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Analyzing the Histological Effects of Laser Therapy in Alleviating Discomfort Post Mid-Urethral Sling Removal: A Case Study and Review

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ABSTRACT

Stress Urinary Incontinence (SUI) impacts many adult women and is commonly addressed with mid-urethral sling (MUS) surgery. Despite its effectiveness, this surgery can lead to complications and discomfort, sometimes necessitating the removal of the MUS. This case report discusses a 55-year-old woman who underwent TFS (Urethral Central Tissue Fixation System) insertion to treat SUI and uterine prolapse. The patient, suffering from significant pain post-insertion, underwent TFS removal via vaginal laparoscopy. The removal significantly alleviated her pain. Following this, non-ablative Er:YAG SMOOTH® laser therapy (VEL and UEL) was proposed and administered. The laser treatment significantly reduced pain (VAS score from 10 to 0) and urinary leakage (1-hour pad test from 102g to 1g at one year post-treatment), resulting in a long-term positive outcome. Additionally, persistent posterior vaginal fornix bleeding, which continued after the TFS removal, ceased following the laser therapy. Pathological analysis of mid-urethral vaginal area biopsies post-laser therapy revealed expansion of healthy mucosal epithelium, absence of cysts and multinucleated giant cells, suggesting tissue regeneration and normalization. This case underscores the potential of Er:YAG laser therapy as a viable option for managing complications following MUS removal. It emphasizes the need for further research and exploration in this area, along with a comprehensive review of the relevant literature.

Key words: mid-urethral sling, laser therapy, stress urinary incontinence, mesh extraction, pain, complications.

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I. INTRODUCTION

Stress Urinary Incontinence (SUI) refers to the sudden leakage of urine that occurs during activities such as coughing, sneezing, or physical exertion when intra-abdominal pressure rises. This condition is estimated to affect approximately 15.7% of adult women [1,2,3].

One of the primary surgical approaches to treating SUI involves the placement of polypropylene mesh tapes. These include three main types: tension-free vaginal tape (TVT), transobturator tape (TOT), and the midurethral sling (MUS) with urethral central tissue fixation system (TFS) [1,2,3].

MUS procedures typically demonstrate patient satisfaction rates exceeding 90%, but complications ranging from approximately 2.7% to 9.8% have been reported within five years [1,2,3]. It's important to note that discomfort associated with the mesh can significantly impact quality of life (QOL) thereafter, and accounts for 1% to 17% of MUS removals [2,3,4,5]. The primary reason for legal actions related to MUS procedures is the emergence of discomfort following transvaginal mesh implantation [6]. However, reports of MUS removal surgeries are limited [2,3,4,5]. This may primarily be due to the belief of both doctors and patients that there are no alternatives other than reinserting the mesh if SUI or other complications recur after mesh removal. Currently, there is no consensus on the management of patients after MUS removal.

Several studies have reported on the effectiveness of VEL and UEL in treating various forms of urinary incontinence, including cases of persistent SUI after MUS placement [8, 9, 11]. This treatment utilizes a laser suitable for the vagina (VEL) and urethra (UEL). VEL has been reported to effectively control incontinence in patients with persistent SUI after MUS placement [9]. The combination of VEL and UEL has been shown to improve severe SUI [8]. VEL itself is highly safe, with minimal observed side effects in a study involving 113,000 subjects [10].

This study presents a case report of a woman who sought treatment for recurrent urinary incontinence following mesh removal. The simultaneous use of VEL and UEL safely prevented the recurrence of pain and SUI, resulting in long-term success.

II. CASE

A 55-year-old woman had a history of two pregnancies and two vaginal deliveries, and a BMI of 26.6. She underwent surgery to place two TFS devices for treating SUI and uterine prolapse. Before this treatment, she experienced genital discomfort, which significantly worsened immediately following the TFS placement. The TFS procedure involved inserting support tapes at both the midurethral support and the posterior fornix of the vagina, a method deviating from standard guidelines. Two years after the MUS procedure, she visited our clinic (T0), seeking to have the TFS removed. The TFS device was utilized during a prior procedure performed at another institution. Further details regarding the device were not available to us.

During the initial visit (T0) to the specialty clinic, the patient's pain was assessed on a 0-10 visual analog scale (VAS), and pain-related terms from her diary were noted. A one-hour pad test was conducted for urinary incontinence. The patient reported severe pain near the urethral mesh and in the external genital area, both rated as 10 on the VAS, the latter described as 'knife-like pain'. The pad test showed no leakage, excluding SUI.

The TFS removal procedure was performed at our clinic in January 2019. During the procedure, the TFS, positioned deep within the vagina, was identified as the source of infection.

