SPECIFICATION

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[USE OF LIZARD OIL IN TREATING SEXUAL IMPOTENCY AND FRIGIDITY]

Background of Invention

[0001] The human sexual response in both the male and female involves a complex interplay between endocrine, neurological and psychological components, which result in certain physiological and anatomical responses in both men, and women.

[0002] While there are obvious differences in the sexual response between men and women, one common aspect of the sexual response is the erectile response. The erectile response in both males and females is result of engorgement of the erectile tissues of the genitalia with blood in response to sexual stimulation (physical, psychological, or both).

[0003] The vasculature, which serves erectile tissue in both men and women, is similar. In particular, in both men and women, the arterial circulation to the erectile tissues of the genitalia derives from the common iliac artery which branches from abdominal aorta. The common iliac artery bifurcates into the internal and external iliac arteries. The internal pudic artery arises from the smaller of two terminal branches of the anterior trunk of the internal iliac artery. In the female, the internal pudic artery branches into the superficial perineal artery, which supplies the labia pudenda. The internal pudic artery also branches into the artery of the bulb, which supplies the bulbi vestibuli, and the erectile tissue of the vagina. The artery of the corpus cavernosum, another branch of the internal pudic artery supplies the cavernous body of the clitoris. Still another branch of the internal pudic artery is the arteria dorsalis clitoridis, which supplies the dorsum of the clitoris and
terminates in the glans and membranous folds surrounding the clitoris, which correspond to the prepuce of the male.

[0004] In the male, the internal pudic artery branches into the dorsal artery of the penis (which itself branches into a left and right branch) and the artery of the corpus cavernosum, all of which supply blood to the corpus cavernosum. The dorsal artery of the penis is analogous to the artery dorsalis clitoridis in the female, while the artery of the corpus cavernosum in the male is analogous to the artery of the same name in the female.

[0005] The male erectile response is regulated by the autonomic nervous system, which controls blood flow to the penis via the interaction of peripheral nerves associated with the arterial vessels in and around the corpus cavernosum. In the non-aroused or non-erect state, the arteries serving the corpus cavernosum are maintained in a relatively constricted state, thereby limiting the blood flow to the corpus cavernosum. However, in the aroused state, the smooth muscles associated with the arteries relax under the influence of catecholamines and blood flow to the corpus cavernosum greatly increases, causing expansion and rigidity of the penis. It is known that smooth muscle contraction opens valves through which blood can flow from the corpus cavernosum into the extracavernosal veins. When the relevant smooth muscles relax, the valves close diminishing venous outflow from the corpus cavernosum. When accompanied by increased arterial blood flow into the corpus cavernosum, this results in engorgement of the corpus cavernosum and an erection.

[0006] Lack of sexual desire or failure to attain orgasm is encountered much more frequently in women than in men. It occurs in a significant percentage of neurotic women, as well as in other females who exhibit no signs of psychic disorder. (See: Principles of Neurology—Adams and Victor—Third Edition—McGraw Hill Book Company). The pre-orgasmic sexual response in females can be broken down into distinct phases. Both the excitement phase and the plateau phase involve vasodilatation and engorgement (vasocongestion) of the genitalia with arterial blood in a manner analogous to the male erectile response.
The excitement phase of the female sexual response is characterized by vasocongestion in the walls of the vagina, which leads to the transudation of vaginal fluids and vaginal lubrication. Further, the inner one-third of the vaginal barrel expands and the cervix and the body of the uterus become elevated. The flattening and elevation of the labia majora and an increase in clitoral size accompany this. [Klodny et al., Textbook of Sexual Medicine, Little and Brown, Boston, Mass. (1979)].

The plateau phase follows the excitement phase in the female sexual response and is characterized by prominent vasocongestion in the outer one-third of the vagina, causing a narrowing of the opening of the vagina and a retraction of the shaft and the glans of the clitoris against the symphysis pubis. These responses are also accompanied by a marked vasocongestion of the labia. [Klodny, supra (1979)].

The vasocongestive aspects of the female sexual response are not restricted to the genitalia in that areolar engorgement also occurs, sometimes to the extent that it masks the antecedent nipple erection that usually accompanies the excitement phase.

As many as half the cases of male impotence may be psychogenic because there is no readily ascertainable organic cause for the disorder. Even when there appears to be an underlying organic cause of impotence, psychologic factors may play a role in the disorder.

