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LASER VAGINAL REJUVENATION®
DESIGNER LASER VAGINOPLASTY®

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1. INTRODUCTION

Modern women all around the world are becoming more beauty conscious. Previously, the concern was mainly on the face and the sculpture of the body; however now a substantial number of patients were reported to enquire their gynecologist to aesthetically enhance their genital structures. Some women have experienced trauma to the genital structures at the time of delivery that often make the labia irregular, while other women are born with large labia (Matlock 2006) and (Hailparn 2003). In either situation women may experience discomfort wearing certain types of clothes, or may experience pain and irritation with intercourse, or they may be self-conscious about the appearance of these structures (Matlock 2006) and (Hailparn 2003).

Many women have difficulty controlling their urine in certain situations or notice changes in their bowel habits. These two symptoms may be related to a common set of problems that may occur as a result of childbirth, aging or a combination of both. Grouped together these problems are referred to as pelvic relaxation. Many women suffer unnecessarily from conditions involving pelvic relaxation. The general symptoms associated with pelvic relaxation depend on which organs are affected. Often there is a feeling of heaviness or fullness. Small or moderate amount of urine may be lost with normal physical activities such as laughing, coughing, walking or running. In more advanced or rare cases a mass may protrude from the vaginal opening. In vaginal relaxation, the muscles are relaxed and have poor tone, strength and control. The internal and external diameters increase. The muscles of the perineum are weak and poorly supported. Under these circumstances, the vagina is no longer at its optimum state. As a result the sensual side of sexual gratification is diminished. Laser Vaginal Rejuvenation® (LVR)® was designed to enhance sexual gratification for women (Matlock 2006).

This technology review was done following the request from the Pharmaceutical Advertisement Board, Ministry of Health, Malaysia.

2. OBJECTIVES

- 2.1** To determine the safety, effectiveness and cost-effectiveness of Designer Laser Vaginoplasty® (DLV)® for enhancement of appearance of women's external genital structures.
- 2.2.** To determine the safety, effectiveness and cost-effectiveness of Laser Vaginal Rejuvenation® (LVR)® for the enhancement of sexual gratification for women and for the correction of stress incontinence.

3. TECHNICAL FEATURES

3.1. Laser Vaginal Rejuvenation® (LVR)®

Laser Vaginal Rejuvenation® (LVR)® is a one-hour outpatient surgical procedure designed to enhance sexual gratification. LVR ® is the modification of a gynecological surgical procedure used for the treatment of stress incontinence. Matlock (2006) claimed that their laser techniques result in gentle precision procedures with controlled accuracy that results in relatively bloodless surgery. The techniques result in rapid healing and resumption of daily activities in a short period of time. Laser Vaginal Rejuvenation® (LVR)® will effectively enhance vaginal tone, strength and control. It will also effectively decrease the internal and external vaginal diameters as well as build up and strengthen the perineal body.

3.2. Designer Laser Vaginoplasty® (DLV) ®

Designer Laser Vaginoplasty® (DLV) ® is a group of cosmetic laser procedures which repair, enhance and beautify the external genital structures of women which include the vulvar structures, labia minora, labia majora, mons pubis, perineum, introitus and hymen. The most common DLV® procedures are as follows:

- **Laser Reduction Labioplasty** for resculpturing the labia minora according to one's specification.
- **Augmentation Labioplasty** to aesthetically enhance the labia majora by autologous fat transplant (removal of the patients' fat via liposculpturing and transplanting it into the labia majora)
- **Laser Perineoplasty** to rejuvenate the relaxed or aging perineum, or enhance the sagging labia majora and minora. Overall, procedure was said to provide an aesthetically appealing vulva.
- **Laser Reduction** of the labia majora via extension of the Laser Perineoplasty
- **Hymenoplasty** (reconstruction of the hymen) to repair the torn hymen
- **Liposculpturing** for the aesthetic reduction of the prominent or protruding mons pubis and labia majora. Vulvar Lipoplasty can remove unwanted fat from the mons pubis and upper parts of the labia majora. Liposculpturing can alleviate the unsightly fatty bulges of this area and produce an aesthetically pleasing contour (Matlock 2006), (Hailparn 2003) and (Smith 2007).

These techniques were developed by Dr David Matlock who combined the basic gynaecologic procedure with modern cosmetic surgical techniques and the improved healing power of the laser to develop Laser Vaginal Rejuvenation® and Designer Laser Vaginoplasty®. The procedure is done under general, epidural or local anaesthesia. The procedure lasts about 60 to 120 minutes depending on whether one procedure is performed or a combination of procedures. Most women can return to work within 5 to 10 days after surgery. Designer Laser Vaginoplasty® can also be done in combination with Laser Vaginal Rejuvenation ® (Matlock 2006).

4. METHODOLOGY

4.1. Searching

The internet databases were searched for any articles regarding LVR® and DLV®. The databases/ search engines include the PUBMED, Ovid, FDA website and several international HTA sites such as AHRQ, AHFMR and AETMIS. Evidence-Based Medical Database like TRIPDatabase and the general search engine Google were also explored.

