

*Clinical Case Report Series*

## Leuprolide Acetate Suppresses Pedophilic Urges and Arousability

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Cognitive-behavioral psychotherapy was compared with cognitive-behavioral psychotherapy augmented by leuprolide acetate (LA) for suppression of pedophilic behavior. Five male pedophiles (*M* age, 50 years; range, 36–58) were administered LA by Depo injection for 12 months, followed by saline placebo for 12 months. Testosterone levels, sexual interest preference by visual reaction time (Abel Assessment), penile tumescence (Monarch Penile Plethysmography, PPG), as well as strong sexual urges toward children and masturbatory frequency involving thoughts of children (polygraph), were measured every 3 months. On LA, testosterone decreased to castrate levels. Penile tumescence was significantly suppressed compared with baseline, but sufficient response remained to detect pedophilic interest. Pedophilic interest was also detected by visual reaction times. When asked about having pedophilic urges and masturbating to thoughts of children, all subjects self-reported a decrease. Polygraph responses indicated subjects were not deceptive. On placebo, testosterone and physiologic arousal eventually rose to baseline. As noted by polygraph, at baseline and on placebo, subjects were deceptive regarding increased pedophilic urges and masturbatory frequency. Interest preference, as measured by Abel Assessment and Monarch PPG, was generally unchanged throughout the study. Cognitive-behavioral psychotherapy augmented with LA significantly reduced pedophilic fantasies, urges, and masturbation; however, pedophilic interest did not change during 1 year of therapy. Deceptive responses by polygraph suggested that self-report was unreliable. Follow-up utilizing objective measures is essential for monitoring efficacy of treatment in pedophilia. Our study supports the premise that suppression of pedophilic behavior is possible. LA may augment cognitive-behavioral psychotherapy and help break the sequence leading to a re-offense.

**KEY WORDS:** leuprolide acetate; pedophilia; sex therapy; paraphilia.

### INTRODUCTION

Traditional treatment of pedophilia has focused on cognitive-behavioral psychotherapy alone and, more recently, cognitive-behavioral psychotherapy combined with treatments to lower sex drive. Lowering sex drive to mediate paraphilic behavior has been attempted with

several modalities, including testosterone-lowering medications, serotonin re-uptake inhibitors, surgical castration, and stereotaxic neurosurgery. Disadvantages of the latter two include intrusiveness and irreversibility.

Pharmacotherapy has focused on the ability of drugs to reduce drive, deviant sexual arousal and fantasy, and the frequency of deviant sexual behavior, including pedophilia and other paraphilias. Measures of success have included recidivism rates and subjective assessments of masturbation frequency and deviant behavior. The ability to sustain a prolonged and efficacious treatment without dropouts and with objective measures is crucial.

Testosterone-lowering agents, such as medroxyprogesterone acetate (MPA) and cyproterone acetate (CPA), luteinizing hormone-releasing hormone (LHRH)

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inhibitors, such as leuprolide acetate (LA), and gonadotropin-releasing hormone agonists (GnRH), such as triptorelin, have been used to treat pedophiles. GnRH agonists and LHRH inhibitors are believed to more specifically and completely inhibit testosterone synthesis and release with fewer side effects than MPA and CPA (Fagan, Wise, Schmidt, & Berlin, 2002; Miner & Coleman, 2001).

LA is one of several synthesized agonist analogs of LHRH, the hypothalamic hormone that stimulates gonadotropin release from the pituitary (Vance & Smith, 1984). LA produces a paradoxical effect on the pituitary, with initial stimulation of the release of luteinizing hormone (LH) and follicle-stimulating hormone (FSH), followed by inhibition after repeated administration (Belchetz, Plant, Nakai, Keogh, & Knobil, 1978; Bergquist, Nillius, & Wide, 1979; Linde et al., 1981; Vilchez-Martinez et al., 1974). These effects are accompanied by a reduction in androgenic hormone release (a decrease in testicular steroidogenesis) that is probably secondary to a primary reduction in LH levels (Vance & Smith, 1984). Agonist analogs have also been shown to decrease the number of LH receptors in Leydig cells of hypophysectomized rats (Bambino, Schreiber, & Hsueh, 1980; Vance & Smith, 1984). The testosterone levels attained with continued administration of LA were lower than those attained with either MPA or CPA (Brotherton & Marcus, 1973; Gagne, 1981; Vance & Smith, 1984). This may result in LA being a more potent inhibitor of erectile responses compared with other agents. Gagne (1981) documented a fall in plasma testosterone levels to less than one-half initial values with MPA (200 mg intramuscular) after four injections. Subjects generally became sexually impotent when plasma testosterone levels were less than one quarter of the initial value. Brotherton and Marcus (1973) reported a fall in testosterone to one fifth the mean levels with a dose range of CPA of 50–150 mg per day. Vance and Smith (1984) reported an injection of LA caused serum testosterone levels to increase initially, but decline thereafter, reaching a nadir at 2–4 weeks. Testosterone levels were reduced to castrate levels (less than 50 ng/dl) or one tenth the mean level. By the second week of treatment, a sustained, profound suppression of testosterone, FSH, and LH continued for duration of treatment.

LA was provided by depo injection once every 3 months. The common side effect profile was minimal and included weight gain and hot flashes. Less common side effects included breast tenderness; rare side effects, swelling of hands and feet, and gynecomastia. Some reports indicated LA has proven successful when other drug therapies have failed (Cooper & Cernovsky, 1994).

In controlled studies, MPA and CPA have effectively decreased sexual tension, fantasies, preoccupations, and the urgency and frequency of masturbation. Sexual thoughts, fantasies, and feelings were inhibited more consistently and to a greater degree than the subject's sexual orientation (Bradford, 1983; Clarke, 1989; Cooper, 1986).

MPA is perhaps the most studied drug. It is a potent progestational agent with dose-dependent inhibition of gonadotropin secretion that reduces testosterone production in the testes. MPA therapy requires either oral administration with concomitant risk of noncompliance or one injection every 3 months. Even with the highest recommended dose, the testosterone level is not reduced to castrate levels. The side effect profile is high for the injection. Common side effects include weight gain, fluid retention, malaise, and dyspepsia. Rare or uncommon side effects include thromboembolism, depression, hepatocellular damage, and muscular cramps (Bradford, 1983).