"Age and Sexual Outlet," in Sexual Behavior in the Human Male; A. C. Kinsey et al., eds., Philadelphia, Pa.: W. B. Saunders, 218–262 (1948). In 1985 in the United States, impotence accounted for more than several hundred thousand–outpatient visits to physicians (National Center for Health Statistics, National Hospital Discharge Survey, 1985, Bethesda, Md., Department of Health and Human Services, 1989 DHHS publication no. 87–1751). More recent findings reports that almost one-third of Americans suffer from different degrees of impotence. Among the primary disease–related causes of erectile dysfunction are atherosclerosis, diabetes, aging, hypertension and antihypertensive medication, chronic renal disease, pelvic surgery and radiation therapy, and psychological anxiety (Feldman, et al. Journal of Clinical Epidemiology 47.5 (1994) 457–67). A number of causes of impotence have been identified, including vasculogenic, neurogenic, endocrinologic and psychogenic. Vasculogenic impotence, which is caused by alterations in the flow of blood to and from the penis, is thought to be the most frequent organic cause of impotence. Common risk factors for vasculogenic impotence include hypertension, diabetes, cigarette smoking, pelvic trauma, and the like. Neurogenic impotence is associated with spinal–cord injury, multiple sclerosis, peripheral neuropathy caused by diabetes or alcoholism and severance of the autonomic nerve supply to the penis consequent to prostate surgery. Erectile dysfunction is also associated with disturbances in endocrine function resulting in low circulating testosterone levels and elevated prolactin levels.

[0012] Impotence can also be a side effect of various classes of drugs, in particular, those that interfere with central neuroendocrine control or local neurovascular control of penile smooth muscle. (Krane et al., New England Journal of Medicine 321:1648 (1989). Penile erection requires (1) dilation of the arteries that regulate blood flow to the lacunae of the corpora cavernosa, (2) relaxation of trabecular smooth muscle, which facilitates engorgement of the penis with blood, and (3) compression of the venules by the expanding trabecular walls to decrease venous outflow.

[0013] Direct cures for the vascular ravages of these manifold and multifaceted disease states are unlikely to occur in the near future, and thus, the last decade
has witnessed the development of several treatment modalities to directly restore diminished erectile capacity. However, all currently available therapies are either non-specific (hormonal therapy), of limited overall success (e.g., vacuum erection devices), invasive (e.g., intracorporal injection therapy) or non-reversible and expensive (e.g., penile prosthetic implant surgery). Despite these therapeutic limitations the FDA approval of Caverject \textsuperscript{®} (prostaglandin E sub 1) for the intracavernous treatment of erectile dysfunction represents a major step forward. In essence, this act of the Federal Government has resulted in both the formal recognition of the medical nature of the problem, and furthermore, legitimized its clinical treatment. The National Institute of Health of the US Government has clearly defined the nature of disease and its amelioration modalities (NIH Consensus Statement 1992 Dec 7–9; 10(4): 1–31.). Depending on the nature and cause of the problem, treatments include psychosexual therapy, hormonal therapy, administration of vasodilators such as nitroglycerin and alpha adrenergic blocking agents ("alpha blockers"), oral administration of other pharmaceutical agents, vascular surgery, implanted penile prostheses, vacuum constriction devices and external aids such as penile splints to support the penis or penile constricting rings to alter the flow of blood through the penis. Trabecular smooth muscle tone is controlled locally by adrenergic (constrictor), cholinergic (dilator) and nonadrenergic, noncholinergic (dilator) innervation, and by endothelium-derived vasoactive substances such as vasoactive intestinal polypeptide (VIP), prostanoids, endothelin and nitric oxide. High sympathetic tone (noradrenergic) is implicated in erectile dysfunction, and, in some patients, the disorder can be successfully treated with noradrenergic receptor antagonists. See, e.g., Krane et al., supra.

There is also evidence that dopaminergic mechanisms are involved in erectile function. For example, pharmacologic agents that elevate the level of brain dopamine or stimulate brain dopamine receptors increase sexual activity in animals (see, e.g., Gessa & Tagliamonte, Life Sciences 14:425 (1974); Da Prada et al., Brain Research 57:383 (1973)). Administration of L-DOPA, a dopamine precursor, enhances sexual activity in male rats. L-DOPA has been used in the treatment of Parkinsonism and is known to act as an aphrodisiac in some patients (Gessa &
Specific dopamine agonists have been studied for their effects on erectile function. Apomorphine, (n-propyl)norapomorphine, bromocryptine, amantidine, fenfluramine, L-DOPA and various other pharmacological activators of central dopaminergic receptors have been found to increase episodes of penile erection in male rats (Benassi-Benelli et al., Arch. Int. Pharmacodynam. 242:241 (1979); Poggioli et al., Riv. di Farm. & Terap. 9:213 (1978); Falaschi et al., Apomorphine and Other Dopaminomimetics, 1:117–121 (Gessa & Corsini, Eds., Raven Press, N.Y.)). In addition, U.S. Pat. No. 4,521,421 to Foreman relates to the oral or intravenous administration of quinoline compounds to treat sexual dysfunction in mammals.

