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Contraceptive efficacy of polyester-induced azoospermia in normal men

Ahmed Shafik, MD
Professor and Chairman, Department of Surgery & Research, Faculty of Medicine, Cairo University, Cairo, Egypt

ABSTRACT

The contraceptive effect of a polyester sling applied to the scrotum was studied in 14 men. The suspensor was worn for 12 months. Follow-up investigations comprised periodic check of semen character, testicular size, rectal-testicular temperature difference, serum reproductive hormones and testicular biopsy. The electrostatic potentials generated by friction between the polyester suspensor and the scrotal skin were determined. Female partners used contraceptives until the men became azoospermic. After 12 months, the suspensor was abandoned and the aforementioned investigations were performed again.

In the suspensor-wearing period, all men became azoospermic after a mean of 139.6±20.8 sd days, with decrease in both testicular volume ($P < 0.05$) and rectal-testicular temperature difference ($P < 0.001$). Serum reproductive hormones showed no significant change ($P > 0.05$). Seminiferous tubules revealed degenerative changes. No pregnancy occurred during this period. The polyester suspensor generated electrostatic potentials (mean 366.4±30.5 sd volt/cm^2 by day and 158.3±13.6 sd volt/cm^2 by night).

In the suspensor-release period, the sperm concentration returned to the pre-test level in a mean period of 156.6±14.8 sd days. Likewise, the testicular volume and rectal-testicular temperature difference were normalized. The 5 couples, who had planned to become pregnant, conceived.

The azoospermic effect of the polyester sling seems to be due to two mechanisms:

1) the creation of an electrostatic field across the intrascrotal structures, and
2) disordered thermoregulation.

To conclude, fertile men can be rendered azoospermic by wearing the polyester sling. It is a safe, reversible, acceptable and inexpensive method of contraception in men.

Send correspondence to:
Ahmed Shafik,
2, Talaat Harb Street,
Cairo, Egypt.

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INTRODUCTION

Safe and effective methods of contraception are needed for population control. Many successful methods have been devised for the female while in the male, there is only vasoligation[1]. Although the latter is an effective male contraceptive method, yet the high incidence of permanent infertility and the surgical risk limits its international usage. Androgen, alone[2,3] or combined with progesterone[4], did not prove to be an efficient method of contraception[5]. For this reason, the search for a reliable, reversible and safe method for male contraception continues.

One of the methods recently investigated is the vulnerable nature of spermatogenesis to polyester (polyethylene terphthlate) material included in textiles[6-8]. A recent study[6] has shown that dogs, while wearing polyester underpants, had a diminished sperm count which was reversible when the pants were removed. In contrast, dogs wearing cotton pants showed insignificant semen changes. Another study[7] revealed that polyester underpants worn by humans generated electrostatic charges which created an "electrostatic field" that traversed the scrotum and seemed to affect the testicle and/or the epididymis, leading to diminished spermatogenesis. Likewise, the effect of textiles on the spermatogenesis in 33 human volunteers was studied during 18 months[8]. There were insignificant changes in testicular temperature and serum reproductive hormones. In the group of 11 subjects wearing polyester underpants, four showed significant decrease of sperm count and testicular degenerative changes by the 14th month; these changes were reversed when the underpants were removed. In the polyester-cotton mix group (11 subjects), only one volunteer became oligospermic in the 16th month of wearing the pants; the sperm count was normalized after removal of the underpants. The cotton-wearing group showed insignificant changes in the semen character.

It was concluded that polyester fabric has a depressive effect on spermatogenesis[8]; the effect was reversible on removal of the pants. Furthermore, it seems that this effect is related to the electrostatic charges generated by the polyester fabric and creating an electrostatic field across the testicle and/or the epididymis.

In view of these studies, it was surmised to use polyester-containing textiles as a contraceptive tool for men. This communication presents the results of this study.