CPA, a competitive testosterone inhibitor, antagonizes the biological effects of testosterone at androgen receptor sites. CPA provides variable testosterone suppression and can be administered in a daily oral dose or by a 3-month injection. When CPA is provided orally, compliance becomes a concern. This drug is not available in the United States. Some reports describe intolerable side effects or insufficient reduction in deviant fantasies (Briken, 2002; Briken, Nika, & Berner, 2001). Common side effects include slight breast swelling and tenderness, fatigue, mood disorder, and mild shortness of breath. Uncommon side effects include nausea, vomiting, and diarrhea and effects on liver function. After several months of treatment, hepatotoxicity, including hepatic failure, hepatitis, and jaundice, has been reported (Bradford, 1983; Hirsch, Kovatz, Bernheim, & Shenkman, 1994).

In controlled studies, MPA and CPA have produced decreases in sexual tension, fantasies, preoccupations, and the urgency and frequency of masturbation. Although these agents have resulted in low recidivism rates among convicted sexual offenders, noncompliance and rare, life-threatening side effects have been reported with CPA and MPA (Bradford & Pawlak, 1993).

Hormone therapy is aimed at modification of the basic sex drive, whereas cognitive-behavioral psychotherapy targets cognitive processes that precede all events leading to pedophilic behavior. Because of a suggested relationship between obsessive compulsive disorder and paraphilias, selective serotonin reuptake inhibitors (SSRIs) have been utilized. Most reports have been documented from individual case studies or uncontrolled, retrospective studies (Kafka, 2000).

Reports of the efficacy of drug therapy for suppression of sexual drive and modification of behavior continue to emerge. The anti-androgens, MPA and CPA, are the most widely used drugs. They provide variable testosterone suppression, dependent on dose. LHRH inhibitors and GNRH agonists also provide profound testosterone suppression. More recently, triptorelin, an agent similar to LA (Rosler & Witztum, 1998), and SSRIs have also been investigated (Raymond, Grant, Kim, & Coleman, 2002; Stein et al., 1992).

Despite recent advances in the use of testosterone-suppressing drugs for the treatment of pedophilia, limited information is available in the form of well-designed, controlled objective studies. The lack of standardized, objective outcome measures have hampered the objective assessment of efficacy of interventions for pedophilia (Briken, Hill, & Berner, 2003; Hanson et al., 2002; Marshall & Barbaree, 1990). A multi-disciplinary team of experts is needed to assess concurrent, objective physiologic measures of response. Though some results of treatment are promising, a reliable, well-tolerated approach that can be *objectively* monitored for efficacy is lacking.

The specific aspects of behavior that are affected by therapy, as well as the efficacy, limitations, and side effects of treatment need to be determined (Briken et al., 2003; Raymond, Robinson, Kraft, Rittberg, & Coleman, 2001). The present study assessed the impact of cognitive-behavioral psychotherapy alone versus cognitive-behavioral psychotherapy augmented with a potent testosterone-lowering drug, LA, for suppression of pedophilic urges and arousability. The psychotherapy program comprised cognitive and behavioral therapy. Objective assessments of sexual interest preference and physical arousal, as well as sexual urges and masturbation, were monitored before, during, and after therapy. The research objectives were to explore the relationship between testosterone level and sexual interest preferences, physiologic responses to sexual stimuli (auditory and visual), and self-reported sexual behaviors.

## METHOD

### Subjects

Five men (*M* age, 50 years; range, 36–58), with a diagnosis of pedophilia (American Psychiatric Association, 1994) and who were “out of denial,” were recruited for study. Subjects were identified by a focus group of judges, attorneys, Probation and Parole officials, representatives from the District Attorney’s office, and psychologists

**Table I.** Inclusion and Exclusion Criteria

Inclusion criteria	Exclusion criteria
Adult male	IQ < 70
Out of denial	Illiterate
Diagnosis of pedophilia (American Psychiatric Association, 1994)	Presence of a medical condition that would contraindicate LA treatment: for example, a seizure disorder treated with phenytoin or barbiturates is contraindicated because of a possible drug–drug interaction (McEvoy, 1990)
Fair to good health	Hormone use before or during study
Normal testosterone levels	Unresponsive to plethysmography Responsive only to adult stimuli

who were invited to a seminar regarding the Lupron Project. After potential subjects were identified, the Principal Investigator screened case histories to determine eligibility for study inclusion (Table I). These potential subjects were contacted by the Principal Investigator. They were interviewed, informed of the study, and invited to participate. Three additional subjects were screened, but excluded. These included one psychotic adult, one adolescent, and one elderly, nonerectile adult. The study was conducted during a 2-year period in a medical research center in northwestern Pennsylvania. The study was reviewed and approved by the local Institutional Review Board. All subjects provided informed consent. Participation was voluntary and not a condition of probation or parole. The subjects were informed that they would receive either a drug or placebo without an indication of duration of dose, the sequence, nor if a sequence would occur. The subjects did not know one another. They lived in diverse geographical locations and their only contact was during group cognitive-behavioral psychotherapy.

IQ data were available for four of the five participants, all of whom had normal IQ. The fifth participant, on whom IQ data were unavailable, was not considered to be intellectually impaired. Four of the five participants reported having been sexually abused during their childhood. Each subject was more than 16 years old and at least 5 years older than the victim when offending was initiated (Table II). At baseline, the self-reported numbers of victims for the five subjects totaled 329.

Four of five had served lengthy prison sentences (*M*, 7.8 years) for conviction of sexual crimes. All subjects had previous treatment in penitentiary or community-based sexual offender programs. Two had a history of major depression and two had a prior diagnosis of alcoholism. Two subjects reported bisexual pedophilic preference; two exclusively heterosexual preference; and

Table II. Victim Demographics

Subject	Victims' sex	Victims' age (years)	Relation to victim	No. of victims	No. of episodes
1	Male	12–17	Parishioners	265	>1000
2	Female	8–14	Stepdaughters, neighbors, nieces	350	>1000
3	Male and female	0–17	Biological children, nieces, nephews	150	5000
4	Male and female	3.5–11	Not related	6	50
5	Female	5–15	Sister-in-law, niece-in-law, and unrelated	32	100

one an exclusively homosexual preference. At baseline and throughout the study, all five subjects met the DSM-IV criteria for pedophilia, as well as antisocial personality disorder (American Psychiatric Association, 1994; Berger, Berner, Bolterauer, Gutierrez, & Berger, 1999).

### Study Design

Five male pedophiles entered a prospective, repeated measures, nonrandomized, masked study. All subjects and investigators, except the Principal Investigator (PI), Project Director, and Study Coordinator, were masked. The PI administered the drug or placebo; the PI and Project Director designed the study and were cognizant of the dosing schedule; and the Coordinator was responsible for supply of study drug. However, the PI, Project Director, and Coordinator were not involved in direct data collection or evaluation of the subjects. Each subject served as his own control. Subjects received weekly cognitive-behavioral psychotherapy for 24 months and LA depot injection, 7.5 mg at baseline and 22.5 mg at months 1, 4, 7, and 10. Flutamide (250 mg TID for 14 days) was only administered with the first injection.

