WHITE PAPER

SmartXide² V²LR

SmartXide Touch V²LR

Fractional CO_2 Laser Treatment: a Novel Approach for Stress Urinary Incontinence Management in Post-Menopausal Women

English translation of:

González Isaza P, et al. Láser de CO_2 fraccionado: un nuevo enfoque de tratamiento para incontinencia urinaria de esfuerzo (IUE) en mujeres posmenopáusicas. Urol Colomb. 2016. http://dx.doi.org/10.1016/j.uroco.2016.10.004

MonaLisa Touch®

DEKA

The Code of Excellence

Fractional CO_2 Laser Treatment: a Novel Approach for Stress Urinary Incontinence Management in Post-Menopausal Women

Pablo González Isaza[a,b], Aura Ibeth Ruiz Rosasc,[d,e,f] and Diana Lorena Vélez Rizog[g]

[a]: Ginecología y Obstetricia, Universidad Militar de Colombia, Bogotá, Colombia
[b]: Uroginecología y Piso pélvico, Cirugía Láser y Reconstructiva ginecológica, Presidente de la Asociación de Ginecólogos Estéticos Colombianos (AGEOC), Miembro Asociación Internacional Uroginecológica (IUGA), Pereira, Risaralda, Colombia
[c]: Medicina Estética Magister, Universitat Les IllesBalears, Espa˜na
[d]: Docente de Dermatología, Universidad Nacional de Colombia, Bogotá, Colombia
[e]: Directora de Laser Medical Care, Bogotá, Colombia
[f]: Miembro ASMLS Bogotá DC, Cundinamarca, Colombia
[g]: Ginecología y Obstetricia, Universidad de la Sabana, Bogotá, Colombia.

Received January 4, 2016; accepted October 9, 2016.

English translation of:
González Isaza P, et al. Láser de CO_2 fraccionado: un nuevo enfoque de tratamiento para incontinencia urinaria de esfuerzo (IUE) en mujeres posmenopáusicas. Urol Colomb. 2016. http://dx.doi.org/10.1016/j.uroco.2016.10.004

Objectiv: To describe the results of the fractional CO_2 laser as an alternative treatment for stress urinary incontinence in post-menopausal women, and to demonstrate an improvement in quality of life after the treatment.

Materials and Methods: A prospective, single centre descriptive study was conducted on 10 post-menopausal patients with diagnosis of stress urinary incontinence. Recruited patients were evaluated with Stress Cough test and urethral Mobility Q-Tip Test, which confirmed the diagnosis. They then began a 3 session treatment protocol; 1 every 3 weeks using the SmartXide² V²LR fractional microablative CO_2 laser system for the MonaLisa Touch™ procedure in the urethrovesical junction. The Urogenital Distress Inventory UDI-6 was performed to evaluate severity and quality of life impact related to stress urinary incontinence in the patients included in the study, before and after treatment. Patients were monitored from July to December 2013.

Results: Analysis of the UDI-6 Scores before and at the end of treatment showed an improvement in the score in comparison to the baseline condition, indicating a subjective improvement in all the symptoms related to SUI included in the score.

Conclusion: The MonaLisa Touch™ procedure performed with SmartXide² V²LR laser system is a complementary alternative to traditional surgical techniques, providing a safe and effective treatment for urinary incontinence in post-menopausal women.

Keywords: vaginal atrophy; menopause; laser CO_2; quality of life; urinary incontinence; vulvovaginal.

Introduction

In recent years, fractional CO_2 laser technology has become increasingly significant and is currently widely used for genitourinary syndrome of menopause and in postmenopausal patients. The literature does not provide much data about its use for stress urinary incontinence (SUI), but it has proven to be an innovative method considering that patients on whom the laser was used with another therapeutic goal showed an incidental improvement in urinary leaks. The method is therefore being converted into an alternative treatment for patients with SUI.

While SUI is the most common type of incontinence, for which there are a multitude of both medical and surgical treatment options, there is no data available regarding treatments based on anti-ageing medicine; however, it was hoped that the benefits for the genitourinary tract[1,2], would be similar to those found when using the fractional CO_2 laser on the anterior vaginal wall, which activated collagen and promoted elastin at a molecular level, and restored all vaginal functions such as elasticity and lubrication by restoring thickness and vascularisation to the vaginal epithelium[3,4].

Once the thickness of the vaginal epithelium in the anterior vaginal wall has been re-established, the urethral coaptation mechanism and support thereof subjectively and objectively improve SUI-related problems[5,6].

The study corresponds to a series of cases.