The currently available dopamine agonists, with few exceptions, have found limited use in the treatment of erectile dysfunction because of their peripheral side effects. These effects include nausea and vomiting, postural hypotension, arrhythmias, tachycardia, dysphoria, psychosis, hallucinations, drowsiness and dyskinesias (See, e.g., Martindale The Extra Pharmacopoeia, 31st Ed., pages 1151–1168). One such drug, apomorphine, has recently been tested for this purpose on a large-scale patient population with limited success since the dose and the rate of absorption into body determines whether the drug acts as an aphrodisiac or as an emetic.

Other pharmaceutical methods for treating erectile dysfunction have also proved to be problematic. For example, with Viagra®, the recently introduced oral drug therapy, not only have significant side effects been encountered, but interaction with other systemically administered medications has posed enormous risks and numerous fatalities have in fact been reported.

Human history is full of anecdotal attempts to design potions to enhance sexual desire and performance. Mr. M. Vezien, a French doctor in the mid-19th century was impressed by the "erensions douloureuses et prolongees" in soldiers returning from North Africa, who had dined on frog legs. The mystery was resolved years later through the discovery of "Spanish fly," a chemical cantharidin, that came from the meloid beetles that the frogs eat. Cantharidin, a urinary tract irritant,
became a favorite of men trying to boost their virility that included Marquis de Sade. Spanish fly is sold widely in the US despite its severe toxic effects.

This exemplifies just one of the hundreds of anecdotal descriptions of aphrodisiacs, substances that arouse or intensify sexual desire and named after Aphrodite, the Greek goddess of sexual love and beauty. Some examples of these include: oysters, caviar, powdered rhinoceros tusk, cocks' combs, figs, eggs, "love potion number nine," ambergris, bulls blood (drawn from the testes), camel's milk, phallic-shaped fruits, or such "lascivious" vegetables as asparagus, to name a few. In some instances, direct proof of efficacy is difficult to obtain but the theory behind the use of products is sensible. For example, oyster contains zinc, the deficiency of which lowers sperm count.

Ginseng, a nutrient plant native to Korea, Russia, and China is reputed to be a tonic for the nervous system in general and thus a boon to potency. A spicy bowl of bird's nest soup provides much phosphorus and other minerals. Asparagus is a rich source of potassium, phosphorus, and calcium all essential for energy and it stimulates the urinary tract and kidneys, which is why the 17th century herbalist Nicholas Culpepper advised that asparagus "stirreth up bodily lust in man and woman." Thousands of Japanese restaurants serving eel with a special pickle coming from an expensive phallic shaped plum similarly believe that unagi (the raw eel) makes a fine aphrodisiac.

Men have often presented women with flowers, chocolates, music, and other pleasurable treats to put them in a romantic mood. Flowers are the plants' sex organs that do evoke pheromones related to sexual desire; chocolate contains mild central nervous system stimulation, as well as amphetamine-like chemicals, pheromones that body produces upon sexual stimulants. Montezuma drank fifty cups of chocolate a day to boost his virility before he visited his harem of six hundred women.