Flutamide is an acetanilid, nonsteroidal, orally active anti-androgen that exerts its anti-androgenic action by inhibiting androgen uptake and/or by inhibiting nuclear binding of androgen in target tissues or both. Flutamide has been demonstrated to interfere with testosterone at the cellular level. This can complement medical castration achieved with LHRH agonists that suppress testicular androgen production by inhibiting luteinizing hormone secretion (Brogden & Clissold, 1989).

After the initial injection, subjects were sequestered for 1 week for community protection. After 1 year of therapy, LA was discontinued and saline placebo substituted. At baseline, 1 month after initiation of LA therapy, and then at 3-month intervals, subjects underwent Abel Assessment, Monarch Penile Plethysmography (PPG), polygraph, physical examinations, laboratory studies, radiologic studies, and psychological testing were done at study initiation.

### Abel Assessment

Abel Assessment, a combination of self-report questionnaire and visual reaction time (VRT), was utilized according to manufacturer's instructions (Abel Screening Inc., Atlanta, Georgia). Assessments were conducted by a trained clinical staff member (Abel, Huffman, Warberg, & Holland, 1998; Letourneau, 2002). The VRT results and questionnaire, which assessed paraphilias, included evaluation for 21 sexual interests.

To assess VRT (the amount of time a subject viewed a picture), a slide projector was used to present still images of models onto a 12-in. computer screen. Models were clothed, generally in swimsuits, and none were in sexual positions. Twenty-one stimulus categories, representing 21 potential sexual interests with approximately seven slides in each category, were viewed by the subject. Slides depicted Caucasian and African American males and females comprising preschool and school-age children, adolescents, and adults.

An examiner met individually with each subject and instructed him on advancing and rating the slides. The subject viewed the slides in a dimly lit, quiet cubicle. After a practice session, the subject completed the VRT in private. After viewing each slide, participants rated each slide on a scale from 1 (*extremely sexually repulsive*) to 7 (*extremely sexually interesting*). A computer recorded the amount of time a subject viewed and rated each slide. Data from the second viewing time were utilized by Abel Screening Inc. to compute the *z*-scores. These were provided to the investigator in graph form, with a score for self-reported interest. Per manufacturer's instructions, the Abel "rule of thirds" was utilized to define the predominant sexual preference. Because of the large number of sexual preference choices generated by the Abel method, a modification was adopted. For this study, predominant sexual preference was defined as a relative visual reaction time *z*-score  $\geq 1$  *SD*. The number of times each stimulus was  $\geq 1$  *SD* was recorded. If only one or none of the *SD*s were  $\geq 1$ , the two highest scores were recorded. This modification resulted in an objective

measure of only those selections that stimulated the longest VRT.

To illustrate the difference in the modified Abel and the Abel "Methods of Thirds," Subject 1 self-reported an interest in adolescent and adult males. His known victims were boys aged 12–17. Using the Abel "Method of Thirds" as per manufacturer instructions, the interest preferences included young and adolescent females, and young, adolescent, and adult males. Using the modified Abel, the selection was truncated to adolescent and adult males, the exact interest preferences self-reported by the subject.

The *z*-scores for each stimulus set were reported at baseline, on LA, and off LA, respectively. Assessments were compared before, during, and after treatment to determine if VRT associated with pedophilic interest preferences changed with treatment.

Given that lowering testosterone to castrate levels would affect penile responsiveness and potentially affect the Monarch PPG monitoring, the Abel Assessment was incorporated into the study with the anticipation that pedophilic sexual preference could still be potentially detected by visual reaction time.

### Monarch PPG

The Monarch Adult Projective Audio Visual Set, Version 5 (Behavioral Technology Inc., Salt Lake City, Utah) was a commercially available set of standardized stimulus materials that was used to assess all subjects. The stimuli contained audio and visual depictions of males and females comprising preschool and grammar school children, adolescents, and adults. The audio scripts were based on a projective, rather than explicit, portrayal of sexual activity. Unlike most other PPG visual stimuli, the set contained clothed pictures of children (all child models were shown in bathing suits or underwear). No lewd or provocative poses were presented (Byrne, 2000).

During this procedure, the subject was seated in a reclining chair located in a private room equipped with an intercom. The audiovisual stimulus materials were presented via headphones on a 14-in. television monitor. Stimulus presentation and collection of penile, galvanic skin response (GSR), and respiration data were recorded and coordinated by a microprocessor-based Monarch Data Recording Device (DRD) (Behavioral Technology Inc., Salt Lake City, Utah).

Penile circumference changes were measured using an indium gallium gauge supplied by Behavioral Technology Inc. The signal from the indium gallium gauge was amplified by 1000; data retrieval was set at a rate of

10 samples per second. Each penile gauge was calibrated to a full range of 3.0 cm before each assessment to ensure that the correlation between circumference and deflection was linear. GSR electrodes and respiration belts were also used for deterrence and potential detection of faking or suppression attempts.

Data from the assessment were compiled and analyzed using Monarch Adult Male Software, Version 3.22f. This software guided the collection, management, and initial analysis of the PPG data. The software analyzed the PPG data and provided maximum scores and area-under-the-curve scores for each of the 22 segments of the test. A maximum penile tumescence score was calculated for each subject for each category of stimuli. For the purposes of this study, maximum penile tumescence was defined as any response above 20 points (.60 cm), which is 20% of the calibration of the gauge. Murphy and Barbaree (1994) argued that a minimum level for significance was 20%. To meet this requirement, a response was considered to be significant if it was at least 20/100-scaled units from the beginning of the stimulus detumescence level. Kuban, Barbaree, and Blanchard (1999) also suggested that this criterion was conservative. Subject's PPG calibration and projected full-scale responding were set to 3.0 cm. Thus, the cutoff of 20 points for significant responding falls within the 20% minimum criterion for significant responding. The subject's PPG calibration and projected full-scale responding were set to 3.0 cm circumference. A repeated measures ANOVA was performed on the PPG data to assess significant changes in arousal level throughout the study ( $\alpha = .05$ ). To assess sexual preferences, raw data for each subject were transformed to *z*-scores. The *z*-scores for each stimulus were recorded at baseline, on LA, and off LA. All the responses  $\geq 1$  *SD*, or the two highest responses, were recorded. Finally, a subject's classification as pedophilic/nonpedophilic was determined by using a deviance differential (Harris, Rice, Quinsey, Chaplin, & Earls, 1992). This was calculated using *z*-score data and taking the highest response to adults (male and female segments) minus the highest response to infants and children (male or female preschool or grammar school age). The adolescent segment was excluded from analysis. For the purposes of data analysis, deviance differential scores greater than 0 were classified as nonpedophilic and scores less than 0 as pedophilic. A deviance differential of 0 would mean that the subject was just as aroused to children as to adults.