The M1 procedure began with a pre-anesthesia examination of tender areas. Localized pain and vaginal wall hardening were noted around the TFS. Vulvodynia at the hymenal scar was linked to the TFS pain. Since the TFS was behind the uterus, laparoscopy was required.

Lumbar anesthesia was administered. Samples were collected from the vaginal epithelium overlying the mesh for analysis. An incision was made in the vaginal wall at the site of the painful mesh for its removal, aimed at preventing an exacerbation of vulvodynia. Following the mesh extraction, the vaginal wall was sutured. Laparoscopy was utilized to remove the mesh positioned behind the uterus. To address uterine prolapse, additional sacrospinous ligament fixation procedures without mesh were performed bilaterally.

A year after the surgical removal of all MUSs (M-T1), a six-month course of treatment was implemented at our clinic. This regimen consisted of local estrogen therapy (LET) using 0.5 mg estriol cream applied vaginally twice weekly, along with pelvic floor muscle training (PFMT) involving 30-minute sessions of guided exercises performed three times per week. Additionally, three sessions of combined VEL and UEL treatments were conducted at monthly intervals (L1, L2, L3). Pain and SUI were reassessed a year post the final VEL + UEL treatment (L3) (L-T1).

For the VEL + UEL treatment, the procedure began with VEL, which was then directly followed by UEL. In the VEL stage, iodine was used to disinfect the urethra, vagina, and labia. Local anesthesia was applied using an 8% Xylocaine spray (Sandoz KK, Tokyo, Japan). The laser treatment utilized was IncontiLase® (SP Dynamis Fotona, Ljubljana, Slovenia). Equipment prepared for the procedure included a special glass vaginal speculum designed for the laser probe, along with the corresponding handpieces PS03, R11, and R09-2 Gu.

During the VEL procedure, a glass speculum was placed in the vagina, and the R11 and PS03 laser handpieces were used for treatment. The R11 handpiece was employed to treat the entire vaginal canal, applying treatment every 5 mm in a full 360-degree rotation. This was set at a 7 mm spot size, 3.0 J/cm^2 pulse fluence, and a 2.0 Hz frequency, and the process was repeated twice. The VEL procedure was performed in two stages. First, the R11 handpiece (7 mm spot size, 3.0 J/cm^2 pulse fluence, 2.0 Hz frequency) was used to treat the entire vaginal canal, applying treatment every 5 mm in a full 360-degree rotation, repeated twice. Subsequently, the PS03 handpiece (7 mm spot size, 6 J/cm^2 pulse fluence, 2.0 Hz frequency) was used to irradiate every 5 mm, repeating this step three times. For the UEL stage, the R09-2 Gu laser handpiece, designed specifically for urethral application, was used post-catheterization to clear residual bladder urine. The settings for this phase included the R09-2 Gu in SMOOTH mode, with a 1.4 Hz frequency and 1.5 J/cm^2 fluence. Four sequential treatments were applied from the urethral meatus to the proximal end in 2.5 mm steps, repeated four times. In total, the VEL + UEL treatment lasted approximately 30 minutes.

The procedural sequence is depicted (Figure 1). The initial step involved removing the TFS (M1). One-year post-surgery, the VAS score dropped to 2, yet the 1-hour pad test result increased to 102g. Despite six months of PFMT, SUI symptoms persisted. Subsequently, three UEL + VEL treatments (L1, L2,

L3) were implemented. These treatments resulted in a marked decrease in both VAS score and SUI complaints. A year after the final session (L-T1), the VAS score was reduced to 0, and the 1-hour pad test showed a substantial decrease in leakage to 1g.

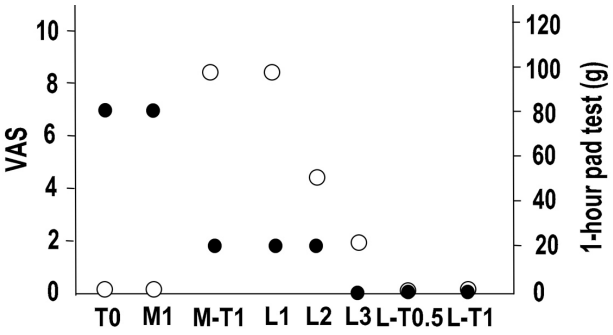

Figure 1 The overall course of pain and SUI. Left vertical axis: degree of pain (VAS), right vertical axis: 1-hour pad test, horizontal axis: time
Black circles: VAS, white circles: 1-hour pad test,
SUI: stress urinary incontinence, VAS: visual analog scale pain score (0: no pain to 10: greatest pain),
T0: first visit, M1: first mid-urethral sling (MUS) removal surgery, M-T1: 1 year after MUS removal surgery, L1: first laser treatment, L2: second laser treatment, L3: third laser treatment, L-T0.5: 0.5 year after the third laser treatment, L-T1: 1 year after the third laser treatment (L3).