Musk is a substance with a strong persistent odor from the abdominal gland of the male musk deer, found in high Asian mountains. The long-lasting odor of musk has made it an important ingredient in perfumes throughout history. Musk
also delays evaporation of more volatile scents in a perfume, and is used as a fixative in blends where other scents are dominant. In Asia it is sought as an aphrodisiac, and it is believed to be medically beneficial as a stimulant. Fresh musk is viscous but dries to a grainy powder and a tincture of this powder is used in perfumes. The basic oil that is the source of the odor has been identified and called muskone. Synthesized muskone is also used in soaps and cosmetics. In the modern times, the value of musk can be discerned by quotation from Theodore H White's book, In Search of History, "Kennedy the politician exuded that musk odor which acts as an aphrodisiac to many women. "Most perfumes contain the essences of flowers mixed with secretions from wild animals (musk, civet, ambergris, etc.) or close laboratory versions of these. Truffles contain a chemical similar to the male pig sex hormone, which is why hot-to-trot sows eagerly dig them up. Interestingly, this chemical is also similar enough to a male hormone. Cappuccino, the drink concocted by the celibate Capuchin monks is the drink of sexually active. Alcohol work well at the outset by relaxing inhibitions but then it depresses the nervous system just when it should be a jubilant moment. Shakespeare warns in Macbeth of alcohol that it, "provokes the desire, but takes away the performance." Ovid swore by onions and Romans had their *liquamen sauce* made from rotting fish entrails. The medieval man preferred a concoction of the flowers and leaves of myrtle marinated in wine. Women have applied to their breasts a mixture of myrtle with rose and orange water to stimulate them.

[M022]

Mandrake is native to the Mediterranean and Himalayan regions and especially to Greece. The whole plant has a fetid odor. As late as the middle Ages, a dose of the oddly shaped root was sometimes given to patients as a narcotic before surgical operations. In the United States *may apple* is often called mandrake. The mandrake has traditionally been the object of superstition, largely because of the resemblance of its forked root to the human figure. Used as an aphrodisiac, the mandrake was also variously regarded as a charm for pregnancy, for invulnerability, and for discovering treasure. The ancients believed in the magic power of the purplish-flowered mandrake root because its branched shape was thought to resemble the human body. In The Odyssey, the sorceress Circe drops
mandrake into her potent brews, and as late as the 17th century it was used in love potions.

Catherine de Medici's love diet included many artichokes, and Paris street vendors used to cry their commercials: "Artichokes! Artichokes! Heats the body and the spirit. Heats the genitals." Garlic is universally celebrated as an aphrodisiac as Culpepper wrote, "It's heat... is vehement." Black beans arouse the lower organs as a result the 4th century cleric St. Jerome would not allow nuns under his spiritual direction to eat black-bean soup.

Crocodile semen is recommended in the medieval "Black Book." The otherwise protected rhinoceros suffers from the large market in Asia for its horn, which is used whole in artistic carving and is also prized as a medicine and aphrodisiac. Because of this market, four of the five rhinoceros species are nearing extinction.

Yocon or Yohimex, made from the bark of the African yohimbine tree, restores erection for some impotent men. Another product widely sold combines yohimbine with puama plant extract, vitamin E and nicotinamide. The "goat's eyelids" were favored by the Mongols of the Yuan dynasty in China as a ring tied to penis to titillate women during intercourse. In many parts of the world it is common to scar the penis or insert objects into it to excite women. For example, men in Borneo pierce the end of the penis with a piece of bamboo or brass wire; the Sumatrans make holes in their penises and press small stones into the wound, the flesh grows over the stone to make them knobby.

In 1989, the US Food and Drug Administration finally clashed with the 5000-yr old recipes and declared that aphrodisiacs in general have no scientific basis of effect. A decade later, the FDA reversed its course and approved drugs that have aphrodisiac characteristics. While many claims made regarding the efficacy of sexual stimulants remain confounded, many patents have been issued wherein a substance is ingested or applied locally to sexual organs to promote sexual desire, reduce impotency and frigidity. Systemic use of drugs invariably results in many side effects and though the sexual response has both the CNS as well as local tissue involvement, the products that produce a local effect remain safer and easier
The following documents are of interest insofar as they relate to the treatment of erectile dysfunction and frigidity by delivering pharmacologically active agents locally to the penis and clitoris: U.S. Pat. No. 4,127,118 to Latorre describes the injection of vasodilator drugs into the corpora cavernosa of the penis to dilate the arteries that supply blood to the erectile tissues, thereby inducing an erection.

U.S. Pat. No. 5,439,938 to Snyder et al. describes the administration of nitric oxide (NO) synthase inhibitors by direct injection of a drug into the corpora cavernosa, by topical drug administration or transurethral drug administration, for inhibiting penile erection due to priapism and for treating urinary incontinence.

Virag et al., Angiology-Journal of Vascular Diseases (February 1984), pp. 79-87, Brindley, Brit. J Psychiat. 143:332-337 (1983) and Stief et al., Urology XXXI: 483-485 (1988) respectively describe the intracavernosal injection of papaverine (a smooth muscle relaxant), phenoxybenzamine or phentolamine (alpha receptor blockers) and a phentolamine-papaverine mixture to treat erectile dysfunction.