All subjects were assessed at baseline. One subject (Subject 1) did not respond to a level of clinical significance (20 points). Further inspection revealed that this client did not obtain a significant response at any point during the 2-year study. He was removed from the

analysis of the PPG data (repeated measures ANOVA) because low-level data generated from a circumferential PPG transducer were not considered reliable (Barbaree & Mewhort, 1994; Kuban et al., 1999).

### **Polygraph**

An Axciton Computerized Polygraph System (Axciton Systems, Houston, Texas) and the Lafayette Instrument LX-4000 (Lafayette Instrument Co., Lafayette, Indiana) were utilized. The examiner was certified by the Colorado Sex Offender Management Board. For purposes of score reliability and validity confirmation, the results were both scored by hand and scored using the Johns Hopkins Applied Physics Laboratory Polyscore computer scoring algorithm (Heil, Ahlmeyer, Simons, & English, 1999). Hand scoring is recognized by the American Polygraph Association as the most accurate and reliable method of scoring. It was the only method used to evaluate the data. The algorithm was used as a quality control check of the hand scoring method. Subjects provided a separate informed consent before the first polygraph examination. The test was administered in a private office. The examination took an average of 2 h. Subjects were tested every 3 months. Polygraph was standardized by an American Polygraph Association approved test procedure and was administered by a single experienced examiner, who was blinded to the dosing protocol. The polygraph examination process contained pretest and posttest components. The examiner worked closely with the psychotherapist in developing appropriate polygraph questions for confirmation of the disclosed number of victims and offenses, discovery of new offenses, and or compliance with study conditions. This study examined past victim and offense admissions data, as well as responses to a questionnaire evaluating 30 paraphilias (Appendix). Pretest questioning was used to identify new admissions of past offending or the absence of accountability statements for known offending behaviors (identified in prison histories). Using polygraph, the subject's cardiovascular, respiratory, and galvanic skin resistance were assessed in response to three specific key questions:

1. In the past 3 months, have you masturbated to sexual thoughts about anyone under the age of 18?
2. In the past 3 months, have you purposely withheld important sexual information from your therapist?
3. In the past 3 months, have you had strong urges to initiate sexual contact with anyone under 18 years old?

No consequences were imposed for deceptive responses. The therapist and polygrapher worked closely and debriefed the subject after each assessment to identify areas for counseling, behaviors to be monitored, and issues detected on polygraph.

### **Cognitive–Behavioral Psychotherapy**

The psychotherapy program comprised cognitive and behavioral therapy. The weekly sessions were co-facilitated by a therapist and physician. After establishing the rules for group therapy, psychotherapists guided participants through a basic group curriculum that included breaking down defense mechanisms, identifying the typology of sex offenders, and discussing the effects of sexual abuse on victims. The counseling component involved insight-oriented cognitive–behavioral psychotherapy. This provided a dynamic understanding of unconscious conflicts and interpersonal issues as they related to each participant's offense cycle. Relapse prevention plans were constructed with and for each participant. This self-controlled program was designed to teach offenders how to recognize and intervene when they were behaving in a manner that would lead to a re-offense. Relapse prevention enabled the individual to maintain the newly adopted behavior pattern, such as refraining from deviant thoughts and actions. The relapse prevention plans described red flags, offense cycles, interventions, and changes in thoughts, feelings, attitudes, and behaviors.

### **Psychopathology**

The Hare Psychopathy Checklist-Revised (PCL-R) was utilized to assess subjects' psychopathology (Hare, 1998). The Minnesota Sex Offender Screening Tool-Revised (MnSOST-R) identified the most violent offenders and those offenders likely to re-offend (Epperson et al., 1999). The Static-99, another sexual offender risk assessment, measured long-term risk potential for child molesters (Hanson & Thornton, 1999). The Yale-Brown Obsessive Compulsive Scale (Y-BOCS) was utilized because of an inferred relationship between obsessive compulsive disorder and sexual paraphilias (Goodman et al., 1989).

**Table III.** Testosterone Levels (ng/dl)

	Baseline	On LA (1 week)	On LA (4 months)	Off LA (3 months)	Off LA (6 months)	Off LA (12 months)
1	272	284	12	214	340	388
2	405	548	17	153	347	368
3	281	584	24	63	217	L
4	468	763	24	366	L <sup>a</sup>	L
5	596	142 <sup>b</sup>	17	177	L	L
Mean	404	545	18.8	195	301	378

<sup>a</sup>Leuprolide acetate reinitiated.

<sup>b</sup>Drawn 2 weeks after 22.5 mg injection; others drawn 1 week after 7.5 mg injection.

## RESULTS

### Testosterone, LH, and FSH Levels

Baseline testosterone levels averaged 404 ng/dl and rose at 2 weeks after injection to a mean of 545 ng/dl (Table III). During the initial testosterone rise, subjects were queried by the principal investigator regarding any increase in pedophilic urges, sex drive, or masturbation; none reported an increase during the testosterone rise. Subsequently, levels fell to a mean of 18.8 ng/dl 4 months after the initial injection and remained low until LA was withdrawn. After testosterone fell to castrate levels, the study subjects self-reported decreased sex drive, decreased pedophilic sexual urges, and decreased masturbation frequency; the latter two were confirmed by polygraph. When LA was replaced with saline placebo, all subjects initially reported no increase in sex drive, pedophilic sexual urges, or masturbation frequency. After 3 months on placebo, testosterone averaged 195 ng/dl. After 3 months of placebo therapy, three subjects continued to report no increase in sex drive, pedophilic sexual urges, or masturbation frequency. At 3 months, two subjects expressed great distress that the medication was losing effectiveness and they were fearful of re-offense. Because of intrusive thoughts and sexual urges, the blind was broken on these two subjects and the LA was reinstated. A third subject resumed LA treatment after 6 months of placebo because of psychologic and polygraph responses indicating potential re-offense possibility. Two subjects remained on placebo for 12 months and testosterone averaged 378 ng/dl; their baseline testosterone averaged 338 ng/dl. Mean baseline LH and FSH were suppressed during treatment with LA (LH 0.3 mIU/ml, FSH 2.5 mIU/ml) and returned to normal ranges on placebo (LH 5.8 mIU/ml, FSH 8.2 mIU/ml). At 6 months, for the remaining three subjects on placebo, testosterone

averaged 301 ng/dl; their baseline testosterone averaged 320 ng/dl.