Materials and Methods

A prospective, descriptive pilot study was carried out between July and December 2013 on 10 patients from the urogynaecology and pelvic floor consulting room. The average age was 58.4 years and ranged from 50-65 years. The patients had a history of at least one pregnancy and were characterised by a high degree of mainly university education. This group of patients presented SUI symptoms without previous treatment. Incontinence made an impact on their quality of life with related sexual dysfunction but without associated prolapse. They were clinically assessed with the Valsalva test and urethral hypermobility test (Q-Tip test), which confirmed the diagnosis.

Inclusion Criteria

- Clinical SUI with or without urgency component.
- Positive Valsalva test.
- No previous anti-incontinence treatment.
- Willingness to participate.
- UI with impact on quality of life.
- Related sexual dysfunction.
- No associated prolapse. POP-Q > 1 anterior compartment.
- Menopause.

Exclusion Criteria

- Urinary incontinence insufficiently classified.
- Previous treatment for urinary incontinence.
- Recurrent infection of the lower urinary tract
- BMI > 35.

The patients recruited for this study belong to the private clinical practice and voluntarily agreed to take part in it. They received the offer to participate before informed consent was obtained, and the study was subsequently registered in writing in accordance with the Declaration of Helsinki, the Belmont Report, CIOMS standards, GCP/ICH and Resolution 008430 of the Government of Colombia established on 4 October 1993. The type of informed consent used was designed specifically for treatment of SUI in postmenopausal patients with fractional CO_2 laser.

Clinical Diagnosis

To quantify urethral hypermobility, the Q-Tip measurement was used by inserting a sterile cotton applicator into the urethral orifice and subsequently asking the patient to perform the Valsalva manoeuvre.

The angles at rest and during exertion were calculated (Valsalva). Urethral hypermobility is defined in the literature as an angle greater than 30° while an angle less than 30° is a normal measurement.

The Valsalva test was performed while coughing. This consists of looking directly at the urethra while a patient with a full bladder coughs. When SUI presents, a urinary leak can be seen[7]. Afterwards, the UDI-6 was applied to subjectively measure the presence, seriousness and symptoms of urinary incontinence on a scale of 0-4 according to the patients' subjective evaluation. This scale is converted into a general percentage of 0-100, with 0 meaning not severe and 100 reflecting maximum compromise by this disease[8].

Methods

The patients underwent a treatment protocol with the SmartXide² V²LR micro-ablative fractional CO_2 laser system (DEKA, Florence, Italy) performing the MonaLisa Touch™ procedure at the ureterovesical junction. The following parameters were applied to all patients: 40W power, DT 1300µs, SPC 800 µm stack 3, DP mode for three sessions with a three-week interval between each session.

The UDI-6 questionnaire was applied to evaluate seriousness before and after treatment. All patients received follow-up for a period of 6 months (July-December 2013).

Results

At the end of the follow-up period, an attempt was made to determine if there had been a change in the UDI-6 questionnaire score before and after treatment.

The average UDI-6 score prior to treatment was 37.05, ranging from 25-50, while the average score following treatment was 15.39, with a 8.33-16.6 range.

Analysis of change in the UDI-6 scores before and at the end of the treatment showed an improvement in relation to the original values.

All patients indicated a subjective improvement in the symptoms associated with SUI shown on the scale.

Discussion

Urinary incontinence is a well-known public health problem[9,10] present in the female population, mainly among menopausal women[11]. Current treatment options are unable to resolve the symptoms with a molecular-type intervention[11]. The MonaLisa Touch™ procedure performed with the SmartXide² V²LR laser system is a supplementary system to traditional surgical techniques and appears safe and efficient to patients[4].

Previous reports have shown the effectiveness of laser treatment at the genital level; Italians Calligaro and Salvatore showed molecular changes in collagen synthesis[12]; Zdenko and Vizintin et al. found improvements to vaginal atrophy in postmenopausal women by the generation of histological changes such as production of elastic fibres and stimulation of neocollagenesis that increases the thickness of the vaginal epithelium, which could be associated with the restoration of the urethral coaptation mechanisms implicated in the pathophysiology of SUI[13–15].

In addition, it has been found that sufficient application of heat at the level of the genitourinary structures, for instance with radio frequency, is associated with structural changes determined by better tissue quality and extrinsic urethral mechanisms for continence[16].

The fractional CO_2 laser with a suburethral application for SUI treatment improved urinary symptoms and quality of life in the patients included in this pilot study and may therefore be an alternative treatment for patients who are not candidates for first-line therapy, such as vaginal tapes[17], or who do not want or are unsuitable for surgical treatment.

In the literature to date, improvements to incontinence have been incidental findings[14], so it is interesting to be able to offer the CO_2 laser as an alternative, innovative and safe treatment to use not only on menopausal patients but also on patients of any age with this complaint, chosen using medical criteria.