It is also claimed to use a topical composition containing cayenne pepper for stimulating the blood flow in the skin according to U.S. Pat. No. 5,384,123, where this is used for rejuvenating skin.

The use of capsaicin, the active component in hot chili pepper is also claimed to have aphrodisiac effect according to US Pat. No. 6,039,951.

The U.S. Patent 6,151,527 describes the use of electrodes for stimulating living tissue such as vaginal, anal, clitoral, penile, and scrotal tissue are shown. Electrical stimulation to such areas is intended to induce excitation and orgasm in either females or males, particularly where frigidity or impotence is a problem. Four
embodiments of the electrode apparatus include a flexible tube shaped base and an electrode either in the form of a loop or a stem coupled to the base. The electrode is formed from one of an electrically conductive solid cord, an electrically conductive tube, and an insulated conductor cable. An electrical contact at one end of the electrode allows the electrode to be connected to an electrical source. Auxiliary members such as conductive beads, conductive end pieces, conductive or nonconductive tube shaped coverings, and vibrators are added to any of the electrode apparatuses to impart specific stimuli in specific regions of the user’s anatomy.

[0034] The U.S. Patent 6,031,002 describes a method for enhancing female sexual response in which topically administered to the clitoris of the female subject and the surrounding tissue is a pharmaceutically-acceptable composition whose primary agent is prostaglandin.

[0035] The U.S. Patent 5,891,915 describes a method for enhancing female sexual response in which topically administered to the clitoris of the female subject and the surrounding tissue is a pharmaceutically-acceptable ointment containing a prostaglandin of the "E" series.

[0036] Voss et al., U.S. Pat. No. 4,801,587, addresses the use of an ointment containing a vasodilator and a carrier agent for topical application to the penis of impotent men. The Voss et al. patent also describes application of such an ointment into the urethra of the penis using a catheter as well as a multi-step regimen for applying a vasodilator to the skin of the penis. In addition, Voss et al. proposes the surgical removal of a portion of the fibrous sheath surrounding the corpora cavernosum, thereby facilitating the penetration of a vasodilator-containing ointment into the corpora cavernosum. Vasodilators suggested for use by Voss et al. include papaverine, hydralazine, sodium nitroprusside, phenoxybenzamine, and phentolamine. The Voss et al. patent, however, provides no information regarding the actual efficacy of the treatments proposed or the nature of the response to such treatments.

[0037] U.S. Pat. No. 4,127,118 to Latorre describes treating male impotence by direct
injection of the vasodilating drugs into the corpus cavernosum and the corpus spongiosum of the penis using a syringe and one or more hypodermic needles. More particularly, the Latorre patent proposes the intracavernosal and intraspongiosal injection of sympathomimetic amines such as nylidrin hydrochloride, adrenergic blocking agents such as tolazoline hydrochloride, and direct acting vasodilators such as isoosuprine hydrochloride and nicotinyl alcohol.

[0038] Brindley, G. S. (Br. J. Pharmac. 87:495–500, 1986) showed that, when injected directly into the corpus cavernosum using a hypodermic needle, certain smooth muscle relaxing drugs including phenoxybenzamine, phentolamine, thymoxamine, imipramine, verapamil, papaverine, and naftidrofuryl caused erection. This study noted that injection of an "appropriate dose of phenoxybenzamine or papaverine is followed by an unrelenting erection lasting for hours." Injection of the other drugs studied induced erections lasting from about 11 minutes to about 6.5 hours.

[0039] Zorgniotti et al., J. Urol. 133:39–41 (1985) demonstrated that the intracavernosal injection of a combination of papaverine and phentolamine could result in an erection in otherwise impotent men. Similarly, Althof et al. J. Sex Marital Ther. 17(2): 101–112 (1991) reported that intracavernosal injection of papaverine hydrochloride and phentolamine mesylate resulted in improved erectile ability in about 84% of patients injected. However, in that study the dropout rate was 57%, fibrotic nodules developed in 26% of the patients, 30% of the patients developed abnormal liver function values, and bruising occurred in 19% of the patients.


[0041] Zorgniotti et al, PCT/US94/09048, describes the transmucosal administration of a variety of vasodilators including phentolamine mesylate for modulating the human sexual response.
[0042] U.S. Pat. No. 5,059,603 to Rubin describes the topical administration to the penis of isoxsuprine and caffeine, and nitroglycerine and caffeine along with suitable carrier compounds for the treatment of impotence.