### Abel Assessment (Modified)

Throughout the study, modified visual reaction time results generally detected the subject's self-reported choice of victim. For example, at baseline, Subject 1 self-reported victims were boys 12–14 years old. The modified Abel Assessment detected interest in “adolescent and adult male” at baseline (single reading). On LA (several readings), subject data indicated the most frequent and highest interest preferences were adolescent and adult males. Adolescent female and adult female interest was also recorded. Off LA, a strong preference in school-age male was noted (Table IV). Subject 1 did self-report interest in adult females on LA.

In Subjects 3 and 4, variability was apparent and may be a reflection of the bisexual nature of the subjects' pedophilic attractions and/or comparison of a single test score (baseline) with multiple test scores. Overall, interest preference indicated no consistent change in pedophilic interest preference as measured by visual reaction time in all five subjects with LA therapy (Table IV).

### Monarch PPG

Interest preference indicated no consistent change in pedophilic interest preference as measured by penile tumescence in all five subjects with LA therapy. This was demonstrated by multiple pairwise comparisons of penile circumferences at baseline versus penile circumferences (Monarch Units, 1 unit = 0.03 cm) while subjects were treated with LA (Table V). In post-hoc pairwise comparisons among all the means, one-tailed tests were employed because of the hypothesized decrease in the

Table IV. z-Scores  $\geq 1$  SD or Two Highest Scores

	Abel (modified)	z-scores	N <sup>a</sup>	Monarch PPG	z-scores <sup>b</sup>	N
<b>Subject 1: Victims boys 12–14</b> by self-report						
Baseline				Preschool male	1.6	1
	Adolescent male	1.55	1			
	Adult male	1.92	1			
On LA				Grammar female	1.6	1
				Preschool male	1.01–1.83	3
	<b>School-age male</b>	1.74	1	<b>Grammar male</b>	1.36, 1.46	2
	Adolescent male	1.16–1.87	6			
	Adult male	1.35–1.8	3			
				Preschool female	2.62, 3.69	2
				Grammar female	2.59	1
Off LA	Adolescent female	1.02–1.25	3			
	Adult female	1.25, 2.3	2			
				Preschool male	1.13	1
	<b>School-age male</b>	1.04–1.87	7	<b>Grammar male</b>	1.79	1
	Adolescent male	1.5–1.8	3			
Off LA	Adult male	1.1–1.25	3	Adult male	1.9	1
				Grammar female	1.44	1
	Adolescent female	1.25, 1.5	2			
	<b>Adult female</b>	1.0–1.16	3	<b>Adult female</b>	1.22	1
<b>Subject 2: Victims girls 8–14</b> by self-report						
Baseline	<b>Preschool female</b>	1.32, 2.2	2	<b>Preschool female</b>	1.44	1
	<b>Adolescent female</b>	1.10	1	<b>Teen female</b>	1.13	1
On LA	<b>Preschool female</b>	2.09	1	<b>Preschool female</b>	2.51	1
	<b>School-age female</b>	1.22–2.03	3	<b>Grammar female</b>	1.14	1
	<b>Adolescent female</b>	.49, 1.67	2	<b>Teen female</b>	3.13, 1.25	2
	<b>Adult females</b>	1.67–2.29	3	<b>Adult female</b>	1.56, 1.42	2
				Preschool males	1.16	1
Off LA				Adult males	2.66, 1.16	2
	Preschool female	1.39	1			
	<b>School-age female</b>	3.2	1	<b>Grammar female</b>	1.14	1
	<b>Adolescent female</b>	1.09–2.83	5	<b>Teen female</b>	1.22	1
	<b>Adult female</b>	1.03–3.32	3	<b>Adult female</b>	1.42, 1.73	2
			Preschool male	1.48	1	
<b>Subject 3: Victims boys and girls 0–17</b> by self-report						
Baseline	School-age female	1.44	1			
	Adult female	1.04, 1.39	2			
On LA (to month 10 only)				Grammar male	1.39	1
				Teen male	2.59	1
				Preschool female	1.88–2.59	3
	School-age female	1.09, 1.28	2			
	<b>Adolescent female</b>	1.38–2.42	5	<b>Teen female</b>	3.5	1
Off LA	School-age male	1.58	1			
	Adult male	1.13	1	Adult male	1.22, 1.53	2
	No data			Preschool female	1.4–3.42	3
				Grammar female	1.40	1
				Teen female	3.14	1
				Adult female	2.45	1
				Grammar male	1.24, 2.04	2
			Adult male	1.07, 1.92	2	

Table IV. Continued

	Abel (modified)	z-scores	N <sup>a</sup>	Monarch PPG	z-scores <sup>b</sup>	N
<b>Subject 4: Victims boys and girls 3–11 by self-report</b>						
Baseline	Preschool female	1.3	1			
	School-age female	1.6	1			
	Adult female	1.6	1	Teen female	1.72	1
On LA				Adult male	1.95	1
	Preschool female	1.3–1.91	3			
	<b>School-age female</b>	2.4, 2.36	2	<b>Grammar female</b>	2.58	1
	<b>Adolescent female</b>	2.2, 2.2	2	<b>Teen female</b>	1.48, 2.11	2
	<b>School-age male</b>	1.39, 1.41	2	<b>Grammar male</b>	1.87–3.51	3
				Teen male	1.65	1
	Adult male	1.8	1	Adult male	1.32	1
Off LA				Preschool female	2.13	1
				Grammar female	2.54	1
	Adolescent female	2.48	1	Adult female	1.34, 2.88	2
				Preschool male	1.33	1
	<b>School-age male</b>	1.32, 2.48	2	<b>Grammar male</b>	2.37	1
<b>Subject 5: Girls 5–15 by self-report</b>						
Baseline	<b>Preschool female</b>	1.13, 1.47	2	<b>Preschool female</b>	1.8	1
	<b>School-age female</b>	1.2	1	<b>Grammar female</b>	1.77	1
	<b>Adolescent female</b>	1.6	1	<b>Teen female</b>	1.64	1
	Adolescent male	1.0	1			
On LA				Preschool female	1.14–2.07	4
	<b>School-age female</b>	1.14–1.72	3	<b>Grammar female</b>	1.56–2.61	5
	Adolescent female	1.14–3.11	5			
Off LA				Grammar female	1.53, 1.8	2
	Adolescent female	2.08	1			
	Adult female	0.93	1			

Note. Bold denotes parity between Abel Assessment and Monarch PPG.

<sup>a</sup>N = Number of times given preference detected.

<sup>b</sup>Responses less than 20. Results unreliable for Subject 1.

mean from baseline. Three of the five means obtained while subjects were on LA (except the observations at months 7 and 10) were significantly different from baseline. The remaining mean comparisons when subjects were being treated with LA were not significant except months 1 and 4 (Table V). This pattern of findings supports the hypothesis that, with one exception (month 10), LA significantly decreased arousal.