Ethical Considerations

The patients recruited for this study belong to the private clinical practice and voluntarily agreed to take part in it. They received the offer to participate before informed consent was obtained, and the study was subsequently registered in writing in accordance with the Declaration of Helsinki, the Belmont Report, CIOMS standards, GCP/ICH and Resolution 8430 of the Government of Colombia established on 4 October 1993. The type of informed consent used was designed specifically for treatment of SUI in postmenopausal patients with fractional CO_2 laser.

Ethical Responsibilities

Protection of persons and animals. The authors declare that the procedures followed conform to the ethical standards of the responsible human experimentation committee and are in accordance with the World Medical Association and the Declaration of Helsinki.

Data confidentiality. The authors declare that they have followed their workplace's protocols on the publication of patient data.

Right to privacy and informed consent. The authors have obtained the informed consent of the patients and/or subjects referred to in the article. This document is the property of the corresponding author.

Conflicts of Interest

The authors declare that they do not have any conflicts of interest.

Acknowledgements

Dr. Natasha Ortiz and Dr Carlos Andrés Fandiño for their collaboration and statistical analysis of the study data.

Bibliography

1. Bachman G. A new option for managing urogenital atrophy in posmenopausal women. Contemp Obstet Gynecol. 1997;42:13-28.
2. Stephens DJ. Cell biology collagen secretion explained. Nature. 2012;482:474-5.
3. Gaspar A. Comparison of two novel laser treatments in aesthetic gynecology. LAHA. 2012;1:S10.
4. Salvatore S, Maggiore U, Origoni M. Microablative fractional CO_2 laser improves dyspareunia related to vulvovaginal atrophy: A pilot study. JEPPD. 2014;00, 00-00.
5. Ronconi L, Galli M. MonaLisa Touch™. The latest frontier in the treatment of vaginal atrophy. Florencia: DEKA Ed. Scientific Series 2012; vol. 2.
6. Gaspar A, Addamo G, Brandi H. Vaginal fractional CO_2 laser: A minimally invasive option for vaginal rejuvenation. Am J Cosm Surg. 2011;28:156-62.
7. Ghoniem G, Stansford E, Kenton K, Achtari C, Goldberg R, Mascarenhas T, et al. Evaluation and outcome measures in the treatment of female urinary stress incontinence: International urogynecological association (IUGA) guidelines for research and clinical practice. Int. Urogynecol J. 2008;19:5-33.
8. Ruiz R, Aznar C, Rubio E. Validación de la version espa˜nola de las formas cortas del urogenital distress inventory UDI6 y del incontinence impact questionnaire IIQ7 en mujeres embarazadas. Gac Sanit. 2011;25:379-84.
9. Bachmann G. Urogenital ageing: an old problem newly recognized. Maturitas. 1995;22 Suppl 1:S1-5.
10. Lewis L. Stress urinary incontinence. The Linde's Operative Gynecology. 8th ed. Alabama (U.S.A): Panamericana 1998;1113.
11. Tritnovsky G, Guzman R, Mann K, Biostat M, Dietz H. Urinary incontinence: The role of menopause. JMM. 2014;21:399-402.
12. Salvatore S, Leone Roberti Maggiore U, Athanasiou S, Origoni M, Candiani M, Calligaro A, et al. Histological study on the effects of microablative fractional CO_2 laser on atrophic vaginal tissue: an ex vivo study. Menopause. 2015;22:845-9.

13. González P, Ruiz AI, Galindo L. Tratamiento de la atrofia vaginal en la menopausia con láser de CO_2 fraccional microablativo. Revista de Enfermedades del Tracto Genital Inferior. 2014;8:36-40.
14. Fistonik I, Findri-Gustek S, Fistonic N. Minimally invasive laser procedure for early stages of stress urinary incontinence. LAHA. 2012;1:67-74.
15. Vizintin Z, Rivera M, Fistonic´I, Sarac¸og˘lu F, Guimares P, Gaviria J, et al. Novel minimally invasive VSP Er:YAG laser treatments in gynecology. Journal of the Laser and Health Academy. 2012;1:46-58.
16. Leibaschoff G, Izasa PG, Cardona JL, Miklos JR, Moore RD. Transcutaneous Temperature Controlled Radiofrequency (TTCRF) for the treatment of menopausal vaginal/genitourinary symptoms. Surg Technol Int. 2016; 10;XXVIII. pii: sti29/772.
17. Lucas MG, Bosch RJL, Burkhard FC, Cruz F, Madden TB, Nambiar AK, et al. Guidelines on urinary incontinence 2012 [consultado 12 Dic 2013]. Disponible en: http://www.uroweb.org/gls/pdf/18 Urinary Incontinence LR.pdf.

Follow us

The Code of Excellence

www.dekalaser.com

DEKA M.E.L.A. s.r.l.
Via Baldanzese,17 - 50041 Calenzano (FI) - Italy
Phone +39 055 8874942 - Fax +39 055 8832884