[0043] There continues to exist a need in the art for effective means for modulating human sexual response and especially for enhancing erectile ability in males suffering from impotence and women suffering from frigidity. Ideally, such means would be convenient and simple to use, would not require a constant dosage regimen or even multiple doses to achieve desired results, would be non-invasive and would allow a rapid and predictable capacity for onset of erectile function on demand and in response to normal sexual stimulation. Such invention would also be equally applicable to treat or ameliorate frigidity in women, specially, since the basic mechanism of arousal and erection are common between man and woman. Drugs or modalities used locally are thus always preferred to avoid systemic toxicity, better control of the timing of response and ease of use.

[0044] The invention described herein provides a means to avoid the above-mentioned problems encountered with the systemic and local administration of some pharmacologically active agents to treat erectile dysfunction in men and frigidity in women. Specifically, the invention relates to methods and formulations for effectively treating erectile dysfunction and frigidity in women by locally administering a selected active agent, wherein the active agent is the adipose tissue derived from lizards.

Summary of Invention

[0045] The present invention relates to the use a natural product, the body fat deposits derived from Uromastix hardwickii having a sexually stimulating action, intended to be applied in undiluted or diluted form to a woman's and/or a man's sexual organs. The adipose tissue of lizard Uromastix hardwickii is a viscous liquid at room temperature and it is applied directly to the sexual organs (clitoris and penis and surrounding areas) to yield a desirable response within 5 minutes as a result of enhanced blood flow to organs without producing any noticeable irritation to the organs and any side effects. This adipose tissue is composed of a variety of
fatty acids, both saturated and unsaturated, is rich in vitamins A and E and
contains steroidal alcohols, all which may contribute in increasing the blood flow to
the applied surface. The "on demand" aspect of the present invention will allow a
more rapid response to sexual stimulation in men along with heightened sensation
associated with excitement and plateau stages in women by virtue of the increased
blood flow to the tissues. The main beneficiaries of this treatment are impotent
men and anorgasmic or intermittently anorgasmic women or women seeking a
more pronounced sexual response. The adipose tissue can be used without any
modification or reformulation or after dilution or reformulation with other oils and
carriers as needed to impart the characteristics of a safe drug delivery form.
Whereas we have studied the properties of fat deposits in Uromastix hardwickii,
the characteristics may be found in other species of Uromastix, in other reptile
fats and in the body fats of other animals. Our finding that the animal fat has a
rubefacient effect enhancing blood flow and stimulating sexual organs is the
primary finding. Such effects may also be obtained through use of plant oils as
well.

Detailed Description

While the invention will now be described in connection with a certain preferred
embodiment in the following example so that aspects thereof may be more fully
understood and appreciated, it is not intended to limit the invention to these
particular embodiments. The invention relates to all alternatives, modifications and
equivalents as may be included within the scope of the invention as defined by the
appended claim. Thus the following examples, which include preferred
embodiments will serve to illustrate the practice of this invention, it being
understood that the particulars shown are by way of example and for purposes of
illustrative discussion of preferred embodiments of the present invention only and
are presented in the cause of providing what is believed to be the most useful and
readily understood description of formulation procedures as well as of the
principles and conceptual aspects of the invention.

The Uromastix is a genus of approximately 13 species of lizards, related to the
iguana, whose members are found in arid regions from northwestern India
throughout southwestern Asia and the Arabian Peninsula to the Sahara of Africa. The members of the genus are popularly called dab lizards or spiny tailed lizards. *Uromastix hardwickii* is one of the most widely distributed desert reptile species. They inhabit the sandy tracts where the vegetation is scanty. They make burrows 6 to 8 feet deep and live there during the summer months and lay large eggs (20 to 30 mm in diameter), which hatch in a few weeks. During the winter months they go into hibernation as their metabolic activity becomes sluggish and body temperature, heart rate and nervous activity decline. The adult animals weigh from 300 to 500 G and ranges in length from 6 inches to well over a foot. The dorsal side of the animal is yellowish gray (usually the color of the sand around) and the ventral side is dirty white. The tail is covered with hard and posterior projected spines, which appear to be the main defense organ of the animal. On the ventral surface of each thigh is a series of 12 to 18 circular discs with central pores.