All subjects' responses decreased significantly,  $F(5, 15) = 3.82, p = .02$ , during the course of treatment (Fig. 1). At month 10, when the LA injection was 1.5 weeks late, a rebound in penile responsiveness occurred in all subjects, whereas testosterone remained at castrate levels.

Using deviance differential, Subjects 1, 3–5 were all classified as pedophilic while being treated with LA. Subject 2 exhibited the most unique response. At baseline

and off LA, his strongest responses were to pedophilic stimuli. On LA, his highest z-scored response was to adult stimuli (.66) rather than preschool (.46) or grammar school (.49) children, but pedophilic interest remained.

### Comparison of Monarch PPG and Abel (Modified)

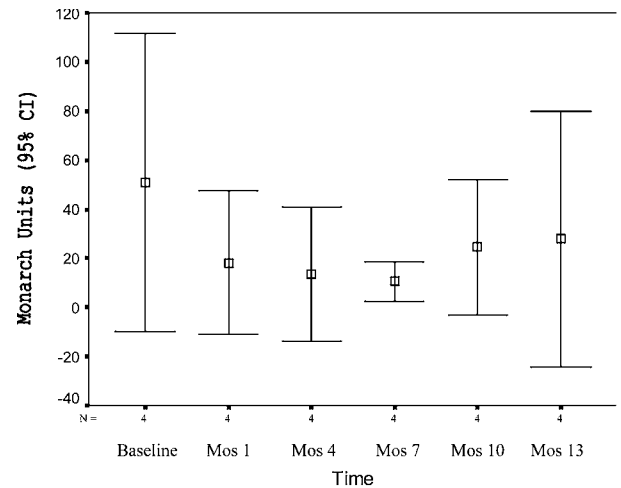
At baseline, Abel Assessment and PPG accurately detected pedophilic interest in 100 and 80% of subjects, respectively. On LA treatment, Abel Assessment and PPG accurately detected pedophilic interest (generally the self-reported victim) in all five of subjects (Table IV). As with the Abel Assessment, in Subjects 3 and 4, variability occurred and may be a reflection of the bisexual nature of the subjects' pedophilic attractions and/or comparison of a single test score (baseline) compared with multiple test scores (Table IV).

**Table V.** Multiple Pairwise Comparisons of Penile Circumferences at Baseline Versus Penile Circumferences While Subjects were Treated with LA (Monarch Units, 1 Unit = 0.03 cm)

Visit	Time (month)	Mean difference	<i>p</i> (one-tailed)
Baseline	Baseline	32.52	.03
	4	37.05	.02
	7	40.08	ns
	10	26.29	ns
	13	22.94	.05
Month 1	Baseline	-32.52	.03
	4	4.53	.03
	7	7.57	ns
	10	-6.22	ns
	13	-9.58	ns
Month 4	Baseline	-37.05	.02
	1	-4.53	.03
	7	3.03	ns
	10	-10.75	ns
	13	-14.11	ns
Month 7	Baseline	-40.08	ns
	1	-7.57	ns
	4	-3.03	ns
	10	-13.79	ns
	13	-17.15	ns
Month 10	Baseline	-26.29	ns
	1	6.22	ns
	4	10.75	ns
	7	13.79	ns
	13	-3.36	ns
Month 13	Baseline	-22.94	.05
	1	9.58	ns
	4	14.11	ns
	7	17.15	ns
	10	3.36	ns

**Polygraph**

On all polygraphic assessments, all subjects responded “No” to all questions. At baseline, almost all responses were classified as 100% deceptive (0% nondeceptive) (Figs. 2–4). Polygraph results of the question, “Since your last polygraph, have you purposely withheld important sexual information about yourself from your therapist?,” revealed that nondeceptive responses increased on therapy and remained high even after LA was discontinued (Fig. 2). This may reflect the subjects having already revealed offenses in prior sessions. Polygraph results to the question, “Since your last polygraph, have you masturbated to any sexual thoughts of anyone under 18?,” indicated increased nondeceptive responses on LA; nondeceptive responses decreased to 0% (100% deceptive) on placebo (Fig. 3). This was also reflected in

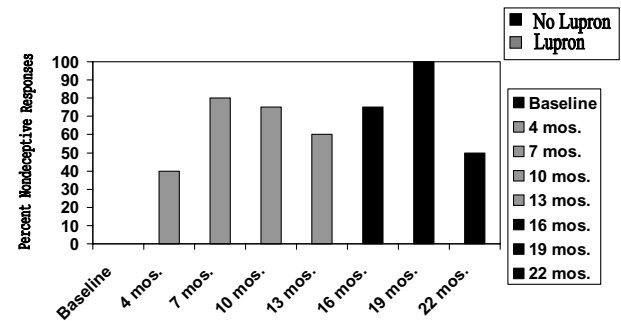


**Fig. 1.** Means and 95% confidence intervals from repeated measures ANOVA at baseline and on LA treatment. With one exception (month 10-delayed injection), LA significantly decreased arousal. The metric on the vertical axis is measured in Monarch units (cm change in circumference) where 1 unit = .03 cm.

self-report of masturbatory frequency (Fig. 5). Polygraph results of the question, “Since your last polygraph, have you had strong urges to initiate sexual contact with anyone under 18?,” revealed 100% nondeceptive responses on LA and 0% nondeceptive responses on placebo (Fig. 4).

In the pretest component of the polygraph examination, subjects were asked several questions regarding new admissions of past offending behavior and paraphilias. From baseline to 22 months, the self-reported numbers of victims increased from 329 to 803, with an associated number of episodes greater than 7000.

Subjects self-reported an average of  $9.4 \pm 4.0$  (range, 4–15) paraphilias; all reported exhibitionism and frottage (Table VI). This finding is not surprising, as a pedophile offender is likely to have several associated



**Fig. 2.** Mean number of deceptive responses at baseline, on LA, and on placebo. (Since your last polygraph, have you purposely withheld important sexual information about yourself from your therapist?)

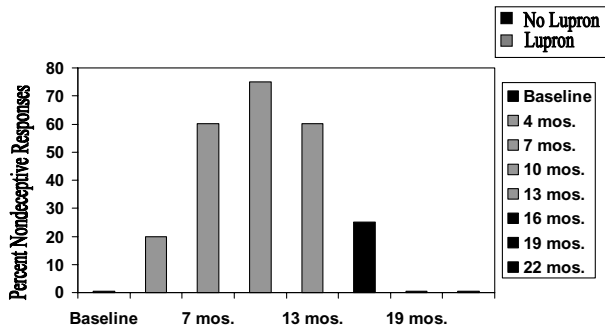


Fig. 3. Mean number of deceptive responses at baseline, on LA, and on placebo. (Since your last polygraph, have you masturbated to any sexual thoughts of anyone under 18?)

paraphilias (Abel & Osborn, 1992). No new offenses or re-offenses occurred during the course of the study.