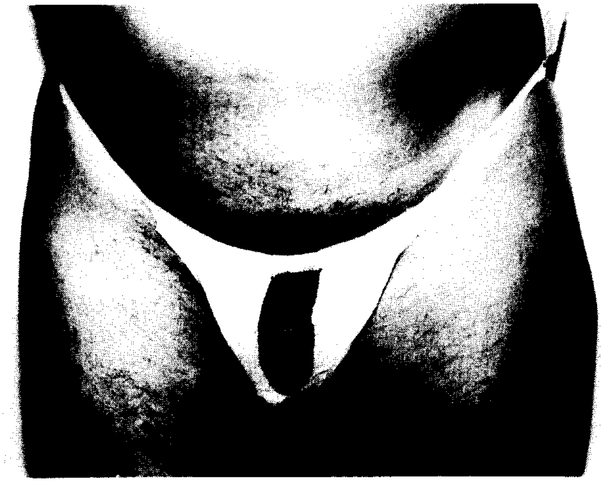

Figure 1: Scrotal sling

SUBJECTS AND METHODS

Fourteen men volunteered for this study. Their ages ranged from 32 to 47 years (mean 38.8 ± 3.6 sd years). Each had fathered between 3 to 7 children (mean 5.3 ± 0.6 sd), in addition to 2 to 6 induced abortions (mean 4.3 ± 1.4 sd), when they presented asking for contraceptive measures. The subjects had no history of active or chronic medical disease. Physical examination was normal. Their partners had mean age of 31.3 ± 3.8 sd years and regular menses with no pelvic inflammatory disease. Two samples of semen, 2-weekly spaced, and blood sample for reproductive hormones assay (serum testosterone, LH, FSH, prolactin) were examined. The testicles were assessed for consistency and size using Schirren orchidometer. All of these parameters were found within normal limits.

Method. A suspensory sling was prepared for each subject. It consisted of polyester fabric (polyethylene terphthalate) and was fashioned so that the scrotum lay within it (Fig. 1). Variable sizes of the sling were made to suit the scrotum and testicles of the different individuals. The polyester suspensor was applied to the scrotum and slung to the waist of the subject by a belt attached to the suspensor. The belt was tied so that the suspensor elevated the testicles towards the abdomen. The subjects were instructed on how to apply the sling by themselves. The suspensor was used day and night, and was changed only when soiled. The female partners were required to use a hormonal contraceptive.

During the 12 months of wearing the polyester suspensor, the testicular size and consistency, rectal and testicular temperature, and the semen were checked every two weeks. The testicular temperature was measured by drawing the anterior scrotal skin over the bulb of a mercury thermometer placed against the scrotum overlying the anterior aspect of the testicle[9]. Hormonal assay (serum testosterone, LH, FSH, prolactin) was done every 3 months. A testicular biopsy was taken at the sixth month of wearing the polyester suspensor. It was fixed in Bouin's solution and stained with hematoxylin and eosin.

Electrostatic potential studies. The electrostatic potentials generated by the friction between the polyester sling and the scrotal skin were measured. This was done during the day between 9 and 11 a.m., and at night between 7 and 9 p.m., and was repeated 4 times monthly, each on a separate day, and the mean for each individual was calculated. The apparatus used for measuring the electrostatic potentials was the electrostatic kilovoltmeter (Model LVE, Hallmark Standards, USA) with a sensitive probe. The measurements were taken by volt/unit area of the probe. The technique of recording comprised applying the probe to the surface of the polyester sling at different areas, and the reading from each area was recorded. The mean of these readings was then calculated.

Suspensor release. After one year, the polyester suspensor was abandoned. Post-release investigations comprised of testicular examination for size and consistency, measuring of the rectal and testicular temperatures, and semen analysis monthly for one year or until the parameters returned to the pre-test level. Testicular biopsy was taken 6 months after testicular release in cases where the semen character had not reached the pre-test level.

Hormonal assay. Serum testosterone, FSH, LH and prolactin were estimated before, and after 3 and 12 months of wearing the suspensor, as well as 3 and 12 months after testicular release. Hormones were measured by radioimmunoassay using Diagnostic Products Corporation kits. The serum testosterone was measured by the method of Smith, Rodriguez-Rigua[10], FSH and LH using Santner et al.[11], and prolactin according to Cowden[12].

Pregnancy during wearing the suspensor and after release. The female partner was asked to use a hormonal contraceptive method until the man became azoospermic. All contraceptive methods were abandoned from the third azoospermic specimen.

After suspensor release, men were followed monthly for 12 months or until the spermatogenesis recovered. Five of the women asked to become pregnant in the release period.