In the posterior vaginal fornix, changes were observed with the mesh removal and laser treatment, respectively. One year after TFS removal (M1), the infection had disappeared, but bleeding continued consistently. With VEL treatment (L1, L2, L3), the bleeding disappeared.

Figure 2 displays the pathological findings in the mid-urethral vaginal area for M1 (Figures 2a, b), M-T1 (Figure 2b), and L-T1 (Figure 2c). In Figure 2a, it is evident that during the slide preparation process, the mesh caused peeling, resulting in the formation of an empty area (Va). The presence of atypical cells (red arrow) was responsible for the glass formation. Numerous multinucleated giant cells were plentiful (blue arrows) in the vicinity of this vacant area (Va), and the detachment of the epithelium was also observed (white arrows). Figure 2b shows that the presence of cystic spaces (Va), the occurrence of multinucleated giant cells (black arrows), and the formation of granulation tissue (gray arrows) are evident. This observation suggests a relationship between the worsening of pain and the presence of the mesh, as it seems to hinder regular cell proliferation while promoting the development of abnormal granulation tissue. Figure 2c shows that there is still noticeable abnormal granulation tissue (indicated by blue arrows), although the cystic spaces have disappeared, and the regeneration of mucosal epithelium remains minimal (Ep). Figure 2d shows the expansion of healthy mucosal epithelium (Ep). No cysts or multinucleated giant cells are detected, suggesting that tissue normalization has occurred due to laser therapy.

Pathology is assessed at each stage as follows: M1: at the time of mid-urethral sling (MUS) removal surgery (a. epithelium, b. deep), M-T1: 1 year after MUS removal (c), L-T1: 1 year after the third laser treatment (d)

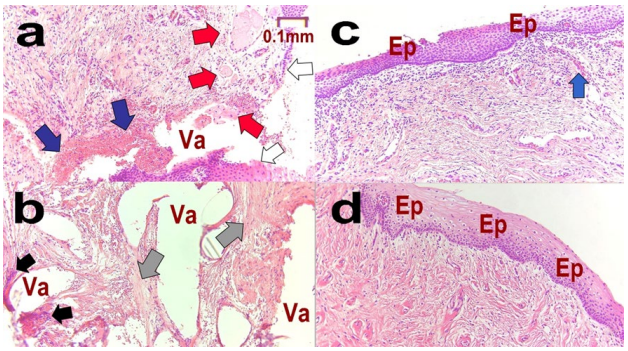

Fig. 2 Pathological tissue. Pathology is assessed at each stage as follows: M1: at the time of mid-urethral sling (MUS) removal surgery (a. epithelium, b. deep), M-T1: 1 year after MUS removal (c), L-T1: 1 year after the third laser treatment (d)
Va: vacuole formed when the mesh became detached during pathological specimen preparation, Ep: mucosa

III. DISCUSSION

Complications associated with surgical mesh have led to international legal actions against manufacturers and domestic safety investigations. There is no consensus on the optimal pain management for post-MUS surgery, and comprehensive research on changes in mesh extraction tissue is lacking. We conducted an extensive literature review.

Firstly, we focused on the complications of MUS surgery and the frequency of resection. Keltie et al. analyzed 92,246 patients who underwent MUS surgery and reported a 9.8% overall complication rate within 5 years, including peri-procedural, 30-day, and long-term complications, with 1.7% in unconfounded and 3.0% in confounded cases experiencing complications within 30 days [11]. Unger et al. discovered that 2.7% of 3,307 women who underwent sling placement required revisions for various symptoms [2]. Gurol-Urganci et al. investigated 95,057 women who underwent midurethral mesh sling insertion. The removal rates for midurethral mesh slings were 1.4% at 1 year, 2.7% at 5 years, and 3.3% at 9 years, with a decreasing risk as age increased [3]. Mengerink et al. surveyed 31 patients, with 26 providing responses. VAS pain scores decreased at follow-up, and some

patients reported minimal SUI incidents. The infrequent MUS extraction procedures may be due to an underestimated rate of MUS removal compared to the complication rate following MUS insertion [4].