Clinical Findings

Genital examination revealed a consistent decrease in penile circumference from a baseline of 9.7 cm to a nadir of 8 cm at 13 months of treatment. Three subjects on placebo for 6–12 months resumed penile size (average 9.3 cm) compared with baseline. Testicular volume was not measured, but a significant decrease in size and firmness of the testes was appreciated on examination. One subject was found to have a prostatic nodule at baseline (no elevation in PSA), which resolved with LA therapy.

After 12 months on LA treatment, subjects experienced a mean weight gain of 22 lbs (range, 9–36 lbs). When placebo was introduced, all subjects lost weight, but none returned to baseline weight. Those that continued on placebo lost a mean of 8.7 lbs (range, 0–14 lbs).

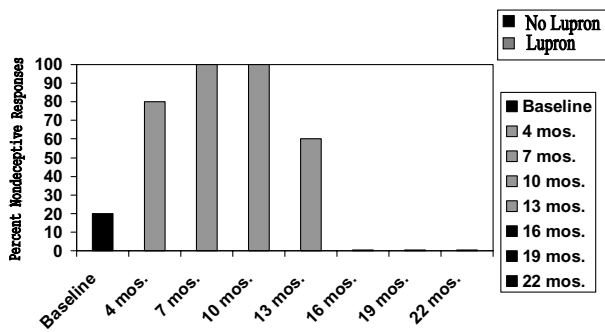


Fig. 4. Mean number of deceptive responses at baseline, on LA, and on placebo. (Since your last polygraph, have you had strong urges to initiate sexual contact with anyone under 18?)

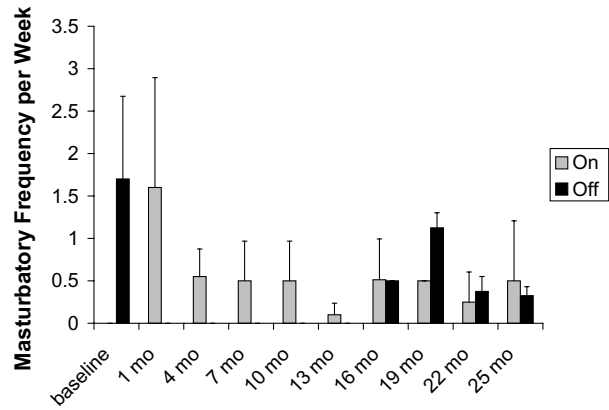


Fig. 5. Self-report of masturbatory frequency. The data for months 16–25 represent subjects on placebo (N = 3 at 16 months; N = 2 at 19, 22, and 25 months) and subjects in whom LA was reinstated (N = 1 at 16 months; N = 2 at 19, 22, and 25 months).

Three subjects entered the study on antihypertensive drugs. After 13 months of LA therapy and despite significant weight gains, all subjects had blood pressures that were either the same as baseline or lower than baseline.

Table VI. Paraphilias Identified by Polygraph

Subject 1 (N = 4)	Exhibitionism	
	Frottage	
	Peeping	
	Public masturbation	
Subject 2 (N = 8)	Exhibitionism	Adult book stores
	Frottage	Strip bars
	Peeping	Voyeurism
	Public masturbation	Pornography
Subject 3 (N = 11)	Exhibitionism	Phone sex
	Frottage	Strip bars
	Public masturbation	Stalking
	Bestiality	Adult book stores
	Cross dressing	Golden showers
	Forced sex	
Subject 4 (N = 15)	Exhibitionism	Bondage
	Frottage	Prostitutes
	Peeping	Voyeur
		Sadomasochism
	Forced sex	Obscene phone calls
	Phone sex	Internet chat rooms
	Strip Bars	Sexual toys
	Adult book stores	Pornography
Subject 5 (N = 9)	Exhibitionism	
	Frottage	
	Peeping	
	Public masturbation	
	Forced sex	
	Strip bars	
	Adult book stores	
	Photograph victim	
	Stalking	

### Side Effects/Adverse Reactions to LA

Initially, four of five subjects noted transient pain at the site of injection. Three of five subjects reported transient hot flashes. During LA treatment, one subject described notable gynecomastia. None observed decreased body, facial, or scalp hair. Two subjects reported complete loss of erections (ages 48, 58) and three subjects reported partial loss (ages 35, 51, 57). Two of these subjects noticed a decrease in penile size, and one, loss of testicular size and softer testes. No muscle pain or asthenia was reported.

During the study, one research-related adverse event was reported. One day after an LA injection, a subject noted erythema and edema of the upper arm around the injection site. The subject, though afebrile, was treated with an oral antibiotic. Symptoms completely resolved within 3 days and did not recur with subsequent injection. No subject was withdrawn due to treatment-related adverse events or side effects.

### Psychological Testing

The Hare Psychopathy Checklist-Revised (PCL-R) suggested all five subjects utilized control; four utilized manipulation and one, intimidation to control victims and satisfy their own needs. No scores were high enough to be identified with psychopathy. Two subjects had subtest scores that suggested their behaviors would likely have psychopathic tendencies. No scores suggested antisocial tendencies.

On the Minnesota Sex Offender Screening Tool-Revised (MnSOST-R), four subjects scored in the moderate range for risk of sexual recidivism and one in the low-risk range.

The Static-99, another sexual offender risk assessment, measured long-term risk potential for child molesters. The tool indicated one subject scored in the high-risk category, two in the medium- to high-risk category and two in the medium- to low-risk category.

The Y-BOCS revealed three subjects (60%) were categorized as "severe" and two "moderate" for obsessive compulsiveness.

During the initial 3 months of cognitive-behavioral psychotherapy and LA administration, a trend toward minimization of reporting was noted compared to results of polygraph reports. As the subjects developed familiarity, they seemed to report more probable responses as verified by polygraph. Intimidation related to the polygraph examination also decreased.

### DISCUSSION

In our study, LA caused profound suppression of testosterone, with minimal side effects. LA was very effective for lowering pedophilic sexual urges and masturbation to pedophilic stimuli. Even with profound testosterone suppression, complete asexualization did not occur. Low levels of arousal and erectile ability persisted with sufficient tumescence to generate detectable levels of pedophilic interest with the Monarch PPG. The Abel Assessment likewise consistently identified pedophilic interest while subjects were on LA. Predominant sexual preference by *z*-score was consistent with the subjects' self-reported age and sex of victim(s).