RESULTS

All the subjects completed the test. No complications or reactions occurred from wearing the polyester suspensor. All of them became azoospermic; the time lapse from the start of the test to the third consecutive azoospermic sample varied from 120 to 160 days (mean 139.6 ± 20.8 sd days) (Table I).

There was decrease in the testicular volume from the mean pre-test level of 22.2 ± 2.3 sd ml to 18.6 ± 1.9 ml ($P < 0.05$). The mean rectal-testicular temperature difference was significantly lower during the suspensor-wearing phase than during the pre-test ($P < 0.001$), and returned to within normal levels three months after suspensor release ($P > 0.05$) (Table II). No significant change ($P > 0.05$) was encountered in the levels of serum reproductive hormones during the period of study (Table III).

After 6 months of wearing the polyester suspensor, the germ cells of the seminiferous tubules showed degenerative changes and some of these cells had sloughed in the center of the tubule.

As regards the contraceptive efficacy, no pregnancy occurred during the 12 months of the suspensor-wearing period. No sperm were detected in specimens obtained after the subject had become azoospermic up to the end of the 12 months.

In the suspensor-release period, the sperm concentration in all of the 14 volunteers recorded values above 20 million/ml in a period varying from 90 to 120 days (mean 109.6 ± 10.8 sd days) (Table IV), and returned to the pre-test levels in periods varying from 140 to 170 days (mean 156.6 ± 14.8 sd days) (Table IV). The testicular volume returned to normal pre-test levels in 75 to 135 days (mean 98.6 ± 13.2 sd days) ($P > 0.05$). Five couples had planned to become pregnant in the release period. All of them conceived with four normal live births and one spontaneous abortion.

Table V depicts the measured day- and night-time readings of the electrostatic potentials from the scrotal area during the wearing of the polyester suspensor. The polyester-generated electrostatic potentials were higher during the day than at night ($P < 0.01$).

The aforementioned results were reproducible in the individual subjects.

Table (I): Sperm count (million/ml) before and after 3 and 6 months of wearing the suspensor in 14 volunteers

	Before wearing suspension			After 3 months of wearing suspensor			After 6 months of wearing suspensor		
Sperm count	21-40	41-60	> 60	0-1	2-10	11-20	0	1-10	11-20
No. subjects	0	9	5	4	10	0	14	0	0
%	0	64.3	35.7	28.6	71.4	0	100	0	0

Table (II): Rectal-testicular temperature difference before and after 3 months of wearing the polyester suspensor, and 3 months after suspensor release+

	Temperature °C				
	Rectal		Testicular		Rectal-testicular Temperature difference
	Range	Mean	Range	Mean	Mean
Before suspensor	37.4-37.7	37.5±0.3	34.1-34.7	34.5±0.2	3.0±0.3
After 3 months of wearing suspensor	37.5-37.7	37.6±0.1	36.0-36.7	36.3±0.4	1.3±0.2
3 months after suspensor release	37.5-37.7	37.5±0.2	34.3-34.8	34.6±0.2	2.9±0.2

+ Values are given as mean ± standard deviation

Table (III): Mean serum levels of reproductive hormones before and after 3 months of wearing the suspensor and 3 months after suspensor release[+]

	Testosterone (ng/ml)	FSH (mIU/ml)	Prolactin (ng/ml)	LH (mIU/ml)
Before wearing of suspensor	6.3±1.6	7.4±2.0	5.3±1.4	5.0±1.1
After 3 months of wearing suspensor	6.0±1.8	7.6±1.9	5.8±1.3	5.4±1.5
3 months after suspensor release	6.6±1.4	7.1±1.7	5.1±1.1	5.3±1.1

+ Values are given as nean ± standard deviation

Table (IV): Sperm count (million/ml) 1, 3 and 6 months after suspensor release in 14 volunteers

	1 month after suspensor release			3 months after suspensor release			6 months after suspensor release		
Sperm count	0	1-10	11-20	11-20	21-40	41-60	21-40	41-60	> 60
No. subjects	2	7	5	5	9	0	0	10	4
%	14.3	50	35.7	35.7	64.3	0	0	71.4	28.6

Table (V): Measured electrostatic potentials from the scrotal area of the 14 subjects wearing polyester suspensors+

	Electrostatic potentials (volt/cm^2)	
	Range	**Mean**
Daytime	326-395	366.4±30.5
Nighttime	142-188	158.3±13.6

+ Values are given as mean ± standard deviation

DISCUSSION

This study demonstrates that enclosing the scrotum in polyester suspensor caused azoospermia in all of the 14 volunteers. This azoospermia was reversible in the release period and five of the couples, who had planned to become pregnant, conceived.