These animals feed on the grass, flowers, fruits and occasionally fecal content. Both males and female animals carry large abdominal fat pads (two leaf-like structures lying on either side of the body cavity in its posterior part and extending almost up to the lungs in most cases) in the winter months. These lipid reserves are depleted at the onset of the summer before the females lay eggs. The extent and the rate of growth of these fat pads vary considerably depending upon the age and physiological state of the animal. On an average, these fat pads weigh about 3.8 G per 100 G body weight (females 4.2 G/100 G and males 3.3 G/100 G). The fat mobilization takes place when the animals come out of hibernation when their plasma triglyceride levels increase as the triglyceride levels reduce in fat pads. During sexual arousal and periods of high activity, the esterified fatty acids (EFAs) are reduced while the free fatty acids (FFAs), diglycerides and monoglycerides are increased creating elevated lipolysis. Despite the alteration in the fatty acid pattern of triglycerides, especially in the levels of palmitic, palmitolic, stearic and linolenic acids, there is little change in total unsaturation during hibernation compared to during sexual arousal and periods of high activity. The fat pads contain primarily triglycerides and very little glycogen, phospholipids and cholesterol. The fat pads
are orange yellow in color and covered by a thin membrane usually containing dark pigment, carotenoid, with characteristic absorption at 440 nm with two minor peaks at 420 and 470 nm. (Biochemistry of *Uromastix hardwickii*, Zain-ul-Abedin, Journal of Science (Karachi), 38–63(4) Suppl, 1976).

[0049] The unsaponifiable fractions have been identified as steroidal alcohols, ester of tocopherol and fatty acids, solid steroidal alcohol and esters of vitamin A and fatty acids. The unsaponifiable component of fat contains vitamin A in amount approximately 40–50,000 IU/G and vitamin E 250–275 mg/G; the fat of *Uromastix hardwickii* is comparable to that of bearded seal liver oil in its vitamin E content and about 17–20 times higher than the concentration of vitamin E in wheat germ oil.

[0050] Samples of adipose tissue of *Uromastix hardwickii* were collected from adult lizards weighing on an average about 350 G. After anesthetizing them with ether, the abdomen were incised and the two large yellow leaf–like fat bodies were carefully removed and transferred to a petri dish and heated to 65 deg C and the temperature maintained for 3 to 4 hours. The molten fat was then strained through muslin and finally through a Whatman 3 filter paper. The filtrate was then subjected to low vacuum at 40 deg C to remove moisture. The final product was viscous yellowish–brown fat.

[0051] Physical and chemical analyses of these fat samples revealed that the average saponification value was about 198 mg KOH/G. The fatty acid profile showed palmitic acid: 3.0–3.3%, palmitoleic acid: 0.3–0.4%, stearic acid: 1.3–1.5%, oleic acid: 13.8 to 19.3%, linoleic acid: 12.4 to 13.5%, linolenic acid: 3.0–4.3%, erusic acid: 13.5–18.8%. The average specific gravity as 0.91 at 27 deg C and congealing point was: 4.5 deg C; the unsaponifiable matter constituted about 20%, of which the major portion was vitamin A and E. One fraction of the unsaponifiable matter showed positive test for steroidal alcohol. Microbiologic testing showed no pathogenic organisms. The finding that *Uromastix hardwickii* adipose tissue contains erusic acid is significant since this compound is found widely in vegetable oils such as rapeseed oil, Lorenzo's oil other edible oils. The source of erusic acid
in animal fat can be traced back to the diet of animals comprising of foods high in erusuc acid. Other components of the adipose tissue, particularly, but not limited to, the steroidal alcohols and vitamins A and E may have significant synergistic effect in inducing enhanced blood flow to sexual organs. The quantity of the adipose tissue that needed to be applied to obtain a response is approximately 1–20 G but this quantity is not limiting depending on the nature of sensitivity of the individual and nature how the product is applied.

[0052] EXAMPLE 1: The preparation was rubbed gently in sufficient quantity to cover the entire penis and surrounding areas including scrotum of a 35 year old man; an erection was observed within 5 minutes of application. No adverse effects were reported.

[0053] EXAMPLE 2: The preparation was applied in sufficient quantity on the penis and surrounding areas including scrotum of a 70-year-old diabetic, who had not had an erection for many years. Within 5 minutes after application he was able to obtain a 60–70% erection. No adverse effects were reported.

[0054] EXAMPLE 3: The preparation was applied in sufficient quantity to several volunteering women's sexual organs, clitoris and surrounding areas, and within 5 minutes after application, there was a sexually stimulating action together with an increase of secretion in the vagina. No adverse effects were reported.