Baseline testosterone levels were normal for all subjects. The occurrence of anticipated mean testosterone rise 2 weeks after the initial injection caused no increase in pedophilic urges, sex drive, or masturbation as self-reported by the subjects. Subsequently, levels fell to castrate 1 month after the initial injection and remained low until LA was withdrawn.

Most physical findings associated with testosterone suppression were anticipated, including weight gain, loss of testicular size, and decreased libido. Decreased volume of the testes with LA treatment has been documented by Rosler and Witztum (1998).

Although previously undocumented in humans, a significant decrease in flaccid penile circumference was noted. This has been previously described in rats (Ichikawa, Akimoto, & Shimazaki, 1988). This decrease in penile circumference was important, as it affected the Monarch PPG evaluation procedure and required changes in gauge size.

Osteopenia and/or osteoporosis are also concerns with long-term testosterone suppression therapy. Not all subjects had a bone scan, but the two that did had a normal scan after 12 months of therapy. A 12-month treatment with LA may not be a long enough interval to manifest the expected bone changes from the drug. With prolonged treatment, yearly assessment with bone scan is prudent.

Both Abel Assessment and Monarch PPG were efficacious in evaluating sexual preferences. The polygraph and Monarch PPG provided indicators of treatment response. Monarch PPG detected increases in arousability that paralleled increases in polygraph deceptive responses and even minimal rises in serum testosterone levels.

A readily apparent relationship existed between deceptive responses and LA treatment. When self-report of urges and masturbation dramatically decreased on LA, polygraph generally indicated almost no deceptive responses about behaviors, those being pedophilic urges,

masturbation, and pedophilic contact. Almost all subjects had polygraph evidence of deception at baseline and on placebo, indicating discordance with self-report. Because of these results at baseline and on placebo, we concluded self-report alone was insufficient and thus a poor outcome measure to evaluate responses to treatment.

We believe the polygraph is, in general, a reliable monitor in these subjects both on and off testosterone suppression. Perhaps this was because the subjects were generally deceptive off testosterone suppression as they had information to hide; they were generally truthful on testosterone suppression, as they had little to hide regarding masturbatory frequency and urges to engage in sexual activity. Certainly, a larger number of subjects could strengthen the findings.

Observed arousability, unchanged interest preferences, and persistence of erectile capability in some subjects led us to believe that even with profound testosterone suppression and cognitive-behavioral psychotherapy, persistent objective monitoring, such as testosterone measurement, polygraph examination, and Monarch PPG were necessary to assess continued treatment efficacy. In terms of sexual arousal, the risk for re-offense was significantly lowered, but not eliminated. Supervision elements of treatment and law enforcement are still required.

Cognitive-behavioral psychotherapy alone is probably insufficient for long-term, ongoing control of pedophilic urges. The obsessive compulsive nature of the paraphilia and the strong influence of sex drive makes incorporation of cognitive behavioral skills difficult. Medications may enhance voluntary control by decreasing sex drive (Berlin, 1983).

While on LA, subjects indicated they were better able to focus on employment, relaxation, and life plan-

ning, without continual interruptions by deviant sexual thoughts. This effect was directly related to drug administration; withdrawal correlated with a return of obsessive thoughts. Cognitive-behavioral psychotherapy taught subjects to recognize triggers to pedophilic behavior. Polygraph examination may have acted as a deterrent to pedophilic behavior; it also facilitated cognitive-behavioral psychotherapy by identifying specific areas of concern.

Abel Assessment and Monarch PPG results from Subjects 2 and 5 were very similar regarding predominant sexual preferences (Table IV). Other differences encountered between the tools may be attributable to several factors including dissimilar stimuli sets, measures (VRT vs. penile tumescence), and interpretations. Differences may also be attributable to individual subject variation, especially when the pedophilic preferences were bisexual, as in Subjects 3 and 4. The variability of response argues strongly for multiple testing of subjects at baseline and throughout studies with both instruments.

The general cost of treatment was approximately \$13,000 per subject per year. Some of the assessments we utilized would not be necessary for clinical usage of this method (PET, CT scan of the head). Some of the testing (Abel, PPG, Polygraph) was repeated at more frequent intervals than would be practical or necessary in a clinical setting. Though modified Abel Assessment is an excellent screening modality, the PPG was chosen for a clinical protocol as the sexual preferences, as well and arousability responses could be assessed. Thus, we recommend an abbreviated protocol for clinical usage. This would cost about \$5500 per subject per year (Table VII).

The limitations of this study included a small sample size. The subjects did not represent the entire spectrum of men with pedophilia. As a group, they had normal

**Table VII.** Suggested Testing Intervals Estimated Cost per Subject per Year (\$5500)

Tests	Baseline	6 months	12 months	2 Years and yearly thereafter
Abel assessment (\$150)	X			
PPG (\$150)	X	X	X	X
Polygraph (\$200)	X	X	X	X
Physical exam (\$150)	X		X	X
Laboratory studies				
Testosterone, CBC (\$150)	X	X	X	X
PSA (\$10)	X			
Complete metabolic profile (\$80)	X		X	X
Bone scan (\$350)				X
Group Psychotherapy (\$30/subject/session)	2-week intervals			
Leuprolide acetate (\$1900/subject/year)	Three injections/year			

intelligence; none were psychotic. The majority had a large number of victims. Some had been in prison for their crimes. Another limitation included a relatively short duration of follow-up to assess recidivism, which would have allowed comparison with other studies. Also, study design negated multiple baseline measures.

Future studies with greater numbers of subjects with different paraphilias treated for longer periods are necessary to fully explore the potential of testosterone suppressing therapy by LA to curb aberrant sexual behaviors.

We believe that LA pharmacotherapy, cognitive-behavioral psychotherapy, and polygraph examination have better efficacy than any single or dual modality in long-term control of pedophilic urges and behavior. Objective physiologic data demonstrated that LA was efficacious in suppressing urges and masturbation in high-risk pedophilic offenders.

## APPENDIX

### The 30 Paraphilias Evaluated by Polygraph

Forced sex	Sexual contact with someone who is sleeping/passed out
Peeping	Public masturbation
Frottage	Voyeurism
Prostitution	Sexual toys/objects
Pornography	Adult bookstores
Stalking	Masturbation using male underwear/female underwear
Bestiality	Golden showers
Phone sex numbers	Obscene phone calls
Bondage	Sadomasochism
Cross dressing	Sexual nude massage
Sexual photos/videos	Internet pornography
Internet adult chat rooms	Subscribe to internet pornographic site
Downloaded internet porno	Sent pornography on internet
Saved internet pornography	Internet child pornography
Exhibitionism	Strip bars

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