There were no limitations during the search. The keywords used were:

- “designer laser vaginoplasty”
- laser AND vaginoplasty
- “laser reduction labioplasty”
- “augmentation labioplasty”
- “laser perineoplasty”
- laser AND perineoplasty
- “laser reduction”
- “laser hymenoplasty”
- laser AND hymenoplasty
- liposculpturing
- “laser vaginal rejuvenation”
- “cosmetic surgery”
- vaginal AND “plastic surgery”
- laser AND “vaginal relaxation”
- “laser vaginal rejuvenation” AND “sexual satisfaction”
- “laser vaginal rejuvenation” AND “safety OR safe OR adverse effects ”
- “laser vaginal rejuvenation” AND “effectiveness OR efficacy”
- “laser vaginal rejuvenation” AND “stress incontinence”
- “laser surgery” AND “stress incontinence”
- “laser surgery” AND vagina
- “ laser vaginal surgery” and “safety”
- “laser surgery” AND “vaginal rejuvenation”

4.2. Selection

Literatures which included the open surgery technique for Vaginoplasty were excluded.

5. RESULTS AND DISCUSSION

5.1. Safety

There was no retrievable evidence found on the safety aspect of this technology. Only anecdotal claims from customers were found during the search (Matlock 2006). This technology was said to cause discomfort like any other surgery, however, it may be successfully reduced by the use of local anesthetics post-operatively. Not many sites reported the immediate or late side effects of this procedure. In the United States, where many of these cosmetic procedures were done, it is important for the obstetrician gynecologist to beware of the extensive training necessary to be certified by the American Board of Plastic Surgery (ABPS). Laube (2006, ^{level 9}) in his foreword of a symposium mentioned that as a result of the ABPS Board meeting in November 2005, a policy decision was made that, beginning with the resident match of 2007, combined programs in plastic surgery in which a resident matches directly out of medical school will be for a minimum of 3 years provided that the plastic surgery component of the program is in the same institution as preceding categorical residency (3 years) in general surgery. In advising patients regarding women's genital aesthetic surgery, it is important for the obstetrician gynecologist to counsel patients regarding the lack of rigorous study of these procedures and non-existing outcomes data, other than select patient testimonials (Laube 2006, ^{level 9}).

5.2. Effectiveness

There was no retrievable evidence regarding the effectiveness of this technology in any of the databases. Matlock (2006) claimed that he is currently conducting numerous studies on the effectiveness of his procedures.

5.3. Cost-effectiveness

There was no retrievable evidence on the cost- effectiveness of this technology. The cost for a Designer Laser Vaginoplasty® and Laser Vaginal Rejuvenation® depends on the type of procedure, the anesthetics used and other factors. However, it was reported that the expense for such procedures is estimated to range between USD\$3000.00 and USD\$20,000 out of pocket cost (Laube 2006, ^{level 9}).

5.4. Legal implications

There was no literature retrieved regarding the legal aspects of DLV®. Consideration should be given as this procedure was done worldwide in the developed countries without the slightest attention being paid to it by medical researchers (Conroy 2006, ^{level 9}). It could also be debated that DLV® is a form of female genital mutilation, as the WHO definition of female genital mutilation is “all procedures involving partial or total removal of the external female genitalia or other injury to the female genital organs whether for cultural, religious, or other non-therapeutic reasons” (Conroy 2006, ^{level 9}).

6. CONCLUSION

Currently there is no retrievable evidence on the safety, effectiveness or cost-effectiveness of Laser Vaginal Rejuvenation® and Designer Laser Vaginoplasty®.

7. RECOMMENDATION

Any patient who wishes to undergo this procedure should be given a thorough explanation by the practitioner regarding the procedure, particularly the safety aspects either be it short term or long term effects. The introduction of this technology into our society should be made with extreme caution, as this procedure may be used for wrong purposes, and its appropriateness or legality according to Islamic law has not yet being discussed by the Majlis Fatwa Negara.

8. REFERENCES

Conroy R. M. (2006). Female genital mutilation: whose problem, whose solution?. *BMJ*, 333(7559):106-107.

Hailparn T. B. (2003). Laser Vaginal Rejuvenation Institute of San Francisco . Cited on 14th May 2007 and 21st May 2007 . Available from <http://www.cosmeticgn.net>

Laube D. W. Cosmetic Surgery (2006). *Clinical Obstetrics & Gynecology*,. 49(2):335-336

Matlock D (2006). The Laser Vaginal Rejuvenation Institute of Los Angeles. Cited 14th May 2007 and 21st May 2007 . Available from <http://www.drmatlock.com>

Smith G W (2007). Innovative Gynecology. Cited on 14th May 2007 and 21st May 2007 . Available from <http://www.lvritn.com>

9.1. Appendix I- Levels of evidence scale

Level	Strength of evidence	Study design
1	Good	Meta-analysis of RCT, Systematic review
2	Good	Large sample RCT
3	Good to fair	Small sample RCT
4		Non-randomised controlled prospective trial
5	Fair	Non-randomised controlled prospective trial with historical control
6	Fair	Cohort studies
7	Fair	Case-control studies
8	Poor	Non-controlled clinical series, descriptive studies multi-centre
9	Poor	Expert committees, consensus, case reports, anecdotes

SOURCE: ADAPTED FROM CATALONIAN AGENCY FOR HEALTH TECHNOLOGY ASSESSMENT (CAHTA), SPAIN