11) had previously not responded to PVS with other devices. In these PVS failures, it should be noted that their semen was subsequently retrieved by the method of electroejaculation [19] using the Seager Model 14 electroejaculation device (Dalzell USA Medical Systems, The Plains, VA).

All participants tolerated PVS with the Ferticare 2.0, and any symptoms of autonomic dysreflexia were well-managed with the protocol used in this study. Participants were administered a questionnaire regarding their experience with the Ferticare 2.0. Overall, the responses were favorable and all participants stated that they would recommend this device to other men with SCI (see Table 3A and D).

A limitation of this study was that it was performed in a selected group of men with SCI, rather than in a naïve group of participants. The participants' ejaculation histories with other PVS devices were known. Follow-up studies will report on the success rate of the Ferticare 2.0 in men with SCI that have no prior history of PVS.

Another limitation of the study was that the Ferticare 2.0 was not directly compared, in a controlled study, with other devices for PVS. Currently, the Viberect X3 is the only other device specifically engineered for PVS of men with SCI. If the Viberect X3 continues to be manufactured, it will be important to compare the effectiveness of the two devices (Viberect X3 and Ferticare 2.0) within a group of the same men with SCI.

Conclusions

A re-engineered device for PVS was found to be safe and effective for inducing ejaculation in men with SCI.

Data availability

All data generated or analyzed during this study are included in this published article in Table 1, Table 2, Table 3a, 3b, 3c and 3d.

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Author contributions EI, CML, and NLB were responsible for designing the study protocol, conducting the search, screening potentially eligible studies, performing the study, extracting and analyzing data, interpreting results, and writing the paper. CFSJ, IS, SE, JS, DAO, CH, and SWJS were responsible for designing the review protocol, conducting the search, interpreting results, providing

feedback on the report and assisted in writing the paper. KJ and TCA were responsible for subject recruitment, setup, performing related specimen analysis and reporting results and data to the study team.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval The study was approved by the University of Miami IRB and all participants signed an informed consent form. We certify that all applicable institutional and governmental regulations concerning the ethical use of human volunteers were followed during the course of this research.

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