Secondly, we compared the outcomes of MUS (Midurethral Mesh Sling) removal surgery with previous research studies. Hou et al. conducted a comprehensive review, screening 11,887 abstracts and identifying 45 eligible and unique studies. Comparative studies revealed that partial mesh removal had a lower incidence of postoperative stress urinary incontinence (SUI) compared to total mesh removal (odds ratio 0.46, 95% CI 0.22–0.96). Single-group studies also supported a lower postoperative SUI rate with partial mesh removal compared to total mesh removal (19.2% [95% CI 13.5–25.7] vs. 48.7% [95% CI 31.2–66.4]). Adverse events were rare.

Thirdly, we examined the adverse effects of mesh removal, such as SUI recurrence and OAB/UUI (Overactive Bladder/Urgency Urinary Incontinence). Ramart et al. conducted a retrospective cohort study involving 117 patients who underwent MUS (Midurethral Sling) removal surgery, primarily due to chronic pain in 80% of cases [13]. Following MUS removal, within a year, 38.6% of all patients with TVT implanted and removed, and 34.0% of patients with TOT implanted and removed experienced severe SUI, necessitating additional SUI treatments [13].

Fourthly, we evaluated the effectiveness of mesh and laser treatment. We chose laser treatment because patients who had undergone MUS removal surgery might decline a MUS reinsertion. In 2008, the US FDA issued its initial notification regarding mesh kit complications in female urology [14]. Around 2011, we observed shorter intervals between MUS insertion and removal surgery, possibly due to increased awareness of complications [15]. It remains uncertain whether patients and surgeons prefer mesh reinsertion for SUI recurrence post-MUS excision.

Fifthly, we discussed the mechanism of VEL/UEL treatment effectiveness utilizing the "Er:YAG laser with SMOOTH mode." Initially, only VEL was prominent, with studies supporting its efficacy for SUI. A previous study collected data from 327 patients who had undergone TVT surgery, VEL, or PFMT only, comparing them using propensity score matching [16]. The TVT and VEL groups exhibited similar improvement after one year, with the distinction being that SUI improved immediately after TVT surgery and gradually after VEL. It was also reported that OAB worsened in the TVT group but improved in the VEL group. UEL, or intraurethral SMOOTH Er:YAG laser, is named for its insertion into the urethra. An initial study involved 22 women with type III SUI (intrinsic sphincter deficiency) who exhibited significant improvement in ICIQ-SF score and 1-hour pad test results [17].

One case report explored the combined use of VEL and UEL in a female athlete with severe SUI, employing MRI to illustrate post-laser treatment changes [8]. Before treatment, adipose tissue was present between the vagina and bladder, disappearing three years after laser intervention. Vaginal thickness increased, indicating tissue regeneration. The urethra's cross-section shifted from elliptical to circular post-laser treatment. This case report also discussed a cross-sectional study involving 113 women without SUI, revealing they had a circular urethra. Thus, the case report demonstrated that the uneven urethral circumference before treatment became uniform after UEL.

Finally, we examined the pathological observations. In this investigation, we compared specimens from MUS resection at 1 year (M-T1) with those from L-T1. As far as we were aware, there had been no prior exploration in this particular domain. Even in the case of M-T1, the tissue in the area from which the mesh was extracted did not exhibit typical proliferation, and it was noteworthy that variations existed among cases. We posit two potential causes for this phenomenon: an issue with the mesh itself or complications arising from the removal of a substantial amount of tissue during the mesh extraction process. Consequently, the pathological evidence strongly supports the benefits of laser therapy for MUS resection. Gaspar et al. documented pathological findings from VEL treatment for ten women suffering from severe genitourinary syndrome of menopause [18]. Their study indicated that the average thickness of the vaginal epithelium prior to treatment increased from 45.0 μm (in severe cases with hemorrhages and nearly no epithelial layer of cells) to 153 μm. This discovery aligns with our own findings.

Okui et al. have been working on mesh-related issues for some time now, using laser therapy for healing after mesh removal in patients undergoing MUS treatment alone. This study specifically focused on mesh issues related to MUS and pelvic organ prolapse, and there is a need for further development in this field in the future [19].

IV. CONCLUSIONS

This case report presents a novel approach involving non-ablative Er:YAG SMOOTH® laser

therapy for patients who have faced recurring urinary incontinence and pain following the removal of MUS. The findings indicated substantial reductions in pain scores and urinary leakage after a series of laser treatments, resulting in long-term success. Pathological observations provided support for the occurrence of tissue regeneration and normalization brought about by the laser therapy. This indicates the potential advantages of Er:YAG laser therapy as a fresh treatment choice for patients post-MUS removal, underscoring the necessity for additional research to confirm its efficacy.

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