[0055] EXAMPLE 4: The preparation was applied in sufficient quantity to penis and clitoris and surrounding areas simultaneously by a married couple aged 48 (male) and 42 (female) and within 5 minutes both experienced excitation and erection and engaged in sexual intercourse. Both partners had simultaneous orgasm, which they had not experienced for several years as husband and wife. No adverse effects were reported.
Claims

[c1] I claim a method for treating frigidity and enhancing sexuality in females having a clitoris comprising the step of topically applying and rubbing to the surface of the clitoris and optionally to its surrounding areas the fat deposits derived from Uromastix hardwickii.

[c2] I claim a method for treating erectile dysfunction in males comprising of local application of a sufficient quantity of the adipose tissue derived from Uromastix hardwickii to penis and optionally to its surrounding areas to achieve an erectile response.

[c3] I claim a method as set forth in claims 1 and 2 wherein the preparation may be a formulation that contains other components to impart pharmaceutical elegance and ease of administration wherein the concentration of fat derived from Uromastix hardwickii ranges from less than % to greater than 99.

[c4] I claim a method as set forth in claims 1 and 2 wherein the formulation is administered transdermally.

[c5] I claim a method as set forth in claims 1 and 2 in which the formulation takes the form of an ointment, cream, solution, liposomal system, gel, gauze, foam, spray or another dosage form or device suitable for administration of the preparation to humans.

[c6] I claim a method as set forth in claim 1, and wherein the primary agent is the body fat or adipose tissue derived from other species of Uromastix.

[c7] I claim a method as set forth in claim 1, and wherein the primary agent is the body fat or adipose tissue derived from other reptilian genus.

[c8] I claim a method as set forth in claim 1, and in which the primary agent is the body fat or adipose tissue or any other part of animal tissue containing sufficient quantity of naturally occurring substances that enhance blood flow to the organs when applied topically to humans.

[c9] I claim a method as set forth in claim 1 and 2 in which the preparation is
applied in such sufficient quantity to adequately cover the sexual organs and surrounding areas as needed and rubbed gently to spread it evenly throughout the surface.

[c10] Al claim a method as set forth in claim 1 and 2, in which the preparation is mixed with another chemical, synthetic or natural, or parts of plants or animals with characteristics of enhancing blood flow to organs to obtain a synergistic effect.

[c11] TI claim a method as set forth in claims 1 and 2 wherein the primary agent may include a substantially water-insoluble transdermal penetration enhancing compound selected from the group consisting of C7 to C16 aliphatic group substituted acetals, hemiacetals and morpholines and further comprising a physiologically acceptable water soluble polar compound selected from the group consisting of alcohols, glycols, lactams, urea, cycloethylene urea, 1,3-dioxolone, 2-methyl-1,3-dioxolone, 1,3-dioxane, 2-methyl-1,3-dioxane, morpholine, N-methylmorpholine, N,N-dimethylformamide, dimethylsulfoxide, methylacetate, ethyl lactate, monosaccharides, polysaccharides, amino acids, amino alcohols, diethylamine and cycloethylene carbonate. The polar compound may be selected from a group consisting of alcohol, glycol, dioxolane, formamide, carbonate, glucose, urea and mixtures thereof. Alternatively, the polar compound may be an alcohol glycol mixture or lactim.
Abstract of Disclosure

The present invention relates to the use a safe natural product, the body fat deposits derived from *Uromastix hardwickii* or other species of *Uromastix hardwickii* or other reptiles or animal species having a sexually stimulating action, intended to be applied in its undiluted or diluted form to a woman's and/or a man's sexual organs and optionally to the surrounding areas. The adipose tissue of *Uromastix hardwickii*, a viscous liquid at room temperature, is applied directly to the sexual organs and an effect is observed within 5 minutes as a result of enhanced blood flow to organs without producing any noticeable irritation to the organs or any side effects or discomfort either during or after the application is made. The effect lasts temporarily and disappears within 10–60 minutes of application. The "on demand" aspect of the present invention will allow a more rapid response to male erection and sexual stimulation along with heightened sensation associated with excitement and plateau stages of the female sexual response by virtue of the increased blood flow to the tissues. The preparation described in this patent can be used undiluted or after dilution with other oils or carriers in a variety of dosage forms or devices in concentrations ranging from less than 1% to greater than 99%.