Furthermore, the study has shown that electrostatic potentials were generated from the polyester sling and the opposing scrotal skin as a result of friction between the two surfaces. They were higher during the day than at night, due probably to the higher temperatures prevailing during the day. The electrostatic charges and, consequently, the potentials are directly proportional to the temperature; the higher the temperature, the higher the number of charges generated.

The azoospermic effect of the polyester sling. The azoospermic effect of the polyester sling seems to be related to two factors: (A) the electrostatic field effect, and (B) the disordered thermoregulatory effect.

(A) **The electrostatic field effect.** Friction between the scrotal skin and the polyester sling creates a negative charge on the inner surface of the sling and a positive charge on the scrotal skin facing the sling (Fig.2). An equal but opposite charge to that on the inner aspect of the sling occurs on its outer surface. The result is that the outer surface

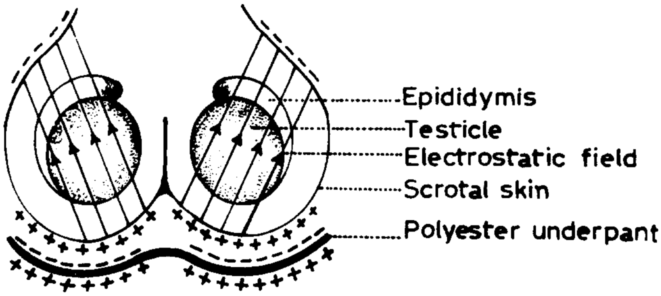

Figure 2: Diagrammatic illustration of the electrostatic potentials created on the polyester suspensor and the scrotal sac. The electrostatic field is demonstrated (from Shafik[7]).

of the scrotal sac facing the sling will have a number of positive charges. The latter produces induced charges with negative sign on the other surface of the scrotal sac.

Eventually, equal but opposite charges are created on the two aspects of the scrotal sac: the one in contact with the sling and the other away from it (Fig. 2). These opposite charges will produce an "electrostatic field" extending from one aspect of the scrotum toward the other through the scrotal sac. This electrostatic field traversing the scrotal contents would disturb the testicles and/or epididymis leading to diminished spermatogenesis.

(B) **Disordered thermoregulation**. The polyester suspensor leads to spermatogenic depression not only by the creation of an electrostatic field but also by disturbing the thermoregulatory mechanism of the testicle. The suspensor induces disturbed thermoregulation by two mechanisms. Firstly, it fixes the two testicles so that they cannot move in reaction to changes in the environmental temperature[13,14]. Secondly, it slings the two testicles up towards the warm abdomen, thus increasing the testicular temperature, with a resulting decrease in the rectal-testicular temperature difference. The testicular temperature may as well affect the frequency of the electrostatic potentials generated on the scrotal skin. As forementioned, the higher the temperature, the higher the number of charges generated. Thus, with the increase of the testicular temperature resulting from the testicle being close to the warm abdomen, the generated electrostatic charges increase, and their possible injurious effect on the intrascrotal structures would consequently increase.

All of the volunteers had recorded decrease in the rectal-testicular temperature difference during the period of wearing the polyester suspensor. However, the temperature difference returned to the pre-test value after the suspensor was released.

The polyester sling as a contraceptive tool. The present study has shown that fertile men can be rendered azoospermic by wearing a polyester suspensor. The effect was, however, reversible when the suspensor was abandoned. There were no contraceptive failures during the sling-wearing period. Furthermore, pregnancy was achieved in the sling-release period.

There was no discontinuation recorded with the method. No side effects were encountered. The safety, reversibility and acceptability of such a method would make it a satisfactory contraception for long periods. Meanwhile, it is less costly when compared to the other contraceptives in common use. The method could be better than vasoligation and condoms if it would be tried on a larger group of subjects. Admittedly, the number of subjects in the present study is small, but the results are encouraging.

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